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COMMERCE COMMISSION

# Decision No. 677

Determination pursuant to the Commerce Act 1986 in the matter of an application for clearance of a business acquisition:

**SCHERING-PLOUGH CORPORATION**

and

**MERCK & CO**

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| **The Commission:** | Dr Mark Berry<br>Anita Mazzoleni<br>Sue Begg |
| **Summary of Application:** | The proposed merger between Schering-Plough Corporation and Merck & Co., Inc. |
| **Determination:** | Pursuant to section 66(3)(a) of the Commerce Act 1986, the Commission determines to give clearance for the acquisition by Schering-Plough Corporation of all of the shares in Merck & Co., Inc. |
| **Date of Determination:** | 20 August 2009 |

**CONFIDENTIAL MATERIAL IN THIS REPORT IS CONTAINED IN SQUARE BRACKETS**

**CONTENTS**

## EXECUTIVE SUMMARY

E1. A notice pursuant to s 66(1) of the Commerce Act 1986 (the Act) was registered on 20 May 2009. The notice sought clearance for the proposed merger of Schering-Plough Corporation (Schering-Plough) and Merck & Co., (Merck).

E2. The proposed acquisition would involve aggregation in both the human and animal health industries although the aggregation in human health products is limited. In this respect, the Commission focused its investigation on the impact in the animal health industry.

E3. Both Schering-Plough and Merck, through Merck's shareholding in Merial S.A.S (Merial), supply a range of animal health products and the Commission identified a number of different markets where competition issues could potentially arise. These were the national markets for the manufacture/import and wholesale supply of:

- treatments for internal parasites for cattle and (separately) internal parasites for sheep;
- treatments for external parasites for cattle and (separately) external parasites for sheep; and
- vaccines for Bovine Viral Diarrhoea (BVD) in cattle.

E4. In parallel to its consideration of this proposed acquisition, the Commission has also considered a proposed acquisition involving Pfizer Inc (Pfizer) and Wyeth Corporation (Wyeth). Both these parties are active in many of the same markets as Schering-Plough and Merck.

E5. In this respect, the Commission has taken the proposed Pfizer/Wyeth acquisition into consideration when assessing the relevant factual and counterfactual scenarios for the proposed Schering-Plough/Merck acquisition. Particularly, the Commission has taken into account that the two proposed acquisitions may, or may not, go ahead.

E6. As a starting point, the Commission has adopted the factual scenario that would give rise to greatest competition concerns for the Commission, which is if the Schering-Plough/Merck and Pfizer/Wyeth transactions proceed contemporaneously. In this instance, the Commission has compared the factual to the most competitive counterfactual scenario in which neither of the proposed acquisitions goes ahead, which is essentially the status quo. It did so because if no significant competition concerns were evident in this comparison, then it is unlikely that other likely factual and counterfactual scenarios would give rise to competition concerns.

E7. The Commission found that in each of the affected parasiticide markets, the combined entity would likely be constrained by the presence of existing competitors. The majority of these competitors are large, international suppliers with an established presence in New Zealand who could readily expand if the combined entity were to increase prices or reduce service levels.

E8. In the BVD market, the Commission considered that in either the factual or counterfactual scenario, the relevant Merck product would only offer a limited competitive constraint so that there is likely to be minimal impact on the market from the proposed acquisition.

E9. Accordingly, the Commission is satisfied that the proposed acquisition will not have, or would not be likely to have, the effect of substantially lessening competition in the affected markets. Therefore, the Commission granted clearance to the proposed acquisition.

## THE PROPOSAL

1. A notice pursuant to s 66(1) of the Commerce Act 1986 (the Act) was registered on 20 May 2009. The notice sought clearance for the proposed merger of Schering-Plough Corporation (Schering-Plough or the Applicant) and Merck & Co., (Merck).

## THE TRANSACTION

2. In accordance with a merger agreement dated 8 March 2009, Merck and Schering-Plough propose to combine by way of a "reverse merger" in which Schering-Plough would acquire Merck, but the merged company would operate under the name "Merck".
3. The transaction involves aggregation in both the human and animal health industries. There are numerous manufacturers and developers of human health products and the Commission notes that the overlap between the human health products manufactured and developed by Schering-Plough and Merck is limited.
4. In this respect, the Commission concludes that the proposed acquisition is unlikely to give rise to competition concerns in respect of human health products.
5. Accordingly, the Commission has focused its investigation and the discussion of competition concerns issues in this report on the impact in the animal health industry.

## DECISION

6. The Commission is satisfied that existing competition in all the relevant markets would be likely to constrain the combined entity. Accordingly, the Commission is satisfied that the proposed acquisition will not have, or would not be likely to have, the effect of substantially lessening competition in any of the relevant markets.

## ANALYTICAL FRAMEWORK

7. The Commission uses an analytical framework[1] for assessing a substantial lessening of competition in the context of an acquisition. The first step is to determine the relevant market or markets. To do this, the Commission identifies the areas of overlap between the acquirer and the target, and then considers what, if any, products and geographic regions, constitute relevant close substitutes from both a customer's and a supplier's point of view.
8. The Commission uses a forward-looking type of analysis to assess whether a lessening of competition is likely, so, an important subsequent step is to establish the appropriate hypothetical future with and without scenarios, defined as the situations expected:
    - with the acquisition in question (the factual); and
    - in the absence of the acquisition (the counterfactual).

[1] Commerce Commission, *Mergers and Acquisitions Guidelines*, January 2004.

9. The impact of the acquisition on competition is then viewed as the prospective difference in the extent of competition in the market between those two scenarios.[2]

10. The Commission analyses the extent of competition in each relevant market for both the factual and counterfactual scenarios, in terms of:

    - existing competition - the degree to which existing competitors compete and their ability and incentives to expand production in the event that the combined entity raises prices;
    - potential competition – the ability of businesses to enter the market and thereafter expand, given an inducement to do so;
    - other competition factors, such as the countervailing market power of buyers - the combined entity may be constrained if purchasers were able to exert a substantial influence on the price, quality or terms of supply of a good or service;
    - coordinated behaviour – whether the acquisition would enhance the ability of market participants to collude either tacitly or explicitly.

11. A comparison of the extent of competition in the relevant markets in both the factual and counterfactual scenarios enables the Commission to assess the probable extent of the lessening of competition under the proposed acquisition, and whether that contemplated lessening is likely to be substantial.

## THE PARTIES

### Schering-Plough

12. Schering-Plough is a global healthcare company with activities in the prescription pharmaceutical, over-the-counter (OTC) human healthcare and animal health sectors. Schering-Plough conducts research in its own right, and is also engaged in various collaborative projects with other parties to develop and manufacture human and animal health products.

13. Of particular relevance to this application are Schering-Plough's activities in the animal health business where it develops, manufactures and markets OTC and prescription veterinary pharmaceuticals, biologicals (vaccines) and various speciality products, including those for livestock animals such as cattle and sheep.

### Merck

14. Merck is a global pharmaceutical company with activities in human health products. In New Zealand, Merck has one operating subsidiary, Merck Sharp & Dohme New Zealand Limited.

15. Merck also has an interest in the animal health sector through its 50/50 joint venture with Sanofi-Aventis Limited, in Merial S.A.S (Merial). The Merial

[2] Where a transaction gives rise to two or more likely counterfactuals, the Commission assesses the possibilities, discards those that have only a remote prospect of occurring, and considers each of the real and substantial possibilities as counterfactuals against which the factual is to be assessed. (See *Decision 650: The Southern Cross Health Trust / Aorangi Hospital Ltd;* 4 September 2008, p 16).

joint venture operates in New Zealand through Merial New Zealand Limited, trading as Merial Ancare New Zealand.[3]

16. Merial is involved in the manufacture and supply of various animal health products in New Zealand. Primarily, these products are for the treatment of internal and external parasites in livestock animals. Merial distributes its entire product range of animal health products exclusively through the veterinary channel.[4]

## OTHER RELEVANT PARTIES

### Pfizer Inc (Pfizer)

17. Pfizer is a global pharmaceutical company operating in the human health and animal health sectors. In particular, Pfizer supplies a range of animal vaccines for both companion and livestock animals and a range of products for the treatment of parasites in or on livestock animals.

18. Like Merial, Pfizer has selected to supply its products exclusively through the veterinary channel in New Zealand.

19. At the same time that it has been considering this application, the Commission has also been considering an application from Pfizer seeking clearance to acquire Wyeth Corporation (Wyeth), which involves aggregation in some of the same markets.

### Wyeth

20. Wyeth is a global pharmaceutical company that supplies a number of human health and animal health products in New Zealand. In particular, Wyeth, under the trading name Fort Dodge Animal Health (Fort Dodge), manufactures and distributes a range of vaccines for both companion and livestock animals, as well as supplying a range of products for the treatment of parasites in or on livestock animals.[5]

### Other Manufacturers/Suppliers

21. Other major manufacturers and suppliers of animal health products of relevance to the proposed merger, together with a description of their activities, are detailed in Table 1.

**Table 1: Manufacturers/Importers and Suppliers of Animal Health Products in New Zealand**

| Company | Activities | Notable Brands |
|---|---|---|
| Bomac Laboratories Limited (Bomac) | Manufacturer/supplier of parasiticides and certain vaccine products for sheep and cattle. | Bomatak, Bomectin |

[3] The Commission notes that Sanofi-Aventis Limited and Merck have announced recently that they have reached a conditional agreement under which Merck will sell its 50% interest in Merial to Sanofi-Aventis Limited.
[4] The Commission has used the Merial name to identify Merck's presence in the animal health industry.
[5] The Commission has used the Fort Dodge name to identify Wyeth's presence in the animal health industry.

| | | |
|---|---|---|
| Bayer New Zealand Limited (Bayer) | Importer/supplier of parasiticides for sheep and cattle. | Baymec, Baycox |
| Novartis New Zealand Limited (Novartis) | Importer/supplier of parasiticides for sheep and cattle. | Fasinex, Rycozole, Leveiben, Levipor |
| Norbrook New Zealand limited (Norbrook) | Importer/supplier of parasiticides for sheep and cattle. | Noromectin, Parafend |
| Jurox New Zealand Limited (Jurox)) | Importer/supplier of parasiticides for sheep and cattle | Strategik, Paramectin |
| Ravensdown Fertiliser Co-operative Limited (Ravensdown) | Supplies directly to farmers a range of parasiticides for sheep and cattle, which it sources from Jurox's parent company in Australia. Ravensdown holds the registration for these products in NZ and markets these products under its own brand name. | Ravensdown branded Abamectin and Albendazole |
| Boehringer Ingelheim NZ Limited (Boehringer Ingelheim) | Importer/supplier of vaccines for companion and livestock animals. | Ontavac |
| Virbac New Zealand Limited (Virbac) | Importer/supplier of parasiticides for sheep and cattle. | Equimax, Virbamec |
| Argenta Manufacturing Limited (Argenta) | Engages in research and development of animal health products and contract manufacturing of various animal health products for a variety of customers. | Clients include [ ] |

Source: Industry participants

**Regulatory Agencies**

*New Zealand Food Safety Authority (NZFSA)*

22. NZFSA is the statutory organisation that is responsible through its Animal Compounds and Veterinary Medicines division, for the registration of veterinary medicine products in New Zealand, and the licensing of animal health manufacturing plants, both of which are requirements in terms of the Agricultural Compounds and Medicines Act 1997.

*Environmental Risk Management Authority (ERMA)*

23. ERMA is the statutory organisation which is responsible for approving any new hazardous substance or new organism in New Zealand in terms of the Hazardous Substance and New Organisms Act 1996. Such approvals are required for some animal health products.

## INDUSTRY BACKGROUND

### Animal Health Products

24. The animal health industry involves the manufacture and supply of products for a range of animal species. The key species for the proposed acquisition are:

    - companion animals (eg dogs and cats);
    - cattle and sheep;
    - pigs (swine); and
    - horses (equine).

25. The key animal health product categories of relevance to the proposed merger are biologicals and pharmaceuticals.

26. Biologicals are the products that trigger an immune response in animals against viral and bacterial diseases in animals. They include vaccines that are used to prevent future infection or to reduce the clinical signs associated with infection or to reduce shedding (contagiousness) by an infected animal.

27. Pharmaceuticals encompass a wide range of products, notably parasiticides that contain a variety of active substances to prevent or treat many animal diseases and disorders.

28. Parasiticides are the most commonly used animal health remedy in New Zealand and can broadly be categorised into three major groups:

    - ectoparasiticides, which are used for the treatment of external parasites such as flies and lice;
    - endoparasiticides, which are used for the treatment of internal parasites such as worms; and
    - endectocides, which are used for the treatment of both external and internal parasites.

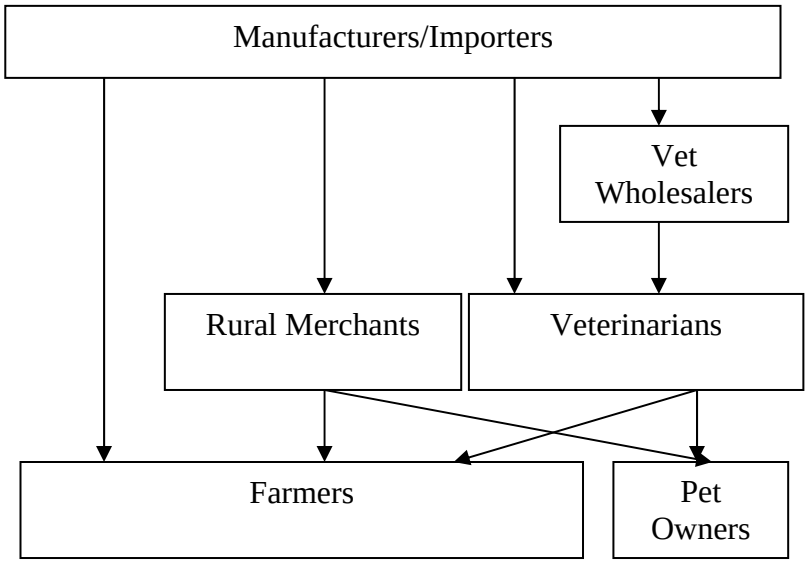
### Industry Structure

29. The manufacture and supply of animal health products involves a number of phases, incorporating in broad terms research and development (R&D), product testing and regulatory approval, manufacture of the products themselves and distribution to customers.

30. Distribution can occur through several channels. The majority of products are supplied to rural merchant stores and veterinarians, who then supply the end-customers, typically farmers and pet owners. Veterinarians also access products from wholesalers. Alternatively, some manufacturers, such as Ravensdown, supply direct to farmers.

31. A general outline of the structure of the animal health industry is provided in Diagram 1.

**Diagram 1: Industry Structure**




**Manufacture/Supply**

32. New or novel animal health products are launched on the market following extensive R&D, which may take 10 years or more to complete. These products and their formulations are protected by patent rights. Once the patent granted to the original developer expires, generic products can then be developed. Generic products are essentially imitations of an off-patent product. Such products are an important feature of the animal health industry in New Zealand, particularly in respect of parasiticides as most of the available formulations and active substances are now off-patent.

33. Before either novel or generic animal health products can be sold in New Zealand, they must be registered with the NZFSA and/or approved by ERMA. Depending on the nature of the product this may be a relatively straightforward process, particularly in the case of an established product for which there is available information to support the claims.

34. However, for a novel product it may involve a lengthier process, which could include the need for evidence from New Zealand-based trial work to support the product's claims and thereby significantly increasing the timeframe for the registration process. Industry participants advised the Commission that the development and introduction of novel products is lengthy and relatively rare. Accordingly, the Commission has focused its investigation on those products that are currently supplied in New Zealand, or those products supplied in other countries that have the potential to be distributed in New Zealand, particularly if a manufacturer is given an incentive to do so.

35. Once approval has been given by the relevant authorities, the supplier has a range of manufacturing and distribution options which can be used either individually or in combination. These include:

    - producing from a local manufacturing plant;
    - manufacturing the products overseas and importing the finished product;

- importing the active substances and entering into a contract manufacturing arrangement with an existing manufacturer in New Zealand, such as Argenta; and
- entering into a supply and distribution arrangement with a local company.

**Distribution**

36. The distribution of animal health products in New Zealand is currently effected through the following channels:
    - veterinary wholesalers, such as Provet NZ Pty Limited and Southern Veterinary Supplies Limited;
    - rural merchant stores, such as PGG Wrightson Limited, Farmlands Trading Society Limited, and Combined Rural Traders Co-operative; and
    - veterinary clinics and practices, of which there are many operations of various sizes and that either purchase directly from a supplier or through a veterinary wholesaler.
37. The mode of distribution depends on the nature of the product, and in some instances, is influenced by the sales policy of the supplier. Prescription animal remedies (PARs), such as vaccines, can only be sold by registered veterinarians. Parasiticides are non-prescription OTC products and, as such, can be sold by veterinarians, wholesalers or the various rural merchant stores. In New Zealand, approximately one half of parasiticide sales are made through the veterinary channel and the balance is made through rural supply stores.
38. Apart from Merial and Pfizer who sell their animal health products exclusively through veterinary wholesalers or veterinary clinics, most suppliers sell their OTC products through the veterinary channel as well as rural supply stores.

## PREVIOUS COMMISSION DECISIONS AND RELEVANT ACQUISITIONS

### Decision 621: Schering-Plough / Organon SB

39. In October 2007, the Commission gave clearance for Schering-Plough to acquire all of the shares in Organon SB. This acquisition involved aggregation of market share in respect of parasiticides for sheep and cattle and certain animal vaccines.
40. Many of the products considered in that Decision are still part of Schering-Plough's current product portfolio. Of note, the acquisition resulted in the divestment of a specific vaccine for sheep. This was in order to alleviate competition concerns arising from high aggregation as well as the barriers to new entry, which were considered to be problematic.

### Merial / Ancare (non notified)

41. Also in October 2007, Merial acquired certain assets of Ancare New Zealand Limited. This acquisition involved aggregation primarily in relation to products for the treatment of internal and external parasites in or on livestock animals. Merial chose not to seek prior clearance for this acquisition as it considered there were a number of other existing manufacturers competing with Merial and Ancare New Zealand Limited at that time.

## MARKET DEFINITION

42. The Applicant submitted that the proposed acquisition might give rise to competition concerns in respect of the following types of animal health products markets:

- products for the treatment of internal parasites in (a) cattle; (b) sheep; or (c) cattle & sheep (endoparasiticides and endectocides);
- products for the treatment of external parasites in cattle;
- products for the treatment of external parasites in sheep (ectoparasiticides); and
- vaccines for bovine viral diarrhoea in cattle.

### Product Market

*Treatments for Parasites*

43. It is difficult to delineate the precise boundaries of the products in question. However, industry participants advised that there are a number of properties, on both the demand and supply sides of the market that differentiate the various types of parasiticides. These include:

- their manufacturing, registration and patenting processes;
- patented or off-patented (or generic) technology;
- the different active ingredients and their different combinations;
- their durations and efficacy;
- the method of application;
- the type of parasite targeted; and
- pricing characteristics.

44. Industry participants advised the Commission that most ectoparasiticides, endoparasiticides, and endectocides are manufactured in a similar way. For example, [ ] advised that, essentially, all the relevant ingredients are dispensed into a stainless steel tank before being stirred together, extracted and packed. This applies to all the various types of parasiticides and a simple clean-down of manufacturing equipment will allow a manufacturer to switch between producing an ectoparasiticide, an endoparasiticide or an endectocide.

45. However, there are reasons why supply-side switching of this nature will not be so straightforward. In particular, some active ingredients and formulations will be on patent, and re-formulating or manufacturing products cost-effectively can be difficult. Also, products must be registered and tested for their specific intended use.

46. Industry participants advised the Commission that there are a large number of products available, including generics, with varying efficacy and pricing characteristics.

47. End users may themselves be able to combine products in order to approximate the efficacy/price characteristics of others. A farmer using a triple-active drench for cattle could potentially get similar results, in terms of the percentage of parasites killed, by applying a double-active drench together with a single active drench, or using three single-active drenches. However, the farmer will

typically pay a price-premium for the convenience of using a multiple-active drench, as applying several products as described will be more time consuming.

Treatments for Internal Parasites

48. Endoparasiticides treat internal parasites, such as worms, that live and breed inside the host animal. Each particular endoparasiticide is differentiated by factors including the active substance and the type of worm being treated.

49. All the various endoparasiticide products have active substances from one of three "action families". These families have been used in the industry for the past 20 years and include:

- macrocylic lactones, which include active substances such as abamectin, ivermectin and moxidectin;
- levamisoles, which include the active substance levamisole; and
- benzimidazoles, which include active substances such as oxfendazole and albendazole.

50. Products with active substances from different action families can be used to treat the same types of worms and are generally substitutable for one another. In addition, there are a number of products that have combinations of two or all three of the action families, as a means of overcoming worm resistance to a particular action family.

51. Industry participants advised that endoparasiticde products often have broad coverage, in that they target a number of different parasites (worm species). However, some products treat only one or two species of worm and may offer a higher level of individual protection against those particular species. Nonetheless, worm species that are treated by narrow spectrum products can also often be treated by broad spectrum products.

**Product Differentiation**

52. The Commission is of the view that for the various internal parasiticide products there are a number of options in terms of efficacy and price, such that a chain of substitution exists. While products at one end of the spectrum of each market (in terms of efficacy and price) would not be close substitutes for those at the other end, at each point within the chain however, there does exist a close enough substitute such that if the price of a particular product were to increase, a farmer would be able to switch to the nearest point within the chain without difficulty.

53. [ ] suggested that Fort Dodge's Cydectin, and more generally moxidectin based products might be sufficiently different to warrant being considered as a distinct product market. [ ]. However, Pfizer advised that Cydectin accounts for [ ] of the sheep market, and only [ ] of the cattle market. This suggests that there are other products available to industry parties for the treatment on internal parasites

54. Further, many industry participants have advised the Commission that, because of problems with parasites developing resistance to various active ingredients over time, it is common practice to change product from time to time. This practice promotes a high degree of switching between the various brands and suppliers of endoparasiticides.

**Endectocides**

55. As noted above, endectocides treat both internal and external parasites. The Commission understands that endectocides tend to be more effective against internal parasites and often treat some (but not all) external parasites. Industry participants emphasised the ability of endectocides to treat lice, which are particularly prevalent in sheep in New Zealand. [ ] advised that the primary purpose of endectocides in New Zealand is for the treatment of internal parasites.

56. [ ] further advised that although endectocides tend to be more expensive than many endoparasiticides, they have fewer problems with resistance, and have a higher level of efficacy than many endoparasiticides.

57. Industry participants advised that many endectocides are marketed towards the treatment of internal parasites and exert a significant competitive constraint on endoparasiticides.

58. Therefore, the Commission is of the view that it is appropriate to include both endoparasiticides and endectocides in the product market for the treatment of internal parasites.

**Animal Type**

59. Internal parasites are prevalent in both sheep and cattle and the same families of active substances are use to treat both types of animals. However, industry participants advised that there are significant differences in the application method for the two types of animals. Sheep, being of a more manageable size than cattle, more often receive the product orally. Cattle, on the other hand, have hides that are more easily penetrable than sheep and thus are more conducive to pour-on products or injection. The dose rates and concentrations of products required for each animal are significantly different and are labelled and packaged specifically for the different animals. Furthermore, there are very few endoparasiticide products that are registered for use in both sheep and cattle.

60. Accordingly, the Commission considers, as it has in the past, that it is appropriate to delineate the internal parasiticide market based on animal species, with sheep and cattle being the major recipients of these products.

<u>Treatments for External Parasites</u>

61. The Commission has found similar product differentiation in respect of the treatments for external parasites, or ectoparasiticides, as it has found in treatments for internal parasites.

62. The two main external parasites in New Zealand are flies and lice. The demand for external treatments is significantly less than the demand for internal treatments, primarily because New Zealand's relatively cold and damp climate means that flies are not a prominent problem. Nevertheless, lice and to a lesser extent flies can create significant animal welfare issues for both cattle and sheep.

63. Flies tend to be more of an issue for sheep, as they are attracted to dirty, wet wool. There are a number of fly-only treatments specifically marketed for use on sheep (and not cattle) in New Zealand. The Commission understands that this is not the case in other countries, where flies are a more significant problem for cattle. In New Zealand, there are ectoparasiticides which are lice-only and combination fly/lice products for sheep. The same ectoparasiticides are available for cattle.

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

65. As with internal treatments, the Commission considers that it is appropriate to delineate the external parasiticides based on animal species.

*Vaccines*

66. Vaccines have different properties and can be distinguished by a number of different factors, including:

- indication of use;
- animal species;
- single or multiple pathogens;
- live or inactivated vaccines; or
- application method.

67. The Commission notes that the development and supply of vaccines is a very complicated and time consuming process. The process involves extensive research, cultivation of the necessary seed stock to produce the vaccine once it has been developed, as well as the actual manufacturing process itself.

68. In this respect, the Commission has concentrated on demand-side considerations when considering the various vaccine products. This is because, in most cases, each vaccine has a specific use and cannot be substituted on the demand side for/by other vaccines or medicines. Most vaccines target a single animal species.

<u>Bovine Viral Diarrhoea Vaccines</u>

69. Bovine Viral Diarrhoea (BVD) is a viral infection in cattle. In adult cattle the disease can have serious reproductive effects (including abortion, congenital defects, stillbirths, and decreased conception rates), weight loss and decreased milk production, and immunosuppression. In young cattle (calves) the disease can cause pneumonia, anorexia, lameness and immunosuppression.

70. The BVD virus spreads by two methods:

- direct transmission between animals; or
- invasion of the foetus in a pregnant cow.

71. To combat this, BVD can be controlled by vaccination of the breeding herd or vaccination of calves prior to mixing with the herd, where vaccination of the breeding herd is not possible.

72. Vaccines to treat the same virus can have different properties. For example, all the BVD vaccines in New Zealand are ‘inactive’ whereas in other countries ‘live’ vaccines are sometimes supplied. The Commission understands that, presently, ‘live’ BVD vaccines cannot be imported into New Zealand.

73. Some vaccines are monovalent in that they only protect against BVD. Schering-Plough’s Bovilis and Pfizer’s Pregsure products are monovalent vaccines which protect both adult cattle and the foetus in pregnant cattle against infection from

BVD. Other vaccines can protect against more than one type of infection. For example, Merial's Viracare 3 product is a trivalent vaccine that also controls against Infectious Bovine Rhinotracheitis (IBR) and parainfluenzea-3, as well aiding in the control of BVD. In this respect, monovalent vaccines listed above are not perfectly substitutable with the trivalent product because of their different properties, for example, Schering-Plough's Bovilis product can not be used to control IBR.

74. The Commission also understands that Merial's Viracare 3 product does not provide foetal protection for BVD whereas the monovalent products do. Invasion of the foetus is one of the main ways in which the BVD virus is spread. Industry participants advised that this is one of the main reasons for vaccinating a cow and/or herd. In this respect, the Commission understands that Merial's trivalent product is not used in adult cows and is primarily used in treating calves for BVD.

75. As such, BVD vaccines have individual characteristics that would indicate differentiated products. In particular, the Commission understands that veterinarians are more likely to substitute between the monovalent vaccines, which offer protection to adults and foetuses, than with the trivalent product which only offers more limited protection against BVD.

76. However, all products can be used for the prevention of BVD. Accordingly, the Commission considers that while BVD vaccines are differentiated to some extent, all the relevant products protect against BVD and so would fall within a discrete market for BVD vaccines.

*Conclusion on Product Markets*

77. The Commission considers that, for the purpose of this analysis, the relevant product markets are:

- treatments for cattle for internal parasites;
- treatments for sheep for internal parasites;
- treatments for cattle for external parasites;
- treatments for sheep for external parasites; and
- vaccines for BVD in cattle.

**Functional Markets**

78. Some animal health products are manufactured in New Zealand while other products, particularly vaccines, are typically manufactured overseas and imported into New Zealand. Suppliers then distribute these products to veterinary wholesalers, veterinarians, retail outlets and, in some instances, directly to end-customers.

79. The Commission concludes that the appropriate functional level for the relevant product markets is the manufacture/import and wholesale supply level.

**Geographic Markets**

80. All manufacturers/importers distribute their products on a national basis. Accordingly, the Commission concludes that the appropriate geographic market for the product markets identified above is national.

**Conclusion on Markets**

81. The Commission considers that the relevant markets for assessing the competition effects of the proposed acquisition are the national markets for the manufacture/import and wholesale supply of:

- treatments for cattle for internal parasites;
- treatments for sheep for internal parasites;
- treatments for cattle for external parasites;
- treatments for sheep for external parasites; and
- vaccines for BVD in cattle (the BVD Market).

**COUNTERFACTUAL AND FACTUAL**

82. The Applicant stated that the proposed transaction would be structured as a "reverse merger" pursuant to which Schering-Plough would acquire Merck, but would operate under the name "Merck."

83. Apart from this application, the Commission is also considering a proposed parallel acquisition involving Pfizer and Wyeth which is relevant because these parties are active in many of the same markets as Schering-Plough and Merck.

84. In this respect, the Commission needs to take the proposed Pfizer/Wyeth acquisition into consideration when assessing the relevant factual and counterfactual scenarios of the proposed Schering-Plough/Merck acquisition.

85. In light of the above factors the Commission considers that several factual scenarios could occur, namely:

- Schering-Plough acquires Merck and contemporaneously Pfizer acquires Wyeth; or
- Schering-Plough acquires Merck but Pfizer does not acquire Wyeth.

86. In the counterfactual, the proposed acquisitions may (or may not) go ahead. In this respect, the following situations could occur:

- Schering-Plough does not acquire Merck but Pfizer does acquire Wyeth; or
- Schering-Plough does not acquire Merck and Pfizer does not acquire Wyeth.

87. As a starting point, for the purpose of analysing the proposed acquisition, the Commission proposes to adopt the factual scenario that would give rise to the greatest competition concerns for the Commission, which is if the Schering-Plough/Merck and Pfizer/Wyeth transactions proceed contemporaneously. In this instance, the Commission will compare that factual to the most competitive counterfactual scenario in which neither of the proposed acquisitions goes ahead, which is essentially the status quo.

88. In this respect, the Commission notes that if there are no significant competition concerns evident by comparing the most problematic factual with the most competitive counterfactual, then it is unlikely that the other likely factual or counterfactual scenario comparisons would give rise to competition concerns.

## COMPETITION ANALYSIS

### Treatments for Internal and External Parasiticides

89. Industry participants advised the Commission that the competitive dynamics in all the four relevant parasiticide markets are similar. To this extent, as a starting point, the Commission has considered all of the affected markets at the same time.

90. Table 2 shows the estimated market share data for the four parasiticides markets, which are based on sales revenue data provided by industry participants. The Commission found that the estimates provided by the Applicant and from various industry parties were broadly consistent with one another, regardless of data source.

**Table 2: Estimated Market Shares for Treatments for Parasiticides in 2008**

| **Supplier** | **Internal Parasiticides for Cattle** | | **Internal Parasiticides for Sheep** | | **External Parasiticides for Cattle** | | **External Parasiticides for Sheep** | |
|---|---|---|---|---|---|---|---|---|
| | **Sales** | **Market Share** | **Sales** | **Market Share** | **Sales** | **Market Share** | **Sales** | **Market Share** |
| Schering-Plough | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] |
| Merial | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] |
| *Combined Entity* | *[ ]* | *[ ]* | *[ ]* | *[ ]* | *[ ]* | *[ ]* | *[ ]* | *[ ]* |
| Pfizer | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] |
| Fort Dodge | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] |
| *Combined Pfizer/Fort Dodge Entity* | *[ ]* | *[ ]* | *[ ]* | *[ ]* | *[ ]* | *[ ]* | *[ ]* | *[ ]* |
| Jurox | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] |
| Ravensdown | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] |
| Bayer | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] |
| Novartis | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] |
| Others* | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] |
| **Total** | **[ ]** | **100%** | **[ ]** | **100%** | **[ ]** | **100%** | **[ ]** | **100%** |

*Others include Bomac, Virbac, Norbrook and The Drench Company Limited.
Source: Industry participants, Commission estimates. # Ravensdown's products are contract manufactured by Jurox in Australia.

91. In the factual, the combined entity would have market shares in each of the affected markets of between [ ]. In each of these markets, the combined Schering-Plough/Merck entity would be the largest competitor.

92. On the whole, the existing competitors are large international companies with established brands, reputations and strong R&D programmes.

93. However, the Commission notes that there is increasing competition from suppliers of 'generic' products particularly as the patents of the technology in the most prominent products in the industry have now expired. As such, the barriers to entry and expansion for many suppliers have decreased and this has facilitated competition in these markets.

94. For example, industry participants noted the entry and expansion of the Ravensdown branded products. Ravensdown commenced supplying its Abamectin products in 2005 and has increased its sales significantly in the subsequent period. Industry participants commented that it has forced a major downward pressure on prices.

95. Another recent entrant in the industry is The Drench Company Limited, which supplies certain parasiticides to one of the large rural supply stores. All industry participants interviewed by the Commission considered that The Drench Company Limited's entry indicated that products at the low end of the price/efficacy spectrum could be manufactured and supplied relatively easily.

96. Further, the Commission considers that, should the merging entity attempt to rise prices in the factual scenario, all existing suppliers can readily expand given that once registration is secured, it is relatively straightforward to either import products in their finished form (as suppliers such as Jurox are currently doing), and/or to import the active ingredients and to contract manufacture with an existing manufacturer based locally with approved facilities, such as Argenta.

97. The Commission's view is that competition is likely to remain strong in the factual due to the presence of a large number of suppliers who have the ability to expand their operations. In addition, several parties have demonstrated that new entry can be easily effected.

*Conclusion on Existing Competition in the Parasiticide Markets*

98. Accordingly, the Commission concludes that the proposed acquisition will not have, or would not be likely to have, the effect of substantial lessening of competition in the national markets for the manufacture/import and wholesale supply of:

- treatments for cattle for internal parasites;
- treatments for sheep for internal parasites;
- treatments for cattle for external parasites; and
- treatments for sheep for external parasites.

**The BVD Market**

99. There are currently three suppliers of BVD vaccines in New Zealand: Schering-Plough; Pfizer; and Merial.

100. Table 3 shows the estimated market shares for the BVD Market based on the sales information provided by industry participants.

**Table 3: Estimated Market shares in the BVD Market for the 2007/08 and 2008/09 years**

| Manufacturer | Brand | Sales 2007/08 | Market Share | Sales 2008/09 | Market Share |
|---|---|---|---|---|---|
| Schering-Plough | Bovilis | [ ] | [ ] | [ ] | [ ] |
| Merial | Viracare 3 | [ ] | [ ] | [ ] | [ ] |
| *Combined entity* | | *[ ]* | *100%* | *[ ]* | *[ ]* |
| Pfizer | Pregsure | - | - | [ ] | [ ] |
| **Total** | | **[ ]** | **100%** | **[ ]** | **100%** |

Source: Industry participants

101. Table 3 indicates that the combined entity would have a market share of [ ]% and the three-firm concentration would be 100%. This is outside the Commission's safe harbour guidelines.

102. Schering-Plough's Bovilis and Pfizer's Pregsure are monovalent vaccines which provide protection for both cattle as well as foetal protection for pregnant adult cows. Merial's Viracare 3 is a trivalent vaccine which can aid in the control of BVD, although it can not provide foetal protection.

103. Industry participants advised that the Schering-Plough product and the Pfizer product offer comprehensive vaccination for cattle against BVD in adults and are supported by significant research and studies, which have documented their effectiveness. The same can not be said for the Merial product. In particular, the Merial product is not a substitute product when a veterinarian is looking to vaccinate against BVD in breeding animals or when vaccinating the entire herd.

104. In addition, various industry participants advised that recently, in New Zealand, there has been significant research in the area of BVD and that this research is increasing awareness and highlighting the importance of vaccinating for BVD, and the associated benefits of vaccination. The Commission notes that this research is focused on the use of the monovalent vaccines currently available in New Zealand.

105. In this respect, industry participants considered that it was likely that the demand for monovalent BVD vaccines would continue to increase. Pfizer advised that this was one of the reasons it introduced its product into New Zealand. It has [
]

106. Merial advised that the demand for its Viracare 3 product has been in decline [
]

107. Merial advised that one of the reasons for this is that its product, Viracare 3, did not have the same level of research on its efficacy as the other products in the market, notably Schering-Plough's Bovilis and more recently Pfizer's Pregsure, and [
].

108. Merial only supplies two animal vaccines in New Zealand and it advised that [

].[6]

109. This is consistent with feedback from industry participants who advised the Commission that, generally, in the treatment of BVD, the Merial product is considered to be inferior to both Schering-Plough's and Pfizer's products and that this situation is unlikely to change. As previously noted, the development of new and/or novel vaccines is lengthy and relatively rare.

110. As such, industry participants advised the Commission that the Merial product offers limited competitive constraint on either the Schering-Plough or the Pfizer product. In this respect, the proposed acquisition is likely to have a limited impact on the market.

111. The Commission notes that the sales for Merial's Viracare 3 product also include sales derived from its other properties. For example, Viracare 3 is also used for the treatment of IBR and the Commission understands that this is the only product sold in New Zealand for this type of infection.

112. The Commission is of the view that, currently, Merial offers only a limited competitive constraint on Schering-Plough and Pfizer and this is unlikely to change in the future. Rather, the main competition in the BVD market, in either the factual or counterfactual scenarios, would be between Schering-Plough and Pfizer and so the loss of Merial as a competitor in the BVD market is unlikely to be of any significance.

*Conclusions on the BVD Market*

113. The Commission considers that there is likely to be minimal difference between the factual and the counterfactual scenarios. Therefore, the proposed acquisition will not have, or would not be likely to have, the effect of substantially lessening competition in the BVD market.

**OVERALL CONCLUSION**

114. The Commission has considered the probable nature and extent of competition that would exist, subsequent to the proposed acquisition, in the national markets for the manufacture/import and wholesale supply of:

- treatments for cattle for internal parasites;
- treatments for sheep for internal parasites;
- treatments for cattle for external parasites;
- treatments for sheep for external parasites; and
- vaccines for BVD in cattle (the BVD Market).

115. The Commission considers that the relevant factual scenario is that where the Schering-Plough/Merck and Pfizer/Wyeth transactions proceed contemporaneously. In this instance, it considers that the relevant counterfactual to be the status quo, with none of the firms merged.

116. In all the parasiticide markets outlined above, the combined entity would be constrained by the presence of existing competitors. The majority of these

[6] Merial's other vaccine, Pneumequine, vaccinates against respiratory disorders in horses [ ].

competitors are large, international suppliers with an established presence in New Zealand and would not be constrained in their ability to expand.

117. In the BVD Market, the Commission considers that there is likely to be minimal difference between the factual and the counterfactual scenarios.

118. Accordingly, the Commission is satisfied that the proposed acquisition will not have, or would not be likely to have, the effect of substantially lessening competition in the relevant markets.

**DETERMINATION ON NOTICE OF CLEARANCE**

119. Pursuant to section 66(3)(a) of the Commerce Act 1986, the Commission determines to give clearance for the acquisition by Schering-Plough Corporation of all of the shares in Merck & Co., Inc.

Dated this 20th August 2009

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Dr Mark Berry
Chair
Commerce Commission