

# Boehringer Ingelheim International GmbH

Notice seeking clearance to acquire

Sanofi's animal health business (Merial)

15 July 2016



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## COMMERCE ACT 1986: BUSINESS ACQUISITION

### SECTION 66: NOTICE SEEKING CLEARANCE

15 July 2016

The Registrar  
Mergers and Authorisations  
Commerce Commission  
PO Box 2351  
WELLINGTON

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

#### EXECUTIVE SUMMARY

- 1 The Boehringer Ingelheim group of companies, through its wholly-owned subsidiary Boehringer Ingelheim International GmbH (Boehringer Ingelheim International GmbH, together with all entities belonging to the Boehringer Ingelheim Group (**BI**), seeks clearance to acquire 100% of the shares and assets in Merial, an international animal health business (**the Transaction**). Merial is currently owned by Sanofi SA (**Sanofi**). The Transaction forms part of an international business swap between BI and Sanofi, and was announced on 15 December 2015.<sup>1</sup>
- 2 Both BI and Merial (**the Parties**) supply animal health products in New Zealand, predominantly to veterinarians and veterinary wholesalers. The Parties' respective portfolios differ greatly in terms of the types of products offered and relative size of each business. However, the Parties do have some overlap in the products they supply to the New Zealand market.
- 3 The relevant product segments where there is likely to be overlap between BI and Merial's business activities are:
  - 3.1 oral non-steroidal anti-inflammatories (**NSAIDs**) for companion animals (principally dogs and cats);
  - 3.2 multi-species injectable NSAIDs; [
  - 3.3 ]
- 4 The proposed transaction would not result in a lessening of competition in any of these animal health product markets for the following reasons:
  - 4.1 in all cases, the increment in market share attributable to the transaction is low;
  - 4.2 there are a number of other well-resourced, international animal healthcare suppliers/manufacturers already present in the relevant New Zealand product

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<sup>1</sup> <https://www.boehringer-ingelheim.com/press-release/sanofi-and-boehringer-ingelheim-enter-exclusive-negotiations-business-swap>.

markets. These companies have the ability and incentive to actively discipline any price rise or quality reduction in the combined entity's products;

- 4.3 BI and Merial are not each other's closest competitors, due to differences in the therapeutic indications, active ingredients and formulations of their respective products;
- 4.4 BI's and Merial's products are complementary rather than closely substitutable;
- 4.5 there is considerable scope for new entry or expansion in response to a price increase by BI post Transaction; and
- 4.6 customers have the ability to exert significant buyer power.

## **PART 1: APPLICANT AND OTHER PARTY DETAILS**

### **Applicant for clearance**

- 5 This notice seeking clearance is given by Boehringer Ingelheim, which is represented in Australia and New Zealand by its subsidiary: Boehringer Ingelheim Pty Limited, contact details for which are set out below.

Postal address: Level 1, 78 Waterloo Road  
North Ryde  
NSW 2113  
Australia

Website: <http://www.boehringer-ingelheim.com.au/>

Contact person: John Heath, Head of Animal Health – Australia and New Zealand  
[john\\_1.heath@boehringer-ingelheim.com](mailto:john_1.heath@boehringer-ingelheim.com)  
Phone: +61 (2) 8875 8674  
Mobile: +61 (0) 412025 113

Relevant related entities: C. H. Boehringer Sohn AG & Co. KG (parent company of the Boehringer Ingelheim Group)

Contact person: Dr. Martin Schwarz  
Legal – General Counsel  
[martin.schwarz@boehringer-ingelheim.com](mailto:martin.schwarz@boehringer-ingelheim.com)  
Tel.: +49 (6132) 77-90148  
Fax: +49 (6132) 77-4080

Address: 173 Binger Str.  
55216 Ingelheim am Rhein  
Germany

- 6 All correspondence and notices in respect of this notice should be directed in the first instance to:

Simon Peart  
Senior Associate  
(04) 498 6338  
[simon.peart@chapmantripp.com](mailto:simon.peart@chapmantripp.com)  
Chapman Tripp

Harriet Hansen  
Solicitor  
(04) 498 4968  
[harriet.hansen@chapmantripp.com](mailto:harriet.hansen@chapmantripp.com)  
Chapman Tripp

### **Other party to the acquisition**

- 7 The other party is Merial.

Postal address: PO Box 76211  
Manukau City 2241

Physical address: Level 3, Merial Building, Osterley Way, Manukau City, New Zealand.

Website: <http://nz.merial.com/>

Contact person: Kim Ellett, Marketing Director, Merial Ancare New Zealand  
kim.ellett@merial.com.  
Phone: (09) 980 1621  
Mobile: 021 416984

Marc Le-Terrier, Associate Vice President, Legal  
Mergers & Acquisitions – Alliances & Partnerships  
Phone: +33 (0) 1.53.77.41.84

54, rue la Boétie - 75008 PARIS – France  
Marc.le-terrier@sanofi.com

Relevant related entities: Sanofi  
<http://en.sanofi.com/>

8 All correspondence and notices in respect of this notice should be directed in the first instance to:

Simon Peart  
Senior Associate  
(04) 498 6338  
[simon.peart@chapmantripp.com](mailto:simon.peart@chapmantripp.com)  
Chapman Tripp

Harriet Hansen  
Solicitor  
(04) 498 4968  
[harriet.hansen@chapmantripp.com](mailto:harriet.hansen@chapmantripp.com)  
Chapman Tripp

## **PART 2: TRANSACTION DETAILS**

### **The proposed transaction**

- 10 The proposed transaction concerns the indirect acquisition by the Boehringer Ingelheim group of companies, through its wholly-owned German subsidiary Boehringer Ingelheim International GmbH, of the animal health business (**Merial**) from the Sanofi SA group (**Sanofi**). (Boehringer Ingelheim International GmbH is referred to, together with all entities belonging to its corporate group, as **BI**. BI and Sanofi together are referred to as the **Parties**).
- 11 BI intends to acquire Merial through a business swap whereby Merial will be transferred to BI in exchange for BI's consumer healthcare business (**BI CHC**). This application does not address Sanofi's proposed acquisition of BI CHC. The Parties will address separately any notification to the Commission of that transaction, noting the Parties' view is that there is a very limited, or no, overlap in New Zealand between Sanofi's consumer healthcare operations and BI's CHC. An additional cash payment from BI to Sanofi will take place in order to bridge the value gap between the two swapped businesses.
- 12 On 15 December 2015 Sanofi and BI entered into an exclusivity agreement for the proposed swap of Merial for BI's CHC business. The Parties signed a share and asset purchase agreement in respect of the Transaction on 26 June 2016. This is attached at **Annex 1**.
- 13 Subject to satisfaction of conditions precedent, the Parties are aiming to complete the Transaction by the end of 2016.

### **Commercial rationale**

- 14 The Transaction involves broadly complementary product portfolios with few overlaps. It aims to fulfil BI's strategic objective of becoming a major global animal health company able to compete more effectively in a competitive market place where many firms aggressively compete for each customer.

### **Other competition agencies being notified of the proposed transaction**

- 15 Completion of the Transaction is subject to a range of conditions including regulatory approvals in a number of jurisdictions.

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### **Overview of Parties to the acquisition**

#### **BI**

- 16 BI is a privately owned business headquartered in Ingelheim, Germany. The parent company of the BI group is C. H. Boehringer Sohn AG & Co. KG (CHBS). Boehringer AG is the managing shareholder of CHBS without holding any financial interest therein. BI is supervised by a Shareholders' Committee chaired by Christian Boehringer and representing the shareholder families.
- 17 BI is active worldwide in the development, production, distribution and marketing of pharmaceuticals, more particularly: (i) prescription products; (ii) CHC products; (iii)

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<sup>2</sup> [

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biopharmaceuticals; and (iv) animal health products. BI operates globally with 146 affiliates and more than 47,700 employees.

- 18 BI's animal health division, which employs more than 3,000 employees globally, focuses on the development, production, and marketing of innovative vaccines and other pharmaceutical products for production and companion animals.
- 19 In New Zealand, BI's activities are in three divisions: prescription medicine, consumer healthcare, and animal health. BI focuses on researching and developing new drugs and treatments that represent major therapeutic advances. In CY 2015, BI's sales in New Zealand were [ ], of which animal health sales were [ ]. BI's New Zealand revenues for the last three years are set out in **Annex 2**. BI's top five customers (by revenue) in the segments in which it overlaps with Merial are set out in **Annex 3**.

[  
]

- 20 More detailed information about BI can be obtained from the company's website at <http://www.boehringer-ingenelheim.com>.

#### ***Merial***

- 21 Merial produces a wide range of pharmaceutical products and biologicals for domestic pets, farm animals, and wildlife. It focuses on anaesthetic, anti-parasitic, antimicrobial, cardiovascular, gastrointestinal, and respiratory medicines, as well as vaccines against viral and bacterial diseases. Merial employs 6,600 people and is headquartered in Lyon, France. Merial is present in more than 150 countries. In CY 2015, Merial's sales in New Zealand were [ ]. Merial's New Zealand revenues for the last three years are set out in **Annex 4**. Merial's top five customers (by revenue) in the segments in which it overlaps with Merial are set out in **Annex 5**.

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- 22 More information on Merial can be found at <http://nz.merial.com/>.
- 23 **Sanofi** is a publicly listed company, headquartered in Paris, France, the shares of which are traded on Euronext and the New York Stock Exchange. It is the ultimate parent company of a global healthcare consolidated group consisting of approximately 400 subsidiaries. Sanofi is active in the research, development, manufacture, and sale of healthcare products, and is organised around three principal activities: (i) pharmaceuticals; (ii) human vaccines; and (iii) animal health.
- 24 In New Zealand Sanofi's activities cover pharmaceuticals, consumer healthcare, vaccines, rare diseases and multiple sclerosis, and animal health. Sanofi has an extensive portfolio of leading prescription medicines across a range of therapeutic areas. Sanofi Consumer Healthcare is one of the largest consumer healthcare businesses in Australia and New Zealand with a diverse portfolio of vitamins, minerals, and supplements, as well as over-the-counter and personal care brands. These include Nature's Own, Cenovis, Ostelin, Telfast, Gastrolyte, Betadine, and Selsun.

25 Further information about Sanofi is available at <http://en.sanofi.com/>.

**Existing overlap between the Parties**

26 There are no pre-existing links between BI and Merial, or as between any of their respective group companies.

**Relevant industry associations**

27 We provide details of the Parties' membership of relevant trade associations at **Annex 6**.

### **PART 3: INDUSTRY BACKGROUND AND RELEVANT PRODUCT MARKETS**

#### **Introduction to the animal health sector**

- 28 Animal health manufacturers develop, produce, and sell a variety of preventive and therapeutic products designed to target specific indications in the following species:
- 28.1 ruminants (cattle, sheep, deer, and goats);
  - 28.2 swine (pigs);
  - 28.3 equine (horses);
  - 28.4 poultry (chicken, ducks, pigeons and turkeys);
  - 28.5 companion animals (dogs and cats); and
  - 28.6 aquaculture animals (farmed fish)
- 29 Broadly speaking, therapeutic products can be differentiated by species (or groups of species), therapeutic functions, as well as their mode of application (injection, oral tablet/liquid, topical formula, etc). Products may also be differentiated by the length of time they are effective within an animal (which ranges from several hours to many months).
- 30 Some therapeutic products are prescription-only, while others can be purchased over the counter. This is another way these products can be differentiated. All of the relevant products in which the Parties overlap in New Zealand are prescription-only products.
- 31 There are three broad categories of animal health products:
- 31.1 **Biologicals:** biologicals are products that trigger an immune response against viral and bacterial diseases, and occasionally fungal and parasitic infections in animals. They encompass vaccines, antisera and colostrum.
  - 31.2 **Pharmaceuticals:** pharmaceuticals are a wide group of medicines containing a large variety of active substances to prevent or treat a range of animal diseases and disorders. Animal health pharmaceuticals are typically divided into the following categories of products:
    - (a) **Parasiticides:** agents or preparations used to destroy different types of parasites, both external and internal, such as fleas, flies, ticks, worms, flukes and protozoa.
    - (b) **Antimicrobials (also known as antibiotics):** products used to kill bacteria and other microbes causing a range of diseases across species.
    - (c) **Endocrine treatments:** hormone products to regulate an animal's physiology.
    - (d) **Anti-inflammatories and analgesics:** steroidal and non-steroidal products used to prevent and treat inflammation and reduce pain and/or associated fever.

- (e) Anaesthetics / central nervous system (CNS) pharmaceuticals: products used to anaesthetise and euthanise animals for health and ethical reasons.
- (f) Performance enhancers and other specialty products.

31.3 **Feed supplements:** Feed supplements are pharmaceutical or nutritional substances that are not natural feedstuffs and are added to made-up and stored feeds for various purposes, but chiefly to control infectious disease or to promote growth.

32 As set out in detail below, the Parties overlap in New Zealand only in relation to certain pharmaceutical product categories. They do not overlap in New Zealand in relation to biologicals (vaccines) or feed supplements.

33 In 2014, global animal health sales were worth NZ\$35 billion. Within animal health products, pharmaceuticals are the largest segment by value, generating approximately 62% of sales in 2014. Biologicals and feed supplements accounted for a further 26% and 12% respectively.

34 In New Zealand, the animal health market is estimated to be worth NZ\$307 million per year.<sup>3</sup> New Zealand's animal health market services the following animal population:

34.1 Cats: 1.4 million<sup>4</sup>

34.2 Dogs: 550,000<sup>5</sup>

34.3 Sheep: 28.6 million (declining)<sup>6</sup>

34.4 Beef cattle: 3.6 million (declining)<sup>7</sup>

34.5 Dairy cattle: 6.2 million<sup>8</sup>

34.6 Deer: 900,000<sup>9</sup>

34.7 Horses: 56,000 (declining).<sup>10</sup>

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<sup>3</sup> Source: Baron Strategic Services.

<sup>4</sup> <http://www.forestandbird.org.nz/files/file/CatFactsheet.pdf>.

<sup>5</sup> [http://www.dogsafety.govt.nz/dogsafety.nsf/wpg\\_URL/FAQs-Index!OpenDocument](http://www.dogsafety.govt.nz/dogsafety.nsf/wpg_URL/FAQs-Index!OpenDocument).

<sup>6</sup> <http://www.beeflambnz.com/Documents/Information/New%20Zealand%20sheep%20trend.pdf>.

<sup>7</sup> <http://www.beeflambnz.com/Documents/Information/New%20Zealand%20beef%20cattle%20trend.pdf>.

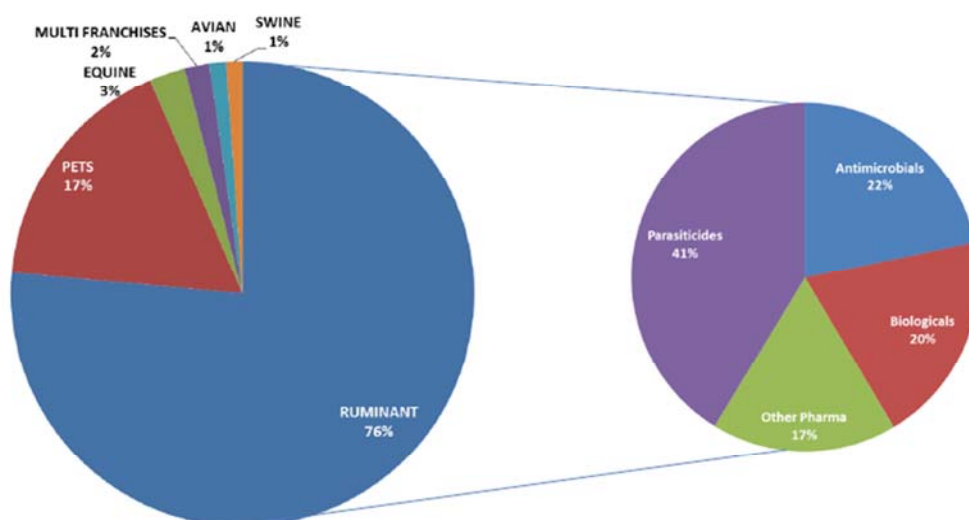
<sup>8</sup> <http://www.beeflambnz.com/Documents/Information/New%20Zealand%20dairy%20cattle%20trend.pdf>.

<sup>9</sup> <http://www.beeflambnz.com/Documents/Information/New%20Zealand%20dairy%20cattle%20trend.pdf>.

<sup>10</sup> <http://www.horsetalk.co.nz/2013/10/03/decline-worlds-horse-population/#axzz4CFysfpNC>.

- 35 As shown by Figure 3, the vast majority of value is driven by ruminant species (76%), followed by companion animals (17%).

**Figure 3: New Zealand animal health market<sup>11</sup>**



- 36 Against this background, BI, Merial, and a number of other international animal health product manufacturers/suppliers compete to provide a range of therapeutic remedies.

#### **Regulatory framework and distribution channels**

- 37 The products that are subject of this application are regulated in New Zealand and cannot be supplied absent regulatory approval. Moreover, animal health products are supplied either directly to larger vet clinics, or through wholesalers.<sup>12</sup>
- 38 In New Zealand, the Agricultural Compounds and Veterinary Medicines Act 1997 (**ACVM Act**) regulates therapeutic products that are used on animal or plants. It is illegal to import, manufacture, sell or use an agricultural compound product if that product has not been properly authorised under the ACVM Act. The ACVM Group of the Ministry for Primary Industries is the Government body that administers the ACVM Act and issues authorisations.
- 39 Under section 2 of the ACVM Act, “agricultural compound” is defined as including any veterinary medicine, which in turn is defined as “any substance, mixture of substances, or biological compound used or intended for use in the direct management of an animal”. A veterinary medicine incorporates a wide variety of products, and includes anything from antibiotics to pet shampoos.
- 40 ACVM products must be authorised before they are imported, manufactured for distribution, sold or used in New Zealand. This is to ensure that the products meet certain standards and do not pose unacceptable risks to:

- 40.1 trade in primary produce;
- 40.2 animal welfare;

<sup>11</sup> Source: Parties.

<sup>12</sup> Commission Decision 496, 3 April 2003, at [21].

- 40.3 agricultural security; and/or
- 40.4 public health.
- 41 The primary way that veterinary medicines are authorised in New Zealand is by obtaining registration under section 21 of the ACVM Act.<sup>13</sup> Once registration is complete, a manufacturer/supplier has approval to market its animal health product in New Zealand. The product may only be targeted at the species (or groups of species) listed on the AVCM register (for instance, a vaccine indicated for use in cattle cannot be used in sheep or deer).
- 42 Applications for registration of a veterinary medicine must include, among other information, technical data and/or scientific arguments to support:
- 42.1 the quality, purity and stability of the product;
- 42.2 the product's effectiveness for all therapeutic claims that relate to the risk areas managed under the ACVM Act. Efficacy of a trade name product is assessed when inefficacy will result in unnecessary pain and distress to the animal;
- 42.3 the safety of the product on target animals;
- 42.4 any possible impact on trade resulting from the use of the veterinary medicine in food-producing animals; and
- 42.5 compliance with domestic food residue standards.
- 43 A summary document is also required, outlining how the manufacturer/supplier intends to support the product's registration, such as label efficacy claims, safety, shelf life, and withholding periods. More information on the specific information required in an application can be found here: <https://mpi.govt.nz/document-vault/4497>.
- 44 BI notes that registering generic formulations of an animal health product which has already been approved in New Zealand is usually more streamlined than registering a novel product. In other words, there are no material barriers to generic entry in practice.
- 45 All registered veterinary medicines have conditions placed on their registration to manage risks. A registered veterinary medicine without additional restrictions is called "unrestricted". A veterinary medicine registered with extra restrictions on its sale, purchase and use is called a "restricted veterinary medicine".
- 46 **Unrestricted veterinary medicines** (non-prescription medicines) have no restrictions on their sale. Anyone can sell them so long as the product is maintained properly (that is, it conforms to the specifications approved during registration).

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<sup>13</sup> There are other forms of authorisation which can be granted under the ACVM Act, although they are unlikely to apply to the animal health products relevant to this application. These other forms of authorisation include provisional registration, exemption from registration under the ACVM Regulations, and approval in special circumstances. More information on these types of authorisations can be found here: <http://www.foodsafety.govt.nz/industry/acvm/vet-medicines/authorisation/>.

Promoting or advertising these products must be consistent with conditions of registration.

- 47 **Restricted veterinary medicines** (prescription - or veterinary authorised - medicines) have extra restrictions on their sale, purchase and use. To buy and use them, people need authorisation. Promoting or advertising these products must be consistent with conditions of registration. Veterinarians are permitted to authorise the purchase and use of restricted veterinary medicines for animals in their care (section 44G, AVCM Act); however, they must abide by the ACVM Notice "Requirements for Authorising Veterinarians".<sup>14</sup>
- 48 When prescribing the use of restricted veterinary medicines, veterinarians must comply with the product's registration requirements as listed on the ACVM register.<sup>15</sup> This means that a veterinarian can only prescribe the medication to treat the specific indications – or symptoms – listed on the product's ACVM registration, and only for the listed species.
- 49 This does not necessarily mean that the veterinarian must be the administrator of the treatment – depending on the nature of the treatment the owner or farmer may do this – but the medicine itself must first be prescribed by a veterinarian.
- 50 All of the products in which the Parties overlap in New Zealand, and which are analysed in this application, are categorised as restricted (or prescription-only) veterinary medicines.
- 51 The practical consequences of this regime are:
- 51.1 that the Parties' customers are either veterinarians or wholesalers/distributors that supply veterinarians. The Parties do not supply the overlap products directly to owners of the animals for which the products are intended;
- 51.2 the use, and therefore substitutability, of products is largely circumscribed by the ACVM registration and the permitted uses, species, and prescribing indicators provided for in the registration.

### **Relevance of generics in New Zealand and ease of market entry**

- 52 Generics play an important role in the animal health sector in general and pharmaceuticals in particular. As explained above, registering generic formulations that have already been approved in New Zealand typically follows a more streamlined process than registering a novel product. Thus, entry of existing animal health suppliers can be carried out in a relatively short period of time (within 40 working days<sup>16</sup>). As such, barriers to entry are, in practice, non-existent.

### **BI's New Zealand portfolio**

- 53 The products in BI's animal health portfolio supplied in New Zealand fall into the following categories:

#### **53.1 Biologicals:**

- (a) swine vaccines.

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<sup>14</sup> [http://www.foodsafety.govt.nz/elibrary/industry/Veterinarians\\_Recognised-Sets\\_Expectations.pdf](http://www.foodsafety.govt.nz/elibrary/industry/Veterinarians_Recognised-Sets_Expectations.pdf).

<sup>15</sup> Clause 1.2(6), ACVM Notice *Requirements for Authorising Veterinarians*.

<sup>16</sup> <https://mpi.govt.nz/document-vault/11977>. See registration requirements for B2 applications.

53.2 **Pharmaceuticals:**

- (a) antibiotics / antimicrobials for sheep/goats, cattle, deer, and swine;
- (b) hormones for horses;
- (c) chemotherapeutic / endocrine treatments for dogs, horses, and cattle; and
- (d) anti-inflammatories and analgesics for cats, dogs, horses, cattle, and swine.

**Merial's New Zealand portfolio**

54 The products in Merial's animal health portfolio supplied in New Zealand fall into the following categories:

54.1 **Biologicals:**

- (a) dog vaccines

54.2 **Pharmaceuticals:**

- (a) antibiotics / antimicrobials for cats, dogs, and cattle;
- (b) chemotherapeutic / endocrine treatments for cats, dogs, and horses;
- (c) anti-inflammatories and analgesics for cats, dogs, horses, cattle, and swine;
- (d) ectoparasiticides for cats, dogs, sheep/goats, and cattle;
- (e) endoparasiticides for dogs, horses, sheep/goats, and deer;
- (f) endectocides for horses, sheep/goats, cattle, and deer; and
- (g) performance enhancers/nutrients for cattle (e.g. mineral supplements).

**Extent of the overlap between the Parties**

55 The overlap between the Parties is currently limited to anti-inflammatories, and specifically:

55.1 oral non-steroidal anti-inflammatory drugs (NSAIDs) for companion animals; and

55.2 multi-species injectable NSAIDs.

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<sup>17</sup> [

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57 We note for completeness that the Parties are both active to a very limited extent in relation to:

57.1 antimicrobials for cattle; and

57.2 sedatives/anaesthetics for horses.

58 However, BI does not consider that the products in these categories are substitutable, as explained below.

**Antimicrobials for cattle**

59 BI’s and Merial’s respective products in this segment are as follows:

Boehringer Ingelheim	Merial
<p><b>Bivatop 200</b> (Oxy-Tet) is an injectable oxytetracycline-based antibiotic for oxytetracycline sensitive organisms. It is used for the treatment of footrot, metritis (uterus inflammation), and respiratory infections, and has a withholding period of 21 days for meat, and seven days for milk</p>	<p><b>Cefanil</b> is an injectable cephalosporin-based antimicrobial for the treatment of respiratory infections, footrot, and acute metritis. The withholding period is two days for meat, with no effect on milk</p>
<p><b>Mamyzin</b> is a non-cephalosporin based injectable antibiotic for treatment of infections that cause mastitis, respiratory infections, footrot, and uterine infections. It is also suitable for acute mastitis, and has a withholding period for meat of seven days, and 48 hours for milk</p>	<p><b>Cefamaster</b> is a cephalosporin-based intramammary treatment used to treat and prevent mastitis in dairy cows at drying off and during the dry period. The preparation is applied directly into the teat by an “easi” syringe (it is not an injection as such). The withholding period is 30 days for meat, and treatment should not occur within 56 days of calving. As such, it is strictly for dry cows</p>
<p><b>Ubrolexin</b> is an intramammary suspension for lactating cows, designed to treat mastitis pathogens. Its contraindications note that it should not be used in non-lactating cattle<sup>18</sup></p>	

60 These products are not substitutable for the following reasons:

60.1 BI’s mastitis treatments (Mamyzin and Ubrolexin) and Merial’s dry-off therapy (Cefamaster) are not substitutable with other antimicrobials (Cefanil and Bivatop) as they have indications specific to the milking cycle of cows.

<sup>18</sup> BI does not currently supply Ubrolexin in New Zealand. The introduction of Ubrolexin is dependent on receiving approval under New Zealand’s ACVM Act 1997. BI’s last application for approval of Ubrolexin was rejected, although BI is appealing this decision. BI considers it has low chances of receiving approval. In any case, BI submits that Ubrolexin does not compete with Merial’s products.

60.2 BI's mastitis treatments (Mamyzin and Ubrolexin) are not substitutable with Merial's dry-off therapy (Cefamaster). This was confirmed by the Commission in its consideration of the merger between Pfizer Laboratories and Pharmacia.<sup>19</sup>

61 As regards BI's Bivatop and Merial's Cefanil, we note that in *Schering-Plough/Organon SB* 4 October 2007) the Commission did not reach a firm conclusion on the precise definition of the market concerning antimicrobials in ruminant animals. For the purposes of that acquisition, it chose to analyse the competitive effects using a broad market definition of all antimicrobials for ruminant animals.<sup>20</sup>

62 However, the Parties consider that these two products are not substitutable with one another, and that prescribing veterinarians would not consider them substitutable, for the following reasons.

63 First, BI's Bivatop and Merial's Cefanil use different technologies and have different active pharmaceutical ingredients - cephalosporin and oxytetracycline respectively. The respective active substances differ in their bacteriostatic/bactericidal characteristic, in their low/high cost, in their common/not common resistance level and their wide/narrow spectrum of activity.

64 Second, Cefanil is classified as a third generation cephalosporin. According to the World Health Organisation, third generation cephalosporins are classified as highest priority critically important antimicrobials (HPCIA's). The use of these substances in livestock husbandry should therefore be restricted in order to minimise the risk of antimicrobial resistance. That is, these drugs should essentially be used as a last resort.

65 Bivatop, on the other hand, is a tetracycline that has been around since the 1950s. It is not a critically important antibiotic, and as such is often recommended as a first choice.

66 This concept of prudent use of antimicrobials ( that is, using older, less important antimicrobials in the first instance, and saving the critically important antibiotics for when they are actually needed) is well accepted and promoted by veterinary bodies around the world. This includes the New Zealand Veterinary Association (NZVA). Page six of the NZVA's publication *Antibiotics judicious use guidelines* outlines a traffic light system for classifying antimicrobials.<sup>21</sup>

**Green: Antimicrobials for first line therapy under therapeutic guidelines**  
Injectable

1. Procaine penicillin
2. Penethemate hydroiodide
3. Oxytetracycline

**Yellow: Antimicrobials restricted to specific indications or used as second line therapy under therapeutic guidelines**

1. Aminoglycosides
2. Injectable semi-synthetic penicillins (ampicillin, amoxicillin/clavulanic acid)
3. 1<sup>st</sup> and 2<sup>nd</sup> generation cephalosporins
4. Cloxacillin
5. Potentiated sulphonamides

**Red: Antimicrobials considered important in treating refractory conditions in human and veterinary medicine**

These will only be used following veterinary diagnosis on a case by case basis with sufficient evidence to indicate need.

1. 3<sup>rd</sup> and 4<sup>th</sup> generation cephalosporins
2. Fluoroquinolones
3. Macrolides

<sup>19</sup> Commerce Commission Decision 496, 3 April 2003, at [57].

<sup>20</sup> Commerce Commission Decision 621, 4 October 2007, at [131].

<sup>21</sup> [http://www.nzva.org.nz/sites/default/files/domain-0/6280\\_AMR\\_Guidelines\\_Dairy\\_4-0\\_DIGITAL.pdf](http://www.nzva.org.nz/sites/default/files/domain-0/6280_AMR_Guidelines_Dairy_4-0_DIGITAL.pdf).

- 67 As can be observed, Bivatop (i.e. oxytetracycline) is green, while Cefanil (i.e. a third generation cephalosporin) is red. For that reason, vets would not consider these products to be substitutable as they have very different roles from a prescribing perspective.
- 68 In any event, BI understands that Bivatop and Cefanil represent, respectively, approximately 5% and <1% of the total parenteral antibiotic segment. Accordingly, we do not propose to consider this segment further.

**Sedatives / anaesthetics for horses**

- 69 BI's and Merial's respective products in this segment are as follows:

<b>Boehringer Ingelheim</b>	<b>Merial</b>
<b>Sedivet</b> is an injectable sedative for horses	<b>Isoflurane</b> and <b>Halothane</b> are inhalable general anaesthetics for horses and dogs

- 70 Depending on the dosage administered, Sedivet can either be used a pre-anaesthetic prior to general anaesthesia, or as a sedative. Isoflurane and Halothane, by contrast, are general anaesthetics.
- 71 Sedatives differ from anaesthetics as they put the animal into a state of relaxation (alleviating feelings of pain, stress and anxiety). On the other hand, general anaesthetics (like Isoflurane and Halothane) bring about a reversible loss of consciousness in the animal.
- 72 Their modes of administration are also different. Sedivet is an injectable and therefore is predominantly used as a sedative in the field, as it is quick and easy to administer. Isoflurane and Halothane, on the other hand, are general anaesthetics, and are administered via tracheal intubation. They are best administered in a controlled environment (typically a vet clinic suitable for dealing with large animals). Being administered via tracheal intubation, Isoflurane and Halothane typically require an initial sedative (like Sedivet) to be administered first.
- 73 In the Parties' view, these products are not substitutable for one another and therefore the Parties' activities in this field do not overlap. In any event, the sales for these products are *de minimis* in New Zealand.<sup>22</sup>

**Relevant markets**

- 74 The Commission has previously considered animal health markets in a number of previous decisions, including:
- 74.1 *Pfizer/Wyeth* (20 August 2009);
- 74.2 *Schering-Plough/Organon SBS* (4 October 2007);
- 74.3 *Provet NZ Pty Limited/National Veterinary Supplies Limited* (5 May 2005); and
- 74.4 *Pfizer/Pharmacia* (3 April 2003).

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<sup>22</sup> [ ]

- 75 In none of those cases has the Commission been required to consider the specific product categories which are the subject of this application. However, the Commission's previous cases outline the Commission's general approach to market definition in this sector:
- 75.1 The Commission has invariably defined national markets for the manufacture/import and wholesale supply of animal health products.
- 75.2 The Commission has tended to distinguish markets based upon:
- (a) species (e.g. cattle) or category of species (e.g. ruminants);
  - (b) therapeutic indication; and
  - (c) method of application.
- 75.3 Within species, the Commission has on occasion distinguished markets based on animal physiology (for example, size, whether a cow is cycling or non-cycling, or whether a cow is dry or lactating).
- 75.4 There is likely to be a degree of substitutability between single purpose and multi-purpose therapeutic treatments.
- 75.5 Therapeutic products can be distinguished by a chain of substitution, depending on price and efficacy. For instance, a cheap product with limited effect may not be closely substitutable with a more expensive but highly effective product, notwithstanding the prescribing indications may be the same.
- 76 The ACCC has taken a similar approach in the cases in which it has examined the animal health sector, including:
- 76.1 *Eli Lilly/Novartis* (2014); and
- 76.2 *Pfizer/Wyeth* (2009).
- 77 With respect to the specific product categories in the case at hand, injectable NSAIDs are often available for multiple species, in a similar presentation, differing only in concentration. In previous decisions, the Commission has indicated that there may be a product market for a number of different animal types, where the same product can be used on a variety of species.<sup>23</sup> This supports our definition of the market for multi-species injectable NSAIDs.
- 78 Oral NSAIDs are much more species specific, both by indication and presentation. In *Pfizer/Wyeth*, the Commission found that mode of application was an important factor in delineating the relevant product markets.<sup>24</sup>
- 79 As regards oral NSAIDs, the European Commission has considered further segmentation by the animal species for which they are intended. However, with respect to injectable NSAIDs the Commission has previously considered that it is not

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<sup>23</sup> For instance, in Decision 621, 4 October 2007, at [131], the Commission determined the market for antimicrobials included all ruminant animals.

<sup>24</sup> Decision 678, 20 August 2009, at [59].

appropriate to segment them by animal species as most injectable NSAIDs are multi-species (although some injectable NSAIDs are specifically designed for certain species). The creation of sub-segments within the injectable NSAID market was considered to be complex and potentially misleading as it could lead to the creation of unrealistically small product markets.<sup>25</sup>

80 In the present case, BI has taken the conservative approach of identifying the narrowest plausible market definition that gives rise to an overlap between the Parties, consistent with the above-mentioned precedents. However, we consider that it is unnecessary for the Commission to reach a conclusive position on the appropriate market definition as, on any plausible market definition, the Transaction will not raise any competition issues in New Zealand.

81 BI has identified the following relevant product segments:

81.1 oral NSAIDs for companion animals; and

81.2 multi-species injectable NSAIDs.

82 We provide further detail on these product segments below.

**General overview of non-steroidal anti-inflammatories (oral and injectable NSAIDs)**

83 Anti-inflammatories generally are used to treat inflammation and to reduce the pain and fever associated with inflammation. Anti-inflammatories are typically divided into two therapeutic sub-groups which have different mechanisms of action: NSAIDs, and corticosteroids.

84 This segmentation is routinely made because:

84.1 although NSAIDs and corticosteroids both have anti-inflammatory properties, only NSAIDs have analgesic (anti-pain) and anti-pyretic (anti-fever) properties.

84.2 NSAIDs can relieve pain and inflammation without the immunosuppressive and metabolic side-effects associated with corticosteroids.

84.3 NSAIDs also tend to be more expensive than corticosteroids (up to twice the price) as corticosteroids are generally viewed as older products and NSAIDs are considered substantially safer than corticosteroids. For the avoidance of doubt, the Parties do not have any overlapping corticosteroids and so products with that mechanism of action will not be considered further.

84.4 NSAIDs and corticosteroids are not substitutable in veterinary practice, as they are used for different purposes and in different indications.

85 NSAIDs interfere with the enzyme cyclo-oxygenase (COX), and prevent it from releasing the prostaglandin chemicals responsible for inflammation, fever, and pain. Due to their long-acting nature and their outstanding efficacy in controlling inflammatory symptoms, NSAIDs help to minimise losses from inflammation and maintain profitability in animals suffering from diseases. At the same time, NSAIDs

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<sup>25</sup> M.4691, Schering-Plough/Organon Biosciences, decision of 11 October 2007, paras 305 and 306.

- effectively control pain and support the restoration of well-being in the animal in question.
- 86 There are numerous NSAID molecules/products available on the animal health market in New Zealand. Examples include:
- 86.1 Meloxicam, used in BI's product Metacam and equivalent generics, such as Apex's Apex Meloxicam, Norbrook's Loxicom, Troy Labs' Ilium Meloxicam, Ethical Agents' Meloxicam Oral Suspension, and Agrihealth NZ's MeloxiVet;
  - 86.2 Carprofen, used in Zoetis' product Rimadyl and equivalent generics, such as Norbrook's Carprieve, Jurox's Prolet, and Bayer's BomaZeal;
  - 86.3 Ketoprofen, used in Merial's Ketofen and equivalent generics, such as Troy Labs' Ilium Ketoprofen injection, Agrihealth's KetoMax, Ceva Animal Health's Key injection, and Bayer's Tylofen;
  - 86.4 Robenacoxib, used in Elanco's product Onsior;
  - 86.5 Firocoxib, used in Merial's products Previcox; and
  - 86.6 Mavacoxib, used in Zoetis' product Trocoxil.
- 87 NSAIDs work by interfering with the COX enzyme. In this process, there are two isoforms of COX (COX-1 and COX-2) involved:
- 87.1 COX-1, which protects the stomach lining from harsh acids and digestive chemicals. It also helps maintain kidney function. Inhibition of COX-1 may result in adverse effects of NSAIDs, e.g. gastric ulceration and renal toxicity; and
  - 87.2 COX-2, which is produced when joints are injured or inflamed. COX-2 is activated in damaged tissue and intensifies the inflammatory response. COX-2 inhibition by NSAIDs results in the antipyretic, analgesic, and anti-inflammatory actions of NSAIDs.
- 88 All NSAIDs have a similar mode of action as they inhibit the COX-2 isoform which leads to an analgesic/anti-inflammatory effect; and, to some degree, they limit the COX 1 isoform, which may lead to potential side effects such as gastrointestinal bleeding or renal failure. The COX ratio therefore is believed to be important. COXIB is a molecule that inhibits COX-2 while "sparing" COX-1. As such, COXIB companies claim superior safety.
- 89 Generally, the more an NSAID inhibits the COX-1 isoform, the more it may harm the animal being treated. This is because inhibiting COX-1 can damage the gastrointestinal system, leading to further complications. So, non-selective COX inhibitors (inhibiting both COX-1 and COX-2) are generally considered less safe than COX-2 preferential or COX-2 selective varieties. At present, there is only one remaining non-selective COX inhibitor available in New Zealand: Ketofen.
- 90 Most of the remaining NSAIDs fall into the second category, being COX-2 preferential inhibitors. Products in this category include Metacam (and its associated generics), and Rimadyl (and generics). These still inhibit COX-1 to some extent (there is a spectrum of effects, depending on the species and/or individual animal),

but are considered have safety and efficacy advantages over non-selective COX inhibitors.

91 Finally, selective COX-2 (or COX-1 sparing) inhibitors are associated with a further reduction in the potential for certain adverse side-effects from COX-1 inhibition. Presently, Previcox, Onsior, and Trocoxil fit this category. Selective COX-2 NSAIDs represent the latest technology in the field.

92 This distinction does not impede substitutability between NSAID products to the extent that they would form separate relevant product markets, as veterinarians select and adapt NSAID treatments according to their effect on individual animals, and may easily switch from a non-selective COX inhibitor, to a COX-2 preferential. However, these products are not directly interchangeable and their closest competitors tend to be other products from the same group. The Commission has not previously defined relevant markets in anti-inflammatories or analgesics in animal health. For present purposes, it would be appropriate to distinguish NSAIDs based on:

92.1 **method of administration:** NSAIDs are available as injections, tablets, pastes, granules, and oral suspensions. Oral and injectable NSAIDs are generally not substitutable. From a demand-side perspective, vets do not see these different methods of administration as interchangeable: they select the most appropriate route for each animal in each case (e.g. an injection for acute use, palatable tablet for long-term use in large dogs, or oral suspension for smaller dogs as this provides dosing accuracy). From a supply-side perspective, BI does not consider oral and injectable NSAIDs to be substitutable as:

- (a) moving from an oral to an injectable formulation for a given product requires substantial research and development, and a separate ACVM registration;
- (b) oral and injectable formulations require different manufacturing techniques and are not typically manufactured in the same factories. For example, the manufacture of injectable formulations requires compliance with stricter sterility regulations than those that apply to oral formulations; and

92.2 **target species:** injectable NSAIDs are often available for multiple species, in a similar presentation but differing in concentration. Oral NSAIDs are much more species specific, both by indication and presentation. We note that the European Commission has previously segmented oral NSAIDs by species, or species category.<sup>26</sup> However, with respect to injectable NSAIDs (and as indicated above) the European Commission has previously considered that it is not appropriate to segment them by animal species as most injectable NSAIDs are multi-species.<sup>27</sup>

Some respondents to the market investigation also suggested that injectable NSAIDs could be further subdivided by species. However, further investigation revealed that although there are some injectable NSAIDs that are specifically targeted for horses, dogs and cats respectively, there are also injectable NSAIDs that are truly

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<sup>26</sup> M.2922, *Pfizer / Pharmacia*, decision of 27 February 2003, para 143.

<sup>27</sup> M.4691, *Schering-Plough/Organon Biosciences*, decision of 11 October 2007, paras 305 and 306.

multispecies, which makes the task of estimating their use for each species very difficult. Such further segmentation could also lead to unrealistically small markets.

The relevant product markets for purposes of assessing the impact of the proposed concentration are ... Injectable NSAIDs for ruminants, swine, horses and companion animals ('multi-species')...

93 On that basis, we consider that the most conservative market definition in this case is as follows:

93.1 the national market for the supply of oral NSAIDs for companion animals;<sup>28</sup>  
and

93.2 the national market for multi-species injectable NSAIDs.

94 As noted above, the Commission need not form a conclusive view on market definition as, even on this narrow and conservative market definition, the Transaction is not likely to substantially lessen competition.

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<sup>28</sup> In the market for oral NSAIDs for animals other than companion animals (such as production livestock) there is no overlap between the parties' products.



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## PART 4: COMPETITION ASSESSMENT

### A. COUNTERFACTUAL

- 101 Absent the proposed Transaction, Merial would continue to operate independently of BI, as it does currently. Accordingly, BI submits that the status quo is an appropriate counterfactual for the Commission's analysis.
- 102 Relative to that counterfactual, the Transaction would not have the effect or likely effect of substantially lessening competition in any of the segments identified in which the Parties overlap. BI addresses these segments in turn.

### B. ORAL NSAIDS FOR COMPANION ANIMALS

#### Overview of Parties' products

- 103 Oral NSAIDs for companion animals are available as an oral suspension and/or tablets, caplets, or chewable tablets. These products are designed to manage the various levels of inflammation and pain associated with the licensed indications.
- 103.1 In dogs, the indications include the alleviation of inflammation and pain in both acute and chronic musculoskeletal disorders, as well as the reduction of post-operative pain following surgery.
- 103.2 In cats, the indications include the alleviation of inflammation and pain in acute and chronic musculoskeletal disorders, as well as for alleviation of mild to moderate post-operative pain following surgical procedures.
- 104 The Parties supply the following oral NSAID products for companion animals in New Zealand:

**Table 1: the Parties' products in the oral NSAIDs for companion animals segment**

	<b>Products</b>	<b>Active ingredient</b>	<b>Indications</b>
<b>Boehringer</b>	<ul style="list-style-type: none"><li>• Metacam Oral Suspension for Dogs</li><li>• Metacam Chewable Tablets for Dogs</li><li>• Metacam Oral Suspension for Cats</li></ul>	<ul style="list-style-type: none"><li>• Meloxicam</li></ul>	<ul style="list-style-type: none"><li>• For the treatment of inflammation and pain in both acute and musculoskeletal disorders in dogs and cats</li></ul>
<b>Merial</b>	<ul style="list-style-type: none"><li>• Previcox (tablet)</li></ul>	<ul style="list-style-type: none"><li>• Firocoxib</li></ul>	<ul style="list-style-type: none"><li>• For the treatment of pain and inflammation associated with osteoarthritis and other musculoskeletal disorders in dogs. It is also indicated for the control of postoperative pain in dogs</li></ul>

			<ul style="list-style-type: none"> <li>• Previcox is not suitable for use in cats</li> </ul>
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105 For completeness, we note that Merial also supplies an oral NSAID product for companion animals called Ketofen 1%, with the active ingredient Ketoprofen. Ketofen 1% is available in New Zealand but generates negligible sales: [ ]worth of sales in 2015 [ ]. It is generally only used as a treatment for long-term arthritis in dogs.

106 Given Ketofen’s negligible presence in the New Zealand segment for oral NSAIDs for companion animals compared with Merial’s Previcox product, we do not consider it further in this application.

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### **Market shares and concentration**

108 **Annex 7** contains estimates of the Parties’ and their competitors’ shares in the supply of oral NSAIDs for companion animals in New Zealand between 2013 and 2015. That share data is summarised in Table 2 below.

109 This share data is sourced from Baron Strategic Services,<sup>30</sup> which collates and reports sales data on the Australian and New Zealand animal health sectors. Baron data is collated from participating suppliers and hence tends to overstate the share of larger market participants, while understating the position of smaller suppliers (many of whom do not participate in the audit). In addition to the six suppliers that participate in the Baron audit (BI, Zoetis, Norbrook, Merial, Elanco and Bayer) there is a long tail of smaller suppliers that do not participate in the Baron audit, including Jurox, Apex Laboratories, Troy Laboratories and Ethical Agents Veterinary Marketing Limited.

110 BI’s best estimate is that the non-participating suppliers represent, collectively, between [ ]of the supply of oral NSAIDs for companion animals. Consequently, in the share data below, BI has included for 2015 both the Baron share estimate (excluding non-participating suppliers) and BI’s estimate (including non-participating suppliers). In its own estimate, BI has assigned to the non-participating suppliers a share of [ ]which is the midpoint of BI’s range estimate, and has pro-rated the shares of participating suppliers in light of its estimate of the share represented by non-participating suppliers.

<sup>30</sup> Baron is a consultancy and market research firm which specialises in the farmer/veterinarian sector. For further information please visit <http://www.baronss.com.au/index.html>.

**Table 2: Supply of oral NSAIDs for companion animals (CY 2013 -2015)**

<b>Oral NSAIDs for companion animals (by value)</b>				
	<b>2015</b>		<b>2014</b>	<b>2013</b>
<b>Source</b>	Baron data	BI's estimate	Baron data	Baron data
<b>Company</b>				
31				
32				
<b>Combined BI+M</b>				
<b>Total</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>

111 We make the following observations in relation to these shares:

111.1 BI and Merial are currently the first and fourth ranked suppliers in the segment, by market share. Zoetis, however, is essentially on a par with BI, and in 2013 and 2014 achieved higher levels of share than BI. Further, the shares of Zoetis and Norbrook over the past three years have been consistently higher than Merial's share.

111.2 The increment in share attributable to the Transaction is low: [                    ]

111.3 Post-merger, BI and Zoetis will continue to be positioned against each other as close competitors in the segment, as measured by share.

111.4 Norbrook also has significant share and competes vigorously in this segment with Loxicom – a generic meloxicam product - which is directly substitutable with Metacam Oral. Its share has consistently grown over the reference period.

111.5 In addition to the four largest suppliers in the New Zealand market, there is a long tail of suppliers of substitutable products, some of which do not feature in the Baron data. Notwithstanding these suppliers currently enjoy low levels of share in this segment, many are significant suppliers of animal health products internationally (and in New Zealand in relation to other product categories). For example, Bayer and Elanco will be immediately recognisable to the Commission. There is no reason to expect that these competitors would be prevented from expanding their share in response to an assumed

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<sup>31</sup> [                    ]

<sup>32</sup> [                    ]

post-merger price increase by BI. Given BI's estimate that other suppliers that do not participate in Baron represent between [ ] of the segment, BI's market share is likely to be in a range of between [ ] (and collectively with Merial, between [ ])

112 As detailed further below, the Transaction will not result in a substantial lessening of competition because:

112.1 post-merger, BI will continue to face vigorous competition from existing and incoming competitors;

112.2 BI's and Merial's products are not close competitors;

112.3 BI's and Merial's products are complementary rather than closely substitutable;

112.4 there is significant potential for new entry or expansion;

112.5 products on neighbouring markets exert competitive constraint; and

112.6 customers enjoy significant buyer power.

**1. Ongoing competitive constraint from existing and incoming competitors**

113 The increment in share attributable to the Transaction is low: [ ] Consequently, there will continue to be at least two other significant suppliers in the market for oral NSAIDs for companion animals after the Transaction, both with sizeable shares. These are (based on BI's best estimate of the market as a whole):

113.1 Zoetis, [ ]; and

113.2 Norbrook, [ ].

114 In addition, there are at least two other significant suppliers of substitutable products currently active in the New Zealand market: Elanco and Bayer. We set out additional information on these competitors below.

115 A number of other competitors listed on the ACVM register also have approval for various oral NSAID therapies for companion animals, such as Ethical Agents Veterinary Marketing Limited, Troy Laboratories, Ceva Animal Health, and Apex Laboratories.<sup>33</sup> BI understands that some of these products – particularly Meloxicam-based generics – have only been registered over the past few months, and as such have not yet been brought to market, but market entry should happen shortly.

116 Further, Virbac is active in the New Zealand animal health market, though is not currently active in the market for NSAIDs. The Parties consider Virbac could easily and quickly expand into this product market by registering generic products. BI notes that generic forms of oral NSAIDs for companion animals are currently registered in New Zealand, including meloxicam- and carprofen-based NSAIDs.

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<sup>33</sup> [https://eatsafe.nzfsa.govt.nz/web/public/acvm-register?p\\_p\\_id=searchAcvm\\_WAR\\_aaol&p\\_p\\_lifecycle=1&p\\_p\\_state=normal&p\\_p\\_mode=view&p\\_p\\_col\\_id=column-2&p\\_p\\_col\\_count=1&searchAcvm\\_WAR\\_aaol\\_action=search](https://eatsafe.nzfsa.govt.nz/web/public/acvm-register?p_p_id=searchAcvm_WAR_aaol&p_p_lifecycle=1&p_p_state=normal&p_p_mode=view&p_p_col_id=column-2&p_p_col_count=1&searchAcvm_WAR_aaol_action=search).

- 117 Therefore, this must be also taken into account by the Commission when analysing the competitive landscape, insofar as the market shares above underestimate the actual competitive constraints that the resulting entity will face post Transaction.

### **Competitor profiles**

- 118 Below we outline a selection of competitors already active in this segment (or already well-established in the New Zealand animal health market), which BI considers will constrain the combined entity in relation to oral NSAIDs for companion animals. The contact details of these competitors are provided at **Annex 8**.

#### ***Zoetis***

- 119 Zoetis is the world's largest producer of pharmaceuticals and biologicals for companion and production animals and currently holds [ ] of the total New Zealand animal health market. Until recently, Zoetis was the animal health business division of Pfizer, and in 2014 the company had revenues of US\$4.8 billion. With more than 60 years of experience in animal health, Zoetis operates in more than 120 countries with approximately 10,000 employees. Its key products include vaccines, parasiticides, anti-infectives, medicinal feed additives and other pharmaceuticals manufactured in 27 sites in ten countries.
- 120 Zoetis New Zealand supplies two main groups of animals: companion animals including dogs, cats, and horses; and livestock, including beef and dairy cows, sheep, and pigs.
- 121 In the segment for oral NSAIDs for companion animals Zoetis supplies Rimadyl, containing the active ingredient Carprofen. Rimadyl is an NSAID that is effective in relieving pain and inflammation associated with canine osteoarthritis and controlling postoperative pain. Rimadyl relieves pain and inflammation associated with osteoarthritis by selectively inhibiting cyclooxygenase (COX)-2, which generates prostaglandins involved in inflammation.
- 122 It is also indicated for postoperative pain associated with soft tissue and orthopaedic surgeries in dogs. Rimadyl is available in two oral formulations: caplets and chewable tablets.<sup>34</sup>
- 123 Zoetis also supplies Trocoxil, which is an NSAID containing the active ingredient Mavacoxib. It is used for the treatment of pain and inflammation associated with degenerative joint disease (disease involving damage to the joints, such as osteoarthritis) in dogs at least one year of age. It is used when continuous treatment for more than one month is needed.<sup>35</sup>

#### ***Norbrook***

- 124 Founded in 1968 and based in Ireland, Norbrook Laboratories Ltd is one of the world's leading generic pharmaceutical companies, with manufacturing facilities on four continents and sales and marketing offices in more than 30 countries. The company exports to over 120 countries worldwide (with a particularly large vet division) and is almost entirely self-contained in its production of raw materials, with facilities to produce tablets, capsules, aerosols, creams, solutions, suspensions, and

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<sup>34</sup> [http://www.zoetis.co.nz/\\_locale-assets/doc/sds/rimadyl-tablets-50mg-30-jun-2014-zoetis-sds.pdf](http://www.zoetis.co.nz/_locale-assets/doc/sds/rimadyl-tablets-50mg-30-jun-2014-zoetis-sds.pdf), [http://www.zoetis.co.nz/\\_locale-assets/doc/sds/rimadyl-chewable-tablets-for-dogs-30-jun-2014-zoetis-sds.pdf](http://www.zoetis.co.nz/_locale-assets/doc/sds/rimadyl-chewable-tablets-for-dogs-30-jun-2014-zoetis-sds.pdf).

<sup>35</sup> [http://www.zoetis.co.nz/\\_locale-assets/doc/sds/trocoxil-chewable-tablets-for-dogs-30-jun-2014-zoetis-sds.pdf](http://www.zoetis.co.nz/_locale-assets/doc/sds/trocoxil-chewable-tablets-for-dogs-30-jun-2014-zoetis-sds.pdf).

powders. Norbrook's animal health activities focus on pharmaceutical products such as antimicrobials, anti-inflammatories, and anaesthetics.

- 125 Norbrook's Carprieve tablets are NSAIDs for the relief of pain and inflammation in dogs, for example in degenerative joint disease.<sup>36</sup>
- 126 Norbrook's Loxicom is a generic version of meloxicam. The Norbrook Loxicom suspension is an NSAID for use in dogs. It is indicated for the alleviation of inflammation and pain in both acute and chronic musculoskeletal disorders such as disco-spondylosis, arthropathy, and soft tissue injury.<sup>37</sup>

### **Elanco/Novartis**

- 127 Elanco, a division of Eli Lilly and Company, develops and markets products to improve animal health and food animal production in more than 80 countries. It merged with Novartis in April 2014. Elanco is currently the second largest animal health company in the world with over US\$4 billion in revenue. It employs more than 7,000 people worldwide and operates in more than 75 countries. Elanco offers a range of health products for companion and production animal species, including parasiticides, pain control medicines, otitis and dermatitis drugs, and vaccines. Its product portfolio has significantly expanded after the acquisition of Novartis Animal Health, as well as the acquisition of Lohmann Animal Health, a German-based company specialising in poultry vaccines.
- 128 In the segment for oral NSAIDs for companion animals, Elanco supplies Onsior tablets which contain robenacoxib, a cyclooxygenase-2 (COX-2) NSAID of the -coxib class. Onsior tablets are used to treat post-operative pain in cats,<sup>38</sup> and are also used for the control of pain and inflammation associated with chronic osteoarthritis or orthopaedic or soft tissue surgery in dogs.<sup>39</sup>

### **Bayer**

- 129 Bayer Animal Health is a global supplier of animal health products since 1919, producing and distributing a wide range of animal health and care products for production and pets worldwide. With turnover of over NZ\$2 billion and over 2,980 employees, Bayer's animal health division is one of the strongest animal health product manufacturers in the world, with activities in more than 100 countries. Bayer's key animal health products are parasiticides and antimicrobials for both companion and production animals.

### **Virbac**

- 130 Founded in 1968, Virbac is exclusively dedicated to animal health, offering a comprehensive range of products to veterinarians, farmers and pet owners in over 100 countries. With global turnover of over NZ\$1 billion in 2014 and more than

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<sup>36</sup> [http://www.norbrook.com/new\\_zealand/products/carprieve-tablets/](http://www.norbrook.com/new_zealand/products/carprieve-tablets/).

<sup>37</sup> [http://www.norbrook.com/new\\_zealand/products/results](http://www.norbrook.com/new_zealand/products/results).

<sup>38</sup> [https://eatsafe.nzfsa.govt.nz/web/public/acvm-register?p\\_p\\_id=searchAcvm\\_WAR\\_aaol&p\\_p\\_lifecycle=0&p\\_p\\_state=exclusive&p\\_p\\_mode=view&p\\_p\\_col\\_id=column-2&p\\_p\\_col\\_count=1&searchAcvm\\_WAR\\_aaol\\_action=document&searchAcvm\\_WAR\\_aaol\\_form-submit=true&searchAcvm\\_WAR\\_aaol\\_documentId=31693](https://eatsafe.nzfsa.govt.nz/web/public/acvm-register?p_p_id=searchAcvm_WAR_aaol&p_p_lifecycle=0&p_p_state=exclusive&p_p_mode=view&p_p_col_id=column-2&p_p_col_count=1&searchAcvm_WAR_aaol_action=document&searchAcvm_WAR_aaol_form-submit=true&searchAcvm_WAR_aaol_documentId=31693).

<sup>39</sup> [https://eatsafe.nzfsa.govt.nz/web/public/acvm-register?p\\_p\\_id=searchAcvm\\_WAR\\_aaol&p\\_p\\_lifecycle=0&p\\_p\\_state=exclusive&p\\_p\\_mode=view&p\\_p\\_col\\_id=column-2&p\\_p\\_col\\_count=1&searchAcvm\\_WAR\\_aaol\\_action=document&searchAcvm\\_WAR\\_aaol\\_form-submit=true&searchAcvm\\_WAR\\_aaol\\_documentId=37135](https://eatsafe.nzfsa.govt.nz/web/public/acvm-register?p_p_id=searchAcvm_WAR_aaol&p_p_lifecycle=0&p_p_state=exclusive&p_p_mode=view&p_p_col_id=column-2&p_p_col_count=1&searchAcvm_WAR_aaol_action=document&searchAcvm_WAR_aaol_form-submit=true&searchAcvm_WAR_aaol_documentId=37135).

4,500 employees, Virbac is the seventh largest animal health company worldwide. Its key products include vaccines and parasiticides for pets and antimicrobials for production animals (particularly swine).

#### ***Ethical Agents Veterinary Marketing Limited***

- 131 Founded in 1968, Ethical Agents is a specialist veterinary marketing company which has partnerships with a number of local and international veterinary companies. Ethical Agents has research and development connections with some of the leading suppliers to the world market, (such as Vétoquinol and Serag Wiessner) which cumulatively spend more than NZ\$140 million on research and development annually. Ethical Agents also uses local New Zealand technology in its products.
- 132 Ethical Agents holds 30 sole agencies from which it selects the best and most suitable products for New Zealand veterinarians. It also has its own large range of products.<sup>40</sup>
- 133 Ethical Agents is listed on the ACVM register as being able to supply Meloxicam Oral Suspension (a generic meloxicam-based product) in New Zealand.

#### ***Troy Laboratories***

- 134 Troy Laboratories is a privately owned company focusing on effective and affordable solutions to New Zealand veterinarians. It produces both proprietary and generic products under two brands: Troy (unrestricted, general market products) and Ilium (vet-only products).
- 135 The New Zealand Veterinary Association (NZVA) website notes that Troy Laboratories is currently undertaking extensive research in the area of pain relief in farm animals. Specifically, Troy Laboratories has:<sup>41</sup>

“... developed a transmucosal analgesic formulation for the alleviation of pain, optimisation of animal welfare, as well as addressing occupational health and safety concerns. Research and development of this oral transmucosal product for cattle and sheep is well advanced.”

- 136 Troy Laboratories is listed on the ACVM register as being able to supply Ilium Meloxicam – a meloxicam-based generic – in New Zealand.

#### ***Ceva Animal Health***

- 137 Ceva Animal Health is based in 42 countries worldwide (including New Zealand), with 13 research and development centres, 21 production sites, and over 3,500 employees. It provides a full suite of animal healthcare products for both companion and production animals, including biologicals, antibiotics, parasiticides, and reproduction management products.<sup>42</sup>
- 138 Ceva Animal Health is listed on the ACVM register as being able to supply a ketoprofen-based injectable product in New Zealand. It does not currently have an oral NSAID for companion animals registered, but there are no material barriers preventing it from registering a generic product.

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<sup>40</sup> <http://www.ethicalagents.co.nz/index-4.html>.

<sup>41</sup> <http://www.nzva.org.nz/pagetroy-laboratories-new-zealand-pty-ltd?destination=node%2F1608>.

<sup>42</sup> [www.ceva.com](http://www.ceva.com).



### **Apex Laboratories**

- 139 Established in 1962, Apex Laboratories is Australia's leading manufacturer of generic and proprietary veterinary pharmaceuticals. Apex Laboratories has a research and development team working on providing generic veterinary medicines to the Australian and New Zealand markets. In New Zealand, Apex Laboratories' products are distributed through SVS and ProVet. It currently supplies a range of animal health products in New Zealand for dogs, cats, and horses.<sup>43</sup>
- 140 Apex Laboratories is listed on the ACVM register as being able to supply Apex Meloxicam – a generic meloxicam-based product – in New Zealand.

### **Jurox**

- 141 Jurox is an Australian-based veterinary pharmaceutical manufacturer that markets in excess of 120 proprietary animal health products. It employs over 100 staff in Australia and New Zealand.
- 142 Jurox has a policy under which it invests 15% of sales in research and development, which highlights its commitment to innovation. At present, it markets products throughout Australia, New Zealand, Asia, the Middle East, the United Kingdom, and Europe. Jurox is now turning its attention towards North America.
- 143 Its products offer a range of treatments for dogs, cats, horses, cattle, and sheep. These include parasiticides, anaesthetics, anti-inflammatories, nutritional and metabolism products, and emetics.<sup>44</sup>
- 144 Jurox is listed on the ACVM register as being able to supply Prolet – an oral carprofen-based NSAID – in New Zealand.

### **Agrihealth NZ**

- 145 Agrihealth NZ is a New Zealand owned and operated company, specialising in marketing veterinary medicines, especially for production animals. Agrihealth provides products and associated technical advice for a range of therapeutic treatments, including reproductive hormones, vaccines, antibiotics, metabolic products, mastitis therapies, and feed additives.
- 146 While Agrihealth does not currently have an oral NSAID registered with the ACVM, it does have registration for Meloxivet – a meloxicam-based generic injectable NSAID, and Ketomax – a ketofen-based injectable NSAID. Further, there are no material barriers preventing it from registering a generic oral NSAID product.

## **2. BI and Merial are not close competitors in oral NSAIDs for companion animals**

- 147 The Parties' products are not each other's closest competitor. BI's Metacam is a COX-2 preferential NSAID, while Merial's Previcox is a COX-2 selective NSAID. Metacam's closest substitute is Loxicom, also a COX-2 preferential NSAID, which is a generic product supplied by Norbrook that utilises meloxicam as an active ingredient (as does Metacam). Conversely, Previcox's closest substitutes are Elanco/Novartis's Onsior, and Zoetis' Trocoxil, both of which are COX-2 selective, new generation NSAIDs.
- 148 We elaborate further on the distinction below.

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<sup>43</sup> <http://apexlabs.com.au/>.

<sup>44</sup> <http://www.nzva.org.nz/pagejurox-nz-ltd>; <http://www.jurox.com.au/products/vets/>.

- 149 All NSAIDs have a similar mode of action as they inhibit the COX-2 enzyme which leads to an analgesic/anti-inflammatory effect; and, to some degree, they limit the COX-1 enzyme. Molecules that also inhibit the COX-1 enzyme are associated with potential side effects such as gastrointestinal bleeding or renal failure. There is a generational difference between older non-selective NSAIDs that inhibit both the COX-2 and COX-1 enzymes, and newer generation highly selective NSAIDs that inhibit the COX-1 enzyme to a lesser extent. Suppliers of selective COX-2 inhibitors market their products as having a better safety profile than older generation non-selective NSAIDs. As a result, NSAIDs tend to compete more closely against other similar products (selective or non-selective, respectively).
- 150 Furthermore, even within these broad categories (selective or non-selective) products compete most closely against those products that utilise the same active ingredient. This is because vets will take into account, when stocking and prescribing products, the active ingredient as some animals will respond better to some molecules than to others. So for example, Metacam competes most closely with its generic competitor (Norbrook) than with other non-selective COX-1 and COX-2 inhibitors.
- 151 In particular, Metacam and Previcox are not close competitors for the following reasons:
- 151.1 Metacam's active pharmaceutical ingredient (**API**) is meloxicam whereas Previcox's API is firocoxib, which means that their different COX sparing properties offer different safety;
- 151.2 Vets usually distinguish significantly between older generation products like BI's Metacam and newer generation highly selective inhibitor products like Merial's Previcox, based on safety concerns and depending on the particular condition of the animal;
- 151.3 Metacam is provided as an oral suspension whereas Previcox is sold in a tablet form. Veterinarians will often choose a tablet for treatment of larger pets, and an oral liquid for smaller breeds to facilitate dosing accuracy;
- 151.4 BI's Metacam is a multi-species product (i.e. it is suitable for the treatment of cats as well as dogs), while Previcox is indicated only for the treatment of dogs;
- 151.5 In terms of dog treatment, Metacam is mainly used for small dogs whereas Previcox is used for large dogs. Owners have differing preferences as regards mode of administration as owners of large breeds of dogs appear to prefer tablets, while owners of small breeds prefer oral suspensions; and
- 151.6 Metacam is frequently used for short term use, whereas Previcox is used for long term use. It should be noted that if injectable formulations are to be followed by oral NSAIDs, the same NSAID should be used.
- 152 In the New Zealand market for oral NSAIDs for companion animals, the closest competitor of BI's products is that supplied by Norbrook, which uses meloxicam, the same active ingredient as BI's Metacam. By value, BI estimates Norbrook had a [ ]share for the supply of oral NSAIDs for companion animals in New Zealand in CY 2015. As mentioned above, there are also a number of other competitors listed on the ACVM register that have approval for various meloxicam-based oral therapies

for companion animals. These include Ethical Agents Veterinary Marketing Limited, Troy Laboratories, Ceva Animal Health, and Apex Laboratories.

- 153 The closest competitors of Merial's Previcox (firocoxib) are the products supplied by Zoetis and Elanco/Novartis (which, according to BI's best estimates, comprise approximately [ ] of the market in total in CY 2015, measured by value). These products are new generation COX-2 selective inhibitor oral NSAID products.

### **3. BI's and Merial's products are complementary rather than closely substitutable**

- 154 In addition to the functional distinctions outlined above, there are a number of other distinctions between the Parties' products that suggest they are considered by vets to be complementary rather than closely substitutable.
- 155 Vets tend to stock and prescribe a range of different products within a treatment category for clinical reasons. Even where products have essentially the same therapeutic role, there are differences in formulation or preparation that suggest that some animals will respond better to one product than to another. Anecdotally, we understand that vets tend to stock three to four different forms of NSAIDs.
- 156 Even in circumstances where two products have essentially the same prescribing indications, sometimes an animal will have an adverse reaction to one product but not to another. Accordingly, vets exercise their clinical judgement to prescribe the product they think will best meet the therapeutic need, and as a consequence tend to stock a range of products.
- 157 By way of example, the Parties' products have different preparations (tablet versus oral suspension), and vets will often choose a tablet for the treatment of larger companion animals and an oral suspension for smaller breeds to facilitate dosing accuracy. Owners of smaller dogs may also prefer suspensions while owners of larger dogs appear to prefer chewable tablets. This can be due to ease of application because of mouth size or food preferences between breeds.
- 158 As a consequence, the Parties' products are complementary rather than closely substitutable.

### **4. New entry and expansion into oral NSAIDs for companion animals**

- 159 The companion animal segment of the pain/inflammation markets is innovative and the importance of pain management in companion animals has increased dramatically in recent years. Sales of companion animal treatments are strongly influenced by an emotional aspect as owners are willing to invest to ensure that their pets do not suffer pain. Thus, this segment is evolving and BI expects further market entries in the short term.
- 160 The availability of generics in New Zealand is also increasing. As noted at paragraph 114 above, a number of meloxicam-based generic therapies have been listed on the ACVM register in the past few months. The suppliers in question are Ethical Agents Veterinary Marketing Limited, Troy Laboratories, Ceva Animal Health and Apex Laboratories. BI expects these products will be brought to market in New Zealand in the near future. We note that Troy Laboratories and Apex Laboratories are both significant suppliers to the Australian market, enjoying [ ] and [ ] market share in Australia in 2015, respectively. In the case of Apex Laboratories, [ ] (from [ ]), showing the significant competitive pressure posed by generic suppliers.

- 161 The barriers to introducing generic therapies into the New Zealand market are non-existent in practice. Generics typically pass the ACVM registration process more quickly, as they are able to trade on the regulator's familiarity with the characteristics of the proprietary branded product, and the track record that those proprietary products have created.
- 162 BI also understands that Zoetis' oromucosal spray RevitaCAM has been registered with the relevant Australian regulatory authority (the AVPMA) for approval. This product has been available in the UK and EU countries for a number of years, and may enter the Australian market within one to two years. This product would be a candidate for potential entry into the New Zealand market in the near future.
- 163 Furthermore, we note that the intellectual property rights in relation to firocoxib (the active ingredient in Previcox) expire on 9 October 2020. For the method of manufacturing firocoxib, the intellectual property rights expire on 5 October 2020. And, in any case, generic meloxicam- and carprofen-based oral NSAIDs for companion animals are already available in the New Zealand market, and so currently compete with Previcox.
- 164 It is therefore reasonable to expect that generic NSAID products containing firocoxib could emerge in the New Zealand market from 2020.

#### **5. Products on neighbouring markets exert competitive constraints**

- 165 The current standard for pain relief for companion animals is the use of NSAIDs; however, there are number of treatments that provide pain relief such as opioids, steroids, and disease modifying osteoarthritis agents (DMOAs) that may also be vets' preferred method of treatment.
- 166 The choice of which form of pain management to use is based on a number of factors, including the severity of the condition, the length of the proposed course of treatment, as well as the age and overall health of the animal. While the Commission may consider that these products do not form part of the same relevant product market, it should take into account that, to a certain extent, these products exert a competitive constraint on oral NSAIDs for companion animals.

#### **6. Customers enjoy significant buyer power**

- 167 BI has observed a growing trend in New Zealand towards the amalgamation of smaller veterinary practices, and with this, a strengthening of the associated buyer power.
- 168 Traditionally, veterinary practices in New Zealand tended to be privately owned (or managed via clubs). However, there is now a trend towards consolidation as owners of smaller practices are looking to exit through sales to larger corporate groups. In addition, younger vets are finishing university with high debt, which means they are more likely to join an established corporate group rather than build their own practice.
- 169 BI understands that there are a number of corporate groups vigorously purchasing veterinary practices across the country. These include:
- 169.1 Pet Doctors;
  - 169.2 Care Vets;

169.3 The Vet Care Group (owned by Green Cross Australia, which operates the Animates stores in New Zealand);

169.4 Quantum (owned by Vetlife and Vetsouth); and

169.5 Vet Enterprises.

170 Likewise, veterinary clubs are also amalgamating so as to enjoy the benefits of buyer power and efficiencies for services. For instance, Anexa has combined with FVC, and VetFocus has combined with Vet Club Rotorua/Reporoa to become VetOra.

171 These larger veterinary practices can and do exercise buyer power. For example, their greater volume of purchases means they can demand better terms from suppliers, including price rebates, bonus stock and concessions in relation to other terms of trade.

172 BI considers that the countervailing power these groups already have would discipline any increase in price or decrease in quality. And, based on the growing consolidation of the downstream market, this countervailing power will continue to increase in strength.

### **C. MULTI-SPECIES INJECTABLE NSAIDS**

173 The Transaction is not likely to substantially lessen competition in relation to multi-species injectable NSAIDs because:

173.1 post-merger, BI will continue to face vigorous competition from existing competitors;

173.2 the Parties' products are not close competitors;

173.3 the Parties' products are complementary rather than closely substitutable;

173.4 there is significant potential for new entry or expansion;

173.5 products on neighbouring markets exert a competitive constraint; and

173.6 customers enjoy significant buyer power.

174 [

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175 [

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### **Overview of Parties' products**

176 The Parties supply the following multi-species injectable NSAID products:

**Table 3: Parties' products in the multi-species injectable NSAID segment**

	<b>Products</b>	<b>Active ingredient</b>	<b>Indications</b>
<b>Boehringer</b>	<ul style="list-style-type: none"> <li>• Metacam 20mg/ml solution for injection, 50ml, 100ml, and 250ml (cattle, pigs, horses)</li> <li>• Metacam anti-inflammatory injectable, 10ml and 20ml (dogs and cats)</li> </ul>	<ul style="list-style-type: none"> <li>• Meloxicam</li> </ul>	<ul style="list-style-type: none"> <li>• For cattle, it is used to treat acute respiratory infections, diarrhoea, acute mastitis, and pain associated with dehorning</li> <li>• For pigs, it is used for acute non-infectious locomotor disorders and for puerperal septicaemia toxaemia</li> <li>• For horses, it is used for musculoskeletal disorders and colic</li> <li>• In dogs, it alleviates inflammation and pain in both acute and chronic musculoskeletal disorders, and the reduction of post-operative pain</li> <li>• For cats, it alleviates post-operative pain, and the management of febrile conditions</li> </ul>
<b>Merial</b>	<ul style="list-style-type: none"> <li>• Ketofen 10% injectable solution (cattle, horses)</li> </ul>	<ul style="list-style-type: none"> <li>• Ketoprofen</li> </ul>	<ul style="list-style-type: none"> <li>• For cattle, it is used for the treatment of musculoskeletal conditions, respiratory conditions, acute mastitis, mammary oedema, and colic</li> <li>• For horses, it is used for the treatment of musculoskeletal disorders such as lameness caused by trauma, anthrosis, arthritis, osteitis, spavin, navicular disease, tendonitis, bursitis, lameness, myositis, and post-surgical</li> </ul>

	<ul style="list-style-type: none"> <li>• Ketofen 1% 20ml injectable solution (dogs, cats)</li> </ul>		<p>inflammation. It is also used to treat colic and fever</p> <ul style="list-style-type: none"> <li>• In dogs and cats it alleviates the inflammation and pain associated with musculoskeletal disorders</li> </ul>
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177 For completeness, we note that BI also supplies a product called Buscopan Compositum, which has an indirect anti-inflammatory effect. Unlike other NSAIDs, Buscopan Compositum has two active ingredients: dipyron (an analgesic) and hyoscine butylbromide (an antispasmodic). Buscopan acts in three ways:

177.1 directly as an anti-spasmodic;

177.2 directly as an analgesic; and

177.3 indirectly as an anti-inflammatory agent.

178 Buscopan is used primarily to treat pain and muscle spasms, including ailments like gastroenteritis, colic, and oesophageal obstructions. It is not prescribed principally as an anti-inflammatory agent, as that is a related (but indirect) action of the product. It is limited in its effects to treat visceral pain associated with muscle spasms in gastrointestinal, urinary, and biliary tracts, and is not typically used for general inflammatory/analgesic actions. BI therefore does not consider it substitutable with other NSAIDs and does not consider it further in this application.

179 BI's principal injectable NSAID product – Metacam – is licensed for use in a wide range of species: it is indicated in cattle suffering from respiratory disease, in calves affected by diarrhoea, and as adjunctive therapy in the treatment of mastitis in lactating cows. Further indications are alleviation of inflammation and pain in musculoskeletal disorders (for swine and horses), after surgery (for swine), during colic (horses), adjunctive treatment of dehorning (cattle), as well as mastitis-metritis-agalactia syndrome (swine).

180 In dogs, Metacam alleviates inflammation and pain in both acute and chronic musculoskeletal disorders, and reduces post-operative pain. For cats, it alleviates post-operative pain, and helps manage febrile conditions.

181 Like its oral counterpart for companion animals, Metacam is a meloxicam-based NSAID.

182 In New Zealand, Merial's product is marketed under the Ketofen brand. Its active ingredient is ketoprofen. Ketofen is indicated for the relief of pain and inflammation associated with musculoskeletal and other painful disorders in cattle and horses, as well as for the alleviation of inflammation associated with musculoskeletal disorders in dogs and cats.

183 [ ]

**Market shares and concentration**

184 **Annex 9** contains estimates of the Parties' and their competitors' shares in the supply of multi-species injectable NSAIDs in New Zealand between 2013 and 2015. That share data is summarised in Table 4 below. As per the oral NSAID market shares, BI has also included its best estimate of the share attributable to those smaller suppliers that do not participate in the Baron audit. BI estimates that unreported sales represent [ ] of the total segment. On this basis, the market shares taken from the Baron data have been pro-rated in the table below to give a more complete picture.

**Table 4: Supply of injectable multi-species NSAIDs (CY 2013 -2015)**

Supply of injectable NSAIDs all species (by value)				
	2015		2014	2013
Source	Baron data	BI's estimate	Baron data	Baron data
Company				
45				
<b>Total</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>

185 We make the following observations in relation to these shares:

185.1 BI and Merial are currently the first and fourth ranked suppliers in the segment, by share. The second largest supplier of multi-species injectable NSAIDs in New Zealand, and BI's closest competitor, is Norbrook. Norbrook has for the entirety of the relevant period comprised nearly [ ] of the segment.

185.2 The increment in share attributable to the Transaction is very low: [ ]

185.3 Post-merger, Norbrook will continue to be a close competitor of BI in this segment, with nearly [ ] of the segment.

185.4 In addition to Norbrook and the Parties, Zoetis also enjoys a substantial share of the segment. Post-merger, Zoetis will remain as a substantial market participant and therefore a competitive constraint on other players in the segment.

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<sup>45</sup> [ ]



185.5 As is the case with oral NSAIDs for companion animals, the large and established players are complemented by a tail of smaller suppliers such as Bayer, Virbac, and Elanco. While those suppliers currently enjoy minimal share in this segment, we note that they are significant suppliers of animal health products internationally. There is no reason to expect that these competitors would face any structural disadvantage that would prevent them from expanding their share in response to a post-merger price increase by BI.

185.6 The share figures also do not include those smaller players that do not report their sales to Baron (from whom this share information is sourced). Those market participants include Agrihealth NZ, Troy Laboratories, and Ceva Animal Health amongst others. In particular, Agrihealth NZ's Ketomax is understood to be making around [ ] per year in sales, and this is after entering the market only two years ago. As such, the shares of the Parties are likely to be overstated. Because these smaller suppliers do not participate in Baron, BI is unable to give a precise estimate of their market share. However, BI's best estimate is that these smaller suppliers represent approximately [ ] of the segment collectively. This would result in BI having a share of supply in this segment of [ ] (and collectively with Merial [ ])

186 As detailed further below, the Transaction is not likely to result in a substantial lessening of competition in this segment because:

186.1 post-merger, BI will continue to face vigorous competition from existing competitors;

186.2 the Parties' products are not close competitors;

186.3 the Parties' products are complementary rather than closely substitutable;

186.4 there is significant potential for new entry or expansion;

186.5 products on neighbouring markets exert competitive constraint; and

186.6 customers enjoy significant buyer power.

### **1. Ongoing competitive constraint from existing competitors**

187 As outlined above, post-merger, BI will continue to be constrained by Norbrook, which holds a strong position in this segment. Rather than lessen competition, BI considers that the Transaction will allow it to compete more effectively against Norbrook, using the Parties' combined suite of products.

188 In addition to Norbrook, Zoetis is a significant player. Its current level of share likely understates its competitive significance.

### **Competitor profiles**

189 The profiles of the Parties' key competitors are outlined in detail above in relation to oral NSAIDs for companion animals. As regards multi-species injectable NSAIDs, further details are set out below.

### **Norbrook**

190 Norbrook's injectable NSAID – Loxicom – is a generic form of Metacam. It is used in cattle to treat acute respiratory infections, diarrhoea, mastitis, and to relieve the

pain from dehorning. In pigs, it is used for non-infectious locomotor disorders, and for puerperal septicaemia and toxæmia. For dogs, it is indicated to alleviate inflammation and pain in musculoskeletal disorders and for post-operative pain, and for cats it reduces post-surgery pain, and helps manage febrile conditions.

- 191 Norbrook also supplies Carprieve, which can be used to treat horses and cattle. It is effective for use in horses to treat musculoskeletal disorders and post-operative inflammation. In cattle, Carprieve is used to treat inflammatory conditions such as acute mastitis and pneumonia.

### ***Zoetis***

- 192 Zoetis' product Rimadyl is a carprofen-based injectable NSAID. It is effective for use in horses to treat musculoskeletal disorders and post-operative inflammation. In cats and dogs, it is used to treat post-operative pain and inflammation.

### ***Bayer***

- 193 Bayer supplies Tylofen, which is an injectable NSAID solution for cattle. Its indications include the treatment of non-infectious inflammatory musculoskeletal conditions, and as an adjunct therapy in treatment of respiratory conditions, acute mastitis, mammary oedema, and colic.

### ***Generics***

- 194 As noted above, Ceva Animal Health, Agrihealth NZ, Troy Laboratories, and Ethical Agents, amongst others, are all registered with the ACVM as having the ability to supply injectable NSAIDs in New Zealand. Agrihealth NZ's Ketomax is understood to be performing strongly in the market after entering only two years ago.

## **2. BI and Merial are not close competitors in injectable multi-species NSAIDs**

- 195 As explained at paragraphs 148 to 149 above, the extent to which NSAIDs inhibit COX-1 and COX-2 (or the ratio in which they inhibit those two isoforms) is a key factor in how closely they compete. As with oral NSAIDs, the Parties' injectable multi-species NSAIDs are not each other's closest competitors.

- 196 Metacam's closest competitor is the generic Loxicom, supplied by Norbrook, which like Metacam uses the active ingredient meloxicam in its formulation. There are a large number of meloxicam-based generic NSAIDs registered with the ACVM: see **Annex 10**.

- 197 In detail, the Parties' multi-species injectable NSAIDs are not closest competitors as:

197.1 Metacam is a COX-2 preferential NSAID, whereas Ketofen is a non-selective COX inhibitor;

197.2 Metacam is long acting whereas Ketofen is short acting (in cattle);

197.3 Metacam has a five day milk withdrawal period whereas Ketofen has no milk withdrawal;

197.4 Metacam is mainly used for mastitis whereas Ketofen is used mainly for lameness; and

197.5 Metacam is mainly used for control of pain and inflammation associated with osteoarthritis in dogs and of postoperative pain and inflammation associated with orthopaedic surgery, ovariohysterectomy, and castration when administered prior to surgery, whereas Ketofen is used mainly for the alleviation of inflammation and lameness.

198 Furthermore, the active ingredient in Ketofen is ketoprofen. Ketofen is a non-selective COX inhibitor, and is the oldest technology available in the market today. From a safety and efficacy perspective, ketoprofen has a substantially greater risk of adverse side-effects than meloxicam-based products such as BI's Metacam. Its closest competitors in the New Zealand market are therefore other ketoprofen generics, of which we understand there are several (predominantly supplied by smaller players such as Troy Laboratories, Agrihealth NZ, and Kela N.V).

### **3. The Parties' products are complementary rather than closely substitutable**

199 As discussed above at paragraphs 153 to 157, vets tend to stock and prescribe a range of different products within a treatment category for clinical reasons. Even where products have essentially the same therapeutic role, there are differences in formulation or preparation that suggest that some animals will respond better to one product than to another. As noted, we understand that vets tend to stock three or four varieties of NSAIDs to cater for the varying needs of different animals.

200 Even in circumstances where two products have essentially the same prescribing indications, sometimes an animal will have an adverse reaction to one product but not to another. Accordingly, vets exercise their clinical judgement to prescribe the product they think will best meet the therapeutic need, and as a consequence tend to stock a range of products.

201 As a consequence, the Parties' products are complementary rather than closely substitutable.

### **4. New market entry into multi-species injectable NSAIDs**

202 As noted above in paragraphs 158 to 163, there is considerable scope for new entry in this segment, whether via proprietary-branded products or generics. Specifically, the injectable NSAIDs sector is mature and highly competitive. The majority of NSAID products have lost patent protection, in particular meloxicam (the API of BI's product) and ketoprofen (the API of Merial's product). As a result, NSAIDs markets feature a large number of generic manufacturers that will continue to exert a competitive constraint on BI post-Transaction. For instance, BI's product, Metacam, is no longer patent protected, thus, generics of this pharmaceutical such as Norbrook's Loxicom successfully compete on the market.

203 Generic competitors are able to exert significant competitive constraint over patent holders once the patent expires as can be seen by the market shares above.

### **5. Products on neighbouring markets exert competitive constraint**

204 As noted at paragraphs 164 – 165, the current standard for pain relief for companion animals is the use of NSAIDs; however, there are number of treatments that provide pain relief such as opioids, steroids, and disease modifying osteoarthritis agents (DMOAs) that may also be vets' preferred method of

treatment. Accordingly, these adjacent products exert competitive constraint on the Parties' products.

**6. Customers enjoy significant buyer power**

205 As noted at paragraphs 166 – 171, the existing corporate groups of veterinary practices in New Zealand are of sufficient scale to discipline any increase in price or decrease in quality from the merged entity. And, based on the growing consolidation of the downstream veterinary market, this countervailing power will continue to increase in strength.

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#### **E. COORDINATED EFFECTS**

206 BI considers the animal health product market in New Zealand is not vulnerable to coordination for the following reasons:

206.1 Animal health products are highly differentiated and vary in terms of their prescribing indications, suitability for different sizes and species of animals, and active ingredients. It would therefore be extremely difficult to sustain coordination in these markets.

206.2 Post-merger, there will be a still be a range of strong competitors, of varying sizes, cost structures, and competitive profiles, which suggests that coordination would be highly unstable.

206.3 The market for animal health products is extremely dynamic, with innovation occurring frequently. The ACVM register contains a full list of products which have been registered over time, and we have observed that a number of products relevant to the markets discussed above have been added over the past months.

206.4 Distribution takes place via contractual supply arrangements with customers, the terms of which are typically not known to competitors. Price transparency is therefore limited, making coordination difficult.

207 Based on these key considerations, BI considers the animal health products sector is not vulnerable to coordination.

#### **PART 5: CONFIDENTIALITY**

208 Confidentiality is requested for all the information contained in this version of the notice.

209 A "public version" of this notice will be provided subsequently that will specifically identify all information that is commercially sensitive to the Applicant.

210 BI requests that it be notified if a request is made to the Commission for release of the information under the Official Information Act 1982.

## DECLARATION

I, Martin Schwarz, 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 me 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/officer of the company and am duly authorised to submit this notice.

**Name and title of person authorised to sign:**

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**Sign:** \_\_\_\_\_

**Date:** \_\_\_\_\_

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## **ANNEX 1: SHARE AND ASSET PURCHASE AGREEMENT**

## ANNEX 2: BI'S NEW ZEALAND SALES IN 2015

<b>BI Group sales in New Zealand</b> <b>(in thousand EUR)</b>		
<b>2015</b>	<b>2014</b>	<b>2013</b>

<b>BI Animal health business sales in New Zealand</b> <b>(in thousand EUR)</b>		
<b>2015</b>	<b>2014</b>	<b>2013</b>

**ANNEX 3: BI'S MAIN CUSTOMERS AND REVENUE**

<b>NSAIDs (oral companion / injectable all species)</b>				
<b>Name</b>	<b>Address</b>	<b>Telephone</b>	<b>Email</b>	<b>Revenue (2015)</b>

#### ANNEX 4: MERIAL'S NEW ZEALAND SALES IN 2015

<b>Sanofi Group sales in New Zealand (in thousand EUR)</b>		
<b>2015</b>	<b>2014</b>	<b>2013</b>

<b>Merial sales in New Zealand (in thousand EUR)</b>		
<b>2015</b>	<b>2014</b>	<b>2013</b>

**ANNEX 5: MERIAL'S MAIN CUSTOMERS AND REVENUE**

<b>NSAIDs (oral companion / injectable all species)</b>				
<b>Name</b>	<b>Address</b>	<b>Telephone</b>	<b>Email</b>	<b>Revenue (2015)</b>

## ANNEX 6: RELEVANT TRADE ASSOCIATIONS

Animal health industry associations in which one or both of the Parties participate				
Name	Address	Telephone	Email / website	Participant
<b>NZVA Diamond</b>	L2, 44 Victoria Street, Wellington	(04) 495 1144	<a href="mailto:leanne.fecser@vets.org.nz">leanne.fecser@vets.org.nz</a>	Merial
<b>AGCARM</b>	Level 5, City Chambers Cnr Johnston & Featherston Streets	(04) 499 4225	<a href="http://www.agcarm.co.nz">www.agcarm.co.nz</a>	BI, Merial



**ANNEX 7: ORAL NSAIDS FOR COMPANION ANIMALS MARKET SHARES (CY 2013 – 2015)<sup>46</sup>**

**1. Market shares from Baron data**

Oral NSAIDs for companion animals (by value, in \$)						
Company	Q4 2015	2015	Q4 2014	2014	Q4 2013	2013
<b>Combined BI+M</b>						
<b>Total</b>		<b>100%</b>		<b>100%</b>		<b>100%</b>

**2. Market shares based on BI’s estimate (including suppliers that do not participate in Baron audit)**

Oral NSAIDs for companion animals (by value, in \$)		
Company	Q4 2015	2015
<b>Combined BI+M</b>		
<b>Total</b>		<b>100%</b>

<sup>46</sup> Source: Baron Strategic Services.

## ANNEX 8: THE PARTIES' MAIN COMPETITORS

Key competitors of BI and Merial			
Name	Address	Telephone	Email
<b>Bayer</b>	Bayer New Zealand Ltd 3 Argus Place Glenfield, Auckland New Zealand	(09) 443 3093	<a href="mailto:richard.emslie@bayer.com">richard.emslie@bayer.com</a>
<b>Elanco</b>	Elanco Level 1 123 Ormiston Rd Botany Junction, Auckland 2016 New Zealand	(09) 272 5420	<a href="mailto:pmyers@elanco.com">pmyers@elanco.com</a>
<b>Norbrook</b>	Norbrook New Zealand Ltd KPMG Centre 18 Viaduct Harbour, Auckland New Zealand	0800 224 022	<a href="mailto:enquiries@norbrook.co.uk">enquiries@norbrook.co.uk</a>
<b>Novartis</b>	Novartis New Zealand Ltd Merck & Dohme Building 109 Carlton Gore Road Newmarket Auckland 1023 New Zealand	(09) 361 8100	(Now part of Elanco)
<b>Virbac</b>	Virbac NZ - Hamilton (Head Office)  26-30 Maui Street Pukete Hamilton 3200 New Zealand	(07) 849 6782	<a href="mailto:matt.wells@virbac.co.nz">matt.wells@virbac.co.nz</a>
<b>Zoetis</b>	Zoetis New Zealand Limited Level 5 8 Mahuhu, Crescent Auckland New Zealand	0800 963 847	<a href="mailto:ContactUs.NZ@zoetis.com">ContactUs.NZ@zoetis.com</a>

**ANNEX 9: MULTI-SPECIES INJECTABLE NSAID MARKET SHARES (CY 2013 – 2015)<sup>47</sup>**

**1. Market shares from Baron data**

<b>Multi-species injectable NSAIDs (by value, in \$)</b>						
<b>Company</b>	<b>Q4 2015</b>	<b>2015</b>	<b>Q4 2014</b>	<b>2014</b>	<b>Q4 2013</b>	<b>2013</b>
<b>Total</b>		<b>100%</b>		<b>100%</b>		<b>100%</b>

**2. Market shares from BI's estimates (including other players)**

<b>Multi-species injectable NSAIDs (by value, in \$)</b>		
<b>Company</b>	<b>Q4 2015</b>	<b>2015</b>
<b>Combined BI+M</b>		
<b>Total</b>		<b>100%</b>

<sup>47</sup> Source: Baron Strategic Services.

**ANNEX 10: MELOXICAM-BASED GENERIC NSAIDS REGISTERED WITH THE ACVM**

<b>Registered company (or, where different, agent)</b>	<b>Product</b>	<b>Mode of application</b>	<b>Companion, production, or both</b>
<b>Ethical Agents Veterinary Marketing Limited</b>	Meloxicam Oral Suspension	Oral	Companion (dogs)
<b>Ethical Agents Veterinary Marketing Limited</b>	Rheumocam 20 mg/mL Solution for Injection	Injection	Production (cattle and pigs)
<b>Ethical Agents Veterinary Marketing Limited</b>	Rheumocam 1 mg Chewable Tablets	Oral	Companion (dogs)
<b>Ethical Agents Veterinary Marketing Limited</b>	Rheumocam 2.5 mg Chewable Tablets	Oral	Companion (dogs)
<b>Ethical Agents Veterinary Marketing Limited</b>	Rheumocam 5 mg/mL Solution for Injection	Injection	Companion (dogs and cats)
<b>Troy Laboratories Pty Ltd</b>	Ilium Meloxicam 0.5 Anti-Inflammatory Oral Suspension	Oral	Companion (cats)
<b>Troy Laboratories Pty Ltd</b>	Ilium Meloxicam Anti-Inflammatory Injection	Injection	Companion (dogs and cats)
<b>Ceva Animal Health (NZ) Limited</b>	Meloxidyl 1.5mg/mL Oral Suspension	Oral	Companion (dogs)
<b>Norbrook NZ Ltd</b>	Loxicom Injection	Injection	Companion (dogs and cats)
<b>Norbrook NZ Ltd</b>	Loxicom LA Injection	Injection	Production (cattle and pigs)
<b>Norbrook NZ Ltd</b>	Loxicom Chewable Tablets	Oral	Companion (dogs)
<b>Norbrook NZ Ltd</b>	Loxicom 1.5 mg/ml Oral Suspension	Oral	Companion (dogs)
<b>Norbrook NZ Ltd</b>	Loxicom 0.5mg/ml Oral suspension	Oral	Companion (cats and dogs)

<b>Randlab New Zealand Ltd</b>	Meloxicam Injection Anti-inflammatory Injection	Injection	Production (cattle and pigs)
<b>Apex Laboratories NZ Ltd</b>	Apex Meloxicam Oral Suspension for Dogs	Oral	Companion (dogs)
<b>Agrihealth NZ Limited</b>	MeloxiVet	Injection	Production (cattle and pigs)
<b>Kahu Veterinary Equipment Ltd</b>	Meloxidolor 5 mg/mL Solution for Injection	Injection	Companion (dogs and cats)
<b>Kahu Veterinary Equipment Ltd</b>	Meloxidolor 20 mg/mL Solution for Injection	Injection	Production (cattle and pigs)



