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More documentation related to this discussion can be found at
www.oecd.org/daf/competition/excessive-pricing-in-pharmaceuticals.htm

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Excessive Pricing in Pharmaceutical Markets

Background Note by the Secretariat*

There are strong arguments for not intervening against exploitative excessive pricing conducts, which have led to the development of stringent enforcement screens for the bringing of such cases. However, recent years have seen significant calls for intervention against high prices for pharmaceutical products, and there have been a number of competition enforcement cases regarding exploitative excessive pricing in this sector. These cases meet the criteria set out in the enforcement screens regarding excessive pricing. At the same time, the conditions that justify bringing such cases in the first place seem to be relatively common in the pharmaceutical sector. This raises questions regarding what is the best response to high prices in this sector, and particularly whether there are alternatives to bringing exploitative excessive pricing cases. The application of competition law against high prices in the pharmaceutical sector requires a deep understanding of market dynamics and sectoral regulation, and of the various regulatory responses that may be deployed to address high prices. As such, it may be appropriate to explore various avenues for intervention, if possible in cooperation with the applicable sector regulator.

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1. Introduction

1. Despite undeniable advances, both policy makers and other stakeholders in many countries have become increasingly concerned about the outputs of the pharmaceutical system. The prices of many novel drugs make affordable access to them very difficult for both payers and patients. The R&D process is costly and complex. The expected market rewards are sometimes insufficient to incentivise the development of some badly needed product. The costs and pricing structure of the pharmaceutical market are often opaque; and there are legitimate questions about the degree of innovation and value offered by increasingly costly new treatments (OECD,(n.d.), p. 2_[1]).

2. In particular, recent years have seen significant calls for intervention against high prices for pharmaceutical products. A number of competition enforcement actions directed against excessive pricing in this sector have also taken place.¹ These actions take place at the intersection of two challenging topics for competition law enforcement – actions against exploitative high pricing and interventions in the pharmaceutical market.

3. Excessive pricing in the absence of exclusionary conduct or cartelisation is perceived mainly as either a temporary and self-correcting market failure, or as a problem to be addressed through sector-specific regulation (OECD, 2011, pp. 8-11_[2]). While many competition laws around the world contain provisions against excessive prices, competition agencies have only exceptionally brought excessive pricing cases. Some jurisdictions even preclude competition enforcers from calling into question the high prices charged by a “pristine monopolist” absent collusive or exclusionary practices² – though it is the incipient threat of future “excessive” prices that motivates enforcement action against unilateral exclusionary behaviour and cartels. This reflects strong arguments for not intervening against exploitative excessive pricing conducts, which have led even the proponents of intervention against such practices to set out stringent enforcement screens.

4. Pharmaceuticals markets have important features that significantly depart from the standard models for competitive markets. These features go a long way towards explaining why pharmaceutical markets are deeply affected by regulation. As a result, a proper understanding of how competition law works in this area – including as regards excessive pricing – requires a solid knowledge of the structure of the relevant pharmaceutical market and its regulation.

5. In the past, the Competition Committee and its Working Parties have pursued in-depth discussions on a number of related topics. In 2011, there was a discussion on exploitative ‘Excessive Prices’ (OECD, 2011_[2]). As regards pharmaceutical markets, in 2000 the Committee organised a roundtable on ‘Competition and Regulation Issues in the Pharmaceutical Industry’ (OECD, 2000_[3]), which was followed by discussions on ‘Generic Pharmaceuticals’ in 2009 (OECD, 2009_[4]), and on ‘Competition and Generic Pharmaceuticals’ in 2014 (OECD, 2014_[5]).

6. This background paper will not repeat the detailed analysis of the issues discussed in those background papers and sessions. Given the overlap in topics, however, the present paper will build on the work pursued then – particularly as regards enforcement against exploitative excessive prices, on the one hand, and as regards the peculiarities of competition in pharmaceutical markets, on the other.

7. This background paper is structured as follows. Section 2 reviews the framework for competition enforcement against ‘pure’ excessive prices. Section 3 looks at recent examples of excessive pricing cases in pharmaceutical markets, and evaluates how these

cases fit within the general competition law and policy framework for enforcement against excessive high prices. Section 4 moves beyond a purely competition-based focus, and looks at the main features of pharmaceutical markets and their regulation. Section 5 takes into account the insights arising from all the previous sections and seeks to understand what types of competition intervention may be appropriate to address high prices in pharmaceutical markets. Section 6 concludes and identifies outstanding questions for discussion.

2. Excessive Pricing

8. Various factors explain the level at which prices are set, including the degree of competition in the relevant market. If the market is competitive, it is expected that the price will be set close to cost. Prices will tend to be higher the further a market deviates from perfect competition. In situations of legal or *de facto* monopoly, economic theory predicts that a *monopoly price* will be imposed – i.e. the price at which the monopolist earns the most profits. For any higher price than the monopoly price, the monopolist would lose sales in excess of what he would gain by the price increase. As a result, economic theory predicts that prices will not be raised above the monopoly price.

9. Given this, a prohibition against excessive prices is superfluous from a purely economic standpoint. Prices above the monopoly price are not possible, or are at least irrational. If a prohibition against excessive prices amounts to a prohibition against monopoly pricing, this would mean that the prohibition of excessive prices would penalise the mere fact that a company holds a dominant position – but this contradicts competition law, which does not prohibit dominant positions *per se*, but only their abuse. If, on the other hand, the prohibition catches all prices above the competitive price but below monopoly price, this would lead to a paradox – because monopoly prices would be allowed, while lower prices would be prohibited as excessive.

10. Given the challenges identified above, it is unsurprising that excessive pricing is an area of limited competition enforcement around the world. Excessive pricing remained for a long time underdeveloped conceptually and underused in practice (Akman and Garrod, 2011, pp. 404-405^[6]; Jenny, 2018, p. 4^[7]). Nonetheless, legal provisions prohibiting excessive prices have been the subject of continuous enforcement over the years.³

2.1. Legal Frameworks

11. Some jurisdictions do not prohibit exploitative excessive pricing as such.⁴ This approach was recently justified by the US Supreme Court, which held that: ‘*the 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.*’⁵ These jurisdictions mainly take high prices as an indicator of underlying competition problems which need to be addressed, rather than as a variable on which competition agencies should intervene directly.⁶

12. In the EU, on the other hand, Article 102 (a) of the Treaty for the Functioning of the European Union (‘TFEU’) prohibits conduct by a dominant company, which consists in ‘*directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions*’. This has been interpreted as prohibiting not only those prices that are unfairly low – such as predatory pricing – but also those which are unfairly high. In *United Brands*, the ECJ explained that a price is abusive if ‘*it has no reasonable relation to the economic*

value of the product', and that an abuse can be identified through a twofold test that considers whether: (i) the price cost margin is excessive and (ii) the price imposed '*is either unfair in itself or when compared to competing products*'.⁷ This decision sets out a two-stage test, which is still deployed in excessive pricing cases.

13. Since most EU Member States' competition laws are borrowed from the Treaty for the Functioning of the European Union, these jurisdictions apply similar regimes to the EU regarding exploitative excessive prices. EU rules on excessive pricing also provide a template for enforcement against exploitative excessive prices in a number of jurisdictions around the world.⁸

14. Over time, the European competition authorities and courts have made use of different methods to determine whether a price is excessive (Motta and Streel, 2007, pp. 33-39^[8]).⁹ One important method is based upon a comparison between production costs and prices.¹⁰ However, price/cost analysis may not be feasible in some cases, e.g. due to lack of data or because the price relates to an intangible good such as an IP right (Whish and Bailey, 2018, p. 740^[9]). A different method relies on benchmarking of some sort. One commonly used benchmark is prices. Price-based benchmarks can be used by comparing the investigated price with prices charged by the dominant firm in different markets or over time;¹¹ or by comparing the prices charged by the dominant firm and those charged by other firms, either (i) in the same market,¹² or (ii) in other markets.¹³ Yet another benchmark focuses on the profitability of the dominant firm, by comparing such profits either with: (i) a normal competitive profit¹⁴ or (ii) the profits of other firms.¹⁵

15. Other methods have been deployed by EU Member States, as is shown in Box 1 below. Since all the methods to determine whether a price is excessive under competition law have weaknesses,¹⁶ excessive pricing analyses should be carried out according to as many of the methods indicated above as possible, and should look for robust evidence that prices are indeed excessive (OECD, 2011, pp. 62-63^[2]).¹⁷

16. These methods, which focus on whether prices are excessive, are often also relevant to determine whether the price is unfair in itself or when compared to competing products. This follows from the ECJ's holding in *United Brands* that economists have developed ways to determine whether a price is 'unfair'.¹⁸ Classifying a price as 'unfair in itself' could imply recognising that demand side considerations might warrant pricing substantially in excess of costs,¹⁹ but leads to a number of difficulties.

17. From an economic perspective, the "value" of a product is typically defined as the maximum amount an individual is willing to pay for a product. Using such a definition of value would therefore define the concept of excessive prices under competition law out of existence, as the observed (and allegedly excessive) price would always be lower than the value ascribed to it by consumers of the product (Jenny, 2018, pp. 27-29^[7]). Determining unfairness by reference to a comparable product also raises serious difficulties, such as the identification of products that are sufficiently similar to the product under investigation to act as a valid benchmark. In general, there are significant challenges regarding how to distinguish unfairness from the assessment of whether the price was excessive in the first place, particularly when the same methods are used to establish both limbs of the legal test (Whish and Bailey, 2018, p. 741^[9]).

Box 1. Excessive Pricing Frameworks in the EU^{*1}

A good example of a legal framework for excessive pricing enforcement in the EU can be found in Germany. Exploitative abuses, such as charging excessive prices or demanding unreasonable terms and conditions, are prohibited under section 19(2) No. 2 of the German Competition Act. The benchmark for an abuse applied by the German competition authority is the "comparable market". Under this approach, prices charged by the dominant undertaking have to be compared with prices that would prevail in structurally comparable markets with effective competition. An abuse can be assumed to exist if the prices charged by the dominant undertaking in the relevant market significantly exceed the prices that would apply in comparable markets. Before the prices are compared, a three-step procedure applies. First, the prices charged on the comparable market need to be adjusted to reflect the characteristics of the market where the undertaking is dominant. Second, since such adjustments will be somewhat inaccurate, a "safety margin" which varies from case to case, must be applied in order to prevent over-enforcement. Finally, it must be found that the prices charged by the dominant company in the relevant market significantly exceed prices in the comparable markets (insofar that an additional premium applies to establish an abuse).

Section 19(2) No. 2 of the German Competition Act also prohibits a dominant undertaking from charging "unreasonable terms and conditions". In principle, the same rules that apply as regards excessive pricing also apply to the determination of whether a company demands excessive terms and conditions.

Following an investigation by the European Commission into the gas and electricity sectors, which showed that the German market was characterised by high concentration, vertical integration and high prices, a legal provision was adopted with the goal of facilitating the prosecution of excessive pricing in the energy sector (section 29 of the German Competition Act).^{*2} Unlike what is stipulated in Section 19 of the German Competition Act, the price of the investigated energy provider can be compared with the price of other firms even if these other firms do not operate in a competitive environment. Second, and very importantly, the investigated dominant firm has to demonstrate why the rejected behaviour was not abusive or that the comparative market concept applied by the Bundeskartellamt was erroneous, i.e. that the alleged deviation of their prices is objectively justified. This inverts the burden of proving that a price is excessive, placing the burden on the investigated company. Furthermore, the provision specifically states that the abuse of dominance can also be fulfilled by demanding prices that unreasonably exceed costs. Finally, the decisions of the Bundeskartellamt regarding the energy sector are immediately enforceable, irrespective of whether the decision is appealed.

In the UK, the Competition Appeals Tribunal has recently held that a competition authority should consider a range of possible analyses when determining whether a price is excessive. If the authority identifies a relevant differential between the investigated price and the relevant benchmark price(s), it must also ensure that the differential is sufficiently significant and persistent to be excessive. When determining if the price is also unfair, the authority may conclude that the price is unfair in itself or unfair compared to competing products. However, the authority must give due consideration to any objective justification advanced by the defendant firm, and to any *prima facie* convincing argument that the pricing is actually fair in itself or in comparison to other products.^{*3}

^{*1} For an overview of other legal systems, including the Czech Republic, Denmark, the Netherlands, Spain, Turkey, see (Jenny, 2018, pp. 15-20[5]).

^{*2} Section 29 of the German Competition Act will only apply until 31 December 2022 because the German legislator considered its special rules to be necessary only for a transitional post-liberalisation period. The original deadline was 31 December 2012, but the legislator extended it twice, first to 31 December 2017, and then to the end of 2022.

^{*3} Flynn Pharma & Pfizer v CMA [2018] CAT 11, para. 443.

2.2. Should There be Competition Enforcement Against Exploitative Excessive Prices?

18. In academic circles, and among policy-makers and enforcers, there has been a longstanding debate about whether competition law should be used to address excessive prices. This sub-section summarises the main arguments for engaging or not engaging in competition enforcement against exploitative excessive prices.

2.2.1. Arguments against intervention

19. A first argument against intervention is that prices operate as a mechanism through which markets self-correct. If a dominant firm is earning excessive profits in a given market, this will typically send a signal to attract new entrants into the market (Motta and Streeck, 2007, p. 18_[8]; Jenny, 2018, p. 21_[7]).

20. In the absence of substantial barriers to entry, any intervention that reduces the profits of an incumbent might not only be unnecessary, but could actually prolong the monopoly situation by blocking efficient signals to promote market entry. For this reason, it would be a sensible policy approach not to intervene against high prices if one expects them to stimulate successful new entry within a reasonable period (Fletcher and Jardine, 2006, p. 534_[10]).

21. The belief in market forces as the solution to (temporary) market failure is often bolstered by the (perceived high) likelihood of regulatory failure, a risk which is compounded in the case of price regulation (OECD, 2011, p. 32_[2]). Even *ex post*, the analysis of situations of excessive pricing face significant difficulties in terms of data availability and analysis, of identifying appropriate assessment standards, and of designing and implementing suitable remedies. This has led some to consider that the identification of excessive prices is a ‘daunting, if not, impossible task’ (Evans and Jorge Padilla, 2005, p. 118_[11]).

22. The issues are still more extreme when trying to set clear rules that allow for *ex ante* compliance with excessive pricing rules. The key problem here is that it is not clear what the appropriate benchmark should be. One obvious option is the “competitive price”; but how does one define the competitive price in a market that is not competitive? Should dominant firms really be required to price at levels which would arise under vigorous price competition, when such prices would not be observed in non-cooperative oligopolies? Another benchmark is the cost of production. However, it is clearly the case that a firm’s short run marginal cost of production cannot be used as a practical benchmark for competitive prices, because pricing at short run marginal cost would not be sustainable whenever a firm incurs fixed costs. A firm’s total costs (including both fixed and marginal costs) would also constitute a poor benchmark for our purposes, since firms may be able to sustain prices that are significantly above this level even under competitive market

conditions – in fact, this is how firms obtain their profits. These benchmarks are, in any event, hardly applicable to multiproduct firms, where costs are often shared across products. It is exceedingly difficult to allocate costs to a specifically over-priced product in the context of multiproduct firms – even before taking into account the possibility that the product is manufactured by multiple company divisions, possibly across multiple countries, over several years, and possibly also relying on IP rights based on considerable past R&D efforts related to a different product (Fletcher and Jardine, 2006, p. 534^[10]; Motta and Streel, 2007, p. 18^[8]; OECD, 2011, pp. 32-34^[2]) (Jenny, 2018, pp. 29-30^[7]).

23. Taken together, these difficulties create substantial risks of enforcement errors; and these risks are compounded by the much greater impact that mistakenly intervening against excessive prices is likely to have when compared to the consequences of mistakenly failing to intervene. If a competition agency fails to act against excessive prices, this high price will send a signal to potential competitors to enter the market. Over-intervention, on the other hand, risks a number of significant long-term anti-competitive effects. It reduces the incentives for dominant firms to invest (due to the risk of excessive pricing actions when they seek to recoup that investment) and for new companies to enter the market (because the incentives for entering the market diminish in line with lower prices). It also creates a chilling effect on new entrants and dominant firms alike as to the terms under which they may compete (due to the lack of clarity around the criteria for intervention) (Motta and Streel, 2007, pp. 17-19^[8]; Jenny, 2018, p. 24^[7]). Particularly in dynamic industries, the “deterrent” effect of excessive pricing rules has the potential to be extremely problematic (Fletcher and Jardine, 2006, p. 537^[10]).

24. Even if price regulation is deemed necessary, such an exercise implies a judgement on the part of a competition agency or court that is closer to the competences of a regulator. Competition authorities themselves harbour concerns with respect to aggressive competition law enforcement against excessive prices, premised on the belief that competition authorities are ill equipped to function as price regulators. Price regulation requires constant monitoring and detailed market knowledge. Occasional intervention against a price freely set by a dominant firm is unlikely to solve the issue that allowed such excessive prices to be set in the first place: on the contrary, intervention may even exacerbate the problem to the extent that it may discourage entry. In other words, excessive pricing situations raise issues that are better suited to dedicated, specialised regulators (Motta and Streel, 2007, pp. 19-20^[8]; OECD, 2011, p. 13^[2]). Instead of dictating pricing terms, competition authorities often seek to facilitate or preserve competition in the market instead (OECD, 2011, p. 10^[2]).²⁰

25. In any event, the distortions associated with the “deterrent” effect of excessive pricing rules provide a good policy argument for steering clear of imposing fines for excessive pricing and not to allow private damages actions in respect of such behaviour. Limiting *ex post* sanctions ensures that firms are likely to be less concerned about breaching excessive pricing rules, and that the distortions associated with such rules are greatly reduced (Fletcher and Jardine, 2006, p. 542^[10]).

2.2.2. Arguments for intervention

26. While acknowledging the strength of arguments against intervention, a number of authors have argued that there are good reasons to engage in enforcement against excessive pricing. Firstly, there is the simple philosophical point that the primary rationales for competition policy are to limit the potential for exploitative behaviour and to lower prices for the benefit of consumers. As such, there is a good fit between enforcement against

excessive pricing and the overarching objectives of competition policy (Motta and Streel, 2007, p. 20^[8]; Fletcher and Jardine, 2006, p. 539^[10]; OECD, 2011, p. 35^[2]).

27. Secondly, it has been argued that intervention against excessive pricing may be justified *in certain circumstances*. There may be markets where high prices would not lead to self-correction, at least within a reasonable period. After all, it is post-entry prices, not pre-entry prices, which ultimately attract entry. If potential competitors are aware that dominant undertakings will decrease prices after their entry, they may not enter that market even if current prices are high (Ezrachi and Gilo, 2009, pp. 255-257^[12]).

28. Furthermore, exploitative abuses taking place over a prolonged period usually occur only where there are high and non-transitory barriers to entry or expansion, preventing competitors from undercutting the dominant firm and eroding its market position. As such, where high margins or high prices are adopted over long periods and there are high barriers to entry, it is far from obvious that entry will take place (Jenny, 2018, p. 21^[7]).

29. Sometimes, entry barriers relate purely to the supply side of the market. For example, potential competitors may lack access to crucial IP, or they may face insurmountable regulatory barriers to entry. Often, however, the most serious barriers to entry and expansion relate to the characteristics and behaviour of buyers. These include: (i) high switching costs; (ii) lack of shopping around by customers; (iii) lack of comparable information across suppliers; and (iv) asymmetric information between firms and customers (Fletcher and Jardine, 2006, pp. 543-544^[10]).

30. Third, even if it were true that the assessment of excessive pricing can be challenging, it would be wrong to overstate the difficulties of pursuing such an assessment. While it can be hard to set out simple guidance that draws a clear line between excessive and lawful pricing, there may nevertheless be cases where pricing is so extreme that it becomes relatively easy to demonstrate that it is excessive by reference to a variety of different measures. Acknowledging the difficulties in identifying a single standard which is able to determine whether prices are excessive in all situations, many competition authorities have instead applied several methodologies in parallel in order to minimise the possibility of erroneous intervention (OECD, 2011, p. 12^[2]).

31. Fourth, certain forms of high pricing are already proscribed under competition and consumer law. For example: (i) the law on exclusionary abuse of dominance can require dominant suppliers to ensure that their pricing is fair and reasonable. High prices charged by an upstream supplier to a downstream firm can constitute a constructive refusal to supply or margin squeeze if they restrict or distort the ability of the latter to compete on the relevant downstream market. (ii) rules on FRAND licensing of standard essential patents require the adoption of fair and reasonable prices. (iii) consumer law often requires prices to be fair. If difficulties in determining what the appropriate price is do not prevent intervention in these cases, it is unclear why such difficulties should prevent intervention against excessive pricing when appropriate (OECD, 2011, pp. 539-540^[2]).

32. Fifth, while price regulation should usually be left to specialised sectoral regulators, competition authorities may have a role to play as residual regulators or regulators of last resort. This is particularly the case if there is no competent regulator or if the sectoral regulator lacks the powers to address the problems underlying excessive prices. If a sector regulator does not exist, competition law enforcement may be justified where there are limited grounds for setting up a permanent regulator – such as when problem is non-recurring – or where the likelihood of setting up a regulator in a timely fashion is small

(OECD, 2011, pp. 47, 51-52_[2]). If there is a regulator but it lacks powers to intervene, then competition intervention may be justified on the same grounds as if there was no sector regulator. In such cases, however, the competition authority is likely to benefit from the involvement of the regulator in the competition investigation, given that the regulator possesses significant market knowledge and technical expertise (OECD, 2011, p. 13_[2]).

33. Sixth, direct price regulation, with its concomitant distortions, is not an inevitable outcome in excessive price cases. Potential distortions from price regulation may be minimised if competition agencies intervene only after careful consideration of the potential distortive impact of any proposed remedy, and in a manner that ensures appropriate returns on sunk investments (Fletcher and Jardine, 2006, p. 541_[10]). For example, competition authorities may implement structural measures necessary to create competitive pressure and that lead to price decreases, instead of imposing fines. Alternatively, a competition agency may merely find that a price is excessive and require the dominant firm to reduce its prices to a reasonable (but unspecified) level. In cases of excessive prices in regulated sectors, competition authorities may wish to involve the regulator in remedy design and implementation (OECD, 2011, pp. 13-14_[2]).

34. A last argument for intervention against excessive prices focuses on the differences between EU- and US-inspired regimes. Unlike the Sherman Act, Article 102 TFEU does not prohibit the unlawful acquisition of a dominant position. This means that there is an enforcement gap in Europe, and European-style regimes, that can only be closed through enforcement against unilateral exploitative conducts (e.g. in cases of excessive royalties charged by a company which has obtained its dominant position as a result of not disclosing its patent when it was involved in discussions regarding the setting of an industry standard) (OECD, 2011, pp. 22-23_[2]; Jenny, 2018_[7]).

2.2.3. Screens for Enforcement

35. Enforcement against excessive pricing presents *high risks* of type I error (i.e. mistaken intervention) with potentially *high costs* (because the market may self-correct in the absence of intervention, and an error will lead to dynamic inefficiency related to low investments and innovation). On the other hand, type II errors (i.e. mistaken failure to intervene) have a relatively *low cost*, mainly related to allocative inefficiency (Jenny, 2018, p. 25_[7]). When taken together with the fact that even arguments for competition enforcement against excessive prices only provide support for intervention in specific market and institutional circumstances, this naturally leads to a presumption against competition enforcement in this field.

36. Only when certain stringent conditions are met will competition enforcement against exploitative excessive pricing be justified. Further, the finding of such a competition infringement must be subject to a high standard of proof (Motta and Streel, 2007, p. 21_[8]; Fletcher and Jardine, 2006, p. 543_[10]). Reflecting this, a number of demanding screens for competition intervention against exploitative excessive pricing can be found in the literature (Evans and Jorge Padilla, 2005, p. 119_[11]) (Motta and De Streel, 2006, p. 91_[13]) (Motta and Streel, 2007, pp. 22-29_[8]) (Röller, 2008_[14]) (Nazzini, 2013, pp. 464-472_[15]) (Jenny, 2018, pp. 37-39_[7]).²¹

37. While differing as to the details, these screens have in common that they require: (i) the offending firm to have significant market power, close to a pure monopoly position in the market. The closer the market structure is to an oligopoly, the less likely it will be that a dominant firm will have sufficient market power to generate excessive prices. In addition, the higher the degree of market power, the less likely it is that the market will

self-correct within a relevant timeframe (OECD, 2011, p. 50^[2]). Some authors also require that market power must be the consequence of current or past exclusive or special rights, or of un-condemned past exclusionary anticompetitive practices (Motta and De Streel, 2006, p. 91^[13]) (Motta and Streel, 2007, pp. 22-29^[8]); (ii) there must be high and durable barriers to entry which make the market unlikely to self-correct. As long as markets can self-correct, high prices and profit margins will be transitory phenomena which may not justify a competition intervention; (iii) intervention should not occur when it may adversely impact research and innovation, where the risks and costs of enforcement errors are highest; (iv) alternative regulatory intervention must be either impossible, extremely unlikely, inappropriate or absent.

3. Excessive Prices in Pharmaceutical Markets

38. There are widespread concerns about pharmaceutical prices, and in particular about how they impose ever-higher financial burdens on the public purse. This section will describe competition interventions that have sought to address pharmaceutical high prices directly as exploitative excessive pricing. However, this is a recent phenomenon: numerous examples of excessive prices were provided in the 2011 OECD Roundtable on Excessive Prices, but only three cases related to pharmaceutical products.

Box 2. The 2011 OECD Roundtable on Excessive Prices – Pharma Cases

Germany

The German contribution discussed a number of cases concerning the excessive pricing of pharmaceutical products in the 1970s. The most representative case was the so-called Valium case.^{*1} Following comparisons of prices charged in Germany and in other European markets – complemented by a comparison of profits and costs – it was found that prices were excessive by approximately 35-40%. The decision of the Bundeskartellamt was appealed and upheld by the Higher Regional Court of Berlin (Kammergericht), which reduced the amount by which the prices were considered excessive on the basis of the benchmark price which the court considered most adequate for comparison. That decision was subject to a further appeal to the Federal Court of Justice (Bundesgerichtshof), which judged in favour of the company.

A more recent case was brought in private proceedings.^{*2} A pharmaceutical manufacturer had suddenly raised prices by 400%, after moderate price increases over several years. The court found that the claimant was entitled to damages amounting to the difference between the price paid by the claimant and the price that would have been charged under competitive conditions.

UK

In 2001, the OFT pursued a case relating to the excessive pricing of a sustained release morphine product.^{*3} This case was arguably not a typical excessive pricing case since there were two elements to the case: exclusionary low pricing to the hospital sector and excessive pricing to the community sector. While the OFT chose to run the case as two separate abuses, this particular instance of excessive pricing could instead have been framed as ongoing recoupment from the dominant company's predatory strategy, rather than as an abuse in its own right.

South Africa

In 2002, the Competition Commission found that manufacturers of antiretroviral treatments for individuals infected with HIV/AIDS had abused their dominant positions by charging excessive prices, refusing to give competitors access to essential facilities, and engaging in exclusionary practices. At the conclusion of the investigation, the Commission announced that it was referring the matter to the Competition Tribunal for adjudication. Before the referral and prosecution of the case, the manufacturers negotiated a settlement agreement under which they admitted no liability.

^{*1} BGH [Federal Court of Justice], decision of 16. 12. 1976, KVR 2/76 – Valium; BGH [Federal Court of Justice], WuW/E 1445 ff., 1454 Valium II.

^{*2} OLG [Higher Regional Court] Frankfurt a.M., decision of 21.12.2010, 11 U 37/09 (Kart) – Arzneimittelpreise.

^{*3} OFT, Case CA98/2/2001 Napp Pharmaceutical Holdings Ltd (30 March 2001). Competition Appeals Tribunal judgment, following appeal: Napp Pharmaceuticals Holdings Limited and Subsidiaries and Director General of Fair Trading, January 2002, 1001/1/1/01.

3.1. Recent Cases

39. A number of cases against excessive pricing have recently been brought in the pharmaceutical sector as regards off-patent drugs. Given the absence of excessive pricing as an antitrust infringement in the US, excessive pricing cases have been brought elsewhere in the world, and particularly in Europe. Nonetheless, concerns about excessive prices of pharmaceuticals have led to a number of interventions in the US.

3.1.1. US

40. Excessive drug prices are not regulated in the United States, and any legal basis for taking action against excessive drug prices must be tied to a recognised violation of antitrust law. Although raising the price of a drug is not illegal conduct on its own, dramatic price increases have been a catalyst for increased regulatory scrutiny and private enforcement claims.

41. After a public outcry in 2016 over the sudden price increase of EpiPens, manufacturer Mylan confirmed that it had received information requests from the Federal Trade Commission concerning possible antitrust violations.²² In late 2016, two members of Congress asked the Department of Justice and the Federal Trade Commission to investigate possible collusion concerning the price of insulin products.²³

42. In 2017, over forty state attorneys general brought a claim against a large number of generics manufacturers concerning allegations that the manufacturers collectively agreed to raise prices for a large number of generic drugs.²⁴ A number of executives were the subject of criminal charges filed by the Department of Justice, which accused them of illegally profiting from the sale of doxycycline hyclate – an antibiotic – and glyburide – an anti-diabetic. The Department of Justice noted that the charges were part of an ongoing investigation, signalling that additional enforcement may follow.²⁵

43. Additionally, there has been a spate of private litigation concerning generic drugs since early 2016.²⁶ Most of the cases allege collusion to fix prices by generic drug manufacturers: in particular, it is argued that, following manufacturers' discussions at Generic Pharmaceutical Association meetings and events in 2013 and 2014, the drug prices of a number of generics suddenly increased. These allegations parallel the claims made by the state attorneys general in the doxycycline and glyburide case above.²⁷ Many of these private litigation cases have been consolidated due to the similarity of their claims concerning the anticompetitive behaviour of the companies.

44. As of the time of writing, these cases are pending and their outcome is unknown.

45. One current case concerns unilateral conduct in violation of Section 2 of the Sherman Act. The allegations centre on a company's attempts to keep competitors out of the market by tying up a product needed for drug production. The company is said to have been able to raise the price of its drug by 2,600% as a result of leveraging its 100% market share (the defendant company is the only company with Food and Drug Administration approval for the sale of the drug in the United States).²⁸

46. Lastly, the US Senate Special Committee on Aging released a report on drug pricing in late 2016, which included four case studies of companies that had made sudden, dramatic price increases to certain drugs.²⁹ The report focused on "gold-standard" drugs — the best available treatment for the disease, likely to be the continued preference of doctors for patient prescription. Each drug had also been off-patent for many years. The report noted that in each case, the company: "*selected a sole-sourced gold standard drug for*

*which there is a small market, created a closed distribution system or other means to block competitors, and engaged in price gouging, exercising elements of the business model to make massive profits from decades-old life-saving therapies.”*³⁰ Highlighting the absence of excessive price regulation in the United States, the report also noted that it is unclear whether the companies violated any antitrust laws, and that the ability to increase prices to such high levels is based on the exploitation of a lawful business model.³¹ As we shall see, these cases seem to bear some resemblance with some of the excessive pricing cases in Europe, in particular those brought in the UK and Italy, and currently being investigated by the EU.

3.1.2. UK

47. In 2017, the CMA adopted an excessive pricing decision regarding an anti-epileptic drug, Epatunin. Although relatively few patients newly diagnosed with epilepsy are now prescribed the active ingredient underpinning this drug – phenytoin – there is a community of established users of this drug who are stabilised on the treatment and for whom it is effective. Epatunin was subject to a principle of continuity of supply by the UK’s Medicines and Healthcare Products Regulatory Agency (MHRA), which meant that patients who were stabilised on Pfizer’s phenytoin were advised to remain on Epatunin, and should not be switched to another manufacturer’s phenytoin drug. Consequently, it was difficult for a new manufacturer to compete for patients and doctors that relied on Epatunin.

48. In the UK, there are two price regulation mechanisms for medicines that are relevant in this case. Under a voluntary scheme, participating companies are free to set their own prices, but their profit is capped at 21% return on capital employed or a 6% return on sales (ROS). This profit cap applies to the overall returns achieved by participating companies across their whole drug portfolio covered by the National Health Service (NHS). Companies which do not sign up to this scheme are regulated by a statutory scheme according to which the Secretary of State (in practice, the Department of Health) has 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. At the time of this case, this statutory scheme did not apply to generic medicines.³²

49. Phenytoin has long been off-patent. Up until 2012, Pfizer sold Epatunin as a branded drug under the voluntary price scheme. In 2012, Pfizer sold Epatunin’s UK marketing authorisation (i.e. the right to sell this product) to Flynn Pharma. As a result, Pfizer became an upstream manufacturer of the drug under an exclusive supply agreement, but granted distribution rights to Flynn Pharma. Elsewhere in Europe, Pfizer continued to manufacture and sell the drug as before. Flynn Pharma then obtained approval in the UK to sell the product as a generic, rebranded it and started marketing it under a new name.

50. As a result, the product was withdrawn from the voluntary scheme. Since generics were not subject to the statutory regime either, this allowed the companies to set prices freely. Pfizer increased the price it sold the drug to Flynn Pharma, which also increased the retail price significantly – the retail price of a pack of 84 capsules of 100 mg increased from GBP 2.83 to GBP 67.50. Flynn also sent a letter to prescribers (published on the MHRA website) explaining that its rebranded product was the same drug as Epatunin, and that doctors should continue to prescribe it to patients that had previously used Epatunin. When wholesalers tried to import the drug from other EU countries under Pfizer’s brand, Flynn sued for trademark infringement.

51. Following a complaint from the Department of Health, the CMA concluded that Flynn and Pfizer explored a regulatory loophole which allowed: (i) Pfizer to sell drug to Flynn at prices 8 to 17 times higher than previous NHS prices; (ii) Flynn to then re-sell drug at prices 25 and 27 times higher than previous final prices. The regulatory loophole arose because the generics market was presumed to be competitive.³³ Applying the framework for excessive pricing developed by the EU courts, the CMA found that the prices applied by Pfizer and Flynn were both excessive and unfair.³⁴

52. To determine that prices were excessive, the CMA adopted a Cost Plus method under which the reasonable rate of return was calculated by using the Return on Sales (RoS) allowed under the voluntary scheme (equal to 6%) and by cross-checking the result with the calculation by the Return on Capital Employed (ROCE). To establish that the prices were unfair, the CMA took into account: (i) the substantial disproportion between the applied price and the benchmark price; (ii) the way the relevant markets operated; (iii) the age of the drug, together with the absence of any R&D effort or commercial risk; (iv) Flynn's and Pfizer's awareness of the adverse effect of the price increase on the end consumer; (v) Pfizer's introduction of Flynn into the supply chain to avoid adverse publicity and reputational damage, rather than genericising the drug itself; and (vi) the fact that similar price increases were not introduced in other EU Member States where the product was, except in one case, sold profitably.

53. On appeal, the Competition Appeals Tribunal (CAT) concluded that the CMA did not correctly apply the legal test for excessive pricing. In particular, the Tribunal held that the CMA should not have relied on a cost plus approach to the exclusion of other methodologies. As regards unfairness, the Tribunal emphasised that the CMA erred by considering unnecessary to prove the unfairness of the price through a comparison between the price of the investigated product with those of comparable products. There were other drugs available in the UK that used the same phenytoin sodium molecule, and which could be said to be priced at a similar level to the one set by Flynn.³⁵ While they were not in the same product market, the Tribunal found that the CMA should have considered the suitability of such phenytoin comparators, and phenytoin tablets in particular, in more depth. This analysis was particularly important for the purpose of assessing whether the prices charged were unfair.³⁶

54. The Tribunal remitted the case to the CMA for further consideration. This decision has had an important impact not only on this case, but also on a number of other ongoing investigations in the UK. In particular, the CMA has sent a statement of objections to Actavis for de-branding 10 mg hydrocortisone tablets and increasing their price by 12,000%; and is currently investigating Concordia International's practice of buying licences to patented drugs, de-branding them and raising prices up to 600%.

3.1.3. Italy

55. In 2016, the Italian competition authority condemned a price increase of a number of cancer medicines ('Cosmos drugs') as excessive pricing.³⁷ Cosmos drugs are niche products that lack substitutes. According to the relevant regulatory body,³⁸ they are essential and non-substitutable medicines used for the treatment of cancer for specific categories of patients (namely old people and children). The lack of substitutability arises from the very low side effects that Cosmos drugs provoke by comparison to other cancer drugs. Given the absence of substitutes (actual and potential) for Cosmos drugs and the preference of doctors and patients for therapeutic continuity, demand is price-inelastic.

56. The drugs were developed long ago, during the 1950s and 1960s. IP protection had long expired when Aspen, a generics company, bought their trademark and marketing rights from the originator, GlaxoSmithKline (GSK). The long commercialisation of Cosmos by GSK allowed for full amortisation of R&D and marketing by the time of their acquisition by Aspen. Only GSK sold Cosmos drugs. Given the small dimension of the relevant markets, potential competitors were unlikely to enter the market as they had little financial incentive to do so.

57. Cosmos drugs are reimbursed by the Italian health service and their price is subject to negotiations with the Italian Regulator, AIFA (*Agenzia Italiana del Farmaco*). The Italian procedure for fixing prices on reimbursable drugs provides that agreements between the registration holder and AIFA can be re-negotiated every second year.

58. In 2013, Aspen started negotiations with AIFA. Aspen aimed to increase the price for the Cosmos drugs and to align with the price applied in other EU countries. In the context of these negotiations, Aspen insisted that the Cosmos drugs should be categorised as non-reimbursable, which would mean the drugs would no longer be subject to price regulation, allowing for price increases. They also threatened to withdraw the Cosmos drugs from the market, and deliberately caused a shortage of Cosmo drugs in the Italian market during price negotiations. This aggressive conduct by Aspen – in a situation where the Cosmos portfolio constituted lifesaving and irreplaceable drugs – led AIFA to agree to price increases of up to 1,500%.

59. When investigating this case, the Italian competition authority applied the two-step test developed by the European courts in *United Brands*.³⁹ To determine whether the prices charged by Aspen were excessive, the Italian competition authority deployed multiple methods to compare Aspen's price to a reasonable measure of the product's economic value. In particular: (i) the authority looked at the percentage gross margin (gross margin/revenues %), and concluded that the new price increased this margin between 300% and 1500%, when the original prices already generated profits; (ii) the authority concluded that revenues were between 150 and 400% higher than a cost-plus price (based on direct variable costs, indirect fixed costs allocated to the product and a measure of profitability, i.e. the Return on Sales – RoS); (iii) the authority compared the net cash flows during a 20 years' time-span, with Aspen's investment in acquiring the drugs in 2009. It concluded that Aspen was enjoying an internal rate of return two to four times in excess of the average rate of return for generics (which is 8%). As a result, it concluded that the prices charged by Aspen were excessive.

60. The authority also concluded that the prices were unfair because there were not any non-cost related justifications, such as improvements in quality or in the level of service, and because the prices amounted to a misuse of national health system's limited resources. Furthermore, Aspen did not incur any R&D or marketing costs. Since there were no competitors or competitive pressure, and the drugs were necessary to treat certain types of cancers, Aspen also did not incur any business risk. While AIFA is normally a monopsonist, in this case it did not have any countervailing buyer power. Lastly, evidence showed that the negotiation with AIFA was conducted by Aspen following a precise and comprehensive strategy, defined centrally and aimed at putting pressure on AIFA. This strategy included: (i) insisting on delisting the Cosmos drugs from the list of drugs reimbursable by the Italian national health service, so as to be able to freely price the Cosmo drugs; (ii) threatening to withdraw the Cosmos drugs from the market; and (iii) deliberately causing a shortage of Cosmo drugs on the Italian market during price negotiations through Aspen's stock management operation.

61. On appeal, the Italian First Grade Administrative Court (TAR) confirmed the Italian competition authority's decision.⁴⁰

Follow on Investigations

62. In February 2017, the Spanish competition authority announced that it was also investigating Aspen's price increases in relation to several of its anticancer drugs. It also opened an investigation into Aspen and its Spanish distributor Deco Pharma SL over alleged abuses of market power, including refusal to supply certain drugs, and agreements to limit distribution and cause deliberate drug shortages.

63. These proceedings were archived as the European Commission opened a formal investigation against Aspen to assess its conduct in the entire European Economic Area except Italy in May 2017.⁴¹ The Commission intends to investigate whether Aspen has imposed unfair and excessive prices in the form of significant price increases for a number of pharmaceutical products. The Commission is also investigating whether, to impose such price increases, Aspen has made use of unfair, abusive negotiation practices with national authorities and/or hindered parallel trade between the Member States. Such practices include reducing the direct medicine supply and/or threatening supply reductions, as well as defining EEA-wide stock allocation strategies and implementing them in cooperation and/or agreement with local wholesalers. This is the European Commission's first investigation into excessive pricing practices in the pharmaceutical industry.

64. Furthermore, in June 2017 the South African competition authority also started investigations against Aspen for excessive pricing of Cosmos drugs, as well as against a number of other pharmaceutical products and companies.⁴² It seems that the case against Aspen has been archived, even as the investigation against other pharmaceutical companies continues.

3.1.4. Denmark

65. On 31 January 2018, the Danish Competition Council ("DCC") ruled that CD Pharma (a pharmaceutical distributor) had abused its dominant position by charging unfair prices for the drug Syntocinon.⁴³ Syntocinon, which is used by public hospitals in Denmark, has existed since the 1950s and its patent expired long ago. Syntocinon contains oxytocin, an active substance given to pregnant women in connection with childbirth. CD Pharma had an exclusive distribution agreement with the producer of Syntocinon, which ensured its ability to supply the market.

66. Amgro is a wholesale buyer for hospitals. Amgro put out a tender on Syntocinon for the period of 1 April 2014 – 31 March 2015. Orifarm, a parallel importer and competitor to CD Pharma, won that tender. However, Orifarm was not capable of providing Amgro with the full amount of Syntocinon it required; Amgro had therefore to buy a residual quantity of Syntocinon from CD Pharma, the only alternative supplier of Syntocinon on the Danish market.

67. During 2007-2014, the price of drug Syntocinon was stable around DKK 44 (EUR 5.9). From 28 April 2014 until 27 October 2014, CD Pharma increased the price on Syntocinon to DKK 945 (EUR 127) – i.e. a price increase of 2,000%. During this six months period, Amgro paid almost six million DKK (approximately EUR 780,000) in excess of the price set in the original contract with Orifarm.

68. The DCC found that there were no objective justifications for the price increase. There were no increased costs incurred by CD Pharma, nor were there special

considerations related to research and development. Consequently, the DCC ruled that CD Pharma's price increase amounted to an abuse of a dominant position and ordered it to refrain from similar abusive behaviour in the future. The DCC has also decided to submit the case to the Danish State Prosecutor for Serious Economic and International Crime.

3.2. Interim conclusions

69. The exploitative excessive pricing cases reviewed at section 3.1 above have a number of similarities. First, they relate to medicines that have long been off-patent, so there are no R&D and investment recoupment justifications for high prices, nor concerns with interfering with innovation. Second, the claim of excessive pricing relates to sudden and significant price increases of products that have long been in the market. Third, the medicines in question are essential to patients, and there was no reasonable prospect of the entity responsible for providing those medicines – usually entities linked to the State and national health services, which bear the cost of those medicines – not purchasing them. As such, demand was extremely price-inelastic. Fourth, the authorities consistently found that there was no prospect of timely market entry of alternative products, either because of supply constraints, the regulatory framework, or the limited size of the market. Fifth, regulatory intervention was perceived to be unable to provide an appropriate, or at least timely, response to the price increase (Colangelo and Desogus, 2018, p. 240^[16]).

70. In the light of this, it seems that these cases reflect the stringent screens reviewed in section 2.2.3 above, which seek to ensure that competition intervention against excessive prices is limited to those situations where this is the least-bad available alternative (Jenny, 2018, p. 40^[7]). However, these screens are unable to explain why there has been a surge of excessive price in the pharma sector, particularly when such cases were virtually unheard of until recently. To understand this, we need to look at pharmaceutical markets in more detail.

4. Regulating Prices in Pharmaceutical Markets

71. Medicines are subject to a dense and comprehensive regulatory framework that implicitly recognises the limited ability of competition enforcement to lower their prices. This is a consequence of how significantly pharmaceutical markets depart from models of perfect competition.

72. From a demand perspective, many consumers do not select or pay for a number of medicines, whose cost is supported by third parties. Furthermore, pharmaceuticals can be indispensable to patients – even critical to preserving life – which leads to inelastic demand for treatment, in particular for medicines for which there are no viable alternatives. At the same time, prescribing doctors select, but do not consume or pay for medicines. Lastly, insurance companies and national health services are liable for the payment of a large number of medicines, but have limited tools to control their consumption and selection (OECD, 2014, p. 5^[17]; National Academies of Sciences, Engineering, 2018, pp. xix-xx^[18]).

73. From a supply perspective, safety and efficacy concerns, and the IP protection of numerous medicines, mean that the pharmaceutical industry is highly regulated (OECD, 2000, p. 7^[3]).

74. Nonetheless, different pharmaceutical markets are subject to different levels of regulation, and of price regulation in particular. The regulatory framework is less

comprehensive as regards off-patent drugs, where competition is relied on to contain prices. Mechanisms to promote generic entry and use are common around the world, even if their adoption varies across jurisdictions, because it is thought that generic entry and competition will lower drug prices. As regards patented drugs, competition enforcement may be sometimes appropriate, particularly against exclusionary practices that seek to remove or prevent the entry of generics into the market.

75. In order to understand the role of competition enforcement in pharmaceutical markets, and particularly the suitability of enforcement against excessive pricing, this section provides an overview of pharmaceutical markets and their regulation.

4.1. Demand-side Considerations

76. People's willingness to pay for life prolonging or quality of life improving medicines is high – which can lead to price-demand inelasticity, particularly as regards essential medicines (OECD, 2014, p. 5_[17]).⁴⁴

77. Furthermore, many medicines are commonly considered merit goods – i.e. goods that should be available to all on the basis of some concept of need, rather than on basis of ability and willingness to pay. As with other merit goods, the provision of medicines cannot be completely left to the market. In much of the world, the need to ensure access to drugs (and health services) to all citizens despite income disparities has led to the creation of public health insurance systems. Over time, concerns about the constantly increasing level of pharmaceutical expenditure have led to cost-containment measures (OECD, 2014, p. 14_[17]).

78. Nevertheless, the principle that consumers should be supported by third-party payers when acquiring medicines remains widespread. Third-party payer financing through health insurance and/or government funds strongly increases the average ability to pay. The presence of ubiquitous health insurance partially insulates final consumers from the prices of the drugs they consume. As a result, it is possible that neither private individuals, nor the doctors who make treatment decisions, are required to take into account the costs of medication to a significant extent – particularly as regards prescription medicines. This, in turn, can lead to higher prices, particularly when therapeutic alternatives and supply are limited, as is often the case as regards patented products. Public and private health insurers have thus adopted a host of mechanisms for controlling the quantity and quality of drug consumption (OECD, 2014, pp. 6-11_[17]).

Table 1. Examples of regulation and intervention aimed at increasing responsiveness to prices

Consumers	Co-payments
	Financial incentives for purchase of lower cost drugs, such as: <ul style="list-style-type: none"> • offering consumers a lower co-payment if they accept to take a generic version of the prescribed drug • limiting amount reimbursed to the price of the cheapest drug in the relevant therapeutic class
Physicians	Voluntary or mandatory prescriptions by substance name rather than by brand name
	Financial incentives for prescribing generics rather than originated products
Physicians	Pharmaceutical budgets, coupled with financial incentives
	Benchmarking of physicians' prescribing patterns, coupled with financial incentives
Physicians	Formularies:
	<ul style="list-style-type: none"> • Negative, e.g. excluding the least cost-effective drugs from reimbursement • Positive, which limit reimbursement to the most cost-efficient drug in each therapeutic class

Pharmacists	Voluntary or mandatory generic, or low-cost, equivalent substitution
	Margin regulation: <ul style="list-style-type: none"> • Regressive margins that encourage the sale of cheaper drugs • Margins that are not linked to the value of the drug sold
Insurers	Bulk-buying
	Tenders to procure drugs directly from manufacturers
	Formularies and discount for drugs flagged as “preferred drugs” (which incur lower co-payments)

Source: OECD (2014) ‘Competition Issues in the Distribution of Pharmaceuticals’ DAF/COMP/GF(2014)3, p. 13

79. To summarise, the separation of roles of consumer, decision-maker and payer fundamentally influences demand for pharmaceuticals. Since the final consumer has little incentive and often lacks the necessary knowledge to control his/her consumption, responsibility falls to the Government and to health insurers (which are often closely linked to the Government) to control the quality and quantity of drug expenditures (OECD, 2014, pp. 39-40^[17]). Medicines therefore weigh on the public budget, which is why governments may intervene in the competition process in order to favour cheaper generic substitutes (OECD, 2014, p. 2^[5]).

80. It is common to distinguish three pharmaceutical markets from the demand side: (a) the market for non-reimbursed or over-the-counter medicines, for which the consumer pays the full price. These medicines may be prescription or non-prescription medicines, depending on the relevant regulatory framework; (b) the market for reimbursed, prescription medicines, for which demand is affected by health insurance; and (c) the market for pharmaceuticals purchased by hospitals. (OECD, 2000, p. 8^[3]).

81. Significant amount of attention is devoted by competition law and health regulation to the market for reimbursed medicines. The market for non-reimbursed medicines is usually treated with a lighter regulatory touch, even as competition enforcement remains a possibility. Non-reimbursed medicines are usually not reimbursed or subsidised by health insurance, which means that the consumer pays their full cost and the market operates similarly to markets for other branded consumer goods. Furthermore, the fact these medicines are not reimbursable usually means that they are not essential, and/or that there are alternative products in the market and competition will bring their price down.

82. However, given switching costs and/or doctors’ insensitivity to price, the market for non-reimbursed mechanisms may not operate as well as one might at first expect. For example, there may be high switching costs as regards some medicines, as a result of (fear of) side effects. When the need for medication is continuous, price increases for non-reimbursable medicines might be profitable if it takes time for users to find and obtain prescriptions for alternative versions – or when doctors are not incentivised to switch their prescriptions to cheaper medicines, particularly if they are unaware of prices. This may even lead to markets that are specific to small customer groups, e.g. sales of Z to prescribed users of Z (Fonteijs, Akker and Sauter, 2018, p. 12^[19]), as in some of the excessive pricing cases reviewed in section 3.1 above.⁴⁵

4.2. Supply-side considerations

83. Supply-side considerations seem to be fundamental to the division of roles between sector regulation and competition law when addressing high prices of pharmaceuticals. It is common to distinguish between three types of supply-side competition in pharmaceutical

markets: (i) therapeutic; (ii) intra-brand; and (iii) inter-brand (Hancher, 2010, pp. 640-642_[20]).

4.2.1. *Therapeutic competition*

84. The pharmaceutical sector has been very successful in developing and delivering effective drugs for improving health and fighting disease. Although the largest pharmaceutical companies may produce competing products, the main form of competition between them is for the development of new, patented, innovative therapies that are superior to existing or future drugs developed by their competitors (OECD, 2000, p. 7_[3]). This is one of the economic sectors with highest R&D-intensity: the industry invests up to around 40% of its gross value added (GVA) in R&D in Japan and the United States. Pharmaceutical industry R&D accounts for 30% of all private R&D in Switzerland and Belgium, and 24-25% in Slovenia and Denmark. Globally, more than three-quarters of all clinical trials of medicines and other health interventions take place in OECD countries (OECD,(n.d.), p. 3_[1]).

85. However, research and development in pharma is an extremely costly, risky, and prolonged endeavour. The canonical statement about the cost of a new drug – “the first pill can cost more than USD 1 billion while the second costs only a dime” – captures an important truth: new drugs are exceptionally expensive to develop and failures are commonplace. Successful development of a new medicine takes an average of 10 to 15 years. The probability of obtaining marketing approval for a drug entering phase I clinical trials ranges from 7% to 45%, depending on the type of drug and approval process. Nearly 9 out of 10 new drugs entering clinical trials fail, yet the cost of the efforts to develop those drugs must be borne by someone. Of 466 novel active substances launched in the United States between 1991 and 2009, half achieved life-time sales of less than USD 1.5bn, and only approximately 10% had sales exceeding USD 10bn (National Academies of Sciences, Engineering, 2018, p. xviii_[18]; OECD,(n.d.), p. 3_[1]).

86. Originators count on IP protection to ensure that a limited number of patented blockbuster drugs provide returns on their entire R&D investments. Research has found that 75 percent of drug company profits come from just 10% of all drugs. For some major firms, three products account for 70–80% of total pharmaceutical sales (OECD, 2000, p. 8_[3]).

87. Arguably as a result of this strong and central role of IP, dominant positions are created relatively frequently in this sector and will usually remain unchallenged until generics or biosimilars can enter the market (Fonteiijn, Akker and Sauter, 2018, pp. 2-3_[19]).⁴⁶ It could be argued that strong buyers of care – such as national health care systems and large insurance companies – should be able to negotiate good prices by exercising countervailing buyer power. However, a buyer’s bargaining power is usually determined by two factors: their ability to walk away from the deal, completely or in part; and the volume of goods they are purchasing. For buyers to be able to negotiate on price, they must have credible alternatives other than purchasing from the seller (OECD, 2008_[21]). Such an alternative could be another drug or treatment. In health care markets, this often means that bargaining power only works where there are therapeutic alternatives, which is frequently not the case (Fonteiijn, Akker and Sauter, 2018, p. 12_[19]).

88. Spending on prescription drugs, particularly IP protected ones, has been rising dramatically, and drug costs are a significant part of countries’ total spending on health care (National Academies of Sciences, Engineering, 2018, p. xviii_[18]). There are widespread concerns about pharmaceutical prices and how they may be imposing ever-

higher financial burdens on the public purse – even as the share of drug spending (at least for drugs sold to outpatients) in GDP terms may seem to have been relatively stable in the past 10 years on average, with variations across countries (OECD,(n.d.), p. 3_[1]).

89. A particularly relevant concept in this context is that of ‘essential medicines’. The WHO has developed a list of essential medicines to assist WHO member states in selecting and procuring medicines and in ensuring quality and reasonable cost. Since 1977, the WHO list has been revised biennially to reflect new therapeutics. The essential medicines on the list are divided into “core” and “complementary” categories. The core list contains safe, efficacious, and cost-effective medicines for priority conditions. The complementary list has essential medicines for priority diseases for which specialized diagnostic or monitoring facilities, medical care, or specialist training is needed (WHO, 2017_[22]).

90. Throughout much of the world, administrative regulation, rather than competition policy, dominates efforts to afford consumers and governments adequate access to affordable drugs (UNCTAD, 2015, p. 3_[23]). Price regulation provides a policy response to mitigate the effects of monopoly power and inadequate competition in the market, and aims to contain costs (WHO, 2015, p. 58_[24]). Specialised agencies and governmental mechanisms for negotiating or controlling prescription drug prices, either directly or de facto, are common (OECD, 2000, p. 9_[3]; UNCTAD, 2015, p. 3_[23]; National Academies of Sciences, Engineering, 2018, p. 83_[18]). There is a variety of mechanisms that health insurers, both public and private, can use to ensure cost-effective drug consumption. Such mechanisms were outlined in Table 1 above, and include the use of co-payments⁴⁷, formularies of reimbursable drugs⁴⁸, and of controls on the prices paid for drugs, on prescribing physicians and on pharmacists⁴⁹ (U.S. Department of Commerce, 2004, pp. 3-5_[25]; WHO, 2015_[24]). More than 100 countries have adopted essential medicines lists as a tool for developing a national formulary which guides its drug reimbursement and insurance benefit design strategies. The lists put together by the individual countries generally differ from the centralised list produced by the WHO (National Academies of Sciences, Engineering, 2018, pp. 84-85_[18]).

91. Current thinking in many countries is that the prices of medicines should reflect their clinical and therapeutic value for patients and society. Methods to determine the entry price of drugs include free pricing, rate-of return regulations, international reference pricing/external price referencing, cost-plus pricing, clinical and cost-effectiveness pricing, maximum price thresholds and other value-based methods (WHO, 2015, pp. 59-63_[24]). All of these levers work by restricting access to the drug in some way or other: if they did not, they would not contribute to the buyer and payer’s bargaining power (National Academies of Sciences, Engineering, 2018, p. 49_[18]).

Box 3. How to Price Pharmaceutical Products

Firms would be able to price freely in the absence of regulation. Critics have argued that in the case of pharmaceuticals, which are merit goods, this is an untenable strategy – at least in situations bereft of competition – because of the critical public needs that such products and their producers serve. A number of different methods have been identified to set the prices of pharmaceutical products, particularly for on-patent products. Countries generally use more than one method to inform their pricing and reimbursement negotiations, and there is overlap between different methods in practice (National Academies of Sciences, Engineering, 2018, pp. xvi, 53-58[17]; WHO, 2015, pp. 73-76[31]).

A first type of approach adopts a number of straightforward comparative methods for setting the price of drugs. These include external/international reference pricing – i.e. the price is set on the basis of the prices charged in other countries for the same drug –; and internal reference pricing – i.e. the price is set on the basis of the prices of other drugs in the same therapeutic class within the same country. These methods are simple to apply, but they have been criticised on a number of grounds related to: (i) their inability to take into consideration the value a particular drug brings to a society; (ii) the distorting effect they have on manufacturers, since they incentivise strategic behaviour regarding the initial placement of pharmaceuticals in order to maximise the reference price; (iii) they discourage price competition within classes of medicines; (iv) in some cases, no comparators are available.

A second type of approach focuses on more complex pricing methodologies. These include rate-of-return regulations, i.e. pricing by reference to the expected profitability of alternative investment opportunities that demand comparable capital commitments and risk acceptance. They also include various forms of value-based pricing. One value-based approach is comparative-effectiveness, i.e. pricing based on the apparent superior effectiveness of a new drug by comparison to existing treatments. Another approach sets a maximum price for pharmaceuticals based on ex ante and ex post evaluations of the value of medicines. All these methods pose significant challenges related to their complexity, including: (i) difficulties in defining the relevant criteria – e.g. ‘effectiveness’ and ‘value’; (ii) methodological and ethical challenges, such as how to identify a link between value and price; and (iii) paucity of evidence available on effectiveness or value at the time when reimbursement decisions need to be taken.

For new medicines, Health Technology Assessments (HTA) are increasingly used to guide reimbursement decisions in Europe and worldwide, in line with WHO recommendations (WHO, 2015[31]). HTA is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased and robust manner. HTA agencies choose to consider different evidence in their analyses, but the types of health outcomes considered tend to be similar^{*1} HTA is a complex undertaking, requiring appropriate resources and skills.

^{*1} The health economic evaluation takes either a societal perspective – taking into account indirect costs of treatment and illnesses (as in the Netherlands, Norway and Sweden) – or a health system perspective, in which only direct costs to the health care system are considered (as in Belgium, England and Scotland). Some countries employ a mix of societal and health system perspectives.

92. Competition enforcement, particularly against excessive pricing, is thought by most to be unsuited to intervene in markets where therapeutic competition predominates. Instead, sectoral regulation prevails. However, competition agencies can intervene through other means, such as market studies.

93. Competition agencies may find that it is worthwhile to advocate for further competition in markets where therapeutic competition predominates. Competing health insurers or pharmacy benefit managers typically use formulary management to foster competition in on-patent markets. However, such purchasers often do not fully exploit competition in on-patent markets. In particular, while tendering is widely used in off-patent markets or/and for hospital purchases of both on and off patent medicines, it remains uncommon for other forms of distribution of patented products, even if some forms of competitive bidding are used in some jurisdictions (OECD,(n.d.), p. 6_[1]). Studying whether there is scope for increased competition as regards on-patent drugs may be a promising avenue for efforts by competition authorities.

Box 4. Market Studies in the Pharma Market

In 2007, the UK's OFT looked at the UK's Pharmaceutical Price Regulation Scheme (PPRS), one of the main instruments employed by the UK to control expenditures on branded drugs. This is a voluntary scheme to which pharmaceutical companies can adhere. It broadly operates as follows: (i) it sets a maximum level for the profits that a company may earn from the supply of branded drugs to the UK's National Health Service (NHS); (ii) it sets price controls, by giving companies freedom to set the initial price of new active substances but imposing restrictions on subsequent price increases; (iii) it provides for price cuts, which may be agreed at the time of scheme renegotiations. If a company does not wish to belong to the PPRS, it will be subject to statutory price controls. The OFT found that neither the profit cap nor the price cut helps secure prices that reflect the therapeutic value of supplied medicines, and recommended that such controls be replaced with a value-based approach to pricing (see definition in Box 3).

Also in 2007, the Canadian Competition Bureau undertook a study of generic drug prices, which were thought to be high by international standards. To perform the study, the Canadian Competition Bureau acquired and analysed data, retained external experts, and conducted interviews with participants and interested parties. The final report found that generic drug manufacturers were competing by offering substantial rebates for shelf space in Canadian pharmacies. However, in many provinces, the benefits of this competition were not passed on to provincial drug plans, consumers or insurance companies. A reason for this was the design of public drug plans, which gave pharmacies limited incentive to pass rebates on to consumers. This led to recommendations on ways to design provincial drug programmes that would allow the passing of benefits of competition between generic manufacturers on to consumers.

In January 2017, the Dutch ACM published a study of entry and expansion barriers for companies on the Dutch health insurance market. This followed an earlier study conducted in 2016 that found room for improvement in the competition between providers of health insurance in the Netherlands. It found that solvency capital requirements and the difficulties insurers face to meet those requirements, alongside licensing requirements and regulatory uncertainty, create important barriers to market entry and expansion. The study provided recommendations to lower entry barriers – such as research into the proportionality of capital requirements and more freedom for health insurers to decide how they use their profits.

4.2.2. Intra-brand competition

94. Intra-brand competition refers to competition between a version of an IP protected product placed in a market and parallel imports – i.e. cheaper versions of the same product imported from lower priced jurisdictions into higher priced markets. This type of competition is common in integrated free trade areas, such as the EU (Sousa, 2019^[26]). As we saw above, restrictions on parallel imports can be relevant for the assessment of excessive pricing cases.

4.2.3. Inter-brand competition

95. Once medicines are out of patent and exclusivity periods have expired, they can become subject to inter-brand competition from generic or biosimilars. When a generic

enters the market, it tends to be priced more closely to the marginal cost of production than the original product (the ‘originator product’, ‘originator drug’ or ‘originator medicine’). This will put pressure on the company that manufactures the originator drug to lower its prices in order to remain competitive (National Academies of Sciences, Engineering, 2018, pp. 76-77^[18]).

96. In most jurisdictions, the competitive effect of generic entry on drug prices is significant. For example, studies of pharmaceutical markets in the United States and EU indicate that the first generic competitor typically enters the market at a price that is 20% to 30% lower than that of the originator medicine, and gains substantial market share from the originator product in a short period. Subsequent generic entrants may enter at even lower prices – discounted as much as 80% or more off the price of the originator drug – and prompt earlier generic entrants to reduce their prices. This may lead to savings of up to 50% (OECD, 2009, p. 18^[4]). As a result, many jurisdictions adopt policies that seek to ease the approval process for generic drugs.

97. The actual impact on market share and prices of generic entry depends on the specific price regulation regimes and on the levels of competition in individual jurisdictions (OECD, 2009, pp. 19-29^[4]). Most jurisdictions actively promote access to, and consumption of off-patent generic drugs, which are usually much less expensive than branded, patented products. (OECD, 2000, p. 37^[3]; National Academies of Sciences, Engineering, 2018, p. xii^[18]; OECD,(n.d.), p. 7^[1]).

98. Competition enforcement has been one of the most important ways through which governments have sought to promote price competition in pharmaceutical markets, predominantly through enforcement against business conduct that seek to prevent or delay inter-brand competition. Enforcement has been pursued in this regards against practices such as pay-for-delay, product-hopping, spreading misleading information, ever-greening or patent clustering, among others (OECD, 2009, p. 23^[4]; OECD, 2014, pp. 2-6^[5]).

5. When is Competition Intervention against High Prices in Pharmaceutical Markets Appropriate?

99. The analysis in section 2 and 3 focused squarely on arguments regarding the suitability of bringing excessive pricing cases in pharmaceutical markets from a competition law and policy perspective. The discussion of pharmaceutical markets’ dynamics and regulation in section 4 allows us to move beyond a strict focus on competition. In particular, it allows us to review the suitability of competition enforcement, particularly against excessive pricing, as a tool to address (excessively) high prices in pharmaceutical markets.

5.1. Therapeutic Market Competition

100. As we saw above, there is broad consensus that high prices in pharmaceutical markets where therapeutic competition prevails – i.e. as regards originator medicines subject to IP protection that precludes market competition – should not be addressed by competition enforcement against excessive pricing. In effect, excessive pricing cases are yet to be brought under competition law against pharmaceutical products that are protected by IP rights.

101. This may be because many of the arguments opposing competition law enforcement against excessive prices apply with even more force whenever the relevant product has market power as a result of an IP right. Monopoly prices are a reward for risky investment. Special caution is warranted in sanctioning excessive pricing with respect to products covered by IP rights because the misapplication of competition law might directly impede innovation. As such, there should be no intervention against excessive prices for innovative products within a pharmaceutical product's patent life (Fletcher and Jardine, 2006, pp. 541-542^[10]).

102. Recently, it has been argued that it is mistaken to absolutely exclude the possibility of bringing excessive pricing cases as regards IP protected pharmaceutical products.⁵⁰ According to these arguments, there is no risk of competition enforcement deterring market entry by prospective competitors, since entry is not possible in such a case. Furthermore, demand-side pressures tend to be weak, and hence supply and demand do not work to set competitive prices – which provides the context for excessive pricing. To minimise the impact of bringing excessive pricing cases on innovation and investment, these authors argue that one can take into account *ex-ante* probabilities of product success. This can be done because, it is said, the purpose of the IP right – to stimulate welfare-enhancing innovation – can be integrated into excessive pricing assessments (Abbott, 2016^[27]; Fonteijn, Akker and Sauter, 2018^[19]).

103. This approach requires the probability of success of a new pharmaceutical product to be integrated into the analysis of costs and profit margins of the investigated company (Fonteijn, Akker and Sauter, 2018, pp. 14-15^[19]). In the case of pharmaceutical products, the cost must include the R&D that goes into the discovery and refinement of the product, including the costs inherent to clinical assessment. Because securing marketing approval for a pharmaceutical product involves trial and error, potential failures to develop a successful drug must also be taken into account. In other words, the calculation of the cost of developing and approving a new product must include a risk factor.⁵¹

104. In addition to price/cost methodologies, these authors suggest that there are a number of alternative methodologies that may serve to incorporate such a risk factor into an analysis of whether a price is excessive (Abbott, 2016, pp. 303-305^[27]). Such approaches seem to borrow from regulatory approaches for the determination of prices of pharmaceutical products such as the ones outlined in Box 4 above. As was discussed in that box, these methodologies are extremely data intensive and pose significant burdens on specialised bodies. Estimates of the cost of bringing new medicines to the market – and methods to identify such estimates – are very controversial, with results often varying widely and no widely accepted methodological standard [(Morgan et al., 2011^[28]; National Academies of Sciences, Engineering, 2018, pp. 80-89^[18]). As such, one may question whether competition agencies should be engaged in such demanding exercises in the first place, or whether sector regulators are better placed to address such cases. In any event, and as far as we are aware, these proposals have not been adopted in practice.

5.2. Inter-Brand Market Competition

105. Inter-brand competition is widely perceived to be a mechanism to lower the price of medicines. It is commonly assumed that competition among generic and originator products results in lower prices and increased access to safe and effective treatments. This argues against extensive regulation. Instead, market forces should be allowed to play themselves out, leading to lower prices through competition.

106. It follows that the protection and promotion of market competition – an activity for which competition agencies are uniquely well placed – should largely replace sectoral regulation. As we saw above, competition enforcement is indeed common in markets where inter-brand competition is possible. As long as the tests set out in the relevant screens are met, excessive pricing may be used as yet another competition enforcement tool, in line with the applicable competition rules.

107. A potential issue with this view is that it builds on assumptions – that multiple generics will enter and remain in the market; that market entry and competition will occur upon the expiry of IP rights; that prices will come down – that may be becoming less accurate than previously thought.

108. It has been found that the median and the mean number of generics suppliers has been declining in recent years in the US, due both to increased exit and reduced entry of generics manufacturers. It has also been found that the share of generics supplied by only one or two manufacturers has increased over time. In effect, it seems that approximately 40% of generics' markets are supplied by a single manufacturer (National Academies of Sciences, Engineering, 2018, pp. 77-80^[18]; Berndt, Conti and Murphy, 2017^[29]; Berndt, Conti and Murphy, 2018^[30]). In the U.S., seven major manufacturers supply the majority of injectable generic products (WHO, 2016, p. 182^[31]).

109. These developments have a number of possible explanations. First, many generic drugs are still supplied by a small number of manufacturers, and limited-distribution networks can obstruct access to drug samples that competing manufacturers need to obtain in order to conduct testing to submit a generic or biosimilar drug application to the relevant regulatory authority. Second, low profit margins may lead to market exit and increasing consolidation in pharmaceutical markets. Third, one increasingly common strategy for generic-drug manufacturers seeking to maximise profit is to enter a market where they have both the capacity to produce enough of a drug to meet market demand and the power to dictate the drug's price. This involves identifying markets for a particular drug which other manufacturers will not enter. In such markets, the start-up costs for entry – in particular the initial investment costs and the cost of obtaining regulatory approval – are substantial relative to the size of the market. The manufacturer charging an extremely high price is then able to threaten to drastically reduce the price of its product if competitors enter the market, imposing a substantial financial risk on prospective market entrants (Liljenquist, Bai and Anderson, 2018^[32]).⁵²

110. The lack of therapeutically equivalent drugs in the market limits competition and may contribute to extraordinary price increases, which have recently become a matter of widespread concern regarding generic drugs (National Academies of Sciences, Engineering, 2018, p. 80^[18]). When the US Government Accountability Office examined the price histories of 1,411 generic drugs between 2010 and 2015, it found that the overall price of medicines had fallen as a result of, among other things, significant price decreases for generics. However, it also found that there were at least 315 instances since 2010 when the price of generic drugs had sudden increases of 100% or greater. Of the 1,411 drugs considered in the study, a price increase of 500% or more was observed in 48 cases. Furthermore, the number of generic drugs that experienced price increases exceeding 100% in a given year more than doubled between 2010 and 2015. 45 drugs experienced such price increases between the first quarter of 2010 and the first quarter of 2011, while comparable price increases affected 103 drugs between the first quarter of 2014 and the first quarter of 2015 (GAO, 2016^[33]).

111. A number of these generics' price increases have been associated with limited competition. In particular, some of these price increases followed market exit from generic producers, leaving a sole remaining generics' supplier in particular markets enjoying an "effective monopoly" (Abbott, 2016, p. 301^[27]).

112. A related explanation has been the increase in shortages of essential medicines across the world (WHO, 2017^[22]). As we saw above, essential medicines are "*those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness*" (WHO, 2003^[34]). While medicines shortages are not a new phenomenon, they have been increasing in recent years. Products in short supply include many commonly used medicines such as antibiotics, cancer medicines, cardiovascular medicines and anaesthetics. Many essential medicines are off-patent products that are difficult to formulate or have a tightly defined shelf life.

113. Reasons for essential drug shortages include unexpected demand changes or fluctuations, particularly in the context of just-in-time inventory control where facilities sometime hold no or insufficient buffer stock; difficulties provoked by procurement processes that may lead to manufacturers not bidding; unreliable data from peripheral facilities; limited manufacturing bases, particularly for those products which are less attractive from a marketing perspective (i.e. for which prices are too low); and quality and raw material problems at the manufacturing level (WHO, 2016, pp. 181-183^[31]).

114. Given the seeming pervasiveness of high prices and price increases in pharmaceutical markets where inter-brand competition would be expected to operate, it can be questioned whether bringing individual excessive pricing cases is the best possible solution to this problem. Excessive pricing cases are unavoidably fact-specific, operate *ex-post*, are subject to high error risks and costs, and rarely set out bright-line guidance on how to set accurate prices. These limits of private enforcement are compounded in an environment as complex as the pharmaceutical market. As we saw in section 3 above, the cases that have been investigated are in line with the restricted conditions for intervention against excessive pricing. However, these conditions seem to be relatively common in the pharmaceutical sector, which would seem to call for less blunt forms of intervention – such as market studies and advocacy for the adoption of suitable regulation.

115. Competition authorities have a variety of tools other than enforcement at their disposal to deal with these developments. One of the ways through which competition authorities can deal with concerns regarding high prices in pharmaceutical markets is by studying markets in order to determine the source of market failures, and either advocate or adopt remedies (if they have the power to do so). In rare cases, where the market investigation finds that a lack of competition conducive to the high prices cannot be corrected by any remedy other than price regulation, the competition authority may also either choose to defer to established regulators or publicly call for the establishment of such a regulator (Jenny, 2018, pp. 41, 44^[7]).

116. It has been argued that, even if the preferable option is regulatory, the application of the competition rules should not be excluded until the regulatory gap is closed (Fonteijs, Akker and Sauter, 2018, p. 15^[19]). The question this raises is what form should competition intervention take, and how to choose between various types of potential intervention. A related challenge is how to prohibit excessive prices without turning the competition authority into a price regulator. In such cases, it may be advisable for the competition authority's actions to be informed by the expertise of the relevant sectoral bodies – e.g.,

either to assist the sectoral regulator, or to obtain its assistance in the design and implementation of remedies (OECD, 2011, p. 14_[2]).

117. In short, the application of competition law against high prices in the pharmaceutical sector requires a deep understanding of market dynamics and sectoral regulation, and of the various regulatory responses that may be deployed to address high prices. As such, it may be appropriate to explore various avenues for intervention, usually in cooperation with the applicable sector regulator, before engaging in competition enforcement.

6. Conclusion

118. While competition enforcement may be appropriate in pharmaceutical markets, and particularly against exclusionary practices that seek to remove or prevent the entry of generics into the market, competition enforcement against high prices was sparse until recently. Instead, medicines are subject to a dense and comprehensive regulatory framework that implicitly recognises the limited ability of competition enforcement to lower their prices.

119. The regulatory framework is less comprehensive as regards off-patent drugs, where inter-brand competition is relied on to contain prices. Increased prices have nonetheless started being observed even in these markets. Potential explanations for this include a trend for consolidation in the generics market, and consequent diminution or absence of inter-brand competition. This reduction in inter-brand competition is sometimes compounded by the absence of therapeutic competition as well. When coupled with the lack of price-elasticity of demand, particularly as regards ‘essential’ drugs, this development may be one explanation why prices have been increasing for some patented and off-patent products.

120. These structural developments seem to have occurred in tandem with the development of business strategies that identify market segments where prices can be successfully increased. For example, companies may identify niche essential drugs that are not under patent and whose market is so small that no competitors will enter the market, or where supply is limited for regulatory or contractual reasons. This strategy may be coupled with attempts to game the regulatory system in order to evade price controls (Colangelo and Desogus, 2018, pp. 240-241_[16]).

121. A reaction to this has been to bring competition enforcement cases for exploitative excessive pricing. The cases brought thus far meet the requirements set in the stringent screens developed in the literature regarding the bringing of excessive pricing cases. At the same time, the conditions that justify bringing such cases in the first place seem not to be uncommon in the pharmaceutical sector, which raises questions about whether bringing exploitative excessive pricing cases is the best alternative to deal with the problem.

122. Competition authorities have a variety of tools at their disposal to deal with these developments. An important one are market studies, which would help competition agencies to understand market developments and fine-tune the most appropriate response. This can be coupled with advocacy for the adoption of appropriate regulation, or the adoption of initiatives in tandem with sectoral regulators. Finally, such understanding of the market may provide support to competition enforcement actions.

Endnotes

¹ It should be noted that this paper focuses on exploitative excessive pricing, which is not in itself harmful to the structure of competition in the relevant market. It does not cover situations in which excessive pricing may be exclusionary, such as margin squeeze or constructive refusal to supply.

² *Berkey photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 297 (2d Cir. 1979). *United States v. Trans-Missouri Freight Ass.*, 166 U.S. 290 (1897); *United States v. Trenton Potteries Co.*, 273 U.S. 392 (1927); *United States v. Aluminium Co. of America*, 148 F.2d 416 (2d Cir. 1945).

³ For a thorough overview of enforcement against excessive prices, see (Jenny, 2018, pp. 2-20^[5]).

⁴ For the US, see (Areeda, Kaplow and Edlin, (n.d.), p. 396^[6])396. (“*At this point in time, courts and commentators are in uncommon accord that monopolization entails something more than monopoly. Monopolization requires undesirable exclusionary conduct*”). In Mexico, under Article 10 of the Federal Law of Economic Competition only those conducts by dominant firms that have the aim or effect of impeding or preventing a firm entering into, or expanding within, a market will be competition offences. Canada, however, takes a different, and original approach: section 32 of the Canada Competition Act, R.S.C. 1985, c C-34 (Can.) provides a number of possible remedies to the unreasonable enhancement of prices of any article or commodity that benefits from exclusive rights arising from IP rights. In addition, the Canadian Patented Medicines Price Review addresses excessive pricing and has the power to order price reductions. Excessive pricing is also not an infringement of competition law in Australia.

⁵ *Verizon Communications Inc. v. Law Offices of Curtis v. Trinko LLP* 540 US 398, 407, 124 S Ct 872 (2004).

⁶ (OECD, 2011, pp. 302-304^[1]), US Contribution. But while excessive prices are not a competition abuse under Mexican law, the competition authority has various powers to determine whether excessive prices are being charged in a market, in which case specific regulation can be imposed or extended – see (OECD, 2011, pp. 272-273^[1]), Mexico’s Contribution.

⁷ Case 27/76 *United Brands Company and United Brands Continental BV v EC Commission* ECLI:EU:C:1978:22, paras 250-252.

⁸ See, as regards South Africa, (Calcagno and Walker, 2010, p. 893^[9]) (“*The prohibition on excessive pricing in the South African Competition Act is clearly based on United Brands*”). For Chile, see (Duque, 2015, p. 26^[10]) (“*The Supreme Court – with few vacillations– has tended to condemn exploitative abuses and has even stated explicitly that excessive prices without economic justification consist of an abuse of dominance punishable by DL 211 [the Competition Act]*”).

⁹ See also the Opinion of AG Wahl in Case C-177/16 *Latvijas Autoru apvienība*’ ECLI:EU:C:2017:286, para. 19-20.

¹⁰ This method was followed in Case 27/76 *United Brands Company and United Brands Continental BV v EC Commission* ECLI:EU:C:1978:22, paras 251; and Case 298/83 *CICCE* [ECLI:EU:C:1985:150, paras. 24-25.

¹¹ This method was followed, for instance, in Case 26/75 *General Motors* ECLI:EU:C:1975:150 and Case 226/84 *British Leyland* ECLI:EU:C:1986:421, para. 28. See also Joined Cases 110, 241 &

242/88 *Lucazeau/SACEM (SACEM II)* ECLI:EU:C:1989:326 and Joined Cases C-147/97 and C-148/97 *Deutsche Post* [2000] ECLI:EU:C:2000:74.

¹² This method was used in Case 24/67 *Parke, Davis* ECLI:EU:C:1968:1155, Case 53/87 *Renault* ECLI:EU:C:1988:472.

¹³ This method was used in Case 78/70 *Deutsche Grammophon* ECLI:EU:C:1971:59; Case 30/87 *Bodson* ECLI:EU:C:1988:225; Joined Cases 110/88, 241/88 and 242/88 *Lucazeau (SACEM)* [1989] ECLI:EU:C:1989:326; Case 395/87 *Tournier* ECLI:EU:C:1989:319.

¹⁴ This method has been used by some national competition authorities – see (O'Donoghue and Padilla, 2006, pp. 629-631^[15]).

¹⁵ Under this approach, a product's price is excessive when the firm's return on capital for that product is greater than its weighted average cost of capital (WACC). This approach was considered by the Commission in the *Port of Helsingborg* case (Case COMP/A.36.568/D3 – *Scandlines Sverige AB v Port of Helsingborg*) but was not followed because of the insuperable difficulties the Commission had in establishing valid benchmarks.

¹⁶ For a detailed overview of the challenges posed by each of the methods used to identify excessive prices – price-cost tests, profitability analyses, price-comparisons, and combinations of various methods – see (Jenny, 2018^[5]), p. 28- 35.

¹⁷ See also Opinion of AG Wahl in Case C-177/16 *Latvijas Autoru apvienība* ECLI:EU:C:2017:286, para. 36-45.

¹⁸ Case 27/76 *United Brands Company and United Brands Continental BV v EC Commission* ECLI:EU:C:1978:22, para. 253.

¹⁹ Case COMP/A.36.568/D3 – *Scandlines Sverige AB v Port of Helsingborg*, para. 227.

²⁰ This helps explain why it is common to see advocacy efforts by competition authorities directed at improved regulation, possibly in parallel to an opening of procedure, when agencies are faced with evidence of excessive prices.

²¹ See also the screen developed in Opinion of AG Wahl in Case C-177/16 *Latvijas Autoru apvienība* ECLI:EU:C:2017:286, para. 48-51, 106-112. These screens are helpfully summarised in (Motta and Streel, 2007, pp. 21-22^[7]) and (Jenny, 2018, pp. 37-39^[5]).

²² *Mylan Faces U.S. Antitrust Investigation on EpiPen*, Bloomberg, Jan. 30, 2017, available at <https://www.bloomberg.com/news/articles/2017-01-30/mylan-faces-u-s-antitrust-investigation-on-epipen-practices>.

²³ Rep. Sanders and Rep. Cummings, Nov. 3, 2016 *Letter to DOJ and FTC*, available at <http://freepdfhosting.com/81a7a67226.pdf>.

²⁴ See *In Re: Generic Pharmaceuticals Pricing Antitrust Litigation / In Re: State Attorneys General Cases* (2:17-cv-03768-CMR), Eastern Dist. of Penn, complaint available at http://ag.nv.gov/uploadedFiles/agnv.gov/Content/News/PR/PR_Docs/2017/2017-10-31_State.AGs_Proposed_AmendedComplaint.PV.pdf

²⁵ US Dept. of Justice, *Press Release*, Dec. 14, 2016, available at <https://www.justice.gov/opa/pr/former-top-generic-pharmaceutical-executives-charged-price-fixing-bid-rigging-and-customer>.

²⁶ *In Re: Generic Digoxin and Doxycycline Antitrust Litigation*, 16-md-02724, Eastern Dist. of Penn. (see also 16-cv-00990); *A.F. of L. - A.C.G. Building Trades Welfare Plan v. Teva Pharmaceuticals USA Inc. et al.*, 16-cv-05056 Eastern Dist. of Penn; *Sergeants Benevolent Association Health & Welfare Fund v. Taro Pharmaceutical Industries Ltd. et al.*, 16-cv-08911 Southern Dist. of New York; *UFCW Local 1500 Welfare Fund v. Dr. Reddy's Laboratories Inc. et al.*, 16-cv-06058 Eastern Dist. of Penn.; *NECA-IBEW Welfare Trust Fund v. Telegent Inc. et al.*, 16-cv-09398 Dist. of New Jersey; *Plumbers & Pipefitters Local 178 Health & Welfare Trust Fund v. Lannett Company Inc.*,

et al., 16-cv-09890 Southern Dist. of New York; *FWK Holdings LLC v. Actavis Elizabeth LLC*, et al., 16-cv-09901, Southern Dist. of New York; *FWK Holdings LLC v. Actavis Holdco US Inc.*, et al., 16-cv-06632, Eastern Dist. Penn; *FWK Holdings LLC v. Fougera Pharmaceuticals Inc.* et al., 16-cv-09897 Southern Dist. of New York (see also 16-cv-09898 and 16-cv-09899, for different products); *Plumbers & Pipefitters Local 178 Health & Welfare Trust Fund v. Actavis Holdco US Inc.* et al., 17-cv-00144, Eastern Dist. of Penn.; *International Union of Operating Engineers, Local 302 and 612 Construction Industry Health and Security Fund v. Aurobindo Pharma USA Inc.* et al., 17-cv-00294 Eastern Dist. of Penn.; *Teamsters Local Union No. 727 Health & Welfare Fund v. Mylan Inc.* et al., 17-cv-01124, Puerto Rico; *FWK Holdings LLC v. Mylan Inc.*, et al., 17-cv-00626, Dist. of New Jersey; *NECA-IBEW Welfare Trust Fund v. Actavis Holdco US Inc.* et al., 17-cv-00629, Dist. of New Jersey; *Philadelphia Federation of Teachers Health and Welfare Fund v. Fougera Pharmaceuticals Inc.* et al., 17-cv-00936 Southern Dist. of New York; *Humana v Actavis et al* 18-cv-03299-CMR Eastern Dist. of Penn.

²⁷ *In Re: Generic Digoxin and Doxycycline Antitrust Litigation*, 16-md-02724, Eastern Dist. of Penn. (see also 16-cv-00990).

²⁸ *Fresenius Kabi USA LLC v. Par Sterile Products LLC* et al, 16-cv-04544 Dist. of New Jersey

²⁹ Turing's drug Daraprim, a toxoplasmosis treatment, went from USD 13.50 a pill to USD 750 a pill; the price of Retrophin's drug Thiola, a treatment for a rare kidney disease, was raised from USD 1.50 a tablet to USD 30 per tablet; the price of Rodelis's medicine Seromycin, a tuberculosis drug, increased from USD 500 for 30 capsules to USD 10,800 for 30 capsules; and Valeant raised the price of four drugs (thirty-day supplies of Cuprimine and Syprine were increased from approximately USD 500 to USD 24,000; the prices of each of Nitropress and Isuprel, previously USD 2,000, were raised to USD 8,800 and USD 17,900, respectively).

³⁰ *Sudden Price Spikes in Off-Patent Prescription Drugs: The Monopoly Business Model that Harms Patients, Taxpayers, and the U.S. Health Care System*, Dec. 2016, p. 4-5, available at <https://www.aging.senate.gov/imo/media/doc/Drug%20Pricing%20Report.pdf>. See also *Senate Aims to Stop Firms From 'Buying Up Drugs and Jacking Up Prices'*, NY Times, Dec. 21, 2016, available at <https://www.nytimes.com/2016/12/21/us/politics/prescription-drug-prices.html>.

³¹ *Sudden Price Spikes in Off-Patent Prescription Drugs: The Monopoly Business Model that Harms Patients, Taxpayers, and the U.S. Health Care System*, Dec. 2016, p. 118, available at <https://www.aging.senate.gov/imo/media/doc/Drug%20Pricing%20Report.pdf>.

³² *Flynn Pharma Ltd and Flynn Pharma (Holdings) Ltd v Competition and Markets Authority* [2018] CAT 11, para. 48.

³³ Recently, the UK closed this regulatory loophole : see Health Service Medical Supplies (Costs) Act 2017, s. 4.

³⁴ Case 27/76 *United Brands Company and United Brands Continental BV v EC Commission* ECLI:EU:C:1978:22, paras 250-252; under section 60 of the Competition Act 98, questions in relation to competition within the UK must be dealt with in a manner which is consistent with the treatment of corresponding questions under EU law in relation to competition within the EU.

³⁵ These include a 100 mg unbranded tablet, while Epatunin was a capsule. Pfizer's/Flynn's tablet was sold in 28 tablet packs, so three packs are equivalent to an 84 pack. A price comparison on per tablet vs per capsule basis showed that a 100 mg capsule was cheaper than a 100 mg tablet.

³⁶ *Flynn Pharma Ltd and Flynn Pharma (Holdings) Ltd v Competition and Markets Authority* [2018] CAT 11.

³⁷ *Autorità garante della concorrenza e del mercato* (ICA), decision No. 26185, 29 Sept. 2016.

³⁸ AIFA (*Agenzia Italiana del Farmaco*)'s scientific committee and expert oncologists.

³⁹ Case 27/76 *United Brands Company and United Brands Continental BV v EC Commission* ECLI:EU:C:1978:22

⁴⁰ Tribunale Amministrativo Regionale del Lazio, s. I, Judgment No. 8945 of 26 July 2017.

⁴¹ Case COMP/40394 – Aspen. For the archiving of the procedure in Spain, see Resolución (Expte. S/DC/0601/17) de la Sala de Competencia de la Comisión Nacional de los Mercados y la Competencia.

⁴² <http://www.compcom.co.za/wpcontent/uploads/2017/01/International-pharmaceutical-companies-investigated-for-cancer-medicine-prices.pdf>

⁴³ <https://www.en.kfst.dk/nyheder/kfst/english/decisions/2018-cd-pharma-has-abused-its-dominant-position-by-increasing-their-price-by-2-000-percent/>

⁴⁴ See, for example, (Radtke et al., 2009^[23]); (Hu et al., 2010^[26]); (Bobinac et al., 2010^[24]); (Beikert et al., 2013^[25]).

⁴⁵ These cases were all concerned with reimbursed medicines, however (i.e. the State paid the cost of purchasing the relevant medicines).

⁴⁶ The distinction between generics and biosimilars relates to the content of the original medicine. Generics replicate originator medicines comprising chemical substances (called ‘active substances’), while biosimilars replicate biological products, usually proteins.

⁴⁷ Since the incentives on an individual consumer to control his/her expenditure on drugs depend on the marginal expenditure or “co-payment” that he or she faces, the amount usually depends on a number of criteria – e.g. it is common for co-payments to be reduced for the poor or chronically sick.

⁴⁸ A formulary is a document that lists drugs which are covered by the insurance, the extent and conditions of that coverage, and any conditions on use or prescribing. Formularies can be “open” or “closed.” An “open” formulary ostensibly covers all drugs, but typically includes mechanisms to constrain usage of drugs the payer considers too expensive, such as tiering, with higher tiers requiring greater patient cost sharing, prior authorization, or more tightly defined permissible indications. A “closed” formulary allows for drugs the payers deems very expensive or otherwise undesirable to be excluded from coverage. Formularies are used to steer patients and prescribing clinicians toward generic substitutes, biosimilars, drugs with similar therapeutic efficacy for the same disease, or other therapeutic options.

⁴⁹ These controls typically take the form of prescribing guidelines or controls on who may prescribe certain medications. Some countries also impose nominal or explicit “budgets” on prescribing physicians or give a financial incentive to doctors who achieve a certain level of generic prescribing (e.g., Spain).

⁵⁰ The same reasoning applies to orphan drugs, which enjoy a ten-year period of exclusivity on the specific disease (the ‘indication’) that they treat.

⁵¹ For a discussion of methods for how to establish the applicable risk factor, see (Abbott, 2016, pp. 310-315^[28]). This approach builds on a distinction between low-risk projects – such as the development of new delivery mechanisms, new dosages and new formulations – and high-risk projects – where the cause of the disease or condition is unclear, or knowledge of the mechanisms for intervening in biological processes is limited.

⁵² These authors propose the creation of non-profit generic-drug manufacturer that will pursue a cost-plus strategy — generating only enough revenue to cover costs and maintain a limited surplus for financial viability — rather than a profit-maximization strategy, with the explicit mission of producing affordable versions of essential drugs and ensuring a stable supply of such products.

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