EUROPEAN COMMISSION
DG Competition

Case M.9554 - ELANCO ANIMAL HEALTH / BAYER ANIMAL HEALTH DIVISION

Only the English text is available and authentic.

REGULATION (EC) No 139/2004
MERGER PROCEDURE

Article 6(1)(b) in conjunction with Art 6(2)
Date: 08/06/2020

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EUROPEAN COMMISSION

Brussels, 8.6.2020
C(2020) 3949 final

PUBLIC VERSION

In the published version of this decision some information has been omitted pursuant to Article 17(2) of Council Regulation (EC) No 139/2004 concerning non-disclosure of business secrets and other confidential information. The RPLVVLRQV DUH VKRZQ ZKHUH possible the information omitted has been replaced by ranges of figures or a general description.

Elanco Animal Health Inc.
2500 Innovation Way
46140 Greenfield, Indiana
United States of America

Subject: Case M.9554 – Elanco Animal Health/Bayer Animal Health Division
Commission decision pursuant to Article 6(1)(b) in conjunction with Article 6(2) of Council Regulation No 139/2004[1] and Article 57 of the Agreement on the European Economic Area[2]

Dear Sir or Madam,

(1) On 14 April 2020, the Commission received notification of a proposed concentration SXUVXDQW WR $UWLFOH RI &RXQFLO 5HJXODWLRQ 5HJXODWLRQ´ E\ ZKLFK (ODQFR ,QF ("Elanco", USA) acquires sole DOWK ,Q

1 OJ L 24, 29.1.2004, p. 1 (the "Merger Regulation"). With effect from 1 December 2009, Treaty on the Functioning of the European Union ("TFEU") has introduced certain changes, such as the replacement of "Community" by "Union" and "common market" by "internal market". The terminology of the TFEU will be used throughout this Decision.
Although the United Kingdom (KH ³8.´ ZLWKGUHZ IURP WKH (XURSHDQ 8QLRQ DV RI Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union DQG WKH (XURSHDQ $WRPLF (QHUJ\ &RPPXQLW\ [2019] OJ L 29, 31.1.2020, p. 7, Union law continues to apply to the UK during the transition period. Accordingly, any reference to Member States shall be understood as including the UK. Similarly any references made to the EEA in this Decision are meant to also include the UK.

2 OJ L 1, 3.1.1994, p. 3 (the "EEA Agreement").

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7UDQVDFWLRQ DQG %$+ DUH GHVLJQDWHG KHUHL
(ODQFR DV WKH 1RWLI\LQJ 3DUW\ WR WKH 7UDQVDF

1. THE PARTIES AND THE OPERATION

(2) Elanco is a US-based animal health company that develops, manufactures and markets veterinary products for companion animals (CA) and production animals (PA). It became a fully independent company in March 2019.

(3) BAH comprises Bayer's animal health business, which develops, manufactures and markets veterinary products for CA and PA worldwide. BAH represents the majority of Bayer's turnover

(4) On 20 August 2019, the Parties entered into a share and asset purchase agreement pursuant to which Elanco will acquire sole control over BAH. The Transaction would therefore give rise to a concentration within the meaning of Article 3(1)(b) of the Merger Regulation.

2. UNION DIMENSION

(5) Based on 2019 data, the combined aggregate worldwide turnover of the Parties was more than EUR 2 500 million (Elanco: EUR 3 724 million; BAH: EUR 1 571 million). Each of the Parties had an EU-wide turnover of more than EUR 100 million (Elanco: > «; BAH: > «) in at least three Member States, the Parties had combined turnover of more than EUR 100 million and individual turnover of more than EUR 25 million (> «). Neither of the Parties achieved more than two-thirds of its aggregate EU-wide turnover within one and the same Member State.

(6) The concentration therefore has a Union dimension pursuant to Article 1(3) of the Merger Regulation.

3. MARKET DEFINITION

3.1. Product market definition

3.1.1. Introduction

(7) The Transaction will combine the number four (Elanco) and five (BAH) players in the animal health industry, creating the number two supplier in the EEA and worldwide (in terms of sales) after Zoetis

(8) As regards product market definition, in previous cases in this sector the Commission has divided animal health products into three main categories: (i) biologicals (such as vaccines); (ii) pharmaceuticals; and (iii) feed supplements.[3]

3 Publication in the Official Journal of the European Union No C 123, 4.4.2020, p. 12

(9) In the present case the Parties' activities overlap in the area of animal pharmaceuticals. Animal pharmaceuticals encompass a wide group of products that contain a variety of active substances to prevent or treat a large range of animal diseases and disorders. Within pharmaceuticals, the Commission's past decisional practice[4] distinguishes: (i) parasiticides[5] (ii) otitis products, (iii) antimicrobials, (iv) endocrine treatments, (v) anti-inflammatories, and (vi) analgesics.

(10) Furthermore, when defining relevant product markets in the area of animal pharmaceuticals, the Commission considered the following factors as important: (i) species (e.g. cats and dogs within CA; poultry, swine and cattle within PA), (ii) active ingredient/chemical class, (iii) targeted pathology/indication, (iv) mode of administration [3 0 R $] (e.g. oral, topical, injection), (v) duration of efficacy for PA; and (vi) duration of the withdrawal period for PA.[11] Not each factor was considered for each type of pharmaceutical.

(11) In the present case, the Transaction gives rise to horizontally affected markets in the supply of pharmaceuticals for PA and CA. The Parties' activities mainly overlap in relation to the following products: (i) CA parasiticides, antimicrobials, and otitis products and (ii) PA anticoccidials, parasiticides and antimicrobials.[12]

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4 See notably cases M.7917 Boehringer Ingelheim/Sanofi Animal Health Business, paragraph 10; M.7277 Eli Lilly/Novartis Animal Health, paragraph 12; M.6205 Eli Lilly/Janssen Pharmaceutical Animal Health Business Assets, paragraph 11; and M.2922 Pfizer / Pharmacia, paragraph 111.

5 Biologicals are products triggering an immune response against viral and bacterial diseases, as well as occasionally [illegible] not give raise to affected markets with regards to vaccines or biologicials more broadly.

6 Feed supplements are pharmaceutical or nutritional substances which are not natural feedstuffs and are added to made [illegible] to minor horizontal overlaps in relation to feed supplements, but without affected market.

7 Additionally, both Parties supply certain additional, miscellaneous products: (i) ketosis products for cattle, (ii) rehydration treatments, (iii) premise applications, (iv) anaesthetics, (v) dermatitis products, (vi) topical ear cleaners, (vii) hormones, (viii) probiotics, (ix) immunostimulants. No competition concern arises with respect to any of these additional products, regardless of the market definition (see Section 4 below).

8 See footnote 4 above.

9 As further explained in Section 3.1.2.1 below, within parasiticides, the Commission distinguished products targeting multi-celled parasites (e.g. fleas and worms) and products targeting single-celled parasites (e.g. [illegible] case M.7277, Eli Lilly/ Novartis Animal Health, paragraph 16). In this Decision, [illegible] be understood as parasiticides targeting multi-celled parasites (i.e. excluding anticoccidials).

10 See cases M.7917 Boehringer Ingelheim/Sanofi Animal Health Business, paragraph 142; M.7277 Eli Lilly/Novartis Animal Health, paragraph 14; M.6205 Eli Lilly/Janssen Pharmaceutica Animal Health Business Assets, paragraph 14; and M.5476 Pfizer/Wyeth, paragraph 120.

11 The withdrawal period corresponds to the period after treatment during which [illegible] unsuitable for human consumption.

12 Within pharmaceuticals, minor overlaps also arise for anti-inflammatories and analgesics. No competition concern arises with respect to these products, regardless of the market definition (see Section 4 below).

3.1.2. Companion animals

3.1.2.1. Parasiticides

(a) & R P P L V V L R Q ¶ V S U H F H G H Q W V

(12) In its previous decisional practice, the Commission considered that feline and canine parasiticides belong to a single market for CA parasiticides.[13]

(13) Within parasiticides, the Commission found that products targeting solid parasites (e.g. fleas and worms) and products targeting single-celled parasites (3 D Q W L F R F F L G L D O V ´ F R Q V W L W X W H G V L Q J O H F H O O H G S D U) belong to separate markets.[14] As regards CA parasiticides, the Commission distinguished three categories: (i) ectoparasiticides (or ecto products), used to control external parasites (e.g. fleas, ticks),[15] (ii) endoparasiticides (or endo products), used to control internal parasites (e.g. flukes, tapeworms, roundworms), and (iii) endectocides (or endecto products), used to control both external and internal parasites. Given the existence of a certain degree of substitutability, the Commission also envisaged alternative market segments comprising (i) ecto/endecto products together and (ii) endo/endecto products together, but ultimately left the market definition open.[16]

(14) The Commission also envisaged additional sub-segmentations of the CA parasiticides markets including (i) a segmentation by mode of administration (e.g. oral, injectable, topical), which was ultimately left open,[17] and (ii) a segmentation based on the indication/targeted parasites, considering that heartworm products constitute a separate market.[18] In contrast, previous decisions did not envisage a segmentation of parasiticides by active ingredient/chemical class (such as isoxazolines ³isox´) or by duration of efficacy.[19]

(b) The Parties¶ views

(15) The Parties do not contest the fact that products targeting solid parasites and anticoccidials are part of distinct product markets. They also agree with the distinction between (i) ectoparasiticides, (ii) endoparasiticides, and (iii) endectocides. However, they consider that market segments comprising (i) ecto/endecto products and (ii) endo/endecto products are not plausible. The Parties also submit that CA parasiticides are usually authorised for use specifically in either cats or dogs, and cannot be used interchangeably. Conversely, they do not consider meaningful to further segment the markets for parasiticides by mode of administration, indication or chemical class. In particular, they contest the existence of a distinct market segment for isox products on the ground that (i) the chemical

13 See cases M.7277 - Eli Lilly/Novartis Animal Health, paragraph 14; M.5476 - Pfizer/Wyeth, paragraph 110; M.4691 - Schering-Plough/Organon Biosciences, paragraph 21; and M.885 - Merck/Rhone-Poulenc-Merial, paragraph 36.

14 See cases M.7277 - Eli Lilly/Novartis Animal Health, paragraph 16; M.5476 - Pfizer/Wyeth, paragraph 287; and M.4691 - Schering-Plough/Organon Biosciences, paragraph 422.

15 See cases M.5476 - Pfizer/Wyeth, paragraph 289; and M.4691 - Schering-Plough/Organon Biosciences, paragraph 422.

16 See case M.7277 - Eli Lilly/Novartis Animal Health, paragraph 24.

17 See cases M.7277 - Eli Lilly/Novartis Animal Health, paragraph 19; and M.4691 - Schering-Plough/Organon Biosciences, paragraph 438.

18 See case M.7277 - Eli Lilly/Novartis Animal Health, paragraph 26.

19 See case M.6205 - Eli Lilly/Janssen Pharmaceutica Animal Health Business Assets, paragraph 57.

class of parasiticides does not drive customer choice and that (ii) products may combine various compounds in order to extract the benefit of multiple different chemical classes. The Parties claim that the differences in terms of mode of administration, indication and chemical class are relevant when assessing closeness of competition rather than identifying separate product markets. The Parties also argue that, within these hypothetical sub-segments, the overlaps between their activities are limited.[20]

(c) The Commission's assessment

Segmentation between ecto, endo and endecto products

(16) Nothing in the market investigation suggested that the Commission should depart in the present case from its previous practice concerning the distinction between endo, ecto and endecto products.

(17) As regards the alternative market segments, which were envisaged in previous decisions, comprising (i) CA ecto/endecto products and (ii) CA endo/endecto products, the market investigation yielded mixed results.

(18) On the one hand, several market participants considered that endo and ecto products are not interchangeable with endecto products as they are generally used for different indications or situations. For instance, a competitor indicated that, in situations ZKHUH YHWHULQDULDQV address a specific issue related either to JDVWURLQWHVWLQDO ZRUPV (QGHFWRFLGHV are not DV DQ relevant from both a medical and customer point of view. $QRWKHU SODYHU VW endecto products are typically used for prevention (e.g., for prevention of heartworm, lungworm, or flea and tick) ZKLOH ENDOS products are used for the treatment of [gastrointestinal] parasites. 6LPLODUO\ D FXV submitted that ³IRU VHULRXV LQIHFWLRQV H[.] OXVLYHO\ HQ

(19) On the other hand, a number of respondents confirmed the existence of a certain degree of substitutability indicating that endecto products may be used interchangeably with ecto or endo products in some situations. For example, customer stressed that endo and endecto products are interchangeable for minor infections´ DQG D FRPSHWLWRU ENDECTO products can replace ENDOS products as they cover the endoparasiticide spectrum. Market participants also explained that ³in practice, this depends very much on the customer and SUHVFULELQJ YHW¶V SUHIHUHQFHV DV ´ Some competitors also emphasised the fact that GHFWR VDOHV impact RQ the revenues and trends of endo and ecto products.[22]

(20) In view of the above, for the purpose of this Decision, the Commission concludes that (i) endo, ecto and endecto products constitute distinct product markets and that (ii) the question of whether there exist alternative product markets comprising endo / endecto products and ecto / endecto products can be left open as it does not affect the &RPPLVVLRQ¶V FRQFOXVLRQ with regard to the compatibility of the Transaction with the internal market.

20 Form CO, paras. 6.93 and ff.

21 Questionnaires Q1 to competitors (question 11) and Q2 to CA customers (questions 10 and 11).

22 Questionnaires Q1 to competitors (question 11) and Q2 to CA customers (questions 10 and 11).

Segmentation by species

(21) The results of the market investigation indicate that CA parasiticides are usually authorised for use specifically in either cats or dogs, and cannot be used interchangeably. In particular, market participants stressed the facts that (i) CA parasiticides are developed for [a particular pet] and vets would not prescribe drugs developed, tested and approved for [particular pet] and should not be used on a different animal (and vets would not do so)[23] and that giving a dog product to a cat is dangerous and can kill the cat.[24] Some competitors also explained that, albeit parasiticides for cats and dogs can be marketed under the same brand and based on the same active ingredient, the dosage and the mode of administration is likely to vary from one species to another as much larger or smaller dose of active depending on their weight.[25] Oral parasiticides are more commonly used on dogs than on cats (as it is difficult to administer pills to cats).[26]

(22) In view of the above, for the purpose of this Decision, the Commission concludes that parasiticides for cats and dogs are likely to constitute distinct product markets.

Segmentation by mode of administration

(23) The market investigation was inconclusive on the question of whether the CA parasiticides markets should be further segmented by mode of administration. Although a majority of market participants indicate that CA parasiticides with different modes of administration can be used interchangeably, a significant number of customers disagree.[27] Moreover, both customers and competitors consider that the mode of administration is an important parameter of competition in the markets for CA parasiticides.[28] This is notably illustrated by the fact that, in some CA parasiticides markets (in particular canine parasiticides), the demand tends to switch to oral products due to their ease of administration.

(24) In any event, for the purpose of this Decision, the segmentation of the markets for CA parasiticides by mode of administration can be left open as it does not affect the Commission's assessment of the Transaction with regard to the internal market.

Segmentation by indication (heartworm)

(25) The results of the market investigation revealed that market participants have a clear preference for products with a broad spectrum of claims as it is more convenient for customers to use products that can be used to treat or prevent several parasites rather than using several different products.[29] > «.@[30] That being said, the market investigation also confirmed that products for the treatment and prevention of heartworms are likely to constitute a distinct product market. Heartworm is an endoparasitic worm residing in the heart of the host animal, which can be fatal and

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23 Questionnaires Q1 to competitors (question 15) and Q2 to CA customers (question 9).

24 Questionnaires Q1 to competitors (question 14) and Q2 to CA customers (question 14).

25 Questionnaires Q1 to competitors (question 17) and Q2 to CA customers (question 15).

26 Questionnaires Q1 to competitors (question 12) and Q2 to CA customers (question 12). For instance, a competitor explained that "[e]xperts usually prescribe specific spectrum products for specific parasites". See Minutes of a conference call with a competitor dated 6 February 2020, Case M.9595 – Mars / Kellanova. Conversely, a competitor explained that "[v]eterinaries generally prescribe two different products to treat ectoparasites like fleas and ticks, and endoparasites like heartworm and lungworm but, since there are products which can treat both at the same time, these would be more appealing to vets and pet owners.

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difficult to treat once contracted. In the EEA, heartworm is endemic only in southern Europe. Given these specific features, market participants consider that heartworm ³LV D YHU\ VSHFLILF FODLP D³QG the results of the market investigation did not suggest the existence of distinct market segments for other indications.[29]

(26) In view of the above, and in line with its previous practice, the Commission concludes that, for the purpose of this Decision, products for the treatment and prevention of heartworm constitute a distinct product market.

Segmentation by chemical class

(27) Subject to isox (see below), the results of the market investigation generally suggest that a segmentation of the markets for CA parasiticides by chemical class is not relevant. All competitors and half of the customers consider that parasiticides for CA with different chemical classes can be used interchangeably.

(28) More specifically, a large number of respondents indicated that products based on isox,[30] i.e. the newest chemical class of ectoparasiticides (which is also used as endecto products in combination with endo chemical classes), are interchangeable with other parasiticides.[31]

(29) However, the Commission also found that isox products are subject to different competitive dynamics, with different pricing (isox products significantly more expensive) and competitive landscape (only a limited number of players have isox-based products). In recent years, isox products have rapidly increased sales at the expense of older ecto/endecto products and market participants expect the demand for isox products to increase further in the coming years. Some respondents consider that isox products ³DUH changing the dynamic LQ &$ SDUDVLWLFLGHV´.[32] The success of isox products is linked to the facts that (i) they are effective against a wide range of ectoparasites (including fleas and ticks), (ii) they can be administered orally, (iii) they have a long duration of efficacy (between one and three months) and (iv) they act systematically, protecting all parts of the animal. ³0RVW RI WKH DQLPDOV¶ ERG\ %\ FRQ ecto chemical classes are either topical or injectable products, only effective against a subset of ectoparasites (or have encountered resistance issues with fleas or ticks) or do not produce systemic effects for one month or longer. For these reasons and also given that isox products are prescription-only (whereas older ecto chemical classes are often also available in other than ³YHW´ GLVWULEXWLRQ (including over-the-counter (³OTC´) and online distribution channels), isox products are increasingly endorsed by vets.[33]

(30) In any event, for the purpose of this Decision, the exact delineation of the product market can be left open since the Transaction gives rise to serious doubts as to its compatibility with the internal market regardless of whether isox-based parasiticides for CA constitute a distinct market segment or are part of broader markets for CA ecto and endecto.

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28 Questionnaires Q1 to competitors (questions 12 and 13) and Q2 to CA customers (question 12).

29 Questionnaires Q1 to competitors (question 12) and Q2 to CA customers (question 12).

30 Isox products are GABA (gamma-aminobuyric acid) receptor antagonists, causing the uncontrolled activity of the nervous system of the ectoparasites, which leads to its paralysis and death.

31 Questionnaires Q1 to competitors (question 16) and Q2 to CA customers (question 13).

32 Questionnaire Q1 to competitors (question 18). See Section 4.2.1.3 below.

33 See Annex 78 to the Form CO.

Segmentation by duration of efficacy

(31) As previously indicated, the past decisional practice did not consider a segmentation of the CA parasiticides markets by duration of efficacy. Nothing in the market investigation suggested that the Commission should depart in the present case from its previous practice.

(d) Conclusion

(32) Based on the results of the market investigation, for the purposes of this Decision, the Commission concludes that (i) endo, ecto and endecto products for CA; (ii) parasiticides for cats and for dogs; and (iii) products for the treatment and prevention of heartworm constitute distinct product markets/market segments.

(33) For the purposes of this Decision, the Commission also considers that it can be left open (i) whether there exist alternative product markets comprising endo / endecto products and ecto / endecto products for CA; (ii) whether the markets for CA parasiticides should be further segmented by mode of administration; and (iii) whether isoxazoline-based parasiticides for CA constitute a distinct market segment or are part of broader markets for CA ecto and endecto, as these alternative market delineations do not DIIHFW WKH &RPPLVVLRQ¶V FRQFOXVLRQV of the Transaction with the internal market.

3.1.2.2. Antimicrobials

(34) Antimicrobials (also known as antibiotics) are pharmaceutical products that destroy or prevent the growth of microbes such as bacteria, mycoplasma or fungi and treat diseases associated with them. Antimicrobials can be administered in various ways, notably by injection and orally (including as a tablet; a soluble powder, concentrate or solution that is added to drinking water; and as a mix). Antimicrobial products can be used to treat multiple species. There are a number of chemical classes used in antimicrobials.

(a) &RPPLVVLRQ¶V SUHFHGHQWV

(35) In previous decisions, the Commission considered possible segmentations based on the following factors (i) the species, (ii) the active ingredient/chemical class (including sulphonamides, penicillins, cephalosporins, phenicols, fluoroquinolones and tetracyclines), and (iii) the mode of administration (oral vs. injectable).[34] The exact delineation of the market was ultimately left open.[35]

(b) The Parties¶ views

(36) 7KH 3DUWLHV DJUHH ZLWK WKH &RPPLVVLRQ¶V SUHFHGHQW that there is demand-side substitutability between antimicrobials based on different chemical classes. For instance, different chemical classes have received different categorisations from the European Medicines Agency (EMA) regarding their impact on disease resistance in humans,[36] and those defined as higher risk are not

34 See cases M.7277 - Eli Lilly/Novartis Animal Health, paragraphs 36 and 39; M.5476 - Pfizer/Wyeth, paragraph 324; and M.4691 - Schering-Plough/Organon Biosciences, paragraph 329.

35 See case M.7277 - Eli Lilly/Novartis Animal Health, paragraph 43.

36 Growing awareness of antimicrobial resistance in bacteria has led to regulation surrounding the use of antibiotics in animals. Prudent and responsible use of antibiotics in both animals and humans can lower the risk of bac

recommended for use except as a last resort. Lower risk classes include macrolides (which form the base of the macrolide-lincosamide-pleuromutilins, various types of penicillins, cephalosporins, aminoglycosides, lincosamides and tetracyclines. Higher risk classes include, in particular, fluoroquinolones, which make up the [redacted] of CA antimicrobials sales.[37] Moreover, different chemical classes have different properties, meaning that they may typically be used at different stages of a given treatment.

(37) As regards the geographic dimension, the Parties argue that there is limited demand-side substitutability between different methods of administration.

(38) As regards a potential segmentation by species, the Parties argue that many antimicrobials can be administered to a range of species and that distinguishing between different species for the purposes of market definition is not appropriate from both a supply- and demand-side perspective.

(c) The Commission's assessment

(39) As regards a segmentation by mode of administration (i.e. oral and injectable), the results of the market investigation were mixed. From the demand side, a large majority of customers do not consider antimicrobials with different modes of administration to be interchangeable and some respondents specified that the choice may depend on the circumstances of the individual animal.[38] On the other side, the majority of suppliers consider them to be interchangeable, specifying that often a vet will administer the same antimicrobial by injection and the pet owner will follow the treatment at home with an oral version.[39]

(40) As regards a segmentation by species (i.e. cats and dogs), the results of the market investigation were mixed. From the demand side, the majority of customers do not consider antimicrobials for different species to be interchangeable, but some respondents specified that most products are indicated for use in both cats and dogs.[40] Most suppliers consider that customers use antimicrobials for different species interchangeably to treat the same disease, confirming that many antimicrobials are authorised for use in both cats and dogs.[41]

(41) Also as regards segmentation by chemical class (with the relevant CA antimicrobials being fluoroquinolones, penicillin and sulphonamides), the results of the market investigation were mixed. From the demand side, a large majority of customers do not consider antimicrobials with different chemical classes to be interchangeable, and some respondents further specified that it is linked to the target

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becoming resistant. This is particularly important for antibiotics that are used to treat both people and animals and for antibiotics that are the last line of treatment for critical infections in people. See https://www.ema.europa.eu/en/documents/report/categorisation-antibiotics-use-animals-prudent-responsible-use_en.pdf

37 See paragraph 89 below.

38 Questionnaire Q2 to CA customers, question 26.

39 Questionnaire Q1 to competitors, question 31.

40 Questionnaire Q2 to CA customers, question 27.

41 Questionnaire Q1 to competitors, question 32.

bacteria.[42] However, most suppliers consider that antimicrobials with different chemical classes are interchangeable, while vets tend to have first and second line preferences to treat certain infections. One supplier mentioned that the choice of[43] active ingredient will usually vary depending on the pathogen/bacteria causing the disease. A disease can be caused by a pathogen and several antibiotics can be acceptable for use´

(d) Conclusion

(42) In the present case, the question of segmentation of the market by mode of administration, species or chemical class can be left open as the transaction does not raise serious doubts as to its compatibility with the internal market under any plausible market definition.

3.1.2.3. Otitis products

(a) Commission precedents

(43) Otitis externa is an inflammation of the external ear canal. Sometimes, otitis may progress further into the ear (otitis media). Otitis is not a disease in itself but rather a symptom of other diseases, such as an infection. It is common in dogs but less frequent in cats.

(44) According to the Commission's past practice, otitis products can be considered as a separate market. Previously, the Commission has left open the exact delineation of the relevant market for otitis products as to whether further segmentation based on the mode of administration was warranted, indicating however that the otitis externa market is mainly a topical market and that oral and injectable products are rarely used.[44]

(b) The Parties' views

(45) The Parties disagree with the Commission's precedent that otitis products form a separate market and submits that there exist significant differences between (i) a new generation of long-acting otitis products that are applied only once or twice by the veterinarian (long-acting otitis products) and (ii) otitis products that are used daily (daily use otitis products). According to the Parties, long-acting otitis products and daily use otitis products are not substitutable. The Parties argue that there is a significant difference in price between both products. According to the Parties, for example, in the UK, Osurnia (long-acting product) was approximately [...] more expensive than Canaural (daily use product) in 2019.

42 Questionnaire Q2 to CA customers, question 28.

43 Questionnaire Q1 to competitors, question 33.

44 See cases M.7277 – Eli Lilly/Novartis Animal Health, paragraph 33; and M.4691 – Schering-Plough/Organon Biosciences, paragraph 327.

(c) 7KH &RPPLVVLRQ¶V DVVHVVPHQW

(46) The market investigation confirmed that in line with previous views, otitis products constitute a separate product market.[45] The market investigation also confirmed the views of the Parties that very significant differences exist based on the duration of efficacy of the products, between long-acting and daily-use otitis products.

(47) Long-acting otitis products currently include in the EEA only the Parties' products: (ODQFR¶V 2VXUQLD DQG %$+¶V UHFHQWO\ ODXQFKHG 1HSWUD which are administered by a veterinarian and only require a single (in the case of Neptra) or a dual (in the case of Osurnia) application. Both products are effective against Gram-positive bacteria and fungal infections. Long-acting products are significantly more expensive than daily dose products.

(48) Daily-use otitis products cover most of the topical otitis products in the market, LQFOXGLQJ (ODQFR¶V 6XURODQ 'HFKUD¶V &DQDX[2UOLGHUP\O (FXSKDU¶V &RQRILWH)RUWH 9LUEDF¶V products normally require daily ear drop administration by pet owners for one to three weeks. Most of these products are effective against Gram-positive and Gram-negative bacteria, as well as fungal infections.

(49) As long-acting products, Osurnia and Neptra only need to be applied once or twice and are administered by a vet. They eliminate or greatly reduce the risk of non-compliance (i.e. non-adherence to the treatment regimen due to difficulties to apply the products to the animal by pet owners without any training). A significant share of customers are ready to pay a significant premium for a convenient solution which eliminates the need for them to apply the product and the risk of ineffective treatment. In contrast, daily dose products are seen as a cheap option, which can be used in cases where compliance is not a primary concern or for pet owners which prefer a more economical alternative.

(50) In this respect, half of the suppliers consider that long-acting and daily-use otitis product are not interchangeable, while the other half indicate they are interchangeable for customers.[46] However, it seems that suppliers that answered that long-acting and daily-use product are interchangeable refer only to substitutability from a medical point of view. For example, one of the suppliers who deemed these products substitutable explains that ³IURP D PHGLFDO SRLQW RI Y interchangeable. The main benefit of long duration products is perceived by pet owners who no longer apply any product at home as it has been administered at YHWHULQDU\[47] Other suppliers, considering the products interchangeable, explain that ease of administration and price are key factors for customers and vets to decide on a specific product, as well as the ability of the owner to administer the product.[48] Some suppliers consider that even if they believe long-acting and daily-

45 Considering that otitis is an inflammation of the external ear canal which sometimes may spread further into the ear, a further sub-segmentation by indication is not meaningful. Moreover, the market investigation did not provide any element suggesting that a further segmentation by chemical class would be adequate.

46 Questionnaire Q1 to competitors, non-confidential replies to question 47.

47 Questionnaire Q1 to competitors, non-confidential replies to question 47.

48 Questionnaire Q1 to competitors, non-confidential replies to question 47.

XVH SURGXFWV DUH long acting treatments and are more used as first line otitis treatment in dogs[49]

(51) Another supplier explains that F R P S O L D Q F H the treatment regime is critical to success. In cases where the vet is concerned about an owners ability to administer WKH WUHDWPHQW RQ D GDLO\ EDVLV WKH\ ZLOO RSW F KRLFH ZRXOG WKHUHIRUH EH the daily product. For the long acting products, the vet can apply the ear suspension for several consecutive days. Both Neptra (Bayer) and Osurnia (Elanco) are applied by the veterinary surgeon in the clinic rather than by the pet owner at home which is ensuring full compliance of treatment and therefore peace of mind for the vets as when a treatment does not work we can never be sure if the diagnostic was not good, if the treatment protocol was not respected by the pet owner at home (not easy to put a liquid in the ear of a dog) or if the product failed. For this reason, vets tend to prescribe these long acting products at the place of the VKRUW DFW LQJ RQHV´[50]

(52) Moreover, the vast majority of customers considers that long-acting and daily-use otitis products cannot be used interchangeably.[51] For example, one customer H [S O D L Q H G WKDW WKH DGYDQWDJH RI long duration products is highly appreciated by customers and veterinarians.[52]

(53) In fact, competitors indicated clearly that the most important parameters to choose an otitis product are duration of efficacy and frequency of administration, while price, chemical class or reputation of suppliers would be less relevant.[53] Customers also identify duration of efficacy and frequency of administration as the most important parameters to select an otitis product, followed by price, while chemical class or reputation of the supplier would be less relevant.[54] Long-acting and daily-use products¶ main differences are precisely duration of effect and frequency of administration.

(54) Based on the significant differences in terms of price, duration of effect, frequency of administration and customer¶s preferences and taking into consideration the results of the market investigation, the Commission considers that long-acting and daily-use products belong to separate product markets.

(55) With regards to mode of administration, the Commission notes that most otitis products are topical and the market investigation did not provide any element suggesting that a segmentation by mode of administration would be meaningful. Moreover, this differentiation would be only relevant for daily-use products. Should the market be segmented by mode of administration, there would be no overlap between the daily-use products of the Parties. Therefore, this distinction will not be further considered in this Decision.

(56) With regards to a distinction by species, it would not be relevant for long-acting products, as long-acting products are only indicated for dogs. With regards to daily-

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49 Questionnaire Q1 to competitors, non-confidential replies to question 47.

50 Questionnaire Q1 to competitors, non-confidential replies to question 47.

51 Questionnaire Q2 to customers, non-confidential replies to question 40.

52 Questionnaire Q2 to customers, non-confidential replies to question 40.

53 Questionnaire Q1 to competitors, non-confidential replies to question 48.

54 Questionnaire Q2 to customers, non-confidential replies to question 41.

use otitis products, the question as to whether a segmentation by species is needed can be left open as the Transaction does not raise concerns with regards to the daily-use otitis products irrespective of the exact product market definition retained.

(d) Conclusion

(57) The Commission concludes, in light of the above, that, for the purposes of this case, long-acting and daily-use otitis products constitute distinct product markets. The precise market definition can be left open as to whether daily-use products for different species (cats and dogs) or via different modes of administration constitute a separate market or form part of a wider daily-use otitis products market, as the Transaction does not raise serious doubts as to its compatibility with the internal market for daily-use otitis products irrespective of whether the relevant product market is defined as comprising all species and all modes of administration or not.

3.1.3. Production animals

3.1.3.1. Parasiticides

(a) &RPPLVVLRQ¶V SUHFHGHQWV

(58) 7KH &RPPLVVLRQ¶V GHFLVLRQDO SUDFWLFH UHIHUUHG to concerning parasiticides for CA is to a large extent also relevant for PA. In particular, in *Eli Lilly/Novartis Animal Health*, the Commission adopted for PA the same approach as for CA, (i) distinguishing ecto, endo and endecto products and (ii) envisaging alternative market segments comprising ecto/endecto products and endo/endecto products. In that decision, the Commission also envisaged to sub-segment the PA parasiticides markets (i) by species, (ii) by mode of administration, and (iii) by indication, but ultimately left open the exact delineation of the market.[55] In contrast, previous decisions did not envisage a segmentation of PA parasiticides by chemical class, period of efficacy or period of withdrawal.

(b) The Parties¶ views

(59) The Parties did not provide any specific views regarding the product market definition for PA parasiticides and referred to the approach taken for CA.[56]

(c) 7KH &RPPLVVLRQ¶V DVVHVVPHQW

Segmentation between ecto, endo and endecto products

(60) Nothing in the market investigation suggested that the Commission should depart in the present case from its previous practice concerning the split between endo, ecto and endecto products. As regards the alternative market segments comprising (i) PA ecto/endecto products and (ii) PA endo/endecto products, the market investigation was inconclusive, with respondents providing mixed responses. For instance, a FRPSHWLWRU VXEPLWWHG WKDW WKHVH SURGXFWV depends on the type of prevention program and breeding conditions of the target DQLPDO, while another competitor submitted that dogs usually do not require treatment for comfort and consider specific products when necessary. VXJJHVWLQJ WKH H[L

[55] See case M.7277 *Eli Lilly/ Novartis Animal Health* paragraphs 44 to 51.

[56] Form CO, para. 6.146. See also section 3.1.2.1(b) above.

a certain degree of demand-side substitutability.[57] In any event, for the purpose of this Decision, the Commission considers that the exact scope of the product market can be left open since the Transaction does not give rise to serious doubts as to its compatibility with the internal market under any plausible product market definition.

Segmentation by species

(61) The results of the market investigation largely confirmed that PA parasiticides for different species (e.g. swine, cattle, etc.) cannot be used interchangeably. For H[DPSOH D FRPSHWLWRU UHSRUWHG WKDW PRVW RI LWV SURGXFWV DUH RQO\ LQGLFDWHG IRU D particular species or group of species. This limitation of use is largely driven by: (i) the size of the animal which may justify a different strength/dosage; and (ii) the DQLPDO¶V LQWHQGHG XVH.[58] In view of the above, and similarly to CA, the Commission considers that, for the purpose of this Decision, the markets for PA parasiticides should be segmented by species.

Segmentation by mode of administration

(62) The results of the market investigation suggest some demand-side substitutability between PA parasiticides with different modes of administration. However, some customers also stressed the fact that depending on the situations products with different modes of administration may not be used interchangeably (it depends whether I have to do mass treatments, if I have to treat only a few animals, it depends on age and how the animals are housed).[59] In any event, for the purpose of this Decision, the segmentation of the markets for PA parasiticides by mode of administration can be left open since the Transaction does not give rise to serious doubts as to its compatibility with the internal market under any plausible product market definition.

Segmentation by indication

(63) The results of the market investigation were inconclusive as to whether the markets for PA parasiticides should be further segmented by indication. In any event, for the purpose of this Decision, the exact relevant product market definition can be left open since the Transaction does not give rise to serious doubts as to its compatibility with the internal market under any plausible product market definition.

Segmentation by chemical class

(64) The market investigation revealed that PA parasiticides with different chemical classes can be used interchangeably and that the chemical class is not a key parameter of competition. For instance, a competitor stated that efficacy and price are WKH PDLQ GULYHUV WKH FKHPLFDO FODVV LV QRW.[60] In any event, for the purpose of this Decision, the exact relevant product market definition can be left open since the Transaction does not give rise to serious doubts as to its compatibility with the internal market under any plausible product market definition.

57 Questionnaires Q1 to competitors (question 62) and Q3 to PA customers (questions 10 and 11).

58 Questionnaires Q1 to competitors (question 64) and Q3 to PA Customers (question 9).

59 Questionnaires Q1 to competitors (question 63) and Q3 to PA customers (question 13).

60 Questionnaires Q1 to competitors (questions 65 and 66) and Q3 to PA customers (questions 12 and 14).

Segmentation by duration of efficacy or withdrawal period

(65) The past decisional practice did not consider a segmentation of the PA parasiticide markets by period of efficacy or by period of withdrawal. Nothing in the market investigation suggested that the Commission should depart in the present case from its previous practice.

(d) Conclusion

(66) Based on the results of the market investigation, for the purposes of this Decision, the Commission concludes that endo, ecto and endecto products for PA constitute distinct product markets/market segments and that the markets for PA parasiticides should be segmented by species.

(67) For the purposes of this Decision, the Commission also considers that it can be left open (i) whether there exist alternative product markets comprising endo / PA endecto products and PA ecto / endecto products, (ii) whether the markets for PA parasiticides should be further segmented by mode of administration, indication or chemical class, since the Transaction does not give rise to serious doubts as to its compatibility with the internal market under any plausible product market definition.

3.1.3.2. Antimicrobials

(a) &RPPLVVLRQ¶V SUHFHGHQWV

(68) 7KH &RPPLVVLRQ¶V GHFLVLRQDO SUDFWLFH DQG WKH considerations in (a) above concerning antimicrobials for CA are also applicable to PA. As regards the mode of administration for PA antimicrobials, the Commission previously also considered a possible further segmentation of oral PA antimicrobials into pre-mixes and solubles, but ultimately left the question open.[61] In previous cases, the Commission has also considered that mastitis treatments for cattle can be distinguished from other forms of antimicrobial treatment on the basis of their singular mode of administration, namely intra-mammary injections.[62] $V WKH 3DUWLHV activities do not overlap in mastitis treatments, this segment will not be considered in the rest of this Decision.

(b) The Parties¶ views

(69) The Parties submit the same views for PA antimicrobials as for CA antimicrobials described in Section 3.1.2.2(b). In respect of defining markets for antimicrobials by reference to chemical class or mode of administration, the Parties agree with the &RPPLVVLRQ¶V practice that there can be limited demand-side substitutability between antimicrobials that make use of different chemical classes or modes of administration. Moreover, within oral antimicrobials, the Parties consider that there is a meaningful difference from a customer perspective between pre-mixes and other products like water solubles. As regards a potential segmentation by reference to species, the Parties do not consider this appropriate both on supply- and demand-side substitutability.

61 See case M.7277 - Eli Lilly/Novartis Animal Health, paragraph 41.

62 See cases M.4691 - Schering-Plough/Organon Biosciences, paragraph 340; M.5476 - Pfizer/Wyeth, paragraph 358; and M.7917 - Boehringer Ingelheim/Sanofi Animal Health Business, paragraph 280.

(c) 7KH &RPPLVVLRQ¶V DVVHVVPHQW

(70) As regards a segmentation by mode of administration (i.e. oral vs. injectable) the results of the market investigation were not conclusive. From the demand side, customers do not consider antimicrobials with different modes of administration to be interchangeable, ZKHUHDV H[FHSWLRQV H[LVW LQ FHUWDLQ FDVHV[63] The majority of suppliers do consider them to be interchangeable, however specifying that it depends on the target indication.[64]

(71) As regards a segmentation by species, the results of the market investigation confirmed that this is not appropriate. The large majority of customers[65] and suppliers responded that most antimicrobials are indicated for multiple species.[66]

(72) As regards a segmentation by chemical class, the results of the market investigation were mixed. From the demand side, the majority of customers do not consider antimicrobials with different chemical classes to be interchangeable,[67] while the large majority of suppliers responded that antimicrobials with different chemical classes are considered interchangeable, specifying that it depends on the target bacteria.[68]

(d) Conclusion

(73) Based on the results of the market investigation, for the purposes of this Decision the Commission does not consider further segmentation of the PA antimicrobials market by species. The question of segmentation of the market by mode of administration or chemical class can be left open in the present case as the Transaction does not raise serious doubts as to its compatibility with the internal market under any plausible market definition.

3.1.3.3. Anticoccidials

(a) &RPPLVVLRQ¶V SUHFHGHQW

(74) Anticoccidials act against single-celled parasites known as coccidia. Various types of drug are used for coccidiosis prevention and control: (i) prophylactic anticoccidials approved on an EEA-wide scale as preventative feed additives to be administered routinely, in particular for poultry (including turkey); (ii) pharmaceutical coccidiostats authorised as veterinary medicinal products available throughout the EEA for prevention, treatment or aid in the control of coccidiosis (dependent on the pharmacokinetic characteristics of their active substances); and (iii) coccidiosis vaccines: used as a preventative preparation, to induce active immunity against coccidiosis, in particular for poultry.

63 Questionnaire Q3 to PA customers, question 41.
64 Questionnaire Q1 to competitors, question 99.
65 Questionnaire Q3 to PA customers, question 42.
66 Questionnaire Q1 to competitors, question 100.
67 Questionnaire Q3 to PA customers, question 44.
68 Questionnaire Q1 to competitors, question 101.

(75) The Commission has considered PA anticoccidials in previous cases.[69] In these cases, the Commission has defined a separate market for poultry anticoccidials compared to anticoccidials for other species. Within poultry anticoccidials, the Commission further defined the following categories: (i) prophylactic anticoccidials, (combining categories (i) and (iii) above in paragraph 74) with a possible market segmentation between vaccines and feed additives, and (ii) pharmaceutical coccidiostats, corresponding to category (ii) above in paragraph 74.[70] The sub-segmentation of prophylactic anticoccidials between vaccines and feed additives was ultimately left open.

(76) As regards other species (cattle, sheep and swine), the Commission has not previously assessed these products and therefore has not considered any potential segmentation.

(b) The Parties' views

(77) As regards poultry, the Parties support the above segmentation distinguishing between pharmaceutical coccidiostats and prophylactic anticoccidials, potentially with separate sub-markets within the latter for vaccines and feed additives.

(78) As regards other species, the Parties submit that only pharmaceutical coccidiostats are available on the market and, that for each of cattle, sheep and swine, there is a single market for species-specific pharmaceutical coccidiostats.

(79) The Parties submit that there is no basis for further segmentation by mode of administration or indication, as the relevant anticoccidials are all administered orally, and all products indicated for each of cattle, sheep and swine target all of the coccidiosis-causing species relevant for the respective species.

(c) The Commission's assessment

(80) As regards the separation of anticoccidials for poultry from other species, and the segmentation of poultry anticoccidials into prophylactic anticoccidials and pharmaceutical coccidiostats, the market investigation did not provide any element to depart from the previous decisional practice and the Parties' views.[71] On this basis, and for the purpose of this Decision, poultry anticoccidial products will not be considered further in this Decision.

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69 See cases M.6205 - Eli Lilly/Janssen Pharmaceutica Animal Health Business Assets, and M.885 - Merck/Rhone Poulenc Merial.

70 See case M.6205 - Eli Lilly/Janssen Pharmaceutica Animal Health Business Assets, paragraph 19.

71 Questionnaires Q1 to competitors (questions 81 and 82) and Q3 to PA customers (questions 27 and 28).

(81) As regards segmentation by single species for non-poultry species, the market LQYHVWLJDWLRQ GLG QRW FRQILUP WKH 3DUWLHV¶ YLHZ of responding competitors and customers confirm that PA pharmaceutical coccidiostats are indicated for multiple species and not single species. Respondents highlighted that there are products indicated for ruminants (i.e. both cattle and sheep) suggesting this possible grouping of species within the non-poultry species.[72]

(82) As only pharmaceutical coccidiostats are available for non-poultry species, further segmentation between prophylactic anticoccidials and pharmaceutical coccidiostats for these species was not considered meaningful and as such was not investigated further.

(83) The Commission does not consider any further segmentation by mode of administration or indication to be meaningful as the relevant anticoccidials are all administered orally, and all products indicated for each of cattle, sheep and swine target all of the coccidiosis-causing species relevant for the respective species. Furthermore, the market investigation results did not indicate that any segmentation by chemical class, period of efficacy or period of withdrawal are relevant and they are not considered for the purpose of this case.

(d) Conclusion

(84) In the present case, the question of segmentation of the poultry PA anticoccidial market by (groups of) species (i.e. considering ruminants and swine separately or together) can be left open as the Transaction raises serious doubts as to its compatibility with the internal market under any plausible market definition.

3.2. Geographic market definition

(a) &RPPLVVLRQ¶V SURHGLQJV DQG WKH 3DUW

(85) The Commission has consistently defined the geographic markets for marketed animal pharmaceuticals as being national in scope.[73] With respect to pipeline pharmaceuticals, the Commission has consistently held that the geographic scope of the market is either global or EEA-wide.[74]

(86) The Parties agree with the above approach but submit that with respect to marketed products, that there is a growing trend towards competition across borders in the EEA (due to the increasing harmonisation of the regulation at European level and the fact that many animal health players are active in multiple EEA countries), which should be taken into account in the competitive assessment.[75]

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72 Questionnaires Q1 to competitors (question 80) and Q3 to PA customers (question 26).

73 See cases M.7917 – Boehringer Ingelheim/Sanofi Animal Health Business, paragraph 148; M.7277 – Eli Lilly/Novartis Animal Health, paragraph 58; M.6205 – Eli Lilly/Janssen Pharmaceutica Animal Health Business Assets, paragraph 15; and M.5476 – Pfizer/Wyeth, paragraph 126.

74 See notably case M.8955 – Takeda/Shire, paragraph 56.

75 In particular, Elanco submits that, although the geographic market for marketed animal pharmaceutical is still national in scope, the barriers to entry/expand to other geographies have been significantly reduced and that suppliers in a given EEA country are constrained not just by actual competitors but also by potential entrants already active in other EEA countries.

(b) & R P P L V V L e s s Q H # D Q G D V V H V V P H Q W D Q G F R Q F O X V L R Q

(87) As regards marketed products, the results of the market investigation confirmed that the geographic market for animal pharmaceuticals should be defined at national level. However, the market investigation also supports, at least to some extent, the growing supranational dimension of competition put forward by the Parties. For example, although most competitors fix prices and organise their sales and marketing teams at national level, this is also done by some players at regional or EEA level.[76] Similarly, although customers typically source animal pharmaceuticals at national level, some of them organise their procurement at regional or EEA level.[77] Therefore, for the purpose of this Decision, the Commission considers that the geographic market for marketed animal pharmaceuticals is national in scope, and it will consider the growing supranational dimension of competition in its competitive assessment.

(88) As regards pipeline products, nothing in the market investigation suggests that the Commission should depart in the present case from its previous decisional practice concerning the geographic market definition. In fact, companies which invest significant resources in R&D to develop new products expect to sell those products in as many countries as possible. It is not possible to allocate pipeline products to specific countries. Therefore, pipeline products should be considered at EEA or global level.

4. COMPETITIVE ASSESSMENT

4.1. Methodology for the identification and the assessment of affected markets

(89) In line with Commission precedents[78] in pharmaceutical mergers with a large number of affected markets (involving numerous product and geographic markets), the Commission has applied a system of filters aimed at determining the group of markets where concerns are most likely and on which it focuses its analysis. In line with Commission precedents in the pharmaceutical sector,[79] affected markets can be classified in four categories:

> Group 1, where the Parties' combined market share exceeds 35% and the increment exceeds 1%;
>
> Group 1+, where either (i) the combined market share is below 35% (but above 20%), and only one other competitor remains on the market, or where (ii) the combined market share exceeds 35% and the increment is below 1%, but the party with the small increment is a recent entrant;
>
> Group 2, where the Parties' combined market share exceeds 35% but the increment is below 1%; and

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76 Questionnaire 1 to Competitors, non-confidential replies to questions 5 and 6.

77 Questionnaires Q2 to CA Customers (question 5), Q3 to PA Customers (question 5) and Q1 to Competitors (question 7).

78 See cases M.8889 - Teva/PGTOTC Assets, paragraph 35; M.7746 - Teva/Allergan Generics, paragraph 58; and M.9044 - CVC/Recordati, paragraph 25.

79 See case M.5778 - Novartis/Alcon, paragraph 25.

Group 3, where the Parties' combined market share is between 20% and 35%, and Group 1+ conditions are not met.

(90) The Commission has analysed all markets affected by the Transaction under all plausible market definitions.

(91) In line with precedents[80], Group 3 markets are not discussed individually in this Decision.[81] The Commission assessed the competitive situation in these markets by considering the combined market shares of the Parties and their competitors over the last three years, other factors including the presence of competitors with a significant presence, the date of patent expiry and competition from generics, the Parties' pipeline products, as well as the results of the market investigation. The Commission reached the conclusion that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to the possible Group 3 markets arising from the Transaction, due to the limited market shares of the Parties and the presence of significant competitors remaining on the market post-Transaction that will likely sufficiently constrain the merged entity.

(92) Similarly, in line with precedents[82], Group 2 markets are not discussed individually in this Decision. Generally, the Parties have combined market shares below 50%[83]

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80 See cases M.8889 – Teva/PGT OTC Assets, paragraph 36; M.7746 – Teva/Allergan Generics, paragraph 58; M.7645 – Mylan/Perrigo, paragraph 30; and M.7379 – Mylan/Abbott EPD-DM, paragraph 36.

81 Based on 2019 market shares provided by the Parties, Group 3 markets arise in the following possible product markets/country pairs: Antimicrobials for CA, oral mode of administration, in Austria; Antimicrobials for PA, oral mode of administration, in Hungary, Ireland and Spain; Antimicrobials for PA, oral premix mode of administration, in Greece and Netherlands; Antimicrobials for cats, oral mode of administration, in Austria; Antimicrobials for dogs, all modes of administration, fluoroquinolones in Spain; Antimicrobials for dogs, oral mode of administration, fluoroquinolones in Spain; Antimicrobials for cats, all modes of administration, fluoroquinolones in Spain; Antimicrobials for cats, oral mode of administration, fluoroquinolones in Spain; Antimicrobials for CA, all modes of administration, fluoroquinolones in Spain; Antimicrobials for CA, oral mode of administration, fluoroquinolones in Spain; Endo products for cats, all modes of administration, in Austria, Bulgaria, Poland and the UK; Ecto and Endecto products for cats, all modes of administration, in Belgium, Czechia, France, Poland, Romania and the UK; Ecto products for dogs, all modes of administration, in Austria, Bulgaria, France, Portugal and Spain; Ecto and Endecto products for dogs, all modes of administration, in Austria, Belgium, Bulgaria, France, Hungary, Ireland, Netherlands, Portugal, Spain and the UK; Ecto and Endecto products for cattle, all modes of administration, in Germany; Ecto and Endecto products for sheep, all modes of administration, in Germany; Endecto products for cattle, all modes of administration, in Germany; Endecto products for dogs, all modes of administration, in Austria and Poland; Endo products for dogs, all modes of administration, in Finland, Italy and Poland; Endo products for dogs, oral mode of administration, in Finland, Italy and Poland; Endo products for dogs against heartworm, all modes of administration, in Greece, Portugal and Spain; Endo and Endecto products for dogs, all modes of administration, in Finland, France, Greece, Hungary, Italy, Netherlands, Poland, Romania and Spain; Endo products for cats, all modes of administration in Hungary and Poland; Endo products for cats against heartworm, all modes of administration, in France; Endo and Endecto products for cats, all modes of administration, in Belgium, Czechia, France, Greece, Hungary, Ireland and Poland; Endo products for poultry, all modes of administration, in Germany; Endo and Endecto products for poultry, all modes of administration, in Germany; Endo and Endecto products for sheep, all modes of administration in France; Endo products for swine, all modes of administration, in Austria; Otitis daily-use products for CA (all species), all modes of administration in Belgium, Czechia, Greece, Italy, Netherlands, Romania and Sweden; Otitis daily-use products for cats, all modes of administration in Italy and Netherlands; Otitis daily-use products for dogs, all modes of administration in Austria, Belgium, Czechia, Greece, Ireland, Italy, Netherlands and Romania; Ketosis products in Spain; Dermatitis products for dogs and for CA in Germany; Rehydration treatments for cattle in Germany; Sedatives and tranquilizers for CA in the UK; Injectable NSAIDS for cats in Germany; and Corticosteroids for all species in Italy.

82 See cases M.7645 – Mylan/Perrigo, paragraph 30; M.7379 – Mylan/Abbott EPD-DM, paragraph 36; and M.5865 – Teva/Ratiopharm, paragraphs 388-390.

83 Based on 2019 market shares provided by the Parties, Group 2 markets arise in the following possible product markets/country pairs: Otitis daily-use products for CA (all species), all modes of administration, in Austria, Finland, Germany, Ireland and the UK; Otitis daily-use products for dogs, all modes of administration, in Germany and the UK; Ecto/Endecto products for dogs, all modes of administration, in Poland; Ecto products for dogs, all modes of administration, in Poland; Endecto products for dogs, all modes of administration in Germany and the UK; Ecto products for cats, all modes of administration in Romania.

with a de minimis increment below 1%. In some markets, combined market shares are above 50%[84] with a de minimis increment below 1%. Post-Transaction, the Parties will face at least three competitors with market shares equal or above the increment (including meaningful players with market share above 5%) in these markets. Moreover, the market investigation did not raise any concerns in these markets. In light of the above, the Commission considers that the Transaction is unlikely to remove any significant competitive constraint in the Group 2 markets and, thus, will not lead to any competition concerns on these markets.

(93) In the following, the Commission individually assesses all Group 1 and 11+ markets.

4.2. Companion animals

4.2.1. Parasiticides

4.2.1.1. Endoparasiticides[85]

(a) Overview of the market and the Parties' positions

(94) As explained in Section 3 above, endoparasiticides are used to control internal parasites, such as flukes, tapeworms and roundworms. Each type of end-product has a different mode of administration and works on endoparasiticides more or less effectively. The Parties estimate that, in 2018, the total size of the endoparasiticides segment in the EEA was [...].[86] The Parties explained that the demand for CA endoparasiticides is growing and expected to further grow in the next years due to increasing pet adoption and expenditure on veterinary healthcare.

(95) Endoparasiticides for CA can be administered (i) topically, with a typical frequency of application/duration of a month or once every three months; (ii) by injection, with a typical frequency of application/duration of one time per year; (iii) orally (including both preventive and treatment endoparasiticides; in the former case, they can be administered monthly or quarterly, while in the latter case, they should be administered daily, for a certain number of days).

(96) There are a number of chemical classes used in endo products. The chemical classes used in currently marketed endo products are: avermectins, benzimidazoles and isoquinoles. Avermectins are a class of endos used also as endectos. This class is effective against intestinal worms, heartworms and lungworms, as well as ectoparasites. Benzimidazoles are a class of endos with a broad spectrum of action and a high safety profile; they are effective against roundworms (such as hookworms and whipworms) and some tapeworms. Isoquinolines include praziquantel and

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84 Based on 2019 market shares provided by the Parties, Group 2 markets with combined market shares above 50% are in the following possible product markets/country pairs: Otitis daily-use products for dogs, all modes of administration, in Finland (Combined market shares: [60-70]%, number of competitors above or equal to increment: 6); Otitis daily-use products for cats, all modes of administration, in Belgium (Combined market shares: [50-60]%, number of competitors above increment: 4), Czechia (Combined market shares: [60-70]%, number of competitors above or equal to increment: 7), Denmark (Combined market shares: [50-60]%, number of competitors above or equal to increment: 6), Germany (Combined market shares: [70-80]%, number of competitors above or equal to increment: 6), Ireland (Combined market shares: [70-80]%, number of competitors above or equal to increment: 4), the UK (Combined market shares: [50-60]%, number of competitors above or equal to increment: 7).

85 Endoparasiticides include heartworm products which are assessed separately in Section 4.2.1.4.

86 See Form CO, paragraph 6.266.

epsiprantel. They are the only widely available and approved class with good efficacy against tapeworms.

(97) As regards market trends, the market is evolving towards products with a broader spectrum of indications, longer duration of efficacy, and oral mode of administration. In the EEA, CA endoparasiticides are mainly distributed through veterinaries but in recent years the rise of alternative distribution channels has been observed, so called OTV distribution channel (including OTC and online distribution).

(98) In the EEA, both Parties market endoparasiticides for dogs and cats. Their main products are detailed below in **Table 1**.

Table 1
Parties' main CA endoparasiticides marketed in the EEA

Product	Species	Main indication	MoA	Duration	% of EEA sales for CA endos
ELANCO					
Milbemax	dogs/cats	heartworm/hookworm/ roundworm/tapeworm. lungworm and angiostrongyl in dogs only	oral	depening on the indication: between once every three weeks/once a month	[...]%
Guardian SR	dogs	heartworm	injection	once for an entire season	[…]%
Interceptor	dogs/cats	heartworm in dogs only. hookworm and roundworm in dogs and cats	oral	1 month	[…]%
Flubenol KH 4.4% Paste	dogs/cats	roundworm, hookworm and most types of tapeworm	oral	depending on the indication: once a day for two or three consecutive days	[…]%
BAH					
Drontal Plus	dogs	roundworm, hookworm, whipworm and tapeworm	oral	3 months	[…]%
Profender	dogs/cats	roundworm, tapeworm. lungworm in cats only	topical (cat) / oral (dog)	depending on the indication: single treatment or two treatments, two weeks apart	[…]%
Drontal	cats	roundworm, hookworm, tapeworm	oral	3 months	[…]%
Droncit	dogs/cats	tapeworm	oral/injectable & topical (cat only)	3 months	[…]%

Source: Form CO

(99) In the EEA, in 2019, the Transaction gives rise to Group 1/1+ markets in the following product/country pairs:

Table 2
Group 1/1+ CA endoparasiticides in the EEA (2019)

Product	Country
Endo for dogs (all MoAs)	Austria, Belgium, Czechia, Denmark, France, Germany, Greece, Hungary, Ireland, the Netherlands, Norway, Portugal, Romania, Spain, Sweden, the UK
Endo for dogs (oral)	Austria, Belgium, Czechia, Denmark, France, Germany, Greece, Hungary, Ireland, the Netherlands, Norway, Portugal, Romania, Spain, Sweden, the UK
Endo/Endecto for dogs (all MoAs)	Austria, Belgium, Czechia, Denmark, Germany, Ireland, Norway, Portugal, Sweden, the UK
Endo for cats (all MoAs)	Austria, Belgium, Czechia, Denmark, Finland, France, Germany, Greece, Ireland, Italy, the Netherlands, Norway, Portugal, Romania, Spain, Sweden, the UK
Endo for cats (oral)	Austria, Belgium, Czechia, Denmark, Finland, France, Germany, Greece, Ireland, Italy, the Netherlands, Norway, Portugal, Romania, Spain, Sweden, the UK
Endo/Endecto for cats (all MoAs)	Austria, Denmark, Finland, Germany, the Netherlands, Norway, Portugal, Sweden, the UK

(b) Market shares

(100) **Table 3** below shows the Parties' market shares in the Group 1/1+ markets for CA endoparasiticides (and potential sub-segments) in the EEA in 2019. Further detailed market share data, based on sales in value,[87] including information on the Parties' competitors, for the years 2017, 2018 and 2019 are included in Annex I, which forms an integral part of this Decision.

Table 3
Parties' market shares in Group 1/1+ markets for CA ENDO (value, 2019)

Geography	Product	VALUE			No. of competitors post-Transaction
#	#	Elanco	BAH	Comb.	#
Austria	Endo dog (all MoAs)	[30-40]%	[20-30]%	[50-60]%	6
	Endo dog (oral)	[30-40]%	[20-30]%	[50-60]%	5
	Endo/Endecto dog (all MoAs)	[20-30]%	[20-30]%	[40-50]%	6
	Endo cat (all MoAs)	[30-40]%	[30-40]%	[60-70]%	4
	Endo cat (oral)	[40-50]%	[10-20]%	[60-70]%	4
	Endo/Endecto cat (all MoAs)	[10-20]%	[20-30]%	[30-40]%	5
Belgium	Endo dog (all MoAs)	[30-40]%	[30-40]%	[60-70]%	7
	Endo dog (oral)	[30-40]%	[30-40]%	[60-70]%	7
	Endo/Endecto dog (all MoAs)	[10-20]%	[20-30]%	[40-50]%	7
	Endo cat (all MoAs)	[20-30]%	[40-50]%	[60-70]%	4
	Endo cat (oral)	[30-40]%	[20-30]%	[50-60]%	4

87 The Parties were not in a position to provide volume-based market share estimates. The Parties computed market share estimates based on the CEESA database, which only reports value data.

Geography	Product	VALUE			No. of competitors post-Transaction
#	#	Elanco	BAH	Comb.	#
Czechia	Endo dog (all MoAs)	[20-30]%	[20-30]%	[50-60]%	13
	Endo dog (oral)	[20-30]%	[20-30]%	[50-60]%	12
	Endo/Endecto dog (all MoAs)	[20-30]%	[20-30]%	[40-50]%	14
	Endo cat (all MoAs)	[5-10]%	[50-60]%	[60-70]%	8
	Endo cat (oral)	[10-20]%	[40-50]%	[50-60]%	8
Denmark	Endo dog (all MoAs)	[30-40]%	[20-30]%	[50-60]%	4
	Endo dog (oral)	[30-40]%	[20-30]%	[50-60]%	4
	Endo/Endecto dog (all MoAs)	[20-30]%	[30-40]%	[60-70]%	4
	Endo cat (all MoAs)	[20-30]%	[30-40]%	[60-70]%	4
	Endo cat (oral)	[40-50]%	[5-10]%	[40-50]%	4
	Endo/Endecto cat (all MoAs)	[20-30]%	[40-50]%	[60-70]%	5
Finland	Endo cat (all MoAs)	[10-20]%	[40-50]%	[50-60]%	3
	Endo cat (oral)	[10-20]%	[20-30]%	[40-50]%	3
	Endo/Endecto cat (all MoAs)	[10-20]%	[30-40]%	[40-50]%	4
France	Endo dog (all MoAs)	[10-20]%	[10-20]%	[30-40]%	9
	Endo dog (oral)	[10-20]%	[10-20]%	[30-40]%	9
	Endo cat (all MoAs)	[20-30]%	[20-30]%	[50-60]%	5
	Endo cat (oral)	[30-40]%	[5-10]%	[40-50]%	5
Germany	Endo dog (all MoAs)	[40-50]%	[10-20]%	[50-60]%	6
	Endo dog (oral)	[40-50]%	[10-20]%	[50-60]%	5
	Endo/Endecto dog (all MoAs)	[20-30]%	[10-20]%	[40-50]%	6
	Endo cat (all MoAs)	[30-40]%	[40-50]%	[70-80]%	5
	Endo cat (oral)	[50-60]%	[0-5]%	[50-60]%	4
	Endo/Endecto cat (all MoAs)	[10-20]%	[20-30]%	[40-50]%	5
Greece	Endo dog (all MoAs)	[20-30]%	[20-30]%	[40-50]%	5
	Endo dog (oral)	[10-20]%	[20-30]%	[40-50]%	5
	Endo cat (all MoAs)	[20-30]%	[30-40]%	[50-60]%	4
	Endo cat (oral)	[20-30]%	[20-30]%	[40-50]%	4