EN

Case No COMP/M.4691 - SCHERING-PLOUGH / ORGANON BIOSCIENCES

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REGULATION (EC) No 139/2004
MERGER PROCEDURE

Article 6(1)b in conjunction with Article 6(2)

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COMMISSION OF THE EUROPEAN COMMUNITIES

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In the published version of this decision, some information has been omitted pursuant to Article 17(2) of Council Regulation (EC) No 139/2004 concerning non-disclosure of business secrets and other confidential information. The omissions are shown thus […]. Where possible the information omitted has been replaced by ranges of figures or a general description.

PUBLIC VERSION

MERGER PROCEDURE
ARTICLE 6(1)(b) DECISION IN CONJUNCTION WITH ARTICLE 6(2)

To the notifying party

Dear Sir/Madam,

Subject: Case No COMP/M.4691 – Schering-Plough / Organon BioSciences Notification of 23/08/2007 pursuant to Article 4 of Council Regulation No 139/2004

1. On 23.08.2007, the Commission received notification of a proposed concentration pursuant to Article 4 of Council Regulation (EC) No 139/2004[1] ("the Merger Regulation") by which the undertaking Schering-Plough Corporation ("Schering-Plough", United States) acquires within the meaning of Article 3(1)(b) of the Council Regulation control of the whole of the undertaking Organon BioSciences N.V. ("Organon BS", the Netherlands) controlled by Akzo Nobel N.V. ("Akzo", the Netherlands) by way of purchase of shares.

2. After examination of the notification, the Commission has concluded that the notified operation falls within the scope of the Merger Regulation. Following submission by the parties of undertakings designed to eliminate serious doubts identified by the Commission, in accordance with Article 6 (2) of the Merger Regulation, the Commission has concluded that the notified operation does not raise serious doubts as to its compatibility with the common market and with the functioning of the EEA Agreement.

[1] OJ L24, 29.01.2004 p.1

I. THE PARTIES

3. Schering-Plough is a New Jersey-based global healthcare company with activities in (i) human prescription and over-the-counter ("OTC") pharmaceutical products; (ii) personal care products (*Dr. Scholl* foot care products and *Coppertone* sun care products); and (iii) animal healthcare products. Schering-Plough's human pharmaceuticals and consumer product division together account for 91% of Schering-Plough's turnover. Its pharmaceutical unit is the most profitable in the company.

4. Organon BS is the holding company for the human and animal healthcare activities of Akzo. It consists of two operating units: (i) Organon International bv, the human pharmaceutical business ("Organon"); and (ii) Intervet International bv, the animal health business. Organon accounts for […] % of Organon BS' turnover and Intervet for […] %. Intervet is the more profitable business of Organon BS.

II. THE CONCENTRATION

5. On 12 March 2007, Schering-Plough made an irrevocable offer to Akzo to enter into a share and purchase agreement with Akzo whereby Schering-Plough will acquire the entirety of the shares of Akzo's wholly-owned subsidiary, Organon BS. Schering-Plough thus intends to acquire sole control of Organon BS.

6. The notified operation will confer on Schering-Plough sole control over Organon BS. It, therefore, constitutes a concentration within the meaning of Article 3(1)(b) of the Merger Regulation.

III. COMMUNITY DIMENSION

7. The undertakings concerned have a combined aggregate world-wide turnover of more than EUR 5 000 million (Schering-Plough 8 437 million EUR, Organon BS […] million EUR)[2]. Each of them have a Community-wide turnover in excess of EUR 250 million (Schering-Plough […] million EUR, Organon BS […] million EUR), but they do not achieve more than two-thirds of their aggregate Community-wide turnover within one and the same Member State. The notified operation therefore has a Community dimension.

IV. COMPETITIVE ASSESSMENT

8. The concentration concerns human health products and animal health products, where both parties are active.

9. According to the parties, Organon's human health business is the primary driver for

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[2] Turnover calculated in accordance with Article 5(1) of the Merger Regulation and the Commission Notice on the calculation of turnover (OJ C66, 2.3.1998, p25). To the extent that figures include turnover for the period before 1.1.1999, they are calculated on the basis of average ECU exchange rates and translated into EUR on a one-for-one basis.

their acquisition. Schering-Plough is looking to broaden its human health products (Schering-Plough is currently over-dependent on a few successful products which are all susceptible to patent expiration) and to increase its portfolio of pipeline products. The concentration will add two new business units (Organon's women's health care (gynaecology and fertility) and central nervous systems) to Schering-Plough's human health business, and fill the gap in Schering-Plough's late-stage pipeline products.

10. In the human health sector, the parties' activities are largely complementary and the concentration does not give rise to any overlaps or vertical issues.

11. By contrast, the concentration gives rise to horizontal overlaps between the activities of Schering-Plough and Organon BS for the manufacture and marketing of vaccines and pharmaceuticals in the animal health sector. There are overlaps in over 40 products markets, in several EEA countries for each product.

12. The present decision first examines the definition of the relevant markets for human health and the competitive assessment of the proposed transaction in the human health sector (**Section A**), and then the relevant market definition for vaccines and pharmaceuticals in the animal health sector and the competitive assessment of the transaction are examined market by market (**Section B**).

13. As explained in the Commission notice on remedies[3], where a concentration raises serious doubts about its compatibility with the common market, the parties may seek to modify the concentration in order to resolve the serious doubts identified by the Commission. In order to remove the serious doubts identified by the Commission in 17 markets in the animal health sector, Schering-Plough submitted remedies on 20 September 2007. The Commission market tested the proposed remedy package with a questionnaire sent to competitors of the parties on 24 September 2007. A revised version taking account of concerns that the Commission raised as a result of the market test of the first set of remedies was submitted by the parties on 10 October 2007 (for further details, please see the non-confidential version in **Attachment 1**).

14. The Commission's competitive assessment of the proposed transaction includes its assessment of the proposed remedies, where applicable. In assessing whether or not the remedy will restore effective competition, the Commission considers the type, scale and scope of the remedies by reference to the structure of and particular characteristics of the markets in which serious doubts arise. In so doing, the Commission has to assess both (i) the independence, the viability and the competitiveness of the divested business on the long term and (ii) the effectiveness of the proposed remedy in removing the serious doubts.

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[3] Commission Notice on remedies acceptable under Council Regulation (EEC° No 4064/89 and under Commission Regulation (EC) No 447/98.

A. Human health

1. Product market definition

15. In previous decisions[4], the Commission has applied the Anatomical Classification Guidelines (or "ATC" classification) devised by the European Pharmaceutical Marketing Research Association (EphMRA). The ATC classification is hierarchical, and it includes 16 categories, each containing up to four levels. In previous decisions, the Commission has relied on the third level of the ATC classification (ATC3) which allows medicines to be grouped in terms of their therapeutic indications, i.e. their intended use, as a starting point for market definition. However, in certain cases, it may be necessary to analyse pharmaceutical products at a higher or lower level than ATC 3 or to combine ATC 3 classes on the basis of demand-related criteria[5].

16. The Commission has in the past[6] defined separate markets for over the counter ("OTC", i.e. non-prescription bound) pharmaceuticals and prescription-bound pharmaceuticals because medical indications (as well as side effects), legal framework, marketing and distribution patterns tend to differ between these categories. The parties have followed this subdivision between OTC and prescribed medicines. The present concentration only concerns prescription pharmaceuticals as Organon is not active in OTC pharmaceuticals and personal care products.

2. Geographic market definition

17. In previous decisions[7], the Commission held that the relevant geographic market for pharmaceutical products was national. The parties share this view. While the harmonisation of technical legislation and marketing authorisation proceedings at EU-level has contributed to the creation of an EU-wide market for pharmaceutical products, at this stage the market is still imperfect. Variations between Member States in relation to price setting, conditions of reimbursement and channels of distribution mean that, geographically, the market for pharmaceutical products is still national in many respects.

3. Competitive assessment

18. The parties' activities as regards human health are complementary, and there are no existing or pipeline horizontal or vertical overlaps. Organon focuses on: (i) fertility; (ii) gynaecology; (iii) neuroscience; and (iv) anaesthesia. Schering-Plough focuses on: (i) allergy/respiratory; (ii) cholesterol/cardiovascular (joint venture with Merck); (iii) anti-infectives; and (iv) anti-inflammatories.

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4 See, e.g., Case COMP/M.4314 – Johnson & Johnson/Pfizer Consumer Healthcare; Case COMP/M.3544 – Bayer Healthcare/Roche (OTC Business), paragraphs 12 *et seq.*; Case COMP/M.3354 – Sanofi-Synthelabo/Aventis, paragraphs 14 *et seq.*; COMP/M.2922 – Pfizer/Pharmacia, pararaphs 15 *et seq.*

5 *Ibid.*

6 See, e.g., Case COMP/M.4314 – Johnson & Johnson/Pfizer Consumer Healthcare; Case COMP/M.3544 – Bayer Healthcare/Roche (OTC Business)

7 *Ibid.*

19. For the sake of completeness, it should be noted that the parties are both active in anti-thrombotic products (that prevent or interfere with the formation of blood clots or thrombi), but the parties submit that their products do not overlap and are not even neighbouring products. Schering-Plough has […] an anti-platelet product, *Intergrilin*, which is classified in the ATC 3 class "B1C platelet aggregation inhibitors"[8]. Organon sells a hirudine-based direct thrombin inhibitor, *Orgaran*, which is classified in the ATC 3 class "B1B Heparins"[9]. The parties' argument is consistent with a 1999 Commission decision which found that "hirudine-based direct thrombin inhibitors belonging to ATC 4 class B1B9 constitute a separate and relevant product market"[10]. […]

20. As regards pipeline anti-thrombotic products, the parties' R&D activities are in their respective areas. Schering-Plough also has […]. Organon has completed […].

B. Animal health

1. Product market definition: general

21. The animal health industry concerns the manufacture and marketing of health products for the following species[11]:

- Cattle, sheep and goats, which are collectively referred to as "ruminants";
- Pigs or swine;
- Poultry, which comprises chickens and turkeys;
- Horses or equine;
- Companion animals, which comprise cats and dogs; and
- Aquaculture animals, which comprises farmed fish.

22. There are very few precedent cases in the animal health sector[12]. In previous cases, animal health products were divided into three core areas, namely (i) biologicals (vaccines); (ii) pharmaceuticals; and (iii) medicinal feed additives. In the present case, there are two main product groups, vaccines and pharmaceutical products, each

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8 Anti-platelet products are medicines that reduce the clumping of platelets in the blood. Anti-platelets medicines assist in thinning the blood to prevent clot formation (thrombus).

9 Hirudine-based direct thrombin inhibitors act as an anti-coagulant by blocking the activity of thrombin (an enzyme triggering the formation of blood clots).

10 Commission decision of 9 August 1999 in Case M.1378 – *Hoechst/Rhône Poulenc*, at paragraph 15.

11 There is insufficient demand for economical mass-production of animal health products aimed at other individual species. Where demand for animal health products for such species is not met by local production (often by veterinarians themselves or local laboratories) vaccines or pharmaceutical products developed for other species are often used (with dosage adapted to the mass of the animal).

12 In particular, Case COMP/M.2922 – Pfizer/Pharmacia, 27 February 2003 and Case COMP/M.1681 – Akzo Nobel/Hoechst Roussel Vet, 22 November 1999.

containing hundreds of relevant markets.

Biologicals

23. Biologicals are products triggering an immune response against viral and bacterial diseases in animals as well as in some cases certain parasitic or fungal infections. They include (i) vaccines; (ii) antisera; and (iii) colostra products. The parties take the view that vaccines are distinct from antisera and colostra products which give an animal a passive immunity which is acute, but short-lasting. Vaccines are used to protect the animal against possible future infection and have a wide spectrum of effectiveness and duration of activity. This is in line with previous Commission decisions[13].

24. In line with previous Commission decisions in animal health[14], the parties take the view that vaccines can be distinguished on the basis of the following factors:

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

- Indication of use: vaccines target a specific disease, and vaccines for different diseases are not substitutable, even within the same species group.

- Single or multiple pathogens: monovalent vaccines, which contain one or multiple strains of only one antigen, protecting against one specific disease, and multivalent vaccines (or combo vaccines), which contain two or more different antigens (either one or multiple strains of each antigen), usually protecting against several diseases, are not substitutable.

- Live or inactivated vaccines: live vaccines are made from natural non-virulent cultivated organisms or from organisms that have been modified to be non-virulent. Inactivated vaccines are made from killed virulent organisms or from inactivated parts of these organisms. Live vaccines are generally more effective and only need to be administered once at a young age to provide life-long protection, but they can create side effects/stress in an animal due to the fact that they trigger a sub-clinical infection in the animal. The onset of immunity is much delayed for inactivated vaccines as opposed to live vaccines.

- Marker vaccines: marker vaccines allow distinguishing between animals that are immunised as a result of vaccination or as a result of exposure to a naturally occurring pathogenic strain of the virus. Non-marker and marker vaccines for the same disease belong to separate product markets in some

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13 In particular, Case COMP/M.1681 – Akzo Nobel/Hoechst Roussel Vet, 22 November 1999, paragraph 44.

14 In particular, Case COMP/M.1681 – Akzo Nobel/Hoechst Roussel Vet, 22 November 1999, paragraph 45.

limited cases, where marker vaccines are required in the context of an eradication campaign.

25. The market investigation broadly confirmed the criteria applied by the parties to define product markets in the area of vaccines, with some exceptions as regards the distinctions between (i) live and inactivated vaccines and between (ii) monovalent and multivalent vaccines.

26. First, the general distinction between live and inactivated vaccines has not been confirmed by the market investigation. It should be noted that this distinction is not always relevant as some vaccines only exist in a live or an inactivated form (e.g., clostridia vaccines for ruminants only exist in inactivated form, as there are no safe alternatives for live vaccines).

27. Respondents to the market investigation questioned the usefulness of the distinction between live and inactivated vaccines for the purposes of defining the relevant product markets. They pointed out that all vaccines can be assumed to be safe and efficacious, and that except for certain circumstances, diseases and species (e.g. poultry[15]), live and inactivated vaccines are in general substitutable. Contrary to the parties' claim, live vaccines do not provide a lifelong protection with one shot, but some live vaccines require administering an annual booster.

28. This issue of market definition can however be left open, as even a broader market definition including both live and inactivated vaccines would not give rise to any additional overlaps between the parties (with the exception of the reovirus vaccine for poultry).

29. Schering-Plough is active in live reovirus vaccines for poultry while Intervet sells an inactivated reovirus vaccine. However, the parties take the view that live and inactivated reovirus vaccines belong to different product markets, as protection against reovirus involves administering both modified live and inactivated vaccines, at different times of the life's bird and cannot thus be used interchangeably. The inactivated vaccine is intended to provide maternal antibodies to offspring and administered to the mother between 16 and 18 weeks of age. For optimal protection, the bird should receive a live 'primer' vaccine within the first week of life. In any event, on a hypothetical reovirus vaccine market comprising live and inactivated vaccines, their activities would overlap only in Spain and generate an estimated market share of [40-50] % in 2006 (competing against Fort Dodge with [50-60]% share). Moreover, Schering-Plough's reovirus vaccine will be withdrawn from the Spanish market […] (as is the case with its Gumboro and largyngotracheitis vaccines – *see* below in recitals 271 and following).

30. Secondly, the market investigation has suggested some substitutability in some cases between (i) monovalent vaccines and a multivalent vaccine targeting the same pathogen; and (ii) similar but not identical multivalent vaccines having at least an identical coverage in terms of the number and pathogens targeted (but one of them targeting a broader range or both targeting different additional pathogens beyond their

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15 With poultry, inactivated vaccines are used with the "long life" birds (layers and breeders) or markets where a very strong booster is needed to control an epidemic or very virulent disease challenge.

identical coverage). The parties themselves take the view that all multivalent clostridia vaccines are substitutable, regardless of the total number and range of clostridia antigens.

31. According to most respondents, the question of substitutability between monovalent and multivalent vaccines is a complex issue that cannot be answered in a general manner, but has to be examined on a case-by-case basis depending on the species and the vaccines.

32. Respondents indicated that from a demand-side perspective, multivalent vaccines are generally able to substitute monovalent vaccines provided they contain the same antigens against the same disease as monovalent vaccines. Customers will generally prefer the convenience of not having to administer several vaccines, due to the added protection granted by the multivalent vaccine and the convenience of not having to stock numerous vaccines. Many respondents took the view that monovalent and multivalent vaccines should therefore generally belong to the same relevant product markets.

33. However, respondents pointed out to differences between species:

- as regards companion animals (cats and dogs), the trend in science appears to be to go back to a more targeted programme (vaccines with less antigens to reflect the immunological status for the animal) with a yearly booster with monovalent vaccines only for some diseases (such as leptospirosis and parvovirus for which the vaccines have a limited duration of immunity), although pet owners favour multivalent vaccines;

- for production animals such as poultry[16], cattle and swine, multivalent vaccines are preferred for ease of handling (avoiding having to vaccinate multiple times); and

- monovalent vaccines such as influenza (mandatory vaccination programmes) and tetanus (excessive dosing of tetanus is not advised and prevention can commence at the time of injury) are important for horses.

34. Some respondents further noted that, although the efficacy of monovalent and multivalent vaccines is in general not substantially different, in some cases a monovalent vaccine may have a different claim than the multivalent vaccine in relation to the same disease.

35. The substitutability between monovalent and multivalent vaccines and exact scope of the relevant product market is therefore examined on a case-by-case basis below for those product markets where this distinction matters for the purpose of the competitive assessment.

Pharmaceuticals

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

16 For poultry, there is a long term trend to substitute monovalent by multivalent vaccines for long-life birds (breeders and layers).

manufacturing process for pharmaceutical products includes two separate steps: the manufacturing of active substances, followed by the manufacturing of pharmaceutical products. Pharmaceutical products are produced by mixing the active substances with other substances and by presenting the result under a suitable form that optimises the absorption of the active substance or offers the most convenient mode of administration (*i.e.*, pills, tablets, injectable liquid etc.).

37. Pharmaceuticals for animal usage can be divided into parasiticides, antimicrobials, endocrine treatments, anti-inflammation and analgesic pharmaceuticals[17].

38. It must be noted that contrary to biologicals, most of the active substances in pharmaceuticals are of synthetic origin, which facilitates the inter-company trade and toll-manufacturing agreements. There are markets for active substances to the extent that such substances are the object of transactions between a producer and a buyer of these substances. The parties therefore suggest that active substances as such constitute separate and specific markets, which are upstream to the markets for existing pharmaceutical specialities[18]. The parties did not identify any vertical relationships in the upstream market conducive to serious doubts, as there are many suppliers and toll-manufacturers of those substances. Therefore, the vertical relationships are not discussed any further in the decision.

39. In pharmaceuticals, the parties' activities overlap in the area of:

- non-steroidal and steroidal anti-inflammatory drugs, including corticosteroids, which are products that prevent and treat inflammation and reduce pain and/or fever associated with inflammation;

- antimicrobials, which are drugs that destroy or prevent the growth of microbes such as bacteria, fungi, and parasites;

- parasiticides, which are agents or preparations used to destroy different sorts of internal or external parasites such as fleas, flies, ticks, worms, flukes, and protozoan organisms;

- endocrine treatments, which are hormone products to regulate an animal's physiology;

- central nervous system, including drugs used to anaesthetise and euthanize animals for health and ethical reasons;

- specialty products that target very specific conditions and that do not easily fit into any of the other product categories, in particular because they lack the significance they enjoy in the human health sector. These products include certain niche products such as insulin (a hormone that regulates how glucose is absorbed) or diuretics which relieve oedemas - swelling or excess fluid.

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17 See Case COMP/M.1681 – Akzo Nobel N.V./Hoechst Roussel Vet, paragraph 13.

18 This approach is also in line with previous Commission decisions, see for example. Commission Decision of 30 March 2000 Case No. COMP/M.1835 - Monsanto/Pharmacia & UpJohn at para. 31.

40. There are many factors that could be relevant in defining product markets in the pharmaceutical sector or influence the closeness of competition between them, the most important being:

- species of animal – although many pharmaceutical products are multi-species, some are effective only for groups of species (such as companion animals) or even single species;

- active substance – in some instances the active substance would be the main driver of the market definition, i.e. in antibiotics because the same active substance is efficacious against the whole range of pathologies and the same pathology can be treated with different active substances;

- target pathology/scope of effectiveness – broadly defined pathology is always at the core of the market definition, however in some instances it is impossible to narrow down the market definitions to very narrowly understood pathologies. Especially in anti-microbials and parasiticides, potent treatments against a single pathology are in full competition with the treatments that are efficacious against the whole spectrum of pathologies;

- route of administration – most of the pharmaceuticals are injectable especially for production animals; for companion animals, a large part is also orally administered in the form of tablets, pastes and granules. However, there exists a whole spectrum of ways of administration depending on the specific needs, i.e. intra-mammary products for mastitis treatment in cows, anti-parasitic collars or spot-on drops for companion animals, inhalable general anaesthesia, etc.;

- duration of efficacy – in some instances, the farmers can be inclined to look for products that act for a long time in the body of the animal usually for preventive purposes, e.g. anti-parasitic products, long-acting preventive antibiotics, hormones for the synchronisation of the oestrus cycle;

- duration of withdrawal periods – this criterion is relevant for farm animals. Withdrawal period means the amount of time during which the animal's meat or milk is not suitable for human consumption due to the fact that the active substance has not been fully discarded from the body of the animal.

41. The exact relevant product market definition on the basis of the factors mentioned above is examined on a case-by-case basis in the competitive assessment below, for each area where the parties' activities overlap.

2. Geographic market definition

42. The parties take the view, in line with previous Commission decisions[19], that the markets in the animal health sector have a national geographic dimension, as most products remain subject to old national and mutual recognition registration systems with the consequence that products are sold according to the indications and uses

[19] See, *e.g.*, as regards pharmaceuticals, Commission decision of 27 February 2003 in Case COMP/M.2922 – Pfizer/Pharmacia, paragraph 117, and, as regards biologicals, Commission decision of 22 November 1999 in Case COMP/M.1681 – Akzo Nobel/Hoechst Roussel Vet, paragraph 56.

prescribed by the national registration and approval requirements. The parties however point out to the fact that the largest suppliers are global and international players active in most or all of the EEA, and to recent regulatory changes (EU centralised registration procedure for new products) in support of a trend away from a strict national scope of the animal health markets.

43. The market investigation broadly confirmed that markets in the animal health sector are still national, both for veterinary biologicals (vaccines) and pharmaceuticals.

44. The sale of pharmaceuticals and biologicals for animal use is still influenced by different regulatory regimes in terms of administrative procedures and approval requirements (national marketing authorisations). The competitive situation also varies widely between the different EEA countries: market penetration, competitors' market shares, price of the competing products, distribution systems and local veterinarian preferences differ widely between Member States. For example, in some countries, veterinary products can be sold by the manufacturers directly to end users while in other countries products have to be sold through veterinarians, distributors or pharmacies. Some countries (e.g., France) prohibit the use of discounts or rebates which are widely prevalent in other Member States.

45. The Commission therefore concludes that the relevant geographic markets in the animal health sector affected by the proposed transaction are national.

3. Competitive assessment

General

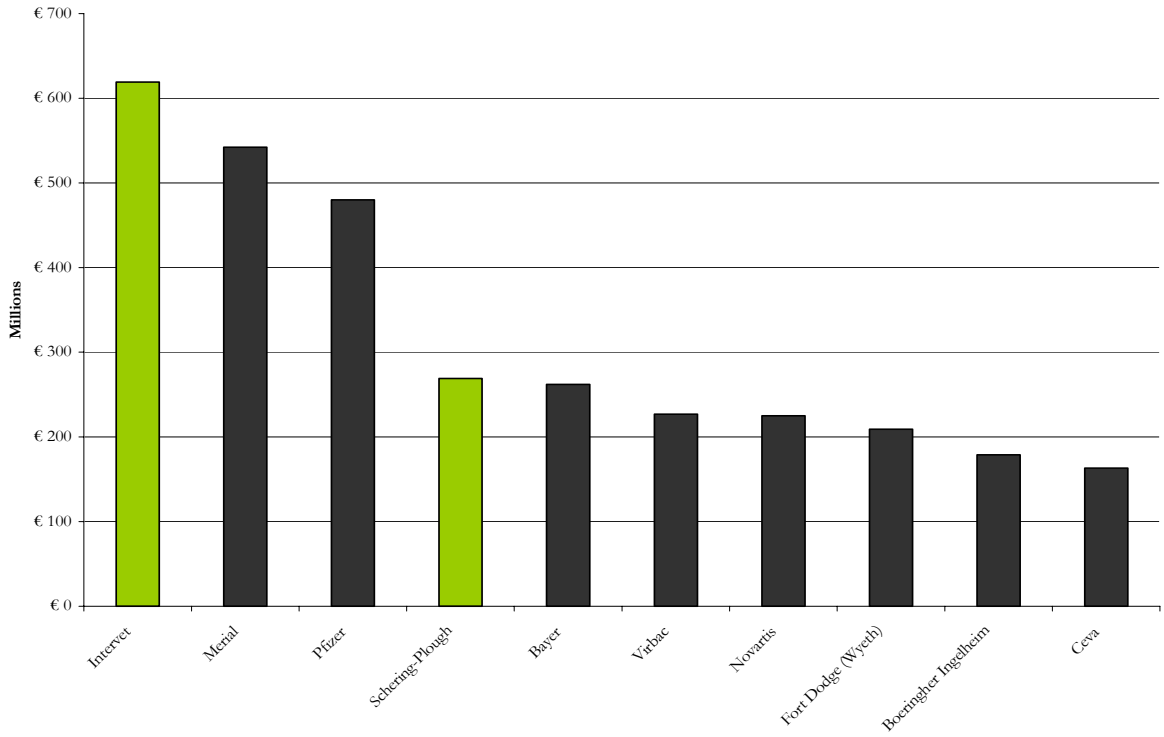
Companies active in the animal health sector

46. There are several types of companies active in the animal health sector. The first category concerns global pharmaceutical companies with significant activities in human health, such as Pfizer and Merial (a 50-50 joint venture between Merck & Co and Aventis), Intervet, Bayer, Schering-Plough, Fort Dodge (the animal health arm of the human pharmaceutical company Wyeth), Novartis, and Elanco (the animal health arm of Eli Lilly). The second type of companies are smaller multinational companies, such as the French companies Virbac, Vétoquinol and CEVA, the Spanish company Hipra, or the German company Boehringer Ingelheim VetMedica ('BI'). The third category concerns producers of generics pharmaceutical products[20] (which are off-patent), such as Norbrook Laboratories of Ireland, Krka of Slovenia, Fatro of Italy, and ScanVet of Sweden.

47. The chart below shows the ranking in turnover of the main companies active in the EEA.

20 There are no generics for biologicals.

Animal Health Companies and 2006 European Sales (Source: Animal Pharm)



The animal health markets in the EEA

48. In 2006, sales in the animal health industry were approximately EUR 12,795 million[21] worldwide, and EUR 4,200 million in the European Union[22]. Animal health sales are relatively concentrated in a small number of Member States – France, the United Kingdom, Germany and Spain. Between them, these countries account for almost two thirds of sales in the 27 EU Member States, as shown in the table below.

21 Wood MacKenzie Animal Health Service, March 2006 Outlook.

22 See Animal Pharm, European Animal Health Market, June 2007, page 87.

Country	Sales (€ M)	Share of EU Total (%)
France	873	20.8
United Kingdom	609	14.6
Spain	596	14.2
Germany	577	13.8
Italy	386	9.2
Netherlands	200	4.8
Belgium	150	3.6
Ireland	103	2.5
Total 8	**3,494**	**83.6**
Others	686	16.4
Total EU	**4,180**	**100**

49. In the EEA, antimicrobials are the largest single segment by value, generating over one quarter (28 %, sales of EUR 1.2 billion in 2006) of all sales in the region. Antiparasitics account for a further 24 % share (sales of EUR 1.1 billion in 2006) and vaccines for more than 22 % (sales of just below EUR 1 billion in 2006). The remaining 26 % of revenues is generated by a broad range of other pharmaceuticals, including anti-inflammatories, endocrine treatments, anaesthetics and euthanasia products.

50. Due to the numerous different animal species and numerous different diseases, and the fact that animal health markets have a geographic dimension (as described above), many animal health markets have quite a small size, sometimes as small as EUR 10,000 (for example the market for monovalent tetanus vaccine for horses in Denmark).

Market share data in the animal health sector

51. There is no comprehensive industry database of sales in the animal health sector equivalent to the IMS database in the human health sector. The parties relied on data from Centre Européen d'Etude pour la Santé Animale ('CEESA'), a non-profit international association which collects sales data on the animal health market in 23 countries worldwide, of which 15 are the 15 EU Member States before 1 May 2004. CEESA data consists in aggregated bi-annual total sales reports and competitor rankings (but not actual competitor sales information). CEESA data, however, do not cover sales by non-Member companies and may report data in categories that do not correspond to the product market definition. The parties also relied on national databases where they exist, Wood Mackenzie and Animal Pharm reports and their own valuations to produce data on market share. The Commission tested with third parties the methodology adopted by the parties to produce market size and market share data. Overall third parties validated the methodology and resulting market sizes and market shares.

Barriers to entry in the animal health sector

52. The market investigation showed that there are significant barriers to entry in the animal health markets, with varying degree of importance on a case-by-case basis. A

distinction can be made between barriers to entry into a new product market and barriers to geographic entry (entry with an existing and already registered product in a new geographic market). Barriers also vary depending on the markets concerned (size of the market, demand for the product and expected evolution, competitive environment). There have generally been very few entries in the animal health markets in the last years. Most recent cases of entry concerned entry by one of the multinational companies (such as Schering-Plough, Intervet, Pfizer, Merial or Fort Dodge) into new member States (Central and Eastern European countries).

(i) Entry into a new product market

53. R&D of a new vaccine product is a lengthy and costly process. Estimates of R&D costs and time to develop a new vaccine provided by respondents to the market investigation ranged from EUR 4 to 30 million and 3 to 10 years. This varies depending on the number and type of antigens (availability of appropriate antigen, difficulties to grow antigens, number of antigens) and expertise of the company. Some antigens or delivery methods may also be patented (more rarely so for manufacturing). The development of pharmaceutical products is characterised by similar costs and length of the development. The key difference being that once the formulation is developed its production can be outsourced to a third party toll-manufacturer [23]and the company does not necessarily have to invest in additional production capacities. Generic development is usually much shorter and estimated at 2 to 4 years.

54. In addition, like the human health industry, the animal health industry is heavily regulated at the EEA and national level. Veterinary products cannot be marketed in the EEA without a prior marketing authorisation. There are currently three procedures to obtain a marketing authorisation in the EEA: (i) European marketing authorisation delivered by the European Commission after assessment by the European Medicines Agency ("EMEA"); (ii) national marketing authorisation granted under national law, but is valid only in the Member State having granted the authorisation unless it is subsequently extended to other Member States by mutual recognition; and (iii) decentralised marketing authorisation procedure, which allows suppliers to submit a single dossier simultaneously in several Member States where a marketing authorisation is sought.

55. In light of the regulatory work required for a first registration of a product (manufacturing process, safety and efficacy studies), respondents estimated the time required to commercially launch a new product at 5 to 10 years.

(ii) Geographic entry

56. There are also significant, albeit lower, barriers for a supplier to enter a new geographic market with an existing product. The barriers are the requirement to obtain a national marketing authorisation (in most cases through mutual recognition), the setting up of a distribution network, marketing, and the opportunity costs of entry.

57. Some respondents to the market investigation estimated that it would take 1 to 3 years

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[23] A toll-manufacturing arrangement consists in the outsourcing to a third party of the manufacture of a product.

and cost EUR 100,000 to 2.5 million to obtain the marketing authorisation and enter a new market with an existing product. In the case of older marketing authorisations, additional studies or explanations to update the original authorisation may be requested by the authorities. It is generally easier to enter a new country and obtain a marketing authorisation for a product which is already registered in another EEA country because the necessary data are already available, even more so in the case of a recent registration.

58. In order to enter a new geographic market, a supplier must also set up a distribution network (contract with wholesalers and licensed distributors). Its situation is different if it is already present in the country for sales of other veterinary products and it can use its existing distribution network, as compared to having no commercial presence yet in this market.

59. The launch of a new product also requires the expenditure of marketing costs, generally information and training of veterinarians, as most veterinary health products can only be dispensed with a veterinarian prescription in the EEA pursuant to Directive 2001/82/EC on the Community code relating to veterinary medicinal products.

60. Last, the local competitive environment and the potential of the product introduced are relevant when assessing the opportunity of entry. Respondents to the market investigation indicated that they would not enter if the costs of entry would exceed expected sales, such as in the case of national markets with already well established competitors and competing products or with a small size and no attractive prospect of growth.

Generics in the animal pharmaceutical sector

61. Generics are the identical copies of the innovative treatments which enter the market after the patent protections afforded to the original developer have expired. Generic producers are only required to demonstrate that their product is an identical version of the original product in respect to composition (same qualitative and quantitative composition in active substances) and the formulation (the same pharmaceutical form), so as to demonstrate bioequivalence with the reference product. Therefore, generics are assumed to be identical in dose, strength, route of administration, safety, efficacy, and intended use. When generic products become available, the market competition often leads to lower prices for both the original brand name product and the generic forms.

62. In the animal pharmaceutical sector[24], the generic competition or the mere threat of such competition is often significant as most of the available formulations and active substances are off-patent. In animal pharmaceutical sector, it also happens that innovative multinational companies launch the generic copies of other innovators, shortly after they go off-patent.

[24] There are no generics for biologicals.

Remedies

63. As indicated above, Schering-Plough submitted remedies whereby it commits to divest for the EEA a number of businesses with the objective of resolving the serious doubts identified by the Commission on several animal health markets.

64. This section presents the general modalities of the divestiture proposed by the parties and the comments received in the market test. The specific divested businesses are described and assessed in turn below in the sections dealing with the respective relevant markets.

65. The remedies generally consist in the transfer of the production of the vaccines or pharmaceuticals of either Schering-Plough or Intervet to a suitable purchaser, except in the case of a few products of the parties which are toll-manufactured for them by third parties (as in the case of Schering-Plough's insulin formulations) where Schering-Plough commits to assign its contract manufacturing agreement with the third party, where there is such a contract.

66. Each divestiture transaction includes the following elements, as more specifically defined in the relevant Schedules:

(a) All tangible and intangible assets (in particular master seeds for vaccines, the relevant intellectual property rights, the trademark, copies of all clinical data and studies), by way of transfer, sale, assignment or licence, which are necessary to ensure the viability and competitiveness of the divested businesses;
(b) All licences, permits and authorisations issued by any governmental organisation for the benefit of the divested businesses (in particular the marketing authorisations currently held by Schering-Plough or Intervet and copies of all relevant dossiers);
(c) All contracts, commitments and customer orders of the divested businesses; and
(d) All customer, credit and other records of the divested businesses.

67. The transfer would be accompanied, at the option of the purchaser, by technical assistance from Schering-Plough to the purchaser for the purchaser to assume responsibility for the manufacture, sale and marketing of the relevant divested businesses for such period as is required by the purchaser to establish the divested businesses as a viable and independent business.

68. The transitional technical assistance agreement shall include appropriate provisions designed to incentivise Schering-Plough to provide technical assistance to the Purchaser expeditiously (such as terms whereby the price payable by the purchaser for technical assistance is reduced over time). Schering-Plough is required to carry out the technical assistance for the technology transfer in accordance with good industry practice including as regards the timing and responsiveness with which this assistance is provided through the different stages of the transfer.

69. During the transfer period, during which the technology will be transferred to the purchaser which will set up manufacturing at its own facilities and obtain the necessary approvals and marketing authorisations, Schering-Plough further commits, at the option of the purchaser, to enter into a toll-manufacturing or supply agreement on terms and conditions equivalent to those at present afforded to the divested businesses, so that the purchaser is immediately in a position to compete with the new

entity.

70. The transitional period during which technical assistance and toll-manufacturing/supply arrangements will be offered to the purchaser is in principle […] in the case of vaccines and […] in the case of pharmaceuticals, which can be extended under exceptional circumstances by the monitoring trustee until such time as the purchaser has established its independent business.

71. The commitments further contain criteria which a suitable purchaser must meet in order to ensure that it can become a viable competitive force in the long term (see each schedule).

72. The commitments do not foresee the transfer of personnel or of any manufacturing facilities from the parties to the purchaser.

73. The Commission's market test validated the main elements of the remedies, in particular:

– Respondents confirmed the suitability of the transfer of the production and marketing to a suitable purchaser. Transfer of the production and marketing authorisations will allow the purchaser to set up its own manufacturing operations and become a viable competitor independent from the parties.

– While periods of […] and […] were confirmed as appropriate and in line with industry practice, respondents to the markets test pointed out the need for additional safeguards and possible time extensions of the technical assistance and toll manufacturing arrangements in case of unexpected delays, for reasons beyond Schering-Plough's and the purchaser's control, in transferring the production and obtaining the marketing authorisation (time needed for ownership transfer, variations, production transfer, validation processes, pilot production, stability data).

– The EEA-wide scope of the remedy was found to be appropriate as having sufficient market potential for a viable business and to justify the costs of the transfer.

– The modalities for the technical transfer and toll-manufacturing/supply arrangements during the transitional period were generally considered as appropriate. A few respondents noted the need to foresee stocking obligations to avoid out-of-stock situations for the purchaser and to incorporate provisions ensuring appropriate priority procedures for the purchaser's orders.

– Respondents confirmed that the purchaser would be able to obtain in a reasonable time and with reasonable efforts the necessary regulatory approvals.

– All respondents confirmed that transfer of personnel from the parties is not necessary (as long as the transitional supply arrangements continues while the personnel of the purchaser acquires the necessary know-how).

74. Respondents to the market test pointed out the need for criteria for suitable purchaser, in particular to have existing experience and know-how in vaccine production, own facilities for vaccine production, and an established marketing and sales organisation

in the animal health field in the various EEA countries concerned.

75. The parties introduced the following changes in the revised remedies submitted on 10 October 2007 in order to take into account the comments received in the market test:

– Pending marketing authorisations will also be transferred to the purchaser;

– Introduction of specific criteria for suitable purchaser according to which the purchaser should be have the financial resources, assets (including pharmaceutical and/or biological manufacturing capabilities, and an established marketing and sales team in the animal health field in the EEA), proven expertise, technical transfer capabilities and incentive to maintain and develop the relevant divested businesses as a viable and active competitive force in competition with Schering-Plough and other competitors;

– The transitional supply or toll-manufacturing arrangement will include appropriate provisions designed to ensure the reasonable continuous supply by Schering-Plough to the purchaser for the concerned product in the EEA for the duration of the arrangement.

– The commitments foresee that under circumstances outside the control of Schering-Plough or the purchaser, the period of […] for the technical assistance and toll-manufacturing supply can be extended by the monitoring trustee until such time that the purchaser has established divested business as its independent business, as certified by the monitoring trustee.

76. Further improvements were also introduced to the specific Schedules, which are discussed below as part of the competitive assessment of each relevant product market.

Biologicals (vaccines)

a) Vaccines for swine

77. Both Schering-Plough and Intervet sell swine vaccines for the prevention of a range of diseases in pigs, such as Aujeszky's disease, clostridia, E.coli, erysipelas, Glässer's disease, influenza, leptosprosis, mycoplasma, parvovirus, pasteurella, porcine reproductive and respiratory syndrome ("PRRS"), rabies, rotavirus, salmonella, and tetanus.

78. Based on data provided by the parties, the only affected markets where Schering-Plough and Intervet would have a combined market share over 25% in the EEA at the national level are:

- *Mycoplasma* vaccines for swine in Greece, Latvia, and Romania; and
- *E.coli* vaccines in Cyprus, Estonia, Germany, Latvia, Lithuania, and Norway.

79. These markets are examined in turn below.

(1) Mycoplasma vaccines for swine

Product market definition

80. Swine mycoplasma vaccines immunise young pigs against respiratory infection by *Mycoplasma hyopneumoniae*, the microbe responsible for enzootic pneumonia, which is one of the most significant respiratory pathogens in swine.

81. Applying the principles for market definition set out above (species, target disease and monovalent/multivalent), the parties submit that monovalent *Mycoplasma* vaccines for swine constitute a distinct product market. The market investigation has not raised any issue concerning the product market definition retained by the parties.

82. The relevant product market for purposes of assessing the impact of the proposed concentration is therefore the market for monovalent mycoplasma vaccines for swine.

Competitive assessment

83. Schering-Plough sells its monovalent mycoplasma vaccines for swine under the brands *M+PAC* and *ThoroVax Vet*. Intervet's products are marketed under the brand *Porcilis M Hyo*.

84. Swine mycoplasma vaccines are one of the most important markets for swine vaccines, and represent [30-40] % of the total swine vaccine sector at the EEA level according to the parties' estimates. At the EEA level, there are a number of significant competitors. The clear market leader is Pfizer (brands *Stellamune* and *Respisure*) with a market share of [40-50] %. Other significant competitors are Boehringer Ingelheim ([10-20] %), Schering-Plough ([10-20] %) and Fort Dodge ([10-20] %), followed by Merial ([0-5] %) and Intervet ([0-5] %).

85. Based on data provided by the parties, the markets where Schering-Plough and Intervet would have a combined market share over 25% are the markets for *mycoplasma* vaccines for swine in Greece, Latvia, and Romania.

86. The table below sets out the market share of the parties and of their competitors in these countries in 2006:

Competitors	Greece	Latvia	Romania
Schering-Plough	[30-40] %	[20-30] %	[20-30] %
Intervet	[0-5] %	[0-5] %	[20-30] %
Combined	[30-40] %	[20-30] %	[40-50] %
Pfizer	[20-30] %	[60-70] %	[10-20] %
BI	[10-20] %	[0-5] %	--
Fort Dodge	[10-20] %	--	--
Merial	[0-5] %	[0-5] %	[5-10] %
Novartis	--	[0-5] %[25]	--
Hipra	--	--	[30-40] %
Others	[0-5] %	[0-5]%	--
Total	100%	100%	100%

87. In Latvia and Greece, other significant competitors are present with a mycoplasma vaccine and will continue to exercise competitive pressure on the parties. In particular, Pfizer is also the clear leader at the national level in Latvia and would become a close second to the parties in Greece. The merger will only lead to a small increment in market share given Intervet's relatively weak position.

88. The only market where the parties will have a strong position is Romania. However, the Spanish company Hipra entered this market in 2004 and within two years already succeeded in capturing a market share of [30-40] % in 2006, becoming the market leader. Schering-Plough also entered the market in 2005 and succeeded in gaining a market share of [20-30] % in 2006. Both entrants gained sales at the expense of Pfizer (whose market share decreased from [60-70] % in 2004 to [10-20] % in 2006). The Romanian market for swine mycoplasma vaccines is perceived by competitors to be

[25] Novartis had a market share of [50-60] % on the market for swine mycoplasma vaccines in Latvia in 2004, but exited the market in the Baltic countries in 2005 following the Baltic countries' accession to the EU for regulatory reasons (Novartis' vaccines are produced at a plant in the U.S. which does not meet EU manufacturing standards). However, the parties indicate that Estonia has granted Novartis permission to start again supplying its swine mycoplasma vaccine in Estonia.

attractive and a growing market[26]. Some respondents to the market investigation indicated that they plan to enter the market. In these conditions, the parties will remain constrained by significant competitors post-merger.

89. The Commission therefore concludes that the proposed transaction does not raise serious doubts as to its compatibility with the common market and the EEA agreement on the markets for swine mycoplasma vaccines.

(2) E.coli vaccines for swine

Product market definition

90. Swine E.coli vaccines immunise against bacterial infection caused by the colonisation of the small intestine by enterotoxigenic strains of *E.coli*, which is a common disease in nursing and weaning piglets. It causes scours (diarrhoea) which can eventually lead to the death of the pig. Without an appropriate vaccination regime, farmers can lose up to 10% of their piglets through *E.coli* infections.

91. Applying the principles for market definition set out above, the parties consider that monovalent *E.coli* vaccines constitute a distinct product market as they are not readily substitutable with any multivalent vaccines containing an *E.coli* component, such as Schering-Plough's multivalent swine clostridia vaccines that also contain *E.coli* antigens, *Gletvax 5* and *Gletvax 6*. According to the parties, veterinarians and farmers view *Gletvax 5* and *Gletvax 6* primarily as vaccines to inoculate against clostridia pathogens in swine and not *E.coli*, and the price of the multivalent E.coli/clostridia vaccine is on the whole […] that of the monovalent *E.coli* vaccine in the EEA, so that customers would not switch to a multivalent vaccine that contains *E.coli* antigens but rather to a competing monovalent *E.coli* product in case of a price increase of 5% for the monovalent *E.coli* vaccine.

92. The market investigation has not confirmed the parties' claim. On the contrary, respondents take the view that monovalent and multivalent vaccines targeting *E.coli* on swine belong to the same relevant product market of vaccines targeting E.coli. This is also in line with the general preference for multivalent vaccines as regards swine.

93. The product market definition can, however, be left open, as the proposed transaction leads to serious doubts on several national markets in the EEA under both alternative market definitions (a market for monovalent *E.coli* vaccines for swine and a market for E.coli vaccines for swine comprising both monovalent *E.coli* and multivalent *E.coli*/clostridials vaccines) and Schering-Plough has proposed a remedy addressing both monovalent *E.coli* swine vaccines and multivalent *E.coli*/clostridials swine vaccines (see below).

Competitive assessment

94. Schering-Plough manufactures and sells a monovalent E.coli vaccine under the brands *Gletvax*, *Neo Gletvax* and *Gletvax Plus*. Schering-Plough also manufactures and sells

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[26] One respondent indicated that the size of the swine market in Romania is expected to double (backyard to industrial)

a multivalent E.coli/clostridial vaccine for swine under the brands *Gletvax 5* and *Gletvax 6* and *Toxicol*. Intervet manufactures and sells a monovalent E.coli vaccine under the brands *Porcilis Porcoli* and *Porcilis Coli*.

95. At the EEA level, Intervet is the clear market leader on the market for (monovalent) *E.coli* vaccines for swine with a market share of [30-40] %. Schering-Plough is the third player with [10-20] %. The only other significant competitor is Merial with a market share of [10-20] %. CEVA, Vetoquinol and Boehringer Ingelheim are much smaller with market shares of [0-5] % and [0-5] % and [0-5] % respectively.

96. Based on data provided by the parties, the affected markets where Schering-Plough and Intervet would have a combined market share over 25% in the EEA at the national level are the markets for monovalent *E.coli* vaccines for swine in Cyprus, Estonia, Germany, Latvia, Lithuania, and Norway.

97. The table below sets out the market share of the parties and of their competitors on the market for monovalent *E.coli* swine vaccines in these countries in 2006:

Competitors	**Cyprus**	**Estonia**	**Germany**	**Latvia**	**Lithuania**	**Norway**
Schering-Plough	[60-70] %	[0-5] %	[0-5] %	[0-5]%	[0-5] %	[20-30] %
Intervet	[30-40] %	[90-100]%	[20-30] %	[70-80] %	[50-60]%	[30-40] %
Combined	[90-100] %	[90-100]%	[20-30] %	[70-80] %	[50-60] %	[60-70] %
BI	--	--	[10-20] %	--	--	--
Merial	[5-10] %	--	[0-5] %	[20-30] %	[40-50] %	[30-40] %
IDT	--	--	[50-60] %	--	--	--
Total	100%	100%	100%	100%	100%	100%

98. The merger would therefore lead to very high market market shares of the new entity, except in Germany. Market shares range from [50-60] % in Lithania to a monopoly in Estonia, leaving Merial as the only competitor (merger from 3 to 2) in all the affected markets except Estonia and Germany.

99. The table below sets out the market share of the parties and of their competitors on the market for monovalent *E.coli* swine vaccines and multivalent *E.coli*/clostridials swine vaccines in these countries in 2006:

Competitors	Cyprus	Estonia	Germany	Latvia	Lithuania	Norway
Schering-Plough	[70-80] %	[50-60] %	[30-40] %	[50-60] %	[20-30] %	[20-30] %
Intervet	[10-20] %	[40-50] %	[5-10] %	[30-40] %	[40-50] %	[30-40] %
Combined	[90-100] %	[90-100] %	[40-50] %	[80-90] %	[60-70]%	[60-70]%
BI	--	--	[10-20] %	--	--	--
Merial	[0-5] %	--	[0-5] %	[10-20]%	[20-30] %	[30-40] %
IDT	--	--	[40-50] %	--	--	--
Total	100%	100%	100%	100%	100%	100%

100. The comparison between the two tables shows that Schering-Plough's position (and the parties' combined position) for swine *E.coli* vaccines is even stronger when taking into account the multivalent *E.coli*/clostridials vaccines. According to information provided by the parties, the only competing suppliers for multivalent *E.coli*/clostridials swine vaccines in the EEA are Hipra (selling in Greece and Spain), Boehringer Ingelheim and IDT (selling in Germany), and CEVA (selling in Portugal).

101. Respondents to the market investigation complained that the merger would lead to restricted choice for *E.coli* vaccines by combining Intervet and Schering-Plough's strong positions in combined *E.coli* and *E.Coli*/clostridium vaccines respectively.

102. Because Schering-Plough only sells its multivalent E.coli/clostridials swine vaccines (instead of the monovalent *E.coli* vaccine) in Austria, the Czech Republic, France, Hungary, Ireland, the Netherlands, Poland, Portugal, Slovakia, Spain, Sweden and the United Kingdom[27], it is expected that the merger would create overlaps in additional EEA countries. The parties however did not provide market shares for the alternative market definition including both the monovalent *E.coli* swine vaccines and the multivalent *E.coli*/clostridials swine vaccines for all other markets in the EEA (but only for those where the proposed transaction leads to an affected market – see table above in recital 98). According to one respondent, taking into account both monovalent *E.coli* swine vaccines and multivalent *E.coli*/clostridium swine vaccines would lead to additional affected markets in France, Ireland, the Netherlands, Poland, Spain and the United Kingdom. Another respondent takes the view that the parties would become the market leader in France and would have a strong position in the United Kingdom and in the Netherlands.

103. In conclusion, the Commission takes the view that the proposed concentration raises

[27] See e-mail of Schering-Plough to the Commission of 27 September 2007.

serious doubts as to its compatibility with the common market as regards the markets for *E.Coli* vaccines for swine (monovalent E.coli and multivalent E.coli/clostridials) in Cyprus, Estonia, Latvia, Lithuania and Norway. The existence or not of serious doubts as regards the market for *E.Coli* vaccines for swine (monovalent E.coli and multivalent E.coli/clostridials) in Germany can be left open for the purposes of the present decision as the remedy submitted by Schering-Plough has an EEA-wide geographic scope.

(3) Remedies

104. With the objective of removing the serious doubts identified by the Commission in the market for *E.Coli* vaccines for swine (monovalent E.coli and multivalent E.coli/clostridials) in Cyprus, Estonia, Latvia, Lithuania and Norway, Schering-Plough committed to the EEA-wide divesture to a suitable purchaser of the monovalent swine E.Coli vaccine currently marketed by Schering-Plough under the brands *Neo Gletvax* and *Gletvax Plus* the multivalent E.coli/clostridials vaccine currently marketed by Schering-Plough under the brands *Gletvax 5* and *Gletvax 6* pursuant to a non-exclusive agreement (see **Schedule 1**).

105. Following the market test, Schering-Plough added to the products to be transferred *Toxicol*, which is the brand under which Scherin-Plough's multivalent E.coli/clostridials vaccine is registered and marketed in some EEA countries (in particular in Estonia, Latvia, Lithuania and Norway). Schering-Plough further clarified that the monovalent *E.coli* vaccines *Neo Gletvax* and *Gletvax Plus* are transferred exclusively to the purchaser, and that the multivalent E.coli/clostridials vaccines *Gletvax 5*, *Gletvax 6* and *Toxicol* are transferred on a co-exclusive basis to the purchaser (both Schering-Plough and the purchaser having the exclusivity). Schering-Plough will retain the right to manufacture the multivalent vaccine, but will have to re-register the products and rebrand them as the trademarks *Gletvax 5*, *Gletvax 6* and *Toxicol* are transferred to the purchaser.

106. The Commission is of the view that the proposed remedy removes the serious doubts and restores effective competition, as it removes the entire overlap in the three Baltic countries, Cyprus and Norway and even beyond. In particular, the divested business will have a sufficient size to constitute a viable competitor for swine *E.coli* vaccines. The fact that the divestment concerns the European-wide business, rather than being limited to the five countries concerned, ensures that the purchaser will acquire a sizeable business with a well-known brand and a complete portfolio of vaccines that it can expand throughout Europe.

107. As confirmed by the market test, the divested business contains all tangible and intangible assets that the purchaser will need to conduct the business as a viable and independent business, i.e. the relevant trademarks, product formulations, know-how and customer details.

108. The transfer of Schering-Plough's existing marketing authorisations and the arrangements for the supply of the purchaser by the merged entity during the transitional period while the purchaser sets up its own manufacturing and obtains the necessary regulatory approvals will ensure that the purchaser is able from day one to compete on a level playing field with the new entity.

109. The Commission, therefore, concludes that the divestiture of the European-wide

Gletvax/Toxicol business of Schering-Plough will restore effective competition and that the proposed transaction does not raise serious doubts on condition of the implementation of this remedy.

b) Vaccines for horses

110. Both Schering-Plough and Intervet sell horse vaccines for the prevention of diseases such as influenza and tetanus mainly.

111. Based on data provided by the parties, the affected markets where Schering-Plough and Intervet would have a combined market share over 25% in the EEA at the national level are:

- *Monovalent equine influenza* vaccines in Finland, Germany, Ireland, Norway, Sweden and the United Kingdom;
- *Monovalent equine tetanus* vaccines in the Czech Republic, Denmark, Germany, Ireland, Sweden and the United Kingdom; and
- *Multivalent equine influenza/tetanus* vaccines in Denmark, Finland, Germany, Ireland, Italy, Norway, Sweden and the United Kingdom.

112. These markets are examined in turn below.

(1) Monovalent influenza vaccines for horses

Product market definition

113. Equine influenza is a highly infectious viral disease which affects a horse's respiratory tract, including its windpipe and lungs. The virus is widespread throughout the horse population and, as a result of its short incubation period of one to three days, it spreads rapidly from animal to animal. Influenza vaccines immunise healthy horses against equine influenza in order to reduce the clinical signs of influenza and also the excretion of the virus after infection.

114. Applying the principles for market definition set out above (species, target disease and monovalent/multivalent), the parties submit that *monovalent influenza vaccines for horses* constitute a distinct product market. The market investigation has not raised any issue concerning the product market definition retained by the parties.

115. The relevant product market for purposes of assessing the impact of the proposed concentration is therefore the market for monovalent influenza vaccines for horses.

Competitive assessment

116. Schering-Plough sells its monovalent influenza vaccines for horses under the brand *Equip F*. Intervet's products are marketed under the brand *Equilis Prequenza*[28].

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[28] Intervet is currently selling two other monovalent equine vaccines in the EEA under the names Equilis Pro and Equilis Equenza. These products are being replaced in 2007 by Intervet's Equilis Prequenza vaccine.

117. At the EEA level, there are four significant competitors. The market leader is Intervet with a market share of [20-30] %. The other significant competitors are Fort Dodge ([20-30] %), Schering-Plough ([10-20] %) and Merial ([10-20] %).

118. Based on data provided by the parties, the affected markets where Schering-Plough and Intervet would have a combined market share of at least 25% in the EEA at the national level are in Finland, Germany, Ireland, Norway, Sweden and the United Kingdom.

Competitors	**Finland**	**Germany**	**Ireland**	**Norway**	**Sweden**	**UK**
Schering-Plough	[40-50] %	[10-20] %	[40-50] %	[30-40] %	[50-60] %	[20-30] %
Intervet	[50-60] %	[40-50] %	[20-30] %	[40-50] %	[30-40] %	[20-30] %
Combined	[90-100] %	[60-70] %	[60-70] %	[80-90] %	[90-100] %	[50-60] %
Fort Dodge	--	[20-30] %	[5-10] %	[10-20] %	[5-10] %	[30-40] %
Merial	--	[10-20] %	[20-30] %	--	[0-5] %	[0-5] %
Others	--	--	--	--	--	--
Total	100%	100%	100%	100%	100%	100%

119. The parties have a very high combined market share in these six countries (between [50-60] % in the United Kingdom and [90-100] % in Finland). These national markets are very concentrated, since the parties face at most two competitors, only one in Norway and none in Finland.

120. There are particular high barriers to entry on the markets for monovalent influenza vaccines for horses since they are mature, without any major expansion, decline and innovations expected[29]. Thus no competitor which might enter these markets in the EEA in the near future has been identified.

121. On the basis of the foregoing the proposed concentration is likely to create a dominant position of the merging parties on the market for monovalent influenza vaccines for horses in Finland, Germany, Ireland, Norway, and Sweden. The existence or not of serious doubts as regards the United Kingdom market for monovalent influenza vaccines for horses can be left open for the purposes of the present decision as the remedy submitted by Schering-Plough has an EEA-wide geographic scope.

122. In conclusion, the Commission takes the view that the proposed concentration raises

[29] See paragraph 745 of the Form Co.

serious doubts as to its compatibility with the common market as regards the markets for monovalent influenza vaccines for horses in Finland, Germany, Ireland, Norway, and Sweden.

(2) Monovalent tetanus vaccines for horses

Product market definition

123. Tetanus vaccines immunise healthy horses to reduce mortality and clinical signs of the disease caused by infection with Clostridium tetani. Tetanus is one of the most serious illnesses that can strike horses which are particularly prone to this infection.

124. Applying the principles for market definition set out above (species, target disease and monovalent/multivalent), the parties submit that *monovalent tetanus vaccines for horses* constitute a distinct product market. The market investigation has not raised any issue concerning the product market definition retained by the parties.

125. The relevant product market for purposes of assessing the impact of the proposed concentration is therefore the market for monovalent tetanus vaccines for horses.

Competitive assessment

126. Schering-Plough sells its monovalent tetanus vaccines for horses under the brand *Equip T*. Intervet's products are marketed under the brand *Equilis Tetanus*.

127. At the EEA level, there are four significant competitors. The market leader is Intervet by far, with a market share of [40-50] %. The other significant competitors are Merial ([10-20] %), Fort Dodge ([5-10] %), and Schering-Plough ([5-10] %).

128. Based on data provided by the parties, the affected markets where Schering-Plough and Intervet would have a combined market share of at least 25% in the EEA at the national level are in the Czech Republic, Denmark, Germany, Ireland, Sweden and the United Kingdom.

Competitors	Czech Republic	Denmark	Germany	Ireland	Sweden	UK
Schering-Plough	[10-20] %	[20-30] %	[10-20] %	[5-10] %	[10-20] %	[10-20] %
Intervet	[20-30] %	[70-80] %	[80-90] %	[80-90] %	[70-80] %	[50-60] %
Combined	[30-40] %	[90-100] %	[90-100] %	[90-100] %	[90-100] %	[60-70] %
Fort Dodge	--	--	[0-5] %	[0-5] %	[0-5] %	[30-40] %
Bioveta	[60-70] %	--	--	--	--	--
Total	100%	100%	100%	100%	100%	100%

129. As a result of the proposed concentration the merging parties would have a monopolistic or nearly monopolistic position in Denmark, Germany, Ireland and Sweden. In these four countries Intervet, with market shares between [70-80] % and [80-90] %, enjoys a dominant position. The parties also have a very high combined market share in the United Kingdom ([60-70] %) where Intervet is by far the first player ([50-60] %). All of these six national markets are very concentrated since there are only two (Denmark) or three players (including Schering-Plough and Intervet) currently active on each of them.

130. As to the Czech Republic, the parties have a combined market share of [30-40] % and would only face Bioveta (a national company) which is by far the first market player ([60-70] %). However, Schering-Plough entered this market very recently (in 2006) and the parties' monovalent tetanus vaccines for horses are close substitutes[30]. Before Schering-Plough's entry, only Intervet and Bioveta were active on this market. The proposed concentration would therefore remove a significant competitive constraint exerted by an EEA player, while Bioveta is a small supplier at the EEA level, and the new entity would face only one competitor on a market where there are high barriers to entry (see below).

131. There are particular high barriers to entry on the markets for monovalent tetanus vaccines for horses since they are mature, without any major expansion, decline and innovations expected[31]. Thus no competitor which might enter the markets for monovalent tetanus vaccines for horses in the EEA in the near future has been identified.

132. On the basis of the foregoing, the proposed concentration is likely to create or strengthen a dominant position of the merging parties on the market for monovalent

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30 The notifying party specifies that *"there are no significant differences in the qualities or attributes of the parties' respective monovalent tetanus vaccines for horses."* (paragraph 748 – Form Co)

31 See paragraph 745 of the Form Co.

tetanus vaccines for horses in Denmark, Germany, Ireland, Sweden and the United Kingdom.

133. In conclusion, the Commission takes the view that the proposed concentration raises serious doubts as to its compatibility with the common market as regards the markets for monovalent influenza vaccines for horses Denmark, Germany, Ireland, Sweden and the United Kingdom. The existence or not of serious doubts as regards the markets for monovalent tetanus vaccines for horses in the Czech Republic can be left open for the purposes of the present decision as the remedy submitted by Schering-Plough has an EEA-wide geographic scope.

(3) Multivalent influenza/tetanus vaccines for horses

Product market definition

134. Multivalent influenza/tetanus combination vaccines are used to immunise horses to reduce mortality and clinical signs of disease caused by infection with equine influenza and *Clostridium tetani*.

135. Applying the principles for market definition set out above (species, target disease and monovalent/multivalent), the parties submit that *multivalent influenza/tetanus vaccines for horses* constitute a distinct product market. The market investigation has not raised any issue concerning the product market definition retained by the parties.

136. The relevant product market for purposes of assessing the impact of the proposed concentration is therefore the market for multivalent influenza/tetanus vaccines for horses.

Competitive assessment

137. Schering-Plough sells its multivalent influenza/tetanus vaccines for horses under the brand *Equip FT*. Intervet's products are marketed under the brand Equilis Prequenza Te[32].

138. At the EEA level, there are four significant competitors. The market leader is Merial, with a market share of [30-40] %, followed by Intervet ([20-30] %), Fort Dodge ([20-30] %), and Schering-Plough ([5-10] %).

139. Based on data provided by the parties, the affected markets where Schering-Plough and Intervet would have a combined market share of at least 25% in the EEA at the national level are in Denmark, Finland, Germany, Ireland, Italy, Norway, Sweden and the United Kingdom.

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32 Intervet is currently selling two other multivalent equine influenza/tetanus vaccines in the EEA under the names Equilis Pro-T and Equilis Equenza-T. These products are being replaced in 2007 by Intervet's Equilis Prequenza Te vaccine.

Competitors	DK	FIN	GER	IRL	IT	NOR	SWE	UK
Schering-Plough	[20-30] %	[30-40] %	[5-10] %	[20-30] %	[5-10] %	[20-30] %	[50-60] %	[20-30] %
Intervet	[40-50] %	[60-70] %	[40-50] %	[70-80] %	[20-30] %	[40-50] %	[30-40] %	[20-30] %
Combined	[70-80] %	[90-100] %	[50-60] %	[90-100] %	[20-30] %	[60-70] %	[90-100]%	[40-50]%
Fort Dodge	--	--	[20-30] %	[0-5] %	[40-50] %	[30-40] %	[5-10] %	[40-50] %
Merial	[20-30] %	[0-5] %	[10-20] %	[0-5] %	[20-30] %	--	[0-5] %	[0-5]%
Bioveta	--	--	--	--	--	--	--	--
Total	100%	100%	100%	100%	100%	100%	100%	100%

140. The merging parties would have a nearly monopolistic position in Finland, Ireland and Sweden. Furthermore, Intervet is already by far the first market player in Denmark ([40-50] %), Norway ([40-50] %) and Germany ([40-50] %). As Schering-Plough is already a significant competitor in these countries, the proposed transaction would significantly strengthen Intervet's position in these countries and thus give rise to a new entity with very high market shares in Denmark ([70-80] %), Norway ([60-70] %) and Germany ([50-60] %). All of these six national markets are very concentrated since there are only three (Denmark, Finland, Norway) or four players (including Schering-Plough and Intervet) currently active on each of them.

141. As to the United Kingdom, the parties have a combined market share of [40-50] % (Schering-Plough: [20-30] %; Intervet: [20-30] %). The only other major competitor is Fort Dodge ([40-50] %), Merial having a low market share ([0-5] %). The proposed concentration would therefore remove a significant competitive constraint exerted by a supplier in the EEA, and the new entity would face only one significant competitor on a market where there are particular high barriers to entry (see below).

142. There are particular high barriers to entry on the markets for multivalent influenza/tetanus vaccines for horses since they are mature, without any major expansion, decline and innovations expected[33]. Thus it is worth noting that IDT exited the German market in 2005 and that no competitor which might enter the markets for multivalent influenza/tetanus vaccines for horses in the EEA in the near future has been identified.

143. On the basis of the foregoing, the proposed concentration is likely to create or strengthen a dominant position of the merging parties on the market for multivalent influenza/tetanus vaccines for horses in Denmark, Finland, Germany, Ireland, Norway and Sweden.

[33] See paragraph 745 of the Form Co.

144. In conclusion, the Commission takes the view that the proposed concentration raises serious doubts as to its compatibility with the common market as regards the markets for multivalent influenza/tetanus vaccines for horses in Denmark, Germany, Ireland, Sweden and the United Kingdom. The existence or not of serious doubts as regards the markets for multivalent influenza/tetanus vaccines for horses in Italy can be left open for the purposes of the present decision as the remedy submitted by Schering-Plough has an EEA-wide geographic scope.

(4) Commitments on horse vaccines

145. With the objective of resolving the serious doubts identified by the Commission in the market for (i) monovalent influenza vaccines for horses in Finland, Germany, Ireland, Norway and Sweden, (ii) monovalent tetanus vaccines for horses in Denmark, Germany, Ireland, Sweden and the United Kingdom., (iii) multivalent influenza/tetanus vaccines for horses in Denmark, Finland, Germany, Ireland, Norway and Sweden, Schering-Plough committed to transfer to a suitable purchaser the production of the monovalent equine influenza, monovalent equine tetanus and multivalent equine influenza/tetanus vaccines currently marketed by Schering-Plough under the respective brands *Equip F, Equip T* and *Equip FT* (see **Schedule 2**).

146. The Commission is of the view that the proposed remedy removes the serious doubts and restores effective competition, as it removes the entire overlap in all the countries mentioned at the previous paragraph (as well as in the countries for which the Commission has left open the question as to whether the proposed concentration raises serious doubts[34]) and even beyond. In particular, the divested business will have a sufficient size to constitute a viable competitor for these equine vaccines. The fact that the divestment concerns the European-wide business, rather than being limited to the countries mentioned above, ensures that the purchaser will acquire a sizeable business with a well-known brand and a complete portfolio of vaccines that it can expand throughout Europe.

147. As confirmed by the market test, the divested business contains all tangible and intangible assets that the purchaser will need to conduct the business as a viable and independent business, i.e. the relevant trademarks, product formulations, know-how and customer details.

148. The Commission, therefore, concludes that the divestiture of the European-wide *Equip F, Equip T* and *Equip FT* business of Schering-Plough will restore effective competition and that the proposed transaction does not raise serious doubts on condition of the implementation of this remedy.

c) Vaccines for ruminants

149. Both Schering-Plough and Intervet sell vaccines for the prevention of a range of diseases in ruminants (cattle, sheep and goats), such as clostridial diseases.

150. Based on data provided by the parties, the affected markets where Schering-Plough and Intervet would have a combined market share over 25% in the EEA at the national

[34] Markets (i) for the supply of monovalent influenza vaccines in the Czech Republic and (ii) for the supply of multivalent influenza/tetanus vaccines in Italy.

level are:

- neonatal diarrhoea disease vaccines in Austria, Belgium/Luxembourg, Cyprus, Germany, Ireland, Italy, the Netherlands, Poland, Portugal, Spain and the United Kingdom;
- multivalent *clostridial* disease vaccines in Greece, Ireland, Italy and the United Kingdom;
- monovalent blackleg disease vaccines in Ireland and the United Kingdom (blackleg is a type of clostridial disease); and
- ovine foot rot vaccines in Italy.

151. These markets are examined in turn below.

(1) Neonatal diarrhoea (scours) vaccines for ruminants

Product market definition

152. Diarrhoea (scours) is common in newborn calves. The acute disease is characterised by progressive dehydration, profound weakness, and death, sometimes in as few as 12 hours from onset. Causes of the disease commonly include *E.coli*, rotavirus, coronavirus, *Cryptosporidium, Salmonella and Clostridium perfringens*[35]. Cases of neonatal diarrhoea are commonly associated with more than one of these agents. Ruminant neonatal diarrhoea vaccines generate active immunity in the dam (mother cow), and consequently transmit antibodies to the calf via the colostrum in order to protect it from *E.coli*, rotavirus and coronavirus.

153. Applying the principles for market definition set out above (species, target disease and monovalent/multivalent), the parties submit that multivalent neonatal diarrhoea (scours) vaccines for ruminants constitute a distinct product market. The market investigation has not raised any issue concerning the product market definition retained by the parties.

154. The relevant product market for purposes of assessing the impact of the proposed concentration is therefore the market for multivalent neonatal diarrhoea (scours) vaccines for ruminants.

Competitive assessment

155. Schering-Plough sells its multivalent neonatal diarrhoea (scours) vaccines for ruminants under the brand *Rotavac Corona*. Intervet's products are marketed under the brand *Lactovac C*.

156. At the EEA level, Schering-Plough is the clear market leader on the market for multivalent neonatal diarrhoea vaccines for ruminants with a market share of [60-70]%. Intervet is a smaller player with [0-5] %. The only other competitors are Pfizer with [5-10] %, Merial with [10-20] % and CEVA with [0-5] %.

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35 Protection against other pathogens causing this disease through vaccination would be possible but has so far not become widespread.

157. Based on data provided by the parties, Schering-Plough and Intervet would have a combined market share over 25% on the markets for neonatal diarrhoea disease vaccines in Austria, Belgium/Luxembourg, Cyprus, Germany, Ireland, Italy, The Netherlands, Poland, Portugal, Spain and the United Kingdom.

158. The tables below set out the market share of the parties and of their competitors in these countries in 2006:

Competitors	**A**	**B/LX**	**CY**	**GER**	**IRL**	**IT**	**NL**	**POL**	**PT**	**SP**	**UK**
Schering-Plough	[70-80] %	[60-70] %	[90-100] %	[50-60] %	[50-60] %	[30-40] %	[70-80] %	[10-20] %	[60-70] %	[50-60] %	[90-100] %
Intervet	[5-10] %	[5-10] %	[5-10] %	[10-20] %	[0-5] %	[0-5] %	[20-30] %	[30-40] %	[10-20] %	[0-5] %	[0-5] %
Combined	[80-90]%	[70-80] %	[90-100] %	[70-80] %	[50-60] %	[40-50] %	[90-100] %	[50-60] %	[80-90] %	[50-60] %	[90-100]%
Pfizer	[10-20] %	[5-10] %	--	[10-20] %	--	[20-30] %	--	--	--	[30-40] %	--
Merial	--	[10-20] %	--	[5-10] %	[40-50] %	[30-40] %	--	[40-50] %	[10-20] %	[0-5] %	[0-5] %
Others	--	[0-5] %	--	[0-5]% (IDT)	--	--	--	--	--	[0-5]% (Syva)	--
Total	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%

159. In Austria, Belgium/Luxembourg, Cyprus, Germany, Ireland, Netherlands, Poland, Portugal, Spain and the United Kingdom, the parties have very high combined market shares (ranging from [50-60] % to [90-100] %) and the new entity would face no competitors or very few competitors with a weaker position.

160. In conclusion, the Commission takes the view that the proposed concentration raises serious doubts as to its compatibility with the common market as regards the markets for neonatal diarrhoea disease (scours) vaccines for ruminants in Austria, Belgium/Luxembourg, Cyprus, Germany, Ireland, Netherlands, Poland, Portugal, Spain and the United Kingdom. The existence or not of serious doubts as regards the market for neonatal diarrhoea disease (scours) vaccines for ruminants in Italy can be left open for the purposes of the present decision as the remedy submitted by Schering-Plough has an EEA-wide geographic scope.

(2) Clostridia vaccines for ruminants (including blackleg vaccines)

Product market definition

161. *Clostridial* vaccines immunise cattle and sheep against the toxins produced by different species of Clostridium bacterium. The genus *Clostridia* comprises a group of bacterial species that cause disease and death in cattle and sheep. *Clostridia* bacteria are found in soil throughout the world, and also may live harmlessly in the gastro

intestinal tract of animals and humans without causing disease or illness. However, when an animal becomes stressed, experiences changes in diet, physical trauma, or changes in the micro environment of the gastro intestinal tract, the *clostridia* bacteria start to produce toxins. The table below identifies the more common species of clostridia pathogens that affect ruminants in the EEA.

CLOSTRIDIA SPECIES	*CLOSTRIDIAL* DISEASE
C. septicum	Braxy (also called False Blackleg and Malignant Oedema)
C. chauvoei	Blackleg and Post-parturient Gangrene
C. tetani	Tetanus
C. perfringens type A	Enterotoxaemia
C. perfringens type B	Lamb Dysentery
C. perfringens type C	Struck
C. perfringens type D	Pulpy Kidney disease
C. novyi	Big Head /Black Disease
C. botulinum	Botulism
C. sordellii	Toxic Shock
C. haemolyticum	Red Water Disease

162. *Clostridial* diseases are difficult to treat because they advance very rapidly. As a result, vaccination is frequently practied for protection of animals against *clostridial* diseases. A wide variety of vaccines is available. *Clostridial* vaccines are mainly multivalent in nature, i.e., they often contain antigens for multiple pathogens, although monovalent vaccines also exist, such as for blackleg. In addition, some vaccines also contain non-*clostridial* antigens that protect against non-*clostridial* pathogens. For example, Intervet's Heptavac P and Ovivac P vaccine provides a narrower range of *clostridial* antigens, but also offer antigens against the *Mannheimia haemolytica* and *Pasteurella trehalosi* pathogens.

163. Blackleg is an acute, febrile disease of cattle and sheep caused by *clostridium chauvoei* and is characterised by emphysematous swelling, usually in the heavy muscles.

164. The parties take the view that the relevant product markets are (i) multivalent clostridia vaccines for ruminants (regardless of the number of clostridia pathogens targeted); and (ii) monovalent blackleg vaccines for ruminants (which the parties consider as a separate product market from the multivalent vaccines).

165. The market investigation has not confirmed the parties' view. Most respondents take the view that there is substitutability between monovalent blackleg vaccines and the broader multivalent clostridia vaccines (in the same way as the market investigation suggested that there is substitutability between a multivalent clostridia vaccine covering a range of pathogens and a multivalent clostridia vaccine covering a broader range).

166. The product market definition can, however, be left open, as the proposed transaction leads to serious doubts on several national markets in the EEA under both alternative

product market definitions (whether or not monovalent blackleg vaccines for ruminants belong to the market for multivalent clostridial vaccines for ruminants or form a separate product market) and Schering-Plough has proposed a remedy addressing both multivalent clostridia vaccines for ruminants and monovalent blackleg vaccines for ruminants (see below).

167. In addition, the market investigation has strongly indicated that the multivalent clostridia disease vaccines for ruminants should also include vaccines that immunize against clostridia as well as other pathogens, such as Intervet's *Heptavac Plus* and *Ovivac-P Plus* vaccines which protects against clostridia diseases and pasteurella on the grounds that the main indication and core component of the multivalent vaccine are the clostridial diseases, and protection against pasteurella is only an added, secondary benefit. A multivalent clostridia/pasteurella vaccine, therefore, competes with the pure clostridia vaccines, in particular in light of the trend in favour of multivalent product for ruminants, and should belong to the same product market.

168. The product market definition can, however, be left open, as the proposed transaction leads to serious doubts on several national markets in the EEA under both alternative product market definitions (see competitive assessment below which takes into account both alternative product market definitions).

Competitive assessment

Multivalent clostridials vaccines

169. Schering-Plough sells its multivalent clostridia vaccines for ruminants under the brands *Xento Vet* (3 antigens, for sheep), *Tribovax T* (5 antigens, for cattle), *Covexin 8A* (7 antigens, for cattle and sheep), *Covexin 8* (8 antigens, for cattle and sheep), *Covexin 9A* (8 antigens, for cattle and sheep), *Covexin 10* (10 antigens, for cattle and sheep). Intervet's products are marketed under the brand *Lambivac* (4 antigens, for sheep), *Ovivac Vet* (4 antigens, for sheep), *Heptavac/Dialuene* (7 antigens, for sheep), and *Clovax* (9 antigens, for cattle and sheep). Intervet also sells multivalent clostridia/pasteurella vaccines under the brands *Heptavac P* and *Ovivac-P Plus*.

170. At the EEA level, Schering-Plough and Intervet are the clear market leaders on the market for multivalent clostridia vaccines for ruminants. The main other competitors which market clostridia vaccines for ruminants in the EEA are Hipra and Merial (each with a 8-antigen vaccines for sheep, cattle and goats) and CEVA (with a 3-antigen vaccine for cattle and sheep and a 6-antigen vaccine for sheep and goats).

171. Based on data provided by the parties, Schering-Plough and Intervet would have a combined market share over 25% on the markets for multivalent clostridia vaccines for ruminants in Greece, Ireland, Italy and the United Kingdom.

172. The tables below set out the market share of the parties and of their competitors in these countries in 2006:

Competitors	Greece	Ireland	Italy	UK
Schering-Plough	[60-70] %	[90-100] %	[20-30] %	[70-80] %
Intervet	[0-5] %	[0-5] %	[5-10] %	[20-30] %
Combined	[60-70] %	[90-100] %	[30-40] %	[90-100] %
CEVA	[20-30] %	--	--	--
Merial	[0-5] %	[0-5] %	[50-60] %	--
Others	[0-5] % (Hipra); [5-10] % (Veterin)	--	[10-20] % (Fatro); [0-5] % (others)	--
Total	100%	100%	100%	100%

173. The merger would therefore lead to very high market shares of the new entity in Greece ([60-70] %), Ireland ([90-100] %) and the United Kingdom ([90-100 %]).

174. The table below sets out the market share of the parties and of their competitors on the broader market for multivalent clostridia vaccines for ruminants, including multivalent clostridials/pasteurella vaccines in these countries in 2006:

Competitors	Greece	Ireland	Italy	UK
Schering-Plough	[50-60] %	[60-70] %	[10-20] %	[10-20] %
Intervet	[20-30] %	[30-40] %	[20-30] %	[80-90] %
Combined	[70-80] %	[90-100] %	[40-50] %	[90-100] %
CEVA	[10-20] %	--	--	--
Merial	[0-5] %	[0-5] %	[40-50] %	--
Others	[0-5] % (Hipra); [0-5] % (Veterin)	--	[10-20] % (Fatro)	--
Total	100%	100%	100%	100%

175. The comparison between the two tables shows that Intervet's position is much stronger when taking into account its *Heptavac Plus* (multivalent clostridials/pasteurella) vaccines. According to information provided by the parties, there are no other suppliers of such multivalent vaccine in Europe. While the parties' combined market share is overall quite similar under this alternative market definition, their respective position is different (with Intervet taking over Schering-Plough's position as market

leader in Italy and the United Kingdom).

176. Intervet sells its multivalent vaccines in Austria, Cyprus, Finland, Germany, Greece, Ireland, Italy, the Netherlands, Portugal, Spain, Sweden and the United Kingdom[36]. Given the strong position of *Heptavac Plus* in these countries, it is expected that the merger would create overlaps in additional EEA countries on a broader market for clostridia vaccines for ruminants including Intervet's multivalent clostridia/pasteurella *Heptavac Plus*[37]. The parties, however, did not provide market shares for the alternative market definition (but only for those where the proposed transaction leads to an affected market – see table above in recital 174).

177. The Commission, therefore, takes the view that the proposed concentration raises serious doubts as to its compatibility with the common market as regards the markets for multivalent clostridials vaccines for ruminants (including multivalent clostridials/pasteurella) vaccines in any event in Greece, Ireland and the United Kingdom, and possibly additional EEA countries. The existence or not of serious doubts as regards the markets for clostridial disease vaccines for ruminants in Italy and in additional EEA countries can be left open for the purposes of the present decision as the remedy submitted by Schering-Plough has an EEA-wide geographic scope.

Monovalent blackleg vaccine

178. The parties are only aware of sales of monovalent blackleg vaccines for ruminants in Ireland and the United Kingdom. Both Schering-Plough and Intervet currently market a vaccine against blackleg, both under the brand *Blackleg* in Ireland and the United Kingdom.

179. Based on data provided by the parties, they would have a combined market share of [90-100] % in Ireland (Schering-Plough [60-70] %, Intervet [30-40] %) and the United Kingdom (Schering-Plough [50-60] %, Intervet [40-50] %).

180. The merger will, therefore, lead to a monopoly of the parties on the markets for monovalent blackleg vaccines for ruminants in Ireland and the United Kingdom. Given the high barriers to entry, in particular the small size and low value nature of these markets (EUR 320,000 in Ireland and EUR 200,000 in the United Kingdom) which concern specific local conditions, specific species and ages, the fact that blackleg vaccines are only sold in the United Kingdom and in Ireland, and the fact that the parties are the only two known suppliers of a monovalent blackleg vaccines in the EEA, the Commission takes the view that the proposed concentration raises serious doubts as to its compatibility with the common market as regards the markets for monovalent blackleg vaccines in Ireland and the United Kingdom.

Conclusion on clostridials vaccines for ruminants

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36 See e-mail of Schering-Plough to the Commission of 27 September 2007.

37 *Ovivac-P* Plus is sold in Ireland, Norway and the United Kingdom (Ireland and the United Kingdom are already affected markets).

181. In conclusion, the Commission takes the view that the proposed concentration raises serious doubts as to its compatibility with the common market as regards the markets for Clostridials vaccines for ruminants: (i) multivalent clostridials (including multivalent clostridials/pasteurella) vaccines in Greece, Ireland and the United Kingdom; and (ii) monovalent blackleg vaccines in Ireland and the United Kingdom.

(3) Ovine foot rot vaccines

Product market definition

182. Ovine foot rot is caused by *Dichelobacter nodosus* and is the most common source of lameness in sheep. Infections generate pain and impair the mobility of the animal, as well as negatively impact the sheep's fertility and feed intake (and therefore growth).

183. Successful eradication of foot rot requires a combination of measures including footbaths/footsoaks in treatment solutions, foot trimming, dry chemicals, oral administration of zinc sulphate, antibiotics, topical medications and vaccination against *Dichelobacter nodosus*. The parties nevertheless do not take the view that all products forming part of the overall foot rot management program would be part of a broad sheep foot rot market. Applying the principles of market definition defined above, the parties consider that ovine foot rot vaccines form part of a distinct product market. The market investigation has not raised any issue concerning the product market definition retained by the parties.

184. The relevant product market for purposes of assessing the impact of the proposed concentration is therefore the market for monovalent ovine foot rot vaccines.

Competitive assessment

185. Both Schering-Plough and Intervet currently market a vaccine against ovine foot rot. Schering-Plough sells its foot rot vaccine throughout the EEA, whilst Intervet only sells its vaccine in Italy.

186. Based on data provided by the parties, they would have a combined market share of [60-70] % in Italy (Schering-Plough [40-50] %, Intervet [10-20] %). According to the parties, the other suppliers of ovine foot rot vaccine in Italy are public health institutes which would have a market share of [30-40] %.

187. However, the parties have not been able to identify this competitor and respondents to the market investigation did not confirm that local public health institutes exercise a strong competitive constraint on the market for foot rot vaccine in Italy. Furthermore, Schering-Plough has a monopoly for ovine foot rot vaccines in several other EEA countries. This shows that the merger would remove one of the few competitors of Schering-Plough, even at the EEA level.

188. However, the parties have provided conclusive evidence showing Intervet's withdrawal from the Italian ovine foot rot market, for reasons unrelated to the present transaction. […][38] The parties provided a copy of an internal memorandum of January

[38] […]

2007 establishing these facts.

189. The Commission, therefore, takes the view that the proposed concentration does not raise serious doubts as to its compatibility with the common market as regards the market for monovalent ovine foot rot vaccines in Italy.

(4) Remedies

Neonatal diarrhoea disease (scours) vaccines for ruminants

190. With the objective of resolving the serious doubts identified by the Commission in the market for neonatal diarrhoea disease (scours) vaccines for ruminants in Austria, Belgium/Luxembourg, Cyprus, Germany, Ireland, Netherlands, Poland, Portugal, Spain and the United Kingdom, Schering-Plough committed to transfer to a suitable purchaser the production of the under the brands *Lactovac-C* and *Bovilis Lactovac-C*, and Intervet's new ruminant neonatal diarrhoea vaccine product which is currently in development (together "the *Lactovac C* business") (see **Schedule 3**).

191. The Commission is of the view that the proposed remedy removes the serious doubts and restores effective competition, as it removes the entire overlap in the ten national markets concerned and even beyond. In particular, the divested business will have a sufficient size to constitute a viable competitor for neonatal diarrhoea disease (scours) vaccines for ruminants. The fact that the divestment concerns the European-wide business, rather than being limited to the ten countries concerned, ensures that the purchaser will acquire a sizeable business with a well-known brand and a complete portfolio of vaccines that it can expand throughout Europe.

192. As confirmed by the market test, the divested business contains all tangible and intangible assets that the purchaser will need to conduct the business as a viable and independent business, i.e. the relevant trademarks, product formulations, know-how and customer details.

193. The transfer of Schering-Plough existing marketing authorisations and the arrangements for the supply of the purchaser by the merged entity during the transitional period while the purchaser sets up its own manufacturing and obtains the necessary regulatory approvals will ensure that the purchaser is able from day one to compete on a level playing field with the new entity.

194. The Commission, therefore, concludes that the divestiture of the European-wide *Lactovac C* business of Intervet will restore effective competition and that the proposed transaction does not raise serious doubts on condition of the implementation of this remedy.

Clostridial disease vaccines for ruminants (including blackleg)

195. With the objective of resolving the serious doubts identified by the Commission in the market for clostridia vaccines for ruminants ((i) multivalent clostridials, multivalent clostridials/pasteurella in Greece, Ireland and the United Kingdom and (ii) monovalent blackleg in Ireland and the United Kingdom), Schering-Plough committed to transfer to a suitable purchaser the ruminant clostridia vaccines currently marketed by Schering-Plough under *Covexin 8, Covexin 8A*, *Tasvac Huit* and *Blackleg* (see **Schedule 4**).

196. Following the market test, Schering-Plough added the *Covexin 10* to the products to be divested. *Covexin 10* is transferred on a co-exclusive basis to the purchaser, similarly to what is foreseen for *Gletvax 5*, *Gletvax 6* and *Toxicol*. Schering-Plough will retain the right to manufacture the ten-strain clostridial vaccine, but will have to re-register and rebrand it as the trademark *Covexin* is transferred to the purchaser.

197. The Commission is of the view that the proposed remedy removes the serious doubts and restores effective competition, as it removes the overlap in the five national markets concerned and even beyond. In particular, the divested business will have a sufficient size to constitute a viable competitor for clostridial disease vaccines for ruminants. The fact that the divestment concerns the European-wide business, rather than being limited to the three countries concerned, ensures that the purchaser will acquire a sizeable business with a well-known brand and a complete portfolio of vaccines that it can expand throughout Europe.

198. As confirmed by the market test, the divested business contains all tangible and intangible assets that the purchaser will need to conduct the business as a viable and independent business, i.e. the relevant trademarks, product formulations, know-how and customer details.

199. The transfer of Schering-Plough existing marketing authorisations and the arrangements for the supply of the purchaser by the merged entity during the transitional period while the purchaser sets up its own manufacturing and obtains the necessary regulatory approvals will ensure that the purchaser is able from day one to compete on a level playing field with the new entity.

200. The Commission, therefore, concludes that the divestiture of the European-wide *Covexin 8 Covexin 8A, Covexin 10, Tasvac Huit,* and *Blackleg* businesses of Intervet will restore effective competition and that the proposed transaction does not raise serious doubts on condition of the implementation of this remedy.

d) Vaccines for companion animals

201. Both Schering-Plough and Intervet sell vaccines for the prophylactic prevention of a range of diseases in companion animals, such as distemper, hepatitis, leptospirosis, and parvovirus in dogs. For cats, these vaccines protect against diseases including feline chlamydial disease (caused by Chlamydophila felis ('C.felis')), feline leukaemia ('FeLV'), panleucopenia, and cat flu due to calicivirus and herpes (rhinotracheitis) virus.

202. Based on data provided by the parties, the only affected markets where Schering-Plough and Intervet would have a combined market share over 25% in the EEA at the national level are:

- *Multivalent cat* vaccine programmes in the United Kingdom;
- *Monovalent FeLV* vaccines for cats in the United Kingdom;
- *Monovalent rabies* vaccines (multispecies) in Finland, Greece and the United Kingdom; and

- *Multivalent dog* vaccine programmes in Austria, Ireland, Italy, Spain and the United Kingdom.

203. These markets are examined in turn below.

(1) Multivalent cat vaccine programmes

Product market definition

204. Veterinarian practice and local needs have led to a number of vaccines for companion animals – including for cats – being regularly administered together. For cats, the vaccines that are affected by this practice immunise the animal against the combination of the feline herpes virus (rhinotracheitis)[39], feline calicivirus[40], feline enteritis (panleucopenia) virus[41], *C.felis*[42] and feline leukaemia.[43]

205. Applying the principles for market definition set out above (species, target disease and monovalent/multivalent), the parties submit that *multivalent cat vaccines programmes* constitute a distinct product market. The market investigation broadly confirmed the product market definition retained by the parties.

206. The relevant product market for purposes of assessing the impact of the proposed concentration is therefore the market for multivalent cat vaccines programmes.

Competitive assessment

207. Schering-Plough sells its multivalent cat vaccines under the brand *Quantum*. Intervet's products are marketed under the brand *Nobivac*.

208. At the EEA level, there are four significant competitors. The market leader is by far Merial, with a market share of [40-50] %. The other significant competitors are Fort Dodge ([10-20] %), Virbac ([10-20] %), Intervet ([10-20] %) and Pfizer ([10-20] %). Schering-Plough is a small player at the EEA level since it has a market share of [0-5]%.

209. Based on data provided by the parties, the only affected market where Schering-Plough and Intervet would have a combined market share of at least 25% in the EEA at the national level is the United Kingdom.

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39 Feline rhinotracheitis (feline herpes virus) can cause acute respiratory illnesses such as sneezing, nasal discharge, rhinitis (inflammation of the nose) and conjunctivitis.

40 Feline calicivirus is a common viral disease that affects cats. It generates upper respiratory symptoms, pneumonia, mouth sores and occasionally arthritis. It is a fairly mild flu-like condition and rarely causes serious complications, but is a commonly administered vaccination for cats.

41 Panleucopenia is a virus very similar to the one that causes parvovirus in dogs: it causes severe vomiting, anorexia and fever in cats, and may cause death.

42 Chlamydial disease causes pneumonia in cats. It also causes eye disease in those cats which contract it, with frequently recurring soreness and discharging eyes, usually for the entire life of the affected animal (chronic conjunctivitis).

43 See below for description of feline leukaemia virus.

Competitors	UK
Schering-Plough	[0-5] %
Intervet	[20-30] %
Combined	[20-30] %
Fort Dodge	[20-30] %
Merial	[20-30] %
Pfizer	[5-10] %
Virbac	[10-20] %
Total	100%

210. The proposed transaction gives rise to a limited market share accretion (Schering-Plough: [0-5] %; Intervet: [20-30] %) and the new entity will face four significant competitors (Fort Dodge: [20-30] %; Merial: [20-30] %; Virbac: [10-20] %; Pfizer: [5-10] %).

211. On the basis of the foregoing, the proposed concentration is not likely to give rise to serious doubts on the market for multivalent cat programmes in the United Kingdom.

(2) Monovalent FeLV cat vaccines

Product market definition

212. Feline leukaemia (FeLV) is a serious and common cause of illness and death in cats. There is currently no approved anti-viral drug for the treatment of FeLV infection. Control is therefore mainly focused on preventing infection by administering FeLV vaccines.

213. Applying the principles for market definition set out above (species, target disease and monovalent/multivalent), the parties submit that *monovalent FeLV cat vaccines* constitute a distinct product market. The market investigation broadly confirmed the product market definition retained by the parties.

214. The relevant product market for purposes of assessing the impact of the proposed concentration is therefore the market for monovalent FeLV cat vaccines.

Competitive assessment

215. Schering-Plough sells its monovalent FeLV cat vaccine under the brand *Quantum*.

Intervet's product is marketed under the brand *Nobivac*.

216. At the EEA level, there are four significant competitors. The market leader is Virbac, with a market share of [30-40] %. The other significant competitors are Pfizer ([20-30] %), Merial ([10-20] %) and Intervet ([10-20] %). Schering-Plough is a small player at the EEA level since it has a market share of 2.5%.

217. Based on data provided by the parties, the only affected market in the EEA where Schering-Plough and Intervet would have a combined market share of at least 25% at the national level is the United Kingdom.

Competitors	**UK**
Schering-Plough	[5-10] %
Intervet	[40-50] %
Combined	[50-60] %
Fort Dodge	[0-5] %
Merial	[0-5] %
Pfizer	[30-40] %
Virbac	[0-5] %
Total	100%

218. The parties have a combined market share of [50-60] % (Schering-Plough: [5-10] %; Intervet: [40-50] %).

219. Despite the high combined market share of the parties, the proposed concentration is not likely to give rise to serious doubts for the following reasons.

220. Firstly, the new entity will continue to face one strong competitor, Pfizer ([30-40] %), and at least two other competitors with smaller market shares, namely Merial ([0-5]%), Virbac ([0-5] %). At the EEA level, these competitors are significant market players and two of them (Virbac, Pfizer) are by far stronger (in terms of market shares) than the merging parties, while Schering-Plough is a small player ([0-5] %). The new entity will therefore still face significant competitive pressure in the United Kingdom.

221. Secondly, the likelihood of a remaining significant competitive pressure is confirmed by the fact that parties' products were not considered as the closest substitutes by the respondents to the market investigation.

222. Thirdly, all competitors questioned considered the United Kingdom market for monovalent FeLV cat vaccines as being attractive, as the cat population is growing in this country and FeLV is one of the most prevalent diseases amongst cats today, which is likely to enhance competition.

223. Fourthly, […][44].

224. On the basis of the foregoing, the proposed concentration is not likely to give rise to serious doubts on the market for monovalent FeLV cat vaccines in the United Kingdom.

(3) Monovalent multispecies rabies vaccines

Product market definition

225. Rabies is a viral disease in mammals, including cats and dogs. It causes acute inflammation of the brain (encephalitis) and is fatal both for animals and humans alike. Active immunisation of cats and dogs is important to prevent the spread of this disease and also mortality due to rabies infection.

226. The parties submit that *monovalent multispecies rabies vaccines* constitute a distinct product market. They apply the principles of target disease for market definition set out above but the criteria of species, since in their view there is no specific rabies vaccine for each species. The market investigation broadly confirmed the product market definition retained by the parties.

227. The relevant product market for purposes of assessing the impact of the proposed concentration is therefore the market for monovalent multispecies rabies vaccines.

Competitive assessment

228. Schering-Plough sells its monovalent rabies vaccine under the brands *Rabdomun* and *Quantum*. Intervet's product is marketed under the brand *Nobivac*.

229. At the EEA level, there are four significant competitors. The market leader is by far Merial, with a market share of [40-50] %. The other significant competitors are Intervet ([20-30] %), Virbac ([10-20] %) and Pfizer ([5-10] %). Schering-Plough is a small player at the EEA level since it has a market share of [0-5] %.

230. Based on data provided by the parties, the affected markets where Schering-Plough and Intervet would have a combined market share of at least 25% in the EEA at the national level are Finland, Greece and the United Kingdom.

[44] […]

Competitors	Finland	Greece	UK
Schering-Plough	[20-30] %	[5-10] %	[5-10] %
Intervet	[30-40] %	[40-50] %	[50-60] %
Combined	[60-70]%	[50-60] %	[60-70]%
Merial	[30-40] %	[40-50] %	[30-40] %
Virbac	--	--	[0-5] %
Total	100%	100%	100%

231. As to Finland, the proposed transaction would remove one significant competitor out of three and the new entity would be by far the dominant player (Schering-Plough: [20-30] %; Intervet: [30-40] %) facing only Merial ([30-40] %) on a market where there are high barriers to entry.

232. As to the United Kingdom, Intervet is already by far the dominant player ([50-60] %) and the new entity would be even more the dominant player ([60-70] %), facing only one significant competitor (Merial: [30-40] %) and a small one (Virbac: [0-5] %) on a market where there are high barriers to entry.

233. As to Greece, the parties have a combined market share of [50-60] % (Schering-Plough: [5-10] %; Intervet: [40-50] %). The only other major competitor is Merial ([40-50] %). The proposed concentration would therefore remove a competitive constraint, and the new entity would face only one significant competitor on a market where there are high barriers to entry.

234. In conclusion, the Commission takes the view that the proposed concentration raises serious doubts as to its compatibility with the common market as regards the markets for monovalent multispecies rabies vaccines in Finland, Greece and the United Kingdom.

(4) Multivalent dog vaccines

Product market definition

235. Veterinarian practice and local needs have led to a number of vaccines for companion animals – in particular for dogs – being regularly administered together. For dogs, the vaccines that are affected by this practise immunise the animal against the combination of the canine bacterial pathogen *Leptospira interrogans*[45] with one or

[45] The disease caused by leptospira is referred to as leptospirosis. It is a serious zoonotic disease (*i.e.*, it can be spread from animals to humans).

more of distemper[46], adenovirus[47], parvovirus and parainfluenza[48] viruses.

236. Applying the principles for market definition set out above (species, target disease and monovalent/multivalent), the parties submit that *multivalent dog vaccines* constitute a distinct product market. The market investigation broadly confirmed the product market definition retained by the parties.

237. The relevant product market for purposes of assessing the impact of the proposed concentration is therefore the market for multivalent dog vaccines.

Competitive assessment

238. Schering-Plough sells its multivalent dog vaccines under the brands *Quantum* and *Procyon*[49]. Intervet's products are marketed under the brand *Nobivac*.

239. At the EEA level, there are five significant competitors. The two market leaders are Intervet, with a market share of [20-30] %, and Merial ([20-30] %). The other significant competitors are Pfizer ([10-20] %), Fort Dodge ([5-10] %) and Virbac ([5-10] %). Schering-Plough has a market share of [0-5] %.

240. Based on data provided by the parties, the affected markets where Schering-Plough and Intervet would have a combined market share of at least 25% in the EEA at the national level are Ireland, Italy, Spain and the United Kingdom.

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46 Canine distemper is a virus related to the virus causing measles in humans. It is a morbillivirus *vi*rus (this group of viruses also includes measles and seal distemper) that causes a highly contagious disease in dogs which can cause mild signs in some individuals, but may be fatal in others.

47 Canine adenovirus vaccines protect against infectious canine hepatitis, a disease of the liver, kidneys, eyes and lungs of a dog caused by canine adenovirus-1 (CAV-1), and against canine respiratory infections caused by CAV-2 (pathogen involved in the kennel cough complex).

48 Canine parainfluenza virus is one of the causes of canine infectious tracheobronchitis, more commonly known as kennel cough.

49 Procyon Dog is the brand name under which Schering-Plough's new Quantum dog vaccine products are sold in the United Kingdom.

Competitors	Ireland	Italy	Spain	UK
Schering-Plough	[5-10] %	[0-5] %	[0-5] %	[5-10] %
Intervet	[40-50] %	[20-30] %	[20-30] %	[30-40] %
Combined	[50-60] %	[30-40] %	[20-30] %	[40-50] %
Fort Dodge	[0-5] %	[0-5] %	[0-5] %	[10-20] %
Merial	[5-10] %	[30-40] %	[20-30] %	[5-10] %
Pfizer	[30-40] %	[10-20] %	[20-30] %	[10-20] %
Virbac	--	[10-20] %	[5-10] %	[5-10] %
Others	--	--	[0-5] %	--
Total	100%	100%	100%	100%

241. The proposed transaction gives rise to a small market share accretion in Spain and Italy, and does not significantly modify the market structure in these two countries.

242. The parties have a high combined market share in Ireland ([50-60] %; Schering-Plough: [5-10] %; Intervet: [40-50] %) and the United Kingdom ([40-50] %; Schering-Plough: [5-10] %; Intervet: [40-50] %). […]. Some competitors claimed that the merger would give rise to serious doubts due to the parties' high combined market share and broad range of dog vaccines.

243. After a thorough examination, the Commission concludes that serious doubts are unlikely on these markets for the following reasons.

244. Firstly, the parties face other significant competitors in both countries, namely Pfizer (Ireland: [30-40] %; United Kingdom: [10-20] %), Merial (Ireland: [5-10] %; United Kingdom: [5-10] %), Fort Dodge (Ireland: [0-5] %; United Kingdom: [10-20] %), and Virbac (United Kingdom: [5-10] %). These competitors sell multivalent dog vaccines, as well as other vaccines for companion animals, throughout the EEA and have significant market shares at the EEA level (Merial: [20-30] %; Pfizer: [10-20] %; Fort Dodge: [5-10] %; Virbac: [5-10] %), while Schering-Plough's market share ([0-5] %) is small at the EEA level. Furthermore, all competitors questioned considered this market as being particularly growing and attractive in the United Kingdom and Ireland, which is likely to enhance competition.

245. Secondly, the new entity will not have a more complete and broader range of multivalent dog vaccines than its main competitors. Indeed, Schering-Plough's and

Intervet's portfolios are not complementary to each other and the other main competitors have a similar range. Furthermore, the respondents to the market investigation did not view Schering-Plough's product as the closest substitute to Intervet's product.

246. Thirdly, Schering-Plough's market share in the United Kingdom has to be put in perspective […][50].

247. Fourthly, […].

248. On the basis of the foregoing, the proposed concentration is not likely to give rise to serious doubts on the market for multivalent dog vaccines in Ireland, Italy, Spain and the United Kingdom.

(5) Remedies

249. With the objective of resolving the serious doubts identified by the Commission in the market for monovalent multispecies rabies in Finland, Greece and the United Kingdom, Schering-Plough committed to transfer to a suitable purchaser the production of the monovalent multispecies rabies vaccines currently marketed by Schering-Plough under the respective brands *Rabdomun* and *Quantum Rabies* (see **Schedule 12**).

250. The Commission is of the view that the proposed remedy removes the serious doubts and restores effective competition, as it removes the entire overlap in all the countries mentioned at the previous paragraph and even beyond. In particular, the divested business will have a sufficient size to constitute a viable competitor for these rabies vaccines. The fact that the divestment concerns the European-wide business, rather than being limited to the countries mentioned above, ensures that the purchaser will acquire a sizeable business with a well-known brand and a complete portfolio of vaccines that it can expand throughout Europe.

251. As confirmed by the market test, the divested business contains all tangible and intangible assets that the purchaser will need to conduct the business as a viable and independent business, i.e. the relevant trademarks, product formulations, know-how and customer details.

252. The Commission, therefore, concludes that the divestiture of the European-wide *Rabdomun* and *Quantum Rabies* business of Schering-Plough will restore effective competition and that the proposed transaction does not raise serious doubts on condition of the implementation of this remedy.

e) Vaccines for poultry

253. Both Intervet and Schering-Plough sell vaccines for poultry in the EEA. Intervet is by far the main supplier of poultry vaccines in the EEA, and has the broadest range. Schering-Plough only sells a few poultry vaccines in the EEA, but has in its portfolio one of the most important vaccines for poultry, the cocciodiosis vaccine (*Paracox 5* and *Paracox 8*).

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[50][…]. Schering-Plough sells these vaccines under the brand 'Quantum Dog' in the United Kingdom.

254. Based on data provided by the parties, the only affected markets where Schering-Plough and Intervet would have a combined market share over 25% in the EEA at the national level are:

- Gumboro vaccines for poultry in Spain; and
- Laryngotracheitis vaccines for poultry in Spain and Portugal.

255. In addition, concerns were raised by some respondents to the market investigation as to the coccidiosis vaccines for poultry. Concerns were first raised that Intervet has a pipeline product for a coccidiosis vaccine which would compete with Schering-Plough's product. Concerns were also raised as to a possible anti-competitive poultry vaccine portfolio effect, as the merger would combine Intervet's very important portfolio of poultry vaccines (Intervet is by far the leading supplier of poultry vaccines in the EEA with an overall market share of around [30-40] %) and Schering-Plough's very strong position with the key coccidiosis vaccines.

256. These markets are examined in turn below.

(1) Gumboro vaccines

Product market definition

257. Gumboro disease (or Infectious Bursal Disease ('IBD')) is a viral disease affecting young chickens. The causative agent is the *Birna* virus which destroys immature B-cells in the bursa of Fabricius (an important organ in young chickens that helps to develop the animal's immune system) resulting in immuno-suppression. B-cells are lymphocytes (a type of white blood cell) that support immunity in animals.

258. The IBD virus is highly virulent and causes symptoms such as ruffled feathers, droopy appearance, dehydration and poor feeding. Gumboro disease can also cause secondary infections (such as *E.coli*) as the animal's immune system is already severely impaired. The mortality rate of young chickens with Gumboro disease is up to 40 percent, and dealing with this problem is best achieved by vaccination. Poultry can be vaccinated against Gumboro disease using a Gumboro vaccine (in Europe, Gumboro is always administered as a monovalent vaccine).

259. Applying the principles of market definition defined above, the parties consider that monovalent gumboro vaccines for poultry form part of a distinct product market. The market investigation has not raised any issue concerning the product market definition retained by the parties.

260. The relevant product market for purposes of assessing the impact of the proposed concentration is therefore the market for monovalent gumboro vaccines for poultry.

Competitive assessment

261. Schering-Plough sells a gumboro vaccine under the brand *Univax BD*, and Intervet sells two gumboro vaccines (with different strains) *Nobilis Gumboro D78* and *Nobilis 228e*.

262. Based on data provided by the parties, the only affected market where Schering-

Plough and Intervet would have a combined market share of at least 25% in the EEA at the national level is Spain.

Competitors	Spain
Schering-Plough	[0-5] %
Intervet	[40-50] %
Combined	[40-50] %
Hipra	[30-40] %
Fort Dodge	[10-20] %
Merial	[0-5] %
Calier[51]	[0-5] %
Total	100%

263. Schering-Plough's sales are very limited and the new entity will continue to face strong competitors, in particular the Spanish company Hipra, Fort Dodge and Merial (which are also two strong suppliers of poultry vaccines at the EEA level).

264. In any event, Schering-Plough intends to withdraw from the Spanish market for […] reasons unrelated to the proposed transaction (see below competitive assessment for laryngotracheitis vaccines).

265. The Commission therefore takes the view that the proposed concentration does not raise serious doubts as to its compatibility with the common market as regards the market for gumboro vaccines for poultry in Spain.

(2) Laryngotracheitis vaccines

Product market definition

266. Infectious laryngotracheitis ("ILT") is an acute infection caused by the *gallid* herpesvirus-*1* (GaHV-1), which is one of the most contagious viruses that affects the poultry industry. In acute form, infectious laryngotracheitis gives rise to gasping, coughing, rattling and extension of the neck of the infected bird during inhalation. The mouth and beak may become blood-stained from the blood, mucus and phlegm exhaled from the bird's windpipe. Infected birds become severely underweight and inactive, which results in reduced productivity. Mortality may reach up to 50 percent in adult animals. In Europe, infectious laryngotracheitis vaccines are always live and monovalent.

267. Applying the principles of market definition defined above, the parties consider that monovalent laryngotracheitis vaccines for poultry form part of a distinct product

51 Distributing a Lohmann Animal Health product.

market. The market investigation has not raised any issue concerning the product market definition retained by the parties.

268. The relevant product market for purposes of assessing the impact of the proposed concentration is therefore the market for monovalent laryngotracheitis vaccines for poultry.

Competitive assessment

269. Schering-Plough sells a gumboro vaccine under the brand *LT-IVAX*, and Intervet sells under the brand *Nobilis ILT*.

270. Based on data provided by the parties, the affected markets where Schering-Plough and Intervet would have a combined market share of at least 25% in the EEA at the national level are Spain and Portugal.

Competitors	**Spain**	**Portugal**
Schering-Plough	[80-90] %	[50-60] %
Intervet	[5-10] %	[40-50] %
Combined	[90-100] %	[90-100] %
Fort Dodge	[0-5] %	--
Total	100%	100%

271. Despite the high combined market shares of the parties on this market in Spain and Portugal, the merger will not have any anticompetitive effect as Schering-Plough is about to withdraw from the Spanish market for laryngotracheitis vaccines for poultry, for […] reasons unrelated to the present transaction.

272. […].

273. […].

274. The parties provided a copy of internal documents establishing these facts[52]. In particular, these internal documents establish the existence of […] and show that Schering-Plough forecasted in 2005 to have no sales in 2007-2008 in Spain following its decision […].

275. This will lead to Schering-Plough's withdrawal from the Spanish […].

276. Schering-Plough's *LT-IVAX* vaccines for poultry are therefore expected to be withdrawn soon from the Spanish market, and would in the near future no longer

52 See […] see […].

exercise any competitive constraint on Intervet on the market for laryngotracheitis vaccines for poultry in Spain.

277. Because […], withdrawal from the Spanish market will also lead to withdrawal from the Portuguese market.

278. The Commission therefore takes the view that the proposed concentration does not raise serious doubts as to its compatibility with the common market as regards the market for laryngotracheitis vaccines for poultry in Spain and Portugal.

(3) Coccidiosis vaccines

279. As mentioned above, Schering-Plough has a small range of poultry vaccines. Indeed, the bulk of Schering-Plough's sales of poultry vaccines in the EEA are achieved with coccidiosis vaccines marketed under the brands *Paracox 5* and *Paracox 8*.

280. Coccidiosis is caused by coccidia parasites that are found most commonly in chickens raised in confinement, where access to each other's droppings mixed with feed on the house floor facilitates the spread of coccidia. As a result, all chickens have some of these parasites in their digestive tracts at all times. The parasites irritate the chickens' gut and interfere with the chickens' efficient conversion of feed into weight gain. As a result, poultry producers must constantly manage the types and levels of coccidia parasites present in the intestinal tract of their chickens in order to minimise interference with the chickens' digestion and feed conversion.

281. Applying the principles for market definition set out above (species, target disease and monovalent/multivalent), it might be relevant to distinguish a product market for coccidiosis vaccines[53].

282. However, the parties submit that coccidiosis vaccines compete with pharmaceutical treatments called 'coccidiostats', which are chemicals administered in feed rations to poultry. Because coccidia are protozoa parasites (not viruses or bacteria), both antibiotic coccidiostats and coccidiosis vaccines can create an immunological response in chickens. As a matter of fact, the parties submitted that in the EEA, around 80% of chickens are treated with coccidiostats as opposed to vaccines.

283. The respondents to the market investigation confirmed that coccidiostats are to a certain extent substitutable for coccidiosis vaccines.

284. However they pointed out that coccidiostats and coccidiosis vaccines cannot be used on a same flock of chickens. They also stressed that coccidiosis vaccines can be needed in several cases, notably when the producer tries to avoid the need to medicate during the whole life of the bird and there is time enough for compensatory growth (bio production or long life birds, namely layers and breeders). Finally, the practice differs between the countries: for instance in Italy and Greece, chickens are massively vaccinated.

285. Although it cannot be excluded that coccidiosis vaccines and coccidiostats belong to separate product market, the exact product market definition may be left open for the

[53] There is no multivalent coccidiosis vaccine.

purpose of the present decision, as serious doubts can be excluded under both alternative market definitions.

286. Several third parties raised two issues relating to the poultry coccidiosis vaccine.

287. Firstly, the merger would remove a potential competitor on the markets for coccidiosis vaccines. Indeed Schering Plough markets a coccidiosis vaccine and has a monopolistic position on this market in most EEA countries, while Intervet has a pipeline coccidiosis vaccine.

288. Secondly, as a result of the concentration, the new entity would be the only competitor able to supply a full range of key poultry vaccines throughout the EEA (conglomerate effect), since Intervet already has a very important portfolio of poultry vaccines and Schering-Plough has a key vaccine (coccidiosis vaccine) that Intervet does not sell.

289. As to the first issue (removal of a potential competitor), the Commission found that serious doubts are not sufficiently grounded.

290. Based on data provided by the parties[54], Schering-Plough has currently a monopolistic position on coccidiosis vaccines in most EEA countries[55]. In parallel, Intervet, the first market player by far on poultry vaccines in the EEA[56], has a pipeline product on coccidiosis vaccine […][57].

291. However, the investigation carried out by the Commission showed that other competitors are entering the coccidiosis market or intend to do so while Intervet is not likely to launch a coccidiosis vaccine before […].

292. Indeed, Hipra, a Spanish supplier of animal vaccines including poultry vaccines, is launching three coccidiosis vaccines (Hipracox) very soon[58] […][59]. Moreover, the Commission found that other competitors intend to launch a coccidiosis vaccine in the EEA or to enter EEA countries with an already existing coccidiosis vaccine. As a matter of fact, coccidioisis vaccines are viewed as a growing market by all competitors.

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54 The notifying party was not able to provide data for Cyprus, Slovenia, Malta, Iceland and Liechtenstein.

55 The only countries were Schering-Plough does not have a strict monopoly are Italy (market share: [90-100]% in value), Hungary ([40-50] %) and Poland ([30-40] %).

56 Intervet has a share of around [30-40] % on sales of poultry vaccines in the EEA. The other significant competitors at the EEA level are Merial ([10-20] %), Fort Dodge ([10-20] %) and Schering-Plough ([10-20] %).

57 See Schering-Plough's internal document: "Poultry business unit – 2006-2007 operating plan, principal factors and critical issues-global market".

58 Three Hipra's coccidiosis vaccines (Hipracox Broilers Oral Suspension, Hipracox Broilers dw, Hipracox Broilers Sprayhave) have already been successfully registered for authorised use in the United Kingdom (see Veterinary Medicines Directorate at http://www.vmd.gov.uk/ProductInfo/AuthMed/categories.htm), two of them having been registered during the last six months. In addition, Hipra has a patent registered for Hipracox in Ireland (see Patents Office Journal-25/01/2006 – Government of Ireland).

59 […].

293. In addition, as specified in some recent Intervet's internal documents[60], Intervet is not likely to launch a coccidiosis vaccine in the EEA before […].

294. As to the second issue (conglomerate effect), the Commission found that serious doubts cannot be substantiated.

295. Firstly, coccidiostats (chemical feed additives used against coccidiodis disease), are to a certain extent substitutable to coccidiosis vaccines and only around 12-13% of the poultry population is treated by means of coccidiosis vaccines (the others being treated with coccidiostats). Therefore, on a market for the treatment of coccidiosis (coccidiosis vaccines and coccidiostats) Schering-Plough's market share would be limited.

296. Secondly, the entry or the potential entry of other competitors on the markets for poultry vaccines in the EEA would allow them to offer a complete portfolio of poultry vaccines, which would reduce the new entity's ability to engage in anticompetitive practices. Moreover, as raised by the respondents to the market investigation, the poultry industry, which is concentrated[61], appears to have countervailing buyer power and usually practices multi-sourcing for vaccines. This would therefore reduce the new entity's incentive to adopt foreclosure behaviour.

Pharmaceuticals

a) Anti-inflammatories

Product market definition

297. Anti-inflammatory drugs are used to treat inflammation (i.e., a localised protective reaction of tissue to irritation, injury, or infection) and to reduce the pain and fever associated with inflammation.

298. In line with Commission precedent in the Pfizer/Pharmacia case, the parties submit that anti-inflammatories may be sub-divided into two categories: (i) non-steroidal anti-inflammatory drugs ("NSAIDs"); and (ii) corticosteroids[62]. Although NSAIDs and corticosteroids both have anti-inflammatory properties, only NSAIDs have analgesic (anti-pain) and anti-pyretic (anti-fever) properties. Furthermore, NSAIDs can relieve pain and inflammation without the immunosuppressive and metabolic side-effects associated with corticosteroids. NSAIDs also tend to be more expensive than corticosteroids (up to twice the price).

299. In Pfizer/Pharmacia, the Commission also considered whether a further delineation should be made between anti-inflammatories prescribed for acute conditions and anti-

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61 For instance, in Italy, the three major poultry integrators (i.e., companies breeding poultry on an industrial scale) have a combined market share of 67% on the national poultry market. In the United Kingdom, the five major poultry integrators have a combined share of 95% on the national poultry market. Around 37% of EEA coccidiosis sales are achieved in Italy and the United Kingdom together (data communicated by the parties).

62 Case COMP/M.2922 – Pfizer/Pharmacia, paras. 143 and following.

inflammatories prescribed for chronic conditions, but left the market definition open. The parties submit that NSAIDs and corticosteroids can be further sub-divided along these lines.

300. Acute inflammation is a short-term process that is characterised by rapid onset and the cardinal signs of inflammation following injury. The parties submit that anti-inflammatory products used to control acute conditions tend to be fast-acting injectables[63] and are generally indicated for all species (i.e., ruminants, swine, horses and companion animals).

301. Chronic inflammation is characterised by longer duration of inflammation due to a continued action of the pathogens inducing inflammatory reaction of the organism. The signs and symptoms of chronic inflammation are not as dramatic as those associated with acute inflammation. If an inflammatory reaction starts as acute but persists, it will enter a chronic phase. Anti-inflammatory products used to control chronic conditions are indicated predominantly for companion animals and are therefore generally orally administered treatments so that they can be dispensed by the owner over the long-term treatment period. The parties submit that the delineation for chronic inflammation should be made only in the case of companion animals and horses as in the case of farm animals chronic inflammation is not treated as it does not make economic sense.

302. Applying the principles set out above, the parties identified the following three relevant product markets:

- NSAIDs for the treatment of acute inflammation in ruminants, swine, horses and companion animals ('multi-species');
- NSAIDs for the treatment of chronic inflammation in companion animals; and
- corticosteroids for the treatment of acute inflammation (multi-species).

303. In Pfizer/Pharmacia, the Commission further found that NSAIDs and corticosteroids may further be subdivided by relevant factors such as the route of administration and the species for which a particular formulation is intended. Following this approach in Pfizer/Pharmacia, the Commission defined two markets: (i) orally administered NSAIDs for horses; and (ii) injectable corticosteroids. The product market definition retained by the parties was therefore not fully in line with the Commission precedents where the species and way of administration constituted a defining factor.

304. The market investigation supported the distinction between NSAIDs and corticosteroids, but did not otherwise support the product market definition retained by the parties. First, respondents took the view that orally administered NSAIDs for horses should be assessed as a distinct product market, as injectable NSAIDs are usually administered by the veterinarian whereas oral ones can be and usually are administered by the animal owner, therefore there is a limited substitution from the demand side. Secondly, respondents did not support the distinction between anti-

63 There are, however, also a few fast-acting oral products for the control of acute inflammation, such as Schering-Plough's Finadyne Paste and Finadyne Granules and Intervet's Quadrisol 100 and Equipalazone.

inflammatories for the treatment of acute and of chronic inflammation as both treatments are usually based on the same active ingredient. In this respect a distinction based on the route of administration is more relevant.

305. Some respondents to the market investigation also suggested that injectable NSAIDs could be further subdivided by species. However, further investigation revealed that although they are some injectable NSAIDs that are specifically targeted for horses, dogs and cats respectively, there are also injectable NSAIDs that are truly multi-species, which makes the task of estimating their use for each species very difficult. Such further segmentation could also lead to unrealistically small markets.

306. The relevant product markets for purposes of assessing the impact of the proposed concentration are the following:

    a. Injectable NSAIDs for ruminants, swine, horses and companion animals ('multi-species');

    b. Orally administered NSAIDs for horses;

    c. Orally administered NSAIDs for dogs and cats; and

    d. Corticosteroids for ruminants, swine, horses and companion animals ('multi-species')

Competitive assessment

307. The proposed transaction gives rise to affected markets as regards multi-species injectable NSAIDs, orally administered NSAIDs for horses and corticosteroid multi-species anti-inflammatories.

(1) Injectable NSAIDs (multi-species)

308. Based on data provided by the parties, the transaction gives rise to the following affected markets where Schering-Plough and Intervet would have a combined market share of at least 25% in the EEA at the national level (2006 data):

Competitors	Italy	Portugal	Sweden
Schering-Plough	[10-20] %	[20-30] %	[0-5] %
Intervet	[5-10] %	[0-5] %	[20-30] %
Combined	[20-30] %	[20-30] %	[20-30] %
Pfizer	[0-5] %	[5-10] %	--
BI	[0-5] %	[0-5] %	[10-20] %
Fort-Dodge	[10-20] %	[10-20] %	--
Ceva	[10-20] %	--	--
Merial	[20-30] %	[0-5] %	[10-20] %
Vetoquinol	[0-5] %	[10-20] %	--
Orion	--	--	[20-30] %
Callier	--	[10-20] %	--
Farmoquil	--	[10-20] %	--
Bimeda	--	--	[10-20] %
Others	[5-10] %	--	[0-5] %
Total	100%	100%	100%

309. In Italy, Portugal and Sweden, numerous other significant competitors are present and will continue to exercise competitive pressure on the parties. Moreover, the market investigation indicated that some segments of the multi-species injectable NSAIDs markets are expected to grow (in particular, for companion animals). Generic competition is also expected to grow for NSAIDs.

310. The Commission therefore concludes that the proposed transaction does not raise serious doubts as to its compatibility with the common market and the EEA agreement on the markets for injectable NSAIDs for ruminants, swine, horses and companion animals ('multi-species').

(2) Orally administered NSAIDs for horses

311. Schering-Plough sells orally administered NSAIDs for horses under the brands *Finadyne Paste* and *Finadyne Granules*, and Intervet under the brands *Quadrisol 100* and *Equipalazone*[64].

312. Based on data provided by the parties, the transaction gives rise to the following affected markets where Schering-Plough and Intervet would have a combined market share of at least 25% in the EEA at the national level (2006 data):

64 Intervet supplies orally administered NSAIDs for horses in France and Germany […]

Competitors	B/LUX	DK	FIN	F	GER	NOR	SWE
Schering-Plough	[40-50] %	[50-60] %	[20-30] %	[10-20] %	[5-10] %	[40-50] %	[20-30] %
Intervet	[5-10] %	[5-10] %	[10-20] %	[60-70] %	[30-40] %	[40-50] %	[0-5] %
Combined	[50-60] %	[60-70] %	[40-50] %	[80-90] %	[40-50] %	[90-100] %	[20-30] %
BI	[40-50] %	[30-40] %	[50-60] %	[10-20] %	[30-40] %	--	[0-5] %
Pfizer	--	--	--	--	[5-10] %	--	--
Vetxx	--	--	--	--	--	[5-10] %	[50-60] %
Aristavet	--	--	--	--	[5-10] %	--	--
N-Vet	--	--	--	--	--	--	[10-20] %
Others	--	--	--	--	[0-5] %	--	--
Total	100%	100%	100%	100%	100%	100%	100%

313. The merger would therefore lead to very high market shares of the new entity in France ([80-90] %) and Norway ([90-100] %), where they would only face a much smaller competitor Boehringer Ingelheim ([10-20] %) in France and Vetxx ([5-10] %) in Norway. Given the barriers to entry, the parties will not face strong competitive constraints in these countries post-merger.

314. The Commission therefore concludes that the proposed transaction raises serious doubts as to its compatibility with the common market and the EEA agreement on the markets for orally administered NSAIDs for horses in France and Norway. The existence or not of serious doubts as regards the markets for orally administered NSAIDs for horses in Belgium/Luxembourg, Denmark, Finland, Germany and Sweden can be left open for the purposes of the present decision as the remedy submitted by Schering-Plough has an EEA-wide geographic scope.

(3) Corticosteroids (multi-species)

315. Based on data provided by the parties, the transaction gives rise to the following affected markets where Schering-Plough and Intervet would have a combined market share of at least 25% in the EEA at the national level (2006 data):

Competitors	France	Greece	Italy
Schering-Plough	[0-5] %	[5-10] %	[0-5] %
Intervet	[20-30] %	[10-20] %	[60-70] %
Combined	[20-30] %	[20-30] %	[60-70] %
Pfizer	[30-40] %	--	[0-5] %
Fort-Dodge	--	--	[5-10] %
Ceva	--	--	[5-10]%
Bayer	--	--	[0-5] %
Merial	[0-5] %	--	--
Veterin	--	[50-60] %	--
Fatro	--	--	[0-5] %
BI	[30-40] %	--	[5-10] %
Hellapharm	--	[10-20] %	--
Others	[0-5] %	[0-5] %	[0-5] %
Total	100%	100%	100%

316. In France and Greece, numerous other significant competitors are present and will continue to exercise competitive pressure on the parties. In France, the parties will face competition from the significant players Boehringer Ingelheim ([30-40] %) and Pfizer ([30-40] %), and in Greece from the local companies Veterin ([50-60] %) and Hellapharm ([10-20] %), which have increased their sales to the detriment of the parties in recent years.

317. In Italy, however, the parties would have a high combined market share of [60-70] %, and its competitors' positions are much weaker (Pfizer [0-5] %, Boehringer Ingelheim [5-10] %, Ceva [5-10] %).

318. The Commission therefore concludes that the proposed transaction raises serious doubts as to its compatibility with the common market and the EEA agreement on the markets for corticosteroids for ruminants, swine, horses and companion animals ('multi-species') in Italy.

(4) Remedies

319. With the objective of resolving the serious doubts identified by the Commission on the markets for orally administered of NSAIDs for horses in France and Norway and on the market for corticosteroids (multi-species) in Italy, Schering-Plough committed to the EEA-wide divesture to a suitable purchaser of the orally administered NSAIDs for horses currently marketed by Intervet under the brand *Equipalazone* and the corticosteroid multi-species anti-inflammatory formulations currently marketed by Intervet under the brand *Predsolan Injectable* (see **Schedule 11**).

320. Respondents to the market test on the commitments indicated that the proposal to divest *Equipalazone* would not address the competition concerns in all the countries concerned and would not constitute a sizable and viable business, as *Equipalazone* is a third party product which Intervet distributes in France and Germany only. Following the market test, Schering-Plough therefore added to the products to be transferred EEA-wide *Quadrisol 100*, which is the brand under which Intervet's oral NSAIDs for horses is registered and marketed in all the EEA countries. Schering-Plough commits to re-brand in the EEA products other than *Quadrisol 100* sold under the *Quadrisol* brand. For the *Equipalazone*, the divestiture will consist in the assignment of the agreements with […] necessary for the sale of *Equipalazone* in the EEA[65].

321. The Commission is of the view that the proposed remedy removes the serious doubts and restores effective competition, as it removes the entire overlap in all the affected national markets for orally administered NSAIDs for horses, and in the market for corticosteroid multi-species anti-inflammatories in Italy. In particular, the divested business will have a sufficient size to create a viable competitor. The fact that the divestment also includes the product *Quadrisol 100* ensures that the purchaser will acquire a sizeable business with a well-known brand and a complete portfolio of NSAIDs for horses that it can expand throughout Europe.

322. As confirmed by the market test, the divested business contains all tangible and intangible assets that the purchaser will need to conduct the business as a viable and independent business, i.e. the relevant trademarks, product formulations, know-how and customer details.

323. The transfer of Schering-Plough's existing marketing authorisations and the arrangements for the supply of the purchaser by the merged entity during the transitional period while the purchaser sets up its own manufacturing and obtains the necessary regulatory approvals will ensure that the purchaser is able from day one to compete on a level playing field with the new entity.

324. The Commission, therefore, concludes that the divestiture of the European-wide *Equipalazone* and *Quadrisol 100* business of Schering-Plough and the *Predsolan Injectable* brand in Italy will restore effective competition and that the proposed transaction does not raise serious doubts on condition of the implementation of this remedy.

b) Antimicrobials

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

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65 The commitments contain some safeguards in case assignment of the agreements with […] is not possible: Schering-Plough will assist the purchaser in negotiating an agreement with […] for the supply of *Equipalazone* to the purchaser on terms and conditions similar to those of the agreement with […], or, if such agreement cannot be concluded, commits to enter into a sub-contract for the supply of *Equipalazone* to the purchaser on a reasonable cost plus basis.

326. Both Schering-Plough and Intervet sell antimicrobials for animals.

327. Based on data provided by the parties, the only affected markets where Schering-Plough and Intervet would have a combined market share over 25% in the EEA at the national level are:

- *Cephalosporin for large animals* in the Czech Republic, Greece, Poland, Portugal, Slovakia, Spain and the United Kingdom;
- *Penicillin for large animals* in Portugal, Spain and the United Kingdom;
- *Fluoroquinilones for companion animals* in the Netherlands;
- *Sulphonamides for large animals* in Austria, Belgium/Luxembourg, Denmark, Finland, Germany, Ireland, Norway, Portugal, Spain, and Sweden;
- *Sulphonamides for companion animals* in Denmark;
- *Phenicols for large animals* in Italy;
- *Mastitis in lactating cows* in France and Germany;
- *Mastitis in dry cows* in Belgium/Luxembourg, France, Greece, Ireland, Italy, Poland, Portugal, Slovenia, Spain and the United Kingdom; and
- *Otitis antimicrobials for companion animals* in Italy.

328. These markets are examined in turn below.

Product market definition

General considerations on market definition

329. In previous decisions[66], the market definition of anti-microbials has been driven by: (i) the active substance: in this respect the following main categories were singled out: (eg. sulphanomides, penicillins, cephalosporins, tetracyclines, etc.); (ii) the route of administration - in this respect the following main categories were singled out: injectable products, products for oral administration and products for topical administration (such as intra-mammary mastitis treatments).

330. The parties agree with the Commission that the class of antimicrobial defined by its basic chemical properties (i.e., active ingredient) and the resulting effect on bacteria is likely to be a good starting point for defining the relevant markets. However, the parties do not consider that beta-lactams should be further subdivided into penicillin and cephalosporin. Therefore, the parties submit that the following classes of antimicrobials should be considered for the purpose of the competition assessment: aminocyclitols, aminoglycosides, beta-lactams, quinolones, lincosamides, macrolides, sulphonamides, tetracyclines, phenicols.

331. For the case at hand, the question of a further distinction between penicillin and cephalosporin can be left open since the proposed transaction does not give rise to serious doubts under any alternative product market definition. However the detailed

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66 See Case COMP/M.2922 – Pfizer/Pharmacia, paragraphs 122-123; Case COMP/M.1681 – Akzo Nobel/Hoechst, paragraph 19.

assessment will be done only for the markets for penicillin and cephalosporin since this segmentation gives rise to more national affected markets and/or to similar or higher parties' combined market shares.

332. The parties also concur with the Commission that the mode of application plays a decisive role only in relation to certain types of products, in particular products used to treat mastitis. These products are usually applied through an intra-mammary infusion. This constitutes a fundamental distinction from other antimicrobials, a fact that is reflected in the existence of dedicated mastitis products. According to the parties, similar considerations apply in the case of topically applied products and products designed to treat otitis (i.e ear infections).

333. The parties also submit that another distinction should be made between large animals (such as horses, ruminants, and swine) and companion animals (cats and dogs). The products indicated for both groups usually differ in terms of respective concentrations of the active substance and the way of administration - products for large animals are predominantly administered by injection, whereas products for small animals are often administered orally.

Alternative way to define anti-microbial markets – target pathology

334. This broad segmentation has been generally approved by the market investigation. However, a minority of respondents pointed out that the market definitions based on the target pathology, in particular bovine respiratory disease ('BRD') would be more appropriate than the ones based on the active substance. This issue was already widely discussed in Pfizer/Pharmacia[67] and the Commission finally decided that at least for penicillins classification by active ingredient is the most appropriate.

335. The parties strongly disagree with an alternative approach to defining anti-microbial markets, based on the target pathology. They submit that it would split the relevant market into a vast number of individual product markets; this would ultimately force the Commission to consider a very large number of competitive relationships that individually would often be too small to produce meaningful results. The parties provided a number of arguments using the specific example of BRD as to why the approach by target pathology is not workable in the context of competitive assessment in merger control. Some of those arguments have also been raised by the respondents to the market investigation.

336. In the first place BRD is not a single 'target pathology' i.e. BRD is not a specific disease caused by an individual pathogen. Rather, the term refers to a number of clinical symptoms that all concern the animal's respiratory system to describe a general clinical state. The underlying diseases are upper respiratory tract infections, diphtheria, and pneumonia (lower respiratory tract infection). Therefore it is doubtful whether BRD as a whole should be treated as a relevant product market or it should be further broken down into specific infections.

337. Second, another distinction would have to be drawn between the treatment itself (which is generally achieved by fast acting substances, eg. cephalosporins) and

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67 Case COMP/M.2922 – Pfizer/Pharmacia , paras. 132-137.

control/prevention where long acting classes (such as macrolides) are more suitable.

338. Third, many different antimicrobials are used to treat BRD and the same antimicrobials are usually also used for a variety of other pathologies, therefore any market data for a given pathology is much more speculative and less reliable than CEESA data based on active ingredient.

339. In light of the additional evidence provided by the parties and the fact that majority of respondents to the market investigation were supportive of the market segmentation by active ingredient, the Commission concludes that target pathology is not the suitable appropriate way to define markets in anti-microbials.

Intra-mammary mastitis treatment

340. Mastitis is an infection of the cow's mammary glands or udder, and is a recurring problem for dairy farming, in particular in the case of lactating cows. These products are administered through a specially-designed syringe (injector tube) that is inserted into the animal's teat canal by which the antibiotic compound is then released into the udder. This mode of application, as well as a special formulation that makes them particularly effective against the relevant bacteria and allows them to function over a certain period of time in their particular environment (inside the cow's udder), distinguish these products from other antimicrobial products. The parties agree with the Commission that the mastitis treatment constitute a separate product market due to their specific way of administration.

341. In previous decisions, the Commission also found that there are two different types of mastitis infections[68]:

    a. 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 as the milk must be discarded during the period in which the drug is active;

    b. Chronic infections (or sub-clinical mastitis) cause an increased number of white blood cells in the milk (somatic cells), 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').

342. The Commission found that the products designed to treat these two types are in separate products markets and the parties do agree with this view.

343. Finally, the Commission also considered that both mastitis products (dry and lactating) based on different anti-infective compounds (mainly cephalosporin and penicillin) could be considered as separate product markets. The parties disagree that an active ingredient should constitute a relevant criterion for the definition of product market. The further segmentation by active ingredient has not been supported by the

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68 Case COMP/M.2922 – Pfizer/Pharmacia, paragraphs 126-131.

majority of the respondents to the market investigation. In any case, this issue can be left open as the key products of the parties are cephalosporin based and the transaction gives rise to serious doubts even if they are considered as part of the wider mastitis dry cow and lactating cow treatments[69].

344. The parties finally considered that in the treatment of mastitis during a cow's dry period "short acting" (i.e. characterised by a 35-40 days withdrawal period) products are not substitutable with "long acting" (i.e. characterised by a 60 days withdrawal period) products. Thus, although both Schering-Plough and Intervet produce dry cow mastitis treatments, in their view, these products are for the most part, not substitutable for one another as Schering-Plough's product is a long acting one whereas Intervet's ones are short acting.

345. The respondents to the market investigation disagreed with the parties' view that withdrawal periods constitute a relevant criterion to define separate product markets in mastitis dry cow treatment and pointed out that the parties products are relatively close competitors and the parties position them as such in advertising campaigns. It has been pointed out that in general all dry cow products are considered as long-term treatments as opposed to lactating cow products which are by definition fast acting products. The key criterion for the choice of a mastitis dry cow product is the perceived product efficacy and the farmer's/veterinarian's brand awareness and habits.

346. Therefore, the Commission considers that for the purposes of this transaction the relevant product market encompasses: (i) mastitis treatment for the lactating cow; (ii) mastitis treatment for the dry cow with a possible further segmentation by active ingredient.

Competitive assessment

(1) Cephalosporin for large animals

347. Based on data provided by the parties, the transaction gives rise to the following affected markets where Schering-Plough and Intervet would have a combined market share of at least 25% in the EEA at the national level (2006 data):

[69] Therefore under such narrower market definition the competition would be even more seriously affected.

Competitors	CZ	GRE	POL	PT	SK	SP	UK
Schering-Plough	[10-20]%	[10-20]%	[10-20]%	[5-10]%	[10-20]%	[5-10]%	[30-40]%
Intervet	[30-40]%	[40-50]%	[10-20]%	[10-20]%	[30-40]%	[20-30]%	[5-10]%
Combined	[40-50]%	[50-60]%	[30-40]%	[20-30]%	[50-60]%	[20-30]%	[40-50]%
Pfizer	[40-50]%	[30-40]%	[50-60]%	[70-80]%	[40-50]%	[60-70]%	[50-60]%
Virbac	[5-10]%	--	[10-20]%	--	[0-5]%	--	--
Novartis	--	[10-20]%	--	--	--	--	--
Veterina	--	--	--	--	--	--	--
Callier	--	--	--	--	--	[0-5]%	--
Norbrook	--	--	--	--	--	--	--
Diana	--	--	--	--	--	[0-5]%	--

348. The parties' combined market share is above [30-40] % in the Czech Republic ([40-50] %, Schering-Plough: [10-20] %, Intervet: [30-40] %), Greece ([50-60] %, Schering-Plough: [10-20] %, Intervet: [40-50] %), Slovakia ([50-60] %, Schering-Plough: [10-20] %, Intervet: [30-40] %) and the United Kingdom ([40-50] %, Schering-Plough: [30-40] %, Intervet: [5-10] %).

349. However, the transaction will not give rise to serious doubts for the following reasons.

350. Firstly, Pfizer would remain by far the first market player in most national markets. In the Czech Republic, Greece and Slovakia, where parties would get mathematically the highest market share, Pfizer would remain an important second best player, exercising a considerable constraint, alongside another competitor (Czech Republic: Virbac, ([5-10] %); Greece: Novartis ([10-20] %); Slovakia: Virbac ([0-5]%)).

351. Secondly, the parties' products are not the closest competitors – Schering-Plough's products are first-generation mainly active against gram-positive bacteria, whereas Intervet's product is fourth-generation also efficient against gram-negative bacteria.

352. Thirdly, in the first generation cephalosporins, Schering-Plough faces a number of credible closest competitors, with Virbac being equally strong as Schering-Plough at the EEA level; in the higher generations Intervet will continue to face competition from much larger Pfizer and the merger does not change anything in this respect.

353. Finally, the generic competition is expected to grow as the key active ingredients are off-patent.

354. The Commission, therefore, concludes that the proposed transaction does not raise serious doubts as to its compatibility with the common market and the EEA agreement on the markets for cephalosporins for large animals.

(2) Penicillin for large animals

355. Based on data provided by the parties, the transaction gives rise to the following affected markets where Schering-Plough and Intervet would have a combined market share of at least 25% in the EEA at the national level (2006 data):

Competitors	**Portugal**	**Spain**	**UK**
Schering-Plough	[10-20] %	[20-30] %	[10-20] %
Intervet	[20-30] %	[5-10] %	[10-20] %
Combined	[30-40] %	[30-40] %	[20-30]%
Pfizer	--	[5-10] %	[40-50] %
BI	[20-30] %	[5-10] %	--
Fort-Dodge	--	[10-20] %	[20-30] %
Ceva	[20-30] %	[0-5] %	--
Veterin	--	--	--
Norbrook	--	--	--
Vetoquinol	--	[5-10] %	--
Bimeda	--	--	--
Others	[10-20] %	[20-30] %	--

356. The parties' combined market shares are below 40% and the new entity would still face significant competitors in each of the three national markets affected. Moreover, the generic competition is expected to grow as the key active ingredients are off-patent. Finally, the market investigation was not indicative of serious doubts as regards the markets for penicillin for large animals.

(3) Fluoroquinolones for companion animals

357. Based on data provided by the parties, the transaction gives rise to the following affected market where Schering-Plough and Intervet would have a combined market share of at least 25% in the EEA at the national level (2006 data):

Competitors	**Netherlands**
SP	[0-5] %
Intervet	[30-40] %
Combined	[30-40] %
Bayer	[60-70]%

358. The proposed concentration gives rise to a very small market share accretion in the Netherlands, and the new entity would face a much stronger competitor (Bayer).

359. The Commission therefore concludes that the proposed transaction does not raise serious doubts as to its compatibility with the common market and the EEA agreement on the market for fluoroquinolones for companion animals in the Netherlands.

(4) Sulphanomides for large animals

360. Based on data provided by the parties, the transaction gives rise to the following affected markets where Schering-Plough and Intervet would have a combined market share of at least 25% in the EEA at the national level (2006 data):

Competitors	**Austria**	**B/Lux**	**DK**	**Finland**	**Germany**	**Ireland**	**Norway**	**Portugal**	**Spain**	**Sweden**
Schering-Plough	[80-90]%	[10-20]%	[20-30]%	[40-50]%	[20-30]%	[30-40]%	[40-50]%	[70-80]%	[20-30]%	[80-90]%
Intervet	[10-20]%	[10-20] %	[40-50] %	[30-40] %	[10-20] %	[10-20]%	[10-20]%	[5-10]%	[5-10] %	[10-20]%
Combined	[90-100]%	[20-30]%	[70-80]%	[80-90]%	[40-50]%	[40-50]%	[50-60]%	[80-90]%	[20-30]%	[90-100]%
Pfizer		[20-30]%							[40-50]% %	
Fort Dodge		[0-5]%			[0-5]%				[5-10] %	
Virbac									[0-5]%	
Bayer		[0-5]%							[5-10] %	
Ceva					[5-10] %	[5-10]%				
Vetoquinol						[10-20]%		[5-10]%		
Elanco		[10-20]%								
Alpharma								[10-20]%		
Eurovet		[20-30]%								
Norbrook			[10-20]%			[20-30]%				
Scan Vet			[10-20]%				[40-50]%			
Orion				[10-20]%						
Albrecht					[0-5]%					
Ani Medica					[0-5]%					
Medistar					[5-10]%					
Veyx					[10-20]%					
Others		[0-5]%			[5-10]%					

361. The merger would lead to very high market market shares of the new entity in Austria (parties' combined market share: [90-100] %; SP: [80-90] %, Intervet: [10-

20]%) and Sweden ([90-100] %, Schering-Plough: [80-90] %, Intervet: [10-20] %) where monopolies are created, Denmark ([70-80] %, Schering-Plough: [20-30] %, Intervet: [40-50] %), Finland ([80-90] %, Schering-Plough: [40-50] %, Intervet: [30-40] %) and Portugal ([80-90] %, Schering-Plough: [70-80] %, Intervet: [5-10] %).

362. On each of these national markets the new entity would face no competitor (Austria and Sweden) or much smaller competitors. Given the barriers to entry, the parties will not face strong competitive constraints in these countries post-merger.

363. The Commission therefore concludes that the proposed transaction raises serious doubts as to its compatibility with the common market and the EEA agreement on the markets for sulphanomides for large animals in Austria, Denmark, Finland, Portugal and Sweden. The existence or not of serious doubts as regards the markets for sulphanomides for large animals in Belgium/Luxembourg, Germany, Ireland, Norway and Spain can be left open for the purposes of the present decision as the remedy submitted by Schering-Plough has an EEA-wide geographic scope.

(5) Sulphanomides for companion animals

364. Based on data provided by the parties, the transaction gives rise to the following affected market where Schering-Plough and Intervet would have a combined market share of at least 25% in the EEA at the national level (2006 data):

Competitors	**Denmark**
Schering-Plough	[80-90]%
Intervet	[5-10]%
Combined	[90-100]%
Others	[0-5]%

365. The proposed concentration would strengthen the already dominant position of Intervet in Denmark, the new entity having a nearly monopolistic position in this country. Moreover, given the barriers to entry, the parties will not face strong competitive constraints in Denmark post-merger.

366. The Commission therefore concludes that the proposed transaction raises serious doubts as to its compatibility with the common market and the EEA agreement on the market for sulphanomides for companion animals in Denmark.

(6) Phenicols for large animals

367. Based on data provided by the parties, the transaction gives rise to the following affected market where Schering-Plough and Intervet would have a combined market share of at least 25% in the EEA at the national level (2006 data):

Competitors	Itaky
SP	[80-90]%
Intervet	[0-5]%
Combined	[80-90]%
ATI	[5-10]%
Fatro	[5-10]%

368. Despite the very small market share accretion in Italy, it is worth noting that Schering-Plough has a nearly monopolistic position (market share of [90-100] %) in the EEA, thanks to its highly successful Nuflor/Resflor product range which still enjoy the patent protection.

369. However the only overlap occurred in Italy and is to be considered as historical one. Indeed, in 2007 Intervet withdrew its product Tiamfenicolo from the Italian market as this product was based on an old technology, had very minor sales (below 1%)[70] and[…]. Thus Intervet's product no longer exercises any competitive constraint on Schering-Plough.

370. The Commission therefore concludes that the proposed transaction does not raise serious doubts as to its compatibility with the common market and the EEA agreement on the markets for fluoroquinolones for companion animals.

(7) Mastitis in lactating cows

371. Based on data provided by the parties, the transaction gives rise to the following affected markets where Schering-Plough and Intervet would have a combined market share of at least 25% in the EEA at the national level (2006 data):

[70] These sales amounted to around [<100k] before 2006, in 2006 following the withdrawal decision they fell three-fold to [<100k]

Competitors	France	Germany
Schering-Plough	[0-5]%	[0-5]%
Intervet	[50-60]%	[60-70]%
Combined	[50-60]%	[60-70]%
CEVA	--	--
Fort Dodge	--	--
BI	--	--
Norbrook	--	--
Pfizer	[30-40]%	[30-40]%
Elancos	[5-10]%	--

372. Although Intervet is the first market player ([60-70] %), the proposed transaction would result in a very small market share accretion in Germany (well below [0-5] %). Moreover, Schering-Plough's sales increased only by [0-5] % over the period 2004-2006, while the market size rose by 30.6% over the same period. This is why Schering-Plough cannot be considered as a competitive constraint in this country.

373. The Commission therefore concludes that the proposed transaction does not raise serious doubts as to its compatibility with the common market and the EEA agreement on the market for mastitis in lactating cows in Germany.

374. As to France, Intervet is by far the first player ([50-60] %) and faces Pfizer ([30-40]%), Schering-Plough ([0-5] %) and Elanco ([5-10] %). Despite being a small competitor in France, Schering-Plough was viewed as a competitive constraint in this country by the respondents to the market investigation. As a matter of fact, it is worth noting that Schering-Plough's sales increased by [20-30] % over the period 2004-2006, while Intervet's sales increased only by [5-10] % over the same period. Schering Plough's competitive constraint on this market is even more credible as it is the key player (see below) on the closely related market for mastitis dry cows.

375. Finally, the majority of the respondents to the market investigation expressed strong concerns as to the consequences of the proposed transaction on this market in France.

376. The Commission therefore concludes that the proposed transaction raises serious doubts as to its compatibility with the common market and the EEA agreement on the market for mastitis lactating cows in France.

(8) Mastitis in dry cows

377. Based on data provided by the parties, the transaction gives rise to the following affected markets where Schering-Plough and Intervet would have a combined market share of at least 25% in the EEA at the national level (2006 data):

Competitors	B/LX	F	GRE	IRL	IT	POL	PT	SLO	SP	UK
Schering-Plough	[5-10] %	[40-50] %	[20-30] %	[40-50] %	[10-20] %	[5-10] %	[10-20] %	[30-40] %	[10-20] %	[20-30] %
Intervet	[30-40] %	[10-20] %	[30-40] %	[0-5] %	[20-30] %	[20-30] %	[10-20] %	[60-70]%	[5-10] %	[5-10] %
Combined	[30-40] %	[50-60] %	[60-70] %	[40-50] %	[40-50] %	[30-40] %	[20-30]%	[90-100]%	[20-30] %	[30-40] %
Pfizer	[20-30] %	[30-40] %	[20-30] %	[10-20] %	[10-20] %	[30-40] %	[40-50]%	--	[30-40] %	[30-40]%
Fort Dodge	[10-20]%	--	--	--	--	--	--	--	--	[0-5]%
Vetoquinol	[5-10] %	[0-5]%	--	--	--	--	--	--	--	--
Kela	[0-5] %	--	--	--	--	--	--	--	--	--
Virbac	[0-5]%	[5-10] %	--	--	--	--	--	--	[0-5] %	--
Merial	[0-5]%	[0-5]%	--	--	[0-5]%	--	[0-5]%	--	--	--
Bayer	[0-5]%	[0-5]%	--	--	[5-10]%	--	--	--	[0-5]%	--
Ceva	[0-5]%	--	--	--	--	--	--	--	[5-10]%	--
Novartis	--	[0-5]%	--	--	--	--	--	--	--	--
Norbrook	--	--	--	--	--	--	--	--	--	[5-10]%
Bimeda	--	--	--	[20-30]%	--	--	--	--	--	--
Norbrook	--	--	--	[10-20]%	--	[30-40]%	--	--	--	--
Cahl	--	--	--	[0-5]%	--	--	--	--	--	--
B.I.	--	--	--	[5-10]%	--	--	[20-30]%	--	[10-20]%	[10-20]%
Fatro	--	--	--	--	[0-5]%	--	--	--	--	--
Biovet	--	--	--	--	[20-30]%	--	--	--	--	--
Hipra	--	--	--	--	--	--	--	--	[0-5]%	--
Others	--	--	[10-20]%	--	--	--	--	--	[5-10]%	--

378. The proposed transaction gives rise to a very small market share accretion in Ireland and does not change the market structure.

379. The parties have a very high combined market share in France ([50-60] %; Schering-Plough: [40-50] %; Intervet: [10-20] %) and Greece ([60-70] %; Schering-Plough: [20-30] %; Intervet: [30-40] %) and the new entity would acquire a monopolistic position in Slovania (Schering-Plough: [30-40] %; Intervet: [60-70] %). Moreover, the new entity would be by far the first market player in France and Greece. In addition, the new entity would be the first supplier on both markets for lactating (see above) and dry cows in France, these two markets being closely related.

380. Finally, the majority of the respondents to the market investigation expressed strong concerns as to the consequences of the proposed transaction throughout the EEA and

in particular in France.

381. The Commission therefore concludes that the proposed transaction raises serious doubts as to its compatibility with the common market and the EEA agreement on the market for mastitis dry cows in France, Greece and Slovenia. The existence or not of serious doubts as regards the markets for mastitis dry cows in Belgium/Luxembourg, Italy, Poland, Portugal, Spain, and the United Kingdom can be left open for the purposes of the present decision as the remedy submitted by Schering-Plough has an EEA-wide geographic scope.

(9) Otitis antimicrobials for companion animals

382. Based on data provided by the parties, the transaction gives rise to the following affected market where Schering-Plough and Intervet would have a combined market share of at least 25% in the EEA at the national level (2006 data):

Competitors	**Italy**
Schering-Plough	[10-20]%
Intervet	[10-20]%
Combined	[30-40]%
Janssen	[30-40]%
Merial	[20-30]%
Vetoquinol	[5-10]%

383. The parties have a combined market share of [30-40] % (Schering-Plough: [10-20] %; Intervet: [10-20] %) in Italy. The new entity would still face three competitors, two of them having strong market shares (Janssen: [30-40] %; Merial: [20-30] %).

384. The Commission therefore concludes that the proposed transaction does not raise serious doubts as to its compatibility with the common market and the EEA agreement on the market for otitis antimicrobials for companion animals in Italy

(10) Remedies

Sulphonamides

385. With the objective of resolving the serious doubts identified by the Commission in the market for sulphonamides for large animals in Austria, Denmark, Finland, Germany, Ireland, Norway, Portugal and Sweden and sulphonamides for companion animals in Denmark, Schering-Plough committed to the EEA-wide divesture to a suitable purchaser of the sulphonamide based formulations for large and companion animals currently marketed in the EEA under the brands *Borgal, Gorban and Gelliprim* (see **Schedule 9**).

386. Schering-Plough commits to re-brand in the EEA Organon BS' *Borgal Tabs*, *Gelliprim Premix* and *Gelliprim Orale* from Closing, in accordance with registration

requirements that govern such changes and in a commercially reasonable manner in agreement with the Purchaser.

387. The Commission is of the view that the proposed remedy removes the competition concerns and restores effective competition, as it removes the entire overlap for sulphonamides for large and companion animals in the all national markets concerned. In particular, the divested business will have a sufficient size to constitute a viable competitor for sulphonamides for large and companion animals.

388. As confirmed by the market test, the divested business contains all tangible and intangible assets that the purchaser will need to conduct the business as a viable and independent business, i.e. the relevant trademarks, product formulations, know-how and customer details.

389. The transfer of Schering-Plough existing marketing authorisations and the arrangements for the supply of the purchaser by the merged entity during the transitional period while the purchaser sets up its own manufacturing and obtains the necessary regulatory approvals will ensure that the purchaser is able from day one to compete on a level playing field with the new entity.

390. The Commission, therefore, concludes that the divestiture of the European-wide *Borgal, Gorban and Gelliprim* business of Schering-Plough, will restore effective competition and that the proposed transaction does not raise serious doubts on condition of the implementation of this remedy.

Mastitis lactating / dry cows

391. With the objective of resolving the serious doubts identified by the Commission in the market for mastitis formulations in dry cows in France, Greece, and Slovenia and mastitis in lactating cows in France, Schering-Plough committed to the EEA-wide divesture to a suitable purchaser of the mastitis formulations currently marketed under the brands *Coliclox, Gentamam* for the treatment of lactating cow, and *Cobactan DC, Cephaguard DC, Super Mastidol DC, Mastitar and Vonapen* (see **Schedule 10**).

392. In addition, Schering-Plough commits to grant of a […] licence for the use of the COBACTAN trademark for the marketing and sale of the 'Cobactan DC' product in the EEA by way of a royalty-free non-exclusive and irrevocable licence, including the possibility of co-branding. The Purchaser/licensee would be allowed to change from Co-branding to the Purchaser's/licensee's own trademark at any time before the end of the Trademark Licence. Schering-Plough also commits not to re-introduce a dry cow formulation under the brand 'Cobactan DC' in the countries for which the licence has been granted. During the period of the Trademark Licence and in the event the Purchaser/licensee uses the COBACTAN trademark, the Purchaser/licensee must sell the products without modifying the COBACTAN logo designs, or damage the overall value of the COBACTAN trademark, or violate any necessary administrative permits and authorisations.

393. The Commission is of the view that the proposed remedy removes the serious doubts and restores effective competition, as it removes the key overlap for dry cow mastitis and all overlap for lactating cow mastitis formulations in all national markets where the Commission had serious doubts. In particular, the divested business will have a sufficient size to constitute a viable competitor.

394. As confirmed by the market test, the divested business contains all tangible and intangible assets that the purchaser will need to conduct the business as a viable and independent business, i.e. the relevant trademarks, product formulations, know-how and customer details.

395. The transfer of the marketing authorisations and the arrangements for the supply of the purchaser by the merged entity during the transitional period while the purchaser sets up its own manufacturing and obtains the necessary regulatory approvals will ensure that the purchaser is able from day one to compete on a level playing field with the new entity.

396. The Commission, therefore, concludes that the divestiture of the European-wide *Coliclox, Gentamam, Cobactan DC* and *Cephaguard DC, Super Mastidol DC, Mastitar and Vonapen* business, will restore effective competition and that the proposed transaction does not raise serious doubts on condition of the implementation of this remedy.

c) Endocrine products for reproductive use

Product market definition

397. Endocrines (hormones) are substances that are normally produced by the endocrine glands of animals and travel to distant organs within the animal's body to regulate the target organ's function or physiological processes. A large variety of hormonal products exist in the animal health area; many of them are used to treat or manage life threatening diseases such as diabetes (insulin). In previous Commission decisions, endocrine products for reproductive use were distinguished from other hormone treatments. The parties follow this logic in the present case.

398. In *Akzo Nobel N.V./Hoest Roussel Vet*[71], the hormones for reproductive use were first segmented according to their type:

    a. Prostaglandin;
    b. Progestagens;
    c. Gonadotrophin Releasing Hormones (GnRH); and
    d. Gonadotrophins.

399. Prostaglandin is a hormone that has an effect on the luteal tissue in the ovaries. Prostaglandins are mainly used for (i) the treatment of ovarian and uterine disorders, (ii) the synchronisation of the oestrus cycle, and (iii) for the induction of labour or abortions in cattle, horses, goats and swine.

400. Progestagens are natural or synthetic hormones which produce effects similar to progesterone. They are primarily secreted by the corpus luteum and later (depending on the species) by the placenta to support the pregnancy. Their main functions are the preparation the uterus for the implantation of the embryo and during pregnancy the

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[71] See Case COMP/M.1681 – Akzo Nobel N.V./Hoechst Roussel Vet, Commission decision of 22 November 1999, paragraphs 22-25.

decrease of the contractility of the uterine smooth muscle. In addition, they transmit messages to the brain and the ovaries that inhibit the secretion of other reproductive hormones such as GnRH.

401. The parties' activities overlap in the area of two hormones, namely prostaglandins and progestagens. Only Intervet is active in GnRH and gonadotrophins. Although Intervet is unilaterally strong as regards GnRH and gonadotropings in a number of countries, the transaction does not give rise to any competitive concerns as Schering-Plough is not at present a credible potential entrant for these two hormones. GnRH and gonadotrophins are therefore not further discussed in this decision.

402. In *Akzo Nobel N.V./Hoechst Roussel Vet*, hormones were further segmented according to their synthetic or natural character. The product market definition can however be left open, as the proposed transaction leads to serious doubts on several national markets in the EEA under both alternative product market definitions (distinguishing or not between natural and synthetic hormones[72]) and Schering-Plough has proposed a remedy which addresses these serious doubts (see below).

403. Last, in *Akzo Nobel N.V./Hoechst Roussel Vet*, the Commission noted that species are also in some instances a relevant criterion to define the product market for hormones. The parties submit that whereas progestagens are usually designed for use for a specific species and cannot be used for other species, prostaglandins can be (and usually are) used for any of the three main large animal species, namely cattle, horses and swine[73]. The market investigation confirmed the market definition submitted by the parties.

404. The relevant product markets for purposes of assessing the impact of the proposed concentration are therefore the following:

- Prostaglandins;
- Progestagens for companion animals; and
- Progestagens for cattle.

Competitive assessment

(1) Prostaglandins

405. Schering-Plough sells prostaglandins under the brands *Estrumate* and *Planate*, and Intervet under the main brands *Cyclix* and *Prosolvin* as well as under the brands *Iliren* and *Preloban*.

406. Based on data provided by the parties, the transaction gives rise to thirteen affected markets where Schering-Plough and Intervet would have a combined market share of

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72 But for one, the parties' products are all based on synthetic hormones and, even on the basis of a broader market including both natural and synthetic hormones, the proposed concentration will lead to serious competition concerns.

73 It should be noted that prostaglandins are not used for cats and dogs.

at least 25% in the EEA at the national level (2006 data):

Competitors	A	B/LX	DK	F	GER	GRE	IT	IRL	NL	RO	SP	SWE	UK
Schering-Plough	[50-60]%	[20-30]%	[70-80]%	[20-30]%	[20-30] %	[30-40] %	[30-40]%	[50-60]%	[20-30]%	[5-10]%	[30-40]%	[80-90]%	[60-70]%
Intervet	[10-20]%	[0-5]%	[10-20]%	[5-10]%	[10-20]%	[10-20]%	[20-30]%	[20-30]%	[20-30]%	[40-50]%	[10-20]%	[5-10]%	[10-20]%
Combined	[70-80]%	[20-30]%	[80-90]%	[30-40]%	[30-40]%	[40-50]%	[50-60]%	[80-90]%	[50-60]%	[40-50]%	[40-50]%	[90-100] %	[70-80]%
Pfizer	[20-30]%	[40-50]%	--	[20-30]%	[30-40]%	[30-40]%	[10-20]%	[10-20]%	[20-30]%	[0-5]%	[20-30]%	--	[10-20]%
Virbac	--	--	--	[0-5]%	--	--	[0-5]%	--	[0-5]%	--	--	--	--
CEVA	--	[20-30]%	--	[30-40]%	[5-10]%	[0-5]%	[20-30]%	--	[10-20]%	--	[5-10]%	--	[0-5]%
Fatro	--	[0-5]%	--	[0-5]%	--	--	--	--	--	--	[10-20]%	--	--
Bioveta	--	--	--	--	--	--	--	--	--	--	--	--	--
Veyx	--	--	--	--	[5-10]%	--	--	--	--	--	--	--	--
Calier	--	--	--	--	--	--	--	--	--	--	--	--	--
Orion	--	--	[5-10]%	--	--	--	--	--	--	--	--	[5-10]%	--
Others	--	--	--	--	[10-20]%*	[5-10]%*	--	[0-5]%*	[0-5]%*	[40-50]%*	[0-5]%*	--	[0-5]%*

*** Others:** GERMANY: Albrecht ([0-5] %), ani Medica ([0-5]%), Bernberg ([0-5]%), CP Pharma ([0-5] %), Medistar ([0-5] %); GREECE: Merial ([0-5] %), various ([0-5] %); IRELAND: Interchem ([0-5] %) and Forte ([0-5] %); NETHERLANDS: Eurovet ([0-5] %); ROMANIA: Pasteur Institute ([40-50] %), Various ([0-5] %); SPAIN: Esteve ([0-5] %), Various ([0-5]%); United Kingdom: Norbrook ([0-5]%).

407. The merger would therefore lead to very high market shares of the new entity in Austria ([70-80] %), Denmark ([80-90] %), Greece ([40-50] %), Ireland ([80-90] %), Romania ([40-50] %), Sweden ([90-100] %) and the United Kingdom ([70-80] %). In Austria, the parties will only face Pfizer ([20-30] %) post-merger. In Denmark and Sweden, the parties would face only one much smaller competitor, Orion. In Greece and Romania, the parties would face only one significant competitor (Pfizer in Greece ([30-40] %) and Institut Pasteur in Romania ([40-50] %)). In the United Kingdom and Ireland, the remaining competitors include Pfizer ([10-20] % and [10-20] % respectively), and the smaller competitors CEVA ([0-5] %) and Norbrook ([0-5] %) in the United Kingdom, and Interchem ([0-5] %) and Forte ([0-5] %) in Ireland. Given the barriers to entry, the parties will not face strong competitive constraints in these

countries post-merger.

408. The Commission therefore concludes that the proposed transaction raises serious doubts as to its compatibility with the common market and the EEA agreement on the markets for prostaglandins in Austria, Denmark, Greece, Ireland, Romania, Sweden and the United Kingdom. The existence or not of serious doubts as regards the markets for prostaglandins in the remaining affected markets can be left open for the purposes of the present decision as the remedy submitted by Schering-Plough has an EEA-wide geographic scope.

(2) Progestagens for companion animals

409. Schering-Plough sells its progestagens for companion animals under the brand *Ovarid*. Intervet's progestagens for companion animals are marketed in the EEA under the brands *Covinan* and *Delvosteron*.

410. Based on data provided by the parties, the transaction gives rise to the following affected markets where Schering-Plough and Intervet would have a combined market share of at least 25% in the EEA at the national level (2006 data):

Competitors	**HUN**	**IRL**	**UK**
Schering-Plough	[70-80]%	[30-40]%	[20-30]%
Intervet	[20-30]%	[50-60]%	[20-30]%
Combined	[90-100]%	[90-100]%	[40-50]%
Pfizer	--	[5-10]%	[50-60]%
Various	[0-5]%	--	--

411. The merger would therefore lead to very high market shares of the new entity in Hungary ([90-100] %) and Ireland ([90-100] %), and there would remain only small competitors ([0-5] % various) in Hungary and Pfizer ([5-10] %) in Ireland. The merger would lead to a high market share ([40-50] %) in the United Kingdom, where the parties will only face one competitor post-merger (Pfizer), thereby removing one very significant competitor. Given the barriers to entry, the parties will not face strong competitive constraints in these countries post-merger.

412. The Commission therefore concludes that the proposed transaction raises serious doubts as to its compatibility with the common market and the EEA agreement on the markets for progestagens for companion animals in Hungary, Ireland and the United Kingdom.

(3) Progestagens for cattle

413. Although the parties have a substantial overlap on the market for progestagens for cattle in France (Intervet – [80-90] %, Schering-Plough – [10-20] %, combined – [90-

100]%)[74], the parties provided satisfactory evidence that their respective products are sufficiently differentiated and they do not in fact exercise a competitive constraint on each other.

414. These two products have indeed different label indications: Intervet's *Crestar* is used for the synchronisation of the oestrus cycle (this is its only label claim), whereas SP's *Progest* is solely used to treat ovarian disorders, mainly cystic ovarian disease. *Progest* is an injectable product. *Crestar* is administered through a subcutaneous implant. These different modes of administration further reinforce the different indications of the two products. The endocrine that is introduced via the implant is released continuously to achieve a certain level of the hormone in the animal's bloodstream over a longer period of time which enables it to synchronise the oestrus cycle; the injectable product cannot be used for this indication. In this context, the products should be treated as if they were in separate product markets. The majority of respondents to the market investigation confirmed the parties' claim that their products "should not be considered as substitutable"[75].

415. The Commission therefore takes the view that the proposed concentration does not raise serious doubts as to its compatibility with the common market as regards the market for progestagens for cattle in France.

(4) Remedies

416. With the objective of resolving the serious doubts identified by the Commission in the market for prostaglandins in Austria, Denmark, Greece, Ireland, Romania, Sweden and the United Kingdom and in the market for prosgestagens for companion animals in Hungary, Ireland and the United Kingdom, Schering-Plough committed to the EEA-wide divesture to a suitable purchaser of the endocrine formulations currently marketed in the EEA under the brands *Prosolvin, Cyclix, Cyclix Porcine* and *Ovarid* (see **Schedule 5**).

417. For the brand *Cyclix*, the divestiture includes the agreement with […] concerning the supply of cloprostenol sodium necessary for the manufacture and sale of *Cylix and Cylix Porcine* in the EEA by way of assignment[76]. The divestiture also includes the supply agreement with […] concerning the supply of luprostiol necessary for the manufacture and supply of *Prosolvin* in the EEA by way of assignment[77].

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74 Crestar has been stopped to be commercialized by Intervet in the whole of EEA since the official ban on the use of estradiol esters entered into force in October 2006. France is the only country where a non-estradiol version of Crestar has been re-introduced.

75 See responses to question 9 of the questionnaire on pharmaceuticals to competitors (the questionnaire amalgamated in the same section questions on product market definition and competitive assessment).

76 The commitments contain some safeguards in case assignment of the agreement with […] is not possible: Schering-Plough will assist the purchaser in negotiating an agreement with […] for the supply of cloprostenol sodium to the purchaser on terms and conditions comparable to those of the agreement with […], or, if such agreement cannot be concluded, commits to enter into a sub-contract for the supply of cloprostenol sodium to the purchaser on a reasonable cost plus basis.

77 The commitments contain some safeguards in case assignment of the agreements with […] is not possible: Schering-Plough will assist the purchaser in negotiating an agreement with […] for the supply of

418. The Commission is of the view that the proposed remedy removes the serious doubts and restores effective competition, as it removes the key overlap for prostaglandins and progestagens for companion animals in all the national markets concerned. In particular, the divested business will have a sufficient size to constitute a viable competitor for prostaglandins and progestagens for companion animals.

419. As confirmed by the market test, the divested business contains all tangible and intangible assets that the purchaser will need to conduct the business as a viable and independent business, i.e. the relevant trademarks, product formulations, third parties agreements, know-how and customer details.

420. The transfer of Schering-Plough's (for *Ovarid*) and Intervet's (for *Prosolvin*, *Cyclix* and *Cyclix Porcine*) existing marketing authorisations and the arrangements for the supply of the purchaser by the merged entity during the transitional period while the purchaser sets up its own manufacturing and obtains the necessary regulatory approvals will ensure that the purchaser is able from day one to compete on a level playing field with the new entity.

421. The Commission concludes therefore that the divestiture of the European-wide of *Prosolvin, Cyclix, Cyclix Porcine* and *Ovarid* business of Intervet and Schering-Plough respectively, will restore effective competition and that the proposed transaction does not raise serious doubts on condition of the implementation of this remedy.

d) Parasiticides

Product market definition

422. Parasiticides are agents or preparations used to control internal and external parasites and/or prevent such parasites from infesting an animal. Within parasiticides, the parties make first a fundamental distinction between: (i) anti-coccidials which act against single-celled parasites (called coccidials); and (ii) other anti-parasitic preparations that treat non-coccidia parasites. This segmentation is in line with a previous Commission decision[78] and was confirmed in the market investigation.

423. Anti-coccidials are not discussed further as the parties' activities do not overlap in this market.

424. In previous Commission decisions[79], parasiticides were subdivided into:

- Ectoparasiticides, used to control external parasites such as fleas, ticks, flies, lice and mange mites, which affect all animal species. Ectoparasiticides are

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luprostiol to the purchaser on terms and conditions comparable to those of the agreements with […], or, if such agreements cannot be concluded, commits to enter into a sub-contract for the supply of luprostiol to the purchaser on a reasonable cost plus basis.

78 Case M.885 – *Merck/Rhône-Poulenc-Merial,* paragraphs 33 and following.

79 Case M.885 – *Merck/Rhône-Poulenc-Merial,* paragraph 42; Case M.737 *Ciba/Sandoz,* paragraphs 186 and following.

applied directly on the animal in the form of sprays, dusting powders, pour-on applications, spot-on applications, shampoos, collars, creams or lotions.

- Endoparasiticides, used to control internal parasites (gastro-intestinal roundworms and tapeworms, lungworms, liver flukes, protozoa etc.) in various species. They are administered either orally or by injection.

- Endectocides, used to concurrently treat external and internal parasites.

425. In the *Merck/Rhône-Poulenc-Merial* decision, the Commission noted "a tendency towards the progressive replacement of endoparasiticides and ectoparasiticides [by endectocides]", but left the market definition open[80].

426. In the *Ciba/Sandoz* decision[81], the Commission also found that a further distinction for farm animals (ruminants and swine) and companion animals is appropriate.

427. In previous decisions, although it left the market definitions open, the Commission did not exclude that other criteria such as the active substance/pathology or the mode of administration could be relevant to define relevant product markets.

428. These possible further sub-distinctions are examined in turn below.

Endoparasiticides and endectocides

429. The parties submit that since the introduction of endectocides, there has been a general trend towards replacing individual endoparasiticide products with endectocides. Particularly, consumers of endoparasiticides see endectocides as a convenient, slightly more expensive means of meeting their requirements for control of internal parasites, while also obtaining some limited protection from external parasites. Consequently, the parties consider that competition from endectocides is sufficient to justify a finding that endoparasiticides and endectocides form part of a single relevant product market.

430. The market investigation generally supported the parties' claim that endectocides belong to the same product market as endoparasiticides, although some respondents disagreed.

431. The parties submitted additional information showing that: (i) customers can and do use both types of products interchangeably to treat internal worms with no significant difference in effectiveness, duration and withdrawal period[82]; (ii) suppliers of

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80 Case M.885 – *Merck/Rhône-Poulenc-Merial,* paragraph 42.

81 Case M.737 *Ciba/Sandoz,* paragraphs 186 and following.

82 Due to the wide variety within each of the endoparasiticide and endectocides categories, it is not possible to base a distinction between endoparasiticides and endectocides on the relative withdrawal times or effective durations of the two types of products. For example, withdrawal times for endectocides can be as short as 0 days in the case of Merial's *Eprinex* or as long as 56 days in the case of Pfizer's *Dectomax*, both brands having substantial sales across the EEA. Endoparasiticides typically fall within this range. Duration of endectocides can also vary from a couple weeks, to up to eight weeks for Pfizer's *Dectomax* or even 150 days in the case of Fort Dodge's *Cydectin LA 10% Injectable*. Endoparasiticides offer similar variety and both types of products can be reapplied to increase duration.

endoparasiticides generally must price their products sufficiently under endectocides in order to maintain competitiveness[83]; (iii) suppliers of endectocides focus advertising of their products primarily (sometimes exclusively) on the endoparasiticidal aspects of their endectocide products[84].

432. In light of the additional evidence submitted by the parties and the fact that most of the respondents to the market investigation accepted the existence of the broader market encompassing both endoparasiticides and endectocides, the Commission concludes that for the purposes of this transaction they form a single relevant market.

Species of animals

433. The parties concur with the Commission that the distinction between parasiticides for different species/species-group is appropriate. First, large and small animals are often afflicted by different types of parasites. Secondly, in the case of farm animals, considerations of the cost of the treatment and indications on the withdrawal period play a significant role in the farmer and veterinarian's decision as to which product to purchase, whereas the economic considerations are evaluated to a limited extent in the case of the treatment of companion animals and equine. Therefore the parties distinguish three separate markets: (i) for food producing animals (farm animals), (ii) companion animals, and (iii) horses.

434. Respondents to the market investigation supported the segmentation of parasiticides on the basis of the three species groups identified by the parties.

Active substance/target pathology

435. With respect to active substance/target pathology, the parties recognise that within each of these groups of products, individual products may contain active substances that are more effective against one or more specific types of parasite. From a functional point of view, targeted parasiticides (treating a single parasite) have no substitutability with other parasiticides that are effective against a different, targeted parasite (*e.g.*, flukicides that treat liver flukes cannot treat lungworms). However, a number of parasiticides are effective against multiple parasites and thus cannot be defined as being part of single market of products that treat individual parasites. Given the sliding scale between potent and targeted parasiticides on the one hand, and broad-

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83 Evidence that endoparasiticides compete against endectocides can also be found in the relative pricing of the two categories of products. Historically, endoparasiticides were the first type of product on the market, and early on were significantly more expensive than they are today. Prices fell, however, when endectocides first came onto the market. At that time, endectocide suppliers also enjoyed significantly higher prices than today because their products were protected by patents. When those patents expired around 2001, another significant fall in prices occurred for endectocides. As a consequence, endoparasiticide prices also fell. This further illustrates the fact that suppliers of endoparasiticides are conscious of the competition they face from endectocides.

84 The direct competition between the two types of products is intensified due to the fact that endectocides are not a replacement for ectoparasiticides. Suppliers of endectocides have therefore targeted endoparasiticides at customers who traditionally used endoparasiticides. Endectocides are often portrayed as an improved endoparasiticide product, and marketing focuses primarily on the effectiveness of the product against internal parasites, while highlighting the effect on external parasites as an added bonus.

coverage products on the other, the parties believe that it is difficult to delineate the precise borders of each of these segments.

436. The only exceptions to this are two groups of products which are single treatments with narrowly targeted application and which cannot be substituted with other broad-coverage products. Products that treat fungal infections (external) and blood parasites (internal) are each very specific treatments with a single target application: no broad-coverage products include any substances that address either of these parasite problems. Therefore the parties treat each of these groups of products as distinct relevant product markets (*i.e.*, finding a relevant product market for fungicides, and a relevant market for blood parasite products) and consider it inappropriate for all other parasiticides to distinguish relevant product markets on the basis of the type of parasite targeted by each product.

437. Respondents to the market investigation generally supported the parties' approach.

Mode of administration

– Ectoparasiticide collars for companion animals

438. With respect to the mode of administration, the parties consider that this criterion is particularly relevant in the companion animal ectoparasiticide segment where a distinction can be made between collar products and other ectoparasiticides (such as a 'spot-on' or shampoo products). For the pet owner, the distinction may be particularly relevant as it has a substantial impact on the ease of use and duration of effectiveness of the product. However, in the case of larger animals (for example ruminants), while certain products have different routes of administration (for example, oral drench solution, granules, or bolus) that may in certain cases lead a farmer to choose one product over another, in terms of therapeutic use products that have the same active substance can ultimately be used interchangeably. Therefore, the parties submit that a distinction on basis of route of administration should only be made in the case of companion animals ectoparasiticides.

439. Respondents to the market investigation generally approved the parties approach with respect to the mode of administration, with the exception of ectoparasiticides for companion animals for which some respondents pointed out that, although collars have a different way of administration and a different duration of effectiveness, they still target the same parasiticides and pet owners consider them as substitutable with other ectoparasiticide treatments.

440. The issue of market definition can be left open as regards ectoparasiticides for companion animals, as the transaction will not give rise to serious doubts irrespective of the market definition.

– Long-acting endoparasiticide boluses for cattle

441. A few respondents to the market investigation took the view that boluses for cattle, *i.e.* a product that provides protection against helmintic worms for a three- to four-month period with a single treatment should be defined as a separate market.

442. The parties however dispute that there is a specific demand for solutions that require only one application. The parties take the view that their long-acting bolus products

face fierce competition from (i) long-acting injectables that provide the same protection, and from (ii) injectables or pour-on products that require two or three applications over the cattle pasture period .

443. First, the parties point out that long-acting injectable products entered the market recently that have a similar or even longer period of coverage than the traditional boluses offered by the parties and have similar efficacy against the helmintic worms. An example of such product is Fort Dodge's *Cydectin 10% LA Injectable*, a new generation endectocide that provides up to 150 days of protection from helmintic worms, compared to about 105 days of anthelmintic protection for Schering-Plough's products and 140 days for Intervet's products. This product is comparable in price to boluses and have some advantages such as adjustable dosage according to the weight of the animal, it easier to administer[85] and has shorter withdrawal periods. *Cydectin LA* has been launched in France in 2005, followed by launches in Belgium, Germany and the United Kingdom in 2006. The parties submit that, due to its advantages, the sales of *Cydectin LA* have been rising successfully. In light of that evidence the Commission is inclined to consider that there is a relative closeness of competition between traditional anthelmintic boluses and recently introduced long-acting endectocides such as *Cydectin LA*.

444. Secondly, the parties contend that the only key difference between bolus formulations and other anthelmintic injections and pour-on formulations available on the market (such as Pfizer's *Dectomax*, Fort Dodges's *Cydectin Pour-on*, Merial's *Ivomec*) are that boluses provide coverage for a longer portion of the season with a single administration. While the need to re-apply the product may be inconvenient to the farmer, this inconvenience is, in their view, insufficient to define a distinct market. Treatment can take place when cattle are transferred from one pasture to another, during periodic herd inspection, or when cattle are being treated for other conditions. In fact, the duration of activity is just one of many factors which the farmer will take into consideration when choosing a parasiticide product. The cost of two or three treatments with such products is typically less expensive than bolus products, making such products an attractive alternative to boluses. In this context any price increases of the bolus products entail the risk of the erosion of their market share at the expense of other injectable or pour-on anthelmintic products characterised by shorter duration of activity. Moreover as pointed out in the paragraph above, the duration of activity of the pour-on and injectable products is being extended which further blurs the boundaries with boluses. In light of that additional evidence, the Commission concludes that boluses can be considered as part of the wider endo/endectocide market. However, within this broader market, the bolus products targeting helmintic worms in cattle appear to be the closest competing products.

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85 *Cydectin LA* can be injected directly behind the ear of the cow, which is particularly insensitive to pain and can be accomplished without any reaction from the animal. This is comparatively easier than administration of a bolus. To administer a bolus, the farmer must first secure the animal in a neck-clamp because the animal will likely attempt to resist administration. The bolus is delivered by means of a 'bolus gun,' which is placed into the animal's mouth past the tongue. Passage of the bolus down the animal's throat is made easier by releasing the bolus into the animal's throat as the animal swallows. Care must be taken not to cause injury by placing the gun too far inside the throat of the animal. Finally, the animal should be observed for a short time after dosing to ensure that the bolus has been successfully swallowed. This is considered a labour-intensive operation.

445. It must be also noted that in the United Kingdom, boluses appear to hold a traditionally stronger position for these treatments, as evidenced by the fact that the British sales of boluses are the largest within the EEA. The United Kingdom sales of boluses are in the range of €6.4m, which account for 14% of total sales in the United Kingdom of endo/endectoparasiticide products, which is significantly higher that, for example in France (the by far the largest cattle market within the EEA), where sales of boluses are €5.7m and account for less than 8% of overall endo/endectoparasiticide sales. This lends support to several comments received in the market investigation that the demand of British farmers could be less elastic with respect to pricing of bolus products, and could justify defining a separate market for endo/endectoparasiticide boluses in the United Kingdom. Having regard to the remedy proposed by the parties for endo/endectoparasiticide products, it is however not necessary to conclude finally on this question.

446. The relevant product markets for purposes of assessing the impact of the proposed concentration are therefore the following:

- Ectoparasiticides (including collars) for companion animals;
- Ectoparasiticides for farm animals (ruminants and swine);
- Endoparasiticides/endectocides for farm animals (ruminants and swine); and
- Fungicides.

Competitive assessment

(1) Ectoparasiticides (including collars) for companion animals

447. Schering-Plough sells ectoparasticides for companion animals under the brands *Exspot/Pulvex*. Intervet sells collars for companion animals under the brand *Scalibor Colar* as well as other treatments *Ectodex* and *Taktic.*

448. Based on data provided by the parties, the transaction gives rise to the following affected markets where Schering-Plough and Intervet would have a combined market share of at least 25% in the EEA at the national level (2006 data):

Competitors	Finland	Germany	Malta	Norway	Slovenia	Sweden
Schering-Plough	[50-60]%	[20-30]%	[20-30]%	[30-40]%	[70-80]%	[5-10]%
Intervet	[10-20]%	[0-5]%	[70-80]%	[30-40]%	[20-30]%	[20-30]%
Combined	[60-70]%	[20-30]%	[90-100]%	[60-70]%	[90-100]%	[30-40]%
Bayer	[20-30]%	[20-30]%	--	[5-10]%	--	[0-5]%
Merial	[5-10]%	[40-50]%	--	[20-30]%	--	[60-70]%
Novartis	--	--	--	--	--	[0-5]%
Vetoquinol	--	--	--	--	--	--
Virvac	--	[0-5]%	--	--	--	--
BI	--	[0-5]%	--	--	--	--
Others	--	--	-	--	--	--

449. Although post-transaction the parties would have significant market shares in four national markets, the Commission takes the view that the merger of the parties will not give rise to serious doubts.

450. First, it must be noted that the products of the parties are not the closest substitutes. Schering-Plough's product *Exspot/Pulvex* is a spot-on[86] product in most of the countries available over the counter, whereas Intervet's key product *Scalibor Collar* is a collar for fastening around the animal's neck and in most of the countries is prescription-only. The other treatments offered by Intervet (*Ectodex* and *Taktic*) have only marginal sales (less than EUR 1 million in the EEA) and do not exercise any considerable constraint on any of the national markets.

451. Secondly, both national markets where the parties would attain a particularly high market shares are extremely small in size, Malta (EUR [<100000]) and Slovenia (EUR [<100000]). These two markets constitute together less than 1% of the EEA-wide market which is valued at around EUR 453 million[87]. The sales of the parties in such small markets are not the result of a strategic decision to market the products, but rather opportunistic sales. Neither of the suppliers is directly active through its own sales and marketing organisation, but rather they operate via local distributors for the marketing as well as the logistical distribution of their products. The merging parties do not themselves have the contact with veterinarians and market knowledge required to successfully sell the products. Should the merged entity increase prices post-merger, this would likely lead to a drop in sales and consequently to a fall of distributors' earnings. Existing or new distributors could then easily offer customers

86 Exspot is a solution that is directly applied to the skin of the animal's back and neck between the shoulder blades

87 As the parties were not able to identify any other competitors they had to assume that the value of the market is limited to their own sales. The value of these markets calculated in this way seems extremely low, it is very unlikely that Slovenia (a country with an average GDP) that accounts for 0.4% of the European population, spends dramatically less (Slovenia would account for only 0.012% of the total ectoparasiticide EEA-wide market according to figures that the parties were able to provide) on the animal treatment. In light of this, it is very likely that other competitors are indeed present in those two countries and their presence is not simply reported in the sources available to the parties.

alternative products from other suppliers, including the European leader Merial, which so far is not represented in these countries.

452. As regards Norway and Finland, the parties will continue to face strong competitive constraint from Merial ([5-10] % in Finland and [30-40] % in Norway) and Bayer ([20-30] % in Finland and [5-10] % in Norway). The key products of Merial *Frontline* and Bayer *Advantage* and *Advantix* are closer competitors to Schering-Plough's *Exspot* as they are a spot-on product.

453. It must be also noted that the market for ectoparasiticides for companion animals in the EEA is characterised by the superior position occupied by Merial, which has a total market share of [40-50] % and leads the European market by a significant margin (Merial's main companion animal ectoparasiticide product in Europe is *Frontline*). Merial's market share is over four times as large as that of the next player, Bayer, who has a market share of around [10-20] %. Novartis and Virbac are well established with around [0-5] % and [0-5] % shares respectively, and together the smaller suppliers such as Janssen, CEVA, Vétoquinol and many other players, make up a varied competitive landscape.

454. The Commission therefore concludes that the proposed transaction does not raise serious doubts as to its compatibility with the common market and the EEA agreement on the markets for ectoparasiticides (including collars) for companion animals.

(2) Ectoparasiticides for farm animals (ruminants and swine)

455. Schering-Plough sells ectoparasiticides for farm animals under the brands *Coopers Spot-On, Sputop, Versatrine, Ectoforce, Coopertix, Fly, Zoogama-D* and Intervet under the main brand *Butox* and as well as under the brands *Taktic* and *Topline Suspension*.

456. Based on data provided by the parties, the transaction gives rise to the following affected markets where Schering-Plough and Intervet would have a combined market share of at least 25% in the EEA at the national level (2006 data):

Competitors	Belgium/Lux	France	Ireland	Portugal	Spain
Schering-Plough	[30-40]%	[30-40]%	[30-40]%	[0-5]%	[5-10]%
Intervet	[20-30]%	[30-40]%	[5-10]%	[20-30]%	[20-30]%
Combined	[50-60]%	[60-70]%	[40-50]%	[20-30]%	[30-40]%
Pfizer					[30-40]%
Fort Dodge	[0-5]%		[5-10]%	[5-10]%	
Janssen					
Virbac	[0-5]%				
Novartis		[10-20]%	[40-50]%		
Merial					
Bayer	[30-40]%	[5-10]%	[5-10]%	[10-20]%	[20-30]%
Bimeda			[0-5]%		
Vetoquinol		[5-10]%			
Calier				[20-30]%	
Belgagri	[0-5]%				
Esteve					[0-5]%
CEVA.				[10-20]%	
Others	[0-5]%				[5-10]%

457. The merger would therefore lead to very high market shares of the new entity in one of the largest EEA market, France ([60-70] %), and high market shares in another relatively large market, Belgium/Luxembourg ([50-60] %). The market investigation pointed out that the parties have very strong and recognised brands in this area: *Butox, Versatrine Spot-On, Sputop,* and that these products are close competitors. Given the barriers to entry, the parties will not face strong competitive constraints in these countries post-merger.

458. Moreover, the parties would become the largest supplier of ectoparasiticides for farm animals in the whole of the EEA with a total market share of around [30-40] %, followed by Merial ([20-30] %) and a distant third player Bayer ([10-20] %).

459. The Commission therefore concludes that the proposed transaction raises serious doubts as to its compatibility with the common market and the EEA agreement on the markets for ectoparasiticides for farm animals in Belgium/Luxembourg and France. The existence or not of serious doubts as regards the markets for ectoparasiticides for farm animals in the remaining affected markets can be left open for the purposes of the present decision as the remedy submitted by Schering-Plough has an EEA-wide geographic scope.

(3) Endoparasiticides/endectocides for farm animals (ruminants and swine)

460. Schering-Plough sells endoparasticides and endectocides for farm animals under the brands *Cooperzole, Ecomectin* (endectocides)*, Systamex, Repidose, Farminitic, Autoworm* (endoparasiticide boluses), *Hapadex, Hapasil, Imena, Levamisol, Nilzan* and *Zanil* (endoparasiticides) and Intervet under the main brand *Panacur* (including *Panacur Bolus)* as well as under the brands *Vectin 8 Sheep Drench, Mectacur*

(endectocides), *Deldrax, Faxicur, Gardal, Levacur, Panafluke* and *Ranigel* (endoparasiticides).

461. Based on data provided by the parties, the transaction gives rise to the following affected markets where Schering-Plough and Intervet would have a combined market share of at least 25% in the EEA at the national level (2006 data):

Competitors	**DK**	**GRE**	**NOR**	**SWE**
Schering-Plough	[5-10]%	[10-20]%	[40-50]%	[60-70]%
Intervet	[20-30]%	[10-20]%	[20-30]%	[20-30]%
Combined	[20-30]%	[20-30]%	[60-70]%	[90-100]%
Pfizer	[10-20]%	--	[20-30]%	--
Fort Dodge	[5-10]%	[5-10]%	--	--
Janssen	[10-20]%	--	[5-10]%	--
Virbac	--	--	--	--
Novartis	[0-5]%	--	--	--
Merial	--	[10-20]%	--	--
Bayer	--	[5-10]%	--	[0-5]%
Ceva	--	[10-20]%	--	--
Vetoquinol	--	--	--	--
Veterin	--	[20-30]%	--	--
Chanelle	--	--	--	--
Univet	--	--	--	--
B.I.	[30-40]%	--	--	--
Others	--	[0-5]%	--	--

462. The merger would therefore lead to very high market shares of the new entity in Sweden ([90-100] %) and Norway ([60-70] %). In Sweden, the parties would face only one competitor – Bayer with marginal market share ([0-5] %) and in Norway only two competitors Janssen ([5-10] %) and Pfizer ([20-30] %). Given the barriers to entry, the parties will not face strong competitive constraints in these countries post-merger.

463. As the parties are almost the only remaining suppliers of boluses within the EEA and currently the only suppliers in the United Kingdom the merger would lead to a monopolistic position if boluses were defined as a sepatate market, which, as discussed above, cannot be excluded to be relevant as far a the United Kingdom is concerned. In order to strengthen the remedy and to remove the Commission's serious doubts in this respect, the parties have, after the market test, added one of their bolus products – Schering-Plough's *Autoworm* to the remedy package.

464. The Commission therefore concludes that the proposed transaction raises serious doubts as to its compatibility with the common market and the EEA agreement on the markets for endoparasiticides/endectocides for farm animals in Sweden, Norway and the United Kingdom.

465. In Denmark and Greece, the Commission concludes that the transaction does not raise serious doubts as to its compatibility with the common market and the EEA agreement, as they face numerous competitors (5 in Denmark and 6 in Greece).

(4) Fungicides in Spain

466. As regards fungicides although the Parties recorded their sales in 2006, the overlap between their activities is only historic. Intervet has discontinued sales of its fungicides in the affected market as of the first quarter of 2007. In addition, […]. As a result, there is currently, and will not in the future be, an overlap in this market. The parties provided the Commission with satisfactory evidence proving Intervet's withdrawal from the Spanish market

(5) Remedies

467. With the objective of resolving the serious doubts identified by the Commission in the market for orally administered ectoparasiticides for farm animals in France and in Belgium/Luxembourg and in the market for endoparasiticides/endectocides for farm animals in Sweden, Norway and the United Kingdom, Schering-Plough committed to the EEA-wide divesture to a suitable purchaser of endoparasiticides currently marketed under the brand *Systamex* and the ectoparasiticides for farm animals currently marketed under the brands *Coopers Spot On, Versatrine, Sputop and Coopertix* (see **Schedule 7**).

468. Following the market test, Schering-Plough added to the products to be transferred EEA-wide the *Autoworm*, which is the brand under which Organon BS product is registered and marketed in the United Kingdom and Ireland. Schering-Plough also committed to fully transfer to the purchaser the brand *Coopertix.* The remedy also includes the grant of a […] licence for the use of the *Coopers* trademark for the sale of Coopers Spot On in the EEA by way of a royalty-free exclusive and irrevocable licence.

469. The Commission is of the view that the proposed remedy removes the serious doubts and restores effective competition, as it removes the key overlaps in all the affected national markets where the commission identified serious doubts. In particular, the divested business will have a sufficient size to create a viable competitor. The fact that the divestment also includes the products *Coopers Spot on* and *Autoworm* ensures that the purchaser will acquire a sizeable business with a well-known brand and a complete portfolio that it can expand throughout Europe.

470. As confirmed by the market test, the divested business contains all tangible and intangible assets that the purchaser will need to conduct the business as a viable and independent business, i.e. the relevant trademarks, product formulations, know-how and customer details.

471. The transfer of Schering-Plough existing marketing authorisations and the arrangements for the supply of the purchaser by the merged entity during the transitional period while the purchaser sets up its own manufacturing and obtains the necessary regulatory approvals will ensure that the purchaser is able from day one to compete on a level playing field with the new entity.

472. The Commission, therefore, concludes that the divestiture will restore effective

competition and that the proposed transaction does not raise serious doubts on condition of the implementation of this remedy.

e) Central nervous system (anaesthetics and euthanasia)

473. Central Nervous System ("CNS") pharmaceutical products are designed to alter or modify the conscious state of the animal. The two main subgroups within the CNS group of products are: (i) anaesthetics, for blocking the perception of pain and other sensations to allow animals to undergo surgery and other procedures without the distress and pain they would otherwise experience; and (ii) euthanasia products, for humane and ethical termination of animals. Other CNS products are designed to change the mood or behaviour of animals, relax or tranquilise the animal. It must be noted that the Commission has not yet dealt with CNS products in the animal health sector.

(1) Anaesthesia

Product market definition

474. The parties submit that anaesthesia products can be divided into the following relevant product markets: (i) general anaesthetic injectables; (ii) general anesthestic inhalants; (iii) local anaesthetics; and (iv) sedatives or pre-anaesthetics.

475. The parties consider that general and local anaesthetics constitute different product markets. Although both general and local anaesthetics are used to block the perception of pain by the animal during surgical procedures, they operate in different ways. General anaesthetics operate directly on the animal's central nervous system and result in a state of total unconsciousness. While usually administered with inhalational agents, general anaesthesia can also be achieved with intravenous or injectable agents. Local anaesthetics on the other hand achieve analgesia by blocking the pain impulses from a particular area from reaching the animal's central nervous system. They combine the loss of pain sensation with varying degrees of muscle relaxation in certain regions of the body but do not induce unconsciousness. They are administered locally through injection to peripheral nerve bundles. Given their very different modes of operation, there is very limited substitutability between general and local anaesthesia products. For human health anaesthetics, the Commission has made a similar distinction between general and local anaesthesia products[88].

476. The parties submit that inhalation anaesthetics tend to be used for longer operations and for larger animals such as ruminants or horses and require specialised equipment for administration. Injectable anaesthetics tend to be used for (i) the induction of inconsciousness and (ii) brief surgery on small animals such as companion animals (cats and dogs).

477. The parties however submit that recent developments make the distinction between injectable or inhalable anaesthetics irrelevant as they are getting increasingly substitutable with each other: (i) inhalants are increasingly used for companion animals; (ii) inhalants can also be used to induce unconsciousness; (iii) injectables are

88 Case COMP/M.1403 - Astra/Zeneca, paragraphs 36 and following.

increasingly used in large animals; and (iv) following technological advances, injectables are used to both induce and maintain unconsciousness, in particular in operations of medium duration, and that only in very short and very long operations is the substitution between injectables and inhalants less pronounced. The parties therefore submit that general anaesthetics inhalants and injectables belong to a single relevant product market. The exact market definition can however be left open as even on the basis of the narrowest product market definition (distinction between inhalants and injectables), the proposed operation does not raise any serious doubts.

478. Respondents to the market investigation confirmed that anaesthesia products can be divided into the following relevant product markets: (i) general anaesthetic injectables; (ii) general anesthestic inhalants; (iii) local anaesthetics; and (iv) sedatives or pre-anaesthetics.

479. The relevant product markets for purposes of assessing the impact of the proposed concentration are therefore the following:

- General anaesthetic inhalants;
- General anaesthetics injectables;
- Local anaesthetics; and
- Sedatives and pre-anaesthetics.

Competitive assessment

480. The parties overlap only in the market for general anaesthesic injectables. Schering-Plough sells its general anaesthesic injectables under the brand *Rapinovet* and *Ketamin* and an inhalant *Isoba* […][89]. Intervet's products are are all injectable products, marketed under the brands *Ketamino*, *Ketavet*, *Narcosyl* and *Penthotal*.

481. The transaction gives rise to the following affected markets where the parties have a combined market share exceeding 25% in the market for general anaesthesics (including inhalants and injectables) (2006 data):

[89] […]

Competitors	Denmark	Italy	Sweden
Schering-Plough	[10-20]%	[20-30]%	[10-20]%
Intervet	[10-20]%	[20-30]%	[10-20]%
Combined	[20-30]%	[40-50]%	[20-30]%
Pfizer	[30-40]%	--	[40-50]%
Bayer	[5-10]%	--	[0-5]%
BI	[0-5]%	--	[0-5]%
Novartis	[10-20]%	--	--
Orion	[20-30]%	--	[5-10]%
Virbac	--	[30-40]%	--
Merial	--	[10-20]%	[0-5]%
Total	100%	100%	100%

482. The transaction gives rise to the following affected markets where the parties have a combined market share exceeding 25% in the market for general anaesthesic injectables (2006 data), with similar combined market shares of the parties:

Competitors	Denmark	Italy
Schering-Plough	[5-10]%	[10-20]%
Intervet	[10-20]%	[20-30]%
Combined	[20-30]%	[40-50]%
Pfizer	[30-40]%	--
Bayer	[5-10]%	--
BI	[0-5]%	--
Novartis	[10-20]%	--
Orion	[10-20]%	--
Virbac	--	[40-50]%
Merial	--	[0-5]%
Total	100%	100%

483. The parties however submit that Schering-Plough's and Intervet's anaesthesic products have different characteristics in terms of duration, muscle relaxation, sedation, sleep induction and species, and are therefore not the closest substitutes. This was confirmed by the market investigation.

484. In Denmark and Sweden, the parties' combined market share does not exceed 30%, and they will face significant competitors (in particular Pfizer and Orion) with products that are closer substitutes. In Italy, although post merger the parties would have a market share of [40-50] % (or [40-50] % depending on the market definition), their products are not the closest substitutes and they will continue to face competitive constraints from Virbac ([30-40] % or [40-50] %) and Merial ([10-20] % or [0-5] %). Virbac's sales have been growing for the last three years with its injectable product *Zoletil*, which is a close competitor to Schering-Plough's *Rapinovet*.

485. In conclusion, the Commission takes the view that the proposed concentration does not raises doubts as to its compatibility with the common market as regards the markets for general anaesthesics or general anaesthetic injectables in Denmark, Finland, and Italy.

(2) Euthanasia

Product market definition

486. As regards euthanasia, the parties submit that three methods of administration can be distinguished: (i) injectable agents, (ii) inhalant agents and (iii) physical methods (e.g., captive bolt, gunshot, decapitation, electrocution). The parties recognise that each of the means is used for different species (inhalants for small animals for which injections are difficult, and injectables for large animals) and are used in different circumstances with the choice being driven by extraneous factors (physical methods are used when other means of euthanasia are impractical or contraindicated by the intended use of the animal). The cost structure of the different means is also very different (injectables and inhalants have large variable costs and limited fixed costs contrary to physical methods).

487. The parties are active only in the market segment of injectable euthanasia products and the transaction has been analysed in the relevant product market for injectable euthanasia which is the narrowest market definition.

Competitive assessment

488. Schering-Plough sells injectable euthanasia products under the brand *Eutha 77*, and Intervet under the brand *T61*.

489. The activities of the parties overlap in two countries and where they parties have a combined market share exceeding 25%, namely Finland and Germany. The table below sets the parties' combined market share in these two countries (2006 data).

Competitors	**Finland**	**Germany**
Schering-Plough	[0-5]%	[10-20]%
Intervet	[90-100]%	[60-70]%
Combined	[90-100]%	[80-90]%
Cia Portuguesa	--	[0-5]%
Merial	--	[5-10]%
Total	100%	100%

490. The transaction will lead to a monopoly in Finland and very high combined market share in Germany. In Finland, Intervet has a quasi-monopolistic position, being in practice the only company active in this product market, and Schering-Plough is the only competitive alternative. Only two other competitors are present on the German market with a much smaller market share, and the merger will remove the main competitor (Schering-Plough with [10-20] % market share). Given the small size of the Finnish market (EUR [<100000]), and the high barriers to entry (in particular the fact that these markets were not considered attractive by respondents to the market

investigation), the parties will not face any significant competitive constraints post-merger.

491. The Commission therefore concludes that the proposed transaction raises serious doubts as to its compatibility with the common market and the EEA agreement on the markets for euthanasia products in Finland and Germany.

(3) Remedies

492. With the objective of resolving the serious doubts identified by the Commission in the market for euthanasia products in Finland and Germany, Schering-Plough committed to the EEA-wide divesture to a suitable purchaser of the pentobarbital-based formulation currently marketed by Schering-Plough in the EEA under the brand *Eutha 77* (see **Schedule 8**)

493. The Commission is of the view that the proposed remedy removes the serious doubts and restores effective competition, as it removes the entire overlap for euthanasia products in the two national markets concerned and even beyond.

494. The divested business will have a sufficient size to constitute a viable competitor for euthanasia products.

495. As confirmed by the market test of the remedies submitted by Schering-Plough, the divested business contains all tangible and intangible assets that the purchaser will need to conduct the business as a viable and independent business, i.e. the relevant trademarks, product formulations, know-how and customer details.

496. The transfer of Schering-Plough's existing marketing authorisations and the arrangements for the supply of the purchaser by the merged entity during the transitional period while the purchaser sets up its own manufacturing and obtains the necessary regulatory approvals will ensure that the purchaser is able from day one to compete on a level playing field with the new entity.

497. The Commission, therefore, concludes that the divestiture of the European-wide of *Eutha 77* business of Schering-Plough will restore effective competition and that the proposed transaction does not raise serious doubts on condition of the implementation of this remedy.

f) Specialty products (insulin and diuretics)

(1) Insulin

Product market definition

498. Insulin is used to treat the symptoms of diabetes mellitus, a disease of the endocrine system. It is caused by a deficiency of, or resistance to, insulin, which is the hormone that regulates how glucose (sugar) is absorbed and utilised by the cells and tissues of the body. In the animal health sector, insulin is only used to treat companion animals. The Commission has not yet examined the market for the treatment of diabetes in

companion animals[90].

499. Insulin products approved for companion animals consist of either porcine or bovine insulin. The parties submit that although there is complete substitutability between bovine and porcine insulin products prior to treatment, once treatment begins, the products are no longer immediately substitutable, and in certain instances, not substitutable at all. Switching the animal from one type of insulin to another requires careful transitioning and the dose of the insulin requires adjustment until adequate pancreatic regulation is achieved. However, switching does occur, and this process can take from approximately one week to six months.

500. The parties submit that insulin treatments also differ according to their peak and duration of action. In general, when the animal is in a ketoacidotic hyperglycaemic state (*i.e.*, it is suffering from severe insulin deficiency) only a rapid-acting/short-duration insulin product (such as Schering-Plough's *Insuvet Neutral*, but not Intervet's *Caninsulin*) can be used. For the treatment of non-ketoacidotic hyperglycaemic animals, products with intermediate onset of action following administration and intermediate to extended duration of activity are used.

501. The parties are the only viable suppliers of the insulin for animal treatment in the EEA. The market investigation did not confirm the distinctions suggested by the parties between the different source of insulin and different onset of action and duration of action of their respective products.

502. The Commission therefore takes the view that the relevant product market for purposes of assessing the present transaction is the market for insulin products.

Competitive assessment

503. Schering-Plough's products are marketed under the brand *Insuvet*. *Insuve*t is a bovine-derived injectable insulin and is sold with differing durations of activities. *Insuvet Neutral* has a rapid peak of action after administration, and short duration of activity. It is used to treat diabetic animals in a ketoacidotic state, i.e., suffering from severe insulin deficiency. *Insuvet Lente* and *Insuvet Protamine Zinc* both have an intermediate peak of action and duration of activity and are used to treat insulin dependent diabetes mellitus in companion animals.

504. Intervet's product is sold under the brand *Caninsulin*. *Caninsulin* is a porcine-based injectable insulin. *Caninsulin* has intermediate peak of action following administration, and duration of activity. It is used to treat insulin dependent diabetes mellitus in companion animals.

505. Based on data provided by the parties, as shown in the table below, the proposed transaction would lead to a monopoly position in Denmark, Ireland, Sweden and the United Kingdom.

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[90] In Case No COMP/M.1846 - *Glaxo Wellcome /Smithkline Beecham* of 8 May 2000, the Commission briefly considered the market for the treatment of human diabetes, but did not reach a definite view as to the relevant product market.

Competitors	Denmark	Ireland	Sweden	UK
Schering-Plough	[0-5]%	[30-40]%	[0-5]%	[60-70]%
Intervet	[90-100]%	[60-70]%	[90-100]%	[30-40]%
Combined	100%	100%	100%	100%
Total	100%	100%	100%	100%

506. In addition, it should be noted that, based on data provided by the parties and confirmed by the market investigation, in all the markets where there is no overlap, Intervet has a quasi-monopoly position and Schering-Plough is the most credible entrant.

507. In light of the high barriers to entry into this market, the Commission takes the view that the proposed concentration raises serious doubts as to its compatibility with the common market in the insulin market in Denmark, Ireland, Sweden and the United Kingdom.

(2) Diuretics

Product market definition

508. Diuretics relieve oedemas (swelling or excess fluid). Diuretic products are used to treat animal suffering from an accumulation of fluid, for example, at joints, in tissue body cavities. Accumulation of fluid can be caused by cardiac insufficiency (which can cause excessive fluid load in the lungs), renal dysfunction, trauma or parasitic disease. The parties submit that pure diuretics (that only treat oedemas) should be defined as a separate product market from combination products (diuretics + corticosteroids). Combination products are often used where an animal is also in pain or is experiencing inflammation and can benefit from the administration of an anti-inflammatory. The parties therefore believe that there is limited substitutability between pure diuretics and combination products: accordingly, the parties consider the relevant product market to be that for pure diuretic products (excluding diuretic/corticosteroid combination products). On this basis, the parties' products would not overlap.

509. However, for completeness given the lack of any market definition precedent in this sector, the parties analyse the transaction on the basis of an alternative market definition, namely that for animal diuretic products (including products containing corticosteroids).

510. On this basis the parties note that it is also meaningful to distinguish the segment by species. Certain products (such as Intervet's Dimazon 5% injectable) are indicated for large animals (ruminants, swine and horses) as well as companion animals. Other products in contrast are used exclusively in the companion animal segment (for example, diuretic tablets). Given the lack of substitutability between large animal diuretics for companion animal products (most the companion animal products are not indicated for large animal use), the parties treat the two species/species groups as forming separate relevant product markets.

511. Respondents to the market investigation has generally confirmed the product market definition proposed by the parties, including the limited substitutability between the two types of diuretics.

512. The Commission therefore takes the view that the relevant product market for purposes of assessing the present transaction are the following:

- the market for diuretics for small animals (companion animals); and
- the market for diuretics for large animals.

Competitive assessment

513. The diuretics segment is one of the smallest segments within the animal health market, currently valued at around EUR 7 million in the EEA.

Diuretics for small animals

514. The transaction gives rise to an affected market where the parties have a combined market share exceeding 25% for the diuretics for small animals only in France (2006 data):

Competitors	**France**
Schering-Plough	[10-20]%
Intervet	[20-30]%
Combined	[40-50]%
Vétoquinol	[50-60]%
Total	100%

515. Although parties' combined market shares are relatively high the Commission did not identify serious doubts in the market for diuretics for small animals. First, the parties' products are not the closest competiors: Intervet's *Dimazon* is a pure diuretic product. It is a very dose-specific product (the dosage administered indicates very specifically the duration of the diuretic effect). It is often used following surgery on the animal or for animals with cardiac problems and associated excess fluid retention. In contrast, Schering-Plough's *Naquadem* is a diuretic/corticosteroid, which is more commonly used for very serious oedemas. It is often used to treat udder oedema in cows, and in horses to reduce swellings, especially in the legs of the animals. Therefore, if a veterinarian wants to target an oedema alone (where there is no loss of function in the animal), he would not necessarily use *Naquadem*. Where, however, the animal is also suffering loss of function (limping, udder oedema, or inability to stand), pain and/or inflammation, relief of such symptoms can be provided with the corticosteroid contained in *Naquadem*. The market investigation confirmed that the parties' products are not close substitutes.

516. In addition, Vétoquinol is Intervet's closet competitor on this market, with a product (*Furozenol)* that acts merely as a diuretic (it contains the same active ingredient (furosemide) as Intervet's *Dimazon* product).

517. In conclusion, the Commission takes the view that the proposed concentration does not raise doubts as to its compatibility with the common market as regards the market for diuretics for small animals.

Diuretics for large animals

518. The transaction gives rise to an affected market where the parties have a combined market share exceeding 25% for the diuretics for large animals only in France (2006 data):

Competitors	**France**
Schering-Plough	[20-30]%
Intervet	[10-20]%
Combined	[40-50]%
Biové	[0-5]%
Coophavet	[0-5]%
Vétoquinol	[50-60]%
Total	100%

519. As mentioned above, the parties' products are not close substitutes. In addition, Schering-Plough's closest competitor on the market for diuretics for large animals is also Vétoquinol whose large animal product, *Diurizone*, also combines a diuretic and corticosteroid.

520. In conclusion, the Commission takes the view that the proposed concentration does not raise doubts as to its compatibility with the common market as regards the market for diuretics for large animals.

(3) Remedies

521. With the objective of resolving the serious doubts identified by the Commission in the market for the insulin products in Denmark, Ireland, Sweden and the United Kingdom, Schering-Plough committed to the EEA-wide divesture to a suitable purchaser of the insulin formulations for companion animals currently marketed in the EEA under the brands *Insuvet Lente, Insuvet Protamine Zinc* and *Insuvet Neutral* (together the "insulin formulations") (see **Schedule 6**).

522. The divestiture includes the licensing agreement with […] for the licensing of *Insuvet Lente* by way of assignment[91]. The divestiture also includes the contract

[91] The commitments contain some safeguards in case assignment of the agreements with […] is not possible: Schering-Plough will assist the purchaser in negotiating an agreement with […] for the licensing of *Insuvet Lente* to the purchaser, or, if such agreement cannot be concluded, commits to enter into a sub-contract for the licensing of *Insuvet Lente* to the purchaser, on terms and conditions equivalent to those of the […] Agreement.

manufacturing agreement with […] for the supply of the insulin formulations by way of assignment[92].

523. The Commission is of the view that the proposed remedy removes the serious doubts and restores effective competition, as it removes the entire overlap for insulin products in the four national markets concerned. In particular, the divested business will have a sufficient size to constitute a viable competitor for insulin products.

524. As confirmed by the market test, the divested business contains all tangible and intangible assets that the purchaser will need to conduct the business as a viable and independent business, i.e. the relevant trademarks, product formulations, third party agreements, know-how and customer details.

525. The transfer of Schering-Plough's existing marketing authorisations and the arrangements for the supply of the purchaser by the merged entity during the transitional period while the purchaser sets up its own manufacturing and obtains the necessary regulatory approvals will ensure that the purchaser is able from day one to compete on a level playing field with the new entity.

526. The Commission, therefore, concludes that the divestiture of the European-wide of *Insuvet Lente, Insuvet Protamine Zinc* and *Insuvet Neutral* business of Schering-Plough, will restore effective competition and that the proposed transaction does not raise serious doubts on condition of the implementation of this remedy.

V. CONCLUSION

527. The decision in this case is conditioned on the full compliance with Section B, points 1 to 7 and Section D of the Commitments and the schedules of the Commitments submitted by the notifying party on 10 October 2007.

528. The remaining requirements set out in the other Sections of the Commitments submitted by the parties on 10 October 2007 are considered to constitute obligations.

529. The Commission has concluded that the remedies submitted by the Parties are sufficient to remove the serious doubts raised by the concentration. Accordingly, subject to the full compliance with the commitments submitted by the notifying party, the Commission has decided not to oppose the notified operation and to declare it compatible with the common market and with the EEA Agreement. This decision is adopted in application of Article 6(1)(b) and Article 6(2) of Council Regulation (EC) No 139/2004.

530. The detailed text of the commitments is annexed to this decision. The full text of the annexed commitments forms an integral part to this decision.

For the Commission

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92 The commitments contain some safeguards in case assignment of the agreements with […] is not possible: Schering-Plough will assist the purchaser in negotiating an agreement with […] for the supply of the insulin formulations to the purchaser on terms and conditions equivalent to those of the […], or, if such agreement cannot be concluded, commits to enter into a sub-contract for the supply of the insulin formulations to the purchaser on a reasonable cost plus basis.

signed
Charlie McCreevy
Member of the Commission

Schering-Plough Corporation/Organon BioSciences N.V.

CASE No. COMP/M.4691

COMMITMENTS TO THE EUROPEAN COMMISSION

Pursuant to Article 6(2) of Council Regulation (EC) No. 139/2004 ('**the Merger Regulation**'), the Schering-Plough Corporation ('**Schering-Plough**') hereby provides the following Commitments ('**the Commitments**') in order to enable the European Commission ('**the Commission**') to declare the acquisition of Organon BioSciences N.V. ('**Organon BS**') by Schering-Plough compatible with the Common Market and the EEA Agreement by its decision pursuant to Article 6(1)(b) of the Merger Regulation ('**the Decision**').

The Commitments shall take effect upon the date of adoption of the Decision.

This text shall be interpreted in the light of the Decision to the extent that the Commitments are attached as conditions and obligations, within the general framework of Community law, in particular in the light of the Merger Regulation, and by reference to the Commission Notice on remedies acceptable under Council Regulation (EEC) No. 4064/89 and under Commission Regulation (EC) No. 447/98.

Section A. Definitions

For the purpose of the Commitments, the following terms shall have the following meaning:

Affiliated Undertakings: undertakings controlled by the Parties and/or by the ultimate parents of the Parties whereby the notion of control shall be interpreted pursuant to Article 3 of the Merger Regulation.

Closing: the transfer of the legal title of the Divestiture Businesses to the Purchaser.

Divestiture Businesses: the assets comprising the businesses that Schering-Plough commits to divest, as further defined in Section B and the attached Schedules (each respective business described in the Schedules herein referred to as a '**Divestiture Business**').

Divestiture Trustee: one or more natural or legal person(s), independent from the Parties, who is approved by the Commission and appointed by Schering-Plough and who has received from Schering-Plough the exclusive mandate to sell the Divestiture Businesses to a Purchaser at no minimum price.

Effective Date: the later of the date of adoption of the Decision or the date of the transfer of the legal title of Organon BS to Schering-Plough.

Extended Divestiture Period: the period of […] from the date of expiry of the First Divestiture Period within which the Divestiture Trustee shall have the irrevocable and exclusive mandate from Schering-Plough to sell those Divestiture Businesses for which a binding agreement is not yet concluded at the end of the First Divestiture Period.

First Divestiture Period: the period of […] from the Effective Date within which Schering-Plough may conclude one or more binding agreements to sell the Divestiture Businesses before providing a mandate to the Divestiture Trustee.

Hold-Separate Manager: the person appointed by Schering-Plough to manage the day-to-day business of a Divestiture Business under the supervision of the Monitoring Trustee.

Monitoring Trustee: one or more natural or legal person(s), independent from the Parties, who is approved by the Commission and appointed by Schering-Plough, and who has the duty to monitor Schering-Plough's compliance with the conditions and obligations attached to the Decision.

Organon BS: Organon BioSciences N.V., incorporated as a limited liability company (naamloze venootschap) under the laws of the Netherlands, with its registered office at Wethouder van Eschstraat 1 5342 AV Oss, The Netherlands, including all of its Affiliated Undertakings.

Parties: Schering-Plough and Organon BS.

Personnel: all personnel currently employed by the Parties and working for each Divestiture Business, including staff seconded to the Divestiture Business.

Purchaser: with regard to each Divestiture Business, the undertaking approved by the Commission as acquirer of the Divestiture Business in accordance with the criteria set out in Section D.

Retained Competing Businesses: with regard to each Divestiture Business, the corresponding competing business retained by Schering-Plough (each corresponding business referred to as a '**Retained Competing Business**').

Schering-Plough: The Schering-Plough Corporation, incorporated under the laws of New Jersey, United States of America with its registered office at 2000 Galloping Hill Road, Kenilworth New Jersey 07033, U.S.A., including all of its Affiliated Undertakings.

Trustee(s): the Monitoring Trustee and/or the Divestiture Trustee.

SECTION B. THE DIVESTITURE COMMITMENT

Commitment to Divest

1. In order to maintain or restore effective competition, Schering-Plough commits to divest, or procure the divestiture of, the Divestiture Businesses as going concerns to one or more Purchasers on terms of sale approved by the Commission in accordance with the procedure described in paragraph 18 below ('**the Divestiture Commitment**'). Schering-Plough commits to divest, or procure the divestiture of, the Divestiture Businesses as going concerns by the end of the First Divestiture Period. To carry out each divestiture, Schering-Plough commits to find, for each Divestiture Business, a Purchaser and to enter into a final binding agreement for the sale of such Divestiture Business within the First Divestiture Period. If Schering-Plough has not entered into such an agreement at the end of the First Divestiture Period, Schering-Plough shall grant the Divestiture Trustee an exclusive mandate to sell the Divestiture Business within the Extended Divestiture Period in accordance with the procedure described in paragraph 28.

2. Schering-Plough shall be deemed to have complied with this commitment if:

   (a) By the end of the First Divestiture Period or if applicable, by the end of the Extended Divestiture Period, Schering-Plough or an Affiliated Undertaking has entered into a final binding sale and purchase agreement for each of the Divestiture Businesses;

   (b) The Commission approves the Purchaser and the terms in accordance with the procedure described in paragraphs 17 and 18; and

   (c) Closing of the sale of each of the Divestiture Businesses take place within a period not exceeding three (3) calendar months after the approval of the Purchaser and the terms of sale by the Commission.

3. In order to maintain the structural effect of the Divestiture Commitment, the Parties shall, for a period of ten (10) years after the Effective Date, not acquire direct or indirect influence over the whole or part of the Divestiture Businesses, unless the

Commission has previously found that the market structure has changed to such an extent that the absence of influence over the Divestiture Business in question is no longer necessary to render the proposed concentration compatible with the Common Market.

Structure and Definition of the Divestiture Businesses

4. The Divestiture Businesses consist of:

(a) The Neo Gletvax and Gletvax Plus branded monovalent swine *E.coli* business, and a co-exclusive licence for the existing formulations of Gletvax 5 and Gletvax 6 (also branded as Toxicol in certain countries), in the European Economic Area ('**EEA**') (together '**the Swine *E.coli* Vaccine Business**'), as described in more detail in Schedule 1;

(b) The Equip F, Equip T, and Equip FT branded horse vaccine businesses in the EEA (together '**the Equine Vaccine Business**'), as described in more detail in Schedule 2;

(c) The Lactovac-C branded ruminant neonatal diarrhoea business in the EEA, and Organon BS's new ruminant neonatal diarrhoea vaccine product which is currently in development ('**the Ruminant Neonatal Diarrhoea Vaccine Business**'), as described in more detail in Schedule 3;

(d) The Covexin 8, Covexin 8a (also branded as Tasvax Huit in France) and Blackleg branded ruminant clostridia businesses, and a co-exclusive licence for the existing formulation of Covexin 10, in the EEA (together '**the Ruminant Clostridia Vaccines Business**'), as described in more detail in Schedule 4;

(e) The Cyclix, Cyclix Porcine, Prosolvin and Ovarid branded endocrine businesses in the EEA (together '**the Endocrine Business**'), as described in more detail in Schedule 5;

(f) The Insuvet Lente, Insuvet Protamine Zinc and Insuvet Neutral branded insulin businesses in the EEA (together '**the Insulin Business**'), as described in more detail in Schedule 6;

(g) The Autoworm, Systamex, Versatrine, Sputop, Coopertix and Coopers Spot-On branded parasiticides businesses in the EEA (together '**the Parasiticides Business**'), as described in more detail in Schedule 7;

(h) The Eutha 77 branded euthanasia business in the EEA ('**the Euthanasia Business**'), as described in more detail in Schedule 8;

(i) The Borgal, Gorban and Gelliprim sulphonamide businesses in the EEA (together '**the Sulphonamide Business**'), as described in more detail in Schedule 9;

(j) The Coliclox, Gentamam, Super Mastidol DC (also branded as Mastitar and Vonapen HL in certain countries), Neo Mastitar (also branded as Neo Mastidol and Vonapen Retard in certain countries), Cobactan DC and Cephaguard DC mastitis businesses in the EEA (together '**the Mastitis Business**'), as described in more detail in Schedule 10;

(k) The Predsolan Injectable business in Italy, the Equipalazone business in France and Germany, and the Quadrisol 100 business in the EEA (together '**the Anti-Inflammatory Business**'), as described in more detail in Schedule 11; and

(l) The Rabdomun and Quantum Rabies branded rabies vaccine business in the EEA (together '**the Rabies Vaccine Business**'), as described in more detail in Schedule 12.

5. The Divestment Businesses will be divested either singly or in combination to one or more Purchasers with the consent of the Commission.

6. The divestiture of the Divestment Businesses will proceed by way of asset transactions, including transfer, sale, assignment, and/or licence as the case may be and in so far as legally permissible. Each divestiture transaction shall include the following elements, as more specifically defined in the relevant Schedules:

   (a) All tangible and intangible assets (including the relevant intellectual property rights), by way of transfer, sale, assignment or licence, which are necessary to ensure the viability and competitiveness of the Divestiture Businesses;

   (b) All licences, permits and authorisations issued by any governmental organisation for the benefit of the Divestiture Businesses;

   (c) All contracts, commitments and customer orders of the Divestiture Businesses;

   (d) All customer, credit and other records of the Divestiture Businesses (items referred to under (a) to (d) hereinafter collectively referred to as '**Assets**'); and

   (e) At the option of the Purchaser, the benefit, for a transitional period of up to three (3) years after Closing and on terms and conditions equivalent to those at present afforded to the Divestiture Businesses, of all current arrangements under which the Parties or Affiliated Undertakings supply products, and/or reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of the relevant Divestiture Businesses for such period as is required by the Purchaser to establish the Divestiture Business as a viable and independent business, but not exceeding thirty-six (36) calendar months from the date of Closing, as detailed in the Schedules.

7. For the avoidance of doubt, the Divestiture Businesses shall not, *inter alia*, include:

   (a) Any manufacturing facilities of the Parties;

   (b) Any Personnel of the Parties;

(c) Intellectual property rights which do not contribute to the current operation or may not be necessary to ensure the viability, marketability and competitiveness of the Divestiture Businesses;

(d) The Schering-Plough, Akzo Nobel, Organon BioSciences, and Intervet name and logo in any form;

(e) Books and records required to be retained pursuant to any statute, rule, regulation or ordinance, provided that copies of such documents necessary for the relevant Divestiture Business shall be provided to the Purchaser, upon request; and

(f) General books of account and books of original entry that comprise the Parties' or Affiliated Undertakings' permanent accounting or tax records provided that copies of such documents necessary for the Divestiture Business shall be provided to the Purchaser, upon request.

SECTION C. RELATED COMMITMENTS

Preservation of Viability, Marketability and Competitiveness

8. Until Closing, Schering-Plough shall preserve the economic viability, marketability and competitiveness of each Divestiture Business, in accordance with good business practice, and shall minimise as far as possible any risk of loss of competitive potential of each Divestiture Business. In particular Schering-Plough commits:

(a) not to carry out any act upon its own authority that might have a significant adverse impact on the value, management or competitiveness of the Divestiture Business or that might alter the nature and scope of activity, or the industrial or commercial strategy or the investment policy of the Divestiture Business; and

(b) to make available sufficient resources for the development of the Divestiture Business, on the basis and continuation of the existing business plans.

Hold-Separate Obligations

9. Until Closing, Schering-Plough shall assist the Monitoring Trustee in ensuring that the Divestiture Businesses are managed as distinct and saleable entities separate from the businesses retained by Schering-Plough, including the Retained Competing Businesses. Schering-Plough shall appoint a Hold-Separate Manager who shall be responsible for the management of the Divestiture Businesses, under the supervision of the Monitoring Trustee. The Hold-Separate Manager shall manage each Divestiture Business independently and in the best interest of the business with a view to ensuring its continued economic viability, marketability and competitiveness and its independence from the businesses retained by Schering-Plough.

10. Schering-Plough commits, until Closing and subject to paragraph 8, to keep the Divestiture Businesses separate from the Retained Competing Businesses and to ensure that Personnel of the Divestiture Businesses – including the Hold-Separate Manager – have no direct involvement in any Retained Competing Business and vice versa. Schering-Plough shall also ensure that the Personnel do not report to any individual directly involved in the Retained Competing Businesses.

11. Schering-Plough commits to take all reasonable steps to ensure that Schering-Plough personnel involved in the transfer of the Divestiture Businesses ('**Technical Transfer Personnel**') shall not use any confidential information from the Purchaser other than information strictly required to assist in the transfer of the Divestiture Business, and they shall disclose such information to other Schering-Plough personnel only to the extent strictly required to assist in the transfer of the Divestiture Business.

Ring-Fencing

12. Schering-Plough shall, to the extent reasonable, implement all necessary measures to ensure that after the adoption of the Decision it does not obtain any business secrets, know-how, commercial information, or any other information of a confidential or proprietary nature relating to the Divestiture Businesses. However, Schering-Plough may obtain information relating to the Divestiture Businesses which is reasonably necessary for the divestiture of each Divestiture Business or whose disclosure to Schering-Plough is required by law.

13. The participation of the Divestiture Businesses in a central information technology network shall be restricted to the extent possible, without compromising the viability of the Divestiture Businesses.

Due Diligence

14. In order to enable potential purchasers to carry out reasonable due diligence of the Divestiture Businesses, Schering-Plough shall, subject to customary confidentiality assurances and dependent on the stage of the divestiture process, provide to potential purchasers sufficient information as regards the relevant Divestiture Business.

Reporting

15. Schering-Plough shall submit written reports in English to the Commission and the Monitoring Trustee on potential purchasers of the Divestiture Businesses and developments in the negotiations with such potential purchasers. Schering-Plough shall submit these written reports no later than ten (10) working days after the end of every month following the Effective Date (or otherwise at the Commission's request).

16. The Parties shall inform the Commission and the Monitoring Trustee on the preparation of the data room documentation and the due diligence procedure and shall submit a copy of an information memorandum or similar document to the Commission and the Monitoring Trustee before sending the memorandum out to potential purchasers.

SECTION D. THE PURCHASER

17. In order to ensure the maintenance of effective competition, the Purchaser, in order to be approved by the Commission, must:

(a) Be independent of and unconnected to the Parties;

(b) Have the financial resources, assets (including (i) pharmaceutical and/or biological manufacturing capabilities or in the case of Ovarid referred to in Schedule 5, Insuvet Lente, Insuvet Neutral, Insuvet Protamine Zinc all referred to in Schedule 6, and Equipalazone referred to in Schedule 11, access to such capabilities, and (ii) an established marketing and sales team in the animal health field in the EEA), proven expertise and incentive to maintain and develop the relevant Divestiture Business as a viable and active competitive force in competition with Schering-Plough and other competitors;

(c) Have technical transfer capabilities;

(d) Neither be likely to create, in the light of the information available to the Commission, *prima facie* competition concerns nor give rise to a risk that the implementation of the Divestiture Commitment will be delayed, and must, in particular, reasonably be expected to obtain all necessary approvals from the relevant regulatory authorities for the acquisition of the Divestiture Business (the before-mentioned criteria for the Purchaser hereafter '**the Purchaser Requirements**').

18. The final binding sale and purchase agreement shall be conditional on the Commission's approval. When Schering-Plough has reached an agreement with a Purchaser, it shall submit a fully documented and reasoned proposal, including a copy of the final agreement(s), to the Commission and the Monitoring Trustee. Schering-Plough must be able to demonstrate to the Commission that the Purchaser meets the Purchaser Requirements and that the Divestiture Business is being sold in a manner consistent with the Commitments. For the approval, the Commission shall verify that the purchaser fulfils the Purchaser Requirements and that the Divestiture Businesses are being sold in a manner consistent with the Commitments. In the event that Schering-Plough receives offers from more than one potential purchaser which, upon verification by the Commission, fulfils the Purchaser Requirements, Schering-Plough shall be free to take whichever offer that Schering-Plough deems the most appropriate to its interests. The Commission may approve the sale of the Divestiture Business without one or more Assets if this does not affect the viability and competitiveness of the Divestiture Business after the sale, taking account of the proposed Purchaser.

SECTION E. TRUSTEE

I. Appointment Procedure

19. Schering-Plough shall appoint a Monitoring Trustee to carry out the functions specified in the Commitments for a Monitoring Trustee.

20. If Schering-Plough has not entered into a binding sale and purchase agreement one (1) calendar month before the end of the First Divestiture Period or if the Commission has rejected a purchaser proposed by Schering-Plough at that time or thereafter, Schering-Plough shall appoint a Divestiture Trustee to carry out the functions specified in the Commitments with regard to the Divestiture Trustee. The appointment of the Divestiture Trustee shall take effect upon the commencement of the Extended Divestment Period.

21. The Trustee(s) shall be independent of the Parties, possess the necessary qualifications to carry out its mandate, for example as an investment bank or consultant or auditor, and shall neither have nor become exposed to a conflict of interest. The Trustee(s) shall be remunerated by Schering-Plough in a way that does not impede the independent and effective fulfilment of its mandate. In particular, where the remuneration package of a Divestiture Trustee includes a success premium linked to the final sale value of the Divestiture Business, the fee shall also be linked to a divestiture within the Extended Divestiture Period.

Proposal by Schering-Plough

22. No later than one (1) calendar week after the Effective Date, Schering-Plough shall submit to the Commission for approval a list of one or more persons whom Schering-Plough proposes to appoint as the Monitoring Trustee. No later than one (1) calendar month before the end of the First Divestiture Period, Schering-Plough shall submit to the Commission for approval a list of one or more persons whom Schering-Plough proposes to appoint as Divestiture Trustee. The proposal shall contain sufficient information for the Commission to verify that the proposed Trustee fulfils the requirements set out in paragraph 21 and shall include:

(a) The full terms of the proposed mandate, which shall include all provisions necessary to enable the Trustee to fulfil its duties under these Commitments;

(b) The outline of a work plan which describes how the Trustee intends to carry out its assigned tasks; and

(c) An indication whether the proposed Trustee is to act as both Monitoring Trustee and Divestiture Trustee or whether different Trustees are proposed for the two functions.

Approval or Rejection by the Commission

23. The Commission shall have the discretion to approve or reject the proposed Trustee(s) and to approve the proposed mandate subject to any modifications it deems necessary for the Trustee to fulfil its obligations. If only one name is approved, Schering-Plough shall appoint or cause to be appointed, the individual or institution concerned as Trustee, in accordance with the mandate approved by the Commission. If more than one name is approved, Schering-Plough shall be free to choose the Trustee to be appointed from among the names approved. The Trustee shall be appointed within one (1) calendar week of the Commission's approval, in accordance with the mandate approved by the Commission.

New Proposal by the Parties

24. If all the proposed Trustees are rejected, Schering-Plough shall submit the names of at least two more individuals or institutions within one (1) calendar week of being informed of the rejection, in accordance with the requirements and the procedure set out in paragraphs 19, 20 and 23.

Trustee Nominated by the Commission

25. If all further proposed Trustees are rejected by the Commission, the Commission shall nominate a Trustee, whom Schering-Plough shall appoint, or cause to be appointed, in accordance with a trustee mandate approved by the Commission.

II. Functions of the Trustee

26. The Trustee shall assume its specified duties in order to ensure compliance with the Commitments. The Commission may, on its own initiative or at the request of the Trustee or Schering-Plough, give any orders or instructions to the Trustee in order to ensure compliance with the conditions and obligations attached to the Decision.

Duties and Obligations of the Monitoring Trustee

27. The Monitoring Trustee shall:

(a) Propose in its first report to the Commission a detailed work plan describing how it intends to monitor compliance with the obligations and conditions attached to the Decision;

(b) Oversee the on-going management of each Divestiture Business with a view to ensuring their continued economic viability, marketability and competitiveness and monitor compliance by Schering-Plough with the conditions and obligations attached to the Decision. To that end the Monitoring Trustee shall:

(i) Monitor the preservation of the economic viability, marketability and competitiveness of the Divestiture Businesses, in accordance with paragraph 8;

(ii) Supervise the management of the Divestiture Businesses as distinct and saleable entities, in accordance with paragraph 9;

(iii) In consultation with Schering-Plough, determine all necessary measures to ensure that the Retained Competing Businesses do not after the adoption of the Decision obtain any business secrets, know-how, commercial information, or any other information of a confidential or proprietary nature relating to the Divestiture Businesses, and in particular, strive for the severing of the Divestiture Businesses' participation in a central information technology network to the extent possible, without compromising the viability of the Divestiture Businesses, and decide whether such information may be disclosed to Schering-Plough as the disclosure is reasonably necessary to allow Schering-Plough to carry out the divestiture or as the disclosure is required by law; and

(iv) Monitor the splitting of assets between the Divestiture Businesses and Schering-Plough or Affiliated Undertakings.

(c) Assume the other functions assigned to the Monitoring Trustee under the conditions and obligations attached to the Decision;

(d) Propose to Schering-Plough such measures as the Monitoring Trustee considers necessary to ensure Schering-Plough's compliance with the conditions and obligations attached to the Decision, in particular the maintenance of the full economic viability, marketability or competitiveness of the Divestiture Businesses, the holding separate of the Divestiture Businesses and the non-disclosure of competitively sensitive information;

(e) Review and assess potential purchasers as well as the progress of the divestiture process and verify that, dependent on the stage of the divestiture process, potential purchasers receive sufficient information relating to the Divestiture Businesses in particular by reviewing, if available, the data room documentation, the information memorandum and the due diligence process;

(f) Provide to the Commission a written report within fifteen (15) calendar days after the end of every month, and send to Schering-Plough a non-confidential copy at the same time. The report shall cover the operation and management of each of the Divestiture Businesses so that the Commission can assess whether the business is held in a manner consistent with the Commitments

and the progress of the divestiture process as well as potential purchasers. In addition to these reports, the Monitoring Trustee shall promptly report in writing to the Commission, sending Schering-Plough a non-confidential copy at the same time, if it concludes on reasonable grounds that Schering-Plough is failing to comply with these Commitments; and

(g) Within one (1) calendar week after receipt of the documented proposal referred to in paragraph 18, submit to the Commission a reasoned opinion as to the suitability and independence of the proposed purchaser and the viability of the relevant Divestiture Business after the sale and as to whether that Divestiture Business is sold in a manner consistent with the conditions and obligations attached to the Decision, in particular, if relevant, whether the sale of that Divestiture Business without one or more Assets affects the viability of that Divestiture Business after the sale, taking account of the proposed purchaser.

Duties and Obligations of the Divestiture Trustee

28. Within the Extended Divestiture Period, the Divestiture Trustee shall sell at no minimum price any Divestiture Business that remains unsold to a purchaser, provided that the Commission has approved both the purchaser and the final binding sale and purchase agreement in accordance with the procedure laid down in paragraph 18. The Divestiture Trustee shall include in the sale and purchase agreement such terms and conditions as it considers appropriate for an expedient sale in the Extended Divestiture Period. In particular, the Divestiture Trustee may include in the sale and purchase agreement such customary representations and warranties and indemnities as are reasonably required to effect the sale. The Divestiture Trustee shall protect the legitimate financial interests of Schering-Plough, subject to Schering-Plough's unconditional obligation to divest at no minimum price in the Extended Divestiture Period.

29. In the Extended Divestiture Period (or otherwise at the Commission's request), the Divestiture Trustee shall provide the Commission with a comprehensive monthly report written in English on the progress of the divestiture process. Such reports shall be submitted within fifteen (15) calendar days after the end of every month with a simultaneous copy to the Monitoring Trustee and a non-confidential copy to Schering-Plough.

III. Duties and Obligations of Schering-Plough

30. Schering-Plough shall provide, and shall cause its advisors to provide, the Trustee(s) with all such cooperation, assistance and information as the Trustee(s) may reasonably require to perform its tasks. The Trustee(s) shall have full and complete access to any of Schering-Plough's, its Affiliated Undertakings' or the relevant Divestiture Business' books, records, documents, Personnel, facilities, sites and technical information necessary for fulfilling its duties under the Commitments and Schering-Plough shall provide the Trustee(s) upon request with copies of any document necessary for fulfilling its duties under the Commitments. The Trustee(s) shall agree in writing to keep any confidential information and business secrets disclosed to it in confidence, except to the extent necessary to perform its duties hereunder. If requested by the Trustee(s), Schering-Plough, its Affiliated Undertakings or the relevant Divestiture Business shall make available to the Trustee(s) one or more offices on its premises and shall be available for meetings in order to provide the Trustee(s) with all information necessary for the performance of its tasks.

31. Schering-Plough shall provide the Monitoring Trustee with all managerial and administrative support that it may reasonably request on behalf of the management of the Divestiture Businesses. This shall include all administrative support functions relating to the Divestiture Businesses which are currently carried out at headquarters level. Schering-Plough shall provide and shall cause its advisors to provide the Monitoring Trustee, on request, with the information submitted to potential purchasers, in particular give the Monitoring Trustee access to the data room documentation and all other information granted to potential purchasers in the due diligence procedure. Schering-Plough shall inform the Monitoring Trustee on possible purchasers, submit a list of potential purchasers, and keep the Monitoring Trustee informed of all developments in the divestiture process.

32. Schering-Plough shall grant or procure Affiliated Undertakings to grant comprehensive powers of attorney, duly executed, to the Divestiture Trustee to effect the sale during the Extended Divestiture Period, the Closing and all actions and declarations which the Divestiture Trustee considers necessary or appropriate to achieve the sale and the Closing, including the appointment of advisors to assist with the sale process. Upon request of the Divestiture Trustee, Schering-Plough shall cause the documents required for effecting the sale and the Closing to be duly executed.

33. Schering-Plough shall indemnify the Trustee(s) and its employees and agents (each an '**Indemnified Party**') and hold each Indemnified Party harmless against, and hereby agrees that an Indemnified Party shall have no liability to Schering-Plough for any

liabilities arising out of the performance of the Trustee(s)'s duties under the Commitments, except to the extent that such liabilities result from the wilful default, recklessness, gross negligence or bad faith of the Trustee(s), its employees, agents or advisors.

34. At the expense of Schering-Plough, the Trustee(s) may appoint advisors (in particular for corporate finance or legal advice), subject to Schering-Plough's approval (this approval not to be unreasonably withheld or delayed) if the Trustee(s) considers the appointment of such advisors necessary or appropriate for the performance of its duties and obligations under the Mandate, provided that any fees and other expenses incurred by the Trustee(s) are reasonable. Should Schering-Plough refuse to approve the advisors proposed by the Trustee(s) the Commission may approve the appointment of such advisors instead, after having heard Schering-Plough. Only the Trustee(s) shall be entitled to issue instructions to the advisors. Paragraph 33 shall apply *mutatis mutandis*. In the Extended Divestiture Period, the Divestiture Trustee may use advisors who served Schering-Plough during the Divestiture Period if the Divestiture Trustee considers this in the best interest of an expedient sale.

IV. Replacement, Discharge and Reappointment of the Trustee(s)

35. If the Trustee(s) ceases to perform its functions under the Commitments or for any other good cause, including the exposure of the Trustee(s) to a conflict of interest:

    (a) The Commission may, after hearing the Trustee(s), require Schering-Plough to replace the Trustee(s); or

    (b) Schering-Plough, with the prior approval of the Commission, may replace the Trustee(s).

36. If the Trustee(s) is removed according to paragraph 35, the Trustee(s) may be required to continue in its function until a new Trustee(s) is in place to whom the Trustee(s) has effected a full handover of all relevant information. The new Trustee(s) shall be appointed in accordance with the procedure referred to in paragraphs 19 to 25.

37. Beside the removal according to paragraph 35, the Trustee(s) shall cease to act as Trustee(s) only after the Commission has discharged it from its duties after all the

Commitments with which the Trustee(s) has been entrusted have been implemented. However, the Commission may at any time require the reappointment of the Monitoring Trustee if it subsequently appears that the relevant remedies might not have been fully and properly implemented.

SECTION F. DISPUTE RESOLUTION

38. Should a dispute arise between Schering-Plough and the Purchaser regarding the implementation of any term of the transitional arrangement or trademark licensing referred to in the Schedules, such dispute shall be submitted to a fast track resolution procedure ('**the Fast Track Resolution Procedure**').

39. The Fast Track Resolution Procedure will operate as follows:

(a) The party who seeks to initiate the Fast Track Resolution Procedure ('**the Initiating Party**') shall notify the other party ('**the Responding Party**') of its request and specify the reasons why it believes that a failure by the Responding Party to meet such request would be inconsistent with these Commitments;

(b) The Purchaser and Schering-Plough (including the relevant Affiliated Undertaking) shall use their best efforts to resolve all differences of opinion and to settle all disputes that may arise through co-operation and consultation within a reasonable period of time not to exceed fifteen (15) calendar days;

(c) Should the Purchaser and Schering-Plough fail to resolve their differences of opinion through co-operation and consultation, the Initiating Party shall within seven (7) calendar days initiate an arbitration process;

(d) To initiate the arbitration process, the Initiating Party shall give written notice to the Responding Party nominating an arbitrator and stating the specific nature of the claim, the factual basis of its position and the relief requested. In such case, the Responding Party shall appoint another arbitrator within fourteen (14) calendar days after receipt of the written notice. The arbitrators so appointed shall appoint a third arbitrator to be president of the arbitration tribunal within seven (7) calendar days after both arbitrators have been nominated. If the arbitrators nominated by the Initiating Party and the

Requesting Party cannot agree on the nomination of a third arbitrator, they shall request that the London Court of International Arbitration appoint the third arbitrator;

(e) Any of the arbitrators will be entitled to request any relevant information from the Purchaser, Schering-Plough or the relevant Affiliated Undertaking(s). The arbitrators shall agree in writing to keep any confidential information and business secrets disclosed to them in confidence. Throughout these Commitments the standards attributed to confidential information and business secrets are those as set out in accordance with European Community law;

(f) The burden of proof in any dispute governed by this Section F shall be as follows:

(i) The Initiating Party must produce evidence of a *prima facie* case; and
(ii) If the Initiating Party produces evidence of a *prima facie* case, the arbitrators must find in favour of the Initiating Party unless the Responding Party can produce evidence to the contrary.

(g) The arbitration procedure shall follow the rules of the London Court of International Arbitration. The arbitration shall be conducted in Kenilworth, New Jersey. The language of the arbitration shall be English. In the event of disagreement between the parties to the arbitration regarding the interpretation of the Commitments, the arbitrators shall inform the Commission and may seek the Commission's interpretation of the Commitments before finding in favour of any party to the arbitration. The Commission may, at any time, issue a submission during the arbitration procedure;

(h) The arbitration award shall, in addition to dealing with the merits of the claim, impose the fees and costs of the prevailing party upon the party that is unsuccessful;

(i) Decisions of the arbitrators shall be final and binding on all persons submitting to arbitration; and

(j) Nothing in the above-described arbitration procedure shall affect the powers of the Commission to take decisions in relation to the Commitments in accordance with its powers under the Merger Regulation and the EC Treaty.

40. Schering-Plough and the Purchaser shall submit a written report in English to the Commission on any matters which the Commission reasonably requests in order to determine whether they have complied with the commitments with regard to dispute resolution. Any such report shall be sent to the Commission within fifteen (15) working days from the date the Commission makes a request.

SECTION G. THE REVIEW CLAUSE

41. The Commission may, where appropriate, in response to a request from Schering-Plough showing good cause and accompanied by a report from the Monitoring Trustee:

(a) Grant an extension of the time periods foreseen in the Commitments; or

(b) Waive, modify or substitute, in exceptional circumstances, one or more of the undertakings in these Commitments.

42. Where Schering-Plough seeks an extension of a time period, it shall submit a request to the Commission no later than one (1) calendar month before the expiry of that period, showing good cause. Only in exceptional circumstances shall Schering-Plough be entitled to an extension within the last month of any period.

Name: Götz Drauz

Title: Partner

Duly authorised by the Power of Attorney dated 11 June 2007, a copy of which is attached, for and on behalf of Schering-Plough

Date: 10 October 2007.

Signature:

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SCHEDULE 1

THE SWINE *E.COLI* VACCINE BUSINESS

1. This Divestiture Business consists of:

   (a) Rights, title and interest in the monovalent swine *E.coli* vaccine currently marketed under the brands Neo Gletvax and Gletvax Plus (together '**the Monovalent Swine *E.coli* Vaccine**' or '**the Monovalent Swine *E.coli* Vaccine Business**', as appropriate), which have already been marketed in the EEA or a part thereof prior to the Effective Date; and

   (b) A commitment to enter into a co-exclusive agreement for the multivalent swine *E.coli* and clostridia vaccines currently marketed under the brands Gletvax 5, Gletvax 6 and Toxicol, and which have already been marketed in the EEA or a part thereof prior to the Effective Date (together '**the Existing Multivalent Swine *E.coli* and Clostridia Vaccines**' or '**the Existing Multivalent Swine *E.coli* and Clostridia Vaccines Business**', as appropriate).

2. For the avoidance of doubt, the Swine *E.coli* Vaccine Business does not contain any rights to sell Neo Gletvax, Gletvax Plus, Gletvax 5, Gletvax 6 and Toxicol outside of the EEA.

3. The Swine *E.coli* Vaccine Business includes:

   (a) Sufficient biological material to produce the Monovalent Swine *E.coli* Vaccine and the Existing Multivalent Swine *E.coli* and Clostridia Vaccines, including sufficient amounts of the master seeds;

   (b) Finished goods inventory, work in process, sales and promotional material (where available) relating to the Monovalent Swine *E.coli* Vaccine Business for sale in the EEA held at the date of Closing;

   (c) All current marketing authorisations and pending applications for marketing authorisations for the Monovalent Swine *E.coli* Vaccine Business in the EEA held by Schering-Plough, including all relevant dossiers relating to the current and/or pending marketing authorisations available to Schering-Plough;[93]

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1 A list of relevant marketing authorisations is included in attached Annex 1a.

(d) All current marketing authorisations and pending applications for marketing authorisations for Gletvax 5 and Gletvax 6 in the EEA held by Schering-Plough, including all relevant dossiers relating to the current and/or pending marketing authorisations available to Schering-Plough, provided that Schering-Plough obtains parallel informed consent marketing authorisations relating to Gletvax 5 and Gletvax 6 for the benefit of Schering-Plough and/or Organon BS;

(e) Copies of all clinical data and studies relating to the Swine *E.coli* Vaccine Business and the Existing Multivalent Swine *E.coli* and Clostridia Vaccines Business existing prior to Closing;

(f) The NEO GLETVAX, GLETVAX PLUS, GLETVAX and TOXICOL trademarks in the EEA (including those EEA countries where the Monovalent Swine *E.coli* Vaccine and the Existing Multivalent Swine *E.coli* and Clostridia Vaccines may not currently be registered)[94];

(g) The commitment by Schering-Plough to re-brand in the EEA Gletvax 5, Gletvax 6 and Toxicol from Closing, in accordance with registration requirements that govern such changes and in a commercially reasonable manner in agreement with the Purchaser;

(h) The intellectual property rights necessary to give a Purchaser the exclusive right to manufacture and sell the Monovalent Swine *E.coli* Vaccine by way of a perpetual, irrevocable licence and the right to manufacture and sell the Existing Multivalent Swine *E.coli* and Clostridia Vaccines in the EEA by way of a co-exclusive, perpetual, irrevocable licence. These intellectual property rights consist of product formulations, manufacturing know-how and other secret know-how, packaging specifications and all related copyright; and

(i) Copies of all relevant data, books, records, and other documents exclusively related to or necessary for the operation of the Monovalent Swine *E.coli* Vaccine Business

2 The trademarks are owned by Schering-Plough. Please find relevant trademark registration information at Annex 2b.

in the EEA, including existing customer records of the Monovalent Swine *E.coli* Vaccine Business in the EEA, provided that Schering-Plough may redact from such copies any information that does not relate to the Monovalent Swine *E.coli* Vaccine Business.

4. At the option of the Purchaser, Schering-Plough or Affiliated Undertakings shall enter into a supply or toll-manufacturing arrangement with the Purchaser for the non-exclusive supply or toll-manufacturing of the Monovalent Swine *E.coli* Vaccine and the Existing Multivalent Swine *E.coli* and Clostridia Vaccines in the EEA, for an appropriate period of time, not to exceed thirty-six (36) calendar months from the date of Closing, and on a reasonable cost plus basis to be agreed with the Purchaser. Under circumstances outside the control of Schering-Plough or the Purchaser, this period can be extended by the Monitoring Trustee until such time that the Purchaser has established the Swine *E.coli* Vaccine Business and/or the Existing Multivalent Swine *E.coli* and Clostridia Vaccines, as certified by the Monitoring Trustee.

5. The transitional supply or toll-manufacturing arrangement referred to in paragraph 4 shall include appropriate provisions designed to ensure the reasonable continuous supply by Schering-Plough to the Purchaser of the Monovalent Swine *E.coli* Vaccine and the Existing Multivalent Swine *E.coli* and Clostridia Vaccines in the EEA for the duration of the arrangement.

6. At the option of the Purchaser, Schering-Plough shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of the Monovalent Swine *E.coli* Vaccine and the Existing Multivalent Swine *E.coli* and Clostridia Vaccines in the EEA for such period as is required by the Purchaser to establish the Swine *E.coli* Vaccine Business as a viable and independent business, but not exceeding thirty-six (36) calendar months from the date of Closing, as certified by the Monitoring Trustee, and on a reasonable cost plus basis to be agreed with the Purchaser. Under circumstances outside the control of Schering-Plough or the Purchaser, this period can be extended by the Monitoring Trustee until such time that the Purchaser has established the Swine *E.coli* Vaccine Business and/or the Existing Multivalent Swine *E.coli* and Clostridia Vaccines, as certified by the Monitoring Trustee. Reasonable technical assistance to the Purchaser is currently envisaged to include:

   (a) Schering-Plough or an Affiliated Undertaking organising a team to ensure the transfer of the Monovalent Swine *E.coli* Vaccine and the Existing Multivalent Swine *E.coli* and Clostridia Vaccines to the Purchaser ('**the Technology Transfer Team**');

(b) The Technology Transfer Team meeting with designated representatives of the Purchaser to develop a written plan for the technical transfer of the Monovalent Swine *E.coli* Vaccine and the Existing Multivalent Swine *E.coli* and Clostridia Vaccines in the EEA;

(c) The provision by Schering-Plough or by an Affiliated Undertaking of a package consisting of copies of the relevant documents including research data, master seed history and lineage, regulatory documents and communications, process flow diagrams, specifications for equipment and materials, outlines of production, detailed manufacturing instructions, bills of materials, vendor information, and quality control testing procedures to the Purchaser;

(d) The provision by Schering-Plough or an Affiliated Undertaking of a critical reagent package for the Monovalent Swine *E.coli* Vaccine and the Existing Multivalent Swine *E.coli* and Clostridia Vaccines including, the master seeds, an agreed upon quantity of any unique reagents needed to perform in-process and final product testing, positive and negative control reagents for quality control tests, and samples to be used for validation of test methods to the Purchaser;

(e) Schering-Plough or an Affiliated Undertaking assisting the Purchaser during the transfer process to assure that the production and testing processes are understood;

(f) Reasonable escorted access of Schering-Plough's or an Affiliated Undertaking's manufacturing and quality control testing facilities during the transfer process to the Purchaser if required to assist in the understanding of the production and/or testing methods and procedures; and

(g) The Purchaser providing limited escorted access to its manufacturing and quality control test facilities to Schering-Plough and/or its Affiliated Undertaking during the transfer process to assist in the manufacturing and/or testing procedures.

7. The transitional technical assistance agreement referred to above shall include appropriate provisions designed to incentivise Schering-Plough to provide technical assistance to the Purchaser expeditiously. These provisions may include terms whereby the price payable by the Purchaser for technical assistance is reduced over time. Schering-Plough shall carry out the technical assistance for the technology transfer in accordance with good industry practice including as regards the timing and responsiveness with which this assistance is provided through the different stages of the transfer.

8. At the option of the Purchaser, Schering-Plough shall provide reasonable technical assistance to the Purchaser to facilitate the procurement of raw materials necessary for the manufacture of the Monovalent Swine *E.coli* Vaccine and the Existing Multivalent Swine *E.coli* and Clostridia Vaccines. If the Purchaser is not able to source such raw materials, Schering-Plough commits to enter, at the option of the Purchaser, into back-to-back supply agreements with certain raw material suppliers and the Purchaser to make such raw materials available to the Purchaser on a reasonable cost plus basis.

9. For the avoidance of doubt, this Divestiture Business shall not include any right, title and/or interest in:

(a) Any manufacturing facility including the manufacturing facility in Burgwedel, Germany;

(b) Any Personnel of the Parties;

(c) Ownership or use of the NEO GLETVAX, GLETVAX PLUS, GLETVAX and TOXICOL trademarks outside of the EEA;

(d) Raw materials and bulk antigens;

(e) Any research and development, clinical data and studies or intellectual property relating to Gletvax 5, Gletvax 6 and Toxicol after Closing;

(f) All marketing authorisations currently held by Schering-Plough outside of the EEA for the Monovalent Swine *E.coli* Vaccine and the Existing Multivalent Swine *E.coli* and Clostridia Vaccines;

(g) Any other vaccine including vaccines that contains *E.coli* and/or clostridia antigens;

(h) Any other asset not part of the Swine *E.coli* Vaccine Business and/or the Existing Multivalent Swine *E.coli* and Clostridia Vaccines as defined in this Schedule 1

and/or which is used in relation to a business of the Parties other than the Swine *E.coli* Vaccine Business and/or the Existing Multivalent Swine *E.coli* and Clostridia Vaccines; and

(i) Monies owed to the Parties by customers for the purchase of the Monovalent Swine *E.coli* Vaccine and the Existing Multivalent Swine *E.coli* and Clostridia Vaccines, and monies owed by the Parties to suppliers for materials used in the production of the Monovalent Swine *E.coli* Vaccine and the Existing Multivalent Swine *E.coli* and Clostridia Vaccines.

ANNEX 1a

INFORMATION ON THE MARKETING AUTHORISATIONS RELEVANT TO THE MONOVALENT SWINE *E.COLI* VACCINE BUSINESS

PRODUCT	COUNTRY	REGISTRATION NO.	APPLICATION DATE
[…]	[…]	[…]	[…]

ANNEX 1b

INFORMATION ON THE TRADEMARKS RELEVANT TO THE SWINE *E.COLI* VACCINE BUSINESS AND THE EXISTING MULTIVALENT SWINE *E.COLI* AND CLOSTRIDIA VACCINES BUSINESS

TRADEMARK	REGISTRATION NO.	COUNTRY WHERE REGISTERED	STATUS
[…]	[…]	[…]	[…]

SCHEDULE 2

THE EQUINE VACCINE BUSINESS

1. This Divestiture Business consists of rights, title and interest in the horse influenza and tetanus vaccines currently marketed under the brands Equip F, Equip T, and Equip FT, which have already been marketed in the EEA or a part thereof prior to the Effective Date ('**the Equine Vaccines**'). For the avoidance of doubt, the Equine Vaccine Business does not contain any rights to sell Equip F, Equip T, and Equip FT outside of the EEA.

2. The Equine Vaccine Business includes:

   (a) Sufficient biological material to produce the vaccines, including sufficient amounts of the master seeds and master cell line;

   (b) Finished goods inventory, work in process, sales and promotional material (where available) relating to the Equine Vaccine Business for sale in the EEA held at the date of Closing;

   (c) All current marketing authorisations and pending applications for marketing authorisations for the Equine Vaccine Business in the EEA held by Schering-Plough, including all relevant dossiers relating to the current and/or pending marketing authorisations available to Schering-Plough;[95]

   (d) Copies of all clinical data and studies relating to the Equine Vaccine Business existing prior to Closing;

   (e) The EQUIP, EQUIP F, EQUIP T, and EQUIP FT trademarks in the EEA (including those EEA countries where the Equine Vaccines may not currently be registered)[96];

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1 A list of relevant marketing authorisations is included in attached Annex 2a.

2 The trademarks are owned by Schering-Plough. Please find relevant trademark registration information at Annex 2b.

(f) The intellectual property rights necessary to give a Purchaser the exclusive right to manufacture and sell the Equine Vaccines in the EEA by way of a perpetual, irrevocable licence. These intellectual property rights consist of product formulations, chromatography and purification technology, manufacturing know-how and other secret know-how, packaging specifications, rights to the trade dress, and all related copyright (information on the relevant patents is provided in Annex 2c);

(g) The licence agreement with **[…]** dated **[…]** ('**the […] Agreement**') concerning the **[…]** technology necessary for the manufacture and sale of Equip F and Equip FT vaccines in the EEA (details of which are provided in Annex 2d) by way of assignment. Where assignment of the **[…]** Agreement is not possible, Schering-Plough will provide reasonable assistance to the Purchaser to negotiate an agreement with **[…]** to obtain a licence on terms and conditions comparable to the terms of the **[…]** Agreement. If the Purchaser is not able to enter into an agreement with **[…]**, Schering-Plough commits to enter into a sub-licence agreement with the Purchaser on terms and conditions equivalent to those of the **[…]** Agreement to make such **[…]** technology available to the Purchaser; and

(h) Copies of all relevant data, books, records, and other documents exclusively related to or necessary for the operations of the Equine Vaccine Business in the EEA, including existing customer records of the Equine Vaccine Business in the EEA, provided that Schering-Plough may redact from such copies any information that does not relate to the Equine Vaccine Business.

3. At the option of the Purchaser, Schering-Plough or an Affiliated Undertaking shall enter into a supply or toll-manufacturing arrangement with the Purchaser for the non-exclusive supply or toll-manufacturing of the Equine Vaccines in the EEA, for an appropriate period of time, not to exceed thirty-six (36) calendar months from the date of Closing, and on a reasonable cost plus basis to be agreed with the Purchaser. Under circumstances outside the control of Schering-Plough or the Purchaser, this period can be extended by the Monitoring Trustee until such time that the Purchaser has established the Equine Vaccine Business, as certified by the Monitoring Trustee.

4. The transitional supply or toll-manufacturing arrangement referred to in paragraph 3 shall include appropriate provisions designed to ensure the reasonable continuous supply by Schering-Plough to the Purchaser of the Equine Vaccines in the EEA for the duration of the arrangement.

5. At the option of the Purchaser, Schering-Plough shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of the Equine Vaccines in the EEA for such period as is required by the Purchaser to establish the Equine Vaccine Business as a viable and independent business, but not exceeding thirty-six (36) calendar months from the date of Closing, as certified by the Monitoring Trustee, and on a reasonable cost plus basis to be agreed with the Purchaser. Under circumstances outside the control of Schering-Plough or the Purchaser, this period can be extended by the Monitoring Trustee until such time that the Purchaser has established the Equine Vaccine Business, as certified by the Monitoring Trustee. Reasonable technical assistance to the Purchaser is currently envisaged to include:

   (a) Schering-Plough or an Affiliated Undertaking organising a team to ensure the transfer of the Equine Vaccines to the Purchaser ('**the Technology Transfer Team**');

   (b) The Technology Transfer Team meeting with designated representatives of the Purchaser to develop a written plan for the technical transfer of the Equine Vaccines in the EEA;

   (c) The provision by Schering-Plough or by an Affiliated Undertaking of a package consisting of copies of the relevant documents including research data, master seed history and lineage, master cell history and lineage, regulatory documents and communications, process flow diagrams, specifications for equipment and materials, outlines of production, detailed manufacturing instructions, bills of materials, vendor information, and quality control testing procedures to the Purchaser;

   (d) The provision by Schering-Plough or an Affiliated Undertaking of a critical reagent package including, the master seeds and master cell stocks, an agreed upon quantity of any unique reagents needed to perform in-process and final product testing, positive and negative control reagents for quality control tests, and samples to be used for validation of test methods to the Purchaser;

(e) Schering-Plough or an Affiliated Undertaking assisting the Purchaser during the transfer process to assure that the production and testing processes are understood;

(f) Reasonable escorted access of Schering-Plough's or an Affiliated Undertaking's manufacturing and quality control testing facilities during the transfer process to the Purchaser if required to assist in the understanding of the production and/or testing methods and procedures; and

(g) The Purchaser providing limited escorted access to its manufacturing and quality control test facilities to Schering-Plough and/or its Affiliated Undertaking during the transfer process to assist in the manufacturing and/or testing procedures.

6. The transitional technical assistance agreement referred to above shall include appropriate provisions designed to incentivise Schering-Plough to provide technical assistance to the Purchaser expeditiously. These provisions may include terms whereby the price payable by the Purchaser for technical assistance is reduced over time. Schering-Plough shall carry out the technical assistance for the technology transfer in accordance with good industry practice including as regards the timing and responsiveness with which this assistance is provided through the different stages of the transfer.

7. At the option of the Purchaser, Schering-Plough shall provide reasonable technical assistance to the Purchaser to facilitate the procurement of raw materials necessary for the manufacture of the Equine Vaccines. If the Purchaser is not able to source such raw materials, Schering-Plough commits to enter, at the option of the Purchaser, into back-to-back supply agreements with certain raw material suppliers and the Purchaser to make such raw materials available to the Purchaser on a reasonable cost plus basis.

8. For the avoidance of doubt, this Divestiture Business shall not include any right, title and/or interest in:

(a) Any manufacturing facility including the manufacturing facilities in Burgwedel, Germany and Upper Hutt, New Zealand;

(b) Any Personnel of the Parties;

(c) Raw materials and bulk antigens;

(d) All marketing authorisations currently held by Schering-Plough outside of the EEA for the Equine Vaccines;

(e) Any other vaccine including vaccines that contain an influenza or tetanus antigen;

(f) Any other asset not part of the Equine Vaccine Business as defined in this Schedule 2 and/or which is used in relation to a business of the Parties other than the Equine Vaccine Business; and

(g) Monies owed to the Parties by customers for the purchase of the Equine Vaccines, and monies owed by the Parties to suppliers for materials used in the production of the Equine Vaccines.

ANNEX 2a

INFORMATION ON THE MARKETING AUTHORISATIONS RELEVANT TO THE EQUINE VACCINE BUSINESS

PRODUCT	COUNTRY	REGISTRATION NO.	APPLICATION DATE
[…]	[…]	[…]	[…]

ANNEX 2b

INFORMATION ON THE TRADEMARKS RELEVANT TO THE EQUINE VACCINE BUSINESS

TRADEMARK	REGISTRATION NO.	COUNTRY WHERE REGISTERED	STATUS
[…]	[…]	[…]	[…]

ANNEX 2c

INFORMATION ON THE PATENTS RELEVANT TO THE EQUINE VACCINE BUSINESS

VACCINE	PATENT INFORMATION	COUNTRY WHERE VALIDATED	EXPIRY
[…]	[…]	[…]	[…]

ANNEX 2d

INFORMATION ON THE AGREEMENT RELEVANT TO THE EQUINE VACCINE BUSINESS

AGREEMENT
[…]

SCHEDULE 3

THE RUMINANT NEONATAL DIARRHOEA VACCINE BUSINESS

1. This Divestiture Business consists of rights, title and interest in the multivalent ruminant neonatal diarrhoea (scours) vaccine currently marketed under the brands Lactovac-C and Bovilis Lactovac-C, which has already been marketed in the EEA or a part thereof prior to the Effective Date ('**the Ruminant Neonatal Diarrhoea Vaccine**') and Organon BS's new ruminant neonatal diarrhoea vaccine product which is currently in development.[97] For the avoidance of doubt, the Ruminant Neonatal Diarrhoea Vaccine Business does not contain any rights to sell Lactovac-C outside of the EEA.

2. The Ruminant Neonatal Diarrhoea Vaccine Business includes:

   (a) Sufficient biological material to produce the vaccine, including sufficient amounts of the master seeds and master cell line;

   (b) Finished goods inventory, work in process, sales and promotional material (where available) relating to the Ruminant Neonatal Diarrhoea Vaccine Business for sale in the EEA held at the date of Closing;

   (c) All current marketing authorisations and pending applications for marketing authorisations for the Ruminant Neonatal Diarrhoea Vaccine in the EEA held by Organon BS, including all relevant dossiers relating to the current and/or pending marketing authorisations available to Organon BS;[98]

   (d) Copies of all clinical data and studies relating to the Ruminant Neonatal Diarrhoea Vaccine Business existing prior to Closing;

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1 Organon BS is currently developing a new ruminant neonatal diarrhoea vaccine which it expects to launch in 2013. The Purchaser would acquire all of the research and development files with regard to this pipeline product.

2 A list of relevant marketing authorisations is included in attached Annex 3a.

(e) The LACTOVAC trademark in the EEA (including those EEA countries where the Ruminant Neonatal Diarrhoea Vaccine may not currently be registered)[99];

(f) The intellectual property rights necessary to give a Purchaser the exclusive right to manufacture and sell the Ruminant Neonatal Diarrhoea Vaccine in the EEA by way of a perpetual, irrevocable licence. These intellectual property rights consist of product formulations, manufacturing know-how and other secret know-how, packaging specifications, rights to the trade dress, and all related copyright; and

(g) Copies of all relevant data, books, records, and other documents exclusively related to or necessary for the operation of the Ruminant Neonatal Diarrhoea Vaccine Business in the EEA, including existing customer records of the Ruminant Neonatal Diarrhoea Vaccine Business in the EEA, provided that Schering-Plough may redact from such copies any information that does not relate to the Ruminant Neonatal Diarrhoea Vaccine Business.

3. At the option of the Purchaser, Schering-Plough or an Affiliated Undertaking shall enter into a supply or toll-manufacturing arrangement with the Purchaser for the non-exclusive supply or toll-manufacturing of the Ruminant Neonatal Diarrhoea Vaccine in the EEA, for an appropriate period of time, not to exceed thirty-six (36) calendar months from the date of Closing, and on a reasonable cost plus basis to be agreed with the Purchaser. Under circumstances outside the control of Schering-Plough or the Purchaser, this period can be extended by the Monitoring Trustee until such time that the Purchaser has established the Ruminant Neonatal Diarrhoea Vaccine Business, as certified by the Monitoring Trustee.

4. The transitional supply or toll-manufacturing arrangement referred to in paragraph 3 shall include appropriate provisions designed to ensure the reasonable continuous supply by Schering-Plough to the Purchaser of the Ruminant Neonatal Diarrhoea Vaccine in the EEA for the duration of the arrangement.

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[3] The trademark is owned by Organon BS. Please find relevant trademark registration information at Annex 3b.

5. At the option of the Purchaser, Schering-Plough shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of the Ruminant Neonatal Diarrhoea Vaccine in the EEA for such period as is required by the Purchaser to establish the Ruminant Neonatal Diarrhoea Vaccine Business as a viable and independent business, but not exceeding thirty-six (36) calendar months from the date of Closing, as certified by the Monitoring Trustee, and on a reasonable cost plus basis to be agreed with the Purchaser. Under circumstances outside the control of Schering-Plough or the Purchaser, this period can be extended by the Monitoring Trustee until such time that the Purchaser has established the Ruminant Neonatal Diarrhoea Vaccine Business, as certified by the Monitoring Trustee. Reasonable technical assistance to the Purchaser is currently envisaged to include:

   (a) Schering-Plough or an Affiliated Undertaking organising a team to ensure the transfer of the Ruminant Neonatal Diarrhoea Vaccine to the Purchaser ('**the Technology Transfer Team**');

   (b) The Technology Transfer Team meeting with designated representatives of the Purchaser to develop a written plan for the technical transfer of the Ruminant Neonatal Diarrhoea Vaccine in the EEA;

   (c) The provision by Schering-Plough or by an Affiliated Undertaking of a package consisting of copies of the relevant documents including research data, master seed history and lineage, master cell history and lineage, regulatory documents and communications, process flow diagrams, specifications for equipment and materials, outlines of production, detailed manufacturing instructions, bills of materials, vendor information, and quality control testing procedures to the Purchaser;

   (d) The provision by Schering-Plough or an Affiliated Undertaking of a critical reagent package including, the master seeds and master cell stocks, an agreed upon quantity of any unique reagents needed to perform in-process and final product testing, positive and negative control reagents for quality control tests, and samples to be used for validation of test methods to the Purchaser;

   (e) Schering-Plough or an Affiliated Undertaking assisting the Purchaser during the transfer process to assure that the production and testing processes are understood;

(f) Reasonable escorted access of Schering-Plough's or an Affiliated Undertaking's manufacturing and quality control testing facilities during the transfer process to the Purchaser if required to assist in the understanding of the production and/or testing methods and procedures; and

(g) The Purchaser providing limited escorted access to its manufacturing and quality control test facilities to Schering-Plough and/or its Affiliated Undertaking during the transfer process to assist in the manufacturing and/or testing procedures.

6. The transitional technical assistance agreement referred to above shall include appropriate provisions designed to incentivise Schering-Plough to provide technical assistance to the Purchaser expeditiously. These provisions may include terms whereby the price payable by the Purchaser for technical assistance is reduced over time. Schering-Plough shall carry out the technical assistance for the technology transfer in accordance with good industry practice including as regards the timing and responsiveness with which this assistance is provided through the different stages of the transfer.

7. At the option of the Purchaser, Schering-Plough shall provide reasonable technical assistance to the Purchaser to facilitate the procurement of raw materials necessary for the manufacture of the Ruminant Neonatal Diarrhoea Vaccine. If the Purchaser is not able to source such raw materials, Schering-Plough commits to enter, at the option of the Purchaser, into back-to-back supply agreements with certain raw material suppliers and the Purchaser to make such raw materials available to the Purchaser on a reasonable cost plus basis.

8. For the avoidance of doubt, this Divestiture Business shall not include any right, title and/or interest in:

(a) Any manufacturing facility including the manufacturing facilities in Salamanca, Spain and Boxmeer, The Netherlands;

(b) Any Personnel of the Parties;

(c) Ownership of the BOVILIS trademark;

(d) Raw materials and bulk antigens;

(e) All marketing authorisations currently held by Organon BS outside of the EEA for the Ruminant Neonatal Diarrhoea Vaccine;

(f) Any other asset not part of the Ruminant Neonatal Diarrhoea Vaccine Business as defined in this Schedule 3 and/or which is used in relation to a business of the Parties other than the Ruminant Neonatal Diarrhoea Vaccine Business; and

(g) Monies owed to the Parties by customers for the purchase of the Ruminant Neonatal Diarrhoea Vaccine, and monies owed by the Parties to suppliers for materials used in the production of the Ruminant Neonatal Diarrhoea Vaccine.

ANNEX 3a

INFORMATION ON THE MARKETING AUTHORISATIONS RELEVANT TO THE RUMINANT NEONATAL DIARRHOEA VACCINE BUSINESS

PRODUCT	COUNTRY	REGISTRATION NO.	APPLICATION DATE
[…]	[…]	[…]	[…]

ANNEX 3b

INFORMATION ON THE TRADEMARKS RELEVANT TO THE RUMINANT NEONATAL DIARRHOEA VACCINE BUSINESS

TRADEMARK	REGISTRATION NO.	COUNTRY WHERE REGISTERED	STATUS
[…]	[…]	[…]	[…]

SCHEDULE 4

THE RUMINANT CLOSTRIDIA VACCINE BUSINESS

1. This Divestiture Business consists of:

   (a) Rights, title and interest in the ruminant clostridia vaccines currently marketed under the brands Covexin 8, Covexin 8a, Tasvax Huit and Blackleg, which have already been marketed in the EEA or a part thereof prior to the Effective Date; and

   (b) A commitment to enter into a co-exclusive agreement for the existing ruminant clostridia vaccine currently marketed in the EEA or a part thereof prior to the Effective Date under the brand Covexin 10 ('**the Ruminant Clostridia Vaccines**').[100]

2. For the avoidance of doubt, the Ruminant Clostridia Vaccine Business does not contain any rights to sell Covexin 8, Covexin 8a, Tasvax Huit, Covexin 10 and Blackleg outside of the EEA.

3. The Ruminant Clostridia Vaccine Business includes:

   (a) Sufficient biological material to produce the vaccines, including sufficient amounts of the master seeds;

   (b) Finished goods inventory, work in process, sales and promotional material (where available) relating to the Ruminant Clostridia Vaccine Business for sale in the EEA held at the date of Closing;

   (c) All current marketing authorisations and pending applications for marketing authorisations for Covexin 8, Covexin 8a, Tasvax Huit and Blackleg in the EEA held by Schering-Plough, including all relevant

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1 Covexin 8 is an '8-way' clostridia vaccine. Covexin 8a is a '9-way' clostridia vaccine (also marketed under the brand name 'Tasvax Huit' in France). Covexin 10 is a '10-way' clostridia vaccine. Blackleg is a monovalent clostridia vaccine indicated for the treatment of blackleg in cattle and sheep.

dossiers relating to the current and/or pending marketing authorisations available to Schering-Plough;[101]

(d) All current marketing authorisations and pending applications for marketing authorisations for Covexin 10 in the EEA held by Schering-Plough, including all relevant dossiers relating to the current and/or pending marketing authorisations available to Schering-Plough, provided that Schering-Plough obtains parallel informed consent marketing authorisations relating to Covexin 10 for the benefit of Schering-Plough and/or Organon BS;

(e) Copies of all clinical data and studies relating to the Ruminant Clostridia Vaccine Business existing prior to Closing;

(f) The COVEXIN trademark in the EEA (including those EEA countries where the Ruminant Clostridia Vaccines may not currently be registered)[102];

(g) The commitment to re-brand in the EEA Covexin 10 from Closing, in accordance with registration requirements that govern such changes and in a commercially reasonable manner in agreement with the Purchaser;

(h) The intellectual property rights necessary to give a Purchaser the exclusive right to manufacture and sell Covexin 8, Covexin 8a, Tasvax Huit and Blackleg in the EEA by way of a perpetual, irrevocable licence and the right to manufacture and sell Covexin 10 in the EEA by way of a co-exclusive, perpetual, irrevocable license. These intellectual property rights consist of product formulations, manufacturing know-how and other secret know-how, packaging specifications, rights to the trade dress, and all related copyright; and

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2 A list of relevant marketing authorisations is included in attached Annex 4a.

3 The trademark is owned by Schering-Plough. Please find relevant trademark registration information at Annex 4b.

(i) Copies of all relevant data, books, records, and other documents exclusively related to or necessary for the operation of the Ruminant Clostridia Vaccine Business in the EEA, including existing customer records of the Ruminant Clostridia Vaccine Business in the EEA, provided that Schering-Plough may redact from such copies any information that does not relate to the Ruminant Clostridia Vaccine Business.

4. At the option of the Purchaser, Schering-Plough or an Affiliated Undertaking shall enter into a supply or toll-manufacturing arrangement with the Purchaser for the non-exclusive supply or toll-manufacturing of the Ruminant Clostridia Vaccines in the EEA, for an appropriate period of time, not to exceed thirty-six (36) calendar months from the date of Closing, and on a reasonable cost plus basis to be agreed with the Purchaser. Under circumstances outside the control of Schering-Plough or the Purchaser, this period can be extended by the Monitoring Trustee until such time that the Purchaser has established the Ruminant Clostridia Vaccines Business, as certified by the Monitoring Trustee.

5. The transitional supply or toll-manufacturing arrangement referred to in paragraph 4 shall include appropriate provisions designed to ensure the reasonable continuous supply by Schering-Plough to the Purchaser of the Ruminant Clostridia Vaccines in the EEA for the duration of the arrangement.

6. At the option of the Purchaser, Schering-Plough shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of the Ruminant Clostridia Vaccines in the EEA for such period as is required by the Purchaser to establish the Ruminant Clostridia Vaccine Business as a viable and independent business, but not exceeding thirty-six (36) calendar months from the date of Closing, as certified by the Monitoring Trustee, and on a reasonable cost plus basis to be agreed with the Purchaser. Under circumstances outside the control of Schering-Plough or the Purchaser, this period can be extended by the Monitoring Trustee until such time that the Purchaser has established the Ruminant Clostridia Vaccines Business, as certified by the Monitoring Trustee. Reasonable technical assistance to the Purchaser is currently envisaged to include:

(a) Schering-Plough or an Affiliated Undertaking organising a team to ensure the transfer of the Ruminant Clostridia Vaccines to the Purchaser ('**the Technology Transfer Team**');

(b) The Technology Transfer Team meeting with designated representatives of the Purchaser to develop a written plan for the technical transfer of the Ruminant Clostridia Vaccines in the EEA;

(c) The provision by Schering-Plough or by an Affiliated Undertaking of a package consisting of copies of the relevant documents including research data, master seed history and lineage, regulatory documents and communications, process flow diagrams, specifications for equipment and materials, outlines of production, detailed manufacturing instructions, bills of materials, vendor information, and quality control testing procedures to the Purchaser;

(d) The provision by Schering-Plough or an Affiliated Undertaking of a critical reagent package including, the master seeds, an agreed upon quantity of any unique reagents needed to perform in-process and final product testing, positive and negative control reagents for quality control tests, and samples to be used for validation of test methods to the Purchaser;

(e) Schering-Plough or an Affiliated Undertaking assisting the Purchaser during the transfer process to assure that the production and testing processes are understood;

(f) Reasonable escorted access of Schering-Plough's or an Affiliated Undertaking's manufacturing and quality control testing facilities during the transfer process to the Purchaser if required to assist in the understanding of the production and/or testing methods and procedures; and

(g) The Purchaser providing limited escorted access to its manufacturing and quality control test facilities to Schering-Plough and/or its Affiliated Undertaking during the transfer process to assist in the manufacturing and/or testing procedures.

7. The transitional technical assistance agreement referred to above shall include appropriate provisions designed to incentivise Schering-Plough to provide technical assistance to the Purchaser expeditiously. These provisions may include terms whereby the price payable by the Purchaser for technical assistance is reduced over time. Schering-Plough shall carry out

the technical assistance for the technology transfer in accordance with good industry practice including as regards the timing and responsiveness with which this assistance is provided through the different stages of the transfer.

8. At the option of the Purchaser, Schering-Plough shall provide reasonable technical assistance to the Purchaser to facilitate the procurement of raw materials necessary for the manufacture of the Ruminant Clostridia Vaccines. If the Purchaser is not able to source such raw materials, Schering-Plough commits to enter, at the option of the Purchaser, into back-to-back supply agreements with certain raw material suppliers and the Purchaser to make such raw materials available to the Purchaser on a reasonable cost plus basis.

9. For the avoidance of doubt, this Divestiture Business shall not include any right, title and/or interest in:

(a) Any manufacturing facility including the manufacturing facility in Upper Hutt, New Zealand;

(b) Any Personnel of the Parties;

(c) Raw materials and bulk antigens;

(d) Any research and development, clinical data and studies or intellectual property relating to Covexin 10 after Closing;

(e) All marketing authorisations currently held by Schering-Plough outside of the EEA for the Ruminant Clostridia Vaccines;

(f) Any other vaccine including vaccines that contain a clostridia antigen;

(g) Any other asset not part of the Ruminant Clostridia Vaccine Business as defined in this Schedule 4 and/or which is used in relation to a business of the Parties other than the Ruminant Clostridia Vaccine Business; and

(h) Monies owed to the Parties by customers for the purchase of the Monovalent Ruminant Clostridia Vaccines, and monies owed by the Parties to suppliers for materials used in the production of the Ruminant Clostridia Vaccines.

ANNEX 4a

INFORMATION ON THE MARKETING AUTHORISATIONS RELEVANT TO THE RUMINANT CLOSTRIDIA VACCINE BUSINESS

PRODUCT	COUNTRY	REGISTRATION NO.	APPLICATION DATE
[…]	[…]	[…]	[…]

ANNEX 4b

INFORMATION ON THE TRADEMARKS RELEVANT TO THE RUMINANT CLOSTRIDIA VACCINE BUSINESS

TRADEMARK	REGISTRATION NO.	COUNTRY WHERE REGISTERED	STATUS
[…]	[…]	[…]	[…]

SCHEDULE 5

THE ENDOCRINE BUSINESS

1. This Divestiture Business consists of rights, title and interest in the endocrine formulations currently marketed under the brands Prosolvin, Cyclix, Cyclix Porcine, and Ovarid, which have already been marketed in the EEA or a part thereof prior to the Effective Date ('**the Endocrine Formulations**'). For the avoidance of doubt, the Endocrine Business does not contain any rights to sell Prosolvin, Cyclix, Cyclix Porcine and Ovarid outside the EEA.

2. The Endocrine Business includes:

   (a) Finished goods inventory, work in process, sales and promotional material (where available) relating to the Endocrine Business for sale in the EEA held at the date of Closing;

   (b) All current marketing authorisations and pending applications for marketing authorisations for Prosolvin, Cyclix, and Cyclix Porcine in the EEA held by Organon BS including all relevant dossiers relating to the current and/or pending marketing authorisations available to Organon BS, and all current marketing authorisations and pending applications for marketing authorisations for Ovarid in the EEA held by Schering-Plough, including all relevant dossiers relating to the current and/or pending marketing authorisations available to Schering-Plough;[103]

   (c) Copies of all clinical data and studies relating to Prosolvin, Cyclix, and Cyclix Porcine, and relating to Ovarid to the extent they are available to Schering-Plough, existing prior to Closing;

   (d) The PROSOLVIN, CYCLIX and OVARID trademarks in the EEA (including those EEA countries where the Endocrine Formulations may not currently be registered)[104];

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1 A list of relevant marketing authorisations is included in attached Annex 5a.

2 The Endocrine Business trademarks PROSOLVIN and CYCLIX are owned by Organon BS. The Endocrine Business trademark OVARID is owned by Schering-Plough. A list of relevant trademarks is included in attached Annex 5b.

(e) The intellectual property rights necessary to give a Purchaser the exclusive right to manufacture (with the exception of Ovarid) and sell (including Ovarid) the Endocrine Formulations in the EEA, by way of a perpetual, irrevocable licence. These intellectual property rights consist of product formulations, manufacturing know-how and other secret know-how, packaging specifications, rights to the trade dress, and all related copyright;

(f) The supply agreement with **[…]** dated **[…]** (the '**[…] Agreement**') concerning the supply of cloprostenol sodium necessary for the manufacture and sale of Cylix and Cylix Porcine in the EEA (details of which are provided in Annex 5c) by way of assignment. Where assignment of the **[…]** Agreement is not possible, Schering-Plough will provide reasonable assistance to the Purchaser to negotiate an agreement with **[…]** for the supply of cloprostenol on terms and conditions comparable to the **[…]** Agreement. If the Purchaser is not able to enter into an agreement with **[…]** and if legally possible, Schering-Plough commits to enter into a sub-contract agreement with the Purchaser on a reasonable cost plus basis to make such supply of cloprostenol available to the Purchaser;

(g) The supply agreement with **[…]** dated **[…]** (the '**[…] Agreement**') concerning the supply of luprostiol necessary for the manufacture and supply of Prosolvin in the EEA (details of which are provided in Annex 5c) by way of assignment. Where assignment of the **[…]** Agreement is not possible, Schering-Plough will provide reasonable assistance to the Purchaser to negotiate an agreement with **[…]** for the supply of luprostiol on terms and conditions comparable to the **[…]** Agreement. If the Purchaser is not able to enter into an agreement with **[…]** and if legally possible, Schering-Plough commits to enter into a sub-contract agreement with the Purchaser on a reasonable cost plus basis to make such supply of luprostiol available to the Purchaser; and

(h) Copies of all relevant data, books, records, and other documents exclusively related to or necessary for the operation of the Endocrine Business in the EEA, including existing customer records of the Endocrine Business in the EEA, provided that the Parties may redact

from such copies any information that does not relate to the Endocrine Business.

3. At the option of the Purchaser, Schering-Plough or an Affiliated Undertaking shall enter into a supply or toll-manufacturing arrangement with the Purchaser for the non-exclusive supply or toll-manufacturing of Prosolvin, Cyclix and Cyclix Porcine in the EEA, for an appropriate period of time, not to exceed twenty-four (24) calendar months from the date of Closing, and on a reasonable cost plus basis to be agreed with the Purchaser. Under circumstances outside the control of Schering-Plough or the Purchaser, this period can be extended by the Monitoring Trustee until such time that the Purchaser has established the Endocrine Business, as certified by the Monitoring Trustee.

4. The transitional supply or toll-manufacturing arrangement referred to in paragraph 3 shall include appropriate provisions designed to ensure the reasonable continuous supply by Schering-Plough to the Purchaser of the Prosolvin, Cyclix and Cyclix Porcine in the EEA for the duration of the arrangement.

5. At the option of the Purchaser, Schering-Plough shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of Prosolvin, Cyclix and Cyclix Porcine in the EEA, and the sale and marketing of Ovarid in the EEA for such period as is required by the Purchaser to establish the Endocrine Business as a viable and independent business, but not to exceed twenty-four (24) calendar months from the date of Closing, as certified by the Monitoring Trustee, and on a reasonable cost plus basis to be agreed with the Purchaser. Under circumstances outside the control of Schering-Plough or the Purchaser, this period can be extended by the Monitoring Trustee until such time that the Purchaser has established the Endocrine Business, as certified by the Monitoring Trustee.

6. The transitional technical assistance agreement referred to above shall include appropriate provisions designed to incentivise Schering-Plough to provide technical assistance to the Purchaser expeditiously. These provisions may include terms whereby the price payable by the Purchaser for technical assistance is reduced over time. Schering-Plough shall carry out the technical assistance for the technology transfer in accordance with good industry practice including as regards the timing and responsiveness with which this assistance is provided through the different stages of the transfer.

7. At the option of the Purchaser, Schering-Plough shall provide reasonable technical assistance to the Purchaser to facilitate the procurement of raw materials necessary for the manufacture of Prosolvin, Cyclix and Cyclix Bovine. If the Purchaser is not able to source

such raw materials, Schering-Plough commits to enter, at the option of the Purchaser, into back-to-back supply agreements with certain raw material suppliers and the Purchaser to make such raw materials available to the Purchaser on a reasonable cost plus basis.

8. At the option of the Purchaser, Schering-Plough shall provide reasonable assistance to the Purchaser to facilitate the purchase of Ovarid from **[…]**.

9. For the avoidance of doubt, this Divestiture Business shall not include any right, title and/or interest in:

(a) Any manufacturing facility including the manufacturing facility in Unterschleißheim, Germany;

(b) Any Personnel of the Parties;

(c) Raw materials;

(d) Any marketing authorisations currently held by Organon BS or Schering-Plough outside of the EEA for the Endocrine Formulations;

(e) A licence to sell or produce any product under the PROSOLVIN, CYCLIX and OVARID trademarks outside the EEA;

(f) Any other asset not part of the Endocrine Business as defined in this Schedule 5 and/or which is used in relation to a business of the Parties other than the Endocrine Business; and

(g) Monies owed to the Parties by customers for the purchase of the Endocrine Formulations, and monies owed by the Parties to suppliers for materials used in the production of the Endocrine Formulations.

ANNEX 5a

INFORMATION ON THE MARKETING AUTHORISATIONS RELEVANT TO THE ENDOCRINE BUSINESS

PRODUCT	COUNTRY	REGISTRATION NO.	APPLICATION DATE
[…]	[…]	[…]	[…]

ANNEX 5b

INFORMATION ON THE TRADEMARKS RELEVANT TO THE ENDOCRINE BUSINESS

TRADEMARK	REGISTRATION NO.	COUNTRY WHERE REGISTERED	STATUS
[…]	[…]	[…]	[…]

ANNEX 5c

INFORMATION ON THE AGREEMENTS RELEVANT TO THE ENDOCRINE BUSINESS

AGREEMENT	EXPIRY
[…]	[…]

SCHEDULE 6

THE INSULIN BUSINESS

1. This Divestiture Business consists of rights, title and interest in insulin formulations currently marketed under the brands Insuvet Lente, Insuvet Protamine Zinc and Insuvet Neutral, which have already been marketed in the EEA or a part thereof prior to the Effective Date ('**the Insulin Formulations**'). For the avoidance of doubt, the Insulin Business does not contain any rights to sell Insuvet Lente, Insuvet Protamine Zinc and Insuvet Neutral outside of the EEA.

2. The Insulin Business includes:

   (a) Finished goods inventory, sales and promotional material (where available) relating to the Insulin Business for sale in the EEA held at the date of Closing;

   (b) All current marketing authorisations and pending applications for marketing authorisations for the Insulin Formulations in the EEA held by Schering-Plough, including all relevant dossiers relating to the current and/or pending marketing authorisations available to Schering-Plough;[105]

   (c) Copies of all clinical data and studies relating to the Insulin Business existing prior to Closing;

   (d) The INSUVET trademark in the EEA (including those EEA countries where INSUVET may not currently be registered)[106];

   (e) The intellectual property rights necessary to give a Purchaser the exclusive right to sell the Insulin Formulations in the EEA by way of a perpetual, irrevocable licence. These intellectual property rights (to the extent owned by Schering-Plough) include product formulations,

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1 A list of relevant marketing authorisations is included in attached Annex 6a.

2 The trademarks are owned by Schering-Plough. Please find relevant trademark information at Annex 6b.

packaging specifications, rights to the trade dress, and all related copyright;

(f) The licensing agreement with **[…]** ('**the […] Agreement**') for the licensing of the Insuvet Lente (details of which are provided in Annex 6c) by way of assignment. Where assignment of the **[…]** Agreement is not possible, Schering-Plough will provide reasonable assistance to the Purchaser to negotiate an agreement with **[…]** for licensing of Insuvet Lente on terms and conditions comparable to the **[…]** Agreement. If the Purchaser is not able to enter into an agreement with **[…]** and if legally possible, Schering-Plough commits to enter into a sub-licence agreement with the Purchaser on terms and conditions equivalent to those of the **[…]** Agreement to make such rights available to the Purchaser;

(g) The contract manufacturing agreement with **[…]** ('**the […] Agreement**') for the supply of the Insulin Formulations (details of which are provided in Annex 6c) by way of assignment. Where assignment of the **[…]** is not possible, Schering-Plough will provide reasonable assistance to the Purchaser to negotiate an agreement with **[…]** for the supply of the Insulin Formulation on terms and conditions comparable to the **[…]** Agreement. If the Purchaser is not able to enter into an agreement with **[…]** and if legally possible, Schering-Plough commits to enter into a sub-contract agreement with the Purchaser on a reasonable cost-plus basis to make such supply of the Insulin Formulation available to the Purchaser; and

(h) Copies of all relevant data, books, records, and other documents exclusively related to or necessary for the operations of the Insulin Business in the EEA, including existing customer records of the Insulin Business in the EEA, provided that the Parties may redact from such copies any information that does not relate to the Insulin Business.

3. At the option of the Purchaser, Schering-Plough shall provide reasonable technical assistance to the Purchaser to assume responsibility for the sale and marketing of the Insulin Formulations in the EEA for such period as is required by the Purchaser to establish the Insulin Business as a viable and independent business, but not exceeding twenty-four (24) calendar months from the date of Closing, as certified by the Monitoring Trustee, and on a reasonable cost plus basis to be agreed with the Purchaser. Under circumstances outside the control of Schering-Plough or the Purchaser, this period can be

extended by the Monitoring Trustee until such time that the Purchaser has established the Insulin Business, as certified by the Monitoring Trustee.

4. For the avoidance of doubt, this Divestiture Business shall not include any right, title and/or interest in:

(a) Any manufacturing facility;

(b) Any Personnel of the Parties;

(c) All marketing authorisations currently held by Schering-Plough outside of the EEA for the Insulin Formulations;

(d) A licence to sell or produce any product under the INSUVET trademark outside of the EEA;

(e) Any other asset not part of the Insulin Business as defined in this Schedule 6 and/or which is used in relation to a business of the Parties other than the Insulin Business; and

(f) Monies owed to the Parties by customers for the purchase of the Insulin Formulations, and monies owed by the Parties to suppliers for materials used in the production of the Insulin Formulations.

ANNEX 6a

INFORMATION ON THE MARKETING AUTHORISATIONS RELEVANT TO THE INSULIN BUSINESS

PRODUCT	COUNTRY	REGISTRATION NO.	APPLICATION DATE
[…]	[…]	[…]	[…]

ANNEX 6b

INFORMATION ON THE TRADEMARKS RELEVANT TO THE INSULIN BUSINESS

TRADEMARK	REGISTRATION NO.	COUNTRY WHERE REGISTERED	STATUS
[…]	[…]	[…]	[…]

ANNEX 6c

INFORMATION ON THE AGREEMENT RELEVANT TO THE INSULIN BUSINESS

AGREEMENT
[…]

SCHEDULE 7

THE PARASITICIDES BUSINESS

1. This Divestiture Business consists of rights, title and interest in the parasiticide formulations currently marketed under the brands Autoworm, Coopers Spot On, Versatrine, Sputop and Coopertix, and the parasiticide bolus formulations currently marketed under the brand Systamex, which have already been marketed in the EEA or a part thereof prior to the Effective Date ('**the Parasiticide Formulations**'). For the avoidance of doubt, the Parasiticides Business does not contain any rights to sell Systamex boli, Autoworm, Coopers Spot On, Versatrine, Sputop and Coopertix outside of the EEA.

2. The Parasiticides Business includes:

   (a) Finished goods inventory, work in process, sales and promotional material (where available) relating to the Parasiticides Business for sale in the EEA held at the date of Closing;

   (b) All current marketing authorisations and pending applications for marketing authorisations for the Parasiticide Formulations in the EEA held by Schering-Plough, including all relevant dossiers relating to the current and/or pending marketing authorisations available to Schering-Plough[107];

   (c) Copies of all clinical data and studies relating to the Parasiticides Business existing prior to Closing;

   (d) The AUTOWORM, SYSTAMEX, VERSATRINE, SPUTOP, SPOT ON, and COOPERTIX trademarks in the EEA (including those EEA countries where the Parasiticide Formulations may not currently be registered)[108];

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1 A list of relevant marketing authorisations is included in attached Annex 7a.

2 The VERSATRINE and SPUTOP trademarks are owned by Schering-Plough. Please find relevant trademark registration information at Annex 7b.

(e) The grant of a three (3) year licence for the use of the COOPERS trademark for the sale of Coopers Spot On in the EEA by way of a royalty-free exclusive and irrevocable licence ('**the Trademark Licence**'). The Trademark Licence would permit the Purchaser/licensee to use the COOPERS trademark and related trade dress alone, or together with the Purchaser's own trademarks during the period of the Trademark Licence ('**Co-branding**'). The Purchaser/licensee would be allowed to change from Co-branding to the Purchaser's/licensee's own trademark at any time before the end of the Trademark Licence. During the period of the Trademark Licence and in the event the Purchaser/licensee uses the COOPERS trademark, the Purchaser/licensee must sell the products without modifying the COOPERS logo design, or damage the overall value of the COOPERS trademark , or violate any necessary administrative permits and authorisations. Should Schering-Plough realise that any of these events occur, it will immediately require from the Purchaser/licensee, by registered letter with acknowledgement of receipt, to remedy this situation. Schering-Plough will also inform the Monitoring Trustee who will address the matter. Should Schering-Plough and the Purchaser/licensee disagree with the Monitoring Trustee's decision, they will refer the matter to an arbitration proceeding in accordance with the dispute resolution provisions set out in Section F of the Commitments;

(f) The commitment to re-brand in the EEA all products other than the Systamex bolus formulations sold under the Systamex brand from Closing, in accordance with registration requirements that govern such changes and in a commercially reasonable manner in agreement with the Purchaser;

(g) The intellectual property rights necessary to give a Purchaser the exclusive right to manufacture and sell the Parasiticide Formulations in the EEA, by way of a perpetual, irrevocable licence. These intellectual property rights consist of product formulations, manufacturing know-how and other secret know-how, packaging specifications, and all related copyright; and

(h) Copies of all relevant data, books, records, and other documents exclusively related to or necessary for the operations of the Parasiticides Business in the EEA including existing customer records of the

Parasiticides Business in the EEA, provided that the Parties may redact from such copies any information that does not relate to the Parasiticides Business.

3. At the option of the Purchaser, Schering-Plough or an Affiliated Undertaking shall enter into a supply or toll-manufacturing arrangement with the Purchaser for the non-exclusive supply or toll-manufacturing of the Parasiticide Formulations for sale in the EEA, for an appropriate period of time, not to exceed twenty-four (24) calendar months from the date of Closing, and on a reasonable cost plus basis to be agreed with the Purchaser. Under circumstances outside the control of Schering-Plough or the Purchaser, this period can be extended by the Monitoring Trustee until such time that the Purchaser has established the Parasiticides Business, as certified by the Monitoring Trustee.

4. The transitional supply or toll-manufacturing arrangement referred to in paragraph 3 shall include appropriate provisions designed to ensure the reasonable continuous supply by Schering-Plough to the Purchaser of the Parasiticide Formulations in the EEA for the duration of the arrangement.

5. At the option of the Purchaser, Schering-Plough shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of the Parasiticide Formulations in the EEA for such period as is required by the Purchaser to establish the Parasiticides Business as a viable and independent business, but not exceeding twenty-four (24) calendar months from the date of Closing, as certified by the Monitoring Trustee, and on a reasonable cost plus basis to be agreed with the Purchaser. Under circumstances outside the control of Schering-Plough or the Purchaser, this period can be extended by the Monitoring Trustee until such time that the Purchaser has established the Parasiticides Business, as certified by the Monitoring Trustee.

6. The transitional technical assistance agreement referred to above shall include appropriate provisions designed to incentivise Schering-Plough to provide technical assistance to the Purchaser expeditiously. These provisions may include terms whereby the price payable by the Purchaser for technical assistance is reduced over time. Schering-Plough shall carry out the technical assistance for the technology transfer in accordance with good industry practice including as regards the timing and responsiveness with which this assistance is provided through the different stages of the transfer.

7. At the option of the Purchaser, Schering-Plough shall provide reasonable technical assistance to the Purchaser to facilitate the procurement of raw materials necessary for the manufacture of the Parasiticide Formulations. If the Purchaser is not able to source such

raw materials, Schering-Plough commits to enter, at the option of the Purchaser, into back-to-back supply agreements with certain raw material suppliers and the Purchaser to make such raw materials available to the Purchaser on a reasonable cost plus basis.

8. For the avoidance of doubt, this Divestiture Business shall not include any right, title and/or interest in:

(a) Any manufacturing facility including the manufacturing facilities in Bray, Ireland and Baton Rouge, United States;

(b) Any Personnel of the Parties;

(c) Ownership of the COOPERS, REPIDOSE or any related trademarks;

(d) Raw materials;

(e) All marketing authorisations currently held by Schering-Plough outside of the EEA for the Parasiticide Formulations;

(f) A licence to use or produce any product under the SYSTAMEX, AUTOWORM, COOPERS, VERSATRINE, SPUTOP and COOPERTIX trademarks outside of the EEA;

(g) A licence to use the COOPERS trademark for any formulation other than the Parasiticide Formulations currently marketed under the COOPERS trademark in the EEA;

(h) Any other bolus parasiticide formulation, including bolus formulations marketed under the Repidose brand name;

(i) Any other asset not part of Parasiticides Business as defined in this Schedule 7 and/or which is used in relation to a business of the Parties other than the Parasiticides Business; and

(j) Monies owed to the Parties by customers for the purchase of the Parasiticide Formulations, and monies owed by the Parties to suppliers for materials used in the production of the Parasiticide Formulations.

ANNEX 7a

INFORMATION ON THE MARKETING AUTHORISATIONS RELEVANT TO THE PARASITICIDES BUSINESS

PRODUCT	COUNTRY	REGISTRATION NO.	APPLICATION DATE
[…]	[…]	[…]	[…]

ANNEX 7b

INFORMATION ON THE TRADEMARKS RELEVANT TO THE PARASITICIDES BUSINESS

TRADEMARK	REGISTRATION NO.	COUNTRY WHERE REGISTERED	STATUS
[…]	[…]	[…]	[…]

SCHEDULE 8

THE EUTHANASIA BUSINESS

1. This Divestiture Business consists of rights, title and interest in the pentobarbital- based formulation currently marketed under the brand Eutha 77, which has already been marketed in the EEA or a part thereof prior to the Effective Date ('**the Euthanasia Formulation**'). For the avoidance of doubt, the Euthanasia Business does not contain any rights to sell Eutha 77 outside of the EEA.

2. The Euthanasia Business includes:

   (a) Finished goods inventory, sales and promotional material (where available) relating to the Euthanasia Business for sale in the EEA held at the date of Closing;

   (b) All current marketing authorisations and pending applications for marketing authorisations for the Euthanasia Formulation in the EEA held by Schering-Plough, including all relevant dossiers relating to the current and/or pending marketing authorisations available to Schering-Plough;[109]

   (c) Copies of all clinical data and studies relating to the Euthanasia Business in the EEA existing prior to closing;

   (d) The EUTHA trademark in the EEA (including those EEA countries where Euthanasia Formulation may not currently be registered);[110]

   (e) The intellectual property rights necessary to give a Purchaser the exclusive right to manufacture and sell the Euthanasia Formulation in the EEA by way of a perpetual, irrevocable licence. These intellectual property rights consist of product formulations, manufacturing know-

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1 A list of relevant marketing authorisations is included in attached Annex 8a.

2 The trademark is owned by Schering-Plough. A list of relevant trademark information is included in attached Annex 8b.

how and other secret know-how, packaging specifications, rights to the trade dress, and all related copyright; and

(f) Copies of all relevant data, books, records, and other documents exclusively related to or necessary for the operations of the Euthanasia Business in the EEA, including existing customer records of the Euthanasia Business in the EEA, provided that Schering-Plough may redact from such copies any information that does not relate to the Euthanasia Business.

3. At the option of the Purchaser, Schering-Plough or an Affiliated Undertaking shall enter into a supply or toll-manufacturing arrangement with the Purchaser for the non-exclusive supply or toll-manufacturing of the Euthanasia Formulation for sale in the EEA for an appropriate period of time, not to exceed twenty-four (24) calendar months from the date of Closing, and on a reasonable cost plus basis to be agreed with the Purchaser. Under circumstances outside the control of Schering-Plough or the Purchaser, this period can be extended by the Monitoring Trustee until such time that the Purchaser has established the Parasiticides Business, as certified by the Monitoring Trustee.

4. The transitional supply or toll-manufacturing arrangement referred to in paragraph 3 shall include appropriate provisions designed to ensure the reasonable continuous supply by Schering-Plough to the Purchaser of the Euthanasia Formulation in the EEA for the duration of the arrangement.

5. At the option of the Purchaser, Schering-Plough shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacturing, sale and marketing of the Euthanasia Formulation in the EEA for such period as is required by the Purchaser to establish the Euthanasia Business as a viable and independent business, but not exceeding twenty-four (24) calendar months from the date of Closing, as certified by the Monitoring Trustee, and on a reasonable cost plus basis to be agreed with the Purchaser. Under circumstances outside the control of Schering-Plough or the Purchaser, this period can be extended by the Monitoring Trustee until such time that the Purchaser has established the Euthanasia Business, as certified by the Monitoring Trustee.

6. The transitional technical assistance agreement referred to above shall include appropriate provisions designed to incentivise Schering-Plough to provide technical assistance to the Purchaser expeditiously. These provisions may include terms whereby the price payable by the Purchaser for technical assistance is reduced over time. Schering-Plough shall carry out the technical assistance for the technology transfer in accordance with good industry

practice including as regards the timing and responsiveness with which this assistance is provided through the different stages of the transfer.

7. At the option of the Purchaser, Schering-Plough shall provide reasonable assistance to the Purchaser to facilitate the purchase of the Euthanasia Formulation necessary for the sale and marketing of the Euthanasia Formulation. If the Purchaser is not able to source such raw materials, Schering-Plough commits to enter, at the option of the Purchaser, into back-to-back supply agreements with certain raw material suppliers and the Purchaser to make such raw materials available to the Purchaser on a reasonable cost plus basis.

8. For the avoidance of doubt, this Divestiture Business shall not include any right, title and/or interest in:

(a) Any manufacturing facility including the manufacturing facility in Friesoythe, Germany;

(b) Any Personnel of the Parties;

(c) All marketing authorisations currently held by Schering-Plough outside of the EEA for the Euthanasia Formulation;

(d) A licence to sell or produce any product under the EUTHA trademark outside of the EEA;

(e) Any other asset not part of the Euthanasia Business as defined in this Schedule 8 and/or which is used in relation to a business of the Parties other than the Euthanasia Business; and

(f) Monies owed to the Parties by customers for the purchase of the Euthanasia Formulation, and monies owed by the Parties to suppliers for materials used in the production of the Euthanasia Formulation prior to Closing.

ANNEX 8a

INFORMATION ON THE MARKETING AUTHORISATIONS RELEVANT TO THE EUTHANASIA BUSINESS

PRODUCT	COUNTRY	REGISTRATION NO.	APPLICATION DATE
[…]	[…]	[…]	[…]

ANNEX 8b

INFORMATION ON THE TRADEMARKS RELEVANT TO THE EUTHANASIA BUSINESS

TRADEMARK	REGISTRATION	COUNTRY WHERE	STATUS
[…]	[…]	[…]	[…]

SCHEDULE 9

THE SULPHONAMIDE BUSINESS

1. This Divestiture Business consists of rights, title and interest in the sulphonamide based formulations currently marketed under the brands Borgal, Gorban and Gelliprim, which have already been marketed in the EEA or a part thereof prior to the Effective Date ('**the Sulphonamide Formulations**'). For the avoidance of doubt, the Sulphonamide Business does not contain any rights to sell Borgal, Gorban and Gelliprim outside of the EEA.

2. The Sulphonamide Business includes:

   (a) Finished goods inventory, work in process, sales and promotional material (where available) relating to the Sulphonamide Business for sale in the EEA held at the date of Closing;

   (b) All current marketing authorisations and pending applications for marketing authorisations for the Sulphonamide Formulations in the EEA held by Organon BS, including all relevant dossiers relating to the current and/or pending marketing authorisations available to Organon BS;[111]

   (c) Copies of all clinical data and studies relating to the Sulphonamide Business in the EEA existing prior to Closing;

   (d) The BORGAL, GORBAN and GELLIPRIM trademarks in the EEA (including those EEA countries where the Sulphonamide Formulations may not currently be registered);[112]

   (e) The commitment to re-brand in the EEA Organon BS' Borgal Tabs, Gelliprim Premix and Gelliprim Orale from Closing, in accordance with registration requirements that govern such changes and in a commercially reasonable manner in agreement with the Purchaser;

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1 A list of relevant marketing authorisations is included in attached Annex 9a.

2 The trademarks are owned by Organon BS. Please find relevant trademark information at Annex 9b.

(f) The intellectual property rights necessary to give a Purchaser the exclusive right to manufacture and sell the Sulphonamide Formulations in the EEA by way of a perpetual, irrevocable licence. These intellectual property rights consist of product formulations, manufacturing know-how and other secret know-how, packaging specifications, rights to the trade dress, and all related copyright; and

(g) Copies of all relevant data, books, records, and other documents exclusively related to or necessary for the operations of the Sulphonamide Business in the EEA, including existing customer records of the Sulphonamide Business in the EEA, provided that Schering-Plough may redact from such copies any information that does not relate to the Sulphonamide Business.

3. At the option of the Purchaser, Schering-Plough or an Affiliated Undertaking shall enter into a supply or toll-manufacturing arrangement with the Purchaser for the non-exclusive supply or toll-manufacturing of the Sulphonamide Formulations in the EEA, for an appropriate period of time, not to exceed twenty-four (24) calendar months from the date of Closing, and on a reasonable cost plus basis to be agreed with the Purchaser. Under circumstances outside the control of Schering-Plough or the Purchaser, this period can be extended by the Monitoring Trustee until such time that the Purchaser has established the Sulphonamide Business, as certified by the Monitoring Trustee.

4. The transitional supply or toll-manufacturing arrangement referred to in paragraph 3 shall include appropriate provisions designed to ensure the reasonable continuous supply by Schering-Plough to the Purchaser of the Sulphonamide Formulations in the EEA for the duration of the arrangement.

5. At the option of the Purchaser, Schering-Plough shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of the Sulphonamide Formulations in the EEA for such period as is required by the Purchaser to establish the Sulphonamide Business as a viable and independent business, but not exceeding twenty-four (24) calendar months from the date of Closing, as certified by the Monitoring Trustee, and on a reasonable cost plus basis to be agreed with the Purchaser. Under circumstances outside the control of Schering-Plough or the Purchaser, this period can be extended by the Monitoring Trustee until such time that the Purchaser has established the Sulphonamide Business as certified by the Monitoring Trustee.

6. The transitional technical assistance agreement referred to above shall include appropriate provisions designed to incentivise Schering-Plough to provide technical assistance to the Purchaser expeditiously. These provisions may include terms whereby the price payable by the Purchaser for technical assistance is reduced over time. Schering-Plough shall carry out the technical assistance for the technology transfer in accordance with good industry practice including as regards the timing and responsiveness with which this assistance is provided through the different stages of the transfer.

7. At the option of the Purchaser, Schering-Plough shall provide reasonable technical assistance to the Purchaser to facilitate the procurement of raw materials necessary for the manufacture of the Sulphonamide Formulations. If the Purchaser is not able to source such raw materials, Schering-Plough commits to enter, at the option of the Purchaser, into back-to-back supply agreements with certain raw material suppliers and the Purchaser to make such raw materials available to the Purchaser on a reasonable cost plus basis.

8. For the avoidance of doubt, this Divestiture Business shall not include any right, title and/or interest in:

   (a) Any manufacturing facility including the manufacturing facilities in Unterschleißheim, Germany and Aprilia, Italy;

   (b) Any Personnel of the Parties;

   (c) Borgal Tabs, Gelliprim Premix and Gelliprim Orale;

   (d) Raw materials;

   (e) All marketing authorisations currently held by Organon BS outside of the EEA for the Sulphonamide Formulations;

   (f) A licence to sell or produce any product under the BORGAL, GORBAN and GELLIPRIM trademarks outside the EEA;

(g) Any other asset not part of the Sulphonamide Business as defined in this Schedule 9 and/or which is used in relation to a business of the Parties other than the Sulphonamide Business; and

(h) Monies owed to the Parties by customers for the purchase of the Sulphonamide Formulations, and monies owed by the Parties to suppliers for materials used in the production of the Sulphonamide Formulations.

ANNEX 9a

INFORMATION ON THE MARKETING AUTHORISATIONS RELEVANT TO THE SULPHONAMIDE BUSINESS

PRODUCT	COUNTRY	REGISTRATION NO.	APPLICATION DATE
[…]	[…]	[…]	[…]

ANNEX 9b

INFORMATION ON THE TRADEMARKS RELEVANT TO THE SULPHONAMIDE BUSINESS

TRADEMARK	REGISTRATION NO.	COUNTRY WHERE REGISTERED	STATUS
[…]	[…]	[…]	[…]

SCHEDULE 10

THE MASTITIS BUSINESS

1. This Divestiture Business consists of rights, title and interest in the mastitis formulations currently marketed under the brands Coliclox, Gentamam, Super Mastidol DC (also branded as Mastitar and Vonapen HL in certain countries), Neo Mastitar (also branded as Neo Mastidol and Vonapen Retard in certain countries), Cobactan DC and Cephaguard DC, which have already been marketed in the EEA or a part thereof prior to the Effective Date ('**the Mastitis Formulations**'). For the avoidance of doubt, the Mastitis Business does not contain any rights to sell Coliclox, Gentamam, Super Mastidol DC, Mastitar, Neo Mastitar, Neo Mastidol, Cobactan DC and Cephaguard DC outside of the EEA, Vonapen HL outside of France, or Vonapen Retard outside Denmark and Finland.

2. The Mastitis Business includes:

   (a) Finished goods inventory, work in process, sales and promotional material (where available) relating to the Mastitis Business for sale in the EEA held at the date of Closing;

   (b) All current marketing authorisations and pending applications for marketing authorisations for Coliclox and Gentamam in the EEA held by Schering-Plough, including all relevant dossiers relating to the current and/or pending marketing authorisations available to Schering-Plough, and all current marketing authorisations and pending applications for marketing authorisations for Super Mastidol DC, Mastitar, Vonapen HL, Neo Mastitar, Neo Mastidol, Vonapen Retard, Cobactan DC and Cephaguard DC in the EEA held by Organon BS, including all relevant dossiers relating to the current and/or pending marketing authorisations available to Organon BS, provided that the Parties may redact any information that does not relate to the Mastitis Business;[113]

   (c) Copies of all clinical data and studies relating to the Mastitis Business existing prior to Closing;

   (d) The COLICLOX, GENTAMAM, MASTIDOL, MASTITAR, and CEPHAGUARD trademarks in the EEA (including those EEA

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1 A list of relevant marketing authorisations is included in attached Annex 10a.

countries where the Mastitis Formulations may not currently be registered);[114]

(e) The grant of a three (3) year licence for the use of the COBACTAN trademark for the marketing and sale of the 'Cobactan DC' product in the EEA and for the use of the VONAPEN trademark for the marketing and sale of the 'Vonapen HL' product in France and for the marketing and sale of the 'Vonapen Retard' product in Denmark and Finland by way of a royalty-free non-exclusive and irrevocable licence ('**the Trademark Licence**'). The Trademark Licence would permit the Purchaser/licensee to use the COBACTAN and VONAPEN trademarks and trade dress alone or together with the Purchaser's own trademarks during the period of the Trademark Licence ('**Co-branding**'). The Purchaser/licensee would be allowed to change from Co-branding to the Purchaser's/licensee's own trademark at any time before the end of the Trademark Licence. Schering-Plough also commits not to re-introduce a dry cow formulation under the brands 'Cobactan DC,' 'Vonapen Retard' and/or 'Vonapen HL' in the countries for which the licence has been granted. During the period of the Trademark Licence and in the event the Purchaser/licensee uses the COBACTAN and/or VONAPEN trademarks, the Purchaser/licensee must sell the products without modifying the COBACTAN and VONAPEN logo designs, or damage the overall value of the COBACTAN and VONAPEN trademarks, or violate any necessary administrative permits and authorisations. Should Schering-Plough realise that any of these events occur, it will immediately require from the Purchaser/licensee, by registered letter with acknowledgement of receipt, to remedy this situation. Schering-Plough will also inform the Monitoring Trustee who will address the matter. Should Schering-Plough and the Purchaser/licensee disagree with the Monitoring Trustee's decision, they will refer the matter to an arbitration proceeding in accordance with the dispute resolution provisions set out in Section F of the Commitments;

(f) The commitment by Schering-Plough to re-brand from Closing products sold in the EEA under the Cephaguard brand other than Cephaguard DC, in accordance with registration requirements that govern such

2 The Mastitis Business trademarks COLICLOX and GENTAMAM are owned by Schering-Plough. The MASTIDOL, MASTITAR and CEPHAGUARD trademarks are owned by Organon BS. A list of relevant trademarks is included in attached Annex 10b.

changes and in a commercially reasonable manner in agreement with the Purchaser;

(g) The intellectual property rights necessary to give a Purchaser the exclusive right to manufacture and sell the Mastitis Formulations in the EEA, by way of a perpetual, irrevocable licence. These intellectual property rights consist of product formulations, manufacturing know-how and other secret know-how, packaging specifications, and all related copyright; and

(h) Copies of all relevant data, books, records, and other documents exclusively related to or necessary for the operations of the Mastitis Business in the EEA, including existing customer records of the Mastitis Business in the EEA, provided that the Parties may redact from such copies any information that does not relate to the Mastitis Business.

3. At the option of the Purchaser, Schering-Plough or an Affiliated Undertaking shall enter into a supply or toll-manufacturing arrangement with the Purchaser for the non-exclusive supply or toll-manufacturing of the Mastitis Formulations for sale in the EEA, for an appropriate period of time, not to exceed twenty-four (24) calendar months from the date of Closing, and on a reasonable cost plus basis to be agreed with the Purchaser. Under circumstances outside the control of Schering-Plough or the Purchaser, this period can be extended by the Monitoring Trustee until such time that the Purchaser has established the Mastitis Business, as certified by the Monitoring Trustee.

4. The transitional supply or toll-manufacturing arrangement referred to in paragraph 3 shall include appropriate provisions designed to ensure the reasonable continuous supply by Schering-Plough to the Purchaser of the Mastitis Formulations in the EEA for the duration of the arrangement.

5. At the option of the Purchaser, Schering-Plough shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of the Mastitis Formulations in the EEA, for such period as is required by the Purchaser to establish the Mastitis Business as a viable and independent business, but not exceeding twenty-four (24) calendar months from the date of Closing, as certified by the Monitoring Trustee, and on a reasonable cost plus basis to be agreed with the Purchaser. Under circumstances outside the control of Schering-Plough or the Purchaser, this period can be extended by the Monitoring Trustee until such time that the Purchaser has established the Mastitis Business, as certified by the Monitoring Trustee.

6. The transitional technical assistance agreement referred to above shall include appropriate provisions designed to incentivise Schering-Plough to provide technical assistance to the Purchaser expeditiously. These provisions may include terms whereby the price payable by the Purchaser for technical assistance is reduced over time. Schering-Plough shall carry out the technical assistance for the technology transfer in accordance with good industry practice including as regards the timing and responsiveness with which this assistance is provided through the different stages of the transfer.

7. At the option of the Purchaser, Schering-Plough shall provide reasonable technical assistance to the Purchaser to facilitate the procurement of raw materials necessary for the manufacture of the Mastitis Formulations. If the Purchaser is not able to source such raw materials, Schering-Plough commits to enter, at the option of the Purchaser, into back-to-back supply agreements with certain raw material suppliers and the Purchaser to make such raw materials available to the Purchaser on a reasonable cost plus basis.

8. For the avoidance of doubt, this Divestiture Business shall not include any right, title and/or interest in:

   (a) Any manufacturing facility including the manufacturing facilities in Boxmeer, The Netherlands, Ségre, France and Unterschleißheim, Germany;

   (b) Any Personnel of the Parties;

   (c) Ownership of the COBACTAN, VONAPEN or any related trademarks;

   (d) Raw materials;

   (e) Any marketing authorisations currently held by Schering-Plough and Organon BS outside of the EEA for the Mastitis Formulations;

(f) A licence to use or produce any product under the COLICLOX, GENTAMAM, MASTIDOL, MASTITAR, VONAPEN, COBACTAN and CEPHAGUARD trademarks outside of the EEA;

(g) A licence to use the COBACTAN and VONAPEN trademarks for any product other than the Mastitis Formulations currently marketed under the Cobactan DC brand in the EEA, under the Vonapen HL brand in France and under the Vonapen Retard brand in Finland and Denmark;

(h) Any other asset not part of Mastitis Business as defined in this Schedule 10 and/or which is used in relation to a business of the Parties other than the Mastitis Business; and

(i) Monies owed to the Parties by customers for the purchase of the Mastitis Formulations, and monies owed by the Parties to suppliers for materials used in the production of the Mastitis Formulations.

ANNEX 10a

INFORMATION ON THE MARKETING AUTHORISATIONS RELEVANT TO THE MASTITIS BUSINESS

PRODUCT	COUNTRY	REGISTRATION NO.	APPLICATION DATE
[…]	[…]	[…]	[…]

ANNEX 10b

INFORMATION ON THE TRADEMARKS RELEVANT TO THE MASTITIS BUSINESS

TRADEMARK	REGISTRATION NO.	COUNTRY WHERE REGISTERED	STATUS
[…]	[…]	[…]	[…]

SCHEDULE 11

THE ANTI-INFLAMMATORIES BUSINESS

1. This Divestiture Business consists of rights, title and interest in the corticosteroid multi-species anti-inflammatory formulations currently marketed under the brand Predsolan Injectable, and the oral non-steroidal anti-inflammatory formulations ('**NSAIDs**') for horses currently marketed under the brands Quadrisol 100 and Equipalazone, which have already been marketed in the EEA or a part thereof prior to the Effective Date ('**the Anti-Inflammatory Formulations**'). For the avoidance of doubt, the Anti-Inflammatories Business does not contain any rights to sell Predsolan Injectable outside of Italy, or Quadrisol 100 and Equipalazone outside of the EEA.

2. The Anti-Inflammatories Business includes:

   (a) Finished goods inventory, work in process, sales and promotional material (where available) relating to the Anti-Inflammatories Business for sale in Italy, Equipalazone for sale in France and Germany, and Quadrisol 100 for sale in the EEA, held at the date of Closing;

   (b) All current marketing authorisations and pending applications for marketing authorisations for Predsolan Injectable in Italy held by Schering-Plough, and all current marketing authorisations and pending applications for marketing authorisations for Quadrisol 100 and Equipalazone in the EEA or a part thereof held by Organon BS, including all relevant dossiers relating to the current and/or pending marketing authorisations available to the Parties;[115]

   (c) Copies of all clinical data and studies relating to the Anti-Inflammatories Business existing prior to Closing;

   (d) The PREDSOLAN trademark in Italy and the QUADRISOL trademark in the EEA (including those EEA countries where the Anti-Inflammatory Formulations may not currently be registered)[116];

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1 A list of relevant marketing authorisations is included in attached Annex 11a.

2 The PREDSOLAN trademark is owned by Schering-Plough. The QUADRISOL trademark is owned by Organon BS. Please find relevant trademark registration information at Annex 11b.

(e) The commitment by Schering-Plough to re-brand in the EEA products other than Quadrisol 100 sold under the Quadrisol brand from Closing, in accordance with the registration requirements that govern such changes and in a commercially reasonable manner in agreement with the Purchaser;

(f) The intellectual property rights necessary to give a Purchaser the exclusive right to manufacture and sell Predsolan Injectable in Italy and Quadrisol 100 in the EEA by way of a perpetual, irrevocable licence. These intellectual property rights consist of product formulations, manufacturing know-how and other secret know-how, packaging specifications, and all related copyright;

(g) The agreements with **[…]** ('**[…]**') ('**the […] Manufacturing Agreements**') necessary for the sale of Equipalazone in France and Germany by way of assignment. Details of the **[…]** Manufacturing Agreements are provided in Annex 11c. Where assignment of the **[…]** Manufacturing Agreements is not possible, Schering-Plough will provide reasonable assistance to negotiate an agreement with **[…]** to supply Equipalazone to the Purchaser on terms and conditions comparable to the terms of the **[…]** Manufacturing Agreements. If the Purchaser is not able to enter into an agreement with **[…]** and if legally possible, Schering-Plough commits to enter into a sub-contract agreement with the Purchaser on a reasonable cost plus basis to make such supply of Equipalazone available to the Purchaser; and

(h) Copies of all relevant data, books, records, and other documents exclusively related to or necessary for the operations of the Anti-Inflammatories Business in Italy in the case of Predsolan Injectable, in France and Germany in the case of Equipalazone, and in the EEA in the case of Quadrisol 100, including existing customer records of the Anti-Inflammatories Business in Italy in the case of Predsolan Injectable, in France and Germany in the case of Equipalazone, and in the EEA in the case of Quadrisol 100, provided that the Parties may redact from such copies any information that does not relate to the Anti-Inflammatories Business.

3. At the option of the Purchaser, Schering-Plough or an Affiliated Undertaking shall enter into a supply or toll-manufacturing arrangement with the Purchaser for the non-exclusive supply or toll-manufacturing of Predsolan Injectable for sale in Italy and of Quadrisol 100 for sale in the EEA for an appropriate period of time, not to exceed twenty-four (24) calendar months from the date of Closing, and on a reasonable cost plus basis to be agreed with the Purchaser. Under circumstances outside the control of Schering-Plough or the Purchaser, this period can be extended by the Monitoring Trustee until such time that the Purchaser has established the Anti-Inflammatories Business, as certified by the Monitoring Trustee.

4. The transitional supply or toll-manufacturing arrangement referred to in paragraph 3 shall include appropriate provisions designed to ensure the reasonable continuous supply by Schering-Plough to the Purchaser of Predsolan Injectable for sale in Italy and of Quadrisol 100 for sale in the EEA for the duration of the arrangement.

5. At the option of the Purchaser, Schering-Plough shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of Predsolan Injectable in Italy and Quadrisol 100 in the EEA, for such period as is required by the Purchaser to establish the Anti-Inflammatories Business as a viable and independent business, but not exceeding twenty-four (24) calendar months from the date of Closing, as certified by the Monitoring Trustee, and on a reasonable cost plus basis to be agreed with the Purchaser. Under circumstances outside the control of Schering-Plough or the Purchaser, this period can be extended by the Monitoring Trustee until such time that the Purchaser has established the Anti-Inflammatories Business, as certified by the Monitoring Trustee.

6. The transitional technical assistance agreement referred to above shall include appropriate provisions designed to incentivise Schering-Plough to provide technical assistance to the Purchaser expeditiously. These provisions may include terms whereby the price payable by the Purchaser for technical assistance is reduced over time. Schering-Plough shall carry out the technical assistance for the technology transfer in accordance with good industry practice including as regards the timing and responsiveness with which this assistance is provided through the different stages of the transfer.

7. At the option of the Purchaser, Schering-Plough shall provide reasonable technical assistance to the Purchaser to facilitate the procurement of raw materials necessary for the manufacture of Predsolan Injectable and Quadrisol 100. If the Purchaser is not able to source such raw materials, Schering-Plough commits to enter, at the option of the Purchaser, into back-to-back supply agreements with certain raw material suppliers and the

Purchaser to make such raw materials available to the Purchaser on a reasonable cost plus basis.

8. For the avoidance of doubt, this Divestiture Business shall not include any right, title and/or interest in:

(a) Any manufacturing facility including the manufacturing facilities in Friesoythe, Germany and Igoville, France;

(b) Any Personnel of the Parties;

(c) Raw materials;

(d) All marketing authorisations currently held by Schering-Plough outside of the EEA for the Anti-Inflammatory Formulations;

(e) Any other asset not part of Anti-Inflammatories Business as defined in this Schedule 11 and/or which is used in relation to a business of the Parties other than the Anti-Inflammatories Business; and

(f) Monies owed to the Parties by customers for the purchase of the Anti-Inflammatory Formulations, and monies owed by the Parties to suppliers for materials used in the production of the Anti-Inflammatory Formulations.

ANNEX 11a

INFORMATION ON THE MARKETING AUTHORISATIONS RELEVANT TO THE ANTI-INFLAMMATORIES BUSINESS

PRODUCT	COUNTRY	REGISTRATION NO.	APPLICATION DATE
[…]	[…]	[…]	[…]

ANNEX 11b

INFORMATION ON THE TRADEMARKS RELEVANT TO THE ANTI-INFLAMMATORIES BUSINESS

TRADEMARK	REGISTRATION NO.	COUNTRY WHERE REGISTERED	STATUS
[…]	[…]	[…]	[…]

ANNEX 11c

THE […] MANUFACTURING AGREEMENT BETWEEN

ORGANON BS AND […]

AGREEMENT	EXPIRY DATE
[…]	[…]

SCHEDULE 12

THE RABIES VACCINE BUSINESS

1. This Divestiture Business consists of rights, title and interest in the multi-species rabies vaccine currently marketed under the brands Rabdomun and Quantum Rabies, which have already been marketed in the EEA or a part thereof prior to the Effective Date ('**the Rabies Vaccine**'). For the avoidance of doubt, the Rabies Vaccine Business does not contain any rights to sell Rabdomun and Quantum Rabies outside of the EEA.

2. The Rabies Vaccine Business includes:

   (a) Sufficient biological material to produce the vaccines, including sufficient amounts of the master seeds and master cell line;

   (b) Finished goods inventory, work in process, sales and promotional material (where available) relating to the Rabies Vaccine Business for sale in the EEA held at the date of Closing;

   (c) All current marketing authorisations and pending applications for marketing authorisations for the Rabies Vaccine Business in the EEA held by Schering-Plough, including all relevant dossiers relating to the current and/or pending marketing authorisations available to Schering-Plough;[117]

   (d) Copies of all clinical data and studies relating to the Rabies Vaccine Business existing prior to Closing;

   (e) The RABDOMUN trademarks in the EEA (including those EEA countries where the Rabies Vaccine may not currently be registered)[118];

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1 A list of relevant marketing authorisations is included in attached Annex 12a.

2 The trademarks are owned by Schering-Plough. Please find relevant trademark registration information at Annex 12b.

(f) The grant of a three (3) year licence for the use of the QUANTUM trademark by way of a royalty-free non-exclusive and irrevocable licence, for the sale of the Rabies Vaccine for the whole of the EEA (including those EEA countries where QUANTUM may not currently be registered) ('**the Trademark Licence**'). The Trademark Licence would permit the Purchaser/licensee to use the QUANTUM trademark alone for the Rabies Vaccine, or together with the Purchaser's own trademarks during the period of the Trademark Licence ('**Co-branding**'). The Purchaser/licensee would be allowed to change from Co-branding to the Purchaser's/licensee's own trademark at any time before the end of the Trademark Licence. Schering-Plough also commits not to re-introduce Quantum Rabies in the countries in which the Trademark Licence has been granted within a period of at least three (3) years after the termination of the Trademark Licence ('**the Blackout Period**'). Should the Purchaser decide not to use the Trademark Licence for the full period of three (3) years, the Blackout Period will be extended accordingly to allow for a total protection period of six (6) years. During the period of the Trademark Licence and in the event the Purchaser/licensee uses the QUANTUM trademark, the Purchaser/licensee must sell the products without modifying the QUANTUM logo design, or damage the overall value of the QUANTUM trademark, or violate any necessary administrative permits and authorisations. Should Schering-Plough realise that any of these events occur, it will immediately require from the Purchaser/licensee, by registered letter with acknowledgement of receipt, to remedy this situation. Schering-Plough will also inform the Monitoring Trustee who will address the matter. Should Schering-Plough and the Purchaser/licensee disagree with the Monitoring Trustee's decision, they will refer the matter to an arbitration proceeding in accordance with the dispute resolution provisions set out in Section F of the Commitments;

(g) The intellectual property rights necessary to give a Purchaser the exclusive right to manufacture and sell the Rabies Vaccine in the EEA by way of a perpetual, irrevocable licence. These intellectual property rights consist of product formulations, manufacturing know-how and other secret know-how, packaging specifications, rights to the trade dress, and all related copyright;

(h) Copies of all relevant data, books, records, and other documents exclusively related to or necessary for the operations of the Rabies Vaccine Business in the EEA, including existing customer records of the Rabies Vaccine Business in the EEA, provided that Schering-Plough may

redact from such copies any information that does not relate to the Rabies Vaccine Business.

3. At the option of the Purchaser, Schering-Plough or an Affiliated Undertaking shall enter into a supply or toll-manufacturing arrangement with the Purchaser for the non-exclusive supply or toll-manufacturing of the Rabies Vaccine in the EEA, for an appropriate period of time, not to exceed thirty-six (36) calendar months from the date of Closing, and on a reasonable cost plus basis to be agreed with the Purchaser. Under circumstances outside the control of Schering-Plough or the Purchaser, this period can be extended by the Monitoring Trustee until such time that the Purchaser has established the Rabies Vaccine Business, as certified by the Monitoring Trustee.

4. The transitional supply or toll-manufacturing arrangement referred to in paragraph 3 shall include appropriate provisions designed to ensure the reasonable continuous supply by Schering-Plough to the Purchaser of the Rabies Vaccine in the EEA for the duration of the arrangement.

5. At the option of the Purchaser, Schering-Plough shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of the Rabies Vaccine in the EEA for such period as is required by the Purchaser to establish the Rabies Vaccine Business as a viable and independent business, but not exceeding thirty-six (36) calendar months from the date of Closing, as certified by the Monitoring Trustee, and on a reasonable cost plus basis to be agreed with the Purchaser. Under circumstances outside the control of Schering-Plough or the Purchaser, this period can be extended by the Monitoring Trustee until such time that the Purchaser has established the Rabies Vaccine Business, as certified by the Monitoring Trustee. Reasonable technical assistance to the Purchaser is currently envisaged to include:

   (a) Schering-Plough or an Affiliated Undertaking organising a team to ensure the transfer of the Rabies Vaccine to the Purchaser ('**the Technology Transfer Team**');

   (b) The Technology Transfer Team meeting with designated representatives of the Purchaser to develop a written plan for the technical transfer of the Rabies Vaccine in the EEA;

   (c) The provision by Schering-Plough or by an Affiliated Undertaking of a package consisting of copies of the relevant documents including

research data, master seed history and lineage, master cell history and lineage, regulatory documents and communications, process flow diagrams, specifications for equipment and materials, outlines of production, detailed manufacturing instructions, bills of materials, vendor information, and quality control testing procedures to the Purchaser;

(d) The provision by Schering-Plough or an Affiliated Undertaking of a critical reagent package including, the master seeds and master cell stocks, an agreed upon quantity of any unique reagents needed to perform in-process and final product testing, positive and negative control reagents for quality control tests, and samples to be used for validation of test methods to the Purchaser;

(e) Schering-Plough or an Affiliated Undertaking assisting the Purchaser during the transfer process to assure that the production and testing processes are understood;

(f) Reasonable escorted access of Schering-Plough's or an Affiliated Undertaking's manufacturing and quality control testing facilities during the transfer process to the Purchaser if required to assist in the understanding of the production and/or testing methods and procedures; and

(g) The Purchaser providing limited escorted access to its manufacturing and quality control test facilities to Schering-Plough and/or its Affiliated Undertaking during the transfer process to assist in the manufacturing and/or testing procedures.

6. The transitional technical assistance agreement referred to above shall include appropriate provisions designed to incentivise Schering-Plough to provide technical assistance to the Purchaser expeditiously. These provisions may include terms whereby the price payable by the Purchaser for technical assistance is reduced over time. Schering-Plough shall carry out the technical assistance for the technology transfer in accordance with good industry practice including as regards the timing and responsiveness with which this assistance is provided through the different stages of the transfer.

7. At the option of the Purchaser, Schering-Plough shall provide reasonable technical assistance to the Purchaser to facilitate the procurement of raw materials necessary for the manufacture of the Rabies Vaccine. If the Purchaser is not able to source such raw materials, Schering-Plough commits to enter, at the option of the Purchaser, into back-to-back supply agreements with certain raw material suppliers and the Purchaser to make such raw materials available to the Purchaser on a reasonable cost plus basis.

8. For the avoidance of doubt, this Divestiture Business shall not include any right, title and/or interest in:

   (a) Any manufacturing facility including the manufacturing facilities in Burgwedel, Germany;

   (b) Any Personnel of the Parties;

   (c) Ownership of the QUANTUM trademark;

   (d) Raw materials and bulk antigens;

   (e) All marketing authorisations currently held by Schering-Plough outside of the EEA for the Rabies Vaccine;

   (f) A licence to use the QUANTUM trademark for any vaccine other than the Rabies Vaccine;

   (g) A licence to use or produce any product under the QUANTUM trademark outside of the EEA for rabies vaccines;

   (h) Any other vaccine including vaccines that contain a rabies antigen;

   (i) Any other asset not part of the Rabies Vaccine Business as defined in this Schedule 12 and/or which is used in relation to a business of the Parties other than the Rabies Vaccine Business;

(j) Any right, title or interest in the agreement between Schering-Plough and **[…]** concerning the supply to **[…]** of companion animal vaccines; and

(k) Monies owed to the Parties by customers for the purchase of the Rabies Vaccine, and monies owed by the Parties to suppliers for materials used in the production of the Rabies Vaccine.

ANNEX 12a

INFORMATION ON THE MARKETING AUTHORISATIONS RELEVANT TO THE RABIES VACCINE BUSINESS

PRODUCT	COUNTRY	REGISTRATION NO.	APPLICATION DATE
[…]	[…]	[…]	[…]

ANNEX 12b

INFORMATION ON THE TRADEMARKS RELEVANT TO THE RABIES VACCINE BUSINESS

TRADEMARK	COUNTRY WHERE REGISTERED	REGISTRATION NO.	STATUS
[…]	[…]	[…]	[…]