Anticipated acquisition by Dechra Pharmaceuticals PLC of the Osurnia business of Elanco Animal Health Incorporated

Decision on relevant merger situation and substantial lessening of competition

ME/6878/20

The CMA's decision on reference under section 33(1) of the Enterprise Act 2002 given on 9 June 2020. Full text of the decision published on 15 July 2020.

Please note that [✂] indicates figures or text which have been deleted or replaced in ranges at the request of the parties or third parties for reasons of commercial confidentiality.

SUMMARY

1. Dechra Limited and Dechra Veterinary Products LLC, subsidiaries of Dechra Pharmaceuticals PLC (**Dechra**), have agreed to acquire the worldwide assets, rights and liabilities relating to a branded drug called Osurnia (the **Target**) for the treatment of otitis externa (**otitis**) in dogs from Elanco Animal Health Incorporated (**Elanco**) (the **Merger**). Dechra and the Target are together referred to as the **Parties** and, for statements referring to the future, the **Merged Entity**.

2. The Competition and Markets Authority (**CMA**) believes that it is or may be the case that each of Dechra and the Target is an enterprise; that these enterprises will cease to be distinct as a result of the Merger; and that the share of supply test is met. Accordingly, the CMA believes that arrangements are in progress or in contemplation which, if carried into effect, will result in the creation of a relevant merger situation.

3. The Parties overlap in the supply of prescription otitis treatments for dogs in the United Kingdom (**UK**) (a prescription is required for the use of all otitis treatments that contain an antibiotic, whereas non-antibiotic otitis treatments may or may not require a prescription):

(a) Dechra markets two otitis treatments in the UK: (i) Canaural (a first-line daily dose antibiotic otitis treatment which has been unavailable since early 2019 but is expected to return to the UK market in [✂] 2020); and (ii) Recicort (a daily dose prescription non-antibiotic otitis treatment).

(b) The Target includes Osurnia (a first-line long-acting antibiotic otitis treatment) and [✂] associated research projects for [✂] otitis treatments, namely [✂].

4. The CMA found that there is limited substitutability between antibiotic and non-antibiotic otitis treatments and has therefore considered the supply of antibiotic and non-antibiotic otitis treatments separately.

(a) With respect to the supply of antibiotic otitis treatments, the CMA has considered long-acting and daily dose otitis treatments in a single product frame of reference on the basis of substitution between them, and has taken any differentiation into account in the competitive assessment. Given limited substitutability between first-line and second-line otitis treatments, the CMA considered the impact of the Merger on the supply of first-line antibiotic otitis treatments separately.

(b) With respect to the supply of non-antibiotic otitis treatments, the CMA found that there is limited substitutability between prescription and non-prescription otitis treatments and has therefore considered the impact of the Merger on the supply of prescription non-antibiotic otitis treatments separately to non-prescription treatments.

5. With regard to the geographic frame of reference, the CMA assessed the impact of the Merger on a national basis.

6. For the reasons set out above, the CMA assessed the impact of the Merger on:

(a) the supply of first-line antibiotic otitis treatments in the UK; and

(b) the supply of prescription non-antibiotic otitis treatments in the UK.

7. The CMA assessed whether the Merger could give rise to horizontal unilateral effects through the loss of competition in the supply of first-line antibiotic otitis treatments in the UK.

8. While the Merger may lead to a relatively high combined share of supply and result in a significant increment, in markets characterised by differentiated products – such as those affected by the Merger – shares of supply may not fully capture the closeness of competition between the Parties or any

expected changes in market dynamics. In particular, the share of supply estimates do not account for any change in Canaural's competitive strength upon its return to the UK market or the strength of the competitive constraint posed by Bayer AG's (**Bayer**) recently launched treatment, Neptra. The CMA has therefore considered the significance of shares of supply in light of the other evidence. The CMA found that the Parties are not particularly close competitors in the supply of first-line antibiotic otitis treatments in the UK and that there are a number of competitors in the market who would continue to act as a constraint on the Merged Entity. The CMA believes that these constraints, taken together, are sufficient to ensure that the Merger does not give rise to a realistic prospect of a substantial lessening of competition (**SLC**) as a result of horizontal unilateral effects in relation to the supply of first-line antibiotic otitis treatments in the UK.

9. The CMA further assessed whether the Merger could give rise to horizontal unilateral effects through the loss of actual potential competition in the supply of prescription non-antibiotic otitis treatments in the UK. In its assessment, the CMA considered whether [✂] development of [✂] would be likely to continue in the absence of the Merger and the likelihood of their launch; and whether the launch of [✂] would lead to greater competition.

10. Based on the facts of this case, the CMA does not believe that there is a realistic prospect that [✂] would be [✂] developed and launched absent the Merger, and therefore did not need to consider whether their launch would lead to greater competition.

11. The CMA also assessed whether the Merger could give rise to horizontal unilateral effects through the loss of innovation in the supply of prescription non-antibiotic otitis treatments in the UK. The CMA believes that [✂] and that, accordingly, the Merger would not reduce innovation in the supply of prescription non-antibiotic otitis treatments in the UK.

12. For these reasons, the CMA believes that the Merger does not give rise to a realistic prospect of an SLC as a result of horizontal unilateral effects in relation to the supply of prescription non-antibiotic otitis treatments in the UK.

13. The Merger will therefore **not be referred** under section 33(1) of the Enterprise Act 2002 (the **Act**).

ASSESSMENT

Parties

14. Dechra is a specialist veterinary pharmaceuticals and related products business that develops, manufactures and supplies a number of products to veterinarians worldwide. Dechra is based in the UK and is listed on the London Stock Exchange. Dechra's turnover in financial year ending 30 June 2019 was approximately £481 million worldwide and approximately £[✂] in the UK.

15. Elanco is a global animal health business that develops, manufactures and supplies animal health products, including pharmaceuticals, to customers worldwide. Elanco is based in the US and is listed on the New York Stock Exchange.

16. The Target includes all of Elanco's global assets, rights, and liabilities in Osurnia, including: (i) the Osurnia product line, SKUs, intellectual property, marketing authorisations (**MA**)[1] and other rights; (ii) a licence with a third party for gel technology; (iii) [✂] associated research projects ([✂]); and (iv) [✂] manufacturing or supply contracts. The Target's turnover in financial year ending 31 December 2019 was approximately £[✂] worldwide and approximately £[✂] in the UK.

Transaction

17. On 3 January 2020, Dechra Limited and Dechra Veterinary Products LLC and a subsidiary of Elanco entered into an asset purchase agreement under which Dechra Limited and Dechra Veterinary Products LLC agreed to acquire the Target.

18. The Merger is related to Elanco's acquisition of Bayer's animal health division (the ***Elanco/Bayer* transaction**) which is being reviewed by the European Commission (the **Commission**) and the Federal Trade Commission (**FTC**).

19. Completion of the Merger is subject to certain conditions, including the Commission and the FTC: (i) requiring the divestment of the Target to remedy concerns in their respective reviews of the *Elanco/Bayer* transaction; (ii) approving Dechra as a suitable buyer; and (iii) approving the terms and conditions under which Dechra will acquire the Target.

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[1] A MA is an approval that allows the holder to market and sell a specific medicinal product in one or more jurisdictions.

20. Dechra informed the CMA that the Merger is also the subject of review by competition authorities in Australia, New Zealand and Canada.

Jurisdiction

21. The CMA believes that the Target is an enterprise because, as described at paragraph 16 above, the Target comprises an extensive collection of assets, the transfer of which to Dechra will enable Dechra to carry on Elanco's business activities associated with the manufacture and sale of Osurnia and any related otitis treatments. The CMA also believes that Dechra is an enterprise. As a result of the Merger, the enterprises of Dechra and the Target will cease to be distinct.

22. The Parties overlap in the supply of prescription otitis treatments for dogs in the UK, with a combined share of supply (based on value) of [30-40]% (with an increment of [0-5]%)[2] in the UK.[3] The CMA therefore believes that the share of supply test in section 23 of the Act is met.

23. The CMA therefore believes that it is or may be the case that arrangements are in progress or in contemplation which, if carried into effect, will result in the creation of a relevant merger situation.

24. The initial period for consideration of the Merger under section 34ZA(3) of the Act started on 21 April 2020 and the statutory 40 working day deadline for a decision is therefore 17 June 2020.

Counterfactual

25. The CMA assesses a merger's impact relative to the situation that would prevail absent the merger (ie the counterfactual). For anticipated mergers the CMA generally adopts the prevailing conditions of competition as the counterfactual against which to assess the impact of the merger. However, the CMA will assess the merger against an alternative counterfactual where, based on the evidence available to it, it believes that, in the absence of the merger, the prospect of these conditions continuing is not realistic, or there is a realistic prospect of a counterfactual that is more competitive than these conditions.[4]

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[2] As at December 2019, based on estimates from the Parties (Merger Notice, Table 14.1) and available evidence from third parties.
[3] The share of supply is different from a market share, and goods and services to which the share of supply test is applied need not amount to the market defined for the economic analysis. *Merger Assessment Guidelines* (OFT1254/CC2), September 2010, paragraph 3.3.5. The *Merger Assessment Guidelines* have been adopted by the CMA (see *Mergers: Guidance on the CMA's jurisdiction and procedure* (CMA2), January 2014, Annex D).
[4] *Merger Assessment Guidelines* from paragraph 4.3.5.

26. Dechra submitted that the appropriate counterfactual against which to assess the Merger is the prevailing conditions of competition. The CMA has considered whether there is a realistic prospect of a counterfactual that is more competitive than the prevailing conditions of competition.

27. Dechra submitted that its otitis treatment Canaural has been unavailable in the UK since early 2019. Dechra submitted that, assuming the relevant regulatory approvals are received from the Veterinary Medicines Directorate (**VMD**) (see paragraph 38 below), it expects that it will be able to re-launch Canaural in the UK in [✂] 2020.

28. Based on Dechra's submissions, internal documents and third party evidence,[5] while there is some uncertainty around the precise timing, the CMA believes that there is a realistic prospect of Canaural being re-launched in the UK during 2020 and that this represents a more competitive counterfactual than the prevailing conditions of competition.

29. The CMA has also considered whether absent the Merger, the Target would have launched new [✂] otitis treatments in the UK. The available evidence does not support a different counterfactual to the prevailing conditions of competition, and Dechra and third parties have not put forward arguments in this respect. Accordingly, the CMA has not adopted a more competitive counterfactual in this regard. A fuller discussion of the potential launch by the Target of new [✂] otitis treatments is included in the competitive assessment ([✂]).

Background

30. The Parties' activities overlap in the supply of prescription otitis treatments for dogs in the UK. This section provides an overview of the otitis condition as it affects pets, treatments for otitis, as well as parameters of competition in the supply of otitis treatments.

Otitis condition

31. Otitis is an inflammation of the external ear canal which is a symptom of other diseases. Primary causes of otitis include allergies, endocrine diseases, autoimmune diseases, keratinisation disorders, ectoparasites, foreign bodies or other idiopathic conditions. Otitis may also be secondary to bacteria and yeast infections.

[5] VMD submitted to the CMA that Dechra's application for authorisation concluded positively in May 2020.

32. Manufacturers (such as Dechra and Elanco) supply otitis treatments to wholesalers, which in turn supply otitis treatments to veterinary practices, where they are prescribed and dispensed by veterinary practitioners (**vets**). There are a number of different business models for veterinary practices, including large corporate groups (**vet groups**), independents who have joined together to form buying groups and small groups of independents or single, independent practices. However, rebates are agreed directly between manufacturers and vet groups.[6]

Otitis treatments

33. The main treatments for otitis typically combine three active ingredients, namely an antibiotic, an antifungal, and a steroid (or anti-inflammatory).[7] The combination of individual ingredients typically differs between each of the treatments on the market (with the exception of generic versions of branded treatments).

34. The following factors influence the prescription options available to treat otitis:

(a) **Species**: some otitis treatments are suitable for dogs only while others work for both dogs and cats.

(b) **Antibiotic** or **non-antibiotic**: most otitis treatments contain an antibiotic to treat any underlying bacterial cause of the otitis while others do not contain antibiotics and target the inflammation itself.[8] A prescription is required for the use of all otitis treatments that contain an antibiotic, whereas non-antibiotic otitis treatments may or may not require a prescription.

(c) **First-line** or **second-line**: antibiotic otitis treatments are typically classified as first-line or second-line, depending on the ingredients (in particular, the antibiotic) they contain.[9]

(d) **Long-acting** or **daily dose**: long-acting otitis treatments are administered by the vet and, based on currently available treatments, require one or

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[6] Vet groups receive additional rebates from the manufacturer relative to the wholesaler list price once evidence of purchase is provided.
[7] However, Dechra currently supplies a treatment called Recicort which does not contain an antibiotic.
[8] Dechra's Recicort is currently the only prescription non-antibiotic otitis treatment in the UK, although non-prescription (eg over-the-counter and unlicensed) non-antibiotic treatments are available.
[9] Vets tend to prescribe a first-line treatment in the first instance based on a short otoscopic examination of the ear in an effort to immediately alleviate the pet's discomfort. If this treatment is not effective, vets may perform a more extensive examination of the ear before prescribing a second-line treatment.

two doses. Daily dose treatments are administered daily (or twice daily) by the pet owner.

(e) **Target pathology**: cases of otitis can be associated with two categories of bacteria, namely Gram-positive or Gram-negative bacteria. Otitis can also be caused by Malassezia[10] and ear mites. Some treatments are suitable for all causes of otitis while others are specialised.

(f) **Acute** or **chronic**: some treatments are only suitable for acute cases of otitis.

35. Dechra provided a list of otitis treatments available in the UK. These treatments and their main characteristics are listed in Table 1 below.

Table 1: Otitis treatments in the UK

Supplier	Treatment	Cats/ Dogs	Long-acting /Daily dose	Gram-positive/negative, Malasezzia, ear mites	Acute/ Chronic	First-line/Second-line
Dechra	Canaural	Both	Daily dose	All	Both	First-line
Dechra	Recicort	Both	Daily dose	Inflammation only	N/A	N/A
Elanco	Surolan	Both	Daily dose	All	Both	First-line
Animalcare	Aurimic	Both	Daily dose	All	Both	First-line
Target	Osurnia	Dogs	Long-acting	Gram-positive, Malasezzia	Acute	First-line
Bayer*	Neptra	Dogs	Long-acting	Gram-positive, Malasezzia	Acute	First-line
Virbac	Easotic	Dogs	Daily dose	Gram positive/negative, Malasezzia	Acute	First-line
MSD	Otomax	Dogs	Daily dose	Gram-positive/negative, Malasezzia	Acute	First-line
MSD	Posatex	Dogs	Daily dose	Gram-positive/negative, Malasezzia	Chronic	Second-line
Vetoquinol	Aurizon	Dogs	Daily dose	Gram-positive/negative, Malasezzia	Chronic	Second-line
Krka	Otoxolan	Dogs	Daily dose	Gram-positive/negative, Malasezzia	Chronic	Second-line

Source: Merger Notice
*Elanco is seeking to acquire Neptra as part of the *Elanco/Bayer* transaction (see paragraph 18).

The Parties' marketed otitis treatments

36. Dechra markets two otitis treatments in the UK:

(a) Canaural is a first-line daily dose otitis treatment which contains an antibiotic. It is suitable for both cats and dogs and can treat acute and chronic otitis cases caused by Gram-positive and Gram-negative bacteria, Malassezia and ear mites.

[10] Malassezia is a fungus and therefore responds to the antifungal in most otitis treatments.

(b) Recicort is a daily dose prescription otitis treatment that only contains a steroid. It is suitable for both cats and dogs but can only treat the inflammation symptoms and not the underlying causes of otitis.

37. The Target includes Osurnia, Elanco's marketed first-line long-acting[11] otitis treatment. Osurnia contains an antibiotic and is suitable for dogs only. Osurnia is suitable for treating acute otitis cases caused by Gram-positive bacteria and Malassezia.

Canaural's supply issues

38. Canaural has been unavailable for sale in the UK due to [✂] issues identified in the manufacturing process. These issues started in February 2019, following which Canaural's UK sales fell to zero within approximately six months.[12] Dechra submitted that it has [✂] which must be approved by the VMD in order for Canaural to be sold in the UK. Following this, Dechra must [✂] before Canaural ultimately returns to market. Dechra submitted that it expects to be able to re-launch Canaural in the UK around [✂] 2020.[13]

The Parties' pipeline otitis treatments

39. Dechra has [✂] otitis treatments in its development pipeline, [✂][14] [✂], as well as [✂] otitis treatments, [✂].[15] [✂].[16]

40. As set out in paragraph 16 above, the Target includes [✂] research projects, namely [✂]. These are [✂] and are [✂] otitis treatments that [✂].[17] Dechra submitted that these treatments target [✂].

Parameters of competition in the supply of otitis treatments

41. Third party responses to the CMA's merger investigation indicated that the key parameters of competition in relation to the supply of otitis treatments are:

(a) **efficacy**: the primary consideration for vets when prescribing a treatment for otitis is the effectiveness of the treatment for the particular case at hand. In most cases, a vet will in the first instance conduct an otoscopic examination and/or a swab test and then prescribe a first-line treatment

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[11] Osurnia is administered by the vet in two doses, seven days apart.
[12] Merger Notice, Annex 10.2 and Figure 15.1.
[13] Merger Notice, paragraphs 203 to 212.
[14] [✂].
[15] [✂].
[16] Dechra explained it [✂].
[17] [✂].

that they consider will be the most effective, taking into account the specific antibiotic, antifungal and steroid the treatment contains;[18]

(b) **frequency of administration**: vets will consider whether a daily dose or long-acting treatment will be the most effective treatment for the case at hand. This is influenced by: (i) the cause of the otitis; (ii) whether the animal is likely to be cooperative when receiving regular daily treatment; and (iii) whether the pet owner will administer the daily treatment correctly and consistently;[19]

(c) **mode of administration**: vets will consider whether a gel or a liquid formulation will be more effective to treat the case at hand;[20]

(d) **price**: manufacturers compete on pricing by regularly negotiating rebates and/or discounts with customers (including wholesalers and/or vet groups). While vets may consider the price of a treatment in their prescription decisions, this tends to be a secondary consideration to a treatment's effectiveness for the case at hand;[21] and

(e) **brand reputation/familiarity**: some vets will prescribe otitis treatments that they are familiar with and for which they have seen positive results.[22]

Frame of reference

42. Market definition provides a framework for assessing the competitive effects of a merger and involves an element of judgement. The boundaries of the market do not determine the outcome of the analysis of the competitive effects of the merger, as it is recognised that there can be constraints on merging parties from outside the relevant market, segmentation within the relevant market, or other ways in which some constraints are more important than others. The CMA will take these factors into account in its competitive assessment.[23]

43. The Parties overlap in the supply of prescription otitis treatments for dogs in the UK (see paragraphs 36-37 above).

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[18] Note of call with [✂]. The majority of third parties who responded to the CMA's merger investigation referred to the importance of choosing a treatment based on which active ingredients are considered most effective for the case at hand.
[19] Note of call with [✂]. The majority of third parties who responded to the CMA's merger investigation indicated that long-acting treatments would likely be chosen over daily dose treatments in cases where compliance with daily administration by the pet owner is a concern.
[20] Note of call with [✂]. Osurnia is a non-alcoholic adaptable gel which coats the ear canal, whereas Canaural is dispensed as ear drops.
[21] Note of call with [✂].
[22] Note of call with [✂].
[23] *Merger Assessment Guidelines*, paragraph 5.2.2.

44. The CMA has considered whether the product frame of reference should be segmented by whether an otitis treatment (i) contains an antibiotic; (ii) is long-acting or daily dose; and (iii) is a first-line or second-line treatment. Finally, the CMA considered whether to widen the frame of reference for prescription non-antibiotic otitis treatments to include non-prescription non-antibiotic treatments.

Product scope

45. Dechra submitted that all prescription otitis treatments should be treated as a single product frame of reference and that the CMA should account for differentiation between treatments in its competitive assessment.[24]

46. The Commission has previously considered that a separate product market for otitis treatments for companion animals could exist, however it has not concluded on the relevant product frame of reference and has left open the question of any further segmentation (eg by mode of administration).[25]

Antibiotic versus prescription non-antibiotic otitis treatments

47. Dechra submitted that the only prescription non-antibiotic otitis treatment available in the UK, its own treatment Recicort, is unlikely to be seen as a substitute for treatments that contain antibiotics. Dechra noted that Recicort is only used to treat cases of otitis that are not caused by bacterial or yeast infection.[26]

48. The CMA has considered whether it is appropriate to segment the product frame of reference by whether an otitis treatment contains an antibiotic.

49. Dechra's internal documents indicate that Recicort is considered to be in a different segment from other otitis treatments and not to have direct competitors.[27] Third parties also indicated that there is limited demand-side substitutability between Recicort and otitis treatments that contain an antibiotic.[28]

50. Based on the evidence set out above, the CMA believes that there is limited substitutability between antibiotic and non-antibiotic otitis treatments and has

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[24] Merger Notice, paragraph 153.
[25] M.7277 *Eli Lilly/Novartis Animal Health* (2015), paragraphs 30 and 33.
[26] Merger Notice, paragraphs 287 and 288.
[27] Merger Notice, Annex 10.4; and Dechra response to section 109 notice dated 25 February 2020, Annex 5.5.
[28] The majority of third parties who responded to the CMA's merger investigation indicated that products containing an antibiotic would not be a good alternative to Recicort. Many third parties noted that Recicort is generally prescribed to avoid the use of antibiotics (note of call with [✂]).

therefore considered the impact of the Merger on the supply of antibiotic and non-antibiotic otitis treatments separately.

Antibiotic otitis treatments

51. With respect to the supply of antibiotic otitis treatments, the CMA considered whether it is appropriate to segment the product frame of reference further by:

    (a) long-acting and daily dose otitis treatments; and

    (b) first-line and second-line otitis treatments.

    Long-acting versus daily dose otitis treatments

52. Dechra's Canaural [✂] daily dose treatments, while the Target's Osurnia is long-acting. While there are a number of other daily dose otitis treatments (as set out in Table 1 above), there is only one other long-acting treatment available in the UK – Bayer's Neptra[29] – which became available for sale in February 2020.[30]

53. The CMA has considered whether long-acting and daily dose otitis treatments should be considered as separate product frames of reference, taking into account (i) Dechra's submissions; (ii) Dechra's and Elanco's internal documents; and (iii) third party views.[31]

54. Although Dechra submitted that all prescription otitis treatments should be considered within a single product frame of reference (see paragraph 45 above), it noted that otitis treatments are segmented by reference to whether they are administered daily by the pet owner (daily dose) or in one or two doses by the vet in the veterinary practice (long-acting).[32] Dechra stated that the most important reason for distinguishing between these types of administration was the need to ensure treatment compliance, as although most dogs will tolerate the application of ear drops by their owner, a vet may decide to prescribe a long-acting treatment if they consider that the pet owner is unreliable or that the dog's behaviour would make at-home treatment difficult.[33]

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[29] Neptra requires one application only, which is administered by the vet.
[30] Bayer launched Neptra in the UK on 7 January 2020, however the product only arrived in the UK on [✂]. The first UK sales were recorded on [✂]. Merger Notice, paragraph 183.
[31] The CMA asked third parties to identify which products they considered to be the closest alternatives to Canaural and Osurnia.
[32] Merger Notice, paragraph 93.
[33] Merger Notice, paragraphs 132 and 264.

55. Dechra's and Elanco's internal documents demonstrate that they monitor [✂] long-acting and daily dose otitis treatments and consider that these treatments exert a competitive constraint on each other. For example, in its internal documents Dechra referred to Osurnia as [✂] and noted Osurnia's [✂]. Elanco's internal documents also demonstrate that [✂].[34]

56. Evidence from third parties indicates that while the choice of otitis treatment depends largely on the individual case at hand (based on an examination of the pet's ear), the mode and frequency of administration are important factors. The majority of third parties who responded to the CMA's merger investigation indicated that long-acting treatments would likely be chosen over daily dose products in cases where compliance with daily administration by the pet owner is a concern as, in those cases, a vet would prefer to administer a treatment once or twice in the practice.[35] Nevertheless, the responses indicated that most third parties consider that long-acting and daily dose otitis treatments can be used as alternatives for each other (in particular, where compliance is not an issue).

57. Based on the evidence set out above, the CMA believes that there is substitutability between long-acting and daily dose antibiotic otitis treatments and has therefore considered the impact of the Merger on the supply of long-acting and daily dose antibiotic otitis treatments together. The CMA has taken differentiation between long-acting and daily dose otitis treatments into account in the competitive assessment.

First-line versus second-line otitis treatments

58. Both Dechra's Canaural and the Target's Osurnia are first-line otitis treatments, ie they can be used in the first instance without conducting detailed testing. Second-line otitis treatments may contain stronger antibiotics and best practice dictates that they should only be used when an animal has responded poorly to a first-line treatment.[36] The CMA has considered whether it is appropriate to widen the product frame of reference to include second-line otitis treatments, taking into account (i) Dechra's submissions; (ii) Dechra's and Elanco's internal documents; and (iii) third party views.

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[34] Merger Notice, Annexes 9.10 and 10.4; Dechra response to section 109 notice dated 11 March 2020, Annexes 2.3 and 6.1; Elanco response to section 109 notice dated 25 February 2020, Annexes ED-002, ED-030, ED-031, ED-032, ED-034 and ED-079; Elanco response to section 109 notice dated 11 March 2020, Annexes ED-108 and ED-147.
[35] Note of call with [✂]; [✂] response to the CMA's merger investigation.
[36] Table 2 sets out first-line and second-line otitis treatments in the UK.

59. Dechra noted that British Veterinary Association (**BVA**) guidelines indicate some distinction between first-line and second-line otitis treatments, but Dechra did not make a submission as to whether it is appropriate to consider these treatments in the same product frame of reference.[37]

60. Dechra's and Elanco's internal documents indicate that they tend to consider first-line and second-line treatments as distinct from one another. Dechra's internal documents note that second-line treatments [✂]. Moreover, both Dechra's and Elanco's internal documents indicate that [✂].[38]

61. Third party responses to the CMA's merger investigation indicated that there are a number of differences between first-line and second-line otitis treatments, with the large majority of third parties specifically identifying first-line treatments as the closest alternatives to the Parties' treatments. In addition, some third parties explained that first-line treatments are prescribed to treat otitis in the first instance and more advanced second-line treatments are subsequently prescribed where the issue is not resolved and after a thorough examination of the pet's ear.[39] Further, very few third parties identified second-line otitis treatments as alternatives to first-line treatments. In particular, on average third party responses to the CMA's merger investigation indicated that vets:

    (a) used second-line treatments to replace Canaural after its supply issues in less than 5% of cases; and

    (b) considered second-line treatments to be the closest alternative to Osurnia in less than 1% of cases.

62. The CMA's analysis of Canaural's exit in 2019, discussed from paragraph 91 below, also indicates that first-line otitis treatments attracted a much greater diversion from Canaural than second-line treatments.

63. Based on the evidence set out above, the CMA believes that there is limited substitutability between first-line and second-line antibiotic otitis treatments. The CMA therefore does not believe that it is appropriate to widen the product frame of reference to include second-line antibiotic otitis treatments and has considered the impact of the Merger on the supply of first-line antibiotic otitis treatments separately.

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[37] The BVA guidelines indicate which otitis treatments should be regarded as second-line (based on the antibiotic they contain) and therefore should only be used where the animal has responded poorly to other treatments. Merger Notice, paragraphs 120 and 121.
[38] Dechra response to section 109 notice dated 11 March 2020, Annex 6.1; Elanco response to section 109 notice dated 25 February 2020, Annexes ED-025 and ED-034.
[39] Note of call with [✂]; [✂] response to the CMA's merger investigation.

Non-antibiotic otitis treatments

64. With respect to non-antibiotic otitis treatments, the CMA notes that Dechra's Recicort is the only prescription non-antibiotic otitis treatment currently available in the UK. The CMA has considered whether it is appropriate to widen the product frame of reference to include non-prescription non-antibiotic otitis treatments, taking into account: (i) Dechra's submissions; (ii) Dechra's and Elanco's internal documents; and (iii) third party views.

Prescription versus non-prescription otitis treatments

65. Dechra submitted that non-prescription non-antibiotic otitis treatments (such as over-the-counter treatments, ear cleaners and unlicensed treatments) do not form part of the otitis treatment market since (i) over-the-counter treatments have a different legal classification to those identified in Table 1 above; (ii) ear cleaners do not form part of the same market as pharmacological otitis treatments[40] (and would only be used as alternatives in mild cases); and (iii) unlicensed treatments cannot legally claim to treat otitis.[41] On this basis, Dechra submitted that such non-prescription non-antibiotic otitis treatments are not direct competitors (or close alternatives) to Recicort.

66. Dechra's internal documents indicate that Dechra considers Recicort to be in its own category of steroid-only (ie non-antibiotic) prescription otitis treatments and not to have direct competitors.[42]

67. A limited proportion of third parties who responded to the CMA's merger investigation indicated that certain non-prescription (unlicensed) non-antibiotic treatments (eg topical steroids) may represent an alternative to Recicort, and a few other third parties indicated that the use of these products would only be appropriate where Recicort or other licenced products were not available or suitable.[43]

68. Based on the evidence set out above, the CMA believes that there is limited substitutability between prescription and non-prescription non-antibiotic otitis treatments. The CMA therefore does not believe that it is appropriate to widen the product frame of reference to include non-prescription non-antibiotic otitis treatments and has considered the impact of the Merger on the supply of prescription non-antibiotic otitis treatments separately.

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[40] Pharmacological treatments refer to medicines that use drugs to treat disease.
[41] Merger Notice, paragraph 158.
[42] Merger Notice, Annex 10.4; Dechra response to section 109 notice dated 25 February 2020, Annex 5.5.
[43] Almost half of respondents said there are no close alternatives to Recicort.

Conclusion on product scope

69. For the reasons set out above, the CMA has considered the impact of the Merger in the following product frames of reference:

(a) the supply of first-line antibiotic otitis treatments; and

(b) the supply of prescription non-antibiotic otitis treatments.

Geographic scope

70. Dechra submitted that the relevant geographic frame of reference is the UK, explaining that regulatory requirements with regard to labelling and marketing of otitis treatments vary between jurisdictions, that pharmacovigilance activities[44] are conducted nationally, and that most companies operate separate distribution systems and set different pricing across EU Member States.[45]

71. The Commission has previously concluded that while markets for veterinary products have some features of wider geographic markets, they remain national in geographic scope because of differences in market penetration, market shares, prices, distribution systems and local veterinary preferences between EU Member States.[46]

72. Third parties who responded to the CMA's merger investigation indicated that customers require treatments that are licensed for prescription in the UK and will not typically consider using an unlicensed treatment as an alternative.[47] Further, Dechra's and Elanco's internal documents generally analyse the UK separately to other geographic areas.[48] They also indicate that the competitor set and competitive conditions for the supply of otitis treatments vary to some degree between countries.[49] Indeed, the CMA notes that Canaural in particular has not had equal strength in all countries and had a particularly significant presence in the UK relative to other countries prior to its supply issues.

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[44] Pharmacovigilance activities relate to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem.
[45] Merger Notice, paragraphs 148 to 151.
[46] M.7917 *Boehringer Ingelheim/Sanofi Animal Health Business* (2016), paragraphs 33 to 36.
[47] Note of call with [✂] and third party responses to the CMA's merger investigation.
[48] For example, Dechra response to section 109 notice dated 25 February 2020, Annexes 1.2 and 6.1; Elanco response to section 109 notice dated 25 February 2020, Annexes ED-030, ED-034, ED-079 and ED-086.
[49] For example, some internal documents state that [✂]. Merger Notice, Annex 15.2; Elanco response to section 109 notice dated 25 February 2020, Annex ED-006.

73. Based on the evidence set out above, the CMA has considered the impact of the Merger in the UK.

Conclusion on frame of reference

74. For the reasons set out above, the CMA has considered the impact of the Merger in the following frames of reference:

(a) the supply of first-line antibiotic otitis treatments in the UK; and

(b) the supply of prescription non-antibiotic otitis treatments in the UK.

Competitive assessment

Horizontal unilateral effects

75. Horizontal unilateral effects may arise when one firm merges with a competitor that previously provided a competitive constraint, allowing the merged firm profitably to raise prices or to degrade quality on its own and without needing to coordinate with its rivals.[50] Horizontal unilateral effects are more likely when the merging parties are close competitors.

76. The CMA assessed whether it is or may be the case that the Merger may be expected to result in an SLC in relation to:

(a) horizontal unilateral effects in the supply of first-line antibiotic otitis treatments in the UK; and

(b) horizontal unilateral effects in the supply of prescription non-antibiotic otitis treatments in the UK.

Horizontal unilateral effects in the supply of first-line antibiotic otitis treatments in the UK

77. In order to assess the likelihood of the Merger resulting in horizontal unilateral effects in the supply of first-line antibiotic otitis treatments in the UK, the CMA has considered:

(a) shares of supply;

(b) closeness of competition between the Parties;

(c) competitive constraints from alternative suppliers; and

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[50] *Merger Assessment Guidelines*, from paragraph 5.4.1.

(d) Dechra's pipeline [✂] otitis treatments.

Shares of supply

78. Table 2 below sets out the CMA's share of supply estimates (by value) based on Dechra's data supplied by market research firm GfK.[51] For completeness, Table 2 presents shares of supply in January 2019, immediately before Canaural's supply disruption, and in December 2019.

Table 2: Shares of supply by value, January and December 2019

Firm	Treatment	Share in January 2019	Share in December 2019
Dechra	Canaural	[30-40]%	0%
Target	Osurnia	[20-30]%	[30-40]%
Merged Entity		**[60-70]%**	**[30-40]%**
Elanco	Surolan	[20-30]%	[30-40]%
Virbac	Easotic	[10-20]%	[10-20]%
MSD	Otomax	[5-10]%	[5-10]%
Animalcare	Aurimic	[0-5]%	[5-10]%
Bayer*	Neptra	0%	0%
Total		**100%**	**100%**

Source: CMA estimates based on the Parties' and GfK data (Merger Notice, Table 14.1)
* Elanco is seeking to acquire Neptra as part of the *Elanco/Bayer* transaction (see paragraph 18).

79. With respect to these figures, the CMA notes the following:

(a) In light of Dechra's planned re-launch of Canaural in 2020 and the counterfactual against which the CMA has assessed the impact of the Merger (see paragraphs 25-29 above), the CMA believes that the December 2019 share of supply estimates have limited relevance to the competitive assessment and do not accurately reflect the competitive strength of the Parties.

(b) Based on January 2019 estimates, the Merged Entity would have a relatively high combined share of supply and the Merger would result in a significant increment. However, the CMA notes that these estimates do not take into account any change in Canaural's competitive strength upon its return to the market (which is discussed at paragraphs 84-90 below).

[51] The CMA also considered share of supply estimates based on industry data from market research firm Kynetec. These estimates were similar to those in Table 2.

80. More generally, in markets characterised by differentiated products – such as those affected by the Merger – measures of concentration such as shares of supply may not fully capture the closeness of competition between the Parties and the extent to which other suppliers of otitis treatments pose a competitive constraint on the Parties.[52] As noted at paragraph 56 above, first-line antibiotic otitis treatments are somewhat differentiated and the choice of treatment tends to be driven by particular characteristics of treatments and their suitability for individual cases. In addition, historical shares of supply do not take into account any expected changes in market dynamics, such as Canaural's future competitive strength and the strength of the competitive constraint posed by the recently launched Neptra (discussed in paragraphs 119-125). In particular, to the extent Neptra can be expected to expand in the future, the share of supply estimates presented in Table 2 would further overstate the future competitive position of the Merged Entity.

81. Accordingly, the CMA has considered the significance of shares of supply in light of the other evidence set out below.

Closeness of competition between the Parties

82. Dechra submitted that the Parties' respective first-line antibiotic otitis treatments (namely Canaural and Osurnia) are not close competitors, given differences in their product characteristics including their frequency and mode of administration, relative prices and active ingredients. Dechra also referred to economic evidence indicating that there was little switching between Canaural and Osurnia following (i) the launch of Osurnia in 2015; and (ii) Canaural's exit from February 2019.[53] In addition, Dechra submitted that Osurnia competes most closely with Neptra, as they are the only available long-acting treatments, and that these treatments compete only to a limited extent with Canaural.

83. The CMA has assessed the closeness of competition between the Parties and considered within its assessment:

(a) Canaural's competitive strength upon its return to the market;

(b) an event study relating to Canaural's exit from the market;[54]

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[52] *Merger Assessment Guidelines*, paragraph 5.3.2.
[53] Merger Notice, paragraphs 20 to 24.
[54] The CMA did not assess the impact of Osurnia's launch in 2015 on Canaural's sales. The CMA believes that it is difficult to make inferences about the impact of this event. In particular, since Osurnia's entry did not result in a sudden increase in its sales, but rather a gradual increase from 2015 onwards, it is not possible to disentangle the impact of its entry on Canaural and other competitors from all the other trends and events happening in the market.

(c) Dechra's and Elanco's internal documents; and

(d) third party views.

Canaural's competitive strength upon its return to the market

84. Dechra submitted that when Canaural is re-launched, its competitive strength will be weaker compared to that before February 2019 as vets will have switched to alternative otitis treatments that are now satisfying their needs in Canaural's absence.

85. In order to assess Canaural's competitive strength upon its return to the market, the CMA has considered evidence from Dechra's and Elanco's internal documents and has sought forward-looking views from third parties based on a scenario in which Canaural has returned to the market.

- *Internal documents*

86. Some of Dechra's internal documents indicate that, despite a loss of sales due to the supply issues, Dechra has a degree of confidence in Canaural's ability to regain its competitive strength [✂].[55] In addition, market research undertaken by Elanco indicated that [✂].[56] However, most of Dechra's and Elanco's internal documents indicate that [✂].[57]

- *Third party views*

87. Third party views were mixed on whether vet groups and practices would be likely to buy Canaural when it becomes available again. Some third parties explained that Canaural had a long-established and strong position in the market as an effective and relatively cheap first-line antibiotic otitis treatment and expected vets with a longer history of use of Canaural to use it again based on their positive experience. However, a few third parties also noted that during the time Canaural has been unavailable, vets may have found other products that are now satisfying their needs such that Canaural may not regain its previous share of supply.[58]

88. To inform the CMA's assessment of Canaural's competitive strength upon its return to the market, the CMA asked Dechra's and Elanco's competitors how different treatments' shares of supply are expected to change in the next two

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[55] Merger Notice, Annexes 10.15 and 9.4.
[56] Elanco response to section 109 notice dated 25 February 2020, Annex ED-034.
[57] Merger Notice, Annex 10.5 and 10.22. The CMA notes that these documents were prepared in the ordinary course of business before the Merger was in contemplation.
[58] Note of call with [✂].

years (considering a scenario in which Canaural has returned to the market) relative to other otitis treatments. The CMA notes that it interprets these forecasts as a description of competitors' perceptions of the relative competitive strength of different otitis treatments in future, rather than as reliable forecasts of their future shares of supply.

89. Competitor responses indicated that Canaural's future share of supply is expected to be lower compared to that in January 2019, and that this change could not be attributed to the entry and expansion of Neptra only. In particular, excluding Neptra's predicted share of supply, Canaural's average forecasted share of supply is 22%, whereas Canaural's share of supply before its exit in in 2019 was [30-40]%. While the CMA does not consider this to be a reliable forecast of Canaural's future share of supply, the CMA believes that this evidence is consistent with third parties having a perception that Canaural's competitive strength in future will have declined to some extent relative to its previous market position.

- *Conclusion on Canaural's competitive strength upon its return to the market*

90. In light of the above evidence, the CMA believes that share of supply estimates based on the period before Canaural's exit in February 2019 overstate Canaural's competitive strength to some degree (relative to other competitors) in a future circumstance where Canaural returns to the market.

Event study – Canaural's exit from the market

- *Dechra's submission*

91. Dechra submitted that, following Canaural's supply issues (see paragraph 38 above), Canaural's sales decreased rapidly from February 2019, with a clear increase in sales of Elanco's Surolan and Animalcare's Aurimic as a result, and a far more modest increase in Osurnia's sales.[59]

92. Dechra noted that the increase in Osurnia's sales post-February 2019 was in line with historic trends in its growth, and therefore may not be a result of diversion from Canaural to Osurnia. It submitted that this showed that Canaural and Osurnia did not compete closely.[60]

93. Dechra submitted diversion ratio estimates based on the changes in sales observed after Canaural's exit. These are reported in Table 3 and Table 4

[59] Merger Notice, paragraphs 245 to 246.
[60] Ibid.

below. Dechra submitted that these estimates indicated that the rate of diversion to Surolan was high (between approximately 40% and 60%), while diversion to Osurnia was limited (less than [10-20]% in all models, and between 0% and 5% in most of them), further supporting the conclusion that Osurnia and Canaural did not compete closely.[61]

Table 3: Value-based diversion ratio estimates

Brand	Diversion ratio, no control for trends		Diversion ratio controlling for linear trend	Diversion ratio controlling for linear trend and non-linear seasonality	
	Jan-Jun	Jan-Dec	Jan-Dec	Jan-Jun	Jan-Dec
Surolan	[50-60]%	[50-60]%	[60-70]%	[40-50]%	[50-60]%
Aurimic	[10-20]%	[20-30]%	[10-20]%	[10-20]%	[20-30]%
Others	[20-30]%	[10-20]%	[20-30]%	[30-40]%	[20-30]%
Osurnia	**[5-10]%**	**[5-10]%**	**[0-5]%**	**[0-5]%**	**[0-5]%**

Source: Merger Notice.

Notes: To correct for pre-existing growth trends, Dechra's economic advisers (RBB) first calculated the annual increase in sales of otitis treatments between 2017 and 2018. They then constructed a 'counterfactual' estimate of sales for each product for 2019 assuming that these trends continue. The counterfactual 2019 sales values for product X are then calculated as: 2018 actual sales plus the growth in sales observed between 2017 and 2018. To control for non-linear seasonality RBB ran an OLS regression with monthly fixed effects.

Table 4: Volume-based diversion ratio estimates

Brand	Diversion ratio, no control for trends		Diversion ratio controlling for linear trend	Diversion ratio controlling for linear trend and non-linear seasonality	
	Jan-Jun	Jan-Dec	Jan-Dec	Jan-Jun	Jan-Dec
Surolan	[30-40]%	[50-60]%	[50-60]%	[40-50]%	[50-60]%
Aurimic	[10-20]%	[20-30]%	[20-30]%	[10-20]%	[20-30]%
Others	[30-40]%	[10-20]%	[20-30]%	[40-50]%	[10-20]%
Osurnia	**[10-20]%**	**[5-10]%**	**[0-5]%**	**[0-5]%**	**[0-5]%**

Source: Merger Notice.

Notes: To correct for pre-existing growth trends and for non-linear seasonality, RBB took the same approach as set out in the notes to Table 3.

- *CMA analysis*

94. The CMA performed checks and produced sensitivities to verify the robustness of Dechra's analysis. With respect to diversion from Canaural to Osurnia, the CMA's results were broadly in line with those presented by Dechra. The CMA also notes that estimates of the diversion to Surolan and Aurimic were always materially higher than the diversion estimates for Osurnia.

95. Moreover, the CMA produced diversion estimates controlling for a non-linear trend and seasonality.[62] Based on this approach, the CMA estimated

[61] Merger Notice, paragraphs 247 and 248.
[62] Visual inspection of the data suggested that Osurnia's sales growth may have been slowing and flattening out and, therefore, a linear trend could overstate Osurnia's growth rate absent Canaural's supply issues.

diversion ratios of up to [10-20]% from Canaural to Osurnia – see Table 5 and Table 6 below.

Table 5: CMA value-based diversion ratio estimates

Brand	Diversion ratio controlling for non-linear trend and seasonality	
	Jan-Jun	Jan-Dec
Surolan	[50-60]%	[60-70]%
Aurimic	[10-20]%	[20-30]%
Others	[20-30]%	[10-20]%
Osurnia	**[0-5]%**	**[0-5]%**

Source: CMA analysis of Dechra's data.

Notes: The model includes a quadratic trend to control for non-linear growth.

To control for seasonality the CMA ran an OLS regression with monthly fixed effects.

Table 6: CMA volume-based diversion ratio estimates

Brand	Diversion ratio controlling for non-linear trend and seasonality	
	Jan-Jun	Jan-Dec
Surolan	[40-50]%	[40-50]%
Aurimic	[20-30]%	[30-40]%
Others	[20-30]%	[10-20]%
Osurnia	**[5-10]%**	**[10-20]%**

Source: CMA analysis of Dechra's data.

Notes: The model includes a quadratic trend to control for non-linear growth.

To control for seasonality the CMA ran an OLS regression with monthly fixed effects.

96. Overall, the CMA considers that its analysis, in addition to the analysis submitted by Dechra, indicates that Osurnia is not a particularly close alternative to Canaural. Instead, Surolan and Aurimic appear to represent closer alternatives to Canaural.

97. The CMA also considers that if the same exit event were to occur in the future (where Canaural is available), the total diversion from Canaural to Osurnia could be further reduced by diversion to Neptra, which was launched in the UK in January 2020. As set out in paragraphs 119-125 below, the CMA considers that Neptra is an alternative that is increasing its competitive constraint and may have a substantial impact on diversion to Osurnia.

Internal documents

98. Some of Dechra's and Elanco's internal documents indicate that Osurnia poses a competitive constraint on Canaural [✂]. Some internal documents also imply that Dechra viewed the entry of Osurnia in 2015 as a threat to Canaural's competitive position (with some Dechra internal documents focused on [✂][63]).

[63] Dechra response to section 109 notice dated 25 February 2020, Annex 2.3; Dechra response to section 109 dated 11 March 2020, Annex 6.3.

99. However, the majority of Dechra's and Elanco's internal documents indicate that Osurnia and Neptra exert a [✂] competitive constraint on one another [✂]. For example, internal documents indicate that:

(a) daily dose otitis treatments (such as Surolan which Dechra deems [✂][64]) exert a [✂] constraint on Canaural [✂];

(b) Dechra views Osurnia as posing a [✂] competitive constraint on Canaural, given its novel and convenient mode of administration [✂];[65]

(c) Elanco is increasingly focused on [✂];[66] and

(d) post-Merger, Dechra's primary strategic focus will be [✂].[67]

Third party views

100. To inform its assessment of the closeness of competition between the Parties, the CMA asked third parties to provide their views on alternatives to Canaural and Osurnia if either Canaural or Osurnia were no longer available.

- *Views on alternatives to Canaural*

101. The CMA asked third parties to list and rank the closest alternatives to Canaural, and to consider the proportion of otitis cases that would likely be treated by alternative treatments if Canaural was no longer available. The CMA asked third parties to consider a scenario in which Canaural was removed from the market and Neptra was not available, replicating Canaural's exit in February 2019.

102. While a relatively limited proportion of third party responses indicated that Osurnia can be used as an alternative to Canaural, overall, daily dose otitis treatments were considered to be Canaural's closest alternatives. The large majority of third parties who responded to the CMA's merger investigation ranked Surolan as the closest alternative to Canaural. On average, third parties estimated that of the cases that were diverted away from Canaural when it exited the market, almost half were taken by Surolan, while just over 20% were taken by Osurnia. In addition to Surolan and Osurnia, third parties identified Aurimic, Otomax and Easotic as alternatives to Canaural.

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[64] Dechra response to section 109 dated 11 March 2020, Annex 6.1; Dechra response to section 109 notice dated 25 February 2020, Annex 1.2.
[65] Dechra response to section 109 notice dated 25 February 2020, Annex 2.2.
[66] Elanco response to section 109 notice dated 11 March 2020, Annexes ED-099, ED-101, ED-102, ED-108.
[67] Dechra response to section 109 notice dated 11 March 2020, Annex 2.1.

103. The CMA notes that Neptra had not yet been launched in the UK when Canaural exited the market, which means that any diversion from Canaural to Osurnia could today be reduced by the availability of Neptra as an alternative. As discussed in paragraph 97 above and paragraphs 119-125 below, the CMA considers that Neptra's competitive constraint is increasing and may have a substantial impact on diversion to Osurnia.

104. Overall, the above evidence from third parties indicates that Osurnia has historically exerted at least some competitive constraint on Canaural, prior to Canaural's exit from the market and Neptra's entry in the UK. However, when accounting for the entry of Neptra, the CMA believes that Osurnia's constraint on Canaural (when it re-launches) will be more limited than that of other treatments, in particular of Surolan.

- *Views on alternatives to Osurnia*

105. The CMA asked third parties to list and rank the closest alternatives to Osurnia and to consider the proportion of otitis cases that would likely be treated by alternative treatments if Osurnia was no longer available. The CMA asked third parties to consider a scenario in which Canaural had returned to the market and Neptra had become established.

106. Most third parties indicated Neptra as the closest alternative to Osurnia, with only a small number of third parties identifying a daily dose treatment as Osurnia's closest alternative. Third parties also estimated that, on average, Neptra was used in place of Osurnia in over 80% of cases.

107. Although around a third of respondents identified Canaural as being the second or third closest alternative to Osurnia, indicating that it is possible to use Canaural in place of Osurnia, no third parties identified Canaural as Osurnia's closest alternative. In addition, third parties estimated that, on average, Canaural was used in place of Osurnia in around only 5% of cases.

108. The above evidence from third parties indicates that Osurnia competes more closely with Neptra than with Canaural and other daily dose otitis treatments.

Conclusion on closeness of competition between the Parties

109. Based on the evidence set out above, the CMA believes that the Parties are not particularly close competitors in the supply of first-line antibiotic otitis treatments in the UK.

Competitive constraints from alternative suppliers

110. Unilateral effects are more likely where customers have little choice of alternative supplier. The CMA has considered whether there are alternative suppliers of first-line antibiotic otitis treatments in the UK which would provide a competitive constraint on the Merged Entity.

Dechra's submissions

111. Dechra submitted that the UK market for the supply of otitis treatments is, and will continue to be, highly competitive with numerous strong suppliers (set out in Table 1 above). In particular, it submitted that Elanco will continue to be an effective constraint in the UK market as it will retain its existing treatment Surolan and acquire Neptra following the *Elanco/Bayer* transaction. Dechra emphasised that it strongly expected that Neptra would quickly gain market share in the UK and act as a strong competitive constraint on the Merged Entity, competing particularly closely with Osurnia.[68]

Alternative suppliers

112. The CMA has assessed the competitive constraints from alternative suppliers of first-line antibiotic otitis treatments in the UK below.

- *Elanco (Surolan)*

113. Elanco supplies a first-line antibiotic otitis treatment brand named Surolan which it will retain post-Merger.

114. Surolan currently has the largest share of supply of first-line antibiotic otitis treatments in the UK. Surolan's share has increased substantially since Canaural became unavailable: from [20-30]% in January 2019 to [30-40]% in December 2019 (see Table 2 above). The Parties' competitors who responded to the CMA's merger investigation estimated that Surolan would continue to have the largest share of supply of first-line antibiotic otitis treatments in the UK in two years' time after the re-launch of Canaural, at 22%[69] (on average). This indicates that, considering a scenario in which Canaural has returned to the market and Neptra has become established, the Parties' competitors expect Surolan to increase its share of supply relative to its share before Canaural's unavailability.

[68] Merger Notice, paragraphs 172 to 178.
[69] Although the CMA does not consider this as a reliable forecast of a treatment's future share of supply, the CMA believes that this indicates third parties' perception of a treatment's competitive strength in the future.

115. The large majority of third parties who responded to the CMA's merger investigation identified Surolan as the closest alternative to Canaural. Third parties noted that Canaural and Surolan have a similar combination of active ingredients, frequency and mode of administration and are used under similar circumstances as a first-line antibiotic otitis treatment.

116. Third parties considered that Surolan attracted the most diversion from Canaural following its supply issues in early 2019 relative to other otitis treatments. On average, third parties estimated diversion to Surolan to have been over 40%. This is in line with the results of the CMA's event study analysis discussed in paragraphs 91-97 above, which indicated that Surolan attracted the highest level of diversion from Canaural following Canaural's removal from the market.

117. While Dechra's internal documents indicate that it monitors a range of otitis treatments that are available, they identify Surolan as [✂].[70]

118. Based on the evidence set out above, the CMA believes that Elanco's Surolan will continue to impose a significant competitive constraint on the Merged Entity (and particularly on Canaural) post-Merger.

- *Elanco/Bayer (Neptra)*

119. Bayer first launched Neptra in the US, Canada and Mexico in 2015 and introduced it in the UK in early 2020. As set out in paragraph 18 above, Elanco is currently in the process of acquiring Neptra from Bayer as part of the *Elanco/Bayer* transaction.

120. The Parties' competitors estimated that Neptra would have a share of supply of around 16%[71] in two years' time, considering a scenario in which Canaural has returned to the market.

121. Almost all third parties who responded to the CMA's merger investigation considered Neptra to be the closest alternative to Osurnia, as discussed in paragraphs 105-108 above. Third parties noted that Neptra has similar characteristics to Osurnia in terms of its active ingredients and mode of administration,[72] and they tend to be used for the same types of otitis cases (ie acute canine otitis caused by Gram-positive bacteria and Malassezia).

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[70] Dechra response to section 109 dated 11 March 2020, Annexes 6.1 and 1.3; Dechra response to section 109 notice dated 25 February 2020, Annex 3.1.
[71] See footnote 69.
[72] In addition to Osurnia, Neptra is the only other long-acting otitis treatment available in the UK, although, unlike Osurnia, Neptra requires one dose rather than two.

122. Third party responses also indicated that, on average, in a scenario where Osurnia was no longer available Neptra would be the closest alternative in over 80% of cases.

123. The CMA received evidence from Bayer in relation to the expected growth of Neptra following its launch in the UK. Bayer's internal documents indicate that Neptra's share of supply estimates in the first few years of its UK launch range from between 10-20%[73] and 30-40%,[74] depending on different assumptions and dates at which these documents were produced. In addition, Bayer told the CMA that it was expecting Neptra to achieve a share of supply of around [10-20]% in the UK within a year of launch, conveying a degree of confidence in the competitive strength of this product.[75] The CMA has not received any evidence to suggest that Neptra's expected growth would differ under Elanco's ownership compared to under Bayer's ownership. Finally, Bayer's sales data indicated that Neptra achieved a share of supply of around [10-20]% in the UK for the last half of February 2020, demonstrating that Neptra has already attracted interest from vet groups and practices.[76]

124. Dechra's and Elanco's internal documents indicate that Neptra already exerts a [✂] competitive constraint on Osurnia. Elanco's internal documents reveal a [✂] focus on strategies aimed at [✂], noting that [✂].[77] Prior to Neptra's launch in the UK, Elanco's internal documents noted that Neptra [✂], and highlight the importance of [✂].[78] Further, Elanco estimates that the impact of Neptra's launch in the UK and Ireland on Osurnia would be [✂].[79] Dechra's internal documents also indicate that Dechra considers that Neptra exerts a constraint on Osurnia. Post-Merger, Dechra intends to [✂].[80]

125. Based on the evidence set out above, the CMA believes that following its recent launch in the UK, Neptra currently exerts a significant constraint on Osurnia, that it will continue to grow its competitive presence in the market and will exert an increasingly significant competitive constraint on the Merged Entity (and particularly on Osurnia) post-Merger.

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[73] Bayer response to section 109 notice dated 3 April 2020, [✂].
[74] Bayer response to section 109 notice dated 3 April 2020, [✂]. The analysis in this document suggests [✂].
[75] Note of call with Bayer.
[76] Bayer response to section 109 notice dated 3 April 2020, [✂].
[77] Dechra response to section 109 notice dated 11 March 2020, Annexes 2.3 and 2.1; Elanco response to section 109 notice dated 25 February 2020, Annex ED-002; Merger Notice, Annex 8.8.
[78] Elanco response to section 109 notice dated 25 February 2020, Annex ED-002, ED-003, ED-032.
[79] Elanco response to section 109 notice dated 25 February 2020, Annexes ED-035 and ED-030.
[80] Merger Notice, Annexes 9.4 and 9.8.

- *Animalcare (Aurimic)*

126. Animalcare supplies a first-line antibiotic otitis treatment, Aurimic. Aurimic is a generic version of Surolan which means that their composition and mode and frequency of administration are identical.

127. Aurimic's share of supply of first-line antibiotic otitis treatments in the UK has increased substantially since Canaural became unavailable: from [0-5]% in January 2019 to around [5-10]% in December 2019 (see Table 2 above). The Parties' competitors estimated that Aurimic would maintain its current share of supply over the next two years, considering a scenario in which Canaural has returned to the market and Neptra has become established.

128. A significant number of third parties who responded to the CMA's merger investigation considered Aurimic to be the closest or second closest alternative to Canaural. On average, third parties estimated that at least 13% of the diversion from Canaural following its removal from the market was attributed to Aurimic. Finally, the CMA's event study analysis indicated that Aurimic attracted the second highest level of diversion from Canaural following Canaural's removal from the market.

129. Dechra's and Elanco's internal documents demonstrate that [✂].[81]

130. Based on the evidence set out above, and considering the similarities between Aurimic and Surolan, the CMA believes that Aurimic will continue to impose a material competitive constraint on the Merged Entity post-Merger.

- *Virbac (Easotic)*

131. Virbac supplies a first-line antibiotic otitis treatment Easotic.

132. According to December 2019 estimates, Easotic's share of supply of first-line antibiotic otitis treatments in the UK is [10-20]%, representing a [0-5]% increase from January 2019 when Canaural was still available (see Table 2 above). On average, the Parties' competitors expected Easotic to have around 9%[82] share of supply in two years' time, considering a scenario in which Canaural has returned to the market and Neptra has become established.

[81] Merger Notice, Annexes 10.4 and 10.12; Dechra response to section 109 notice dated 25 February 2020, Annex 3.1; Elanco response to section 109 notice dated 25 February 2020, Annex ED-034.
[82] See footnote 69.

133. A substantial number of third party responses indicated that Easotic could be used as an alternative to Osurnia while a more limited proportion indicated that it could be an alternative to Canaural. This indicates that Easotic is considered an alternative to the Parties' treatments for some customers (albeit a more distant alternative relative to Surolan, Neptra and Aurimic). Dechra's and Elanco's internal documents also demonstrate [✂].[83]

134. Overall, based on the available evidence, the CMA believes that Easotic will impose a competitive constraint on the Merged Entity post-Merger.

- *MSD (Otomax)*

135. MSD supplies a first-line antibiotic otitis treatment Otomax.

136. According to December 2019 estimates, Otomax's share of supply of first-line antibiotic otitis treatments in the UK is [5-10]%, representing a [0-5]% increase from January 2019 when Canaural was still available (see Table 2 above). The Parties' competitors expected Otomax to have around 5%[84] share of supply in two years' time, considering a scenario in which Canaural has returned to the market and Neptra has become established.

137. A significant number of third parties who responded to the CMA's merger investigation referred to Otomax when identifying alternatives for Canaural, while only a few third parties indicated that Otomax could be an alternative to Osurnia. Overall, the responses from third parties indicated that Otomax is considered a more distant alternative to the Parties' otitis treatments relative to Surolan, Neptra and Aurimic. Dechra's and Elanco's internal documents also demonstrate [✂].[85]

138. The CMA therefore believes that Otomax will impose at least some competitive constraint on the Merged Entity post-Merger.

Conclusion on constraints from alternative suppliers

139. In light of the evidence set out above, the CMA believes that there will remain sufficient competitors post-Merger to effectively constrain the Merged Entity.

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[83] Merger Notice, Annex 15.2; Elanco response to section 109 notice dated 25 February 2020, Annexes ED-034, ED-079, ED-086; Dechra response to section 109 notice dated 11 March 2020, Annex 1.3; Elanco response to section 109 notice dated 11 March 2020, Annex ED-146.
[84] See footnote 69.
[85] Merger Notice, Annexes 10.4, 10.12, and 15.2; Dechra response to section 109 notice dated 11 March 2020, Annex 1.3; Elanco response to section 109 notice dated 25 February 2020, Annexes ED-079 and ED-086.

Dechra's pipeline [✂] otitis treatments

140. As set out in paragraph 39 above, Dechra has [✂] treatments in its pipeline, [✂]. Dechra submitted that [✂].[86] Dechra submitted that [✂] and provided internal documents to the CMA dated between February 2018 and February 2020 comprising [✂].[87]

141. The CMA considers that Dechra's internal documents [✂].[88] The CMA therefore does not believe that [✂]. With respect to the [✂], the CMA notes that [✂].[89,90] In addition, [✂]. The CMA therefore believes that [✂].

142. However, even if [✂] to be launched in the UK, the CMA believes that [✂].

143. The CMA also believes that the Merged Entity would continue to be constrained effectively by a sufficient number of other competitors. In particular, the CMA believes that (i) Elanco's Surolan and Animalcare's Aurimic would continue to impose a significant competitive constraint on the Merged Entity (and particularly on Canaural [✂]); (ii) Neptra would continue to grow its competitive presence in the market and exert an increasingly significant competitive constraint on the Merged Entity (and particularly on Osurnia); and (iii) Easotic and Otomax would also continue to constrain the Merged Entity. In addition, [✂]. [✂].[91] The CMA believes that this would impose a further competitive constraint on the Merged Entity [✂].

144. Accordingly, while the CMA believes that there is very limited likelihood that [✂] will be launched in the foreseeable future, even if it is launched, [✂] and the Merged Entity would continue to be constrained effectively by a sufficient number of competitors.

Conclusion on horizontal unilateral effects in the supply of first-line antibiotic otitis treatments in the UK

145. For the reasons set out above, the CMA believes that the Parties' combined share of supply of first-line antibiotic otitis treatments in the UK (once Canaural is re-launched) may be relatively significant, but given that there are dimensions of differentiation between otitis treatments and that share of supply estimates do not take into account any expected changes in market dynamics (such as any change in Canaural's competitive strength upon its

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[86] Merger Notice, Tables 18.3 and 18.4.
[87] Dechra response to section 109 notice dated 25 February 2020.
[88] Dechra response to section 109 notice dated 25 February 2020, Annex 5.23; and Dechra response to section 109 notice dated 6 May 2020, stating that [✂].
[89] Dechra response to section 109 notice dated 25 February 2020, Annexes 5.2 to 5.23.
[90] Moreover, Dechra's internal documents indicate that [✂] – the CMA considers that [✂].
[91] [✂].

return to the market and the strength of the competitive constraint posed by the recently launched Neptra), the CMA has considered the significance of shares of supply in the light of other evidence related to closeness of competition between the Parties and other competitive constraints.

146. The CMA believes that the Parties are not particularly close competitors in the supply of first-line antibiotic otitis treatments in the UK and that there will remain sufficient competitors post-Merger to effectively constrain the Merged Entity. Accordingly, the CMA found that the Merger does not give rise to a realistic prospect of an SLC as a result of horizontal unilateral effects in relation to the supply of first-line antibiotic otitis treatments in the UK.

Horizontal unilateral effects in the supply of prescription non-antibiotic otitis treatments in the UK

147. Unilateral effects may arise from the elimination of potential competition. Where the merger involves a potential entrant that could have increased competition, such actual potential competition is a constraint only if and when it occurs.[92]

148. While Dechra's Recicort is currently the only prescription non-antibiotic otitis treatment available in the UK (see paragraph 34(b) above), [✂] (see paragraphs 39-40 above).

149. In order to assess the likelihood of the Merger resulting in horizontal unilateral effects through the loss of actual potential competition in the supply of prescription non-antibiotic otitis treatments in the UK, the CMA, consistent with its established guidance,[93] has considered:

(a) Whether [✂] would be likely to [✂] develop and launch [✂] absent the Merger; and

(b) whether the launch of [✂] would lead to greater competition.

150. Moreover, the CMA has separately considered whether Elanco could be considered to be currently competing by investing in the research and development (**R&D**) of new prescription non-antibiotic otitis treatments and, as such, whether the Merger could reduce the Merged Entity's incentive to continue with current investment levels in new products and, therefore, reduce innovation in this area.

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[92] *Merger Assessment Guidelines*, paragraphs 5.4.13 to 5.4.15.
[93] *Merger Assessment Guidelines*, paragraph 5.4.15.

Likelihood of [✂] development and launch of [✂]

Dechra's and Elanco's submissions

151. Elanco submitted that the Merger would not lead to a loss of actual potential competition because [✂]. In particular, they explained that:[94]

(a) [✂]; and

(b) [✂].[95] [✂].

152. Dechra also submitted that [✂] the probability of [✂] being developed and launched would [✂] be around [✂] since [✂].[96]

CMA assessment

153. With respect to the likelihood that the [✂] pipeline [✂] otitis treatments would come to market, the CMA notes Dechra's submission that the probability of launch, [✂], would be [✂] (see paragraph 152 above). However, the CMA notes that this probability is conditional on [✂].

154. Therefore, the CMA considered the cu[✂] and the likelihood that they would be [✂] in the absence of the Merger.

- *[✂]*

155. As set out in paragraph 151(a) above, Elanco submitted that [✂]. Elanco's internal documents confirm this decision and that [✂].[97]

156. For these reasons, the CMA believes that [✂], and that it is unlikely that [✂] would be [✂] developed and launched absent the Merger.

- *[✂]*

157. Although [✂] development of [✂] (see paragraph 151(b) above), the CMA found that [✂].[98]

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[94] Elanco response to section 109 notice dated 1 May 2020. The CMA notes that the Merger was not in contemplation at the time when Elanco's [✂] decisions with respect to [✂] were taken.
[95] Merger Notice, paragraph 295. The Parties submitted that [✂].
[96] Merger Notice, paragraph 296.
[97] For example, [✂] (Elanco response to section 109 notice dated 1 May 2020, Annexes ED-176 and ED-183).
[98] For example, Elanco response to section 109 notice dated 1 May 2020, Annexes ED-180 and ED-182.

158. Elanco submitted that [✂]. The CMA also found a number of Elanco's internal documents that indicate that the probability of [✂] being developed and launched was [✂]. For example:

(a) [✂];[99]

(b) [✂];[100]

(c) [✂];[101] and

(d) [✂].[102]

159. Based on the evidence set out above, the CMA believes that [✂].

Conclusion on the likelihood of [✂] development and launch of [✂]

160. For the reasons set out above, the CMA believes that [✂] and does not believe there is a realistic prospect that [✂] would be [✂] developed and launched absent the Merger.

Impact of the launch of [✂] on competition

161. Since the CMA does not believe that there is sufficient likelihood that [✂] would be [✂] developed and launched absent the Merger, the CMA did not need to consider whether their launch would lead to greater competition.

Loss of innovation

162. The CMA also considered whether Elanco could be considered to be currently competing by investing in the R&D of new prescription non-antibiotic otitis treatments and, as such, whether the Merger could reduce the Merged Entity's incentive to continue with current investment levels in new products and, therefore, reduce innovation in this area.

163. The CMA notes that:

(a) as set out above, [✂]; and

(b) Elanco's pipeline [✂].

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[99] Elanco response to section 109 notice dated 1 May 2020, Annex ED-179.
[100] Elanco response to section 109 notice dated 1 May 2020, Annex ED-183.
[101] Elanco response to section 109 notice dated 1 May 2020, Annex ED-184.
[102] Elanco response to section 109 notice dated 1 May 2020, Annex ED-185.

164. For these reasons, the CMA believes that [✂], and that the Merger would not reduce innovation in the supply of prescription non-antibiotic otitis treatments in the UK.

Conclusion on horizontal unilateral effects in the supply of prescription non-antibiotic otitis treatments in the UK

165. For the reasons set out above, the CMA does not believe there is a realistic prospect that [✂] would be [✂] developed and launched in the absence of the Merger. The CMA also believes that the Merger would not reduce innovation in the supply of prescription non-antibiotic otitis treatments in the UK. Accordingly, the CMA found that the Merger does not give rise to a realistic prospect of an SLC as a result of horizontal unilateral effects in relation to the supply of prescription non-antibiotic otitis treatments in the UK.

Barriers to entry and expansion

166. Entry, or expansion of existing firms, can mitigate the initial effect of a merger on competition, and in some cases may mean that there is no SLC. In assessing whether entry or expansion might prevent an SLC, the CMA considers whether such entry or expansion would be timely, likely and sufficient.[103]

167. However, the CMA has not had to conclude on barriers to entry or expansion as the Merger does not give rise to competition concerns on any basis.

Third party views

168. The CMA contacted customers (including vet groups and vets) and competitors of the Parties. A limited number of third parties raised concerns in relation to a reduction in the number of otitis treatments available post-Merger and changes to which treatments are stocked by vets (which can cause confusion for staff and/or pet owners), as well as a concern about the Merged Entity having a commercial advantage in its negotiations with vet groups post-Merger. No other third parties (including vet groups) raised concerns about the Merger.

169. Third party comments have been taken into account where appropriate in the competitive assessment above.

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[103] *Merger Assessment Guidelines*, from paragraph 5.8.1.

Decision

170. Consequently, the CMA does not believe that it is or may be the case that the Merger may be expected to result in an SLC within a market or markets in the UK.

171. The Merger will therefore **not be referred** under section 33(1) of the Act.

Eleni Gouliou
Director, Mergers
Competition and Markets Authority
9 June 2020