Public Version

Commerce Act 1986: Business Acquisition

Notice seeking clearance

19 May 2009

The Registrar
Market Structure Group
Commerce Commission
PO Box 2351
Wellington
registrar@comcom.govt.nz

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

This Notice relates to the merger of Merck & Co., Inc. and Schering-Plough Corporation, in particular, their respective interests in the animal health and human health markets in New Zealand through their New Zealand subsidiaries and, in the case of Merck & Co., Inc., through Merial New Zealand Limited.

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1.7	Merial New Zealand Limited financial Statements for the year ended 31 December 2007 (as filed at the New Zealand Companies Office). (www.companies.govt.nz)
1.8	Schering-Plough Corporation: Form 10-K for the period December 31 2008, as filed with the United States Securities and Exchange Commission. (http://phx.corporate-ir.net/phoenix.zhtml?c=89839&p=irol-irhome)
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3.2	Copy of *Rural News* April 21 2009 Issue 444.

Glossary of industry terms used in this Notice

Applicant	Schering-Plough Corporation.
Baron data	Animal health industry data collected by Baron Strategic Services Pty Limited (contributed by Schering-Plough, Pfizer, Novartis, Boehringer Ingelheim and Virbac).
BVD	Bovine viral diarrhoea.
Commission	The New Zealand Commerce Commission.
DHB	District Health Boards established by the New Zealand Public Health and Disability Act 2000.
IMS	Intercontinental Medical Statistics.
IVS	Index of Veterinary Specialities Annual 2009 published by CMP Medica (New Zealand) Limited.
Johnson & Johnson/Pfizer	Decision of the New Zealand Commerce Commission dated 8 December 2006 (Decision 594).
Merck	Merck & Co., Inc.
Merial	In Part 1: Merial Limited In Part 3: Merial New Zealand Limited.
MSD	Merck Sharp & Dohme (New Zealand) Limited.
NZFSA	New Zealand Food Safety Authority.
Organon BS	Organon BioSciences N.V.
OTC	Over-the-counter.
parties	Merck & Co., Inc. and Schering-Plough Corporation or their relevant New Zealand operations, including in the case of Merck, Merial and Merial New Zealand Limited.
Proposed Transaction	The merger of Merck & Co., Inc. and Schering-Plough Corporation.
R&D	Research and development.
Schering-Plough	In Part 1: Schering-Plough Corporation. In Part 3: Schering-Plough Animal Health Limited (New Zealand).
Schering-Plough/Organon	Decision of the New Zealand Commerce Commission dated 4 October 2007 (Decision 621).
SPNZ	The human health business of Schering-Plough Animal Health Limited.

Executive Summary

The Proposal and the Parties

1 This Notice relates to the proposed merger of Merck & Co., Inc. and Schering-Plough Corporation. The Proposed Transaction will be structured as a "reverse merger" pursuant to which Schering-Plough will acquire Merck, but will operate under the name "Merck".

2 The Proposed Transaction affects the human health and animal health industries.

3 In New Zealand, Merck operates its human health business through Merck Sharp & Dohme (New Zealand) Limited. Merck's interests in the animal health industry are through its 50% shareholding with Sanofi-Aventis in the Merial joint venture, operating in New Zealand through Merial New Zealand Limited.

4 Schering-Plough operates its human and animal health businesses in New Zealand through Schering-Plough Animal Health Limited.

Affected markets

5 In New Zealand, using broad market definitions, only two human health markets are affected by the Proposed Transaction, both only to a very minor degree:

- **allergic rhinitis treatments**
- **anti-fungals**

6 In animal health, the following markets are affected, some only to a very minor degree.

- **intramammary antibiotics for the treatment of mastitis in dry cows**
- **antibiotics for the treatment of infection in ruminant animals and swine**
- **products for the treatment of external parasites in cattle (ectoparasiticides and endectocides);**
- **products for the treatment of internal parasites in (a) cattle; (b) sheep; or (c) cattle & sheep (endoparasiticides and endectocides)**
- **products for the treatment of external parasites in sheep (ectoparasiticides)**
- **products for the treatment of internal parasites in horses**
- **nutrients for selenium deficiency in cattle**
- **vaccines for bovine viral diarrhoea**

The Counterfactual

7 If the Proposed Transaction did not take place, the counterfactual, at least for the time being, is likely to be the status quo: Schering-Plough and Merck would continue running their respective operations. However, that counterfactual would

deprive the parties of the opportunity to create greater efficiencies for continued focus on R&D and product innovation.

Human Health Markets

8 In the two apparent areas of overlap in the human health area, the Merck and Schering-Plough products differ in their mode of action and therapeutic use and therefore do not result in actual overlaps.

9 Even if the parties' products in these areas are treated as overlapping products, no competition concerns arise, because:

- the parties' shares of sales in the respective markets are low;
- the merged entity will continue to face intense competitive pressure from a large number of global and smaller human healthcare companies; and
- many of the products in these product categories are off-patent and face competition from a broad range of generic manufacturers.

10 In addition, as the Commission is aware, the market power of pharmaceutical companies, regardless of market share and regardless of whether they focus on branded or generic products, is constrained by the high degree of regulation that characterizes this industry and the role of PHARMAC in pricing decisions.

Animal Health Markets

11 In some of the animal health markets, the combined market shares of Merial and Schering-Plough fall within the Commission's safe-harbour guidelines. In some markets, they fall outside the safe-harbours, but the level of aggregation is minimal.

12 There are three markets where the combined market shares will be relatively high and where the Proposed Transaction will fall outside the safe-harbour guidelines. These are:

- **products for the treatment of external parasites in cattle (ectoparasiticides and endectocides)**
- **products for the treatment of external parasites in sheep (ectoparasiticides)**
- **products for the treatment of internal parasites in sheep (endoparasiticides and endectocides)**

13 However, the Proposed Transaction will not substantially lessen competition in any of these markets, for the following reasons:

- There are a number of existing competitors, all of which are significant businesses with established reputations in the animal health industry. These include companies that develop new products through research and

development (such as Pfizer, Virbac, Bayer, Norbrook, Fort Dodge and Novartis) and those that manufacture and/or sell generic products (such as Bomac, Jurox and Ravensdown).

- The barriers to entry and expansion in animal health pharmaceuticals are low, particularly for generic products. (The Commission reached this conclusion in October 2007 in relation to the *Schering-Plough/Organon* transaction.)

- In each of these product markets, there are active substances that are off-patent. Formulations and ingredients are readily available.

- There are a wide variety of products on the market, ranging from innovative formulations and combinations to cheaper, generic offerings with little or no technical differentiation.

14 In summary, both the human health and animal health markets are highly competitive, with manufacturers and suppliers being under constant price pressure from generic products.

A. The Merger Parties

1 **Acquirer**

1.1 This notice is given by **Schering-Plough Corporation**.

1.2 Details for **Schering-Plough Corporation**.

Name and position of person responsible for giving this Notice:	Thomas J. Sabatino, Jr., Executive Vice President and General Counsel
Registered Office:	Schering-Plough Corporation 2000 Galloping Hill Road Kenilworth N.J. 07033-0530 U.S.A.
Postal Address:	Schering-Plough Corporation 2000 Galloping Hill Road Kenilworth N.J. 07033-0530 U.S.A.
Physical Address:	Schering-Plough Corporation 2000 Galloping Hill Road Kenilworth N.J. 07033-0530 U.S.A.
Telephone:	+1 (908) 298-4000
Fax:	+1 (908) 298-7555
Website:	www.schering-plough.com
Contact Person:	Thomas J. Sabatino, Jr., Executive Vice President and General Counsel
E-mail Address:	thomas.sabatino@spcorp.com

1.3 In the first instance, please direct all inquiries to:

Lindsey Jones, Partner, Chapman Tripp
lindsey.jones@chapmantripp.com
Telephone: (649) 357 9020

2 Details of other merger parties

2.1 Details for **Merck & Co., Inc.**

Registered Office:	1 Merck Drive Whitehouse Station N.J. 08889-0100 U.S.A.
Postal Address:	1 Merck Drive P.O.Box 100 Whitehouse Station N.J. 08889-0100 U.S.A.
Physical Address:	1 Merck Drive Whitehouse Station N.J. 08889-0100 U.S.A.
Telephone:	+1 (908) 423 1000
Fax:	+1 (908) 735 1246
Website:	www.merck.com
Contact Person:	George Shiebler, Vice President and Assistant General Counsel
E-mail Address:	george_shiebler@merck.com

2.2 In the first instance, please direct all inquiries regarding both **Merck and Merial** to:

Lindsey Jones, Partner, Chapman Tripp
lindsey.jones@chapmantripp.com
Telephone: (649) 357 9020

3 Ownership and control of the merger parties

Merck

3.1 Merck is a global research-driven pharmaceutical company with activities in human health products.

3.2 Merck is a New Jersey-based corporation. Its shares are listed on the New York Stock Exchange, held by the public and are widely dispersed. As at March 13, 2009, no person or group held more than 5% of outstanding shares of Merck common stock.

3.3 Merck & Co., Inc. is the ultimate parent company of the Merck group of companies. Merck (including through its interest in Merial) has business operations in more than 150 countries.

3.4 A list of Merck's principal subsidiaries is set out in Appendix 1.1.

3.5 In New Zealand, Merck has one operating subsidiary, Merck Sharp & Dohme New Zealand Limited.

3.6 Merck also has an interest in the animal health sector, through its joint venture with Sanofi-Aventis Limited, in Merial. For further information on Merial, see http://corp.merial.com/company_history/index.asp (copy at Appendix 1.2.)

3.7 The Merial joint venture operates in New Zealand through Merial New Zealand Limited, trading as "*MERIAL Ancare New Zealand*".

Schering-Plough

3.8 Schering-Plough is a global science-based healthcare company with activities in the prescription pharmaceutical, over-the-counter (OTC) consumer healthcare and animal health sectors. Schering-Plough conducts research, manufacturing and distribution in its own right, and is also engaged in various collaborative projects with others to develop and manufacture both human and animal health products.

3.9 Schering-Plough is a New Jersey-based corporation. Its shares are listed on the New York Stock Exchange, held by the public and are widely dispersed.

3.10 Schering-Plough is the ultimate parent company of the Schering-Plough group of companies. It has more than 55 subsidiaries outside the United States and the majority of its operations are outside the United States.

3.11 Details of the ownership and control of Schering-Plough, together with a list of Schering-Plough Corporation's subsidiaries and other companies (with assets of $10 million or more) in which Schering-Plough holds a minority interest (between 5% and 49%), are set out in Appendix 1.3.

3.12 The following countries accounted for 5% or more of consolidated net sales during any of the past three years: United States, France, Japan, Germany and Canada.

3.13 In New Zealand, there is one local operating company, Schering-Plough Animal Health Limited, which operates both the animal health and human health b*usinesses. The animal health business* **t**rades under the name *Intervet Schering-Plough Animal Health*.

Links, formal or informal, between the merger parties, including interconnected bodies corporate and other persons identified in question 3 above and its/their existing competitors in each market.

3.14 Within both the human and animal health industries, there is a range of agreements between market participants, including for example, manufacturing agreements, distribution agreements and research and development agreements. The key agreements between the parties that affect the New Zealand markets are listed below and, in relation to Schering-Plough, in confidential Schedule 1.2.

Merck

3.15 The Applicant is aware that Merck has the following formal or informal links with its competitors:

Human Health

- Globally, Merck is engaged in various collaboration projects with other pharmaceutical business partners to develop and manufacture human health products and the licensing in or out of compounds for R&D.
- In May 2000, Merck and Schering-Plough entered into two separate sets of agreements to jointly develop and manage certain products in the United States, including (1) two cholesterol-lowering drugs and (2) an allergy/asthma drug. The allergy/asthma joint venture was terminated in the second quarter of 2008. (Further detail on these agreements is set out in Part 2: Human Health.)
- Merck is a party to a limited partnership agreement with AstraZeneca in relation to the development and distribution of certain prescription medicines in the United States.
- Merck is a party to a joint venture with Johnson & Johnson to develop and market a range of non-prescription medicines for consumers in the United States and Canada. The most significant joint venture products are OTC ulcer medications.
- Merck is party to a joint venture with Sanofi Pasteur SA which markets human vaccines in parts of Europe and collaborates in the development of combination vaccines in parts of Europe.
- Merck has an arrangement with CSL Biotherapies (NZ) Limited for the distribution of its vaccines in New Zealand.

- Merck is a member of the Researched Medicines Industry (details at http://www.rmianz.co.nz/index.php)

Animal Health

- Merck and Sanofi-Aventis SA are parties to the Merial joint venture, a standalone fully integrated animal health company.
- Merial is a member of the European-based International Federation for Animal Health.
- Merial New Zealand is a member of the New Zealand Association for Animal Health and Crop Protection.

Schering Plough

3.16 Schering-Plough has the following formal or informal links with its competitors:

Human Health

- See above for relationships with Merck.
- An agreement with Centocor, Inc. (a Johnson & Johnson company) pursuant to which Schering-Plough has distribution rights outside of the United States to a number of products, including REMICADE, a product for the treatment of inflammatory diseases.
- Globally, Schering-Plough is engaged in various collaboration projects with other pharmaceutical business partners to develop and manufacture human health products and the licensing in or out of compounds for R&D.
- Schering-Plough globally is party to an agreement with Johnson & Johnson pursuant to which it has marketing rights to Caelyx (indicated for breast and ovarian cancer). This agreement terminates at 31 December 2010.
- Schering-Plough is party to a licensing arrangement with Daiichi Sankyo Company Limited for Olmesartan (indicated for hypertension). New Zealand and Australia were added as licensed countries to the 2005 Global Licensing Agreement (which applied to Latin American countries) by way of an amendment dated 29 November 2006. Schering-Plough has launched this product in Australia, but not in New Zealand.
- Together with Novartis, Schering-Plough is developing two combination products for the long-term development of asthma and COPD, which are at Phase III of clinical development.

Animal Health

- The agreements listed in Confidential Schedule 1.2.
- In New Zealand, Schering-Plough Animal Health Limited has manufacturing agreements with:
    - Argenta (New Zealand), for the manufacture and supply of endoparasiticides and ectoparasiticides by Argenta;

- Norbrook (Ireland), for the supply of intramammaries and injectable products (and potentially certain endoparasiticides and ectoparasiticides in the future) by Norbrook;

- An agreement between Schering-Plough Animal Health Limited and Pfizer, pursuant to which Schering-Plough Animal Health distributes sheep ectoparasiticide and endoparasiticide products under brands owned by Pfizer.

- An agreement between Schering-Plough Animal Health Limited and Ecolab Limited under which Schering-Plough Animal Health has granted to Ecolab the exclusive right to market and distribute products for teat care and the treatment of mastitis under the HIBITANE brand in New Zealand.

- Following Schering-Plough's acquisition of Organon BS in 2007, Schering-Plough divested certain products to Virbac, Pfizer and Fort Dodge. There are various ongoing licence and manufacturing arrangements associated with these divestments (including in relation to the divestment of Campylovexin in New Zealand).

- Schering-Plough Animal Health Limited is a member of the New Zealand Association for Animal Health and Crop Protection (as are most of its competitors, with the exception of Pfizer).

- Schering-Plough (and all other multinational companies in the affected animal health markets) belongs to the European-based International Federation for Animal Health.

- Internationally Schering-Plough is engaged in various collaboration projects with other pharmaceutical business partners to develop and manufacture animal health products.

3.17 Other than in relation to the cholesterol joint venture referred to above, so far as the Applicant is aware, neither Merck nor any of its interconnected bodies corporate has any beneficial interest in, or is beneficially entitled to, any shares or other pecuniary interest in Schering-Plough or any of its interconnected bodies corporate or associated companies.

3.18 Other than the Merck/Schering-Plough joint venture referred to above, neither Schering-Plough nor any of its interconnected bodies corporate has any beneficial interest in, or is beneficially entitled to, any shares or other pecuniary interest in Merck or any of its interconnected bodies corporate or associated companies.

3.19 So far as the Applicant is aware, no directors of Merck or Merial hold directorships in any other pharmaceutical or animal health companies in New Zealand.

3.20 No directors of Schering-Plough hold directorships in any other pharmaceutical or animal health companies in New Zealand.

B. The Transaction

4 What will be acquired

4.1 Pursuant to a Merger Agreement, dated March 8, 2009, Merck and Schering-Plough will combine in a stock and cash transaction. The Proposed Transaction will be structured as a "reverse merger" pursuant to which Schering-Plough will acquire Merck, but will operate under the name "Merck".

4.2 Under the terms of the Merger Agreement, Schering-Plough shareholders will receive 0.5767 shares of the combined company and $10.50 (USD) in cash for each share of Schering-Plough. Each Merck share will automatically become one share of the combined company.

4.3 Based on the closing price of Merck stock on March 6, 2009, the consideration to be received by Schering-Plough shareholders is valued at $23.61 (USD) per share, or $41.1 billion (USD) in the aggregate. Merck shareholders are expected to own approximately 68 percent of the combined company, and Schering-Plough shareholders are expected to own approximately 32 percent.

4.4 The Proposed Transaction is subject to approval by Merck and Schering-Plough shareholders and the satisfaction of customary closing conditions and regulatory approvals, including the expiration or termination of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and approval of the European Commission under the EC Merger Regulation.

4.5 Merck and Schering-Plough expect to complete the Proposed Transaction in the fourth quarter of 2009.

5 Rationale for the transaction

5.1 The Proposed Transaction involves the merger of two companies listed on the New York Stock Exchange. The Proposed Transaction offers the following strategic and financial benefits.

- The combination of the parties' complementary businesses will result in a pharmaceutical company with a more diverse portfolio across important therapeutic areas, including cardiovascular, respiratory, oncology, neuroscience, infectious disease, immunology, women's health, and other areas.
- The combined company will have a product pipeline with greater depth and breadth, and numerous promising drug candidates. In particular, the Proposed Transaction will double the number of potential medicines that Merck has in Phase III development. Further, the increased financial flexibility of the combined company will allow it to invest in these candidates, as well as in external R&D opportunities.

- The Proposed Transaction will result in a merged entity with a more geographically diverse mix of business. Schering-Plough generates about 70% of its revenue outside of the United States. By contrast, Merck only generates approximately 44% of its revenue outside of the United States.
- The combined company will have considerably greater manufacturing capabilities, with more capacity to support the company's anticipated growth in biologicals and sterile medicines.
- Merck expects to achieve substantial cost savings as a result of the Proposed Transaction, particularly through the full integration of the existing Merck/Schering-Plough cholesterol joint venture. Total cost savings are expected to be around US$3.5 billion (€2.4 billion) annually beyond 2011.

6 Transaction documents

The most recent version of the document bringing about the proposed merger is the Agreement and Plan of Merger dated March 8, 2009. A copy of this document is in Appendix 1.4.[1]

7 Other competition agencies notified

7.1 The Proposed Transaction has been, or will be, notified to the following competition agencies in the following countries (all dates are 2009):

Country	Date (or anticipated date) of filing	Country	Date (or anticipated date) of filing
Argentina	15 June	Pakistan	May
Australia	May	Russia	15 May
Brazil	27 March	Serbia	May
Canada	17 April	South Africa	May
China	May	South Korea	First notification approved on 24 April 2009
Colombia	15 May	Switzerland	July
European Union	End of June	Taiwan	May
		Turkey	May
Israel	13 May	Ukraine	May
Mexico	15 May	United States	17 April

7.2 Merck and Schering-Plough are willing to provide the Commission with a waiver allowing it to exchange confidential information with competition agencies in other jurisdictions in respect of the Proposed Transaction. A

[1] No public offer documents are available.

draft of the form of waiver has been provided to the Commission. A final signed waiver will be provided once the Commission advises the particular agency or agencies with which it wishes to exchange confidential information.

C. The Industry

8 Goods and services supplied by the merger parties

Merck

Human Health

8.1 Internationally, Merck's operations are principally managed on a products basis and are comprised of two reportable segments:

- the pharmaceutical segment and;
- the vaccines and infectious diseases segment.

8.2 The pharmaceutical segment includes human health pharmaceutical products marketed either directly by Merck or through joint ventures. These products consist of therapeutic and preventive agents, sold by prescription, for the treatment of human disorders. Merck sells these human health pharmaceutical products primarily (depending on the jurisdiction) to drug distributors, wholesalers and retailers, hospitals, government agencies and managed health care providers such as health maintenance organizations, pharmacy benefit managers and other institutions.

8.3 The vaccines and infectious diseases segment includes human health vaccine and infectious disease products marketed either directly by Merck or, in the case of vaccines, also through a joint venture.

- Vaccine products consist of preventative paediatric, adolescent and adult vaccines. Merck sells these human health vaccines primarily to physicians, wholesalers, physician distributors and government entities.
- Infectious disease products consist of therapeutic agents for the treatment of infection sold primarily to drug wholesalers and retailers, hospitals and government agencies.

8.4 The funding and supply chain for human health pharmaceuticals in New Zealand is set out in Part 2: Human Health.

8.5 In New Zealand, Merck has one operating subsidiary, Merck Sharp & Dohme (New Zealand) Limited. It has no New Zealand manufacturing facilities.

8.6 Further details on Merck's New Zealand pharmaceuticals business is set out in Part 2: Human Health.

Animal health

8.7 In 1997, Merck and Rhone-Poulenc SA (now Sanofi-Aventis SA) combined their respective animal health businesses to form Merial, a fully integrated animal health company, which is a stand-alone joint venture, 50% owned by each party.

8.8 The Merial joint venture operates in New Zealand through Merial New Zealand Limited, trading as "*MERIAL Ancare New Zealand*". The 2008

turnover of Merial Limited was €1,797 million (US$2,643 million), of which US$33.6 million was earned in New Zealand.

8.9 Merial's fundamental policies and strategy are determined by, and all significant decisions are taken by, it's Board of Directors. The Board consists of six members, with each party appointing three directors. Resolutions of the Board must be passed unanimously by all directors present at a meeting in order to be valid.

8.10 Although Merial is operated as an independent company, for the purpose of this Notice, Merial has been treated as an "associated person" under section 47 of the Commerce Act.

8.11 The majority of products sold by MERIAL Ancare New Zealand are either manufactured in New Zealand at the Ancare manufacturing site in Auckland or toll manufactured in New Zealand. Some products are imported from France, Brazil, China and Australia.

8.12 Internationally, Merial provides a comprehensive range of pharmaceuticals and vaccines to enhance the health, well-being and performance of a wide range of animal species. Products are manufactured and marketed for the following major animal groups:

- *Livestock:* treatments for internal and external parasites and vaccines such as vaccines against bovine rhinotracheitis;
- *Swine:* products for immunisation against specific infections and lesions; treatment and control of gastro-intestinal parasites; and vaccines reducing various viral-caused reproductive disorders.
- *Equine:* products for parasite control and vaccines for the prevention of abortions and stillbirths caused by Equine Herpes Virus.
- *Avian:* a range of vaccines are available combating various avian health challenges, for example, vaccines against Marek's disease, Infectious Bursal disease, Newcastle disease and Infectious Bronchitis.
- *Companion animal:* industry-leading products such as FRONTLINE for flea and tick control; HEARTGARD worm treatment for cats and dogs.

8.13 Further details of Merial's New Zealand animal health business are set out in Part 3: Animal Health.

Schering-Plough

8.14 At a global level, Schering-Plough operates in three reportable segments:

- prescription human pharmaceuticals;
- animal health; and
- consumer healthcare.

Prescription Pharmaceuticals

8.15 Schering-Plough's prescription pharmaceuticals division discovers, develops, manufactures and markets human pharmaceutical products.

Within the prescription pharmaceuticals division, Schering-Plough has a broad range of research projects and markets products in six therapeutic areas:

- cardiovascular;
- central nervous system;
- immunology and infectious disease;
- oncology;
- respiratory; and
- women's health.

8.16 The prescription pharmaceuticals division also includes:

- Nobilon, a human vaccine development unit; and
- Diosynth, a third party manufacturing unit.

8.17 Further details on Schering-Plough's New Zealand prescription pharmaceuticals business are set out in Part 2: Human Health.

Animal Health

8.18 At a global level, Schering-Plough's animal health division discovers, develops, manufactures and markets animal health products, including vaccines. Principal products in this segment include:

- *Livestock:* antibiotics; vaccines; anti-inflammatories; combination broad spectrum antibiotic and non-steroidal anti-inflammatories; products for the treatment of fertility disorders and fertility management; products to improve production efficiencies in beef cattle; products for the treatment of respiratory disease; and a data management tool for cattle;
- *Poultry:* vaccines;
- *Companion Animal:* vaccines; ear ointment; diabetes mellitus treatment; broad spectrum anthelmintic (de-wormer); products for protecting against bites from fleas, ticks, mosquitoes and sandflies;
- *Aquaculture:* parasiticides; vaccines; and antibiotics;
- *Swine:* parasiticides; vaccines; and antibiotics; and
- *Equine:* parasiticides; analgesics; anti-inflammatories; and nutrients.

8.19 Further details on Schering-Plough's New Zealand animal health business are set out in Part 3: Animal Health.

Consumer Healthcare

8.20 The consumer healthcare division develops, manufactures and markets over-the-counter (OTC), foot care and sun care products. Internationally, principal products in this segment include:

- *Over-the-Counter Products:* CLARITIN non-sedating antihistamines (branded in New Zealand as CLARATYNE); MIRALAX treatment for occasional constipation; CORICIDIN HBP decongestant-free cold/flu medicine for people with high blood pressure; AFRIN nasal decongestant spray; and CORRECTOL laxative tablets.
- *Foot Care:* DR. SCHOLL'S foot care products; LOTRIMIN topical antifungal products; and TINACTIN topical antifungal products and foot and sneaker odour/wetness products.
- *Sun Care:* COPPERTONE sun care lotions, sprays, dry oils and lip-protection products and sunless tanning products; and SOLARCAINE sunburn relief products.

8.21 Schering-Plough does not market the footcare and sun care products in New Zealand.

8.22 The specific areas where aggregation occurs between the merger parties in New Zealand are identified and discussed in Part 2: Human Health and Part 3: Animal Health.

9 Describe the industries affected by the transaction

In relation to human health, please refer to Part 2. In relation to animal health, please refer to Part 3.

10 Industry trends and developments

In relation to human health, please refer to Part 2. In relation to animal health, please refer to Part 3.

11 Other mergers in the industry in the past 3 years

11.1 The Applicant is aware of the following mergers in the human health and animal health industries affecting the New Zealand market in the past three years:

- In November 2007, Schering-Plough acquired the shares in Organon SB, a European human and animal health products company, trading in New Zealand as Organon for its human health products and Intervet for its animal health products.
- In October 2007, Merial acquired certain assets of Ancare New Zealand Limited and all of the issued and outstanding capital stock of certain of

its subsidiaries (Ancare Ireland Limited, Ancare Australia Pty Limited and Animal Health Care South Africa Pty Limited).

- In 2006 & 2007, the global pharmaceuticals company Bayer acquired Schering AG[2] and was renamed Bayer Schering Pharma AG.
- In 2007, Johnson & Johnson acquired the consumer healthcare division of Pfizer Inc.

11.2 The Commission will also be aware that Pfizer and Wyeth have entered into a merger agreement pursuant to which Pfizer will acquire Wyeth in a cash-and-stock transaction.

Market definition

12 **Horizontal aggregation**

12.1 In relation to human health products, please refer to Part 2. In relation to animal health products, please refer to Part 3.

12.2 Merck, Schering-Plough and Merial products are distributed nationally. The geographic scope of the markets is national.

12.3 All of the Merck and Schering-Plough human pharmaceutical products for distribution in New Zealand are manufactured off-shore and imported into New Zealand. The majority of Merial's products for distribution in New Zealand are manufactured in New Zealand. Schering-Plough makes animal vaccines in New Zealand, has some animal health pharmaceutical products made by third party manufacturers in New Zealand and imports the balance.

12.4 The functional market is therefore manufacture, import and wholesale distribution.

13 **Product differentiation**

In relation to human health, please refer to Part 2. In relation to animal health please refer to Part 3.

14 **Vertical integration**

The Proposed Transaction will not result in vertical integration in any of the markets identified. The parties are already vertically integrated through their offshore and New Zealand based manufacturing divisions.

15 **The counterfactual**

If the merger did not take place, the counterfactual, at least for the time being, is likely to be the status quo: Schering-Plough and Merck would

[2] Schering is not related to Schering-Plough.

continue running their respective operations. However, that counterfactual would deprive the parties of the opportunity to create greater efficiencies for continued focus on R&D and product innovation.

16 – 28 Competition analysis

Responses to the questions in this part of the Clearance Application form are contained in separate sections for human health and animal health. Please refer to Parts 2 and 3.

D. Further Information & Confidentiality

Further information and supporting documentation

29 Contact details of relevant competitors, buyers and suppliers and other relevant market participants are set out in Schedule 1.1.

30 **Annual Reports**

30.1 The following documents relating to Merck are contained in Appendices 1.5 – 1.7:

- Merck & Co, ..: Form 10-K for the period December 31, 2008, as filed with the United States Securities and Exchange Commission.
- Merck Sharp & Dohme (New Zealand) Limited Financial Statements for the year ended 31 December 2007, as filed at the New Zealand Companies Office.
- Merial New Zealand Limited financial Statements for the year ended 31 December 2007, as filed at the New Zealand Companies Office.

30.2 The following documents relating to Schering-Plough are contained in Appendices 1.8 and 1.9:

- Schering-Plough Corporation: Form 10-K for the period December 31, 2008, as filed with the United States Securities and Exchange Commission.
- Schering-Plough Animal Health Limited financial report for the year ended 31 December 2007, as filed at the New Zealand Companies Office.

Confidentiality

31 Confidentiality is sought for specific information contained in or attached to the Notice, details of which are [in square brackets and shaded] and have been removed from the Public Version of this Notice.

32 The confidential information is set out in:

- Schedule 1.2 at the end of Part 1;
- Schedule 2.2 at the end of Part 2: Human Health;
- Schedule 3.1 at the end of Part 3: Animal Health.

33 Confidentiality is sought indefinitely or until the Applicant advises the Commission that it can make public disclosure of particular details. Confidentiality is sought under section 9(2)(b) of the Official Information Act on the grounds that:

- the information is commercially sensitive and valuable information which is confidential to the parties; and
- disclosure of the information is likely to give unfair advantage to competitors of the parties and unreasonably prejudice the commercial position of the parties.

34 The Applicant also requests that it is notified of any request made under the Official Information Act for the confidential information, and that the Commission seeks the Applicant's views as to whether the information remains confidential and commercially sensitive at the time those requests are being considered.

35 The above applies equally in respect of any additional information provided to the Commission that is expressed to be confidential.

Declaration

This Notice is given by Schering-Plough Corporation.

Thomas J. Sabatino, Jr., Executive Vice President and General Counsel, Schering-Plough Corporation, hereby confirms that:

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

Thomas J. Sabatino, Jr., undertakes to advise the Commission immediately of any material change in circumstances relating to the Notice.

Dated: 2009

I am a director/officer of Schering-Plough Corporation and am duly authorised to make this application/notice.

Schedules

Schedule 1.1

Contact details for competitors, buyers and suppliers

A. Human Health

Name of company (legal and trading names)	**Contact details** (Postal & physical address, telephone and fax, website)	**Relevant contact person** (Name, position and contact details including telephone, fax, email)
COMPETITORS		
Abbott Laboratories	Ground Floor, Bldg. D 4 Pacific Rise Mount Wellington, P.O. Box 22-801 Otahuhu Auckland, New Zealand Phone: +64 9 573 6030 Fax: +64 9 573 6040	NZ Commercial Director Nick Leach Phone: +64 4 586 4975 Fax: +64 4 586 2417
AFT Pharmaceuticals	Level 2, 9 Anzac Street, Takapuna PO Box 33-203 Takapuna, Auckland Phone +64 9 488 0232 Fax +64 9 488 0234	
Apotex NZ Limited	32 Hillside Road Glenfield Auckland New Zealand Phone: +64 9 444 2073 Fax: +64 9 444 2951	
AstraZeneca New Zealand Limited	303 Manukau Road, Epsom, Auckland, Phone: +64 9 623 6300	General Manager Lance Gravatt Phone: +64 9 623 6300 Fax: +64 9 623 6301
Boehringer Ingelheim	42 Ormiston Rd, East Tamaki, PO Box 76 216, Manukau City Auckland Phone: +64 9 274 8664 Fax: +64 9 271 0629	Managing Director Darcy Downey Phone: +64 9 274 8664 Fax: +64 9 271 0629
Bristol-Myers Squibb	P O Box 62627 Mt Wellington Phone: +64 9 571 5251	

Name of company (legal and trading names)	**Contact details** (Postal & physical address, telephone and fax, website)	**Relevant contact person** (Name, position and contact details including telephone, fax, email)
Eli Lilly & Co	Level 3, Axon House 414-422 Khyber Pass Road Newmarket PO Box 109197 Auckland 1031 Phone: +64 9 523 9300 Fax: +64 9 523 9301	General Manager Katherine Lester Phone: +64 9 523 9304 Fax: +64 9 523 9301
CSL Biotherapies (NZ) Limited	666 Great South Road Central, Park Penrose PO Box 62-950, Kalmia Street Auckland	Country Manager Mike Taylor Phone: +64 9 579 8105 Fax: +64 9 579 8106
Gilead Sciences	Level 1 128 Jolimont Road East Melbourne, Victoria 3002 Australia Phone: +61 3 9 272 4400 Fax: +61 3 9 272 4411	
Douglas Pharmaceuticals	Central Park Drive, Lincoln, 0610 P0 Box 45 027, Te Atatu Peninsula, Auckland 0651, New Zealand Phone +64 9 835 0660 Fax +64 9 835 0665	
GlaxoSmithKline	8th Floor, Quay Tower Cnr Customs & Albert Sts Private Bag 106600 Downtown Auckland Auckland Phone: +64 9 367 2900 Fax: +64 9 367 2910	General Manager Geoff McDonald Phone: +64 9 367 2900 Fax: +64 9 367 2907
Hospira NZ Limited	23 Haining Street Te Aro Wellington New Zealand Phone: +64 4 384 7463	
Janssen-Cilag (New Zealand) Limited	Ericcson House Ground Floor 105 Carlton Gore Road PO Box 9222 Newmarket Auckland	Associate Director Andy Paige Phone: +64 9 523 8700 Fax: +64 9 523 1646

Name of company (legal and trading names)	**Contact details** (Postal & physical address, telephone and fax, website)	**Relevant contact person** (Name, position and contact details including telephone, fax, email)
Johnson & Johnson	13a Gabador Plc Mt Wellington Auckland 1641 Phone: +64 9 574 1783 Fax +64 9 573 6234	
Multichem	8 Apollo Drive Mairangi Bay Private Bag 93527 Takapuna Auckland 1332 Phone: 64 9 488 0330 Fax: 64 9 478 3841	
Mylan New Zealand Limited	PO Box 11183 Ellerslie, 1542 Auckland New Zealand Phone: +64 9 579 2792 Fax: +64 9 579 7072	
Novartis New Zealand	6-8 Mackelvie Street Grey Lynn Private Bag 47909 Ponsonby Auckland Phone: 0800 652 422	General Manager Sean Evans Phone: +64 9 361 8100 Fax: +64 9 361 8181
Pfizer New Zealand	Level 3, Pfizer House 14 Normanby Road Mt Eden Auckland Phone: +64 9 638 0000 Fax: +64 9 638 0021	Managing Director Frances Benge Phone: +64 9 638 0000 Fax: +64 9 638 0021
Roche Products (NZ)	8 Henderson Place Te Papapa Auckland 1061 New Zealand Phone: +64 9 635 1500 Fax: +64 9 635 1549	Managing Director Svend Peterson Phone: +64 9 633 0700 Fax: +64 9 633 0759
Sanofi-Aventis	James & Wells Tower, Part Level 8, 56 Cawley St, Ellerslie, PO Box 12851 Penrose, Auckland Phone: +64 9 580 1810	Country Manager Alan Carter Phone: +64 9 580 1829 Fax: +64 9 580 1811

Name of company (legal and trading names)	**Contact details** (Postal & physical address, telephone and fax, website)	**Relevant contact person** (Name, position and contact details including telephone, fax, email)
Sigma Pharmaceuticals Pty	1408 Centre Road Clayton Victoria 3168 Locked Bag 268 (96 Merrindale Drive) Croydon Vic 3136 Australia Phone: +61 3 9839 2800	
Wyeth	15b Vestey Drive Mt Wellington PO BOX 12736 Penrose Auckland Phone: 0800 447 400 Fax: +64 9 573 0257	Pharmaceutical Business Director, Australia & New Zealand Candy Braithwaite Phone: +61 2 8850 8188 Fax: +61 2 9023 0000
DISTRIBUTORS		
Healthcare Logistics	58 Richard Pearse Drive Mangere, Auckland, New Zealand 2022 Phone: +64 9 918 5100	
Pharmaco (NZ) Ltd	PO Box 4079 Auckland New Zealand Phone: +64 9 377 3336 Facsimile: +64 9 307 1307	
DHL	2C Bell Rd, Gracefield, Lower Hutt, Wellington Phone: +64 4 924 9444	
WHOLESALERS		
Propharma	54 Carbine Road, P O Box 62027 Mount Wellington, Auckland 1060 Phone: +64 9 570 1080 Fax: +64 9 915 9581	
CDC Pharmaceuticals	284 Cashel Street, P O Box 1073 Christchurch 8011 Phone: +64 3 379 5480 Fax: +64 3 379 5911	

Name of company (legal and trading names)	**Contact details** (Postal & physical address, telephone and fax, website)	**Relevant contact person** (Name, position and contact details including telephone, fax, email)
Wainhouse Distribution	2-6 Argyle St, Morningside PO Box 41-014, St Lukes Auckland, New Zealand Phone: +64 9 815 1020 Fax +64 9 815 1036	
SUPPLIERS		
IMS Health (NZ) Limited	Unit 3 112 Bush Road North Harbour North Shore City Auckland 0632 Phone +64 9 414 9010 www.imshealth.com	
TRADE ASSOCIATIONS		
New Zealand Self Medication Industry Association Inc	PO Box 6473, Auckland, New Zealand	Tim Roper, BPharm MPS Executive Director Phone/fax: +64 9 235 5260 Mobile: +64 21 992 113 tim.roper@nzsmi.org.nz

B. Animal Health

Name of company (legal and trading names)	**Contact details** (Postal & physical address, telephone and fax, website)	**Relevant contact person** (Name, position and contact details including telephone, fax, email)
COMPETITORS		
Pfizer New Zealand Limited	Level 3, Pfizer House 14 Normanby Road Mt Eden Auckland New Zealand Phone: +64 9 638 0000 Fax: +64 9 638 0021 Email: ContactUs.NewZealand@pfizer.com	Division Director – Animal Health Paul Fitzpatrick Paul.fitzpatrick@pfizer.com
Fort Dodge New Zealand Limited	Level 1, 15 Vestey Drive Mount Wellington Auckland City Auckland 1060 New Zealand Phone: +64 9 276 9393 Fax: +64 9 276 9292	Managed from Sydney General Manager Rob Barclay
Bomac Laboratories Limited	Cnr Wiri Station Road & Hobill Ave P.O Box 76-369 Manukau City Auckland New Zealand Phone: +64 9 262 3169 Fax: +64 9 262 3008 Website: www.bomac.co.nz	General Manager Connell McLaren c.mclaren@bomac.co.nz
Bayer New Zealand Limited	3 Argus Place Glenfield Auckland New Zealand Phone: +64 9 443 3093 Fax: +64 9 443 3094 Website: www.bayer.co.nz	General Manager Graham Donkin
Norbrook New Zealand Limited	C/-KPMG 18 Viaduct Harbour Avenue Maritime Square Auckland New Zealand Phone: 0800 224 022 Fax: 0800 224 033 Email: enquiries@norbrook.com.au Website: www.norbrook.com.au	Managed from Australia

Name of company (legal and trading names)	**Contact details** (Postal & physical address, telephone and fax, website)	**Relevant contact person** (Name, position and contact details including telephone, fax, email)
Boehringer Ingelheim NZ Limited	Level 1, 9/42 Ormiston Road East Tamaki Auckland 2016 P O Box 76216 Manukau City New Zealand Phone: +64 9 274 8664 Fax: +64 9 271 0629 Website: www.boehringer-ingelheim.com	Managed from Australia
Jurox Pty Limited	85 Gardiner Road Rutherford NSW 2320 Australia Phone: +61 2 4931 8200 Fax: +61 2 4931 8222 Email Enquiries: jenq@jurox.com.au	Tim Balmer 8 Kordel Place East Tamaki Auckland 0800 587 696
Ravensdown Fertiliser Co-operative Limited	Level 1, 32 Oxford Terrace PO Box 1049 Christchurch New Zealand Phone: +64 3 353 4600 Fax: +64 3 353 4625 email: customer.centre@ravensdown.co.nz Website: www.ravensdown.co.nz	Dr Gavin Goble Gavin.Goble@ravensdown.co.nz
Stockguard Laboratories (NZ) Limited	Stockguard Laboratories (NZ) Limited 26-30 Maui Street Hamilton New Zealand Phone: +64 7 849 6782 Fax: 64 7 849 5079 Email: info@stockguard.co.nz Web site address: http://www.stockguard.co.nz	Managing Director Kevin Burke Kevin@stockguard.co.nz
Novartis New Zealand Limited	Novartis New Zealand Limited, Ponsonby Private Bag 47909 Auckland, 1034 New Zealand Phone: +64 9 361 8100 Fax: +64 9 361 8181 Website: http://www.novartis.com/	NZ Manager Colin McKay colin.mckay@ah.novartis.com

Name of company (legal and trading names)	**Contact details** (Postal & physical address, telephone and fax, website)	**Relevant contact person** (Name, position and contact details including telephone, fax, email)
Parnell Laboratories (Aust) Pty Limited	PO Box 73160 Auckland Airport Manukau 2150 nzinfi@parnell.biz.nz	
Animal Health Direct Limited	Animal Health Direct Limited P.O Box 8015, Havelock North Hawke's Bay New Zealand Phone: +64 6 877 3201 Fax: +64 6 877 3205 Email: info@animalhealthdirect.co.nz	
Nutritech International Limited	Nutritech International Limited 12 Fisher Crescent Mt Wellington PO Box 62-121 Auckland 1060 New Zealand Phone: +64 9 276 1185 Fax: +64 9 276 6357	Bruce McNeill
Ecolab Limited	Ecolab Limited 2 Daniel Place PO Box 10061 Te Rapa Hamilton 3241 New Zealand Phone: +64 7 958 2333 Fax: +64 7 958 2361 Website: http://www.ecolab.com/	National Farm Manager Roger Swann Roger.swan@ecolab.co.nz Phone: +64 7 849 4829
Lloyd Laboratories NZ Limited	Lloyd Laboratories NZ Limited 233 Porchester Road Takanini Auckland New Zealand	Dr Andrew Grierson Andrew@caledonian.biz.nz Phone: +64 9 298 3072
Vetpharm NZ Limited	Vetpharm NZ Limited 3 Whetu Place Sunset North North Shore City Auckland, 0632 New Zealand Phone: +64 9 476 7391 Fax: +64 9 479 5555 Website: http://www.phoenixpharm.co.nz	Graham Webb

Name of company (legal and trading names)	**Contact details** (Postal & physical address, telephone and fax, website)	**Relevant contact person** (Name, position and contact details including telephone, fax, email)
Phoenix Pharm Distributors Limited	65 Birkenhead Ave, Birkenhead, Auckland PO Box 31-363, Mairangi Bay, Auckland New Zealand Phone: +64 9 476 7391 Fax: +64 9 479 5555 Website: http://www.phoenixpharm.co.nz	Graham Webb
Provet NZ Pty Limited	Colin Wilson RSM Prince Level 9, 50 Anzac Avenue Auckland 1010 New Zealand Phone: +64 9 920 4440 Fax: +64 9 920 4459 website: http://www.provet.co.nz/go/contact-provet	General Manager Dean Gurney dgurney@provet.net.nz
FIL New Zealand Limited	FIL New Zealand Limited Address: 72 Portside Drive Mount Maunganui Postal: PO Box 4144 Mt Maunganui South 3149, New Zealand Phone: +64 7 575 2162 Fax: +64 7 575 2161 E-mail: office@fil.co.nz website: http://www.fil.co.nz	Arthur Jordan Managing Director Phone: +64 7 928 2802
BASF New Zealand Limited	3 Airpark Drive Airport Manukau City Auckland 2022 P O Box 407 Shortland Street Phone: +64 9 255 4300 Fax: +64 9 255 4307	John Gray Technical Manager – Regulatory Affairs Phone : +64 9 255 4342 Fax: +64 9 255 4307 john.gray@basf.com
Elanco New Zealand	Address: Elanco, Level 1, 123 Ormiston Rd, Botany Junction, Auckland 2016 Postal: Elanco, PO Box 259354, Greenmount Auckland 2141 Phone: +64 9 523 9320 Fax: +64 9 271 6881	General Manager Derek Moore MOORE_DEREK@lilly.com

Name of company (legal and trading names)	**Contact details** (Postal & physical address, telephone and fax, website)	**Relevant contact person** (Name, position and contact details including telephone, fax, email)
Virbac New Zealand Limited	30 Stonedon Dve East Tamaki Auckland Phone: +64 9 273 9501	Michael Perdix General Manager Phone: +64 9 272 7660 Fax: +64 9 272 7667
BUYERS		
SVS Veterinary Supplies Limited	c/- Walker Davey Ltd 3rd Floor 148 Victoria Street Christchurch	
Veterinary Enterprise Group	PO Box 83, Te Awamutu 3840 Phone: +64 7 872 0248 Fax: +64 7 872 0254 info@vetent.co.nz	
PGG Wrightson Limited	57 Waterloo Road Christchurch Postal: P O Box 292 Christchurch Phone: +64 3 372 0800 Email: enquiries@pggwrightson.co.nz	Supply Chain Manager Murray Ross mross@pggwrightson.co.nz
Farmlands Trading Society Limited	1010 Southampton Street Private Bag 9004 Hastings New Zealand Phone: +64 6 873 1090 Fax: +64 6 873 8190 Email: enquiries@farmlands.co.nz website: www.farmlands.co.nz	National Category Manager Rachael Glendining Rachael.glendining@farmlands.co.nz
CRT limited	84 Cumberland Street Dunedin 9016 New Zealand Postal: Private Bag 1968 Dunedin 9054 New Zealand Phone: +64 3 477 9040 Fax: 0800 278 329 Email: jo.morrison@crt.co.nz Website: www.crt.co.nz	Category Manager Dan McKay Dan.mckay@crt.co.nz

Name of company (legal and trading names)	**Contact details** (Postal & physical address, telephone and fax, website)	**Relevant contact person** (Name, position and contact details including telephone, fax, email)
Elders Rural Holdings Limited	Level 1,3 Melrose Street, Newmarket Postal: Private Bag 92211, Auckland Phone: +64 9 529 8800 Fax: 09 529 8801 Website: www.elders.co.nz	Product Manager Ian Giles Ian.giles@elders.co.nz
RD1 Limited	c/- Fonterra Group Limited, 9 Princes Street, Auckland Phone: +64 9 374 9000 Fax: +64 9 374 9001 Website: Fonterra.com	
SUPPLIERS		
Argenta Manufacturing Limited	2 Sterling Avenue PO Box 75 340 Manurewa Auckland Phone: +64 9 250 3100 Fax: +64 9 268 1843	
Stockguard Laboratories (NZ) Limited	Stockguard Laboratories (NZ) Limited 26-30 Maui Street Hamilton New Zealand Phone: +64 7 849 6782 Fax: 64 7 849 5079 Email: info@stockguard.co.nz Web site address: http://www.stockguard.co.nz	Managing Director Kevin Burke Kevin@stockguard.co.nz
TRADE ASSOCIATIONS		
New Zealand Association for Animal Health and Crop Protection (AGCAM)	Level 8, City Chambers, Cnr Johnston & Featherston Sts, Wellington Postal: Agcarm, PO Box 5069, Wellington, 6145, New Zealand Phone: +64 4 499 4225 Fax: +64 4 499 4223	Chief Executive Graham Peters gpeters@agcarm.co.nz
Animal Remedies and Plant Protection Association (ARRPA	Paekakariki Hill Road Pautahanui R D 1 Phone: +64 4 237 5085 Email: g.deuss@xtra.co.nz	Gabrielle Deuss

Schedule 1.2

Confidential Information

PART 1

Paragraph 3.14
Schering-Plough is party to the following agreements with other industry participants:

PART 2 – HUMAN HEALTH

All of the information in Schedule 2.2.

PART 3 – ANIMAL HEALTH

All of the information in Schedule 3.1.

Declaration

This Notice is given by Schering-Plough Corporation.

Thomas J. Sabatino, Jr., Executive Vice President and General Counsel, Schering-Plough Corporation, hereby confirms that:

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

Thomas J. Sabatino, Jr., undertakes to advise the Commission immediately of any material change in circumstances relating to the Notice.

Dated: 5-19 2009

I am a director/officer of Schering-Plough Corporation and am duly authorised to make this application/notice.

Public Version

Human health

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The pharmaceuticals industry

1 Medicines in New Zealand are generally divided into two categories: prescription and over-the-counter (*OTC*) medicines.

2 Prescription medicines, as defined by Part 1 of Schedule 1 of the Medicines Regulations 1984, are only available from a pharmacy with a prescription from a doctor.

3 OTC products fall into three categories determined by the degree of regulation imposed. These are:

- restricted medicines that can be sold under the direction of a pharmacist without a doctor's prescription but are not available for self-selection from the pharmacy shelves;
- pharmacy-only medicines that can only be sold through the pharmacy channel, but may be self-selected by end-users;
- general medicines which can be sold in any retail outlet, such as pharmacies, supermarkets, service stations and department stores.

4 Schering-Plough and Merck both supply prescription medicines. Schering-Plough also supplies some OTC medicines but Merck does not.

Regulation of pharmaceuticals in New Zealand

5 There are two government agencies involved in the pharmaceutical industry in New Zealand: Medsafe and PHARMAC.

6 Medsafe is the New Zealand Medicines and Medical Devices Safety Authority. It is a business unit of the Ministry of Health and is the authority responsible for the regulation of therapeutic products in New Zealand.

7 PHARMAC, the Pharmaceutical Management Agency, is a Crown entity established by the New Zealand Public Health and Disability Act 2000. The Agency is directly accountable to the Minister of Health. PHARMAC manages the "purchase" of a list of subsidised pharmaceuticals, the Pharmaceutical Schedule, on behalf of the Crown. It does not purchase pharmaceuticals itself.

8 Pharmaceutical suppliers may apply to PHARMAC to have a medicine listed on the Pharmaceutical Schedule for subsidy, usually following Ministry of Health approval of the product. Decisions on listing, subsidy levels, and prescribing guidelines and conditions, are made by PHARMAC with input from independent medical experts and ultimate approval by the PHARMAC Board.

The supply chain

9 The majority of pharmaceuticals sold in New Zealand are manufactured off-shore. There is some local manufacture. For example, Douglas Pharmaceuticals manufactures generics (from imported ingredients) at its manufacturing facility in Auckland.

10 Pharmaceutical companies, through their marketing organisations and teams of trained professional sales representatives, introduce and make known their prescription drugs to health care providers such as physicians, pharmacists and private and public hospitals.

11 They do this through journal advertising, direct mail advertising and the distribution of samples to physicians, and in some cases, through communications directly to consumers through television, radio, internet, print and other advertising media. Promotion of pharmaceuticals in New Zealand is regulated by the RMI Code of Conduct.[1]

12 Most of the pharmaceutical companies do not have their own distribution networks in New Zealand. They appoint distributors who either sell directly to the purchasers (hospitals, retail and specialty pharmacists and medical clinics) or sell the products to wholesalers who then on-sell to the purchasers.

PHARMAC and DHB funding

13 PHARMAC and the District Health Boards (DHBs) have related but distinct roles in the purchase of pharmaceuticals.

14 The DHBs are responsible for providing, or funding the provision of, health and disability services in their district. They are also responsible for purchasing their pharmaceuticals from suppliers, often on a bundled basis.

15 PHARMAC negotiates the prices and levels of subsidy for community pharmaceuticals and pharmaceutical cancer treatments that the DHBs purchase, but DHBs also purchase non-subsidised pharmaceuticals for use in their hospitals. PHARMAC may assist them in these purchases.

16 A diagram showing the pharmaceutical supply and funding chain follows.

17 PHARMAC approval is not required to sell a product in New Zealand. Drugs that do not receive a PHARMAC subsidy can still be marketed to hospitals or physicians, and in some cases, directly to consumers. However, failure to win PHARMAC subsidisation means the patient rather than the government has to pay and this will usually affect the competitiveness of the product in New Zealand. In some cases, this results in the supplier electing to withdraw its product from the New Zealand market.

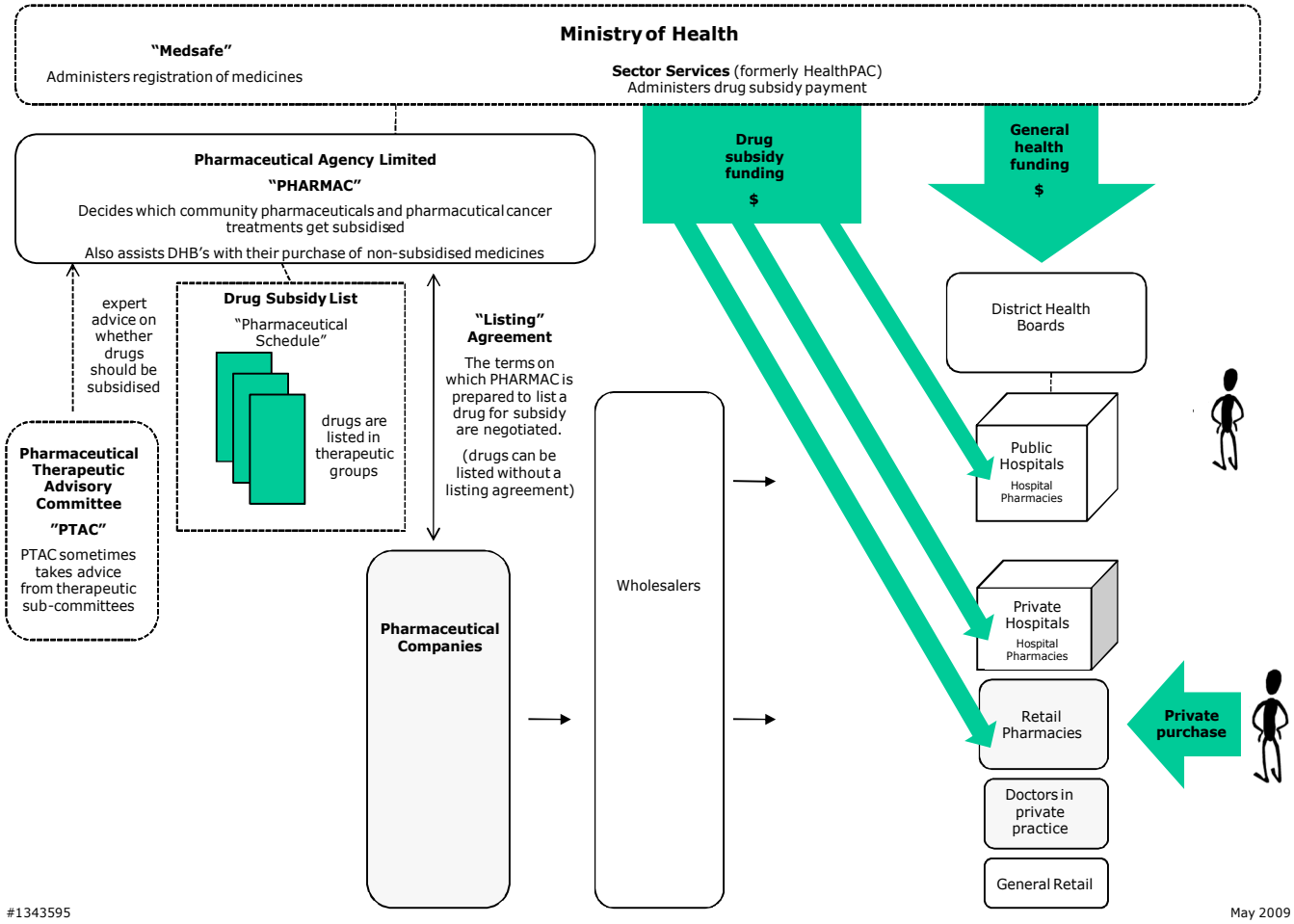
[1] Researched Medicines Industry Association of New Zealand.

Industry trends

18 The pharmaceuticals industry is highly competitive and includes several large international companies with substantial resources for research, product development, advertising, promotion and field selling support, as well as, local and multinational suppliers of generics.

Pressure from PHARMAC to reduce the price of pharmaceuticals at patent expiry, via for example sole supply tenders, can significantly reduce the sales of certain products when they, or competing products in the same therapeutic category, are no longer protected by patents.

The New Zealand Pharmaceutical Market



The parties' prescription pharmaceutical activities in New Zealand

Merck

1 Internationally, Merck's human healthcare business operates in two distinct areas:

- The pharmaceutical segment, which consists of therapeutic or preventive agents, sold by prescription for the treatment of human disorders including cancer, neurodegenerative diseases, endocrine and metabolic disorders and cardiovascular diseases.

- The vaccines and infectious diseases segment comprising:

  (a) vaccine products consisting of preventative pediatric, adolescent and adult vaccines, primarily administered at physician offices; and

  (b) infectious disease products consisting of therapeutic agents for the treatment of infection.

2 Merck is represented in New Zealand by Merck Sharp & Dohme New Zealand Limited (*MSD*).

3 MSD does not carry out any manufacturing of human health products in New Zealand. While MSD has a team of professional sales representatives in New Zealand, its pharmaceutical products are sold and distributed through an independent distributor, Healthcare Logistics Limited[2], and its vaccines are distributed by CSL Biotherapies (NZ) Limited.

4 For the year ended 31 December 2007, MSD's turnover (reported at the New Zealand Companies Office) was $59,570,000.

5 A list of Merck's prescription pharmaceutical products registered with Medsafe (together with comment as to whether they are marketed in New Zealand) is attached as Appendix 2.1.

Schering-Plough

6 Internationally, Schering-Plough's human healthcare business operates in two distinct areas:

- The pharmaceuticals segment, in which it discovers, develops, manufactures and markets advanced drug therapies for humans in six therapeutic areas: cardiovascular, central nervous system, immunology and infectious disease, oncology, respiratory and women's health. The pharmaceuticals segment also includes a human vaccine development unit.

[2] Product arrives into New Zealand and is shipped directly to HCL who then sell either directly to purchasers (hospital, retail and specialty pharmacists and medical clinics) or sell products to wholesalers who then on-sell to the purchasers. For FOSAMAX, HCL distributes to Arrow, who on-distributes.

- The consumer healthcare business, which develops, manufactures and markets OTC healthcare products (such as antihistamines), foot care and sun care products.[3]

7 Schering-Plough's New Zealand human health activities (*SPNZ*) are conducted as a business unit of the company Schering-Plough Animal Health Limited.

8 SPNZ does not carry out any R&D or manufacturing of human health products in New Zealand. While SPNZ has a team of professional sales representatives in New Zealand, its products are sold and distributed through independent distributors Healthcare Logistics Limited and Pharmaco (NZ) Limited.

9 The turnover of Schering-Plough Animal Health Limited for the year ended 31 December 2007 reported at the New Zealand Companies Office was $41,191,000. The turnover of the human health business is not separately reported but is set out in confidential Schedule 2.2.

10 A list of Schering-Plough pharmaceutical products registered with Medsafe (together with comment as to whether they are marketed in New Zealand) is attached as Appendix 2.2.

Broad areas of overlap

11 This section illustrates that the MSD and SPNZ human health businesses are highly complementary businesses.

12 The lists in Appendices 2.1 and 2.2 of Merck and Schering-Plough products registered with Medsafe identify the products that are marketed, and those that are no longer marketed, in New Zealand.

13 Of the products that are sold in New Zealand, the only broad categories where both Merck and Schering-Plough products are supplied are in the treatment of conditions in the following areas:

- cardiovascular;
- allergy/respiratory;
- immunology and infectious disease;
- neuroscience; and
- oncology.

14 Table 2.1 identifies the Merck and Schering-Plough prescription pharmaceutical products supplied in New Zealand within these broad categories and the treatments for which the products are indicated (based on the ATC classifications[4]).

[3] Schering-Plough does not market footcare and suncare products in New Zealand.

[4] Refer to pages 9 and 10 for discussion of ATC classifications.

Table 2.1

Broad areas where there is overlap in New Zealand

Broad Category	Merck			Schering-Plough		
	Product name	Indication	ATC	Product name	Indication	ATC class
Cardiovascular	LIPEX	lipid management	C10A			
	EZETROL [5]	lipid management	C10A			
	VYTORIN[6]	lipid management	C10C			
	TREDAPTIVE	lipid management				
	AGGRASTAT	**anti-platelet**	**B1C**	**INTEGRILIN**	**anti-platelet**	**B1C**
	COZAAR	hypertension	C9C	ORGARAN	anti-coagulant	B1X
	HYZAAR	hypertension	C9D			
	PRINIVIL	hypertension	C9A			
	RENITEC	hypertension	C9A			
Allergy/Respiratory	SINGULAIR	asthma	R3J	**AERIUS (formerly CLARAMAX)**	**allergic rhinitis**	**R6A**
	PERIACTIN [7]	**allergic rhinitis**	**R6A**	**CELESTONE**	**allergic rhinitis**	**H2A**
				CLARATYNE	**allergic rhinitis**	**R6A**
				POLARAMINE	**allergic rhinitis**	**R6A**
Neuroscience	MAXALT	migraine	N2C	REMERON	anti-depressant	N6A
	SINEMET	Parkinson's disease and syndrome	N4A	TOLVON	anti-depressant	N6A
				BRIDION	anaesthesia reversal	
				ESMERON	surgical muscle relaxant	M3A
				NORCURON	muscle relaxant	M3A

[5] In New Zealand EZETROL and VYTORIN are marketed solely by MSD pursuant to a joint venture agreement between Merck and Schering-Plough. Further details of the Joint Venture Agreement are set out in Schedule 2.1.

[6] See Footnote 1 above.

[7] This product has not been marketed since early 2009.

Oncology	EMEND	nausea prevention during chemo	A4A	TEMODAL	Brain tumour treatment	L1A
				ONCOTICE	bladder cancer treatment	L3A
				CAELYX	breast L1D cancer treatment	
				INTRON A	Forms of leukaemia, lymphoma, malignant melanoma and multiple myeloma	L3B
Immunology and Infectious Disease	ARCOXIA	treatment for signs and symptoms of arthritis	M1A	REMICADE	TNFα antagonist lgG1 monoclonal antibody	L4A
	AVAXIM ()	Hepatitis A vaccine	J7A	CELESTONE	corticosteroid with anti-inflammatory, antirheumatic and antiallergic effects	D7A/H2A
	HB VAX	Hepatitis B vaccine	J7A	ELOCON	corticosteroid	D7A
	PNEUMO 23	prevention of pneumococcal infections	J7A	PEGATRON	Hepatitis C	J5B
	VARIVAX ()	Chickenpox vaccine	J7A	REBETOL	Hepatitis C	
	PROQUAD	Measles, Mumps, Rubella and Varicella vaccine		INTRON A	Chronic Hepatitis B and Hepatitis C	L3B
	MMR II	Measles, Mumps, Rubella	J7B			
	ROTATEQ	Rotavirus gastroenteritis				
	ZOSTAVAX	Shingles virus				
	PRIMAXIN	antibiotic				
	CANCIDAS	**anti-fungal**	**J2A**	**NOXAFIL**	**anti-fungal**	**J2A**
	INVANZ	antibiotic	J1P			
	STROMECTOL	anthelmintic	P1B			
	ISENTRESS	HIV	J5C			
	CRIXIVAN	HIV	J5C			
	STOCRIN	HIV	J5C			
	JANUVIA	Type 2 Diabetes	A10B			
	JANUMET	Type 2 Diabetes	A10B			

15 It can be seen from Table 2.1 that most of the Merck and Schering-Plough products treat different conditions within the broad categories.

16 Based on the broad indications set out above, the actual areas of overlap are only in the following limited number of treatment areas:

- cardiovascular: anti-platelets;
- allergy/respiratory: allergic rhinitis treatments; and
- immunology and infectious disease: anti-fungals.

17 These areas are examined in more detail on pages 12 to 26.

18 In most of the apparent overlap areas, the parties' products differ in their mode of action and therapeutic use and therefore do not result in actual overlaps. Even if the parties' products in these areas are treated as overlap products, no competition concerns arise, because the parties' shares of sales are low, and the combined company will continue to face intense competitive pressure from a large number of global and smaller human healthcare companies. Moreover, many of these products are off-patent and face competition from a broad range of generic companies.

19 Both parties have products in the development pipeline and products which are available in other countries, but not New Zealand (as will be the case with many other pharmaceutical companies). Information about these products has not been provided with this Notice as entry conditions for new products are the same for all pharmaceutical companies. However, please refer to confidential Schedule 2.2.

Market definition

Product market

OTC and prescription medicines

1 In *Johnson & Johnson/Pfizer Consumer Healthcare,* the Commission concluded that OTC products do not compete with prescription-only medicines.[8] Although a doctor can prescribe OTC medicines, these are generally not substitutable for prescription-only medicines for three main reasons:

- *Severity.* Prescription-only medicines are typically used to treat more severe illnesses than OTC medicines.

- *Clinical Risk.* In instances where prescription-only and OTC medicines are indicated for the treatment of the same ailment, generally prescription-only medications are used only when OTC products have failed to provide relief. Prescription-only medications are often used in this way, as a 'measure of last resort', as these typically carry a greater level of clinical risk (i.e., contraindications, interaction with other medicines, and risk of overdose).

- *Regulation.* Given the higher clinical risks associated with prescription-only products, these are generally more heavily regulated than OTC products. For example, Medsafe classifies OTC products as 'low-risk medicines'. The registration fees and clinical data requirements for these are significantly lower than those for prescription-only products ('high' or 'intermediate-risk' medicines). Further, OTC products are more accessible to consumers as these may either be self-selected or sold through pharmacist-referral. In contrast, prescription-only products can only be accessed on the advice of a medical doctor.

2 Accordingly, OTC products fall outside the boundaries of the markets relevant to this Notice.

ATC3 classification

3 Human health products can be divided into relevant product markets using the third level of the Anatomical Classification Guidelines (*ATC3*) devised by the European Pharmaceutical Marketing Research Association (*EphMRA*)[9] as a starting point, with additional possible refinement where appropriate.

4 The ATC system, which subdivides medicines into different therapeutic classes, is used internationally and is controlled by the World Health Organisation Collaborating Centre for Drug Statistics Methodology.

[8] At paragraphs 42 – 43.

[9] The ATC3 system is maintained by EphMRA and Intercontinental Medical Statistics (IMS).

5 The ATC system is hierarchical and has 16 categories (A, B, C, D, etc.) each with up to four levels. The first level (ATC1) is the most general and the fourth level (ATC4) the most detailed. The third level (ATC3) allows medicines to be grouped in terms of their therapeutic indications (their intended use), and can therefore be useful in defining markets on the demand-side. These groups of products generally have the same therapeutic indication and cannot be substituted for products belonging to other ATC3 classes.

6 The ATC3 classification has been used by the Commission as a starting point for the definition of markets.[10]

7 The overlapping treatment areas identified in the previous section have the following ATC classifications:

- anti-platelets B1C
- allergic rhinitis treatments R6A, R1A, R1B, R3J[11]
- anti-fungals J2A

8 In Decision 398, the Commission noted:[12]

> "there may be instances where broader or narrower classifications are necessary, dependent upon the particular circumstances of the pharmaceuticals and the condition requiring treatment".

9 A closer examination of the parties' products within each of the above ATC3 classifications indicates that the products are highly differentiated and that narrower market definitions are more appropriate in this instance. [13] In fact the only areas of overlap between the Merck and Schering-Plough products are:

- allergic rhinitis treatment; and
- anti-fungal treatment.

10 Despite these apparent areas of overlap, the Applicant submits that Merck and Schering-Plough's products are not substitutable.

Product differentiation

11 In most therapeutic categories, there are differences between products, for example in:

[10] For example, Decision 398 (*Glaxo Wellcome/SmithKline Beecham*), Decision 496 (*Pfizer Laboratories/Pharamacia*) and Decision 621 (*Schering-Plough/Organon*).

[11] R3J includes asthma treatments that are also indicated for treatment of allergic rhinitis.

[12] At paragraph 52

[13] Medsafe data sheets for the Merck and Schering-Plough products in the categories listed at paragraph 7 above are set out in Appendix 2.4.

- active ingredient;
- method of administration;
- spectrum of action (eg anti-fungal or antibiotic);
- mode of action; and
- duration of effectiveness.

12 For further detail, please refer to the separate discussion on pages 12 to 26.

Geographic scope

13 Merck and Schering-Plough products are distributed nationally. Pricing is set at head-office level and is applied nationally. Consistent with *Johnson & Johnson/Pfizer*[14], where the Commission found that the relevant OTC markets were national in scope, the Applicant considers the markets to be national.

Functional level

14 All of the Merck and Schering-Plough human health products supplied in New Zealand are manufactured overseas and imported into New Zealand (subject to regulatory approval from Medsafe). They are sold to wholesale and specialty distributors, hospitals, retail and specialty pharmacists and medical clinics.

15 There is some local manufacture of generic pharmaceuticals, including products in the affected categories. Consistent with *Johnson & Johnson/Pfizer*,[15] the Applicant considers the relevant functional market to be manufacture, importation and wholesale supply.

Conclusion on market definition

16 The Applicant submits that, although the Merck and Schering-Plough products are not treated as substitutable, if the Commission proposed to assess the competitive effects of the Proposed Transaction by reference to the wider treatment area, the relevant markets would be the national markets for the manufacture, importation and wholesale supply of:

- allergic rhinitis treatments in R6A and R3J; and
- anti-fungals in ATC3 class J2A.

[14] Decision 594, paragraph 73.

[15] At paragraph 77

Individual Product Markets

1. Anti-platelets

1 Anti-platelets fall within the broader treatment group of anti-thrombosis products. These products are used to prevent blood clots (thrombi). Blood clots form through the aggregation of platelets and fibrin in blood.

2 Blood clots can form in either the arteries (arterial thrombi) or the veins (venous thrombi), with the composition of the clot varying in each. Arterial thrombi are composed mainly of platelets, while venous thrombi are mainly composed of fibrin.

3 Anti-platelets treat arterial thrombi by decreasing platelet aggregation and inhibiting the formation of thrombi in the context of the so-called "platelet cascade".

MSD and SPNZ

4 Both MSD and SPNZ have products registered in the anti-platelet area under the ATC3 classification B1C (platelet aggregation inhibitors excluding heparin).

5 Table 2.2 on the following page sets out the products supplied by MSD and SPNZ in New Zealand and the respective indications for each product.

Product differentiation

6 The indications in Table 2.2 show that whilst the two products have similar practical applications (ie treatment of unstable angina or non-Q-wave myocardial infarction) they have different indications and accordingly are used for different purposes.

7 AGGRASTAT is used for the treatment of unstable angina or certain types of heart attacks in combination with heparin. It takes approximately 12 hours to take effect.

8 INTEGRILIN is primarily used in acute cases to prevent blood clots or heart attack in people with severe chest pain or other conditions, and in those who are undergoing an angioplasty. This product is typically used prior to the patient receiving a stent as it takes approximately five to ten minutes to take effect.

9 Doctors choose which drug to use based on the clinical status of the patient. For example, a doctor may elect to use AGGRASTAT if the patient does not need immediate surgery. INTEGRILIN may then be used prior to an operation as well.

10 The two products are not directly substitutable as INTEGRILIN is used in acute cases and for patients undergoing an angioplasty. AGGRASTAT is used more generally to prevent a cardiac ischaemic event and does not take effect as quickly as INTEGRILIN.

11 The Applicant considers that the products do not compete directly and as a result fall within separate markets.

Table 2.2

MSD and SPNZ anti-platelet products (B1C)

	Product	ATC3	Indicated use	How Sold	PHARMAC funded?[16]
Merck	AGGRASTAT [17]	B1C	In combination with heparin, is indicated for patients with unstable angina or non-Q-wave myocardial infarction to prevent cardiac ischaemic events. Administration: intravenous Active: tirofiban hydrochloride	Prescription	No
Schering Plough	INTEGRILIN [18]	B1C	For patients undergoing non-urgent percutaneous coronary intervention (PCI) with intercoronary stenting for the reduction of death, myocardial infarction, urgent revascularisation and the need for acute antithrombotic rescue therapy. INTEGRILIN is indicated for the reduction of death and myocardial infarction in patients presenting with unstable angina or non-Q-wave myocardial infarction (chest pain with ST-segment depression >0.5 mm or definitive T-wave inversion >1 mm or transient ST-segment elevation >0.5 mm of less than 30 minutes or persistent ST-segment elevation >0.5 mm not requiring reperfusion therapy or thrombolytic agents, or chest pain in patients without persistent ST-segment elevation with CK-MB greater than the upper limit of normal). INTEGRILIN is indicated in patients who are managed with standard medical therapies and/or with percutaneous coronary intervention INTEGRILIN is intended for use with aspirin, heparin and clopdigrel. Administration: intravenous Active: eptifibatide solution	Prescription	No

12 On the basis that these products are not substitutable, no further consideration is given to this product segment.

[16] PHARMAC Schedule April 2009

[17] http://www.medsafe.govt.nz/profs/datasheet/a/aggrastatvialinf.htm

[18] http://www.medsafe.govt.nz/profs/datasheet/i/integrilininj.htm

2. Allergic rhinitis treatments

1 Allergic rhinitis is the inflammation of the mucous membrane of the nasal passages caused by an allergic reaction. The disease is usually associated with rhinorrhea (watery nasal discharge), nasal congestion, sneezing, and itching of the nose, eyes and palate.

2 Allergic rhinitis is sometimes divided into "seasonal" and "perennial" categories. The usual triggers for seasonal allergic rhinitis are pollen or moulds, while the triggers for perennial allergic rhinitis are usually house dust mites or pet dander.

3 There is no known cure for allergic rhinitis. The treatment of allergic rhinitis is largely focused on the alleviation of the symptoms to exposure. The traditional treatments – antihistamines, nasal corticosteroids and systemic nasal preparations – cover different indications and offer different modes of action.

MSD and SPNZ

4 Both MSD and SPNZ are active in the allergic rhinitis treatment area. However, Merck's SINGULAIR product is primarily an asthma medication and its treatment of allergic rhinitis is generally limited to the treatment of asthma patients suffering from allergic rhinitis. Table 2.3 at the end of this section sets out the products supplied by MSD and SPNZ in New Zealand and the respective indications for each product.

Product differentiation

5 The Applicant submits that the appropriate approach to allergic rhinitis treatments is to distinguish between separate markets based on the treatments' ATC3 classification and that allergic rhinitis medications should therefore be divided into separate product markets for:

- topical nasal preparations (R1A);
- systemic nasal preparations (R1B);
- systemic antihistamines (R6A).

6 The Applicant does not support a broader market definition encompassing all allergic rhinitis treatments or a combination of these treatments, as these treatments differ too greatly in their modes of action and administration to belong to the same market, as illustrated in Table 2.5 on page 20.

7 The Applicant considers that Merck's SINGULAIR (R3J) is not appropriately classified as an allergic rhinitis treatment. SINGULAIR is marketed for use by people with asthma. Physicians tend to prescribe SINGULAIR only in patients with concomitant asthma and as an add-on therapy when nasal steroids are not sufficient and more corticosteroids cannot be used due to the risk of over dosage.

8 SINGULAIR is therefore more properly viewed as complementary to Schering-Plough's asthma and allergic rhinitis treatments, as opposed to a substitute.

9 The Applicant further considers that CELESTONE (ATC3 H2A) is not substitutable for other general perennial and allergic rhinitis products. CELESTONE is only used in severe cases of asthma where an injected corticosteroid is required. Accordingly it

is only used in acute situations and would not be used to treat perennial or seasonal allergic rhinitis.

10 The Applicant considers that there are separate markets for each of the ATC3 classifications: R1A, R1B, R6A and R3J. On this basis, the only area of overlap is in the R6A classification.

Market shares

11 Although the Applicant does not support a broader market encompassing all allergic rhinitis treatments listed above (including leukotriene receptor antagonists such as SINGULAIR), market data has been provided for the combination of ATC3 categories R6A & R3J (including sales of SINGULAIR prescribed for the alleviation of allergic rhinitis in asthma patients).

12 The value of sales and estimated market shares for each of this "market" is set out in confidential Schedule 2.2 in Table 2.4.

13 Table 2.6 at the end of this section lists competitor suppliers of allergic rhinitis products in New Zealand.

14 The market shares and three-firm concentration ratio following the Proposed Transaction are set out in confidential Schedule 2.2. They are within the Commission's safe harbour guidelines and the level of aggregation is minimal.

Conclusion on competition

15 The following factors indicate that the Proposed Transaction will not substantially lessen competition in allergic rhinitis treatments:

- Merck's share is minimal and based entirely on sales of PERIACTIN (a product which Merck ceased marketing in early 2009).
- SINGULAIR is not properly viewed as a competitor for Schering-Plough's allergic rhinitis products. Even if a broad market definition is adopted, the level of aggregation is not significant.
- There are a number of existing competitors, all of which are significant businesses with established reputations in the human pharmaceuticals industry. Sanofi-aventis, Douglas Pharmaceuticals and Pharmabroker all have substantial market shares.
- The barriers to entry are low.
- Generic substitutes containing loratadine are already available in New Zealand.
- Other generic products are available offshore and barriers to entry of generics are particularly low. (Refer to section on potential competition on 32 for further discussion).

Table 2.3

MSD and SPNZ Allergic Rhinitis products (R6A & R3J)

	Product	ATC3	Indicated use	How Sold	PHARMAC funded?[19]
Merck	SINGULAIR[20]	R3J	SINGULAIR is also indicated in adult and paediatric patients 2 years of age and older for the prophylaxis and chronic treatment of asthma, including the prevention of day- and night-time symptoms and the prevention of exercise-induced bronchospasm. SINGULAIR is indicated in adults and paediatric patients 2 years of age and older for the relief of daytime and nighttime symptoms of seasonal allergic rhinitis and perennial allergic rhinitis. Administration: tablet Active: montelukast	Prescription	No
	PERIACTIN[21]	R6A	**As an Antiallergic-Antipruritic** PERIACTIN has a wide range of antiallergic and antipruritic activity and can be used successfully in the treatment of acute and chronic allergies and pruritus, such as: dermatitis, including neurodermatitis and neurodermatitis circumscripta, eczema, eczematoid dermatitis, dermatographism, mild local allergic reactions to insect bites, hay fever and other seasonal rhinitis, perennial allergic and vasomotor rhinitis, allergic conjunctivitis due to inhalant allergens and foods, urticaria, angioneurotic oedema, medicine and serum reactions, anogenital pruritus and pruritus of chickenpox. PERIACTIN may be used as therapy for anaphylactic reactions, adjunctive to epinephrine and other standard measures after the acute manifestations have been controlled. **In Migraine and Vascular Types of Headache** PERIACTIN has been reported to have beneficial effects in a significant number of patients diagnosed as having vascular types of headache, such as migraine and histamine cephalalgia. Many patients who have not been able to obtain adequate relief from any other agent have reported amelioration of symptoms with PERIACTIN. The characteristic headache and feeling of malaise may disappear within an hour or two after the first dose. Administration: tablet Active: cyproheptadine hydrochloride	Prescription	Yes

[19] PHARMAC Schedule April 2009

[20] http://www.medsafe.govt.nz/profs/datasheet/s/singulairtab.htm

[21] http://www.medsafe.govt.nz/profs/datasheet/p/periactintab.htm

Schering-Plough	AERIUS[22] (formerly CLARAMAX)	R6A	A second generation antihistamine indicated for the relief of symptoms associated with seasonal and perennial allergic rhinitis, such as sneezing, nasal discharge and itching, congestion, as well as ocular itching, tearing and redness, itching of palate and coughing. Also for the relief of symptoms associated with chronic idiopathic urticaria such as the relief of itching and the size and number of hives. Administration: tablet, syrup Active: desloratadine	Pharmacy Medicine	No
	CELESTONE [23]	H2A	Recommended in the therapy of both severe and moderate diseases, in acute and chronic self-limiting diseases responsive to systemic corticosteroid therapy, especially useful in patients for whom treatment with oral corticosteroid medication is not feasible. Corticosteroid hormone therapy is an adjunct to, and not a replacement for, conventional therapy. **Representative conditions**: *Rheumatic disorders*. Rheumatoid arthritis, acute and subacute bursitis, epicondylitis, acute nonspecific tenosynovitis, myositis, fibrositis, tendonitis, psoriatic arthritis. *Collagen diseases*. Systemic lupus erythematosus, scleroderma, dermatomyositis. *Allergic states*. Status asthmaticus, chronic bronchial asthma, seasonal or perennial allergic rhinitis, severe allergic bronchitis, contact dermatitis, atopic dermatitis, hypersensitivity reactions to drugs and insect bites. *Dermatological conditions*. Localised, hypertrophic, infiltrated lesions of lichen planus, psoriatic plaques, granuloma annulare and lichen simplex chronicus (neurodermatitis), keloids, discoid lupus erythematosus, necrobiosis lipoidica diabeticorum, alopecia areata. *Antepartum use in the prevention of respiratory distress syndrome in premature infants*. When it is deemed necessary to induce labour prior to the thirty-second week of gestation or when premature birth before the thirty-second week of gestation becomes inevitable because of obstetric complication. Celestone Chronodose Injection should also be considered for prophylactic treatment if the fetus is known to have a low lecithin/sphingomyelin ratio (or decreased foam stability test on amniotic fluid). Corticosteroids are not indicated in the management of hyaline membrane disease after birth. Administration: injection Active: betamethasone	Prescription	Partially funded

[22] http://www.medsafe.govt.nz/profs/datasheet/a/aeriustabsyr.htm

[23] http://www.medsafe.govt.nz/profs/datasheet/c/celestonechronodoesinj.htm

	CLARATYNE [24]	R6A	Relief of symptoms associated with seasonal and perennial allergic rhinitis, such as sneezing, nasal discharge and itching, congestion/stuffiness, as well as ocular itching, tearing and redness, itching of palate and coughing. Also for the relief of symptoms associated with chronic idiopathic urticaria such as the relief of itching and the size and number of hives. Administration: tablet Active: loratadine	Pharmacy Medicine	No
	POLARAMINE[25]	R6A	For symptomatic treatment of perennial and seasonal allergic rhinitis, vasomotor rhinitis, allergic conjunctivitis, mild uncomplicated allergic skin manifestations of urticaria and angioedema. Polaramine may relieve itching due to skin conditions such as allergic eczema, pruritus ani, pruritus vulvae, atopic dermatitis, contact dermatitis, insect bites, dermographism and drug reactions, including serum sickness. Administration: tablet Active: dexchlorpheniramine	Pharmacy Medicine	Partially funded

[24] http://www.medsafe.govt.nz/profs/datasheet/c/claramaxtabsyr.htm

[25] http://www.medsafe.govt.nz/profs/datasheet/p/polaraminetabsyrup.htm

Table 2.5

Comparison of products in ATC3 classes R1A, R1B and R6A

ATC3 Class	Therapeutic use	Speed of Action	Mode of Administration
R1A (Topical Nasal Preparations)	Effective at remedying nasal congestion	Generally requires up to two weeks of administration.	Administered locally at the site of congestion by means of a nasal spray.
R1B (Systemic Nasal Preparations)	Effective at remedying nasal congestion	Varies.	Administered orally, having limited effect on the receptor sites in the nasal mucosa.
R6A (Systemic Antihistamines)	Effective at remedying symptoms mediated by histamine, including rhinorrhea, sneezing, nasal and ocular itching. Effective against urticaria (hives). Not effective against nasal congestion.	Varies.	Usually administered orally, having limited effect on the receptor sites in the nasal mucosa.
R3J (Antileukotrienes)	Effective in both the upper airways and the lungs. Not effective against ocular symptoms, such as allergic conjunctivitis, urticaria (hives) or nasal congestion.	2-3 days	Administered orally, having limited effect on the receptor sites in the nasal mucosa.

Table 2.6

Allergic Rhinitis products (R6A & R3J)

Company Name	Product (active)	PHARMAC funded?
Sanofi-Aventis	TELFAST (Fexofenadine hydrochloride) PHENERGAN (Promethazine hydrochloride) VALLERGAN (Trimeprazine tartrate)	Partially subsidised Partially subsidised Partially subsidised
Schering-Plough	AERIUS (formerly CLARAMAX) (Desloratadine) CLARATYNE (Loratadine) POLARAMINE (Dexchlorpheniramine maleate)	No No Partially subsidised
Pharmabroker	ZYRTEC[26] (Cetirizine hydrochloride)	No
Apotex NZ	APO-CETIRIZINE (Cetirizine hydrochloride) APO-LORATADINE (Loratadine)	No No
AFT Pharmaceuticals	ALLERSOOTHE (Promethazone hydrochloride) AFT-CETIRIZINE (Cetirizine hydrochloride) AFT-LORAPAED (Loratadine) AFT HISTACLEAR (Cetirizine hydrochloride) AFT LORACLEAR (Loratadine)	Yes Yes Yes No Yes
Douglas	ATARAX (Hydroxyzine hydrochloride) HISTAFEN (Chlorpheniramine maleate)	No Partially subsidised
Multichem	ALLERID C (Cetirizine hydrochloride)	Partially subsidised
Hospira	PROMETH/HYDROCHLOR (Promethazine hydrochloride)	No
Merck	SINGULAIR (Montelukast) PERIACTIN (Cyproheptadine hydrochloride)	No Yes
Arrow Pharmaceuticals	ARROW-ZETOP (Cetirizine hydrochloride)	Yes
Mylan	LORA-TABS (Loratadine) RAZENE (Cetirizine hydrochloride) XERGIC (Fexofenadine hydrochloride)	No Partially subsidised No

[26] The ZYRTEC brand is owned by UCB and licensed in New Zealand to Pharmabroker.

3. Anti-fungals

1 Anti-fungal medicines are used to treat infections caused by different kinds of pathogenic fungi, such as Candida and Aspergillus.

MSD and SPNZ

2 Both MSD and SPNZ are active in the anti-fungals area under the ATC3 classification J2A (antimycotics for systemic use). Table 2.7 sets out the products supplied by MSD and SPNZ in New Zealand and their respective indications.

Table 2.7

MSD and SPNZ anti-fungal products (J2A)

	Product	Indicated use	How Sold	PHARMAC funded?[27]
Merck	CANCIDAS[28]	Empirical therapy for presumed fungal infections in febrile, neurtopaenic patients. Treatment of Invasive Candidiasis, including Candidaemia, in neutropaenic and non-neutropaenic patients. Treatment of Oesophageal Candidiasis. Treatment of Oropharyngeal Candidiasis. Invasive Aspergillosis in patients who are refractory to or intolerant of other therapies. Administration: intravenous Active: caspofungin acetate	Prescription	No
Schering-Plough	NOXAFIL[29]	NOXAFIL (posaconazole) is indicated for use in the treatment of the following invasive fungal infections in patients 18 years of age or older. Invasive aspergillosis in patients with disease that is refractory to, or are intolerant of, amphotericin B, itraconazole or voriconazole. Oesophageal candidiasis or candidemia in patients with disease that is refractory to, or who are intolerant of, amphotericin B, fluconazole or itraconazole. Fusariosis, zygomycosis, cryptococcosis, chromoblastomycosis, and mycetoma in patients with disease refractory to other therapy, or patients who are intolerant of other therapy. Coccidioidomycosis.	Prescription	No

[27] PHARMAC Schedule April 2009

[28] http://www.medsafe.govt.nz/profs/datasheet/c/cancidasinj.htm

[29] http://www.medsafe.govt.nz/profs/datasheet/n/noxafilsusp.htm

	Product	Indicated use	How Sold	PHARMAC funded?[27]
		NOXAFIL is also indicated for the:Treatment of oropharyngeal candidiasis in immunocompromised adults, including patients with disease that is refractory to itraconazole and fluconazole. Prophylaxis of invasive fungal infections, including both yeasts and moulds, in patients 13 years of age and older who are at high risk of developing these infections, such as patients with prolonged neutropenia or haematopoietic stem cell transplant (HSCT) recipients. Adminsitration: oral suspension Active: posaconazole		

Product differentiation

3 Three main groups of anti-fungal medicines may be distinguished: azoles, echinocandins, and polyenes. These three groups differ by their formulation, their mode of action, which targets different aspects of the fungal cell, and their spectrum of action. A distinction among them may be warranted for product market definition purposes:

- Azoles inhibit the synthesis of ergosterol, a key component of fungal cell membrane; some azoles are only available in oral formulation, others are available both in oral and intravenous (*IV*) formulations.

- Echinocandins inhibit the synthesis of glucan in the fungal cell wall; they are only available in IV formulations and are thus usually delivered in hospital settings.

- Polyenes bind to ergosterol in the fungal cell membrane, altering its permeability and ultimately causing cell death; they are available in both oral and IV formulations.

4 The differences among classes have implications for both their efficacy and tolerability: echinocandins have a low potential for toxic effects, whereas drugs that target sterols (polyenes, azoles) may have a greater potential for adverse effects than those that do not. In particular, polyenes may have severe and potentially damaging side effects (nephrotoxicity). While they were the most common antifungal treatment from the 1950s to the 1980s, the much better safety profile of azoles, which were introduced in the late 1980s and early 1990s, led to their extensive use. In the last ten years, due to increasing signs of azole resistance, new pharmaceuticals have been developed to treat fungal infections displaying signs of such resistance.

5 MSD and SPNZ produce and sell different anti-fungal medicines. They differ in their mode of action, therapeutic indication and form of administration.

- Merck's product CANCIDAS, with the active ingredient caspofungin, is an intravenous echinocandin. It is indicated for the treatment of Candida infections and invasive Aspergillosis in patients who are refractory (i.e., resistant) to, or intolerant of, other therapies, including treatment with azoles.

- Schering-Plough's product NOXAFIL, with the active ingredient posaconazole (an azole), is an orally administered triazole antifungal agent. Noxafil is indicated for:

  - The first-line treatment of oropharyngeal Candidiasis in immunocompromised adults, including patients with disease that is refractory to other types of azoles, e.g., itraconazole and/or fluconazole;

  - Prophylaxis of invasive fungal infections which are resistant to amphotericin B, itraconazole or fluconazole including infections caused by Aspergillus, Fusariosis, Zygomycosis, Coccidiodomycosis, Chromoblastomycosis and Mycetoma.

  - The treatment of selected invasive fungal infections which are resistant to amphotericin B, itraconzole or fluconazole including infections caused by Apergillud, Fusariosis, Zygomycosis, Coccidiodomycosis, Chromoblastomycosis and Mycetomia.

6 In addition, NOXAFIL can treat a wider spectrum of fungi in comparison to CANCIDAS and has certain prophilaxis indications, whereas CANCIDAS has none.

7 Internationally, NOXAFIL is typically a first choice for prescription by doctors for self-administration by patients, while CANCIDAS is typically administered in hospitals to seriously ill patients. Thus, there is little overlap between CANCIDAS and NOXAFIL in clinical practice, and the products are complementary rather than substitutable.

8 In New Zealand, however, NOXAFIL is purchased by hospitals because it treats a particular rare fungal infection (Zygomysetis) that is potentially life threatening and is not covered by other drugs. Please refer to confidential Schedule 2.2.

9 For the reasons outlined above, the Applicant considers that a distinction should be made between azoles, echinocandins and polyenes and that NOXAFIL and CANCIDAS fall within separate markets. MSD and SPNZ's activities in the anti-fungal area do not overlap so the Proposed Transaction will not result in any aggregation in this respect.

10 However, for completeness, the Applicant has analysed the market based on ATC3 classification J2A.

Market shares

11 Although the Applicant does not consider the products to be substitutable, Table 2.8 list competitor supplies of products in class J2A. The value of sales and estimated market shares are set out in Table 2.9 in confidential Schedule 2.2.

Table 2.8

Anti-fungal products (J2A)

Company Name	Product (active)	PHARMAC funded?[30]
Gilead Sciences	AMBISOME (Liposomal Amphotericin B)	No
Jansen-CIlag	SPORANOX (Itraconazole)	Yes
Johnson & Johnson	DIFLUCAN ONE (Fluconazole) NIZORAL (Ketoconazole)	No Yes
Merck	CANCIDAS (Caspofungin)	No
Apotex	APO-TERBINAFINE (Terbinafine)	Yes
Pfizer New Zealand	VFEND (Voriconazole) DIFLUCAN (Fluconazole)	No No
Mylan (Pacific Pharmaceuticals)	FLUCAZOLE (Fluconazole) FLUCONAZOLE Pacific (Fluconazole)	No Yes
Schering-Plough	NOXAFIL (Posaconazole)	No
Sigma Pharmaceuticals	NILSTAT (Nystatin)	Yes
Multichem	M-FLUCONAZOLE (Fluconazole)	No
Bristol-Myers Squibb	FUNGIZONE (Amphotericin B)	No
Baxter	AMPHOTERICIN (Amphotericn B)	No

12 The market shares and three-firm concentration ratio following the Proposed Transaction are set out in confidential Schedule 2.2. These are within the Commission's safe harbour guidelines.

Conclusion on competition

13 The following factors indicate that the Proposed Transaction will not substantially lessen competition:

- The Merck and Schering-Plough products are not fully substitutable. NOXAFIL treats the fungal infection Zygomysetis which the Merck product CANCIDAS does not treat.

- Merck and Schering-Plough products are not PHARMAC funded but other competitors' products are.

[30] PHARMAC Schedule April 2009

- Even if a broad market definition is adopted, the level of aggregation is not significant.

- There are a number of existing competitors, all of which are significant businesses with established reputations in the human pharmaceuticals industry. Gilead, Johnson & Johnson and Pfizer, in particular, have substantial market shares.

- The barriers to entry are low and generic substitutes containing the active ingredient fluconazole are available.

Competition Analysis

Existing competitors

1 The human healthcare sector is intensely competitive, and the combined company will continue to face competitive pressure across its product lines. The large number of companies competing in the development, production and marketing of medicines for human health in New Zealand is apparent from the list of competitors set out below (listed in alphabetical order).

Abbott Laboratories Inc.

2 Headquartered in Abbott Park, Illinois, Abbott had net sales of $29.5 billion in 2008 and invested US$2.5 billion in R&D in 2007. Further information concerning Abbott can be found at www.abbott.com.

AFT Pharmaceuticals

3 AFT Pharmaceuticals is a privately owned company with operations in Australia and New Zealand. Sales are in excess of AUD$10 million for both Australia and New Zealand, with growing exports to Asia Pacific. Further information regarding AFT Pharmaceuticals can be found at: www.aftpharm.com.

4 Of the markets relevant to the Proposed Transaction, AFT Pharmaceuticals is active in allergic rhinitis products.

Apotex NZ Limited

5 The Apotex Group of Companies is a Canadian-owned and operated pharmaceutical company that researches, develops and manufactures generic as well as innovative drugs. Apotex is headquartered in Ontario with over 6,500 employees in various R&D and manufacturing facilities, and exports to over 115 countries around the world. Further information regarding Apotex can be found at: www.apotexnz.co.nz.

6 Of the markets relevant to the Proposed Transaction, Apotex is active in:

- allergic rhinitis products; and
- anti-fungal products.

AstraZeneca plc.

7 Headquartered in London, England, AstraZeneca had net sales of €24.5 billion and invested over €3.4 billion in R&D in 2008. Further information regarding AstraZeneca can be found at: www.astrazeneca.com.

Boehringer Ingelheim GmbH

8 Headquartered in Ingelheim, Germany, Boehringer Ingelheim had net sales of €10.9 billion and spent one-fifth of the net sales from its largest business segment, prescription medicines, on R&D in 2007. Further information regarding Boehringer Ingelheim can be found at: www.boehringer-ingelheim.com.

Bristol-Myers Squibb Co.

9 Headquartered in New York, NY, Bristol-Myers Squibb had net sales of €14 billion and invested €2.8 billion in research and development in 2008. Further information regarding Bristol-Myers Squibb can be found at: www.bms.com.

10 Of the markets relevant to the Proposed Transaction, Bristol-Myers Squibb is active in the market for anti-fungal products.

Eli Lilly & Co.

11 Headquartered in Indianapolis, Indiana, Eli Lilly had net sales of €13.9 billion and invested €2.6 billion in R&D in 2008. Further information regarding Eli Lilly can be found at: www.lilly.com.

Gilead Sciences Inc.

12 Headquartered in Foster City, California, Gilead had sales of US$5.3 billion and invested US$721 million in research and development in 2008. Further information regarding Gilead can be found at: www.gilead.com.

13 Of the markets relevant to the Proposed Transaction, Gilead is active in anti-fungal products.

Douglas Pharmaceuticals

14 Founded in 1967, Douglas Pharmaceuticals is one of the fastest growing pharmaceutical companies in Australasia. Douglas Pharmaceuticals has two large modern manufacturing plants in New Zealand and Fiji. It undertakes contract manufacturing and product development. Further information regarding Douglas Pharmaceuticals can be found at www.douglas.co.nz.

15 Of the markets relevant to the Proposed Transaction, Douglas Pharmaceuticals is active in allergic rhinitis products.

GlaxoSmithKline plc.

16 Headquartered in Brentford, England, GlaxoSmithKline had net sales of €35.7 billion and invested €5.4 billion in R&D in 2008. Further information regarding GlaxoSmithKline can be found at www.gsk.com.

Hospira

17 Hospira is a global specialty pharmaceutical and medication delivery company. In February 2007, Hospira acquired Mayne Pharma Limited to become the world leader in specialty generic injectable pharmaceuticals. Further information regarding Hospira can be found at www.hospira.co.nz.

18 Of the markets relevant to the Proposed Transaction, Hospira is active in allergic rhinitis products.

Johnson & Johnson

19 Headquartered in New Brunswick, New Jersey, Johnson & Johnson's pharmaceutical segment had net sales of €16.7 billion and invested €5.2 billion in R&D in 2008. Further information regarding Johnson & Johnson can be found at: www.jnj.com.

20 Of the markets relevant to the Proposed Transaction, Johnson & Johnson is active in anti-fungal products.

Multichem

21 Established in 1966, Multichem is a privately owned New Zealand company supplying the healthcare industry. It supplies customers with pharmaceuticals, registered and unregistered OTC products, gift lines and dispensing containers. Further information regarding Multichem can be found at: www.multichem.co.nz

22 Of the markets relevant to the Proposed Transaction, Multichem is active in:

- allergic rhinitis products; and
- anti-fungal products.

Mylan New Zealand

23 Mylan New Zealand Limited is part of the international group Mylan of the USA, the third largest generics and specialty pharmaceutical company in the world. It markets more than 570 products to consumers in more than 140 countries.

24 In New Zealand, Mylan began its commercial operations in 1977 from a small office and warehouse in Newmarket, as a pharmaceutical distributor under its original name Pacific Pharmaceuticals Ltd. Further information regarding Mylan can be found at: www.pacificpharmaceuticals.co.nz.

25 Of the markets relevant to the Proposed Transaction, Mylan is active in anti-fungal products.

Novartis AG

26 Headquartered in Basel, Switzerland, Novartis had net sales of €28.2 billion and invested €4.9 billion in R&D in 2008. Further information regarding Novartis can be found at: www.novartis.com.

Pfizer Inc.

27 Headquartered in New York, New York, Pfizer had net sales of €32.8 billion and invested €5.4 billion in R&D in 2008. On January 26, 2009, Pfizer and Wyeth announced that they had entered into a merger agreement pursuant to which Pfizer will acquire Wyeth in a cash-and-stock transaction. Further information regarding Pfizer can be found at: www.pfizer.com.

Roche AG

28 Headquartered in Basel, Switzerland, Roche had sales of CHF45.6 billion and invested CHF8.8 billion in R&D in 2008. Further information regarding Roche can be found at: www.roche.com.

Sanofi-Aventis SA

29 Headquartered in Paris, France, Sanofi-Aventis had net sales of €27.6 billion and invested €4.6 billion in R&D in 2008. Further information regarding Sanofi-Aventis can be found at: www.sanofi-aventis.com.

19 Of the markets relevant to the Proposed Transaction, Sanofi-Aventis is active in allergic rhinitis products.

Sigma Pharmaceuticals

30 Sigma Pharmaceuticals Limited is a leading Australian manufacturer and marketer of prescription, OTC and generic pharmaceutical products. Further information regarding Sigma can be found at www.sigmaco.com.au.

20 Of the markets relevant to the Proposed Transaction, Sigma is active in anti-fungal products.

Wyeth

31 Headquartered in Madison, New Jersey, Wyeth had net sales of €15.2 billion and invested €2.2 billion in research and development in 2007. Further information regarding Wyeth can be found at: www.wyeth.com.

Potential Competition

Internationally

1 Competition in the human healthcare markets is further intensified by the low barriers to entry or expansion that characterise the industry. Numerous paths are available for new entrants, including, at the highest level, the choice between developing new branded pharmaceuticals or focusing on manufacturing and selling generic versions of existing, off-patent branded pharmaceuticals.

2 In the branded pharmaceuticals business, entering a new product area requires a significant investment, particularly the cost of R&D and the cost of developing clinical trial information to obtain marketing authorisations. These costs can be reduced in several ways, however, including licensing-in products from other firms and focusing R&D efforts on the final development stages. Pharmaceutical companies can reduce entry costs related to manufacturing through contract manufacturing, which is common in the pharmaceutical industry.

3 There are many examples of successful entry or expansion into branded pharmaceuticals. Entry may be made by focusing on specific therapeutic areas. For example, U.S.-based Gilead Sciences was founded in 1987 and focuses primarily on HIV/AIDS, liver disease and serious cardiovascular and respiratory conditions. It has expanded very rapidly, growing its sales by 76%, to US$5.3 billion, in the last three years.

4 Examples of expansion into new therapeutic areas include the successful development and introduction of Pfizer's Viagra (erectile dysfunction treatment) and SUTENT (renal cell carcinoma treatment).

5 Entry into generic products is easier, since entrants need only replicate well-established products and generally are not required to submit extensive clinical trial information to obtain a marketing authorization. Entry costs related to manufacturing and distribution are low. Generic reproduction decreases the need for significant investment in research and development, significantly expediting the registration process.

New Zealand

6 Local manufacture of pharmaceuticals is not a significant feature of the New Zealand market. However, a number of the multi-national pharmaceutical companies have manufacturing facilities in Australia. These include Astra Zeneca[31]; Bristol Myers Squibb[32]; Baxter;[33] and Pfizer.[34]

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[31] http://www.astrazeneca.com.au/manufacturing

[32] http://www.bmsa.com.au/divisions.html

[33] http://www.baxter.co.nz/about_baxter/company_profile/sub/company_statement.html

[34] http://www.pfizer.com.au/ProductInfo.aspx

7 In addition there are two Australian based manufacturers: Sigma Pharmaceuticals[35]; and CSL Biotherapies.[36]

8 Pharmaceuticals are typically sold in New Zealand through distributors, such as Healthcare Logistics, that are appointed by the pharmaceutical company. These distributors then supply the products direct to the customer or to wholesalers, such as ProPharma, who deliver to the customer.

9 In *Johnson & Johnson/Pfizer*, the Commission considered potential competition in the market for OTC human worm treatments. The Commission considered four factors that might impede market entry:

- ability to source the product;
- access to distribution channels;
- marketing and advertising; and
- regulatory approval through Medsafe[37].

10 These considerations apply equally to prescription pharmaceuticals.

Ability to source product

11 New prescription pharmaceuticals in the three broad categories affected by the Proposed Transaction could be introduced into New Zealand market by, or sourced from, one of the many multinational pharmaceutical companies with their own manufacturing facilities offshore. They may also be made here by a manufacturer of generics such as Douglas Pharmaceuticals.

12 A new entrant would be likely to distribute its product through independent distributors or wholesalers.

Access to distribution channels

13 Distribution services are widely available. Key distributors and wholesalers of pharmaceuticals in New Zealand include:

Distributors

- Healthcare Logistics
- Pharmaco
- DHL

[35] http://www.sigmaco.com.au/

[36] http://www.cslbiotherapies.com.au/s1/cs/aucb/1196562670171/content/1196562670068/content.htm

[37] At paragraph 116.

Wholesalers

- Propharma
- CDC (Wellington and Christchurch)
- Wainhouse Distribution (Auckland)

Marketing and advertising

14 To support a prescription pharmaceutical, a new entrant would need to invest in a level of sales support in order to make the product known to buying agencies, physicians, pharmacists and other referrers.

Regulatory approval through Medsafe

15 A company wishing to market a medicine that has not previously been marketed in New Zealand must obtain the consent of the Minister of Health (or the Minister's delegate) to distribute a "new medicine". Such medicines fall into three categories:

- *Innovator medicines that contain new active substances or are administered in a novel way*. To obtain consent, the company must submit an application dossier containing detailed information about the safety, quality and efficacy of the medicine. The application is considered by the Medicines Assessment Advisory Committee, which is a committee of experts set up to advise the Minister of Health.
- *Multi-source or generic medicines that don't have new active substances or novel dose forms, but are a different brand from the previously approved product.* To obtain consent to market the new brand, the company must submit an abridged application dossier that contains information about the safety, quality and efficacy of the new medicine for assessment by Medsafe evaluators.
- *Over-the-counter medicines that contain active ingredients with a well-established record of use.* These may be new products containing active ingredients in different combinations, or new brands of previously approved over-the-counter medicines. To obtain consent to market a new over-the-counter medicine, the company must submit an abridged application dossier for assessment by Medsafe evaluators.

16 If an application for consent to market a new medicine is acceptable, the Minister of Health or his delegate approves the medicine. Notification of the consent is published in the New Zealand Gazette, and the medicine can then be marketed. The consent applies only to a single brand of the medicine made by a particular manufacturer. [38]

[38] http://www.medsafe.govt.nz/Consumers/regulate.asp

17 There are a number of factors that will affect how quickly Medsafe can grant regulatory approval - but if the requisite clinical programme for a prescription pharmaceutical had been completed off-shore then this could be done within 12 – 18 months.

Countervailing power of buyers

1 The market power of pharmaceutical companies, regardless of market share and regardless of whether they focus on branded or generic products, is constrained by the high degree of regulation that characterizes this industry and the role of PHARMAC in pricing decisions.

2 For these reasons, prices are not set independently by pharmaceutical companies but negotiated with PHARMAC and other health authorities, who take into account policy considerations such as patients' access to products and the control of healthcare budgets.

PHARMAC

3 The purchasers of pharmaceuticals are public and private hospitals and retail pharmacies. Although PHARMAC is not a purchaser of pharmaceuticals, the competitive landscape is extensively shaped by PHARMAC's role as agent of the Crown in managing government expenditure on pharmaceuticals. Through its ability to influence prices and set subsidy levels, PHARMAC can markedly alter market shares in pharmaceutical markets.

4 The role of PHARMAC as a monopsonist is well recognised, including by the Court of Appeal.

> "Pharmac determines which pharmaceuticals should be listed, which subsidies are payable for each and negotiates the terms upon which the subsidised pharmaceuticals are supplied. In short, Pharmac has a substantial degree of power in the markets for the supply of subsidised pharmaceuticals in New Zealand. As a monopsonist, Pharmac has the ability to control the entry of different pharmaceuticals onto the pharmaceutical schedule[39]

5 The high degree of power held by PHARMAC is acknowledged by a statutory exemption[40] to prevent PHARMAC's buying practices from breaching the Commerce Act.

District Health Boards

6 Where products used by public hospitals are not subsidised by PHARMAC, the hospitals will either purchase these at the supplier's list price or at prices negotiated by PHARMAC. Section H of the Pharmaceutical Schedule includes pharmaceuticals that can be purchased at a national price by DHB's for use in their hospitals. These are referred to as National Contract Pharmaceuticals.

[39] *Astrazeneca Limited v Commerce Commission [2008] NZCA 479,* paragraph 19.

[40] The exemption is contained in section 53 of the New Zealand Public Health and Disability Act 2000.

Schedules

Schedule 2.1
Schering Plough/Merck joint venture

1 In May 2000, Schering-Plough and Merck entered into two separate sets of agreements to jointly develop and manage certain products in the United States, including:

- two cholesterol-lowering drugs;
- an allergy/asthma drug.

2 In general, the companies agreed that the collaborative activities under these agreements would operate in a virtual joint venture that relies to the maximum degree possible on the respective infrastructures of the two companies. These agreements generally provide for equal sharing of development costs and for co-promotion of approved products by each company.

The cholesterol joint venture

3 In December 2001, the cholesterol agreements were expanded to include all countries of the world except Japan.

4 Pursuant to the cholesterol agreements:

- Schering-Plough granted to the joint venture a limited but exclusive license to Schering-Plough's proprietary ezetimibe molecule and technology.
- Schering-Plough and Merck develop and commercialise ezetimibe in the cholesterol management field:
    - as a once-daily monotherapy (marketed as ZETIA in the U.S. and Asia and EZETROL in Europe, Australia and New Zealand);
    - in co-administration with various approved statin drugs; and
    - as a fixed-combination tablet of ezetimibe and simvastatin (ZOCOR/LIPEX), Merck's cholesterol-modifying medicine. This combination medication (ezetimibe/simvastatin) is marketed as VYTORIN in the U.S., Australia and New Zealand and as INEGY in many international countries.

5 ZETIA/EZETROL (ezetimibe) and VYTORIN/INEGY (the combination of ezetimibe/simvastatin) are approved for use in the USA and have been launched in many international markets including New Zealand.

6 Schering-Plough and Merck are developing a single-tablet combination of ezetimibe and atorvastatin as a treatment for elevated cholesterol levels.

7 The cholesterol agreements do not provide for any jointly owned facilities and, as such, products resulting from the joint venture are manufactured in facilities owned by either Schering-Plough or Merck.

8 Costs of the joint venture that the companies contractually share are a portion of manufacturing costs, specifically identified promotion costs (including direct-to-consumer advertising and direct and identifiable out-of-pocket promotion) and other agreed upon costs for specific services such as market support, market research, market expansion, a speciality sales force and physician education programmes.

9 Certain specified R&D expenses are generally shared equally by Schering-Plough and Merck.

10 Under the master agreement governing the Joint Venture, New Zealand is designated as a single presence country. Accordingly Merck holds the sole right to supply EZETROL and VYTORIN in New Zealand (but Schering-Plough is credited with its share of the profits from the sales of those products).

The allergy/asthma joint venture

11 The allergy/asthma agreements provided for the joint development and marketing by the companies of a once-daily, fixed-combination tablet containing loratadine/montelukast. In April 2008, the Merck/Schering-Plough joint venture received a not-approvable letter from the U.S. Food and Drug Administration (*FDA*) for the proposed fixed combination of loratadine/montelukast.

12 During the second quarter of 2008 the respiratory (allergy/asthma) joint venture was terminated in accordance with the agreements. This action has no impact on the cholesterol joint venture.

Schedule 2.2
Confidential Information

Public version

Animal health

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The Animal Health Industry - Overview

1 The animal health industry can be divided into three key segments:

- *Biologicals:* Biologicals are products that trigger an immune response against viral and bacterial diseases in animals. In certain cases, they also trigger immune responses against parasitic or fungal infections. Biologicals can be sub-divided into: (i) vaccines; (ii) antisera; and (iii) colostra products.

- *Pharmaceuticals*: Pharmaceuticals encompass a wide range of products that contain a variety of active substances to prevent or treat many animal diseases or disorders. Pharmaceutical products are produced by mixing certain active substances with other substances. The result is presented in a suitable form that provides a suitable balance of efficacy and usability (eg pills, tablets, injectable liquids etc).

- *Medicinal Feed Additives:* Medicinal feed additives are products that have a medicinal indication when added to animal feedstock. These substances inhibit bacteria or parasites, and they prevent disease or improve the economic performance of the animal.

2 The Proposed Transaction affects only the pharmaceuticals and biological products (including vaccines) categories.

Regulation of animal health products

3 A veterinary medicine product cannot be sold, used, manufactured or imported in New Zealand unless it is registered with the NZFSA under the Agricultural Compounds and Veterinary Medicines Act 1997. This Act seeks to prevent or manage risks to (among other things) public health and animal welfare and ensure that domestic food residue standards are not breached.

4 In some instances registrations are granted subject to certain conditions. For example, the registration may stipulate that the product can only be sold or used in accordance with its label content or that the product can only be sold through an approved trader or used at the discretion of a registered veterinarian.

The supply chain

5 The animal health market in New Zealand is characterised by the presence of local subsidiaries or branches of large multi-national animal health companies as well as some New Zealand owned and operated companies.

6 Distribution by suppliers is undertaken on a national level.

7 The main customers for animal pharmaceuticals and biological products are either veterinarians, veterinary wholesalers or rural supply stores or a combination of

them. Schering-Plough sells its products through all of these channels whereas Merial only sells its products through veterinary clinics and veterinary wholesalers.

8 The ultimate end users of many of the products are farmers. In relation to the products for companion animals (cats and dogs) the end-users are veterinarians and private pet owners.

9 Veterinarians purchase products either directly from the suppliers or through veterinary wholesalers. The two main veterinary wholesalers are:

- Southern Veterinary Supplies which supplies through a web-based ordering service called 'vetchannel' and warehouses in Hamilton, Palmerston North and Christchurch;[1]

- Provet, which has warehouses in Auckland, Palmerston North, and Christchurch. It supplies a network of over 1900 independent veterinary practices in Australasia.[2]

10 The veterinary wholesalers are significant customers in the sense that they are purchasers of the relevant products, and because they supply a significant proportion of the ultimate acquirers/users of the products, i.e. veterinarians.

Industry trends

11 The animal health markets affected by the Proposed Transaction in New Zealand are directly affected by the strength or weakness of New Zealand's agriculture sector, on-farm returns and considerations such as exchange rates and commodity prices.

12 Over recent years, farmers have sought out products that deliver substantial productivity gains and the market has seen growth in productivity enhancers such as dry cow intramammary products and products that are more effective with fewer treatments or applications.

13 Most animal health pharmaceuticals are imported, or in the case of parasiticides, active ingredients are imported and the products are made up locally. There has been some increase in the export of animal vaccines from New Zealand.

14 The animal health industry (like human health) is highly competitive and manufacturers and suppliers of pharmaceuticals are under constant price pressure from generic products.[3]

[1] See www.svs.co.nz.

[2] See www.provet.co.nz

[3] There are no generic vaccine products as each antigen has to be individually created.

Industry data

15 Until early 2008, monthly surveys of sales of animal health products, based on data obtained from a farmer panel, were produced by A.C. Neilson. Similar to the A.C. Neilson supermarket scan data, information about different product groups was available on a subscriber basis. Known as the *Farm Market Index*, the last published statistics were for the 12 months up to and including March 2008.

16 Some animal health industry data is now collected by Baron Strategic Services Pty Limited from Schering-Plough, Pfizer, Novartis, Boehringer Ingelheim and Virbac.

17 The conditions on which the Farm Market Index and the Baron data is provided to subscribers means that any of that data provided to the Commission in connection with this Notice is provided on the basis that it is subject to the confidentiality provisions in paragraphs 31 – 35 of Part 1 of this Notice.

The Parties' Animal Health Activities in New Zealand
Market definition

Merck

1 Merck's interests in animal health are carried out through Merial New Zealand Limited, a wholly owned subsidiary of Merial Limited.[4]

2 Merial has traded in New Zealand as MERIAL Ancare New Zealand since its acquisition of the New Zealand animal health company Ancare New Zealand Limited in 2007. Further information about MERIAL Ancare can be found at www.merialancare.co.nz.

3 The majority of products sold by MERIAL Ancare New Zealand are either manufactured in New Zealand at the Ancare manufacturing site in Auckland or toll manufactured by third parties in New Zealand. Some products are imported from France, Brazil, China and Australia.

Schering-Plough

4 Schering-Plough's animal health activities in New Zealand (including the Intervet[5] business) are conducted through Schering-Plough Animal Health Limited, trading as Intervet Schering-Plough Animal Health. Further information about Intervet Schering-Plough Animal Health can be found at:

- http://www.spah.co.nz/
- http://www.intervet.co.nz/

5 Schering-Plough has a biological manufacturing facility in Upper Hutt, which exports vaccines worldwide in addition to supplying the New Zealand market. Schering-Plough does not have its own animal pharmaceutical manufacturing facility in New Zealand. Its animal pharmaceutical products are either toll manufactured by third parties in New Zealand or imported.

Areas of overlap

6 Table 3.1 shows the NZFSA animal health classifications in which Merial and Schering-Plough have products registered in New Zealand.[6] The highlighted rows show classifications in which both parties have registrations.

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[4] Merial SAS holds 100% of the shares of Merial New Zealand Limited and Merial Limited holds 100% of the shares in Merial SAS.

[5] Acquired with the 2007 purchase by Schering-Plough of Organon BioSciences N.V. Clearance was sought and granted by the Commerce Commission for that transaction. Decision 621, 4 October 2007.

[6] A copy of the relevant pages from the NZSFSA register supporting the identification of the areas of overlap is available should the Commission wish to see it.

Table 3.1

Merial & Schering-Plough product categories *(using NZSFA classifications)*

NZFSA Category	Merial	Schering-Plough
Adjuvant	X	X
Anaesthetic	√	√
Analgesic	√	√
Anti-inflammatory	√	√
Anti-sapstain	X	X
Antibiotic	√	√
Anticonvulsant agent	X	X
Antidote	X	X
Antiemetic	X	X
Antifungal	X	√
Antimicrobial	√	√
Antiprotozoal	X	X
Bactericide	X	X
Bee repellent	X	X
Behaviour modifier	X	X
Bloat remedy	√	X
CNS stimulant	X	X
Cardiovascular agent	X	√
Coccidiostat	X	√
Diagnostic Antigens	X	X
Diluent	X	X
Ectoparasiticide	√	√
Ectoparasiticide, Endoparasiticide (PARIS)	√	X
Endocrine Agent	X	√
Endoparasiticide	√	√
Euthanasia Agent	X	X
Fungicide	X	X
Gastrointestinal Tract Monitor	X	√
Herbicide	X	X
Hormonal Growth Promotant	X	√
Immune Stimulant	X	X
Immunomodulator	X	√
Insecticide	X	X
Miticide	X	X
Mulluscicide	X	X
Musculoskeletal Modifier	X	X
Nutrients – Oral Medicated/Antibiotics	X	X
Nematicide	X	X
Other – P, Other A* (Paris)	X	X
Obstetric Aid	X	X
Oral Nutrient Electrolyte	√	√
Parenteral Nutrient/ electrolyte	√	√
Plant Growth Regulator	X	X
Poultice	X	X
Renal and Urinary Tract Modifier	X	√
Sedative	X	X
Skin/coat conditioner	X	X
Vertebrate Toxic Agent	√	X
Vaccine	√	√
Vertebrate Toxic Agent	X	X
Viricide	X	X

7 Appendix 3.1 contains lists of all animal health products in the above overlapping categories for which Merial and Schering-Plough have NZFSA registrations. (This includes NZFSA registrations under Merial New Zealand Limited, Merial NZ Limited, Ancare Limited, Schering-Plough and Intervet.)

8 Table 3.1 suggests that there are ten broad categories in which Merial and Schering-Plough overlap:

1	Anaesthetics	drugs administered to induce anaesthesia
2	Analgesic	drugs that reduce or eliminate pain
3	Anti-inflammatory	non-steroidal and steroidal anti-inflammatory drugs, including corticosteroids, which prevent and treat inflammation and reduce pain and/or fever associated with inflammation
4	Antibiotic	substance or compound that kills or inhibits the growth of bacteria
5	Antimicrobial	drugs that destroy or prevent the growth of microbes such as bacteria, fungi and parasites
6	Ectoparasiticide	agents or preparations used to prevent or destroy different sorts of external parasites such as flies and lice
7	Endoparasiticide	agents or preparations used to prevent or destroy different sorts of internal parasites such as worms
8	Oral Nutrient Electrolyte	substance or compound that is administered orally to treat mineral deficiency
9	Parenteral Nutrient/ electrolyte	substance or compound that is administered by injection to treat mineral deficiency
10	Vaccines	biological preparation that establishes or improves immunity to a particular or variety of diseases

9 Within each of these categories, an examination of Schering-Plough and Merial's product listings indicates that, in some instances, there is no actual competition between Schering-Plough and Merial. There are a variety of reasons for this.

- Despite the registrations, not all the parties' respective products are actually sold in New Zealand. Some have never been sold here; others have been withdrawn from sale either because they are obsolete or have been superseded by a new improved product or the volume of sales has not warranted the continued availability of the product.

- The product's registration may stipulate that the product can only be sold or used in accordance with its label content which specifies that the product is only for use with certain animals or in certain circumstances.

- In practice, some products are marketed (and hence used) for a narrower purpose or a narrower range of animals than the registrations permit.

10 The lists in Appendix 3.1 identify the registered products that are no longer available in New Zealand and products that are available but have a narrower use than the registration permits. In this regard, please also see the *Index of Veterinary Specialities (IVS)* which lists animal health products sold in New Zealand in 2008

and the purposes for which they are marketed. (A copy of IVS accompanies this Notice.)

11 In summary:

1	Anaesthetics	Schering-Plough product registered but not sold in NZ.
2	Analgesic	Overlap in analgesic products for horses.
3	Anti-inflammatory	Overlap in anti-inflammatories for companion animals.
4	Antibiotic	Overlap in antibiotics for treatment of: o mastitis in dry cows; o infections in ruminant animals and swine.
5	Antimicrobial	This classification includes products for teat care and the treatment of mastitis. Schering-Plough does not operate in this market. While it holds the products registrations, the products are marketed and distributed by Ecolab Limited.
6	Ectoparasiticide	Overlap in products for the control of lice in cattle and flies and lice in sheep.
7	Endoparasiticide	Overlap in products for the control of internal parasites in cattle, sheep and horses.
8	Oral Nutrient Electrolyte	Schering-Plough product registered but not sold in NZ.
9	Parenteral Nutrient/ electrolyte	Overlap in products for selenium deficiency in cattle.
10	Vaccines	Overlap in vaccines for bovine viral diarrhoea.

Products available off-shore and products in development

12 Other companies in the Schering-Plough and Merial groups sell, in global markets, products that are not available in New Zealand (as will be the case with many other pharmaceutical companies). In addition, both have products in development, many of which will not be made available here. Reasons that certain products are not sold in New Zealand include:

- the particular disease or ailment is not a feature of the New Zealand environment so there is no current demand for the product; or
- New Zealand does not have a large industry in that sector (eg aquaculture) and the market is too small to warrant introducing the product.

13 Information about these potential new products has not been provided with this Notice as entry conditions for new products are the same for all pharmaceutical companies.

Product Market definition

14 On the basis of the above, the competition implications of the Proposed Transaction have first been assessed against the following broad categories:

- analgesics for horses (but the further analysis on pages 35 to 38 indicates that the Merial and Schering-Plough products in this category are not substitutable);

- anti-inflammatories for companion animals (but the further analysis on pages 39 to 45 indicates that the Merial and Schering-Plough products in this category are not substitutable);
- intramammary antibiotics for the treatment of mastitis in dry cows;
- antibiotics for the treatment of infection in ruminant animals and swine;
- products for the treatment of external parasites in:
    - cattle;
    - sheep;
- products for the treatment of internal parasites in:
    - cattle and sheep;
    - horses;
- nutrients for selenium deficiency in cattle; and
- vaccines for bovine viral diarrhoea (*BVD*).

15 Further comment on product market definition and the competition analysis in relation to each of the above categories is addressed in separate sections on pages 35 to 95.

Functional Market

16 Some animal health products in the relevant product markets are manufactured in New Zealand, while others are manufactured overseas and imported into New Zealand.

17 Manufacturers and importers of animal health products are also involved in the wholesale supply/distribution of the products to rural resellers and veterinarians. As a general principle, manufacturers/importers do not sell products directly to end consumers.

18 Consistent with the approach taken by the Commission *in Schering-Plough/Organon*,[7] the Applicant considers that the functional market is manufacture/import and wholesale supply.

Geographic Markets

19 In the supply of animal health products, distribution by suppliers is undertaken on a national level. Accordingly, the geographic market for the supply of animal health

[7] At paragraph 163.

products is national. This is consistent with the approach taken by the Commission in *Schering-Plough/Organon*.[8]

[8] At paragraph 166.

Existing Competitors

1 The animal health markets in New Zealand are characterised by a large number of significant competitors. A distinction can be drawn between companies that develop new products through research and development and those that manufacture generic products.

Pfizer New Zealand Limited (Pfizer NZ)

2 Pfizer Incorporated, a multinational research and development company, is the world's largest research-based biomedical and pharmaceutical company, founded in 1849. Its animal health business is one of the largest in the world. Its corporate headquarters are located in New York, with major research and development locations in the United States and England. Pfizer NZ has grown to be one of New Zealand's leading providers of prescription medicines, consumer healthcare products and animal health products, including vaccines.[9] Further information regarding Pfizer can be found at www.pfizer.com.

3 Of the markets relevant to the Proposed Transaction, Pfizer NZ is active in:

- analgesics for horses;
- anti-inflammatories for companion animals;
- intramammary treatments for dry cattle;
- antibiotics for the treatment of infection in ruminant animals and swine;
- ectoparasiticides for cattle;
- ectoparasiticides for sheep;
- endoparasiticides for cattle and sheep; and
- vaccines for protection against BVD.

4 Pfizer NZ sells its products through veterinary channels only.

Fort Dodge New Zealand Limited (Fort Dodge NZ)

5 Fort Dodge Animal Health, a multinational research and development company, was founded in 1912 and has been a division of Wyeth Holdings Corporation since 1945. Fort Dodge Animal Health is a leading manufacturer and distributor of prescription and OTC animal health care products for the livestock and companion animal industries. Fort Dodge Animal Health distributes products in more than 100 countries. (As at 2007, it ranked first in veterinary vaccine sales in North America.)[10] Fort Dodge had global turnover of €680 million in 2008. Further information regarding Fort Dodge can be found at http://www.wyeth.com/divisions/fort_dodge.asp.

6 Of the markets relevant to the Proposed Transaction, Fort Dodge NZ is active in:

[9] Decision 621, at paragraphs 25 & 26.

[10] Decision 621, at paragraphs 28 & 29.

- ectoparasiticides for cattle;
- ectoparasiticides for sheep;
- endoparasiticides for cattle and sheep; and
- endoparasiticides for horses.

7 Pfizer and Wyeth have entered into a merger agreement pursuant to which Pfizer will acquire Wyeth in a cash-and-stock transaction. This will also give Pfizer control over Fort Dodge and will result in a strong animal health business with a broad product portfolio.

Bomac Laboratories Limited (Bomac)

8 Bomac is a local producer of generic products and is New Zealand's largest privately owned animal health company. Although a local producer, Bomac is a strong competitor, present in most segments of the animal health market. It was founded in 1958 as a dedicated supplier of generic animal health products. Bomac is based in Auckland and manufactures over 400 products for sale in New Zealand and in over 60 countries worldwide. It has products in the bovine, equine, pig and poultry, sheep and companion animal categories.[11] Further information regarding Bomac can be found at www.bomac.co.nz.

9 Of the markets relevant to the Proposed Transaction, Bomac is active in:

- analgesics for horses;
- anti-inflammatories for companion animals;
- intramammary treatments for dry cattle;
- antibiotics for the treatment of infection in ruminant animals and swine;
- ectoparasiticides for cattle;
- ectoparasiticides for sheep;
- endoparasiticides for cattle and sheep;
- endoparasiticides for horses; and
- nutrients for selenium deficiency in cattle.

Virbac New Zealand Limited (Virbac NZ)

10 Virbac NZ is a subsidiary of Virbac Australia Pty Limited, and has been operating in New Zealand since 1984. Virbac Australia Pty Limited's parent company is a multinational company engaged in research and development. It designs, manufactures and markets a broad range of products and services for veterinarians and animal owners, and operates in 22 countries, exporting to 100 countries worldwide. Virbac NZ supplies a number of animal health products to the New Zealand market; half of its business relates to companion animal products. Virbac NZ also supplies the New Zealand market with Leptospirosis vaccines for cattle, fertility vaccines for sheep, minerals and calf products. Its vaccines are

[11] Decision 621, at paragraphs 33 & 34.

manufactured in Australia and the United States.[12] Further information regarding Virbac can be found at: www.virbac.co.nz.

11 Of the markets relevant to the Proposed Transaction, Virbac NZ is active in:

- anti-inflammatories for companion animals;
- intramammary treatments for dry cattle;
- antibiotics for the treatment of infection in ruminant animals and swine:
- ectoparasiticides for cattle;
- endoparasiticides for sheep; and
- endoparasiticides for horses.

Bayer New Zealand Limited (Bayer NZ)

12 Bayer AG is a multinational research and development company with major business in healthcare, nutrition and materials. Bayer AG has a portfolio of over 5,000 products and operations in nearly all countries of the globe. Worldwide operations are managed from the Group's headquarters in Germany. Bayer NZ was incorporated in 1964. Bayer NZ imports products (from its parent company in Germany) and other third party distributors; it also has some products toll manufactured in New Zealand and in Australia by third parties.[13]

13 Bayer recently increased its competitive position by divesting many of its older livestock products to focus its efforts on core major brands, resulting in increased competitiveness in its markets. It also focuses its product development on new formulations or combinations of established active ingredients. Further information regarding Bayer can be found at: www.bayer.com.

14 Recently Bayer NZ has experienced rapid market share growth in the large animal health market with a broadened range of internal and external parasiticide products.

15 Of the markets relevant to the Proposed Transaction, Bayer NZ is active in:

- ectoparasiticides for cattle;
- ectoparasiticides for sheep;
- endoparasiticides for cattle and sheep; and
- nutrients for selenium deficiency in cattle.

Norbrook New Zealand Limited (Norbrook NZ)

16 Norbrook Laboratories Limited (*Norbrook*) was established in Ireland in 1968. Norbrook is a multinational research and development company that manufactures a comprehensive range of generic veterinary and medical pharmaceuticals, contract manufactured products and pharmaceutical active ingredients (raw materials) and finished dose forms. It exports to over 110 countries. Norbrook NZ was

[12] Decision 621, at paragraphs 39 & 40..

[13] Decision 621, at paragraphs 42 & 43.

incorporated in New Zealand in 1997 and is operated from Australia.[14] Further information regarding Norbrook can be found at www.norbrook.com.au.

17 Of the markets relevant to the Proposed Transaction, Norbrook NZ is active in:

- analgesics for horses;
- anti-inflammatories for companion animals;
- intramammary treatments for dry cattle;
- antibiotics for the treatment of infection in ruminant animals and swine:
- ectoparasiticides for cattle;
- ectoparasiticides for sheep;
- endoparasiticides for cattle and sheep; and
- endoparasiticides for horses.

Boehringer Ingelheim NZ Limited (Boehringer Ingelheim NZ)

18 Boehringer Ingelheim Auslandsbeteiligungs GmbH is a multinational research and development company which has some 140 affiliated companies in 42 countries worldwide, focused on human pharmaceuticals and animal health. It has a wide range of products covering the vaccines, pharmaceuticals and natural health care segments of the animal health industry. Boehringer Ingelheim NZ has been operating in New Zealand since 1973.[15] Further information regarding Boehringer Ingelheim can be found at: www.boehringer-ingelheim.com.

19 Of the markets relevant to the Proposed Transaction, Boehringer Ingelheim NZ is active in:

- analgesics for horses;
- anti-inflammatories for companion animals;
- intramammary treatments for dry cattle; and
- antibiotics for the treatment of infection in ruminant animals and swine.

Jurox Pty Limited (Jurox)

20 Jurox is an Australian-based privately-owned veterinary pharmaceuticals company producing generic products. It is mostly active in Australia and New Zealand. Jurox now offers more than 200 proprietary veterinary lines to diverse animal health markets internationally. Jurox New Zealand Limited (*Jurox NZ*) was incorporated in 1996 and is a wholly-owned family company which services the New Zealand market.[16] Further information regarding Jurox can be found at www.jurox.com.au.

21 Of the markets relevant to the Proposed Transaction, Jurox NZ is active in:

- anti-inflammatories for companion animals;

[14] Decision 621, at paragraphs 45 & 46.

[15] Decision 621, at paragraphs 48 & 49.

[16] Decision 621, at paragraphs 51 & 52.

- antibiotics for the treatment of infection in ruminant animals and swine;
- ectoparasiticides for cattle;
- ectoparasiticides for sheep;
- endoparasiticides for cattle and sheep;
- endoparasiticides for horses; and
- nutrients for selenium deficiency in cattle.

Ravensdown Fertiliser Co-operative Limited (Ravensdown)

22 Ravensdown is 100% owned by New Zealand farmers and directly supplies more than half of all the fertiliser used in New Zealand agriculture. Ravensdown entered the ecto/endoparasiticide markets in 2005 by becoming licensed to distribute generic Jurox products, which it rebrands under the Ravensdown name and sells directly to farmers.[17] Further information regarding Ravensdown can be found at www.ravensdown.co.nz.

23 Of the markets relevant to the Proposed Transaction, Ravensdown is active in:

- ectoparasiticides for cattle; and
- endoparasiticides for cattle and sheep.

Stockguard Laboratories (NZ) Limited (Stockguard)

24 Stockguard is a private New Zealand company incorporated in 1987 that specialises in the development and manufacture of generic veterinary products. The Applicant understands that Stockguard is the only manufacturer of veterinary antibiotic products in New Zealand.[18] Further information regarding Stockguard can be found at www.stockguard.co.nz.

25 Of the markets relevant to the Proposed Transaction, Stockguard is active in:

- intramammary treatments for lactating cattle;
- antibiotics for the treatment of infection in ruminant animals and swine: and
- parenteral nutrients for selenium deficiency in cattle.

Novartis International AG (Novartis)

26 Novartis is a multinational pharmaceutical company engaged in research and development based in Basel, Switzerland. Novartis Animal Health is a company that focuses on the well-being of companion animals and on the health and productivity of farm animals. Novartis Animal Health manufactures a number of vaccines in the United States for cattle and sheep. Novartis New Zealand Limited (*Novartis NZ*), previously Sandoz Pharma Limited, was incorporated in New Zealand in 1955.[19]

27 Novartis recently acquired the animal health business of Daiichi Sankyo (a Japanese pharmaceutical company), a deal which added a range of veterinary vaccines to the

[17] Decision 621, at paragraphs 53 & 54.

[18] Decision 621, at paragraphs 36 & 37.

[19] Decision 621, at paragraphs 58 – 60.

portfolio. Further information regarding Novartis can be found at www.novartis.com.

28 Of the markets relevant to the Proposed Transaction, Novartis NZ is active in:

- anti-inflammatories for companion animals;
- ectoparasiticides for cattle;
- ectoparasiticides for sheep;
- endoparasiticides for cattle and sheep; and
- nutrients for selenium deficiency in cattle.

Parnell Laboratories (Aust) Pty Limited (Parnell)

29 Parnell was founded over 40 years ago in Australia. Parnell is now an Australasian manufacturer of generic animal health products. Parnell New Zealand Limited (*Parnell NZ*) was incorporated in 1988.[20]

30 Of the markets relevant to the Proposed Transaction, Parnell NZ is active in:

- analgesics for horses;
- anti-inflammatories for companion animals; and
- intramammary treatments for cattle.

Animal Health Direct Limited (AHD)

31 AHD was established in 2001. AHD is a local manufacturer of generic products. In most cases the products offered by AHD are unique formulations offering new benefits to the end users. All formulations (except third party products) are manufactured in New Zealand.[21] Further information regarding AHD can be found at www.ahdltd.co.nz.

32 Of the markets relevant to the Proposed Transaction, AHD is active in nutrients for selenium deficiency in cattle.

Nutritech International Limited (Nutritech)

33 Nutritech was formed in 1915 in New Zealand. Nutritech manufactures a range of nutritional and mineral supplements to improve animal health, prevent deficiencies and improve productivity.[22] Further information regarding Nutritech can be found at www.nutritech.co.nz.

34 Of the markets relevant to the Proposed Transaction, Nutritech is active in nutrients for selenium deficiency in cattle.

[20] Decision 621, at paragraphs 62 & 63.

[21] http://www.ahdltd.co.nz/ahd.php

[22] http://www.nutritech.co.nz/about_us

Ecolab Limited (Ecolab)

35 Ecolab is a multinational research and development company and is the global leader in cleaning, sanitizing, food safety and infection prevention products and services.[23] Further information regarding EcoLab can be found at www.ecolab.com.

Lloyd Laboratories NZ Limited (Lloyd Laboratories)

36 Lloyd Laboratories is one of the leading contract toll manufacturers of generic pharmaceuticals and other related products and services in the Philippines and elsewhere in the world. Lloyd Laboratories is capable of manufacturing a variety of veterinary products.[24] Further information regarding Lloyd Laboratories can be found at www.lloydlab.com.

37 Of the markets relevant to the Proposed Transaction, Lloyd Laboratories is active in analgesics for horses.

Vetpharm NZ Limited (Vetpharm)

38 Vetpharm was incorporated in June 1994. Vetpharm is a local supplier of generic products. It markets and distributes a range of animal health products to the New Zealand veterinary profession and animal health industry. It distributes products sourced from Australia, the USA, and Europe, as well as from local manufacturers. Vetpharm is a sister company of Phoenix Pharm Distributors and operates out of the same premises.[25] Further information regarding Vetpharm can be found at www.phoenixpharm.co.nz.

39 Of the markets relevant to the Proposed Transaction, Vetpharm is active in:

- analgesics for horses;
- anti-inflammatories for companion animals; and
- endoparasiticides for horses.

Phoenix Pharm Distributors Limited (Phoenix)

40 Phoenix was incorporated in September 1983 and is a local wholesale distributor of generic pharmaceuticals, surgical, nutritional, OTC and general consumable supplies to the animal health industry, primarily through veterinary practices and selected equine outlets (Phoenix does not sell directly to the public).[26] Further information regarding Phoenix can be found at www.phoenixpharm.co.nz.

41 Of the markets relevant to the Proposed Transaction, Phoenix is active in:

- analgesics for horses;
- anti-inflammatories for companion animals; and
- antibiotics for the treatment of infection in ruminant animals and swine.

[23] http://www.ecolab.com/CompanyProfile/Default.asp

[24] http://www.lloydlab.com/index.html

[25] http://www.phoenixpharm.co.nz/pages/vetpharmprofile.htm

[26] http://www.phoenixpharm.co.nz/pages/aboutus.htm

Provet NZ Pty Limited (Provet)

42 Provet is Australasia's leading veterinary distributor. Provet supplies generic products to over 1900 independent veterinary practices in Australasia and this has generated strong buyer power. Provet is now an organisation approaching $A185million in sales and has an Australasian warehouse network including locations in Auckland, Palmerston North and Christchurch.[27] Further information regarding Provet can be found at www.provet.co.nz.

43 Of the markets relevant to the Proposed Transaction, Provet is active in:

- analgesics for horses;
- anti-inflammatories for companion animals; and
- nutrients for selenium deficiency in cattle.

FIL New Zealand Ltd (FIL)

44 FIL is a local dairy hygiene and animal health supplier supplying generic products from Mount Maunganui in the North Island and Timaru in the South Island. Since inception the company has focused on developing an impressive product range to include dairy detergents and sanitisers, teat care products, bloat remedies, spray marker dyes and its award winning and globally recognised range of oestrus detection tailpaints.[28] Further information regarding FIL can be found at www.fil.co.nz.

45 Of the markets relevant to the Proposed Transaction, FIL is active in:

- ectoparasiticides for sheep; and
- parenteral nutrients for selenium deficiency in cattle.

BASF New Zealand Limited (BASF)

46 BASF is a multinational research and development company involved in the creation of dependable pest management solutions for agriculture.[29] Further information regarding BASF can be found at www.agro.basf.co.nz.

47 Of the markets relevant to the Proposed Transaction, BASF is active in:

- ectoparasiticides for cattle; and
- endoparasiticides for sheep.

Elanco New Zealand (Elanco)

48 Elanco, a multinational research and development company, is a division of Eli Lilly and Company, a leading innovation-driven human healthcare company. Elanco markets animal health, welfare and performance products. In New Zealand, Elanco has been active since 1965. Its products are used in dairy, beef, sheep, poultry and pig production and marketed through veterinarians, merchant groups and feedmills

[27] http://www.provet.co.nz/go/home

[28] http://www.fil.co.nz/newsite/Online/company.html

[29] http://www.agro.basf.co.nz/

nationwide.[30] Further information regarding Elanco can be found at: www.elanco.com.

49 Of the markets relevant to the Proposed Transaction, Elanco is active in:

- antibiotics for the treatment of infection in ruminant animals and swine; and
- endoparasiticides for sheep.

[30] http://www.elanco.co.nz/

Potential Competition

Introduction

1 This section applies to each of the product markets discussed at pages 35 to 95.

2 The New Zealand Courts and the Commission have stated that, regardless of the combined entity's market share, an acquisition is unlikely to substantially lessen competition if barriers to entry or expansion are low because the combined entity will be constrained by:

- the threat of new entry; or
- the threat of expansion by existing competitors.

3 In 2007, in *Schering-Plough/Organon*, the Commission considered, in some detail, the barriers to entry in animal health product markets and the likelihood of new entry occurring.

4 For the reasons outlined further below, the Commission concluded that:

- overall, the barriers to entry in animal health pharmaceutical markets are generally relatively low, at least for a generic product; and
- in response to a price increase or other manifestation of market power, entry from generic products is likely to occur within the Commission's two year time frame for new entry.

5 The Applicant does not consider there to have been any change in market conditions such that the same conclusions would not be reached today in relation to the product markets affected by the Proposed Transaction.

Requirements for new entry

6 In *Schering-Plough/Organon,* the Commission identified the following as the key requirements for entry into animal health product markets:[31]

- product research and development;
- establishing Good Manufacturing Practice (GMP) manufacturing facilities;
- sourcing product ingredients;
- testing the safety and efficacy of the product;
- registration of the product with the New Zealand Food Safety Authority (NZFSA) Agricultural Compounds and Veterinary Medicine (ACVM) Group;
- manufacturing; and

[31] At paragraph 227.

- marketing and distribution.

7 Each of these requirements is now addressed in turn in light of the Commission's comments in earlier decisions.

Product research and development

8 In *Schering-Plough/Organon*, the Commission noted[32]:

> "The extent to which product research and development represents a barrier to entry will depend on whether the product is novel or generic. A novel product is one which is based on original research into an active substance or combination of active substances, while a generic product is essentially a copy of a novel product and its (off-patent) active substance(s). A novel product would require a significant investment in research and development, which is likely to act as a high entry barrier. …. In contrast, developing a generic product requires very little in the way of research and development investment, as the formulations of existing novel formulations are readily available and can be easily copied (provided the novel product is off-patent)."

9 Most of the animal health products sold in New Zealand have active ingredients that were discovered some time ago. Consequently, most products are not subject to patent protection. With the exception of vaccines, the markets affected by the Proposed Transaction all contain products with ingredients that are 'off patent' and for which the ingredients and formulations are readily available. (Formulations for a wide range of treatments are readily available on the Internet.)

10 The bulk of 'research and development' in the animal health industry in New Zealand is focussed on the development of new formulations of already existing active ingredients which provide different benefits to existing products in terms of withholding periods, ease of application etc. Most of the animal health companies in New Zealand have the ability to engage in development of this kind and do so. This is illustrated by the number of new product registrations with the NZFSA since the *Schering-Plough* decision in October 2007. (For details, see the sections on the individual product markets on pages 35 to 95).

11 Most animal health companies produce 'generic' drugs as they all produce drugs which are reformulations of (or in some cases the same formulation as) products which were previously patent protected. This means that competition in the animal health industry in New Zealand is driven both by:

- large global R&D companies such as Pfizer, Fort Dodge, Bayer, Novartis, Virbac, Norbrook ,Elanco and Boehringer Ingelheim); and

- local and global generic only suppliers such as Bomac, Jurox, Stockguard, Parnell, ADH and Lloyd Laboratories.

[32] At paragraph 229.

12 To the extent that there are similarities between Merial and Schering-Plough's products, other competitors could readily adjust their own products to compete head on with any perceived point of difference.

Manufacturing facilities

13 With regard to manufacturing facilities, in *Schering-Plough/Organon,* the Commission noted[33]:

> "A manufacturing facility must be approved and validated as being compliant with the standard for GMP, as assessed by NZFSA. GMP requires that all manufacturing and testing equipment has been qualified as suitable for use, and that all operational methodologies and procedures (such as manufacturing, cleaning, and analytical testing) utilised in the drug manufacturing process have been validated, to demonstrate that they can perform their purported function(s).
>
> The GMP approval itself by NZFSA is a relatively quick process, which usually takes between two and four days provided NZFSA has been involved during the development of the facility. Validation that the facility works as it is purported to do can be a longer process, with NZFSA stating that Schering-Plough's Upper Hutt manufacturing facility, for example, took 18 months to validate.
>
> It is not necessary for an entrant to have its own manufacturing facility, as entry could be achieved by having the product toll manufactured by an existing manufacturer, based either in New Zealand or overseas. Such arrangements are relatively commonplace in the animal health industry, and appear to be relatively straightforward to establish, at least in the case of animal health pharmaceuticals."

14 The use of contract manufacturers in New Zealand is common. Table 3.2 on the following page lists New Zealand based manufacturers with the authority to manufacture products in the categories affected by the Proposed Transaction. This table has been prepared from information available on the New Zealand Food Safety Authority website).[34]

[33] At paragraphs 232 – 233.

[34] www.nzfsa.govt.nz

Table 3.2: NZFSA Approved Manufacturers of Veterinary Medicines

Manufacturer	**Immunobiologicals**	**Non-sterile veterinary preparations**	**Ectoparasiticides** *(large volume)*
Aakland Chemicals (1997) Ltd		√	
Agmax Industries		√	
Agri-feeds Ltd		√	
AgriQuality	√		
Alaron Products Ltd		√	
Aqui-S NZ Ltd		√	
Argenta Manufacturing Ltd	√	√	√
Baxter Healthcare Ltd		√	
Bio-Start Ltd		√	
Biocell Corporation Ltd	√		
Bomac Laboratories Ltd	√	√	√
Brooklands Aquarium Ltd		√	
Chem Laboratories Ltd		√	
Chemcolour Industries Ltd			√
Damar Industries Ltd		√	
DEC (Manufacturing) Ltd		√	
DeLaval Ltd		√	
Desoan Manufacturing Ltd		√	
Douglas Manufacturing Ltd		√	
Dynea NZ Ltd		√	
Ecolab Ltd		√	
ES Plastics Ltd		√	
FIL Industries Ltd		√	
Greyhorse Vet NZ Ltd		√	
Grow Plus (1998) Ltd		√	
Image Holdings Ltd		√	
Jasol New Zealand Ltd		√	
Jaychem Industries Ltd		√	
MainFeeds Ltd		√	
Masterchem Manufacturing Ltd		√	
Merial NZ Ltd		√	√
Nufarm NZ			√
Nutritech International Ltd		√	
Nutrizeal Ltd		√	
Pacificvet Ltd		√	
Pauling Industries Ltd		√	
Pfizer New Zealand Ltd	√		
Provet NZ Pty Ltd		√	
Robin Pharmaceuticals Ltd		√	
Schering-Plough Animal Health Ltd	√		
South & Mid Canterbury Veterinary		√	
SPS Cell Culture Ltd	√		
Stockguard Laboratories (NZ) Ltd	√		
Trace Biosciences NZ Ltd		√	
Unitech Industries Ltd		√	
Veterinary Remedies (2008) Ltd	√	√	

Sourcing of product ingredients

15 The Commission concluded in relation to the products affected by the Schering-Plough/Organon transaction, that sourcing product ingredients is not a high barrier to entry.[35]

Testing the safety & efficacy of the products

16 In *Schering-Plough/Organon,* the Commission noted:[36]

> "All animal health products imported, manufactured, sold or used in New Zealand must be registered with NZFSA under the Agricultural Compounds and Veterinary Medicines Act 1997. Registration requires submission of a data package to be assessed by NZFSA. This package sets out technical and scientific data, including, among other things, data relating to the:
>
> - chemical formulation of the product;
> - manufacturing process;
> - safety of the product in the target animal;
> - efficacy of the product; and
> - product's compliance with maximum residue limits.
>
> In Decision 496, the Commission noted that industry participants indicated the costs and timeliness of testing lactating cow intramammary products were not significant. The same is likely to be the case for dry cow intramammary treatments, although the testing requirements for a novel product may be more onerous. The Commission understands that the testing requirements (in the registration process with NZFSA) for generic products can often be cross-referenced to the testing of the novel product on which the generic is based.

Registration with NZFSA

17 The Commission has concluded that registration with NZFSA is a relatively low barrier to entry, stating:[37]

> NZFSA's assessment of the registration package itself is generally not considered to be particularly onerous in terms of either time or cost. NZFSA stated that it aims to complete the process in 40 working days for a generic product and 75 working days for a novel product. The cost is based on an hourly rate, but the total charge is typically in the range of $5,000 to $7,000. The Commission is of the view that registration is thus a relatively low barrier to entry.

18 These costs have not changed materially since the *Schering-Plough/Organon* decision in October 2007.

Marketing & distribution

19 The Commission did not see marketing and distribution for existing animal health companies as being a barrier: [38]

[35] At paragraph 233.

[36] At paragraphs 234 & 235.

[37] *Schering-Plough/Organon, a*t paragraph 236.

In relation to marketing a product and building market share, one market participant noted that branding may act as an entry barrier, in that a generic entrant may struggle against established brands. Nonetheless, the success of companies such as Ancare and Stockguard, which supply generic products, shows that this barrier can be overcome.

Some industry participants suggested that access to distribution channels can be difficult, as veterinarians and rural resellers tend to stock only their preferred brands or look for suppliers able to offer a wide range of products across different markets. This may act as a relatively high barrier to entry for a de novo entrant with a few or no existing animal health products.

20 There are several factors that have reduced the extent of brand loyalty.

- The absence of patent protection. Veterinarians and farmers are aware that they can purchase effectively the same product under more than one brand name. Rural merchants tend to stock a range of branded and generic products.
- Brand loyalty becomes less important when there is a focus on cost minimisation and a range of substitutable products is available.
- The issue of developing resistance to animal health products means that farmers need to use a variety of products, and therefore a variety of brands, in their treatment of a particular condition over time. In an effort to delay resistance problems, farmers are encouraged to rotate different brands/formulations even with newer products that have not developed the same level of resistance.

21 The steady increase in the use of generic products in the animal health industry is evidence that brand loyalty, while still a factor for consumers, is not their primary motivation and as such is not a significant barrier to competition.

Conclusion on barriers to entry

22 In *Schering-Plough/Organon,* the Commission concluded that, overall, the barriers to entry in the dry cow intramammary market and in other animal health pharmaceutical markets more generally are relatively low, at least for a generic product. The Commission considered the largest barrier is likely to be establishing a manufacturing facility, although as explained above this is not a necessary requirement because toll manufacturing is reasonably common for pharmaceutical products. Barriers to entry for a novel product appear to be higher, largely due to the significant investment required in research and development and testing.

23 The Applicant has considered the above factors in relation to each of the animal health pharmaceutical markets affected by the Proposed Transaction and submits they apply equally in relation to those markets. Refer to the summary in Table 3.3 at the end of this section. (A number of the products affected are the same as those under consideration in *Schering-Plough/Organon*.)

[38] At paragraphs 237 & 238.

24 In relation to the production of animal vaccines, the barriers to entry for local manufacture are likely to be higher than for animal health pharmaceuticals. The research and development costs will be higher and a specialised facility would be required.

25 However, where a vaccine is already registered in New Zealand, the entry barriers for an equivalent vaccine produced off-shore are low. Equivalence with the existing registered vaccine must be established. Storage is in non-specialised coolstores.

Likelihood and timeliness of new entry

26 The Commission takes the view that in order for market entry to be a sufficient constraint, entry of new participants in response to a price increase or other manifestation of market power must be:

- likely in commercial terms;
- sufficient in extent to cause market participants to react in a significant manner; and
- feasible within two years from the point at which market power is first exercised.

27 In *Schering-Plough/Organon*, the Commission noted:

> "A number of market participants have stated that they are always looking for opportunities to enter other markets that they are not already active in…".[39]
>
> "More generally, there are numerous other examples of recent or impending entry into other animal health pharmaceutical markets by companies with an existing range of animal healthcare products."[40]
>
> "Most market participants considered that entry into any animal health pharmaceutical market would be relatively timely, at least for a generic product. …. Fort Dodge estimated that a generic product would take approximately two years to enter the market, while a novel product would take approximately 10 years."[41]

28 Again, the Applicant concurs with these conclusions and believes that a generic product could be established within the 2 years suggested by Fort Dodge. Table 3.3 identifies recent entry in most product markets.

[39] At paragraph 241

[40] At paragraph 243

[41] At paragraph 248.

Table 3.3

Overview of Requirements for new entry in affected markets

Market	Generics available?	Standard NZFSA GMP manufacturing facilities with no unusual requirements?	Key ingredients.	Costs and timing to test safety & efficacy of product are not significant	Standard registration process, nothing unusual or out of the ordinary?	Recent entry evidencing marketing & distribution not a barrier
Analgesics (for horses)	Yes	Yes	Carprofen, Ketoprofen, Flunixon, Xylazine, Detomidine or Butorphanol Readily available	Yes	Yes	Pfizer
Anti-inflammatories (for companion animals)	Yes	Yes	Ketoprofen, Pentosan polysulphate, Flunixin, Meloxicam, Carprofen, Prednisolone or Dexametbasone Readily available	Yes	Yes	Boehringer Ingelheim Bomac Norbrook Pfizer Virbac
Intramammary antibiotics for treatment of mastitis in dry cows	Yes	Yes	Cephalonium, Amoxycillin, Penicillin or Cloxacillin Readily available	Yes	Yes	Bomac, Jurox, Merial and Virbac
Antibiotics for treatment of infections in cattle & pigs	Yes	Yes	Oxytetracycline, Penicillin, Amoxycillin, Ceftiofur, Dihydrostreptomycin or Sulfadiazine Readily available	Yes	Yes	Bomac, Bayer, Jurox, Merial, Norbrook, Pfizer and Stockguard
Endoparasiticides (cattle, horse & sheep)	Yes	Yes	Levamisole, Ivermectin, Albendazole, Oxfendazole, Moxidectin, or Abamectin	Yes	Yes	Bomac, Seneca Holdings, Merial, Bayer, Norbrook, Fort Dodge, Virbac, Schering-Plough, Jurox and Novartis.

Market	Generics available?	Standard NZFSA GMP manufacturing facilities with no unusual requirements?	Key ingredients.	Costs and timing to test safety & efficacy of product are not significant	Standard registration process, nothing unusual or out of the ordinary?	Recent entry evidencing marketing & distribution not a barrier
			Readily available (other than Moxidectin)			
Ectoparasiticides (cattle & sheep)	Yes	Yes	Deltamethrin, Diflubenzuron Chlorpyrifos, Cypermethrin, or Cyromazine Readily available	Yes	Yes	Bomac, Merial, Norbrook, Schering-Plough, Bayer, Virbac, Elanco and Jurox .
Nutrients for treating selenium deficiency in cattle	Yes	Yes	Sodium selenate Readily available	Yes	Yes	Bayer, Bomac, Merial and Novartis (among others).
Vaccines for bovine viral diarrhoea	No	Yes	Bovine viral diarrhoea antigen (inactivated) Readily available	Yes	Yes	AsureQuality, Biosecurity NZ, Boehringer Ingelheim, Fort Dodge, Schering-Plough and Novartis have registered other vaccines. Pfizer has registered a BVD vaccine.

Countervailing power of buyers

1 This section applies to each of the product markets discussed at pages 35 to 95.

2 The acquirers of animal health products do impose constraint on suppliers. Schering-Plough's customers are a combination of veterinarians, veterinary wholesalers and rural supply stores. Merial's customers are veterinarians and veterinary wholesalers.

Major customers

SVS Veterinary Supplies Limited (SVS)

3 SVS is a New Zealand owned wholesaler of veterinary products. SVS supplies approximately 5,000 different products to the New Zealand market with 50% relating to companion animals, 45% to dairy and 4% to sheep.[42]

Provet Australasia Pty Limited (Provet)

4 Provet is Australasia's leading veterinary distributor. Provet has an extensive warehouse network across Australasia including warehouses in Auckland, Palmerston North and Christchurch. Provet fulfils over 3,500 orders per week across a holding of 12,000 product lines.[43] Further information on Provet can be found at www.provet.co.nz.

PGG Wrightson Limited (PGG Wrightson)

5 PGG Wrightson was formed in 2005 through the merger of Pyne Gould Guinness Limited and Wrightson Limited. The company has many different lines of business, including approximately 124 PGG Wrightson rural supply stores. The stores supply farms nationwide with many products including animal health and nutrition products.[44] Further information on PGG Wrightson can be found at www.pggwrightson.co.nz.

Farmlands Trading Society Limited (Farmlands)

6 Farmlands was formed in 1962 when a group of farmers and growers joined together to purchase goods. It is owned by its customer shareholders, and offers a number of products to the rural sector, including animal remedies.[45] Further information on Farmlands can be found at www.farmlands.co.nz.

Combined Rural Traders Co-operative (CRT)

7 CRT is a farmer co-operative, owned by farmers in the South Island. CRT is a co-operative owned by more than 24,000 South Island farmers. CRT is the largest buying group of its type in New Zealand and now has 30 CRT FarmCentres throughout the South Island stocking a full range of farm inputs.[46] Further information on CRT can be found at www.crt.co.nz.

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[42] *Schering-Plough/Organon* at paragraph 78.

[43] *www.provet.com.au/go/provet-services/warehousing-and-distribution*

[44] *Schering-Plough/Organon* at paragraph 70.

[45] *Schering-Plough/Organon* at paragraph 76.

[46] http://www.crt.co.nz/AboutUsPage

RD1

8 RD1 is New Zealand's largest retailer of agricultural supplies to dairy farmers. It operates a network of over 40 stores in the North Island, and seven in the South Island. RD1 is focused primarily on the dairy sector through its involvement with Fonterra Co-operative Group Limited.[47] Further information on RD1 can be found at www.rd1.com.

Veterinarians

9 There are a number of large veterinary operations in New Zealand. Veterinarians may choose to purchase other animal remedies either directly or through a wholesaler.

Buyer power

10 In *Schering-Plough/Organon,* the Commission concluded that veterinarians, many of whom have significant buying power, would have sufficient countervailing power to constrain the combined entity from exercising market power in the market for campylobacter vaccines for sheep, due to the presence of an alternative supplier.[48] The Commission noted:[49]

> "Many veterinarians are relatively large and sophisticated buyers, due to a trend of rationalisation in the veterinary industry. For example, Veterinary Enterprises Limited, [ ] has seven[50] veterinarian practices and an approximate annual turnover of $23 million. [ ] believed that his company did have buyer power over the suppliers, and that there were other large veterinarian groups or practices that would have similar countervailing power. Other veterinarians spoken to by the Commission said that the availability of both products was important as it allows them to play one off the other."

11 In each of the product markets affected by the Proposed Transaction, there is a range of other suppliers. The veterinarian practices and the large rural supplies stores have the ability to switch suppliers if they are unhappy with the price or service offering made available to them. They will continue to represent a considerable constraint on Schering-Plough and Merial following the Proposed Transaction.

12 In Decision 566 (*Gallagher Group/Greyson Gates),* the Commission considered that the large rural resellers had strong countervailing power and would continue to constrain the combined entity from exercising market power.[51] Rural resellers have increased their market power through consolidation over the last few years and are well able to obtain and promote products from competitors.

13 The buying power of these customers is illustrated by reference to Farm Market Index data on the value of parasiticide purchases in the 12 months to 31 January 2008. Please see tables 3.4 to 3.6 in confidential Schedule 3.1.

14 These customers could readily sponsor the new entry or expansion of a generic supplier or source their own generic product. This ability to introduce and market a new product will

[47] *Schering-Plough/Organon* at paragraph 73.

[48] At paragraph 305.

[49] At paragraphs 303 & 304.

[50] Veterinary Enterprises now has 10 practices. Refer http://www.vetent.co.nz/vetent_About_Us.cfm

[51] At paragraph 123.

continue to impose a constraint on Merial and Schering-Plough following the Proposed Transaction.

Co-ordinated market power

1 This section applies to each of the product markets discussed at pages 35 to 95.

2 Whether an acquisition will increase the scope for the exercise of co-ordinated market power depends on the degree of market share concentration, the product in question, and the nature of the competitive process in the relevant market(s). In considering the scope for co-ordinated conduct, it is necessary to assess whether the market currently shows signs of co-ordinated market power, and assess whether the acquisition affects any of those factors currently precluding or facilitating the exercise of co-ordinated market power.

3 In the Applicant's view, none of the markets affected by the Proposed Transaction display signs of co-ordinated market power. Key factors currently precluding the exercise of coordinated market power are:

- the absence of pricing transparency (suppliers provide a range of discounts to a large number of customers);
- the large number of competitors – both branded and generic suppliers – and the presence of an active competitive fringe; and
- sophisticated customers, who are well placed to detect and thwart any attempt to exercise coordinated market power.

4 None of these factors will change as a result of the Proposed Transaction and hence the Proposed Transaction cannot be said to facilitate tacit collusion.

5 The following assessment of the various factors the Commission considers indicate the scope for coordinated conduct and the ability to detect it, and the impact of the Proposed Transaction on those factors, apply to all of the relevant markets.

Table 3.7

Scope for co-ordination

Scope for co-ordinated market power	Present	Effect of Acquisition
High seller concentration	In some markets, yes (CR3>70%)	Market share increase over 10% only in products for the treatment of external parasites in cattle and in sheep
Undifferentiated product	No	No change
Static production technology	No	No change
New entry slow	No – not for generic products	No change
Absence of fringe competitors	No	No change
Acquisition of an unusually vigorous or effective competitor	No	No change
Price inelastic market demand	No	No change
History of anti-competitive behaviour	No	No change
Absence of countervailing power of acquirers	No	No change
Frequent sales	Yes	No change
Lack of vertical integration	Some	No change
Stable/slow growth in demand	Demand varies	No change
Cost similarities between businesses	Cost of production likely to be similar	No change
Existence of excess capacity	No	No change
Multi-market contact	Yes	No change
Price transparency	No	No change
Industry associations/fora	Yes	No change

Individual product markets

1. Analgesics

Introduction

1 Analgesics are drugs that reduce or eliminate pain.

2 Some products have both analgesic and anti-inflammatory properties. Other products are analgesics only. Anti-inflammatories tend to have a dual effect: they reduce inflammation and thereby reduce the pain caused by the inflammation.

3 The *Analgesics* product table in Appendix 3.1 shows that Merial and Schering-Plough both have products listed in the NZFSA classification for analgesics: Merial has products for cattle, horses and companion animals; Schering-Plough has one product for use with horses.

4 The only area of overlap is in relation to products used for the alleviation of pain in horses.

- Merial has one product, KETOFEN 10%, with the active ingredient Ketoprofen.
- Schering-Plough has one product, DOLOREX, with the active ingredient Butorphanol Tartrate.

Product differentiation

5 Within the animal analgesics category, as with drugs that reduce or eliminate pain in humans, there is a range of products to treat pain of different severity or pain caused by different conditions.

6 For example, pain killers for human use range from relatively low strength products such as aspirin and paracetamol through to heavy pain killers such as morphine. There is a chain of substitution, but at either end of the spectrum, the products are not substitutable.

7 This is also the case with pain killers for animals. For example:

- drugs with the active ingredient ketoprofen, carprofen, copper indomethican, flunixin, and flunixin meglumine are non-steroidal products used for pain at the lower end of the pain spectrum;
- drugs with the active ingredient xylazine, detomidine or detomidine hydrochloride have pain killing properties but are primarily used as sedatives;
- drugs with the active ingredient hyoscine-n-butylbromide are used to reduce spasm in the muscles of the gut and the pain associated with it; and
- drugs with the active ingredient butorphanol tartrate or pethidine are used for pain at the upper end of the pain spectrum.

8 A veterinarian is unlikely to substitute products within one of the above groups with a product from another.

9 Table 3.8 shows the range of analgesic products for horses that are available, ranging from mild up to the strongest analgesic products.

Table 3.8

Analgesics for horses

Company Name	Product Name and Description	Active Ingredient	IVS Page Reference
Merial	**KETOFEN 10%: For the alleviation of inflammation and pain associated with musculo-skeletal disorders in cattle and horses. Also for use in dogs and cats for the treatment of painful, inflammatory conditions, especially musculoskeletal disorders.**	**Ketoprofen**	**35, 186**
Parnell Laboratories	TERGIVE INJECTION: for the relief of pain and inflammation in dogs, cats and **horses.**	Carprofen	26
Vetpharm NZ	CU-ALGESIC ORAL PASTE: Anti-inflammatory agent and analgesic for use in treating acute and sub acute musculoskeletal conditions in **horses.**	Copper Indomethacin	30
Bomac	FLUNIX INJECTION: for the treatment of conditions in **horses, cattle, pigs and dogs** requiring anti-inflammatory analgesic.	Flunixin	32
Norbrook	FLUNIXIN INJECTION: for the treatment of conditions in **horses, cattle, pigs and dogs** requiring anti-inflammatory analgesic.	Flunixin Meglumine	32
Bomac	FLUXIMINE INJECTION: for the treatment of inflammatory and painful conditions in **horses, cattle and dogs.**	Flunixin Meglumine	33
Bomac	FLUXIMINE PASTE: for the treatment of inflammation and pain associated with musculoskeletal disorders in **horses.**	Flunixin Meglumine	33
Phoenix Pharm	KELAPROFEN 10%: An anti-inflammatory and analgesic treatment of musculoskeletal disorders.	Ketoprofen	34
Parnell	KEY INJECTION: Non-steroidal anti-inflammatory analgesic and antipyretic for **horses.**	Ketoprofen	36
Pfizer	RIMADYL INJECTION: for treatment of musculoskeletal disorders and for anti-inflammatory treatment after surgery.	Carprofen & benzyl alcohol	41
Pfizer	RIMADYL LA: an anti-inflammatory, antipyretic and analgesic for **cattle and horses.**	Carprofen	41

Company Name	Product Name and Description	Active Ingredient	IVS Page Reference
Bomac	BOMAZINE 5%: analgesic and muscle relaxant in **horses, cattle and deer**. Used for routine examination, minor surgery or immobilisation of animals for transportation.	Xylazine	20
Bomac	BOMAZINE 10%: for sedation, analgesia, and muscle relaxation of large animals such as **horses, cattle and deer.**	Xylazine	20
Lloyd Laboratories	ANASED 2% INJECTION: for sedation, analgesia, and muscle relaxation of **cattle, horses, deer, sheep, goats, dogs and cats.**	Xylazine	27
Lloyd Laboratories	ANASED 10% INJECTION: for sedation, analgesia, and muscle relaxation of **horses and deer.**	Xylazine	27
Vetpharm NZ	DETOMO VET INJECTION: For use in **horses** as an analgesic and sedative to facilitate examinations, minor surgery, dental and clipping procedures.	Detomidine hydrochloride	31
Pfizer	DORMOSEDAN: For use in **horses and cattle** as an analgesic and sedative to facilitate examinations, minor surgery, etc.	Detomidine	32
Boehringer Ingelheim	BUSCOPAN COMPSITUM SOLUTION: provides spasmolytic, analgesia and anti-inflammatory activity that specifically affects the gastrointestinal and urinary tracts. For **horses, cattle, calves, pigs, dogs.**	Hyoscine-n-butylbromide; dipyrone	29
Lloyd Laboratories	BUTORPHIC INJECTION: In **horses**, for the relief of pain and as an analgesic when given in combination with other drugs.	Butorphanol (as tartrate)	30
Provet	PETHIDINE VET: Acts as an analgesic and sedative when given by intramuscular injection to cats, **dogs, pigs, sheep, goats, deer, cattle and horses**.	Pethidine HCI	37
Schering-Plough	**DOLOREX: For the relief of moderate to severe pain in horses. Especially abdominal pain associated with torsion, impaction, spasmodic and tympanic colic and post-partum pain.**	**Butorphanol Tartrate**	**31**

10 Merial and Schering-Plough's analgesic products are at opposite ends of the pain spectrum:

- Merial's product, with the active ingredient Ketoprofen, is a non-steroidal anti inflammatory used for the reduction of pain and inflammation in cattle, horses and companion animals, and is at the lower end of the pain spectrum;

- Schering-Plough's product, with the active ingredient Butorphanol Tartrate, is an opioid for the relief of acute or chronic pain in horses only and is at the upper end of the pain spectrum.

11 These products are not substitutable and, while listed in the same NZFSA classification, they are not truly within the same market or viewed by veterinarians as substitutable products. Accordingly, no further analysis of the analgesics category is provided.

2. Anti-inflammatories

Introduction

1 Anti-inflammatories are non-steroidal and steroidal anti-inflammatory drugs, including corticosteroids, that are used to treat inflammation and to reduce the pain and fever associated with inflammation in ruminants, swine, horses and companion animals. Inflammation is a localised protective reaction of tissue to irritation, injury or infection.

2 The *Anti-inflammatories* product table in Appendix 3.1 shows that Merial and Schering-Plough both have products listed in the NZFSA classification for anti-inflammatories: Merial has products for cattle and companion animals; Schering-Plough has one product for use with companion animals only.

3 Therefore, the only area of overlap is in relation to products used for treating inflammation in companion animals:

- Merial has four products: KETOFEN 1%, KETOFEN TABLETS 5MG, and KETOFEN TABLETS 20MG (all with the active ingredient Ketoprofen; these products are also analgesics) and PREVICOX with the active ingredient Firocoxib.
- Schering-Plough has one product DEXADRESON with the active ingredient dexamethasone.

Product differentiation

4 Within the anti-inflammatories category, there is a range of products with different active ingredients for different types of inflammation. These include:

- non-steroidal inflammatories (*NSAIDs*) which are used to treat inflammation caused by musculoskeletal disorders or trauma when the overarching symptom is pain; these products can relieve mild-moderate pain (analgesia), inflammation and fever (anti-pyretic properties) without the immunosuppressive and metabolic side-effects associated with corticosteroids. NSAIDs work to block the effect of an enzyme called cyclooxygenase which is critical in the body's production of prostaglandins. Prostaglandins cause swelling and pain, so by interfering with cyclooxygenase, the NSAID decreases the production of prostaglandins, and decreases pain and swelling associated with these conditions; and
- corticosteroids that act as immunosuppressants for the treatment of severe inflammation or hyperimmune responses (allergies or anaphylactic reactions). They work to stabilise individual cells and their internal structures so that they do not release the substances which initiate or perpetuate the irritation, pain and swelling. While they can be very effective in suppressing or preventing inflammation, their anti-inflammatory effects are inherently linked with the suppression of the immune response and associated consequences.

5 Although both NSAIDs and corticosteroids have anti-inflammatory properties, NSAIDs have analgesic and anti-pyretic properties. Also, NSAIDs can relieve pain

and inflammation without the immunosuppressant and metabolic side-effects associated with corticosteroids.

6 Table 3.9 (on the following pages) shows the range of anti-inflammatories available for companion animals in New Zealand.

7 A veterinarian is unlikely to substitute products within one of the above groups with a product from another.

8 Merial's anti-inflammatory products are non-steroidal products for inflammation of the musculoskletel system. Schering-Plough's anti-inflammatory product is a corticosteroidal product that acts as an immunosuppressant for the treatment of inflammation caused by allergic reactions or injury.

9 NSAIDs tend to be more expensive than corticosteroids.

10 These products are not substitutable and, while listed in the same NZFSA classification, they are not truly within the same market. Accordingly, no further analysis of the anti-inflammatory category is provided.

Table 3.9

Anti-inflammatories for companion animals

Company Name	Product Name	Active Ingredient	IVS Page Reference
Products listed under Musculoskeletal System: (a) Anti-inflammatory agents			
Merial	**KETOFEN 1%*: A non-steroidal treatment for use in dogs and cats for the treatment of painful, inflammatory conditions, especially musculoskeletal disorders.** *** Also listed under Anaesthetics and Analgesics: Analgesics**	**Ketoprofen**	**185, 34**
Merial	**KETOFEN TABLETS 5MG*: A non-steroidal treatment for use in dogs and cats for the treatment of painful, inflammatory conditions, especially musculoskeletal disorders.** *** Also listed under Anaesthetics and Analgesics: Analgesics**	**Ketoprofen**	**186, 35**
Merial	**KETOFEN TABLETS 20MG*: A non-steroidal treatment for use in dogs and cats for the treatment of painful, inflammatory conditions, especially musculoskeletal disorders.** *** Also listed under Anaesthetics and Analgesics: Analgesics**	**Ketoprofen**	**186, 35**
Merial	**PREVICOX : A non-steroidal treatment. A highly selective COX-2 inhibitor* for relief of pain and control of inflammation associated with osteoarthritis, other musculo-skeletal disorders. For dogs.** *** Also listed under Anaesthetics and Analgesics: Analgesics**	**Firocoxib**	**194, 38**
Virbac New Zealand	ANTIHISTALONE TABLETS*: for the relief of a variety of conditions in **dogs and cats** requiring a corticosteroid combined with an antihistamine. * Also listed under Endocrine System: Corticosteroid hormones and related compounds	Prednisolene acetate and chlorpheniramine maleate	177, 158
Caledonian Holdings	ARTHROPEN VET INJECTION: to aid in the treatment of non-infectious inflammatory joint disease in **dogs (and horses).**	Sodium pentosan polysulphate	177
Boeheringer Ingelheim	BUSCOPAN COMPSITUM SOLUTION: spasmolytic, analgesic and anti-inflammatory activity that affects the gastrointestinal and urinary tracts. **Dogs (as well as horses and other farm animals).**	Hyoscine-n-butylbromide	178

Company Name	Product Name	Active Ingredient	IVS Page Reference
Provet	CARTROPHEN VET: to aid in the treatment of non-infectious inflammatory joint disease in **dogs (and horses).**	Sodium pentosan polysulphate	179
Vetpharm	C-U ALGESIC TABLETS: short and long-term treatment for pain and inflammation in **dogs**, e.g. osteroarthritis, tendonitis etc	Copper infomethacin	179
Novartis	DERAMAXX CHEWABLE TABLETS FOR DOGS: for the control of pain and inflammation associated with osteoarthritis and orthopaedic surgery in **dogs.**	Deracoxib	181
Jurox	DOMOSO ROLL-ON: topical application to reduce acute swelling caused by trauma. For **dogs (and horses)**.	Dimethyl Sulfoxide	182
Bomac	EQUIZONE IV: an anti-inflammatory treatment of muscoskeletal conditions in **dogs** (**and horses**).	Phenylbutazone	183
Bomac	FLUNIX INJECTION*: for treatment of conditions requiring anti-inflammatory analgesic (**Dogs**, **horses, cattle and pigs**). * This product is also listed under Anaesthetics and Analgesics: Analgesics	Flunixin (as meglumine)	183, 32
Norbrook NZ	FLUNIXIN INJECTION*: provides anti-inflammatory and analgesic action in a wide range of muscoskeletal disorders in **dogs, horses, cattle and pigs**. * This product is also listed under Anaesthetics and Analgesics: Analgesics	Flunixin meglumine	184, 32
Bomac	FLUXIMINE INJECTION: treatment of inflammatory and painful conditions in **dogs, horses and cattle**. * This product is also listed under Anaesthetics and Analgesics: Analgesics	Flunixin meglumine	184, 33
Boehringer Ingelheim	METACAM 0.5 MG/ML ORAL SUSPENSION FOR CATS: for the alleviation of inflammation and pain in acute and chronic muscoskeletal disorders. For **cats.**	Meloxicam	187
Boehringer Ingelheim	METACAM 1MG and 2.5MG CHEWABLE TABLETS FOR DOGS: for the alleviation of inflammation and pain in acute and chronic muscoskeletal disorders. For **dogs**.	Meloxicam	188

Company Name	Product Name	Active Ingredient	IVS Page Reference
Boehringer Ingelheim	METACAM ANTI-INFLAMMATORY INJECTABLE FOR DOGS AND CATS: for the alleviation of inflammation and pain in acute and chronic muscoskeletal disorders. For **dogs and cats.** * This product is also listed under Anathestics and Analgesics: Analgesics	Meloxicam	188, 36
Boehringer Ingelheim	METACAM ANTI-INFLAMMATORY ORAL SUSPENSION FOR DOGS: for the alleviation of inflammation and pain in acute and chronic muscoskeletal disorders. For **dogs.** Oral administration. * This product is also listed under Anaesthetics and Analgesics: Analgesics	Meloxicam	188, 37
Norbrook	NOROCARP 20MG TABLETS: for analgesia and reduction of inflammation e.g. degenerative joint disease in **dogs**.	Carprofen	190
Norbrook	NOROCARP 50MG TABLETS: for analgesia and reduction of inflammation e.g. degenerative joint disease in **dogs**.	Carprofen	190
Norbrook	NOROCARP INJECTION: for the control of post-operative pain and inflammation following orthopaedic and soft tissue surgery in **cats and dogs**. Also for treatment of muscoskeletal and inflammatory conditions in horses.	Carprofen	191
Virbac	PENTARTHRON: aids in the treatment of non-infectious inflammatory joint disease in **dogs (and horses)**.	Pentosan polysulphate	191
Vetpharm	PENTOSAN VET: aids in the treatment of non-infectious inflammatory joint disease in **dogs (and horses).**	Pentosan polysulphate	192
Jurox	PROLET 50MG TABLETS FOR DOGS: for the relief of pain and inflammation in **dogs**. * This product is also listed under Anaesthetics and Analgesics: Analgesics	Carprofen	194, 39
Pfizer	RIMADYL CHEWABLE TABLETS FOR DOGS: for the relief of chronic and acute pain and inflammation in **dogs** * This product is also listed under Anaesthetics and Analgesics: Analgesics	Carprofen	194, 39

Company Name	Product Name	Active Ingredient	IVS Page Reference
Pfizer	RIMADYL INJECTION: for the control of post-operative pain and inflammation following orthopaedic and soft-tissue surgery. For use in **dogs, cats and horses.** * This product is also listed under Anaesthetics and Analgesics: Analgesics	Carprofen	195, 41
Pfizer	RIMADYL TABLETS 50MG: for the relief of chronic and acute pain and inflammation in **dogs.**	Carprofen	196, 41
Provet	SYLVET CAPSULES: aids in the treatment of non-infectious joint inflammatory disease in dogs and for the management of degenerative joint disease in aged **dogs.**	Calcium Pentosan Polysulphate	197
Parnell Laboratories	TERGIVE 10: for the relief of pain and inflammation in **dogs.** Oral administration	Carprofen	197
Parnell Laboratories	TERGIVE 30: for the relief of pain and inflammation in **dogs**. Oral administration	Carprofen	198
Parnell Laboratories	TERGIVE INJECTION: for the relief of pain and inflammation in **dogs, cats and horses.**	Carprofen	198
Boehringer Ingelheim	VOREN DEPOT*: for the treatment of conditions that respond to corticosteroids that affect the respiratory tract, the muscoskeletal system or the skin of **cattle, horses, dogs and cats.** *This product is also listed Endocrine System: Corticosteroid hormones and related compounds	Dexamethasone	199
Boehringer Ingelheim	VOREN SUSPENSION*: for use as a general anti-inflammatory and anti-allergic agent for use in **dogs, cats, cattle, horses and pigs** *This product is also listed Endocrine System: Corticosteroid hormones and related compounds	Dexamethasone 2l-isonicotinate	199
Products listed under Endocrine System: Corticosteroid hormones and related compounds			
Intervet/ Schering-Plough	**DEXADRESON: used in the management of acute inflammation and allergic reactions in cattle, horses, pigs, dogs and cats as well as ketosis in cattle.**	**Dexamethasone sodium phosphate**	**159**
Pfizer	DEPO MEDROL: treatment of inflammatory ocular conditions and overwhelming infections in **dogs**	Methylprednisolone acetate	158

Company Name	Product Name	Active Ingredient	IVS Page Reference
Phoenix Pharm	DEXA 0.2 INJECTION: For treatment of various ailments, including inflammatory muscle and joint conditions. For use in **dogs, cats, sheep, goats, pigs, horses and cattle**.	Dexamethason	159
Jurox	PREDNIL TABLETS: for the treatment of allergic reactions, dermatitis, and as an aid in the treatment of arthritic and rheumatic joint diseases	Prednisolone and Chlorpheniramine maleate	160
Pfizer	SOLU-DELTA-CORTEF: for use when rapid and intense adrenal glucocorticoid and/or anti-inflammatory effect is necessary (e.g. severe injury, trauma, emergency surgery. For use in **cats, dogs and horses**.	Prednisolone sodium succinate	161
Products listed under Anaesthetics and Analgesics: Analgesics (see earlier section for Merial and Schering-Plough products)			
Boehringer Ingelheim	BUSCOPAN COMPSITUM SOLUTION: provides spasmolytic, analgesic and anti-inflammatory activity that specifically affects the gastrointestinal and urinary tracts. For use in **dogs, horses, cattle, pigs.**	Hyoscine-n-butylbromide; dipyrone	29
Vetpharm	CU-ALGESIC ORAL PASTE: for treatment of short and longterm inflammation and pain in **dogs,** e.g. arthritis	Copper Indomethacin	30
Vetpharm	CU-ALGESIC TABLETS: for treatment of short and longterm inflammation and pain in **dogs**, e.g. arthritis	Copper Indomethacin	30
Pfizer	RIMADYL TABLETS 20MG: for the relief of chronic and acute pain and inflammation in **dogs**.	Carprofen	41
Pfizer	RIMADYL TABLETS 50MG: for the relief of chronic and acute pain and inflammation in **dogs.**	Carprofen	42

3. Antibiotics

Introduction

1 Anti-microbials are pharmaceutical products that belong to the general group of anti-infectives for systemic, local or topical use. They destroy or prevent the growth of microbes such as bacteria, mycoplasma (bacteria that lack cell walls) or fungi, and treat diseases associated with them.

2 Antibiotics are the sub-group of antimicrobial drugs that act against bacteria.

3 The *Antibiotics* product table in Appendix 3.1 shows that Merial and Schering-Plough both have products listed in the NZFSA classification for antibiotics.

4 Merial has antibiotics for treating watery mouth disease in sheep; infections in companion animals; a general anti-bacterial product for treating infections in ruminant animals and swine; and intramammary antibiotic treatments for mastitis in cattle.

5 Schering-Plough has a range of broad spectrum antibacterial formulations for the treatment of infections in ruminants (such as respiratory diseases, footrot and pinkeye) and other animals; antibiotics for endometritis in cattle; and intramammary antibiotic treatments for mastitis in cattle.

6 The only areas of overlap are in:

- intramammary antibiotic treatments for mastitis in dry cows; and
- broad spectrum anti-bacterial formulations for treatment of infection in ruminant animals and swine.

7 The competition analysis for these areas is set out in the following sections on pages 47 to 58.

3A. Intramammary treatments for mastitis in dry cows

1 Mastitis is an infection of the cow's mammary glands (udder), and is a recurring problem for dairy farming – in particular in the case of lactating cows.

2 Anti-microbials used to treat mastitis are administered through a specially designed syringe that is inserted into the animal's teat canal and then releases the antibiotic compound into the udder. This mode of application, as well as a special formulation that makes the treatment particularly effective against the relevant bacteria, distinguishes these products from other anti-microbial products. Intramammary antibiotic treatments are the most common type of mastitis treatment.

3 As the Commission noted in *Schering–Plough/Organon*[52], there are also some treatments for mastitis in cattle in injectable form. However, these treatments are typically broad spectrum antibiotics that also treat other diseases, and as such are considered to be part of the antibiotics market rather than the market for mastitis treatments.

Market definition

Different treatments for dry cows and lactating cows

4 Mastitis infections can be differentiated based on severity and duration:

- chronic (or sub-clinical) mastitis; and
- acute (or clinical) mastitis.

5 Chronic infections (or sub-clinical mastitis) cause an increased number of white blood cells in the cow's milk, but do not have any obvious clinical symptoms. Sub-clinical mastitis is typically treated during the days of the year when the cow is not milked (the "dry period").

6 The treatment is routinely applied through a preventive (single) administration of one syringe per mammary gland (with a total of four) at the end of the lactation period. The substance will remain effective in the udder for a certain period of time, killing existing bacteria and preventing the introduction of new bacteria.

7 Clinical (or acute) mastitis is identified by symptoms such as a swelling of the udder and most commonly occurs during the lactation period (i.e., when the cow is producing milk). Treatment requires daily and repeated administration of therapeutic formulations ('lactating cow products'). The drugs must produce results quickly and have a carefully controlled time of effectiveness (they must be 'short-acting') as the cow must be withdrawn from milk production during the period in which the drug is active.

8 Different intramammary products are used for the treatment of sub-clinical mastitis in dry cows and clinical mastitis in lactating cows. A primary difference between

[52] At paragraph 111, footnote 13.

these products is the length of time the antibiotic is maintained in the udder (above a certain allowed threshold), and thus the period for which any milk produced must be withheld from human consumption:

- dry cow products have milk withholding periods of between 28 and 56 days;
- lactating cow products have milk withholding periods ranging from two to six days.

9 In Decision 496 (*Pfizer/Pharmacia*) and Decision 621 (*Schering-Plough/Organon*) the Commission noted that there is no demand-side substitutability between dry cow intramammary treatments and lactating cow intramammary treatments and consequently concluded that they are separate markets.

10 Merial markets antibiotics only for the treatment of mastistis in dry cows; Schering-Plough has products for both dry cows and lactating cows. Accordingly, only the dry cow products need to be considered.

The Dry Cow Products

11 Merial and Schering-Plough market the following antibiotics for the treatment of mastitis in dry cows.

Merial	**Schering-Plough**
CEFAMASTER (long acting)	CEPRAVIN (long acting) BOVACLOX (short acting) CEFA-SAFE (short acting) NAFPENZAL DC (short acting)

12 CEFAMASTER and CEPRAVIN have the same active ingredient: cephalonium. The active ingredients in BOVACLOX are ampicillin trihydrate and cloxacillin benzathine. CEFA-SAFE has the active ingredient cephapirin. NAFPENZAL DC has the active ingredients streptomycin and nafcillin.

13 CEPRAVIN is the leading mastitis treatment in New Zealand. CEFAMASTER is a more recently introduced generic product.

Product differentiation

14 Different intramammary antibiotics have different active ingredients. Some are short acting and some are long acting. The Commission's analysis of both active ingredients, and duration, as factors in market definition are set out below.

Active ingredients

15 In *Schering-Plough/Organon,* the Commission:

- referred to investigations by the European Commission into the Akzo Nobel/Hoechst Roussel Vet and Pfizer/Pharmacia mergers[53] where the European Commission further narrowed the markets for dry cow intramammary treatments and lactating cow intramammary treatments by active substance;

- referred to Decision 496 (*Pfizer/Pharmacia*) where the Commission did not narrow the dry cow and lactating cow markets by active substance but noted that:

> "different products contain different active substances, although most products contained some form of penicillin. Further, each product may contain more than one active substance. There are likely to be different degrees of substitutability between the different active substances".

- conducted further market investigations and confirmed that substitution between dry cow intramammary treatments with different active substances does occur; and

- concluded that neither of these markets needed to be further narrowed by active substance.[54]

16 The Applicant concurs that there is no reason to differentiate products in this market by reference to active ingredient.

Long acting and short acting

17 In *Schering-Plough/Organon,* the Commission noted Schering-Plough's submission that:

- in relation to dry cow intramammary treatments nearly all cows in New Zealand are dried off for a six week period from 31 May each year;

- in many European countries, the dry period can be either short or long and thus farmers need to use a short-acting or long-acting dry cow intramammary treatment;

- since the drying off periods in New Zealand do not vary, there is no need to further narrow the dry cow intramammary market into markets for short-acting and long-acting treatments.

18 The Commission reported that its market investigations did not support this view. It said:[55]

> "Most market participants indicated that there is variation in the length of the dry period in New Zealand, both across different farms and even within a herd on a given farm. Moreover, dry cow intramammary products in New Zealand have different durations of effectiveness, based on the length of time the antibiotic is maintained in the udder at effective levels to treat mastitis. For most (although not all) products, the longer the period

[53] At pargraph 115

[54] At paragraph 117.

[55] At paragraphs 188 – 121.

in which the antibiotic is effective in the udder, the longer is the milk withholding period over which any milk obtained from the cow cannot be sold for human consumption.

A number of market participants considered that dry cow intramammary products fall into two separate markets of short-acting and long-acting treatments, with the length of the milk withholding period used as the differentiating factor. Whilst there appears to be limited demand-side substitutability between short-acting and long-acting products, the Commission found that there is no clear break in the chain in terms of milk withholding period between what constitutes a short-acting product and what constitutes a long-acting product. Specifically, while products of 28-30 day milk withholding periods can generally be considered short-acting, and products of 49 day milk withholding periods are considered long-acting, there are some remaining products with 35 day milk withholding periods where it is not clear if they should be considered as short-acting or long-acting products.

Further, some products claim to provide effective antibiotic levels for longer periods than their milk withholding periods suggest. The Commission understands that such claims can be made because the milk withholding period is based on reducing the antibiotic level below an allowed level, but even below that level the antibiotic can still be effective in treating mastitis."

19 The Commission concluded that, whilst there may be markets for short-acting and long-acting treatments, this further breakdown was not necessary for the purposes of that application.

20 The Applicant maintains that there is no need to further narrow the dry cow intramammary market into markets for short-acting and long-acting treatments.

Conclusion on market definition

21 Consistent with the approach taken by the Commission in *Schering-Plough/Organon*, the Applicant considers that there are separate markets for intramammary treatments for mastitis in lactating cows and intramammary treatments for mastitis in dry cows.

22 Of these, the only market affected by the Proposed Transaction is intramammary treatments for mastitis in dry cows.

Market shares

23 Table 3.10 lists the competitors and their products in the market for intramammary treatments for mastitis in dry cows. The value of sales and estimated market shares are set out in Table 3.10A in confidential Schedule 3.1.

24 The market shares and three-firm concentration ratio following the Proposed Transaction are also set out in confidential Schedule 3.1. These are outside the Commission's safe harbour guidelines but the level of aggregation is minimal.

25 The Applicant notes that Bomac's 2008 introduction of CEPHA-FORTE DC with the active ingredient Cephalonium (the same active ingredient as Merial's CEFAMASTER and Schering-Plough's CEPRAVIN) was interrupted by production difficulties in 2008. The product was launched again in 2009 and it is expected that Bomac's market share will increase in 2009 as a consequence.

Table 3.10

Intramammary treatments for mastitis in dry cows

Company Name	Product Name	Active Ingredient	IVS Page Reference
Merial	**CEFAMASTER (long acting)**	**Cephalonium**	**96**
Schering-Plough	**CEPRAVIN (long acting)**	**Cephalonium**	**97**
	BOVACLOX (long acting)	**Ampicilin Trihydrate & Cloxacillin benzathine**	**95**
	CEFA-SAFE (short acting)	**cephapirin**	**96**
	NAFPENZAL DC	**Penicillin, streptomycin, and nafcillin**	**103**
Pfizer	ORBENIN DRY COW (long acting)	Cloxacillin	104
	ORBENIN ENDURO (long acting)	Cloxacillin	105
	TEATSEAL	Bismuth subnitrate	106
Bomac	CEPHA-FORTE DC (long acting)	Cephalonium	97
	DRYCLOX DC (long acting)	Cloxacillin and Ampicillin	100
	DRYCLOX EXTRA (long acting)	Cloxacillin and Ampicillin	100
Norbrook	CLOXAMP DC 500 (long acting)	Cloxacillin and Ampicillin	98
	CLOXAMP DC 600 (long acting)	Cloxacillin and Ampicillin	99
Jurox	JURACLOX LA 600 DRY COW (long acting)	Cloxacillin Benzathine	101
Virbac	CLOXAGEL 1000 DC	Cloxacillin Sodium and Cloxacillin Benzathine	98

Potential competition

26 The Applicant considers that after the Proposed Transaction, existing competition will be sufficient to constrain Merial and Schering-Plough. In addition, as discussed earlier:

- the barriers to entry in animal pharmaceutical markets generally are relatively low, at least for a generic product (such as Bomac's CEPHA-FORTE DC)– as is the case here where a key active ingredient (cephalonium) is off patent; and

- in response to a price increase or other manifestation of market power, entry from generic products is likely to occur within the Commission's two year time frame for new entry.

27 In *Schering-Plough/Organon*, the Commission noted:

"A number of market participants have stated that they are always looking for opportunities to enter other markets that they are not already active in, and there are a number of existing animal healthcare companies without dry cow intramammary products that could be considered potential entrants." [56]

More generally, there are numerous other examples of recent or impending entry into other animal health pharmaceutical markets by companies with an existing range of animal healthcare products. For example, Bomac has recently launched a generic product in the lactating cow intramammary market, while [ ]. [57]

28 Table 3.11 shows intramammary antibiotic products registered with NZFSA over the last two and a half years. There have been six intramammary antibiotics registered with the NZFSA since the *Schering-Plough/Organon* decision in October 2007.

Table 3.11
Recently registered products – intramammary antibiotic

Company Name	Product Name	Active Ingredient	Date of Registration
Bomac	LACTAPEN	Penicillin q Procaine	16 Feb 2007
	LACTAPEN G	Penicillin q Procaine	26 June 2007
	LACTACLAV	Amoxycillin, Clavulanic acid, and prednisolone	12 Oct 2007
	LACTACLAV GT	Amoxycillin, Clavulanic acid, and prednisolone	30 Nov 2007
	LACTOCLAV NP	Amoxycillin, Clavulanic acid, and prednisolone	11 Feb 2008
	CEPHA FORTE DC (dry)	Cephalonium	11 Jan 2008
	DRY FORTE DC (dry)	Cephalonium	18 March 2008
Jurox	MAXALAC LC	Cefuroxime sodium	20 Dec 2007
Merial	CEFAMASTER DRY COW (dry)	Cephalonium	14 Jan 2008
Virbac	Quadrant DC (dry)	Cephalonium	27 Sept 2008

29 While in *Schering-Plough/Organon*, the Commission noted that generic products may struggle to build market share against established brands (such as Schering-Plough's Cepravin product), it also noted that there are some companies which are counter-examples to this and the Commission concluded that entry into the dry cow intramammary market was likely to occur in a timely fashion.

Conclusion on competition

30 The following factors indicate that the Proposed Transaction will not substantially lessen competition in the market for intramammary antibiotic treatments for mastitis in dry cows:

- There are a number of existing competitors, all of which are significant businesses with established reputations in the animal health industry. Pfizer and Bomac, in particular, have solid market shares.
- The level of aggregation is low.

[56] At paragraph 241.

[57] At paragraph 243.

- Barriers to entry and expansion are low. New entry or expansion by generics is likely. (Refer to earlier section on 'Potential Competition'.)

31 In addition, as discussed in the earlier sections, purchasers have countervailing power and co-ordination effects are unlikely.

3B. Treatments for infection in ruminants and swine

Introduction

1 Treatments for infections in ruminants and swine comprise a number of related substances which belong to a group of antibiotics used in the treatment of bacterial infections caused by susceptible, usually gram positive, organisms such as *Staphylococcus* species, *Streptocccus* species, *Pasteurella* species, *Salmonella* species, *Proteus* species, *E Coli*, *Klebsiella* species, *Brucella* species, *Vibrio* species, *Pseudomona* species, *Leptospira* species and others.

2 These antibiotics are effective against diseases such as respiratory infections, uro-genital tract infections, alimentary tract infections, and other infections such as bacterial agalactia of sows.

3 Antibiotics are used in food-producing animals (ruminants, swine, poultry, aquaculture and equine) as well as companion animals. The same antibiotic product can usually be used on various types of animals.

4 The *Antibiotics* product table in Appendix 3.1 shows that Merial and Schering-Plough both market products indicated for the treatment of infection in cattle and sheep (ruminants) and swine.[58]

5 Merial and Schering-Plough market the following products for the treatment of infection in ruminant animals and swine:

Merial (active ingredient)	**Schering-Plough** (active ingredient)
CEFANIL (Ceftiofur)	COBACTAN 2.5% (Cefquinome)
	TRIBRISSEN 48% (Sulfadiazine and trimethoprim)
	ENGEMYCIN (Oxytetracycline)
	NEOMYCIN PENICILLIN (Neomycin and Penicillin)
	DUPLOCILLIN LA (Penicillin)
	DEPOCILLIN (Penicillin)
	DEPOMYCIN (Dihydrosteptomycin and Penicillin)

[58] In *Schering-Plough/Organon*, consistent with Schering-Plough's application, the Commission assessed the Schering-Plough products in this section under the heading "antimicrobials". This application uses their NZFSA classification as antibiotics.

6 Both the Merial and the Schering-Plough products are indicated for use with both ruminant animals and swine.

Product differentiation

7 As the Commission noted in *Pfizer/Pharmacia,*[59] the animal antibiotics sector consists of a number of products that are used to treat different diseases or a combination of different diseases. The product used will depend on the bacteria, the route of administration, the active ingredient required, the veterinarian's preference and the track record of the product.

8 In the *Schering-Plough/Organon* clearance application, Schering-Plough submitted that there is substitutability between different types of antibiotics (such as penicillins, tetracyclines and beta-lactams) in New Zealand, such that it is not relevant to draw any distinction between the different types. However, while veterinarians tend to have their preferred type of antibiotic, if that product was not available, there would be another equally effective and similarly priced substitute.

9 In *Schering-Plough/Organon* the Commission noted that its market investigations found a range of views on whether a broader or narrower market was appropriate.[60]

10 Each substance, or combination of substances, has a slightly different focus but they are generally substitutable in terms of indication and use, although they can be distinguished by route of administration and active ingredient.

11 In *Schering-Plough/Organon,* the Commission noted that:[61]

> "An examination of the product lines for antimicrobials, as recorded in the 2007 IVS Annual, reveals that there is a high degree of product differentiation. Products are differentiated in terms of (among other things): family of active substance and the specific active substance within each family; amount of the active substance; route of administration (although, as noted above, the majority of antimicrobials are injectable); treatment for which the product is indicated for; range of animals that can be treated; and withholding times for milk and/or meat."

12 In that decision the Commission took the view that, on balance, for the purposes of that application, it was not necessary to come to a firm conclusion on the precise definition of the market concerning antimicrobials in ruminant animals. Accordingly the Commission analysed the competitive effects using a broad market definition of all antimicrobials for ruminant animals.

13 The Applicant considers that the Merial and Schering-Plough products are not substitutable for the following reasons:

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[59] At paragraph 130.

[60] At paragraph 126.

[61] At paragraph 130.

- Schering-Plough's COBACTAN has a very specific requirement in that it must not be used to treat groups of food-producing animals unless bacteriology has confirmed the diagnosis, and sensitivity tests have shown that it is the only active ingredient or treatment likely to be effective against the bacteria in question; and

- Merial's CEFANIL is a cephalosporin and has a nil milk withholding period. Further, it has a different bacterial control spectrum to the Schering-Plough products which are all sulphonamides, tetracyclines or penicillins.

14 On this basis the Merial and Schering-Plough products are not in the same market and the Proposed Transaction will not result in any aggregation in the relevant markets.

15 In this regard, the Applicant notes the views of Dr Nigel Coddington of Totally Vets as reported by the Commission in *Schering-Plough/Organon*:[62]

> "antimicrobials with different active substances (such as penicillins, tetracyclines, and beta-lactams) are not substitutable. He noted that the different families have different powers of penetration for treating particular diseases."

Market shares in a broader market/conclusion on competition

16 Notwithstanding the Applicant's view that a distinction should be drawn between different classes of antimicrobials, should the Commission consider that a broader market definition is appropriate, the Proposed Transaction is unlikely to substantially lessen competition for the following reasons:

- there will continue to be a large number of other products available in the market (see Table 3.12 on the following page);

- the market shares and three-firm concentration ratio following the Proposed Transaction are within the Commission's safe harbour guidelines (estimated market shares and the three-firm concentration ratio are set out in Table 3.12A in confidential Schedule 3.1);

- the level of aggregation is minimal; and

- Bomac, Bayer, Jurox, Pfizer and Stockguard (amongst others) have all registered new antibiotic products with the NZFSA in the past 18 months.

[62] At paragraph 127.

Table 3.12

Antibiotics for the treatment of infection in ruminant animals and swine

Company Name	Product Name	IVS Page Ref	Active Ingredient
Parenteral Antibiotics			
Merial	As set out above	75	As set out above
Schering-Plough	As set out above	71-92	As set out above
Pfizer	CLAVULOX READY TO USE INJECTION	76	Clavulanic acid as potassium clavulanate
	EXCENEL	80	Ceftiofur sodium
	EXCENEL RTU	81	Ceftiofur hydrochloride
Ausrichter New Zealand Ltd	TRIPRIM ANTIBACTERIAL INJECTION	91	Sulphadimethylpyrimide; trimethoprim
Bayer	BAYTRIL 10% INJECTABLE SOLUTION	73	Enrofloxacin
Elanco	TYLAN 200 INJECTION	91	Tylosin
Bomac	ACCENT	71	Ceftiofur sodium
	BOVICILLIN	74	Procaine penicillin BP
	PENETHAJECT	88	Penethamate hydriodide
	TETRAVET 100 FLEXIDOSE	89	Oxytetracycline
	TETRAVET 200 LA	90	Oxytetracycline hydrochloride BP
Norbrook	ALAMYCIN 10	71	Oxytetracycline hydrochloride
	ALAMYCIN LA	72	Oxytetracycline dihydrate BP
	ALAMYCIN LA 300	72	Oxytetracycline, magnesium oxide
	BETAMOX LA	73	Amoxycillin trihydrate; butylhydroxyanisole; butylhydroxytoluene
	CEPHALEXIN INJECTION	76	Cephalexin as the sodium salt
	NOROCILLIN INJECTION	84	Procaine benzyl penicillin; methyl paraben
	NOROCILLIN LA	84	Procaine benzyl penicillin; benzathine penicillin; methyl paraben
	NOROCLAV INJECTION	85	Amoxicillin as amoxicillin trihydrate; clavulanic acid
	NORODINE 24	85	Trimethoprim; sulphadiazine
	ULTRAPEN LA	92	Benzyl penicillin; butylhydroxyanisole; butylyhydroxytoluene
Virbac	AMPHOPRIM INJECTION	72	Trimethoprim; sulphadimethylpyrimidine
	TECAMOX LA	89	Amoxycillin trihydrate
	TETRAGUARD LA	89	Oxytetracycline
Boehringer Ingelheim	BIVATOP 200	74	Oxytetracycline dihydrate
	MAMYZIN	82	Penethamate hydriodide
Stockguard	BOVIPEN	74	Procaine penicillin G
	MASTICILLIN RTU INJECTION	83	Procaine penicillin G
	CEFAGUARD	75	Ceftiofur as the hydrochloride
	DURAPEN 3 IN 1 HIGH POTENCY	80	Crystalline penicillin G; procaine penicillin G; benzathine penicillin G
	INTRACILLIN	82	Procaine penicillin G
Stockguard	INTRACILLIN LA	82	Procaine penicillin G; benzathine penicillin G
	OVIPEN	86	Procaine penicillin G; benzathine penicillin G
	PROCAL 500	88	Crystalline penicillin; Procaine penicillin G

Company Name	Product Name	IVS Page Ref	Active Ingredient
	STREPCIN	89	Procaine penicillin G; dihydrostreptomycin
	TYLOGUARD	92	Tylosin base
	VIBROSTREP	92	Streptomycin
Caledonian Holdings	CALEFUR	75	Ceftiofur as sodium salt
Phoenix Pharm	OXYTETRA LA	86	Oxytetracycline as hydrochloride
	OXYTETRA MA 10%	87	Oxytetracycline as hydrochloride
	PHOENIX PHARMACILLIN 300	88	Procaine penicillin G
Jurox	MOXYLAN READY-TO-USE BROAD SPECTRUM ANTIBIOTIC	83	Amoxycillin
Oral Antibiotics			
Pfizer	CLAVULOX PALATABLE TABLETS 500MG	63	Amoxycillin; clavulanic acid.
Bomac	SCOURPLAN PLUS	65	Sulphaguanidine; sulphadimidine; sulphdiazine; neomycin sulphate; streptomycin sulphate; kaolin; hyoscine hydrobromide; glycine; pectin.
	TETRAVET 100 SOLUABLE ANTIBIOTIC POWDER	68	Oxytetracycline HCI
	TETRAVET 200 SOLUABLE ANTIBIOTIC POWDER	68	Oxytetracycline hydrochloride
	TRISULFIN ANTIBACTERIAL BOLUS	69	Sulphadiazine; trimethoprim
Norbrook	NOROCLAV TABLETS	64	Amoxycillin; clavulanic acid
Phoenix Pharm	DOXYCYCLINE 5% SOLUBLE POWDER	63	Doxycycline as doxycycline hyclate
Virbac	AMPHOPRIM BOLUS	58	Trimethoprim; sulphamethgoxypyridazine
Jurox	JUROCLAV BROAD SPECTRUM ANTIBIOTIC TABLETS	64	Clavulanic acid; amoxicillin
Mainfeeds	TERASOL	67	Oxytetracycline; di-decyl di-methyly ammonium bromide
Livestock Solutions + Services	TERRAMYCIN 200 FEED SUPPLEMENT	68	Oxytetracycline HCI
Topical Antibiotics			
Bomac	BLACK POCK OINTMENT	93	2-hydroxy benzoic acid; iodine; sulphathiazole
	TETRAVET BLUE	94	Oxytetracycline hydrochloride
	TETRAVET SPRAY	95	Gentian violet; Oxytetracycline hydrochloride
Pfizer	MASTALONE	94	Neomycin sulphate; oleandomycin; Oxytetracycline hydrochloride ; prednisolone
	TERRAMYCIN POWDER	94	Oxytetracycline hydrochloride
Norbrook	ALAMYCIN AEROSOL	93	Oxytetracycline hydrochloride
Virbac	AEROTET FORTE	93	Gentian violet; Oxytetracycline hydrochloride

4. Treatments for external parasites

Introduction

1 Ectoparasiticides treat external parasites such as fleas, ticks, lice and mange mites, which affect all animal species.

2 Ectoparasiticides are applied directly on the animal in the form of sprays, dusting powders, pour-on applications, spot-on applications, shampoos, collars, creams or lotions. They are based on active substances such as amitraz, diazinon, chlorfenvinphos, and pyrethroids.

3 Endectocides are agents or preparations that are used to destroy both different sorts of internal parasites such as worms and external parasites such as flies and lice.

4 Endectocides protect the treated animal in one convenient treatment against a large number of infestations by various parasites (external and internal). As far as food producing animals are concerned, anti-parasiticides are often used where animals are left grazing for longer periods of time; in those instances, a farmer may protect the animals against a broad range of internal and external parasites in a convenient, single treatment.

5 The *Ectoparasiticide* product table in Appendix 3.1 shows overlap between Merial and Schering-Plough in relation to products for treating external parasites.

- Merial has ectoparasiticides and endectocides for cattle, sheep, swine and companion animals.

- Schering-Plough has ectoparasiticides for cattle and sheep only.

6 There are different products for cattle and sheep (with differing concentrations and dosage rates) and, consistent with the Commission's approach in *Schering-Plough/Organon*, they have been treated as separate markets for the purposes of this Notice.

Market definition

7 In *Schering-Plough/Organon*, the Commission concluded that, for the purposes of assessing the proposed acquisition, the markets were at least as broad as the market for ectoparasiticides for cattle[63] and ectoparasiticides for sheep.[64]

8 The Commission also considered whether the market is in fact broader than ectoparasiticides and includes endectocides. However, since neither Schering-Plough nor Intervet supplied endectocides in New Zealand, and there was no aggregation with respect to endoparasiticides, the Commission's view was that, for

[63] At paragraph 141.

[64] At paragraph 151.

the purposes of assessing that acquisition, the competitive effects of that transaction were best analysed with products market consisting only of ectoparasiticides.

9 However, the Proposed Transaction differs in that Merial has an extensive range of endectocides for both cattle and sheep. Therefore, it is necessary to consider again whether the market should be defined to include both ectoparasiticides and endectocides.

Cattle

10 A cattle farmer can decide to treat his cattle either for worms (internal), lice (external) or both. At different times of the year one has precedence over the other. In New Zealand, worms are the biggest problem and most treatments are done for worms, with lice secondary. The farmer who only wants to treat for lice (particularly older cattle where worms are not such a problem) can choose to use a straight ectoparasiticide or spend slightly more and get the added benefit of worm control even though that might not be the major problem.

11 Farmers generally prefer to treat for both worms and lice – as evidenced by the approximately 9 million treatments of endectocides as against 1 million treatments of straight ectoparasiticides in cattle in the 12 months to January 2008.[65]

12 In *Schering-Plough/Organon*, in relation to cattle the Commission noted:[66]

> "Schering-Plough submitted that endectocides impose a constraint on the pricing of ectoparasiticides, but did not place the products in the same market for the purpose of calculating market shares because neither Schering-Plough nor Intervet supply endectocides.
>
> In the merger of Merck and Rhone-Poulenc-Merial, the European Commission considered whether endectocides compete with ectoparasiticides and/or endoparasiticides (which treat internal parasites only). The European Commission noted that the differences between endectocides and ectoparasiticides/endoparasiticides in terms of parasite treated, efficacy, and consumer uses, as well as large absolute price differences, may mean there is a separate relevant market for endectocides. However, it also found that endectocides have been progressively replacing ectoparasiticides/endoparasiticides and there is a "certain degree of interchangeability" between the products. The European Commission did not come to any final conclusion on market definition in this instance, although it did conservatively adopt separate narrow markets of ectoparasiticides, endoparasiticides and endectocides for the purposes of determining market shares.
>
> Market investigations found that, in New Zealand, there has been a substantial shift from ectoparasiticides/endoparasiticides to endectocides in recent years, suggesting a large degree of demand-side substitutability between the two products. The Commission understands that this shift been motivated by a various factors, including that:

[65] Farm Market Index

[66] At paragraphs 142 - 146

- organo-phosphates, the family of active substances in many ectoparasiticides, are considered to be less environmentally friendly than the active substances in endectocides;

- endectocides are more convenient, as they replace two animal treatments with one; and

- endectocides are considered to be more efficacious.

Moreover, on the arguments presented above for combination fly/lice and lice only ectoparasiticide products, endectocides could be placed in the same relevant market as both ectoparasiticides and endoparasiticides. That is, a hypothetical monopolist of endectocides, when imposing a SSNIP, would likely face substitution to ectoparasiticides and endoparasiticides, such that these three groups of products would be in the same market."

13 The Commission also had quantitative evidence supporting the proposition that there is relatively little price difference between endectocides and ectoparasiticides/endoparasiticides purchased separately.[67] This remains the case today.

14 With regard to cattle, although the Applicant does not produce an endectocide that treats external parasites in cattle, for the purpose of this Notice, the Applicant has treated the market as comprising both ectoparasiticide products and endectocides.

Sheep

15 In relation to sheep, as the Commission noted in *Schering-Plough/Organon*,[68] while there are some products that are marketed as endectocides for sheep, these products are mainly used as endoparasiticides as their primary activity is against internal parasites.

16 Accordingly, with regard to sheep, the Applicant considers that the relevant market comprises only ectoparasiticide products.

Product differentiation

17 Different ectoparasiticide and endectocide products have different active ingredients, but in this instance, they serve the same purpose of treating external parasites.

18 There are different types of external parasites. Some products treat a broad spectrum and some treat only certain parasites. For example:

- Schering-Plough has a product that treats ticks on cattle. None of Merial's products treat ticks on cattle (but they do treat cattle ticks on other animals).

- Some of Merial's products are specified for the treatment of nasal bot and itch mite in sheep. Schering-Plough does not have products that are limited to these

[67] At paragraph 264.

[68] At paragraph 148.

treatments. However, both Merial and Schering-Plough have broad spectrum products that treat these conditions as well as other parasites.

19 With regard to cattle, in *Schering-Plough/Organon* the Commission noted:[69]

> "The market investigation confirmed that fly problems for cattle are generally restricted to the summer months. However, there were different accounts given of the geographic extent of the problem, with views from industry participants suggesting the problem can extend from north of Levin or even north of Canterbury, and others agreeing that only farms north of Taupo are affected. Nonetheless, there was general agreement that the cattle fly problem is relatively small in New Zealand. Lice are generally a more significant problem for cattle, occurring predominantly in the winter months and nationwide.
>
> Some industry participants have suggested that there are separate markets for fly control in summer and lice control in winter. However, as there are no fly-only products and combination fly and lice products would span both markets, the Commission considered whether combination fly/lice products and lice-only products fall into discrete product markets. Schering-Plough submitted that "if the combined entity attempted to increase the price of a combination fly and lice product, it would lose significant sales to suppliers of lice products such as to undermine that attempted increase". There appears to be some merit in this argument. For example, Dr John Harrison, of Veterinary Enterprises Group, noted that the majority of the sales of combination fly/lice products through Veterinary Enterprises Group are for lice treatments, and that this determines the price of these products. Thus, a hypothetical monopolist of combination fly/lice products, when imposing a SSNIP, would face significant substitution towards lice-only products, such that these two groups of products would be in the same market."

20 With regard to sheep, in *Schering-Plough/Organon* the Commission noted:[70]

> "The market definition issues for ectoparasiticides for sheep are similar to those identified above for cattle, although the extent of the problem differs. Flies are a larger problem for sheep than they are for cattle (as flies are attracted to wet or dirty wool and to docking wounds) and occur throughout the country, as do lice on sheep. There is a similar seasonal occurrence as for cattle – generally, flies in summer and lice in winter – although the boundaries are not necessarily well defined, as discussed below.
>
> Because the extent of the fly problem is more significant for sheep than it is for cattle, there are a number of fly-only treatments for sheep, as well as lice-only and combination fly/lice products.
>
> An argument could be made that distinct product markets can be defined for fly control products in summer and lice control products in winter. However, combination fly/lice products would span both markets, creating a chain of substitution between fly-only and lice-only products. If combination fly/lice treatments were to be defined as a separate

[69] At paragraphs 139 & 140.

[70] At paragraphs 147 – 151.

> 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.
>
> Moreover, one veterinarian noted that there is some overlap in the seasonal use of fly and lice products for sheep. Dr Ian Walker, of Vet Services Hawkes Bay, noted that in autumn a farmer may use either a combination fly/lice product or a lice only product. A combination product would be used to give some fly protection in the remaining months before winter, while at the same time providing lice protection for winter. Dr Walker also suggested that a farmer might use a combination fly/lice product in summer to provide lice protection for the forthcoming winter, as some products offer up to 12 months lice protection. This suggests that the break between fly treatments in summer and lice treatments in winter is not well defined.
>
> The Commission is therefore of the view that, for the purposes of assessing the proposed acquisition, the relevant market is the market for ectoparasiticides for sheep."

21 Some products have different withholding periods and, while substitutable in most instances, there are occasions when one product might not be able to be used. For example, Merial's product EXIT has a long meat withholding period preventing its use in lambs destined for slaughter.

22 There are various methods of application of ectoparasiticides and endectocides: injection, pour-on or saturation techniques (jetting or dipping). The particular method used by a farmer in any particular circumstance will largely depend on the farmer's preference. Relevant also will be the size of the animal (it is easier to use a pour-on with a larger animal than to administer an injection; the nature of the animal (it is hard to inject a sheep through thick wool); and weather conditions (rain can dilute a pour-on before it has a chance to be effective).

23 Provided the customer can be assured of a product's efficacy (via his or her own knowledge or on the advice of a veterinarian), safety and usability, the purchasing decision will be based principally on price.

24 Naturally, other factors such as relationships and perceptions of the suppliers' involvement in the industry) will be relevant but these 'intangible' factors are secondary to price. The success of generic products is testament to this.

25 In any event, in a situation where a particular product characteristic (such as its duration of effectiveness) might cause that product to be differentiated to some extent, it is difficult for any supplier to predict the type and characteristics of products farmers will require year to year, or even during an individual season.

26 The type of product the farmer chooses will depend on the characteristics of a particular farm, taking into account seasonal features, economic conditions and the farmer's own personal preference. On this basis, suppliers cannot afford to assume

that a particular product characteristic will cause it to remain successful year upon year.

Conclusion on market definition

27 In summary, the Applicant considers that, for the purposes of the analysis of the Proposed Transaction the appropriate product markets are:

- the market for the treatment of external parasites (not including cattle ticks) in cattle (using ectoparasiticide products and endectocides);

- the market for the treatment of external parasites in sheep (using ectoparasiticide products only).

4A. Treatments for external parasites in cattle

Merial and Schering-Plough

1 Merial and Schering-Plough market the following ectoparasiticides and endectocides for cattle.

Merial	Endectocide	Schering-Plough	Endectocide
TEMPOR	No	BLAZE (pour-on)	No
IVOMEC POUR ON	Yes	TAKTIC (ticks only)[71]	No
IVOMEC INJECTION	Yes		
IVOMEC PLUS INJECTION	Yes		
GENESIS POUR ON	Yes		
GENESIS ULTRA POUR-ON	Yes		
GENESIS INJECTION	Yes		
ECLIPSE POUR ON	Yes		
ALPHA^2 POUR ON	Yes		

2 Table 3.13 (on the following page) shows the competitors and their products. The value of sales and estimated market shares are set out in Table 13A in confidential Schedule 3.1.

3 Market shares and the three-firm concentration ratio following the Proposed Transaction are also set out in confidential Schedule 3.1. These are outside the Commission's safe harbour guidelines.

[71] Please see confidential Schedule 3.1.

Table 3.13

Products for the treatment of external parasites in cattle

asterisks identify endectocides

Company Name	Product Name	IVS Page Ref
Merial/Ancare	See above	387 - 426
Schering-Plough	See above	387 and 417
Bayer	DESTRUCT	396
	BAYMEC INJECTION *	311
	BAYMEC POUR ON *	312
	SATURN	New product
Fort Dodge	CYDECTIN INJECTION *	390
	CYDECTIN POUR ON *	392
	LYPOR	408
	VENGEANCE	420
	VETDECTIN INJECTION *	421
	VETDECTIN POUR ON *	422
Ravensdown	CATTLE LICE POUR ON	Not listed in IVS
	ABAMECTIN INJECTION*	Not listed in IVS
	ABAMECTIN POUR ON*	Not listed in IVS
Jurox	PARAMECTIN INJECTION *	414
	PARAMECTIN POUR ON *	414
	POURACIDE NF	415
BASF	RIPCORD	415
Bomac	BOMECTIN GOLD POUR ON *	388
	BOMECTIN INJECTION *	388
	BOMECTIN POUR ON *	389
Norbrook N	NOROMECTIN INJECTION *	410
	NOROMECTIN PLUS INJECTION *	412
	NOROMECTIN POUR ON *	412
Pfizer	DECTOMAX POUR-ON *	395
	DECTOMAX INJECTABLE *	395
Virbac	NILTIME LV	409

Potential competition

4 As discussed earlier, the barriers to entry and expansion in animal pharmaceutical markets generally are relatively low, at least for a generic product.

5 To illustrate, Ravensdown was a new entrant into this market in 2007 with the product Cattle Lice Pour-on, a combination fly/lice treatment. Within two years Ravensdown has achieved a strong market share. Bayer has also seen significant growth in the last few years.

6 Table 3.14 (on the following page) shows the ectoparasiticides for cattle registered with NZFSA over the last two and a half years. There have been 11 ectoparasiticides registered with the NZFSA since the *Schering-Plough/Organon* decision in October 2007.

Table 3.14
Recently registered products – ectoparasiticides (cattle)
asterisks identify endectocides

Company Name	Product Name	Date of Registration
Bomac	BOMATAK A CATTLE POUR ON *	17 January 2007
	BOMECTIN GOLD POUR ON *	16 February 2007
	IMAX INJECTION *	23 February 2007
	ABAMECTIN CLORSULON INJECTION	27 March 2008
	BOMECTIN SUPER INJECTION *	12 November 2007
Merial	GENESIS INJECTION WITH B12 AND SELENIUM * (cattle & sheep)	9 January 2008
	EXODUS POUR ON *	9 February 2009
Norbrook	CLOSAMECTIN INJECTION *	20 November 2007
	NOROMECTIN PLUS INJECTION *	24 October 2007
Bayer	IPLUS *	27 March 2008
Virbac	COMBAT TOPLINE *	8 August 2008

7 There is also a high degree of supply side substitutability between the various parasiticides. Ectoparasiticides almost invariably use off-patent and readily available active ingredients manufactured either locally or offshore by large international players or smaller local players such as Ravensdown, The Drench Company (PGG Wrightson supplier) and Bomac.

8 The reformulation technology is relatively simple and registration of products is straightforward. Consequently, a manufacturer that has the ability to create an endoparasiticide could, with very little effort, change its manufacturing process to produce an ectoparasiticide or endectocide.

9 Ectoparasiticide and endectocide products are usually manufactured using a simple process involving 'one tank, dispense, add, stir and pack' manufacturing (i.e. ingredients are dispensed into a stainless steel tank before being stirred together, extracted and packed). A manufacturer of an endoparasiticide product could, for example, use this same manufacturing process to produce an ectoparasiticide. A simple clean down of manufacturing equipment will allow a manufacturer to switch between manufacturing ectoparasiticides, endoparasiticides and endectocides or to switch between different products within the same category.

Conclusion on competition

10 In *Schering-Plough/Organon*, the Commission concluded that the proposed acquisition would not result in a substantial lessening of competition in the market for ectoparasiticides for cattle. The combined entity would be constrained by existing competitors, particularly Ancare (now owned by Merial), Bayer and Fort Dodge. The combined entity would also be constrained by a number of strong competitors with endectocide products.

11 This same conclusion can be reached today.

- Bayer and Fort Dodge will continue to act as a constraint on pricing by Merial and Schering-Plough. While Bayer and Fort Dodge sell lice-only ectoparasiticides for cattle, as the Commission noted in *Schering-Plough Organon*, these products are likely to constrain the pricing of Merial and Schering-Plough's fly/lice products.

- There remain a number of other strong competitors with endectocide products.

- The barriers to entry and expansion are low and manufacturers of other ectoparasiticide and endoparasiticide products can easily switch production. New entry or expansion by generics is likely. (Refer also to earlier section on 'Potential Competition'.)

12 In addition, as discussed in the earlier sections, purchasers have countervailing power and co-ordination effects are unlikely.

4B. Treatments for external parasites in sheep

Market shares

1 Merial and Schering-Plough market the following ectoparasiticides for sheep.

Merial	Schering-Plough
CYPERCARE	WIPE-OUT
CYRAZIN LIQUID	ZENITH
CYRAZIN SPRAY-ON	MAGNUM
XTERMINATE 10	LICE-ENZ
FLYPEL	VANQUISH
FLEECEMASTER	ERASE JETTING LIQUID
EXIT POUR ON FOR SHEEP	FLEECECARE
TRITON TAPE LIQUID FOR LAMBS[72] (Argenta)	BLITZ[73]
TRITON LIQUID with Selenium & Cobalt for Sheep (Argenta)	ZENITH SPRAY-ON

2 Table 3.15 (on the following page) shows competing suppliers of ectoparasiticides for sheep. The value of sales and estimated market shares are set out in Table 3.15A in confidential Schedule 3.1

3 Market shares and the three-firm concentration ratio following the Proposed Transaction are also set out in confidential Schedule 3.1. These are outside the Commission's safe harbour guidelines.

[72] The registrations for the TRITON branded products are held by Argenta Manufacturing.

[73] Refer confidential Schedule 3.1

Table 3.15

Products for the treatment of external parasites in sheep (ectoparasiticides)

Company Name	Product Name	IVS Page Ref
Schering-Plough	See above	387 - 426
Merial/Ancare	See above	387 - 426
Novartis	CLIK	390
	CLIPGUARD POUR ON	390
	ECTOGARD	396
	VETRAZIN LIQUID	423
	VETRAZIN SPRAY ON	423
Bayer	MAGGO	409
	SERAPHOS 500	416
	SERAPHOS 1250	416
	SWAT LIQUID	417
	SWAT SPRAY ON	417
	ZAPP	425
	ZAPP JETTING LIQUID	425
Orion	TOP CLIP 40	Not listed in IVS
Elanco	EXTINOSAD	399
Norbrook	LUCIFLY LIQUID	406
	LUCIFLY SPRAY ON	406
	LUZINE LIQUID	407
	LUZINE SPRAY ON	408
Jurox	CYRO-FLY 500 DIP and JETTING FLUID	394
	CYRO-FLY 50 SPRAY ON	394
	EPIC EZY POUR ON	397
FIL	STRIKE POWDER	416

4 Of the competitor products, there are individual products that have significant market shares (please refer to confidential Schedule 3.1).

Potential competition

5 See comments above in relation to treatments for external parasites for cattle. Note also that in *Schering-Plough/Organon*[74], the Commission found that the merged entity would face competition from only four competitors in the sheep ectoparasiticides market: Ancare; Bayer, Jurox and Novartis. Since October 2007, Orion, Elanco, and FIL have entered the market.

6 Table 3.16 shows the ectoparasiticides for both sheep registered with NZFSA over the last two and a half years. There have been over a dozen ectoparasiticides registered with the NZFSA since the *Schering-Plough/Organon* decision in October 2007.

[74] At paragraph 268.

Table 3.16

Recently registered products – ectoparasiticides

(sheep)

Company Name	Product Name	Date of Registration
Elanco	EXTINOSAD AEROSOL	18 February 2008
	OUTBACK LIQUID	12 December 2007
Merial	EXODUS	9 May 2007
	EXODUS SE	9 January 2008
	EXODUS HI MINERAL	25 January 2008
	EXODUS TAPE HI MINERAL	21 August 2008
Norbrook	LUCIFLY LIQUID	31 May 2007
	STRIKEOUT LIQUID	19 November 2007
	STRIKEOUT SPRAY-ON	19 November 2007
	LUZINE SPRAY-ON	1 August 2007
	LUZINE LIQUID	1 August 2007
Bayer	SWAT SPRAY-ON	25 August 2008
	SWAT LIQUID	29 August 2008
Elanco	EXTINOSAD POUR-ON	6 March 2009

Conclusion on competition

7 The following factors indicate that the Proposed Transaction would not substantially lessen competition in the market for treatments for external parasites in sheep (ectoparasiticides):

- There are a number of existing competitors, all of which are significant businesses with established reputations in the animal health industry. In particular, Novartis and Bayer have significant market shares.

- While Merial and Schering-Plough will, between them have over a dozen products in this market, several of the competitors also have a number of differentiated products registered which could be positioned to compete against the combined entity. Novartis has five products and Bayer has seven, Norbrook has four and Jurox has three.

- Barriers to entry and expansion are low. New entry or expansion by generics is likely. (Refer to earlier section on 'Potential Competition'.)

8 In addition, as discussed in the earlier sections, purchasers have countervailing power and co-ordination effects are unlikely.

5. Treatments for internal parasites

1 Endoparasiticides are agents or preparations used to control internal parasites (including gastrointestinal roundworms and tapeworms, lungworms and liver flukes) in various species.

2 They are administered either orally (in the form of tablets or 'bolus' (a large tablet)) or parenterally (by intravenous or subcutaneous injection). Treatments of groups of animals are usually done by administering a suspension or powder / granules mixed into the animals' feed or drinking water.

3 The overall group of endoparasiticides encompasses dewormers, flukicides and anti-protozoals. Dewormers (so called anthelminthics) combat gastro-intestinal roundworms (nematodes), hookworms, tapeworms (cestodes) as well as lungworms (dictyocaulus viviparous). Flukicides are targeted at liver flukes. Anti-protozoals are targeted at protozoa (animal-like single celled organisms, causing e.g. cryptosporidial infections).

4 Endoparasiticide products often have broad therapeutic coverage (i.e, target a number of different parasites). Some products are effective against various types of parasiticides while others are focussed on specific parasites with a higher individual level of protection. Manufacturers position their products at various points of this sliding scale. All products, however, compete within the same space defined by the fact that they all target internal parasites.

5 Endectocides are agents or preparations that are used to treat both external and internal parasites concurrently. These can be used in place of both an endoparasiticide and an ectoparasiticide. Endectocides protect the treated animal in one convenient treatment against a large number of infestations by various parasites (external and internal).

6 The *Endoparasiticide* product table in Appendix 3.1 shows overlap between Merial and Schering-Plough in relation to products for treating internal parasites.

- Merial has endoparasiticides and endectocides for cattle, sheep, deer, horses, swine and companion animals.

- Schering-Plough has endoparasiticides for cattle, sheep, and horses.

Market definition

7 As set out in the previous section, in *Schering-Plough/Organon*, in relation to cattle the Commission noted that:[75]

[75] At paragraphs 145 & 146

> Market investigations found that, in New Zealand, there has been a substantial shift from ectoparasiticides/endoparasiticides to endectocides in recent years, suggesting a large degree of demand-side substitutability between the two products. The Commission understands that this shift been motivated by a various factors, including that:
>
> - organo-phosphates, the family of active substances in many ectoparasiticides, are considered to be less environmentally friendly than the active substances in endectocides;
> - endectocides are more convenient, as they replace two animal treatments with one; and
> - endectocides are considered to be more efficacious.
>
> Moreover, on the arguments presented above for combination fly/lice and lice only ectoparasiticide products, endectocides could be placed in the same relevant market as both ectoparasiticides and endoparasiticides. That is, a hypothetical monopolist of endectocides, when imposing a SSNIP, would likely face substitution to ectoparasiticides and endoparasiticides, such that these three groups of products would be in the same market."

8 In relation to sheep the Commission stated:[76]

> "… some products are marketed as endectocides for sheep, and the Commission understands these products to be mainly used as endoparasiticides. Schering-Plough submitted that "[w]hile there are numerous sheep endectocides available in New Zealand, their primary activity is against internal parasites rather than external parasites such as flies and lice". Neither Schering-Plough nor Intervet supplies endectocides in New Zealand. Therefore no aggregation in endectocides would occur as a result of this acquisition."

9 Accordingly the Commission's view was that the competitive effects of that transaction were best analysed with a products market consisting only of endoparasiticides.

10 The Proposed Transaction differs in that Merial has endectocide products for sheep and cattle.

11 Although the Applicant does not produce an endectocide, for the purpose of this Notice the Applicant has treated the market as comprising both endoparasiticide products and endectocide products.

Horses

12 There are both endoparasiticide and endectocide products for the treatment of horses in New Zealand. However, the endectocide products are indicated primarily for the treatment of internal parasites. Consistent with the Commission's approach set out above, the Applicant considers that, in relation to horses, the relevant market comprises both endoparasiticide and endectocide products.

[76] At paragraphs152 – 157.

Product differentiation

Active ingredients; single and combination products

13 Different endoparasiticide and endectocide products have different active ingredients, but in this instance, they serve the same purpose of treating internal parasites.

14 Most of Merial and Schering-Plough's products are broad spectrum and as such treat a variety of internal parasites. However, some products target a specific worm species.

15 In *Schering-Plough/Organon* the Commission noted:[77]

> There are a significant number of endoparasiticides on the market, differentiated by factors including the active substance and the type of worm treated.
>
> All the endoparasiticide products on the market have active substances from one of three "action families":
>
> - Macrocylic Lactones: includes active substances such as abamectin, ivermectin and moxidectin;
> - Levamisoles: includes the active substance levamisole; and
> - Benzimidazoles: includes active substances such as oxfendazole and albendazole.
>
> Products with active substances from different action families can be used to treat the same types of worms and are generally substitutable for one another. In addition, there are a number of products that have combinations of two or all three of the action families, as a means of overcoming worm resistance to a particular action family.
>
> Most products are broad spectrum, treating a number of different worm species, although there are a small number of products that treat only a particular species of worm. Nonetheless, worm species that are treated by such narrow spectrum products can also typically be treated by other broad spectrum products.

16 The farmer's decision as to whether to purchase an endoparasiticide, an ectoparasiticide or an endectocide or a combination drench product[78] will depend on what that farmer believes (or knows if the farmer has invested in testing) to be infecting or infesting his/her animals at a given point in time. Many farmers follow what is known as a "parasite control plan" which indicates what parasites are likely to be present in stock at a given time. The farmer makes his/her decision on what products to use based on that plan and any other relevant information and criteria available.

[77] At paragraphs 152 - 155

[78] A 'combination drench' is an endoparasiticide, ectoparasiticide or an endectocide that has more than one active ingredient targeted at the same parasite. A product with two actives that work on different parasites is not a 'combination drench'.

17 Generally a farmer will presume that young stock have internal parasites (so could use an endoparasiticide), but the farmer may also see external parasites on the animal (eg lice), in which case the farmer could change to an endectocide to treat both the intemal parasttes and the lice with one treatment.

18 Alternatively, the farmer may decide to use a separate ectoparasiticide treatment and a separate endoparasticide treatment if he/she perceives this to be less costly, not excessively slower and have similar efficacy to the endectocides. For example, if the farmer suspects or knows that:

- there are no external parasites present in the animals, but has a suspicion or knows that some of the internal parasites have a level of drug resistance to certain active ingredients, the farmer could use a combination drench product so the two active ingredients work synergistically to give a high efficacy against the parasites; or

- the animals have lice and internal parasites, and the farmer suspects or knows that these parasites have a level of drug resistance, the farmer could use an ectoparasiticide and a combination drench product against the parasites.

19 Ultimately a farmer's decision as to what product to use will be based on a number of factors including price, parasite control plan, suspected resistance status of the parasites concerned, previous personal experience, reputation of the product based on the experience of other farmers, advice from third parties and product promotional activities of the manufacturer and/or distributor.

Methods of administration

20 There are various methods of administration of endoparasiticides and endectocides: orally by way of liquid or capsule, pour-on or parenterally (by subcutaneous injection). As with ectoparasiticides, the particular method used by the farmer in any particular circumstance will largely depend on the farmer’s preference and which method is most appropriate given the circumstances.

Different animals

21 Both Merial and Schering-Plough supply endoparasiticides for a variety of species. Some of these products are indicated for the treatment of a number of different species - in cases where the dose rate is suitable for use over a range of animal liveweights. Other products have dosages that are suitable only for specific species.

22 In general, parasitic nematodes (worms) are animal species-specific but all ruminant animals in New Zealand are susceptible to worms of similar families with similar drug susceptibility (based on classification order of family, genus and species). In other words, the same active ingredient can be used to treat a variety of worms in a variety of animals. Accordingly manufacturers often target cattle, sheep, deer and goats with the same product, although there are some exceptions where an active ingredient in a product will target a worm species in a particular animal.

23 However, horses are not ruminant animals and as such they are generally susceptible to different species of internal parasites than cattle or sheep. Further, horses do not tolerate levamisole as ruminants do, and are not tolerant of injection, pour-on or oral liquid dosing in most cases. Accordingly, there are separate endoparasiticide products for the treatment of internal parasites in horses, usually based on low volume oral paste application. These products are generally not substitutable with products for the treatment of internal parasites in cattle and sheep.

Conclusion on market definition

24 In summary, the Applicant considers that, for the purposes of this analysis the appropriate product markets are:

- the market for the treatment of internal parasites in cattle and sheep (using endoparasiticide products and endectocides);

- the market for the treatment of internal parasites in horses.

5A. Treatments for internal parasites in cattle and sheep

1 Although the Applicant considers that the relevant market against which to test the competition effects of the Proposed Transaction is the market for the treatment of internal parasites in cattle **and** sheep, this section provides information about the cattle and sheep segments separately and in combination.

Cattle products

2 Merial markets nine endoparasiticide products and nine endectocide products for cattle, including the leading GENESIS, EPRINEX and IVOMEC brands (see Appendix 3.1 for a full list of Merial products).

2 Schering-Plough markets six endoparasiticide products for cattle, under the NILVERM, VALBAZEN and SCANDA brands (see Appendix 3.1 for a full list of Schering-Plough products).

3 Table 3.17 shows the competitors and their products for the treatment of internal parasites in cattle only. The value of sales and estimated market shares are set out in Table 3.17A in confidential Schedule 3.1.

4 The market shares and three-firm concentration ratio following the Proposed Transaction are also set out in confidential Schedule 3.1. This is outside the Commission's safe harbour guidelines. However, the level of aggregation is minimal.

Table 3.17

Products for the treatment of internal parasites in cattle

asterisks identify endectocides

Company Name	Product Name	IVS Page Ref
Merial/Ancare	See above	309 - 378
Schering-Plough	See above	309 - 378
Ravensdown	ABAMECTIN POUR ON*	Not listed in IVS
	ABAMECTIN INJECTION*	Not listed in IVS
	ALBENDAZOLE MINERALISED DRENCH	Not listed in IVS
	LEVAMISOLE MINERALISED	Not listed in IVS
	COMBO MINERALISED	Not listed in IVS
Fort Dodge	CYDECTIN INJECTION *	320
	CYDECTIN POUR ON *	323
	VETDECTIN INJECTION *	374
	VETDECTIN POUR ON *	376
Pfizer	DECTOMAX POUR ON *	324
	DECTOMAX INJECTABLE *	325
Bayer	BAYMEC INJECTION *	311
	DUELL CATTLE	326
	IPLUS *	343

Bayer	CONCUR CATTLE HIMIN	319
	BAYMEC POUR ON *	312
	SATURN	New product
Jurox	CLEAR DRENCH MINERALISED	318
	PARAMECTIN INJECTION *	364
	PARAMECTIN POUR ON *	365
	STRATEGIK MINERALISED CATTLE BROAD SPECTRUM WORM DRENCH	370
	STRATEGIK MINERALISED COMBO DRENCH FOR CATTLE	370
Bomac	BOMATAK POUR ON	313
	BOMATAK C	314
	BOMATAK C MINERALISED	314
	BOMATAK S MINERALISED	314
	BOMECTIN GOLD POUR ON *	314
	BOMECTIN INJECTION *	315
	BOMECTIN POUR ON *	315
Novartis	FASIMEC POUR ON *	337
	FASINEX 10	337
	LEVIBEN CATTLE	350
	LEVIPOR	351
	RYCOZOLE MINERALISED PLUS SELENIUM	368
Norbrook	NOROMECTIN INJECTION *	356
	NOROMECTIN PLUS INJECTION *	359
	NOROMECTIN POUR ON *	359
	PARAFEND LV	363

Potential competition

5 As discussed earlier, the barriers to entry in animal pharmaceutical markets generally are relatively low, at least for a generic product.

6 Table 3.20 (at the end of this section) shows endoparasiticide products registered with NZFSA over the last two years. There have been 35 endoparasiticides registered with the NZFSA since the *Schering-Plough/Organon* decision in October 2007.

7 There is also a high degree of supply side substitutability between the various parasiticides. Endoparasiticides invariably use off-patent and readily available active ingredients manufactured either locally or offshore by large international players or smaller local players such as Ravensdown, The Drench Company (PGG Wrightson supplier) and Bomac.

8 The reformulation technology is relatively simple and registration of products is straightforward. Consequently, a manufacturer that has the ability to create an

ectoparasiticide could, with very little effort, change its manufacturing process to produce an endoparasiticide or endectocide.

9 As noted earlier in relation to ectoparasiticides, endoparasiticides and endectocide are usually manufactured using a simple process whereby ingredients are dispensed into a stainless steel tank before being stirred together, extracted and packed. A manufacturer of an ectoparasiticide product could, for example, use this same manufacturing process to produce an endoparasiticide. A simple clean down of manufacturing equipment will allow a manufacturer to switch between manufacturing ectoparasiticides, endoparasiticides and endectocide or to switch between different products within the same category.

Conclusion on competition for cattle products

10 The following factors indicate that the Proposed Transaction will not substantially lessen competition in treatments for internal parasites in cattle:

- There are a number of existing competitors, all of which are significant businesses with established reputations in the animal health industry. Pfizer, Ravensdown, Bayer, Bomac, Jurox and Fort Dodge, in particular, have smaller, but still substantial market shares.

- The barriers to entry and expansion are low and manufacturers of other ectoparasiticide and endoparasiticide products can easily switch production. New entry and expansion through generics is likely. (Refer earlier section 'Potential Competition'.)

- The level of aggregation is small.

11 In addition, as discussed in the earlier sections, purchasers have countervailing power and co-ordination effects are unlikely.

Sheep products

12 Merial markets 30 endoparasiticide products and six endectocide products for sheep, including the strong IVOMEC, ARREST and GENESIS brands (see Appendix 3.1 for a full list of Merial products).

13 Schering-Plough markets eight endoparasiticide products for sheep, under the CLOSAL, VALBAZEN and SCANDA brands (see Appendix 3.1 for a full list of Schering-Plough products).

14 Table 3.18 (on the following page) shows the competitors and their products for the treatment of internal parasites in sheep. The value of sales and estimated market shares are set out in Table 3.18A in confidential Schedule 3.1.

15 The market shares and three-firm concentration ratio following the Proposed Transaction are also set out in confidential Schedule 3.1. This is outside the

Commission's safe harbour guidelines. However, the level of aggregation is not high.

Table 3.18

Products for the treatment of internal parasites in sheep

asterisks identify endectocides

Company Name	Product Name	IVS Page Ref
Merial/Ancare	See above and Appendix 3.1	309 - 378
Schering-Plough	See above and Appendix 3.1	309 - 378
Fort Dodge	CYDECTIN INJECTION *	320
	CYDECTIN LONG ACTING INJECTION *	321
	CYDECTIN ORAL DRENCH *	322
	CYDECTIN PLUS FLUKE *	322
	CYDECTIN PLUS TAPE	322
	CYDECTIN S *	323
	EWEGUARD *	332
	EWEQUARD PLUS SE B12	333
	EWEGUARD PLUS SELENIUM *	333
	VETDECTIN INJECTION *	374
	VETDECTIN ORAL DRENCH *	375
	VETDECTIN PLUS TAPE	375
	VETDECTIN S *	422
Ravensdown	ALBENDAZOLE MINERALISED DRENCH	Not in IVS
	COMBO MINERALISED DRENCH	Not in IVS
	ABAMECTIN MINERALISE DRENCH	Not in IVS
	ABAMECTIN TAPE MINERALISED DRENCH	Not in IVS
	QUAD SHEEP DRENCH	Not in IVS
	LEVAMISOLE MINERALISED DRENCH	Not in IVS
	COMBO PLUS TAPE MINERALISED DRENCH	Not in IVS
Novartis	COMBITAPE MINERALISED PLUS	318
	FASINEX 10	337
	LEVIBEN	350
	LEVIBEN MINERALISED PLUS SELENIUM	350
	RYCOBEN SHEEP AND LAMB MINERALISED PLUS SELENIUM	367
	RYCOMECTIN	367
	RYCOMECTIN MINERALISED PLUS SELENIUM	367
	RYCOZOLE MINERALISED PLUS SELENIUM	368
Bayer	BAYMEC SHEEP HIMIN	312
	CONCUR SHEEP HIMIN	319
	DUELL SHEEP HIMIN	326
	DUELL TAPE HIMIN	326
Jurox	CLEAR DRENCH MINERALISED	318
	PARAMECTIN INJECTION *	364
	PARAMECTIN MINERALIESED ORAL DRENCH	364

Jurox	PARAMECTIN TAPE MINERALISED	365
	Q DRENCH MULTI COMBINATION DRENCH	365
	STRATEGIK COMBO + TAPE MINERALISED	369
	STRATEGIK COMBO DUAL ACTION MINERALISED	370
	STRATEGIK MINERALISED SHEEP & LAMB BROAD SPECTRUM WORM DRENCH	371
Norbrook NZ	NOROMECTIN INJECTION *	356
	NOROMECTIN ORAL *	357
	NOROMECTIN ORAL PLUS SELENIUM	358
	NOROMECTIN PLUS INJECTION *	359
	OVIMECTIN PLUS SELENIUM	360
	PARAFEND	363
	PARAFEND LV	363
	ZOOMEC PLUS SELENIUM	378
Bomac Laboratories	BOMATAK C	314
	BOMATAK C MINERALISED	314
	BOMATAK S MINERALISED	314
	BOMECTIN ORAL *	316
Pfizer Animal Health	DECTOMAX INJECTABLE *	325
Virbac New Zealand	VIRBAMEC MINERALISED ORAL DRENCH *	377

16 In addition, since the Farm Market Index results (on which the market share estimates are based) were published:

- Novartis has launched a brand new endoparasitide for sheep called ZOLVIX (registered with the NZFSA on 13 January 2009) with a new active ingredient (monepantel). Please see Appendix 3.3 for a copy of a recent article in the Rural Press on this product.

- The Applicant has recently seen Jurox become a strong competitor in the sheep endectocides segment.

- The Applicant has seen strong growth from Bayer with an enlarged range of products available nationally through Farmlands, CRT, and Taranaki Farmers.

- The Applicant has seen Bomac take significant share with its sales of Bomectin products through RD1 and as a supplier or second brands to a number of other players.

Potential competition

17 See comments above in relation to treatments for internal parasites in cattle.

Conclusion on competition for sheep products

18 The following factors indicate that the Proposed Transaction will not substantially lessen competition in treatments for internal parasites in sheep:

- There are a number of existing competitors, all of which are significant businesses with established reputations in the animal health industry. In particular:

    - Fort Dodge markets the leading CYDECTIN product and the EWEGUARD product, both of which hold strong market shares. Please refer to confidential Schedule 3.1.

    - Ravensdown and Novartis also have smaller, but still substantial, market shares.

- The barriers to entry and expansion are low and manufacturers of other ectoparasiticide and endoparasiticide products can easily switch production. New entry or expansion through generics is likely. (Refer also to earlier section on 'Potential Competition'.)

19 In addition, as discussed in the earlier sections, purchasers have countervailing power and co-ordination effects are unlikely.

Combined sheep and cattle

20 There are a number of products that are indicated for the treatment of cattle, deer and sheep. Table 3.19 in confidential Schedule 3.1 shows the value of sales and combined market shares. The market shares and three-firm concentration ratio following the Proposed Transaction are also set out in confidential Schedule 3.1. These are outside the Commission's safe-harbours but the level of aggregation is relatively low.

Conclusion on competition

21 The following factors indicate that the Proposed Transaction will not substantially lessen competition in this market:

- There are a number of existing competitors, all of which are significant businesses with established reputations in the animal health industry. Fort Dodge and Ravensdown both hold significant market shares.

- There will be constraint from suppliers of sheep only and cattle only products, as noted above.

- The barriers to entry and expansion are low and manufacturers of other ectoparasiticide and endoparasiticide products can easily switch production. New entry or expansion through generics is likely. (Refer also to earlier section on 'Potential Competition'.)

22 In addition, as discussed in the earlier sections, purchasers have countervailing power and co-ordination effects are unlikely.

Table 3.20

Recently registered products – endoparasiticides

(cattle & sheep)

Company Name	Product Name	Date of Registration
Bomac	BOMANTEL PREMIX	17 April 2008
	BOMATAK L CATTLE POUR ON	29 January 2007
	EQUITAK EXCEL MULTIDOSE	12 February 2007
	BOMATAK OLA MINERALISED	26 September 2007
	BOMATAK A CATTLE POUR ON	17 January 2007
	BOMATAK OL SHEEP ORAL MINERALISED	26 June 2007
	BOMECTIN GOLD POUR ON	16 February 2007
	IMAX INJECTION	23 February 2007
	BOMATAK COMBO FLUKE	6 August 2007
	BOMATAK COMBO	19 July 2007
	BOMATAK PALA	12 October 2007
	BOMATAK LACA SHEEP ORAL MINERALISED	8 November 2007
	ABAMECTIN CLORSULON INJECTION	27 March 2008
	BOMECTIN SUPER INJECTION	12 November 2007
	BOMATAK ABAMECTIN POUR ON	11 June 2008
	PARATAK PPF 5	3 November 2008
	PARATAK PPF 10	3 November 2008
	BOMATAK LAC SHEEP ORAL MINERALISED	4 March 2009
	BOMATAK PAL SHEEP ORAL MINERALISED	4 March 2009
	MOUSETRAP BOLUS (BEEF)	4 February 2009
	MOUSETRAP CATTLE (DI-ACTIVE)	4 February 2009
Bomac	IMAX GOLD LIQUID BROAD SPECTRUM WORMER, TAPEWORMER AND BOTICIDE FOR HORSES	22 December 2008
Ethical Agents	FIPROVET SPRAY	23 January 2007
Seneca Holdings	MECTIN PLUS TAPE FOR SHEEP	23 January 2007
	COMBINATION PLUS TAPE DRENCH FOR SHEEP.	14 March 2007
	COMBINATION CATTLE DRENCH	27 April 2007
	MECTIN DRENCH FOR SHEEP	27 June 2007
	GOLD DRENCH FOR SHEEP AND CATTLE	13 September 2007
	COMBINATION SHEEP DRENCH PLAIN	12 December 2007
	MECTIN POUR-ON	17 January 2008
Ancare Scientific Ltd	SWITCH C HI MINERAL	9 February 2009
Caledonian Holdings	FEN-IVERQUANTEL	4 September 2007
	FEN-IVERQUANTEL LIQUID	17 June 2008
Merial	GENESIS ULTRA HI MINERAL	16 January 2007
	OXFEN C PLUS	26 February 2007
	GENESIS INJECTION WITH B12 AND SELENIUM	9 May 2007
	SWITCH HI MINERAL	12 September 2007
	EXODUS	9 January 2008
	EXODUS SE	9 January 2008

Merial	EXODUS HI MINERAL	25 January 2008
	TRIUMPH LIQUID	6 November 2008
	TRIUMPH PASTE	6 November 2008
	IVER-MATRIX TAPE HI MINERAL	16 June 2008
	MATRIX C HI MINERAL	2 September 2008
	MATRIX MINIDOSE HI MINERAL	2 September 2008
	EXODUS TAPE HI MINERAL	21 August 2008
	EXODUS POUR ON	9 February 2009
Bayer	SATURN POUR-ON	2 December 2008
	DUELL SHEEP HIMIN	9 March 2007
	BAYMEC SHEEP HIMIN	1 May 2007
	DUELL TAPE HIMIN	2 May 2007
	ABAPOR POUR-ON	14 July 2008
	UNIPOR POUR-ON	3 September 2007
	CONCUR SHEEP HIMIN	20 September 2007
	CONCUR CATTLE HIMIN	20 September 2007
	IPLUS	27 March 2008
	UNIPLAIN	3 October 2008
	UNIMIN	3 October 2008
Agpro (NZ) Ltd	OPTAMECTIN PLUS HORSE GEL	14 March 2007
	OPTACOMBO MINERALISED SHEEP	14 March 2007
	OPTALBEN MINERALISED CATTLE DRENCH	18 April 2007
	OPTAMECTIN MINERALIZED TAPE SHEEP	29 MAY 2007
	OPTAMECTIN MINERALIZED SHEEP	29 AUGUST 2007
	OPTAMECTIN POUR-ON FOR CATTLE	26 SEPTEMBER 2007
Norbrook	ZOOMEC PLUS SELENIUM	6 July 2007
	CLOSAMECTIN INJECTION	20 November 2007
	NOROMECTIN PLUS INJECTION	24 October 2007
	OVIMECTIN PLUS SELENIUM	16 July 2008
Fort Dodge	CYDECTIN LONG ACTING INJECTION FOR SHEEP	21 November 2007
Schering-Plough	SCANDA TAPE	6 September 2007
	CONVERGE	30 July 2008
Argenta Manufacturing	TRITON - A MULTIPHASE DRENCH FOR SHEEP	20 May 2008
Virbac	COMBAT TOPLINE	8 August 2008
Novartis	ZOLVIX	13 January 2009
Jurox	TROIKA COMBINATION DRENCH FOR SHEEP.	9 April 2009

5B. Treatments for internal parasites in horses

1 Merial and Schering-Plough market the following endoparasiticide and endectocides for horses.

Merial	Endectocide	Schering-Plough	Endectocide
EQVALAN PASTE	Yes	PANACUR 100	No
EQVALAN GOLD	Yes		
GENESIS HORSE WORMER	Yes		
PARADE EQUINE GEL	Yes		
ADTAPE	No		

2 Table 3.20 shows the competitors and their products for the treatment of internal parasites in horses.

Table 3.21

Products for the treatment of internal parasites in horses

asterisks identify endectocides

Company Name	Product Name	IVS Page Ref
Schering-Plough	As above	362
Merial	As above	308-362
Vetpharm	AMMO ALL WORMER PASTE FOR HORSES *	309
Bomac	BOMATAK PASTE	313
	BOMATAK-C	314
	EQUITAK	329
	EQUITAK EXCEL	330
	EQUITAK EXCEL MULTIDOSE	331
Fort Dodge	EQUEST PLUS TAPE	328
Virbac	EQUIMAX LV ORAL PASTE FOR HORSES	329
International Animal Products	FARNAM MECWORMA & BOT BROAD SPECTRUM PASTE FOR HORSES	337
Caledonian Holdings	FEN-IVERQUANTEL*	338
	FEN-IVERQUANTEL LIQUID*	338
	IVERQUANTEL*	344
	IVERQUANTEL LIQUID *	344
Norbrook	NOROMECTIN PASTE FOR HORSES *	358
Jurox	PROMECTIN PLUS ALLWORMER PASTE FOR HORSES	365

3 The Applicant does not have market share data for this market but believes that the level of aggregation is minimal. Please refer to confidential Schedule 3.1.

4 The following factors indicate that the Proposed Transaction will not substantially lessen competition in this market:

- The level of aggregation is not significant.
- There are a number of existing competitors, all of which are significant businesses with established reputations in the animal health industry.
- The barriers to entry and expansion are low. New entry and expansion through generics is likely. (Refer to earlier section on 'Potential Competition'.)

6. Nutrients for Selenium Deficiency

1 The *Parenteral Nutrient/Electrolyte* product tables in Appendix 3.1 shows overlap in products for the treatment of selenium deficiency in cattle.

2 Merial and Schering-Plough market the following products for the treatment of selenium deficiency in cattle.

Merial	Schering-Plough
SELPOR	SE-HYPO

3 Treatments for other mineral deficiencies are not substitutable for products for treating selenium deficiency (although producers of one type of mineral or vitamin deficiency treatment are well placed to produce other mineral or vitamin deficiency treatments).

Product differentiation

4 Nutrients for selenium deficiency can be administered in a number of ways;

- directly by injection or a topical pour-on product;
- indirectly by adding to the water in drinking troughs; and
- by including in endoparasiticides and ectoparasiticides (for example, some of the Merial and Schering-Plough endoparasiticides and ectoparasiticides have additional selenium and other minerals).

5 These methods of administration are broadly substitutable. Which method is chosen will depend on factors such as the extent of the deficiency at a particular property, whether the need for treatment coincides with other treatments (such as for parasite control) and farmer preference. Generally farmers will look for options that mean they can reduce the number and type of treatments that they need to administer to their animals.

6 Some supplements, such as the Merial SELPOR and Schering-Plough SE HYPO products can be sold as OTC products (although both Merial and Schering-Plough sell these only through the veterinary channel).

Market shares

7 Table 3.21 at the end of this section shows the competitors and their products for the treatment of selenium deficiency in cattle.

8 The Applicant does not have market share data for this market but believes that the level of aggregation is minimal. Please refer to confidential Schedule 3.1.

Table 3.22

Products for the treatment of selenium deficiency in cattle

Company Name	Product Name	Active Ingredient	IVS Page Reference
Merial	SELPOR: Selenium Pour-on for the prevention and treatment of Selenium deficiency and Selenium responsive diseases in cattle and deer.	Selenium as sodium selenate	266
Schering-Plough	SE-HYPO: For the treatment of Selenium deficiency in cattle and sheep. Injectable.	Sodium selenate	290
FIL	DIAMOND V SELENOSOURCE AF 2000: dietary supplement in powder form as source of selenomethionine. As an aid in the prevention of selenium deficiency. Doesn't specify which animals it is intended for.	Selenium yeast in powder form	243
Nutritech	HI-TRACE SELENIUM: purpose not specified, but referred to as a selenium supplement. Oral administration.	Selenium	252
	HI-TRACE IODINE AND SELENIUM: purpose not specified, but referred to as a selenium supplement. Oral administration.	Iodine and selenium	252
	TRI-TRACE 3: Copper/selenium supplement for cattle. Administered via oral dosing, for use in drench systems, direct trough dispensers (etc.).	Copper; cobalt; selenium	270
	TRI-TRACE 3 POWDER: Copper/selenium supplement for cattle. Administered via oral dosing, for use in drench systems, direct trough dispensers (etc.).	Copper; cobalt; selenium	270
AHD	SEL-HEALTH 0.5% ORAL DRENCH: for the treatment and prevention of selenium-responsive ill-thrift and white muscle disease in sheep and cattle. To be used when selenium deficiency has been diagnosed. Oral drench.	Selenium as sodium selenate	264
Provet	SELMITT 1: for the treatment and prevention of selenium-responsive ill-thrift and white muscle disease in sheep and cattle. To be used when selenium deficiency has been diagnosed. For oral administration.	Sodium selenate	264
	SELMITT 5: for the treatment and prevention of selenium-responsive ill-thrift and white muscle disease in sheep and cattle. To be used when selenium deficiency has been diagnosed. For oral administration.	Sodium selenate	265
Jurox	COBALEX 2000 PLUS SELENIUM INJECTION: treatment and prevention of cobalt and selenium-responsive conditions in sheep and cattle. For use when selenium deficiency has been diagnosed. Injectable.	Hydroxocobalamin; sodium selenate	280
Novartis	DEPOSEL MULTIDOSE: for the treatment and prevention of selenium deficiency in sheep and cattle. Injectable.	Selenium as barium selenate	283

Company Name	Product Name	Active Ingredient	IVS Page Reference
Bayer	ELEVATE B12 1000 PLUS SELENIUM: for the treatment and control of cobalt and selenium deficiency in lambs, sheep and cattle grazing cobalt and selenium deficient pastures. Injectable.	Hydroxocobalamin; sodium selenate	284
	ELEVATE B12 2000 PLUS SELENIUM: for the treatment and control of cobalt and selenium deficiency in lambs, sheep and cattle grazing cobalt and selenium deficient pastures. Injectable.	Hydroxocobalamin; sodium selenate	284
Bomac	SELOVET-5: for the treatment and prevention of selenium-responsive ill-thrift and white muscle disease in sheep and cattle. To be used when selenium deficiency has been diagnosed. For oral administration.	Sodium selenate	265
	BOLT 1000 B12+ SELENIUM: for the treatment of cobalt and selenium deficiencies in sheep and cattle. Injectable.	Hydroxocobalamin; sodium selenate	276
	BOLT 2000 B12+ SELENIUM: for the treatment of cobalt and selenium deficiencies in sheep and cattle. Injectable.	Hydroxocobalamin; sodium selenate	277
	PROLAJECT B12 1000 PLUS SELENIUM FOR SHEEP AND CATTLE: to treat and control cobalt and selenium deficiencies in sheep and cattle. Also for the treatment of selenium responsive diseases such as ill thrift, infertility and white muscle disease. Injectable. *N.B the animal must be deficient in *both* selenium *and* another trace mineral before use can be prescribed.	Hydroxocobalamin; sodium selenate	288
Bomac	PROLAJECT B12 2000 PLUS SELENIUM FOR SHEEP AND CATTLE: to treat and control cobalt and selenium deficiencies in sheep and cattle. Also for the treatment of selenium responsive diseases such as ill thrift, infertility and white muscle disease. Injectable. *N.B the animal must be deficient in *both* selenium *and* another trace mineral before use can be prescribed.	Hydroxocobalamin; sodium selenate	289
	SELOVIN LA: prevention and treatment of selenium deficiency, ill-thrift, white muscle disease and all other selenium-responsive diseases in sheep and cattle. Injectable.	Barium selenate; chlorocresol as a preservative	290
	SELOVIN-5: prevention and treatment of ill-thrift, white muscle disease and all other selenium-responsive diseases in sheep and cattle and horses. Injectable.	Selenium as sodium selenate	291
Mainfeeds	SELTEC: A selenium supplement to be used to treat selenium deficiency in livestock and poultry. Powder.	Selenium as sodium selenate	291
Stockguard	SMARTSHOT B12 PLUS SE: for long term prevention and treatment of cobalt and selenium deficiencies in sheep and cattle.	Selenium as barium selenate; Hydroxocobalamin hydrochloride.	292

Conclusion on competition

9 The following factors indicate that the Proposed Transaction will not substantially lessen competition in this market:

- The level of aggregation is not significant.
- There are a number of existing competitors, all of which are significant businesses with established reputations in the animal health industry.
- The barriers to entry and expansion are low. New entry and expansion through generics is likely. (Refer to earlier section on 'Potential Competition'.)

10 Table 3.21 shows new products registered with NZFSA over the last two years. There have been five products for the treatment of nutrient deficiencies registered with the NZFSA since the *Schering-Plough/Organon* decision in October 2007.

Table 3.23

Recently registered products for the treatment of nutrient deficiency

Company Name	Product Name	Date of Registration
Bayer	Glutellac	15 March 2007
	Elevate B12 1000 for Sheep and Cattle	22 March 2007
	Elevate B12 2000 Plus Selenium for Sheep & Cattle	22 March 2007
	Elevate B12 2000 for Sheep and Cattle	22 March 2007
	Elevate B12 1000 Plus Selenium for Sheep and Cattle	22 March 2007
Bomac	Calprophos	25 March 2008
	CalproVet	8 November 2007
	Calprophos Xtra	29 April 2008
	Calpromax	7 March 2008
	Vetade	30 January 2008
Centaur Registry Limited	ViBe-Se	27 September 2007
	ViBe	27 September 2007
AgResearch Ltd	SMARTShot Selenium	23 June 2008
Merial	Genesis Injection with B12 and Selenium	9 May 2007
Novartis	B12 2000 Plus Selenium	9 March 2007
Warburton Technology	Multimin Plus Copper for Sheep	2 August 2007
	Multimin Cattle & Sheep	2 August 2007

7. Vaccines

1 The purpose of a vaccine is to protect the animal against future disease or illness caused by bacterial, viral, parasitical or fungal infection.

2 Merial and Schering-Plough have a range of vaccines. However the *Vaccines* table in Appendix 3.1 indicates that the only overlap with Merial is in relation to vaccines for Bovine Viral Diarrhoea (*BVD*).

3 BVD is a pestivirus infection of cattle. It causes a variety of clinical outcomes that range from the inapparent (sub-clinical) to the more severe including abortion, infertility, an immuno-suppression that underlies calf respiratory and enteric diseases, and most dramatically, the fatal mucosal disease.[79]

4 BVD virus spreads by two methods: (i) direct transmission between animals through physical contact and, (ii) by the virus invading the foetus in a pregnant cow. BVD is ideally controlled by vaccination of the breeding herd or vaccination of calves prior to mixing where vaccination of the breeding herd is not possible.[80]

5 Merial and Schering-Plough market the following products for the vaccination of BVD:

Merial	Schering-Plough
VIRACARE 3	BOVILIS BVD

Product differentiation

6 BVD vaccines have a specific use, and cannot be substituted on the demand side for or by other vaccines or medicines.

7 In *Schering-Plough/Organon* the Commission noted that:[81]

> "Campylobacter vaccines have a specific use, and cannot be substituted on the demand side for/by other vaccines or medicines. Nor is there any supply-side substitution, as it is unlikely that entry would be timely enough to suggest the presence of near competitors (the timeliness of entry is discussed later in this Decision). Therefore, for the purpose of the present Application, the Commission is of the view that the market should be defined as a discrete product market for campylobacter vaccines for sheep."

8 The Applicant agrees with the above and accordingly considers that the relevant market, for present purposes, is the market for vaccinations against BVD in cattle.

[79] http://www.rvc.ac.uk/BVD/Index.cfm

[80] http://www.foetalloss.co.nz/Treatment-And-Control/BVD/bvd-vaccination-protocol.html

[81] At paragraph at 160

9 However, BOVILIS BVD and VIRACARE 3 are different in that Merial's VIRACARE 3 is a trivalent vaccine that also provides protection against Infectious Bovine Rhinotracheitis virus and parainfluenza-3, whereas Schering-Plough's BOVILIS BVD is a monovalent vaccine that protects against BVD only.[82]

10 Consequently, while VIRACARE 3 is substitutable for BOVILIS BVD to the extent that both products provide protection against BVD in cattle, BOVILIS BVD cannot be substituted with VIRACARE 3 to the extent that VIRACARE 3 also covers infectious bovine rhinotrocheitis and parainfluenza-3.

Market shares

11 Table 3.22 shows the competitors and their products for BVD vaccinations in cattle. The estimated market shares are set out in Table 3.24A in confidential Schedule 3.1.

12 Market shares and the three-firm concentration ratio following the Proposed Transaction are also set out in confidential Schedule 3.1. This is outside the Commission's safe harbour guidelines.

Table 3.24

Vaccines for BVD

Company Name	Product Name
Merial	VIRACARE 3
Schering-Plough	BOVILIS BVD
Pfizer	PREGSURE BVD

13 The level of aggregation between Merial and Schering-Plough in this market is minimal. The competition in this market is between Schering-Plough and Pfizer. Schering-Plough's BOVILIS BVD is more directly substitutable with the Pfizer product PREGSURE BVD than it is with VIRACARE 3.

- Pfizer's PREGSURE BVD is a monovalent vaccine similar to Schering-Plough's BOVILIS BVD vaccine. Customers are more likely to substitute between monovalent vaccines than between a monovalent and a trivalent vaccine.

- BOVILIS BVD and PREGSURE BVD are further indicated for the prevention of transplacental infection and the birth of persistently infected calves whereas VIRACARE 3 is not.

[82] The Applicant understands that, in some cases, depending on the type of vaccine and the species of animal, the European Commission has defined monovalent vaccines as forming distinct markets from multivalent vaccines.

Potential competition

14 There are a number of large international suppliers active in the supply of vaccines in New Zealand, including:

- Pfizer (with thirty four vaccines);
- Fort Dodge (with sixteen vaccines);
- Virbac (with seven vaccines);
- Bomac (with four vaccines); and
- Boehringer Ingelheim (with one vaccine).

15 Of these, the following suppliers manufacture and market BVD vaccinations internationally:

- *Novartis*: Novartis markets the ARSENAL 4.1 vaccination which is indicated for protection against a broad range of BVD viral strains.[83]
- *Boehringer* Ingelheim: Boehringer Ingelheim markets ten products that provide immunisation against BVD[84] including EXPRESS 10, its newest modified live vaccine.
- *Pfizer*: Pfizer also manufactures the CATTLEMASTER GOLD FP 5[85] product although this product is not currently registered for sale in New Zealand.
- *Fort Dodge*: Fort Dodge manufactures the Triangle 4 + Type II BVD vaccination.[86]

16 There are also numerous other international suppliers active across a range of animal health markets that would be well placed to expand their current vaccine product range to include a BVD vaccine.

17 Pfizer registered its PREGSURE BVD product relatively recently in November 2007 and has obtained a significant market share in less than two years. Boehringer Ingelheim, Fort Dodge and Novartis would be well placed to register their products in New Zealand. Table 3.23 at the end of this section lists other vaccines that have been registered in the last two years, illustrating the ease of introduction of new vaccines. There have been 13 vaccines registered with the NZFSA since the *Schering-Plough/Organon* decision in October 2007.

[83] http://www.livestock.novartis.com/aresenal_dairy.html

[84] http://www.boehringer-ingelheim.ca/vetmedica/bovine.asp

[85] http://www.jefferslivestock.com/ssc/prodcut.asp

[86] http://www.valleyvet.com/ct_detail.html

18 In *Schering-Plough/Organon* the Commission stated that: [87]

> "NZFSA's assessment of the registration package itself is generally not considered to be particularly onerous in terms of either time or cost. NZFSA stated that it aims to complete the process in 40 working days for a generic product and 75 working days for a novel product. The cost is based on an hourly rate, but the total charge is typically in the range of $5,000 to $7,000. The Commission is of the view that registration is thus a relatively low barrier to entry."

Countervailing power

19 In *Schering-Plough/Organon* in relation to Campylobacter vaccines, where the transaction (following divestment) would leave two New Zealand suppliers, the Commission said:[88]

> "Campylobacter vaccines in New Zealand are only sold through veterinarians. Many veterinarians are relatively large and sophisticated buyers, due to a trend of rationalisation in the veterinary industry. For example, Veterinary Enterprises Limited, [ ] has seven[89] veterinarian practices and an approximate annual turnover of $23 million.
>
> Under the factual, veterinarians have two different suppliers of campylobacter vaccines: the combined entity and the purchaser of Campylovexin. [ ] believed that his company did have buyer power over the suppliers, and that there were other large veterinarian groups or practices that would have similar countervailing power. Other veterinarians spoken to by the Commission said that the availability of both products was important as it allows them to play one off the other.
>
> The Commission concludes that veterinarians, many of whom have significant buying power, would have sufficient countervailing power to constrain the combined entity from exercising market power in the counterfactual, due to the presence of an alternative supplier of a campylobacter vaccine for sheep."

20 The Commission concluded that, following the divestment, the combined entity would face constraint from the second vaccine supplier and from the countervailing power of veterinarians. The BVD vaccine is also supplied through veterinarians.

Conclusion on competition

21 The following factors indicate that the Proposed Transaction will not substantially lessen competition in this market:

- The level of aggregation is not significant.
- There are several major international firms with existing BVD vaccines.

[87] At paragraph 236.

[88] At paragraphs 303 – 305.

[89] Veterinary Enterprises Limited now has 10 practices.

- The barriers to entry are low for companies with existing vaccines.
- Veterinarians have countervailing buying power.

Table 3.23

Recently registered vaccines

Company Name	Product Name	Date of Registration
Biosecurity New Zealand	EQUIP F	28 August 2007
	AFTOPUR DOE	25 January 2007
	POULVAC FLUFEND I AI H5N3 RG	25 January 2007
	PORCILIS PESTIS	25 January 2007
	NOBILIS INFLUENZA H5N2	25 January 2007
	EQUILIS PREQUENZA TE	12 August 2008
Boehringer Ingelheim	INGELVAC CIRCOFLEX SUSPENSION FOR INJECTION IN PIGS	13 February 2008
	INGELVAC MYCOFLEX SUSPENSION FOR INJECTION IN PIGS	5 February 2009
Fort Dodge	INNOVATOR EHV-1/4	5 November 2007
Intervet Ltd	ANDROVAX PLUS	2 August 2007
	FLUVAC INNOVATOR	25 February 2008
	SUVAXYN PCV2	17 April 2008
Novartis	PORCINE PILI SHIELD	2 March 2009
Pfizer	BOPRIVA	22 November 2007
	PREGSURE BVD	22 November 2007
	SCOURGUARD 4(K)	25 February 2008
	ULTRAVAC SD 6 IN 1	23 December 2008
Schering-Plough	NETVAX	27 March 2008

Schedules

Schedule 3.1

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