Commerce Act 1986: Business Acquisition

Section 66

Notice Seeking Clearance

7 June 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 give seeking clearance of a proposed business acquisition.

PUBLIC VERSION

Contents

Executive Summary

Proposed Merger

On 25 January 2009, Pfizer Inc and Wyeth Corp entered into a merger agreement under which Pfizer Inc proposes to acquire Wyeth Corp (**Proposed Merger**).

Pfizer (together with its subsidiaries including Pfizer New Zealand Limited, **Pfizer**) and Wyeth (together with its subsidiaries, **Wyeth**) are both biopharmaceutical companies with operations in a range of countries including New Zealand.

Pfizer and Wyeth (**Parties**) make an application for clearance from the New Zealand Commerce Commission (**NZCC**) for the Proposed Merger.

Merger of human health businesses

Both Pfizer and Wyeth are involved in the supply of human health products in New Zealand. Pfizer's New Zealand human health business is conducted by Pfizer New Zealand Limited. Wyeth has a minimal presence in New Zealand and all Wyeth human health products are sponsored by a local distribution company, Pharmacy Retailing (trading as Healthcare Logistics).

Relevant markets

Consistent with previous approaches of the NZCC, Pfizer has used the third level of the Anatomical Therapeutic Chemical classification (**ATC3**) as the starting point for product market definition.

Pfizer has considered the overlaps in the context of national markets for the import and wholesale supply of the following medicines:

- hormonal contraceptives (excluding emergency contraceptive pills (**ECPs**));
- antidepressants and mood stabilisers (excluding over the counter (**OTC**) products); and
- immunosuppressive agents.

Pfizer has also considered the potential pipeline overlaps in relation to:

- other anti-bacterials;
- treatments for rheumatoid arthritis (**RA**);
- treatments for Alzheimer's disease (**AD**);
- treatments for osteoporosis; and
- oncology treatments.

In a number of these markets, there is limited overlap between the Parties.

No substantial lessening of competition in any relevant market

There will be no substantial lessening of competition in any relevant human health market due to:

- the role of Pharmaceutical Management Agency (**Pharmac**), essentially a monopsonist, which largely determines the shares of competitors through its tender policy;
- continued strong competition from large, global pharmaceutical

companies;

- the presence of generic products, which act as a major competitive constraint; and
- the fact that, in most relevant markets, the increment in share as a result of the Proposed Merger is very small.

Countervailing power of buyers and high degree of regulation

All pharmaceutical competitors are constrained by the high degree of regulation present in the industry. The role of Pharmac and the District Health Boards in regulating price through negotiations with pharmaceuticals suppliers exerts a high level of countervailing power. Pharmac, essentially a monopsonist, plays a key role in the market by negotiating pricing with pharmaceutical suppliers and attempting to limit government expenditure on pharmaceuticals. Whether a product receives Pharmac reimbursement or not has a large impact on the product's success and market share. District Health Boards also exercise substantial countervailing power as they purchase a substantial quantity of pharmaceuticals for use in hospitals.

Merger of animal health businesses

Pfizer and Wyeth are also involved in the supply of animal health products. Pfizer's animal health operations in New Zealand and internationally is known as Pfizer Animal Health. Wyeth's animal health subsidiary is Fort Dodge Animal Health (International) and Fort Dodge New Zealand Limited (together, **Fort Dodge**).

Relevant markets

Pfizer submits that the relevant animal health markets for reviewing the Proposed Merger are national markets for the manufacture and/or supply of the following products:

- multivalent vaccines for cats;
- multivalent vaccines for dogs;
- *Bordetella bronchiseptica* (***B. bronchiseptica***) (canine cough) vaccines;
- Leptospirosis vaccines for dogs;
- monovalent *Mycoplasma hyopneumoniae* (***M. hyopneumoniae***) vaccines for swine;
- multivalent *M. hyopneumoniae H parasuis* vaccines for swine;
- Parvovirus vaccines for swine;
- *Streptococcus equi* (***S. equi***) vaccines for horses;
- multivalent clostridial vaccines for sheep and cattle;
- endoparasiticides and endectocides for sheep; and
- endoparasiticides and endectocides for cattle.

In a number of these markets, there is either limited or no overlap between the Parties.

No substantial lessening of competition in a market

There will be no substantial lessening of competition in any of the relevant animal health markets for the following reasons:

- there will continue to be strong competition from large, global pharmaceutical companies;
- in most markets, there will be only small increases in concentration levels;
- in several markets, the demand for the particular product is very low and the Proposed Merger will enable the merged entity to achieve efficiencies in research and development and distribution;
- generics will competitively constrain the behaviour of the merged entity;
- as the NZCC has previously found, there are low barriers to entry and expansion in the animal health industry and importing and contract manufacturing arrangements are commonplace; and
- continued presence of the countervailing power of large distributors and wholesalers.

Competition from global and local suppliers

Post-merger, the merged entity will continue to face strong competition from suppliers who have a significant presence in the pharmaceutical industry globally.

Companies such as Virbac New Zealand Limited (**Virbac**), Bayer New Zealand Limited (**Bayer**), Intervet/Schering-Plough Animal Health (**Intervet/Schering-Plough**), Merial Ancare New Zealand (**Merial Ancare**) and Novartis New Zealand Limited (**Novartis**) will continue to compete aggressively with the merged entity. The global nature of these companies means that they are able to utilise their international research and development (**R&D**) and production expertise and their international portfolio of products to commence supplying new products in New Zealand and to expand their presence in other markets where they are already active.

In addition, there are local suppliers such as Bomac Laboratories (**Bomac**), PacificVet Limited (**PacificVet**) and Ravensdown Fertiliser Co-operative (**Ravensdown**) that will continue to be able to compete effectively against the merged entity at the wholesale supply level. Bomac, which started as a New Zealand only animal health business and is now an international competitor, will be a particularly strong local competitor.

Countervailing power of distributors

The Parties currently distribute their products through veterinary wholesalers and rural supplies stores. These distributors will continue to be able to exercise countervailing power over the merged entity because they are sophisticated buyers who purchase animal health products in large volumes and offer suppliers some costs savings.

Conclusion

For the reasons outlined above, and discussed in more detail in this clearance application, the Proposed Merger will not have the effect or likely effect of substantially lessening competition in any relevant human health or animal health market in New Zealand.

Part A Transaction details

1 The transaction

1.1 The Acquirer

This notice is given by Pfizer Inc, represented in New Zealand by its related company Pfizer New Zealand Limited.

Details for Pfizer New Zealand Limited:

Name and position of person responsible for giving this Notice:	***Jan Tennent,*** ***Director, Business Development & Global Alliances*** **(Person duly authorised to give this Notice on behalf of Pfizer New Zealand Limited)**
Registered Office:	***Pfizer New Zealand Limited*** ***Level 3, Pfizer House,*** ***14 Normanby*** ***Road, Mt Eden*** ***Auckland***
Postal Address:	***As above***
Physical Address:	***As above***
Telephone:	***64 9 638 0000***
Fax:	***64 9 638 0021***
Website:	***www.pfizer.co.nz***
Contact person:	***Jan Tennent***
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All correspondence and notices in respect of this Notice should be directed to:

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1.2 Details of the other merger party

Details for Wyeth Australia Pty Ltd:

Name and position of person responsible for giving this Notice:	***Alice Gianni,*** ***Chief Counsel, Australia & NZ***
Registered Office:	***17-19 Solent Circuit,*** ***Norwest Business Park,*** ***Baulkham Hills, NSW, 2153*** ***Australia***
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Please direct all inquiries regarding Wyeth to:

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Blake Dawson
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Sydney NSW 2000

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Email: peter.armitage@blakedawson.com

1.3 Ownership and control of the merger parties

(a) Pfizer

Pfizer is a global research-based pharmaceutical company operating in the human health and animal health sectors. The company was incorporated in the United States of America (**US**) and its headquarters are located in New York City. Pfizer's shares are listed on the New York, London, Euronext and Swiss Stock Exchanges.

Pfizer manufactures and distributes both prescription and OTC human and animal health care products. In 2008, Pfizer's revenue was US$48.3 billion. Pfizer's human health (or pharmaceutical) business unit accounted for 91.5% of this revenue, with the remaining 8.5% coming from Pfizer's animal health unit.

In 2008, Pfizer spent US$7.9 billion on research and had 106 projects in development. These research activities are undertaken internally at 6 key locations across the US and England. These are:

- Groton and New London, Connecticut, US;
- La Jolla, California, US;
- St Louis, Missouri, US;
- Cambridge, Massachusetts, US;
- Rinat, South San Francisco, California, US; and
- Sandwich, England.

Pfizer also collaborates with third parties such as universities, biotechnology companies and other pharmaceutical firms to undertake research and development activities.

Pfizer Inc is the parent company of Pharmacia International BV. Pharmacia International BV was incorporated in Sweden and has one wholly owned subsidiary in New Zealand – Pfizer New Zealand – which supplies both human and animal health care products.

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[**]** Pfizer acquired **[** **]** Catapult Global Ltd and its 2 wholly owned subsidiaries – Catapult Genetics New Zealand Limited and Catapult Systems LLC. **[**
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Related companies of Pfizer are set out in confidential Attachment A.

Pfizer has the following formal or informal links with its competitors:

Human Health

- Pfizer is a member of the Researched Medicines Industry.
- Globally, Pfizer is engaged in various collaboration projects with other pharmaceutical business partners to research and develop new human health products.

Animal Health

- Pfizer has entered into an agreement with Intervet/Schering-Plough under which Intervet/Schering-Plough distributes sheep endoparasiticides and ectoparasiticides products in Australia and New Zealand under brands owned by Pfizer.
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- Pfizer belongs to the European-based International Federation for Animal Health.
- Pfizer is a member of the Agricultural Compound & Animal Remedies Manufacturers Association (**AGCARM**). AGCARM is an industry association representing New Zealand animal health and crop protection companies. Its

members include Fort Dodge New Zealand Limited, Merial Ancare, Intervet Schering Plough, Elanco New Zealand and Bayer.

- Globally, Pfizer is engaged in various collaboration projects with other business partners to research and develop new animal health products.

(b) Wyeth

Wyeth is a publicly held corporation listed on the New York Stock Exchange.

Wyeth operates manufacturing facilities on 4 continents and has approximately 47,500 employees worldwide. In 2008, Wyeth's revenue was US$22.8 billion. Research and development expenses for 2008 exceeded US$3.3 billion.

Wyeth's activities include the discovery, development, manufacture, distribution and sale of prescription and OTC human health care products. Wyeth also manufactures and distributes animal health products under the trading name Fort Dodge Animal Health. Wyeth's operations are headquartered in New Jersey, while the Fort Dodge Animal Health business is based in Kansas.

Wyeth (a company incorporated in the US) is the ultimate parent company of, and owns directly or indirectly 100% of the issued shares in:

- Wyeth (New Zealand) Ltd (**Wyeth NZ**). The human health products of Wyeth are supplied in New Zealand from its facilities in Australia and the United Kingdom; and

- Fort Dodge, which distributes animal health care products. Fort Dodge has an office in Auckland but no manufacturing facility. It imports products supplied in New Zealand from its facilities in Australia, Spain and the US.

The list of related companies of Fort Dodge is set out in Attachment A.

Wyeth has the following formal or informal links with its competitors:

Human Health

- Wyeth is a member of the Researched Medicines Industry.

- Wyeth purchases empty two piece hard gelatine capsules from Pfizer's "Capsugel" division for use in its Efexor anti-depressant product. **[**

] However, only a very small proportion of these sales related to products sold in New Zealand.

- Globally, Wyeth is engaged in various collaboration projects with other business partners to research and develop new human health products.

- Wyeth is a member of the Vaccines Industry Alliance NZ, a vaccine industry group.

Animal Health

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- PacificVet is a distributor of Fort Dodge's swine, equine and poultry products in New Zealand. It also holds a number of registrations of Fort Dodge products under the Pacific Vet name.

- Fort Dodge is a member of AGCARM.

1.4 Details on what is to be acquired

Pursuant to an Agreement and Plan of Merger dated 25 January 2009 between Pfizer and Wyeth, Pfizer or a company in the Pfizer group will acquire the stock and/or assets of Wyeth in a cash and stock transaction. Once the Proposed Merger is completed, Wyeth will survive as a wholly owned subsidiary of Pfizer. A copy of the Agreement and Plan of Merger (**Merger Agreement**) is included as Attachment B.

Under the merger agreement, Pfizer will acquire all outstanding Wyeth common shares. Wyeth shareholders will receive US$33.00 in cash and 0.985 of a share of Pfizer common stock (valued at $17.19[1]) for each Wyeth common share they own.

The Proposed Merger is subject to the approval of Wyeth shareholders and the satisfaction of customary closing conditions.

Pfizer and Wyeth expect to complete the Proposed Merger at the end of the third quarter of 2009.

1.5 Commercial rationale for the proposed merger

The Proposed Merger is part of an international merger.

Pfizer and Wyeth are both global biopharmaceutical companies with significant operations in a wide range of countries in the Americas, Europe, Africa and the Asia Pacific. The Wyeth and Pfizer human health businesses are largely complementary, with a merger of the two businesses providing the foundation for a strong, diversified health care company. The Wyeth business will provide Pfizer with greater expertise in biologics and biotechnology, where it currently has little focus. In particular, Wyeth is strong in biotherapeutics and vaccines (for example, its pneumococcal vaccine, Prevenar), and brings substantial biomedical expertise that can be used for novel treatment approaches.

Combined with the increased resources for investment in research and development resulting from the merger, the new company will have greater innovation potential in respect of both human health and animal health products. The merged company will also possess increased manufacturing capabilities.

The merger will enable the merged entity to accelerate its growth in emerging markets – Latin America, the Middle East and China – in view of Wyeth's strong presence in infant nutritionals and Pfizer's standing in pharmaceuticals in these important regions.

With its combined geographic presence and diverse portfolio, the merger will create new opportunities for established products and create a lower, more flexible cost base.

[1] Based on the closing price of Pfizer stock on the New York Stock Exchange on 23 January 2009.

1.6 Clearance in other jurisdictions

The Proposed Merger has been, or will be, notified to competition agencies in a number of jurisdictions. The Parties notified the transaction in the US in early March 2009, in Canada towards the end of April 2009, and in the EU and Australia at the end of May 2009. **[**

] The Parties will inform the NZCC as soon as any other formal filings are made.

Part B Human health

2 The Industry

2.1 Description of goods / services supplied by the Parties

(a) Pfizer

Pfizer established its business in New Zealand more than 40 years ago. Since its establishment, Pfizer has grown to become one of New Zealand's leading providers of pharmaceuticals and animal health products. Pfizer employs more than 180 staff in New Zealand.

In New Zealand, Pfizer operates in two major areas:

- prescription medicines; and
- animal health (discussed in Part C below).

Pfizer also supplies a very small number of consumer medicines.[2]

Pfizer currently supplies a number of leading medicines in New Zealand. These medicines include treatments for: infections, arthritis, depression, schizophrenia, hypertension and other heart disorders and some cancers.

The majority of products supplied by Pfizer are manufactured in Australia and imported into New Zealand from Australia.

(b) Wyeth

Wyeth is now one of the leading research-based pharmaceutical and health care products companies in the world, selling products in over 145 countries.

Wyeth's human health business is divided into two main sections:

- Wyeth Pharmaceuticals, including research and development; prescription products; vaccines; biopharmaceuticals; and nutritionals; and
- Wyeth Consumer Healthcare.

All Wyeth human health products are sponsored by a local distribution company, Pharmacy Retailing (trading as Healthcare Logistics). All Wyeth human health products are imported into New Zealand from Australia or the United Kingdom.

2.2 Industry background

(a) Initial approval process

Before a new medicine can be marketed in New Zealand, the consent of the Minister of Health must be obtained.[3] The level of information required for each application depends

[2] The vast majority of Pfizer's consumer medicines were sold to Johnson and Johnson in 2006.

[3] Medsafe New Zealand Medicines and Medical Devices Safety Authority, *Information for Consumers: How Medicines are Regulated*, <http://www.medsafe.govt.nz/Consumers/Regulate.asp> at 4 June 2009.

on the classification of the medicine: as an innovator medicine, a multi-source (or generic) medicine or an OTC medicine. The Medicines Assessment Advisory Committee (an advisory body to the Minister) assesses applications for innovator medicines and Medsafe assesses generic or OTC medicines.[4]

In terms of the application, the requirements are:

- for innovator medicines, the application must include a detailed dossier containing information on safety, quality and efficacy of the medicine;
- for multi-source medicines, an abridged application containing information on the safety, quality and efficacy of the new medicine is sufficient; and
- for OTC medicines, a further abridged application dossier is sufficient.[5]

Changed medicines, those where the medicine is reformulated or the manufacturing process changes, must obtain consent from the Director-General of Health before marketing of the product can commence.[6]

Post-marketing approval, Medsafe undertakes surveillance of marketed medicines (for example, by monitoring adverse reactions in New Zealand).[7]

(b) Role of the District Health Boards

District Health Boards hold the funding for most health services provided by the Government, including the Community Pharmaceutical Budget, and are responsible for providing these services in their particular district.[8] In discharging their functions, the District Health Boards are informed by their statutory objectives, including that of improving, promoting and protecting the health of communities.[9]

Whilst District Health Boards hold the funds to purchase medicines, manages the spending on medicines on their behalf.

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[4] Medsafe New Zealand Medicines and Medical Devices Safety Authority, *Information for Consumers: How Medicines are Regulated*, <http://www.medsafe.govt.nz/Consumers/Regulate.asp> at 4 June 2009.

[5] Medsafe New Zealand Medicines and Medical Devices Safety Authority, *Information for Consumers: How Medicines are Regulated*, <http://www.medsafe.govt.nz/Consumers/Regulate.asp> at 4 June 2009.

[6] Medsafe New Zealand Medicines and Medical Devices Safety Authority, *Information for Consumers: How Medicines are Regulated*, <http://www.medsafe.govt.nz/Consumers/Regulate.asp> at 4 June 2009.

[7] Medsafe New Zealand Medicines and Medical Devices Safety Authority, *Information for Consumers: How Medicines are Regulated*, <http://www.medsafe.govt.nz/Consumers/Regulate.asp> at 4 June 2009.

[8] Ministry of Health, *District Health Boards,* <http://www.moh.govt.nz/districthealthboards> at 4 June 2009.

[9] Ministry of Health, *District Health Boards,* <http://www.moh.govt.nz/districthealthboards> at 4 June 2009.

(c) Pharmac

Pharmac was created in 1993, in response to increasing medicine prices in New Zealand during the 1980s, with the aim of actively managing Government spending on medicines.[10] Pharmac's objective was to "introduce price competition to a market where it had not previously existed".[11]

Pharmac continues this role as a Crown entity,[12] managing the pharmaceutical budget on behalf of District Health Boards and determining the medicines funded by Government.[13] Pharmac negotiates prices of medicines on behalf of District Health Boards and also undertakes educational activities promoting the optimal use of medicines.[14] These activities are conducted in line with Pharmac's statutory objective of securing the best health outcomes for people in need of pharmaceuticals within the budgeted amount as set by the Minister of Health.[15]

One of Pharmac's main roles is to manage the list of Government-subsidised community medicines (the Pharmaceutical Schedule). Pharmac also manages the subsidy of some medicines in public hospitals.[16]

(d) The Pharmaceutical Schedule

The Pharmaceutical Schedule is a list of more than 2000 prescription medicines and therapeutic products subsidised by the Government.[17] On behalf of District Health Boards, Pharmac determines which medicines to list. Pharmac also negotiates the prices and sets the subsidy levels for those products appearing on the Pharmaceutical Schedule.

The Listing Process

Pharmaceutical suppliers, health professionals and consumer groups may apply to Pharmac to have a medicine listed on the Pharmaceutical Schedule for subsidy.[18] In determining the listing of medicines, Pharmac is advised principally by the Pharmacology and Therapeutics Advisory Committee (**PTAC**) as well as specialist subcommittees.[19]

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[10] Pharmaceutical Management Agency PHARMAC, *Information Sheet: PHARMAC's History,* <http://www.pharmac.govt.nz/2008/12/16/02_PHARM_Infsheet_HISTORY.pdf> at 4 June 2009.

[11] Pharmaceutical Management Agency PHARMAC, *Information Sheet: PHARMAC's History,* <http://www.pharmac.govt.nz/2008/12/16/02_PHARM_Infsheet_HISTORY.pdf> at 4 June 2009.

[12] Section 46 of the *New Zealand Public Health and Disability Act 2000*.

[13] Pharmaceutical Management Agency PHARMAC, *About PHARMAC,* <http://www.pharmac.govt.nz/patients/AboutPHARMAC> at 4 June 2009.

[14] Pharmaceutical Management Agency PHARMAC, *About PHARMAC,* <http://www.pharmac.govt.nz/patients/AboutPHARMAC> at 4 June 2009.

[15] Section 47 of the *New Zealand Public Health and Disability Act 2000;* Pharmaceutical Management Agency PHARMAC, *Information Sheet: Introduction to PHARMAC,* <http://www.pharmac.govt.nz/2008/12/16/01_PHARM_Infsheet_INTRO.pdf> at 4 June 2009.

[16] Pharmaceutical Management Agency PHARMAC, *Information Sheet: Introduction to PHARMAC,* <http://www.pharmac.govt.nz/2008/12/16/01_PHARM_Infsheet_INTRO.pdf> at 4 June 2009.

[17] The Pharmaceutical Schedule is available at Pharmaceutical Management Agency PHARMAC, *Pharmaceutical Schedule*, <http://www.pharmac.govt.nz/Schedule> at 4 June 2009.

[18] Ministry of Health, *Appointments to Health Statutory Bodies: PHARMAC,* <http://www.moh.govt.nz/moh.nsf/wpg_Index/About-SBC+-+Crown+Entities+-+Pharmac> at 4 June 2009; see also Pharmacology and Therapeutics Advisory Committee PTAC, *Funding Applications,* <http://www.pharmac.govt.nz/PTAC/fundingapps> at 4 June 2009.

[19] Pharmacology and Therapeutics Advisory Committee PTAC, *Pharmacology and Therapeutics Advisory Committee (PTAC)* <http://www.pharmac.govt.nz/PTAC> at 4 June 2009.

PTAC members, expert doctors, are appointed by the Director General of Health. The Consumer Advisory Committee may also inform Pharmac's decision.[20]

Decisions as to which medicines should be funded are determined according to the Pharmac's nine decision making criteria. Criteria include the availability and suitability of existing medicines; the budgetary impact of any changes to the Pharmaceutical Schedule; and direct cost to health service users.[21]

Following evaluation of an application for funding, the PTAC can make a recommendation on whether to fund the medicine and what priority level it should be given by Pharmac, although it is the District Health Boards that actually fund the medicines (Pharmac manages the funding on behalf of these Boards). A proposal regarding the application is ultimately produced to the Pharmac Board. The Pharmac Board may accept the proposal, in which case the health sector is notified and the Pharmaceutical Schedule updated.[22]

Reference Pricing

Pharmac also determines subsidy levels and negotiates prices for those medicines which appear on the Pharmaceuticals Schedule. In order to maximise the amount of medicines that New Zealand can subsidise, Pharmac encourages competition between pharmaceutical companies and applies a range of pricing strategies.[23]

In setting subsidy levels, Pharmac may apply its policy of reference pricing, where pharmaceuticals in the same therapeutic subgroup are subsidised at the level of the lowest priced pharmaceutical in that sub-group.[24] Expert committees advise Pharmac as to which medicines should be reference priced.[25] Currently, oral contraceptives are reference priced.[26] Pharmac considers that its policy of reference pricing has been a "significant strategy in achieving lower [drug] prices" as a response to the marked increase in drug prices during the 1980s.[27]

Reference pricing, whilst still used, is one of the older mechanisms employed by Pharmac to manage Government spending on medicines listed in the Pharmaceutical Schedule. Pharmac now also uses tendering processes and multi-product agreements.[28]

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[20] Ministry of Health, *Appointments to Health Statutory Bodies: PHARMAC,* <http://www.moh.govt.nz/moh.nsf/wpg_Index/About-SBC+-+Crown+Entities+-+Pharmac> at 4 June 2009.

[21] Pharmaceutical Management Agency PHARMAC, *Decision Criteria,* <http://www.pharmac.govt.nz/DecisionCriteria> at 4 June 2009.

[22] Pharmaceutical Management Agency PHARMAC, *New Funding Applications,* <http://www.pharmac.govt.nz/NewFundingApplications> at 4 June 2009.

[23] Pharmaceutical Management Agency PHARMAC, *New Funding Applications,* <http://www.pharmac.govt.nz/NewFundingApplications> at 4 June 2009.

[24] Pharmaceutical Management Agency PHARMAC, *New Funding Applications,* <http://www.pharmac.govt.nz/NewFundingApplications> at 4 June 2009.

[25] Pharmaceutical Management Agency PHARMAC, *Information Sheet: Purchasing Medicines,* <http://www.pharmac.govt.nz/2008/12/16/06_PHARM_Infsheet_PURCHASING.pdf> at 4 June 2009.

[26] Pharmaceutical Management Agency PHARMAC, *Information Sheet: Purchasing Medicines,* <http://www.pharmac.govt.nz/2008/12/16/06_PHARM_Infsheet_PURCHASING.pdf> at 4 June 2009.

[27] Pharmaceutical Management Agency PHARMAC, *Information Sheet: PHARMAC's History,* <http://www.pharmac.govt.nz/2008/12/16/02_PHARM_Infsheet_HISTORY.pdf> at 4 June 2009

[28] Pharmaceutical Management Agency PHARMAC, *Information Sheet: PHARMAC's History,* <http://www.pharmac.govt.nz/2008/12/16/02_PHARM_Infsheet_HISTORY.pdf> at 4 June 2009

Tendering

Pharmac uses a tender to negotiate sole-supply contracts for off-patent pharmaceuticals,[29] although as noted above, Pharmac acts on behalf of District Health Boards. Expert committees advise Pharmac as to which drugs should be the subject of a tender.[30] Pharmac issues a tender document to pharmaceutical suppliers, inviting bids for a set list of pharmaceuticals. The successful bidder generally is granted sole subsidised supply of the medicine for a fixed term (usually three years).[31]

Tendering by Pharmac commenced in 1997 with nearly half of all subsidised medicines now purchased through the tender.[32] Pharmac estimates that more than $300 million has been saved using tendering.[33]

Multi-product agreements

Where a pharmaceutical company has a portfolio of medicines, Pharmac will often negotiate (on behalf of District Health Boards) multi-product agreements. Pharmac considers that, without multi-product agreements, certain new medicines would not otherwise be affordable.[34] By way of example, Pharmac refers to products purchased using multi-product agreements like the heart failure drug carvedilol (Dilatrend) and the anti-anemia drug erythropoeitin-beta (Recormon).[35]

Expenditure Caps

Expenditure caps are another pricing strategy employed by Pharmac in managing spending on pharmaceuticals. In negotiating the purchasing of medicines on behalf of District Health Boards, Pharmac may negotiate for the inclusion of expenditure caps in pharmaceutical supply contracts. Where annual spending exceeds the agreed cap, the balance (or a portion of it) is refunded.[36]

(e) Fully subsidised and partially subsidised medicines

Once a medicine has been listed on the Pharmaceutical Schedule, there are still a number of limited payments that a consumer may be required to make to purchase the medicine. The price of medicine payable by a consumer depends on whether the

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[29] Pharmaceutical Management Agency PHARMAC, *Information Sheet: Purchasing Medicines,* <http://www.pharmac.govt.nz/2008/12/16/06_PHARM_Infsheet_PURCHASING.pdf> at 4 June 2009.

[30] Pharmaceutical Management Agency PHARMAC, *Information Sheet: Purchasing Medicines,* <http://www.pharmac.govt.nz/2008/12/16/06_PHARM_Infsheet_PURCHASING.pdf> at 4 June 2009.

[31] Pharmaceutical Management Agency PHARMAC, *New Funding Applications,* <http://www.pharmac.govt.nz/NewFundingApplications> at 4 June 2009; Pharmaceutical Management Agency PHARMAC, *Information Sheet: Purchasing Medicines,* <http://www.pharmac.govt.nz/2008/12/16/06_PHARM_Infsheet_PURCHASING.pdf> at 4 June 2009.

[32] Pharmaceutical Management Agency PHARMAC, *Information Sheet: Purchasing Medicines,* <http://www.pharmac.govt.nz/2008/12/16/06_PHARM_Infsheet_PURCHASING.pdf> at 4 June 2009.

[33] Pharmaceutical Management Agency PHARMAC, *Information Sheet: Purchasing Medicines,* <http://www.pharmac.govt.nz/2008/12/16/06_PHARM_Infsheet_PURCHASING.pdf> at 4 June 2009.

[34] Pharmaceutical Management Agency PHARMAC, *Information Sheet: Purchasing Medicines,* <http://www.pharmac.govt.nz/2008/12/16/06_PHARM_Infsheet_PURCHASING.pdf> at 4 June 2009.

[35] Pharmaceutical Management Agency PHARMAC, *Annual Review 2002: Building Relationships* (2002).

[36] Pharmaceutical Management Agency PHARMAC, *Information Sheet: Purchasing Medicines,* <http://www.pharmac.govt.nz/2008/12/16/06_PHARM_Infsheet_PURCHASING.pdf> at 4 June 2009.

medicine is fully or partially subsidised and the type of health card (if any) held by the consumer. Most medicines listed on the Pharmaceutical Schedule are fully subsidised.[37]

The price paid by the Government (specifically, District Health Boards) for a fully subsidised medicine consists of the cost of the medicine,[38] a pharmacy margin[39] and a patient dispensing fee.[40] The cost of the medicine, for example, may be on average $15 with the accompanying pharmacy margin and fee totaling $5, thus giving an average prescription cost of $20.[41] Some medicines, however, will have a far higher cost per prescription.[42]

For fully subsidised medicines, consumers pay the co-payment or Government prescription charge.[43] The level of the Government prescription charge is dependent on the type of health card held by the consumer and is generally less than the full cost of the prescription.[44] The maximum prescription charge for a three month course of medicines varies between $0 and $15 depending on the consumer's status.[45]

The price paid by District Health Boards for partially subsidised medicines consists of the cost of the medicine plus the pharmacy margin and a patient dispensing fee.[46] The cost of the medicine, however, includes a manufacturer's surcharge or premium which is ultimately recouped from the consumer.[47]

For partially subsidised medicines, consumers pay the Government prescription charge (between $0 and $15) as well as a product premium (which covers the manufacturer's surcharge).[48] The product premium is the difference between the subsidy and the manufacturer's price, with a retail pharmacy mark-up applied.[49] Consequently, partially subsidised medicines are usually more expensive to consumers than the fully-subsidised counterparts in the same therapeutic sub-group and general practitioners (**GPs**) are

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[37] Pharmaceutical Management Agency PHARMAC, *Pharmaceutical Charges Explained,* <http://www.pharmac.govt.nz/Schedule/charges> at 4 June 2009.

[38] As determined by negotiations between Pharmac and the manufacturer.

[39] Negotiated between District Health Boards and pharmacies to cover pharmacies' cost of holding the stock.

[40] Negotiated between DHBs and pharmacies to cover the dispensing of medicines. New Zealand Commerce Commission, *The Pharmacy Guild of New Zealand (Inc): Draft Determination* (26 April 2002) at [62]. The Pharmacy Guild of New Zealand (Inc) ultimately withdrew its application for authorisation of a restrictive trade practice: see New Zealand Commerce Commission, "Pharmacy Guild withdraws application for authorisation" (Media release no 52, 17 May 2002).

[41] New Zealand Commerce Commission, 2002, Commerce Act: *The Pharmacy Guild of New Zealand (Inc), Draft Determination,* 26 April 2002, at paragraph 62

[42] New Zealand Commerce Commission, 2002, Commerce Act: *The Pharmacy Guild of New Zealand (Inc), Draft Determination,* 26 April 2002, at paragraph 62

[43] New Zealand Commerce Commission, 2002, Commerce Act: *The Pharmacy Guild of New Zealand (Inc), Draft Determination,* 26 April 2002, at paragraph 68

[44] New Zealand Commerce Commission, 2002, Commerce Act: *The Pharmacy Guild of New Zealand (Inc), Draft Determination,* 26 April 2002, at paragraph 68

[45] New Zealand Commerce Commission, 2002, Commerce Act: *The Pharmacy Guild of New Zealand (Inc), Draft Determination,* 26 April 2002, at paragraph 63

[46] New Zealand Commerce Commission, 2002, Commerce Act: *The Pharmacy Guild of New Zealand (Inc), Draft Determination,* 26 April 2002, at paragraphs 69-70

[47] New Zealand Commerce Commission, 2002, Commerce Act: *The Pharmacy Guild of New Zealand (Inc), Draft Determination,* 26 April 2002, at paragraph 70

[48] New Zealand Commerce Commission, 2002, Commerce Act: *The Pharmacy Guild of New Zealand (Inc), Draft Determination,* 26 April 2002, at paragraph 71; see also Pharmaceutical Management Agency PHARMAC, *Pharmaceutical Charges Explained,* <http://www.pharmac.govt.nz/Schedule/charges> at 4 June 2009.

[49] New Zealand Commerce Commission, 2002, Commerce Act: *The Pharmacy Guild of New Zealand (Inc), Draft Determination,* 26 April 2002, at paragraphs 70-71; see also Pharmaceutical Management Agency PHARMAC, *Pharmaceutical Charges Explained,* <http://www.pharmac.govt.nz/Schedule/charges> at 4 June 2009.

disinclined to prescribe them where a fully-subsidised counterpart is available.[50] In 2002, it was estimated that partially subsidised medicines accounted for less than 5% of all prescriptions issued.[51]

2.3 Industry trends

(a) Rise in generics

Over recent years, the introduction of generic pharmaceuticals has become more commonplace,[52] with the rise in generics expected to continue.[53] As stated in Pharmac's *Annual Review 2008*, "sales of generic medicines are…outpacing sales of brands for the first time".[54] Many 'blockbuster drugs', including some antidepressants, have come off-patent recently, with more patents expected to expire over the next five years.[55]

New Zealand is well-placed to maximise competition from the expected increased in generic medicines over the next 5 years. New Zealand is considered "a world leader in generic acquisition" with Pharmac's "well-established generic acquisition strategies…ensur[ing] that generic medicines are priced at truly competitive levels."[56]

The rise in generics will be supported by Pharmac's commitment to improve the flow of information about generic medicines to medical practitioners.[57] In 2007, following the introduction of the generic version of paroxetine (an antidepressant), Pharmac worked with BPACNZ[58] to help health professionals and patients adjust to the brand change.[59] More generally, BPACNZ has published newsletters for health professionals about best practice generic prescribing.[60] Pharmac, in its *Annual Review 2008*, considers generic medicines to be one of its focal points.[61]

(b) Increasing prescription of antidepressants but decreasing prices

During the 2007-08 year, there was strong growth in the prescription of antidepressant medicines, continuing the recent pattern evident from 2004 onwards.[62] The increasing prescription of antidepressants may have been in part prompted by changes to government policy providing greater subsidisation of these medicines.[63] Prescriptions for

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[50] New Zealand Commerce Commission, 2002, Commerce Act: *The Pharmacy Guild of New Zealand (Inc), Draft Determination,* 26 April 2002, at paragraphs 70-71

[51] New Zealand Commerce Commission, 2002, Commerce Act: *The Pharmacy Guild of New Zealand (Inc), Draft Determination,* 26 April 2002, at paragraphs 70-71

[52] Pharmaceutical Management Agency PHARMAC, *Annual Review 2008* (13 December 2008) at 7.

[53] Pharmaceutical Management Agency PHARMAC, *Annual Review 2008* (13 December 2008) at 11.

[54] Pharmaceutical Management Agency PHARMAC, *Annual Review 2008* (13 December 2008) at 11.

[55] Pharmaceutical Management Agency PHARMAC, *Annual Review 2008* (13 December 2008) at 11; Pharmaceutical Management Agency PHARMAC, *Annual Review 2007* (21 November 2007) at 21.

[56] Pharmaceutical Management Agency PHARMAC, *Annual Review 2008* (13 December 2008) at 11-12.

[57] Pharmaceutical Management Agency PHARMAC, *Annual Review 2008* (13 December 2008) at 7-8; Pharmaceutical Management Agency PHARMAC, *Annual Review 2007* (21 November 2007) at 21.

[58] BPACNZ is an independent organisation that promotes healthcare interventions which meet patients needs and are evidence based, cost effective and suitable for the New Zealand context. It is funded through contracts with Pharmac and the District Health Boards.

[59] Pharmaceutical Management Agency PHARMAC, *Annual Review 2007* (21 November 2007) at 21.

[60] For example, see BPACNZ, *Best Practice: Issue 14* (June 2008).

[61] See Pharmaceutical Management Agency PHARMAC, *Annual Review 2008* (13 December 2008), covering letter.

[62] Pharmaceutical Management Agency PHARMAC, *Annual Review 2008* (13 December 2008) at 25; Pharmaceutical Management Agency PHARMAC, *Annual Review 2007* (21 November 2007) at 21.

[63] Pharmaceutical Management Agency PHARMAC, *Annual Review 2007* (21 November 2007) at 21.

newer antidepressants, mainly selective serotonin reuptake inhibitors (**SSRIs**), account for much of the growth.[64]

Spending on antidepressants increased from 2004 onwards but decreased in 2007-08,[65] reflecting the impact of the introduction of Loxamine, the generic version of paroxetine, in late 2006-07 financial year. As observed in Pharmac's *Annual Review 2007*, the price of antidepressants continues to fall.[66] In light of the increased competition provided by generic paroxetine, prices should continue to decrease in the future.[67]

2.4 Recent mergers in the pharmaceutical industry

Table 1 below sets out mergers in the human health pharmaceutical industry in the last three years:

Table 1 - recent human health mergers

Name of Parties	NZCC Decision	Date of NZCC Determination
Schering-Plough Corporation / Organon Biosciences N.V.	NZCC – Decision No 621 Clearance granted	4 October 2007
Johnson & Johnson / Pfizer Consumer Healthcare	NZCC – Decision No 594 Clearance granted.	8 December 2006
Reckitt Benckiser PLC / Boots Healthcare International Limited	NZCC – Decision No 567 Clearance granted.	30 November 2005
Pfizer / Pharmacia Limited	NZCC - Decision No 496 Clearance granted.	3 April 2003

3 Market Definition

3.1 Horizontal Aggregation

The Parties are both active in the research and development, production and marketing of human pharmaceuticals. However, there are no overlaps between the Parties in either consumer products or nutritionals. As a result of the merger, Pfizer will become a much more diversified company, and this diversification is at the core of the strategic rationale for the transaction.

Pfizer and Wyeth's human health businesses are largely complementary. The Wyeth business has a greater emphasis on biologics and biotechnology, areas in which Pfizer currently has little focus. In particular, Wyeth is strong in biotherapeutics and vaccines. Around 70% of Wyeth's global turnover for human health pharmaceuticals is comprised of products that do not overlap with Pfizer's existing products. These products include some

[64] Pharmaceutical Management Agency PHARMAC, *Annual Review 2006* (24 November 2006) at 24.

[65] In 2007-08, overall spending on antidepressants decreased by NZ$10 million compared with the previous year: Pharmaceutical Management Agency PHARMAC, *Annual Review 2008* (13 December 2008) at 25.

[66] Pharmaceutical Management Agency PHARMAC, *Annual Review 2007* (21 November 2007) at 21.

[67] Pharmaceutical Management Agency PHARMAC, *Annual Review 2007* (21 November 2007) at 21.

of Wyeth's leading or blockbuster drugs such as Prevenar (pneumococcal vaccine) and Enbrel (etanercept), an antirheumatic biologic.

Similarly, there is limited overlap with respect to the Parties' pipeline portfolios. The Parties' R&D portfolios complement each other and do not give rise to substantial overlaps.

This application provides an overview and analysis of affected markets, and an analysis of pipeline overlaps where either Party has a Phase III product that may compete with an existing or Phase III product of the other Party.[68]

3.2 Product market: ATC3

The NZCC and the European Commission (**EC**) have consistently applied the ATC classification used by the European Pharmaceutical Marketing Research Association (**EphMRA**) and by Intercontinental Medical Statistics (**IMS**) [69] as the starting point in human pharmaceutical product market definition in a number of decisions.[70] The ATC classification is hierarchical, including 16 categories, each containing up to four levels. The first level (ATC1) is the most general and the fourth level (ATC4) is the most specific.

In particular, the NZCC has stated that the third level of ATC classification (**ATC3**) allows medicines to be grouped in terms of their therapeutic indications (ie their intended use) and has therefore been used as a starting point for product market definition.[71] However, the NZCC has also stated that it may be necessary to analyse pharmaceutical products at a broader, narrower or mixed level of ATC classification in order to arrive at an accurate assessment of the product market definition.[72] For example:

- a mixed level of ATC classifications may be appropriate where certain products from different ATC classes are substitutes for the treatment of a specific illness or disease; or

- a narrower market definition may be appropriate where some medicines within the ATC3 are prescription only and others can be sold OTC. In this respect, the NZCC has found that OTC products do not compete with prescription medicines for three key reasons:

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[68] The assessment applies only to drugs sold to end users rather than intermediate products, ie inputs.

[69] We note that there is also a World Health Organisation (**WHO**) version of the ATC classification that differs slightly from the EphMRA version. According to a publication by the EphMRA, *Comparison of the WHO ATC Classification & EphMRA/PBIRG Anatomical Classification* available at: http://www.ephmra.org/pdf/WHO%20Harmonisation%20Booklet%202007.pdf , the WHO system generally classifies substances according to the therapeutic or pharmaceutical aspects and in one class only (although particular formulations or strengths can be given separate codes, eg clonidine in C02A as antihypertensive agent, N02C as anti-migraine product and S01E as ophthalmic product).

The EphMRA classifies products, mainly according to their indications and use. Therefore, it is possible to find the same compound in several classes, eg NAPROXEN tablets can be classified in M01A (antirheumatic), N02B (analgesic) and G02C if indicated for gynaecological conditions only.

The purposes of classification are also different: The main purpose of the WHO classification is for international drug utilisation research and for adverse drug reaction monitoring. The EphMRA classification has a primary objective to satisfy the marketing needs of the pharmaceutical companies. Therefore, a direct comparison is sometimes difficult due to the different nature and purpose of the two systems.

[70] See for example, European Commission, Case No. COMP/M.2922 – *Pfizer/Pharmacia* (paragraph 15 onwards), European Commission, Case No. COMP/M.3354 – *Sanofi-Synthelabo/Aventis* (paragraph 14 onwards), European Commission, Case No. COMP/M.4691 – *Schering-Plough/Organon BioSciences*, Decision of 11 October 2007.

[71] See for example, *Glaxo Wellcome Plc/SmithKline Beecham Plc,* NZCC Decision 398, 1 September 2000; *Pfizer Laboratories Ltd/Pharmacia Ltd,* NZCC Decision 496, 3 April 2003; and *Schering-Plough Corporation/Organon Biosciences N.V.*, NZCC Decision 621, 4 October 1997. In the EC, see for example, COMP/M.2922 – Pfizer/Pharmacia, paragraph 15.

[72] *Glaxo Wellcome Plc/SmithKline Beecham Plc,* NZCC Decision 398.

- severity – prescription medicines generally treat more severe conditions;
- clinical risk – prescription medicines generally have a higher clinical risk (eg contraindications, side effects); and
- regulation – prescription medicines are significantly more highly regulated than OTC products.[73]

(a) Pfizer's approach

Pfizer has taken the ATC3 classification as a starting point for providing share data, and have included some references to shares at the ATC4 level for completeness. However, in the context of this application, Pfizer has considered the appropriateness of defining the relevant markets by ATC3 class or an alternative market definition for each overlap.

Pfizer has therefore presented shares and analysis based on the following product markets:

- **contraceptives**: G03A, Hormonal contraceptives (Pfizer has excluded emergency contraceptives as they are sold OTC);
- **antidepressants:** N06A, Antidepressants and mood stabilisers (Pfizer has excluded OTC products such as St John's Wort); and
- **other ATC3 affected markets**: L04A, Immunosuppressive agents.

Finally, the Parties have included analysis of potential product overlaps based on pipeline products that are still in development. With respect to Phase III products, there are overlaps with respect to:

- other anti-bacterials;
- RA;
- AD;
- osteoporosis; and
- oncology.

3.3 Geographic market: national

The Parties consider that the national market is the relevant geographic market. The Parties products are distributed and priced nationally. This is consistent with the NZCC's decision in *Johnson & Johnson / Pfizer*, where the NZCC concluded the relevant markets for OTC products were national.[74]

[73] *Johnson & Johnson/Pfizer Consumer Health Care*, NZCC Decision 594, 8 December 2006.
[74] *Johnson & Johnson/Pfizer Consumer Health Care*, NZCC Decision 594, 8 December 2006, paragraph 73.

3.4 Functional market: importation and wholesale supply

All Pfizer and Wyeth's human health products are imported into New Zealand. These products are manufactured overseas, imported into New Zealand (subject to relevant regulatory approvals), and supplied by distributors to retail outlets such as pharmacies.

Consistent with the NZCC's decision in *Johnson & Johnson / Pfizer*, the Parties consider the relevant functional market is the importation and wholesale supply of medicines.[75]

3.5 Product differentiation

Many pharmaceutical products within the same ATC3 category can be differentiated on a number of bases. These bases include:

- amount and type of active ingredient;
- method of administration (eg intravenous or tablet form);
- spectrum of action (eg anti-fungal or antibiotic);
- mode of action (**MOA**);
- duration of effectiveness; and
- side-effect profile.

Differences between products are discussed in further detail below.

3.6 Conclusion

Pfizer has considered the overlaps in the context of national markets for the import and wholesale supply of the following medicines:[76]

ATC3 classification	Market
G03A	Hormonal contraceptives (excluding ECPs)
N06A	Antidepressants and mood stabilisers (excluding OTC products)
L04A	Immunosuppressive agents
Pipeline overlaps (Phase III)	
J01X	Other anti-bacterials
	Treatments for RA
	Treatments for AD
	Treatments for osteoporosis
	Oncology treatments

[75] *Johnson & Johnson/Pfizer Consumer Health Care*, NZCC Decision 594, 8 December 2006, paragraphs 75 – 77.

[76] We note that historical market share figures may show an overlap between Pfizer's Cytotec and Wyeth's Zoton, which are antiulcerants within the ATC3 class A02B. Wyeth does not currently supply Zoton in New Zealand. Therefore, this overlap has not been discussed in the submission.

3.7 Vertical Integration

The Proposed Transaction does not raise vertical concerns in New Zealand.

Only a very small human health vertical overlap exists between the Parties in New Zealand, as Wyeth uses hard gelatine capsules produced by Pfizer as an input mainly for its antidepressant Effexor on a global basis.

Through its "Capsugel" division, Pfizer produces and sells an empty two-piece hard gelatine capsule manufactured from animal and non-animal gelatine. **[**

] Wyeth currently sources the hard gelatine capsules for Effexor from Pfizer globally. However, there are numerous other suppliers available that can supply equivalent capsules.

In sum, Wyeth's demand for hard gelatine capsules is very small when compared with the demand of other third parties. Switching to another supplier is very easy to implement and Wyeth also sources gelatine capsules from another supplier. Customer foreclosure is therefore highly unlikely to arise. Equally, there is no prospect of input foreclosure, as there are alternatives to hard gelatine capsules for many pharmaceutical drugs delivered by oral dosage (such as tablets, soft gelatine capsules, powder and liquid). There are generally no pharmaceutical drugs for which hard gelatine capsules are the sole or preferred method of oral dosage, or for which hard gelatine capsules offer significant performance advantages over tablets and soft gelatine capsules (the two closest oral dosage substitutes for hard gelatine capsules).

4 Counterfactual

If the Proposed Merger did not take place, the counterfactual is likely to be the status quo: Pfizer and Wyeth would continue running their separate businesses.

5 Competition analysis - overview

5.1 Existing Competitors

There are a large number of strong, existing human health competitors. The table below sets out a brief description of the existing human health competitors, many of which are part of large global pharmaceutical companies. Further information can be found on the website listed for each. Contact details are for these competitors are also included in section 14.1 below.

Table 2 - human health existing competitors

Competitor	Description	Relevant markets in which the competitor is active
Abbott Laboratories (NZ) Limited[77]	Abbott is 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.	Immunosuppressive agents
AFT Pharmaceuticals Ltd[78]	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 region.	Anti-depressants
Apotex NZ Ltd[79]	Apotex is a part of Canadian-owned and operated pharmaceutical company that researches, develops and manufactures generic as well as innovative drugs. Apotex is headquartered in Ontario, and exports to over 115 countries around the world.	Anti-depressants
Arrow Pharmaceuticals[80]	Arrow Pharmaceuticals Pty Ltd is now a division of Sigma Pharmaceuticals Ltd.[81] Sigma is an Australian manufacturer and marketer of prescription, OTC and generic pharmaceutical products. Cash generated from operations was AU$246 million in 2008	Anti-depressants
Aspen Pharmacare	Aspen is part of Aspen Pharmacare Holdings Limited, the largest listed pharmaceutical company in South Africa, with market capitalization in excess of A$2.5 billion[82]	Anti-depressants
AstraZeneca Limited[83]	AstraZeneca is headquartered in London, UK and had net sales of €24.5 billion and invested over €3.4 billion in R&D in 2008.	Oncology
Baxter[84]	Baxter is a global healthcare company with sales of US$12.3 billion in 2008	Immunosuppressive agents, AD
Bayer[85]	Bayer is headquartered in Berlin, Gemany and its sales in 2008 were €10.7 billion	Hormonal contraceptives, oncology
Bristol-Myers Squibb[86]	Headquartered in New York, NY, Bristol-Myers Squibb had net sales of €14 billion and invested	RA, AD

[77] http://www.abbottdiagnostics.com.au
[78] http://www.aftpharm.com/
[79] http://www.apotexnz.co.nz/apotex.php
[80] http://www.arrowpharma.com/index.cfm
[81] http://www.sigmaco.com.au/
[82] http://www.aspenpharma.com.au/our_company.asp
[83] http://www.astrazeneca.com/
[84] www.baxter.com
[85] www.bayer.com

Competitor	Description	Relevant markets in which the competitor is active
	€2.8 billion in research and development in 2008.	
Eli Lilly & Co[87]	Lilly is headquartered in Indianapolis, Indiana. Lilly had net sales of €13.9 billion and invested €2.6 billion in R&D in 2008.	Anti-depressants, AD
Douglas Pharmaceuticals Ltd[88]	Douglas was founded in 1967 and is one of the fastest growing pharmaceutical companies in Australasia. Douglas has two large manufacturing plants in New Zealand and Fiji. It also undertakes contract manufacturing and product development.	Hormonal contraceptives, anti-depressants, immunosuppressive agents
GlaxoSmithKline New Zealand[89]	GSK is headquartered in Brentford, UK. GSK had net sales of €35.7 billion and invested €5.4 billion in R&D in 2008.	Anti-depressants, immunosuppressive agents, RA, AD, oncology
Janssen-Cilag (New Zealand) Limited[90]	Janssen-Cilag is a leading research-based pharmaceutical company. Janssen-Cilag companies operate in virtually all countries of the world and are active in a number of therapeutic areas.	Immunosuppressive agents, AD
Link Pharmaceuticals[91]	Link is headquartered in Sydney with a regional office in Auckland. Link's business is focused on marketing a diverse range of specialist and vitally important therapeutic products in Australia and New Zealand.	Anti-depressants
Lundbeck[92]	Lundbeck is headquartered in Copenhagen, Denmark. Lundbeck has production facilities in Italy and Denmark and research centres in Denmark and the US. Lundbeck generated revenue of approximately DKK 11.3 billion in 2008.	Anti-depressants, AD
Merck Sharp & Dohme New Zealand Limited[93]	Merck was established in 1891 and is headquartered in Whitehouse Station New Jersey. Merck had revenue of $23.9 billion in 2008 and $4.8 billion in R&D.	Osteoporosis
Novartis New Zealand Limited[94]	Novartis is headquartered in Basel, Switzerland. Novartis had net sales of €28.2 billion and invested €4.9 billion in R&D in 2008.	Anti-depressants, immunosuppressive agents, AD,

[86] www.bms.com
[87] http://www.lilly.co.nz
[88] http://www.douglas.co.nz
[89] http://www.gsk.co.nz
[90] www.janssen-cilag.com ,
[91] http://www.linkpharma.com.au/templates/redirect.jsp?id=165
[92] www.lundbeck.com
[93] http://www.msd-newzealand.com

Competitor	Description	Relevant markets in which the competitor is active
		osteoporosis
Pacific Pharmaceuticals[95]	Pacific Pharmaceuticals is now part of Mylan New Zealand, which is part of the Mylan group. Pacific Pharmaceuticals is one of New Zealand's largest generic pharmaceutical companies and effectively poised to respond to changes in the tender market environment. Mylan is headquartered in Pennsylvania, US and had revenue of US$5.14 billion in 2008.	Anti-depressants, immunosuppressive agents
Rex Medical Limited[96]	Rex is a medical device manufacturer and pharmaceutical agent and distributor.	Anti-depressants
Roche Products (New Zealand) Limited[97]	Roche is headquartered in Basel, Switzerland. Roche had sales of CHF45.6 billion and invested CHF8.8 billion in R&D in 2008.	Anti-depressants, immunosuppressive agents, RA, oncology
Sanofi-Aventis[98]	Sanofi is headquartered in Paris, France. Sanofi-Aventis had net sales of €27.6 billion and invested €4.6 billion in R&D in 2008.	AD
Solvay[99]	Solvay is headquartered in Belgium and had sales of €9.5 billion in 2008.	Anti-depressants
Schering-Plough[100]	Schering-Plough is headquartered in New Jersey, US. Schering-Plough had net sales of US$18.5 billion in 2008 and its R&D investment was US$3.5 billion.	Hormonal contraceptives, anti-depressants, immunosuppressive agents, RA

5.2 Potential Competition

(a) Ease of generic entry

In order to market a generic product, a pharmaceutical company only needs to undergo an abridged approval process. Originator drugs are authorised and marketed on the basis of a full application dossier which may include chemical, biological, pharmaceutical, pharmacological-toxicological and clinical data.

However, unlike originator companies, generic drugs do not incur "sunk" costs, eg discovery costs for the search for a new compound, when a medical target is identified and active substances synthesised on a laboratory scale, and a patent is filed because they are by definition off patent. Further, they can be approved by submitting an abridged

[94] http://www.novartis.co.nz
[95] http://www.pacificpharmaceuticals.co.nz/
[96] http://www.rexmedical.com/
[97] http://www.roche.co.nz/
[98] http://www.sanofi-aventis.com.au/live/au/en/
[99] http://www.solvaypharmaceuticals-asia.com/
[100] http://www.schering-plough.com

application dossier if they are similar to an originator product approved on a full application. For generic (or multi-source medicines), the abridged application only requires information on the safety, quality and efficacy of the new medicine.[101]

Therefore, where the clinical data provided with the originator product are not protected by patent, Medsafe will accept applications to register generic products without clinical data on the basis of data that demonstrate that the generic and originator products are bioequivalent, or a justification that bioequivalence data are not required.

Where product details are substantially different to the originator product (eg different indications or directions for use), bridging data will be required to support the difference. New clinical trials may take place to satisfy this requirement. This would also affect timing in bringing a drug to market and cost of entry.

Further details regarding Medsafe requirements are discussed in section 2.2(a) above.

(b) Entry possible without local manufacturing facilities

Many pharmaceutical companies active in New Zealand do not have local manufacturing facilities. A number of the multi-national pharmaceutical companies, including Pfizer have manufacturing facilities in Australia and import products into New Zealand. Other companies with manufacturing facilities in Australia which export to New Zealand include: Merck Sharpe and Dohme,[102] AstraZeneca,[103] Bristol-Myers Squibb;[104] Baxter;[105] and Sigma Pharmaceuticals.[106]

Competitors without local manufacturing facilities are able to sell products in New Zealand through distributors. This is the model that Wyeth currently uses. Distribution services are readily available through companies such as Healthcare Logistics, Pharmaco and DHL. These distributors then supply the products direct to the customer or to other wholesalers. Pharmaceutical wholesalers include: Propharma, CDC and Wainhouse distribution. Therefore, a new entrant would be easily able to distribute its products through existing wholesalers and distributors provided it is able to satisfy regulatory requirements regarding security of supply.

New prescription pharmaceuticals in the relevant markets discussed above could be manufactured by a number of global pharmaceutical companies with offshore manufacturing facilities. Some generic manufacturers such as Douglas Pharmaceuticals also have local manufacturing capabilities.

5.3 Countervailing power of buyers

All pharmaceutical competitors are constrained by the high degree of regulation present in the industry. The role of Pharmac and the District Health Boards in regulating price

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[101] Medsafe New Zealand Medicines and Medical Devices Safety Authority, *Information for Consumers: How Medicines are Regulated* <http://www.medsafe.govt.nz/Consumers/Regulate.asp> at 4 June 2009.

[102] Merck Sharp & Dohme, *About Us,* <http://www.msd-australia.com.au/page.asp?e_page=376739&3570=376573&section=376565&subsection=377268&article=376573> at 4 June 2009.

[103] AstraZeneca Australia, *Manufacturing*, <http://www.astrazeneca.com.au/manufacturing/> at 4 June 2009.

[104] Bristol-Myers Squibb Australia, *Australia Divisions,* <http://www.bmsa.com.au/divisions.html> at 4 June 2009.

[105] Baxter, *Company Statement,* <http://www.baxter.co.nz/about_baxter/company_profile/sub/company_statement.html> at 4 June 2009.

[106] Sigma Pharmaceuticals, *Welcome to Sigma Pharmaceuticals LImited*, <http://www.sigmaco.com.au> at 4 June 2009.

through negotiations with pharmaceuticals suppliers exerts a high level of countervailing power.

Although Pharmac does not actually purchase pharmaceuticals, it plays a key role in the market by negotiating pricing with pharmaceutical suppliers and attempting to limit government expenditure on pharmaceuticals. Whether a product receives Pharmac reimbursement or not has a large impact on the product's success and market share. Therefore, Pharmac is essentially acting as a monosponist.

Pharmac's role as a monopsonist is well recognised both by statute and in a number of cases. Pharmac's high degree of power is acknowledged by a statutory exemption to Part 2 of the *Commerce Act*, set out in section 53 of the *New Zealand Public Health and Disability Act 2000*, which prevents Pharmac's pharmaceutical buying practices from amounting to contraventions of the *Commerce Act*.

The Court of Appeal has also discussed Pharmac's role as a monopsonist in *Astrazeneca Limited v Commerce Commission*:[107]

> *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*.

District Health Boards also exercise substantial countervailing power as they purchase a substantial quantity of pharmaceuticals for use in hospitals. Where pharmaceutical products required 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 District Health Boards for use in hospitals. These are known as National Contract Pharmaceuticals.

5.4 Coordinated market power

In relation to human health, the Proposed Merger would not be likely to facilitate the use of coordinated market power. Pharmac's role, as discussed above, is a key factor that would preclude the exercise of coordinated conduct, and would continue post-merger.

5.5 Efficiencies

The Wyeth business will provide Pfizer with R&D efficiencies. Combined with the increased resources for investment in R&D resulting from the Proposed Merger, the merged entity will have greater innovation potential. The merged entity will also possess increased manufacturing capabilities.

With its combined geographic presence and diverse portfolio, the Proposed Merger will create new opportunities for established products and create a lower, more flexible cost base.

[107] [2008] NZCA 479, paragraph 19.

6 Competition analysis – existing overlaps

6.1 Hormonal contraceptives

(a) Product description

Hormonal contraceptives are used to alter a woman's reproductive system in order to prevent pregnancy. While hormonal contraceptives often take the form of oral contraceptives, whether as an oestrogen/progrestogen (combination) or progestogen only pill, hormonal contraception is also available in the form of injectable hormones, intrauterine devices, implants and contraceptive rings.

- **Combined contraceptive pills**: The combined pill contains two hormones, oestrogen and progestogen. These oral contraceptives are taken daily to prevent pregnancy, and depending on the relative strengths of the two hormones over the course of the prescription cycle, may be monophasic (one phase), biphasic (two phase) or triphasic (three phase) pills. Monophasic pills contain the same fixed amount of oestrogen and progrestogen (in the hormonally active pills) throughout the prescription cycle. Biphasic and triphasic pills, however, have differing amounts of oestrogen and progestogen depending on the stage of the cycle.[108] Combined pills work to prevent the release of the ovum, as well as altering the uterine lining and mucus in the cervix. Most combined pills are packaged as 28 day pill packs, with hormonally active pills for 21 days, and inactive or placebo pills for 7 days.[109]

  The combined pill may also be taken for non-contraceptive purposes, including for the treatment of premenstrual syndrome, endometriosis and acne;[110] and

- **Progestogen-only pills**: Traditional progestogen-only pills include those containing levonorgestrel, norethisterone or etynodiol diacetate.[111] Whilst progestogen - only pills are also indicated for contraception, as they are slightly less effective and require a higher level of patient compliance (eg taking at the same time every day), they are more usually taken by women who are unable to take the combined pill for oestrogen-related reasons; for example, women aged over 35 years or those who smoke.[112]

There are also a number of long-term hormonal contraceptives available, with the benefit of lesser dependence on user adherence. These include:

- **Injectable hormones**: The most common injectable contraceptive is a progestogen-only injection, injected into the muscle every 12 weeks. Over the 12 weeks, the progestogen is slowly released into the body, preventing the monthly release of ova.[113]

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[108] NHS, *Combined Contraceptive Pill: Overview,* <http://www.nhs.uk/conditions/combined-contraceptive-pill/Pages/Introduction.aspx?url=Pages/what-is-it.aspx> at 4 June 2009.

[109] Family Planning Association of Western Australia, *Combined Oral Contraceptive Pill* <http://www.fpwa.org.au/healthinformation/informationsheets/coc/> at 23 March 2009.

[110] NHS, *Combined Contraceptive Pill: Overview* <http://www.nhs.uk/conditions/combined-contraceptive-pill/Pages/Introduction.aspx?url=Pages/what-is-it.aspx> at 23 March 2009.

[111] Faculty of Sexual & Reproductive Healthcare Clinical Guidance, *Progestogen-only Pills* (November 2008).

[112] NHS, *Progestogen-only Pill: Overview,* <http://www.nhs.uk/conditions/Progestogen-only-pill/Pages/Introduction.aspx?url=Pages/what-is-it.aspx> at 23 March 2009.

[113] Family Planning Association of Western Australia, *Injectable Hormonal Contraception: Depa* (June 2008).

- **Implants**: Contraceptive implants generally contain progestogen only and are inserted under the skin on the inside of the upper arm. Once implanted, the hormone is slowly released into the bloodstream, preventing the release of an ovum and altering the cervical mucus and uterus lining. The implant provides contraceptive effect for three years.[114]

- **Intrauterine devices** (**IUDs**): Hormone-releasing IUDs are another form of hormonal contraception. An IUD is inserted into a woman's uterus, slowly releasing the progestogen hormone. These IUDs can provide effective contraception for five years. [115]

- **Contraceptive rings:** Contraceptive rings generally contain both the oestrogen and progestogen hormones. Once inserted, the rings release a steady stream of hormones. Contraceptive rings are generally inserted on the first day of the menstrual cycle, and remain inserted for three weeks, during which ovulation is prevented. The ring is removed during the fourth week of the menstrual cycle, with a new ring inserted seven days later.[116]

As noted above, ECPs have been excluded from the market definition (and the market share analysis) on the basis that:

- they are not likely to be considered close substitutes on a demand-side analysis; and

- ECPs are available OTC unlike other hormonal contraceptives, meaning that they are regulated and marketed differently.

(b) The Parties' products

Wyeth

Wyeth supplies the following hormonal contraceptive products:[117]

Table 3 - Wyeth hormonal contraceptives

Brand	Type	Active ingredients
Combination pills (oestrogen and progesterone)		
**Trifeme	Triphasic	Ethinylestradiol, Levonorgestrel (30mcg/ 50mcg; 40mcg/75mcg; 30mcg/125mcg)
*Triphasil		
*Loette	Monophasic	Ethinylestradiol (20mcg), Levonorgestrel (100mcg)
**Monofeme		Ethinylestradiol (30mcg), Levonorgestrel (150mcg)
*Nordette		
*Minulet		Ethinylestradiol (30 mcg), Gestodene (75mcg)

[114] Family Planning Association of Western Australia, *Contraceptive Implant,* <http://www.fpwa.org.au/healthinformation/informationsheets/contraceptiveimplant/> at 23 March 2009.

[115] Family Planning Association of Western Australia, *Intrauterine Devices,* <http://www.fpwa.org.au/healthinformation/informationsheets/iud/> at 23 March 2009.

[116] Family Planning Association of Western Australia, *Vaginal Contraceptive Ring* <http://www.fpwa.org.au/healthinformation/informationsheets/vaginalring> at 23 March 2009.

[117] Wyeth no longer supplies Microval.

* indicates Pharmac funding[118]
** indicates product is fully subsidised by Pharmac
*** indicates Pharmac sole subsidised supply product

Wyeth has recently released a new product in the US called Lybrel, which is a continuous-use combined contraceptive pill. Unlike the conventional combination pills described above (which generally have 28 day pill packs which contain hormonally active pills for 21 days and inactive pills for 7 days) Lybrel is a continuous-use (or continuous-dosing) pill.[119] In other words, Lybrel contains only hormonally active pills. Lybrel, eliminates, or at least reduces the frequency of, monthly periods, making it especially attractive to women who otherwise suffer painful menstrual periods. Although there are other continuous use products available in the US, eg Seasonique which is supplied by Duramed Pharmaceuticals, Inc .[120] Lybrel is the first continuous-dose combiation pill that aims to eliminate menstruation indefinitely.

Lybrel was approved by the United States Food and Drug Administration (**FDA**) in 2007,[121] making it the first and only FDA-approved low dose combination pill that is taken 365 days per year.[122] **[**
]

As indicated in Table 3 above, all Wyeth's products receive Pharmac funding.

Pfizer

Pfizer supplies the following hormonal contraceptive products:

Table 4 - Pfizer hormonal contraceptives

Brand	Type	Active ingredients
Combination pills (oestrogen and progesterone)		
**Norimin	Monophasic	Ethinylestradiol (35mcg), Norethisterone (500mcg)
***Brevinor		
***Brevinor-1		Ethinylestradiol (35mcg), Norethisterone (1mg)
*Norinyl		Mestranol (50mcg), Norethisterone (1mg)
Progestogen-only products		
***Noriday		Norethisterone (350mcg)
**Depo-Provera	IM injection	Medroxyprogesterone acetate (150mg)

* indicates Pharmac funding[123]

[118] Pharmaceutical Management Agency PHARMAC, Pharmaceutical Schedule, May 2009.

[119] See the Lybrel website, *What is Lybrel?* available at: http://www.lybrel.com/what_is_lybrel/ (accessed 23 March 2009).

[120] See Seasonique's website, *Seasonique*, available at http://www.seasonique.com/default.aspx (accessed 23 March 2009). Seasonique reduces menstruation to four times per year.

[121] Reuters, "Wyeth says FDA approves oral contraceptive Lybrel" (22 May 2007) available at : http://www.reuters.com/article/governmentFilingsNews/idUSWEN833320070522 (accessed 23 March 2009).

[122] See Lybrel website, *Birth control with no regular monthly periods*, available at: http://www.lybrel.com/ (accessed 23 March 2009).

[123] Pharmaceutical Management Agency PHARMAC, Pharmaceutical Schedule, May 2009.

** indicates product is fully subsidised by Pharmac
*** indicates Pharmac sole subsidised supply product

As indicated in Table 4 above, all of Pfizer's products receive Pharmac funding.

(c) Product differentiation

There is an overlap between Pfizer and Wyeth's products within the ATC3 class G03A, Systemic hormonal contraceptives. [124] However, there are differences between the Parties' products, for example, all of Wyeth's products are combination pills, whereas a number of Pfizer's products are progestogen-only products including the Depo Provera IM injection. As noted above, progestogen-only products are quite different and are often used as a "second line" only if combination products are not appropriate for the particular patient. Therefore, for a number of patients (eg those wanting the convenience of a 3 month IM injection), Wyeth's products would not be a particularly close substitute to Pfizer's products.

(d) Market shares and concentration

Table 5 and Table 6 below set out the market shares by value and volume for all hormonal contraceptive products.

Table 5 - Hormonal contraceptives market shares (by volume)

Rank	Supplier	Product name	Volume	% of market share for each product (volume)	Total volume	Total % of market share (volume)

[124] We note that Depo-Provera also has indications for endometriosis, breast and RCC, but this would account for less than 5% of sales internationally.

Rank	Supplier	Product name	Volume	% of market share for each product (volume)	Total volume	Total % of market share (volume)

* indicates Pharmac funding[126]
** indicates product is fully subsidised by Pharmac
*** indicates Pharmac sole subsidised supply product

Table 6 - hormonal contraceptives market shares (by revenue)

Rank	Supplier	Product name	Revenue (NZD)	% of market share for each product (revenue)	Total revenue (NZD)	Total share (revenue)

[125] Pfizer has been unable to obtain data from IMS regarding the sales of Jadelle. This product appears to be supplied predominantly and directly to family planning clinics. [
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[126] Pharmaceutical Management Agency PHARMAC, Pharmaceutical Schedule, May 2009.

Rank	Supplier	Product name	Revenue (NZD)	% of market share for each product (revenue)	Total revenue (NZD)	Total share (revenue)

]

The merged entity's combined share would be **[ ]** (by revenue) and **[ ]** (by volume). While this share (by volume) is above the NZCC's safe harbour guidelines, we note that this is largely due to Pharmac's decisions regarding reimbursement of particular products. A large number of hormonal contraceptives are funded by Pharmac under sole supply agreements, as indicated in Table 5 above. These agreements give the supplier of a molecule exclusive rights to reimbursement of the medicine creating an effective monopoly for three years. However, renewal of that monopoly position is entirely dependent on the supplier winning the subsequent tender round. In relation to hormonal contraceptives, Pfizer was awarded a tender for three products:

- Noriday: the tender was awarded in 2006 – Pfizer expendcts that a new tender process will be conducted in 2009; and

- Brevinor 0.5 and Brevinor 1: the tender was awarded in 2007 – Pfizer expexts that a new tender process will be conducted in 2010.

Bayer, with a **[ ]** market share (by revenue) is a strong competitor in the supply of hormonal contraceptives, with leading products Levlen and Yasmin (both monophasic combination pills), that would continue to be an effective constraint on the merged entity post-transaction.

The pre-merger CR3 would be **[ ]** (by revenue) and **[ ]** (by volume) and post-merger CR3 would be **[ ]** (revenue) and **[ ]** (volume). While this measure would be above the NZCC's safeharbour guidelines, we note that the change in CR3 as a result of the transaction would be relatively small.

(e) Summary of competition analysis

The Proposed Merger would not be likely to significantly lessen competition in relation to the supply of hormonal contraceptives. Importantly, the Parties' product ranges are quite different. Wyeth only supplies combination pills, whereas a number of Pfizer's products are progestogen-only products, including the Depo-Provera intra-muscular (**IM**) injection, **[ ]**. In addition, the merged entity would continue to be constrained by other large global players, including Bayer and Intervet/Schering-Plough.

Further, there are a number of important factors affecting the market which would continue to constrain the merged entity:

- a key determinant of success in the hormonal contraceptives market is the quality of the product, that is, efficacy and/or better side effect profile. For this reason, many of the newer products (often with fewer side-effects) are more successful, even without being fully subsidised by Pharmac (eg Yasmin);

- market shares of competitors in the hormonal contraceptives market is largely determined by Pharmac's national tender policy (described in detail above);

- neither of the Parties has been a particularly vigorous competitor in the market. **[**

  ]. **[**

  ] ; and

- most active ingredients are off-patent. Most oestrogen and progestogen hormones used to manufacture hormonal contraceptives are off-patent (eg ethinylestradiol, levonorgestrel), meaning that barriers to entry are relatively low for a new entrant.

6.2 Anti-depressants

An antidepressant is a medication used to treat Major Depressive Disorder (**MD**)[128] and some anxiety disorders.[129] Antidepressants can be classified by MOA:[130]

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[127] **[ ]**.

[128] Some antidepressants are also used for the treatment of fibromyalgia. Fibromyalgia refers to muscle and connective tissue pain, and is a disorder classified by the presence of chronic widespread pain and a heightened and painful response to gentle touch.

- *Selective Serotonin Reuptake Inhibitor* (**SSRI**) antidepressants are used for depression and anxiety disorders and are considered to be the current standard of drug treatment;

- *Selective Norepinephrine Reuptake Inhibitor* (**SNRI**) antidepressants are similar to SSRIs as they are also used for depression and anxiety disorders. However, they reduce the intake of noradrenalin (which results in the patient feeling less lethargic), which differs from SSRIs;

- *Norepinephrine Reuptake Inhibitor* (**NARI**) antidepressants act via noradrenaline. NARIs are thought to have a positive effect on concentration and motivation;

- *Norepinephrine Dopamine Reuptake Inhibitors* (**NDRI***)* antidepressants stop the reabsorption of the neurotransmitters norepinephrine and dopamine in the brain; and

- *Tricyclic Antidepressants* (**TCAs**) are mainly prescribed to patients suffering from severe depression and have more severe side effects[131] than SSRIs, which are more targeted and have a quicker uptake. TCAs are the first generation of antidepressants and are rarely used now due to the development of more selective and safer drugs.

Despite similar effectiveness, the choice of an antidepressant depends on the precise clinical diagnosis, tolerability, the likelihood of adherence, use of non psychiatric drugs, patient preference and cost of medication. Generally, the initial treatment option is an SSRI antidepressant followed by an SNRI as a second line.

(a) The Parties' products

Wyeth

Wyeth's Efexor XR (venlafaxine hydrochloride) is an SNRI within the ATC3 category N06A and is one of the leading antidepressants. Efexor XR is used in all lines of treatment of MD and General Anxiety Disorder (**GAD**). The original version (an immediate release formulation) of Efexor was first launched in the US in 1994. In 1997, Wyeth launched an extended release formulation of Efexor with the same active ingredient, known as Efexor XR. Efexor XR is the only Efexor-branded product Wyeth supplies in New Zealand.

In New Zealand, Efexor XR is indicated for MD (including for the prevention of relapse and recurrence of MD where appropriate), GAD, Social Anxiety Disorder (**SAD**) and panic disorder (**PD**).[132] However, Efexor XR is essentially only reimbursed for its use as a third line treatment for MD as Efexor XR only receives (full) Pharmac subsidy where it is

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[129] Anxiety disorders include: General Anxiety Disorder (**GAD**), Panic Disorder (**PD**), Social Anxiety Disorders (**SAD**), Obsessive Compulsive Disorder (**OCD**), Post-Traumatic Stress Disorder (**PTSD**), Acute Stress Disorder (**ATS**), Specific Phobia (**SP**), Agoraphobia (**AG**)**,** Premenstrual Dysphoric Disorder (**PMDD**) and Other Anxiety Disorders (**OAD**).

[130] Other antidepressants include: Noradrenergic and Specific Serotonergic Antidepressants (NASSAs) that form a new class of antidepressants, rare in clinical use; and, Monoamine Oxidase Inhibiters (MAOI) that may be used if other antidepressant medications are ineffective, but are rarely prescribed due to their negative side effects.

[131] For example, memory difficulties, hypersensitive reactions, cognitive difficulties, urinary retention.

[132] Medsafe New Zealand Medicines and Medical Devices Safety Authority, *Information for Health Professionals: Efexor Data Sheet* <http://www.medsafe.govt.nz/profs/datasheet/e/efexorxrcap.htm> at 4 June 2009.

prescribed on authority for the MD indication. Such an authority is subject to the following restrictions:[133]

- the patient has 'treatment-resistant' depression; and
- either:
  - the patient must have had a trial of two different antidepressants and failed to respond to an adequate dose over an adequate period of time (usually at least four weeks); or
  - both:
    - the patient is currently a hospital in-patient as a result of an acute depressive episode; and
    - the patient must have had a trial of one other antidepressant and failed to respond to an adequate dose over an adequate period of time.

The patent on Efexor's active ingredient (venlafaxine) expired in 2008 (in the EU) for the immediate-release formulation, while the patent on the extended-release formulations and the use of the extended release capsule form will expire in New Zealand in **[ ]**. Two companies (Pacific Pharmaceuticals and Rex Medical) have already registered generic extended release products and an additional application for registration is pending (Dr. Reddy's New Zealand Limited).

(b) Pfizer

Pfizer's antidepressants fall into ATC3 class N06A. The patents for both of Pfizer's antidepressants have expired in New Zealand and these products are not actively promoted by Pfizer. Neither of Pfizer's anti-depressants receive any Pharmac reimbursement for any indication. Pfizer's antidepressants are Zoloft (sertraline hydrochloride) and Edronax (reboxetine mesylate).

Zoloft is an SSRI approved for the following indications in New Zealand: depression / MD (including prevention of relapse), PD, Obsessive Compulsive Disorder (**OCD**) (adults and children), SAD, Premenstrual Dysphoric Disorder (**PMDD**) and post-traumatic stress disorder (**PTSD**). Zoloft does not receive Pharmac reimbursement for any indication, and therefore has a very low sales share (less than **[ ]** by value or volume).[134]

Edronax is a NARI: it does not inhibit the reuptake of serotonin, therefore it can be safely combined with an SSRI. In New Zealand, Edronax is only indicated for the treatment of depression / MD. Based on recent medical studies, it is less effective than SSRIs or SNRIs in the treatment of MD, hence its lower share relative to other antidepressants (see Table 8 and Table 9 below). Further, Edronax does not receive Pharmac reimbursement for any indication, and therefore has a very low sales share (less than **[ ]** by value or volume).[135]

[133] Pharmaceutical Management Agency PHARMAC, Pharmaceutical Schedule, May 2009.
[134] IMS, MAT Jan 2009.
[135] IMS, MAT Jan 2009.

(c) Product differentiation

Pfizer and Wyeth's products have a very small overlap in relation to the treatment of MD based upon ATC3 class. However, the Parties' products are not particularly close substitutes because:

- they have different MOAs and they are used for different indications (see Table 7 below);
- the patents for Pfizer's medicines, Zoloft and Edronax have expired and the available generic alternatives (with identical molecules) are the closest substitutes to Pfizer's products; and
- other antidepressants are closer substitutes to the Parties' products based on MOA. Other SSRIs, such as Lexapro, will be closer substitutes to Zoloft, other SNRIs will be closer substitutes to Efexor XR.

Table 7 - Pfizer and Wyeth anti-depressant comparison

Supplier	Product	Type	MD	SAD	OCD	PMDD	GAD	PD	PTSD
Pfizer	Zoloft	SSRI	Yes	Yes	Yes	Yes		Yes	Yes
	Edronax	NARI	Yes						
Wyeth	Efexor XR	SNRI	Yes*[136]	Yes			Yes	Yes	

* indicates Pharmac funding for this indication

(d) Market shares

Table 8 and Table 9 below set out the market shares by value and volume for all anti-depressant products.

Table 8 – anti-depressant market shares (by volume)

Rank	Supplier	Product name	Volume	% of market share for each product (volume)	Total volume	Total % of market share (volume)

[136] Pharmac reimbursement is subject to authority on the basis of the conditions set out above.

Rank	Supplier	Product name	Volume	% of market share for each product (volume)	Total volume	Total % of market share (volume)
		TOTAL				100%

]

* indicates Pharmac funding[137]
** indicates product is fully subsidised by Pharmac
*** indicates Pharmac sole subsidised supply product

Table 9 – anti-depressant market shares (by revenue)

Rank	Supplier	Product name	Revenue	% of market share for each product (revenue)	Total revenue (NZD)	Total share (revenue)

[137] Pharmaceutical Management Agency PHARMAC, Pharmaceutical Schedule, May 2009.

Rank	Supplier	Product name	Revenue	% of market share for each product (revenue)	Total revenue (NZD)	Total share (revenue)

]

The merged entity's combined share would be **[ ]** (by revenue) and **[ ]** (by volume). While this share (by revenue) is above the NZCC's safeharbour guidelines, we note that the increment would be very small (less than **[ ]** by revenue and volume) as neither of Pfizer's anti-depressants receive any reimbursement from Pharmac. Also, as with hormonal contraceptives, we note that market share is largely determined by Pharmac's decisions regarding reimbursement of particular products.

Table 8 and Table 9 show that the market for antidepressants is fragmented with many competitors, both originator brands and generic alternatives.

The pre-merger CR3 would be **[ ]** (by revenue) and **[ ]** (by volume) and post-merger CR3 would be **[ ]** (by revenue) and **[ ]** (by volume). While this measure would be above the NZCC's safeharbour guidelines, we note that the change in CR3 as a result of the transaction would be very small (less than **[ ]**).

(e) Summary of competition analysis

Antidepressants are grouped in the ATC3 class N06A, Antidepressants and mood stabilisers. Pfizer and Wyeth are both present in this class. However, at the ATC4 level, the Parties' products are not categorised in the same class, therefore there is no overlap at the ATC4 level.

The Proposed Merger does not give rise to competition concerns as:

- the increment in share as a result of the Proposed Merger is very small (less than **[ ]** by revenue and volume) as Pfizer's anti-depressants do not receive Pharmac reimbursement and therefore have very low shares;
- market shares are largely determined by Pharmac reimbursement and sole supply agreements, which would continue to be controlled by the Pharmac tender process post-merger; and

- the Parties' products are not particularly close therapeutic substitutes, as they have different MOAs and indications. More importantly, many of the products compete directly with generic alternatives, which are the closest substitutes, as well as with other molecules that have the same MOAs.

6.3 Immunosuppressive agents

(a) Product description

Immunosuppressive agents act to suppress the body's immune response through various mechanisms. In organ transplantation, immunosuppressants are used to prevent the body from either recognising or attacking the foreign organ via various immune responses.

(b) The Parties' products and product differentiation

There is a small overlap between Pfizer's Atgam (equine antithymocite immunoglobulin) and Wyeth's Rapamune (sirolimus), which both are within the ATC3 class L04A, Immunosuppressive agents. Atgam and Rapamune are both fully subsidised[138]

The Parties' products are not particularly close substitutes with different MOAs and indications. Atgam is a lymphocyte immune globulin indicated for treatment of renal transplant patients for reduction of peripheral T lymphocyte function. Rapamune is a macrocyclic lactone selective immunosuppressant indicated for rejection prophylaxis in renal transplant patients at mild to moderate immunological risk.

(c) Market shares

Table 10 and Table 11 below set out the market shares by volume and value for all immunosuppressive agents.

Table 10 – immunosuppressive agents market shares (by volume)

Rank	Supplier	Product name	Volume	% of market share for each product (volume)	Total volume	Total % of market share (volume)

[138] We note that Atgam is a pharmaceutical cancer treatment only and is therefore purchased by the District Health Boards. Also, Rapamune is available only with an authority from a hospital pharmacy.

Rank	Supplier	Product name	Volume	% of market share for each product (volume)	Total volume	Total % of market share (volume)

]

* indicates Pharmac funding[139]
** indicates product is fully subsidised by Pharmac
*** indicates Pharmac sole subsidised supply product

Table 11 – immunosuppressive agents market shares (by revenue)

Rank	Supplier	Product name	Revenue (NZD)	% of market share for each product (revenue)	Total revenue (NZD)	Total % of market share (revenue)

[139] Pharmaceutical Management Agency PHARMAC, Pharmaceutical Schedule, May 2009.

Rank	Supplier	Product name	Revenue (NZD)	% of market share for each product (revenue)	Total revenue (NZD)	Total % of market share (revenue)

]

As can be seen from Table 10 and Table 11 above, the merged entity would have a low combined share: **[ ]** (by revenue) or **[ ]** (by volume). The CR3 is **[ ]** (by revenue) or **[ ]** (by volume), which is below the NZCC's threshold of 70%. The CR3 does not change as a result of the Proposed Merger.

(d) Summary of competition analysis

The Proposed Merger does not raise any issues in relation to immunosuppressive agents. The Parties' combined share would be less than **[ ]** (by revenue and volume) with a very small level of post merger aggregation. The CR3 would be below the NZCC's threshold of 70% and would not change as a result of the Proposed Merger. Further, the Parties' products are not particularly close substitutes with different MOAs and indications. Finally, there are a number of strong competitors including Novartis, Douglas, Baxter and Janssen-Cilag.

7 Competition analysis - pipeline products

7.1 Pipeline overview

(a) R&D portfolios

The Parties note that their R&D activities are generally conducted at a global level. For this reason, the majority of the discussion and analysis presented below has been extracted from the Parties' submission to regulators in Europe and United States, with some amendment where relevant for New Zealand.

The Parties' R&D portfolios are highly complementary with few overlaps. This is partially explained by the different focus of existing products. For instance, Wyeth has a strong presence in biotherapeutics and vaccines (spending approximately **[ ]** in R&D – **[ ]** of its research spending) where it naturally seeks to expand, whereas Pfizer's R&D spend for such biologics is much smaller (around **[ ]** of its total R&D budget for 2009). The Parties' R&D budgets and R&D portfolios underline the difference in focus and the complementary nature of the Proposed Merger.

In 2009, the majority of Pfizer's R&D spend by therapeutical area will be in oncology, inflammation/immunology, and cardiovascular metabolic disease. By contrast, the majority of Wyeth's spending in 2008 by therapeutic area was in vaccines and neuroscience.

(b) Overview of product development phases

In the development of medicines, a distinction is normally made between drug *discovery*, consisting of the search for a new compound, and drug *development*, which involves preclinical testing for safety and various stages of clinical trials.

In general, there is no difference in approach or timing between the development of biologics and molecules (large or small).[140] Discovery can range from 1-3 years, clinical research can range from 1-2 years, and marketing authorisation approval can range from 2 months - 7 years.[141] There are two key factors that can influence timing: (1) the underlying illness may make it difficult to see any effects in a short period so that trials take years rather than months to complete, eg cancer or other chronic conditions; and (2) patient recruitment may take several years. For example, if a drug is intended to show a strong effect like disease modification, this would require a large trial for statistical purposes. Seeking the right patient profile may take some time.

The first step in the drug discovery is the *search* for a new compound, when a medical target is identified and active substances synthesised on a laboratory scale. At this point, a patent for the compound is usually filed. These substances are screened to find a development candidate with the necessary attributes, such as potency at the molecular target, selectivity over other pathways and features such as solubility, pharmacokinetics and stability, all of which make a chemical entity "drugable."

The new compound is subsequently subjected to *preclinical testing*. Laboratory and, often, animal studies are conducted to show biological activity of the compound against the targeted disease and the compound is evaluated for safety.

After a compound has been identified and sufficiently tested, it is ready for the development phase, which tests compounds for safety and efficacy. First, the new compound is synthesised on a large scale and formulated for clinical use. The new compound is subsequently subject to preclinical testing, such as laboratory and animal studies to show biological activity against the targeted disease. After completing preclinical testing and having demonstrated suitable stability and chemical quality (purity) tests, an application is filed with the relevant body to begin clinical trials to test the drug in people. This involves the following different stages:

- ***Phase I***: These tests involve about 20 to 100 healthy volunteers (except in the case of cancer and HIV, for which first trials are often first carried out on patients). The tests study a drug's safety profile, including the safe dosage range. These studies also determine how a drug is absorbed, distributed, metabolised and excreted as well as any measures of drug activity on physiological or biochemical pathways. The objective here is to identify a narrow range of dose levels, and a dose interval, or frequency, which will be used in Phase II.

- ***Phase II***: In this phase, controlled trials of approximately 100 to 500 volunteer patients (people with the disease) assess a drug's effectiveness. Safety, tolerance, and pharmacokinetic data are also obtained in Phase II.

- ***Phase III***: This phase usually involves 1,000 to 5,000 patients in clinics and hospitals, and the objective is to confirm the efficacy and safety of the test compound versus placebo and/or the standard of care for a given disease. Doctors monitor patients closely to confirm efficacy and identify adverse events. The larger Phase III clinical trials usually involve multiple sites in different countries.

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[140] Small molecule drugs are typically composed of only 20 to 100 atoms. Large molecules and small biologics, such as hormones, are typically composed of 200 to 3000 atoms, while large biologics, such as antibodies, are typically composed of 5000 to 50,000 atoms. Many small molecule drugs can be taken orally, and tend to work in the body within cells. Since biologics are significantly larger in size, they are typically injected and interact within the body in the bloodstream or on the surfaces of cells, rather than within the cells.

[141] These are estimates published by the US Food and Drug Administration; there may be slight variations in New Zealand.

Following the completion of all three phases of clinical trials, the data is further analysed. If the data successfully demonstrate both safety and effectiveness, and if the pharmaceutical (chemical) quality of the compound can be demonstrated, an application for registration is made to the Minister of Health. Once the product is approved, large scale manufacturing, distribution and marketing starts. Post-marketing clinical studies and surveillance will take place on a larger scale (allowed by the marketing authorisation), often referred to as Phase IV testing.

(c) Assessment of pipeline products in previous decisions

In the *Pfizer / Pharmacia* decision,[142] the NZCC had regard to possible overlaps of products in development. However, these products were ultimately divested worldwide to remove the aggregation.

In its previous decisions in the pharmaceuticals sector, the EC has taken the view that a full assessment of the competitive position merger parties requires an analysis of products that are not yet on the market but are at an advanced stage of development. The EC has thus considered that products in R&D are relevant for an assessment of the competitive situations on existing product markets as well as on possible future markets.

Most recently in the EC's decisions in *Teva / Ivax,*[143] *Sanofi-Synethelabo / Aventis*,[144] *Pfizer / Pharmacia,*[145] and *GlaxoWellcome / SmithKline Beecham*[146] the EC indicated that an analysis of projects in Phase III of development gives a more accurate estimation of new compounds entering the market in the near future than earlier phases. The *Ciba-Geigy / Sandoz*[147] and *GlaxoWellcome / SmithKline Beecham*[148] decisions noted that statistically projects in Phase I generally have no more than a 10% chance of being approved. According to industry estimates from 2002-2007 (top 13 large pharmaceutical companies), projects in Phase I have a 12% chance of being approved, projects in Phase II have a 22% chance of being approved, and projects in Phase III have a 64% chance of being approved.[149] Pfizer's equivalent approval rates are **[ ]**.[150]

Therefore, the Parties emphasise that an analysis of projects at an earlier stage of development cannot give a reliable indication of products likely to enter the market for the purposes of a merger assessment, particularly for the development of originator drugs (as opposed to generic drugs). Originator drugs require more extensive and longer trials for R&D in areas where the ultimate therapeutic indication can only be determined with any degree of certainty in Phase III. Indeed, even for the Phase III products identified as overlaps, the period until launch is uncertain and, on average, still takes three years.

With respect to Phase III products, there are overlaps only with respect to:

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[142] *PfizerLaboratories Limited/Pharmacia Limited*, NZCC Decision 496, 3 April 2003, paragraph 70.

[143] European Commission, Case No. COMP/M.3928 *Teva/Ivax*, Decision of 24 November 2005, at paragraph 51.

[144] European Commission, Case No. COMP/M. 3354 *Sanofi-Synthelabo/Aventis*, Decision of 26 April 2004, at paragraph 17.

[145] European Commission, Case No. COMP/M.2922 *Pfizer/Pharmacia*, Decision of 27 February 2003, at paragraph 22.

[146] European Commission, Case No COMP/M.1846 *GlaxoWellcome/Smithkline Beecham,* Decision of 8 May 2000, at paragraph 190.

[147] European Commission, Case No. IV/M.737, *Ciba-Geigy/Sandoz,* Decision of 17 July 1996.

[148] European Commission, Case No. COMP/M.1846 *GlaxoWellcome/Smithkline Beecham,* Decision of 8 May 2000, at paragraph 70.

[149] R&D Performance: Success Rates & Cycle Time by the Pharmaceutical Benchmarking Forum (January 2009).

[150]

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- RA;
- AD;
- osteoporosis; and
- oncology.

In analysing these overlaps, the Parties have looked at the following factors:

- ***Current market position*****:** if there is an overlap with an existing product, the current market position can be used as a proxy for the market position at the time of the expected launch of the other Party's competing pipeline product. Obviously the future market position will be affected by the degree of protection that the product will then enjoy;
- ***Closeness of therapeutic substitution:*** even if products have broadly the same therapeutic indications, they can still differ significantly in terms of MOA, positioning (e.g. first line or second line treatment), administration (IV versus oral), pricing, safety profile or side effects. This analysis is inevitably difficult as the exact future positioning of pipeline products is not clear even in Phase III; and
- ***Existing and pipeline competition:*** the existence of substitutable products from third parties whether on the market or in the pipeline needs to be taken into account. There can be a competitive concern only if the potential entrant is a unique entrant. If there are other pipeline products with a similar profile, it is difficult to qualify the Parties' pipeline products as unique particularly if these competing pipeline products will be brought to the market before, or at around the same time, as the Parties' products.

7.2 Other anti-bacterials

(a) The Parties' products

Wyeth

] Tygacil (tigecycline) is a broad spectrum antibiotic, administered intravenously and used exclusively in hospitals. Tygacil can be used for the treatment of both aerobic and anaerobic Gram negative bacteria and including antibiotic resistant strains such as MRSA and vancomycin resistant *Eneterococcus sp* (**VRE**).[151]

Elsewhere in the world, Tygacil is indicated for the treatment of infections caused by susceptible strains of Escherichia, enterococci, staphylococci or streptococci in adults.[152] The prescribing information for Tygacil also includes dosage guidance for complicated skin and skin-structure infections (**cSSSIs**) and complicated intra-abdominal infections (**cIAIs**). **[**
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Tygacil is the first in the new class of antibiotics known as glycylcyclines, derived from tetracyclines but distinguished by the presence of a glycylamido moiety. IMS categorises

[151] VRE is very rare and represents a tiny fraction of total prescriptions.

[152] Registered indications in Australia.

Tygacil in the ATC3 class J01X, the class for all antibiotics that do not fit into a specific J1 class. This classification is inconsistent with the classification in the WHO version of the ATC, which groups Tygacil under ATC3 class J01A, Tetracyclines. The Parties consider that this is a more appropriate classification, since glycylcyclines are derived from tetracyclines. If WHO classification is adopted, there is no ATC3 overlap.

Pfizer

Pfizer's product, Zyvox (linezolid), is a Gram positive only agent, in the J01X category.[153] It is a synthetic narrow spectrum antibiotic of the oxazolidinone class. Zyvox is indicated for suspected or proven infections due to Gram-positive organisms including those associated with concurrent bacteraemia such as:

- pneumonia (community acquired and nosocomial);
- complicated skin and soft tissue infections (**cSSTIs**); and
- Enterococcal infections (including MRSA and VRE).

Zyvox is specifically marketed by Pfizer as an MRSA agent, and not as a general use antibiotic.

Zyvox is available both in an intravenous and an oral tablet form. Zyvox is not listed on the Pharmaceutical Scheudle.

(b) Pipeline overlap

Therefore, there would be some overlap between Zyvox and Tygacil in the following indications:

- treatment of gram-positive infections (mainly streptococcus, staphylococcus) in adults with MRSA cSSTIs and cSSSIs;
- treatment of a suspected mixed pathogen (eg cSSTIs, IAIs, complicated DFIs); and
- treatment of enterococcus infections.

However, the products are not particularly close therapeutic substitutes for the following reasons:

- **Bacteria**: Tygacil is a broad spectrum agent that is effective against both aerobic and anaerobic gram positive and gram negative bacteria whereas Zyvox is a narrow-spectrum agent that can be used only against gram positive bacteria. As such, there is an overlap only with respect to gram positive bacteria. Both agents can be used against MRSA but whereas Zyvox is positioned as a MRSA agent; Tygacil is not (the majority of Tygacil usage is for non-MRSA infections); and
- **Therapy stage and administration**: Tygacil is approved for both suspected and confirmed SSTI cases whereas Zyvox is only approved when the infection is confirmed as a Gram positive infection. Zyvox also has a stronger position among discharged patients as it is offered as an IV and an oral agent (Tygacil is IV only).

[153] We note that Pfizer is also listed in the data as supplying Colymycin. Although this data has been included in our analysis, Pfizer no longer supplies Colymycin.

(c) Existing products

The main alternatives to Tygacil and Zyvox for the treatment of MRSA infections are Targocid and Vancomycin. Table 12 below summarises the treatments for MRSA infections.

Table 12 - Antibiotics effective against MRSA

	Zyvox (Pfizer)	Tygacil (Wyeth)	Targocid (generic)	Vancomycin (generic)
Compound	Linezolid	Tigecycline	Teicoplanin	Vancomycin
Class	Oxazolidinone	Glycylcycline	Glycopeptide	Glycopeptide
Gram positive/ negative	Positive	Negative/ positive	Positive	Positive
-IV	✓	✓	✓[154]	✓
-Oral	✓			
Dosing	2x daily	2x daily	1x daily	2x daily

Source: Pfizer internal

- ***Vancomycin*** remains the leading anti MRSA drug with a share over **[ ]**. Vancomycin has been used to treat MRSA since 1958 and was the only treatment option until the mid 1990s. Vancomycin has been generic for more than twenty years. Vancomycin belongs to the glycopeptide class and is administered intravenously. It is the drug of choice for skin infections because it treats a wide range of pathogens, has an established safety profile, is well known by doctors, and is relatively inexpensive.

- ***Targocid*** (Sanofi-Aventis) is the first streptogram, a new antibiotic class. As with Vancomycin, it belongs to the Glycopeptide class.

(d) Phase III pipeline products

Pfizer has a product in Phase III clinical trials Dalbavancin (Exulett). Dalbavancin is similar in class to Vancomycin and is a Gram positive agent from the Glycopeptide class. It is administered only intravenously. Zyvox may be used as a complement if the patient does not respond to Dalbavancin, or has a VRE infection. Further, the two drugs have different pathways and Dalbavancin is likely to be more directly substitutable with Vancomycin (ie Glycopeptide users). It is not likely to be a good alternative to Tygacil as it is not a broad spectrum agent and it is unlikely to focus on the same indications or infection sites.

On 9 September 2008, Pfizer withdrew its application for a marketing authorisation for Exulett for the treatment of SSTI after the Committee for Medicinal Products for Human Use (**CHMP**) expressed concerns that the results of the single main study were too limited to support the approval of the product. **[ ]**

Apart from Exulett, a number of other competitors have pipeline products that are in Phase III, including:

[154] Targocid is also available as an intramuscular injection.

- ***Ceftobripole*** (Johnson & Johnson): Ceftobripole is the first broad spectrum agent in the Cephalosporin class for the treatment of MRSA. The Cephalosporin class is appealing as it has a long history of use in the treatment of lung infections, and possibly DFI, but not skin infections. The product was recently approved in Canada and Switzerland for use in complicated skin infections including DFIs. However, in Europe the EMEA is currently conducting inspections and has suspended the EU Commission Decision process. In the US, further clinical site audits will be undertaken following a FDA Complete Response Letter (November 2008). The product is expected to launch in 2010;

- ***Televancin*** (Astellas) is a Gram positive IV agent in the glycopeptide class that can be used for both lung and skin infections. It is awaiting US FDA approval for SSTI and is in phase III trials for HAP. Its efficacy for treatment of lung infection is comparable to Vancomycin. It is administered as a single dose per day, which makes it a cost effective product; and like Zyvox and Tygacil it is also suitable for the treatment of VRE. The marketing application in the EU was withdrawn in November 2008 due to a lack of risk/benefit data; Astellas plans to resubmit with HAP data;

- ***Iclaprim*** (Arpida): is a broad spectrum IV antibiotic of the Diaminopyrimidines class. It is now undergoing Phase III trials for treatment of SSTI, including those caused by MRSA.[155] An oral formulation is being tested in Phase II trials.[156] The product will likely be launched in 2010;

- ***Oritavancin*** (Targanta) is a Gram positive IV agent in the glycopeptide class. An oral form has been developed but only for the treatment of Clostridium Difficile infections (a bacterium that causes diarrhoea and more serious intestinal conditions such as colitis). The Medicines Company announced its intention to acquire Targanta in January 2009. The product is expected to be launched in 2010; and

- ***Ceftaroline*** (Forest Laboratories) is a second broad spectrum cephalosporin covering MRSA. Ceftaroline is in phase III development in the US and the EU for cSSTI and CAP. It is developed with an IV and Intramuscular form. The launch is expected in 2011.

- ***Cubicin*** (Novartis) is a Gram positive Lipopeptide specifically indicated for the treatment of SSTI. It is also used for bacteremia. It is an IV agent that competes most directly with Vancomycin. Cubicin is already available in other countries, including the EU and Australia.

(e) Summary of competition analysis

The Parties consider that the combination of Zyvox and Tygacil would not give rise to concerns. First, the EphMRA ATC3 classification is inconsistent with the classification in the WHO version of the ATC, which groups Tygacil and Zyvox under different ATC3 classes.[157] The Parties consider that this is a more appropriate classification, since glycylcyclines are derived from tetracyclines. Therefore, if the NZCC adopts the WHO classification, there is no ATC3 overlap.

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[155] The FDA has voted against the approval in November 2008; an approval has been requested from the European Medicines Agency (EMEA) and the EMEA accepted Iclaprim for review in August 2008.

[156] It received an unfavourable opinion from the FDA Advisory Committee and approval is not expected in 2009.

[157] Under the WHO version, Tygacil would be within the J01A, Tetracyclines, category.

Irrespective of the ATC3 classification, these antibiotics are not particularly close therapeutic substitutes (different product positioning and focus). The only meaningful competitive overlap between the Parties' products would be with respect to the treatment of a sub-population of patients with Gram positive infections including methicillin-resistant staphylococcus sp. (**MRSA**) but there they face numerous actual and potential therapeutic substitutes. In particular, generic alternatives such as Vancomycin impose substantial competitive constraints and will continue to do so post merger.

7.3 RA treatments

(a) Product description

RA is a chronic, systemic inflammatory disorder that principally attacks the joints causing inflamed membranes and stiffness and often leads to cartilage erosion.

Treatment of RA can be divided into the following categories:

- palliative care through analgesics and non-steroidal anti-inflammatory drugs (**NSAIDs**);
- corticosteroids;
- traditional disease modifying antirheumatic drugs (**DMARDs**); and
- biological DMARDs (**Biologics**).

Analgesics such as ibuprofen and aspirin are available OTC, and are generally used first to treat pain. NSAIDs, such as COX-2 inhibitors like Celebrex, are then used to control the symptoms and signs of the local inflammatory process by inhibiting the generation of prostaglandins by blocking cyclooygenase enzymes, COX-1 and COX-2. However, these drugs appear to exert minimal effect on the progression of RA.

Corticosteroids such as prednisone have both anti-inflammatory and immunoregulatory activity. They can be used in adjunctive therapy with DMARDs.

DMARDs work by reducing the rate of damage to bone and cartilage. Traditional DMARDs include methotrextate and sulfasalazine, which are both generic. Methotrextate has emerged as the DMARD of choice because of its relatively rapid onset of action, its capacity to effect sustained improvement with ongoing therapy, and the higher level of patient retention on therapy. The research pipeline has a number of new DMARDs that are kinase inhibitors, such as JAK3 inhibitors, which work by interrupting the transfer of chemical signals involved in inflammation. JAK3, in particular, is a kinase involved in the chemical signal transfer in B cells, T cells and natural killer cells – all of which are implicated in RA pathology.

Traditional DMARDs remain the standard first line of treatment for RA. Methotrextate is used in around 55% of patients and biologics are used in around 25% of patients (biologics account for 89% of the total market value due to higher prices). According to a recent study 33% of patients used one DMARD, 36% used two, 16% used three and 8% used more than three before switching to biologics.[158]

[158] See HCP Insights, EU5 RA Monitor, 1H07.

Biologic agents are typically used in second line treatment for the treatment of moderate to severe RA after a patient's failure to respond to traditional DMARDs. The disadvantages of biologic agents are (a) high costs,[159] and (b) side effects. Biologics include the following subcategories: (a) tumour necrosis factor inhibitors (**TNFs**) (e.g. Enbrel) (b) selective costimulation modulator (**SCM**); and (c) B cell depleting antibodies.

(b) The Parties' products

Wyeth

Wyeth's Enbrel (etanercept) is the leading specific antirheumatic drug, with an estimated global share (based on value) of around **[ ]**%. Enbrel is classified as an immunosuppressive agent in ATC3 class L04A.[160] Enbrel is a biological agent that is approved for the treatment of RA, including when the patient has had an inadequate response to DMARDs or severe cases at high risk of erosive disease.[161] It is also indicated for polyarticular juvenile chronic arthritis, ankylosing spondylitis and psoriasis. Biologics represent around 10% of all psoriasis treatment (similarly around 12% of Enbrel global sales concern treatment of psoriasis).[162]

In New Zealand, Enbrel received full Pharmac reimbursement only for the second line treatment of Juvenile Idiopathic Arthritis (**JIA**). Such reimbursement requires a special authority and a number of other conditions must be satisfied.[163]

Wyeth also markets Act 3 (ibuprofen) in New Zealand, an analgesic and NSAID available OTC, which is used for pain and inflammation associated with osteoarthritis and RA, among other conditions.

Pfizer

Pfizer does not have a biologic for treatment of RA in its portfolio. As such, there is no direct overlap with Enbrel. Pfizer has a minor presence in analgesics, NSAIDs, and traditional DMARDs:

- ***NSAIDs***: Pfizer's most prominent drug indicated for RA is Celebrex (celecoxib).[164] Celebrex is an NSAID, (M01A, Antirheumatic Non-Steroid) available on prescription.[165] NSAIDs include aspirin, ibuprofen, and naproxen, which are also analgesics available OTC; and

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[159] There are strict controls on Pharmac reimbursement for biologics such as Enbrel, including that the patient has failed to respond to DMARD treatment.

[160]

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[161] Medsafe New Zealand Medicines and Medical Devices Safety Authority, *Information for Health Professionals: Enbrel Data Sheet* <http://www.medsafe.govt.nz/profs/datasheet/e/enbrelinj.htm> at 4 June 2009.

[162] According to IMS MAT data (6/2008): Other indications include Psoriatic Arthritis (**[ ]**), Anklylosing Spondylitis (**[ ]**), Other Autoimmune (**[ ]**) and Chrone's (**[ ]**).

[163] Pharmaceutical Management Agency PHARMAC, Pharmaceutical Schedule, May 2009.

[164] Other NSAIDs are Mobic, Dynastat and Ponstan. The use of Celebrex is associated with a greater cardiovascular risk (FDA alert) and Pfizer is currently conducting a trial to show the benefits (efficacy and side effects) compared with more often used NSAIDs. This trial will not be completed before 2010.

[165] It is a COX-2 inhibitor (Coxib), which selectively inhibits COX-2 and not COX-1 (as classic NSAIDs do). Although Coxibs reduce some of the side effects of NSAIDs (eg gastro-intestinal side effects), they suffer from other side effects e.g., hypertension, and have no improved efficacy.

- ***Traditional DMARDs:*** Pfizer markets Salazopyrin (sulfasalazine), which is already generic. This product does not compete directly with Enbrel: first, it is not an immunosuppressive agent as it belongs to ATC3 class A07E, Intestinal anti-inflammatory agents; and secondly, as explained above, it is a complement rather than a substitute as it is primarily used as a first line treatment, i.e. it would be used before treatment with biologics such as Enbrel.

(c) Pipeline overlap

Wyeth has no Phase III RA treatments in clinical study.[166]

Pfizer has a JAK3 oral agent, CP690, in clinical study for the treatment of moderate to severe RA.[167] **[**

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(d) Existing products

We note there are also numerous alternative immunosuppressive or biologic agents, which are currently available, including:

- Humira (Adalimumab), Abbott;

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[167] It was discovered in Groton Labs.

[168] **[** **]**

[169]

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[170] **[** **]**

- Remicade (Infliximab), Intervet/Schering-Plough;
- Mabthera (rituximib), Roche; and
- Orencia (abatecept), Bristol-Myers Squibb.

Enbrel, Humira and Remicade block TNF, while Mabthera blocks 'B'-cells and Orencia blocks 'T'-cells.

(e) Competitors' Phase III Pipeline

Significantly, there are several promising Phase III pipeline biologics, which would be closer therapeutic substitutes to Enbrel. These include:[171]

Product	Company	MOA	Administration	Launch date
Cimzia	UCB	TNF-mAb pegylated	Twice monthly sc injection	2010
Golimumab	Centocor/SGP/Tanabe	TNF-mAb	IV and monthly sc injection	2010
RoActemra (tocilizumab)	Roche/Chugai	IL-6 inhibitor	Monthly IV	2010
Ocrelizumab	Roche/Biogen/Genentech	B-cell inhibitor	Monthly IV	2011
Ofatumumab	GSK/Genmab	Anti-CD20	Twice monthly IV	2011

- ***Cimzia (UCB/Celltech):*** According to clinical trial results, it would likely provide the fastest onset of RA symptom relief. It has already been approved for treatment of Crohn's disease in the US and Switzerland.[172]
- ***Golimumab (Centocor/Schering/Tanabe)***: Golimumab will be marketed by Schering Plough as a best in class follow on to Remicade.
- ***RoActemra (Roche/Chugai)***: RoActemra will be a novel MOA in RA treatment - a mAb targeting IL-6 receptors, which disrupts the IL-6 signalling pathway, thereby reducing the cytokine's effects on inflammation and inhibiting the progression of RA. Clinical trials showed signs and symptoms of moderate to severe RA in patients for whom TNF inhibitors are not effective. Actemra has recently been approved for use in Australia.
- ***Ocrelizumab (Roche/Biogen/Genentech)***: Similar to Mabthera, Ocrelizumab, is a fully human monoclonal antibody against CD20 (B-cell), which may have less immunogenicity and less complement activation than Mabthera which, theoretically, may reduce the development of drug neutralising antibodies and infusion reactions.
- ***Ofatumumab (GSK/Genmab)***: Ofatumumab is likely to be used for the treatment of chronic lymphocytic leukaemia (CLL), and RA in the near future.

[171] There are also several pipeline biologics in Phase I and II including a P2X7 inhibitor from Astra Zeneca, GSK-856553 (GSK), Ocrelizumab (Roche/Biogen), R-788 (Rigel), Ofatumumab (Genmab/GSK) and Belimumab (AZ).

[172] The FDA approval for RA was delayed in January 2009 when the FDA requested additional safety data due to hypertension risks (these would not require further trials) and are expected to be submitted in the second quarter of 2009.

In addition to the biologics in the pipeline, there are many small molecule DMARDs more similar to Pfizer's pipeline compound CP690. Pfizer estimates that there are 44 compounds in Phase II development, 30 of which are small molecules. These will be closer competitors to Pfizer's JAK3 agent than Wyeth's biologics and include Rigel's R788 (JAK3), Incyte's INCB28050 (JAK inhibitor), and INCB 18424 (JAK2), all of which are in Phase II, and Vertex's VX-509 (JAK3), which is in Phase I. Moreover, all of these pipeline products are anticipated to be at least as equivalent to Enbrel as Pfizer's JAK3 pipeline compound. The RA field is large and highly competitive with many companies pursuing products in development.

(f) Summary of competition analysis

The Proposed Merger does not give rise to competition concerns in relation to RA treatments. First, there is no existing overlap between Pfizer and Wyeth at the ATC3 level:

- Pfizer's two on-market drugs, Celebrex (celecoxib) and Salazopryin (Sulfasalazine) fall under ATC3 classes M01A and A07E respectively;
- Wyeth's on-market drug, Enbrel (etanercept), is classified as an immunosuppressive agent in ATC3 class L04A; and
- the Parties' products are substantially different and are therapeutic complements rather than substitutes.

Secondly, there is no elimination of a unique entrant given the existence of other significant pipeline products. For example, Pfizer's Phase II pipeline JAK3 agent is unlikely to be a direct substitute to Wyeth's existing product Enbrel (different MOA and positioning, e.g. administration mode).

7.4 AD treatments

(a) Overview

AD is a terminal, progressive, degenerative disease that is the most common cause of dementia (approximately 60% to 70% of all cases). An estimated 26.6 million people worldwide currently suffer from AD. It is characterised by memory loss, confusion, changes in personality, and loss of motor skills; the terminal event in most patients is usually infection. There is a strong correlation with age with the rate of diagnoses doubling every 5 years after age 65.

During the course of AD, amyloid 'plaques' and 'tangles' containing hyperphosphorylated tau protein develop in many structures within the brain, eventually leading to the degeneration of millions of brain cells. During this process there is also an imbalance in the concentration of neurotransmitters (molecules that are involved with the transmission of electrical signalling within the brain).

There are a number of hypotheses to explain the cause and progression of AD - but the mechanisms giving rise to this disease are poorly understood.

(b) Market overview

The global AD market is currently worth an estimated US$4.5 billion. It is a growth market that has attracted, and will continue to attract, substantial investment from all major pharmaceutical players with a number of acquisitions and partnerships with biotech companies. According to the registry for US government and privately funded clinical studies worldwide, there are currently 589 clinical studies for AD under way.[173]

AD products are still in relative infancy compared to other pharmaceutical products in large part because of the uncertainty and speculation surrounding its cause and progression. According to a study presented at the 2008 International Conference for Alzheimer's disease, people with Alzheimer's disease who took antidementia drugs consistently over a longer time frame lived longer than those who took the medications for shorter time intervals.[174] Therefore, pharmaceutical companies expect treatment to increase further.

(c) Current treatment for AD

Currently available treatments offer a small symptomatic benefit, ie they enhance cognition and improve behavioural dysfunction only. However, there are no marketed treatments to delay or halt the progression of AD. There are two types of drug treatments currently marketed:

- ***Acetylcholinesterase Inhibitors (AChEIs):*** AChEIs correspond with the Cholinergic hypothesis. They work by inhibiting the cholinesterase enzyme from breaking down acetylcholine in order to increase both the level and duration of action of the neurotransmitter acetylcholine. They are indicated primarily for mild to moderate AD; and

- ***NMDA receptor antagonists:*** NMDA drugs relate to the glutamate pathway in neurotransmission in the brain. They act by blocking the overexcitation of N-methyl d-aspartate (**NMDA**) receptors by glutamate in the neural pathways associated with learning and memory which occurs in AD and leads to neuronal cell dysfunction and death. They are indicated primarily for moderate to severe AD.

(d) Direction of research

The research pipeline is focussed primarily, but not exclusively, on the development of disease modifying drugs, which have the potential to alter the course of AD. There are no such products on the market today and this type R&D is particularly speculative because the cause of, and thus the cure for, AD remains unknown.

The R&D pipeline is active with a significant (but not exclusive) focus on therapies to address Beta amyloid plaques. Many theories are being explored, as described below:

- ***Immunotherapy:*** Immunotherapy seeks to either mobilise the immune system to produce antibodies to bind to and remove the toxic Aβ peptide (*vaccine*), or to administer laboratory produced antibodies directed at beta amyloid (*passive*

[173] US National Institutes of Health, *List results for Search on Alzheimer,* <http://www.clinicaltrials.gov/ct2/results?term=alzheimer>.

[174] Study of the persistent use of antidementia drugs and their influence on survival by the Alzheimer's disease and Memory Disorders Center of in Houston, Texas. The researchers followed 641 people diagnosed with Alzheimer's at an academic medical clinic between 1989 and 2005. These individuals had been on drug therapy over the course of their Alzheimer's for variable amounts of time and the majority had used one or more of the commercially available antidementia drugs (donepezil, galantamine, rivastigmine, tacrine, or memantine).

immunization). Antibodies attack substances foreign to the body called antigens; each antibody binds to and attacks one particular antigen. An initial attempt at immunotherapy resulted in adverse events in a fraction of the treated individuals necessitating the halting of the trial prior to the Phase III, proof of concept studies.[175] Nevertheless, immunotherapy is viewed as an exciting possibility for the treatment of AD because of its efficacy in reducing Aβ levels, the total plaque load, and cognitive deficits in preclinical models, and the potential for long lasting effects in humans. Vaccination approaches work by administering peptide antigens that use the body to produce Beta amyloid antibodies, eg ACC-01 (a Phase II pipeline product that Wyeth is co-developing with Elan). Passive immunotherapy approaches have an advantage in that the antibodies are laboratory produced; thus, they can be given in predetermined doses which can be lowered, or the antibodies even removed if needed, e.g. M-266 (a Phase III pipeline product developed by Lilly) and **[** **]** are humanised monoclonal antibodies (mAb) that seek out and destroy Beta amyloid. Kiovig, an intravenous immunoglobulin liquid (IVIg) (a Phase III pipeline product developed by Baxter) contains natural amyloid antibodies, which may reduce Beta amyloid levels.

- ***Secretase inhibitors/modulators:*** To decrease Beta amyloid production, secretase inhibitors/modulators seek to decrease the activity of the enzymes that cleave the amyloid precursor protein (APP) twice to excise the beta amyloid peptide. There are a number of programs directed at either beta secretase or gamma secretase currently being tested in clinical trials, e.g. LY-450139 (a Phase III pipeline product developed by Lilly, BMS-708163, a gamma secretase inhibitor being developed by Bristol-Myers Squibb, and CTS-21166, a Phase I BACE inhibitor being developed by Astellas/Comentis.[176]

- ***Beta amyloid aggregation agents:*** These agents attempt to stop Beta amyloid from "aggregating" into plaques toxic oligomers, fibrils, and plaques (e.g. Prana is developing PBT2 in Phase II clinical trials; Transition Therapeutics/Elan is developing ELND-005 in Phase II trials).[177]

- ***RAGE modulators:*** Receptors for advanced glycation endproducts (**RAGE**) are expressed at increased levels in the brains of Alzheimer's patients. These receptors can be bound by numerous ligands including Ab peptides. At the blood brain barrier binding of Ab can lead to the translocation of this peptide from the periphery to the brain, hence allowing the 're-importation' of this toxic peptide into the brain. Activation of RAGE receptors can also lead to alterations in blood flow, and inflammatory responses. Thus, RAGE antagonists work by blocking the interaction of RAGE ligands with their receptor and have the potential to reduce brain Ab levels, decrease inflammatory responses and renormalize blood flow.

- ***Beta amyloid catabolising enzymes:*** Researchers have found several enzymes that work by breaking down Beta amyloid, e.g., insulin degrading enzyme (IDE), plasmin, Neprilysin (NEP), endothelin converting enzyme (ECE), and matrix metalloprotease-9 (MMP-9).

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[175] Wyeth/Elan's first generation vaccine AN-1792 showed promised in animal studies but human trials were halted when study participants developed brain inflammation.

[176] Flurizan, R-flurbiprofen, is the single enantiomer of the racemate NSAID flurbiprofen, which failed in Phase III trials in 2008.

[177] Alzhemed (Tramiprostate), which failed in Phase III trials in 2007 is an example. It was the first anti-amyloid drug to reach Phase III trials.

- ***Tau aggregation agents:*** These agents attempt to prevent the development of neurofibrillary tangles in the brain, which develop when tau protein becomes hyperphosphorylated, e.g. Rember (a Phase III pipeline product being developed by TauRx).

- ***Ketone bodies:*** Another approach to blocking brain cell death in Alzheimer's patients is to give these cells an energy source other than glucose (sugar) to nourish them, eg AC-1202 that is converted to substances normally found in the body called ketone bodies that can be metabolised by brain cells even when they cannot metabolise glucose.

- ***GSK3 Inhibitors***: specifically selective small molecule glycogen synthase kinase-3 (GSK3) inhibitors work by slowing or halting the hyperphosphorylation of tau protein.

- ***Nicotinic acetylcholine receptor agonists:*** Nicotinic acetylcholine receptor agonists, or nAChR agonists, are activators of cholinergic receptors that act to re-establish neurotransmission through cholinergic brain circuits affected by the degeneration of cholinergic neurons making up part of the AD pathology. To overcome potential side effect issues related to the peripheral expression of these receptors numerous companies have focussed on specific subsets of nicotinic receptors such as a4b2 and a7 nicotinic receptors.

- ***Other neurotransmitter modulators:*** Drugs that modulate neurotransmitter activity seek to re-establish more normal levels of certain neurotransmitters, particularly cholinergic, monoaminergic, and glutamatergic transmission. Nerve pathways in the brain that depend on the chemical messenger, 5-hydroxytryptamine also known as serotonin (**5-HT**) play a key role in modulating the levels of other neurotransmitters such as acetylcholine and glutamate. Antagonists are believed to remove inhibitory pathways allowing increased release of these neurotransmitters in brain. Ampakines have modulatory effects on AMPA receptors attempting to renormalize glutamate signalling through AMPA receptors.

- ***PDE Inhibitors:*** Beta amyloid plaques inhibit the function of several important key pathways in learning and memory processes. Inhibitors of phosphodiesterases (**PDE**) are known to enhance these memory pathways. PDE9 inhibitors act by preventing cGMP breakdown modulating cGMP pools relevant to synaptic plasticity, which could improve Alzheimer's symptoms.

(e) Products of the Parties

Wyeth

Wyeth currently does not supply an anti Alzheimer's drug in New Zealand.

Pfizer

Pfizer markets Aricept (donepezil hydrochloride), a small molecule classified under ATC3: N07D, Anti Alzheimer's products. The patent expired in New Zealand mid-2008, prior to the launch of the pipeline products described below. Aricept acts as an AChEI and is indicated for treatment of mild to severe AD and for the treatment of vascular dementia in

New Zealand.[178] As noted above, such drugs address the symptoms of AD only. They do not modify the progression of the disease. This product is not funded by Pharmac.

Eisai[179] has been conducting Phase III clinical trials for sustained release and patch formulations of Aricept. [ ] Furthermore, Eisai has recently terminated a joint development agreement with Nitto Denko for the patch formulation.[180]

As Wyeth does not currently market any anti-AD drug in New Zealand, there is no existing overlap.[181]

(f) Existing products

There are three other products marketed in New Zealand:

- Reminyl, Janssen Cilag,
- Exelon, Novartis, and
- Ebixa, Lundbeck.

Similar to Aricept, Reminyl and Exelon are AChEIs. Studies have shown that Aricept performs better in terms of efficacy and side effects as compared to Exelon. However, now that Exelon is available in a patch formulation, which reduces its side effects, it is viewed as a serious competitive threat. Ebixa is an NMDA modulator. These drugs treat the symptoms of AD only and not the progression of the disease. Moreover, Reminyl and Ebixa are already off-patent in New Zealand. Most products will have generic alternatives in advance of the potential launch dates of the products in the AD pipeline.[182]

(g) Pipeline overlap

The AD pipeline is very active. According to Pfizer's estimates, there are currently over 50 Alzheimer's compounds in development, and 589 registered clinical studies. Virtually, every major pharmaceutical company has an anti Alzheimer's agent in development.

However, as discussed, developing a safe and effective AD drug and receiving regulatory approval is particularly difficult and unpredictable, as there is no precedent for a disease modifying agent and the root cause of the disease is unknown. The limited range of patient profiles, and toxic side effects have plagued clinical trials of early promising drugs, eg Wyeth/Elan's first generation anti-beta amyloid. While many potential AD drugs have failed at the Phase I or Phase II stage, even drugs that reach Phase III frequently fail to reach market. As the past few years have shown, at least four much hyped drugs have failed and none have succeeded. Those that failed to show any effects in mild to moderate dementia include: Neurochem's Alzehemed (tramiprosate), a Beta amyloid agent; Myriad/Lundbeck 's Flurizan (Rflurbiprofen), a gamma secretase modulator; Forest's Neramexane, a NMDA receptor antagonist; and Sanofi-Aventis' Xaliproden, a neurotrophic.

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[178] Medsafe New Zealand Medicines and Medical Devices Safety Authority, *Information for Health Professionals: Aricept Data Sheet* <http://www.medsafe.govt.nz/profs/datasheet/a/aricepttabariceptdtab.htm> at 4 June 2009.

[179] In some jurisdictions, Eisai and Pfizer co-promote Aricept.

[180] See Eisai Co, 'Eisai Announces Termination of Joint Development Agreement with Nitto Denko on a Transdermal Patch Formulation of Aricept' (Media Release, 26 February 2009) available at <http://www.eisai.co.jp/enews/enews200905.html> .

[181] Wyeth markets Aricept in Brazil and Mexico.

[182] Eg galantamine is already off patent in the US, Ebixa will go off patent in Germany and Spain this year.

As noted above, competition regulators generally view products at the Phase III of development as being more relevant to the competitive assessment than products that are at a much earlier stage of development. However, even in Phase III the likelihood of success is less than 50% (and may be significantly lower in the Alzheimer's field given the unknowns about the disease and the recent Phase III failures described above).

The Parties' Phase III Pipeline trials are as follows:

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(h) Competitors' pipeline

All leading pharmaceutical companies have committed substantial resources to the development of anti-AD drugs. The key anti-AD drugs in Phase III are:

- Eli Lilly's mAb immunotherapy compound, ***M-266***, went directly into Phase III trials from Phase I (Lilly also has a gamma secretase inhibitor LY4501439 in Phase III).

  Eli Lilly's compound was promising enough to secure key financial partnerships to help finance its clinical trials. Last year, Eli Lilly announced an agreement with NovaQuest and TPG-Axon Capital Management, L.P. for the phase III development of Lilly's two lead molecules, a gamma secretase inhibitor, and an A-beta antibody for the treatment of AD.

- GSK's ***Avandia*** (Rosiglitazone) is a thiazolidinediones (**TZDs**), which works by activating intracellular receptors of the peroxisome proliferator activated receptor types (**PPARs**), specifically PPAR gamma. Rosiglitazone is a selective ligand of PPAR, and has no PPAR binding action. It is typically used in diabetes treatment, as it improves insulin sensitivity and has a beneficial effect on insulin resistance. But, it appears to have an anti-inflammatory effect: nuclear factor kappa-B (NFκB) levels fall and inhibitor (IB) levels increase in patients on rosiglitazone. **[ ]** it shows some benefit in AD patients, who do not express the ApoE4 allele. However, rosiglitazone appears to raise some safety concerns.[184]

- Baxter International's **Kiovig**, an IVIg, is being pursued as an immunotherapy for AD. It contains a broad spectrum of antibodies, and is currently indicated as a therapy for people with primary immunodeficiency disorders. IVIg contains antibodies that bind to the beta amyloid aggregates that are thought to be central to AD. In two previous open label studies, patients with mild to moderate dementia have showed cognitive improvement when treated with IVIg for six months.

- TauRx's ***Rember*** is an oral therapy containing methylthioninium chloride, which works an inhibitor of tau protein aggregation. Encouraging results of a Phase II UK study were presented at ICAD 2008. Recruitment for Phase III clinical study is currently underway.

(i) Summary of competition analysis

The Proposed Merger does not give rise to competition concerns as:

- there is no existing overlap between Pfizer and Wyeth's products;

- the Parties' Phase III pipeline products are **[ ]**; and

- the R&D pipeline is full of potential competitors pursuing a wide variety of potential methods to develop safe and effective Alzheimer's drugs. Some are pursuing disease modifying therapies, symptomatic treatments or both.

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[184] See Steven Reinberg, 'Avandia's Heart Risk Higher Than Others in Its Class', *Healthday Reporter* (24 November 2008) available at <http://health.usnews.com/articles/health/healthday/2008/11/24/avandias-heart-risk-higher-than-others-in-its-class.html>.

Therefore, even if the Parties' pipeline products successfully launched, they would face competition from other pharmaceutical companies at or near potential launch.

7.5 Osteoporosis

(a) Overview

Osteoporosis is a bone disease that leads to an increased risk of fracture. Osteoporosis in women is defined by the World Health Organization (**WHO**) as a bone mineral density 2.5 standard deviations below peak bone mass (20 year old healthy female average) as measured by a DAY (bone density x-ray scan); the term "established osteoporosis" includes the presence of a fragility fracture. Osteoporosis is most common in women after menopause, when it is called postmenopausal osteoporosis,[185] but may also develop in men, and may occur in anyone in the presence of particular hormonal disorders and other chronic diseases or as a result of medications, specifically glucocorticoids.

The potential overlap between the Parties is with regard to treatment of postmenopausal osteoporosis.

Osteoporosis treatment falls under two broad categories:

- ***Antiresorptive Agents***: These agents block resorption (bone breakdown) thus slowing the rate of bone remodelling; however, they cannot rebuild bone. In fact, because resorption and reformation occur naturally as a continuous process, blocking resorption may eventually also reduce bone formation. Antiresorptives include bisphosphonates, hormone replacement therapy, SERMs, and calcitonin, which are described below.

- ***Anabolic, or Bone Forming, Agents***: Agents that rebuild bone are known as anabolics. The primary anabolic agent is low dose parathyroid hormone (**PTH**), which is administered as injections. It is proving to be very effective in restoring bone and preventing fractures. PHT is still relatively new and long term effects are still unknown.

Current treatment options include:

- ***Oral bisphosphonates:*** Oral bisphosphonates inhibit osteoclast action and the resorption of bone. The nitrogenous class of bisphosphonates act on bone metabolism by binding and blocking the enzyme farnesyl diphosphate synthase (FPPS) in the HMG-CoA reductase pathway (also known as the mevalonate pathway).

- ***Oral strontium ranelate:*** Oral strontium ranelate works as a "dual action bone agent" (DABA) insofar as it both increases deposition of new bone osteoblasts and reduces the resorption of bone by osteoclasts.

- ***Teriparatide:*** Teriparatide is the portion of PTH, amino acid sequence 1 through 34 of the complete molecule, which contains amino acid sequence 1 to 84. Endogenous PTH is the primary regulator of calcium and phosphate metabolism in bone and kidney. Daily injections of teriparatide stimulate new bone formation leading to increased bone mineral density.

[185] Up to 20% of a woman's expected lifetime bone loss can occur in the years immediately following menopause.

- ***Selective (o)estrogen receptor modulator (SERMs):*** SERMs work by slipping like a key in a lock into the oestrogen receptors in some tissues (like bone) but not others (like the uterus). Thus, a SERM can act like oestrogen on certain tissues (such as bone), but not on other tissues (such as the uterus). In fact, some women use SERMs to reduce the risk of breast cancer, although it has not been indicated for this use. By modulating the oestrogen reception in bones, SERMs work by slowing bone resorption by the osteoclasts.

- ***Oestrogen replacement therapy***: Until recently oestrogen replacement was the primary treatment for osteoporosis prevention in postmenopausal women; however, there is uncertainty and controversy about whether oestrogen should be recommended in women in the first decade after the menopause. The disadvantages of oestrogen/progestin combinations are negative side effects, such as the increased risk of breast, uterine cancer and heart disease. As there are other drugs on the market, oestrogen replacement therapy is generally not recommended unless there are other indications for its use as well.

Drug treatment typically begins with oral bisphospohonates as a first line treatment in women. Oral strontium ranelate is also given as an alternative oral treatment, particularly for the prevention of vertebral fracture. If bisphosphonates have failed or are contraindicated, then Forteo (teriparatide) is indicated as second line/first line treatment, as it acts like parathyroid hormone and stimulates osteoblasts, thus increasing their activity. Doctors may also prescribe a SERM in first line treatment, particularly if the patient has a risk of breast cancer.

(b) The Parties' pipeline products

Neither party has existing products.

Wyeth

Wyeth's pipeline product Aprela, a combination therapy with oestrogen and bazedoxifene, is in Phase III trials for a hormone replacement therapy and osteoporosis indication. **[ ]**.

Pfizer

Pfizer's pipeline product, Fablyn/Oporia (lasofoxifene) for osteoporosis is a SERM like Viviant and recently received marketing authorisation in Europe at the end of February 2009.[186]

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[186] There are also trials for a vaginal atrophy indication.

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(c) Existing products

As shown in Table 13 below, there are a number of competing alternatives already in the market for osteoporosis treatment, from across a number of ATC3 categories including: G03X, Other Sex Hormones and Similar Products; H04A, Calcitonins; H04V, Other Hormones and Preparations with Similar Actions; and, M05B, Bone Calcium Regulators.

Table 13 - overview of existing products

Compound	Company	ATC	MOA	Admin-istration	Indication
Evista (raloxifene)	Eli Lilly	G3X	SERM	Tablet	Osteoporosis prevention and treatment in postmenopausal women, reduction in risk of invasive breast cancer in post menopausal women
Forteo (teriparatide)	Eli Lilly	H4V	PTH	Injection	Treatment of established osteoporosis in postmenopausal women with one or more vertebral fractures (in combination with calcium and vitamin D)
Fosamax (alendronate) Fosamax plus (Alendronate sodium trihydrate and colecalciferol)	Merck	M5B	OB	Tablets	Prevention and treatment of osteoporosis in postmenopausal women with low bone mass and patients on long-term corticosteroids and for the treatment of osteoporosis in men
Aclasta (zoledronic acid)	Novartis	M5B	OB	Tablets	Postmenopausal osteoporosis

Source: Medsafe data sheets

In relation to the table above, we note:

- ***Fosamax plus*** is specifically indicated for reducing the risk of vertebral and hip fractures and postmenopausal osteoporosis with risk of Vitamin D deficiency; and
- ***Evista*** (raloxifene) was the first SERM on the market launched in 1998. In New Zealand, Evista is also indicated for invasive breast cancer risk reduction in postmenopausal women at high risk, including women with osteoporosis. Eli Lilly has a second generation SERM, Arzoxifene (described below), currently in Phase III trials.

(d) Competitors' pipeline

There are some additional pipeline products in Phase III with varied MOAs: Eli Lilly's Arzoxifene and Amgen's Denosumab for treatment of osteoporosis. Merck's Odanacatib is also in Phase III for treatment of osteoporosis in women with breast cancer.

- ***Arzoxifene*** (LY353381): Arzoxifene is a third-generation SERM, which also has promise in reducing breast cancer risk. Lilly is expected to file a MAA in 2009;

- ***Denosumab*** (AMG 162): Denosumab is a fully humanised monocolonal antibody (**mAb**), a vaccine, which specifically targets the receptor activator of nuclear factor kappa B ligand (RANKL) and neutralises its activity. Thus, it inhibits osteoclast differentiation, activation, and survival. Denosumab is administered every six months by subcutaneous injection in a dose ranging from 60-180 mg. Denosumab is being studied across a range of conditions including osteoporosis, treatment-induced bone loss, bone metastases, multiple myeloma and RA; and

- ***Odanacatib*** (MK-0822): Odanacatib is a highly selective, potent inhibitor of the cathepsin K enzyme. Cathepsin K enzyme plays a key role in breaking down the protein in bone. It is administered orally in a 5 mg dose.

(e) Summary of competition analysis

The Proposed Merger does not give rise to competition concerns in relation to osteoporosis treatments. As described below, for reasons completely unrelated to this transaction, **[**
: **]**

- osteoporosis is an active area that crosses ATC classes. The existence of several alternatives (which will offer increased competition due to the advance of generics) and potential competition imply that the merged entity will not have market power post merger; and

- if anything, the Parties' combined products will challenge the incumbents and thereby increase competition to the benefit of consumers.

7.6 Oncology

(a) Overview

Both Parties have existing and pipeline oncology products for targeted therapy. Targeted therapy can be distinguished from other general or system treatment used after local (surgery) and regional treatment (radiation therapy):[187]

- ***Chemotherapy***: chemotherapy stops or slows the growth of cancer cells. As it is not targeted, it can also harm healthy cells that divide quickly, eg hair;

- ***Hormone therapy***: hormone therapy uses the sex hormones produced by the body, or drugs that block them, to treat cancer, particularly in hormone dependent cancers, eg breast cancer, prostate cancer and uterine cancer;

[187] Therefore, this overview excludes Cytotoxics (Pfizer's Camptosar for colorectal cancer and Pharmorubicin for breast cancer) and hormone therapy (Pfizer's Aromasin).

- ***Immunotherapy***: immunotherapy boosts or restores the ability of the immune system to fight cancer; and

- ***Targeted therapy***: targeted therapy blocks the growth and spread of cancer by interfering with specific molecules involved in tumour growth. By focusing on molecular and cellular changes that are specific to cancer, targeted cancer therapies may be more effective than current treatments and less harmful to normal cells.

All the drugs set out in Table 14 below are targeted therapies that are used either as mono agents or in combination with other therapies including chemotherapy for the treatment of metastatic or advanced forms of cancer.

Table 14 – the Parties' oncology phase III pipeline products

	Phase III		
	Product	MOA	Indication
Pfizer	Axitinib	VEGFR Tyrosine Kinase inhibitor	Second line RCC
	Sutent	VEGF inhibitor	Breast (first / second line); CRC; Prostate; Hepatocellular carcinoma Pancreatic neuroendocrine tumours (pNET)
	CP-751871	IGF1R inhibitor	NSCL cancer
Wyeth	Torisel combo with Avastin		First line, good to intermediate prognosis RCC in combination with Avastin
	Bosutinib	SRC/ABL Tyrosine kinase inhibitor	Chronic Myeloid Leukaemia
	Neratinib	Her-2/EGFR kinase inhibitor	Breast cancer (first / second line)
Wyeth	Inotuzomab ozagamycin (CMC-544)	CD22-targeted cytotoxic immunoconjudate	Non-Hodgkin's Lymphoma

Different types of targeted therapies can be distinguished. These different types can be used for different indications; although some types are more suitable for treatment of specific cancers. Each type has a distinct MOA and as such these therapies can sometimes be combined or used in sequence, to achieve greater efficacy. For these reasons, pipeline oncology compounds are often tested for different indications.

As can be seen from the table above, there is little overlap between the Parties' Phase III portfolios in terms of therapeutic indication.

Neither Pfizer nor Wyeth is a leading oncology player. The Parties seek to expand their combined presence in the oncology market with their respective R&D portfolios, which are largely complementary in terms of MOAs as the overview above shows. This means that Pfizer's and Wyeth's products may be combined or used in sequence to provide more effective therapies even if they are tested in clinical trials for the same indications.

Furthermore, this lack of overlap also implies that there is no reduced incentive to invest in Wyeth's pipeline compounds.

All pharmaceutical companies, the Parties included, invest substantial amounts in the development of oncology products as this is not only a very large market but also a growth market. The difference in MOAs may provide valuable synergies.

The Proposed Merger would therefore create a more competitive player that is better positioned against existing market leaders to introduce innovative products.

(b) Leukaemia

Wyeth

Bosutinib is in Phase III and is not expected to launch prior to **[ ]**.[188] Bosutinib is a Src and Bcr/Abl inhibitor and its primary indication is leukaemia. Bosutinib is only tested in Phase III for treatment of leukaemia, its likely indication is monotherapy for the treatment of first line chronic CML in chronic phase. Bosutinib may be tested for the treatment of other types of cancer including solid tumours especially breast cancer. It is tested in combination with chemotherapy in Phase II for the treatment of HER+ breast cancer[189] (both first and second line treatment).[190]

Pfizer

Pfizer does not have pipeline products for the treatment of leukaemia.

(c) Breast cancer

Wyeth

Neratinib (HKI-272 Breast) is in Phase III and the projected launch date is **[ ]** Neratinib is an irreversible Her-2/EGFR kinase inhibitor for HER2+ metastatic breast cancer. In particular, Neratinib **[**

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Pfizer

Pfizer does not have an existing targeted product for the treatment of breast cancer (excluding hormone therapy).[191] Pfizer has a product, Sutent, which is in two Phase III trials for the treatment of breast cancer[192] one where Sutent is combined with capecitabine for second line treatment of advanced breast cancer and one where Sutent

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[188] **[ ]**

[189] The HER family of transmembrane tyrosine kinase receptors regulate cell growth, differentiation, and survival. Amplification of the HER2 gene occurs in 20%-25% of breast cancers. It is associated with resistance to therapy, higher rates of recurrence, a greater incidence of brain metastases, and poorly differentiated, high-grade tumours. Therefore, this type of breast cancer is more aggressive and tends to have poorer outcomes for patients

[190] Pfizer is currently conducting Phase III trials for first and second line treatment of breast cancer. Therefore, a future overlap between Pfizer's Sutent and Wyeth's Bosutinib is possible. However, it is difficult to say conclusively whether there will be an overlap as this will depend on the label of the products, which is still uncertain at this stage of development.

[191] We note that Pfizer has a product called Aromasin which is used to treat breast cancer, but which is listed as an endocrine therapy. Aromasin is off-patent.

[192] **[ ]**

is combined with docetaxel for first line treatment of advanced breast cancer.[193] Although there is overlap with respect to likely therapeutic indication, Neratinib is based on a different MOA[194] and is currently in testing for only the HER2+ subset of breast cancer patients and as such is unlikely to compete with Sutent.

Existing products

Breast cancer is the most common form of cancer diagnosed in women and therefore the highest value oncology market. Due to the high awareness and extensive screening, the understanding of the different types of breast cancer has improved, making breast cancer one of the most understood but also the most complex and fragmented cancer indication. Consequently, the market for treatment of breast cancer is highly fragmented with multiple drugs and multiple regimens. More than 100 companies are involved in drug development for breast cancer and focused mainly on the metastatic setting. Treatment options will depend on the type and location of the disease, the patient's age, health status, the tumour biology[195] and the stage of disease progression:

- ***Early or adjuvant disease (stage I-III)***: at this early stage where the tumour is still local or regional, the typical treatment regimen is to cure the patient through a combination of surgery, radiation, hormone therapy and chemotherapy, as well as targeted agents (e.g., Herceptin). Chemotherapy refers to the use of Cytoxic agents; these are administered as the standard therapy in all stages of breast cancer.

- ***Metastatic breast cancer (stage IV)***: the goal at this stage of the disease is to increase the overall survival, progression free survival and importantly maintain a patient's quality of life. There are multiple lines of therapy and because of the advanced stage of the cancer, the duration of treatment is shorter than adjuvant therapy. Metastatic breast cancer represents around 25% of patients. Both Pfizer's and Wyeth's products will potentially be used for treatment of metastatic breast cancer.

The leading targeted agents for treatment of breast cancer are:

- ***Herceptin (trastuzumab), Roche***[196]: is a humanized monoclonal antibody targeted to a specific breast cancer population (tumours over-expressing HER2) and it is marketed by Roche. It is approved for the adjuvant treatment of HER2-positive early breast cancer following surgery and chemotherapy and it is also indicated for the treatment of metastatic breast cancer in combination with chemotherapy (taxanes) or as a single agent in patients who have received one or

[193] See Pfizer's press release: http://www.pfizer.com/news/press_releases/pfizer_press_releases.jsp . We note that Pfizer has recently discontinued one of its Phase III trials of Sutent (SUN 1094 trial of sunitinib plus Paclitaxel in advanced breast cancer) as is would be unable to meet the primary endpoint of superior progression-free survival

[194] Neratinib binds to the HER-2 receptor irreversibly, thereby reducing autophosphorylation in cells. Treatment of cells with Neratinib results in inhibition of downstream signal transduction events and cell cycle regulatory pathways; arrest at the G1-S (Gap 1/DNA synthesis) – phase transition of the cell division cycle; and ultimately decreased cellular proliferation. Neratinib also inhibits the epidermal growth factor receptor (EGFR) kinase and the proliferation of EGFR-dependent cells. Sutent o n the other hand inhibits multiple receptor tyrosine kinases (RTKs), which are implicated in tumour growth, pathologic angiogenesis and metastatic progression of cancer.

[195] Eg HER2+ breast cancer. If a breast cancer patient is HER2+, an overabundance of HER2 genes is located inside of the cancer cells. This overabundance causes a large number of receptors on the surface of those breast cancer cells. These receptors send signals from the outside of the cell to the inside of the cell directing the cell when to grow and when to divide. A large number of these receptors allows the cancer cells to grow and divide more rapidly and out of control. Therefore HER2+ breast cancers are more aggressive and tend to have poorer outcomes for patients.

[196] Roche is currently conducting phase II trials for a follow-up product, Pertuzumab.

more chemotherapy regimens for metastatic disease; Herceptin is the leading targeted therapy in this setting; and

- ***Tykerb (lapatinib), GSK***: Tykerb is a reversible EgFR/HER2 inhibitor. In New Zealand, Tykerb in combination with chemotherapy (capecitabine) is indicated for second line treatment for patients with advanced / metastatic tumours over expressing HER2 and with progressing disease following treatment with an anthracycline, a taxane and Herceptin. .

In addition to these existing agents, there are a number of targeted agents for treatment of breast cancer in development:

- ***Nexavar (sorafenib), Bayer***: already approved for treatment of mRCC and tested for treatment of breast cancer. Currently a phase II study is being conducted for first line treatment of patients with local or metastatic breast cancer; and

- ***Armala (pazopanib), GSK***: will likely be launched for treatment of metastatic breast cancer in 2010.

Amgen has recently started trials of an agent (motesanib) that can potentially be used for treatment of breast cancer, and AstraZeneca currently has two multi-targeted agents in development for breast cancer and other tumour types.

(d) Non-Hodgkin's lymphoma

Wyeth

CMC-544 diffuse large B-cell NHL or inotuzomab ozagamycin will likely be launched in **[ ]**. It is a targeted therapy for Non-Hodgkin's lymphoma. It is a mAb immunoconjugate of calicheamicin targeting CD22 and acts as an immuno-chemotherapy for Non-Hodgkin's Lymphoma.

Pfizer

Pfizer does not have any existing or pipeline products with the same mechanism of action or similar products with the same indication.

(e) Summary of competition analysis

The Proposed Merger does not give rise to competition concerns in relation to other oncology treatments as:

- there is limited overlap between the Parties' Phase III portfolio in terms of therapeutic indication;

- the Parties' Phase III portfolios contain agents with different MOAs which are complementary; and

- neither Pfizer nor Wyeth is a leading oncology player. Therefore, the Proposed Merger would create a more competitive player that can challenge the incumbents.

Part C Animal health

8 Background

8.1 The Parties

Pfizer is active in the research and development, manufacture and supply of animal health products. Its portfolio includes a broad range of products for livestock such as dairy and beef cattle, sheep and swine, as well as vaccines and prescription medicines to veterinarians for dogs and cats. Pfizer also has a range of products for horses, including vaccines, anti-inflammatories, antibiotics and analgesics. Pfizer manufactures components for its animal health products at its facility in Upper Hutt **[**

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Founded in 1912 and a division of Wyeth since 1945, Fort Dodge is a manufacturer and distributor of prescription and over-the-counter animal health products for livestock and companion animals. Its headquarters are in Overland Park, Kansas. Fort Dodge employs over 3,500 employees worldwide. The Fort Dodge New Zealand office is in Mount Wellington, Auckland. Fort Dodge does not have manufacturing facilities in New Zealand. It imports its vaccines and parasiticides mainly from Australia, Spain and the US.

It should be noted that there are a number of products for which the Parties have registrations, but which are not supplied to customers. For example, Pfizer's Dectomax Oral Drench for Sheep is a registered product but is not currently sold in New Zealand and **[** **]**.
Similarly, Fort Dodge's swine vaccine, Suvaxyn Mh One, is registered with the New Zealand Food Safety Authority (**NZFSA**) but not sold because of **[** **]**.
Other registered products may not be supplied because their formulations have been superseded by newer products.

8.2 Description of goods / services supplied by the merger parties

The animal health industry includes products for the following species:

- companion animals (being cats and dogs for the purposes of this submission, although this term may be used elsewhere to also refer to birds and horses);
- cattle, sheep and goats (collectively referred to as "ruminants");
- pigs (swine);
- poultry (chickens and turkeys);
- horses (equine); and
- aquaculture animals (farmed fish).

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Key products relevant to the Proposed Merger include biological products (also known as "biologicals") and pharmaceutical products.

(a) Biologicals

Biologicals are products that trigger a protective immune response in animals against viral and bacterial disease agents as well as in some cases against certain parasitic or fungal infections. They include:

- vaccines;
- antisera; and
- colostrum products.

Vaccines are used to prevent future infection or to reduce the clinical signs associated with infection or to reduce the degree of shedding (ie, contagiousness) by an infected animal. They have a wide spectrum of effectiveness and duration of activity. Vaccines are distinct from antisera and colostrum products which give an animal a temporary passive immunity. The Parties do not have competitive overlaps in relation to the manufacture and supply of antisera or colostrum products. Therefore, these products are not discussed any further in this submission.

(b) Pharmaceuticals

Pharmaceuticals encompass a wide group of products that contain a variety of active substances to prevent or treat a large range of animal diseases and disorders.

Pharmaceuticals for animal usage can be divided into parasiticides, antimicrobials, endocrine treatments, anti-inflammatories and analgesics. The main area of overlap between the Parties is in the area of parasiticides, so antimicrobials, endocrine treatments, anti-inflammatories and analgesics are not discussed further in this application.

Parasiticides are products used to control internal and / or external animal parasites. These products may also prevent parasites from infesting an animal.

Most livestock parasiticides and some companion animal parasiticides are available OTC.

9 The Industry

9.1 Industry background

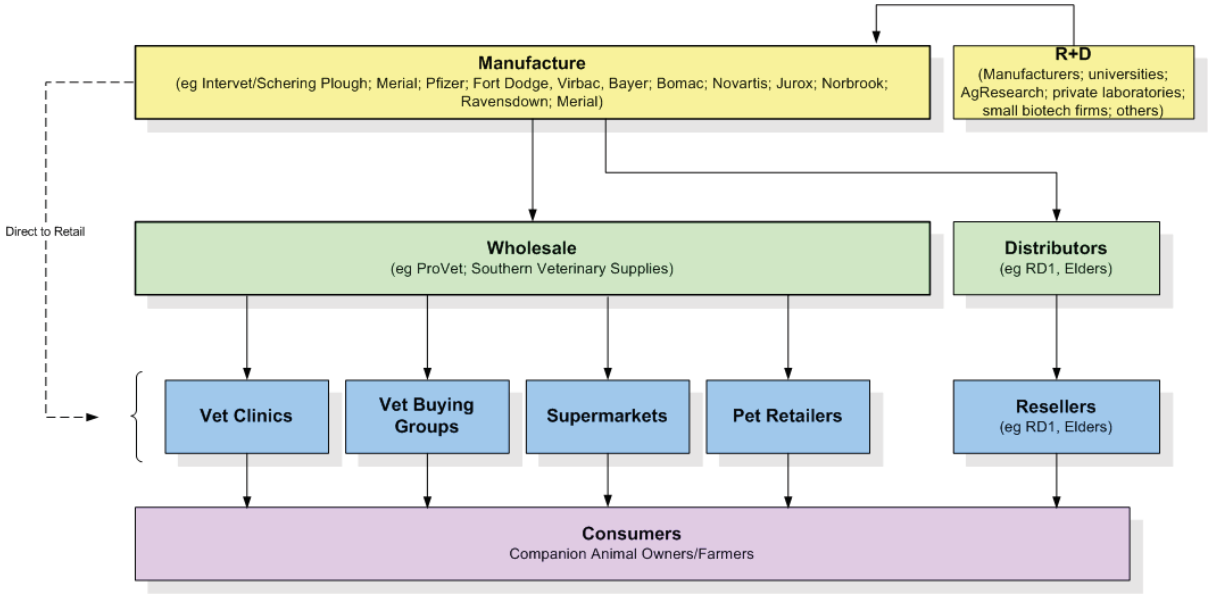
Animal health product manufacture and human health product manufacture involve similar expertise, similar capital and many similar manufacturing processes. Indeed, the majority of animal health manufacture is undertaken by companies that are also involved in human health manufacture (either directly or through group companies) due to transferable expertise and capabilities common to these sectors. In addition to the Parties, companies that are engaged in both the animal and human health sectors include Bayer, Merial (joint venture between Merck and Sanofi-Aventis), Novartis and Boehringer Ingelheim.

A few animal health manufacturers, such as Virbac and Bomac, are involved exclusively in the manufacture of animal health products.

The animal health industry thus constitutes a segment of the much larger human and animal health pharmaceutical manufacturing industry and many of the economic factors affecting industry structure and performance are common to both.

The industry is broadly structured as depicted in the following diagram. As the diagram shows, manufacturers and suppliers of animal health products supply their products directly to vet clinics and other retailers as well as to distributors with their own network of retail rural supplies stores.

Animal Health Industry Structure



Each functional level is discussed in more detail below.

(a) Manufacture

The manufacture of animal health products broadly involves R&D, testing and regulatory approval, production, marketing, technical, pharmacovigilance and sales support and activities.

Research and development

New or novel animal health products are introduced into the market after extensive R&D.

The R&D process for new animal health products typically includes three main phases:

- **the discovery phase** begins when a molecule or antigen is identified as having potential therapeutic or prophylactic use. This discovery is typically made by scientists focusing on animal health issues. A testing period of approximately 18 months follows, during which a range of *in-vitro* testing and safety and efficacy testing is carried out in laboratory models. There may also be initial testing carried out in the target species for the product. The main aim of the discovery phase is to provide a proof of concept which would justify moving on to the exploratory development of the discovery;

- **the exploratory development phase** is aimed at providing proof of efficacy and safety of the product, as well as determining the key elements, or profile, of the end product (eg, likely formulation, target species and the details of dosage and

administration). It takes a further 18 months or so to conduct safety and efficacy testing, formulation development and dosage comparisons. Depending upon the desired duration of effect of the product, these studies may take longer than 18 months to determine if the product is efficacious. Pfizer estimates that around 70% of projects do not get past the exploratory development phase; and

- **the full development phase** takes between four to five years and includes the regulatory approvals process, that determines what testing and development occurs in this phase. The length of this phase is also influenced by the need to demonstrate the shelf-life stability of the product.

Manufacturers of animal health products do not necessarily establish R&D capabilities in every country in which they are active. R&D can be conducted at overseas R&D laboratories and by universities, the AgResearch and other government and private venture laboratories. For example, **[**

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Vaccine R&D costs and the timeline to bring a vaccine to market will differ depending on the number and type of antigens in the vaccine and on the expertise and experience of the company. Some antigens are more difficult to grow and/or prepare than others. It may therefore take a number of years to get a new product to market. Animal health pharmaceutical products typically take longer to develop than vaccines. R&D costs and time are reduced in the case of generic pharmaceutical products which are essentially a copy of a product and its off-patent active pharmaceutical ingredient.

While the time and cost of R&D are considerable, it is a process that all global manufacturers of animal health products undertake in relation to the products that they ultimately supply. Furthermore, it is possible to reduce R&D expenditure by licensing another manufacturer's technology or, as discussed below, purchasing a finished product and repackaging it for supply to customers.

Production

Suppliers of animal health products in New Zealand have a range of manufacturing options, including:

- producing from a local manufacturing plant;
- manufacturing products in an overseas plant and importing them into New Zealand (many suppliers of animal health product in New Zealand are multi-national companies);
- entering into a contract manufacturing arrangement with an existing manufacturer in New Zealand or overseas;
- purchasing products from another animal health product manufacturer and repacking and rebranding them; and
- entering into a supply and distribution arrangement (ie, acting as a distributor for another manufacturer's product) wherein and the relevant regulatory registrations are held by the other manufacturer.

Suppliers may choose a combination of manufacturing options to support their business. For example, Pfizer has a manufacturing facility in Upper Hutt but imports a number of products from its plants in Australia and the United States. Fort Dodge does not manufacture any products in New Zealand and imports all products from its overseas plant, including from Australia, the United States and Spain. Fort Dodge also supplies **[**

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It should be noted that the New Zealand animal health industry is relatively small and most products are manufactured overseas and imported into New Zealand by the local subsidiaries of the international manufacturers. The NZCC recognised this in its decision on Provet's acquisition of National Veterinary Supplies Limited (**NVS**) in 2005.[198]

Suppliers who choose to establish manufacturing plant in New Zealand must be licensed by the NZFSA.

(b) Wholesale distribution

A majority of animal health products are distributed through animal health wholesalers (eg, Provet, Southern Veterinary Supplies) and resellers with their own rural supplies stores (eg, Elders, RD1, PGG Wrightson, Allied Farmers). There are also farmers co-operatives such as Farmlands Trading Society (**Farmlands**) and Combined Rural Trades Co-operative (**CRT**) that act as buying groups for their customer shareholders. Both Farmlands and CRT have their own retail outlets. Manufacturers can also supply directly to veterinary clinics and veterinarians and this is an important distribution method in New Zealand.

Swine, equine and companion animal vaccines are distributed through the veterinary channel because they are registered as prescription only products. They are therefore distributed through a veterinary wholesaler such as Provet or are delivered to clinics and veterinarians direct from the manufacturer.

(c) Retail distribution

The retail distribution is done by veterinary clinics, veterinary buying groups, pet stores, supermarket chains, rural supplies stores and more recently, pharmacies and online stores. Prescription animal health products are only available through registered veterinary practitioners. Other products (eg, parasiticides) may be available OTC from any/all of the various retailers.

Further information on distribution (and its impact on the competitive assessment of the Proposed Merger) is set out in section 12.4.

9.2 Industry trends

(a) Growth of generics

While some animal health anti-parasitics are protected by patent, there are many generic products available in New Zealand. Generics are particularly strong in the companion animal sector, and generic endectocides have become increasingly strong in the livestock sector, following the patent expiry of a number of active pharmaceutical ingredients including moxidectin and ivermectin.

(b) Increasing investment in R&D

Investment in R&D is a key feature of the pharmaceutical industry. There is a strong worldwide growth trend in R&D expenditure by pharmaceutical companies in both human

[198] *Provet NZ Pty Ltd/National Veterinary Supplies Limited*, NZCC Decision 549, 5 May 2005, at paragraph 30.

and animal health. In 2008 it was reported that the global biopharma industry R&D expenditure reached US$65 billion.[199] Many competitors invest tens of millions of dollars in animal health R&D annually. In 2006, Pfizer invested more than US$290 million in its animal health R&D.

(c) Trends in New Zealand's agricultural sector

The demand for, and supply of, livestock animal health products in New Zealand is also directly affected by trends in the New Zealand agriculture sector. According to the Ministry of Agriculture and Forestry (**MAF**), while the dairy industry is prospering and the outlook for beef prices is positive, large scale de-stocking is underway in the sheep industry.[200] While drought is one reason for the de-stocking, MAF reports that: [201]

> *"to a greater extent poor lamb and wool farm-gate prices are encouraging conversion to more profitable dairy farming. Lamb production is expected to decline in coming years. This is creating excess meat processing capacity and, as a consequence of this, the Oringi and Burnside meat processing plants closed down in May 2008. More closures may follow."*

Lamb production is expected to decrease by 5% for the year ending 30 June 2008 and is likely to be down again for the year ending 30 June 2009.[202] The production decrease will continue to 2012, but at a slower rate after 2009. Furthermore, the demand from New Zealand's largest export market for lamb, the European Union, is static and in other markets where demand is increasing prices are at much lower levels than in the EU.[203]

While beef export earnings were down 4% for the year ended 31 March 2008, export earnings in Canada and Indonesia did not decrease. Indonesia is becoming one of the major export markets for New Zealand beef and the volume of beef exported has doubled since 2006.[204] While the recent drought has reduced the number of calves born in 2008-2009, and will lead to a drop in beef production numbers in 2009-2010, beef production is expected to increase again before 2012.[205]

While the dairy industry has also been affected by the drought, which caused a drop in milk production in 2007-2008, revenue from dairy exports grew by 25% for the one-year period ending 31 March 2008 largely as a result of increased demand from China, for milk powders especially, and countries in the Organisation of Petroleum Exporting Countries (**OPEC**).[206] New Zealand is currently the largest dairy exporter in the world and MAF expects that milk production and manufactured exports from New Zealand will steadily

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[199] Burrill & Company, Analysis for PhRMA, 2005-2009; Pharmaceutical Research and Manufacturers of America, PhRMA Annual Member Survey (Washington, DC: PhRMA, 1981-2009).

[200] MAF, *Situation and Outlook for New Zealand Agriculture and Forestry*, August 2008, chapter 2, <http://www.maf.govt.nz/mafnet/rural-nz/statistics-and-forecasts/sonzaf/2008/page-02.htm> at 1 June 2009.

[201] MAF, *Situation and Outlook for New Zealand Agriculture and Forestry*, August 2008, chapter 2, <http://www.maf.govt.nz/mafnet/rural-nz/statistics-and-forecasts/sonzaf/2008/page-02.htm> at 1 June 2009.

[202] MAF, *Situation and Outlook for New Zealand Agriculture and Forestry*, August 2008, chapter 16, <http://www.maf.govt.nz/mafnet/rural-nz/statistics-and-forecasts/sonzaf/2008/page-16.htm> at 1 June 2009.

[203] MAF, *Situation and Outlook for New Zealand Agriculture and Forestry*, August 2008, chapter 16, <http://www.maf.govt.nz/mafnet/rural-nz/statistics-and-forecasts/sonzaf/2008/page-16.htm> at 1 June 2009.

[204] MAF, *Situation and Outlook for New Zealand Agriculture and Forestry*, August 2008, chapter 18, <http://www.maf.govt.nz/mafnet/rural-nz/statistics-and-forecasts/sonzaf/2008/page-18.htm> at 1 June 2009.

[205] MAF, *Situation and Outlook for New Zealand Agriculture and Forestry*, August 2008, chapter 18, <http://www.maf.govt.nz/mafnet/rural-nz/statistics-and-forecasts/sonzaf/2008/page-18.htm> at 1 June 2009.

[206] MAF, *Situation and Outlook for New Zealand Agriculture and Forestry*, August 2008, chapter 19, <http://www.maf.govt.nz/mafnet/rural-nz/statistics-and-forecasts/sonzaf/2008/page-19.htm> at 1 June 2009.

increase, despite competition from Australia and developing countries that have expanded their dairy production (eg China, India and some countries in South America).

Milk production is expected to increase again as dairy cows and heifer numbers increase and milk solids yield per cow grows.

These trends are likely to have an impact on the merged entity's supply of products for sheep and cattle post-merger.

9.3 Recent mergers in the pharmaceutical industry

We set out below mergers in the animal health industry in the last six years:

Name of Parties	NZCC Decision	Date of announcement / NZCC Determination
Merial Limited / Ancare NZ Limited	N/A	24 October 2007[207]
Schering-Plough Corporation/ Organon Biosciences N.V.	Commerce NZCC – Decision No 621 Clearance granted	4 October 2007
Provet NZ Pty Limited/ National Veterinary Supplies Limited	Commerce NZCC – Decision No 549 Clearance granted	5 May 2005
Pfizer Laboratories Limited/ Pharmacia Limited	Commerce NZCC - Decision No 496 Clearance granted.	3 April 2003

10 Market Definition

10.1 Horizontal Aggregation

The Parties overlap in relation to the manufacture and/or supply of the following products:

- vaccines for cats, dogs, swine, sheep, cattle and horses; and
- parasiticides for sheep and cattle.

The following section discusses some general principles that are applicable when determining the relevant markets for these products.

(a) Vaccines

Markets for the manufacture of vaccines for companion animals and farm animals received detailed consideration in a recent decision by the EC involving the acquisition of Organon BioSciences by Schering-Plough (**Schering-Plough Decision**).[208]

[207] See Merck, 'Merck and Schering-Plough to Merge' (Media Release, 9 March 2009) available at <http://www.merck.com/newsroom/press_releases/corporate/2009_0309.html> at 27 May 2009.

In the Schering-Plough Decision, the EC considered that substitution possibilities for vaccines need to be analysed on the basis of various factors:

- **animal species**: most vaccines target a single animal species, with the exception of some, such as the vaccine for rabies, which is a multi-species vaccine. Vaccines for different animal species are generally not substitutable even when they target the same disease;

- **indication of use**: vaccines for different diseases are not generally substitutable, even within the same species group;

- **single or multiple pathogens**: vaccines can be monovalent (ie, containing one or multiple strains of a single antigen and designed to protect against one specific disease) or multivalent (ie, containing two or more different antigens, usually capable of protecting against several diseases). Monovalent and multivalent vaccines can be substitutable in some instances, depending on the diseases being targeted;

- **live or inactivated vaccines**: live vaccines are made from natural non-virulent organisms or from organisms that have been modified to be non-virulent. Inactivated vaccines (also known as "killed" vaccines) are made from killed virulent organisms or from inactivated parts of these organisms. Live vaccines are generally more effective at stimulating a protective immune response and for some vaccines may only need to be administered once to an animal at a young age to provide life-long protection, but they can create side-effects/stress in an animal or may be harmful to the foetus in pregnant animals as they trigger a sub-clinical infection in the animal. The onset of immunity is typically more rapid for live vaccines as compared to inactivated vaccines; and

- **marker vaccines**: marker vaccines allow veterinarians to distinguish between animals that are immunized as a result of vaccination or as a result of exposure to a naturally occurring pathogenic strain of the virus.

As regards the distinction between monovalent and multivalent vaccines, Pfizer believes that it is not possible to make a generalised statement as regards substitutability. Instead, a case-by-case examination is required because the degree of substitutability depends on the species and pathogen in question, as well as other factors such as safety considerations, veterinary practice in individual jurisdictions and disease localisation.

As regards the distinction between live and inactivated vaccines, evidence suggests increased levels of competition between the use of live and inactivated vaccines. In addition, not all live vaccines are administered only once, as there are some products where booster shots are recommended and/or required to achieve protection. Therefore, Pfizer considers that the distinction between live and inactivated vaccines is not relevant to the definition of the relevant markets for the purpose of the Proposed Merger.

In relation to marker vaccines, there may be some exceptional circumstances where marker vaccines are the only viable option, such as in the context of an eradication campaign, and as a result may form a distinct product market. However, these exceptional circumstances do not apply in the context of the Proposed Merger.

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[208] See European Commission, Case No. COMP/M.4691 – *Schering-Plough/Organon BioSciences*, Decision of 11 October 2007.

Therefore, applying the principles set out above, Pfizer submits that the relevant markets for the manufacture and supply of vaccines are to be defined on the basis of:

- species;
- target disease; and
- monovalent or multivalent vaccines (as may be relevant in each case).

In all cases, the relevant markets are national.

An exception to these principles is made in respect of clostridial vaccines. Pfizer considers that clostridial vaccines for sheep and cattle are in the same product market for reasons discussed in detail in section 13.9.

(b) Parasiticides

Parasiticides can broadly be categorised into:

- **ectoparasiticides**, used to control external parasites such as fleas, ticks, flies, lice and mange mites, which affect all animal species. Ectoparasiticides are applied directly on the animal in the form of sprays, dips, showers, jetting solutions, dusting powders, pour-ons, spot-ons, shampoos, collars, creams or lotions;
- **endoparasiticides**, used to control internal parasites (gastro-intestinal roundworms and tapeworms, lungworms, liver flukes, etc) in various species. They are administered either orally, topically or by injection; and
- **endectocides**, used to concurrently treat external and internal parasites and may be administered by various means, in sheep commonly as an oral liquid drench but may also be administered as an injection or rumen bolus. For cattle the most common form of administration is as a topical "pour-on" formulation, though these products can also be administered as an injection or oral formulation.

There is a fundamental distinction between parasiticides which act against single-celled parasites (protozoa) and parasiticides which act against multi-celled organisms (fleas, ticks, flies, lice, mites and worms).[209] This distinction has been accepted in previous EC decisions.[210] There is no overlap between the Parties in relation to single-celled parasites and thus those products are not discussed further. The term "parasiticide" is used in this submission to include the multi-celled external and internal parasites outlined above.

Market definition for parasiticides will also depend upon the species that the parasiticides are used for. Demand and supply side substitutability between ectoparasiticides, endoparasiticides and endectocides changes from one species to the next:

- large and small animals are typically afflicted by different types and species of parasites. For instance, in ruminants the most common internal parasites targeted are (depending on geographic region and whether sheep or cattle) stomach and

[209] The physiology and life-cycles of coccida species (eg *Isospora spp* and *Eimeria spp*) are very different from multi-celled parasites (eg insects and worms) Accordingly, anti-coccidials (eg Ionophores such as monensin and lacalocid), comprise different chemicals and modes of action to those (eg Macrocyclic lactones and Benzimidazoles) utilised in ectoparasiticides, endoparasiticides and endectoparasiticides.

[210] European Commission, Case No. COMP/M. 4691 – *Schering-Plough/Organon Biosciences*, Decision of 11 October 2007, at paragraph 422; European Commission, Case No. COMP/M. 885 – *Merck/Rhone-Poulenc-Merial*, Decision of 2 July 1997, para 33.

intestinal worms (*Haemonchus spp., Ostertagia spp., Trichostrongylus spp., Cooperia and Nematodirus spp.*), liver fluke (*Fasciola hepatica*), lice (*Bovicola ovis/bovis* and *Linognathus spp.*), ticks (*Rhipicephalus microplus*) and Buffalo flies; and

- in the case of production animals, considerations of the cost of the treatment (including both parasiticide costs and labour costs) and indications on the withdrawal period play a significant role in the farmer and veterinarian's decision as to which product to purchase.

For the purposes of this application, Pfizer considers that a different approach to market definition applies to parasiticides for sheep and cattle, which have been recently considered by the ACCC, the NZCC and the EC.

In the NZCC's Schering-Plough/Organon Biosciences decision, the NZCC specifically noted at paragraph 144 that its market inquiries found in relation to parasiticides for sheep that "*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*".[211] However, the NZCC decided that, because of the lack of aggregation between the merger parties in respect of endectocides, the Proposed Merger was best analysed in a market consisting only of ectoparasiticides.

In the Schering-Plough Decision, the EC considered the question of market definition in a context where there were overlaps in relation to all three types of products. It accepted evidence that:

- customers can and do use endoparasiticides and endectocides interchangeably to treat internal worms with no significant difference in effectiveness, internal parasite spectrum and withdrawal period;

- suppliers of endoparasiticides generally must price their products sufficiently lower than endectocides in order to maintain competitiveness; and

- suppliers of endectocides focus advertising of their products primarily (sometimes exclusively) on the endoparasiticidal aspects of their endectocide products.

Based on that evidence, the EC took the view that there was substitutability between endoparasiticides and endectocides, and held that both products were part of the same market.[212] This is the approach that Pfizer has adopted for the purpose of this application.

While the EC has also noted, in an earlier decision,[213] a "*tendency towards the progressive replacement of endoparasiticides and ectoparasiticides* [by endectocides]", the competition analysis presented in this application does not include ectoparasiticides. As there is no overlap between the Parties in respect of ectoparasiticides, Pfizer does not consider their exclusion from the product market definition to be material.

While the EC has adopted the approach of treating parasiticides for sheep and cattle as part of the same market, Pfizer considers that there are separate markets for sheep and for cattle endo/endectocides in New Zealand. The vast majority (over 90%) of cattle

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[211] *Schering-Plough Corporation/Organon Biosciences N.V.*, NZCC Decision 621, 4 October 1997, at paragraph 144.
[212] See European Commission, Case No. COMP/M.4691 – *Schering-Plough/Organon BioSciences*, Decision of 11 October 2007, at paragraphs 429-432.
[213] European Commission, Case M.885 – *Merck/Rhone-Poulenc-Merial*, Decision of 2 July 1997, at paragraph 42.

endo/endectocides in New Zealand are pour-on products, which cannot be used on sheep due to lack of efficacy. Sheep endo/endectocide products tend to be administered either orally or by injection, a method of application hardly ever used with cattle because of the inconvenience and time costs involved in administering the product. Manufacturers of endo/endectocide products must also register their products for particular species, with very few products registered for both cattle and sheep. Given these facts, the EC's approach is therefore not applicable for New Zealand.

With respect to active substance/target pathology, individual products may contain active substances that are more effective against one or more specific types of parasite. From a functional point of view, targeted parasiticides (treating a single parasite) have no substitutability with other parasiticides that are effective against a different, targeted parasite (eg, flukicides that treat liver flukes cannot treat lungworms). However, a number of products are effective against multiple parasites (ie, they are considered "broad spectrum") and thus cannot be defined as being part of a single market of products that treat individual parasites. Therefore, a decision on market definition needs to consider on a case by case basis whether the product treats a single parasite or is a broad spectrum product.

Therefore, applying the principles set out above, Pfizer submits that the relevant markets for the manufacture and supply of parasiticides for sheep and cattle are to be defined on the basis of:

- whether they are endoparasiticides/endectocides, or ectoparasiticides;
- the animal species treated; and
- whether they are broad spectrum, or target a particular parasite.

In all cases, the relevant markets are national.

(c) Application of principles

Based on the above principles, Pfizer submits that the relevant markets for assessing the Proposed Merger are as following:

- multivalent vaccines for cats;
- multivalent vaccines for dogs;
- *B. bronchiseptica* (canine cough) vaccines;
- Leptospirosis vaccines for dogs;
- monovalent *M. hyopneumoniae* vaccines for swine;
- multivalent *M. hyopneumoniae H parasuis* vaccines for swine;
- Parvovirus vaccines for swine;
- *S. equi* vaccines for horses;
- multivalent clostridial vaccines for sheep and cattle;
- endoparasiticides and endectocides for sheep; and
- endoparasiticides and endectocides for cattle.

In a number of these markets, there is either limited or no overlap between the Parties.

10.2 Vertical Integration

The Proposed Merger does not result in any vertical integration post-merger.

11 Counterfactual

In the event that the Proposed Merger does not take place, the likely counterfactual is the status quo, that is, the Parties would continue to operate their respective businesses.

12 Competition Analysis – Overview

12.1 Existing Competitors

There are a large number of global companies who are active in the animal health industry in New Zealand and compete with the Parties in one or more of the relevant markets. The profiles below focus on the competitors that are active in manufacturing and/or supplying animal health products in New Zealand rather than those who may be operate in another segment of the industry.

(a) Merial Ancare

Merial Ancare describes itself as New Zealand's leading animal health company. It is the result of the merger of the multinational Merial Ltd, and the New Zealand owned Ancare NZ Ltd.[214] Merial Ancare's headquarters are located in Manukau City.

Merial Ltd was formed in 1997 as a joint venture between Merck & Co and Aventis SA (formerly Rhone-Poulenc). Merial S.A.S., its parent company, has the largest research and development investment in the animal health industry with nine research and development centres around the world and has a network of 15 manufacturing sites globally.[215]

Merial Ancare is advancing developments in four main areas: parasiticides, antibiotics, pain control, and products for treating chronic conditions in companion animals. They are also exploring and developing new ranges of vaccines which employ both conventional and novel technologies with the objective of offering enhanced protection to a wide range of animal species.

Merial Ancare distributes exclusively through veterinary clinics or vet associated companies. Merial Ancare is strong in both the production and companion animal markets with a large range of products for sheep and cattle including the IVOMEC, EPRINEX, GENESIS, ECLIPSE, MATRIX and BIONIC brands as well as FRONTLINE and PREVICOX brand for cats and dogs. The production animal products are predominantly internal and external parasite control products, but also include antibiotics, intra-mammaries, and vaccines.[216]

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[214] Merial Ancare, *Our Company* (2009) <http://nz.merial.com/corporate_content/our_company/index.asp> at 27 May 2009.
[215] Merial ,*Welcome to Merial,* <http://corp.merial.com/> at 27 May 2009.
[216] Merial Ancare, *Our Company* (2009) <http://nz.merial.com/corporate_content/our_company/index.asp> at 27 May 2009.

On 9 March 2009, Merck & Co announced that it would enter into a merger agreement with Schering-Plough Corporation, also a competitor in the animal health industry in New Zealand.[217] The Parties understand that a Notice seeking clearance in respect of this merger was lodged with the NZCC on 19 May 2009.

Of the markets relevant to the Proposed Merger, Merial Ancare is active in the following:

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

(b) Virbac New Zealand Limited (**Virbac**)

Virbac was founded 30 years ago and focuses on the development of products for companion animals (dogs, cats, horses, tropical fish, ornamental birds etc), traditional livestock (dairy cows, beef cattle and sheep) and intensive animal production (pigs and poultry). Virbac's head office is in France. Virbac's global operations are divided into 7 geographic regions, which operate in an autonomous manner.

Virbac New Zealand Limited is a subsidiary of Virbac Australia Pty Limited, and has been operating in New Zealand since 1984. Virbac Australia Pty Limited's parent company 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.[218] In 1993, Virbac NZ acquired the majority shares of Techvet.[219]

Virbac's vaccines are manufactured in Australia and the US, with a repacking/labelling facility in East Tamaki, Auckland. Virbac NZ's major international suppliers apart from Virbac include Codan, Genesis, Heska, ICPBio, Sergeants, and 3M.[220]

Of the markets relevant to the Proposed Merger, Virbac is active in the following:

- multivalent vaccines for dogs
- multivalent vaccines for cats; and
- *B. bronchiseptica* (canine cough) vaccines.;

Virbac NZ supplies a number of other animal health products to the New Zealand market and half of its business relates to companion animal products. It also supplies fertility vaccines for sheep, minerals and calf products.

(c) Intervet/Schering-Plough Animal Health Limited (**Intervet/Schering-Plough**)

Schering-Plough Corporation is a New Jersey based corporation, listed on the New York Stock Exchange. It is a global science-based healthcare company with activities in the prescription and OTC pharmaceutical, consumer and animal health sectors. In New Zealand, Schering-Plough's animal health activities are conducted through Schering-

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[217] See Merck, 'Merck and Schering-Plough to Merge' (Media Release, 9 March 2009) available at <http://www.merck.com/newsroom/press_releases/corporate/2009_0309.html> at 27 May 2009.

[218] Virbac, *About Virbac New Zealand Ltd,* <http://www.virbac.co.nz/about_nz.asp> at 27 May 2009.

[219] Virbac, *About Virbac New Zealand Ltd,* <http://www.virbac.co.nz/about_nz.asp> at 27 May 2009.

[220] Virbac, *About Virbac New Zealand Ltd,* <http://www.virbac.co.nz/about_nz.asp> at 27 May 2009

Plough Animal Health Limited, which is trading as Intervet/Schering-Plough Animal Health.

Intervet/Schering-Plough has a large manufacturing plant in Upper Hutt. It holds regulatory licences allowing export to Australia, as well as other jurisdictions (North and South America, the European Union and Africa).[221] Large volumes of vaccines are produced at Upper Hutt with over 80% exported to other countries, including Australia.[222]

Intervet/Schering-Plough NZ provides its wide range of products to veterinarians, pet owners and farmers.[223]

Of the markets relevant to the Proposed Merger, Intervet/Schering-Plough is active in the following:

- multivalent vaccines for cats;
- multivalent vaccines for dogs;
- canine cough vaccines for dogs;
- Leptospirosis vaccines for dogs; and
- clostridial vaccines for sheep and cattle.

(d) Bayer New Zealand Limited (**Bayer**)

Bayer Animal Health is active in 120 countries and has turnover of approximately €0.8 billion.[224] It is at the forefront of technology used to manufacture anti-infectives, parasiticides and foot-and-mouth disease vaccines. The Bayer Animal Health has 2 production sites and 5 main regional sites.

In New Zealand, Bayer was incorporated in 1964 and imports all products from Germany and other third party distributors; it has some products toll manufactured in New Zealand and in Australia by third parties.[225] It operates a repackaging/labelling facility in East Tamaki, Auckland.

Of the markets relevant to the Proposed Merger, Bayer NZ is active in the following:

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

(e) Novartis New Zealand Limited (**Novartis**)

Novartis International AG was formed in 1996 through the merger of Ciba-Geigy and Sandoz (two companies). Its headquarters are in Basel, Switzerland and is present in

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[221] Intervet Schering-Plough Animal Health, *Global Vaccine Unit*, <http://www.spah.co.nz/global_vaccine_unit.html> at 27 May 2009.

[222] Intervet Schering-Plough Animal Health, *Global Vaccine Unit*, <http://www.spah.co.nz/global_vaccine_unit.html> at 27 May 2009.

[223] Intervet Schering-Plough Animal Health, *Intervet New Zealand,* <http://www.intervet.co.nz/company/intervet_new_zealand.asp> at 27 May 2009.

[224] Bayer Animal Health, *At a Glance*, <http://www.animalhealth.bayerhealthcare.com/3459.0.html> at 27 May 2009.

[225] *Schering-Plough Corporation/Organon Biosciences N.V.*, NZCC Decision 621, 4 October 1997, at paragraph 43.

almost 40 countries.[226] Novartis Animal Health manufactures a number of vaccines in the United States for cattle and sheep.

In New Zealand, Novartis (previously Sandoz Pharma Ltd) was incorporated in 1955.

Of the markets relevant to the Proposed Merger, Novartis is active in the following:

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

(f) Stockguard Laboratories (NZ) Limited (**Stockguard**)

Stockguard is a private New Zealand company that specialises in the development and manufacture of veterinary products, including veterinary antibiotic products in New Zealand.[227] It operates out of Hamilton New Zealand.[228]

Stockguard also handles the marketing and distribution of Vetpack products (Independent Veterinary Suppliers of Te Awamutu, NZ), veterinary pharmaceuticals from France, and Ausrichter products from Australia.[229]

(g) Boehringer Ingelheim NZ Limited (**Boehringer**)

Boehringer Ingelheim Auslandsbeteiligungs GmbH was founded in 1885 in Germany. It is a worldwide operating affiliated group of companies with almost 40,000 employees, with its global headquarters located in Ingelheim, Germany. [230]

Boehringer has been operating in New Zealand since 1973,[231] and is currently located in East Tamaki Auckland.[232]

- Of the markets relevant to the Proposed Merger, Boehringer is active in the supply of *B. bronchiseptica* (canine cough) vaccines.

(h) Norbrook New Zealand Limited (**Norbrook**)

Norbrook Laboratories Limited was established in Ireland in 1968. Internationally, Norbrook 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 was incorporated in New Zealand and is operated from Australia.[233]

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[226] Novartis Animal Health, *About Us,* <http://www.ah.novartis.com/about/en/index.shtml> at 27 May 2009.

[227] Stockguard Laboratories (NZ), *Stockguard Laboratories – Company Profile*, <http://www.stockguard.co.nz/company-profile/company_profile.html> at 27 May 2009.

[228] Stockguard Laboratories (NZ), *Facilities*, <http://www.stockguard.co.nz/company-profile/facilities/building.html> at 27 May 2009.

[229] Stockguard Laboratories (NZ), *Stockguard Laboratories – Company Profile*, <http://www.stockguard.co.nz/company-profile/company_profile.html> at 27 May 2009.

[230] Boehringer Ingelheim, *Organisation*, <http://www.boehringer-ingelheim.com/corporate/corp/organisation.asp> at 27 May 2009.

[231] *Schering-Plough Corporation/Organon Biosciences N.V.*, NZCC Decision 621, 4 October 1997, at paragraphs 48 and 49.

[232] Boehringer Ingelheim, *Global Activities – New Zealand,* <http://www.boehringer-ingelheim.com/corporate/asp/global/activities_detail.asp?continent=Australasia&country=New+Zealand> at 27 May 2009.

[233] *Schering-Plough Corporation/Organon Biosciences N.V.*, NZCC Decision 621, 4 October 1997, at paragraphs 45 and 46.

Of the markets relevant to the Proposed Merger, Norbrook is active in the following:

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

(i) Elanco New Zealand (**Elanco**)

Elanco is a division of Eli Lilly and Co, a leading human healthcare company listed on the New York Stock Exchange. Elanco is a multinational research and development company.

In New Zealand, Elanco has been active since 1965. Elanco's product line concentrates on antibacterials, parasiticides, anticoccidials and productivity enhancers for livestock, as well as medicines for pets.

Elanco markets its products through veterinarians, merchant groups and feedmills nationwide.[234]

(j) Ethical Agents Limited (**Ethical Agents**)

Ethical Agents was founded in 1968 to supply the NZ animal health market, marketing and distributing a wide selection of products to all sectors of the market.[235] The company was purchased in 2002 (keeping its name) and now holds sole agencies for 27 international companies and also have their own range of products.[236] Ethical Agents currently employs 17 staff.

Ethical Agents supply products for horses, livestock, cats and dogs, mostly sourced from other companies. Ethical Agents has a repackaging/labelling facility in Wiri, Auckland.

(k) Jurox New Zealand Limited (**Jurox**)

Jurox Pty Limited is an Australian-based privately-owned veterinary pharmaceuticals company mostly active in Australia and New Zealand. Jurox New Zealand Limited was incorporated in 1996 and is a wholly-owned family company which services the New Zealand market.[237]

Jurox NZ provides products for cats, dogs, pigs, sheep, cattle and horses, as well as vet-only products.[238]

Of the markets relevant to the Proposed Merger, Jurox is active in the following:

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

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[234] Elanco New Zealand, *Welcome to Elanco,* <http://www.elanco.co.nz/> at 27/05/2009.

[235] Ethical Agents, *About Us,* <http://www.ethicalagents.co.nz/pages/aboutus.phtml?s=CB144FE61235625879527> at 27 May 2009.

[236] Ethical Agents, *About Us,* <http://www.ethicalagents.co.nz/pages/aboutus.phtml?s=CB144FE61235625879527> at 27 May 2009.

[237] *Schering-Plough Corporation/Organon Biosciences N.V.*, NZCC Decision 621, 4 October 1997, at paragraphs 51 and 52.

[238] Jurox, *Products,* <http://www.jurox.com.au/custom/products/html/index.cfm?menukey=17> at 27 May 2009.

(l) PacificVet Limited (**PacificVet**)

PacificVet is an independent operator established in 1993 by Bruce Graham and Kent Deitemeyer, "who have since become the market leaders in supply of vaccines and veterinary immunology products", the pig and poultry industries in particular.[239]

PacificVet operates a facility in Christchurch, NZ for the manufacture of non-sterile veterinary preparations and repackaging/labelling. PacificVet's market ranges from New Zealand through the Pacific Islands, stocking 35 products. It is also the distributor of Fort Dodge swine, equine and poultry products in New Zealand.

Of the markets relevant to the Proposed Merger, PacificVet is active in the following:

- monovalent *M. hyopneumoniae* vaccines for swine;
- multivalent *M. hyopneumoniae H parasuis* vaccines for swine;
- Parvovirus vaccines for swine; and
- *S. equi* vaccines for horses.

(m) Bomac Laboratories Limited (**Bomac**)

Bomac was founded in 1958 in New Zealand as a dedicated supplier of generic animal health products. Bomac is New Zealand's largest privately owned animal health company, based in Auckland, manufacturing over 200 products for sale in NZ to over 60 countries.[240] Bomac Laboratories Ltd is also responsible for all new product development and the preparation of technical dossiers to support product registrations worldwide.[241]

Bomac researches, develops, manufactures, promotes and distributes a range of products for cattle, sheep, pigs, horses, goats, deer, dogs, cats and other animals.

Bomac's customers include farmers, pet owners, "horse lovers", trainers, veterinarians, wholesalers and distributors.[242] Bomac is in the unusual position of having a very strong pipeline of new products coming to market over the next few years. These products include products from all suppliers as well as products developed and registered by Bomac.[243]

On 30 June 2008, Bomac and Parnell Laboratories agreed to the sale of a range of quality veterinary products. The sale includes the rights to the brands, registrations, formulations and the majority of stock on hand of the following products: Antidiarrhoea Powder, Bolt 1000, Bolt 1000 + Se, Bolt 2000, Bolt 2000 + Se, Calsenate, Contran-H, Fentazin 5, Fentazine 10, Flunix, Gastric Stimulant Powder, Giafen, Histantin, Magnesate, Metrin, Musca Ban, Pethidine, Prilocaine, Reverzine, Reverzine SA, Triclovet, Xylaze and Xylaze Forte. Under the sale agreement Bomac will manufacture, distribute and sell all of the products listed.[244]

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[239] PacificVet, *Business Profile,* <http://www.pacificvet.co.nz/index2.html> at 27 May 2009.

[240] Bomac, *Bomac First for Animal Health,* <http://www.bomac.co.nz/page.cfm?pid=1&sid=53> at 27 May 2009.

[241] Bomac, *Bomac First for Animal Health,* <http://www.bomac.co.nz/page.cfm?pid=1&sid=53> at 27 May 2009.

[242] Bomac, *Welcome,* <http://www.bomac.net.au/> at 27 May 2009.

[243] Bomac, *Company Profile*, <http://www.bomac.net.au/default.cfm?l1=1> at 27 May 2009.

[244] Bomac, *News,* <http://www.bomac.net.au/default.cfm?l1=2> at 27 May 2009.

Of the markets relevant to the Proposed Merger, Bomac is active in the following:

- endoparasiticides and endectocides for sheep;
- endoparasiticides and endectocides for cattle; and
- clostridial vaccines for sheep and cattle.

(n) Ravensdown Fertiliser Co-Operative Limited (**Ravensdown**)

Ravensdown is the largest supplier of fertiliser in New Zealand, directly supplying more than half of the fertiliser used in New Zealand agriculture.[245] Ravensdown is 100% owned by farmers.

Ravensdown's product range includes; minerals and vitamins, nutritional products, anthelmintics (ie, parasiticites), applicator guns, facial eczema and testing services.[246] In 2005, Ravensdown commenced supplying a range of parasiticides by becoming licensed to distribute Jurox products, which it rebrands under the Ravensdown name and sells directly to farmers.[247]

Of the markets relevant to the Proposed Merger, Ravensdown is active in the following:

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

(o) Phoenix Pharm Distributors Limited (**Phoenix Pharm**)

Phoenix Pharm was incorporated as a company in 1983, with the objective of marketing, selling and distributing animal health products to the animal health industry and the New Zealand veterinary profession.[248] It is a wholesale distributor of pharmaceutical, surgical, nutritional, over the counter and general consumable supplies. Phoenix Pharm has a sister company, Vetpharm (NZ) which operates out of the same premises. The head office is in Auckland, NZ.

Phoenix Pharm does not sell directly to the public.[249] Phoenix Pharm represents several agencies in NZ, including; Nature Vet Pty Ltd Australia, KELA/Phenix Pharma Belgium, Quali-Tech US, B Braun Vet Care Germany, Bectin Dickson US and Simcro Tech NZ.

(p) Parnell New Zealand Limited (**Parnell NZ**)

Parnell Laboratories (Aust) Pty Limited (**Parnell**) was founded over 40 years ago in Australia and is now an international supplier of generic animal health products. Parnell NZ was incorporated in 1988. [250]

Parnell NZ is active in intramammary treatments for cattle and analgesics for horses.

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[245] Ravensdown, *About us,* <http://www.ravensdown.co.nz/About/default.htm> at 27 May 2009.
[246] Ravensdown, *Animal Health,* <http://www.ravensdown.co.nz/Products/Animal+Health/Default.htm> at 27 May 2009.
[247] *Schering-Plough Corporation/Organon Biosciences N.V.*, NZCC Decision 621, 4 October 1997, at paragraph 55.
[248] Phoenix Pharm, *Welcome to Phoenix Pharm Online,* <http://www.phoenixpharm.co.nz/index.htmll> at 27 May 2009.
[249] Phoenix Pharm, *Welcome to Phoenix Pharm Online,* <http://www.phoenixpharm.co.nz/index.html> at 27 May 2009.
[250] *Schering-Plough Corporation/Organon Biosciences N.V.*, NZCC Decision 621, 4 October 1997, at paragraphs 62 and 63.

(q) VetPharm NZ limited (**VetPharm**)

VetPharm was incorporated in 1994 with the objective to market and distribute a range of quality animal health products to the NZ veterinary profession and animal health industry.[251] VetPharm is the sister company of Phoenix Pharm Distributors, and operates out of the same location.

VetPharm distributes products sourced from Australia, the US, and Europe, as well as from local manufacturers. The product range includes; proscription products such as antibiotics, anaesthetics, anti-inflammatories and hormones, surgical supplies, nutritional supplements, equine products and dermatological products.[252]

(r) BioCell Corporation Limited (**BioCell**)

BioCell has manufacturing and production facilities in Papatoetoe, Auckland and a testing facility in Wanaka, Otago. BioCell produces a number of vaccines for scabby mouth (Orf virus), some under licence from Schering-Plough (UK) and Schering-Plough (NZ), in addition to colostrum supplements and milk supplements for Fonterra Co-operative Group Ltd.[253]

12.2 Market shares and competitive constraints posed by existing competitors

Estimated market shares and a discussion of the competitive constraints posed by existing competitors in each relevant market are set out in sections 13 of this application.

12.3 Potential Competition

In the Schering-Plough Decision, the Commission concluded that:

- 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.[254]

Pfizer considers these conclusions continue to apply in the context of the Proposed Merger.

In particular, Pfizer notes:

- a new competitor does not need to set up new manufacturing facilities in order to supply animal health products. Rather, it is quite common to enter into supply agreements with existing manufacturers of animal health products. Several examples of such supply agreements are discussed in sections 1 and 13 of this application;

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[251] Phoenix Pharm, *Vetpharm (NZ) – Company Profile,* <http://www.phoenixpharm.co.nz/pages/vetpharmprofile.htm> at 27 May 2009.

[252] Phoenix Pharm, *Vetpharm (NZ) – Company Profile,* <http://www.phoenixpharm.co.nz/pages/vetpharmprofile.htm> at 27 May 2009.

[253] Biocell Corporation Limited, *About Us,* <http://www.biocellcorp.co.nz/index2.html> at 28 May 2009.

[254] European Commission, Case No. COMP/M. 4691 – *Schering-Plough/Organon Biosciences*, Decision of 11 October 2007, at paragraph 422

- registration of products with the NZFSA is inexpensive, with registration costs ranging from less than $2,000 (for registration of a generic product that is identical to another product already registered) to less than $6,000 (for registration of a product which is similar to a product that is already registered);

- marketing and distribution costs are not a barrier. Customers are not loyal to specific brands and will switch to cheaper, generic brands. Several animal health companies have been able to enter and expand at the expense of existing players by supplying generic products. For example, Ancare was a strong supplier of generic parasiticides when it commenced its operations in 1985[255] and was able to take market share from Merial, the leading supplier at the time and with whom Ancare merged with in 2007. More recently, Ravensdown has been able to gain market share in a relatively short period by supplying generic endo/endecto products.

Many of the participants in the New Zealand animal health industry are able to quickly enter or expand into the supply of new products by importing.

Global pharmaceutical companies have extensive portfolios of products that they can rely on to expand their prescence in New Zealand. The process for importing animal health products into New Zealand is not an onerous one compared to other countries such as Australia. Registration with the NZFSA can be completed in a relatively relatively short timeframe without incurring significant costs, particularly if a similar product is already available in New Zealand. Even if it is a new product, that is, a product with an active ingredient that is not already registered with the NZFSA, Pfizer estimates that registration with the Environmental Risk Management Authority (**ERMA**) could be achieved within 12 months. Lastly, these companies do not have to establish a new distribution network and can rely on their existing relationships with veterinary wholesalers and other distributors.

Participants are also able to enter and expand by entering into toll manufacturing or distribution arrangements with competitors and manufacturers in New Zealand and overseas. There are many examples of such arrangements in the industry, as will be discussed in more detail in section 13.

The likelihood, timeliness and sufficiency of this entry is likely to pose a major constraint on the behaviour of the merged entity.

12.4 Countervailing Power of Buyers

(a) Buyers of animal health products in New Zealand

As noted above in section 9.1, veterinary wholesalers and rural supply stores are the main channels through which animal health products are distributed.

Pfizer supplies its products almost entirely through the veterinary channels, that is, through a veterinary wholesaler or direct to vet clinics.

Pfizer's main customers are the two main veterinary wholesalers in New Zealand, Provet and SVS:

- Provet is the NZ subsidiary of Provet Pty Ltd, an Australian company. It commenced its veterinary wholesaling business in New Zealand in August 2002

[255] Ancare, *About Ancare*, < http://www.ancare.co.nz/main.cfm?id=2> at 5 June 2009.

with a sole distribution warehouse in Auckland.[256] It expanded to service customers in South Island and in 2005 acquired NVS, another veterinary wholesaler with distribution warehouses in Auckland, Palmerston North and Christchurch. Provet considers itself as Australasia's leading veterinary distributor, with over 320 employees, approximately A$185 million in sales and 12,500 product lines on shelf;[257] and

- SVS is a privately owned and operated company which commenced wholesaling animal health products to registered veterinary practices in 1987. Initially, it operated only in the South Island but expanded operations to the North Island in December 2000. Its distribution warehouses are located in Hamilton, Palmerston North and Christchurch.[258]

In addition, Pfizer supplies approximately 10 large veterinary clinics directly, including **[ ]**. These clinics mainly purchase Pfizer's pharmaceutical and/or vaccine products for dairy and beef cattle and sheep.

Fort Dodge, on the other hand, distribute through both veterinary wholesalers and rural supply stores. Approximately **[ ]** of sales of Fort Dodge animal health products are through rural supplies stores.

Major rural supplies stores in New Zealand include:

- RD1 – the largest retailer of agricultural services to dairy farmers, RD1 operates a network of over 50 stores across New Zealand.[259] RD1 is a wholly owned subsidiary of Fonterra and plans to expand its store network to cater to Fonterra suppliers in the South Island;[260]

- Elders NZ – another Australasian company, Elders stock a wide range of animal health products supplied by Jurox, Fort Dodge, Novartis, Intervet/Schering-Plough and Bayer;[261] and

- PGG Wrightson – formed in 2005 through the merger of Pyne Gould Guinness and Wrightson Limited, PGG Wrightson supplies a range of products, including animal health products, to the agricultural sector in New Zealand. It assets and annual turnover each exceed $1 billion. In the lower North Island, its rural supplies stores operated under the brand Williams & Kettle.[262]

There are also a number of farmers' co-operatives (eg Farmlands, CRT) which supply animal health products to end-customers. Farmlands, for example, stocks drenches,

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[256] *Provet NZ Pty Ltd/National Veterinary Supplies Limited*, NZCC Decision 549, 5 May 2005, at paragraph 12.

[257] Provet, *About Provet*, <http://www.provet.co.nz/AboutProvet/tabid/54/Default.aspx> at 2 June 2009.

[258] *Provet NZ Pty Ltd/National Veterinary Supplies Limited*, NZCC Decision 549, 5 May 2005, at paragraphs 17-18.

[259] RD1, *RD1 – The story so far!*, <http://www.rd1.com/web/content?in_section=9&in_item=1941> at 2 June 2009.

[260] Fonterra, 'Fonterra and Landmark Expand Rural Retail on Both Sides of the Tasman' (Media Release, 22 May 2006) available, at <http://www.fonterra.com/wps/wcm/connect/fonterracom/fonterra.com/our+business/news/media+release+archive/fonterra+and+landmark+expand+rural+retail+on+both+sides+of+the+tasman> at 2 June 2009.

[261] Elders NZ, *Merchandise*, <http://www.elders.co.nz/merchandise> at 2 June 2009.

[262] PGG Wrightson, *Company Profile*, <http://www.pggwrightson.co.nz/standard.cfm?page_id=627c3174-fd68-4150-bbbf-26f58d7d39e4&&> at 2 June 2009.

dips, vaccines, penicillin, endectocides, capsules, applicators and minerals from suppliers such as Bayer, Novartis, Intervet/Schering-Plough and Fort Dodge.[263]

(b) Countervailing power of buyers

In its decision on Provet's acquisition of NVS in 2005, the NZCC noted the following in relation to the purchase and distribution of animal health products:

- the major purchaser of animal health products were registered veterinarians, of which there were approximately 2000 practicing in 500 clinics;[264]
- veterinary wholesalers offered a broad portfolio of products to veterinarians. By having a large portfolio of products, wholesalers could offer veterinarians the convenience of acting as a "one-stop-shop";[265]
- manufacturers of animal health products found it more efficient to use a wholesaler to supply companion animal health products to a wholesaler as it reduced transaction costs;[266] and
- veterinarians purchased products through wholesalers to reduce inventory costs.[267]

Two years later, the NZCC has recognised that veterinarians exercise countervailing power over manufacturers of animal health products. In its decision on Schering-Plough/Organon Biosciences, the NZCC noted that many veterinarians are "*relatively large and sophisticated buyers, due to a trend of rationalisation in the veterinary industry*".[268] The NZCC accepted that veterinarians, many of whom have significant buying power, would have sufficient countervailing power to constrain the combined entity in the market for the supply of a campylobacter vaccine for sheep due to the presence of an alternative supplier.[269]

Pfizer submits that the above findings are applicable in the context of the Proposed Merger, especially as there is at least one alternative supplier in each of the relevant markets.

Veterinarians and veterinary wholesalers, as well as rural supplies stores, are likely to exert a significant degree of countervailing power over the actions of the merged entity for the reasons previously identified by the NZCC in relation to the Provet / NVS and Schering-Plough / Organon Biosciences transactions. Wholesalers, in particular, are able to exercise countervailing power because they offer cost-savings to manufacturers as well as convenience to veterinarians. The sophisticated buying practices of veterinarians further indicate that the merged entity is unlikely to be able to increase its prices to a significant extent post-merger.

It should also be noted that the availability of generics has had an impact on the countervailing power exercised by veterinary wholesalers and rural supplies stores. Generics enable these distributors to bypass existing suppliers by sourcing their own

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[263] Farmlands, *Animal Health*, <http://www.farmlands.co.nz/web/guest/products/animalhealth> at 2 June 2009.
[264] *Provet NZ Pty Ltd/National Veterinary Supplies Limited*, NZCC Decision 549, 5 May 2005, at paragraph 31.
[265] *Provet NZ Pty Ltd/National Veterinary Supplies Limited*, NZCC Decision 549, 5 May 2005, at paragraph 32.
[266] *Provet NZ Pty Ltd/National Veterinary Supplies Limited*, NZCC Decision 549, 5 May 2005, at paragraph 54.
[267] *Provet NZ Pty Ltd/National Veterinary Supplies Limited*, NZCC Decision 549, 5 May 2005, at paragraph 55.
[268] *Schering-Plough Corporation/Organon Biosciences N.V.*, NZCC Decision 621, 4 October 1997, at paragraph 303.
[269] *Schering-Plough Corporation/Organon Biosciences N.V.*, NZCC Decision 621, 4 October 1997, at paragraph 305.

generic products or sponsoring new entry or expansion. It terms of sourcing their own products, distributors could have the generic product manufactured by a toll manufacturer in New Zealand or overseas. As the NZCC noted in its Schering-Plough / Organon Biosciences decision, such arrangements are relatively commonplace in the animal health industry and are relatively straightforward to establish, at least in relation to pharmaceutical products.[270]

12.5 Coordinated Market Power

There is little or no risk that the Proposed Merger will change the characteristics of the relevant markets such that co-ordination between the participants in those markets is facilitated. In regards to the principal market structure and conduct features that the NZCC considers in assessing the likelihood of collusive behaviour, Pfizer notes the following:[271]

- **high seller concentration**: the Proposed Merger will not result in high levels of concentration in any relevant market, as discussed in sections 13;
- **undifferentiated product**: animal health products are differentiated products. While some products may use the same active ingredient, manufacturers and suppliers are able to add other features to distinguish their product or allow customers to administer the product in a number of different ways. For example, sheep endo/endectocides can also have a vitamin supplement for B12 or selenium deficiency and be administered orally, through an injection or slow-release capsule;
- **static production technology**: as noted above, R&D is a key feature of the pharmaceutical industry and participants spend millions of dollars on animal health R&D annually. Production technology is therefore not static and participants are constantly developing new methods and formulations to deal with animal health diseases;
- **slow speed of new entry**: as noted in sections 13 of this application, entry of new products (particularly generics) in each of the relevant markets under consideration is likely and occurs regularly;
- **lack of fringe competitors**: there are many fringe competitors in the animal health industry. In addition to small contract manufacturing companies, there are a range of biotech companies and small laboratories who compete, and assist, major pharmaceutical companies with developing new products. These fringe competitors could easily expand to compete with the merged entity and other animal health product suppliers;
- **acquisition of a maverick business**: the Proposed Merger does not involve the acquisition of a maverick business;
- **price inelastic market demand**: customers of animal health products are very sensitive to price changes. This is particularly evident in regards to parasiticides, which comprise a large proportion of the animal health products supplied in New Zealand. As discussed in more detail in sections 13.10 and 13.11, a number of competitors have been able to grow their business very quickly by supplying cheaper generic products;

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[270] *Schering-Plough Corporation/Organon Biosciences N.V.*, NZCC Decision 621, 4 October 1997, at paragraphs 232 to 239.
[271] NZCC, *Merger and Acquisitions Guidelines*, 1 January 2004, chapter 9.

- **history of anti-competitive behaviour**: Pfizer is not aware of anyhistory of anti-competitive behaviour in the relevant markets; and

- **characteristics of buyers**: as discussed in detail in section 12.4, the relevant buyers in this case are the distributors of animal health products. These distributors have a significant degree of countervailing power and have the ability to undermine any attempts to co-ordinate pricing.

12.6 Efficiencies

The Proposed Merger will allow the Parties to achieve synergies in relation to sales and marketing costs.

13 Competition analysis – Relevant markets

13.1 Multivalent vaccines for cats

(a) Product description

Feline vaccines are vaccinations administered to cats for the prophylactic prevention of a range of diseases, generally caused by viruses. The diseases against which the vaccine protects depends on the antigens, usually viral antigens, contained within each vaccine.

The multivalent cat vaccines supplied by the Parties are often classified in accordance with the type of protection offered, as shown in the table below.

Table 15 – Multivalent cat vaccines categories

Vaccine type	Protection offered against
F3	Feline rhinotracheitis virus; Feline calicivirus; Feline panleucopenia virus.
F4	Same as F3 vaccines plus *Chlamydophila felis*.
F5	Same as F4 vaccines plus feline leukaemia virus.

Multivalent cat vaccines supplied in New Zealand by the Parties and others are set out below. Fort Dodge imports all its vaccines from its production plant in the US.

Manufacturer	Product	Type
Fort Dodge	Fel-O-Guard Plus 3	F3
	Fel-O-Vax 3	F3
	Fel-O-Vax 4	F4
	Fel-O-Vax 5	F5
Pfizer	Felocell 3	F3
	Felocell 4	F4
	Fevac 3	F3
Intervet/Schering-Plough	Nobivac Tricat	F3
	Nobivac Forcat	F4
Virbac	Feligen RCP Cat Vaccine	F3

(b) Market definition

Veterinarian practice and local needs have led to a number of vaccines for companion animals - including for cats - being regularly administered together. For cats, the vaccines that are affected by this practice immunise the animal against the combination of feline herpes virus,[272] feline calicivirus,[273] feline panleucopenia virus,[274] *Chlamydophila felis*[275] and feline leukaemia virus.[276] These vaccines are often administered in kittens from around 8 weeks of age.

Applying the principles for market definition set out above (species, target disease and monovalent/multivalent), Pfizer submits that multivalent cat vaccines constitute a distinct market.

This definition of the market has been accepted in previous mergers subject to competition assessments, including the Schering-Plough Decision.

(c) Overlap and concentration

Pre-merger, Pfizer's share is approximately **[ ]** and Intervet/Schering-Plough is the second largest supplier on **[ ]**. As the table below shows, post-merger, the merged entity will have a share of **[ ]**.

Table 16 - Market share table for multivalent cat vaccines (post merger)

Manufacturer	Product	Doses %	Doses % total

[272] Feline herpes virus, also known as feline rhinotracheitis virus, can cause acute respiratory illnesses such as sneezing, nasal discharge, rhinitis (inflammation of the nose) and conjunctivitis. Current vaccines reduce the severity of the disease and the load of latent virus but they do not prevent infection.
[273] Feline calicivirus is a common viral disease that affects cats. It generates upper respiratory symptoms, pneumonia, mouth sores, conjunctivitis and occasionally arthritis. It is a fairly mild flu-like condition and rarely causes serious complications, but as it is one of the two most common causes of upper respiratory disease in cats it is commonly vaccinated against.
[274] Feline panleucopenia virus, also known as feline infectious enteritis, is a feline parvovirus closely related to canine parvovirus. It causes, in kittens (typically 6 to 24 weeks old), a severe depletion in white blood cells, vomiting, anorexia and fever and may cause death. Ataxia, head tremors and other central nervous system signs may present in kittens infected from 2 weeks before to 2 weeks after birth.
[275] Feline chlamydial disease causes conjunctivitis, rhinitis and respiratory problems. The disease is often subclinical. Vaccination protects from marked clinical disease but does not prevent infection.
[276] Feline leukaemia virus (FeLV) is a retrovirus associated with three major syndromes: a) Cancer (in particular lymphosarcoma); b) Anaemia; and c) Immune suppression. Approximately 30% of cats infected with the virus will contract disease and will have an average survival time of 3 months to 3 years.

Manufacturer	Product	Doses %	Doses % total
Total		100.0%	100%

(d) Competition analysis

In May 2004, the NZCC conduct an internal investigation into Pfizer's acquisition of CSL Limited's Animal Health Division in the United States, Australia and New Zealand. In respect of a market for "all-in-one" vaccines for cats and dogs, the NZCC concluded that there was sufficient existing competition in this market and no further action was required.[277] Pfizer submits that the NZCC should reach the same decision in regards to the Proposed Merger.

Post-merger, the merged entity will continue to face strong competition from Intervet/Schering Plough and Virbac, both being global animal health companies. In particular, Intervet/Schering Plough will continue to competitively constrain the merged entity's F3 vaccines, with F3 vaccines, as evidenced from the table above, being the most popular type of multivalent feline vaccine. In terms of sales by doses, Intervet/Schering Plough's Nobivac Tricat product is currently the second best selling F3 vaccine in New Zealand behind Pfizer's Felocell 3.

Intervet/Schering Plough's has maintained its strong position in the multivalent feline market, reporting similar sales, both by value and doses, in 2007 and 2008 for its Nobivac Tricat product. Its Nobivac Forcat product achieved a sales growth of **[ ]**, both by value and doses, between November 2007 and November 2008.

Intervet/Schering-Plough would be in a strong position to expand in the market and constrain the merged entity. Intervet/Schering-Plough currently imports its multivalent feline vaccines from Holland and has manufacturing operations spread across a number of countries, including a modern production plant based in Victoria, Australia.[278] This Australian production plant, known for the production of companion animal vaccines, currently manufactures multivalent feline vaccines for both Intervet/Schering Plough and Virbac for sale by the two companies in Australia.

13.2 Multivalent vaccines for dogs

(a) Product description

Canine vaccines are vaccinations administered to dogs for the prophylactic prevention of a range of diseases, generally caused by viruses. The diseases against which the vaccine protects depends on the antigens contained within each vaccine.

The most common multivalent dog vaccines are often referred to as:

- **"C3" vaccines**: immunising against distemper,[279] adenovirus,[280] parvovirus; and

[277] *Schering-Plough Corporation/Organon Biosciences N.V.*, NZCC Decision 621, 4 October 1997, at paragraph 87.

[278] Intervet Schering-Plough Animal Health, *Intervet Australia Pty Ltd*, <http://www.intervet.com.au/company/intervet-australia.asp> at 3 June 2009.

[279] Canine distemper is a virus related to the virus causing measles in humans.

- **"C4" vaccines**: immunising against the same three viruses as the C3 vaccines as well as the parainfluenza virus.[281]

The C3 and C4 vaccines are sometimes sold in packs in combination with other vaccines, such as:

- vaccines immunising against certain pathogens of canine cough (eg "BB"/"CCi" vaccines). These vaccines immunise against *B. bronchiseptica* which causes canine cough (some vaccines may additionally include antigens derived from other pathogens which also cause canine cough); and

- vaccines that immunise against two serovars of the bacterial genus *Leptospira* (*L. canicola* and *L. icterohaemorrhagiae*) in order to protect against the disease leptospirosis.

These packs (ie, containing C3 or C4 plus an additional vaccine) are generally known as combination products. In New Zealand, however, currently there are no C3 or C4 vaccines supplied in combination with a *B. bronchiseptica* (canine cough) vaccine.

Multivalent dog vaccines available in New Zealand are set out in the table below:

Manufacturer	Product	Type	Additional active ingredients
Fort Dodge	Protech C3	C3	-
	Duramune Adult C3	C3	-
	Protech C3+2i	C3	Leptospira interrogans
	Protech C4	C4	-
	Duramune Adult C4	C4	-
	Protech C4+2i	C4	Leptospira interrogans
Pfizer	Vanguard 5	C4	-
	Vanguard Plus 5	C4	-
Virbac	Canigen DHA2PPI	C4	-
Intervet/Schering Plough	Nobivac DHP	C3	-
	Nobivac DHPPI	C4	-

(b) Market definition

Veterinarian practice and local needs have led to a number of vaccines for dogs being regularly administered together. In New Zealand, the vaccines that are affected by this practice immunise dogs against distemper virus, adenovirus and parvovirus, either alone or in conjunction with canine parainfluenza virus and the canine bacterial pathogen *Leptospira.*

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[280] Canine adenovirus vaccines protect against canine respiratory infections caused by CAV-2 (a pathogen involved in the canine cough complex). This virus is closely related to canine adenovirus type 1 (CAV1) which is responsible for infectious canine hepatitis. Vaccination with CAV2 induces resistance to infections with both CAV1 and CAV2.
[281] Canine parainfluenza virus is one of the causes of canine infectious tracheobronchitis, more commonly known as canine cough.

In the Schering-Plough Decision, the EC concluded that there was a separate market for multivalent dog vaccines immunising against leptospirosis, and one or more of distemper, adenovirus (hepatitis), parvovirus and parainfluenza viruses.

Applying the principles for market definition set out above (species, target disease and monovalent/multivalent), Pfizer submits that multivalent canine vaccines constitute a separate market for the purposes of the Proposed Merger.

(c) Overlap and concentration

As the table below shows, Pfizer's pre-merger share is around **[ ]**. Post-merger, the merged entity will have a combined share of **[ ]**.

Table 17 - Market share table for multivalent dog vaccines (post merger)

Manufacturer	Product	Doses %	Doses % total
Total		100.0%	100%

(d) Competition analysis

Both Intervet/Schering-Plough and Virbac compete in the multivalent canine vaccine market; Intervet/Schering-Plough is particularly strong in this market.

Intervet/Schering-Plough has obtained a substantial share of the multivalent canine vaccine market with its Nobivac DHP product (a C3 vaccine) and its Nobivac DHPPI product (a C4 vaccine). Both these products are imported from Holland and are the only products with an extended duration of immunity (**DOI**) comparable to the DOI claimed by Fort Dodge's Duramune products and Pfizer's Vanguard Plus 5 product.

[282] This market share is based on sales of Virbac's Canigen Combi Pack, which is no longer being supplied in New Zealand as it has been replaced by the Canigen DHA2PPI product.

Intervet/Schering-Plough's multivalent canine vaccines continue to exhibit strong growth, with Nobivac DHP and Nobivac DHPPI achieving sales growth, both by value and doses, of around **[ ]** and **[ ]** respectively between November 2007 and November 2008.

13.3 *B. bronchiseptica* (canine cough) vaccines

(a) Product description

Canine cough vaccines are available as either stand-alone vaccines against *B. bronchiseptica*, or as vaccines for *B. bronchiseptica* in conjunction with other pathogens contributing to canine cough complex.

In New Zealand it is recommended that all puppies be vaccinated against *B. bronchiseptica*. Puppies can be vaccinated with either:

- a parenteral (intramuscular or subcutaneous injection) vaccine followed by a booster (2-4 weeks apart) and then revaccinated annually; or
- an intranasal vaccine is available which requires only one initial dose followed by annual revaccination.

For dogs that have not been vaccinated in the previous 6 months and are about to be housed in close proximity to other dogs, such as when boarding, a single booster vaccine administered intranasally is recommended at least 5 days prior to exposure.

The following table sets out the BB products available in New Zealand:

Manufacturer	Product	Active ingredient	Registration Number
Fort Dodge	Protech Bronchi-Shield I	*B. bronchiseptica*	A007928
	Protech Bronchi-Shield III	*B. bronchiseptica* Canine adenovirus type 2 Canine parainfluenza virus	A007929
Pfizer	Canvac CCi	*B. bronchiseptica*	A009667
Boehringer	Ontavac CPB	*B. bronchiseptica* Canine parainfluenza virus	A007779
Intervet/ Schering Plough	Nobivac KC	*B. bronchiseptica* Canine parainfluenza virus	A007865
Virbac	Canigen KC	*B. bronchiseptica* Parainfluenza-3 virus	A007377

(b) Market definition

Canine cough is one of the most common infectious diseases of dogs. Control is focused on preventing infection by administering canine cough vaccines. The bacterium *B. bronchiseptica* is the most common pathogen causing canine cough.

Other pathogens may contribute to the canine cough complex including canine parainflueza type 2 virus, canine adenovirus types 1 and 2, canine herpesvirus, *Mycoplasma spp*. and other bacteria such as *Streptococcus spp.*, *Pasteurella spp.*, *E. coli*

and *Klebsiella spp.* However, in most cases of canine cough, *B. bronchiseptica* is the primary pathogen which initiates the damage that allows colonisation by these secondary pathogens. In addition, it is *B. bronchiseptica* (rather than the secondary pathogens) that makes canine cough a highly contagious respiratory disease and a risk in high density population environments such as boarding kennels.

Accordingly, veterinary practice in New Zealand considers the canine cough vaccine to mean the vaccine against the primary pathogen, *B. bronchiseptica*, whether or not it includes other canine cough complex pathogens.

Vaccines immunising against *B. bronchiseptica* were not considered in the Schering-Plough Decision. However, adopting the principles for market definition set out above, Pfizer submits that the relevant market is the market for vaccines against *B. bronchiseptica*, including stand-alone *B. bronchiseptica* vaccines (including intranasal and parenteral vaccines) as well as vaccines in which *B. bronchiseptica* is provided in conjunction with other canine cough pathogens.

(c) Overlap and concentration

Pre-merger, Pfizer's product accounts for **[ ]** of dosage sales. The merged entity will have a combined share of **[ ]**, with Intervet/Schering-Plough and Virbac close behind on **[ ]** and **[ ]** respectively.

Table 18 - Market share table for canine cough vaccines (post merger)

Manufacturer	Product	Doses %	Doses % total
Total		100.0%	100%

(d) Competition analysis

Post-merger, Intervet/Schering-Plough and Virbac will continue to compete vigorously in the canine cough vaccine market, as will Boehringer. Intervet/Schering-Plough and Boehringer will supply intranasal canine cough vaccines, just like Fort Dodge's Protech Bronchi-Shield products. Virbac will supply an injectable canine cough vaccine similar to Pfizer.

Intervet/Schering-Plough's Nobivac KC vaccine is a live vaccine which also provides immunity against canine parainfluenza virus, another pathogen which causes canine cough. While Intervet/Schering Plough reported a slight decrease in Nobivac KC's growth between November 2007 and 2008 – around **[ ]** loss by value and **[ ]** loss by doses – it currently holds the largest share of the market, by reference to doses.

Virbac supplies Canigen KC, an inactivated canine cough vaccine. Virbac vigorously competes in this market, having recorded notable sales growth over the last couple of years. Between November 2006 and November 2007, Virbac's Canigen KC product exhibited growth of around **[ ]** by value and **[ ]** by doses; between November 2007 and November 2008, its market share continued to increase, recording growth of **[ ]** by value and **[ ]** by doses.

Boehringer also supplies a canine cough vaccine. Despite reporting negative growth between 2006 and 2007 – of around **[ ]** by value and **[ ]** by doses – it managed to achieve growth, by both value and doses, of over **[ ]** in the following year.

13.4 Leptospirosis vaccines for dogs

(a) Product description

Leptospirosis is a bacterial infection that colonises the kidney and genital tract of the host with potential involvement of the hepatic and central nervous system. The clinical manifestations of the disease include peracute, acute, chronic and subclinical forms. Chronic and subclinical infections are the most common. Chronic infections can cause fever, uveitis, renal and/or hepatic disease. The disease can be spread to humans and other animals when leptospires are shed in the urine and from the genital tract into the surrounding environment.[283]

The Parties supply vaccines immunising against the bacterial genus *Leptospira* which cause the disease. The vaccine is available in monovalent form as well in bivalent form with the canine coronavirus antigen.[284]

The following table sets out the Parties' vaccines as well as other vaccines available in New Zealand:

Manufacturer	Product	Active ingredient	Registration Number
Fort Dodge	Protech C2i	*Leptospira interrogans* Canine coronavirus	A007943
Pfizer	Leptoguard	*Leptospira interrogans*	A006526
Intervet/Schering-Plough	Nobivac Lepto I	*Leptospira interrogans*	A007832

(b) Market definition

Veterinarian practice and local needs in New Zealand have led to the vaccine against leptospirosis being predominantly administered as either a monovalent vaccine or as a bivalent leptospirosis-coronavirus vaccine.

In the Schering-Plough Decision, the EC concluded that there was a separate market for multivalent dog vaccines immunising against leptospirosis, and one or more of distemper, adenovirus (hepatitis), parvovirus and parainfluenza viruses. However note that a point

[283] Pfizer Animal Health, *Leptospirosis*, <http://www.pfizeranimalhealth.com.au/diseases/210/leptospirosis.aspx> at 28 May 2009.

[284] Note that coronarvius is not prevalent in New Zealand and its inclusion in dog vaccines is arguably more for marketing purposes than therapeutic purposes.

of differentiation between canine vaccination practice in the EC versus practice in New Zealand is that leptospirosis is considered to be included in the "core" vaccines in the EC unlike in New Zealand where leptospirosis only occurs in the North Island. In the EC the majority of leptospirosis vaccines are administered as part of a multivalent "core" vaccine package compared to NZ where the vast majority (approximately 94%) of leptospirosis vaccine doses is administered as a separate vaccine rather than part of the core vaccines.

Adopting the market definition principles set out above, Pfizer submits that the relevant market is the market for the supply of monovalent and bivalent canine leptospirosis vaccines including vaccines for leptospirosis alone and vaccines for leptospirosis plus coronavirus.

(c) Overlap and concentration

Pfizer currently has a **[ ]** share of dosage sales of leptospirosis vaccines for dogs. Post-merger the merged entity will have a combined share of **[ ]**.

Table 19 - Market share table for Leptospirosis vaccines for dogs (post merger)

Manufacturer	Product	Doses %	Doses % total
Total		100.0%	100%

It should be noted that the above table, includes combination products, that is, Fort Dodge's Protech C3 + 2i and Protech C4 + 2i products. These products have been included to fully capture the number of doses of leptospirosis vaccine (the 2i component) sold in New Zealand. Fort Dodge's stand-alone leptospirosis vaccine is in fact its Protech C2i product, while the other two products, the Protech C3+2i and Protech C4+2i merely have been packaged to include a leptospirosis vaccine along with the core C3 or C4 vaccines. If the competition analysis was to consider monovalent leptospirosis vaccines only (and so exclude the combination products), post-merger, the merged entity would only have increased its market share concentration by around **[ ]** and Intervet/Schering-Plough would retain around one third of the market share, constituting a significant competitor.

(d) Competition analysis

Intervet/Schering-Plough supplies an inactivated leptospirosis vaccine, its Nobivac Lepto I product, administered by injection. Between November 2007 and November 2008, this product exhibited growth of around **[ ]** and **[ ]** by value and doses respectively.

Intervet/Schering-Plough currently imports its Nobivac Lepto I product from Holland and consequently, in the event the merged entity attempted to increase the prices of its

leptospirosis vaccines, could quickly increase sales of its own product in order to counter this.

13.5 Monovalent *M. hyopneumoniae* vaccines for swine

(a) Product description

M. hyopneumoniae is a bacterium known to cause porcine enzootic pneumonia, one of the most significant respiratory diseases in swine. The disease usually manifests as chronic coughing and reduced growth rate of pigs.[285] Vaccination is used as a supplement to herd management practices and improved piggery housing conditions, to reduce the spread of enzootic pneumonia in piggeries.

The Parties vaccines are set out in the table below:

Manufacturer	Product	Active ingredient	Registration Number
Fort Dodge	Suvaxyn Respifend MH	M. *hyopneumoniae*	A009141
Pfizer	Respisure 50	M. *hyopneumoniae*	A006665
	Respisure	M. *hyopneumoniae*	A008250

While Fort Dodge manufactures the Suvaxyn Respifend MH vaccine, the registration is held by PacificVet. It is also marketed and distributed by PacificVet **[ ]**. Fort Dodge has a registration for the Suvaxyn MH One vaccine but does not market this vaccine in New Zealand because of **[ ]**.

(b) Market definition

Consistent with the principles outlined above, Pfizer submits that the relevant market is a national market for the supply of monovalent *M. hyopneumoniae* vaccines for swine.

In the Schering-Plough Decision, in the context of an overlap between Schering-Plough's and Intervet/Schering-Plough vaccines for swine, the EC considered a product market for monovalent *M. hyopneumoniae* vaccines. Its market investigation did not raise any issues in respect of that market definition.

Pfizer considers that multivalent *M. hyopneumoniae H parasuis* vaccines for swine, which immunise swine against *Haemophilus parasuis (**H. parasuis**)* as well as *M. hyopneumoniae*, are not part of the same market. The *H. parasuis* bacterium causes Glässers disease and there are many strains of the bacterium that are often unique to a particular country or region, or even a particular farm. Multivalent *M. hyopneumoniae H parasuis* vaccines and monovalent *H. parasuis* vaccines available overseas are therefore not always suitable for use in New Zealand.

From a demand-side perspective, monovalent and multivalent *M. hyopneumoniae* vaccines for swine do not appear substitutable. First, the higher price of the multivalent *M. hyopneumoniae* / *H. parasuis* vaccine may also mean that customers are unlikely to

[285] This particular form of pneumonia is chronic and contagious, and is usually accompanied by a secondary bacterial pathogen Pasteurella multocida type A. It can also lead to further serious respiratory diseases as it damages the pig's lungs and weakens natural barriers to infection: Pfizer Animal Health, *Respisure*, <http://www.pfizeranimalhealth.com.au/products/296/respisurereg.aspx> at 18 May 2009.

consider the multivalent vaccine substitutable for the monovalent vaccine.[286] Secondly, the multivalent vaccine is also a two-shot vaccine, which makes it less convenient for customers to administer unless Glässers disease is a problem in their piggery.

However, as discussed below, even if the relevant market was defined to include multivalent vaccines that include an *M. hyopneumoniae* vaccine, the competition analysis would not be significantly affected.

(c) Overlap and concentration

Pfizer's Respisure vaccines currently have a **[ ]** share of the market. As Fort Dodge's vaccine is marketed and distributed by PacificVet, the merged entity's share will be the same post merger.

Table 20 - Market share table for monovalent *M. hyopneumoniae* vaccines for swine (post merger)

Manufacturer/Supplier	Product	Doses %	Doses % total
Pfizer/Fort Dodge	Respisure	**[**	
	Respisure One		
PacificVet*	Suvaxyn Respifend MH		**]**
Total		100.0%	100%

* PacificVet markets and distributes Fort Dodge's Suvaxyn Respifend MH product in New Zealand **[ ]**

(d) Competition analysis

Post-merger, the merged entity will continue to be constrained by the threat of new entry into the supply of *M. hyopneumoniae* vaccines market by existing global competitors.

These competitors do not necessarily have to conduct further R&D or build or expand a production plant in order to commence supplying an *M. hyopneumoniae* vaccine in New Zealand. Indeed, as they already supply the vaccine in other countries around the world, they would be able to rely on existing technology and knowledge to commence supplying in New Zealand.

Indeed, in February 2009, Boehringer registered a *M. hyopneumoniae* vaccine in New Zealand, the Ingelvac MucoFLEX Suspension for Injection in Pigs.[287] Boehringer will therefore compete with the merged entity and attempt to win over customers who are currently using the Suvaxyn Respifend or Respisure vaccine.

Other global competitors such as Invervet/Schering-Plough, Merial, Novartis and Hipra could similarly import their *M. hyopneumoniae* vaccines into New Zealand by undertaking the steps necessary to apply for registration with the NZFSA. These steps are unlikely to be substantial barriers for global pharmaceutical companies that have undergone similar processes to register their vaccines in other countries.

[286] We understand one dose of the multivalent vaccine is 84 units, against 52 units for one dose of the monovalent vaccine.

[287] New Zealand Food Safety Authority – Agricultural Compounds & Veterinary Medicines, Registration No. A010147, see http://www.nzfsa.govt.nz/acvm-register/labels/A010147-label-Jan09.pdf.

The Australian regulator, APVMA, is valuating an application summary filed by Intervet/Schering-Plough in September 2007 in relation to its M+Pac *M. hyopneumoniae* Inactivated Vaccine for Pigs.[288] This product could also be registered in New Zealand.

New entry in the supply of *M. hyopneumoniae* vaccines in New Zealand is therefore not only likely, it is timely and likely to provide customers with a competitive alternative post-merger. Furthermore, as competing vaccines are a direct substitute for the vaccines produced by the Parties, entry is also likely to be sufficient to provide an effective competitive constraint.

Any attempt by the merged entity to impose a price increase, or reduce the quality of its products is also likely to be defeated as a result of the existence of non-vaccine alternatives for the control and treatment of porcine enzootic pneumonia.

For instance, a key element in the control of porcine enzootic pneumonia is the optimisation of management practices and housing conditions.[289] These include all-in/all-out production systems, general herd health, optimal stocking densities, prevention of other respiratory diseases and optimal housing, ventilation and climatic conditions.

In addition, antibiotics are used for the treatment of porcine enzootic pneumonia. Suppliers of antibiotic alternatives include Pharm Tech (Tiamupharm Soluable Powder) and Elanco Animal Health, a division of Eli Lilly Australia Pty Limited (Pulmotil AC Aqueous Concentrate).

13.6 Multivalent *M. hyopneumoniae H parasuis* vaccines for swine

(a) Product descriptiption

Multivalent *M. hyopneumoniae H parasuis* vaccines for swine immunise swine against *H.parasuis* as well as *M. hyopneumoniae*. The *H. parasuis* bacterium causes Glässers disease and there are many strains of the bacterium that are often unique to a particular country or region, or even a particular farm. Multivalent *M. hyopneumoniae H parasuis* vaccines and monovalent *H. parasuis* vaccines available overseas are therefore not always suitable for use in New Zealand.

There is only only multivalent vaccine available in New Zealand:

Manufacturer	Product	Active ingredient(s)	Registration Number
Fort Dodge	Suvaxyn Respifend MH/HPS	*H. parasuis* serovar 4 (strain 2170b) *H. parasuis* serovar 5 strain ia 84-29755 *M. hyopneumoniae*	A008117

While Fort Dodge manufactures the Suvaxyn Respifend MH/HPS vaccine, it is marketed and distributed by PacificVet **[ ]**.

[288] APVMA, Gazette, 1 January 2008, at p 20; see also http://www.apvma.gov.au/data_protection/September_2007.shtml (application summary listing) and http://www.apvma.gov.au/data_protection/42286.pdf (application summary).
[289] Maes D, Segales J, Meyns T, Sibila M, Pieters M and Haesebrouck F, 'Control of Mycoplasma hyopneumoniae infection in pigs', (2008) 126(4) *Veterinary Microbiology* 297-309.

(b) Competition analysis

There is currently no overlap between the Parties in respect of multivalent *M. hyopneumoniae H parasuis* vaccines for swine.

13.7 Parvovirus vaccines for swine

(a) Product description

Porcine Parvovirus (**PPV**) infection typically causes returns to service, small litters, mummified foetuses, stillbirths or abortion. It occurs either as an endemic infection or as an epidemic infection involving larger numbers of animals. PPV is a very tough, resistant virus that can survive in the environment for many months. Routine preventative vaccination against PPV is recommended worldwide.[290]

Manufacturer	Product	Active ingredient	Registration Number
Fort Dodge	Suvaxyn P	Parvovirus	A004540
Pfizer	Porcine Parvac	Porcine parvovirus	A005781

The Fort Dodge vaccine is marketed and distributed by PacificVet.

(b) Market definition

Vaccination of gilts (at least 2 weeks before breeding), sows (8-2 weeks before breeding) and boars (annually) against PPV in New Zealand is a widely adopted practice. In New Zealand the available vaccines are inactivated monovalent porcine parvovirus vaccines.

Adopting the principles of market definition outlined in section 10, Pfizer submits that the relevant market definition is the market for the supply of monovalent parvovirus vaccines for swine.

(c) Overlap and concentration

In terms of doses, Pfizer's Porcine Parvac and the Suvaxyn P vaccine supplied by PacificVet currently accounts for

Table 21 - Market share table for parvovirus vaccines for swine (post merger)

Manufacturer/Supplier	Product	Doses %	Doses % total
Pfizer/Fort Dodge	Porcine Parvac	**[**	
PacificVet*	Suvaxyn P		**]**
Total		**100.0%**	**100%**

* PacificVet markets and distributes Fort Dodge's Suvaxyn P product in New Zealand **[**

[290] Pfizer Animal Health, *Porcine Parvovirus,* <http://www.pfizeranimalhealth.com.au/diseases/227/porcine-parvovirus.aspx> at 28 May 2009.

(d) Competition analysis

Pfizer submits that the Proposed Merger will have little impact on competition in this market. Sales of the parvovirus vaccine in New Zealand are low. This is due to the fact that New Zealand's pig industry is relatively small. According to MAF, approximately 45,000 breeding sows are farmed in New Zealand, producing around 700,000 pigs for slaughter each year.[291]

Currently, the registration for Fort Dodge's Suvaxyn P product is held by PacificVet. The vaccine is also marketed by PacificVet. For the 2008 calendar year, sales to PacificVet amounted to only **[ ]**. Post-merger, PacificVet will continue to compete with the merged entity as a wholesale supplier.

The merged entity will also be constrained by potential new entry from suppliers of parvovirus vaccines in other parts of the world. While Intervet/Schering-Plough and Merial Ancare do not currently supply their Porcilis Parvo vaccine and Parvoject vaccine in New Zealand, they are capable of entering the market in response to any attempt by the merged entity to increase prices.

13.8 *S. equi* vaccines for horses

(a) Product description

The *S. equi* bacteria causes "strangles" in horses; an infectious, contagious disease characterized by abscessation of the lymphoid tissue of the upper respiratory tract.[292] Younger horses and old and debilitated horses are often most at risk of developing strangles. After infection, most horses are immune to re-infection for at least a few years.[293]

S. equi vaccines are either injected to stimulate the immune system to produce antigens contained in the vaccine, or are injected intranasally to elicit a mucosal immunological response.[294]

The Parties manufacture the following *S. equi* vaccines:

Manufacturer	Product	Active ingredient	Registration Number
Fort Dodge	Pinnacle I.N.	*S. equi*	A007902
Pfizer	Equivac S	*S. equi*	A003352
	Equivac 2in1	*Clostridium tetani toxoid* *S. equi*	A006587

Pfizer's Equivac 2in1 vaccine is a two-antigen vaccine that protects horses against both strangles and tetanus. Equivac S and Pinnacle are both single-antigen vaccines.

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[291] MAF, *New Zealand Pig Farming,* Ministry of Agriculture and Forestry, http://www.maf.govt.nz/mafnet/rural-nz/overview/nzoverview011.htm, at 3 June 2009.

[292] Merck Veterinary Manual, *Strangles*, <http://www.merckvetmanual.com/mvm/index.jsp?cfile=htm/bc/121309.htm&word=strangles> at 28 May 2009.

[293] Massey University Veterinary Teaching Hospital, *Strangles*, <http://www.equinehospital.co.nz/articles/Strangles.pdf> at 1 June 2009.

[294] Merck Veterinary Manual, *Strangles*, <http://www.merckvetmanual.com/mvm/index.jsp?cfile=htm/bc/121309.htm&word=strangles> at 28 May 2009.

Pfizer's imports its vaccines into New Zealand from its production plant in Australia, which is also the source for Equivac vaccines imported into Korea and a number of countries into south-east Asia.

Pinnacle is imported from Fort Dodge's facilities in the US, which also exports the vaccine to Canada, Mexico, South America and a number of other countries. As with Fort Dodge's swine vaccines, PacificVet markets and distributes the Pinnacle vaccine in New Zealand.

(b) Market definition

Applying the principles set out above Pfizer considers that there is a market for the manufacture and supply of vaccines to prevent *S. equi*. Pfizer considers that this is narrowest product market definition that would be relevant in assessing the competitive overlap between the Parties.

(c) Overlap and concentration

Pfizer's sales of its *S. equi* vaccine in 2008-2009 was largely attributed to the outbreak of strangles across New Zealand.[295]

Table 22 - Market share table for S. equi vaccines for horses (post merger)

Manufacturer/Supplier	Product	Doses %	Doses % total
Pfizer/Fort Dodge	Equivac S	[	
	Equivac 2in1		
PacificVet*	Pinnacle I.N.		]
Total		100.0%	100%

* PacificVet markets and distributes Fort Dodge's Pinnacle I.N. product in New Zealand **[ ]**

Sales of the *S. equi* vaccine are generally low and strangles is not a common disease that afflicts horses in New Zealand. In Pfizer's experience, demand is typically at 50 vaccinations per month.[296] In 2008, however, following the outbreak of strangles in New Zealand, Pfizer had to boost supplies of the *S. equi* vaccine by freighting additional supplies from Australia and conducting a special processing run of the Equivac S and Equivac 2in1 vaccines at its Australian plant. Pfizer estimated that in September 2008 alone, up to 7000 vaccinations occurred.[297] The above market share data should therefore be considered in that context.

[295] See 'Strangles may have come from Cambridge', The Press, 1 September 2009, at http://www.stuff.co.nz/the-press/sport/racing/607822 (viewed 1 June 2009).

[296] Pfizer, 'Pfizer working to secure strangles vaccine supplies' (Media Release, 18 September 2009) available at <http://www.pfizeranimalhealth.co.nz/sites/pfizeranimalhealth/Pages/StranglesVaccineSupplies.aspx> at 1 June 2009.

[297] Pfizer, 'Pfizer working to secure strangles vaccine supplies', (Media Release, 18 September 2009) available at <http://www.pfizeranimalhealth.co.nz/sites/pfizeranimalhealth/Pages/StranglesVaccineSupplies.aspx> at 1 June 2009.

(d) Competition analysis

As noted above, sales of the *S. equi* vaccine are typically very low and althought there was an outbreak of strangles in 2008, strangles is not a common disease affecting horses in New Zealand.

Currently, Fort Dodge's Pinnacle vaccine is marketed and supplied on a wholesale basis by PacificVet. For the calendar year 2008, sales to PacificVet amounted to only **[ ]**. Post-merger, PacificVet will continue to compete with the merged entity as a wholesale supplier.

Competition may also come from other suppliers of strangles vaccines overseas. Boehringer (Strepvax) and Intervet/Schering-Plough (Equilis). Given that the Equivac and Pinnacle vaccines are imported into New Zealand, Pfizer submits that import barriers are low and Stepvax and Equilis could be brought into New Zealand to compete with the merged entity.

The merged entity will also be constrained in its behaviour by the non-vaccine alternatives for treating and preventing strangles. Indeed, the fact that horse owners have the option to not vaccinate their horse(s) will continue to constrain the merged entity from imposing a price increase post-merger.

The *S. equi* bacterium that causes strangles can be killed by many antibiotics, including penicillin. While antibiotics may not be used at certain stages of the disease, veterinarians can recommend anti-inflammatory medication and the application of hot towels or poultices to the swollen glands to encourage abscesses to burst or to grow to a size and maturity that allows them to be safely and successfully lanced.[298]

Strangles can also be prevented by good horse management and taking quick action to quarantine horses that may have the symptoms of strangles.[299]

Lastly, it should be noted that New Zealand is one of the few places where there is currently more than one supplier of *S. equi* vaccines. In many other countries, including Australia and Korea, only one *S. equi* vaccine is registered, manufactured and supplied because of low demand.

13.9 Multivalent clostridial vaccines for sheep and cattle

(a) Product description

Multivalent clostridial vaccines for sheep contain either three, five or six antigens (3 in 1, 5 in 1 or 6 in 1, respectively). Of these vaccines, only the 5 in 1 is indicated for use in sheep and cattle, as it immunises against the following five common clostridial diseases that can afflict flocks of sheep and herds of cattle:[300]

- tetanus, caused by the toxin produced by *Clostridium tetani*, can paralyse the breathing muscles;

[298] Massey University Veterinary Teaching Hospital, *Strangles*, <http://www.equinehospital.co.nz/articles/Strangles.pdf> at 1 June 2009.

[299] Massey University Veterinary Teaching Hospital, *Strangles*, <http://www.equinehospital.co.nz/articles/Strangles.pdf> at 1 June 2009

[300] Pfizer Animal Health, *All disease*, <http://www.pfizeranimalhealth.com.au/diseases/diseases.aspx> at 11 May 2009.

- malignant oedema results from the infection of wounds with *Clostridium septicum* and certain other clostridia bacteria and causes swelling and discoloration, followed by blood poisoning and death;

- blackleg, in most cases, is caused by the *Clostridium chauvoei* and is a disease causing localised inflammation of muscle with heat, swelling and gas formation (gas gangrene). Blood poisoning and death occurs shortly after;

- black disease, caused by the bacterium *Clostridium novyi*, produces toxins in the liver usually following damage to the liver by migrating liver fluke, causing death; and

- enterotoxaemia, or pulpy kidney, is caused by the toxin of the *Clostridium perfringens* type D bacterium when it is absorbed from the intestinal tract. The bacteria can exist normally in small numbers in the gut of healthy sheep but environmental factors such as increased feed intake, new or better pasture, and a dramatic change in diet can dramatically increase the number of bacteria and toxin production. As with the other clostridial diseases, pulpy kidney is fatal.

Clostridial vaccines for sheep can be combined with selenium and/or vitamin B12 for the treatment and prevention of selenium and/or B12 deficiency in farming areas that are deficient in selenium or cobalt respectively. Selenium plays an important role in an animal's growth and fertility, and conditions such as white muscle disease, infertility, poor milk production and ill thrift are known to respond to selenium supplements.[301] Vitamin B12 or cobalt deficiency also affects growth and fertility and can reduce fleece quality.

As shown by the table below, the vast majority of clostridial vaccines supplied in New Zealand contain five antigents:

Manufacturer	Product	Type	Other active ingredients
Fort Dodge*	FD 5 in 1	5 in 1	-
	FD 5 in 1 Sel	5 in 1	Selenium
Pfizer	Ultravac 5 in 1	5 in 1	-
	Ultravac 5 in 1 + Selenium	5 in 1	Selenium
Intervet/ Schering-Plough	Multine	5 in 1	
	Multine Sel	5 in 1	Selenium
	Lamb Vaccine (previously PK Antitet)	2 in 1	-
	Lamb Vaccine Sel (previously PK Antitet Sel)	2 in 1	Selenium
	Covexin	10 in 1	Clostridium sordellii Clostridium haemolyticum
Bomac	Prolavax 5	5 in 1	Hydroxocobalamin
	Prolavax 5 Plus SE	5 in 1	Hydroxocobalamin Selenium

[301] Pfizer Animal Health, *Selenium Deficiency,* <http://www.pfizeranimalhealth.com.au/diseases/222/selenium-deficiency.aspx> at 18 May 2009.

* These Fort Dodge vaccines are registered with the NZFSA but not sold in New Zealand.

** [ ]

Intervet/Schering-Plough's Lamb Vaccine is a product that vaccinates only against pulpy kidnet and tetanus in lambs, while Covexin contains antigens for *Clostridium perfringens* type A, B and C.

The 6 in 1 clostridial vaccine, which immunises sheep against caseous lymphadenitis (or cheesy gland), is not supplied in New Zealand and cheesy gland is not a disease afflicting flocks in New Zealand.

(b) Market definition

This market was previously considered by the EC in the context of the Schering-Plough Decision in 2007. The parties had submitted that there were separate product markets for multivalent clostridia vaccines for ruminants (regardless of the number of clostridial pathogens targeted) and for monovalent blackleg vaccines for ruminants. The EC's market investigations found that:

- there was substitutability between monovalent blackleg vaccines and broader multivalent clostridial vaccines;[302] and
- the product market for multivalent clostridial vaccines should include vaccines that immunise against the clostridia as well as other pathogens (eg, a multivalent clostridial/pasteurella vaccine competes with pure clostridial vaccines).[303]

The EC, however, left the final product market definition open as the transaction raised serious competition concerns under alternative market definitions.

Pfizer submits that the delineations considered by the EC are an appropriate basis on which to assess the Proposed Merger, particularly given that the majority of clostridial vaccines in New Zealand are 5 in 1 vaccines which can be administered to both sheep and cattle.

(c) Overlap and concentration

As shown in the table below, Fort Dodge does not market its 5 in 1 clostridial vaccine. **[**

Post-merger, therefore, there will be no increase in concentration levels.

Table 23 - Market share table for clostridial vaccines for cattle and sheep (post merger)

Manufacturer/Supplier	Product	Doses %	Doses % total
[			

[302] See European Commission, Case No. COMP/M.4691 – *Schering-Plough/Organon BioSciences*, Decision of 11 October 2007, at paragraph 165.
[303] See European Commission, Case No. COMP/M.4691 – *Schering-Plough/Organon BioSciences*, Decision of 11 October 2007, at paragraph 167.

Manufacturer/Supplier	Product	Doses %	Doses % total
Total		100.0%	100%

* [ ]

(d) Competition analysis

Post-merger there will be no increase in market concentration as Fort Dodge's does not currently market its clostridial vaccines in New Zealand.

Existing competitors Intervet/Schering-Plough and Bomac will continue to compete with the merged entity. Intervet/Schering-Plough's range of clostridial vaccines are the leading range in New Zealand.

Importantly, both Intervet/Schering-Plough and Bomac are able to offer clostridial vaccines with a selenium supplement. Customers whose sheep flocks and cattle herds face selenium deficiency will therefore have an alternative to the merged entity's UV Selenium product.

13.10 Endoparasiticides and endectocides for sheep

(a) Product description

Sheep endoparasiticides are used to control internal parasites (eg, gastro-intestinal roundworms and tapeworms, lungworms). Depending on the active ingredients within the endoparasiticide, the endoparasiticide may kill a narrow range of susceptible internal parasites, perhaps one or two parasite species, or they may kill a wider range of susceptible internal parasites. These products are usually administered orally.

Sheep endectocides are used to control both internal parasites and external parasites (eg, itchmite and nasal bot). These products are administered either orally or by injection and are broad spectrum macrocyclic lactones.

The following table sets out the range of endo/endecto products for sheep available in New Zealand and the active ingredient in each:

Manufacturer	Product	Active ingredient
Merial Ancare	Genesis (oral and injection)	Abamectin
	Ivomec (oral)	Ivermectin
	First Drench (oral)	Albendazole Levamisole hydrochloride Praziquantel
	Arrest (oral)	Albendazole Levamisole hydrochloride
	Matrix (oral)	Abamectin Levamisole hydrochloride Oxfendazole
	Triton (oral)	Albendazole Levamisole Ivermectin Cobalt Selenium
	Exodus (oral)	Moxidectin
	Extender Max (capsule)	Albendazole Ivermectin
	Bionic (capsule)	Abamectin Albendazole Disodium cobalt edta Selenium edta
Fort Dodge	Cydectin (oral and injection)	Moxidectin
	Vetdectin (oral and injection)	Moxidectin
	Eweguard (endect inject)	Moxidectin plus Clostridial 5 in 1
Intervet/Schering-Plough	Scanda (oral)	Levamisole hydrochloride Oxfendazole
	Nilvax (endect inject)	Levamisole phosphate plus Clostridial 5 in 1
Ravensdown	Abamectin (oral)	Abamectin
Norbrook	Noromectin (oral)	Ivermectin
Novartis	Combitape (oral)	Levamisole hydrochloride Praziquantel Ricobendazole
	Leviben (oral)	Levamisole hydrochloride Ricobendazole
	Rycomectin (oral)	Abamectin
Bayer	Duell (oral)	Albendazole Cobalt sulphate heptahydrate Copper sulphate pentahydrate Levamisole hydrochloride

Manufacturer	Product	Active ingredient
		Sodium selenate
Jurox	Q-Drench (oral)	Abamectin Albendazole Closantel Levamisole hydrochloride
Pfizer	Dectomax (endect inject)	Doramectin

[

]

(b) Market definition

Farmers tend to rotate the products used for the "drenching" of sheep depending on the parasites prevalent on their farm as well as any resistance developed by the stock or herd to particular anthelmintics. Anthelmintic resistance is typically more common amongst sheep than cattle.[304]

A number of strategies have emerged to increase the efficacy of drenches in regions of resistance and/or to reduce the rate of development of resistance. An accepted approach, for example, is to use combinations of drenches from unrelated drench groups (ie, drenches with different modes of action) in rotation. Farmers will often develop a drench rotation program with vets in order to effectively manage the challenge posed by internal and external parasites. It is therefore not uncommon for farms to use a drench with particular features one year and choose an entirely different drench for use in the next year, so that their flock does not develop a strong resistance to a particular anthelmintic for that parasite.

The nature of the parasites being targeted, the issue of anthelmintic resistance and the use of rotational programs by customers suggest that demand-side substitution occurs in respect of a wide variety of endo/endecto products that are not necessarily homogenous in terms of their active constituents, functionality and price. In relation to the latter, it should be noted that the price for endo/endecto products for sheep varies widely because of the availability of different products.

Therefore, Pfizer is of the view that there is a market for the manufacture and supply of endo/endecto products for sheep that encompasses differentiated endo/endecto products for sheep, including those which also have a vaccination function or a vitamin or other supplement. It is a market in which customers have a range of substitution possibilities in the sense that they are able to, and do, choose from these differentiated products.

[304] Wormwise, *Management of internal nematode parasites on beef rearing farms in the North Island of New Zealand* (February 2006), see introduction.

For these reasons, Pfizer considers that it is appropriate to analyse its acquisition of Fort Dodge's Eweguard product in the context of an endo/endecto market. While Eweguard combines a clostridial vaccine with an endectocide, it is considerably more expensive (2-3x) than clostridial vaccines alone. Given the technical issues arising from anthelmintic resistance, a farmer wishing to vaccinate a sheep flock against clostridial diseases may not have the option of switching to Eweguard as it may disrupt the rotational drench program. It would be more likely that the farmer would switch to another clostridial vaccine and purchase a separate drenching product.

(c) Overlap and concentration

Post-merger, the merged entity will have a share of only **[ ]**. It will still be second behind Merial Ancare with a share of **[ ]**.

Table 24 - Market share table for endoparasiticides and endectocides for sheep (post merger)

Manufacturer	Product	Doses %	Doses % total

Manufacturer	Product	Doses %	Doses % total
Total		100%	100%

(d) Competition analysis

Pfizer is currently only a small competitor in the supply of sheep endo/endecto products. Post-merger, therefore, there will only a minor increase in concentration levels.

The Proposed Merger is unlikely to substantially lessen competition in the relevant market for the following reasons:

- there are a range of competitors who will be able to competitively constrain the merged entity post-merger, including global players such as Merial Ancare and Novartis. The latter has recently registered a new product to treat intestinal worms in sheep.[305] Zolvix is being marketed by Novartis as a breakthrough in worm control and includes a drenching system which has been developed based on input from farmers and vets worldwide. Jurox has also recently registered, in April 2009, a new sheep endectocide, its Troika Combination Drench for Sheep, demonstrating that existing competitors are continuing to introduce new products into this market;

- generic versions of endo/endecto products will continue to be developed as patents expire. The availability of generics can have a significant impact on the price of a product and allow new competitors to enter the market. For example, Ravensdown, who commenced supplying its generic Abamectin product in 2005, has been able to grown its share to **[ ]**. A further example is the launch of a generic moxidectin product (Exodus) by Merial Ancare in 2008 at a price **[ ]** lower than the branded product Cydectin, which is marketed by Fort Dodge. **[ ]** Pfizer expects that more generic applications for moxidectin products are likely to follow in the near future, which will undoubtedly have a similar impact on the pricing of those products; and

- **[**

]

13.11 Endoparasiticides and endectocides for cattle

(a) Product description

Cattle endoparasiticides are used to control internal parasites (gastro-intestinal roundworms and tapeworms, lungworms etc). They are administered either orally or by

[305] Novartis, 'Novartis Animal Health launches Zolvix, de-worming treatment for sheep' (Media Release, 31 May 2009) available at <http://www.novartis.com/newsroom/news/2009-03-31_zolvix.shtml> at 19 May 2009; New Zealand Food Safety Authority – Agricultural Compounds & Veterinary Medicines, Registration No. A010095, <http://www.nzfsa.govt.nz/acvm-register/labels/A010095-Label1-Apr09.pdf> at 19 May 2009.

injection. Cattle endoparasiticides generally belong to the benzimidazole or levamisole groups.

Cattle endectocides are used to control both internal parasites and external parasites (eg, fleas, ticks, flies, lice, mites) and may be applied either as a pour-on (where the product is poured along the cow's back and is absorbed through the skin) or by injection. Pour-on products are easier to administer and therefore represent the vast majority of sales of endectocides. Endectocides are generally broad spectrum macrocylic lactones.

As noted above, there has been a general trend towards replacing individual endoparasiticide products with endectocides. Endectocides are often seen as a convenient way of controlling internal parasites, while also obtaining some protection from external parasites.

All cattle endectocides and endoparasiticides are sold OTC.

The following table sets out the range of cattle endectocides and endoparasiticides available in New Zealand and their active ingredient(s):

Manufacturer	Product	Active ingredient
Merial Ancare	Eprinex (endect pour-on)	Eprinomectin
	Genesis (endect pour-on and inject)	Abamectin
	Genesis Ultra (endect pour-on)	Abamectin Triclabendazole
	Ivomec (endect pour-on and inject)	Ivermectin
	Eclipse (endect pour-on)	Abamectin Levamisole
	Alpha 2 (endect pour-on)	Abamectin Levamisole
	Arrest (oral)	Albendazole Levamisole
	Matrix (oral)	Abamectin Levamisole Oxfendazole
Fort Dodge	Cydectin (endect pour-on)	Moxidectin
	Vetdectin (endect pour-on)	Moxidectin
Ravensdown	Abamectin	Abamectin
Pfizer	Dectomax (endect pour-on)	Doramectin
	Dectomax (endect inject)	Doramectin
Bayer	Baymec (endect pour-on)	Abamectin
	Baymec (endect inject)	Abamectin
Jurox	Paramectin (endect pour-on)	Abamectin
Bomac	Bomectin (endect pour-on)	Ivermectin
Norbrook	Noromectin (endect pour-on)	Ivermectin
Novartis	Levipor (oral)	Levamisole
Schering-Plough	Scanda (oral)	Levamisole

Manufacturer	Product	Active ingredient
		Oxfendazole

(b) Market definition

Pfizer considers the relevant market is a national market for broad spectrum endoparasiticides and endectocides for cattle. This is consistent with Pfizer's approach to market definition. As discussed in section 10.1(b), the vast majority (over 90%) of cattle endo/endectocides are pour-on products, which cannot be used on sheep due to marking of the wool and lack of efficacy. For those reasons, Pfizer considers that endoparasiticides and endectocides for cattle and sheep are separate product markets.In the Schering-Plough Decision, the EC accepted evidence of the interchangeability between endoparasiticides and endectocides, and decided that both products were part of the same market.[306] This is the approach adopted by Pfizer.

Similarly, Pfizer notes that in New Zealand:

- customers can and do use both types of products (endoparasiticides and endectocides) interchangeably to treat internal worms with no significant difference in effectiveness, internal parasite spectrum and withdrawal period;
- suppliers of endoparasiticides generally must price their products sufficiently lower than endectocides in order to maintain competitiveness; and
- suppliers of endectocides focus advertising of their products primarily (sometimes exclusively) on the endoparasiticidal aspects of their endectocide products.

Pfizer considers that the relevant market excludes pure flukicides (ie, products that control fluke only), but includes endoparasiticides and endectocides combined with flukicides, which control fluke as well as other internal/external parasites.

Therefore, Pfizer has analysed the overlaps in the context of a national market for the supply of cattle endo/endectocide products.

(c) Overlap and concentration

Post-merger, the merged entity will only have a share of **[ ]** of sales. Merial Ancare will have a share of **[ ]**.

Table 25 - Market share table for endoparasiticides and endectocides for cattle (post merger)

Manufacturer	Product	Doses %	Doses % total

[306] See European Commission, Case No. COMP/M.4691 – *Schering-Plough/Organon BioSciences*, Decision of 11 October 2007, at paragraphs 429-432.

Manufacturer	Product	Doses %	Doses % total
Total		100%	100%

(d) Competition analysis

There are a substantial number of alternative suppliers in the market, including particularly strong global players such as Bayer, Merial Ancare, Virbac and Intervet/Schering-Plough that would continue to constrain the merged entity.

Merial Ancare, in particular, is the dominant supplier in the market at present and its Eprinex and Genesis range is more popular than most other brands. Merial Ancare has also developed and registered endo/endecto products containing moxidectin, which was previously the patented active ingredient in Fort Dodge's Cydectin product. As a result of this patent expiring in New Zealand, Merial Ancare registered in February 2009 a moxidectin-based product under the Exodus brand.

Merial Ancare is also a particularly strong competitor as it has its own development and manufacturing facilities in New Zealand. It is an innovative player in this market, and recently, in April 2009, successfully registered a new cattle endoparasiticide product, Switch C Hi Mineral, containing active ingredients abamectin and levamisole and with B12 and selenium additives.

Pfizer expects that more generic applications for cattle moxidectin products are likely to be introduced in the near future. Competitive pricing pressure is also likely to increase in the near future as the patent for doramectin, the molecule used in Dectomax, has expired. A number of companies are already manufacturing generic doramectin products outside of New Zealand. For example, Agrovet Market Animal Health manufactures and markets generic doramectin under the brand Doramec in South America, Latin America, Asia and Africa. Cipla Ltd is an Indian company that manufactures and markets a doramectin injectable product under the name Doramax.

Given the competitive constraints posed by existing competitors as well as generic products, the merged entity will not have the ability or incentive to increase prices significantly post-merger if it wishes to remain competitive in the market.

Part D Further information, confidentiality and declaration

14 Further information

14.1 Contact details for competitors, buyers and suppliers

(a) Human Health

Name of company (legal and trading names)	Contact details (postal and physical address, telephone and fax, website)	Relevant contact person (name, position and contact details including telephone, fax and email)
Competitors		
Abbott Laboratories (NZ) Limited	PO Box 22-801 Otahuhu Auckland, New Zealand Ground Floor, Bldg D 4 Pacific Rise Mount Wellington Auckland, New Zealand Telephone: +64 9 573 6030 Fax: +64 9 573 6040 Website: http://www.abbottdiagnostics.com.au	Nick Leach NZ Commercial Director Telephone: +64 4 586 4975 Fax: +64 4 586 2417
AFT Pharmaceuticals Ltd	PO Box 33-203 Takapuna Auckland, New Zealand Level 2 9 Anzac Street Takapuna Auckland, New Zealand Telephone: +64 9 488 0232 Fax: +64 9 488 0234 Website: http://www.aftpharm.com/	
Apotex NZ Ltd	Private Bag 102995 North Shore City Auckland, New Zealand, 0745 32 Hillside Road Glenfield Auckland, New Zealand Telephone: +64 9 444 2073 Fax: +64 9 444 2951 Website:	

Name of company (legal and trading names)	Contact details (postal and physical address, telephone and fax, website)	Relevant contact person (name, position and contact details including telephone, fax and email)
	http://www.apotexnz.co.nz/apotex.php	
AstraZeneca Limited	PO Box 1301 Shortland Street Auckland, New Zealand Telephone: +64 9 623 6300 Fax: +64 9 623 6301 Website: http://www.astrazeneca.com/	Lance Gravatt General Manager Telephone: +64 9 623 6300 Fax: +64 9 623 6301
Boehringer Ingelheim (NZ) Ltd	42 Ormiston Road East Tamaki Manukau Auckland, New Zealand, 2016 Telephone: +64 9 274 8664 Fax: +64 9 271 0629 Website: http://www.boehringer-ingelheim.com	
Bristol-Myers Squibb	PO Box 62627 Mt Wellington, New Zealand Telephone: +64 9 571 5251	
Eli Lilly & Co	PO Box 109197 Auckland, New Zealand, 1031 Level 3, Axon House 414-422 Khyber Pass Road Newmarket Auckland, New Zealand, 1031 Telephone: +64 9 523 9300 Fax: +64 9 523 9301 Website: http://www.lilly.co.nz	Katherine Lester General Manager Telephone: +64 9 523 9304 Fax: + 64 9 523 9301
CSL Biotherapies (NZ) Limited	PO Box 62-590 Central Park Auckland, New Zealand Central Park 666 Great South Road Penrose Auckland, New Zealand Telephone: +64 9 579 8105	Mike Taylor Country Manager Telephone: +64 9 579 8105 Fax: +64 9 579 8106

Name of company (legal and trading names)	Contact details (postal and physical address, telephone and fax, website)	Relevant contact person (name, position and contact details including telephone, fax and email)
	Fax: +64 9 579 8106 Website: http://www.cslbiotherapies.co.nz	
Gilead Sciences Pty Ltd	Level 1 128 Jolimount Road East Melbourne Victoria, Australia, 3002 Telephone: +61 3 9 272 4400 Fax: +61 3 9 272 4411 Website: http://www.gilead.com	
Douglas Pharmaceuticals Ltd	PO Box 45 027, Te Atatu Peninsula Auckland, New Zealand, 0651 Central Park Drive Lincoln Auckland, New Zealand, 0610 Telephone: +64 9 835 0660 Fax: + 64 9 835 0665 Website: http://www.douglas.co.nz	
GlaxoSmithKline New Zealand	Private Bag 106600 Auckland, New Zealand 8th Floor Quay Towers Cnr Customs & Albert Streets Auckland, New Zealand Telephone: +64 9 367 2900 Fax: +64 9 367 2910 Website: http://www.gsk.co.nz	Geoff McDonald General Manager Telephone: +64 9 367 2900 Fax: + 64 9 367 2907
Hospira NZ Limited	23 Haining Street Te Aro Wellington, New Zealand Telephone: +64 4 384 7463 Website: http://www.hospira.co.nz	
Janssen-Cilag (New Zealand) Limited	PO Box 9222, Newmarket Auckland, New Zealand Ground Floor	Andy Paige Associated Director Telephone: +64 9 523 8700

Name of company (legal and trading names)	Contact details (postal and physical address, telephone and fax, website)	Relevant contact person (name, position and contact details including telephone, fax and email)
	Ericcson House 105 Carlton Fore Road Auckland, New Zealand	Fax: +64 9 523 1646
Johnson & Johnson (New Zealand) Ltd	PO Box 9222, Newmarket Auckland, New Zealand Ground Floor Erricsson House 105 Carton Gore Road Newmarket Auckland, New Zealand Telephone: +64 9 523 8700 Fax: +64 9 523 1646 Website: http://www.jnjnz.co.nz	
Merck Sharp & Dohme New Zealand Limited	PO Box 99-851, Newmarket Auckland, New Zealand 109 Carlton Gore Road Newmarket Auckland, New Zealand Telephone: +64 9 523 6000 Fax: +64 9 523 6001 Website: http://www.msd-newzealand.com	
Multichem	8 Apollo Drive Mairangi Bay Private Bag 93527 Takapuna Auckland, New Zealand Telephone: +64 9 488 0330 Fax: +64 9 478 3841	
Mylan New Zealand Limited	PO Box 11183 Ellerslie Auckland, New Zealand, 1542 Telephone: +64 9 579 2792 Fax: +64 9 579 7072 Website: www.mylan.co.nz	
Novartis New	Private Bag 47909, Ponsonby	Sean Evans

Name of company (legal and trading names)	Contact details (postal and physical address, telephone and fax, website)	Relevant contact person (name, position and contact details including telephone, fax and email)
Zealand Limited	Auckland, New Zealand, 1034 6-8 Mackelvie Street Grey Lynn Auckland, New Zealand, 1002	General Manager Telephone: +64 9 361 8100 Fax: +64 361 8181
Roche Products (New Zealand) Limited	PO Box 12-492, Penrose Auckland, New Zealand, 1642 8 Henderson Place Te Papapa Auckland, New Zealand, 1061 Telephone: +64 9 635 1500 Fax: +64 9 635 1549 Website: http://www.roche.co.nz/	Svend Peterson Managing Director Telephone: +64 9 633 0700 Fax: +64 9 633 0759
Sanofi-Aventis	PO Box 12851, Penrose Auckland, New Zealand James & Wells Tower Part Level 8 56 Cawley Street Ellerslie Auckland, New Zealand Telephone: +64 9 580 1810 Website: http://www.sanofi-aventis.com.au/live/au/en/	Alan Carter Country Manager Telephone: +64 9 580 1829 Fax: +64 9 580 1811
Schering-Plough Animal Health Limited, trading as Intervet Schering-Plough Animal Health	Private Bag 908 Wellington, New Zealand 33 Whakatiki Street Upper Hutt Wellington, New Zealand Website: http://www.spah.co.nz/	
Sigma Pharmaceuticals Limited	95 Merrindale Drive South Croydon Victoria, Australia, 3136 Telephone: +61 3 9839 2800 Fax: +61 3 9839 2801 Website: http://www.sigmaco.com.au/	

Name of company (legal and trading names)	Contact details (postal and physical address, telephone and fax, website)	Relevant contact person (name, position and contact details including telephone, fax and email)
Distributors		
Healthcare Logistics	58 Richard Pearse Drive Mangere Auckland, New Zealand Telephone: +64 9 918 5100 Fax: +64 9 918 5101	
Pharmaco (NZ) Ltd	PO Box 4079 Auckland, New Zealand Phone: +64 9 377 3336 Fax: +64 9 307 1307 Website: http://www.pharmaco.co.nz/	
DHL	2C Bell Road Gracefield Lower Hutt Wellington, New Zealand Telephone: +64 4 924 9444 Webiste: http://www.dhl.co.nz	
Wholesalers		
Propharma	PO Box 62027 Auckland, New Zealand 54 Carbine Road Mount Wellington Auckland, New Zealand Telephone: +64 9 570 1080 Fax: +64 9 915 9581 Website: www.propharma.co.nz	
CDC Pharmaceuticals Ltd	PO Box 1073 Christchurch, New Zealand 284 Cashel Street Christchurch, New Zealand Telephone: +64 3 379 5480 Fax: +64 3 379 5911	

Name of company (legal and trading names)	Contact details (postal and physical address, telephone and fax, website)	Relevant contact person (name, position and contact details including telephone, fax and email)
Wainhouse Distribution Limited	PO Box 41-014, St Lukes Auckland, New Zealand 2-6 Argyle Street Morningside Auckland, New Zealand Telephone: + 64 9 815 1020 Fax: +64 9 815 1036 Website: http://www.wainhousedist.co.nz/	
Suppliers		
IMS Health (NZ) Limited	Unit 3, 112 Bush Road North Harbour North Shore City Auckland, New Zealand Telephone: +64 9 414 9010 Website: www.imshealth.com.au	
Trade Associations		
New Zealand Self Medication Industry Association Inc	PO BOX 6473 Auckland, New Zealand Telephone/Fax: +64 9 299 8327 Website: http://www.nzsmi.org.nz/home/	Tim Roper Executive Director Telephone: +64 9 235 5260 Email: tim.roper@nzsmi.org.nz

(b) Animal Health

Name of company (legal and trading names)	Contact details (postal and physical address, telephone and fax, website)	Relevant contact person (name, position and contact details including telephone, fax and email)
Competitors		
Animal Health Direct Limited	PO Box 8015, Havelock North Hawke's Bay, New Zealand Telephone: +64 6 877 3201 Fax: +64 6 877 3205 Website: http://www.ahdltd.co.nz	

Name of company (legal and trading names)	Contact details (postal and physical address, telephone and fax, website)	Relevant contact person (name, position and contact details including telephone, fax and email)
Bomac Laboratories Limited	PO Box 76-369, Manukau City Auckland, New Zealand Cnr Wiri Station Rd and Hobil Ave Auckland, New Zealand Telephone: +64 9 262 3196 Fax: +64 9 262 3008 Website: www.bomac.co.nz	Connell McLauren General Manager Email: c.mclaren@bomac.co.nz
BASF New Zealand Limited	PO Box 407 Auckland, New Zealand 3 Airpark Drive Manukau City Auckland, New Zealand, 2022 Telephone: +64 9 255 4300 Fax: +64 9 255 4307 Website: http://www.agro.basf.co.nz	John Gray Technical Manager – Regulatory Affairs Telephone: +64 9 255 4342 Fax: +64 9 255 4307 Email: john.gray@basf.com
Bayer New Zealand Limited	PO Box 2825 Auckland, New Zealand 3 Argus Place Glenfield Auckland, New Zealand Telephone: +64 9 443 3093 Fax: +64 9 443 3094 Website: www.bayer.co.nz	Graham Donkin General Manager
Boehringer Ingelheim (NZ) Limited	PO Box 76 216 Manukau City Auckland, New Zealand 42 Ormiston Road East Tamaki Manukau Auckland, New Zealand, 2016 Telephone: +64 9 274 8664 Fax: +64 9 271 0629 Website: http://www.boehringer-ingelheim.com	Managed from Australia

Name of company (legal and trading names)	Contact details (postal and physical address, telephone and fax, website)	Relevant contact person (name, position and contact details including telephone, fax and email)
Ecolab Limited	PO Box 10061 Hamilton, New Zealand, 3241 2 Daniel Place Te Rapa Hamilton, New Zealand, 3241 Telephone: +64 7 958 2333 Fax: +64 7 958 2361 Website: http://www.ecolab.com	Roger Swann National Farm Manager Telephone: +64 7 849 4829 Email: Roger.swan@ecolab.co.nz
Elanco New Zealand	Elanco, PO Box 259354 Greenmount Auckland, New Zealand, 2141 Level 1 123 Ormiston Road Botany Junction Auckland, New Zealand, 2016 Telephone: +64 9 523 9320 Fax: +64 9 271 6881 Website: http://www.elanco.co.nz	Derek Moore General Manager Email: moore_derek@lilly.com
FIL New Zealand Limited	PO Box 4144 Mt Maunganui South New Zealand, 3149 72 Portside Drive Mount Maunganui New Zealand Telephone: +64 7 575 2162 Fax: +64 7 575 2161 Website: http://www.fil.co.nz	Arthur Jordan Managing Director Telephone: +64 7 928 2802
Jurox Pty Limited	85 Gardiner Road Rutherford New South Wales, Australia, 2320 Telephone: +61 2 4931 8200 Fax: +61 2 4931 8222 Website: www.jurox.com.au	Tim Balmer 8 Kordel Place East Tamaki Auckland, New Zealand Telephone: 0800 587 696

Name of company (legal and trading names)	Contact details (postal and physical address, telephone and fax, website)	Relevant contact person (name, position and contact details including telephone, fax and email)
Lloyd Laboratories NZ Limited	233 Porchester Road Takanini Auckland, New Zealand	Dr Andrew Grierson Telephone: +64 7 849 4829 Email: Andrew@caledonian.biz.nz
Merck Sharp & Dohm New Zealand Limited	PO Box 99-851, Newmarket Auckland, New Zealand 109 Carlton Gore Road Newmarket Auckland, New Zealand Telephone: +64 9 523 6000 Fax: +64 9 523 6001 Website: http://www.msd-newzealand.com	
Novartis New Zealand Limited	Private Bag 47909, Ponsonby Auckland, New Zealand, 1034 Telephone: +64 361 8100 Fax: +64 9 361 8181 Website: http://www.novartis.com	
Norbrook New Zealand Limited	C/O KPMG 18 Viaduct Harbour Avenue Maritime Square Auckland, New Zealand Telephone: 0800 224 022 Fax: 0800 224 033 Website: www.norbrook.com.au	Managed from Australia
Nutritech International Limited	PO Box 62-121 Auckland, New Zealand, 1060 12 Fisher Crescent Mt Wellington, New Zealand Phone: +64 9 276 1185 Fax: +64 9 276 6357 Website: www.nutritech.co.nz	Bruce McNeill Managing Director

Name of company (legal and trading names)	Contact details (postal and physical address, telephone and fax, website)	Relevant contact person (name, position and contact details including telephone, fax and email)
Parnell Laboratories NZ Limited	PO Box 58502, Greenmount Auckland, New Zealand Phone: +64 9273 7270	
Phoenix Pharm Distributors Ltd	PO Box 31-363, Mairangi Bay Auckland, New Zealand Telephone: +64 9 476 7391 Fax: + 64 9 479 5555 Website: http://www.phoenixpharm.co.nz	Graham Webb
Ravensdown Limited	PO Box 1049 Christchurch, New Zealand Level 1 32 Oxford Terrace Christchurch, New Zealand Telephone: +64 3 353 4600 Fax: +64 3 353 4625 Website: www.ravensdown.co.nz	Dr Gavin Globe Email: Gavin.Globe@ravensdown.co.nz
Schering-Plough Animal Health Limited, trading as Intervet Schering-Plough Animal Health	Private Bag 908 Wellington, New Zealand 33 Whakatiki Street Upper Hutt Wellington, New Zealand Website: http://www.spah.co.nz/	
Stockguard Laboratories (NZ) Limited	26-30 Maui Street Hamilton, New Zealand Phone: +64 7 849 6782 Fax: + 64 7 849 5079 Website: http://www.stockguard.co.nz	Kevin Burke Managing Director Email: Kevin@stockguard.co.nz
Vetpharm NZ Limited	PO Box 31-363, Mairangi Bay Auckland, New Zealand Telephone: +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 and physical address, telephone and fax, website)	Relevant contact person (name, position and contact details including telephone, fax and email)
Virbac New Zealand Limited	30 Stonedon Drive East Tamaki Auckland, New Zealand Telephone: +64 9 273 9501 Fax: +64 9 272 7667 Website: www.virbac.co.nz	Michael Perdix General Manager Telephone: +64 9 272 7660 Fax: + 64 9 272 7667
Buyers		
CRT Limited	Privte Bag 1968 Dunedin, New Zealand, 9054 84 Cumberland Street Dunedin, New Zealand, 9016 Phone: +64 3 477 9040 Fax: 0800 278 329 Website: www.crt.co.nz	Dan McKay Category Manager Email: Dan.mckay@crt.co.nz
Elders Rural Holdings Limited	Private Bag 92211 Auckland, New Zealand Level 1 3 Melrose Street Newmarket Auckland, New Zealand Telephone: +64 9 529 8800 Fax: +64 9 529 8801 Website: www.elders.co.nz	Ian Giles Product Manager Email: Ian.giles@elders.co.nz
Farmlands Trading Society Limited	Private Bag 9004 Hastings, New Zealand, 4156 Phone: 0800 327 652 Website: www.farmlands.co.nz	Rachael Glendining National Category Manager Email: Rachael.glendining@farmlands.co.nz
PGG Wrightson Limited	PO Box 292 Christchurch, New Zealand 57 Waterloo Road Christchurch, New Zealand Phone: +64 3 372 0800 Website: www.pggwrightson.co.nz	

Name of company (legal and trading names)	Contact details (postal and physical address, telephone and fax, website)	Relevant contact person (name, position and contact details including telephone, fax and email)
Provet NZ Pty Ltd	PO Box 64149 Botany Town Centre Auckland 1730	Dean Gurney General Manager dgurney@provet.net.nz Tel: (09) 920 4444
RD1 Limited	C/O Fonterra Group Limited 9 Princes Street, Auckland, New Zealand Telephone: +64 9 374 9000 Fax: +64 9 374 9001 Website: Fonterra.com	
Riverside Veteinary Services	1 Smallbone Drive PO Box 211 Ashburton	Alan Piercy Head Veterinarian Tel: (03) 308 2321
SVS Veterinary Supplies Limited	541 Te Rapa Road PO Box 10304 Hamilton , New Zealand	John Elstob Managing Director John@svs.co.nz Tel: (07) 850 9599
Veterinary Enterprises Limited	PO Box 83 Te Awamutu, New Zealand, 3840 Telephone: +64 7 872 0248 Fax: +64 7 872 0254 Website: http://www.vetent.co.nz	John Harrison CEO John @vetent.co.nz
Suppliers		
Argenta Manufacturing Limited	PO Box 75 340, Manurewa Auckland, New Zealand 2 Sterling Avenue Manurewa Auckland, New Zealand Telephone: +64 9 250 3100 Fax: +64 9 268 1843 Website: www.argenta.co.nz	
Stockguard Laboratories (NZ) Limited	26-30 Maui Street Hamilton, New Zealand	Kevin Burke Managing Director

Name of company (legal and trading names)	Contact details (postal and physical address, telephone and fax, website)	Relevant contact person (name, position and contact details including telephone, fax and email)
	Telephone: +64 7 849 6782 Fax: +64 7 849 5079 Website: http://www.stockguard.co.nz	Email: Kevin@stockguard.co.nz
Trade Associations		
Animal Remedy and Plant Protection Association (ARRPA)	Paekakariki Hill Road Pautahanui RD 1 Telephone: +64 4 237 5085	Gabrielle Deuss
New Zealand Association for Animal Health and Crop Protection (AGCARM)	PO Box 5069 Wellington, New Zealand, 6145 Level 8 City Chambers Cnr Johnston and Featherston Sts Wellington, New Zealand Telephone: +64 4 499 4225 Fax: +64 4 499 4223 Website: http://www.agcarm.co.nz	Graham Peters Chief Executive Email: gpeters@agcarm.co.nz

14.2 The parties annual reports

A copy of Pfizer's 2008 annual report is included as Attachment C. A copy of Pfizer NZ's Financial Statements for the year ended 30 November 2008 is included as Attachment D.

A copy of Wyeth's 2008 annual report is included as Attachment E. A copy of Fort Dodge NZ's Financial Statements for the year ended 31 December 2007 is included as Attachment F.

15 Confidentiality

Confidentiality is not sought for the fact of the Proposed Merger.

Confidentiality is sought in respect of all items deleted from the public copy of this application (**confidential information**). The items are indicated in the non-public version in square brackets (**[ ]**).

In respect of the confidential information, confidentiality is claimed under section 9(2)(b)(ii) of the Official Information Act 1982, on the grounds that the information is commercially sensitive and valuable information which is confidential to the participants, and disclosure of it is likely to give unfair advantage to competitors of the participants and/or unreasonably prejudice the commercial position of the persons involved.

Pfizer and Wyeth request that they be notified of any request made to the NZCC under the Official Information Act for release of their own confidential information, and that the NZCC seeks their views as to whether the information remains confidential and commercially sensitive, at the time responses to such requests are being considered.

Pfizer and Wyeth are willing to provide the NZCC with a waiver allowing it to exchange confidential information with competition agencies in other jurisdictions in respect of the Proposed Merger.

16 Declaration

THIS NOTICE is given by:

Pfizer Inc, represented in New Zealand by its related company Pfizer New Zealand Limited.

Pfizer Inc hereby confirm(s) 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(s) which is relevant to the consideration of this application/notice has been supplied; and
- all information supplied is correct as at the date of this application/notice.

Pfizer Inc undertake(s) to advise the Commission immediately of any material change in circumstances relating to the application/notice.

Dated this 7th day of June 2009

Signed by Pfizer Inc:

Jan Tennent
Director, Business Development & Global Alliances

I am duly authorised to make this application/notice.

J. Tennent

Authorised signatory

Attachment A Related companies

Related companies of Pfizer NZ

Company name	Country/state of incorporation	Relationship to Pfizer
Pharmacia International BV	Sweden	Parent company
Pfizer Inc	United States of America	Parent company of Pharmacia International BV
Catapult Genetics Australia Pty Ltd	Australia	
Catapult Genetics New Zealand Limited	New Zealand	
Catapult Systems LLC		
Pfizer Australia Pty Limited	Australia	
Pfizer Animal Health SA Belgium	Belgium	
Pfizer Overseas LLC Export Division Belgium		
Pfizer Finance Share Service Co Ltd China		
Pfizer Corporation Hong Kong Limited	Hong Kong	
Pfizer Global Trading Hong Kong		
Pfizer Overseas Inc Export Division Hong Kong		
Capsugel Indonesia	Indonesia	
Pfizer Export Company Ireland	Ireland	
Pfizer Global Supply Ireland	Ireland	
Pfizer Global Trading Ireland	Ireland	
Pfizer Manufacturing Services Ireland	Ireland	
Pfizer Italia S.r.l. Italy	Italy	
Pfizer Enterprises SARL Luxembourg	Luxembourg	
Pfizer Overseas Inc Export Panama		
Pfizer Asia Manufacturing Pte Ltd Singapore	Singapore	
Pfizer Pte Ltd Singapore	Singapore	
Pfizer Laboratories Pty Limited South Africa	South Africa	

Company name	Country/state of incorporation	Relationship to Pfizer
Pfizer Health AB Sweden	Sweden	
Capsugel Co Ltd Thailand	Thailand	
Pfizer International Inc	New York, US	
Pfizer Overseas LLC	Delaware, US	
Warner-Lambert Company LLC	Delaware, US	

Related companies of Fort Dodge

Company name	Country of incorporation	Relationship to Fort Dodge
Wyeth Holdings Corporation	United States of America	Parent company
FD Animal Health Division (Iowa)		
FD Animal Health (Princeton)		
FD Veterinaria SA (Spain)		
FD Australia Pty Ltd		
Cyanamid International Corporation (Zurich)		
FD Asia Exports		
AHP Finance Ireland		

Attachment B Agreement and Plan of Merger [Confidential]

[CONFIDENTIAL]

Attachment C Pfizer's 2008 Annual Report

Attachment D Pfizer NZ Financial Statements

Attachment E Wyeth's 2008 Annual Report

Attachment F Fort Dodge NZ Financial Statements