COMMERCE ACT 1986: BUSINESS ACQUISITION CLEARANCE

SECTION 66: NOTICE SEEKING CLEARANCE

The Registrar
Competition Branch
Commerce Commission
PO Box 2351
WELLINGTON 6140
and email: records@comcom.govt.nz

Pursuant to section 66(1) of the Commerce Act 1986 notice is hereby given seeking clearance of a proposed business acquisition.

ANTICIPATED ACQUISITION BY DECHRA OF THE OSURNIA BUSINESS OF ELANCO

Dechra Pharmaceuticals PLC, Dechra Limited and Dechra Veterinary Products LLC apply for clearance to purchase all of the worldwide assets, rights and liabilities relating to Osurnia (a branded drug for the treatment of otitis externa (or **"otitis"**) in dogs) from Elanco Tiergesundheit AG.

PART 1: TRANSACTION DETAILS

1 Provide the name of the applicant for clearance, and the name of the individual responsible for the application.

Dechra Limited is a private limited company incorporated in the UK. Dechra Veterinary Products LLC is a US limited liability company (together with Dechra Limited, the "**Purchasers"**).

The purchasers are part of the same corporate group, which is headed by Dechra Pharmaceuticals PLC, a public limited company listed on the London Stock Exchange and incorporated in the UK (together with the Purchasers and each other subsidiary of Dechra Pharmaceuticals PLC, **"Dechra"**).

Dechra Pharmaceuticals PLC and the purchasers, Dechra Limited and Dechra Veterinary Products LLC, are the applicants for clearance, with Nim Cassidy being the individual responsible for the application.

1.1 postal address, physical address, telephone number and web address of the applicant.

Postal Address: Dechra Pharmaceuticals PLC, 24 Cheshire Avenue, Cheshire Business Park, Lostock Gralam, Northwich, CW9 7UA, UK.
Physical Address: Dechra Pharmaceuticals PLC, 24 Cheshire Avenue, Cheshire Business Park, Lostock Gralam, Northwich, CW9 7UA, UK.
Telephone Number: + 44 (0) 1606 814730
Web address: https://www.dechra.com/

1.2 email address, telephone number and position of the contact person.

[ ]

In the first instance, please contact Alicia Murray of DLA Piper:

Email address: alicia.murray@dlapiper.com

Telephone number: +64 9 300 3830

1.3 names of any relevant related entities (showing shareholdings).

1.3.1 The relevant corporate entity in New Zealand is Dechra Veterinary Products NZ Ltd.

1.3.2 A diagram showing the relevant corporate structure is below. A full corporate chart is provided at Annex 2.

[ ]

Dechra's Corporate Structure

2 Provide the name of the other party to the merger and provide the:

The other party to the transaction is Elanco Tiergesundheit AG, a private limited company incorporated in Switzerland (the **"Seller"**).

The Seller forms part of the corporate group of Elanco Animal Health Incorporated, a public limited company listed on the New York Stock Exchange (together with the Seller and each other subsidiary of Elanco Animal Health Incorporated, **"Elanco"**).

2.1 postal address, physical address, telephone number and web address for each party.

Physical Address: Elanco Animal Health Incorporated, 2500 Innovation Way, Greenfield, IN 46140, United States

Web Address: https://www.elanco.com/

2.2 name, email address, telephone number and position of the contact person for each party.

[ ]

In the first instance, please contact Torrin Crowther and Michael Tilley of Bell Gully:

Email address: torrin.crowther@bellgully.com; and Michael.tilley@bellgully.com

Telephone number: +64 9 916 8621 and +64 9 916 8827

3 Set out details of the merger for which you are seeking clearance including, where relevant:

3.1 The type of transaction; what is to be acquired; how the merger is structured; the purchase price; and anticipated timing of the merger

3.1.1 The Purchasers have agreed to acquire the Seller's worldwide assets, rights and liabilities relating to a branded drug for the treatment of otitis externa (or **"otitis"**) in dogs, Osurnia (the **"Target"**). Otitis is *"an inflammation of the external ear canal. It is not a disease in itself but rather a symptom of some other diseases."* [1] Otitis may also be secondary to bacteria and yeast infections.

3.1.2 [ ] [2]

3.1.3 Elanco currently supplies two otitis products in New Zealand, Osurnia and Surolan. Dechra has supplied two otitis products in New Zealand, Canaural and PMP. PMP is currently available, however, since the end of Q1 2019, Canaural has been out of stock, [ ].

3.1.4 The Transaction is related to Elanco's acquisition of Bayer's animal health division (the **"Bayer Transaction"**), which is subject to review by various competition agencies, including – in addition to the Commerce Commission – the Australian Competition and Consumer Commission (**"ACCC"**), the US Federal Trade Commission (**"FTC"**) and the European Commission (**"EC"**).

3.1.5 The Purchasers will acquire certain assets of the Seller as listed above (the Asset Purchase Agreement (the **"APA"**) is attached).

3.1.6 Completion of the Transaction is conditional upon the FTC and the EC:

(a) directing that Elanco divest the Target to remedy concerns in their respective reviews of the Bayer Transaction;

(b) approving the Purchasers as the acquirers of the Target (irrespective of any conditions imposed by those authorities); and

(c) approving the terms and conditions under which the Purchasers will acquire the Target.

3.1.7 The purchase price is USD $135,000,000 in cash, subject to adjustment as set out in clause 2.5.1 of the APA.

[1] European Commission decision, M.7277 – *Eli Lilly / Novartis Animal Health*, para 29
[2] A marketing authorisation is an approval that allows the holder to market and sell a specific medicinal product in one or more jurisdictions.

3.1.8 The APA was signed by the Purchasers and the Seller on 3 January 2020. Completion is anticipated by 1 July 2020.

3.2 The rationale of the merger

Dechra

3.2.1 Dechra's primary strategic and economic rationale for the Transaction is to add Osurnia to its dermatology portfolio, which will enhance its presence in this key therapeutic area and complete its otitis offering to vets with a **"long acting"**[3] product that is complementary to its existing **"daily dose"**[4] otitis products.[5]

[ ].

3.2.2 In addition, Dechra considers that the Transaction will allow it to deliver increased shareholder returns and strengthen its relationship with the current manufacturer of Osurnia, [ ] which Dechra considers to be a key contract manufacturing partner for it in the future.

Elanco

3.2.3 Elanco took the decision to divest Osurnia in the context of its discussions with the FTC regarding the Bayer Proposed Transaction. In the US, Claro and Osurnia are two of the leading otitis treatments by revenue market share. The decision was taken to divest the product globally, bearing in mind the need to preserve value for a potential buyer.

3.3 How the merger changes the control of the company, including a diagram of how the structure of ownership and affiliated companies are to change.

3.3.1 Prior to the Transaction, the assets and liabilities forming the Target are being held entirely by the Seller.

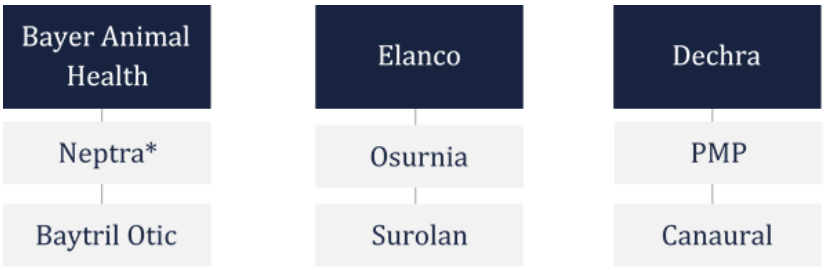
3.3.2 Following the Transaction, the assets forming the Target will be held entirely by companies within Dechra's corporate group, primarily the Purchasers. [ ].[6]

3.3.3 There are no pre-Transaction links between Dechra and Elanco, whether by corporate connections or associated persons.[7]

3.3.4 Diagrams showing the ownership structure and the effect of the Transaction and the Bayer Transaction are below. Attached at Annex 2 is a diagram showing where the Purchasers (and therefore the Target, following the Transaction) sit within Dechra's corporate group.

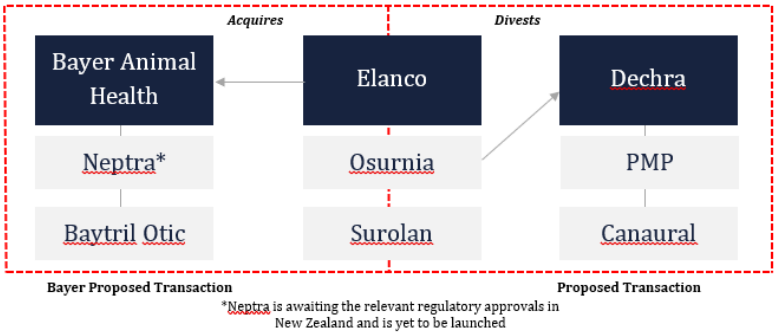
[3] Refers to products that are administered on one or two occasions, and which have a long acting effect.
[4] Refers to products that are administered daily, or multiple times a day.
[5] See further Dechra's, *Project Osiris Board Paper,* which is contained at Annex 22
[6] **[ ].**
[7] **[ ].**

Structure of Ownership pre-transactions



*Neptra is awaiting the relevant regulatory approvals in New Zealand and is yet to be launched

The Bayer Transaction and the Transaction



Parties and products post-transactions

3.4 A description of relevant ancillary agreements associated with the merger, such as long-term supply agreements between the target and the acquirer, and

Table 1.0 Relevant ancillary agreements:

[ ]

3.5 The likely relevant scenario(s) for each merging party if the merger does not go ahead

Dechra

3.5.1 If the Transaction does not go ahead, Dechra will continue to supply PMP. It will also seek to bring Canaural back to the market, [ ].

Elanco

3.5.2 If the Transaction does not go ahead, then it is possible that Elanco will need to find an alternative purchaser for Osurnia in order to obtain merger control approval for the Bayer Transaction from the EC and FTC.

4 If the merger forms part of an international transaction, list the other competition agencies that are being notified and the date on which those agencies were or will be notified, where relevant, indicate the status of reviews by other agencies.

4.1.1 The Transaction forms part of an international deal.

Competition agencies reviewing the Transaction

[ ]

4.1.2 [ ].

The Bayer Transaction

4.1.3 We note that other competition agencies (i.e. in addition to the EC and FTC, as discussed above), including the ACCC and Canada's Competition Bureau are also reviewing the Bayer Transaction.

4.1.4 Elanco anticipates that the FTC and/or the EC may require the divestment of the Target to remedy concerns arising in their respective reviews in the Bayer Transaction. In the event that this is the case, the Transaction would allow it to satisfy those requirements and progress the Bayer Transaction.

PART 2: THE INDUSTRY

5 Describe the relevant products and/or services of the merging parties and provide the following for each:

Dechra

Dechra is a UK-based specialist veterinary pharmaceuticals and related products business, with a FY19 turnover of £481.8 million. It develops, manufactures, markets and sells a number of high quality products exclusively to veterinarians worldwide, participating in the highly competitive veterinary pharmaceutical sector, which includes large multinationals such as Elanco, Zoetis, MSD, Bayer, Boehringer Ingelheim, Vetoquinol and Virbac.

Dechra's products can be divided into four main categories, namely:

companion animal products (~70.7% of global turnover in FY19) (**"CAP"**) – products for dogs and cats in several key therapeutic sectors, namely endocrinology, dermatology (including otitis), analgesia and anaesthesia, antibiotics, cardiovascular and critical care;

food producing animal products (~11.9%) (**"FAP"**) – products for pigs, poultry and cattle in several key therapeutic sectors, namely water soluble antibiotics, poultry vaccines, locomotion (lameness) and pain management;

equine products (~7.1%) – products for horses and ponies in two key therapeutic areas, namely lameness and pain management;

nutrition products (~6%) – products designed to support the wellbeing of dogs and cats with numerous therapeutic conditions, such as allergies, obesity, heart and kidney disease.

Elanco

Elanco is a global fully-dedicated[8] animal health business based in the US which develops, manufactures, markets and sells animal health products (including pharmaceutical products) for and to customers worldwide. Its FY18 turnover was USD $3.1 billion. It has a diverse portfolio of products under more than 125 brands and it identifies four main categories for its products:

companion animal disease prevention products (together with companion animal therapeutics products, ~35% of global turnover in FY18) – vaccines plus a parasiticide portfolio based on indications, species and formulations, with products that protect pets from various ecto- and endo-parasites;

companion animal therapeutics products – a pain and osteoarthritis portfolio across species, modes of action, indications and disease stages. Covers treatments for otitis, as well as cardiovascular and dermatology indications;

food animal future protein and health products (together with food animal ruminants and swine products, ~61%) – a portfolio that covers vaccines, nutritional enzymes and animal-only antibiotics; and

[8] Following its listing on the New York Stock Exchange on 20 September 2018.

food animal ruminants and swine products – a range of food animal products used extensively in cattle, sheep and goats (together, **"ruminants"**) and swine production.

5.1 The Applicant's view on the appropriate market definition

Product Dimension

5.1.1 Demand for veterinary pharmaceuticals (and therefore substitutability) is based on the need to treat the condition or disease in the animal in question, and the suitability for the animal based on animal species, the method of administration and the active substance included (and where relevant, the stage in the animal's reproductive cycle). In previous decisions, the EC has stated that the "*most important*" factors to be taken into account when defining relevant product markets in the area of animal health pharmaceuticals are the following:

"*(i.) Animal species: Although many pharmaceuticals are multi-species, some are effective only for a particular species or group of species (such as companion animals). In this regard the Commission has considered that animal health products are mainly produced for the following main groups of animals: (a) Ruminants (cattle, sheep and goats); (b) Swine; (c) Poultry (chickens and turkeys); (d) Equine (horses); (e) Companion animals (cats and dogs) and (f) Aquaculture animals (farmed fish).*

(ii.) Active ingredient: In some cases the active substance is the main determinant for the product market definition, e.g. in antibiotics, because the same active substance is effective against the whole range of pathologies.

(iii.) Target pathology / scope of effectiveness: Pathology is often at the core of the market definition. However, in some instances it is impossible to limit market demarcation to very narrowly defined pathologies.

(iv.) Mode of administration: Most animal health pharmaceuticals are injectable (especially for production animals). For companion animals a large number of pharmaceuticals are administered orally (tablets, pastes and granules). There is a large number of additional modes of administration such as intra-mammary products for mastitis treatment in cows, anti-parasitic collars or spot-on drops for companion animals, etc.

(v.) Duration of efficacy: Farmers may demand products that remain active for long periods of time, usually for preventive purposes, e.g. anti-parasitic products or long acting preventive antibiotics. (vi.) Duration of the withdrawal period: For production animals, the withdrawal period – i.e. the period after treatment

during which an animal's meat or milk is deemed unsuitable for human consumption – is of large economic importance".[9]

5.1.2 The Transaction relates to the purchase of a particular product to treat otitis in dogs and the parties overlap in the supply of veterinary pharmaceuticals to treat otitis in dogs.[10]

5.1.3 As the EC has noted in a previous decision, otitis is "*an inflammation of the external ear canal. It is not a disease in itself but rather a symptom of some other diseases*". Otitis may also be secondary to bacteria and yeast infections. It is a common condition in dogs, and occurs less frequently in cats.

5.1.4 Acute otitis is typically treated with a topical ear product that is effective against a number of pathogens, and commonly combines three drug classes into one product: an antifungal, an antibiotic and a steroid. An ear cleaner product may be used in conjunction with an otitis product as part of the treatment regimen.

5.1.5 In some cases a systemic antibiotic and/or steroids may be used instead of, or in combination with, topical otitis products. For example, if there is severe inflammation and the otitis has progressed further into the ear (otitis media), there are proliferative changes to and/or narrowing of the ear canal or there are other difficulties in administering topical products.[11] There is an extensive range of general purpose antimicrobials that can be used for otitis (although they are not authorised for that specific purpose).

5.1.6 There are therefore a number of products available in New Zealand to treat otitis. However, each of the otitis treatments have features that may make them more or less suitable for individual cases. The degree of closeness and desirability will depend on the condition of the animal in question, and the veterinarian's view of the pet-owner's ability to administer a daily drop medication.

5.1.7 For example, PMP, Surolan, Otomax, Aurizon and Easotic compete closely with one another as they are daily dose products that contain either the same antibiotic or the same antifungal APIs (i.e. those that are active against the most common pathogens) or both.[12] On the other hand, Osurnia is currently the only available long acting product in New Zealand. Subject to approval in New Zealand, Dechra expects Neptra to competitively constrain Osurnia given the drugs' similarities and the constraint imposed by Neptra in comparable overseas markets.

5.1.8 Therefore, in Dechra's view it is appropriate to consider the effect of the Transaction in the market for the supply of veterinary

[9] For example, *Eli Lilly / Novartis*, para 14.
[10] While otitis does occur in cats, sales of otitis treatment products for dogs represent 94% of sales globally.
[11] Nuttall T., Successful management of otitis externa in practice 2016, 38:17-21.
[12] For example, PMP and Surolan contain the same antibiotic and antifungal and the active ingredients are identical. Otomax and Easotic contain the same antibiotic as each other (gentamicin) but a different antifungal and different steroids. Easotic, PMP and Surolan share the same antifungal agent (miconazole) but Easotic has a different antibiotic and different steroids. Otomax and Aurizon have the same antifungal (clotrimazole) but different antibiotics and different steroids.

pharmaceuticals to treat otitis generally, taking into account how closely products compete.

5.1.9 Further, as mentioned above, there are other products that are not primarily used to treat otitis, but which may be appropriate for use instead of, or in combination with, typical otitis products, including oral antibiotic tablets, antibiotic injections and ear cleaners. These products also impose some constraint on otitis products, but the parties are comfortable not to include them in the formal market definition for the purposes of this application.

Geographic Dimension

5.1.10 Product is sold nation-wide and therefore Dechra submits that the market(s) is/are national in geographic scope.

Previous decisions

5.1.11 The ACCC has previously identified markets based on the supply of pharmaceuticals to treat and/or prevent specific conditions in both humans and animals.**[13]** The EC has regarded otitis pharmaceuticals as a single market in two reviews,**[14]** although it has not concluded definitively on the scope of the market (for example, it left open segmentation by mode of administration).[15] Defining the market for veterinary pharmaceuticals is complicated by the fact that prescribing decisions are based on different clinical situations and ultimate users.

5.1.12 Consistent with the product market for otitis treatment as a whole posited above, the ACCC, in its market inquiries letter relating to the Bayer Transaction, sought market participant's views on '*whether Elanco and Bayer compete closely in the manufacture and supply of otitis treatments for companion animals*'.[16]

[13] See, eg, ACCC, Statement of Reasons in respect of an exclusive dealing notification lodged by Equestrian Australia, 18 December 2015, 6.2 <https://www.accc.gov.au/system/files/public-registers/documents/D15%2B190656.pdf>; ACCC, Public Competition Assessment – Pfizer Inc – proposed acquisition of Wyeth Corp, 18 November 2009, 6 <https://www.accc.gov.au/system/files/public-registers/documents/D09%2B185734.pdf>.

[14] *Eli Lilly/Novartis Animal Health (Commission decision 2014/7228/EU)* (European Commission, COMP/M.7277, 3 October 2014) [29]; *Schering Plough/Organon Biosciences (Commission decision 2008/C80/EU)* (European Commission, COMP/M.4691, 11 October 2007 [327].

[15] *Eli Lilly/Novartis Animal Health (Commission decision 2014/7228/EU)* (European Commission, COMP/M.7277, 3 October 2014) [34].

[16] ACCC, Market inquiries letter: Request for submissions: Elanco Animal Health Incorporated's proposed acquisition of Bayer Aktiengesellschaft's animal health business, 20 December 2019, page 1, https://www.accc.gov.au/system/files/public-registers/documents/Elanco%20Bayer%20-%20market%20inquiries%20letter%20PR%20version%20-%2020%20December%202019_1.pdf

5.2 each merging party's total sales revenues, volumes, and, where relevant, capacity and excess capacity figures for the past three financial years.

Sales Revenue (NZD)

	2017 total sales	2018 total sales	2019 total sales
Dechra - Canaural	[ ]	[ ]	[ ]
Dechra - PMP	[ ]	[ ]	[ ]
Elanco - Osurnia	[ ]	[ ]	[ ]
Elanco - Surolan	[ ]	[ ]	[ ]

5.3 The names and contact details for each merging party's main competitors, and any trade or industry associations in which one or more of the merging parties participate, and

5.3.1 The main competitors and product names are listed in the table below. More detail about each product can be found in Annex 7.

Table 3.0: Main competitors

Name (product)	Contact details
Bayer (Neptra)	PO Box 76369, Manakau City, Auckland. Ph 09 262 3169
Virbac (Easotic)	PO Box 10305, Hamilton. 07 849 6782
Vetoquinol (Aurizon)	Unit 302.2, 6-12 Boronia Road, Da Vinci Business Park. Brisbane Airport, Brisbane, Australia. +61 1800 032 355
MSD (Otomax)	Private Bag 908, Upper Hutt. 0800 800 543
Elanco (Surolan)	PO Box 259354, Botany, Auckland. 09 275 5423

5.4 ***The names and contact details for each merging party's key customers, including at least the top five by value, and the revenue earned from each in the last financial year.***

Dechra top 5 customers by value

Customer	Revenue	Contact details
[ ]	[ ]	[ ]
[ ]	[ ]	[ ]
[ ]	[ ]	[ ]
[ ]	[ ]	[ ]
[ ]	[ ]	[ ]

Elanco top 5 customers by value

Customer	Revenue	Contact details
[ ]	[ ]	[ ]
[ ]	[ ]	[ ]

PART 3: COMPETITION ANALYSIS

6 Explain why you consider the merger is unlikely to result in a substantial lessening of competition in any market having regard to the Mergers and Acquisitions Guidelines.

The NZ market for the supply of treatment for otitis in dogs is a competitive market.

It is submitted that the Transaction does not raise competition concerns for the following reasons:

(a) Dechra will continue to face strong competition from existing suppliers of otitis treatments;

(b) Dechra's PMP and Canaural do not compete closely with Osurnia and acquiring Osurnia will not enable Dechra to raise prices for PMP or Canaural;

(c) Subject to approval in New Zealand, Dechra considers that Neptra will act as a strong competitive constraint, in particular on Osurnia;

(d) Barriers to entry and expansion for an existing animal health player are low and there are existing products available in other markets overseas for the treatment of otitis that are not currently available in New Zealand but which could enter the market; and

(e) Customers have countervailing buyer power.

6.1 how firms compete in the relevant markets, including how the merging parties seek to acquire and retain customers, how sales are made and the key dimensions of competition, such as price, quality or innovation.

Strong competition from existing suppliers of otitis treatments

6.1.1 The veterinary pharmaceuticals industry is highly competitive. Regardless of the market definition adopted, there are numerous vigorous competitors comprised of global pharmaceutical giants. The Transaction allows Dechra to remain competitive in the face of strong competition in all of the markets in which Dechra operates.

6.1.2 Following the Transaction, the otitis market in New Zealand will continue to be highly competitive with effective constraints imposed by Easotic (Virbac), Aurizon (Vetoquinol), Surolan (Elanco), Otomax (MSD) and other currently out of market brands supplied by major global animal health businesses.

Limited transaction-specific effects

6.1.3 As set out above, there are a number of factors that will be taken into account in deciding which treatment to use, and some products compete more closely than others.

6.1.4 PMP and Canaural, on the one hand, and Osurnia, on the other, are not close competitors and there are a number of differentiating factors. PMP and Canaural are low priced products that require daily application by pet owners and accordingly compete most

closely with other daily dose otitis products with these characteristics, including Surolan.

6.1.5 By contrast Osurnia is a long acting product that is applied by vets and is prescribed most regularly when there is concern that pet owners cannot apply the daily dose products effectively.

6.1.6 Other than Osurnia, current competitors are all daily dose products that compete closely with PMP and Canaural, but on only a limited basis with Osurnia. This means that Osurnia is highly differentiated in this regard, and the only long acting constraint will be seen in the launch of Neptra (see below).

6.1.7 Given that PMP and Canaural do not compete closely with Osurnia, the Proposed Transaction is unlikely to substantially lessen competition in the market, as Osurnia was not providing a material constraint on Dechra in the first place. As customers are not particularly loyal to otitis products in general (especially those like PMP, which are generic), there is no incentive for Dechra to bundle PMP or Canaural with Osurnia.

6.1.8 In substance, it is not different from Elanco currently having Osurnia and Surolan in its portfolio.

Anticipated competition from Neptra

6.1.9 If Neptra is granted regulatory approval in New Zealand, it is expected to be launched in 2020. Subject to this and to the completion of the Bayer Proposed Transaction, Neptra will be acquired by Elanco and marketed in New Zealand alongside Surolan.

6.1.10 Neptra is a long acting product with the same antibiotic and antifungal active ingredients as Osurnia (florfenicol and terbinafine). Osurnia is currently the only available long acting product in New Zealand, and if launched, Neptra has the potential to be a close competitor to Osurnia for customers who place a premium on convenience. However, there remain some differences between the products:

(a) Neptra only requires a single dose, whereas Osurnia requires two separate doses a week apart;

(b) the products contain different steroid active ingredients; and

(c) unlike Osurnia (which is an adaptable gel), Neptra will be administered as liquid ear drops and contains alcohol.

6.1.11 In terms of its global presence, Neptra is marketed in the US under the brand name Claro, [ ]. Claro was launched in 2015 in the US [ ]. Subsequently, Neptra was launched in the UK and Germany (in January 2020), with rollout across the rest of the EU expected in early 2020.

6.1.12 In light of Neptra's track record in the US, Dechra's expectation is that, if approved in the same form, Neptra will be a significant competitive constraint on the New Zealand otitis market going forward, and, although it can be distinguished from Osurnia in some respects, will closely compete with Osurnia.

6.1.13 As such, the impact of Neptra on the already competitive New Zealand market, in particular on Osurnia, is another reason why the Proposed Transaction will not have the effect of substantially lessening competition.

6.1.14 [ ].

[ ].

6.2 The merging parties' existing competitors, including approximate market shares (explaining how these have been calculated), and the extent to which these competitors will constrain the merged firm.

6.2.1 Please see the below tables, which set out shares of supply by value for the parties and each of their principal competitors for the sale of otitis products in New Zealand.

6.2.2 As stated above, this is a competitive market, and the other competitors and products in the market will continue to provide significant constraints on Dechra following the completion of the Transaction.

Shares of Supply by Value in NZ*

Product	2019		2018		2017	
	Value (NZD)	Share (%)	Value (NZD)	Share (%)	Value (NZD)	Share (%)
Canaural*	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
PMP	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
Osurnia	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
Dechra / Osurnia combined	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
Otomax	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
Surolan	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
Aurizon	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
Easotic	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
Total	[ ]	**100%**	[ ]	**100%**	[ ]	**100%**

Note: some numbers do not sum due to rounding.

*Please note that, as Canaural is currently out of stock, this is not an accurate reflection of the market at the current date. [ ].

[ ].

6.3 The likelihood, extent and timeliness of entry and expansion by potential competitors (including conditions of entry and expansion) and the extent to which such entry or expansion will constrain the merged firm.

6.3.1 A completely new entrant to the supply of veterinary pharmaceuticals would incur certain costs of entry, but these are not considered to insulate incumbents from the threat of entry. In any event, for an existing veterinary pharmaceutical company with experience of developing and bringing to market new products, barriers are low.

6.3.2 Otitis treatments comprise:

(a) steroid, antifungal and antibiotic active ingredients designed to reduce the inflammation and combat the infection in the animal's ear; and

(b) other substances that optimise the distribution of the active substance and offer the most convenient method of administration (i.e. daily drops and long acting).

6.3.3 Successful market entry can therefore be achieved with a different combination of steroid, antifungal and antibiotic active ingredients and/or delivery mechanism. Such entry is significantly cheaper and easier than developing an entirely new pharmaceutical product.

6.3.4 Successful market entry might also be achieved with an existing pharmaceutical product that is successful in other geographic markets, but has never been marketed in New Zealand. This includes products available in Australia that are not currently available in New Zealand.

6.3.5 Generic entry is also possible and will be expected, if profitable, once patents for treatments expire. Surolan is no longer covered by patents and there are two generic versions on the market in New Zealand (PMP and Dermotic).

6.3.6 Dechra's products, in particular its potentially acquired Osurnia product, will in the near future be subject to significant constraints from the soon to be launched Neptra product, which it is expected to be launching in New Zealand in 2020. As set out above, this product has been sold in the US since 2015 and was launched in the UK and Germany in January 2020 (with the rest of the EU to follow). Neptra will be a new long acting product to the New Zealand market and, for multiple reasons, Neptra is expected to be a significant competitive constraint on Osurnia following the Transaction. Elanco will be acquiring Neptra as part of the Bayer Transaction.

6.3.7 Dechra is not aware of any other likely entry or expansion, but as noted above considers it is possible.

6.4 The countervailing power of customers and the extent to which that countervailing power will constrain the merged firm, and

6.4.1 Following the Transaction, Dechra will be subject to significant countervailing buyer power. This dynamic, which exists at present and will not be affected by Dechra's acquisition of Osurnia, occurs because of the strength of the eventual 'decision-makers' with respect to Dechra's products. Those decision-makers, namely the practices which decide which products to stock and prescribe, hold a substantial amount of power in the veterinary pharmaceuticals market by virtue of the consolidation that has taken place in the vet practice sector in New Zealand.

6.4.2 This consolidation has resulted in the creation of a number of well-financed and sophisticated (and often international) **"corporate groups"**, where corporate entities acquire and combine independent vet practices. At the same time, the formation of **"buying groups"**, where independent practices or smaller corporates agree to purchase products jointly, has allowed smaller businesses to combine their purchasing power. This corporatisation of the veterinary practice sector is advanced in New Zealand, with 15 customers now controlling over 75% of vet practices.

6.4.3 These groups (details of which are set out below) are therefore able to leverage their scale to achieve better rebates and terms from product suppliers. They are also able to capitalise on the cost savings associated with procuring products on scale. Not only does Dechra feel this effect in New Zealand, but groups leverage their position in Australia to achieve better terms locally (and vice versa).

6.4.4 Relevant groups in New Zealand are:

(a) NVC/Vet Partners (Au/NZ) – approx. 60 clinics;

(b) Animates VetCare/Greencross (Au/NZ) – 18 clinics;

(c) CareVets (NZ only) – 18 clinics;

(d) VetENT (NZ only) – 21 clinics; and

(e) Franklin Vets (NZ only) – 10 clinics.

6.5 Any other relevant factors.

Ease of switching

6.5.1 Veterinarians are not tied down to the acquisition of any particular product by long-term supply contracts. At any point, a clinic could switch its preferences for any competing product. The ease with which veterinarians can switch from prescribing one product to another is demonstrated by the entry, and rapid growth, of Osurnia

in 2015. Further support is seen through the example of the US launch of Claro (Neptra).

6.5.2 Since Canaural has been out of stock, Dechra has seen an increase in sales of PMP, indicated that vets have switched to other daily dose products as a result of these supply issues.

Dynamic characteristics of the market

6.5.3 Both Neptra and Osurnia have only launched globally within the last five years. Within that time, both have taken significant market share within each jurisdiction. This rapid growth demonstrates the dynamism of the market and ability for innovation to disrupt incumbents.

6.5.4 As detailed in this submission, Dechra submits that the Transaction will not have the effect or likely effect of substantially lessening competition in any market. As such, Dechra requests that the Commerce Commission grant this clearance application.

Efficiencies and customer benefits

6.5.5 Dechra's primary rationale for the Transaction is to complete its otitis offering with the addition of a product that is complementary to its existing otitis products. The key benefit for the customer of this wider range of otitis products is that the customer will have an alternative supplier (in addition to Elanco). By adding Osurnia to its range, Dechra will be able to offer both daily treatments and long acting solutions.

6.5.6 [ ]**.**

No co-ordinated effects

6.5.7 The market is currently competitive and there are no indications of any co-ordinated effects exhibited in the current market.

6.5.8 The Transaction will not substantially change the competitive conditions in the market nor any of the factors (such as a lack of price transparency, product differentiation, etc) which currently preclude the exercise of co-ordinated market power.

PART 4: FURTHER INFORMATION AND SUPPORTING DOCUMENTATION

7 ***Copies of the final or most recent versions of any documents bringing about the merger such as the sale and purchase agreement, contracts, ancillary agreements or offer documents.***

7.1 A copy of the APA and other related agreements are attached as Annexures 1, 3, 4, 5 and 6.

8 ***Copies of any documents (including planning documents, due diligence reports, strategy documents, minutes of meetings, customer research, pricing studies, reports, presentations, surveys, analyses, industry/market reports and recommendations) in the applicant's possession which:***

8.1 ***Have been prepared for, seen or considered by senior management and/or any member of the board of directors (or equivalent body) whether prepared internally or by external consultants) and***

8.2 ***Either:***

8.2.1 ***set out the rationale for the merger (including but not limited to the benefits of, and/or investment case for the merger) and/or plans following the merger, or***

8.2.2 ***assess or analyse the merger with respect to competitive conditions, competitors (actual and potential), potential for sales growth or expansion into new product or geographic areas, market conditions, market shares and/or the price to be paid, or***

8.2.3 ***within the last two years, set out the competitive conditions, market conditions, market shares, competitors, or the applicant's business plans in relation to the relevant product(s) or service(s) as identified in response to question 5 above.***

Relevant documents are attached as Annexures 9 to 27.

9 ***Provide copies of, or links to, the most recent annual report, audited financial statements and management accounts for the relevant business units as identified in response to question 5.***

Dechra's Management Accounts are attached as Annexures 10, 11 and 12.

PART 5: CONFIDENTIALITY

Confidentiality is sought in respect of the information in this application that is highlighted in accordance with the key below, in bold and contained within square brackets (the **Confidential Information**).

Confidentiality is sought for the Confidential Information for the purposes of section 9(2)(b) of the Official Information Act 1982 on the following grounds.

- The Confidential Information is commercially sensitive and valuable information which is confidential to either, or both, parties.
- Disclosure of the Confidential Information would be likely to unreasonably prejudice the commercial position of the parties.
- The parties request that they are notified if the Commission receives any request under the Official Information Act 1982 for the release of any part of the Confidential Information. They also request that the Commission seek and consider their views as to whether the Confidential Information remains confidential and commercially sensitive before it responds to such requests.

Declaration

I, **Ian Page,** have prepared, or supervised the preparation of, this notice seeking clearance.

To the best of my knowledge, I confirm that:

- all information specified by the Commission has been supplied;
- if information has not been supplied, reasons have been included as to why the information has not been supplied;
- all information known to the applicant that is relevant to the consideration of this notice has been supplied; and
- all information supplied is correct as at the date of this notice.

I undertake to advise the Commission immediately of any material change in circumstances relating to the notice.

I understand that it is an offence under the Commerce Act to attempt to deceive or knowingly mislead the Commission in respect of any matter before the Commission, including in these documents.

I am a director of the applicant and am duly authorised to submit this notice.

Name of person authorised to sign

Date: 24 March 2020

Signature: 

List of Annexures

[ ]

8 Product Information

[ ]

ANNEX 7 - PRODUCT INFORMATION

DECHRA – CANAURAL

Company		Dechra Veterinary Products NZ Ltd
Species		Dog and cats
API	**Antibiotic**	Fusidic acid and Framycetin
	Antifungal	Nystatin
	Steroid	Prednisolone
Target pathology		Gram +ve, Gram -ve, Malassezia
Pharmaceutical form and mode of administration		Ear drop, suspension
Product Type		Daily ear drop
Route of administration		Apply five to ten drops. Direct into ear.
Indication for use		For the treatment of otitis externa including the ear mite, Otodectes cynotis, infestation in the dog and cat
Licensed for ear mites		Yes
Frequency of administration / number of doses		Twice daily, no set limit on duration
Duration of efficacy		Not established due to application being daily drops

[ ].

ELANCO – SUROLAN

Company		Elanco Australasia Pty Ltd
Species		Dog and cat
API	**Antibiotic**	Polymyxin B
	Antifungal	Miconazole nitrate
	Steroid	Prednisolone acetate
Target pathology		Gram +ve, Gram -ve, Malassezia
Pharmaceutical form and mode of administration		Ear Drops and Cutaneous Suspension
Product Type		Daily ear drop
Route of administration		Apply 3-5 drops. Direct into ear.
Indication for use		For the treatment of otitis externa and skin infections caused by fungi, yeasts, gram-negative and gram-positive bacteria and *Otodectes cynotis* in dogs and cats
Licensed for ear mites		Yes
Frequency of administration / number of doses		Twice daily until a few days after resolution. For up to two to three weeks.
Duration of efficacy		Not established due to application being daily drops

Note that Surolan is no longer covered by patents and there are a number of generic versions on the market in the EU, including PMP.

ELANCO – OSURNIA

Company		Elanco Australasia Pty Ltd
Species		Dog
API	**Antibiotic**	Florfenicol
	Antifungal	Terbinafine
	Steroid	Betamethasone acetate
Target pathology		Gram +ve, Malassezia and Gram_ve except Pseudomonas aeruginosa
Pharmaceutical form and mode of administration		Ear gel
Product Type		Long acting leave in
Route of administration		One tube (1 ml) Direct into ear. Clean ear beforehand – saline solution
Indication for use		Treatment of acute otitis externa and acute exacerbation of recurrent otitis externa caused by Malassezia pachydermatis, Staphylococcus pseudintermedius, Proteus spp., Eschericia coli and beta-haemolytic Streptococci.
Licensed for ear mites		No
Frequency of administration / number of doses		Two applications seven days apart
Duration of efficacy		Over 35 days

The key differentiator compared to other otitis products in the market is that Osurnia only requires two applications to have a long term effect and is applied by a vet in surgery. The anticipated launch of Neptra means that for the first time in this market Osurnia is competing against an otitis product with similar characteristics to it.

VIRBAC – EASOTIC

Company		Virbac New Zealand Ltd
Species		Dog
API	**Antibiotic**	Gentamycin sulphate
	Antifungal	Miconazole nitrate
	Steroid	Hydrocortisone Aceponate
Target pathology		Gram +ve, Gram -ve, Malassezia
Pharmaceutical form and mode of administration		Ear drops suspension
Product Type		Daily measured dose spray
Route of administration		One pump spray (1 ml per ear). Direct into ear
Indication for use		For the treatment of otitis externa of bacterial, yeast or inflammatory origin.
Licensed for ear mites		No
Frequency of administration / number of doses		Once daily for five days.
Duration of efficacy		Not established due to application being daily spray

VETOQUINOL – AURIZON

Company		Vetoquinol [Registered in New Zealand by Ethical Agents Veterinary Marketing Ltd]
Species		Dog
API	**Antibiotic**	Marbofloxacin
	Antifungal	Clotrimazole
	Steroid	Dexamethasone
Target pathology		Gram +ve, Gram -ve, Malassezia
Pharmaceutical form and mode of administration		Ear drops suspension
Product Type		Daily ear drop
Route of administration		Apply ten drops. Direct into ear
Indication for use		Treatment of otitis externa of both bacterial and fungal origin respectively due to bacteria sensitive to marbofloxacin, and fungi especially Malassezia pachydermatis sensitive to clotrimazole. The product should be used based on susceptibility testing
Licensed for ear mites		No
Frequency of administration / number of doses		Once daily for seven to fourteen days
Duration of efficacy		Not established due to application being daily drops

MSD – OTOMAX

Company		MSD [Registered in New Zealand by Schering-Plough Animal Health Ltd]
Species		Dog
API	**Antibiotic**	Gentamycin sulfate
	Antifungal	Clotrimazole
	Steroid	Betamethasone valerate
Target pathology		Gram +ve, Gram -ve, Malassezia
Pharmaceutical form and mode of administration		Ointment
Product Type		Daily ear drop
Route of administration		Apply four drops dogs (under 15 kg) or eight drops (over 15 kg). Direct into ear
Indication for use		For the treatment of canine acute and chronic otitis externa associated with yeast (Malassezia pachydermatitis) and/or bacteria susceptible to gentamicin
Licensed for ear mites		No
Frequency of administration / number of doses		Twice daily for seven days
Duration of efficacy		Not established due to application being daily drops

BAYER – NEPTRA

9 Neptra is not currently registered in New Zealand. The information below is taken from the UK submissions.

Company		Bayer
Species		Dog
API	**Antibiotic**	Florfenicol
	Antifungal	Terbinafine
	Steroid	Mometasone
Target pathology		Gram +ve only, Malassezia
Pharmaceutical form and mode of administration (from SPC[17])		Ear drops solution
Product Type		Long acting leave in
Route of administration		One tube (1 ml) direct into ear. Clean ear beforehand – saline solution
Indication for use		For the treatment of acute canine otitis externa or acute exacerbations of recurrent otitis caused by mixed infections of susceptible strains of bacteria sensitive to florfenicol (Staphylococcus pseudintermedius) and fungi sensitive to terbinafine (Malassezia pachydermatis)
Licensed for ear mites		No
Frequency of administration / number of doses		Once only
Duration of efficacy		Not specified

Bayer launched Neptra in the UK on 7 January 2020. Elanco is acquiring Neptra as part of the Bayer Transaction. Neptra is the EU brand name under which Bayer is commercialising its highly successful US long acting product, Claro, which was launched in the US, Canada and Mexico in 2015 and has quickly penetrated those markets. In those countries, Claro has established a strong market position for otitis as a result of its effectiveness as a treatment, and ease and convenience of application, as it is in the form of a topical drop and requires a single application. As noted, Claro was launched in 2015 in the US and became the highest selling otitis treatment three years from launch [ ].[18] Neptra is expected to achieve a significant market position at an early stage. [ ].[19]

[17] A summary of product characteristics ("**SPC**") is a legal document that accompanies a MA. The European Medicines Agency ("**EMA**") defines a SPC as being a "*document describing the properties and the officially approved conditions of use of a medicine. Summaries of product characteristics form the basis of information for healthcare professionals on how to use the medicine safely and effectively*".

[18] [ ].

[19] [ ].