PUBLIC VERSION

COMMERCE ACT 1986: BUSINESS ACQUISITION

SECTION 66: NOTICE SEEKING CLEARANCE

Date: 5 July 2007

The Registrar

Market Structure Team

Commerce Commission

PO Box 2351

WELLINGTON

Pursuant to s66(1) of the Commerce Act 1986 notice is hereby given seeking **clearance** of a proposed business acquisition.

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PART I: TRANSACTION DETAILS

1. **What is the business acquisition for which clearance is sought?**

On 12 March 2007, Schering-Plough Corporation (**Schering-Plough**) made an irrevocable offer to Akzo Nobel N.V. (**Akzo**) to enter into a share purchase agreement with Akzo, pursuant to which Schering-Plough will acquire 100 per cent of the shares of Organon BioSciences N.V. (**Organon BS**), a wholly owned subsidiary of Akzo.

Accordingly, Schering-Plough or any interconnected body corporate of Schering-Plough, seeks clearance to acquire 100 per cent of the shares in, or assets of, Organon BS or any interconnected body corporate of Organon BS (the **Acquisition**).

The Person Giving Notice

2. **Who is the person giving this Notice?**

This notice is given by:

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

Bell Gully
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3. **Confidentiality**

Confidentiality is not sought for the fact of the Acquisition.

Confidentiality is sought in respect of the information in this Notice that is shaded in yellow.

Confidentiality is sought under section 100 of the Commerce Act 1986 and under section 9(2)(b) of the Official Information Act 1982 on the grounds that:

- the information is commercially sensitive and contains valuable information which is confidential to Schering-Plough, Organon BS and Akzo; and

- disclosure is likely to give an unfair advantage to Schering-Plough, Organon BS and AFZO's competitors and prejudice unreasonably the commercial positions of Schering-Plough, Organon BS and Akzo.

Schering-Plough also requests it is notified of any request made to the Commerce Commission (the **Commission**) under the Official Information Act for the confidential information, and that the Commission seeks Schering-Plough's views as to whether the information remains confidential and commercially sensitive at the time those requests are being considered.

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

Details of the Participants

4. **Who are the participants (i.e. the parties involved)?**

The participants are Schering-Plough and Akzo.

The participants each request that all correspondence to it in respect of this matter be addressed in the first instance to Bell Gully. Bell Gully's contact details are listed at paragraph 2.

5. **Who is interconnected to or associated with each participant?**

5.1 Acquirer group/associates

Schering-Plough

Schering-Plough Corporation (http://www.schering-plough.com/schering_plough/index.jsp) is a New Jersey-based corporation, with principal executive offices at 2000 Galloping Hill Road, Kenilworth, NJ 07033, United States. Its shares are listed on the New York Stock Exchange, held by the public and are widely dispersed. Schering-Plough Corporation is the ultimate parent company of the Schering-Plough group of companies, and has business operations in more than 120 countries worldwide, and more than 50 subsidiaries.

Schering-Plough is a global science-based healthcare company with activities in the prescription and over-the-counter (**OTC**) pharmaceutical, consumer and animal health sectors. In New Zealand, Schering-Plough's animal health business operates as Schering-Plough Coopers (http://www.spah.co.nz/home.html). There is one local New Zealand operating

company, Schering-Plough Animal Health Limited, which operates both the animal health and human health businesses, and which is ultimately owned by Schering-Plough Corporation. For clarity, all references to "Schering-Plough" in the following sections of this Notice are to its New Zealand operations, unless otherwise indicated.

5.2 **Target company group/associates**

Organon BS

Organon BS is a public limited liability company incorporated in the Netherlands, whose corporate seat is in Oss, the Netherlands.

Organon BS is a wholly-owned subsidiary of Akzo. Organon BS is the holding company for the human and animal health activities of Akzo. Organon BS consists of two operating units:

(i) Organon International bv, the human pharmaceutical business (**Organon**) (http://www.organon.com/authfiles/index.asp); and

(ii) Intervet International bv, the animal health business (**Intervet**) (http://www.intervet.com/).

In New Zealand, Organon BS operates as Organon and Intervet (http://www.organon.co.nz/authfiles/index.asp and http://www.intervet.co.nz/). There is one local New Zealand company, Intervet Limited,[1] which is ultimately owned by Akzo.[2] For clarity, all references to "Organon BS", "Organon" and "Intervet" in the following sections of this Notice are to its New Zealand operations, unless otherwise indicated.

Akzo

Akzo is a public limited liability company incorporated in the Netherlands, whose corporate seat is in Arnhem, the Netherlands, and whose address is at Velperweg 76, 6824 BM, Arnhem, the Netherlands.

Akzo is the ultimate parent company of a number of the companies within the Akzo Group. The shares of Akzo are listed both on the Euronext Amsterdam and the NASDAQ stock exchanges. Its shares are held by the public and are widely dispersed. Akzo is not controlled by any undertaking or person.

[1] Intervet Australia Pty Limited, an Australian company, is also registered in New Zealand.

[2] Livestock Nutritional Technologies (an Intervet subsidiary) also supplies a very small quantity (on average one container load/24 tonnes per annum) of one product, Teric Bloat Block, through Pharmaco.

6. **Does any participant, or any interconnected body corporate thereof, already have a beneficial interest in, or is it beneficially entitled to, any shares or other pecuniary interest in another participant?**

Neither Schering-Plough nor any of its interconnected bodies corporate have any beneficial interest in, or are beneficially entitled to, any shares or other pecuniary interest in any other participant.

Schering-Plough understands that neither Organon BS nor any of its interconnected bodies corporate have any beneficial interest in, or are beneficially entitled to, any shares or other pecuniary interest in any other participant.

7. **Identify any links, formal or informal, between any participant/s including interconnected bodies corporate and other persons identified at paragraph 5 and its/their existing competitors in each market.**

Other than the arrangements listed below, Schering-Plough is not aware of any links between any participants/their interconnected bodies corporate or other persons identified at paragraph 5 and their existing competitors in relation to the relevant markets:

- An agreement between Schering-Plough (the animal health business) and Fort Dodge pursuant to which Schering-Plough supplies [CONFIDENTIAL] to Fort Dodge.[3]

- Manufacturing agreements with:

  - Argenta (New Zealand), for the manufacture and supply of [CONFIDENTIAL] to Schering-Plough;

  - Norbrook (United Kingdom) for the supply of [CONFIDENTIAL

    ] by Norbrook to Schering-Plough in New Zealand; and

  - Livestock Nutritional Technologies (**LNT**) (an Intervet subsidiary), pursuant to which LNT contract manufactures a small amount of [CONFIDENTIAL] for Schering-Plough in New Zealand.

    (Schering-Plough has in the past manufactured products on behalf of other competitors, e.g. it previously supplied AgVax.)

- [CONFIDENTIAL

].

[3] [CONFIDENTIAL]

- Schering-Plough purchases two [CONFIDENTIAL] products from Schering-Plough in Australia, which are supplied to Schering-Plough by Intervet. Schering-Plough had sales of [CONFIDENTIAL] in New Zealand of NZ$[CONFIDENTIAL] in 2006. Intervet does not supply [CONFIDENTIAL] products in New Zealand.

- A distribution agreement between Schering-Plough and Pfizer, pursuant to which Schering-Plough distributes Pfizer's [CONFIDENTIAL] products.

- A collaborative agreement with [CONFIDENTIAL] in relation to research and development (**R&D**).

- Schering-Plough is a member of the New Zealand Association for Animal Health and Crop Protection (as are most of its competitors, although Intervet and Pfizer are notable exceptions).

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

- Intervet and Pfizer (and the majority of New Zealand based generic manufacturers) are members of the AARPA group (the Animal Remedies and Plant Protection Association).

8. **Do any directors of the 'acquirer' also hold directorships in any other companies which are involved in the markets in which the target company/business operates?**

No directors of Schering-Plough hold directorships in any other companies which are involved in the New Zealand markets in which Organon BS operates.

9. **What are the business activities of each participant?**

Schering-Plough

Schering-Plough is a global science-based healthcare company with pharmaceutical products, non-prescription OTC products and animal health products. It has activities in three core areas.

(i) The prescription pharmaceuticals business, in which it discovers, develops, manufactures and markets advanced drug therapies for humans, comprising the following segments:

(A) 'primary care', which includes allergy/respiratory drugs, antibiotics, and dermatologicals (skin treatments);

(B) 'speciality care', including anti-inflammatories, anti-virals, oncology, anti-fungals, and acute and coronary care; and

(C) the 'cholesterol franchise' including cholesterol-absorption inhibitors and cholesterol-lowering tablets. In the cholesterol

franchise, R&D is undertaken partly in collaboration with [CONFIDENTIAL].

(ii) The consumer healthcare business, which develops, manufactures and markets OTC healthcare products, including foot care and sun care products.

(iii) The animal healthcare business, which discovers, develops, manufactures and markets OTC and prescription veterinary pharmaceuticals, biologicals and speciality products for numerous animal species, including ruminants,[4] swine (pigs), poultry (chickens and turkeys), equine (horses), aquaculture (fish) and companion animals (cats and dogs). Schering-Plough's veterinary pharmaceuticals product range includes:

(A) antimicrobials (drugs that destroy or prevent the growth of microbes such as bacteria, fungi and parasites);

(B) anti-inflammatories (non-steroidal and steroidal anti-inflammatory drugs, including corticosteroids, which prevent and treat inflammation and reduce pain and/or fever associated with inflammation);

(C) analgesics (drugs that reduce or eliminate pain);

(D) anaesthetics (used to temporarily put animals to sleep during surgery and other procedures);

(E) fungicides (anti-fungal chemical formulations);

(F) parasiticides (agents or preparations used to destroy different sorts of parasites such as flies, lice and worms); and

(G) performance enhancers (which improve the growth, production or feeding efficiency of animals).

The biologicals segment of Schering-Plough develops and manufactures vaccines against various bacterial and viral diseases.

Schering-Plough conducts its R&D activities in its own Schering-Plough Research Institute, with laboratories in New Jersey, Massachusetts, and California in the United States, and in Italy and Switzerland in Europe. In addition, internationally Schering-Plough is engaged in various collaboration projects with other pharmaceutical business partners to develop and manufacture human and animal health products such as the collaboration with [CONFIDENTIAL] in the cholesterol franchise.

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[4] Ruminant animals are any animals that digest their food in two steps, first by eating the raw material and regurgitating a semi-digested form known as cud, then eating the cud, a process called ruminating. Ruminants include cattle, goats, sheep, llamas, giraffes, bison, buffalo, deer, wildebeest, and antelope. For the purposes of Schering-Plough and Organon's New Zealand businesses, "ruminant" refers to cattle, sheep, goats and deer.

Organon BS

Organon BS was incorporated on 1 September 2006 to be the holding company for the human pharmaceutical and animal health activities of Akzo. Organon BS develops, manufactures and markets products that target selected therapeutic areas in human pharmaceuticals, and that cover a wide range of species in animal health.

As mentioned above, Organon BS is structured into two discrete business units, Organon and Intervet.

(i) **Organon**

Organon develops, manufactures and markets women's health products (gynaecology and fertility, contraception and hormone replacement therapy products), mental care health products (neuroscience products), anaesthesia, and products for other therapeutic uses, including oncology and urology products. In addition, Organon has R&D activities in the [CONFIDENTIAL].Organon also generates revenues from third-party manufacturing and sales of active pharmaceutical ingredients as well as from services and royalties received from third parties.

(ii) **Intervet**

Intervet is active in R&D and in the manufacture and sale of animal health products, providing a portfolio of pharmaceuticals and biologicals to treat farm animals such as ruminants, poultry, equine, swine and companion animals. Intervet's pharmaceutical range includes parasiticides, antimicrobials, endocrine treatment (such as fertility treatments and reproductive aids as well as insulin and adrenal steroids used for anti-inflammatory treatment) and various speciality products, in addition to biological products, (mainly vaccines for the local New Zealand market).

In addition, Intervet generates limited revenues from other sources, mainly the production of medicinal feed additives on behalf of third parties. The medicinal feed additives business represented less than [CONFIDENTIAL]% of Intervet's revenues as of 31 December 2006. Intervet has recently divested all of its medicinal feed additive product range in Europe. In addition to Organon and Intervet, Organon BS is also the parent company of the Nobilon business, which is active in the discovery, development, production and commercialisation of human vaccines at Organon BS's manufacturing facility in Boxmeer in the Netherlands.

10. **What are the reasons for the proposal and the intentions in respect of the acquired or merged business?**

The human pharmaceutical side is the principal driver of the Acquisition. The Acquisition builds upon Schering-Plough's core activities in primary care and will give the company access to Organon's central nervous system and women's health care products. At present, Schering-Plough is wholly dependent upon a narrow revenue stream that is based upon a limited number of pharmaceutical products, which are all vulnerable to patent expiration. It is

also a company that suffers from a persistent gap in its late-stage R&D pipeline. In addition, Schering-Plough envisages that the combined entity will have a greater potential to develop human vaccines.

Organon will also add two additional business units (women's health care (gynaecology and fertility) and central nervous system treatments) to Schering-Plough's existing allergy/respiratory, cholesterol/cardiovascular, anti-infectives and oncology businesses. Organon has a long and rich history in both of these businesses, and is renowned worldwide for its products, depth of expertise, R&D capabilities and sales and marketing expertise. In addition, Organon adds strength in anaesthesia products.

On the animal health side, the Acquisition will complement Schering-Plough's animal pharmaceutical and biological product lines. The merged animal health business, which will be headquartered in Boxmeer in the Netherlands, will be in a better position to compete globally with the leading animal health suppliers. Through the Acquisition, Schering-Plough seeks to obtain a more balanced geographic spread and an enhanced product range that allows it to compete more effectively with the prominent global animal pharmaceutical companies.

PART II: IDENTIFICATION OF MARKETS AFFECTED

Horizontal Aggregation

11. **Are there any markets in which there would be an aggregation of business activities as a result of the proposed acquisition?**

Both parties are active in respect of human and animal health, although aggregation in a "market" only occurs in respect of animal health products.

11.1 Human health markets

There is no aggregation in any human health market as a result of the Acquisition. While there are two broad areas of overlap in the parties' human health products – cardiovascular products and cancer therapies/oncology – the actual products in these broad areas are quite different and fall within separate "markets".[5]

In its decision in relation to the acquisition by Pfizer Laboratories of Pharmacia (***Pfizer/Pharmacia***), the Commission said that the third level of the ATC classification (the **ATC3 level**), which allows medicines to be grouped in terms of their therapeutic indications, provides an appropriate starting point from which to assess market definition.[6] As the following explains, Schering-Plough and Organon's cardiovascular and cancer therapies/oncology products belong to separate ATC3 levels, and have different uses.

(a) Cardiovascular (anti-thrombosis) products

Within cardiovascular products, both parties are active in the anti-thrombosis field. Anti-thrombotic drugs are used for the treatment and prevention of blood clots, or thrombi. Within the broad category of anti-thrombotics there are three principal groups of drugs:

- thrombolytics;
- anti-coagulants; and
- anti-platelets.

[5] Schering-Plough is also active in the areas of allergy and respiratory; arthritis and immunology; cough, cold and flu products; dermatological and skin disorders; and infectious diseases including hepatitis and fungal diseases, although these are not relevant to the Acquisition as there is no overlap with Organon's business. Organon is also active in the areas of gynaecology, including hormone therapy and contraception; fertility; neuroscience; products for the digestive system; anabolic steroids; and anaesthesia, although these are not relevant to the Acquisition as there is no overlap with Schering-Plough's business.

[6] Pfizer Laboratories Limited/Pharmacia Limited, Decision 496, 3 April 2003.

Neither Schering-Plough nor Organon manufactures or develops thrombolytics. Organon, with its product Orgaran®, develops and markets only anti-coagulants.[7] Schering-Plough, with its product Integrilin®, develops and markets only anti-platelets.

Anti-coagulants stop clots forming and prevent new clots from growing larger. Anti-platelets decrease platelet aggregation and inhibit the formation of thrombi in the context of the so called "platelet cascade". Specifically, anti-platelets are effective in arterial circulation, where anti-coagulants have little effect.

The ATC3 level distinguishes between platelet aggregation inhibitors (or anti-platelets) and heparin products and their uses are quite different. Accordingly, these pharmaceuticals compete in different product markets.

(b) **Cancer therapies/oncology products**

Organon sells OncoTICE®, an immunotherapeutic agent which uses a specific bacteria (known as BCG), for the treatment of bladder cancer. Schering-Plough sells Intron A®, a drug primarily for treatment of Hepatitis B and C (it is also used for melanoma treatment). Intron A® has been used in explanatory clinical studies for the treatment of bladder cancer, but is not marketed or commercially promoted by Schering-Plough as such (and indeed Schering-Plough is legally prevented from advertising or promoting Intron A® as a bladder cancer treatment). As a single agent, its role has primarily been in the event of failure by a BCG treatment. Organon's OncoTICE® and Schering-Plough's Intron A® products do not compete with each other.

Bladder cancer can be treated in several ways, depending on the type of cancer, the stage of the disease, and the patient. Treatments can be surgery, chemotherapy, radiation therapy and biological therapy. The parties' products are both biological therapies in that they use the body's immune system, either directly or indirectly, to produce a natural defence against infections as well as tumours. However, both products work differently: Organon's OncoTICE® is a vaccine therapy (i.e. it uses an external organism to treat cancer), whereas Schering-Plough's Intron A® is a protein therapy (i.e. it uses a modified human protein to treat cancer).

The parties' activities do not overlap in the field of treatment of bladder cancer. Intron A® does not have an approved indication of bladder cancer, and it is not being (and cannot be) promoted by Schering-Plough to treat bladder cancer.

(c) **Human health – conclusion**

In light of the above, the Acquisition will not lead to a substantial lessening of competition in any human health market and accordingly human health is not discussed further in this Notice (although further detailed information about both cardiovascular and cancer therapies is contained in Appendix A). If the Commission has any questions in relation to human health, Schering-Plough would be happy to address these.

[7] Orgaran® treats a particular type of coagulation cause by heparin.

11.2 **Animal health markets**

The Acquisition is relevant to the pharmaceuticals and biological (including vaccines) animal health product categories.[8]

The parties' activities in animal health are largely complementary. Intervet's products are predominantly focused on vaccines for companion animals, biologicals and on intensive markets such as swine, poultry and feedlots. Schering-Plough's products focus primarily on products for sheep and cattle and, to a lesser extent, on pharmaceutical products for companion animals. A list of the major products sold by Schering-Plough and Intervet for use in New Zealand can be found at http://www.spah.co.nz/products.html and http://www.intervet.co.nz/ respectively.

For the reasons set out in the discussion from page 17 onwards, Schering-Plough believes that the relevant markets are those for:

- intramammary (mastitis) treatments for dry cows;
- intramammary (mastitis) treatments for lactating cows;
- antimicrobials (antibiotics) for ruminant animals;
- prostaglandins (which are used in assisted reproduction);
- ectoparasiticides (fly and lice control) for cattle;
- ectoparasiticides (fly and lice control) for sheep;
- endoparasiticides (worm control) for sheep;[9] and
- campylobacter vaccines for sheep.

The Acquisition's impact on the various markets is discussed from page 17 below.

[8] The other three broad animal health areas (namely, medicinal food additives; nutritional feed additives; and hygiene products) are not relevant to this Notice.

[9] There is no overlap in respect of the supply of endoparasiticides for cattle.

Differentiated Product Markets

The following applies to all markets (unless otherwise noted) and is therefore not repeated for each of the affected markets discussed in this Notice.

12. **Please indicate whether the products in each market identified in question 11 are standardised (buyers make their purchases largely on the basis of price) or differentiated (buyers make their purchases largely on the basis of product characteristics as well as price).**

Provided the customer can be assured of a product's efficacy (via his or her own knowledge or a veterinarian's prescription), the purchasing decision will be based principally on price. Naturally, other factors will be relevant, such as the duration of effectiveness (for some products), relationships, and perception of the suppliers' involvement in the industry (membership in associations etc.), but these 'intangible' factors are secondary to price. The success of generic products is testament to this fact. In any event, in a situation where a particular product characteristic (such as its duration of effectiveness) might cause that product to be differentiated to some extent, it is difficult for any supplier to predict the type and characteristics of products farmers will require year to year, or even during an individual season. The type of product the farmer chooses will depend on the characteristics of a particular farm, taking into account seasonal features, economic conditions and the farmer's own personal preference. On this basis, suppliers cannot afford to assume that a particular product characteristic will cause it to remain successful year upon year.

13. **For differentiated product markets:**

13.1 **Please indicate the principal characteristics of products that cause them to be differentiated one from another.**

NA

13.2 **To what extent does product differentiation lead firms to tailor and market their products to particular buyer groups or market niches?**

NA

13.3 **Of the various products in the market, which are close substitutes for the products of the proposed combined entity and which are more distant substitutes?**

NA

13.4 **Given the level of product differentiation, to what extent do you consider that the merged entity would be constrained in its actions by the presence of other suppliers in the affected market(s)?**

While there is some element of differentiation (as outlined at paragraph 12 above), this is not a merger of the two closest firms on a differentiated product spectrum. Schering-Plough, Organon/Intervet and their competitors supply a range of products that compete across each of the relevant markets. To the

extent that there are similarities between Schering-Plough and Intervet's products (for example, the dual fly and lice effectiveness of the parties' cattle ectoparasiticides), the parties' competitors could readily adjust their own products to compete head on with any perceived point of difference. Accordingly, the merged entity will be significantly constrained by the presence of other suppliers in the affected markets.

Vertical Integration

The following applies to all markets (unless otherwise noted) and is therefore not repeated for each of the affected markets discussed in this Notice.

14. **Will the proposal result in vertical integration between firms involved at different functional levels?**

The Acquisition will not *result* in vertical integration. The parties are already vertically integrated through their offshore manufacturing divisions. Schering-Plough also has a biological manufacturing facility in Upper Hutt, which exports clostridial vaccines worldwide.

15. **Previous Acquisitions**

In respect of each market identified in questions 11 and/or 14 identify briefly:

15.1 **all proposed acquisitions of assets of a business or shares involving either participant (or any interconnected body corporate thereof) notified to the Commission in the last three years:**

There have been no such acquisitions.

15.2 **any other acquisition of assets of a business or shares which either participant (or any interconnected body corporate) has undertaken in the last three years.**

In August 2005, Intervet acquired AgVax Developments in New Zealand, a company specialising in the development of livestock biologicals.

Schering-Plough has not acquired any assets of a business or shares in New Zealand in the last three years.

The following sections respond to the questions 16 – 41 in the Commission's clearance application form as these questions relate to each market separately.

16. Intramammary (mastitis) treatments for dry cows and for lactating cows

16.1 Question 11: Market definition

(a) Product market

In *Pfizer/Pharmacia*, the Commission noted that the most common type of infection in dairy cows is mastitis. The most common type of mastitis treatments are intramammary antibiotic treatments, which are tubes designed for infusion into individual cow quarters via the teat end canal.

There are two different types of mastitis infections:

- chronic infections (or sub-clinical mastitis) that cause an increased number of white blood cells (somatic cells) in the milk, but do not have any obvious clinical symptoms. Sub-clinical mastitis is typically treated during the days of the year when the cow is not milked (the so called 'dry period'). It is routinely applied through a preventive (single) administration of one injection per mammary gland with a total of four) at the end of the lactation period. The substance will remain effective in the udder for a certain period of time, killing existing bacteria and preventing the introduction of new bacteria; and

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

As the Commission noted in *Pfizer/Pharmacia*, different intramammary products are used to treat dry and lactating cows and there is no demand side substitutability between these products. The Commission noted that in the supply of lactating intramammary treatments, different products contain different active substances, although most products contained some form of penicillin. Further, each product may contain more than one active substance. There is likely to be different degrees of substitutability between the different active substances. Accordingly, the Commission (referring to the European Commission's decision in *AKZO Nobel/Hoechst Roussel Vet*) reached the view that there are separate markets for intramammary treatments for dry cows and for lactating cows.[10]

In New Zealand, nearly all cows are "dried off" for a six week period from 31 May each year, as plants are closed for maintenance. This is unlike many other countries (including European countries) where cows are milked year round, other than during a dry or withholding period, of a length of time determined by each individual farmer. In such countries, where farmers have a discretion and flexibility as to the length of

[10] In addition to mastitis treatments, there is a wide variety of antibiotics that can treat other cattle infections. These would fall within the antibiotics market (discussed at section 17), and as such, the lactating and dry cow intramammary markets are essentially markets for mastitis treatments.

the relevant dry period, farmers required to choose either a 'short-acting' product or a 'long-acting product' *after* determining the length of the withholding period the farmer prefers. Schering-Plough believes that in those countries, there are two separate dry cow intramammary markets, namely those for short-acting dry cow intramammary products and long-acting dry cow intramammary products. However, given that drying off periods do not vary as between farmers in New Zealand, and in light of the Commission's comments in *Pfizer/Pharmacia*, Schering-Plough believes that the relevant product markets are:

- the supply of intramammary (mastitis) treatments for dry cows; and
- the supply of intramammary (mastitis) treatments for lactating cows.

(b) **Functional market**

Animal health products are generally sold by manufacturers to rural resellers/wholesalers (in the case of large animal products) and to veterinary wholesalers and some veterinary practices (in the case of veterinary products and companion animal products). As the Commission noted in decision in relation to the acquisition by Provet NZ of National Veterinary Supplies (***Provet***) in respect of a New Zealand market for "animal health remedies", this is a relatively small market in New Zealand and, as such, the remedies are typically manufactured off-shore and imported into New Zealand by local subsidiaries of the international manufacturers.[11] Schering-Plough has some manufacturing capability in New Zealand, with a vaccine manufacturing facility in Upper Hutt, which manufactures and exports clostridial vaccines. Intervet does not manufacture any products in New Zealand.

The functional level of this market is therefore that for the wholesale supply.

Given the similarities in the functional dimension for each of the relevant markets, it is not discussed further in the discussion of market definition in the sections below.

(c) **Geographic market**

As the Commission noted in the *Pfizer/Pharmacia*, in the supply of animal and human health products, the relevant geographic market can be considered to be national. This is because sales are made on a nationwide basis. Again, this is the same geographic market as each of the other relevant markets and accordingly the geographic aspect of each relevant market is not considered separately below.

Dry cow intramammary treatments

16.2 PART III: CONSTRAINTS ON MARKET POWER BY EXISTING COMPETITION

(a) **Overview**

The Acquisition will not substantially lessen competition in this market having regard to:

[11] Provet NZ Pty Limited/National Veterinary Supplies Limited, Decision 549, 5 May 2005.

- the low level of market share aggregation (Intervet has less than a [CONFIDENTIAL]% market share);

- the presence of Pfizer, a well-known and effective competitor; and

- the low barriers to entry and expansion, and hence the constraint from firms active in respect of lactating cow intramammary treatments (and other animal health markets).

Schering-Plough's products are Bovaclox and Cepravin. Intervet's products are Cefa-Safe and Nafpenzal DC.

(b) **Question 16: Existing competitors**

The post-Acquisition market shares for intramammary (mastitis) treatments for dry cows are shown in the table below.

[CONFIDENTIAL MARKET SHARE DATA REMOVED]

MASTITIS DRY COW		
Firm	**2006 Sales (USD 000)**	**Share %**
Intervet		
Schering-Plough		
Combined Entity		
Pfizer		
Norbrook		
Bomac		
Virbac		
Parnell		
Boehringer Ingelheim		
Total		**100.00%**
3 Firm Concentration Ratio		

Source: 2006 Index of Veterinary Specialities (IVS) Annual, and Schering-Plough and Intervet's own estimates

As the above table indicates, the combined entity's share of this market is outside of the Commission's safe harbours.

In this market, Pfizer has two products and each of the others have one. All of the suppliers in this market have products in a number of other affected markets, and given the low barriers to expansion discussed at paragraph (c) below, will impose a significant constraint on the combined entity. Indeed, Schering-Plough expects that the suppliers would increase supply in response to any attempt by the combined entity to increase price post-Acquisition. Each supplier is briefly described as follows.

(i) *Pfizer*: Pfizer is listed on the New York, London, Euronext and Swiss stock exchanges. It was founded in 1849 and employs over 100,000 people worldwide. The total revenue for Pfizer Inc and its subsidiaries for 2006 was more than US$48.4 billion. Pfizer's animal health business is one of the largest in the world, and in 2006 reported total revenue of US$2.3 billion (see http://www.pfizer.com/pfizer/main.jsp).

(ii) *Norbrook*: Norbrook, established in 1968, is a world leader in the animal health care industry, and exports to more than 120 countries. Norbrook manufactures a comprehensive range of generic veterinary and medical pharmaceuticals, contract manufactured products and pharmaceutical active ingredients and finished dose forms (see http://www.norbrook.co.uk/).

(iii) *Bomac*: Bomac is a New Zealand-based supplier of generic animal health products, and provides an extensive range of products to customers in New Zealand and internationally. Bomac has developed over the last 40 years to become a leading supplier to the animal health and nutrition industry worldwide (see http://www.bomac.co.nz/).

(iv) *Virbac*: Virbac designs, manufactures and markets a broad range of products and services for veterinarians and animal owners, and is active in more than 100 countries. In 2006, Virbac reported sales of €401.6 million (see http://www.virbac.com).

(v) *Parnell*: Founded over 40 years ago in Australia, Parnell is now a leading international supplier of generic animal health products (see http://www.parnell.biz/).

(vi) *Boehringer Ingelheim*: Boehringer Ingelheim has a wide range of products covering the biologicals, pharmaceuticals and natural health care segments of the animal health industry. In 2006, the global Boehringer Ingelheim group had net sales of €10,574 million (an increase of 11% on 2005) (see http://www.boehringer-ingelheim.com/).

The key issue in terms of the impact on competition is the *change* in the level of competition as a result of the Acquisition. The change that results is not large because Intervet has only a [CONFIDENTIAL]% market share.

Intervet is only the [CONFIDENTIAL] ranked supplier in this market, behind Schering-Plough, Pfizer, [CONFIDENTIAL]. Pfizer, with a [CONFIDENTIAL]% market share, will impose considerable constraint. [CONFIDENTIAL] market shares suggest they would impose at least the same level of constraint in the market as Intervet would have pre-Acquisition.

Although Intervet has been innovative in developing and promoting vaccines and biologicals, Schering-Plough does not believe it has been unique in its innovation nor has it been innovative in a different way from other players in the industry in their fields of endeavour. Accordingly, Schering-Plough does not consider Intervet has behaved in such a way as to suggest that it is a 'maverick' in any animal health market.

(c) Questions 17 – 22: Conditions of entry and expansion

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

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

With the exception of vaccines, the markets the subject of this Notice all contain products containing ingredients that are 'off patent' and for which the ingredients and formulations are readily available. The animal health markets are not comprised of products for which there are barriers to entry in terms of extensive R&D requirements and complicated registration processes. The success and presence of 'generic' products in the animal heath markets is testament to this fact. Indeed, Ancare, which supplies only generic (as opposed to 'novel') products, is the largest supplier of animal health products to the New Zealand market.

As the Commission found in *Pfizer/Pharmacia*, animal health care products are registered under the Agricultural Compounds and Veterinary Medicines Act 1997. Novel or new products also require approval from the Environment Risk Management Authority under the Hazardous Substances and New Organisms Act 1996.

The Commission did not consider barriers to entry and expansion in the dry cow intramammary market in *Pfizer/Pharmacia* on the basis that the low level of aggregation and the presence of existing competitors were sufficient to preclude a substantial lessening of competition in that market. However, in *Pfizer/Pharmacia*, the Commission made the following comments in relation to the *lactating* intramammary market:[12]

> "It is the view of the Commission that the introduction of a new lactating intramammary for the treatment of mastitis would not be particularly difficult. The introduction of a generic antibiotic, it is suggested, would be even easier.
>
> …The question of the extent of any new entry would vary on a case by case basis. Veterinarians and farmers may exhibit some resistance in terms of switching brands. A product that can prove itself in terms of safety and efficacy may be able to grow its market share and if competitive in terms of price may be more widely accepted. The Commission believes that there are no significant capacity constraints or mobility barriers that would suggest entry could not be sufficient in extent.
>
> A generic copy of an existing lactating intramammary could enter the market relatively quickly. Generic reproduction decreases the need for significant investment in research and development expediting the process. Pharmaceutical companies also normally employ independent contractors to handle the intricacies of the registration process which increases the efficiency of the entire process.
>
> The Commission considers that entry is likely, would be sufficient in extent and would be timely in the supply of lactating intramammary treatments."

[12] *Pfizer/Pharmacia* at paragraphs 170 – 175.

Schering-Plough considers that the above analysis applied to the lactating intramammary market is directly relevant to the dry cow market.

As the above passage attests, in *Pfizer/Pharmacia* the Commission did not consider that the introduction of a new (lactating intramammary) product would be particularly difficult. The introduction of a generic antibiotic, the Commission noted, "would be even easier". There are numerous examples of successful entry (particularly by suppliers of generic products) that reinforce the Commission's observations from *Pfizer/Pharmacia*. Generic suppliers in the dry cow intramammary market include Norbrook, Bomac and Parnell. Stockguard and Ancare, both of which also supply generic products, have made significant inroads into other animal health markets within a relatively short period of time. The success of generic products in the dry cow market and other animal health markets shows that entry (or indeed, expansion) can be achieved relatively quickly, and that entry or expansion would occur should the combined entity attempt to increase price.

Schering-Plough notes that all registrations in New Zealand since 1984 have been for generic products. Generic registration applications require information to be submitted on safety, quality and efficacy, but can be submitted in an abridged application. Registration of a generic product can be achieved within three months, although four to six months is considered the standard time period. The cost of registering a generic product is still within the $5,000-10,000 bracket the Commission identified in *Pfizer/Pharmacia*. In terms of novel products, the length and cost of registration differs on a case by case basis, although a standard time for registration varies between 12-18 months. Schering-Plough notes that for a new compound, the cost of registration could be up to $500,000. However, again, the last novel product that was introduced in New Zealand was registered (by Merck Sharp & and Dohme) in 1984. Since that time, all new registrations have been for generic products.

To illustrate the number of new animal health products that have been registered in New Zealand in recent years, a list of all animal health products registered since 1 January 2003 to 1 June 2007 is attached at Appendix B (this information is also available online at http://www.nzfsa.govt.nz/acvm/registers-lists/acvm-register/index.htm). This list shows that more than 200 new products (all generic products) have been registered since 1 January 2003.

With regard to the Commission's observation on the ease at which generic copies of an existing product can be made, Schering-Plough notes that Stockguard, which is active in a number of markets including the supply of intramammaries for lactating cows (and is discussed in more detail under 16.5(b) below), has built its business on supplying generic copies of existing products. Stockguard entered the lactating intramammary market in the mid-late 1990s to take advantage of supply issues Schering-Plough faced at the time, and now commands a market share of over [CONFIDENTIAL]%, with Schering-Plough having less than a [CONFIDENTIAL]% share. The success of Stockguard reinforces the Commission's comment in *Pfizer/Pharmacia* that products that are on par in terms of safety, efficacy and price will not face any significant barriers to entry. In addition to Stockguard, there are a number of other suppliers of generic products in the New Zealand animal health markets, including Ancare, Parnell and Jurox, and all have illustrated that generic products are a viable and trusted option for farmers.

Generally (including in relation to dry cow intramammary treatments), barriers to expansion by existing players in the animal health industry are low. As shown in the market share table above, there is a large number of players in this industry, many of

which are international companies. Indeed, many of the existing competitors in the animal health industry are subsidiaries or business divisions of international pharmaceutical companies, which manufacture both human health and animal health products. Such players typically import some of the animal health products they sell in New Zealand, and could source more product from offshore to meet additional local demand should this be necessary. In fact, Schering-Plough estimates that in excess of 70% of veterinary pharmaceuticals are imported (this includes antibiotics, anaesthetics and non-steroidal anti-inflammatories).

Manufacturing capability does not constitute a barrier to entry or expansion in the dry cow intramammary market (or indeed, any animal health pharmaceutical market). A new entrant or an existing player seeking to enter a related animal health market could import products manufactured offshore (the ease of which is evident from the level of imported product in the relevant markets) or alternatively, establish a local manufacturing facility. The costs of establishing a New Zealand manufacturing facility are not great, and Schering-Plough estimates that this could be achieved within 6-9 months for plant and equipment, and within 18 months for all necessary approvals and validations.

Market entry or expansion can be also effected relatively easily by engaging a contract manufacturer. While local contract manufacturers would not necessarily have idle capacity throughout the year, Schering-Plough understands that a new entrant or an existing firm wanting to expand could set up a manufacturing arrangement on a couple of months' notice. There is a large number of contract manufacturers of animal health products in New Zealand and overseas who manufacture animal health products for sale in New Zealand. These include Argenta and Unitech Industries, both of which are based in Auckland. In addition, Ancare and Stockguard both manufacture products on behalf of other suppliers. Schering-Plough understands that the cost to a new entrant of engaging a contract manufacturer would not be significant, and would not be greater than the cost to an existing competitor. Stockguard's success in the lactating intramammary market is indicative of the extent to which new entrants can gain sales and market share from the incumbent suppliers within a relatively short period. The threat of further entry of a supplier (particularly one with a generic product(s)) would significantly constrain the combined entity.

As the Commission found in *Provet*, entry by firms that are already active in other animal health markets would appear to be particularly feasible. Expansion of firms that are already active in each of the markets would appear to be even more likely. In particular, international suppliers active in animal health markets in New Zealand would not generally find it difficult to expand their product offerings into a market in which they had previously not participated, in the event that there was a change in competitive behaviour by existing manufacturers. The absence of patent protection and the relative ease in registering a generic product would in particular facilitate entry by such suppliers into related animal health markets. Generic reproduction decreases the need for significant investment in R&D, significantly expediting the registration process. As noted above, there are very few animal health product formulations or active ingredients still under patent. Formulations for a wide range of treatments are readily available on the Internet (given the lack of patent protection for most products), and access to raw materials is not difficult. Indeed, Schering-Plough estimates that the cost of active ingredients has reduced by approximately 20% in the last 5 years.

In relation to sales and distribution, for existing players wishing to expand their product range, there will be economies of scale in distribution. There are no frontier, legislative/regulatory, industrial/business or incumbent response factors that would operate as a barrier to entry or expansion. In addition, there is a large range of alternative products in most markets that are able to treat most conditions.

In summary, in the dry cow intramammary market and in the other animal pharmaceutical markets the subject of this Notice, there are a number of large, multinational suppliers, each of which has a presence in a number of other animal health markets. None of the large suppliers currently active in New Zealand would face any significant barriers to entry or expansion should the combined entity attempt to raise price post-Acquisition. In particular, Pfizer, which is a significant player in the dry cow market and in the lactating cow market, and Stockguard, which is a significant player in the lactating cow market, will continue to impose a real constraint on the combined entity post-Acquisition.

(d) Questions 23 – 26: Co-ordinated market power

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

In Schering-Plough's view, the market does not currently display signs of co-ordinated market power. The factors currently precluding the exercise of coordinated market power are:

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

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

The following tables assess the various factors of the dry cow intramammary market against the various factors that the Commission considers indicate the scope of coordinated conduct, and the impact of the Acquisition on those factors.

Scope for co-ordinated market power	Present	Effect of Acquisition
High seller concentration	Yes (CR3>70%)	No material increase
Undifferentiated product	Minimal differentiation	No change
Static production technology	No	No change
New entry slow	No – not for generic products	No change
Absence of fringe competitors	No	No change
Acquisition of an unusually vigorous or effective competitor	No	No change
Price inelastic market demand	No	No change
History of co-ordinated conduct	No	No change
Absence of countervailing power of acquirers	Some constraint	No change
Existence of excess capacity	No	No change
Industry associations/fora	Yes	No change

Detection of deviation from co-ordination	Present	Effect of Acquisition
High Seller concentration	Yes (CR3>70%)	No material increase
Frequent sales	Yes	No change
Vertical integration	Some	No change
Growth in demand	Demand varies	No change
Cost similarities	Cost of production likely to be similar	No change
Multi market contact	Yes	No change
Price transparency	No	No change

The foregoing applies to all markets (unless otherwise noted) and is therefore not repeated for each of the affected markets discussed in this Notice.

16.3 PART IV: CONSTRAINTS ON MARKET POWER BY POTENTIAL COMPETITION

(a) Questions 27 – 35: Conditions of entry

See 16.2(c) above.

16.4 PART V: OTHER POTENTIAL CONSTRAINTS

(a) Questions 36 – 41: Countervailing power

For the purposes of this Notice, Schering-Plough has not placed any weight on the constraint imposed by suppliers to the animal health markets.

The acquirers of Schering-Plough's products do impose constraint. Schering-Plough's customers are a combination of veterinarians, veterinary wholesalers and rural supply stores. There are some large customers, such as the Vet Plan Group, and SVS Wholesalers. Collectively, veterinarians make up approximately [CONFIDENTIAL]% of Schering-Plough's sales, and by and large are sophisticated customers who can and do make decisions based on efficacy, price and service levels. Veterinarians also have the ability to be supplied directly by one of two veterinary wholesalers.

Lactating cow intramammary treatments

16.5 PART III: CONSTRAINTS ON MARKET POWER BY EXISTING COMPETITION

(a) Overview

The Acquisition will not substantially lessen competition in this market having regard to:

- the very low level of post-acquisition market share (less than [CONFIDENTIAL]%);
- the presence of large, capable competitors, in particular Pfizer ([CONFIDENTIAL]%) and Stockguard ([CONFIDENTIAL]%); and
- the low barriers to entry and expansion.

Schering-Plough's products are Spectrazol and Penalone. Intervet's products are Cobactan LC and Nafpenzal MC.

(b) Question 16: Existing Competitors

The post-Acquisition market shares for intramammary (mastitis) treatments for lactating cows are shown in the table below.

[CONFIDENTIAL MARKET SHARE DATA REMOVED]

MASTITIS LACTATING COW		
Firm	**2006 Sales (USD 000)**	**Share %**
Intervet		
Schering-Plough		
Combined Entity		
Pfizer		
Virbac		
Stockguard		
Norbrook		
Boehringer Ingelheim		
Parnell		
Total		**100.00%**
3 Firm Concentration Ratio		

Source: 2006 Index of Veterinary Specialities (IVS) Annual, and Schering-Plough and Intervet's own estimates

As the above table indicates, the combined entity's share of this market is within the safe harbours.

In this market, Pfizer has five products, Virbac has two and each of the other suppliers have one product. All of the suppliers active in this market, other than Stockguard, are also active in the dry cow intramammary market. However, Stockguard is active in this and a number of other markets relevant in this Notice. As noted above, Stockguard is a generic supplier which has, relatively quickly, risen to become the [CONFIDENTIAL] largest supplier of lactating cow intramammaries. Stockguard is a private New Zealand company that specialises in the production of generic products (see http://www.stockguard.co.nz/). Although Stockguard has done some development work, its success has been based entirely on the supply of generics, and it has not registered any novel products.

The combined entity's post-Acquisition market share of [CONFIDENTIAL]% is well within the Commission's safe harbours. There are several other suppliers of lactating intramammary treatments, most of which are major international companies.

(c) Questions 17 – 22: Conditions of entry and expansion

Schering-Plough considers that the conclusion from *Pfizer/Pharmacia* applies in respect of the Acquisition.

Given the low level of market share and the low barriers to entry and expansion, no further comment on this market is made. Further information can be made available if the Commission wishes.

17. Antimicrobials

17.1 Question 11: Market definition

As discussed at 16.1(a), the main type of infection in dairy cows is mastitis, which is treated with either a lactating cow product or a dry cow product, both of which are administered using an intramammary device. However, animal antibiotics (i.e. antimicrobials) in injectable and oral forms are also used to treat other infections, such as eye infections and infected wounds.

Antimicrobials are a large group of pharmaceutical products that belong to the general group of anti-infectives for systemic, local or topical use. They destroy or prevent the growth of microbes such as bacteria, mycoplasma (specific pathogens that lack cell walls) or fungi and treat or prevent diseases that are associated with them. Antimicrobials are used in food-producing animals (ruminants, swine, poultry, aquaculture and equine) as well as companion animals. The same antimicrobial product can usually be used on various types of animals.

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

Both Schering-Plough and Intervet supply a range of ruminant antibiotics, and both parties supply antibiotics with beta-lactams and tetracyclines as their respective active ingredients.

Schering-Plough submits that there is substitutability between different types of antibiotics (such as penicillins, tetracyclines and beta-lactams) in New Zealand, such that it is not relevant to draw any distinction between the different types. Although veterinarians tend to have their preferred type of antibiotic, if that product was not available, there would be another equally effective and similarly priced substitute. Different types of antibiotics can be used to treat the same disease. For example, a penicillin-based product containing cloxacillin, and a beta-lactam-based product containing cephalonium, are both used for the treatment of subclinical mastitis in dry cows. There are many examples of this occurring in New Zealand. In Schering-Plough's experience, if for some reason the preferred course of treatment is not available, then New Zealand veterinarians are invariably willing to substitute a different product, and for each antibiotic, there are a number of different options. As noted above, most antimicrobials can be used on a range of animals.

Accordingly, Schering-Plough submits that there are good arguments the relevant market is that for the supply of antibiotics for ruminant animals. However, Schering-Plough also acknowledges that antimicrobials can usually be distinguished by route of administration and active ingredient.

17.2 PART III: CONSTRAINTS ON MARKET POWER BY EXISTING COMPETITION

(a) Overview

The Acquisition will not substantially lessen competition in this market because:

- the post-Acquisition share of an anti-microbials market is relatively low at [CONFIDENTIAL]%, which is within the safe harbours because the market is "unconcentrated";

- the presence of strong and effective competitors; and

- the low barriers to entry and expansion.

Schering-Plough's products are Ceporex, Oxytetrin LA, Tribrissen 48% Injection and Nuflor. Intervet's products are Cobactan 2.5%, Biodexamine, Depocillin, Depomycin, Duplocillin LA, Neomycin – penicillin 100-200, Engemycin and Metricure.

(b) **Question 16: Existing competitors**

The post-Acquisition market shares for antimicrobials are shown in the table below.

[CONFIDENTIAL MARKET SHARE DATA REMOVED]

ANTIMICROBIALS		
Firm	**2006 Sales (USD 000)**	**Share %**
Intervet		
Schering-Plough		
Combined Entity		
Bomac		
Norbrook		
Pfizer		
Boehringer Ingelheim		
Phoenix		
Stockguard		
Jurox		
Virbac		
Elanco		
Others		
Total		**100.00%**
3 Firm Concentration Ratio		

Source: 2006 Index of Veterinary Specialities (IVS) Annual, and Schering-Plough and Intervet's own estimates

As the above table indicates, the combined entity's share of this market is within the safe harbours for an unconcentrated market.

In this market, Bomac has three products, Norbrook and Stockguard each have ten products, Pfizer, Boehringer Ingelheim, Phoenix, Virbac and Elanco each have two products, and Jurox has one product.

As the table above shows, post-Acquisition, the combined entity would be constrained by a number of firms, in particular Pfizer, Boehringer Ingelheim and Stockguard. There are a number of smaller firms, each of which would impose varying degrees of constraint. In addition, the actual change in the level of competition would be minimal, given Schering-Plough's small market share.

If the Commission determined that a separate market for tetracycline-based antimicrobials was warranted, the parties would have a combined share of [CONFIDENTIAL]%, although the degree of aggregation would be very low – Schering-Plough having only a [CONFIDENTIAL]% share. Strong constraint would be imposed by Boehringer Ingelheim, with [CONFIDENTIAL]%, and also by the smaller players, Stockguard and Bomac (with an estimated [CONFIDENTIAL]% each). While those players are small, it is relevant that they are actually larger than Schering-Plough (which is relevant to the *change* in the level of concentration and constraint as a result of the Acquisition).

In any separately defined market for beta-lactams the combined entity would have a market share of less than [CONFIDENTIAL]%.

(c) Questions 17 – 22: Conditions of entry and expansion

Schering-Plough's comments on barriers to entry and expansion outlined in section 16 above are relevant here, particularly with regard to the expansion of generic suppliers such as Stockguard. The low barriers to entry and expansion apply with equal force to the supply of tetracycline-based antimicrobials.

(d) Questions 23 – 26: Co-ordinated market power

See 16.2(d) above, although Schering-Plough notes that the antimicrobials market is unconcentrated.

For this reason and the other reasons given above, Schering-Plough does not consider that there would be a substantial lessening of competition in the antimicrobials market, or in any more narrowly defined market.

Accordingly, Schering-Plough has not answered any further questions from the clearance application form in relation to antimicrobials but can do so if the Commission wishes.

18. Prostaglandins

18.1 Question 11: Market definition

Endocrine (hormone) treatments are used to regulate an animal's physiological processes leading to improved performance. Besides treatments that focus on the management of life threatening diseases such as diabetes or improving the quality of animal life (through insulins and thyroid hormones) they mainly concern the improvement of the animal's reproduction efficacy. In fact, Schering-Plough estimates that approximately 95% of sales of endocrine treatments are sold for this purpose. Treatments concern mainly the synchronisation of the oestrus (reproductive) cycle, the induction of parturition (birth), and the termination of normal and abnormal pregnancies of ruminants, swine and equine. These treatments include various types of hormone products that fall into separate hormone groups, for example:

- gonadotrophin releasing hormones;
- gonadotrophins;
- prostaglandins; and
- progestagens.

Prostaglandins are hormones that exert a wide range of physiological effects on the reproductive, respiratory, vascular and digestive systems. Commercial prostaglandins are used, in particular, for the management of the oestrus cycle to induce labour or abortions, as well as for the treatment of various ovarian disorders (persistent corpus luteum) and uterine disorders (endometritis). Prostaglandins are used in other species, although they are used predominantly for cattle in the dairy industry. Progestagens (which contain the hormone progesterone) are used in dogs and cats as means of controlling sexual behaviour in both male and female animals.

In *Pfizer/Pharmacia*, again, referring to the EC's decision in *AKZO Nobel/Hoechst Roussel Vet*, the Commission found (in respect of cattle breeding devices) that the different types of hormones used to regulate an animal's fertility process constitute separate product markets as they are used for differing purposes. Schering-Plough agrees with the Commission's view expressed in *Pfizer/Pharmacia* and considers that in the context of the supply of hormones, it is appropriate to define separate markets for individual hormones. There is overlap between the parties in respect of prostaglandin-based products and hence Schering-Plough considers that there is a market for the supply of prostaglandin-based products.

18.2 PART III: CONSTRAINTS ON MARKET POWER BY EXISTING COMPETITION

(a) Overview

The Acquisition will not substantially lessen competition in this market having regard to:

- the low level of market share ([CONFIDENTIAL]%);

- the overwhelming presence of the larger Pfizer ([CONFIDENTIAL]%) and Parnell ([CONFIDENTIAL]%); and

- the low level of barriers to expansion.

Schering-Plough's prostaglandin product is Estrumate. Intervet's product is Prosolvin. Estrumate and Prosolvin are indicated for use in cattle, sheep, horses and pigs. Intervet also supplies one progestagen-based product, Chronogest 40 for Sheep, which is used for ovine reproductive cycle manipulation (although it has a limited use in New Zealand). Schering-Plough does not supply progestagen-based products.

(b) **Question 16: Existing Competitors**

The post-Acquisition market shares for prostaglandins are shown in the table below.

[CONFIDENTIAL MARKET SHARE DATA REMOVED]

PROSTAGLANDINS		
Firm	**2006 Sales (USD 000)**	**Share %**
Intervet		
Schering-Plough		
Combined Entity		
Parnell		
Jurox		
Pfizer		
Total		**100.00%**
3 Firm Concentration Ratio		

Source: 2006 Index of Veterinary Specialities (IVS) Annual, and Schering-Plough and Intervet's own estimates

As the above table indicates, the combined entity's share of this market is outside of the safe harbours for a "concentrated" market. Each of the competing suppliers has one product.

Jurox is active in a number of markets discussed in this Notice. Its prostaglandin product is a generic product (as is Parnell's product). Jurox is an Australian-based veterinary pharmaceuticals company, and states on its website (see http://www.jurox.com.au/index.cfm?menukey=24) that it is "preparing for a major expansion on the back of some exciting new technology". Since it was acquired by its current owners (the O'Brien family) in 1992, the business has grown from sales of AU$0.5 million to over AU$20 million. Jurox now offers more than 200 proprietary veterinary lines to widely diverse animal health markets internationally.

As shown in the table above, Schering-Plough is currently only the [CONFIDENTIAL] ranked supplier in this market after [CONFIDENTIAL], and would remain so post-Acquisition with a market share of [CONFIDENTIAL]%. Further, Intervet's very small market share of [CONFIDENTIAL]% means that the *change* in market share distribution is minimal. Post-Acquisition, [CONFIDENTIAL] would both have a larger market share than the combined entity, and would continue to impose a constraint. In addition, there would be constraint from Jurox, which is involved in a number of other animal health markets.

(c) Questions 17 – 22: Conditions of entry and expansion

There are a number of large, multinational suppliers active in this market, each of which has a presence in a number of other animal health markets. In particular, Pfizer and Parnell are present in a wide range of animal health markets. The concerns that the Commission raised in *Pfizer/Pharmacia* in relation to barriers to *entry* are unlikely to be *as* applicable to existing competitors such as Pfizer and Parnell who are already *existing* competitors. It is therefore the existence of barriers to *expansion* that are relevant to those firms. Given the absence of any material barriers to expansion, in Schering-Plough's view the threat of expansion by Pfizer, Parnell or the other existing firms in this or other related markets would provide a sufficient constraint on the combined entity.

(d) Questions 23 – 26: Co-ordinated market power

See 16.2(d) above.

18.3 PART IV: CONSTRAINTS ON MARKET POWER BY POTENTIAL COMPETITION

(a) Questions 27 – 35: Conditions of entry

See 18.2(c) above.

18.4 PART V: OTHER POTENTIAL CONSTRAINTS

(a) Questions 36 – 41: Countervailing power

See 16.4(a) above.

19. Ectoparasiticides – fly and lice control for cattle and for sheep

(a) Question 11: Market definition

Parasiticides are agents or preparations used to eliminate and/or prevent external or internal invasion of an animal by different sorts of parasites. They target the adult parasite and/or the larvae of the parasite but do not harm the host animal itself. Parasiticides are administered to all species (ruminants, swine, poultry, equine and companion animals). For animals kept in confined environments, such as poultry, parasiticides are often used over a long time period or even constantly. In such a case, the product has to be rotated on a regular basis so that the pathogens do not build up a resistance to the given product(s). As found by the Commission in *Merck/Rhône-Poulenc-Merial*,[13] parasiticides fall into two distinct classes of products:

- anti-coccidials, which act against single celled parasites (so called 'coccidia') and are used to treat animals that are being raised in confined and high density environments (for example in the poultry farming industry, calf farms and pig finishing farms); and

- other anti-parasitic preparations which treat non-coccidia parasites. This broad group of anti-parasitic preparations can be further sub-divided into ectoparasiticides and endoparasiticides.

Ectoparasiticides, which control *external* parasites such as flies and lice, are applied directly on the animal in the form of sprays, dusting powders, pour-on applications, spot-on applications, shampoos, collars, creams or lotions.

Endoparasiticides, which control *internal* parasites (most commonly worms), are administered either orally (in the form of tablets or a 'bolus' (a large tablet)) or parenterally (by intravenous or subcutaneous injection).

Endectocides impose some constraint on endoparasiticides as well as ectoparasiticides, because farmers (albeit for an extra cost), could elect to use an endectocide in place of both an ectoparasiticide and an endoparasiticide. Endectocides protect the treated animal in one convenient treatment against a large number of infestations by various parasites (external and internal). As far as food producing animals are concerned, endectocides are often used where animals are left grazing for longer periods of time. In those instances, a farmer may protect the animals against a broad range of internal and external parasites in a convenient, single treatment.

Fly and Lice

In respect of cattle and sheep there are a number of "combination" products that treat both flies and lice, and also a number of products that only treat lice. The demand for lice control substantially exceeds the demand for fly control in New Zealand and certain suppliers chose to service the customer base by offering combination products. Indeed, Schering-Plough considers that combination products are in fact "lice control" products that can also treat flies. In fact, the only products that are indicated for the control of flies in New Zealand are combination fly and lice products.

[13] Case No. IV/M. 885, 1997.

In New Zealand, demand for cattle fly treatment products is seasonal, and in light of temperature considerations, generally only farms north of Taupo tend to require fly control products, and then only in the summer months. Lice are at their most prevalent in winter. Therefore, while some farmers do require fly products for some months of the year, the fact that some products also treat flies is largely ancillary to the lice control function.

The pricing of Schering-Plough's Blaze (a combination fly and lice treatment) is largely based on that of competing lice products, rather than the fact that it can also treat flies. Schering-Plough considers that if the combined entity attempted to increase price of a combination fly and lice product, it would lose significant sales to suppliers of lice products such as to undermine that attempted increase. Sales of lice only products outstrip demand for fly products for both cattle and sheep (for cattle by around three times).

Having regard to the above, combination products must be (and indeed are) priced to ensure competitiveness with lice-only products. Accordingly, Schering-Plough believes the appropriate market is that for:

- ectoparasiticides (fly and lice control) in cattle; and
- ectoparasiticides (fly and lice control) in sheep.

Ectoparasiticides – fly and lice control for cattle

19.2 PART III: CONSTRAINTS ON MARKET POWER BY EXISTING COMPETITION

(a) Overview

The Acquisition will not substantially lessen competition in this market having regard to:

- the presence of Ancare ([CONFIDENTIAL]%) and Bayer ([CONFIDENTIAL]%) ([CONFIDENTIAL]) and also by Fort Dodge ([CONFIDENTIAL]%); and
- the low barriers to entry and expansion.

Schering-Plough supplies a range of ectoparasiticides in New Zealand, although the product that is specifically marketed for the treatment of flies and lice in cattle is Blaze. Blaze contains the same active ingredient as Schering-Plough's Wipeout product (which is used to control parasites in sheep), but in a stronger concentration given the relative size of cattle to sheep. Intervet sells Stampede Easy Dose which is indicated for the control of flies and lice in cattle.

(b) Question 16: Existing Competitors

The post-Acquisition market shares for ectoparasiticides for cattle are shown in the tables below.

ECTOPARASITICIDES (FLY & LICE) - CATTLE		
Firm	**2006 Sales (USD 000)**	**Share %**
Intervet		
Schering-Plough		
Combined Entity		
Bayer		
Fort Dodge		
Virbac		
Jurox		
Ancare		
Total		**100.00%**
3 Firm Concentration Ratio		

Source: 2006 Index of Veterinary Specialities (IVS) Annual, and Schering-Plough and Intervet's own estimates

The combined entity's share of this market is outside of the safe harbours, given that the market is concentrated.

In this market, Bayer and Fort Dodge each have two products, and each of the other suppliers have one.

Constraint is principally imposed by Ancare ([CONFIDENTIAL]%) Bayer ([CONFIDENTIAL]%) and Fort Dodge ([CONFIDENTIAL]%).[14]

Ancare, which post-Acquisition will be the [CONFIDENTIAL] supplier in this market, is active in a number of the markets relevant to this Notice. Since commencing operations in 1985, Ancare has grown rapidly to become the leading supplier of animal health products to the New Zealand market (a position it is has reached based solely on its supply of generic products), and is a growing force internationally. Ancare supplies through veterinary outlets in New Zealand, and has associate companies in Australia and Ireland as well as distributors in a number of other locations (see http://www.ancare.co.nz/main.cfm?id=1).

(c) Questions 17 – 22: Conditions of entry and expansion

Barriers to entry are very low, and entry could easily be achieved within six months maximum for very little cost. This applies equally to the lice and fly segments. Formulations for ectoparasiticides are available on the internet and chemicals are readily available from China. Accordingly, there is no reason why a supplier of a cattle lice product could not supply a fly control product, should the incentive arise to do so. Active ingredients are not animal specific, meaning that a concentrated form of the Bayer product for fly control in sheep (Seraphos) could be used to treat cattle, subject to regulatory approval being sought.

As discussed above with regard to prostaglandins, barriers to expansion are likely to be even lower than barriers to entry. Constraint is imposed on Schering-Plough and

[14] Further, farmers wanting to control flies also have the option of spraying the shed rather than treating their cattle. One commonly used product is "Ripcord". These sprays are popular with farmers, but as they are not animal specific products they are not included in the sales data. If the price of fly control products were to rise, farmers could easily use a spray instead of an animal treatment, and could expect similar level of effectiveness from such a product.

Intervet by the presence of strong competitors such as Ancare, Bayer and Fort Dodge, due to the constraint their lice products impose on the pricing of the combination products, and also via their ability to enter the fly segment if they wished. Sales of Ancare and Bayer's products are [CONFIDENTIAL], although the Ancare and Bayer products can only treat lice. Ancare (similarly to Stockguard, discussed above under the lactating cow intramammary section) supplies generic copies of other products rather than developing new forms of treatments.

Again, suppliers of ectoparasiticides are also constrained to an extent by the presence of "endectocides" (combination ectoparasiticide and endoparasiticides products), many of which can treat flies and lice. The data in the above tables does not take account of sales of endectocides as neither Schering-Plough nor Intervet supply them, although Novartis, Merial, Ancare and a number of other firms all do.

(d) Questions 23 – 26: Co-ordinated market power

See 16.2(d) above. It is acknowledged that the level of aggregation is not immaterial, although the combined entity will have only a [CONFIDENTIAL]% market share.

19.3 PART IV: CONSTRAINTS ON MARKET POWER BY POTENTIAL COMPETITION

(a) Questions 27 – 35: Conditions of entry

See 19.2(c) above.

19.4 PART V: OTHER POTENTIAL CONSTRAINTS

(a) Questions 36 – 41: Countervailing power

See 16.4(a) above.

Ectoparasiticides – fly and lice control for sheep

19.5 PART III: CONSTRAINTS ON MARKET POWER BY EXISTING COMPETITION

(a) Overview

The Acquisition will not substantially lessen competition in this market having regard to:

- the fact the level of post-Acquisition market share of [CONFIDENTIAL]% is not particularly high;
- the presence of Novartis ([CONFIDENTIAL]%), Ancare ([CONFIDENTIAL]%) and Bayer ([CONFIDENTIAL]%); and
- the low barriers to entry and expansion.

Schering-Plough's products are Duracide, Magnum, Vanquish, Wipeout (all of which treat lice) and Blitz (which treats both flies and lice). Intervet's products are Zenith Pour On and Zenith Dip (which are indicated for flies and lice in sheep) and Taktic (which is indicated for the control of lice in sheep).

Intervet also supplies Lice Enz/Lice Off (which is indicated for the control of lice in sheep and is similar to Schering-Plough's Wipeout product), and Fleececare (which treats flies and lice in sheep and is very similar to the Zenith products, and to Schering-Plough's Blitz). Schering-Plough understands that Lice Enz/Lice Off and Fleececare are sold as housebrand products by rural resellers (namely, PGG Wrightson in the case of Lice Enz/Lice Off). Sales of these products do not register in the IVS market data, and are not included in the market share table below. However, Internet's internal records indicate that in 2006, sales of Lice Enz/Lice Off and Fleececare were US$[CONFIDENTIAL] and US$[CONFIDENTIAL] respectively.

(b) Question 16: Existing competitors

The post-Acquisition market shares for ectoparasiticides for sheep are shown in the table below.

[CONFIDENTIAL MARKET SHARE DATA REMOVED]

ECTOPARASITICIDES (FLY & LICE) - SHEEP		
Firm	**2006 Sales (USD 000)**	**Share %**
Intervet		
Schering-Plough		
Combined Entity		
Novartis		
Ancare		
Jurox		
Bayer		
Elanco		
Total		**100.00%**
3 Firm Concentration Ratio		

Source: 2006 Index of Veterinary Specialities (IVS) Annual, and Schering-Plough and Intervet's own estimates

The combined entity's share of this market is outside of the safe harbours, given that the market is concentrated.

In this market, Novartis has seven products, Ancare has six, Bayer has four, Jurox has two and Elanco has one.

Novartis, Ancare and Bayer are all strong, large international competitors, with established sales networks and presence. [CONFIDENTIAL].

(c) Questions 17 – 22: Conditions of entry and expansion

Barriers to entry in this market are low, and entry could easily be achieved within six months maximum for very little cost. As with ectoparasiticides for cattle, formulations for ectoparasiticides are available on the internet and chemicals are readily available from China. Accordingly, there is no reason why a supplier already active in another

animal health market could not supply a sheep ectoparasiticide, should the incentive arise to do so.

Again, barriers to expansion are likely to be even lower than barriers to entry and Schering-Plough refers the Commission to the discussion above with regard to prostaglandins and ectoparasiticides for cattle.

(d) Questions 23 – 26: Co-ordinated market power

See 16.2(d) above, although it is acknowledged that the level of aggregation is not immaterial, although the combined entity will have only a [CONFIDENTIAL]% market share.

19.6 PART IV: CONSTRAINTS ON MARKET POWER BY POTENTIAL COMPETITION

(a) Questions 27 – 35: Conditions of entry

See 19.5(c) above.

19.7 PART V: OTHER POTENTIAL CONSTRAINTS

(a) Questions 36 – 41: Countervailing power

See 16.4(a) above.

20. Endoparasiticides – worm control in sheep

(a) Question 11: Market definition

Both parties supply endoparasiticides for sheep, (some of Schering-Plough's products are indicated for and may be used in cattle) as in general, worms are not species specific and all types of ruminant animals are susceptible. Accordingly, manufacturers generally target cattle and sheep with the same product, although there are some exceptions where an active ingredient in a product will target a worm species in a particular animal species.[15] However, all of Schering-Plough and Intervet's products are broad spectrum, as are most worm treatment products in the market. This is because worm treatment products are relatively expensive so the relative cost of administering a number of different treatments is disproportionate to the cost of applying one broad spectrum product.

There will frequently be more than one chemical/combination of chemicals that can be used to treat the target worms. Since different formulations are in general substitutable to treat the same types of worms and drench resistance means that different active ingredients will be required at different times to treat the same types of worms, Schering-Plough submits that the product market is that for the treatment of worms.

20.2 PART III: CONSTRAINTS ON MARKET POWER BY EXISTING COMPETITION

(a) Overview

The Acquisition will not substantially lessen competition in this market because the post-Acquisition share is less than [CONFIDENTIAL]%.

Schering-Plough's products are Closal, Nilverm, Scanda and Valbazen. Intervet's product is Panacur 100.

(b) Question 16: Existing competitors

The post-Acquisition market shares for endoparasiticides (worm control) for sheep are shown in the table below.

[CONFIDENTIAL MARKET SHARE DATA REMOVED]

[15] For example, Schering Plough's Closal treats Barbers' Pole, in addition to "closantel and albendazole susceptible mature and immature gastrointestinal roundworms, lungworm, tapeworm, nasal bot, liver fluke and to reduce the output of viable worm and fluke eggs".

ENDOPARASITICIDES - SHEEP		
Firm	**2006 Sales (USD 000)**	**Share %**
Intervet		
Schering-Plough		
Combined Entity		
Ancare		
Merial		
Bomac		
Novartis		
Fort Dodge		
Norbrook		
Jurox		
Virbac		
Total		**100.00%**
3 Firm Concentration Ratio		

Source: 2006 Index of Veterinary Specialities (IVS) Annual, and Schering-Plough and Intervet's own estimates

The combined entity's share of this market is within the safe harbours.

In this market, Ancare has 11 products, Merial and Novartis have five products, Jurox has four, Bomac and Norbrook have two and Fort Dodge and Virbac have one.

There will be no substantial lessening of competition in this market, as the combined entity would be among the smaller players post-Acquisition. It would be constrained by larger firms, in particular, Merial and Fort Dodge.

(c) Questions 17 – 22: Conditions of entry and expansion

The comments made above at paragraphs 19.2(c) and 19.5(c) apply equally to this market.

(d) Questions 23 – 26: Co-ordinated market power

See 16.2(d) above, although Schering-Plough notes that the combined entity would not be among the three largest firms in this market post-Acquisition.

20.3 PART IV: CONSTRAINTS ON MARKET POWER BY POTENTIAL COMPETITION

(a) Questions 27 – 35: Conditions of entry

See 19.5(c) above.

20.4 PART V: OTHER POTENTIAL CONSTRAINTS

(a) Questions 36 – 41: Countervailing power

See 16.4(a) above.

21. Vaccines – campylobacter in sheep

21.1 Question 11: Market definition

The purpose of a vaccine is to protect the animal against future diseases or illness caused by bacterial, viral parasitical or fungal infection (a 'pathogen'). Vaccines achieve this by containing a harmless antigenic preparation (the 'antigen') against which protection is sought. When administered, the animal's immune system recognises and destroys the non-virulent antigen contained in the vaccine. Following vaccination, the animal's immune system will continue to recognise the antigen so that if the animal is later exposed to the virulent form of the pathogen, the animal's own immune system will respond by producing antibodies to destroy the agent before it can attack targeted cells, or by recognising and destroying infected cells before the agent can cause clinical illness. The protection afforded to an animal is usually direct (i.e. to prevent disease or illness in the vaccinated animal itself), but vaccines can also be administered in order to immunise a treated animal's off-spring (where antibodies are passed from the mother to a calf through milk).

Most cattle and sheep get vaccinated against a range of diseases, and both Schering-Plough and Intervet manufacture vaccines to immunise against a number of diseases that commonly occur in ruminant animals. Most of these vaccines protect against one specific disease only. Schering-Plough also manufactures clostridial vaccines, which protect against a variety of commonly occurring ruminant diseases, including tetanus, pulpy kidney, black leg, black disease and malignant oedema.[16] Intervet does not manufacture clostridial vaccines, and none of its specific vaccines offer protection against any of the diseases that Schering-Plough's clostridial vaccines protect against.

Some types of specific and clostridial vaccines can be used to protect against different types of ruminant animals, although others are only used for one type of animal. For example, the campylobacter vaccines listed in the following table contain a strain of campylobacter that is specific to sheep. Schering-Plough's salmonella vaccine can be used for sheep and cattle.

Schering-Plough and Intervet's ruminant vaccines and the disease each vaccine immunises against are shown in the table at Appendix C.

The only overlap between Schering-Plough and Intervet's ruminant vaccines relates to vaccines for campylobacter in sheep.[17] Schering-Plough's product is Campylovexin. Intervet's product is Campyvax4.

Intervet's Campyvax 4 immunises against campylobacter fetus fetus and campylobacter jejuni, whereas Schering-Plough's Campylovexin only immunises against campylobacter fetus fetus.[18]

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[16] Clostridial bacteria cause infectious diseases such as black leg, malignant oedema, gangrene, red water, tetanus, and botulina are found in the soil and water and are very common in the environment where livestock (cattle, sheep and pigs) are typically pastured.

[17] There are no campylobacter vaccines available in New Zealand for animals other than sheep. Schering-Plough's understanding is that campylobacter is relatively rare in other animals.

[18] [CONFIDENTIAL].

In New Zealand, not all farmers vaccinate their sheep against campylobacter. Farmers make a trade off between the cost of vaccination and the risk (and cost) of sheep contracting the bacteria. As the costs/risks change, so does the incidence of vaccination. Where the return for farmers is likely to be close to or lower than the cost of vaccinating, often the decision will be made not to vaccinate. This means that products must be priced at a level that leads to sufficient farmers choosing to vaccinate.

In New Zealand, Schering-Plough estimates that only about [CONFIDENTIAL]% of sheep are vaccinated against campylobacter. Schering-Plough's estimate is that, based on the current high value of the New Zealand dollar relative to the American dollar and other currencies in New Zealand's major export markets (which has impacted profitability), the percentage of unvaccinated sheep will rise to approximately [CONFIDENTIAL]% in 2007 as farmers substitute to a no-vaccine policy – which is close to a [CONFIDENTIAL]% increase in the number of sheep that are not vaccinated. This indicates the extent of the willingness to substitute away from vaccination, which, coupled with the sheer volume of sheep that are not vaccinated, indicates that a "no vaccine" decision is not one that only comparatively few farmers make. Rather, this is a real option for farmers, and therefore an option the suppliers must take into account in setting price.

Further, suppliers are unable to identify and hence discriminate against those farmers that might not, for whatever reason, be willing to choose not to vaccinate their animals. This means that the suppliers must price to all customers to encourage farmers to vaccinate.

In 2003 AgVax, which was purchased by Intervet in 2005, introduced a campylobacter vaccine called Campyvax3. Prior to that time, the only campylobacter vaccine on the market was Schering-Plough's Campylovexin. At the time Campyvax3 was introduced, the efficacy and pricing between the two products was largely similar, reflected in the market share obtained by Campyvax3 (estimated at 20%). In 2005, Intervet launched Campyvax4, replacing Campyvax3. As noted above, in addition to the campylobacter fetus fetus strain, Campyvax4 offers protection against campylobacter jejuni. Campybax4 has proven to be very successful, and in the year since the introduction of Campyvax4, Intervet has rapidly grown sales and believes it has around a 60% share of total campylobacter sales.

A key constraint on pricing is the willingness of farmers to adopt a "no vaccine" policy. Of those farmers choosing to vaccinate, there are two vaccines available: Campyvax4 and Campylovexin. However, these products are different (in terms of coverage) and the constraint that Schering-Plough's Campylovexin product imposes on Intervet's Campyvax4 is comparatively minor as a result. In addition, the relative strength of the Intervet product is amplified where the jejuni bacteria is prevalent. If the rate of growth of the Intervet product continues, the level of Schering-Plough sales will continue to fall, suggesting that Schering-Plough's product will impose even less constraint over time.

In terms of market definition, other than Schering-Plough's clostridial vaccines, the parties' vaccines only immunise against one type of disease.[19] Accordingly, given that the Acquisition only gives rise to aggregation in respect of campylobacter vaccines, and because these are only given to sheep, Schering-Plough considers

[19] [CONFIDENTIAL].

that the relevant product market is that for sheep campylobacter vaccines, notwithstanding the differences between the parties' products discussed above.

21.2 PART III: CONSTRAINTS ON MARKET POWER BY EXISTING COMPETITION

(a) Question 16: Existing competitors

The post-Acquisition market shares for campylobacter vaccines for sheep are shown in the table below.

[CONFIDENTIAL MARKET SHARE DATA REMOVED]

CAMPYLOBACTER VACCINES		
Firm	**2006 Sales (USD 000)**	**Share %**
Intervet		
Schering-Plough		
Combined Entity		**100.00%**

Source: 2006 Index of Veterinary Specialities (IVS) Annual, and Schering-Plough and Intervet's own estimates

(b) Questions 17 – 22: Conditions of entry and expansion

There are a number of large international suppliers active in the supply of vaccines in New Zealand, including:

- Pfizer (with five vaccines);
- Fort Dodge (with three vaccines);
- Virbac (with two vaccines);
- Ancare; and
- Bomac (each with one vaccine).

While none of these suppliers currently manufacture a campylobacter vaccine, they are all capable of introducing such a vaccine, having R&D capabilities and resources, and the financial ability to support new entry.

Schering-Plough acknowledges that there may be some lead time for the introduction of any new vaccine, including a campylobacter vaccine, given the technicalities involved with the development of a vaccine. Section 18.2(c) above discussed the fact that manufacturing capability is not a barrier to entry in the animal health pharmaceutical markets. Schering-Plough agrees that it may take longer in the animal health biological markets to establish a manufacturing facility, although notes that its own biological manufacturing facility (in Upper Hutt) was operational in under two years.

While the development of a campylobacter vaccine is technically more complex than the development/manufacturing of a pharmaceutical product, the same could be said for all vaccines and the large international players have a proven ability to develop and successfully sell vaccines. This suggests there are no barriers that would

foreclose entry by any of the suppliers listed into the campylobacter vaccine market, should the incentive arise for them to do so, albeit entry would take longer than it would in respect of pharmaceuticals (and could involve years). As discussed in previous sections of this Notice, in addition to the suppliers listed above, there are numerous other international suppliers active across a range of animal (and human) health markets that would be well placed to expand their current vaccine product range to include a campylobacter vaccine.

(c) Questions 23 – 26: Co-ordinated market power

N/A.

21.3 PART IV: CONSTRAINTS ON MARKET POWER BY POTENTIAL COMPETITION

(a) Questions 27 – 35: Conditions of Entry

See 21.2(b) above.

21.4 PART V: OTHER POTENTIAL CONSTRAINTS

(a) Questions 36 – 41: Countervailing power

As discussed under section 16.4(a), for the purposes of this Notice, Schering-Plough has not placed any weight on the constraint imposed by suppliers to the animal health markets.

However, for the reasons discussed at 21.1 above, the acquirers of Schering-Plough's products, namely, farmers who have the choice not to vaccinate their sheep, do impose constraint.

THIS NOTICE is given by

Thomas J. Sabatino Jr

I hereby confirm that:

- all information specified by the Commission has been supplied;
- all information known to the applicant which is relevant to the consideration of this Notice has been supplied; and
- all information supplied is correct as at the date of this Notice.

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

Dated this day of 2007

Signed by Thomas J. Sabatino Jr

_____

Executive Vice President and General Counsel

I am an officer of the company and am duly authorised to make this Notice.

APPENDIX A

The information in this appendix supplements the information on the parties' human health products contained in section 11.

HUMAN HEALTH

Cardiovascular (anti-thrombosis) products

Thrombi (clots) are formed as the result of a highly complex process called aggregation and/or coagulation that changes blood from its liquid state to a solid state, or clot. Clotting is an important part of haemostasis, the cessation of blood loss from a damaged vessel, whereby the process stops the loss of blood. However, in some disorders, clots can form within an intact blood vessel. Such clots (or thrombi) can cause heart attack, stroke or other problems. In most heart attack cases, for example, the clot blocks the coronary artery, preventing the blood from reaching the heart muscle.

Thrombosis, the formation of blood clots, involves two major components, namely platelets and fibrin. Depending on the nature of the injured blood vessel, the composition of a blood clot can vary significantly. On the one hand, arterial thrombi (i.e. clots that form in the arteries) are predominantly rich in platelets. On the other hand, venuous thrombi (i.e. clots that form in the veins) are predominantly rich in fibrin. Anti-thrombotic drugs reflect these differences and their therapeutic use is aimed at a specific effect in the coagulation cascade. Anti-platelets are used to treat the risk of arterial thrombi and anti-coagulants are used to prevent venous thrombi.

Anti-coagulants stop the coagulation cascade, thereby stopping blood from clotting. When a blood clot is formed, the administration of anti-coagulants can prevent the clots from growing larger and keep new clots from forming. Anti-coagulants, however, do not dissolve existing clots. Importantly, anti-coagulants only inhibit fibrin formation, but they do not have an effect on platelet rich clots. For this reason, they are most commonly associated with thrombi in venous circulation.

Organon's anti-coagulant product Orgaran®, treats a particular type of coagulation caused by heparin. Heparin is a porcine-based biological substance widely used as an injectable anti-coagulant for the treatment and prevention of thrombotic diseases. However, heparin can sometimes cause thrombocytopenia (known as heparin-induced thrombocytopenia or 'HIT'). HIT is an uncommon, but potentially fatal, immunemediated reaction to heparin and is strongly associated with thrombosis. Without prompt and effective treatment, up to 50% of patients will experience a blood clot (thrombosis) – of which 10-20% can be fatal. Orgaran® is a non-heparin (heparinoid) anti-thrombotic drug indicated for the treatment or prevention of thromboembolic complications due to HIT. Schering-Plough neither markets nor plans to develop anti-coagulant drugs.

By comparison, anti-platelets treat arterial thrombi that form under high blood flow conditions and consist of platelet aggregates bound together. Therefore, strategies to inhibit arterial thrombosis focus primarily on drugs that block platelet function. Anti-platelets decrease the platelet aggregation thereby inhibiting the formation of thrombi in the context of the so called platelet cascade. Specifically, anti-platelets are effective in arterial circulation, where anti-coagulants have little effect. On the other hand, they do not have an effect on the formation of fibrin rich clots. Schering-Plough markets an anti-platelet drug, Integrilin®. This product is a glycoprotein

IIb/IIIa inhibitor. Nearly all patients requiring anti-platelet therapy are given aspirin, a cyclo-oxygenase inhibitor. In addition, the leading anti-platelet drug is Clopidogrel, which is marketed by Bristol-Myers Squibb and Sanofi-Aventis under the trade name Plavix®.

In relation to anti-thrombotic agents, the ATC classification is as follows:

First level:	B Blood and blood forming organs
Second level:	B01 Anti-thrombotic agents
Third level:	B1A Vitamin K antagonists
	B1B Heparins
	B1C Platelet aggregation inhibitors
	B1D Ibrinolytics
	B1E Direct thrombin inhibitors
	B1X Other anti-thrombotic agents

Schering-Plough is only active in B1C platelet aggregation inhibitors. Organon is only active in B1B Heparins. Orgaran® falls within ATC-4 B1B-9 Other heparins.

Schering-Plough is not aware of any previous decisions by the Commission regarding market definition in the cardiovascular field, other than decisions in relation to cardiovascular devices which are not relevant to the Acquisition. The European Commission has reached a product market distinction between anti-platelets and oral anti-coagulants in *Sanofi/Synthelabo*[20] and in *Hoechst/Rhône Poulenc*.[21] The European Commission also stated in *Hoechst/Rhone Poulenc* that "hirudine-based direct thrombin inhibitors (DTI) belonging to ATC4 class B1B9 constitute a separate and relevant product market".[22]

Both Schering-Plough and Organon have [CONFIDENTIAL]. However, as mentioned above, [CONFIDENTIAL]. Schering-Plough therefore submits that the Acquisition does not give rise to any overlaps in pipeline products.

Schering-Plough therefore submits that the activities of Schering-Plough and Organon do not overlap in relation to the sale of their respective cardiovascular products. For the reasons given above, anti-coagulants and anti-platelets cannot be used interchangeably. If at all, in certain cases they can complement each other as they address different critical situations that can give rise to a thrombosis. Thus, it is necessary to distinguish a product market for anti-coagulant pharmaceuticals that is

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[20] Commission Decision of 17 May 1999 Case No COMP/M.1397 *Sanofi/Synthelabo* at paragraph 30.

[21] Commission Decision of 30 January 2004 Case No COMP/M.1378 *Hoechst/Rhone Poulenc* at paragraph 15.

[22] M.1378 *Hoechs /Rhone Poulenc* at paragraph 15.

distinct from the product market on which anti-platelet drugs compete. Therefore, in Schering-Plough's view, Organon's Orgaran® and Schering-Plough's Integrilin® do not belong to the same product market.

Cancer therapies/oncology products

The parties both have products with indications in the field of superficial bladder cancer. However, these products do not compete with each other. Organon sells OncoTICE®, an immunotherapeutic agent which uses a specific bacteria (known as **BCG**), for the treatment of bladder cancer. Schering-Plough sells Intron A®, a drug primarily for treatment of Hepatitis B and C and melanoma treatment, but which is also indicated for the treatment of bladder cancer.

OncoTice® is an effective intravesical therapy for bladder cancer[23]. Intron A® has been used in explanatory clinical studies, but not marketed or commercially promoted by Schering-Plough, for the treatment of superficial bladder cancer, either as a single agent therapy or in combination with BCG. As a single agent, its role has primarily been in the event of failure by a BCG treatment.

However, Intron A® does not have an approved indication for bladder cancer, although it is studied in exploratory clinical trials to treat bladder cancer in combination with OncoTICE®. In addition, Schering-Plough does not promote its products off-label; therefore, Intron A® is not promoted in the therapeutic area of bladder cancer.[24]

Bladder cancer can be treated in several ways, depending on the type of cancer, the stage of the disease, and the patient. Treatments can be surgery, chemotherapy, radiation therapy and biological therapy. The parties' products are both biological therapies in that they use the body's immune system, either directly or indirectly, to produce a natural defence against infections as well as tumours. However, both products work differently: OncoTICE® is a vaccine therapy (i.e. uses an external organism to treat cancer), whereas Intron A® is a protein therapy (i.e. uses a modified human protein to treat cancer).

OncoTice® uses a specific bacteria (BCG), to stimulate the immune system. This bacillus has been attenuated (made less virulent). This is similar to what is commonly done in many vaccines. Intron A® uses interferon alfa-2b, a protein that occurs naturally in the body. Interferons were produced in the laboratory for use as biological response modifiers, i.e. they alter the interaction between the body's immune defences and cancer. Interferons improve the way a cancer patient's immune system acts against cancer cells. In addition, interferons may act directly on cancer cells by slowing their growth or promoting their development into cells with more normal behaviour.

Although Intron A® can be used as a complementary drug to treat bladder cancer, its primary use in New Zealand is for the treatment of hepatitis B and hepatitis C (and a small proportion of sales of Intron A® is for melanoma treatments). Indeed, Schering-

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[23] Intravesical therapies are inserted in the bladder.

[24] In the US, the Federal Drug Administration has not approved labelling or selling that way, although it is Schering-Plough's belief that many physicians and oncologist do in fact use Intron A® "off label" for treatment of, among other things, bladder cancers.

Plough does not even advertise or promote Intron A® as a bladder cancer product, as it cannot legally do so. Furthermore, Intron A®'s side effects are very strong and it is not adequate to treat superficial bladder cancer.

Therefore the parties' activities do not overlap in the field of treatment of bladder cancer, as Intron A ® does not have an approved indication of bladder cancer, and it is not being promoted by Schering-Plough to treat bladder cancer.

APPENDIX B

List of new products registered between 1/1/2003 and 1/6/2007 from ACVM website.

APPENDIX C

Schering-Plough and Intervet's ruminant vaccines and the disease each vaccine immunises against are shown in the following table.

Disease	Schering-Plough product	Active ingredient	Intervet product	Active ingredient
Campylobacter *(in sheep only)*	Campylovexin	Campylobacter fetus fetus	Campyvax 4	Campylobacter fetus fetus and campylobacter jejuni
Dichlobacter nodosus footrot	Footvax	Dichlobacter nodosus	-	-
Leptospira	Leptavoid	Leptospira pomona, Hardjo + Copenhagenii	-	-
Moraxella bovis	Piliguard	Moxarella bovis	-	-
Rotavirus	Rotavec	Rotavirus + E coli	-	-
Salmonella	Salvexin	Typhimurium, Bovis morbificans, Hindmarsh + Brandenburg	-	-
Orf virus	Scabine	Orf virus	-	
BVD	-	-	Bovilis BVD	Inactivated cytopathenogenic BVD virus C86
Ovarian stimulation	-	-	Androvax	Freeze dried androstenedione protein with DEAE adjuvant
Neospora canium	-	-	Bovilis neoguard	Killed protozoa containing neospora caninum
Toxoplasma gondii	-	-	Toxovax	Attenuated live toxoplasma gondii
Yersinia pseutotuberculosis	-	-	Yersiniavax	Killed culture of yersinia pseudotuberculosis
General active immunisation for lamb		-	Oviplast plus	Mannheimia haemolytica and pasteurella trehalosi
Clostridials				
10 strains of clostridia	Covexin 10	10 strains of clostridia	-	-
2 strains of clostridia	Lambvac	Tetanus and Perfingens D	-	-
5 strains of clostridia	Multine 5	5 strains of clostridia	-	-
5 strains of clostridia	Nilva	5 strains clostridia and levamisole	-	-