# COMMERCE ACT 1986: BUSINESS ACQUISITION SECTION 66: NOTICE SEEKING CLEARANCE

Date: 10 February 2020

The Registrar Competition Branch 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.

# Part A: Summary of Application

# 1. **Executive Summary**

- 1.1 This clearance application concerns the proposed acquisition by Elanco Animal Health Inc. (Elanco) of Bayer AG's (Bayer's) animal health business (BAH) (the Proposed Transaction). The Proposed Transaction was announced on 20 August 2019.
- 1.2 Elanco and BAH (the **Parties**, each a **Party**) overlap in the supply of animal health products in New Zealand, including products that treat parasites in companion and production animals, and antimicrobials in production animals. In particular, a relevant horizontal overlap arises in seven markets in New Zealand. The Proposed Transaction will not give rise to competition issues (horizontal or otherwise) due to:
  - (a) the continued presence of and strong competition from major global players;
  - (b) robust competition, new and potential entry and expansion from generics that can gain market share quickly;
  - (c) the different strategic focus of each Party; and
  - (d) the fact the Parties' products tend not to compete closely in areas where they do overlap.

The treatment of internal parasites in companion animals

- 1.3 The combined share of the Parties is ~[]%, however Elanco's share of this market is very small (~[]%), and is also declining, as its products have come under pressure from competitors, including generics. The Parties' product ranges also have different emphases and therefore do not compete closely.
- 1.4 Post-merger, the merged entity will continue to be constrained by competitors with leading brands, such as Boehringer Ingelheim, MSD Animal Health (MSD, a Merck subsidiary), Virbac and Zoetis. Local and regional generic competitors such as Jurox also supply products substitutable for those supplied by the Parties. For example, Jurox supplies Popantel F, a Drontal generic. Recent entry and new products will therefore continue to be an ongoing competitive constraint on the merged entity in this market post-merger.

The treatment of external parasites in companion animals

- 1.5 The combined share of the Parties is modest at ~[]%, and Elanco's share is estimated to be just ~[].<sup>1</sup> The increment in this market is therefore *de minimis*. In addition, the Parties' product ranges do not compete closely. Notably, the Parties' products have different application methods, with Elanco's products being in chewable form while BAH's are topical applications.
- 1.6 As with internal parasites, competition is strong in this market, with the likes of Boehringer Ingelheim, MSD and Zoetis all having strong brands that will constrain the merged entity's ability to exercise market power. There are also examples of new and potential entry and expansion.

#### The treatment of internal parasites in sheep

1.7 The overlap between the Parties in this market is very limited and, in any event, the combined share of the Parties in this market is very small, at less than []%. BAH has a single product that is *indicated* for the treatment of internal parasites in sheep, but in reality it is rarely used for this purpose due to parasite resistance to its active ingredient, oxfendazole. There is very strong

competition from market leader Boehringer Ingelheim (est. market share of ~[]%), together with Zoetis, MSD, Nexan and several others.

The treatment of external parasites in sheep

- 1.8 The combined share of the Parties is estimated to be ~[]%, with an increment of ~[]%. However, the Parties' product ranges are largely complementary, with Elanco focussing more on flystrike prevention, and BAH focussing more on lice control. Where products do achieve the same treatment aims, they are generally not used as substitutes, but rather complements for one another as part of a rotation of products to reduce parasite resistance to active ingredients.
- 1.9 The merged entity will continue to face strong competition from multiple, well-resourced competitors post-merger, including Boehringer Ingelheim and MSD, which have significant market positions. In particular, MSD prices its products particularly aggressively. The threat of new entry is also very real, as evidenced by the presence of numerous generic products on the market, including those supplied by regional and local players such as Jurox, Ravensdown and PGG Wrightson.

## The treatment of liver fluke in cattle

1.10 The Parties have a *de minimis* presence in the supply of liver fluke<sup>2</sup> products for use in cattle, with an estimated combined share of ~[] and an increment of ~[]%. []. There is strong competition from multiple large global suppliers (including Boehringer Ingelheim with over []% of the market) as well as Zoetis, Virbac and several others. Elanco's products are differentiated from [], as they do not treat the same stages of liver fluke, have different withholding periods and use alternative methods of application. These products therefore do not compete closely.

#### Anticoccidials for use in poultry

1.11 Elanco's poultry anticoccidials *prevent* coccidiosis, whereas BAH's Baycox formulation for poultry is a *treatment* for coccidiosis. This means that the Parties' respective products belong in different product markets and do not compete. In any event, even in any broader anticoccidials market comprising both preventative and curative products, competition issues do not arise: the combined share of Parties in the broader market is ~[]% and the increment is *de minimis* at ~[]%.

#### Antimicrobials for use in ruminant animals

1.12 The Parties' product ranges do not compete closely in this market, with differences in the chemical classes that their active ingredients belong to, and in the ailments that they are indicated to treat. The Parties also have a low combined market share (~[]%, with a small increment ([]%), and will continue to be constrained by competitors in this area, including Virbac, MSD, Zoetis and Boehringer Ingelheim.

# Pipeline products

# 1.13 []

1.14 [] There is no meaningful current overlap between the Parties in relation to the treatment of otitis in companion animals, with BAH having no specialty product in this area. Combined shares on a broader market would be low, with a *de minimis* increment. Neptra would not compete closely with either of Elanco's products, one of which (Osurnia) is to be sold in any event.

<sup>&</sup>lt;sup>2</sup> Liver fluke are internal blood sucking parasites.

No vertical or coordinated effects concerns

1.15 The Proposed Transaction does not result in any increased vertical integration in New Zealand and coordinated effects do not arise given, *inter alia*, the presence of many strong competing products, including generics.

Conclusion: no SLC in any relevant market

1.16 In light of the above, Elanco submits that the Proposed Transaction is unlikely to give rise to a substantial lessening of competition in any New Zealand market.

# Part B: The Parties

# 2. The Applicant: Elanco

- 2.1 Elanco is a US animal health company that develops, manufactures and markets products for companion and production animals. It is headquartered in Greenfield, Indiana and listed on the New York Stock Exchange.
- 2.2 []
- 2.3 Elanco does not manufacture any companion animal products for third parties in New Zealand (and vice versa).
- 2.4 Elanco's 2018 Annual Report is available at: <u>https://investor.elanco.com/investors/financials-and-filings/sec-filings/sec-filings-details/default.aspx?FilingId=13239239</u>.
- 2.5 []
- 2.6 Further information in relation to Elanco in New Zealand can be found at: <u>https://www.elanco.co.nz</u>.
- 2.7 Contact details for Elanco:

Address	Elanco Animal Health Inc. 2500 Innovation Way Greenfield, Indiana 46140 United States of America
Contact person	[]
	[]
Email Address	[]
Telephone	[]
Website	www.elanco.com

2.8 Please direct all correspondence and notices for Elanco to:

Address	Bell Gully Barristers and Solicitors PO Box 4199 Auckland 1140
Attention	Torrin Crowther / Michael Tilley
Email Address	torrin.crowther@bellgully.com / michael.tilley@bellgully.com
Telephone	+64 9 916 8621 / +64 9 916 8827

#### 3. The Target: BAH

- 3.1 Bayer is a German company headquartered in Leverkusen and listed on various stock exchanges in Germany.<sup>3</sup> Bayer is a life sciences company, active in pharmaceuticals, consumer health, agro-chemicals and animal health. BAH is a collection of business assets and Bayer group companies<sup>4</sup> engaged in the animal health business, and represented approximately [] of Bayer's global turnover in 2018. Bayer publicly announced that it intended to sell BAH in November 2018 as part of a wide restructuring of Bayer's business.
- 3.2 BAH is active in the development, production and marketing of prescription and non-prescription veterinary products, in particular for companion animals, which account for around [] of total BAH revenues.

#### BAH's New Zealand business

- 3.3 BAH's products are sold in both the "over the counter" (OTC)<sup>5</sup> and veterinary (vet) channels in New Zealand. BAH supplies to rural distributors (e.g. PGG Wrightson), farming cooperatives (e.g. Farmlands), vet distributors (e.g. Fortis), general wholesalers, pet specialty stores (via wholesalers) and veterinary clinics, who sell to end customers (i.e. farmers and pet owners).
- 3.4 []:
  - (a) [].<sup>6</sup>
  - (b) [].
  - (c) [].<sup>7</sup>[].
- 3.5 Bayer's 2018 Annual Report is available at: <u>https://www.annualreport2018.bayer.com/</u>. The most recent audited accounts of the commercial operations of BAH's animal health business in New Zealand (excluding product supply and development centre) are at **Annex 2**.
- 3.6 Further information in relation to BAH in New Zealand can be found at: <u>https://www.bayeranimal.co.nz/</u>.

<sup>&</sup>lt;sup>3</sup> Bayer is listed on the following stock exchanges in Germany: Berlin, Dusseldorf, Frankfurt, Hamburg, Hannover, Munich and Stuttgart.

<sup>&</sup>lt;sup>4</sup> Comprising Bayer Animal Health GmbH, KVP Pharma+Veterinär Produkte Gmbh, Bayer (Sichuan Animal Health Co., Ltd and Bayer HealthCare Animal Health Inc.

<sup>&</sup>lt;sup>5</sup> Also sometimes referred to as the 'other than vet', or 'OTV' channel.

<sup>&</sup>lt;sup>6</sup>[]

<sup>&</sup>lt;sup>7</sup> Registration requirements under the Agricultural Compounds and Veterinary Medicines Act 1997, discussed in detail further below.

3.8

Address	Bayer AG Law, Patents & Compliance Mergers & Acquisitions Building Q 26, 1.000 51368 Leverkusen, Germany
Contact person	[]
	[]
Email Address	[]
Tolophono	[]
Telephone	[]
Website	www.bayer.com
Please direct all correspondence and notices	o for Bayer to:
Address	Simpson Grierson Level, 27 Lumley Centre 88 Shortland St Auckland 1010
Attention	James Craig / Nina Blomfield
	james.craig@simpsongrierson.com / nina.blomfield@simpsongrierson.com
Telephone	+64 9 977 5125 / +64 9 977 5111

# Part C: The Proposed Transaction

#### 4. Transaction structure

4.1 Elanco proposes to acquire all of the shares in the four relevant BAH entities (Bayer Animal Health GmbH, KVP Pharma+Veterinär Produkte GmbH, Bayer (Sichuan) Animal Health Co., Ltd. and Bayer HealthCare Animal Health Inc.) and the business assets that form BAH, as more particularly described in the Share and Asset Purchase Agreement (**SAPA**) provided at **Annex 3**. Following the Proposed Transaction, Elanco will wholly own and control BAH.

### 5. Rationale

Elanco

- 5.1 The Proposed Transaction aims to combine Elanco and BAH's largely complementary animal health businesses globally to create a merged entity capable of competing more effectively in serving animals, veterinarians and pet-owners in the animal health industry.
- 5.2 The Proposed Transaction will broaden the Parties' largely complementary portfolios, help them to innovate to compete with other manufacturers of animal health products and increase their productivity, and allow Elanco to compete more effectively in segments in which it is not particularly active, notably in segments relating to companion animals and in products distributed outside the veterinarian channel without threatening to lessen competition in any relevant market in New Zealand.

Bayer

5.3 Following a strategic review of its business, and as part of a broader restructuring, Bayer AG announced in November 2018 its intention to sell BAH and exit the animal industry.

# 6. Transaction documents

6.1 A copy of the SAPA is attached at **Annex 3**.

# 7. Clearance sought

7.1 This application seeks clearance in New Zealand for Elanco to acquire up to 100% of the shares in the four relevant BAH entities (Bayer Animal Health GmbH, KVP Pharma+Veterinär Produkte GmbH, Bayer (Sichuan) Animal Health Co., Ltd. and Bayer HealthCare Animal Health Inc.) and the business assets that form BAH, as more particularly described in SAPA provided at **Annex 3**.

# 8. Global filings

8.1 Table 1, below, sets out the jurisdictions in which the Proposed Transaction is or will be notified, and the dates or expected dates that the relevant agencies have been or will be notified.

Jurisdiction	Agency	Date of notification	
European Union	European Commission	[]	
USA	Federal Trade Commission	8 November 2019	
Australia	Australian Competition and Consumer Commission	ACCC's assessment commenced 20 December 2019	
Brazil	Conselho Administrativo de Defesa Economica	24 January 2020	
Canada	Competition Bureau/Bureau de la concurrence	22 November 2019	
China	State Administration for Market Regulation	Clearance received 6 January 2020	
Columbia	Superintendence of Industry and Commerce	20 January 2020	
Mexico	Comisión Federal de Competencia Económica	20 December 2019	
South Africa	Competition Commission of South Africa	3 February 2020	
Turkey	Rekabet Kurumu	16 December 2019	
Ukraine	Anti-Monopoly Committee	24 December 2019	
UK <sup>9</sup>	Competition and Markets Authority	[]	
Vietnam	National Competition Committee (Ministry of Industry and Trade)	22 January 2020	

# Table 1 - Overseas competition agencies notified<sup>8</sup>

8.2 Closing is expected to take place in mid-2020, subject to the necessary approvals.

<sup>&</sup>lt;sup>8</sup> Should they have jurisdiction, filings may also be made with the competition authorities in Israel and Ecuador.
<sup>9</sup> If the Competition and Markets Authority has jurisdiction to review the Proposed Transaction following the outcome of the Brexit process.

# Part D: Background to the animal health industry and relevant products

# 9. Background to the animal health industry

- 9.1 The global animal health industry has revenues estimated at USD 55 billion (in 2017), of which USD 30 billion are therapeutic products manufactured for companion animals and production animals. The animal health industry is estimated to grow at a rate of 5-6% per annum for the next five to six years across both these segments. The industry is worth over NZD 550 million in New Zealand.<sup>10</sup>
- 9.2 The animals that comprise the animal health industry can be broadly segmented into 'companion animals' and 'production animals'. For the purposes of this application:
  - (a) companion animals generally means cats and dogs;<sup>11</sup> and
  - (b) production animals generally means cattle, sheep and poultry.<sup>12</sup>

#### Companion animals

9.3 There are over 4.6 million pets in New Zealand, which includes approximately 1.8 million cats and dogs. 64% of New Zealand households are home to at least one pet. Only the United States has a marginally higher percentage of households that are home to pets, at 65%.<sup>13</sup>

#### Production animals

- 9.4 As at 2017, New Zealand had 10.1 million cattle and 27.5 million sheep across 52,300 farms.<sup>14</sup> In 2017, cattle and sheep meat exports exceeded NZD 6 billion and dairy product exports exceeded NZD 13 billion.<sup>15</sup>
- 9.5 With over 95% of dairy products and a large percentage of beef and sheep meat exported, New Zealand farmers are sophisticated and cost-sensitive consumers of animal health products. Farmers seek to minimise their input costs to protect their business from volatile export prices while maximising their production animals' output. Farmers are well serviced by the animal health industry in New Zealand, benefiting from the significant buying power of large co-operatives such as Ravensdown and Farmlands, nationwide suppliers such as PGG Wrightson, large veterinary groups such as Quantum Vet Group and Vetora, and other distributors in the agricultural sector.

 <sup>&</sup>lt;sup>10</sup> Based on the estimated value of the veterinary pharmaceutical and medicinal product manufacturing industry. See <a href="https://www.ibisworld.com.au/industry-trends/nz-market-research-reports/manufacturing/veterinary-pharmaceutical-medicinal-product-manufacturing.html">https://www.ibisworld.com.au/industry-trends/nz-market-research-reports/manufacturing/veterinary-pharmaceutical-medicinal-product-manufacturing.html</a>. Accessed 21 November 2019.
 <sup>11</sup> This term may be used elsewhere to also refer to birds and horses, but these animals are not relevant to the assessment of the

<sup>&</sup>lt;sup>11</sup> This term may be used elsewhere to also refer to birds and horses, but these animals are not relevant to the assessment of the Proposed Transaction in New Zealand.

<sup>&</sup>lt;sup>12</sup> This term may be used elsewhere to also refer to goats, pigs, deer, turkeys and aquaculture animals (farmed fish), but these animals are not relevant to the assessment of the Proposed Transaction in New Zealand.

<sup>&</sup>lt;sup>13</sup> <u>https://www.nzvna.org.nz/site/nzvna/files/Documents/Companion%20Animals\_in\_New\_Zealand\_2016\_Report\_web.pdf</u>. Accessed 21 November 2019.

<sup>&</sup>lt;sup>14</sup> <u>https://www.stats.govt.nz/indicators/livestock-numbers.</u> Accessed 22 November 2019.

<sup>&</sup>lt;sup>15</sup> https://beeflambnz.com/knowledge-hub/PDF/compendium-farm-facts. Accessed 22 November 2019.

#### 10. Background to products relevant to this application

Categories of animal health products

- 10.1 Animal health products can be divided into three main categories:
  - (a) <u>Pharmaceuticals</u>: products that contain a variety of active substances notably parasiticides to prevent or treat a large range of animal diseases and disorders;
  - (b) <u>Biologicals</u>: products which trigger an immune response against viral and bacterial diseases as well as occasionally parasitic or fungal infections in animals. Biologicals include, in particular, animal vaccines; and
  - (c) <u>Feed supplements</u> (medicinal and nutritional): pharmaceutical or nutritional substances which are not natural feedstuffs and are added to made-up and stored feeds, chiefly to control infectious disease or to promote growth.
- 10.2 The Parties only overlap in pharmaceuticals in New Zealand.<sup>16</sup>

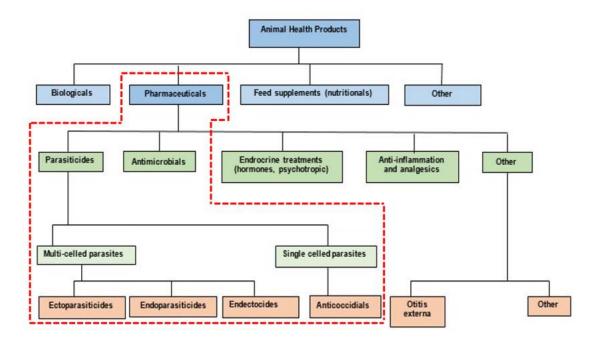
#### Pharmaceuticals

- 10.3 The pharmaceuticals category can be sub-divided into: antimicrobials, parasiticides, endocrine treatments, anti-inflammation (non-steroidal and corticosteroids) and analgesics. The Parties both manufacture antimicrobials and parasiticides for distribution in New Zealand.
  - (a) <u>Antimicrobials</u> are pharmaceutical products that destroy or prevent the growth of microbes such as bacteria, mycoplasma or fungi, and that therefore treat diseases associated with such microbes. They are also known as antibiotics.
  - (b) <u>Parasiticides</u> are used to kill or prevent parasites from infesting an animal, whether internally or on the body.
- 10.4 The parasiticides segment can be sub-divided as follows:
  - (a) products used to treat single-celled parasites (i.e. anticoccidial products);<sup>17</sup> and
  - (b) products used to treat multi-celled parasites<sup>18</sup> that act externally on animals (ectoparasiticides or ectos), internally within an animal (endoparasiticides or endos) or that combine the two (endectocides or endectos).
- 10.5 Figure 1, below, shows the animal health products framework in New Zealand. The area within the red hatched line indicates the product categories relevant to the assessment of the Proposed Transaction in New Zealand.

<sup>&</sup>lt;sup>16</sup> Both Parties supply anticoccidial products for use in poultry, however only Elanco's product is a feed supplement.

<sup>&</sup>lt;sup>17</sup> Coccidiosis is a parasitic disease of the intestinal tract of animals caused by pathogenic coccidian. The disease affects young animals in particular and typically spreads through contact with infected faeces or ingestion of infected tissue.

<sup>&</sup>lt;sup>18</sup> Multi-celled parasites are distinguished by their location. External parasites (ectoparasites) live and breed on the skin or in the fur/hair of animals, and include flies, lice, fleas, keds, ticks and mites. Internal parasites (endoparasites) live in an animal's internal organs such as the gut or heart, and include gastro-intestinal roundworms and tapeworms, lungworms, liver flukes and protozoa.



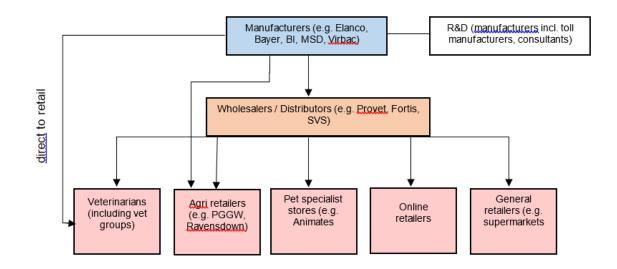
#### Figure 1 - Animal health products framework

#### 11. Distribution channels

11.1 Two broad sales channels for animal health products exist in New Zealand:<sup>19</sup>

- (a) the vet channel; and
- (b) the OTC channel, which encompasses all other outlets, including specialty pet stores (e.g. Animates), specialist agriculture stores (e.g. PGG Wrightson, Farmlands and Farm Source), large generalist retailers (e.g. supermarkets, Mitre10) and online retailers (e-commerce).
- 11.2 Products that have a regulatory status/registration as "vet only" products can only be distributed in the veterinary (including online veterinary) channel. For example, the antimicrobial products of the Parties are all vet only products. However, "non-vet" products are also sold in this channel.
- 11.3 The distribution channels for products in the New Zealand animal health industry are depicted in Figure 2, below.

<sup>&</sup>lt;sup>19</sup> Elanco sells certain products through the 'feed mill' channel, and direct to end customers such as Inghams. The products relevant to the assessment of the Proposed Transaction in New Zealand are anticoccidials for use in poultry. Given concerns are unlikely to arise on any view of the relevant anticoccidials market, this channel is not discussed further.



# Figure 2 - Animal health products distribution in New Zealand

### Vet channel

- 11.4 Historically, for both companion animal and production animal products, the vet channel has been the predominant route to market for manufacturers. Indeed, most companion animal health products including "non-vet" products are also still acquired from vets in New Zealand.
- 11.5 Vets are overwhelmingly considered as the best source of information for companion animal related issues, with 72% of people with companion animals holding this view.<sup>20</sup> That said, other trusted sources of information include the internet (51%), the SPCA (32%) and pet shops (31%).<sup>21</sup>

#### OTC channel

11.6 A large proportion of animal health products are distributed through animal health distributors (such as Provet) and resellers with their own rural supplies stores (such as PGG Wrightson and Allied Farmers). Cooperatives, such as Farmlands, Ravensdown and Farm Source, also have retail arms that source products and sell to their customer shareholders (including, in the case of Ravensdown, under its own brand). The OTC channel is therefore categorised by large, sophisticated distributors with significant countervailing power (particularly in respect of the distribution of animal health products for production animals).

#### Trends in distribution

- 11.7 The relative importance of the above channels is evolving, with an increase in the popularity of the OTC channel, particularly in relation to companion animals. As the range of animal health products has increased, so too has the number of both traditional specialty "bricks and mortar" and online stores, as well as the number of retailers introducing or developing their pet care offerings.
- 11.8 Major pet retail stores, such as market leader Animates, have both physical and online stores to meet the evolving needs and spending habits of consumers. As the 2015 New Zealand Companion Animal Survey found, a third of people have purchased products for their animals online. This percentage has almost certainly increased in the past four years, as consumers

<sup>&</sup>lt;sup>20</sup> https://www.nzvna.org.nz/site/nzvna/files/Documents/Companion%20Animals in New Zealand 2016 Report web.pdf. Accessed 22 November 2019.

<sup>&</sup>lt;sup>21</sup> <u>https://www.nzvna.org.nz/site/nzvna/files/Documents/Companion%20Animals\_in\_New\_Zealand\_2016\_Report\_web.pdf</u>. Accessed 22 November 2019.

become increasingly comfortable purchasing online.<sup>22</sup> Some veterinary clinics and groups also have online stores.

#### 12. Overview of the competitive landscape

Strong competition from global players

- 12.1 A large number of global animal health companies supply their products in New Zealand, either through distributors, wholesalers and/or direct to vets and customers. They include the following.
  - (a) Zoetis is the world's largest animal health player (formerly part of Pfizer until 2012), with an estimated 16% share of the global animal health industry. Its product portfolio contains over 300 animal health products across a range of segments including microbials, vaccines, parasiticides and medicinal feed additives. It operates 25 manufacturing facilities worldwide.<sup>23</sup> Key products include the companion animal parasiticides Simparica and Revolution, as well as products focussed on production animals such as the anticoccidials Avatec and Cygro.
  - (b) Boehringer Ingelheim is the world's second largest animal health player, with an estimated 13% share of the global animal health industry and the largest companion animal player (28% worldwide share), with almost two-thirds of its sales being derived from this segment. Boehringer Ingelheim operates 24 manufacturing facilities worldwide.<sup>24</sup> Key products relevant to this application include the companion animal parasiticides Frontline and NexGard, and sheep parasiticides Cyrazin, Bionic and Matrix.
  - (c) Merck/MSD has an estimated 12% share of the animal health industry globally. It operates 16 manufacturing facilities and also has a significant animal health vaccines business. MSD is particularly active and aggressive on price in relation to the supply of external parasiticides for both companion and production animals. Key products relevant to this application include the Bravecto range (for companion animals), and Magnum, Vanquish and Wipeout (for the treatment of external parasites on sheep).
  - (d) Norbrook is a large, family owned, veterinary pharmaceutical company with a portfolio of animal health products that are distributed around the world through its own sales team and a network of longstanding distribution partners. Its stated aim is "to be the first to market with generic veterinary pharmaceutical products with differentiators or enhancements in comparison to pioneer products."<sup>25</sup> Norbrook is regarded as being aggressive on price, []
  - (e) Virbac has an estimated 3% share of the global animal health industry. Its product portfolio is split fairly evenly between production and companion animals. It operates 11 manufacturing facilities worldwide as well as eight R&D centres. Key products include the companion animal parasiticide Milpro.

<sup>&</sup>lt;sup>22</sup> <u>https://www.nzvna.org.nz/site/nzvna/files/Documents/Companion%20Animals\_in\_New\_Zealand\_2016\_Report\_web.pdf</u>. Accessed 22 November 2019.

<sup>&</sup>lt;sup>23</sup> <u>http://www.annualreports.com/HostedData/AnnualReports/PDF/NYSE\_ZTS\_2018.pdf</u>. Accessed 22 November 2019.

<sup>&</sup>lt;sup>24</sup> <u>http://kcanimalhealth.thinkkc.com/news/media-coverage/boehringer-becomes-top-spender-on-animal-health-r-d.</u> Accessed 22 November 2019.

<sup>&</sup>lt;sup>25</sup> <u>https://www.norbrook.com/</u>. Accessed 22 November 2019.

Strong competition from local/regional players

- 12.2 In addition to the above, the following local/regional players also compete strongly in New Zealand:
  - (a) Nexan is a leading New Zealand-owned developer, manufacturer and marketer of animal health products in New Zealand. It focusses on products for the treatment of production animals, which are supplied under the Vetmed brand.<sup>26</sup>
  - (b) **Alleva** is a New Zealand-based animal health company specialising in the development and marketing of novel animal health products. It commenced operations in early 2011 and its range has grown to include an array of treatments for production animals.<sup>27</sup>
  - (c) Jurox is an Australian veterinary and pharmaceutical manufacturer developing solutions for livestock producers, veterinarians and pet owners. It researches, develops and manufactures a wide range of veterinary medicines which are sold throughout Australia, New Zealand, the US, Europe, and North America. Its global head office is located in NSW and it has offices in Auckland, the UK and the US.<sup>28</sup>
  - (d) Ravensdown is a cooperative company 100% owned by farmers. It distributes a wide range of generic animal health products under its own branding. Some of its key products include the Abamectin and Combo brands for treatment of production animal parasites, the Cyromazine range for treatment of flystrike in sheep, and the Saturate brand for the treatment of lice in sheep.<sup>29</sup>
  - (e) **Donaghys** is a New Zealand company that has traded continuously for 140 years. It offers a range of animal health products, with a focus on production animals. It supplies animal health products for cattle and sheep, as well as cropping and horticulture products, crop packaging, and rope/cordage.<sup>30</sup>
  - (f) Animal Health Direct (AHD) is a New Zealand owned and operated company established in 2002. It supplies an extensive product range through rural outlets and veterinary clinics. It provides leading equine, dairy and animal health products and is focused on being New Zealand's best locally owned animal health company that adapts to meet customer demands.<sup>31</sup>
  - (g) AgriHealth is a New Zealand veterinary medicine research and product developer, as well as a marketing and distribution partner to a large number of global manufacturers. It provides an extensive range of animal health products for production animals. It is a subsidiary of AgriHealth International.<sup>32</sup>
  - (h) The Drench Company is a New Zealand company that has supplied animal health products to livestock farmers since 2007. It initially produced product ranges for sheep, cattle and horse parasite control. It has since expanded into the dairy industry with a range of teat sprays, bloat oils, and acid and alkali detergents.<sup>33</sup>

Strong competition from generics

12.3 As discussed below, in the case of products where the active ingredients (or combinations of active ingredients or product formulation) have gone off-patent, it is relatively straightforward for third parties to manufacture their own version of that product, or engage toll manufacturers to

<sup>&</sup>lt;sup>26</sup> <u>http://www.nexan.co.nz/</u>.

<sup>&</sup>lt;sup>27</sup> https://www.alleva.co.nz/about\_us.html.

<sup>&</sup>lt;sup>28</sup> <u>https://www.jurox.com/au/about</u>.

<sup>&</sup>lt;sup>29</sup> https://www.ravensdown.co.nz/products/animal-health.

<sup>&</sup>lt;sup>30</sup> https://www.donaghys.com.

<sup>&</sup>lt;sup>31</sup> <u>https://www.animalhealthdirect.co.nz/</u>.

<sup>&</sup>lt;sup>32</sup> https://agrihealth.co.nz/.

<sup>&</sup>lt;sup>33</sup> http://drenchco.co.nz/.

manufacture on their behalf. As a result, there are a number of generic manufacturers that are effective competitors to both Parties, including for many of their popular companion animal brands such as BAH's Advantage family of products and Elanco's Milbemax, and their key production animal brands such as Elanco's CLiK. []

- (a) Milpro, registered by Virbac in 2016, is a generic of Elanco's Milbemax and has []
- (b) Popantel F, marketed by Jurox, is a generic of BAH's Drontal.
- (c) A key active ingredient for Elanco which has come off-patent recently is dicyclanil. This ingredient is used in the CLiK range. This development has led to a surge in the production and availability of generic products in this space in Australia, and Jurox's dicyclanil products Strikeforce S and Luci-Guard are available in New Zealand.
- (d) Elanco has recently withdrawn a number of products from New Zealand due to poor performance caused by increased pressure from generic products. For example:
  - Micotil was recently withdrawn because Elanco could not supply this product to its distributor at a price that allowed it to compete with AgriHealth's generic product, Tilmicosin (manufactured by Huvepharma AD); and
  - Elanco's sheep parasiticides Pyrimide and Vetrazin are both being discontinued in New Zealand due to steadily declining margins over the past three to five years and an inability to compete with numerous generic competitors (both local and global).
     Existing stock will continue to be sold down, however both products will no longer be for sale by the end of Q3, 2020.
- 12.4 As a result, across all product areas where the Parties overlap, there are a large number of wellresourced, multinational and local competitors that currently supply in New Zealand. These entities will continue to exert a strong competitive constraint on the merged entity.
- 12.5 The Elanco products relevant to the consideration of the Proposed Transaction do not contain any active ingredients that are subject to patent protection. As such, they face competition (including potential competition) from products that contain these active ingredients (and those that contain other active ingredients). Moreover, []

Trend of global players increasing their focus on their animal health businesses

- 12.6 The supply of animal health products has traditionally come under the umbrella of broader human health/pharmaceuticals companies, however in recent years the animal health divisions have been broken out to form separate, exclusively animal-focused businesses. Examples of this include:
  - (a) Zoetis (the world's largest animal health player) being split out of Pfizer in 2012/2013;<sup>34</sup> and
  - (b) Elanco being spun out of Eli Lily in 2019.<sup>35</sup>
- 12.7 Moreover, Boehringer Ingelheim acquiring Sanofi's animal health business (Merial) in 2016 (and in turn selling its consumer healthcare business to Sanofi) underlines that even traditional pharmaceutical companies see value in investing in animal health over expansion in human health pharmaceuticals.<sup>36</sup>

<sup>35</sup> <u>https://www.elanco.com/news/press-releases/elanco-completes-separation-from-lilly</u>. Accessed 22 November 2019.

<sup>&</sup>lt;sup>34</sup> <u>https://www.pfizer.com/news/press-release/press-release-detail/pfizer\_announces\_plan\_for\_split\_off\_of\_zoetis</u>. Accessed 22 November 2019.

<sup>&</sup>lt;sup>36</sup> https://www.boehringer-ingelheim.com/press-release/sanofi-and-boehringer-ingelheim-confirm-closing-business-swap-january-

<sup>1</sup>st-2017. Accessed 22 November 2019.

12.8 The effect of this trend is that there are now a greater number of companies devoted to animal health, and this has spurred competition in the sector. The rise of specialist animal health companies has accelerated innovation and led to more competition.

Countervailing power of distributors and retail outlets

- 12.9 As noted above, animal health products are sold via a number of different wholesale and retail outlets, including veterinary clinics, pet stores, farm specialty stores, distributors, online and supermarkets. Many of these customers are large, well-resourced players that have significant bargaining power vis-à-vis manufacturers and wholesalers. Farmer-owned co-operatives such as Farmlands are incentivised to ensure prices for their members are as low as possible, and others such as Ravensdown supply their animal health products under their own branding.
- 12.10 The Commission has previously recognised that veterinarians exercise countervailing power over manufacturers of animal health products. In its decision in *ScheringPlough/Organon*, the Commission noted that many veterinarians are "relatively large and sophisticated buyers, due to a trend of rationalisation in the veterinary industry".<sup>37</sup> In the time since the Commission's decision in this case there has been further consolidation of veterinary clinics, increasing the buying power in particular of the large veterinary groups.<sup>38</sup> Wholesalers in particular are also likely to exercise countervailing power given the position they hold in offering distribution cost savings to animal health suppliers, but also convenience to customers downstream (such as individual vets).
- 12.11 In general, the high purchasing volume of all key rural, farming cooperative and vet customers means that they can demand particular supply terms from manufacturers.
  - (a) As large purchasers they use their position as high volume buyers, together with offers from rivals, to leverage better prices and terms.
  - (b) []
    - (i) []
    - (ii) []
  - (c) []
  - (d) []
  - (e) []

12.12 Key customer-distributors with countervailing power include:

- (a) PGG Wrightson (PGGW): a major supplier to the agricultural sector in New Zealand. It provides farmers with a full service offering including animal health products, farming equipment and agricultural supplies. It has a nationwide retail supplies store network of 94 stores supporting approximately 570 staff throughout New Zealand, servicing all farming and horticultural requirements (including animal health).<sup>39</sup> PGGW stocks a wide range of animal health products and accordingly has significant buyer power vis-a-vis suppliers. Its operating revenue for FY19 was NZD 808,695,000.<sup>40</sup> []
- (b) **Farmlands**: New Zealand's largest farmer owner co-operative, with over 64,000 shareholders. It was established more than 50 years ago with the specific intention of

<sup>&</sup>lt;sup>37</sup> Schering-Plough Corporation/Organon Biosciences N.V., Commission Decision 621, 4 October 2007, (**Schering** *Plough/Organon*) at [303].

<sup>&</sup>lt;sup>38</sup> Examples of subsequent consolidation among veterinary practices include Quantum Vets, Vet Company South Island, Vetora and Vet Alliance.

<sup>&</sup>lt;sup>39</sup> <u>https://www.pggwrightson.co.nz/Locations/Retail-Store</u>. Accessed 22 November 2019.

<sup>&</sup>lt;sup>40</sup> PGGW 2019 Annual Report, p.40.

providing competition in the retail farm supply industry to reduce farmers' input costs. It has an extensive nation-wide network and exists "for one simple reason – to use the collective power of our shareholders to negotiate better deals and improve individual profitability".<sup>41</sup> With its focus on reducing shareholders' costs, and its significant buyer power, it is a significant constraint on pricing at the wholesale level.

- (c) Ravensdown: a cooperative company that distributes animal health, agrochemical and agricultural products, both under its own brand name and on behalf of other manufacturers. Its animal health range focuses on production animals. The demonstrated ability of Ravensdown (and others) to bring generic products to market under its own brand acts as a significant constraint on pricing in the relevant markets. For example, Ravensdown has a total of 52 of its own-branded products (spanning animal and plant health) registered with the Ministry for Primary Industries, 12 of which are animal health products competing in production animal health markets in which the Parties overlap.
- (d) Distributors/wholesalers: such as SVS, which is a large distributor to the vet channel that emphasises "our buying power and our investment in the best of people and technology" as reasons that it delivers great value prices and service.<sup>42</sup> Similarly, Provet markets itself as a distributor that offers "an extensive selection of Veterinary products at highly competitive prices". Fortis is a large supplier of wholesale veterinary products to veterinary clinics nationwide. It is owned by a network of veterinarians and has strong relationships with veterinary clinics. As a result, it is committed to providing a large range of companion and production animal products at low prices.
- (e) Animates is a speciality pet retailer with a New Zealand-wide network of more than 60 stores, as well as an online store. It also has a network of 18 vet clinics. Animates has a "price match" promise, ensuring that its products are available for the lowest retail price anywhere in New Zealand.<sup>43</sup> This is a reflection of the confidence it has in its buying ability at the wholesale level. Animates is part of Greencross Limited in Australia.
- (f) **Major vet groups** also provide a constraint on the market. These groups can represent significant sources of income for manufacturers. [] Major Australian corporate vet companies have also expanded to New Zealand, such as NVC and Vet Partners.
- (g) **Big box retailers** such as the major supermarkets, The Warehouse and Mitre 10. Each of these retailers has significant buyer power in this space, placing a significant constraint on pricing at the wholesale level.
- (h) [].
  - (i) [].
  - (ii) [].

#### 13. Entry and expansion requirements

Research and Development (R&D)

- 13.1 Animal health products must go through the below regulatory process.
  - (a) Research and development: most animal health products contain an active ingredient, a formulation and/or another innovation<sup>44</sup> that is patented and sold to customers. Once the

<sup>&</sup>lt;sup>41</sup> https://www.farmlands.co.nz/Aboutus/. Accessed 22 November 2019.

<sup>&</sup>lt;sup>42</sup> <u>https://svs.co.nz/</u>. Accessed 22 November 2019.

<sup>&</sup>lt;sup>43</sup> https://www.animates.co.nz/price-promise. Accessed 22 November 2019.

<sup>&</sup>lt;sup>44</sup> Many of the most successful products in the animal health industry result from companies innovating using off-patent active ingredients. Examples of such innovations include BAH's Seresto collar, where the key innovation was the ability to ensure protection over a significantly greater period of time (eight months) through the administration of a collar. Seresto (inidacloprid,

patent on this innovation expires, other manufacturers may develop a generic product based on the "originator" product.

- (b) Regulatory approval: before any animal health product can be sold in New Zealand, it has to be registered in accordance with the Agricultural Compounds and Veterinary Medicines Act 1997. Registration requires suppliers to prove that their products meet the required standards around quality, efficacy and safety and that products do not pose unacceptable risk to trade in primary produce, animal welfare, agriculture security and public health.
- (c) Distribution to the customer: how the product is delivered to customers can depend on whether it can be purchased with or without a veterinary prescription. In New Zealand, products registered as Restricted Veterinary Medicines are sold by registered sellers and prescribed by veterinarians to customers.
- 13.2 Elanco considers that barriers to entry and expansion across the animal health industry are relatively low, and reduced further once a product that has been developed by another manufacturer is off-patent. Market conditions are such that incumbents are generally constrained by the threat of new entry, including because it is possible to outsource all or part of the manufacturing, distribution and marketing of products to independent third parties, and in many cases the key products and formulations are off-patent. More particularly:
  - (a) R&D costs are significantly lower in the animal health industry than for human pharmaceuticals, meaning that a wide range of companies can invest in R&D. In the case of products where the active ingredients (or combinations of active ingredients or product formulation) are off-patent, R&D costs and time are significantly reduced.
    - Unlock and Fleeceguard/Saturate Gold (treatments for external parasites in sheep) were developed by Agvet, a New Zealand development and regulatory consulting company, and are marketed by Animal Health Direct and Ravensdown, respectively. The Unlock range was registered in October 2018;
    - (ii) Elanco understands that Donaghys is currently in late registration with a novel eprinomectin/levamisole combination treatment for roundworm in sheep;
  - (b) [], and Elanco uses a third party distributor (Provet) in New Zealand;
  - (c) there are a range of toll manufacturers providing services to suppliers to the New Zealand market e.g. Jaychem (Alleva), Nexan (PGGW, Virbac, Ravensdown and others), Argenta (MSD, Elanco, BI) and Chem Colour NZ (Alleva); and
  - (d) raw materials (including active ingredients) can easily be obtained from multiple suppliers.

#### Generic products

- 13.3 The regulatory processes associated with registering a generic product as a new product on the market is relatively straightforward. As a result, generics present a significant competitive constraint on the merging parties and can gain market share quickly.
- 13.4 There is a specific application process for registration of a competing product in New Zealand i.e. an equivalent generic product with the same active ingredient and use pattern as a product already in the New Zealand market.<sup>45</sup> The regime is mandated under the Agricultural Compounds

flumethrin) is comprised of active ingredients that have been used in the Advantage family since 1996 (in the case of imidacloprid), and for Bayer's Kiltix collar since 2003 (in the case of flumethrin). BAH's Claro otitis externa product's key innovation was to be the first single administration solution for otitis externa, avoiding the need for at-home administration. Claro (florfenicol, terbinafine, mometasone furoate) is also comprised of active ingredients that are all off-patent.

<sup>&</sup>lt;sup>45</sup> (Application type B1 "Identical to existing TNP [Trade Name Product]" or B2 "Similar to existing TNP").

and Veterinary Medicines (ACVM) Act 1997 and Regulations (together, the **ACVM**), and is administered by the Ministry of Primary Industries (**MPI**).

- 13.5 New copies of existing products must fulfil the same basic requirements, in terms of quality, as the original product. However, if the new copy can demonstrate that the formulation is the same or very similar to the pioneer product, the data requirements are significantly reduced as compared with an application for registration of 'innovator' products.
- 13.6 The ACVM also contains arrangements for harmonised registrations with Australia for companion animal products. If the product is registered in Australia, the applicant can consent to the Australian Pesticides and Veterinary Medicines Authority (**APVMA**) providing its assessment documents to MPI for its assessment. This streamlines the application process in New Zealand.
- 13.7 Registering a generic product can take little as 40 working days.<sup>46</sup> The cost of registering a generic is less than NZD 1,000 for an identical product, and less than NZD 3,000 for a 'similar' product.<sup>47</sup> A new entrant can either manufacture the product themselves or engage a third party to manufacture for them, such as toll manufactures Jay Chem, Argenta Chem Colour and BioCell.
- 13.8 There is a well-established history of new entrants into New Zealand undertaking this work and gaining registration where innovator products have succeeded and come off patent. For example:
  - (a) Milpro, registered by Virbac in 2016, is a generic of Elanco's Milbemax (registered 2002). The two products now [];
  - (b) there are approximately 15 generic copies of Elanco's innovator product Vetrazin Spray-On and 15 copies of Vetrazin Liquid registered in New Zealand. [];
  - (c) in the past two years alone there have been 11 new registrations of parasiticides for companion animals, and eight new registrations of parasiticides for sheep, with all bar three of these products available for sale in New Zealand:
    - Jurox, an Australian-based animal health company, entered the New Zealand sheep ectoparasiticide market in 2016. Jurox researches, develops and manufactures a wide range of animal health products and veterinary medicines which are sold throughout the world;
    - (ii) Alleva, a New Zealand based animal health company specialising in the development and marketing of novel animal health products, commenced operations in early 2011 and continues to register new products. For example, it has registered two mineralised oral drenches for the treatment of internal parasites in sheep in December 2018 and September 2019 respectively;
    - (iii) Laboratorios Calier, S.A., a Spanish animal health company, registered two Zipryan branded companion animal treatments for internal parasites in August 2018. These products contain the same active ingredients as Bayer's Drontal product; and
    - (iv) Neove Pharma Australia has recently registered two companion animal parasiticides, Neovet for Cats and Neovet for Dogs, in October 2018 and April 2019 respectively. These products contain the active ingredients (imidacloprid and moxidectin), in the same formulation as Bayer's Advocate.

<sup>&</sup>lt;sup>46</sup> <u>https://www.mpi.govt.nz/dmsdocument/11977.</u> Accessed 22 November 2019.

<sup>&</sup>lt;sup>47</sup> An 'identical' product is identical to an existing registered product (apart from the trade name), and a 'similar' product has the same active ingredient, formulation type, dose regime and use patterns as a registered product. https://www.mpi.govt.nz/dmsdocument/11977. Accessed 22 November 2019.

#### Innovator products

13.9 If a new product is a truly innovative product (i.e. new active constituent, or an existing active constituent in a new product with new claims or use patterns), then a full registration data package is required. The ACVM's requirements in this situation are broadly similar to Australia or the EU. For production animal products, local efficacy trials are expected. The costs of assessment are low, with ACVM's functions being partly subsidised by the government in order to encourage entry of innovator products to the New Zealand market. This lowers the entry and expansion barriers and makes New Zealand an attractive market for entry and expansion.

#### 14. Trade or industry associations

14.1 Relevant trade or industry associations that the Parties have involvement with are set out at **Annex 4**.

# Part E: Relevant Markets

#### 15. **Overlap between the Parties**

- 15.1 The Parties' products compete in the following broad areas:
  - (a) treatment of multi-celled parasites in companion animals;
  - (b) treatment of multi-celled and single celled parasites in production animals; and
  - (c) antimicrobials for use in production animals.

#### 16. The treatment of multi-celled parasites in companion animals

16.1 The Commission has not previously considered markets for the treatment of parasites in companion animals in the mergers context, although these markets have been considered by regulators in other jurisdictions, in particular by the Australian Competition and Consumer Commission (ACCC) (as well as the European Commission (EC)). There are differences in the approaches taken by these authorities, and Elanco considers that there is more than one plausible way to define markets for the treatment of parasites, depending on the particular facts of each case in each jurisdiction, including particular local market conditions.

#### Overlap in relation to multi-cell parasites

16.2 As noted above, there are two types of parasites: multi-cell and single cell. The Commission has not considered whether treatments for multi-cell and single cell parasites (in the production animal context) should comprise separate markets in relation to companion animals, although the EC has previously segmented markets between single cell and multi-cell parasiticides.<sup>48</sup> The Parties only overlap in the treatment of multi-cell parasites in companion animals and Elanco is content to follow the EC's decisional practice segmenting between single cell and multi-cell parasiticides in this case.

#### Single market for companion animal parasiticides

- 16.3 In previous cases, the ACCC has considered a single market for companion animal parasiticides (inclusive of both feline and canine parasiticides).<sup>49</sup> Elanco is following this approach in this case, and notes in particular:
  - (a) many brands within this market are used for both cats and dogs (e.g. BAH's Advantage and Drontal, and Elanco's Milbemax and Capstar);
  - (b) pricing is similar between species for the same product (e.g. the price of Advantage for Cats over 4kg and Advantage for Dogs over 4-10kg retail for approximately NZD 59.99 – NZD 54.99, respectively);<sup>50</sup>
  - (c) many cat-only products contain the same active ingredient(s) as dog-only treatments; and
  - (d) most manufacturers supply products for use in both dogs and cats.

<sup>49</sup> For example, see ACCC, Eli Lily – proposed acquisition of Novartis Animal Health, 19 November 2014 (<u>https://www.accc.gov.au/public-registers/mergers-registers/public-informal-merger-reviews/eli-lilly-proposed-acquisition-of-</u> novartis-animal-health). The European Commission has also previously considered this approach – see for example Case

novartis-animal-health). The European Commission has also previously considered this approach – see for example Case M.7277 *Eli Lilly/Novartis Animal Health*, paras. 14, 16-34, 64-127.

<sup>&</sup>lt;sup>48</sup> See for example, Case M.7917 Boehringer Ingelheim/Sanofi Animal Health Business, para. 142; Case M.4691 Eli Lilly/Novartis Animal Health (**Eli Lilly/Novartis**), para. 14; Case M.5476 Pfizer/Wyeth, para. 122; and Case M.4691 Schering-Plough/Organon Biosciences, para. 40.

<sup>&</sup>lt;sup>50</sup> <u>https://www.animates.co.nz/catalogsearch/result/?q=advantage</u>. Accessed 15 November 2019.

16.4 In light of the above, Elanco accepts that in New Zealand there are significant demand-side and supply-side similarities between dog and cat products, and accept the approach of the ACCC in finding that they should be considered to form part of the same market(s).

#### Interplay between endo, ecto and endecto products

- 16.5 The three main types of parasiticide are endo (to treat internal parasites), ecto (to treat external parasites) and endecto (to treat both internal and external parasites). Both the EC and ACCC have considered the relevant market definition by reference to these classifications. However, each authority has taken a slightly different approach, taking into account the specific facts of the case in the different jurisdictions. This indicates that local factors are likely to be important in determining the appropriate market definition in each case.
  - In the EC's most recent decision concerning multi-celled parasiticides, *Eli Lilly/Novartis Animal Health* (2014), treatments for companion animals were considered, without any definitive conclusion, on the basis of(a) ecto only, (b) endo only, (c) endecto only, (d) combined ecto/endecto and (e) combined endo/endecto.<sup>51</sup>
  - (b) Conversely, in considering the same transaction, the ACCC examined the transaction on the basis of (a) combined endo/endecto and (b) combined ecto/endecto markets.<sup>52</sup>
- 16.6 While it has not considered this issue in relation to companion animals, the Commission has previously considered the interplay between different parasiticides in relation to production animals. For example, in *Schering Plough/Merck* it defined a market for the treatment of internal parasites in production animals, which included ecto and endecto products.<sup>53</sup>
- 16.7 Elanco acknowledges this precedent, and notes that in New Zealand there is a degree of substitutability between endo and endecto, and ecto and endecto, products for companion animals, as consumers wishing to treat both internal and external parasites at the same time can use an endecto product. Whether a customer chooses an ecto or an endo product will be a function of the particular protection profile they seek to achieve, and the differentiating factors most influential to that customer (including price, duration of efficacy, application type, etc.).
- 16.8 In addition, the substitutability between endo, ecto and endecto products in New Zealand has increased over time as the relative price of endecto products vis-à-vis endo and ecto products has decreased. The price of endectos in New Zealand is comparable with (and in some cases more cost effective than) buying two single-treatment products. For example, a customer wanting to buy six months' worth of treatments to de-flea and de-worm a cat weighing 5kgs could choose to purchase:<sup>54</sup>
  - (a) a single six month pack of BAH's Advocate (for cats over 4kg), an endecto which treats fleas and worms monthly with a single spot-on application, for NZD 99.99; or
  - (b) a combination of two packs of MSD's Bravecto Spot-on (for cats 2.8 6.25kg), an ecto which treats fleas, for NZD 63.99 each, and Elanco's Milbemax (for cats), an endo which treats gastrointestinal (**GI**) worms, for NZD 43.99 (NZD 171.91 total).
- 16.9 Elanco therefore considers that, on the basis of local conditions in New Zealand, the supporting precedent from the ACCC, and the approach identified in previous Commission cases in relation

<sup>&</sup>lt;sup>51</sup> Case M.7277 *Eli Lilly/Novartis*. The EC has not come to a concluded view on whether endecto products should be considered in the same market as endo and ecto products.

 <sup>&</sup>lt;sup>52</sup> https://www.accc.gov.au/public-registers/mergers-registers/public-informal-merger-reviews/eli-lilly-proposed-acquisition-ofnovartis-animal-health. Accessed 21 November 2019.
 <sup>53</sup> Schering-Plough / Merck & Co [2009] NZCC 677 (Schering Plough/Merck). In Schering-Plough / Organon, the Commission

<sup>&</sup>lt;sup>53</sup> Schering-Plough / Merck & Co [2009] NZCC 677 (**Schering Plough/Merck**). In Schering-Plough / Organon, the Commission assessed the acquisition on the basis of an ecto market only, given that the merger parties in that case did not supply any endecto products. Its market enquiries in that case revealed, however, that endectos could be included in both the markets for treatment of internal and external parasites, respectively.

<sup>&</sup>lt;sup>54</sup> https://www.animates.co.nz/catalogsearch/result/?q=advantage. Accessed 28 November 2019.

to production animals, Elanco is content to proceed in this notification on the basis that there are relevant markets for:

- (a) the treatment of internal parasites in companion animals (including endo and endecto products); and
- (b) the treatment of external parasites in companion animals (including ecto and endecto products).
- 16.10 However, Elanco contends that it is not necessary to come to a definitive view on market definition. What is important is to recognise the constraints that the Parties face from rivals' products, whether these come from within a relevant market or from outside it.

No delineation by distribution channel

- 16.11 The ACCC and EC have in previous cases not delineated markets on the basis of distribution channel, and the Commission has not done so in relation to equivalent markets concerning production animals. Consistent with this decisional practice, Elanco contends that there is also no basis to do so in this case in New Zealand.
  - (a) The Parties' products are all available from veterinary clinics, pet stores and online.
  - (b) []
  - (c) All of Bayer's products are sold direct to its three wholesalers SVS, Provet and Fortis which then sell throughout New Zealand.
  - (d) None of the companion animal parasiticide products relevant to the assessment of the Proposed Transaction in New Zealand are classified as "vet only", and can be acquired through all channels.

No delineation by application method

- 16.12 The ACCC and EC have not in previous cases delineated markets on the basis of application method, and the Commission has not done so in relation to related markets in production animals. Consistent with this decisional practice, Elanco contends there is also no basis to do so in this case.
- 16.13 The Parties' experience is that the choice of application method largely comes down to personal preference and the circumstances of individual animals. Certain pet owners will prefer spot-on treatments for ease of application, while others will favour oral tablets or chewables (e.g. those with young children that may have regular contact with family pets). Similarly, some pets may not tolerate pills so topical applications may be more effective. Prices are determined having regard to this substitutability.

#### Markets are national

- 16.14 The ACCC and EC have in previous cases defined national markets, and the Commission has defined national markets in the related production animals markets. Consistent with this decisional practice, Elanco contends the markets are national in this case:
  - (a) the Parties' products and those of their competitors are available nationally;
  - (b) [];
  - (c) []; and

(d) there are no variations in conditions between provinces in New Zealand that give rise to significant pricing variations across regions.

#### 17. Treatment of multi-cell parasites in production animals

17.1 The Commission has previously considered markets for the treatment of multi-cell parasites in production animals. In both *Schering Plough/Organon* and *Schering Plough/Merck*, the Commission delineated markets by type of parasite (internal or external) and by species (sheep or cattle).

#### Delineation by species

- 17.2 The Parties only overlap in the treatment of multi-cell parasites in sheep and cattle. The Commission has previously delineated markets by animal species because (unlike companion animals):
  - (a) there are significant differences in the application method for different types of production animals, due to their different physical characteristics (and the different emphasis on particular parasites for each species); and
  - (b) there are very few ecto products that are registered for equivalent use across both sheep and cattle (being the two production animals previously considered by the Commission in this regard).
- 17.3 By contrast, in its latest decision (*Eli Lilly/Novartis*) the EC did not conclude on whether segmentation by species was appropriate, noting that certain products were suitable for multiple species.
- 17.4 Elanco is content to follow the Commission's established decisional practice in this area, and has accordingly assessed competition on the basis of separate markets for individual species.

The interplay between endo, ecto and endecto products

- 17.5 The Commission has previously defined separate markets for the treatment of internal and external parasites.<sup>55</sup>
- 17.6 Whether endecto products form part of a relevant production animal market can vary according to the circumstances of each case.
  - (a) In *Pfizer/Wyeth* and *Schering Plough/Merck*, the Commission included endo and endecto products in the same markets.
  - (b) In Schering Plough/Organon, the Commission assessed competition effects on the basis of an ecto market only, given that the merger parties in that case did not supply any endecto products. However, its market enquiries in that case revealed that endectos could be included in both the endo and ecto markets.
  - (c) In its most recent case in the animal health sector, *Eli Lilly/Novartis*, the EC left open whether production animal endos and endectos constitute two separate, or one combined, product market(s).
- 17.7 Elanco is content to follow the Commission's approach in previous cases and has defined markets for, separately, the treatment of external parasites, and the treatment of internal

<sup>&</sup>lt;sup>55</sup> Pfizer Inc./Wyeth Corporation [2009] NZCC 678, Schering-Plough/Merck.

parasites. However, as noted above, what is important is to recognise the constraints that the Parties face from rivals' products, whether they come from inside or outside each relevant market.

Interplay between broad and narrow spectrum products

- 17.8 Broad spectrum products are those that are indicated for the treatment of a wide variety of ailments (sometimes referred to as 'combo' products), whereas narrow spectrum products are used to treat a smaller number of ailments, and sometimes just a single ailment.
- 17.9 In relation to external parasites, the Commission has previously defined a single market for the treatment of lice and flies, on the basis that:<sup>56</sup>

"combination fly/lice products compete with single parasite products, creating a chain of substitution between fly-only and lice-only products. If combination fly/lice treatments were to be defined as a separate product market, then a hypothetical monopolist of combination treatments, when imposing a SSNIP, would likely face substitution to fly-only and lice-only treatments, such that these three groups of products would in fact be in the same market."

- 17.10 Elanco is content to follow the Commission's precedent and have assessed competition in external parasiticides on this basis.
- 17.11 In relation to internal parasites, in previous cases the Commission has found that parasites that are treated by narrow spectrum products can also often be treated by broad spectrum products<sup>57</sup> and has not delineated markets by broad or narrow indication. The ACCC and EC have similarly not, to date, segmented markets on this basis.
- 17.12 In the present case, Elanco's only parasiticide actively marketed for the treatment of internal parasites in cattle is Fasinex 24, a narrow spectrum product that only treats liver fluke.<sup>58</sup> BAH has a broad spectrum product that is indicated for the treatment of liver fluke, but also roundworm, lungworm, and lice and mites in cattle.
- 17.13 Given that the only material overlap between the indications of the Parties' products is in the treatment of liver fluke in cattle, Elanco contends that the most appropriate lens through which to assess competition in this particular transaction is a market for the treatment of liver fluke.

No delineation of the market by distribution, application method or geography

17.14 For substantively the same reasons as those outlined regarding the treatment of parasites in companion animals, Elanco contends that there is no basis to further delineate markets by distribution channel, application method or geography.

#### 18. Treatment of single cell parasites in production animals

- 18.1 The Commission has not expressly considered markets for products for the treatment of singlecell parasites (also known as anticoccidials) in production animals, although it has by implication excluded them from the markets for the treatment of multi-cell parasites.<sup>59</sup>
- 18.2 The EC has previously considered anticoccidials in relation to production animals. In *Eli Lilly/Janssen Pharmaceutica* (*Eli Lilly/Janssen*), the Commission considered anticoccidials for use in poultry.

<sup>&</sup>lt;sup>56</sup> Schering Plough/Merck at [64].

<sup>&</sup>lt;sup>57</sup> Schering Plough/Merck; Schering Plough/Organon.

<sup>&</sup>lt;sup>58</sup> Elanco has a broad spectrum treatment for internal parasites in sheep, Zolvix Plus, that has recently also been approved for use in cattle. [] Thus, while there is overlap between this product and BAH's broad spectrum product, this is not assessed in detail in this application. Given that the share increment would be tiny, [], no competition concerns can arise.

<sup>&</sup>lt;sup>59</sup> See, for example Pfizer Inc./Wyeth Corporation [2009] NZCC 678 and Schering-Plough/Merck.

18.3 Per the EC's decisional practice, Elanco considers that the market for production animal anticoccidials can be segmented on a species by species basis, given that different products are supplied for different species. Even where products carry a multispecies indication, the characteristics of the same products are specific to a particular species (for instance dose, weight/age restrictions and pathology). In this case, poultry is the only species for which both Parties market anticoccidial products in New Zealand. Accordingly, Elanco proceeds in this notification by reference to a market for the supply of anticoccidial treatments.

Segmentation by preventative and curative treatments

- 18.4 Elanco also considers that the poultry anticoccidials treatments should be further segmented into 'preventative' and 'curative' treatments.
- 18.5 The EC previously considered, without reaching a definitive conclusion, in *Eli Lilly/Janssen* that there are three types of coccidiosis products that could each potentially be segmented into different markets:
  - (a) coccidiosis vaccines, which trigger an immunological response against coccidia (preventative);
  - (b) coccidiostats, feed additives that are substances intended to inhibit protozoa (preventative); and
  - (c) coccidiosis treatments, approved as veterinary medical products, which contain a variety of active substances that target coccidiosis (curative for sporadic outbreaks, but could be used in certain preventative programmes).
- 18.6 In that case, the EC also considered the possibility of a separate market for preventative anticoccidial products overall (vaccines and coccidiostats), with curative coccidiosis treatments in a different market.
- 18.7 Elanco agrees with the EC's decision in *Eli Lilly/Janssen*. On this basis, the Parties' respective poultry anticoccidials would belong to different product markets i.e. preventative, feed additive anticoccidials (Elanco) and curative anticoccidials (BAH). Even if the Parties' products were included in the same market, they compete only very weakly with each other. Nevertheless, for completeness a competitive assessment of the Proposed Transaction on the basis of a single poultry anticoccidials market is set out further below.

#### 19. Antimicrobials in production animals

19.1 The Commission has previously considered antimicrobials for use in production animals in *Schering Plough/Organon*. In that case, it defined a market for antimicrobials encompassing all ruminant animals, although it did not need to reach a conclusion on market definition.<sup>60</sup> The ACCC and EC have similarly not previously come to a concluded view on product market definition in relation to antimicrobials.

#### Intra-mammary mastitis products comprise a separate market

19.2 Notwithstanding that it did not come to a concluded view on the scope of the market for antimicrobials for use in ruminant animals in *Schering Plough/Organon*, in the same case the Commission did consider that separate markets exist for the treatment of mastitis in, separately, dry and lactating cows. The Commission further found that products indicated to treat a wide variety of products, including mastitis, fall within the broader antimicrobials market.

<sup>&</sup>lt;sup>60</sup> Schering Plough/Organon at [125].

- 19.3 BAH offers a number of intra-mammary products for the treatment of mastitis. Elanco agrees with the Commission's decision in *Schering Plough/Organon* and contends that, in this case, such mastitis products comprise a separate market.
  - (a) The delivery method being intra-teat is significantly different from the antimicrobials offered by the Elanco, which are intra-muscular injections.
  - (b) Intra-mammary products only treat mastitis, and are not substitutable for more general antimicrobials that treat a wide variety of ailments.
  - (c) The active ingredients in BAH's intra-mammary suspensions belong to a different class of chemicals (penicillin) to Elanco's product (macrolide).

Ruminants and non-ruminant animals

- 19.4 The Parties both have antimicrobial products indicated for use in both ruminant and non-ruminant animals (pigs).
- 19.5 Consistent with the Commission's past decisional practice, Elanco is content to segregate the market into ruminant and non-ruminant for the purposes of this clearance application. In relation to non-ruminant antimicrobials, the Parties both have products indicated for use in pigs. However:
  - (a) BAH's Baytril product is heavily regulated and cannot be used as a 'first line' antibiotic treatment it can only be used once other treatments have failed;
  - (b) Baytril also belongs to a different chemical class to Elanco's product and is indicated for significantly different ailments in pigs; and
  - (c) BAH has also earnt [] from Baytril (NZD ~[] per annum for each of the past three years).
- 19.6 As such, the Parties' antimicrobial products for non-ruminant animals do not compete closely. Moreover, BAH's product has a relatively small position in the market. Competition issues therefore cannot arise in relation to antimicrobials in non-ruminant animals, and this overlap is not discussed further in this application.

#### 20. Conclusion on market definition

- 20.1 Having regard to the above, Elanco has assessed the Proposed Transaction by reference to the following markets:
  - (a) the national market for the supply of internal parasite treatments for companion animals;
  - (b) the national market for the supply of external parasite treatments for companion animals;
  - (c) the national market for the supply of internal parasite treatments for sheep;
  - (d) the national market for the supply of external parasite treatments for sheep;
  - (e) the national market for supply of liver fluke treatments for cattle;
  - (f) the national market for the supply of anticoccidials for poultry; and
  - (g) the national market for the supply of antimicrobials for ruminant animals.

# Part F: Competitive Assessment

# 22. The counterfactual

- 22.1 Following a strategic review of its business, and as part of a broader restructuring, Bayer AG announced in November 2018 its intention to sell BAH and exit the animal industry.
- 22.2 If the Proposed Transaction does not proceed, []. As such, the status quo is the appropriate counterfactual in this case.

# 23. Note on market shares

- 23.1 [].
- 23.2 []:
  - (a) [];
  - (b) [];<sup>61</sup> and
  - (C) [].
  - []
- 23.3 [].
- 23.4 [].
  - (a) [].
  - (b) [].

### **OVERLAP 1 – TREATMENT OF INTERNAL PARASITES IN COMPANION ANIMALS**

#### 24. Introduction

- 24.1 Internal parasites live in an animal's internal organs such as the gut or the heart, and include gastro-intestinal roundworms and tapeworms, whipworms, hookworms, lungworms and liver flukes.
- 24.2 Owners of companion animals looking for protection against internal parasites can choose from either endo products (which treat internal parasites only) or endecto products (which treat both internal and external parasites).
- 24.3 Whether a customer chooses an endo or an endecto product will be a function of their particular protection needs, and how they decide to meet those needs. As noted above, the Parties consider that broad spectrum endectocide products can be price competitive (and in some cases more cost effective) compared to buying multiple treatment products.

#### 25. The Parties' products

- 25.1 Elanco offers two relevant products in New Zealand: **Milbemax** (for the prevention of GI worms) and **Comfortis Plus** (for the prevention of GI worms in dogs only). Comfortis Plus is also indicated for the treatment of fleas.
- 25.2 BAH offers four relevant products: **Drontal** (for the treatment of GI worms), **Droncit** (for the treatment of tapeworm), **Profender** (for the treatment of GI worms in cats only) and **Advocate** (for the treatment of GI worms and feline lungworm). Advocate is also indicated for the prevention of fleas, lice, sarcoptic mange and ear mites.

#### 26. Competitive assessment

The Parties are not close competitors

- 26.1 The Parties' product ranges have different emphases and therefore most of their products do not compete closely.
  - (a) BAH's products are indicated for the treatment of internal parasites, whereas Elanco's products are mainly focussed on prevention.
  - (b) Elanco's internal parasite products are all consumed orally as tablets or chewables. While some of BAH's internal parasite protection products are consumed orally, the product/brand which accounts for the overwhelming majority of Bayer's sales in this space ([]) is applied topically as a spot-on.

# Table 2 - Parties' products indicated for the treatment of internal parasites in companion animals

Product (active ingredient)	Indication Application		Frequency of application	
Elanco				
Milbemax (milbemycin oxime; praziquantel)	Prevention of GI worms	Tablet	3 monthly	
Comfortis Plus <sup>62</sup> (Spinosad; milbemycin oxime)	Prevention of GI worms <sup>63</sup>	Chewable tablet	Monthly	
ВАН				
Drontal (pyrantel embonate; praziquantel;			3 monthly	
Drontal Dog (pyrantel embonate; praziquantel; febantel) <sup>64</sup>			3 monthly	
Droncit (praziquantel)	Treatment of tapeworm	Tablet	3 monthly	
Profender <sup>65</sup> (emodepside; praziquantel)	Treatment of GI worms	Topical drops	3 monthly	
Advocate (imidacloprid; moxidectin)	Treatment of GI worms and feline lungworm <sup>66</sup>	Topical drops	Monthly	

Elanco's market position is small and declining

26.2 Table 3 below sets out market shares based on Baron data and supplemented by information from the Parties.

 $<sup>^{\</sup>rm 62}$  Indicated for dogs only. [ ]

<sup>&</sup>lt;sup>63</sup> Also indicated for the treatment of fleas, and prevention of heartworm, though heartworm does not exist in New Zealand. Does not treat tapeworm.

<sup>&</sup>lt;sup>64</sup> Indicated for dogs only.

<sup>&</sup>lt;sup>65</sup> Indicated for cats only.

<sup>&</sup>lt;sup>66</sup> Also indicated for the treatment and prevention of fleas, lice and ear mites and mange in dogs. Does not treat tapeworm.

Competitor	Revenue (NZD)	Est. share	2018 est. revenue	2018 est. share	2017 est. revenue	2017 est. share
Elanco	[]	[]	[]	[]	[]	[]
BAH	[]	[]	[]	[]	[]	[]
Merged entity	[]	[]	[]	[]	[]	[]
Boehringer Ingelheim	[]	[]	[]	[]	[]	[]
MSD	[]	[]	[]	[]	[]	[]
Zoetis	[]	[]	[]	[]	[]	[]
Virbac	[]	[]	[]	[]	[]	[]
Masterpet	[]	[]	[]	[]	[]	[]
Merial	[]	[]	[]	[]	[]	[]
Others	[]	[]	[]	[]	[]	[]
Total	[]	100.00%	[]	100.00%	[]	100.00%

Table 3 - Estimated market shares – treatment of internal parasites in companion animals<sup>67</sup>

- 26.3 On the basis of the above, it is clear that Elanco has only a very limited presence in the companion animal internal parasite market in New Zealand, with an estimated share of less than []. At present, Elanco provides only a weak competitive constraint on the market. Other manufacturers, discussed below, provide a far stronger constraint. Further, the competitive position of each of Elanco's companion animal internal parasite products has been declining.
  - (a) Milbemax is a legacy product. It was registered for use in New Zealand in 2002 and it has long been off patent. The generic version, Virbac's Milpro, [].
  - (b) Similarly, [] The [] also needs to be put in the context of an overall market that is growing.

The merged entity will continue to be constrained by strong competitors

- 26.4 There are a range of large, well-resourced competitors in this space that impose a significant constraint on the market. A full list of the many products available on the market is set out in **Annex 8A**, but to highlight the market leaders:
  - (a) **Boehringer Ingelheim** has two market-leading products: Nexgard Spectra and Broadline. Both products achieve significant sales in New Zealand, each generating [] Nexgard Spectra in particular has seen strong performance over the past three years, []
  - (b) **MSD**'s Bravecto Plus Spot On is a relatively new entrant that has gained significant market share in a very short space of time. In the first year of its introduction in New Zealand, []
  - (c) **Zoetis**, a large international player noted above, has three endectocide products, two of which (Revolution Cat and Revolution Dog) are well established with a combined market share of almost []. It has also launched in the past 12 months its Revolution Plus product, which in its first year has already captured [] market share.
  - (d) **Virbac** supplies two leading dog and cat products in New Zealand, Milpro (a Milbemax generic) and the Endogard range, both of which compete closely with the Parties' products.

<sup>&</sup>lt;sup>67</sup> Notes on market share estimates: there are several products not included in the Baron data for this category, Including Popantel F (supplied by Jurox), Aristopet's range of worming products (supplied by Masterpet), and Pet Science All Wormer for Dogs and Cats. BAH has estimated these and other undocumented products ('Others') comprise approximately [[]] of sales of endos ([] of the sales of endos/endectos combined. []. Panoramis has also been discontinued and had no sales for 2019, but its sales for 2018 and 2017 have been included in the shares above.

In particular, as noted above Milpro has rapidly gained market share, [], since its introduction into New Zealand in late 2016.

(e) **Jurox's** Popantel F is a generic version of Drontal, an all wormer that controls roundworms, whipworms, hookworms and tapeworms and competes closely with the Parties' products.

New and potential entry and expansion

- 26.5 There are three key chemical classes of endos: avermectins, benzimidazoles and isoquinolines. These classes were developed several decades ago, so are no longer patent protected, meaning that endo generics are widely available.
- 26.6 As can be seen above, new entrants are able to come into the market and have an immediate impact on existing players.
  - (a) MSD which did not previously have a product in this market has been able to [].
  - (b) Virbac recently launched Milpro, a Milbemax generic in New Zealand, and has successfully [] and continued to grow in each of its three years on the market.
  - (c) Zoetis has brought a new product to market (Revolution Plus) which has achieved significant sales in its first 12 months.
  - (d) In the past two years, five separate new products have been registered for use in New Zealand, of which four have been launched and are on the market.<sup>68</sup>
    - In August 2018, Laboratorios Calier registered two Zipryan branded companion animal endoparasiticides. These products contain the same active ingredients as Bayer's Drontal (although in a slightly different formulation).
    - (ii) Neove Pharma Australia has recently registered two companion animal parasiticides, Neovet for Cats and Neovet for Dogs, in October 2018 and April 2019 respectively. These products contain the active ingredient (imidacloprid and moxidectin) in the same formulation as Bayer's Advocate, and is a spot-on treatment to treat fleas and worms.
- 26.7 The next anticipated market entrant in this space is a broad spectrum endecto version of Zoetis' Simparica (Simparica Trio), which will feature indications for internal parasites. The product is currently estimated to be in the New Zealand market [].

#### Countervailing power of customers

26.8 This market contains a broad range of competing suppliers. The key customers in this market such as veterinarian practices and pet stores all make high volume purchases, and all have the ability to switch between these suppliers if they are unhappy with the price or service offering made available to them. The countervailing power of these customers will continue to represent a considerable constraint on the parties post merger. This is discussed in more detail at section 54 below.

<sup>&</sup>lt;sup>68</sup> Zipyran Plus Flavour and Zipyran XL (Calier), Revolution Plus (Zoetis), Prazitel Cat Tablets (Chanelle) and Neovet for Cats (Neove, not currently sold in New Zealand).

# **OVERLAP 2 – TREATMENT OF EXTERNAL PARASITES IN COMPANION ANIMALS**

#### 27. Introduction

- 28. External parasites (ectoparasites) live and breed on the skin or in the fur/hair of animals, and include lice, fleas, ticks and mites. Ectoparasites can damage host animals in a number of ways, including abstraction of nourishment (blood sucking), production of toxins, traumatic damage or discomfort, and secondary infection of wounds.
- 29. As with internal parasites, owners of companion animals can choose from either ecto products or endecto products. Whether a customer chooses an ecto or an endecto product will be a function of their particular protection needs.

#### 30. The Parties' products

- 30.1 Elanco currently sells three products into New Zealand: **Capstar** (for the treatment of fleas and ticks), **Comfortis** (for the treatment and prevention of fleas)<sup>69</sup> and **Comfortis Plus** (for the treatment of fleas in dogs only).<sup>70</sup> Comfortis Plus is also indicated for the treatment of GI worms. [].<sup>71</sup>
- 30.2 BAH sells three products in New Zealand: **Seresto** (a collar for the prevention of fleas and ticks), **Advantage** (for the prevention and treatment of fleas) and **Advocate** (for the prevention and treatment of fleas). Advocate is also indicated for the treatment of GI worms and feline lungworm.

30.3 []

<sup>&</sup>lt;sup>69</sup> []

<sup>&</sup>lt;sup>70</sup> As noted above, [] <sup>71</sup> []

Table 4 - Parties' products indicated for the treatment of external parasites in companion animals

Product (active ingredient)	Indication	Application	Frequency of application
Elanco			
Capstar (nitenpyram)	Treatment of fleas	Tablet	On any day fleas are present
Comfortis (spinosad)	Treatment and prevention of fleas	Chewable tablet	1 month
Comfortis Plus <sup>72</sup> (spinosad; milbemycin oxime)	Treatment of fleas <sup>73</sup>	Chewable tablet	1 month
ВАН			
Seresto (imidacloprid and flumethrin)	Prevention of fleas and ticks	Topical collar	8 months
Advantage (imidacloprid)	Prevention and treatment of fleas	Topical (spot on)	1 month
Advocate (imidacloprid; moxidectin)	Treatment and prevention of fleas, lice and ear mites <sup>74</sup>	Topical drops (spot on)	1 month

#### 31. **Competitive assessment**

The Parties are not close competitors

- 31.1 The Parties' products do not compete closely, for several reasons.
  - BAH's Seresto is a collar that offers up to eight months' protection against fleas and ticks. (a) The longest lasting protection offered by any comparable Elanco product is one month. The convenience of a 'set and forget' collar makes Seresto attractive to many consumers vis-à-vis Elanco's products.
  - BAH's Advocate offers protection against a wider range of parasites than Elanco's closest (b) equivalent product, Comfortis Plus.
  - (c) The product ranges have different application methods, with Elanco's products coming in tablet or chewable tablet form while BAH's are topical. As previously noted, application method can be an important determinant for some consumers, who may be unwilling (or unable, due to their pet's preferences) to switch between oral and topical treatment methods.

<sup>&</sup>lt;sup>72</sup> Indicated for dogs only. []

<sup>&</sup>lt;sup>73</sup> Also indicated for the prevention of GI worms, and the prevention of heartworm, although heartworm does not exist in New Zealand. <sup>74</sup> Also indicated for the prevention of GI worms and treatment of lungworm. Treatment of lice is in dogs only.

#### The combined share of the Parties is modest and the increment is de minimis

31.2 The combined share of the Parties is estimated to be ~[], while Elanco's share is estimated to be just ~[], []. Given the proportionately low combined shares, and the *de minimis* increment, the Proposed Transaction does not give rise to any competition issues in this market.

Competitor	2019 est. revenue	2019 est. share	2018 est. revenue	2018 est. share	2017 est. revenue	2017 est. share
Elanco	[]	[]	[]	[]	[]	[]
BAH	[]	[]	[]	[]	[]	[]
Merged entity	[]	[]	[]	[]	[]	[]
MSD	[]	[]	[]	[]	[]	[]
Boehringer Ingelheim	[]	[]	[]	[]	[]	[]
Masterpet	[]	[]	[]	[]	[]	[]
Zoetis	[]	[]	[]	[]	[]	[]
Merial	[]	[]	[]	[]	[]	[]
Others	[]	[]	[]	[]	[]	[]
Total	[]	100.00%	[]	100.00%	[]	100.00%

#### Table 5 - Estimated market shares - treatment of external parasites in companion animals<sup>75</sup>

The merged entity will continue to face strong competition

- 31.3 In addition to not being close competitors, the Parties having a modest combined market share, and the Proposed Transaction giving rise to a very small share increment, the merged entity will continue to face strong competition from a host of well-resourced and strong competitors, including Boehringer Ingelheim, MSD, Masterpet and Zoetis.
  - (a) MSD's Bravecto is the leading product in this category. It is indicated for the treatment of both fleas and ticks, and comes in both a chewable tablet for dogs and a spot-on treatment for dogs and cats. It offers the longest lasting protection of any spot-on product on the market, with six months' flea protection in dogs using the Spot-on variation. The Bravecto Plus variation (an endecto that also offers protection against GI worms) also competes strongly in this market.
  - (b) **Boehringer Ingelheim**'s NexGard, NexGard Spectra, Frontline and Broadline ranges all compete strongly in this space, with a combined estimated share of [].
  - (c) Masterpet's []
  - (d) **Zoetis**' Revolution and Simparica products are both established, strong brands in the market, and Revolution Plus has been successfully launched, quickly gaining market share.
- 31.4 A list of competitor products available in the market, illustrating the extensive choice available to consumers, is at **Annex 8B**.

31.5 []

<sup>&</sup>lt;sup>75</sup> Notes on market shares estimates: Baron does not record sales for [] The estimate for []'s sales are based on Bayer's understanding that [] accounts for ~[] of sales made in supermarkets ([] accounts for virtually all of the other ~[]). []. Panoramis has also been discontinued and had no sales for 2019, but its sales for 2018 and 2017 have been included in the shares above. Sales of the discontinued Elanco product Prac-Tic have not been included in the calculation of market shares as there is no equivalent Elanco product.

New and potential entry and expansion

- 31.6 As with products for the treatment of internal parasites, new entrants are able to come into the market and have an immediate impact.
  - (a) Bravecto Plus and Revolution Plus have both commenced sales in New Zealand in the last twelve months and have been able to establish significant market share.
  - (b) In the past two years, there have been seven new products registered for use in New Zealand, of which five are now on the market.<sup>76</sup>
    - (i) Virbac registered two Effipro products in December 2017 that are currently available in New Zealand: Effipro Duo for Dogs and Effipro Duo for Cats.<sup>77</sup> These products are indicated for the treatment and prevention of fleas and claim a longer-lasting protection against fleas than all of the Parties' products with the exception of Seresto.
    - (ii) Neovet Pharma Australia has registered two companion animal parasiticides, Neovet for Cats and Neovet for Dogs, in October 2018 and April 2019 respectively. These products contain the active ingredient imidacloprid and moxidectin, in the same formulation as Bayer's Advocate, and are a spot-on treatment to treat fleas and worms. Neither of these products is yet in New Zealand, but they have already been registered for use here.

#### Countervailing power of customers

31.7 This market contains a broad range of competing suppliers. The key customers in this market such as veterinarian practices and pet stores all make high volume purchases, and all have the ability to switch between these suppliers if they are unhappy with the price or service offering made available to them. The countervailing power of these customers, which has been previously recognised by the Commission, will continue to represent a considerable constraint on the parties post merge. This is discussed in more detail at section 54 below.

 <sup>&</sup>lt;sup>76</sup> Neove Imidacloprid Spot On, Neovet for Dogs\* and Neovet for Cats\* (Neove), Effipro Duo for Dogs and Effipro Duo for Cats (Virbac) and Inca Pestene Insect Powder (Inca). \*denotes not currently sold in New Zealand.
 <sup>77</sup> https://nz.virbac.com/products/parasite-treatments/effipro-duo.

## **OVERLAP 3 – TREATMENT OF INTERNAL PARASITES IN SHEEP**

#### 32. Introduction

32.1 As noted above, internal parasites live in an animal's internal organs such as the gut or the heart, and include gastro-intestinal roundworms and tapeworms, whipworms, lungworms and liver flukes. Typical effects of worms include decreased appetite, decreased feed conversion and mild weight loss. Diarrhoea, weight loss and even death can result.

#### 33. The Parties' products

- 33.1 Elanco offers two products in this market: **Zolvix Plus** (for the prevention and treatment of roundworms) and **Pyrimide** (for the prevention and treatment of roundworms, lungworm, itchmite and nasal bot (larval stages)). []
- 33.2 BAH offers only one product that is indicated for the treatment of internal parasites in sheep: Bomatak C, an oral drench indicated for the treatment of roundworms, lungworm and tapeworm in sheep, cattle, deer and goats.<sup>78</sup> However, in practical terms this product cannot properly be considered a competitor to Elanco's products in this market. Bomatak C contains the active ingredient oxfendazole. There is widespread resistance to this active in New Zealand, such that it is rarely now used for the treatment of internal parasites in sheep or cattle. It is almost exclusively targeted to equine usage.

Prevention and treatment of roundworms	Sheep, cattle	Oral drench	14 days
Treatment and control of roundworms, lungworm <sup>81</sup>	Sheep	Oral drench	21 days
Cattle: Prevention of roundworms, lungworm and tapeworm	Horses, sheep, cattle, deer and goats	Oral drench	Cattle: 10 days
	treatment of roundworms Treatment and control of roundworms, lungworm <sup>81</sup> Cattle: Prevention of roundworms, lungworm and	treatment of       Sheep         Treatment and       Sheep         control of       Sheep         roundworms,       Horses, sheep,         Cattle: Prevention of       Horses, sheep,         roundworms,       cattle, deer and         ungworm and       goats	treatment of roundworms       Sheep       Oral drench         Treatment and control of roundworms, lungworm <sup>81</sup> Sheep       Oral drench         Cattle: Prevention of roundworms, lungworm and       Horses, sheep, cattle, deer and goats       Oral drench

#### Table 6 - Parties' products indicated for the treatment of internal parasites in sheep

<sup>78 [ ]</sup> 

<sup>&</sup>lt;sup>79</sup>[] <sup>80</sup>[]

<sup>&</sup>lt;sup>81</sup> Also indicated for the treatment of itchmite and nasal bot (larval stages).

#### 34. Competitive assessment

- 34.1 The Proposed Transaction will not raise concerns in this market, for the below reasons.
  - (a) As noted above, BAH's only product, Bomatak C, is rarely used for the treatment of internal parasites in either sheep or cattle, due to widespread resistance to its active ingredient oxfendazole, and a range of significantly more effective products on the market.
  - (b) The products each have a [] share of this market, in particular [], which has a [] share of less than ~[] – and this assumes that all the turnover of this product is attributable to use in sheep which, as discussed above, would significantly over-state its position in the market. Elanco's share is only ~[].
  - (c) The Parties face strong competition from market leader, Boehringer Ingelheim, which has a share of ~[], along with Zoetis (~[]) and MSD (~[]). Virbac and Ravensdown also supply products in this category.

Competitor	2019 est. revenue	2019 est. share	2018 est. revenue	2018 est. share	2017 est. revenue	2017 est. share
Elanco	[]	[]	[]	[]	[]	[]
BAH	[]	[]	[]	[]	[]	[]
Merged entity	[]	[]	[]	[]	[]	[]
Boehringer Ingelheim	[]	[]	[]	[]	[]	[]
Zoetis	[]	[]	[]	[]	[]	[]
MSD	[]	[]	[]	[]	[]	[]
Merial <sup>83</sup>	[]	[]	[]	[]	[]	[]
Nexan	[]	[]	[]	[]	[]	[]
Alleva	[]	[]	[]	[]	[]	[]
Ravensdown	[]	[]	[]	[]	[]	[]
Donaghys	[]	[]	[]	[]	[]	[]
Virbac	[]	[]	[]	[]	[]	[]
Total	[]	100.0%	[]	100.0%	[]	100.0%

## Table 7 - Estimated market shares - internal parasite treatments in sheep<sup>82</sup>

#### Countervailing power of customers

34.2 This market contains a broad range of competing suppliers. The key customers in this market such as veterinarian practices and rural supply stores all make high volume purchases, and all have the ability to switch between these suppliers if they are unhappy with the price or service offering made available to them. The countervailing power of these customers, which has been previously recognised by the Commission, will continue to represent a considerable constraint on the parties post merger. This is discussed in more detail at section 54 below

<sup>&</sup>lt;sup>82</sup> Notes on market share estimates: sales of products supplied by [[ ]] are not recorded in Baron. Elanco has estimated market shares and revenues for these products based on its industry experience. [ ] The products of this competitor have not been included in Elanco's estimate of market shares. [ ]Taking into account these estimates would obviously result in reductions in the Parties' shares.

<sup>&</sup>lt;sup>83</sup> Acquired by Boehringer Ingelheim in 2017.

## **OVERLAP 4 – TREATMENT OF EXTERNAL PARASITES IN SHEEP**

#### 35. Introduction

- 35.1 As noted above, external parasites (ectoparasites) live and breed on the skin or in the fur/hair of animals, and include flies, lice, fleas, ticks and mites. They can damage host animals in a number of ways, including abstraction of nourishment (blood sucking), production of toxins, traumatic damage or discomfort, and secondary infection of wounds.
- 35.2 The Parties overlap in treatments for flystrike and lice in sheep.
  - (a) Flystrike results from blowfly maggots (hatched from eggs laid in the moist wool of sheep) hatching and consuming the sheep's flesh. Flystrike is extremely painful for sheep. Sheep afflicted by flystrike exhibit increased temperature, rapid breathing and weight loss caused by loss of appetite. If untreated, flystrike can lead to blood poisoning and death.
  - (b) Lice feed on flakes of dead skin, secretions and bacteria normally found at the surface of the skin. This causes irritation and results in sheep biting, rubbing and pulling at their wool.
- 35.3 The choice of which product to use includes the below considerations.
  - (a) <u>Rotation of active ingredients</u>: a farmer will consider rotating products with different active ingredients to reduce the risk of insecticidal resistance.
  - (b) <u>Duration of effectiveness</u>: some products will be indicated to prevent flystrike for a longer duration.
  - (c) <u>Wool type/length</u>: some spray/pour-on products are only indicated for use in certain types of breeds, or certain wool length 'off shears' (time since the sheep was last shorn).
  - (d) <u>Meat withholding period</u>: this is the minimum time after an animal is treated with a medicine before it can be legally slaughtered for human consumption.
  - (e) <u>Cost</u>: farmers look to treat sheep in the most cost-efficient way possible.
- 35.4 Of particular importance is the need to ensure that parasites do not develop resistance to active chemicals. Resistance can be defined as a genetic change in response to exposure to a pesticide that enables a parasite to survive doses that would normally kill all trace of the parasite. Continued use of the same chemical or chemical group allows the resistant parasite to survive, breed and increase in numbers until they make up the majority of the population.
- 35.5 This is an increasingly common problem, and so farmers will consider rotating active ingredients or chemical classes on sheep, which means products from different chemical classes are considered to be complementary and competition predominantly occurs between products *within* each chemical class rather than *between* chemical classes. Reflecting this, product literature for Elanco's Extinosad Pour-On provides guidance on the rotation of products containing different active ingredients.<sup>84</sup> Similarly, Elanco's Australian Extinosad webpage<sup>85</sup> includes an interactive graphic with a rotation button to illustrate to farmers how to rotate between the following chemical classes (including to rotate to products supplied by Elanco's competitors).

<sup>&</sup>lt;sup>84</sup> Enclosed with this application.

<sup>&</sup>lt;sup>85</sup> See <u>https://www.extinosad.com.au/</u>.

## 36. The Parties' products

36.1 The Parties' products and their key characteristics are set out in Table 8, below.

Table 8 - Parties'	products indicated for the treatment of external parasites in she	ер
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Brands / active ingredients	Label indication	Wool type	Application	Label protection period flystrike	Meat withholding period
Elanco					
CLiK (dicyclanil)	Prevention of flystrike	All	Spray / Pour on	Up to 18 weeks	35-56 days
CLiKExtra (dicyclanil)	Long term prevention of flystrike	All	Spray / Pour on	14 – 26 weeks	21 days
CLiKZiN (dicyclanil)	Prevention of flystrike	All	Spray / Pour on	6 – 9 weeks	7 days
Vetrazin Liquid (cyromazine)	Prevention of flystrike	All	Saturation / Jetting	Up to 12 weeks	7 days
Vetrazin SO (cyromazine)	Prevention of flystrike (typically used at docking stage)	All	Spray / Pour on	Up to 6 weeks	7 days
Cyrex (cyromazine; spinosad) <sup>86</sup>	Prevention and treatment of flystrike; prevention of lice; treatment of lice	Lice prevention: coarse wool; lice treatment: long wool	Saturation / Jetting	Up to 12 weeks	7 days
Extinosad Liquid <sup>87</sup> (spinosad)	Treatment and short term prevention of flystrike; treatment of lice; prevention of lice	Lice prevention: coarse wool; lice treatment: long wool merino	Saturation / Jetting	2-4 weeks	Nil
Expo (spinosad) <sup>88</sup>	Prevention of lice	All	Spray / Pour on	N/A	Nil
BAH					
Maggo (propetamphos)	Treatment of flystrike; prevention of re-strike as a docking medication	All	Saturation / Jetting	N/A	14 days
Seraphos (propetamphos)	Prevention of flystrike and ticks; treatment of lice and keds	All	Saturation / Jetting	Not on label	14 days
Zapp Encore (trifllumuron; imidacloprid)	Treatment and prevention of flystrike; treatment and prevention of lice	Flystrike: coarse wool	Spray / Pour on	At least 8 weeks	56 days

[]

## 37. Competitive assessment

The Parties' ranges are largely complementary and do not compete closely

- 37.1 As can be seen in the above table, the Parties' product ranges have different characteristics they do not compete closely, and are more complementary in nature.
  - (a) The focus of Elanco's product range is the prevention of flystrike. By contrast, BAH's product range is focussed more on lice treatment and prevention, it only having a single

flystrike-only product (which is for treatment of maggots on sheep, and which has flystrike preventative qualities as a docking medication only).

- (b) Almost all of Elanco's flystrike prevention products have a longer period of protection than BAH's equivalent products.
- (c) With the exception of long term flystrike protection products CLiK and CLiK Extra (for which BAH does not have an equivalent product) Elanco's flystrike prevention products have a shorter meat withholding period than BAH's equivalent products.
- (d) Zapp Encore is now predominantly used to treat lice, and is becoming progressively less effective against flystrike due to resistance to the active ingredient triflumuron. []
- 37.2 The Parties' products also have different active ingredients, which means that they are more commonly used in a complementary fashion, as part of a 'rotation' of products in order to avoid parasite resistance in a flock.
- 37.3 In this regard, Elanco's CLiK range and Vetrazin products are part of the insect growth regulator (IGR) chemical class and the Extinosad and Expo products are part of the spinosyn chemical class. By contrast, BAH's Maggo and Seraphos products are part of the organophosphate chemical class.<sup>89</sup>
- 37.4 Zapp Encore is the only BAH product that contains a chemical from the same class as Elanco's products, and contains the IGR triflumuron (as well as the neonicotinoid, imidacloprid).
- 37.5 In relation to IGRs, nearly all suppliers of external parasiticides in New Zealand offer a product in this class, including Boehringer Ingelheim (triflumuron, cyromazine, ivermectin, diflubenzeron), Jurox (dicyclanil), MSD (diflubenzeron), Nexan (cyromazine), Ravensdown (diflubenzeron, cyromazine) and Seneca (cyromazine).

The Parties will continue to face strong competition from existing competitors

- 37.6 The Parties will continue to face strong competition from multiple, well-resourced and strong 'big brand' competitors post-merger, as well as comparable products from other suppliers, including Boehringer Ingelheim and MSD.
- 37.7 Table 9, below, sets out Elanco's estimates of market shares, based on Baron data and its experience in the market. The Baron dataset excludes a significant number of products in this market that are available for sale in New Zealand. [], the below share estimates are based on Elanco's estimates.

<sup>86 []</sup> 

<sup>&</sup>lt;sup>87</sup> Predominantly used for lice.

<sup>&</sup>lt;sup>88</sup> [ ]

<sup>&</sup>lt;sup>89</sup> Regulation and safer alternative chemicals have seen the use and availability of organophosphates decrease in New Zealand, and these two products are the only two products remaining on the market, after diazinon-based products were withdrawn from the sale in New Zealand in 2016.

Competitor	2019 est. revenue	2019 est. share	2018 est. revenue	2018 est. share	2017 est. revenue	2017 est. share
Elanco	[]	[]	[]	[]	[]	[]
BAH	[]	[]	[]	[]	[]	[]
Merged entity	[]	[]	[]	[]	[]	[]
Boehringer Ingelheim	[]	[]	[]	[]	[]	[]
MSD	[]	[]	[]	[]	[]	[]
Ravensdown	[]	[]	[]	[]	[]	[]
Merial	[]	[]	[]	[]	[]	[]
PGGW (Nexan)	[]	[]	[]	[]	[]	[]
Donaghys	[]	[]	[]	[]	[]	[]
Jurox	[]	[]	[]	[]	[]	[]
Animal Health Direct	[]	[]	[]	[]	[]	[]
Alleva	[]	[]	[]	[]	[]	[]
Norbrook	[]	[]	[]	[]	[]	[]
Total (est.)	[]	100.00%	[]	100%	[]	100%

#### Table 9 - Estimated market shares - external parasite treatments in sheep<sup>90</sup>

- 37.8 **Boehringer Ingelheim** has a strong presence in this market and will continue to constrain the Parties post-merger. It has a range of products in this area substitutable for those supplied by the Parties for the treatment of both flies and lice, including the Exit and Cyrazin ranges.
- 37.9 MSD also has a strong presence in this market, with established products, Magnum, Vanquish, Wipeout and Zenith, all of which off comparable protection against flystrike and lice to products supplied by the Parties. MSD has recently been particularly aggressive in relation to the pricing of its Magnum product, which contains the IGR diflubenzeron and competes closely with the IGR products offered by the Parties (Elanco's CLiK range and Vetrazin, and BAH's Zapp Encore). For example, 20L of Magnum fly/lice pour on can be purchased from Ruralco for NZD 469.20, whereas 20L of the Bayer equivalent Zapp Encore costs NZD 700.90.<sup>91</sup> MSD provides a "louse free guarantee" for its Magnum product and promotes up to 8 weeks flystrike control.
- 37.10 **Generic manufacturers** impose a significant constraint on the market. There is a long tail of such products which farmers can use as substitutes for the products supplied by the Parties. For example:
  - (a) Jurox's Strikeforce contains the same active ingredient as Elanco's CLiK range, dicyclanil, and provides up to 18 weeks' flystrike protection with a withholding period of just 18 days. This makes it a very close substitute for Elanco's entire CLiK range, including products still under patent. []
  - (b) **Donaghys**, **Nexan**, **Alleva**, **Animal Health Direct** and **Ravensdown** all supply cyromazine-based products, providing comparable flystrike protection to Vetrazin, and most

<sup>&</sup>lt;sup>90</sup> Notes on market share estimates: there are several products not included in the Baron dataset, including those supplied by []. Elanco has estimated market shares and revenues for these products based on its industry experience. Elanco's Zapp Pour-On, Zapp Jetting Liquid, and Vetrazin products have been discontinued and are not included in the share estimates for 2019. One of Elanco's Extinosad Pour-on SKUs has also been discontinued but its sales have been reflected in the shares above on the basis that they may be absorbed by the remaining Extinosad SKUs.

<sup>&</sup>lt;sup>91</sup> Prices accurate at 27 November 2019 from <u>https://www.ruralco.co.nz/</u>.

with the same meat withholding period of seven days. [] Elanco estimates that they comprise ~[]%, and BAH estimates that they comprise approximately []% of the market.

- 37.11 Although the more local suppliers tend not to have individual market shares as high as the major international players based on revenues, in aggregate they account for a significant share of the market. Downstream animal health customers are not loyal to specific brands and will quickly switch to cheaper generic brands if it is more cost-effective to do so.
- 37.12 For example, Jurox's products Luci-Gard and Strikeforce have the active ingredient dicyclanil and are generics of Elanco's CLiK range. Any attempted price raise for this product would see its market share decline.
- 37.13 A table setting out the extensive choice of the over 35 third party products that farmers have in this market is set out at **Annex 8D**.

New and potential entry and expansion

- 37.14 New and existing suppliers can also easily expand by registering new generic products and either importing these or entering into toll manufacturing/distribution arrangements with competitors if they do not have facilities to manufacture products themselves. As noted above, there are numerous toll manufacturers in New Zealand, and which do not compete downstream, including Jaychem, Argenta and Chem Colour.
- 37.15 There are many examples of companies obtaining image registration for existing registered and off-patent products; that is, registering a generic version of a product without making any adjustments to the formula. Such examples include:
  - (a) Cyroshield Spray On and Cyroshield Liquid are image registrations of Venus Spray On and Venus Liquid. These products are registered to Seneca Holdings, a company related to Jaychem, a New Zealand-based toll manufacturer.
  - (b) Strike Out Spray On and Strike Out Liquid, which is supplied by Donaghys and manufactured by Zagro.

Countervailing power of customers

37.16 This market contains a broad range of competing suppliers. The key customers in this market such as veterinarian practices and rural supply stores all make high volume purchases, and all have the ability to switch between these suppliers if they are unhappy with the price or service offering made available to them. [] The countervailing power of these customers, which has been previously recognised by the Commission, will continue to represent a considerable constraint on the parties post merge. This is discussed in more detail at section 54 below.

## **OVERLAP 5 – TREATMENT OF LIVER FLUKE IN CATTLE**

#### 38. Introduction

- 38.1 Liver fluke are internal blood sucking parasites. In cattle, liver fluke can cause acute, sub-acute and chronic liver fluke disease. The main effects are reduced weight gain in young cattle, decreased milk production and condemnation of infected livers at slaughter.
- 38.2 Eradication of liver fluke is considered impossible because it is usually not practical to prevent reinfestation of pastures and animals, however good control can be achieved by the strategic use of drenches which kill different stages of the liver fluke as well as injections.

## 39. []

- 39.1 Elanco offers one product indicated for cattle liver fluke in New Zealand: Fasinex 24 (for the treatment and control of early immature, mature and adult stages of liver fluke in cattle).<sup>92</sup> []
- 39.2 []. Invicta is indicated for the treatment and control of GI worms, lungworm, adult liver fluke, lice and mites.
- 39.3 [] there is no meaningful competitive overlap between the Parties in this market. [], competition issues do not arise.

#### 40. **Competitive assessment**

40.1 There will be no substantial lessening of competition in the supply of products indicated for the treatment of cattle fluke (and therefore the Internal Parasites in Cattle market) for the reasons set out below.

#### Parties do not compete closely

40.2 Fasinex 24 and Invicta do not treat the same stages of liver fluke, have different withholding periods and use alternative methods of application. Fasinex 24 is narrow spectrum and treats all three stages of liver fluke (early immature, immature and adult), whereas Invicta is effective against five therapeutic indications (liver fluke being one) but only treats the 'adult' stage of liver fluke.

Product	Indication	Species	Application	Withholding periods
Elanco				
Fasinex 24 (tricalbenzadole)	Treatment and control of immature, mature and adult stages of liver fluke	Cattle	Oral	Milk: 35 days Meat: 28 days
[]				
[]	[]	[]	[]	[]

## Table 10 - Products for the treatment of liver fluke in cattle

Low combined share and strong competition from large global players

40.3 Table 11 below sets out the share of supply for products indicated for the treatment of cattle liver fluke in New Zealand.

Competitor	2019 est. revenue	2019 est. share	2018 est. revenue	2018 est. share	2017 est. revenue	2017 est. share
Elanco	[]	[]	[]	[]	[]	[]
[]	[]	[]	[]	[]	[]	[]
Merged entity	[]	[]	[]	[]	[]	[]
Boehringer Ingelheim	[]	[]	[]	[]	[]	[]
Zoetis	[]	[]	[]	[]	[]	[]
Virbac	[]	[]	[]	[]	[]	[]
Merial	[]	[]	[]	[]	[]	[]
Total	[]	100.00%	[]	100%	[]	100%

## Table 11 - Estimated market shares - treatment of liver fluke in cattle<sup>93</sup>

- 40.4 There are three large suppliers with strong product offerings in New Zealand for the treatment of liver fluke in cattle. These global suppliers will continue to constrain the merged entity post-Transaction. In particular, Boehringer Ingelheim is the clear market leader with its products that treat liver fluke having an estimated share of [].
- 40.5 A list of competitor products available in the liver fluke market, illustrating the extensive choice available to consumers, is at **Annex 8E**. Nearly all competitors' products in this market generate more revenue than the Parties' respective products.

#### Countervailing power of customers

40.6 This market contains a broad range of competing suppliers. The key customers in this market such as veterinarian practices and rural supply stores all make high volume purchases, and all have the ability to switch between these suppliers if they are unhappy with the price or service offering made available to them. The countervailing power of these customers, which has been previously recognised by the Commission, will continue to represent a considerable constraint on the parties post merge. This is discussed in more detail at section 54 below.

<sup>&</sup>lt;sup>93</sup> Notes on market share estimates: shares have been calculated based on products that are predominantly used to treat liver fluke in cattle. Estimated shares are based on products contained in the Baron dataset. The combined shares of the Parties' (and their competitors) are therefore likely over-stated. In addition, several products that have label indications for liver fluke are broad spectrum products that are generally used for treatment of other intestinal parasites (such as roundworm). Products that Elanco advises are used for liver fluke less than 1% of the time have been excluded from market shares.

## **OVERLAP 6 – ANTICOCCIDIALS IN POULTRY**

#### 41. Introduction

- 41.1 Coccidiosis is one of the key diseases afflicting poultry in New Zealand. It affects both broiler birds (i.e. birds raised specifically for meat production) and laying birds (birds raised to lay eggs) although each of these may be treated differently in combating the disease. Birds afflicted with coccidiosis tend to suffer a loss of appetite, weight loss or decreased weight gain, diarrhoea (which can contain blood), dehydration and death.
- 41.2 Poultry coccidiosis is combated by administrating preventative anticoccidials (vaccines or coccidiostats as feed additive) or administering curative coccidiocides to treat sporadic coccidiosis outbreaks. Accordingly, anticoccidials fall into two categories:
  - (a) coccidiostatic preparations that arrest the development of the parasite at specific stages of its lifecycle (Preventative Anticoccidials); and
  - (b) coccidiocidal preparations that kill or irreversibly damage the parasite at most lifecycle stages, with no sign of disease relapse following drug withdrawal (Curative Anticoccidials).

#### Preventative Anticoccidials

- 41.3 Preventative Anticoccidials are generally administered in-feed or as vaccines. Elanco offers three Preventative Anticoccidials in New Zealand. BAH does not offer any preventative products.
- 41.4 In-feed preventative products are the most popular and common products used. Feed delivery can be planned and executed as a preventative strategy. These coccidiostats are provided to broiler birds through their lifespan before slaughter (approximately 49 days) and are not given to laying birds.

#### Curative Anticoccidials

41.5 Curative Anticoccidials are generally administered in liquid form and are used when an outbreak of coccidiosis has been observed and medication needs to be swiftly delivered to treat the birds. Sick birds will continue to ingest liquids but may stop eating. As in-feed preventative products are administered consistently and for the entirety of a broiler bird's life, it is rare for an outbreak to occur. In-solution products are therefore only used sporadically on a "need-only" basis. BAH sells a Curative Anticoccidial in New Zealand. Elanco does not have any product in New Zealand that is indicated as a Curative Anticoccidial.

#### 42. The Parties' products

- 42.1 As noted above, Elanco offers Preventative Anticoccidials, whereas BAH's product is a Curative Anticoccidial. Aside from the different functional uses, the Parties' products also differ significantly in terms of veterinary prescription requirements and withdrawal periods, the latter factor being of great importance in production animal farming.
- 42.2 Further information about the Parties poultry anticoccidial products is provided in the table below.

Product	Preventative or curative	Species	Application	Active ingredient	Withholding period
Elanco					
Monteban (Narasin)	Preventative	Broiler chickens	In-feed	Narasin	Nil
Maxiban (Narasin, Nicarbazin)	Preventative	Broiler chickens	In-feed	Narasin Nicarbazin	Nil
Rumensin 200 <sup>94</sup> (Monesin as sodium monesin)	Preventative	Broiler chickens Layer chickens	In-feed	Monensin as sodium monesin	Nil for broiler chickens 10 days for layer chickens
ВАН					
Baycox 2.5% (toltrazuril)	Treatment	Broiler chickens	In-water	Toltrazuril	14 days prior to slaughter

## Table 12 - Parties' anticoccidial products for use in poultry

## 43. Competitive assessment

The Parties' products do not compete

- 43.1 Even if the Commission adopts a broad anticoccidials market, competition concerns do not arise for the below reasons.
  - (a) As noted above, the Parties' products serve different functions: Elanco's products are administered in feed as part of the preventative strategy, whereas Bayer's product is administered in liquid form during outbreaks as liquid medications are faster to deliver and sick birds may stop eating.
  - (b) In-solution products such as Baycox are priced higher than in-feed preventative products and are generally used much less frequently. This is evidenced by Baycox's revenue being less than NZD [] compared to Elanco's over NZD [].

The merged entity will remain constrained by strong competitors

43.2 Even in a broad poultry anticoccidials market, Elanco estimates the combined market share would be ~[] with an increment less than ~[], although this significantly over-states the position, given the differences in the Parties' products.

<sup>&</sup>lt;sup>94</sup> Rumensin 200 is a multi-species product that is predominantly indicated for use in cattle. [].

Competitor	2019 est. revenue	2019 est. share	2018 est. revenue	2018 est. share	2017 est. revenue	2017 est. share
Elanco	[]	[]	[]	[]	[]	[]
BAH	[]	[]	[]	[]	[]	[]
Merged entity	[]	[]	[]	[]	[]	[]
Zoetis	[]	[]	[]	[]	[]	[]
MSD	[]	[]	[]	[]	[]	[]
Others	[]	[]	[]	[]	[]	[]
Total	[]	100.00%	[]	100%	[]	100%

## Table 13 - Estimated market shares - anticoccidial products for use in poultry<sup>95</sup>

43.3 A list of competitor products available in the poultry anticoccidial market, illustrating the extensive choice available to consumers, is at **Annex 8F**.

#### Strong existing competitors

43.4 The market is highly competitive, with the majority of sales in this market made by competing suppliers. While Elanco does not have an estimate for its share of the market, it considers AgriHealth to be a very strong player in this market. Zoetis alone has five separate in-feed anticoccidial products that compete with Elanco's in-feed products, and MSD, Philbro and Biopharm each have multiple products.

#### New and potential entry and expansion

- 43.5 Similar to other markets discussed in this application, new entry and expansion will constrain the merged entity's ability to exercise market power. A recent example demonstrating the ease of new entry is from April 2018, when AgriHealth registered and launched a generic product in this market (Toltravet Poulty 2.5%). It contains the active ingredient toltrazuril and is a direct substitute for Bayer's Baycox 2.5%.
- 43.6 Glenmark has also registered a new product in each of the past three years that could be introduced into this market.

#### Countervailing power of customers

43.7 The key customers in this market (such as veterinarian practices, rural supply stores and chicken processors/integrators) all make high volume purchases, and all have the ability to switch between these suppliers if they are unhappy with the price or service offering made available to them. The countervailing power of these customers, which has been previously recognised by the Commission, will continue to represent a considerable constraint on the parties post merge. This is discussed in more detail at section 54 below.

<sup>&</sup>lt;sup>95</sup> Notes on market share estimates: Elanco estimates that Baycox is used to treat poultry []% of the time, and Rumensin is used to treat poultry []% of the time. The revenue of each product has been adjusted accordingly in estimating shares. Elanco advises that MSD's Paracox has been discontinued and is not included in the calculation of market shares for 2019. Elanco has estimated the size of this market to be NZD [] million for 2019, and this figure has been used to estimate the sales value and aggregate share of all competitors that are not reported in Baron (the 'Others' category). However, Elanco does not have sufficient information to be able to provide revenue or market share estimates of suppliers that do not report to Baron. It also does not have sufficient information to estimate the market size for previous years, []. Accordingly, the above market share data for 2017 and 2018 has been estimated on the assumption that the share change of 'Others' is the same as the average share change of all competitors in Baron.for the past three years.

## **OVERLAP 7 – ANTIMICROBIALS FOR RUMINANT ANIMALS**

#### 44. Overview

44.1 Antimicrobials are pharmaceutical products that destroy or prevent the growth of microbes such as bacteria, mycoplasma or fungi, and that therefore treat diseases associated with such microbes. They are also known as antibiotics. In ruminant animals, antimicrobials are commonly used to treat ailments such as respiratory infections, mastitis and foot-rot.

#### 45. The Parties' products

- 45.1 Elanco offers **Tylan 200**, a broad spectrum antibiotic that is primarily used to treat acute mastitis in cattle ([]). It is also indicated for dysentery in pigs ([]) and respiratory infections, foot-rot, acute mastitis and metritis in cattle and agalactia in sheep and goats.
- 45.2 BAH<sup>96</sup> offers three products:
  - (a) **Baytril** indicated for several ailments, and is most commonly used to treat respiratory disease, however it is also indicated for the treatment of foot-rot in cattle;
  - (b) Tylofen a broad spectrum antibiotic indicated for the treatment of infections, caused by tylosin-sensitive organisms in cattle where an adjunct therapy with a NSAID<sup>97</sup> is indicated; and
  - (c) the **Penethaject** range indicated for the treatment of mastitis in cows caused by certain bacteria. It is also indicated for the treatment of metritis, respiratory infections and foot-rot in cattle and horses.

#### 46. **Competitive assessment**

Parties are not close competitors

- 46.1 The Parties' product ranges do not compete closely in this market.
  - (a) Only one of BAH's products belongs to the same chemical family as Tylan 200. However, Tylofen contains the pain killing active ketoprofen and so is only used in circumstances where pain relief is also required e.g. when treating an infection associated with inflammation. It is also significantly more expensive than Tylan 200.
  - (b) BAH's remaining products have active ingredients in different chemical classes from Elanco's single product, Tylan.
  - (c) Elanco's Tylan product is indicated for acute mastitis only, compared with the more general indication for the Penethaject range and Baytril.
  - (d) Baytril is labelled and regulated more heavily than tylosin-based products, being a critically important product to human health under the WHO guidelines. It cannot be used as a first line treatment, rather it can only be prescribed by vets in the event of failure of first line antimicrobials.

<sup>&</sup>lt;sup>96</sup> BAH products that have been excluded from the market are: Dryclox, Dryseal and Ultraclox 24. All are intra-mammary suspensions specifically indicated to only treat mastitis in cows. As noted above, the Commission has previously defined separate markets for mastitis treatments: see *Schering Plough/Organon*. In that case, it noted that there are certain injectable treatments indicated for the treatment of mastitis, but they were also indicated for other ailments and so belonged in the broader antibiotics market: see footnote 13 of the Commission's decision in that case. []

<sup>97</sup> Non-steroidal anti-inflammatory drug.

Product	Indication(s)	Species	Active ingredient	Chemical family
Elanco				•
Tylan 200 <sup>98</sup>	Respiratory infections, foot-rot, calf diphtheria, metritis, acute mastitis	Cattle	tylosin	macrolide
	agalactia	Sheep and goats		
	Dysentery, enteritis	Pigs	-	
BAH		L		
Tylofen	Infections sensitive to tylosin	Cattle	tylosin, ketoprofen	macrolide
Penethaject	Mastitis, metritis, respiratory infections and foot-rot	Cattle, horses	penethamate	penicillin
Penethaject RTU	treatment and control of infections caused by susceptible Gram- positive bacteria that cause mastitis	cattle	penethamate	penicillin
Baytril 10%	Bacterial infections of bones	Cattle, pigs	enrofloxacin	fluoroquinolone
	Mastitis caused by e.coli or pseudomonas strains or sensitive to enroflaxin	Cattle		
	Infection of male reproductive tract of bulls	Cattle	_	
	Infections where poor tissue penetration by other antimicrobials can be expected and relevant organism does not respond readily to other antibiotics	Cattle, pigs		

## Table 14 - Parties' antimicrobial products for use in ruminant animals

Combined market shares are low, and the increment is de minimis

46.2 In addition to the lack of substitutability between the Parties' products, the combined shares of the Parties are low, and the increment is *de minimis*.

<sup>&</sup>lt;sup>98</sup> Two other Tylan products currently appear on the ACVM register: Tylan 250 pre-mix, a feed mix additive which had [] of turnover in 12 months to June 2019, and Tylan soluble, which is no longer sold in New Zealand and had [] in 12 months to June 2019.

Competitor	2019 est. revenue	2019 est. share	2018 est. revenue	2018 est. share	2017 est. revenue	2017 est. share
Elanco	[]	[]	[]	[]	[]	[]
BAH	[]	[]	[]	[]	[]	[]
Merged entity	[]	[]	[]	[]	[]	[]
Virbac	[]	[]	[]	[]	[]	[]
MSD	[]	[]	[]	[]	[]	[]
Zoetis	[]	[]	[]	[]	[]	[]
Boehringer Ingelheim	[]	[]	[]	[]	[]	[]
Norbrook	[]	[]	[]	[]	[]	[]
Merial	[]	[]	[]	[]	[]	[]
Others	[]	[]	[]	[]	[]	[]
Total	[]	100.00%	[]	100%	[]	100.0%

## Table 15 - Estimated market shares - antimicrobial products for ruminant animals<sup>99</sup>

Competition is strong and will continue

- 46.3 The merged entity will continue to face strong competition, in particular from other suppliers of macrolides, including AgriHealth, Virbac, Vetpak and Kela. Each of these companies supplies into New Zealand an injectable tylosin product.
- 46.4 Evidence of this strong competition can be seen in []
  - (a) Tylan's revenues have [] in 2019.
  - (b) Tylofen's revenues have [] in 2019.
- 46.5 In addition, the use of macrolides such as tylosin is expected to reduce in the coming years given as the use of antimicrobials that are of importance in human health declines in the animal health industry.<sup>100</sup>
- 46.6 A list of competitor products available in the ruminant animal antimicrobial market, illustrating the extensive choice available to consumers, is at **Annex 8G.**

New and potential entry and expansion

46.7 Elanco considers that entry and expansion barriers to the antimicrobial market are relatively low. To take one example, AgriHealth's Tylovet product, which is a generic copy of Elanco's Tylan, was registered in June 2015, and launched in 2016. Its sales are represented in the "others" category in the table above.

<sup>&</sup>lt;sup>99</sup> Notes on market share estimates: estimates based on Baron data. In addition, Elanco estimates that products not recorded in Baron ('Others') accounted for approximately NZD [] million in sales for 2019. This figure has been used to calculate 2019 market shares and total market size. However, Elanco does not have sufficient information to be able to provide revenue or market share estimates of suppliers that do not report to Baron. It also does not have sufficient information to estimate the size of this segment for previous years, []. Accordingly, the above market share data for 2017 and 2018 has been estimated on the assumption that the share change of 'Others' is the same as the average share change of all competitors in Baron.for the past three years. The discontinued Elanco products Tylan Soluble and Micotil have not been reflected in the market share estimates for 2019.

<sup>&</sup>lt;sup>100</sup> See, for example, *Antibiotic judicious use guidelines for the New Zealand veterinary profession: Dairy*, available online at: <u>https://cdn.ymaws.com/www.nzva.org.nz/resource/resmgr/docs/policies\_and\_guidelines/guide\_dairy.pdf</u>. Accessed 21 November 2019.

## Countervailing power of customers

46.8 This market contains a broad range of competing suppliers. The key customers in this market such as veterinarian practices and rural supply stores all make high volume purchases, and all have the ability to switch between these suppliers if they are unhappy with the price or service offering made available to them. The countervailing power of these customers, which has been previously recognised by the Commission, will continue to represent a considerable constraint on the parties post merge. This is discussed in more detail at section 54 below.

## PIPELINE PRODUCTS

#### 47. Introduction

## 47.1 []

- 47.2 BAH is currently undergoing the registration approval process to introduce a product known as Claro in the US (Neptra outside the US) in New Zealand. Neptra is a product for the treatment of otitis externa (otitis) in dogs. Otitis is an inflammation of the external ear canal. It is not a disease in itself but rather a symptom of some other diseases, such as an infection. It is a common condition in dogs and occurs less frequently in cats.<sup>101</sup>
- 47.3 The Commission has not previously considered otitis products in the merger context. The EC considered the issue in *Eli Lilly/Novartis*. In that case, the EC's market investigation found that:<sup>102</sup>
  - (a) a separate product market for otitis externa for companion animals could exist as the products that treat otitis are not substitutable by or for any other companion animal health products given that they target a specific pathology; and
  - (b) the market for otitis externa is comprised principally of topical treatments, with oral or injectable products seldom used.
- 47.4 However, the EC left open any further segmentation by mode of administration.

## 48. No substantive overlap between the Parties' existing products

- 48.1 Elanco has two specialty otitis products available for sale in New Zealand: Osurnia and Surolan. Both are topical aural treatments. BAH does not currently offer a specialty otitis product in New Zealand (Baytril Otic is available in Australia but not in New Zealand).
- 48.2 For completeness, BAH does offer two broad spectrum companion animal antibiotics Baytril Injection and Baytril Oral however these are indicated to treat a wide variety of infections. While it is *possible* for these types of medicines to be used to treat otitis, they are not indicated for the treatment of otitis and are therefore not 'first line' treatments. This is because:
  - (a) systemic treatment is not the best way to treat otitis externa (topical is preferred) therefore vets would not primarily choose Baytril (or indeed, any other systemic antibiotic) to deal with the condition. Indeed, the New Zealand Veterinary Association Guidelines for the treatment of otitis remarks that "[s]ystemic therapy is not relevant";<sup>103</sup> and
  - (b) even when a systemic treatment is chosen, as Baytril is a fluoroquinolone, it would not be a first-choice treatment. Where it is used, it would be more likely in challenging cases that are failing to respond to topical treatment.
- 48.3 As such, BAH considers Baytril's use for otitis (to the extent that it is used at all) is likely to be *de minimis* and competition concerns cannot arise, even in a hypothetical market for the supply of otitis products and broad spectrum companion animal antibiotic products in New Zealand.
- 48.4 Further, Elanco has taken a decision to divest the Osurnia brand globally, including in New Zealand and on 6 January 2020 announced that it had entered into an agreement to divest Osurnia to Dechra.<sup>104</sup> The agreement is conditional on the Proposed Transaction receiving relevant regulatory approvals. Post-divestment, Elanco would have ~[]% share of supply of a hypothetical otitis treatment plus broad spectrum companion animal antibiotic products in New

<sup>&</sup>lt;sup>101</sup> Case M.7277 Eli Lily / Novartis Animal Health, para 29.

<sup>&</sup>lt;sup>102</sup> At paragraphs 33-34.

<sup>&</sup>lt;sup>103</sup> https://cdn.ymaws.com/www.nzva.org.nz/resource/resmgr/docs/policies\_and\_guidelines/guide\_comp.pdf.

<sup>&</sup>lt;sup>104</sup> https://www.elanco.com/news/press-releases/elanco-signs-agreement-with-dechra-to-divest-osurnia.

Zealand (based on Baron data). However even absent the decision to divest Osurnia, the Proposed Transaction cannot give rise to competition issues in relation to the treatment for otitis.

#### 49. Neptra would not compete closely with Osurnia

- 49.1 Elanco's Osurnia and Bayer's [] Neptra are differentiated by method of administration, application frequency and formulation.
  - (a) Osurnia is a non-alcoholic adaptable gel. It is applied in a liquid form into the ear canal and then turns into a gel to coat the entire ear canal. By contrast, Neptra is administered as liquid ear drops and contains alcohol. Some veterinarians prefer products without alcohol because alcohol may cause additional irritation to the ear canal. In addition, liquid ear drop formulations may also be disfavoured as they can pool at the ear drum instead of spreading evenly throughout the ear canal.
  - (b) Osurnia must be applied twice, with applications given one week apart. By contrast, Neptra is applied once only. Veterinarians consider this to be a significant differentiator between the products because Osurnia's second administration means that pet owners must return to the clinic. Some pet owners may not return for a second clinic appointment (meaning that treatment success is jeopardised) and/or some vets may be reluctant to charge patients for this additional visit.
  - (c) Osurnia contains the steroid betamethasone whereas Neptra contains mometasone. Mometasone is considered to be a "soft steroid". This means the body does not absorb it centrally and therefore it does not affect the adrenal glands. Some vets may therefore consider it to be less efficacious.

## 50. Neptra will not compete closely with Surolan

- 50.1 Neptra will not be a close competitor with Elanco's Surolan product.
  - (a) Neptra only needs to be applied once, whereas Surolan requires several applications over a number of weeks. As noted above, veterinarians consider this to be a significant differentiator between the products because pet owners must return to the clinic for subsequent doses of Surolan. Some pet owners may not return (meaning that treatment success is jeopardised) and/or some vets may be reluctant to charge patients for this additional visit.
  - (b) [].

## 51. Strong competition from global players

51.1 Virbac, in particular, has a strong position, and has a specialty otitis product that []. Furthermore, if the announced divestment of Osurnia to Dechra – an existing supplier of otitis products in New Zealand – is completed, Neptra will also face additional competition from this competitor.<sup>105</sup>

<sup>&</sup>lt;sup>105</sup> []. Bayer estimates Dechra would have a share of []% of specialty otitis products in New Zealand.

#### 52. Barriers to entry and expansion are relatively low

- 52.1 As can be seen from the above discussion, Elanco considers that barriers to entry and expansion are relatively low in all markets relevant to the assessment of the Proposed Transaction, particularly where a product has been developed by a multi-national and is off-patent. The markets relevant to the Proposed Transaction all comprise products containing ingredients that are 'off patent' and for which the formulations are publically available. There is accordingly no extensive R&D requirements to enter the market with a new generic product. In addition, the ACVM registration process is streamlined for new products with formulations already registered in New Zealand, or registered in overseas countries with similar regulatory bodies to New Zealand (such as Australia). The success and presence of 'generic' products in these markets is testament to this fact.
- 52.2 In particular:
  - registering a generic product can take as little as 40 working days.<sup>106</sup> The cost of registering a generic is less than NZD 1,000 for an identical product, and less than NZD 3,000 for a 'similar' product;<sup>107</sup>
  - (b) a new entrant can either manufacture the product themselves or engage a third party to manufacture for them, such as toll manufactures Jay Chem, Argenta, Chem Colour and BioCell;
  - (c) there are multiple well-resourced global players that are continually launching new generic and innovator products, such as:
    - (i) Virbac, which released its product Milpro in 2016. Milpro is a generic of Elanco's Milbemax internal parasite treatment for companion animals. []; and
    - (ii) MSD, which has been able to establish a significant share of over [] of the companion animal external parasiticide market with its product Bravecto since the launch of this product in 2014.
  - (d) A wide range of companies invest in R&D, and a significant proportion of new products are developed by smaller and/or local companies. For example:
    - (i) []
    - (ii) Elanco understands []; and
    - (iii) Unlock and Fleeceguard/Saturate Gold (treatments for external parasites in sheep) were developed by New Zealand development and regulatory consulting company, Agvet, and are now marketed by Animal Health Direct and Ravensdown, respectively.

#### 53. Significant constraint from generics

53.1 Generics are a significant source of competitive constraint in all markets relevant to this application. There are numerous generic competitors, including products supplied by smaller and/or local competitors (Jurox, Donaghys, Nexan, Alleva, Animal Health Direct and Ravensdown) in addition to the huge multinational competitors such as Boehringer Ingelheim, MSD, Zoetis, and Virbac. Although the revenue shares of the smaller/local participants appear to

<sup>&</sup>lt;sup>106</sup> <u>https://www.mpi.govt.nz/dmsdocument/11977.</u>

<sup>&</sup>lt;sup>107</sup> Where a product is identical to an existing registered product (apart from the trade name), and a similar product has the same active ingredient, formulation type, dose regime and use patterns as a registered product. https://www.mpi.govt.nz/dmsdocument/11977.

suggest the presence of these firms within each market is limited, in aggregate they account for a significant share of the industry.

- 53.2 In addition, because the strength of these players lies in generics, their business strategy tends to be to compete aggressively on price. This means the volume shares of the generics-only firms are likely to be much higher than their revenue shares would suggest, and they provide a robust pricing constraint over all generic products, including those supplied by the large multinational 'innovator' firms.
- 53.3 Downstream animal health customers are not loyal to specific brands and will quickly switch to cheaper generic brands if it becomes more cost-effective to do so. This is particularly true of production animal health customers (for whom animal health products are a business input), but companion animal customers are also price sensitive and are likely to be additionally motivated by convenience. Accordingly, the presence of generic suppliers constrains price increases across all markets. Any attempted price raise for an off-patent product will see market share absorbed by the expansion of existing generics and/or new entry from competing generics (from all suppliers). This constraint is what motivates the R&D suppliers to continue creating new and more effective innovator formulations.
- 53.4 The Parties' customers, which have significant countervailing power, could also readily sponsor the new entry or expansion of a generic supplier or source their own generic product if the need arose.

## 54. Parties are subject to countervailing power

- 54.1 The Parties' customers include a range of large agricultural cooperatives with retail arms and major vet groups and speciality pet food chains, each of which make high volume purchases and, as discussed below, have considerable countervailing power.
- 54.2 The Commission has previously recognised that veterinarians exercise countervailing power over manufacturers of animal health products. In its decision in *Schering Plough/Organon Biosciences*, the Commission noted that many veterinarians are "relatively large and sophisticated buyers, due to a trend of rationalisation in the veterinary industry".<sup>108</sup> Wholesalers in particular are also likely to exercise countervailing power given the position they hold in offering distribution cost savings to animal health suppliers, but also convenience to customers downstream (such as individual veterinarians).
- 54.3 In general, the high purchasing volume of all key rural, farming cooperative and vet customers means that they can demand particular supply terms from manufacturers. []
- 54.4 [].
- 54.5 [].
- 54.6 In each of the product markets affected by the Proposed Transaction, there are numerous other suppliers. The veterinarian practices and the large rural supplies stores therefore have a considerable degree of choice when weighing up supply options, and can easily switch product or supplier if they are unhappy with the price, service or general supply offering made available to them by the Parties.
- 54.7 Any attempt by the merged entity to raise price, or refusal by the merged entity to cooperate with the demands of its customers (as illustrated in the examples above), would see these crucial customers switch to competing products and would render the price increase unprofitable.

<sup>&</sup>lt;sup>108</sup> Schering-Plough/Organon at [303].

#### 55. No vertical effects

55.1 There is no vertical relationship between the Parties that is relevant to the assessment of the Proposed Transaction.

#### 56. No coordinated effects

- 56.1 Elanco considers the animal health product market in New Zealand is not vulnerable to coordination for the following reasons:
  - (a) The relevant markets are characterised by the presence of multiple large, well-resourced, and vigorous competitors that would quickly disrupt any attempt to coordinate behaviour.
  - (b) 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.
  - (c) The Proposed Transaction will not result in the removal of a maverick competitor.
  - (d) For each market there are strong competitors outside the market and new products being developed that could easily enter the New Zealand market in response to prices 'drifting up'. This kind of entry has been observed, for example, with sheep blowfly treatment, in which there are approximately 15 generic copies of Elanco's innovator product Vetrazin Spray-On and 15 copies of Vetrazin Liquid (cyromazine) registered in NZ [].
  - (e) 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.
  - (f) 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 many products relevant to the markets discussed above have been added over the past two year(s).
- 56.2 The Proposed Transaction will not give rise to coordinated effects. The transaction does not impact any of the factors which contribute to the current absence of co-ordinated behaviour.
  - (a) The products are not homogenous. Products are highly differentiated both by composition/active ingredient and therapeutic use.

## Part G: Confidentiality

## 57. Reasons for seeking confidentiality

- 57.1 Confidentiality is sought in respect of the information in this application that is highlighted, in bold and contained within square brackets (the **Confidential Information**). Confidentiality is sought for the Confidential Information for the purposes of section 9(2)(b) of the Official Information Act 1982 on the following grounds.
  - (a) The Confidential Information is commercially sensitive and valuable information which is confidential to either, or both, Parties.
  - (b) Disclosure of the Confidential Information would be likely to unreasonably prejudice the commercial position of the Parties.
- 57.2 The Parties request that they are notified if the Commission receives any request under the Official Information Act 1982 for the release of any part of the Confidential Information. They also request that the Commission seek and consider their views as to whether the Confidential Information remains confidential and commercially sensitive before it responds to such requests.

## Part H: Declaration

I, \_\_\_\_\_\_, 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 the 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.

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

I am a director/officer of the company and am duly authorised to submit this notice.

## Name and title of person authorised to sign:

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

# Part I: Annexures

## Contents

A A	
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Annex 8A	Competitor products – treatment of internal parasites in companion animals
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Annex 1: Elanco New Zealand's latest audited financial accounts (confidential)

Annex 2: Bayer New Zealand's latest audited financial accounts and accounts for the commercial operations of Bayer New Zealand's animal health business (confidential)

Annex 3: Transaction documents – SAPA (confidential)

Trade / industry associations in animal health market		
Association	Brief description	Contact details
AGCARM	Industry Association representing Animal Health and Crop Protection manufacturers and Distributors. Derek Bartlett of Bayer is a current elected Board member of AGCARM.	Contact name: Mark Ross Phone: + 64 4 499 4225 Email: <u>mark.ross@agcarm.co.nz</u>
New Zealand Veterinary Association	The New Zealand Veterinary Association (NZVA) is the only membership association representing New Zealand veterinarians.	Address: Level 2/44 Victoria St, Wellington, 6011, New Zealand Phone: +64 4-471 0484

# Annex 4 – Trade / Industry Associations

# Annex 5: Competitor contact details

Treatment of internal parasites in companion animals		
Party	Contact details	
Boehringer Ingelheim	[]	
MSD	[]	
Virbac	[]	
Zoetis	[]	
Masterpet	[]	

Treatment of external parasites in companion animals		
Party	Contact details	
MSD	[]	
Boehringer Ingelheim	[]	
Masterpet	[]	
Zoetis	[]	

Treatment of internal parasites in sheep		
Party	Contact details	
Boehringer Ingelheim	[]	
Zoetis	[]	
MSD	[]	
Nexan	[]	
Alleva	[]	
Ravensdown	[]	

Treatment of external parasites in sheep		
Party	Contact details	
Boehringer Ingelheim	[]	
MSD	[]	
Ravensdown	[]	
Nexan	[]	
Jurox	[]	

Treatment of external parasites in sheep	
Party	Contact details
Alleva	[]
Norbrook	[]

Treatment of liver fluke in cattle	
Party	Contact details
Boehringer Ingelheim	[]
Virbac	[]
Zoetis	[]

Anticoccidials for use in poultry	
Party	Contact details
Zoetis	[]

Antimicrobials for use in ruminant animals		
Party	Contact details	
Virbac	[]	
MSD	[]	
Zoetis	[]	
Boehringer Ingelheim	[]	
Norbrook	[]	

Treatment of internal parasites in companion animals		
Customer	Net revenue in last financial year (NZD) <sup>109</sup>	Contact details
[]	[]	[]
[]	[]	[]
[]	[]	[]

# Annex 6: Elanco's Key Customers (confidential)

Treatment of external parasites in companion animals		
Customer	Net revenue in last financial year (NZD)	Contact details
[]	[]	[]
[]	[]	[]
[]	[]	[]
[]	[]	[]
[]	[]	[]

Treatment of internal parasites in sheep		
Customer	Net revenue in last financial year (NZD)	Contact details
[]	[]	[]
[]	[]	[]
[]	[]	[]
[]	[]	[]
[]	[]	[]

Treatment of external parasites in sheep			
Customer Net revenue in last financial year (NZD) Contact details			
[]	[]	[]	
[]	[]	[]	
[]	[]	[]	

<sup>&</sup>lt;sup>109</sup> "Net revenue" is effectively net sales, i.e. sales value after discounts, trading terms and customer promotional expenses.

Treatment of external parasites in sheep					
Customer Net revenue in last financial year (NZD) Contact details					
[]	[]	[]			
[]	1 [] []				

Treatment of liver fluke in cattle		
CustomerNet revenue in last financial year (NZD)Contact details		Contact details
[]	[]	[]
[]	[]	[]
[]	[]	[]
[]	[]	[]
[]	[]	[]

Anticoccidials for use in poultry			
Customer Net revenue in last financial year (NZD) Contact details			
[]	[]	[]	
[]	[]	[]	
[]	[]	[]	

Antimicrobials for use in ruminant animals		
Customer     Net revenue in last financial year (NZD)     Contact details		
[]	[]	[]
[]	[]	[]
[]	[]	[]
[]	[]	[]
[]	[]	[]

Treatment of internal parasites in companion animals		
CustomerNet revenue in last financial year (NZD)111Contact details		
[]	[]	[]
[]	[]	[]
[]	[]	[]
[]	[]	[]
[]	[]	[]

## Annex 7: Bayer's Key Customers<sup>110</sup> (confidential)

Treatment of external parasites in companion animals						
Customer	Net revenue in last financial year (NZD)	Contact details				
[]	[]	[]				
[]	[]	[]				
[]	[]	[]				
[]	[]	[]				
[]	[]	[]				
Treatment of external parasites in sheep						
Treatment of ext	ernal parasites in shee	р				
Treatment of ext Customer	ernal parasites in shee Net revenue in last financial year (NZD)	p Contact details				
	Net revenue in last					
Customer	Net revenue in last financial year (NZD)	Contact details				
Customer	Net revenue in last financial year (NZD)	Contact details				
Customer [] []	Net revenue in last financial year (NZD) [] []	Contact details [] []				

Treatment of internal parasites in sheep					
Customer	Customer Net revenue in last financial year (NZD) Contact details				
[] <sup>112</sup>	[] <sup>112</sup> [] []				

<sup>&</sup>lt;sup>110</sup> For the year to June 2019. <sup>111</sup> "Net revenue" is effectively net sales, i.e. sales value after discounts, trading terms and customer promotional expenses. <sup>112</sup>[]

Treatment of liver fluke in cattle				
Customer	Customer Net revenue in last financial year (NZD) Contact details			
[] <sup>113</sup>	[] <sup>113</sup> [] []			

Anticoccidials for use in poultry		
Customer     Net revenue in last financial year (NZD)     Contact details		Contact details
[]	[]	[]
[]	[]	[]
[]	[]	[]
[]	[]	[]
[]	[]	[]

Antimicrobials for use in ruminant animals			
Customer Net revenue in last financial year		Contact details	
[]	[]	[]	
[]	[]	[]	
[]	[]	[]	
[]	[]	[]	
[]	[]	[]	

#### Annex 8A: Competitor products - treatment of internal parasites in companion animals

Supplier / Product	Indication	Species	Application	Duration <sup>114</sup>
Boehringer Ingelheim				
Broadline (fipronil; (S)-methoprene; eprinomectin; praziquantel)	GI worms <sup>115</sup>	Cats	Topical solution	4 to 6 weeks
Nexgard Spectra (afoxolaner; milbemycin)	GI worms <sup>116</sup>	Dogs	Chewable tablet	1 month
Dolpac				
Dolpac (oxantel pamoate; pyrantel pamoate; praziquantel) <sup>117</sup>	GI worms	Dogs	Tablet	3 months
Jurox			I	
Popantel F (febantel; pyrantel; praziquantel) <sup>118</sup>	GI worms	Dogs	Tablet	3 months
Wormicide Tape (praziquantel) <sup>119</sup>	Tapeworm	Dogs	Chewable tablet	3 months
Laboratorios Calier				
Zipyran <sup>120</sup> (prazinquantel; pyrantel; febantel)	Round and tapeworm	Dogs	Flavoured tablets	3 months
Masterpet				
Aristopet All Wormer (oxantel embonate; pyrantel embonate; praziquantel)	GI worms	Dogs	Tablet	3 months
Vitapet All Wormer (oxantel embonate; pyrantel embonate; praziquantel (dogs); oxibendazole; praziquantel (cats))	GI worms	Dogs, cats	Tablet	3 months
Vitapet Wormaway paste (nicolsamide; pyrantel pamoate)	GI worms	Cats	Paste	3 months

<sup>&</sup>lt;sup>114</sup> Duration specified is for healthy (and not breeding) adult companion animals (ages of greater than 6 months). <sup>115</sup> Also controls fleas (prevention and treatment) and can be used for the control of tick infestations and biting lice. <u>https://broadlineforcats.co.nz/how/#how-s1</u>.

<sup>&</sup>lt;sup>116</sup> Also treats fleas and ticks.

 <sup>&</sup>lt;sup>117</sup> http://www.petmart.co.nz/cart\_products2861-1.html?Title=DOLPAC%20DOG%20WORMER&Master\_Category=PET%20HEALTH&Source\_Category\_ID=223.
 <sup>118</sup> https://www.jurox.com/nz/product/popantel-f.
 <sup>119</sup> https://parasitipedia.net/index.php?option=com\_content&view=article&id=4725&Itemid=4316.
 <sup>120</sup> https://www.kahuvet.co.nz/webstore/product?code=ZPFXXX. Registered 22 August 2018 by Laboratorios Calier, S.A.: http://www.calier.com/.

Vitapet worming tablets (pyrantel pamoate)	Roundworm, hookworm (dogs), roundworm (cats)	Dogs, cats	Tablet	3 months
MSD		L		
Bravecto Plus Spot On (fluralaner; moxidectin)	GI worms <sup>121</sup>	Dogs, cats	Topical solution	3 months
Virbac		L		
Milpro (oxibendazole; praziquantel)	GI worms	Dogs, cats	Flavoured tablet	3 months
Endogard (oxibendazole; praziquantel	GI worms	Dogs, cats	Flavoured tablet	3 months
Wormicide Tape (praziquantel)	Tapeworm	Dogs	Tablet	3 to 6 weeks
Ultra All Wormer (Pet Science) (oxibendazole; praziquantel)	GI worms	Cats	Flavoured tablet	Routine prevention: 3 to 6 months Treatment: each month for 3 months
Zoetis				
Revolution Plus <sup>122</sup> (selamectin; sarolaner)	Treatment of hookworm and roundworm <sup>123</sup>	Cats	Topical (Spot-on)	1 month

 <sup>&</sup>lt;sup>121</sup> Also a flea and tick treatment.
 <sup>122</sup> <u>https://myvet.co.nz/discount-flea/revolution-plus/revolution-plus-for-cats-large-5-10kg.html</u>.
 <sup>123</sup> Also indicated for the treatment of fleas, ticks, lice and ear mites.

### Annex 8B: Competitor products – treatment of external parasites in companion animals

Supplier / Product	Indication	Species	Application	Duration	
Boehringer Ingelheim					
Frontline (fipronil)	Prevention and control of flea, tick and lice	Dogs, cats	Spray	Fleas: 6 weeks (cats); 2 months (dogs) Ticks: up to 4 weeks	
Frontline Plus (fipronil; (S)-methoprene)	Treatment and prevention of fleas and ticks	Dogs, cats	Topical (spot on)	Fleas: 6 weeks (cats); 2 months (dogs) Ticks: 1 month	
NexGard (afoxolaner)	Treatment and prevention of fleas	Dogs	Chewable tablet	1 month	
Nexgard Spectra (afoxolaner; milbemycin)	Fleas and ticks <sup>124</sup>	Dogs	Chewable tablet	1 month	
Broadline (fipronil; (S)-methoprene; eprinomectin; praziquantel)	Treatment and prevention of fleas and treatment and prevention of tick infestations and biting lice <sup>125</sup>	Cats	Topical (spot-on)	4-6 weeks	
Masterpet		<u> </u>			
VitaPet Evance (imidacloprid)	Prevention and treatment of fleas	Dogs, Cats	Topical (Spot-on)	4 weeks	

 <sup>&</sup>lt;sup>124</sup> Also treats GI worms.
 <sup>125</sup> Also treats GI worms. <u>https://broadlineforcats.co.nz/how/#how-s1</u>.

MSD				
Bravecto (fluralaner)	Treatment and prevention of fleas and ticks	Dogs, cats	Chewable tablet (dogs only); topical (spot-on)	Dogs: 3 months (tablet); 6 months flea and 4 months tick (spot-on)
				Cats: 3 months
Bravecto Plus Spot On (fluralaner; moxidectin)	Treatment and prevention of fleas and ticks <sup>126</sup>	Cats	Topical (spot-on)	3 months
Activyl (indoxacarb)	Treatment and prevention of fleas	Dogs, cats	Topical (spot-on)	At least 4 weeks.
Norbrook				
Pestigon (fipronil)	Treatment and	Dogs, cats	Topical (Spot-on)	Fleas: 5 weeks
	prevention of fleas and ticks			Ticks: 2 weeks
Virbac				
Effipro Duo for Dogs (finopril, pyriproxyfen)	Treatment and prevention of fleas and ticks	Dogs	Topical (Spot-on)	Fleas: 7 weeks Ticks: 4 weeks
Effipro Duo for Cats (finopril, pyriproxyfen)	Treatment and	Cats	Topical (Spot-on)	Fleas: 5 weeks
	prevention of fleas and ticks			Ticks: 2 weeks
Pet Science Flealine (fipronil)	Treatment and	Dogs, cats	Topical (Spot-on)	Fleas: 5 weeks
	prevention of fleas and ticks			Ticks: 2 weeks
Zoetis			н 	1
Simparica (sarolaner)	Treatment of fleas, ticks, lice and sarcoptic mange	Dogs	Chewable tablet	5 weeks

<sup>126</sup> Also treats GI worms.

Revolution (selamectin)	Prevention of fleas, ear mites, sarcoptic mange <sup>127</sup>	Dogs, cats	Topical (spot-on)	1 month
Revolution Plus (selamectin; sarolaner)	Treatment and prevention of fleas, ticks, lice and ear mites <sup>128</sup>	Cats	Topical (Spot-on)	1 month

 <sup>&</sup>lt;sup>127</sup> Also indicated for the treatment of heartworm, which is not present in New Zealand.
 <sup>128</sup> Also indicated for the treatment of hookworm and roundworm.

# Annex 8C: Competitor products – treatment of internal parasites on sheep

Supplier / Product	Indication	Species	Application	Dose period / duration	Withholding period
Alleva					
Boss Triple (cobalt; abamectin; levamisole; selenium; oxfendazole)	Treatment and control of internal parasites (gastrointestinal nematodes and lungworm)	Sheep	Oral Drench	Not specified on label.	Meat: 14 days Milk: 35 days
Corporal (oxfendazole; levamisole)	Treatment and control of internal parasites	Sheep Cattle	Oral Drench	Not specified on label.	Meat: 10 days Milk: 35 days
Corporal + Tape (cobalt chelate; potassium iodate; zinc edetate; copper chelate; sodium selenite; levamisole hydrochloride; praziquantel; albendazole)	Control of tapeworms (heads and segments), adult liver fluke and susceptible gastrointestinal roundworms and lungworms	Sheep	Oral Drench	Not specified on label.	Meat: 10 days Milk: 35 days
Boehringer Ingelheim	·		·		·
Adtape (praziquantel)	Treatment and control of tapeworms, heads and segments and control of sheep measles.	Sheep	Oral drench	Not specified on label.	Milk: 35 days Meat: 7 days
	Treatment and control of tapeworms heads and segments	Horses			Meat: 63 days
Arrest (albendazole; levamisole)	Control of roundworms, tapeworms, lungworms and adult fluke.	Sheep	Oral drench	Not specified on label.	Milk: 35 days Meat: 10 days

Arrest Hi Mineral (levamisole; albendazole, selenium, cobalt; copper)	Control of roundworms, tapeworms, lungworms and adult fluke.	Sheep	Oral drench	Not specified on label.	Milk: 35 days Meat: 10 days
Bionic (abamectin; levamisole HCl; abamectin; albendazole; selenium; cobalt)	Treatment and 100 day control of internal parasites <sup>129</sup>	Sheep	Oral capsule	100 days	Meat and milk: 128 days
Exodus Long Acting Injection (moxidectin)	Control & treatment of internal parasites, nasal bot and itchmite.	Sheep	Injection	Between 42 and 112 days, depending on the parasite. <sup>130</sup>	Milk: 180 days Meat: 91 days
Exodus SE (moxidectin; sodium selenate)	Control & treatment of internal parasites and itch mite.	Sheep	Oral drench	Between 21 and 25 days, depending on the parasite. <sup>131</sup>	Milk: 35 days Meat: 10 days
Extender (selenium)	Continuous protection against gastrointestinal parasites.	Sheep	Oral capsule	3 months	Meat: nil Milk: not yet assessed
First Drench (praziquantel; albendazole; levamisole)	Control of roundworm, tapeworm, lungworm and adult fluke.	Sheep	Oral drench	Not specified on label.	Milk: 35 days Meat: 10 days
Genesis Hi-Mineral (copper disodium edta; selenium; abamectin;	Control & treatment of roundworms in sheep.	Sheep	Oral drench	Not specified on label.	Milk: 35 days Meat: 14 days
disodium zinc edta; disodium cobalt edta;					

 <sup>&</sup>lt;sup>129</sup> Also aids in the control of dags and associated flystrike caused by gastrointestinal parasites; is for the promotion of growth and productivity through the control of gastrointestinal parasites; reduces pasture contamination with worm eggs for at least 100 days; and aids in the reduction of gastrointestinal parasites prior to weaning in lambs born to treated ewes.
 <sup>130</sup> Ostertagia circumcincta - 112 days; Haemonchus contortus 91 days; and Trichostrongylus colubriformis 42 days.
 <sup>131</sup> Exodus Se prevents reinfection with Haemonchus contortus for 35 days and Ostertagia (Teladorsagia) circumcincta for at least 21 days following a single oral dose.

ethylenediamine dihydroiodide)					
Genesis Ultra Oral (closantel; abamectin)	Control & treatment of roundworms and liver fluke.	Sheep	Oral drench	Up to 42 days against Haemonchus contortus.	Meat and milk: 56
Iver Matrix Mini-Dose (ivermectin; levamisole HCl; oxfendazole; selenium; cobalt) <sup>132</sup>	Treatment and control of internal parasites	Sheep Cattle	Oral drench	Not specified on label.	Milk: 35 days Meat: 14 days
Iver Switch Minidose (sodium selenite; ivermectin; levamisole; disodium cobalt edta) <sup>133</sup>	Treatment and control of gastrointestinal parasites and lungworm	Sheep Cattle	Oral drench	Not specified on label.	Milk: 35 days Sheep Meat: 14 days Cattle Meat: 21 days
Ivomec Maximizer (ivermectin)	Treatment and 100 day control of internal and external parasites, nasal bot, keds and itchmite <sup>134</sup>	Sheep	Oral capsule	100 days	126 days
Ivomec Sheep and Goats (sodium selenite; ivermectin)	Treatment and control of internal including lungworm, and itch mite and nasal bot.	Sheep	Oral drench	Minimum 3 weeks	Milk: 35 days Sheep Meat: 10 days Goat Meat: 14 days
	Treatment and parasites, control of internal parasites, including lungworm.	Goats			
Levicare (levamisole hydrochloride)	Controls roundworms and lungworms.	Sheep	Oral drench	Not specified on label.	Milk: 24 hours

 <sup>&</sup>lt;sup>132</sup> Also exists as Iver Matrix Tape, which includes an additional active ingredient, praziquantel, and is only for sheep.
 <sup>133</sup> Also exists as Iver Switch Tape, which includes an additional active ingredient, praziquantel, and is only for sheep.
 <sup>134</sup> Also aids in the prevention of dags and in the control of blowfly strike in the breech area and reduces pasture contamination with worm eggs for at least 100 days.

		Cattle			Meat: 10 days
Matrix (levamisole hydrochloride; oxfendazole; abamectin)	Treatment and control of internal parasites (gastrointestinal parasites and lungworm).	Sheep	Oral drench	Not specified on label.	Milk: 35 days Meat: 14 days
Switch (levamisole hydrochloride; abamectin)	Treatment and control of internal parasites (gastrointestinal parasites and lungworm).	Sheep	Oral drench	Not specified on label.	Milk: 35 days Meat: 14 days
Switch Hi-Mineral (levamisole hydrochloride; abamectin; selenium; cobalt)	Treatment and control of internal parasites (gastrointestinal parasites and lungworm).	Sheep	Oral drench	Not specified on label.	Milk: 35 days Meat: 14 days
Trimox (levamisole hydrochloride; moxidectin; sodium selenate; cobalt)	Treatment and control of internal parasites (gastrointestinal parasites and lungworm).	Sheep	Oral drench	21 days and up to 35 days.	Milk: 35 days Meat: 28 days
Donaghys					
Evolve (abamectin; levamisole HCl; oxfendazole (micronised); copper;	Treatment and control of gastrointestinal parasites	Sheep	Oral drench	Not specified on label.	Milk: 35 days Meat: 21 days
zinc; cobalt; iodine; selenium)					
Evolve Tape (praziquantel; albendazole; levamisole hydrochloride; abamectin;	Treatment and control of all major gastrointestinal parasites, treatment and control of lungworm, itch mite, nasal bot and	Sheep	Oral drench	Not specified on label.	Milk: 35 days Meat: 21 days

copper; zinc; cobalt; iodine; selenium)	tapeworms, and control of adult liver fluke				
Saturn (levamisole HCI; abamectin; copper; zinc; cobalt; iodine; selenium)	Treatment and control of all gastrointestinal roundworms and lungworms	Sheep	Oral drench	Not specified on label.	Milk: 35 days Meat: 21 days
MSD					
Alliance (oxfendazole; abamectin; levamisole hydrochloride; cobalt; selenium)	Management of internal parasites (roundworms)	Sheep Cattle	Oral drench	Not specified on label.	Sheep Meat: 14 days Cattle Meat: 10 days Milk: 35 days
Converge (abamectin ; levamisole hydrochloride; cobalt; selenium)	Management of internal parasites (roundworms, lungworm, tapeworm)	Sheep Cattle	Oral drench	Not specified on label.	Sheep Meat: 14 days Cattle Meat: 10 days Milk: 35 days
Scanda (oxfendazole; levamisole hydrochloride) <sup>135</sup>	Management of internal parasites (roundworms, lungworm, tapeworm)	Sheep Cattle	Oral drench	Not specified on label.	Meat: 10 days Milk Sheep: 35 days Milk Cattle: 12 days
Nexan		L			
CentraMax (abamectin; albendazole; cobalt; selenium)	Treatment and control of internal parasites (abomasum and small and large intestine)	Sheep	Oral Drench	Active for 100 days after treatment.	128 days
Vet Med Bi Max Oral (abamectin; levamisole hydrochloride; cobalt; selenium)	Treatment and control of internal parasites (roundworms – abomasum, small and large intestine, and lungworm)	Sheep Cattle	Oral Drench	Not specified on label.	Meat: 14 days Milk: 35 days

<sup>&</sup>lt;sup>135</sup> Also available in a selenised version which contains cobalt, zinc and selenium.

Vet Med Triple Max Oral (abamectin; oxfendazole; levamisole hydrochloride; cobalt; selenium)	Treatment and control of internal parasites (roundworms – abomasum, small and large intestine, and lungworm)	Sheep Cattle	Oral Drench	Not specified on label.	Meat: 14 days Milk: 35 days
VetMed Triple Max I Tape (levamisole hydrochloride; praziquantel; sodium selenite; ivermectin; cobalt; oxfendazole)	Treatment and control of tapeworm and internal parasites	Sheep	Oral Drench	Not specified on label.	Meat: 14 days Milk: 35 days
Ravensdown					
Abamectin Plus Tape (abamectin; macrocyclic lactone; praziquantel; iodine; cobalt; copper; zinc; selenium)	Treatment and control of roundworms, lungworms and tapeworms	Sheep	Oral drench	Minimum 3 weeks	Meat: 14 days Milk: 35 days
Abamectin Sheep (abamectin; iodine; cobalt; copper; zinc; selenium)	Treatment and control of roundworms and lungworms	Sheep	Oral drench	Minimum 3 weeks	Meat: 14 days Milk: 35 days
Combo Plus Tape (albendazole; levamisole hydrochloride; praziquantel; cobalt; copper; zinc; iodine; selenium)	Treatment and control of roundworms, lungworms, tapeworms and adult fluke	Sheep	Oral drench	Not specified on label.	Meat: 10 days Milk: 35 days
Combo Sheep (albendazole; levamisole hydrochloride; cobalt; copper; zinc; selenium)	Treatment and control of roundworms, control of lungworms, tapeworms and liver fluke, and reduces output of worm and fluke eggs	Sheep	Oral drench	Minimum 3 weeks	Meat: 10 days Milk: 10 days

Moximax Sheep (moxidectin; iodine; cobalt; copper; zinc; selenium)	Control of gastrointestinal roundworms and lungworms	Sheep	Oral drench	Minimum 3 weeks	Meat: 7 days Milk: 35 days
Trio Sheep (abamectin; albendazole; levamisole hydrochloride; iodine; cobalt; copper; zinc; selenium)	Treatment and control of gastrointestinal roundworms, lungworms, tapeworm, adult liver fluke, nasal bot and itch mite	Sheep	Oral drench	Minimum 3 weeks	Meat: 14 days Milk: 35 days
The Drench Company (Se	neca)				
Combination plus Tape Drench for Sheep (albendazole; levamisole; praziquantel; selenium; cobalt; copper; zinc; iodine)	Control of tapeworms, adult liver fluke an gastrointestinal roundworms and lungworms)	Sheep	Oral Drench	Not specified on label.	Meat: 10 days Milk 35 days
Combination Sheep Drench (albendazole; levamisole; selenium; cobalt; copper; zinc)	Control of internal parasites (gastrointestinal roundworms and lungworms)	Sheep	Oral Drench	Not specified on label.	Meat: 10 days Milk: 35 days
Gold Drench for Sheep and Cattle (levamisole; selenium; cobalt; copper; iodine; zinc)	Control of internal parasites (gastrointestinal roundworms and lungworms)	Sheep Cattle	Oral Drench	Not specified on label.	Meat: 10 days Milk: 35 days
Mectin Drench for Sheep (abamectin; selenium; cobalt; copper; zince; iodine)	Control of internal parasites (gastrointestinal roundworms and lungworms)	Sheep	Oral Drench	Not specified on label.	Meat: 21 days Milk: 35 days
Virbac	1	<u>I</u>		1	1

Triple A (levamisole hydrochloride; disodium cobalt; abamectin; sodium selenite; oxfendazole)	Treatment and control of internal parasites (abomasum, small and large intestine, and lungworm)	Sheep Cattle	Oral drench	Not specified on label.	Meat: 21 days Milk: 35 days			
Zoetis								
Cydectin Injection (moxidectin)	· · · · · · · · · · · · · · · · · · ·	Is active for between 7 and 35 days depending on the parasite.	Sheep Meat: 28 days Cattle Meat: 35 days Milk: 35 days					
	Treatment and control of gastrointestinal roundworms, lungworm and nasal bot	Sheep						
Cydectin LA Injection (moxidectin)	Treatment and control of internal parasites, nasal bot and itch mite	Sheep	Injection	Is active for between 42 and 91 days depending on the parasite.	Meat: 91 days Milk: 180 days			
Cydectin Oral (moxidectin)	Treatment of gastrointestinal and pulmonary nematodes and itch mite	Sheep	Oral drench	Is active for between 21 and 35 days depending on the parasite.	Meat: 10 days Milk: 7 days			
Eweguard (moxidectin and antigens of enterotoxaemia; blackleg; malignant oedema; black disease; tetanus; caseous lymphadenitis; thiomersal)	Treatment and control of internal parasites and nasal bot. Prevention of five clostridial diseases and caseous lymphadenitis.	Sheep	Vaccine (injection)	Two injections 4 to 6 weeks apart.	49 days			
Eweguard SE + B12 (moxidectin; antigens of enterotoxaemia, blackleg, malignant oedema, black disease, tetanus, caseous	Treatment and control of internal parasites and nasal bot.	Sheep	Vaccine (injection)	Two injections 4 to 6 weeks apart.	49 days			

lymphadenitis, and pseudotuberculosis; selenium; vitamin B12; thiomersa)	Prevention of five clostridial diseases and caseous lymphadenitis. Supplementary source of selenium and vitamin B12.				
Startect (derquantel; abamectin)	Treatment and control of gastrointestinal nematodes (roundworms), lungworm, nasal bot and itch mite	Sheep	Oral Drench	Not specified on label.	Meat: 14 days Milk: 35 days

# Annex 8D: Competitor products – treatment of external parasites on sheep

Supplier / Product	Parasites controlled	Wool type	Application	Label protection period flystrike	Meat withholding period
Abbey Laboratories					
Banish Liquid (cyromazine)	Prevention of flystrike	Long wool	Saturation / Jetting	Up to 12 weeks	7 days
Banish SO (cyromazine)	Prevention of flystrike	All breeds	Spray / Pour on	Up to 12 weeks	7 days
Lucifly Liquid (cyromazine)	Prevention of flystrike	Long wool	Saturation / Jetting	Up to 12 weeks	7 days
Lucifly SO (cyromazine)	Prevention of flystrike	All breeds	Spray / Pour on	Up to 6 weeks	7 days
Strike Out Liquid (cyromazine)	Prevention of flystrike	Long wool	Saturation / Jetting	Up to 12 weeks	7 days
Strike Out SO (cyromazine)	Prevention of flystrike	All breeds	Spray / Pour on	Up to 6 weeks	7 days
Alleva					
Cyroshield CO (cyromazine)	Prevention of flystrike	Coarse wool	Spray / Pour on	Up to 8 weeks	21 days
Cyroshield Liquid (cyromazine)	Prevention of flystrike	Not specified	Saturation / Jetting	Up to 12 weeks	7 days
Animal Health Direct					
Cyguard Liquid (cyromazine)	Prevention of flystrike	Not specified	Saturation / Jetting	Up to 12 weeks	7 days
Cyguard SO	Prevention of flystrike	All breeds	Spray / Pour on	Up to 6 weeks	21 days

(cyromazine)					
Unlock (diflubenzuron, deltamethrin)	Prevention of flystrike; control of lice	Fine and coarse wool breeds	Spray / Pour on	Up to 14 weeks	7 days
Unlock Liquid (cyromazine, diflubenzuron)	Prevention of flystrike; control of lice	All breeds	Saturation / Jetting	Up to 12 weeks	10 days
Boehringer Ingelheim					
Cypercare (cypermethrin)	Control of lice; control of keds	Shorn and long wool sheep	Spray / Pour on	N/A	14 days
	Control of lice	Goats			
Cyrazin KO (cyromazine, ivermectin)	Prevention of flystrike; control of existing body lice infections; control of maggots in existing strike areas	Coarse wool	Saturation / Jetting	Up to 14 weeks	21 days
Cyrazin Liquid (cyromazine)	Prevention of flystrike	Not specified	Saturation / Jetting	Up to 12 weeks	7 days
Cyrazin SO (cyromazine)	Prevention of flystrike	Coarse wool	Spray / Pour on	Up to 6 weeks	14 days
Exit Extreme (triflumuron,	Prevention of flystrike	Coarse wool	Spray / Pour on	At least 8 weeks	49 days
cypermethrin)	Control of lice	Coarse wool; Fine wool up to six months of age		Up to 20 weeks	
Exit (triflumuron)	Prevention of flystrike	Coarse wool	Spray / Pour on	At least 8 weeks	49 days
	Control of lice	Coarse wool; Fine wool up to six months of age		Up to 20 weeks	

Fleecemaster (diflubenzuron)	Prevention of flystrike; control of lice	Not specified	Saturation / Jetting	Up to 12 weeks.	Nil
Donaghys		1			
Strike Out (cyromazine)	Prevention of flystrike	All breeds	Spray / Pour on	Up to 6 weeks	7 days
Strike Out Liquid (cyromazine)	Prevention of flystrike	All breeds	Saturation / Jetting	Up to 12 weeks	7 days
Jurox			1		
Luciguard (dicyclanil)	Prevention of flystrike	Not specified	Spray / Pour on	Up to 18 weeks	14
Strikeforce S (dicyclanil)	Prevention of flystrike	Not specified	Spray / Pour on	Up to 18 weeks	14
MSD				·	
Magnum (diflubenzuron)	Prevention of flystrike;	Not specified	Spray / Pour on	At least 8 weeks	Nil
	Control of lice	Strong-wool up to three months off- shears and Merino type breeds off-shears			
Vanquish (alpha- cypermethrin)	Prevention of flystrike; emergency lice outbreak treatment	All breeds	Spray / Pour on	Up to six weeks	7 days
Wipe Out (deltamethrin)	Control of lice; control of keds	British and European Breeds with up to six months wool growth or Merinos with up to three months wool growth; Goats	Spray / Pour on	N/A	3 days

Zenith Liquid (diflubenzuron)	Prevention of flystrike; control of lice	All sheep; lambs; ewes hoggets and rams	Saturation / Jetting	Up to 12 weeks.	Nil
Nexan					
Cyromax Liquid (cyromazine)	Prevention of flystrike	All sheep (preferably minimum 6-8 weeks wool)	Saturation / Jetting	Up to 12 weeks	7 days
Cyromax SO (cyromazine)	Prevention of flystrike	All sheep	Spray / Pour on	Up to 6 weeks	7 days
Ravensdown					
Fleeceguard/Comboguard (diflubenzuron; deltamethrin)	Prevention of flystrike	Fine and coarse wool	Spray / Pour on	Up to 14 weeks	7 days
	Control of lice	Fine and course wool (up to 6 week's wool growth)			
Ravensdown Flysafe Liquid (cyromazine)	Prevention of flystrike	Long wool	Saturation / Jetting	Up to 12 weeks	7 days
Ravensdown Flysafe SO (cyromazine)	Prevention of flystrike	All breeds	Spray / Pour on	Up to 6 weeks	7 days
Saturate (diflubenzuron)	Prevention of flystrike; protection from developing larvae; control of lice; aid in cockle damage	All sheep; lambs; ewes hoggets and rams	Saturation / Jetting	Up to 12 weeks.	Nil
Saturate Gold (cyromazine, diflubenzuron)	Prevention of flystrike; protection from developing larvae; control of lice; aid in cockle damage	All sheep; lambs; ewes hoggets and rams	Saturation / Jetting	Up to 12 weeks	10 days

Seneca holdings						
Venus SO (cyromazine)	Prevention of flystrike	Coarse wool	Spray / Pour on	Up to 8 weeks	7 days	
Venus liquid (cyromazine)	Flystrike	Not specified	Saturation / Jetting	Up to 12 weeks	21 days	

### Annex 8E: Competitor products – treatment of liver fluke in cattle

Supplier / Product	Indication	Species	Application	Withholding period
Boehringer Ingelheim				
Arrest C (albendazole; levamisole)	Roundworms, lungworm, adult liver fluke, tapeworms	Cattle Deer	Oral	Milk: 35 days Meat: 14 days
Ivomec Plus (ivermectin; clorsulon)	Roundworms, lungworm, sucking lice, adult liver fluke	Cattle	Injection	Meat: 28 days Milk: 14 days
Oxfen C Plus (oxfendazole; levamisole; selenium)	Sensitive roundworms, lungworm, adult liver fluke (control not treatment), tapeworm (control not treatment)	Cattle Deer	Oral	Milk: 35 days Meat: 10 days
Genesis Ultra Pour On (abamectin; triclabendazole)	Roundworms, lungworm, sucking and biting lice, early immature, immature and adult liver fluke	Cattle	Pour on	Meat: 49 days Milk: do not use
Switch Fluke10 (abamectin; levamisole; triclabendazole)	Early immature, immature and adult liver fluke, roundworms, lungworm,	Cattle	Oral	Meat: 49 days Milk: 35 days
Ravensdown				
Combo Low Dose (oxfendazole; levamisole)	Adult liver fluke, roundworms, lungworm, tapeworm	Cattle Sheep	Oral	Meat: 10 days Milk: 35 days
Virbac	1		1	1

Combat Flukecare (triclabendazole)	Early immature, immature and adult liver fluke, sensitive intestinal parasites	Cattle Sheep	Oral	Meat: 28 or 56 days Milk: 35 days
Combat Nitromect Injection (nitroxynil; clorsulon; ivermectin)	Early immature, immature and adult liver fluke	Beef cattle	Oral	Meat: 56 days
Zoetis				
Cydectin Plus Fluke (moxidectin; triclabendazole)	Late immature and adult liver fluke, internal and external parasites	Beef cattle	Pour on	Meat: 84 days Milk: 84 days

# Annex 8F: Competitor products – anticoccidials in poultry

Supplier / Product	Preventative or Curative	Type of chicken	Application	Withholding period			
Active Bio-Tech							
Agvance Monensin 200 (monensin)	Preventative	Broiler chickens and Layer replacement chickens	Mixed with feed	Meat: Nil Eggs: 10 days			
AgriHealth	-						
Advent (E.tenella, E.maxima and E.acervulina)	Preventative	Broiler chickens	Oral	Nil			
Coxipol 25% (clopidol)	Preventative	Broiler chickens	Mixed with feed	Meat: 2 days Eggs: do not use			
Coxiril 0.5% Premix (diclazuril)	Preventative	Broiler chickens and Layer replacement chickens	Mixed with feed	Meat: Nil Eggs: do not use			
Monotec 100 (monensin sodium)	Preventative	Broiler chickens and Layer replacement chickens	Mixed with feed	Meat: Nil Eggs: 10 days			
Monotec 200 (monensin)	Preventative	Broiler chickens and Layer replacement chickens	Mixed with feed	Meat: nil Eggs: 10 days			
NicarbMax 100% (nicarbazin)	Preventative	Broiler chickens	Mixed with feed	Meat: Nil Eggs: Do not use			
Sacox (salinomycin)	Preventative	Broiler chickens and Layer replacement chickens	Mixed with feed	Meat: Nil Eggs: 10 days			

Stenorol (halofuginone hydrobromide)	Preventative	Broiler chickens	Mixed with feed	Meat: 2 days Eggs: Nil		
ToltraVet Poultry 2.5% (toltrazuril)	Treatment	Broiler chickens	In water	Meat: 14 days Eggs: 10 days		
Yumamycin (maduramicin)	Preventative	Broiler chickens	Mixed with feed	Meat: Nil Eggs: Nil		
Agvance						
Agvance Monensin 200 (monensin sodium)	Preventative	Broiler chickens and Layer replacement chickens	Mixed with feed	Meat: nil Eggs: 10 days		
Avivet						
Coxiprol (amprolium)	Treatment	Broiler chickens, Layer replacement chickens and turkeys	In water	Meat: 5 days Eggs: 10 days		
Biopharm						
Livacox Q (E. maxima; E.acervulina; E.tenella; E.necatrix)	Preventative	Breeder and layer pullets	Spray on / in water	Nil		
Livacox T (E.tenella; E.maxima; E.acervulina)	Preventative	Broiler chickens	Spray on / in water	Nil		
GVL						
Rumenox 200 Premix (monensin sodium)	Preventative	Broiler chickens and Layer replacement chickens	Premix mixed with feed	Meat: nil Eggs: 10 days		

Rumenox 400G (monensin sodium)	Preventative	Broiler chickens and Layer replacement chickens	Mixed with feed	Meat: nil Eggs: 10 days
Rumenox in feed (monensin sodium)	Preventative	Broiler chickens and Layer replacement chickens	Mixed with feed	Meat: nil Eggs: 10 days
Huvepharma				
Coxidin 400 (monensin sodium)	Preventative	Broiler chickens and Layer replacement chickens	Mixed with feed	Meat: nil Eggs 10 days
International Animal Health Product	S	1	1	Γ
Moneco 200 Granular (monensin)	Preventative	Broiler chickens and Layer replacement chickens	Mixed with feed	Meat: nil Eggs: 10 days
MSD				
Paracox-5 (E.acervulina HP; E.brunetti HP; E.maxima CP; E. maxima MFP; E.mitis HP; E.necatrix HP; E.praecox HP; E.tenella HP)	Preventative	Broiler chickens	Spray on / mix with feed / in water	Nil
Paracox-8 (E.acervulina HP; E.maxima CP; E.maxima MFP; E.mitis HP; E.tenella HP)	Preventative	Broiler chickens	Spray on / in water	Nil
Philbro Animal Health				·
Coxistac 120 (salinomycin sodium)	Preventative	Broiler chickens and Layer replacement chickens	Mixed with feed	Meat: Nil Eggs: Do not use
Phibromonensin 100 (monensin sodium)	Preventative	Broiler chickens and Layer replacement chickens	Mixed with feed	Meat: nil

				Eggs: Do not use
Phibromonensin 200 (monensin sodium)	Preventative	Broiler chickens and Layer replacement chickens	Mixed with feed	Meat: nil Eggs: 10 days
Phibromonensin 400 (monensin)	Preventative	Broiler chickens and Layer replacement chickens	Mixed with feed	Meat: nil Eggs: 10 days
PhiCarb 1000 (nicarbazin)	Preventative	Broiler chickens	Mixed with feed	Meat: 4 days Eggs: Do not use
Zoetis				
Avatec (lasalocid sodium)	Preventative	Broiler chickens and Layer replacement chickens	Mix with feed	Meat: nil Eggs: 14 days
Bovatec 20CC (lasalocid)	Preventative	Broiler chickens and Layer replacement chickens	Mix with feed	Meat: Eggs: 14 days
Cycostat (robenidine hydrochloride)	Preventative	Broiler chickens	Mix with feed	5 days
Cygro (maduramicin)	Preventative	Broiler chickens	Mix with feed	Meat: nil Eggs: nil
Deccox (decoquinate)	Preventative	Broiler chickens	Mix with feed	Nil

Supplier / Product	Indication	Species	Application	Dose period	Withholding period
Boehringer Ingelheim					
Bivatop (oxytetracycline dihydrate)	For the treatment of a wide range of common infections caused by organisms sensitive to Oxytetracycline.	Cattle Deer Sheep Goats Pigs	Injection	Not specified on label.	Meat (Cattle, pigs): 21 days Meat (Sheep, goats, deer): 35 days Milk (Cattle): 7 days Milk: (Sheep, goats) 35 days
Mamyzin (penethamate hydriodide)	Treatment of infections caused by gram-positive bacteria that cause mastitis, respiratory infections, foot- rot and uterine infections.	Horses Cattle Sheep Pigs	Injection	Daily for 1-5 days (for 3 days in lactating cattle)	Meat: 7 days Milk (Cattle): 48 hours after the last treatment of 5 g daily dosage; 60 hours after the last treatment of 10 g plus 5 g. Milk (Sheep): 35 days
MSD				-	·
Cobactan 2.5% injection (cefquinome)	Treatment of bacterial infections in cattle and pigs caused by the Gram positive and Gram negative microorganisms sensitive to cefquinome.	Cattle Pigs	Injection	Daily for 3-5 days	Meat (cattle): 5 days Meat (pigs): 2 days Milk 12 hours (1 milking)
Duplocillin (penicillin procaine; penicillin g benzathine)	For the treatment of infections caused by bacteria sensitive to penicillin, where long-acting therapy is required.	Horses Cattle Sheep Pigs Dogs	Injection	Not specified on label	Milk (cattle): 120 hours (10 milkings) Milk (sheep): 35 days Meat (horses) 63 days Meat (non-horses) 30 days

		Cats			
		Horses Cattle Sheep Pigs	Injection	Short acting: every 24 hours for up to 5 doses.	Meat: 10 days Meat (Horses): 63 days
Engemycin (oxytetracycline)				Long acting: every 48 hours up to 2 doses	Milk: 72 hours (6 milkings)
Oxytetrin (oxytetracycline)	Treatment and control of a wide range of common systemic, respiratory and local infections caused by or associated with organisms sensitive to oxytetracycline	Cattle Sheep Pigs	Injection	Not specified on label.	Meat: 28 days Milk (cattle): 7 days Milk (sheep): 35 days
Tribrissen (trimethoprim)	Treatment and control of a wide range of respiratory, gastrointestinal and urogenital tract infections. Also foot infections, severe mastitis, bacterial agalactia of sows, and infections of the eye, ear and mouth.	Cattle Sheep Goats Pigs Horses	Injection	Single injection may be sufficient, daily for up to 5 days if necessary	Meat (Cattle, sheep, goats and pigs): 28 days Meat (horses): 63 days Milk (cattle) 48 hours (4 milkings) Milk (sheep and goats): 35 days
Norbrook					
Alamycin 10 (oxytetracycline)	Treatment of infections caused by, or associated with, organisms sensitive to oxytetracycline.	Horses Cattle Sheep Pigs	Injection	Once daily for 5 days	Milk (Cattle): 96 hours. Meat (Cattle): 21 days Meat (Sheep): 14 days Meat (Pigs): 10 days Meat (Horses): 63 days
Alamycin Aerosol (oxytetracycline hydrochloride)	Treatment of superficial infections of the foot and skin caused by organisms sensitive to oxytetracycline	Cattle Sheep Pigs	Aerosol	Twice daily for 3-5 days	Nil

Alamycin LA (oxytetracycli	ne)	Treatment of infections caused by, or associated with, organisms sensitive to oxytetracycline.	Cattle Sheep Pigs	Injection	Not specified on label.	Milk (Cattle, Sheep): 168 hours (14 milkings) Meat (Cattle, Sheep, Pigs): 28 days
Alamycin LA (oxytetracycli		Treatment of infections caused by, or associated with, organisms sensitive to oxytetracycline.	Cattle Pigs	Injection	Not specified on label.	Milk (Cattle): 168 hours (14 milkings) Meat (Cattle): 35 days Meat (Pigs): 28 days
Betamox (am	noxycillin)	Treatment of infections caused by, or associated with, organisms sensitive to Amoxycillin.	Horses Cattle Sheep Pigs Dogs Cats	Injection	If signs persist at 48 hours, repeat the dose	Milk (Cattle): 60 hours (5 milkings) Meat (Horses): 63 days Meat: 14 days
Ultrapen (per procaine)	nicillin g	Treatment of infections caused by, or associated with, penicillin sensitive organisms.	Cattle Pigs	Injection	If signs persist at 72 hours, repeat the dose	Milk (cattle): 108 hours (9 milkings) Meat (cattle): 14 days Meat (pigs): 7 days
Virbac		·				
Aerotet (oxyto gentian violet		Treatment of infections of the skin and open wounds	Cattle Horses Deer Dogs	Aerosol	Every 12 hours as required	Nil
Amphoprim	Bolus	Treatment of intestinal infections, diarrhoea and its complications,	Cattle	Oral or Intra- uterine	Not specified on label.	Milk: 5 days (10 milkings)

		pneumonia and bronchitis, urogenital infections, metritis, pyometra, septicaemias and joint infections.	Horses Sheep Goats			Meat: 21 days
	Injection	Treatment of primary and secondary infections due to susceptible Gram-positive and Gram-negative organisms.	Cattle Sheep Pigs Goats Horses Dogs Cats	Injection	Not specified on label.	Meat (Cattle, sheep, goats, pigs): 5 days Meat (horses): 63 days Milk (cattle): 48 hours (4 milkings) Milk (sheep and goats) 35 days
Bovipen (per procaine)	nicillin g	Treatment of infection caused by penicillin-sensitive organisms.	Cattle	Injection	Once in the absence of clinical symptoms, otherwise daily for 3 days	Meat: 10 days Milk: One dose – 48 hours (4 milkings); two doses – 60 hours (5 milkings); 3 or more doses – 72 hours (6 milkings)
Intracillin (pe procaine)	nicillin g	Treatment of infection caused by penicillin-sensitive organisms.	Cats Dogs Sheep Calves Foals Pigs Horses Cattle	Injection	Once / once daily for up to 3 days if necessary	Meat: 30 days Meat (horses): 63 days Milk (cattle): 108 hours (9 milkings); Milk (Sheep): 35 days
Masticillin (pe procaine)	enicillin g	Treatment of clinical and subclinical mastitis sensitive to penicillin.	Cattle Label not definitive.	Injection	Once	Milk: milking twice a day - 132 hours (11 milkings); milking once per day – 144 hours (6 milkings) Meat: 10 days

Ovipen (penicillin procaine; penicillin g benzathine)	Long acting treatment of infections which are caused by organisms susceptible to treatment with penicillin.	Sheep	Injection	Not specified on label.	Meat: 30 days Milk: 35 days
Tetraguard LA (oxytetracycline)	Treatment of bacterial infectious disease (especially useful in the treatment of respiratory, arthritic, reproductive, enteric and intramammary diseases).	Cattle Sheep Pigs	Injection	Single dose is sufficient but a second dose may be given after 72 hours if necessary	Meat: 28 days Milk: 168 hours (14 milkings)
Tyloguard (tylosin)	Treatment of bacterial and mycoplasmal infections caused by Tylosin-sensitive organisms.	Cattle Sheep Goats Pigs	Injection	Daily (Cattle, sheep, goats: for no more than 5 days) (Pigs for no more than 3 days)	Milk (Cows): 72 hours (6 milkings) Milk (sheep): 35 days Meat: 21 days
Vibrostrep (streptomycin; dihydrostreptomycin)	For the treatment of Vibrioisis (Campylobacteriosis), Leptospirosis, Actinobacillosis (Woody Tongue) and other infections caused by organisms susceptible to Streptomycin and Dihydrostreptomycin	Cattle Pigs Cheep	Injection	Not specified on label.	Meat: 30 days Milk: 72 hours (6 milkings)
Zoetis	1			1	
	Treatment of bacterial disease susceptible to tulathromycin including respiratory disease and pinkeye	Cattle	Injection	Single injection	Meat: 35 days Milk: 70 days
	Treatment of foot-rot	Sheep			Meat: 21 days Milk: nil
Draxxin	Treatment of respiratory disease	Pigs	]		Meat: 14 days Milk: nil

Excede (ceftiofur)	Treatment of bacterial diseases susceptible to ceftiofur, including bovine respiratory disease, foot rot, metritis and endometritis	Cattle Horses	Injection	Two doses 96 hours apart	Meat (Cattle neck): 56 days Meat (Cattle ear): 14 days Milk (Cattle): nil Meat (Horses): 189 days (27 weeks)
	Treatment of respiratory disease	Cattles Pigs Horses	Injection	Every 24 hours for 3 days	Nil
Excenel (ceftiofur)	Treatment of bovine foot rot	Cattle			
Linco-Spectin (spectinomycin; lincomycin)	Prevention and treatment of Chronic Respiratory Disease caused (and CRD complex) associated with infections susceptible lincomycin and/or spectinomycin	Chickens	Oral	Not specified on label.	Meat (Chickens): 2 days Meat (Pigs): 8 days Eggs: 10 days
	Treatment of dysentery, bacterial, and infectious arthritis caused by organisms susceptible to lincomycin and/or spectinomycin	Pigs			