

# **Decision of the Competition and Markets Authority**

Unfair pricing in respect of the supply of  
phenytoin sodium capsules in the UK

Case CE/9742-13

7 December 2016

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Confidential information in the original version of this Decision has been redacted from the published version on the public register. Redacted confidential information in the text of the published version of the Decision is denoted by [✂].

The names of individuals mentioned in the description of the infringement in the original version of this Decision have been removed from the published version on the public register. Names have been replaced by a general descriptor of the individual's role.

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# 1. EXECUTIVE SUMMARY

## A. Introduction

1.1 This decision of the Competition and Markets Authority (the 'CMA')<sup>1</sup>, of which Annexes A to M form an integral part (the 'Decision'), is addressed to:

- Pfizer Limited and Pfizer Inc (collectively, 'Pfizer'); and
- Flynn Pharma Limited and Flynn Pharma (Holdings) Limited (collectively, 'Flynn').

1.2 In this Decision, the CMA concludes that Pfizer and Flynn (each a 'Party', together the 'Parties') have infringed the prohibition imposed by section 18 (the 'Chapter II prohibition') of the Competition Act 1998 (the 'Act') and Article 102 of the Treaty on the Functioning of the European Union (the 'TFEU').

1.3 The CMA finds that Pfizer, a multinational pharmaceutical company, and Flynn, a smaller pharmaceutical company, have each abused their respective dominant positions by imposing unfair prices for phenytoin sodium capsules manufactured by Pfizer ('Pfizer-manufactured phenytoin sodium capsules') in the UK. This has resulted in the National Health Service ('NHS') being overcharged by tens of millions of pounds.

1.4 The CMA has imposed a financial penalty of £84.2 million on Pfizer and £5.2 million on Flynn and has directed them to reduce their prices.

## B. Background

1.5 Phenytoin sodium is a prescription drug primarily used to treat epilepsy. It is available in a variety of forms, including as capsules and tablets. It was originally synthesised in 1908 and it became the first widely available treatment for epilepsy. It has since been superseded by newer drugs which have fewer side effects and it is no longer recommended as a first-line or second-line treatment. Consequently very few newly diagnosed epilepsy patients are prescribed phenytoin sodium capsules and demand for the product is declining. The CMA estimates that there are around 48,000

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<sup>1</sup> References to the CMA in this Decision should be read as referring to the Office of Fair Trading (the 'OFT') where they concern matters prior to 1 April 2014 (the date on which the CMA formally came into existence and it took over the OFT's functions under the Competition Act 1998 and the TFEU).

patients taking phenytoin sodium capsules in the UK; this is approximately 10% of epilepsy patients in the UK.

- 1.6 Phenytoin sodium has a narrow therapeutic index ('NTI') and non-linear pharmacokinetics. These characteristics mean that even small changes to the dose delivered to the circulation can give rise to a disproportionate change in the level of the drug in the body and this can give rise to the risk of therapeutic failure and even toxicity.
- 1.7 These potentially significant risks have resulted in clinical guidance, including guidance published by the National Institute for Health and Care Excellence ('NICE'), in October 2004 and January 2012, and the Medicines and Healthcare Products Regulatory Agency ('MHRA'), in November 2013, recommending that patients who are stabilised on a particular manufacturer's phenytoin sodium capsule should be maintained on that manufacturer's product and should not be switched to another manufacturer's capsule. This principle is referred to as Continuity of Supply in this Decision.
- 1.8 There are two companies which manufacture and supply phenytoin sodium capsules to the United Kingdom; these are Pfizer and NRIM Limited ('NRIM').
- 1.9 Pfizer's phenytoin sodium capsules were sold under the brand name *Epanutin* up to and including 23 September 2012. *Epanutin* was first marketed in 1938 and was acquired by Pfizer in 2000 by which time it was off-patent. Pfizer's phenytoin sodium capsules are available in four strengths: 25mg, 50mg, 100mg and 300mg. The 100mg capsule is by far the biggest selling capsule strength, accounting for over 70% of all phenytoin sodium capsule dispensed in the UK.
- 1.10 NRIM began supplying its phenytoin sodium capsules in April 2013. Its capsules are only available in the 100mg strength. They are sold under the name *Phenytoin Sodium NRIM Capsules*.
- 1.11 Prior to 24 September 2012, Pfizer manufactured *Epanutin* in Germany before delivering the capsules to a logistics company, United Drugs Group ('UDG'), which delivered them to pharmacies. During this time, the prices of *Epanutin* were regulated as part of Pfizer's portfolio of branded drugs under the NHS's Pharmaceutical Price Regulation Scheme (the 'PPRS').

- 1.12 During the course of 2012, Pfizer and Flynn entered into agreements under which Pfizer transferred its Marketing Authorisations ('MAs') for *Epanutin* to Flynn for [a nominal fee]. Pfizer continued to manufacture its phenytoin sodium capsules which it exclusively supplied to Flynn for distribution in the UK.
- 1.13 Following the transfer of the MAs, Flynn genericised *Epanutin* and the product was withdrawn from the PPRS, meaning it was no longer subject to any form of price regulation. From 24 September 2012 to at least the date of this Decision, Flynn has distributed the product under the name '*Phenytoin Sodium Flynn Hard Capsules*' and the Drug tariff price (the sum pharmacies are paid for dispensing the product) has been set by reference to Flynn's list price.
- 1.14 There was little discernible change to the supply chain following Flynn's introduction on 24 September 2012. Pfizer continued to manufacture its capsules in Germany and to deliver them directly to [redacted] within the UK, which processed orders for them on behalf of Flynn. Accordingly, Flynn does not take receipt of the products at any time and only undertakes minimal activities, such as placing orders for the products with Pfizer and setting its own prices. Moreover, Flynn has taken on very limited commercial risk. As the MA holder, Flynn is subject to the legal obligations that come with that role, however it has contracted out many of these responsibilities to either Pfizer or other entities in the supply chain.
- 1.15 A key feature of the negotiations between Pfizer and Flynn concerning Pfizer's divestment of its *Epanutin* MAs was that genericisation would provide the basis for a significant increase in the prices of phenytoin sodium capsules. Indeed, the evidence suggests that one of the key reasons Flynn was introduced into the supply chain was for it to be the focus of any adverse reaction to the price increases and therefore to mitigate the risk of Pfizer suffering reputational damage.
- 1.16 Having been broadly stable for years, the prices of phenytoin sodium capsules increased significantly overnight when Flynn commenced distribution on 24 September 2012. Prior to that date Pfizer's average selling price ('ASP') for 100mg capsules was £2.21. Flynn's ASP for the same capsule for the period from September 2012 to March 2014 was [£51 - £60.99]. Flynn's ASP decreased a little after March 2014, but still stood at [£41- £50.99] – approximately [19 - 23] times Pfizer's pre-September 2012 ASP – in the period from May 2014 to June 2016. These prices do not reflect

the Parties' costs and have been achieved in respect of a very old drug, which is long off patent and has been genericised and superseded by other AEDs. The product has not been subject to any recent innovation, development or additional commercial risks and no additional benefits have been provided for patients.

1.17 Table 1.1 below shows that Pfizer's ASPs to Flynn for each capsule strength are now [at least 488%] greater than those it charged pharmacies until September 2012.

**Table 1.1: Pfizer's ASPs per pack before and after the debranding of phenytoin sodium capsules**

	<b>Pre-September 2012</b>	<b>September 2012 to June 2016</b>	<b>Increase (%)</b>
<b>25mg</b>	£0.51	[£3 - £5.99]	[Over 488%]
<b>50mg</b>	£0.52	[£6 - £8.99]	[Over 1,054%]
<b>100mg</b>	£2.21	[£31 - £40.99]	[Over 1,303%]
<b>300mg</b>	£2.20	[£31 - £40.99]	[Over 1,309%]

Note: All calculations are based on the sales value and sales volume data submitted by Pfizer (see document 02129.2).  
Pre-September 2012 ASPs are based on sales value and volume data for the period from 1 March 2004 to 23 September 2012. These ASPs refer to the prices charged by Pfizer to wholesalers and/or pharmacists.  
Post-September 2012 ASPs are based on sales value and volume data for the period from 24 September 2012 to 30 June 2016. These ASPs refer to the prices charged by Pfizer to Flynn.  
Pre-September 2012 and post-September 2012 ASPs have been presented to two decimal places; the percentage increases have been calculated using data that has not been rounded.

1.18 Table 1.2 below shows that Flynn's ASPs to wholesalers and pharmacies are now [at least 2,015%] greater than those charged which Pfizer charged directly to pharmacies until September 2012.



**Table 1.2: Flynn's ASPs per pack– percentage changes relative to Pfizer's pre-September 2012 ASPs**

	<b>Pre-September 2012</b>	<b>September 2012 to June 2016</b>	<b>Increase (%)</b>
<b>25mg</b>	£0.51	[£11 - £20.99]	[Over 2,057%]
<b>50mg</b>	£0.52	[£11 - £20.99]	[Over 2,015%]
<b>100mg</b>	£2.21	[£51 - £60.99]	[Over 2,208%]
<b>300mg</b>	£2.20	[£51 - £60.99]	[Over 2,218%]

Note: Flynn's prices are based on documents 00505.22, 00872.3, 00915.1, 01148.2, 01148.3, 01293.2, 01839.13 and 02115.2.  
Pre-September 2012 ASPs are based on sales value and volume data for the period from 1 March 2004 to 23 September 2012. These ASPs refer to the prices charged by Pfizer to wholesalers and/or pharmacists (see document 02129.2).  
Post-September 2012 ASPs are based on sales value and volume data for the period from 24 September 2012 to 30 June 2016. These ASPs refer to the prices charged by Flynn to wholesalers and/or pharmacists.  
Pre-September 2012 and post-September 2012 ASPs have been presented to two decimal places; the percentage increases have been calculated using data that has not been rounded.

1.19 These increased ASPs have resulted in a significant increase in the NHS's annual expenditure on phenytoin sodium capsules through consequential increases in the Drug Tariff price. Prior to September 2012, the NHS's annual expenditure on phenytoin sodium capsules was approximately £2 million. Despite the volumes purchased by the NHS falling year-on-year, this expenditure stood at approximately £50 million in 2013, approximately £42 million in 2014 and approximately £37 million in 2015.

1.20 Pfizer also sells phenytoin sodium capsules in other European countries. These capsules are identical to the capsules that Pfizer manufactures for supply to the UK and they are manufactured in the same German facility. Prices in all other European countries are significantly lower than the corresponding prices in the UK. For example, none of Pfizer's ASPs in those other countries are higher than [£6 - £8.99] per 100mg pack. Pfizer has confirmed that, with one exception, all of its prices in other European countries are profitable.

**C. Dominance**

1.21 Pfizer and Flynn have held dominant positions in their respective relevant markets throughout the relevant period (24 September 2012 to at least the date of this Decision).

- 1.22 Both Parties have profitably sustained supra-competitive prices and very high market shares (at all times comfortably in excess of 60 percent) for a prolonged period of time, thus demonstrating that they have been able to act independently of competitors, customers and consumers in their respective markets.
- 1.23 The competitive constraints that the Parties face, and have faced, are weak.
- 1.24 NRIM's phenytoin sodium capsule has not constrained Pfizer's or Flynn's pricing behaviour despite it being cheaper for the overwhelming majority of the time since its launch. Although NRIM did initially gain sales, Pfizer and Flynn were able to profitably maintain their very high prices because the majority of pharmacies observed the principle of Continuity of Supply when dispensing phenytoin sodium capsules. Any material switching was brought to an end following the publication of the MHRA guidance in November 2013, after which all major pharmacies sought to ensure Continuity of Supply.
- 1.25 Pharmacies' adherence to the principle of Continuity of Supply has resulted in Pfizer and Flynn effectively having a captive customer base. Flynn (directly) and Pfizer (indirectly) are unavoidable trading partners for the NHS.
- 1.26 Continuity of Supply has also meant that other formulations of phenytoin sodium – namely, phenytoin sodium tablets ('Tablets') – and other anti-epileptic drugs ('AEDs') have not competitively constrained Pfizer or Flynn.
- 1.27 Parallel imports of Pfizer-manufactured phenytoin sodium capsules ('Parallel Imports') from lower-priced jurisdictions can be used as a direct substitute for the capsules that Flynn supplies. However, they are not seen as a reliable source of supply by pharmacies and they are not available in sufficient volumes to be able to constrain Pfizer or Flynn's dominance.
- 1.28 The principle of Continuity of Supply, together with the small and declining patient base, means that there is little incentive for potential entrants to take the risk of investing in developing a new phenytoin sodium capsule product and bringing it to market. NRIM abandoned its development of 25mg, 50mg and 300mg capsule strengths, and at least one other potential entrant has abandoned its development of a 300mg capsule for this very reason.
- 1.29 Neither of the Parties has been constrained by buyer power. The NHS does not have the power, either in law or in practice, to limit the price that it pays for phenytoin sodium capsules.

## D. **Infringements**

- 1.30 Pfizer and Flynn have each abused their respective dominant positions by charging unfair prices for each capsule strength of phenytoin sodium capsules.
- 1.31 Charging an unfair price constitutes an abuse of a dominant position in circumstances where the dominant undertaking has used its dominant position to reap trading benefits which it would not have reaped if there had been normal and sufficiently effective competition.
- 1.32 A dominant company's price will be unfairly high and infringe competition law if it has no reasonable relation to the economic value of the product being sold. This is the case where:
- the difference between price and the costs actually incurred plus a reasonable rate of return is excessive; and
  - the price is either unfair in itself or unfair when compared to competing products.

## I. ***Pfizer's and Flynn's prices are excessive***

- 1.33 The CMA has found that:
- Pfizer's ASPs for each of the four capsule strengths are excessive because they materially exceed Pfizer's costs plus a reasonable rate of return; and
  - Flynn's ASPs for each of the four capsule strengths are excessive because they materially exceed Flynn's costs plus a reasonable rate of return.
- 1.34 Pfizer's and Flynn's excesses (the amount by which their respective prices exceed their respective costs plus a reasonable rate of return) are set out in Tables 1.3 and 1.4 below.

**Table 1.3: Pfizer's excesses on sales of phenytoin sodium capsules between September 2012 and June 2016**

	25mg	50mg	100mg	300mg	Total
<b>Excess (revenue)</b>	[X]	[X]	[X]	[X]	[£49m - £57m]
<b>Excess (per pack)</b>	[£1 - £2.99]	[£3 - £5.99]	[£31 - £40.99]	[£31 - £40.99]	n/a
<b>Excess (%)*</b>	29%	100%	705%	690%	443%

\* Excess in percentage terms is calculated by dividing nominal excess by the Party's costs plus a reasonable rate of return.

**Table 1.4: Flynn's excesses on sales of phenytoin sodium capsules between September 2012 and June 2016**

	25mg	50mg	100mg	300mg	Total
<b>Excess (revenue)</b>	[X]	[X]	[X]	[X]	[£27.5m - £32.5m]
<b>Excess (per pack)</b>	[£6 - £8.99]	[£3 - £5.99]	[£11 - £20.99]	[£11 - £20.99]	n/a
<b>Excess (%)</b>	133%	70%	31%	36%	41%

1.35 The CMA finds that each of the above excesses are material. This finding is strengthened when various other factors are taken into account. For example, each of the excesses have been sustained for over four years and are higher than the percentage excesses found to have been excessive in other cases.

1.36 Flynn's excesses must also be considered in the context of the limited activities it performs and risks it incurs in relation to the distribution of phenytoin sodium capsules. Further, the high supply price that Flynn pays to Pfizer for phenytoin sodium capsules means that the scale of its excesses as expressed in percentage terms do not reflect the full extent of its absolute excesses.

## II. *Pfizer's and Flynn's Prices are unfair*

1.37 For an excessive price to be abusive, it must also be demonstrated that the price is unfair.

1.38 A price can be unfair either in itself or when compared to competing products. This is an alternative, not a cumulative, test.

a. ***Unfair in itself***

- 1.39 The CMA has found that each of Pfizer's and Flynn's respective prices for each of the four capsule strengths are unfair in themselves.
- 1.40 In drawing this conclusion, the CMA first assessed whether there are any additional, non-cost related factors that should increase the economic value of the products in this case. The CMA found that there are none. In the absence of any such non-cost related factors, the very excessiveness of a price can be sufficient to establish that the price bears no reasonable relation to the economic value of the product being supplied.
- 1.41 The CMA then considered whether Pfizer's prices and Flynn's prices are unfair in themselves.
- 1.42 In line with previous case law, the CMA has concluded that, in the absence of non-cost related factors, the substantial disparities between: (i) the economic value of Pfizer's products and the prices that Pfizer charges to Flynn; and, (ii) the economic value of Flynn's Products and the prices that Flynn charges to pharmacies and wholesalers are sufficient for their respective prices to be unfair in themselves.
- 1.43 The CMA also considered whether Pfizer's prices and Flynn's prices are unfair in themselves in the context of a range of factors, which the CMA has considered in the round. These factors include the following:
- As set out above, there is a substantial disparity between the economic value of each Party's products the prices they charge.
  - Pfizer and Flynn have each been able to sustain excessive prices because both Parties are shielded from effective competition and have a captive market of patients stabilised on Pfizer-manufactured phenytoin capsules. Both Parties have reaped trading benefits that would not have been available if they had faced competition. Their respective excessive prices have been sustained for over four years and are not likely to be reduced through market forces in the near future.
  - The Parties' respective excessive prices have had an adverse effect on the end customer, the NHS. Indeed, the Parties were aware that would be the case and imposed their respective prices anyway. As a result of the Parties' prices, NHS expenditure on phenytoin sodium capsules

has increased dramatically and resources have needed to be diverted from other services and treatments to meet those increased costs.

- In respect of Pfizer, the prices it has charged since 24 September 2012 are significantly higher than both those it charged before that date and those that it charges for exactly the same product in other European countries. Pfizer has submitted that its pre-September 2012 prices were loss-making. However, to the extent that this was the case, the scale of Pfizer's prices since September 2012 mean that it will have recovered any losses it incurred within just two months.
- In respect of Flynn, its excesses alone are significantly above Pfizer's pre-September 2012 prices. Flynn has sustained these excesses despite performing a very limited role in the supply chain and incurring little commercial risk. Flynn has also delivered no discernible benefits for patients.

1.44 In conducting an in the round assessment, the CMA has also taken account of the characteristics of phenytoin sodium capsules – in particular, the age of the product, the fact it has long been off-patent and has been genericised, the fact it has not been subject to any recent innovation, and the fact that the arrangement between Pfizer and Flynn has not produced any benefits for patients.

***b. Unfair when compared to competing products***

1.45 Having established that Pfizer's and Flynn's prices are unfair in themselves it is not necessary for the CMA to consider whether the Parties' prices were also unfair when compared to competing products. However, the CMA has nevertheless considered whether there are any other products that could provide a meaningful comparison. The CMA has concluded that there are no such products in this case.

***c. The Parties' key representations***

1.46 The Parties have made a number of representations and submissions to support their contention that their prices are not unfair. These representations have been carefully considered and rejected within this Decision. However, the key representations submitted by the Parties are summarised below:

- The Parties have sought to justify their prices by reference to the Drug Tariff price of Tablets which the Parties claim was ‘sanctioned’ by the Department of Health (‘DH’).
- Pfizer has submitted that its sales of phenytoin sodium capsules were loss-making and that without the price increase it may have needed to discontinue their production.

- 1.47 However, the CMA considers that the Parties cannot justify their prices by reference to the Drug Tariff price of Tablets. This Decision concerns the prices that the Parties have imposed in respect of phenytoin sodium capsules. It is clear that the DH was unhappy with the Parties’ prices and that Pfizer and Flynn would have been aware of this, yet the DH had no power to limit them.
- 1.48 Moreover, contrary to the Parties’ assumption, the DH has never endorsed or approved the Drug Tariff price in the, separate and much smaller, Tablets market. Nor does the DH have any meaningful power to regulate or limit the price it pays for Tablets. In fact, the DH believes that a lower price may have been justified and made it clear to Flynn that it should not assume that the DH was ‘happy’ with the price of Tablets when Flynn tried to defend its prices. Additionally, the assessment of whether a price is unfairly high and abusive is an objective one and is not subject to reactions from third parties, particularly reactions in relation to different products.
- 1.49 The characteristics of the Tablets market mean that it is unlikely to produce a reasonable relationship between price and economic value. Tablets are subject to the same guidance regarding Continuity of Supply as phenytoin sodium capsules and pharmacies have confirmed that they are reluctant to switch patients stabilised on one manufacturer’s Tablets to those of another. This means inter-brand competition is limited and individual Tablet manufacturers are likely to have market power enabling them to profitably sustain prices above the competitive level. In this respect it is also notable that a key Pfizer member of staff described Teva UK Limited (‘Teva’) (the main supplier of Tablets in the UK) as making ‘*supernormal profits*’ on its sales of Tablets, [✂].
- 1.50 With regard to Pfizer’s submission that phenytoin sodium capsules were loss making, the evidence shows that Pfizer did not consider that discontinuation was a realistic option. In any event, it is not the CMA’s case that Pfizer could not make a profit on its sales of phenytoin sodium capsules, but rather that it must not charge excessive and unfairly high prices. Pfizer could have

avoided breaking the law by setting lower, yet profitable, prices. The scale of Pfizer's excesses are reflected by the fact it recouped any losses it made in the period 2007 to 2012 within two months of increasing its prices. It has also continued to sell its phenytoin sodium capsules in other European countries at significantly lower prices than the ones it is charging Flynn in the UK.



## 2. INTRODUCTION

### A. Summary of Pfizer's Infringements

2.1 By this Decision, the CMA finds that:

- Pfizer has, from 24 September 2012 to at least the date of this Decision (the 'Relevant Period'), held a dominant position in the market for the manufacture of phenytoin sodium capsules by Pfizer that are distributed in the UK. Alternatively, during the period from 24 September 2012 to November 2013, Pfizer has held a dominant position in the market for the manufacture of phenytoin sodium capsules that are distributed in the UK. Throughout this Decision, the four different capsule strengths of phenytoin sodium capsules sold by Pfizer for distribution in the UK are collectively referred to as 'Pfizer's Products'.
- Throughout the Relevant Period, Pfizer has abused its dominant position by charging Flynn unfairly high selling prices in respect of each of Pfizer's Products (collectively referred to as 'Pfizer's Prices'), thereby infringing the Chapter II prohibition and Article 102 of the TFEU.

2.2 As Pfizer charges different prices and incurs different costs for each of Pfizer's Products, the CMA finds that Pfizer has engaged in four separate abuses of dominance. The CMA therefore reaches four separate infringement decisions in respect of Pfizer's conduct – one for each of Pfizer's Products and in respect of each of Pfizer's Prices.

2.3 The CMA collectively refers to the four separate abuses of dominance it finds in respect of Pfizer as 'Pfizer's Infringements'.

### B. Summary of Flynn's Infringements

2.4 By this Decision, the CMA finds that:

- Flynn has, throughout the Relevant Period, held a dominant position in the market for the distribution of Pfizer-manufactured phenytoin sodium capsules in the UK. Alternatively, during the period from 24 September 2012 to November 2013, Flynn has held a dominant position in the market for the distribution of phenytoin sodium capsules in the UK. Throughout this Decision, the four different capsule strengths of Pfizer-

manufactured phenytoin sodium capsules sold by Flynn are collectively referred to as 'Flynn's Products'.

- Throughout the Relevant Period, Flynn has abused its dominant position by charging its customers (wholesalers and pharmacies) unfairly high selling prices in respect of each of Flynn's Products, thereby infringing the Chapter II prohibition and Article 102 of the TFEU.

2.5 As Flynn charges different prices and incurs different costs for each of Flynn's Products, the CMA finds that Flynn has engaged in four separate abuses of dominance. The CMA therefore reaches four separate infringement decisions in respect of Flynn's conduct – one for each of Flynn's Products and in respect of each of Flynn's Prices.

2.6 The CMA collectively refers to the four separate abuses of dominance it finds in respect of Flynn as 'Flynn's Infringements'.

### C. **The burden and standard of proof**

2.7 The burden of proving an infringement of the Chapter II prohibition and Article 102 of the TFEU lies with the CMA.<sup>2</sup> However, this burden does not preclude the CMA from relying, where appropriate, on inferences or evidential presumptions.<sup>3</sup>

2.8 The standard of proof that the CMA is required to meet is the civil standard of balance of probabilities,<sup>4</sup> nothing more and nothing less.<sup>5</sup>

### D. **The CMA's action**

2.9 The CMA finds that each of Pfizer and Flynn has separately infringed the Chapter II prohibition and Article 102 of the TFEU by imposing unfair selling prices, as set out in section 2.A and 2.B above. Throughout this Decision,

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<sup>2</sup> *Napp Pharmaceutical Holding Limited and Subsidiaries v Director General of Fair Trading* [2002] CAT 1 ('Napp'), [95] and [100]. See also, more recently, *Tesco Stores Limited v Office of Fair Trading* [2012] CAT 31 ('Tesco Stores'), [88].

<sup>3</sup> *Napp*, [100].

<sup>4</sup> *AH Willis and Sons Limited v Office of Fair Trading* [2011] CAT 13, [46] and [47]. See also, more recently, *Tesco Stores*, [88].

<sup>5</sup> *Re S-B* [2010] 2 WLR, paragraph 34. See also *Re H (Minors)* [1996] AC 563, paragraph 586; *Re D* (Northern Ireland) [2008] 1 WLR, paragraph 28; and *Re B* [2009] 1 AC 11, paragraph 13.

Pfizer's Infringements and Flynn's Infringements are collectively referred to as 'the Infringements'.

- 2.10 The CMA considers that each of Pfizer's Infringements and each of Flynn's Infringements is ongoing at the time of issue of this Decision. Accordingly, the CMA issues directions to Pfizer and Flynn to bring their respective Infringements to an end.
- 2.11 Section 36 of the Act provides that the CMA may impose a financial penalty on an undertaking which has intentionally or negligently committed an infringement of the Chapter II prohibition. The CMA has found that Pfizer and Flynn each committed their respective Infringements intentionally or, at the very least, negligently.
- 2.12 In imposing the penalties, the CMA has had regard to the seriousness of the Infringements and the need to deter not just the Parties, but also other undertakings more generally, from engaging in similar infringements in the future.

## **E. The Parties and attribution of liability**

- 2.13 The Chapter II prohibition and Article 102 of the TFEU apply to conduct on the part of one or more undertakings. The concept of undertaking has been held to cover '*every entity engaged in an economic activity, regardless of the legal status of the entity or the way in which it is financed*',<sup>6</sup> which includes any activity '*of an industrial or commercial nature*' consisting in '*offering goods and services on the market*'.<sup>7</sup>
- 2.14 This section sets out the details of all of the undertakings which the CMA finds liable for each of the Infringements, including, the joint and several liability of the parent company of the legal entities directly involved in each of the Infringements which form part of the relevant undertaking.

### **I. The relevant law on attributing liability**

- 2.15 It is settled in EU case law that the conduct of a subsidiary may be imputed to its parent company where, although having a separate legal personality, that subsidiary does not decide independently upon its own conduct on the

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<sup>6</sup> Judgment in *Höfner and Elser v Macrotron* C-41/90, EU:C:1991:161, paragraph 21.

<sup>7</sup> Judgment in *Commission v Italy* 118/85, EU:C:1987:283, paragraph 7.

market, but carries out, in all material respects, the instructions given to it by the parent company, having regard in particular to the economic, organisational and legal links between those two legal entities.<sup>8</sup> This is the case because, in such a situation, the parent company and its subsidiary form a single economic unit and therefore a single undertaking for the purposes of the relevant prohibitions.<sup>9</sup>

2.16 The Court of Justice of the EU has made it clear that, where a parent company has a 100% shareholding in a subsidiary which has infringed the European Union's competition rules:

- (a) that parent company is able to exercise '*decisive influence*' over the conduct of its subsidiary; and
- (b) there is a rebuttable presumption that the parent company does in fact exercise such decisive influence over the conduct of its subsidiary,

such that the two entities can be regarded as a single economic unit and thus jointly and severally liable.<sup>10</sup>

2.17 In such circumstances, it is sufficient for the CMA to prove that the subsidiary is wholly-owned by the parent company in order to presume that the parent exercises a decisive influence over the conduct of the subsidiary, subject to rebuttal of that presumption. It is for the party in question to rebut the presumption by adducing sufficient evidence to show that its subsidiary acts independently on the market.<sup>11</sup> This also applies to situations where the parent company indirectly holds a 100% ownership in a subsidiary, for example, via one or more intermediary companies.<sup>12</sup>

2.18 Additional indicia of decisive influence, other than the parent's shareholding in the subsidiary, may also be relied on.<sup>13</sup> Such indicia have been found to

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<sup>8</sup>Judgment in *Alliance One & Others v Commission* joined cases C-628/10 P and C-14/11 P, EU:C:2012:479 ('*Alliance One*'), paragraph 44 citing the judgment in *Akzo Nobel v Commission* C-97/08 P, EU:C:2009:536 ('*Akzo Nobel*'), paragraphs 58 to 59.

<sup>9</sup> *Alliance One*, paragraph 44, citing *Akzo Nobel*, paragraphs 58 to 59.

<sup>10</sup> *Alliance One*, paragraphs 46 to 48.

<sup>11</sup> *Alliance One*, paragraph 47, citing *Akzo Nobel*, paragraph 61.

<sup>12</sup> Judgment in *General Química and Others v Commission* C-90/09 P, EU:C:2011:21, paragraphs 86 to 87.

<sup>13</sup> *Akzo Nobel*, paragraphs 60 to 62; judgment in *Stora Kopparbergs Bergslags AB v Commission* C-286/98 P, EU:C:2000:630, paragraphs 23 and 27 to 29; and judgment in *AEG-Telefunken v Commission* C-107/82 P, EU:C:1983:293, paragraphs 49 to 50. See also *Durkan Holdings Ltd v Office of Fair Trading* [2011] CAT 6, [22].

include direct instructions being given by a parent to a subsidiary<sup>14</sup> or the two entities having shared directors.<sup>15</sup>

## II. ***The CMA's approach to assessing liability in this case***

- 2.19 In determining which legal entity or entities are liable for an infringement committed by an undertaking and, therefore, if applicable, subject to any financial penalty which the CMA may impose, it is necessary to identify the legal and/or natural persons who form part of the undertaking in question.
- 2.20 For each of the Infringements, the CMA has first identified the legal entity directly involved in the Infringement during the Relevant Period. It has then determined whether liability for the Infringement should be shared with another legal entity, in which case each legal entity's liability will be joint and several.
- 2.21 Where a company had the ability to exercise decisive influence, whether directly or indirectly, over the commercial policy of a legal entity which was directly involved in an Infringement, the CMA has exercised its discretion as to whether to propose to find that company jointly and severally liable with the latter.
- 2.22 The Parties to which this Decision is addressed are set out in paragraph 1.1 above. They comprise:
- the legal entities directly involved in the Infringements during the relevant period; and
  - the legal entities which the CMA finds had the ability to and did, in fact, exercise decisive influence over a legal entity directly involved in the relevant Infringements during the Relevant Period.
- 2.23 Where more than one legal entity is named in respect of a particular Party, the CMA considers that they form part of the same undertaking and should be held jointly and severally liable for the relevant Infringements and, if applicable, any financial penalty imposed by the CMA.

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<sup>14</sup> Judgment in *ICI Limited v Commission* C-48/69, EU:C:1972:70, paragraphs 132 to 133.

<sup>15</sup> *Sepia Logistics Limited v Office of Fair Trading* [2007] CAT 13, [77] to [80].

### III. ***The Parties***

#### a. ***Pfizer***

##### i. *Summary*

2.24 The CMA addresses this Decision to the following entities:

(a) Pfizer Limited;<sup>16</sup> and

(b) Pfizer Inc.<sup>17</sup>

2.25 Pfizer Limited is an indirectly wholly-owned subsidiary of Pfizer Inc in the United Kingdom.<sup>18</sup> It is managed on an integrated basis with other Pfizer Inc group companies.<sup>19</sup> The principal activities of Pfizer Limited are the discovery, development, manufacture, marketing, and sale of pharmaceutical products.<sup>20</sup>

2.26 Pfizer Inc is a research-based, global biopharmaceutical company. Its global portfolio includes medicines and vaccines, as well as consumer healthcare products.<sup>21</sup>

2.27 The CMA finds these legal entities jointly and severally liable for Pfizer's Infringements and for the resulting financial penalty.

##### ii. *Reasoning*

2.28 Pfizer Limited was directly involved in Pfizer's Infringements. Accordingly, the CMA attributes liability to Pfizer Limited for Pfizer's Infringements and for the resulting financial penalty.

2.29 For the duration of Pfizer's Infringements, Pfizer Limited was an indirectly wholly-owned subsidiary of Pfizer Inc.<sup>22</sup> Accordingly, Pfizer Inc had the power to exercise decisive influence over Pfizer Limited's commercial policy

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<sup>16</sup> Company number: 00526209, registered in the United Kingdom.

<sup>17</sup> Incorporated in the State of Delaware in the United States.

<sup>18</sup> See document 01357.1.

<sup>19</sup> See the annual accounts for Pfizer Limited for the year ended 30 November 2013 at page 2.

<sup>20</sup> See the annual accounts for Pfizer Limited for the year ended 30 November 2013 at page 4.

<sup>21</sup> See Pfizer 10-K for 2014, at page 1.

<sup>22</sup> Pfizer has confirmed to the CMA that Pfizer Limited has been 100% indirectly owned by Pfizer Inc. for the period, 1 January 2010 to 25 June 2015 and the CMA has no reason to believe that this position has changed subsequently; see document 01357.1.

and it can be presumed that it did in fact exercise decisive influence over Pfizer Limited's commercial policy for the duration of Pfizer's Infringements.

2.30 Pfizer has not submitted to the CMA that Pfizer Inc has not, in fact, exercised decisive influence over Pfizer Limited's commercial policy for the duration of Pfizer's Infringements.

2.31 Therefore, the CMA finds that Pfizer Inc formed part of the same undertaking for the duration of Pfizer's Infringements and attributes liability to Pfizer Inc on a joint and several liability basis with Pfizer Limited for Pfizer's Infringements and for the resulting financial penalty.

2.32 The CMA considers that Pfizer was and is engaged in an economic activity and, accordingly, finds that Pfizer is and was an undertaking for the purposes of the Chapter II prohibition and Article 102 of the TFEU throughout the Relevant Period.

*b. Flynn*

*i. Summary*

2.33 The CMA addresses this Decision to the following entities:

(a) Flynn Pharma Limited;<sup>23</sup> and

(b) Flynn Pharma (Holdings) Limited.<sup>24</sup>

2.34 The CMA finds these legal entities jointly and severally liable for Flynn's Infringements and for the resulting financial penalty.

*ii. Reasoning*

2.35 Flynn Pharma Limited was directly involved in Flynn's Infringements. Accordingly, the CMA attributes liability to Flynn Pharma Limited for Flynn's Infringements and for the resulting financial penalty.

2.36 For the duration of Flynn's Infringements, Flynn Pharma Limited was a wholly-owned subsidiary of Flynn Pharma (Holdings) Limited. Accordingly, Flynn Pharma (Holdings) Limited can be presumed to have exercised

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<sup>23</sup> Company number: IE210742, registered in the Republic of Ireland.

<sup>24</sup> Company number: 05875486, registered in the United Kingdom.

decisive influence over Flynn Pharma Limited's commercial policy for the duration of Flynn's Infringements.

- 2.37 This presumption is further supported by the fact that two directors of Flynn Pharma (Holdings) Limited also sat on the board of Flynn Pharma Limited during the Relevant Period.<sup>25</sup>
- 2.38 Flynn has not submitted to the CMA that Flynn Pharma (Holdings) Limited has not in fact exercised decisive influence over Flynn Pharma Limited's commercial policy for the duration of Flynn's Infringements.
- 2.39 Therefore, the CMA finds that Flynn Pharma (Holdings) Limited formed part of the same undertaking for the duration of Flynn's Infringements and attributes liability to Flynn Pharma (Holdings) Limited on a joint and several liability basis with Flynn Pharma Limited for Flynn's Infringements and for the resulting financial penalty.
- 2.40 The CMA considers that Flynn was and is engaged in an economic activity and, accordingly, finds that Flynn is and was an undertaking for the purposes of the Chapter II prohibition and Article 102 of the TFEU throughout the Relevant Period.

## **F. The Investigation**

- 2.41 In this section, the CMA sets out a summary of the main steps and key events in its investigation of the matters that are the subject of this Decision (the 'Investigation').

### **I. *Origins of the Investigation***

- 2.42 The subject matter of this Decision was first brought to the CMA's attention by the DH in September 2012 and was subsequently raised with the CMA by a number of Clinical Commissioning Groups ('CCGs') and individual complainants both prior to, and during the course of, the Investigation.

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<sup>25</sup> [X] and [X] are directors of both companies. See the annual accounts for: (i) Flynn Pharma (Holdings) Limited for the year ending 31 March 2013, page 3; (ii) the annual accounts for Flynn Pharma (Holdings) Limited for the year ending 31 March 2014, page 3; (iii) the annual accounts for Flynn Pharma Limited for the year ending 31 March 2013, page 1; and (iv) the annual accounts for Flynn Pharma Limited for the year ending 31 March 2014, page 1. See, in this regard, *Sepia Logistics Limited v Office of Fair Trading* [2007] CAT 13, [77] to [80].



## II. ***Scope and commencement of the Investigation***

2.43 In May 2013, the CMA opened a formal investigation under the Act, having determined that it had reasonable grounds for suspecting that Pfizer and Flynn had infringed the prohibition imposed by section 2 of the Act (the 'Chapter I prohibition') and Article 101 of the TFEU and that Pfizer had infringed the Chapter II prohibition and Article 102 of the TFEU. In particular, the CMA had reasonable grounds for suspecting that:

- In respect of the Chapter I prohibition and Article 101 of the TFEU, there was, or had been at some time in the past, one or more agreements and/or concerted practices between Pfizer and Flynn which may have affected trade within the UK and/or between Member States which had as their object or effect the prevention, restriction or distortion of competition within the UK and the EU.
- In respect of the Chapter II prohibition and Article 102 of the TFEU, (a) the transfer to Flynn of Pfizer's UK MAs for phenytoin sodium capsules may have circumvented, or may have been designed to circumvent, the PPRS; and/or (b) the Pfizer supply prices and/or the price at which it sold its UK MA for phenytoin sodium capsules to Flynn may have been excessive and unfair.

2.44 In February 2014, the CMA extended the scope of the Investigation to include Flynn's pricing conduct under the Chapter II prohibition and Article 102 of the TFEU, having determined that the CMA had reasonable grounds for suspecting that Flynn had abused a dominant position by imposing excessive and unfair selling prices.

## III. ***Evidence gathered from the Parties prior to the issue of the SO***

2.45 In May 2013, the CMA requested information from each of Flynn and Pfizer under section 26 of the Act. At the same time, the CMA also requested documents from each of Flynn and Pfizer under section 27 of the Act and conducted onsite inspections of those documents.

2.46 The CMA requested information and/or documents from each of Flynn and Pfizer under section 26 of the Act on the following further occasions:

- Flynn: On 5 March 2014, 6 June 2014, 15 September 2014, 23 February 2015 and 2 June 2015.

- Pfizer: On 5 March 2014, 6 June 2014, 16 September 2014, 23 February 2015, 2 June 2015 and 25 June 2015.

#### **IV. *Evidence gathered from other sources prior to the issue of the SO***

- 2.47 During 2013, 2014 and 2015, the CMA requested information from a number of third parties, including: the Chief Pharmaceutical Officers of England, Ireland, Scotland and Wales; the DH; the MHRA; NICE; NHS Confederation; Dispensing Doctors' Association; Royal College of Physicians; Royal Pharmaceutical Society; Epilepsy Action; Epilepsy Scotland; Epilepsy Wales; Teva; NRIM; AAH Pharmaceutical Limited ('AAH'); Auden McKenzie (Pharma Division) Limited ('Auden McKenzie'); Asda Group Limited ('Asda'); Boots UK Limited ('Boots')<sup>26</sup>; Co-Op Healthcare Holdings Limited, Belfast Co-Operative Chemists Limited, National Co-Operative Chemists Limited (collectively the 'Co-Op')<sup>27</sup>; Day Lewis Plc ('Day Lewis'); Lloyds Pharmacy Limited ('Lloyds')<sup>28</sup>; WM Morrison Supermarkets Plc ('Morrison's'); L Rowland & Company (Retail) Limited ('Rowlands'); J Sainsbury Plc ('Sainsbury's')<sup>29</sup>; Superdrug Stores Plc ('Superdrug'); and Tesco Plc ('Tesco').
- 2.48 The CMA also met a number of third parties during the course of the Investigation, including the DH, the MHRA and NRIM.

#### **V. *Other contact with the Parties prior to the issue of the Statement of Objections***

- 2.49 Prior to the issue of the CMA's Statement of Objections ('SO'), the CMA met Flynn on 16 July 2013 and 29 July 2014, and the CMA met Pfizer on 20 August 2013 and 11 July 2014.
- 2.50 The CMA also provided Flynn and Pfizer with updates on the Investigation on 20 August 2013, 26 February, 6 June, 21 August 2014, 27 March and 11 May 2015.

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<sup>26</sup> Affiliated with Alliance Healthcare Distribution Limited ('Alliance') as Alliance Boots a wholesaler of pharmaceuticals.

<sup>27</sup> The Co-Op's pharmacy business was acquired by the Bestway Group – Bestway (Holdings) Limited in July 2014 and the pharmacies rebranded to 'Well' in February 2015.

<sup>28</sup> Owned by Celesio AG.

<sup>29</sup> In July 2016 Celesio AG, the owner of Lloyds Pharmacy, acquired all Sainsbury pharmacies and were rebranded as Lloyds Pharmacy effective from 1 September 2016.

2.51 [✂].

2.52 [✂].

## VI. ***Issue of the SO and the appointment of a Case Decision Group***

2.53 On 6 August 2015,<sup>30</sup> the CMA issued an SO to the Parties setting out its provisional findings. In the SO, the CMA set out the facts and the evidence on which it relied, the objections it raised in terms of the alleged infringements of the Chapter II prohibition and Article 102 of the TFEU, the action it proposed to take and its reasons for the proposed actions.

2.54 Following the issue of the SO, a Case Decision Group was appointed within the CMA to decide whether or not, based on the facts and evidence before it, and taking account of the Parties' representations, the legal test for establishing an infringement had been met, and whether the Investigation remained an administrative priority.<sup>31</sup>

2.55 Following the issue of the SO;

- Pfizer submitted written representations on the matters referred to in the SO on 20 November 2015 and oral representations on 21 January 2016; and
- Flynn submitted written representations on the matters referred to in the SO on 2 December 2015 and oral representations on 27 January 2016.

## VII. ***Further evidence gathered by the CMA following the representations on the SO***

2.56 Following the receipt of the Parties' written and oral representations on the SO, the CMA requested further information and/or documents from the Parties under section 26 of the Act on a number of further occasions:

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<sup>30</sup> On 15 September 2015, the CMA provided the Parties with amendments to the SO, principally regarding certain common cost calculations and footnote references. A consolidated (revised) SO was issued to the Parties on 17 September 2015.

<sup>31</sup> The role of the Case Decision Group is described in the [guidance on the CMA's investigation procedures in Competition Act 1998 cases \(CMA8, March 2014\)](#) ('CMA8'), paragraphs 9.11 and 11.30-11.34.

- Flynn: On 17 February 2016, 9 March 2016, 4 May 2016, 2 August 2016 and 23 August 2016.
- Pfizer: On 11 February 2016 and 2 August 2016.

2.57 The CMA also requested further information and/or documents from a number of third parties, including DH, the MHRA, NRIM, [Wholesaler 1], [Pharmacy 6] and [Pharmacy 3].

### VIII. *Issue of Draft Penalty Statements*

2.58 On 16 May 2016, the CMA issued a Draft Penalty Statement ('DPS') to each of Pfizer and Flynn. The DPSs set out the CMA's provisional decisions regarding the directions and financial penalties that it proposed to impose on Pfizer and Flynn respectively if the CMA were to reach an infringement decision against that Party. The CMA provided each Party with a non-confidential version of the other Party's DPS on 19 May 2016.

2.59 The Parties submitted written representations on their DPS to the CMA on 16 June 2016.

### IX. *Issue of Letters of Facts*

2.60 On 25 May 2016,<sup>32</sup> the CMA sent a Letter of Facts to both Flynn and Pfizer which identified additional evidence supporting the CMA's provisional findings, as set out in the SO, on which it proposed to rely.<sup>33</sup>

2.61 Flynn and Pfizer each submitted written representations to the CMA on the matters referred to in the Letter of Facts on 24 June 2016.

### X. *State of Play meetings prior to issue of the Decision*

2.62 The CMA held a state of play meeting with Pfizer on 13 October 2016 at which the CMA informed Pfizer that it expected to proceed towards findings of four infringements against Pfizer.

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<sup>32</sup> Revised versions of the Letter of Facts were sent on 27 May 2016 to both Flynn and Pfizer.

<sup>33</sup> For further detail on the procedure relating to a letter of facts, see CMA8, paragraph 12.27.

2.63 The CMA held a state of play meeting with Flynn on 20 October 2016 at which the CMA informed Flynn that it expected to proceed towards findings of four infringements against Flynn.

### 3. **FACTUAL BACKGROUND**

#### A. **Introduction**

3.1 This section sets out background relevant to the Infringements. The areas it covers include, in particular:

- the treatment of epilepsy;
- the background to, development, and product characteristics of phenytoin sodium capsules;
- the supply of phenytoin sodium capsules to the NHS including how phenytoin sodium capsules are prescribed and dispensed to patients;
- the pricing framework for pharmaceuticals in the UK;
- Pfizer's and Flynn's pricing during the Relevant Period;
- the chronology of events leading up to the Infringements including Pfizer's and Flynn's dealings with the DH and other NHS bodies;
- the reaction of the DH and CCGs to the Pfizer's and Flynn's pricing; and
- the background and pricing of Tablets, an alternative form of phenytoin sodium.

## B. Background on phenytoin sodium capsules

### Summary

The key evidence in the following section shows that:

- Phenytoin sodium capsules are a medicine which is primarily used to treat epilepsy. Epilepsy is a serious condition with potentially significant and life-changing implications.
- In the UK, licences for the supply of phenytoin sodium capsules are currently held by two companies; namely, Flynn and NRIM. Phenytoin sodium capsules are available in four different strengths - 25mg, 50mg, 100mg and 300mg. Flynn supplies all four strengths of phenytoin sodium capsules. NRIM only supplies the 100mg strength.
- Phenytoin sodium capsules are characterised by their having a '*narrow therapeutic index*'. Clinical guidance states that patients being treated with phenytoin sodium capsules should not normally be moved onto another medicine, including phenytoin sodium capsules which are manufactured by a different company. This is known as 'Continuity of Supply'.
- Phenytoin sodium capsules are an old medicine that has been on the market for around 80 years and which has been superseded by a number of newer and more effective products. Very few new patients are now prescribed phenytoin sodium capsules.
- Despite being an old medicine, the importance of maintaining Continuity of Supply of phenytoin sodium capsules means that many patients who were previously stabilised on this treatment continue to be prescribed (and depend on) phenytoin sodium capsules.
- Pfizer purchased the MAs for phenytoin sodium capsules in 2000. On 23 September 2012, Pfizer stopped supplying phenytoin sodium capsules in the UK having transferred its MAs for these products to Flynn. Flynn began selling phenytoin sodium capsules on 24 September 2012. NRIM began selling its own version of phenytoin sodium capsules in March 2013.

## I. ***Epilepsy***

- 3.2 Phenytoin sodium capsules are a medicine which is primarily used to treat epilepsy.<sup>34</sup>
- 3.3 Epilepsy is not a single condition but is a complicated group of conditions varying in severity. A person suffering from epilepsy is prone to recurrent epileptic seizures.<sup>35</sup> An epileptic seizure is a transient occurrence which results from changes to the electrical activity in the brain.<sup>36</sup>
- 3.4 Epilepsy has been estimated to affect between 362,000 to 415,000 people in England, although accurate estimates are difficult to achieve because identifying people who may have epilepsy is difficult.<sup>37</sup> Incidence is estimated to be 50 per 100,000 persons per year and the prevalence of active epilepsy in the UK is estimated to be 5 to 10 cases per 1,000.<sup>38</sup>
- 3.5 Epilepsy is a serious condition. Its symptoms (seizures) can have significant and life-changing implications for an individual, including:
- (a) Risk of injury.
  - (b) Impact on work and home life.
  - (c) Loss of self-confidence.
  - (d) Suspension of driving licence.<sup>39</sup>

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<sup>34</sup> Phenytoin sodium can also be used for the treatment of seizures occurring during or following neurosurgery and/or severe head injury and trigeminal neuralgia. However, the volumes of phenytoin sodium capsules used to treat indications other than epilepsy are small. In particular, phenytoin sodium is not a first-line treatment for trigeminal neuralgia. In fact, phenytoin is not licenced for the treatment of trigeminal neuralgia and it should only be used as second-line therapy if another medicine, carbamazepine, is ineffective or patients are intolerant to carbamazepine. In addition, trigeminal neuralgia is a rare condition. It is estimated that it affects around 0.1% of the UK population. For treatment following neurosurgery or a severe head injury, phenytoin sodium is more likely to be used in a hospital setting rather than in primary care. See also documents 00248.2, PD 35 and PD 36.

<sup>35</sup> See document PD13, page 107.

<sup>36</sup> See document PD13, page 107.

<sup>37</sup> See document PD13, page 7.

<sup>38</sup> See document PD13, page 7.

<sup>39</sup> Guidance issued by the Drivers Medical Unit of the Driver and Vehicle Licensing Agency (DVLA) recommends that patients who have a first or single epileptic seizure must not drive for six months (5 years in the case of larger goods or passenger carrying vehicles). See also document PD 25.



3.6 In extreme situations seizures can also result in 'sudden unexpected (or unexplained) death in epilepsy'.<sup>40</sup>

a. ***The treatment of epilepsy***

3.7 Medicines used to treat epilepsy are known as AEDs. These are taken daily to prevent the recurrence of epileptic seizures.<sup>41</sup>

3.8 NICE has estimated that two-thirds of people with active epilepsy have their epilepsy controlled satisfactorily with AEDs.<sup>42</sup>

3.9 The choice of which AED to use will depend on the type of seizure experienced, the epilepsy syndrome diagnosed, whether the patient is taking any other medication and whether the patient has any other additional diseases or conditions, known as co-morbidities.<sup>43</sup> Clinical guidelines indicate the different first-line treatments which should be prescribed in the first instance.<sup>44</sup> If the chosen first-line treatment is not effective or not tolerated, generally an alternative first-line or second-line treatment will then be used.<sup>45</sup>

3.10 Only one AED (rather than a combination of them) should be prescribed wherever possible.<sup>46</sup> For reasons detailed further at sections 3.B.II.c. and 3.B.II.d. below, changing from one AED to another (where it does occur) should be approached with caution, with the first medicine being slowly withdrawn only when the new regime has been established.<sup>47</sup> Combination

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<sup>40</sup> See document PD13, page 113. See also document 00267, page 3, which states '*It could also increase their risk of sudden unexpected death in epilepsy*' and document 00325.1, page, which states '*Risks are more seizures with the risk of injury and sudden death (very rare) or even more intolerable side effects*'. Both quotes were provided to the CMA in response to a question regarding the circumstances under which a health professional would switch a patient from one AED to another and the benefits and risks associated with switching.

<sup>41</sup> ATC third level class N03A (*Antiepileptics*). EPhMRA class N3A (*anti-epileptics*) and BNF Guidelines at 4.8 (*antiepileptic drugs*). (See documents PD 28 and PD 29).

<sup>42</sup> See document PD13, page 7. There are other possible forms of treatment, including surgery.

<sup>43</sup> See document PD13, page 10.

<sup>44</sup> See document PD13, page 78. See also PD 29.

<sup>45</sup> See document PD13, page 24.

<sup>46</sup> Commonly referred to as monotherapy; as compared to combination therapy, which involves a patient being treated with a combination of medicines.

<sup>47</sup> See document PD 29. It also states that when monotherapy with a first-line antiepileptic drug has failed, monotherapy with a second drug should be tried; the diagnosis should be checked before starting an alternative drug if the first drug showed lack of efficacy. Combination therapy with two or more antiepileptic drugs may be necessary, but the concurrent use of antiepileptic drugs increases the risk of adverse effects and drug interactions. If combination therapy does not bring about worthwhile benefits, the patient should be moved back

or adjunctive therapy is only recommended if treatment by a single AED is ineffective.<sup>48</sup>

- 3.11 The Anatomical Therapeutic Chemical ('ATC') classification system developed by the World Health Organisation (the 'WHO') divides active substances into groups according to their composition and therapeutic properties.<sup>49</sup> At the first level, the system divides medicines into fourteen main groups based on the physiological organ or system on which they act. The second level divides medicines into pharmacological/therapeutic subgroups. The third and fourth levels divide medicines into chemical/pharmacological/therapeutic subgroups. The fifth level is the chemical substance.
- 3.12 In the ATC system, AEDs are listed as the third-level class N03A (Antiepileptics).<sup>50</sup> Phenytoin belongs to the fourth-level class N03AB Hydantoin derivatives.<sup>51</sup> Combinations of phenytoin and barbiturates are classified in this group.
- 3.13 Under classifications published by the British National Formulary (the 'BNF')<sup>52</sup>, phenytoin falls under section 4.8 (antiepileptic drugs). Within 4.8, the relevant subsections are 4.8.1 (control of the epilepsies) and 4.8.2 (drugs used in status epilepticus)<sup>53</sup> and 4.8.3 (febrile convulsions).<sup>54</sup>

## II. ***Phenytoin sodium***

3.14 Phenytoin sodium is available in several formulations:

- phenytoin sodium capsules;

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to the regimen (monotherapy or combination therapy) that provided the best balance between tolerability and efficacy.

<sup>48</sup> See document PD13, page 24.

<sup>49</sup> See document PD 27.

<sup>50</sup> See document PD 28.

<sup>51</sup> Other antiepileptics are divided at this level between the seven remaining fourth level classes, which are Barbiturates and derivatives (N03AA), Oxazolidine derivatives (N03AC), Succinimide derivatives (N03AD), Benzodiazepine derivatives (N03AE), Carboxamide derivatives (N03AF), Fatty acid derivatives (N03AG) and Other antiepileptics (N03AX).

<sup>52</sup> The BNF is a joint publication of the British Medical Association and the Royal Pharmaceutical Society. It is published biannually under the authority of a Joint Formulary Committee which comprises representatives of the two professional bodies, the UK Health Departments, the MHRA, and a national guideline producer.

<sup>53</sup> Status epilepticus is an epileptic seizure of greater than five minutes or more than one seizure within a five minute period without the person returning to normal between them.

<sup>54</sup> A febrile seizure is a convulsion that occurs in some children with a high temperature (fever).

- phenytoin sodium tablets; and
- 'Epanutin Ready Mixed Parenteral 250mg/5ml solution for Injection or Infusion', which is Pfizer's solution for injection or infusion designed for treating severe epileptic seizures.<sup>55</sup>

a. **Phenytoin sodium capsules**

3.15 In the UK, licences for the supply of phenytoin sodium capsules are currently held by two companies, Flynn and NRIM.

3.16 Phenytoin sodium capsules are available in the UK in four different strengths – 25mg, 50mg, 100mg and 300mg. Flynn holds a licence for all four capsule strengths whereas NRIM holds a licence for 100mg only. 100mg capsules account for the majority of UK sales, as shown by table 3.1 below.

**Table 3.1: Proportion of phenytoin sodium capsules by capsule strength.**

	2011	2012	2013	2014	2015
<b>25mg</b>	6%	6%	6%	6%	6%
<b>50mg</b>	12%	12%	13%	13%	13%
<b>100mg</b>	74%	74%	73%	73%	73%
<b>300mg</b>	8%	8%	8%	8%	8%

Notes: All calculations are based on prescription cost analysis ('PCA') data for England, Wales, Northern Ireland and Scotland. See documents PD 38, PD 37, PD 33 and PD 39  
The PCA data for England, Wales and Northern Ireland are presented by calendar year, however, the PCA data for Scotland is presented by financial year.

3.17 In the UK, 25mg, 50mg and 300mg capsules are typically sold in packs of 28 capsules while 100mg capsules are typically sold in packs of 84 capsules.<sup>56, 57</sup>

3.18 Phenytoin sodium capsules have been available in the UK from different sources at different times. In particular:

<sup>55</sup> See document 00086.1. Pfizer also supplies *Epanutin* Infatabs 50mg Chewable Tablets ('Infatabs') which are chewable tablets designed for infants and *Epanutin* 30mg/5ml Oral Suspension designed to be administered orally as a liquid. However, these products are phenytoin based and not phenytoin sodium.

<sup>56</sup> See, for example, document 00086.1, pages 11 to 12. In contrast, 100mg capsules are typically sold in other EU Member States (where Pfizer-manufactured phenytoin sodium capsules are sold), in packs of 100 capsules (See, for example, document 00505.40).

<sup>57</sup> [Not used]

- From 2000 to September 2012, phenytoin sodium capsules were available in the UK either directly from Pfizer in the UK or as Parallel Imports. In both cases the product was supplied under the brand name *Epanutin* and was manufactured by Pfizer.
- Between September 2012 and April 2013, Pfizer-manufactured phenytoin sodium capsules were available either from Flynn (under the name Phenytoin Sodium Flynn Hard Capsules) or as Parallel Imports.
- In April 2013, NRIM started to supply a different version of phenytoin sodium capsules in the UK (under the name *Phenytoin Sodium NRIM Capsules*), but only as 100mg capsules.

3.19 Thus, from April 2013 until the present time, phenytoin sodium capsules have been available in the UK as:

- Flynn's 25mg, 50mg, 100mg and 300mg capsules (which are manufactured by Pfizer), sold as Phenytoin Sodium Flynn Hard Capsules (i.e. Flynn's Products);
- NRIM's 100mg capsules, sold as Phenytoin Sodium NRIM Capsules ('NRIM's Product'); and
- Parallel Imports (principally 100mg capsules but also small volumes of 25mg, 50mg and 300mg capsules) which are manufactured by Pfizer.

**b. *The development and history of phenytoin sodium capsules***

3.20 Phenytoin was originally synthesized in 1908 by a German scientist named Heinrich Blitz<sup>58</sup> and was subsequently developed in the US by a pharmaceutical company named Parke-Davis as an AED due to its anticonvulsant properties.<sup>59</sup> Phenytoin became the first widely available treatment for epilepsy.<sup>60</sup>

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<sup>58</sup> See document PD 1 (in German), p1379–1393.

<sup>59</sup> See document PD 2, p1003–1015. See also document PD 4, p363–367.

<sup>60</sup> See document PD 26.

- 3.21 From 1938, Parke-Davis marketed phenytoin sodium capsules under the *Epanutin* brand in the UK and in several other countries worldwide.<sup>61</sup> *Epanutin* was registered as a trademark in the UK in 1938.<sup>62</sup>
- 3.22 In 1970, Parke-Davis was acquired by Warner Lambert.
- 3.23 In 2000, Pfizer acquired Warner Lambert<sup>63</sup> and consequently became the owner of *Epanutin*.<sup>64</sup> From 2000 to September 2012, Pfizer sold phenytoin sodium capsules in the UK under the brand name *Epanutin*. *Epanutin* had come off patent before Pfizer purchased it and Pfizer has not invested in the development of the product.
- 3.24 On 23 March 2012 Flynn acquired Pfizer's UK MAs and received approval to de-brand (or genericise) *Epanutin* on 29 August 2012.<sup>65</sup> Pfizer ceased selling *Epanutin* on 23 September 2012 and Flynn started selling its phenytoin sodium capsules from 24 September 2012. As part of its acquisition of the MA, Flynn entered into three agreements (together, 'the Agreements') with Pfizer:
- An asset sale agreement between Pfizer and Flynn dated 27 January 2012 ('the Asset Sale Agreement') – to arrange for the transfer of Pfizer's *Epanutin* UK MAs to Flynn. Flynn paid Pfizer a nominal fee [X] for the MAs.<sup>66</sup>
  - An exclusive supply and purchase agreement between Pfizer and Flynn dated 17 April 2012 ('the Exclusive Supply Agreement') – which provided for Pfizer to supply Flynn with *Epanutin*.<sup>67</sup>
  - A quality technical agreement between Pfizer and Flynn dated 11 June 2012 ('the Quality Agreement') – relating to the production of finished packs of phenytoin sodium capsules from Pfizer to Flynn.<sup>68</sup>

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<sup>61</sup> In certain countries, including the US, the brand was named Dilantin. See Blair, Bailey and McGregor, 'Treatment of Epilepsy with *Epanutin*', *Lancet*, Volume 234, Issue 6050, 12 August 1939, page 363 (See PD 4).

<sup>62</sup> See document PD 3.

<sup>63</sup> See document PD 26.

<sup>64</sup> Pfizer documents state that the MAs for *Epanutin* capsules were transferred from Warner Lambert to Pfizer Limited in the period February to March 2004, see document 00141.465.

<sup>65</sup> The terms 'de-brand' and 'genericise' are used interchangeably throughout this Decision to refer to the process of withdrawing the brand name and varying the product name such that a generic name is used.

<sup>66</sup> See document 00145.236.

<sup>67</sup> See document 00145.64

<sup>68</sup> See document 00145.299.

c. ***The product characteristics of phenytoin sodium capsules***

3.25 Phenytoin sodium capsules and a number of other AEDs are particularly characterised by having a NTI.<sup>69</sup> Although there is no universally accepted definition of a medicine that has an NTI, the MHRA has stated that [a] *definition [of NTI] that has some value is a drug for which the ratio between the dose associated with toxicity and the normal therapeutic dose is [less than two]*.<sup>70</sup> This means that there is a small difference between the blood level of the drug that is necessary to achieve therapeutic efficacy and the blood level that, once exceeded, might result in adverse events and/or drug toxicities.<sup>71</sup> It is therefore very important for epilepsy patients to achieve a high degree of stability of the drug level in their blood because even a small change in blood level may lead to a seizure or toxic side effects.

3.26 The MHRA has explained that:<sup>72</sup>

*'Phenytoin should be introduced in small dosages with gradual increments until control is achieved or until toxic effects appear. Dosage needs to be individualised as there may be wide inter-individual variability in phenytoin serum levels with equivalent dosage. Dose limiting undesirable effects are often seen at doses required for optimal efficacy.'*

3.27 Phenytoin is further characterised by a concept known as non-linear pharmacokinetics. This means that the relationship between dose and plasma-drug concentration (that is, the level of the drug in the blood stream) is non-linear such that a small change in dose can result in disproportionately large change in plasma concentrations. As a result, small dosage changes in some patients may produce large changes in plasma-drug concentration. This can result in acute toxic side effects where the dosage is increased. Similarly, a few missed doses or a small reduction in drug absorption may result in therapeutic failure, which can cause loss of seizure control or other adverse effects.<sup>73</sup>

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<sup>69</sup> See BNF Guidance.

<sup>70</sup> See document PD 18, page 6.

<sup>71</sup> See PD 18, page 7.

<sup>72</sup> See PD 18, page 7.

<sup>73</sup> See BNF Guidance and document 00248.2.

d. **Clinical guidance on anti-epileptic drugs including phenytoin sodium capsules**

3.28 NICE has published a number of clinical guidelines on AEDs.

3.29 In January 2012, NICE published CG137, The epilepsies: the diagnosis and management of the epilepsies in adults and children in primary and secondary care ('CG137').<sup>74</sup>

3.30 CG137 recommended 'continuity of supply' of a particular manufacturer's product for epilepsy patients:

*'Consistent supply to the child, young person or adult with epilepsy of a particular manufacturer's AED preparation is recommended unless the prescriber, in consultation with the child, young person, adult and their family and/or carers as appropriate, considers that this is not a concern.'*<sup>75</sup>

3.31 Throughout this Decision, the term 'Continuity of Supply' is used to refer to this principle; i.e. that patients who are stabilised on certain categories of AED (including phenytoin sodium capsules) should continue to be treated with the same formulation (for example, the tablet or the capsule formulation) and the same preparation (that is, a particular manufacturer's preparation) of that particular AED.

3.32 The reason for this recommendation was because different preparations – that is, different manufacturers' versions of an AED – may have different bioavailability or pharmacokinetic profiles:

*'Different preparations of some AEDs may vary in bioavailability or pharmacokinetic profiles and care needs to be taken to avoid reduced effect or excessive side effects.'*<sup>76</sup>

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<sup>74</sup> See document PD 13 and document PD 5.

<sup>75</sup> See document PD13, page 24.

<sup>76</sup> See document PD13, page 24.

- 3.33 These guidelines updated and replaced the earlier NICE guidance from 2004<sup>77</sup> and are also consistent with guidance published by Scottish Intercollegiate Guidelines Network ('SIGN') in April 2003.<sup>78</sup>
- 3.34 In July 2013, an ad hoc expert group of the Commission on Human Medicines ('CHM') made recommendations on issues relating to brand/generic prescribing and switching between formulations for AEDs. A report summarising the recommendations of the CHM was published by the MHRA (the 'CHM Report').<sup>79</sup> In particular, the CHM found that:
- a number of published studies on the issue of potential harm arising from generic substitution of AEDs did not show clear evidence of actual harm arising from switching formulations. In the CHM's view, however, the lack of robust evidence of harm did not exclude the possibility that significant harm may sometimes occur, given the inherent limitations in the design of the mostly observational studies;
  - in general terms, there was a need to maintain Continuity of Supply of a specific product for certain AEDs;
  - Continuity of Supply from the same manufacturer was the key issue, as opposed to whether the product was branded or a generic;
  - AEDs should be categorised according to the risk associated with switching between formulations;
  - Phenytoin sodium was allocated to 'Category 1', which raise '*definite concerns*' and '*need specific prescribing, supply and dispensing measures to ensure consistent supply of a particular product*'.<sup>80</sup>
- 3.35 Following the CHM's recommendations, the MHRA took the unusual step<sup>81</sup> of publishing its own guidance on 11 November 2013 ('MHRA Guidance').<sup>82</sup>

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<sup>77</sup> 'CG20', paragraph 4.8.8: '*Changing the formulation or brand of AED is not recommended because different preparations may vary in bioavailability or have different pharmacokinetic profiles and, thus, increased potential for reduced effect or excessive side effects*'.

<sup>78</sup> Document PD 30, page : '*Formulations of AEDs are not interchangeable and generic substitution should not be employed*'.

<sup>79</sup> See document PD18

<sup>80</sup> See document PD18.

<sup>81</sup> See document 00400.1, paragraph 29.

<sup>82</sup> See document PD 19



3.36 The MHRA Guidance essentially repeated and reinforced the recommendation to ensure Continuity of Supply for AEDs. Consistent with the CHM recommendations, the MHRA Guidance distinguished between three groups of AEDs which were identified with relation to the risks of switching between products. Phenytoin<sup>83</sup> was categorised as a Category 1 drug and for this category of AEDs the MHRA Guidance states:

*'Category 1 – Phenytoin, carbamazepine, phenobarbital, primidone*

*For these drugs, doctors are advised to ensure that their patient is maintained on a specific manufacturer's product'<sup>84</sup>*

3.37 The MHRA Guidance also provided specific advice for prescribers, dispensers and patients regarding all AEDs.

3.38 For prescribers, the MHRA Guidance recommended that:

*'If a patient should be maintained on a specific manufacturer's product, this should be prescribed either by specifying a brand name or by using the generic drug name and name of the manufacturer (marketing authorisation holder).'*

3.39 For dispensers, the MHRA Guidance recommended that:

*'Dispensing pharmacists should ensure the continuity of supply of a particular product when the prescription specifies it. If the prescribed product is unavailable, it may be necessary to dispense a product from a different manufacturer to maintain continuity of treatment of that AED. Such cases should be discussed and agreed with both the prescriber and patient (or carer).*

*Usual dispensing practice can be followed when a specific product is not stated.'*

3.40 For patients, the MHRA Guidance recommended that:

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<sup>83</sup> All forms of phenytoin were covered by this, including the Pfizer-manufactured phenytoin sodium capsules, NRIM's Product and Tablets.

<sup>84</sup> See document PD19. This recommendation in the MHRA Guidance followed on from and was consistent with the recommendation in the CHM Report that *'in general terms there was a need to maintain continuity of supply of a specific product for certain AEDs. The specific product could be either a branded product or a generic. Continuity of supply from the same manufacturer was the key issue, rather than whether the product was branded or generic.'* [Emphasis in original] (See document PD 18, page 3).

*'Patients should take careful note of the name and manufacturer of their antiepileptic medicine and should check with their doctor or pharmacist if they are dispensed an unfamiliar medicine.'*

3.41 The CHM also wrote to healthcare professionals on 11 November 2013 to draw their attention to the MHRA Guidance<sup>85</sup> and both CG137<sup>86</sup> and the BNF<sup>87</sup> were updated to include the MHRA Guidance. While the MHRA Guidance essentially repeated and reinforced the recommendation to ensure Continuity of Supply is maintained, in practice the MHRA Guidance further strengthened perceptions amongst pharmacies that different preparations of phenytoin sodium capsules are not substitutable.<sup>88</sup>

3.42 The particular relevance of the principle of Continuity of Supply to this Decision is set out in further detail in sections 3.C.II.d. and 4.B.IV. below.

**e. *The patient base of phenytoin sodium capsules***

3.43 Phenytoin sodium has been superseded by a number of newer medicines with improved efficacy, fewer side effects and/or better safety profiles. This has meant that older drugs like phenytoin sodium are not the first - or second - choice treatment for epilepsy.<sup>89</sup> As a result, in any given period, very few patients are newly prescribed phenytoin sodium capsules.

3.44 While the precise number of epilepsy patients that are prescribed phenytoin sodium capsules for the first time is unknown,<sup>90</sup> from the following evidence the CMA has concluded that the numbers are very small:

- (a) The Chief Pharmaceutical Officer for England told the CMA that phenytoin is '*Never [prescribed] for a newly diagnosed patient now*' except where the patient is given phenytoin intravenously while in

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<sup>85</sup> See [www.mhra.gov.uk/home/groups/comms-ic/documents/websiteresources/con335045.pdf](http://www.mhra.gov.uk/home/groups/comms-ic/documents/websiteresources/con335045.pdf).

<sup>86</sup> (See document PD 13: CG137 now states '*In November 2013, the MHRA issued new advice about oral AEDs and switching between different manufacturers' products of a particular drug. Following a review of the available evidence, the CHM has classified AEDs into 3 categories depending on the level of potential concerns related to switching between different manufacturers' products. Consult the MHRA advice for more information'* (see PD 13a), pages 63 and 149; and paragraph 1.9.1.4).

<sup>87</sup> The BNF entry reads '*Category 1 Phenytoin, carbamazepine, phenobarbital, primidone. For these drugs, doctors are advised to ensure that their patient is maintained on a specific manufacturer's product'* (see [www.evidence.nhs.uk/formulary/bnf/current/4-central-nervous-system/48-antiepileptic-drugs/481-control-of-the-epilepsies](http://www.evidence.nhs.uk/formulary/bnf/current/4-central-nervous-system/48-antiepileptic-drugs/481-control-of-the-epilepsies)).

<sup>88</sup> See section 4.B.IV.b.iv.

<sup>89</sup> CG137: document PD 13; and document 00086.1.

<sup>90</sup> See document 01792.

hospital and then could be transferred to tablet form if the drug is still required.<sup>91</sup>

- (b) The Royal College of Physicians told the CMA that *'Phenytoin is very rarely used now'*.<sup>92</sup>
- (c) NICE guidance does not advise or recommend phenytoin as a first-line AED. It is listed as an adjunctive treatment for only one indication (convulsive status epilepticus, and even then, by intravenous route only).<sup>93</sup> It is also not recommended at all for the treatment of three of the eight different seizure types.<sup>94</sup>
- (d) Total volumes of phenytoin sodium capsules show a constant year-on-year decline (both before and during the Relevant Period), which is consistent with an established and declining customer base. The evidence available to the CMA does not suggest any significant level of increased demand from newly diagnosed patients.<sup>95</sup>
- (e) Pfizer told the CMA that *'given the age of phenytoin-based products and the number of AEDs with better benefit-risk profiles now available to patients, phenytoin products continue to be established products that are declining in usage'*.<sup>96</sup>
- (f) In its oral representations on the SO, Pfizer asserted that new patients account for *'between 2 and 5 per cent of patients'*.<sup>97</sup> Pfizer subsequently clarified that this figure was an internal estimate for which there was no available data.<sup>98</sup> Pfizer tried to verify the above estimate by reference to the QuintilesIMS<sup>99</sup> ('IMS') Medical Data Index.<sup>100</sup> Based on Pfizer's interpretation of that data, the CMA estimates that between 1% and 2.9% of phenytoin sodium prescriptions in the quarterly periods covered (2013 Q4 to 2015 Q3) would be classified as being for new patients.<sup>101</sup> However, interpretation of some of the data headings used

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<sup>91</sup> See document 00275.1.

<sup>92</sup> See document 00325.1 at Q6 (ii).

<sup>93</sup> See document PD 13, page 80.

<sup>94</sup> See document PD 13, pages 78 and 79.

<sup>95</sup> See figure 4.7 below. See also for example [www.nhsbsa.nhs.uk/PrescriptionServices/3494.aspx](http://www.nhsbsa.nhs.uk/PrescriptionServices/3494.aspx).

<sup>96</sup> See document 00519.2, page 16.

<sup>97</sup> See documents 01757.1 and 01720.1 (question 13).

<sup>98</sup> See document 01792.

<sup>99</sup> Formerly known as IMS Health.

<sup>100</sup> See documents 01794.1, 01928.2, 01928.3.

<sup>101</sup> See document 01928.2 and 01794.1

(for example, 'Change of Drug') is not straightforward, and translating the data into an annual figure would require a number of assumptions to be made.<sup>102</sup> The CMA therefore treats this evidence with a high degree of caution, but in any event considers that it is consistent with the finding that new patient numbers are small.

- (g) Flynn told the CMA that one of the factors that it took into account in determining its pricing was *'the declining demand for phenytoin as an AED in light of unfavourable guidance and supercession by other products that are regarded as more effective or safer'*.<sup>103</sup>
- (h) Flynn told the DH that *'The drug is no longer first-line or even recognised as adjunctive therapy in the treatment or management of any specific epilepsy seizure types. Indeed current advice (NICE CG137, January 2012) specifically discourages its use in certain instances. [...] Notwithstanding new guidance and the availability of newer drug treatments, many patients continue to be prescribed phenytoin chronically and some new patients may be newly prescribed it in the future. It is our view that the declining usage observed in the current year (10-15% decrease over 2011) will continue in light of current treatment advice and the emergence of newer more effective, and albeit more expensive, drug treatment options'*.<sup>104</sup>
- (i) NRIM told the CMA that *'The market size for the products [...] is continuously declining and will continue to do so. This is because Phenytoin Sodium capsules are an old product which is only rarely prescribed to new patients, as there are new, more recently developed AED products available in the UK [...] Due to the age demographic of patients stabilised on Phenytoin Sodium capsules, and the fact that there are hardly any new patients who are prescribed and are stabilised on the Phenytoin Sodium capsules, the market in the UK for this product is in a steady decline'*.<sup>105</sup>

3.45 Notwithstanding the above, sales to patients stabilised on phenytoin sodium capsules are still significant. The CMA estimates that there are around

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<sup>102</sup> Flynn raised the same concerns about the reliability of the data set. See document 02077.1.

<sup>103</sup> See document 00505.1, paragraph 28.1(a).

<sup>104</sup> See document 00367.18.

<sup>105</sup> See document 00512.2, page 10. See also document 00474.1, paragraph 32: *'Phenytoin is very rarely prescribed now to new patients as there are large numbers of better drugs available to a Doctor to treat Epilepsy'*.

48,000 patients taking phenytoin sodium capsules in the UK<sup>106</sup> which equates to over 10% of epilepsy patients.<sup>107</sup> This is principally due to the NTI and the applicable prescribing guidance in place which advises that patients who are stable on phenytoin sodium capsules should not normally be switched to other AEDs.

**f. Phenytoin sodium tablets**

- 3.46 Phenytoin sodium is also available in a tablet formulation (referred to in this decision as 'Tablets').
- 3.47 Tablets are supplied in the UK by Teva,<sup>108</sup> which is the main supplier; Wockhardt UK Limited<sup>109</sup> ('Wockhardt'); and Milpharm Limited ('Milpharm').<sup>110</sup> None of these firms manufacture or sell phenytoin sodium capsules. Tablets are generally available in 100mg dosage strength only.<sup>111</sup> Tablets have the same NTI as phenytoin sodium capsules and are subject to the same clinical guidance outlined above.
- 3.48 The total cost of Tablets in the UK to the NHS is around one-quarter of the total cost of phenytoin sodium capsules. In 2015, for example, the CMA calculates that the total cost of Tablets to the NHS was approximately £9 million, whereas phenytoin sodium capsules cost approximately £37 million.<sup>112</sup>
- 3.49 Further information on Tablets, including the structure of supply and pricing is set out at section 3.F. below.

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<sup>106</sup> Based on PCA data, the total volume of phenytoin sodium capsules dispensed in 2015 in DDD terms was 17,646,166. Dividing that figure by 365 days gives an estimate of 48,346 patients. See also document 00389.3.

<sup>107</sup> NICE has estimated that epilepsy affects between 362,000 and 415,000 people in England, see section 3.B.I.

<sup>108</sup> See document 00100.1.

<sup>109</sup> Teva informed the CMA that Actavis supplied the products supplied by Wockhardt. We have not been able to confirm this information. The MHRA states that Actavis' MAs were cancelled 2000 (see document 00248.3).

<sup>110</sup> Milpharm Ltd GUO is Aurobindo. Milpharm's MA for 100mg was granted 19/06/2012 (see document 00248.3) and its MA for 50mg was granted 12/07/2013 (see document 00822.1).

<sup>111</sup> Between January 2003 and August 2003, Teva supplied tablets in two dosages, 50mg and 100mg. Teva stopped manufacturing 50mg dosage due to difficulties associated with the manufacturing process. At this stage, Teva's sales of 50 mg Tablets accounted for less than 1% of its Tablets sales (Teva's MA for 50mg Tablets was cancelled on 30 October 2009). IMS prescription data shows that less than 15,000 50mg Tablets were dispensed in 2015 in the UK (see document 01754A.1).

<sup>112</sup> Volumes dispensed are available from the PCA data for England, Wales, Scotland and Northern Ireland. The Drug Tariff prices are published monthly at <http://www.nhsbsa.nhs.uk/PrescriptionServices/4940.aspx>.

## C. The supply of phenytoin sodium capsules in primary care

### Summary

The key evidence in the following section shows that:

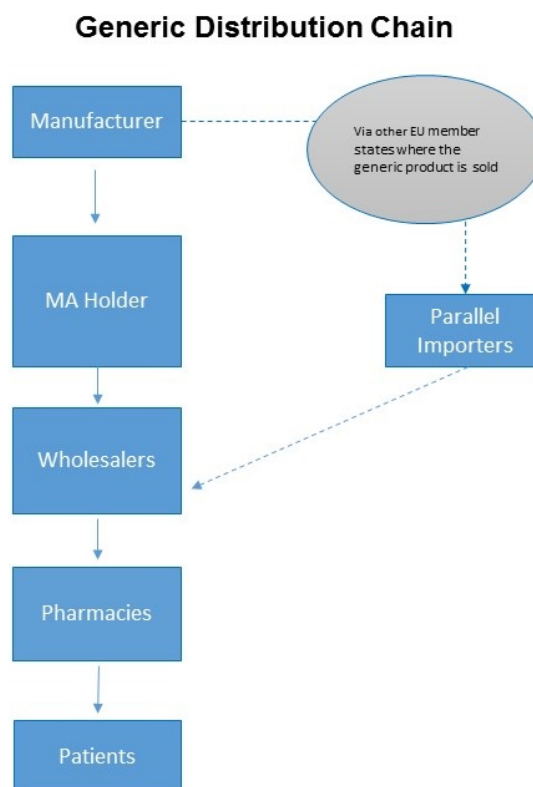
- While Flynn holds the MAs for the phenytoin sodium capsules it supplies, the products continue to be manufactured by Pfizer.
- The supply chain has not changed significantly since the MAs were transferred to Flynn. In particular, Pfizer continues to deliver the phenytoin sodium capsules to the same distribution company that it used when it was the MA holder. That company then delivers the phenytoin sodium capsules to Flynn's customers - just as it did for Pfizer. Flynn does not at any point take receipt of, or dispatch, Pfizer's Products.
- Prescribers (i.e. consultants or general practitioners ('GPs')) may write 'open' or 'closed' prescriptions. Open prescriptions allow a pharmacist to choose what brand or supplier's product should be dispensed. Closed prescriptions specify a particular brand or supplier's product that must be dispensed. Most prescriptions for phenytoin sodium capsules are open.
- Where a pharmacist receives an open prescription for phenytoin sodium capsules it should follow the relevant clinical guidelines, which emphasise the importance of the principle of Continuity of Supply .
- Most of the major pharmacy chains told the CMA that because of the clinical guidance that applies to phenytoin sodium capsules, they do not switch stabilised patients between different manufacturers' products. The two pharmacy groups that did switch patients, stopped doing so following the publication by the MHRA in November 2013 of new clinical guidance which reinforced the importance of maintaining Continuity of Supply for products with an NTI.
- Pharmacies are reimbursed by the NHS at the level published in the Drug Tariff (less any 'clawback' discount) regardless of the actual price paid for a specific manufacturer's product. Pharmacy reimbursement is funded out of the NHS's regional prescribing budgets. In England, CCGs are responsible for these budgets and must prescribe within them.
- Notwithstanding the significant scale of the NHS budget, legitimate demands for healthcare will always exceed its levels and resources have to be prioritised. In recent years the NHS has also been required to find significant efficiency savings.
- The NHS (and, in particular, the DH) does not regulate the price of generic medicines and save in certain specific circumstances has limited power to do so. The DH's policy is to rely on competition to constrain prices.

3.50 This section sets out details regarding the supply and funding of pharmaceutical products in primary care in the UK.<sup>113</sup>

## I. ***The manufacture and distribution of pharmaceutical products***

3.51 Figure 3.1 sets out the key stages of the pharmaceutical supply chain, which are discussed below.

**Figure 3.1: The pharmaceutical supply chain**



### a. ***Marketing Authorisations for pharmaceutical products***

3.52 An MA from the MHRA is required before any medicine can be used to treat people in the UK.<sup>114</sup> An MA is the regulatory permission to sell that particular

<sup>113</sup> In the NHS, GPs are the main source of primary care. While the initial diagnosis of epilepsy and the choice of AED is undertaken by a specialist, it is GPs who manage and issue repeat prescriptions.

<sup>114</sup> See <https://www.gov.uk/guidance/apply-for-a-licence-to-market-a-medicine-in-the-uk>. A company may also obtain a parallel import licence from the MHRA, which allows a medicine authorised in another EU Member State to be marketed in the UK, as long as the imported product has no therapeutic difference from the same UK product.

pharmaceutical product and it specifies how and where the product will be manufactured.<sup>115</sup>

- 3.53 Obtaining an MA involves submitting the results of pre-clinical toxicological and pharmacological tests as well as clinical trials, which together allow an assessment of the safety and efficacy of the medicine. The MHRA will grant an MA only if the pharmaceutical product meets satisfactory standards of safety, quality and efficacy in treating the condition for which it is intended.
- 3.54 The MA holder is legally responsible for making sure the drug complies with the terms of the MA and other applicable legislation or regulatory requirements. Where the MA holder contracts out certain parts of its responsibilities, it may benefit from indemnities from the sub-contractor.
- 3.55 As set out above, prior to 23 March 2012, Pfizer was the MA holder for *Epanutin* capsules. From 24 March 2012 to the date of the Decision, Flynn has been the MA holder for all four capsule strengths (25, 50, 100 and 300mg strengths) of Phenytoin Sodium Flynn Hard Capsules.

***b. The manufacture of pharmaceutical products***

- 3.56 A company which holds an MA may either manufacture the pharmaceutical product itself or contract with a third party contract manufacturing organisation ('CMO') to manufacture the pharmaceutical product on its behalf. The company which holds an MA is primarily responsible for ensuring the drug complies with its licence and other applicable legislation, rather than a third party manufacturer. However, a third party manufacturer may, for example, have contractual liabilities to the holder of an MA.
- 3.57 In the present case, Flynn (as the MA holder for Phenytoin Sodium Flynn Hard Capsules) contracts out the manufacture of phenytoin sodium capsules to Pfizer. As noted at section 3.B.II.b. above, the Parties entered into a Quality Agreement which, among other things, requires Pfizer to ensure that the phenytoin sodium capsules it supplies to Flynn comply with the relevant MAs and applicable regulatory requirements.

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<sup>115</sup> Therapeutic indications are set out in the 'Summary Product Characteristics' document, which is published for each medicine by the MHRA.



c. ***The distribution of pharmaceutical products***

3.58 Pharmaceutical products in the UK are usually distributed in one of the three following ways:<sup>116</sup>

- (i) a traditional wholesale model;
- (ii) a reduced wholesaler model; and
- (iii) a direct to pharmacy model.

3.59 Under the traditional wholesale model, the product is sold to all pharmaceutical wholesalers who wish to stock the product, often at the industry's conventional discount of 12.5% off the list price as set out in the Drug Tariff (see section 3.C.III.b. below). Wholesalers then compete to supply pharmacies and offer discounts from list prices to attract business.<sup>117</sup>

3.60 A reduced wholesaler model ('RWM') is very similar to the traditional wholesaler model but with a reduced number of wholesalers. Discounts are negotiated with each wholesaler and these may be lower than the industry convention of 12.5% off the list price.

3.61 Under a direct to pharmacy model ('DTP'), the product is sold direct to pharmacies and the supplier sets the prices paid by pharmacies. One or more wholesalers is typically appointed by the manufacturer to provide logistics services.<sup>118</sup> There is no convention covering the level of discounts to pharmacies in these circumstances.

3.62 For Pfizer-manufactured phenytoin sodium capsules, the following distribution models applied during the Relevant Period:

- (a) Up to 23 September 2012, Pfizer operated:
  - (i) A traditional wholesale model until March 2007.
  - (ii) A DTP model from March 2007.
- (b) Between 24 September 2012 and May 2014, Flynn operated a traditional wholesale model. Under that distribution model, Flynn's

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<sup>116</sup> See document PD 8, pages 3 to 4.

<sup>117</sup> See document PD 8, page 1.

<sup>118</sup> For example, Pfizer appointed UniChem as its logistics service provider when Pfizer first moved to a DTP model in 2007; see document PD8, page 15.

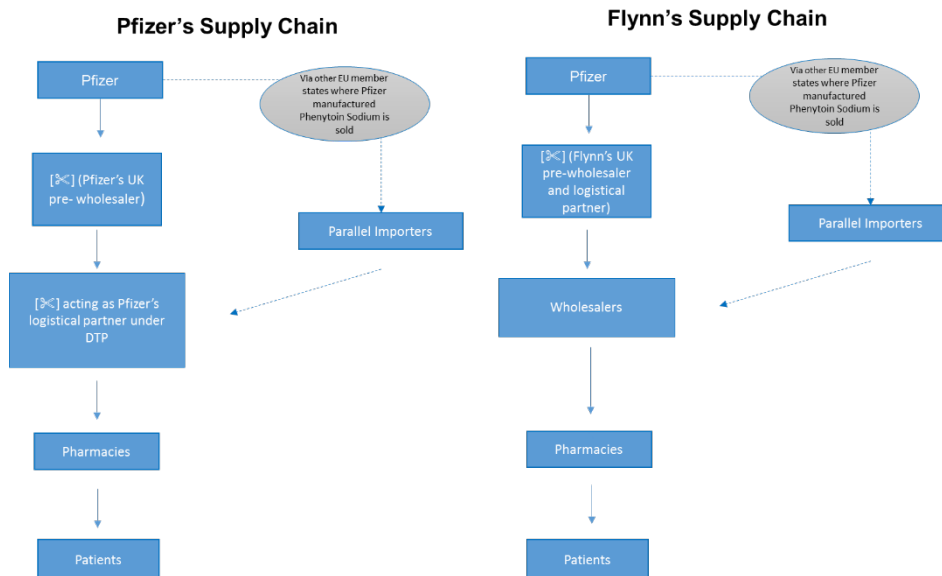
standard discount was the industry convention of 12.5% off the list price.<sup>119</sup>

- (c) From May 2014, Flynn moved to an RWM. Under that distribution model, Flynn sells directly to two wholesalers only: [Wholesaler 1] and [Wholesaler 3].<sup>120</sup> [Wholesaler 1] and [Wholesaler 3] then sell to all customers – who may be pharmacies or other wholesalers. Under its RWM, Flynn's discounts reduced from 12.5% off the list price to [X] for [Wholesaler 1] and [X] for [Wholesaler 3].<sup>121</sup>

3.63 Despite being the MA holder under the Agreements, Flynn's actual involvement in the supply chain for phenytoin sodium capsules is limited.

3.64 The below figures show the supply chain for Pfizer-manufactured phenytoin sodium capsules before and after Pfizer divested the MAs to Flynn and the product was genericised.

**Figure 3.2: Pfizer's supply chain for phenytoin sodium capsules prior to the divestment and price increases and Flynn's supply chain for phenytoin sodium capsules after the divestment and price increases**



3.65 Prior to Flynn taking on the MAs, phenytoin sodium capsules were manufactured by Pfizer in Germany and delivered to [X], Pfizer's pre-wholesaler in the UK. [X] stored and delivered the capsules to [X] (Pfizer's appointed logistics service provider under its DTP model) who in turn

<sup>119</sup> See paragraph 9.1 of document 00872.1.

<sup>120</sup> As an exception and at their requests, Flynn also [X]; see paragraph 22.1 of document 00872.1.

<sup>121</sup> See paragraph 9.1 of document 00872.1.

distributed the products to pharmacies. Since Flynn became MA holder very little has changed in the supply chain. Flynn does not at any point take receipt of, or dispatch, the phenytoin sodium capsules. The phenytoin sodium capsules sold by Flynn are still manufactured by Pfizer in Germany and delivered to [REDACTED]. Likewise, [REDACTED] continues to store and deliver them to Flynn's wholesale customers. [REDACTED].

3.66 Table 3.2 sets out in further detail the allocation of responsibilities between Pfizer and Flynn and their distributors and wholesalers. Flynn's submissions on this table and the CMA's responses are set out in Annex K.

**Table 3.2: Activities involved in supplying phenytoin sodium capsules in the UK during the relevant period**

	Pfizer	Flynn	Distributor	Wholesaler
<b>Manufacturing</b>				
Purchasing API	X			
Manufacturing	X			
Packaging	X			
Delivery to UK pre-wholesaler	X			
<b>Supply to pre-wholesaler</b>				
Ordering from supplier		X		
Processing orders	X			
Delivery to customer	X			
Invoicing	X			
Receipt of goods			X	
Storage			X	
<b>Supply to wholesalers</b>				
Ordering from supplier				X
Processing orders			X	
Delivering to customer			X	
Invoicing			X	
Receipt of goods				X
Storage				X
<b>Supply to pharmacies and hospitals</b>				

	Pfizer	Flynn	Distributor	Wholesaler
Processing orders				X
Delivering to customer				X
Invoicing				X
<b>Marketing and promotion</b>				
Communications to customers (prescribers, pharmacists, patients)		X		
Customer support (one clinical nurse)		X		
Marketing and promotion (generics manager)		X		
<b>Licensing and compliance</b>				
Regulatory compliance		X		

3.67 Flynn has purchased additional reserves of safety stocks from Pfizer in order to reduce the risk of stock shortages. Flynn has also submitted to the CMA that it had a number of ideas for how it might improve the resilience of the supply chain for phenytoin sodium capsules including, in the longer term, by developing alternative and lower cost alternatives to Pfizer as to the source of the active pharmaceutical ingredients ('API') and/or the finished product.<sup>122</sup>

3.68 However, Flynn has not implemented any plans to develop alternative sources of the API or the finished product. Further, the CMA considers that any expectations that Flynn had with regard to its ability to do this were both speculative and unrealistic for the reasons set out below.<sup>123</sup>

<sup>122</sup> See paragraph 11.2 of document 00505.1 and document 01639.2, paragraphs 2.14 to 2.19.

<sup>123</sup> Flynn has submitted that it was prevented from taking its plans forward due to the uncertainty created by the CMA's investigation and that the work required would be significant and complex. Flynn estimated that it would cost between [X] and take about [X]. In addition to the arguments set out in the rest of this section, the CMA rejects this submission for two reasons. Firstly, there is no evidence on the CMA's file to suggest that Flynn was seriously pursuing these proposals prior to the CMA opening its investigation. Secondly, Flynn continued to raise these issues with Pfizer after the start of the CMA's investigation (at least until January 2014). Pfizer was not however interested in taking these forward because it considered the proposals to be unnecessary (see document 00519.4). Furthermore, as set out elsewhere in this section, Pfizer considered a change in the production facilities or even a small change in the production process would pose a potential risk to patient safety and that maintaining the same production facilities was 'necessary and non-negotiable' (see document 00412.1).

- 3.69 First, Pfizer has denied repeated requests from Flynn to purchase additional stocks of API on the basis that Pfizer considers that its supply chain is already sufficiently resilient as to make this unnecessary.<sup>124</sup>
- 3.70 Second, Flynn would have required Pfizer's co-operation to establish an alternative source of API.<sup>125</sup> The evidence on the CMA's file shows that Flynn raised the possibility of a second source of API with Pfizer in October 2012,<sup>126</sup> but Pfizer has not accepted Flynn's requests.<sup>127</sup> Flynn stopped its engagement with alternative API suppliers around the end of 2012.<sup>128</sup>
- 3.71 Flynn continued to seek Pfizer's approval to establish an alternative source of API up until at least January 2014 and Pfizer continued to oppose such proposals because it saw them as unnecessary. This is clear from the notes of a meeting between Pfizer and Flynn in 2014:

*'Flynn want second source of API + packaging. Also want to buy in additional safety stocks from [Pfizer] (2 years). Adding value to DoH. [Pfizer] can investigate feasibility of second source, [✂], so very unlikely.'*

[...]

*2<sup>nd</sup> source API + packaging + safety stock API*

[✂]

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From this evidence, it appears that Flynn was not deterred by the CMA's investigation but rather by Pfizer's unwillingness to agree to the proposals. Thirdly, Flynn estimates that it would have cost [✂] to have implemented its proposals. However, Flynn has earned over [✂] million of operating profit from its sales of phenytoin sodium capsules between September 2012 and June 2016. Even given the context of the CMA's investigation Flynn could have afforded to progress such plans had it wished, and been able, to do so.

<sup>124</sup> See for example, document 00519.4.

<sup>125</sup> In its written representations on the SO, Flynn submitted that it could have independently sought a licence variation with an alternative source of API approved. In practice, however, Pfizer remains responsible for the operation of the production process and delivery of the products to the wholesaler and therefore Flynn would need Pfizer's agreement to introduce a second source of API into the supply chain. Flynn acknowledges that Pfizer's approval and support would have been an important part of implementing its plans (see paragraph 2.17 of document 01639.2). This is also recognised by Flynn in its contemporaneous documents. See for example document 00145.576, which records a meeting of Flynn's board on 24 October 2012 during which it was noted that Flynn was looking at alternative sources of API and that follow up would be required *'if approved by Pfizer.'* The action point arising from this is for [Flynn's CEO] to seek a meeting with Pfizer's senior management.

<sup>126</sup> See documents 00141.488 and 00145.562.

<sup>127</sup> See document 00519.4.

<sup>128</sup> See for example document 00145.679

*We have confidence in our supply + safety margins*

*(additional)*

*3<sup>rd</sup> party arrangements are not catered for*

[✂]

*Critical medicines managed by large plants. If there was an issue, it would take precedence over other medicines.<sup>129</sup> [Emphasis as original]*

3.72 Further, there is no evidence on the CMA's file to suggest that Flynn meaningfully sought to establish an alternative manufacturing site. The CMA is not in possession of any evidence which suggests that Flynn was pursuing this strategy during the negotiations leading up to the Agreements.<sup>130</sup> Nor does Flynn appear to have done so since then. Flynn mentioned to the DH that it was *'looking to create a dual source for both API, secondary manufacture and packaging, supported in principal by Pfizer'* during a meeting with the DH on 6 November 2012. However, that was *'subject to detailed negotiations, to be commenced at earliest opportunity'*.<sup>131</sup> There is no evidence that such negotiations ever occurred and there does not appear to have been any agreement between Flynn and Pfizer over the future of the product. For example, Pfizer has submitted to the CMA that it is unrealistic to consider that Flynn would set up a new manufacturing site and indicated that this was part of the rationale for agreeing a supply arrangement between Pfizer and Flynn:

*'the declining market for the product range made the prospect of Flynn establishing de novo facilities practically impossible, even leaving aside the safety concerns of doing so.'*<sup>132</sup>

3.73 In addition, Flynn has acknowledged that obtaining the required regulatory approvals for its plans would be facilitated with input from Pfizer, for example, by having Pfizer:

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<sup>129</sup> Document 00519.4

<sup>130</sup> The Exclusive Supply Agreement contains exclusivity provisions expressly prohibiting Flynn from purchasing Pfizer's Product or a substantially similar products from any other source.

<sup>131</sup> See documents 00367.16 and 00145.585.

<sup>132</sup> See document 01633.2, paragraph 122.

- (a) verify the suitability of alternative sources of API;
- (b) carry on laboratory testing and manufacturing trials; and
- (c) transferring know-how to the second manufacturing site.<sup>133</sup>

3.74 The evidence in the CMA's possession strongly supports the conclusion that Pfizer would not have agreed to Flynn establishing an alternative site of manufacture because of the consequent risks to patient safety. In a submission to the CMA dated 29 May 2013, Pfizer stated:

*'Due to the NTI of Phenytoin, a change in the production facilities or even a small change in the production process was considered to pose a potential risk to patient health. Divestment of production was therefore considered not to be an appropriate option for patient safety.'*<sup>134</sup>

3.75 Further, on 20 August 2013, Pfizer informed the CMA that it considered it *'necessary and non-negotiable'* that the supply of phenytoin sodium capsules was maintained from the same factory and for *'an audit trail to exist in this regard'*.<sup>135</sup>

3.76 Given the emphatic nature and the timing of Pfizer's submissions to the CMA on this point (29 May 2013 and 20 August 2013), it is reasonable to conclude that if Flynn had approached Pfizer regarding establishing an alternative site of manufacture at any stage it would likely have been rebuffed.

3.77 Moreover, even if Flynn had obtained Pfizer's agreement to an alternative site of manufacture, or it had been able to establish an alternative site without needing Pfizer's approval, the NTI and non-linear pharmacokinetics of phenytoin sodium capsules means that any product manufactured at the new site would likely be treated as a new product, rather than a continuation of Pfizer's Product.<sup>136</sup> It would then have faced the same significant barriers to entry and expansion as those considered in sections 4.B and 4.C below. Indeed, Flynn was aware of this challenge. In March 2013 one of Flynn's advisers emailed [Flynn's CEO] and [Flynn's Director] about possible future options for Flynn's Product. This email stated that Flynn could try to seek a new licence for a new phenytoin sodium capsule product manufactured at

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<sup>133</sup> See paragraph 2.17 of document 01648.2.

<sup>134</sup> See page 8 of document 00086.1.

<sup>135</sup> See document 00412.1, paragraph 49.

<sup>136</sup> In fact, Flynn recognised the challenges it would face; see document 00505.1, paragraphs 20.5 to 20.11 .

another site but also recognised that *'there is the possibility of confusion as the product manufactured elsewhere may not be identical to the Pfizer product due to the narrow therapeutic range issues'*.<sup>137</sup>

## II. ***The provision of pharmaceuticals within the National Health Service***

### a. ***The structure of the National Health Service***

3.78 The basic structure of the NHS in England is set out in the National Health Service Act 2006, as amended (the 'NHS Act'). Similar arrangements apply in Scotland, Wales and Northern Ireland.

3.79 The NHS does not, however, exist as a corporate entity. In practice, the operation of the NHS is devolved to numerous executive or advisory bodies or agencies.<sup>138</sup> These include the following:

- The Secretary of State for Health (the 'Secretary of State') who, among other things, has duties under section 1 and 1A of the NHS Act, to continue the promotion (and the continuous improvement) of a comprehensive health service in England which is designed to improve:
  - the physical and mental health of the people of England, and
  - the prevention, diagnosis and treatment of physical and mental illness.
- The DH which creates national policies and legislation for health services and acts for the Secretary of State in exercising the Secretary of State's powers and responsibilities.
- NHS England, NHS Scotland, NHS Wales, and Health and Social Care in Northern Ireland, which each lead the NHS in their respective jurisdictions. The organisations set the priorities and direction of the NHS and encourage and inform the national debate to improve health and care.
- CCGs, which replaced Primary Care Trusts ('PCTs') in April 2013 and are responsible for providing and funding health services in their local

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<sup>137</sup> See document 00145.779

<sup>138</sup> The following list applies for the NHS in England. Similar arrangements exist for Scotland, Wales and Northern Ireland.



areas. There are over 200 CCGs in England, accounting for around 75% of the total NHS budget. Prescription pharmaceuticals dispensed through the community pharmacies are funded out of CCG's budgets. The equivalents to CCGs in the devolved nations are: in Scotland, Regional Boards which devolve responsibility for health service budgets to Community Health Partnerships; in Wales, Local Health Boards; in Northern Ireland, the Health and Social Care Board which works with six Health and Social Care Trusts.<sup>139</sup>

- Special Health Authorities such as:
  - NHS Business Services Authority ('NHSBSA') which is, amongst others, responsible for the reimbursement of pharmacists and the publication of the Drug Tariff; and
  - NICE, which provides guidance on best clinical practice.
- NHS Hospital Trusts, which are responsible for providing hospital services and healthcare in their local areas.
- Executive Agencies, including:
  - the MHRA which regulates medicines, medical devices and blood components for use in the UK, ensuring that the applicable safety, quality and efficacy standards are met; and
  - the NHS Supply Chain, which advises on purchasing and procurement policy and contracts on a national basis for certain NHS contracts, mainly those of strategic importance. NHS Supply Chain was formed from the NHS Logistics Authority and parts of the previous NHS Purchasing and Supply Agency.
- Other advisory bodies, for example the National Commissioning Group, which advises Ministers on which NHS services are best commissioned nationally rather than locally. The National Commissioning Group is a Standing Committee of the National Specialised Services Commissioning Group which, oversees the national commissioning of highly specialised services and facilitates collaborative working at a pan-Specialised Commissioning Group level.

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<sup>139</sup> For ease of reference, the CMA uses the term 'CCGs' in the remainder of this Decision to refer collectively to CCGs in England and the equivalent bodies in Scotland, Wales, and Northern Ireland.

- 3.80 Of these, the main NHS bodies that are relevant to the facts and matters at issue in this Decision are:
- The DH, which complained to the CMA about Pfizer's and Flynn's pricing of phenytoin sodium capsules. It also had discussions with both Pfizer and Flynn before and shortly after the significant increase in the prices of their capsules.
  - CCGs, which pay for the prescribed phenytoin sodium capsules in their local area.<sup>140</sup>

*b. Prescribing and dispensing of phenytoin sodium capsules*

- 3.81 AEDs, such as phenytoin sodium capsules, are not available to patients for purchase over-the-counter. Instead, they need to be prescribed to patients by a GP or other qualified healthcare professional.
- 3.82 A number of individuals or bodies are involved in the process of choosing, paying for and consuming AEDs:
- (a) Diagnosis of epilepsy and the choice of appropriate AED is undertaken by a specialist healthcare professional with training and expertise in epilepsy (e.g. a Consultant Neurologist).<sup>141</sup> He or she exercises their clinical judgement to choose the medicine that will be the most therapeutically appropriate and effective, having regard to applicable clinical guidance. The choice of medicine is not typically driven by price. Repeat prescriptions are managed by a patient's GP.
  - (b) The prescriptions are filled by retail pharmacists who buy their stock from specialist pharmaceutical wholesalers and/or direct from manufacturers.
  - (c) CCGs are required to fund the reimbursement of pharmacies for the medicine dispensed to CCGs' patients out of CCGs' budgets. Hence, although the CCG pays, it neither chooses nor dispenses the drug.

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<sup>140</sup> Phenytoin and phenytoin sodium are listed as a prescription-only medicine in SI 1830/1997 The Prescription Only Medicines (Human Use) Order 1997, Schedule 1. See further the SI 2012/1916 Human Medicines Regulations 2012 Part 12, Schedule 1. Although the 2012 regulations repealed most of the 1997 order, some provisions including Schedule 1 remain in effect.

<sup>141</sup> See documents PD 13 and 00325.1.

(d) The consumer of the prescription medicine is, of course, the patient; he or she generally does not choose or pay for the medicine.<sup>142</sup>

**c. Prescribing**

3.83 Most prescriptions for pharmaceuticals are written in the course of primary care by a doctor. Prescriptions can either be 'open' or 'closed':

(a) 'open prescriptions' (sometimes called 'generic prescriptions') allow the pharmacist to choose either the branded pharmaceutical product or generic products if they exist;

(b) 'closed prescriptions' specify the specific brand or manufacturer of the medicine, which must then be dispensed by the pharmacy.

3.84 A prescriber can choose how specific they are when writing a prescription for a medicine, which, in turn, has implications for the degree of choice that a dispenser may have when fulfilling a prescription.<sup>143</sup> Prescribers are generally encouraged to write prescriptions using a medicine's generic name, regardless of whether a generic product is actually available, unless there are specific clinical reasons not to.<sup>144</sup>

3.85 A prescriber prescribing phenytoin sodium can write either:

(a) a 'generic' or 'open' prescription, which will specify the active ingredient, the formulation and the relevant strength (e.g. 'phenytoin sodium capsules 100mg'); or

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<sup>142</sup> Patients are typically required to make a payment towards the cost of medicines they are prescribed on an NHS prescription. The current prescription charge is £8.40 per item. However, a patient is entitled to free NHS prescriptions if they have a specified medical condition and have a valid medical exemption certificate. Epilepsy is listed as a specified medical condition and so epilepsy patients with a valid medical exemption certificate are not required to make a contribution towards the cost of their NHS prescriptions. See <http://www.nhs.uk/NHSEngland/Healthcosts/Pages/Prescriptioncosts.aspx>

<sup>143</sup> The implications for dispenser choice are considered at section 3.C.II.d. below. GPs may use prescribing software to inform their prescribing decisions. GP prescribing software provides GPs with national and locally authored patient safety information messages, recommendations and other prescribing information. (See document PD 17). To facilitate generic prescribing, GP prescribing software is usually able to identify if a generic name is available, so that where a prescriber types in a brand name they can use a function key to prompt them with the generic name. Where a prescription specifies only the generic name of a drug, this enables a pharmacy to dispense any applicable product available. Although the generic prescribing function is generally available for phenytoin sodium capsules the software typically provides warnings informing GPs of the relevant prescribing guidance and the risks of switching patients from their usual supply of phenytoin products.

<sup>144</sup> See, for example, document PD 7, paragraph 2.34.

(b) a 'closed' prescription specifying the particular brand, manufacturer or supplier and the relevant strength (e.g. 'Epanutin 100mg', 'Phenytoin Sodium Flynn Hard Capsules 100mg', or 'Phenytoin Sodium NRIIM Capsules 100mg').

3.86 Notwithstanding the clinical guidance applicable to phenytoin sodium capsules, in practice, the majority of phenytoin sodium capsule prescriptions are generic or open.<sup>145</sup>

3.87 Official NHS data for England for 2011<sup>146</sup> shows that 60% of prescriptions for phenytoin sodium capsules were open during that period. For the first eight months of 2012 (before Flynn began distributing phenytoin sodium capsules in the UK), 62% of prescriptions for phenytoin sodium capsules in England were open.<sup>147</sup>

3.88 More recently, evidence submitted by Flynn and by Pfizer indicates that over the period April 2014 to March 2015, 91% of prescriptions for phenytoin sodium capsules were open.<sup>148</sup>

**d. Pharmacy dispensing**

3.89 Pharmacy dispensing is a specialised and heavily regulated profession. For example, in England and Wales, the activities of pharmacies are governed

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<sup>145</sup> See PCA Data at [www.nhsbsa.nhs.uk/PrescriptionServices/3494.aspx](http://www.nhsbsa.nhs.uk/PrescriptionServices/3494.aspx).

<sup>146</sup> The PCA data for England records the number of prescription items dispensed where the prescription was written generically but only a proprietary product was available. This enables the CMA to calculate the number of open prescriptions pre-September 2012 when only *Epanutin* capsules were available.

<sup>147</sup> Based on PCA data for England, available at: [www.nhsbsa.nhs.uk/PrescriptionServices/3494.aspx](http://www.nhsbsa.nhs.uk/PrescriptionServices/3494.aspx).

Documents provided by Flynn and Pfizer present a mixed view of the number of open prescriptions for phenytoin sodium capsules. For example, document 00141.119 provides a brief outline of the [Flynn's] proposal for *Epanutin*. It states that 'A generic presentation would provide uniformity across the range of phenytoin capsules prescribed as approximately 60% are prescribed generically'. In addition, a proposal for *Epanutin* drafted by Flynn in October 2010 states 'Scripts for Phenytoin capsules are already largely written generically (70%) so few will need to be referred back to prescriber' (see document 00145.1022). On the other hand, a note of a teleconference between Flynn and the MHRA on 25 June 2012 explains that '1/3rd of the capsule prescriptions are written generically i.e. as phenytoin capsules' (see document 00145.305). Finally, a note of a meeting between Flynn and DH on 18 July 2012 states that '30% of *Epanutin* scrips [sic] are already written generically' (see document 00145.936).

<sup>148</sup> See document 01840.1 (Flynn submitted a response to a Freedom of Information Act request made on 17 April 2015 to the NHSBSA requesting the number of phenytoin sodium capsule prescriptions that are written with identifiers (Flynn, NRIIM or *Epanutin*) for all four dosage strengths over a 12 month period. The CMA's analysis of this data shows that 91% of prescriptions for phenytoin sodium capsules were open over the period April 2014 to March 2015). See document 01928.1. Flynn also said in a meeting with the OFT on 16 June 2013 that 97% of prescriptions were written generically. See document 00313.1 See also document 00145.66 where Flynn stated that 30% of prescriptions specified the brand.

by various regulations, particularly the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.<sup>149</sup> Similar regulations apply in Scotland and Northern Ireland.

- 3.90 The ability of a pharmacy to decide which AED to dispense is affected by (1) the prescriber's decision and (2) applicable clinical guidance.
- 3.91 The impact of the prescriber's decision depends upon whether the prescription is open or closed and, if open, how open it is. In the case of phenytoin sodium capsules, this means that:
- if a prescription specifies a particular type of medicine, for example, 'phenytoin sodium 100mg capsules', then a pharmacist must dispense capsules in that dosage strength, but he or she must choose (having regard to the applicable clinical guidance) which manufacturer's formulation to supply.
  - if a prescription is presented to a pharmacist with the branded name prescribed – for example, 'Epanutin or Phenytoin Sodium Flynn Hard Capsules' – then the pharmacist must dispense that medicine and no other. The same is true where a particular manufacturer's or MA holder's medicine is prescribed.
- 3.92 There are limited exceptions to this. In particular, a pharmacist may go back to the prescriber if the medicine prescribed is out of stock or otherwise unavailable.<sup>150</sup> However, the prescriber would need to issue a new prescription in order for the pharmacist to dispense a different medicine.<sup>151</sup>
- 3.93 Pharmacies are also able to dispense a parallel imported product provided the parallel import is marketed under the same brand as that for which the prescription is written. Alternatively, the name of the product in the source

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<sup>149</sup> SI 2013/349 The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.

<sup>150</sup> See document PD19 which states that: '*Dispensing pharmacists should ensure the continuity of supply of a particular product when the prescription specifies it. If the prescribed product is unavailable, it may be necessary to dispense a product from a different manufacturer to maintain continuity of treatment of that AED. Such cases should be discussed and agreed with both the prescriber and patient (or carer)*'.

<sup>151</sup> Otherwise the pharmacist may be considered to be breaching SI 2013/349 The National Health Service (Pharmaceutical and Local Services) Regulations 2013.

country can be used, providing this will not lead to any confusion or doubt over whether Continuity of Supply will be maintained for the patient.<sup>152</sup>

- 3.94 Pharmacies receive payment for the prescriptions they fulfil from the NHS from the patient's CCG. The amount they receive is set by the price of the product listed in the Drug Tariff (less any clawback discount).<sup>153</sup> The reimbursement price to the pharmacist is the same whether an open prescription is filled by a branded product or a generic.<sup>154</sup> Subject to clinical guidance, pharmacies therefore have an incentive to dispense the cheapest medicine available. Further information on the Drug Tariff and how it applies to phenytoin sodium capsules is set out in section 3.C.III.b. below.
- 3.95 As set out at section 3.B.II.d above, clinical guidance means that pharmacists are more restricted in their dispensing decisions for phenytoin sodium capsules than they would be for most generic prescriptions. The vast majority of the ten major pharmacy groups contacted by the CMA<sup>155</sup> told the CMA that they adhered to the Continuity of Supply, even when asked to fill an open prescription. Pharmacies therefore did not normally switch patients between phenytoin sodium capsules produced by different manufacturers.
- 3.96 [Pharmacy 4] confirmed they had purchased NRIM's Product, however it estimated that 95% of its purchases were from Flynn and explained that:

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<sup>152</sup> See document PD 19, which states for parallel import product names that: '*The product name for a parallel imported AED product should be the name under which the UK cross-referred product is marketed. Alternatively, the name of the product in the source country can be used, providing this will not lead to any confusion or doubt over continuity of supply to the patient.*

<sup>153</sup> See the NHS Act, sections 164 and 165 and the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013/349, Regulation 89. It is recognised that pharmacies can buy their medicines cheaper than the Drug Tariff price. As such, the NHS applies a discount to pharmacies' payments. This discount is often referred to as 'clawback' and was designed to share with the NHS the profits pharmacies can make by purchasing medicines at below the price at which they are reimbursed. However, there are some drugs that are not subject to a discount and these drugs are listed on the Discount Not Given list, which is published in Part 2 of the Drug Tariff. Phenytoin sodium 100mg and 300mg capsules are listed on the Discount Not Given list. See document PD 24 for which discounts are not deducted.

<sup>154</sup> See document PD 7, page 28.

<sup>155</sup> The CMA contacted the ten largest pharmacy groups in the UK; namely, Alliance Boots, Asda, Celesio (Lloyds), the Co-Op (the Co-Op pharmacy business was acquired by the Bestway Group in July 2014 and the pharmacies rebranded to 'Well' in February 2015), Day Lewis, Morrisons, Rowlands, Sainsbury's, Superdrug and Tesco. The pharmacy groups contacted by the CMA cover approximately 50% of pharmacies in the UK and account for over 75% of NRIM's total sales.

*'If a prescription is simply written generically, the pharmacist will ask the patient what they have previously used as regard will need to be given to bio-equivalence concerns'.<sup>156</sup>*

- 3.97 [Pharmacy 1] also purchased both NRIM's Product and Flynn's Products, however it explained that its pharmacists followed the principle of Continuity of Supply when deciding which capsule to dispense:

*'Where the prescription is written generically, the pharmacist will complete a clinical check to determine what product the patient is currently using, and that product will be ordered. If no product is currently being used by the patient and the script is written generically, the pharmacist will have a choice of which product (Flynn or NRIM) they dispense.'<sup>157</sup>*

- 3.98 [Pharmacy 2]'s pharmacists also focused on ensuring Continuity of Supply, when dispensing phenytoin sodium capsules, explaining that NRIM's Product would only be dispensed in limited circumstances, namely:

*'...if a patient was already on this particular brand, or if the patient was initiating therapy for the first time. In addition they may be used if stock shortages mean no alternative is available and the doctor has agreed to a change in brand being offered'.<sup>158</sup>*

- 3.99 Similarly, [Pharmacy 10] explained that NRIM's Product would only be dispensed where either:

*'... (i) the patient is a newly diagnosed patient therefore has no dispensing history for a particular generic and NRIM is the generic product held in our system for dispensing; or (ii) the patient has previously been dispensed NRIM in which case we would continue to dispense this.'<sup>159</sup>*

- 3.100 [Pharmacy 7] also sought to ensure Continuity of Supply:

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<sup>156</sup> See document 00693.2. As discussed in section 3.C.II.c, PCA data for England for 2011 shows that 60% of prescriptions for phenytoin sodium capsules were open. For the first eight months of 2012 (before Flynn began distributing the Focal Product in the UK), 62% of prescriptions for phenytoin sodium capsules in England were open.

<sup>157</sup> See document 00679.1.

<sup>158</sup> See document 00813.1

<sup>159</sup> See document 00817.1

*'If our pharmacists are unclear as to the variant (e.g. Flynn or NRIM) required by the customer, they should speak with the customer and check with the prescriber.*

*The pharmacist/ prescriber and customer should then jointly agree on the way forward.'*<sup>160</sup>

3.101 [Pharmacy 8], [Pharmacy 9]<sup>161</sup> and [Pharmacy 5]<sup>162</sup> all informed the CMA that they did not purchase NRIM's Product during the period April to November 2013 with all being concerned about the risk of therapeutic failure and therefore focused on ensuring Continuity of Supply.

3.102 [Pharmacy 8] explained that it never purchased NRIM's Product: '*[p]rimarily due to how Rx [prescriptions] are written by the prescriber but also bio equivalence issues and bio availability*'.<sup>163</sup>

3.103 [Pharmacy 9] explained:

*'The buyer, [of Flynn's Products within Pharmacy 9] who himself is a pharmacist, was mindful of the existing concerns within the industry that had been expressed regarding the bioavailability issues with anti-convulsant drugs, especially Phenytoin, and consulted the [Pharmacy 9] Pharmacy Superintendent's Office. He was advised that because of the potentially serious patient safety issues that could arise because of bioavailability issues he should seriously consider remaining with the existing manufacturer whose product our patients had already been using.*

*He accepted this advice and did not purchase any NRIM Phenytoin sodium hard capsules. This decision was supported by the advice given in the BNF at the time and subsequently further vindicated by the contents of the MHRA press release on the subject some months later.'*<sup>164</sup>

3.104 [Pharmacy 5] explained that it had always been able to source its requirements for phenytoin sodium capsules from Flynn and Parallel

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<sup>160</sup> See document 00666.1

<sup>161</sup> See document 00649.1

<sup>162</sup> See document 00662.1

<sup>163</sup> See document 00657.1

<sup>164</sup> See document 00869.1



Imports.<sup>165</sup> However, it also explained that if its pharmacists were presented with an open prescription for phenytoin sodium capsules they would seek to ensure Continuity of Supply rather than be influenced by any financial incentives by checking the *'previous brand supplied, indicated on PMR or confirmed with the patient'*.<sup>166</sup> Additionally, [Pharmacy 5] explained that:

*'If no specific brand is indicated, pharmacists would need to get additional reassurances from the patient or prescriber. As phenytoin has a narrow therapeutic index caution is required between switching brands.'*

3.105 [Pharmacy 5]'s and [Pharmacy 9]'s submissions have been corroborated by NRIM. In its submissions to the CMA, NRIM explained that it had experienced difficulties in attracting potential customers prior to November 2013 and that a number of pharmacies (including the [Pharmacy 5] and [Pharmacy 9]) had declined to purchase its product as a result of switching concerns.

3.106 In respect of [Pharmacy 5], NRIM stated:

*'[Pharmacy 5] was not interested, as it was considered that new patients would be unlikely to be prescribed Phenytoin Sodium 100mg capsules and that existing patients might be reluctant to switch from their existing product to NRIM's generic product.'*<sup>167</sup>

3.107 All eight pharmacies who did not switch patients between different phenytoin sodium capsule products prior to the MHRA Guidance informed the CMA that they continued to hold this position following the publication of the MHRA Guidance.<sup>168</sup>

3.108 The two exceptions to this trend prior to November 2013 were [Pharmacy 3] and [Pharmacy 6], both of whom switched to dispensing NRIM's Product when it was launched in 2013.<sup>169</sup>

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<sup>165</sup> See document 00662.1

<sup>166</sup> See document 00662.1.

<sup>167</sup> See document 00512.2 and 00872.15

<sup>168</sup> See documents 00693.2, 00662.1, 00649.1, 00643.1, 00657.1, 00679.1, 00653.1 and 00666.1.

<sup>169</sup> [REDACTED].

3.109 [Pharmacy 3] stated that it selected NRIM's Product following '*an economic decision on what was best for the [Pharmacy 3].*<sup>170</sup> As a result:

*'prior to the November 2013 MHRA guidance, if no specific manufacturer's product had been requested by the patient or the prescriber, then the pharmacist would dispense the product which was the most commercially viable option'.<sup>171</sup>*

3.110 In practice this meant that [Pharmacy 3] chose to dispense NRIM's Product where it could because the '*cost is lower than Flynn [sic] product.*<sup>172</sup>

3.111 Likewise, [Pharmacy 6] stated that it began to purchase NRIM's Product because it '*was considered to be commercially attractive because of the pricing of NRIM.*<sup>173</sup>

3.112 However, both [Pharmacy 3] and [Pharmacy 6] stated that they began to follow the principle of Continuity of Supply after the MHRA issued its guidance in November 2013.<sup>174</sup>

3.113 [Pharmacy 3] explained that, further to the MHRA Guidance, when presented with an open prescription it would take steps to determine whether the patient was already on a treatment and, if so, seek to ensure Continuity of Supply:

*'Following the issue of the November 2013 MHRA guidance, if a prescription does not specify a particular manufacturer's brand, then the pharmacist would review the patient's medication history and discuss the matter with the patient (or carer) and/or the prescriber to determine which brand had previously been dispensed so the same brand can be dispensed again.'<sup>175</sup>*

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<sup>170</sup> See document 00838.1

<sup>171</sup> See document 00661.4, question 10.v.

<sup>172</sup> See document 01068.20.

<sup>173</sup> See document 00669.1, question 5.i.b.

<sup>174</sup> See section 4.B.IV.b.iv.

<sup>175</sup> See document 00661.4. See also: '*When presented with a generic prescription for phenytoin sodium hard capsules, in accordance with the November 2013 MHRA guidance, the pharmacist would take into account any brand previously given to the patient in order to dispense the most appropriate brand*' and '*Even where the prescription is written generically, in accordance with the MHRA guidance, [Pharmacy 3] would review its patient medication history or speak to the patient (or carer) to determine which brand had been previously given in order to dispense the same brand.*

- 3.114 [Pharmacy 3]'s policy is the same regardless of whether the patient in question is stabilised on the Flynn's Products or NRIM's Product.<sup>176</sup>
- 3.115 [Pharmacy 3] has communicated its policy to all of its pharmacists<sup>177</sup> and also informed Flynn on 21 January 2014. Accordingly, Flynn is aware that [Pharmacy 3] will dispense phenytoin sodium capsules on the basis of Continuity of Supply rather than commercial considerations.
- 3.116 [Pharmacy 6] explained that when it receives an open prescription for phenytoin sodium capsules it will take steps to determine whether the patient is already on a particular form of capsule and, if so, seek to ensure Continuity of Supply:

*[I]f a patient is taking the NRIM Product then the pharmacist will dispense the NRIM Product. This will be the case where:*

- 1. the NRIM Product is specified on the prescription; and*
- 2. no brand or manufacturer is specified on the prescription but following enquiry of the patient or prescriber, the pharmacist ascertains that the patient is taking the NRIM Product.*

*Equally, if a prescription specified the Flynn product or following enquiry the pharmacist ascertained that the patient was taking the Flynn product, the pharmacist will dispense the Flynn product.*

*Commercial attractiveness plays no role in these decisions. In circumstances where no brand or manufacturer is specified on the prescription or requested by the patient and the pharmacist is satisfied that there is no clinical reason why the patient needed product continuity, the pharmacist has a discretion as to which product to dispense. At this point, commercial considerations could come into play.<sup>178</sup>*

- 3.117 [Pharmacy 6] also explained that its decision to issue specific guidance regarding phenytoin was quite exceptional and that '*Phenytoin was perhaps one of only two examples where the Superintendent Pharmacist at [Pharmacy 6] has issued internal guidance*'.<sup>179</sup>

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<sup>176</sup> See document 00838.3.

<sup>177</sup> See document 00661.4, question 11.

<sup>178</sup> See document 00852.1, question 4.

<sup>179</sup> See document 00852.1.

### III. **Pricing framework for pharmaceutical products**

3.118 The following sections address the key components of the UK's system of pharmaceutical pricing regulation that are relevant to this Decision.

#### **a. NHS funding**

3.119 As set out above, the clinical decision to prescribe a pharmaceutical product to a patient is taken by a healthcare professional (such as a patient's individual GP). In general, prescribers choose which product to prescribe to patients based on clinical reasons and what is most suitable for the patient. The funding is then provided by the patient's local CCG and, in practice, once the prescribing decision is taken by the prescriber, the NHS - in the form of the patient's local CCG - has no option but to fund the product.

3.120 The NHS is principally funded by UK taxpayers.<sup>180</sup> Within the NHS's overall budget, there are budgets allocated for certain activities, such as prescribing pharmaceutical products – from which the cost of dispensing phenytoin sodium capsules is met. Each year NHS England sets each CCG a prescribing budget and GP practices are expected to prescribe within this budget.<sup>181</sup>

3.121 Notwithstanding the significant scale of the NHS budget, legitimate demands for healthcare will always exceed its levels and resources have to be prioritised.

3.122 In recent years the NHS has also been required to find significant efficiency savings. For example, in the period from 2010 to 2015, the NHS Efficiency Policy (also known as the Quality, Innovation, Productivity and Prevention Plan ('QIPP')) tasked the NHS to make up to £20 billion of efficiency savings by 2015 in order to make more funds available to treat patients.<sup>182</sup> While the NHS's overall funding is being increased, the need to continue to find efficiencies and savings continues to be important. Looking forward, the NHS expects there to be a potential unmitigated gap of around £30bn in its total funding by 2020/21.<sup>183</sup> To help address this funding gap, the NHS will

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<sup>180</sup> See [www.nhs.uk/NHSEngland/thenhs/about/Pages/overview.aspx](http://www.nhs.uk/NHSEngland/thenhs/about/Pages/overview.aspx). The NHS also derives some revenue from user charges – for example prescription payments.

<sup>181</sup> See [www.nhsbsa.nhs.uk/PrescriptionServices/3996.aspx](http://www.nhsbsa.nhs.uk/PrescriptionServices/3996.aspx) and [bma.org.uk/practical-support-at-work/gp-practices/service-provision/prescribing/the-gp-practice/the-gp-practice-prescribing-budget](http://bma.org.uk/practical-support-at-work/gp-practices/service-provision/prescribing/the-gp-practice/the-gp-practice-prescribing-budget).

<sup>182</sup> See [www.gov.uk/government/publications/2010-to-2015-government-policy-nhs-efficiency/2010-to-2015-government-policy-nhs-efficiency](http://www.gov.uk/government/publications/2010-to-2015-government-policy-nhs-efficiency/2010-to-2015-government-policy-nhs-efficiency).

<sup>183</sup> See <https://www.england.nhs.uk/wp-content/uploads/2014/10/5yfv-web.pdf> ('PD 46').

receive approximately £8 billion in extra funding but the NHS is expected to make up the remaining £22 billion in efficiency savings.<sup>184</sup>

**b. The Drug Tariff**

3.123 All NHS prescription drugs dispensed are paid for by CCGs. Increases in the price of prescription drugs result in increased costs for CCGs and may impact on the range of services and treatments that they can provide for their patients.

3.124 The reimbursement that pharmacies can claim from the NHS when fulfilling prescriptions is governed by the Drug Tariff. The Drug Tariff is produced monthly by the Prescription Pricing Authority.<sup>185</sup> It outlines, amongst other things, the amounts that pharmacy contractors (or dispensing doctors) are to be reimbursed for the cost of medicines which they have supplied against NHS prescriptions.

3.125 The Drug Tariff provides that a pharmacist is reimbursed for medicines dispensed at a 'basic price' minus any clawback discount. The basic price for products covered by the Drug Tariff are listed under Part VIII of the Drug Tariff. This price is referred to throughout this Decision as 'the Drug Tariff price'. However, some contemporaneous evidence refers to the Drug Tariff price as the 'reimbursement price'.

3.126 Medicines under the Drug Tariff fall under one of three categories. Those categories determine how the Drug Tariff price is determined:<sup>186</sup>

- Category A – Drugs which are readily available. Category A prices are based on the list price (i.e. the supplier's price before customer specific discounts) of commonly used generics that are usually readily available from several sources. The price of a drug within Category A is set using a weighted average of list prices from a basket of two wholesalers and three generic manufacturers. There is a minimum

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<sup>184</sup> See for example <https://www.england.nhs.uk/wp-content/uploads/2016/05/fyfy-tech-note-090516.pdf> ('PD 47').

<sup>185</sup> See [www.nhsbsa.nhs.uk/prescriptionservices.aspx](http://www.nhsbsa.nhs.uk/prescriptionservices.aspx). The DH's responsibilities in relation to Part IX of the Drug Tariff extend only to England. The National Assembly for Wales operates a common policy with the DH and therefore the Drug Tariff currently covers both England and Wales. Arrangements regarding Scotland and Northern Ireland are unchanged and both countries continue to maintain and publish separate Drug Tariffs. Part VII of the Scottish Drug Tariff is based on that used by the DH for Category M of the English Drug Tariff. This means that the English Category M price list is used in Scotland. See document PD 34.

<sup>186</sup> See document PD 31.

requirement that products in Category A are listed either (i) by both wholesalers, or (ii) by one wholesaler and by two manufacturers.

- Category C – Drugs which are not readily available as a generic. This is most often seen when a product is only available as a branded product or from one or two sources. The price of a drug within Category C is based on a list price for a particular proprietary product, manufacturer or supplier.
- Category M – Drugs which are readily available. Lists prices of commonly used generics that are usually readily available from several sources. The price of a drug within Category M is set using a weighted average from retrospective sales and volume data supplied to the DH by manufacturers under Scheme M.<sup>187</sup> These prices are then adjusted by a formula to ensure that pharmacy contractors retain the profit margin agreed as part of the funding of the community pharmacy contractual framework.<sup>188</sup>

3.127 Flynn's phenytoin sodium capsules fall under Category C of the Drug Tariff. The Category C 'based on product' was agreed by the DH and the Pharmaceutical Services Negotiating Committee ('PSNC') to be Flynn's product and this was added to the Drug Tariff in October 2012.<sup>189</sup> As such, the Drug Tariff price is determined by reference to Flynn's list price. This is the case for reimbursement regardless of whether a pharmacy dispenses Flynn's phenytoin sodium capsules, a Parallel Import or NRIM's Product.

c. ***The Voluntary Schemes***

3.128 The DH primarily relies on voluntary regulatory schemes agreed with industry bodies pursuant to section 261 of the NHS Act to (directly or indirectly) control the prices of most pharmaceutical products within the UK. The following schemes have been classed as voluntary schemes during the Relevant Period for the purposes of section 261 of the NHS Act:

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<sup>187</sup> Scheme M applies to manufacturers and suppliers of generic medicines for use in the NHS within the meanings set out in section 266(6) of the National Health Service Act 2006 but not distributors; that is, it applies to those who manufacture or supply generic medicines at the manufacturer level of the NHS medicines supply chain, supplying generic medicines to wholesalers, community pharmacies and dispensing doctors for use within the NHS, but not those who act solely as wholesalers.

<sup>188</sup> Each year in conjunction with the PSNC, the DH conducts a 'margins survey' to investigate how much medicine margin (that is, the difference between what they have bought the product for and how much they have been reimbursed) the average pharmacy contractor has retained in the previous year; see document PD 22.

<sup>189</sup> See document 01207.1.

- the PPRS;
- Scheme M; and
- Scheme W.

3.129 None of these schemes apply directly to phenytoin sodium capsules but they are helpful for understanding the economic context in which the Infringements have occurred. For example:

- (a) both Pfizer and Flynn are members of the PPRS and *Epanutin* was sold under the PPRS until Pfizer sold its MAs to Flynn and the products were genericised in September 2012; and
- (b) Tablets are covered by the operation of Scheme M (though Scheme M does not regulate the supply prices of the medicines to which it applies).

*i. The Pharmaceutical Price Regulation Scheme*

3.130 The PPRS is a voluntary agreement between the DH and the Association of the British Pharmaceutical Industry ('ABPI') to control the prices of branded medicines sold to the NHS.<sup>190</sup> The PPRS is designed with the aim of providing stability and predictability to the Government and the industry and helping the NHS.<sup>191</sup> The PPRS is intended to ensure '*that safe and effective medicines are available on reasonable terms to the National Health Service*' and '*a strong, efficient and profitable pharmaceutical industry*'.<sup>192</sup>

3.131 The PPRS does this by regulating:

- the maximum prices of branded medicines; and
- the profits that manufacturers are allowed to make on their sales to the NHS.

3.132 There have been several PPRS schemes, each typically with a five year term. The PPRS schemes which operated during the Relevant Period are:

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<sup>190</sup> See document PD20, paragraph 1.4.

<sup>191</sup> See document PD20, paragraph 1.4.

<sup>192</sup> See document PD20, paragraph 1.2.

- the 2009 PPRS, which applied from 1 January 2009 to 31 December 2013; and
- the 2014 PPRS, which applies from 1 January 2014 to 31 December 2018.

3.133 The PPRS comprises two key components which relate to the entire portfolio of branded, licensed medicines (both in-patent and out-of-patent) sold by a medicines manufacturer to the NHS.<sup>193</sup>

3.134 First, while a scheme member has freedom to set the price of new active substances,<sup>194</sup> once the price is set, the PPRS prevents the scheme member from increasing the price except in very limited circumstances. In order to increase its price, the scheme member can either:

- Apply to the DH for approval to increase a price. However, it is, very rare for a scheme member to seek individual price increases.<sup>195</sup>
- Modulate its prices. Under modulation, a scheme member can increase the price of an individual drug by up to 20%. However, that increase needs to be offset by reductions in the price of other medicines so that the overall total spend for the NHS would need to be in line with PPRS commitments. A scheme member can rely on the modulation provisions of the PPRS without DH approval.<sup>196</sup>

3.135 Further, price cuts are sometimes agreed at the time of scheme renegotiations.<sup>197</sup> As an alternative to an across the board reduction, it has been an option for scheme members to deliver the price cuts by modulating the prices of some or all of their products covered by the PPRS.

3.136 Second, the PPRS includes a profit cap. This is based on a target rate of return and applies to all the branded products sold by a scheme member to

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<sup>193</sup> Further information about the operation of the PPRS can be found in document PD 7; see, in particular, Annexes G, H and J of the 2009 PPRS (document PD 9).

<sup>194</sup> See document PD20, paragraph 7.14, which states that '*New medicines launched in the UK market following the granting of an EU or UK new active substance MA from the appropriate licensing authority may be priced at the discretion of the scheme member on entering the market. It is assumed that prices at launch will be set at a level that is close to their expected value as assessed by NICE.*'

<sup>195</sup> For example, in the Twelfth Report to Parliament on the PPRS, the DH stated that in the period 2009 to 2013 no major companies were permitted to increase prices within the PPRS and no applications had been made to increase prices under the PPRS flexible pricing provisions; see document PD 21, paragraph 2.23 and 2.29.

<sup>196</sup> See document PD 9 paragraph 7.46 of the 2009 PPRS and document PD20 paragraph 7.34.

<sup>197</sup> See document PD 9 for example, page 19.



the NHS. There are allowances for research and development ('R&D'), marketing and information costs.

3.137 The allowable returns pursuant to the 2009 and 2014 PPRS are:

- A target rate of return on capital of 21%.<sup>198</sup>
- A target rate of return on sales of 6%.<sup>199</sup>

3.138 A company may choose not to become a member of the PPRS, or may be excluded by the Secretary of State. In such circumstances a statutory pricing scheme ('the Statutory Scheme') would apply to the company.<sup>200</sup> In order to remove a manufacturer or supplier from the PPRS, it would be necessary for the Secretary of State to show that the PPRS was 'ineffective' as regards that company. It will be difficult to find that the PPRS was 'ineffective' where the scheme member has complied with the provisions of the scheme.<sup>201</sup>

#### ii. *Scheme M*

3.139 Scheme M is a voluntary scheme for setting the Drug Tariff price of generic<sup>202</sup> medicines and applies to manufacturers and suppliers of generic medicines for use in the NHS.<sup>203</sup> It was first introduced in June 2005 and was revised in 2010.<sup>204</sup> The way Category M prices are set is described in section 3.C.III.b. above.

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<sup>198</sup> See document PD 9, paragraph 8.12. ABPI and DH and document PD 20, paragraph 8.14.

<sup>199</sup> See document PD 9, paragraph 8.19. ABPI and document PD 20, paragraph 8.13.

<sup>200</sup> SI 2008/3258 The Health Service Branded Medicines (Control of Prices and Supply of Information) No. 2 Regulations 2008 and SI 2011/2955 The Health Service Branded Medicines (Control of Prices and Supply of Information) Amendment Regulations limit the maximum price of prescription only, branded medicines supplied to the NHS and require manufacturers and suppliers of branded pharmaceutical companies to provide the DH with information on sales income and discounts.

<sup>201</sup> See *Genzyme v OFT* [2004] CAT 4, [273].

<sup>202</sup> Within Scheme M, the term '*generic medicine*' has a specific meaning. A generic medicine shall be understood to be any human pharmaceutical product for which an MA has been awarded and to which the proprietor does not apply a brand name that enables the product to be identified without reference to the generic title or to any nomenclature published in the official list of recommended International Non-proprietary Names (rINNs) or any similar standing.

<sup>203</sup> Scheme M applies to manufacturers and suppliers of generic medicines for use in the NHS within the meanings set out in section 266(6) of the National Health Service Act 2006 but not distributors; that is, it applies to those who manufacture or supply generic medicines at the manufacturer level of the NHS medicines supply chain, supplying generic medicines to wholesalers, community pharmacies and dispensing doctors for use within the NHS, but not those who act solely as wholesalers.

<sup>204</sup> Scheme M was first introduced in June 2005 - see DH publication: '*Revised long-term arrangements for reimbursement of generic medicines*' (June 2005) and was revised in March 2010 - see DH publication: '*Revised*

- 3.140 The DH uses Scheme M to ensure that pharmacies are able to recover sufficient margin for their community prescribing services to be provided sustainably. The DH has agreed an £800 million funding target<sup>205</sup> (as part of a £2.8 billion total commitment) to be delivered to pharmacies through the margin that pharmacies make on sales of generic products (the retained margin). This target is primarily delivered by adjusting the Drug Tariff prices of drugs in Category M of the Drug Tariff.<sup>206</sup>
- 3.141 The margins made on other generic drugs outside of Scheme M may also contribute to this funding target, but adjusting the margins on Scheme M drugs is the key mechanism used by the DH to ensure that the target is met. Consequently, it is not unusual for the Drug Tariff price for drugs in Category M to be set substantially above the manufacturer's price. Allowing pharmacies to recover margins in this way also incentivises them to make more efficient purchasing decisions.<sup>207</sup> This means the Category M Drug Tariff prices may not be an accurate representation of the cost to the NHS of purchasing the drug since part of the price will be made up of costs which the NHS will have to pay in any event (i.e. lower margins on one Category M drug will, in practice, need to be offset by higher margins on another to make up the £800 million funding target).
- 3.142 The overall revenue provided to pharmacies through the retained margin is monitored through the DH's margin surveys and the prices are adjusted if the earnings on these margins deviate significantly from the target.
- 3.143 Scheme M is not intended to regulate the prices charged by manufacturers and suppliers and has never been used by the DH for this purpose. Scheme M allows its members to alter the price at which a medicine is sold to wholesalers or dispensing contractors without any requirement to discuss such changes with the DH in advance. The intention is that competition and pressure from pharmacies will restrain suppliers' pricing.<sup>208</sup> The National Audit Office found that there had been an overall cost saving to the NHS

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*long-term arrangements for reimbursement of generic medicines. Revised long-term arrangements for reimbursement of generic medicines Scheme M' (March 2010).*

<sup>205</sup> This commitment has increased since 2010 when it was £500 million.

<sup>206</sup> For further details see for example <http://psnc.org.uk/funding-and-statistics/funding-distribution/retained-margin-category-m/>. See also [https://www.nao.org.uk/wp-content/uploads/2010/03/0910\\_Community-Pharmacy.pdf](https://www.nao.org.uk/wp-content/uploads/2010/03/0910_Community-Pharmacy.pdf).

<sup>207</sup> See document PD 41.

<sup>208</sup> See for example PD 41, paragraph 12.

from this framework of around £1.8 billion over the period 2005-06 to 2008-09.

- 3.144 The Scheme M arrangements do include one paragraph which states that the DH *'may intervene to ensure that the NHS pays a reasonable price for the medicine(s) concerned'* if it identifies *'any significant events or trends in expenditure that indicate the normal market mechanisms have failed to protect the NHS from significant increases in expenditure'*.<sup>209</sup> To allow the DH to consider prices and reimbursement, a Scheme M Member may be required to provide to the DH on reasonable request information such as its costs and margins.<sup>210</sup> In the DH's examination of the reasonableness of the member's costs and prices, Scheme M also provides that the DH will have regard to a number of relevant factors which are listed in the arrangements.<sup>211</sup>
- 3.145 Scheme M does not, however, include any detail as to what such an intervention by the DH would involve or what the threshold(s) for intervention would be. The DH told the CMA that in practice *'this [X] clause had never been acted upon'*. The DH also described Scheme M as *'currently fairly limited'*<sup>212</sup> and further stated that:
- '...there is in practical terms nothing that the DH could use as 'leverage' to reduce the price of a particular drug'*.<sup>213</sup>
- 3.146 Scheme M also contains a dispute resolution procedure although this procedure has never been used to effect a reduction in a price of a drug in Scheme M.<sup>214</sup>
- 3.147 A Scheme M Member may withdraw from the Scheme M arrangements at any time.<sup>215</sup>

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<sup>209</sup> Department of Health – Revised long-term arrangements for reimbursement of generic medicines. Scheme M. March 2010, paragraph 30 ('Scheme M 2010').

<sup>210</sup> (Scheme M 2010), paragraph 31.

<sup>211</sup> (Scheme M 2010), paragraph 32. These include trends in the member's and other companies' prices for the product; any special features of the member's operation; any ratios inferred from the member's non-generics business; each member's reported costs and profit margins and the average of other similar companies; and information from external sources relating to the generics industry.

<sup>212</sup> See document 00468.1, paragraph 53.

<sup>213</sup> See document 02032.1, paragraph 42.

<sup>214</sup> See document 02032.1, paragraph 42.

<sup>215</sup> (Scheme M 2010), paragraph 44. It would do so by withdrawing consent for the voluntary Scheme to be treated as applying to it.

*iii. Scheme W*

3.148 Like Scheme M, Scheme W is a voluntary scheme to facilitate the setting of pharmacy reimbursement prices for Category M products, but it applies to wholesalers of Category M generic products. It provides for the regular provision of pricing information from wholesalers to the DH.

*d. The Secretary of State's powers to control prices*

3.149 The Secretary of State also has certain powers to monitor and control drug pricing in specific circumstances, which are contained in sections 261 to 266 of the NHS Act 2006 (as amended). The Secretary of State's role is discharged through the DH, and so this section will generally refer to the DH.

3.150 As already set out above, section 261 of the NHS Act grants the DH the power to enter into voluntary schemes with industry members (such as the PPRS) for the purpose of controlling the cost of pharmaceutical medicines.

3.151 In addition, sections 262 and 263 of the NHS Act grant the Secretary of State the power to, respectively;

- (a) impose direct price controls on specific medicines; and
- (b) introduce an industry wide statutory scheme to control the price of medicines not covered by a voluntary scheme.

3.152 The regulations governing the Statutory Scheme enacted under section 263 during the Relevant Period are set out in:

- (c) the Health Service Branded Medicines (Control of Prices and Supply of Information) (No.2) Regulations 2008; and
- (d) the Health Service Medicines (Information Relating to Sales of Branded Medicines etc.) Regulations 2007, as amended (together the 'Statutory Scheme Regulations').

3.153 However, the Regulations apply only to branded medicines and the DH is not intended to act as a price regulator for generic medicines. In particular:

- (a) the DH does not use (and throughout the relevant period, has not used) its statutory powers to set the prices of individual generic medicines.

Instead, its policy is to rely primarily on competition to control the prices of generic medicines.<sup>216</sup>

- (b) the DH does not have (and throughout the relevant period, has not had) the statutory power to require the provision of financial and cost information for generic medicines. This makes it very difficult for the DH to investigate or meaningfully assess potential anomalies or abuses in pharmaceutical pricing;
- (c) [redacted];<sup>217</sup>
- (d) the DH has very limited resources and has to use those resources most efficiently;<sup>218</sup> and
- (e) the DH now has a policy of referring suspected cases of excessive prices directly to the CMA.<sup>219</sup>

3.154 The DH's statutory powers under sections 262 and 263 of the NHS Act are also subject to certain limits. For example, the DH must consult the ABPI before it exercises any of its price control powers under either section 262 or 263 of the NHS Act. Furthermore, the DH told the CMA that:

*'the effect of sections 262(2) and 263(7) is that neither statutory Regulations nor direct price limiting by the Secretary of State can be used to control the prices of health service medicines (or the profits derived from them) supplied by members of a voluntary scheme, even to cover any gaps where the voluntary scheme does not extend to particular medicines or classes of medicine.'*<sup>220</sup>

3.155 Many generic medicines are supplied by licence holders who are also members of a voluntary scheme (e.g. the PPRS). Consequently, these medicines are exempt from all statutory price controls under sections 262

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<sup>216</sup> See document 02032.1, paragraph 13.

<sup>217</sup> See document 02032.1, paragraph 9.

<sup>218</sup> See document 02032.1, paragraph 10.

<sup>219</sup> See for example <http://www.parliament.uk/business/publications/written-questions-answers-statements/written-question/Commons/2016-02-03/25781/> (PD 49) and <http://www.parliament.uk/business/publications/written-questions-answers-statements/written-question/Commons/2016-07-15/42887/> (PD 50).

<sup>220</sup> See document 00367.2. See also document 01904.1. This was confirmed by the CAT in *Genzyme*, [272] and [273].

and 263 of the NHS Act.<sup>221</sup> Only if the licence holder is not a member of any voluntary scheme could the generic medicines they sell potentially be subject to statutory price controls. [✂].<sup>222</sup>

- 3.156 This regulatory framework means that Flynn's sales of phenytoin sodium capsules are exempt from statutory price controls. Up to September 2012, Pfizer sold *Epanutin* in the UK as a branded medicine. As Pfizer was (and continues to be) a member of the PPRS, its sales of *Epanutin* were subject to the terms of the PPRS. However, since September 2012, Flynn's Products have been sold as generics and have not been subject to any price regulation. Flynn's Products are not covered by the PPRS or any other voluntary scheme and, because Flynn is also a member of the PPRS,<sup>223</sup> all the products it sells are exempt from the DH's statutory price controls under sections 262 and 263 of the NHS Act.
- 3.157 In September 2016, the DH introduced the Health Service Medical Suppliers (Costs) Bill before Parliament. If enacted, this Bill will change the UK's pharmaceutical price regulation framework in several respects. These include:
- making drugs outside of a voluntary scheme subject to statutory regulation even if the licence holder is a member of a voluntary scheme; and
  - requiring licence holders to provide cost and other financial information to the DH upon request.<sup>224</sup>
- 3.158 At the second reading of the Health Service Medical Suppliers (Costs) Bill on 24 October 2016, the Secretary of State stated that key reasons for introducing the Bill were to remedy the fact that the Government's existing powers do not allow it to place price controls on unbranded generic medicines where a company is a member of the PPRS and to prevent such firms from being able to exploit such freedom of pricing for unbranded generic medicines where there is no competition in the market:

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<sup>221</sup> As set out above, the Statutory Scheme does not, in any event, apply to generic medicines. Even if the regulations were to be extended to apply to generic products the exemption in section 263(7) of the NHS Act would prevent the regulations applying to generic drugs whose suppliers are members of a voluntary scheme.

<sup>222</sup> See document 02032.1, paragraph 11.

<sup>223</sup> See: <http://www.abpi.org.uk/our-work/commercial/pprs/Pages/default.aspx>.

<sup>224</sup> Health Service Medical Supplies (Costs) Bill (HC Bill 72), [http://www.publications.parliament.uk/pa/bills/cbill/2016-2017/0072/cbill\\_2016-20170072\\_en\\_1.htm](http://www.publications.parliament.uk/pa/bills/cbill/2016-2017/0072/cbill_2016-20170072_en_1.htm). (PD 45)

*'The second key element of this Bill amends the 2006 Act to strengthen the Government's powers to set prices of medicines where companies charge unreasonably high prices for unbranded generic medicines. We rely on competition in the market to keep the prices of these drugs down. That generally works well and has, in combination with high levels of generic prescribing, led to significant savings. However, we are aware of some instances where there is no competition to keep prices down, and companies have raised their prices to what looks like an unreasonable and unjustifiable level. As highlighted by the investigation conducted by The Times earlier this year, there are companies that appear to have made it their business model to purchase off-patent medicines for which there are no competitor products. They then exploit a monopoly position to raise prices. We cannot allow this practice to continue unchallenged. My Department has been working closely with the Competition and Markets Authority to alert it to any cases where there may be market abuse and provide evidence to support this, but we also need to tackle it within our framework for controlling the cost of medicines and close the loophole of de-branding medicines. Although the Government's existing powers allow us to control the price of any health service medicine, they do not allow controls to be placed on unbranded generic medicines where companies are members of the voluntary PPRS scheme. Today, most companies have a mixed portfolio of branded medicines and unbranded generic medicines. For that reason, all the manufacturers of the unbranded generic medicines mentioned in the investigation by The Times are able to use their PPRS membership to avoid government control of their prices.*

*It should be said that that practice is not widespread, but a handful of companies appear to be exploiting our freedom of pricing for unbranded generic medicines where there is no competition in the market, leaving the NHS with no choice but to purchase the medicine at grossly inflated prices or to transfer patients to other medicines that are not always suitable. Alongside the Government, many in the industry would also like to see this inappropriate behaviour stamped out.'*<sup>225</sup>

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<sup>225</sup> See [https://hansard.parliament.uk/commons/2016-10-24/debates/16102429000001/HealthServiceMedicalSupplies\(Costs\)Bill](https://hansard.parliament.uk/commons/2016-10-24/debates/16102429000001/HealthServiceMedicalSupplies(Costs)Bill).

3.159 The Secretary of State also set out that another element of the Bill was to strengthen the Government's powers to gather information for purposes including determining value for money and controlling prices:

*'strengthen the Government's powers to collect information on the costs of medicines, medical supplies and other related products from across the supply chain, from factory gate to those who supply medicines to patients. We currently collect information on the sale and purchases of medicines from various parts of the supply chain under a range of different arrangements and for a range of specific purposes. Some of these arrangements are voluntary, whereas others are statutory. The Bill will streamline the existing information requirements in the 2006 Act relating to controlling the cost of healthcare products. It will enable the Government to make regulations to require all those involved in the manufacture, distribution or supply of health service medicines, medical supplies or other related products to record, keep and provide at request information on sales and purchases. The use of this information would be for defined purposes: the reimbursement of community pharmacies and GPs, determining the value for money that the supply chain or products provide; and controlling the cost of medicines. This will enable the Government to put the current voluntary arrangements for data provision with manufacturers and wholesalers of unbranded generic medicines and manufactured specials on a statutory footing. As the arrangements are currently voluntary, they do not cover all products and companies, which limits the robustness of the reimbursement price setting mechanism.'*<sup>226</sup>

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<sup>226</sup> [https://hansard.parliament.uk/commons/2016-10-24/debates/16102429000001/HealthServiceMedicalSupplies\(Costs\)Bill](https://hansard.parliament.uk/commons/2016-10-24/debates/16102429000001/HealthServiceMedicalSupplies(Costs)Bill).



## D. Prices

### Summary

The key evidence in the following section shows that:

- Prior to September 2012, Pfizer's prices to wholesalers and/or pharmacies for *Epanutin* were broadly stable, as were the Drug Tariff prices.
- While Pfizer continued to manufacture phenytoin sodium capsules, Flynn began to distribute them in September 2012. Pfizer's and Flynn's pricing decisions led to significant increases in the prices for 25mg, 50mg, 100mg and 300mg capsules to wholesalers and pharmacies.
- With effect from October 2012, the Drug Tariff prices for phenytoin sodium capsules increased significantly.
- In January 2014 Pfizer reduced its supply prices for 50mg, 100mg and 300mg phenytoin sodium capsules. Following this, Flynn reduced its prices for 100mg and 300mg phenytoin sodium capsules in April 2014 and this resulted in the Drug Tariff prices for 100mg and 300mg capsules being reduced.
- In May 2014, Flynn moved to an RWM and, as a result, its prices for 25mg, 50mg, 100mg and 300mg capsules to wholesalers increased.
- Phenytoin sodium capsules have been (and continue to be) sold by Pfizer in a number of other EU Member States under the *Epanutin* brand. The prices in these other Member States have not changed materially during the Relevant Period.

### I. Introduction

3.160 There are three sets of prices which are relevant to this decision. These are:

- (a) Pfizer's Prices for its supply of phenytoin sodium capsules to Flynn pursuant to the Exclusive Supply Agreement.
- (b) Flynn's Prices for the phenytoin sodium capsules it sells to wholesalers. [X]. The CMA has therefore assessed Flynn's pricing on the basis of its ASPs (i.e. the actual prices at which Flynn sells its Products to pharmacies and wholesalers, which is a discount to the Drug Tariff prices).

- (c) Category C Drug Tariff prices for phenytoin sodium capsules. These prices (less any clawback discount) determine the reimbursement prices paid to pharmacies for the drugs they dispense. The Drug Tariff prices for phenytoin sodium capsules are determined by reference to the list prices set by Flynn.<sup>227</sup> They are the prices that CCGs (i.e. the NHS), ultimately pay.<sup>228</sup>
- 3.161 This section explains how each of these prices have changed during the relevant period.
- 3.162 In this section all prices refer to the price of a single pack of phenytoin sodium capsules.<sup>229</sup>
- 3.163 There have been a number of price changes during the Relevant Period. Each of these is summarised below:
- (a) Up to September 2012, and since at least 2003, Pfizer both manufactured and distributed phenytoin sodium capsules for use in the UK under the brand name *Epanutin*. Over this period, Pfizer's prices to wholesalers and/or pharmacies were broadly unchanged, as were the Drug Tariff prices.
- (b) In September 2012, Flynn began to distribute phenytoin sodium capsules in the UK and Pfizer and Flynn set their respective prices. This led to significant **increases** in the price for 25mg, 50mg, 100mg and 300mg capsules to wholesalers and pharmacies.
- (c) In November 2012, the DH **increased** the published Drug Tariff prices for 25mg, 50mg, 100mg and 300mg capsules. These revised Drug

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<sup>227</sup> As phenytoin sodium capsules fall within Category C of the Drug Tariff, reimbursement prices are determined by reference to a proprietary product. The proprietary products for phenytoin sodium capsules are Flynn's products and, as such, the Drug Tariff prices for phenytoin sodium capsules are determined by reference to Flynn's list prices, see section 3.C.III.b. above.

<sup>228</sup> Subject to any clawback by the NHS. Clawback applies only to 25mg and 50mg capsule strengths. See section 3.C.III.b. above.

<sup>229</sup> 84 capsules for 100mg capsules and 28 capsules for all other capsule strengths, see section 3.B.II.a. above. The CMA is aware that Parallel Imports may be sold in different pack sizes, such as packs of 100 capsules. However, this is not relevant for this section as it does not focus on the price of Parallel Imports.

Tariff prices were in effect for prescriptions dispensed by pharmacists in October 2012.<sup>230</sup>

- (d) In January 2014, Pfizer **decreased** its prices for 50mg, 100mg and 300mg capsules, following the conclusion of its negotiations with Flynn on the supply prices in the Exclusive Supply Agreement.<sup>231</sup>
- (e) In April 2014, Flynn **decreased** its prices for 100mg and 300mg capsules.
- (f) In May 2014, the DH **decreased** the published Drug Tariff prices for 100mg and 300mg capsules. These revised Drug Tariff prices were in effect for prescriptions dispensed by pharmacists in May 2014.<sup>232</sup>
- (g) In May 2014, Flynn moved to a RWM<sup>233</sup> and decreased the standard discounts it offered wholesalers from the Drug Tariff price. As a result, Flynn **increased** its prices for 25mg, 50mg, 100mg and 300mg capsules to wholesalers. The Drug Tariff prices were unaffected.

3.164 The remainder of this section discusses these price changes in more detail.

3.165 It also sets out the prices at which Pfizer-manufactured phenytoin sodium capsules have been (and continue to be) sold in a number of other EU Member States.

## II. ***Drug Tariff prices***

3.166 Table 3.3 below summarises the Drug Tariff prices for each capsule strength.

3.167 Prior to September 2012, and since at least January 2003, the Drug Tariff prices for 25mg and 50mg capsules were £0.66 and £0.67 respectively

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<sup>230</sup> See document 01207.1, which explains that if the NHSBSA is informed of a price change up to and including the 8th of the month, it will take effect for prescriptions dispensed in the following month. If the price change takes effect after the 8th of the month, the price change will be applied for reimbursement purposes one month later.

<sup>231</sup>The CMA notes that, although the reduction in the supply price was only actually agreed in February 2014, it was backdated to January 2014; see document 00505.48.

<sup>232</sup> See document 01207.1

<sup>233</sup> See section 3.C.i.c.

whilst the Drug Tariff prices for 100mg and 300mg capsules were both £2.83.<sup>234</sup>

3.168 With effect from October 2012<sup>235</sup> there were substantial increases in the Drug Tariff prices for all four capsule strengths. The new Drug Tariff prices for 25mg and 50mg capsules were £15.74 and £15.98 respectively whilst the new Drug Tariff prices for both 100mg and 300mg capsules were £67.50. These prices each represent an increase of 2,285% when compared to the previous Drug Tariff prices.

3.169 The Drug Tariff prices for 100mg and 300mg capsules were subsequently reduced, with effect from May 2014, by 20% and 15% respectively. Consequently, the Drug Tariff prices for 100mg and 300mg capsules are currently £54 and £57.38 respectively.<sup>236</sup>

**Table 3.3: Phenytoin sodium capsule Drug Tariff prices\***

	Pre-September 2012	October 2012 to April 2014	% change	May 2014 to present date**	% change	% increase since pre-September 2012
<b>25mg</b>	£0.66	£15.74	2,285%	£15.74	0%	2,285%
<b>50mg</b>	£0.67	£15.98	2,285%	£15.98	0%	2,285%
<b>100mg</b>	£2.83	£67.50	2,285%	£54.00	-20%	1,808%
<b>300mg</b>	£2.83	£67.50	2,285%	£57.38	-15%	1,928%

\*Drug Tariff prices are shown for the period for which they were in effect. For example, the published Drug Tariff price for 25mg was increased from £0.66 to £15.74 in November 2012. However, the £15.74 price was applied to all prescriptions dispensed in October 2012 and so was in effect from that date.

\*\*The Drug Tariff prices shown in this table are those for England, Wales and Northern Ireland. The CMA is aware that for Scotland the Drug Tariff prices for 100mg and 300mg phenytoin sodium capsules were not adjusted until April 2015.

Source: [www.nhsbsa.nhs.uk/PrescriptionServices/4940.aspx](http://www.nhsbsa.nhs.uk/PrescriptionServices/4940.aspx) and document 01287.1

3.170 These Drug Tariff prices continue to be significantly above the prices that prevailed prior to September 2012. As a result, each Drug Tariff price currently exceeds the Drug Tariff price which was in effect prior to September 2012 by the following percentages:

<sup>234</sup> At this point in time phenytoin sodium capsules were manufactured and distributed by Pfizer and the maximum price was regulated under the PPRS; see section 3.C.III.c. above.

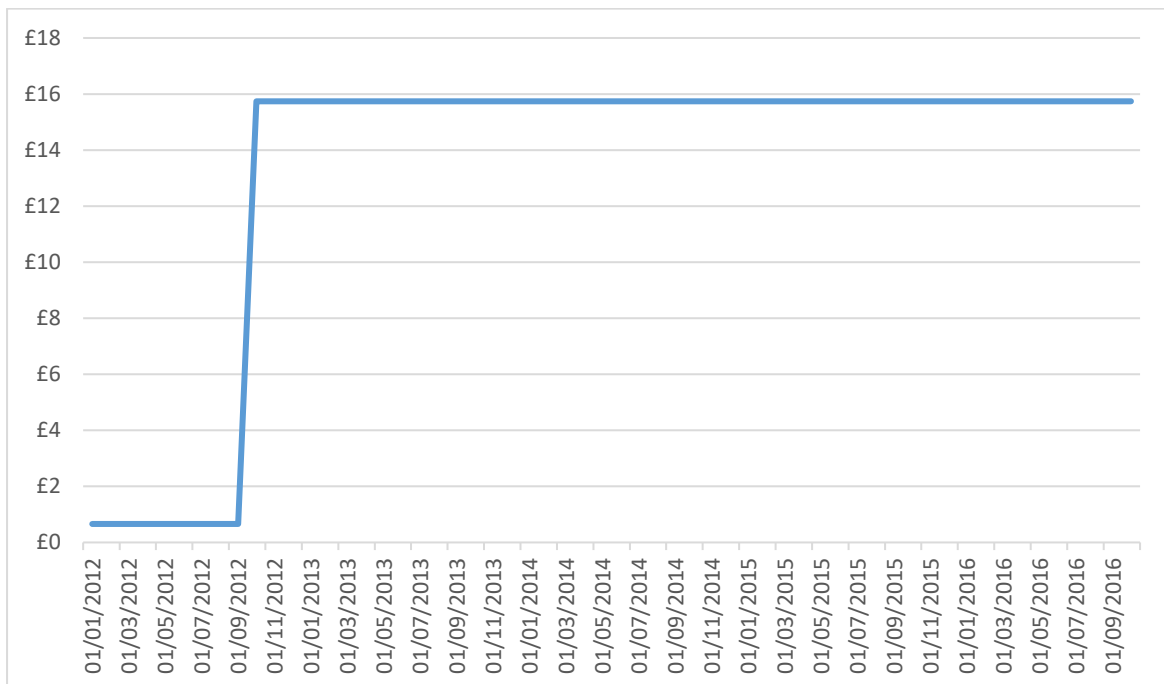
<sup>235</sup> Flynn began to distribute the products in the UK from the end of September 2012 (having acquired Pfizer's MAs in March 2012); see section 3.B.II.b. above.

<sup>236</sup> The CMA is aware that the reduced prices for 100mg and 300mg capsules were reflected in the Scottish Drug Tariff in April 2015.

- 25mg: 2,285% higher
- 50mg: 2,285% higher
- 100mg: 1,808% higher
- 300mg: 1,928% higher

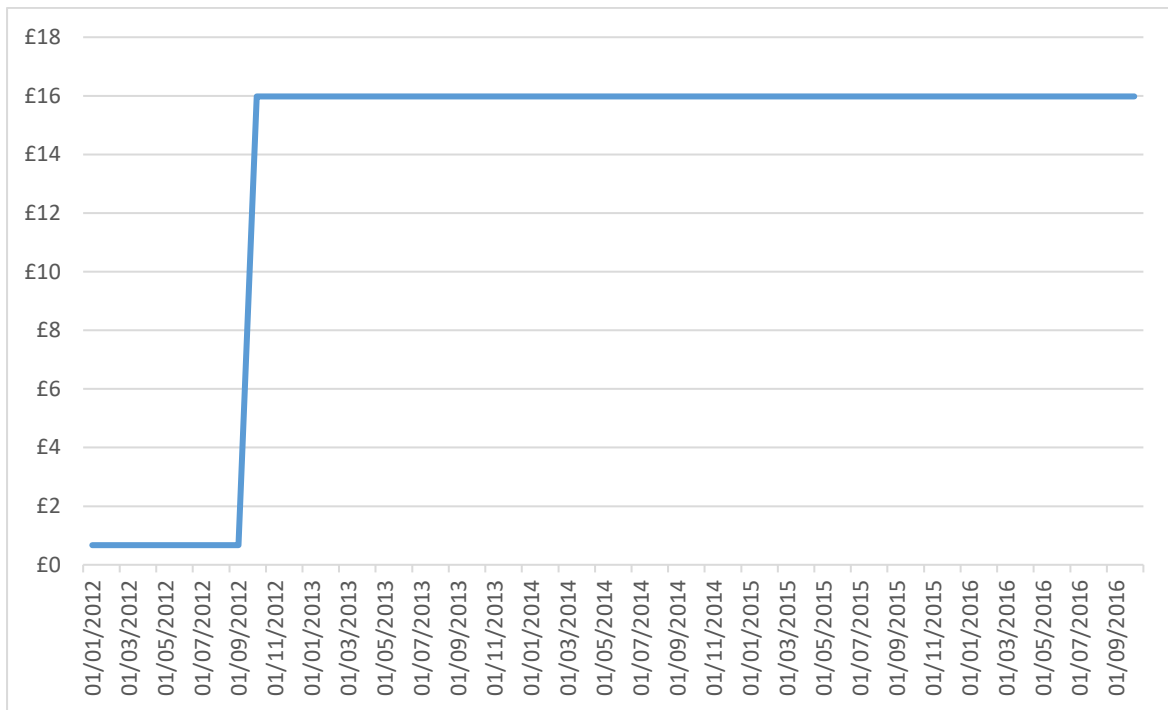
3.171 The evolutions of these prices are also shown in Figures 3.3 to 3.6 for 25mg, 50mg, 100mg and 300mg capsule strengths respectively.<sup>237</sup>

**Figure 3.3: 25mg phenytoin sodium capsule Drug Tariff price**

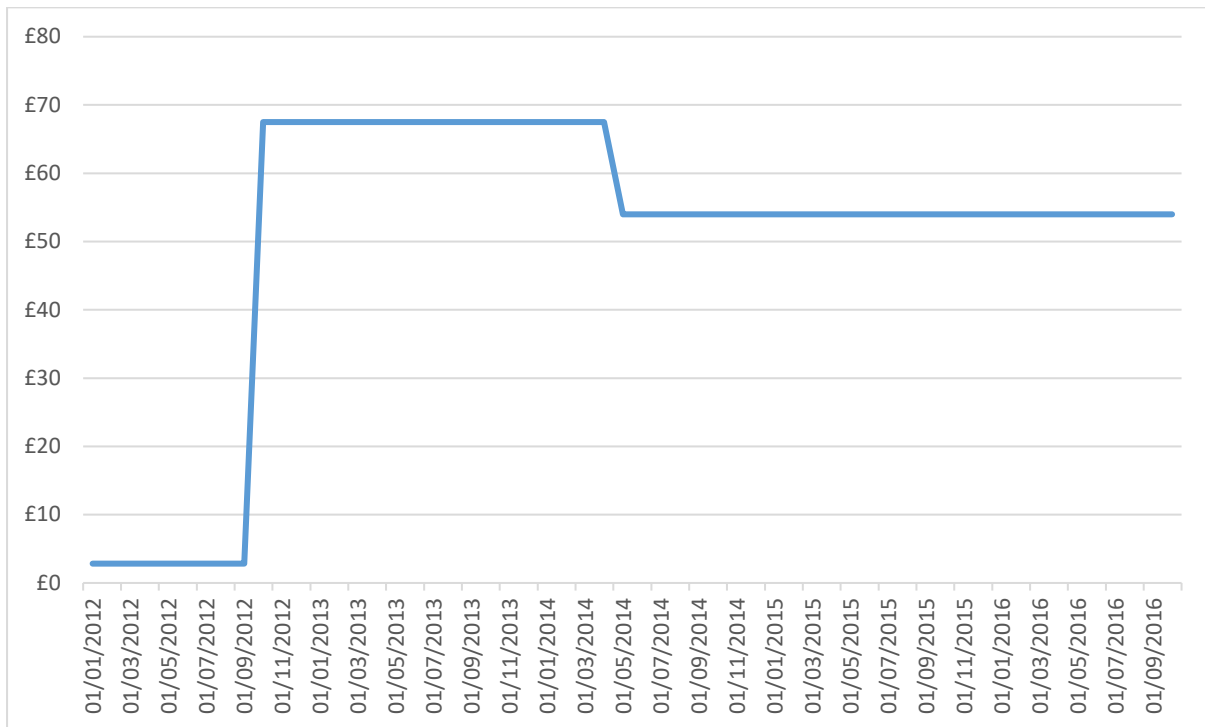


<sup>237</sup> Figures 3.3 to 3.6 show the Drug Tariff prices which were in effect at any point in time. For example, although the published Drug Tariff was only updated to reflect the higher prices in November 2012, these higher prices were applied to prescriptions dispensed from October 2012.

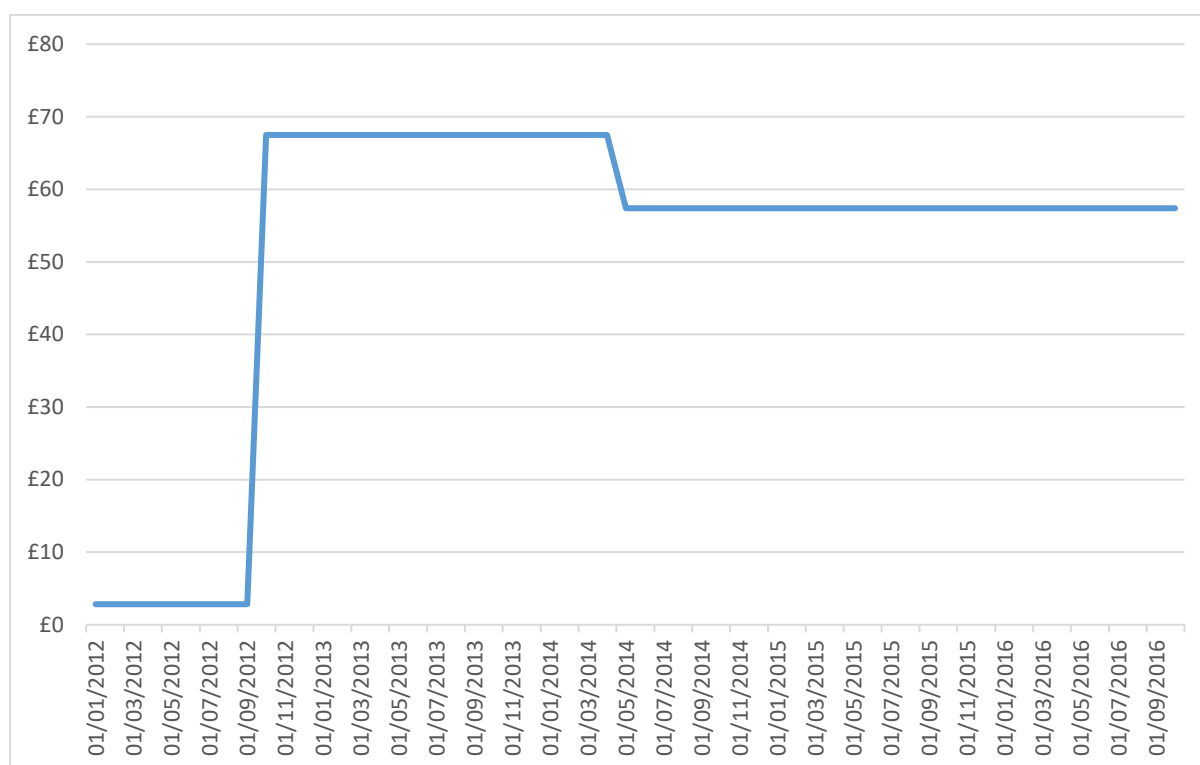
**Figure 3.4: 50mg phenytoin sodium capsule Drug Tariff price**



**Figure 3.5: 100mg phenytoin sodium capsule Drug Tariff price**



**Figure 3.6: 300mg phenytoin sodium capsule Drug Tariff price**



### III. **Pfizer's Prices**

3.172 This section presents the ASPs charged by Pfizer during the Relevant Period. The ASPs are based on the sales value and sales volume data provided by Pfizer during the Investigation.<sup>238</sup>

3.173 Table 3.4 shows Pfizer's ASPs for each capsule strength during the Relevant Period. Table 3.5 presents the percentage change in Pfizer's ASPs for each capsule strength relative to the pre-September 2012 ASP.

**Table 3.4: Pfizer average selling prices**

	<b>Pre-September 2012</b>	<b>Post-September 2012</b>	<b>September 2012 to December 2013*</b>	<b>March 2014 to June 2016</b>
<b>25mg</b>	£0.51	[£3 - £5.99]	[£3 - £5.99]	[£3 - £5.99]
<b>50mg</b>	£0.52	[£6 - £8.99]	[£6 - £8.99]	[£6 - £8.99]
<b>100mg</b>	£2.21	[£31 - £40.99]	[£31 - £40.99]	[£31 - £40.99]
<b>300mg</b>	£2.20	[£31 - £40.99]	[£41 - £50.99]	[£31 - £40.99]

Notes: All calculations are based on the sales value and sales volume data submitted by Pfizer (see document 02129.2)

<sup>238</sup> See document 02129.2.

Pre-September ASPs are based on sales value and volume data for the period March 2004 until September 2012 (excluding September 2012 sales by Pfizer to Flynn). These ASPs refer to the prices charged by Pfizer to wholesalers and/or pharmacists.

Post-September 2012 ASPs are based on sales and volumes data for Pfizer's sales to Flynn for the period September 2012 until June 2016.

\*[§]. The CMA has not been able to include ASPs for Pfizer for January and February 2014 [§] therefore any ASP calculated would not be meaningful.

The unadjusted (i.e. without a rebate adjustment) figures for the period September 2012 to December 2013 are: [£3 - £5.99], [£6 - £8.99], [£41 - £50.99] and [£41 - £50.99] for the 25mg, 50mg, 100mg, and 300mg capsule strengths respectively. [§].

**Table 3.5: Pfizer average selling prices – percentage changes relative to Pfizer's pre-September 2012 average selling price**

	<b>Pre-September 2012</b>	<b>Post-September 2012</b>	<b>September 2012 to December 2013</b>	<b>March 2014 to June 2016</b>
<b>25mg</b>	£0.51	[Over 488%]	[Over 488%]	[Over 488%]
<b>50mg</b>	£0.52	[Over 1,054%]	[Over 1,054%]	[Over 1,054%]
<b>100mg</b>	£2.21	[Over 1,303%]	[Over 1,755%]	[Over 1,303%]
<b>300mg</b>	£2.20	[Over 1,309%]	[Over 1,764%]	[Over 1,309%]

Notes: CMA's own calculations based on Table 3.4 above.  
The ASPs presented in Table 3.4 have been presented to two decimal places; the percentage increases in Table 3.5 have been calculated using data that has not been rounded.

- 3.174 There are several points to note. First, it can be seen that Pfizer's ASPs for all dosage strengths have been significantly and persistently higher since September 2012 than they were prior to September 2012.<sup>239</sup>
- 3.175 Second, between September 2012 and December 2013, Pfizer's ASP for 25mg capsules was equal to the price agreed by Pfizer and Flynn in the Exclusive Supply Agreement and Pfizer's ASPs for 50mg, 100mg and 300mg capsules were slightly below those set out in the Exclusive Supply Agreement.<sup>240</sup>

<sup>239</sup> Pfizer's pre-September 2012 ASPs are shown for context. However, the CMA notes that the comparability of these prices is somewhat limited since Pfizer's role in the supply chain has changed over time. In particular, the pre-September 2012 ASPs reflect the prices received by Pfizer from wholesalers and pharmacies. Meanwhile, ASPs after September 2012 reflect the prices received by Pfizer from Flynn and it is Flynn who sells to wholesalers.

<sup>240</sup> These prices were [£3 - £5.99] for 25mg capsules, [£6 - £8.99] for 50mg capsules and [£41 - £50.99] for both 100mg and 300mg capsules; see document 00086.1.



- 3.176 The reason for these differences is that in February 2014 Pfizer and Flynn revised the Exclusive Supply Agreement and agreed new supply prices for 50mg, 100mg and 300mg capsules.<sup>241,242</sup> [REDACTED].<sup>243</sup> [REDACTED].<sup>244,245</sup>
- 3.177 Third, Pfizer's ASPs for 50mg, 100mg and 300mg capsules were lower between March 2014 and June 2016 (the period after the rebate was provided) relative to the preceding period, September 2012 to December 2013. However, it is important to note that Pfizer's ASPs for this latter period (March 2014 to June 2016) have remained significantly above the ASPs which prevailed prior to September 2012. Moreover, Pfizer's ASPs have been slightly above the prices set out in the Exclusive Supply Agreement between March 2014 and June 2016.<sup>246</sup>

#### IV. *Flynn's Prices*

- 3.178 This section presents Flynn's ASPs, which are based on the sales value and sales volume data provided by Flynn during the Investigation.<sup>247</sup> Its prices are consistent across the UK.
- 3.179 Table 3.6 summarises Flynn's ASPs for each capsule strength over the Relevant Period. Pfizer's pre-September 2012 ASPs are also included for comparison and context. Both sets of prices are comparable since they both reflect the ASPs being charged to wholesalers and pharmacies over the relevant time periods.<sup>248</sup> Table 3.7 presents the percentage change in Flynn's ASPs for each capsule strength relative to Pfizer's pre-September 2012 ASP. Flynn's ASPs since September 2012 have significantly exceeded those of Pfizer for the period prior to September 2012.

<sup>241</sup> Under the revised Exclusive Supply Agreement the agreed supply prices are: [£3 - £5.99] for 25mg capsules, [£6 - £8.99] for 50mg capsules, [£31 - £40.99] for 100mg and 300mg capsules; see document 00476.1.

<sup>242</sup> The CMA understands that the change in the price for 50mg capsules reversed an uplift which was originally applied to compensate Pfizer following the delays Flynn faced introducing their products; see document 00086.1.

<sup>243</sup> See document 00505.48.

<sup>244</sup> [REDACTED].

<sup>245</sup> The effect of this rebate is reflected in Pfizer's lower (unadjusted) ASPs for the period January to April 2015. Over this period Pfizer's ASPs were [£3 - £5.99], [£6 - £8.99], [£31 - £40.99] and [£31 - £40.99] for 25mg, 50mg, 100mg and 300mg capsules respectively.

<sup>246</sup> During this period the prices in the Exclusive Supply Agreement were [£3 - £5.99] and [£6 - £8.99] per pack for the 25mg and 50mg capsules and [£31 - £40.99] per pack for the 100mg and 300mg capsules.

<sup>247</sup> See documents 00505.22, 00872.3, 00915.1, 01148.2, 01148.3, 01293.2, 01839.13 and 02115.2.

<sup>248</sup> Pfizer sold phenytoin sodium capsules to wholesalers until 2007 when it switched to a DTP model; see document 01287.1.

**Table 3.6: Flynn's average selling prices**

	<b>Pfizer Pre-September 2012</b>	<b>Post-September 2012</b>	<b>September 2012 to March 2014</b>	<b>May 2014 to June 2016</b>
<b>25mg</b>	£0.51	[£11 - £20.99]	[£11 - £20.99]	[£11 - £20.99]
<b>50mg</b>	£0.52	[£11 - £20.99]	[£11 - £20.99]	[£11 - £20.99]
<b>100mg</b>	£2.21	[£51 - £60.99]	[£51 - £60.99]	[£41 - £50.99]
<b>300mg</b>	£2.20	[£51 - £60.99]	[£51 - £60.99]	[£51 - £60.99]

Notes: All calculations are based on sales value and sales volume data provided by Flynn (see documents 00505.22, 00872.3, 00915.1, 01148.2, 01148.3, 01293.2, 01839.13 and 02115.2).  
Flynn adjusted its prices in April 2014 and then moved to an RWM from May 2014. The move to an RWM involved a reduction in the discount wholesalers were provided from the Drug Tariff prices for Flynn's Products and led to an increase in Flynn's ASPs since May 2014 relative to those for April 2014. Flynn's ASPs for April 2014 are not included in Table 3.6 as Flynn's price changed during this month, however, they were: [£11- £20.99], [£11 - £20.99], [£41- £50.99] and [£51- £60.99] for the 25mg, 50mg, 100mg and 300mg capsules respectively.

**Table 3.7: Flynn's average selling prices – percentage changes relative to Pfizer's pre-September 2012 average selling price**

	<b>Pfizer Pre-September 2012</b>	<b>Post-September 2012</b>	<b>September 2012 to March 2014</b>	<b>May 2014 to June 2016</b>
<b>25mg</b>	£0.51	[Over 2,057%]	[Over 2,057%]	[Over 2,057%]
<b>50mg</b>	£0.52	[Over 2,015%]	[Over 2,015%]	[Over 2,015%]
<b>100mg</b>	£2.21	[Over 2,208%]	[Over 2,208%]	[Over 1,755%]
<b>300mg</b>	£2.20	[Over 2,218%]	[Over 2,218%]	[Over 2,218%]

Notes: CMA's own calculations based on Table 3.6 above.  
The ASPs presented in Table 3.6 have been presented to two decimal places; the percentage increases in Table 3.7 have been calculated using data that has not been rounded

3.180 Figures 3.7 to 3.10, below, show the evolution of Flynn's ASPs, as well as the Drug Tariff prices for 25mg, 50mg, 100mg, and 300mg capsules respectively.<sup>249</sup>

**a. 25mg capsules**

3.181 As figure 3.7 shows, between September 2012 and March 2014, Flynn's monthly ASPs for 25mg capsules were stable, fluctuating only between [£11 - £20.99] and [£11- £20.99], and Flynn's ASP for 25mg capsules for this period was [£11- £20.99]. Throughout this period the Drug Tariff price was

<sup>249</sup>The CMA has included Figures 3.7 to 3.10 to illustrate the evolution of Flynn's ASPs and the discount from the Drug tariff that these ASPs represented (this is relevant to Flynn but not to Pfizer's ASPs and so this is not shown in section 3.D.III. above). The CMA does not have similar graphs for Pfizer above because Pfizer supplies to Flynn directly and not to pharmacies and wholesalers.

£15.74 (meaning that Flynn's ASP was a [less than 15%] discount from the Drug Tariff price between September 2012 and March 2014).

**Figure 3.7: 25mg Flynn monthly ASP and Drug Tariff price**

[✂]

3.182 In May 2014, Flynn moved to a RWM and consequently reduced the standard discount from the Drug Tariff price which it had offered to wholesalers and pharmacies.<sup>250</sup> This is reflected in the increase in Flynn's monthly ASP for 25mg capsules from May 2014. Between May 2014 and June 2016, Flynn's monthly ASPs for 25mg capsules fluctuated between [£11- £20.99] and [£11- £20.99] and Flynn's ASP for 25mg capsules for this period was [£11- £20.99] (a [less than 10%] discount from the Drug Tariff price between May 2014 and June 2016).

**b. 50mg capsules**

3.183 As Figure 3.8 shows, between September 2012 and March 2014, Flynn's monthly ASPs for 50mg capsules were stable, fluctuating between [£11 - £20.99] and [£11 - £20.99], and Flynn's ASP for 50mg capsules for this period was [£11 - £20.99]. Throughout this period the Drug Tariff price was £15.98 (showing that Flynn's ASP was a [less than 15%] discount from the Drug Tariff price between September 2012 and March 2014).

**Figure 3.8: 50mg Flynn monthly ASP and Drug Tariff price**

[✂]

3.184 Flynn's monthly ASP for 50mg capsules then increased following Flynn's switch to an RWM in May 2014. Consequently, between May 2014 and June 2016 Flynn's monthly ASPs for 50mg capsules fluctuated between [£11 - £20.99] and [£11- £20.99]. Flynn's ASP for 50mg capsules for the entire period May 2014 until June 2016 was [£11- £20.99] (representing an [less than 15%] discount from the Drug tariff price).

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<sup>250</sup> See section 3.C.I.c. below.

**c. 100mg capsules**

3.185 As Figure 3.8 shows, between September 2012 and March 2014, Flynn's ASP for 100mg capsules was [£51- £60.99] ( [less than 15%] discount from the Drug Tariff price). For this period, Flynn's monthly ASPs for 100mg capsules fluctuated between [£51 - £60.99] and [£61- £70.99].

**Figure 3.9: 100mg Flynn monthly ASP and Drug Tariff price**

[✂]

3.186 In April 2014, Flynn reduced its price for 100mg capsules and the Drug Tariff price fell. As a result, Flynn's ASP for 100mg capsules fell to [£41- £50.99] in April 2014. However, Flynn then moved to an RWM in May 2014 which led to an increase in Flynn's ASPs for 100mg capsules. Specifically, between May 2014 and June 2016 Flynn's ASP for 100mg capsules was [£41 - £50.99] (representing a [less than 10%] discount from the Drug Tariff price between May 2014 and June 2016). Throughout this period, Flynn's monthly ASPs for 100mg capsules fluctuated between [£41- £50.99] and [£41- £50.99].

**d. 300mg capsules**

3.187 Between September 2012 and March 2014, Flynn's ASPs for 300mg capsules were stable with its monthly ASPs for 300mg capsules fluctuating between [£51- £60.99] and [£51- £60.99], as shown by Figure 3.10. Flynn's ASP for 300mg capsules for this period was [£51 - £60.99] (representing a [less than 15%] discount from the Drug Tariff price between September 2012 and March 2014).

**Figure 3.10: 300mg Flynn ASP and Drug Tariff price**

[✂]

3.188 In April 2014, Flynn reduced its price for 300mg capsules and the Drug Tariff price fell. Consequently, Flynn's ASP for 300mg capsules for April 2014 was [£51- £60.99].

3.189 However, Flynn's ASPs for 300mg capsules increased again following Flynn's switch to an RWM. Specifically, between May 2014 and June 2016 Flynn's ASP for 300mg capsules was [£51 - £60.99] (a [less than 10%] discount from the Drug Tariff price between May 2014 and June 2016) and in this period Flynn's monthly ASPs for 300mg capsules fluctuated between [£51 - £60.99] and [£51 - £60.99].

e. ***Differences between Flynn's ASPs and the Drug Tariff prices***

3.190 Table 3.8 below shows the differences between Flynn's ASPs and the Drug Tariff prices for all four strengths of phenytoin sodium capsules over two periods, September 2012 to March 2014 and post-May 2014. It can be seen that the difference between Flynn's ASPs and the Drug Tariff prices are lower post-May 2014 compared with September 2012 to March 2014. For example, between September 2012 and March 2014 the difference between Flynn's 100mg ASP and the 100mg Drug Tariff price was [less than 15%]. However, since May 2014 this has been reduced to [less than 10%].

**Table 3.8: Differences between Flynn's ASPs and the Drug Tariff prices**

	October 2012 to March 2014		Post-May 2014	
	£	Percentage	£	Percentage
<b>25mg</b>	[£1 - £2.99]	[7% - 23%]	[£1 - £2.99]	[7% - 23%]
<b>50mg</b>	[£1 - £2.99]	[7% - 23%]	[£1 - £2.99]	[7% - 23%]
<b>100mg</b>	[£6 - £8.99]	[10% - 15%]	[£3 - £5.99]	[6% - 12%]
<b>300mg</b>	[£6 - £8.99]	[10% - 15%]	[£3 - £5.99]	[6% - 12%]

Sources: [www.nhsbsa.nhs.uk/PrescriptionServices/4940.aspx](http://www.nhsbsa.nhs.uk/PrescriptionServices/4940.aspx) and data provided by Flynn (see documents 00505.22, 00872.3, 00915.1, 01148.2, 01148.3, 01293.2, 01839.13 and 02115.2 )

V. ***Pfizer's prices for 100mg capsules in other EU Member States***

3.191 During the Relevant Period, Pfizer-manufactured phenytoin sodium capsules have been (and continue to be) sold in a number of other EU Member States under the *Epanutin* brand. In contrast to the position in the UK, the prices in

these other Member States are significantly lower and have not changed materially during the Relevant Period. [REDACTED].<sup>251</sup>

3.192 Table 3.9 below sets out Pfizer's prices for phenytoin sodium capsules in the other EU Member States where Pfizer-manufactured phenytoin sodium capsules are sold, during the Relevant Period.<sup>252</sup> These prices reflect only the 100mg strength capsule because it is that capsule strength that is predominantly sold elsewhere in the EU. The prices presented in Table 3.9 are significantly lower than Flynn's ASP for 100mg capsules, which is [£51 - £60.99] for the period September 2012 to June 2016.

**Table 3.9: Prices and volumes of 100mg packs of Pfizer-manufactured phenytoin sodium capsules, EU Member States (where Pfizer-manufactured phenytoin sodium capsules are sold)**

	Capsule strength (mg)	Average wholesale price (£)		Average end price (£)		Average monthly volume (packs)
		Jan 11 to Aug 12	Sep 12 to Jun 16	Jan 11 to Aug 12	Sep 12 to Jun 16	
<b>Belgium</b>	100	[£3 - £5.99]	[£3 - £5.99]	[£6 - £8.99]	[£6 - £8.99]	[REDACTED]
<b>Greece</b>	100	[£1 - £2.99]	[£1 - £2.99]	[£1 - £2.99]	[£3 - £5.99]	[REDACTED]
<b>Ireland</b>	100	[£3 - £5.99]	[£3 - £5.99]	[£6 - £8.99]	[£6 - £8.99]	[REDACTED]
<b>Spain</b>	100	[£1 - £2.99]	[£1 - £2.99]	[£1 - £2.99]	[£1 - £2.99]	[REDACTED]
<b>Sweden</b>	100	[£1 - £2.99]	[£6 - £8.99]	[£3 - £5.99]	[£6 - £8.99]	[REDACTED]

Source: Documents 00519.2, 00725.1, 01357.2 and 02129.3; converted to GBP using monthly average spot exchange rates for the period January 2011 to June 2016 from the Bank of England

<sup>251</sup> See document 01836.2.

<sup>252</sup> The countries listed in Table 3.9 are those countries for which Pfizer has provided data in response to the CMA's request for information. However, Pfizer's response to a separate request for information states that Pfizer also sells *Epanutin* in Cyprus and Malta (see document 01836.2).

## E. Chronology of events relating to the price increases

### Summary

#### The key evidence in the following sections shows that:

- Pfizer considered *Epanutin* was loss-making and wanted to find a way to return *Epanutin* to profitability.
- Pfizer engaged with two companies ([Company A] and Flynn) about possible options for increasing the price of *Epanutin* before ultimately proceeding with Flynn's proposal.
- Some of Pfizer's staff had ethical concerns about the appropriateness of significantly increasing the prices of phenytoin sodium capsules at a time when the NHS was under financial pressure.
- Pfizer and Flynn viewed Flynn's role in the supply chain as being, primarily, to reduce the reputational risk to Pfizer of increasing the price of *Epanutin*.
- The Parties had some concerns about the impact of Parallel Imports on their pricing strategy but considered these to be manageable. There is no evidence to suggest that the Parties believed there were any other barriers to their proposed conduct.
- After signing the Agreements, Flynn began to engage with the MHRA to seek approval to change the name of the *Epanutin* product. The MHRA was concerned about the proposed change of name and Flynn's lack of a strategy for communicating this to patients. The MHRA required Flynn to include a manufacturer's designation in the names of Flynn's Products – i.e. *Phenytoin Sodium Flynn Hard Capsules*.
- Flynn told the DH and the MHRA that the supply prices Pfizer was charging meant that, if Flynn was not able to charge its prices, Flynn would be unable to keep phenytoin sodium capsules on the market.
- The DH refused to allow Flynn to increase the prices of its phenytoin sodium capsules within the PPRS. Flynn then genericised its phenytoin sodium capsules in order to remove the product from the PPRS and then increased the prices outside of the constraints of the PPRS.
- After Flynn's Products were launched in September 2012, the DH told Flynn that it had concerns about its prices.
- Flynn provided the DH with inaccurate and/or misleading information about the justifications for the price increases.
- The DH asked that Pfizer and Flynn reconsider their prices and that they provide the DH with cost information to verify why their prices had increased. The Parties did not reduce their prices and refused to provide the requested cost information. The DH then referred the matter to the CMA.

## I. **Pfizer’s consideration of its options regarding Epanutin**

3.193 Pfizer has submitted to the CMA that its sales of *Epanutin* had been loss-making since 2007 and only marginally profitable for the years immediately before that.<sup>253</sup> Pfizer has submitted the following table to the CMA as evidence of its net profits and losses for *Epanutin*:<sup>254</sup>

**Table 3.10: Pfizer’s net profits/losses on phenytoin sodium capsules, 2004-2012**

Net profits/losses for the Products (2004 - 2012) <sup>255</sup>									
	2004	2005	2006	2007	2008	2009	2010	2011	2012
Revenue (£)	[X]	[X]	[X]	[X]	[X]	[X]	[X]	[X]	[X]
Contribution (£)	[X]	[X]	[X]	[X]	[X]	[X]	[X]	[X]	[X]
Contribution (%)	[X]	[X]	[X]	[X]	[X]	[X]	[X]	[X]	[X]

3.194 Pfizer’s submissions do not provide the CMA with sufficient detail to allow it to conclude on the actual extent to which *Epanutin* was loss-making during this period.<sup>256</sup> The CMA recognises that contemporaneous evidence shows that Pfizer believed that *Epanutin* was loss-making for its UK operations prior to September 2012, but it is unclear how much of these losses resulted from Pfizer’s internal allocation of its costs. It is not necessary for the CMA to reach a final conclusion on the extent to which Pfizer’s sales of *Epanutin* were loss-making as, in any case, Pfizer would have been, and is, entitled to increase the prices of its products so long as it does so legally.

3.195 When considering what it might do with *Epanutin* prior to the Agreements, Pfizer explained that it identified and considered four options:<sup>257</sup>

<sup>253</sup> See document 01622.2, paragraphs 50 to 55.

<sup>254</sup> See document 01622.2, Table 3.

<sup>255</sup> Pfizer has stated that 2004 was a partial year as the data was only available from March 2004 (ERP system switch at that date) and that 2012 only covers the months Dec 2011 – August 2012, i.e., the period before the Flynn divestment.

<sup>256</sup> For example, [X].

<sup>257</sup> See document 00086.1, pages 7 to 8.



- (a) Maintain the status quo;
- (b) Discontinue supply of phenytoin sodium capsules;
- (c) Seek permission for a price increase from the DH within the PPRS; and
- (d) Divest phenytoin sodium capsules to a third party.<sup>258</sup>

3.196 Each option will be explained in turn, below, followed by a fifth option to genericise *Epanutin* and for Pfizer to continue selling the product itself.

- (a) **Maintain the status quo.** Pfizer did not pursue this option because it viewed *Epanutin* as a loss-making product and '*Other more commercially viable options were therefore considered*'.<sup>259</sup> Pfizer has since told the CMA that no internal analysis was done to understand what level of price increase would have returned the product to profitability<sup>260</sup>.
- (b) **Discontinue supply of phenytoin sodium capsules.** Pfizer has submitted to the CMA that discontinuation was '*not just a theoretical possibility*'<sup>261</sup> and that *Epanutin*'s sales in the UK were loss-making and that there was 'considerable' pressure on Pfizer's management either to discontinue the *Epanutin* range or find an alternative solution to mitigate the financial losses incurred with continued supply.

The CMA understands, however, that Pfizer did not pursue this option because of concerns about patient safety. In particular, Pfizer explained to the CMA that:

*'Pfizer was the only supplier of Phenytoin Sodium capsules in the UK. Phenytoin has a Narrow Therapeutic Index ('NTI') which means that great care needs to be taken in switching a patient from an ongoing therapy treatment. Given the potentially severe health and economic consequences associated with epileptic seizures, discontinuation of*

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<sup>258</sup> See also document 01622.2, paragraphs 85 to 91.

<sup>259</sup> See page 8 of document 00086.1.

<sup>260</sup> See document 01836.5, paragraph 3.2 and document 01836.2, question 6.

<sup>261</sup> See document 01622.2.

*supply was considered not to be appropriate for the benefit of patients.*<sup>262</sup>

The CMA issued a written notice under section 26 of the Act requiring Pfizer to provide all contemporaneous documents that evidence the submission recorded in paragraph above.<sup>263</sup> Pfizer was unable to provide any such documents, and specifically no internal documents showing that it seriously considered discontinuing *Epanutin*.<sup>264</sup> The CMA cannot, in the absence of some evidence, assume, still less conclude, that Pfizer would have discontinued the supply of phenytoin sodium capsules.

Pfizer did refer to a Flynn document in support of its claim that it was under 'considerable' pressure to improve the profitability of *Epanutin*. That document shows, however, that Flynn understood that Pfizer also felt discontinuing the product '*would be both ethically and morally unjustifiable given the clinical need.*'<sup>265</sup>

The 'clinical need' is corroborated by the WHO's inclusion of phenytoin sodium capsules as an essential medicine. Accordingly, likely that Pfizer would have faced substantial pressure from the DH and the NHS to continue to supply *Epanutin* if it proposed to withdraw it.<sup>266</sup>

The implausibility of Pfizer discontinuing the supply of *Epanutin* is further confirmed by the need for it to take account of the regulatory and financial positions in the other EU Member States (where Pfizer sold, and sells, *Epanutin*). All of Pfizer's European supplies of *Epanutin* are manufactured in one location (Freiburg, Germany). This means that, unless it completely discontinued the supply of *Epanutin* across Europe, Pfizer would continue to incur manufacturing costs for the product even if it ceased supply in the UK. At no point has Pfizer suggested that it has considered discontinuing all supplies of *Epanutin*

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<sup>262</sup> See document 00086.1, page 8. This is commensurate with what Pfizer told the CMA in a meeting 20 August 2013 that Pfizer's goals when considering its options were two-fold: first, to ensure the identical product remained available to patients; and second, to ensure commercial viability of the product (see document 00412.1).

<sup>263</sup> See document 01836.2, response to question 9. Every document that Pfizer has cited in support of these submissions has been a third party document speculating about Pfizer's intentions (in particular an email sent internally within Flynn and NRIM's submission to the CMA).

<sup>264</sup> Pfizer had, in fact, turned down a number of previous offers from third parties to take over the product. See for example page 7 of document 00086.1 and document 01836.3 ([REDACTED] and [REDACTED]), 00141.63 ([Company A])

<sup>265</sup> See document 00145.306.

<sup>266</sup> See document PD 16.

across Europe and the CMA therefore does not consider this to be a likely outcome. Among other things, Pfizer has an obligation not to withdraw supply of *Epanutin* in [REDACTED] without the consent of the [REDACTED] and Pfizer has acknowledged that this was unlikely to be forthcoming:

*[i]t was common knowledge within the business that the [REDACTED] would in practice not approve an application to withdraw Epanutin capsules, due to the Narrow Therapeutic Index [...] This understanding of [REDACTED] practice resulted in Pfizer [REDACTED] neither actively discussing discontinuation as an option, nor actively dismissing it.<sup>267</sup>*

For the reasons set out above, the CMA has concluded that it is unlikely that Pfizer would have discontinued the supply of phenytoin sodium capsules in the absence of the conduct subject to the Decision.

(c) **Seek permission for a price increase from the DH within the PPRS.**

Pfizer submitted to the CMA that it did not pursue this option because:

*'Any increase in price would have been limited to 20% under the PPRS. Previous experience had demonstrated that approaching the Department of Health for a price increase above the standard limit had not been successful. Other options were therefore considered.'<sup>268</sup>*

(d) **Divest phenytoin sodium capsules to a third party.<sup>269</sup>** The divestiture option was in reality two options:

- Pfizer could have sold its full interest in *Epanutin* capsules, including the capsule manufacturing process and relevant trademarks; or
- Pfizer could have sold the right to distribute *Epanutin* only, i.e. Pfizer's MAs for the product.

Pfizer submitted to the CMA that it did not pursue the first option because of patient safety concerns over any change in the production process:

*'Due to the NTI of Phenytoin, a change in the production facilities or even a small change in the production process was considered to pose*

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<sup>267</sup> See document 01836.2, response to questions 2(b). See also response to question 4.

<sup>268</sup> See page 8 of document 00086.1 and 01622.2, paragraphs 59 to 72.

<sup>269</sup> See document 01622.2, paragraphs 85 to 91.

*a potential risk to patient health. Divestment of production was therefore considered not to be an appropriate option for patient safety.*<sup>270</sup>

Accordingly, Pfizer considered divestment of its UK MAs to be an option:

*[t]his option satisfied the commercial concerns due to the product's negative contribution to profitability by allowing Pfizer to exit the commercial sale of the product, but allowed Pfizer to ensure the continued safe production of Phenytoin Sodium capsules and meet the needs of patients on the medicine.*<sup>271</sup>

This was the option that Pfizer ultimately pursued.

**(e) Genericise and continue to sell *Epanutin***

3.197 A fifth option available to Pfizer would have been to genericise *Epanutin* and continue to sell the product itself. This was recognised by Pfizer itself during its negotiations with [Company A] regarding the possibility of genericising *Epanutin* (see section 3.E.III.b below):

*'Clearly, we do not need [Company A] to do this and could just try to go down this route ourselves, however I believe that we would struggle to get the price increase required with the DOH [Department of Health].'*<sup>272</sup>

3.198 When Pfizer approached Flynn regarding the genericisation of *Epanutin*, Flynn's immediate reaction was to ask why Pfizer was not doing that itself:

*'If the plan is to genericise the product, we don't really understand why Pfizer just don't just do this themselves. You don't really need a third party.'*<sup>273</sup>

3.199 The fact that Pfizer could genericise *Epanutin* was raised again during the negotiations with Flynn. An internal Pfizer email recorded that:

*'I spoke briefly to [Flynn's Director] at Flynn.'*

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<sup>270</sup> See page 8 of document 00086.1.

<sup>271</sup> See page 8 of document 00086.1.

<sup>272</sup> See document 00141.21.

<sup>273</sup> See document 00145.4

[...]

*Regarding the question of why not do it ourselves:-*

1. *We could, he doesn't think there are any PPRS issues.*
2. *It's ALL about reputation.*<sup>274</sup>

3.200 While Pfizer has submitted to the CMA that its preferred option was to divest to a third party '*with a proven track record*', and that may have been the easiest option, Pfizer has not provided any evidence as to why it would not have been able to genericise *Epanutin* itself, had it chosen to do so.<sup>275</sup>

## II. ***Early approaches to Pfizer regarding a partnership for phenytoin sodium capsules***

3.201 Pfizer engaged in detailed discussions with, both Flynn and [Company A], another specialist generic manufacturer, before ultimately completing the Agreements with Flynn. Pfizer also received three other provisional approaches in relation to *Epanutin*. These were from:

- [X], a large US pharmaceutical company;
- [X], an independent broker acting on behalf of [X]; and
- [X], an independent broker.

3.202 However, those approaches were not pursued in any level of detail.<sup>276</sup>

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<sup>274</sup> See document 00141.137.

<sup>275</sup> See also document 01622.2, paragraphs 82 to 84. Pfizer has only been able to cite Flynn's view that Pfizer's '*red tape and corporate glue would probably stop us from doing it ourselves*' as support for the proposition that it was '*not realistic for Pfizer to genericise Epanutin capsules itself*'.

<sup>276</sup> See page 7 of document 00086.1 and document 01836.3

### III. ***The approach by [Company A] to Pfizer regarding a partnership for phenytoin sodium capsules***

3.203 [Company A] approached Pfizer in mid-2009 with a '*fostering proposal*' for *Epanutin* ('[Company A]'s Proposal').<sup>277, 278</sup> [Company A]'s business model is to supply niche pharmaceutical products to wholesalers.

#### a. **[Company A]'s Proposal**

3.204 [Company A]'s Proposal was based on a proposition to 'genericise' *Epanutin*. Under the proposal, Pfizer would have licensed *Epanutin* to [Company A] and [Company A] would have changed the name of the product to 'phenytoin sodium hard capsules' and sold it as a generic product.

3.205 Under [Company A]'s Proposal, Pfizer would provide [Company A] with a licence for the exclusive supply of *Epanutin* in the UK and [Company A] would distribute the product as a generic product at an increased price.<sup>279</sup> [Company A] would be appointed as the MA holder in the UK although Pfizer would continue to manufacture the products.<sup>280</sup>

3.206 [Company A] believed that genericising *Epanutin* would move the product from a Category C branded product under the Drug Tariff to a Category M generic product with the result that it would be free from the PPRS's pricing restrictions.<sup>281</sup>

3.207 The CMA has confirmed with the DH that [Company A]'s analysis was broadly correct. By genericising *Epanutin* and thereby removing it from the PPRS, Pfizer and [Company A] would have been able to increase the price beyond the limits of the PPRS. [X].<sup>282</sup> However, [Company A] was wrong to state that the products would move from Category C to Category M of the Drug Tariff.<sup>283</sup>

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<sup>277</sup> See, for example, document 00141.31, which stated that '*this idea came from [Company A] rather than ourselves and we might want to recognise that*'.

<sup>278</sup> The first meeting between Pfizer and [Company A] appears to have been around 6 July 2009 between [X] of [Company A] and [Pfizer's Portfolio Manager – Mature Brands] and [Pfizer's Head of Customer and Channel Marketing - Established Products UK]; see document 00141.19.

<sup>279</sup> See document 00141.28.

<sup>280</sup> See document 00141.28.

<sup>281</sup> See document 00141.656

<sup>282</sup> See document 00367.2.

<sup>283</sup> Since genericisation in September 2012, phenytoin sodium capsules have remained within Category C of the Drug Tariff.

3.208 According to [Company A], partnering with it would have provided Pfizer with a benefit in that any questions from the DH about higher prices would be fronted by itself rather than Pfizer. In response to questions from Pfizer employees as to the need to use [Company A],<sup>284</sup> [Company A] explained that an advantage to Pfizer of using a partner such as [Company A] was that:

*'There would be no need for PFIZER to answer questions to the DoH in relation to a generic presentation or product price; the responsibility for reporting to the NPA [National Pharmacy Association] would be that of the generic company.'*<sup>285</sup>

3.209 In response to questions from Pfizer in relation to the sustainability of the proposals, [Company A] considered that it would be *'extremely challenging'* for another entrant to enter the market with phenytoin sodium capsules due to the age of the product and that [Company A]'s Proposal would likely be sustainable for *'realistically 3 to 5 years'*.<sup>286</sup>

3.210 [Company A] provided a short question and answer briefing to Pfizer in which [Company A] stated that:

*'This switch allows all patients taking phenytoin capsules to receive the same prescription. There is no alternative product so no substitutions can be made, nor will another company have the dossier of data to gain a license for phenytoin capsules.'*

*'This proposal **does not change patient medicine in any way.** [...] When the generic switch occurs, the prescribing will be unified and all patients will receive exactly the same medication. The packaging will state phenytoin capsules and this will be the only change.'*<sup>287</sup> [Emphasis in original]

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<sup>284</sup> See documents 00141.636, 00141.44 and 00141.31: *'There seems to be a strong concern/reluctance on the advisability of doing this form [sic] a patient care / Trust perspective'*. See also document 00141.51: *'the discussion will be more around what the risk to our reputation is and how do we mitigate this'* and [Company A]'s response that: *'I fully understand the argument around reputation mitigation etc; and if I thought it was an unfeasible proposition, then I wouldn't [sic] even suggest for a moment bringing the idea to market as a generic and I wouldn't be pursuing it so rigorously only to fall at some later unseen hurdle'*.

<sup>285</sup> See document 00141.636.

<sup>286</sup> See document 00141.636.

<sup>287</sup> See document 00141.636.

3.211 [Company A] proposed to increase the price of phenytoin sodium capsules so that the 100mg capsules would be priced just below the Drug Tariff price of Tablets (which was £30). [Company A] provided '*Illustrative Financials*', which reveal the significance of this commercial opportunity to both Pfizer and [Company A]. [Company A]'s proposed Drug Tariff price for 100mg capsules was £25.50 for 28 capsules (£0.91 per capsule). [Company A] estimated that the Cost of Goods Sold for 28 100mg capsules was [REDACTED]. On this basis, [Company A] estimated that, after wholesalers costs, the net profit would be approximately [REDACTED] per pack. [Company A] proposed that this profit would be split with [REDACTED] to Pfizer and [REDACTED] to [Company A].<sup>288</sup>

**b. Pfizer's consideration of [Company A]'s Proposal**

3.212 When considering [Company A]'s Proposal Pfizer focused predominantly on three key issues: (i) the ethics of the proposal, (ii) the impact the proposal might have on patient safety and (iii) its viability. Each of these is considered below.

**i. The ethics of the proposal**

3.213 On 23 July 2009, [REDACTED] (Pfizer's Portfolio Manager – Mature Brands) sent an email to [Pfizer's Head of Customer and Channel Marketing – Established Products UK] and [REDACTED] (Pfizer's Senior Finance Business Partner), summarising and considering [Company A]'s Proposal.<sup>289</sup>

3.214 [Pfizer's Portfolio Manager – Mature Brands] started by setting out the potential revenue impact, concluding that [Company A]'s Proposal would increase Pfizer's revenues by £19 million a year. [Pfizer's Portfolio Manager – Mature Brands] then set out some detail on [Company A]'s Proposal, noting, in particular, that it would distance Pfizer from the price increase and that Pfizer could carry out the action itself but that it may face difficulties with the DH:

*[Company A]'s proposal is that we do it via [Company A] to distance ourselves from the price increase.*

*Clearly, we do not need [Company A] to do this and could just try to go down this route ourselves, however I believe that we would struggle to get the price increase required with the DOH [Department of Health].*

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<sup>288</sup> See document 00141.636.

<sup>289</sup> See document 00141.21.



*Also, this idea came from [redacted] rather than from ourselves and my view is that we need to recognize that.*<sup>290</sup>

3.215 [Pfizer's Portfolio Manager – Mature Brands] went on to set out some further detail on [Company A]'s Proposal and noted that *'the opportunity is largest for Epanutin and we have a profitability issue with this product'*.<sup>291</sup>

3.216 [Pfizer's Portfolio Manager – Mature Brands] concluded by setting out a concern as to whether [Company A]'s Proposal was 'ethical':

*'My other concern is just an ethical one – the top line looks great, however this would increase the price of phenytoin capsules to the NHS drastically and to be frank, doesn't feel right.'*

*Clearly we need to make money on the product and therefore, I wonder if a conversation with the DOH with these findings could simply increase our pack price to enable profitability. It would certainly not add £19m to the top line but might sit better?*

*Or on the other hand, maybe I'm just being to [sic] nice!!'*

3.217 Pfizer appears to have grappled with this particular concern on a number of occasions but ultimately decided to proceed with genericising *Epanutin* (by partnering with Flynn rather than with [Company A]). On 13 September 2009, [redacted] (Pfizer's Head of Established Products Business Unit ('EPBU')) emailed colleagues, outlining [Company A]'s Proposal and the potential financial implications for Pfizer. Much of [Pfizer's Head of EPBU] email replicated [Pfizer's Portfolio Manager – Mature Brands] email of 23 July 2009 but also presented a number of '*questions to be answered*'. The first question concerned the significant financial implications that implementing the proposal would have on the NHS:

*'This could generate significant upside, but whilst legal, would increase the price of phenytoin capsules to the NHS significantly. How does that fit with out [sic] Trust initiative?'*<sup>292</sup>

3.218 There then followed a series of internal Pfizer emails setting out various views on [Company A]'s Proposal. On 22 September 2009, [Pfizer's Head of EPBU] forwarded these internal discussions to [redacted] (Pfizer's Head of

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<sup>290</sup> See document 00141.21.

<sup>291</sup> See document 00141.21.

<sup>292</sup> See document 00141.31.

Customer and Channel Marketing, Established Products UK). In his cover email, [Pfizer's Head of EPBU] highlighted concerns about patient care and 'Trust' (relating to [Pfizer's Portfolio Manager – Mature Brands] earlier 'ethical' concern<sup>293</sup>):

*'There seems to be a strong concern/reluctance on the advisability of doing this form [sic] a patient care/Trust perspective. I echo these.'*<sup>294</sup>

- 3.219 [Pfizer's Head of EPBU] also put forward a potential alternative proposal – that Pfizer could approach the DH and point out the anomaly that existed with Tablets with a view to the DH remedying the situation:

*'Is there not an option to point out to the DH this anomaly and how much it is costing them, and getting them to reset the tablets Cat M tariff in line with the Cat C branded tariff; thus saving them tens of millions and allowing us a level playing field on which we should be able to win [a] higher share.'*<sup>295</sup>

- 3.220 The reference to 'winning a higher share' was most likely based on a misunderstanding by [Pfizer's Head of EPBU] as to the substitutability of phenytoin sodium capsules and Tablets. As the following subsection shows, other Pfizer employees were clear that substitution was not appropriate for products with NTIs.

- 3.221 [Company A] subsequently met Pfizer on 29 January 2010 and gave a presentation on its proposal.<sup>296</sup> Following the meeting, [Pfizer's Head of EPBU] emailed colleagues, explaining that Pfizer needed to progress [Company A]'s Proposal as the '*potential upside is huge*' and that Pfizer could not '*afford to dismiss this lightly*'. However, [Pfizer's Head of EPBU] had a number of unresolved questions. One of these was resolving the dilemma between convincing patients that nothing would change while at the same time explaining to '*DH and payers*' that things would change:<sup>297</sup>

*'Trust*

*3. We need to work out how we can position this as "no change" with patients & physicians; and at the same time "change" with DH and*

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<sup>293</sup> See discussed above.

<sup>294</sup> See document 00141.31.

<sup>295</sup> See document 00141.31.

<sup>296</sup> See document 00141.56.

<sup>297</sup> See document 00141.57.

*payers without being accused of hypocrisy by pursuing a trust agenda, yet taking the opportunity to fleece the NHS in [a] time of funding crisis.'*

3.222 [Pfizer's Head of EPBU] again raised the potential of approaching the DH directly:

*'May be a "no-goer" but as an alternative; is there an opportunity to go to DH and have a sensible debate with them about the inequity in the tabs/caps prices, and explain (in the spirit of openness) that we cannot afford to sell it [Epanutin] at this price and that we could implement a scheme such as this (without going in to details). The aim being to obtain a special price increase outside of PPRS; or at least get them to cut the Cat M price of tabs to the same as caps and prevent TEVA making supernormal profits'.<sup>298</sup>*

3.223 Pfizer did not, however, ultimately pursue this option or otherwise seek to engage with the DH on *Epanutin* in advance of Flynn genericising the products.

ii. *The impact on patient safety*

3.224 While recognising the potentially significant financial benefit of genericising *Epanutin*, Pfizer's discussions also demonstrates concerns about potential patient safety given the nature and characteristics of *Epanutin* and epilepsy.<sup>299</sup>

3.225 On 13 September 2009, [✂] (Pfizer's Head of Primary Care, Country Lead, UK) responded to [Pfizer's Head of EPBU] email, suggesting that Pfizer needed to carefully consider whether it should proceed with this opportunity and whether there may be some alternative option:

*'Let's talk at UKMF [UK Management Forum] in the morning. Industry has, rightly, made a big deal of epilepsy drugs being one of the key medicines where you shouldn't mess with the presentation that a patient is stabilised on – with a great deal of expert medical and pharmacy support. I think we have to ask ourselves how this action might sit alongside that position, particularly given the narrow therapeutic window of phenytoin.*

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<sup>298</sup> See document 00141.57.

<sup>299</sup> See document 00141.31.

*My first reaction is that I suggest we have to think long and hard before considering any withdrawal of a branded AED. There are some alternative ways of achieving some upside here though aren't there?*<sup>300</sup>

- 3.226 On 18 September 2009, [X] (Pfizer's Medical Director, UK) replied, agreeing with [Pfizer's Head of Primary Care, Country Lead, UK] view and presenting the issue of patient safety concerns even more starkly than [Pfizer's Head of Primary Care, Country Lead, UK]:

*I have to agree*

*I do not believe it is medically safe to switch between branded and generic AEDs and particularly with phenytoin as it has such a narrow therapeutic window. Loss of seizure control would have a major impact clinically and also in terms of losing a driving licence which may have been regained after a long period free of seizures. We also used AEDs in our feedback on the PPRS generic substitution initiative as an example of a class of drugs where this would not be recommended.*<sup>301</sup>

- 3.227 On 18 September, [X] (Pfizer's Speciality Care Business Unit Director for the UK) replied, generally agreeing but also suggesting that they had an obligation to do the 'right thing for business':

*Interesting dilemma. Agree that we have an obligation to do the right thing for patients, but equally we have obligation to do right thing for business.*

*I guess my view would be to explore the options and consider going with the one that has the least patient/customer impact but still achieves some of the revenue/upside potential.*<sup>302</sup>

- 3.228 [X] (Pfizer's, Head of Oncology in the UK) then replied on the same day (18 September 2009), drawing attention to prescribing guidance:

*If it helps there is specific guidance against switching and indeed that these products should be written by brand name to ensure consistency of medication within the BNF.*<sup>303</sup>

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<sup>300</sup> See document 00141.31.

<sup>301</sup> See document 00141.31.

<sup>302</sup> See document 00141.31.

<sup>303</sup> See document 00141.31.

iii. *The viability of the proposal*

3.229 In an email dated 17 September 2009, [X] of [Company A] explained:

*'I see the opportunity re Epanutin for us sustaining realistically for 3 to 5 years...[Pfizer's Portfolio Manager – Mature Brands] actually said in the meeting [in July 2009] that Epanutin is such an old license [sic], that it would be Nigh [sic] on impossible to get a license granted for a generic based on the old trials and license that currently exist – the brand being @70 years old.. therefore, even if a generic company decided to throw tons of cash at it to go for it from scratch (which is exceedingly unlikely, due to costs and time for trials being @minimum 2 years), and then they would then have to prove stability data etc; which they couldn't base on your brand – it would render it not viable as a short term opportunity ... the only reason you would have a license granted for the generic at Pfizer as an 'own livery product' as a generic own livery is because you possess the brand license'<sup>304</sup>*

3.230 Pfizer had some reservations about the viability of [Company A]'s Proposal however. For example, in an email of 22 September 2009, [Pfizer's Head of EPBU] raised a concern about how sustainable the proposal may be, saying that he had:

*'a fundamental problem with the sustainability of it (what is to stop DH changing Cat M reimbursement, once this hits their radar)'.<sup>305</sup>*

3.231 The question of whether the DH could or would be likely to intervene on pricing was not raised again. Instead, Pfizer focused on whether higher prices for *Epanutin* in the UK might result in increased levels of Parallel Imports into the UK. On 4 January 2010, [Pfizer's Head of Customer and Channel Marketing - Established Products UK] emailed [X] ([Company A]) to ask that [Company A] consider the potential risk that Parallel Imports presented to its proposals:

*'We have been asking our colleagues around Europe of whether or not they have Epanutin available to assess the PI [Parallel Import] risk for moving ahead with our genericisation plan. This info may help you consider the risk for our meeting on the 29th Jan.'<sup>306</sup>*

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<sup>304</sup> See document 00141.28.

<sup>305</sup> See document 00141.31.

<sup>306</sup> See document 00141.51.

3.232 On 11 January 2010, [X] ([Company A]) responded to [Pfizer's Head of Customer and Channel Marketing - Established Products UK]:

*'The only short term issues I have are PI [parallel imports] over production in the EU, as the key to controlling that will make a difference'<sup>307</sup>*

3.233 The potential for new entry appears to have been a key question for Pfizer. In an email following a meeting between [Company A] and Pfizer on 29 January 2010, the first point [Pfizer's Head of EPBU] raised was whether [Company A]'s Proposal would be sustainable given that the proposed price increases may incentivise new entry:<sup>308</sup>

*'a. Other companies may enter if caps are at a much more attractive price (caps are generally easier & cheaper to make than tablets) and inevitable discounts would become reflected in a reduced DT reimbursement price.'*

3.234 [Pfizer's Head of EPBU] also questioned whether the proposed price increases would increase the amount of parallel imported product sold in the UK given *'the low prices in Europe'* and also noted that increased volumes of parallel imported product into the UK from other countries *'would cause great difficulties for our colleagues in the other markets in supplying this essential medicine domestically.'*<sup>309</sup>

c. **Pfizer's decision on [Company A]'s Proposal**

3.235 Ultimately, Pfizer did not pursue [Company A]'s Proposal. On 15 April 2010, [Pfizer's Head of Customer and Channel Marketing - Established Products UK] informed [X]([Company A]) of Pfizer's decision:

*'I am not in a position to move forward with a divestment to [Company A] at this time. Having discussed not specific but certain aspects at a business review with European Leadership recently, it was not deemed to be an appropriate step to take at this time for Epanutin'.<sup>310</sup>*

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<sup>307</sup> See document 00141.51.

<sup>308</sup> See document 00141.57.

<sup>309</sup> See document 00141.57.

<sup>310</sup> See document 00141.63.

3.236 Pfizer explained to the CMA that [REDACTED].<sup>311</sup>

#### IV. ***Flynn's proposal***

3.237 In this section, the CMA sets out the details of Pfizer's and Flynn's discussions leading up to the Agreements, and specifically, Flynn's proposal that Pfizer transfer to it the MAs for *Epanutin*.

##### ***a. Pfizer's approach to Flynn***

3.238 After rejecting [Company A]'s Proposal, Pfizer continued to explore options for *Epanutin*. Pfizer's first contact with Flynn was in early January 2010, when [REDACTED] (Pfizer's Commercial Account Director) approached [REDACTED] (Flynn's Director) 'to discuss a range of divestment opportunities concerning Pfizer's tail-end products'. The products discussed included *Epanutin*, as well as three other products.<sup>312</sup> In contrast to [Company A], it was Pfizer that first approached Flynn.<sup>313</sup>

3.239 Pfizer has explained that it approached Flynn because it considered Flynn to be a more credible organisation than [Company A], with a greater level of experience.<sup>314</sup> In addition, [REDACTED] (Pfizer's Commercial Account Director) had experience of working with Flynn previously.<sup>315</sup> Flynn was also one of a number of pharmaceutical companies with which Pfizer was in intermittent contact over a number of years regarding potential commercial opportunities for Pfizer's tail-end products.<sup>316</sup>

3.240 Pfizer explained to the CMA that the proposal that it took forward with Flynn (and that ultimately resulted in the conduct that is the subject of this Decision) was different from [Company A]'s Proposal. In particular, Pfizer's proposal to Flynn involved divesting Pfizer's MAs while [Company A]'s proposal was not a divestment: *Pfizer would have remained the MA*

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<sup>311</sup> See page 9 of document 00086.1. See also section 3.E.IV.a and 3.E.IV.b below. It is not necessary for the purposes of this Decision for the CMA to reach a conclusion on the reason(s) why Pfizer did not proceed with [Company A]. Accordingly, the CMA has not reached a conclusion on this point in this Decision.

<sup>312</sup> See document 00086.1, page 10. Those products are not the subject of this Decision and are therefore not considered further.

<sup>313</sup> See paragraphs 9 ('Pfizer had approached Flynn'), 20 ('Pfizer approached Flynn to discuss opportunities with *Epanutin*') and 37 ('with regards to *Epanutin*, Pfizer approached Flynn') of document 00412.1.

<sup>314</sup> See page 9 of document 00086.1.

<sup>315</sup> See page 9 of document 00086.1 and paragraph 35 of document 00412.1 ('[Pfizer's Commercial Account Director] explained that in his previous role at [REDACTED] he had worked with Flynn in relation to divesting and he had managed the relationship. Flynn had paid and delivered on its promises').

<sup>316</sup> See page 10 of document 00086.1.

*holder*.<sup>317</sup> Notwithstanding this difference, the other key elements of the proposals (i.e. genericising *Epanutin* and implementing significant price increases) were the same.<sup>318</sup>

3.241 At first it was unclear to Flynn why Pfizer needed it in order to genericise *Epanutin*. Shortly after an initial discussion early in January 2010, [Flynn's Director] sent an email to [Pfizer's Commercial Account Director] on 8 January 2010:<sup>319</sup>

*'We have looked at other processes, but they don't work for various reasons. If the plan is to genericise the product, we don't really understand why Pfizer just don't just do this themselves. You don't really need a third party. You should be aware though that there are a number of PI licence holders in the UK.'*

3.242 Flynn's view that Pfizer '*don't really need a third party*' was consistent with Pfizer's previous internal view of [Company A]'s Proposal that '*we [Pfizer] do not need [Company A] to do this and could just try to go down this route ourselves*'.<sup>320</sup>

**b. *The initial discussions between Pfizer and Flynn***

3.243 Despite Flynn's initial uncertainty about its role in relation to *Epanutin*, discussions between Flynn and Pfizer progressed for two years (from January 2010 to January 2012) before the Asset Sale Agreement was signed between Pfizer and Flynn on 27 January 2012.<sup>321</sup>

3.244 Pfizer met Flynn in March 2010 to discuss the potential opportunities concerning *Epanutin*.<sup>322</sup> Flynn's note of that meeting stated that '*Pfizer is*

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<sup>317</sup> See paragraph 36 of document 00412.1. It is not necessary for the purposes of this Decision for the CMA to reach a conclusion on whether [Company A]'s and Flynn's proposals were different. Accordingly, the CMA has not reached a conclusion on this point in this Decision.

<sup>318</sup> Consequently the CMA considers that the concerns that [Pfizer's Portfolio Manager – Mature Brands] and [Pfizer's Head of EPBU] raised about the ethics and fairness of imposing significant price increases on the NHS in the context of the [Company A] proposal remain relevant to proposal it took forward with Flynn. Pfizer have not been able to provide the CMA with any reasons to substantiate their submission that these concerns are irrelevant to the proposal it took forward with Flynn. See document 01622.2, paragraph 88.

<sup>319</sup> See document 00145.4.

<sup>320</sup> See document 00141.21.

<sup>321</sup> See document 00145.241

<sup>322</sup> The attendees at the meeting were [X] (Pfizer's Commercial Account Director), [X] (Pfizer Head of Customer and Channel Marketing - Established Products UK), [X] (Flynn's Director) and [X] (Flynn's Commercial Director).



*interested in partnerships with other companies for older products such as Epanutin*'.<sup>323</sup>

- 3.245 During the meeting, Pfizer also explained that it had previously had some discussion with another company about *Epanutin* but that it had decided against progressing that option, apparently because of concerns over increased parallel imported product being sold in the UK. While the note does not identify which company Pfizer was referring to, the CMA considers that it is reasonable to infer that Pfizer was referring to its discussions with [Company A]. Flynn's note of the meeting stated:

*'Have already had some discussion with a Pharma Consultancy about Epanutin and possibilities of genericising it in the UK (they have the only licence for capsules), Pfizer has decided against this strategy since they believe it will result in parallel imports from the lower price markets, e.g. Greece.*'<sup>324</sup>

- 3.246 Despite Pfizer's concerns about Parallel Imports, Flynn was confident that Pfizer's concerns could be addressed:

*'We believe this may be controllable. If, for example, Flynn were to acquire the brand in Europe in return for an exclusive supply agreement with Pfizer at a price which is profitable to Pfizer, [redacted].'*<sup>325</sup>

- 3.247 Flynn's note of the meeting also records that Pfizer explained that it *'currently makes a loss on selling Epanutin at its current prices'*.<sup>326</sup>

- 3.248 [redacted] (Flynn's Commercial Director) also took a manuscript note of the meeting, which included a reference to the possibility of de-branding *Epanutin* and increasing prices, as well as Pfizer's concerns about Parallel Imports:

*'Epanutin, could; debrand it, foster it via Flynn, they would raise prices as generic product? no reason shouldn't be similar to the generic tabs.*

*would need to manage the P.I.'s as there are a number of licenses.*

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<sup>323</sup> See document 00145.7.

<sup>324</sup> See document 00145.7.

<sup>325</sup> See document 00145.7.

<sup>326</sup> See document 00145.7.

[...]

*Epanutin – manufactured in just one site in Europe? If more than one factory, any mileage in stopping P.I.'s?*<sup>327</sup>

- 3.249 Following that meeting, Flynn requested IMS data from Pfizer so that Flynn could analyse the level of *Epanutin* parallel imports in the UK. On 16 April 2010, Pfizer emailed Flynn with this data to which [Flynn's Commercial Director] replied to Pfizer that '*On the face of it we could definitely do something with Epanutin*'.<sup>328</sup>
- 3.250 Flynn's response shows that Pfizer's previous concern (that [Company A]'s Proposal '*will result in parallel imports from the lower price markets, e.g. Greece*') did not concern Flynn and that the level of Parallel Imports '*may be controllable*'.<sup>329</sup>
- 3.251 Following this, Flynn continued to correspond with Pfizer. At some point on or before 17 June 2010, [Flynn's Commercial Director] contacted [Pfizer's Head of Customer and Channel Marketing - Established Products UK] to further discuss *Epanutin*. On 17 June 2010, [Flynn's Commercial Director] emailed [Flynn's Director] to summarise his call with Pfizer. It is apparent from this email that Pfizer had had concerns about both increased Parallel Imports into the UK and patient safety and disruption, but that Flynn appears to have been able to allay Pfizer's concerns:

*'I had [sic] good discussion with [Pfizer's Head of Customer and Channel Marketing - Established Products UK] and he is fired up again to take this forward. I think they had semi-shelved it on the basis of not wanting to disrupt patients and, also, PIs issue but I talked through this.*

*I asked for a meeting at which we would present a model, in the next couple of weeks.*<sup>330</sup>

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<sup>327</sup> See document 00145.8.

<sup>328</sup> See document 00145.13.

<sup>329</sup> See document 00145.7

<sup>330</sup> See document 00145.20.

c. ***Flynn's proposal***

- 3.252 The meeting referred to in [Flynn's Commercial Director] email of 17 June 2010 took place on 1 July 2010. At this meeting Flynn proposed that Pfizer transfer its UK MAs for *Epanutin* to Flynn.<sup>331</sup>
- 3.253 The detail of Flynn's proposal is set out in a copy of its presentation entitled '*Epanutin® proposal July 2010*', which [Flynn's Commercial Director] sent to [Pfizer's Head of Customer and Channel Marketing - Established Products UK] on 2 July 2010.<sup>332</sup> The presentation set out the proposed structure of the deal and how Flynn would address Pfizer's concerns about patient safety and Parallel Imports.<sup>333</sup>
- 3.254 Slide five of Flynn's presentation set out the '*current position*'. While Flynn recognised that the price of Tablets was higher than the price of phenytoin sodium capsules, it also recognised that the different formulations were '*not easily interchangeable*' and that capsules needed to '*continue to be available to patients*':
- '*Epanutin in the UK is economically unattractive at its current list price*
  - '*Competitor products (tablets) are sold at ~30x the price*
  - '*Tablets & capsules are not easily interchangeable*
  - '*Pfizer is unable to change the price of this branded product due to the PPRS*
  - '*Nevertheless, phenytoin capsules must continue to be available to patients.*
  - '*This document explores the ways in which Pfizer can continue to fulfil patient needs and turn Epanutin into an economically attractive product*

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<sup>331</sup> See document 00086.1, page 10.

<sup>332</sup> That presentation appears to have differed slightly from the presentation that Flynn gave during the meeting on 1 July 2010 as it '*incorporat[ed] one or two changes that we discussed*'; see documents 00145.26 and 00145.27.

<sup>333</sup> See document 00145.27.

3.255 Slide six of Flynn's presentation set out what the value of *Epanutin* sales would be if sold at varying proportions of the price of Tablets:

	'50%	75%	100%
<i>Epanutin</i>	£56.7M	£85.1M	£113.5M'

3.256 From this, Flynn recommended that the price of *Epanutin* 'is pitched at half of the price for phenytoin tabs initially, i.e. £15 for 28 caps x 100mg'.

3.257 Slide seven identified four 'Potential Issues', including the need to maintain the availability of phenytoin sodium capsules and potential reputational harm ('Pharmacopolitical damage'):

- 'Continued patient access to phenytoin caps
- Pharmacopolitical damage (Pfizer)
- Parallel imports
- PPRS considerations'

3.258 Slide eight set out the essence of Flynn's proposal. Under the heading 'Strategic options', Flynn proposed that:

- 'Pfizer uses Flynn Pharma as the MA holder to avoid pharmacopolitical damage
  - Flynn debrands the product in the UK
  - Flynn sets the UK price of the generic capsules
- Flynn enters into exclusive supply and technical agreements with Pfizer
- The structure of the deal is flexible
  - UK and/or EU
  - Supply price
  - Milestone payments, royalties

- *Flynn can, if required, take over responsibility for the supply chain at any stage present or future'*

3.259 Slide 10 considered Parallel Imports and set out a number of '*strategic options which Pfizer could adopt to help prevent stock-out situations in lower-priced markets*'.<sup>334</sup>

3.260 Slide 11 considered the potential impact of Parallel Imports on sales in the UK. It suggested that there would be no impact for 25mg, 50mg and 300mg capsule strengths and that Flynn's proposal would be profitable even if Parallel Imports of 100mg capsules were to increased considerably:

- *'Should be no impact on 25mg, 50mg and 300mg in UK. These alone could be worth £15m*
- *Even if 50% sales of 100mg were lost to PI the upside would still be >£20m'*

3.261 Slide 12 set out '*Other considerations*'. On patient impact, Flynn considered that any impact would be '[m]inimal' as:

*'this strategy ensures continued availability in all markets; packaging in the UK would be designed to resemble Epanutin; the change will be communicated to all HCPs [healthcare professionals]'*

*i. Draft Heads of Terms dated 30 July 2010*

3.262 Following consideration of Flynn's proposal, [Pfizer's Head of Customer and Channel Marketing - Established Products UK] emailed [✂] (Flynn's Commercial Director) on 27 July 2010 confirming that Pfizer would be '*looking to progress work on this project*' and requested a draft Heads of Terms to be agreed by Pfizer.<sup>335</sup>

3.263 On 30 July 2010, [Flynn's Director] sent a draft Heads of Terms and timeline to [Pfizer's Head of Customer and Channel Marketing - Established Products UK].<sup>336</sup> Under the proposed Heads of Terms, Pfizer would divest its UK

<sup>334</sup> An earlier internal draft of Flynn's presentation that was sent by [Flynn's Commercial Director] to [Flynn's Director] referred to '*The strategic options in preventing parallel imports to the UK include a combination of some or all of the following [...]*'; see document 00145.91.

<sup>335</sup> See document 00145.28.

<sup>336</sup> See documents 00145.31 and 00145.35.

[redacted]<sup>337</sup> MAs for *Epanutin* to Flynn for [a nominal fee] and enter into an exclusive supply agreement to provide Flynn with finished packs of phenytoin sodium capsules. The proposed supply price was [redacted] of Flynn's net selling price [redacted]. Flynn's draft Heads of Terms were set out as follows:

<b>'Divestment of the Product</b>	<i>Pfizer shall sell to Flynn its MAAs for the Product in the UK [redacted] (the Territory) provided that the conditions below have been fulfilled.</i>
<b>Conditions</b>	<i>Flynn shall enter into an exclusive Supply Agreement, together with a Quality Technical Agreement, with Pfizer for the production of finished packs of Epanutin/phenytoin capsules for sale in the Territory.</i>  <i>[...]</i>
<b>Price and Payment</b>	<i>Flynn shall pay Pfizer [a nominal fee] for the Product's MAAs in the Territory.</i>
<b>Supply Price</b>	[redacted].  [...]  [redacted].
<b>Saleable Stock</b>	[...]
<b>Negotiations</b>	<i>Pfizer and Flynn shall cooperate with one another to reach agreement as soon as possible and will execute a written agreement as soon as practicably possible and no later than 31 October 2010.'</i>

3.264 Under Flynn's proposal, Pfizer [redacted] (the draft Heads of Terms set out that Flynn would pay Pfizer [a nominal fee] for the four MAs). However Flynn was, prepared to be '*flexible on the deal structure*'.<sup>338</sup> [redacted].

<sup>337</sup> The CMA notes that the Agreements ultimately only covered the UK and did not extend to [redacted]. It is not clear from evidence on the CMA's file why the Agreements were limited to the UK only. However, evidence on the CMA's file also shows that Flynn at various times raised the possibility of it also acquiring Pfizer's MAs for phenytoin sodium capsules in the other EU Member States where Pfizer-manufactured phenytoin sodium capsules are sold but Pfizer did not pursue that option; see, for example, document 00145.31.

<sup>338</sup> See document 00145.35.

ii. *Flynn's detailed proposal dated 29 October 2010*

3.265 In October 2010, Pfizer requested a more detailed proposal from Flynn to use for its internal approvals process. On 29 October 2010, [Flynn's Director] emailed [Pfizer's Head of Customer and Channel Marketing - Established Products UK] three documents: a briefing document detailing Flynn's proposal (entitled '*Epanutin* proposal'), a frequently asked questions document (entitled '*Flynn Pharma Epanutin* proposal October 2010, FAQs') and responses to certain questions received from Pfizer's lawyers (entitled '*Epanutin* Heads of Agreement queries and responses, Oct 10').<sup>339</sup> The detail of these documents is set out below.

iii. *Flynn's briefing document*

3.266 The briefing document started by setting out the issue:

*'Epanutin (phenytoin in capsule presentation) in the UK is economically unattractive to Pfizer at its current ex-factory price. PPRS restrictions prevent Pfizer achieving a price increase for the brand without modulating the price of other products.'*<sup>340</sup>

3.267 It then highlighted three issues if *Epanutin* was discontinued in the UK: the cost to the NHS; potential negative impact on patient welfare; and potential '*pharmaco-political issues*' for Pfizer:

- *'If Epanutin were to be discontinued in the UK, prescribers would be obliged to switch patients to the closest alternative, phenytoin tablets.'*<sup>341</sup> *The financial cost to the NHS of discontinuing Epanutin and switching to phenytoin tablets would be in excess of £100M.*
- *More importantly, there is a possibility that welfare of the patient might be impacted, as the capsules and tablets are not readily interchangeable. Such discontinuation would inevitably cause considerable pharmaco-political issues to Pfizer.'*<sup>342</sup>

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<sup>339</sup> See documents 00145.63 and 00145.64, 00145.65 and 00145.66.

<sup>340</sup> See also document 00145.65.

<sup>341</sup> See also document 00145.65: '*Were Pfizer to discontinue Epanutin, patients would have to be switched to generic phenytoin tablets*'.

<sup>342</sup> See also document 00145.65: '*Furthermore, there would be a potential patient safety issue in that tablets and capsules are not readily interchangeable due to the narrow therapeutic index of phenytoin. This could give rise to significant pharmaco-political issues for Pfizer*'.

3.268 The briefing document next highlighted that the **'potential increased revenues to Pfizer are approximately £26M p.a.'** [emphasis in original] and summarised Flynn's proposed strategy (which essentially had not changed from Flynn's initial proposal in January 2010):

- *'Flynn acquires the product from Pfizer.*
- *Pfizer assigns use of the trademark in the UK to Flynn.*
- *Flynn enters into an exclusive supply agreement with Pfizer at economically attractive supply prices.*
- *As the MA holder, Flynn de-brands the product in the UK and re-launches as a generic product thereby removing the current ceiling price. The tariff price of a generic alternative would be, until such time as there are other entrants to the market, that of the current product.'*

3.269 The briefing document then proceeded to set out the 'current situation' and explained that:

*'Flynn Pharma Ltd, has submitted a proposed strategy in which phenytoin capsules would become more economically attractive to Pfizer, whilst maintaining excellent value for money for the DH and without impacting on patient safety or Pfizer's reputation.'*

3.270 The briefing document then considered 'potential issues' that arose from Flynn's proposal, including: impact on patients; pharmacopolitical issues; and, Parallel imports. The briefing document's consideration of these issues is outlined below.

*iv. Impact on patients*

3.271 Flynn considered that it would need to convince the MHRA that patient safety would not be compromised in order for it to approve the transfer of Pfizer's MAs. Flynn proposed that it would communicate with patients and healthcare professionals regarding the change of name of the capsules so that any impact on patients would be minimal; noting that the product formulations would not change and the packaging would retain the 'image and feel' of *Epanutin*. The briefing document explained that:

*'Healthcare professionals and other stakeholders (e.g. patient groups) would be notified of the change. Flynn stores and distributes its goods through [Flynn's pre-wholesaler/distributor], so this will require little*



change.<sup>343</sup> Given good communication to all stakeholders, the impact on patients will be minimal for the following reasons:

- *The product formulation will not change.*
- *Generic packaging will retain the image and feel of the current brand. Capsule colour will remain exactly the same.*
- *The changes will be only to the packaging and foil. Flynn believes that the capsule shells, currently marked "Epanutin 100" could remain unchanged (there are precedents with other generic products).*
- *Scripts for Phenytoin capsules are already largely written generically (70%) so few will need to be referred back to prescriber.*
- *The product pipeline will be stocked with generic pack prior to withdrawal of brand to ensure continuity.'*

v. *Pharmaco-political issues*

3.272 Flynn then considered how its proposal would address potential reputational concerns for Pfizer. In essence, Flynn would be publicly seen as the company that had increased the prices and the proposed higher prices would be perceived as preferable to the NHS having to pay for patients to switch to Tablets if capsules had been discontinued:

*'Pfizer UK's position would be simple: Pfizer has divested the product to Flynn Pharma Ltd. Flynn would defend its right to make profit on the product within the bounds of PPRS and generic pricing regulations. The cost implications to the NHS would be preferable, in any event, to the alternative of discontinuing the product in the UK and switching patients to more expensive tablet presentations.'*

vi. *Parallel imports*

3.273 Flynn considered that Parallel Imports may increase if prices increased and put forward a proposal for addressing that issue. However, Flynn also noted

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<sup>343</sup> Pfizer already used [☒] to distribute its goods.

that the proposed '*strategy*' would nonetheless remain attractive even if Parallel Imports did increase:

*'A price increase in the UK would lead to potential parallel imports from other EU markets, subject to local availability. Assignment of the trademark to Flynn in the UK would mean that parallel imports would risk infringing Flynn's trademark. In any event, some parallel importing would reduce but not remove the attractiveness of this strategy to Pfizer.'*<sup>344</sup>

vii. *Flynn's frequently asked questions document*

3.274 The second question posed in Flynn's frequently asked questions document<sup>345</sup> concerned whether Flynn's proposal would open the product to potential competition. According to this document, at the time, 30% of prescriptions specified the brand, meaning that only *Epanutin* could be dispensed for those prescriptions.<sup>346</sup> Genericising *Epanutin* would result in those 30% of prescriptions no longer being guaranteed Pfizer/Flynn sales:

*'This change will mean loss of the brand equity inherent in the 30% of scripts that are written by brand and leave the business open to generic competition.'*

3.275 Flynn considered that this should not be a concern given that '*There have been no generic competitors to date*'.

3.276 Flynn also considered that it might be possible to (re)introduce a version of branded prescriptions whereby prescribers specified the supplier's name on the prescription:<sup>347</sup>

*'As continuity and consistency of medication is encouraged in this therapeutic area prescribers could specify "phenytoin capsules, Flynn".'*

3.277 This development did, in fact, transpire, albeit at the request of the MHRA when approving Flynn's application to vary the product name.

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<sup>344</sup> See document 00145.65.

<sup>345</sup> See document 00145.66

<sup>346</sup> See section 3.C.II.d.

<sup>347</sup> Where a prescription specifies a particular product (whether by reference to the brand or by reference to a particular supplier), the dispenser needs to dispense that particular product (unless the dispenser goes back to the prescriber to change the prescription). As such, where a prescription specified 'phenytoin capsules, Flynn' the dispenser would need to dispense Flynn's product (see section 3.C.II.d).

3.278 However, Flynn believed that any new generic entry would most likely result in all prescriptions being written generically:

*'Even if Epanutin is not genericised proactively by Flynn then the advent and availability of a generic competitor would quickly lead to scripts being written generically, driven by PCOs [Primary Care Organisations].'*

3.279 On potential reputational damage ('*pharmaco-political fall-out*'), Flynn proposed that it '*carries this risk*'. That is, that Flynn would front any reputational damage.<sup>348</sup>

3.280 Flynn then set out whether its proposal – in particular, the proposed price increase – would encourage Parallel Imports. Flynn considered that Parallel Imports would naturally be limited by the stock available:

*'There is currently a level of PI which is limited by the availability of stock. No more stock would be available to importers.'*

3.281 Flynn also suggested that it may be possible to make it more difficult to sell Parallel Imports in the UK if Pfizer transferred its trademark to Flynn:

*'Transfer of the Trademark to Flynn would act as a further barrier to imports and sale of stock branded as Epanutin.'*

viii. *Flynn's responses to questions from Pfizer's lawyers*

3.282 Flynn's '*Epanutin Heads of Terms queries and responses*' document provided answers to a number of questions from Pfizer's lawyers regarding the proposed Heads of Terms.<sup>349</sup>

3.283 In particular, Pfizer's lawyers asked what the appropriate price was for Pfizer's MAs and where the value to Pfizer was in Flynn's proposal. The answer given was that:

*'The [X] is a nominal fee; the value of the deal is in the supply price to Flynn which will be higher than current ex-factory selling price.'*

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<sup>348</sup> This is consistent with Flynn's earlier suggestion that '*Pfizer uses Flynn Pharma as the MA holder to avoid pharmacopolitical damage*', see section 3.E.IV.c above.

<sup>349</sup> See document 00145.64.

## V. **Subsequent discussions between Pfizer and Flynn**

3.284 On 10 December 2010, [X] (Flynn's Commercial Director) emailed [Pfizer's Head of Customer and Channel Marketing - Established Products UK], suggesting a catch up to *'reassess where we are with things'*.

3.285 [Pfizer's Head of Customer and Channel Marketing - Established Products UK] replied on the same day (10 December 2010), explaining that Flynn's proposal was due to be discussed at a Pfizer leadership team meeting on 20 December 2010 and that he *'may need to call on your [Flynn's] services on Thursday pm or Friday to get any further info together for Monday [20 December 2010]'*. [Pfizer's Head of Customer and Channel Marketing - Established Products UK] then set out the *'two key areas'*: *'Trust'* and Parallel Imports, which were recurring issues:

*'the "Trust" agenda – [Pfizer's Head of Primary Care, Country Lead, UK] chairs the ABPI [Association of the British Pharmaceutical Industry] group on this subject and minimising the impact on patients for these two [sic]. I think we have all the info we need for this.*

*The braider [sic] area is still one regarding parallel trade and as long as we have a level of control over the supply we can manage this. Do you have any further tactics to add which would help manage the supply challenges across the EU?*

*Overall, I think we are OK: the Established Products team are all aligned; our legal advisor and medical advisor are comfortable with the proposal so far, so if we get the UKMF [UK Management Forum] onside, I am confident we can press forward.*

*Let me know if you think you have further info that can support our case otherwise I'll let you know the outcome of the discussion wit [sic] [Pfizer's Head of Primary Care, Country Lead, UK] and [Pfizer's Medical Director, UK] next week.'*<sup>350</sup>

3.286 [Flynn's Director] updated Flynn's Board of Directors on the status of negotiations with Pfizer on 15 December 2010,<sup>351</sup> noting, in particular, that phenytoin sodium capsules and Tablets are not interchangeable meaning

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<sup>350</sup> See document 00145.87.

<sup>351</sup> See document 00145.80.

that prescriptions (and therefore sales volumes) should not change once *Epanutin* was genericised:

*'Pfizer. The planned meeting on 6<sup>th</sup> December of the Pfizer UK leadership group was postponed until 20<sup>th</sup> December. They had raised a small number of questions which have been addressed. If our proposal is accepted by Pfizer, the product rights will be acquired by Flynn and a profit sharing agreement will be drawn up. Epanutin capsules & tablets are not interchangeable, so the number of scripts should be maintained when the product is sold generically. Need to get feedback from the meeting. ACTION: [Flynn's Director]'*

3.287 At the meeting on 20 December 2010, Pfizer's UK Management Forum ('UKMF') approved Flynn's proposal in principle but requested the project team consider certain points and report back.<sup>352</sup> Pfizer's UKMF raised 'two main hurdles' which needed to be considered: engagement with patient groups and regulatory issues.<sup>353</sup>

3.288 In early 2011, Pfizer engaged with patient groups as requested by Pfizer's UKMF. On 11 March 2011, [Pfizer's Head of Customer and Channel Marketing - Established Products UK] updated [✂] (Flynn's Commercial Director) and [Flynn's Director] by email:

*'We have engaged with Patient groups and they have seen this approach as very positive in terms of helping them prepare their clients for any change and progress will be conditional on this being taken forward by Pfizer/ Flynn.*

*I (Finally) managed to nail the Medical/ regulatory piece and earlier this week had confirmation that, even at a European regulatory level, there were not any significant challenges.<sup>354</sup>*

3.289 As a result of addressing the 'two main hurdles raised by the UKMF', [Pfizer's Head of Customer and Channel Marketing - Established Products

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<sup>352</sup> Pfizer's UK Management Forum inter alia included [Pfizer's Speciality Care Business Unit Director for the UK], [Pfizer's Head of Primary Care, Country Lead, UK], [Pfizer's UK Head of Oncology Business Unit], [Pfizer's Head of EPBU], [Pfizer's UK Customer Access Director], [Pfizer Legal Team Leader], [Pfizer's Vice president Finance, PECANZ and UK Finance Director], [Pfizer's Head of HR UK for Manager Operational Support], [Pfizer's UK/EU Director of Communications], [Pfizer's BT Country Lead, UK] and [Pfizer's Medical Director, UK] (see document 00086.1, page 9).

<sup>353</sup> See document 00145.34.

<sup>354</sup> See document 00145.34.

UK] was planning on further presenting Flynn's proposal to the UKMF 'in the next few weeks'<sup>355</sup> and requested a meeting with Flynn 'in the next couple of weeks to be clear on what we need to do with the view to getting back to UKMF by mid April'.

- 3.290 Flynn Board minutes on 8 April 2011 show that it considered phenytoin sodium capsules as 'the [✂] opportunity we have' and that it was hoping that Flynn's proposal would go back to Pfizer's UKMF in the next few weeks.<sup>356</sup>
- 3.291 An internal Pfizer presentation was prepared for a 'Follow up meeting' with the UKMF in April 2011. Slide two set out actions taken since the UKMF meeting in December 2010:
- 'Patient groups engaged'
  - Regulatory query answered
  - Legal framework of Pfizer UK/ EPUK involvement in process
  - Trademark transfer clarified'
- 3.292 Slide 10 set out 'UK MF Key Challenges', noting that 'Patient Group Impact' had been '[a]ligned with stakeholder strategy' and that no regulatory restrictions had been identified. The presentation also considered Flynn's proposal to sell Pfizer's *Epanutin* trademark to Flynn and recommended that the trademark should instead be licensed to Flynn.<sup>357</sup>
- 3.293 Following the approval by Pfizer UKMF's, Pfizer and Flynn began to draft the relevant agreements for discussion and Pfizer continued to seek internal approval from the EPBU European President.
- 3.294 In preparation for a meeting with Pfizer's European management in Zurich, [Pfizer's Commercial Account Director] had a discussion with [Flynn's Director] on 17 June 2011. [Pfizer's Commercial Account Director] reported the details of this discussion to [Pfizer's Head of EPBU] and [Pfizer's Head of Customer and Channel Marketing - Established Products UK] by email on 17 June 2011. The contents of the email suggest that questions were being asked within Pfizer as to why it was not proceeding to genericise *Epanutin*

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<sup>355</sup> See document 00145.34: 'These were the two main hurdles raised by the UKMF. I think we can be in a position to re-present our case to them in the next few weeks'.

<sup>356</sup> See documents 00145.116 and 00145.117.

<sup>357</sup> See document 00141.117.

on its own. Consistent with its initial reaction,<sup>358</sup> Flynn considered that Pfizer could proceed on its own. It is clear from [Pfizer's Commercial Account Director] email that [Flynn's Director] believed that Pfizer could genericise the products by itself but that it should proceed by using Flynn in order to mitigate any reputational fallout Pfizer might suffer as a result of the price increases:

*'I spoke briefly to [Flynn's Director].*

*[...]*

*Regarding the question of why not do it ourselves:-*

*1. We could, he doesn't think there are any PPRS issues.*

*2. It's ALL about reputation.*

*a. He suggests Google Daily Mail Hydrocortizone.....I did and here is a link to the Daily Mail Article <http://www.dailymail.co.uk/news/article-1295610/NHS-doesnt-care-cost-medicine-Drugs-firms-accused-profiteering-raising-prices-ONE-THOUSAND-cent.html>*

*b. He says would Pfizer execs want the Daily Mail camped on their doorstep.*

*3. Also, he points out that we have been working with them under and [sic] NDA [Non-Disclosure Agreement] to look at strategies on a range of products. He claims this was their idea and proposal and we might want to argue it would be a bit disingenuous to then do it ourselves.*

*4. He made the point that Pfizer red tape and corporate glue would probably stop us from doing it ourselves in anything like the timescales needed.*

*He also pointed out that Actavis have recently launched a tablet at £30.<sup>359</sup>*

3.295 On 20 June 2011, [Pfizer's Head of EPBU] and [Pfizer's Head of Customer and Channel Marketing - Established Products UK] met with Pfizer EU

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<sup>358</sup> See document 00145.4: *'If the plan is to genericise the product, we don't really understand why Pfizer just don't just do this themselves. You don't really need a third party'*; see section 3.E.IV.a.

<sup>359</sup> See document 00141.137.

Leadership in Zurich to discuss Flynn's proposal. [Pfizer's Head of EPBU] and [Pfizer's Head of Customer and Channel Marketing - Established Products UK] then sent an email on 23 June 2011 to [Flynn's Commercial Director] and [Flynn's Director] to update on that meeting:

*'the meeting on Monday with our EU Leadership was very productive. [Pfizer's Head of EPBU] and I presented the plan and our reasons for working with you on this project. The response was very positive.*

*[X], our [Regional President, Established Products Europe], want [sic] us to put this Epanutin case into our operating plan which we will present in the last week of July.*

*Accordingly: we need to work up a full business case, including financials and timelines. We should look to meet up in early July to discuss, thrash out details and proposed timelines for transfer, generic application, brand withdrawal and Gx launch.'*<sup>360</sup>

3.296 In August 2011, the Pfizer team briefed [X], the President of the Pfizer EPBU on Flynn's proposal. In the briefing, the Pfizer team stated that if Flynn was to increase the price to 35% of the price of Tablets, Flynn's revenues would be approximately £19.5m per annum, while Pfizer's potential revenues would be approximately £20m per annum. This compared to the total of £2.3m that Pfizer was achieving per annum at the time. Pfizer also noted that it believed that the proposed price levels were close to *'the optimum level and would still represent an attractive offering for the NHS'*.<sup>361</sup>

3.297 The briefing estimated that it would take a competitor a minimum of two years to bring a different phenytoin capsule product to the market:

*'We estimate that it would take a competitor a minimum of 2 years to bring a competitor phenytoin capsules to the market and trigger price reductions. Until that time we can expect the Drug Tariff (reimbursement) price to remain unchanged.'*

3.298 [Pfizer's Head of Customer and Channel Marketing - Established Products UK] emailed [Flynn's Commercial Director] on 2 September 2011 to confirm that Pfizer's European management team had approved Flynn's proposal:<sup>362</sup>

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<sup>360</sup> See document 00145.100.

<sup>361</sup> See document 00141.154.

<sup>362</sup> See document 00145.142.



'[Pfizer's Head of EPBU] *has had a very productive meeting and we have been given a "go" form [sic] our EP [Established Products] President, subject to the contract and usual caveats etc. This is very good news and we need to progress the legal documents*'.

## VI. **The Agreements**

3.299 The Flynn proposal envisaged that the following agreements would be entered into:

- the Asset Sale Agreement;.
- the Exclusive Supply Agreement; and
- the Quality Agreement.

3.300 [Pfizer's Head of EPBU] and [Pfizer's Head of Customer and Channel Marketing - Established Products UK] were principally responsible for negotiating these agreements on behalf of Pfizer.

3.301 [Flynn's Director] and [Flynn's Commercial Director] were principally responsible for negotiating these agreements on behalf of Flynn.

3.302 In addition to negotiating the terms of the agreements, Pfizer and Flynn also needed to clear several regulatory hurdles in order to ensure that the transfer of Pfizer's UK MAs to Flynn was, in fact, approved by the MHRA. Flynn's and Pfizer's discussions with the MHRA and the DH are both considered in further detail below.

### **a. The Asset Sale Agreement**

3.303 The Asset Sale Agreement was executed on 27 January 2012 and was signed by [Pfizer's Head of EPBU] on behalf of Pfizer and by [Flynn's Director] on behalf of Flynn.<sup>363</sup>

3.304 The key terms of the Asset Sale Agreement for the purposes of this Decision are set out below:

- Pfizer agreed to sell the relevant MAs for *Epanutin* to Flynn for the nominal sum of [£]. In addition to the MAs, Pfizer also agreed to

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<sup>363</sup> See document 00145.241

provide certain sales and marketing know-how, medical information, and documents to Flynn.<sup>364</sup>

- Flynn would submit an application to the MHRA for the transfer of the MAs within 10 business days of receipt of the relevant documents and MAs from Pfizer.<sup>365</sup>
- The Asset Sale Agreement would terminate [✂].<sup>366</sup> [✂]

**b. Change of ownership application**

3.305 It was necessary for Flynn to engage with the MHRA in order to receive approval for the change of ownership of Pfizer's MAs from Pfizer to Flynn (in order to effect the Asset Sale Agreement).

3.306 On 3 February 2012, Flynn submitted a change of ownership application to the MHRA for *Epanutin* capsules (25mg, 50mg, 100mg and 300mg).<sup>367</sup> At that point, the MHRA was unaware that Flynn intended to change the name of the products.<sup>368</sup>

3.307 On 23 March 2012, the MHRA approved the change of ownership to Flynn for all four presentations, 25mg, 50mg, 100mg, and 300mg.<sup>369</sup>

3.308 The MHRA agreed a six month transition period so that Pfizer's MAs would not be cancelled until 23 September 2012.<sup>370</sup> This gave Flynn and Pfizer six months to arrange for the transfer of the MAs. Pfizer would continue to sell *Epanutin* capsules under the *Epanutin* brand name on Flynn's behalf until 23 September 2012 after which Pfizer would no longer hold the relevant MAs. Flynn would then sell the product in the UK from 24 September 2012.

**c. The Exclusive Supply Agreement**

3.309 Once the MHRA had approved the change of ownership, Flynn and Pfizer finalised the Exclusive Supply Agreement on 17 April 2012. It was at this

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<sup>364</sup> See Clauses 4, 5 and 6 of document 00145.241.

<sup>365</sup> See Clause 6 of document 00145.241.

<sup>366</sup> See Clause 9 of document 00145.241.

<sup>367</sup> See documents 00248.2 (question 7); 00248.4, 00145.242; 00145.243; 00145.244; 00145.245; and 00145.246.

<sup>368</sup> See document 00400.1.

<sup>369</sup> See documents 00141.310; 00141.311; 00141.312; and 00141.313.

<sup>370</sup> See documents 00145.242; 00380.9; 00380.10; 00380.11; and 00380.12.

point that Flynn and Pfizer finalised the supply prices that Flynn would pay to Pfizer for the products.<sup>371</sup>

3.310 On 28 March 2012, after the MHRA had approved the change of ownership (on 23 March 2012), [Flynn's Director] updated the Flynn Board on the finalisation of the Exclusive Supply Agreement [redacted]:<sup>372</sup>

- **'Pfizer Epanutin.** [redacted] *as well as shorted [sic] payments terms for payments from our distributor [redacted]. Regulatory processes are now underway. ACTION: [Flynn's CEO].*

[...]

- [redacted]
- [redacted].'

3.311 On 3 April 2012, Flynn added the agreed supply prices to Schedule 1 of the draft Exclusive Supply Agreement as follows:<sup>373</sup>

<b>PRODUCT NAME</b>	<b>DOSAGE</b>	<b>MARKETING AUTHORISATION NO.</b>	<b>PRODUCT PRICE (PER UNIT)</b>
<i>Phenytoin Capsules</i>	<i>100mg</i>	<i>PL 13621/0063</i>	<i>[£31 - £40.99] per pack of 84 capsules</i>
<i>Phenytoin Capsules</i>	<i>25mg</i>	<i>PL 13621/0061</i>	<i>[£3 - £5.99] per pack of 28 capsules</i>
<i>Phenytoin Capsules</i>	<i>300mg</i>	<i>PL 13621/0064</i>	<i>[£31 - £40.99] per pack of 28 capsules</i>
<i>Phenytoin Capsules</i>	<i>50mg</i>	<i>PL 13621/0062</i>	<i>[£6 - £8.99] per pack of 28 capsules</i>

<sup>371</sup> See document 00145.280.

<sup>372</sup> See document 00145.269.

<sup>373</sup> See documents 00145.272 and 00145.273.

- 3.312 On 17 April 2012, Pfizer and Flynn finalised the Exclusive Supply Agreement<sup>374</sup> which was signed by [Pfizer's Head of EPBU] and [Flynn's CEO].
- 3.313 At the end of the negotiations an internal Pfizer email stated that the deal it had agreed with Flynn was *'at the top end of our expectations, in line with the aspirational figures that we shared with you.'*<sup>375</sup>
- 3.314 The key terms of the Exclusive Supply Agreement for the purposes of this Decision are set out below:

*'Supply of the Products. During the Term, SUPPLIER [Pfizer] shall supply and PURCHASER [Flynn] shall purchase such quantities of Product as PURCHASER may order under clause 4 [Orders] in accordance with the terms and conditions of this Agreement.'* (Clause 2.1)

*'Exclusivity. During the Term:*

*SUPPLIER agrees to supply the Products to PURCHASER on an exclusive basis in respect of the Territory; and*

*PURCHASER agrees not to purchase the Product or any product substantially similar to the Product from any other source.'* (Clause 2.2)

*'Changes in Market Conditions. Where there is any change in the commercial or market environments relating to the Products or this Agreement either party may request that the parties meet to discuss in good faith whether any variation to this Agreement is required, giving due regard to any change in the allocation of cost and risk to each party.'* (Clause 2.4)

*'Manufacture of the Products. SUPPLIER [Pfizer] shall Manufacture the Products [...]'* (Clause 5)

*'Pricing. During the Term SUPPLIER shall accept and fill all firm Orders for the Products from PURCHASER at the effective prices for such Products on the date such firm order is shipped to PURCHASER ("**Effective Prices**"). The Effective Prices for the period from the*

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<sup>374</sup> See document 00145.280.

<sup>375</sup> See document 00141.191.

Commencement Date to 31 December 2012 shall be the price set out in schedule 1.' (Clause 14.1)

*'Annual Price Review. The Effective Prices for the Products will be reviewed and adjusted annually [✂] for the next calendar year ("Annual Price Review"), and/or on agreement between both parties as may be deemed necessary outside of the Annual Price Review whereby should agreement not be met the Effective Price will be maintained. In agreeing Effective Prices for the following year, the parties shall have regard to the following factors:*

- *changes to SUPPLIER's costs of Manufacturing the Products;*
- *the volume of Products ordered by, and supplied to, PURCHASER;*
- *the net prices after deducting any rebates or trade related discounts at which comparable products are supplied by other suppliers in the open market; and*

*changes to PURCHASER'S storage and distribution costs.'* (Clause 14.2)

*'Schedule 2: agreed forecast volume' .*

<b>PRODUCT NAME</b>	<b>DOSAGE</b>	<b>PACK SIZE</b>	<b>FORECAST VOLUME</b>
<i>Phenytoin Capsules</i>	<i>100mg</i>	<i>84</i>	[✂]
<i>Phenytoin Capsules</i>	<i>25mg</i>	<i>28</i>	[✂]
<i>Phenytoin Capsules</i>	<i>300mg</i>	<i>28</i>	[✂]
<i>Phenytoin Capsules</i>	<i>50mg</i>	<i>28</i>	[✂]

**VII. Flynn's application to the MHRA to change the product name of Epanutin**

3.315 This section sets out Flynn's engagement with the MHRA on changing the product name of *Epanutin*.

a. **Flynn's initial application to the MHRA**

- 3.316 On 25 April 2012, shortly after the Exclusive Supply Agreement was finalised, [X] Flynn's appointed regulatory consultants,<sup>376</sup> sent a proposal to the MHRA to vary the product name *Epanutin* to 'Phenytoin Sodium Capsules' for 25mg, 50mg, 100mg and 300mg presentations by a 'Type 1B' group submission.<sup>377</sup> On 1 May 2012, the MHRA informed [Flynn's appointed regulatory consultants] that its proposal was 'acceptable' as a Type 1B submission.<sup>378</sup> On 2 May 2012 Flynn submitted its application for a change of name.
- 3.317 At the time, a change of name application was supposed to be a 28 day process, but due to a backlog at the MHRA, applications were generally taking longer.<sup>379</sup>
- 3.318 On 19 June 2012, [MHRA Official 1] set out his concerns regarding Flynn's change of name application in an email to [MHRA Official 2]. [MHRA Official 1]'s concerns focused on potential confusion, particularly given the characteristics of phenytoin sodium capsules:

*'It seems that Flynn have taken over Epanutin capsules (originator) from Pfizer and want (or have been told by Pfizer) to change to a generic name. This could surely cause some confusion out in the real world, esp with such a narrow therapeutic index drug.*

*Furthermore, the basis for an expedited request ('due to the recent change of ownership the manufacturer is unable to produce stock in the Epanutin livery and the current stock will be exhausted at the end of July') [...] i.e. current artwork with Flynn's MAH n+a and MA no.. Pfizer provided the necessary CoO statement saying that they would continue to manufacture for Flynn. Would you like me to send an e-mail to the applicant forewarning them that approval may not go smoothly and they would be well advised to produce stock in the Epanutin livery?'<sup>380</sup>*

- 3.319 The MHRA's first discussions with Flynn on its planned name change appear to have occurred around 21 June 2012. An email of 21 June 2012 from [MHRA Official 1] to [MHRA Official 2] summarised a telephone

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<sup>376</sup> See document 00380.21.

<sup>377</sup> See document 00380.14.

<sup>378</sup> See document 00380.14.

<sup>379</sup> See document 00141.336.

<sup>380</sup> See document 00380.19.

conversation that [MHRA Official 1] had had with [X] of [Flynn's appointed regulatory consultants]. During that discussion, [MHRA Official 1] was informed that Flynn *'originally wanted to have both the Epanutin and generic name on the MAs, but were told that this was not possible. The Flynn plan was to keep the Epanutin markings on the capsules, but to market the product under the generic name'*.<sup>381</sup>

3.320 During this telephone conversation between [MHRA Official 1] and [X] one of [Flynn's appointed regulatory consultants], the MHRA raised concerns about Flynn's proposed name change. [MHRA Official 1]'s email explained that:

*'I told [X] that we [the MHRA] had real concerns with the proposal\* and it would be extremely unlikely that the variation will be approved. I said that she should go back to Flynn to advise them of this and that Flynn should liaise with Pfizer to arrange further stocks with the Epanutin name. The argumentation provided below that 'the manufacturer is unable to produce stock in the Epanutin livery' is not accepted since the proposed labelling only differs in the name of the product and thus the currently approved labelling is actually closer to the Pfizer Epanutin livery (Flynn Pharma have not changed the livery yet).'*<sup>382</sup>

3.321 The MHRA's concerns (as denoted by '\*' in the quote above) were about patient confusion resulting from the nature of epilepsy as a condition and the characteristics of phenytoin sodium capsules:

*'\* Because: a narrow therapeutic index product for epilepsy. It is unusual for patients on Epanutin to switch to other phenytoin preparations. Removal of the Epanutin brand name could cause undue alarm and confusion for patients, prescribers and other health care professionals. There appears to have been no consideration of this and there is no indication as to how the change would be communicated to all necessary stakeholders.'*<sup>383</sup>

3.322 The MHRA's concerns were also reported in an email from Flynn to [Flynn's appointed regulatory consultants] on 22 June 2012:

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<sup>381</sup> See document 00380.20.

<sup>382</sup> See document 00380.20

<sup>383</sup> See document 00380.20.

*'I gather from a conversation with [Flynn's Director] today that the Assessor has two issues with on the generic variation.*

#### *1. Markings.*

*The capsules are marked with Epanutin and then the strength i.e. Epanutin 300.*

*This is, in essence, an identicode. Other than the 300mg the capsules are in bottles and the capsules do, therefore, require unique markings. The retention of the identicode could also be considered an element for patient safety i.e. the marking on the capsule would reassure the patient that they are continuing to receive the same formulation of phenytoin that their epilepsy has been stabilised on.*

#### *2. Rationale behind genericisation*

*This is a commercial decision. A communication programme to stakeholder groups e.g. the Epilepsy Society, Epilepsy Scotland and Epilepsy Action, retail pharmacies and the wholesale distribution chain has been put in to place.*

*See note above on markings with regard to patient safety.*

*If the MHRA has concerns on the generic availability of phenytoin then why did it recently approve the NRIM 100mg phenytoin generic licence (<http://www.mhra.gov.uk/home/groups/par/documents/websiteresources/con134906.pdf>) PL 20620/0021.*

*I think we need to emphasise to the Assessor that supplies of the branded product will be exhausted in the next 4 – 6 weeks and the only product available to meet patients' needs will be the generic formulations. A discontinuity of supply may lead to fatalities.*

*A change in markings may be possible but not to the next one or two production runs.<sup>384</sup>*

- 3.323 [Flynn's Director] also reported the MHRA's concerns to [Pfizer's Head of Customer and Channel Marketing - Established Products UK] and [Pfizer's Head of EPBU]. An internal Pfizer email from [Pfizer's Head of Customer and Channel Marketing - Established Products UK] to [Pfizer's Head of

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<sup>384</sup> See document 00145.303.



EPBU] on 22 June 2012 shows that Pfizer was considering a number of options which could be adopted by Flynn in response:

*'The assessor is failing to see that they were happy to approve a generic license for another company but completely paradoxically not happy to approve the generic of the original brand. It is a circle that cannot be squared but these are regulators and they are not obliged to apply logic to a situation; they only need to assess on a case by case basis.*

*Obviously this means another delay.*

*Options: 1) as stated on the other email, we give ourselves some breathing space to negotiate / comply with the assessors request of a "risk management / communications" plan as part of the submission.*

*2) play hardball and say we have produced at risk as they failed to meet their 28 day commitment and consequently forcing an OOS [out of stock] which will cause px [patient] safety issues, unless they approve a batch specific variation to allow to use Flynn phenytoin. Once in the market it would be unlikely that it will be withdrawn*

*3) Flynn seek our permission and the regulators permission to keep Epanutin as a brand and ask the DH to allow them to change the price thus making it commercially viable for them, or else they will not be able to continue the supply etc.'*<sup>385</sup>

3.324 It was at this point that the MHRA first contacted the DH to make it aware of Flynn's proposed actions. This appears to be the first time that the DH became aware of Flynn's and Pfizer's plans. On 21 June 2012, [MHRA Official 1] of the MHRA sent an email to [DH Official 1] of the DH, providing Flynn's proposed name change and requesting 'thoughts':

*'I would be very grateful if you could provide any thoughts (positive or negative) on the matter below.*

*As you may or may not be aware, Flynn Pharma have recently acquired ownership of the MAs for Epanutin Capsules (from Pfizer).*

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<sup>385</sup> See document 00141.358.

*They have submitted a variation to change the product name from Epanutin to the generic name, phenytoin sodium.*

*My immediate reaction (supported by [MHRA Official 2] ) is that this is not approvable, since Epanutin is a narrow therapeutic index product for epilepsy and it is unusual for patients on Epanutin to switch to other phenytoin preparations. Removal of the Epanutin brand name could cause undue alarm and confusion for patients, prescribers and other healthcare professionals. There appears to have been no consideration of this and there is no indication as to how the change would be communicated to all necessary stakeholders.*

*I have informed the company informally of the above, but I did say that we would discuss this further just in case we can provide some guidance going forward, although at the moment this seems very unlikely.'<sup>386</sup>*

3.325 This was the first time that the DH became aware of Flynn's and Pfizer's plans.

3.326 [DH Official 1] replied on 25 June 2012, outlining that the DH also had concerns with Flynn's application due to patient safety issues:

*'Anecdotal feedback has always suggested that, where possible, patients should be maintained on the same manufacturer's antiepilepsy medicine as small differences in bioequivalence and pharmacokinetics, which may lead to a loss of control of epilepsy and seizures, can have big consequences. A DTB (Vol. 47, No. 12) analysis, attached for information, concluded that patients who are seizure-free and those on phenytoin should stay on the same make of drug. The BNF says: "On the basis of single dose tests there are no clinically relevant differences in bioavailability between available phenytoin sodium tablets and capsules but there may be a pharmacokinetic basis for maintaining the same brand of phenytoin in some patients."*

[...]

*As you can see, generic alternatives of the 100mg presentations are available, however as these are a different presentation to Epanutin capsules, you shouldn't get switching between these if Epanutin were to become available only as a generic phenytoin capsules. Having said*

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<sup>386</sup> See document 00367.3

*that, if a presentation were written as 'phenytoin 100mg x 100' you might conceivably be given either.*

[...]

*If Flynn market the product as a generic medicine, they will be free to price at a point decided by market forces as the controls of the PPRS would not apply. For both of these reasons, Flynn may decide that branded phenytoin capsules are not commercially viable and this calls in to question the long term future of this medicine.*

*We would regard continued supply of this medicine as essential and can seek assurances from the two companies involved about their future plans for Epanutin/phenytoin.<sup>387</sup>*

3.327 On 25 June 2012, the MHRA, Flynn and [Flynn's appointed regulatory consultants] held a telephone conference to discuss the MHRA's concerns about Flynn's application.<sup>388</sup>

3.328 On 27 June 2012, [MHRA Official 2] provided his comments to [MHRA Official 1] on the note of the telephone conference of 25 June 2012.<sup>389</sup> [MHRA Official 2] said that [MHRA Official 2] found the previous day's call 'very difficult' and that Flynn had effectively said that if it was not allowed to genericise *Epanutin* it would 'cease to manufacture' the product. [MHRA Official 2] also noted that Flynn's proposed change of name had been preceded by 'absolutely no communication strategy whatsoever':

*'Flynn (who I have no previous experience of dealing with) bought the MA for Epanutin Capsules from Pfizer. Pfizer agreed to continue to manufacture. In a very difficult TC [telephone call], Flynn effectively said 'allow us this name change or we'll cease to manufacture Epanutin'. It's a commercial decision – the pricing for Epanutin versus generic phenytoin is a nonsense – and so Flynn see this name change as an angle to charge more. However, this name change has been preced [sic] with absolutely no communication strategy whatsoever.*

*In the long term – I think we'll have to agree to the name change (as, if communicated correctly and our brand prescribing advice for phenytoin*

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<sup>387</sup> See document 00367.3.

<sup>388</sup> See documents 00380.22; 00380.23; and 00145.713.

<sup>389</sup> [MHRA Official 2] also copied his email to [MHRA Official 3], who was 'the Agency lead in terms of brand prescribing and AEDs and I think should be made aware of this unfortunate situation'; see document 00380.18.

*is in place, then the fact that Epanutin is still available albeit under a generic name must be preferable to it being removed from the market). For now, we're trying to get them to product [sic] some more batches under Epanutin livery so this doesn't come as one big, unpleasant surprise to patients and pharmacists.'*<sup>390</sup>

3.329 On 28 June 2012, the MHRA emailed its comments on Flynn's note of the telephone conference of 26 June 2012. In its cover email the MHRA stated that:

*'Whilst there are a number of action points going forward, could Flynn Pharma please address the following as a matter of urgency:*

*As we all agree, patient safety is paramount and this is best served by a non-rushed assessment and an orderly, well communicated change in product name. This is surely also in the interests of Flynn and Pfizer so that their reputations in the eyes of the patient and healthcare professional are not adversely affected. It is therefore not acceptable to push the regulatory authority into a corner and expect an expedited assessment. It is the responsibility of the marketing authorisation holder to ensure that product continues to be made in accordance with the registered marketing authorisation details until any change is approved. The new stocks of product have not been packed. Flynn Pharma should therefore as a matter of urgency make every effort to obtain packaging components under the currently approved Epanutin livery. For the 25, 50 and 100 mg strengths, only the HDPE container is affected. It is appreciated that blister foil for the 300mg may take some weeks to order. Should foil not be available in time, the MHRA could look favourably on the use of alternative foil (e.g. Epanutin foil with the Pfizer MA name) providing a suitable batch specific variation were to be submitted.'*<sup>391</sup>

3.330 The MHRA's comments on Flynn's note of the meeting highlighted that it was particularly concerned that Flynn's application did not adequately address how it would inform healthcare professionals and patients about the proposed name change:

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<sup>390</sup> See document 00380.18.

<sup>391</sup> See document 00380.22.

*'The proposed name change to Epanutin removes the Epanutin name from the market.*

*For those prescribers who wish only Epanutin to be dispensed, this is no longer ensured since the Flynn product effectively becomes just another generic. The variation package had no indication of how this would be addressed.*

[...]

*NICE guidance and NHS area formularies already advise against switching [AEDs].<sup>392</sup>*

3.331 The MHRA advised that, before any future name change for *Epanutin*, Flynn:

*'should discuss their proposal with a doctor (or other relevant healthcare professional) who has experience in the applicable therapeutic field.'<sup>393</sup>*

3.332 The MHRA further advised that Flynn's proposals to communicate the product name change should have first been *'discussed and agreed with DoH and MHRA prior to the product name change variation'*.<sup>394</sup>

3.333 Following this, Flynn agreed to withdraw its application and submit a new application which included a communication plan which met with the MHRA's approval.<sup>395</sup>

3.334 Following the telephone conference, [MHRA Official 1] reported back to [DH Official 1] on his discussions with Flynn and registered his view that Flynn's approach was *'completely irresponsible'*:

*'They [Flynn] are playing hard ball on this one and, although the MHRA do not agree with the name change, Flynn effectively threatened to stop the product if they do not get the generic name approved. [✂].*

*To make matters worse, they claim that current stocks of Epanutin 50, 100 & 300mg caps will run out in early Aug and 25mg in early Oct. It is 'impossible' to make further Epanutin since Pfizer do not have the*

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<sup>392</sup> See document 00380.23.

<sup>393</sup> See document 00380.23.

<sup>394</sup> See document 00380.23.

<sup>395</sup> See document 00380.23.

*packaging and thus will need to supply generic product from early Aug ('already manufactured at risk').*

[...]

*Whilst this is completely irresponsible of Flynn, we do not see an easy way out of this situation. Judging by the people we spoke with today I do not think they would make any effort to re-package in Epanutin livery, although I wish we had the power to make them do so.*

*We have told them that if they wish to press ahead with the change then the next stage is to supply us (incl. DoH) with their proposed healthcare professional communications.<sup>396</sup>*

- 3.335 On 26 June 2012, [Flynn's Director] sent an email to the MHRA, outlining the measures that Flynn had already taken to identify any concerns that patient groups might have around the proposed name change of *Epanutin*.

*'We agree with the MHRA's view that patient safety is paramount and, with this in mind, we submit that both Pfizer and Flynn have acted in a responsible manner through this process.*

*Pfizer UK has sold the marketing authorisation to Flynn, and Pfizer Germany has agreed to continue supply of phenytoin capsules (marked with the alphanumeric identicode including the word "Epanutin"). The product is qualitatively and quantitatively identical in every aspect bar product name to the Pfizer Epanutin product. That is to say, there is no change in the formulation or in the capsule markings, both of which we consider most important to patient safety. We (Pfizer & Flynn) have already engaged with the patient support groups to discuss any concerns they had with the proposed changes and we have committed to actions to support patients during this period.<sup>397</sup>*

**b. Flynn's withdrawal of its application to the MHRA**

- 3.336 On 26 June 2012, the MHRA sent Flynn a 'Notification with Grounds' in which it stated that the change of product name was 'not approvable' and set out the reasons for this decision. In particular, the MHRA cited patient safety concerns and observed that it appeared that Flynn had given 'no

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<sup>396</sup> See document 00367.3.

<sup>397</sup> See document 00145.713.

consideration' to this nor 'how the change [of Epanutin's name] would be communicated to all necessary stakeholders':

*'Epanutin is a narrow therapeutic index product for epilepsy. It is unusual for patients on Epanutin to switch to other phenytoin preparations. Removal of the Epanutin brand name could cause undue alarm and confusion for patients, prescribers and other healthcare professionals. There appears to have been no consideration of this and there is no indication as to how the change would be communicated to all necessary stakeholders. The change in product name is therefore not approvable.'*<sup>398</sup>

3.337 The MHRA also noted that it understood that Flynn would withdraw (and resubmit) its application:

*'from the subsequent telephone discussions of 25 June [2012] that Flynn Pharma, the marketing authorisation holder intends, to withdraw the variation. This information should be received in writing within 30 calendar days of the date of this letter, otherwise the submission will be refused'*

**c. *Flynn's response to the MHRA's decision on its application***

3.338 In a telephone call with Flynn on 25 June 2012, the MHRA noted that, unlike with NRIM's product, Flynn's proposals were to remove the *Epanutin* brand from the market and replace it with a generic version. The MHRA was concerned that there was an inherent risk of patients involuntarily switching from *Epanutin* to another phenytoin sodium hard capsule product if the *Epanutin* brand was removed:

*'The proposed name change to Epanutin removes the Epanutin name from the market. (Approval of the NRIM product did not remove the Epanutin name.)*

*For those prescribers who wish only Epanutin to be dispensed, this is no longer ensured since the Flynn product effectively becomes just another generic. The variation package had no indication of how this would be addressed.*

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<sup>398</sup> See document 00145.308. and 00145.309

*Generic presentations of Epanutin capsules, albeit as tablets, have been available for over 30 years. Under Article 10 of Directive 2001/83/EC (as amended), for the purposes of a generic marketing authorisation application, immediate release capsules and tablets are considered to be one and the same pharmaceutical form.*<sup>399</sup>

*For some patients (e.g. for second line treatment of trigeminal neuralgia<sup>400</sup>) the prescriber may judge that the dispensed brand or generic is not important, but for the majority of epileptic patients switching between preparations is unusual. This is widely known and it is surprising that this information seems not to have been shared between the previous and current MAH.*<sup>401</sup>

- 3.339 Flynn responded to the MHRA on 26 June 2012. In his response, [Flynn's Director] questioned the MHRA's requirement for a detailed communication plan, citing instances where the MHRA had allowed similar changes of product name without communication plans.<sup>402</sup> In particular, [Flynn's Director] stated that the MHRA had not required NRIM, another supplier of phenytoin sodium capsules, to have a communication plan approved by the MHRA before granting an MA for its product.<sup>403</sup>

*'The MHRA has previously approved three different phenytoin generic licences, two tablet formulations and one capsule formulation. The most recent approval (Sept 2011) to NRIM Ltd was granted on the basis of bioequivalence data. As soon as this approved capsule formulation is placed on the market, patients currently taking Epanutin will be switched to the generic, which is a different formulation, with no communication to the patient or to the prescriber.*

*Conversely, changing the name of Epanutin to phenytoin sodium (Flynn Pharma) would result in the patients taking exactly the same product as*

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<sup>399</sup> See document 00248.10 and Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on The Community Code Relating to Medicinal Products for Human Use Official Journal L – 311, 28/11/2004, pages 67 to 128.

<sup>400</sup> Trigeminal neuralgia is sudden, severe facial nerve pain.

<sup>401</sup> See document 00248.10.

<sup>402</sup> See document 00145.312.

<sup>403</sup> On 13 September 2011, the MHRA granted an MA to NRIM for Phenytoin Capsules (100mg); see Module 2 of document 00512.5.



*Epanutin. Flynn Pharma has committed to a communications plan which includes communications to **all** stakeholders.*

*If the MHRA and the DH believe that prescribing by brand is essential for patient safety, it is our view that the licence for the NRIM generic should be withdrawn, or it should be branded.*

*As an alternative, prescribers could be guided to prescribe by generic + manufacturer, i.e. "phenytoin Flynn" or "phenytoin NRIM".<sup>404</sup> [Emphasis in original.]*

- 3.340 Flynn wrote further to the MHRA on 29 June 2012, explaining that it believed that it had correctly followed the MHRA's product name variation guidance, and believed that both it and Pfizer had '*acted responsibly with regard to patient safety and maintenance of supply*':

*'Flynn and its regulatory consultant have submitted the name change variation strictly according to current guidance. Nowhere in the guidance does it state a requirement for communication plans, nor are we aware of any precedent for such. There is no specific section in the guidance on narrow therapeutic index products. If the Agency now regards this to be essential, the guidance should be reviewed. Flynn was influenced by the recent approval of NRIM's generic presentation, the PAR [Public Assessment Report] for which did not require any communication strategy whatsoever.*

*In our view, both Pfizer and Flynn have acted responsibly with regard to patient safety and maintenance of supply. It is not that Flynn has no communication plan; an outline communication plan was submitted in the minutes of our teleconference.<sup>405</sup>*

- 3.341 On 2 July 2012, [MHRA Official 1] further replied to [Flynn's Director], stating that:

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<sup>404</sup> See document 00145.312. The MHRA later required NRIM to include the manufacturer's name in the name of its product as phenytoin sodium NRIM Xmg hard capsules; see document 00400.1.

<sup>405</sup> See document 00380.22.

*'Guidance is guidance and cannot cover each individual scenario. It is a rare, if not unique, situation where a brand name for a narrow therapeutic index is being removed.'*<sup>406</sup>

**d. Flynn's submission that a price rise was necessary for continued supply**

3.342 In its engagements with the MHRA, Flynn submitted that it was commercially necessary for it to be able to sell the products at significantly higher prices in order to be able to continue supply.

3.343 In an internal email, on 26 June 2012, [REDACTED] (Flynn's Medical Director), who was in attendance on the telephone call with the MHRA on the preceding day, circulated to the other Flynn attendees ([Flynn's CEO and Director]) further points that Flynn would need to put to the MHRA concerning Flynn's rationale for genericising *Epanutin*:

*'Pfizer Germany have agreed to continue supply of phenytoin capsules (marked with the identicode Epanutin followed by the strength suffix) on an arms-length commercial basis. The supply prices agreed mean that Flynn is not in a financial position to provide Epanutin branded product to the UK market.'*[REDACTED].<sup>407</sup>

3.344 On 29 June 2012, Flynn advised the MHRA *'that it is not commercially viable for Flynn to supply the UK market with Epanutin™ branded product'*.<sup>408</sup>

3.345 Flynn informed the MHRA that:

*'Unless the Department of Health is prepared to treat this as a special case, the only way continuity of supply of the physical product which is identical in formulation (and markings) to Epanutin can be guaranteed, under the current constraints of the Pharmaceutical Price Regulation Scheme (PPRS), is for this formulation to be supplied as a generic.'*<sup>409</sup>

3.346 The idea of the DH treating *Epanutin* as a 'special case' appears to have been first discussed within Pfizer in response to the MHRA's concerns about

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<sup>406</sup> See document 00380.22. Following the eventual genericisation of *Epanutin*, the MHRA requested that the NRI company name appears on the generic title of its product; see document 00400.1.

<sup>407</sup> See document 00145.306.

<sup>408</sup> See document 00380.22.

<sup>409</sup> See document 00380.22.

Flynn's change of name application. [Pfizer's Head of Customer and Channel Marketing - Established Products UK] stated that:

*'Flynn seek our permission and the regulators permission to keep Epanutin as a brand and the DH to allow them to change the price thus making it commercially viable for them, or else they will not be able to continue the supply etc.'*<sup>410</sup>

3.347 Pfizer also informed the CMA that it had not previously approached the DH to raise the price of *Epanutin* under the PPRS, as any such price rise would have been limited to a maximum of 20% of the current price:

*'Any increase in price would have been limited to 20% under the PPRS. Previous experience had demonstrated that approaching the Department of Health for a price increase above the standard limit had not been successful. Other options were therefore considered'*.<sup>411</sup>

3.348 On 2 July 2012, [MHRA Official 1] responded to [Flynn's Director] stating that *'Pricing issues are outside MHRA remit'*.<sup>412</sup>

3.349 Flynn formally withdrew its application to vary the name of the products on 4 July 2012, pending submission of its communication plan.<sup>413</sup>

e. ***The MHRA's request that a genericised Epanutin product should include Flynn's name***

3.350 On 6 July 2012, Flynn submitted its draft communication plan to the MHRA.<sup>414</sup> On 11 July 2012, the MHRA responded to Flynn with its comments on Flynn's draft communication plan. The MHRA informed Flynn that the formal name of the genericised product should now include Flynn's name:

*'In the event of the name change being acceptable to the MHRA, we would wish to see the formal product name as 'Phenytoin Sodium Flynn x mg Hard Capsules' in Section 1 of the SmPC [Summary of Product Characteristics]. However, we would not need or want the name 'Flynn'*

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<sup>410</sup> See document 00141.358.

<sup>411</sup> See document 00086.1, question 6.

<sup>412</sup> See document 00380.22.

<sup>413</sup> See document 00145.319.

<sup>414</sup> See document 00145.325.

*to appear within the product name on the labelling and packaging intended for marketing.*<sup>415</sup>

- 3.351 The MHRA also emphasised that it remained concerned about the possible confusion which might be caused through changing the name of *Epanutin*:

*'MHRA review of this documents has, however, generated further concern about the potential for confusion if the Epanutin trade name were to be replaced by a generic name. It may now be necessary to take the name change variation to expert committee for their review, comment and decision. This would obviously impact upon timelines and it would therefore be advisable to plan for further stocks in the Epanutin livery.*

*As the desire to change the product name is driven by the current price for Epanutin capsules, we have had further communications with our DH colleagues. Could Flynn Pharm please contact the relevant PPRS DH colleague, who is [DH Official 2]... to explore options.*<sup>416</sup>

- 3.352 Flynn's internal discussions also show its understanding of the implications of the MHRA's request to include Flynn's name within the product name. An internal email from [Flynn's CEO] to [Flynn's Director] on 10 August 2012 stated:

*'As I understand it from a regulatory perspective, the MHRA has requested that the product name (Phenytoin Sodium) be additionally distinguished by the addition of the company name 'Flynn'? The effect here I presume is to enhance the identification of the product and therefore reduce the likelihood of unintentional interchange between one source and another. This gives the product the characteristics of a branded generic not unlike the practice in some other generic markets like Germany for example or indeed in the UK, where Almas and Teva for example have sought to create a branded identity or visual imagery to differentiate their generic product offering and capitalise on the value and recognition of the company name. It is however, unless I am missing something, not a brand and as such MHRA has agreed that the generic name need not appear with equal prominence to a brand name. Equally am I correct in my assumption that the DH also do not consider the*

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<sup>415</sup> See document 00145.329.

<sup>416</sup> See documents 00248.11; 00145.328; and 00380.22.

*product a brand and therefore it falls outside of Flynn's branded portfolio and PPRS consideration.*<sup>417</sup>

**f. Internal MHRA discussions**

3.353 Flynn revised its communication plan in the light of MHRA's review and resubmitted it to the MHRA.<sup>418</sup>

3.354 However, internal discussion shows that the MHRA still had concerns about patient safety following the name change of *Epanutin*:

*'I don't think that we will be able to prevent Flynn from changing the brand name of the product and the issue is whether we allow them to use a generic name. According to our (still draft) brand name position, the continuity of supplier should be maintained for phenytoin. So the question is how can patients be reassured that they will be maintained on the same manufacturer's product. This would seem to be the question that Flynn have to convince us on.'*<sup>419</sup> [Emphasis as original]

**g. The MHRA's approval of Flynn's communication plan**

3.355 The MHRA approved Flynn's communication plan on 19 July 2012.<sup>420</sup>

**h. Discussion between the MHRA and Pfizer about the *Epanutin* trademark**

3.356 On 19 July 2012, the MHRA also contacted Pfizer to understand the reasons why Pfizer was not transferring the *Epanutin* trademark to Flynn.<sup>421</sup>

3.357 On 20 July, Pfizer provided the MHRA with an explanation of why it would not be transferring the *Epanutin* trademark to Flynn. Pfizer explained that it would not consider it appropriate for a trademark relating to a global brand to be used, in one country, by a third party and added that there were other forms of *Epanutin* which remained the property of Pfizer in the UK which would continue to carry the trademark. Pfizer also explained that as part of

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<sup>417</sup> See document 00145.349.

<sup>418</sup> See document 00248.12.

<sup>419</sup> See document 00248.12.

<sup>420</sup> See document 00248.12.

<sup>421</sup> See document 00141.375.

the change of ownership Pfizer had agreed that the actual capsules would retain the marking referring to *Epanutin*.<sup>422</sup>

- 3.358 On 23 July 2012, [MHRA Official 1] informed [MHRA Official 2] of his current thinking on the preferred use of a brand rather than a generic name for Flynn's phenytoin sodium capsules:

*'We've informed DH that we would prefer a new brand name rather than a generic name, but not mentioned this to Flynn, or at least not directly or recently. I could now do so indicating that the MHRA preferred stance would be a new brand name instead of a generic name. [REDACTED] .*

*However, as you rightly mentioned, whilst it would be initially reassuring it could ultimately be confusing (esp. for new patients) having the Epanutin name on the capsule shells. Would we insist on this changing? I doubt we could get it changed in time for the next stocks, but also could imagine some resistance from Pfizer and Flynn since this would mean that they would need to have unique capsule shells for the UK market resulting in increased cost of goods and less flexible production procedures.'*<sup>423</sup>

***i. Flynn's resubmission of its application to change the Epanutin product name***

- 3.359 Flynn resubmitted its application for the change of name on 31 July 2012. Flynn also informed the MHRA that it had discussed the possibility of a re-branded *Epanutin* product remaining within the PPRS with the DH but that it had not been possible to increase the price of a re-branded product to levels which Flynn would find '*economically viable*'.<sup>424</sup>

- 3.360 An internal Flynn email on 26 June 2012 from [Flynn's Medical Director] to [Flynn's CEO], [Flynn's Director] and [Flynn's Finance Director] summarised Flynn's position on price:

*'The supply prices agreed mean that Flynn is not in a financial position to provide Epanutin branded product to the UK market. [REDACTED]*<sup>425</sup>

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<sup>422</sup> See document 00145.334.

<sup>423</sup> See document 00380.27.

<sup>424</sup> See document 00380.28.

<sup>425</sup> See document 00145.306.

3.361 On 31 July 2012 [redacted] of [Flynn's appointed regulatory consultants] emailed [Flynn's Director], [Flynn's Finance Director] and [Flynn's Medical Director] advising that Flynn should highlight its commercial necessity to genericise *Epanutin*:

*'I think perhaps you need to re-stress that the DoH position really means that unless this is prescribed and marketed as the generic, it is not a viable product commercially due to the price constraints. Maybe acknowledge that you recognize price is not the MHRA remit, but unfortunately it plays an integral role in how to continue with the product.'*<sup>426</sup>

3.362 [Flynn's Director] then emailed [MHRA Official 1] on 31 July 2012, copying [DH Official 1]. In his email, [Flynn's Director] explained that genericising *Epanutin* was Flynn's only option as a result of the decision taken by the DH's PPRS Pricing Committee not to allow Flynn to increase the price of a re-branded *Epanutin* product to the levels which it would find 'economically viable':

*'Following our meeting with the Department of Health and their subsequent referral of the matter to the Pricing Committee, they have now confirmed that there is no flexibility under PPRS to increase the price to an economically viable level as a brand.*

*Thus, we have no option but to pursue the generic route and re-submit our application with the proposed name change and Communication Plan as discussed and agreed with you, emphasising the need to prescribe as Phenytoin Sodium Flynn Hard Capsules.*

*The timing is becoming critical. Pfizer has sufficient stock of all presentations to meet demand up until the third week of September, with the exception of the 50mg, for which there is a current stock-out. We will need at least four weeks to produce the components and the stock to continue supplies to the market.'*<sup>427</sup>

3.363 The MHRA ultimately approved Flynn's name change variations on 29 August 2012.<sup>428</sup>

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<sup>426</sup> See document 00145.341.

<sup>427</sup> See document 00380.28.

<sup>428</sup> See document 00145.469.

*j. Flynn's implementation of its communication plan*

3.364 Once the MHRA had approved the name change, Flynn took steps to implement the communications plan it had agreed with the MHRA. The plan included a number of actions that Flynn would undertake to notify patients and healthcare professionals about the name change, including:

- liaising with major epilepsy advocacy groups;
- introduction of a freephone helpline;
- mailing all UK GPs, secondary care based epilepsy and neurology clinics and UK pharmacies;
- journal and trade announcements;
- wholesaler communications; and
- discussions with all major retail pharmacy chains.<sup>429</sup>

3.365 The communications plan also involved Flynn writing to healthcare professionals about the changes Flynn would be implementing.<sup>430</sup> This was done on 21 September 2012, three days before Flynn started selling its product. Among other things the letter made clear that:

*'the Flynn Pharma product is identical to Epanutin. There are no differences in formulation and the site of manufacture remains unchanged. The capsules continue to contain the same identicode markings as Epanutin, including the word 'Epanutin.'*

**VIII. Discussions between the Department of Health and Flynn and Pfizer**

3.366 As set out in section 3.E.VII.a above, the MHRA brought Flynn's proposal to the DH's attention (on 21 June 2012) and the DH contacted both Pfizer and Flynn to discuss the proposal. As part of that process, Flynn discussed with the DH whether it might be possible to increase the price for phenytoin sodium capsules within the current PPRS. That option was, however,

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<sup>429</sup> See document 00145.358.

<sup>430</sup> See document PD 15.



ultimately not possible, so Flynn proceeded with its plan to genericise the products.

- 3.367 The DH first contacted Pfizer by email on 21 June 2012 to request details of the divestment noting that the DH was not previously aware of this development:

*'It has been brought to the Department's attention that Pfizer has divested Epanutin to Flynn Pharmaceuticals. As the Department has not been notified regarding this transfer, in order for me to update my records, could you let me have details of the presentations that were divested and the date that the divestment took place.'*<sup>431</sup>

- 3.368 Pfizer provided confirmation of the divestment on the following day (22 June 2012):

*'This transaction is still commercially sensitive and currently all the product being [sic] is being sold by Pfizer. The products that are part of a divestment to Flynn Pharmaceuticals are the capsules presentations*

*EPANUTIN CAPS 100MG X 84 UK*

*EPANUTIN CAPS 25MG X 28 UK*

*EPANUTIN CAPS 300MG X 28 UK*

*EPANUTIN CAPS 50MG X 28 UK'*<sup>432</sup>

- 3.369 On 3 July 2012, [X] (Flynn's Finance Director) emailed [DH Official 1] (copying [MHRA Official 1] as well as [Flynn's CEO and Director]) to request a meeting. [Flynn's Finance Director] also outlined the progress of Flynn's discussions with the MHRA and warned that any further delays by the MHRA in processing Flynn's application could result in stock shortages:

*'As I believe you are aware, Flynn has recently made an application for a Variation to change the name of Epanutin® Capsules to the generic form, Phenytoin Sodium Hard Capsules. During the assessment process, MHRA had raised some questions as to potential impact on patient safety and the need to appropriately communicate to interested parties. Following our discussions with the MHRA, Flynn agreed that [sic]*

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<sup>431</sup> See document 00367.4.

<sup>432</sup> See document 00367.5.

*to withdraw the existing application and submit a Communications Plan to a) mitigate patient and healthcare professionals' concerns regarding continued availability of the product branded as Epanutin, and b) to ensure seamless supply chain transition to the generic product. Once this plan has been approved, the MHRA has agreed to accept an expedited application for the variation.*

*However, the Department of Health should be aware that further delays in the processing of the Variation could lead to stock issues in the market place. Continued availability of the product as Epanutin under the Flynn marketing authorisation, under the current contractual and reimbursement arrangements is not viable for Flynn. The supply of physical product which is a qualitatively and quantitatively identical formulation (and markings) to Epanutin can be guaranteed, provided the product(s) are supplied as a generic.<sup>433</sup>*

3.370 Between 4 July 2012 and 3 August 2012, Flynn and the DH discussed and exchanged correspondence on stock levels of *Epanutin* and contingency planning.<sup>434</sup>

**a. *Discussions between the MHRA and the DH about Epanutin remaining in the PPRS***

3.371 During its discussions with Flynn, the MHRA contacted the DH to discuss options for keeping the brand name *Epanutin*. One of the options explored was whether it might be possible for prices to increase while maintaining the brand name *Epanutin*.

3.372 On 10 July 2012, [MHRA Official 1] emailed [DH Official 3]. In his email, [MHRA Official 1] highlighted the MHRA's concerns about patient safety:

*'Further to recent correspondence about Flynn Pharma's proposal to 'genericise' Epanutin capsules (and their threat to withdraw the product if this proposal is not approved), we are getting increasingly nervous about the ramifications (esp, the confusion) such a change could cause.'*<sup>435</sup>

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<sup>433</sup> See documents 00145.316 and 00145.322.

<sup>434</sup> See, for example, documents 00145.322; 00145.325; and 00145.348.

<sup>435</sup> See document 00367.8.

3.373 [MHRA Official 1] then explained that they needed to explore options available and enquired whether there might be scope to increase the price of *Epanutin* within the PPRS:

*'We therefore need to explore every avenue to avoid this undesired change. One such avenue is the driver for this change, i.e. the current Epanutin vs phenytoin sodium tablet pricing differential (30 fold difference in 100mg pricing). If this differential were addressed, then this would remove the need for the name change.'*

3.374 On 10 July 2012, [DH Official 4] emailed [DH Official 3] providing some list price data and noting that *'I don't think that there is anything in the current PPRS agreement that allows us to prevent this sort of genericisation'*.<sup>436</sup>

3.375 [DH Official 3] then replied to [DH Official 4] on the same day (10 July 2012), noting that Flynn only wanted to genericise *Epanutin* because current prices made the product commercially unviable:

*'The company only wants to genericise the product as it is not commercially viable for it to market at the current price agreed under the PPRS. Since genericisation in this instance introduces a real safety concern, what measures are open to the company to increase the price? If there is no flexibility under the PPRS can the company opt out and join the statutory scheme – would this allow it to increase the price?'*<sup>437</sup>

3.376 [DH Official 4] replied to [DH Official 3]'s queries the following day (11 July 2012). He noted that there had not been much discussion with Flynn and suggested that the DH should contact Flynn. Consistent with Flynn's approach to engagement with the DH to this point, he also noted that Flynn had not approached the DH to request a price increase:

*'I don't think that there has been much discussion with Flynn and the PPRS team on this issue – and perhaps we should contact Flynn in the first instance to find out the company's reasoning and intentions. The company has not approached us to request a price increase.'*<sup>438</sup>

3.377 He then set out what options might be available to Flynn to achieve price increases:

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<sup>436</sup> See document 00367.8.

<sup>437</sup> See document 00367.8.

<sup>438</sup> See document 00367.7.

*'As far as the PPRS is concerned, it could be possible to modulate the price of the branded medicine, but I'm not sure that Flynn would have the scope to do so within its product portfolio; and does Pfizer want Flynn to market the medicine as Epanutin? The company could leave the PPRS and fall under the statutory arrangement, but I guess it has already made a commercial decision to remain in the scheme, perhaps because of the modulation provisions it currently enjoys which aren't available under the regulations.*

*One option could be for the company to launch a new brand of this medicine, which the Pricing Committee would need to agree the price of.*

*Initially, [DH Official 2] will arrange for Flynn to be contacted to discuss the issue further.<sup>439</sup>*

- 3.378 [DH Official 3] replied to [MHRA Official 1] by email on 11 July 2012 to inform him of the outcome of the DH's internal consideration, suggesting that the MHRA put Flynn in contact with the DH:

*'I have discussed this with colleagues who deal with pricing under the PPRS. If as I understand it, the reason for genericisation is purely down to pricing, it might be helpful for the company to contact PPRS colleagues direct to explore the options. The contact is, [DH Official 2] and I am copying him into this e-mail'.<sup>440</sup>*

- 3.379 On the same day (11 July 2012), the MHRA emailed Flynn to request that it contact the DH:

*'As the desire to change the product name is driven by the current price for Epanutin capsules, we have had further communication with our DH colleagues. Could Flynn Pharma please contact the relevant PPRS DH colleague, who is [DH Official 2] ([DH Official 2] [@dh.gsi.gov.uk](mailto:dh.gsi.gov.uk)), to explore options'.<sup>441</sup>*

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<sup>439</sup> See document 00367.7.

<sup>440</sup> See document 00367.10.

<sup>441</sup> See document 00248.11.

**b. Meeting between Flynn and the DH on 18 July 2012**

3.380 On 18 July 2012, the DH met with [Flynn's Finance Director] and [Flynn's Director].<sup>442</sup>

3.381 The DH's note of this meeting note records that Flynn told the DH that it would not be '*economically viable*' for it to sell at the prevailing prices:

*'The company advised that if [sic] it would not be economically viable for Flynn to continue selling Epanutin capsules as a brand without an uplift in price.'*<sup>443</sup>

3.382 Flynn then identified two options available to it:

*'They [Flynn] could genericise the product or alternatively if they were awarded an increase on the current price of Epanutin capsules, they could create their own brand e.g. EpaFlynn.'*<sup>444</sup>

3.383 Flynn also set out the prices that it expected to charge depending on whether it had to sell its product as a brand or a generic:

*'Using the 100mg tablet presentation as an example, the company confirmed that if sold generically, this presentation would be priced 10%-20% lower than the Drug Tariff. If sold as a branded product, it would be priced at 25%-30% below the DT price.'*<sup>445</sup>

3.384 The DH then set out some of the factors that would be taken into account when considering pricing and explained that there would likely be difficulties in a price significantly higher than the prevailing price:

*'DH confirmed that when looking at pricing of new products, some of the factors the Pricing [sic] Committee would consider is the effect on the drugs bill and the prices of comparable products. Whilst DH acknowledged the need for this product to remain on the market, DH expressed the difficulties in agreeing to a launch price that was significantly higher than [the existing price of] Epanutin.'*<sup>446</sup>

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<sup>442</sup> See document 00367.9.

<sup>443</sup> See document 00367.9.

<sup>444</sup> See document 00367.9.

<sup>445</sup> See document 00367.9.

<sup>446</sup> See document 00367.9.

3.385 The DH advised Flynn to submit a product launch application for the DH's PPRS Pricing Committee to review under the terms of the PPRS.<sup>447</sup>

**c. Internal DH discussion concerning Flynn's proposal**

3.386 On 19 July 2012, [DH Official 2] emailed colleagues outlining his discussions with Flynn the previous day. [DH Official 2] summarised the situation and noted the MHRA's concerns:

*'The MHRA review of Flynn's communication plan for genericising the product has, however, generated concerns about the potential for confusion if the Epanutin trade name were to be replaced by a generic name (the company felt this was somewhat surprising given that the MHRA has already approved a generic version for a company called Enzon Pharamceuticals [sic, NRIM]). They have decided that it may now be necessary to take the name change variation to their expert committee for their review, comment and decision.'*<sup>448</sup>

3.387 [DH Official 2] then summarised Flynn's position on pricing, noting, in particular, Flynn's view that it would make a significant loss if it sold the product at the current prevailing prices, and the prices that Flynn was intending to launch its product at:

*'Not surprisingly the company confirmed that it is not a viable option for them to market either a generic or branded generic version of Epanutin at the current NHS list prices as they would be making a significant loss.'*

*We asked them what their intentions were on pricing if the MHRA granted a licence for a generic product. They informed us that they would initially price the 100mg presentation at between 10%-20% below the drug tariff price of the 100mg tablet presentation, which as you can see above is currently £30 for a 84 tablet pack. They stated that they had considered launching a branded generic but felt that the PPRS would not allow them to launch at a price above the price of Epanutin. Having discussed the difficulties that the Department might have in agreeing to a significantly higher price for a branded generic, we did ask them whether they would be prepared to lower the NHS list price further for the brand given that they would gain greater stability in the market. They indicated that they would consider a price for a brand at 30% below*

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<sup>447</sup> See document 00367.9.

<sup>448</sup> See document 00367.11.

*the drug tariff price for the tablets. All other presentations would be pro rata in price. Having contacted the MHRA, they have confirmed that they would prefer to see a new brand name rather than them genericise the product.*<sup>449</sup>

- 3.388 [DH Official 2] closed his email by setting out the next steps (discussing Flynn's proposed pricing with the Pricing Committee) and noting that a significant price increase was likely whatever the outcome:

*'We agreed that we would discuss their pricing proposal for a new branded generic with the pricing committee and come back to them next week with an indication as to whether they should submit a formal pricing proposal. Unfortunately, we will have to move quickly on this issue as this involves Flynn applying for a variation to the MHRA and Pfizer will cease manufacture of Epanutin capsules in September 2012.*

*So, it looks like whatever happens there is going to be a significant increase in price whether as a brand or a generic.*<sup>450</sup>

- 3.389 On the same day (19 July 2012), [DH Official 4] emailed [DH Official 2] to highlight the importance of Continuity of Supply with regard to *Epanutin*:

*'It might also be worth adding that this product has a narrow therapeutic index. I'm sure our pharmaceutical advisors can tell us more about this, but my understanding is that for epilepsy patients, it is important that once stabilised on a product, they receive exactly the same medication: a generic equivalent is not always appropriate. So this gives more weight to keeping Epanutin on the market.'*<sup>451</sup>

- 3.390 [DH Official 5] replied to [DH Official 4] the following day (20 July 2012), agreeing with his view:

*'It is important for patients to stay on the same product. While it won't be Epanutin printed on the packet (but it will on the capsule), the purpose of the new brand name will help ensure that patients get the same product.*

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<sup>449</sup> See document 00367.11.

<sup>450</sup> See document 00367.11.

<sup>451</sup> See document 00367.12.

*Are MHRA happy for a different brand name to be on the box and the blister foil from the capsule itself? Will MHRA insist that the name on the capsule is changed too?*<sup>452</sup>

- 3.391 On 26 July 2012, [DH Official 6] emailed [Flynn's Finance Director], explaining that Flynn's proposal to increase the price within the PPRS had been rejected by the Pricing Committee:

*'Under the terms of the PPRS rules on the pricing of new products, the PC was unable to agree with your proposal to re-brand Epanutin and launch the new product at an increased price of approximately 30% below the current Drug Tariff price [of Tablets].*

*The PC also noted the provisions of chapter 7.41.3 of the scheme, which state that a company may not increase the price of an acquired medicine until three months following the date of acquisition. At the end of the three months, you may choose to apply for a price increase. If so, your company's overall profitability of your branded NHS business is assessed through an Annual Financial Return (please see below). This is further explained at chapters 7.22-7.29 of the 2009 PPRS.*<sup>453</sup>

- 3.392 [Flynn's Finance Director] replied on 31 July 2012 to confirm that Flynn would 're-submit [to the MHRA] the [name change] variation application as requested by the MHRA Assessor this morning'.<sup>454</sup>

## **IX. Launch of a genericised version of Epanutin**

- 3.393 Pfizer's MAs terminated on 23 September 2012 and Pfizer stopped all supplies of this product in the UK from this date. On 24 September 2012, Flynn launched its products under the MHRA-approved product name 'Phenytoin Sodium Flynn Hard Capsules'.<sup>455</sup>

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<sup>452</sup> See document 00367.12.

<sup>453</sup> See documents 00367.13 and 00145.339.

<sup>454</sup> See document 00145.343.

<sup>455</sup> See document 00145.386.



3.394 The Drug Tariff price introduced in October 2012 for 100mg capsules as a result of Pfizer's and Flynn's pricing decisions was [32% - 65%] higher than the price levels discussed during Pfizer's and Flynn's negotiations.<sup>456</sup>

## X. ***Further discussions between the DH and Flynn and Pfizer***

3.395 Following the launch of Flynn's products, the DH remained concerned about Flynn's higher prices and sought to engage with Flynn on the issue.

### a. ***Correspondence between the DH and Flynn on costs***

3.396 On 23 October 2012, [DH Official 2] spoke with [Flynn's Finance Director] to seek further information on Flynn's costs. On 24 October 2012, he reported back on this conversation to his colleagues:

*'Not surprisingly, he [Flynn's Finance Director] said that he could not divulge details of their arrangements with Pfizer as they were bound by strict confidentiality clauses in the contract. He did say that it was a simple 3rd party manufacturing supply contract [redacted]. He also said that he would be happy for the contract details to be released to the Department if Pfizer agreed to this. His only other comment was that he expected other generics to enter the market which would drive down the price. I read from this that it would force Pfizer to lower the selling price to Flynn.'*<sup>457</sup>

3.397 On the same day (24 October 2012), [DH Official 7] replied to [DH Official 2] to clarify what he had spoken with Flynn about:

*'Can I take it from this email that you did not in anyway [sic] 'challenge' the price and ask them to consider bringing it down? It was more an exploratory conversation as to the cost of the manufacturer by the third party?'*<sup>458</sup>

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<sup>456</sup> The presentations prepared by Pfizer and Flynn during their negotiations considered a price of [£11 - £20.99] for 28 100mg phenytoin sodium capsules (or [£41 - £50.99] for a pack of 84 capsules) (see documents 00145.27, 00141.74 and 00141.97). The Drug Tariff price for a pack of 84 100mg phenytoin sodium capsules increased to [£61 - £70.99] with effect from October 2012, which is [32% - 65%] higher than [£41 - £50.99] per pack.

<sup>457</sup> See document 00367.15.

<sup>458</sup> See document 00367.15. Flynn has stated in its submissions that this email was sent on 24 November 2012. This is incorrect.

3.398 [DH Official 7] also noted the limited scope for generic competition in respect of phenytoin sodium capsules:

*'We are not so convinced about the potential of generic competition - there is only one other MA for one strength the 100mg and as we all know patients are meant to be established on the same manufacturer's product.'*<sup>459</sup>

**b. Meeting between Flynn and the DH and follow-up correspondence**

3.399 On 6 November 2012, the DH and Flynn met to discuss *'the prices and supply of phenytoin sodium capsules'*.<sup>460</sup> The DH was *'keen to find out [how Flynn arrived at the current prices] so that it could decide whether they were justified'*.

3.400 During that meeting, Flynn defended its prices by reference to the Drug Tariff price of Tablets (see section 3.F below) and the DH responded that it had never confirmed that it was content with the price of Tablets:

*'The company defended the current price. It was 25% below the tablet presentations. It said that the tablets accounted for £48 million of NHS sales – not insignificant. In response, DH said that it had never confirmed that it was content with the price of the tablets but it would be inappropriate to comment further on this because a third party was involved in the supply of this presentation.'*<sup>461</sup>

3.401 This was corroborated by Flynn's own note of the meeting, which stated:

*'We felt that the discussion with DH PPRS on price at launch was sanctioned by default as it went unchallenged. [DH Official 7] stated that this could not be the case as PPRS had no remit on pricing of generic products and that Scheme M was not a pricing approval. We should not (in [DH Official 7]) view; assume that the DH and NHS are happy with the price of the tablets...'*<sup>462</sup>

3.402 The DH explained to Flynn that the larger sales volumes of phenytoin sodium capsules sold as compared to Tablets meant that the adverse

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<sup>459</sup> See document 00367.15.

<sup>460</sup> See documents 00367.16 and 00145.585.

<sup>461</sup> See document 00367.16.

<sup>462</sup> See document 00145.585

financial impact on the NHS of the increased prices of phenytoin sodium capsules was greater than the financial impact of the price of Tablets:

*'DH (II) [DH Official 3] had commented that the much larger market share of the capsules made the total cost very difficult for them, more visible and hitting hard NHS pockets. The DH were struggling and trying to understand the [justification].'*<sup>463</sup>

3.403 Further, the £48 million figure quoted by Flynn in this meeting is inaccurate and Flynn's basis for quoting this figure is unclear. The CMA's own calculations show that the total cost of Tablets for the NHS in England (which accounts for the vast majority of total sales in of Tablets in the UK) in 2011 was approximately £11.5 million. This was significantly less than the total cost to the NHS for phenytoin sodium capsules since 24 September 2012 which, for example, was approximately £42 million in 2013 in England.<sup>464</sup>

3.404 The DH wanted to understand how Flynn had arrived at its prices, but Flynn provided limited information in this respect:

*'Flynn said that there were many additional costs involved (e.g. it was planning to create a dual supply chain to secure future supplies of the medicine). More importantly, it had a commercially confidential agreement in place with Pfizer that prevented the sharing of cost of goods information.'*<sup>465</sup>

3.405 The DH has told the CMA that Flynn went on to say that it was not earning significant margins on the products.<sup>466</sup> This is not consistent with Flynn's financial data.<sup>467</sup>

3.406 Flynn's note of the meeting records that Flynn stated that it had considered the fact that the DH had not challenged Flynn's prices at the time of the price rises meant that the DH had sanctioned the prices. However, the DH clarified that that could not be have been the case:

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<sup>463</sup> See document 00145.569.

<sup>464</sup> The cost to the NHS is calculated using PCA data and the published Drug Tariff prices that were in effect at the time.

<sup>465</sup> See document 00367.16.

<sup>466</sup> See document 00468.1

<sup>467</sup> See section 5.C.

*'We [Flynn] felt that the discussion with DH PPRS on price at launch was sanctioned by default as it went unchallenged. [DH Official 7] stated that this could not be the case as PPRS had no remit on pricing of generic products and that Scheme M [which the main supplier of Tablets was a member of] was not a pricing approval.'*<sup>468</sup>

3.407 During the meeting, the DH also explained its views on the supply of phenytoin sodium capsules; specifically, that this was not competitive, and that comparisons with Tablets were not relevant:

*'Due to the narrow therapeutic index of the medicine in question, the Department did not consider that this was a competitive market. Further, it did not consider comparisons with the table [sic] relevant, as the products are not interchangeable. They were different formulations, which may incur different costs, and the tablets had significantly less of the market so had less economies of scale. Although a price increase might have been justified for Flynn's product, the scale of it was the concern.'*<sup>469</sup>

3.408 At the same meeting Flynn agreed to consider what information it could provide as justification for its prices:

*'Flynn recognised the Department's concerns and agreed to consider what additional information it could provide by way of justification. It would come back to the Department on this but immediate thoughts centred on the one-off cost of the Marketing Authorisation; third party manufacturing costs; the cost of the active pharmaceutical ingredients (API); dual sourcing and buffer-stock building costs; bioequivalence studies; and packaging.'*<sup>470</sup>

3.409 These statements by Flynn were inaccurate and/or misleading and demonstrate the difficulties that the DH faced in verifying the claims made by Flynn and Pfizer regarding the reasonableness of their prices. In particular:

(a) the one off cost of the MAs that Flynn paid to Pfizer was just [a nominal fee] (see section 3.E.VI.a);

(b) [redacted];

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<sup>468</sup> See document 00145.569.

<sup>469</sup> See document 00367.16.

<sup>470</sup> See document 00367.16.

- (c) Flynn had not incurred any material costs in relation to dual sourcing (and, as set out at sections 5.C.V.a.iii and 5.C.V.a.iv below, the evidence on the CMA's file indicates that Flynn has not incurred any material costs related to dual sourcing since then either). Further, as set out at section 3.C.I.c above, it is highly unlikely that such plans would have been feasible for phenytoin sodium capsules;
- (d) Flynn's submissions to the CMA do not include any details of specific costs incurred in relation to bioequivalence studies for phenytoin sodium capsules (see sections 5.C.V.a.iii and 5.C.V.a.iv); and
- (e) even with its high input (and other) costs Flynn was still making a significant margin (see section 5.C.v.d).

3.410 Flynn has since submitted to the CMA that the DH never asked it to reduce its prices.<sup>471</sup> However, Flynn had told the DH that the issue was the supply price from Pfizer which it was tied in to.<sup>472</sup> Further, Flynn agreed to contact Pfizer to discuss whether Pfizer might lower its supply prices to Flynn so that Flynn could in turn lower its prices to the NHS. As Flynn's note of its meeting with the DH states:

*'ACTIONS for Flynn:*

*1. Approach Pfizer to discuss [sic] reactions to and pressures on product pricing and to release cost information'.<sup>473</sup>*

3.411 Subsequently, on 16 November 2012, Flynn wrote to the DH on the points discussed in the meeting on 6 November 2012. In its letter, Flynn acknowledged that there had been a '*significant price increase*' but believed that this was the result of '*an exceptional if not unique set of circumstances*'.<sup>474</sup> Flynn first outlined Pfizer's rationale for divesting *Epanutin*:

*'We cannot speak for or represent the thinking of Pfizer, but it seemed clear to us that a key driver in Pfizer UK's decision to divest the product was that they were finding the product economically and logistically*

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<sup>471</sup> See for example document 02077.1, paragraph 3.13. Flynn bases this submission, in part, on an incorrect chronology of events.

<sup>472</sup> See document 00468.1.

<sup>473</sup> See document 00145.569. See also document 00367.16, paragraph 9.

<sup>474</sup> See document 00367.18.

*challenging and were it not for their recognition of its continued place in the drug management of epilepsy and importance to patients, would likely have been discontinued.'*<sup>475</sup>

3.412 Flynn told the DH that genericising *Epanutin* was '*the only basis on which commercially viable prices could be achieved*' and that Flynn had been '*totally transparent with the Department of Health throughout this process*', including having '*engaged in early discussions with the Department to explore the possibility that the original brand be maintained by Flynn*'.

3.413 Flynn also stated that it:

*'was also of the view that the capsule market would become open to generic competition both based on the 2011 NRIM approval and potential future entrants and that these factors will inevitably impact on volume and market pricing'*.<sup>476</sup>

3.414 Flynn also repeated its claim made at the meeting that '*[c]onsiderable effort is being invested by Flynn in strategies to increase the resilience of the supply chain*'. Flynn said that these included:

*'Identification of alternate/additional suppliers of the active ingredient  
Identification of alternate/additional manufacturers and packaging facilities for the finished product.*

*Putting in place safety stock policies throughout the supply chain to eliminate or significantly reduce the consequences of temporary interruptions.*

*Flynn establishing dedicated resource to manage the UK distribution and wholesaler network and provide medical information and patient support services to healthcare professionals and patients.'*<sup>477</sup>

3.415 At no point however did Flynn provide the DH with the cost data that the DH had requested or otherwise attempt to substantiate the above claims. Flynn informed the DH that Pfizer had also declined to provide permission for Flynn to disclose its costs of goods data to the DH:

*'You asked us to request Pfizer's permission to disclose our cost of goods data. Their response to our request was, "As a global supplier of*

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<sup>475</sup> See document 00367.18.

<sup>476</sup> See document 00367.18.

<sup>477</sup> See document 00367.18.

*phenytoin, information relating to the cost structure for production and delivery of Phenytoin Sodium Flynn Hard Capsules is commercially sensitive and confidential”*.<sup>478</sup>

3.416 Consequently, the DH was unable to verify Flynn’s claims regarding the reasonableness of its prices.

**c. Meeting between the DH and Pfizer and follow-up correspondence**

3.417 The DH also met Pfizer on 10 January 2013. Under the item '*any other business*', the DH '*sought comments from the company [Pfizer] in respect of the increased expenditure to the NHS*' on *Epanutin*.<sup>479</sup> In particular, DH was seeking information on Pfizer’s costs.<sup>480</sup>

3.418 Pfizer explained that *Epanutin* had been '*sold to Flynn Pharma as it was no longer economically viable to keep it on*' and agreed to look into the DH’s concerns and revert in due course. In response to the DH’s query as to whether *Epanutin* was still manufactured by Pfizer '*they confirmed that it was manufactured in Ireland*<sup>481</sup> and therefore [they] could offer no more information at the moment but would investigate the issues raised'.<sup>482</sup>

3.419 [Pfizer’s Financial Controller] emailed [DH Official 4] on 26 February 2013 to explain Pfizer’s decision to divest *Epanutin* to Flynn:

*'Pfizer's decision to divest Epanutin followed a review of our portfolio and was in part based on the fact that for several years Pfizer had not realised a sustainable margin on Epanutin [...] Given the narrow therapeutic index of this medicine, Pfizer continues to manufacture the capsules to ensure the product is unchanged for UK patients and supplies phenytoin capsules to Flynn Pharma.*<sup>483</sup>

3.420 Like Flynn, Pfizer failed to provide the DH with any details of its costs or prices. Pfizer also declined to comment on Flynn’s pricing:

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<sup>478</sup> See document 00367.18.

<sup>479</sup> See document 00367.19.

<sup>480</sup> See document 00468.1.

<sup>481</sup> This was incorrect. Pfizer manufactures phenytoin sodium capsules in its Freiburg plant.

<sup>482</sup> See document 00367.19.

<sup>483</sup> See document 00367.22.

*'Since Pfizer no longer holds the UK marketing authorisation it would not be appropriate for us to comment on Flynn Pharma's marketed product nor its [sic] pricing strategy.'*<sup>484</sup>

## **XI. Industry and PCT/CCG's reactions to Flynn's Prices**

3.421 The increase in the price of phenytoin sodium capsules proved to be controversial and unpopular. A Daily Telegraph article of 12 October 2012 brought attention to the significance and consequences of the price increase. It reported that the annual bill for phenytoin had increased from just over £2million a year to '£46.6m' and stated that the *'extra money that will be spent on the drug could have paid for about 1,800 more nurses'*.<sup>485</sup>

### **a. PCT/CCG's reactions to Flynn's Prices – cost effects**

3.422 Contemporaneous documentary evidence on the CMA's file demonstrates the unpopularity of the price increases, which attracted strong criticism from the PCTs and CCGs' who had to cover the extra costs incurred.

3.423 The main issues raised by the PCTs/CCGs were that the price increases: were unjustified; would significantly impact on budgets and therefore the scope of services that the PCT/CCG would be able to deliver; and would deliver no benefits to patients.

3.424 A letter, dated 10 October 2012, from the Greater Manchester Medicines Management Group ('GMMM')<sup>486</sup> to the Secretary of State and other key figures in the healthcare system<sup>487</sup> complained that the manufacturers of phenytoin sodium capsules had engaged in what *'appears to be [a] clear case of abuse of a virtual monopoly position for purely commercial gains'*.<sup>488</sup>

3.425 The GMMM highlighted that CCGs were left with no alternative but to pay Flynn's prices as *'the product cannot be switched to an alternative'* and indicated that paying Flynn's prices would impact *'patient care'*.

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<sup>484</sup> See document 00367.22.

<sup>485</sup> See <http://www.telegraph.co.uk/news/health/news/9604683/Pharma-firm-hikes-cost-of-epilepsy-drug-24-times.html>.

<sup>486</sup> The GMMM is a representative body of the 12 CCGs and 13 provider trusts in the Greater Manchester conurbation, covering a population of 2.8 million.

<sup>487</sup> The other addressees of the letter were the Chief Pharmaceutical Officer, [redacted] (National QIPP Lead Medicines Use and Procurement) [redacted] (Chief Financial Officer, National Commissioning Board).

<sup>488</sup> See document 00145.527.



*'We would contend that the needs of the NHS and patients are not best served by this cynical increase in costs, as the product cannot be switched to an alternative, equivalent formulation for the majority of indications.*

*This is an abuse of a monopoly supply position and the DH should mandate that the price being paid for the Pfizer Epanutin ® brand should remain the price of Phenytoin Sodium capsules in the UK Drug tariff. The only credible alternative is that the companies must make a case for a **modest** price increase, but this must stand up to economical and clinical justification.*

*The NHS must make a stand that this is unethical, anti-competitive behaviour at the expense of patient care will not be tolerated.'* [Emphasis as original.]

- 3.426 The GMMMG voiced very strong concerns regarding the financial impact of Pfizer's and Flynn's *'unethical, anticompetitive behaviour'* which did not *'deliver VFM [value for money] for the NHS'*:

*'In Greater Manchester we are spending **£24,450/quarter** on Epanutin® at current prices, which will potentially increase to **£583K/quarter**. **This equates to an estimated £1,676K/year of extra costs for Greater Manchester.***

***The NHS will be adversely affected by £36Million per year, based on the same methodology. This increase in cost will provide no additional health benefit for patients.***<sup>489</sup> [Emphasis as in original.]

and:

*'This scheme places 'unforeseen', unjustifiable and unacceptable 'burdens' on the NHS, leading to a potentially unstable and unpredictable market in epilepsy treatment.'*

- 3.427 A complaint by West Sussex PCT to the CMA also highlighted the likely significant financial impact of the price of phenytoin sodium capsules on the NHS budget and stated that resources would need to be switched from other medical services to fund it:

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<sup>489</sup> See document 00145.527.

*'As I have pointed out before, this will cost the NHS approximately £50m / year with absolutely no improvement in patient care, and indeed will need disinvestment in other medical services to fund.'*<sup>490</sup>

- 3.428 The impact of Flynn's prices on national and local health services was also raised by a representative of the South Devon and Torbay CCG in an email to [Flynn's Director] on 7 October 2012 to request an explanation of the '*unacceptable*' price increase of phenytoin sodium capsules. The representative observed that it was:

*'A staggering increase, not just sizeable, of 2000% plus!*

*A [sic] increase of £102k to Torbay alone. Some £50m nationally. Very difficult to understand.'*<sup>491</sup>

- 3.429 Nene CCG, in a letter to the Chief Pharmaceutical Officer dated 25 October 2012, also drew attention to the expectation that the increased cost of phenytoin sodium capsules would '*compromise*' the scope of the services that the CCG would be '*able to afford to commission*':

*'We estimate that the financial impact for the NHS nationally is likely to be in the order of £43 million per year. This increase in cost will provide no additional health benefit for patients, but will undoubtedly compromise other services that we will not be able to afford to commission as a result.'*<sup>492</sup>

- 3.430 In an internal Flynn email, dated 28 November 2012, [Flynn's Key Account Manager] reported to [Flynn's Director] on a '*rather uncomfortable conversation*' he had had with Norfolk and Waveney PCT, in which the PCT stated that the increase in the purchase price of phenytoin sodium capsules would cost it £750,000 per annum.<sup>493</sup>

- 3.431 In a letter to the CMA, dated 23 July 2013 (which provided a copy of a letter from the Chief Pharmaceutical Officer), a representative of the Somerset CCG used precisely the same language as was used by Nene CCG in its letter, including a statement that meeting the increased cost of phenytoin sodium capsules would '*undoubtedly compromise other services*':

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<sup>490</sup> See document 00014.

<sup>491</sup> See document 00145.455.

<sup>492</sup> See document 00210.2.

<sup>493</sup> See document 00145.614.

*'We estimate that the financial impact for the NHS nationally is likely to be in the order of £43 million per year. This increase in cost will provide no additional health benefit for patients, but will undoubtedly compromise other services that we will not be able to afford to commission as a result.'*<sup>494</sup>

**b. CCG's reactions to Flynn's Prices – wider effects**

3.432 The implications of Flynn's prices were also described in terms of 'Non drug costs and risks to the NHS' by the GMMMG:

*'There are considerable logistical difficulties for GP practices and pharmacies as Epanutin® ceases to be available and as the Flynn product enters the supply chain; this may ultimately cause inconvenience and concern for patients.'*<sup>495</sup>

3.433 The GMMMG said it would also not help meet the savings targets set for the NHS under the QIPP challenge:

*'If we consider the **QIPP** challenge the change does not benefit: **Quality** (although the switch is a risk), is not **Innovative**, does not **Prevent** additional epileptic seizures, or Trigeminal neuralgia cases, nor does it demonstrate **Productivity**, in fact it is 24 time less productive than current practice.'*<sup>496</sup> [Emphasis in original]

3.434 The adverse impact on QIPP of Flynn's prices was also highlighted by a representative of the Ipswich and East Suffolk CCG in a letter to an MP, dated 25 October 2012. The representative not only referred to the 'significant adverse impact' that the increase in the cost of phenytoin sodium capsules would have on the prescribing budget but also the wider financial challenges it presented to the CCG in meeting its QIPP target:

*'For our CCG alone we have estimated this will cost an additional £350k per annum which will have a significant adverse impact on our prescribing budget. Our practices have been working extremely hard to ensure that the CCG remains on track to meet our QIPP target and this huge price rise is a blow to all prescribers trying to meet the*

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<sup>494</sup> See document 00279.

<sup>495</sup> See document 00145.527.

<sup>496</sup> See document 00145.527.

*government's challenging targets and ensure the best possible use of NHS resources.*<sup>497</sup>

3.435 The GMMMG observed that both Pfizer and Flynn were members of the 2009 PPRS scheme, and stated that the GMMMG believed that the pricing activity in respect of phenytoin sodium capsules *'breaches the spirit of this agreement on every objective'*.<sup>498</sup>

3.436 In respect of the PPRS objective of delivering value for money the GMMMG observed that:

*'This scheme does not deliver VFM for the NHS as it is not a 'reasonable' increase and does not demonstrate 'competitive' market behaviours but abuse of a dominant or monopoly position.'*

3.437 In respect of the PPRS objective of encouraging innovation, the GMMMG observed that:

*'This scheme does not benefit Research and development investment it hinders the usual price reductions expected in a competitive generic market'*.

3.438 In respect of the PPRS objective of providing stability, sustainability and predictability the GMMMG observed that:

*'This scheme places unforeseen, unjustifiable and unacceptable 'burdens' on the NHS, leading to a potentially unstable and unpredictable market in epilepsy treatment.'*

3.439 In respect of the PPRS objective of promoting access and uptake for new medicines the GMMMG observed that:

*'This MA transfer may make innovative new medicines less affordable for the NHS, due to £41 Million being avoidably wasted into continued supply of an existing freely available product'*.

**c. Parliamentary questions raised in response to Flynn's Prices**

3.440 Flynn's price increases were also the subject of a number of Parliamentary Questions. For example, Andrew Stunnell MP asked about the '[a]dditional

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<sup>497</sup> See document 00254.1.

<sup>498</sup> See document 00145.527.

*cost to the NHS of the repricing of the Epanutin form of phenytoin consequent being transferred from Pfizer to Flynn Pharma...'. Norman Lamb MP, responding on behalf of the Secretary of State, confirmed that:*

*'The Department has estimated the additional cost to the national health service, from the repricing of the Epanutin form of phenytoin, to be around £44 million per annum'.<sup>499</sup>*

3.441 Mr Stunnell also asked for details of any representations that Parliament had received regarding Flynn's price increases (the same question was also asked by Andrew Bingham MP). Mr Lamb again responded on behalf of Secretary of State:

*'We have received a number of representations from hon. Members, and colleagues in the NHS about the recent increase in the price of phenytoin capsules, following the acquisition of the marketing authorisation by Flynn Pharma Ltd from Pfizer and the effects on NHS budgets'.<sup>500</sup>*

## **XII. The DH's approach to the CMA**

3.442 In late 2012 and early 2013 the DH contacted the CMA regarding the concerns that it had about the price of certain drugs including phenytoin sodium capsules. The DH made clear to the CMA that there was nothing further that it could do to address the situation and that, while Flynn claimed that the prices were justified, the DH was unable to assess the validity of Flynn's claims.<sup>501</sup>

3.443 The CMA subsequently opened the Investigation in May 2013.

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<sup>499</sup> PD 48, page 16 (Hansard Written Answers – Andrew Stunnell – 8 November 2012 Column 680W)  
<http://www.publications.parliament.uk/pa/cm201213/cmhansrd/cm121108/text/121108w0001.htm>

<sup>500</sup> See document PD48.

<sup>501</sup> See documents 00001, 00012, 00015, 00026.

## F. Phenytoin sodium tablets

### Summary

The key evidence in the following section shows that:

- The Parties have submitted to the CMA that the drug tariff price for Tablets provides a benchmark for what is a reasonable price for phenytoin sodium capsules.
- In the period 2005 to 2007 the drug tariff price of Tablets increased from £1.70 to £113.62.
- In 2008, the DH asked Teva, the main supplier of Tablets, to reduce its prices and Teva agreed to do so. Teva reduced its list price to £29.50. This price was not set by, or agreed with, the DH and was still approximately 15 times the pre-2005 price.
- Following these fluctuations, the Drug Tariff price for Tablets was set at £30.
- The DH does not believe that there was anything it could, in practice, itself have done to compel Teva to reduce its prices further.
- The DH referred the pricing conduct of the suppliers of Tablets to the CMA.
- The overall cost to the NHS of Tablets is significantly less than the overall cost of phenytoin sodium capsules.
- The clinical guidance recommending that Continuity of Supply be maintained for certain AEDs applies to Tablets and this has been followed by the majority of pharmacies.

### I. *Introduction*

3.444 As set out at section 3.B.II.f above Tablets are a second formulation of phenytoin sodium sold in the UK.

3.445 Pfizer and Flynn have each submitted to the CMA that the Drug Tariff price of Tablets is relevant to assessing the fairness of their prices.<sup>502</sup> The CMA's assessment in this regard is set out in section 5.D.IV.b.ii.

3.446 This section sets out further relevant factual background regarding the supply of Tablets in the UK.

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<sup>502</sup> See in particular documents 01622.2, 01622.3, 02076.1, 01639.3, 02077.1.

## II. ***The DH's complaint to the CMA regarding Tablets***

- 3.447 At the same time that the DH made its complaint to the CMA about the price of phenytoin sodium capsules, the DH also raised concerns about the price of Tablets.<sup>503</sup>
- 3.448 Having considered the matter, the CMA decided not to open an investigation into the price of Tablets, on the basis that doing so did not meet its administrative priorities. In reaching this decision the CMA took into account, among other things, the overall size of the market for Tablets compared to the overall size of the market for phenytoin sodium capsules.

## III. ***Background on Tablets***

- 3.449 Like phenytoin sodium capsules, Tablets are primarily used to treat epilepsy and have a NTI which means that it is important to maintain Continuity of Supply for patients. As a result, Tablets have been (and are) subject to the same guidance on switching as phenytoin sodium capsules including CG137 and the MHRA Guidance. As with phenytoin sodium capsules, Tablets are classed as Category 1 AEDs under the MHRA Guidance and consequently *'doctors are advised to ensure that their patient is maintained on a specific manufacturer's product'*.<sup>504</sup>
- 3.450 Following the publication of the MHRA Guidance,<sup>505</sup> the MHRA took further action to ensure that the manufacturers of Tablets were *'in-line with advice from the MHRA on anti-epileptic drugs that was published on 14 November 2013'*.<sup>506</sup> The advice to prescribers was that patients should be maintained on a specific manufacturer's product and that this should be prescribed either by a brand name or by using the generic drug name and name of the manufacturer (otherwise known as the MA Holder). In order to allow prescribers, pharmacists and patients to differentiate between generic

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<sup>503</sup> See documents 00012, 00015, 00016.

<sup>504</sup> See document PD 19.

<sup>505</sup> See document PD 19.

<sup>506</sup> See document 01780.1 [www.gov.uk/drug-safety-update/antiepileptic-drugs-new-advice-on-switching-between-different-manufacturers-products-for-a-particular-drug](http://www.gov.uk/drug-safety-update/antiepileptic-drugs-new-advice-on-switching-between-different-manufacturers-products-for-a-particular-drug). Teva was granted a change of the product name from Phenytoin sodium 100mg tablets to Phenytoin Sodium Teva tablets by the MHRA on 15 July 2014 (PL 00289/5236R-0063). See document 01780.1. Milpharm was granted a change of the product name from Phenytoin sodium 100 mg film-coated tablets to Phenytoin sodium Milpharm 100 mg film coated tablets on 17 February 2014 (PL 16363/0279-0007) See document 01780.1.

brands of phenytoin, the names of generic phenytoin products were amended to include the name of the MA Holder.<sup>507</sup>

- 3.451 The CMA understands that the main supplier of Tablets in the UK is Teva. Teva's Tablets are only available in 100mg dosage strength.<sup>508</sup> Teva does not supply phenytoin sodium capsules.
- 3.452 Teva holds one MA<sup>509</sup> in relation to 100mg Tablets. The authorisation was granted on 9 October 1989, although Teva had been supplying tablets for a number of decades prior to that date.<sup>510</sup> Teva has not held, and does not hold, any patent in relation to Tablets.<sup>511</sup>
- 3.453 Other current suppliers of Tablets<sup>512</sup> include Wockhardt<sup>513</sup> and Milpharm.<sup>514, 515</sup>
- 3.454 The PCA data for England, Scotland, Wales and N Ireland shows that approximately 312,000 packs of 100mg Tablets were dispensed in the UK in 2015,<sup>516</sup> which at £30 per pack (the prevailing Drug Tariff price in 2015) resulted in a cost to the NHS of approximately £9 million.<sup>517</sup>

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<sup>507</sup> See document number 01799.

<sup>508</sup> See document 00100.1. Between January 2003 and August 2003, Teva supplied tablets in two dosages, 50mg and 100mg. Teva stopped manufacturing 50mg dosage due to difficulties associated with the manufacturing process. At this stage, Teva's sales of 50 mg Tablets accounted for less than 1% of its Tablets sales (Teva's MA for 50mg Tablets was cancelled on 30 October 2009).

<sup>509</sup> Number PL00289/5236R. The letter 'R' at the end of the MA number denotes that Teva was granted a product licence of right in respect of the product (PLR). Such PLRs were issued in respect of all products that were already on the market before 1971 when the Medicines Act 1968 came into force.

<sup>510</sup> Teva has been unable to provide the exact date from when it began supplying Tablets in the UK, although it believes that it is likely to have started supply pre- 1968.

<sup>511</sup> See document 00100.1.

<sup>512</sup> See document 00100.1.

<sup>513</sup> Teva informed the CMA that Actavis supplied the products supplied by Wockhardt. We have not been able to confirm this information. The MHRA states that Actavis' MAs were cancelled 2000 (see document 00248.3).

<sup>514</sup> Milpharm GUO is Aurobindo. Milpharm's MA for 100mg was granted 19/06/2012 (see document 00248.3) and its MA for 50mg was granted 12/07/2013 (see document 00822.1).

<sup>515</sup> See document 00822.1.

<sup>516</sup> [www.hscic.gov.uk/article/2021/Website-](http://www.hscic.gov.uk/article/2021/Website-Search?productid=20437&q=prescription+cost+analysis&sort=Relevance&size=10&page=1&area=both#top)

[Search?productid=20437&q=prescription+cost+analysis&sort=Relevance&size=10&page=1&area=both#top](http://www.hscic.gov.uk/article/2021/Website-Search?productid=20437&q=prescription+cost+analysis&sort=Relevance&size=10&page=1&area=both#top) (England), <http://isdscotland.org/Health-Topics/Prescribing-and-Medicines/Community-Dispensing/Prescription-Cost-Analysis/>. (Scotland), <http://gov.wales/statistics-and-research/prescriptions-dispensed-community/?lang=en> (Wales) and <http://www.hsctbusiness.hscni.net/services/1806.htm> (N. Ireland)

<sup>517</sup> This calculation does not take into account the 50 mg Tablets dispensed in the UK in 2015.



a. **Pharmacy dispensing practices regarding Tablets**

3.455 The CMA contacted the major pharmacy groups to request information regarding their dispensing practices in relation to Tablets.<sup>518</sup> Most of the pharmacies contacted by the CMA confirmed that, as with phenytoin sodium capsules, they follow the principle of Continuity of Supply and in particular the MHRA guidance when dispensing Tablets.

3.456 [Pharmacy 1] told the CMA that:

*'.. all pharmacists will follow current guidance on dispensing all AED drugs. It is well known that phenytoin has a narrow therapeutic index and continuation of supply of a particular manufacturer is recommended to avoid loss of seizure control or increased side effects.*

[...]

*In principal [sic] the prescriber should make the intention clear with regards to precise manufacturer. Therefore the pharmacist would follow the current MHRA guidance in conjunction with the prescriber's intentions to ensure the product dispensed is of the same manufacturer as always supplied. This should be confirmed with the patient/carer at the point of supply.*

*If the prescriber's intentions are not clear or are at variance to previous supplies of the same product from the pharmacy [for the same patient], then the pharmacist would:*

- *speak to the patient/carer;*
- *review the patient's medication record (PMR) if one is available; and/or*
- *Contact the prescriber to discuss the matter.*

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<sup>518</sup> The CMA contacted the ten largest pharmacy groups in the UK; namely, Alliance Boots, Asda, Celesio (Lloyds), the Co-Op (the Co-Op pharmacy business was acquired by the Bestway Group in July 2014 and the pharmacies rebranded to 'Well' in February 2015), Day Lewis, Morrisons, Rowlands, Sainsbury's, Superdrug and Tesco.

*This enables the pharmacist to obtain the clarity required to ensure the prescriber's intentions are carried out, or to advise the prescriber accordingly.*<sup>519</sup>

3.457 [Pharmacy 3] told the CMA that:

*'.. when presented with a generic prescription for phenytoin sodium tablets, in accordance with the November 2013 MHRA guidance, the pharmacist would take into account any brand previously given to the patient in order to dispense the most appropriate brand. When presented with a prescription for phenytoin sodium tablets that specifies the brand, the pharmacist would dispense that particular brand.'*<sup>520</sup>

3.458 [Pharmacy 6] told the CMA that:

*'Pharmacists should ascertain which brand has previously been supplied, either from dispensing history or through discussion with the patient or prescriber. Brand continuity is important [...] and [Pharmacy 6] pharmacists have access to a range of generic versions of phenytoin sodium tablets. The preferred brand of Phenytoin 100mg tablets is the Teva Brand. However the Pharmacist can pick from an alternative list of brands if a particular brand is required for clinical continuity.'*<sup>521</sup>

3.459 [Pharmacy 10] told the CMA that:

*'[Pharmacy 10] follows standard industry practice in relation to this. We would normally check the patient medication record ("PMR") on the pharmacy computer to check which brand the patient usually receives. If there is no record of the brand or the patient is new to the pharmacy then the second step would be to ask the patient which brand they normally receive. If they do not know then at that stage the pharmacy would contact the doctor's surgery to confirm. We would then make a note on our PMR for future reference.'*<sup>522</sup>

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<sup>519</sup> See document 01898.1.

<sup>520</sup> See document 01888.1.

<sup>521</sup> See document 01883A.1.

<sup>522</sup> See document 01880.1.

3.460 [Pharmacy 8] told the CMA that:

*'We would expect the Pharmacist to check with a new patient whether they have been stabilised on a particular brand. If so, we would keep the patient on that particular brand. If the patient has not taken the product before we would use the Aurobindo [Milpharm] product.'*<sup>523</sup>

3.461 [Pharmacy 5] told the CMA that:

*'we mainly only purchase Phenytoin Tablets from Teva. As it is a category 1 antiepileptic drug, we only change livery when Teva cannot supply as per MHRA guidance.*

[...]

*The available agreed generics and any brands will be listed and the pharmacist can select the appropriate one for the patient. Our Patient Medication Records (PMR) records the product which the patient is normally supplied with. Where possible we would always aim to keep the patient on the product from the same supplier. However we would never leave a patient without medication just to maintain the supplier and will change supplier if the product is not available.'*<sup>524</sup>

3.462 [Pharmacy 7] told the CMA that:

*'If presented with a prescription for phenytoin sodium tablets, pharmacists should supply the brand requested by the prescriber if the prescription specifies it. Customers may also request a specific brand and if this happens pharmacists are expected to comply with this request.*

[...]

*Where there are any concerns or doubt as to the prescriber's intentions, the pharmacist should speak with the customer and check with the prescriber. If a specific variant was specified and was unavailable, then the pharmacist would speak to the prescriber to decide the best way forward for that patient.'*<sup>525</sup>

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<sup>523</sup> See document 01865.1.

<sup>524</sup> See document 01922.1.

<sup>525</sup> See document 01870A.1.

3.463 [Pharmacy 4] told the CMA that:

*'if the prescription specifies a particular manufacturer's product, the pharmacist will dispense the requested manufacturer's product if it is in stock. If the specified manufacturer is not in stock, the pharmacist will not automatically switch to another manufacturer's product, as regard will need to be given to bio-equivalence concerns (see below). The pharmacist therefore will contact its wholesale partners to see if it has the specified manufacturer's product brand in stock and if it can be delivered the same day. If this is not possible, the pharmacist will refer the patient to another pharmacist;*

*if a prescription is written generically, but a GP indicates that the patient would like a particular manufacturer's product, this is taken into consideration by the pharmacist, in accordance with drug guidance (including Anti-Epileptic drug guidance) issued by the MHRA. If it is not in stock, the pharmacist will follow the same procedure set out above (i.e. contact the wholesaler);*

*if a prescription is written generically, the pharmacist will ask the patient what product they have previously used as regard will need to be given to bio-equivalence concerns. If it is not in stock, the pharmacist will follow the same procedure set out above.<sup>526</sup>*

3.464 [Pharmacy 2] told the CMA that:

*'[Pharmacy 2]'s pharmacists are expected to take into account all published guidance when fulfilling prescriptions. The advice issued by the MHRA in November 2013 (Changing or switching antiepileptics drugs- Medicines and Healthcare Products Regulatory Agency (MHRA) Notification) was highlighted to the company's pharmacists via a weekly communication issued on 18th November 2013.'*

3.465 It also told the CMA that:

*'The cheapest variant is supplied by [Wholesaler 2]. Unless the prescription is brand specific or the pharmacist considers it clinically necessary (see below), this is what will be dispensed*

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<sup>526</sup> See document 01889.1.

[...]

[Pharmacy 2] *pharmacists are recommended (via the PMR) to dispense the cheapest variant unless the prescription is brand specific. The use of a generic variant can also be influenced by patient's choice / strength / clinical preference due to bioavailability of the drug.*<sup>527</sup>

3.466 [Pharmacy 9] informed the CMA that:

*'Our understanding of the guidance is that patients should receive a consistent product in terms of manufacturer and form. Therefore [...] we have decided centrally on one supplier (i.e. Teva). This means that the pharmacist does not have a decision to make.'*<sup>528</sup>

3.467 From follow up questions, it appears that this approach is predicated on the assumption that [Pharmacy 9] has an established and stable customer base so continuity of supply is maintained in this way. [Pharmacy 9] has confirmed that if a prescription were to specify a Tablet produced by a different manufacturer then this would be ordered and dispensed.<sup>529</sup>

3.468 As set out in section 3.B.II.d above, the MHRA Guidance essentially repeated and reinforced the recommendation to ensure Continuity of Supply. In practice however, the evidence on the CMA's file shows that, as for phenytoin sodium capsules, the MHRA Guidance further strengthened perceptions amongst pharmacies that different Tablets products are not substitutable. In particular, [Pharmacy 3] and [Pharmacy 6] have told the CMA that they had adopted stricter guidelines on Continuity of Supply following the introduction of the MHRA Guidance in 2013.<sup>530</sup> The response received from [Pharmacy 7] also indicates that [Pharmacy 7]'s dispensing practice has changed, although it is not clear from the response whether this change was introduced as a result of the MHRA guidance or for other reasons. Nor is it clear whether [Pharmacy 7] adhered to the principle of Continuity of Supply prior to the change. However the evidence on the CMA's file indicates that [Pharmacy 7] appeared to follow Continuity of Supply for phenytoin sodium capsules prior to the MHRA guidance,<sup>531</sup> so it is probable that they would also have done so for Tablets (since both are

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<sup>527</sup> See document 01881.1.

<sup>528</sup> See document 01872.1.

<sup>529</sup> See document 01893.

<sup>530</sup> See documents 01888.1 and 01883A.1

<sup>531</sup> See document 00666.1

covered by the same guidance). The other seven pharmacies from which the CMA has received evidence have confirmed to the CMA that they maintained the same dispensing practices since at least 2008.<sup>532</sup>

#### IV. ***The Drug Tariff price for Tablets***

- 3.469 Just as for phenytoin sodium capsules, the reimbursement that pharmacies can claim when fulfilling prescriptions is based on the Drug Tariff (subject to any clawback).
- 3.470 In April 2005, the Drug Tariff introduced a new Category M of generic medicines under Part VIII, along with the introduction of the new community pharmacy contracts. Tablets are included within Category M of the Drug Tariff.<sup>533</sup> Category M is used to adjust the Drug Tariff prices of certain generic medicines.<sup>534</sup>
- 3.471 The Drug Tariff price of a drug within Category M is set using a weighted average from retrospective sales and volume data supplied to the DH by the generic drug manufacturers and suppliers who are members of Scheme M (see paragraphs 3.C.III.b. above). These prices are then adjusted by a formula to ensure that pharmacy contractors retain the profit margin agreed as part of the funding of the community pharmacy contractual framework.<sup>535</sup> As set out at paragraph 3.C.III.c.ii. above, pharmacy reimbursement for products under Category M is the key tool used by the DH to meet its funding commitments to community pharmacies.
- 3.472 The prices for Category M are typically updated on a quarterly basis.

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<sup>532</sup> See documents 01898.1, 01880.1, 01865.1, 01922.1, 01889.1, 01881.1 and 01872.1.

<sup>533</sup> In April 2005, the Drug Tariff introduced a new Category M of generic medicines under Part VIII, along with the introduction of the new community pharmacy contracts. '[Category M] is the principal price adjustment mechanism to ensure delivery of the retained margin guaranteed as part of the contractual framework.' ([www.psn.org.uk/funding-and-statistics/structure-of-pharmacy/funding-distribution/retainedmargin-category-m](http://www.psn.org.uk/funding-and-statistics/structure-of-pharmacy/funding-distribution/retainedmargin-category-m)); 'As part of the contract funding arrangements, it was agreed that £500m would remain in retained purchase margin through generics and other purchases', general funding FAQ ([www.archivepsnc.org.uk/pages/funding-faqs.html](http://www.archivepsnc.org.uk/pages/funding-faqs.html)). This has now been increased to £800m.

<sup>534</sup> 'As Category M prices are set to include an element of purchase profit, a fundamental part of the funding arrangements, reimbursement prices may be higher than the manufacturer's list prices' (<http://psnc.org.uk/funding-and-statistics/structure-of-pharmacy-funding/drug-tariff-reimbursement/>).

<sup>535</sup> Each year in conjunction with the PSNC, the DH conducts a 'margins survey' to investigate how much medicine margin (that is, the difference between what they have bought the product for and how much they have been reimbursed) the average pharmacy contractor has retained in the previous year; see document PD 22.

a. ***Teva's Tablet pricing policy lead to significant increases in the price of Tablets***

3.473 Before the introduction of Category M in 2005, the Drug Tariff price for 100mg Tablets rose from £0.20 in 1991 to £1.70 in March 2005.

3.474 Following the introduction of Category M however, the Drug Tariff price for Tablets<sup>536</sup> rose dramatically (see Table 3.11 below) from £1.70 in March 2005 to £113.62 in October 2007 (an increase of over 6,500%) and Teva's retail price increased from '*...from £3.87 in October 2005 to approximately £59.82*'.<sup>537</sup>

3.475 Teva's pricing policy for Tablets was '*to set its prices by reference to the reimbursement price*'.<sup>538</sup> Teva explained to the CMA that an increase to the Drug Tariff price for Tablets therefore led to Teva increasing its retail price for Tablets which, because of Category M's use of a weighted average to determine the Drug Tariff, in turn led to an upward spiral in both prices:

*'The first Category M reimbursement price calculated in October 2005 lead [sic] to an increase in the reimbursement price to £8.56. As Teva's policy was to base its retail price on the prevailing reimbursement price, this resulted in an increase of Teva's retail price.*

*This increase in Teva's retail price would have been factored into the subsequent Category M calculation.*

*For this reason, from the introduction of Category M until October 2007, there was a steady increase in the level of the reimbursement price... and similarly, a steady increase in Teva's retail price.*<sup>539</sup>

3.476 The increases in the Drug Tariff price for Tablets from 2005 to 2007 are set out below.

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<sup>536</sup> per pack of 28 x 100mg.

<sup>537</sup> See document 00100.1, page 3.

<sup>538</sup> See document 00100.1.

<sup>539</sup> See document 00100.1.

**Table 3.11: Drug Tariff price of tablets from 1 March 2005 to 1 October 2007**

Date	Category	Drug Tariff price
1 March 2005	A	£1.70
1 April 2005	M	£3.87
1 July 2005	M	£3.23
1 October 2005	M	£8.56
1 January 2006	M	£9.82
1 April 2006	M	£24.73
1 July 2006	M	£13.85
1 October 2006	M	£52.25
1 January 2007	M	£48.58
1 April 2007	M	£62.29
1 July 2007	M	£53.51
1 October 2007	M	£113.62

3.477 The increase in Teva's retail price from '*...from £3.87 in October 2005 to approximately £59.82*' represents an increase of over 1,400%. The fact that Teva was able to impose such a price increase indicates that Teva is likely to have had substantial market power.<sup>540</sup> The CMA believes that this is likely to have resulted from a combination of Teva's share of supply<sup>541</sup> and the importance of maintaining Continuity of Supply for Tablets which would have limited the ability of pharmacies to switch to cheaper alternatives if these exist.

<sup>540</sup> The CMA has not however, concluded on whether Teva was, or is, dominant in any relevant market.

<sup>541</sup> The CMA does not have share of supply data for Teva but method used to set the Drug Tariff price of a drug within Category M (using a weighted average from retrospective sales and volume data) suggests that Teva must have had a large share of the total supply to be able to influence the price in the way that it did. This is supported by the fact that the DH approached Teva when it had concerns about the pricing of Tablets (see below for further details).



**b. The DH's discussions with Teva**

3.478 In December 2007, the DH and Teva discussed the DH's concerns about the steady rise in the price of Tablets since the introduction of Category M. This discussion led to Teva reducing its prices:

*'In December 2007, the Department of Health sought to deviate from the complex Category M formula with respect to phenytoin sodium tablets and agreed with Teva on a gradual price reduction for the product'.<sup>542</sup>*

3.479 The DH told the CMA that it did not actually set Teva's revised price or negotiate this with Teva. Rather the DH asked Teva whether:

*'... there was something it [Teva] was able to do about the price of tablets.'<sup>543</sup>*

3.480 The DH has subsequently emphasised to the CMA that:

*'...[Scheme M] is voluntary [✂] and it would therefore need to refer to the CMA for this.'<sup>544</sup>*

3.481 The DH has told the CMA that it is unusual for the DH to have such conversations with regard to generics.<sup>545</sup>

3.482 Although documentary evidence regarding these discussions is not held on the DH's file, and the relevant official from the DH has since retired, the DH informed the CMA that it did not consider that the DH's discussions with Teva regarding the pricing of Tablets would have been based on:

*'...an assessment of Teva's costs or by reference to the 'value' of the product [to the DH].'<sup>546</sup>*

3.483 Indeed, the DH has submitted to the CMA that it has *'...never investigated whether the price of a generic medicine was fair or reasonable'* and, furthermore, the DH has not:

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<sup>542</sup> See document 00100.1.

<sup>543</sup> See documents 00468.1 and 02032.1.

<sup>544</sup> See document 02032.1.

<sup>545</sup> See document 02032.1.

<sup>546</sup> See document 02032.1.

*‘...attached a ‘value’ to phenytoin sodium whether in tablet or capsule form’<sup>547</sup>*

**c. Teva’s price reduction in 2008**

3.484 Following its discussion with the DH, Teva gradually reduced the price of its Tablets from £59.82 per pack in 2007 and ultimately set its list price at £29.50 per pack in October 2008.<sup>548</sup> From October 2007 to October 2008 the Drug Tariff price of Tablets also declined from 113.62 to £30.00. As noted above, Teva told the CMA that along with Teva’s price reduction the DH *‘sought to deviate from the complex Category M formula’* used to set the Drug Tariff price for Tablets.<sup>549</sup>

**Table 3.12: Drug Tariff price of tablets from 1 October 2007 to 1 October 2008**

Date	Category	Drug Tariff price
1 October 2007	M	£113.62
1 January 2008	M	£40.00
1 April 2008	M	£35.00
1 October 2008	M	£30.00

3.485 While the reduction in the Drug Tariff price of Tablets in 2008 was large, the resulting price (£30.00) was still around 17 times what it was when Category M was introduced (£1.70). The DH views the discussions it had with Teva as being the limit of its capabilities to effect a decrease in the retail price of Tablets, as in practice:

*‘...there was nothing more (besides the discussion it held with Teva) that it [DH] could have done to achieve a further reduction to Teva’s tablet price’<sup>550</sup>.*

3.486 Consequently, notwithstanding the reduction that did occur, Teva was still able to maintain a price significantly above the prices that had prevailed

<sup>547</sup> See document 02032.1.

<sup>548</sup> See document 00100.1.

<sup>549</sup> See document 00100.1.

<sup>550</sup> See document 02032.1.

historically, suggesting that it still retained a significant degree of market power.

3.487 The DH also informed the CMA that it would have been faced with potentially diminishing returns if it had tried to seek a further price reduction from Teva, in circumstances where the DH had no way of knowing whether the price charged by Teva was reasonable.<sup>551</sup> The CMA calculates that the reduction in Teva's prices (and consequently the Drug Tariff price for Tablets) had already resulted in an approximate reduction in the overall cost of Tablets of around £42m a year (from just under £57m a year (if the price decrease had not occurred) to around £17m a year).<sup>552</sup>

3.488 The DH has submitted to the CMA that where a company had voluntarily reduced its price, as Teva had done for its Tablets in 2007, the DH had to balance the cost of devoting further resources against any additional savings it might achieve:

*'...pushing for a further reduction against the time and resource costs to the DH of doing so...it may be that a larger reduction would be justified, but it may also be after further investigation (which would represent a significant cost to the DH) only a small additional saving would be made.'*<sup>553</sup>

3.489 The DH went on to tell the CMA that:

*'The DH said that while it would have liked to have seen a further decrease to the price of phenytoin sodium tablets, it had not actively sought a further decrease [✂]. The DH said that this did not mean it was "happy" with the prevailing price of tablets'*<sup>554</sup>

3.490 This final point was emphasised to Flynn when it met the DH on 6 November 2012. Flynn's note of this meeting shows that Flynn was made aware that DH was not 'happy' with the price of Tablets:

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<sup>551</sup> See document 02032.1, paragraph 34.

<sup>552</sup> These calculations are based on a comparison of the Drug Tariff price for Tablets for October 2007 and through 2008 (see document 00100.1) and the number of Tablets dispensed in 2008 as reported in the 2008 PCA data for England, which is available at:

<http://content.digital.nhs.uk/searchcatalogue?productid=202&q=title%3a%22prescription+cost+analysis%22&sort=Relevance&size=50&page=1#top>.

<sup>553</sup> See document 02032.1, paragraph 10.

<sup>554</sup> See document 02032.1, paragraph 34.

'[DH Official 7] stated [...] that Scheme M was not a pricing approval. We should not (in [DH Official 7]'s view; assume that the DH and NHS are happy with the price of the tablets'<sup>555</sup>.

**d. Subsequent developments**

- 3.491 The Drug Tariff Price for Tablets remained at £30 per pack from October 2008 to March 2016, and Teva kept its list price as £29.50 until at least mid-2013. Teva's ASPs to wholesalers did, however, decrease to approximately [£11 - £20.99] pounds by 2013.<sup>556</sup> The difference between Teva's ASP and the Drug Tariff price represents the margin which is split between wholesalers and pharmacies. There is a significant variation in Tablets wholesaler's margins and their selling prices range from around £20 up to nearly £30 pounds.<sup>557</sup>
- 3.492 During 2016 the drug tariff price for Tablets began to gradually decrease. As of October 2016 the price is £24.50. The below table sets out these changes.

**Table 3.13: Drug Tariff price of tablets from 1 October 2008 to 1 October 2016**

Date	Category	Drug Tariff Price
1 October 2008	M	£30.00
1 April 2016	M	£28.50
1 June 2016	M	£26.75
1 July 2016	M	£25.75
1 October 2016	M	£24.50

<sup>555</sup> See document 00145.585.

<sup>556</sup> See document 00100.1, response to question 2.

<sup>557</sup> See documents 01888.3 and 01883A.3

## 4. MARKET DEFINITION AND DOMINANCE

### A. Introduction

4.1 The following sections define the relevant markets (section 4.B) and determine whether Pfizer and/or Flynn held a dominant position within their respective relevant markets during the Relevant Period (section 4.C).

4.2 Dominance is defined as the ability to behave to an appreciable extent independently of competitors, customers and ultimately of consumers<sup>558</sup> and can be thought of as the ability profitably to sustain prices above competitive levels or restrict output or quality below competitive levels.<sup>559</sup>

4.3 Market definition is a key step in identifying the competitive constraints acting on a supplier of a given product and in identifying whether an undertaking is dominant.

#### I. ***Overview: Pfizer and Flynn have profitably sustained significant price increases over a prolonged period***

4.4 The CMA considers that the fact that the Parties have both, separately, profitably sustained supra-competitive prices for a prolonged period (for over four years; since September 2012) provides cogent evidence that neither Party is subject to effective pricing constraint and that both have been able to act independently of competitors, customers and consumers to an appreciable extent. If the Parties had faced an effective competitive constraint they would not have been able to sustain very high prices for such an extended period of time.

4.5 As set out in section 3.D and below in section 4.B.IV.b.iii, Pfizer's and Flynn's phenytoin sodium capsule prices for the period since September 2012 are significantly greater than the prevailing prices prior to that date. For example, Pfizer's ASP for 100mg capsules since September 2012 is over [1,303%] greater than its pre-September 2012 ASP. After adding its own mark-up, Flynn's ASP for the same capsule strength is over [2,208%]

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<sup>558</sup> *United Brands v Commission* C-27/76, EU:C:1978:22 ('*United Brands*'), paragraph 65.

<sup>559</sup> OFT415 *Assessment of market power* (December 2005), adopted by the CMA (the '*Assessment of market power guidelines*'), paragraph 1.4 and Communication from the Commission: Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings, OJ C 45/7, 24.2.2009, ('*Enforcement Priorities Guidance*'), paragraph 11.

greater than Pfizer's pre-September 2012 ASP.<sup>560</sup> Further, the level of Flynn's list prices resulted in the Drug Tariff prices for phenytoin sodium capsules increasing by 2,285% with effect from October 2012.<sup>561</sup> Figure 4.1 below shows the evolution of the Drug Tariff price and the ASP to pharmacies and wholesalers for 100mg capsules over the period January 2012 to June 2016.<sup>562</sup>

**Figure 4.1: Average selling price of 100mg capsules to pharmacies and wholesalers, the 100mg capsule Drug Tariff price and key events**

[✂]

- 4.6 Pfizer's and Flynn's pricing decisions led to supra-competitive prices to pharmacies and wholesalers, which provides evidence that other potential substitute products were not a sufficient competitive constraint on either Pfizer or Flynn over the Relevant Period to warrant being included in the relevant markets. As a result, Pfizer and Flynn have both been able to earn supernormal profits. For example, in the period September 2012 to June 2016, Pfizer earned a gross profit of [£31 - £40.99] per pack of 100mg capsules (a gross profit of [greater than 90%]), while Flynn earned a gross profit of [£11 - £20.99] (a gross profit of [25% - 35%]).<sup>563</sup>
- 4.7 Pfizer and Flynn have profitably sustained these significantly higher prices<sup>564</sup> for a considerable period of time despite the availability of Parallel Imports and NRIM's Product. Accordingly, neither of these alternatives have sufficiently constrained either Pfizer's or Flynn's pricing conduct to the extent that they are not dominant on their respective relevant markets.

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<sup>560</sup> See Section 3.D.

<sup>561</sup> Pfizer's supply price to Flynn effectively acts as a minimum price at which Flynn can set its list price. Flynn offers phenytoin sodium capsules to wholesalers at a discount from its list price. After setting its initial list prices, Flynn notified the NHSBSA of these prices and these prices were then reflected in the published drug tariff as Flynn's Products are the reference products for phenytoin sodium capsules in the published Drug Tariff. As such, any changes in Flynn's list prices will also be notified to the NHSBSA and then subsequently reflected in the drug tariff.

<sup>562</sup> See section 3.D.IV for graphs showing the Drug tariff prices and ASPs for 25mg, 50mg and 300mg capsules.

<sup>563</sup> See section 5.C.V.b.ii for a discussion of the activities undertaken, and the risks incurred, by Flynn in earning their gross profit of [25% - 35%].

<sup>564</sup> Pfizer reduced the supply price to Flynn of 100mg capsules and 300mg capsules by 20% from January 2014. The increased ASPs to wholesalers and pharmacies were maintained until Flynn subsequently reduced its list price, which determines the NHS drug tariff price, for 100mg and 30mg capsules by 20% and 15% respectively in March 2014 and Flynn's ASPs to wholesalers and pharmacies reduced as a result. However, these reduced ASPs are still significantly higher than the pre-September 2012 prices. See section 3.D for a detailed discussion of prices.

4.8 The CMA sets out its formal assessment of the relevant markets and dominance below, which includes a detailed discussion of the points included in this overview. While the maintenance of very high prices for a prolonged period of time provides evidence in and of itself that Pfizer and Flynn each held a dominant position, the CMA has taken care to conduct an in-depth analysis of the competitive conditions for the supply and distribution of phenytoin sodium capsules. In particular, the CMA has identified and assessed the subsequent limited substitution away from the focal product in the context of these high prices and also the factors that influenced this switching. In addition, the CMA has identified that both Pfizer's and Flynn's conduct has not been sufficiently constrained by existing competition, potential competition nor the existence of countervailing buyer power to prevent them from each holding a dominant position in their respective relevant markets.

## **B. Market definition**

### **I. *Summary of the CMA's findings on market definition***

4.9 The CMA has defined the following relevant markets for the purposes of this Decision for the entire Relevant Period:

- The manufacture of Pfizer-manufactured phenytoin sodium capsules that are distributed in the UK (which includes Parallel Imports as they are distributed in the UK).
- The distribution of Pfizer-manufactured phenytoin sodium capsules in the UK (which includes Parallel Imports as they are also Pfizer-manufactured phenytoin sodium capsules).

4.10 The CMA recognises that this represents a very narrow product market. However, the CMA considers that this is appropriate based on its assessment of the specific circumstances of this case and the products involved.

4.11 The evidence demonstrates that, in the period between April 2013 and November 2013, some pharmacies substituted NRIM's Product for Flynn's Product. This enabled NRIM to achieve an estimated [20%-30%] of 100mg phenytoin sodium capsules distributed in the UK in this period. Any material switching to NRIM's Product was brought to an end in, or very shortly after,

November 2013, following the publication of the MHRA Guidance in that month.

4.12 The switching that occurred between April 2013 and November 2013 demonstrates that there was some, albeit limited, competition between Flynn's Products and NRIM's Product. Given the purpose of market definition is to provide a framework within which to assess whether an undertaking holds a dominant position, the CMA has also assessed whether Pfizer and Flynn held dominant positions in wider alternative relevant markets which include NRIM. These alternative markets only apply for the period September 2012 to November 2013 (when the MHRA Guidance was published) and are:

- The manufacture of phenytoin sodium capsules that are distributed in the UK.
- The distribution of phenytoin sodium capsules in the UK.

4.13 From December 2013, the relevant markets are the same as those set out at paragraph 4.9 above (i.e. they do not include NRIM).

## II. ***Framework for defining the relevant markets***

### a. ***Legal and economic background for defining the relevant markets***

4.14 In order to determine whether an undertaking holds a dominant position it is first necessary to define the relevant market.<sup>565</sup> The concept of the relevant market implies the existence of effective competition between the products forming part of it, which '*...presupposes that there is a sufficient degree of interchangeability between all the products forming part of the same market in so far as a specific use of such products is concerned.*'<sup>566</sup>

4.15 Market definition is a step in assessing dominance rather than an end in itself; it is a tool to identify and define the boundaries of competition between

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<sup>565</sup> Judgment in *Europemballage Corporation and Continental Can Company v Commission* C-6/72, EU:C:1973:22, paragraph 32. See also, for example, the judgments in *United Brands*, paragraph 10; *Hoffmann-La Roche v Commission* C-85/76, EU:C:1979:36 (*Hoffmann-La Roche*), paragraph 21; and *Aberdeen Journals v Director General of Fair Trading* [2002] CAT 4 (*Aberdeen Journals I*), [88].

<sup>566</sup> *Hoffmann-La Roche*, paragraph 28.



undertakings.<sup>567</sup> In general, the definition of the relevant market should not be an abstract exercise detached from the question of dominance.<sup>568</sup>

- 4.16 A market definition will typically contain two dimensions: a product and a geographic area. The concept of the relevant market implies that there can be effective competition between the products which form part of it.<sup>569</sup> As such, the key question when assessing the relevant market is whether the products concerned are '*close enough*' substitutes to be sensibly regarded as being in the same market.<sup>570</sup>
- 4.17 A further possible dimension to market definition is time.<sup>571</sup> A firm may find itself exposed to competitive constraints at one point in time but may be free from them at another.
- 4.18 The relevant product market '*is to be defined by reference to the facts in any given case, taking into account the whole economic context*'.<sup>572</sup> The economic context that may be taken into account includes, but is not limited to: (i) the objective characteristics of the products; (ii) the degree of substitutability or interchangeability between the products, having regard to their relative prices and intended use; (iii) the competitive conditions; (iv) the structure of supply and demand; and (v) the attitudes of consumers and users.<sup>573</sup>
- 4.19 These factors are not, however, fixed or exhaustive and each will depend on its own facts. As the Competition Appeal Tribunal ('CAT')<sup>574</sup> has explained:

*'Each case will depend on its own facts, and it is necessary to examine the particular circumstances in order to answer what, at the end of the day, are relatively straightforward questions: do the products concerned sufficiently compete with each other to be sensibly regarded as being in the same market? The key idea is that of a competitive constraint: do the*

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<sup>567</sup> See, for example, *Albion Water and Another v Water Services Regulation Authority and Others* [2006] CAT 36 ('*Albion Water I*'), [90]; and Commission Notice on the definition of the relevant market for the purposes of Community competition law, OJ C 372, 9.12.1997, p.5 to 13 (the '*Commission Notice on Market Definition*'), paragraph 2.

<sup>568</sup> *Aberdeen Journals I*, [101].

<sup>569</sup> *Hoffman-La Roche*, paragraph 28.

<sup>570</sup> OFT403 *Market definition*, paragraph 2.5.

<sup>571</sup> See OFT403 *Market definition*, paragraph 5.1.

<sup>572</sup> *Aberdeen Journals I*, [96].

<sup>573</sup> *Aberdeen Journals v Director General of Fair Trading* [2003] CAT 11 ('*Aberdeen Journals II*'), [96].

<sup>574</sup> References to the CAT should be read as including reference to the Competition Commission Appeal Tribunal where appropriate. See section 12 of the Enterprise Act 2002.

*other products alleged to form part of the same market act as a competitive constraint on the conduct of the allegedly dominant firm?*<sup>575</sup>

- 4.20 The process of defining a market typically begins by establishing the closest substitutes to the product that is the focus of the investigation (this is referred to as the 'focal product'). In order to establish which products are close enough substitutes to be in the relevant market, a conceptual framework known as the hypothetical monopolist test is usually employed.<sup>576</sup>
- 4.21 The hypothetical monopolist test seeks to establish whether a hypothetical monopolist of the focal product in the geographic area in which the product is sold could profitably sustain a small but significant non-transitory increase in price (a 'SSNIP') above the competitive level.<sup>577</sup> If such a price increase would be profitable then the test is complete and the focal product is the relevant market. If it would not be profitable, then the test is repeated by assuming that the hypothetical monopolist controls both the focal product and its closest substitute. That test is repeated until it is profitable for the hypothetical monopolist to sustain a SSNIP.
- 4.22 In practice a SSNIP is often interpreted as a price rise of 5 to 10% above the competitive level. However, if it is shown that a hypothetical monopolist could profitably sustain a higher price rise above the competitive level, then the test is complete and the relevant market is defined.<sup>578</sup>
- 4.23 Functional interchangeability or similarity of characteristics will not, in themselves, provide sufficient criteria to determine whether two products are demand substitutes because the responsiveness of customers to relative changes in price may be determined by other considerations as well.<sup>579</sup>
- 4.24 In this respect, the European Commission has repeatedly rejected the proposition that pharmaceutical products that are used to treat the same medical condition can necessarily be regarded as demand substitutes. For example, in *AstraZeneca*, the European Commission noted that:

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<sup>575</sup> *Aberdeen Journals I*, [97].

<sup>576</sup> OFT403 *Market definition*, paragraphs 2.5 to 2.13.

<sup>577</sup> This contrasts with the process of defining the relevant market in a merger case, where the test applied asks if the hypothetical monopolist could profitably sustain a SSNIP above the current price level rather than above the competitive level.

<sup>578</sup> OFT403 *Market definition*, paragraph 2.10.

<sup>579</sup> Commission Notice on Market Definition, paragraph 36.

*'In determining the functional substitutability of medicines it is not enough, for the purposes of product market definition, to state that different medicines are prescribed for the same general illness or disease.'*<sup>580</sup>

- 4.25 The key consideration is the extent to which different product types can be expected to significantly constrain the conduct of a given undertaking:

*'When products such as pharmaceutical products can be broadly used for the same purpose, but differ in terms of price, quality, consumer preferences or other significant attributes, the products are considered to be differentiated. Although differentiated products may 'compete' in some dimensions, a relevant market in competition cases should only include those products that are capable of significantly constraining an undertaking's behaviour and of preventing it from behaving independently of an effective competitive pressure.'*<sup>581</sup>

- 4.26 There is no '*hierarchy*' of evidence in EU or UK law on issues such as market definition<sup>582</sup> and it is a matter for the authority to determine what evidence it chooses to rely on to establish a relevant market.<sup>583</sup>
- 4.27 Where available, evidence of actual substitution arising from past events or shocks will normally be '*fundamental for market definition*', including reactions to changes in relative prices and to the launch of new products.<sup>584</sup>
- 4.28 The CAT also held in *Aberdeen Journals I* that evidence of how an undertaking sees the market is likely to be '*particularly significant*'<sup>585</sup> and depending on the particular circumstances it may be of '*decisive importance*'.<sup>586</sup>

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<sup>580</sup> Commission decision, Case COMP/A. 37.507/F3, *AstraZeneca*, 15 June 2005, paragraph 381.

<sup>581</sup> Commission Decision Case COMP/A. 37.507/F3, *AstraZeneca*, 15 June 2005. paragraph 370. See also Commission Decision Case COMP/AT39612, *Perindopril (Servier)*, 9 July 2014, footnote 3215 where the Commission confirmed that: '*As a matter of principle, if constraints from other products are gauged insufficient, those other products cannot belong to the same relevant market.*'

<sup>582</sup> *Aberdeen Journals II*, [127].

<sup>583</sup> *Aberdeen Journals II*, [128].

<sup>584</sup> Paragraph 38 of the Commission Notice on Market Definition.

<sup>585</sup> *Aberdeen Journals I*, [103].

<sup>586</sup> *Aberdeen Journals I*, [104].

### III. ***The approach taken in this Decision***

#### a. ***The Focal Product***

4.29 For the purposes of this Decision, the focal product is the same for Pfizer and Flynn and is Pfizer-manufactured phenytoin sodium capsules (the 'Focal Product').

4.30 Pfizer manufactures the Focal Product and supplies it to Flynn and indirectly to parallel importers. Pfizer's Products and Flynn's Products and Parallel Imports are identical in every material respect and, as such, there are no clinical issues with switching patients between these products. Accordingly, the CMA has treated the Focal Product in this case as including Pfizer-manufactured phenytoin sodium capsules distributed by both Flynn and by parallel importers.

#### b. ***Assessment of constraints***

4.31 The CMA has defined the markets within this Decision by reference to the specific facts of this case. It has assessed the evidence to establish whether any of the potential substitutes it has identified for the Focal Product have been able to impose a sufficient constraint on Pfizer's and Flynn's pricing conduct such that they should be included in the relevant markets.<sup>587</sup>

4.32 In its assessment of the extent of any constraints, rather than needing to undertake a hypothetical SSNIP test, the CMA has been able to observe that Pfizer's and Flynn's respective pricing conduct has not been sufficiently constrained by any potential substitute such as would justify including that potential substitute in the relevant markets.

4.33 In particular, both Parties have each maintained very substantial and profitable increases in the ASPs of the Focal Product which they

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<sup>587</sup>In its response to the SO, Pfizer submitted that [w]hen defining generic drug markets, both the CMA and the Commission have consistently used as a starting point the third level of the European Pharmaceutical Market Research Association ('EphMRA') Anatomical Classification of pharmaceuticals (ATC3), which groups medicines according to therapeutic indication i.e., intended use', document 01622.2, paragraph 245. Pfizer goes on to note that in the current case the CMA has deviated from this precedent without explaining why. Similarly, Flynn submitted in document 01639.3 (paragraphs 4.8-4.9) that the main factor in determining the scope of the relevant market is therapeutic interchangeability and the basis of this assessment is the existence of a classification system. Market definition must, however, ultimately be assessed on the specific facts of each case. As set out in the remainder of this section, the CMA has considered the facts of the case and assessed what actually happened in practice. From this assessment the CMA has concluded that the actual characteristics of the market are not consistent with a market definition of the type proposed by the Parties.

implemented in September 2012. The CMA has identified and assessed the subsequent limited substitution away from the Focal Product in the context of these very high prices and also the factors that could, and did, influence this switching.<sup>588</sup> As explained further below, it is clear that neither Party has been sufficiently constrained by any product to warrant its inclusion in the relevant markets.

- 4.34 In its assessment of this substitution, the CMA has been mindful of the complications of (and the need for caution in) using observed substitution patterns in cases, such as this one, where the undertaking in question appears to have already exercised its market power by raising its prices above competitive levels. In particular, where this is the case, one may observe consumers switching to other products, but it would be incorrect to conclude that the dominant undertaking lacks market power and to include those other products within the relevant market.<sup>589</sup> As set out below, in this case the CMA has found that there has been limited switching away from the Focal Product despite the Parties having raised their respective prices considerably above competitive levels. Further, the switching that occurred has not threatened the profitability of the Parties' significant price increases. Accordingly, the CMA has concluded that the relevant markets should be defined as being no wider than the Focal Product during the Relevant Period (or alternatively, no wider than the wider market definition set out in Section 4.B.I from 24 September 2012 to November 2013).
- 4.35 Although Pfizer and Flynn operate at different levels of the supply chain, the competitive constraints they face are generally the same. The fact that Pfizer exclusively supplies its phenytoin sodium capsules to Flynn and Flynn exclusively purchases phenytoin sodium capsules from Pfizer means that the downstream constraints faced by Flynn to a significant extent determine the upstream constraints faced by Pfizer. Therefore, the CMA assesses the evidence which is relevant for the assessment of market definition generally rather than considering each level of the supply chain separately. The implications of this evidence are similar regardless of the level of the supply chain being considered. However, where it is appropriate to distinguish between different levels of the supply chain this is clearly indicated.

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<sup>588</sup> Commission Notice on Market Definition, paragraph 38, explains that evidence of actual substitution would be fundamental to defining markets where this evidence is available.

<sup>589</sup> This is commonly known as the 'Cellophane fallacy' following the *US v El Du Pont de Nemours & Co*, [1956] 351 US 377 case. See, also, paragraph 5.5 of OFT403 *Market definition* (December 2004).

#### IV. *The relevant product market*

- 4.36 The CMA has identified the following products, beginning with the closest potential substitute, as the most likely candidate substitutes for the Focal Product:
- (a) NRIIM's Product;
  - (b) Tablets; and
  - (c) other AEDs.
- 4.37 Neither Pfizer nor Flynn have identified any other candidate substitutes for the Focal Product.
- 4.38 In the following sections, the CMA assesses the extent to which substitution from the Focal Product to any (or all) of these products would be sufficient to warrant widening the relevant product markets beyond the Focal Product.
- 4.39 The CMA has focused its analysis on pharmacist dispensing behaviour.<sup>590</sup> Although it is prescribers, such as consultants and GPs, who write prescriptions, the large majority of prescriptions for phenytoin sodium capsules are open,<sup>591</sup> and so pharmacists have, in effect, a choice as to which type of phenytoin sodium capsule (that is, the Focal Product or NRIIM's Product) they dispense to a patient.<sup>592</sup> As such, the key substitution decisions in this case are taken by pharmacists.

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<sup>590</sup> In its response to the SO, Pfizer submitted that '*it is the prescribing doctor, exercising his clinical discretion, who determines whether drugs are substitutable, while pharmacists dispense the prescriptions they are given*' (document 01622.2, paragraph 259). Pfizer's submission was based on the judgement of the Court of Appeal in *Chemistree Homecare Limited v. Abbvie Ltd* which found that the customer in pharmaceutical markets comprises the patient, the prescriber and the budget holder who is the ultimate payer. While the CMA agrees that prescribers do play a role in deciding whether there is scope for substitution between products by writing open or closed prescriptions the implications of this need to be considered in light of the specific facts of the case at issue. In the Chemistree case relied on by Pfizer, the drug at issue, Kaletra, was under patent and would normally be prescribed by brand, meaning the prescription was closed and the pharmacist had to dispense Kaletra. In contrast, in this case the products are generics and most prescriptions are written as open prescriptions so the actual decision about which product is dispensed (and therefore whether any substitution occurs) is made by the pharmacist and is driven by the pharmacists' incentives and their interpretation of the relevant NICE guidance and MHRA Guidance.

<sup>591</sup> NHSBSA data shows that over the period April 2014 to March 2015, 91% of prescriptions for phenytoin sodium capsules were open (see document 01840.1).

<sup>592</sup> Where prescriptions are closed the pharmacist would have to dispense the specific drug prescribed and therefore the decision of the clinician writing the prescription is relevant. Given that this represents a very small

4.40 The CMA has focused on substitution decisions that were taken in respect of patients who were stabilised on phenytoin sodium capsules. It is common ground between the CMA and Pfizer and Flynn that phenytoin sodium capsules are a very old pharmaceutical product and that, although there are new patients each year (either newly diagnosed with epilepsy or existing patients initiated on phenytoin for the first time), they form a low proportion of the total market size<sup>593</sup> (this is reflected in the steady decline in demand for phenytoin sodium capsules set out in section 3.B.II.e).<sup>594</sup> As such patients who were stabilised on phenytoin sodium capsules represent the vast majority of the market.<sup>595, 596</sup>

*a. Relevant context*

4.41 In assessing the relevant markets in this case, it is important to bear in mind the reality and commercial context in which switching decisions may be made.<sup>597</sup> Accordingly, the CMA considers below the nature of epilepsy, the specific characteristics of phenytoin (with a particular focus on phenytoin sodium capsules), the risks and implications of therapeutic failure, and what this means for prescribing and dispensing decisions.

4.42 Epilepsy is not uncommon, with between 260,000 and 416,000 people affected in England and Wales.<sup>598</sup> It is a serious condition and its symptoms (seizures) can have significant and life-changing implications for an

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proportion of the market, the CMA considers that an analysis of prescribing decisions would be unlikely to change the conclusions reached on the appropriate market definition.

<sup>593</sup> See section 3.B.II.e

<sup>594</sup> In their responses to the SO, both Pfizer (document 01622.2, paragraphs 250-256) and Flynn (document 01639.3, paragraphs 4.22-4.24) submitted that the CMA has ignored competition for patients newly diagnosed with epilepsy and those switched from their current treatment to a phenytoin-based AED. The Parties submitted that this group of patients is a source of potential customers for NRIM. However, as set out in section 3.B.II.e, the number of new patients is small. Consequently, the CMA considers that competition for new patients is incapable of being an effective competitive constraint on the Parties' pricing behaviour.

<sup>595</sup> There may be some form of competitive interaction between different types of phenytoin sodium capsule, phenytoin sodium tablets and indeed other AEDs, for new patients. However, given that the proportion of new patients is low, the CMA considers that an analysis of such interactions would be unlikely to change the conclusions reached on the appropriate market definition.

<sup>596</sup> In its oral hearing, Flynn stated that the CMA had not considered hospital tenders in its analysis (see document 01767.1). However, the CMA understands that the use of phenytoin sodium capsules in hospitals is limited to instances where the medication would be administered in the hospital itself, such as to new patients (which form a low proportion of the total market size) or for treatments other than epilepsy. The CMA has focused its analysis on patients who were stabilised on phenytoin sodium capsules, who represent the vast majority of the market.

<sup>597</sup> This section includes information that is also set out in sections 3.B and 3.C, which is relevant for defining the relevant markets in this case.

<sup>598</sup> CG137 (Full Guidance), page 22.

individual. Epilepsy is typically treated with AEDs, with the aim being to prevent seizures. As explained in clinical guidelines on epilepsy:

*'The mainstay of treatment for epilepsy is antiepileptic drugs (AEDs) taken daily to prevent the recurrence of epileptic seizures.'*<sup>599</sup>

- 4.43 As set out in section 3.B.I, a seizure can affect an individual's life in a number of different ways, including: suspension of driving licence;<sup>600</sup> risk of injury; loss of self-confidence; impact on work and home life; and, potential loss of employment. At its extreme, a seizure can even result in sudden unexpected (or unexplained) death in epilepsy.<sup>601</sup>
- 4.44 The impact of therapeutic failure for an epilepsy patient can, therefore, be particularly critical.<sup>602</sup>
- 4.45 There is a risk of therapeutic failure when a patient is moved onto a new treatment and there are anecdotal reports of serious consequences of switching AED for some individuals.<sup>603</sup> In these circumstances, cost is unlikely to be a compelling reason to switch a stabilised patient to a different AED.<sup>604</sup> In contrast, patient-specific factors such as intolerable side effects,

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<sup>599</sup> CG137 (Full Guidance), page 130.

<sup>600</sup> The driving licence will be suspended for between 6 and 12 months following a seizure ([www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/383428/aagv1.pdf](http://www.gov.uk/government/uploads/system/uploads/attachment_data/file/383428/aagv1.pdf)). It is also recommended that patients should be advised not to drive during withdrawal of AEDs, and for six months afterwards (see [www.gov.uk/current-medical-guidelines-dvla-guidance-for-professionals-neurological-chapter-appendix](http://www.gov.uk/current-medical-guidelines-dvla-guidance-for-professionals-neurological-chapter-appendix)).

<sup>601</sup> PD13, page 113; sudden unexpected (or unexplained) death in epilepsy is estimated to account for 500 deaths a year in the UK (CG137 (Full Guidance) page 22). PD13 also identifies that one of the ways of minimising the risk of sudden unexpected (or unexplained) death in epilepsy is by '*optimising seizure control*' (paragraph 1.3.12).

<sup>602</sup> See, for example: PD18, page 4: '*the consequences of therapeutic failure can be very severe*' and '*the very severe consequences of therapeutic failure*'.

<sup>603</sup> See document 00400.1, paragraph 30. Also CG137 (Full Guidance), page 150, states that '*[t]he GDG members were all aware of examples of people changing brands with subsequent relapse in their seizures. They also recognised that stress associated with change (not just in medication) can make people vulnerable to seizures*'. Additionally, '*[h]istorically, there has been a tendency to avoid switching phenytoin, as some time ago, a company changed the excipient causing an outbreak of overdose and many patients ended up in hospital due to toxicity*' (CG137 (Full Guidance) page 151).

<sup>604</sup> See documents 00261.1 and 00325.1.



existing therapeutic failure<sup>605</sup> or planning for a family<sup>606</sup> are likely to be reasons to switch a patient from their existing treatment.

- 4.46 In general, prescribers choose which drug to prescribe to patients based on clinical reasons and what is most suitable for the patient. As set out in section 3.B.II.e above, it is very rare for new patients to be prescribed phenytoin sodium capsules. As such, the vast majority of patients taking phenytoin sodium capsules are already stabilised on this treatment. Rather than competing for new patients or seeking to find ways to expand demand, incumbent suppliers and potential new entrants primarily compete for an existing and established patient base. Accordingly, the key consideration for market definition in this case is whether a patient can be switched from their current treatment, particularly when they are already stabilised (that is, their seizures are under control) on that treatment and may have been for a number of years.
- 4.47 Prescribers are typically encouraged to write open prescriptions,<sup>607</sup> which allow the pharmacist to dispense the most cost-effective version of that drug.<sup>608</sup> The overwhelming majority of prescriptions for phenytoin sodium capsules are left open. Accordingly, as set out above in section 4.B.IV the CMA has focussed its analysis on pharmacy dispensing behaviour. It is at the pharmacy level of the supply chain where substitution, on the basis of price, between different phenytoin sodium capsules products will (if and where possible) primarily take place.<sup>609</sup>
- 4.48 However, there is very limited scope for pharmacists to substitute between different manufacturer's phenytoin sodium capsules on the basis of cost. The characteristics of phenytoin sodium (in particular, low solubility and a NTI)<sup>610</sup> are such that very small changes in the dose delivered to the circulation can result in disproportionate changes in the level of the drug in the body,<sup>611</sup> a

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<sup>605</sup> The principle of Continuity of Supply would not apply when a patient is not stabilised on their medication and so is experiencing therapeutic failure.

<sup>606</sup> This is consistent with documents 00275.1, 00277.1, 00267 and 00325.1, which explain that the key reasons for switching a patient are either therapeutic failure (in which case any concern around maintaining stability for the patient no longer exists so continuity of supply is not a relevant factor) or pregnancy.

<sup>607</sup> See section 3.C.II.c above.

<sup>608</sup> NHSBSA data shows that over the period April 2014 to March 2015, 91% of prescriptions for phenytoin sodium capsules were open, see document 01840.1.

<sup>609</sup> As discussed further in section 4.B.IV.c.iii, the CMA recognises that if relevant, substitution from phenytoin sodium capsules to Tablets or other AEDs would be determined by prescriber decisions.

<sup>610</sup> See section 3.B.II above for more information on the characteristics of phenytoin sodium.

<sup>611</sup> See page 3 of PD18: *'Problems related to small differences in bioavailability of different manufacturers products (branded, generic) are of concern for some drugs (most notably phenytoin)'*. This appears to be

concept known as non-linear pharmacokinetics. Such changes can lead to therapeutic failure or toxicity. In essence, even a phenytoin sodium capsule product that is proven to be bioequivalent to the original product (i.e. Pfizer-manufactured phenytoin sodium capsules, previously *Epanutin*)<sup>612</sup> is not guaranteed to be therapeutically equivalent<sup>613</sup> and may perform or behave differently for different individuals. This issue is particularly applicable to NRIM's Product.<sup>614</sup>

- 4.49 These concerns and uncertainties regarding the potential for therapeutic failure or toxicity, and the critical consequences for the patient should it arise, are unusual and important factors in this case, and are one of the reasons why clinical guidelines have consistently recommended that prescribers and dispensers ensure Continuity of Supply. This issue is discussed in detail in section 3.B.II.d but, in summary, Continuity of Supply in the context of phenytoin means that a patient who is currently taking a particular manufacturer's or MA holder's phenytoin sodium capsule product should be maintained on that specific product.
- 4.50 The importance of maintaining Continuity of Supply is also reflected in the evidence of pharmacists' dispensing practices that the CMA has gathered from the major pharmacy groups.<sup>615</sup> The CMA contacted ten pharmacy groups during the course of its investigation covering approximately 50% of pharmacies in the UK and accounting for over 75% of NRIM's total sales. Eight of these pharmacy chains have taken their dispensing decisions based on maintaining Continuity of Supply throughout the Relevant Period. These pharmacy groups have not switched patients who are stabilised on Pfizer-manufactured phenytoin capsules to NRIM's Product, despite the fact that they would have made more money by doing so.

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particularly so for phenytoin: *'At the upper end of therapeutic levels a small change in dose delivered to the circulation can result in disproportionately large changes in plasma concentrations'* (PD18, page 7). See also, for example, document 00248.2.

<sup>612</sup> As explained in PD18, page 3: *'Normally, if a generic medicinal product is shown to be bioequivalent to the innovator product, as defined by the relevant regulations and guidelines, it follows that the product should be considered to be clinically equivalent'*.

<sup>613</sup> As explained in PD18, page 2: *'Concerns have been raised that demonstration of bioequivalence, even according to the more stringent regulatory standards for drugs considered to have a narrow therapeutic index, might be insufficient to exclude the possibility of clinically important non-equivalence to the innovator product for certain antiepileptic drugs'*.

<sup>614</sup> See section 4.B.IV.b.v and 4.B.IV.b.iv; in particular, the efforts that NRIM had to go to in order to persuade customers to purchase NRIM's Product.

<sup>615</sup> Section 4.B.IV.b.iv sets out further detail on pharmacy dispensing practices.

- 4.51 The two [X] pharmacy chains that did take price into account [X], stopped doing so following the introduction of the MHRA Guidance in November 2013 which reiterated the principle of Continuity of Supply.
- 4.52 Evidence from the Parties shows that they were aware of the principle of Continuity of Supply and the challenges it presented in terms of switching between different preparations of phenytoin sodium capsules. For instance, Pfizer has acknowledged that it had '*never claimed switching between phenytoin antiepileptics was easy.*'<sup>616</sup> As set out in section 4.B.IV.b.iv below, this is consistent with the Parties' contemporaneous documents which recognise the importance of Continuity of Supply given the NTI and non-linear pharmacokinetics of phenytoin sodium capsules.

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<sup>616</sup> See document 02076.1, paragraph 59.

*b. NRIM's Product*

**Summary**

The key evidence in the following sections shows that:

- Both Pfizer and Flynn were able to maintain significantly inflated and highly profitable prices throughout the Relevant Period.
- The introduction of NRIM's Product did not prompt a timely competitive response by either Pfizer or Flynn. Flynn only reduced its prices 11 months after NRIM's entry despite NRIM having been significantly the cheaper product throughout that period. When Flynn did reduce its prices, it (i) failed to fully pass on the discounts that Pfizer had granted it and (ii) switched to a RWM which offered smaller profit margins to wholesalers and pharmacies (thereby increasing Flynn's own profit).
- Prior to November 2013, NRIM had some success in attracting customers. However, the vast majority of the major pharmacy groups believed that the existing clinical guidance precluded the switching of patients from Flynn's Products to NRIM's Product.
- Following the publication in November 2013 of the MHRA Guidance, all major pharmacy groups have adhered to the principle of Continuity of Supply as recommended in the guidance.
- NRIM's sales volume data shows that sales of NRIM's Product have not grown materially since November 2013.

*i. Summary of the CMA's conclusion*

4.53 The CMA has concluded that NRIM's Product is not in the CMA's preferred relevant markets and sets out the reasons for this conclusion below. However, for the reasons set out below, the CMA has also defined wider, alternative relevant markets which include NRIM's Product for the period from 24 September 2012 to November 2013.<sup>617</sup>

*ii. Background*

4.54 NRIM was granted an MA in September 2011 for its 100mg phenytoin sodium capsule product on the basis of its bioequivalence with the Focal Product. NRIM launched its product in April 2013.

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<sup>617</sup> After November 2013 the relevant markets are the CMA's preferred relevant markets.

- 4.55 Between April 2013 and November 2013, NRIM's Product was significantly cheaper to dispense than Flynn's Product. By November 2013, NRIM was distributing an estimated [10% - 20%] of all phenytoin sodium capsules in the UK ([10% - 20%] on a Defined Daily Dosage ('DDD') basis) and an estimated [20% - 30%] of all 100mg phenytoin sodium capsules in the UK.<sup>618</sup> These sales were principally achieved through [Pharmacy 6] and [Pharmacy 3] choosing to dispense the cheapest phenytoin sodium capsule product available. [Pharmacy 3] and [Pharmacy 6] ceased this practice shortly after the publication of the MHRA Guidance in November 2013. NRIM's sales volumes did not increase significantly in the period that followed.
- 4.56 The CMA considers that the switching that occurred towards NRIM's Product was not at a scale that meant NRIM's Product exerted a sufficient competitive constraint on the Focal Product such that it would be included in the relevant markets. If NRIM had been a sufficient constraint it would have gained a much larger market share given its significantly lower prices. Moreover, NRIM did not constrain either Pfizer's or Flynn's pricing behaviour.

*iii. Pfizer's and Flynn's pricing conduct during the Relevant Period*

Introduction

- 4.57 The Overview to this section summarised the fact that the Parties have sustained extremely high and profitable ASPs for phenytoin sodium capsules from 24 September 2012 until at least the date of this Decision. This is cogent evidence that neither Party's pricing has been sufficiently constrained by NRIM's Product to warrant the latter being included in the relevant market.
- 4.58 However, given that some substitution did occur between Flynn's Products and NRIM's Product, particularly in the period April to November 2013, the CMA has considered the Parties' pricing of 100mg capsules over the period in more detail, taking into account the prices that were charged by NRIM and the gross profit that the Parties earned on their sales.
- 4.59 Figure 4.2 and Table 4.1 below show the ASPs for Flynn's 100mg capsules and NRIM's Product over the period September 2012 to June 2016. Figure 4.2 and Table 4.1 show that for most of the period April 2013 to June 2016, NRIM's Product was sold to wholesalers and pharmacies at a lower ASP

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<sup>618</sup> Estimates based on IMS data provided by Pfizer (document 02129.4) and documents 00512.2 and 00505.22.

than Flynn’s 100mg capsules. Between April 2013 and March 2014, Flynn’s ASP was on average [£] greater than NRIM’s ASP. At no stage during this time period were Flynn’s ASPs lower than NRIM’s. NRIM’s ASP was higher than Flynn’s in April and May 2014 (for only two months during the Relevant Period). Following this, between June 2014 and May 2015, the average difference between Flynn’s and NRIM’s ASPs was [£] and between June 2015 and June 2016 it was [£]. Again, at no stage during this period were Flynn’s ASPs lower than NRIM’s.

**Figure 4.2: Flynn’s and NRIM’s average selling prices for a pack of 100mg capsules**

[£]

**Table 4.1: Comparison of Flynn’s and NRIM’s average selling price for 100mg capsules between September 2012 and June 2016**

Period*	Flynn average selling price	NRIM average selling price**	Difference
September 2012 to March 2013	[£51 - £60.99]	N/A	N/A
April 2013 to March 2014	[£51 - £60.99]	[£51 - £60.99]	[£]
April 2014	[£41 - £50.99]	[£51 - £60.99]	[£]
May 2014	[£41 - £50.99]	[£41 - £50.99]	[£]
June 2014 to May 2015	[£41 - £50.99]	[£41 - £50.99]	[£]
June 2015 to June 2016	[£41 - £50.99]	[£41 - £50.99]	[£]

\*The periods selected reflect the different pricing adjustments which were made over this period. Flynn adjusted its prices in April 2014 and then again in May 2014 when it moved to a RWM (see document 0872.1, paragraph 9.1 and document 00721.3).

\*\* The NRIM price shown here is the average price at which NRIM’s Product was supplied to wholesalers and is thus directly comparable with the Flynn price.

Sources:  
 Flynn: documents 00505.22, 00872.3, 00915.1, 01044.1, 01044.2, 01148.2, 01148.3, 01293.2, 01839.13 and 02115.2  
 NRIM: documents 00721.3, 01161.1 and 01285.2 01787.1 and 02109.2  
 Drug Tariff: [www.nhsbsa.nhs.uk/PrescriptionServices/4940.aspx](http://www.nhsbsa.nhs.uk/PrescriptionServices/4940.aspx)

4.60 Tables 4.2a and 4.2b show the profit levels Pfizer and Flynn have individually earned on sales of the 100mg capsules of the Focal Product since September 2012. Pfizer’s and Flynn’s gross profits as a percentage have remained stable over the Relevant Period.

**Table 4.2a: Pfizer's profit levels for 100mg capsules**

Period	Gross Profit (£)	Gross Profit (%)
September 2012 to June 2016	[£31 - £40.99]	[Greater than 90%]
September 2012 – December 2013	[£31 - £40.99]	[Greater than 90%]
January 2014 – June 2016	[£31 - £40.99]	[Greater than 90%]
Source: Document 02129.2		

**Table 4.2b: Flynn's profit levels for 100mg capsules**

Period	Gross Profit (£)	Gross Profit (%)
September 2012 – June 2016	[£11 - £20.99]	[25% - 35%]
September 2012 – March 2014	[£11 - £20.99]	[25% - 35%]
April 2014 – June 2016	[£11 - £20.99]	[25% - 35%]
Source: Documents 00505.22, 01148.2, 01148.3, 01293.1, 01839.13 and 02115.2		

*Pfizer's and Flynn's pricing conduct from September 2012 to March 2014*

- 4.61 Table 4.1 and Tables 4.2a and 4.2b demonstrate that Pfizer and Flynn were each sustaining highly profitable prices, which led to increased prices to pharmacies and wholesalers, throughout the period from September 2012 to March 2014. The CMA finds that this is cogent evidence that neither Pfizer's nor Flynn's pricing behaviour was sufficiently constrained by NRIM's Product such that the relevant markets should be wider than the Focal Product.
- 4.62 From September 2012 to March 2014, Pfizer's ASP for 100mg phenytoin sodium capsules was [£31 - £40.99] per pack, which provided Pfizer with a gross profit of [£31 - £40.99] per pack on its sales to Flynn. Flynn's ASP for 100mg phenytoin sodium capsules was [£51 - £60.99] a pack. This ASP provided Flynn with a gross profit of [£11 - £20.99] per pack.
- 4.63 Table 4.1 also shows that, from its launch in April 2013 to March 2014, NRIM's Product was significantly cheaper to dispense than Flynn's Product, with the price at which it was sold to wholesalers and/or pharmacists being on average [£] less per pack. NRIM was offering pharmacists and

wholesalers a margin of [£11- £20.99], whereas Flynn was offering a margin of [£6 - £8.99].<sup>619</sup>

4.64 In these circumstances the CMA considers that pharmacists would have had a commercial incentive to dispense NRIM's Product, especially as:

(a) it is common ground that the overwhelming majority of prescriptions for phenytoin sodium capsules are open; and

(b) the Drug Tariff price is the same for both Flynn's 100mg Product and NRIM's Product, meaning that pharmacists are reimbursed at the same level regardless of which 100mg phenytoin sodium capsule product they dispense when presented with an open prescription.

4.65 However, NRIM's entry and the fact that its product was cheaper to dispense than Flynn's did not act as an effective competitive constraint on Flynn's pricing conduct. Had NRIM's Product been within the relevant markets, the CMA would have expected a timely competitive response by means of Flynn reducing its ASPs. Flynn's profit margin on the 100mg capsule was sufficiently large for it to have had scope to reduce its prices both unilaterally and in a timely manner without it needing recourse to Pfizer. However, no such timely response occurred. On the contrary, Flynn was able to sustain the ASPs introduced in September 2012 until April 2014 – a full year after NRIM had launched its product.

4.66 Additionally, there is no evidence to suggest that Pfizer and/or Flynn considered there was any urgent need for either or both of them to react to NRIM's entry by reducing their respective prices. In fact, the evidence suggests a lack of urgency.

4.67 In this respect, it is notable that the Exclusive Supply Agreement itself contained provisions regarding conducting '*an annual price review* [~~✂~~]' and also enabled either Party to request amendments to the Agreement (including supply prices) where there had been a change in the commercial or market environment.<sup>620</sup> These provisions would clearly have provided the basis for Flynn to request a reduction in Pfizer's supply price if this had been

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<sup>619</sup> The CMA has calculated the pharmacist and wholesaler margins by subtracting Flynn's and NRIM's ASPs from the Drug Tariff price of a pack of 100mg phenytoin sodium capsules.

<sup>620</sup> Clause 2.4 of document 00145.738 stated that '*Changes in Market Conditions. Where there is any change in the commercial or market environments relating to the Products or this Agreement either party may request that the parties meet to discuss in good faith whether any variation to this Agreement is required, giving due regard to any change in the allocation of cost and risk to each party*'.



considered necessary in the face of competition from NRIM.<sup>621</sup> However, there is no evidence on the CMA's file to suggest that either Pfizer or Flynn attempted to initiate discussions about pricing outside of the annual price review.

- 4.68 Further, although Flynn and Pfizer initially began to discuss timings for the annual price review in September 2013<sup>622</sup> no meetings took place until December 2013<sup>623</sup> and a revised Supply Agreement was not signed until February 2014.<sup>624</sup> Nor is there any evidence on the CMA's file to indicate that, when speaking to one another about carrying out the pricing review, either party raised NRIM's entry as a reason to expedite the review.
- 4.69 Accordingly, the CMA finds that the lack of any competitive response by Flynn in the form of it lowering any of its ASPs (as shown by the steady ASPs between September 2012 and November 2013 in Figure 4.1) or list prices, the apparent lack of urgency in conducting the annual price review and the fact that no negotiations were proposed or held outside of the annual price review all support the conclusion that NRIM's Product did not sufficiently constrain Pfizer's and Flynn's pricing conduct.<sup>625</sup>
- 4.70 In addition, although Flynn and Pfizer may have lost some sales to NRIM it clearly remained profitable for them to maintain their respective price levels. Internal documents submitted by Pfizer and Flynn show that they were both aware that even the loss of significant sales volumes would not render each of their price increases unprofitable.<sup>626</sup> This evidence supports a finding that NRIM's Product did not provide a sufficient competitive constraint on Pfizer and/or Flynn such that it should be included in the relevant markets.
- 4.71 The lack of a price response is even more significant in view of the fact that Pfizer and Flynn both acknowledge that the overwhelming majority of phenytoin sodium capsule prescriptions are open.<sup>627</sup> If, as Flynn and Pfizer submit, NRIM's Product was perceived as a strong substitute by pharmacies, this would mean that Flynn took a decision to leave a significant amount of

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<sup>621</sup> [REDACTED].

<sup>622</sup> See document 00505.43.

<sup>623</sup> See document 00505.44.

<sup>624</sup> See document 00505.37. Pfizer sent a revised Supply Agreement to Flynn dated 3 February 2014 and Flynn dated this agreement 12 February 2014.

<sup>625</sup> See document 00505.1, paragraph 22.7.

<sup>626</sup> See documents 00145.27, slide 11, and 00141.74, which state '*Even if 50% of sales of 100 mg were lost to PI [Parallel Imports] the upside would still be > £20m.*'

<sup>627</sup> See section 3.C.II.c above.

custom vulnerable to switching during this 11 month period. In its response to the SO, Pfizer itself acknowledged that pharmacists were likely to make substitution decisions based on commercial incentives and in doing so will 'put pressure on price'.<sup>628</sup> However, it is evident from Flynn's and Pfizer's own pricing conduct that they did not feel constrained by any such pressure.

Flynn reduces its ASPs in April 2014

- 4.72 Table 4.1 shows that Flynn reduced its prices in April 2014, resulting in its ASPs for April and May 2014 being lower than NRIM's. Pfizer and Flynn have both submitted that this price reduction was a response to pricing pressure being exerted by NRIM's Product.<sup>629,630</sup> However, as is set out below, this proposition is not supported by the surrounding context.
- 4.73 Flynn's price reduction was preceded by amendments to the pricing terms within the Exclusive Supply Agreement which were agreed in February 2014. As a result of these amendments Pfizer immediately reduced its supply price to Flynn for both 100mg and 300mg phenytoin sodium capsules by 20% and also backdated these reductions to 1 January 2014.<sup>631</sup>
- 4.74 However, rather than immediately passing on these reductions Flynn waited a further two months until April 2014 before it reduced its list prices for 100mg and 300mg capsules by 20% and 15% respectively, which led to lower ASPs to pharmacies and wholesalers, and did not backdate them. Accordingly, Flynn actually accrued additional profits of approximately [X] over this four month period.<sup>632</sup> Flynn has not offered any explanation as to why it did not decrease its prices at the same time as Pfizer (or more quickly than it did). This conduct does not suggest that NRIM's Product was an effective competitive constraint on Flynn.<sup>633</sup> It suggests quite the opposite.

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<sup>628</sup> In its response to the CMA's SO, Pfizer stated that prescribers 'left the dispensing option open', meaning dispensers were given 'freedom to put pressure on price through substitution'. See document 01622.2, paragraph 261.

<sup>629</sup> See document 00476.1.

<sup>630</sup> See document 00505.1, paragraphs 37.3 and 37.4.

<sup>631</sup> The decreases were backdated as 'a one-off concession due to the enhanced stockholdings that you [Flynn] have built'. See document 00505.48.

<sup>632</sup> This figure was calculated by subtracting the revenues that Flynn would have earned from its sales in January, February and March 2014 had it priced at its post-March 2014 ASPs, see Annex H, from the sales revenue figures it actually earned during those three months.

<sup>633</sup> In its response to the SO, Pfizer submitted that it is not clear how it can be argued that Flynn could act independently of competitors and the indirect constraint from NRIM 'was passed through to Pfizer in the form of a price decrease' (document 01622.2, paragraphs 290-291).

- 4.75 It is also important to note that, even after Flynn reduced its prices in April 2014, Flynn's ASPs were still very high compared to historic price levels for the Focal Product and still highly profitable for Flynn. After the price decrease Flynn's ASP for 100mg capsules was [£41 - £50.99] and Flynn earned gross profits of [25% - 35%] per pack at this level.
- 4.76 The month after reducing its list prices and ASPs, Flynn switched to an RWM. In May 2014 Flynn reduced the number of wholesalers it supplied to two – [Wholesaler 3] and [Wholesaler 1] – and reduced the standard discount that it offered wholesalers from 12.5% off the Drug Tariff price to [✂] for [Wholesaler 3] and [✂] for [Wholesaler 1].<sup>634</sup>
- 4.77 The effect of these changes was to reduce the difference between the Drug Tariff price and Flynn's ASPs for every capsule strength (as summarised in Table 4.3 below). This is significant since the difference between the Drug Tariff price and Flynn's ASP is the margin that Flynn provides to wholesalers and pharmacies. By reducing this margin, Flynn reduced the commercial attractiveness of its product relative to NRIM's Product. This action is inconsistent with NRIM's Product exerting a sufficient competitive constraint on the Focal Product such that it should be included in the Relevant Markets.

**Table 4.3: Differences between Flynn's ASPs and the Drug Tariff prices**

	September 2012 to March 2014		Post-May 2014	
	Absolute	Percentage	Absolute	Percentage
<b>25mg</b>	[£1 - £2.99]	[7% - 23%]	[£1 - £2.99]	[7% - 23%]
<b>50mg</b>	[£1 - £2.99]	[7% - 23%]	[£1 - £2.99]	[7% - 23%]
<b>100mg</b>	[£6 - £8.99]	[10% - 15%]	[£3 - £5.99]	[6% - 12%]
<b>300mg</b>	[£6 - £8.99]	[10% - 15%]	[£3 - £5.99]	[6% - 12%]

Sources: [www.nhsbsa.nhs.uk/PrescriptionServices/4940.aspx](http://www.nhsbsa.nhs.uk/PrescriptionServices/4940.aspx)  
 Flynn: documents 00505.22, 00872.3, 00915.1, 01044.1, 01044.2, 01148.2, 01148.3, 01293.2, 01839.13 and 02115.2

*NRIM's price reduction*

- 4.78 Following Flynn's price reduction, NRIM reduced its prices between April 2014 and June 2014.<sup>635</sup> From June 2014 to May 2015 NRIM's Product was,

<sup>634</sup> See document 00872.1.

<sup>635</sup> NRIM had to reduce its prices at this time in order for its prices to remain below the Drug Tariff Price. NRIM's ASP in the period April 2014 to March 2014 was [£51 - £60.99] (as shown in Table 4.1), which is greater than the Drug Tariff price which came into effect from May 2014 (as set out in section 3.D.II.v, the Drug Tariff Price for 100mg capsules reduced from £67.50 to £54 with effect from May 2014).

on average, [£] per pack cheaper to dispense than Flynn's and between June 2015 and June 2016 it was [£] cheaper on average. Given that the large majority of prescriptions for phenytoin sodium capsules are open, if the markets were subject to normal competition this difference should have provided an incentive for pharmacies to choose to dispense NRIM's Product instead of Flynn's.

- 4.79 However, despite this incentive for pharmacies, Pfizer and Flynn each continued to sustain high prices that were highly profitable. The CMA considers that the lack of any competitive response by either Pfizer or Flynn to NRIM's June 2014 price reduction (let alone a timely one) further demonstrates that NRIM's Product did not provide a sufficient competitive constraint on either Pfizer's Product or Flynn's Products such that it should be included in the relevant markets.
- 4.80 In its response to the CMA's Letter of Facts, Pfizer provided an explanation as to why there had been no further price reductions since April 2014. Pfizer stated that it had opposed further reductions to the supply prices set out in the Supply Agreement '*for fear that any amendment would give credence to the misplaced allegations in the CMA investigation*' and therefore that the lack of any further price reduction '*cannot be misinterpreted as an absence of constraints on the market.*' Pfizer concluded by stating that '*it ought to be a matter of concern to the CMA that the effect of the intervention to date has been to forestall price reductions by each of Pfizer and Flynn.*'<sup>636</sup>
- 4.81 The CMA does not accept this explanation for two reasons. Firstly, Pfizer has not provided any contemporaneous documents to support its assertion. Secondly, it shows that Pfizer and Flynn are able to choose to ignore market developments in terms of claimed ongoing price competition. This further shows that neither Pfizer's nor Flynn's pricing conduct was sufficiently constrained by NRIM's Product such that the latter should be included in the Relevant Markets. If they had been subject to such constraints they would not be able to adopt this strategy.

#### Assessment of switching behaviour in the context of Pfizer's and Flynn's Prices

- 4.82 As has been stated, by November 2013 NRIM had gained an estimated share of [20% - 30%] of all 100mg phenytoin sodium capsules in the UK.<sup>637</sup>

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<sup>636</sup> See document 02076.1, paragraph 50.

<sup>637</sup> Estimates based on IMS data provided by Pfizer (document 02129.4) and documents 00512.2 and 00505.22

As previously stated, the CMA considers that if there was unconstrained competition between NRIM's Product and Flynn's Products and NRIM's Product had provided a sufficient competitive constraint on Flynn's Products to be included in the relevant market, NRIM would have gained more sales and market share given its significantly lower prices and the fact that the large majority of prescriptions for phenytoin sodium capsules are open.

- 4.83 The CMA notes that it is evaluating substitution patterns in circumstances where Pfizer and Flynn have both exercised their market power by substantially increasing the price of the Focal Product to pharmacies and wholesalers from September 2012.
- 4.84 These significantly higher ASPs provide important context in which to assess switching to NRIM's Product. Substitution which occurs at inflated prices may not be a reliable indicator of substitution that would take place at or near to the competitive price. In the circumstances of this case, Pfizer's and Flynn's inflated prices provided NRIM with considerable scope to offer wholesalers and pharmacies a much greater financial incentive to substitute Flynn's Products with its product than would otherwise have been the case. For example, between April 2013 and March 2014, NRIM's Product was sold [redacted] to Flynn's ASP (as shown in table 4.1).<sup>638</sup> Given the Drug Tariff price for 100mg phenytoin sodium capsules was only £2.83 prior to September 2012, any discount relative to the ASP of the Focal Product that NRIM would have been able to offer at pre-September 2012 prices would necessarily have been far smaller.
- 4.85 However, as shown above, it is apparent that even with the substitution that took place at these elevated prices levels, NRIM's Product was unable to sufficiently constrain Pfizer or Flynn's pricing conduct such that it would warrant widening the relevant markets beyond the Focal Product.

*iv. Pharmacy dispensing practices*

Introduction

- 4.86 This section considers pharmacy dispensing behaviour and the guidance that influenced that behaviour.<sup>639</sup> It shows that pharmacies did not consider switching patients between the Focal Product and NRIM's Product in the

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<sup>638</sup> This difference, when combined with reimbursement at the Drug Tariff price, generated a 'retail' margin for wholesalers and pharmacies of [£11 - £20.99] for NRIM's Product compared with [£6 - £8.99] for Flynn's 100mg capsules providing a significant commercial incentive for pharmacies to dispense NRIM's Product.

<sup>639</sup> This information is also set out in sections 3.B.II.d and 3.C.II.d.

way that would be expected if NRIM's Product was in the Relevant Markets, thereby explaining why Pfizer and Flynn have been able to profitably sustain very high prices since September 2012.

- 4.87 There are two distinct periods in which this pharmacy dispensing behaviour is assessed:
- (a) First from the launch of NRIM's Product in April 2013<sup>640</sup> up to the publication of the MHRA Guidance in November 2013, during which time the majority of pharmacies followed the principle of Continuity of Supply as set out in the clinical guidance which had been published and thus did not switch patients from Flynn's Products to NRIM's Product.
  - (b) Second, from the publication of the MHRA Guidance in November 2013 onwards after which all the pharmacies contacted by the CMA stated that they followed the principle of Continuity of Supply and thus did not switch patients from Flynn's Products to NRIM's Product.

#### Clinical Guidelines

- 4.88 As set out in section 3.B.II.d, prior to November 2013, long-standing guidance from regulatory and advisory bodies, such as NICE, recommended maintaining Continuity of Supply for epilepsy patients.<sup>641</sup>
- 4.89 In particular, NICE clinical guideline CG20, which was introduced in October 2004, cautioned against switching established epilepsy patients away from their current drug (including the same AED manufactured by a different company – which would include switching between phenytoin sodium capsule products supplied by different manufacturers, such as Pfizer and NRIM), stating that:

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<sup>640</sup> April 2013 and the launch of NRIM's Product is the first point at which pharmacists would have had a choice between the Focal Product and another phenytoin sodium capsules product when fulfilling an open prescription for phenytoin sodium capsules.

<sup>641</sup> CG137 (Full Guidance), page 149. See also page 151: '*The GDG felt strongly that in the absence of a formal evidence review it should remain the case that the best practice is to maintain consistency of supply of an AED preparation/manufacturer and the prescriber needs to consider carefully in partnership with the individual (and families or carers as appropriate) whether it is safe or acceptable for an individual patient to switch between brands and therefore changed the focus of the original 2004 recommendation to this end*'. Similar guidance was also issued by the SIGN. See documents PD 6 and PD 30, page 8: '*Formulations of AEDs are not interchangeable and generic substitution should not be employed*'.

*'Changing the formulation or brand of AED is not recommended because different preparations may vary in bioavailability or have different pharmacokinetic profiles, and, thus increased potential for reduced effect or excessive side effects.'*

- 4.90 CG20 was replaced in January 2012 by an updated clinical guideline, CG137, which repeated and reinforced the principle of Continuity of Supply, recommending that:

*'Consistent supply to the child, young person or adult with epilepsy of a particular manufacturer's AED preparation is recommended, unless the prescriber, in consultation with the child, young person or adult, considers that this is not a concern [...] Different preparations of some AEDs may vary in bioavailability or pharmacokinetic profiles and care needs to be taken to avoid reduced effect or excessive side effects.'*

- 4.91 In making this recommendation, the guidance recognised the risks and impact associated with changing an epilepsy patient's treatment and that the risk of therapeutic failure is best minimised by ensuring Continuity of Supply:

*'Abrupt changes in AED levels within the blood can lead to loss of previously gained seizure control, or in extreme circumstances status epilepticus. Maintenance of constant levels where possible minimises the risk to the individual'.<sup>642</sup>*

- 4.92 In November 2013, the MHRA published the MHRA Guidance on Continuity of Supply in relation to AEDs, including phenytoin sodium capsules. The MHRA Guidance was the culmination of a review by an Ad Hoc Expert Group of the CHM and the CHM Report<sup>643</sup> and was unusual, if not unique, as the MHRA rarely publishes guidance itself.<sup>644</sup>

- 4.93 The CHM Report had recommended that *'in general terms there was a need to maintain continuity of supply of a specific product for certain AEDs. The specific product could be either a branded product or a generic. Continuity of supply from the same manufacturer was the key issue, rather than whether the product was branded or generic [Emphasis in original]'.<sup>645</sup>*

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<sup>642</sup> CG137 (Full Guidance), page 149.

<sup>643</sup> PD18.

<sup>644</sup> See document 00400.1, paragraph 29.

<sup>645</sup> PD18, page 4.

4.94 Consistent with the CHM Report, the MHRA Guidance distinguished between three groups of AEDs which were identified in relation to the risks of switching between products. Phenytoin<sup>646</sup> was categorised as a Category 1 drug and for this category of AEDs the MHRA Guidance states:

*'Category 1 – Phenytoin, carbamazepine, phenobarbital, primidone*

*For these drugs, doctors are advised to ensure that their patient is maintained on a specific manufacturer's product<sup>647</sup>*

4.95 The MHRA Guidance also provided specific advice for prescribers, dispensers and patients.

4.96 For prescribers, the MHRA Guidance recommended that:

*'If a patient should be maintained on a specific manufacturer's product, this should be prescribed either by specifying a brand name or by using the generic drug name and name of the manufacturer (marketing authorisation holder).<sup>648</sup>*

4.97 For dispensers, the MHRA Guidance recommended that:

*'Dispensing pharmacists should ensure the continuity of supply of a particular product when the prescription specifies it. If the prescribed product is unavailable, it may be necessary to dispense a product from a different manufacturer to maintain continuity of treatment of that AED. Such cases should be discussed and agreed with both the prescriber and patient (or carer).*

*Usual dispensing practice can be followed when a specific product is not stated.<sup>649</sup>*

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<sup>646</sup> All forms of phenytoin were covered by this, including the Focal Product, NRM's Product and Tablets.

<sup>647</sup> PD19.

<sup>648</sup> PD19.

<sup>649</sup> PD19.



4.98 For patients, the MHRA Guidance recommended that:

*'Patients should take careful note of the name and manufacturer of their antiepileptic medicine and should check with their doctor or pharmacist if they are dispensed an unfamiliar medicine.'*<sup>650</sup>

4.99 The CHM also wrote to healthcare professionals on 11 November 2013 to draw their attention to the MHRA Guidance<sup>651</sup> and both CG137<sup>652</sup> and the BNF<sup>653</sup> were updated to include the MHRA Guidance.

4.100 Evidence on the CMA's file shows that Pfizer believed that these clinical guidelines and the need to adhere to Continuity of Supply applied specifically to the Focal Product. For example, on 13 September 2009, when considering [Company A]'s Proposal, [Pfizer's Head of Primary Care, Country Lead, UK] wrote in an internal email<sup>654</sup> that:

*'Industry has, rightly, made a big deal of epilepsy drugs being one of the key medicines where you shouldn't mess with the presentation that a patient is stabilised on – with a great deal of medical and pharmacy support.'*<sup>655</sup>

4.101 [Pfizer's Medical Director, UK] replied on 18 September 2009 stating that:

*'I do not believe it is medically safe to switch between branded and generic AEDs and particularly with phenytoin as it has such a narrow therapeutic window [...] We also used AEDs in our feedback on the PPRS generic substitution initiative as an example of a class of drugs where this would not be recommended.'*<sup>656</sup>

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<sup>650</sup> PD19.

<sup>651</sup> See document 00444.1

<sup>652</sup> CG137 now states 'In November 2013, the MHRA issued new advice about oral anti-epileptic drugs (AEDs) and switching between different manufacturers' products of a particular drug. Following a review of the available evidence, the CHM has classified AEDs into 3 categories depending on the level of potential concerns related to switching between different manufacturers' products. Consult the MHRA advice for more information' (see CG137 (full guideline), pages 63 and 149; and paragraph 1.9.1.4).

<sup>653</sup> The BNF entry reads 'Category 1 Phenytoin, carbamazepine, phenobarbital, primidone. For these drugs, doctors are advised to ensure that their patient is maintained on a specific manufacturer's product' (see PD29).

<sup>654</sup> To [Pfizer's Head of EPBU], [Pfizer's Speciality Care Business Unit Director for the UK], [Pfizer's UK Customer Access Director], [Pfizer's UK Head of Oncology Business Unit], [Pfizer's Legal Team Leader], [Pfizer's Vice president Finance, PECANZ and UK Finance Director], [Pfizer's Head of HR UK for Manager Operational Support] and [Pfizer's Medical Director, UK].

<sup>655</sup> See document 00141.31

<sup>656</sup> See document 00141.31.

4.102 [Pfizer's UK Head of Oncology Business Unit] replied on the same day (18 September 2009), saying:

*'If it helps there is specific guidance against switching and indeed that these products should be written by brand name to ensure consistency of medication with the BNF'*<sup>657</sup>

4.103 On 22 September 2009, [Pfizer's Head of EPBU] forwarded these internal discussions to [Pfizer's Head of Customer and Channel Marketing - Established Products UK] In his cover email, [Pfizer's Head of EPBU] said that:

*'There seems to be a strong concern/reluctance on the advisability of doing this form [sic] a patient care/Trust perspective. I echo these'*<sup>658</sup>

4.104 Flynn's documents show that it was also aware of the perceived risks in switching stabilised patients between different phenytoin sodium capsule products. For example, Flynn's communication plan for the introduction of Flynn's Products stated:

*'Phenytoin is a drug with a narrow therapeutic index (NTI) and, as such, there are concerns amongst patients and healthcare professionals (HCPs) regarding any change to the product.'*<sup>659</sup>

4.105 Further, Flynn's correspondence with both [Pharmacy 3] and [Pharmacy 6] in February 2014 corroborates that Flynn was aware of the risks in switching patients. In that correspondence, Flynn set out its view that:

*'the principle of consistency of supply was long since established and should in our [Flynn's] view have prevented substitution [between alternative phenytoin sodium capsule products] without appropriate authority or consultation.'*<sup>660</sup>

4.106 Flynn further stated its view that any switching of stabilised patients between different phenytoin sodium capsule products was not *'ever consistent with guidance or best practice'*.<sup>661</sup>

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<sup>657</sup> See document 00141.31.

<sup>658</sup> See document 00141.31.

<sup>659</sup> See document 00145.581, page 2.

<sup>660</sup> See documents 01068.16, 00505.19 and 00505.20.

<sup>661</sup> See documents 01068.14, 00505.19 and 00505.20.

## Pharmacies' dispensing decisions

### *Introduction*

- 4.107 As set out above, various pieces of clinical guidance have recommended that prescribers and dispensers follow the principle of Continuity of Supply for phenytoin sodium capsules and other AEDs. Pfizer staff were aware of this guidance and expected that the principle would be observed. Accordingly, this evidence raises the question as to whether NRIM's Product could sufficiently constrain Pfizer's and Flynn's pricing such that NRIM's Product should be within the relevant markets and helps explain why the pricing analysis does not suggest that NRIM's Product provided a sufficient competitive constraint on the Parties.<sup>662</sup>
- 4.108 In order to test this, the CMA has examined the extent to which substitution from the Focal Product to NRIM's Product has occurred in practice. The CMA has focused its analysis on the dispensing behaviour and practices of the major pharmacy chains and wholesalers,<sup>663</sup> which account for approximately 50% of pharmacies in the UK.<sup>664</sup> The sample includes all of NRIM's major customers, meaning that the portion of the pharmacy market which the CMA has not examined has experienced, at the most, a low level of switching.<sup>665</sup>
- 4.109 The evidence, which is set out below, demonstrates that over the Relevant Period, the majority of the pharmacy groups (eight out of ten) sought to ensure Continuity of Supply as recommended by the NICE guidance and did not switch stabilised patients from the Focal Product to NRIM's Product despite the very clear financial incentives to do so.

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<sup>662</sup> As noted above, the vast majority of patients are stabilised on phenytoin sodium capsules. The CMA considers that the fact that the principle of Continuity of Supply would not apply to new patients would not change the analysis on market definition given that the number of new patients is very small.

<sup>663</sup> The CMA has sought evidence from the following pharmacies: Alliance Boots, Asda, Celesio (Lloyds), the Co-Op (the Co-Op's pharmacy business was acquired by the Bestway Group in July 2014 and the pharmacies rebranded to 'Well' in February 2015), Day Lewis, Morrisons, Rowlands, Sainsbury's, Superdrug and Tesco.

<sup>664</sup> The OFT's 2007 Medicines distribution market study estimated that Alliance Boots, Asda, Celesio (Lloyds), the Co-Op, Morrison's Rowlands, Superdrug and Tesco accounted for 47.9% of the market (based on NHS revenue) in 2006. More recently the Keynote Retail Pharmacies Market Report 2014 states that the Company Chemists Association (CCA), which includes all of the pharmacies contacted by the CMA except for Day Lewis, represents '*nearly 50% of the pharmacies in the UK*'.

<sup>665</sup> Prior to the MHRA guidance, NRIM had won only two customers of any significance; [Pharmacy 3] (supplied via [Wholesaler 2], in turn, supplied via Auden McKenzie) and [Pharmacy 6] (supplied via [Wholesaler 1]); see section 4.B.IV.b.iv.

- 4.110 The evidence also demonstrates that the remaining two pharmacy groups ([Pharmacy 6] and [Pharmacy 3]) were initially prepared to switch stabilised patients to NRIM's Product and accounted for [%] of NRIM's sales. However, both ceased switching stabilised patients shortly after the publication of the MHRA Guidance after which they also took steps to ensure Continuity of Supply.<sup>666</sup>
- 4.111 Finally, the evidence demonstrates that demand for NRIM's Product has not grown significantly since November 2013 despite the clear commercial incentives for pharmacies to switch to it. This supports the CMA's conclusion that NRIM's Product has not sufficiently constrained Pfizer's and Flynn's pricing conduct to warrant inclusion in the relevant markets. This is because pharmacies do not see it as an effective substitute for the Focal Product for stabilised patients because of the need to ensure Continuity of Supply.

*Assessment of pharmacy dispensing decisions*

- 4.112 Eight out of the ten pharmacy groups contacted informed the CMA that, in the period April to November 2013, they followed the principle of Continuity of Supply, rather than commercial incentives, when determining which phenytoin sodium capsule product to dispense. These pharmacies were sufficiently concerned by the risk of therapeutic failure that they did not view the Focal Product and NRIM's Product as substitutes. This is consistent with what would be expected based on applicable clinical guidelines at the time.<sup>667</sup>
- 4.113 Of the eight pharmacy groups that followed the principle of Continuity of Supply, three did not purchase NRIM's Product, and those that did purchase NRIM's Product (five of eight) only dispensed it in limited circumstances (as

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<sup>666</sup> While technically the MHRA Guidance only required pharmacists to maintain continuity of supply when a specific formulation was prescribed the evidence set out below shows that, in practice, pharmacies (including [Pharmacy 3] and [Pharmacy 6]) interpreted the Guidance as emphasising the importance of maintaining Continuity of Supply in all cases where a patient has been stabilised, regardless of whether the prescription specified a particular formulation.

<sup>667</sup> See document 01639.3, 2 December 2015, paragraph 4.15) that NRIM's MA was granted on the basis of its Product being bioequivalent with Pfizer's product (*Epanutin* as it was at the time) and, as such, the MHRA determined that NRIM's Product and Flynn's Products are bioequivalent and are fully substitutable. Pfizer stated (see document 00519.2, question 28) that: '*although the NRIM generic would (technically) fall under the MHRA guidance, the risks of switching between the Flynn product and this bioequivalent version is rather different in terms of risk profile to a switch between Phenytoin Sodium and other forms of phenytoin product (e.g. suspension). This recognition of bioequivalence is clearly having an effect on the market, as NRIM continues to compete for sales. Prescribers are therefore clearly willing to switch to this alternative product, even if care should be taken when doing so.*'

set out in below), such as when the patient had not been prescribed phenytoin sodium before, or when they were already stabilised on NRIM's product.

- 4.114 [Pharmacy 4] confirmed they had purchased NRIM's Product, however it estimated that 95% of its purchases were from Flynn and explained that:

*'If a prescription is simply written generically, the pharmacist will ask the patient what they have previously used as regard will need to be given to bio-equivalence concerns'.<sup>668</sup>*

- 4.115 [Pharmacy 1] also purchased both NRIM's Product and the Focal Product, however it explained that its pharmacists followed the principle of Continuity of Supply when deciding which capsule to dispense:

*'Where the prescription is written generically, the pharmacist will complete a clinical check to determine what product the patient is currently using, and that product will be ordered. If no product is currently being used by the patient and the script is written generically, the pharmacist will have a choice of which product (Flynn or NRIM) they dispense'.<sup>669</sup>*

- 4.116 [Pharmacy 2]'s pharmacists also focused on ensuring of Continuity of Supply, when dispensing phenytoin sodium capsules, explaining that NRIM's Product would only be dispensed in limited circumstances, namely:

*'...if a patient was already on this particular brand, or if the patient was initiating therapy for the first time. In addition they may be used if stock shortages mean no alternative is available and the doctor has agreed to a change in brand being offered'.<sup>670</sup>*

- 4.117 Similarly, [Pharmacy 10] explained that NRIM's Product would only be dispensed where either:

*'... (i) the patient is a newly diagnosed patient therefore has no dispensing history for a particular generic and NRIM is the generic*

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<sup>668</sup> See document 00693.2. As discussed in section 3.C.II.c, PCA data for England for 2011 shows that 60% of prescriptions for phenytoin sodium capsules were open. For the first eight months of 2012 (before Flynn began distributing the Focal Product in the UK), 62% of prescriptions for phenytoin sodium capsules in England were open.

<sup>669</sup> See document 00679.1.

<sup>670</sup> See document 00813.1.

*product held in our system for dispensing; or (ii) the patient has previously been dispensed NRIM in which case we would continue to dispense this.*<sup>671</sup>

4.118 [Pharmacy 7] also sought to ensure Continuity of Supply:

*'If our pharmacists are unclear as to the variant (e.g. Flynn or NRIM) required by the customer, they should speak with the customer and check with the prescriber.*

*The pharmacist/ prescriber and customer should then jointly agree on the way forward.*<sup>672</sup>

4.119 [Pharmacy 8], [Pharmacy 9]<sup>673</sup> and [Pharmacy 5]<sup>674</sup> all informed the CMA that they did not purchase NRIM's Product during the period April to November 2013 with all being concerned about the risk of therapeutic failure and therefore focused on ensuring Continuity of Supply.

4.120 [Pharmacy 8] explained that it never purchased NRIM's Product: '*[p]rimarily due to how Rx [prescriptions] are written by the prescriber but also bio equivalence issues and bio availability*'.<sup>675</sup>

4.121 [Pharmacy 9] explained:

*'The buyer, [of Flynn's Products within Pharmacy 9] who himself is a pharmacist, was mindful of the existing concerns within the industry that had been expressed regarding the bioavailability issues with anti-convulsant drugs, especially Phenytoin, and consulted the [Pharmacy 9] Pharmacy Superintendent's Office. He was advised that because of the potentially serious patient safety issues that could arise because of bioavailability issues he should seriously consider remaining with the existing manufacturer whose product our patients had already been using.*

*He accepted this advice and did not purchase any NRIM Phenytoin sodium hard capsules. This decision was supported by the advice given*

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<sup>671</sup> See document 00817.1.

<sup>672</sup> See document 00666.1.

<sup>673</sup> See document 00649.1.

<sup>674</sup> See document 00662.1.

<sup>675</sup> See document 00657.1.

*in the BNF at the time and subsequently further vindicated by the contents of the MHRA press release on the subject some months later.*<sup>676</sup>

4.122 [Pharmacy 5] explained that it had always been able to source its requirements for phenytoin sodium capsules from Flynn and Parallel Imports.<sup>677</sup> However, it also explained that if its pharmacists were presented with an open prescription for phenytoin sodium capsules they would seek to ensure Continuity of Supply rather than be influenced by any financial incentives by checking *[p]revious brand supplied, indicated on PMR or confirmed with the patient*.<sup>678</sup> Additionally, [Pharmacy 5] explained that:

*'If no specific brand is indicated, pharmacists would need to get additional reassurances from the patient or prescriber. As phenytoin has a narrow therapeutic index caution is required between switching brands.'*

4.123 The [Pharmacy 5]'s and [Pharmacy 9]'s submissions have been corroborated by NRIM. In its submissions to the CMA, NRIM explained that it had experienced difficulties in attracting potential customers prior to November 2013 and that a number of pharmacies (including the [Pharmacy 5] and [Pharmacy 9]) had declined to purchase its product as a result of switching concerns.

4.124 In respect of the [Pharmacy 5], NRIM stated:

*'The [Pharmacy 5] was not interested, as it was considered that new patients would be unlikely to be prescribed Phenytoin Sodium 100mg capsules and that existing patients might be reluctant to switch from their existing product to NRIM's generic product.'*<sup>679</sup>

4.125 Finally in this regard, all of the above pharmacies confirmed that they continued to maintain Continuity of Supply following the publication of the MHRA Guidance.<sup>680</sup>

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<sup>676</sup> See document 00869.1.

<sup>677</sup> See document 00662.1.

<sup>678</sup> See document 00662.1.

<sup>679</sup> See document 00512.2 and 00872.15.

<sup>680</sup> See documents 00693.2, 00662.1, 00649.1, 00643.1, 00657.1, 00679.1, 00653.1 and 00666.1.

[Pharmacy 3]'s and [Pharmacy 6]'s *dispensing practices prior to the publication of the MHRA Guidance*

4.126 [Pharmacy 3] and [Pharmacy 6] were the only pharmacies to state that, prior to the MHRA Guidance being published and when presented with an open prescription,<sup>681</sup> they dispensed phenytoin sodium capsule based on commercial considerations.<sup>682</sup>

4.127 [Pharmacy 3] stated that it selected NRIM's Product following '*an economic decision on what was best for the [Pharmacy 3]*'.<sup>683</sup> As a result:

*'[p]rior to the November 2013 MHRA guidance, if no specific manufacturer's product had been requested by the patient or the prescriber, then the pharmacist would dispense the product which was the most commercially viable option'.<sup>684</sup>*

4.128 In practice this meant that [Pharmacy 3] chose to dispense NRIM's Product where it could because the '*cost is lower than Flynn [sic] product*'.<sup>685</sup>

4.129 Likewise, [Pharmacy 6] stated that it began to purchase NRIM's Product because it '*was considered to be commercially attractive because of the pricing of NRIM*'.<sup>686</sup>

4.130 NRIM had only two customers in the UK prior to November 2013: [Wholesaler 1] and Auden McKenzie, which then sold NRIM's Product to [Wholesaler 2].<sup>687</sup> <sup>688</sup> [Wholesaler 1] and [Wholesaler 2] then sold NRIM's Product to pharmacies and were the only wholesalers in the UK to sell NRIM's Product.<sup>689</sup> Sales data from [Wholesaler 1] and [Wholesaler 2] show

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<sup>681</sup> As explained above, a pharmacist must dispense the product specified on the prescription when presented with a closed script. In that scenario, the pharmacist faces no choice and is therefore unable to substitute between different phenytoin sodium capsule products.

<sup>682</sup> [redacted].

<sup>683</sup> See document 00838.1.

<sup>684</sup> See document 00661.4, question 10.v.

<sup>685</sup> See document 01068.20.

<sup>686</sup> See document 00669.1, question 5.i.b.

<sup>687</sup> See document 00512.2, page 2.

<sup>688</sup> See document 00684.1, page 5.

<sup>689</sup> More recently, other wholesalers have listed NRIM's Product. However, this has only been the case following Auden McKenzie's acquisition of NRIM in July 2014.



that [Pharmacy 3] and [Pharmacy 6] accounted for approximately [X] of their sales of NRIM's Product up to November 2013.<sup>690</sup>

[Pharmacy 3]'s and [Pharmacy 6]'s *dispensing decisions post November 2013*

- 4.131 It is common ground between the CMA and both of the Parties that the MHRA Guidance of November 2013 merely reiterated the pre-existing and well-known clinical guidance regarding the principle of Continuity of Supply.<sup>691</sup>
- 4.132 It is not so much the substantive content of the MHRA Guidance as its practical effect that matters for present purposes. The evidence on the CMA's case file demonstrates that the MHRA Guidance significantly reduced the likelihood of pharmacies, in particular [Pharmacy 3] and [Pharmacy 6], switching stabilised patients from the Focal Product to NRIM's Product. [Pharmacy 3] and [Pharmacy 6] specifically told the CMA that they had changed their dispensing behaviour as a result of the MHRA Guidance. From around November 2013 onwards, they fell into line with the other pharmacies and prioritised Continuity of Supply when determining what form of phenytoin sodium capsules would be dispensed to stabilised patients.
- 4.133 [Pharmacy 3] explained that, further to the MHRA Guidance, when presented with an open prescription it would take steps to determine whether the patient was already on a treatment and, if so, seek to ensure Continuity of Supply:

*'Following the issue of the November 2013 MHRA guidance, if a prescription does not specify a particular manufacturer's brand, then the pharmacist would review the patient's medication history and discuss the matter with the patient (or carer) and/or the prescriber to determine which brand had previously been dispensed so the same brand can be dispensed again.'*<sup>692</sup>

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<sup>690</sup> See documents 00838.10 and 00853.2. The remaining [X] of sales of NRIM's Product were predominantly to hospitals and other pharmacies.

<sup>691</sup> CG137 (Full Guidance).

<sup>692</sup> See document 00661.4. See also: *'When presented with a generic prescription for phenytoin sodium hard capsules, in accordance with the November 2013 MHRA guidance, the pharmacist would take into account any brand previously given to the patient in order to dispense the most appropriate brand'* and *'Even where the prescription is written generically, in accordance with the MHRA guidance, [Pharmacy 3] would review its patient medication history or speak to the patient (or carer) to determine which brand had been previously given in order to dispense the same brand'*.

- 4.134 [Pharmacy 3]’s policy is the same regardless of whether the patient in question is stabilised on the Focal Product or NRIM's Product.<sup>693</sup>
- 4.135 [Pharmacy 3] communicated its policy to all of its pharmacists in November 2013 via its internal website and again in March 2014 by hard copy monthly professional bulletin.<sup>694</sup> In January 2014, [Pharmacy 3] informed Flynn that it would dispense phenytoin sodium capsules on the basis of Continuity of Supply rather than commercial considerations.<sup>695</sup>
- 4.136 [Pharmacy 6] explained that when it receives an open prescription for phenytoin sodium capsules it will take steps to determine whether the patient is already on a particular form of capsule and, if so, seek to ensure Continuity of Supply:

*[I]f a patient is taking the NRIM Product then the pharmacist will dispense the NRIM Product. This will be the case where:*

3. *the NRIM Product is specified on the prescription; and*
4. *no brand or manufacturer is specified on the prescription but following enquiry of the patient or prescriber, the pharmacist ascertains that the patient is taking the NRIM Product.*

*Equally, if a prescription specified the Flynn product or following enquiry the pharmacist ascertained that the patient was taking the Flynn product, the pharmacist will dispense the Flynn product.'*

- 4.137 Commercial attractiveness plays no role in these decisions. In circumstances where no brand or manufacturer is specified on the prescription or requested by the patient and the pharmacist is satisfied that there is no clinical reason why the patient needed product continuity, the pharmacist has a discretion as to which product to dispense. Only in such circumstances might commercial considerations come into play.<sup>696</sup>
- 4.138 [Pharmacy 6] communicated this revised policy to its pharmacists.<sup>697</sup> [Pharmacy 6] explained that its decision to issue specific guidance regarding phenytoin was quite exceptional and that '*Phenytoin was perhaps one of*

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<sup>693</sup> See document 00838.3.

<sup>694</sup> See document 00661.4, question 11.

<sup>695</sup> See document 01068.13.

<sup>696</sup> See document 00852.1, question 4.

<sup>697</sup> See, for example, document 00669.3.

*only two examples where the Superintendent Pharmacist at [Pharmacy 6] Pharmacy has issued internal guidance'.<sup>698</sup>*

4.139 [Pharmacy 6] has also communicated its position to Flynn, meaning that Flynn was, and is, aware that [Pharmacy 6] will dispense on the basis of Continuity of Supply.<sup>699</sup>

*Flynn submission on [Pharmacy 3] online dispensing practices*

4.140 Flynn submitted evidence to the CMA concerning the dispensing practices of the [Pharmacy 3] online pharmacy services.<sup>700</sup> In particular, Flynn stated that it had a private prescription for phenytoin sodium capsules fulfilled by [Pharmacy 3]'s online dispensing service without any check on whether the patient was stabilised on a specific product. Flynn contended that this showed that [Pharmacy 3] online dispensing service was not in practice following the MHRA Guidance.<sup>701</sup>

4.141 The CMA asked [Pharmacy 3] about this evidence. [Pharmacy 3] responded that:<sup>702</sup>

- (a) [Pharmacy 3] has policies and procedures in place to ensure that Continuity of Supply is respected for patients stabilised on a particular brand of phenytoin sodium capsules (both for its in-store and online pharmacies);<sup>703</sup>
- (b) Excluding Flynn's own 'mystery shopping' order, only one patient had ordered phenytoin sodium capsules through [Pharmacy 3]'s online dispensing service in the preceding 12 months and, for that regular customer, [Pharmacy 3] had discussed with the customer which brand to supply and had continued to supply that agreed brand; and
- (c) [Pharmacy 3]'s process for dispensing private prescriptions is the same as its process for dispensing 'one off' prescriptions. The private

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<sup>698</sup> See document 00852.1.

<sup>699</sup> See documents 00505.19 and 00853.22

<sup>700</sup> See documents 01963.1, 01963.2 and 01965.1.

<sup>701</sup> Flynn has also carried out some other 'mystery shopping' exercises at bricks-and-mortar pharmacies. In the majority of cases the pharmacies involved acted in accordance with the MHRA guidance. See documents 02000.1, 02000.2.

<sup>702</sup> See documents 02009.1, 02009.2, 02009.3, 02009.4.

<sup>703</sup> However, [Pharmacy 3] acknowledged that the checks that should have been made and had been advised to [Pharmacy 3] pharmacists were not carried out for the private prescription in that instance.

prescription did not include within the 'Additional Details' box a request for a particular brand of phenytoin sodium capsules to be dispensed

4.142 The CMA considers that the very small number of prescriptions for phenytoin sodium capsules which are dispensed by [Pharmacy 3]'s online dispensing service, which represented 0.016% of all prescriptions for phenytoin sodium capsules dispensed by [Pharmacy 3] in the period May 2015 to April 2016, are too small to have any impact on market definition considerations.

[Pharmacy 3]'s and [Pharmacy 6]'s *purchase volumes*

4.143 [Pharmacy 3]'s and [Pharmacy 6]'s submissions that they seek to ensure Continuity of Supply for stabilised patients following the publication of the MHRA Guidance are corroborated by purchase data set out in Figures 4.3 and 4.4 below.

4.144 Figure 4.3 shows the volume of NRIM's Product that [Pharmacy 3] has purchased since the MHRA Guidance was published. Despite the unusual level of purchases in September 2013 and November 2013, the figure broadly declined in the period from publication of the MHRA guidance to early 2015 and has remained broadly stable since then. This is entirely consistent with [Pharmacy 3] not continuing to switch stabilised patients from Flynn's Products to NRIM's Product following the publication of the MHRA Guidance.<sup>704</sup>

4.145 Figure 4.4 shows the volume of NRIM's Product purchased by [Pharmacy 6] since the MHRA Guidance was published and demonstrates that the figure has also shown a steady decline (with the exception of a more significant drop in volume for one month in September 2014).<sup>705</sup> As with [Pharmacy 3], this is entirely consistent with [Pharmacy 6] not continuing to switch stabilised patients from Flynn's Products to NRIM's Product following the publication of the MHRA Guidance.

**Figure 4.3: [Pharmacy 3] monthly purchases of NRIM's Product**

[X]

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<sup>704</sup> See Figure 4.3. [Pharmacy 3] has purchased between [X] and [X] packs of NRIM's Product per month between December 2013 and January 2016.

<sup>705</sup> See Figure 4.3. Excluding September 2014, [Pharmacy 6] has purchased between [X] and [X] packs of NRIM's Product per month between December 2013 and January 2016.

#### Figure 4.4: [Pharmacy 6] monthly purchases of NRIM's Product

[X]

##### v. NRIM's sales volumes following the MHRA Guidance

- 4.146 Pfizer and Flynn both submitted to the CMA that NRIM's sales volumes increased following the publication of the MHRA guidance and that this is evidence of the constraint that NRIM's Product imposes on each of them.<sup>706</sup> To assess these representations, the CMA has considered evidence from NRIM, including NRIM's sales volumes over the period since its launch.
- 4.147 NRIM's submissions to the CMA support and corroborate the information provided by pharmacies, in particular [Pharmacy 3] and [Pharmacy 6], and demonstrates that, since the MHRA Guidance, NRIM has failed to gain any new customers that have been prepared to purchase significant volumes of its product. Two potential customers ([Pharmacy 7] and the [Pharmacy 5]) have declined to make any purchases.<sup>707</sup> NRIM also informed the CMA that, following the publication of the MHRA Guidance, it discontinued its development of 25mg, 50mg and 300mg phenytoin sodium capsules as *[t]his guidance would significantly limit NRIM's ability to gain market share if it were to successfully develop and launch Phenytoin 25mg, 50mg and 300mg capsules in the UK market.*<sup>708</sup>
- 4.148 NRIM's failure to achieve any significant sales growth after November 2013 is reflected by its sales data. Figure 4.5 illustrates that NRIM went through a period of building its sales between April 2013 and November 2013 but that it has not significantly expanded its sales volumes since November 2013.<sup>709</sup>

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<sup>706</sup> See document 01622.2, paragraph 285 and document 01639.3, paragraph 4.25 and 4.30.

<sup>707</sup> See document 01152.2, Annex 4. The CMA is aware that, following Auden McKenzie's acquisition of NRIM in July 2014, NRIM's Product is now sold to Phoenix, DE Pharmaceuticals, Eclipse Generics and Sigma Pharmaceuticals. However, these new customers have not enabled NRIM to significantly expand its sales. See documents 00896.2, 01151.2, 01783.1 and 02109.2.

<sup>708</sup> See document 00896.2.

<sup>709</sup> Both Pfizer and Flynn submitted that since the MHRA published its guidance, NRIM has continued to grow its share (see document 01639.2, paragraphs 4.14 – 4.20). In a submission to the CMA by Pfizer on 11 March 2016, Pfizer submitted that NRIM captured significant volumes of sales pre-November 2013 and that Pfizer's and Flynn's shares have continued to decline steadily since this date (see document 01836.5). However, the data provided by Pfizer, Flynn, NRIM and IMS does not show that NRIM has increased its market share over this period. As shown in Figure 4.5, NRIM's sales volumes have not increased significantly post-November 2013. Figures 4.3 and 4.4 also show that [Pharmacy 3]'s and [Pharmacy 6]'s (which account for [X] of NRIM's sales) purchases of NRIM's Product have remained stable post-November 2013.

**Figure 4.5: NRIM volume of capsules (3 month moving average)**

[✂]

4.149 The CMA has also considered total 100mg phenytoin sodium capsules dispensed, as well as Flynn's sales of 100mg phenytoin sodium capsules and NRIM's sales for the period November 2013 to June 2016, as shown by Figure 4.6. Figure 4.6 illustrates that after an initial period where Flynn's, and NRIM's volumes fluctuate significantly following the publication of the MHRA Guidance, their sales (based on three month rolling averages) have remained relatively stable. Since both sales by NRIM and Flynn and the total phenytoin sodium capsules dispensed have been broadly constant since late 2014, it cannot be the case that NRIM has significantly increased its sales at the expense of Pfizer and Flynn.

**Figure 4.6: Volume of 100mg capsules dispensed, Flynn and NRIM sales; 3 month moving average**

[✂]

4.150 NRIM's failure to achieve significant growth was despite the fact its ASP was lower than Flynn's ASPs for all but two months of this period,<sup>710</sup> thus supporting the CMA's conclusion that NRIM's Product did not act as a sufficient constraint on Pfizer's and Flynn's pricing conduct following the publication of the MHRA Guidance.

*vi. Conclusion on NRIM's Product*

4.151 The evidence set out above on pharmacy dispensing decisions and NRIM's sales volumes is consistent with the pricing analysis in showing that NRIM's Product does not provide a sufficient competitive constraint on either Pfizer or Flynn to warrant NRIM's inclusion in the relevant markets.

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<sup>710</sup> The exception are the months of April and May 2014 during which Flynn's 100mg capsules were sold at a lower price, on average, than NRIM's Product. This reflects the delays in NRIM responding to the changes in the Drug Tariff price which occurred during this period.

### c. **Tablets and other AEDs**

#### **Summary**

The key evidence in the following sections shows that:

- Prescribers write prescriptions for either phenytoin sodium capsules or Tablets but would not normally write a prescription for just phenytoin sodium. Consequently, pharmacists would be restricted to dispensing the formulation prescribed.
- Tablets and other AEDs are covered by the same clinical guidance which applies to phenytoin sodium capsules. Therefore, even if a pharmacist were to receive an open prescription, they would normally maintain the patient on their existing treatment.
- There have previously been significant and sustained price disparities between the prices of phenytoin sodium capsules and Tablets yet switching was not observed.

#### i. *Summary of the CMA's conclusion*

4.152 The CMA has concluded that Tablets and other AEDs are not in the relevant markets and sets out its reasons for this below.

#### ii. *Introduction*

4.153 As with its assessment of NRIM's Product, the CMA considers the relevant means of establishing whether or not Tablets and other AEDs are in the relevant markets is to assess whether either or both candidate substitutes impose a sufficient competitive constraint on Flynn's and Pfizer's pricing conduct and sets out this assessment below.<sup>711</sup>

4.154 In conducting this analysis the CMA has focused on the potential constraints imposed by Tablets since these are an alternative formulation of the same molecule (i.e. phenytoin sodium).<sup>712</sup> Accordingly, if Tablets do not impose a sufficient competitive constraint on phenytoin sodium capsules to be deemed

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<sup>711</sup> In document 01639.3, paragraph 4.10, Flynn submitted that the starting point should '*be that the relevant product market for phenytoin-based AEDs (including the phenytoin sodium capsules marketed by Flynn) can in principle comprise all the other AEDs that are prescribed to patients when they are put on level 3 treatment for the same epileptic syndromes as the phenytoin-based AEDs.*'

<sup>712</sup> In document 01639.3, paragraph 4.12, Flynn submitted that the market should include all Phenytoin-based AEDs prescribed to patients as a minimum. Flynn also explained that Tablets and capsules '*contain the same API, have the same dosage strength (100mg) and are used to treat the same indications*'. Flynn also noted (paragraph 4.13), that the MHRA recognises the therapeutic equivalence between Tablets and phenytoin sodium capsules.

to fall within the same market then it can be inferred that other AEDs will also not be within the relevant market.

- 4.155 Similarly, if NRIM's Product does not impose a sufficient competitive constraint on Pfizer's and Flynn's Products to be deemed to fall within the same market then it can be inferred that that less close substitutes such as Tablets will also not be within the relevant market. However, the CMA has assessed the evidence on this point given that:
- (a) the CMA has also assessed whether Pfizer and Flynn held dominant positions in the period prior to November 2013 by reference to the alternative wider relevant markets, which also include NRIM's Product, for the period September 2012 to November 2013; and
  - (b) phenytoin sodium Tablets were the closest substitute to phenytoin sodium capsules prior to the entry of NRIM's Product in April 2013.
- 4.156 The CMA's analysis:
- (a) first, considers the qualitative evidence on the possibilities for substitution between the Focal Product and Tablets, and other AEDs; and
  - (b) second, considers the quantitative evidence on the possibilities for substitution between the Focal Product and Tablets.
- 4.157 Having considered the quantitative and qualitative evidence in the round the CMA concludes that Tablets and other AEDs do not provide a sufficient competitive constraint on the Focal Product such that the relevant markets should be wider than the Focal Product.
- iii. *Qualitative evidence*
- 4.158 The CMA finds that the qualitative evidence on its case file shows that neither Tablets nor other AEDs impose a sufficient competitive constraint on the Focal Product to fall within the relevant markets in this case.
- 4.159 First, prescribing practices should significantly restrict the possibility of substitution between phenytoin sodium capsules and other AEDs, including Tablets. This is because prescriptions for phenytoin sodium ought to specify the formulation (i.e. tablets or capsules) to be dispensed, meaning



pharmacists are not able to take a switching decision.<sup>713</sup> This is significant because, as has been seen in the analysis of switching from the Focal Product to NRIM's Product, it was certain pharmacists who took the decision to switch patients. This route should not be available in this context.

- 4.160 Accordingly, the prescriber is primarily responsible for the decision as to which type of AED or the formulation of phenytoin sodium a patient should take. Therefore, in respect of stabilised patients, substitution of the Focal Product with Tablets will only occur if the prescriber switches the patient. However, any such switching will be exceptional because prescribers should write prescriptions based on the principle of Continuity of Supply set out in the clinical guidelines, as described in section 3.B.II.d, and should only change the formulation or the AED as a result of therapeutic rather than financial considerations.<sup>714</sup>
- 4.161 Second, in the unlikely event that a prescription was sufficiently open to enable a pharmacist to choose to dispense Tablets instead of the Focal Product, then any switching is again unlikely.
- 4.162 Any pharmacist who received such a prescription would be expected to follow the principle of Continuity of Supply and therefore enquire what formulation of phenytoin sodium the patient had previously been on and dispense that formulation. Consistent with this, the pharmacies contacted by the CMA have submitted that they would not switch patients between phenytoin sodium capsules and Tablets unless the change had been agreed by the prescriber.<sup>715</sup> For example, [Pharmacy 4] submitted that:

*'[Pharmacy 4] believes that a pharmacist would not substitute tablets for capsules without first seeking advice and authorisation from the patient's doctor'*<sup>716</sup>

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<sup>713</sup> For example, see documents 00661.4, question 7 ('The prescription will also include the strength and formulation required'), 00662.1, question 7 ('Prescription have been written as Phenytoin Sodium xxmg capsules, Phenytoin Sodium Flynn xxmg capsules, Phenytoin Sodium Flynn xxmg hard capsules, Phenytoin Sodium xxmg hard capsules, Epanutin xxmg capsules, Phenytoin Sodium NRIM xxmg capsules and Phenytoin Sodium NRIM xxmg hard capsules'); and 00857.11, where each formulation is listed separately in the prescription software.

<sup>714</sup> See documents 00261.1, 00248.2, 00277.1 and 00325.1. These responses suggested that a patient might be switched from phenytoin to another AED if there had been therapeutic failure, during pregnancy or due to intolerable side effects, such as toxicity. However, even in these cases it is not clear why a patient would be switched from phenytoin sodium capsules to tablets rather than to another AED altogether.

<sup>715</sup> See documents 00661.4, 00669.1, 00662.1, 00649.1, 00643.1, 00657.1, 00679.1, 00653.1 and 00666.1.

<sup>716</sup> See document 00693.2.

- 4.163 Third, despite their representations to the contrary, the Parties themselves have accepted that there is limited, if any, substitution between the Focal Product and Tablets.
- 4.164 In this respect, contemporaneous internal Flynn documents demonstrate that key Flynn staff understood that there was limited, if any, substitution between the Focal Product and Tablets based on observable data. In particular, an email from [Flynn's Director] to [Flynn's Non-executive Director] on 16 March 2010 explains *'[t]his is an area where the tablets and capsules are recognised as NOT being readily interchangeable, so doctors and patients would be reluctant to switch.'*<sup>717</sup> In addition, internal Flynn Board minutes from December 2010 states *'Epanutin capsules & tablets are not interchangeable, so the number of scripts should be maintained when the product is sold generically.'*<sup>718</sup>
- 4.165 Further, on 15 April 2013, [Flynn's CEO] wrote in an email to [redacted] ([redacted]), [Flynn's Director] and [Flynn's Group Financial Controller]:

*'The generic table [sic] has for many years been significantly more expensive than the capsule yet its market share has been [sic] broadly constant. Even in the period in 2007 when its price was ~ x 80 the Epanutin capsule, it did not provoke a significant switch to the capsule.*

*More recently we have examined the PCA data for 2010-12 which show 132K, 125K and 115K scripts for the tablet and 507K, 505K and 491K scripts for the Epanutin (100mg) capsule. Throughout this period up until the Flynn launch Sept 24th 2012, the tablet was~ 34 times more expensive, yet its share of the market in script terms varied only marginally. This is the evidence of real-life practice over a number of years suggesting at patient and prescriber level, practice in AED prescribing (as far as phenytoin is concerned) is relatively insensitive to price.'*<sup>719</sup>

- 4.166 Likewise, Pfizer explained to the CMA that *'the volume of capsules and the volume of tablets are both generally in decline rather than there being a switch between capsules and tablets.'*<sup>720</sup>

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<sup>717</sup> See document 00145.12

<sup>718</sup> See document 00145.80. See also internal Flynn documents 00145.25 and 00145.44 which both state that *'Tablets & capsules are not easily interchangeable'*.

<sup>719</sup> See document 00145.814.

<sup>720</sup> See document 00412.1, paragraph 28.

4.167 Overall, the CMA considers that qualitative evidence shows that neither Tablets nor other AEDs impose a sufficient competitive constraint on the Focal Product to be included in the relevant markets in this case.

iv. *Quantitative evidence*

4.168 The CMA's conclusion that Tablets and other AEDs are not within the relevant markets is also strongly supported by the quantitative evidence.

4.169 The qualitative evidence set out above demonstrates that the prescriber is responsible for taking any decision to switch the formulation of phenytoin sodium a patient is stabilised on through a change in the patient's prescription.<sup>721</sup> As set out in section 3.B.II.d, prescribers should apply the principle of Continuity of Supply when writing prescriptions for phenytoin sodium formulations (and other AEDs) which will result in patients continuing to receive the same formulation of phenytoin sodium which they are stabilised on. As such there should be little if any price sensitivity between different formulations of phenytoin sodium.

4.170 In order to further test this finding the CMA has assessed the effects of variations in Drug Tariff prices<sup>722</sup> for phenytoin sodium capsules and Tablets on the volumes of phenytoin sodium capsules and Tablets dispensed.

4.171 The CMA has been able to observe demand patterns for both the Focal Product and Tablets based on significant changes to the Drug Tariff prices<sup>723</sup> that have occurred since April 2005. In particular:

(a) The increase in the Drug Tariff price of Tablets between April 2005 and December 2007 and the subsequent moderation of the Drug Tariff price of Tablets up to October 2008.

(b) The increase in the Drug Tariff prices of the Focal Product in September 2012.

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<sup>721</sup> As a prescription will state the form of the drug prescribed (either tablet or capsule for example), pharmacists will be unable to switch patients between alternative forms and the switching decision takes place at the prescriber level.

<sup>722</sup> The Drug Tariff Price is the price a medicine costs the NHS less any discounts.

<sup>723</sup> Drug Tariff Prices are used for this analysis because they are published monthly and so prescribers may have sight of these prices. Prescribers are unlikely to be aware of the ASPs to wholesalers and pharmacies.

4.172 These events enable the CMA to assess quantitatively whether the Tablets act as a constraint on the Focal Product.

Changes in the Drug Tariff price of Tablets

4.173 Figure 4.7 below plots the Drug Tariff price of a 28-pack of 100mg Tablets and the total volume of 100mg phenytoin sodium capsules purchased.<sup>724, 725</sup>

4.174 It shows that between April 2005 and December 2007 there were a series of significant increases in the Drug Tariff price of Tablets, such that the price increased by 6,584%. The Drug Tariff price for Tablets was reduced in October 2008,<sup>726</sup> yet even at this stage it was still 1,665% higher than it had been prior to April 2005.<sup>727</sup>

4.175 If the Focal Product and Tablets were substitutable then the CMA would expect to observe noticeable and significant shifts in the volumes of the Focal Product purchased as a result of these dramatic price increases. However, no such shifts occurred.<sup>728</sup>

4.176 Further, the CMA considers that the very large price difference between the Drug Tariff prices for the Focal Product and Tablets which existed between 2007 and 2012 would have been unsustainable if the Focal Product and Tablets were genuine substitutes for most patients.

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<sup>724</sup> See document 00745.1.

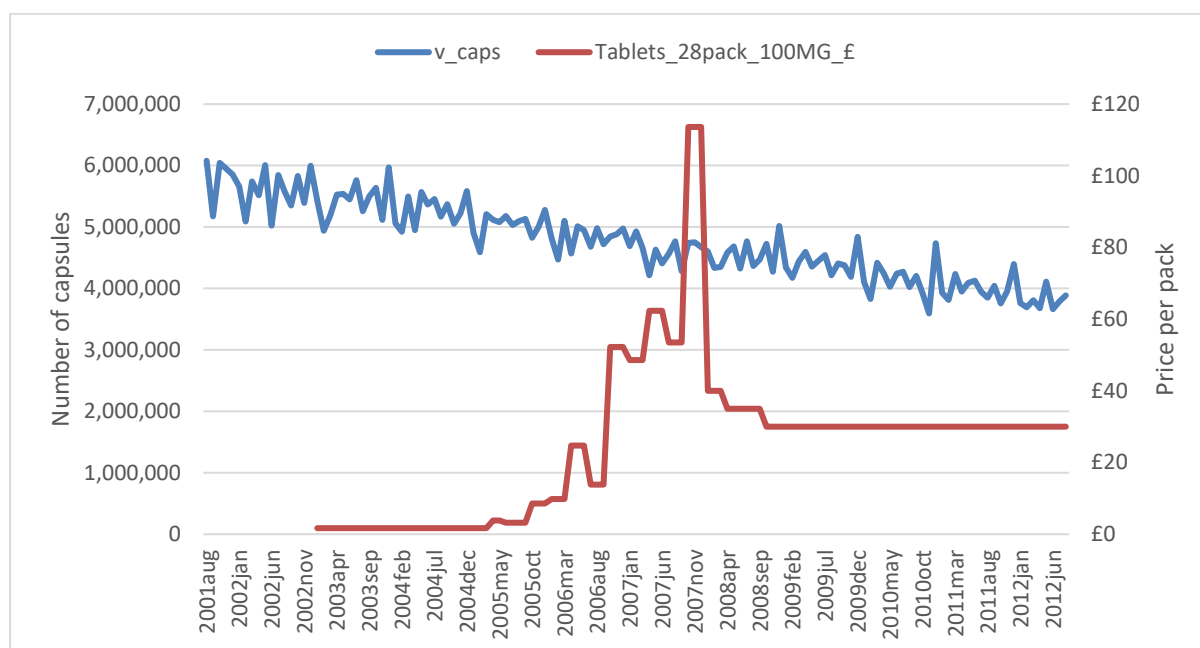
<sup>725</sup> The CMA has used IMS purchasing data which covers retail sales to pharmacies and usage within hospitals. The data covers the whole of the UK.

<sup>726</sup> See document 00367.2, question 12.

<sup>727</sup> The CMA notes that there was no contemporaneous change in the phenytoin sodium capsule price. Consequently, the changes in the Tablets prices also led to substantial changes in the relative prices of the two products.

<sup>728</sup> The CMA notes that, strictly speaking, this evidence relates to possible substitution from Tablets to phenytoin sodium capsules, and that the constraint could be asymmetric (that is, Tablets could constrain phenytoin sodium capsules more than phenytoin sodium capsules constrain Tablets). However, the CMA has no reason to believe that the constraint between phenytoin sodium capsules and Tablets is not symmetric and neither Pfizer nor Flynn have submitted that the constraint is asymmetric. As a result, the CMA believes that evidence on the extent to which phenytoin sodium capsules constrain Tablets is probative for understanding the extent to which Tablets constrain the actions of Pfizer and Flynn as suppliers of phenytoin sodium capsules.

**Figure 4.7: Drug Tariff price of 28 pack of 100mg Tablets (£) and total volumes of 100mg capsules**



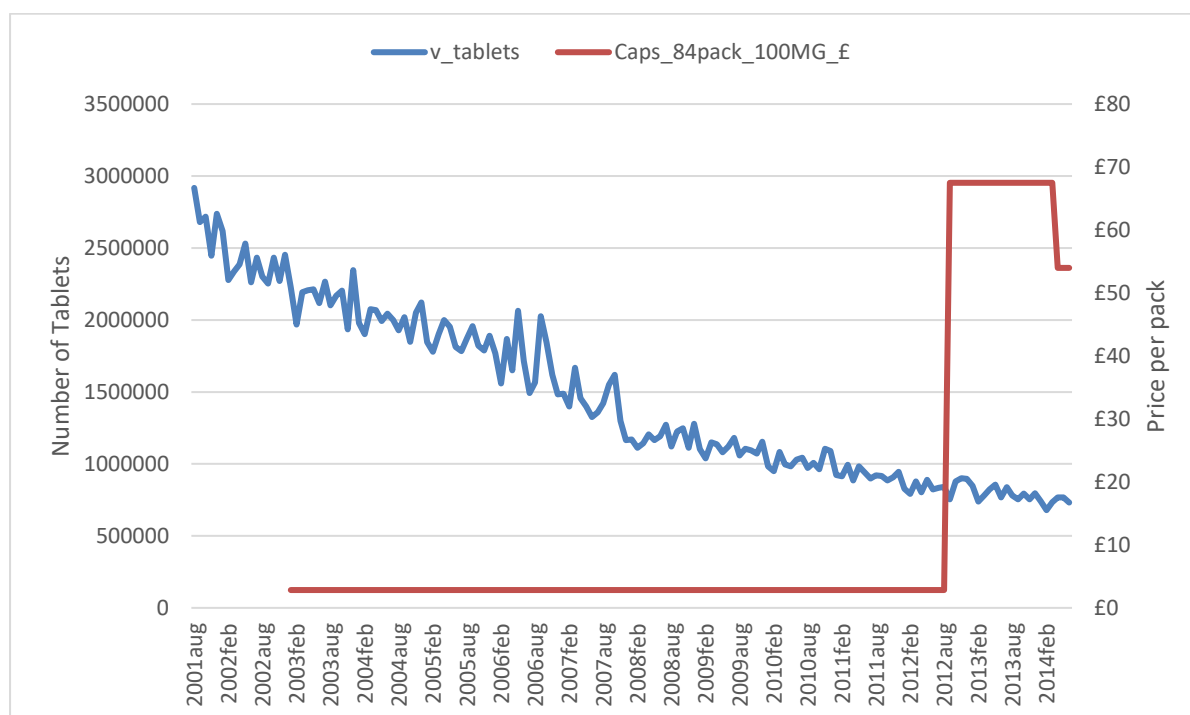
Source: IMS wholesaler data and [www.nhsbsa.nhs.uk/PrescriptionServices/4940.aspx](http://www.nhsbsa.nhs.uk/PrescriptionServices/4940.aspx)

*Changes to the Drug Tariff price of the Focal Product*

- 4.177 Figure 4.8 below plots the Drug Tariff price of a pack of 84 100mg phenytoin sodium capsules against the total volume of 100mg Tablets.<sup>729</sup> In September 2012, the Drug Tariff prices of the Focal Product increased substantially.
- 4.178 Figure 4.8 demonstrates that there was no apparent substitution between the Focal Product and Tablets as a result of the increased Drug Tariff Price of the Focal Product. If the Focal Product and Tablets were close substitutes then the CMA would have expected to observe noticeable and significant shifts in the volumes of the Tablets purchased.

<sup>729</sup> The CMA has used IMS purchasing data which covers retail sales to pharmacies and usage within hospitals. The data covers the whole of the UK.

**Figure 4.8: Drug Tariff price of 84 pack of 100mg capsules (£) and total volumes of 100mg Tablets**



Source: IMS wholesaler data and [www.nhsbsa.nhs.uk/PrescriptionServices/4940.aspx](http://www.nhsbsa.nhs.uk/PrescriptionServices/4940.aspx)

4.179 Overall, the CMA considers that the pricing events assessed above show that there has been no meaningful substitution between the Focal Product and Tablets. Rather, the volumes of phenytoin sodium capsules and Tablets appear to continue to decline in line with the long term trends resulting from the fact that they are both old drugs with declining patient bases.

**d. Conclusions on product market definition**

4.180 Taken together this evidence shows, in particular, that:

- (a) Both Pfizer and Flynn were able to profitably maintain significantly inflated prices throughout the Relevant Period. The CMA considers that this provides *prima facie* evidence that neither Party is subject to effective pricing constraint such that the relevant markets should be wider than the Focal Product.<sup>730</sup> Had the Parties faced an effective competitive constraint they would not have been able to sustain very high prices for an extended period of time.

<sup>730</sup> See section 4.B.IV.b.iii.

- (b) Tablets and other AEDs do not impose a sufficient competitive constraint on phenytoin sodium capsules such that either should be included in the relevant product markets. There is no noticeable evidence of any competitive interaction between Tablets and the Focal Product. Given that there is little, or no, competitive interaction between Tablets and the Focal Product then it can be inferred that the same will be true for other AEDs and the Focal Product.
- (c) NRIM's Product did not impose a sufficient competitive constraint on the Focal Product to be included in the relevant markets for the reasons set out below.
- i. The introduction of NRIM's Product did not prompt a timely competitive response by either Pfizer or Flynn.
  - ii. Prior to November 2013, NRIM had some success in attracting customers and consequently between April 2013 and November 2013 NRIM supplied an estimated [10% - 20%] of all phenytoin sodium capsules in the UK ([10% - 20%] on a DDD basis) and [20% - 30%] of all 100mg phenytoin sodium capsules in the UK. [Pharmacy 3] and [Pharmacy 6] in particular were willing to substitute stabilised patients from the Focal Product to NRIM's Product at this point in time and accounted for [X] of NRIM's sales. However, the vast majority of pharmacies considered that the existing clinical guidance precluded the substitution from the Focal Product to NRIM's Product. This clearly implies a limit to the extent to which NRIM's Product could exert a competitive constraint on the Focal Product during this period.
  - iii. Further, the substitution that did occur followed the substantial increase in the ASPs of phenytoin sodium capsules to wholesalers and pharmacies in September 2012 that resulted from the pricing decisions of both Pfizer and Flynn. This allowed NRIM to offer a significantly larger financial incentive for pharmacies to select its product than would otherwise have been the case. Substitution which occurs at inflated prices may not be a reliable indicator of substitution that would take place at or near to the competitive price.

- iv. Following the publication in November 2013 of the MHRA Guidance, all pharmacies contacted, including [Pharmacy 3] and [Pharmacy 6], have adhered to the Continuity of Supply principle laid down in that guidance by taking measures to ensure that substitution of the Focal Product with NRIM's Product for stabilised patients does not occur.
- v. NRIM's sales volume data shows that sales of NRIM's Product have not grown materially since November 2013, which is consistent with pharmacies adhering to Continuity of Supply and not substituting the Focal Product with NRIM's Product (or vice versa) for stabilised patients.

4.181 The above list is not intended to be an exhaustive synthesis of all of the evidence set out in section 4.B. However, overall, the CMA considers that the evidence presented and analysed above demonstrates that Tablets, other AEDs and NRIM's Product did not impose a sufficient competitive constraint on the Focal Products to be included in the relevant markets. Accordingly, the CMA finds that the relevant product markets, for the entire Relevant Period, are:

- the manufacture of Pfizer-manufactured phenytoin sodium capsules; and
- the distribution of Pfizer-manufactured phenytoin sodium capsules.

4.182 However, market definition is only a step towards determining whether an undertaking is dominant, not an end in itself. As set out above, evidence on the CMA's file shows that at least some pharmacies – namely, [Pharmacy 3] and [Pharmacy 6] – did substitute NRIM's Product for the Focal Product for some stabilised patients prior to November 2013. Therefore, taking this into account, and given that the purpose of market definition is to provide a framework within which to assess dominance, in section 4.C below the CMA has also assessed whether Pfizer and Flynn held dominant positions by reference to wider alternative candidate relevant markets for the period September 2012 to November 2013 (that is, the part of the Relevant Period prior to the MHRA Guidance). These wider alternative markets, which also include NRIM's Product subsequent to its entry, are:

- the manufacture of phenytoin sodium capsules; and
- the distribution of phenytoin sodium capsules.



4.183 Even if, hypothetically, NRIM did exercise a sufficient competitive constraint to be part of the relevant markets prior to November 2013, the evidence on the CMA's file is clear that such a constraint comes to an end after the publication of the MHRA guidance in November 2013. Therefore the CMA's analysis in section 4.C below of these wider alternatives covers only the period from 24 September 2012 up to the publication of the MHRA guidance in November 2013.<sup>731</sup>

## V. *The relevant geographic market*

4.184 In previous cases in the pharmaceutical sector the relevant geographic market has been defined as national in scope. For example, that conclusion was reached in both the *AstraZeneca*<sup>732</sup> and *Reckitt Benckiser*<sup>733</sup> decisions, on the basis of factors such as differences between countries in the regulatory schemes for authorising and reimbursing medicines, in the marketing strategies used by pharmaceutical companies, in doctors' prescribing practices, and in prices.

4.185 The CMA considers that it is similarly appropriate to define national markets in this case. In particular, the CMA notes that Flynn's ASPs for sales of the Focal Product to wholesalers and pharmacies increased significantly in the UK in September 2012 despite prices of phenytoin sodium capsules in other EU member states remaining stable. As a result, ASPs for the Focal Product have been significantly higher than prices for phenytoin sodium capsules in other EU Member States since September 2012.<sup>734</sup>

4.186 In addition, the CMA considers that the existence of Parallel Imports is not inconsistent with the relevant markets being national in scope.<sup>735</sup> Indeed, Parallel Imports are a response to commercial opportunities which arise due to differences in market conditions between countries.

4.187 In light of the above, the CMA concludes that the relevant geographic markets are national (UK-wide) in scope.

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<sup>731</sup> After November 2013 the relevant markets are the CMA's preferred relevant markets.

<sup>732</sup> See Commission decision Case COMP/A 37.507/F3 *AstraZeneca* (15 June 2005), paragraph 503.

<sup>733</sup> See OFT decision CA98/02/2011 *Reckitt Benckiser* (12 April 2011), paragraphs 4.170 to 4.171.

<sup>734</sup> See documents 00519.3 and 01357.2.

<sup>735</sup> OFT403 Market definition, paragraph 4.6 provides that '*the presence of imports in a territory will not always mean that the market is international*'.

## VI. **Conclusions on market definition**

4.188 On the basis of the evidence presented and analysed above, the CMA finds that the relevant markets in this case are:

- (a) The manufacture of Pfizer-manufactured phenytoin sodium capsules that are distributed in the UK (which includes Parallel Imports as they are distributed in the UK).
- (b) The distribution of Pfizer-manufactured phenytoin sodium capsules in the UK.

4.189 In the alternative, for the period prior to November 2013, the CMA proposes to assess dominance within markets for:

- (a) The manufacture of phenytoin sodium capsules that are distributed in the UK.
- (b) The distribution of phenytoin sodium capsules in the UK.

## C. **Dominance**

### I. **Summary of the CMA's findings on dominance**

4.190 For the reasons set out in this section, the CMA concludes that Pfizer and Flynn have each separately held a dominant position within their respective relevant markets throughout the Relevant Period. In particular:

- (a) Pfizer and Flynn have separately and consistently held **very high market shares** in their respective relevant markets throughout the Relevant Period (see section 4.C.III below).
- (b) Pfizer's and Flynn's **pricing behaviour and financial performance**, as reflected in their respective price-setting decisions and the profitability of their pricing conduct clearly shows they are each able to exercise significant market power (see section 4.C.IV below).
- (c) Pfizer and Flynn have faced only **very weak competitive constraints from Parallel Imports and NRIM** (see section 4.C.V.a below).
- (d) Significant **barriers to entry** prevented other potential entrants from acting as an effective competitive constraint on either Pfizer or Flynn (see section 4.C.V.b below).

(e) The NHS (through, for example, CCGs and the DH) did not hold sufficient countervailing **buyer power** to effectively constrain either Pfizer's or Flynn's conduct (see section 4.C.VI below).

4.191 The CMA has assessed Pfizer's and Flynn's potential dominance during the Relevant Period based on the CMA's preferred market definitions. The CMA has also assessed Pfizer's and Flynn's potential dominance by reference to the CMA's alternative market definitions, which also include NRIM's Product subsequent to its entry, for the period September 2012 to November 2013 (that is, the part of the Relevant Period prior to the MHRA Guidance). The CMA's conclusions that Pfizer and Flynn have each separately held a dominant position within their relevant markets throughout the Relevant Period holds true even on the alternative market definitions.

4.192 As discussed in section 4.B.III.b above, although Pfizer and Flynn operate at different levels of the supply chain, the competitive constraints they face are generally the same. The facts that Pfizer exclusively supplies its phenytoin sodium capsules to Flynn and that Flynn exclusively purchases phenytoin sodium capsules from Pfizer, mean that the downstream constraints faced by Flynn to a significant extent determine the upstream constraints faced by Pfizer. Therefore, the CMA assesses the evidence which is relevant for the assessment of dominance generally rather than considering each level of the supply chain separately. In particular, the CMA has taken careful account of any indirect competitive constraints that may be exerted on Pfizer through competition at the retail level. The implications of this evidence are similar regardless of the level of the supply chain being considered. However, where it is appropriate to distinguish between different levels of the supply chain this is clearly indicated.

## II. ***Legal background***

4.193 The Court of Justice of the EU has defined a dominant position as:

*'a position of economic strength enjoyed by an undertaking which enables it to prevent effective competition being maintained on the relevant market by giving it the power to behave to an appreciable extent independently of its competitors, customers and ultimately of its consumers'.<sup>736</sup>*

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<sup>736</sup> *United Brands*, paragraph 65.

4.194 While a dominant position is characterised as the ability to act independently, the existence of some degree of competition does not preclude a finding that an undertaking holds a dominant position:

*'Such a position does not preclude some competition [...] but enables the undertaking which profits by it, if not to determine, at least to have an appreciable influence on the conditions under which that competition will develop, and in any case to act largely in disregard of it so long as such conduct does not operate to its detriment'.<sup>737</sup>*

4.195 Even the existence of 'lively competition' on a particular market does not rule out the possibility that there is a dominant position on that market since:

*'...the predominant feature of such a position is the ability of the undertaking concerned to act without having to take account of this competition in its market strategy and without for that reason suffering any detrimental effects from such behaviour.'<sup>738</sup>*

4.196 Thus, the fact that there may be competition on the market is a relevant factor but it is not in itself a decisive factor for ascertaining whether a dominant position exists.<sup>739</sup>

4.197 The CMA considers that an undertaking will not be in a dominant position unless it has substantial market power.<sup>740</sup> In assessing the existence and degree of market power the CMA will consider the strength of any competitive constraints that may prevent an undertaking from profitably sustaining prices above competitive levels. Competitive constraints include:<sup>741</sup>

- actual competition from existing competitors in the relevant market;
- potential competition (from new entrants who are not currently active in the relevant market); and

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<sup>737</sup> *Hoffmann-La Roche*, paragraph 39.

<sup>738</sup> *Hoffmann-La Roche*, paragraph 70. See also *France Télécom v Commission* T-340/03, EU:T:2007:22 (*'France Télécom'*), paragraph 101.

<sup>739</sup> *France Télécom*, paragraph 101.

<sup>740</sup> OFT402 *Abuse of a dominant position* (December 2004), paragraph 4.11.

<sup>741</sup> *Assessment of market power guidelines*, paragraphs 3.2 to 3.3.

- buyer power.<sup>742</sup>

4.198 Two of the factors relevant to assessing dominance are market shares and the conduct of the undertakings in question. These factors are discussed in further detail below. Other relevant factors may also include economic regulation<sup>743</sup> and the financial performance of the undertaking in question.<sup>744</sup>

4.199 Market shares can be an important factor in determining whether an undertaking holds a dominant position. The Court of Justice has held that:

*'although the importance of the market shares may vary from one market to another the view may legitimately be taken that very large shares are in themselves, and save in exceptional circumstances, evidence of the existence of a dominant position. An undertaking which has a very large market share and holds it for some time [...] is by virtue of that share in a position of strength which makes it an unavoidable trading partner and which, already because of this secures for it, at the very least during relatively long periods, that freedom of action which is the special feature of a dominant position'.<sup>745</sup>*

4.200 In applying this principle, the Court of Justice has held that market shares in excess of 50% are in themselves, and save in exceptional circumstances, evidence of the existence of a dominant position.<sup>746</sup> A market share of between 70% and 80% is, in itself, a clear indication of the existence of a dominant position.<sup>747</sup>

4.201 The General Court has also held in *AstraZeneca* that the European Commission could not disregard the importance to be attached to a very large market share held throughout the entire relevant period.<sup>748</sup> A decline in

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<sup>742</sup> Assessment of market power guidelines, paragraphs 6.1 to 6.4. See also *National Grid v GEMA* [2009] CAT 14 ('*National Grid*'), [60] and *Genzyme*, [243].

<sup>743</sup> Assessment of market power guidelines, paragraph 3.4.

<sup>744</sup> Assessment of market power guidelines, paragraph 3.5.

<sup>745</sup> *Hoffmann-La Roche*, paragraph 41. See also, for example, *Aberdeen Journals II*, [310].

<sup>746</sup> Judgment in *Akzo v Commission* C-62/86, EU:C:1991:286 ('*Akzo*'), paragraph 60. Undertakings with market shares of below 50% may still be dominant if other relevant factors mean that they still have substantial market power.

<sup>747</sup> Judgments in *Telefónica v Commission* T-336/07, EU:T:2012:172 ('*Telefónica*'), paragraph 150 and *AstraZeneca v Commission* T-321/05, EU:T:2010:266 ('*AstraZeneca*'), paragraph 243.

<sup>748</sup> *AstraZeneca*, paragraph 245.

market shares which are still very large cannot in itself constitute proof of the absence of a dominant position.<sup>749</sup>

- 4.202 In addition, the market shares of other undertakings operating in the same market and how those have changed over time are relevant.<sup>750</sup> An undertaking is more likely to hold a dominant position if its competitors hold relatively weak positions and the undertaking in question has enjoyed a high and stable market share.<sup>751</sup> The existence of a particularly high market share that is much higher than the market shares of competitors constitutes a '*highly significant indicator*' of dominance.<sup>752</sup>
- 4.203 An undertaking which has a very large market share and holds it for some time is '*...by virtue of that share in a position of strength which makes it an unavoidable trading partner...*'.<sup>753</sup> Where those seeking a particular product or service are placed in a position of economic dependence this is characteristic of a dominant position.<sup>754</sup>
- 4.204 The European Courts have held that an undertaking's conduct can also be an indicator of whether it holds a dominant position.<sup>755</sup> The European Commission has followed this approach on a number of occasions,<sup>756</sup> including in *Hilti*:

*'Hilti's commercial behaviour [...] is witness to its ability to act independently of, and without due regard to, either competitors or customers on the relevant markets in question. In addition, Hilti's pricing policy [...] reflects its ability to determine, or at least to have an appreciable influence on the conditions under which competition will develop. This behaviour and its economic consequences would not normally be seen where a company was facing real competitive pressure'.<sup>757</sup>*

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<sup>749</sup> *France Télécom*, paragraph 104.

<sup>750</sup> Assessment of market power guidelines, paragraph 3.3.

<sup>751</sup> Assessment of market power guidelines, paragraph 4.2.

<sup>752</sup> See judgments in *British Airways v Commission* T-219/99, EU:T:2003:343, paragraphs 210 and 211, *AstraZeneca*, paragraph 253 and *Telefónica*, paragraph 163.

<sup>753</sup> *Hoffmann-La Roche*, paragraph 41

<sup>754</sup> Judgments in *British Leyland v Commission* C-226/84, EU:C:1986:421, paragraph 9 and *Deutsche Bahn v Commission* T-229/94, EU:T:1997:155, paragraph 57.

<sup>755</sup> *United Brands*, paragraphs 66 to 68.

<sup>756</sup> See, for example, Commission Decisions (Case No IV/30.698) *ECS/AKZO* OJ [1985] L 374/1, paragraph 56 and (Case E-2/36.041) *PO-Michelin* OJ [2001] L 143/1, paragraphs 197 to 199.

<sup>757</sup> Commission Decision (Case IV.30.787) *Eurofix-Bauco v Hilti* OJ [1998] L 65/19, paragraph 71.

4.205 The European Commission's finding was upheld by the EU's General Court which found, while assessing dominance, that:

*'as the Commission rightly contended, it is highly improbable in practice that a non-dominant supplier will act as Hilti did, since effective competition will normally ensure that the adverse consequences of such behaviour outweigh any benefits.'*<sup>758</sup>

4.206 An undertaking's pricing conduct and financial performance is a relevant factor when assessing market power:

*'An undertaking's conduct in a market or its financial performance may provide evidence that it possesses market power. Depending on other available evidence, it might, for example, be reasonable to infer that an undertaking possesses market power from evidence that it has set prices consistently above an appropriate measure of costs, or persistently earned an excessive rate of profit.'*<sup>759</sup>

4.207 For example, the European Commission found in *Napier-Brown/British Sugar* that:

*'On 1 July 1986 BS [British Sugar] increased its retail sugar price to all its clients by £10 per tonne. BS subsequently made a further increase in its retail sugar price by £10 per tonne on 20 October 1986. BS has been able to maintain these price rises, and the other producers of retail sugar have also increased their price by similar amounts.*

*This indicates that BS has 'the power to determine prices [...] for a significant part of the products in question', and furthermore has 'the power to behave to an appreciable extent independently of its competitors, customers and ultimately of the consumers'*<sup>760</sup>

4.208 An undertaking with significant market power may not be dominant if its customer has a sufficient degree of countervailing buyer power to effectively constrain the undertakings conduct. Whether a customer has countervailing buyer power is not a binary question. As the CAT set out in *National Grid*:

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<sup>758</sup> Judgment in *Hilti AG v Commission* T-30/89, EU:T:1991:70, paragraph 93.

<sup>759</sup> Assessment of market power guidelines, paragraph 6.5.

<sup>760</sup> See Commission Decision (Case No IV/30.178) *Napier Brown — British Sugar*, OJ [1988] L 284/41, paragraph 55.

*'[T]he right question is not the binary one of whether CBP [countervailing buyer power] exists or not. In other words, it is not enough to ask whether there is CBP, and if so to hold that there cannot be [dominance]. CBP is the power of counterparties to offset the powers of the party whose allegedly superior powers are under consideration, and the important question is what degree of CBP is there, and (bearing in mind all the circumstances) does it operate to a sufficient extent so as to mean that there is no [dominance]? CBP is not an absolute concept in terms of its strength. It is a concept which embodies a possible range of strengths. In any case where it is relevant, the relevant question is likely to be not whether there is CBP or not, but whether there is any CBP, and if so how much and what effect does it have.*

*The question to be addressed in this context is thus not just the presence or absence of CBP on the part of British Gas, but the degree of such CBP and the extent to which it operated as a constraint on National Grid's ability to exert market power.<sup>761</sup>*

4.209 To be applicable, Article 102 TFEU requires that an undertaking hold a dominant position within the internal market or a substantial part of it. A dominant position covering the entire territory of a single Member State is sufficiently large in size to be considered a dominant position in a substantial part of the internal market within the meaning of Article 102 TFEU.<sup>762</sup>

### III. **Market shares**

#### a. **Pfizer's share of the relevant markets**

4.210 This section sets out Pfizer's market shares on both the CMA's preferred market definition and the alternative market definition which are respectively:

- the market for the manufacture of Pfizer-manufactured phenytoin sodium capsules that are distributed in the UK (which includes Parallel Imports as they are distributed in the UK); and

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<sup>761</sup> *National Grid*, [60].

<sup>762</sup> See paragraph 96 of the Commission's Guidelines on the effect on trade concept contained in Articles 81 and 82 of the Treaty, OJ C 101, 27.4.2004, p.81 to 96.



- for the period between September 2012 and November 2013 only, the market for the manufacture of phenytoin sodium capsules that are distributed in the UK.<sup>763</sup>

4.211 Pfizer has held a market share of **100%** on the CMA's **preferred** market definition throughout the Relevant Period reflecting the fact it is the only manufacturer of Pfizer-manufactured phenytoin sodium capsules that are distributed in the UK.<sup>764</sup>

4.212 Table 4.4 below sets out Pfizer's market shares on the CMA's alternative market definition.<sup>765</sup> The table shows that Pfizer supplied in excess of **80%** on the CMA's **alternative** market definition of all phenytoin sodium capsules supplied to the UK. This is regardless of whether shares are assessed on a share of capsules or DDD basis. Market shares at these levels provide a clear indication of the existence of a dominant position without further analysis.<sup>766</sup> Moreover, Table 4.4 also shows that there was a considerable market-share gap to Pfizer's only competitor on the alternative market (NRIM) which held a [10% - 20%] market share based on volume of capsules supplied and [10% - 20%] based on DDDs. This significant market share gap is, in itself, a highly significant indicator of dominance.

**Table 4.4: Pfizer's and NRIM's market shares on the CMA's alternative market definition between September 2012 and November 2013.**

<i>Period</i>	<i>Share of capsules</i>		<i>Share of DDDs</i>	
	<i>Pfizer</i>	<i>NRIM</i>	<i>Pfizer</i>	<i>NRIM</i>
September 2012 to March 2013	100%	N/A	100%	N/A

<sup>763</sup> After November 2013 the relevant markets are the CMA's preferred relevant markets.

<sup>764</sup> Pfizer has submitted that the CMA's analysis its market power at the wholesale level is cursory and the CMA's description of Pfizer as a 'monopoly' supplier fails to take account of the direct and indirect constraints it faces on the downstream market (see for example document 01622.2, paragraphs 271 to 274). However, as set out at section 4.C.I above and in the analysis below, the CMA recognises that constraints on Flynn's market power do indirectly constrain Pfizer's market power and has taken this into account when assessing whether Pfizer is dominant. The CMA has also taken account of Pfizer's arguments regarding its market power vis-à-vis Flynn directly in section 4.C.VI.i below.

<sup>765</sup> After November 2013 the relevant markets are the CMA's preferred relevant markets.

<sup>766</sup> *Hoffman-La Roche*, paragraphs 53-56

April to November 2013	[80% - 90%]	[10% - 20%]	[80% - 90%]	[10% - 20%]
Sources: IMS data provided by Pfizer (document 02129.4). Pfizer: document 02129.2 NRIM: documents 00512.2, 00721.3, 00896.2, 00847.2 and 01161.2 *Percentages may sum to more than 100% due to rounding.				

**b. Flynn's share of the relevant markets**

4.213 Tables 4.5 and 4.6 below set out Flynn's market shares on both the CMA's preferred and alternative markets which are respectively:

- the market for the distribution of Pfizer-manufactured phenytoin sodium capsules that are distributed in the UK (which includes Parallel Imports as they are distributed in the UK); and
- for the period between September 2012 and November 2013 only, the market for the distribution of phenytoin sodium capsules that are distributed in the UK.<sup>767</sup>

4.214 Table 4.5 below sets out the annual market shares for Flynn and Parallel Imports on the CMA's preferred market definition and Table 4.6 below sets out the market shares for Flynn, Parallel Imports and NRIM's Product on the CMA's alternative market definition.

4.215 These tables show that Flynn has held a market share comfortably in excess of 60% throughout the Relevant Period on both the CMA's preferred market definition and, when relevant, the alternative market definition. This is regardless of whether shares are assessed on a capsule or DDD basis.

4.216 On the CMA's **preferred** market definition, Flynn supplied between **[60% - 70%]** and **[80% - 90%]** of all Pfizer-manufactured phenytoin sodium capsules based on number of capsules and between **[60% - 70%]** and **[80% - 90%]** based on DDD over the Relevant Period, as shown by table 4.5. Market shares at these levels provide a clear indication of the existence of a dominant position.

4.217 This is all the more so when the fact that the remaining share of the market was accounted for by Parallel Imports is taken into account. The market

<sup>767</sup> After November 2013 the relevant markets are the CMA's preferred relevant markets.

share gained by Parallel Imports is likely to overestimate the competitive constraint exerted on Flynn. This is because Parallel Imports are relatively scarce and are also likely to be supplied by several companies rather than just one.<sup>768</sup> There are a total of 99 licences held by 24 companies to import Pfizer-manufactured phenytoin sodium capsules.<sup>769</sup> These licence holders will compete for a limited volume of capsules that are available at a given time with stock reported to be frequently auctioned.<sup>770</sup> As such the individual market shares of each undertaking would be lower than the aggregate figure presented in the table. The competitive constraint provided by Parallel Imports on Flynn is discussed further in section 4.C.V.a.i below.

**Table 4.5: Flynn’s and Parallel Importer’s market shares on the CMA’s preferred market definition between September 2012 and June 2016.**

Period	Share of capsules		Share of DDD	
	Flynn	Parallel Imports	Flynn	Parallel Imports
2012 (September-December)	[80% - 90%]	[10% - 20%]	[80% - 90%]	[10% - 20%]
2013	[80% - 90%]	[10% - 20%]	[80% - 90%]	[10% - 20%]
2014	[60% - 70%]	[30% - 40%]	[60% - 70%]	[30% - 40%]
2015	[60% - 70%]	[30% - 40%]	[60% - 70%]	[30% - 40%]
2016 (January-June)	[60% - 70%]	[30% - 40%]	[60% - 70%]	[30% - 40%]

Sources: IMS data provided by Pfizer (document 02129.4).  
Flynn: documents 00505.22, 00872.3, 00915.1, 01148.2, 01148.3, 01293.2, 01839.13 and 02115.2  
\*Percentages may sum to more than 100% due to rounding.

4.218 On the CMA’s **alternative** market definition (which applies only to the period from September 2012 to November 2013), Flynn supplied **[80% - 90%]** of all phenytoin sodium capsules distributed in the UK in the period from September 2012 to April 2013 based on number of capsules and **[80% - 90%]** based on DDDs and **[70% - 80%]** (based on both number of capsules and DDDs) in the period April 2013 to November 2013

<sup>768</sup> See Commission’s decision in case COMP/A.37.507/F3 - AstraZeneca paragraph 529.

<sup>769</sup> See documents 01780.1, 01780.2 and 01780.3.

<sup>770</sup> See section 4.C.V.a.i5

**Table 4.6: Flynn’s, Parallel Importer’s and NRIM’s market shares on the CMA’s alternative market definition between September 2012 and November 2013.**

Period	Share of capsules			Share of DDDs		
	Flynn	Parallel Imports	NRIM	Flynn	Parallel Imports	NRIM
September 2012 to March 2013	[80% - 90%]	[10% -20%]	N/A	[80% - 90%]	[10% -20%]	N/A
April 2013 to November 2013	[70% - 80%]	[10% -20%]	[10 - 20]%	[70% - 80%]	[10% -20%]	[10% - 20%]

Sources: IMS data provided by Pfizer (document 02129.4).  
Flynn: documents 00505.22, 00872.3, 00915.1, 01148.2, 01148.3 and 01293.2  
NRIM: documents 00512.2, 00721.3, 00896.2, 00847.2 and 01161.2  
\*Percentages may sum to more than 100% due to rounding.

**c. Conclusions on market shares**

- 4.219 The evidence set out above demonstrates that Pfizer and Flynn each have market shares persistently and significantly in excess of 50% in their respective Relevant Markets (howsoever defined). The Court of Justice has previously found that, save in exceptional circumstances, market shares of 50% are evidence of the existence of a dominant position.<sup>771</sup>
- 4.220 Pfizer’s market shares comfortably exceed [70% - 80%] on both the CMA’s preferred and alternative market definitions and the General Court has found market shares at this level to be a clear indication of the existence of a dominant position.<sup>772</sup>
- 4.221 Flynn’s market shares are at least [60% - 70%] throughout the Relevant Period on both the CMA’s preferred and alternative market definitions, and prior to the introduction of the MRHA guidance in November 2013 exceeded [70% - 80%] even when calculated on the basis of the CMA’s alternative market definition. The CMA considers that market shares at this level are a clear indication of the existence of a dominant position, especially when the

<sup>771</sup> Akzo, paragraph 60.

<sup>772</sup> Telefónica, paragraph 150 and AstraZeneca, paragraph 243.

market share gap to the competition is considered. As set out in the remainder of this section, the CMA has found that other evidence supports a finding that Pfizer and Flynn each hold dominant positions in the relevant markets and that there are no exceptional circumstances that would justify a conclusion that either Pfizer or Flynn were not dominant in their respective relevant markets.

#### IV. ***Pricing behaviour and financial performance***

4.222 Pfizer and Flynn have both been able to consistently set prices significantly above appropriate measures of cost plus a reasonable rate of return and have both persistently earned an excessive rate of profit (as shown in section 5).<sup>773</sup> The CMA considers that this provides cogent evidence that each of Pfizer and Flynn have been able to act independently of their competitors, customers and consumers in their respective relevant markets throughout the Relevant Period and that they have each been able to exercise significant market power.<sup>774</sup> This is all the more so when this behaviour is considered in conjunction with the fact that both Parties have been able to maintain very high market shares over a prolonged period of time.

4.223 As shown in section 3.D.III and 3.D.IV above, in particular:

(a) Pfizer's ASPs for the four capsule strengths during the Relevant Period were [at least 488%] higher than its pre-September 2012 ASPs; and

(b) Flynn's ASPs for the four capsule strengths during the Relevant Period were [at least 2,015%] higher than Pfizer's pre-September 2012 ASPs.<sup>775</sup>

4.224 Further, Pfizer's Prices and Flynn's Prices have been, throughout the Relevant Period, consistently and significantly above an appropriate measure of their respective costs plus a reasonable rate of return. As is set out in more detail in section 5.C.IV and 5.C.V:

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<sup>773</sup> Assessment of market power guidelines, paragraph 6.5.

<sup>774</sup> See the Commission's decision (Case No IV.30.787) *Eurofix-Bauco v Hilti* OJ [1998]L 65/19 , paragraph 71 and the judgment in *Hilti AG v Commission* T-30/89, EU:T:1991:70, paragraph 93. See also *Enforcement Priorities Guidance*, paragraph 11.

<sup>775</sup> See section 3.D above. As set out in Tables 3.5 and 3.7.

- (a) Pfizer's Prices during the Relevant Period, on average, exceeded Pfizer's costs, including a reasonable rate of return, by between 29% and 705% depending on capsule strength;
- (b) Pfizer's Prices for its 100mg capsules, which account for [X] of its sales volumes of phenytoin sodium capsules over the Relevant Period, exceeded Pfizer's costs, including a reasonable rate of return, by an average of 705% during the Relevant Period;
- (c) Flynn's Prices during the Relevant Period, on average, exceeded Flynn's costs, including a reasonable rate of return, by between 31% and 133% depending on capsule strength;
- (d) Flynn's Prices for its 100mg capsules, which account for [X] of its sales volumes of phenytoin sodium capsules, exceeded Flynn's costs, including a reasonable rate of return, by an average of 31% (that is, [£11 - £20.99] per pack) during the Relevant Period.<sup>776</sup>

4.225 These high returns are significantly above those which would be expected to prevail in a competitive market characterised by similar levels of risk and do not represent a return on previous innovation.<sup>777</sup> Pfizer's and Flynn's respective pricing and profitability clearly shows that that each of them has the '*power to behave to an appreciable extent independently of its competitors, its customers and ultimately of consumers*'.<sup>778</sup>

## V. **Assessment of possible constraints on dominance**

4.226 The CMA considers that the evidence it has set out regarding Pfizer's and Flynn's market shares and pricing behaviour individually and collectively demonstrate that Pfizer and Flynn have been able to act independently of their competitors and customers to an appreciable extent and therefore have held and continue to hold dominant positions in their respective relevant markets (howsoever defined) without any further analysis being necessary.

4.227 However, for completeness, the CMA has also assessed the level of competitive constraint that Pfizer and Flynn each faced from existing and potential competition. This assessment, which is set out below, further supports and reinforces the CMA's conclusion that Pfizer and Flynn have

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<sup>776</sup> See sections 5.C.IV and 5.C.V

<sup>777</sup> Assessment of market power, paragraph 6.6

<sup>778</sup> *United Brands*, paragraph 65.

held dominant positions on their respective relevant markets. In particular, this assessment demonstrates that there are no exceptional circumstances to suggest that the market shares identified above are not a strong indicator of both Pfizer and Flynn holding dominant positions in their respective relevant markets.

**a. *Analysis of the constraints imposed by Parallel Imports and NRI***

**i. *Parallel Imports***

4.228 Parallel Imports could potentially constrain Flynn directly (through lost sales) and Pfizer indirectly (through having to reduce the price it charges Flynn to meet any competition).

4.229 As set out in section 3.D.V, Pfizer also supplies phenytoin sodium capsules to a small number of other EU Member States<sup>779</sup> at prices which are significantly lower than in the UK.

4.230 However, the evidence in this section demonstrates that the supply of Parallel Imports of Pfizer-manufactured phenytoin capsules was limited and also not sufficiently reliable to constrain either Pfizer's dominance or Flynn's dominance in their respective relevant markets.

4.231 In fact, in line with the European Commission's decision in *AstraZeneca*, the CMA considers that the evidence in this section demonstrates that the market shares achieved by Parallel Imports in the Relevant Period overstates their actual market power for the reasons set out in section 4.C.III.b above.<sup>780</sup>

4.232 Parallel importers are entirely dependent on whether, and to what extent, Pfizer supplied its phenytoin sodium capsules in lower priced countries.<sup>781</sup> In this respect, the volume of 25mg, 50mg and 300mg capsules distributed in other Member States is very small relative to UK volumes so Parallel Imports are likely to be low.<sup>782</sup> Although 100mg capsules are more widely available outside of the UK, the UK accounts for a significant proportion of the total

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<sup>779</sup> These are Belgium, Greece, Ireland, Spain, Sweden, Cyprus and Malta.

<sup>780</sup> See Commission's decision in case COMP/A.37.507/F3 - *AstraZeneca* paragraph 529.

<sup>781</sup> See Commission's decision in case COMP/A.37.507/F3 - *AstraZeneca*, paragraph 529

<sup>782</sup> The CMA notes that several parallel import licences have been granted in respect of 25, 50 and 300mg Pfizer-manufactured phenytoin capsules indicating that there is likely to be some parallel trade in respect of these strengths

volume distributed, meaning the stock available for parallel importation is also likely to be relatively limited.<sup>783</sup>

- 4.233 Contemporaneous documentary evidence demonstrates that parallel importers did struggle to get sufficient supply of stock following the price increases of September 2012, with stock being put up for auction. A '*Phenytoin Market Status*' report prepared by Flynn in advance of a meeting with Pfizer on 30 January 2014 stated:

*'Initially the pricing for the PI [Parallel Imports] had been very competitive, but, due to more licenses [sic] being granted but not the stock available, stock is effectively put up for "auction" on a monthly basis.'*<sup>784</sup>

- 4.234 The limited volumes of Parallel Imports has resulted in pharmacies viewing them as an unreliable source of Pfizer-manufactured phenytoin sodium capsules.
- 4.235 Four out of the ten major pharmacy groups<sup>785</sup> informed the CMA that, while they had purchased Parallel Imports in the past, they had ceased doing so because of the lack of reliable supply. Three of these pharmacy groups ([Pharmacy 4], [Pharmacy 10] and [Pharmacy 1]) ceased purchasing Parallel Imports in 2012 and one ([Pharmacy 3]<sup>786</sup>) ceased purchasing them in 2013.
- 4.236 A further three of the major pharmacy groups informed the CMA that, while they continued to purchase Parallel Imports, the volumes available are sporadic and/or they cannot rely on volumes being available. In particular:

- (a) [Pharmacy 8] stated that:

*'Pfizer Epanutin can still be obtained as a PI, however supply is limited and subject to market forces and is therefore totally unreliable';*<sup>787</sup>

- (b) [Pharmacy 6] stated that:

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<sup>783</sup> See documents 00145.27 and 00141.74

<sup>784</sup> See document 00505.40, page 2.

<sup>785</sup> See section 4.B.IV.b.iv above for further details on the pharmacies surveyed by the CMA.

<sup>786</sup> [Pharmacy 3] explained that '*during August 2013, [Pharmacy 3] was unable to secure parallel imported Pfizer Epanutin (from Spain) and supply ceased entirely shortly after that*' (see document 00661.4, page 5).

<sup>787</sup> See document 00657.1, page 3.



*'When Epanutin was discontinued by Pfizer [in the UK], its availability became limited and eventually [Wholesaler 1] was unable to secure sufficient stock for its requirements';<sup>788</sup> and*

(c) [Pharmacy 5] stated that:

*'We have not been able to source all of our requirement through parallel import products'.<sup>789</sup>*

4.237 The decisions by major pharmaceutical chains to cease purchasing Parallel Imports and the fact that Parallel Imports are regarded as an unreliable source of supply, supports the CMA's conclusion that Parallel Imports were not a sufficient constraint on Flynn's conduct (directly) or Pfizer's conduct (indirectly) such that they did not hold dominant positions on their respective relevant markets.

4.238 Contemporaneous internal documents confirm that Flynn's pricing behaviour was not constrained by Parallel Imports. Minutes from a Flynn Board meeting on 5 March 2013 (six months after the higher prices to pharmacies and wholesalers were introduced) shows that, despite an anticipated increase in Parallel Imports of 100mg capsules, Flynn did not consider it necessary to adjust its prices:

*'Phenytoin. [...] The budget for 2014 assumes a 20% decline in volume on 100mg strength only that could be the subject of P.I. [Parallel Imports], however the prices have been maintained at the same level as launch.'<sup>790</sup>*

4.239 Similarly the note of an internal Flynn 'Sales and Operational Meeting' on 20 May 2013 indicated that Parallel Imports had impacted Flynn's sales volumes to some degree. However, there is no evidence to indicate that this prompted Flynn to consider lowering their respective prices and indeed, the evidence has demonstrated that Pfizer and Flynn have maintained prices significantly above their costs, plus a reasonable rate of return, throughout the Relevant Period:

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<sup>788</sup> See document 00669.1, page 3.

<sup>789</sup> See document 00662.1, page 2.

<sup>790</sup> See document 00145.825.

*'PI [Parallel Imports] is hitting sales of the 100mg. Forecast to be dropped to 70% of market.'*<sup>791</sup>

4.240 The CMA considers that these documents (especially when considered in conjunction with the market share evidence and pricing behaviour evidence set out above) further demonstrate that Flynn was able to act independently of its competitors to an appreciable extent. Similarly, it follows that as Flynn was not directly sufficiently constrained by Parallel Imports, Pfizer would not have been indirectly constrained by Parallel Imports.

4.241 Contemporaneous documentary evidence demonstrates that both Pfizer and Flynn considered the possible impact of Parallel Imports when considering the potential for implementing and sustaining significant increases in the price of phenytoin sodium capsules.

4.242 A frequently asked questions paper accompanying a Flynn presentation to Pfizer on 1 July 2010 explained that:

*'There is currently a level of PI [Parallel Imports] which is limited by the availability of stock. No more stock would be available to importers.'*<sup>792</sup>

4.243 The July 2010 presentation stated:

*'How much could PIs impact sales?*

*Should be no impact on 25mg, 50mg and 300mg in UK. These alone could be worth £15m*

*Even if 50% of sales of 100 mg were lost to PI [Parallel Imports] the upside would still be > £20m.'*<sup>793</sup>

4.244 This point was also later included in an internal Pfizer presentation from December 2010, entitled '*Epanutin® proposal For UKMF DEC-2010*'.<sup>794</sup>

4.245 Accordingly, the presentations of July 2010 and December 2010 demonstrate that Pfizer and Flynn did not expect any significant level of constraint from Parallel Imports on the proposed price increases for 25mg,

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<sup>791</sup> See document 00145.944.

<sup>792</sup> See document 00145.34, page 7.

<sup>793</sup> See documents 00145.27, slide 11, and 00141.74.

<sup>794</sup> See document 00141.97.

50mg and 300mg. This is consistent with the low volumes of these capsule strengths traded in other Member States.

4.246 It is clear that Pfizer and Flynn anticipated greater potential for competition from Parallel Imports in respect of the 100mg strength capsule, but they did not expect the constraint to be of a sufficient level to impact on each of their pricing decisions. Based on the pricing proposals in these presentations, both Parties anticipated making significant profits when compared to the pre-September 2012 price even if they lost 50% of their sales of 100mg capsules. It is notable that the Drug Tariff price introduced in October 2012 for 100mg capsules as a result of Pfizer's and Flynn's pricing decisions was 50% higher than the price levels used in the presentations.<sup>795</sup> This demonstrates that, having considered the potential constraint from Parallel Imports at a certain price point, both Parties introduced significantly higher ASPs clearly demonstrating that both believed they could act independently of this potential competitive constraint to an appreciable extent.

Conclusion on the constraint imposed by Parallel Imports

4.247 In conclusion, the CMA considers that neither Flynn nor Pfizer were sufficiently constrained by Parallel Imports at any point over the Relevant Period to prevent them from each holding a dominant position in their respective relevant markets. It is clear that both Parties have been able to behave independently of this potential competitive constraint to an appreciable extent.

ii. *NRIM's Product*

4.248 In section 4.B above, the CMA concluded that NRIM's Product did not provide a sufficient competitive constraint on either Pfizer or Flynn to fall within the CMA's preferred market definitions during the Relevant Period. It follows that NRIM's Product was also not capable of preventing Pfizer or Flynn from holding dominant positions on those markets.

4.249 However, the CMA also considered whether or not NRIM's Product provided a sufficient constraint on Pfizer and Flynn to prevent them from holding dominant positions on alternative markets for the manufacture and distribution of phenytoin sodium capsules in the UK in the period September

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<sup>795</sup> The presentations considered a price of £15 for 28 100mg phenytoin sodium capsules (or £45 for a pack of 84 capsules) (see documents 00145.27, 00141.74 and 00141.97). The Drug Tariff price for a pack of 84 100mg phenytoin sodium capsules increased to £67.50 with effect from October 2012, which is 50% higher than £45 per pack.

2012 to November 2013 only (that is, the part of the Relevant Period prior to the publication of the MHRA Guidance).

- 4.250 The assessment of Pfizer's and Flynn's pricing behaviour set out in section 4.B.IV.b.iii demonstrates that any competitive constraint NRIM exerted was weak and not sufficient to constrain the Parties' conduct in their respective relevant markets. As the CMA finds in sections 5.C.IV and 5.C.V, despite the presence of NRIM's Product, Pfizer and Flynn both maintained prices for all strengths of Pfizer-manufactured phenytoin sodium capsules at levels consistently and significantly above their respective costs and a reasonable rate of return.
- 4.251 As set out in detail in section 4.B.IV.b.iv, the evidence additionally demonstrates that, in the period April 2013 to November 2013, the majority of the pharmacy groups contacted by the CMA were unwilling to switch to NRIM's Product, with the majority following the principle of Continuity of Supply. As set out at section 4.B.IV.b.iv, [Pharmacy 3] and [Pharmacy 6] were the only pharmacy groups that switched significant numbers of patients to NRIM's Product and accounted for [X] of NRIM's sales between April 2013 and November 2013.<sup>796</sup> The fact that the other major pharmacy groups, including the majority of those that were not surveyed, did not switch patients to NRIM's Product, despite NRIM's Product being significantly cheaper to dispense than Flynn's 100mg Product, limited the extent to which NRIM's Product could provide a sufficient constraint to prevent the Parties from each holding a dominant position in their respective relevant markets.
- 4.252 As set out in section 4.B.IV.b.iv, after November 2013 [Pharmacy 3] and [Pharmacy 6] changed their dispensing practice and sought to maintain Continuity of Supply. As a result, NRIM has not significantly expanded its sales volumes since November 2013 and its volumes stabilised, as shown by Figure 4.5.<sup>797</sup>

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<sup>796</sup> Sales data from [Wholesaler 1] and [Wholesaler 2] show that [Pharmacy 3] and [Pharmacy 6] accounted for approximately [X] of their sales of NRIM's Product up to November 2013. The remaining [X] is made up of sales to hospitals and other pharmacies.

<sup>797</sup> Consequently the CMA has found that NRIM was not within the preferred relevant markets during the Relevant Period. Flynn has submitted that NRIM continued to gain market share and exercise a competitive constraint post November 2013. The CMA has considered and rejected these representations in section 4.B.IV.b.v above.

Conclusion on constraint from imposed by NRIM's Product

4.253 In conclusion, the CMA considers that NRIM's Product has imposed, at most, only a limited constraint on Pfizer's and Flynn's conduct which was not at any point during the Relevant Period sufficient to prevent Pfizer or Flynn from holding dominant positions in their respective relevant markets. It is clear that both Parties have been able to behave independently of this potential competitive constraint to an appreciable extent.

iii. *Conclusion on existing competitors*

4.254 On the basis of the evidence assessed above, the CMA concludes that competitive constraints from existing competitors were not sufficient to prevent Pfizer or Flynn from holding dominant positions in their respective relevant markets at any point over the Relevant Period. It is clear that both Parties have been able to behave independently of this potential competitive constraint to an appreciable extent.

b. **Potential competition**

4.255 Where barriers to entry are low it might not be profitable for an undertaking to sustain prices above competitive levels because this would attract entry which would drive the price down.<sup>798</sup> In order for potential competition to effectively constrain an undertaking, entry would need to have the potential to occur on a timely basis.

4.256 The evidence demonstrates that potential competition has not acted, and would be extremely unlikely to act, as a sufficient constraint on either Pfizer's conduct or Flynn's conduct such that they were not dominant on their respective relevant markets (howsoever defined).

4.257 The evidence presented above on Pfizer's and Flynn's pricing and financial behaviour demonstrates that neither Pfizer nor Flynn have been sufficiently constrained by the threat of entry.<sup>799</sup> Similarly, Pfizer and Flynn are unlikely to be constrained in the future by potential entry as any potential entrant would need to incur significant costs and risks before it would be able to launch a new phenytoin sodium product and then would face significant

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<sup>798</sup> Assessment of market power guidelines, paragraph 5.2.

<sup>799</sup> Documents 00141.191, 02060.1 and 00145.312 shows that Flynn and Pfizer were both aware that NRIM had been granted an MA for NRIM's Product before September 2012. However, this threat of entry did not sufficiently constrain Pfizer or Flynn's conduct.

challenges in finding customers meaning there is very limited incentive to enter.

- 4.258 The Drug Tariff price (the publicly available price that any potential entrant would be aware of) has been significantly higher during the Relevant Period compared to its level prior to September 2012 and both Pfizer and Flynn have profitably sustained prices significantly above their respective cost plus levels throughout this time. The existence of such high profit levels provides strong evidence that neither Pfizer nor Flynn were sufficiently constrained by the threat of entry to prevent each of them from holding a dominant position in their respective markets. In addition, the high profit levels have not prompted the entry of any new phenytoin sodium capsule products in the four years since Pfizer and Flynn implemented their substantial price increases and this fact alone shows that no timely entry has occurred.<sup>800</sup> Moreover, NRIM did launch an alternative 100mg phenytoin sodium capsule during the Relevant Period and it has been unable to effectively constrain either Pfizer's or Flynn's ability to profitably maintain prices significantly above the competitive level (before, or indeed after, its entry).
- 4.259 The scope for potential competition having constrained Pfizer's dominance and Flynn's dominance on the CMA's preferred markets is very limited. This is because any potential entrant to these markets would have faced absolute barriers to entry throughout the Relevant Period. At the manufacturing level, only Pfizer can manufacture Pfizer-manufactured phenytoin sodium capsules<sup>801</sup> and, at the distribution level, the exclusive supply clause in the Exclusive Supply Agreement means that only Flynn is permitted to distribute such capsules in the UK.<sup>802</sup> As such, there is no scope for new entry into the respective markets as a manufacturer or authorised distributor of Pfizer-manufactured phenytoin sodium capsules.<sup>803</sup>
- 4.260 Even on the CMA's alternative market definition, the scope for entry was limited. Even prior to the publication of the MHRA Guidance in November 2013, the majority of pharmacies in the UK did not switch patients to NRIM's

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<sup>800</sup> The CMA notes that both NRIM and another company began to develop their products prior to the increase in prices in September 2012 (in 2006 and 2010 respectively).

<sup>801</sup> See section 4.B.IV.d. The CMA recognises that this represents a very narrow product market, however, the CMA considers this appropriate based on the specific circumstances of this case and the products involved.

<sup>802</sup> See document 00145.738, Clause 2.2.

<sup>803</sup> A Parallel Importer will need a Parallel Import Licence to import Pfizer-manufactured phenytoin sodium capsules into the UK.

Product with many confirming that they followed the principle of Continuity of Supply as set out in pre-existing clinical guidance.

- 4.261 Although it is not impossible that a company might develop and launch a new phenytoin sodium capsule, the prospect of that launch being commercially successful and capable of exercising any form of meaningful or timely constraint on Pfizer and Flynn is (and was) limited.
- 4.262 Since phenytoin sodium capsules are not recommended as a first-line or second-line treatment<sup>804</sup> and pharmacies practise Continuity of Supply, any potential entrant would clearly face significant challenges in attracting new customers. A new entrant's ability to gain sales would depend on pharmacies being willing to stock at least two manufacturers' capsules and on its product being dispensed to patients newly diagnosed with epilepsy or to patients that are switched to a phenytoin-based AED. As set out in section 3.B.II.e, this patient group represents a low proportion of overall demand in the declining market for phenytoin sodium capsules.
- 4.263 In addition, any potential entrant would face considerable sunk costs and risks in developing a phenytoin sodium capsule product with no guarantee of success and this clearly further reduces any further incentives to enter.<sup>805</sup>
- 4.264 Sunk costs would include development costs and costs of the regulatory procedure required to gain a UK MA. The regulatory procedure itself would be more costly and stringent for products with a NTI (such as phenytoin sodium capsules) when compared to usual testing requirements.<sup>806</sup> The MHRA has estimated that once it has received a dossier of evidence from an applicant *[i]t would be expected to take about 15 – 18 months to obtain the marketing authorisation (MA), but this can vary considerably depending on the quality of the data and the speed of the applicant in responding to questions'*<sup>807</sup> Additionally, the MHRA requires separate applications for MAs for each capsule strength.

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<sup>804</sup> See section 3.B.II.e

<sup>805</sup> For example, the CMA understands that NRIM has lost approximately over £500,000 in its unsuccessful efforts to develop a phenytoin sodium tablet product (see document 00474.1, paragraph 13).

<sup>806</sup> During a meeting with the CMA, NRIM explained that the testing procedure for a product with an NTI was stricter compared to a product without an NTI. In general, with regards to the C-Max measure, the results for a product with an NTI need to be within a band of 90-110 compared to a band of 80-120 for a product without an NTI (see document 00474.1 paragraph 20).

<sup>807</sup> See document 00248.2, question 4.

- 4.265 These regulatory requirements would lengthen the timeframe over which successful development and market entry could be achieved and obviously limit the strength of any constraint on Pfizer and Flynn.
- 4.266 For example, NRIM's Product took over six years and cost approximately £1 million<sup>808</sup> and NRIM informed the CMA that this was double the length of time it would usually expect the process to take.<sup>809</sup> NRIM also informed the CMA that the MHRA Guidance was the key factor in its decision to discontinue development of the 25mg, 50mg and 300mg capsule strengths demonstrating that the scope for potential competition to act as a constraint after the publication of the MHRA Guidance is limited.<sup>810</sup>
- 4.267 Additionally, a further pharmaceutical company started developing a phenytoin sodium capsule product in December 2010. However, four and a half years after commencing this development the company in question had only managed to successfully develop a 300mg capsule, and did not subsequently receive a UK MA for that product.<sup>811</sup> The company in question later informed the CMA that even if it had obtained an MA, the product '*will not be prescribed by doctors thus rendering commercialisation impossible*'.<sup>812</sup>

iv. *Conclusion on potential competition*

- 4.268 In light of the above, the CMA concludes that any constraint imposed by potential competition was very limited and was not at any point sufficient to prevent Pfizer or Flynn from holding dominant positions in their respective relevant markets. It is clear that both Parties have been able to behave independently of this potential competitive constraint to an appreciable extent.

## VI. **Countervailing buyer power**

- 4.269 The strength of buyers and the structure of the buyers' side of the market may constrain the market power of a seller.<sup>813</sup>

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<sup>808</sup> See document 00512.2, page 22.

<sup>809</sup> See document 00474.1, paragraph 14.

<sup>810</sup> See document 00896.2, question 1.v.

<sup>811</sup> See document 00898.1. It is not clear whether the company withdrew its application or an MA was not granted by the MHRA.

<sup>812</sup> See document 00898.1, question 11.

<sup>813</sup> Assessment of market power guidelines, at paragraph 6.1.



4.270 The relevant question is not just the presence or absence of countervailing buyer power, but the degree of such countervailing buyer power and the extent to which it operated as a constraint on an undertaking's ability to exert market power.<sup>814</sup>

4.271 In this context the end customer is the NHS, and in particular the CCGs, who must pay for the medicines prescribed to patients. The CMA sets out its analysis of whether the NHS (or a constituent part of the NHS) has sufficient countervailing buyer power to negate each of the Parties' dominant positions in their respective relevant markets by reference to the following sections:

- (a) The structure and purpose of the NHS;
- (b) The ability of the NHS to exercise choice (primarily in relation to the CCGs); and
- (c) The NHS's statutory powers (primarily in relation to the Secretary of State and the DH).

**a. *The structure and purpose of the NHS***

4.272 The question of whether national health authorities have sufficient buyer power to constrain the high degree of market power that can exist in pharmaceutical markets has been considered and rejected in a series of judgments and decisions at both an EU and UK level.<sup>815</sup>

4.273 In *Genzyme*,<sup>816</sup> the CAT pointed out that '*the NHS is not a single trading entity; it is a collection of different parts which exercise different functions, and which cannot be relied upon to act as an effective counterweight to anticompetitive behaviour by drug companies*'.<sup>817</sup> The different entities which comprise the NHS are summarised in section 3.C.II.a above. This fragmented system, and key aspects of how it operates, significantly limits the NHS's ability to exert countervailing buyer power. Of particular relevance for these purposes are:

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<sup>814</sup> *National Grid*, [60].

<sup>815</sup> At European level see for example, the Commission's decision in case COMP/A.37.507/F3 – *AstraZeneca*, paragraph 554. This specific point was explicitly upheld on appeal by the General Court (see *AstraZeneca*, paragraph 262).

<sup>816</sup> *Genzyme*, [456]; for a detailed discussion of the NHS's alleged buyer power see [241] to [289]

<sup>817</sup> Further detail on the structure of the NHS is set out in section 3.C.II.a.

- (a) Clinicians (including neurologists and GPs) who treat patients suffering from epilepsy by prescribing AEDs;
- (b) NICE and the MHRA, which provided guidance on best clinical practice for prescribing and dispensing AEDs;<sup>818</sup>
- (c) CCGs which were (and are) responsible for providing and funding health services in their local areas;
- (d) the Secretary of State who had (and has) certain reserve powers to limit prices or control profits of health service products under the NHS Act 2006.

4.274 Further, there is an important distinction between:

- (a) the person who consumes the medicine (i.e. the patient);
- (b) the person who chooses the type of medicine to be prescribed (i.e. the prescribing clinician);
- (c) the person who dispenses a particular preparation of the medicine, which may or may not be determined by the terms of the prescription (i.e. the pharmacist);
- (d) the person that pays for the drug that is prescribed and dispensed (i.e. the CCGs).

4.275 The reason the above distinction is important is that it confers more market power on pharmaceutical companies as opposed to a situation where the final consumer bears the full cost of the medicines.<sup>819</sup> The split between the roles of patient, prescriber, dispenser and payer often gives rise to very inelastic demand. Neither the patient, the prescriber or the pharmacist ultimately pays for the drug. Conversely, once a prescribing clinician has written a prescription for a particular pharmaceutical product, the relevant CCG has no choice but to fund the medicine dispensed against that prescription.<sup>820</sup>

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<sup>818</sup> See section 3.B.II.d.

<sup>819</sup> See Commission's decision in case COMP/A.37.507/F3 - *AstraZeneca*, paragraph 554.

<sup>820</sup> See similarly *Genzyme*, [248]-[249]. In the current case the responsible clinician is usually a GP, who retains prescribing independence even when a particular prescribing decision is being recommended by his or her CCG (since 2013 PCTs have been replaced by CCGs).

**b. *The ability of the NHS to exercise choice***

- 4.276 Even in circumstances where a buyer is a single, large corporate entity (which, as set out above, the NHS is not), this is not usually, in itself, sufficient for a purchaser to have buyer power. Typically the buyer also has to have a choice to switch between suppliers of substitute products.
- 4.277 The CMA finds that the NHS, or any of its constituent parts, were not able to exercise such a choice.
- 4.278 The very pricing practices that form the subject-matter of this Decision indicate the ability of the Parties to disregard the wishes of its customers and consumers. There is no evidence that any part of the NHS had the ability to constrain the prices set for Pfizer-manufactured phenytoin sodium capsules.
- 4.279 CCGs are responsible for funding prescriptions for phenytoin sodium capsules out of their prescribing budgets. However, as set out in section 3.C.II.b, CCGs do not negotiate the prices of phenytoin sodium capsules with pharmaceutical suppliers or purchase the medicines directly from them. Moreover, CCGs have no formal powers enabling them to limit the price they pay for pharmaceutical products.
- 4.280 CCGs have no choice but to pay for Flynn's Product. As set out above, the result of pharmacists adopting the principle of Continuity of Supply is that Flynn (directly) and Pfizer (indirectly) have become unavoidable trading partners. Even if a prescriber writes an open prescription for phenytoin sodium capsules, the dispensing pharmacist normally seeks to ensure that the patient is maintained on the particular preparation of the product which the patient is stabilised on. The CCGs have no realistic alternatives except to continue to pay for Flynn's Product. Without such an alternative, the ability of CCGs to constrain Pfizer's and Flynn's market power is limited and not sufficient prevent Pfizer or Flynn from holding dominant positions in their respective markets.
- 4.281 Moreover, the NHS has the duty to continue the promotion of a comprehensive health service designed to treat physical and mental illness.<sup>821</sup> The scope of this role serves to further reduce the extent of any buyer power the NHS may possess compared with what would be the case if it was operating on a purely commercial basis.

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<sup>821</sup> See section 1 of the NHS Act 2006 referred to at section 3.C.II.a above.

c. ***The Secretary of State's powers under the NHS Act 2006***

- 4.282 As set out in section 3.C.III.d, the Secretary of State has certain powers to monitor and control drug pricing in specific circumstances, which are contained in sections 261 to 266 of the NHS Act 2006. The Secretary of State's role is discharged through the DH, and so this section will generally refer to the DH. However, as set out in section 3.C.III.d, the DH is not designed to regulate the price of specific generic products and relies on competition to control prices.
- 4.283 In the circumstances of this case, the DH has no power to regulate or control Pfizer's Prices or Flynn's Prices. Phenytoin sodium capsules fall within the Category C Drug Tariff resulting in their prices being completely unconstrained by regulations. The Category C Drug Tariff is simply the list price that is chosen and notified to the NHS by the MA holder, in this case Flynn.
- 4.284 Since their genericisation in September 2012, phenytoin sodium capsules have not been subject to the pricing mechanisms within the PPRS or the Statutory Scheme<sup>822</sup> because these schemes only apply to licensed branded medicines.<sup>823</sup> Further, although section 262 of the NHS Act 2006 provides that the Secretary of State may limit the price that may be charged for the supply of a drug, this power cannot be exercised on a manufacturer or supplier who is a member of a voluntary pricing scheme.<sup>824</sup>
- 4.285 Pfizer submitted that section 262 of the NHS Act should give the DH the statutory powers to regulate Flynn's prices.<sup>825</sup> However, the DH has repeatedly confirmed the interpretation of section 262 set out in the preceding paragraph stating, for example, that:

*'the effect of sections 262(2) and 263(7) is that neither statutory Regulations nor direct price limiting by the Secretary of State can be used to control the prices of health service medicines (or the profits derived from them) supplied by members of a voluntary scheme, even to*

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<sup>822</sup> A pharmaceutical company that chooses not to be a member of the PPRS is automatically subject to the Statutory Scheme. The Statutory Scheme is set by the DH following consultation and the terms are different to the PPRS. See <http://www.england.nhs.uk/wp-content/uploads/2014/05/pharm-price-reg-qa.pdf>

<sup>823</sup> See document 00367.2.

<sup>824</sup> Section 262 of the NHS Act 2006. See also section 3.C.III.d. The Secretary of State must also consult with the industry body before exercising the power to limit a price.

<sup>825</sup> This, and the following paragraph, address representations made by Pfizer at paragraphs 195-215 and 303-310 of document 01622.2.

*cover any gaps where the voluntary scheme does not extend to particular medicines or classes of medicine.*<sup>826</sup>

4.286 Further, the DH has recently introduced the Health Service Supplies (Costs) Bill in order to extend the application of the statutory scheme to cover all products outside of voluntary schemes, regardless of whether the supplier is a member of a voluntary scheme for other products. The introduction of the Bill, thus, recognises that the DH cannot currently limit the price of a company's generic medicine where the company is a member of the PPRS.<sup>827</sup> As the Secretary of State told Parliament during the second reading of this Bill, where this loophole has been exploited the NHS has '*no choice but to purchase the medicine at grossly inflated prices or to transfer patients to other medicines that are not always suitable*'.

4.287 Accordingly, during the Relevant Period, as Flynn and Pfizer are both members of the voluntary PPRS scheme for the purpose of their branded products, the Secretary of State is unable to impose any price limit on Flynn's Prices or Pfizer's Prices under section 262 of the NHS Act.<sup>828</sup>

***d. The Parties' actions regarding the DH's purported buyer power***

4.288 Contemporaneous evidence also confirms that the DH did not have sufficient countervailing buyer power in its dealings with Pfizer and Flynn and shows the Parties were each able to act independently of the DH.<sup>829</sup>

4.289 First, the Parties have been unable to adduce any contemporaneous evidence showing that they had considered there to be a real risk that DH

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<sup>826</sup> See document 00367.2. See also document 01904.1, page 5 '*if a company is in a voluntary scheme which falls under section 261 of the NHS Act 2006 then the powers to apply a statutory price limit cannot be imposed on that company for any of its products*' [emphasis as in original]. In addition these powers cannot be imposed unilaterally by the Secretary of State but must first be consulted on with the ABPI as the industry body.

<sup>827</sup> See, in particular, the Secretary of State stated reasons for introducing the Bill, as set out at in section 3.C.III.d.

<sup>828</sup> See document 00367.2, pages 2 and 8.

<sup>829</sup> Pfizer argued that the Parties were '*acutely aware of the DH's potential for intervention at the time Flynn presented its Epanutin capsules proposal to Pfizer...*' (see document 01622.2, paragraphs 304 to 310). Flynn has made a similar contention (see for example document 02076.1, paragraphs 3.1 to 3.16). However, there is no contemporary evidence that the Parties considered that there to be a real risk that DH could compel them to reduce their prices. As set out in sections 3.E.IV and 3.E.V, the focus of the Parties during their negotiations was whether Parallel Imports would constrain price their pricing. Nor does the Parties' conduct support the conclusion that the Parties believed that the DH was able to constrain their pricing. As set out above the Parties were able to impose and maintain significant price increase. Further, as the following paragraphs show, that the Parties were able, for example, to disregard the DH's requests for the Parties to provide their cost data and reassess their pricing.

could, or would, compel them to reduce their prices. As set out in sections 3.E.IV and 3.E.V, the only possible pricing constraint identified by the Parties during their negotiations was the one presented by Parallel Imports (a constraint they ultimately felt able to ignore).

4.290 Second, the DH informed the CMA that where it had (and has) concerns over the price a company is charging for a drug and it has no formal powers to intervene to regulate the price, it will meet with the company concerned and try to persuade it to reduce its prices.<sup>830</sup> In such circumstances, it is ultimately up to the company concerned whether it meets with the DH, and if so whether it wishes to reduce its prices and by how much.

4.291 In this case, the DH met with Flynn on the basis that it '*was concerned about the prices that Flynn was setting for Phenytoin hard capsules.*'<sup>831</sup> However, these discussions were unsuccessful and '*Flynn effectively threatened to stop the product*'<sup>832</sup> by informing the DH that it would not be able to continue in business unless it maintained its prices because of the prices it was paying to Pfizer.<sup>833</sup>

4.292 Flynn has submitted that the DH did not engage with Flynn on pricing. However, the DH did ask Flynn to seek a price reduction from Pfizer:

*'Flynn also agreed to contact Pfizer to establish whether it might be possible for it to renegotiate downwards the cost of manufacturing, which would enable it to pass a lower price on to the NHS.'*<sup>834</sup>

4.293 However, neither Pfizer nor Flynn were willing to offer any reduction.<sup>835</sup>

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<sup>830</sup> See document 01904.1, page 7.

<sup>831</sup> See document 01904.1, page 7.

<sup>832</sup> See documents 00367.2, 00367.3, 00248.2.

<sup>833</sup> For example '[t]he supply prices agreed mean that Flynn is not in a financial position to provide Epanutin branded product to the UK market.[§]'; see document 00145.306

<sup>834</sup> See document 00367.16. See also document 00145.585.

<sup>835</sup> Flynn has submitted to the CMA that it stated in a follow up letter to the DH that it '*welcomed further discussions on these matters*' (see document 00367.16). However, Flynn also told the DH that it would '*continue to discuss supply pricing with Pfizer.*' This is particularly important since Flynn had told the DH that Pfizer's prices were primarily responsible for the price increase. For example, according to Flynn's note of its meeting with the DH on 6 November 2012, Flynn told the DH it '*could not disclose our cost of goods that we pay Pfizer under our supply agreement as this would breach our confidentiality agreement with them...* [§][Flynn's Director] *stated that the main element of our costs was the cost of the finished product we are supplied*' (see document 00145.585). As noted, no proposed reduction ever resulted from any discussions between Pfizer and Flynn. Further, as set out below the Parties refused to provide the DH with any cost information that would have allowed

4.294 Third, the DH lacked the power to gather information that may have enabled it to assess the credibility of Flynn's or Pfizer's claims. For example, the DH asked Flynn to request that Pfizer provide the DH with their supply prices to Flynn<sup>836</sup> but the Parties refused. Flynn told the DH:

*'You asked us to request Pfizer's permission to disclose our cost of goods data. Their response to our request was, "As a global supplier of phenytoin, information relating to the cost structure for production and delivery of Phenytoin Sodium Flynn Hard Capsules is commercially sensitive and confidential.'"*

4.295 Further, when the DH asked Flynn to consider what information it could provide as justification for its prices, Flynn agreed to come back to the DH on this point but Flynn's immediate justification centred on:

*'...the one-off costs of the Marketing Authorisation; third party manufacturing costs; the cost of the active pharmaceutical ingredients (API); dual sourcing and buffer-stock building costs; bioequivalence studies; and packaging.'*<sup>837</sup>

4.296 As set out in section 3.E.X above, this and other similar statements that Flynn made to the DH show the difficulties that the DH faced in assessing the credibility and accurateness of the justifications put forward by Flynn. On this occasion, the information Flynn provided was misleading:

- (a) Flynn would have known that the one-off cost of the MAs was just [a nominal fee];
- (b) third party manufacturing and API costs only amounted to a [✂] proportion of Pfizer's supply price to Flynn;
- (c) Flynn had not incurred any material costs in relation to dual sourcing; and
- (d) other costs regarding bioequivalence studies and packaging were minimal when compared to Flynn's margins.

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the DH to potentially assess the reasonableness of their costs. The CMA does not consider this conduct shows a genuine willingness to engage with the DH.

<sup>836</sup> See for example documents 00367.16 and 00145.585.

<sup>837</sup> See document 00367.16.

- 4.297 Flynn's follow up correspondence did not provide the DH with any further information to help the DH to verify whether Flynn's Prices were justified.<sup>838</sup>
- 4.298 Similarly, the DH also had a meeting with Pfizer where the significant price increase of *Epanutin* was discussed and where the DH '*...sought comments from the company in respect of the increased expenditure to the NHS.*'<sup>839</sup> Apart from inaccurately confirming that the Product was manufactured in Ireland, Pfizer was unable to provide any further information but agreed to investigate the issues raised and revert in due course. However, Pfizer's subsequent response was unsatisfactory and incomplete. As the DH stated:
- 'The company has told us nothing that we do not already know. My recollection from the meeting is that we asked the company to let us know whether the cost of goods it is charging Flynn has increased significantly.'*<sup>840</sup>
- 4.299 As already noted, the DH had no means of obtaining information (for example, on costs) that would have enabled it to assess the credibility of Flynn's or Pfizer's claims. Indeed, [redacted].<sup>841</sup>
- 4.300 In conclusion, the DH's lack of any real buyer power during its discussions with Flynn was stark. It was clearly concerned about the significant price increase in relation to phenytoin sodium capsules and the resulting very high prices.<sup>842</sup> However, it had no power to intervene and regulate Flynn's (or Pfizer's) prices and was unsuccessful in trying to persuade Flynn to reduce its prices, as demonstrated by the paragraphs above. Indeed, the DH had no evidence with which to directly challenge the reasonableness of Flynn's Prices nor the means to gather the evidence.
- 4.301 The NHS was left in the invidious position where it either accepted Flynn's Prices or would have been forced to stop buying phenytoin sodium capsules – a step that would have left a vulnerable patient group at risk of therapeutic failure. This was not a realistic choice given the nature of the product and is not consistent with the NHS having any level of countervailing buyer power

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<sup>838</sup> See document 00367.18.

<sup>839</sup> See document 00367.19.

<sup>840</sup> See document 00367.22.

<sup>841</sup> See document 02032.1, paragraph 9.

<sup>842</sup> See for example, documents 00367.16 and 00145.585.



sufficient to prevent either Pfizer or Flynn from holding dominant positions in their respective markets.

**e. *The Parties' submissions on section 261(4) of the NHS Act 2006***

- 4.302 The Parties submitted that the DH could have removed Flynn from the PPRS and imposed a statutory price limit on Flynn with respect to phenytoin sodium capsules.<sup>843</sup>
- 4.303 Section 261(4) of the NHS Act 2006 provides that the Secretary of State does have the power to remove a manufacturer or supplier from the PPRS where the scheme has been shown to be '*ineffective*' in either:
- (a) limiting the prices which may be charged by any manufacturer or supplier to whom the scheme relates for the supply of any health service medicines; or
  - (b) limiting the profits which may accrue to any manufacturer or supplier to whom the scheme relates in connection with the manufacture or supply of any healthcare medicines.<sup>844</sup>
- 4.304 Before a scheme member can be removed from the voluntary scheme in question, the Secretary of State must first serve written notice on the member stating that the scheme will no longer apply to it.<sup>845</sup> This notice must set out the Secretary of State's reasons for giving the notice and may not be issued until he has given the scheme member an opportunity to make representations about the acts or omissions in question.
- 4.305 This was not a reasonable or viable option for the DH for the following reasons.
- 4.306 First, the PPRS does not apply to phenytoin sodium capsules. It is highly unlikely that the DH would be able to exclude a company from the PPRS for its actions in relation to a product sold outside of the scheme. As set out above, in order to remove a manufacturer or supplier from the PPRS, it is necessary to show that the PPRS is '*ineffective*' as regards that scheme member. In *Genzyme* the CAT held that it would be difficult to find that the PPRS was '*ineffective*' where the scheme member had fully complied with

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<sup>843</sup> See for example document 01622.2, paragraph 202, document 02076.1 paragraphs 38 and 39 and document 02077.1 paragraphs 3.3. to 3.5.

<sup>844</sup> See section 261 of the NHS Act 2006, in particular 261(4) and 261(1).

<sup>845</sup> See section 261(4) NHS Act 2006

the provisions of the PPRS.<sup>846</sup> The fact that the company in question had engaged in (potentially) exploitative behaviour in respect of generic medicines would not have demonstrated the ineffectiveness of the PPRS. Rather, it would be no more than the unavoidable consequence of the fact that the PPRS applied to branded medicines only.

- 4.307 Indeed, for most of the Relevant Period, the DH believed that it could only remove a company from the PPRS if the company was failing to comply with the terms of the PPRS.<sup>847</sup> Although the DH has recently changed its view of the relevant statutory position, and told the CMA in March 2016 that it now considers it could, in theory, potentially remove a company from the PPRS because of the company's conduct outside the PPRS,<sup>848</sup> to date, this has never been tested and it remains legally uncertain – especially given previous interpretations of the provision. The DH has also told the CMA that it must still consider the effectiveness of the PPRS in the round for that company.<sup>849</sup>
- 4.308 Second, even if the DH considered that removing Flynn from the PPRS was legally possible, it was not a realistic option. Before a company can be removed from the PPRS, the Secretary of State must set out the reasons why he or she considers that the PPRS is ineffective and give the company concerned the opportunity to make representations on the decision.<sup>850</sup> The practical problem for the DH was (and would have been) the lack of any power to gather information in respect of Flynn's Prices.
- 4.309 The DH told the CMA that,<sup>851</sup> without the power to obtain information on Flynn's (and Pfizer's) costs<sup>852</sup> the Secretary of State would have been unable to justify properly any proposal to remove Flynn from the PPRS. The DH (like any public authority) must have a reasonable basis for the decisions it takes. As set out above, Flynn and Pfizer both declined to provide the cost and price information requested by the DH. In these circumstances, any decision to remove Flynn from the PPRS would have been susceptible to judicial review. The inability to require the production of the information

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<sup>846</sup> See *Genzyme*, [273].

<sup>847</sup> See documents 00454.1, 02032.1 and 00367.2.

<sup>848</sup> See document 01904.1

<sup>849</sup> See document 01904.1, page 6.

<sup>850</sup> The NHS Act 2006, sections 261(4) and 261(5)

<sup>851</sup> See document 02032.1.

<sup>852</sup> Specifically, the DH lacks the ability to require the production of cost information for generic drugs.

therefore limits any power the DH may have to remove a company from the PPRS in these circumstances.

- 4.310 The DH has also told the CMA that [redacted].<sup>853</sup>
- 4.311 Third, there is no evidence from the Relevant Period that the DH, Pfizer or Flynn thought it was a possible option. As such, the option is at best a theoretical option that has had no practical effect on the commercial relationship between DH (or the NHS) and Flynn.<sup>854</sup>
- 4.312 Accordingly, the CMA considers that DH had no formal regulatory power it could have exercised to directly or indirectly limit Flynn's Prices.
- 4.313 The Parties' submission also ignores the practical reality that the DH is not in a position to regulate the price of individual generic products. As set out in section 3.C.III.d, the DH is not intended to act as a price regulator for generic medicines. In particular:
- (a) the DH does not use its statutory powers to set the prices of individual generic drugs. Instead, its policy is to rely primarily on competition to set the prices of generic medicines.<sup>855</sup>
  - (b) the DH does not have the statutory power to require the provision of financial and cost information for generic drugs. This makes it very difficult for the DH to investigate or meaningfully assess potential anomalies or abuses in pharmaceutical pricing;
  - (c) [redacted];<sup>856</sup> and
  - (d) the DH has very limited resources and has to use those resources most efficiently.<sup>857</sup>
- 4.314 Further, even if the DH could, and did, remove Flynn from the PPRS, the DH would also have to remove Pfizer from the PPRS before it could regulate

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<sup>853</sup> See sections 3.E.X.b and 3.C.III.d.

<sup>854</sup> The Parties have also submitted that the DH could have, alternatively, moved Flynn into Scheme M and used this as a mechanism to control Flynn's price (see for example, document 02076.1 paragraph 3.16). However, a company must consent to join scheme M so the DH would still have been dependent on Flynn's co-operation. The DH has also questioned whether Flynn's Products would be suitable for inclusion in Category M (see document 02032.1, paragraph 28). In any event, as the CMA has separately concluded, Scheme M does not give the DH effective countervailing buyer power over suppliers' prices.

<sup>855</sup> See document 02032.1, paragraph 13.

<sup>856</sup> See document 02032.1, paragraph 9.

<sup>857</sup> See document 02032.1, paragraph 10.

Pfizer's upstream supply price to Flynn. If it did not, Pfizer would still be able to set a highly inflated supply price and the DH could not reasonably require Flynn to supply Flynn's Products to the NHS at a loss. It would, however, be unrealistic and uneconomic for the DH to remove Pfizer's entire portfolio of branded drugs from the PPRS. Consequently, and regardless of whether the DH could control Flynn's margins, the DH would, in practice, still lack sufficient countervailing buyer power as against Pfizer.

**f. *The Parties' submissions regarding scheme M***

4.315 The Parties have also submitted that the DH could have moved Flynn into Scheme M and used this as a mechanism to control Flynn's price.<sup>858</sup> The CMA rejects this submission.

4.316 First, Scheme M is primarily intended to regulate the retained margins earned by pharmacies, not the prices charged by the suppliers of generic pharmaceuticals.<sup>859</sup>

4.317 Second, the Parties' argument on this point overlooks the fact that a company has to consent to join scheme M, with the result that the DH would still have been dependent on Flynn's co-operation.<sup>860</sup> As set out above, Flynn had already shown itself to be unwilling to co-operate with the DH's requests. There is, therefore, no reason to think Flynn would consent to joining Scheme M.

4.318 Third, the DH has questioned whether Flynn's phenytoin sodium capsules would have been suitable for inclusion in Category M. That category was and is designed for commoditised generic drugs with multiple suppliers.<sup>861</sup>

**g. *The Parties' submissions relating to Tablets***

4.319 In their representations on the SO, Pfizer and Flynn also submitted that the CMA ignored other relevant evidence of the DH's buyer power. In particular, the Parties argued that Teva's reduction of its Tablets prices in 2008 was the

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<sup>858</sup> See for example, document 02076.1 paragraph 3.16

<sup>859</sup> See section 3.C.III.c.ii for more details

<sup>860</sup> In any event, for the reasons set out in section 5.D.II.b.ii below, Scheme M would not give the DH sufficient countervailing buyer power over the Parties' prices. The DH's ability to compel Flynn to reduce its prices would also be restricted by the input price it pays to Pfizer.

<sup>861</sup> See document 02032.1, paragraph 28

result of an intervention by the DH and therefore relevant evidence in this regard.<sup>862</sup>

- 4.320 The CMA does not accept this submission.
- 4.321 The purpose of this assessment is to establish whether the DH has countervailing buyer power as against Pfizer and Flynn in the supply of phenytoin sodium capsules. As set out above, the evidence in relation to phenytoin sodium capsules clearly demonstrates that the DH does not have this power.
- 4.322 Given this, it is not necessary for the purposes of this assessment for the CMA to consider whether the DH has countervailing buyer power in relation to Tablets. In any case, the CMA does not accept the Parties' submission that the price reduction that occurred in relation to Teva's Tablets resulted from the exercise of sufficient buyer power by the DH. The DH has no power to limit the price of Tablets and Teva's 2008 Tablet price reduction was a voluntary act. The evidence showing this is set out in section 5.D.II.b.ii below.

*h. Conclusion on NHS buyer power*

- 4.323 In light of the above, the CMA finds that:
- the structure of the NHS means that it is difficult for the NHS to exert buyer power over Pfizer and Flynn;
  - CCGs are not able to exercise any choice of product;
  - the DH does not have material countervailing buyer power through the power to regulate prices of phenytoin sodium capsules.
- 4.324 In summary, for the reasons set out above, the CMA considers that neither the NHS (including CCGs) nor the DH was able to sufficiently constrain Pfizer's or Flynn's conduct during the Relevant Period so as to prevent Pfizer and Flynn from holding dominant positions in their respective relevant markets. It is clear that both Parties have been able to behave independently of this potential competitive constraint to an appreciable extent.

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<sup>862</sup> See for example document 01622.2, paragraphs 306 to 308 and document 02077.1, paragraph 3.6 and 3.7.

*i. Flynn's buyer power in relation to Pfizer*

4.325 Pfizer submitted to the CMA that, irrespective of whether the NHS has buyer power, Pfizer was not dominant at the 'wholesale level' with regard to its customer – Flynn – during their initial negotiations.<sup>863</sup> Pfizer has argued that its ability to obtain value from its phenytoin sodium capsules was dependant on its ability to negotiate a suitable divestiture and that Flynn was free to walk away from the negotiations at any time. Pfizer submits that it was therefore unable to act independently of Flynn and thus cannot be dominant.

4.326 The CMA rejects Pfizer's representations for the following reasons:

- (a) Pfizer's strong upstream position as manufacturer combined with the limited downstream substitution between products generates Pfizer's dominant position in its relevant market. As the CMA has already concluded, Pfizer's Prices are not effectively constrained by actual competition, potential competition or NHS buyer power. Therefore Pfizer was able to set its supply price above competitive levels.
- (b) The ability of Flynn to walk away from the deal does not mean Pfizer was not dominant (at the time of the negotiations or subsequently). If that was the case, then only certain suppliers of essential facilities could be held to be in a dominant position.
- (c) Contrary to how Pfizer portrays the negotiation with Flynn, the CMA considers that Pfizer did in fact have significant leverage over Flynn. There would have been no agreement without Pfizer and it could have opted not to proceed with the agreement if it did not like the terms or was otherwise unhappy with the proposals (as it did with [Company A] as explained in section 3.E.III). There is no evidence to suggest that Flynn was a necessary trading partner and it was always open to Pfizer to find another partner or to proceed with genericising *Epanutin* itself.<sup>864</sup> Pfizer may have suffered some commercial downside due to any resultant delays in implementing new prices, but given the overall size of Pfizer's business this would have been limited. In contrast, Flynn could neither proceed with the proposal on its own nor with any partner other than Pfizer. In addition, Flynn's sales of phenytoin sodium capsules during the Relevant Period accounted for around [ ] of

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<sup>863</sup> See document 01622.2, paragraphs 271-272.

<sup>864</sup> See section 3.E.I.

Flynn's revenues (and a [X] in its profit contribution).<sup>865</sup> Therefore Flynn had every incentive to agree to Pfizer's terms in order to secure these revenues. The fact that Pfizer and Flynn arrived at mutually acceptable supply prices does not undermine a finding of dominance, given that these prices far exceeded Pfizer's relevant costs (as set out in Section 5.C.IV below). Any negotiating position enjoyed by Flynn did not prevent Pfizer from setting and sustaining supply prices to Flynn that are significantly above competitive levels.

- (d) Further, Pfizer has not been able to produce any contemporaneous evidence of Flynn exerting buyer power on Pfizer.<sup>866</sup> In contrast the evidence on the CMA's file shows that, if anything, the terms of the deal shifted in Pfizer's favour during the course of the negotiation.<sup>867</sup> At the end of the negotiations an internal Pfizer email stated that the deal it had agreed with Flynn was '*at the top end of our expectations, in line with the aspirational figures that we shared with you.*'<sup>868</sup>
- (e) Pfizer has also demonstrated ongoing independence with respect to Flynn by refusing to engage with it on its proposals on alternative manufacturers and API supply.<sup>869</sup> Pfizer has also told the CMA that it is now unilaterally vetoing any price negotiations with Flynn.<sup>870</sup> That Pfizer is able to do this demonstrates that it is able to act independently of Flynn.

4.327 Consequently the CMA is satisfied that Flynn does not exert countervailing buyer power on Pfizer sufficient to prevent it from holding a dominant position.

## VII. **Conclusions on dominance**

4.328 The evidence presented and analysed above clearly shows that both Pfizer and Flynn have enjoyed positions of economic strength which have enabled them both to behave to an appreciable extent independently of their competitors, customers and ultimately their consumers.

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<sup>865</sup> See section 5.D.III.b.iv.

<sup>866</sup> See document 01836.2, question 10.

<sup>867</sup> See for example document 01622.2, paragraph 101.

<sup>868</sup> See document 00141.191

<sup>869</sup> See, for example, documents 00519.4 and 01839.1.

<sup>870</sup> See document 02076.1 (paragraph 50) for further details.

- 4.329 Accordingly, the CMA finds that throughout the Relevant Period:
- (a) Pfizer held a dominant position in the market for the manufacture of Pfizer-manufactured phenytoin sodium capsules that are distributed in the UK.
  - (b) Flynn held a dominant position in the market for the distribution of Pfizer-manufactured phenytoin sodium capsules that are distributed in the UK.
- 4.330 With regard to the alternative market, defined for the period September 2012 to November 2013, the CMA finds that:
- (a) Pfizer held a dominant position in the market for the manufacture of phenytoin sodium capsules that are distributed in the UK.
  - (b) Flynn held a dominant position in the market for the distribution of phenytoin sodium capsules in the UK.



## 5. ABUSE

### A. Introduction

5.1 For the reasons set out in this section, the CMA concludes that each of Pfizer's Prices and Flynn's Prices was excessive and unfair throughout the Relevant Period.

5.2 This section is structured as follows:

- In section 5.B, the CMA sets out the relevant legal background relating to abuse of dominance and introduces the *United Brands* Test for assessing whether a price is excessive and unfair.
- In section 5.C, the CMA first sets out the relevant legal background relating to stage one of the *United Brands* Test; that is, establishing whether a price is 'excessive'. The CMA then sets out its assessment of whether each of Pfizer's Prices and Flynn's Prices is excessive.
- In section 5.D, the CMA first sets out the relevant legal background relating to stage two of the *United Brands* Test; that is, establishing whether a price is 'unfair'. The CMA then sets out its assessment of whether each of Pfizer's Prices and Flynn's Prices is unfair.
- In section 5.E, the CMA sets out the lack of objective justification for Pfizer's and Flynn's respective conduct.
- In section 5.F, the CMA sets out that no exclusion from the Chapter II prohibition nor any derogation from Article 102 of the TFEU applies in respect of any of the Infringements
- In section 5.G, the CMA concludes on whether each of Pfizer and Flynn has abused its respective dominant position by charging unfair prices, thereby infringing the Chapter II prohibition and Article 102 of the TFEU.

## B. Legal background: Abuse of dominance and the *United Brands Test*

- 5.3 The Chapter II prohibition and Article 102 TFEU prohibit a dominant undertaking from abusing a dominant position and in particular from '*directly or indirectly imposing unfair purchase or selling prices*'.<sup>871</sup>
- 5.4 The holding of a dominant position is not itself prohibited under competition law. Rather, it is the abuse of such a dominant position which is prohibited. A dominant undertaking has a special responsibility to ensure that its conduct does not impair genuine competition on the market.<sup>872</sup>
- 5.5 The EU's General Court has held that the scope of the special responsibility imposed on a dominant undertaking must be considered in light of the specific circumstances of each case, reflecting the fact that competition is weakened as a result of the very presence of that undertaking on the market.<sup>873</sup>
- 5.6 An abuse of a dominant position is an objective concept:
- '...relating to the behaviour of an undertaking in a dominant position which is such as to influence the structure of a market where, as a result of the very presence of the undertaking in question, the degree of competition is weakened and which, through recourse to methods different from those which condition normal competition in products or services on the basis of the transactions of commercial operators, has the effect of hindering the maintenance of the degree of competition still existing in the market or the growth of that competition.'*<sup>874</sup>
- 5.7 More specifically, charging an unfairly high price would constitute such an abuse in circumstances where the dominant undertaking:

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<sup>871</sup> Section 18(2)(a) of the Act and Article 102(a) TFEU.

<sup>872</sup> Judgment in *Michelin v Commission* C-322/81, EU:C:1983:313, paragraph 57. See also *Attheraces*, [107] and *Albion Water II*, [217].

<sup>873</sup> Judgment in *Tetra Pak v Commission* Case, T-83/91, EU:T:1994:246, paragraphs 114 and 115.

<sup>874</sup> *Hoffmann-La Roche*, paragraph 91 and *Akzo*, paragraph 69. Conduct which has an objective justification is not an abuse. The onus is on the Parties to bring any objective justification for their conduct to the attention of the CMA.

*'has made use of the opportunities arising out of its dominant position in such a way as to reap trading benefits which it would not have reaped if there had been normal and sufficiently effective competition.'*<sup>875</sup>

5.8 In *United Brands* the Court of Justice of the EU held that:

*'In this case charging a price which is excessive because it has no reasonable relation to the economic value of the product supplied would be such an abuse.'*<sup>876</sup>

5.9 Although different methods and approaches may reasonably be used to establish whether a price is unfairly high,<sup>877</sup> the Court of Justice held in *United Brands* that the following cumulative two-stage test (the '*United Brands Test*') could be used to establish whether a price had no reasonable relation to the economic value of the product supplied – i.e. whether a price was unfair:

- i. *'whether the difference between the costs actually incurred and the price actually charged is excessive'* (see section 5.C below); and, if yes
- ii. *'whether a price has been imposed which is either unfair in itself or when compared to competing products'* (see section 5.D below).<sup>878</sup>

5.10 The application of the *United Brands Test* to a particular set of data involves a *'...considerable margin of appreciation.'*<sup>879</sup>

5.11 The judgment of the Court of Justice of the EU in *United Brands* is *'[t]he seminal judgment in this area of the law...'*<sup>880</sup> and *'...has consistently been applied by the Commission of the European Communities, the OFT, the Tribunal and the Court of Appeal.'*<sup>881</sup>

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<sup>875</sup> *United Brands*, paragraph 249. See also *Albion Water and Another v Water Services Regulation Authority and Others* [2008] CAT 31 ('*Albion Water II*'), [14] and [274], '*Napp*', [402] and *Kanal 5 v STIM* C-52/07, EU:C:2008:703 ('*Kanal 5*'), paragraph 27.

<sup>876</sup> *United Brands*, paragraph 250. In this respect see also judgments in *General Motors Continental NV v Commission* C-26/75, EU:C:1975:150, paragraph 12, *Kanal 5*, paragraph 28 and *OSA v Léčebné lázně Mariánské Lázně a.s.* C-351/12, EU:C:2014:110, paragraph 88.

<sup>877</sup> *United Brands*, paragraph 253. See also *Napp*, [392].

<sup>878</sup> *United Brands*, paragraph 252. See also *Albion Water II*, [7]; *Attheraces Limited v the British Horseracing Board Limited* [2005] EWHC 3015 (Ch) ('*Attheraces High Court*'), [294]; and Commission decision COMP/36.568 – *Scandlines Sverige AB v Port of Helsingborg* [2004] ('*Scandlines*'), paragraphs 102, 149, 150 and 215.

<sup>879</sup> *Albion Water II*, [261]. See also *Albion Water and Another v Water Services Regulation Authority and Others* [2006] CAT 23 ('*Albion Water I*'), [310].

<sup>880</sup> *Albion Water II*, [14].

<sup>881</sup> *Albion Water II*, [21].

## C. Excessive pricing

5.12 For the reasons set out below, the CMA concludes that each of Pfizer's Prices and Flynn's Prices is excessive by reference to the first stage of the *United Brands* test (as set out in paragraph 5.9.i above). This section is structured as follows:

- Section 5.C.I sets out legal background to the first stage of the *United Brands* Test.
- Section 5C.II sets out the overall approach and methodology by which the CMA has assessed whether each of Pfizer's Prices and Flynn's Prices is excessive.
- Section 5.C.III sets out the CMA's approach to establishing costs for each of Pfizer's Products and Flynn's Products and the possible measures of rates of return which may be used to calculate the 'Plus' element of Cost Plus.
- Section 5.C.IV sets out the CMA's assessment of whether Pfizer's Prices are excessive.
- Section 5.C.V sets out the CMA's assessment of whether Flynn's Prices are excessive.

### I. *Legal background*

5.13 The first stage of the *United Brands* Test to assess whether a price charged by a dominant firm is unfairly high is to establish '*whether the difference between the costs actually incurred and the price actually charged is excessive*'.<sup>882</sup>

#### a. **Costs**

5.14 According to the Court of Justice in *United Brands*, the starting point in this analysis is to measure '*the costs actually incurred*'<sup>883</sup> in supplying the product in question. These will include:

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<sup>882</sup> *United Brands*, paragraph 252.

<sup>883</sup> *United Brands*, paragraph 252. See also *Albion Water II*, [20].

- (a) the costs directly incurred in supplying the product or service; and
- (b) an appropriate apportionment of the indirect costs that are 'reasonably attributable'<sup>884</sup> to the product or service.<sup>885</sup>

5.15 There is no legally prescribed methodology for measuring cost in excessive pricing cases. In *Albion Water II*, the CAT stated that, rather, 'it is a matter of fact, accounting technique and economic assessment'.<sup>886</sup> The CAT went on to state that:

*'Because there may be times when a competition authority or court needs the flexibility to examine more than one measure of cost in order to evaluate an allegedly excessive price, we do not prescribe a cost measure that would apply in all cases. [...]he use of more than one credible methodology, even if only as a cross-check, helps to minimise the risk of false positives and to assure confidence in the results obtained.'*<sup>887</sup>

5.16 The Court of Justice in *United Brands* also recognised the need for flexibility in the methods used for calculating costs because of the:

*'...the considerable and at times very great difficulties in working out production costs which may sometimes include a discretionary apportionment of indirect costs and general expenditure and which may vary significantly according to the size of the undertaking, its object, the complex nature of its set up, its territorial area of operations, whether it manufactures one or several products, the number of subsidiaries and their relationship with each other...'*<sup>888</sup>

5.17 However, all costs must be reasonably incurred.<sup>889</sup>

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<sup>884</sup> *Albion Water II*, [198]. See also *Scandlines*, Appendix 3.1, paragraph 29.

<sup>885</sup> *United Brands*, paragraph 254.

<sup>886</sup> *Albion Water II*, [88].

<sup>887</sup> *Albion Water II*, [93].

<sup>888</sup> *United Brands*, paragraph 254. See also *Scandlines*, paragraph 117.

<sup>889</sup> See *Albion Water II*, [88]. See also judgment in *Ministere Public v Tournier* C-395/87, EU:C:1989:319, paragraph 42.

**b. Reasonable rate of return**

- 5.18 In addition to establishing '*the costs actually incurred*' it will normally be necessary to allocate a reasonable rate of return on that amount and include it in the cost figure before comparing costs to the price actually charged.<sup>890</sup>
- 5.19 The CAT has recognised that determining what is a reasonable rate of return will be an exercise of the CMAs judgement and '*[t]he actual margin to be set is not a matter of precise mathematics*'.<sup>891</sup>

*'We note that the determination of an appropriate margin is necessarily a question of judgment and appreciation. That is particularly so when the Tribunal, as here, is required to deal with markets affected by the intricate operation of the NHS arrangements and regulatory systems more fully described in our earlier judgment. Despite the highly technical nature of the submissions made to us, there are inevitably some areas of uncertainty on matters upon which experts may well take differing views. In those areas the Tribunal is required to exercise its own judgment.*

*In exercising our judgment we have had regard, in particular, to the interests of Gaucher patients and to the interests of the customer, the NHS. Those are the interests which the legislation is primarily designed to protect although, of course, the interests of Genzyme and of healthcare providers are also important.'*<sup>892</sup>

**c. Cost/price comparison**

- 5.20 Having established the '*costs actually incurred*' plus a reasonable rate of return (collectively referred to as '*Cost Plus*' in this Decision) it is then necessary to assess whether the difference between Cost Plus and the '*price actually charged*' is excessive.
- 5.21 This assessment '*involves a proper degree of discretionary judgment by the decision-maker*'<sup>893</sup> and requires the exercise of judgement,<sup>894</sup> having regard to the specific circumstances of the individual case, in particular the specific features of the product concerned and competitive conditions in the relevant markets.

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<sup>890</sup> See, for example, *Albion Water II*, [89].

<sup>891</sup> *Genzyme Limited v Office of Fair Trading* [2005] CAT 32 ('*Genzyme Remedy*'), paragraph 279.

<sup>892</sup> *Genzyme Remedy*, [255] and [256].

<sup>893</sup> *Albion Water II*, [193].

<sup>894</sup> *Albion Water II*, [194].

5.22 In *Albion Water II*, the CAT, when applying the first stage of the *United Brands Test*, stated that:

*'The term 'excessive' is an ordinary English word, which may be applied in accordance with its ordinary meaning, having regard to the overall purpose of the Chapter II prohibition. We note that the Authority submitted that a price may not be 'excessive' within the meaning of the first United Brands question where the price exceeds costs but not by a material extent (see paragraph 11.3 of the Report). While we are prepared to accept that a material difference between price and cost must be shown, we see no need to specify, in this case, when a particular difference is sufficiently large to be deemed excessive'*<sup>895</sup>

5.23 The following differences between the price actually charged and the costs actually incurred (plus a reasonable rate of return) have previously been found to be excessive based on the specific facts of the following cases:<sup>896</sup>

- (a) In *Albion Water II*, the CAT held that a price 46.8% above the costs reasonably attributable to the product was material and excessive.
- (b) In *Deutsche Post*, the European Commission found that a price 25% above the costs reasonably attributable to the product was excessive.<sup>897</sup>

## II. ***The overall approach and methodology by which the CMA has assessed whether Pfizer's Prices and Flynn's Prices are excessive***

5.24 The first stage of the *United Brands Test* requires an assessment of whether each of Pfizer's Prices and Flynn's Prices for each of Pfizer's Products and Flynn's Products is excessive when compared to their Cost Plus. Cost Plus is composed of:

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<sup>895</sup> *Albion Water II*, [199].

<sup>896</sup> In addition, in *Napp*, [393] the CAT found, among other evidence, that '*Napp's gross profit margin of [...] [in excess of 80%]*' was evidence that its prices were excessive. The CMA notes that an assessment of gross margin does not take account of common costs or a reasonable rate of return and therefore the excesses in that case (if assessed consistently with the approach adopted in this Decision) would have been lower than the margins identified by the CAT.

<sup>897</sup> Commission decision COMP/36.915 – *Deutsche Post AG – Interception of cross border mail* [2001] (*Deutsche Post*), paragraphs 166 and 167.

- (a) The costs that Pfizer and Flynn each incurred in respect of each of their products. For both Pfizer and Flynn, those costs will include direct costs and an appropriate apportionment of indirect costs.
- (b) A reasonable rate of return for each for Pfizer and Flynn in respect of each of their products.

5.25 Once these have been identified, it is then necessary to assess whether and, if so, by what amount each of Pfizer's Prices and Flynn's Prices exceed Cost Plus. Throughout this section, the CMA refers to the amount by which a price exceeds Cost Plus as the 'excess'. Following the approach taken in both *Deutsche Post*<sup>898</sup> and *Albion Water II*,<sup>899</sup> this can also be expressed as a percentage, by subtracting Cost Plus from the price and then dividing the result by Cost Plus.

5.26 If a price exceeds Cost Plus, consideration then needs to be given to whether the excess is (in the words of the *Albion Water II* judgment) 'material' and 'sufficiently large to be deemed excessive' for the purposes of the *United Brands* Test.

### III. ***The CMA's approach to establishing Cost Plus for each of Pfizer's Products and Flynn's Products***

#### a. ***General framework***

5.27 As explained above, the first step in establishing Cost Plus is to determine the costs that each Party incurred in producing and supplying their products. This section sets out the approach that the CMA has adopted in determining those costs.

5.28 Following the Court of Justice in *United Brands*, the CMA has calculated the costs for each of Pfizer's Products and Flynn's Products by considering, separately:

- (a) Direct costs. Direct costs are those costs that can be directly attributed to a particular line of business; in this case the production, purchase and/or distribution of phenytoin sodium capsules sold in the UK.
- (b) Indirect costs. In addition to direct costs, businesses also incur costs that are indirectly but necessarily incurred in order to supply a given

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<sup>898</sup> See, for example, *Deutsche Post*, paragraph 166.

<sup>899</sup> See, for example, *Albion Water II*, [197].



product. A proportion of these costs needs to be included in the overall costs of phenytoin sodium capsules to fully reflect the total costs actually incurred by each of Pfizer and Flynn.

5.29 This approach to cost identification makes allowance for direct and indirect costs, both variable and fixed (including administrative overheads), attributable to the relevant product. This is consistent with economic theory that long-run average cost is an appropriate measure of costs to use in cases concerning unfairly high prices.<sup>900</sup> This is because, with price equal to long-run average cost (including a reasonable rate of return), efficient companies are just covering their total costs and not earning any excess returns; that is, they are making a 'normal' level of profits. A price below long-run average costs would not allow a company to remain in the market in the long run, whereas a price at or above long-run average costs would be sustainable for a company in the long run.

*b. Approach to establishing indirect costs*

5.30 Indirect costs include: (i) costs which are common across a number of products; and (ii) joint costs that arise when two or more products are necessarily produced together.

5.31 Neither Pfizer nor Flynn have any joint costs in relation to phenytoin sodium capsules because no other products are produced as a direct result of the manufacturing process for phenytoin sodium capsules. Accordingly, only common costs are relevant to the assessment of the level of indirect costs that are actually incurred by each of Pfizer and Flynn in supplying phenytoin sodium capsules.

5.32 Common costs are those costs that are incurred in the supply of more than one product.<sup>901</sup> Typically, they include costs related to matters such as administrative employees (for example, finance and legal departments), manufacturing and distribution facilities and head office overheads (for example, utilities, rent and rates). To determine the relevant common costs

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<sup>900</sup> See, for example, the submission from the European Union to the Roundtable on Excessive Prices held by the OECD Competition Committee (Working Party No. 2 on Competition and Regulation) in October 2011, <http://www.oecd.org/daf/competition/abuse/49604207.pdf>, which is attached to this Decision at Annex M, page 68.

<sup>901</sup> In this case, Pfizer incurs costs related to the supply of all medicines that it sells into the UK. This includes but is not limited to phenytoin sodium capsules. Similarly Flynn sells a number of medicines in the UK with phenytoin sodium capsules being just one of these.

for a particular product, a portion of total attributable common costs should be allocated to each of the products that a company supplies.

- 5.33 In this case, the CMA first identified the categories of common costs that it considered to be partly attributable to the supply of phenytoin sodium capsules.
- 5.34 The CMA made several requests to the Parties to help it determine the various types and proportion of common costs which should be allocated to phenytoin sodium capsules. However, Pfizer and Flynn provided only high level cost data to the CMA, covering broad categories of costs; for example, employee costs, IT expenses and depreciation.<sup>902</sup> Using such data, it has not been possible for the CMA to identify the specific costs in these categories that should be allocated wholly, or in part, to phenytoin sodium capsules.
- 5.35 The CMA has, nevertheless, sought to carry out a robust analysis and where only the totals of a cost category (for example employment costs) are known and the CMA considers that a cost may reasonably be allocated to the production of phenytoin sodium capsules in respect of that cost category, then the *total* cost attributable to that cost category has been treated as relevant (i.e. used as the starting point for the allocation calculation).<sup>903, 904</sup> This approach means that the CMA has estimated Pfizer's and Flynn's costs to be higher than they would have been if a more detailed costs breakdown had been available. The result of this approach is favourable to the Parties because it reduces the differences between price and costs.
- 5.36 Having identified the categories of common costs relevant to phenytoin sodium capsules, the CMA has then used an allocation methodology to allocate part of these costs to phenytoin sodium capsules.
- 5.37 The CAT has recognised that there are a number of different methodologies that can be used to allocate common costs<sup>905</sup> and has also stated that

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<sup>902</sup> See documents 00519.2, 00664.1, 00863.1, 00505.1 and 00607.1.

<sup>903</sup> Exceptions were made to this approach for certain specific costs, see Annexes E and F for individual explanations.

<sup>904</sup> Given the lack of detail provided by the Parties, the CMA has only had limited scope to assess to what extent the Parties' costs have been efficiently incurred.

<sup>905</sup> *British Telecommunications PLC v Office of Communications* [2011] CAT 5 ('*Partial Private Circuits*'), [85].

[e]stimates and allocations of costs will always have a degree of arbitrariness'.<sup>906</sup>

- 5.38 The OFT's *Profitability Assessment Report* (produced by the economic consultancy OXERA) also notes there is no single correct method for cost allocation and that, depending on the circumstances, some methods may be more appropriate than others.<sup>907</sup> The report states that broadly there are three types of cost driver that can be used separately or in combination:
- (a) **input-based cost drivers**, where indirect costs are allocated to a particular line of business based on other known inputs employed in the production of that line of business, such as labour employed, raw-material, or costs of floor space used;<sup>908</sup>
  - (b) **output-based cost drivers**, where indirect costs are allocated using output indicators, such as production or sales volumes; and
  - (c) **value-based cost drivers**, where indirect costs are allocated based on demand factors, such as prices, revenues or consumers' willingness to pay.<sup>909</sup>
- 5.39 The CMA has used output-based cost drivers to allocate Pfizer's and Flynn's respective common costs for the reasons set out below.
- 5.40 Although the CMA believes that using input-based cost drivers would have been likely to provide the most accurate method to apportion common costs, it is not possible to do so in this case. This is because Pfizer and Flynn have not been able to provide sufficiently detailed information to enable cost drivers to be quantified and related to the indirect cost categories.<sup>910</sup>
- 5.41 The CMA does not consider it is appropriate to use value-based cost drivers when assessing pricing abuses under competition law, as such an approach is inconsistent with the principle of cost causality (according to which costs

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<sup>906</sup> *Genzyme Remedy*, [277].

<sup>907</sup> OFT657 Assessing profitability in competition policy analysis, Economic discussion paper 6, July 2003, prepared by OXERA ('*Profitability Assessment Report*'), paragraph 6.15.

<sup>908</sup> See for example the Institute of Management Accountants' (2006) *Implementing activity-based costing*, page 1. For example, if electricity charges vary according to the length of time machines operate then equipment hours per product will be an appropriate basis for apportioning these costs.

<sup>909</sup> *Profitability Assessment Report*, paragraph 6.16.

<sup>910</sup> For example, document 00725.4 shows that [§] to [§] of all of Pfizer's common costs are classified within an 'other' department between 2011 and 2013 and document 00607.1, question 6, Flynn notes that it could not provide data on the number of orders received from its customers.

should be allocated to the source that caused the costs to be incurred) and is likely to give rise to a circularity problem (as indirect costs would be weighted towards the allegedly excessively priced product).<sup>911</sup>

- 5.42 In light of this, the CMA considers that output-based cost drivers provide the most appropriate cost allocation method given the particular circumstances of this case. The CMA has used the same approach when allocating both Pfizer's and Flynn's common costs and has not identified any reason why a different approach should be used for either.
- 5.43 The CMA considered the following output-based cost drivers, all of which are linked to volume: sales volumes by number of packs; sales volume by number of capsules; and sales volume on a DDD basis for phenytoin sodium.<sup>912</sup>
- 5.44 The CMA considers that sales volume by pack, which allocates indirect costs according to total sales volumes across a company's portfolio of products, is the most appropriate available method to allocate indirect costs to phenytoin sodium capsules as a whole. This is because the number of packs ordered drives activities from procurement to invoicing, all of which require support activities which result in common costs such as employee costs, marketing expenses, professional/consulting fees and office expenses.
- 5.45 However, an outcome of the simple sales volume methodology is that all capsule strengths incur the same common cost per unit (i.e. per pack). This has a distortionary effect on the smaller capsule strengths, which also have the lowest prices, as they incur a higher proportion of indirect costs to total costs. This results in lowering overall margins for the lower capsule strengths relative to the higher capsule strengths. Although the CMA considers sales volumes by pack to be the most appropriate methodology for allocating common costs, sales volumes are unlikely to be completely correlated with common costs.
- 5.46 Therefore, additionally and consistent with the CAT's view that the use of more than one credible methodology is desirable as a cross-check,<sup>913</sup> the

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<sup>911</sup> See Annex D for the CMA's detailed assessment of the various cost allocation methodologies considered by the CMA as well as the Parties' representations.

<sup>912</sup> The CMA requested order and transaction data from the Parties. However, this the provision of this data was not ultimately pursued as it would have been a significant undertaking for both Pfizer and Flynn to collate and submit and would not necessarily have provided a meaningful allocation. See, for example, document 00664.1, question 5.ii; and document 00607.1, paragraph 6.2.

<sup>913</sup> *Albion Water II*, [93].

CMA has performed a sensitivity analysis. The CMA has adopted two other approaches as part of its sensitivity analysis. These methods add a second step to the allocation process whereby the resultant cost is then allocated across the different capsule strengths according to the number of DDDs and the number of capsules available in a pack.<sup>914</sup>

- 5.47 The main effects of these methodologies compared with sales volume per pack are:
- (a) Sales volume per capsule shifts common costs from all other capsule strengths towards the 100mg packs, to reflect their larger pack size (i.e. 84 capsules per pack compared with 28 capsules per pack for all other capsule strengths).
  - (b) Sales volume per DDD allocates costs across capsule strengths based on the assumed average maintenance dosage of a product. The effect, for instance, is that four 25mg capsules are treated as equivalent to one 100mg capsule for the purposes of this calculation. Therefore, twelve packs of 25mg should have as much common cost allocated to it as one pack of 100mg (given that 100mg packs contain 84 capsules whilst 25mg packs contain 28 capsules). The effect is the same as taking a per mg of API per pack approach.

**c. Possible measures of rate of return**

- 5.48 Once a party's costs have been determined, it is necessary to apply a reasonable rate of return to those costs to establish the party's Cost Plus.<sup>915</sup>
- 5.49 The purpose of a reasonable rate of return is to acknowledge that an undertaking will require a financial incentive to engage in the activity of supplying a good or service, as a return on capital invested and/or as a reward for taking on any risks associated with these activities. As set out above, *'the determination of an appropriate margin is necessarily a question*

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<sup>914</sup> Flynn submitted that a weakness of the CMA's assessment is that the methods adopted as part of its sensitivity analysis only allocate common costs across the different strengths of phenytoin sodium capsules rather than Flynn's portfolio of products (document 01639.3, paragraph 5.21). However, for the reasons outlined in Annex D, the CMA considers that sales volumes by pack is the only available and appropriate method for allocating common costs across Flynn's portfolio of products. Furthermore, for the reasons outlined in section 5.C.V.a.iv, the CMA considers that its method already allocated a significant portion of common costs to phenytoin sodium capsules as a whole, which is favourable to the Flynn.

<sup>915</sup> See, for example, *Albion Water II*, [89].

*of judgment and appreciation*<sup>916</sup> and '[t]he actual margin to be set is not a matter of precise mathematics'.<sup>917</sup>

- 5.50 Determining what the CMA considers to be a reasonable rate of return is a necessary step in its cost-plus analysis. The reasonable rate of return identified does not, however, determine the maximum return an undertaking is permitted to earn on a product. It is possible for an undertaking to price above Cost Plus without those prices being either excessive or unfair.
- 5.51 Furthermore, the assessment of what is a reasonable rate of return will depend on the specific facts of a case. The fact that the CMA finds that a particular rate of return is reasonable for one product or undertaking does not mean that it will necessarily be applicable for another undertaking supplying a different product, even if these are within the same industry.
- 5.52 The CMA considered three possible measures for each Party's rate of return, namely: Return on Capital Employed ('ROCE'); Return on Sales ('ROS'); and gross margins.<sup>918</sup> A brief description of each these different measures is set out below.

*i. ROCE*

- 5.53 ROCE measures profits against the capital employed to produce them.<sup>919</sup> ROCE is a well-known profitability measure and it is widely accepted in the pharmaceutical industry where it is used in, among other things, the PPRS scheme.<sup>920</sup> The principal problem with ROCE is the difficulty that can be encountered when measuring capital employed. The standard approach is to use balance sheet asset values. However this can give rise to three main problems: (i) asset values may be historical and, if this is the case, would not be an accurate reflection of current values;<sup>921</sup> (ii) asset values may be inflated to reflect any 'excess profit' they are able to generate and therefore a

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<sup>916</sup> *Genzyme Remedy*, [255].

<sup>917</sup> *Genzyme Remedy*, [279].

<sup>918</sup> The CMA notes that Internal Rate of Return ('IRR') can also be used to measure profitability. However, it did not consider it as suitable in this case principally because the lack of suitable benchmarks meant that it was not possible to estimate what a reasonable IRR would be. To estimate IRR would require knowledge of the IRR of comparator companies. These are not publicly available. Furthermore, even if there were obtainable the activity that the IRR was calculated on would need to be comparable to the supply of phenytoin sodium capsules. Neither party suggested that the CMA should adopt an IRR measure.

<sup>919</sup> ROCE is defined as total assets less current liabilities or fixed assets plus working capital.

<sup>920</sup> The PPRS uses Return on Capital ('ROC') in the scheme agreement. This is broadly equivalent to ROCE.

<sup>921</sup> The CMA considers that, when determining asset values, the net book value of assets is preferable to their gross book value as this is a more accurate measure of the asset's market and replacement value. Depreciation will be accounted for separately, as an expense within costs, so that the fall in value of the asset is recorded.

return based on that value would allow the business an excessive return; and (iii) the economic activity of the undertaking in question may not be separately recorded on the balance sheet or not completely recorded. The latter problem is one of cost allocation and/or cost identification.

5.54 The ability to accurately calculate ROCE is further affected where the industry in question has a low level of capital assets, such as a sales and marketing operation. This is because the value of the capital employed may bear little relationship to the overall asset value because of the presence of intangibles.

*ii. ROS*

5.55 ROS is a measure of the return on sales after the deduction of both direct and indirect costs. ROS is a straightforward measure of profit. Like ROCE, it is widely used and understood in the pharmaceutical industry.

5.56 The CMA considers that, given that this Decision relates to unfair pricing, it would not be appropriate to calculate the reasonable ROS allowance based on actual revenue generated from prevailing prices. This approach is consistent with the rejection of sales value as an appropriate method to allocate common costs. Instead, a reasonable ROS should be calculated through an uplift on costs.

*iii. Gross margin*

5.57 Gross margin is defined as the difference between revenue and costs of goods sold.<sup>922</sup> Gross margin is a well-understood, common measure of profitability that is easily calculated. It is not, however, a complete measure of profitability because it does not take into account all of the support activities which may be essential to achieve sales. It is generally used where ROS cannot be calculated with sufficient accuracy due to the difficulty in allocating indirect costs.

**IV. *The CMA's assessment of whether Pfizer's Prices are excessive***

5.58 For the reasons set out below, the CMA finds that Pfizer's Prices for each Pfizer's Products are excessive and have been throughout the Relevant

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<sup>922</sup> In order to express gross margin as a percentage, this difference is then divided by revenue.

Period. The CMA's analysis, set out below, follows the overall approach and methodology set out in sections 5.C.II and 5.C.III above.

**a. Pfizer's Prices and costs**

*i. Data used to calculate Pfizer's Prices and costs*

- 5.59 The CMA has relied on the data it has obtained from Pfizer during the course of the Investigation in order to assess whether its prices are excessive. However, data is not available up to the date of this Decision because there is a time delay between actual sales activity and the relevant financial data becoming available.
- 5.60 In the case of prices and direct costs, the CMA has obtained data from Pfizer for the period from September 2012 to June 2016. The CMA has not identified any reason why Pfizer's prices or direct costs would be expected to have changed significantly between June 2016 and the date of this Decision, and the CMA has received no submissions from Pfizer suggesting that they have.
- 5.61 In the case of indirect costs, the CMA has obtained data from Pfizer for the period September 2012 to November 2013. The CMA has not identified any reason why Pfizer's indirect costs attributable to Pfizer's Products would be expected to have changed significantly between November 2013 and the date of this Decision.<sup>923</sup> In particular, Pfizer has confirmed to the CMA that *'common costs in 2014 may be likely to be reasonably approximated using 2013 data.'*<sup>924</sup> Pfizer also confirmed to the CMA that it had reviewed both Pfizer Limited's 2014 accounts and its 2015 final draft accounts and considered that there were no changes to indirect costs (either in total, or for the EPBU) which would materially affect the CMA's estimate. Pfizer also stated that it did not consider that the position to 30 June 2016 would show any material changes.<sup>925</sup>
- 5.62 Given the above, the CMA considers that its conclusion that each of Pfizer's Prices are excessive would not change if cost data up to the date of this Decision were used in this assessment.

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<sup>923</sup> Pfizer provided data for 2014, however that data was unaudited and therefore less reliable. [REDACTED]; accordingly their use would increase any excess.

<sup>924</sup> See document 00725.1, question 6.

<sup>925</sup> See document 02129.1.



ii. *Pfizer's Prices*

5.63 The CMA's analysis of Pfizer's Prices over the Relevant Period is set out at Section 3.D.III above. Following that analysis, Table 5.1 below shows Pfizer's revenue and ASPs for each capsule strength during the Relevant Period.

**Table 5.1: Pfizer's revenues and Pfizer's Prices for Pfizer's Products, September 2012 to June 2016**

	Revenue	Price per pack
25mg	[REDACTED]	[£3 - £5.99]
50mg	[REDACTED]	[£6 - £8.99]
100mg	[REDACTED]	[£31 - £40.99]
300mg	[REDACTED]	[£31 - £40.99]

Source: Document 00863.2 and 02129.2.

5.64 In its assessment of whether Pfizer's Prices are excessive, the CMA has used revenue rather than prices. However, the overall result is identical whether revenue or prices are used.<sup>926</sup>

iii. *Pfizer's direct costs for Pfizer's Products*

5.65 The CMA has taken account of Pfizer's production, purchase and distribution costs for the supply of Pfizer's Products.

5.66 Pfizer records a Corporate Cost of Goods Sold ('COGS') for each pack of its own-manufactured products and submitted to the CMA that this is the most appropriate measure of its manufacturing costs.<sup>927</sup> COGS represents the internal price that Pfizer Manufacturing Deutschland GmbH (which manufactures the phenytoin sodium capsules) charges Pfizer Limited for each pack of phenytoin sodium capsules. It comprises:

(a) [REDACTED];<sup>928</sup> [REDACTED].<sup>929</sup>

<sup>926</sup> Converting revenues into ASPs would simply require actual revenues to be divided by actual volumes. A similar conversion would be required for costs in order to compare like-for-like.

<sup>927</sup> See document 00725.1, question 1.

<sup>928</sup> The API is manufactured by Pfizer in [REDACTED].

<sup>929</sup> The manufacture of phenytoin sodium capsules for the European market (including the UK) is carried out by Pfizer Manufacturing Deutschland GmbH at its factory in Freiburg, Germany.

(b) Global overhead contribution comprising an inter-company adjustment to cover a share of unallocated global common costs. This charge is included so that Pfizer Limited makes a contribution to global head office staff and management costs. (Pfizer Limited's common costs are allocated under indirect costs.<sup>930</sup>)

5.67 The CMA agrees that COGS is the most appropriate available measure of Pfizer's manufacturing costs as it includes all of the costs directly attributable to manufacturing Pfizer's Products. As well as COGS, the CMA has included the distribution costs incurred by Pfizer Limited to deliver Pfizer's Products from the Pfizer Manufacturing Deutschland GmbH factory at Freiburg to Flynn's UK pre-wholesaler<sup>931</sup> ([REDACTED]) for supply to the UK market within its measure of Pfizer's direct costs. Table 5.2 sets out Pfizer's total direct costs (COGS and distribution)<sup>932</sup> for each of Pfizer's Products throughout the Relevant Period. These costs are also shown split on a per pack basis.

**Table 5.2: Pfizer's direct costs for Pfizer's Products in total and on a per pack basis, September 2012 to June 2016**

	Total direct costs	Direct costs per pack
25mg	[REDACTED]	[REDACTED]
50mg	[REDACTED]	[REDACTED]
100mg	[REDACTED]	[REDACTED]
300mg	[REDACTED]	[REDACTED]

Source: CMA calculation based on document 00863.2 and 02129.2.

5.68 Packs of 100mg phenytoin sodium capsules contain three times as many capsules as the packs containing other capsule strengths. As a result, the direct cost of a 100mg pack is similar to that of a 300mg pack.

5.69 To understand the relationship between costs per pack size and capsule strength (in particular, the differences between the 25mg and 50mg packs on the one hand, and the 100mg and 300mg packs on the other hand), the

<sup>930</sup> See Annex E for further details.

<sup>931</sup> 'Pre-Wholesaler' refers to the logistics company which receives and stores the products and transfers them to Flynn's wholesalers (Flynn itself does not receive or distribute the products).

<sup>932</sup> A detailed breakdown of Pfizer's direct costs is included in Annex C.

CMA looked at the detailed composition of direct costs. This analysis is set out in Annex C. The CMA has found that the differences in costs do not undermine the use of Pfizer's COGS and distribution costs as the measure of Pfizer's direct costs for Pfizer's Products.

*iv. Pfizer's common costs for Pfizer's Products*

5.70 Pfizer accounts for its common costs (not including the global overhead costs referred to in the preceding section) under the heading 'Sales, Informational and Administrative expenses' ('SI&A'). These costs cover expenses such as employee costs and office expenses and were incurred at both the business unit level and the whole entity level which, respectively, were:

(a) The EPBU within Pfizer Limited. The EPBU was the commercial business unit which managed the supply of Pfizer's Products until November 2013.<sup>933</sup>

(b) Pfizer Limited. These costs relate to all products supplied by Pfizer Limited.

5.71 Summary figures for the CMA's allocation of Pfizer's indirect cost are set out in Table 5.3: Pfizer's common costs allocated to Pfizer's Products in total and on a per pack basis, September 2012 to June 2016. With the exception of R&D and general marketing expenses, Pfizer has not raised any issues with regards to the CMA's calculations. The CMA addresses Pfizer's representations with regards to R&D in Annex L and general marketing expenses in Annex E. Full details of the CMA's assessment of Pfizer's indirect costs, including the CMA's allocation of Pfizer's indirect costs to Pfizer's Products and comparative figures for 2012, are set out in Annex E.

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<sup>933</sup> At the beginning of 2014 Pfizer undertook a restructuring resulting in phenytoin sodium capsules moving from being managed by the EPBU to the Global Established Products division. For the reasons set out in section 5.C.IV.a.i above, the CMA has used pre-November 2013 data for its analysis as this was the most comprehensive and the most conservative basis to assess cost after November 2013.

5.72 Table 5.3 below summarises Pfizer's common costs allocated to each of Pfizer's Products on a per pack basis using sales volumes.

**Table 5.3: Pfizer's common costs allocated to Pfizer's Products in total and on a per pack basis, September 2012 to June 2016**

	Total common costs	Common costs per pack
25mg	[REDACTED]	[REDACTED]
50mg	[REDACTED]	[REDACTED]
100mg	[REDACTED]	[REDACTED]
300mg	[REDACTED]	[REDACTED]

Source: Documents 00725.3 and 00725.4

5.73 As a cross-check to the CMA's allocation of common costs to Pfizer's Products, the CMA has calculated how much common cost would have been allocated to Pfizer's Products using Pfizer's average direct costs to common costs ratio instead of the sales volumes per pack basis. The common cost to direct cost ratio across Pfizer Limited's entire business was [REDACTED] in 2013 ([REDACTED]). Under this alternative methodology, the total amount of common costs allocated to Pfizer's Products between September 2012 and June 2016 would be [REDACTED]; significantly lower than the balance allocated to Pfizer's Products by the CMA, which is [REDACTED].<sup>934</sup> Consequently, the CMA's approach to common cost allocation results in around twice the level of overall costs (direct and indirect) being allocated to Pfizer's Products than would have been the case had the CMA allocated Pfizer's common costs in line with Pfizer Limited's average common costs to direct costs ratio.<sup>935</sup> The CMA considers that this cross-check highlights the generous approach, which is favourable to Pfizer, that the CMA has taken to allocating common costs to Pfizer's Products.

<sup>934</sup> This alternative approach would also reduce the amount of common cost per pack of phenytoin sodium capsules from [REDACTED] across capsule strengths to [REDACTED] and [REDACTED] per pack of 25mg and 50mg phenytoin sodium capsules respectively and [REDACTED] and [REDACTED] per pack of 100mg and 300mg phenytoin sodium capsules.

<sup>935</sup> This, in turn, means that any ROS rate which the CMA applies to the costs it has allocated to Pfizer's Products will be equivalent, in terms of the resultant absolute allowance for a reasonable rate of return, to a ROS of around double that rate had the CMA allocated Pfizer's common costs in line with Pfizer Limited's average common costs to direct costs ratio.

5.74 Table 5.4 below shows the results of the CMA’s sensitivity analysis (as described in paragraphs 5.C.III.b) in which it assessed how Pfizer’s common costs would be allocated to each of Pfizer’s Products using the alternative volume allocations of per DDD and per capsule.

**Table 5.4: CMA sensitivity analysis on Pfizer’s common costs allocated to Pfizer’s Products, September 2012 to June 2016**

	Sales volume (per pack)		Sales volume (DDD)		Sales volume (per capsule)	
	Total common cost	Common cost per pack	Total common cost	Common cost per pack	Total common cost	Common cost per pack
<b>25mg</b>	[X]	[X]	[X]	[X]	[X]	[X]
<b>50mg</b>	[X]	[X]	[X]	[X]	[X]	[X]
<b>100mg</b>	[X]	[X]	[X]	[X]	[X]	[X]
<b>300mg</b>	[X]	[X]	[X]	[X]	[X]	[X]

5.75 An impact of the sensitivity analyses is to increase the common costs allocated to the 100mg capsule strength. Using DDD, the common costs allocated to the 25mg and 50mg packs are lower at [X] and [X] respectively whilst the common costs allocated to the 100mg and 300mg packs are higher at [X] per pack.

5.76 Using the per capsule sales volumes method, common costs get allocated towards the 100mg packs and away from all other capsule strengths, reflecting the fact that 100mg packs contain more capsules. The impact is significant for the 25mg, 50mg and 300mg packs for which common costs are [X] per pack rather than [X] per pack.

5.77 The CMA has set out how the above sensitivity analysis of Pfizer’s common cost allocation affects Pfizer’s excesses in section 5.C.IV.e below.

***b. Establishing a reasonable rate of return for Pfizer***

5.78 Having estimated the total costs actually incurred in, or reasonably attributable to, the supply of each of Pfizer’s Products, the CMA must

establish the 'Plus' element of Cost Plus: that is, a reasonable rate of return.<sup>936</sup> In order to establish a reasonable rate of return for Pfizer's Products, it is necessary for the CMA to determine: first, what is the most appropriate measure of return to use; and second, what would be a reasonable rate using that measure. The CMA's assessment of these is set out below.

*i. The appropriate measure of the rate of return*

- 5.79 As set out in Section 5.C.II.c above, the CMA considered three possible measures of Pfizer's rate of return: ROCE; ROS; and gross margins. In assessing which of these measures was the most appropriate for the calculation of Cost Plus for Pfizer's Products, the CMA took the following into account: how well known, understood and used the measures are in the sector; the financial data provided by Pfizer; the types of activities that Pfizer undertakes in the supply of Pfizer's Products; and Pfizer's views.
- 5.80 ROCE would be the CMA's preferred measure of return for Pfizer's Products as it is a well-known profitability measure which assesses profits against the capital employed and it is widely accepted in the pharmaceutical industry. However, there are limitations in applying ROCE in this case.
- 5.81 First, Pfizer submitted that there is no dedicated production line for Pfizer's Products or any other specific product at its manufacturing facility in Freiburg, Germany. It would only be appropriate to allocate assets at the individual capsule strength level if the different capsule strengths were produced using different capital assets or if the capsule strengths had different market risks. However, each capsule strength shares the same capital employed, since no single capsule strength is produced in isolation, and the products' characteristics mean that they are likely to face the same market risks. Consequently, it would not be appropriate to consider individual capsule strengths of phenytoin sodium capsules in a ROCE analysis.
- 5.82 Second, given that there is no dedicated line for Pfizer's Products or any other product at its manufacturing facility in Freiburg, a bottom-up approach to assessing its phenytoin sodium production assets is not possible.<sup>937</sup> Consequently, in order to determine capital employed for the purposes of

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<sup>936</sup> The need to take into account, in appropriate circumstances, not only the costs of production but also a reasonable rate of return was acknowledged by the CAT in *Albion Water II* at [89]. The same general point was made by the Court of Appeal in *Attheraces Limited v the British Horseracing Board Limited* [2007] EWCA Civ 38 (*'Attheraces'*), [209].

<sup>937</sup> See document 00903.1 and 00903.2.

calculating ROCE, Pfizer proposed and produced a capital asset valuation based on a top-down approach. However, the information made available to calculate capital, which is necessary for a ROCE approach, contained a number of limitations which reduce the reliance the CMA can place on the figures. In particular, fixed assets data was only provided on a book value basis, rather than current value, and was submitted in general categories such as land, buildings and manufacturing equipment.

5.83 As stated in section 5.C.III.c.ii ROS is a measure of the return on sales after both direct and indirect costs, whereas gross margin does not take into account all of the support activities which may be essential to achieve sales. Given that the CMA can identify and allocate Pfizer's indirect costs to Pfizer's Products, the CMA has concluded that gross margin is an incomplete and less informative measure than ROS and therefore not a suitable measure of rate of return in this case.

5.84 In view of the difficulties measuring ROCE, as set out above, the CMA has used ROS as its primary method to determine a reasonable rate of return for the calculation of Cost Plus for Pfizer's Products. The CMA has, however, also carried out a rate of return assessment based on the capital employed data provided by Pfizer in order to provide a cross-check against the results of the CMA's ROS analysis (see section 5.C.IV.c.ii below).

*ii. Assessment of a reasonable rate of return*

5.85 Determining what a reasonable rate of return should be is an exercise of judgement and will depend on the specific facts of each case. Having assessed the overall appropriateness of possible measures for the rate of return, this section sets out the CMA's assessment of what would be a reasonable rate of return under each measure for the calculation of Cost Plus for Pfizer's Products.

ROS

5.86 Under the CMA's primary method for determining a reasonable rate of return for the calculation of Cost Plus for Pfizer's Products (i.e. ROS), the CMA finds that a ROS of 6% is an appropriate reasonable rate of return. The CMA's reasoning for this is set out below.

5.87 The CMA considered whether there are any benchmarks which may indicate what would be a reasonable rate of return for the calculation of Cost Plus for Pfizer's Products. There is no directly applicable and generally accepted

industry benchmark within the UK for what is a reasonable rate of return for manufacturers of generic drugs.<sup>938</sup> However, the CMA considered the following possible benchmarks:

- Pfizer's internal ROS;
- the allowable ROS under the PPRS; and
- other companies' ROS rates.

5.88 As set out below, in considering the relevance of these benchmarks to what might be a reasonable rate of return for the calculation of Cost Plus for Pfizer's Products, the CMA took into account the nature of phenytoin sodium capsules, the nature of the activities undertaken by Pfizer and the risks that Pfizer incurs with respect to its supply of Pfizer's Products.

*Pfizer's internal ROS*

5.89 In respect of Pfizer's internal profit margins, Pfizer submitted data to the CMA that showed in the years 2009 to 2013 it had a ROS of 0%, 2%, -42% (i.e. a negative ROS), 4% and 5% respectively across its UK business as a whole.<sup>939</sup> The CMA has taken account of Pfizer's submissions that phenytoin sodium capsules were loss-making during some of this period and has adjusted these figures to remove Pfizer's revenue and costs for phenytoin sodium capsules. Based on these calculations, Pfizer's yearly profit margins across the rest of its business from 2009 to 2013 [redacted] respectively.

5.90 The CMA recognises that these internal ROS figures represent Pfizer's average yearly returns across its UK business and that Pfizer could, legitimately, earn higher returns on its sales of Pfizer's Products. Nevertheless, the CMA considers that these figures are informative in assessing what would be a reasonable rate of return for the calculation of Cost Plus for Pfizer's Products under the *United Brands* Test.

5.91 First, the CMA considers that a reasonable ROS for the calculation of Cost Plus for Pfizer's Products should not be materially higher than the returns Pfizer earned across its UK business as a whole, because:

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<sup>938</sup> In particular Scheme M, the main regulatory framework for generic drugs, does not regulate the prices charged by drug manufacturers or contain any provisions on rates of return.

<sup>939</sup> See document 00903.3. [redacted].



- phenytoin sodium capsules are a very old drug which have not undergone any recent development or innovation by Pfizer which required any investment that the CMA has been made aware of; *and*
- Pfizer's supply of Pfizer's Products involves very low risks since there is an established and sizable base of stabilised patients who, due to the principle of Continuity of Supply, will continue to be treated with the product.

5.92 Second, in exercising the CMA's judgement as to what would be a reasonable rate of return for the calculation of Cost Plus it is important, as the CAT has recognised to have '*regard, in particular, to the interests of [...] patients and to the interests of the customer, the NHS. Those are the interests which the legislation is primarily designed to protect although, of course, the interests of [suppliers] are also important.*'<sup>940</sup> Given the absence of another directly applicable benchmark and the lack of effective competition to constrain Pfizer's market power, adopting a reasonable rate of return which is broadly in line with the average returns earned across the rest of Pfizer's UK business (excluding phenytoin sodium capsules) allows the CMA to calculate a rate of return for Pfizer's Products that preserves Pfizer's overall financial position. Using a rate of return around this level will ensure that Pfizer's overall position would be made neither materially better nor worse.

#### *The allowable ROS under the PPRS*

5.93 The appropriateness of a rate of return around Pfizer's ROS is confirmed by reference to the allowable ROS under the PPRS. Pharmaceutical companies are allowed to earn a ROS of up to 6% on their portfolio of branded products within the PPRS.<sup>941, 942</sup> This rate was agreed through negotiation between

<sup>940</sup> *Genzyme Remedy*, [255] and [256].

<sup>941</sup> See *The Pharmaceutical Price Regulation Scheme 2014* ('PPRS 2014'), published by the DH and the Association of the British Pharmaceutical Industry, [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/282523/Pharmaceutical\\_Price\\_Regulation.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/282523/Pharmaceutical_Price_Regulation.pdf), paragraph 8.14.

<sup>942</sup> ROS has been included as a measure of the allowable return under the PPRS since 1999. The allowable return under the scheme was originally determined using ROC as the sole measure, reflecting the high manufacturing base of pharmaceutical companies in the UK. As the UK manufacturing base moved overseas a large number of pharmaceutical companies' UK entities became sales and distribution operations meaning ROC was less relevant in assessing their profits. This led to ROS being included as an alternative measure to ROC in the 1999 PPRS. At this point, the allowable return under ROC was 21%. ROS was calculated from ROC on the basis of a sales to capital ratio of 3.5:1. This resulted in a ROS of 6%. ROS has been included in at least the last two PPRS schemes (the 2009 PPRS and the 2014 PPRS) and the allowable rate of 6% ROS remained

the DH (on behalf of the NHS) and the ABPI (on behalf of scheme members) and, accordingly, it strikes a balance between the sellers' and the customers' interests.<sup>943</sup> to ensure that it is compensated for paying unduly high prices in that year.

- 5.94 The CMA recognises that there are limits to the PPRS ROS rate of 6% as an indicator of a reasonable rate of return for the calculation of Cost Plus for Pfizer's Products. In particular, the CMA recognises that the purpose of the PPRS is to control pharmaceutical companies' profits on their portfolio of branded products, rather than the prices of individual generic products.<sup>944</sup> Moreover, the CMA recognises that Pfizer could legitimately achieve a rate of return on Pfizer's Products which was higher than the allowable rate of return under the PPRS without its prices being excessive.
- 5.95 The CMA considers, however, that the allowable ROS under the PPRS is useful and informative for determining a reasonable rate of return for the purpose of calculating Cost Plus for Pfizer's Products. The reasons for this are set out below.
- 5.96 First, until the start of the Infringements, *Epanutin* was sold under the PPRS. Indeed, apart from being removed from the PPRS, and the relevant MAs being transferred to Flynn, very little about Pfizer's Products has changed. The product itself is identical. Under the PPRS, *Epanutin* was not subject to competition and the CMA has found that Pfizer's Products continue to be

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consistent across both of those schemes; that is, for a 10 year period (as each scheme runs for five years). Pfizer is assessed under the PPRS using ROS.

<sup>943</sup> Pfizer has noted that the PPRS also allows for a margin of tolerance ('MOT') above the ROS target of 6% and has stated that the CMA failed to take into account the MOT in its analysis (see document 01622.2 at paragraph 337). Members of the 2009 PPRS scheme were allowed to earn up to 140% of the ROS target and this increased to 150% in the 2014 scheme. However, the MOT was not intended to routinely apply to a PPRS member's returns. Rather, according to the ABPI, it is in place to ensure companies are not penalised if they '*introduce a new, clinically and cost effective medicine which finds high acceptance by patients and prescribers*' (see '*Understanding the 2014 Pharmaceutical Price Regulation Scheme*', [http://www.abpi.org.uk/our-work/policy-parliamentary/Documents/understanding\\_pprs2014.pdf](http://www.abpi.org.uk/our-work/policy-parliamentary/Documents/understanding_pprs2014.pdf), page 8). That description does not apply to Pfizer's Products. Further, there are specific limits on the application of the MOT; in particular, the MOT will not be available to a scheme member for any year in which it has implemented a price increase agreed by the DH, and where a price increase is agreed by the DH in the second half of a year, the MOT will not be available to the scheme member for the year following the increase (see *PPRS 2014*, paragraph 8.18). For these reasons, as well as the reasons set out in this section for why the CMA considers a ROS of 6% to be a reasonable rate of return, the CMA does not consider that it would be appropriate to include the PPRS MOT in its determination of a reasonable rate of return for Pfizer's Products.

<sup>944</sup> As Pfizer submitted to the CMA (see document 00903.1), under the PPRS '*the returns earned by pharmaceutical companies should not be regulated on a product-by-product basis, but rather should take a broader holistic approach and simply ensure that across their overall product portfolios they are not earning excessive profits*.'

free from any effective competitive constraint (see section 4.C above). Indeed, Pfizer's Products continue to be supplied to downstream customers by Flynn as a quasi-brand ('*Phenytoin Sodium Flynn Hard Capsules*') due to the principle of Continuity of Supply and the MHRA's requirement that phenytoin sodium capsules include the MA holder's name in their title. These factors mean that the PPRS ROS rate is informative in determining a reasonable rate of return for the calculation of Cost Plus for Pfizer's Products in this case.

- 5.97 Second, the allowable ROS under the PPRS is the closest the UK comes to an agreed industry standard for returns on pharmaceutical products. Further, this allowable ROS has been agreed for branded drugs which also include new and highly innovative products. By contrast, phenytoin sodium capsules are an old and off-patent drug. In the CMA's judgement the allowable ROS under the PPRS should, therefore, provide a reasonable financial incentive for Pfizer to supply Pfizer's Products.
- 5.98 Third, using the allowable PPRS ROS means that the CMA will adopt a rate of return for the purposes of the *United Brands* test that will broadly preserve Pfizer's previous overall financial position. In this respect, the allowable ROS of 6% under the PPRS approximates (indeed is slightly higher than) Pfizer's average internal ROS (and is in fact higher than Pfizer's annual ROS in any of the years from 2009 to 2013 for which Pfizer submitted data to the CMA). It is also likely to be higher than the actual average that most companies will earn on their PPRS portfolio, as the allowable return under the PPRS is a target rate of return. [REDACTED].<sup>945</sup>
- 5.99 Fourth, the application of a 6% ROS is equivalent to an overall contribution margin that is more than [REDACTED] times greater than the target rate below which Pfizer puts a product under review. Pfizer has told the CMA that it has a policy to put a product under review if the returns on the product fall below a [REDACTED] contribution margin threshold, defined as revenue minus COGS.<sup>946</sup> ROS, on the other hand, is measured after also accounting for distribution and common costs. This means that a ROS of 6% is equivalent to a contribution margin of [REDACTED] for 25mg capsule strengths, [REDACTED] for 50mg capsule strengths, and [REDACTED] for 100mg and 300mg capsule strengths.<sup>947</sup> Such margins are clearly well in excess of Pfizer's own internal target. This

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<sup>945</sup> [REDACTED].

<sup>946</sup> See document 00519.2.

<sup>947</sup> Across the four dosage strengths of Pfizer's Products, a ROS of 6% is equivalent to an average contribution margin of [REDACTED].

corroborates the CMA's conclusion that a ROS of 6% is a reasonable rate of return for the calculation of Cost Plus for Pfizer's Products.

- 5.100 Taking all of the above in the round, the CMA considers that a ROS of 6% is a reasonable rate of return for the purpose of calculating Cost Plus for Pfizer's Products.<sup>948</sup> It strikes a reasonable balance between Pfizer's legitimate commercial interests, on the one hand, and the interests of the NHS (in the form of CCGs) on the other. To further reduce the risk of error, the CMA has cross-checked its findings using ROS with a ROCE analysis, set out in section 5.C.IV.c.ii below.
- 5.101 This finding is not, as Pfizer suggests, the misapplication of the allowable ROS under the PPRS to products falling outside the PPRS. Rather, it represents the CMA's conclusion that, in the particular circumstances of this case, a 6% ROS is a reasonable rate of return for Pfizer's Products for the purposes of the first stage of the *United Brands* test.
- 5.102 For the avoidance of doubt, the CMA does not consider that generic medicines may not legitimately earn returns which are greater than a 6% ROS. Further, the CMA does not suggest that a ROS of 6% would necessarily be a reasonable rate of return for an assessment of Cost Plus for generic products other than Pfizer's Products. For example, in cases (unlike this one) where substantial investment was made, or substantial capital employed, or where there were significant commercial risks, a rate of return greater than a 6% ROS could be fully justified for the purpose of calculating Cost Plus.

#### *Other companies' ROS rates*

- 5.103 Pfizer submitted to the CMA that a 6% ROS would not reflect the average returns earned by three other pharmaceutical companies which sell off-patent drugs. Those three companies earned a ROS of between 16.4% and 25.1% across their portfolio of products in, or during, 2015.<sup>949</sup>

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<sup>948</sup> As set out in section 5.C.IV.a.iv above, the CMA's approach to common cost allocation results in around twice the level of overall costs (direct and indirect) being allocated to Pfizer's Products than would have been the case had the CMA allocated Pfizer's common costs in line with Pfizer Limited's average common costs to direct costs ratio. This, in turn, means that the application of a ROS of 6% to the costs that the CMA has allocated to Pfizer's Products is equivalent, in terms of the resultant absolute allowance for a reasonable rate of return, to the application of a ROS of just under 12% had the CMA allocated Pfizer's common costs in line with Pfizer Limited's average common costs to direct costs ratio.

<sup>949</sup> See document 01622.2, paragraph 338.

- 5.104 The CMA does not consider that it is appropriate or necessary to rely on these companies' ROS rates in determining a reasonable rate of return for calculating Cost Plus for Pfizer's Products in this case, for the following reasons.
- 5.105 First, it is not clear what cost basis was used to calculate these rates of return or whether a consistent approach was adopted across companies, or indeed whether costs were allocated consistently with the approach adopted in this Decision.<sup>950</sup>
- 5.106 Second, the rates are average returns across the relevant company's portfolio and cannot be conclusive of what a reasonable rate of return would be for a specific product. For example, some of the company's products may be new generics which will have required investment to be brought to market and therefore require a return on capital employed which may justify higher returns.

### ROCE

- 5.107 As set out above, the CMA has carried out a ROCE assessment, in order to provide a cross-check against the results of the CMA's ROS analysis.
- 5.108 The CMA has considered both Pfizer's and other pharmaceutical companies' Weighted Average Cost of Capital ('WACC') and the PPRS Return on Capital ('ROC') as potential benchmarks for the ROCE measure.
- 5.109 Pfizer's WACC represents Pfizer's own risk profile and its expected return over all of its products. Pfizer provided figures for Pfizer Limited's WACC for the two years ending 30 November 2012 and 2013, which were [X] and [X] respectively. Pfizer also stated that this benchmark was not materially different for Pfizer Inc or Pfizer's Freiburg facility.<sup>951</sup>
- 5.110 The CMA notes that there are a number of listed and unlisted pharmaceutical companies that were reasonably comparable to Pfizer and

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<sup>950</sup> Pfizer also highlighted the recital of a 2008 EU Regulation dealing with subsidies for imports from India which, according to Pfizer, states that '*a profit margin below 10% is insufficient in the context of [the EU Pharmaceutical] industry*' (see document 01622.2, paragraph 339). However, it is not clear what measure of profitability the recital is referring to and given that the 10% ROS is only a target average return, it cannot be conclusive on what a reasonable rate of return should be for a specific product.

<sup>951</sup> [X].

which state their WACC in their annual reports.<sup>952</sup> The WACC for these companies ranged between 9% and 12%.<sup>953</sup> The similarity between Pfizer's WACC and those of a number of other pharmaceutical companies suggests that Pfizer's WACC is representative of what would be a common level of return in the pharmaceutical industry.

5.111 A possible alternative benchmark for ROCE is the rate used for ROC under the PPRS. Under the PPRS, the maximum allowable annual profit that a company can make on its portfolio of branded medicines supplied to the NHS is calculated in pounds sterling using either a ROC or ROS percentage.<sup>954</sup> ROC has been included as a measure under the PPRS since its inception and so is well understood. However, the CMA notes that the vast majority of PPRS members which produce an Annual Financial Return ('AFR')<sup>955</sup> use ROS<sup>956</sup> when submitting their AFR. [X].<sup>957</sup>

5.112 However, given the availability of an internal measure which is specific to the company in question, the CMA considers that the ROC measure used in the

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<sup>952</sup> The CMA notes that to ensure these WACCs are directly comparable to Pfizer's WACC, the WACC of these comparator companies should be adjusted for the different financial structure of the comparators (differences in, for example, the equity and debt ratios, and debt profile) as well as the differences in risk profile (risk profile will include, for example, the lifecycle of the company's medicines, location of its operations). These adjustments require a detailed knowledge of comparator companies as well as assumptions to be made in the estimations; details the CMA does not have access to. The CMA though considers that the financial structure and risk profile of these companies is unlikely to be materially different to that of Pfizer given the global nature and stated strategies of their operations. As such, the WACC of both Pfizer and comparator companies is considered to be an appropriate benchmark for determining a reasonable rate of return.

<sup>953</sup> The companies looked at and their WACC's were: AstraZeneca 10% (pre-tax); GSK 9% (pre-tax); Bayer 9.0 - 9.3% (pre-tax) Alliance Pharmaceuticals Limited stated its WACC was lower than its 10% discount rate; Meda 12% in Europe (excluding Nordic countries); Recordati 9.65% (pre-tax) excluding Turkey and Stada 11.2% in Central Europe and 8.9% in Germany. Where it was not explicitly stated the CMA has assumed that the stated WACCs are pre-tax as this is the usual figure given. The CMA did not look at all potential comparator companies given the similarity in values which arose from its initial review.

<sup>954</sup> To measure this, each company (that meets revenue thresholds) produces an annual financial return which is reviewed by the DH. Both Pfizer and Flynn are members of the PPRS. Pfizer meets the relevant criteria for producing an AFR. Flynn does not meet the AFR criteria; it does though provide audited accounts and a certificate of turnover. Any scheme member with total home sales of NHS medicines of more than £35 million under the 2009 scheme, (increased to £50 million 2014) had to submit an AFR. Any scheme member with total home sales of NHS medicines of more than £5 million and less than £35 million in its financial year was required to provide a copy of its audited accounts and a certificate (signed by the managing director or chief executive) giving a breakdown of turnover between sales of home NHS medicines, export sales of NHS medicines and sales of other products. Scheme members with NHS medicine sales below £5m were exempt from supplying financial information. Thirty one companies produced an AFR in 2011.

<sup>955</sup> Scheme members need to file an AFR when their revenue from sales to the NHS is greater than £35 million.

<sup>956</sup> 12<sup>th</sup> Report to parliament, April 2014 (covering the 2009 PPRS) states that it was not possible to produce a schedule of aggregate data from companies which submitted AFRs based on ROC as a result of the further increase in companies choosing ROS as their method of assessment.

<sup>957</sup> See document 00863.3.

PPRS is a less appropriate measure for determining a reasonable rate of return for the calculation of Cost Plus for Pfizer's Products. As such, the CMA has used a ROCE of 9% as the reasonable rate of return for the calculation of Cost Plus for Pfizer's Products under its alternative ROCE analysis.<sup>958</sup>

**c. Calculation of the reasonable rate of return and Cost Plus**

5.113 Having assessed what is a reasonable rate of return under each measure, this section sets out the results of the calculation of the reasonable rate of return and the resultant Cost Plus for each of Pfizer's Products.

**i. ROS**

5.114 Using a ROS figure of 6%, Table 5.5 below sets out the allowance for a reasonable return and the resultant Cost Plus figures for each of Pfizer's Products on a revenue basis. Table 5.6 below sets out the equivalent allowance and Cost Plus figures on a per pack basis (calculated by dividing the figures in Table 5.5 by sales volumes).

**Table 5.5: Pfizer's allowances for a reasonable rate of return and the resultant Cost Plus figures for each of Pfizer's Products, using a ROS of 6%,<sup>959</sup> on a total sales basis, September 2012 to June 2016**

	Capsule strength				Total sales
	25mg	50mg	100mg	300mg	
<b>Revenue</b>	[X]	[X]	[X]	[X]	[£60m – £69.9m]
<b>Direct costs</b>	[X]	[X]	[X]	[X]	[X]
<b>Common cost</b>	[X]	[X]	[X]	[X]	[X]
<b>Allowance for reasonable return</b>	[X]	[X]	[X]	[X]	[X]
<b>Cost Plus</b>	[X]	[X]	[X]	[X]	[X]

<sup>958</sup> [X], see this section above.

<sup>959</sup> Mathematically, a ROS of 6% translates into an uplift on costs of approximately 6.38%. Given that, for the reasons outlined in 5.C.III.c.ii, in this case a reasonable ROS should be calculated through an uplift on costs, the CMA has uplifted costs by 6.38% in order to calculate a ROS of 6%.

**Table 5.6: Pfizer's allowances for a reasonable rate of return and the resultant Cost Plus figures for each of Pfizer's Products, using a ROS of 6%, on a per pack basis, September 2012 to June 2016**

	Capsule strength			
	25mg	50mg	100mg	300mg
<b>Price</b>	[£3 - £5.99]	[£6 - £8.99]	[£31 - £40.99]	[£31 - £40.99]
<b>Direct costs</b>	[✂]	[✂]	[✂]	[✂]
<b>Common cost</b>	[✂]	[✂]	[✂]	[✂]
<b>Allowance for reasonable return</b>	[✂]	[✂]	[✂]	[✂]
<b>Cost Plus</b>	[✂]	[✂]	[✂]	[✂]

*ii. ROCE*

5.115 In order to cross-check that the CMA's assessment of Pfizer's allowance for a reasonable return on a ROS basis is appropriate, the CMA has also calculated an allowance for a reasonable return on a ROCE basis. Using this approach, it is first necessary to estimate the capital employed by Pfizer in producing and supplying Pfizer's Products.

5.116 The CMA estimates the value of the average capital employed by Pfizer in FY2013 for the production and supply of Pfizer's Products to have been [✂] on a gross book value ('GBV') basis and [✂] on a net book value ('NBV') basis.<sup>960</sup> [✂].<sup>961</sup> Therefore, the CMA considers that it is appropriate to treat these assets values as representative of the NBV and GBV of Pfizer's fixed asset base during the entire Relevant Period. Detailed workings and explanations for the CMA's estimates of capital employed are included in Annex I.

<sup>960</sup> Fixed asset values are affected by the age of the assets and the entity's depreciation policy. As such, they are usually revalued to reflect value to the entity. As a top down approach using the total assets of the entity was used a revaluation was not practical. To compensate for this ROCE was calculated on both a GBV and NBV basis. The CMA considered that using both values would mean that the resultant range would be highly likely to include the actual fixed assets' value following a revaluation.

<sup>961</sup> See document 02129.1, question 4.



5.117 Table 5.7 sets out Cost Plus for Pfizer's Products (in aggregate) using a ROCE of 9%, as established in section 5.C.IV.b above, on both a NBV and GBV basis.

**Table 5.7: Pfizer's allowances for a reasonable rate of return, using ROCE of 9%, and the resultant Cost Plus figures for Pfizer's Products, September 2012 to June 2016**

<b>Total phenytoin sodium capsules sales</b>		
	<b>GBV</b>	<b>NBV</b>
<b>Revenue</b>	[£60m - £69.9m]	[£60m - £69.9m]
<b>Direct costs*</b>	[✂]	[✂]
<b>Common cost **</b>	[✂]	[✂]
<b>Allowance for reasonable return (ROCE of 9%) ***</b>	[✂]	[✂]
<b>Cost Plus</b>	[✂]	[✂]
<p>* Direct costs under ROCE differ from ROS as they include the standard manufacturing costs incurred by the Freiburg facility, rather than the Corporate COGS. See Annex I.</p> <p>** This common cost figure was allocated using the total number of packs of phenytoin sodium capsules sold as a proportion of all products sold.</p> <p>*** The average capital employed for FY2013 has been used for the whole period under investigation. This is in line with the approach adopted for common costs.</p>		

5.118 Table 5.7 shows that the allowance provided on an NBV basis yielded similar results as under a ROS of 6% (see Table 5.5). The CMA considers that the NBV of assets provide a more accurate measure of the replacement value of the relevant assets and is therefore a more appropriate basis on which to perform this assessment than GBV.<sup>962</sup>

5.119 As explained in section 5.C.III.c.i above, the CMA places only limited reliance on the ROCE results. However, the CMA considers that these results further support the CMA's conclusion that the allowable return it has calculated for Pfizer under a ROS of 6% is reasonable.

<sup>962</sup> This is because depreciation is accounted for as an expense within the costs so that the fall in value of the asset is recorded.

5.120 As such, the CMA has used a ROS of 6% as the basis for calculating Pfizer's excesses and the CMA has not further considered ROCE in its assessment set out below.

*d. The amount by which Pfizer's Prices exceed Cost Plus*

5.121 Having established Pfizer's Prices, Pfizer's costs (both direct and indirect) and a reasonable rate of return for Pfizer's Products, this section sets out the CMA's findings regarding the amount by which Pfizer's Prices exceed Cost Plus: that is, the size of Pfizer's excesses.

5.122 The CMA expresses Pfizer's excesses in the following two ways:

- as the absolute amount (in pounds sterling) by which Pfizer's Prices exceed Cost Plus (calculated by subtracting Cost Plus from Pfizer's Prices); and
- as the percentage by which Pfizer's Prices exceed Cost Plus (calculated by subtracting Cost Plus from Pfizer's Price then dividing the result by Cost Plus).

5.123 In calculating Cost Plus for each of Pfizer's Products, the CMA has adopted an approach which fully allocates costs – both all direct costs and an appropriate allocation of all relevant indirect costs – as well as a reasonable rate of return. As such, the amount by which each of Pfizer's Prices exceed Cost Plus reveals the excess that Pfizer is earning over and above what would be a reasonable return for its activities in the production and supply of Pfizer's Products. In short, this is pure excess profit.

5.124 Further, the CMA considers that the CMA's generous approach to allocating indirect costs to Pfizer's Products, as demonstrated in section 5.C.IV.a.iv, is likely to have led to Pfizer's excesses being underestimated. As such, the CMA finds that Pfizer's excesses on each of Pfizer's Products are *at least* the figures which it has calculated.

5.125 The results set out in Table 5.8 below show that Pfizer's Prices exceeded Cost Plus by at least 29% for 25mg capsules, at least 100% for 50mg capsules, at least 705% for 100mg capsules and at least 690% for 300mg capsules (where common costs are allocated on a sales volume per pack basis).

**Table 5.8: Pfizer's excesses on Pfizer's Products, September 2012 to June 2016**

	Capsule strength				Total sales
	25mg	50mg	100mg	300mg	
<b>Revenue</b>	[✂]	[✂]	[✂]	[✂]	[£60m - £69.9m]
<b>Cost Plus</b>	[✂]	[✂]	[✂]	[✂]	[✂]
<b>Excess (revenue)</b>	[✂]	[✂]	[✂]	[✂]	[£49m - £57m]
<b>Excess (per pack)</b>	[£1 - £2.99]	[£3 - £5.99]	[£31 - £40.99]	[£31 - £40.99]	[✂]
<b>Excess (%)</b>	29%	100%	705%	690%	443%

5.126 Figure 5.1 below illustrates the size of Pfizer's excesses in absolute terms on a per pack basis, compared to Cost Plus (including the generous allocation of common costs) for each of Pfizer's Products.

**Figure 5.1: Pfizer's costs and excesses (per pack) on Pfizer's Products, September 2012 to June 2016**

[✂]

**e. Conclusion on whether Pfizer's Prices are excessive**

5.127 The CMA has concluded that each of the excesses set out in Table 5.8 is (in the words of the *Albion Water II* judgment) '*material*' and '*sufficiently large to be deemed excessive*' in the context of the *United Brands* Test.

5.128 In addition to the scale of each of Pfizer's excesses, the CMA's conclusion is confirmed by the following factors.

5.129 First, Pfizer has maintained the excesses set out above on each of Pfizer's Products for a substantial period of time (over four years). The persistence of Pfizer's significantly high returns on each of Pfizer's Products relative to those that would have prevailed in a competitive market confirm that each of Pfizer's Prices are excessive, rather than them being a temporary anomaly in an otherwise competitive market.

- 5.130 In this respect, as set out in Table 5.8, Pfizer's excesses on all four capsule strengths of Pfizer's Products amounted to at least [£49m - £57m] million between September 2012 and June 2016.
- 5.131 Further, that Pfizer's Prices for each of Pfizer's Products are excessive continues to hold true if Pfizer's Prices are considered separately before and after its price decreases in January 2014. These figures are shown in Annex H.
- 5.132 Second, while they are not determinative, the CMA has had regard to the magnitude of the excesses that have been found to be excessive in other cases. In particular, an excess of 25% was found to be excessive in *Deutsche Post* and an excess of at least 46.8% was found to be excessive in *Albion Water II*. The CMA considers that a comparison of Pfizer's excesses to those established in *Deutsche Post* and *Albion Water II* further supports the conclusion that each of Pfizer's Prices are excessive. Pfizer's excesses on each of Pfizer's Products throughout the Relevant Period are above the excesses found to have been excessive in *Deutsche Post*. Further, Pfizer's excesses on 50mg, 100mg and 300mg capsules are clearly and significantly above the level of excess found to be excessive in *Albion Water II*.
- 5.133 Third, the CMA has carried out sensitivity analyses to verify whether and to what extent Pfizer's excesses are affected by the choice of methodology for allocating common costs. This is a useful cross-check for determining whether the scale of Pfizer's excesses are sufficiently large to be properly regarded as excessive. Table 5.9 sets out the results of the CMA's sensitivity analyses using the alternative allocation methodologies for indirect costs.

**Table 5.9: Sensitivity analyses on Pfizer's excesses on Pfizer's Products, September 2012 to June 2016**

	Sales volume (per pack)		Sales volume (DDD)		Sales Volume (per capsule)	
	Excess (per pack)	Excess (%)	Excess (per pack)	Excess (%)	Excess (per pack)	Excess (%)
<b>25mg</b>	[£1 - £2.99]	29%	[£3 - £5.99]	237%	[£1 - £2.99]	87%
<b>50mg</b>	[£3 - £5.99]	100%	[£3 - £5.99]	332%	[£3 - £5.99]	194%
<b>100mg</b>	[£31 - £40.99]	705%	[£31 - £40.99]	515%	[£31 - £40.99]	491%
<b>300mg</b>	[£31 - £40.99]	690%	[£31 - £40.99]	504%	[£31 - £40.99]	924%

5.134 These alternative methods clearly show that the excesses vary according to the CMA's sensitivity analysis of Pfizer's common costs. For example, there is a significant increase in the excesses for packs of 25mg and 50mg capsules under the sensitivity analyses. Using DDD, for example, the percentage excess for 25mg capsules goes up to 237% and for 50mg to 332%. Conversely, the excess on the 100mg capsules falls, although it remains above 500%. The excess on the 300mg capsules is lower using the DDD method, due to its high strength, but is higher using the volumes by capsules method due to its lower pack size.

5.135 In the CMA's view, the results set out in Table 5.9 provide a useful cross-check on its finding that each of Pfizer's Prices are excessive. They show that the method chosen for allocating common costs has a significant bearing on the size of the excesses. They also show how the CMA's allocation of Pfizer's common costs to Pfizer's Products (which was favourable to Pfizer) has had a greater impact on the products containing lower capsule strengths. The CMA considers that the excesses on each of Pfizer's Products under the sensitivity analysis are sufficiently large to be deemed excessive under the *United Brands* test, thus bolstering the CMA's conclusion that each of Pfizer's Prices is excessive.

5.136 Fourth, Pfizer's per-pack excesses on each of Pfizer's Products are each considerably higher than the ASPs at which Pfizer sold *Epanutin* to

wholesalers and pharmacies prior to September 2012. Indeed, for 50mg, 100mg and 300mg capsule strengths, Pfizer's excesses are many multiples of those ASPs. Specifically:

- Pfizer's excess on 25mg capsules ([£1 - £2.99]) is [~~3~~] Pfizer's pre-September 2012 ASP for that product (£0.51);
- Pfizer's excess on 50mg capsules ([£3 - £5.99]) is more than [~~3~~] times Pfizer's pre-September 2012 ASP for that product (£0.52);
- Pfizer's excess on 100mg capsules ([£31 - £40.99]) is almost [~~3~~] times Pfizer's pre-September 2012 ASP for that product (£2.21); and
- Pfizer's excess on 300mg capsules ([£31 - £40.99]) is almost [~~3~~] times Pfizer's pre-September 2012 ASP for that product (£2.20).

5.137 For all the reasons set out above, the CMA concludes that Pfizer's Prices on each of Pfizer's Products are excessive and have been throughout the Relevant Period, thereby satisfying the first stage of the *United Brands* Test.

## V. ***The CMA's assessment of whether Flynn's Prices are excessive***

5.138 For the reasons set out below, the CMA finds that Flynn's Prices for each Flynn's Products are excessive. The CMA's analysis, set out below, follows the overall approach and methodology set out in section 5.C.II and 5.C.III above.

### a. ***Flynn's Prices and costs***

#### i. *Data used to calculate Flynn's Prices and costs*

5.139 The CMA has relied on the data it has obtained from Flynn during the course of the Investigation to assess whether Flynn's Prices are excessive. However, data is not available up to the date of this Decision because of the time delay between actual sales activity and the relevant financial data becoming available.

5.140 In the case of prices and direct costs, the CMA has obtained data from Flynn for the period September 2012 to June 2016. The CMA has not identified any reason why Flynn's Prices or direct costs would be expected to have

changed significantly between June 2016 and the date of this Decision, and the CMA has received no submissions from Flynn suggesting that they have.

5.141 In the case of indirect costs, the CMA has obtained data from Flynn for the period September 2012 to June 2016. The CMA has not identified any reason why Flynn's indirect costs attributable to phenytoin sodium capsules would be expected to have changed significantly between June 2016 and the date of this Decision. This can be seen from the data that Flynn has provided during the Investigation, which shows little difference over the Relevant Period.<sup>963</sup>

5.142 Given the above, the CMA finds that its conclusions that Flynn's Prices are excessive would not change if indirect cost data up to the date of this Decision was adopted in this assessment.

*ii. Flynn's Prices*

5.143 The CMA's analysis of Flynn's Prices over the Relevant Period is set out at Section 3.D.IV above. Following that analysis, Table 5.10 below shows Flynn's revenue and Flynn's Prices for each of Flynn's Products during the Relevant Period.

**Table 5.10: Flynn's revenues and Flynn's Prices, September 2012 to June 2016**

	Revenue	Price per pack
<b>25mg</b>	[ <del>£</del> ]	[£11 - £20.99]
<b>50mg</b>	[ <del>£</del> ]	[£11- £20.99]
<b>100mg</b>	[ <del>£</del> ]	[£51- £60.99]
<b>300mg</b>	[ <del>£</del> ]	[£51- £60.99]

Source: Document 00505.22, 01148.2, 01148.3, 01293.1, 01839.13 and 02115.2.

5.144 In its assessment of whether Flynn's Prices are excessive, the CMA has used revenue rather than prices. However, the overall result is identical whether revenue or prices are used.<sup>964</sup>

<sup>963</sup> The one change of any significance occurred in February 2014 when Pfizer and Flynn agreed that Pfizer would reduce certain of its supply prices to Flynn; see section 3.D.IV above.

<sup>964</sup> Converting revenues into ASPs would simply require actual revenues to be divided by actual volumes. A similar conversion would be required for costs in order to compare like-for-like.

*iii. Flynn's direct costs for Flynn's Products*

5.145 The CMA has taken account of Flynn's purchase, distribution and sale costs for the supply of Flynn's Products.

5.146 Flynn identified the following direct costs in relation to Flynn's Products:

(a) [REDACTED]; and

(b) [REDACTED].<sup>965</sup>

5.147 In its submission to the CMA, Flynn allocated distribution costs to different capsule strengths of phenytoin sodium capsules based on Flynn's selling prices.<sup>966</sup> However, the CMA considers it more appropriate to allocate distribution costs based on volume as that is more likely to drive distribution cost than the price of the product.<sup>967</sup> As such, the direct costs outlined in Table 5.11 include distribution costs which have been allocated based on the volume of packs sold by Flynn.<sup>968</sup> In any case, due to the high input price faced by Flynn, adopting a volume allocation approach rather than price allocation approach has a negligible effect (less than 2%) on the total direct costs allocated to any particular capsule strength.

5.148 Table 5.11 shows Flynn's direct costs for each of Flynn's Products during the Relevant Period. These costs are also shown split on a per pack basis.

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<sup>965</sup> See document 00505.1, question A.2.1.

<sup>966</sup> Flynn's estimates of costs on a purchase price basis are set out in section 16 of Annex 11 of document 00505.15.

<sup>967</sup> Volumes is one of the most common methods a distribution company will use when pricing its deliveries. The CMA notes that this is also the approach taken by Pfizer when allocating its distribution costs.

<sup>968</sup> This approach also means distribution costs are allocated on the same basis as indirect costs.



**Table 5.11: Flynn's direct costs for Flynn's Products in total and on a per pack basis, September 2012 to June 2016**

	<b>Total direct costs</b>	<b>Direct costs per pack</b>
<b>25mg</b>	[X]	[X]
<b>50mg</b>	[X]	[X]
<b>100mg</b>	[X]	[X]
<b>300mg</b>	[X]	[X]

Source: Documents 00505.22, 01148.2, 01148.3 and 01293.2.

5.149 Packs of 100mg phenytoin sodium capsules contain three times as many capsules as the packs containing other capsule strengths. As a result, the direct cost of a 100mg pack is similar to that of a 300mg pack.

*iv. Flynn's common costs for Flynn's Products*

5.150 Table 5.12 sets out Flynn's total common costs attributable to each of Flynn's Products on a total and a per pack basis using sales volumes.

**Table 5.12: Flynn's common costs allocated to Flynn's Products in total and on a per pack basis, September 2012 to June 2016**

	<b>Total common costs</b>	<b>Common costs per pack</b>
<b>25mg</b>	[X]	[X]
<b>50mg</b>	[X]	[X]
<b>100mg</b>	[X]	[X]
<b>300mg</b>	[X]	[X]

Source: Documents 00607.2 and 00607.3, annexes 4.1 and 6.3.

5.151 Table 5.13 below shows how Flynn's common costs would be allocated to each of Flynn's Products using the alternative volume allocations of per DDD and per capsule.<sup>969, 970</sup>

**Table 5.13: CMA sensitivity analysis on Flynn's common costs allocated to Flynn's Products, September 2012 to June 2016**

	Sales volume (per pack)		Sales Volume (DDD)		Sales volume (per capsule)	
	Total common cost*	Common cost per pack	Total common cost*	Common cost per pack	Total common cost*	Common cost per pack
<b>25mg</b>	[X]	[X]	[X]	[X]	[X]	[X]
<b>50mg</b>	[X]	[X]	[X]	[X]	[X]	[X]
<b>100mg</b>	[X]	[X]	[X]	[X]	[X]	[X]
<b>300mg</b>	[X]	[X]	[X]	[X]	[X]	[X]
* The sum of the total common cost balances do not agree because the ratio of sales volumes across dosages has not remained exactly the same across the relevant period.						

5.152 [X].

5.153 [X].

**b. Establishing a reasonable rate of return for Flynn**

5.154 Having estimated the total costs actually incurred in, or reasonably attributable to, the supply of each of Flynn's Products, the CMA must

<sup>969</sup> In its representations on the SO (see document 01639.3 paragraph 5.9), Flynn submitted that the CMA had only made limited attempts to neutralise any disproportionate effects which result from allocating common costs by volume because the CMA limited its sensitivity analysis to the allocation of common costs across phenytoin sodium capsules dosage strengths, rather than between phenytoin sodium capsules and Flynn's other products. However, the CMA considers that its allocation to phenytoin sodium capsules of approximately 20% of Flynn's costs which cannot be directly attributed to any one product is already highly generous. This is especially so given that phenytoin sodium capsules represent just one of at least 14 products sold by Flynn over the Relevant Period, and in light of the limited activities that Flynn performs and risk it takes on with regard to phenytoin sodium capsules.

<sup>970</sup> In its representations on the SO (see document 01639.3), Flynn submitted that the CMA should have used sales value as an alternative approach for allocating common costs. However, the CMA does not consider this to have been an appropriate basis on which to allocate common costs to phenytoin sodium capsules and has addressed Flynn's representations within Annex D.

establish the 'Plus' element of Cost Plus: that is, a reasonable rate of return.<sup>971</sup>

5.155 In order to establish a reasonable rate of return for the calculation of Cost Plus for Flynn's Products it is necessary for the CMA to determine: first, what the best measure of return to use is; and second, what would be a reasonable rate using that measure.

*i. The appropriate measure of the rate of return*

5.156 As set out in Section 5.C.II.c above, the CMA considered three possible measures of the rate of return for Flynn's Products: ROCE; ROS; and gross margins. In assessing which of these measures was the most appropriate for the calculation of Cost Plus for Flynn's Products, the CMA took the following into account: how well known, understood and used the measures are in the sector; the financial data provided by Flynn; the types of activities that Flynn undertakes in the supply of Flynn's Products; and Flynn's views.

5.157 The CMA has concluded that ROCE would not be an appropriate measure of the reasonable rate of return to calculate Cost Plus for Flynn's Products [✂]. The CMA considers that ROS is the most appropriate measure of return for Flynn, as the calculation of ROS does not use any measure of assets employed.

5.158 The CMA does not consider that gross margin is a suitable measure of rate of return in the particular circumstances of this case. It is not a complete measure of profitability because it does not take into account all of the support activities which may be essential to achieve sales. Gross margin is generally used where ROS cannot be calculated with sufficient accuracy due to the difficulty in allocating indirect costs. As such, ROS is the more informative and appropriate measure in this case.

*ii. Assessment of a reasonable rate of return*

5.159 Having established that ROS is the appropriate measure of rate of return for Flynn's Products, this section sets out the CMA's findings as to what would be a reasonable rate of return under the ROS measure.

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<sup>971</sup> The need to take into account, in appropriate circumstances, not only the costs of production but also a reasonable rate of return was acknowledged by the CAT in *Albion Water II*; see [89]. The same general point was made by the Court of Appeal in *Attheraces*; see paragraph 209.

- 5.160 For the reasons set out below, the CMA finds that a ROS of no greater than 6% and possibly much less would be a reasonable rate of return for the calculation of Cost Plus for Flynn's Products, but the CMA has, very conservatively, used a ROS of 6% for this exercise.
- 5.161 The CMA considered whether there are any benchmarks which may indicate what an appropriate rate of return would be for the calculation of Cost Plus for Flynn's Products. There is no directly applicable and generally accepted industry benchmark within the UK for what is a reasonable rate of return for manufacturers of generic drugs.<sup>972</sup>
- 5.162 For the reasons set out more fully below, the rate of return for the calculation of Cost Plus for Flynn's Products should take into account the following facts:
- Pfizer-manufactured phenytoin sodium capsules are a very old, off-patent drug;
  - Flynn undertakes very limited activities and incurs very low risks with respect to its supply of Flynn's Products; and
  - Flynn pays a high supply price to Pfizer for phenytoin sodium capsules which inflates Flynn's Cost Plus figures and in turn significantly increases any return in absolute terms.
- 5.163 The CMA has considered the following possible benchmarks for a reasonable rate of return:
- Flynn's internal ROS;
  - other companies' ROS rates; and
  - the allowable ROS under the PPRS.
- 5.164 As will be apparent from the details set out below, some of these possible benchmarks pull in different directions. In relation to Flynn's internal ROS and other companies' ROS rates, insofar as they do provide a helpful comparator (which for the reasons given below, the CMA has approached with caution), they suggest a higher ROS than 6%. However, the nature of the activities that Flynn undertakes, the nature of the drug in question and

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<sup>972</sup> In particular Scheme M, the main regulatory framework for generic drugs, does not regulate the prices charged by drug manufacturers or contain any provisions on rates of return.

the prices at which phenytoin sodium capsules are supplied to Flynn all point to a lower ROS than 6%. Weighing up all of these factors in the round, the CMA has determined for the reasons set out below that a 6% figure represents a reasonable, albeit very generous, ROS for the purpose of calculating Cost Plus for Flynn's Products.

*The nature of phenytoin sodium capsules*

- 5.165 The nature of phenytoin sodium capsules is an important factor for determining the reasonable rate of return. While pharmaceutical companies can expect to receive (and often do receive) high levels of return on many products, this will include new and highly innovative products. By contrast, phenytoin sodium capsules are far from new and innovative and are, in fact, an old drug that has been off-patent for a very long time and for which there has been no recent innovation. The determination of what is a reasonable rate of return for the purpose of calculating Flynn's Cost Plus figures over the Relevant Period should reflect this fact.

*The activities undertaken, and the risks incurred, by Flynn*

- 5.166 As has been stated, the underlying purpose of a rate of return is to provide an appropriate reward for the costs and risks a firm incurs in the supply of a product. A reasonable return will therefore reflect the level of investment and risks incurred in order to sufficiently incentivise a company to undertake the activity.
- 5.167 In this respect, the CMA notes that Flynn performs a nominal role in the distribution of phenytoin sodium capsules and incurs little, if any, risk.
- 5.168 Table 5.14 below sets out the activities involved in the supply of Flynn's Products which are undertaken by Flynn and those which are undertaken by other entities.

**Table 5.14: The allocation of activities involved in supplying Flynn's Products during the relevant period<sup>973</sup>**

		Pfizer	Flynn	Distributor	Wholesaler
<b>Manufacturing</b>					
Purchasing API		X			
Manufacturing		X			
Packaging		X			
Delivery to UK pre-wholesaler		X			
<b>Supply to pre-wholesaler</b>					
Ordering from supplier			X		
Processing orders		X			
Delivery to customer		X			
Invoicing		X			
Receipt of goods				X	
Storage				X	
<b>Supply to wholesalers</b>					
Ordering from supplier					X
Processing orders				X	
Delivering to customer				X	
Invoicing				X	
Receipt of goods					X
Storage					X
<b>Supply to pharmacies and hospitals</b>					
Processing orders					X

<sup>973</sup> Flynn has submitted (see documents 01767.1, 01839.1, and 01790.1) that the CMA has misrepresented Flynn's role in the supply chain of phenytoin sodium capsules by characterising it as a distributor for a MA holder when Flynn is actually the MA holder for phenytoin sodium capsules. The CMA does not believe it has confused Flynn's role with the role of a distributor and the SO clearly stated that Flynn became the MA holder for phenytoin sodium capsules on 24 September 2012. Further, the role of a distributor was clearly distinguished through the use of a separate column in the equivalent to Table 5.14 in the SO and activities such as 'Marketing and Promotion' and 'Licensing and Compliance' are clearly allocated to Flynn in Table 5.14 (as they were in the SO). Flynn also submitted that the table does not accurately reflect its legal obligations and responsibilities as the MA holder of phenytoin sodium capsules in the UK. The CMA does not agree that those obligations and responsibilities justify a high return and has addressed Flynn's submission to this effect in Annex K.

		Pfizer	Flynn	Distributor	Wholesaler
Delivering to customer					X
Invoicing					X
<b>Marketing and promotion</b>					
Communications to customers (prescribers, pharmacists, patients)			X		
Customer support (one clinical nurse)			X		
Marketing and promotion (generics manager)			X		
<b>Licensing and compliance</b>					
Regulatory compliance			X		

- 5.169 Flynn was brought into the pre-existing supply chain for phenytoin sodium capsules in the UK in September 2012 and its key activity is placing orders with Pfizer on a fortnightly basis.
- 5.170 Once it has received these orders, Pfizer transports the products from its facility in Germany to [redacted] (Flynn's pre-wholesaler) in the UK. [Flynn's pre-wholesaler/distributor] then receives and accepts the products from Pfizer; stores the products until it receives orders from Flynn's customers; delivers the products on behalf of Flynn; and invoices the customers and collects debtor balances.<sup>974</sup> [Flynn's pre-wholesaler/distributor] then provides Flynn with information relating to the order and invoices Flynn's customers on Flynn's behalf.<sup>975</sup>
- 5.171 Besides Flynn ordering the product, the route to market for the supply of Pfizer-manufactured phenytoin sodium capsules in the UK is largely identical to that which existed prior to September 2012. In that period, Pfizer also transported product destined for the UK to [Flynn's pre-wholesaler/distributor] which then managed onward delivery.

<sup>974</sup> See document 00607.1, question 6.

<sup>975</sup> See document 00505.1.

- 5.172 Flynn also incurs very little financial risk in relation to the role it performs in the supply chain. [REDACTED].
- 5.173 [REDACTED].<sup>976</sup> [REDACTED].
- 5.174 Moreover, as described in section 4.B and section 4.C, Flynn has an assured and essentially captive customer base as a consequence of pharmacies following the Continuity of Supply principle, meaning that Flynn faces little commercial risk in relation to Flynn's Products. Even if Flynn was not able to clear all of the stock it ordered from Pfizer in a particular month it would be able to offset the surplus against future orders.<sup>977</sup>
- 5.175 [REDACTED].<sup>978</sup> [REDACTED].
- 5.176 [REDACTED].
- 5.177 [REDACTED].<sup>979</sup>
- 5.178 [REDACTED].<sup>980</sup> [REDACTED].<sup>981</sup> [REDACTED].
- 5.179 In terms of customer relationship management, Flynn set up a patient helpline specifically for patients taking phenytoin sodium capsules. Between its introduction on 24 September 2012 and 31 August 2014, the helpline received 385 calls, averaging less than one call per day.<sup>982</sup>
- 5.180 The factors outlined above demonstrate the limited activities that Flynn carries out and operational risks that Flynn has incurred with respect to phenytoin sodium capsules, particularly when compared to its other products. The CMA considers that this is highly relevant in considering what would be a reasonable rate of return for the calculation of Cost Plus for Flynn's Products.
- 5.181 The CMA also considers that [Flynn's pre-wholesaler/distributor] provides a useful broad comparator for the consideration of what would be a reasonable

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<sup>976</sup> See document 00145.280, paragraph 4.2 and schedule 3.

<sup>977</sup> Until this stock is sold, and subsequently accounted for as a direct cost, any additional stock purchased by Flynn will form part of its working capital balance. Consequently, this stock should be treated as capital employed by Flynn and the cost associated with holding this stock is compensated for through Flynn's reasonable rate of return (see section 5.C.III.c).

<sup>978</sup> This is based on the average input price faced by Flynn throughout the relevant period.

<sup>979</sup> [REDACTED].

<sup>980</sup> See document 00872.1, paragraph 6.1 and 6.2.

<sup>981</sup> See document 00607.7.

<sup>982</sup> See document 00872.1, paragraph 6.2.



rate of return for the calculation of Cost Plus for Flynn's Products. Flynn explained that [Flynn's pre-wholesaler/distributor]:

*'purchases stocks from suppliers and those products are dispatched directly from all of Flynn's manufacturers to [Flynn's pre-wholesaler/distributor]. [Flynn's pre-wholesaler/distributor] is responsible for the receipt and acceptance of these goods on behalf of Flynn. [Flynn's pre-wholesaler/distributor] stores the products for Flynn as consignment stock until such time as it receives orders for such products from Flynn's customers, i.e. wholesalers and hospitals. [Flynn's pre-wholesaler/distributor] then delivers the goods in accordance with those orders. [Flynn's pre-wholesaler/distributor] invoices the customers on Flynn's behalf and provides Flynn with information relating to the order.*

*[Flynn's pre-wholesaler/distributor]'s costs are reviewed annually and are calculated according to the number of receipts, the number of pallets stored, any special storage conditions (e.g. cold chain, controlled drugs) and the number of deliveries made to customers on Flynn's behalf'.<sup>983</sup>*

5.182 [REDACTED].

*Flynn's rate of return in absolute terms*

- 5.183 When assessing what is a reasonable rate of return for the calculation of Cost Plus for Flynn's Products, it is relevant to consider the high supply price which Flynn pays to Pfizer. This is because a higher supply price means that any given percentage ROS translates into a higher absolute return for Flynn. Hence, all other things being equal, what might be a modest percentage return for a company paying a low supply price would be a very generous return for a company which, like Flynn, pays a very high supply price.
- 5.184 Table 5.15 below sets out what a ROS of 1%, 2%, 3%, 4%, 5% and 6% would provide Flynn in absolute terms. Because of the high supply price which Flynn pays to Pfizer, a 6% ROS would provide Flynn with a return in absolute terms of [REDACTED] between September 2012 and June 2016.
- 5.185 Accordingly, consideration needs to be given as to whether a rate of return of [REDACTED] would be sufficient to incentivise Flynn (or another firm) to carry out the limited activities and take on the limited risks which Flynn currently does in relation to the supply of Flynn's Products. It is the CMA's view that a return

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<sup>983</sup> See document 00505.1, paragraphs 4.2 to 4.3.

of considerably less than [redacted] would be a sufficient incentive for Flynn or another firm to perform such activities and take on such risks.

**Table 5.15: Flynn's return on Flynn's Products in absolute terms between September 2012 and June 2016 allowing for a ROS of 1%, 2%, 3%, 4%, 5% and 6%**

ROS	1%	2%	3%	4%	5%	6%
Return in absolute terms	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

5.186 Further, as Table 5.15 shows, Flynn's ROS would need to be as low as [0 - 2%] in order to approximate, in absolute terms, the reasonable return which has been allocated to Pfizer (as set out in Table 5.5, Pfizer's total allowance in absolute terms, based on a 6% ROS, is [redacted]). Given the low risks faced by Flynn and the minimal level of activities it undertakes with respect to phenytoin sodium capsules, the CMA considers that this further demonstrates that a ROS of 6% for the purpose of calculating Cost Plus for Flynn's Products is very generous and should represent an upper bound rate of return for Flynn.

*Flynn's internal ROS*

5.187 Flynn submitted data to the CMA which shows that its average annual ROS on its products other than phenytoin sodium capsules were [5% - 9%], [10% - 14%] and [15% - 19%] in the financial years 2013, 2014 and 2015 respectively.

5.188 For the reasons set out below, the CMA considers that these internal ROS figures are not informative to its assessment of what would be a reasonable rate of return for the purpose of calculating Cost Plus for Flynn's Products for the following reasons.

5.189 First, the fact that Flynn pays a very high supply price to Pfizer for phenytoin sodium capsules means that the costs which it incurs in supplying Flynn's Products are significantly higher than it incurs for most of its other products. The extent to which this is the case is shown in Figure 5.3 in section 5.C.V.e below. As a direct result of these very high costs (which come about due to the high supply price which Flynn pays to Pfizer, rather than the very limited

activities which Flynn itself carries out),<sup>984</sup> any given percentage ROS which is calculated for Flynn's Products translates into much higher absolute returns than would be achieved if that same ROS were applied to most of Flynn's other products. In light of the above, the CMA considers that a ROS which is in fact much lower than the average ROS which Flynn has achieved on its other products during the last three financial years would be reasonable for the purpose of calculating Cost Plus for Flynn's Products.

- 5.190 Second, as set out above, Flynn performs limited activities and takes on few risks with regards to the supply of Flynn's Products. Consequently, a lower return would be appropriate for Flynn's Products than may be the case for Flynn's other products.
- 5.191 Third, Flynn's internal ROS figures for its other products relate to a small range of products (in 2015, Flynn had only 14 products). As such, even notwithstanding the above factors, the CMA considers that it would be necessary to treat the ROS figures for such other products with caution.
- 5.192 Fourth, Flynn's internal ROS figures are average figures that Flynn's other products achieve in practice. However, for the purpose of calculating Cost Plus, what is required is a *reasonable* rate of return – that is, a rate of return which provides a reasonable financial incentive to engage in the activity of supplying a good or service. The latter may, of course, be lower than the returns which are achieved in practice.

#### Other companies' ROS rates

- 5.193 Flynn submitted to the CMA that its margins on Flynn's Products '*are entirely consistent with those in the industry*'.<sup>985</sup> Flynn also provided gross margin figures for a number of '*multinational generic pharmaceutical companies*' which it stated were '*consistent with the margin performance for Flynn and Phenytoin in particular*'.<sup>986</sup>
- 5.194 However, the CMA does not consider that it would be appropriate to rely on those other companies' margins when assessing what is a reasonable rate of return for the calculation of Cost Plus for Flynn's Products for the following reasons.

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<sup>984</sup> See this section above which sets out the limited activities which Flynn performs in relation to the supply of phenytoin sodium capsules.

<sup>985</sup> See document 01639.3, paragraph 5.58.

<sup>986</sup> See document 00730.1.

- 5.195 First, as set out above, Flynn performs limited activities and bears few commercial risks with regard to the supply of phenytoin sodium capsules. As such, the margins earned by generic pharmaceutical companies that engage in a broad range of activities and/or which have to bear significant commercial risks in the supply of their products will not provide an appropriate benchmark for a reasonable rate of return for the purpose of calculating Cost Plus for Flynn's Products.
- 5.196 Second, as set out above, the high supply price which Flynn pays to Pfizer for phenytoin sodium capsules means that any given percentage ROS or gross margin translates into a higher absolute return for Flynn than it would for companies which do not have similarly inflated input costs. This significantly reduces the utility of other companies' margins as a benchmark for the reasonable rate of return for the purpose of calculating Cost Plus for Flynn's Products.
- 5.197 Third, it is not clear what cost basis was used to calculate these rates of return or whether a consistent approach was adopted across companies, or indeed whether costs were allocated consistently with the approach adopted in this Decision.<sup>987</sup>
- 5.198 Fourth, the rates are average returns across each company's portfolio and cannot be conclusive of what a reasonable rate of return would be for a specific product. For example, some of the companies' products may be new generics which will have required investment to be brought to market and therefore require a return on capital employed which may justify higher returns. As set out above, phenytoin sodium capsules are an old drug which has been off-patent for many years and for which there has been no recent innovation or significant investment. As such, they should not be expected to earn similar margins to newer generics drugs which have required investment to be brought to market.

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<sup>987</sup> Flynn itself recognised (see document 00730.1, paragraph 3.4) the difficulties and limitations of such comparisons with other companies: *'Any interpretation of accounts for individual entities operating as part of a global business must be undertaken with caution. This is because given the complex corporate structures of multinational corporations, certain revenues and costs may be recognised in other tax jurisdictions, such that UK margins and profits reported may be understated. As in all benchmarking exercises, differences in strategy, scale, product mix and customer groups will also have an effect.'*

### The allowable ROS under the PPRS

- 5.199 Pharmaceutical companies are allowed to earn a ROS of up to 6% on their portfolio of branded products within the PPRS.<sup>988, 989</sup> This rate was agreed through negotiation between the DH (on behalf of the NHS) and the ABPI (on behalf of scheme members) and, accordingly, it strikes a balance between the sellers' and the customers' interests.<sup>990</sup>
- 5.200 The CMA considers that there are limits to the appropriateness of the PPRS ROS rate of 6% as an indicator of a reasonable rate of return for the purpose of calculating Cost Plus for Flynn's Products. In particular, the purpose of the PPRS is to control pharmaceutical companies' profits on their portfolio of branded products, rather than the prices of individual generic products.<sup>991</sup>
- 5.201 Nevertheless, for the reasons set out below, the CMA considers that the allowable ROS of 6% under the PPRS has some probative value for assessing what would be a reasonable rate of return for the purpose of calculating Cost Plus for Flynn's Products.

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<sup>988</sup> See *PPRS 2014*, paragraph 8.14.

<sup>989</sup> ROS has been included as a measure of the allowable return under the PPRS since 1999. The allowable return under the scheme was originally determined using ROC as the sole measure, reflecting the high manufacturing base of pharmaceutical companies in the UK. As the UK manufacturing base moved overseas a large number of pharmaceutical companies' UK entities became sales and distribution operations meaning ROC was less relevant in assessing their profits. This led to ROS being included as an alternative measure to ROC in the 1999 PPRS. At this point, the allowable return under ROC was 21%. ROS was calculated from ROC on the basis of a sales to capital ratio of 3.5:1. This resulted in a ROS of 6%. ROS has been included in at least the last two PPRS schemes (the 2009 PPRS and the 2014 PPRS) and the allowable rate of 6% ROS remained consistent across both of those schemes; that is, for a 10 year period (as each scheme runs for five years).

<sup>990</sup> Flynn has noted that the PPRS also allows for a MOT above the ROS target of 6% and has stated that the CMA failed to take into account the MOT in its analysis (see document 01639.4). Members of the 2009 PPRS scheme were allowed to earn up to 140% of the ROS target and this increased to 150% in the 2014 scheme. However, the MOT was not intended to routinely apply to a PPRS member's returns. Rather, according to the ABPI, it is in place to ensure companies are not penalised if they '*introduce a new, clinically and cost effective medicine which finds high acceptance by patients and prescribers*' (see '*Understanding the 2014 Pharmaceutical Price Regulation Scheme*', [http://www.abpi.org.uk/our-work/policy-parliamentary/Documents/understanding\\_pprs2014.pdf](http://www.abpi.org.uk/our-work/policy-parliamentary/Documents/understanding_pprs2014.pdf), page 8). That description does not apply to Flynn's Products. Further, there are specific limits on the application of the MOT; in particular, the MOT will not be available to a scheme member for any year in which it has implemented a price increase agreed by the DH, and where a price increase is agreed by the DH in the second half of a year, the MOT will not be available to the scheme member for the year following the increase (see *PPRS 2014*, paragraph 8.18). For these reasons, as well as the reasons set out in this section for why the CMA considers a ROS of 6% to be a reasonable rate of return, the CMA does not consider that it would be appropriate to include the PPRS MOT in its determination of a reasonable rate of return for Pfizer's Products.

<sup>991</sup> As Flynn submitted to the CMA (see documents 01639.3, paragraph 1.7): '*the PPRS does not apply to generic medicines and is only ever applied on a portfolio basis.*'

- 5.202 First, until the start of the Infringements, *Epanutin* was sold under the PPRS. Indeed, apart from being removed from the PPRS, and the relevant MAs being transferred to Flynn, very little about Flynn's Products is different to *Epanutin*. The product itself is identical. Under the PPRS, *Epanutin* was not subject to competition and the CMA has found that Flynn's Products continue to be free from any effective competitive constraint (see section 4.C above). Indeed, Flynn's Products continue to be supplied to customers as a quasi-brand ('*Phenytoin Sodium Flynn Hard Capsules*') due to the principle of Continuity of Supply and the MHRA's requirement that phenytoin sodium capsules include the MA holder's name in their title. These factors mean that the PPRS ROS rate is informative when determining a reasonable rate of return for the calculation of Cost Plus for Flynn's Products in this case.
- 5.203 Second, the allowable ROS under the PPRS is the closest the UK comes to an agreed industry standard for returns on pharmaceutical products. Further, this allowable ROS has been agreed for branded drugs which also include new and highly innovative products for which significant investment has been required to bring to market. By contrast, phenytoin sodium capsules are an old, off-patent drug which have not required any recent innovation or investment. In the CMA's judgement, the allowable ROS under the PPRS should, therefore, provide a generous financial incentive for Flynn to supply Flynn's Products.
- 5.204 Third, as set out above, Flynn performs limited activities and bears few commercial risks with regard to the supply of phenytoin sodium capsules. The allowable ROS under the PPRS, on the other hand, applies to pharmaceutical companies that engage in a broad range of activities and which bear significant commercial risks in the supply of their products. Again, in the CMA's judgement, the allowable ROS under the PPRS should, therefore, provide a generous financial incentive for Flynn to supply Flynn's Products.
- 5.205 Fourth, the allowable PPRS ROS of 6% will be higher than most pharmaceutical companies earn on their portfolio of branded drugs as the allowable return is a target rate which most companies do not achieve in practice. This further reinforces the CMA's conclusion that a 6% ROS would be a generous rate of return for the calculation of Cost Plus for Flynn's Products.
- 5.206 Fifth, as set out above, the high supply price which Flynn pays to Pfizer for phenytoin sodium capsules means that a 6% ROS translates into a much

higher absolute return for Flynn than it would if Flynn's input costs were not inflated by Pfizer's excessive supply prices. Again, this further reinforces the CMA's conclusion that a 6% ROS would be a generous rate of return for the calculation of Cost Plus for Flynn's Products.

- 5.207 In exercising the CMA's judgement as to what would be reasonable rate of return, it is important, as the CAT has recognised, to have '*regard, in particular, to the interests of [...] patients and to the interests of the customer, the NHS. Those are the interests which the legislation is primarily designed to protect although, of course, the interests of [suppliers] are also important.*'<sup>992</sup>
- 5.208 In exercising its judgement, and taking account of the factors set out above, the CMA considers that the allowable ROS of 6% under the PPRS would be a generous upper bound for a reasonable rate of return for Flynn's Products.
- 5.209 This finding is not, as Flynn has suggested, the misapplication of the allowable ROS under the PPRS to products falling outside the PPRS. Rather, it represents the CMA's conclusion that, in the particular circumstances of this case, a 6% ROS is a reasonable rate of return for Flynn's Products for the purposes of the first stage of the *United Brands* test.

*iii. Conclusion on reasonable rate of return*

- 5.210 The CMA believes that, taking account of the high input price Flynn pays, the minimal activities it performs, and the low risks it incurs, a rate of return well below the PPRS ROS of 6% would be reasonable and would incentivise a firm to perform Flynn's activities in relation to the supply of Flynn's Products.
- 5.211 However, the CMA has, very conservatively, used a ROS of 6% to calculate Cost Plus for Flynn's Products. Given that the CMA is satisfied that, having done so, the excesses on each of Flynn's Products are excessive for the purposes of the first stage of the *United Brands* test (see section 5.C.V.e below), the CMA has not sought to establish what an appropriate lower ROS rate should be.
- 5.212 For the avoidance of doubt, the CMA does not consider that generic medicines may not legitimately earn returns which are greater than a 6% ROS. Further, the CMA does not suggest that a ROS of 6% would necessarily be a reasonable rate of return for an assessment of Cost Plus for generic products other than Flynn's Products. For example, in cases (unlike

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<sup>992</sup> *Genzyme Remedy*, [255] and [256].

this one) where substantial investment was made, or substantial capital employed, or where there were significant commercial risks, a rate of return greater than 6% ROS could be fully justified for the purpose of calculating Cost Plus. However, this does not mean that a ROS of 6% is not a reasonable rate of return for the purpose of calculating Cost Plus for Flynn's Products when carrying out the first stage of the *United Brands* test.<sup>993</sup>

**c. Calculation of the reasonable rate of return and Cost Plus**

5.213 The amount allowed for a reasonable rate of return and the resultant Cost Plus figures, using an upper bound ROS figure of 6%, are set out in Table 5.16 and Table 5.17. Table 5.16 shows these figures for each of Flynn's Products on a revenue basis. Table 5.17 shows the figures for each of Flynn's Products on a per pack basis.

**Table 5.16: Flynn's allowances for a reasonable rate of return and the resultant Cost Plus figures for Flynn's Products, using the upper bound ROS of 6%,<sup>994</sup> on a total sales basis, September 2012 to June 2016**

	Capsule strength				Total
	25mg	50mg	100mg	300mg	
<b>Revenue</b>	[X]	[X]	[X]	[X]	[£100m - £109.9m]
<b>Direct costs</b>	[X]	[X]	[X]	[X]	[X]
<b>Common cost</b>	[X]	[X]	[X]	[X]	[X]
<b>Allowance for reasonable return</b>	[X]	[X]	[X]	[X]	[X]
<b>Cost Plus</b>	[X]	[X]	[X]	[X]	[X]

<sup>993</sup> For these reasons, we consider that Flynn's representations in document 01639.3, paragraph 5.15, are unfounded.

<sup>994</sup> Mathematically, a ROS of 6% translates into an uplift on costs of approximately 6.38%. Given that, for the reasons outlined in section 5.C.III.c.ii, in this case a reasonable ROS should be calculated through an uplift on costs, the CMA has uplifted costs by 6.38% in order to calculate a ROS of 6%.



**Table 5.17: Flynn's allowances for a reasonable rate of return and the resultant Cost Plus figures for Flynn's Products, using the upper bound ROS of 6%, on a per pack basis, September 2012 to June 2016**

	Capsule strength			
	25mg	50mg	100mg	300mg
<b>Price</b>	[£11 - £20.99]	[£11 - £20.99]	[£51 - £60.99]	[£51 - £60.99]
<b>Direct costs</b>	[✂]	[✂]	[✂]	[✂]
<b>Common cost</b>	[✂]	[✂]	[✂]	[✂]
<b>Allowance for reasonable return</b>	[✂]	[✂]	[✂]	[✂]
<b>Cost Plus</b>	[✂]	[✂]	[✂]	[✂]

**d. The amount by which Flynn's Prices exceed Cost Plus**

5.214 Having established Flynn's Prices, Flynn's costs (both direct and indirect) and a reasonable rate of return for Flynn's Products, this section sets out the CMA's findings regarding the amount by which Flynn's Prices exceed Cost Plus. That is, the size of Flynn's excesses.

5.215 The CMA expresses Flynn's excesses in the following two ways:

- as the absolute amount (in pounds sterling) by which Flynn's Prices exceed Cost Plus (calculated by subtracting Cost Plus from Flynn's Prices); and
- as the percentage by which Flynn's Prices exceed Cost Plus (calculated by subtracting Cost Plus from Flynn's Price, then dividing the result by Cost Plus).

5.216 In calculating Cost Plus for each of Flynn's Products, the CMA has adopted an approach which fully allocates costs: both all direct costs and an appropriate allocation of all relevant indirect costs, as well as a reasonable rate of return. As such, the amount by which each of Flynn's Prices exceed Cost Plus reveals the excess that Flynn is earning over and above what would be a reasonable return for its activities in the supply of Flynn's Products. In short, this is pure excess profit.

5.217 Further, the CMA considers that its application of what it considers to be a very generous rate of return in its calculation of Flynn's Cost Plus figures means that each of Flynn's excesses will be underestimates. As such, the CMA finds that Flynn's excesses on each of Flynn's Products are *at least* the figures which it has calculated.

5.218 The results set out in Table 5.18 below show that Flynn's Prices under a sales volume per pack basis exceed Cost Plus by at least 133% for 25mg capsules, at least 70% for 50mg capsules, at least 31% for 100mg capsules and at least 36% for 300mg capsules.

**Table 5.18: Flynn's excesses on Flynn's Products, September 2012 to June 2016**

	Capsule strength				Total
	25mg	50mg	100mg	300mg	
<b>Revenue</b>	[X]	[X]	[X]	[X]	[£100m - £109.9m]
<b>Cost Plus</b>	[X]	[X]	[X]	[X]	[X]
<b>Excess (revenue)</b>	[X]	[X]	[X]	[X]	[£27.5m - £32.5m]
<b>Excess (per pack)</b>	[£6 - £8.99]	[£3 - £5.99]	[£11 - £20.99]	[£11 - £20.99]	N/A
<b>Excess (%)</b>	133%	70%	31%	36%	41%

5.219 Table 5.18 shows that Flynn has lower percentage margins on the 100mg and 300mg capsule strengths than on 25mg and 50mg capsule strengths. However, the full extent of Flynn's excesses on the 100mg and 300mg capsule strengths are not evident when they are considered in percentage terms alone. This is because Flynn's excesses in percentage terms are calculated by reference to Flynn's costs, which are inflated by the excessive supply prices that Flynn pays to Pfizer. This means that every percentage point of Flynn's excesses translates into a much greater excess, in absolute terms, than would be the case if Flynn's direct costs were not inflated by Pfizer's excessive supply prices.

5.220 This is particularly true for 100mg and 300mg capsules for which the supply prices which Flynn pays to Pfizer are particularly high. As set out in Figure 5.2 below as well as the excess revenue and excess per pack figures in

Table 5.18 above, Flynn's excesses on each pack of its 100mg and 300mg capsules in absolute terms are in fact much greater than its excesses on its 25mg and 50mg capsules, despite the latter having higher excesses in percentage terms. Flynn's excess on each pack of 100mg capsules is [£11 - £20.99] while its excess on each pack of 300mg capsules is [£11 - £20.99].

5.221 Figure 5.2 below illustrates the size of Flynn's excesses in absolute terms on a per pack basis, compared to Cost Plus (including a generous ROS of 6%) for each of Flynn's Products.

**Figure 5.2: Flynn's costs and excesses (per pack) on Flynn's Products, September 2012 to June 2016**

[✂]

**e. Conclusion on whether Flynn's Prices are excessive**

5.222 The CMA has concluded that each of the excesses set out in Table 5.8 is (in the words of the *Albion Water II* judgment) '*material*' and '*sufficiently large to be deemed excessive*' in the context of the *United Brands* Test.

5.223 In addition to the scale of each of Flynn's excesses, the CMA's conclusion is confirmed by the following factors.

5.224 First, Flynn has maintained the excesses set out above on each of Flynn's Products for a substantial period of time (over four years). The persistence of Flynn's significantly high returns on each of Flynn's Products relative to those that would have prevailed in a competitive market confirm that each of Flynn's Prices are excessive, rather than them being a temporary anomaly in an otherwise competitive market.

5.225 In this respect, as set out in Table 5.18, Flynn's excesses on all four capsule strengths of Flynn's Products amounted to at least [£27.5m - £32.5m] between September 2012 and June 2016.

5.226 Further, that Flynn's Prices for each of Flynn's Products are excessive continues to hold true if Flynn's Prices are considered separately before and after some of its prices changed in April 2014. These figures are shown in Annex H.

5.227 Second, while they are not determinative, the CMA has had regard to the excesses that have been found to be excessive in other cases. In particular, an excess of 25% was found to be excessive in *Deutsche Post* and an

excess of at least 46.8% was found to be excessive in *Albion Water II*. The CMA considers that a comparison of Flynn's excesses to those established in *Deutsche Post* and *Albion Water II* further supports the conclusion that each of Flynn's Prices is excessive. Flynn's percentage excesses on each of Flynn's Products throughout the Relevant Period are above the excesses found to have been excessive in *Deutsche Post*. Further, Flynn's percentage excesses for 25mg and 50mg capsules are clearly and significantly above the level of excess found to be excessive in *Albion Water II*.

5.228 Third, the CMA has carried out sensitivity analyses to verify whether and to what extent Flynn's excesses are affected by the choice of methodology for allocating common costs. This is a useful cross-check for determining whether the scale of Flynn's excesses are sufficiently large to be properly regarded as excessive. Table 5.19 below sets out the results of the CMA's sensitivity analysis using the alternative allocation methodologies for indirect costs.

**Table 5.19: CMA sensitivity analyses on Flynn's excesses on Flynn's Products, September 2012 to June 2016**

	Sales volume (per pack)		Sales Volume (DDD)		Sales volume (per capsule)	
	Excess (per pack)	Excess (%)	Excess (per pack)	Excess (%)	Excess (per pack)	Excess (%)
<b>25mg</b>	[£6 - £8.99]	133%	[£9 - £10.99]	176%	[£6 - £8.99]	150%
<b>50mg</b>	[£3 - £5.99]	70%	[£6 - £8.99]	88%	[£6 - £8.99]	79%
<b>100mg</b>	[£11 - £20.99]	31%	[£11 - £20.99]	28%	[£11 - £20.99]	28%
<b>300mg</b>	[£11 - £20.99]	36%	[£11 - £20.99]	34%	[£11 - £20.99]	38%

5.229 Table 5.19 shows that, under the sensitivity analyses, both the percentage excess and excess per pack figures for the 25mg and 50mg capsule strengths are higher while the excesses for 100mg capsules are slightly lower. The excesses for 300mg capsules are slightly lower on a DDD basis and slightly higher on a sales volume per capsule basis. The CMA considers that the excesses on each of Flynn's Products under the sensitivity analyses

are material and sufficiently high to be deemed excessive under the *United Brands* test, thus bolstering the CMA's conclusion that Flynn's Prices are excessive.

5.230 Fourth, as set out above, in calculating Flynn's Cost Plus figures, the CMA has applied what it considers to be the maximum rate of return that might be reasonable in the circumstances of this case (and, in fact, as set out above, the CMA considers that a lower rate of return would likely be reasonable for Flynn). This means that Flynn's excesses are likely to be underestimates. Despite this being the case, Flynn's excesses on each of Flynn's Products are material.

5.231 Fifth, as set out in section 5.D.III.b.v below, Flynn's per-pack excesses are several multiples of the ASPs at which Pfizer sold phenytoin sodium capsules to wholesalers and pharmacies prior to September 2012. Specifically:

- in respect of 25mg capsules, Flynn's excesses are [at least 11] times Pfizer's pre-September 2012 ASPs;
- in respect of 50mg capsules, Flynn's excesses are [at least 11] times Pfizer's pre-September 2012 ASPs;
- in respect of 100mg capsules, Flynn's excesses are [at least 5] times Pfizer's pre-September 2012 ASPs; and
- in respect of 300mg capsules, Flynn's excesses are [at least 5] times Pfizer's pre-September 2012 ASPs.

5.232 Sixth, Flynn's excesses should be considered in light of the limited activities which it carries out and the limited commercial risks it incurs with regard to the supply of Flynn's Products (as set out in section 5.C.V.b.ii above). In this context, Flynn's excesses are particularly material.

5.233 Seventh, as set out above, Flynn's percentage excesses are affected by the high supply prices which Flynn pays to Pfizer for phenytoin sodium capsules, each of which include a significant excess over Pfizer's Cost Plus. As a cross-check, the CMA has, therefore, also calculated what Flynn's percentage excesses would be if the supply prices which Flynn pays to

Pfizer were adjusted to remove Pfizer's excesses from those prices.<sup>995</sup> The CMA calculates that on this basis, Flynn's excesses on each of Flynn's Products would be over 100%.

5.234 [REDACTED].<sup>996</sup>

5.235 However, Flynn's submission to the CMA in this regard only presented its profit margins across its portfolio of products, including phenytoin sodium capsules, on a percentage basis.<sup>997</sup> The CMA considers that restricting this analysis to percentage margins is misleading because it does not show the absolute margins that Flynn earned on its sales of phenytoin sodium capsules or the contribution that those margins made to Flynn's overall financial performance. The CMA has, therefore, augmented Flynn's analysis in order to show both the absolute and percentage margins that Flynn earned on Flynn's Products as compared to its other products. This analysis for the year ending 31 March 2015 is shown in Figure 5.3 below.<sup>998</sup>

**Figure 5.3: Flynn's cost and profit stacked bar charts and percentage contribution margins across its portfolio of products in the year ending 31 March 2015**

[REDACTED]

5.236 [REDACTED].

5.237 [REDACTED].

5.238 In light of the above, the CMA considers that the basis for Flynn's analysis is flawed [REDACTED]. When absolute margins are considered, it is clear that the

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<sup>995</sup> Under this assessment, Flynn's alternative Cost Plus figures are calculated by adding Pfizer's Cost Plus figures (in place of the supply price which Flynn pays to Pfizer) to Flynn's distribution costs, its allocation of common costs and its allowance for a reasonable rate of return (the figures for each of which are set out in Table 5.16). Flynn's absolute excesses (as set out in table 5.18) are then used to calculate percentage excesses using the same methodology set out in section 5.C.II.

<sup>996</sup> See document 01639.5. In response to the SO, Flynn also submitted to the CMA that [REDACTED] when using gross margins or return on sale measures. However, as already explained above, CMA also does not consider it appropriate to assess the profitability of phenytoin sodium capsules using gross margins as this measure fails to account for clearly identifiable costs, such as amortisation costs, which are necessarily incurred to achieve sales. Additionally, Flynn's ROS calculations have allocated common costs based on sales revenue. As discussed above, the CMA has determined that it is not appropriate to assess ROS on this basis due to its circularity problem and the lack of a relationship between its price and cost base, both of which can lead to skewed and unrepresentative margin calculations. As such, neither of these measures were considered in this assessment.

<sup>997</sup> Document 01639.5, figures 1, 3 and 5.

<sup>998</sup> [REDACTED].

profitability of Flynn's sales of phenytoin sodium capsules bears no resemblance to that of its other products.

5.239 For all of the reasons set out above, the CMA concludes that Flynn's Prices for each of Flynn's Products are excessive and have been throughout the Relevant Period, thereby satisfying the first stage of the *United Brands* Test.

## D. Unfair pricing

### I. Introduction

5.240 For the reasons set out in this section, the CMA concludes that each of Pfizer's Prices and Flynn's Prices is unfair by reference to the second stage of the *United Brands* test (as set out in paragraph 5.9 above).

5.241 In order to infringe the Chapter II prohibition or Article 102 of the TFEU a price charged by a dominant undertaking must be both excessive and unfair.<sup>999</sup> A price which is excessive will not necessarily be abusive. For an excessive price to be abusive, it must also be demonstrated that the price is unfair.

5.242 A price which is both excessive and unfair is one which bears '*no reasonable relationship to the economic value of the product*'<sup>1000</sup> and which results in the dominant undertaking accruing '*trading benefits which it would not have reaped if there had been normal and sufficiently effective competition*'.<sup>1001</sup>

5.243 In *United Brands*, the Court of Justice stated that an excessive price can be shown to be unfair either:

- '*in itself*'; or
- '*when compared to competing products*'.<sup>1002</sup>

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<sup>999</sup> A price that is only excessive will not infringe competition law; see *Attheraces*, [207] to [209] and *Albion Water II*, [190].

<sup>1000</sup> *United Brands*, paragraph 250.

<sup>1001</sup> *United Brands*, paragraph 249.

<sup>1002</sup> *United Brands*, paragraph 252.

5.244 This is an alternative and not a cumulative test.<sup>1003</sup> Accordingly, it is sufficient to demonstrate that one of its limbs is satisfied in order to establish an infringement.

5.245 As set out in section 5.C above, the CMA finds that each of Pfizer's Prices and each of Flynn's Prices are excessive and have been throughout the Relevant Period. In this section the CMA assesses whether each of Pfizer's Prices and each of Flynn's Prices are also unfair and therefore abusive.

5.246 In accordance with the approach used by the CAT in *Albion Water II* the CMA has:

- (a) first assessed the economic value of Pfizer's Products and Flynn's Products; and
- (b) then considered whether Pfizer's Prices and Flynn's Prices are unfair.

## II. ***Economic value***

5.247 In light of the evidence considered below, the CMA finds that there are no non-cost related factors which would increase the economic value of Pfizer's Products or Flynn's Products beyond their cost of production plus a reasonable rate of return. Therefore, the CMA finds that:

- the economic value of each of Pfizer's Products is Pfizer's Cost Plus for that product; and
- the economic value of each of Flynn's Products is Flynn's Cost Plus for that product.

### a. ***Legal Background***

5.248 The concept of economic value is a matter of judgment which involves a considerable margin of appreciation,<sup>1004</sup> based on an objective assessment of the particular case.<sup>1005</sup> As a matter of law, the Parties' subjective beliefs as to what is a 'fair' or 'reasonable' price are not relevant for this assessment.

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<sup>1003</sup> Judgment in *Isabella Scippacercola and Ioannis Terezakis v Commission* C-159/08 P, EU:C:2009:188, paragraph 47. See also *Albion Water II*, [255], where the CAT also held that the test was alternative in nature.

<sup>1004</sup> *Albion Water II*, [216].

<sup>1005</sup> *Albion Water II*, [225].



- 5.249 The economic value of a product may exceed its Cost Plus, as a result of non-cost related factors including,<sup>1006</sup> where applicable, *'additional benefits not reflected in the costs of supply'*<sup>1007</sup> or any *'particular enhanced value from the customer's perspective'*.<sup>1008</sup>
- 5.250 This was for instance the case in *Scandlines*<sup>1009</sup> and *Attheraces*<sup>1010</sup> where the European Commission and the Court of Appeal found, respectively, that the *'unique location close to Elsinore'* of the port of Helsingborg and *'the relevance of the value of the pre-race data to ATR'* increased the economic value of the product and services concerned beyond their costs of production.
- 5.251 However, economic value is not simply whatever price a product or service will fetch or which *'the market will reasonably bear'*.<sup>1011</sup> That position was rejected by the Court of Appeal in *Attheraces*:
- 'On the one hand, the economic value of a product in market terms is what it will fetch. This cannot, however, be what Article [102] and section 18 envisage, because the premise is that the seller has a dominant position enabling it to distort the market in which it operates.'*<sup>1012</sup>
- 5.252 The Court of Appeal's approach reflects the established principle that a dominant undertaking should not be able to earn *'trading benefits which it would not have reaped if there had been normal and sufficiently effective competition.'*<sup>1013</sup>
- 5.253 Further, if the economic value of a product or service were primarily determined by what price the dominant undertaking's customers are willing to pay, this would automatically prevent a finding that a price was unfair whenever a customer was purchasing the product. The European

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<sup>1006</sup> See *Albion Water II*, [222] and *Scandlines*, paragraph 226. See also *Attheraces*, [218].

<sup>1007</sup> *Albion Water II*, [7].

<sup>1008</sup> *Albion Water II*, [222].

<sup>1009</sup> See *Scandlines*, paragraph 241.

<sup>1010</sup> See *Attheraces*, [218].

<sup>1011</sup> See *Attheraces*, [210] to [211]. The Court of Appeal rejected this argument even when *'reasonably'* was added to the proposition; see paragraph 211. See also *Albion Water II*, where the CAT distinguished between cases where the customer who was *'readily willing to pay a premium'* and ones where the customer was not. The CAT found that while Albion was paying the price charged, it was only doing so under protest. Consequently, the CAT held that Albion was *'not a willing purchaser'* for the purposes of assessing economic value.

<sup>1012</sup> See *Attheraces*, [205].

<sup>1013</sup> See *United Brands*, paragraph 249.

Commission has confirmed that, for this reason, economic value should not be based on what customers are willing to pay:

*'By introducing demand side features in the assessment of the economic value of a product, some might say that it [the European Commission in its Scandlines decision] arguably went beyond the [United Brands] test, by making it more demanding than [sic] the Court might have intended originally. The Court in its judgments [...] has always based the economic value of a product on its costs of production including a necessary profit margin to attract sufficient capital. It is thus clear that a definition of economic value based on what customers are willing to pay would not be aligned with the case law, as it would define away any possible excessive price' [emphasis added].<sup>1014</sup>*

- 5.254 This is particularly relevant where the customer has no real choice when purchasing the product in question. In *Hoffmann-La Roche* the Court of Justice recognised that being an '*unavoidable trading partner*' necessarily gives a dominant undertaking '*freedom of action*' as to how it prices.<sup>1015</sup> The potential for abuse in such situations was also recognised by Advocate General Jacobs in his *Tournier* Opinion. When assessing the fairness of a product's price, he stated that it could be '*superficially attractive*' to do so by reference to the product's importance to the customer but that:

*'the usefulness of this criterion breaks down where a given category of users is completely dependent on the supply of [the product] and where, because of the absence of competition [those users] must, in effect pay whatever price is required.'*<sup>1016</sup>

- 5.255 This is consistent with *Albion Water II* where the CAT had regard to the Court of Appeal's judgment in *Attheraces* and concluded that in that case the economic value was greater than the cost of production because the customer was '*readily willing to pay a premium*' for the product.<sup>1017</sup>

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<sup>1014</sup> Submission from the European Union to the Roundtable on Excessive Prices held by the OECD Competition Committee (Working Party No. 2 on Competition and Regulation) in October 2011, paragraph 58, attached to this Decision as Annex M.

<sup>1015</sup> See *Hoffmann-La Roche*, paragraph 41.

<sup>1016</sup> See AG Opinion in *Ministere Public v Tournier*, C-395/87, EU:C:1989:215, paragraph 65.

<sup>1017</sup> *Albion Water II*, [226].

5.256 In *Attheraces*, the Court of Appeal also considered the interests of, and effect on, the end customer, not just the immediate purchaser. It said that:

*'the principal object of Article [102] of the Treaty is the protection of consumers, in this case the punters, not of business competitors. [...] We need to look beyond ATR's immediate interests to the market served by ATR.'*<sup>1018</sup>

5.257 In that case, the Court of Appeal found that *'it was incontestable that the overseas bookmakers were paying ATR, in a competitive market, amounts which afforded it a handsome profit'* [emphasis added] and *'there is little, if any, evidence that competition in the market is being distorted by the demands made by BHB.'* The Court of Appeal found that, in such a situation, the profits ATR could make selling on the competitive downstream market should be taken into account when determining the economic value of the product. However, the Court of Appeal went on to consider a hypothetical situation where the end customer was being affected and stated that, in such a situation, the end customer might require protection.<sup>1019</sup> The Court of Appeal also stated that:

*[there is a] possibility of a monopoly supplier not quite killing the goose that lays the golden eggs, but coming close to throttling her. We do not exclude the possibility that this could be held to be abusive, not least because of its potential impact on the consumer'* [emphasis added].<sup>1020</sup>

5.258 This was confirmed by the CAT in *Albion Water II*. When considering the economic value of the service of the transportation and partial treatment of water by Dŵr Cymru, generally and through the Ashgrove system in particular, the CAT found that the situation was different to *Attheraces* because, among other things, *'unlike the situation in Attheraces, the First Access Price has led both to a distortion of competition and to an adverse effect on the end user'*.<sup>1021</sup>

5.259 Thus, the existence and scale of any *'non-cost related factors'* varies on a case by case basis and depending on the product or service in question. Some products may have *'non-cost related factors'* which increase the economic value above their cost of production. Some products or services

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<sup>1018</sup> *Attheraces*, [215].

<sup>1019</sup> *Attheraces*, [214] to [216].

<sup>1020</sup> *Attheraces*, [217].

<sup>1021</sup> *Albion Water II*, [226].

may have either no, or few, '*non-cost related factors*' and, if so, the economic value of the product or service in question is '*not more, or not significantly more, than*' the cost of production.<sup>1022</sup> For example, in *Albion Water II*, the CAT found that there was no additional economic value beyond the cost of providing the service in question.<sup>1023</sup> This approach is also consistent with that taken by the European Commission in *Deutsche Post*.<sup>1024</sup>

**b. The economic value of Pfizer's Products and Flynn's Products is Cost Plus**

*i. Introduction*

5.260 As stated above, the economic value of a product or service may exceed its Cost Plus if it is demonstrated that there are additional non-cost related factors.<sup>1025</sup>

5.261 Having exercised its judgment with a margin of appreciation,<sup>1026</sup> the CMA has concluded that there are no non-cost related factors that would increase the economic value of Pfizer's Products or Flynn's Products beyond Cost Plus.

5.262 Accordingly, the CMA finds that:

- the economic value of Pfizer's Product is Pfizer's Cost Plus as set out at in section 5.C.IV.c. above.
- the economic value of Flynn's Product is Flynn's Cost Plus as set out in section 5.C.V.c. above.

5.263 These findings do not establish the upper limit of what Pfizer and Flynn may legally charge. However, their prices must have a reasonable relationship to these levels.

5.264 The CMA also considers that the economic value of Flynn's Products is artificially increased by Pfizer's excessive supply prices. Objectively, there should be very little difference between the economic value of Pfizer's Products and the economic value of Flynn's Products because Flynn adds very little value to Pfizer-manufactured phenytoin sodium capsules. If this

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<sup>1022</sup> *Albion Water II*, [249].

<sup>1023</sup> *Albion Water II*, [249].

<sup>1024</sup> See *Albion Water II*, [225].

<sup>1025</sup> See section 5.D.II.a above.

<sup>1026</sup> *Albion Water II*, [216].

distortion was removed, the economic value of Flynn's Products should be much closer to Pfizer's Cost Plus.

- 5.265 The CMA considers that this artificial increase resulting from Pfizer's excessive supply prices, is a relevant factor when assessing whether or not Flynn's Prices are unfair, in particular when considering the disparity between Flynn's Prices and the economic value of Flynn's Products.<sup>1027</sup>
- 5.266 In reaching its conclusions regarding the economic value of Pfizer's Products and Flynn's Products, the CMA has taken account of:
- the characteristics of phenytoin sodium capsules; and
  - the Parties representations regarding factors which they consider increase the economic value of phenytoin sodium capsules above cost plus.

*The characteristics of phenytoin sodium capsules*

- 5.267 The CMA considers that the characteristics of Pfizer-manufactured phenytoin sodium capsules, as summarised below, demonstrate that there is no additional value not reflected in the costs of production plus a reasonable rate of return.
- 5.268 Pfizer-manufactured phenytoin sodium capsules are a very old drug that were first marketed under the *Epanutin* brand name in the 1930s. *Epanutin* has long been off patent.
- 5.269 Phenytoin sodium has been superseded by other AEDs and is no longer used as a first or second line treatment for epilepsy – indeed it is now only seen as an adjunctive treatment for a small number of types of epilepsy.
- 5.270 *Epanutin* was genericised by Flynn in 2012 and subject to a substantial, overnight price increases on 24 September of that year. Prior to this they were sold by Pfizer at a much lower price for a number of years.<sup>1028</sup>
- 5.271 The price increases are not the result of any material change to the costs of production or supply of Pfizer-manufactured capsules. Nor has either party conducted any innovation in relation to the capsules or incurred any product-specific risks that would justify the September 2012 price increases.

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<sup>1027</sup> See section 5.D.III.b.i. below.

<sup>1028</sup> See section 3.B.II.b.

- 5.272 Pfizer's and Flynn's Products are identical to *Epanutin*: there has been no change to its formulation or its site of manufacture and it carries the same identicode markings as *Epanutin*. Accordingly, Pfizer's Prices and Flynn's Prices do not reflect any changes to the product nor any additional benefits having been created for patients.
- 5.273 The only significant changes in the supply of phenytoin sodium capsules were Pfizer's transfer of its *Epanutin* MAs to Flynn, Flynn's subsequent genericisation of the product and NRIM's generic entry in April 2013. Generic competition generally leads to lower prices.<sup>1029</sup> This has not occurred in this case.

*No customer willingness to pay a premium*

- 5.274 The evidence shows that CCGs are not '*readily willing to pay a premium*' and are actually paying the prices under protest.<sup>1030</sup>
- 5.275 Further, it demonstrates that the DH does not consider that the prices charged by the Parties represent '*value for money*.'<sup>1031</sup>

*The Parties' representations on economic value*

- 5.276 The Parties' submitted that the following factors increase the economic value of phenytoin sodium capsules above Cost Plus. These factors, which are assessed and rejected below, are as follows:
- the economic value of phenytoin sodium capsules should be increased as a result of the MHRA guidance;
  - the Drug Tariff price for Tablets provides a reasonable benchmark for assessing the economic value of the phenytoin sodium molecule generally; and
  - the economic value of phenytoin sodium capsules should reflect the costs that would have been incurred in the event of the product being discontinued.

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<sup>1029</sup> In the period 2004-2006 the average (weighted by sales) price reduction for a medicine in the UK one year after generic entry was 42 per cent (see CMA's Decision of 12 February 2016 in case CE-9531/11, paragraph 3.62 and OFT's Decision No. CA98/02/2011 of 12 April 2011 in case CE-8931/08, paragraph 2.88).

<sup>1030</sup> See sections 3.E.XI. and 5.D.III.b.iii.

<sup>1031</sup> See sections 3.E.VIII., 3.E.X. and 5.D.II.b.ii.

- 5.277 Pfizer has additionally submitted that the economic value of its products should reflect the revenue earning potential to Flynn of phenytoin sodium capsules, and should also include Pfizer's R&D costs.
- 5.278 Flynn submitted that the economic value of its products should take account of the additional benefits created by Flynn to increase the resilience and robustness of the supply chain.
- ii. *No additional non-cost related factors relevant to the economic value of Pfizer's Products and/or Flynn's Products*

*The value placed on phenytoin sodium capsules by the MHRA*

- 5.279 The Parties submitted that the economic value of phenytoin sodium capsules should take account of the therapeutic value to patients of Continuity of Supply. According to the Parties, in reducing switching between different manufacturers' versions of phenytoin sodium capsule, the MHRA Guidance has served to increase the economic value of Flynn's Product (and by extension the economic value of Pfizer's Product).<sup>1032</sup>
- 5.280 The CMA has concluded that no additional economic value should be attached to phenytoin sodium capsules as a result of the MHRA Guidance (or the previous pieces of clinical guidance issued by NICE and the Scottish Intercollegiate Guidelines Network).<sup>1033</sup>
- 5.281 The guidance provides clinical advice designed to protect a vulnerable patient group with a view to avoiding the risk and serious consequences of therapeutic failure. The guidance applies to a range of AEDs and does not identify phenytoin sodium capsules as a more effective treatment for epilepsy than any other AED. Nor does the guidance reward any innovation or product development by either Pfizer or Flynn which might have a bearing on the economic value of phenytoin sodium capsules.
- 5.282 The way the various pieces of clinical guidance have been followed in practice, combined with the absence of effective countervailing buyer power, has resulted in Pfizer and Flynn holding dominant positions in their respective relevant markets,<sup>1034</sup> which the Parties have exploited by imposing supra-competitive prices. Accordingly, the logic underpinning this representation is that the economic value of phenytoin sodium capsules (and

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<sup>1032</sup> See for example documents 01622.2, paragraphs 149 to 151 and 01639.3, paragraph 5.46.

<sup>1033</sup> See section 3.B.II.d. above.

<sup>1034</sup> See sections 4.B.IV.b.iii. and 4.C.VI.

by extension the Parties' ability to raise their prices) should be increased to reflect these dominant positions.

5.283 The CMA does not accept this proposition. To do so would mean that a supplier of a drug which is essential and non-substitutable for clinical reasons can set a supra-competitive price without any risk of infringing competition law. This would run counter to the premise of the prohibition on unfair pricing under Article 102 of the TFEU and the Chapter II prohibition.<sup>1035</sup> It is also inconsistent with the case law set out above.<sup>1036</sup> In the words of Advocate General Jacobs in his *Tournier* Opinion, while it could be '*superficially attractive*' to assess the fairness or value of a product by reference to that product's importance to the customer, '*the usefulness of this criterion breaks down where a given category of users is completely dependent on the supply of [the product] and where, because of the absence of competition [those users] must, in effect pay whatever price is required.*'<sup>1037</sup>

#### *The value placed on Tablets by the NHS*

5.284 The Parties submitted that the Drug Tariff price for Tablets, which had remained higher throughout the Relevant Period, provides a reasonable benchmark for assessing the economic value of the phenytoin sodium molecule generally (covering both phenytoin sodium capsules and Tablets). These submissions are based on the assumption that the circumstances and competitive conditions in the market for Tablets can be meaningfully used as a benchmark for other forms of phenytoin sodium products because: (i) the DH '*sanctioned*'<sup>1038</sup> the price it pays for Tablets through negotiation with Teva in 2007/2008 which resulted in the Drug Tariff price for Tablets being reduced by 70%; and (ii) the reimbursement price remained unchanged for over seven years after the DH's '*initial intervention*' which the Parties submit shows that the DH considered the '*tablet price to represent value for money.*'<sup>1039</sup>

5.285 The Parties' submissions in this respect are misconceived and have been rejected for the following reasons which are assessed in detail below:

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<sup>1035</sup> See *Attheraces*, [210] to [211].

<sup>1036</sup> See section 5.D.II.a. above.

<sup>1037</sup> AG Opinion in *Ministere Public v Tournier*, C-395/87, EU:C:1989:215, paragraph 65.

<sup>1038</sup> See document 02076.1, paragraph 2.1 and 02077.1, paragraph 3.2(b).

<sup>1039</sup> See document 02076.1, paragraph 24. The Drug Tariff price for Tablets is more expensive on a per unit basis than Flynn's Price for 100mg phenytoin sodium capsules.



- The economic value of a product should not be determined by reference to a customers' reactions to the price of another product, particularly if there are significant differences between the products.
- The subject of this Decision are the prices charged by the Parties for phenytoin sodium capsules and not the price of Tablets and it is clear that the DH and CCGs do not consider that the prices of capsules represent value for money.
- The features of the Tablets market are such that there is unlikely to be a reasonable relationship between price and the economic value of the product.
- the DH did not endorse, approve or authorise the price of Tablets in October 2008 and the Parties were wrong to assume this was the case. The DH has no means to intervene even though it considered a further reduction might have been justified.
- The assessment of economic value and unfair is an objective one and is not subject to reactions from third parties which cannot absolve the Parties from their special responsibility.

*The economic value of a product should not be determined by reference to customers' reactions to the price of another product*

5.286 The analysis of potential non-cost related factors is based on demand side factors that directly concern the product the price of which is being scrutinised. Therefore, the CMA considers that the economic value of a product should not be determined by reference to customers' reactions to the price of another product, which is manufactured and supplied by other companies in different relevant markets and which has different cost implications to the customer, at a different point in time and under a different regulatory framework. Moreover, the regulatory framework in question does not provide the DH with the power to intervene and regulate prices.

5.287 As set out below in this section, Tablets have a much smaller overall impact on CCGs budgets (i.e. in 2015 the overall cost to the NHS of Tablets was approximately £9 million in the UK),<sup>1040</sup> the price reduction the Parties refer to in their representations took place several years before Pfizer's Prices and

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<sup>1040</sup> See section 3.F.III above.

Flynn's Prices were introduced (i.e. October 2008) and Tablets are under a different regulatory framework (i.e. Scheme M instead of Category C).

*The subject of this Decision are the prices charged for phenytoin sodium capsules*

- 5.288 The subject of this Decision are the prices charged by the Parties for phenytoin sodium capsules. Regardless of what occurred in respect of Tablets, it is clear that the DH has not endorsed or approved these prices and it does not consider they represent '*value for money*'.
- 5.289 The DH was concerned by the scale of the capsule price increase implemented in September 2012, but had no power to intervene. It opened discussions with Flynn and Pfizer to try to understand why prices had increased.<sup>1041</sup> For instance, during a meeting between Flynn and the DH on 6 November 2012, the DH representatives informed Flynn that '*the scale*' of the phenytoin sodium capsule price increase was '*a concern*' and was '*hitting hard the NHS pockets*' and that the DH '*were struggling to understand the justification*' for the price increases.<sup>1042</sup>
- 5.290 These discussions were unsuccessful, in part, because Flynn provided inaccurate and/or misleading information in relation to its costs and, when the DH sought to verify Flynn's claims, neither of the Parties provided the DH with the cost information it had requested.<sup>1043</sup> In particular, Flynn stated it was not making significant margins on the product and would not be able to continue to supply the product if it could not maintain its prices.<sup>1044</sup> This is not consistent with Flynn's financial data.<sup>1045</sup> Discussions reached an impasse and the DH brought the size of the price increase to the CMA's attention for its consideration.<sup>1046</sup>

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<sup>1041</sup> See section 3.E.X. above.

<sup>1042</sup> See doc 00145.569.

<sup>1043</sup> See section 3.E.X. above.

<sup>1044</sup> See document 02032.1, paragraphs 25 and 37.

<sup>1045</sup> See sections 3.E.X.b. and 5.C.V.d.

<sup>1046</sup> See document 00001. The Parties have sought to argue that the DH has abdicated its regulatory responsibilities to the CMA (see for example document 02076.1, paragraph 42). The CMA finds this to be both irrelevant and inaccurate. As already set out the DH tried to obtain the Parties' cost information but was unable to do so. The DH has recognised that the CMA is better placed to assess whether the Parties' pricing was unfair and that it believed bringing the DH's concerns to the CMA was the most effective method of having them addressed (see document 02032.1, paragraphs 7 to 12). Among other things the CMA has the power to compel undertakings to provide cost data. Further, regulation of generic pricing in the UK is very light touch and premised on competition keeping prices down. It has always been the CMA's role to intervene when anti-competitive conduct creates harm. Indeed it is now the DH's publicly stated policy to refer cases of suspected unfair pricing

5.291 As a matter of law, the CMA considers that it is the DH's views regarding the prices of phenytoin sodium capsules which matter for the present purposes of assessing that products' economic value and not the DH's views on the price of Tablets (which in any event are misconceived as demonstrated below). As stated earlier in this section, the analysis of potential non-cost related factors is based on demand side factors that directly concern the product whose price is being scrutinised. As Pfizer itself recognised in its written representations, '*...under the United Brands case law, the "economic value" is that "of the product [or service] supplied"*'.<sup>1047</sup>

*The features of the Tablets market are unlikely to produce a reasonable relationship between price and economic value*

5.292 In any event, as is set out in section 5.D.IV.b).ii below, an objective assessment of the Tablets market demonstrates that it is unlikely to produce a reasonable relationship between price and the economic value of the product.<sup>1048</sup> In other words, the price of Tablets is unlikely to be reflective of their economic value.

*The DH did not approve the price of Tablets and it has no means to intervene*

5.293 Additionally, the Parties have not substantiated their submission that the DH '*sanctioned*' the price of Tablets from October 2008. The evidence set out below demonstrates that the DH did not approve the price of Tablets and was not '*happy*' with its level and the DH communicated this to Flynn shortly after the capsule price increases in September 2012. Additionally, it is clear from the evidence below that key Pfizer staff regarded the profits generated by Tablets as '*supernormal*' which is not consistent with Tablets providing value for money.

5.294 In order to properly assess the Parties' representations it is necessary to consider Teva's October 2008 price reduction in its full context.

5.295 Prior to the reduction, the price of Tablets had been subject to a significant price increases. In the period April 2005 to October 2007 Teva's list price increase from £1.69 to approximately £59.82, an increase of over 3,400%. This in turn resulted in the Category M Drug Tariff price increasing by over

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to the CMA (see for example <http://www.parliament.uk/business/publications/written-questions-answers-statements/written-question/Commons/2016-07-15/42887/>) (PD 50)

<sup>1047</sup> See document 01622.2, paragraph 145.

<sup>1048</sup> See also *Albion Water II*, [268].

from £1.70 to £113.62, an increase of approximately 6,500%. If the Drug Tariff price for Tablets had remained at £113.62, throughout 2008, their annual cost to the NHS in England alone would have been approximately £57 million in 2008.<sup>1049</sup>

- 5.296 The DH was clearly concerned about the scale of the Tablets price increase and asked Teva to consider reducing it.<sup>1050</sup>
- 5.297 Teva subsequently '*voluntarily*'<sup>1051</sup> reduced its prices, with the reimbursement price being set at £30 and Teva's list price at £29.50.<sup>1052</sup> However, these revised prices were still over 15 times higher than the pre-March 2006 levels.
- 5.298 It is these events, together with the fact that the reimbursement price of Tablets went unchanged for over seven years, which are the basis for the Parties' submissions that the reimbursement price was approved by the DH.<sup>1053</sup>
- 5.299 However, as set out in section 3.E.X.b, in a meeting between the DH and Flynn on 6 November 2012, the DH representatives informed Flynn that it had not '*sanctioned*' or approved the Reimbursement Price for Tablets and that it was wrong for Flynn assume that the DH/NHS were '*happy*' with the Reimbursement Price itself. This is clear from Flynn's note of a meeting with DH representatives:

[The DH said that] *Scheme M was not a pricing approval. We should not (in [the DH's]) view; assume that the DH and NHS are happy with the price of the tablets...*<sup>1054</sup>

- 5.300 This is corroborated by the DH's own note of the same meeting.<sup>1055</sup>

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<sup>1049</sup> This is based on PCA data for 2008 for England shows that approximately 500,000 packs of Tablets were dispensed in England in 2008.

<sup>1050</sup> See document 02032.1, paragraph 32.

<sup>1051</sup> See document 02032.1, paragraph 10.

<sup>1052</sup> Teva told the CMA that the DH stopped using the normal Category M method of calculating the reimbursement price for Tablets and the reimbursement price was '*essentially set independently of the Scheme M formula*'. This would have prevented Teva from inflating the retail price as it had done previously. Teva's list price remained at £29.50 until at least 2013. See document 00100.1

<sup>1053</sup> See for example document 02076.1, section 2.1.

<sup>1054</sup> See document 00145.585.

<sup>1055</sup> See document 00367.16: '[The] DH said that it had never confirmed that it was content with the price of the tablets but it would be inappropriate to comment further on this because a third party was involved in the supply of this presentation [...] Further, it did not consider comparisons with the table [sic] relevant, as the products are

5.301 Key Pfizer staff also concluded that the post October 2008 Tablets price was abnormally high, which is not consistent with Tablets representing ‘value for money’. In an internal Pfizer email, dated 2 February 2010 [Pfizer’s Head of EPBU] described Teva’s profits as ‘supernormal’:

*‘May be a ‘no-goer’ but as an alternative; is there an opportunity to go to the DH and have a sensible debate with them about the inequity in the tabs/caps prices, and explain (in spirit of openness) that we cannot afford to sell it [Epanutin] at this price and that that we could implement a scheme such as this (without going in to details). The aim being to obtain a special price increase outside PPRS; or at least get them to cut the Cat M price of tabs to the same as caps and prevent TEVA making supernormal profits.’<sup>1056</sup>*

5.302 Rather than thinking the price of Tablets represented ‘value for money’, the DH considers that a larger reduction in the price of Tablets may have been justified.<sup>1057</sup> However, any further steps it may have considered taking also need to be considered in their wider context as set out below.

5.303 Teva’s voluntary price reduction resulted in a significant reduction in the overall cost of Tablets to the NHS with their annual cost to the NHS in England falling from potentially £57 million to £17 million. This was clearly a significant saving for the DH to take into account when considering whether further action should be considered and prioritised.

5.304 [REDACTED].<sup>1058</sup> [REDACTED].

5.305 Accordingly, the DH did not consider it appropriate to seek a further price reduction from Teva. The DH informed the CMA:

*‘that while [the DH] would have liked to have seen a further decrease to the price of phenytoin sodium tablets, it had not actively sought a further decrease [REDACTED]. The DH said that this did not mean it was “happy” with the prevailing price of tablets.’<sup>1059</sup>*

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*not interchangeable. They were different formulations, which may incur different costs, and the tablets had significantly less of the market so had less economies of scale.’*

<sup>1056</sup> See document 00141.57.

<sup>1057</sup> See document 02032.1, paragraphs 10 and 34.

<sup>1058</sup> See document 02032.1, paragraph 10.

<sup>1059</sup> See document 02032.1, paragraph 34.

- 5.306 Moreover, the DH was not in a position to quickly and efficiently achieve a further price reduction. As set out in section 3.C.III.d, the DH is not intended to act as a price regulator for specific generic products and relies on competition to control prices. Tablets fall within Scheme M, which is primarily intended to control the retained margins earned by pharmacies, not the prices charged by the suppliers of generic pharmaceuticals.<sup>1060</sup>
- 5.307 The CMA recognises that paragraph 30 of the Scheme M arrangements provide that the DH may 'intervene' if the DH identifies *'significant events or trends in expenditure that indicate the normal market mechanisms have failed to protect the NHS from significant increases in expenditure.'* However, it is not clear what this means in legal or practical terms, and the DH has informed the CMA *'that this [redacted] clause had never been acted upon.'*<sup>1061</sup> The DH has also told the CMA that it believes that *'...there is in practical terms nothing that the DH could use as 'leverage' to reduce the price of a particular drug'*.<sup>1062</sup>
- 5.308 Any intervention would also have presented the DH with the challenge of establishing a reasonable price for Tablets. [redacted].<sup>1063</sup> Indeed, Flynn itself acknowledged this in its written representations on the Letter of Facts stating: *'[redacted]'*.<sup>1064</sup>
- 5.309 Further, Scheme M is voluntary in nature and a member of the scheme may withdraw from it at any time.<sup>1065</sup> If this occurred the DH would need to resort to its statutory price control powers under section 262 of the NHS Act 2006 if it wanted to intervene on prices. However, like Pfizer and Flynn, Teva is a member of the PPRS and therefore exempt from the DH's statutory price control powers.<sup>1066</sup> Even if removing Teva from the PPRS for its actions in relation to a product outside of that scheme was legally possible (which the CMA does not accept<sup>1067</sup>), in practice it would not be a realistic option. This

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<sup>1060</sup> See section 3.C.III.c.ii. for more details

<sup>1061</sup> See document 00468.1, paragraph 53.

<sup>1062</sup> See document 02032.1, paragraph 42.

<sup>1063</sup> See document 02032.1, paragraphs 9, 11 and 12. See also section 3.C.III.d. above.

<sup>1064</sup> See document 02077.1, paragraph 6.5.

<sup>1065</sup> Ibidem, paragraph 41. It would do so by withdrawing consent for the voluntary Scheme to be treated as applying to it.

<sup>1066</sup> See section 4.C.VI.c. above.

<sup>1067</sup> As set out in section 4.C.VI.e, for most of the Relevant Period, the DH believed that it could only remove a company from the PPRS if the company was failing to comply with the terms of the PPRS. Although the DH has recently changed its view of the relevant statutory position, and told the CMA in March 2016 that it now considers it could, in theory, potentially remove a company from the PPRS because of the company's conduct outside the PPRS, to date, this has never been tested and it remains legally uncertain – especially given previous

is for the same reasons as set out in the Dominance section in relation to Category C.<sup>1068</sup> Consequently the DH would have had no effective sanction if it had sought a further price decrease from Teva and it had refused to make one.

5.310 Given the savings already achieved by Teva's voluntary reduction, and the relatively small size of the Tablets market, it was reasonable for the DH, as a prudent public authority with finite resources, to have decided not to prioritise seeking a further reduction in Teva's prices. This prioritisation decision does not mean that the price was objectively fair or a good indicator of economic value.

5.311 Accordingly, there is nothing in the DH's actions to support the conclusion that the Drug Tariff price for Tablets accurately reflects the economic value of phenytoin sodium products. The Parties' submission that the chain of events set out above demonstrate that the DH had '*sanctioned*' the price reduction is incorrect and based on a misplaced assumption. The Parties have no foundation for this claim. It is also clear from Flynn's own note of its November 2012 meeting with DH representatives that it was told the DH was not '*happy*' with the price of Tablets and that the DH had not '*sanctioned*' the price Teva implemented in 2008.

*The assessment of economic value and unfair is an objective one and is not subject to reactions from third parties*

5.312 Even if the DH could have formally or informally reduced the Drug Tariff price of Tablets, either in 2008 or subsequently, (which it did not do) this does not absolve the Parties from their special responsibility as dominant undertakings and should not interfere with the objective assessment of economic value and whether or not a price bears a reasonable relation to the economic value of the product or service concerned. As the CAT held in *Albion Water II* when assessing similar representations by Dŵr Cymru about the economic value of its own services:

*[A dominant undertaking's belief that its prices were approved] does not absolve it from its special responsibility under the Chapter II prohibition. Even if the position of the regulator [...] and or the regulatory framework*

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interpretations of the provision. The DH has also told the CMA that it must still consider the effectiveness of the PPRS in the round for that company.

<sup>1068</sup> See section 4.C.VI.e. above for more details. See also section 3.C.III.d. above.

*encouraged or made it easier for water companies to engage in anti-competitive conduct those undertakings remained subject to the Act.*<sup>1069</sup>

This case law is all the more important when (as here) the actions that a dominant undertaking is relying on relates to a purported decision taken by a third party in respect of another product, supplied by another undertaking, with different overall cost implications to the customer, at a different time and under a different regulatory framework with no power to limit the price it paid.

*The costs that would be incurred by the NHS if Pfizer's Products and Flynn's Products were discontinued*

- 5.313 The Parties have also argued that the economic value of phenytoin sodium capsules should take account of the costs that the NHS would incur if Pfizer's Product was discontinued.<sup>1070</sup> Specifically, the Parties have alleged that patients would have been transferred to Tablets at a higher cost to the NHS. In this respect, Pfizer has submitted that discontinuation was '*not just a theoretical possibility*'. It has stated that *Epanutin's* sales in the UK were loss-making and that there was '*considerable*' pressure on Pfizer's management to either discontinue the *Epanutin* range or find an alternative solution to mitigate the financial losses incurred with continued supply.<sup>1071</sup>
- 5.314 The CMA rejects the suggestion that the economic value of a drug could be determined by reference to the additional costs that would be incurred by the NHS if the product was discontinued. If accepted, this would allow undertakings with licences for essential or very important treatments to charge supra-competitive prices under threat of withdrawing the product.

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<sup>1069</sup> *Albion Water II*, [242]. See by analogy *Deutsche Telekom AG v Commission* C-280/08, EU:C:2010:603 ('*Deutsche Telekom*'), paragraphs 81 to 88; *AstraZeneca v Commission*, C-457/10, EU:C:2012:770, paragraph 111 and *Hoffmann-La Roche*, paragraph 89. Regulatory involvement may, however, be a mitigating factor as to penalty and the CMA had considered this at Section 7.B.VI.a.ii. below.

<sup>1070</sup> See for example documents 02076.1, paragraph 69(d), 01836.5, paragraph 2.21.1 and 01767.1 page 13.

<sup>1071</sup> See document 01622.2, paragraph 77. In some of its submissions Flynn appears to suggest that it should be able to benefit from the fact that it believed that Pfizer would discontinue its production of phenytoin sodium capsules. See document 02077.1, paragraphs 2.1 and 2.2. However, this sort of subjective belief cannot provide '*additional benefits*' or any '*particular enhanced value from the customer's perspective*'. Further, there are also documents which indicate that Flynn was aware that Pfizer did not want to discontinue the product. See for example documents 00145.306 and 00313.1. In any event, even if theoretically the risk of discontinuation was a realistic possibility that should confer additional value to Pfizer's Products beyond Cost Plus (which the CMA does not accept), there would nevertheless be no justification for any additional value in relation to Flynn's Products.



Consequently, such costs should, as a matter of principle, be excluded from the calculation of economic value.<sup>1072</sup>

5.315 In any event, the argument is misconceived for the reasons set out below.

5.316 First, Pfizer has presented its options as a binary choice of either discontinuing the product or charging the supra-competitive prices which are the subject of this investigation. However, there is an obvious third choice. Pfizer could have chosen to charge a lower, but still profitable, price which would not have been excessive.

5.317 The scale of Pfizer's price increases were such that Pfizer more than recovered all its claimed losses on phenytoin sodium capsule sales within two months of increasing its prices in September 2012. Using Pfizer's own measure of contributions, it incurred losses amounting to [§] from January 2007 up to September 2012.<sup>1073</sup> Using the same measure of profitability, Pfizer earned profits of [§] between September 2012 and October 2012 alone,<sup>1074</sup> therefore more than covering any losses it claims to have incurred in the preceding five years.

5.318 Second, there is no evidence to support the proposition that Pfizer ever seriously considered discontinuing the product<sup>1075</sup> and Pfizer has not been able to substantiate its submission by reference to any internal documents.<sup>1076</sup> In fact, Pfizer informed the CMA that given the '*...potentially severe health and economic consequences associated epileptic seizures, discontinuation of supply was considered not to be appropriate for the benefits of patients.*'<sup>1077</sup> It is notable that the document which Pfizer relies on to support its claim that it might have discontinued the product is a Flynn internal document which also records that Pfizer believed discontinuing the product '*would be both ethically and morally unjustifiable given the clinical need.*'<sup>1078</sup> If Pfizer genuinely was considering discontinuation it would be

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<sup>1072</sup> In this respect see *Albion Water II*, paragraphs 232 to 236 where the CAT rejected including within economic value costs that would have, if included, undermined the objectives of the regulatory framework within which the pricing took place.

<sup>1073</sup> See table 3.9 above.

<sup>1074</sup> See document 02129.2.

<sup>1075</sup> Pfizer had, in fact, turned down a number of previous offers from third parties to take over the product. See for example documents document 00086.1 and 01836.3.

<sup>1076</sup> See document 01836.2, response to question 9. Every document that Pfizer has cited in support of these submissions has been a third party document speculating about Pfizer's intentions (in particular an email sent internally within Flynn and NRIM's submission to the CMA).

<sup>1077</sup> See document 00086.1, page 8.

<sup>1078</sup> See document 00145.306.

expected that it could provide internal documents showing this (particularly given the sensitivities that would be involved in any such decision) rather than relying on a third party document.

5.319 The Parties' submissions also fail to account for the fact that Pfizer manufactures all the phenytoin sodium capsules that it supplies in Europe in one manufacturing plant. Unless Pfizer were to discontinue *Epanutin* across Europe it would continue to incur manufacturing costs for the product even if it ceased supply in the UK. Pfizer would also potentially lose economies of scales as the UK is the largest European market by volume and value across all strengths. However, Pfizer has never suggested that it has considered discontinuing all supplies of *Epanutin* and the CMA does not consider this to be a likely outcome. Indeed, given regulations in other countries it is questionable whether Pfizer could legally do so even if it wished to.<sup>1079</sup>

iii. *No additional non-cost related factors relevant to the economic value of Pfizer's Products*

*The value placed on Pfizer's Products by Flynn*

5.320 Pfizer has submitted that the CMA must take the 'revenue-earning potential [to Flynn]' and the fact that Flynn 'is making a healthy margin' into account when determining the economic value of Pfizer's Products.<sup>1080</sup> In particular, Pfizer relies on the conclusions of the Court of Appeal in *Attheraces* to support this submission.

5.321 The CMA rejects this submission. The facts of this case differ materially from those in *Attheraces*. In *Attheraces*, ATR was able to make 'a handsome profit' in a competitive downstream market, resulting in the Court of Appeal concluding that there was no evidence that the end consumer was being harmed by BHB's excessive upstream prices. In this case, Flynn does not operate in a competitive downstream market and its prices (as well as Pfizer's) have had a negative impact on the end consumer (the NHS, in the form of CCGs). This assessment is explained in detail below.

5.322 In *Attheraces* the Court of Appeal stated it was necessary not only to examine the interests of the immediate purchaser (ATR), but also the end

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<sup>1079</sup> See document 01836.2, response to questions 2(b) and 4.

<sup>1080</sup> See document 01622.2 paragraphs 117 to 123 and 141 to 146. See also document 02076.1 paragraphs 2, 11 and 65.

customer ('overseas bookmakers') when considering non-cost related factors from the customer's perspective:

*'the principal object of Article [102] of the Treaty is the protection of consumers, in this case the punters, not of business competitors. [...] We need to look beyond ATR's immediate interests to the market served by ATR.'*<sup>1081</sup>

5.323 The CAT drew a similar conclusion in *Albion Water II* where it held that '*...the primary interest to be protected under the Chapter II prohibition is that of the consumer...*'<sup>1082</sup> and stated that given this overriding purpose of the Chapter II prohibition it was necessary to look beyond the immediate customer and take the interests of end customers into account.<sup>1083</sup>

5.324 In *Attheraces*, ATR was making its '*healthy margin*' in a competitive market. The Court of Appeal stated that:

*'...it was incontestable that the overseas bookmakers were paying ATR, in a competitive market, amounts which afforded it a handsome profit which it wanted, so far as possible, to keep.'*<sup>1084</sup> [Emphasis added]

5.325 This meant that there was no harm to consumers on the downstream market, as the Court of Appeal held:

*'There is little, if any evidence that competition in the market is being distorted by the demands made by BHB upon ATR.'*<sup>1085</sup>

5.326 However, *Attheraces* does not provide authority for the proposition that an upstream supplier can never be found to be charging an unfair price where its downstream customer is able to make a healthy margin. Indeed, the Court of Appeal itself stated that it did '*...not exclude the possibility that this could be held to be abusive, not least because of its potential impact on the consumer.*'<sup>1086</sup>

5.327 In the circumstances of this case, Flynn is not subject to effective competitive conditions on the downstream market and is an unavoidable

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<sup>1081</sup> *Attheraces*, [215].

<sup>1082</sup> *Albion Water II*, [218].

<sup>1083</sup> *Albion Water II*, [271].

<sup>1084</sup> *Attheraces*, [214].

<sup>1085</sup> *Attheraces*, [215].

<sup>1086</sup> *Attheraces*, [217].

trading partner for the NHS. Flynn's '*handsome profit*' results from its exploitation of a dominant position enabling it to impose supra-competitive prices which have a negative impact on the end customer.<sup>1087</sup> This is clearly different to the position evaluated by the Court of Appeal in *Attheraces* and falls squarely within the type of behaviour the Court of Appeal considered could be abusive.

5.328 Although Pfizer has no control over Flynn's Prices, its own prices have an impact on the end customer and the price paid by CCGs because they set a minimum price floor which Flynn cannot price below.

5.329 Accepting Pfizer's argument that the fairness of its price must always (and only) be assessed by the impact on the immediate customer (in this case Flynn) would allow dominant companies to circumvent the prohibition on unfair pricing simply by introducing intermediaries into the downstream supply chain and then sharing the profits generated by unfairly high prices with them. If the impact on the end customer is not taken into account then a dominant company could charge an intermediary whatever price it chooses and, so long as that intermediary could still make a profit, the undertaking would not be abusing its dominant position.

5.330 Since the primary interest to be protected under the Chapter II prohibition and Article 102 of the TFEU is that of the consumer,<sup>1088</sup> it would not be appropriate in such circumstances, and particularly when dealing with exploitative abuses, to take into account profits and revenues earned by Flynn at the expense of the end customer when determining the economic value of Pfizer's Product.<sup>1089</sup>

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<sup>1087</sup> See section 5.D.III.b.iii below.

<sup>1088</sup> See *Attheraces*, [215] and *Albion Water II*, [218].

<sup>1089</sup> Pfizer has submitted that the economic value to Flynn should also include the avoided cost of having to establish de novo production facilities (see document 01622.2, paragraph 122). The inclusion of such costs within the calculation of economic value was rejected in *Albion Water II*. Pfizer has submitted that this was because the supplier was vertically integrated and competed with the customer on the downstream market. While true, this does not preclude the same conclusion being reached in the current case. As the CAT noted in *Albion Water II*, whether such avoided costs will be relevant to economic value will depend on the particular circumstances of each case. In the current case, like in *Albion Water II*, there would be no consumer benefit to taking these costs into account. Firstly, Pfizer's Excesses greatly exceed what Flynn has estimated it would have cost to establish an alternative production facility, therefore there is no overall efficiency saving to the consumer. Secondly, Flynn is not a new entrant into the market offering an alternative, better or cheaper product (as was the case in *Albion Water II*). Flynn's involvement simply adds another level to the supply chain. No additional consumer benefit results from Flynn supplying the product as opposed to Pfizer supplying the product directly.

### Pfizer's R&D Costs

- 5.331 Pfizer also submitted that the economic value of its products should include a reasonable allocation of its R&D costs. Pfizer's submission is that the pharmaceutical industry operates on a very high fixed cost base, '*particularly due to extremely high research and development costs*', and that recovering these costs requires '*profitability to be maximised on all products within a portfolio, including established products*',<sup>1090</sup> and that there is a '*need for successful products to cover the costs of products which never make it to market*'.<sup>1091</sup>
- 5.332 In this respect, Pfizer argues that '*...the CMA's approach prevents Pfizer from recouping any portfolio R&D costs*',<sup>1092</sup> and that there is '*...no sound basis for the SO's approach of not allowing any R&D cost allocation to phenytoin sodium capsules*'.<sup>1093</sup>
- 5.333 The CMA considers that the representations summarised in the preceding paragraphs do not concern the question of whether or not general R&D expenditure should be regarded as a non-cost related factor increasing the economic value of Pfizer's Product, but concern instead the question, as Pfizer itself recognises, of whether or not '*[r]easonably allocated R&D costs should be reflected in the CMA's costs benchmark*'.<sup>1094</sup>
- 5.334 These submissions have been addressed in Annex L and they should be rejected on the basis of the reasons provided in that Annex.
- iv. *No additional non-cost related factors relevant to the economic value of Flynn's Product*

### Flynn's Supply Chain Management

- 5.335 Flynn has submitted that the CMA should also take account of the additional benefits created from Flynn's supply chain management when the CMA is assessing economic value.

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<sup>1090</sup> See document 00519.1. See also page 2 of document 00519.2, in which Pfizer submitted that '*pricing to cover the cost of supply only would not be sufficient to recover*' these costs.

<sup>1091</sup> See document 01622.2, paragraph 319.

<sup>1092</sup> See document 01622.2, paragraph 38.

<sup>1093</sup> See document 01622.2, paragraph 325.

<sup>1094</sup> See document 01622.2, section VII. B.

- 5.336 Flynn submitted that it had incurred or planned to incur costs in its attempts to 'increase resilience and robustness of a fragile supply chain to assure continuity of supply'.<sup>1095</sup> Flynn submitted that there were two principal means by which it sought to achieve this objective: (i) the building of 'safety stocks' – essentially keeping greater stocks of Pfizer's Products to enable Flynn to deal with any stock shortages; and (ii) establishing an alternative source of supply of phenytoin sodium capsules – through either an alternative source of API and/or an alternative site of manufacture.<sup>1096</sup>
- 5.337 These representations do not concern the possible existence of non-cost related factors increasing the economic value of Flynn's Product, but concern instead the question of whether or not these incurred or planned to incur costs should be included in Flynn's Cost Plus figures.
- 5.338 These submissions have been addressed in sections 3.C.I.c. and 5.C.V.b.ii. above, where the CMA demonstrated that (i) Flynn's plans for an alternative source of API and/or alternative site of manufacture were not viable and no substantial costs were actually incurred; and (ii) any additional stocks should be treated as capital employed and, as such, any costs associated are compensated for through Flynn's generous rate of return. Therefore, these submissions are rejected on the basis of the reasons provided in those sections.

### III. ***Unfair in itself***

5.339 For the reasons set out below, the CMA finds that:

- each of Pfizer's Prices is unfair in itself; and
- each of Flynn's Prices is unfair in itself.

#### a. ***Legal Background***

5.340 As the European Commission recognised in *Scandlines*, there is little guidance arising from EU case law or the European Commission's decisional practice on how to determine whether a price is unfair in itself.<sup>1097</sup>

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<sup>1095</sup> See document 00505.1, paragraph 11.2.

<sup>1096</sup> See document 01639.3, paragraphs 5.45 to 5.54.

<sup>1097</sup> *Scandlines*, paragraph 217.

The question of whether an excessive price is also unfair is a matter to be looked at in the round.<sup>1098</sup>

5.341 The CAT held in *Albion Water II* that:

*'it would not be appropriate to specify a particular amount by which a price must exceed the economic value of a product or service in order to infringe the Chapter II prohibition. The measure of excess is not an exact science and it is not practically possible to specify a precise arithmetic relation between price and the economic value of a product or service for it to be judged fair or unfair. Determining how far above "the economic value" a price has to be before it can be said to bear "no reasonable relation" to the economic value is a matter of judgment, having regard to the circumstances of the individual case.'*<sup>1099</sup>

5.342 Accordingly, there is no quantitative threshold by which the price actually charged must exceed economic value in order for it to be considered to amount to an unfair pricing abuse. This is instead a matter of fact and degree<sup>1100</sup> which involves a considerable margin of appreciation.<sup>1101</sup>

5.343 However, the CAT has held in *Albion Water II* that:

*'...neither Scandlines nor Attheraces "excludes the possibility that, in the absence of relevant non cost-related factors, the very excessiveness of a price could be sufficient to establish that the price bears no reasonable relation to the economic value of the product/service being provided." This approach is also consistent with that taken by the European Commission in Deutsche Post.'*<sup>1102</sup>

5.344 The Court of Justice has also recognised that absent some objective justification a '*particularly high*' excessive price may be a '*determining factor*' in assessing whether a price is also unfair.<sup>1103</sup> This has been confirmed by both the High Court and the Court of Appeal in *Attheraces*.<sup>1104</sup>

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<sup>1098</sup> *Albion Water II*, [260].

<sup>1099</sup> *Albion Water II*, [263].

<sup>1100</sup> *Albion Water I*, [310] and *Albion Water II*, [216].

<sup>1101</sup> *Albion Water I*, [310] and *Albion Water II*, [216] and [261].

<sup>1102</sup> *Albion Water II*, [225]. See also *Albion Water II*, [264].

<sup>1103</sup> Judgment in *Sirena Srl v Eda Srl and Others* C-40/70, EU:C:1971:18, paragraph 17.

<sup>1104</sup> See *Attheraces High Court*, [295] and *Attheraces*, [204].

- 5.345 The CAT has also found that, when assessing the potential unfairness of a price, it is also necessary to *'take into account the competitive conditions and any related abusive conduct that may enable the undertaking concerned to fulfil its pricing ambitions'*.<sup>1105</sup>
- 5.346 In this respect, the CAT found that factors establishing a dominant position may be relevant to assessing whether an excessive price is unfair:
- 'factors that establish a dominant position, notably barriers to entry, may well be relevant to determining whether a price is so high as to amount to an abuse by an undertaking of its dominant position. This is particularly true in excessive pricing cases, in which it is important to distinguish excessive prices shielded from effective competitive pressure from temporarily high prices that are the subject of normal market forces in a competitive market'*.<sup>1106</sup>
- 5.347 Such factors are naturally case-specific and the CAT found that, where they are present, such factors *'suggest that the Tribunal should review with care the lawfulness of a price which was unconstrained by any competitive considerations whatsoever'*.<sup>1107</sup> For instance, in *Albion Water II*, the CAT looked at *'whether the relevant market is capable of functioning in a manner that is likely to produce a reasonable relationship of price to economic value of the services to be supplied'*.<sup>1108</sup>
- 5.348 In *Albion Water II*, the CAT also considered the impact on final customers and consumer welfare, on the basis that *'the primary interest to be protected under the Chapter II prohibition is that of the consumer, rather than the private interest of a particular competitor'*.<sup>1109</sup> The CAT recognised the importance of taking end customers' interests into account and looking beyond the immediate interests of competitors.<sup>1110</sup>
- 5.349 The actual value that is added by the activities that are carried out by the undertaking charging the excessive price may also be relevant to assessing

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<sup>1105</sup> *Albion Water II*, [266]. See also the following judgments on the importance of taking into account the competitive conditions prevailing on the market when assessing whether an abuse of a dominant position has been committed: *Napp*, [400] and *Post Danmark v Konkurrencerådet* C-23/14, EU:C:2015:651, paragraph 30.

<sup>1106</sup> *Albion Water II*, [213].

<sup>1107</sup> *Albion Water II*, [268]. See also the Opinion of Advocate General Jacobs in *Ministere Public v Tournier* C-395/87, EU:C:1989:215, paragraph 43.

<sup>1108</sup> *Albion Water II*, [268].

<sup>1109</sup> *Albion Water II*, [218]. See also *Attheraces*, [215].

<sup>1110</sup> *Albion Water II*, [271].



whether a price is unfair in itself (for example, by comparing the value that is added by the undertaking charging the excessive price to the value that is added by other undertakings in the supply chain). In *Attheraces*, the Court of Appeal found that BHB incurred none of the risks and few, if any, of the costs of supplying the product to the end customer, but that it was taking half the profits. It stated that this '*may be thought to be unfair*'. While the Court of Appeal ultimately did not consider that BHB's prices were unfair, it did so because on the facts of that particular case no harm resulted to the end customer.<sup>1111</sup> Consequently, it was not a matter for competition law. However, as set out above, the Court of Appeal was clear that the position may be different where the end customer is harmed by an undertaking's conduct.

**b. *Assessment of whether Pfizer's Prices and/or Flynn's Prices are unfair in themselves***

5.350 The CMA considers that Pfizer's Prices and Flynn's Prices bear no reasonable relationship to the economic value of Pfizer's Products and Flynn's Products respectively and are each therefore unfair in themselves.

5.351 In reaching this conclusion, the CMA has adopted the analytical framework used by the CAT in *Albion Water II* and, as set out in the following sections, has had regard to the following factors:

- (a) the substantial disparity between Pfizer's Prices and the economic value of Pfizer's Products and between Flynn's Prices and the economic value of Flynn's Products;
- (b) the fact that competitive conditions prevailing on both relevant markets demonstrate that the relevant markets do not function in a manner that is likely to produce a reasonable relationship between price and economic value; and
- (c) the fact that Pfizer's Prices and Flynn's Prices have an adverse effect on the end customer (in this case the NHS in the form of CCGs).

5.352 In addition to the factors considered in *Albion Water II*, the CMA has identified and considered additional contextual factors specific to this case

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<sup>1111</sup> As set out above, the dispute in *Attheraces* was over how to divide the profits that had been legitimately earned on a competitive market, between members of the supply chain.

which are relevant to establishing whether Pfizer's Prices and/or Flynn's Prices are unfair.

- 5.353 The CMA has conducted its analysis of these factors in the round.<sup>1112</sup> However, in *Albion Water II* the CAT held that “...the very excessiveness of a price could be sufficient to establish that the price bears no reasonable relation to the economic value of the product/service being provided.” This approach is also consistent with that taken by the European Commission in *Deutsche Post*.<sup>1113</sup>
- 5.354 Further, and as noted above, case law has made clear that a ‘*particularly high*’ price is a ‘*determining factor*’ in assessing whether a price is also unfair.<sup>1114</sup>
- 5.355 Accordingly, in addition to its assessment in the round, the CMA has additionally assessed whether the excessiveness of each of Pfizer's Prices and each of Flynn's Prices are such they bear ‘*no reasonable relation to the economic value of*’ Pfizer-manufactured phenytoin sodium capsules and are consequently unfair in themselves and abusive.
- 5.356 The CMA considers that the various characteristics of phenytoin sodium capsules set out in section 5.D.II.b.i. above provide context and information against which to assess whether Pfizer's Prices and/or Flynn's Prices are unfair, in particular the fact that:
- Phenytoin sodium capsules are a very old drug that have long been off-patent.
  - Phenytoin sodium has been superseded by other AEDs and is no longer used as a first or second line treatment for epilepsy.
  - Prior to the substantial price increases that took place on 24 September 2012 following the de-branding of *Epanutin*, phenytoin sodium capsules were sold by Pfizer at a much lower price for a number of years.
  - The substantial price increases are not the result of any change in costs, investments or risks. Pfizer's and Flynn's Products are

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<sup>1112</sup> *Albion Water II*, [260].

<sup>1113</sup> *Albion Water II*, [225].

<sup>1114</sup> See section 5.D.III.a above.

identical to *Epanutin*, not reflecting any changes or additional benefits for patients.

- The only significant changes in the supply of phenytoin sodium capsules were Pfizer's transfer of its *Epanutin* MAs to Flynn, Flynn's subsequent genericisation of the product and NRIM's generic entry in April 2013, but these have not led to any decrease in prices as would be expected when generic competition enters the market.

*i. The substantial disparity between price and economic value*

5.357 The CMA has given detailed consideration to whether there are relevant non-cost related factors in this case and has concluded that there are none. Consequently, the CMA has found that the economic value of each of Pfizer's Products is Pfizer's Cost Plus for that product and the economic value of each of Flynn's Products is Flynn's Cost Plus for that product.<sup>1115</sup>

5.358 As set out above (section 5.D.III.a), in the absence of any relevant non-cost related factors the very excessiveness could be sufficient to establish that Pfizer's Prices and Flynn's Prices bear no reasonable relation to the economic value of Pfizer-manufactured phenytoin sodium capsules.<sup>1116</sup>

*The substantial disparity between Pfizer's Prices and the economic value of Pfizer's Products*

5.359 There is a substantial disparity between Pfizer's Prices for each of its products and the economic value of those products.<sup>1117</sup> The CMA considers that these disparities are both:

- sufficient to establish that each of Pfizer's Prices is unfair in itself; and
- a relevant factor when assessing, in the round, whether Pfizer's Prices are unfair in themselves.

5.360 Table 5.20 below sets out Pfizer's excesses on each of Pfizer's Products between September 2012 and June 2016. These excesses are expressed in the following two ways:

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<sup>1115</sup> See section 5.D.II.b. above. See also *Albion Water II*, [264].

<sup>1116</sup> See section 5.D.III.a. above. See also *Albion Water II*, [225] and [264].

<sup>1117</sup> *Albion Water II*, [265].

- (a) as the absolute amount (in pounds sterling) by which Pfizer's Prices exceed economic value (calculated by subtracting Cost Plus from Pfizer's Prices); and
- (b) as the percentage by which Pfizer's Prices exceed economic value (calculated by subtracting Cost Plus from Pfizer's Price then dividing the result by Cost Plus).

**Table 5.20: Pfizer's excesses on Pfizer's Products between September 2012 and June 2016**

	Capsule strength				Total sales
	25mg	50mg	100mg	300mg	
<b>Revenue</b>	[✂]	[✂]	[✂]	[✂]	[£60m - £69.9m]
<b>Cost Plus</b>	[✂]	[✂]	[✂]	[✂]	[✂]
<b>Excess (revenue)</b>	[✂]	[✂]	[✂]	[✂]	[£49m - £57m]
<b>Excess (per pack)</b>	[£1 - £2.99]	[£3 - £5.99]	[£31 - £40.99]	[£31 - £40.99]	N/A
<b>Excess (%)</b>	29%	100%	705%	690%	443%

- 5.361 The CMA considers that the scale of Pfizer's excesses, as set out in Table 5.20, demonstrate that there is a '*substantial disparity*' between Pfizer's Prices for each of Pfizer's Products and the economic value of those products.
- 5.362 In previous cases the following levels of excess have been found to be unfair in themselves:
- *Deutsche Post*: 25%
  - *Albion Water II*: at least 46.8% (the '*Albion Water excess*').
- 5.363 In *Albion Water II*, the CAT also took into account the level of excesses found to be abusive in previous cases (i.e. *Deutsche Post*) when assessing whether the price was unfair in itself.<sup>1118</sup>
- 5.364 The CMA notes that Pfizer's excesses in respect of:

<sup>1118</sup> *Albion Water II*, [265].

- 25mg capsules are higher than the level of excess in *Deutsche Post*;
- 50mg capsules are more than double the *Albion Water* excess;
- 100mg capsules are more than 15 times the *Albion Water* excess; and
- 300mg capsules are more than 14 times the *Albion Water* excess.

5.365 It follows from the above that the disparity between Pfizer's Prices for each of Pfizer's Products and the economic value of those products is '*substantial*'. Indeed, the excesses above the economic value for each of these capsule strengths are such that the prices charged by Pfizer for each of these capsule strengths bear no reasonable relation to the economic value of each strength and are unfair in themselves and therefore abusive.

5.366 The CMA's conclusion that the substantial disparities between each of Pfizer's Prices and Pfizer's Cost Plus figures are sufficient to show that Pfizer's Prices are unfair in themselves is strengthened when the characteristics of phenytoin sodium capsules are considered. These excesses have been achieved in respect of a very old drug, which is long off-patent and has been genericised and superseded by other AEDs. The product has not been subject to any recent innovation or development and no additional benefits have been provided for patients. Prior to September 2012, it had been sold by Pfizer at a significantly lower price.

5.367 In respect of 25mg capsules, the CMA considers that an excess of at least 29% over economic value, while lower than the excesses achieved on the other capsule strengths, nevertheless represents a '*substantial disparity*' between price and economic value, particularly when the characteristics of phenytoin sodium capsules, as summarised above, are considered.

5.368 Moreover, the relatively low excesses on 25mg capsules compared to those for the other dosage strengths is chiefly a result of the way the CMA allocated common costs across the different dosage strengths. For the reasons set out in section 5.C.III.b and 5.C.IV.a.iv above, the CMA has allocated Pfizer's common costs according to sales volume by number of packs. This results in the same level of common cost being attributed to a pack of 25mg capsules which contains 28 capsules as to a pack of 100mg capsules which contains 84 capsules.

5.369 The CMA could have used a number of other ways to allocate Pfizer's common costs and, on the CMA's sensitivity analysis of Pfizer's excesses,

it's excesses on the 25mg capsule increase to 87% when common costs are allocated on a sales volume per capsule basis and to 237% when common costs are allocated on a DDD basis.<sup>1119</sup>

5.370 Accordingly, the CMA considers that the excesses Pfizer has achieved on 25mg capsules are sufficient to demonstrate that Pfizer's Prices bear no reasonable relation to the economic value of this capsule strength and are unfair in themselves and therefore abusive.

5.371 Moreover, Pfizer's excesses in respect of all capsules strengths are likely to be an underestimate as a result of the generous approach the CMA has taken to the allocation of Pfizer's indirect costs.<sup>1120</sup>

*The substantial disparity between Flynn's Prices and the economic value of Flynn's Products*

5.372 There is a substantial disparity between Flynn's Prices for each of its products and the economic value of those products.<sup>1121</sup> The CMA considers that these disparities are:

- sufficient to establish that each of Flynn's Prices is unfair in itself; and
- a relevant factor when assessing, in the round, whether Flynn's Prices are unfair in themselves.

5.373 Table 5.21 below sets out Flynn's excesses on each of Flynn's Products between September 2012 and June 2016.

5.374 These excesses are expressed in two ways:

- (a) as the absolute amount (in pounds sterling) by which Flynn's Prices exceed economic value (calculated by subtracting Cost Plus from Flynn's Prices); and
- (b) as the percentage by which Flynn's Prices exceed economic value (calculated by subtracting Cost Plus from Flynn's Price then dividing the result by Cost Plus).

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<sup>1119</sup> See section 5.C.IV.e. For the avoidance of doubt the CMA is satisfied that Pfizer's excesses for the other strengths also remain excessive regardless of the method used to allocate common costs. The lowest alternative excesses found for each strength under the CMA's sensitivity analysis are 194% for the 50mg capsules, 491% for the 100mg capsules and 504% for the 300mg capsules.

<sup>1120</sup> See section 5.C.V.b.ii. above.

<sup>1121</sup> *Albion Water II*, [265].

**Table 5.21: Flynn's excesses on Flynn's Products between September 2012 and June 2016**

	Capsule strength				Total
	25mg	50mg	100mg	300mg	
<b>Revenue</b>	[X]	[X]	[X]	[X]	[£100m - £109.9m]
<b>Cost Plus</b>	[X]	[X]	[X]	[X]	[X]
<b>Excess (revenue)</b>	[X]	[X]	[X]	[X]	[£27.5m - £32.5m]
<b>Excess (per pack)</b>	[£6 - £8.99]	[£3 - £5.99]	[£11 - £20.99]	[£11 - £20.99]	N/A
<b>Excess (%)</b>	133%	70%	31%	36%	41%

5.375 The CMA considers that the scale of the excesses set out in Table 5.21 demonstrate that there is a '*substantial disparity*' between Flynn's Prices for each of Flynn's Products and the economic value of those products.

5.376 In previous cases the following levels of excess have been found to be unfair in themselves:

- *Deutsche Post*: 25%
- *Albion Water II*: at least 46.8%

5.377 As stated earlier in this section, in *Albion Water II* the CAT also took into account the level of excesses found to be abusive in previous cases when assessing whether the price was unfair in itself.<sup>1122</sup>

5.378 The CMA notes that Flynn's percentage excesses for each of its Products are greater than the excess in *Deutsche Post*. Further, Flynn's percentage excesses in respect of 25mg capsules and 50mg capsules are significantly above the *Albion Water* excess, with its excess on the 25mg capsules more than double that which was found to be unfair in *Albion Water II*.

5.379 In respect of Flynn's 100mg and 300mg capsules, the CMA considers that excesses of at least 31% and 36% respectively over economic value, while lower than Flynn's excesses on its other capsule strengths, nevertheless represent a '*substantial disparity*' between price and economic value and are

<sup>1122</sup> *Albion Water II*, [265].

materially above the level found to be both excessive and unfair in *Deutsche Post*.

- 5.380 Further, Flynn's excesses in respect of each of Flynn's Products are likely to be underestimates because the CMA applied a very generous rate of return in its calculation of Flynn's Cost Plus figures.<sup>1123</sup>
- 5.381 Moreover, the scale of Flynn's excesses are not truly represented when expressed in percentage terms alone because of the high input price it pays Pfizer. As set out in section 5.C.V.d, Flynn's excesses on its 100mg and 300mg capsules in *absolute* terms are particularly high and are, in fact, much greater than its excesses on its 25mg and 50mg capsules, despite the latter having higher excesses in percentage terms. Flynn's excess on each pack of 100mg capsules is [£11 - £20.99] while its excess on each pack of 300mg capsules is [£11- £20.99].
- 5.382 As a cross-check, the CMA has calculated what Flynn's excesses would be if the supply prices which Flynn pays to Pfizer were adjusted to remove Pfizer's excesses from those prices and, when calculated on this basis, Flynn's excesses on each of Flynn's Products would be over 100%.<sup>1124</sup> This cross-check is appropriate because not only is Pfizer's supply price a distortion in the supply chain, it is not representative of any significant commercial risk for Flynn. This is because Flynn essentially has a captive market for its sales of phenytoin sodium capsules meaning it is effectively guaranteed to sell the capsules it purchases at the price it chooses (as the Drug Tariff price is set by reference to Flynn's list price).
- 5.383 As an absolute amount, Flynn's excesses on each of Flynn's Products are [at least 5] times Pfizer's pre-September 2012 ASPs.<sup>1125</sup>
- 5.384 It follows from the above that the disparity between Flynn's Prices for each of Flynn's Products and the economic value of those products is '*substantial*'. Indeed, the excesses above the economic value on all capsule strengths are such that Flynn's Prices bear no reasonable relation to the economic value of each capsule strength and are unfair in themselves and therefore abusive.
- 5.385 The CMA's conclusion that the substantial disparities between each of Flynn's Prices and Flynn's Cost Plus figures are sufficient to show that Flynn's Prices are unfair in themselves is strengthened when the

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<sup>1123</sup> See section 5.C.V.b.ii. above.

<sup>1124</sup> See section 5.C.V.e. above.

<sup>1125</sup> See section 5.D.III.b.iv below.



characteristics of phenytoin sodium capsules, and Flynn's role in the supply chain, are considered. Flynn has achieved these excesses for the distribution of a very old drug which is long off-patent and has been genericised, and which has been superseded by other AEDs. The product has not been subject to any recent innovation or development and no additional benefits have been provided for patients. Moreover, as set out in section 5.C.V.b.ii, Flynn performs a relatively limited number of tasks in the supply chain and has also incurred few risks. Prior to September 2012, Pfizer-manufactured phenytoin sodium capsules had been sold by Pfizer at a significantly lower price.

ii. *The competitive conditions prevailing on the relevant markets*

5.386 The competitive conditions prevailing on the relevant markets further support the conclusion that Pfizer's Prices and Flynn's Prices are unfair in themselves.

5.387 When assessing the potential unfairness of a price, it is necessary to *'take into account the competitive conditions and any related abusive conduct that may enable the undertaking concerned to fulfil its pricing ambitions'*<sup>1126</sup> and whether the relevant market is *'capable of functioning in a manner that is likely to produce a reasonable relationship of price to economic value'*.<sup>1127</sup>

5.388 It is clear that the *'competitive conditions'* in Pfizer's and Flynn's respective relevant markets have enabled them to impose and sustain supra-competitive prices for over four years and that neither market is *'capable of functioning in a manner that is likely to produce a reasonable relationship of price to economic value.'*

5.389 Pfizer and Flynn have both set and maintained their respective supra-competitive prices independently of any actual or potential competitive constraints.

5.390 The characteristics of phenytoin sodium capsules – in particular its NTI and its non-linear pharmacokinetics – mean that even small changes to the dose delivered to the circulation can give rise to disproportionate changes in the level of the drug in the body, giving rise to the risk of therapeutic failure and even toxicity.<sup>1128</sup> These risks have resulted in various pieces of clinical

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<sup>1126</sup> *Albion Water II*, [266].

<sup>1127</sup> *Albion Water II*, [268].

<sup>1128</sup> See section 3.B.II.c.

guidance recommending that prescribers and dispensers follow the principle of Continuity of Supply meaning that patients who are stabilised on a particular manufacturer's phenytoin sodium capsules should be maintained on that manufacturer's product.<sup>1129</sup>

5.391 Pharmacies have followed the principle of Continuity of Supply to such an extent that Pfizer and Flynn have both been '*shielded from effective competitive pressure*'<sup>1130</sup> with both Parties holding dominant positions in their respective relevant markets.<sup>1131</sup> Patients who are stabilised on Pfizer-manufactured phenytoin capsules are effectively captive customers.

5.392 These dominant positions are chiefly the result of the way the various pieces of clinical guidance (designed to protect a vulnerable patient group from the risk of therapeutic failure) have been followed in practice combined with the absence of effective countervailing buyer power, rather than, for example, being brought about by any innovation or investment by the Parties.

5.393 As dominant undertakings, and unavoidable trading partners to the NHS, Pfizer and Flynn each have a special responsibility not to abuse their respective dominant positions. However, both Parties exploited their market power by imposing and sustaining supra-competitive prices from 24 September 2012 to at least the date of this Decision. The sustained nature of these prices and the continued implementation of the principle of Continuity of Supply demonstrates that Pfizer's Prices and Flynn's Prices are not '*temporarily high*' and are unlikely to be reduced through market forces in the foreseeable future.

iii. *Pfizer's Prices and Flynn's Prices have an adverse effect on the end customer*

*Pfizer's Prices and Flynn's Prices have had an adverse effect on the NHS*

5.394 When exercising its judgment, the CMA has had regard to the fact that Pfizer's Prices and Flynn's Prices have had an adverse effect on the NHS, further demonstrating that they are unfair in themselves.

5.395 When assessing whether a price is unfair it is necessary to look beyond the immediate customer and take the interests of end customers into

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<sup>1129</sup> See section 3.B.II.d.

<sup>1130</sup> *Albion Water II*, [213].

<sup>1131</sup> See section 4.C.VII.

account.<sup>1132</sup> The end customer in this case is the NHS (in the form of CCGs) who pay the cost of phenytoin sodium capsules from their prescribing budgets.<sup>1133</sup>

- 5.396 CCG budgets are finite and legitimate demands for healthcare will always exceed their capacity. Accordingly, CCG's financial resources need to be prioritised. In this respect, in the period 2010 to 2015 the NHS Efficiency Policy (also known as the QIPP) tasked the NHS with making £20 billion of efficiency savings in order to make more funds available to treat patients. Budgetary constraints and efficiency savings continue to pose a very significant challenge to the NHS and its constituent parts with a funding gap of £30 billion needing to be covered in the period 2015 to 2020/21.<sup>1134</sup>
- 5.397 The Drug Tariff price for phenytoin sodium capsules is set by reference to Flynn's list price. The Drug Tariff prices of phenytoin sodium capsules increased by 2,285% with effect from October 2012 as a direct result of Pfizer's Prices and Flynn's Prices. This significantly increased the NHS's annual expenditure on phenytoin sodium capsules at the very time it was seeking to achieve the QIPP's challenging efficiency savings.<sup>1135</sup>
- 5.398 Prior to the September 2012 price increases, the NHS's annual spend on phenytoin sodium capsules was approximately £2.3m. In contrast, the NHS's annual spend on phenytoin sodium capsules was approximately £50 million in 2013, £42 million in 2014 and £37 million in 2015.<sup>1136</sup> Pfizer accounted for [£20 - £29.9] million of the 2013 figure, [£10 - £19.9] million of the 2014 figure, and [£10 - £19.9] million of the 2015 figure. Flynn accounted for [£5 - £9.9] million of the 2013 figure, [£5 - £9.9] million of the 2014 figure and [£5 - £9.9] million of the 2015 figure.<sup>1137</sup>
- 5.399 As a consequence of these increased costs, CCGs have needed to commit extra money from their constrained budgets in order to continue to fund the supply of phenytoin sodium capsules to patients. This in turn has compromised the scope of other healthcare services that CCGs have been

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<sup>1132</sup> *Albion Water II*, [271]. See also *Attheraces*, [215].

<sup>1133</sup> See section 4.C.VI.

<sup>1134</sup> See section 3.C.III.a.

<sup>1135</sup> See section 3.C.III.b.

<sup>1136</sup> The NHS's annual spend on phenytoin sodium capsules has been calculated using the quantity data contained within the PCA data for England, Wales, Scotland and Northern Ireland and the published Drug Tariff prices for phenytoin sodium capsules that were in effect at the time.

<sup>1137</sup> Pfizer's and Flynn's revenues from phenytoin sodium capsules have been calculated using data provided by Pfizer and Flynn. Flynn's revenue is net of Pfizer's revenue to avoid double counting.

able to provide because they have needed to transfer funds earmarked for other services to pay for phenytoin sodium capsules.

5.400 This budgetary impact is clearly reflected in the complaints raised by various PCTs and CCGs which have been submitted to the CMA during the course of the Investigation. These pieces of correspondence also demonstrate that Pfizer's and Flynn's price increases were unjustified, did not provide value for money, and did not reflect any improvement in patient care.

5.401 First, in its letter, dated 10 October 2012, to the Secretary of State (copied to both Flynn and Pfizer and other key figures in the healthcare system), the GMMMG voiced very strong concerns regarding the financial impact of Pfizer's and Flynn's *'unethical, anticompetitive behaviour at the expense of patient care'* which did not *'deliver VFM [value for money] for the NHS'*:

*'In Greater Manchester we are spending £24,450/quarter on Epanutin® at current prices, which will potentially increase to £583K/quarter. This equates to an estimated £1,676K/year of extra costs for Greater Manchester.*

*The NHS will be adversely affected by £36Million per year, based on the same methodology. This increase in cost will provide no additional health benefit for patients.*

[...]

*'This scheme places 'unforeseen', unjustifiable and unacceptable 'burdens' on the NHS, leading to a potentially unstable and unpredictable market in epilepsy treatment.'* [Emphasis as in original]<sup>1138</sup>

5.402 The GMMMG also did not consider that the negative impact of Pfizer's and Flynn's behaviour was likely to be limited to increased costs. It also stated that there was a *'risk'* that the change of branding (which was necessary for the Parties to implement their prices) would cause logistical problems for healthcare professionals in taking prescribing and dispensing decisions and consequent concern for patients:

*'There are considerable logistical difficulties for GP practices and pharmacies as Epanutin® ceases to be available and as the Flynn*

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<sup>1138</sup> See document 00145.527.

*product enters the supply chain; this may ultimately cause inconvenience and concern for patients.*

*Prescriptions will need to be written as 'Phenytoin Sodium Flynn Hard Capsules' rather than as Epanutin®, a major change for many thousands of patients.*<sup>1139</sup>

- 5.403 Second, in correspondence with the CMA, the West Sussex PCT referred to the likely significant financial impact of the price of phenytoin sodium capsules on the NHS budget and stated that resources would need to be switched from other medical services to fund it and also observed there was no improvement in patient care:

*'As I have pointed out before, this will cost the NHS approximately £50m / year with absolutely no improvement in patient care, and indeed will need disinvestment in other medical services to fund.'*<sup>1140</sup>

- 5.404 Third, in a letter to the Chief Pharmaceutical Officer, dated 25 October 2012, the Nene CCG also referred to the expectation that the increased cost of phenytoin sodium capsules would '*compromise*' the scope of the services that the trust would be '*able to afford to commission*' and noted the price increase had not delivered any additional benefits for patients:

*'We estimate that the financial impact for the NHS nationally is likely to be in the order of £43 million per year. This increase in cost will provide no additional health benefit for patients, but will undoubtedly compromise other services that we will not be able to afford to commission as a result.'*<sup>1141</sup>

- 5.405 Fourth, in a letter to an MP, dated 25 October 2012, a representative of the Ipswich and East Suffolk CCG referred not only to the '*significant adverse impact*' of the increase in phenytoin sodium capsules costs on the CCG's prescribing budget but also the wider financial challenges it presented to the CCG in meeting its QIPP target and ensuring the best possible use of NHS resources:

*'For our CCG alone we have estimated this will cost an additional £350k per annum which will have a significant adverse impact on our prescribing budget. Our practices have been working extremely hard to*

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<sup>1139</sup> See document 00145.527.

<sup>1140</sup> See document 00014.

<sup>1141</sup> See document 00210.2.

*ensure that the CCG remains on track to meet our QIPP target and this huge price rise is a blow to all prescribers trying to meet the government's challenging targets and ensure the best possible use of NHS resources.*<sup>1142</sup>

- 5.406 Fifth, in a letter to the CMA, dated 23 July 2013, (which provided a copy of a letter from the Chief Pharmaceutical Officer), a representative of the Somerset CCG used the same language as was used by Nene CCG in its letter – including stating that meeting the increased cost of phenytoin sodium capsules would '*undoubtedly compromise other services*' and provided 'no additional health benefit for patients':

*'We estimate that the financial impact for the NHS nationally is likely to be in the order of £43 million per year. This increase in cost will provide no additional health benefit for patients, but will undoubtedly compromise other services that we will not be able to afford to commission as a result.'*<sup>1143</sup>

- 5.407 Sixth, an email from the Eastern and Coastal Kent PCT to [Flynn's Director] stated that there was '*no justification for increasing the cost [of phenytoin sodium capsules] 25%*' and '*[i]t is clear that Flynn have added no value to the product and have only rebranded an existing compound to "justify the cost to the NHS".'*<sup>1144</sup>

- 5.408 Seventh, in an internal Flynn email, dated 28 November 2012, [Flynn's Key Account Manager] reported to [Flynn's Director] on a '*rather uncomfortable meeting*' he had had with Norfolk and Waveney PCT, in which the PCT stated that the increase in the purchase price of phenytoin sodium capsules would cost it £750,000 per annum.<sup>1145</sup>

- 5.409 Eighth, a representative of the South Devon and Torbay CCG emailed [Flynn's Director] on 7 October 2012 to request an explanation of the '*unacceptable*' price increase of phenytoin. The representative observed that it was:

*'A staggering increase, not just sizeable, of 2000% plus!*

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<sup>1142</sup> See document 00254.1.

<sup>1143</sup> See document 00279.

<sup>1144</sup> See document 00145.516.

<sup>1145</sup> See document 00145.614.

*A increase of £102k to Torbay alone. Some £50m nationally. Very difficult to understand.*<sup>1146</sup>

*Pfizer and Flynn understood the price increase would have an adverse effect on the NHS*

- 5.410 Although the CMA is not required to demonstrate that the Parties were aware of this adverse effect, the evidence on the CMA's file shows that Pfizer and Flynn implemented and maintained the September 2012 price increases in the knowledge that doing so would significantly and adversely impact CCG budgets.
- 5.411 Internal Pfizer correspondence in 2009 regarding [Company A]'s Proposal that it partner with Pfizer to genericise and significantly increase the prices of phenytoin sodium capsules shows that key Pfizer staff recognised and understood the implications of such a price increase on NHS budgets at a time when the NHS was attempting to achieve financial savings.
- 5.412 Although this correspondence does not relate to Pfizer's arrangements with Flynn, it is nevertheless relevant when assessing Pfizer's understanding of the impact of a significant increase in the price of phenytoin on NHS budgets. The price increases envisaged during Pfizer's discussions with [Company A] in 2009 are not materially different to those price increases which were implemented by Pfizer and Flynn in September 2012.<sup>1147</sup>
- 5.413 When considering [Company A]'s Proposal to genericise *Epanutin* in 2009, [X] (Pfizer's Portfolio Manager for Mature Brands) observed that she had an 'ethical' concern with the drastic increase in NHS costs that would arise from implementing [Company A]'s Proposal and that the proposal, as such, did not 'feel right':

*'My other concern is just an ethical one – the top line looks great, however this would increase the price of phenytoin capsules to the NHS drastically and to be frank, doesn't feel right.'*<sup>1148</sup>

- 5.414 Similarly, in an email to Pfizer colleagues, [X] (Pfizer's Head of EPBU) asked how [Company A]'s strategy, which 'would increase the price of

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<sup>1146</sup> See document 00145.455.

<sup>1147</sup> [Company A] had proposed to increase the Drug Tariff to £25.50 for 28 100mg capsules. See section 3.E.III.a. and also document 000141.636.

<sup>1148</sup> See document 00141.21.

*phenytoin capsules to the NHS significantly', fitted with Pfizer's 'Trust initiative'.<sup>1149</sup>*

5.415 [Pfizer's Head of EPBU] also observed that Pfizer needed to consider how it positioned the price increases to avoid being seen as taking '*the opportunity to fleece the NHS in [a] time of funding crisis*'.<sup>1150</sup> This is consistent with the sentiments expressed by the various CCGs earlier in this section.

5.416 Flynn was also aware of the significant negative impact on the NHS of its and Pfizer's proposed actions. For example, an internal Pfizer email from [Pfizer's Commercial Account Director], dated 17 June 2011, recounted a discussion he had had with [Flynn's Director] regarding why Pfizer did not want to genericise and increase the price of Pfizer-manufactured phenytoin capsules on its own. [Flynn's Director] explained that Pfizer could do this on its own, but that it should use Flynn to mitigate the reputational fall-out that might arise, while also pointing out that other substantial drug price increases had attracted negative publicity in the national press because of their impact on the NHS:

*'Regarding the question of why [Pfizer] not do it ourselves:-*

*1. We could, he [Flynn's Director] doesn't think there are any PPRS issues.*

*2. It's ALL about reputation.*

*a. He suggests Google Daily Mail Hydrocortizone.....I did and here is a link to the Daily Mail Article  
<http://www.dailymail.co.uk/news/article-1295610/NHS-doesnt-care-cost-medicine-Drugs-firms-accused-profiteering-raising-prices-ONE-THOUSAND-cent.html>*

*b. He says would Pfizer execs want the Daily Mail camped on their doorstep.<sup>1151</sup>*

5.417 The clear implication of [Pfizer's Commercial Account Director] record of his conversation with [Flynn's Director] is that [Flynn's Director] foresaw that the

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<sup>1149</sup> See document 00141.31.

<sup>1150</sup> See document 00141.57.

<sup>1151</sup> See document 00141.137.



proposed phenytoin sodium capsules price increase would be controversial because of its negative financial impact on the NHS.

- 5.418 The various pieces of correspondence set out above between CCGs and Flynn further demonstrate that Flynn knew that the September 2012 price increases would have an adverse impact on CCGs budgets. Flynn (along with Pfizer) was copied on the GMMMG letter to the Secretary of State and received further complaints from, at least, the Eastern and Costal Kent PCT and the Norfolk and Waveney and South Devon and Torbay CCGs.
- 5.419 As set out in section 3.D.VIII.X.b, the DH also raised concerns with Flynn regarding the phenytoin sodium capsule price increases they had implemented in September 2012. During a meeting between Flynn and the DH on 6 November 2012, the DH representatives informed Flynn that '*the scale*' of the price increases '*was a concern*' and was '*hitting hard the NHS pockets*' and that the DH '*were struggling to understand the justification*' for the price increases.<sup>1152</sup>
- 5.420 Despite recognising the financial impact on the NHS's finances, Pfizer and Flynn not only implemented substantial price increases in respect of phenytoin sodium capsules in September 2012 but also maintained those substantially increased prices despite receiving strong objections from CCGs regarding the impact of the price increases on their budgets and despite the concerns expressed by the DH.
- iv. Additional contextual factors that are relevant to the assessment of whether Pfizer's Prices and/or Flynn's Prices are unfair in themselves*
- 5.421 The CMA has identified additional contextual factors which, although not a requirement for establishing the existence of an infringement, reinforce the CMA's respective findings that all of Pfizer's Prices and all of Flynn's Prices are unfair in themselves.
- 5.422 In particular, the CMA has taken into account the fact that one of the key reasons for including Flynn in the supply chain was to manage '*pharmacopolitical*' risk, which the CMA considers to be relevant to the assessment of whether both Pfizer's Prices and Flynn's Prices are unfair in themselves.

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<sup>1152</sup> See doc 00145.569.

5.423 Additionally, the CMA has also considered a number of additional factors that are specific to one or other of the Parties.

5.424 With regard to the assessment of whether Pfizer's Prices are unfair in themselves, the CMA has taken into account:

- the significant scale of Pfizer's price increases; and
- the fact that Pfizer has not implemented similar price increases in other EU Member States.

5.425 In relation to the assessment of whether Flynn's Prices are unfair in themselves, the CMA has taken into account:

- the activities undertaken by Flynn in comparison to the financial benefits obtained; and
- the fact that Flynn's excesses alone are significantly above pre-September 2012 ASPs in the UK.

*Additional context relevant to the assessment of whether both Pfizer's Prices and Flynn's Prices are unfair in themselves*

*Flynn's role in the supply chain and the management of 'pharmacopolitical' risk*

5.426 The evidence set out in section 4.D.III.b.ii. clearly demonstrates that Pfizer and Flynn knew that the September 2012 price increases would have an adverse impact on the NHS budget and could give rise to adverse publicity.

5.427 The evidence on the CMA's file also demonstrates that an important reason why Pfizer introduced Flynn to the supply chain was to mitigate its exposure to adverse publicity and therefore manage reputational risk. In this respect, Flynn, as the MA holder for phenytoin sodium capsules, would defend the price increase with both the media and the DH.

5.428 The assessment of whether or not a price is unfair is an objective one. Accordingly, the parties' intentions and motives are not necessarily relevant to the assessment of whether there has been an infringement.

5.429 However, the CMA considers that the evidence set out below provides further relevant context against which to assess whether Pfizer's Prices and Flynn's Prices are unfair in themselves. This is because:

- (a) The evidence regarding Pfizer's negotiations with [Company A] demonstrates that key Pfizer staff were concerned as to whether a significant increase in the price of phenytoin sodium capsules was 'ethical'. This and Pfizer's subsequent use of Flynn to reduce its reputational exposure is not consistent with Pfizer believing its own prices were fair.
- (b) Second, Flynn's role in managing Pfizer's reputational risk is important context against which to assess whether its prices are unfair, particularly when this is considered in conjunction with the limited activities it performs and the limited risks it has incurred.

5.430 A presentation entitled '*Epanutin® proposal July 2010*', which [redacted] (Flynn's Commercial Director) sent to [redacted] (Pfizer's Head of Customer and Channel Marketing, Established Products UK) on 2 July 2010, stated that:

*'Pfizer uses Flynn Pharma as the MA holder to avoid pharmacopolitical damage'*<sup>1153</sup>

5.431 The CMA asked Flynn what was meant by the term '*pharmacopolitical damage*' and received the following explanation:

*'Pfizer had indicated that it did not want to genericise Epanutin itself due to potential reputational damage risks.'*<sup>1154</sup>

5.432 Pfizer explained that the term referred to its concerns about the reputational impact of the price increase:

*'...while Pfizer is a commercial organisation it also recognises its responsibilities as a supplier to the NHS and to patients, and that there can be a lot of criticism of pharmaceutical companies which it tries to pre-empt. So, Pfizer considers how its actions could be perceived by people who may take its actions out of context. Pfizer asks itself if it is comfortable with a course of action. Internal approvals for this took the longest in relation to Epanutin. Pfizer recognised that a price increase was going to be subject to criticism.'*<sup>1155</sup>

5.433 The CMA recognises that the need to manage '*pharmacopolitical damage*' may arise also in circumstances where a pharmaceutical company has not

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<sup>1153</sup> See document 00145.27.

<sup>1154</sup> See document 00413.1, paragraph 9.

<sup>1155</sup> See document 00412.1, paragraph 61.

acted abusively and that it is normal to try to pre-empt criticism and consider how certain actions can be perceived when taken out of context.

- 5.434 However, the CMA considers that the circumstances of this case go well beyond such a scenario. Pfizer's internal correspondence during its discussions with [Company A], when considering a similar level of price increase, shows that key Pfizer staff had ethical concerns regarding the prospect of implementing a significant increase in the price of phenytoin sodium capsules. [X] (Pfizer's Portfolio Manager for Mature Brands) observed that she had an '*ethical*' concern with the drastic increase in NHS costs that would arise from implementing [Company A]'s Proposal and that the proposal, as such, did not '*feel right*'.<sup>1156</sup> Similarly, [Pfizer's Head of EPBU] was concerned that Pfizer might be seen as taking an '*opportunity to fleece the NHS in [a] time of funding crisis*'.<sup>1157</sup> The language [Pfizer's Head of EPBU] used is consistent with a belief that the NHS would have been over-charged for phenytoin sodium capsules as a result of the proposed conduct. Neither [Pfizer's Portfolio Manager – Mature Brands] nor [Pfizer's Head of EPBU] language is consistent with them believing that a price increase of the scale that was implemented in September 2012 was fair.
- 5.435 Pfizer's use of Flynn to mitigate its exposure to reputational risk was a theme of discussions that took place between the Parties.
- 5.436 In October 2010, Pfizer requested a detailed proposal from Flynn to be used as part of its internal approvals process. In response to this request, [Flynn's Director] emailed [Pfizer's Head of Customer and Channel Marketing - Established Products UK] a briefing document detailing Flynn's proposal (entitled '*Epanutin proposal*').<sup>1158</sup> Under the heading '*Pharmaco-political issues*', the briefing document stated:
- 'Pfizer UK's position would be simple: Pfizer has divested the product to Flynn Pharma Ltd. Flynn would defend its right to make profit on the product within the bounds of PPRS and generic pricing regulations.'*<sup>1159</sup>
- 5.437 [Pfizer's Commercial Account Director]'s email summary of his discussion with [Flynn's Director] as to why Pfizer could not itself genericise *Epanutin* also highlighted Flynn's role in mitigating Pfizer's exposure to reputational risk. The email, which is set out in this section above, stated that [Flynn's

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<sup>1156</sup> See document 00141.21.

<sup>1157</sup> See document 00141.57.

<sup>1158</sup> See documents 00145.63 and 00145.65.

<sup>1159</sup> See document 00145.65.

Director] case for Flynn's inclusion in the supply chain was '*ALL about reputation*'. [Flynn's Director] had also referred to an earlier Daily Mail article criticising price increases implemented in respect of hydrocortizone tablets and had asked [Pfizer's Commercial Account Director] whether '*Pfizer executives*' would want '*the Daily Mail camped on their doorstep*'. The clear implication of this contemporaneous record of [Flynn's Director] statements is that he saw Flynn's primary role in the supply chain as mitigating Pfizer's reputational risk.

- 5.438 Accordingly, by transferring its MAs to Flynn prior to increasing its phenytoin sodium capsules prices, Pfizer hoped to mitigate its own reputational risk through Flynn becoming the focus of any adverse publicity.

*Additional context specific to the assessment of whether Pfizer's Prices are unfair in themselves*

*The significant scale of Pfizer's price increases*

- 5.439 A comparison of Pfizer's Prices against those it charged for *Epanutin* prior to September 2012, further supports the conclusion that each of Pfizer's Prices is unfair in itself.
- 5.440 Since September 2012, Pfizer's Prices for Pfizer's Products have, on average, been [at least five] times greater than those it charged for *Epanutin* before September 2012. More specifically:
- Pfizer's Price for 25mg capsules is [X] times greater than Pfizer's pre-September 2012 price (an increase of [at least 488%]);
  - Pfizer's Price for 50mg capsules is [X] times greater than the Pfizer's pre-September 2012 price (an increase of [at least 1,054%]); and
  - Pfizer's Prices for 100mg capsules (which account for [X] of Pfizer's Products, by volume) and 300mg capsules are both [X] times greater than Pfizer's pre-2012 prices (increases of [at least 1,303% and 1,309%] respectively).
- 5.441 The scale of these price increases is even more striking given that Pfizer's pre-September 2012 prices were those that it charged to wholesalers and pharmacies while its post-September 2012 prices are those which it charges to Flynn as a distributor which then adds its own margin on its sales to pharmacies and wholesalers.

- 5.442 Pfizer has only been able to impose and sustain price increases of the scale set out above because, in the words of the CAT in *Albion Water II*, it has been ‘*shielded from effective competitive pressure*’ and holds a dominant position in its relevant market.<sup>1160</sup> Pfizer would not have been able to profitably sustain such price increases if it had been subject to effective competitive pressure.
- 5.443 Pfizer has submitted that ‘[t]here is no way’ its pre-September 2012 prices ‘*can constitute a reasonable competitive benchmark*’, because those prices were set under the PPRS which required Pfizer to ‘*consider issues of portfolio-wide pricing and returns on sale*’ and because phenytoin sodium capsules ‘*were not covering their share of fixed costs*.’<sup>1161</sup>
- 5.444 The CMA rejects this submission for the reasons set out below.
- 5.445 First, the CMA considers that the prices at which Pfizer was prepared to sell *Epanutin* in the UK for a number of years are a relevant benchmark for determining whether Pfizer’s Prices bear a reasonable relation to the economic value of that product. This does not mean that Pfizer’s pre-September 2012 ASPs constitute the only competitive benchmark. Rather, the CMA considers that Pfizer’s pre-September 2012 ASPs in the UK provide a useful indication of the prices that could be fairly charged for an old, off-patent product (especially when there had been no changes to the product or the costs of making it). The CMA has consistently stated in this Decision that Pfizer could have profitably increased its prices above its pre-September 2012 levels without having to abuse its dominant position.<sup>1162</sup>
- 5.446 Second, the Parties themselves compared the two regulatory frameworks and considered the options for increasing the prices both under the PPRS and Category C of the Drug Tariff. In fact, the rationale for divesting the MAs was to enable Flynn to de-brand Pfizer-manufactured phenytoin sodium capsules, launch it as a generic product thereby removing it from the pricing constraints under the PPRS.<sup>1163</sup>
- 5.447 Third, the CMA has taken into account the differences between the operation of the PPRS and Category C of the Drug Tariff.<sup>1164</sup> Even so, the sheer scale of the price increase in September 2012 cannot be explained by those

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<sup>1160</sup> See *Albion Water II*, [213].

<sup>1161</sup> See document 01622.2, paragraph 179.

<sup>1162</sup> See section 3.E.I. above.

<sup>1163</sup> See section 3.E.IV above.

<sup>1164</sup> See section 3.C.III. above.

differences. The fact that Pfizer claims it was making a loss on *Epanutin* prior to September 2012 did not entitle it to increase prices to the levels which it did. The price increases actually introduced by Pfizer went far beyond what was necessary to render *Epanutin* profitable. Furthermore, to the extent Pfizer was making a loss on *Epanutin* before September 2012, those losses were more than off-set within two months of the price increases having been introduced in September 2012.<sup>1165</sup>

5.448 Finally, in spite of the portfolio nature of the PPRS, it is clear that Pfizer nevertheless measures the profitability of its products on an individual basis, even those products which are included in the PPRS.<sup>1166</sup>

*Pfizer has not implemented similar price increases in other EU Member States*

5.449 In exercising its judgment, the CMA has had regard to Pfizer's pricing conduct in other EU Member States, which reinforces its conclusion that Pfizer's Prices are not only excessive but also unfair. Table 5.22 below sets out Pfizer's prices for 100mg capsules in the UK against its prices in all the other EU Member States where Pfizer-manufactured phenytoin sodium capsules are sold.<sup>1167</sup> All packs are manufactured in the same Pfizer facility in Germany.

**Table 5.22: Prices and volumes of 100mg packs of Pfizer-manufactured phenytoin sodium capsules in the UK and other EU Member States**

	Capsule strength (mg)	Average wholesale price (£)		Average end price (£)		Average monthly volume
		Jan 2011 to Aug 2012	Sep 2012 to June 2016	Jan 2011 to Aug 2012	Sep 2012 to June 2016	
<b>UK</b>	100	-	[£31 - £40.99]	[£1 - £2.99]	[£61 - £70.99]	[✂]
<b>Belgium</b>	100	[£3 - £5.99]	[£3 - £5.99]	[£6 - £8.99]	[£6 - £8.99]	[✂]
<b>Greece</b>	100	[£1 - £2.99]	[£1 - £2.99]	[£1 - £2.99]	[£3 - £5.99]	[✂]
<b>Ireland</b>	100	[£3 - £5.99]	[£3 - £5.99]	[£6 - £8.99]	[£6 - £8.99]	[✂]
<b>Spain</b>	100	[£1 - £2.99]	[£1 - £2.99]	[£1 - £2.99]	[£1 - £2.99]	[✂]

<sup>1165</sup> See section 5.D.II.b).ii. above.

<sup>1166</sup> See document 00519.2, answer to questions 12 and 13.

<sup>1167</sup> The CMA has used the price of the 100mg strength capsule because it is the only capsule strength that is sold in Belgium, Greece, Spain and Sweden. All capsule strengths are sold in Ireland.

	Capsule strength (mg)	Average wholesale price (£)		Average end price (£)		Average monthly volume
		Jan 2011 to Aug 2012	Sep 2012 to June 2016	Jan 2011 to Aug 2012	Sep 2012 to June 2016	
Sweden	100	[£1 - £2.99]	[£6 - £8.99]	[£3 - £5.99]	[£6 - £8.99]	[✂]

Source: Document 02129.3; converted to GBP using monthly average spot exchange rates from the Bank of England

5.450 The UK is the second largest EU market in terms of volume of 100mg phenytoin sodium capsule sales and the largest market for all phenytoin sodium capsule sales. Since September 2012, Pfizer's average wholesale price for a pack of 100mg phenytoin sodium capsules in the UK (that is, the price at which Pfizer sells to Flynn) has been several multiples of its average end prices in each of the other EU Member States. Pfizer's average wholesale price which it charges to Flynn for a pack of 100mg capsules is:

- over [4 to 6] times the average end price for the same product in Sweden during the same time period (that is, since September 2012);
- over [5 to 7] times the average end price for the same product in Belgium and Ireland;
- over [9 to 13] times the average end price for the same product in Greece; and
- over [18 to 24] times the average end price for the same product in Spain.

5.451 Pfizer has informed the CMA that, with the exception of [✂], its prices in these other countries are all profitable.<sup>1168</sup>

5.452 The CMA considers that the fact that Pfizer has not increased the price of its phenytoin sodium capsules in any other Member State to anywhere near the same price as it has in the UK further supports the CMA's conclusion that there is no justification for Pfizer's Prices and that each of Pfizer's Prices is unfair in itself.

<sup>1168</sup> See document 01836.2, response to question 2.



*Additional context specific to the assessment of whether Flynn's Prices are unfair in themselves*

*The activities undertaken by Flynn in comparison to the financial benefits obtained*

- 5.453 The value that is added, or the activities that are carried out, by the undertaking charging excessive prices are also relevant to assessing whether the price is unfair in itself.<sup>1169</sup>
- 5.454 Flynn performs very limited activities, incurs limited risk, has delivered no benefit to patients and adds little value in relation to the supply of phenytoin sodium capsules.
- 5.455 As set out in section 5.C.V.b.ii. Flynn does not actually take receipt of Flynn's Product at any point in the supply chain. Phenytoin sodium capsules are manufactured by Pfizer in Germany and are delivered to [Flynn's pre-wholesaler/distributor] in the UK. [Flynn's pre-wholesaler/distributor] then stores and delivers them to Flynn's customers. Flynn has [⌘] (as can be seen from the CMA's assessment of its common costs). Flynn only performs limited activities such as ordering stock from Pfizer and setting its own prices.
- 5.456 Flynn has also taken on little commercial risk.<sup>1170</sup> It has made very limited investments (whether upfront or otherwise) in phenytoin sodium capsules. It paid Pfizer [a nominal fee] for the MAs for phenytoin sodium capsules. As the MA holder, Flynn is subject to the standard legal obligations that come with that role, however, as demonstrated in section 5.C.V.b.ii,<sup>1171</sup> it has contracted out a substantial number of these responsibilities to Pfizer or other entities in the supply chain. Flynn has purchased additional stocks of Pfizer manufactured capsules to enable it to manage possible stock shortages. However, this is effectively a risk-free act of limited, if any, commercial significance. Flynn is an essential trading partner for CCGs in relation to the supply of Pfizer-manufactured sodium capsules and is effectively guaranteed to sell these additional stocks at prices it chooses (as the Drug Tariff price is set by reference to Flynn's list prices).
- 5.457 In fact, and as demonstrated earlier in this section, one of the key reasons for Flynn's role in the supply chain has been to mitigate Pfizer's exposure to

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<sup>1169</sup> See section 5.D.III.a. above.

<sup>1170</sup> See section 5.C.V.b.ii.

<sup>1171</sup> See also section 3.C.I.c. above and Annex K attached to this Decision.

reputational risk. In addition to the evidence set out in this section above, this fact is also recognised in an email to Flynn from one of its external advisers:

*'it would not be logical for Pfizer to go back to selling under their brand name or appoint another company to market the product [sic] as the publicity will not be good for them and they will be seen to be "milking" profits from a product much needed by a small group of patients.'*<sup>1172</sup>

5.458 When the CMA asked Pfizer why it included Flynn in its plan to genericise *Epanutin*, Pfizer explained that it did not have the necessary expertise to genericise the product but that Flynn did:

*'...at that time Pfizer had no history or knowledge of working with generics and it was not an area Pfizer was comfortable with. [redacted] [Pfizer's Commercial Account Director] explained that this was not something that Pfizer had done before. All resources, such as legal and finance, were aimed at the big brands and there was not the technical expertise in the organisation for generics [...] genericising a drug demanded different regulatory skills than branded products and was a regulatory piece that Pfizer was not familiar with. Management was not interested. Flynn is an expert in this and had the resource to make it happen.'*<sup>1173</sup>

5.459 However, even to the extent that Flynn's inclusion may have been to provide expertise that Pfizer did not have, the surrounding evidence suggests that this expertise was not as strong as Pfizer suggests.

5.460 First, Flynn engaged consultants to assist in navigating the regulatory process. Internal Flynn documents and information provided by the MHRA show that Flynn employed the services of [Flynn's appointed regulatory consultants] during their interactions with the MHRA. For example, [redacted] at [Flynn's appointed regulatory consultants] liaised with and received correspondence from the MHRA on behalf of Flynn.<sup>1174</sup>

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<sup>1172</sup> See document 00145.779.

<sup>1173</sup> See document 00412.1, paragraphs 22 to 23.

<sup>1174</sup> Document 00380.35 shows that the name change approval document from the MHRA was received by [redacted] [Flynn's appointed regulatory consultants] on behalf of Flynn. Document 00380.20 shows that the MHRA had spoken to [Flynn's appointed regulatory consultants] regarding the packaging for phenytoin sodium capsules. Similarly, document 00380.23 also shows that [Flynn's appointed regulatory consultants] were present at the teleconference between the MHRA and Flynn on the 25 June 2012.

5.461 Second, in an internal Pfizer email on 22 June 2012 [Pfizer's Head of EPBU] questioned Flynn's expertise:

*'What is your view in how Flynn are handling this? – I thought they viewed this opportunity as a way of demonstrating their expertise to us with a view to us doing further deals with them; however, I'm rapidly losing faith in them, so they have an enlarging credibility gap to close with me, and quickly.'*<sup>1175</sup>

5.462 Despite the limited value it has added to the supply chain, Flynn's sales of phenytoin sodium capsules have had a very significant impact on its overall profitability [REDACTED]

[REDACTED].<sup>1176</sup>

5.463 The contribution of Flynn's Products to Flynn's EBITDA is particularly striking given that [REDACTED].

5.464 [REDACTED].

5.465 [REDACTED]. The impact of Flynn's Prices on Flynn's statutory accounts was also evident and sustained: Flynn's operating profit rose from £9.6m for the year ending 31 March 2013 to £11.3m for the year ending 2014.

5.466 The CMA considers that the significant positive impact sales of phenytoin sodium capsules have had on Flynn's EBITDA, revenues and profitability further demonstrate that its prices are unfair in themselves. These financial results have been achieved through sales of a single product line which is a very old drug, which is long off patent, and which has been genericised and superseded by other AEDs. Further, Flynn undertakes few activities and incurs very little risk in distributing the product and sells to a captive customer base at prices it chooses. Returns of the level that Flynn has been achieving in this context are clearly unfair as these are not justified by the role played by Flynn in the supply chain.

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<sup>1175</sup> See document 00141.359 .

<sup>1176</sup> See document 00145.269.

*Flynn's excesses alone are significantly above pre-September 2012 ASPs in the UK*

5.467 The CMA's conclusion that Flynn's Prices are unfair is further supported by a comparison of Flynn's excesses (in absolute terms) with Pfizer's pre-September 2012 ASPs in the UK.

5.468 Table 5.23 below sets out both Flynn's excesses in absolute terms and Pfizer's pre-September 2012 ASPs.

**Table 5.23: Flynn's excesses (September 2012 to June 2016) and Pfizer's pre-September 2012 ASPs**

	<b>Flynn's excesses</b>	<b>Pfizer's pre-September 2012 ASPs</b>
<b>25mg</b>	[£6 - £8.99]	£0.51
<b>50mg</b>	[£3 - £5.99]	£0.52
<b>100mg</b>	[£11 - £20.99]	£2.21
<b>300mg</b>	[£11 - £20.99]	£2.20

5.469 As shown by Table 5.23 above:

- Flynn's excesses on 25mg capsules are [at least 11] times Pfizer's pre-September 2012 ASPs for that product.
- Flynn's excesses on 50mg capsules are [at least 11] times Pfizer's pre-September 2012 ASPs for that product.
- Flynn's excesses on 100mg capsules are [at least 5] times Pfizer's pre-September 2012 ASPs for that product.
- Flynn's excesses on 300mg capsules are [at least 5] times Pfizer's pre-September 2012 ASPs for that product.

5.470 Flynn has argued that this comparison is flawed because:

- the alleged excesses set out in the SO are not correct; and

- Pfizer's pre-September 2012 price was loss-making and Pfizer's selling price to Flynn is, on average, [around 10] times greater than the pre-September 2012 price.<sup>1177</sup>

5.471 The CMA does not accept that the excesses in the SO were not correct and has addressed Flynn's representations regarding its analysis of Flynn's excesses in section 5.C.V.d. above.<sup>1178</sup>

5.472 With regard to the second submission above, Flynn's argument that Pfizer's selling price to Flynn is substantially greater than its pre-September 2012 ASPs either misunderstands or misrepresents the CMA's case. The CMA is not comparing Flynn's Prices but Flynn's excesses in absolute terms (which obviously do not include Pfizer's post-September 2012 supply price) against Pfizer's pre-September 2012 ASPs.

5.473 The CMA considers this comparison provides further context which supports it finding that Flynn's Prices are unfair despite Pfizer's claims that its pre-September 2012 ASPs were loss-making. As has been previously stated, it has not been possible for the CMA to substantiate whether Pfizer's phenytoin sodium capsules were, in fact, loss-making based on the information Pfizer has submitted. However, giving Pfizer the benefit of the doubt, at worst it may have made a small loss in the period 2007 to September 2012 [X]. The figures set out in this section show that Flynn earns in pure profit (on top of an already very generous reasonable rate of return) several multiples of the pre-September 2012 ASPs in the UK which had remained stable for several years.

5.474 Accordingly, the CMA considers that the significant difference between the Flynn's excesses and Pfizer's pre-September 2012 prices provides further cogent evidence that Flynn's Prices are unfair in themselves. This is particularly the case given the age of the product, the very limited activities that Flynn performs in the supply chain and the very low risk it incurs in performing those activities. Further, Flynn has delivered no benefit to patients.

**c. *Conclusion on whether Pfizer's Prices and Flynn's Prices are unfair in themselves***

5.475 In light of the matters set out above, the CMA finds that:

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<sup>1177</sup> See document 01639.3, paragraph 5.63.

<sup>1178</sup> See section 5.C.V.d. above.

- (a) each of Pfizer's Prices is unfair in itself; and
- (b) each of Flynn's Prices is unfair in itself.

#### IV. ***Unfair when compared to competing products***

5.476 Having reached the conclusion that each of Pfizer's Prices and Flynn's Prices is unfair in itself, it is not necessary for the CMA to reach a conclusion as to whether those prices are also unfair when compared to competing products.

5.477 This is because, as set out in section 5.D.I., the two limbs within the second stage of the *United Brands* Test are alternative and not cumulative.<sup>1179</sup> Accordingly, where an excessive price is established as unfair in itself it will infringe the Chapter II prohibition/Article 102 and there is no additional requirement to establish whether that price is also unfair when compared to competing products.

5.478 However, for completeness, and because the Parties submitted representations to the CMA on the issue of whether their respective prices are unfair when compared to competing products, the CMA has considered whether such a comparison could be conducted.

5.479 For the reasons set out below, the CMA has concluded that there are no products that would provide a '*meaningful comparison*' for the purpose of conducting the 'when compared' limb of the second stage of the *United Brands* Test. In drawing this conclusion, the CMA has identified and assessed three potential products that could provide the basis for a comparison, they are:

- Parallel Imports;
- NRIM's Product; and
- Tablets.

##### a. ***Legal Background***

5.480 Although in *United Brands* the Court of Justice did not define the concept of '*competing products*', a product that falls within the relevant market, as defined for a particular case, may provide an appropriate comparator as it

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<sup>1179</sup> See section 5.D.I. above.

would, by definition, be a *'competing product'*. This interpretation is consistent with the CAT's assessment in *Albion Water II*, where it held that:

*'there is no substitute for the service of the transportation and partial treatment of water here in question [...]. It is therefore impossible to compare the level of the common carriage price charged by Dŵr Cymru with that of direct competitors because there are none.'*<sup>1180</sup>

5.481 This interpretation is also consistent with the European Commission's approach in *Scandlines* where it considered that the price of competing products that fell within the same relevant market as the product under investigation may assist in assessing the unfair element of the test:

*'If it were possible to find a substitutable product or service provided by competitors on the same relevant market, the price of such a product/service on this market could serve as a reference for the price of the product/service in question.'*<sup>1181</sup>

5.482 However, even if a product falls within the same relevant market it is still necessary to ensure that the comparator allows for a *'meaningful'* comparison. In *Albion Water II*, the CAT stated that:

*'The Tribunal notes that products do not have to be identical for the purposes of the unfairness test. However, the comparator has to be sufficiently similar to the product concerned in order for any comparison to be meaningful.'*<sup>1182</sup>

5.483 In *Albion Water II*, the CAT quoted the following passage from *Scandlines* to the effect that, for this exercise to be valid, it is necessary that:

*'a comparison of the prices must be made on a consistent basis. This notably implies that:*

- the products/services provided must be comparable; and*
- the charging systems must allow a meaningful comparison'.<sup>1183</sup>*

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<sup>1180</sup> *Albion Water II*, [256], also citing *Deutsche Post*, paragraph 159 and *Scandlines*, paragraph 170. See AG Opinion in *Ministere Public v Tournier*, C-395/87, EU:C:1989:215, paragraph 53.

<sup>1181</sup> *Scandlines*, paragraph 170.

<sup>1182</sup> *Albion Water II*, [252].

<sup>1183</sup> *Scandlines*, paragraph 175 and *Albion Water II*, [253].

5.484 Accordingly, regardless of whether the comparator product is a competing product or sufficiently similar to the product in question, the determining factor is whether the result of any comparison is meaningful.

5.485 For the result of the comparison to be '*meaningful*' it must be ensured that '*the figures which are compared are really comparable*'. As the European Commission stated in its *Scandlines* decision:

*'It may be possible in the abstract, as Scandlines suggests, to make a comparison between different figures representing prices of products or services. The problem is to assure that the comparison is valid and that the result of the comparison is meaningful. It must be ensured that the figures which are compared are really comparable. The conditions under which such a comparison is made are therefore of the utmost importance.'*<sup>1184</sup>

5.486 To be a meaningful comparison, products must also be '*sufficiently reliable comparators*'.<sup>1185</sup> Care should be taken when assessing whether a price can be deemed fair as a result of a comparison with prices charged for comparable products in other relevant markets. Such a comparison cannot be considered meaningful simply on the basis that the customer is paying the price imposed.<sup>1186</sup>

5.487 Among other things, the CMA considers that comparisons should not be drawn with other products the prices of which may also have been inflated by the exercise of substantial market power.<sup>1187</sup> This is important in order to ensure that the dominant undertaking under investigation is not able to earn '*trading benefits which it would not have reaped if there had been normal and sufficiently effective competition*'.<sup>1188</sup> If the comparator product's price is itself excessive, or if one would expect it to be excessive given the lack of competition it faces, then the comparison will not be informative as to whether the price of the product under investigation is unfair. In such a case, the price of the comparator product would not reflect the true economic value

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<sup>1184</sup> *Scandlines*, paragraph 169.

<sup>1185</sup> *Albion Water II*, [258].

<sup>1186</sup> See for example *Albion Water I*, [754] to [756] and section 5.D.II.a. above.

<sup>1187</sup> This is consistent with the CAT's findings in *Albion Water I*, [757] and *Albion Water II*, [257]. It is also consistent with the submission from the European Union to the Roundtable on Excessive Prices held by the OECD Competition Committee (Working Party No. 2 on Competition and Regulation) in October 2011, paragraphs 49 and 50.

<sup>1188</sup> *United Brands*, paragraph 249.



of either the comparison product or the product under investigation. As the CAT has noted:

*'If the [price under consideration] is not cost-justified, and since the evidence strongly suggests that that price was excessive, it does not in our view assist that that price is based on a comparison with other prices which are not cost justified either.'*<sup>1189</sup>

5.488 These concerns are similarly reflected in the CAT's conclusion that even where a number of other companies providing the same service engage in similar pricing practices, this will *'not, in itself, show that the [price in question] is not unfair.'*<sup>1190</sup>

5.489 In addition to products which are in same relevant market, the European Commission in *Scandlines* also said that, according to case law and the decisional practice of the European Commission, the contested price may *'be compared to (i) other prices charged by the dominant company on a market different from the relevant market or (ii) prices charged by other firms providing similar products/services on other relevant markets.'*<sup>1191</sup>

5.490 In such circumstances, it is particularly important to ensure that the result of the comparison is *'meaningful'* and that *'the figures which are compared are really comparable'*.<sup>1192</sup> The aim of such comparisons is to look at the price of sufficiently comparable products which are sold in markets where substantial market power is not present.

**b. Assessment of whether there are sufficiently similar products that could allow for a meaningful comparison**

*i. Parallel Imports and NRIM's Product*

5.491 The CMA considers that neither Parallel Imports nor NRIM's Product provide the basis for a meaningful comparison to assess whether Pfizer's Prices or Flynn's Prices are unfair. This is because both Parallel Imports and NRIM's Product are price-takers in that their respective prices are set by reference to Flynn's Prices and/or the Drug Tariff prices for phenytoin sodium capsules which are, themselves, determined by reference to Flynn's list prices.<sup>1193</sup> As

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<sup>1189</sup> *Albion Water I*, [757].

<sup>1190</sup> *Albion Water II*, [257].

<sup>1191</sup> *Scandlines*, paragraph 171.

<sup>1192</sup> *Scandlines*, paragraph 169.

<sup>1193</sup> See section 3.C.III.b. above.

such, any assessment of whether Pfizer's Prices and/or Flynn's Prices are unfair when compared to either Parallel Imports or NRIM's Product would be circular and therefore not a meaningful comparison.

- 5.492 Any pharmacy which dispenses phenytoin sodium capsules will be reimbursed according to the Drug Tariff price for the relevant capsule strength of phenytoin sodium capsules (subject to any clawback discount). This is the case regardless of whether the pharmacist in question dispenses Flynn's Products, Parallel Imports or NRIM's Product.
- 5.493 In respect of NRIM's Product, the principle of Continuity of Supply means that it is not substitutable for Flynn's Products. As a result, NRIM does not have an incentive to price at a significant discount below the Drug Tariff price for 100mg phenytoin sodium capsules because doing so would reduce its per-pack margin without increasing its sales (because pharmacists would not be induced to substitute from Flynn's Products to NRIM's Product).<sup>1194</sup> As such, and as confirmed by NRIM to the CMA,<sup>1195</sup> the price of NRIM's Product is set by reference to the Drug Tariff price for 100mg phenytoin sodium capsules which is, in turn, determined by reference to Flynn's list price for its 100mg phenytoin sodium capsules.
- 5.494 Parallel Imports are substitutable for Flynn's Product and parallel importers therefore have an incentive to price Parallel Imports at a level below Flynn's Prices in order to win sales. However, parallel importers do not have an incentive to price at a significant discount below Flynn's Prices because doing so would reduce their per-pack margin but would not increase their sales volumes due to the capacity constraints on Parallel Imports (as set out in section 4.C.V.a.i.above). As such, the prices of Parallel Imports are, in practice, set by reference to Flynn's Prices.
- 5.495 The conclusion that NRIM and parallel importers are both price-takers is strongly supported by observable pricing behaviour. The prices of Parallel Imports have increased since the prices of Pfizer-manufactured phenytoin sodium capsules increased in September 2012.<sup>1196</sup> [✂].<sup>1197</sup>

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<sup>1194</sup> Even in the period prior to November 2013, when [Pharmacy 3] and [Pharmacy 6] were willing to switch some patients from Flynn's Product to NRIM's Product on the basis of price, the evidence shows that Flynn did not react in a timely manner to reduce its prices which meant that NRIM also did not need to do so.

<sup>1195</sup> See document 00512.2, in particular answer to Q7.

<sup>1196</sup> See document 00505.40.

<sup>1197</sup> See section 4.C.V.b. above.

ii. *Tablets*

5.496 The CMA has already considered and dismissed a number of submissions the Parties have made regarding the Drug Tariff for Tablets, in particular submissions suggesting that the DH had '*sanctioned*' the price it pays for Tablets and submissions suggesting that the DH considered the '*tablet price to represent value for money*.'<sup>1198</sup>

5.497 In this section the CMA sets out the reasons for finding that the Drug Tariff for Tablets does not provide the basis for a meaningful comparison to assess whether either Pfizer's Prices or Flynn's Prices are unfair.

5.498 In this regard, the Parties have argued that the CMA's analysis of the competitive dynamics in the Tablets market is inadequate<sup>1199</sup> and that, in any event, '*...the competitiveness or otherwise of the tablet wholesale market is irrelevant*'<sup>1200</sup> and the CMA has not '*...put forward any analysis as to why a benchmark has to be competitive*'.<sup>1201</sup> The Parties have also submitted that the characteristics of Scheme M are not sufficient to conclude that the price of Tablets cannot serve as benchmark<sup>1202</sup> and, indeed, that this fact means that the price of Tablets provides a better, rather than worse, benchmark.<sup>1203</sup>

5.499 The CMA considers that Tablets do not offer the basis for meaningful comparison for the purpose of conducting the 'when compared' element of the *United Brands* Test. The CMA's reasoning for this conclusion is set out below.

5.500 First, it is established case law that where other companies are engaged in similar pricing practices to the price being scrutinised, this will '*not, in itself, show that the [price being scrutinised] is not unfair*.'<sup>1204</sup> Accordingly, it is incorrect for the Parties to conclude that the price of phenytoin sodium capsules is not unfairly high based on the Drug Tariff price of Tablets.

5.501 Using the price of another product (in this case the Drug Tariff price of Tablets) as a benchmark to assess the economic value of the product under

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<sup>1198</sup> See section 5.D.II.b.ii. above.

<sup>1199</sup> See document 01622.2, paragraph 135 and document 02076.1, paragraph 32. See also document 01639.3, paragraph 5.74 and document 02077.1, paragraph 9.8.

<sup>1200</sup> See document 02076.1, paragraph 32.

<sup>1201</sup> See document 02077.1, paragraph 9.8.

<sup>1202</sup> See document 02076.1, paragraphs 25 to 30.

<sup>1203</sup> See document 01622.2, paragraph 137. See also document 02077.1, paragraphs 9.7 and 9.8.

<sup>1204</sup> *Albion Water II*, [257]

scrutiny (in this case phenytoin sodium capsules) is especially problematic where the price of the supposed benchmark product is not cost-justified:

*'If the [price under consideration] is not cost-justified, and since the evidence strongly suggests that that price was excessive, it does not in our view assist that price is based on a comparison with other prices which are not cost justified either.'*<sup>1205</sup>

- 5.502 Both Parties acknowledge that [REDACTED]. In his email to various colleagues, dated 2 February 2010, [REDACTED] (Pfizer's Head of EPBU) described Teva's profits as '*supernormal*'<sup>1206</sup> which is clearly not consistent with the price being cost-based. Additionally, in its representations on the SO, Pfizer stated that [REDACTED].<sup>1207</sup> Similarly, in its representations Flynn stated that [REDACTED].<sup>1208</sup>
- 5.503 Second, an objective assessment of the dynamics of the Tablets market demonstrates that it is unlikely to operate in a way that would result in a reasonable relationship between the price of Tablets and their economic value, but instead that they provide Tablet manufacturers with market power and the ability to generate the type of '*supernormal profits*' that [Pfizer's Head of EPBU] himself identified.
- 5.504 The CMA rejects the Parties' representations suggesting that the competitiveness or otherwise of the tablets market is irrelevant<sup>1209</sup> or that the CMA must put forward an analysis as to why a benchmark has to be competitive.<sup>1210</sup> Comparisons should not be drawn with other products the prices of which may also have been inflated by the exercise of market power as these will not be informative as to whether the price of the product under investigation is unfair. In such a case, the price of the comparator product would also not reflect the true economic value of either the comparison product or the product under investigation.<sup>1211</sup> This is an obvious reason why the fact that other companies may engage in similar pricing practices will '*not, in itself, show that the [price being scrutinised] is not unfair.*'<sup>1212</sup>

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<sup>1205</sup> *Albion Water I*, [757].

<sup>1206</sup> See document 00141.57.

<sup>1207</sup> See document 01622.2, paragraph 132

<sup>1208</sup> See document 01639.3, paragraph 5.41.

<sup>1209</sup> See document 02076.1, paragraph 32.

<sup>1210</sup> See document 02077.1, paragraph 9.8.

<sup>1211</sup> See section 5.D.IV.a. above.

<sup>1212</sup> *Albion Water II*, [257].

- 5.505 The CMA also rejects submissions that its analysis of the competitive dynamics in the Tablets market is inadequate.<sup>1213</sup> The two limbs within the second stage of the *United Brands* Test are alternative and the CMA has already established that Pfizer's Prices and Flynn's Prices are unfair in themselves. Further, the consideration of comparators under the *United Brands* Test does not require a full analysis of the competitive conditions prevailing in the markets where such potential comparator products are sold. This would not be consistent with previous case law<sup>1214</sup> and it would be unreasonable and onerous to require an authority to also undertake an in-depth investigation into all of the markets concerning potential comparators, in order to be able to successfully establish an unfair pricing abuse, particularly when the test is alternative.
- 5.506 Accordingly, the CMA has not conducted such an analysis in this case. However, it has identified a number of features of the Tablets market which mean that it is unlikely to function in a manner which produces a reasonable relation between price and economic value, as set out in section 5.D.II.b.ii above and further below. In conducting this analysis the CMA has gone significantly beyond the assessment undertaken by the CAT when dismissing possible comparators in *Albion Water II*.<sup>1215</sup>
- 5.507 In its written representations on the SO, Flynn stated that the markets for both Tablets and phenytoin sodium capsules function in broadly the same way: *[T]he demand side factors which drive the competitive dynamics of phenytoin tablets and phenytoin capsules are largely identical.*<sup>1216</sup> The CMA agrees with this statement. Tablets, like phenytoin sodium capsules, are used to treat the same condition, have a NTI and non-linear pharmacokinetics and are also subject to the same clinical guidance recommending Continuity of Supply.<sup>1217</sup> The ten major pharmacy chains contacted by the CMA during the course of its investigation have all confirmed that they endeavour to follow the principle of Continuity of Supply when dispensing Tablets.<sup>1218</sup> Consequently, inter-brand competition and switching between the different manufacturers' versions of Tablets is likely to be limited, meaning that price competition is also limited. Accordingly,

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<sup>1213</sup> See document 01622.2, paragraph 135 and document 02076.1, paragraph 32. See also document 01639.3, paragraph 5.74 and document 02077.1, paragraph 9.8.

<sup>1214</sup> See for instance the analysis conducted by the CAT in *Albion Water II*, [254] to [259].

<sup>1215</sup> See *Albion Water II*, [258] and [259].

<sup>1216</sup> See document 01639.3, paragraph 5.41.

<sup>1217</sup> See section 3.F.III..

<sup>1218</sup> See section 3.F.III.

individual Tablet manufacturers are likely to possess significant market power enabling them to profitably sustain prices above the competitive level.

- 5.508 The significant increase in the Tablets Drug Tariff price since 2005 is a further indicator of the manufacturers and/or suppliers holding market power. In the period April 2005 to October 2007, this price increased by approximately 6,584%. Even after Teva voluntarily reduced its price in October 2008, the price remained significantly above the historic norm which [Pfizer's Head of EPBU] regarded as generating '*supernormal profits*'. Both Parties acknowledge that Tablets [✂].
- 5.509 Further, section 5.D.II.b.ii. demonstrated that the Drug Tariff price for Tablets implemented in October 2008 was not subject to any regulatory approval by the DH, and that the DH was not happy with the level of that price and communicated that to Flynn shortly after the capsule price increase of September 2012. It is also clear that Scheme M does not provide the DH with any effective powers to intervene on pricing, [✂].
- 5.510 There are further reasons why Tablets do not provide the basis for a meaningful comparison with either Pfizer's Prices or Flynn's Prices.
- 5.511 First, Tablets are only supplied in 100mg strength and therefore do not provide a meaningful comparison for the 25mg, 50mg and 300mg capsule strengths supplied by Pfizer and Flynn for sale in the UK.
- 5.512 In its representations on the SO, Pfizer submitted that the price of the 100mg strength Tablet formed the basis for its pricing decision across all capsule strengths on a pro-rata basis and that consequently evidence demonstrating that the price of 100mg was not unfair should also apply to the prices of other capsule strengths.<sup>1219</sup> However, when assessed on a pro-rata basis the Drug Tariff price set by Flynn was not even consistently below the Drug Tariff for Tablets but rather varied between 75% and 210% of this price.<sup>1220</sup> Therefore, the Drug Tariff for Tablets should not be applied (pro-rated) to the price of other capsule strengths.
- 5.513 Second, Tablets fall within Category M, whereas phenytoin sodium capsules fall within Category C, meaning their pricing structures are different, therefore further supporting the conclusion that Tablets do not provide a meaningful comparison. As set out in Section 5.D.II.b.ii., the Drug Tariff is

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<sup>1219</sup> See document 01622.2, paragraph 136.

<sup>1220</sup> When prorated the 100mg and 300mg strengths were set at 75% but the 50mg and 25mg strengths were set at 107% and 210% respectively.

not a pure monetary cost or price measure in the way that Pfizer Prices and Flynn's Prices are. Instead it encompasses a number of different policy goals. In particular, the Drug Tariff prices of Category M products are intended to be set significantly above the manufacturer's price with the intention that this allows for community pharmacies to earn a sufficient return on the prescriptions they dispense to fund their dispensing operations.

- 5.514 The Parties have argued that because Tablets are covered by Scheme M they provide a better, rather than worse, benchmark.<sup>1221</sup> Pfizer has also argued that because both Pfizer and Flynn have priced significantly lower than the Drug Tariff for Tablets, the price differential '*...is sufficient to have covered any hypothetical upwards adjustment to the tablet price due to the retained pharmacy margin.*'<sup>1222</sup>
- 5.515 As demonstrated in section 5.D.II.b.ii above, the CMA considers that in practice Scheme M provides the DH with no real powers to intervene on pricing.
- 5.516 In addition, even if Pfizer's submission on retained pharmacy margin had been established as being factually accurate (which it has not), this would still not change the fact that these are two separate regulatory frameworks, which have material differences and pursue different policy goals. In particular, Scheme M is primarily intended to control the retained margins earned by pharmacies, not the prices charged by the suppliers of generic pharmaceuticals.<sup>1223</sup>
- 5.517 These differences between the two regulatory frameworks have a direct impact on the level of pricing and determine how the Drug Tariff for each of the products is arrived at.
- 5.518 On this basis, the CMA rejects the Parties' submissions that because Tablets are covered by Scheme M they provide a better, rather than worse, benchmark.
- 5.519 Finally, the CMA considers that it is notable that the Parties ignore a more meaningful benchmark for assessing whether Pfizer's Prices and Flynn's Prices are unfair, in the form of Pfizer-manufactured phenytoin sodium capsules sold by Pfizer in other EU countries. Whilst it is not necessary to assess whether Pfizer's Prices and Flynn's Prices are also unfair when

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<sup>1221</sup> See document 01622.2, paragraph 137. See also document 02077.1, paragraphs 9.7 and 9.8.

<sup>1222</sup> See document 02076.1, paragraph 28.

<sup>1223</sup> See section 3.C.III.c.ii. for more details.

compared to competing products (having established that these are unfair in themselves), the CMA considers that prices in other EU countries would offer a more meaningful basis for comparison because they concern the same product, manufactured by the same company, in the same strengths, in the same German facility and sold in other EU countries.

- 5.520 As set out in section 5.D.III.b.iii. above, the prices charged by Pfizer for 100mg phenytoin sodium capsules in other EU countries are significantly lower than Pfizer's Prices.
- 5.521 Table 5.22 above shows that Pfizer's average UK wholesale price for 100mg phenytoin sodium capsules during the Relevant Period is [4 to 6] times the average end price in Sweden; [5 to 7] times the average end prices in Ireland and Belgium; [9 to 13] times the average end price in Greece and some [18 to 24] times the average end price in Spain. Pfizer has confirmed that all its prices in each of these Member States were profitable in 2015 except for those in [✂].<sup>1224</sup>
- 5.522 Table 5.24 below, shows that Flynn's excesses (the amount, in pounds, by which Flynn's Prices exceed Flynn's Cost Plus) throughout the Relevant Period are significantly higher than Pfizer's wholesale prices in every other EU Member State. In fact, in the period September 2012 to June 2016 Flynn's excesses were at least double Pfizer's prices in every other EU Member State.

**Table 5.24: Flynn's excess on 100mg Pfizer-manufactured phenytoin sodium capsules and Pfizer's average wholesale prices for 100mg Pfizer-manufactured phenytoin sodium capsules in other EU member states (September 2012 to June 2016)**

Capsule strength	Flynn's excess (£)	Average wholesale price (£)				
		Belgium	Greece	Ireland	Spain	Sweden
100mg	[£11 - £20.99]	[£3 - £5.99]	[£1 - £2.99]	[£3 - £5.99]	[£1 - £2.99]	[£6 - £8.99]

Sources: Table 5.22 and document 02129.3

- 5.523 This means that Flynn earns significantly more in terms of pure profit (on top of an already very generous rate of return) for distributing phenytoin sodium capsules in the UK than the average wholesale price at which those products are sold in other EU Member States.

<sup>1224</sup> See document 01836.2.



5.524 In such circumstances it is settled case law from the Court of Justice that:

*‘...it is for the undertaking in question to justify the difference by reference to objective dissimilarities between the situation in the Member State concerned and the situation prevailing in all the other Member States.’<sup>1225</sup>*

5.525 Apart from some general submissions made by Pfizer<sup>1226</sup> and Flynn<sup>1227</sup> on the relevance of the prices charged by Pfizer for phenytoin sodium capsules in other EU Member States, the Parties have failed to provide any ‘*objective dissimilarities*’ between the situation in the UK and the situation prevailing in other Member States.

5.526 Whilst the CMA recognises that each country has a specific regulatory regime, it considers that the differences between the prices charged in the UK and those charged in other EU Member States are so significant that it is unlikely there would be any ‘*objective dissimilarities*’ that could justify such differences.

## **E. Lack of objective justification**

5.527 It is open to a dominant undertaking to provide a justification for behaviour that is liable to be caught by the Chapter II prohibition or Article 102 of the TFEU. A dominant undertaking may do so either by demonstrating that its conduct is objectively necessary or by demonstrating that its conduct produces substantial efficiencies which outweigh any anticompetitive effects on consumers.<sup>1228</sup>

5.528 It is incumbent upon the dominant undertaking to provide all the evidence necessary to demonstrate that the conduct concerned is objectively justified. As the CAT recognised in *Albion Water II*:

*‘It is for the party alleging an infringement to prove it and not for the dominant undertaking to demonstrate its absence. It is then for the*

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<sup>1225</sup> See judgment in *OSA v Léčebné lázně Mariánské Lázně a.s.* C-351/12, EU:C:2014:110, paragraph 87, citing *Ministère Public v Jean-Louis Tournier* C-395/87, EU:C:1989:319, paragraph 38 and *Lucazeau and Others v SACEM* C-110/88, EU:C:1989:326, paragraph 25.

<sup>1226</sup> See document 01622.2, paragraph 184.

<sup>1227</sup> See document 01639.3, paragraph 5.65.

<sup>1228</sup> See judgment in case *Post Danmark v Konkurrencerådet* C-209/10, EU:C:2012:172, paragraphs 40 and 41 and case law cited therein. See also case law cited in *Enforcement Priorities Guidance*, paragraph 28.

*dominant undertaking to raise any plea of objective justification and to support it with arguments and evidence.*<sup>1229</sup>

- 5.529 In this case, the Parties have failed to provide any objective justification for imposing price increases of this scale for an 80 year old generic drug which has been superseded by superior treatments and which had been previously sold by the same manufacturer at a much lower price for a number of years, without there having been any relevant change in costs or risks or any recent innovation.<sup>1230</sup>
- 5.530 Neither Pfizer's Prices nor Flynn's Prices are reflective of any additional benefits having been created. As Flynn itself recognised in its announcement to healthcare professionals, Flynn's Products are identical to *Epanutin*, there are no differences in formulation, the site of manufacture remains unchanged and the capsules continue to contain the same identicode markings as *Epanutin*.<sup>1231</sup> CCGs are also clear that the price increases do not reflect any discernible benefit to patients and indeed there have been no improvements to the products for many years.<sup>1232</sup> Indeed the only changes that have been made to the product have been to the name and the packaging, which in fact introduced risks of patient confusion and concern rather than any patient benefits.<sup>1233</sup>
- 5.531 The CMA, therefore, finds that the Parties have failed to provide an objective justification for either Pfizer's Prices or Flynn's Prices.

## **F. Exclusions and Derogations**

- 5.532 Section 19 of the Act provides that the Chapter II prohibition does not apply to any of the cases in which it is excluded by or as a result of Schedules 1 or 3 of the Act.
- 5.533 In certain circumstances a derogation from Article 102 of the TFEU may be applicable to conduct which would otherwise be abusive.

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<sup>1229</sup> *Albion Water II*, [70].

<sup>1230</sup> This is reflected in the economic value of Pfizer's Products and Flynn's Products and, in particular, the CMA's finding that there are no non-cost related factors to increase the economic value of any of Pfizer's Products or Flynn's Products beyond Cost Plus.

<sup>1231</sup> See document 00145.388.

<sup>1232</sup> See section 3.E.XI.

<sup>1233</sup> See section 3.E.IV.c.iv.

5.534 The CMA finds that none of the exclusions from the Chapter II prohibition provided for by section 19 or under schedule 3 of the Act or any derogation from Article 102 of the TFEU applies in respect of any of the Infringements. Accordingly, the CMA finds that none of the Infringements benefit from an exclusion from the Chapter II prohibition or a derogation from Article 102 of the TFEU.

## **G. Conclusions on abuse of dominance**

5.535 For the reasons set out in sections 5.C and 5.D above, the CMA finds that throughout the Relevant Period:

- each of Pfizer's Prices is unfair within the meaning of section 18(2)(a) of the Act and Article 102(a) of the TFEU; and
- each of Flynn's Prices is unfair within the meaning of section 18(2)(a) of the Act and Article 102(a) of the TFEU.

## 6. EFFECT ON TRADE

### A. Effect on trade within the UK

- 6.1 The Chapter II prohibition applies only to conduct by a dominant undertaking which may affect trade within the UK.<sup>1234</sup>
- 6.2 The CMA considers that the Infringements are capable of affecting trade within the UK throughout the Relevant Period.
- 6.3 To infringe the Chapter II prohibition, a dominant undertaking's conduct does not actually have to affect trade as long as it is capable of doing so.<sup>1235</sup> For the purposes of the Chapter II prohibition, the UK includes any part of the UK.<sup>1236</sup>
- 6.4 The Chapter II prohibition is not read as importing a requirement that the effect on trade within the UK should be appreciable.<sup>1237</sup>
- 6.5 Each of the Infringements was implemented within the UK and had an effect on the price paid in the UK for the relevant goods. Accordingly, the CMA finds that each of the Infringements may have affected (and indeed did affect) trade in the buying and selling of drugs within the whole or part of the UK.

### B. Effect on trade between EU Member States

- 6.6 The CMA concludes that the Infringements are capable of affecting trade between EU Member States throughout the Relevant Period. It is foreseeable with a sufficient degree of probability on the basis of a set of objective factors that the Infringements can influence the pattern of cross-border economic activity.
- 6.7 Where the CMA applies national competition law to an abuse of a dominant position which has an effect on trade between EU Member States, the CMA must also apply Article 102 of the TFEU.<sup>1238</sup>

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<sup>1234</sup> Section 18(1) of the Act.

<sup>1235</sup> See, for example, the judgment in *Irish Sugar plc v Commission* T-228/97, EU:T:1999:246, paragraph 170.

<sup>1236</sup> Section 18(3) of the Act.

<sup>1237</sup> *Aberdeen Journals II*, [459] to [460].

<sup>1238</sup> Article 3 of Council Regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty.

- 6.8 For the purposes of assessing whether trade between EU Member States may be affected the CMA follows the approach set out in the Commission's Guidelines on the effect on trade concept contained in Articles 81 and 82 of the Treaty (the '*Effect on Trade Guidelines*')<sup>1239</sup> and the case law of the European Courts.
- 6.9 The conduct may have a direct or indirect, actual or potential effect, on the pattern of trade between at least two EU Member States and it is not required that the conduct will actually have or has had an effect on trade between Member States. It is sufficient that the conduct is '*capable*' of having such an effect.<sup>1240</sup> The effect on trade between EU Member States must be appreciable.<sup>1241</sup>
- 6.10 The concept of trade is a wide concept that covers all cross border economic activity between EU Member States including establishment<sup>1242</sup> and encompasses cases when practices have an effect on the competitive structure of the market.<sup>1243</sup> The nature of the relevant products also provides an indication of whether trade between EU Member States is capable of being affected. An effect of trade between EU Member States is more likely to exist when by their nature products are easily traded across borders.<sup>1244</sup> Trade between EU Member States may also be affected in cases where the relevant market is national or sub-national.<sup>1245</sup>
- 6.11 In order for there to be an effect on trade between EU Member States, it is not required that trade is reduced. Instead, it is sufficient that an appreciable change is capable of being caused in the pattern of trade between EU Member States and this change can be positive or negative.<sup>1246</sup>

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<sup>1239</sup> Guidelines on the effect on trade concept contained in Articles 81 and 82 of the Treaty, OJ C 101, 27.4.2004, p.81 to 96.

<sup>1240</sup> *Effect on Trade Guidelines*, paragraph 26.

<sup>1241</sup> *Effect on Trade Guidelines*, paragraphs 44 to 49.

<sup>1242</sup> *Effect on Trade Guidelines*, paragraph 19. See also, for example, the judgment in *Züchner v Bayerische Vereinsbank* C-172/80, EU:C:1981:178, paragraph 18 and the judgment in *Ambulanz Glöckner* C-475/99, EU:C:2001:577, paragraph 49.

<sup>1243</sup> *Effect on Trade Guidelines*, paragraph 20.

<sup>1244</sup> *Effect on Trade Guidelines*, paragraph 30.

<sup>1245</sup> *Effect on Trade Guidelines*, paragraph 22.

<sup>1246</sup> *Effect on Trade Guidelines*, paragraphs 33 to 35 and 77; Commission decision COMP/F-2/36.693 – *Volkswagen* – relating to a proceeding under Article 81 of the EC Treaty [2001] OJ L262/32, paragraph 88.

- 6.12 The CMA considers that the Infringements are capable of affecting trade between EU Member States for the following reasons.<sup>1247</sup>
- 6.13 First, as explained above, the CMA finds that the relevant markets are UK-wide, that both Pfizer and Flynn held dominant positions covering the entire territory of the UK and have committed Infringements that also cover the entire territory of the UK. The UK constitutes a substantial part of the internal market and is the largest national market in the EU for phenytoin sodium capsules.<sup>1248</sup>
- 6.14 Second, the level of price differences between Member States is recognised as being a factor which significantly affects trade between Member States.<sup>1249</sup> An effect on trade between Member States is not confined to cases where a measure results in compartmentalisation of markets through exclusionary effects. The potential for the Infringements to increase (or decrease) parallel importation exists because the Parties imposed significant price rises for phenytoin sodium capsules in the UK. This resulted in significant differences between the prices in the UK and the prices charged in other Member States for all strengths of phenytoin sodium capsules. Consequently, the commercial incentives for importing phenytoin sodium capsules from other EU Member States has significantly increased while the incentive to export has decreased. Consequently, the Infringements have created a change in the competitive structure of the single market and therefore the Infringements are capable of effecting trade between EU Member States.<sup>1250</sup>
- 6.15 Indeed, the Infringements have been proven to have had actual effects on the market. For example, the Infringements have caused an increase in parallel importation of 100mg phenytoin sodium capsules into the UK from other Member States where *Epanutin* is sold at significantly lower prices.<sup>1251</sup> Flynn itself confirmed that '*...it is a matter of record that, shortly after the initial price increase that was implemented, the Spanish market went out of*

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<sup>1247</sup> For a similar finding see Commission decision COMP/F-2/36.693 – *Volkswagen* – relating to a proceeding under Article 81 of the EC Treaty [2001] OJ L262/32, paragraph 91.

<sup>1248</sup> See for example *Irish Sugar v Commission*, T-228/97, EU:T:1999:246, paragraph 99.

<sup>1249</sup> Commission decision COMP/F-2/36.693 – *Volkswagen* – relating to a proceeding under Article 81 of the EC Treaty [2001] OJ L 262/32, paragraph 84.

<sup>1250</sup> See for example judgement in *Commercial Solvents v Commission*, C-6/73, EU:C:1974:18, paragraphs 32 and 33.

<sup>1251</sup> See for example documents 00141.593, 00141.599 and 00145.896. See also section 4.C.III for market share tables.

*stock*.<sup>1252</sup> The number of applications and licences in the UK for Parallel Imports of all strengths of phenytoin sodium capsules has also increased.<sup>1253</sup> In June 2013 (the date at which the CMA was provided with a list of Parallel Import licences) there were 24 parallel import licences for 100 mg phenytoin sodium capsules, held by 12 separate companies. There were no licences granted for the parallel importation of any other dosage strength. By February 2016 there were:<sup>1254</sup>

- (a) 12 parallel import licences for 25mg capsules granted to 6 separate companies;
- (b) 12 parallel import licences for 50mg capsules granted to 7 separate companies;
- (c) 64 parallel import licences for 100mg capsules granted to 24 separate companies;
- (d) 11 parallel import licences for 300mg capsules granted to 7 separate companies.

6.16 Twenty-one of the new licences for the parallel importation of 100mg capsules were granted in 2013, a further 18 in 2014 and the final 3 in 2015. The first Parallel Import licence for a dosage strength other than 100mg was granted in 2013. There were 15 such licences granted in 2013, a further 11 parallel import licences for dosages other than 100mg granted in 2014 and in 2015 another 7 were granted.<sup>1255</sup> These companies would not have applied for the licences if they did not expect that they would be able to use them, either at the time or in the future.

6.17 Third, the Parties' supply chain for all four strengths of phenytoin sodium capsules already includes trade between Member States because they are manufactured by Pfizer in one Member State (Germany) before being delivered to Flynn's wholesaler in another Member State (the UK) and then ultimately to the UK-based patient. This trade between Member States has been affected by the Infringements (albeit indirectly in the case of Flynn)

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<sup>1252</sup> See document 01767.1 page 63.

<sup>1253</sup> See for example document 00505.40.

<sup>1254</sup> See document 01780.3.

<sup>1255</sup> See document 01780.3. This document also shows that in the first two months of 2016 there were two licences granted for the parallel importation of dosage strengths other than 100mg.

because the Infringements have involved the Parties' supply prices changing appreciably compared to the previous levels.

- 6.18 Fourth, Flynn Pharma Limited is a company based in Ireland holding a dominant position and abusing such a position in relevant markets geographically covering the UK. The concept of trade includes but is not limited to traditional exchanges of goods and services across borders. It is a wider concept, covering all cross-border economic activity, including establishment.<sup>1256</sup>
- 6.19 Finally, the CMA considers that the effect on trade between EU Member States arising from the Infringements is appreciable given the economic significance of the UK in the commercialisation of phenytoin sodium capsules within the internal market, the significant position of strength enjoyed by both Pfizer and Flynn in their respective relevant markets, and the magnitude of the price changes caused by the Infringements.<sup>1257</sup>
- 6.20 Flynn has submitted<sup>1258</sup> that it is relevant that the CMA finds that Flynn has committed four separate infringements of Article 102 of the TFEU, one for each of the four strengths of phenytoin sodium capsules that Flynn sells on the UK market. According to Flynn, in order for the CMA to find these Infringements, it is necessary to show that Flynn's conduct has had an effect on trade between Member States for each strength. In this respect, as demonstrated above, there is clear evidence of actual effects on importation of 100mg capsules. As regards other dosage strengths, all four strengths are also available in Ireland as well as the UK, and strengths other than 100mg are also periodically supplied to Greece. This means that the potential for effects on parallel importation exists for all strengths of phenytoin sodium capsules satisfying the test for there to be an effect on trade. Additionally, as set out above, the Parties' own supply chain for all four strengths includes trade between Member States because they are manufactured in one Member State (Germany) before being delivered to Flynn's wholesaler in another Member State (the UK), and this supply chain has obviously been affected by the Infringements. Further, Flynn's profits from all four strengths flow from the UK customers to its Irish holding company.

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<sup>1256</sup> This is consistent with the fundamental objective of the TFEU to promote the free movement of goods, services, persons and capital. See the *Effect on Trade Guidelines*, paragraph 19. See also judgement in *Manfredi* C-295/04, EU:C:2006:461, paragraphs 43 and 44.

<sup>1257</sup> In addition to the other factors noted, and regardless of how the relevant markets are defined, Pfizer and Flynn both have market shares well in excess of 50 per cent.

<sup>1258</sup> Document 02060.1.



## 7. DIRECTIONS AND PENALTIES

### A. Directions

- 7.1 Section 33(1) of the Act provides that if the CMA has made a decision that conduct infringes the Chapter II prohibition or Article 102 of the TFEU, it may give to such person or persons as it considers appropriate such directions as it considers appropriate to bring the infringement to an end.
- 7.2 The CMA considers that each of the Infringements is ongoing at the date of this Decision and therefore the CMA gives directions to each of Pfizer and Flynn requiring them to bring to an end the infringing conduct and not to engage in the same or similar conduct in the future.
- 7.3 The directions that the CMA makes to Pfizer and Flynn are set out in Annex B (the 'CMA's Directions').<sup>1259</sup>
- 7.4 While the CMA's Decision is that Pfizer and Flynn have each committed four separate Infringements, in the specific circumstances of the Investigation the CMA considers that the Infringements would be brought to an end most effectively through the use of a set of combined directions. In particular, it is relevant for these purposes that Pfizer and Flynn are part of the same vertical supply chain and therefore Pfizer's Prices directly impact upon Flynn's costs. As such the CMA finds that Flynn's Infringements can most reliably be brought to an end, and the same or similar conduct be prevented from occurring, if the directions take account of the changes to Flynn's input price once Pfizer ceases its Infringements. The Directions make it clear which provisions apply to Pfizer and which to Flynn.
- 7.5 The Directions do not specify a specific price that the Parties must each respectively charge as the CMA is not a price regulator and it is for an undertaking to self-assess their own compliance with competition law.<sup>1260</sup>

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<sup>1259</sup> Flynn has submitted that the timeframe by which Flynn must comply with the CMA's directions should be made clearer (see document 02060.1, paragraph 3.4) The CMA has adopted Flynn's proposed drafting in the final version of its Directions.

<sup>1260</sup> The Parties have submitted (see documents 02059.1 paragraph 8.2 and 02060.1, paragraph 3.6) that this approach does not give them sufficient certainty in setting their prices. However, it is for an undertaking to self-assess their own compliance with competition law and this includes cases relating to pricing conduct (see for example the judgement in *Microsoft v Commission* ('*Microsoft*'), Case T-167/08, EU:T:2012:323, paragraphs 84 to 91). In line with that decision, the CMA's decision and directions give the Parties sufficient certainty as to the factors they should take into account when setting their prices.

The Directions do, however, provide that the Parties should, when setting their revised prices, be guided by the CMA's decision.

## **B. Financial penalties**

### **I. *The CMA's power to impose penalties***

7.6 For the reasons given below, the CMA finds that each of the Infringements has been committed intentionally or negligently because each of Pfizer and Flynn must have been aware, or could not have been unaware, or at least ought to have known, that its conduct amounted to an abuse of dominance.

#### **a. *Legal framework***

7.7 Section 36(2) of the Act provides that on making a decision that conduct has infringed the Chapter II prohibition or Article 102 of the TFEU, the CMA may require a party to pay it a penalty in respect of the infringement.

7.8 Any such penalties are calculated in accordance with the steps described in the CMA's published penalties guidance.<sup>1261</sup> No penalty fixed by the CMA may exceed 10 per cent of the worldwide turnover of the undertaking calculated in accordance with the provisions of the Competition Act 1998 (Determination of Turnover for Penalties) Order 2000 (SI 2000/309), as amended by the Competition Act 1998 (Determination of Turnover for Penalties) (Amendment) Order 2004 (SI 2004/1259).<sup>1262</sup>

7.9 The CMA may impose a penalty on an undertaking which has infringed the Chapter II prohibition and/or Article 102 of the TFEU only if the CMA is satisfied that the infringement has been committed intentionally or negligently.<sup>1263</sup> However, the CMA is not obliged to specify whether it considers the infringement to have been committed intentionally or merely negligently.<sup>1264</sup>

7.10 The CAT has defined the terms 'intentionally' and 'negligently' as follows:

*'...an infringement is committed intentionally for the purpose of section 36(3) of the Act if the undertaking must have been aware, or could not have been unaware, that its conduct had the object or would have the*

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<sup>1261</sup> OFT423 OFT's guidance as to the appropriate amount of a penalty (September 2012).

<sup>1262</sup> Section 36(8) of the Act.

<sup>1263</sup> The Act, section 36(3).

<sup>1264</sup> *Napp*, [453] to [457]; see also *Argos Limited and Littlewoods Limited v OFT* [2005] CAT 13, [221].

*effect of restricting competition. An infringement is committed negligently for the purposes of section 36(3) if the undertaking ought to have known that its conduct would result in a restriction or distortion of competition. The OFT is not, however, obliged to decide whether an infringement is committed intentionally or negligently...*<sup>1265</sup>

7.11 This is consistent with the approach taken by the Court of Justice which has confirmed:

*'the question whether the infringements were committed intentionally or negligently... is satisfied where the undertaking concerned cannot be unaware of the anti-competitive nature of its conduct, whether or not it is aware that it is infringing the competition rules of the Treaty.'*<sup>1266</sup>

7.12 The circumstances in which the CMA might find that an infringement has been committed intentionally include the following:

- (a) the conduct has as its object the restriction or distortion of competition;
- (b) the undertaking in question is aware that its actions will be, or are reasonably likely to restrict or distort competition but still wants, or is prepared, to carry them out; or
- (c) the undertaking could not have been unaware that its conduct would have the effect of restricting or distorting competition, even if it did not know that it would infringe Article 102 of the TFEU and/or the Chapter II prohibition.<sup>1267</sup>

7.13 In the context of exploitative abuses, this includes conduct by a dominant undertaking which it could not have been unaware amounted to it imposing unfairly high prices and reaping '*trading benefits which it would not have reaped if there had been normal and sufficiently effective competition.*'<sup>1268</sup>

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<sup>1265</sup> *Argos Limited and Littlewoods Limited v OFT* [2005] CAT 13, [221]. See also *Napp*, [466].

<sup>1266</sup> *Deutsche Telekom*, paragraph 124, referring to judgment in *IAZ v Commission*, 96/82, EU:C:1983:310, paragraph 45, and to judgment in *Nederlandsche Banden-Industrie Michelin v Commission*, 322/81, EU:C:1983:313, paragraph 107. See also the reference to the '*prudent commercial operator*' standard in *Hoffman La-Roche*, [133].

<sup>1267</sup> See *OFT407 Enforcement* (December 2004, adopted by the CMA Board), paragraph 5.9.

<sup>1268</sup> *United Brands*, paragraphs 249 and 250.

- 7.14 The CMA may infer that an infringement has been committed intentionally where consequences giving rise to an infringement are plainly foreseeable from the pursuit of a particular policy by an undertaking.<sup>1269</sup>
- 7.15 Ignorance or a mistake of law is no bar to a finding of intentional infringement, even where such ignorance or mistake is based on independent legal advice.<sup>1270</sup> The CMA is not obliged to show that an undertaking knew that its conduct infringed the Act.<sup>1271</sup>
- 7.16 Section 40 of the Act precludes the imposition of a penalty for an infringement of the Chapter II prohibition if the abuse is '*conduct of minor significance*'. Section 40 applies where an undertaking's relevant turnover is less than £50 million. Section 40 does not preclude the imposition of a penalty for an infringement of Article 102 of the TFEU.

**b. Pfizer acted intentionally or negligently**

- 7.17 Pfizer at least ought to have known<sup>1272</sup> that it was in a dominant position. For example, Pfizer implemented and maintained its conduct in the knowledge that:
- (a) it could profitably raise the prices by the large amount it did;<sup>1273</sup>
  - (b) it had high market shares;<sup>1274</sup>
  - (c) there was insufficient constraint from competitors, particularly as a result of the principle of Continuity of Supply;<sup>1275</sup> and

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<sup>1269</sup> See OFT407 *Enforcement* (December 2004, adopted by the CMA Board), paragraph 5.11. See also *Napp*, [456].

<sup>1270</sup> See the CJ's comments in Judgment in *Bundeswettbewerbsbehörde v Schenker & Co. AG* ('Schenker') C-681/11, EU:C:2013:404, paragraph 38: '*the fact that the undertaking concerned has characterised wrongly in law its conduct upon which the finding of the infringement is based cannot have the effect of exempting it from imposition of a fine in so far as it could not be unaware of the anti-competitive nature of that conduct*' and at [41] '*It follows that legal advice given by a lawyer cannot, in any event, form the basis of a legitimate expectation on the part of an undertaking that its conduct does not infringe Article 101 TFEU or will not give rise to the imposition of a fine.*' See also OFT407 *Enforcement*, paragraph 5.10.

<sup>1271</sup> *Napp*, [456].

<sup>1272</sup> i.e Pfizer 'must have been aware, or could not have been unaware, or at least ought to have known.'

<sup>1273</sup> For example, Pfizer estimated that '[e]ven if 50% of sales of 100mg were lost to PI the upside would still be >£20m'. See for example document 00141.97. See also section 4.C V.a.

<sup>1274</sup> See section 4. C. III. a.

<sup>1275</sup> See section 4.C. V and sections 4.B.IV.b. and 4.B.IV.c. Pfizer submitted (see document 02059.1, paragraph 3.5.3) that the MHRA Guidance was issued in November 2013 so it is wrong to use events which post-date Pfizer's pricing decisions as evidence of Pfizer's intent when it set its prices. However, as Pfizer itself recognises

(d) the end customers lacked buyer power and therefore, despite showing clear dissatisfaction with the higher prices, did not constrain Pfizer's Prices or Flynn's Prices.<sup>1276</sup>

7.18 As a dominant undertaking, Pfizer at least ought to have known that it had (and has) a special responsibility to ensure that it does not exploit its dominant position.<sup>1277</sup>

7.19 Pfizer at least ought to have known that its prices for phenytoin sodium capsules were excessive. Pfizer did not consider its costs when deciding the prices it should set<sup>1278</sup> and ought to have known that the prices it was charging materially exceeded any reasonable measure of its costs (including a reasonable rate of return). Instead, Pfizer imposed price increases of [more than 488%]<sup>1279</sup> for an 80 year old generic drug, which was no longer used as a first-line or even second-line of treatment and the prices of which had been stable at a much lower level for a significant number of years. Pfizer knew that this was in the context of there having been no investment, innovation or any material changes in Pfizer's costs or risk.

7.20 Pfizer at least ought to have known that its prices for phenytoin sodium capsules were unfair. For example, Pfizer was aware of the concerns raised by the DH<sup>1280</sup> and CCGs<sup>1281</sup> in relation to the price increases and the lack of justification for them. In the context of considering [Company A]'s similar

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(see document 01622.2, paragraph 293), the NICE guidelines that were in existence prior to November 2013 already '*...cautioned against the switching of stabilised epilepsy patients onto other treatments*', either between different anti-epileptic drugs or between the same anti-epileptic drugs manufactured by different companies. In any event, Pfizer's pricing decisions are ongoing and, therefore, even if such argument was found to be valid (which the CMA does not accept) this could only have an impact on duration.

<sup>1276</sup> See section 4.C.VI. a-h.. Pfizer submitted (see document 01622.2, Annex IV, paragraph 5) that the DH did not approach Pfizer to ask it to address its supply price to Flynn but it is clear from the evidence that both Pfizer and Flynn were approached by the DH which raised questions about the price increases and the justifications for these (see for example documents 00367.16, 00367.18, 00367.19 and 00367.22). The DH also asked Flynn to discuss a price reduction with Pfizer. Pfizer did not reduce its prices and refused to disclose its costs and prices to the DH. See section 3.E.XI.

<sup>1277</sup> Judgment in *Michelin v Commission* C-322/81, EU:C:1983:313, paragraph 57. See also *TeliaSonera* C-52/09, EU:C:2011:83, paragraph 24.

<sup>1278</sup> See document 01757.1, pages 48 to 50.

<sup>1279</sup> Pfizer Prices for each of Pfizer's Products were [over 488%] higher (25mg), [over 1,054%] higher (50mg), [over 1,303%] higher (100mg) and [over 1,309%] higher (300mg) than Pfizer's prices for the products immediately prior to September 2012.

<sup>1280</sup> See for example section 3.E.X.

<sup>1281</sup> See section 3.E.XI.

proposal that Pfizer debrand and raise the price of its phenytoin sodium capsules, an internal Pfizer email stated:

*'We need to work out how we can position this as "no change" with patients & physicians; and at the same time "change" with DH and payers without being accused of hypocrisy by pursuing a trust agenda, yet taking the opportunity to fleece the NHS in [a] time of funding crisis.'*<sup>1282</sup>

7.21 The fact that Pfizer was seriously concerned with the reputational and pharmacopolitical impact of the price increases,<sup>1283</sup> coupled with, among other things, the DH's PPRS Pricing Committee's rejection of Flynn's proposal to increase the prices to these levels within the PPRS<sup>1284</sup> demonstrates that Pfizer was ought to have known that Pfizer's Prices were unfair and represented a significant cost to the NHS and the taxpayer with no corresponding additional benefit to either the NHS or patients.<sup>1285</sup>

7.22 Pfizer has submitted that the CMA cannot conclude that Pfizer's Infringements have been committed either intentionally or negligently. Pfizer submitted that, in particular:

- Pfizer believed that it would be constrained by NRIM's entry.<sup>1286</sup> In other words, Pfizer submits that it did not know that it was dominant.
- Pfizer '*clearly intended, and took action*'<sup>1287</sup> to avoid discontinuation of *Epanutin* which would have resulted in higher prices for the NHS;
- when setting its prices Pfizer relied on the Drug Tariff price for Tablets, which Pfizer believes was an appropriate and reasonable

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<sup>1282</sup> See document 00141.57.

<sup>1283</sup> See sections 5.D.III.b.iii and 5.D.III.b.iv.

<sup>1284</sup> See section 3.E.VIII.b. and document 00145.339.

<sup>1285</sup> Pfizer has submitted that it did not impose a direct cost on the NHS and that it should not be liable for the prices that Flynn chose to set (see document 02059.1, paragraph 3.2). However, Pfizer's conduct set a price floor below which the prices that Flynn charges to wholesalers and pharmacies could not realistically fall and that would, therefore, result in the NHS, as the end customer, paying significantly more for phenytoin sodium capsules. As Pfizer should have known the ultimate purpose of Article 102 and the Chapter II prohibition is to protect the end customer.

<sup>1286</sup> See document 02059.1, paragraph 3.5.1.

<sup>1287</sup> See document 02059.1, paragraph 3.6

comparator reflecting the fair economic value of phenytoin sodium capsules;<sup>1288</sup> and

- the CMA's case is '*wholly novel*' and therefore Pfizer could not have reasonably predicted that its conduct would be an infringement of competition law.<sup>1289</sup>

7.23 The CMA rejects these submissions for the reasons set out below.

7.24 Pfizer did not believe that it would be sufficiently constrained by NRIM's entry – or at least it ought to have known that NRIM did not impose a sufficiently strong competitive constraint on Flynn, and indirectly, on Pfizer – to undermine Pfizer's dominance. In any case Pfizer ought to have known it was dominant. First, Pfizer believed generic entry was unlikely and would take at least two years to occur.<sup>1290</sup> Indeed, evidence on the CMA's file demonstrates that Pfizer only discovered that NRIM had been granted an MA for 100mg phenytoin sodium capsules after Pfizer had concluded its commercial negotiations with Flynn.<sup>1291</sup> Second, Pfizer did not reduce its prices after it learned of NRIM's potential entry. This is consistent with other evidence which shows that Pfizer (rightly) expected that its and Flynn's large price rises would remain profitable notwithstanding NRIM's entry.<sup>1292</sup> Third, the CMA has found that NRIM has not been (either directly or indirectly) an effective constraint on Pfizer's pricing decisions.<sup>1293</sup>

7.25 With regard to the risk of discontinuation of *Epanutin*, the CMA has already found this was not an option that Pfizer was realistically considering.<sup>1294</sup> As the CMA has already set out, Pfizer's submission depends on the assumption that the only options available to Pfizer were to impose excessive prices or discontinue the product. This is incorrect because an obvious commercial option was to restore the viability of phenytoin sodium capsules by increasing the price to a non-excessive level. It is negligent for Pfizer to have failed to consider whether it could charge higher but non-excessive prices. Pfizer is aware that Pfizer's Prices are well above what

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<sup>1288</sup> See document 02059.1, paragraphs 1.10.2, 3.4 and 3.5.2

<sup>1289</sup> See document 02059.1, paragraphs 3.7 to 3.11.

<sup>1290</sup> See for example document 00141.154 and section 3.E.V.and 4.C.V.b.

<sup>1291</sup> See document 00141.191.

<sup>1292</sup> See document 00141.191.

<sup>1293</sup> See section 4.C.V.a.ii.

<sup>1294</sup> See section 3.E.I.b.

would be necessary to ensure the viability of the product,<sup>1295</sup> even including the recoupment of any alleged losses.<sup>1296</sup>

- 7.26 In relation to Tablets, Pfizer at least ought to have known that the Drug Tariff price for Tablets was not an appropriate benchmark reflecting the economic value of phenytoin sodium capsules.<sup>1297</sup> In particular:
- (a) Given the special responsibility that arises from its dominant position, Pfizer at least ought to have known that it could not rely on such a benchmark to justify its excessive prices without considering whether a similar price level for its own product was reasonable. Indeed, irrespective of the price of Tablets, and what the DH may or may not have done in that market, the DH made clear to Pfizer that it had concerns about its prices and asked it to consider reducing them.<sup>1298</sup>
  - (b) It is established case law that the fact that other companies providing the same, or a similar, product engage in similar pricing practices does not, in itself, show that the price in question is not unfair.<sup>1299</sup> Similarly, Pfizer at least ought to have known that, even if the DH had facilitated or even approved the high pricing of Tablets, DH's actions (or absence of action) in that separate market could not absolve Pfizer from its special responsibility as dominant undertaking and should not interfere with the objective assessment of whether the price was fair for the purposes of Article 102 of the TFEU and the Chapter II prohibition even for Tablets, let alone phenytoin sodium capsules.<sup>1300</sup> To disregard these legal precedents is at least negligent.
  - (c) Pfizer at least ought to have known that the market dynamics for Tablets were unlikely to result in a competitive price. Like phenytoin sodium capsules, Tablets have an NTI and are subject to the same clinical guidance and pharmacy dispensing practises that result in the principle of Continuity of Supply. Indeed, Pfizer has submitted that it believed that the costs of manufacturing tablets were similar to capsules and, therefore, by implication believed the suppliers of Tablets

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<sup>1295</sup> See for example section 5.C.IV.b.ii.

<sup>1296</sup> See section 5.D.II.b.ii. Even using Pfizer's own cost calculations Pfizer would have recovered all the losses it had previously made on sales of phenytoin sodium capsules within two months of the Infringements.

<sup>1297</sup> See section 5.D.II.b.ii.

<sup>1298</sup> See section 3.E.X.

<sup>1299</sup> *Albion Water II*, [257].

<sup>1300</sup> See *Albion Water II*, [242]. See also *Deutsche Telekom*, paragraphs 81 to 88. See further section 5.D.II.b.ii. above.



were likely to be earning significant margins.<sup>1301</sup> This is consistent with contemporaneous documentary evidence which demonstrates that Pfizer did believe that Teva was making '*supernormal profits*' on its sales of Tablets.<sup>1302</sup> Pfizer was also aware that prior to the reduction in the Drug Tariff price for Tablets that occurred in 2008, the price of Tablets had been subject to a significant price increase of over 6,500% and that even after the reduction the price was still around 17 times the previous price levels.

- (d) Pfizer at least out to have known that Tablets had (and have) much lower sales volumes than phenytoin sodium capsules and therefore Pfizer should also have known that Tablets have a much smaller impact on CCGs' budgets than phenytoin sodium capsules. Pfizer also knew that Tablets are priced under a different regulatory framework to phenytoin sodium capsules.<sup>1303</sup> The Drug Tariff price for Tablets is the price paid by the NHS to pharmacies for the products they dispense while Pfizer's Prices are what it charges to Flynn at a different level of the supply chain. Pfizer did not know what prices were actually paid by pharmacies to manufacturers or suppliers of Tablets when setting its own prices. Failure to take account of this is negligent given that the Drug Tariff price for Tablets is a Category M price and such prices are often set at a higher level than normal in order to meet the DH's funding targets for pharmacies.<sup>1304</sup>

7.27 Pfizer's submission that the CMA's case is novel and that Pfizer could not therefore have reasonably predicted that its conduct would be an infringement of competition law is incorrect.<sup>1305</sup>

7.28 Pfizer is a well-resourced company with experienced external and internal legal and economic advisers. Unfairly high pricing is a well-established and well known competition law abuse. Unfair pricing is explicitly listed as an abuse in both the Chapter II prohibition and Article 102 of the TFEU. It has also been the subject of several high profile UK and EU cases and decisions

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<sup>1301</sup> See document 01622.2, paragraph 132. In the event that Pfizer was mistaken, and the cost and prices of Tablets were aligned, this, in itself, would have provided an obvious and objective reason why the prices of Tablets could not provide a reliable indicator as to the fair price for Pfizer's Products. Therefore on any view Pfizer should have known that it was exploiting its dominant position by benchmarking its prices against the drug Tariff price for Tablets.

<sup>1302</sup> See section 3.E.III.b.i. and document 00141.57

<sup>1303</sup> See for example document 00141.31.

<sup>1304</sup> See section 3.B.III.c.ii.

<sup>1305</sup> See *Napp*, [470].

which set out the legal test for assessing the abuse of unfairly high pricing.<sup>1306</sup> Indeed, protecting customers against exploitation is one of the underlying purposes of competition law and unfair pricing is an obvious example of such exploitation.<sup>1307</sup>

- 7.29 The implementation of the Infringements was preceded by over two years of negotiations and planning. During this period, and given the level and nature of the price increases, Pfizer had ample time to consider the legal implications of the prices it ultimately set. Further, the prospect that the price increases constituted an abuse of a dominant position was raised in a letter from a CCG to the Secretary of State, and which was copied to Pfizer, very shortly after the beginning of the Infringements.<sup>1308</sup> However, Pfizer still failed to amend its conduct.
- 7.30 Further, Pfizer knew that Pfizer's Prices amounted to several multiples of the prices it charged in other EU Member States for exactly the same product. This, in itself, should have alerted Pfizer to at least consider whether its prices were potentially abusive.<sup>1309</sup>
- 7.31 Pfizer has submitted that the CMA's adoption of a 6% rate of return in its Cost Plus calculation was unpredictable.<sup>1310</sup> This is misconceived. It is sufficient that Pfizer at least ought to have known that Pfizer's Prices materially exceeded its costs plus a reasonable rate of return. For the reasons given in section 5.C.IV.b.ii., a 6% rate of return is a reasonable rate of return for Pfizer's Products and, therefore, not unpredictable. Competition law, and in particular abusive pricing conduct, involves a degree of discretion as to how the law is applied to the specific circumstances of the case in question. This does not prevent the imposition of a sanction when an infringement has been found.<sup>1311</sup>
- 7.32 Nor is the CMA's conclusion that there are no additional non-cost related factors relevant to the economic value of Pfizer's Products novel or unpredictable. It is clear from the case law that, as a matter of principle, such factors may increase the economic value of a product beyond its costs of

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<sup>1306</sup> See in particular: *United Brands, Napp, Albion Water II, Attheraces*.

<sup>1307</sup> See for example, *Attheraces*, [215].

<sup>1308</sup> See document 00145.527.

<sup>1309</sup> See judgment in *OSA v Léčebné lázně Mariánské Lázně a.s.* C-351/12, EU:C:2014:110, paragraph 87, citing *Ministère Public v Jean-Louis Tournier* C-395/87, EU:C:1989:319, paragraph 38 and *Lucazeau and Others v SACEM* C-110/88, EU:C:1989:326, paragraph 25.

<sup>1310</sup> See document 02059.1, paragraph 3.9.

<sup>1311</sup> See for example the judgement in *Microsoft*, paragraph 91. See also *Schenker*, paragraph 38.

production plus a reasonable rate of return.<sup>1312</sup> As the CMA found in section 5.D.II.b., no such factors are present in this case, and given the nature of phenytoin sodium capsules Pfizer at least ought to have known that this would be the case.

**c. Flynn acted intentionally or negligently**

7.33 Flynn at least ought to have known<sup>1313</sup> that it was in a dominant position. For example, Flynn implemented and maintained its conduct in the knowledge that:

- (a) it could profitably charge prices which were several multiples of the pre-September 2012 prices;<sup>1314</sup>
- (b) it had high market shares;<sup>1315</sup>
- (c) there was insufficient constraint from competitors, particularly as a result of the principle of Continuity of Supply;<sup>1316</sup> and
- (d) the end customers lacked buyer power and therefore, despite showing clear dissatisfaction with the higher prices, did not constrain Flynn's Prices.<sup>1317</sup>

7.34 As a dominant undertaking, Flynn at least ought to have known that it had (and has) a special responsibility to ensure that it does not exploit its dominant position.<sup>1318</sup>

7.35 Flynn at least ought to have known that its prices for phenytoin sodium capsules were excessive. Flynn knew its own cost base and thus that its

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<sup>1312</sup> For example, an equivalent finding in relation to the common carriage of water was adopted by the CAT in *Albion Water II*.

<sup>1313</sup> i.e. Flynn *'must have been aware, or could not have been unaware, or at least ought to have known'*.

<sup>1314</sup> For example, the Flynn estimated that '[e]ven if 50% of sales of 100mg were lost to PI the upside would still be >£20m'. See for example documents 00145.27. Indeed Flynn's internal view appears to have been that '[e]ven if they [Pfizer] lost 75% to PIs they would still be considerably better off'. See document 00145.79. See also section 4.C.V.a.

<sup>1315</sup> See section 4.C.III.b.

<sup>1316</sup> See section 4.C.V. and sections 4.B.IV.b. and 4.B.IV.c.

<sup>1317</sup> See section 4.C.II.a-h. Flynn submitted that the DH did not seek to negotiate with it (see for example 02060.1, paragraph 2.4) but it is clear from the evidence that both Pfizer and Flynn were asked by the DH about the price increases and the justifications for these and requested that they reconsider their pricing (see for example documents 00367.16, 00367.18, 00367.19 and 00367.22). Flynn did not reduce its prices and refused to disclose its costs to the DH. See also section 3.E.XI.

<sup>1318</sup> Judgment in *Michelin v Commission* C-322/81, EU:C:1983:313, paragraph 57. See also *TeliaSonera* C-52/09, EU:C:2011:83, paragraph 24.

prices materially exceeded any reasonable measure of costs plus a reasonable rate of return. Among other things, Flynn imposed prices that were [for all strengths more than 24%]<sup>1319</sup> higher than the supply prices that it paid to Pfizer, which were themselves [for all strengths more than 488%] higher than Pfizer's pre-September 2012 prices. This was for an 80 year old generic drug, which was no longer a first or even second-line of treatment and the prices of which had been stable at a much lower level for a significant number of years. Flynn knew that there had been no new investment, risk or innovation in relation to phenytoin sodium capsules.

7.36 Flynn at least ought to have known that its prices for phenytoin sodium were unfair. For example, Flynn was aware of the concerns raised by the DH<sup>1320</sup> and CCGs<sup>1321</sup> in relation to the price increases and the lack of justification for these. The DH's PPRS Pricing Committee rejected Flynn's proposal to increase the prices to these levels<sup>1322</sup> and the fact that Flynn told Pfizer that its key role was to protect Pfizer's reputation<sup>1323</sup> demonstrates that Flynn ought to have known that Flynn's Prices were well above a competitive level, representing a significant cost to the NHS and the taxpayer with no corresponding additional benefit to either the NHS or patients. As set out in sections 5.C.V.b.ii and 5.D.III.b.v., Flynn performs very limited activities, incurs limited risk, and adds little value in relation to the supply of phenytoin sodium capsules.

7.37 Flynn has submitted that the CMA could not conclude that Flynn's Infringements had been committed either intentionally or negligently. Flynn submitted that, in particular:

- Flynn had recognised the possibility of generic entry as a potential competitive constraint.<sup>1324</sup> In other words, Flynn submits that it did not know it was dominant.
- Flynn believed that Pfizer would have considered discontinuing *Epanutin* if Flynn had not agreed to take over the product and was

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<sup>1319</sup> The % increases above Pfizer's Prices were [91% - 250%] (25mg), [24% - 150%] (50mg), [25% - 98%] (100mg) and [25% - 98%] (300mg).

<sup>1320</sup> See for example section 3.E.X.

<sup>1321</sup> See section 3.E.XI.

<sup>1322</sup> See section 3.E.VIII.b. and, in particular, document 00145.339.

<sup>1323</sup> See for example section 5.D.III.b.iii and 5.D.III.b.iv.

<sup>1324</sup> See document 02060.1, paragraph 2.5.

therefore '*playing an important role in rescuing an end-of-life product*';<sup>1325</sup>

- when setting its prices, Flynn relied on the Drug Tariff price for Tablets, which Flynn believes is an appropriate and reasonable comparator reflecting the fair economic value of the phenytoin sodium capsules;<sup>1326</sup> and
- the CMA's case is '*entirely novel*' and therefore Flynn could not have reasonably predicted that its conduct would be an infringement of competition law.<sup>1327</sup>

7.38 The CMA rejects these submissions for the reasons set out below.

7.39 Flynn knew, or ought to have known, that it was dominant. Flynn did not believe that its prices would be likely to be materially constrained by competition when it was negotiating with Pfizer.<sup>1328</sup> Flynn only discovered that NRIM had been granted an MA for 100mg phenytoin sodium capsules in late 2011.<sup>1329</sup> As set out above, Flynn (rightly) expected that it would be able to maintain its prices and Flynn did not reduce its prices after it learned of NRIM's potential entry.

7.40 As stated above, with regard to the risk of discontinuation of *Epanutin* the CMA has already found this was not an option Pfizer was realistically considering and Flynn was aware of this. Its own internal document states that while Flynn believed that Pfizer senior management were under pressure to improve the profitability of *Epanutin* Flynn also understood that Pfizer saw discontinuation as '*ethically and morally unjustifiable*'.<sup>1330</sup> In any event, even if the CMA were to accept that Pfizer might have discontinued *Epanutin* (which the CMA does not), and Flynn genuinely believed Pfizer's Prices were necessary to prevent this, this would still not justify Flynn itself imposing its own unfair prices.

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<sup>1325</sup> See document 02060.1, paragraphs 2.9

<sup>1326</sup> See document 02060.1, paragraphs 2.3 and 2.6 to 2.8.

<sup>1327</sup> See document 02060.1, paragraphs 2.13 to 2.20.

<sup>1328</sup> See for example section 3.E.IV.c.

<sup>1329</sup> See document 02060.1, paragraph 2.5.

<sup>1330</sup> See document 00145.306.

7.41 In relation to Tablets, as stated above for Pfizer, Flynn also at least ought to have known that the Drug Tariff price for Tablets was not an appropriate benchmark reflecting the economic value of phenytoin sodium capsules.<sup>1331</sup>

7.42 In particular:

- (a) Given the special responsibility that arises from its dominant position Flynn at least ought to have known, that it could not rely on such a benchmark to justify its excessive prices without considering whether a similar price level for its own product was reasonable. Indeed, as already noted, Flynn was aware from its dealings with the DH that it should not have relied on the price of Tablets to justify its own prices. When Flynn sought a price increase under the PPRS this was rejected by the DH indicating that the DH was not readily willing to pay Flynn's Prices. Further, Flynn's own note of its meeting with the DH in October 2012 recorded:

*'We [Flynn] felt that the discussion with DH PPRS on price at launch was sanctioned by default as it went unchallenged. [DH Official 7] stated that this could not be the case as PPRS had no remit on pricing of generic products and that Scheme M was not a pricing approval. We should not ([DH Official 7]) view; [sic] assume that the DH and NHS are happy with the price of the tablets...*

[...]

*[DH Official 7] asked us to approach Pfizer for discussion on supply pricing and release of the supply prices to us – we agreed to ask them [Pfizer].<sup>1332</sup>*

- (b) It is established case law that just because other companies providing the same product/service engage in similar pricing practices does not, in itself, show that the price in question is not unfair.<sup>1333</sup> Similarly, Flynn at least ought to have known that, even if the DH had facilitated or even approved the high pricing of Tablets, DH's actions (or absence of action) in that separate market could not absolve Flynn from its special responsibility as dominant undertaking and should not interfere with the objective assessment of whether the price was fair for the purposes of

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<sup>1331</sup> See section 5.B.II.b.ii.

<sup>1332</sup> See document 00145.585.

<sup>1333</sup> *Albion Water II*, [257].

Article 102 of the TFEU and the Chapter II prohibition even for Tablets, let alone phenytoin sodium capsules.<sup>1334</sup> To disregard these legal precedents is at least negligent.

- (c) Flynn at least ought to have known that the market dynamics for Tablets were unlikely to result in a competitive price. Like phenytoin sodium capsules, Tablets have a NTI and are subject to the same clinical guidance that results in the principle of Continuity of Supply. Indeed, Flynn has submitted that [§].<sup>1335</sup> Flynn was also aware that prior to the reduction in the Drug Tariff price for Tablets that occurred in 2008, the price of Tablets had been subject to a significant price increase of over 6,500% and that even after the reduction the price was still around 17 times the previous price levels.
- (d) Flynn ought to have known that Tablets had (and have) much lower sales volumes and therefore Flynn should also have known that Tablets have a much smaller impact on CCGs' budgets than phenytoin sodium capsules. As already set out, Flynn knew that Tablets are priced under a different regulatory framework to phenytoin sodium capsules.<sup>1336</sup> The Drug Tariff price for Tablets is the price paid by the NHS to pharmacies for the products they dispense while Flynn's Prices are what it charges to wholesalers. Flynn did not know what the actual costs paid to suppliers of Tablets were when it set its own prices. Failure to take account of this is negligent given that the Drug Tariff price for Tablets is a Category M price and such prices are often set at a higher level than normal in order to meet the DH's funding targets for pharmacies.<sup>1337</sup>

7.43 Flynn's submission that the CMA's case is novel and that Flynn could not therefore have reasonably predicted that its conduct would be an infringement of competition law is incorrect.<sup>1338</sup>

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<sup>1334</sup> See *Albion Water II*, [242]. See also *Deutsche Telekom*, paragraphs 81 to 88. See further section 5.D.II.b.ii. above.

<sup>1335</sup> See document 02077.1, paragraph 9.4(a). In the event that Flynn was mistaken and the costs and prices of Tablets were aligned, this, in itself, would have provided an obvious and objective reason why the prices of Tablets could not provide a reliable indicator as to the fair price for Flynn's Products. Therefore on any view Flynn should have known that it was exploiting its dominant position by benchmarking against the drug Tariff price for Tablets.

<sup>1336</sup> See for example document 00145.585.

<sup>1337</sup> See section 3.B.III.c.ii.

<sup>1338</sup> See *Napp*, [470].

- 7.44 Flynn has (and had) experienced external legal advisers. As already noted above, unfairly high pricing is a well-established and well known competition law abuse. Unfair pricing is explicitly listed as an abuse in both the Chapter II prohibition and Article 102 of the TFEU. It has also been the subject of several high profile UK and EU cases and decisions which set out the legal test for assessing the abuse of unfairly high pricing.<sup>1339</sup> Indeed, protecting customers against exploitation is one of the underlying purposes of competition law and unfair pricing is an obvious example of such exploitation.<sup>1340</sup>
- 7.45 The implementation of the Infringements was preceded by over two years of negotiations and planning. During this period, Flynn had ample time to consider the legal implications of the prices it was proposing to set. Flynn knew that its profits alone were significantly higher than the prices charged by Pfizer in other EU Member States for exactly the same product, which is also manufactured by Pfizer.<sup>1341</sup> This, in itself, should have alerted Flynn to at least consider whether its prices were potentially abusive.<sup>1342</sup>
- 7.46 Further, the prospect that the price increases constituted an abuse of a dominant position was raised by a CCG in a letter to the Secretary of State, and which was copied to Flynn, very shortly after the beginning of the Infringements.<sup>1343</sup> However Flynn still failed to amend its conduct even though it was advised by one of its consultants to seek legal advice specifically on the issue of whether or not it had committed an abuse of a dominant position.<sup>1344</sup>
- 7.47 Flynn has submitted that the CMA's adoption of a 6% rate of return in its cost plus calculation was unpredictable.<sup>1345</sup> This is misconceived. It is sufficient that Flynn at least ought to have known that its Prices materially exceed its costs plus a reasonable rate of return. For the reasons given in section

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<sup>1339</sup> See in particular: *United Brands, Napp, Albion Water II, Attheraces*.

<sup>1340</sup> See for example, *Attheraces*, [215].

<sup>1341</sup> See for example section 3.E.IV.b.

<sup>1342</sup> See judgment in *OSA v Léčebné lázně Mariánské Lázně a.s.* C-351/12, EU:C:2014:110, paragraph 87, citing *Ministère Public v Jean-Louis Tournier* C-395/87, EU:C:1989:319, paragraph 38 and *Lucazeau and Others v SACEM* C-110/88, EU:C:1989:326, paragraph 25.

<sup>1343</sup> See document 00145.527.

<sup>1344</sup> See document 00145.535.

<sup>1345</sup> See document 02060.1, paragraphs 2.13 to 2.20. Flynn's additional submissions that it could not have expected (i) a relevant market to be found on the basis of a single molecule and (ii) standalone excessive pricing to be a potential infringement (see document 02060.1, paragraph 2.19(b)) are errors of law and have no exculpatory value. In respect of the latter, for example, this was explicitly rejected by the CAT in *Napp*, [434].



5.C.V.b.ii, a 6% rate of return is a generous rate of return for Flynn's Products and therefore not unpredictable. Competition law, and in particular abusive pricing conduct, always involves a degree of discretion as to how the law is applied to the specific circumstances of the case in question. This does not prevent the imposition of a sanction when an infringement has been found.<sup>1346</sup>

**d. Conduct of minor significance**

7.48 Flynn has submitted that it should benefit from the immunity from penalties conferred by section 40 of the Act even though Flynn has infringed Article 102.<sup>1347</sup> The CMA rejects this submission.

7.49 The statutory wording of the Act is explicit: immunity from penalties due to 'conduct of minor significance' under section 40 of the Act applies exclusively to infringements of the Chapter II prohibition, and not to infringements of Article 102 of the TFEU. This is also confirmed in the CMA's own Penalty Guidance.<sup>1348</sup>

7.50 Further, the power of the CMA to impose penalties for infringements of Article 102 of the TFEU is set out specifically in Regulation 1/2003 and the effective application of Regulation 1/2003 cannot be precluded by UK law. The CMA also rejects Flynn's submission that paragraph 1.18 of the Penalty Guidance precludes the CMA imposing a penalty under Article 102 of the TFEU when section 40 of the Act applies to the Chapter II prohibition. That paragraph exclusively addresses cases where a penalty is applied under both provisions and must be read in the context of the preceding paragraph which states that undertakings will not be penalised twice for the same infringements.

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<sup>1346</sup> See for example the judgement in *Microsoft*, paragraph 91 and *Schenker*, paragraph 38. Flynn has also submitted that it should not be found to be negligent because the CMA has not stated what a fair price is (and therefore Flynn has not known how it should amend its conduct). See for example document 02060.1, paragraph 2.17. The fact that the CMA has not set a specific lawful price for the Parties to adopt does not prevent the imposition of a penalty. It is always for an undertaking to self-assess its conduct. Taking Flynn's submission to its logical conclusion would mean that no pricing conduct could be an intentional or negligent infringement until an authority had taken a decision to that effect. This is wrong in law. For example, see again *Microsoft*, paragraph 91.

<sup>1347</sup> See document 01639.3, paragraph 7.2 to 7.8.

<sup>1348</sup> OFT's Guidance as to the appropriate amount of a penalty (OFT423, September 2012) (*'Penalty Guidance'*), paragraph 1.14. Indeed, Flynn has acknowledged that section 40 only applies to the Chapter II prohibition. See document 01639.3, paragraph 7.6.

## II. *The CMA's decision to impose penalties*

- 7.51 For the reasons set out below, the CMA considers that it is appropriate in the circumstances of this case to exercise its discretion under section 36(2) of the Act to impose financial penalties in respect of the Infringements on both Pfizer and Flynn, the addressees of this Decision (as set out in section 1.A.).
- 7.52 On making a decision that certain conduct has intentionally or negligently infringed the Chapter II prohibition, the CMA may require the undertaking(s) concerned to pay a penalty in respect of the relevant infringement(s).<sup>1349</sup> The CMA has discretion whether to impose, and if so the appropriate amount of, a penalty under the Act.<sup>1350</sup> In exercising its discretion, the CMA must have regard to the guidance on penalties being in force at the time, currently the *Penalty Guidance*.<sup>1351</sup>
- 7.53 The CMA is not bound by its decisions in relation to the calculation of financial penalties in previous cases under the Act.<sup>1352</sup> Rather, the CMA makes its assessment on a case-by-case basis,<sup>1353</sup> having regard to all relevant circumstances and the objectives of its policy on financial penalties. In line with statutory requirements, and the twin objectives of the CMA's policy on financial penalties as reflected in the guidance on penalties in force at this time (currently, the *Penalty Guidance*), the CMA will also have regard to the seriousness of the infringement and the desirability of deterring the undertaking on which the penalty is imposed and others from engaging in

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<sup>1349</sup> The Act, section 36(2).

<sup>1350</sup> Provided that any penalty that the CMA imposes under the Act is within the range of penalties permitted by section 36(8) of the Act, calculated in accordance with The Competition Act 1998 (Determination of Turnover for Penalties) Order 2000, SI 2000/309 as amended by The Competition Act 1998 (Determination of Turnover for Penalties) (Amendment) Order 2004, SI 2004/1259 (the 'Turnover Order'), and calculated having regard to the *Penalty Guidance* in accordance with section 38(8) of the Act. *Argos Limited and Littlewoods Limited v OFT* [2005] CAT 13, [168] and *Umbro Holdings Limited and others v OFT* [2005] CAT 22, [102].

<sup>1351</sup> The Act, section 38(8). The guidance currently in force is the *Penalty Guidance*, adopted by the CMA Board, available at [www.gov.uk/government/publications/appropriate-ca98-penalty-calculation](http://www.gov.uk/government/publications/appropriate-ca98-penalty-calculation). In accordance with paragraph 1.11 of the *Penalty Guidance*, the CMA has had regard to the calculation mechanism contained in this version of the penalty guidance as it was in force at the time the SO in the Investigation was issued on 19 April 2013.

<sup>1352</sup> See, for example, *Eden Brown and Others v OFT* [2011] CAT 8, [78].

<sup>1353</sup> See, for example, *Kier Group and Others v OFT* [2011] CAT 3, [116] where the CAT noted that '*other than in matters of legal principle there is limited precedent value in other decisions relating to penalties, where the maxim that each case stands on its own facts is particularly pertinent*'. See also *Eden Brown and Others v OFT* [2011] CAT 8, [97], where the CAT observed that '*[d]ecisions by this Tribunal on penalty appeals are very closely related to the particular facts of the case*'.

behaviour that breaches any prohibition under the Act or the TFEU, as the case may be.<sup>1354</sup>

- 7.54 The CMA's penalty must be proportionate and reflect the importance of treating undertakings equally. The CMA is not, however, required to ensure, that where penalties are imposed on a number of undertakings involved in the same or similar infringements, that the final amounts of the penalties (or the proportions of the undertakings' total turnover that these penalties represent) are the same.<sup>1355</sup> To do so '*would be tantamount to conferring an advantage on the least diversified undertakings on the basis of criteria that are irrelevant in the light of the gravity and the duration of the infringement.*'<sup>1356</sup>
- 7.55 Pfizer has submitted that because the CMA's case is (in Pfizer's view) '*novel*' only a nominal penalty should be imposed.<sup>1357</sup> Pfizer submits that this is consistent with the European Commission's past decisional practice.
- 7.56 The CMA rejects this submission.
- 7.57 The appropriate penalty for each case is to be judged on its own facts. As set out above, the CMA's findings are not '*novel*'. In this case, there is already precedent addressing unfair pricing in the UK pharmaceutical industry.<sup>1358</sup>
- 7.58 In any event, it is well established law that the '*novelty*' of an infringement alone is not sufficient to justify the imposition of a nominal penalty. The fact that conduct with the same features has not been examined in past decisions does not exonerate an undertaking where its conduct is manifestly contrary to competition on the merits.<sup>1359</sup> The same must also apply to manifestly exploitative abuses where '*a diligent undertaking in the applicant's position could not at any time have been unaware of the consequences of its conduct.*'<sup>1360</sup> The CMA has already found that the Parties were aware, or should have been aware, that they were imposing unfair prices and making use of the opportunities arising out of their dominant position to '*reap trading*

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<sup>1354</sup> The Act, section 36(7A); *Penalty Guidance*, paragraph 1.4.

<sup>1355</sup> See judgement in *Pilkington v Commission* ('*Pilkington*'), C-101/15, EU:C:2016:631, paragraphs 64 and 65.

<sup>1356</sup> *Pilkington*, paragraph 66.

<sup>1357</sup> See document 02059.1, paragraph 4.5.

<sup>1358</sup> See *Napp*.

<sup>1359</sup> See the judgments in *Michelin v Commission* C-322/81 EU:C:1983:313, paragraph 107 and *AstraZeneca*, paragraph 901/

<sup>1360</sup> See judgment in *Lucchini SpA v Commission* Case T-91/10 EU:T:2014:1033

*benefits which it would not have reaped if there had been normal and sufficiently effective competition.*<sup>1361</sup>

7.59 In contrast, in cases where the Commission has chosen to impose nominal fines there had been genuine uncertainty as to whether the conduct would result in anticompetitive or abusive effects.<sup>1362</sup>

### III. ***The CMA's penalty calculation***

7.60 To address the fact that all four of Pfizer's Infringements have taken place in the same relevant product and geographic market, the CMA has chosen to issue one single fine in relation to all four of Pfizer's Infringements and has used Pfizer's relevant turnover for all of its UK sales of phenytoin sodium capsules when calculating the penalty.

7.61 Similarly, to address the fact that all four of Flynn's Infringements have taken place in the same relevant product and geographic market, the CMA has chosen to issue one single fine in relation to all four of Flynn's Infringements and has used Flynn's relevant turnover for all of its UK sales of phenytoin sodium capsules when calculating the penalty.

7.62 The following tables set out a summary of the CMA's penalty calculations for Pfizer and Flynn. The remainder of this section then explains the reasoning underpinning the penalty calculations. The CMA's calculations follow the six 'step' process outlined in the CMA's Penalty Guidance.

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<sup>1361</sup> *United Brands*, paragraph 249.

<sup>1362</sup> In particular; (i) the conduct was objectively complex with the result that it was not obviously anti-competitive or abusive, (ii) there had been no previous infringement decisions dealing with that sector, (iii) conclusions could not be easily drawn from previous Commission decisions or case-law, or (iv) that national courts had previously held the conduct to be lawful. None of these factors apply in this case.

**Table 7.1: Summary of the CMA’s penalty calculation in respect of Pfizer**

	<b>Adjustment</b>	<b>Penalty at end of step</b>
Relevant turnover		[X]
Step 1 – starting point	30%	[X]
Step 2 – adjustment for duration	x4.25	[X]
Step 3 – adjustment for aggravating and mitigating factors	[X]	£16,839,400
Step 4 – adjustment for specific deterrence and proportionality	400% uplift for specific deterrence	£84,196,998
Step 5 – adjustment to ensure statutory cap is not exceeded and to avoid double jeopardy	No adjustment required	£84,196,998
Step 6 – adjustment for leniency and/or settlement	No adjustment required	£84,196,998
<b>Final penalty</b>	<b>£84,196,998</b>	

**Table 7.2: Summary of the CMA’s penalty calculation in respect of Flynn**

	<b>Adjustment</b>	<b>Penalty at end of step</b>
Relevant turnover	-	[X]
Step 1 – starting point	30%	[X]
Step 2 – adjustment for duration	x4.25	[X]
Step 3 – adjustment for aggravating and mitigating factors	[X]	[£25m - £29.9m]
Step 4 – adjustment for specific deterrence and proportionality	No adjustment required - see step 4 below for further detail	Not applicable due to the application of the statutory maximum at step 5.
Step 5 – adjustment to ensure statutory cap is not exceeded and to avoid double jeopardy	Adjustment required	£5,164,425
Step 6 – adjustment for leniency and/or settlement	No adjustment required	£5,164,425
Final penalty	<b>£5,164,425</b>	

#### IV. **Penalty Calculation Step 1 – Starting point**

7.63 For the reasons set out below, the CMA considers that the Infringements are among the most serious infringements of competition law and that a starting point of 30% is appropriate for each of Pfizer and Flynn.

a. **Assessment of seriousness – the application of percentage rate to relevant turnover**

7.64 The starting point for determining a penalty is calculated having regard to the seriousness of the infringement and is applied to the undertaking's relevant turnover.<sup>1363</sup> The starting point (expressed as a percentage rate applied to the relevant turnover) depends in particular upon the nature of the infringement: the more serious and widespread the infringement, the higher the starting point is likely to be.<sup>1364</sup>

7.65 As set out in the following section, the Infringements are ongoing at the date of this Decision. Accordingly, when calculating Pfizer's and Flynn's respective penalties the CMA will use the relevant turnover of Pfizer in the financial year ended 31 December 2015 and the relevant turnover of Flynn in the financial year ended 31 March 2016. As set out in section 4.B.II., the CMA finds that the relevant product and geographic market affected by the Infringements is no wider than the supply of phenytoin sodium capsules in the UK. Accordingly, based on the financial data provided to the CMA in this case, the CMA has used a figure of [£] for Pfizer's relevant turnover and a figure of [£] for Flynn's relevant turnover.<sup>1365</sup>

7.66 The CMA will apply a rate of up to 30% to an undertaking's relevant turnover in order to reflect adequately the seriousness of the particular infringement

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<sup>1363</sup> *Penalty Guidance*, paragraphs 2.3 and 2.7. 'Relevant turnover' is the turnover of an undertaking in the relevant product market and geographic market affected by the infringement in the undertaking's last business year, which for the purposes of determining the penalty starting point is the financial year preceding the date when the infringement ended. Relevant turnover is calculated after the deduction of sales rebates, value added tax and other taxes directly related to turnover. Generally, the CMA will base relevant turnover on figures from an undertaking's audited accounts. However, in exceptional circumstances it may be appropriate to use a different figure as reflecting the true scale of an undertaking's activities in the relevant market.

<sup>1364</sup> *Penalty Guidance*, paragraph 2.4.

<sup>1365</sup> Flynn has submitted that Pfizer's turnover should be excluded from its own turnover (see document 02060.1, paragraph 4.10). The CMA rejects this submission. The calculation of turnover is provided for in the Competition Act 1998 (Determination of Turnover for Penalties) Order 2000 (SI 2000/309), as amended. Turnover is also only a starting point and it is normal for the relevant turnover of downstream companies to necessarily incorporate the relevant turnover of its upstream suppliers. The CMA's penalty calculations allow for an adjustment for proportionality at Step 4 if appropriate.

and, in so doing, to deter the infringing undertaking and other undertakings generally from engaging in that particular practice or type of practice in the future. A starting point towards the upper end of the range will be used for the most serious infringements of competition law, including hardcore cartel activity and the most serious abuses of a dominant position.<sup>1366</sup>

7.67 When making this assessment, the CMA will consider a number of factors, including the nature of the product or service, the structure of the market and the market shares of the undertakings involved in the infringement. The seriousness assessment will also take into account the need to deter other undertakings from engaging in such infringements in the future. The damage caused to consumers whether directly or indirectly will also be an important consideration. The assessment will be made on a case-by-case basis for all types of infringement, taking account of all the circumstances of the case.<sup>1367</sup>

**b. *The seriousness of the Infringements***

7.68 The Infringements involve unfairly high pricing which the CMA considers amounts to one of the most serious forms of abuse of a dominant position. The CAT has confirmed that such conduct is a serious abuse.<sup>1368, 1369</sup>

7.69 Protecting customers against exploitation is one of the underlying purposes of competition law. Unfair pricing, by its very nature, goes to the heart of one of the key harms that competition law is designed to avoid – namely, customers (especially end customers) being exploited by supra-competitive prices. While other types of abuse of dominance (e.g. exclusionary conduct such as predatory pricing), and indeed hard-core cartels, seek to restrict competition with a view to the infringing parties being able to charge supra-competitive prices, unfair pricing directly and deliberately imposes prices which materially exceed competitive levels.

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<sup>1366</sup> *Penalty Guidance*, paragraph 2.5.

<sup>1367</sup> *Penalty Guidance*, paragraph 2.6.

<sup>1368</sup> *Napp*, [531]. The CAT also found that there were several mitigating circumstances in that case which reduced the overall seriousness of Napp's conduct. The only one of these potentially relevant to this case is the fact that the Director had not specified the price at which Napp should have set its prices. As set out at section 7.B.VI. below the CMA has found that this does not warrant a reduction for mitigation in the current case.

<sup>1369</sup> Flynn submits that the judgment states that the conduct is 'a serious' abuse but not that it is 'the most serious' abuse (see document 02060.1, paragraph 4.3). However, the court was not required to decide whether the conduct in that case was the most serious abuse, so the court's view is not known. The CMA's penalties guidance has of course also changed since that time in any case. There is no basis to suggest that conduct must be the most serious possible conduct (as opposed to being among the most serious) to justify a 30% starting point.



7.70 The prices resulting from unfair pricing can, and the CMA considers are likely to be, considerably higher, and more certain, than those which might ordinarily be achieved through many forms of exclusionary conduct or the cartelisation of a market. Where the structure of a market allows for unfair pricing, the harmful effects of this abuse may, absent intervention, be more sustainable and persist for longer than other forms of serious anticompetitive practice such as cartelisation, and without having to incur the risks and costs normally associated with such other forms of anticompetitive practice (for example, the risk that one of the cartelists may apply for leniency and the costs of monitoring compliance with the cartel). Consequently, the CMA considers that the harm to consumers which results from unfair pricing is amongst the most serious types of harm caused by any form of anti-competitive practice and therefore excessive pricing constitutes one of the most serious abuses of a dominant position.<sup>1370</sup> The CMA has also taken the following factors into account when determining the appropriate starting point for financial penalties in respect of the Infringements committed by Pfizer and Flynn:

- (a) The nature of the product, market shares, market structure, and entry conditions.<sup>1371</sup>
  - (i) Phenytoin sodium capsules are an essential AED medication required by around 10% of epilepsy patients in the UK.<sup>1372</sup> As set out in section 3.B.I., the effects of epilepsy can be severe and may be triggered by a change in medication. The quality of life of these patients therefore depends maintain a stable course of treatment

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<sup>1370</sup> A 30% starting point may be justified where a type of conduct is among the most serious abuses. The Penalty Guidance does not require that an undertaking's abusive conduct be the most serious abusive conduct possible.

<sup>1371</sup> Pfizer has submitted that the starting point for its penalty should be reduced because there has been no impact on competitors and it alleges that its conduct actually facilitated NRIM's entry (see document 02059.1, paragraph 3.5.1). The CMA rejects this submission. The harm caused by exploitative abuses is not measured by the effect that they have on competitors but customers, and in particular the end customer, in this case the CCGs and ultimately taxpayers. One of the key aims of competition law enforcement is to restrict the ability of undertakings to artificially raise prices or otherwise act to the detriment of consumers. To reduce a penalty because the conduct only harms customers not competitors would be directly counter to this aim and there is no support in law for such a proposition. Furthermore the CMA rejects Pfizer's alternative submission that it has facilitated the introduction of effective competition. The evidence on the CMA's File indicates that NRIM planned to begin supplying phenytoin sodium capsules irrespective of the Parties' conduct. Nor has NRIM's entry effectively constrained Pfizer's Prices or Flynn's Prices or provided any other customer benefits.

<sup>1372</sup> See for example a similar finding in *Genzyme*, [702].

and phenytoin sodium capsules are vital for their health and well-being.

- (ii) The supply of phenytoin sodium capsules in the UK is highly concentrated. At the start of the relevant period Pfizer had a monopoly in the production of phenytoin sodium capsules and throughout the Relevant Period Pfizer always manufactured at least [80% - 90%] of the phenytoin sodium capsules distributed within the UK.<sup>1373</sup> Flynn always had a market share of at least [60% - 70%] of the relevant market during the Relevant Period.<sup>1374</sup>
- (iii) Due to phenytoin sodium capsules' NTI, patients who are stabilised on the product should not be switched to other AEDs including phenytoin sodium capsules that are produced by other manufacturers. As a result, patients who are stabilised on Pfizer-manufactured phenytoin sodium capsules are largely captive.

(b) Damage caused to consumers.

- (i) One of the key aims of competition law enforcement is to restrict the ability of undertakings to artificially raise prices or otherwise act to the detriment of consumers. In most situations this is achieved by preventing anti-competitive agreements or exclusionary conduct which may indirectly lead to such forms of harm. Unfair pricing, however, causes direct harm to consumers through the charging of artificially high prices. As set out in section 5.D.III.b.iii., the Infringements impose direct and substantial harm on the end customer, the NHS and in particular the direct purchasers such as CCGs,<sup>1375</sup> as a result of the unfair prices charged in respect of an essential medicine that is provided to patients for whom switching to alternative drugs is not recommended.
- (ii) Despite the significant scale of the NHS budget, legitimate demands for healthcare will always exceed its level and resources have to be prioritised. Both Pfizer's Prices and Flynn's Prices

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<sup>1373</sup> See section 4.C.III.a.

<sup>1374</sup> See section 4.C.III.b.

<sup>1375</sup> The NHS is the end customer in this context because it purchases the phenytoin sodium capsules and then provides these to patients for potentially no charge. Those patients in the UK who have epilepsy which needs continuous anticonvulsive therapy may obtain a medical exemption certificate which entitles them to free NHS prescriptions in the UK.

have resulted in the NHS paying significantly more for all strengths of phenytoin sodium capsules than it should. Prior to September 2012, the NHS's annual spend on phenytoin sodium capsules was approximately £2.3m. In contrast, the NHS's annual spend on phenytoin sodium capsules was £50 million in 2013, £42 million in 2014 and £37 million in 2015. Of this Flynn's Prices accounted for £30 - £39.9] million in 2013, [£20 - £29.9] million in 2014 and [£20 - £29.9] million in 2015.<sup>1376</sup> The consequence of these increased costs is that CCGs have committed extra money to fund the continued purchase of phenytoin sodium capsules thereby affecting the scope of the services they are able to provide. The increased cost of phenytoin sodium capsules has resulted in CCGs having to relocate funding from other services and treatments.<sup>1377</sup> Therefore, the harm caused by the Infringements is not restricted to phenytoin sodium capsules.

- (c) The need to deter other undertakings from engaging in such infringements.
  - (i) Unfairly high pricing shall, by definition, tend to directly create significant excess profits for undertakings which engage in such conduct. Since the potential gains from such conduct are so great, and so certain, the CMA considers that a high starting point is appropriate in order to ensure that other dominant firms with captive customers are deterred from engaging in such conduct in the future.
  - (ii) Pfizer's and Flynn's Infringements are unlikely to be isolated examples of such conduct within the pharmaceutical sector in the UK and similar cases have been, or are being, investigated in both the UK and other EU Member States.<sup>1378</sup>

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<sup>1376</sup> Based on sales value data provided by Flynn (see documents 00505.22, 00872.3, 00915.1, 01148.2, 01148.3, 01293.2 and 01943.1).

<sup>1377</sup> See section 5.D.III.b.iii.

<sup>1378</sup> See for example the decision taken by the Autorità Garante della Concorrenza e del Mercato in case A480 against the multinational pharmaceutical company Aspen on 29 September 2016 and the CMA case opening notice of 25 October 2016 stating that the CMA is investigating suspected unfair pricing by way of charging excessive prices in the supply of certain pharmaceutical products, including to the National Health Service. <http://www.agcm.it/en/newsroom/press-releases/2339-a480-price-increases-for-cancer-drugs-up-to-1500-the-ica-imposes-a-5-million-euro-fine-on-the-multinational-aspen.html>

- 7.71 Pfizer has submitted that a 30% starting point is unprecedented and unjustified in comparison to the starting points used in previous cases.<sup>1379</sup> The CMA does not accept this submission.
- 7.72 First, the CMA has set out above why Pfizer's and Flynn's conduct has had a significant and direct impact such that a 30% starting point is justified. As already set out, the harm caused by the unfair pricing can be as bad as or worse than that caused by other types of anticompetitive conduct or agreements. The fact that purely exploitative abuses may be less common does not mean they are any less serious when they do occur. The Penalty Guidance makes no distinction between the level of fine to be imposed on the most serious anticompetitive agreements and the level of fine to be imposed on the most serious abuses of a dominant position.
- 7.73 Second, the appropriate penalty to each infringement is to be decided on a case by case basis. Most of the starting points cited by the Parties (and in particular Pfizer) predate the recent amendments to the Act and the adoption of the Penalty Guidance. Each of the more recent cases which have adopted a lower starting point had particular reasons for doing so and these case specific considerations cannot make the starting point adopted in the current Decision unreasonable.
- 7.74 Third, the CMA's predecessor organisation, the OFT imposed a maximum starting point in *Aberdeen Journals* so a maximum starting point is not unprecedented.<sup>1380</sup>
- 7.75 For the above reasons, the CMA considers that the Infringements are among the most serious infringements of competition law and that a starting point of 30% is appropriate in relation to both Pfizer's Infringements and Flynn's Infringements.<sup>1381</sup>
- 7.76 The CMA therefore calculates, using the relevant turnover set out above, that at the end of step 1 Pfizer's penalty is [X].
- 7.77 The CMA therefore calculates, using the relevant turnover set out above, that at the end of step 1 Flynn's penalty is [X].

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<sup>1379</sup> See document 02059.1, paragraph 4.2.

<sup>1380</sup> OFT Decision No. CA98/5/2001 *Predation by Aberdeen Journals Ltd* [2001].

<sup>1381</sup> Pfizer argues that the maximum starting point should not be adopted for the Infringements for all the capsule sizes (see document 02059.1, paragraph 4.9) because the level of excess is far less significant for the 25mg and 50mg strengths. The CMA has however, found that all of Pfizer's prices are unfair and it is the type of conduct that it to be taken into account at Step 1.

## V. **Penalty Calculation Step 2 – Adjustment for duration**

7.78 The CMA may adjust the penalty reached at the end of step 1 to take into account the duration of the infringement. Where the total duration of an infringement is more than one year, the CMA will round up part years to the nearest quarter year, although the CMA may in exceptional cases decide to round up the part year to a full year.<sup>1382</sup>

### a. **Adjustments made at this step**

7.79 The CMA has found that the duration of the Infringements for both Parties was from 24 September 2012 to the date of this Decision, which is a period of just over four years.<sup>1383</sup>

7.80 Accordingly, applying the relevant principles of the Penalty Guidance (summarised above), the CMA has increased the relevant penalties at the end of step 1 by a factor of 4.25, such that at the end of step 2 Pfizer's penalty is [X] and Flynn's penalty is [X].

## VI. **Penalty Calculation Step 3 – Adjustment for aggravating and mitigating factors**

7.81 The CMA may, at step 3, increase a penalty where there are aggravating factors, and/or decrease it where there are mitigating factors. A non-exhaustive list of aggravating and mitigating factors is set out in the Penalty Guidance.<sup>1384</sup>

7.82 For example, the CMA may decrease a penalty at step 3 for cooperation which enables the enforcement process to be concluded more effectively and/or speedily. For these purposes, respecting time limits specified by the CMA is a necessary but not sufficient criterion at this step, and cooperation over and above this will be expected in order to merit a reduction.<sup>1385</sup>

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<sup>1382</sup> *Penalty Guidance*, paragraph 2.12.

<sup>1383</sup> Pfizer and Flynn have both argued that the duration of infringements should be adjusted for the purposes of the imposing a penalty, however, there is no reasonable basis for the CMA to do so (see documents 02059.1, paragraphs 5.1-5.3 and 02060.1, paragraphs 4.11-4.12). The Parties' arguments replicate submissions made by the party in respect of liability that have already been dismissed by the CMA.

<sup>1384</sup> *Penalty Guidance*, paragraphs 2.14 and 2.15.

<sup>1385</sup> *Penalty Guidance*, paragraph 2.15 and footnote 28.

a. ***Adjustments made at this step – Pfizer***

i. *Aggravating factors*

7.83 The CMA considers that the involvement of Pfizer’s directors and senior management both within the UK and internationally should be taken into account as an aggravating factor at step 3. In particular:

- (a) Pfizer’s conduct was primarily driven by senior managers in Pfizer Limited such as the Commercial Director and Business Unit Head for the EPBU; and
- (b) Pfizer Inc’s President and General Manager of Established Products was briefed on the plan to increase prices by the Regional President of Established Products Europe.<sup>1386</sup>

ii. *Mitigating factors*

7.84 The CMA’s view is that there are no relevant mitigating factors to be taken into account at step 3 for Pfizer.

7.85 Pfizer has submitted to the CMA that:

- (a) it had no reason to think that it was infringing competition law;
- (b) phenytoin sodium capsules were loss-making or borderline profitable for years even while other products were significantly more expensive;
- (c) it took steps to keep phenytoin sodium capsules on the market sustainably and safely;
- (d) it has competition law compliance programmes in place and the novel nature of the infringement means that the programme could not be expected to cover this type of infringement; and
- (e) it has provided full co-operation with the CMA’s investigation.

7.86 The CMA does not accept any of these arguments constitute mitigating factors for the following reasons:

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<sup>1386</sup> See section 3.E.V. See also document 00141.147.

- (a) there is no uncertainty that excessive and unfair pricing may infringe competition law, it being listed as an infringement in the TFEU and the Act and being the subject matter of several high profile cases;<sup>1387</sup>
- (i) it is not relevant at step 3 whether phenytoin sodium capsules were or were not profitable prior to September 2012, the infringement relates to Pfizer's Prices since September 2012;
  - (ii) continuing to supply phenytoin sodium capsules is not a relevant mitigating factor at step 3 and, in any event, Pfizer's Prices were far in excess of what was required to make its sales of phenytoin sodium capsules profitable;
  - (iii) as set out above, this is not a novel infringement.<sup>1388</sup> Furthermore Pfizer has not provided any details of its competition law compliance programme other than asserting that it has one. The existence of a programme is not sufficient to warrant a discount at step 3, and Pfizer has not shown that the programme is adequate (especially in the light of senior managers have been involved in the Infringements) or submitted that any changes have been made to the programme to take account of the events under investigation in this case; and
  - (iv) Even excluding the events that led to the CMA imposing a financial penalty on Pfizer under section 40A of the Act on 12 April 2016, Pfizer has co-operated with the CMA broadly to the extent the CMA would expect, but not to the extent that would warrant a discount at step 3. Pfizer has complied with most deadlines but has not provided any particular additional assistance to the CMA.

7.87 The CMA has also considered whether any mitigation should be given for Pfizer's reliance on the Drug Tariff price of Tablets as a benchmark to use when setting its prices.<sup>1389</sup> The CMA is aware that in previous cases

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<sup>1387</sup> See section 7.B.1.b.

<sup>1388</sup> See section 7.B.1.b.

<sup>1389</sup> See document 02059.1, paragraph 7.1.

discounts have been given where a public authority was actively involved in setting, or actually approved, an undertakings conduct.<sup>1390</sup>

7.88 However, the current case is very different to those cases. In the current case, the DH has not approved, nor been involved in the setting of, Pfizer's prices. Indeed, DH did not even know what Pfizer's Prices were because both Pfizer and Flynn refused to disclose them.<sup>1391</sup> Even when pricing for the supply of Tablets is taken into account the context is very different. As the CMA has found at section 5.D.II.b.ii., the Drug Tariff price for Tablets does not provide a meaningful comparison and, in any case, the decisions taken by the DH regarding the Drug Tariff price of Tablets have, at most, only facilitated the prices being charged by the suppliers and wholesalers of Tablets. Consequently, the CMA does not consider that it would be appropriate in the context of this case to provide a discount for mitigation based on Pfizer's reliance on the Drug Tariff price for Tablets as a benchmark for its own pricing.

iii. *Adjustments at step 3*

7.89 For Pfizer, the CMA considers that an uplift of [X] or [X] is appropriate at step 3 taking into account the involvement of Pfizer's directors and senior managers and the lack of mitigating factors.

7.90 The CMA therefore calculates that at the end of step 3 Pfizer's penalty is £16,839,400.

b. ***Adjustments made at this step – Flynn***

i. *Aggravating factors*

7.91 The CMA considers that the involvement of Flynn's directors and senior management, particularly [Flynn's CEO and Director], in the planning and

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<sup>1390</sup> See *Deutsche Telekom*, paragraphs 278 to 279 and *National Grid*, [111] to [115]. In *Deutsche Telekom* the General Court and the Court of Justice found that a 10% discount was sufficient mitigation to account for the fact that in that case the relevant regulator had actively approved Deutsche Telekom's prices. A larger discount was awarded by the Court of Appeal in *National Grid* but this was in the context of the public authority that had been involved in the ex-ante process that lead to the relevant agreements then taking the ex-post decision to penalise National Grid.

<sup>1391</sup> See section 3.E.X.b.



implementation of the proposed infringement should be taken into account as an aggravating factor at step 3.<sup>1392</sup>

ii. *Mitigating factors*

7.92 The CMA finds that there are no relevant mitigating factors to be taken into account at step 3 for Flynn.

7.93 Flynn has submitted to the CMA that:

- (a) it will not be aware of the CMA's final position until this Decision is issued; the Infringements are novel; Flynn could not have known what benchmark to use in setting its price; there are no comparable cases and there was at least genuine uncertainty about the Infringements being contrary to competition law;
- (b) the duration of the Infringements is, for the above reasons, outside Flynn's control; and
- (c) it has provided full co-operation with the CMA's investigation.<sup>1393</sup>

7.94 The CMA does not accept any of these arguments as a mitigating factor for the following reasons:

- (a) there is no uncertainty that excessive and unfair pricing may infringe competition law, it being listed as an infringement in the TFEU and the Act and being the subject matter of several high profile cases (and, unlike the undertaking in *Napp*, Flynn has the benefit of that case and subsequent cases as guidance on the law).<sup>1394</sup> Nor does the fact that the CMA has not set a specific lawful price for Flynn to adopt justify a reduction in Flynn's penalty. This is not something that is provided for in the Penalty Guidance because it is widely recognised that it is always for an undertaking to self-assess its own compliance with competition law and it has always been open to Flynn to reduce its excesses. Flynn has, however, failed to make any attempt to do so. Indeed, the only

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<sup>1392</sup> Flynn has submitted that the CMA has not imposed uplifts for senior management involvement in Article 102 TFEU / Chapter II prohibition cases in the past (see document 02060.1, paragraph 4.15). The CMA is not bound by its past practice, however, and every penalty must be decided on its own facts. The CMA's Penalty Guidance makes no distinction between Article 101 TFEU / Chapter I prohibition cases and Article 102 TFEU / Chapter II prohibition cases.

<sup>1393</sup> See document 02060.1, paragraph 4.16.

<sup>1394</sup> See section 7.B.1.c.

significant adjustment to its prices that Flynn has made during the Infringements actually had the effect of increasing its excesses;<sup>1395</sup>

- (i) the CMA does not agree that the duration of the Infringements is outside Flynn's control and, as set out in the preceding paragraph, it has always been for Flynn to self-assess its conduct and bring each of its Infringements to an end; and
- (ii) Flynn has co-operated with the CMA broadly to the extent the CMA would expect, but not to the extent that would warrant a discount at step 3. Flynn has complied with most deadlines but has not provided any particular additional assistance to the CMA.

7.95 The CMA has also considered whether any mitigation should be given for Flynn's reliance on the Drug Tariff price of Tablets as a benchmark to use when setting its prices. For the same reasons set out for Pfizer in section 7.B.VI.a. above the CMA does not consider that it would be appropriate in the context of this case to provide a discount for mitigation based on Flynn's reliance on the Drug Tariff price for Tablets as a benchmark for its own pricing.

iii. *Adjustments at step 3*

7.96 The CMA considers that an uplift of [X] or [X] is appropriate at step 3 taking into account the involvement of Flynn's directors and senior managers and the lack of mitigating factors.

7.97 The CMA therefore calculates that at the end of step 3 Flynn's penalty is [£25m - £29.9m].

VII. ***Penalty Calculation Step 4 – Adjustment for specific deterrence and proportionality***

7.98 The CMA may adjust any penalty at step 4 for specific deterrence (that is, to ensure that the penalty imposed on the infringing undertaking will deter it from engaging in anti-competitive practices in the future) or proportionality, having regard to appropriate indicators of the size and financial position of the relevant undertaking, as well as any other relevant circumstances of the

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<sup>1395</sup> See sections 3.D.IV. and Annex H.

case. At step 4, the CMA will assess whether, in its view, the overall penalty is appropriate in the round. Adjustments at step 4 may result in either an increase or a decrease to the penalty.<sup>1396</sup>

7.99 For the reasons set out below:

- (a) Pfizer's penalty is subject to an uplift of 400% at step 4 to ensure that the level of Pfizer's penalty for the Infringements is both proportionate and appropriate for the purpose of specific deterrence.
- (b) The CMA has not adjusted Flynn's penalty at step 4. Having weighed those factors supporting an uplift against those factors supporting a reduction, the CMA considers that it would not be necessary or appropriate to reduce Flynn's penalty to an amount below the statutory maximum penalty that could be imposed on Flynn in relation to the Infringements. Consequently, it is not necessary for the CMA to determine the precise level of any adjustment to the penalty that would be appropriate at step 4.

**a. *Factors relevant to specific deterrence***

7.100 The CMA has a statutory responsibility to have regard to the desirability of deterring infringing undertakings (and others) from engaging in conduct which infringes the Chapter II prohibition and or Article 102.<sup>1397</sup> The CMA may increase a penalty figure reached after steps 1 to 3 for specific deterrence purposes, taking into account the specific size and financial position of the undertaking and any other relevant circumstances of the case.<sup>1398</sup> Such increases will generally be limited to situations in which an undertaking has a significant proportion of its turnover outside the relevant market or where the CMA has evidence that the infringing undertaking has made or is likely to make an economic or financial benefit from the infringement exceeding the penalty reached at the end of step 3.<sup>1399</sup> Where the CMA is considering the appropriate level of any uplift for specific deterrence, it will ensure that the uplift does not result in a penalty that is

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<sup>1396</sup> *Penalty Guidance*, paragraphs 2.16 to 2.20. The CMA has taken into account a range of financial indicators in this regard, based on accounting information publicly available and/or provided by the Decision Addressees to the CMA. Those financial indicators are set out in this section of this Decision.

<sup>1397</sup> The Act, Section 36(7A)(b)

<sup>1398</sup> *Penalty Guidance*, paragraph 2.17.

<sup>1399</sup> *Penalty Guidance*, paragraph 2.17.

disproportionate or excessive having regard to the undertaking's size and financial position and the nature of the infringement.<sup>1400</sup>

**b. Factors relevant to proportionality**

7.101 Conversely, where necessary, the CMA may decrease the penalty reached at the end of step 3 to ensure that the level of penalty is not disproportionate or excessive, having regard to the undertaking's size and financial position, the nature of the infringement, the role of the undertaking in the infringement and the impact of the undertaking's infringing activity on competition.<sup>1401</sup>

**c. Adjustments made at this step – Pfizer**

7.102 The CMA has assessed whether any specific deterrence and/or proportionality adjustment(s) should be made at step 4 to Pfizer's penalty.

7.103 The CMA considers that the penalty reached at the end of step 3 should be increased. This is for the following three reasons, each of which on their own is sufficient to justify an uplift.<sup>1402</sup>

7.104 First, the CMA considers that in light of Pfizer's overall size and financial position, a significant uplift is required to ensure that Pfizer is deterred from engaging in anti-competitive conduct in the future. The CMA observes that, unadjusted, Pfizer's penalty for the Infringements would be £16,839,400. Pfizer earns a significant proportion of its worldwide turnover (over 99.9%) outside of the relevant market.<sup>1403</sup> Pfizer's total worldwide turnover for its last financial year was approximately \$48.9bn and it earned approximately \$7bn in profit.<sup>1404</sup> As a result, the unadjusted penalty would represent approximately:<sup>1405</sup>

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<sup>1400</sup> *Penalty Guidance*, paragraph 2.19.

<sup>1401</sup> *Penalty Guidance*, paragraph 2.20.

<sup>1402</sup> These factors reflect the key situations that are cited in paragraphs 2.17 and 2.18 of the *Penalty Guidance* as indicators of when it would be appropriate to impose an uplift. Pfizer has submitted that there is less need for deterrence in this case because there is direct and indirect price regulation for the pharmaceutical industry. The CMA recognises that there is such regulation but this has not prevented the Parties from abusing their dominant positions.

<sup>1403</sup> *Penalty Guidance*, paragraphs 2.17.

<sup>1404</sup> Pfizer Financial Report 2015,

[http://www.pfizer.com/system/files/presentation/2015\\_Pfizer\\_Financial\\_Report.pdf](http://www.pfizer.com/system/files/presentation/2015_Pfizer_Financial_Report.pdf)

<sup>1405</sup> Pfizer has submitted that its penalty should only be assessed against its UK business (see document 02059.1, paragraph 6.4). The CMA rejects this submission. Firstly, it is well established that penalties should be set and assessed on the basis of an undertaking's worldwide turnover, there is nothing unusual about the CMA's approach in this respect. Secondly, it is important that a penalty does have a material impact on Pfizer's

- (a) 0.05% of Pfizer's average annual worldwide turnover in its last three financial years, and 0.05% of Pfizer's worldwide turnover in its latest financial year;
- (b) 0.29% of Pfizer's average annual profit after tax for the latest three years for which accounts have been provided and 0.37% of Pfizer's profit after tax in the last year for which accounts have been provided;
- (c) 0.4% of Pfizer's average annual dividends for the latest three years for which accounts have been provided;
- (d) 0.04% of Pfizer's net assets in the last year for which accounts have been provided; and
- (e) 0.03% of the sum of Pfizer's net assets in the last year, and Pfizer's total annual dividends in the last three years, for which accounts have been provided.

7.105 This means that while the Infringements have had a significant negative impact on customers and consumers within the UK, the penalty as at the end of step 3 would have very little impact on Pfizer's overall financial position and thus would be insufficient to deter Pfizer from engaging in anti-competitive conduct in future.

7.106 Second, the CMA considers that Pfizer's relevant turnover (which forms the starting point for the calculation of Pfizer's penalty at step 1) does not accurately reflect the impact of Pfizer's Infringements or the likely harm to competition caused by the Infringements across the relevant period. In this respect the CMA notes that Pfizer's relevant turnover [redacted] is significantly less than its equivalent turnover during, for example, its first full financial year within the relevant period, ending 31 December 2013, which amounted to [redacted].<sup>1406</sup>

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worldwide business to ensure that Pfizer Inc's senior management see compliance with competition law as important.

<sup>1406</sup> Pfizer submits that this point is a means to circumvent the operation of the relevant turnover figure at step 1 (see document 02059.1, paragraph 6.5). The CMA disagrees. The CMA needs to consider at step 4 the penalty in its overall context and its deterrent effect on Pfizer. The purpose of step 4 is to look at deterrence in the round and where necessary to adjust the penalty accordingly. Further, the reasons for Pfizer's decreasing revenue does not change the fact that the impact of its conduct was materially greater in previous years. This does not mean that any variation in turnover across time should result in an adjustment to the penalty at step 4 but material variations must be taken into account by the CMA when assessing whether a penalty is appropriate.

- 7.107 Third, the unadjusted penalty as at the end of step 3 would also be significantly less than the revenues and profits that the CMA estimates that Pfizer has accrued from the sale of phenytoin sodium capsules during the Relevant Period. This penalty, for instance, represents only [redacted] of Pfizer's total turnover in the relevant market from the beginning of the Infringements to June 2016.<sup>1407</sup>
- 7.108 Overall, the CMA estimates that from the start of the Infringements to June 2016<sup>1408</sup> Pfizer accrued approximately:
- (a) [redacted] of total profits in the relevant market;<sup>1409</sup> and
  - (b) [£49m - £57m] of excesses above Cost Plus in the relevant market.<sup>1410</sup>
- 7.109 While some of these earnings will have been profit that Pfizer could legitimately have accrued absent the Infringements, the size of the excesses identified by the CMA<sup>1411</sup> indicate that it is likely that most of these earnings would not have been accrued absent the Infringements.<sup>1412</sup> The CMA therefore considers that Pfizer would still have accrued a significant, direct and foreseeable financial benefit from having carried out the Infringements if the penalty is not adjusted at step 4. <sup>1413</sup> Expected gain is a relevant factor when determining the appropriate penalty and it is not necessary for the CMA to have calculated the precise gains that Pfizer has accrued from the infringements to take into account the fact that those gains will, on any reasonable basis, be significant.<sup>1414</sup>
- 7.110 It is an important part of effective deterrence that an undertaking should not be in a position in which it is clearly able to make a profit from infringing

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<sup>1407</sup> Pfizer's total revenue in the relevant market was [£60m - £69.9m] million up to 30 June 2016. Consequently, the proposed fine at step 3, £16.8 million is approximately [redacted] of total relevant turnover.

<sup>1408</sup> Pfizer's Infringements have continued to the date of this Decision, so these figures are an underestimate.

<sup>1409</sup> Total profits are calculated by subtracting direct and common costs attributable to phenytoin from phenytoin sales revenues. Common costs allocated to phenytoin are assumed to amount to [redacted] per pack, in line with the calculation in Annex E. This figure was the common cost calculated for the year ended 30 November 2013 and as stated, the CMA have no reason to believe that this figure would have varied materially after this period.

<sup>1410</sup> Excesses are calculated by subtracting a reasonable rate of return from total profits. As per section 5.C.IV.c.i., a 6% ROS has been used and is applied by multiplying total costs by 6.38%.

<sup>1411</sup> See section 5.C.IV.d.

<sup>1412</sup> As set out in section 5.C.IV.b.ii. the CMA considers that a 6% ROS is the maximum reasonable rate of return that should be considered to be reasonable for phenytoin sodium capsules.

<sup>1413</sup> Pfizer has also submitted that the CMA should take into account the fact that its sales of capsules had previously been loss making (see document 02059.1, paragraph 7.2). The CMA rejects this submission. First, Pfizer has no right to recover past losses. Second, the losses it made (even by its own calculations) are insignificant compared to the excesses it has accrued through the Infringements.

<sup>1414</sup> See for example the approach adopted in *Reckitt Benckiser*, paragraphs 8.42 to 8.44.

competition law even after having paid any penalty which is levied in respect of an infringement. Nor is it sufficient for any penalty to only remove Pfizer's likely gains from the Infringements. If the penalty imposed on an undertaking which infringes competition law only removes the gains made (i.e. puts the undertaking in the same position as it would have been absent the infringement) there is little economic incentive for the undertaking not to infringe competition law as it has the potential to gain without the risk of any material losses, even if the undertaking is caught and sanctioned. Therefore, to constitute an effective deterrent in this context any penalty imposed in relation to the Infringements should also exceed Pfizer's likely gains from the Infringements by a material amount. This is particularly relevant for unfair pricing where the gains are accrued as a direct result of the infringing conduct (i.e. charging excessive and unfair prices).

7.111 Further, in addition to the revenues which Pfizer has already directly gained as a result of the Infringements to date, the CMA considers that, absent its own enforcement action, Pfizer would have been reasonably able to expect to continue to make significant and direct financial gains as a result of the Infringements for a considerable time to come<sup>1415</sup> (given the high barriers to entry and the lack of competitive constraint that the CMA has found in this Decision). Again, it is not necessary or indeed feasible for the CMA to estimate the actual size or longevity of such future financial gains to take into account the fact that, in the absence of CMA intervention, substantial future gains would have been foreseeable, significant and persistent. The CMA must also take account of the likelihood of any instance of unfair pricing being detected and enforcement action being taken against it, when considering what level of penalty will be sufficient to deter Pfizer from engaging in future infringements of competition law.<sup>1416</sup>

7.112 The CMA considers that, in light of the above factors, the figure of £16,839,400 would not be sufficient to effectively deter Pfizer from engaging

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<sup>1415</sup> Unlike many other types of competition law infringement where the actual gains may be uncertain (e.g. in the case of a cartel) the gains from unfair pricing are relatively certain and predictable. This makes it correspondingly more important that such gains are directly accounted for in any penalty imposed in unfair pricing cases.

<sup>1416</sup> Pfizer submits that the CMA should not take Pfizer's gain into account when assessing deterrence and that this should be properly accounted for in private litigation (see document 02059.1, paragraph 6.8). This submission ignores the fact that the CMA's published guidance explicitly lists an undertaking's gains as one of the factors to be taken into account when assessing a penalty at step 4. Further, private litigation (including whether a claim is brought at all and the likelihood of its success against Pfizer in this case) is inherently remote and uncertain. The CMA would not be taking proper account of the need for effective deterrence if it relied on private litigation to achieve such deterrence.

in conduct which infringes the Chapter II prohibition and/or Article 102 of the TFEU and in particular from engaging in unfair pricing.<sup>1417</sup>

- 7.113 The CMA has considered what level of adjustment to the penalty reached at the end of step 3 would be appropriate. Following this assessment, the CMA considers that the penalty as at the end of step 3 should be subject to an uplift of 400% in order to deter Pfizer from infringing competition law in the future. This results in a penalty of £84,196,998 at the end of step 4.<sup>1418</sup>
- 7.114 In reaching this conclusion the CMA considered the following factors, either of which on their own is sufficient to justify the uplift.<sup>1419</sup>
- 7.115 First, as set out above, the CMA's conclusion is that, in order to ensure effective deterrence, it is necessary for it to impose a penalty which is materially higher than the excesses Pfizer has accrued to date as a result of the Infringements. In reaching this conclusion the CMA has taken account of both the likelihood of unfair pricing being detected and enforcement being taken against it. In addition, also as noted above, absent intervention by the CMA, Pfizer would have continued to be able to earn significant excesses for the foreseeable future.
- 7.116 In this respect, when assessed against the earnings that Pfizer accrued from the start of the Infringements to June 2016<sup>1420</sup> an uplift of 400% results in a penalty that is:
- (a) [REDACTED] of Pfizer's total profits in the relevant market; and

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<sup>1417</sup> Section 36(7A) of the Act.

<sup>1418</sup> Pfizer has submitted that the CMA should take into account the steps that it had taken to avoid *Epanutin* being discontinued (see document 02059.1, paragraphs 3.6 and 7.3). However, as the CMA has previously set out, while it has no problem with Pfizer (or any other undertaking) seeking to return a genuinely loss making product to profitability, Pfizer's conduct has gone far beyond what was required to achieve this aim. In any event, when assessing the appropriate level of deterrence the CMA has excluded Pfizer's legitimate costs by focusing on the profits and excesses that Pfizer has accrued.

<sup>1419</sup> Pfizer has submitted that the CMA's approach is '*incoherent and extreme*' because it suggests that unfair pricing cases require more deterrence than cartel cases (see document 02059.1, paragraph 6.2). The CMA rejects this submission. Step 4 is about case specific deterrence in light of the specific circumstances relevant to the undertaking and infringement in question. A significant uplift is required to impose an effective deterrent on Pfizer given the specific facts of this case.

<sup>1420</sup> See the figures set out above.



(b) [140% - 168%] of Pfizer's total excesses above cost-plus in the relevant market.<sup>1421</sup>

7.117 Taking all of these factors into account, the CMA considers that a penalty of £84,196,998 is appropriate and proportionate in light of the CMA's statutory obligation to ensure that its penalties are effective at deterring future infringements of competition law.

7.118 Second, in accordance with the Penalty Guidance, the CMA has assessed the penalty, further to the uplift of 400% at this step, against a range of Pfizer's financial indicators.<sup>1422</sup>

7.119 As noted above, over 99% of Pfizer's worldwide turnover is outside the relevant market. In addition, Pfizer's turnover in the relevant market in the last financial year is lower than in previous years covered by the Infringements. The CMA considers that these factors mean that a significant uplift to Pfizer's penalty should be made at step 4 in order to ensure that the penalty is likely to deter Pfizer from infringing competition law in the future.

7.120 Having assessed the penalty, further to the uplift of 400% at this step, against a range of Pfizer's financial indicators, the CMA considers that the penalty will be a sufficiently material penalty for Pfizer in terms of deterrence, without having a disproportionate impact on its overall financial position. For example, the penalty of £84,196,998 would represent approximately:

- (a) 0.27% of Pfizer's average annual worldwide turnover in its last three financial years, and 0.26% of Pfizer's worldwide turnover in its latest financial year;
- (b) 1.45% of Pfizer's average annual profit after tax for the latest three years for which accounts have been provided and 1.85% of Pfizer's profit after tax in the last year for which accounts have been provided;
- (c) 1.96% of Pfizer's average annual dividends for the latest three years for which accounts have been provided;
- (d) 0.19% of Pfizer's net assets in the last year for which accounts have been provided; and

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<sup>1421</sup> The actual amounts earned as at the date of this Decision will be higher because Pfizer's Infringements are ongoing and therefore these figures overestimate the size of the penalty as a proportion of Pfizer's Relevant Turnover.

<sup>1422</sup> *Penalty Guidance*, paragraph 2.20.

- (e) 0.15% of the sum of Pfizer's net assets in the last year, and Pfizer's total annual dividends in the last three years, for which accounts have been provided.

7.121 A penalty of £84,196,998 will also be:

- (a) 10% of Pfizer's average UK turnover for the latest three years for which accounts have been provided and 7% of Pfizer Limited's turnover in the last year for which accounts have been provided; and
- (b) 118% of Pfizer's average UK annual profit after tax for the latest three years for which accounts have been provided.

7.122 Assessing the penalty in the round, and having had regard to the above factors, the CMA considers this would be an appropriate penalty to deter Pfizer from infringing competition law in the future, without being disproportionate or excessive.

7.123 Therefore, at the end of step 4, Pfizer's penalty is £84,196,998.

*d. Adjustments made at this step – Flynn*

7.124 The CMA has assessed whether any specific deterrence and/or proportionality adjustment(s) should be made at step 4 to Flynn's penalty.

7.125 The CMA considers that there are factors which, absent the statutory maximum penalty, indicate it would be appropriate for the penalty reached at the end of step 3 to be increased. This is for the following reasons, each of which on their own is sufficient to justify an uplift.<sup>1423</sup>

7.126 First, the CMA considers that Flynn's relevant turnover (which forms the starting point for the calculation of Flynn's penalty at step 1) does not accurately reflect the impact of Flynn's Infringements or the likely harm to competition caused by the Infringements across the relevant period. In this respect the CMA notes that Flynn's relevant turnover [§]) is significantly less than its equivalent turnover during, for example, its first full financial year within the relevant period, ending 31 March 2014, which amounted to [§].

7.127 Second, the penalty as at the end of step 3 would also be significantly less than the profits and excesses that the CMA estimates that Flynn has

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<sup>1423</sup> These factors reflect the situations that are cited in paragraphs 2.17 and 2.18 of the *Penalty Guidance* as indicators of when it would be appropriate to impose an uplift.

accrued from the sale of phenytoin sodium capsules from the start of the Relevant Period to the date of this decision.

7.128 Overall, the CMA estimates that from the start of the Infringements to April 2016<sup>1424</sup> Flynn has accrued approximately:

(a) [£27.5m] of total profits in the relevant market;<sup>1425</sup> and

(b) [£27.5 - £32.5m] of excesses above cost-plus in the relevant market.<sup>1426</sup>

7.129 While some of these earnings will have been profit that Flynn could legitimately have accrued absent the Infringements, the size of the excesses identified by the CMA<sup>1427</sup> indicate that it is more likely than not that much of these earnings would not have been accrued absent the Infringements. The CMA therefore considers that Flynn would still have accrued a significant, direct and foreseeable financial benefit from the Infringements if the penalty is not adjusted at step 4. Expected gain is a relevant factor when determining the appropriate penalty and it is not necessary for the CMA to have calculated the precise gains that Flynn has accrued from the infringements to take into account the fact that these gain will, on any reasonable basis, be significant.<sup>1428</sup>

7.130 It is an important part of effective deterrence that an undertaking should not be in a position in which it has made a profit from infringing competition law even after having paid any penalty which is levied in respect of the infringement. Nor is it sufficient for any penalty to simply remove Flynn's likely gains from the Infringements. To constitute an effective deterrent in this context any penalty imposed in relation to the Infringements should, where possible, also exceed Flynn's likely gains from the Infringements by a material amount.

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<sup>1424</sup> The CMA has found that Flynn's Infringements have continued to the date of this Decision, so these figures are an underestimate.

<sup>1425</sup> Total profits are calculated by subtracting direct and common costs attributable to phenytoin from phenytoin sales revenues. Common costs allocated to phenytoin are assumed to amount to [£2.5m] per pack, in line with the calculation in Annex F. This figure was calculated using data from September 2012 to December 2014. The CMA have no reason to believe that this would have varied materially after this period.

<sup>1426</sup> Excesses are calculated by subtracting a reasonable rate of return from total profits. As per section 5.C.V.c., a 6% ROS has been used and is applied by multiplying total costs by 6.38%.

<sup>1427</sup> See section 5.C.V.d.

<sup>1428</sup> See for example the approach adopted in *Reckitt Benckiser*, [8.42] -[8.44]

- 7.131 Further, in addition to the revenues which Flynn has already directly gained as a result of the Infringements to date, the CMA considers that, absent its own enforcement action, Flynn would have been reasonably able to expect to continue to make significant and direct financial gains as a result of the Infringements for a considerable time to come (given the high barriers to entry and the lack of competitive constraint on Flynn's prices that the CMA has identified in the SO). Again, it is not necessary or indeed feasible for the CMA to estimate the actual size or longevity of such future financial gains to take into account the fact that, in the absence of CMA intervention, substantial future gains would have been foreseeable, significant and persistent. The CMA must also take account of the likelihood of any instance of unfair pricing being detected and enforcement action being taken against it, when considering what level of penalty will be sufficient to deter Flynn from engaging in future infringements of competition law.
- 7.132 Consequently, the CMA considers that the factors set out above indicate that it may be appropriate to make an uplift to the unadjusted penalty reached at the end of step 3.
- 7.133 The CMA has also taken account of the size of the penalty as at the end of step 3 and compared this against a range of Flynn's financial indicators. The unadjusted penalty at the end of step 3 would represent approximately:
- (a) [48% - 58%] of Flynn's average annual worldwide turnover in its last three financial years;
  - (b) [284% - 340%] of Flynn's average annual profit after tax for the latest three years for which accounts have been provided;
  - (c) [395% - 474%] of Flynn's average annual dividends for the latest three years for which accounts have been provided;
  - (d) [123% - 147%] of Flynn's net assets in the last year for which accounts have been provided; and
  - (e) [64% - 76%] of the sum of Flynn's net assets in the last year, and Flynn's total annual dividends in the last three years, for which accounts have been provided.
- 7.134 The CMA considers that the factors set out above indicate that it would be appropriate to make a reduction to the unadjusted penalty reached at the end of step 3.

- 7.135 Having weighed those factors supporting an uplift against those factors supporting a reduction, the CMA considers that it would not be necessary or appropriate to reduce Flynn's penalty to an amount below the statutory maximum penalty that could be imposed on Flynn in relation to the Infringements.<sup>1429</sup> Indeed, the likely gains made by Flynn as a result of the Infringements, and the need for specific deterrence, mean that Flynn's overall penalty at the end of step 4 should still be significantly above the statutory maximum penalty.<sup>1430</sup>
- 7.136 It is not, however, necessary for the CMA to determine the precise level of overall adjustment that would be appropriate at step 4 since any penalty that might be imposed would, in any case, still be limited by the statutory maximum at step 5.
- 7.137 For completeness, the CMA has also assessed a penalty set at the statutory maximum against the above financial indicators and its view is that such a penalty would not have a disproportionate adverse effect on Flynn's overall financial position. A penalty at the statutory maximum (£5,164,425) would represent approximately:
- (a) 10% of Flynn's average annual worldwide turnover in its last three financial years;
  - (b) 59% of Flynn's average annual profit after tax for the latest three years for which accounts have been provided and 56% of Flynn's profit after tax for the last year for which accounts have been provided;
  - (c) 82% of Flynn's average annual dividends for the latest three years for which accounts have been provided;<sup>1431</sup>

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<sup>1429</sup> See step 5 below for further details.

<sup>1430</sup> The CMA notes that to reduce the penalty below the statutory maximum the CMA would have had to consider it appropriate to reduce the level of the penalty to around [1/5<sup>th</sup> to 1/6<sup>th</sup>] of the penalty at the end of step 3. In the CMA's judgement a penalty below the statutory maximum at the end of step 4 would be disproportionality low. Such a penalty would not address the seriousness of the Infringements or the need to achieve effective deterrence, both of which the CMA has a statutory obligation (under section 36(7A) of the Act) to have regard to when setting penalties.

<sup>1431</sup> Flynn did not pay out any dividends in the financial year ending 31 March 2016 despite reporting a profit on ordinary activities after tax of £9,219,510. Consequently this indicator over-estimates the impact of such a penalty on Flynn's financial position.

- (d) 25% of Flynn's net assets in the last year for which accounts have been provided;<sup>1432</sup> and
- (e) 13% of the sum of Flynn's net assets in the last year, and Flynn's total annual dividends in the last three years, for which accounts have been provided.

7.138 Further, a penalty at the statutory maximum would also be only:

- (a) [~~8%~~] of Flynn's total profits in the relevant market; and
- (b) [14% - 23%] of Flynn's total excesses above Cost Plus in the relevant market.

### VIII. ***Penalty Calculation Step 5 – Adjustment to prevent maximum penalty from being exceeded and to avoid double jeopardy***

#### a. ***Adjustments to prevent maximum penalty from being exceeded***

7.139 The final amount of the penalty calculated according to the method set out above may not in any event exceed 10% of the worldwide turnover of the undertaking in its last business year.<sup>1433</sup> The relevant business year for these purposes will be the one preceding the date on which the decision of the CMA is taken or, if figures are not available for that business year, the one immediately preceding it. The penalty will be adjusted if necessary to ensure that it does not exceed this maximum.<sup>1434</sup>

#### b. ***Adjustments to avoid double jeopardy***

7.140 In addition, the CMA must, when setting the amount of a penalty for a particular agreement or conduct, take into account any penalty or fine that has been imposed by the European Commission, or by a court or other body in another Member State in respect of the same agreement or conduct.<sup>1435</sup>

#### c. ***Adjustments made at this step – Pfizer***

7.141 The latest accounts available to the CMA for Pfizer are for the financial year ended 31 December 2015. In this year, Pfizer's worldwide turnover was

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<sup>1432</sup> Flynn has very limited assets and describes its business model as 'infrastructure-light' (see document 01767.1, page 71). Flynn's financial statements also state that it had cash reserves of £8,981,857 as of 31 March 2016, comfortably exceeding the value of the penalty.

<sup>1433</sup> Calculated in accordance with the Turnover Order; see the *Penalty Guidance*, paragraphs 1.12 and 2.21.

<sup>1434</sup> *Penalty Guidance*, paragraph 2.21.

<sup>1435</sup> *Penalty Guidance*, paragraph 2.24.

£32.0 billion. The maximum penalty which could be applied to Pfizer in respect of the Infringements is 10% of this total, which is £3.2 billion.

7.142 The CMA has assessed the penalty figure reached in respect of Pfizer at the end of step 4 against the statutory cap thresholds set out above. This assessment has not necessitated any reductions to the penalty at step 5 of the penalty calculations.

7.143 In addition, the CMA is not aware that any adjustment needs to be made to the level of the penalty figure reached at the end of step 4 in order to avoid double jeopardy.

7.144 The CMA has not made adjustments to Pfizer's penalty at this step, so the Pfizer's penalty at the end of step 5 remains the same as at the end of step 4.

**d. *Adjustments made at this step – Flynn***

7.145 The latest accounts currently available to the CMA for Flynn are for the financial year ended 31 March 2015. In that year, Flynn's worldwide turnover was £51,644,247. The maximum penalty which could be applied to Flynn in respect of the Infringements is 10% of this total, which is £5,164,425. As a result, the penalty on Flynn has been reduced to that figure.

7.146 The CMA is not aware that any adjustment needs to be made to the level of the penalty figure reached at the end of step 4 in order to avoid double jeopardy.

7.147 The CMA therefore calculates that at the end of step 5 Flynn's penalty is £5,164,425.

**IX. *Penalty Calculation Step 6 – Application of reductions for leniency and settlement***

7.148 The CMA will reduce an undertaking's penalty at step 6 where the undertaking has a leniency agreement with the CMA and/or agrees to settle with the CMA.<sup>1436</sup>

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<sup>1436</sup> *Penalty Guidance*, paragraphs 2.25-2.26.

**a.        *Adjustments made at this step***

7.149 Neither Pfizer nor Flynn has not entered into a leniency or settlement agreement with the CMA.

7.150 Therefore, the CMA does not make any adjustments at step 6 for either Pfizer or Flynn. Accordingly, at the end of step 6:

(a) Pfizer's penalty in respect of the Infringements is £84,196,998; and

(b) Flynn's penalty in respect of the Infringements is £5,164,425.



## 8. THE CMA'S ACTIONS

8.1 This section sets out the actions that the CMA is taking in connection with each of the Infringements and the CMA's reasons.

### A. The CMA's decision

8.2 In respect of Pfizer, the CMA finds on the basis of the evidence set out in this Decision that:

- i. Throughout the Relevant Period, Pfizer has held a dominant position in the market for the manufacture of Pfizer-manufactured phenytoin sodium that are distributed in the UK. Alternatively, during the period from 24 September 2012 to November 2013, Pfizer has held a dominant position in the market for the manufacture of phenytoin sodium capsules that were distributed in the UK.
- ii. Throughout the Relevant Period, Pfizer has abused its dominant position by charging Flynn unfairly high selling prices in respect of each of Pfizer's Products, thereby infringing the Chapter II prohibition and Article 102 of the TFEU.
- iii. As Pfizer charges different prices and incurs different costs for each of Pfizer's Products, the CMA finds four separate abuses – and therefore takes four separate infringement decisions in respect of Pfizer's conduct – one for each of Pfizer's Products and in respect of each of Pfizer's Prices.

8.3 In respect of Flynn, the CMA finds on the basis of the evidence set out in this Decision that:

- i. Throughout the Relevant Period, Flynn has held a dominant position in the market for the distribution of Pfizer-manufactured phenytoin sodium capsules in the UK. Alternatively, during the period from 24 September 2012 to November 2013, Flynn has held a dominant position in the market for the distribution of phenytoin sodium capsules in the UK.
- ii. Throughout the Relevant Period, Flynn has abused its dominant position by charging its customers (wholesalers and pharmacies) unfairly high selling prices in respect of each of Flynn's Products, thereby infringing the Chapter II prohibition and Article 102 of the TFEU.

- iii. As Flynn charges different prices and incurs different costs for each of Flynn's Products, the CMA finds four separate abuses – and therefore takes four separate infringement decisions – one for each of Flynn's Products and in respect of each of Flynn's Prices.

## **B. Directions**

- 8.4 In accordance with Section 33(1) of the Act, in order to end the Infringements and ensure that the Parties do not engage in the same or similar conduct in the future the CMA requires each of Pfizer and Flynn to comply with the CMA's Directions, which are set out in Annex B.

## **C. Financial penalties**

- 8.5 In accordance with Section 36(2) of the Act the CMA requires Pfizer to pay a penalty of £84,196,998.
- 8.6 In accordance with Section 36(2) of the Act the CMA requires Flynn to pay a penalty of £5,164,425.

**Signed by the following who are members of, and together constitute, the Case Decision Group:**

[✂]

**Professor Philip Marsden**, Inquiry Chair, for and on behalf of the CMA; and

[✂]

**Dr Jennifer Haydock**, Economics Director, for and on behalf of the CMA.

## ANNEX A – KEY DEFINED TERMS

### A. Key defined terms specific to the Investigation

Term	Definition
<b>Asset Sale Agreement</b>	An agreement between Pfizer and Flynn dated 27 January 2012 which provides for the transfer of Pfizer's <i>Epanutin</i> UK Marketing Authorisations to Flynn.
<b>CMA's Directions</b>	The directions that the CMA has made to Pfizer and Flynn as set out in Annex B.
<b>Cost Plus</b>	The costs actually incurred in the supply of a product or service plus a reasonable rate of return.
<b>Decision</b>	This decision issued by the CMA.
<b>DPS</b>	The draft penalty statements issued by the CMA to each of the Pfizer and Flynn.
<b>Exclusive Supply Agreement</b>	An agreement between Pfizer and Flynn dated 17 April 2012 which provided for Pfizer to supply Flynn with <i>Epanutin</i> .
<b>Flynn</b>	Flynn Pharma Limited and Flynn Pharma (Holdings) Limited collectively.
<b>Flynn's Infringements</b>	The four separate abuses of a dominant position that the CMA has found to have been committed by Flynn.
<b>Flynn's Prices</b>	Flynn's ASPs to wholesalers and pharmacies.
<b>Flynn's Products</b>	The four different capsule strengths (25mg, 50mg, 100mg, 300mg) of Pfizer manufactured phenytoin sodium capsules sold by Flynn as 'Phenytoin Sodium Flynn Hard Capsules'.
<b>Focal Product</b>	Pfizer-manufactured phenytoin sodium capsules.

<b>Infringements</b>	Pfizer's Infringements and Flynn's Infringements collectively.
<b>Investigation</b>	The CMA's investigation into the matters that are the subject of this Decision.
<b>NRIM's Product</b>	Phenytoin Sodium NRIM Capsules (100mg).
<b>Parallel Imports</b>	<i>Epanutin</i> /Pfizer-manufactured phenytoin sodium capsules imported from other markets into and sold in the UK.
<b>Parties</b>	Pfizer and Flynn collectively.
<b>Party</b>	Either Pfizer or Flynn as applicable.
<b>Pfizer</b>	Pfizer Limited and Pfizer Inc.
<b>Pfizer's infringements</b>	The four separate abuses of a dominant position that the CMA has found to have been committed by Pfizer.
<b>Pfizer-manufactured phenytoin sodium capsules</b>	Phenytoin sodium capsules manufactured by Pfizer.
<b>Pfizer's Prices</b>	Pfizer's ASPs to Flynn.
<b>Pfizer's Products</b>	The four different capsule strengths (25mg, 50mg, 100mg, 300mg) of Pfizer-manufactured phenytoin sodium capsules.
<b>Pre-September 2012 prices</b>	The ASPs charged by Pfizer up to and including 23 September 2012.
<b>Quality Agreement</b>	An agreement between Pfizer and Flynn dated 11 June 2012 which related to the production of finished packs of phenytoin sodium capsules from Pfizer to Flynn.
<b>Relevant Period</b>	The period from 24 September 2012 to the date of this Decision.

<b>SO</b>	The Statement of Objections issued by the CMA on 6 August 2015 addressed to Pfizer and Flynn.
<b>Tablets</b>	Phenytoin sodium tablets.
<b>[Company A]'s Proposal</b>	[Company A]'s proposal to Pfizer in mid-2009 that Pfizer transfer the license for <i>Epanutin</i> to [Company A] and that [Company A] genericise <i>Epanutin</i> and increase the price.

## B. Key general defined terms

<b>Term</b>	<b>Definition</b>
<b>AAH</b>	AAH Pharmaceutical Limited. A wholesaler and distributor of pharmaceuticals. AAH has been part of Celesio AG since 1995.
<b>ABPI</b>	The Association of the British Pharmaceutical Industry.
<b>Active ingredient</b>	See API.
<b>AED</b>	An anti-epilepsy drug.
<b>AFR</b>	The annual financial return submitted by members of the PPRS.
<b>Alliance</b>	Alliance Healthcare Distribution Limited. A pharmaceutical wholesaler. Affiliated with Boots as Alliance Boots.
<b>API</b>	Active Pharmaceutical Ingredient (of a pharmaceutical product).
<b>ASDA</b>	Asda Group Limited. Operates a pharmacy chain.
<b>ASP</b>	Average Selling Price.
<b>ATC</b>	The Anatomical Therapeutic Chemical classification system developed by the World Health Organisation.
<b>Auden McKenzie</b>	Auden McKenzie (Pharma Division) Limited. A pharmaceutical company. Acquired by Actavis UK Limited in 2015.
<b>BNF</b>	The British National Formulary.

<b>Boots</b>	Boots UK Limited. Operates a pharmacy chain. Affiliated with Alliance as Alliance Boots acting as a wholesaler of pharmaceuticals.
<b>CCGs</b>	Clinical Commissioning Groups who are responsible for providing and funding health services in their local areas. The equivalents to CCGs in the devolved nations are: in Scotland, Regional Boards which devolve responsibility for health service budgets to Community Health Partnerships; in Wales, Local Health Boards; in Northern Ireland, the Health and Social Care Board which works with six Health and Social Care Trusts. CCGs were preceded in England by PCTs.
<b>CG137</b>	NICE Clinical Guidance CG137: The epilepsies: the diagnosis and management of the epilepsies in adults and children in primary and secondary care.
<b>CHM</b>	Commission on Human Medicines.
<b>CHM Report</b>	A report summarising the recommendations of the CHM published by the MHRA in July 2013.
<b>Continuity of Supply</b>	The principle that a patient who is currently taking a particular manufacturer's or MA holder's phenytoin sodium capsule product should be maintained on that specific manufacturer's product.
<b>CMA</b>	Competition and Markets Authority. References to the CMA should be read as referring to the OFT where they concern matters prior to 1 April 2014.
<b>COGs</b>	Cost of goods sold.



<b>Co-Op</b>	Co-Op Healthcare Holdings Limited, Belfast Co-Operative Chemists Limited, National Co-Operative Chemists Limited. Operates a pharmacy chain. The Co-Op's pharmacy business was acquired by the Bestway Group – Bestway (Holdings) Limited in July 2014 and the pharmacies rebranded to 'Well' in February 2015.
<b>Day Lewis</b>	Day Lewis Plc. Operates a pharmacy chain.
<b>[Flynn's appointed regulatory consultants]</b>	[X] [Flynn's appointed regulatory consultants]
<b>DDD</b>	Defined daily dose. The defined daily dose is the assumed average maintenance dose per day for a drug used for its main indication in adults.
<b>DH</b>	The Department of Health.
<b>DTP</b>	Direct to Pharmacy. A distribution system where the product is sold direct to pharmacies and the supplier sets the prices paid by pharmacies.
<b>EBITDA</b>	Earnings before interest, taxes, depreciation, and amortization.
<b>EPBU</b>	Pfizer's Established Products Business Unit.
<b>EU</b>	European Union.
<b>Epanutin</b>	The brand name for Pfizer manufactured phenytoin sodium capsules sold by Pfizer in other EU Member States and in the UK until 23 September 2012.
<b>GBV</b>	Gross book value.
<b>GMMMG</b>	The Greater Manchester Medicines Management Group.
<b>GP</b>	General Practitioner.
<b>IMS</b>	QuintilesIMS formerly known as IMS Health.
<b>IRR</b>	Internal Rate of Return.

<b>Lloyds</b>	Lloyds Pharmacy Limited. Operates a pharmacy chain. Owned by Celesio AG.
<b>Morrisons</b>	WM Morrison Supermarkets Plc. Operates a pharmacy chain.
<b>MOT</b>	A margin of tolerance for returns above the ROS target of 6% under the PPRS.
<b>MA</b>	Marketing Authorisation. Sometimes referred to as a licence. An authorisation to sell a medicine in the UK.
<b>MHRA Guidance</b>	The guidance issued by the Medicines and Healthcare Products Regulatory Agency in November 2013 entitled: 'Formulation switching of antiepileptic drugs, A Report on the Recommendations of the Commission on Human Medicines from July 2013'.
<b>MHRA</b>	The Medicines and Healthcare Products Regulatory Agency.
<b>Milpharm</b>	Milpharm Limited. A pharmaceutical company.
<b>MP</b>	Member of Parliament.
<b>NBV</b>	Net book value.
<b>NHS</b>	National Health Service.
<b>NHSBSA</b>	NHS Business Service Authority.
<b>NICE</b>	National Institute for Health and Clinical Excellence.
<b>NRIM</b>	NRIM Limited. A pharmaceutical company. Acquired by Auden McKenzie Holdings Limited in 2014.
<b>NTI</b>	Narrow therapeutic index.
<b>OFT</b>	The Office of Fair Trading. Predecessor to the Competition and Markets Authority.

<b>PCT</b>	Primary Care Trust. Abolished on 31 March 2013 as part of the Health and Social Care Act 2012, with their work taken over by CCGs.
<b>PCA</b>	Prescription Cost Analysis.
<b>PPRS</b>	The Pharmaceutical Price Regulation Scheme.
<b>PSNC</b>	The Pharmaceutical Services Negotiating Committee.
<b>QIPP</b>	Quality, Innovation, Productivity and Prevention Plan.
<b>R&amp;D</b>	Research and development (of pharmaceutical products).
<b>ROCE</b>	Return on capital employed.
<b>ROS</b>	Return on sales.
<b>Rowlands</b>	L Rowland & Company (Retail) Limited. Operates a pharmacy chain.
<b>RWM</b>	Reduced Wholesaler Model. A distribution system similar to the traditional wholesaler model but with a reduced number of wholesalers.
<b>Sainsbury's</b>	J Sainsbury Plc. Operates a pharmacy chain. In July 2016 Celesio AG, the owner of Lloyds Pharmacy, acquired all Sainsbury pharmacies and were rebranded as Lloyds Pharmacy effective from 1 September 2016.
<b>Secretary of State</b>	The Secretary of State for Health.
<b>SIGN</b>	Scottish Intercollegiate Guidelines Network.
<b>SSNIP</b>	A small but significant non-transitory increase in price.
<b>Superdrug</b>	Superdrug Stores Plc. Operates a pharmacy chain.
<b>Teva</b>	Teva UK Limited. A pharmaceutical company.

<b>Tesco</b>	Tesco Plc. Operates a pharmacy chain
[✂]	[✂]
[✂]	[✂] [Flynn's pre-wholesaler/distributor].
<b>UKMF</b>	Pfizer's UK Management Forum.
<b>WACC</b>	Weighted Average Cost of Capital.
<b>WHO</b>	World Health Organisation.
<b>Wockhardt</b>	Wockhardt UK Limited. A pharmaceutical company.

## C. Key legal terms, guidance and documents

<b>Term</b>	<b>Definition</b>
<b>Aberdeen Journals I</b>	Aberdeen Journals v Director General of Fair Trading [2002] CAT 4.
<b>Aberdeen Journals II</b>	Aberdeen Journals v Director General of Fair Trading [2003] CAT 11.
<b>Act</b>	The Competition Act 1998.
<b>Albion Water excess</b>	The level of excess identified in Albion Water judgment.
<b>Albion Water I</b>	Albion Water and Another v Water Services Regulation Authority and Others [2006] CAT 36.
<b>Albion Water II</b>	Albion Water and Another v Water Services Regulation Authority and Others [2008] CAT 31.
<b>Akzo</b>	Akzo v Commission C-62/86, EU:C:1991:286.
<b>Akzo Nobel</b>	Akzo Nobel v Commission C-97/08 P, EU:C:2009:536.
<b>Alliance One</b>	Alliance One & Others v Commission joined cases C-628/10 P and C-14/11 P, EU:C:2012:479.
<b>Article 102</b>	Article 102 of the TFEU.
<b>Assessment of market power guidelines</b>	OFT415 Assessment of market power (December 2005), adopted by the CMA.
<b>AstraZeneca</b>	AstraZeneca v Commission T-321/05, EU:T:2010:266.
<b>Attheraces</b>	Attheraces Limited v the British Horseracing Board Limited [2007] EWCA Civ 38.
<b>Attheraces High Court</b>	Attheraces Limited v the British Horseracing Board Limited [2005] EWHC 3015 (Ch).

<b>CAT</b>	The Competition Appeal Tribunal. Formally the Competition Commission Appeal Tribunal.
<b>Chapter II prohibition</b>	The prohibition imposed by the Competition Act 1998.
<b>CMA8</b>	Guidance on the CMA's investigation procedures in Competition Act 1998 cases (March 2014)
<b>Commission Notice on Market Definition</b>	Commission Notice on the definition of the relevant market for the purposes of Community competition law, OJ C 372, 9.12.1997.
<b>Effect on Trade Guidelines</b>	Commission's Guidelines on the effect on trade concept contained in Articles 81 and 82 of the Treaty, OJ C 101, 27.4.2004.
<b>Enforcement Priorities Guidance</b>	Communication from the Commission: Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings, OJ C 45/7, 24.2.2009.
<b>Deutsche Post</b>	Commission decision COMP/36.915 – Deutsche Post AG – Interception of cross border mail [2001].
<b>Deutsche Telecom</b>	Deutsche Telekom AG v Commission C-280/08, EU:C:2010:603.
<b>France Télécom</b>	France Télécom v Commission T-340/03, EU:T:2007:22.
<b>Genzyme</b>	Genzyme v OFT [2004] CAT 4.
<b>Genzyme Remedy</b>	Genzyme Limited v Office of Fair Trading [2005] CAT 32.
<b>Hoffmann-La Roche</b>	Hoffmann-La Roche v Commission C-85/76, EU:C:1979:36.
<b>Kanal 5</b>	Kanal 5 v STIM C-52/07, EU:C:2008:703.

<b>Napp</b>	Napp Pharmaceutical Holding Limited and Subsidiaries v Director General of Fair Trading [2002] CAT 1.
<b>National Grid</b>	National Grid v GEMA [2009] CAT 14.
<b>NHS Act</b>	The National Health Service Act 2006 as amended.
<b>Scandlines</b>	Commission decision COMP/36.568 – Scandlines Sverige AB v Port of Helsingborg [2004].
<b>Penalties Guidance</b>	OFT’s Guidance as to the appropriate amount of a penalty (OFT423, September 2012).
<b>Pilkington</b>	Pilkington v Commission C-101/15, EU:C:2016:631.
<b>Profitability Assessment Report</b>	OFT657 Assessing profitability in competition policy analysis, Economic discussion paper 6, July 2003, prepared by OXERA.
<b>Reckitt Benckiser</b>	OFT Decision No. CA98/02/2011 Reckitt Benckiser [2011].
<b>Statutory Scheme</b>	The statutory pricing regulations for controlling the cost of branded medicines to the NHS enacted under the Statutory Scheme Regulations.
<b>Statutory Scheme Regulations</b>	The statutory regulations governing the Statutory Scheme set out in: the Health Service Branded Medicines (Control of Prices and Supply of Information) (No.2) Regulations 2008; and the Health Service Medicines (Information Relating to Sales of Branded Medicines etc.) Regulations 2007.
<b>Telefónica</b>	Telefónica v Commission T-336/07, EU:T:2012:172.
<b>Tesco Stores</b>	Tesco Stores Limited v Office of Fair Trading [2012] CAT 31.
<b>TFEU</b>	Treaty on the Functioning of the European Union.

<b>Turnover Order</b>	The Competition Act 1998 (Determination of Turnover for Penalties) Order 2000 as amended by The Competition Act 1998 (Determination of Turnover for Penalties) (Amendment) Order 2004, SI 2004/1259.
<b>United Brands</b>	United Brands v Commission C-27/76, EU:C:1978:22
<b>United Brands Test</b>	A test for assessing unfair pricing set out by the Court of Justice in the United Brands case.



## ANNEX B – THE CMA’S DIRECTIONS

1. The CMA gives the Parties the following directions:
  - (a) The Parties shall bring the Infringements to an end and shall refrain from any conduct having the same or equivalent effect.
  - (b) Without prejudice to the generality of paragraph (a) of these directions:
    - (i) Pfizer shall, within thirty (30) Working Days from the date of these directions, apply revised supply prices for the supply of phenytoin sodium capsules by Pfizer to Flynn and any other potential purchaser in the UK ('the Pfizer Revised Supply Prices') which will replace the Pfizer Current Supply Prices;
    - (ii) Flynn shall, within thirty (30) Working Days from the date of these directions, replace its Current NHS List Prices with a revised set of NHS List Prices using the Pfizer Current Supply Prices (or, if different, it shall use the prices Flynn actually paid for the phenytoin sodium capsules stock that it holds) as its input prices ('the First Revised List Prices') and notify the NHSBSA of the First Revised List Prices; and
    - (iii) Flynn shall, within two working days of the date of having sold any phenytoin sodium capsules that Flynn purchased at the Pfizer Revised Supply Prices and in any case by no later than four (4) months from the date of these directions, replace the First Revised List Prices with a second set of revised NHS List Prices using the Pfizer Revised Supply Prices as its input prices ('the Second Revised List Prices') and notify the NHSBSA of the Second Revised List Prices.
  - (c) When setting the Pfizer Revised Supply Prices, the First Revised NHS List Prices or the Second Revised NHS List Prices (each 'Revised Prices'), reviewing the Revised Prices and/or making any future adjustment to the Revised Prices, Pfizer and Flynn, as applicable, shall each have regard to the content of this Decision.
  - (d) For the avoidance of doubt, nothing in these directions or the Decision should be taken to mean that the Parties are precluded from earning a profit margin greater than the reasonable rate of return adopted by the CMA for the purposes of establishing Cost Plus in this Decision.

- (e) The Parties shall, within five (5) Working Days of notifying the NHSBSA of the Revised Prices, notify the CMA of those Revised Prices.
- (f) If, within ten (10) years of the date of these directions, the Parties vary any of the Revised Prices (or, if the Revised Prices have been previously varied, the prices in effect at the relevant time) the Parties shall notify the CMA within five (5) Working Days of notifying the NHSBSA of the variation(s).
- (g) Each Party shall procure that each of its Subsidiaries complies with these directions.
- (h) Nothing in these directions should be taken to mean that Pfizer is obliged to supply phenytoin sodium capsules to Flynn or that Flynn is obliged to buy such products from Pfizer.
- (i) Nothing in these directions should be taken to apply to phenytoin sodium capsules not manufactured by Pfizer.
- (j) The CMA may, by written notice given to each Party, vary, supersede or withdraw these directions if, by reason of any change of circumstances, it considers that they are no longer appropriate. Before doing so, the CMA will give each Party a reasonable opportunity to make representations.
- (k) Each Party shall promptly provide to the CMA such information as the CMA may from time to time require for the purpose of ascertaining whether these directions are being or will be complied with or for the purpose of ascertaining whether they should be varied, superseded or withdrawn.
- (l) For the purposes of these directions the following definitions (in addition to those previously defined in this Decision) are adopted:
  - (ii) 'Current NHS List Price' means the NHS List Price for phenytoin sodium capsules as at the date of these directions;
  - (iii) 'Drug Tariff' means the list of prices and other information produced monthly by the Prescription Pricing Authority which outlines, amongst other things, the amounts pharmacy contractors (or dispensing doctors) are to be reimbursed for the cost of medicines or appliances which they have supplied against NHS prescriptions.

- (iv) 'NHS' means the National Health Service.
  - (v) 'NHSBSA' means the NHS Business Services Authority or any successor organisation;
  - (vi) 'NHS List Prices' means the prices submitted from time to time by Flynn to the NHSBSA for the supply of phenytoin sodium capsules, which is then published monthly by the NHSBSA in the Drug Tariff;
  - (vii) 'Pfizer Current Supply Prices' means Pfizer's price for the supply of phenytoin sodium capsules to Flynn as at the date of these directions;
  - (viii) 'Subsidiary' has the meaning given by section 1159 of the Companies Act 2006 (as amended); and
  - (ix) 'Working Day' means any day other than a Saturday, Sunday or any other day which is a public holiday in England.
- (m) The Interpretation Act 1978 shall apply to these directions as it applies to Acts of Parliament.

## ANNEX C – PFIZER'S DIRECT COSTS

- C.1 This annex sets out the components of Pfizer's direct costs in the manufacture and transport of phenytoin sodium capsules and the internal transfer prices incurred by Pfizer Limited.
- C.2 Pfizer provided the CMA with a breakdown of its standard manufacturing costs of each capsule strength by component.<sup>1</sup>
- C.3 Pfizer stated that *'the Active Pharmaceutical Ingredient ('API') is manufactured in [REDACTED] by Pfizer. The phenytoin sodium capsules are manufactured and turned into finished goods in Freiberg, Germany in a Pfizer facility. The capsules are then transported to the [REDACTED]'*.<sup>2</sup> The main change in the supply chain following the transfer of marketing rights to Flynn is that 'the ownership of the capsules transfer from Pfizer to Flynn at the [REDACTED] warehouse. Flynn is then responsible for the distribution of the capsules in the UK'. This distribution is still performed by [REDACTED].
- C.4 The main change in cost terms for Pfizer is a reduction in distribution costs as the transportation from [REDACTED] to pharmacies is now the responsibility of Flynn.
- C.5 Pfizer's direct costs for phenytoin sodium capsules are calculated on a standard costing basis. To calculate the actual direct costs it is necessary to adjust the standard cost for actual costs incurred. Pfizer stated though that '[REDACTED]'.<sup>3</sup> As such standard costs represent the best proxy for actual costs.
- C.6 Pfizer stated that [REDACTED].<sup>4</sup> Pfizer submitted that *'the corporate cost of goods sold is therefore a much better measure'*<sup>5</sup> of direct costs as it is more representative of the price Pfizer would have to pay a third party manufacturer to produce these products.
- C.7 Table C.1, Table C.2, Table C.3 and Table C.4 outline Pfizer's direct costs, including the breakdown of the various standard costs, the contributions to

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<sup>1</sup> Pfizer's manufacturing costs for phenytoin sodium capsules are calculated on a standard costing basis. To calculate the actual direct costs it is necessary to adjust the standard cost for actual costs incurred. Pfizer stated though that '[REDACTED]' (See document 00725.1, question 1, Annex A). As such standard costs represent the best proxy for actual costs.

<sup>2</sup> See document 00086.1, question 1.

<sup>3</sup> See document 00725.1, question 1, Annex A.

<sup>4</sup> As explained in document 00725.1, question 1, 'corporate COGS are the costs that Pfizer Ltd must cover and therefore, in effect, [REDACTED].

<sup>5</sup> See document 00725.1, question 1, Annex A.

overheads and the distribution costs. These figures are presented on a per pack basis.

**Table C.1: Direct cost per pack, 28 x 25mg capsules**

[REDACTED]

**Table C.2: Direct costs per pack of 28 x 50mg capsules**

[REDACTED]

**Table C.3: Direct costs per pack of 84 x 100mg capsules**

[REDACTED]

**Table C.4: Direct costs per pack of 28 x 300mg capsules**

[REDACTED]

- C.8 Table C.5 outlines Pfizer's weighted average standard manufacturing cost between October 2012 and September 2014. These figures are presented on a per pack basis.

**Table C.5: Weighted average standard manufacturing costs between October 2012 - September 2014**

[REDACTED]

- C.9 As shown in Table C.1 and Table C.2, the API costs of the packs of 25mg and 50mg of phenytoin sodium capsules are [REDACTED]. However, equipment costs of the 25mg packs are [REDACTED] than those of the 50mg packs and this [REDACTED]. Pfizer explained that this reflects economies of scale as '[REDACTED]'.<sup>6</sup>
- C.10 The 100mg and 300mg packs [REDACTED]. As shown in Table C.3 and Table C.4, the 100mg packs incur [REDACTED]<sup>7</sup> [REDACTED]. 100mg packs contain three times as many capsules as the 300mg packs, which drives the excipient requirements, and 100mg capsules are packaged in bottles which is [REDACTED] than the blister packs are used to package the 300mg capsules. However, these [REDACTED].

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<sup>6</sup> See document 00863.1, question 3.

<sup>7</sup> Excipients are the inactive substances that serve as the vehicle or medium for a drug or other active substance, such as phenytoin sodium.

C.11 The figures in Table C.1 to Table C.5 also show that Pfizer's standard manufacturing costs for the 50mg and 100mg capsules [REDACTED]. However, [REDACTED]. In response to this observation, Pfizer explained that '[REDACTED]'.<sup>8</sup> Since these differences are not material, the CMA considers it reasonable to continue using Pfizer's COGS as the measure of Pfizer's manufacturing cost of phenytoin sodium capsules.

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<sup>8</sup> See document 00725.1, question 2.i.

## **ANNEX D – COMMON COST ALLOCATION METHODOLOGIES**

### **A. Introduction**

- D 1. The CAT has recognised that where the alleged conduct relates to only one part of the business of a dominant firm, certain common costs may need to be allocated to the business in question.<sup>9</sup> There are various methods for making such allocations (e.g. by volume, value, time, etc.) but the most appropriate yardstick to use may depend on the particular circumstances of the case.
- D 2. The CMA considers that sales volume by number of packs should be its primary method, see section 5.C.III.b. This is because the number of packs ordered drives activities from procurement to invoicing, all of which require support activities which result in common costs such as employee costs, marketing expenses, professional/consulting fees and office expenses.
- D 3. In addition and as set out in section 5.C.III.b, the CMA has sought to verify the reliability of its preferred methodology by carrying out a sensitivity analysis in order to consider whether and to what extent different output-based methods of allocating costs may affect the amount of Cost Plus and, if so, alter the difference between Cost Plus and the Parties' Prices.
- D 4. This annex sets out the common cost allocation methodologies considered but rejected by the CMA (paragraphs D 5 to D 20).

### **B. Methodologies considered and rejected by the CMA**

#### ***I. Sales value***

- D 5. The data necessary to apply this method is easily obtainable since common costs are allocated according to the sales value of the relevant products.
- D 6. The PPRS states that '*scheme members are required to make such apportionments [i.e. the allocation of common costs] on the most realistic and reasonable basis possible*'.<sup>10</sup> When following this guidance, Pfizer used sales

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<sup>9</sup> *Claymore Dairies Ltd v OFT* [2005] CAT 25, [210].

<sup>10</sup> See paragraph 2.1 of the 2009 PPRS.

value to allocate common costs to Phenytoin sales.<sup>11</sup> It is also the allocation method suggested by Flynn.<sup>12</sup>

- D 7. The CMA does not consider that sales value is an appropriate or reliable method for allocating common costs in the particular circumstances of this case for the following reasons.
- D 8. First, sales value does not establish any meaningful link between the product and its costs. In *Claymore Dairies* the CAT held that “[s]o far as possible, cost allocations should reflect the underlying business reality”;<sup>13</sup> yet there is no necessary correlation between the sales revenues of phenytoin sodium capsules and their costs. On the contrary, this type of cost allocation is inconsistent with the principle of cost causality, according to which costs should be allocated to the source that caused those costs to be incurred. If costs are allocated on the basis of net sales revenues, where some of the prices that generated those revenues are potentially excessive, there is a significant risk that costs will be misallocated, possibly materially. The value-based methodology results in more costs being allocated to the products with the highest prices. The CMA considers that such an allocation method based on sales value would be incompatible with the task at hand, namely assessing whether prices were excessive.
- D 9. Second, value-based cost assessments are likely to give rise to a circularity problem because indirect costs would be weighted towards the potentially excessively priced product or service. This would have an effect on the resultant margin, which could lead to inaccurate or misleading margins across products by reducing the margin on the highest price products and inflating margins on the lowest price products.<sup>14</sup> This problem was recognised by the CAT in *Genzyme* where it confirmed that the OFT was right to reject *'Healthcare at Home's submission that certain costs should be allocated solely according to turnover: such an approach would allocate an unduly high proportion of overheads to Cerezyme, because of the high cost of the drug'*.<sup>15</sup>
- D 10. As such, this allocation method does not help to establish the costs attributable to phenytoin sodium capsules. In conclusion, the CMA finds that sales value provides

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<sup>11</sup> See document 00903.2.

<sup>12</sup> See document 00505.1, question 9.

<sup>13</sup> *Claymore Dairies v Office of Fair Trading* [2005] CAT 30, [211].

<sup>14</sup> An illustrative example is that during Q2 of FY12, when Pfizer sales were made direct to pharmacy (DTP), Pfizer received orders of phenytoin sodium capsules. In the same period of FY13, after the Agreements came into effect, this number fell to [§]. As such, one would expect administrative expenses relating to phenytoin sodium capsules to have fallen. Yet using sales value as an allocation method, the common cost allocated to phenytoin sodium capsules would rise from [§] in FY11, during which all sales were made DTP, to [§] in FY13, under a full year of the Exclusive Supply Agreement. In this regard, see also, for example, document 00664.1, question 5.ii.

<sup>15</sup> *Genzyme Remedy*, [268].



neither an accurate nor a consistent basis on which to allocate common costs in this case.

## **II. Direct costs**

- D 11. Under this method, common costs would be allocated to a product based on the size of its direct costs. This method was rejected as direct costs are not deemed to be an accurate driver of common costs. The manufacturing cost or purchase price of products will not affect administrative costs such as employee costs or premises and utilities costs. As such it is wrong to draw a relationship between these two expenses.
- D 12. Furthermore, the use of direct costs as an allocation method was considered and expressly rejected by the CAT in *Genzyme*.<sup>16</sup> In the present case, the high price paid by Flynn would lead to a high proportion of Flynn's common costs being attributed to that product, regardless of the amount of common costs that are incurred as a result of supplying the product. It is wrong in principle to use a cost allocation method that risks overstating the actual costs of supply for one product and, as a corollary, understating the costs of supply of other products.

## **III. Number of orders processed / Number of customers**

- D 13. As Pfizer has stated, using the number of orders processed or the number of customers leads to results which '*will depend hugely on the specific nature of the distribution model used for that drug e.g. direct supply to pharmacies or direct supply mainly to hospitals etc*'.<sup>17</sup>
- D 14. As illustrated in Pfizer's response,<sup>18</sup> the number of orders placed fell from [X] in Q2 of FY12 to [X] in Q2 of FY13 whilst the number of customers fell from [X] to 1 over the same period. Yet [X]. These differences in the distribution models mean that neither method will provide consistent or comparable results across different products. Furthermore '[X]'.<sup>19</sup> As such, these methods have not been pursued as viable method for allocating common costs.

## **IV. Time spent by each employee / Square footage**

- D 15. Methods of common cost allocation that allocate costs based on time spent by each employee or square footage only provide good drivers for very specific

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<sup>16</sup> *Genzyme Remedy*, [268].

<sup>17</sup> See document 00863.1, question 5.ii, Annex A.

<sup>18</sup> See document 00863.1, question 5.ii, Annex A.

<sup>19</sup> See document 00863.1, question 5.ii, Annex A.

costs, such as employee costs and premises costs or depreciation. Whilst the CMA did consider using separate allocation methods for each common cost, depending on their individual nature, these methods are not deemed appropriate.

- D 16. Asking each member of staff to allocate how much time they spend on phenytoin sodium capsules would be a very onerous exercise for both parties. Using a sample was considered, but given the variety of departments that employees work in, how their time commitments will differ, and the level of judgement involved, any sample is unlikely to provide a reliable indicator.
- D 17. Square footage is likely to be impossible to measure given there is not a phenytoin sodium dedicated team or a department which deals specifically with this product.
- D 18. Additionally, these methods would not provide bases for allocating any other common cost. Therefore, the CMA has decided not to adopt this method.

#### ***V. Equipment hours***

- D 19. Equipment hours is a good basis for allocating common manufacturing costs as it provides a good proxy for the driver of these costs which include engineering and the site leader's salary. Indeed it was used by Pfizer to allocate these costs.
- D 20. However they are not an appropriate indicator of the drivers of Pfizer or Flynn's common costs as there will be no correlation between the level of equipment hours each product requires and the types of costs included within administrative expenses. Therefore this method was also rejected.

#### **C. Pfizer's submission regarding its proposed allocation methodology**

- D 21. Pfizer submitted that it [redacted]. As such the profitability that Pfizer records for each product is a contribution margin (i.e. gross margin minus distribution costs) [redacted]. However, [redacted], contribution margin is not a sufficiently complete profitability measure for the purposes of the CMA's assessment.
- D 22. Pfizer did not propose an allocation methodology for common costs and therefore, for the reasons outlined in section 5.C.III.b, the CMA adopted volumes-related measures to allocate common costs across its portfolio of products.

## D. Flynn's submission regarding its proposed allocation methodology

D 23. [REDACTED].<sup>20</sup>

D 24. Flynn also submitted that by rejecting the allocation of common costs by revenue, the CMA had departed from the principles that underpin the PPRS because '*general administrative expenses are allocated pro rata to sales revenue under the PPRS*'.<sup>21</sup> Flynn submitted that '*Insofar as the CMA is seeking to model its assessment of profitability on how the PPRS analyses the profitability of the branded products of scheme members, it should, as a bare minimum, not depart from some of the key principles which underpin the PPRS and which reflect the specificities of the pharmaceutical industry (albeit only as regards branded pharmaceuticals)*'.<sup>22</sup>

D 25. The CMA rejects Flynn's contention for several reasons.

D 26. First, Flynn's preferred method of allocating costs on the basis of net product sales suffer from the inadequacies of value-based cost drivers for the assessment of pricing abuses under competition law: see paragraphs D 5 to D 20 above.

D 27. Second, and in any event, the CMA is not seeking (and has never sought) to model its assessment of the parties' conduct on how the PPRS analyses profitability. Rather, it has allocated common costs on a sales volume basis (by number of packs, and then cross-checked by capsules and DDD) in order to arrive at a sufficiently reliable and robust measure of the costs actually incurred in the production or distribution of phenytoin sodium capsules.

D 28. Third, the practical implication of using Flynn's preferred method would be that more than [REDACTED] of Flynn's common costs would be allocated to phenytoin sodium capsules, thereby producing inaccurate and highly misleading profitability findings. It is only by using this flawed methodology that Flynn recalculates its overall excess on the sale of phenytoin sodium capsules to be [REDACTED].<sup>23</sup> Additionally, under this method, the profitability of Flynn's other products would increase significantly solely due to phenytoin sodium capsules being added to Flynn's portfolio of products.

D 29. Fourth, Flynn's suggested use of product contribution as a measure of profitability is inconsistent with the approach it has adopted when recalculating the excesses under the assumptions set out in the PPRS. That is because under the product

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<sup>20</sup> See document 00505.1, paragraph 6.2.

<sup>21</sup> See document 01639.3, paragraph 5.20.

<sup>22</sup> See document 01639.3, paragraph 5.19.

<sup>23</sup> See document 01639.3, paragraph 5.24.

contribution measure, particular administrative expenses that can be individually associated with specific products are allocated in full to those products. This approach is desirable since it links individual costs to the products that generate them. However, it differs from the PPRS methodology which allocates all administrative expenses across products in line with their net sales revenue proportions. This further supports the conclusion that the PPRS methodology for allocating common costs is inappropriate in this case.

- D 30. For all these reasons, the CMA is satisfied that it has adopted the correct methodology for allocating common costs and that sales revenue should not be adopted as an alternative method within its sensitivity analysis.

## ANNEX E – PFIZER LIMITED’S COMMON COSTS

### A. Introduction

- E.1. This annex sets out the details of the common costs that Pfizer considered were in part related to phenytoin sodium capsules<sup>24</sup> and the CMA’s allocation of these costs.
- E.2. The CMA’s approach has been to allocate common costs to Phenytoin products as a whole using sales volumes by pack, see section 5.C.III.b.
- E.3. The CMA has approached the task of allocating costs in a manner that is favourable to the Parties. With the exception of general marketing expenses, see paragraphs E.12 and E.13, this has meant that if there has been a degree of uncertainty as to whether a cost category is attributable to phenytoin sodium capsules, the CMA has erred on the side of including this cost as part of its allocated costs. The CMA has had to take this approach where Pfizer failed to provide the CMA with sufficient details to the CMA regarding the nature and origin of the cost. Therefore, where Pfizer could provide the total value of a cost category only and the CMA considered that at least part of that cost should be allocated to phenytoin sodium capsules, then the total cost has been used as the basis for the allocation. The CMA recognises that an inevitable consequence of this approach to the allocation of common costs is that the estimated common costs attributed to phenytoin sodium capsules are likely to be overstated. The corollary is also true: this approach to common cost allocation will tend to understate Pfizer’s profits. Nevertheless, the CMA considers Pfizer’s prices to be excessive even though the CMA has applied this generous approach.

### B. Pfizer Group structure and reorganisation prior to 1 December 2013

- E.4. [REDACTED].
- E.5. [REDACTED].
- E.6. [REDACTED]<sup>25</sup> [REDACTED].
- E.7. [REDACTED].

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<sup>24</sup> See document 00725.4.

<sup>25</sup> [REDACTED].

E.8. [REDACTED].

**Table E 1: Pfizer, common costs (Sales, Informational and Administrative) allocation to phenytoin sodium capsules for the year ended 30 November 2012**

[REDACTED]

**Table E 2: Pfizer, common costs (Sales, Informational and Administrative) allocation to phenytoin sodium capsules for the year ended 30 November 2013**

[REDACTED]

### ***I. EPBU common costs***

E.9. [REDACTED]

- a. [REDACTED].<sup>26</sup>
- b. [REDACTED].<sup>27</sup> [REDACTED].<sup>28</sup>
- c. [REDACTED]
- d. [REDACTED].

### ***II. Pfizer Limited common costs***

- E.10. The information provided by Pfizer in response to the CMA's requests for information did not enable the CMA to carry out a detailed analysis of Pfizer Limited's common costs. Pfizer did not propose the inclusion or exclusion of any of Pfizer Limited's costs or make submissions on which allocation method would be most appropriate to use.
- E.11. Only one adjustment was made to Pfizer Limited's common costs before apportioning them to phenytoin sodium capsules: the exclusion of general marketing expenses.
- E.12. Pfizer submitted to the CMA that it had wrongly excluded general marketing expenses from its cost analysis. It was said this category of cost included expenses such as business analytics and stock option costs, which applied across multiple product lines and were therefore applicable to phenytoin sodium capsules.<sup>29</sup> The CMA rejects the inclusion of these costs for two reasons. The first reason is that it

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<sup>26</sup> See document 00725.1, question 6.

<sup>27</sup> See document 00725.1, question 6.

<sup>28</sup> See document 00725.1, question 4.

<sup>29</sup> See document 01622.2, paragraphs 326 and 327.

has been calculating costs in respect of phenytoin sodium capsules after Pfizer divested its MAs to Flynn, i.e. since 24 September 2012. It follows that general marketing expenses should be excluded from the CMA's common cost allocation exercise.

- E.13. The second reason is that the CMA's approach to allocating common costs to phenytoin sodium capsules has been very generous to Pfizer.<sup>30</sup> This means that any risk of understating any indirect costs attributable to capsules from this category will be offset by the likely overstating of other cost categories.<sup>31</sup> Finally, Pfizer has only provided very high level data with regards to its common costs, despite the CMA requesting more detailed information,<sup>32</sup> and Pfizer has made no attempt in any of its submissions, including in its representations on the SO, to quantify the size of these costs or the impact that their inclusion would have on the CMA's assessment. As such, the CMA considers that the exclusion of general marketing expenses from this analysis is both appropriate and unlikely to affect materially the estimation of Pfizer's costs.

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<sup>30</sup> As demonstrated by the common cost to direct cost ratios outlined in section 5.C.IV.a.iv.

<sup>31</sup> For instance, the CMA has allocated employee costs of [REDACTED] per year to phenytoin sodium capsules. The CMA considers that this is a very generous allocation, particularly as it is a product with only one customer submitting its product orders once every fortnight.

<sup>32</sup> See documents 00519.2, 00664.1 and 00863.1.

## ANNEX F – FLYNN'S COMMON COSTS

- F.1. This annex sets out the details of Flynn Pharma Limited's common costs that Flynn considered were in part related to phenytoin sodium capsules,<sup>33</sup> and the CMA's allocation of these costs.
- F.2. The CMA's approach has been to allocate common costs to phenytoin products as a whole, using sales volumes by pack, see section 5.C.III.b.
- F.3. The CMA has approached the task of allocating costs in a manner that is favourable to the Parties. This has meant that if there has been a degree of uncertainty as to whether a cost category is attributable to phenytoin sodium capsules, the CMA has erred on the side of including this cost as part of its allocated costs. Therefore, where Flynn could provide the total value of a cost category only and the CMA considered that at least part of that cost should be allocated to phenytoin sodium capsules, then the total cost has been used as the basis for the allocation. The CMA recognises that an inevitable consequence of this approach to the allocation of common costs is that the estimated common costs attributed to phenytoin sodium capsules are likely to be overstated. The corollary is also true: this approach to common cost allocation will tend to understate Flynn's profits. Nevertheless Flynn's prices to be excessive even though the CMA has applied this generous approach.
- F.4. Table F 1 shows the common costs (administrative expenses) and the amounts the CMA allocated to phenytoin sodium capsules between 1 April 2012<sup>34</sup> and 30 June 2016. [✂].

**Table F 1: Flynn Pharma Limited's common costs (administrative expenses) for the period 1 April 2012 and 30 June 2016**

[✂]

- F.5. The CMA considered that the following administrative expenses could reasonably be expected to have been incurred as part of Flynn's activities when it sold phenytoin sodium capsules during the Relevant Period —Premises and Utilities costs, Computer and Telephone, Insurance, Stationery and Printing expenses and Consultancy, Legal and Professional costs. For this reason, no adjustments were

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<sup>33</sup> See documents 00607.2, 02115.4 and 02115.5.

<sup>34</sup> Common costs from 24 September 2012 to 31 March 2013 were accounted for within the financial year ending 31 March 2013. Although this covers a period over which Flynn was not selling phenytoin sodium capsules in the UK, the CMA has allocated these common costs using sales volumes across Flynn's entire portfolio of products for the 12 months from 1 April 2012. Therefore, the CMA considers that this methodology leads to a reasonable proxy for the level of common costs that would have been attributed to phenytoin sodium capsules if data between 24 September 2012 up to 31 March 2013 were available.



made to any of these cost categories before they were allocated to phenytoin sodium capsules.

F.6. [X]

a. [X]

b. [X].

c. [X].

d. [X].<sup>35</sup>

e. [X].

f. [X].<sup>36</sup>[X].

g. [X].<sup>37</sup> [X] .

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<sup>35</sup> See document 00607.6.

<sup>36</sup> See document 00607.6 and 00607.7.

<sup>37</sup> See document 00872.1, question 8.

## ANNEX G – COMMON COST ALLOCATION SENSITIVITY ANALYSES

### A. Introduction

G.1. This Annex sets out details of the CMA’s sensitivity analyses for each of Pfizer and Flynn using the two alternative common cost allocation methods described in section 5.C.III.b: sales volume by capsule; and sales volume by DDD. Both of these alternative allocation methods apply after common costs are first allocated to phenytoin sodium capsules as a whole using sales volumes. Ratios are then calculated using the number of capsules and DDD of each pack. These ratios are then used to allocate the common costs across the different capsule strengths.

### B. Pfizer’s common cost sensitivity analysis

G.2. The following three tables set out the results of the three allocation methods: Sales volume by pack (main method used by CMA); sales volume by capsule; and sales volume by DDD.

**Table G 1: Pfizer’s return on sales between September 2012 and June 2016 after allowing for a reasonable return using a sales volume by pack common cost allocation method**

Allocated using sales volumes by pack	25mg	50mg	100mg	300mg	Total PS	Total Pfizer	Total EPBU
Pack volumes FY2013	[X]	[X]	[X]	[X]	[X]	[X]	[X]
% of Pfizer Ltd volume	[X]	[X]	[X]	[X]	[X]		
% of EPBU volume	[X]	[X]	[X]	[X]	[X]		
Allocated Pfizer Ltd common cost per pack	[X]	[X]	[X]	[X]			
Allocated EPBU common cost per pack	[X]	[X]	[X]	[X]			
Total allocated common cost per pack	[X]	[X]	[X]	[X]			
Revenue per pack	[X]	[X]	[X]	[X]			
Direct costs per pack	[X]	[X]	[X]	[X]			
Common costs per pack (as shown above)	[X]	[X]	[X]	[X]			
Allowance for reasonable return	[X]	[X]	[X]	[X]			
<b>Excess per pack (£)</b>	<b>[£1.00-£2.99]</b>	<b>[£3.00-£5.99]</b>	<b>[£31 - £40.99]</b>	<b>[£31 - £40.99]</b>			
<b>Excess (%)</b>	<b>29%</b>	<b>100%</b>	<b>705%</b>	<b>690%</b>			

**Table G 2: Pfizer's return on sales between September 2012 and June 2016 after allowing for a reasonable return using a sales volume by capsules common cost allocation method**

<b>Allocated using</b>	<b>25mg</b>	<b>50mg</b>	<b>100mg</b>	<b>300mg</b>	<b>Total phenytoin</b>
Capsules volumes FY13	[✂]	[✂]	[✂]	[✂]	[✂]
% of PS total	[✂]	[✂]	[✂]	[✂]	
Allocated Pfizer Ltd common cost	[✂]	[✂]	[✂]	[✂]	
Allocated EPBU	[✂]	[✂]	[✂]	[✂]	
<b>Total allocated common cost</b>	[✂]	[✂]	[✂]	[✂]	
Revenue per	[✂]	[✂]	[✂]	[✂]	
Direct costs	[✂]	[✂]	[✂]	[✂]	
Common costs per pack (as	[✂]	[✂]	[✂]	[✂]	
Allowance for reasonable	[✂]	[✂]	[✂]	[✂]	
<b>Excess per</b>	<b>[£1.00-£2.99]</b>	<b>[£3.00-£5.99]</b>	<b>[£31-£40.99]</b>	<b>[£31-£40.99]</b>	
<b>Excess (%)</b>	<b>87%</b>	<b>194%</b>	<b>491%</b>	<b>924%</b>	

**Table G 3: Pfizer's return on sales between September 2012 and June 2016 after allowing for a reasonable return using a sales volume by defined daily dosage common cost allocation method**

Allocated using DDD	25mg	50mg	100mg	300mg	Total phenytoin
Defined daily dosages FY13	[X]	[X]	[X]	[X]	[X]
% of PS total	[X]	[X]	[X]	[X]	
Allocated Pfizer Ltd common cost per pack	[X]	[X]	[X]	[X]	
Allocated EPBU common cost per pack	[X]	[X]	[X]	[X]	
<b>Total allocated common cost per pack</b>	[X]	[X]	[X]	[X]	
Revenue per pack	[X]	[X]	[X]	[X]	
Direct costs per pack	[X]	[X]	[X]	[X]	
Common costs per pack (as shown)	[X]	[X]	[X]	[X]	
Allowance for reasonable return	[X]	[X]	[X]	[X]	
<b>Excess per pack (£)</b>	<b>[£3.00-£5.99]</b>	<b>[£3.00-£5.99]</b>	<b>[£31-£40.99]</b>	<b>[£31-£40.99]</b>	
<b>Excess (%)</b>	<b>237%</b>	<b>332%</b>	<b>515%</b>	<b>504%</b>	

### C. Flynn's common cost sensitivity analysis

G.3. The following three tables set out the results of the three allocation methods: Sales volume by pack (main method used by CMA); sales volume by capsule; and sales volume by DDD.

**Table G 4: Flynn's return on sales between September 2012 and June 2016 after allowing for a reasonable return using a sales volume by pack common cost allocation method**

<b>Allocated using pack</b>	<b>25mg</b>	<b>50mg</b>	<b>100mg</b>	<b>300mg</b>	<b>Flynn total</b>
<u>FY2013</u>					
Pack	[X]	[X]	[X]	[X]	[X]
% of Flynn	[X]	[X]	[X]	[X]	
Flynn common					
<u>FY2014</u>					
Pack	[X]	[X]	[X]	[X]	[X]
% of Flynn	[X]	[X]	[X]	[X]	
Flynn common	[X]	[X]	[X]	[X]	
<u>January 2015 – June 2016<sup>38</sup></u>					
Pack	[X]	[X]	[X]	[X]	[X]
% of Flynn	[X]	[X]	[X]	[X]	
<u>FY2015</u>					
% of Flynn	[X]	[X]	[X]	[X]	
Flynn common	[X]	[X]	[X]	[X]	
<u>FY2016</u>					
% of Flynn	[X]	[X]	[X]	[X]	
Flynn common	[X]	[X]	[X]	[X]	
<u>3 months to</u>					
% of Flynn	[X]	[X]	[X]	[X]	
Flynn common	[X]	[X]	[X]	[X]	
Revenue	[X]	[X]	[X]	[X]	
Direct costs	[X]	[X]	[X]	[X]	
Common costs per	[X]	[X]	[X]	[X]	
Allowance	[X]	[X]	[X]	[X]	
<b>Excess per</b>	<b>[£6.00-£8.99]</b>	<b>[£3-£5.99]</b>	<b>[£11-£20.99]</b>	<b>[£11-£20.99]</b>	
<b>Excess (%)</b>	<b>133%</b>	<b>70%</b>	<b>31%</b>	<b>36%</b>	

**Table G 5: Flynn's return on sales between September 2012 and June 2016 after allowing for a reasonable return using a sales volume by capsules common cost allocation method**

<b>Allocated using capsules sales volumes</b>	<b>25mg</b>	<b>50mg</b>	<b>100mg</b>	<b>300mg</b>	<b>Total PS</b>
Capsules volumes	[X]	[X]	[X]	[X]	[X]
% of PS total	[X]	[X]	[X]	[X]	
Flynn common cost per pack	[X]	[X]	[X]	[X]	
Revenue per pack	[X]	[X]	[X]	[X]	
Direct costs per pack	[X]	[X]	[X]	[X]	
Common costs per pack	[X]	[X]	[X]	[X]	
Allowance for reasonable return	[X]	[X]	[X]	[X]	
<b>Excess per pack (£)</b>	<b>[£6-£8.99]</b>	<b>[£6-£8.99]</b>	<b>[£11-£20.99]</b>	<b>[£11-£20.99]</b>	
<b>Excess (%)</b>	<b>150%</b>	<b>79%</b>	<b>28%</b>	<b>38%</b>	

<sup>38</sup> From 1 April 2014, Flynn's total volumes figures were only made available between January 2015 and June 2016. Therefore, the volumes ratio over that period were used to allocate common costs during FY2015, FY2016 and the 3 months to 30 June 2016.

**Table G 6: Flynn's return on sales between September 2012 and June 2016 after allowing for a reasonable return using a sales volume by defined daily dosage common cost allocation method**

<b>Allocated using DDD</b>	<b>25mg</b>	<b>50mg</b>	<b>100mg</b>	<b>300mg</b>	<b>Total PS</b>
Defined daily dosages	[✂]	[✂]	[✂]	[✂]	[✂]
% of PS total	[✂]	[✂]	[✂]	[✂]	
Flynn Pharma Ltd common cost per pack	[✂]	[✂]	[✂]	[✂]	
Revenue per pack	[✂]	[✂]	[✂]	[✂]	
Direct costs per pack	[✂]	[✂]	[✂]	[✂]	
Common costs per pack	[✂]	[✂]	[✂]	[✂]	
Allowance for reasonable return	[✂]	[✂]	[✂]	[✂]	
<b>Excess per pack (£)</b>	<b>[£9-£10.99]</b>	<b>[£6-£8.99]</b>	<b>[£11-£20.99]</b>	<b>[£11- £20.99]</b>	
<b>Excess (%)</b>	<b>176%</b>	<b>88%</b>	<b>28%</b>	<b>34%</b>	

## ANNEX H – THE EFFECT OF THE PARTIES’ PRICE CHANGES ON THEIR RESPECTIVE EXCESSES

### A. Introduction

H.1. At the beginning of 2014, Pfizer and Flynn decreased their respective prices of phenytoin sodium capsules. In February 2014, Pfizer decreased its prices retrospectively for all sales from January 2014 and going forward. A rebate was also provided for all stock held by Flynn based on the new supply price. Subsequently, Flynn decreased its supply price to wholesalers from April 2014.

### B. Pfizer

H.2. From February 2014, Pfizer lowered the price of the 50mg, 100mg and 300mg phenytoin sodium capsules it sold to Flynn. The new prices were set retrospectively for all sales from the 1 January 2014 and for all stock held by Flynn as of the 31 December 2013. The CMA believes that the prices remain excessive after the price change but has decided to present the Parties' results for the different time periods. Since the price changes were backdated to the 1 January 2014, the CMA believes Pfizer has two relevant time periods:

- a. First period: September 2012 to 31 December 2013, which includes the rebate on all stock held as at 31 December 2013.
- b. Second period: 1 January 2014 to 30 June 2016, from the date these sales were backdated.

H.3. The CMA has calculated the value of Pfizer's rebate on the stock held by Flynn as at the 1 January 2014. The approach taken was to apply the prices from 1 March 2014 to the volumes sold during January and February 2014 to determine what the revenue figures would have been over this period had been applied as of 1 January 2014. This calculation is outlined in Table H.1.

**Table H.1: Pre January 2014 rebate value**

[✂]

H.4. [✂]

H.5. Using the rebate adjustment set out in Table H.1, Pfizer’s excesses during the periods of September 2012 to December 2013, period to some of Pfizer’s Prices decreasing, and between January 2014 to June 2016, subsequent to Pfizer’s Prices decreasing, are set out in Table H.2 and Table H.3 respectively.



**Table H.2: Pfizer's excesses on sales of phenytoin sodium capsules between September 2012 and December 2013 (prior to some of Pfizer's Prices decreasing)**

	Capsule strength (mg)				Total sales
	25mg	50mg	100mg	300mg	
Revenue	[✂]	[✂]	[✂]	[✂]	[£30m - £39m]
Cost Plus	[✂]	[✂]	[✂]	[✂]	[✂]
Excess (revenue)	[✂]	[✂]	[✂]	[✂]	[£25.2m - £33.5]
Price per pack	[£3.00 - £5.99]	[£6.00 - £8.99]	[£31.00 - £40.99]	[£31.00 - £40.99]	N/A
Excess per pack	[£1.00 - £2.99]	[£3.00 - £5.99]	[£31.00 - £40.99]	[£31.00 - £40.99]	N/A
Excess (%)	<b>29%</b>	<b>109%</b>	<b>771%</b>	<b>785%</b>	<b>526%</b>

**Table H.3: Pfizer's excesses on sales of phenytoin sodium capsules between January 2014 and June 2016 (after some of Pfizer's Prices decreased)**

	Capsule strength (mg)				Total sales
	25mg	50mg	100mg	300mg	
Revenue	[✂]	[✂]	[✂]	[✂]	[£30m - £39m]
Cost Plus	[✂]	[✂]	[✂]	[✂]	[✂]
Excess (revenue)	[✂]	[✂]	[✂]	[✂]	[£23.7m - £31.6m]
Price per pack	[£3.00 - £5.99]	[£6.00 - £8.99]	[£31.00 - £40.99]	[£31.00 - £40.99]	N/A
Excess per pack	[£1.00 - £2.99]	[£3.00 - £5.99]	[£21.00 - £30.99]	[£21.00 - £30.99]	N/A
Excess (%)	<b>29%</b>	<b>94%</b>	<b>629%</b>	<b>630%</b>	<b>379%</b>

H.6. As can be seen, while Pfizer's excesses for its 50mg, 100mg and 300mg capsules were lower following the price decreases than they had been prior to then,<sup>39</sup> the CMA considers that each of those excesses are nevertheless both material and sufficiently large to be deemed 'excessive' in the context of the *United Brands* Test.

<sup>39</sup> Pfizer's excess for 25mg capsules do not change as Pfizer did not change its price for 25mg capsules.

## C. Flynn

H.7. Flynn subsequently introduced their own price decreases in April 2014, although they were not backdated and did not include any rebate. As such Flynn's two relevant time periods are:

- a. First period: September 2012 to 31 March 2014.
- b. Second period: 1 April 2014 to 30 June 2016.

H.8. Table H.4 sets out what Flynn's excesses are for the period of September 2012 to March 2014, prior to some of Flynn's Prices decreasing, and Table H.5 sets out Flynn's excesses between April 2014 to June 2016, subsequent to some of Flynn's Prices decreasing.

**Table H.4: Flynn's excesses on sales of phenytoin sodium capsules between September 2012 and March 2014 (prior to some of Flynn's Prices decreasing) after allowing for a rate of return on sales of 6%**

	Capsule strength (mg)				Total sales
	25mg	50mg	100mg	300mg	
Revenue	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[£50m-£59m]
Cost Plus	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Excess (revenue)	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[£10m - £15m]
Price per pack	[£11-£20.99]	[£11-£20.99]	[£51 - £60.99]	[£51-£60.99]	N/A
Excess per pack	[£6 - £8.99]	[£3 - £5.99]	[£11- £20.99]	[£11- £20.99]	N/A
Excess (%)	121%	58%	30%	31%	36%

**Table H.5: Flynn's excesses on sales of phenytoin sodium capsules between April 2014 and June 2016 (after some of Flynn's Prices decreased) after allowing for a rate of return on sales of 6%**

	Capsule strength (mg)				Total sales
	25mg	50mg	100mg	300mg	
Revenue	[ <del>£</del> ]	[ <del>£</del> ]	[ <del>£</del> ]	[ <del>£</del> ]	[£40m - £49m]
Cost Plus	[ <del>£</del> ]	[ <del>£</del> ]	[ <del>£</del> ]	[ <del>£</del> ]	[ <del>£</del> ]
Excess (revenue)	[ <del>£</del> ]	[ <del>£</del> ]	[ <del>£</del> ]	[ <del>£</del> ]	[£12.8m - £16m]
Price per pack	[£11-£20.99]	[£11-£20.99]	[£41 - £50.99]	[£51 - £60.99]	N/A
Excess per pack	[£6 - £8.99]	[£6 - £8.99]	[£11 - £20.99]	[£11 - £20.99]	N/A
Excess (%)	143%	81%	31%	41%	47%

H.9. As can be seen, due to the fall in Pfizer's Prices and the change in Flynn's distribution model, Flynn's percentage excesses in the second of these periods actually increased and are greater than its percentage excesses across the whole of the Relevant Period. Accordingly, the CMA considers that Flynn's excesses remain excessive by any reasonable measure.

## ANNEX I - CALCULATION OF PFIZER'S ROCE

- I.1. This annex sets out the CMA's calculation of Pfizer's ROCE.
- I.2. Pfizer submitted that it employs capital at four stages of its supply chain:<sup>40</sup>
  - a. Assets associated with the production of API in [X]
  - b. Assets at the Freiburg production facility (Germany)
  - c. Assets supporting the management functions in the UK
  - d. Working capital.
- I.3. The API is manufactured by Pfizer in [X] and purchased by the manufacturing facility in Freiburg where it is used in the production of phenytoin sodium capsules. In its response to the CMA, Pfizer did not provide details of the capital employed to produce the API at [X]<sup>41</sup> As such the CMA has assumed that the charge to the Freiburg facility of purchasing their API from [X] follows Pfizer's typical process of being '[X]'<sup>42</sup> The inter-company adjustment represents a margin which should satisfy [X] return on capital requirement. Therefore the CMA's ROCE analysis starts from the point at which the data was made available; the Freiburg facility.
- I.4. Pfizer stated that *'Freiburg is a multi-purpose plant that produces several products and there is no dedicated line for phenytoin or any other product'*.<sup>43</sup> As such, it believed that a bottom-up approach of its phenytoin production assets was not possible. Furthermore, it stated that there were no dedicated parts of the Freiburg facility for phenytoin sodium capsules. Therefore, Pfizer proposed, and produced, a capital asset valuation based on a top down approach.
- I.5. The value of the assets will have a significant impact on the resulting ROCE figures. The asset figures provided to the CMA were valued at GBV and NBV, as recorded within Pfizer's financial statements. As a result, the age and depreciation policies of a company can have a material effect on the ROCE. To compensate for this, assets are usually revalued to reflect their current cost. As Pfizer did not produce a bottom up valuation of its assets and therefore also did not revalue them to current cost, the CMA has calculated a range for ROCE using both NBV and GBV to reduce the risk of a material misstatement of ROCE.

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<sup>40</sup> See documents 00903.1 and 00903.2.

<sup>41</sup> See documents 00903.1 and 00903.2.

<sup>42</sup> See document 00725.1, question 2.

<sup>43</sup> See document 00903.1 and 00903.2.

- I.6. The Freiburg site's assets' GBV and NBV were provided by Pfizer for the years ending 30 November 2012 and 2013 and are outlined in Table I.1.<sup>44</sup> The CMA allocated these assets to all phenytoin sodium capsules produced at this facility based on the proportion of phenytoin sodium capsule equipment hours at Freiburg compared with all other products, details of which are provided in Table I.2.<sup>45</sup>
- I.7. Once this amount was attributed to phenytoin sodium capsules as a whole, it was allocated to UK phenytoin sodium capsules using the number of capsules sold in the UK as a proportion of the total number of capsules produced at the Freiburg facility. These volumes are provided in Table I.3 and the results of this allocation are outlined in Table I.4.
- I.8. Pfizer did not provide any specific data in respect of its capital assets employed in supporting the management functions in the UK. For consistency the CMA decided to adopt a similar approach to that suggested by Pfizer to assign the Freiburg facility assets to phenytoin sodium capsules. Capital was attributed using the GBV and NBV of Pfizer Limited's fixed assets for the year ended 30 November 2012 and 2013 which are provided in Table I.5. These assets were allocated to phenytoin sodium capsules using the sales volume figures of Pfizer Limited, outlined in Table I.6. The results of this allocation are provided in Table I.7. This is also the approach adopted by the CMA for allocating common costs.
- I.9. Pfizer's fixed assets are tangible, intangible and financial. The tangible assets of Pfizer Limited as set out in its financial statements include freehold land and building, leasehold improvements and plant and equipment. All these categories of fixed assets are included in the CMA's assessment. Pfizer Limited's intangible assets include concessions, patents, licenses and trademarks. The CMA considers that no intangible assets were applicable to phenytoin sodium capsules as the product is off patent. As such, they have been excluded from the assessment. Financial fixed assets comprise shares in group undertakings, partnerships and joint ventures. None of these are considered to be applicable to phenytoin sodium capsules and as such, these assets have also been excluded from the CMA's analysis.
- I.10. It is the CMA's view that working capital should be included in Pfizer's capital employed balance. Pfizer only included stock in its calculation of working capital. It stated that whilst phenytoin sodium capsule stock is separately identified within its management accounts, other elements of working capital (e.g. debtors and creditors) are not. Pfizer's stock calculation included: API ([~~⊗~~]), Work in Progress/Finished Product (Freiburg) and Finished Products

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<sup>44</sup> See document 00903.2.

<sup>45</sup> See document 00903.2.

(UK). The first two categories have been allocated to the UK using total production volumes. The final category is fully allocated to the UK.

- I.11. Pfizer stated that debtor and creditor balances would be too difficult to produce. The CMA considers that as a result of the price for Flynn, debtors are likely to exceed creditors. This would increase the capital employed figures and consequently reduce the ROCE. However, since all debtor balances are settled within one month, the CMA considers the excess is unlikely to be material. Therefore the CMA is comfortable proceeding with stock as its only working capital balance. These working capital figures and the amounts allocated to phenytoin are outlined in Table I.8.
- I.12. Throughout the analysis, the CMA has looked to use the average capital employed over FY2013. Fixed asset data was not made available after December 2013. The CMA considered using capital employed as of the 31 November 2013, however due to the risks associated with picking an asset value at a specific moment in time, the CMA deemed it more appropriate to use the only available average as representative over the full period. Table I.9 shows the highest and lowest estimates of capital employed using the GBV and NBV of the fixed assets.
- I.13. In the ROCE calculation a different profit figure is used to that in the ROS calculations. The ROS analysis focuses on UK profitability only and so the direct cost is the purchase price charged by Freiburg. The ROCE analysis focuses on the profitability of Pfizer's manufacturing and distribution process. As such, it uses the standard manufacturing costs incurred by the Freiburg facility, rather than the Corporate COGS it charges Pfizer Ltd. The standard costs are outlined in Annex C and the analysis covers a period of 27 months, from September 2012. The restated costs and profit figures are shown in Table I.10.

## A. Freiburg fixed assets

**Table I.1: Fixed assets at Freiburg facility as at the 30 November 2012, 30 November 2013 and on average between these two dates**

[✂]

**Table I.2: Total and Phenytoin Equipment hours at Freiburg facility during the year ending 30 November 2013**

[✂]

**Table I.3: Total Phenytoin volumes produced at Freiburg and sold in the UK during the year ended 30 November 2013**

[✂]

**Table I.4: Fixed assets from Freiburg facility allocated to UK phenytoin**

[✂]

## **B. UK fixed assets**

**Table I.5: UK Fixed assets as at the 30 November 2012, 30 November 2013 and on average between these two dates**

[✂]

**Table I.6: Total sales volumes of Pfizer Ltd and of Phenytoin sodium capsules by Pfizer Ltd during the year ended 30 November 2013**

[✂]

**Table I.7: Average value UK fixed assets allocated to Phenytoin in the UK during the year ended 30 November 2013**

[✂]

## **C. Working capital**

**Table I.8: Working capital figures and allocation to UK Phenytoin at the 30 November 2012, 30 November 2013 and on average between these dates**

[✂]

## **D. Total Capital Employed**

**Table I.9: Highest and lowest estimates of total capital employed in the production of UK phenytoin using the Gross Book Value and Net Book Value of assets**

[✂]

## E. Restated Profitability

**Table I.10: Profitability of phenytoin sales in the UK using the standard manufacturing costs, provided in Annex C, between September 2012 and June 2016**

[✂]



## ANNEX J - FLYNN'S COSTS AND PROFITS ACROSS ITS PORTFOLIO OF PRODUCTS

J.1. This annex sets out the profitability of phenytoin sodium capsules for Flynn against the profitability of its other products in the years ending 31 March 2013 and 31 March 2014 in Figure J. 1 and Figure J.2 respectively.

**Figure J. 1: Flynn's cost and profit stacked bar charts and percentage contribution margins across its portfolio of products in the year ending 31 March 2013<sup>46</sup>**

[✂]

**Figure J.2: Flynn's cost and profit stacked bar charts and percentage contribution margins across its portfolio of products in the year ending 31 March 2014<sup>47</sup>**

[✂]

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<sup>46</sup>[✂]  
<sup>47</sup>[✂]

## ANNEX K – FLYNN’S RESPONSIBILITIES AS AN MA HOLDER

- K.1. Flynn has argued that, as an MA holder, it is responsible for an extensive framework of legal obligations and, even if certain activities are outsourced, this does not divorce Flynn from these legal obligations. Flynn suggests that these responsibilities, such as its responsibility for pharmacovigilance, justify its high returns. Further, Flynn’s has submitted that only including one line in Table 5.14 for 'Regulatory Compliance' does not reflect the full extent of Flynn’s legal obligations as the MA holder of phenytoin sodium capsules. Flynn submits that this doesn’t properly reflect the full scope of its pharmacovigilance activities, a *“critical area of monitoring, reporting and compliance, which is also a key area of differentiation between a MA holder and a distributor.”*<sup>4849</sup>
- K.2. The CMA disagrees with Flynn’s submission. The returns a company can reasonably expect to earn are not be based simply on the number of legal obligations the company is subject to but the actual commercial risk incurred as a result of those obligations. Flynn’s responsibilities as the MA holder for phenytoin sodium capsules do not differ from the responsibilities of any other MA holder of pharmaceutical products in the UK. Despite this, Flynn’s returns appear to be in excess of what might normally be expected for holding an MA in this context, such as the returns it earns on its other products for which it holds an MA, for example [REDACTED]. Flynn have not provided the CMA with any reason why the legal obligations it is under as the MA holder for phenytoin sodium capsules justify the returns that it is currently able to earn.
- K.3. The CMA has assessed the pharmacovigilance activities that Flynn carries out for phenytoin. Most of the regulatory compliance activities that Flynn points to appear to be primarily administrative in nature and the staffing and other administrative costs associated with these are included in the CMA’s analysis of Flynn’s costs. Consequently, these activities do not create any abnormally high commercial or legal risk of the sort that might justify Flynn’s returns.<sup>50</sup> The CMA therefore concludes that these activities cannot be used to justify Flynn’s excesses. [REDACTED].<sup>51</sup>

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<sup>48</sup> See document 01839.1, paragraph 2.9.

<sup>49</sup> Table 5.14 is only intended to be a summary of the key areas of work that are undertaken by Flynn or other undertaking in the supply chain. It is not intended to represent the full extent of the CMA’s analysis.

<sup>50</sup> The actual costs of compliance are taken into account as part of the CMA’s Cost Plus calculation.

<sup>51</sup> See document 01839.1, paragraph 3.10.

K.4. [REDACTED]

- o [REDACTED];<sup>52</sup> and
- o [REDACTED].

K.5. [REDACTED].<sup>53</sup> [REDACTED].

K.6. [REDACTED].

K.7. Flynn also submits that responsibility for many of the activities currently allocated to other undertakings (especially Pfizer) in Table 5.14 are actually shared between Flynn and the other undertakings. Even where some activities are outsourced, Flynn believes it is incorrect to only allocate responsibility for them to one of Pfizer, Flynn or a third party.

K.8. Examples of “shared responsibility” given by Flynn are:

- (a) [REDACTED];
- (b) [REDACTED]
- (c) [REDACTED].

K.9. The CMA has assessed the contractual agreements between Flynn and Pfizer and Flynn and [Flynn’s pre-wholesaler/distributor] as well as having considered the examples provided by Flynn with regards to its shared responsibilities and Table 5.14 accurately summarises the division of key responsibilities and activities between Flynn and other parties:

- [REDACTED].<sup>54</sup>
- [REDACTED].<sup>55</sup>
- [REDACTED]<sup>56</sup> [REDACTED].<sup>57</sup>

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<sup>52</sup>[REDACTED].

<sup>53</sup>[REDACTED].

<sup>54</sup> See document 00145.299.

<sup>55</sup> See document 00145.299.

<sup>56</sup> See document 01790.3.

<sup>57</sup> See document 00145.299.

K.10. As outlined above, it is the actual activities that Flynn undertakes directly, and the capital costs it incurs to do so, that impact on the commercial and legal risk that it actually incurs and therefore the reasonableness of the returns that it actually makes.

## ANNEX L - PFIZER'S R&D COSTS

- L.1. Pfizer submitted that the CMA's assessment should include a reasonable allocation of Pfizer's overall R&D costs.<sup>58</sup>
- L.2. Pfizer submitted that the pharmaceutical industry operates on a very high fixed cost base (*'particularly due to extremely high research and development costs'*) and that recovering these costs required *'profitability to be maximised on all products within a portfolio, including established products'*.<sup>59</sup>

- L.3. Pfizer expanded on this point by explaining that:

*'The majority of R&D costs are incurred in the development of pipeline products; many of which never reach commercial status [...] Thus, even though very limited R&D costs are incurred with respect to Pfizer's established products that have been on the market for some time, Pfizer needs to recoup its substantial overall R&D expense through a contribution margin on the sales of all its products'*.<sup>60</sup>

- L.4. Pfizer then stated that:

*'simply to break-even overall, pharmaceutical companies such as Pfizer must earn significant margins on those products that are successfully brought to market, due to the need to cover the upfront investments made both into these products themselves, and also into other products that were ultimately not successfully commercialised. As a result, any analysis of profitability in this sector must go beyond a simplistic focus on the margins made on individual products in isolation, as the only way that Pfizer can continue to fund its pipeline products is to try to ensure that all of its current products make a reasonable contribution towards these substantial R&D overheads'*.<sup>61</sup>

- L.5. CMA does not consider that its Cost Plus assessment of Pfizer's Products should include a portion of Pfizer's overall R&D costs.

- L.6. As a general proposition, the CMA accepts that pharmaceutical companies may properly seek to recover substantial R&D overheads through higher prices. This

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<sup>58</sup> See document 00488.1.

<sup>59</sup> See document 00519.1. See also page 2 of document 00519.2, in which Pfizer submitted that *'pricing to cover the cost of supply only would not be sufficient to recover'* these costs.

<sup>60</sup> See document 00519.2, page 8.

<sup>61</sup> See document 00519.1, paragraph 4.2.

is the role of the patent protection, which allows a period of exclusivity in which a patentee can earn supra-competitive margins as a reward for pharmaceutical innovation. That does not mean, however, that a manufacturer of an old, non-patented pharmaceutical product can demand or expect to sustain prices significantly above the competitive level. When patent exclusivity has expired, it is expected that prices and/or market share will drop as a result of competitive entry. Such entry has not occurred in this case, which has allowed the Parties to charge unfairly high prices.

- L.7. Pfizer's argument is very similar to the one advanced by Napp before the CAT *in Napp Pharmaceutical Holdings Ltd v Director General of Fair Trading*. Napp argued that only a "portfolio-based" approach, which assessed profitability across a range of products, could determine whether a firm was enjoying excessive profits. The CAT rejected the argument, as follows:

*'Napp's whole argument based on "portfolio pricing", impermissibly directs attention away from the specific product market which we are required to consider when deciding whether there is an abuse of a dominant position under section 18 of the Act. In our view, it is not appropriate, when deciding whether an undertaking has abused a dominant position by charging excessive prices in a particular market, to take into account the reasonableness or otherwise of its profits in other, unspecified, markets comprised in some wider but undefined "portfolio" unrelated to the market in which dominance exists.*

[...]

*[...] a manufacturer with an innovative product cannot demand or expect prices to remain at excessively high levels indefinitely. Indeed, one of the principle purposes of the patent system is to confer a degree of exclusivity, thus enabling companies to recover substantial research and development costs and investment in new medicines [...] In the present case, it is now 20 years since the launch of MST, and Napp's formulation patent expired 10 years ago.*

*We do not accept that, after such a long period, the price of MST can credibly be defended on a 'portfolio pricing' theory. The evidence we have is that, in the case of many pharmaceutical products, the expiry of a patent leads to competitive (often generic) market entry, with the consequence*

*that the incumbent supplier either lowers prices, or loses market share, or both, perhaps quite rapidly.*<sup>62</sup>

- L.8. The CMA considers that the CAT's reasoning in *Napp* applies to Pfizer's assertion that all of its current products should make a reasonable contribution towards its portfolio R&D costs. Phenytoin sodium capsules benefitted from patent protection a very long time ago. That patent protection provided a period of exclusivity to enable the patent holder to earn above-competitive margins as a reward for pharmaceutical innovation. As the CAT stated in *Napp*, however, 'a manufacturer with an innovative product cannot demand or expect prices to remain at excessively high levels indefinitely'.<sup>63</sup> Once patent protection has expired, competition, in particular, from generic pharmaceutical products, should lead to lower prices or market shares or both.
- L.9. Further still, the factual context of the present case weakens Pfizer's portfolio pricing argument. Unlike 'MST' in *Napp*, which was 20 years old by the time of the abuse and had only just come off patent, phenytoin sodium capsules were almost 80 years old and have long been off patent.<sup>64</sup> The CMA considers that Pfizer's submission that it should be entitled to charge higher prices for phenytoin sodium capsules so as to contribute to its portfolio R&D costs is therefore unsustainable.<sup>65</sup>
- L.10. A further reason for rejecting Pfizer's argument is the principle that a dominant undertaking should not be able to exploit its dominant position on a market to earn '*trading benefits which it would not have reaped if there had been normal and sufficiently effective competition.*'<sup>66</sup> The possibility that Pfizer could increase the price of phenytoin sodium capsules in order to recover R&D costs only arises because it held a dominant position. As the CAT recognised in *Napp*, if Pfizer's prices had been effectively constrained by competition, as is the case for most

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<sup>62</sup> *Napp*, [413] to [417]. Similarly, portfolio pricing was considered and rejected by the Commission in *Scandlines*; see paragraphs 134 to 138.

<sup>63</sup> *Napp*, [416].

<sup>64</sup> See section 3.B.II.b above.

<sup>65</sup> Pfizer submits that the PPRS allows companies to earn an allocation for R&D on the returns made for all branded products, not just those on patent. Pfizer submits that the CMA is therefore wrong to rely on the fact that phenytoin sodium capsules are off patent to exclude recovery of costs for R&D. Pfizer misconstrues the CMA (and the CAT's) position however. The CMA has not found that Pfizer is always precluded from earning a contribution towards its R&D costs when a product is off patent, only that it has no automatic entitlement to do so. This is entirely constant with the operation of the PPRS which permits, but does not guarantee, such returns. Indeed, according to Pfizer's own submissions Epanutin was loss making under the PPRS.

<sup>66</sup> *United Brands*, paragraph 249

products where there is generic competition, Pfizer would not have been able to impose unfairly high prices.

- L.11. Taking Pfizer's argument to its logical conclusion would amount to allowing pharmaceutical companies which hold dominant positions to set prices for their successful off-patent drugs which indefinitely cross-subsidise R&D investment in other drugs and effectively provide the sector with an exclusion from an aspect of competition law. Legislation does not provide for any such exclusion.
- L.12. Consequently, such costs must be excluded from the CMA's Cost Plus assessment.



**DIRECTORATE FOR FINANCIAL AND ENTERPRISE AFFAIRS  
COMPETITION COMMITTEE**

**Working Party No. 2 on Competition and Regulation**

**EXCESSIVE PRICES**

-- European Union --

**17 October 2011**

*The attached document is submitted to Working Party No.2 of the Competition Committee FOR DISCUSSION under item III of the agenda at its forthcoming meeting on 17 October 2011.*

Please contact Mr. Frank Maier-Rigaud if you have any queries regarding this document [phone number: +33 1 45 24 89 78 -- Email address: frank.maier-rigaud@oecd.org].

**JT03308232**



## ARTICLE 102 AND EXCESSIVE PRICES

### 1. Introduction

1. This Roundtable is dedicated to excessive prices. This is not the first time that excessive prices or more generally exploitative conduct and its assessment under competition law are discussed, here in the OECD and in other forums. However, there still seems only limited experience with exploitative abuse cases and little agreement around the world on the issues involved.

2. This is in contrast with the assessment of exclusionary abuse. Guidelines and other documents, describing more or less elaborate frameworks for the assessment of exclusionary conduct in general and specific forms of conduct such as predation and exclusive dealing, have seen the light in recent years.<sup>1</sup> Based on a vast and growing number of cases, there seems a trend of convergence between jurisdictions, as exemplified by recent work and publications of the ICN in the area of unilateral conduct.<sup>2</sup>

3. In this paper we try to not only raise questions concerning the possible application of Article 102 of the TFEU to excessive prices but also to provide some answers. Given the limited experience of the Commission with cases concerning excessive prices, these answers will sometimes only answer part of the question and some questions will remain unanswered for the moment. This paper does not deal with other forms of exploitative conduct such as unfair non-price conditions and (price) discrimination.

### 2. Why intervene against exploitative conduct?

4. The first question that many seem to have when discussing exploitative conduct and thus also excessive prices, is whether competition authorities should at all be concerned with such conduct: whether it would not be better to focus enforcement activity exclusively on exclusionary conduct.<sup>3</sup>

5. In the EU context there are, at least, three main reasons to intervene against exploitative conduct. The first reason is that Article 102, its text and its history make it clear that exploitative conduct can be abusive. In particular Article 102(a) states that an abuse may consist in "directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions." This example of an abuse is generally

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<sup>1</sup> See for instance the 2009 Communication from the Commission – Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings, which can be found at <http://ec.europa.eu/competition/antitrust/art82/index.html> Guidelines have also been adopted, for instance, by the Canadian Competition Bureau, the Korean Fair Trade Commission, the Japan Fair Trade Commission and the Competition Commission of Singapore.

<sup>2</sup> See for instance the ICN Unilateral Conduct Working Group Documents at: [www.internationalcompetitionnetwork.org/working-groups/current/unilateral.aspx](http://www.internationalcompetitionnetwork.org/working-groups/current/unilateral.aspx)

<sup>3</sup> This and the next section are in good part based on E. Paulis, Article 82 EC and Exploitative Conduct, in *European Competition Law Annual 2007: A Reformed Approach to Article 82 EC* (C.D. Ehlermann & M. Marquis eds. 2008) and on Luc Peeperkorn, Price Discrimination and Exploitation, in *Annual Proceedings of the Fordham Competition Law Institute - International Antitrust Law & Policy* (Barry E. Hawk ed. 2009).

understood to cover conduct such as charging excessive prices. In the early days of European competition policy, some commentators were even of the opinion that Article 102 from a legal perspective was exclusively concerned with exploitative abuses.<sup>4</sup> Also more recent research suggests that the legislative intent for Article 102 was to apply only to exploitative abuses and not exclusionary abuses.<sup>5</sup>

6. The second reason is linked to the goal of competition policy. Like many other competition authorities, the Commission claims that the central goal of competition policy is to protect consumer welfare. In this light it would be strange to protect consumers only indirectly, i.e. by intervention against exclusionary conduct to protect the competitive process, and not also directly by intervening against too high or unfair prices. Where there are two types of intervention possible to achieve a certain aim – in this case protecting consumer welfare - it is highly unlikely that under all circumstances one type of intervention is superior to achieve the aim. In other words, the relevant question seems to be how to find the right balance in allocating enforcement resources between prohibiting exclusionary conduct and prohibiting exploitative conduct.

7. The third reason concerns the so-called "gap" cases. Article 102 does not prohibit the acquisition of dominance. It only applies to abusive conduct of firms already having a dominant position. This means that there may be cases where intervention against unilateral exclusionary conduct is legally not possible. In such cases intervention against exploitative conduct may be the only possibility to effectively protect consumers. An example could be action taken against the charging of excessive royalties by a company who has obtained its dominant position as a result of not disclosing its patent when it was involved in discussions on setting a standard for the industry.<sup>6</sup> The possibility under U.S. law to effectively intervene against acquisition of dominance may also partly explain why the possibility to intervene against exploitative conduct is not included in the Sherman Act or other U.S. antitrust laws.

### **3. How to find the right balance between addressing exclusionary and exploitative conduct?**

8. Finding the right balance in allocating enforcement resources between prohibiting exclusionary conduct and prohibiting exploitative conduct does not mean that both areas of enforcement have to be similarly prominent. It may very well be that there are good reasons to tilt the enforcement effort towards preventing exclusionary abuse, as many have argued in the recent debate on Article 102.<sup>7</sup>

9. The various arguments that have been brought forward to tilt the balance in favour of intervention against exclusionary conduct can be divided in two types. One type of argument focuses on the practical difficulties of competition authorities to intervene against exploitative conduct, in particular exploitative pricing conduct. The other type of argument focuses on what could be called the "positive effects" of high prices and high profits in a market economy.

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<sup>4</sup> See, for example, R. Joliet, *Monopolization and Abuse of Dominant Position*, 1970.

<sup>5</sup> See P. Akman, *Searching for the Long-Lost Soul of Article 82 EC*, *Oxford Journal of Legal Studies*, Vol. 29, No. 2 (2009), p. 267-303.

<sup>6</sup> See the *Rambus* case described later in this paper.

<sup>7</sup> See for example D.S. Evans & A.J. Padilla, *Excessive Prices: Using Economics to Define Administrable Legal Rules*, *Journal of Competition Law & Economics*, Vol. 1 (2005), p. 97-122; B. Lyons, *The Paradox of the Exclusion of Exploitative Abuse*, *Centre for Competition Policy Newsletter*, (Spring 2007); M. Motta & A. de Streel, *Exploitative and Exclusionary Excessive Prices in EU Law*, in *European Competition Law Annual* (CD Ehlermann & I Atanasiu eds. 2003); R. O'Donoghue & A. Jorge Padilla, *What Is an Abuse of Dominant Position?* in *The Law and Economics of Article 82 EC* (Oxford 2006); M. Furse, *Excessive Prices, Unfair Prices and Economic Value: The Law of Excessive Pricing under Article 82 and the Chapter II Prohibition*, *European Competition Journal*, June 2008, p.59.

10. The more extreme version of the "positive effects" argument has been expressed eloquently by Justice Scalia in his opinion in *Trinko* where he argued that "[t]he mere possession of monopoly power, and the concomitant charging of monopoly prices, is not only not unlawful; it is an important element of the free-market system. The opportunity to charge monopoly prices – at least for a short period – is what attracts 'business acumen' in the first place; it induces risk taking that produces innovation and economic growth."<sup>8</sup> The argument that can be drawn from this – at least if we ignore for the moment the qualification 'at least for a short period' – is that monopoly profits are good, perhaps even necessary, because that is what attracts the type of risk taking and investment that drives innovation and economic growth.

11. While it certainly seems true that much risk taking and investment are indeed done not just for the excitement of being innovative but (also) in the hope of achieving significant financial returns, this does not necessarily imply that the only - or the optimal - way of giving the correct incentives is allowing firms to charge monopoly prices without any possibility of intervention on the part of competition authorities. Competition law regularly intervenes to limit the possibilities of firms to maximise their profits. One notable area is the application of the competition rules to vertical restraints, also if these restraints "only" limit intra-brand competition. Otherwise resale restrictions agreed by a manufacturer with its distributors to support price discrimination and thereby enhance the manufacturer's and possibly also the distributors' profits, should be dealt with as per se legal. Taking the "positive effects" argument to its extreme, it would even seem difficult to justify interventions against cartels that fix the price and share markets. Prohibiting the cartel members to increase their joint profits could be argued to have a negative impact on the risk taking and innovation of the cartel members and possible entrants.

12. It is nonetheless important to recognise that high profits may often be the result of superior innovation and risk taking, which should not be penalised as this would work as a disincentive to innovate and invest. It should also be recognised that even where high profits do not result from superior innovation but from the exercise of market power, such profits will in most markets attract entry and expansion of competitors and taking away such profits may thus undermine the markets own mechanism to restore competition. However, this does not mean that intervention against exploitative conduct should necessarily be totally excluded but it indicates that it may be better to tilt the balance in favour of addressing exclusionary conduct.

13. Equally convincing to tilt the balance of enforcement away from exploitative conduct is the other type of argument, concerning the practical difficulties competition authorities face when intervening against exploitative conduct, in particular excessive prices. There are two sets of practical difficulties related to enforcement actions against excessive prices. The first is linked to establishing when a price is excessive, including establishing what price is acceptable as a remedy, and the second is linked to monitoring the implementation of the remedy over time.

14. Determining whether a specific price is excessive may involve difficult comparisons of prices with costs of production and investment and/or comparisons of the return on invested capital of the firm with the weighted average cost of capital of the sector or similar sectors. Determining whether a price is excessive may also involve comparisons with prices obtained in other markets or other periods that can be used as benchmarks. Some of the problems involved in these comparisons – for example, comparing the price to a particular cost benchmark and the issue of cost allocation in multi-product firms - are also present for other price based abuses, such as predation and margin squeeze. However, establishing an excessive price requires that also a second decision is taken, on how much deviation from the benchmark is allowed, for instance how much the price or the profitability is allowed to exceed the cost level respectively the average cost of capital. This extra step is not required in other price abuse cases such as

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<sup>8</sup> *Verizon Communications Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 US 398, 407 (2004).

predation and margin squeeze, where in general the question is "simply" whether the price is higher or lower than the relevant cost benchmark.

15. The second set of practical difficulties is linked to monitoring the implementation of the remedy over time. Intervening against excessive prices may entail the risk of a competition authority finding itself in the situation of a semi-permanent quasi-regulator. The authority may have to come back time and again to the pricing of the dominant firm when cost or other conditions change in the industry, something that a "generalist" competition authority is much less equipped for than proper regulators with their deep knowledge of and continuous involvement in their industries. However, in a particular case an authority may be able to establish a simple price comparison rule that can avoid such a situation. An example of such a rule could be that the dominant firm cannot charge more (or only x % more) in market A than it does in market B where the freely determined price in market B for some reason is more acceptable than the freely determined price in market A. While the dominant firm may come back after a few years claiming that conditions have changed and the rule needs to be revised, the problems seem of lesser magnitude than a rule establishing a link between price and costs, as costs normally are less easy to monitor than other prices.

16. In other words, as can be expected with practical difficulties, their relevance in part depends on the specificities of each individual case. Again this is no reason to totally exclude intervention against exploitative conduct but this has influenced and will influence the balance in allocating enforcement resources between prohibiting exclusionary conduct and prohibiting exploitative conduct.

17. As a consequence the balance in the EU over the last 50 years has been tilted towards addressing exclusionary conduct, to prevent that exclusionary conduct leads to market conditions which allow exploitation of consumers, rather than intervening directly against exploitative conduct. This has resulted in a rather limited case law concerning excessive prices.

#### 4. The EU experience

18. *General Motors*<sup>9</sup>: General Motors appealed a Commission decision which found that the company had infringed Article 102 TFEU by charging, for a period of four months, an excessive fee for conformity inspections of five vehicles manufactured in another Member State and imported in Belgium. The fee that General Motors charged for the conformity inspections of the imported European vehicles was at the amount usually charged for the conformity inspection of American cars despite the fact that the inspection of European vehicles was much less costly.

19. According to Belgium public law, the performance of the conformity inspection for each make of car was reserved exclusively to the manufacturer or its exclusive agent. Although the State entrusted the task of inspection to private undertakings it did not take measures to fix or limit the charge imposed for the service rendered. The Court therefore agreed with the Commission that General Motors enjoyed a dominant position as it had a legal monopoly for the inspection certification and freedom to determine prices.

20. The Court did not exclude the possibility that an undertaking in such a position may commit an abuse by charging prices which are excessive in relation to the economic value of the service provided and which has the effect of curbing parallel imports.<sup>10</sup> However, the Court did not find that on the facts of the

<sup>9</sup> General Motors Continental NV v Commission Case 26/75 [1975].

<sup>10</sup> In fact, a few years later in Case 226/ 84 British Leyland Public Limited Company v Commission [1986] the Court of Justice upheld the Commission decision finding that British Leyland, which enjoyed a legal monopoly in issuing national certificates of conformity for vehicles in Great Britain, had abused its

case, General Motors had indeed abused its dominant position. The Court was persuaded by the arguments that the activity in question was an unusual activity for General Motors, as the company had assumed responsibility for it shortly before the alleged abusive conduct took place. It was also an occasional activity, as General Motors was performing inspections primarily for vehicles manufactured in Belgium and was not used to provide the service for imported European vehicles. In addition, the Court took into account the fact that General Motors very quickly had brought its rates into line with the real economic cost of the operation and had reimbursed the persons who had complained about the unfair price. The Court concluded that the Commission's intervention was unjustified in the actual temporal and factual circumstances in which it took place.

21. *United Brands*<sup>11</sup>: In its decision the Commission found that United Brands Company (UBC) had abused its dominant position in the market for bananas by, amongst other, charging unfair (excessive) prices for the sale of Chiquita bananas to customers in Belgium-Luxembourg, Denmark and Germany. The relevant geographic market consisted of several Member States: Germany, Denmark, Ireland, the Netherlands and Belgium-Luxembourg. The Court upheld the Commission's market definition and the finding that UBC enjoyed a dominant position. In considering whether UBC held a dominant position the Court took into account that UBC's market share was nearly 45% and several times greater than the share of its closest competitor, that UBC was vertically integrated to a high degree, that it was an unavoidable partner (distributors could not afford not to offer UBC's Chiquita bananas) and that owing to its advertising campaigns UBC had won customers' preference.

22. In the analysis of the abusive conduct the Commission compared UBC's and competitors' prices, as well as the prices for branded and unbranded bananas. However, the most important comparison was between UBC's prices in different Member States. In particular, the Commission found that the price in Ireland was half the price in Belgium, Luxembourg, Denmark and Germany. As internal documents of the company indicated that UBC made profits in Ireland, the Commission concluded that the prices in the other mentioned Member States, which were twice higher, were excessive. The Court did not agree with the Commission's analysis.

23. In the context of this case the Court set out a test for whether a particular price is liable to be considered abusive: "The questions therefore to be determined are whether the differences between the costs actually incurred and the price actually charged is excessive, and, if the answer to this question is in the affirmative, whether a price has been imposed which is either unfair in itself or when compared to competing products."<sup>12</sup> The Court's concern was that the Commission had not analyzed UBC's production costs, although it could have done so. It was doubtful as to whether the price in Ireland could be used as a relevant benchmark, especially in view of the fact that UBC presented documents indicating that prices in Ireland had produced losses. In addition, the Court noted that the price difference with UBC's competitors was only 7% which could not be automatically regarded as excessive and consequently unfair.

24. *Bodson*<sup>13</sup>: In this preliminary ruling, one of the questions that the European Court of Justice had to consider was whether Pompes Funèbres, which had been given an exclusive concession to provide the

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dominant position by charging excessive prices. British Leyland charged significantly higher price (six times greater) for the issuance of certificates for left-hand drive cars than for right-hand drive cars, despite the fact that the cost of inspection for left and right hand drive cars were almost the same. The Court concluded that in those circumstances the fee was clearly disproportionate to the economic value of the service provided. The Court was convinced that the fee was fixed at that level solely with the aim to make the re-importation of left-hand drive vehicles more difficult.

<sup>11</sup> United Brands Co. v Commission Case C-27/76 [1978].

<sup>12</sup> Case 27/76 United Brands, paragraph 252.

<sup>13</sup> Corinne Bodson v SA Pompes funèbres des régions libérées Case 30/87 [1988].



"external services" for funerals (e.g. the carriage of the body after it has been placed in the coffin, the provision of hearses, coffins, external hangings of the house of the deceased, etc) in 2800 communes in France, could be held liable for abusing its dominant position by charging excessive prices in a particular town.

25. As regards the issue of dominance, the Court considered that although the exclusive concession was given for operating the services in less than 10% of the communes in France, the population of these communes accounted for more than one third of the total population of the country. The size of the population and thus the number of burials, rather than the number of communes, was relevant for determining the holding of a dominant position.

26. The Court then held that, given that more than 30 000 communes in France had not granted exclusive concessions but had left the services unregulated or operated it themselves, it should be possible to make a comparison between the prices charged by undertakings with exclusive concessions and other undertakings. The Court opined that such a comparison could provide a basis for assessing whether or not the prices charged by the concession holder were fair.

27. *SACEM*<sup>14</sup>: In this case the Court of Justice had to give a preliminary ruling on the question whether a dominant association of authors, composers and publishers of music in France, which is bound by reciprocal representation contracts with copyright societies in other countries of the EU, infringes Article 102 if it imposes aggregate royalties on the basis of 8,25% of the gross turnover of a discotheque and if that rate is manifestly higher than the rate applied by identical copyright societies in other Member States.

28. The Court held that Article 102 must be interpreted as meaning that a dominant undertaking imposes unfair conditions where the royalties charged to discotheques are appreciably higher than those charged in other Member States and where the rates are compared on a consistent basis. However, there would be no abuse if the copyright-management society in question were able to justify such a difference by reference to objective and relevant dissimilarities between copyright management in the Member State concerned and copyright management in the other Member States. In this particular case, the Court was not persuaded by the arguments put forward by the copyright society as a justification for the difference. These arguments pertained to high prices charged by discotheques in France, the traditionally high level of protection provided by copyright in France, the peculiar features of the French legislation and the customary methods of collection of royalties used in France. The Court considered that the mentioned factors could not account for a very appreciable difference between the rates of royalties charged in the various Member States.

29. *Deutsche Post*<sup>15</sup>: The case arose from a complaint from the public postal operator of the UK which alleged that Deutsche Post had frequently intercepted, surcharged and delayed international mail from the UK arriving in Germany. The dispute between the British Post Office and Deutsche Post stemmed from a disagreement how to identify the sender of international mailings. On the one hand, Deutsche Post argued that any incoming international mail containing a reference to Germany usually in the form of a German reply address should be considered as having a German sender, regardless of where the mail was produced or posted. Under the allegation that mailings of this type were in fact circumvented domestic

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<sup>14</sup> F. Lucazeau v Société des Auteurs, Compositeurs et Editeurs de Musique Cases 110/88, 241/88 & 242/88 [1989]. See also Case 395/87 Ministère Public v Tournier [1989] in which the Court was asked to rule on similar questions concerning the royalties charged by SACEM. See also Case 402/85 G. Basset v Société des Auteurs, Compositeurs et Editeurs de Musique [1987], an earlier preliminary ruling case in which the Court stated that Article 102 can apply to a royalty which is unfair, but did not rule on possible assessment criteria.

<sup>15</sup> Commission decision COMP/36.915 – Deutsche Post AG – Interception of cross border mail [2001].

mail (so-called A-B-A remail), Deutsche Post intercepted the mailings and refused to deliver the letters to its addressees unless the full domestic tariff applicable in Germany was paid. This refusal of Deutsche Post resulted in long delays, up to several weeks, and higher prices. On the other hand, the complainant argued that all outgoing mail produced and posted in the UK should be processed like international mail, regardless of its contents.

30. The Commission's investigation revealed that the disputed mailings did not have German senders. The mailings were produced and posted in the UK, or alternatively, produced in Sweden or in the Netherlands and posted to Germany via the UK. The mail was not circumvented domestic mail - as Deutsche Post maintained - and should therefore have been treated as normal international mail when entering Germany from the UK.

31. The Commission found that Deutsche Post abused its dominant position in the German market for the delivery of international mail in four ways, three of which (discrimination, refusal to supply and hindering the development of markets) were of an exclusionary nature. It also found that the price Deutsche Post charged for the delivery service was excessive and unfair. It established that the price charged exceeded the economic value (the average cost including a reasonable profit margin) by at least 25%.

32. During the course of the proceedings, Deutsche Post gave an undertaking to no longer intercept, surcharge or delay international mail of the type concerned by this case. In addition, for years the behaviour of Deutsche Post had consistently been condoned by German courts and at the time there was no Community case law that concerned international mail services. The legal situation therefore had been unclear. Bearing these considerations in mind, the Commission decided to impose only a symbolic fine of € 1,000 on Deutsche Post.

33. *Helsingborg*<sup>16</sup>: In this case the Commission examined a complaint against Helsingborgs Hamn AB (HHAB), a company wholly owned by the City of Helsingborg in Sweden and fully responsible for the running of the port of Helsingborg. The operating of the port included construction and maintenance of the port facilities, the provision of facilities and services to vessels using the port, such as ferries, and the determination of the fees that each user of the port has to pay for the use of those facilities and services. HHAB was the only provider of the services on the Swedish end of the Helsingborg-Elsinore route. The complainant alleged, amongst other, that HHAB had infringed Article 102 by levying excessive port charges for services provided to ferry operators. The complainant argued that the charges were excessive because they did not reflect the actual costs borne by HHAB.

34. The Commission followed the United Brands test and considered that the questions to be determined were (i) whether the difference between the costs actually incurred and the price actually charged is excessive and if the answer to this question is in the affirmative, (ii) whether the price is either unfair in itself or when compared to the prices of competing products.

35. As regards the first limb of the test, the Commission carried out an approximate cost/price analysis and reached the conclusion that the revenues from the port charges derived from ferry operations would seem to exceed the costs actually incurred by the port to provide services and facilities to these users. The ferry operations seemed to generate profits whereas in general the other operations of the port generated losses. The Commission did not decide whether the question of the first limb was answered affirmative, but proceeded to the second limb of the test.

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<sup>16</sup> Commission decision COMP/36.568 – Scandlines Sverige AB v Port of Helsingborg [2004].



36. As regards the second limb, the Commission compared HHAB's prices with the prices charged for the same services in other ports and in addition compared the prices of different services provided by HHAB in its own port. The comparison between different ports turned out to be full of difficulties as each port differed substantially in terms of activities, size of assets and investment, level of revenues and costs of each activity. However, based on such a comparison the Commission found that there was no evidence that the prices of HHAB stood out compared to other ports. Similarly, the comparison between prices for different services at the port of Helsingborg was hindered by difficulties as the facilities used for these services differed significantly and the other operations were run at a loss. The Commission found that also this comparison did not provide evidence that the port fees charged to the ferry operators were unfair.<sup>17</sup>

37. Finally, the Commission considered whether the price was unfair in itself. The Commission focused on the economic value of the service. It considered that the economic value of a service cannot simply be determined by adding to the approximate costs incurred in the provision of the service a profit margin which would be a pre-determined percentage of the costs. Rather, the economic value must be determined with regards to the particular circumstances of the case and take into account also non-cost related factors such as the demand for the product/service. In this case the excellent location of the port of Helsingborg which allows ferries to cross the Øresund in an expeditious way was deemed relevant. The Commission concluded that there was not sufficient evidence to establish that the port charges were unfair/excessive.

38. *Rambus*<sup>18</sup>: In the Rambus case, the Commission had preliminary concerns that Rambus could have abused its dominant position on the world-wide technology market for DRAM (Dynamic Random Access Memory) interface technology. A vast majority of DRAM chips sold worldwide comply with the synchronous DRAM standard developed by JEDEC, an industry wide US-based standard setting organisation. As Rambus asserts patents on all JEDEC-compliant synchronous DRAM chips and, in addition, owns its own proprietary DRAM technology, the percentage of worldwide DRAM production exposed to Rambus' patent claims was more than 90%. Rambus has been the only company asserting patents on DRAM interface technology.

39. The Commission's concerns were that Rambus may have engaged in intentional deceptive conduct in the context of the JEDEC standard-setting process for DRAM technology by not disclosing the existence of the patents and patent applications which it later claimed were relevant to the adopted standard (patent ambush). Rambus thus may have been abusing its dominant position by claiming royalties for the use of its patents from JEDEC-compliant DRAM manufacturers at a level which, absent its allegedly deceptive conduct, it would not have been able to charge.

40. In response to the Commission's preliminary conclusions expressed in a Statement of Objections, Rambus offered a package of commitments which addressed the Commission's concerns and in which it agreed, amongst others, for a period of five years (i) not to charge any royalties for DRAM

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<sup>17</sup> See also the decision to reject a complaint concerning alleged excessive rental charges in Commission decision COMP/37.761 – Euromax v IMAX [2004]. Euromax complained about alleged excessive rental charges of IMAX for the 15/70 mm format IMAX system for the projection of films on giant screens. In its decision the Commission, referring to the United Brands test as a two limb test, based its analysis only on the second limb of the test, because, even under the assumption that the first limb would be met, the second limb of the test was not fulfilled. In addition, the Commission concluded that the competition law issues could very appropriately be decided by national courts and it noted that the same issues were also subject in Germany to court procedures of which, at the time, some had been decided in favour of IMAX and others were still ongoing.

<sup>18</sup> Commitment Decision of 09/12/2009, see the non-confidential version of the decision on the Commission's website: [http://ec.europa.eu/competition/antitrust/cases/dec\\_docs/38636/38636\\_1203\\_1.pdf](http://ec.europa.eu/competition/antitrust/cases/dec_docs/38636/38636_1203_1.pdf)

chips based on JEDEC standards adopted when Rambus was a member of JEDEC, and (ii) to charge a maximum royalty rate of 1.5% for the subsequent DRAM chips standards adopted after Rambus was no longer a member of JEDEC (i.e. below 3.5% it had been previously charging).

## **5. Very high and long lasting barriers to entry and expansion as a pre-condition for intervention?**

41. The case law described above shows that the Commission and European Courts addressed the question of excessive prices only in markets with an entrenched dominant position where entry and expansion of competitors could not be expected to ensure effective competition in the foreseeable future. In *General Motors* and *Deutsche Post* there was a legal monopoly, in *Bodson* the dominant position was based on an accumulation of exclusive concessions which shielded a significant part of the market from competition, in *SACEM* a national monopoly based on network effects, in *Helsingborg* a kind of natural monopoly and in *Rambus* a dominant position based on a lock-in effect once an industry standard has been adopted. The only exception is the *United Brands* case, which concerned the market for (green) bananas, but in the end the Court did not find excessive prices in this case.

42. This cautious enforcement practice fits the arguments described in section 3 above to concentrate enforcement on addressing exclusionary conduct. It seems that enforcement action against excessive prices has only been considered as a last resort, in markets where high prices and high profits do not have their usual signalling function to attract entry and expansion because of very high and long lasting barriers to entry and expansion. This recognises that even though in many markets prices may be temporarily high, due to a mismatch of demand and supply or the exercise of market power, it is preferable to give market forces the time to play out and entry and expansion to take place, thereby bringing prices back to more normal levels. We have not seen enforcement activity in such markets, recognising that it would be unwise to run the risk of taking a wrong decision and furthermore spend enforcement resources on solving a problem that would solve itself over time anyway. This is so even in markets characterised by sufficient entry barriers where there can be dominant firms. Of course, it may be that a dominant firm tries to prevent this process of entry and expansion taking place by artificially raising entry barriers. However, in such a situation it is more efficient for the competition authority to tackle the raising of these entry barriers directly since this will likely amount to an exclusionary abuse. If, however, the market is characterized by such entry barriers that it is unlikely that market forces over time will bring prices down, enforcement actions aimed directly against excessive prices may indeed be appropriate.<sup>19</sup>

## **6. The United Brands test**

43. In *United Brands* the European Court of Justice has set out a test for whether a particular price is liable to be considered abusive: "The questions therefore to be determined are whether the differences between the costs actually incurred and the price actually charged is excessive, and, if the answer to this question is in the affirmative, whether a price has been imposed which is either unfair in itself or when compared to competing products."<sup>20</sup>

44. This test consists of two limbs. The first limb implies that high prices, even if compared to prices in other markets, are not abusive in themselves if they do not lead to an "excessive" difference between price and costs, i.e. if they do not lead to an excessive profit margin. Prices which are high by comparison

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<sup>19</sup> Also in other recent exploitative abuse cases, not concerning excessive prices, the markets were characterised by such high entry barriers: see the Commitment Decisions in Case 39.351 – Swedish Interconnectors [2010], Case COMP/39.388 – German Electricity Wholesale Market [2008] and Case COMP/39.389 - German Electricity Balancing Market [2008].

<sup>20</sup> Case 27/76 *United Brands*, paragraph 252.

with other comparable prices charged by the dominant company or by other undertakings could, for instance, be explained by differences in cost conditions.<sup>21</sup> However, a very high profit margin may thus be indicative of abusive pricing.

45. Determining the magnitude of the profit margin requires an assessment of the true underlying costs incurred by the dominant company. High profit margins might be, for instance, the reward for taking risks and for innovating. When calculating the profit margin proper consideration should be given not only to the cost of capital but also to the investment risks involved in the industry concerned. Profit margins are typically calculated on the basis of the prices and costs of products that actually reach the market. Moreover, the products of a dominant company will often be among the most successful of those products that are brought to market. However, in many industries there are substantial risks involved in developing products before they reach the market. Indeed, there may be several unsuccessful products developed for each product that is successfully brought to market. These risks should be taken into account when assessing the costs and profit margin.<sup>22</sup>

46. The second limb of the test implies that it cannot be determined from a comparison of prices and costs alone whether prices are abusive. A high profit margin may result both from the exercise of market power by setting high prices and from superior efficiency of the dominant firm leading to low costs or a superior product. It is therefore necessary to find out whether a high profit margin originates from the exercise of market power due to a lack of effective competition or from superior efficiency in terms of costs or innovation, in other words whether it originates from high prices or from low costs/a superior product.

47. If the high profit margin results from the dominant company being very efficient, it cannot be said that the prices are unfair in themselves. To test this it may be useful to compare the prices of the dominant company with the costs of other companies, for instance with the costs of the next most profitable competitor. If the profit margin based on such a comparison is not high, it is likely that the high profit margin of the dominant company is a result of superior efficiency.

48. A number of price comparisons may be made in order to determine whether prices are unfair. Often several of such comparisons need to be performed. The following comparisons may be relevant.

49. A comparison of the prices charged by the dominant company with prices it charges in other markets. This comparison tries to compare the potentially excessive prices with prices charged in competitive markets. Other markets could be other geographic markets where the dominant company sells the same product, but does not possess substantial market power, or other product markets which are closely linked to the product in question. Care must here be taken to control for any difference in, for instance, product quality and distribution costs.

50. A comparison of the prices charged by the dominant company with prices other companies charge in other markets. This comparison is only valid if the products are identical or at least comparable. It would be particularly relevant if the prices of the dominant company can be compared to prices that other companies charge in competitive markets. Care must also here be taken to control for differences in, for instance, product quality and distribution costs.

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<sup>21</sup> United Brands, paragraph 228.

<sup>22</sup> Exceptionally it may be necessary to not take into account certain cost elements when these elements mask the profitability of the dominant firm, in particular when the dominant firm has grown very inefficient due to the lack of competitive pressure.

51. A comparison of the prices charged by the dominant company over time. It may be possible to show that the dominant company increased its prices substantially after it became dominant. This comparison is only valid if there are no other good explanations for the price increase, such as for instance a substantial increase in costs.

## 7. Application of the United Brands test to the EU case law

52. It is important to recall that the Court has made it clear that the test it developed in *United Brands* is not the only way to assess excessive prices: “Other ways may be devised – and economic theorists have not failed to think up several – of selecting the rules for determining whether the price of a product is unfair.”<sup>23</sup> However, it is nonetheless interesting to see how the different cases described earlier ‘fit’ the test.

53. In *General Motors* there is no explicit investigation of the Commission into the cost of conformity inspections or the profit margin obtained. However, while this case preceded *United Brands*, implicitly a price-cost comparison was made. It was established that the price charged was the same as the one charged for imported American cars while the conformity inspection of European vehicles was much less costly. It was suggested that the proper benchmark was the price charged for non-imported European cars. The (implicit) comparison made it obvious that the service did not correspond to the cost of the operation for the imported European cars.

54. In *United Brands* the Court developed its test because the Commission had not analysed UBC's production costs, although it could have done so. It was necessary to consider UBC's costs as the price in Ireland could not be used as a relevant benchmark to assess its profit margin in view of the fact that UBC presented documents indicating that prices in Ireland had produced losses. Similarly, the price difference with UBC's competitors could not be used as a benchmark as this difference was only 7% which could not be automatically regarded as excessive and consequently unfair.

55. In *Bodson* the Court seems to suggest that for finding unfair prices it is sufficient to establish that the prices of a legal monopoly are different from the prices charged in competitive conditions in other communes. Even assuming that to make a correct comparison such a higher price must be corrected for possible differences in the quality of the provided services, the Court seems to apply the *United Brands* test in a reduced way by concentrating only on the second limb. It is apparently considered that in case the exclusive concessionaire is asking a higher price than the one asked in a (more) competitive market, it can be taken for granted that the concessionaire will either make a high profit margin or sustain a high level of inefficiency as a result of its legal monopoly. While not being considered in this case, it seems likely that the Court would have taken into account possible cost justifications of the dominant undertaking as to why its prices are higher (see also the next case).

56. In *SACEM* the Court seems to suggest that prices charged by a monopolist in one Member State will be excessive, as long as they are appreciably different (being higher) from the prices charged by another monopolist in another Member State.<sup>24</sup> Although the test appears on its face to be based only on a comparison between prices (the second limb of the *United Brands* test), by considering that the copyright society is still able to justify the difference, the Court in fact accepts that an abuse will be established only if also the margin between cost and price is unreasonable (the first limb of the *United Brands* test). The

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<sup>23</sup> Case 27/76 *United Brands*, paragraph 253.

<sup>24</sup> See also Case 395/87 *Ministère Public v Tournier* [1989] in which the Court was asked to rule on similar questions concerning the royalties charged by SACEM and ruled along the same lines.

Court's reasoning however suggests that the burden of proof for the first limb of the United Brands test should be on the dominant undertaking in case of a (legal) monopoly charging higher prices.<sup>25</sup>

57. In its *Deutsche Post* decision the Commission referred to General Motors and United Brands. The decision states that the fairness of a certain price may be tested by comparing this price to the economic value of the product, where the latter is also described as the average cost including a reasonable profit margin. As Deutsche Post did not have a transparent cost accounting system for the relevant period, the Commission could not make a detailed cost analysis of Deutsche Post's average cost for the service in question. As an alternative cost benchmark the Commission used 80% of the domestic tariff, as Deutsche Post and other public postal operators, when notifying the Reims II agreement, had argued that the average cost of forwarding and delivering incoming cross-border mail (including a reasonable profit margin) may be approximated to 80% of the domestic tariff. By charging the full domestic tariff for this 'virtual' A-B-A remail, Deutsche Post obtained a price which was 25% above the estimated average cost and the estimated economic value of that service, while usual profit margins in this sector were only around 3% per item. If the terminal dues were set at 70% of the domestic tariff, as some public postal operators had agreed between themselves, the price of Deutsche Post was 43% above the estimated economic value. The Commission concluded that the tariff charged by Deutsche Post had no sufficient or reasonable relationship to real cost or real value of the service provided, exploited customers excessively and should therefore be regarded as an unfair selling price within the meaning of Article 102.

58. In its *Helsingborg* decision the Commission applied the United Brands test. By introducing demand side features in the assessment of the economic value of a product, some might say that it arguably went beyond the test, by making it more demanding than the Court might have intended it originally. The Court in its judgements described above has always based the economic value of a product on its costs of production including a necessary profit margin to attract sufficient capital. It is thus clear that a definition of economic value based on what customers are willing to pay would not be aligned with the case law, as it would define away any possible excessive price. The Commission's decision could be understood as an attempt to avoid that the port might be punished for providing a superior product. While the services

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A similar reasoning was followed in the more recent *Daft Punk* rejection of complaint decision. This case did not concern excessive prices but unfair conditions. Members of the Daft Punk music group claimed in particular that SACEM abused its dominant position by obliging its members to entrust all their rights to SACEM and thus not allowing them to manage certain types of their rights individually (without entrusting them to any other collecting society). SACEM argued that such limitation is aimed at protecting the authors who would individually have very weak negotiating position vis-à-vis music publishers. Further, SACEM argued that this limitation prevents "cream skimming", i.e. the practice that the authors would entrust to the collecting society only those rights where the management is particularly difficult and costly. However, the Commission considered that in view of the developments in the music industry, this limitation is indeed no longer indispensable and proportional and could be considered as an abuse of dominance by SACEM. The Commission found that (i) the technical progress had made it possible for the authors to manage at least some of their rights individually, (ii) a corresponding obligation had been removed by most collecting societies in other countries and was applied only by a very limited number of other collecting societies, (iii) the "cream skimming" was not a real issue as demonstrated by the fact that most collecting societies in other countries already for some time allowed individual management of rights without any apparent problems with "cream skimming". In reaction, SACEM decided voluntarily to change its statutes so that, on the basis of a reasoned request by the author, its Administrative Council could allow individual management of some authors' rights. This was considered by the Commission as sufficient to remove the possible abuse and the complaint was thus rejected (as the complainant insisted that this change of the statutes was not sufficient). See the non-confidential version of the decision on the Commission's webpage: [http://ec.europa.eu/competition/antitrust/cases/dec\\_docs/37219/37219\\_11\\_3.pdf](http://ec.europa.eu/competition/antitrust/cases/dec_docs/37219/37219_11_3.pdf)

See also Case 127/73 *Belgische Radio en Televisie v SV SABAM and NV Fonior* [1973], an early preliminary ruling case where the Court decided along the same lines.



provided by HHAB were not necessarily superior to the services provided elsewhere at other ports, the fact that the services were provided at Helsingborg allowed ferry operators to cross the Øresund in an expeditious way, which, according to the Commission, is in itself valuable.<sup>26</sup> This would fit the second limb of the test.

59. Although in *Rambus* no final decision was taken and thus no abuse was established, the concern of the Commission that Rambus charged excessive prices was based on a comparison between prices that would have prevailed had Rambus disclosed its patents, and prices that it charged following its deceptive conduct. The case thus suggests that in case of improper conduct of a dominant undertaking in a standard setting context, even though the conduct itself does not necessarily need to be illegal under the antitrust rules, excessive prices can be established if the price prior and after the deceptive conduct is (appreciably) different.<sup>27</sup> In other words, the focus is on the second limb of the United Brands test.

## 8. Conclusion

60. In view of the limited experience with cases concerning excessive prices, not all questions can be answered at this stage. At the same time, the relatively small number of cases that we have been able to deal with, may already indicate that addressing excessive prices is an area of antitrust where limited and very cautious intervention is warranted.

61. Indeed, the case law indicates that enforcement against excessive prices is generally only contemplated in markets with an entrenched dominant position where entry and expansion of competitors can not be expected to ensure effective competition in the foreseeable future, that is markets where high prices and high profits do not have their usual signalling function to attract entry and expansion.

62. In the case law the United Brands test has a central place, even though the Court has stressed that it is not the only way to assess excessive prices. In particular, the case law shows that, depending on the circumstances of the case, the assessment focuses more on the second limb of the test, especially where it is obvious that the dominant firm is not providing a superior product.

63. The United Brands test implies in essence that prices are only excessive if the profit margin is excessive and this is not the result of superior efficiency but of the exercise of durable market power. However, this does not answer the question how high the profit margin/price must be to be found excessive; just appreciably above the competitive level or significantly higher? The case law described above seems sometimes to indicate that any appreciable deviation from competitive levels could be deemed excessive. To the extent that cases are only pursued in markets where high prices and profits have lost their signalling function to attract entry, it could be argued that such a clear but strict comparator is not inappropriate. The enforcement practice indicates that generally only cases concerning large deviations from competitive levels are pursued. In view of the complexity of excessive pricing cases this is arguably a wise use of enforcement resources.

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<sup>26</sup> Commission decision COMP/36.568 – Scandlines Sverige AB v Port of Helsingborg [2004], paragraph 242.

<sup>27</sup> See also paragraphs 287-291 of the Communication from the Commission – Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements, OJ C 11, p. 1-72, 14.1.2011 (also found at: <http://ec.europa.eu/competition/antitrust/legislation/horizontal.html>).