EN

Case No COMP/M.5195 - PFIZER / SP ASSETS

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REGULATION (EC) No 139/2004
MERGER PROCEDURE

Article 6(1)(b) NON-OPPOSITION
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PUBLIC VERSION

MERGER PROCEDURE
ARTICLE 6(1) (b) DECISION

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 Where possible the information omitted has been replaced by ranges of figures or a general description.

To the notifying party:

Dear Sir/Madam,

Subject: Case No COMP/M.5195 – Pfizer/ SP Assets
Notification of 22.07.2008 pursuant to Article 4 of the Council Regulation No 139/2004 [1]

1. On 22 July 2008, the Commission received a notification of a proposed concentration pursuant to Article 4 and following a referral pursuant to Article 4(5) of Council Regulation (EC) No 139/2004 of 20 January 2004 on the control of concentrations between undertakings ("Merger Regulation") by which the undertaking Pfizer Inc. ("Pfizer", United States of America) acquires within the meaning of Article 3(1)(b) of the Council Regulation certain businesses in the field of animal health ("SP Assets") of Schering-Plough Corporation ("Schering-Plough", United States of America) by way of purchase of assets.

2. After examination of the notification, the Commission has concluded that the notified operation falls within the scope of the Merger Regulation and raises no serious doubts as to the compatibility with the common market.

[1] OJ L 24, 29.1.2004 p. 1.

(1) THE PARTIES

3. Pfizer is one of the world's largest research-based biomedical and pharmaceutical companies active in human and animal healthcare products. Pfizer is not controlled by any individual shareholder or undertaking.

4. The SP Assets are currently wholly-owned by Schering-Plough. The SP Assets consist of nine business packages, encompassing 26 products (Swine *E.coli* vaccines; Influenza and Tetanus vaccines for horses; Ruminant neonatal diarrhoea vaccines; Ruminant Clostridial vaccines; Rabies vaccines; Insulin products; Euthanasia products; Parasiticides; and Anti-Inflammatory products). The portfolio comprises a broad range of products for both companion and farm animals including various vaccines, specialty pharmaceuticals, parasiticides and other products. The EEA-wide rights, title and interest in the above mentioned products are included in the SP Assets[2]. Schering-Plough is pursuing the sale of these assets following the commitments made for the approval by the European Commission of its acquisition of Organon BioSciences N.V. and its animal health business - Intervet[3].

(2) THE CONCENTRATION

5. Pfizer and Schering-Plough entered into an Asset Purchase Agreement (APA) on 23 April 2008, pursuant to which Pfizer is acquiring the SP Assets.

6. The SP Assets constitute a business with a market presence, to which a market turnover can be clearly attributed[4].

7. The proposed transaction is therefore an acquisition of sole control of the parts of an undertaking and it constitutes a concentration within the meaning of Article 3 (1)(b) of the Merger Regulation.

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2 For some products, which are transferred on a co-exclusive basis, the purchaser will acquire such rights, title and interest on the basis of a co-exclusive license. For some other products (rabies product and certain parasiticide products), the purchaser is granted a three-year license to use the relevant products' trademarks.

3 See Commission decision in Case COMP/M.4691, 11 October 2007.

4 See paragraph 24 of the Commission consolidated jurisdictional notice under Council Regulation (EC) No 139/2004 on the control of concentrations between undertakings.

(3) COMMUNITY DIMENSION

8. The notified concentration does not meet the turnover thresholds of Article 1(2) and 1(3) of the Merger Regulation and is capable of being reviewed under the national competition laws of eight Member States[5].

9. On 24 June 2008, Pfizer informed the Commission by means of a reasoned submission (RS), that the concentration should be examined by the Commission pursuant to Article 4(5) of the Merger Regulation.

10. The RS was transmitted to all Member States. No Member State competent to examine this concentration under its national competition law has expressed its disagreement, within 15 working days of receiving the RS, as regards the request to refer the case to the Commission.

11. Accordingly, pursuant to Article 4(5) of the Merger Regulation, the proposed transaction is deemed to have a Community dimension.

(4) RELEVANT PRODUCT AND GEOGRAPHIC MARKETS

12. In its *Schering-Plough/Organon BioSciences* decision ("*SP/Organon* decision"), the Commission has divided animal health products into three core areas: (i) medicinal food additives, (ii) biologicals and (iii) pharmaceuticals[6]. The SP Assets include biologicals and pharmaceuticals, but no medicinal food additives.

13. Biologicals are products that trigger an immune response against viral and bacterial diseases in animals as well as in some cases against certain parasitic or fungal infections. They include vaccines, and antisera and colostra products. In its *SP/Organon* decision, the Commission held that vaccines are distinct from antisera and colostra products[7]. Vaccines are the only biologicals being part of the SP assets.

14. Pharmaceuticals encompass a wide group of products that contain a variety of active substances to prevent or treat a large range of animal diseases and disorders. Pharmaceuticals are the largest single segment among animal health products in the EEA.

15. In its *Schering-Plough/Organon* decision, the Commission defined several distinct product markets for vaccines and pharmaceuticals, and found that these animal health products markets are all national in scope.

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5 Austria, Bulgaria, Ireland, Italy, Latvia, Portugal, Slovakia, Spain.

6 Commission's decision in Case COMP/M.4691, at paragraph 22.

7 Commission's decision in Case COMP/M.4691, at paragraph 23.

16. For the purpose of the present transaction, Pfizer has based itself on the product and geographic market definitions retained by the Commission in its *Schering-Plough/Organon* decision. Below, we describe the relevant product markets to which the SP assets relate.

A. Vaccines

Monovalent influenza vaccines for horses; Monovalent tetanus vaccines for horses; Multivalent influenza/tetanus vaccines for horses

17. In its *Schering-Plough/Organon* decision, the Commission defined three separate relevant product markets for (i) monovalent influenza vaccines for horses; (ii) monovalent tetanus vaccines for horses; and (iii) multivalent influenza and tetanus vaccines for horses.

Multivalent clostridia vaccines for ruminants (including blackleg vaccines)

18. The Commission's market investigation in the *Schering-Plough/Organon* case suggested that a distinction could be drawn between multivalent clostridia vaccines for ruminants (regardless of the number of clostridia pathogens targeted) and monovalent blackleg vaccines for ruminants. However, the Commission ultimately left open whether monovalent blackleg vaccines for ruminants constitute a distinct product market.

19. For the purposes of the present transaction, it can also be left open whether multivalent clostridia vaccines for ruminants and monovalent blackleg vaccines for ruminants belong or not to the same product market since Pfizer does not market any of these vaccines in the EEA.

Multivalent neonatal diarrhoea (scours) vaccines for ruminants

20. In its *Schering-Plough/Organon* decision, the Commission defined the relevant product market as neonatal diarrhoea (scour) vaccine for ruminants.

Monovalent multispecies rabies vaccines

21. In its *Schering-Plough/Organon* decision, the Commission defined the relevant product market as monovalent multispecies rabies vaccines.

Monovalent E.Coli vaccines for swine and multivalent E.Coli/Clostridia vaccines for swine

22. The *Schering-Plough/Organon* decision mentioned that the parties had argued that monovalent *E.coli* vaccines for swine constituted a distinct product market and were not substitutable with any multivalent vaccines containing an *E.coli* component. In this respect they had regard to differences in use and differences in price. The Commission's market investigation however did not confirm this approach. Rather, respondents argued that monovalent vaccines targeting *E.coli* on swine belong to the same relevant product market as multivalent vaccines targeting *E.coli* and clostridia. However, the Commission ultimately left the market definition open as Schering-Plough offered a remedy addressing any potential concerns irrespective of the market definition.

23. For the purposes of the present transaction, it can also be left open whether monovalent vaccines targeting *E.coli* on swine belong to the same relevant product market as multivalent vaccines targeting *E.coli* and clostridia, since the proposed transaction does not give rise to competition concern under any alternative product market definition.

B. Pharmaceuticals

Euthanasia

24. In its *Schering-Plough/Organon* decision, the Commission analysed the transaction under the narrowest possible product market definition, namely injectable euthanasia products.

25. The exact product market definition can be left open for the purposes of the present transaction, as Pfizer does not market any euthanasia products in the EEA and no overlaps arise.

Insulin

26. In its *Schering-Plough/Organon* decision, the Commission defined the relevant market as insulin products for companion animals (dogs and cats).

Anti-inflammatories

27. In its *Schering-Plough/Organon* decision, the Commission retained the following product market definitions in the area of anti-inflammatories: (i) injectable multispecies non-steroidal anti-inflammatory drugs ("NSAIDs"); (ii) orally-administered NSAIDs for horses; (iii) orally-administered NSAIDs for dogs and cats; and (iv) multispecies corticosteroids.

Parasiticides

28. In its *Schering-Plough/Organon* decision, the Commission retained the following product market definitions in the area of parasiticides: (i) ectoparasiticides (including collars) for companion animals; (ii) ectoparasiticides for farm animals (ruminants and swine); (iii) endoparasiticides/endectocides for farm animals (ruminants and swine); and (iv) fungicides. The Commission also noted that the following additional criteria should be taken into account with respect to assessing the closeness of competition: species, active substance and mode of administration.

(5) COMPETITIVE ASSESSMENT

29. Pfizer does not market any of the following products in the EEA: tetanus and/or influenza vaccines for horses, multivalent clostridia vaccines for ruminants (including blackleg vaccines), euthanasia products, and insulin products. The proposed transaction does not therefore lead to any overlaps in these product markets.

30. Below, the Commission assesses the impact of the proposed transaction on all the markets where Pfizer and the SP Assets have overlapping activities with a combined market share leading to affected markets (combined market share of 15% or more).

Multivalent neonatal diarrhoea (scours) vaccines for ruminants

31. The proposed concentration gives rise to affected markets in Austria, Estonia, Germany, Italy, Lithuania and Spain.

32. The proposed concentration leads to affected markets in Austria (combined market share: [20-30] %; Pfizer: [10-20] % and SP Assets: [5-10] %), Germany (combined market share: [30-40] %; Pfizer: [20-30] % and SP Assets: [10-20] %), Italy (combined market share: [20-30] %; Pfizer: [20-30]% and SP Assets: [5-10] %) and Spain (combined market share: [30-40] %; Pfizer: [20-30] % and SP Assets: [5-10] % -). In all these countries Schering-Plough would remain a clear market leader with its product *Rotavec Corona* which has a market share between [40-50] % and [70-80] % in each of these countries (Austria: [70-80] %; Germany: [60-70]`%; Italy: [40-50] %; and Spain: [60-70] %). Furthermore, Pfizer will continue to face a competitive pressure from Merial (Germany: [5-10] %; Italy: [30-40] %; and Spain: [0-5] %).

33. In Estonia and Lithuania, *Lactovac* (SP Assets) and *Scourguard* (Pfizer) were the only available multivalent neonatal diarrhoea vaccines for ruminants until recently. In Lithuania, the sales of *Lactovac* were EUR [CONFIDENTIAL] and the sales of *Scourguard* EUR [CONFIDENTIAL]. In Estonia, the sales of *Lactovac* were EUR [CONFIDENTIAL] and the sales of *Scourguard* EUR [CONFIDENTIAL].

34. However, for the reasons set out below, the proposed transaction is unlikely to give rise to any competition concerns in Estonia and Lithuania.

35. In Estonia, *Scourguard* is not registered and the sales of the vaccine are accounted for by limited imports made by wholesalers under special licenses issued on the basis of specific requests by farmers and veterinarians for supply of the vaccines. The licenses are issued to wholesalers on a case-by-case basis and are limited to importation of volumes ordered by named end-users. As Pfizer itself does not hold a registration or license for the sale of *Scourguard 3K* in Estonia, it is prevented from marketing or promoting the product in any manner, it has no involvement in or influence over the orders placed. Prices are set by the wholesalers entirely independently of Pfizer. Moreover the Estonian Veterinary Agency confirmed that Schering-Plough's *Rotavec Corona* is the only vaccine for multivalent neonatal diarrhoea for ruminants that has marketing authorization in Estonia and after its launch the sales of *Scourguard* will have to be stopped.

36. In Lithuania, a large proportion of Pfizer's sales ([>70] %) are accounted for by *Scourguard 4K/C*, which is a multivalent vaccine targeting *E.coli*, rotavirus and coronavirus as well as *Clostridium perfringens*. *Scourguard 4K/C* is not EU GMP certified and therefore its sales have only a temporary character. In 2005, Pfizer was granted the first temporary import license for *Scourguard 3K/C* (an earlier version of *Scourguard 4K/C*) as there was an outbreak of *Clostridium perfringens* in Lithuania. No scours vaccine then registered in Lithuania contained a clostridia component and therefore farmers requested to be supplied with *Scourguard 3K/C*. As farmers continued to request the vaccine, subsequent licenses were issued to Pfizer in 2006, 2007 and 2008. Products sold in Lithuania under special import licenses cannot be marketed. Instead, sales are made only in response to specific orders from farmers. The Lithuanian Chief

Veterinary Office confirmed the temporary character of Pfizer's license and the fact that *Scourguard 4K/C* sales will have to be stopped in the nearest future.

37. The rest of Pfizer's sales are accounted for by *Scourguard 3K*, which provides protection against *E.coli*, rotavirus and coronavirus but not clostridia, and which is the EU GMP certified version of the vaccine.

38. Furthermore, Schering-Plough has launched its scour vaccine *Rotavec Corona* in all three Baltic States in August 2008. *Rotavec Corona* has consistently proven itself to be a product that yields immediate success following its launch, in all the countries where it was launched, and there are no reasons or special features that would not allow anticipating the same outcome upon entry in the Baltic States. Upon its EEA launch in 2002, *Rotavec Corona* was a significant and quick success and, by 2003, had already managed to acquire a [40-50] % market share in the EEA for multivalent ruminant neonatal diarrhoea vaccines. By 2006, its market share had grown to an estimated [60-70] %, which it has maintained in 2007. *Rotavec Corona* currently occupies, by a substantial margin, the leading position as regards scours vaccines at the EEA level.

39. The market investigation has confirmed that *Rotavec Corona* is the most advanced scour vaccine available on the EEA market and that its key advantage over the competitors is that it requires only one injection at primo vaccination[8].

40. Therefore, given that most of the sales of Pfizer's *Scourguard* vaccine […] and given Schering Plough's recent entry with *Rotavec Corona* into the Baltic States, the proposed transaction is unlikely to result in a significant impediment to effective competition in the market for multivalent neonatal diarrhoea (scours) vaccines for ruminants in Lithuania and Estonia.

Monovalent E.Coli vaccines for swine and multivalent E.Coli/Clostridia vaccines for swine

41. The only overlap is in Lithuania where Pfizer and the SP Assets have a combined market share of [50-60] % (Pfizer: [30-40] % and SP Assets: [10-20] %).

42. However, for the reasons set out below, the proposed transaction is unlikely to give rise to any competition concerns.

43. First, Pfizer is a minor player in the EEA with a share of [0-5] %. Its share is furthermore decreasing because its product is not EU GMP certified. As a matter of fact, […]. In Lithuania the registration of its product expired following this country's accession to the EU. Pfizer's product is thus sold under a temporary permit that […].

44. Secondly, the remedy for a multivalent *E.Coli* vaccine is a co-exclusive licence and Pfizer expects that its market share for the acquired product will fall when Schering-Plough re-introduces its multivalent *E.Coli* vaccine under a different brand name.

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8 Therefore *Rotavec Corona* has the advantage that farmers do not need to round up the cattle herd twice in order to administer the vaccine, which can entail significant costs, both monetary and time.

45. Thirdly, there is a significant competitive pressure from another strong company, Merial (market share of about [10-20] % in Lithuania and [10-20] % at the EEA level).

46. Therefore, the proposed transaction is unlikely to result in a significant impediment to effective competition in the market for monovalent *E.coli*/multivalent *E.coli*/clostridia vaccines for swine in Lithuania.

Monovalent multispecies rabies vaccines

47. The parties' activities in rabies vaccines overlap only in Germany, where Pfizer and the SP Assets have a combined market share of [30-40] % (Pfizer: [20-30] % and SP Assets [10-20] %).

48. Post-transaction, Pfizer would face competitive pressure from five other large players, including Merial, the market leader ([30-40] %).

49. Therefore, the proposed transaction is unlikely to result in a significant impediment to effective competition in the market for monovalent multispecies rabies vaccines in Germany.

Endoparasiticides/endectocides for farm animals

50. The proposed concentration leads to affected markets in Belgium/Luxembourg (combined market share: [20-30] %; Pfizer: [0-5] % and SP Assets: [20-30] %), Germany (combined market share: [20-30] %; Pfizer: [10-20] % and SP Assets: [5-10] %), and the UK (combined market share: [20-30] %; Pfizer: [10-20] % and SP Assets: [10-20] %).

51. The affected markets are characterised by the presence of a multitude of players, both originator and generic companies, which exercise a significant competitive pressure over the merged entity. These players include, inter alia, Fort Dodge (Belgium/Luxembourg: [10-20] %; Germany: [20-30] %; UK: [10-20] %), Janssen (Belgium/Luxembourg: [20-30] %; Germany: [10-20] %; UK: [10-20] %) and Merial (Belgium/Luxembourg: [10-20] %; Germany: [10-20] %; UK: [20-30] %).

52. Therefore, the proposed transaction is unlikely to result in a significant impediment to effective competition in any of these affected markets.

53. For the sake of completeness, it can be noted that SP Assets (*Systamex* and *Autoworm*) and Pfizer (*Valbazen* and *Dectomax*) are also sold in Denmark (SP Assets: [10-20] %, Pfizer: [5-10] %), Norway (SP Assets: [40-50] %, Pfizer: [10-20] %) and Sweden (SP Assets: [50-60] %, Pfizer: [20-30] %).

54. However, for the reasons set out below, the proposed transaction is unlikely to give rise to any competition concerns on these national markets.

55. In these markets, Pfizer has no local manufacturing, marketing, sales or distribution operations and its products are marketed, sold and distributed in these countries by Orion Corporation pursuant to a long term exclusive agreement[9].

56. Under this agreement, Orion controls all the commercial factors relating to the marketing and sale of Pfizer's products (*Valbazen* and *Dectomax*). In particular, Orion (i) […], (ii) […], (iii) determines and executes its strategy in an annual marketing plan, and (iv) is indicated on the labelling as the company selling the products in the country concerned. Moreover, under the terms of the agreement, Pfizer has no ability to influence Orion's pricing strategy.

57. In light of the above, the Commission concludes that the sales of Pfizer's endoparasiticides/endectocides products (*Valbazen* and *Dectomax*) have to be attributed to Orion rather than to Pfizer in Denmark, Norway and Sweden. Accordingly, no overlap arises on these national markets for endoparasiticides/endectocides for farm animals.

VI. CONCLUSION

58. For the above reasons, 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) of Council Regulation (EC) No 139/2004.

For the Commission,
(signed)
Siim KALLAS
Vice President of the Commission

9 The agreement was signed on 8 April 2005 and its initial term expires on 31 December 2013.