EN

Case No COMP/M.5476 - PFIZER/ WYETH

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REGULATION (EC) No 139/2004
MERGER PROCEDURE

Article 6(1)(b) in conjunction with Art 6(2)
Date: 17/07/2009

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COMMISSION OF THE EUROPEAN COMMUNITIES

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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.5476 - PFIZER/ WYETH**
Notification of 29 May 2009 pursuant to Article 4 of Council Regulation No 139/2004

1. On 29 May 2009, the Commission received a notification of a proposed concentration pursuant to Article 4 of Council Regulation (EC) No 139/2004[1] ("the Merger Regulation") by which the undertaking Pfizer Inc. ("Pfizer"), United States of America ("USA"), acquires - within the meaning of Article 3(1)(b) of the Merger Regulation - sole control of the whole of the undertaking Wyeth[2], USA, by way of purchase of shares.

2. The Commission has concluded that the notified operation falls within the scope of the Merger Regulation. Having finalised its first-phase market investigation, the Commission concluded that the notified operation raised serious doubts. During the course of the proceedings, Pfizer has submitted commitments in accordance with Article 6(2) of the Merger Regulation, which are designed to eliminate the competition concerns identified by the Commission. In the light of these modifications to the notified operation, the Commission concludes that the

1 OJ L 24, 29.1.2004 p. 1.

2 According to the Certificate of Corporation the name of the undertaking is Wyeth and is a corporation registered in the State of Delaware, USA. Restated Certificate of Corporation, 26.4.2007 as published on www.wyeth.com.

notified operation no longer raises serious doubts as to its compatibility with the common market and EEA Agreement.

1. THE PARTIES

3. Pfizer is a global research-based biomedical and pharmaceutical company active in discovering, developing, manufacturing, marketing and selling innovative medicines for humans and animals. Pfizer has a separate division dedicated to animal health products, Pfizer Animal Health.

4. Wyeth is a pharmaceutical and healthcare company active in the discovery, development, manufacturing and marketing of pharmaceuticals, vaccines, biotechnology products, nutritionals and non-prescription medicines worldwide. The company's main divisions include Wyeth Pharmaceuticals, Wyeth Consumer Healthcare and Wyeth's animal health division Fort Dodge Animal Health.

2. CONCENTRATION

5. Pfizer intends to acquire Wyeth in a cash-and-stock transaction at a total value of approximately USD 68 billion. A specially created Pfizer subsidiary will be merged with and into Wyeth. Each outstanding share of Wyeth common stock will be converted into the right to receive USD 33 in cash and 0.985 of a share of Pfizer common stock. Pfizer's shareholders will own approximately 84% and Wyeth's shareholders will own approximately 16% of the resulting entity, which will retain Pfizer's name. As a result of the transaction, Wyeth will become a wholly-owned subsidiary of Pfizer and Pfizer will thus acquire sole control over Wyeth.

6. The transaction constitutes a concentration within the meaning of Article 3(1)(b) of the Merger Regulation.

3. COMMUNITY DIMENSION

7. Both undertakings concerned have a combined aggregate world-wide turnover exceeding EUR 5 billion[3] (Pfizer: EUR 32,837 million, Wyeth: EUR 15,525 million). Each undertaking has a Community-wide turnover in excess of EUR 250 million (Pfizer: EUR […] million, Wyeth, EUR […] million). Neither Pfizer, nor Wyeth, achieve more than two-thirds of their aggregate Community-wide turnover within one and the same Member State.

8. The notified operation therefore has a Community dimension pursuant to article 1(2) of the Merger Regulation.

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3 Turnover calculated in accordance with Article 5(1) of the Merger Regulation and the Commission Notice on the calculation of turnover (OJ C 66, 2.3.1998, p. 25).

4. COMPETITIVE ASSESSMENT

4.1. Introduction

9. The notified operation concerns a large number of markets in the field of human health as well as a very large number of markets in the field of animal health.

10. As regards human health pharmaceuticals, the merging Parties' activities are complementary to a relatively large extent, but substantial horizontal overlaps arise in several areas such as cancer treatments, antibiotics, tranquillisers and anti-depressants. In addition, the merging firms have a number of pipeline human health products, e.g. in the treatment of Alzheimer's disease.

11. In the field of animal health, there are substantial overlaps between the Parties' activities in a large number of markets for biologicals (in particular vaccines), pharmaceuticals and, to a limited extent, medicinal feed additives. In addition, the merging firms have a number of pipeline animal health products.

12. As in previous human health cases, the Parties were required to group all affected human pharmaceuticals markets in three categories. In order to ensure consistency, the Parties were requested to use the same groupings also for affected markets in animal health. These groupings are:

    Group 1: The Parties' joint market share exceeds 35% and the increment exceeds 1%.
    Group 2: The Parties' joint market share exceeds 35% but the increment is less than 1%.
    Group 3: The Parties' joint market share is between 15% and 35%.

13. The Commission has focused its investigation in particular on affected markets falling into category 1 ("Group 1 markets"). This decision summarises the outcome of the market investigation in all Group 1 markets and a number of markets where either one or both Parties have pipeline products which may be launched on markets where one or both Parties already have substantial market shares ("pipeline markets").

14. For all other markets where the Parties' activities overlap and their joint market shares do not exceed 35% under any plausible market definition and/or where the increment is below 1%, competition concerns may be excluded. According to the market data provided by the Parties, there are no competition concerns. Also third Parties did not indicate that competition would be significantly impeded on any of these markets. It may therefore be concluded that none of these markets raises serious doubts as to its compatibility with the Common market and the EEA-agreement in the sense of Article 6(1)(c) of the Merger Regulation (hereafter referred to as "serious doubts").[4] All affected markets in the fields of human health and animal health are listed in Annex 1 to this Decision.

4.2. Human Health Markets - Pharmaceuticals

4.2.1 Relevant Product Markets

ATC classification

15. In previous decisions, the Commission noted that pharmaceuticals may be subdivided into therapeutic classes by reference to the "Anatomical Therapeutic Chemical" classification ("ATC"), devised by European Pharmaceutical Marketing Research Association ("EphMRA") and maintained by EphMRA and Intercontinental Medical Statistics ("IMS"). The ATC has 16 categories (A, B, C, D etc.) each with different levels. At the third ATC level ("ATC3") pharmaceuticals are grouped in terms of their therapeutic indication, i.e. their intended use. This level is generally used as the starting point for investigating and defining relevant product markets in competition cases, in particular, for competition between innovator companies.

16. However, it is appropriate to carry out analyses also at other ATC levels, or a mixture thereof, if the circumstances of a case show that sufficiently strong competitive constraints faced by the undertakings involved are situated at another level and there are indications that ATC3 class does not lead to a correct market definition.[5] The Commission has previously departed from the ATC3 class in cases where the market investigation indicated that another market definition was more appropriate, for example the ATC4 class or medicines based on the same active pharmaceutical ingredient (molecule level) [6].

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4 The Commission has previously used the same methodology for focussing its investigation, e.g. case COMP/M.5295 – *Teva/Barr*, para 23.

5 Case COMP/M.3751 – *Novartis/Hexal*.

6 See e.g. cases COMP/M.3751 – *Novartis/Hexal* and COMP/M.5295 – *Teva/Barr*.

Prescription pharmaceuticals and over-the-counter pharmaceuticals

17. In the past, the Commission has considered that drugs available over-the-counter ("OTC") – i.e. without prescription – normally belongs to a different product market than drugs available only on prescription.[7] Medical indications, side effects, legal framework, distribution and marketing tend to differ between these drug categories, even if the active ingredients are sometimes identical. OTC pharmaceuticals may be advertised to the general public, whereas advertising of prescription pharmaceuticals is restricted in most Member States. In most cases, consumers choose OTC pharmaceuticals themselves and purchases are not reimbursed. Prescription pharmaceuticals are prescribed by a doctor and part of the patient's purchase price is reimbursed by the public health-care system. Marketing of prescription pharmaceuticals is therefore targeted at the prescribers and not the patients.

18. In the present case, the market investigation has largely confirmed that OTC and prescription pharmaceuticals constitute separate product markets.

Originator pharmaceuticals and generic pharmaceuticals

19. In line with previous decisions, the Commission considers that originator drugs and their generic copies belong to the same relevant product market. It was found in previous decisions that generics can efficiently substitute originator drugs after patent expiry, especially if the regulatory system encourages switching.[8] When assessing the competitive situation in a given product market, the Commission takes into account the fact that the originator drug is exposed to generic competition. Most off-patent drugs are available both in their original version and as generic copies. Once a drug goes off-patent and generic producers enter the market, the originator tends to lose market share, unless he reduces his price.

4.2.2. Relevant Geographic Markets

20. The Commission has previously defined the geographic markets for pharmaceutical products as being national in scope. The market investigation has confirmed that this is still the case. Competition between research pharmaceutical firms still predominantly takes place at a national level and the same approach is appropriate for generic pharmaceutical firms.

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7 See for instance cases COMP/M.3544 *Bayer Healthcare/Roche*, decision 19.11.2004; COMP/M.3394 *Johnson & Johnson/Johnson & Johnson MSD Europe*, decision 29.03.2004.

8 Case COMP/M.3751 – *Novartis/Hexal*.

4.2.3. Markets without Serious Doubts

Markets with horizontal overlaps

Metastatic renal cell carcinoma (mRCC)

Market definition

21. Both Parties have products for the treatment of renal cell carcinoma ("RCC"), the most common form of kidney cancer. Kidney cancer represents less than 5% of all cancers. RCC accounts for 80-85% of all malignant kidney tumours. Approximately one third of RCC patients have, at initial diagnosis, a metastatic or advanced form of the disease where the tumour has spread ("mRCC"). The Parties estimate that in 2009 there are 26,500 mRCC patients in Europe. For most mRCC patients systemic treatment, i.e. targeted therapy or immunotherapy, is required. Some of the drugs used in the treatment of RCC are "orphan drugs".[9]

22. Both Parties' products are used for targeted therapy of mRCC. Pfizer markets the product *Sutent* and Wyeth markets the product *Torisel,* which are both still under patent protection and are classified in the ATC3 class L1X – All other antineoplastics. The Parties' combined market share at the ATC3 level in the EU and in individual EEA countries are very low. However, the Parties themselves agree that the ATC3 level would not be the appropriate product market.

23. The Commission previously examined existing drugs in the oncology sector and stated that for cancer treatment, defining relevant product markets for pharmaceuticals according to their ATC3 classification may not always be appropriate because treatments vary depending on the type of cancer, its location and whether the cancer is in an initial or an advanced stage. In that decision, the treatment regime used for a specific type of cancer as well as the role and substitutability of individual molecules in the regime were used as a basis for the competitive analysis.[10]

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9 The term orphan drug refers to a pharmaceutical agent that has been developed specifically to treat a rare medical condition, the condition itself being referred to as an orphan disease. The assignment of orphan status to a disease and to any drugs developed to treat it is a matter of public policy in many countries, and has resulted in medical breakthroughs that would not have otherwise been achieved due to the economics of drug research and development. Pfizer's *Sutent* is no longer an EMEA-orphan drug. Upon Pfizer's request, it has been removed from the Community Register of Orphan Medicinal Products. Pfizer withdrew *Sutent* from the Community Register in order to be able to file for additional non-orphan indications and keeping the *Sutent* trademark. Before removal, *Sutent* had an orphan drug status for renal cell carcinoma and malignant gastrointestinal stromal tumours. Wyeth's *Torisel* has an EMEA-orphan drug status for renal cell carcinoma and an orphan drug designation for mantle cell lymphoma. *Nexavar* has an EMEA-orphan drug status for renal cell carcinoma and hepatocellular carcinoma.

10 The Commission considered whether two drugs belonging to different ATC3 categories (L1D and L3A respectively) were in the same relevant product market because both drugs were used for treating the same type of cancer. However, the Commission concluded that the two products did not compete directly with each other because they were always used one after the other (one drug was the first alternative and the other the second or third alternative). Therefore, the two drugs did not belong to the same relevant product market. COMP/M.3354 – *Sanofi/Aventis*, decision 26.042004, paras. 55-63.

24. The market definition proposed by the Parties, based on the treatment of mRCC without a differentiation into separate lines of treatment, mechanism of action ("MOA") or form of administration was confirmed by the market investigation. It was clearly indicated by most respondents that the relevant product market ought to be defined according to cancer type. It was also confirmed that the products are approved for a certain line of treatment but that there is off-label usage to a certain extent.

25. Furthermore, it is likely that the products for the treatment of mRCC in all lines of treatment constitute the relevant product market. The market share data provided by the Parties for the different lines of the treatment do not reflect a differentiation into different lines and different prognosis patients, i.e. all products, to a different extent, are used in 1st and 2nd line of treatment. Even if a product is approved for a certain line in mRCC treatment, there is "off-label" use to a certain extent. For example, Wyeth's *Torisel*, which is approved only for the application in 1st line poor prognosis patients (i.e. patients with three out of six risk factors), is also used in 2nd and further lines of treatment. This was also indicated by the market investigation where not a single respondent indicated a separation of the market into different lines of treatment. Furthermore, it was not indicated by any respondent that the market should be defined based on the MOA, or the form of administration.

26. The exact market definition may, however, be left open in this case since the notified transaction would not result in serious doubts in any of the affected countries, regardless of the market definition considered.

Assessment

27. According to a market for the treatment of mRCC in all lines, there would be Group 1 markets in most EEA countries, where the combined market shares of the Parties range from [50-60]% in the United Kingdom[11] to [90-100]% in Latvia, where only eight mRCC patients were treated with Pfizer's *Sutent*.[12]

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11 So far in the UK *Sutent* is the only product approved for reimbursement, for the treatment of mRCC patients with ECOG status 0 and 1 in 1st line, following a positive opinion by NICE in March 2009. The combined market share of the Parties of [50-60]% dates from 2008. The Parties themselves expected a shift to *Sutent* in 2009. The sales of *Sutent* in UK have increased by around [30-40]% between March and May 2009. The marketing authorization holders for *Torisel*, *Avastin* and *Nexavar*, have appealed the negative reimbursement recommendation by NICE. However, the products will remain available. It has to be taken into account that neither *Sutent*, nor any other agent, is recommended by NICE for second or further lines of treatment.

12 France [60-70]% (Pfizer: [60-70]%), United Kingdom [50-60]% (Pfizer: [30-40]%; Wyeth: [10-20]%), Germany [80-90]% (Pfizer: [60-70]%; Wyeth: [10-20]%), Spain [70-80]% (Pfizer: [70-80]%; Wyeth: [0-5]%), Italy [60-70]% (Pfizer: [60-70]%; Wyeth: [0-5]%), Austria [40-70]% (Pfizer: [30-50]%; Wyeth: [5-20]%), Belgium [60-70]% (Pfizer: [60-70]%; Wyeth: [0-5]%), Czech Republic [20-80]% (Pfizer: [20-80]%; Wyeth: [0-5]%), Denmark [70-80]% (Pfizer: [60-70]%; Wyeth: [0-5]%), Greece [60-70]% (Pfizer: [60-70]%; Wyeth: [0-20]%), Ireland [60-70]% (Pfizer: [60-70]%; Wyeth: [5-10]%), Latvia [90-100]% (Pfizer: [80-90]%; Wyeth: [20-30]%), the Netherlands [60-80]% (Pfizer: [60-80]%; Wyeth: [0-5]%), Poland [30-40]% (Pfizer: [30-40]%; Wyeth: [0-5]%), Portugal [70-100]% (Pfizer: [70-100]%; Wyeth: [0-5]%), Slovakia [70-80]% (Pfizer: [60-70]%; Wyeth: [0-5]%), Slovenia [60-70]% (Pfizer: [60-70]%; Wyeth: [0-5]%), Sweden [10-70]% (Pfizer: [10-60]%; Wyeth: [0-5]%). The market share ranges in a number of countries are based on the different estimates of the Parties. For Luxembourg, Cyprus and Malta the Parties were not able to provide market shares. They state that on average there are only 26

Furthermore, Pfizer has a pipeline product[13] for the treatment of mRCC in phase III and Wyeth has phase III trials for a broader indication for its product *Torisel*, i.e. for 2nd line treatment.

28. Both Parties have products for targeted therapy of mRCC. Pfizer markets the product *Sutent* (*Sunitinib*), an oral multikinease inhibitor ("MKI") and Wyeth markets the product *Torisel* (*Temsirolimus*), an intravenous mTOR inhibitor which are both still under patent protection (*Torisel* has patent protection until 2020 and market exclusivity until 2017, *Sutent* has patent protection until 2021). The MOA and the form of administration are different. MKI inhibitors, like *Sutent*, decrease cell proliferation and inhibit angiogenesis by inhibiting multiple intracellular and cell surface kinease and receptor tyrosine kineases while mTOR inhibitors, like *Torisel*, inhibit the mTOR kinease, which is involved in cell cycle progression and cell proliferation. *Sutent* is approved for 1st and 2nd line treatment of mRCC while *Torisel* is only approved for the 1st line treatment of mRCC in poor prognosis patients.

29. Competing products in the treatment of mRCC are Roche's *Avastin/IFN* (*Bevacizumab+Interferon*, patent expiry for *Avastin* in […]), Bayer's *Nexavar* (*Sorafenib*), (patent expiry […]) and cytokines which are used in immunotherapy (e.g. *Interleukin*). Competitor's have a number of pipeline products which are already used to a limited extent, e.g. in phase III clinical trials and expanded access programmes for compassionate use. These are mainly the pipeline products of Novartis (*Everolimus*), GlaxoSmithKline (*Pazopanib*) and Pfizer itself (*Axitinib*).

30. According to the Parties, their products are not close substitutes due to their different MOA and forms of administration. The market investigation also indicated that MOA and form of administration play an important role, though less important than the results of clinical studies. However, despite the fact that the Parties' products are based on different MOA and different forms of administration, they are the only competitors for 1st line treatment in poor prognosis patients in some countries, while in other countries further products are used for 1st line treatment. In most affected countries, e.g. in France and Italy for example, *Avastin* and *Avastin/INF* are used in 1st line treatment in addition to *Sutent* and *Torisel,* and *Avastin* is regarded as a closer substitute to *Sutent* than *Torisel*.

31. On the other hand, in Belgium cytokines, i.e. *Interferon* and *Interleukin*, are not used any more for the treatment of mRCC, *Avastin* is not yet reimbursed and it is not used yet. *Nexavar* is exclusively used in 2nd line treatment. Therefore, the choice of drugs in 1st line treatment is made only between *Sutent* and *Torisel*.

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mRCC patients per year in Luxembourg and approximately one third is poor prognosis. The figures are similar for Cyprus and Malta.

13 After a pipeline product has completed preclinical testing and having demonstrated suitable stability and chemical quality tests, a application is filed with any relevant national authority in Europe to begin clinical trials to test the drug in people. This involves different phases: Phase I test involve about 20 to 100 healthy volunteers (except for cancer and HIV); in phase II the effectiveness of the pipeline product is tested within trials of approximately 100 to 500 volunteer patients; phase III usually involves 1,000 to 5,000 patients in clinics and hospitals, and the objective is to confirm the efficacy and safety of the test compound versus placebo and/or standard of care for a given disease. The larger phase III clinical trials usually involve multiple sites in different countries.

However, the market investigation indicated that also in this case competition is limited to poor prognosis patients within the 1st line treatment. According to the respondents, the proportion of poor prognosis patients ranges from less than 1% up to 30%. In Belgium the indicated range is 10% to 25%. Therefore, it may be concluded that *Sutent* and *Torisel* are only regarded as close competitors for a certain segment of the 1st line treatment, in particular in poor prognosis patients, where no other available product is used in 1st line treatment.

32. In the UK the situation also differs from the situation in the other affected countries. There, at present *Sutent* is the only product approved for reimbursement for the treatment of mRCC.

33. Prices for a monthly treatment range between EUR 2,800 and EUR 3,800. They are on the same level for the main products (*Sutent*, *Torisel* and *Nexavar*). The also used combination *Avastin/IFN* is on the same price level. The Parties' argument that there is little room for price increases because of price regulation was confirmed by most respondents in the market investigation, in particular the responsible regulatory bodies.

34. In addition, a number of pipeline products in an advanced stage are likely to enter the market in the near future. Novartis has the pipeline product *Afinitor* (*Everolimus*), an oral mTOR inhibitor tested for 2nd line treatment that received a positive opinion by EMEA on 29 May 2009. Novartis is awaiting marketing authorisation in the EU and plans to launch *Afinitor* in […]. For *Pazopanib*, an oral MKI by GlaxoSmithKline tested for 1st and 2nd line treatment in phase III, launch is expected in […]. In addition, Pfizer itself has a phase III pipeline product *Axitinib*, an oral MKI, which according to the market investigation is a much closer substitute to *Sutent* than to *Torisel*. The market investigation also indicated that *Afinitor* is a closer substitute to *Torisel* than *Sutent*, despite the fact that it is tested for 2nd line treatment, given that it has the same MOA as *Torisel* and that there is off-label usage.

35. Potential competition by pipeline products may already be regarded as actual competition to a certain extent. The pipeline products that are in phase III or beyond are already in use. Specialised cancer physicians in hospitals and cancer centres indicated that they were already using these products for the treatment of mRCC. It was indicated by some respondents that this is also the case in 1st line treatment, although there are already different products available. This is due to the fact that mRCC is a small market with a very limited number of patients. As indicated above, in 2009 there are an estimated 26,500 mRCC patients in Europe. Worldwide, phase III clinical trials usually involve 1,000 to 5,000 patients per product in clinics and hospitals. Despite the low total number of mRCC patients in Europe, the market investigation indicated that the products tested for mRCC in phase III include the same number of patients as the trials for pipeline products in other therapeutical areas. Therefore, a clinical study for an mRCC pipeline product may be considered as a substitute or complement to the existing products to a certain extent for the duration of the clinical trial. In addition to the clinical trials, *Everolimus* is already available through expanded access programmes for compassionate use in the treatment of mRCC in some Member State. The Parties have no estimates regarding the usage of *Everolimus* through the expanded access programme. However, they state that Wyeth has already noticed that the sales of *Torisel* have decreased *inter alia* due to use of *Everolimus* via the expanded access programme. The market investigation did neither indicate any

impact of Pfizer's pipeline product *Axitinib* for use in 2nd line treatment, a MKI which is generally regarded as a very similar product to *Sutent*, nor of Wyeth's phase III trials for the application of *Torisel* in 2nd line treatment. This might be due to the fact, that *Torisel* is already used "off-label" in 2nd line. Given that the market investigation confirmed that after the failure of a product, mostly a product with a different MOA is used in next line treatment, the Parties existing and pipeline products are rather complementary from a clinical point of view.

36. […]. The clinical trials for the combined use of *Torisel* and *Avastin* are conducted by Wyeth. There are no indications that the merged entity would stop these clinical trials after the merger.

37. The Parties have conducted a customer survey in the field of mRCC covering some larger Member States.[14] The survey results are generally in line with the results of the Commission's market investigation. The survey emphasises the fact that physicians regard *Nexavar* as a closer alternative to *Sutent* than *Torisel* and that *Nexavar* is also used in 1st phase but to a lesser extent than in 2nd phase. According to the survey results, approximately 80% of the physicians who prescribe *Torisel* for 1st line treatment of poor prognosis patients never use *Sutent* in this setting and vice versa. This means that approximately 20% of these physicians choose between *Sutent* and *Torisel* in 1st line treatment of poor prognosis patients. However, the survey showed that a majority of physicians expect entry of new products, i.e. *Everolimus* and *Pazopanib*. These products are expected to be used in 1st and 2nd line treatment of mRCC and to have an impact on the market shares of the existing products.

38. Given the present market structure and taking into consideration the expected market entry of pipeline products, in particular *Everolimus* and *Pazonapib*, the Commission concludes that merger does not raise serious doubts in any mRCC market.

Antibiotics

39. Both Parties produce and sell antibiotics. There are many classes of antibiotics which have different pathways to either stop harmful bacteria from growing or kill them. Based on the ATC3 classification, the combination of the Parties' products results in two distinct overlaps: (i.) Broad spectrum penicillin (ATC3 class J1C), and (ii.) Other antibacterials (ATC 3 class J1X).

Broad spectrum penicillin (ATC3 class J1C)

Introduction

40. Bacteria can be divided, *inter alia*, into gram positive and gram negative bacteria, depending on the structure of their cell walls, which in turn results in different pathogens and different susceptibility to antibiotics. Broad spectrum agents are effective against both gram positive and gram negative bacteria and are preferred over narrow spectrum agents for patients that have an unknown infection and where speed of treatment is of the utmost importance. The J1C

14 The survey covers France, Germany, Italy, Spain, UK, Greece, the Netherlands and Sweden.

class contains all systemic penicillin derivates which are used as broad spectrum agents.

41. Wyeth produces *Tazocin*, an intravenous (IV) antibiotic used for serious infections in hospitals. Its patent expired in 2007. The Parties explained that, following patent expiration, it has taken some time for generics to enter the market but they should be available in all EU countries already this year. In this respect, Wyeth anticipates that market entry of *Tazocin's* generic versions will result in significant (approximately […]%) price and value share decline in […].

42. Pfizer produces *Unasyn*, *Antibiopen* and *Amplital* (all off patent). Only *Unasyn* has significant sales. It is also an IV antibiotic but has different indication and usage than *Tazocin*.

Market Definition

43. The Commission previously examined antibiotics markets and considered that the ATC3 level was the most appropriate market definition (except for "catch-all classes", see below under ii).[15]

44. The Parties are of the view that a market definition based on ATC3 respectively ATC4 classification does not adequately reflect therapeutic applications. They propose instead two alternative market definitions: a wider market definition, [16] not leading to any affected country (as the Parties' combined market shares would not exceed 35% in any EEA country); a narrower market definition[17] leading to the same affected countries as under the ATC3 classification.

45. As regards the definition of the relevant product market, the results of the market investigation indicate a mixed preference for the ATC3 class J1C (mostly by hospitals) and the wider market definition proposed by the Parties (mostly by competitors). The market investigation did not indicate that a market definition based on ATC4 class would be appropriate. Competition problems appear unlikely under either solution. The exact definition of the relevant product market may thereforebe left open.

Assessment

46. Taking into account the ATC3 class J1C (Broad spectrum penicillin), the transaction results in two Group 1 markets: Austria[18] and Germany[19]. In all cases Wyeth's *Tazocin* accounts for the largest market share. The Parties' main

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15 Cases COMP/M.1846 – *Glaxo Welcome/Smithkline Beecham*; COMP/M.3354 – *Sanofi Synthelabo/Aventis*.

16 It includes oral and injectable antibiotics used in the treatment of moderate to severe infections in hospitals based on molecules alternatives to Wyeth's *Tazocyn* including amoxicillin+ clavulanic acid, ciprofloxacin, ceftriaxone, ceftazidime, cefuroxime axetil, cefotaxime, ampicillin+sulbactam (sultamicillin), piperacillin+tazobactam (including preparations incorporating edetic acid).

17 It includes oral and injectable broad spectrum penicillin with a beta lactamase inhibitor including amoxicillin+clavulanic acid, ampicillin+sulbactam (sultamacillin), piperacillin tazobactam (including preparations incorporating Edetic Acid).

18 Austria: [30-40]% ([30-40]% + [5-10]%).

19 Germany: [30-40]% ([20-30]% + [10-20]%).

competitors are GlaxoSmithKline and Novartis, as well as a number of smaller generics producers.

47. Under the ATC3 class market definition (J1C), it seems unlikely that the proposed merger would lead to competition problems in Austria or in Germany. In Austria, the merged entity would not be the largest player (combined market share [30-40]%) but would only be the second market player behind GSK ([30-40]%). In addition, respondents to the market investigation have consistently pointed out that generic drugs are valid substitutes to *Unasyn* and *Tazocin* (despite the fact that the patent for *Tazocin* has only recently expired)[20] which exert a downward pressure on the prices and sales of original products.

48. With respect to Germany, the merged entity would barely exceed the 35% threshold (combined market share [30-40]%) and, in any event, the merged firm would be subject to competitive pressure from Ratiopharm ([20-30]%) and Novartis ([10-20]%). In addition, respondents to the market investigation consistently indicated that generic drugs are available to customers and pose a competitive constraint in terms of sales and prices.

49. The market investigation also indicated that, in case of a 10% increase in the price of *Tazocin* and *Unasyn*, customers would be ready to switch to alternative products. In such an event, the Parties' products are not considered as each other's closest substitutes.

50. In the light of the above considerations, the Commission concludes that the merger does not raise serious doubts in the markets for broad spectrum pennicillins.

Other antibacterials (ATC3 class J1X)

Introduction

51. Wyeth produces *Tygacil*, a broad spectrum antibiotic administered only intravenously, which is used exclusively in hospitals particularly for the treatment of complicated intra-abdominal infections and complicated skin and soft tissue infections (SSTI). *Tygacil* is a more expensive "high end" broad spectrum antibiotic than *Tazocin* and picks up the most prevalent gram positive "superbugs", *i.e. Methicillin Resistant Staphylococcus Aureus* (MRSA) and *Vancomycin Resistant Enterococci* (VRE). *Tygacil* will go off patent in 2017.

52. Pfizer has a narrow spectrum agent, *Zyvox*, only effective against gram positive bacteria, including antibiotic resistant strains such as MRSA and VRE. It is indicated for the treatment of hospital and community acquired pneumonia and complicated SSTI. It is offered both as an intravenous and as an oral agent. *Zyvox* will go off patent in 2016.

53. In this category, Pfizer also has a pipeline product in phase III clinical trials, namely *Dalbavancin* (*Exulet*). Like *Zyvox*, *Dalbavancin* is a gram positive agent. It will be classified in class J1X and it will be administered only IV. However, in this respect, the Parties submit that on 9 September 2008, Pfizer withdrew its

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20 Generic alternatives include *Ampicillin* and *Subactom* for *Unasyn* and *Piperacillin* and *Tazobactam* for *Tazocin*.

application for a marketing authorisation for *Dalbavancin* for the treatment of SSTI after the Committee for Medicinal Products for Human Use (CHMP) expressed concerns that the results of the single study were too limited to support the approval of the product.

54. Wyeth's *Tygacil* and Pfizer's *Zyvox* overlap in the ATC3 class J1X (other antibacterials), as well as in the ATC 4 class J1X9 (all other antibacterials).

Market Definition

55. Both the ATC3 class J1X and ATC4 class J1X9 are "catch-all classes" that do not group interchangeable products but products that do not fit in the remaining categories.[21] Due to this product heterogeneity, unlike other ATC categories, the J1X and J1X9 classes are of limited or no relevance for market definition purposes.

56. The Parties are also of the view that the ATC3 class J1X and the ATC4 class J1X9 are meaningless in this respect. They state that *Tygacil* is the first in a new class of antibiotics known as glycylcyclines, which is classified by the European Medicines Agency ("EMEA") in class J1A (while EphMRA categorises *Tygacil* in ATC class J1X). Therefore, according to the EMEA ATC classification, there would be no ATC3 overlap among the Parties' products.

57. The Parties consider that there is a limited degree of substitution between *Tygacil* and *Zyvox* for the treatment of the gram positive MRSA and VRE.

58. The Parties submit that MRSA is a "superbug", which poses serious health concerns and whose prevalence has increased at hospitals, particularly in cases where no proper sanitary and screening procedures are in place.[22] In some EEA countries improved sanitary and screening procedures seem to have reduced the spread of MRSA. The demand for MRSA agents therefore varies greatly within the EEA.

59. In the segment of VRE infections for which Vancomycin cannot be used, the Parties would still compete with *Cubicin* and *Targocid* but their market shares would be higher. According to the Parties, VRE is a niche segment.

60. The Commission focused its market investigation on the issue whether the EphMRA (i.e. both products belong to the ATC3 class J1X) or EMEA classification (i.e. *Zyvox* belongs to ATC3 class J1X, while *Tygacil* belongs to ATC3 class J1A) should apply. In any case, respondents indicated differences between the Parties' products. The Commission detected a tendency towards the EMEA classification. Using this market definition, there would be no overlap between the Parties' products.

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21 Case COMP/M.3354 – *Sanofi Synthelabo/Aventis*, para. 47 ff.

22 A distinction is made between community acquired MRSA (CA MRSA) and hospital acquired MRSA (HA MRSA); the latter is generally more severe and therefore more difficult to treat. Most MRSA infections are hospital acquired: nearly 80% of all MRSA infections in the EU5. The proportion of CA MRSA is, however, increasing. The MRSA strain is mutating and there is evidence suggesting that some MRSA agents are no longer effective.

61. Should the EphMRA classification apply, the actual therapeutic indication of the drugs would be relevant, as the J1X class is a "catch-all" category comprising drugs with very different applications. In this respect, the market investigation generally confirmed that MRSA is the main overlapping area between *Tygacil* and *Zyvox*. Another minor overlap occurs in the VRE segment but the market investigation indicated that the latter is a niche market, generally considered as a part of the MRSA market and that the Parties would be unable to price-discriminate between antibiotics used for MRSA and those used for VRE given that, with the exception of *Vancomycin*, *Tygacil*, *Zyvox* and their alternative drugs are used for treatment of MRSA and VRE alike. The relevant market, therefore, would include antibiotics used for the treatment of MRSA infection.

62. The Commission considers that the exact definition of the relevant product market can ultimately be left open, since neither market definition would result in competition concerns.

Assessment

63. In the ATC3 segment J1X, the combined market shares of the Parties would result in seven Group 1 markets[23]. In all cases Pfizer's *Zyvox* accounts for the largest market share. If total sales figures are adjusted by taking into account only MRSA usage, two markets would be excluded.[24] In terms of volume, the Parties' market shares are significantly lower. This reflects the importance of the leading product in this field, the generic drug *Vancomycin*. Other products competing with the Parties' drugs are *Cubicin* (Cubist/Novartis) and the generic drug *Targocid*.

64. Therefore, under a market definition based on EphMRA's classification, in the market for MRSA treatment, the Group 1 markets are Belgium, Finland, Germany, Ireland and Spain.[25] First, it ought to be noted that Belgium and Finland do not seem to pose competition problems, due to the large market shares of *Vancomycin*, which would be even higher if volume is taken into account, since the market share is in value and *Vancomycin*, is a generic drug with a low price. In Ireland and Spain, the market share increment brought about by the proposed transaction is modest.[26] In Germany, customers which buy *Tygacil* and *Zyvoxid* also buy *Cubicin* and *Vancomycin*. They indicate that *Vancomycin* is the leader treatment for MRSA, that *Tygacil* and *Zyvox* are "reserve antibiotics" in this area and have different indications, depending on the infection site (*Zyvox* is more indicated for pulmonary infections, while *Tygacil* is better for intra-abdominal infections). In all the affected countries, market shares in volume are significantly lower that market shares in value, indicating a significant presence of cheaper generic alternatives.

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23 Austria: [30-40]% ([30-40]% + [5-10]%); Belgium: [30-40]% ([30-40]% + [0-5]%); Finland: [40-50]% ([30-40]% + [10-20]%); Germany: [60-70]% ([40-50]% + [10-20]%); Greece: [30-40]% ([30-40]% + [0-5]%); Ireland: [40-50]% ([30-40]% + [0-5]%); and Spain: [60-70]% ([50-60]% + [0-5]%).

24 Austria and Greece.

25 Belgium (Pfizer: [40-50]%, Wyeth: [0-5]%), Finland (Pfizer: [40-50]%, Wyeth: [5-10]%), Germany (Pfizer: [50-60]%, Wyeth: [0-5]%), Ireland (Pfizer: [40-50]%, Wyeth: [0-5]%), Spain (Pfizer: [60-70]%, Wyeth: [0-5]%).

26 In Ireland the increment amounts to [0-5]% and in Spain to [0-5]%.

65. In addition, the market investigation indicated a number of factors which contribute to the conclusion that competition concerns may be excluded. Firstly, the existence of valid alternatives to *Tygacil* and *Zyvox* for the treatment of both 1st and 2nd line MRSA. Indeed, *Vancomycin* is the leader antibiotic for 1st line treatment of MRSA, which in the majority of cases accounts for the largest share of MRSA cases handled by hospitals. *Zyvox* is more used in 2nd line treatment, but, even in such case, there are viable alternatives (*e.g. Vancomycin*, *Rifampicin*, *Cubicin*, *Linezolid*, *Daptomycin*, etc.). Secondly, demand appears relatively elastic and, despite some mixed replies in the market investigation, there are several indications that a hypothetical 10% price increase would result in hospitals switching to other products. In any event, most hospitals see *Vancomycin*, a generic alternative to the Parties' products as the leading treatment for infections caused by MRSA. Competitors report several originator alternatives in phase III, covering MRSA infections (in particular SSTI and pneumonia).

66. In the light of the above considerations, the Commission concludes that the merger does not raise serious doubts .

Tranquillisers

Introduction

67. Tranquillisers are classified in the ATC3 class N5C, Tranquillisers. They are generally divided in benzodiazepines and non-benzodiazepines. Currently, most tranquillisers included in the ATC3 class N5C are benzodiazepines. Benzodiazepines are minor tranquillisers with sedative, hypnotic, anxiolytic, anticonvulsant and muscle-relaxant properties. They are often used for short term relief of severe, disabling anxiety or insomnia. The Parties make reference to the Commission precedent in the case *Teva/Barr*[27] and agree with the Commission's conclusions that the market for tranquillisers should be defined on a broader basis than molecule level.

68. The Parties are both active in the production and marketing of tranquillisers. Wyeth manufactures *Ativan (Lorazepam)* and Pfizer manufactures several tranquillisers: *Xanax* (*Alprazolam*), and *Xanax XR*. None of these products is under patent protection.

Market Definition

69. In relation to the definition of the relevant product market, the Parties submit that tranquillisers of the ATC3 class N5C might also face terapeuthic substitutability with hypnotics and sedatives belonging to the N5B class. In this respect, although mixed replies have been provided, the market investigation indicates that substitutability is only partial. The Commission therefore concludes that, for the purposes of assessing the effects of the transaction, the relevant product market should include only drugs belonging to the ATC3 class N5C. In relation to the potential distinction between benzodiazepines and non-benzodiazepines, the Commission considers that, even under a narrow market hypothesis,

27 COMP/M.5295 – *Teva/Barr*, decision of 19 December 2008, para. 158.

including benzodiazepines only, the Parties' market shares and the market characterics are such that competition problems are unlikely.

Assessment

70. Post-merger, the Parties' products would give rise to combined market shares (in value) exceeding 35% with significant increments in a number of EEA countries, namely in Belgium, Luxembourg, Ireland, Greece and Spain. [28] On all such markets there are a number of competitors with a market share exceeding 5% and, in Belgium Greece and Ireland, with a market share in the range of [20-30]%[29].

71. In relation to the above markets, the market investigation has indicated a number of factors which contribute to the conclusion that competition problems may be excluded. Firstly, there is a significant competitive pressure from generic products and customers seem ready to switch to alternative products, in case of a price increase. The Parties' products are not regarded as each other's closest substitutes (different MOA and indications). The market investigation also indicated that wholesalers are normally not bound by exclusivity agreements for the supply of tranquillisers. To the contrary, wholesalers normally buy a range of products from multiple suppliers. As a consequence, access to distribution is not a barrier to entry and drug producers have the possibility to create their own network of distribution agreements with independent wholesalers, as an alternative to selling their production directly to pharmacies. The Commission therefore considers that barriers to entry are sufficiently low to make a post-merger price increase unprofitable for the merged firm.

72. In the light of the above considerations, the Commission concludes that the merger does not raise serious doubts in the markets for tranquillisers.

Anti-depressants

Introduction

73. Both Parties are active in the production and marketing of drugs used for the treatment of major depressive disorders ("MDD") and some anxiety disorders. Such drugs are classified in the ATC3 category N6A, anti-depressants and mood stabilisers.

74. The Parties submit that, within the ATC3 category N6A, anti-depressants may be classified according to their MOA. The Parties make reference to the

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28 In Belgium the post-merger combined share would amount to [40-50]% (Pfizer [30-40]%, Wyeth [5-10]%), in Luxembourg to [60-70]% (Pfizer [40-50]%, Wyeth [10-20]%), in Ireland to [30-40]% (Pfizer [30-40]%, Wyeth [0-5]%), in Greece to [40-50]% (Pfizer [20-30]%, Wyeth [10-20]%) and in Spain to [40-50]% (Pfizer [20-30]%, Wyeth [10-20]%).

29 In Belgium: Stada [20-30]%, Roche [5-10]%, Sanofi [5-10]%, generic Lorazepam/Alprazolam [10-20]%. In Greece: Roche [20-30]%, Vianex [10-20]%, UCB [5-10]%. In Ireland: Roche [20-30]%, Stada [5-10]%, Bristol-Myers [5-10]%, Meda [5-10]%, generic Lorazepam/Alprazolam [5-10]%. In Luxembourg: Roche [10-20]%, Sanofi [5-10]%, Will Pharma [5-10]%. In Spain: Roche [10-20]%, Sanofi [10-20]%, UCB and Faes [5-10]%, Novartis [5-10]%, generic Lorazepam/Alprazolam [10-20]%.

Commission precedent in the case *Teva/Barr*[30] and agree with the Commission's conclusion that the market for anti-depressants should be defined on a broader basis than molecule level.

75. Wyeth manufactures and markets an anti-depressant under the name *Efexor* which is no longer under patent protection. Wyeth also launched an extended release formulation of *Efexor*, based on the same active ingredient (venlafaxine), under the brand name *Efexor XR* which is protected by a patent expiring in 2017.

76. Pfizer manufactures and markets two anti-depressants, namely *Zoloft* and *Edronax*. The patents for both drugs have expired. On an ATC4 level there is no overlap between the Wyeth and the Pfizer products, neither on a molecule level.

Market Definition

77. As regards the relevant product market, the Parties submit that relevant differences exist between the drugs included in the ATC3 class N6A, as to their MOA. Although replies to the market investigation were mixed in this respect, the market investigation indicated that such differences are not decisive when identifying separate products markets. However, the market definition can be left open as the transaction does not raise serious doubts under any alternative market definition.

Assessment

78. Under a market definition based on the ATC4 level or the molecule, there would be no overlap between the Parties' products. On a market definition based on the ATC3 level, the proposed merger leads to a significant overlap only in the Netherlands, where the Parties' combined market share, following the transaction, would amount to [30-40]% with an increment of [0-5]% by Pfizer.

79. In relation to the Dutch market for anti-depressants, the exiguous market share increment (only [0-5]%) brought about by the transaction must be considered. There are also a number of well-established competitors: Teva ([10-20]%), Lundbeck ([5-10]%), Novartis ([5-10]%), Ratiopharm ([5-10]%) and Lilly ([5-10]%).

80. In addition, the market investigation provided elements that contribute to the conclusion that competition concerns may be excluded in the Dutch market for anti-depressants. Firstly, there is competitive pressure from generic products. (in the Netherlands there is a "preferential" reimbursement scheme for generics). Competitors do not regard the Parties' products as each other's closest substitites.

81. In the light of the above considerations, the Commission concludes that the merger does not raise serious doubts in the Dutch market for anti-depressants.

30 COMP/M.5295 – *Teva/Barr*, decision of 19 December 2008, paras. 163, 164.

Pipeline markets

Alzheimer's disease

Market definition

82. Drugs against Alzheimer's disease (AD) are classified in the ATC3 class N7D – Anti-Alzheimer products. This ATC3 class consists of two ATC4 classes, N7D1 and N7D9.

83. Currently available treatments for AD offer only symptomatic relief. There are no disease-modifying products available yet. The market investigation indicated that products for the treatment of the symptoms and disease-modifying products would become complementary rather than substitutes. However, it may be difficult to make a clear-cut distinction between symptom treatment and disease modifiers and there will be substitution to a certain extent.

84. The exact market definition may, however, be left open in this case, since the notified transaction would not result in serious doubts in any EEA-country, regardless of the market definition considered.

Assessment

85. There is no existing overlap between the Parties' products. Pfizer, together with Eisai, co-markets *Aricept* (*Donepezil*). In […] Eisai entered into a strategic alliance and development agreement with Pfizer. According to that agreement, […]. Furthermore, Pfizer was granted various licences to commercialise *Aricept* (semi-exclusive in Italy, exclusive in Spain). Eisai is the owner of the *Aricept* compound and all related patents and rights. Eisai has terminated the strategic alliance with regard to *Aricept*. Pfizer does not consider that Eisai has the right to do so and will contest the termination of the agreement. *Aricept* is classified in ATC3 class N7D and ATC4 class N7D1. The drug is the leading product for the symptomatic treatment of AD in Europe. The market share of *Aricept* exceeds 35% in Austria, Belgium, France […], Hungary, Ireland, Luxembourg, Portugal and Romania. Wyeth currently does not market any AD drugs in Europe.

86. *Donepezil*, the compound of *Aricept*, is a small molecule which acts as an acetylcholinesterase inhibitor ("AchEI") and is indicated for the treatment of mild to moderate dementia in the EU. In the EEA, the basic patents will expire from 2012 onwards. The Parties stated that marketing authorisations for generic versions of *Aricept* have been filed (and many have been approved) in all EU countries save for Cyprus, Malta, and Netherlands where *Aricept* is not sold. Generic *Aricept* is currently on the market in those countries where the basic patent was not filed, i.e. the Czech Republic, Hungary, Ireland, Lithuania, Poland, Slovakia and Slovenia, or where the basic patent has process-only claims i.e. Finland, Norway, Portugal. Therefore, the Parties are of the view that generics will enter the remaining markets as soon as the basic patents are expired.

87. The Parties estimate the turnover in the global AD market to EUR 3.3 billion with approximately 26.6 million patients worldwide. There are not yet any disease-modifying drugs in the market and existing products, like *Aricept*, are mere symptom treatments. The cause of AD is still unclear. R&D of disease

modifying drugs is therefore based on different disease hypotheses. All this was confirmed by the market investigation.

88. Both Parties, as well as several competitors, have a number of pipeline products in the field of AD. Wyeth's phase III pipeline product *Bapineuzumab*, a passive immunotherapeutic, would, if ultimately approved, become the first humanised monoclonal antibody against A-Beta amyloid for mild to moderate AD and it is hoped that the drug will be disease modifying. The Parties do not expect approval until […]. Pfizer's phase III pipeline product *Dimebon*, a small molecule, is an old Russian antihistamine which is tested as symptom treatment.

89. The market investigation confirmed that the results of the phase III clinical trials for Wyeth's *Bapineuzumab* are not expected before […]. It was also confirmed that the MOA of Pfizer's *Dimebon* is unknown. Furthermore, the market investigation indicated that any new disease-modifying products would be complementary to existing products rather than replacing them. However, replacement may occur to a certain extent if the new products turn out to be able to treat symptoms as well. In addition, some respondents indicated that it is difficult to make a clear distinction between symptom treatment and disease-modifying drugs.

90. One respondent stated that both Parties' pipeline products would be superior to competitors' pipeline products. The other respondents do not consider that the Parties' pipeline products have any particular advantages but that Wyeth's *Bapineuzumab* has the potential to become the first AD disease modifier. Furthermore, the market investigation confirmed that Pfizer's *Dimebon* is not proved to be disease modifying but rather a new (improved) symptom treatment.

91. The Parties' allegation that AD pipeline products in phase III are more likely to be abandoned than in other therapeutic fields was confirmed. Given that the cause of the disease is unclear, the success rate is likely to be lower than in other fields. For AD it is estimated to be below 50%. With regard to the Parties' pipeline products, there is no clear picture for the likelihood of their success. The estimates of the respondents range from very low to very high. Respondents indicated that the Parties would continue or even intensify their R&D efforts. Given the uncertainty of the disease cause and based on the high likelihood that pipeline products will fail as well as the number of competitors' pipeline products, it seems unlikely that potential competition would be harmed by the merger.

92. According to a minority of respondents, the merger would have an overall negative impact on AD research. According to a few competitors, the Parties could possibly dominate access to clinical trial centres and access to prescribers. It was also stated that it might become more difficult for small companies to find development partners. However, most respondents expect no or only little effect. Given the fact that Eisai is conducting all clinical trials for *Aricept* and that there are competitors on the market with existing products for symptom treatment and a number of pipeline products in phase III being tested whether they are disease modifying, it seems unlikely that the merged entity would have the potential to hinder competitors from conducting clinical trials. Furthermore, the clinical trial centres indicated that they conduct clinical trials in the field of AD for several pharmaceutical companies. Most clinical trial centres stated that they expect beneficial effects because the merged firm will intensify R&D activities. There are no indications that the Parties would obtain unrivalled access to prescribers,

e.g. via physicians' AD programmes and given that Wyeth at present does not have any existing products for the treatment of AD.

93. With regard to the possibility of the Parties of blocking competitor's R&D projects, the market investigation has not shown any concerns. In particular, the merged entity would neither own the patents for the existing product *Aricept* nor for Pfizer's pipeline product *Dimebon.* All clinical trials for *Aricept* are and were conducted by Eisai. Eisai owns all relevant patents and rights related to the *Aricept* compound. In any event, the patent for *Aricept* expires from […] onwards in the EEA. For Pfizer's pipeline product *Dimebon*, there is no patent protection either, given that it is an old compound used as an antihistamine in Russia in the 1980s.[31] Pfizer acquired the rights to market *Dimebon* from [..]. *Dimebon* is no longer IP protected. […]. Therefore, the only patent belonging to the merged entity would be the ones for Wyeth's *Bapineuzumab*. It therefore seems very unlikely that the merged entity would have the potential to foreclose or delay the development or launch of competitors' AD products.

94. The merger does not affect actual competition and it seems unlikely that potential competition would be impeded by the merger. *Dimebon* and *Bapineuzumab* are different in several respects. Pfizer's small molecule *Dimebon* has an unknown MOA and is tested as a symptom treatment. It is different from Wyeth's *Bapineuzumab*, a biological IV immunotherapy which is tested as disease-modifying product. Most competitors have pipeline products in different phases, including phase III. TauRX has one disease-modifying pipeline product that […], Eli Lilly has two disease-modifying pipeline products […] and Eisai has one potentially disease-modifying product […].

95. In the light of the above considerations, it can be concluded that the merger does not raise serious doubts in the markets for AD.

Rheumatoid Arthritis

96. In the area of rheumatoid arthritis, Wyeth has the product *Enbrel*, a biological agent that is approved for the treatment of moderate to severe rheumatoid arthritis grouped in ATC3 class L4A – Immunosuppressive Agents. Although, in some countries, e.g. in Gemany, *Enbrel* is classified in M1C – Specific Anti-Rheumatic Agents. It is the leading product to date and is still under patent protection. In the EEA the patent will expire in France, Germany, Ireland, Italy and Spain in 2015 while it will expire in 2010 in Canada and 2012 in the USA. In addition, Pfizer has two existing products which belong to different ATC3 classes than Wyeth's *Enbrel*. Pfizer's *Celebrex* is classified in M1A and *Salazopyrin* is classified in A7E. According to the Parties, these products are rather complements than substitutes in the treatment of rheumatoid arthritis. Furthermore, Pfizer has one pipeline product.

Market definition

97. The market investigation indicated that the product market could be defined on the ATC 3 level L4A – Immunosuppressive Agents. This class includes *Enbrel*

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31 Pfizer acquired the rights to market *Dimebon* from […]

and it is likely that Pfizer's pipeline product in phase III, a JAK3 oral agent that is a small molecule, will be classified in L4A, too.

98. The exact market definition may, however, be left open in this case, since the notified transaction would not result in serious doubts in any EEA-country, regardless of the market definition considered.

Assessment

99. The market investigation did not indicate that JAK3 is a unique pipeline product. There are a number of competitors with phase III pipeline products, e.g. Hoffmann-LaRoche with *Ocrelizumab* which is registered, UCB SA with *Certolizumab pregol* for which a marketing authorization application has already been filed. The product is expected to be launched in […], GlaxoSmithKline has *Ofatumumbab IV* which is likely to be launched in […] and Johnson&Johnson has *Golimumab* which is expected to […]. In addition, the market investigation indicated that generic companies will enter the market for the treatment of rheumatoid arthritis.

100. In the light of the above considerations, it can be concluded that the merger does not raise serious doubts in the markets for rheumatoid arthritis.

Vertically affected markets

Hard Gelatine Capsules

101. Hard gelatine capsules are one form of oral dosage in which a drug can be delivered. Hard gelatine capsules are a commodity product manufactured from animal gelatine. Other oral dosage methods include tablets, soft gelatine capsules, powder and liquid.

102. The Parties submit that the product market may be wider than hard empty gelatine capsules and that the geographic scope should be worldwide.

103. In its previous decision, the Commission left the product and geographic market definition open.[32]

104. For the purposes of this decision, the exact market definition can be left open, since regardless of the product respectively geographic market considered, no competition concerns would arise.

105. Pfizer produces and sells hard gelatine capsules through its subsidiary Capsugel. Pfizer's market share in the EEA is [70-80]% and [60-70]% worldwide. Main competitors are Qualicaps with a market share in the EEA of [10-20]%, Associated with [5-10]% and SU Hueng with [0-5]%. Wyeth does not manufacture or supply hard gelatine capsules. However, it purchases from Pfizer approximately [90-100]% of its global capsule requirements which represents just [0-5]% of Capsugel's total sales.

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32 Case COMP/M.2922-*Pfizer/Pharmacia*, decision of 27 February 2003, para. 104.

106. The Parties submit that there is no risk of foreclosure of the market as Wyeth's demand is very small when compared with the demand of third parties. Wyeth, on the other hand, is already sourcing almost all of its hard gelatine capsules from Pfizer. If Wyeth were to transfer all its sourcing to Pfizer, this would have no appreciable effect on the availability of hard gelatine capsules in the EEA.

107. On the basis of the foregoing, the Commission concludes that even under the narrowest market definitions considered (hard gelatine capsules at the EEA-wide level), the operation would not give rise to serious competition concerns.

4.3. Animal Health Markets – Vaccines, Pharmaceuticals and Medicinal Feed Additives

Companies active in the animal health sector

108. 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), Schering-Plough/Intervet, Bayer, Fort Dodge (the animal health arm of Wyeth), Novartis International AG, and Elanco (the animal health arm of Eli Lilly). The second type of companies are smaller multinational companies, such as the Laboratorios Hipra S.A.,Virbac, Vétoquinol and Ceva Sante Animale, Boehringer Ingelheim VetMedica ('BI'). In some geographic areas, there are a few regional or local players, such as Czech company Bioveta, the Belgium company Fendigo, Fatro/Fatro Iberica, or Spanish company Syva. The third category concerns producers of generic pharmaceutical products[33] (which are off-patent), such as Norbrook Laboratories, Krka, Janssen Animal Health, division of Janssen Pharmaceutica NV, Chanelle Veterinary, Laboratorios Calier, S.A., and ScanVet.

109. In should be noted, however, that there are only a few players, active in the field of vaccines. The markets are dominated by multinational companies, such as Schering-Plough/Intervet, Merial, Virbac and the Parties, with some presence of a few regional players in certain countries, e.g. Hipra in Spain and Portugal.

4.3.1. Product Market Definition

Introduction

110. Animal health products are mainly produced for the following groups of species[34]:

(i.) Ruminants (cattle, sheep and goats);
(ii.) Swine;

33 There are no generics for biologicals.

34 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).

(iii.) Poultry (chickens and turkeys);
(iv.) Equine (horses);
(v.) Companion animals (cats and dogs); and
(vi.) Aquaculture animals (farmed fish).

111. In previous decisions[35], the Commission has consistently divided animal health products into three main categories:

(i.) biologicals (vaccines);
(ii.) pharmaceuticals;
(iii.) medicinal feed additives.

Biologicals (vaccines)

112. 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 vaccines, antisera and colostra products. Vaccines are used to protect the animal against possible future infection and have a wide spectrum of effectiveness and duration of activity, whereas antisera and colostra products give an animal a passive immunity, which is acute, but short-lasting.

113. The activities of the Parties overlap only in the field of vaccines.

114. When defining relevant product markets for the purposes of competition law in the area of animal health vaccines, the most important factors to be taken into account are the following.

(i.) Animal species: Most vaccines target a single animal species or group of species (except for multispecies rabies vaccine). Vaccines for different animal species are usually not substitutable even when they target the same disease.

(ii.) Indications of use: Vaccines target a specific disease. Vaccines for different diseases are usually not substitutable, even within the same species.

(iii.) Single or multiple pathogens: Monovalent vaccines - which contain one or multiple strains of only a single antigen - protect against one specific disease, whereas multivalent vaccines - which contain two or more different antigens (either one or multiple strains of each antigen) - usually protect against several diseases.

(iv.) 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.

(v.) Marker or non-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.

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35 See e.g. cases COMP/M.1681 – *Akzo Nobel/Hoechst Roussel Vet*, 22.11.1999; COMP/M.2922 – *Pfizer/Pharmacia*, 27.02.2003 and COMP/M4691 *Schering-Plough/Organon Biosciences*, 11.11.2007.

115. When defining relevant product markets, a case-by-case analysis is often called for, in particular as regards the distinction between monovalent and multivalent vaccines and between live and inactivated vaccines.

116. First, the distinction between live and inactivated vaccines cannot be drawn in a general manner. It should be noted that in some instances the distinction is not relevant; as some vaccines exist or are permitted only in a live or inactivated form in the EEA[36]. A number of respondents indicated that both live and inactivated vaccines, once registered, could be assumed to be safe and efficacious and would be in general substitutable. On the other hand, due to the fact that live and inactivated vaccines offer different immunological response, the choice between live or inactivated vaccines may sometimes depend on the efficacy and safety considerations[37].

117. This issue of market definition can however be left open, as it cannot be answered in a general manner and does not appear to be relevant for the purposes of the present competitive assessment, as discussed for each respective market.

118. Second, the market investigation has also confirmed that the question of substitutability between monovalent and multivalent vaccines cannot be answered in a general manner, but has to be examined on a case-by-case basis. Respondents indicate that from the demand side perspective, monovalent vaccines are generally able to substitute multivalent vaccines that confer the same immunity, however because of the costs, impracticability to administer multiple monovalent vaccines and additional stress caused to the animal of administering multiple shots, the customers would not view them as interchangeable. Conversely, multivalent vaccines may not be interchangeable with monovalent vaccines because the customers would not generally include vaccination against additional pathogens, when this not needed. Also, in some cases monovalent vaccines may have a different claim than a multivalent vaccine in relation to the same disease.

119. This issue of market definition can however be left open, as the exact scope of the relevant product market has to be examined on a case-by-case basis below for those product markets where this distinction matters for the purposes of the competitive assessment.

Pharmaceuticals

120. Animal health pharmaceuticals are usually divided into:

(i.) parasiticides;

(ii.) antimicrobials;

(iii.) endocrine treatments;

(iv.) anti-inflammatory treatments; and

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36 e.g. monovalent multispecies rabies vaccines exist only in an inactivated form and only inactivated Blue Tongue Vaccines for serotype 8 are permitted in the EEA.

37 e.g. use of live IBR marker vaccine of Pfizer is recommended for animals under 3 months of age.

(v.) analgesics.

121. Contrary to biologicals, most active substances in pharmaceutical products are of synthetic origin. As in human health, the production of active substances constitute distinct product markets situated upstream of the markets for finished dose animal health pharmaceuticals.

122. When defining relevant product markets for the purposes of competition law in the area of animal health pharmaceuticals, the most important factors to be taken into account are the following.

(i.) Animal species: Although many pharmaceuticals are multi-species, some are effective only for a particular species or group of species (such as companion animals).

(ii.) Active substance: In some cases the active substance is the main determinant for the product market definition, e.g. in antibiotics because the same active substance is effective against the whole range of pathologies.

(iii.) Target pathology/scope of effectiveness: Pathology is often at the core of the market definition. However, in some instances it is impossible to limit market demarcation to very narrowly defined pathologies. In the field of anti-microbials and parasiticides treatments against a single pathology may compete with alternative treatments that are effective against a whole spectrum of pathologies.

(iv.) Mode of administration: Most animal health pharmaceuticals are injectable (especially for production animals). For companion animals a large number of pharmaceuticals are administered orally (tablets, pastes and granules). There is a large number of additional modes of administration such as intra-mammary products for mastitis treatment in cows, anti-parasitic collars or spot-on drops for companion animals, etc.

(v.) Duration of efficacy: Farmers may demand products that remain active for long periods of time, usually for preventive purposes, e.g. anti-parasitic products or long-acting preventive antibiotics.

(vi.) Duration of the withdrawal period: For farm animals, the withdrawal period - i.e. the period after treatment during which an animal's meat or milk is deemed unsuitable for human consumption – is of large economic importance.

Medicinal Feed Additives

123. Feed additives are pharmaceutical or nutritional substances that are not natural feedstuffs which are added to made-up and stored feeds for various purposes but chiefly to control infectious disease or to promote growth. Improper use may cause poisoning in the subject animals or undesirable residues in food for human consumption produced by the animals. The use of additives in this way is strictly controlled by legislation in most countries. Some of them require a prescription by a veterinarian.

4.3.2. Geographic Market Definition

124. The Commission has previously considered that relevant geographic markets in the animal health sector have a national dimension.[38] Animal health products remain subject to national and mutual recognition registration systems with the consequence that products are sold according to the indications and uses prescribed by national registration and approval requirements. 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.

125. The Parties agree with the approach to geographic market definition, but note that introduction of pan-European registration procedures for some products as well as presence of large multinational players across the EEA, may over the time erode the reasoning behind the market definition at the national level.

126. The market investigation has confirmed that markets in the animal health sector are still national. This applies to vaccines, pharmaceuticals as well as medicinal feed additives, the latter also being primarily regulated at national level.

127. It may be concluded that the relevant geographic markets for animal health vaccines, pharmaceuticals and medicinal feed additives are national in scope.

4.3.3. Calculation of market shares in animal health markets

128. There is no comprehensive industry database of sales in the animal health sector equivalent to the IMS database in the field of human health, which makes it difficult to reliably calculate market shares in animal health markets. Given the absence of independent data capturing the entire animal health industry in the EEA, the Parties have relied on available third party resources and internal estimates.

129. The main third-party data source used by the Parties is data from the Centre Européen d'Etude pour la Santé Animale ("CEESA"), a non-profit international association which collects sales data covering 16 Member States. Where available CEESA data was used as the primary source. However, the CEESA data does not allow detailed analyses in narrowly defined product markets such as those adopted in the Commission's previous decision[39]. In order to estimate

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38 See e.g. case COMP/M.4691 – *Schering-Plough/Organon BioSciences*.

39 Cases COMP/M.2922-*Pfizer/Pharmacia*, decision of 27 February 2003, para 114; COMP/M.4691-*Schering-Plough/Organon*, decision of 11 October 2007, para. 51. CEESA data is limited in geographic scope (16 Member States), it captures only the suppliers that report to the organisation,

competitors' sales in these markets, Pfizer developed a series of calculations based on an algorithm based on Pfizer's sales. Using national third party or trade association data or their own best estimates, the Parties have adjusted the CEESA data to account for those companies that do not report sales to CEESA. According to the Parties, it is difficult to adequately reflect the presence of generic competitors.

130. To address countries not covered by CEESA data, the Parties relied on national trade association data, industry reports as well as their own estimates. Although CEESA data was not generally available, the Parties adopted the same general methodology for all countries.

131. The market investigation has largely confirmed the accuracy of the market share estimates provided by the Parties.

4.3.4. Research and development in animal health markets

132. Research and development (R&D) in the field of animal health uses substances or antigens discovered by scientists specialised in animal health or uses human health research or crop research and tests the suitability for combating animal diseases. Animal health research programmes include three main phases: (i.) the discovery phase, (ii.) the exploratory development phase and (iii.) the full development phase. It should be noted that in animal health there is no equivalent to pre-clinical trials in human health because in animal health projects are put through a series of clinical trials earlier in the procedure.

133. The discovery phase begins when a molecule or antigen is identified as having potential therapeutic or prophylactic utility. A testing period lasting approximately 18 months follows. The aim of the discovery phase is to obtain proof of concept justifying going into the next phase.

134. The exploratory development phase is aimed at showing proof of efficacy and safety as well as determining key elements of the end product (e.g. formulation, target species, dosage etc.). This phase takes on average approximately 18 months. Some 70% of projects are discarded in this phase.

135. The full development phase takes four to five years, including regulatory review and approval. The testing and development taking place in this phase are largely determined by the regulators involved. Moreover, testing aims at proving shelf-life stability of the product. Animal health products must have a shelf life of one year as a minimum. The rationale for dose selection and the efficacy of the selected dose are tested and safe withdrawal periods are determined (for livestock). An environmental impact assessment is also mandatory. The data from these tests are summarised and presented to the relevant authorities for regulatory review and approval. No animal health products may be sold in the EEA without prior marketing authorisation.

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and does not provide competitor sales figures, but their respective rankings only. CEESA classifies animal health products by species, route of administration, active ingredients, and indication.

136. There are currently three alternative procedures to obtain marketing authorisation for animal health products: (i.) European marketing authorisation from the European Commission after assessment by the European Medicines Agency ("EMEA"); (ii.) national marketing authorisation and (iii.) the decentralised authorisation procedure which following review by a reference Member State allows the submission of a single dossier in several Member States.

4.3.5. Barriers to entry in animal health markets

Introduction

137. 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.

Entry into a new product market

138. The most important barriers to entry into pharmaceutical markets are the development costs and intellectual property rights associated with new products. Typically, animal health manufacturers spend around 5 to 10% of turnover on R&D.

139. The development of pharmaceutical products is characterised by high costs and length of the development. It can take from 3 up to 10 years, and an investment between 2.5-10 million Euros might be needed to introduce a new and innovative product in the market, taking into account the time needed during the R&D, patent issues, commercial barriers, etc. The time may be very different from project to project depending on the kind of product, technical difficulties, target species, need or not need to acquire new equipment or increase production capacities, etc. Again, depending on the pharmaceutical product, the same production line may be used for more than one medicinal product. Special difficulties are not expected with regards to the access to raw materials.

140. The key difference between pharmaceutical products and vaccines is that the molecule of a pharmaceutical may be patented, which increases the barriers to entry for competitors during the patent validity period. However, once the patents expire the markets are open for generic copies (see below).

141. Once the formulation of a pharmaceutical is developed, its production can be outsourced to a third party toll-manufacturer and the company does not necessarily have to invest in additional production capacities even though some products require specific equipment for the manufacturing technology used. The costs are very high and can result in entry barriers for small and medium-sized enterprises ("SMEs") in terms of costs of access to new molecules, low number of R&D employees, and costs of regulatory authorisations. The size of the market

does also play a certain role for the expected pay-back of the investment. Generic development is usually much shorter and estimated at 2 to 4 years.

142. R&D of a new vaccine product is a even more lengthy and costly process. Besides the costs for regulatory authorisation etc., the R&D costs are generally higher than for pharmaceutical products. 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 5- up to 20 years (or even more according to some respondents) and can vary considerably depending on such factors as animal species, indication, formulation, complexity of the vaccine, consumer or environment safety considerations and others. This also varies depending on the expertise of the company. Typically, animal health manufacturers spend up to 15% of turnover on R&D for vaccines.

143. R&D activities of vaccines are directed to both development of new products and regular updates, maintenance of the existing vaccines. The ability to develop new products and catch up with changes in serotype prevalence or technological advances depend on the expertise of the company. Antigenic shifts are more relevant for companion animal vaccines, whereas R&D for large animals is more concentrated towards newly discovered diseases.

144. The distinction can be made between the entry with a new product by an existing vaccine supplier and the entry by a new player. Existing multinational players may generally develop and enter with new vaccines with costs of few million Euros and within a few years, whereas a new entrant (or a smaller company) would generally face not only regulatory and high product development barriers, but also difficulties in access to manufacturing sites.

145. As regards intellectual property rights (IPR), a distinction also needs to be made between vaccines and pharmaceuticals. The antigens contained in vaccines are generally isolated from the pathogens and are not patented[40]. What may be patented is the particular technology used to convey the antigen (e.g. vector) or that needed to combine different antigens in a multivalent vaccine or the manufacturing process. Although companies are free to look for alternative production means, access to advanced production technology or updated vaccine strains is not easily available to all the competitors.

146. In vaccine development the role of production equipment and production know-how is significantly more important than compared to pharmaceuticals. For the manufacture of vaccines, specialist equipment (e.g. fermenters) is necessary as are highly controlled manufacturing facilities which must provide sterile environment conditions for biological fermentation. Manufacturing of vaccines in the EEA has to be carried out in cGMP approved sites.

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40 It should be noted however, that the situation might change in the future, given that the antigens in some new vaccines are no longer natural organisms (e.g. genetically modified organisms, naked DNAs, peptides).

147. There are much less arrangements for the third party contract manufacturers for the production of vaccines than in the field of pharmaceuticals. Generally, biological production plants run at 80-90% capacity utilisation rate.

Geographic entry

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

149. Some respondents to the market investigation estimated that it would take 1 to 6 years and cost EUR 100,000 to 300,000 to obtain the marketing authorisation and enter a new market with an existing product. This will mainly depend on the type of product, the distribution network in the relevant market and – for pharmaceuticals – in addition the situation of the pioneer product in that market and the presence or absence of generic products. In the case of older marketing authorisations, additional studies or explanations to update the original authorisation may be requested by the authorities.

150. 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.

151. 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.

152. 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.

153. There are indications that successful geographic entry lies in the chance of introducing a line of vaccines, at least for one animal species, as setting up a distribution network, sales and marketing activities depend on the portfolio range. Access to independent distributors is also much easier for companies with a portfolio which is sufficient to fund dedicated support from the distribution partner.

154. Given that marketing efforts are directed to veterinarians, the existence of well established companies is a de facto barrier to entry for less experienced companies. A number of respondents have indicated that due to the existence of discount/rebate schemes for the customers, the switching of customers to

alternative supplier might be economically inefficient, except where the same supplier cannot offer a particular product.

4.3.6. Generic competition in animal health markets

155. 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 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), the formulation (the same pharmaceutical form), and 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 may lead to lower prices for both the original brand name product and the generic forms. However, on a weighted average basis, it can take some time for generic entry to occur once originator medicines lost exclusivity, even though the time-to-market is shorter compared to the entry of products by innovators. According to the replies of the respondents in the market test, the time frame for the entry of new generics products is mainly determined by formulation development, setting up and validation of the manufacturing site, bioequivalence and target animal safety work and registration. The entire process would take about 3 to 5 years. Costs could roughly be estimated between 0.75 and 1.7 million € dependent on whether the generic company purchases a dossier or develops its own in-house through trial work. Entry barriers would be registration route, competition (i.e. number of generics and time to market), size of market, additional studies required in some markets.

156. There are no generic vaccines, as understood in the field of pharmaceuticals, as all the vaccine products, either new or old, are subject to the same regulatory requirements and because vaccines are biological products which do not exhibit bioequivalence and are manufactured by isolating the pathogen that causes infection in the animals.

4.3.7. Vaccines

Markets with horizontal overlaps

Multivalent feline vaccination programmes in Belgium, Denmark, Greece and Ireland

157. Both Pfizer and Wyeth sell vaccines for the prophylactic prevention of a range of diseases in cats. Veterinarian practice and local needs have led to a number of vaccines for cats being regularly administered together as feline vaccination programmes. For cats, the vaccines that are affected by this practice immunise the animal against the combination of the feline herpes virus (rhinotracheitis), feline calcivirus, feline enteritis (panleucopenia) virus (main respiratory feline indications), and *C.felis* and feline leukaemia (other feline pathogens that may be important to administer once exposure is predicted).

158. In view of the Parties, monovalent vaccines that do not cover main feline respiratory indications, such as monovalent feline leukaemia, monovalent feline infectious peritonitis (FIP) and monovalent feline immunodeficiency virus (FIV),[41] or vaccines that cover a less prevailing respiratory condition caused by *bordatella bronchiseptica*, would not normally form part of the feline vaccination programmes.

159. Applying the principles for market definition set out above (species, target disease, monovalent/multivalent), and in line with previous Commission decisions,[42] the Parties submit that multivalent feline vaccination programmes constitute a distinct product market. In view of the Parties, the distinction between live and inactivated vaccines is not appropriate for the purposes of the competitive assessment.[43] Moreover, there are multivalent feline vaccines that contain both live and inactivated components[44].

160. The market investigation has confirmed the product market definition retained by the Parties. The vast majority of the respondent has indicated that vaccination programmes of the main suppliers are substitutable, although there might be slight differences in coverage of the viruses that are not main feline respiratory pathogens (e.g. *C. Felis* or feline leukaemia), duration of immunity or side effects.

161. The relevant product market for the purposes of assessing the impact of the proposed concentration is therefore the market for multivalent feline vaccination programmes.

162. Pfizer sells its multivalent feline vaccines under the brand name *Felocell.* Wyeth's products are marketed under the brands *Fevaxyn* and *Felovax* in Belgium, Denmark, Greece and Ireland.

163. Based on the data provided by the Parties, the affected markets where the Parties' combined position would amount to Group 1 markets at national level are Belgium, Denmark, Greece and Ireland.

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41 Monovalent feline immunodeficiency virus vaccines currently are not marketed in the EEA.

42 COMP/M.4691-*Schering-Plough/Organon*, decision of 11 October 2007.

43 Wyeth has minor sales of its older live feline vaccines (*Katavac*, *Felopack* and *Dohycat*) in France, Spain and the United Kingdom, where the Commission has not identified serious doubts.

44 e.g. Merial's *Purevax* range.

Competitors	BE	DK	GR	IE
Pfizer	[10-20]%	[0-5]%	[10-20]%	[10-20]%
Wyeth	[20-30]%	[40-50]%	[40-50]%	[20-30]%
Combined	**[30-40]%**	**[40-50]%**	**[50-60]%**	**[30-40]%**
SP/Intervet	[10-20]%	[0-5]%	[10-20]%	[40-50]%
Merial	[30-40]%	[50-60]%	[20-30]%	[20-30]%
Virbac	[10-20]%	-	-	-

164. In Greece, the overlap of the Parties activities is significant ([10-20]%) and results in the new dominant entity with a market share of [50-60]%, facing only two other competitors with significantly smaller market shares ([20-30]% for Merial, [10-20]% for SP/Intervet). In 2008 the market in Greece has shown growth, due to new product launches by Merial, which gained a market share of 5 to 10%. For the future, the market test identified only one company with a comparable feline vaccination programme product portfolio, which could enter into this market, that is Virbac. According to the results of the market investigation, further entries are not expected in the coming years. The market shares, therefore, are expected to remain stable. Despite the new entries in 2008 the barriers to entry remain high in this mature market. Still, the market is highly concentrated, with well established competitors, and without major expansion or decline expected. In addition, Wyeth's relatively strong position in Greece is explained by its choice of distributor, which is highly active and well positioned. As discussed above, the market test has indicated that access to distributors, in particular in small markets, like Greece with a market size of below […] Euro, might constitute a significant entry barrier for companies not yet established in a particular market, at least for the same species.

165. In Denmark, the overlap of the Parties' activities is small ([0-5]%), but results in the new entity with a market share of [40-50]%, with Merial ([50-60]%) as the only appreciable competitor, followed by *de minimis* presence of SP/Intervet with less than [0-5]% market share. Although Merial would retain the leading market share in Denmark, the new entity would approach this position, with only 10% difference and facing only negligible presence of SP/Intervet ([0-5]%). Given that there was not much change in the last years, the market shares are expected to remain stable. Moreover, there are particularly high barriers to entry in this market, which is highly concentrated, with well established competitors, mature, stable and without major expansion or decline expected. The market test identified only one company with a comparable feline vaccination programme product portfolio, which could enter into this market, that is Virbac.

166. In Belgium, the overlap of the Parties' activities is significant ([10-20]%) and results in a new entity as a leading player with a market share of [30-40]%, facing only three other competitors with smaller market shares ([30-40]% for Merial, [10-20]% for SP/Intervet and [10-20]% for Virbac). Although there was an

impact on the market shares, this has been due to launch of new products.[45] Given that there was only a minor change of market shares in 2006-2008, the market shares are expected to remain quite stable. Despite the market share below 40% in Belgium, there are particularly high barriers to entry in this market, which is highly concentrated, with well established competitors, mature, stable and without major expansion or decline expected. The market test identified only one company with a comparable feline vaccination programme product portfolio, which could enter into this market, that is Virbac. In addition, the Parties state that in Belgium there is a move towards more consistent vaccination against feline leukaemia. Therefore, it may be concluded that the merged entity gains a competitive advantage due to Wyeth's more innovative products.

167. In Ireland, the proposed transaction would remove one competitor out of four and would result in the new entity with a market share of [30-40]%, facing only two competitors ([40-50]% SP/Intervet and [20-30]% Merial). Although SP/Intervet would retain the leading market share in Ireland, the new entity would approach this position, with only 5% difference and facing only one further active player, Merial. Given that there was not much change in 2006-2008, the market shares are expected to remain stable. Moreover, there are particularly high barriers to entry in this market, which is highly concentrated, with well established competitors, mature, stable and without major expansion or decline expected. The market test identified only one company with a comparable feline vaccination programme product portfolio, which could enter into this market, that is Virbac. The market test indicated that the entry cannot be anticipated within the next two years. As discussed above, market test has indicated that access to distributors in small markets, like Ireland with a market size below […] Euro, might constitute a significant entry barrier for companies not yet established in a particular market, at least for the same species.

168. Moreover, the new entity would have a broader range of feline vaccines for regular vaccinations as a result of Wyeth's more innovative feline products. The Parties submit that the range of Wyeth is more closely comparable to the range of Merial than Pfizer's range, in particular due to the fact that products of Pfizer are perceived as less innovative, as Pfizer's multivalent products do not cover feline leukaemia and *C.Felis* components (the latter except for Belgium).

169. On the basis of the foregoing, 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 feline vaccination programmes in Belgium, Denmark, Greece and Ireland.

Monovalent cattle *pasteurella* vaccines

170. Both Pfizer and Wyeth have products for the prevention of pasteurellosis in cattle. Pasteurellosis is a respiratory disease of cattle caused by a mixture of viruses and bacteria. The existing vaccines against pasteurellosis in cattle are normally against two types of bacteria (*Manheimia haemolytica* and *Pasteurella multocida*)

45 E.g. SP/Intervet's *Nobivac Forcat/Ducat* products in Belgium.

found in the upper respiratory track of cattle and that may lead to a disease when animal's normal defences are compromised.

171. Consistent with general market definition criteria set out above, the Parties submit that monovalent cattle *pasteurella* vaccines would constitute a separate product market. The distinction between live or inactivated vaccines is not relevant for the purposes of the competitive assessment, given that vaccines of both Parties are only inactivated and no additional affected markets would be created if the distinction between live and inactivated would be applied.

172. Although there are some differences between the Parties' products, in particular as regards animals' vaccination age, the market test has not indicated that a deviation from the product market definition advocated by the Parties would be called for.

173. Pfizer sells its monovalent cattle *pasteurella* vaccines under the brand name *Rispoval Pasteurella.* Wyeth's products are marketed under the brand *Presponse*. The two vaccines are monovalent, inactivated, containing the antigens against *Manheimia haemolytica* and are used to vaccinate against the same condition in cattle.

174. Based on the data provided by the Parties, the affected markets where the Parties' combined position would amount to Group 1 markets at national level are Italy and Spain.

Competitors	Italy	Spain
Pfizer	[40-50]%	[50-60]%
Wyeth	[10-20]%	[20-30]%
Combined	**[60-70]%**	**[70-80]%**
SP/Intervet	[5-10]%	-
Merial	[30-40]%	[5-10]%
Hipra	-	[10-20]%

175. In Italy, the proposed transaction would lead to significant overlaps and would result in a new dominant entity with market share of [60-70]%, facing only two competitors with significantly lower market shares. The market investigation has indicated that *Rispoval Pasteurella* and *Presponse* are close products covering the same antigen and treating the same indication. Given the different animal vaccination ages of the Parties' products,[46] the merged entity would gain a competitive advantage to offer a wider range of cattle *pasteurella* vaccines. Moreover, it has to be noted that the product of SP/Intervet sold in Italy offers protection against both *Manheimia haemolytica* and *Pasteurella multocida* pathogens and therefore is not a monovalent product to protect against pasteurellosis.

46 *Rispoval P* is addressed to feedlot cattle of 5-8 months of age, whereas *Presponse* is addressed to very young cattle of less than one month.

176. In Spain, the proposed transaction would lead to significant overlaps and would result in a new dominant entity with market share of [70-80]% in Spain, facing only two competitors with significantly lower market shares, in highly concentrated markets with very high barriers to entry. The market investigation has indicated that *Rispoval Pasteurella* and *Presponse* are close products covering the same antigen and treating the same indication. Given the different animal vaccination ages of the Parties' products,[47] the merged entity would gain a competitive advantage to offer a wider range of cattle *pasteurella* vaccines.

177. There are particularly high barriers to entry on the markets for cattle vaccines as they are highly concentrated, with a few well established competitors, and without major expansion or decline expected. In Italy the Parties' market shares have remained stable in the last three years and are expected to remain stable. In Spain, Pfizer's shares did not change materially, whereas as Wyeth's share has dropped due to entry of Hipra in 2007, which has achieved [10-20]% market share. The market investigation has not confirmed that Hipra could exert a substantial competitive pressure on the merged entity.

178. On the basis of the foregoing, 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 cattle *pasteurella* vaccines in Spain and Italy.

Multivalent cattle respiratory vaccines

179. Both Pfizer and Wyeth have products for the prevention of bovine respiratory disease. The term cattle respiratory disease refers to a number of symptoms concerning the animal's respiratory system caused by a complex of viruses and bacteria. Vaccination against bovine respiratory disease is based on the use of multivalent vaccines designed to inoculate against a range of pathogens associated with the condition; the most important are: *Bovine Respiratory Syncytial Virus*, *Parainfluenza 3*, *Bovine Viral Diarrhoea*[48] and *Infectious Bovine Rhinotracheitis*, although not all respiratory vaccines contain antigens for all these pathogens.

180. Applying the principles for market definition set out above (species, target disease, monovalent/multivalent), the Parties submit that multivalent cattle respiratory vaccines constitute a distinct product market. In view of the Parties, the distinction between live and inactivated is not appropriate for the purposes of the assessment, as Wyeth sells only inactivated vaccines, whereas as Pfizer's vaccines are live or a combination of live and inactivated.

181. The market investigation has not indicated that a deviation from the product market definition advocated by the Parties would be called for.

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47 Idem.

48 The Parties note that BVD, although not truly a respiratory pathogen, is commonly included in multivalent bovine respiratory vaccines.

182. Pfizer sells products under the brand names *Rispoval 3*, *Rispoval 4*, *Rispoval RS BVD*, *Rispoval RS*, *Rispoval Intranasal*, *CattleMaster 4*, *CattleMaster RIP* and *Imuresp RAP*. Wyeth sells products under the brand names *Triangle 3*, *Triangle 4*, *Triangle 4 PH-K*, *Triangle 4+L*, *Triangle 4+L/9* and *Pyramid MLV 4*.

183. In addition, Wyeth has a pipeline project in the full development phase aiming at […],[49] predicted for launch in […], although with only […]% chance of launch based in internal estimates.

184. The Parties indicate that all of their products are designed to vaccinate against the same disease, although the coverage of the antigens in the products of the Parties sometimes differs (see below). *Cattle Master 4* and *Triangle 4* are very close products from the end-user perspective, containing the same antigens against the same condition. The Parties submit that the products with narrower ranges can be useful for more targeted vaccination. Some products can also be positioned for use in particular types of cattle or particular life stages, these factors, however, tend to play secondary role to the effectiveness or perceived effectiveness.[50]

185. Based on the data provided by the Parties, the affected markets where the Parties' combined position would amount to Group 1 markets at national level are Italy, Portugal, and Spain.

Competitors	IT	PT	ES
Pfizer	[70-80]%	[30-40]%	[50-60]%
Wyeth	[0-5]%	[30-40]%	[20-30]%
Combined	**[70-80]%**	**[60-70]%**	**[70-80]%**
SP/Intervet	[20-30]%	[10-20]%	[0-5]%
Merial	[0-5]%	[0-5]%	[0-5]%
Hipra	-51	[10-20]%	[10-20]%
Syva	-	-	[0-5]%

49 The pipeline project […].

50 *Rispoval 4* and *Triangle 9* both position themselves mainly for use in veal calves, young animals and animals on their arrival at feedlot programmes, whereas *CattleMaster* can be used to address respiratory and reproductive issues for animals of any age and any physiological status. *Triangle 4-Ph-K* has a claim for diary cows with a zero day withdrawal period. *Pyramid MLV 4* addresses respiratory diseases in heavy animals.

51 Hipra has reported a minimal presence in Italy in reply to market investigation. Sales of Hipra are EUR […], which is more than half less than the sales reported by Merial. Hipra presence in Italy can be estimated to be [0-5]%.

186. The merger would lead to very high market shares of the new entity in Spain ([70-80]%), Italy ([70-80]%) and Portugal ([60-70]%) and the new entity would become by far the dominant player in highly concentrated markets with very high barriers to entry.

187. In view of the Parties Hipra is a recent entrant generating tough price competition and a strong competitor, in particular given the differences in usage of the Parties' products. The market investigation has not confirmed that Hipra could exert a substantial competitive pressure on the merged entity. Moreover, the new entity would be able to offer a much wider range of multivalent cattle respiratory vaccines in the affected countries.

188. In Portugal, the merged entity would eliminate its largest competitor and would result in a new entity with a combined market share of [60-70]%, facing only two competitors with significantly lower market shares, Hipra ([10-20]%) and SP/Intervet ([10-20]%), and minor presence of Merial ([0-5]%). In Portugal, both Parties offer products that cover all main antigens: Pfizer offers *Rispoval 4* and Wyeth - *Pyramid MLV 4*, *Triangle 4 Ph-K*, *Triangle 4+L, Triangle 4+L/9*. The latter three Wyeth's products additionally offer protection against *Mannheimia haemolytica* or *Leptospira* pathogens.

189. In Spain, the merged entity would eliminate its largest competitor and would result in a new entity with a very high combined market share of [70-80]%, facing only one competitor with a lower market share, Hipra ([10-20]%), and minor presence of SP/Intervet ([0-5]%), Syva ([0-5]%) and Merial ([0-5]%). In Spain, both Parties' products cover all main antigens: Pfizer sells *Cattle Master4, Rispoval RS*, *Rispoval Intranasal*, and *Imuresp RAP*, and Wyeth offers the whole range. Certain of Pfizer's products offer different combinations, whereas Wyeth's products offer protection against *Mannheimia haemolytica* or *Leptospira* pathogens.

190. In Italy, despite a small increment ([0-5]%), the merged entity would have a combined market share of [70-80]%, facing only one competitor with a lower market share: SP/Intervet ([20-30]%), and minor presence of Merial ([0-5]%). In Italy, both Parties offer products that cover all main antigens, these are *Cattle Master4* and *Triangle 4*. In addition, Pfizer offers *Rispoval RS*, *Rispoval Intranasal*, *Cattle Master RIP* and *Imuresp RAP* that offer different combinations of the main antigens.

191. There are particularly high entry barriers on the markets for cattle vaccines, as they are highly concentrated, with a few well established competitors, and without major expansion or decline expected. The size of the market and market shares of the Parties did not alter significantly in the last three years in Italy, Spain and Portugal.

192. On the basis of the foregoing, 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 cattle respiratory disease vaccines in Portugal, Spain and Italy. The existence or not of serious doubts as regards the

effect of Wyeth's pipeline product can be left open as the serious doubts can not be excluded even in the absence of the pipeline product. Moreover, the remedy submitted by Pfizer includes the rights to pipeline products relating to cattle vaccines produced and sold by Wyeth in the EEA.

Monovalent swine mycoplasma hyopneumoniae vaccines in Austria, Belgium, Czech Republic, Denmark, France, Germany, Greece, Italy, Lithuania, the Netherlands, Poland, Portugal, Slovakia, Spain and the United Kingdom

193. Both Pfizer and Wyeth have products for the prevention of swine against the respiratory infection caused by *Mycoplasma hyopneumoniae*, the bacteria responsible for porcine enzootic pneumonia, which is one of the most significant respiratory pathogens in swine.

194. In line with the principles of market definition set out above and in line with the previous Commission's decisions[52], the Parties have submitted that monovalent swine *mycoplasma hyopneumoniae* vaccines constitute a separate product market. The distinction between live and inactivated is not relevant for the purposes of the competitive assessment, given the fact that the products exist in an inactivated form only.

195. The market investigation has not indicated that a deviation from the product market definition advocated by the Parties would be called for.

196. Pfizer markets monovalent swine *mycoplasma hyopneumoniae* vaccines under the brands *Stellamune/ Respisure* and *Stelamune One /Respisure One,* whereas Wyeth sells the products branded *Suvaxyn MH* and *Suvaxyn MH-One*. Both Parties offer products that are administered by injection, either as one shot or as a two shot vaccine.

197. In addition Pfizer has a pipeline project for […]. The project is predicted for launch in late […] with […]% chance of launch.

198. In view of the Parties, the Parties compete more closely in relation to two shot vaccines, as in some countries Wyeth does not offer its one shot vaccine (i.e. in Austria, Denmark, Greece, Italy, Latvia, Lithuania, Poland and Portugal)[53]. The two shot vaccines supplied by both Parties are close substitutes, because antigens and method of administration are virtually identical. The Parties also admit that Wyeth's sales derived from one shot vaccines are often small. Wyeth has entered with its new one shot products later compared to other competitors.

199. Market test indicates that not all of the competitors can offer the same vaccination regimes, i.e. one and two shot vaccines. Moreover, a number of respondents view

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52 COMP/M.4691-*Schering-Plough/Organon*, decision of 11 October 2007.

53 One shot products, in view of the Parties, are preferred due to ease of handling, less stress to an animal, cost savings and flexibility to administer other vaccines.

both, one shot and two shot, vaccines as closely competing due to other factors, such as their efficacy, pathogen coverage, ease of administration, and the duration of immunity.

200. Based on the data provided by the Parties, there are 15 affected markets where the Parties' combined position would amount to Group 1 markets at a national level, i.e. Austria, Belgium, Czech Republic, Denmark, France, Germany, Greece, Italy, Lithuania, the Netherlands, Poland, Portugal, Slovakia, Spain and the United Kingdom.

Competitors	AT	BE	CZ	DK	FR	DE	GR	IT
Pfizer	[50-60]%	[40-50]%	[70-80]%	[30-40]%	[40-50]%	[50-60]%	[60-70]%	[30-40]%
Wyeth	[5-10]%	[10-20]%	[0-5]%	[10-20]%	[5-10]%	[5-10]%	[10-20]%	[20-30]%
Combined	**[60-70]%**	**[60-70]%**	**[70-80]%**	**[40-50]%**	**[50-60]%**	**[60-70]%**	**[70-80]%**	**[50-60]%**
SP/Intervet	[10-20]%	[10-20]%	[0-5]%	[30-40]%	[10-20]%	[10-20]%	[10-20]%	[10-20]%
Merial	[10-20]%	[0-5]%	[0-5]%	[0-5]%	-	[0-5]%	[0-5]%	[5-10]%
Boehringer	[5-10]%	[20-30]%	[10-20]%	[10-20]%	[30-40]%	[10-20]%	[5-10]%	[20-30]%
Hipra[54]	-	-	[0-5]%	[0-5]%	-	-	-	[0-5]%

Competitors	LT	NL	PL	PT	SK	ES	UK
Pfizer	[30-40]%	[50-60]%	[30-40]%	[50-60]%	[50-60]%	[50-60]%	[50-60]%
Wyeth	[0-5]%	[5-10]%	[0-5]%	[5-10]%	[5-10]%	[5-10]%	[0-5]%
Combined	**[30-40]%**	**[60-70]%**	**[30-40]%**	**[50-60]%**	**[60-70]%**	**[60-70]%**	**[60-70]%**
SP/Intervet	[50-60]%	[5-10]%	[30-40]%	[20-30]%	[0-5]%	[20-30]%	[20-30]%
Merial	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	-	-
Boehringer	[0-5]%	[20-30]%	[20-30]%	[10-20]%	[10-20]%	[10-20]%	[10-20]%
Hipra	-	[0-5]%	[0-5]%	[0-5]%	[10-20]%	[0-5]%	-

201. In Austria, Belgium, Czech Republic, Germany, Greece, the Netherlands, Slovakia, Spain and the United Kingdom the merged entity would have combined market shares above 60% or even close to [70-80]% in Greece and Czech Republic, including the overlaps of [10-20]% in Belgium and [10-20]% in Greece, and facing only two or three competitors with significantly lower market shares.

54 Market test indicates that products of Hipra […].

202. The shares of the closest competitors are two, three or even four times lower: [10-20]% (SP/Intervet, Austria), [20-30]% (Boehringer, Belgium), [10-20]% (Boehringer, Czech Republic), [10-20]% (SP/Intervet, Germany), [10-20]% (SP/Intervet, Greece), [20-30]% (Boehringer, the Netherlands), [10-20]% (Boehringer, Slovakia), [20-30]% (SP/Intervet, Spain), [20-30]% (SP/Intervet, the UK). The presence of other competitors is very small and often *de minimis*: [0-5]% for Merial (except for [10-20]% in Austria) and [0-5]% for Hipra.

203. In Italy and Portugal, the merged entity would have combined market shares above 50%, including an overlap of [20-30]% in Italy, and facing a few competitors with significantly lower market shares. The shares of the closest competitors are nearly two times lower in Italy and Portugal: [20-30]% (Boehringer, Italy), [20-30]% (SP/Intervet, Portugal); followed by SP/Intervet ([10-20]% in Italy) and Boehringer ([10-20]% in Portugal). The presence of other competitors is very smaller and often *de minimis*: Merial ([5-10]% in Italy, [0-5]% in Portugal) and Hipra ([0-5]% in Portugal, [0-5]% in Italy).

204. In France, the merged entity would have combined market share of [50-60]%, facing only two competitors with much lower market shares: Boehringer with [30-40]% and SP/Intervet with [10-20]%.

205. In Denmark, the merged entity would have combined market shares of [40-50]%, including an overlap of [10-20]%, and facing only two competitors with much lower market shares: [30-40]% for SP/Intervet, followed by Boehringer with [10-20]%, and *de minimis* presence of Hipra ([0-5]%). Despite the presence of other competitors, albeit with lower market positions, the segment is subject to very high entry barriers specific to the vaccines; it is highly concentrated and dominated by a few well established multinational players (see below). The market is mature and has been stable in the last three years, there is no significant growth or decline expected.

206. In Poland, the merged entity would have combined market shares of [30-40]%, facing only three competitors with much lower market shares: [30-40]% for SP/Intervet, followed by Boehringer with [20-30]%. The presence of Merial is very small [0-5]%, whereas Hipra's market share is *de minimis* ([0-5]%). Despite lower combined market share in Poland and presence of other two competitors, albeit with lower market positions, the segment is subject to very high entry barriers specific to the vaccines; it is highly concentrated and dominated by a few well established multinational players (see below). The market is mature and has been stable in the last three years, there is no significant growth or decline expected.

207. In Lithuania, the merged entity would have a combined market share of [30-40]%, facing only one strong competitor, SP/Intervet ([50-60]%), whereas the presence of Merial ([0-5]%) and Boehringer ([0-5]%) is minor. Despite lower combined market share compared to other markets and a higher share of SP/Intervet, the segment is subject to very high entry barriers specific to the vaccines; it is highly concentrated and dominated by a few well established multinational players (see below). The market is mature and has been stable in the last three years; there is no significant growth or decline expected.

208. All theses markets are highly concentrated and with significant entry barriers, in particular for smaller competitors or new entrants, as described in a general section above.

209. In addition, the market test indicates that the registration of new swine MH vaccine might be particularly difficult because of the regulatory requirements to carry out field trials in order to demonstrate statistically significant differences in clinical conditions between vaccinated and non-vaccinated animals, and the lack of available/suitable farms for such trials. Swine industry which is highly specialized and concentrated, therefore marketing is of high importance. This makes working though a third party distributor very difficult, in particular for smaller companies or companies with ranges insufficient to fund dedicated support from the distribution partner.

210. The market test also indicates that an ability to offer swine *mycoplasma hyopneumoniae* vaccines conveys a broader competitive advantage in the supply of swine vaccines in general, as customer seeking to purchase swine vaccines would typically seek to purchase those from the company providing swine MH vaccine. In should be noted in this regard, that both Parties have unique existing and/or pipeline products for […](see section on pipeline products below).

211. On the basis of the foregoing, 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 swine *mycoplasma hyopneumoniae* vaccines in Austria, Belgium, Czech Republic, Denmark, France, Germany, Greece, Italy, Lithuania, the Netherlands, Poland, Portugal, Slovakia, Spain and the United Kingdom. The existence or not of serious doubts as regards the effect of Pfizer's pipeline product can be left open as the serious doubts can not be excluded even in the absence of the pipeline product. Moreover, the remedy submitted by Pfizer includes the rights to a pipeline product for Pfizer's respective vaccines produced and sold in the EEA.

Monovalent influenza vaccines for horses in Denmark, Germany, Slovakia, Sweden, and the United Kingdom

212. 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 increase the excretion of the virus after infection.

213. Applying the principles for market definition set out above (species, target disease and monovalent/multivalent), and in line with previous Commission's decisions[55], the Parties submit that monovalent influenza vaccines for horses constitute a distinct product market. In view of the Parties, the distinction between live and inactivated vaccines is not relevant for the purposes of the

55 COMP/M.4691-*Schering-Plough/Organon*, decision of 11 October 2007.

competitive assessment, given that vaccines of both Parties are inactivated only and no additional affected market would occur under alternative market definition.

214. The market investigation has not indicated that a deviation from the product market definition advocated by the Parties would be called for.

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

216. Pfizer sells its monovalent influenza vaccines for horses under the brand *Equip F*. Wyeth's products are marketed under the brands *Duvaxyn IE Plus*, *Duvaxyn IE PlusQF, Duvaxyn IE Vet Plus, Duvaxyn IE Plus Vet QF 5+10*.

217. Based on the data provided by the Parties, there are five affected markets where the Parties' combined position would amount to Group 1 markets at a national level, i.e. in Denmark, Germany, Slovakia, Sweden, and the United Kingdom.

Competitors	Denmark	Germany	Slovakia	Sweden	the United Kingdom
Pfizer	[40-50]%	[5-10]%	[0-5]%	[40-50]%	[20-30]%
Wyeth	[10-20]%	[30-40]%	[80-90]%	[5-10]%	[30-40]%
Combined	**[60-70]%**	**[40-50]%**	**[80-90]%**	**[50-60]%**	**[50-60]%**
SP/Intervet	[10-20]%	[30-40]%	[5-10]%	[30-40]%	[30-40]%
Merial	[20-30]%	[10-20]%	[0-5]%	[5-10]%	[10-20]%
Bioveta	-	-	[0-5]%	-	-

218. In Slovakia, the merged entity would have a combined market share [80-90]%, with minor presence of other competitors. The new entity would therefore enjoy a quasi-monopoly position in Slovakia.

219. In Denmark, the merged entity would have a leading position with combined market share above 60% by eliminating its second largest competitor, Wyeth ([10-20]%). The presence of two remaining competitors is almost three or even more times lower.

220. In Sweden and the United Kingdom, the merged entity would have a leading combined position with market shares above 50%, with only two other competitors present, and a significant overlap in the United Kingdom ([20-30]%). The shares of the closest competitor, SP/Intervet, are bellow 40%, whereas the presence of Merial is significantly lower.

221. In Germany, the merged entity would also gain a leading position with a combined market share of [40-50]%, followed by its competitor SP/Intervet with [30-40]% and much smaller player Merial with [10-20]%.

222. All the markets for equine vaccines are highly concentrated and with significant entry barriers, in particular for smaller competitors or new entrants, as described more in a general section above.

223. On the basis of the foregoing, the Commission takes the view that the proposed concentration raises serious doubts as to its compatibility with the common market as regards the markets monovalent influenza vaccines for horses in Denmark, Germany, Slovakia, Sweden, and the United Kingdom.

Monovalent tetanus vaccines for horses

224. 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.

225. Applying the principles for market definition set out above (species, target disease and monovalent/multivalent), and in line with previous Commission decisions[56], the Parties submit that monovalent tetanus vaccines for horses constitute a distinct product market. In view of the Parties, the distinction between live and inactivated vaccines is not relevant for the purposes of the competitive assessment, given that vaccines of both Parties are inactivated only and no additional affected market would occur under alternative market definition.

226. The market investigation has not indicated that a deviation from the product market definition advocated by the Parties would be called for.

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

228. Pfizer sells its monovalent tetanus vaccines for horses under the brand *Equip T*. Wyeth's products are marketed under the brands *Duvaxyn T*.

56 COMP/M.4691-*Schering-Plough/Organon*, decision of 11 October 2007.

229. Based on the data provided by the Parties, there is one affected market where the Parties' combined position would amount to a Group 1 market at a national level, i.e. the United Kingdom.

Competitors	the United Kingdom
Pfizer	[10-20]%
Wyeth	[20-30]%
Combined	**[30-40]%**
SP/Intervet	[60-70]%

230. In the United Kingdom, the merged entity would have a combined market share of [30-40]% by eliminating one of its two competitors, and would result in a duopoly with SP/Intervet.

231. All the markets for equine vaccines are highly concentrated and with significant entry barriers, in particular for smaller competitors or new entrants, as described more in a general section above.

232. On the basis of the foregoing, the Commission takes the view that the proposed concentration raises serious doubts as to its compatibility with the common market as regards the markets monovalent tetanus vaccines for horses in the United Kingdom.

Multivalent influenza/tetanus vaccines for horses

233. 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*.

234. Applying the principles for market definition set out above (species, target disease and monovalent/multivalent), and in line with previous Commission decisions[57], the Parties submit that multivalent influenza/tetanus vaccines for horses constitute a distinct product market. In view of the Parties, the distinction between live and inactivated vaccines is not relevant for the purposes of the competitive assessment, given that vaccines of both Parties are inactivated only and no additional affected market would occur under alternative market definition.

235. The market investigation has not indicated that a deviation from the product market definition advocated by the Parties would be called for.

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57 COMP/M.4691-*Schering-Plough/Organon*, decision of 11 October 2007.

236. 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.

237. Pfizer sells its multivalent influenza/tetanus vaccines for horses under the brand *Equip FT*. Wyeth's products are marketed under the brands *Duvaxyn IE-T Plus*.

238. In addition, Wyeth has a pipeline project for […], aimed at […].

239. Based on the data provided by the Parties, there are seven affected markets where the Parties' combined position would amount to Group 1 markets at a national level, i.e. Denmark, Finland, Germany, Ireland, Italy, Sweden and the United Kingdom.

Competitors	Denmark	Finland	Germany	Ireland	Italy	Sweden	the United Kingdom
Pfizer	[30-40]%	[40-50]%	[10-20]%	[10-20]%	[10-20]%	[70-80]%	[10-20]%
Wyeth	[5-10]%	[0-5]%	[30-40]%	[20-30]%	[40-50]%	[0-5]%	[30-40]%
Combined	**[40-50]%**	**[50-60]%**	**[40-50]%**	**[30-40]%**	**[60-70]%**	**[70-80]%**	**[50-60]%**
SP/Intervet	[30-40]%	[40-50]%	[40-50]%	[40-50]%	[20-30]%	[20-30]%	[30-40]%
Merial	[20-30]%	[0-5]%	[10-20]%	[10-20]%	[10-20]%	[0-5]%	[10-20]%

240. In Italy and Sweden, the merged entity would have market shares above 60% and even [70-80]% in Sweden. The presence of the closest competitor, SP/Intervet, is nearly three times lower ([20-30]% in Italy; [20-30]% in Sweden), followed by Merial ([10-20]% Italy and [0-5]% in Sweden).

241. In Finland and the United Kingdom, the merged entity would have market shares above 50%, followed by SP/Intervet ([40-50]% in Finland, and [30-40]% in the UK) and much lower presence of Merial ([0-5]% in Finland, [10-20]% in the UK).

242. In Denmark and Germany, the merged entity would have market shares above 40%, including an overlap of [10-20]% in Germany, and facing only two competitor with lower market shares: SP/Intervet ([30-40]% in Denmark, [40-50]% in Germany) and Merial ([20-30]% in Denmark, [10-20]% in Germany). Despite lower combined market share of the Parties in these segments and similar, albeit lower position of closest competitor SP/Intervet, only three multinational players would remain active in these markets with very high entry barriers. The shares of the Parties in these markets did not change significantly in the last three years and are expected to remain stable.

243. In Ireland, the merged entity would have a market share of [30-40]%, facing only two competitors SP/Intervet ([40-50]%) and Merial ([10-20]%). Despite the leading market share of SP/Intervet in this market, only three multinational players would remain active in this market with very high entry barriers. The

shares of the Parties in these markets did not change significantly in the last three years and are not expected to alter significantly.

244. All the markets for equine vaccines are highly concentrated and with significant entry barriers, in particular for smaller competitors or new entrants, as described more in a general section above.

245. On the basis of the foregoing, the Commission takes the view that the proposed concentration raises serious doubts as to its compatibility with the common market as regards the markets multivalent influenza and tetanus vaccines for horses in Denmark, Finland, Germany, and the United Kingdom.

Pipeline markets

[..] vaccine in Austria, Belgium, Czech Republic, Germany, Greece, Ireland, the Netherlands, Portugal, Slovakia, Spain and the United Kingdom.

246. […].

247. In line with the principles of market definition set out above, the Parties have submitted that […] vaccines constitute a separate product market.

248. The market test did not question the market definition proposed by the Parties. The respondents have indicated that […] vaccines are not substitutable with […] from the consumer perspective, given the technical limitations of usage, possibly dosage and price differences.

249. Although the merger does not result in any horizontal overlaps in these countries, the fact that Pfizer has a […] vaccine in the pipeline must be considered.

250. Wyeth has launched its […] vaccine branded […] for the prevention of […] in […]. Wyeth is […]. Therefore Wyeth […]. Wyeth's […] product covers […], is administered by […] in […] and has the duration of immunity of […]. The product is patent protected until […].

251. Pfizer has plans to enter the EEA markets with its new […] vaccine that is expected to be launched in […] (with […]% chance of launch). The product will cover […], would be administered by […] and would have a duration of immunity of […].

252. Although Pfizer's project is expected to include […], the products of the Parties cover […]. Accordingly, the products of the Parties would be viewed by the end-users as close substitutes depending on […]. Moreover, the combined Parties' product offering would broaden their range of vaccines for the prevention of […] caused indications […].

253. On the basis of the foregoing, 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 […] vaccines in Austria, Belgium, Czech

Republic, Germany, Greece, Ireland, the Netherlands, Portugal, Slovakia, Spain and the United Kingdom.

[…] vaccines in the Czech Republic, France, Hungary, Italy, Portugal and Spain

254. […].

255. All […] vaccines currently marketed in the EEA are monovalent since they offer protection against one disease only, i.e. […]. Therefore, there are currently no multivalent vaccines that are substitutable with monovalent […] vaccines. […] vaccines sold in the EEA typically contain […]. Furthermore, the Parties are of the opinion that as regards […] vaccines, making a distinction for market definition purposes between live and inactivated vaccines is inappropriate. The Parties therefore submit that monovalent […] vaccines form a distinct product market with a possible sub-segmentation by […].

256. The market investigation has not indicated that a deviation from the product market definition advocated by the Parties would be called for. Although Wyeth's products are mono-species, the market investigation indicates that most products are multi-species (i.e. licensed for […]) so a market sub-segmentation depending on the species treated does not seem appropriate.

257. Of the two parties, only Wyeth currently markets […] vaccines in the EEA. Under the brand […] Wyeth produces monovalent […] vaccines for […] for […] respectively. In 2008 Wyeth obtained very high market shares in the Czech Republic ([90-100]%), France ([50-60]%), Hungary ([90-10]%), Italy ([70-80]%), Portugal ([80-90]%) and Spain ([40-50]%).

258. Although the merger does not result in any horizontal overlaps in these countries, the fact that both Wyeth and Pfizer have […] vaccines in the pipeline must be considered.

259. Wyeth has two pipeline projects for […] vaccines. Firstly, an […] vaccine against […] for the prevention of […]. The vaccine is projected for launch in […]. Secondly, […] vaccine (i.e. against […]) for the prevention of […]. Wyeth obtained a provisional licence for Spain in […]. Full EEA-level registration is projected for […].

260. In addition, Pfizer has a pipeline product for the development of […] vaccine against […]. The vaccine will be an […] formulation for […] to be launched in the EEA. The vaccine is […] [58] and […][59]. The projected launch time is […] and the estimated probability of launch is […]%.

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58 […].

59 […].

261. The Parties claim and the market investigation has confirmed that procurement of […] vaccines in all the above-mentioned countries takes place in the form of tender procedures organised by state authorities. These markets must therefore be regarded as monopsony markets where the state acts as the exclusive buyer. Certain countries have awarded a single contract for the country's entire demand. Such "winner-takes-it-all" tenders explain Wyeth's [90-100]% market shares in the Czech Republic and Hungary. Other countries have awarded several contracts, sometimes to smaller, national producers unable to satisfy these countries' entire demand of […] vaccines. In such cases, additional contracts have been awarded to "top-up" the demand. Member States have to comply with EU rules on public procurement as stipulated in the EC Procurement Directive.[60] In addition, Member States wishing to obtain EU subsidies for eradication schemes targeting […], must organise public tenders in accordance with the EC Procurement Directive.[61]

262. The market investigation indicates that a number of companies participated in some of the tenders organised in the above-mentioned countries, namely Merial, Schering-Plough, Virbac, CZ Veterinaria S.A. (Spain) and Laboratorios SYVA, S.A. (Spain). It is possible that additional firms that were not included in the market investigation participated in some of these tenders.

263. According to the market investigation, several competitors have competing […] vaccines in the pipeline aimed for launch in the EEA. […], whereas Merial has a […] vaccine that has already received a positive opinion from the EMEA […].

264. […] vaccines are procured by public tenders in the Czech Republic, France, Hungary, Italy, Portugal and Spain. High market shares in such bidding markets are not indicative of market power if tenders are carried out regularly and in a competitive manner and the market investigation has not indicated that this would not be the case in the countries concerned. State monopsony buyers may be presumed to have sufficient counter-veiling buyer power to counteract any attempt by the merged firm to raise prices post merger. In addition, there seems to be a sufficient number of alternative suppliers – larger multinational firms as well as smaller national players - to ensure a competitive bidding process. There are no indications that the merged firm's pipeline projects are unique in any substantial manner and there are several competitors also have new […] vaccines in the pipeline. For these reasons, the Commission excludes serious doubts in the markets for the provision of […] vaccines in Czech Republic, France, Hungary, Italy, Portugal and Spain. This conclusion would not change if the relevant markets were to be sub-segmented depending on […].[62]

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60 Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public works contracts, public supply contracts and public service contracts, OJ L 134, 30.4.2004.

61 Commission Decision 2008/897/EC of 28.11.2008, article 19(1).

62 In a bidding market, the closeness of substitution between […] vaccines depends on the terms of the tender. If a tender will call for a […], bidders may be able to offer all […] vaccines including the required […], unless there will be reasons to believe that […] vaccines will not be equivalent products.

[…] vaccines for […] in Belgium, the Czech Republic, Estonia, Germany, Hungary, Italy, Lithuania, Slovakia and United Kingdom

265. […].

266. […] vaccines are mostly sold in the EEA under national eradication programmes.[63] In general only […] vaccines (as opposed to […] vaccines) are allowed in countries with eradication programmes. Therefore, the Parties maintain that making a distinction between […] vaccines is appropriate. There are currently no multivalent vaccines with […] component available in the EEA so the Parties submit that monovalent […] vaccines constitute a distinct relevant product market. Moreover, the Parties consider that a distinction between live and inactivated […] vaccines would be inappropriate, because both forms exist within the EEA and most veterinarians regard them as substitutable to a large extent.[64]

267. The market investigation has not indicated that a deviation from the product market definition advocated by the Parties would be called for.

268. Pfizer currently markets […] vaccines in the EEA under the brand […].[65] This vaccine has both live and inactivated forms and is administered intranasally by spray (live vaccines only) or intramuscularly by injection. The vaccine requires a primary course of two vaccinations and subsequent booster vaccinations. Pfizer has […], which aims at […]. If successful, the […] vaccine will be launched in […].

269. In 2008 Pfizer obtained substantial market shares in a number of Member States, namely Belgium ([30-40]%), the Czech Republic ([50-60]%), Estonia ([30-40]%), Germany ([40-50]%), Hungary ([40-50]%), Italy ([40-50]%), Lithuania ([30-40]%), Slovakia ([40-50]%) and United Kingdom ([80-90]%). The main competitor to Pfizer is Schering-Plough with market shares ranging from 50-70% in the above-mentioned countries (except for the United Kingdom where the company accounts for the remaining [10-20]%). Merial is also present with market shares ranging from 1-10% (except in the United Kingdom). Schering-Plough's and Merial's […] vaccines both have a duration of immunity of six months.

270. Although the merger does not result in any horizontal overlaps in these countries, the fact that Wyeth has an […] vaccine in the pipeline must be considered.

This means that […] vaccines may be substitutable from a demand-side perspective in public procurement markets.

63 National eradication programmes have been implemented in Belgium, the Czech Republic, Germany, Hungary and Slovakia.

64 Substitutability applies at least to all non-pregnant animals older than three months.

65 The product is based on IP-rights orginally licenced by […]. Pfizer's licence agreement will expire in […].

271. Wyeth has a pipeline product underway, the […]. This vaccine is expected to be […]. In the notification, the Parties submitted that the vaccine was projected for […]. However, at a very late stage in the investigation, the Parties submitted a revised projection, forecasting product launch only in […], due to licensing complications.[66] The project is still at the very beginning of the full development stage. The […] project is […].[67] The probability of a successful launch is estimated at […]%.

272. The Parties allege that for several reasons, Pfizer's acquisition of Wyeth's […] pipeline project does not give rise to competition concerns post merger. Firstly, they expect the […] to complement Pfizer's existing […] vaccine rather than being close substitutes. When Wyeth's product comes to market, […]. Secondly, by the time that the […] is launched, Pfizer's […] vaccine will have lost its patent protection for […]. Thirdly, the Parties submit that multivalent vaccines with […] component are being developed.[68] When introduced, for economic and practical reasons multivalent vaccines may be expected to gain sales at the expense of monovalent vaccines. According to the Parties, sales of […] vaccines in countries where there are no eradication schemes (such as the United Kingdom) may be caused by the fact that […] is exported for fattening to countries with eradication schemes. In such cases, vaccination is a pre-requisite for export. In addition, some farmers may run their own "on farm" eradication schemes.

273. The market investigation has not contradicted the Parties' competitive assessment as outlined in the previous paragraph.

274. Already pre-merger, Pfizer has a very strong market position in a number of national markets, also in countries where there are no eradication schemes in place. Pfizer's success may possibly be explained by the fact that the company's […] vaccine is versatile (it is available both as live and inactivated and injection as well as spray). If Pfizer's […] is successful, Pfizer's product will have another competitive advantage in relation to its competitors. However, the […] is not merger specific, i.e. it would occur also in the absence of the merger.

275. Wyeth's product will only offer an immunity duration of […] and is less versatile than Pfizer's existing product (the Wyeth pipeline product is only […]). There are several existing vaccines with a similar profile as Wyeth's pipeline product (i.e. […]), e.g. vaccines produced by Merial and Schering-Plough[69]. In addition, there is another pipeline […] vaccine with the same profile, which is projected for launch in […], i.e. well before Wyeth's product. Due to these circumstances, the market impact of the future launch of Wyeth's pipeline vaccine is unlikely to be more than marginal. Any competitive impact is difficult to predict because the projected launch lies so far into the future and at a point in time when new entries

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66 E-mail from Pfizer's legal representatives of 8.7.2009.

67 According to the Parties […].

68 […].

69 Schering-Plough also has a live […] vaccine.

may have occurred due to the patent expiry of Pfizer's […]. In addition, the possible introduction of multivalent vaccines with an […] component may already have changed the competitive landscape for […]vaccines at that time.

276. For these reasons, the Commission excludes serious doubts in the markets for the provision of monovalent […] vaccines in Belgium, the Czech Republic, Estonia, Germany, Hungary, Italy, Lithuania, Slovakia and United Kingdom.

[…] vaccines for […] in the Czech Republic, France, Italy, Lithuania, Poland, Slovakia and Spain

277. […].

278. The Parties submit that monovalent […] vaccines for […] constitute a distinct relevant product market. According to the Parties, […] vaccines are not substitutable with […] vaccines for […]. The Parties do not consider monovalent and multivalent vaccines as substitutable, because in Europe there is no true substitution between the two vaccine types on the basis of the pathology treated. Moreover, the Parties consider making a distinction between live and inactivated […] vaccines to be inappropriate for the purposes of market definition. Although only inactivated monovalent […] vaccines have been authorised for use in certain EEA countries (e.g. Ireland and the United Kingdom), in those countries where both modified live and inactivated vaccines are allowed, they tend to be used interchangeably, at least in non-pregnant animals. In certain countries, e.g. Germany, a two-step procedure, using first inactivated and then live monovalent […] vaccines is currently a "well accepted vaccination procedure".

279. The market investigation has not indicated that deviating from the Parties' product market definition would be called for.

280. Pfizer currently markets the […] vaccine in the EEA. This inactivated vaccine is indicated for […] to prevent […]. Primary vaccination by subcutaneous injection consists of two doses three weeks apart followed by a booster vaccination with immunity duration of 12 months. Pfizer also markets […] live vaccine against […] administered by […].

281. In 2008, Pfizer obtained substantial market shares in a number of Member States, namely the Czech Republic ([60-70]%), France ([50-60]%), Italy ([40-50]%), Lithuania ([30-40]%), Poland ([70-80]%), Slovakia ([80-90]%) and Spain ([40-50]%). The main competitors in these markets are Schering-Plough with market shares ranging from 1-70% and Merial with market shares ranging from 1-30%.

282. Although the merger does not result in any horizontal overlaps in these countries, the fact that Wyeth has a […] vaccine in the pipeline must be considered.

283. Wyeth has a pipeline project in development called […]. If the project is successful, it will be […]. Primary vaccination will be given to […]. The expected immunity duration is […]. The projected time of launch is […]. The Parties estimate the probability of a successful product launch […]%.

284. The Parties maintain that Pfizer's acquisition of the […] pipeline project will not give rise to competition concerns post merger. Firstly Wyeth's pipeline product will not be a close substitute to Pfizer's […] vaccine, because […]. Secondly, the Parties predict that demand for […] vaccines may diminish due to the existence or introduction of eradication programmes. According to the Parties, eradication programmes have typically not included […] vaccines. In addition, in countries where […] has been eliminated (e.g. the Nordic countries), […] vaccines are prohibited. In countries where the number of […] infections becomes negligible vaccination is often discontinued. Thirdly, the Parties are of the view that the markets for monovalent […] vaccines for […] are highly competitive. In addition to Pfizer, Schering-Plough, Merial and Novartis/Virbac[70] offer monovalent […] in the EEA. […].

285. The market investigation indicates that at least one competitor has a monovalent […] vaccine in the pipeline. Several firms, including Pfizer, have pipeline projects for multivalent vaccines including not only […] but also […] components. Upon request from the Commission, Wyeth has provided plausible explanations for estimating the chance of success at […] %. Wyeth maintains *inter alia* that this project has been ongoing since 1995 and that it still has to make significant progress.

286. Although the market investigation did not clearly confirm the Parties' arguments, considering the low probability of success, it seems inappropriate to consider Wyeth's […] as a product at a late stage in development which is sufficiently likely to be launched within the timeframe of the Commission review. In addition, there is at least one competing pipeline project for a […] vaccine covering […]. For these reasons, the Commission excludes serious doubts in the markets for the provision of monovalent […] vaccines for […] in the Czech Republic, France, Italy, Lithuania, Poland, Slovakia and Spain.

70 […].

4.3.8. Pharmaceuticals

Markets with horizontal overlaps

Parasiticides

Product market definition

287. 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 a distinction between anti-coccidials which act against single-celled parasites and other-parasitic preparations that treat non-coccidia parasites.

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

289. In previous Commission's decisions[71] 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 applied directly on the animal in the form of sprays, dusting powders, pour-on applications, spot-on application, shampoos, collars, creams and 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. They are administered orally, by injection or topically.

290. The Parties presented data at the level of endoparasiticides-endectocides distinguishing markets for (i) production animals, (ii) companion animals and (iii) horses, on the basis that, in particular for production animals, control of external parasites is less of a focus for veterinarians and animal owners than control of internal parasites, as external parasites do not typically impact on animal productivity to the same degree as internal parasites (and thus the return on the investment in the treatment is less clear) or on the basis that in any case customers can and do use both types of product interchangeably to treat worms with no significant difference in effectiveness, duration and withdrawal period[72].

291. According to the Parties, the Parties' activities overlap in the following segments:

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71 Case M.4691 – *Schering-Plough/Organon Biosciences*, paragraph 422 and following; Case M.885 – *Merck/Rhône-Poulenc-Merial*, paragraph 42; Case M.737 – *Ciba/Sandoz*, paragraphs 186 and following.

72 The Parties submit that ectoparasiticides should be seen as a separate product market.

- production animal endoparasiticides and endectocides
- production animal ectoparasiticides
- endoparasiticides and endectocides for horses
- pets (dogs and cats) endoparasiticides and endectocides

292. However the results of the market test do not fully support the Parties' allegation with regard to a market definition encompassing both endoparasiticides and endectocides for production animals and for companion animals. In the field of production animals, considerations including cost of treatment and the duration of the withdrawal period do play a major role and result in limited substitutability between endoparasiticides and endectocides from the demand side[73]. Also from the supply side, the respondents point out that the animal species extension requires a pharmaceutical development, either generic or not, involving time and costs, and if a company is active in manufacturing and marketing endoparasiticides and endectocides for sheep, it may not be able to successfully develop a cattle product. This is also because sheep endoparasiticides and endectoparasiticides are mainly delivered as oral suspensions while cattle endoparasiticides and endectoparasiticides are primarily delivered as pour on solutions or as injectables and different formulations require different R&D and manufacturing technology[74]. In the field of companion animals endoparasiticides and endectocides are not always substitutable from a consumer (i.e. pets' owners) perspective since external parasites (which are treated only by endectocides, as well as by ectoparasiticides) represent the main concerns.

293. The market for parasiticides is generally increasing and it is characterised by the recent or future entry of some innovator drugs. Therefore a number of products are still patent protected and enjoy large market shares. Compared to other markets in the animal health pharmaceuticals, this is still a market with high profit margins both for production and companion animals (including horses).

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73 According to almost half the respondents there is no substitutability from the demand side since a distinction should be made among animal species, type of parasites to be controlled, perceived cost effectiveness, possible resistance towards molecules experienced by the farmer, and age of animals to be treated.

74 More than half respondents point out that the endoparasiticides and endectocides for production animal are not substitutable from the supply side. According to a competitor, in the case of sheep there are huge barriers for other manufacturers gaining access to EU-approved Active Pharmaceutical Ingredients ("APIs") and then having suitable premises to manufacture. Such products, for example, may not be suitable to be made in the same factory together with penicillins.

Production animal endoparasiticides and endectocides in Belgium, Germany and the United Kingdom

294. The Parties note that endoparasiticides and endectocides for use in production animals are based on three main methods of administration (oral, topical and injectable) and three main active ingredients classes for roundworm control. Whereas all active ingredients are used across species, cattle and sheep formulations are differentiated by concentration of active ingredient (dose rate) and mode of administration (cattle are treated by pour-on or injectable product and sheep are often orally treated).

295. Pfizer sells both endoparasiticides and endectocides for production animals under the brands *Valbazen/Bilutax* (endoparasiticides), *Exhelm* (endoparasiticides), *Dectomax* (endectocides) and *Autoworm* (endoparaciticides). Wyeth sells only endectocides for production animals under the brands *Duotech*, and *Cydectin*/*Zermex*.

296. The combination of the Parties' products results in high market shares in the UK market for endoparasiticides and endectocides for production animals. The main competitors of the resulting entity would be Merial, Novartis, Janssen and Schering Plough. The combination of the Parties' activities results in one Group 1 market: the United Kingdom.

Country	Pfizer	Wyeth	Combined	Competitors
United Kingdom	**[20-30]%**	**[10-20]%**	**[30-40]%**	**Merial [10-20]%; Janssen [10-20]%; Novartis [10-20]%; Schering Plough [5-10]%**

297. In case of an alternative market definition comprising only endectocides for production animals[75], the combination of the Parties' products results in higher market shares in the UK, Belgium and Germany. In Belgium the Parties would face four competitors and a local rival. In Germany the Parties would face three competitors and a local rival. In the UK the Parties will compete with four other players.

298. The combination of the Parties' activities results in three Group 1 markets: Belgium, Germany and the United Kingdom.

75 The Parties' activities do not overlap in the segment of endoparasiticides for production animals.

Country	Pfizer	Wyeth	Combined	Competitors
Belgium	**[20-30]%**	**[20-30]%**	**[40-50]%**	**Janssen [10-20]%, Schering Plough [10-20]%, Merial [10-20]% Fendigo [0-5]%**
Germany	**[10-20]%**	**[20-30]%**	**[40-50]%**	**Janssen [5-10]%, Schering Plough [10-20]%, Merial [10-20]% IDT [5-10]%**
United Kingdom	**[30-40]%**	**[10-20]%**	**[40-50]%**	**Merial [10-20]%, Janssen [10-20]%, Novartis [10-20]% and Schering Plough [5-10]%**

299. Both Parties have patent protected products (*Dectomax* and *Cydectin*, injectable, oral and pour-on), as well as pipeline projects in their portfolio. Some of the competitors' products are also patent protected[76], thus resulting in generic competition only to a limited extend in this segment. There are no generics available for both Pfizer's *Dectomax* and Wyeth's *Cydectin* branded products, which are the Parties' leading products, although they submit that Pfizer's *Dectomax* will be subject to generic competition when it will go off-patent in 2009 and 2010.

300. The market definition proposed by the Parties encompasses endoparasiticides and endectocides for production animals. However, the majority of the respondents to the market investigation indicate that there is limited supply-side substitutability and that from demand perspective the products are not always substitutable as endectocides are generally more expensive than endoparasiticides so that end-users would not choose them without considering their real added value in each specific circumstance and also because substitution between delivery technologies for particular species only occurs in limited circumstances[77].

301. Moreover a number of respondents expressed concerns on the possible "dominant position/very strong position" of the resulting entity in the segment of endectocides for production animals (with the *Dectomax* and *Cydectin* brands) as well as on Pfizer's offering rebates conditional upon the purchase of certain volumes of bundled products[78]. According to the respondents this can result in a

76 Merial's *Eprinex* which has a zero day withdrawal period for milk as Wyeth's *Cydectin*.

77 According to the respondents, typically for swine endectocides are rarely used for internal protection against parasites and they do not compete with endoparasiticides. Pour-on endectocides are used for cattle due to ease of administration while oral suspensions are primarily used for sheep and the easier application of pour-on products together with their broader spectrum of efficacy against ectoparasites make them not substitutable with endoparasiticides.

78 The majority of the customers revealed the existence of a widespread practice (at least in Ireland, Germany and the UK) by Pfizer of target-based incentive schemes. Specifically, it has been remarked that Pfizer offers incentive scheme and rebates on bundled products dependent on the purchase made of *Dectomax*, Pfizer's blockbuster. Additionally it has been pointed out that Pfizer works in a number of countries with a purchasing model where veterinarians get more discount when they buy more products out of their range. A number of competitors also expressed concern in view of the concentration of the *Dectomax* and *Cydectin* ranges of products that may be detrimental to customers and competitors.

significant entry barrier and/or barrier to expansion both for generic manufacturers and for companies with a portfolio not comparable to the one offered by the resulting entity.

302. For the purposes of this transaction the market definition can be left open since, irrespective of the market definition followed, post-transaction the Parties will become the clear market leader in the UK, Belgium and Germany thanks to a significant increment in share. Furthermore contrary to the Parties' submission on the complementarity of their products, the market investigation reveals that *Dectomax* and *Cydectin* products in their respective formulation (injectable, oral and pour-on) are seen as the closest competitors and are both long-acting innovator endectocides. Wyeth's market share increased by [10-20]% in 2007 and [10-20]% in 2008 in the UK following the introduction of a new *Cydectin* branded product. This increase will be further enhanced by the entry of three other products (*Cydectin* long acting for sheep already launched in March 2009, *Cydectin* Triclabendazole oral drench for sheep to be launched in […], and *Cydectin* Triclabendazole pour-on for cattle to be launched in […]).

303. The Commission therefore concludes that the proposed transaction raises serious doubts for the production animal endoparasiticides and endectocides market in Belgium, Germany and the United Kingdom.

Endoparasiticides and endectocides for horses in Austria and the United Kingdom

304. Pfizer sells endoparasiticides and endectocides for horses under the brands *Strongid/Nemex*, *Strongid/Pirantel P Grans*. Wyeth sells endectocides for horses under the brands *Equest gel*, *Equitape* and *Equest Pramox*.

305. The market definition provided by the Parties has not been contested by the participants in the market test. Therefore, the effects of the transaction are evaluated in an overall market comprising both endoparasiticides and endectocides which are administered externally or internally either orally or by injection.

306. The combination of the Parties' products gives raise to two Group 1 markets: Austria and the UK. Particularly in the UK there are high market shares with non-negligible overlaps, where the resulting entity will become the market leader. In the UK the Parties would face competition from Virbac, Schering Plough and Merial. There will also be other small competitors, such as Bimeda and Janssen. In Austria the Parties would face competition from Merial and Virbac and two small players.

Country	Pfizer	Wyeth	Combined	Competitors
Austria	**[10-20]%**	**[20-30]%**	**[30-40]%**	**Merial [10-20]% and Virbac [40-50]%, Janssen [0-5]%, Prozoon [0-5]%**
United Kingdom	**[5-10]%**	**[40-50]%**	**[50-60]%**	**Virbac [20-30]%, Schering Plough [5-10]% and Merial [10-20]%, Bimeda [0-5]% and Janssen [0-5]%**

307. Wyeth's products are still patent protected[79] and are the market leader in the UK.

308. According to the Parties, in the UK Wyeth's share has increased over the period 2006-2008 by approximately [10-20]% due to the launch of *Equest Pramox* in 2006, which in such a short elapse of time has already gained more than [20-30]% market share, while Pfizer's shares have remained stable.

309. The Parties submit that their products are not each other's closest substitutes and that significant players will remain post-transaction both in the UK and in Austria, as well as some generic competition. They also refer to product rotation in the UK. However the market test does not support the Parties' claim on closeness of competition[80] and product rotation[81] and points to the existence of entry barriers[82], particularly in the UK where volume based multi-product discounts are widespread[83], and limited scope for generic competition[84].

310. Therefore, taking into account the Parties' high market shares and the results of the market test, not clearly backing the Parties' arguments and pointing at barriers

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79 The active ingredients in Wyeth's *Equest Pramox* are *moxidectin* and *praziquantel*. The patent on the *praziquantel* compound expired in the late 1990s. The patent on the *moxidectin* compound will expire on 30 December 2009 in Austria and on 29 December 2009 in the UK. Wyeth has a formulation patent that covers the particular formulation of the two active ingredients. This patent will expire on 22 August 2022.

80 According to the majority of the respondents (11 out of 17) the Parties' product are not complementary but close competitors as both Pfizer's product (*Strongid*) and Wyeth's product (*Equest Pramox*) are active against tapeworms and roundworms.

81 The market test shows that product rotation is not always implemented in practice in the UK. Product rotation is effectively implemented only in the Scandinavian countries.

82 Some competitors state that there are barriers to entry in the UK market: marketing, brand establishment, size of a supplier's sales' network, heavy regulatory costs for registrations, entry costs too high. According to a respondent in the UK there will be significant licensing restrictions. A competitor regards the access to the various distribution channels specific to the UK a key success factor. According to another competitor an obstacle is represented by establishing sales force organisation targeting horse vets, and OTC (over the counter) channels.

83 Volume based multi-product discounts make access to the market difficult for companies with limited product range.

84 Many respondents explicitly reported that they do not expect further generic producers to enter these markets.

to entry, the Commission concludes that the proposed transaction raises serious doubts as regards the United Kingdom market for endoparasiticides and endectocides for horses.

Companion animals endoparasiticides-endectocides in Italy

311. Pfizer sells endoparasiticides and endectocides for companion animals under the brands *Nemex/Felex* (endoparasiticides), *Stronghold/Revolution* (endectocides). Wyeth sells endoparasiticides for companion animals under the brands *Guardian tablet/injection.*

312. According to the market definition proposed by the Parties encompassing endoparasiticides and endectocides for companion animals, the combination of the Parties' products results in one Group 1 market, Italy, where the resulting entity will become the clear market leader. The Parties' main competitors in this market would be Merial, Bayer and Novartis.

Country	Pfizer	Wyeth	Combined	Competitors
Italy	**[20-30]%**	**[20-30]%**	**[40-50]%**	**Merial [20-30]%, Bayer [10-20]% and Novartis [5-10]%**

313. Wyeth's products (*Guardian*) are patent protected and used only for the treatment of *dirofilaria* (heartworms), which is very common in the Mediterranean countries. Wyeth has also pipeline products. Pfizer's product Stronghold is used as an endectocides as well for the treatment of *dirofilaria,* as a secondary indication.

314. The market investigation also indicates that endectocides and endoparasiticides should be considered separate product markets as, when it comes to companion animals, end-users view endectocides mainly as products for coverage against external parasites rather than as products for coverage against both external and internal parasites. This is also acknowledged by the Parties.

315. According to the majority of the respondents, the market definition presented by the Parties does not fully reflect market and competitive dynamics in the parasiticides area. A respondent maintains that it is most appropriate to divide companion animal parasiticides into the following separate markets: ectoparasiticides and endectocides for companion animals; and endoparasiticides for companion animals (with further sub-division into markets for the treatment of: (1) heartworm; and (2) gastro-intestinal and other parasites). Customers in this area typically seek products to prevent or treat either external parasites (primarily fleas and ticks) or internal parasites (such as heartworms or gastro-intestinal worms). Endectocides, which treat both internal and external parasites, are most comparable to (and are most commonly used as substitutes for) ectoparasiticides in the companion animal segment. Endectocides have similar protection levels and are generally sold at comparable price levels as ectoparasiticides. In practice, a customer seeking to eradicate fleas and ticks could either turn to an ectoparasiticide or could achieve similar results using an endectocide – the only difference being that endectocides would also offer some internal parasite

protection. In relation to endoparasiticides, a number of competitors and customers consider that products for the treatment of heartworm or *dirofilaria* are not substitutable from a customer's perspective with products that target other internal parasites such as gastro-intestinal parasites, suggesting that the market for endoparasiticides for companion animals could be further sub-divided along these lines.

316. The Parties have provided market shares for the alternative segments proposed by the Commission.

317. Having regard to the small overlap[85] and increment in shares and the fact that the Parties' combined share does not exceed 35% in any national sub-segment in the EEA, the Commission concludes that on the market for companion animals endectocides and ectoparasiticides the proposed transaction does not raise serious doubts as to its compatibility with the common market.

318. The Parties' activities do not overlap in the alternative market covering only endectocides for companion animals.

319. Finally for companion animals endoparasiticides the Parties' combined share in Italy, which is the only Group 1 market, would be [30-40]% (i.e. [5-10]% for Pfizer and [30-40]% for Wyeth), facing competition from three rivals (Merial [20-30]%, Bayer [10-20]% and Novartis [5-10]%[86]).

320. According to the Parties, if treatment for *dirofilaria* (or heartworms) was considered separately their combined market share in Italy would be [40-50]%, i.e. [0-5]% for Pfizer and [40-50]% for Wyeth. The Parties would face competition from Merial [30-40]%, Novartis [5-10]% and Bayer [5-10]%. It is to be noted however that Pfizer's market shares have been adjusted according to Pfizer's estimates on the low usage of *Stronghold* as a treatment against *dirofilaria,* since it has as a primary indication the treatment of fleas[87].

321. Although the Parties claim that their products are not each other's closest substitutes (due to spectrum of activity, different species focus, mode of

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85 It is to be noted that the Parties in the Form CO failed to disclose an overlap in the segment of ectoparasiticides which was then only revealed due to specific request from the Commission's services.

86 In this scenario Schering Plough would only have [0-5]% market share.

87 According to Pfizer the first therapeutic indication of *Stronghold* is the treatment of fleas for dogs and cats and this is confirmed also by its higher price compared to heartworm products, and its different method of administration (topical rather than injectable) with a much shorter duration of prevention. For these reasons they estimate that […]% of *Stronghold* sales are to be attributes to its external parasites control and […]% to the prevention of *dirofilaria*. Some respondents in the market investigation also confirmed that the two products are not the closest substitutes even though they can be reliably seen as part of the same market.

administration and prices), the market test does not fully support this argument[88]. Furthermore in the 2005 *Stronghold* marketing plan provided by the Pfizer it is indicated that *Stronghold* is intended to be marketed for both cat heartworms (where it had [40-50]% of the market facing competition only from *Cardotex* (Merial), the first endectocides for dogs and cats, with [50-60]% market share[89]) and for puppies (which cannot be treated by *Guardian injectable*)[90].

322. For the purposes of the assessment of the present transaction the market definition can be left open since irrespective of the segmentation followed, in view of the relatively concentrated market, the high market share of the Parties, and the patent protection, the Commission concludes that the proposed transaction raises serious doubts in the Italian market for companion animals endoparasiticides and endectocides.

Antimicrobials

General considerations on market definition

323. Antimicrobials are pharmaceutical products that destroy or prevent the growth of microbes such as bacteria, mycoplasma (pathogens that clack cell walls) or fungi and treat diseases associated with them.

324. In previous decisions[91] the market definition of anti-microbials has been driven by the following factors:

- active substance (sulphanomides, penicillins, cephalosporins, tetracyclines, etc.)
- route of administration (injectable products, products for oral administration and products for topical administration such as intra-mammary mastitis treatments)
- animal's size (large animals such as horses, ruminant and swine and companion animals such as dogs and cats)

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88 The respondents draw a clear distinction between the markets where the *dirofilaria* is spread out, where the Parties' product are competing as they both treat this disease, and the markets where no *dirofilaria* is present where Wyeth's product is not sold while Pfizer's product, which is an endectocides, is still sold thanks to its dual indications (treating also fleas, i.e. external parasites). The majority of the respondents regard the two products as competing in the same market for *dirofilaria*. This is also confirmed by some customers.

89 In fact neither *Guardian* (Wyeth) nor *Interceptor* (Novartis) is registered for heartworms prevention for cats. However the Parties submit that the cat segment is a negligible one compared to dogs and there is little commercial interest in this segment.

90 Furthermore in the same document it is indicated that as for the product positioning "*Stronghold is the ideal product for treatment and prevention of fleas, for prevention of heartworms and other ectoparasiticides […] in dogs and cats. Thanks to its ease of use (spot on formulation) and the broad spectrum of activity, Stronghold is more convenient than Frontline and Cardotex*". As far as the marketing strategies are concerned, it is also indicated that in the short term Pfizer […].

91 Case COMP M. 4691-*Schering-Plough/Organon Biosciences*, paragraphs 325-346; Case COMP/M.2922-*Pfizer/Pharmacia*, paragraphs 122-123; Case COMP M. 1681-*Akzo Nobel/Hoechst*, paragraph 19.

325. The Parties submit that a review at the level of active substance, further segmented by size of animal or by route of administration will fail to capture all the competitive constraints faced by the products. However, they do not dispute the findings of the Commission in previous cases. They have adopted a primary segmentation based on the active substance and on a distinction between large and small animals as they consider such distinction more appropriate than a distinction based purely on route of administration. Nonetheless, for some products (oral penicillins for companion animals, tetracycline sprays and mastitis) the market definition, as initially proposed by the Parties, is based on a segmentation also driven by the mode of administration.

Alternative market definitions

326. The possibility to define the market on the basis of the target pathology was discussed and excluded in *Pfizer/Pharmacia* and in *Schering-Plough/Organon Biosciences*[92]. Nothing in the market investigation prevents from excluding such possible market definition also in this case.

327. The possibility of defining a broad market encompassing all Beta lactams has been suggested by one of the respondents to the market test. Beta lactams is a broad class of antibiotics including any antibiotic agent containing a Beta lactam nucleus in its molecular structure such as penicillin/synthetic penicillin and cephalosporin. The possibility of retaining beta-lactams as relevant market definition instead of further distinguishing between penicillin and cephalosporin was also considered in *Schering-Plough/Organon Biosciences*[93]. In that case the question was left open and the analyses was conducted on the narrower segmentation (e.g. separate markets for penicillin and cephalosporin) giving raise to more national affected markets and/or to similar or higher Parties' combined market shares.

328. In the case at hand the category Beta lactams is relevant for production animal antimicrobials and for companion animal antimicrobials.

329. In the field of production animals, although the Parties' activities do only overlap in penicillin, the higher market shares and the largest number of Group 1 markets arises in the broader market definition encompassing both penicillins and cephalosporins. This is due to Pfizer's strong position in the field of cephalosporins as well as to the fact that since cephalosporins are newer molecules than penicillin and, to some extent, still under patent protection, they are positioned as premium products for use under specific circumstances and, as such, are typically priced higher than penicillin.

330. According to the Parties, while some limited degree of demand-side substitutability exists between penicillin and cephalosporin, they differ significantly in the way they are used by a veterinarian for treatment of

92 Case COMP M. 4691-*Schering-Plough/Organon Biosciences*, paragraphs 334-339; Case COMP/M.2922-*Pfizer/Pharmacia*, paragraphs 132-137.

93 Case COMP M. 4691-*Schering-Plough/Organon Biosciences*, paragraphs 330-331

production animals. In support of their arguments the Parties have submitted EMEA's new guidelines according to which the decision to use 3rd and 4th generation cephalosporins[94] should be undertaken carefully as it is important to preserve these molecules, which demonstrates differing resistance patterns to other antibiotics including penicillins, for use in cases where antibiotic resistance is an increasing concern.

331. The results of the market investigation do also show limited substitution between penicillin and cephalosporin. The majority of the respondents consider that there are important differences between these two products including, apart from price, different spectrums of activity and resistance status of the bacterial infections. The most acute cases will only be sensitive to cephalosporin and in those cases penicillin will not be considered a substitute whereas in the milder cases the use of cephalosporin will not be a cost effective solution and, in addition, it will run against EMEA's recommendations aimed to limit the development of antibiotic resistance. Finally, it shall be taken into account that, as Wyeth does not have any cephalosporin premium products, Pfizer's strength in a hypothetical broad market encompassing all Beta lactams for production animals will not be altered by the transaction.

332. In the field of companion animals, the main overlap among the Parties' activities relates to oral penicillin products for companion animals. There is also a limited overlap in the field of cephalosporins where Wyeth has an oral cephalosporin product sold only in Italy (*Therios 60*) and Pfizer has an injectable product, *Convenia*, which is sold throughout the EU. In a broad Beta lactams market (penicillin + cephalosporin) including oral and injectable products the combination of the Parties activities results in higher market shares and in more Group 1 markets than in separate markets for penicillin and for cephalosporin products. This is due to the importance of Pfizer's sales of its injectable product *Convenia* which is a third generation cephalosporin. According to the Parties, the substitution between cephalosporin and penicillin is also limited for companion animals. In support of this argument the Parties refer to the EMEA's Summary of Product Characteristics for Pfizer's product *Convenia* recommending the use of third generation cephalosporin for the treatment of clinical conditions, which have responded poorly, or are expected to respond poorly, to other classes of antimicrobials. This provides an indication of the limited substitutability between penicillin and cephalosporin also for companion animals and leads to consider that any competitive concern arising as a result of the concentration can be better addressed in the narrower separate segments for penicillin and cephalosporin encompassing closer substitute products.

333. In light of the above, in this case the Commission will analyse the effects of the proposed transaction at the level of the active substance (i.e. separate markets for penicillins and cephalosporins) and not at the level of the broader class Beta lactams.

Assessment

94 According to the Parties all cephalosporins used in production animal medicine fit into this category.

334. Tetracyclines are broad-spectrum antibiotics that were first discovered in natural form in 1948. After penicillin they are the oldest antibiotic family and are used regularly to treat infection in production animals. The group includes tetracycline, oxytetracycline, doxycycline and chlortetracycline. They cure infection by inhibiting the growth of the bacteria.

335. Pfizers' products are *Terramycin Soluble Powder, Terramycin intra-uterine oblets, Neo-Terramycin Soluble Powder, TMLA, TM Injectable 100/Panterramicina, TM Tablets, TM Premix, Tetramin.* Pfizer manufactures these products in its plant located in Amboise (France), except for *Terramycin intra-uterine oblets* which are manufactured for Pfizer by a third party[95]. Wyeth's products are mainly sold under the trademark *Aureomycin* (Soluble Powder, Top Powder, Oblets, Bolus) and *Duphacycline* and all of them are manufactured by a third party[96]. As the Parties indicate, tetracyclines are well established ingredients and no products are patent protected.

336. According to the Parties, the methods of treatment for products in this segment fall into 3 categories:

- Injection, which is the most common form of treatment;
- Oblet, also referred to as intra-uterine products, which are tablets inserted into the uterus of an animal to treat infection;
- Pre-mixed and water soluble powders.

337. As the Parties indicate, injections are used most widely for ruminants and horses, although they may also be used for swine, depending on the circumstances. Injection will be the method of administration for swine, when an individual animal is already showing signs of a particular infection but not for mass preventive treatment. In the case of ruminants injection rather than oral treatment is used because if a tablet were administered this would eliminate the very important bacteria contained in ruminant's stomachs and could kill the animal.

338. The market definition initially proposed by the Parties included all categories (injections, oblets, pre-mixed and water soluble products) of anti-infective (AIF) tetracyclines (excluding sprays) for the treatment of production animals, disregarding the mode of administration.

339. The market investigation however indicated limited substitution between injectable and oral products as they are used in different situations and with different species. Respondents state that veterinaries prescribe injectable products for the early stage of the outbreak of a disease when the number of animals to be treated is reduced and also later for animals which don't eat anymore. Oral treatments would be generally prescribed as a preventive measure or in the early stage of a disease particularly if the number of animals to be treated is large, as

95 […].

96 […].

the administration of injectable treatment entails additional costs. The substitution between injectable and oral products from the supply side is also limited as special production facilities are required to produce sterile injectable products.

340. In view of the limited substitution between injectable and oral treatments, widely recognised in the market test, the first phase analysis in the present case will be conducted in the narrower segments of non-injectable and injectable tetracyclines for production animals where the Parties' market shares and the number of Group 1 markets are higher.

341. In the segment of non-injectable tetracyclines for production animals the combination of the Parties activities does not result in any Group 1 market whereas in the segment of injectables the combined market share of the Parties results in four Group 1 markets: Austria, Finland, Italy, and Belgium.

Production Animal Tetracyclines-Injectable				
Country	PAH	FD	Combined	Competitors
Austria	**[30-40]%**	**[0-5]%**	[40-50]%	**Virbac [40-50]%; Animal Med [10-20]%; Richter Pharma, [0-5]%; Bayer, [0-5]%**
Finland	**[30-40]%**	**[20-30]%**	[50-60]%	**Orion, [20-30]%; SP/Intervet [5-10]%; Norbrook [5-10]%**
Italy97	**[60-70]%**	**[5-10]%**	[70-80]%	**Tre I [0-5]%; Chemifarma, [0-5]%; Ceva S.A., [0-5]%; Ceva Vetem [0-5]%**
Belgium	**[5-10]%**	**[30-40]%**	[40-50]%	**Elanco, [30-40]%; SP/Intervet, [10-20]%; Virbac [0-5]%, Eurovet, [0-5]%**

342. In Austria, with a market share of [40-50]%, the resulting entity will not be the leader and will face competition from a significant multinational player, Virbac ([40-50]%), and at least from one additional credible competitor with market shares above 10% (Animal Med, [10-20]%). The overlap among the Parties' activities is limited ([0-5]%).

343. In Belgium, Wyeth was already the market leader and the resulting entity will have a clearer leading position with a market share of [40-50]%. Although the overlap among the Parties' activities is significant ([5-10]%), two significant competitors (Elanco, [30-40]% and SP/Intervet [10-20]%) will remain post transaction as well two additional players.

344. In Finland ([50-60]%) the resulting entity will become the clear market leader and the overlap among the Parties' activities is very significant ([20-30]%). The market share of the resulting entity will be significantly higher than that of the next competitor post-transaction (Orion, [20-30]%) and there will be only two more players with market shares of less than 10% (SP/Intervet [5-10]% and Norbrook, [5-10]%). In addition, although tetracyclines are very well established active ingredients and no products in the segment are patent protected, according

97 Tre I and Chemifarma report in the market test that they do not have sales of injectable tetracycline products for production animals. This is in contradiction with the statements of the Parties.

to the Parties, Nordic countries are becoming less and less tolerant of certain antibiotics and the tetracycline segment is experiencing decline. Therefore it could be considered that new entry at a scale sufficient to compensate for the lost of Wyeth as a competitor is unlikely.

345. In Italy none of the competitors of the resulting entity will have market shares above 5%. Therefore, none of them will be in a position to exert significant competitive pressure on the market leader whose already high market share ([60-70]%) will be increased by [5-10]% as a result of the transaction[98].

346. In view of the above, there are serious doubts as regards the effects of the proposed transaction in Finland and Italy.

AIF Penicillins/synthetic penicillins for production animals in Italy Portugal and the United Kingdom

347. Penicillins/synthetic penicillins belong to the oldest antibiotic family (penicillin was discovered in 1928) and are used regularly to treat infection in production animals. All the products of the Parties contain basic penicillin and synthetic penicillin such as Amoxicillin or Ampicillin. Some products are standard products which need to be administered every 24 hours and others have a long lasting action permitting to administer the medication only every 48 hours. Withdrawal periods (i.e. necessary medication-free waiting period before slaughter or sale of milk) vary depending on the product formulation from 1 to 28 days for meat or 48 to 264 hours for milk.

348. The main products of the Parties are Pfizer's *Clamoxyl, Clavamox/Clavulox/Synulox, PenStrep/Combiotic*. Wyeth's products in this market are *Duphamox, Suphapen, Duphacillin, Nisamox, PensSrtep*. Both Wyeth and Pfizer have their products manufactured by third parties[99]. The products of the Parties and their competitors do not differ in their efficacy or uses because the active ingredients are the same. All products in this market are off patent.

349. As it is the case for tetracyclines, penicillins' administration methods fall into three categories: injection, large palatable tablets called bolus (can be given to young calves or lambs that have not yet started ruminating) and oblets.

350. The market definition initially proposed by the Parties included anti-infective (AIF) penicillin products (injections, bolus and oblets) used for the treatment of production animals, disregarding the mode of administration.

351. The market investigation shows however that, as in the case of tetracycline, substitution between injectable and oral products both from a demand and a supply perspective is limited. Therefore upon Commission's request the Parties

98 The market share of the resulting entity could be higher as Tre I and Chemifarma indicate that they do not have sales in this market.

99 […] in the case of Pfizer and […] in the case of Wyeth.

have also provided separate market share information for oral and injectable products.

352. In view of the limited substitution between injectable and oral treatments for production animals, the first phase analysis in the present case will be conducted in the narrower segments of non-injectable and injectable penicillin for production animals, where the Parties' market shares are higher[100].

353. In the segment of non-injectable penicillin for production animals there is no overlap in the EEA among the Parties' activities. In the injectables segment, the proposed transactions results in three Group 1 markets: Italy, Portugal and the UK.

Production Animal Penicillins-Injectable				
Country	PAH	FD	Combined	Competitors
UK	**[20-30]%**	**[10-20]%**	[30-40]%	**Norbrook, [10-20]%; Vetoquinol [10-20]%; SP/Intervet [10-50]%; Virbac [5-10]%**
Portugal	**[40-50]%**	**[5-10]%**	[40-50]%	**SP/Intervet [20-30]%; Boehringer [10-20]%; Ceva S.A. [5-10]%; Sorologico [5-10]%**
Italy	**[40-50]%**	**[5-10]%**	[50-60]%	**Ceva S.A. [20-30] %; Boehringer [5-10]%; Virbac [5-10]%; SP Intervet [0-5]%**

354. With a market share of [40-50]% Pfizer will remain post-transaction the largest player in Portugal but it will still face one significant competitor (SP/Intervet, [20-30]%), as well as a credible competitor with a market share above [10-20]% (Boehringer, [10-20]%) and two further players with market shares above 5%. The overlap among the Parties activities is of [5-10]%.

355. In the UK the resulting entity will become the market leader with a market share of [30-40]%. The overlap among the Parties' activities is significant ([10-20]%). However three credible competitors with market shares above 10% will remain (Norbrook, [10-20]%; Vetoquinol, [10-20]% and SP/Intervet, [10-20]%), as well as a small but dynamic player, Virbac, with a market share of [5-10]%. Although difficulties to access the UK market have been reported by some competitors in the market test[101], the coexistence in this market of several strong players leads to consider that any such difficulties are not, as far as injectable penicillins are concerned, insurmountable, at least for large pharmaceutical companies.

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100 The Group 1 markets in the broad market definition encompassing injectable and oral products and in the narrower segment of injectable penicillins are the same.

101 Three significant competitors report difficulties in having access to the distribution channels in general, and two of them refer to commercial practices by Pfizer in the UK consisting in trading terms (global multi-product volume discounts) encouraging vets to source all their needs from a single supplier (Pfizer's programs *Pfizer Vet365+Scheme* and the *New Pfizer Vetsave scheme, the Total Purchasing Solution*).

356. In Italy Pfizer will remain post-transaction the largest player with a market share of [50-60]%. The overlap amongst the Parties' activities is significant ([5-10]%) although the resulting entity will still face competition from at least one significant rival, Ceva ([20-30]%), and three multinational companies with limited market share: Boehringer ([5-10]%), SP/ Intervet ([0-5]%), Virbac ([5-10]%). No specific barriers to access the Italian market have been reported. According to the Parties, Pfizer has lost its license permitting usage of *Clamoxil Long Acting* for cattle and sheep. This means that the product can now be used only for swine. Share is therefore expected to decrease for this reason by [0-5]% in 2009.

357. In view that all products in this market are off patent and that sufficient competition will remain post transaction in all countries, along with the expected decline in Pfizer's market share in Italy, serious doubts as regards injectable penicillins for production animals can be excluded as regards all Group 1 markets.

Mastitis in lactating cow in the Czech Republic, Slovakia and the United Kingdom

358. The market definition provided by the Parties is in line with the Commission's precedent in *Schering-Plough/Organon Biosciences* and has been confirmed by the participants in the market test. Therefore, the effects of the transaction are evaluated in the market comprising products for the treatment of acute mastitis mostly occurring during the lactation period, which requires daily and repeated administration of lactating cow products through a specially-designed syringe (injector tube) inserted into the animal's teat canal by which an antibiotic compound is then released into the udder.

359. Pfizer's products in this market are *Prisue, Tetra Delta, Lincocin Forte, Ampliclox LC, Pathozone/Peracef/Fortiperazone, Synulox LC, Orbenin LA*. With the exception of *Lincocin Forte*, all these products are manufactured for Pfizer by a third party[102]. Wyeth's products are *Nisamox LC* and *Kloxerate Plus MC*. Wyeth's products are also manufactured by a third party[103].

360. There is little product differentiation in this market as the active substances are basic antibiotics and the method of administration tends to be similar.

361. The combination of the Parties' activities in this market results in three Group 1 markets: Czech Republic, Slovakia and the UK.

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102 […], except for Tetra Delta which is manufactured by […].

103 […].

Country	PAH	FD	Combined	Competitors
Czech Republic	**[40-50]%**	**[0-5]%**	[40-50]%	**SP/Intervet [10-20]%; Virbac [0-5]%; Norbrook [20-30]%**
Slovakia	**[50-60]%**	**[0-5]**	[50-60]%	**SP/Intervet, [0-5]%; Merial, [0-5]%; Virbac [0-5]% Norbrook [30-40]%**
UK	**[50-60]%**	**[0-5]%**	[50-60]%	**SP/Intervet [20-30]%; Boehringer [10-20]%**

362. As shown in the table, the combination of the Parties' products results in very high market shares in the Czech Republic ([40-50]%, i.e. [40-50]% for Pfizer and [0-5]% for Wyeth), Slovakia ([50-60]%, i.e. [50-60]% for Pfizer and [0-5]% for Wyeth) and the United Kingdom ([50-60]%, i.e. [50-60]% for Pfizer and [0-5]% for Wyeth).

363. In the Czech Republic, the rivals of the merged entity will be Schering-Plough ([10-20]%), Virbac ([0-5]%) and the generics producer Norbrook ([20-30]%). In Slovakia the main rivals will be Schering-Plough ([0-5]%), Virbac ([0-5]%) and Norbrook ([30-40]%). In the UK the resulting entity will face competition from SP/Intervet ([20-30]%) and Boehringer ([10-20]%).

364. The Parties argue that overlaps in the three markets mentioned are limited (Wyeth, [0-5]% Czech Republic, [0-5]% in Slovakia and [0-5]% in the UK), as well as lack of specific entry barriers, threat resulting from generic competition, and rival's capacity to increase production to respond to supra competitive prices. They also refer to competition from mastitis vaccines.

365. In the market test the majority of the respondents are of the view that, as the Parties argue, there are no barriers to enter this market, particularly if an entrant aims at gaining a small market share and follows a generic strategy.

366. However one respondent indicates that if a high market share is targeted entry barriers are high because a differentiated/new product/brand strategy would be required and as this is a mature market with low margins the investment could be risky. The same respondent refers also to difficulties in the availability of raw material (antibiotic active ingredient), although only with respect to raw materials required for the production of old products based on antibiotics not used (or with limited use) in human medicine. Another respondent reports scarcity of manufacturing capabilities given that a specially-designed syringe is required for the administration of mastitis products and companies are either obliged to afford the specific required investment or to subcontract to one of their competitors in animal health.

367. The investigation shows that the entry barriers reported by the two respondents mentioned do not constitute a significant obstacle, particularly for large players or for innovative companies. The differentiation required for entry at large scale is not specific to mastitis and the Parties report the example of a small Spanish

company, Laboratorios Hipra S.A. ("Hipra"), which has recently entered small markets by means of a differentiated launch strategy[104]. This company has in addition developed a mastitis vaccine, Starvac, which received marketing authorisation from the Commission on 11 February 2009 and is now authorised for sale throughout the EU. The results of the market test indicate that Hipra is considered by some large players as a company likely to exert competitive pressure with its new entry strategy and its new product, as vaccination could replace to a certain extent traditional mastitis products. As regards the scarcity of manufacturing capabilities alleged, which would limit the ability of competitors to react to supra-competitive prices, the main companies producing mastitis products, including those producing the products sold by the Parties, have confirmed the availability of spare capacity as well as the inexistence of legal or contractual obstacles limiting its capacity to supply the needs of existing or potential new entrants in this market. This, along with the fact that both Parties rely on third party manufacturers for the production of their products, shows that the required specific facilities for the production of mastitis products does not constitute a significant barrier.

368. Therefore, in view of the above, taking into account the limited overlap among the Parties' activities (less then 5% in all cases), as well as the fact that at least one significant competitor with market shares above 20% will remain post transaction in all the Group 1 markets mentioned, along with other credible competitors, serious doubts can be excluded in all Group 1 markets analysed.

Mastitis in dry cow in the Czech Republic and Slovakia

369. The market definition provided by the Parties is in line with the Commission's precedent in *Schering-Plough/Organon Biosciences* and has been confirmed by the participants in the market test. Therefore, the effects of the transaction are evaluated in the market comprising products for the treatment of chronic infections causing an increased number of white blood cells in the milk, which is typically treated during the days of the year when the cow is not milked (dry-period).

370. Pfizer's products in this market are *Albadry Plus, Orbenin DC, Orbenin DC Extra*.Wyeths' products are *Kloxerate DC, Kloxerate Plus DC, Kloxerate Gold DC*. All these products are manufactured by a third party.

The combination of the Parties' activities results in two Group 1 markets: Czech Republic and Slovakia.

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104 According to the Parties, in general terms market participants will tend to launch their products in one of more of the larger national markets, which then helps to keep costs of goods low as manufacturing is expanded to supply more sub-segments. However companies such as the Spanish company Laboratorios Hipra S.A. ("Hipra") have pursued a strategy of launching in smaller sub-segments and building a reputation locally, demonstrating that entry in the smaller markets can be equally successful if focus is placed upon the launch strategy. Hipra has recently entered the market in the Czech Republic and is competing vigorously for share.

Country	PAH	FD	Combined	Competitors
Czech Republic	**[50-60]%**	**[0-5]%**	[60-70]%	**Norbrook [10-20]%; Virbac [10-20]%; SP/Intervet [5-10]%**
Slovakia	**[50-60]%**	**[0-5]%**	[50-60]%	**Virbac [5-10]%; SP/Intervet [5-10]%; Norbrook [10-20]%; Kela [5-10]%**

371. As shown in the table, the combination of the Parties' products results in very high market shares in Czech Republic ([60-70]%, i.e. [50-60]% for Pfizer and [0-5]% for Wyeth) and Slovakia ([50-60]%, i.e. [50-60]% for Pfizer and [0-5]% for Wyeth), although the overlap among the Parties' activities and, therefore, the impact of the proposed transaction on the pre-existing competitive situation, will be limited.

372. In the Czech Republic the rivals of the resulting entity will be SP/Intervet ([5-10]%), Virbac ([10-20] %) and the generics producer Norbrook ([10-20]%). The innovative company Hipra has recently entered the market and, according to the Parties, it is competing fiercely for share. In Slovakia the main rivals will be SP/Intervet ([5-10]%), Virbac ([5-10]%), Norbrook ([10-20]%) and Kela ([5-10]%).

373. The Parties' arguments and the results of the market test are comparable to those in the field of mastitis for lactating cow. The market test does not show any specific difficulties to entry these markets or to have access to the distribution channels in these countries.

374. Taking into account the limited overlap among the Parties' activities and the existence of credible competitors in these market, as well as the absence of specific entry barriers and the recent entry by Hipra in the Czech Republic, serious doubts can be excluded as regards the two Group 1 markets analysed.

Tetracycline Sprays for production animals in Portugal, Spain and the United Kingdom

375. Tetracycline Sprays are used regularly by farmers to spray external parts of production animals that either are at risk of infection or already infected. In serious cases of external infection, a spray may be used in conjunction with an injectable/oral antibiotic to help accelerate the healing process. Sprays have two primary functions: to apply the antibiotic directly to external area requiring treatment and to cover the area with a protective, highly resistant coating designed to stay on the animal's skin. Sprays tend to be applied once and must be sold by prescription only. Withdrawal periods vary, being longer for wounds than for treatment of the udder.

376. Pfizer's product is *Terramycin Spray*. Wyeth's products are *Dyphacycline spary/Nixal Spray*. These products and those of the Parties' competitors do not differ in efficacy or use because the active ingredients are the same. No products are patent protected in this segment. As the manufacturing of pressurised aerosols

requires dedicated facilities both Parties rely on toll manufacturing agreements for the production of their products[105].

377. The market definition proposed by the Parties is in line with the principles for market segmentation in the existing Commission precedents quoted in the market definition section insofar as it takes into account the active ingredient, the size of the animal and the mode of administration. Nothing in the market test leads to consider that this market definition is not appropriate in this case. This market encompasses all tetracycline sprays for production animals sold by the Parties.

378. The combination of Pfizer and Wyeth's activities results in three Group 1 markets: Portugal, Spain and the UK.

Country	PAH	FD	Combined	Competitors
Portugal	**[70-80]%**	**[5-10]%**	[80-90]%	**Norbrook [10-20]%**
Spain	**[10-20]%**	**[10-20]%**	[30-40]%	**Syva [10-20]%; Chemical Ibérica, [5-10]%; Hipra, [5-10]%; Invesa [5-10]%; Fatro [5-10]%; Ovejero [5-10]%**
UK	**[60-70]%**	**[0-5]%**	[60-70]%	**Ceva Sante Animale [10-20]%; Norbrook, [10-20]%; SP/Intervet, [0-5]%**

379. As show in the table the proposed transaction will result in very high market shares in Portugal where Pfizer will reinforce its already leading position as a result of the merger and will attain a market share of [80-90]%. The overlap is of [5-10]% and the only competitor remaining is Norbrook with a market share of [10-20]%. Although Norbrook is a strong generics' producer that according to the Parties entered the market 3 years ago, the transaction still results in the consolidation of Pfizer's leading position, in the elimination of the only existing branded competition and in the reduction of the already limited number of competitors from 3 to 2. New entries at a scale sufficient to compensate for the lost of Wyeth's as a competitor are unlikely in view of the *per se* reduced size of the market and the decreasing trend in terms of value reported by the Parties. The competitive pressure that could be exerted by local Spanish players that according to the Parties would have sales in Portugal without the requisite license would neither constitute a sufficient competitive constraint.

380. In Spain the resulting entity will become the market leader with a market share of [30-40]% but it will still face competition from 1 competitor with market shares above 10% (Laboratorios SYVA, S.A., [10-20]%) and up to 5 competitors with market shares of more than 5%. According to the Parties these competitors are active local players with production facilities near to market that benefit in rural areas from a competitive advantage. Therefore although the overlap among the Parties' activities is significant ([10-20]%) and the concentration operates a substantial change in the pre-existent competitive situation where multiple players of moderate size competed against each other and there was not a clear leader, sufficient competition remains. In addition, in view of the already existing

105 Wyeth's products are manufactured […] by […] or supplied by the generics' producer […] Pfizer's products are manufactured by […] under a […].

situation and taking into account the size of the Spanish market and the increasing trend in size reported by the Parties, new entries are more likely than in Portugal.

381. In the UK, the resulting entity will have a market share of [60-70]%. Although the Parties report a decline in Pfizer's share of over 10% during the period 2006-2008, pre-merger it still has a clear leading position with a market share more than 4 times higher than that of its next competitor (Ceva Sante Animale, [10-20]%). Wyeth's share would have remained stable during the mentioned period. Although the overlap among the Parties' activities is limited ([0-5]%) and two credible competitors will remain (Ceva Sante Animal, [10-20]% and Norbrook, [10-20]%) as well as a small player (SP/Intervet, [0-5]%) the concentration further deteriorates a pre-existing weak competitive situation in a country where, according to the market test, there are difficulties to access the market due to generalised multi-product volume discounts.

382. In view of the above, the proposed concentration gives raise to serious doubts as regards to its compatibility with the common market in view of its effects in the UK and the Portuguese markets for production animals tetracycline sprays.

Penicillin for companion animals (oral) Czech Republic, Italy, Slovakia, Spain and the United Kingdom

383. Penicillins, the oldest antibiotic class, are also used to treat infections in companion animals.

384. According to the Parties, the vast majority of penicillin products for companion animals is administered in an oral form as injectable penicillins need to be administered daily (or twice daily) by a vet. There are no *ad hoc* injectable penicillin products for companion animals but only products with claims for use in cattle, swine, dogs and cats and, therefore, there is no means of offering a reliable assessment of usage of injectable penicillin products for companion animals. In the Parties' view such usage would in any case be negligible. Therefore, the Parties have provided market share information for the market for oral companion animal penicillins. This was the market definition retained in *Pfizer-Pharmacia*. Nothing in the market test indicates that this market definition is not appropriate for the analysis of this case, with the exception to the reference made by one respondent to the possibility to undertake the analysis in the broad Beta lactams markets which has already been discussed.

385. The methods of administration of oral penicillin for companion animals fall into three categories: (i) tablets which are the most common form of oral treatment; (ii) drops for smaller animals usually administered by pipette into the mouth; and, (iii) palatable tablets with added flavourings. All products in the market are sold by prescription only and contain basic penicillins and synthetic penicillins.

386. Pfizer's products in this market are *Amoxi/Clamoxyl Oral, Clavamox/Clavulox/Synulox Oral, Clavamox/Clavulox/Synulox Oral, Synulox*

Drops, Synulox/Clavamox Tablets. These products are manufactured for Pfizer by a third party[106].

387. Wyeth's products are *Duphamox Tablets, Duphamox Drops, Nixsamox Tablets, Amoxival Tablets*. FD does not manufacture any of these products but only acts as a distributor[107] for these products.

388. The products of the Parties and their competitors do not differ in their efficacy or uses because the active substances are the same. All products in the market are off patent.

389. The combination of the Parties' activities in this market results in five Group 1 markets: Czech Republic, Italy, Slovakia, Spain and the UK.

Country	PAH	FD	Combined	Competitors
Czech Republic	**[30-40]%**	**[5-10]%**	[30-40]%	**GSK, [20-30]%; Novartis, [10-20]%; Norbrook [10-20]%; SP/Intervet [0-5]%, Vetoquinol, [0-5]%; Virbac, [0-5]%**
Italy	**[80-90]%**	**[0-5]%**	[90-100]%	**SP/Intervet, [0-5]%, Bayer, [0-5]%, Ceva Sante Animale [0-5]%**
Slovakia	**[30-40]%**	**[10-20]%**	[40-50]%	**GSK (Beecham), Lek [20-30]%; Novartis, [10-20]%; Norbrook, [10-20]%**
Spain	**[60-70]%**	**[5-10]%**	[60-70]%	**Vetoquinol, [10-20]%, Bayer [5-10]%, Karizoo, [5-10]%, Calier, [0-5]%, Esteve, [0-5]%, Fatro Uriach, [0-5]%, Divasa Farmavic, [0-5]%**
UK	**[40-50]%**	**[5-10]%**	[50-60]%	**Norbrook, [20-30]%, Vetoquinol, [10-20]%, Animal Care, [0-5]%**

390. In the Czech Republic Pfizer was already the market leader before the merger. Its market share will increase by [5-10]% from [30-40]% to [30-40]%. It will however still face competition from one significant competitor (GSK, [20-30]%) and two credible competitors with market shares above 10% (Novartis, [10-20]% and Norbrook, [10-20]%) as well as from three further players with limited market shares below 5%. Therefore although Wyeth was a relatively new entrant in this market having launched its product at the end of 2007 and, according to the Parties, having seen some growth since then, the number and strength of the competitors remaining post-merger would be sufficient to exert a competitive constraint on the resulting entity. In this regard account shall be taken that, according to the Parties, Novartis is a relatively new entrant that has already gained a strong share of [10-20]%.

391. In Slovakia, as a result of the concentration Pfizer will consolidate its position as clear market leader with a market share of [40-50]%. The overlap among the Parties' activities is significant ([10-20]%) and Wyeth is a new entrant in this market having successfully launched its product at the end of 2007 and having

106 […].

107 […].

been able to gain substantial market share. According to the Parties, the market will increase by 5% each year. Thus although the proposed concentration eliminates a new successful competitor in this market, Wyeth's success and the increasing market trend are indicators leading to consider that new entries are still possible. In addition, one significant competitor with a market share of [20-30]% (GSK) and two credible competitors with market shares above 10% will remain (Novartis [10-20]% and Norbrook, [10-20]%).

392. In the UK, Pfizer will reinforce its leading position. Post-merger it will have a market share of [50-60]%. The overlap is of [5-10]%. The resulting entity will face two competitors with market shares of [20-30]% (Norbrook) and [10-20]% (Vetoquinol), as well as other minor players with minimal sales. According to the Parties, it is expected that the size of the market will decrease. This along with the difficulties in having access to the distribution channels in the UK reported during the market test leads to consider that new entries are not likely at least at a scale sufficient to compensate the lost of Wyeth as a competitor.

393. In Spain, the proposed concentration will result in an increase of Pfizer's market share of [5-10]% and in the consolidation of its leading position with a market share of [60-70]%. Only one competitor with a market share above 10% will remain (Vetoquinol, [10-20]%). According to the Parties neither their shares nor the overall size of the market have altered in the period 2006-2008 and a decrease of 4-6% is expected for the next couple of years. Therefore new entries do not seem likely and the competitors remaining post merger seem weak if compared with the reinforced strength of Pfizer.

394. In Italy the resulting entity will have a market share of [90-100]%. Although the overlap among the Parties activities is limited ([0-5]%) and two competitors remain (Bayer, [0-5]% and SP/Intervet [0-5]%) the proposed concentration further deteriorates the pre-existing competitive situation. It cannot be considered that the companies remaining in the market will be in a position to exert a sufficient competitive constraint on the new entity.

395. In view of the above the proposed concentration results in serious doubts as regards its compatibility with the common market in view of its effects in the UK, Spain and Italy.

Cephalosporin for companion animals in Italy

396. Cephalosporins are new generation antibiotics priced higher than penicillin and tetracycline. Pfizer's sales in this market relate to its injectable cephalosporin product named *Convenia* sold throughout the EU, whereas Wyeth's sales are related to an oral product under the brand *Therios* 60, which is only sold in Italy.

397. The combination of the Parties' activities results in one Group 1 market: Italy.

CA Oral & Injectable Cephalosporins	Sales in euro	Shares of Sales
Total Segment Sales	**[…]**	**100,0%**
Pfizer Total	**[…]**	**[30-40]%**
Convenia	[…]	[30-40]%
Fort Dodge Total	**[…]**	**[10-20]%**
Therios 60	[…]	[10-20]%
Total Pfizer/Fort Dodge	**[…]**	**[40-50]%**
SP/Intervet	[…]	[30-40]%
Virbac	[…]	[5-10]%
Vetoquinol	[…]	[5-10]%

398. The overlap among the Parties' activities in this field has only arisen at a very late stage of the investigation. The substitutability between the oral and injectable cephalosporin products of the Parties for companion animals has not been market tested. Consumers of products for companion animals are less price sensitive than consumers of products for production animals. In addition the distinction between mass treatments and individual treatments which is relevant for production animals does not apply to the segment of companion animals. Therefore the conclusion drawn on the substitutability between oral and injectable treatments in the field of production animals cannot be extrapolated to the field of companion animals.

399. In view of the above the effects of the proposed transaction will be analysed in the broad market of cephalosporin (oral and injectable) for companion animals. There would be no overlap if only oral or only injectable products were considered.

400. As a result of the proposed transaction Pfizer will become the market leader in Italy with a market share of [40-50]%. It will still face as rivals SP/Intervet with a share of [30-40]% and the two dynamic French companies Virbac and Vetoquinol with market shares of [5-10]% and [5-10]% respectively.

401. According to the Parties *Convenia* could be considered a class or market of its own and, therefore, would be differentiated from Wyeth's product *Therios* 60: *Convenia* is an injectable niche product for skin and urinary tract infections applied only once with an efficacy of 14 days whereas *Therios* 60 is an oral product to be administered daily indicated for respiratory infections. *Convenia* is priced around [30-40]% higher than *Therios* 60. For a small cat or dog *Therios* 60 has a net price of € […] while the price of *Convenia* is around € […]. According to the Parties, if anything, Wyeth's cephalosporin product complements Pfizer's product.

402. The above considerations made by the Parties could in principle lead to consider that *Convenia* and *Therios* 60 are not close competitors. However the Parties' views have not been contrasted with third Parties and the characteristics of the remaining products in the market have not been investigated. In addition, the possibility for the Parties to apply supra competitive prices as a result of the transaction cannot be excluded in view of Pfizer's volume based multi-product discounts commercial practices.

403. In view of the above and as a result of the investigation in first phase, the proposed transaction raises serious doubts in view of its effect in the Italian market of cephalosporin for companion animals.

Analgesics and Anti-inflammatories

Sedatives in France, Germany, Ireland, Italy, Spain and the UK

404. In *Schering-Plough/Organon Biosciences* the analysis of anaesthesia products was conducted in the following separated markets: (i) general anaesthetic inhalants; (ii) general anaesthetics injectables; (iii) local anaesthetics; and, (iv) sedatives and pre-anaesthetics.

405. The Parties do not challenge the market definition adopted in the mentioned precedent, although they consider that a broader approach as regards this segment would be appropriate. They have provided data at the level of sedatives (all species) where their products overlap. Nothing in the market test leads to consider that this is not the correct market definition to be retained also in this case.

406. Pfizer sedative products are *Domosedan* (equine sedative), *Calmo Neosan* (companion animals), *Antisedan* (companion animals), *Dexomitor* (companion animals) and, *Domitor* (dogs). With the exception of *Calmo Neosan* all these products are produced by […] and sold by Pfizer in the EEA under a distribution arrangement.

407. Wyeth's products are *Equimidine/Detogesic* (horses), which is the generic version of Pfizer's *Domosedan*, and *Dorbene* (dogs), the generic version of Pfizer's *Domitor*. Other companies do also offer generic versions of *Domosedan* (CP-Pharma, Virbac, Divasa) and Debitor (Virbac). Wyeth's products are manufactured by the multinational company […] and by […]). Wyeth acts only as a distributor for these products.

408. With the exception of Pfizer's *Dexdomitor* which was just introduced recently the products offered by branded manufacturers in the sedatives market are off patent. The market is mature and there is a high degree of substitutability among all products. Sedatives are only sold under prescription.

409. The combination of the Parties' activities in the sedatives market results in six Group 1 markets: France, Germany, Ireland, Italy, Spain and the UK.

Country	PAH	FD	Combined	Competitors
France	**[40-50]%**	**[0-5]%**	[40-50]%	**SP/Intervet, [10-20]%; Ceva Sante Animale, [10-20]%; Virbac, [5-10]%; Bayer, [5-10]%, Novartis, [5-10]%, Boehringer, [0-5]%, Vetoquinol, [0-5]%**
Germany	**[40-50]%**	**[0-5]%**	[40-50]%	**CP-Pharma, [10-20]%; Bayer, [10-20]%; Vetoquinol, [5-10]%; Ceva Sante Animale, [5-10]%; Boehringer, [5-10]%; Albrecht, [5-10]%; Novartis, [0-5]%.**
Ireland	**[30-40]%**	**[0-5]%**	[30-40]%	**Ceva, [20-30]%; Vetoquinol, [20-30]%; Dechra, [10-20]%; Boehringer, [0-5]%; Chanelle, [0-5]%.**
Italy	**[40-50]%**	**[0-5]%**	[40-50]%	**SP/Intervet, [10-20]%; Virbac, [10-20]%; Ceva Sante Animale, [5-10]%; Novartis, [5-10]%; Bayer [0-5]%; Fatro, [0-5]%; Boehringer, [0-5]%**
Spain	**[50-60]%**	**[0-5]%**	[60-70]%	**Divasa, [10-20]%; Esteve, [5-10]%; Bayer, [5-10]%; Boehringer, [0-5]%; Virbac, [0-5]%; Vetoquinol, [0-5]%; Labiana, [0-5]%; Karizoo, [0-5]%**
United Kingdom	**[50-60]%**	**[10-20]%**	[60-70]%	**Vetoquinol, [10-20]%; Boehringer, [5-10]%; Novartis, [5-10]%; Dechra, [5-10]%; Bayer, [0-5]%; Virbac, [0-5]%; Alstowe Animal Health, [0-5]%; Ceva Sante Animale, [0-5]%; Vetapharma, [0-5]%; Animal Care, [0-5]%; Millpledge, [0-5]%.**

410. In France, the Parties' combined market share is [40-50]% (i.e Pfizer, [40-50]% and Wyeth, [0-5]%). Although Wyeth is a new entrant in the French market, the overlap amongst the Parties' activities is only of [0-5]%, Pfizer was already the market leader before the merger and it was confronted to two credible players with market shares above 10% (SP/Intervet, [10-20]%, Ceva Sante Animale [10-20]%), three players with market shares above 5% (Virbac, [5-10]%; Bayer, [5-10]% and Novartis, [5-10]%) and three minor competitors with market shares below 5% (Boehringer, [0-5]%, Vetoquinol, [0-5]% and Wyeth, [0-5]%). The proposed concentration will only have as a result the reduction of the number of minor players from three to two.

411. The situation in Germany is similar to the situation in France. The Parties' combined market share will be of [40-50]% (i.e. Pfizer [40-50]% and Wyeth [0-5]%). The overlap is of only [0-5]%. Pfizer was already the market leader in this market. Post-transaction it will still face competition from seven large players, two of which have market shares above 10% (Bayer, [10-20]% and CP-Pharma, [10-20]%), instead of the eight existing before the merger.

412. In Ireland, the Parties' combined market shares is [30-40]% (i.e Pfizer [30-40]% and Wyeth [0-5]%). The overlap is of [0-5]%. The resulting entity will remain the market leader and will still face competition from five companies, two of them with market shares above 20% (Vetoquinol, [20-30]% and Ceva [20-30]%).

413. In Italy, the resulting entity would have a market share of [40-50]% (i.e, Pfizer [40-50]% and Wyeth, [0-5]%). The increment in share is of [0-5]%. The major competitors post-merger would be SP/Intervet ([10-20]%), Virbac ([10-20]%) and Ceva Sante Animale ([5-10]%). A number of large players with lower market shares (Novartis, [5-10]% and Bayer, [0-5]%, Boehringer, [0-5]%) and the local

company Fatro (2,7%) would also remain. The proposed concentration will not modify Pfizer's leading position and will only eliminate one of Pfizer's smallest competitors in this market.

414. The combined market share of the Parties in Spain would be of [60-70]% (i.e. Pfizer [50-60]% and Wyeth, [0-5]%). The overlap is of [0-5]%. Post-transaction, the resulting entity will compete with four multinational players with non-negligible market shares (Bayer, [5-10]%; Boehringer, [0-5]%; Virbac, [0-5]%; Vetoquinol, [0-5]%), with two local players with a well established presence (Divasa, [10-20]%; Esteve [5-10]%) and with a number of smaller players. Ease of entry is illustrated by the fact that five new generic products entered the market in the last two years[108]. Therefore the effects of the transaction on the competitive situation are limited in view of the reduced overlap, the presence of well established local players and the openness of the market to new entries.

415. In the UK, the increment of [10-20]% will bring Pfizer's share to [60-70]%. There are three competitors having a share in the range of [5-10]%-[10-20]% (Vetoquinol, Boehringer and Novartis) and the generics producer Dechra achieves [5-10]%. However, before the merger Wyeth was in this market the second largest player with a market share having increased by around [5-10]% in the period 2006-2008. Therefore, the transaction will have as a result the elimination of a dynamic company with increasing shares which is Pfizer's closest competitor.

416. In view of the above it can be concluded that the proposed transaction results in serious doubts as to its compatibility with the common market in view of its effect in the UK market. Serious doubts can however be excluded as regards its effects in France, Germany, Ireland, Italy and Spain.

Corticosteriods in the United Kingdom

417. Corticosterioids are anti-inflammatory products acting on the immune system by blocking the production of substances that trigger inflammatory actions.

418. The market definition proposed by the Parties is in line with the Commission's precedent in *Schering-Plough/Organon Biosciences* and has not been contested by the participants in the market test. Therefore the proposed concentration has been analysed in a market including corticosteroids multispecies.

419. The combination of the Parties' products in this field results in one Group 1 market, the UK. Pfizer's products sold in the UK are *Solumedrol, Medrol* and *Moderin/Medrone*. Wyeth sells *Duphacort Q.*

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[108] According to the Parties, Divasa Farmavic S.A. launched Domidine in 2007, a generic version of *Domosedan* and in 2008 it launched. The same company also launched *Sedator* in 2008, a generic of *Domitor*. Wyeth launched 2 generic products in 2008, *Dorbene* and *Detogesic*. Virbac launched 3 generic products in 2008, *Medetor*, *Revertor* and *Medesean*.

420. The combination of the Parties activities in the UK results in a market share of [50-60]% (i.e. Pfizer [40-50]% and Wyeth [0-5]%). The resulting entity will have as rivals Boehringer ([10-20] %), Dechra ([10-20]%) and Animalcare ([5-10]%). This is a highly generisised market of decreasing value where all products are off patent. Pfizer's market share fell [5-10]% in the period 2006-2008.

421. The participants in the market test have not raised concerns as regards this market.

422. Therefore, in view of the result of the market test and taking into consideration the above mentioned factors, serious doubts can be excluded.

4.3.8. Medicinal Feed Additives

Oral rehydration salts

Product market definition

423. Oral rehydration products are medicinal feed additives that correct dehydration, particularly as a consequence of diarrhoea. Administration is some orally by dissolving the table or powder in water. The products generally contain similar components to redress electrolyte imbalances in the diarrhoeic animal, with minor differences in formulation.

424. The Parties submit that no significant differences exist between products presented for companion animals and production animal, except in dosage size. Nothing in the market investigation leads to consider that this is not the correct market definition. However for the purposes of the assessment of the present transaction the market definition can be left open since the Parties plan to remove the sales overlap by way of a divestment at the EEA level.

Assessment

425. Pfizer sells oral rehydration salts under the brands *Lectade*, *Biodiet 50*, *Scour Formula*. Pfizer manufactures these products at its facility in Amboise, France. Wyeth sells oral rehydration salts under the brands *Effydral* and *Efferhydran* and manufactures its products through a toll manufacturer. The finished product is released by the quality assurance and control department at Wyeth's facility in […].

426. The combination of the Parties' activities results in four Group 1 markets: Austria, Germany, Ireland and the United Kingdom.

Country	Pfizer	Wyeth	Combined	Competitors
Austria	**[0-5]%**	**[40-50]%**	**[40-50]%**	**Virbac [10-20]%; Richter Phama [5-10]%; Vetoquinol [5-10]%; Prozoon [5-10]%; Bayer [0-5]%; Others [5-10]%**
Germany	**[5-10]%**	**[30-40]%**	**[40-50]%**	**Ceva [10-20]%; Virbac [40-50]%**
Ireland	**[70-80]%**	**[10-20]%**	**[80-90]%**	**Schering Plough [5-10]%; Ceva [0-5]%**
United Kingdom	**[60-70]%**	**[10-20]%**	**[70-80]%**	**Norbrook [10-20]%; Ceva [5-10]%; Forum [0-5]%; Others [0-5]%**

427. According to the Parties due to the generic nature of the product, all oral rehydration salts are substitutable. However some of the products are over the counter products and are easier for veterinarians to distribute. The non-negligible overlap between the Parties' activities makes the resulting entity the market leader in each of the affected Group 1 markets. With the exception of Austria, the market is very concentrated and the resulting entity would face competition mainly from local or small players.

428. In Austria the Parties will remain the market leader in a market that, according to the Parties, is expected to remain stable or to decrease. In Germany the Parties would face competition from two rivals only, thus reducing the already low number of players in the market. In Ireland and in the UK the resulting entity would have very high market share facing competition from few small players.

429. Given the barriers to entry, the small incentive in entering a mature or decreasing market, the Commission concludes that the proposed transaction raises serious doubt as to its compatibility with the common market and the EEA agreement on the market for oral rehydration salts in Austria, Germany, Ireland and the United Kingdom.

4.4. Conclusion – Serious Doubts

430. For the reasons set out above, the Commission concludes that the notified operation gives rise to serious doubts as regards its compatibility with the common market and the EEA-agreement for the following markets in the field of animal health:

Vaccines:

(1) Multivalent feline vaccination programmes in Belgium, Denmark, Greece and Ireland

(2) Cattle *pasteurella* vaccines in Spain and Italy

(3) Multivalent cattle respiratory vaccines in Portugal, Spain and Italy

(4) Monovalent swine *mycoplasma hyopneumoniae* vaccines in Austria, Belgium, the Czech Republic, Denmark, France, Germany, Greece, Italy, Lithuania, the Netherlands, Poland, Portugal, Slovakia, Spain and the United Kingdom

(5) Monovalent influenza vaccines for horses in Denmark, Germany, Slovakia, Sweden and the United Kingdom

(6) Monovalent tetanus vaccines for horses in the United Kingdom

(7) Multivalent influenza/tetanus vaccines for horses in Denmark, Finland, Germany and the United Kingdom

(8) […] vaccines in Austria, Belgium, the Czech Republic, Germany, Greece, Ireland, the Netherlands, Portugal, Slovakia, Spain and the United Kingdom

Pharmaceuticals:

(9) Production animal endoparasiticides and endectocides in Belgium, Germany and the UK

(10) Endoparasiticides and endectocides for horses in the UK

(11) Companion animals endoparasiticides and endectocides in Italy

(12) Production animals tetracycline in Finland and Italy

(13) Tetracycline sprays, in the UK and Portugal

(14) Penicillin for companion animals (oral) in the UK, Spain and Italy

(15) Cephalosporins for companion animals in Italy

(16) Sedatives in the UK

Medicinal feed additives:

(17) Oral rehydration salts in Austria, Germany, Ireland and the United Kingdom.

5. MODIFICATION OF THE PROPOSED OPERATION

5.1. Description of the Commitments

431. In order to remove the serious doubts resulting from the proposed transaction, Pfizer formally submitted commitments to the Commission on 29 June 2009. The commitments were modified on 3 July 2009 and modified further on 7 July 2009 and on 16 July 2009.

432. The commitments consist in the divestiture of specific products for each of the markets with serious competition concerns. In the field of vaccines a manufacturing plant is also divested in addition to the relevant products because the existing production capacity is scarce and building new capacity is a lengthy and complex process. In the field of pharmaceuticals, as production capacity is not a key issue, production plants are not divested. However, the commitments foresee the provision of the necessary technical assistance to allow the purchaser(s) to manufacture the products or to make the necessary arrangements for third party manufacturing, as well as the transfer of personnel. Transitional supply arrangements are also included in order to avoid supply disruptions. As regards products for which the Parties act only as distributors Pfizer commits to provide adequate technical assistance and personnel in order to ensure the rapid replacement of the Parties as distributors by the purchaser. The divestiture of alternative products is foreseen in order to ensure the removal of competition concerns in case such replacement could not be implemented.

433. The detailed text of these commitments is annexed to this Decision. The main elements of the commitments, as modified, are summarised below.

5.1.1. Animal vaccines

434. In the field of animal vaccines, Pfizer commits to divest the vaccines businesses listed below ("the Vaccines Divested Businesses") and Wyeth's manufacturing facility in Sligo, Ireland ("the Sligo Manufacturing Facility"). The Vaccines Divested Businesses and the Sligo Manufacturing Facility shall be divested as a bundle to a single purchaser. However, Pfizer may divest the Vaccines Divested Businesses singly or in combination(s) to one or more purchasers with consent of the Commission without the Sligo Manufacturing Facility if the respective purchaser or the respective purchasers have access to a production facility that has capacity for the relevant vaccine available. This is a compulsory requirement that applies in addition to the remaining purchaser requirements defined in the remedies.

435. The Vaccines Divested Businesses are the following:

(1) Wyeth's *Presponse* branded monovalent cattle pasteurella vaccine business in the EEA and the *Triangle 4 PH-K, Triangle 4, Triangle 4 +L/9, Triangle 3, and Pyramid MLV-4* branded multivalent cattle respiratory disease vaccine business in the EEA;

(2) Wyeth's *Duvaxyn IE Plus, Duvaxyn IE Vet and Duvaxyn Vet* branded monovalent equine flu vaccine business in the EEA; *Duvaxyn T and Tetanus Toxois* branded monovalent equine tetanus vaccine business in the EEA; *Duvaxyn IE-T Plus, Duvaxyn IE-T Vet, Duvaxyn-T Vet, and Duvaxyn Plus Vet* branded multivalent equine flu/tetanus vaccines business in the EEA and rights to a pipeline product for […].

(3) Pfizer's *Stellamune/Respisure* and *Stellamune One/Respisure One* (monovalent swine mycoplasma hyopneumoniae vaccines) branded swine vaccine business in the EEA, and the pipeline project […], including at the option of purchaser update of […] product;

(4) Pfizer's *Felocell CVR*, *Felocell CVR-C* and *Felocell RC* branded multivalent feline vaccine business in the EEA.

436. The divestiture of the Vaccines Divested Businesses will proceed by way of one or more asset divestiture transactions. Each divestiture shall include, inter alia, the following elements: (i) the non-exclusive right to manufacture the products and the exclusive right to sell the above products; (ii) all the improvements existing at the effective date and the rights to improve the transferred products; (iii) all tangible and intangible assets, including intellectual property rights necessary to ensure the viability and competitiveness of the Vaccines Divestment Businesses; (iv) all licenses, permits and authorisations issued for the benefit of the Vaccines Divestment Business; (v) all contracts, leases, commitments and customer orders of the Vaccines Divestment Businesses; and (vi) all customer credit and other records of the Vaccines Divestment Businesses[109].

437. As an option of the purchaser, the Vaccines Divested Businesses will also include the transfer of sufficiently qualified sales and marketing personnel employed by the Parties, as well as the benefit from all current arrangements under which the Parties supply products and/or reasonable technical assistance to enable the purchaser to assume responsibility for the manufacture, sale and marketing of the relevant Vaccines Divested Businesses, for a transitional period of 36 months after Closing, on a reasonable cost plus basis[110].

438. The Monitoring Trustee may also extend the duration of the transitional arrangements if, under circumstances outside the control of Pfizer or the

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[109] The Parties confirmed that, amongst other things, the following elements are included: access to documents on animal testing arrangements, quality testing reagents, working seeds and cell seeds, master batch records, periodic safety reports, pharmacological vigilance reports, access to materials supply contracts.

[110] With the exception of technical assistance related to the procurement of equine tetanus toixoid for the production of equine vaccines that ends in […].

purchaser, such extension is required by the purchaser to establish the Vaccines Divested Business[111].

439. The Sligo Manufacturing Facility is located in the Finisklin Industrial Estate in Sligo, Ireland, and has been in operation since 1992. It currently employs 102 persons and manufactures a range of both modified live (MLV) and inactivated veterinary vaccines. The Sligo Manufacturing Facility was designed specifically to manufacture veterinary vaccines to EU GMP standards. The current Sligo Manufacturing Facility has the capability to manufacture a range of vaccines, though not all of the Vaccines Divestment Businesses[112]. However, the Sligo Divestment Business will have the capability to manufacture all of the vaccines manufactured by the Vaccines Divestment Businesses acquired by the purchaser following certain modifications and capital improvements which Pfizer will commit, at the option of the purchaser, to undertake and/or fund, to ultimately deliver the Sligo Manufacturing Facility as a fully functional manufacturing facility capable of manufacturing each one of the vaccines divested.

440. The scope of the divestment of the Sligo Manufacturing Facility will include, inter alia: (i) the existing manufacturing facility with its buildings and equipment and other assets necessary for the production and testing of veterinary biological products; (ii) the capital expenditures and improvements that Pfizer commits to undertake at the purchaser's option to enable the manufacturing of the divested vaccines; (iii) the opportunity to hire the existing manufacturing, support and administrative personnel; (iv) technical assistance to operate the plant; (v) assistance in obtaining necessary permits and registrations; and (vi) copies of all relevant data, books, records and other elements necessary for the operations of the Sligo Manufacturing Facility.

441. The scope and elements of the technical assistance will be negotiated by Pfizer with the purchaser under the supervision of the Monitoring Trustee.

442. An *ad hoc* hold separate manager (the "Sligo Hold Separate Manager"), under the supervision of the Monitoring Trustee, shall ensure that appropriate capital expenditures and improvements are undertaken by Pfizer at the purchaser's option after signing in order to enable the facility to accept and manufacture the divested vaccines.

5.1.2. Animal Health Pharmaceuticals

443. In the field of animal health pharmaceuticals, Pfizer commits to divest a number of businesses ("Pharmaceuticals Divested Businesses") and distribution businesses ("Pharmaceuticals Divested Distribution Businesses")

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111 With the exception of the duration of the technical assistance related to the procurement of equine tetanus toixoid for the production of equine vaccines that […].

112 The following subset of the […] vaccines are the only Vaccines Divested Businesses manufactured at the Sligo Plant: […].

444. The Pharmaceuticals Divested Businesses are the following:

(1) Pfizer's *Banminth* for horses and the *Strongid* for horses branded equine endoparasaticides-endectocides products in the UK;

(2) Wyeth's *Guardian* branded companion animals endoparasaticides-endectocides products in the EEA;

(3) Pfizer's *Valbazen* and *Dectomax* branded production animal endoparasaticides-endectocides products in Belgium[113], Germany and the UK;

(4) Wyeth's tetracycline sprays products sold by Wyeth in Portugal, including the *Duphacycline Spra*y and/or *Nixal* trademarks currently held by Wyeth in Portugal.

445. The elements and transitional arrangements of the Pharmaceuticals Divested Businesses are equivalent to those applying to the Vaccines Divested Businesses.

446. The Pharmaceuticals Divested Distribution Businesses are listed below:

(1) Distribution agreement between Pfizer and […] for the distribution of *Domosedan, Domitor, Dexdomitor* and *Antisedan* sedative products in the UK ("[…] Agreement");

(2) Distribution arrangement between Wyeth and […] for the distribution of *Duphamox* (tablets and drop) and *Nisamox* (tablets) companion animal oral penicillin products in the EEA; oxytetracycline sprays in Austria, the Czech Republic, Belgium, France, Germany, Hungary, Iceland, Italy, the Netherlands, Slovakia and the UK; *Duphacycline LA* and *Dyphacycline 300 LA* AIF production animal tetracycline products in Finland and Italy ("[…] Agreement").

(3) Distribution agreement between Wyeth and […] for the distribution of *Amoxival* oral companion animal penicillin products in Italy and for the distribution of *Therios 60* companion animal cephalosporin products in Italy ("[…] Agreement").

447. The transfer of the […] and […] Agreements will include, inter alia: (i.) finished goods inventory, work in process, sales and promotional material; (ii.) marketing authorisations held by the Parties and pending applications; (iii.) copies of clinical reports; (iv.) trademarks used in connection with the sale of the products covered by the commitments to the extent this is legally feasible; and (v.) copies of all relevant data, books or records, and other documents necessary for the operations of the Pharmaceuticals Divested Distribution Businesses.

113 Includes also Luxembourg.

448. At the option of the purchaser, the relevant Pharmaceuticals Divested Distribution Businesses will also include the transfer of sufficient qualified sales and marketing personnel employed by the Parties, as well as the technical assistance required for the purchaser to assume responsibility for the sale and marketing of the products. Such technical assistance will be provided by Pfizer on a reasonable cost plus basis during a period of up to 24 months from the Closing date.

449. In order to achieve the transfer of the mentioned Agreements, Pfizer commits to use all reasonable best efforts to agree with the corresponding counterparty (i.e. […] or […]) the transfer of the corresponding agreement to one or more third parties or to the counterparty for distribution by that counterparty.

450. During the First Divestiture Period, Pfizer can choose instead of transferring the relevant Pharmaceuticals Divested Distribution Businesses to divest part of the respective competing business retained by Pfizer. To the extent that at the end of the First Divestiture Period Pfizer has not reached an agreement with the counterparty of the Agreements, Pfizer shall grant to the Divestiture Trustee an exclusive mandate to sell the alternative divestment businesses listed below.

451. The alternative divestment businesses ("Alternative Divestment Businesses") consist of:

(1) […] branded companion animal oral penicillin business in […];

(2) […] branded tetracycline sprays in the UK and/or in Portugal;

(3) […] branded AIF Production animal tetracycline products in Finland and Italy;

(4) […] branded companion animal cephalosporin business in Italy.

452. The elements and transitional arrangements of the Alternative Divestment Businesses are equivalent to those applying to the Vaccines Divested Businesses.

5.1.3. Medicinal Feed Additives

453. In the field of animal health medicinal feed additives, Pfizer commits to divest:

(1) Pfizer's Lectade, Lectade Plus, Lectade Small Animals, Scour Formula and Scout Formula Extra branded oral rehydration salts business in the EEA.

454. The elements and transitional arrangements of this commitment are equivalent to those applying to the Vaccines Divested Businesses.

5.2. Assessment of the Commitments

5.2.1 Suitability for removing the serious competition concerns

455. The commitments submitted by Pfizer address the competition concerns. The divestiture of specific products leads to a complete removal of the overlap. There are only a few exceptions where the complete overlap is not removed but in these cases the divesture leads to a significant reduction in market share that permits to eliminate the competition concerns identified. As an example, in the UK market for production animal endo-endectocides where Pfizer committed to divest its own business instead of Wyeth's business, Pfizer's product *Autoworm/Systamex* will not be divested. However, as other viable products and brands with significant market share are divested (i.e. *Valbazen and Dectomax* branded products) the commitment leads to a reduction in Pfizer's market share of [10-20]% and a combined market share of less than [20-30]%, which permits to eliminate the serious competition concerns in this market, even without the product *Autoworm/Systamex*.[114]

456. The technical assistance, transfer of personnel and transitional supply arrangements foreseen in the commitments ensure with the necessary degree of certainty the timely implementation of the commitments and the removal of the competition concerns, as well as continuity in customer's supply.

457. In relation to the Pharmaceuticals Divested Distribution Businesses the Commission concluded that the necessary degree of certainty of the implementation of those commitments was not met since the transfer of those businesses would depend on the approval by the supplier of the products. This problem was generally addressed by including the Alternative Divestment Businesses in the commitments package. The divestiture of those businesses will also ensure the elimination of the competition problems and meets the necessary degree of certainty in relation to the implementation of the commitments for those markets.

458. A geographic scope covering other countries in addition to those with serious competition concerns was required in view of the viability issues raised during the market test. However, Pfizer has the right to narrow the scope of the commitments, but in no event to less than the Member States where the Commission has raised serious doubts in the present Decision, if the purchaser may prevented from acquiring one or more of the Vaccines and/or Pharmaceuticals Divested Business or Pharmaceutical Divested Distribution Business because of overlaps in countries not identified in the Decision as rising competition concerns or because of lack of interest of the purchaser in one or more of these countries. The final purchase agreement is subject to Commission's approval and the Commission may approve such purchase agreement without one or more Member States not raising serious competition concerns only if this does not affect the viability and competitiveness of the transferred business.

5.2.2 Viability and modification of the initial commitments in view of the market test

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114 *Autoworm* is a product which was transferred by Schering Plough to Pfizer in the framework of the implementation of the remedies agreed in the *Schering Plough/Organon Biosciences* decision (Case M. 4691). The process of the transfer is still on-going.

459. The market test confirmed that the approach of the divestiture of certain products for specific markets was acceptable. However, the market test also revealed certain issues of viability in relation to the initial commitments proposal and enabled the Commission to identify certain issues that needed to be rectified and which are further described below. The market test also gave more specific indications regarding the need for the transfer of a vaccines production facility and the transfer of sales staff.

460. In order to address the issues raised in the market test, Pfizer modified the commitments. Some elements of the commitments and the main modifications are summarised below.

Divestment of the Sligo Manufacturing Plant

461. The Parties had initially foreseen the possibility to divest the Vaccines Divested Businesses singly or in combination to different purchasers without the Sligo Manufacturing Plant, disregarding whether the purchaser had or not access to production capacity. The divestment of the plant was foreseen at the option of the purchaser only in case the purchaser would acquire all or a minimum set of Vaccines Divested Businesses and "to the extent reasonably required".

462. The market test confirmed that production capacity for vaccines is scarce in the EEA and that the building or transfer of production capacity is a lengthy and complex process (see also above in relation to the entry barriers for the vaccine markets). Therefore, in order to ensure the implementation of the commitment and the viability of the vaccines divestiture package, Pfizer committed to divest the Vaccines Divested Businesses and the Sligo Manufacturing Plant as a bundle to a single purchaser, except if the purchaser or purchasers have access to a production facility that has capacity for the relevant vaccines available. In this case the consent of the Commission is required. The inclusion of a plant was required as this will widen the scope of the potential purchasers to those which may not yet be active to a significant extent in the supply of animal health vaccines in the EEA or do not have the spare capacity to supply the divested vaccines. Generally, a divestiture of the vaccines without the transfer of the plant will likely only be viable if the purchaser already has access to a production facility that has sufficient spare capacity available for the specific vaccine.

463. The Sligo plant may require some modifications and improvements to enable the production of the vaccines transferred to the Sligo Manufacturing Plant, as not all of the divested vaccines are produced at this plant. Pfizer has committed to modify the plant and to fund those modifications once they have come to a conclusion of a contract with a purchaser. In the modified version of the commitments Pfizer committed to appoint the Sligo Hold Separate Manager in order to ensure that the modifications and improvements required to enable the manufacture at the Sligo Manufacturing Plant of the vaccines transferred are carried out in a timely and appropriate manner permitting the purchaser to operate the Vaccines Divested Businesses as viable and competitive businesses.

Scope of the Vaccines Divested Business

464. The scope of the Vaccines Divested Businesses as initially proposed by the Parties was EEA, except for the Vaccines Divested Business concerning feline vaccines which was limited to the countries were competition concerns had been raised. In the schedule of the commitments the Parties had offered the possibility to proceed to an EEA wide divestiture also in respect of feline vaccines, should viability concerns arise during the market test, provided Pfizer was allowed to retain a copycat licence to allow it to manufacture and sell these vaccines under a new brand name in the EEA countries, with the exception of those countries were competition concerns had been identified.

465. The results of the market test confirmed that in view of the scale of the investment required for R&D, maintaining product authorizations, manufacturing, sale and successfully market vaccines, only an EEA-wide divestment is viable. Therefore, Pfizer modified the commitment extending the geographic scope of the Vaccines Divested Businesses concerning feline vaccines to be EEA-wide[115].

466. The market test has also indicated that vaccines are regularly changing and may take significant time to improve. For this reason, the future versions of divested vaccines as well as the rights to improve them should be available to the purchaser. Given that the commitments initially did not cover all the relevant pipeline projects, the parties have further committed to divest the following: the pipeline project for […] Wyeth's […] equine […] vaccine and, at the option of the purchaser, the rights to the pipeline project for […] Pfizer's […] swine […] vaccines. In addition, the parties committed to include all the product improvements existing at the effective date and the rights to improve the divested products.

Scope of the Pharmaceuticals Divested Businesses

467. The market test revealed concerns also as regards the viability of the Pharmaceuticals Divested Businesses concerning production animal endo-endectocides in view of the geographic scope initially proposed (Belgium, Germany and the UK). According to some respondents, for this Pharmaceuticals Divested Business to be viable and in order to reach a minimum critical mass, France should be added to the list of countries where products were to be divested. Pfizer provided arguments showing that the sales of this Pharmaceuticals Divested Business amount to € […], which is already [30-40]% of the entire EEA sales of Pfizer's business, and that its EBITDA in the three divested countries is positive and healthy. The addition of the French business would amount to the addition of […] EUR (i.e. almost doubling the size of the divested business). Therefore, the Commission concluded that the addition of France was not required.

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115 Pfizer will be allowed to retain a copycat licence to be able to manufacture the feline vaccines under a new brand name(s) except in the countries where the Commission has raised serious doubts.

Concerns were raised during the market test also as regards access to supply to the active pharmaceutical ingredients (APIs) required for the production of Wyeth's companion animals endoparasiticides at the end of the transitional arrangements given that these APIs are patent protected. Pfizer provided evidence showing that the patent will expire at the end of 2009 and they committed to supply the APIs until such date plus one additional year.

Scope of the Pharmaceuticals Divested Distribution Businesses

468. Pfizer added to the initial commitments the Pharmaceuticals Divested Distribution Business concerning companion animal cephalosporins in Italy (the only country where Wyeth is active) because concerns regarding this market aroused only at a very late stage of the review process.

Pharmaceuticals Divested Distribution Businesses, Crown Jewels

469. The Commission considered that as the transfer of the Pharmaceuticals Divested Distribution Business is dependent upon consent by the corresponding counterparty in each of the agreements, as well as on the legal feasibility of the transfer of certain assets (e.g. trademarks not owned by the Parties)[116], Crown Jewels were required in order to ensure the removal of the competition concerns identified. Therefore, Pfizer committed to divest as Crown Jewels the above mentioned Alternative Divestment Businesses.

470. Only the Pharmaceuticals Divested Distribution Business concerning sedatives is not backed by a crown jewel. The Commission considered this acceptable in view that Pfizer submitted a […] for the transfer of the Pharmaceuticals Divested Distribution Business on sedatives to […], that should either act for the countries where concerns have been identified as distributor in substitution of Pfizer, or appoint a new distributor meeting the purchaser requirements in this Decision. […] would be in principle a purchaser not raising *prima facie* competition concerns.

116 For example there are legal obstacles to the transfer of some trademarks used by the Parties in relation to […] under the […] Agreement. Should the parties not manage to overcome these legal obstacles, the alternative divestment becomes relevant.

Technical assistance and transitional arrangements

471. Most respondents considered the two-year duration of the transitional arrangements and technical assistance originally foreseen as regards the majority of the Vaccines Divested Businesses and Pharmaceuticals Divested Businesses insufficient. Therefore, Pfizer committed to extend such period in all cases to 36 months[117] with the possibility for the Monitoring Trustee to further extend its duration if, under circumstances outside the control of Pfizer or the purchaser, such extension is required by the purchaser to establish the Vaccines Divested Business or the Pharmaceuticals Divested Businesses .

472. In addition, Pfizer committed to provide technical assistance and transitional arrangements on a […] basis in all cases, instead of […]rate[…] as initially proposed.

5.2.3. Conclusion

473. In view of the above modifications, the Commission considers that the Vaccines Divested Businesses along with the Sligo Manufacturing Plant, or the Vaccines Divested Businesses alone, if the purchaser has access to manufacturing facilities that have enough spare capacity for the production of the vaccines transferred, as well as the Pharmaceuticals Divested Businesses and the Pharmaceuticals Divested Distribution Businesses are viable businesses and that the modalities foreseen for their transfer will enable their operation by the corresponding purchaser(s) in a competitive and viable manner. The market test confirms the viability of all the businesses to be transferred, including the Pharmaceuticals Divested Distribution Businesses and the Alternative Divested Businesses as there is a number of potential purchasers for each of them.

474. The commitments will permit to address the competition concerns identified in the present Decision. They remove the overlap between Pfizer and Wyeth, with few exceptions where, nevertheless, significant reductions in market shares are achieved, in all markets rising serious competition concerns.

475. The Commission therefore considers that the commitments, as modified, are sufficient to eliminate all serious doubts as to the compatibility of the transaction with the common market and the EEA Agreement.

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117 With the exceptions already mentioned concerning technical assistance for the procurement of equine tetanus toxoid for the manufacturing of equine vaccines.

5.3. Conditions and obligations

476. In order to ensure that Pfizer complies with these commitments, the Commission attaches conditions and obligations to this decision. The commitments set out in Section B paragraphs 1, 2, 3, 4 and 5, Section C paragraphs 7, 8, 11 and 12, Section D paragraphs 13, 14, 15, 16 and 17 of the commitments annexed to the present Decision constitute conditions, since only by fulfilling them may the structural change on the relevant markets be achieved so as to eliminate the serious doubts identified by the Commission. The other commitments constitute obligations, since they concern the implementing steps necessary to achieve the structural change intended to eliminate the serious doubts identified by the Commission.

6. CONCLUSION

477. For the reasons set out above, the Commission has decided not to oppose the notified operation and to declare it compatible with the common market and the EEA Agreement, subject to full compliance with: (i.) the conditions in Section B paragraphs 1, 2, 3, 4 and 5, Section C paragraphs 7, 8, 11 and 12, and Section D paragraphs 13, 14, 15, 16 and 17 of the commitments annexed to the present decision, and (ii.) the obligations in the other Sections of the commitments. This decision is adopted in application of Articles 6(1)(b) and 6(2) of Council Regulation (EC) No 139/2004.

478. The full text of these commitments is annexed to this decision. These commitments form an integral part of this decision.

For the Commission,
(signed)
Stavros DIMAS
Member of the Commission

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Please note that third Parties showing a sufficient interest can obtain a copy of this decision. You are therefore invited to inform the Commission, within 7 days following notification of this decision, whether you consider that this decision contains business secrets which you wish to have deleted before distribution to third parties. You should give reasons for any such request which the Commission will evaluate before distributing copies of the decision to third parties. Your request should be sent by registered letter or telefax to:

Commission of the European Communities
Competition DG
Merger Control Services
Rue Joseph II / Jozef II-straat 70
B-1000 Brussels
Fax No 32 2 296.43.01

Affected markets in human health

- mRCC in France, the United Kingdom, Germany, Spain, Italy, Austria, Belgium, Czech Republic, Denmark, Greece, Ireland, Latvia, the Netherlands, Poland, Portugal, Slovak Republic, Slovenia, Sweden, Cyprus, Luxembourg and Malta;
- Broad spectrum penicillins in Austria and Germany;
- Other antibacterials in Austria, Belgium, Finland, Germany, Greece, Ireland and Spain;
- Anti-depressants in the Netherlands.

Affected markets in animal health

Biologicals

Companion animal vaccines

- Monovalent multispecies rabies vaccines in France and Spain;
- Multivalent canine vaccines in Austria, Bulgaria, Czech Republic, France, Greece, Hungary, Ireland, Italy, Poland, Romania, Slovakia, Spain and the United Kingdom;
- Multivalent feline vaccines in Belgium, Denmark, France, Germany, Greece, Ireland, Italy, the Netherlands, Spain and the United Kingdom;
- Monovalent feline FeLV vaccines in Austria, Belgium, France, Italy, Spain and the United Kingdom.

Cattle vaccines

- Cattle Pasteurella vaccines in Italy and Spain;
- Cattle respiratory vaccines in Italy, the Netherlands, Portugal, Romania and Spain.

Equine vaccines

- Monovalent equine flue vaccines in Denmark, Finland, Germany, Sweden and the United Kingdom;
- Monovalent equine tetanus vaccines in Germany, Ireland and the United Kingdom;
- Multivalent equine flue/tetanus vaccines in Denmark, Finland, Germany, Ireland, Italy, Sweden and the United Kingdom.

Swine vaccines

- Monovalent swine mycoplasma hyopneumoniae vaccines in Austria, Belgium, Czech Republic, Denmark, France, Germany, Greece, Italy, Lithuania, the Netherlands, Poland, Portugal, Spain and the United Kingdom.

Pharmaceuticals

Anti-inflammatories and analgesics

- Injectable non-steroidal anti-inflammatories drugs (NSAIDS) in: Czech Republic, Slovakia;
- Oral NSAIDS for companion animals (dogs and cats) in: Germany, Italy, and the United Kingdom;
- Corticosteroids (multispecies) in: Italy, the Netherlands and the United Kingdom.

Antimicrobials

- Production animal tetracyclines sprays in: Austria, Italy, Portugal, Spain, and the United Kingdom;
- Production animal anti-infective tetracyclines (excluding sprays) in: Austria, Belgium, Finland, Italy, Portugal, and the United Kingdom;
- Production animal anti-infective quinolones in: Finland and Italy;
- Mastitis in lactating cows in: Czech Republic, Finland, Hungary, Spain, Slovakia and the United Kingdom;
- Mastitis in dry cows in: Belgium, Czech Republic, the Netherlands, Slovakia and the United Kingdom;
- Production animal anti-infective penicillins/synthetic penicillins in: Austria, Belgium, Germany, Italy, Portugal and the United Kingdom;
- Companion animal oral penicillins/synthetic penicillins in: Austria, Belgium, Czech Republic, Finland, France, Italy, Slovakia, Spain and the United Kingdom;
- Companion animal cephalosporin in Italy.

Parasiticides

- Production animal ectoparasiticides in: Belgium, France, Ireland, Portugal and the United Kingdom;
- Production animal endoparasiticides - endectocides in: Austria, Belgium, France, Germany and the United Kingdom;
- Pets (dogs and cats) endoparasiticides - endectocides in: Greece, Italy, Portugal and Spain;
- Equine endoparasiticides – endectocides in: Austria, Belgium, France, Ireland, Italy, the Netherlands and the United Kingdom.

Performance enhancers and others

- Sedatives in: Belgium, France, Germany, Ireland, Italy, the Netherlands, Spain and the United Kingdom.

Medicinal feed additives

- Oral Rehydratation salts (all species) in: Austria, Belgium, France, Germany, Ireland, Spain and the United Kingdom.

By hand and by fax: 00 32 2 296 4301
European Commission
DG Competition
Rue Joseph II 70 Jozef-II straat
B-1000 BRUSSELS

Case M.5476 – Pfizer/ Wyeth

COMMITMENTS TO THE EUROPEAN COMMISSION

Pursuant to Article 6(2) of Council Regulation (EC) No. 139/2004 (the "**Merger Regulation**"), Pfizer Inc. ("**Pfizer**") hereby provides the following Commitments (the "**Commitments**") in order to enable the European Commission (the "**Commission**") to declare the acquisition of Wyeth by Pfizer compatible with the common market and the EEA Agreement by its decision pursuant to Article 6(1)(b) of the Merger Regulation 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, in 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 (EC) No. 139/2004 and under Commission Regulation (EC) No 802/2004.

SECTION A. DEFINITIONS

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

Affiliated Undertakings: undertakings controlled from time to time by the Parties and/or by the ultimate parents of the Parties, whereby the notion of control shall be interpreted pursuant to Article 3 Merger Regulation and in the light of the Commission Jurisdictional Notice on the concept of concentration under Council Regulation (EC) No 139/2004.

Alternative Divestment Businesses: the businesses as defined in Section D and Schedule 2 (each individual business is referred to as an "**Alternative Divestment Business**").

Closing: The transfer of the legal title of a Divestment Business or, as the case may be, of an Alternative Divestment Business, to the Purchaser; or the date on which a Distributorship is transferred to the Counterparty or the third party distributor appointed by the Counterparty.

Completion: the date on which Pfizer acquires control of Wyeth in the sense of Article 3(2) of the Merger Regulation.

Counterparty: for the Sedatives Distribution Agreement: [...] Corporation; for the [...] Distribution Agreement: [...] Laboratories Limited; for the [...] Distribution Agreement: [...] SA; for the Tetracycline Toll Manufacturing Agreement: [...] SA (collectively the "**Counterparties**").

Distribution Divestment Businesses: the businesses described in Section C and Sections 5, 9, 10, 11 and 12 of Schedule 1 (each individual business is referred to as a "**Distribution Divestment Business**").

Distribution Agreements: the Sedatives Distribution Agreement, the [...] Distribution Arrangement and the [...] Distribution Agreement (individually also referred to as the "**Distribution Agreement concerned**").

Distributorship: the distribution by PAH of the [...] Sedatives pursuant to the Sedatives Distribution Agreement; or the distribution by Wyeth of the [...] CAOP Products, the [...] Tetracycline Sprays or the [...] AIF PA Tetracyclines pursuant to the [...] Distribution Arrangement; or the distribution by Wyeth of the [...] CAOP Products pursuant to the [...] Distribution Agreement.

Divestment Businesses: the businesses as defined in Section B and Sections 1, 2, 3, 4, 6, 7, 8, 11 and 13 of Schedule 1 (each individual business is referred to as a "**Divestment Business**").

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

Effective Date: the date of adoption of the Decision.

First Divestiture Period: the period of [...] from Completion.

Hold Separate Manager: the person appointed by Pfizer for the Divestment Businesses and the Divestment Distribution Businesses, with the exception of the Sligo Divestment Business, to manage the day-to-day business under the supervision of the Monitoring Trustee.

Key Personnel: all personnel necessary to maintain the viability and competitiveness of the Sligo Divestment Business, as listed in Section 14 of Schedule 1.

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

[...]: [...] [...].

[...] **Distribution Arrangement:** the agreement concluded between [...] and Wyeth on [...] as amended on [...] and the purchase order arrangement with [...] for the distribution of [...] produced products by Wyeth:

(a) *Duphamox* (tablets and drops) and *Nisamox* (tablets) in the EEA (the "[…] **CAOP Products**");

(b) Oxytetracycline sprays in Austria, the Czech Republic, Belgium, France, Germany, Hungary, Iceland, Italy, The Netherlands, Slovakia and the United Kingdom (the "[…] **Tetracycline Sprays**"); and

(c) *Duphacycline LA* and *Duphacycline 300 LA* in Finland and Italy (the "[…] **AIF PA Tetracyclines**").

PAH: Pfizer Animal Health S.A.

Parties: Pfizer and Wyeth.

Personnel: all personnel currently employed by the Parties that are working for each Divestment Business, including staff seconded to the Divestment Business.

Pfizer: Pfizer Inc., incorporated under the laws of Delaware, with its registered office at 235 East 42nd Street, New York, NY 10017, United States of America and registered with the Commercial/Company Register at Delaware (no registration number available).

Purchaser: with regard to each Divestment Business and – if applicable – Alternative Divestment Business, the entity approved by the Commission as acquirer in accordance with the criteria set out in Section F.

Retained Competing Businesses: with regard to each Divestment Business and Distribution Divestment Business, the corresponding competing business retained by Pfizer (each corresponding business referred to as a "**Retained Competing Business**").

Sedatives Distribution Agreement: agreement concluded between [...] and PAH on [...] as amended on [...] to the extent it relates to the distribution by PAH in the United Kingdom of the following products: *Domosedan*, *Domitor, Dexdomitor* and *Antisedan* (the "**Sedatives**").

Signing: signing of a final binding sale and purchase agreement for each of the respective Divestment Businesses and – to the extent applicable –Alternative Divestment Businesses.

Sligo Hold Separate Manager: the person appointed by Pfizer to manage the day-to-day business of the Sligo Divestment Business under the supervision of the Monitoring Trustee.

[...] **Distribution Agreement**: agreement concluded between [...] SA and [...] on [...] and assigned by [...] to Wyeth on [...] for the distribution by Wyeth in Italy of:

(d) Companion animal oral penicillin under the *Amoxival* brand ("[…] **CAOP Products**"); and

(e) Cephalosporins under the *Therios 60* brand (the "[…] **Cephalosporin Product**").

Transfer Date: the date on which the Distributorship is transferred.

Tetracycline Sprays Toll Manufacturing Agreement: agreement concluded between [...] and [...] on [...] for the manufacturing of tetracycline sprays under the *Aureomicina Violete de Genciana* brand.

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

Trustee Divestiture Period: the period of [...] from the end of the First Divestiture Period.

Vaccines Divestment Businesses: Divestment Businesses listed in paragraph 4 (b) – 4 (e) of these Commitments.

Wyeth: Wyeth, incorporated under the laws of Delaware, with its registered office at 2711 Centerville Road, Suite 400, Wilmington, Delaware 19808 and registered with the Commercial/Company Register at Delaware Secretary of State (no registration number).

SECTION B. THE DIVESTMENT BUSINESSES

Commitment to divest

1. In order to maintain or restore effective competition, Pfizer commits to divest, or procure the divestiture of, the Divestment Businesses as going concerns to one or more Purchasers and on terms of sale approved by the Commission in accordance with the procedure described in paragraph 34 below (the "**Divestiture Commitment**"). To carry out each divestiture, Pfizer commits to find one or more Purchasers and to enter into a final binding sale and purchase agreement for the sale of each of the Divestment Businesses within the First Divestiture Period. If Pfizer has not entered into such an agreement at the end of the First Divestiture Period, Pfizer shall grant the Divestiture Trustee an exclusive mandate to sell the Divestment Business within the Trustee Divestiture Period in accordance with the procedure described in paragraph 43 below.

2. Pfizer shall be deemed to have complied with this commitment if, by the end of the First Divestiture Period or, if applicable, by the end of the Trustee Divestiture Period, Pfizer or an Affiliated Undertaking has entered into a final binding sale and purchase agreement for each of the Divestment Businesses, if the Commission approves the Purchaser(s) and the terms in accordance with the procedure described in paragraph 34 and if the Closing of the sale of each of the Divestment Businesses takes place within a time frame agreed with the Purchaser(s) as approved by the Commission in accordance with the procedure described in paragraph 34.

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

Commission has previously found that the structure of the market has changed to such an extent that the absence of influence over the Divestment Business concerned is no longer necessary to render the proposed concentration compatible with the common market.

Structure and definition of the Divestment Businesses

4. The Divestment Businesses consist of:

(a) At the option of the Purchaser of the Vaccines Divestment Businesses, the manufacturing facility in Sligo, Ireland, as described in more detail in Section 14 of Schedule 1 (the "**Sligo Divestment Business**");

(b) The *Presponse* branded cattle Pasteurella business in the EEA and the *Triangle 4 PH-K*, *Triangle 4, Triangle 4+L/9, Triangle 3* and *Pyramid MLV-4* branded cattle respiratory business in the EEA as described in more detail in Section 1 of Schedule 1 (the "**Cattle Vaccines Divestment Business**");

(c) The *Duvaxyn* branded monovalent equine flu vaccines, the *Duvaxyn* branded multivalent equine vaccines (flu and tetanus) and the *Duvaxyn* and *Tetanus Toxoid* branded monovalent equine tetanus vaccines business in the EEA and the right to develop and commercialise an […] product in the EEA […](the "Equine Pipeline Product") as described in more detail in Section 2 of Schedule 1 (the "**FD Equine Vaccine Divestment Business**");

(d) The *Stellamune/Respisure* and *Stellamune One/Respisure One* branded swine mycoplasma business in the EEA and the right to develop and commercialise a new vaccine for […]in the EEA (the "**Pipeline Product**") as described in more detail in Section 3 of the Schedule (the "**SMH Divestment Business**");

(e) The *Felocell CVR*, *Felocell CVR-C* and *Felocell RC* branded multivalent feline vaccines business in the EEA as described in more detail in Section 4 of Schedule 1 (the "**MV Feline Vaccines Divestment Business**");

(f) The *Banminth for horses* and the *Strongid for horses* branded equine endoparasiticides-endectocides products in the UK as described in more detail in Section 6 of Schedule 1 (the "**Equine Endo/Endecto Divestment Business**");

(g) The *Guardian* branded CA endoparasiticides-endectocides products in the EEA as described in more detail in Section 7 of Schedule 1 (the "**Pet Endo/Endecto Divestment Business**");

(h) The *Valbazen Suspension, Valbazen Drench, Valbazen Bolus, Dectomax pour-on* and *Dectomax injectable* branded PA endoparasiticides-endectocides products in Belgium, including Luxembourg, Germany and the UK as described in more detail in Section 8 of Schedule 1 (the "**PA Endo/Endecto Divestment Business**");

(i) The tetracycline spray products sold by Wyeth in Portugal as described in more detail in Section 11 of Schedule 1 (the "**Tetracycline Sprays Divestment Business")**; and

(j) The *Lectade*, *Lectade Plus, Lectade Small Animals, Pfizer Scour Formula* and *Pfizer Scour Formula Extra* branded oral rehydration salts business in the EEA as described in more detail in Section 13 of Schedule 1 (the "**ORS Divestment Business**");

5. The Vaccines Divestment Businesses and the Sligo Divestment Business shall be divested as a bundle to a single Purchaser. However, Pfizer may divest the Vaccines Divestment Businesses singly or in combination(s) to one or more Purchasers with consent of the Commission without the Sligo Divestment Business if the respective Purchaser or the respective Purchasers have access to a production facility that has capacity for the relevant vaccine available. This does not affect the possibility for Pfizer to sell the Divestment Businesses as a whole to a single Purchaser. For the avoidance of doubt, in the event that Pfizer receives offers from more than one potential purchaser which, upon verification by the Commission fulfils the Purchaser Requirements, Pfizer shall be free to take whichever offer that Pfizer deems the most appropriate to its interests.

6. The divestiture of the Divestment Businesses will proceed by way of one or more asset divestiture transactions, including transfer, sale, assignment and/or license 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 respective Sections of Schedule 1:

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

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

(c) all contracts, leases, commitments and customer orders of the Divestment Businesses;

(d) all customer, credit and other records of the Divestment Businesses (items referred to under (a)-(d) hereinafter collectively referred to as "**Assets**");

(e) At the option of the Purchaser and subject to applicable local employment legislation, sufficiently qualified sales and marketing personnel employed by one of the Parties, to the extent reasonably necessary for the Purchaser to operate the acquired Divestment Businesses in accordance with normal market practice and to the extent legally permitted; and

(f) At the option of the Purchaser, the benefit for a transitional period (depending on the Divestment Business as detailed in the relevant Section of Schedule 1)

after Closing and on a reasonable cost plus basis to be negotiated between Pfizer or Affiliated Undertakings and the Purchaser, of all current arrangements under which the Parties supply products and/or of reasonable technical assistance to the Purchaser to enable the Purchaser to assume responsibility for the manufacture, sale and marketing of the relevant Divestment Businesses for such a period as is required by the Purchaser to establish the Divestment Businesses as a viable and independent business, as detailed in relevant Sections in Schedule 1.

SECTION C. THE DISTRIBUTION DIVESTMENT BUSINESSES

7. In order to maintain effective competition, Pfizer commits to transfer the Distribution Agreements and – at least in relation to sales of tetracycline sprays in Portugal - the Tetracycline Sprays Toll Manufacturing Agreement (the "**Distribution Divestment Businesses**"*)*.

8. Pfizer commits to use all reasonable best efforts to agree with the Counterparties by the end of the First Divestiture Period reasonable terms and conditions for the transfer of the corresponding Distribution Agreement to one or more third parties or to the Counterparty for distribution by that Counterparty. At the option of the Counterparty, Pfizer will:

   (i) assist in finding a new distributor for the Distribution Divestment Business concerned; and/or

   (ii) provide transitional services to be reasonably agreed between Pfizer and the Counterparty to aid in the performance of (i).

9. Upon the Transfer Date, Pfizer undertakes to transfer to the relevant Counterparty or to the new distributor appointed by it one or more of the following assets, as more specifically defined in relevant Sections in the Schedule:

   (a) Finished goods inventory, work in process, sales and promotional material (where available);

   (b) Marketing authorisations and pending applications held by Pfizer or Wyeth and that Pfizer or Wyeth is legally permitted to transfer to a Purchaser;

   (c) Copies of relevant clinical reports;

   (d) Trademarks that Pfizer or Wyeth owns, by way of an irrevocable license, that Pfizer or Wyeth used in connection with the sale of the products covered by the Distribution Agreements; and

   (e) Copies of all relevant data, books, records, and other documents necessary for the operations of the Distribution Divestment businesses.

10. At the option of the Counterparty or the third party appointed by it and subject to applicable local employment legislation, sufficiently qualified sales and marketing personnel employed by one of the Parties will be made available to the Counterparty or the third party appointed by it, to the extent reasonably necessary for the Counterparty or the third party appointed by it to operate the relevant Distribution Divestment Businesses in accordance with normal market practice and to the extent legally permitted.

11. Pfizer shall be deemed to have complied with this commitment if, by the end of the First Divestiture Period Pfizer or an Affiliated Undertaking has agreed with the Counterparties on the transfer of the Distribution Divestment Businesses, (ii) has entered into a final binding sale and purchase agreement for the Tetracycline Divestment described in paragraph 34 below and (iii) the Closing of the transfer of each of the Distribution Divestment Businesses takes place within a time frame agreed with the Counterparty or the third party distributor appointed by the Counterparty and as approved by the Commission.

12. In order to maintain the structural effect of the commitment in relation to the Distribution Divestment Businesses, Pfizer shall, for a period of 10 years after the Effective Date:

(a) Not acquire direct or indirect influence over the whole or part of any of the Distribution Divestment Businesses;

(b) Not be appointed by […] as the distributor of Sedatives in the United Kingdom;

(c) Not be appointed by […] as a distributor of the […] CAOP Products in Belgium, Czech Republic, France, Italy, Slovakia, Spain or the United Kingdom;

(d) Not be appointed by […] as a distributor of the […] Tetracycline Sprays in Austria, Belgium, Czech Republic, France, Germany, Hungary, Iceland, Italy, the Netherlands, Slovakia or the United Kingdom;

(e) Not be appointed by […] as a distributor of the […] AIF PA Tetracyclines in Austria, Finland or Italy;

(f) Not be appointed by […] SA as a distributor of the […] CAOP Products in Italy;

(g) Not to be appointed by […] SA as a distributor of the […] Cephalosporin Product in Italy; and

(h) Not sell any Chlortetracycline sprays under the *Aureomycin Spray* trademark in Portugal;

unless the Commission has previously found that the structure of the market has changed to such an extent that the absence of influence over the Distribution

Divestment Business concerned is no longer necessary to render the proposed concentration compatible with the common market.

SECTION D. THE ALTERNATIVE DIVESTMENTS BUSINESSES

Commitment to divest as an alternative

13. During the First Divestiture Period, Pfizer can choose to divest part of the respective Retained Competing Business instead of transferring the relevant Distribution Divestment Businesses and/or the Tetracycline Sprays Divestment Business to remove competition concerns in those Member States where the European Commission has found serious doubts as to the compatibility of the Transaction with the common market (the "**Alternative Divestiture Commitment**"). To carry out each divestiture, Pfizer commits to find one or more Purchasers and to enter into a final binding sale and purchase agreement for the sale of each of the Alternative Divestment Businesses within the First Divestiture Period. To the extent that at the end of the First Divestiture Period Pfizer has not entered into such an agreement and has not reached agreement with the Counterparties referred to in paragraph 8 above or signed a sale and purchase agreement for the Tetracycline Sprays Divestment Business, Pfizer shall grant the Divestiture Trustee an exclusive mandate to sell the Alternative Divestment Business within the Trustee Divestiture Period in accordance with the procedure described in 43 below.

14. Pfizer shall be deemed to have complied with this commitment if, by the end of the First Divestiture Period Pfizer or an Affiliated Undertaking (i) has agreed with the Counterparties on the transfer of the Distribution Divestment Businesses and (ii) has entered into a final binding sale and purchase agreement for the Tetracycline Divestment Business or (iii) has entered into a final binding sale and purchase agreement for each of the Alternative Divestment Businesses or (iv) if applicable, by the end of the Trustee Divestiture Period, has entered into a final binding sale and purchase agreement for each of the Alternative Divestment Businesses, provided the Commission approves the Purchaser(s) and the terms in accordance with the procedure described in paragraph 34 below and the Closing of the sale of each of the Alternative Divestment Businesses takes place within a time frame agreed with the Purchaser(s) as approved by the Commission in accordance with the procedure described in paragraph 34.

15. In order to maintain the structural effect of the Alternative Divestiture Commitment, the Parties shall, for a period of 10 years after the Effective Date, not acquire direct or indirect influence over the whole or part of any of the Alternative Divestment Businesses if these have been sold to a Purchaser, unless the Commission has previously found that the structure of the market has changed to such an extent that the absence of influence over the Divestment Business concerned is no longer necessary to render the proposed concentration compatible with the common market.

Structure and definition of the Alternative Divestment Businesses

16. The Alternative Divestment Businesses consist of:

(a) The […] branded CA oral penicillin business in the Czech Republic, Slovakia, Spain and the United Kingdom and the […] branded CA oral penicillin business in Italy (the "**CAOP Alternative Divestment Business**"; the products are also referred to as the "**CAOP Products**");

(b) The […] branded tetracycline sprays in the United Kingdom and / or in Portugal (the "**Tetracycline Sprays Alternative Divestment Business**"; the products are also referred to as the "**Alternative Tetracycline Sprays**");

(c) The […] branded AIF PA tetracyclines in Finland and Italy (the "**AIF PA Tetracyclines Alternative Divestment Business**"; the products are also referred to as the "**AIF PA Tetracyclines** "); and

(d) The […] branded cephalosporins in Italy as described in more detail in Schedule 2 (the "**Cephalosporins Alternative Divestment Business**"; the products are also referred to as the "**PAH Cephalosporins**").

17. The Alternative Divestment Businesses will be divested as a bundle to a single Purchaser or alternatively singly or in combinations to one or more Purchasers with consent of the Commission. For the avoidance of doubt, in the event that Pfizer receives offers from more than one potential purchaser which, upon verification by the Commission fulfils the Purchaser Requirements, Pfizer shall be free to take whichever offer that Pfizer deems the most appropriate to its interests.

18. The divestiture of the Alternative Divestment Businesses will proceed by way of one or more asset divestiture transactions, including transfer, sale, assignment and/or license 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 Schedule 2:

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

(b) all licences, permits and authorisations issued by any governmental organisation for the benefit of the Alternative Divestment Businesses;

(c) all contracts, leases, commitments and customer orders of the Alternative Divestment Businesses;

(d) all customer, credit and other records of the Alternative Divestment Business (items referred to under (a)-(d) hereinafter collectively referred to as "**Assets**");

(e) At the option of the Purchaser, sufficiently qualified sales and marketing personnel employed by one of the Parties, to the extent reasonably necessary for the Purchaser to operate the acquired Alternative Divestment Business(es) in accordance with normal market practice and to the extent legally permitted;

(f) At the option of the Purchaser, the benefit for a transitional period (as detailed in Schedule 2) after Closing and on a reasonable cost plus basis to be negotiated between Pfizer or Affiliated Undertakings and the Purchaser, of all current arrangements under which the Parties supply products and/or of reasonable technical assistance to the Purchaser to enable the Purchaser to assume responsibility for the manufacture, sale and marketing of the relevant Alternative Divestment Business for such a period as is required by the Purchaser to establish the Alternative Divestment Business as a viable and independent business, as detailed in Schedule 2.

SECTION E. RELATED COMMITMENTS

Preservation of Viability, Marketability and Competitiveness

19. From the Effective Date until Signing, Pfizer shall preserve the economic viability, marketability and competitiveness of the Divestment Businesses and the Distribution Divestment Businesses, in accordance with good business practice, and shall minimise as far as possible any risk of loss of competitive potential of the Divestment Businesses and the Distribution Divestment Businesses. In particular Pfizer undertakes:

(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 Divestment Businesses or Distribution Divestment Businesses or that might alter the nature and scope of activity, or the industrial or commercial strategy or the investment policy of the Divestment Businesses or Distribution Divestment Businesses;

(b) to make available sufficient resources for the development of the Divestment Businesses and Distribution Divestment Businesses, on the basis and continuation of the existing business plans; and

(c) to take all reasonable steps, including appropriate incentive schemes (based on industry practice), to encourage all Key Personnel to remain with the Sligo Divestment Business.

20. The obligation described in paragraph 19 above shall also apply to the Alternative Divestment Businesses that Pfizer chooses to sell in the First Divestiture Period or that will have to be sold within the Trustee Divestiture Period pursuant to paragraph 13, in which case the obligation applies from the moment that Pfizer chooses to sell the Alternative Divestment Business or the start of the Trustee Divestiture Period, whichever is the soonest, until Signing.

Hold-separate obligations of Parties

21. Pfizer commits, from the Effective Date until Signing, to the extent reasonably practical, to firewall the Divestment Businesses and the Distribution Divestment Businesses from the Retained Competing Businesses. Pfizer also commits to ensure that Personnel of the Divestment Businesses and the Distribution Divestment Businesses - including the Hold Separate Manager - have their involvement in any Retained Competing Business limited and vice versa, to the extent reasonably practical and recognising that the Personnel and Key Personnel will inevitably have to deal with products from the Retained Competing Businesses and from the Divestment Businesses and/or Distribution Divestment Businesses, without compromising the viability of the Divestment Businesses or the Distribution Divestment Businesses or the Retained Competing Business.

22. Until Signing or Transfer Date, Pfizer shall assist the Monitoring Trustee in ensuring that the Divestment Businesses and the Distribution Divestment Businesses are managed in accordance with provision 21 above. Pfizer shall appoint a Hold Separate Manager who shall be responsible for the management of the Divestment Businesses (with the exception of the Sligo Divestment Business) and the Distribution Divestment Businesses, under the supervision of the Monitoring Trustee. Pfizer shall also appoint a Sligo Hold Separate Manager who shall be responsible for the management of the Sligo Divestment Business, under the supervision of the Monitoring Trustee. The Hold Separate Manager and the Sligo Hold Separate Manager shall manage the Divestment Businesses and the Distribution Divestment Businesses in the best interest of the businesses with a view to ensuring their continued economic viability, marketability and competitiveness and their independence from the businesses retained by the Parties, to the extent reasonably possible without compromising the viability of the Divestment Businesses or the Distribution Divestment Businesses.

23. The hold separate obligations described in paragraphs 21 and 22 above will also apply to the Alternative Divestment Businesses, with the proviso that the obligation of paragraph 21 will commence from the moment that Pfizer chooses to sell the Alternative Divestment Business or the start of the Trustee Divestiture Period, whichever is the soonest.

24. Pfizer commits to take all reasonable steps to ensure that Pfizer personnel involved in the transfer of the Divestment Businesses, the Distribution Divestment Businesses and – if applicable – the Alternative Divestment 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 Divestment Business concerned, and they shall disclose such information to other Pfizer personnel only to the extent strictly required to assist in the transfer of the Divestment Business concerned.

Ring-fencing

25. Pfizer shall, to the extent possible, implement all necessary measures to ensure that it does not after the Effective Date obtain any business secrets, know-how, commercial information, or any other information of a confidential or proprietary nature relating to the Divestment Businesses or the Distribution Divestment Businesses. Pfizer may obtain information relating to the Divestment Businesses or the Distribution Divestment Businesses (i) which is reasonably necessary for the divestiture of the Divestment Businesses or the discontinuation of the Distribution Divestment Businesses, (ii) which is reasonably required to maintain the viability of the Divestment Businesses or the Distribution Divestment Businesses or (iii) whose disclosure to Pfizer is required by law.

26. The ring fencing obligation described in paragraph 25 above will also apply to the Alternative Divestment Businesses, with the proviso that the obligation of paragraph 25 will commence from the moment that Pfizer chooses to sell the Alternative Divestment Business or the start of the Trustee Divestiture Period, whichever is the soonest.

Non-solicitation clause

27. Pfizer undertakes, subject to customary limitation, not to solicit, and procure that Affiliated Undertakings do not solicit, the Key Personnel transferred with the Sligo Divestment Business for a period of 12 months after Closing.

Due Diligence

28. In order to enable potential purchasers to carry out a reasonable due diligence of the Divestment Businesses and – if applicable – the Alternative Divestment Businesses, Pfizer 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 Divestment Business.

Reporting

29. Pfizer shall submit written reports in English on potential purchasers of the Divestment Businesses and – if applicable – the Alternative Divestment Businesses and developments in the negotiations with such potential purchasers to the Commission and the Monitoring Trustee no later than 10 working days after the end of every month following the Effective Date (or otherwise at the Commission's request).

30. 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 to the Commission and the Monitoring Trustee, where possible before sending the memorandum out to potential purchasers.

Other

31. It is understood that as soon as any of the related commitments of paragraphs 19 – 30 above apply to one or more of the Alternative Divestment Businesses, that commitment

no longer applies to the corresponding Distribution Divestment Business(es) or the Tetracycline Sprays Divestment Business.

SECTION F. THE PURCHASER

32. In order to ensure the immediate restoration of effective competition, the Purchaser, in order to be approved by the Commission, must:

(d) be independent of and unconnected to the Parties;

(e) have the financial resources, proven expertise, manufacturing capacity or ability to expand such or ability to outsource manufacturing, and incentive to maintain and develop the Divestment Business or – if applicable – the Alternative Divestment Business as a viable and active competitive force in competition with the Pfizer and other competitors;

(f) 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 Commitments will be delayed, and must, in particular, reasonably be expected to obtain all necessary approvals from the relevant regulatory authorities for the acquisition of one or more of the Divestment Businesses or – if applicable – the Alternative Divestment Businesses (the before-mentioned criteria for the purchaser hereafter the "**Purchaser Requirements**").

33. If a purchaser (including a Counterparty or third party distributor appointed by it) that would otherwise be acceptable to the Commission (a "**Prospective Purchaser**") (i) may be prevented from acquiring one or more of the Divestment Businesses, Distribution Divestment Businesses or Alternative Divestment Businesses because of overlaps between that Prospective Purchaser and a specific Divestment Business, Distribution Divestment Business or Alternative Divestment Business in one or more Member States that are not identified in the Decision as Member States involving potential concerns for which Pfizer needed to provide a commitment (each such member State, an "**Other Member State**"), or (ii) is not interested in acquiring one or more of the Divestment Businesses, Distribution Divestment Businesses or Alternative Divestment Businesses in one or more Other Member States, then, in order to enable the Commission to approve such Prospective Purchaser as a Purchaser in accordance herewith, Pfizer reserves the right in such narrow circumstances to change the scope of the relevant Divestment Business, Distribution Divestment Business or Alternative Divestment Business (or Divestment Businesses, Distribution Divestment Businesses or Alternative Divestment Businesses) by removing from such relevant Divestment Business, Distribution Divestment Business or Alternative Divestment Business (or Divestment Businesses, Distribution Divestment Businesses or Alternative Divestment Businesses) each Other Member State that the Prospective Purchaser could be prevented from

purchasing due to potential competition concerns not identified in the Decision or that the Prospective Purchaser does not wish to acquire.

34. The final binding sale and purchase agreement shall be conditional on the Commission's approval. When Pfizer 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. Pfizer must be able to demonstrate to the Commission that the purchaser meets the Purchaser Requirements and that the Divestment 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 Divestment Business is being sold in a manner consistent with the Commitments. The Commission may approve the sale of the Divestment Business without parts of the Personnel or one or more Assets or excluding businesses in one or more Other Member States if Pfizer has exercised its rights under paragraph 33, if this does not affect the viability and competitiveness of the Divestment Business after the sale, taking account of the proposed Purchaser.

SECTION G. TRUSTEE

I. Appointment Procedure

35. Pfizer shall appoint a Monitoring Trustee to carry out the functions specified in the Commitments for a Monitoring Trustee. If Pfizer has not entered into a binding sale and purchase agreement **[…]** before the end of the First Divestiture Period or if the Commission has rejected a purchaser proposed by Pfizer at that time or thereafter, Pfizer shall appoint a Divestiture Trustee to carry out the functions specified in the Commitments for a Divestiture Trustee. The appointment of the Divestiture Trustee shall take effect upon the commencement of the Trustee Divestiture Period.

36. The Trustee 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 shall be remunerated by Pfizer 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 Divestment Businesses or – if applicable – the Alternative Divestment Businesses, the fee shall also be linked to a divestiture within the Trustee Divestiture Period.

Proposal by the Parties

37. No later than one week after the Effective Date, Pfizer shall submit a list of one or more persons whom Pfizer proposes to appoint as the Monitoring Trustee to the Commission for approval. No later than one month before the end of the First Divestiture Period, Pfizer shall submit a list of one or more persons whom Pfizer proposes to appoint as Divestiture Trustee to the Commission for approval. The proposal shall contain sufficient information for the Commission to verify that the proposed Trustee fulfils the requirements set out in paragraph 36 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;

    (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

38. 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. The Commission shall liaise with other relevant competition authorities, a list of which is to be provided by Pfizer, that are reviewing the acquisition of Wyeth by Pfizer, before approving or rejecting the proposed Trustee(s). If only one name is approved, Pfizer 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, Pfizer shall be free to choose the Trustee to be appointed from among the names approved. The Trustee shall be appointed within one week of the Commission's approval, in accordance with the mandate approved by the Commission.

New proposal by the Parties

39. If all the proposed Trustees are rejected, Pfizer shall submit the names of at least two more individuals or institutions within one week of being informed of the rejection, in accordance with the requirements and the procedure set out in paragraphs 37 and 38.

Trustee nominated by the Commission

40. If all further proposed Trustees are rejected by the Commission, the Commission shall nominate a Trustee, whom Pfizer shall appoint, or cause to be appointed, in accordance with a trustee mandate approved by the Commission. The Commission shall liaise with

other relevant competition authorities, a list of which is to be provided by Pfizer, that are reviewing the acquisition of Wyeth by Pfizer, before nominating a Trustee(s).

II. Functions of the Trustee

41. 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 Pfizer, 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

42. The Monitoring Trustee shall:

(i) 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.

(ii) Oversee the on-going management of the Divestment Businesses and the Distribution Divestment Businesses or – if applicable – the Alternative Divestment Businesses with a view to ensuring their continued economic viability, marketability and competitiveness and monitor compliance by Pfizer with the conditions and obligations attached to the Decision. To that end the Monitoring Trustee shall:

(a) monitor the preservation of the economic viability, marketability and competitiveness of the Divestment Businesses and the Distribution Divestment Businesses or – if applicable – the Alternative Divestment Businesses, and the keeping separate of the Divestment Businesses and the Distribution Divestment Businesses or – if applicable – the Alternative Divestment Businesses from the business retained by the Parties, in accordance with paragraphs 19, 20, 21 and 23 of the Commitments;

(b) supervise the management of the Divestment Businesses and the Distribution Divestment Businesses or – if applicable – the Alternative Divestment Businesses as a distinct and transferable entities, in accordance with paragraphs 22 and 23 of the Commitments;

(c) (i) in consultation with Pfizer, determine all necessary measures to ensure that Pfizer does not after the Effective Date obtain any business secrets, know-how, commercial information, or any other information of a confidential or proprietary nature relating to the Divestment Businesses and the Distribution Divestment Businesses or – if applicable – the Alternative Divestment Businesses, in particular strive for the severing of the Divestment Businesses' and the Distribution Divestment Businesses' or – if applicable – the Alternative Divestment Businesses'

participation in a central information technology network to the extent possible, without compromising the viability of the Divestment Businesses and the Distribution Divestment Businesses or – if applicable – the Alternative Divestment Businesses, and (ii) decide whether such information may be disclosed to Pfizer as the disclosure is reasonably necessary to allow Pfizer to carry out the divestiture or as the disclosure is required by law;

(d) monitor the splitting of assets between the Divestment Businesses and the Distribution Divestment Businesses or – if applicable – the Alternative Divestment Businesses on the one hand and Pfizer or Affiliated Undertakings on the other hand;

(iii) assume the other functions assigned to the Monitoring Trustee under the conditions and obligations attached to the Decision;

(iv) propose to Pfizer such measures as the Monitoring Trustee considers necessary to ensure Pfizer'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 Divestment Businesses and the Distribution Divestment Businesses or – if applicable – the Alternative Divestment Businesses, the holding separate of the Divestment Businesses and the Distribution Divestment Businesses or – if applicable – the Alternative Divestment Businesses and the non-disclosure of competitively sensitive information;

(v) 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 Divestment Businesses and – if applicable – the Alternative Divestment Businesses in particular by reviewing, if available, the data room documentation, the information memorandum and the due diligence process;

(vi) supervise the negotiations with a Purchaser in relation to the improvements of the Sligo manufacturing facility, which Pfizer commits to undertake at the option of the Purchaser, that are necessary to enable the facility to accept and manufacture the Divested Vaccines acquired by the Purchaser;

(vii) provide to the Commission, sending Pfizer a non-confidential copy at the same time, a written report within 15 days after the end of every month. The report shall cover the operation and management of each of the Divestment Businesses and Distribution Divestment Businesses or – if applicable – Alternative Divestment Businesses so that the Commission can assess whether the businesses are 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 Pfizer a non-confidential copy at the same time, if it

concludes on reasonable grounds that Pfizer is failing to comply with these Commitments;

(viii) within one week after receipt of the documented proposal referred to in paragraph 34, submit to the Commission a reasoned opinion as to the suitability and independence of the proposed purchaser and the viability of the relevant Divestment Business or – if applicable – the Alternative Divestment Businesses after the Sale and as to whether the relevant Divestment Business or Alternative Divestment Business is sold in a manner consistent with the conditions and obligations attached to the Decision, in particular, if relevant, whether the sale of one or more of the Divestment Businesses or – if applicable –Alternative Divestment Businesses without one or more Assets affects the viability of the Divestment Business(es) or Alternative Divestment Business(es) after the sale, taking account of the proposed purchaser.

Duties and obligations of the Divestiture Trustee

43. Within the Trustee Divestiture Period, the Divestiture Trustee shall sell at no minimum price the Divestment Businesses 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 34. 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 Trustee 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 Pfizer, subject to the Pfizer's unconditional obligation to divest at no minimum price in the Trustee Divestiture Period.

44. In the Trustee 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 15 days after the end of every month with a simultaneous copy to the Monitoring Trustee and a non-confidential copy to the Parties.

III. Duties and obligations of Pfizer

45. Pfizer shall provide and shall cause its advisors to provide the Trustee with all such cooperation, assistance and information as the Trustee may reasonably require to perform its tasks. The Trustee shall have full and complete access to any of Pfizer's, the Divestment Businesses' and the Distribution Divestment Businesses' or – if applicable – the Alternative Divestment Businesses' books, records, documents, management or other personnel, facilities, sites and technical information necessary for fulfilling its duties under the Commitments and Pfizer, the Divestment Businesses and the Distribution Divestment Businesses or – if applicable – the Alternative Divestment Businesses shall provide the Trustee upon request with copies of any document. Pfizer,

the Divestment Businesses and the Distribution Divestment Businesses or – if applicable – the Alternative Divestment Businesses shall make available to the Trustee one or more offices on their premises and shall be available for meetings in order to provide the Trustee with all information necessary for the performance of its tasks.

46. Pfizer shall provide the Monitoring Trustee with all managerial and administrative support that it may reasonably request on behalf of the management of the Divestment Businesses and the Distribution Divestment Businesses or – if applicable – the Alternative Divestment Businesses. This shall include all administrative support functions relating to the Divestment Businesses and the Distribution Divestment Businesses or – if applicable – the Alternative Divestment Businesses which are currently carried out at headquarters level. Pfizer 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. Pfizer 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.

47. Pfizer shall grant or procure Affiliated Undertakings to grant comprehensive powers of attorney, duly executed, to the Divestiture Trustee to effect the sale, the Closing and all actions and declarations which the Divestiture Trustee considers necessary or appropriate to achieve the sale, including the appointment of advisors to assist with the sale process. Upon request of the Divestiture Trustee, Pfizer shall cause the documents required for effecting the sale to be duly executed.

48. Pfizer shall indemnify the Trustee 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 Pfizer for any liabilities arising out of the performance of the Trustee'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, its employees, agents or advisors.

49. At the expense of Pfizer, the Trustee may appoint advisors (in particular for corporate finance or legal advice), subject to Pfizer's approval (this approval not to be unreasonably withheld or delayed) if the Trustee 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 are reasonable. Should Pfizer refuse to approve the advisors proposed by the Trustee the Commission may approve the appointment of such advisors instead, after having heard Pfizer. Only the Trustee shall be entitled to issue instructions to the advisors. Paragraph 48 shall apply *mutatis mutandis*. In the Trustee Divestiture Period, the Divestiture Trustee may use advisors who served Pfizer 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

50. If the Trustee ceases to perform its functions under the Commitments or for any other good cause, including the exposure of the Trustee to a conflict of interest:

    (a) the Commission may, after hearing the Trustee, require Pfizer to replace the Trustee; or

    (b) Pfizer, with the prior approval of the Commission, may replace the Trustee.

51. If the Trustee is removed according to paragraph 50, the Trustee may be required to continue in its function until a new Trustee is in place to whom the Trustee has effected a full hand over of all relevant information. The new Trustee shall be appointed in accordance with the procedure referred to in paragraphs 35-40.

52. Beside the removal according to paragraph 50, the Trustee shall cease to act as Trustee only after the Commission has discharged it from its duties after all the Commitments with which the Trustee 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 H. THE REVIEW CLAUSE

53. The Commission may, where appropriate, in response to a request from Pfizer showing good cause and accompanied by a report from the Monitoring Trustee:

    (i) Grant an extension of the time periods foreseen in the Commitments, or

    (ii) Waive, modify or substitute, in exceptional circumstances, one or more of the undertakings in these Commitments.

Where Pfizer seeks an extension of a time period, it shall submit a request to the Commission no later [...] before the expiry of that period, showing good cause. Only in exceptional circumstances shall Pfizer be entitled to request an extension within [...] of any period.

Duly authorised by the power of Attorney dated 16 July 2009, a copy of which is attached,

for and on behalf of Pfizer Inc.

Date: 16 July 2009

(signed)

……

SCHEDULE 1

Commitments

Case M. 5476 – Pfizer/Wyeth

Divestment Businesses and Distribution Divestment Businesses

VACCINES

SECTION 1

CATTLE VACCINES

The Cattle Vaccines Divestment Business will consist of certain rights, including the right to develop and improve, in intellectual property and other assets related to the Cattle Vaccines in the EEA and may form part of the larger divestment of FD's cattle vaccines businesses in the US, Canada and South Africa. For the avoidance of doubt, the Cattle Vaccines Divestment Business will not include any right to sell cattle vaccines outside of the EEA.

The Cattle Vaccines Divestment Business includes:

(a) Sufficient biological material to produce Cattle Vaccines, including sufficient amounts of the master seeds;

(b) Finished goods inventory, work in process, rights to pipeline products, product improvements, sales and promotional materials (where available) relating to the Cattle Vaccines produced by FD and sold in the EEA, held by FD at the date of Closing[1];

(c) All current marketing authorisations and pending applications for marketing authorisations for the Cattle Vaccines in the EEA or a part thereof held by FD, including all relevant dossiers relating to the current and/or pending marketing authorisations in the EEA available to the Parties;

(d) Copies of all clinical reports relating to the Cattle Vaccines in the EEA existing prior to Closing;

(e) The trademarks in the EEA for the Cattle Vaccines (including those EEA countries where the Cattle Vaccines may not currently be registered) by way of a exclusive, perpetual, irrevocable licence or assignment;

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[1] As previously stated, the Cattle Vaccines Divestment Business contains products which may also be offered for sale in the United States and Canada. In order to effectuate a transfer of all relevant assets of the Cattle Vaccines Divestment Business, including all trademarks in the EEA, the Cattle Vaccines Divestment Business may therefore be transferred, subject to the approval of the Commission, to the same Purchaser [...].

(f) The intellectual property rights where available and necessary to give a Purchaser of the Cattle Vaccines Divestment Business the non-exclusive right to manufacture the Cattle Vaccines anywhere in the world for sale solely in the EEA and the exclusive right to sell the Cattle Vaccines in the EEA by way of a perpetual, irrevocable licence or assignment. These intellectual property rights include product formulations, manufacturing know-how, other secret know-how, packaging specifications and all related copyright information (with non-product specific know-how being licensed on a non-exclusive basis);

(g) Copies of all relevant data, books, records, and other documents to the extent exclusively related to or necessary for the operations of the Cattle Vaccines Divestment Business in the EEA, including existing customer records in the EEA, provided that Pfizer may redact from such copies any information that does not relate to the Cattle Vaccines Divestment Business; and

(h) All inventory and sales and promotional materials (provided such inventory and materials are paid for) relating to the Cattle Vaccines Divestment Business.

Pfizer will be including FD's 5th Street and Riverside manufacturing facilities as part of the potential animal health divestment package for the United States and Canada, along with certain FD personnel, including R&D personnel and cost accounting employees. As previously mentioned, the Cattle Vaccines Divestment Business may be transferred, subject to the approval of the Commission, to the same Purchaser as the US, Canada and South Africa cattle vaccines businesses if FD's cattle vaccines will be divested in the US and Canada.

At the option of the Purchaser, Pfizer or an Affiliated Undertaking shall enter into, or procures that a third party enters into, a supply or toll-manufacturing arrangement with the Purchaser for the non-exclusive supply or toll-manufacturing of the Cattle Vaccines for sale in the EEA for an appropriate period of time, not to exceed thirty-six (36) calendar months from the date of Closing (with the option to extend this period by up to 12 calendar months as mutually agreed by Pfizer and the Purchaser), and on a reasonable cost plus basis to be agreed with the Purchaser. Under circumstances outside the control of Pfizer or the Purchaser, this period can be extended by the Monitoring Trustee until such time that the Purchaser has established the Cattle Vaccines Divestment Business.

At the option of the Purchaser, Pfizer shall provide, or cause to be provided, reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of the Cattle Vaccines in the EEA, for such period as is required by the Purchaser to establish the Cattle Vaccines Divestment Business as a viable and independent business, but not exceeding 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 Pfizer or the Purchaser, this period can be extended by the Monitoring Trustee until

such time that the Purchaser has established the Cattle Vaccines Divestment Business.

At the option of the Purchaser, Pfizer shall provide, or cause to be provided, reasonable technical assistance to the Purchaser to facilitate the procurement of raw materials necessary for the manufacture of any Cattle Vaccines. If the Purchaser is not able to source such raw materials, at the option of the Purchaser, Pfizer commits to enter into, or procures that a third party enters into, back-to-back supply agreements with certain raw material suppliers and to make such raw materials available to the Purchaser on a reasonable cost plus basis to be agreed with the Purchaser, for such period as required by the Purchaser to establish the Cattle Vaccines Divestment Business as a viable and independent business, but not exceeding thirty-six (36) calendar months from the date of Closing. Under circumstances outside the control of Pfizer or the Purchaser, this period can be extended by the Monitoring Trustee until such time that the Purchaser has established the Cattle Vaccines Divestment Business.

The scope and elements of the reasonable technical assistance referred to above will have to be negotiated with the Purchaser, as this will largely depend on the requirements of the Purchaser. Pfizer envisages that reasonable technical assistance could include one or more of the following elements: advising on technical knowledge documentation, supporting the Purchaser in acquiring specific equipment, providing staff with suitable experience and skills to assist and/or advise on technical issues, assisting in trainings for the Purchaser's staff, providing guidance on regulatory and legal aspects related to the transfer of licenses.

At the option of the Purchaser and subject to applicable local employment legislation, sufficiently qualified sales and marketing personnel employed by one of the Parties will be made available to the Purchaser, to the extent reasonably necessary for the Purchaser to operate the Cattle Vaccines Divestment Business in accordance with normal market practice.

For the avoidance of doubt, the Cattle Vaccines Divestment Business shall not include any right, title and/or interest in:

(a) Any manufacturing facility in the EEA or elsewhere, potentially with the exception of the manufacturing facility in Sligo, Ireland[2];

(b) All marketing authorisations or other regulatory approvals in any territory outside the EEA;

(c) Any other asset not part of the Cattle Vaccines Divestment Business or which is used in relation to a business of Pfizer or FD other than the Divestment Business;

(d) Monies owed (including accounts receivables and unbilled accounts) to FD by customers for the purchase of the Cattle Vaccines Products, and monies owed

[2] The 5th Street and Riverside manufacturing facilities in Fort Dodge, Iowa in the United States that currently manufacture some antigens for the Cattle Vaccines may be included in the divestment of the cattle vaccines business in the United States, Canada and South Africa.

(including accounts payables and unbilled accounts) by FD to suppliers for materials used in the production of the Cattle Vaccines at the time of Closing; and

(e) Raw materials, other than the raw materials in stock used to produce the Cattle Vaccines for the EEA.

SECTION 2

FD EQUINE VACCINES

The FD Equine Vaccines Divestment Business will consist of the Current FD Equine Vaccines Divestment Business and the Equine Pipeline Product.

Current FD Equine Vaccines Divestment Business

The Current FD Equine Vaccines Divestment Business will consist of rights, title and interests, including the right to develop and improve, in the FD Equine Vaccines, which have already been marketed in the EEA or a part thereof. For the avoidance of doubt, the Current FD Equine Vaccines Divestment Business will not include any right to sell the FD Equine Vaccines outside of the EEA.

The Current FD Equine Vaccines Divestment Business includes:

(a) Sufficient biological material to produce FD Equine Vaccines, including sufficient amounts of the master seeds;

(b) Finished goods inventory, work in process, rights to product improvements, sales and promotional materials (where available) relating to the FD Equine Vaccines Divestment Business in the EEA held at the date of Closing;

(c) All current marketing authorisations and pending applications for marketing authorisations for the FD Equine Vaccines in the EEA or a part thereof held by FD, including all relevant dossiers relating to the current and/or pending marketing authorisations available to FD;

(d) Copies of all clinical reports relating to the FD Equine Vaccines Divestment Business in the EEA existing prior to Closing;

(e) The trademarks in the EEA for the FD Equine Vaccines by way of an exclusive, perpetual, irrevocable licence;

(f) The intellectual property rights where available and necessary to give a purchaser the non-exclusive right to manufacture the FD Equine Vaccines anywhere in the world for sale solely in the EEA and the exclusive right to sell the FD Equine Vaccines in the EEA by way of a perpetual, irrevocable licence. These intellectual property rights include product formulations, manufacturing know-how and other secret know-how, packaging specifications, 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 FD Equine Vaccines Divestment Business in the EEA, including existing customer records of the FD Equine Vaccines Divestment Business in the EEA, provided that the Parties may redact from such copies any information that does not relate to the Current FD Equine Vaccines Divestment Business.

At the option of the Purchaser, Pfizer 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 FD Equine Vaccines for sale 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 Pfizer or the Purchaser, this period can be extended by the Monitoring Trustee until such time that the Purchaser has established the Current FD Equine Vaccines Divestment Business.

At the option of the Purchaser, Pfizer shall provide reasonable technical assistance to the purchaser to assume responsibility for the manufacture, sale and marketing of the FD Equine Vaccines in the EEA, for such period as is required by the Purchaser to establish the Current FD Equine Vaccines Divestment Business as a viable and independent business, but not exceeding 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 Pfizer or the Purchaser, this period can be extended by the Monitoring Trustee until such time that the Purchaser has established the Current FD Equine Vaccines Divestment Business.

At the option of the Purchaser, Pfizer shall provide reasonable technical assistance to the Purchaser to facilitate the procurement of raw materials necessary for the manufacture of any FD Equine Vaccine. If the Purchaser is not able to source such raw materials, Pfizer commits to enter, at the option of the Purchaser, into back-to-back supply agreements with certain raw material suppliers and to make such raw materials available to the Purchaser on a reasonable cost plus basis to be agreed with the Purchaser, for such period as is required by the Purchaser to establish the Current FD Equine Vaccines Divestment Business as a viable and independent business, but not exceeding thirty-six (36) calendar months from the date of Closing (or, to the extent reasonably required for the transfer of the antigen tetanus toxoid for all Duvaxyn vaccines containing tetanus toxoid and the Tetanus Toxoid vaccine for a period from Closing until 31 December 2015). Under circumstances outside the control of Pfizer or the Purchaser, this period can be extended by the Monitoring Trustee, with the exception of the period for tetanus toxoid, until such time that the Purchaser has established the Current FD Equine Vaccines Divestment Business.

The scope and elements of the reasonable technical assistance referred to above will have to be negotiated with the Purchaser, as this will largely depend on the requirements of the Purchaser. Pfizer envisages that reasonable technical assistance could include one or more of the following elements: advising on technical knowledge documentation, supporting the Purchaser in acquiring specific equipment, providing staff with suitable experience and skills to assist and/or advise on technical issues, assisting in trainings for the Purchaser's staff, providing guidance on regulatory and legal aspects related to the transfer of licenses.

At the option of the Purchaser and subject to applicable local employment legislation, sufficiently qualified sales and marketing personnel employed by one of the Parties will

be made available to the Purchaser, to the extent reasonably necessary for the Purchaser to operate the Current FD Equine Vaccines Divestment Business in accordance with normal market practice.

For the avoidance of doubt, the assets transferred to the purchaser of the Current FD Equine Vaccines Divestment Business shall not include any right, title and/or interest in:

(a) Any manufacturing facility;

(b) Raw materials, other than the raw materials in stock used to produce the FD Equine Vaccines for the EEA;

(c) All marketing authorisations or other regulatory approvals in any territory currently held by FD outside of the EEA for the FD Equine Vaccines;

(d) The trademarks for *Fluvac Innovator*;

(e) Any other asset not part of the Current FD Equine Vaccines Divestment Business or which is used in relation to a business of the Pfizer or FD other than the Current FD Equine Vaccines Divestment Business; and

(f) Monies owed (including accounts receivables and unbilled accounts) to FD by customers for the purchase of the FD Equine Vaccines, and monies owed (including accounts payables and unbilled accounts) by FD to suppliers for materials used in the production of the FD Equine Vaccines at the time of Closing.

[…] *(the "Equine Pipeline Product")*

The Equine Pipeline Product consists of FD's rights to develop and commercialise […] product in the EEA […]. For the avoidance of doubt, the Equine Pipeline Product does not include any right to develop or commercialise the Equine Pipeline Product outside of the EEA.

The Equine Pipeline Product includes:

(a) Sufficient biological material already developed by FD to allow the Purchaser to continue the development of the Equine Pipeline Product, including sufficient amounts of any available master seeds in the EEA;

(b) All relevant data generated during the development project, including all material technical, preclinical, clinical and marketing files, reports, plans, know-how and records in the possession of or under control of FD or

Affiliated Undertakings existing prior to Closing, which is related to the development or commercialisation of […] product in the EEA;

(c) Copies of all clinical data and studies relating to the development of the Equine Pipeline Product existing in the EEA prior to Closing;

(d) All correspondence pertaining to regulatory filings and approvals (if any) relating to the commercialisation of the Equine Pipeline Product in the EEA;

(e) The intellectual property rights where available and necessary to give a Purchaser the exclusive right to continue to develop the Equine Pipeline Product for sale in the EEA by way of a perpetual, irrevocable licence. These intellectual property rights include product formulations, manufacturing know-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 development and commercialisation of the Equine Pipeline Product in the EEA provided that the Parties may redact from such copies any information that does not relate to the Pipeline Product.

At the option of the Purchaser, Pfizer shall provide reasonable technical assistance to the Purchaser in relation to the transfer of the Equine Pipeline Product, on a reasonable cost plus basis to be agreed with the Purchaser. Pfizer envisages that reasonable technical assistance could include one or more of the following elements: advising on technical knowledge documentation, supporting the Purchaser in acquiring specific equipment, providing staff with suitable experience and skills to assist and/or advising on technical issues relating to the research, assisting in trainings for the Purchaser's staff, providing guidance on regulatory and legal aspects related to the transfer of any license.

For the avoidance of doubt, the Equine Pipeline Product shall not include any right, title and/or interest in:

(a) Any Personnel of the Parties;

(b) Raw materials, other than any raw materials in stock used to develop the Equine Pipeline Product for the EEA;

(c) All regulatory approvals in any territory currently held by […] (if any) outside of the EEA for Equine Pipeline Product; and

(d) Any other asset not part of Equine Pipeline Product or which is used in relation to a business of the Parties other than the Equine Pipeline Product.

SECTION 3

MONOVALENT SWINE MYCOPLASMA HYOPNEUMONIAE VACCINES AND [...] VACCINES

The SMH Divestment Business will consist of the Mono SMH Divestment Business and the Pipeline Product.

Monovalent Swine Mycoplasma Hyopneumoniae (Mono SMH) Divestment Business

The Mono SMH Divestment Business will consist of rights, title and interests, including the right to develop and improve, in the Mono SMH Vaccines, which have already been marketed in the EEA or a part thereof prior to the Effective Date. For the avoidance of doubt, the Mono SMH Divestment Business does not contain any right to sell the Mono SMH Vaccines outside of the EEA.

The Mono SMH Divestment Business includes:

(a) Sufficient biological material to produce the Mono SMH Vaccines, including sufficient amounts of the master seeds;

(b) Finished goods inventory, work in process, rights to product improvements, sales and promotional material (where available) relating to the Mono SMH Divestment Business in the EEA, held at the date of Closing;

(c) All current marketing authorisations and pending applications for marketing authorisations for the Mono SMH Vaccines in the EEA or a part thereof held by Pfizer, including all relevant dossiers relating to the current and/or pending marketing authorisations available to the Parties;

(d) Copies of all clinical reports relating to the Mono SMH Divestment Business existing prior to Closing;

(e) The trademarks, by way of an exclusive, perpetual, irrevocable license, for: (i) the Stellamune branded Mono SMH Vaccines in the EEA (including those EEA countries where the Mono SMH Vaccines may not currently be registered); and (ii) the Respisure branded Mono SMH Vaccines in those EEA Member States where the Mono SMH Vaccines are currently registered under the Respisure brand, namely in Bulgaria, Czech Republic, Denmark, Estonia, Greece, Hungary, Latvia, Lithuania, Poland, Romania, Slovakia, Slovenia and Sweden.

(f) The intellectual property rights where available and necessary to give a Purchaser the non-exclusive right to manufacture the Mono SMH Vaccines anywhere in the world for sale solely in the EEA and the exclusive right to sell the Mono SMH Vaccines by way of a perpetual, irrevocable licence: (i) under the Stellamune brand in the EEA; and (ii) under the Respisure brand in those EEA Member States where the Mono SMH Vaccines are currently

registered under the Respisure brand, namely in Bulgaria, Czech Republic, Denmark, Estonia, Greece, Hungary, Latvia, Lithuania, Poland, Romania, Slovakia, Slovenia and Sweden. These intellectual property rights include product formulations, manufacturing know-how and other secret know-how, packaging specifications, 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 Mono SMH Divestment Business in the EEA, including existing customer records of the Mono SMH Divestment Business in the EEA, provided that the Parties may redact from such copies any information that does not relate to the Mono SMH Divestment Business.

In order to maintain the structural effect of the SMH Divestiture Business Commitment, the Parties shall, for a period of 10 years after the Effective Date, not re-enter the monovalent swine mycoplasma hyopneumoniae vaccine segment using the Respisure brand in any national market in the EEA identified in the Commission's Decision as raising serious doubts, unless the Commission has previously found that the structure of the market has changed to such an extent that this obligation is no longer necessary to render the proposed concentration compatible with the common market.

At the option of the Purchaser, Pfizer 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 Mono SMH Vaccines for sale 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 Pfizer or the Purchaser, this period can be extended by the Monitoring Trustee until such time that the Purchaser has established the Mono SMH Divestment Business.

At the option of the Purchaser, Pfizer shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of any Mono SMH Vaccines in the EEA, for such period as is required by the Purchaser to establish the Mono SMH Divestment Business as a viable and independent business, but not exceeding 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 Pfizer or the Purchaser, this period can be extended by the Monitoring Trustee until such time that the Purchaser has established the Mono SMH Divestment Business.

At the option of the Purchaser, Pfizer shall provide reasonable technical assistance to the Purchaser to facilitate the procurement of raw materials necessary for the manufacture of any Mono SMH Vaccines. If the Purchaser is not able to source such raw materials, Pfizer commits to enter, at the option of the Purchaser, into back-to-back supply agreements with certain raw material suppliers and to make such raw materials available to the Purchaser on a reasonable cost plus basis to be agreed with

the Purchaser for such period as is required by the Purchaser to establish the Mono SMH Divestment Business as a viable and independent business, but not exceeding thirty-six (36) calendar months from the date of Closing. Under circumstances outside the control of Pfizer or the Purchaser, this period can be extended by the Monitoring Trustee until such time that the Purchaser has established the Mono SMH Divestment Business.

The scope and elements of the reasonable technical assistance referred to above will have to be negotiated with the Purchaser, as this will largely depend on the requirements of the Purchaser. Pfizer envisages that reasonable technical assistance could include one or more of the following elements: advising on technical knowledge documentation, supporting the Purchaser in acquiring specific equipment, providing staff with suitable experience and skills to assist and/or advising on technical issues, assisting in trainings for the Purchaser's staff, providing guidance on regulatory and legal aspects related to the transfer of licenses.

At the option of the Purchaser and subject to applicable local employment legislation, sufficiently qualified sales and marketing personnel employed by one of the Parties will be made available to the Purchaser, to the extent reasonably necessary for the Purchaser to operate the Mono SMH Divestment Business in accordance with normal market practice.

For the avoidance of doubt, the Mono SMH Divestment Business shall not include any right, title and/or interest in:

(a) Any manufacturing facility, potentially with the exception of the manufacturing facility in Sligo, Ireland;

(b) Raw materials, other than the raw materials in stock used to produce the Mono SMH Vaccines for the EEA;

(c) All marketing authorisations or other regulatory approvals in any territory currently held by Pfizer outside of the EEA for the Mono SMH Vaccines;

(d) Any other asset not part of the Mono SMH Divestment Business or which is used in relation to a business of the Parties other than the Mono SMH Divestment Business; and

(e) Monies owed (including accounts receivables and unbilled accounts) to the Parties by customers for the purchase of the Mono SMH Vaccines, and monies owed (including accounts payables and unbilled accounts) by the Parties to suppliers for materials used in the production of the Mono SMH Vaccines at the time of Closing.

[…]*(the Pipeline Product)*

The Pipeline Product consists of Pfizer's rights to develop and commercialise a new vaccine […], which have been the subject of clinical trials prior to the Effective Date. For the avoidance of doubt, the Pipeline Product does not include any right to develop or commercialise the Pipeline Product outside of the EEA.

The Pipeline Product includes:

(a) Sufficient biological material of any already developed by Pfizer to allow the Purchaser to continue the development of the Pipeline Product, including sufficient amounts of any available master seeds in the EEA;

(b) All relevant data generated during the development project, including all material technical, preclinical, clinical and marketing files, reports, plans, know-how and records in the possession of or under control of Pfizer or Affiliated Undertakings existing prior to Closing, which is related to the development or commercialisation of the new […]vaccine in the EEA;

(c) Copies of all clinical data and studies relating to the development of the Pipeline Product existing in the EEA prior to Closing;

(d) All correspondence pertaining to regulatory filings and approvals (if any) relating to the commercialisation of the Pipeline Product in the EEA;

(e) The intellectual property rights where available and necessary to give a Purchaser the exclusive right to continue to develop the Pipeline Product in the EEA by way of a perpetual, irrevocable licence. These intellectual property rights include product formulations, manufacturing know-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 development and commercialisation of the Pipeline Product in the EEA provided that the Parties may redact from such copies any information that does not relate to the Pipeline Product.

At the option of the Purchaser, Pfizer shall provide reasonable technical assistance to the Purchaser in relation to the transfer of the Pipeline Product, on a reasonable cost plus basis to be agreed with the Purchaser. Pfizer envisages that reasonable technical assistance could include one or more of the following elements: advising on technical knowledge documentation, supporting the Purchaser in acquiring specific equipment, providing staff with suitable experience and skills to assist and/or advising on technical issues relating to the research, assisting in trainings for the Purchaser's staff, providing guidance on regulatory and legal aspects related to the transfer of any license.

At the option of the Purchaser, Pfizer has a project underway […] which can be included in the Pipeline Product. Pfizer is willing to provide all reports relating to the EEA-related R&D to the Purchaser as part of the SMH Divestment Business.[3]

For the avoidance of doubt, the Pipeline Product shall not include any right, title and/or interest in:

(a) Any Personnel of the Parties;

(b) Raw materials, other than any raw materials in stock used to develop the Pipeline Product for the EEA;

(c) All regulatory approvals in any territory currently held by Pfizer (if any) outside of the EEA for Pipeline Product; and

(d) Any other asset not part of Pipeline Product or which is used in relation to a business of the Parties other than the Pipeline Product.

[3] This information will not include data that relates to any US products.

SECTION 4

MULTIVALENT FELINE VACCINES

The MV Feline Divestment Business will consist of rights, title and interests, including the right to develop and improve, in the MV Feline Vaccines, which have already been marketed in the EEA or a part thereof prior to the Effective Date. For the avoidance of doubt, the MV Feline Vaccines Divestment Business does not contain any right to sell the MV Feline Vaccines outside the EEA.

The MV Feline Vaccines Divestment Business includes:

(a) Sufficient biological material to produce the MV Feline Vaccines, for sale in the EEA including sufficient amounts of the master seeds.

(b) Finished goods inventory, work in process, rights to product improvements, sales and promotional material (where available) relating to the MV Feline Vaccines Divestment Business in the EEA, held at the date of Closing;

(c) All current marketing authorisations and pending applications for marketing authorisations for the MV Feline Vaccines in the EEA held by Pfizer, including all relevant dossiers relating to the current and/or pending marketing authorisations available to the Parties;

(d) Copies of all relevant clinical reports relating to the MV Feline Vaccines Divestment Business existing prior to Closing;

(e) The trademarks in the EEA for the MV Feline Vaccines in the EEA by way of an exclusive, perpetual, irrevocable license;

(f) The intellectual property rights where available and necessary to give a Purchaser the non-exclusive right to manufacture the MV Feline Vaccines anywhere in the world for sale solely in the EEA and the right to sell the MV Feline Vaccines in the EEA, which right will be granted for exclusive sales in Belgium, Denmark Greece and Ireland only, by way of a perpetual, irrevocable licence. These intellectual property rights include product formulations, manufacturing know-how and other secret know-how, packaging specifications, 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 MV Feline Vaccines Divestment Business in the EEA, including existing customer records of the MV Feline Vaccines Divestment Business the EEA, provided that the Parties may redact from such copies any information that does not relate to the MV Feline Vaccines Divestment Business.

For the avoidance of doubt, the divestment of the MV Feline Vaccines will not prevent Pfizer from introducing the MV Feline Vaccines under a new brand name (or new

brand names) in all EEA Member States, with the exception of Belgium, Denmark, Greece and Ireland.

At the option of the Purchaser, Pfizer 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 MV Feline Vaccines for sale in the EEA for an appropriate period of time, not to exceed thirty-six (36) calendar months from the date of Closing (with the option to extend this period by up to 12 calendar months as mutually agreed by Pfizer and the Purchaser), and on a reasonable cost plus basis to be agreed with the Purchaser. Under circumstances outside the control of Pfizer or the Purchaser, this period can be extended by the Monitoring Trustee until such time that the Purchaser has established the MV Feline Vaccines Divestment Business.

At the option of the Purchaser, Pfizer shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of any MV Feline Vaccines in the EEA, for such period as is required by the Purchaser to establish the MV Feline Vaccines Divestment Business as a viable and independent business, but not exceeding 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 Pfizer or the Purchaser, this period can be extended by the Monitoring Trustee until such time that the Purchaser has established the MV Feline Vaccines Divestment Business.

At the option of the Purchaser, Pfizer shall provide reasonable technical assistance to the Purchaser to facilitate the procurement of raw materials necessary for the manufacture of any MV Feline Vaccines. If the Purchaser is not able to source such raw materials, Pfizer commits to enter, at the option of the Purchaser, into back-to-back supply agreements with certain raw material suppliers and to make such raw materials available to the Purchaser on a reasonable cost plus basis to be agreed with the Purchaser, for such period as is required by the Purchaser to establish the MV Feline Vaccines Divestment Business as a viable and independent business, but not exceeding thirty-six (36) calendar months from the date of Closing. Under circumstances outside the control of Pfizer or the Purchaser, this period can be extended by the Monitoring Trustee until such time that the Purchaser has established the MV Feline Vaccines Divestment Business.

The scope and elements of the reasonable technical assistance referred to above will have to be negotiated with the Purchaser, as this will largely depend on the requirements of the Purchaser. Pfizer envisages that reasonable technical assistance could include one or more of the following elements: advising on technical knowledge documentation, supporting the Purchaser in acquiring specific equipment, providing staff with suitable experience and skills to assist and/or advise on technical issues, assisting in trainings for the Purchaser's staff, providing guidance on regulatory and legal aspects related to the transfer of licenses.

At the option of the Purchaser and subject to applicable local employment legislation, sufficiently qualified sales and marketing personnel employed by one of the Parties will

be made available to the Purchaser, to the extent reasonably necessary for the Purchaser to operate the MV Feline Vaccines Divestment Business in accordance with normal market practice.

For the avoidance of doubt, the MV Feline Vaccines Divestment Business shall not include any right, title and/or interest in:

(a) Any manufacturing facility, potentially with the exception of the manufacturing facility in Sligo, Ireland;

(b) Raw materials, other than the raw materials in stock used to produce the MV Feline Vaccines for the EEA;

(c) All marketing authorisations or other regulatory approvals in any territory currently held by Pfizer outside of the EEA for the MV Feline Vaccines;

(d) Any other asset not part of the MV Feline Vaccines Divestment Business or which is used in relation to a business of the Parties other than the MV Feline Vaccines Divestment Business; and

(e) Monies owed (including accounts receivables and unbilled accounts) to the Pfizer by customers for the purchase of the MV Feline Vaccines, and monies owed (including accounts payables and unbilled accounts) by Pfizer to suppliers for materials used in the production of the MV Feline Vaccines at the time of Closing.

B: PHARMACEUTICALS

SECTION 5

COMPANION ANIMAL ORAL PENICILLINS

The CAOP Distribution Divestment Business will consist of: (i) the transfer of the […] Distribution Arrangement for the distribution of the […] CAOP Products in the EEA and the transfer of certain rights, title and interest in assets related to the […] CAOP Products to […] for distribution by […] or to a third party distributor approved by […] (the "[…] **CAOP Distribution Divestment Business**"); and (ii) the transfer of the […] Distribution Agreement for the distribution of the […] CAOP Products in Italy, and the transfer of certain rights, title and interest in assets related to the […] CAOP Products to […] for distribution by […] or to a third party distributor approved by […] (the "[…] **CAOP Distribution Divestment Business**"). At the option of […], Pfizer will use all reasonable best efforts to assist […] to find a third party distributor to ensure that the […] CAOP Products currently distributed by FD on the basis of the […] Distribution Arrangement are replicated under a similar or equivalent arrangement with a third party distributor. At the option of […], Pfizer will use all reasonable best efforts to assist […] to find a third party distributor to ensure that the […] CAOP Products currently distributed by FD on the basis of the […] Distribution Agreement are replicated under a similar or equivalent arrangement with a third party distributor.

The CAOP Distribution Divestment Business includes:

The […] CAOP Distribution Divestment Business including:

(a) Finished goods inventory, work in process, sales and promotional materials (where available) relating to the […] CAOP Products that are sold in the EEA, held by FD and that FD is legally permitted to transfer at the date of Closing;

(b) All current marketing authorisations and pending applications for marketing authorisations for the […] CAOP Products in the EEA or a part thereof held by FD and that FD is legally permitted to transfer to […] (or a third party distributor approved by […]), including all relevant dossiers relating to the current and/or pending marketing authorisations available to the parties;

(c) The Duphamox and Nisamox trademarks currently held by FD and that FD is legally permitted to transfer to […] or a third party distributor approved by […] in the EEA for the […] CAOP Products (including those EEA countries where the […] CAOP Products may not currently be registered) by way of an exclusive, perpetual, irrevocable license. Pfizer will also use all reasonable best efforts to assign the right to use any other […] CAOP Product trademark currently licensed to but not currently owned by FD;

(d) Copies of all clinical reports relating to the […] CAOP Products existing prior to Closing held by FD and that FD is legally permitted to transfer; and

(e) Copies of all relevant data, books, records, and other documents exclusively related to or necessary for the operations of the CAOP Distribution Divestment Business in the EEA held by FD and that FD is legally permitted to transfer, including, for example, existing customer records, sales and financial data, price lists, competitor analyses, and correspondence with third parties in the EEA, provided that Pfizer may redact from such copies any information that does not relate to the CAOP Distribution Divestment Business.

At the option of […] or the third party distributor approved by […], Pfizer shall provide reasonable technical assistance to […] or the third party distributor approved by […] to assume responsibility for the sale and marketing the […] CAOP Products in the EEA, for such period as is required by the […] or the third party distributor approved by […] to establish the CAOP Distribution Divestment Business as a viable and independent business, but not exceeding twenty-four (24) calendar months from the date of Closing, and on a reasonable cost plus basis to be agreed with […] or the third party distributor.

At the option of […] or the third party distributor approved by […] and subject to applicable local employment legislation, sufficiently qualified sales and marketing personnel employed by one of the Parties will be made available, to the extent reasonably necessary for the […] or the third party distributor to operate the CAOP Distribution Divestment Business in accordance with normal market practice.

The […] CAOP Distribution Divestment Business including:

(a) Finished goods inventory, work in process, sales and promotional materials (where available) relating to the […] CAOP Products that are sold in Italy, held by FD and that FD is legally permitted to transfer at the date of Closing;

(b) Copies of all clinical reports held by FD and that FD is legally permitted to transfer relating to the […] CAOP Products existing prior to Closing; and

(c) Copies of all relevant data, books, records, and other documents exclusively related to or necessary for the operations of the […] CAOP Products portion of the CAOP Distribution Divestment Business in Italy held by FD and that FD is legally permitted to transfer, including, for example, existing customer records, sales and financial data, price lists, competitor analyses, and correspondence with third parties in Italy, provided that Pfizer may redact from such copies any information that does not relate to the Italy CAOP Products portion of the CAOP Distribution Divestment Business.[4]

At the option of […] or the third party distributor approved by […], Pfizer shall provide reasonable technical assistance to […] or the third party distributor approved

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4 [...] holds the marketing authorizations and trademarks for the [...] CAOP Products.

by […] to assume responsibility for the sale and marketing the […] CAOP Products in Italy, for such period as is required by […] or the third party distributor approved by […] to establish the CAOP Distribution Divestment Business as a viable and independent business, but not exceeding twenty-four (24) calendar months from the date of Closing, and on a reasonable cost plus basis to be agreed with […] or the third party distributor.

At the option of […] or the third party distributor approved by […] and subject to applicable local employment legislation, sufficiently qualified sales and marketing personnel employed by one of the Parties will be made available, to the extent reasonably necessary for the […] or the third party distributor to operate the CAOP Distribution Divestment Business in accordance with normal market practice.

For the avoidance of doubt, the CAOP Distribution Divestment Business shall not include any right, title and/or interest in:

(a) Any manufacturing facilities;

(b) Any raw materials;

(c) All marketing authorisations or other regulatory approvals for FD's CAOP Products in any territory outside the EEA;

(d) Any other asset not part of the CAOP Distribution Divestment Business or which is used in relation to a business of Pfizer of FD other than the CAOP Distribution Divestment Business; and

(e) Monies owed to FD by customers for the purchase of the […] CAOP Products or the […] CAOP Products (including accounts receivables and unbilled accounts), and/or monies owed by FD to suppliers of the […] CAOP Products or the […] CAOP Products (including accounts payables and unbilled accounts) at the time of Closing.

SECTION 6

ENDOPARASITICIDES-ENDECTOCIDES FOR HORSES

The Equine Endo/Endecto Divestment Business will consist of rights, title and interests, including the right to develop and improve, in the Equine Endo/Endecto Parasiticides, which have already been marketed in the United Kingdom prior to the Effective Date. For the avoidance of doubt, the Equine Endo/Endecto Divestment Business does not contain any right to sell the Equine Endo/Endecto Parasiticides outside the United Kingdom.

The Equine Endo/Endecto Divestment Business includes:

(a) Finished goods inventory, work in process, rights to product improvements, sales and promotional material (where available) relating to the Equine Endo/Endecto Divestment Business in the United Kingdom, held at the date of Closing;

(b) All current marketing authorisations and pending applications for marketing authorisations for the Equine Endo/Endecto Parasiticides in the United Kingdom held by Pfizer, including all relevant dossiers relating to the current and/or pending marketing authorisations available to the Parties;

(c) Copies of all relevant clinical reports relating to the Equine Endo/Endecto Divestment Business existing prior to Closing;

(d) The trademarks in the United Kingdom for the Equine Endo/Endecto Parasiticides in the United Kingdom by way of an exclusive, perpetual, irrevocable license;

(e) The intellectual property rights where available and necessary to give a Purchaser the non-exclusive right to manufacture the Equine Endo/Endecto Paraciticides anywhere in the world for sale solely in the United Kingdom and the exclusive right to sell the Equine Endo/Endecto Parasiticides in the United Kingdom by way of a perpetual, irrevocable licence. These intellectual property rights include product formulations, manufacturing know-how and other secret know-how, packaging specifications, 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 Equine Endo/Endecto Divestment Business in the EEA, including existing customer records of the Equine Endo/Endecto Divestment Business in the United Kingdom, provided that the Parties may redact from such copies any information that does not relate to the Equine Endo/Endecto Divestment Business.

At the option of the Purchaser, Pfizer 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 Endo/Endecto Parasiticides in granule form

for sale in the United Kingdom 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 Pfizer or the Purchaser, this period can be extended by the Monitoring Trustee until such time that the Purchaser has established the Equine Endo/Endecto Divestment Business.

At the option of the Purchaser, Pfizer or an Affiliated Undertaking, will use all reasonable best efforts to arrange transfer of Pfizer's toll-manufacturing arrangement with its third party toll manufacturer for the non-exclusive supply of the Equine Endo/Endecto Parasiticides in paste form for sale in the United Kingdom.

At the option of the Purchaser, Pfizer shall provide reasonable technical assistance to the Purchaser to assume responsibility for the sale and marketing of any Equine Endo/Endecto Parasiticides in the United Kingdom, for such period as is required by the Purchaser to establish the Equine Parasiticides Divestment Business as a viable and independent business, but not exceeding 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 Pfizer or the Purchaser, this period can be extended by the Monitoring Trustee until such time that the Purchaser has established Equine Endo/Endecto Divestment Business.

At the option of the Purchaser, Pfizer shall provide reasonable technical assistance to the Purchaser to facilitate the procurement of raw materials necessary for the manufacture of any Equine Endo/Endecto Parasiticides in granule form. If the Purchaser is not able to source such raw materials, Pfizer commits to enter, at the option of the Purchaser, into back-to-back supply agreements with certain raw material suppliers and to make such raw materials available to the Purchaser on a reasonable cost plus basis agreed with the Purchaser, for such period as is required by the Purchaser to establish the Equine Endo/Endecto Divestment Business as a viable and independent business, but not exceeding thirty-six (36) calendar months from the date of Closing. Under circumstances outside the control of Pfizer or the Purchaser, this period can be extended by the Monitoring Trustee until such time that the Purchaser has established Equine Endo/Endecto Divestment Business.

Pfizer commits to continue to support the ongoing transfer of the manufacturing of the Equine Endo/Endecto Parasiticides in paste form from Pfizer's manufacturing facility in […] to a 3rd party toll manufacturer, in order for commercial production to commence in the 3rd or 4th quarter of 2009.

The scope and elements of the reasonable technical assistance referred to above will have to be negotiated with the Purchaser, as this will largely depend on the requirements of the Purchaser. Pfizer envisages that reasonable technical assistance could include one or more of the following elements: advising on technical knowledge documentation, supporting the Purchaser in acquiring specific equipment, providing staff with suitable experience and skills to assist and/or advise on technical issues, assisting in trainings for the Purchaser's staff, providing guidance on regulatory and legal aspects related to the transfer of licenses.

At the option of the Purchaser and subject to applicable local employment legislation, sufficiently qualified sales and marketing personnel employed by one of the Parties, will be made available to the Purchaser to the extent reasonably necessary for the Purchaser to operate the Equine Endo/Endecto Divestment Business in accordance with normal market practice.

For the avoidance of doubt, the Equine Parasiticides Divestment Business shall not include any right, title and/or interest in:

(a) Any manufacturing facility;

(b) Raw materials, other than the raw materials in stock used to produce the Equine Parasiticides for the United Kingdom;

(c) All marketing authorisations or other regulatory approvals in any territory currently held by Pfizer outside of the United Kingdom for the Equine Parasiticides;

(d) Any other asset not part of the Equine Parasiticides Divestment Business or which is used in relation to a business of the Parties other than the Equine Parasiticides Divestment Business; and

(e) Monies owed (including accounts receivables and unbilled accounts) to Pfizer by customers for the purchase of the Equine Parasiticides, and monies owed (including accounts payables and unbilled accounts) by Pfizer to suppliers for materials used in the production of the Equine Parasiticides at the time of Closing.

SECTION 7

PETS ENDOPARASITICIDES-ENDECTOCIDES

The Pet Endo/Endecto Divestment Business will consist of rights, title and interests, including the right to develop and improve, in the Pet Endo/Endecto Products, which have already been marketed in the EEA or a part thereof prior to the closing of the transaction (the "Closing"). For the avoidance of doubt, the Pet Endo/Endecto Divestment Business does not contain any right to sell the Pet Endo/Endecto Products outside of the EEA.

The Pet Endo/Endecto Divestment Business includes:

(a) Finished goods inventory, work in process, rights to product improvements, sales and promotional material (where available) relating to the Pet Endo/Endecto Divestment Business, held at the date of Closing;

(b) All current marketing authorisations and pending applications for marketing authorisations for the Pet Endo/Endecto Products in the EEA or a part thereof held by FD, including all relevant dossiers relating to the current and/or pending marketing authorisations available to the Parties that are related to the Pet Endo/Endecto Products;

(c) Copies of all relevant clinical reports relating to the Pet Endo/Endecto Divestment Business existing prior to Closing;

(d) The trademarks in the EEA for the Pet Endo/Endecto Products in the EEA (including those EEA countries where the Pet Endo/Endecto Products may not currently be registered) by way of an exclusive, perpetual, irrevocable license or assignment;

(e) The intellectual property rights where available and necessary to give a Purchaser the non-exclusive right to manufacture the Pet Endo/Endecto Products anywhere in the world for sale solely in the EEA and the exclusive right to sell the Pet Endo/Endecto Products in the EEA by way of a perpetual, irrevocable licence or assignment. These intellectual property rights include product formulations, manufacturing know-how and other secret know-how, packaging specifications, 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 Pet Endo/Endecto Divestment Business, including existing customer records of the Pet Endo/Endecto Divestment Business, provided that the Parties may redact from such copies any information that does not relate to the Pet Endo/Endecto Divestment Business.

[…] shall enter into a supply or toll-manufacturing arrangement with the Purchaser for the non-exclusive supply or toll-manufacturing of the Pet Endo/Endecto Products for sale 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 Pfizer or the Purchaser, this period can be extended by the Monitoring Trustee until such time that the Purchaser has established the Pet Endo/Endecto Divestment Business.

At the option of the Purchaser, Pfizer shall provide, or procures that a third party shall provide, reasonable technical assistance to the Purchaser to assume responsibility for the sale and marketing of any Pet Endo/Endecto Product in the EEA and for the manufacture of any Pet Endo/Endecto Product in the EEA, including, at the option of the Purchaser, the supply of APIs manufactured by FD at its facility in […], for such period as is required by the Purchaser to establish the Pet Endo/Endecto Divestment Business as a viable and independent business, but not exceeding 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 Pfizer or the Purchaser, this period can be extended by the Monitoring Trustee until such time that the Purchaser has established the Pet Endo/Endecto Divestment Business.

At the option of the Purchaser, Pfizer shall provide, or procures that a third party shall provide, reasonable technical assistance to the Purchaser to facilitate the procurement of raw materials necessary for the manufacture of any Pet Endo/Endecto Product, including, at the option of the Purchaser, the supply of APIs manufactured by FD at its facility in […]. If the Purchaser is not able to source such raw materials, Pfizer commits to enter, at the option of the Purchaser, into back-to-back supply agreements with certain raw material suppliers and to make such raw materials available to the Purchaser on a reasonable cost plus basis to be agreed with the Purchaser, for such period as is required by the Purchaser to establish the Pet Endo/Endecto Divestment Business as a viable and independent business, but not exceeding thirty-six (36) calendar months from the date of Closing. Under circumstances outside the control of Pfizer or the Purchaser, this period can be extended by the Monitoring Trustee until such time that the Purchaser has established the Pet Endo/Endecto Divestment Business.

The scope and elements of the reasonable technical assistance referred to above will have to be negotiated with the Purchaser, as this will largely depend on the requirements of the Purchaser. Pfizer envisages that reasonable technical assistance could include one or more of the following elements: advising on technical knowledge documentation, supporting the Purchaser in acquiring specific equipment, providing staff with suitable experience and skills to assist and/or on technical issues, assisting in trainings for the Purchaser's staff, providing guidance on regulatory and legal aspects related to the transfer of licenses.

At the option of the Purchaser and subject to applicable local employment legislation, sufficiently qualified sales and marketing personnel employed by one of the Parties will be made available to the Purchaser, to the extent reasonably necessary for the Purchaser to operate Pet Endo/Endecto Divestment Business in accordance with normal market practice.

For the avoidance of doubt, the Pet Endo/Endecto Divestment Business shall not include any right, title and/or interest in:

(a) Any manufacturing facility;

(b) Raw materials, other than the raw materials in stock used to produce the Pet Endo/Endecto Products for the EEA;

(c) All marketing authorisations or other regulatory approvals in any territory currently held by FD outside of the EEA for the Pet Endo/Endecto Products;

(d) Any other asset not part of the Pet Endo/Endecto Divestment Business or which is used in relation to a business of the Parties other than the Pet Endo/Endecto Divestment Business; and

(e) Monies owed (including accounts receivables and unbilled accounts) to FD by customers for the purchase of the Pet Endo/Endecto Products, and monies owed (including accounts payables and unbilled accounts) by FD to suppliers for materials used in the production of the Pet Endo/Endecto Products at the time of Closing.

SECTION 8

PRODUCTION ANIMAL ENDOPARASITICIDES-ENDECTOCIDES

The PA Endo-Endecto Divestment Business will consist of rights, title and interests, including the right to develop and improve, in the PA Endo-Endecto Products, which have already been marketed in Belgium, including Luxembourg, Germany and the United Kingdom prior to the Effective Date. For the avoidance of doubt, the PA Endo-Endecto Divestment Business does not contain any right to sell the PA Endo-Endecto Products outside Belgium, Germany or the United Kingdom.

The PA Endo-Endecto Divestment Business includes:

(a) Finished goods inventory, work in process, rights to product improvements, sales and promotional material (where available) relating to the PA Endo-Endecto Divestment Business in Belgium, Germany and the United Kingdom, held at the date of Closing;

(b) All current marketing authorisations and pending applications for marketing authorisations for the PA Endo-Endecto Products in Belgium, Germany and the United Kingdom held by Pfizer, including all relevant dossiers relating to the current and/or pending marketing authorisations available to the Parties;

(c) Copies of all relevant clinical reports relating to the PA Endo-Endecto Divestment Business existing prior to Closing;

(d) The trademarks in Belgium, Germany and the United Kingdom for the PA Endo-Endecto Products in Belgium, Germany and the United Kingdom by way of an exclusive, perpetual, irrevocable license;

(e) The intellectual property rights where available and necessary to give a Purchaser the non-exclusive right to manufacture the PA Endo-Endecto Products anywhere in the world for sale solely in Belgium, Germany and the United Kingdom and the exclusive right to sell the PA Endo-Endecto Products in Belgium, Germany and the United Kingdom by way of a perpetual, irrevocable licence. These intellectual property rights include product formulations, manufacturing know-how and other secret know-how, packaging specifications, 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 PA Endo-Endecto Divestment Business in the EEA, including existing customer records of the PA Endo-Endecto Divestment Business in Belgium, Germany and the United Kingdom, provided that the Parties may redact from such copies any information that does not relate to the PA Endo-Endecto Divestment Business.

At the option of the Purchaser, Pfizer 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 PA Endo-Endecto Products for sale in Belgium, Germany and the United Kingdom 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 Pfizer or the Purchaser, this period can be extended by the Monitoring Trustee until such time that the Purchaser has established the PA Endo-Endecto Divestment Business.

At the option of the Purchaser, Pfizer shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of any PA Endo-Endecto Products in Belgium, Germany and the United Kingdom, for such period as is required by the Purchaser to establish the PA Endo-Endecto Divestment Business as a viable and independent business, but not exceeding 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 Pfizer or the Purchaser, this period can be extended by the Monitoring Trustee until such time that the Purchaser has established the PA Endo-Endecto Divestment Business.

At the option of the Purchaser, Pfizer shall provide reasonable technical assistance to the Purchaser to facilitate the procurement of raw materials necessary for the manufacture of any PA Endo-Endecto Products. If the Purchaser is not able to source such raw materials, Pfizer commits to enter, at the option of the Purchaser, into back-to-back supply agreements with certain raw material suppliers and to make such raw materials available to the Purchaser on a reasonable cost plus basis to be agreed with the Purchaser, for such period as is required by the Purchaser to establish the PA Endo-Endecto Divestment Business as a viable and independent business, but not exceeding thirty-six (36) calendar months calendar months from the date of Closing. Under circumstances outside the control of Pfizer or the Purchaser, this period can be extended by the Monitoring Trustee until such time that the Purchaser has established the PA Endo-Endecto Divestment Business.

The scope and elements of the reasonable technical assistance referred to above will have to be negotiated with the Purchaser, as this will largely depend on the requirements of the Purchaser. Pfizer envisages that reasonable technical assistance could include one or more of the following elements: advising on technical knowledge documentation, supporting the Purchaser in acquiring specific equipment, providing staff with suitable experience and skills to assist and/or advise on technical issues, assisting in trainings for the Purchaser's staff, providing guidance on regulatory and legal aspects related to the transfer of licenses.

At the option of the Purchaser and subject to applicable local employment legislation, sufficiently qualified sales and marketing personnel employed by one of the Parties will be made available to the Purchaser, to the extent reasonably necessary for the

Purchaser to operate the PA Endo-Endecto Divestment Business in accordance with normal market practice.

For the avoidance of doubt, the PA Endo-Endecto Divestment Business shall not include any right, title and/or interest in:

(a) Any manufacturing facility;

(b) Raw materials, other than the raw materials in stock used to produce the PA Endo-Endecto Products for Belgium, Germany and the United Kingdom;

(c) All marketing authorisations or other regulatory approvals in any territory currently held by Pfizer outside of Belgium, Germany and the United Kingdom for the PA Endo-Endecto Products;

(d) Any other asset not part of the PA Endo-Endecto Divestment Business or which is used in relation to a business of the Parties other than the PA Endo-Endecto Divestment Business; and

(e) Monies owed (including accounts receivables and unbilled accounts) to Pfizer by customers for the purchase of the PA Endo-Endecto Products, and monies owed (including accounts payables and unbilled accounts) by Pfizer to suppliers for materials used in the production of the PA Endo-Endecto Products at the time of Closing.

SECTION 9

PRODUCTION ANIMAL TETRACYCLINES

The PA Tetracycline Distribution Divestment Business will consist of the transfer of the […] Distribution Arrangement for the distribution of the […] PA Tetracyclines in Finland and Italy and the transfer of certain rights, title and interest in assets related to the […] PA Tetracycline Distribution Divestment Business to […] for distribution by […] or to a third party approved by […]. At the option of […] Pfizer will use all reasonable best efforts to assist […] to find a third party distributor to ensure that the […] PA Tetracyclines currently distributed by FD on the basis of the […] Distribution Arrangement are replicated under a similar or equivalent arrangement with a third party distributor. For the avoidance of doubt, the PA Tetracycline Distribution Divestment Business does not contain any right to sell the […] PA Tetracyclines outside Finland and Italy.

The PA Tetracycline Distribution Divestment Business includes:

(a) Finished goods inventory, work in process, sales and promotional material (where available) relating to the PA Tetracycline Distribution Divestment Business, held by FD and that FD is legally permitted to transfer (to […] or the third party distributor approved by […]) at the date of Closing;

(b) All current marketing authorisations and pending applications for marketing authorisations for the PA Tetracyclines in Finland and Italy held by FD and that FD is legally permitted to transfer, including all relevant dossiers relating to the current and/or pending marketing authorisations available to the Parties;

(c) Copies of all relevant clinical reports relating to the PA Tetracycline Distribution Divestment Business held by FD and that FD is legally permitted to transfer, existing prior to Closing;

(d) The trademarks for the […] PA Tetracyclines in Finland and Italy held by FD and that FD is legally permitted to transfer by way of an exclusive, perpetual, irrevocable license;

(e) Copies of all relevant data, books, records, and other documents exclusively related to or necessary for the operations of the PA Tetracycline Distribution Divestment Business held by FD and that FD is legally permitted to transfer, including, for example, existing customer records, sales and financial data, price lists, competitor analyses, and correspondence with third parties in Finland and Italy, provided that the Parties may redact from such copies any information that does not relate to the PA Tetracycline Distribution Divestment Business.

At the option of the […] or the third party distributor approved by […], Pfizer shall provide reasonable technical assistance to […] or the third party distributor approved

by […] to assume responsibility for the sale and marketing of the […] PA Tetracyclines in Finland and Italy, for such period as is required by […] or the third party distributor approved by […] to establish the PA Tetracycline Distribution Divestment Business as a viable and independent business, but not exceeding twenty-four (24) calendar months from the date of Closing, and on a reasonable cost plus basis to be agreed with […] or the third party distributor approved by […].

At the option of […] or the third party distributor approved by […] and subject to applicable local employment legislation, sufficiently qualified sales and marketing personnel employed by one of the Parties will be made available to […] or the third party distributor approved by […], to the extent reasonably necessary for […] or the third party distributor approved by […] to operate the PA Tetracycline Distribution Divestment Business in accordance with normal market practice.

For the avoidance of doubt, the PA Tetracycline Distribution Divestment Business shall not include any right, title and/or interest in:

(a) Any manufacturing facility;

(b) Any raw materials;

(c) All marketing authorisations or other regulatory approvals in any territory currently held by FD outside of Finland and Italy for the PA Tetracyclines;

(d) Any other asset not part of the PA Tetracycline Distribution Divestment Business or which is used in relation to a business of the Parties other than the PA Tetracycline Distribution Divestment Business; and

(e) Monies owed (including accounts receivables and unbilled accounts) to FD by customers for the purchase of the […] PA Tetracyclines, and monies owed (including accounts payables and unbilled accounts) by FD to suppliers of the […] PA Tetracyclines at the time of Closing.

SECTION 10

SEDATIVES

The Sedatives Distribution Divestment Business will consist of the transfer of the […] Distribution Agreement for the distribution of […] 's sedatives by Pfizer to the extent it relates to the United Kingdom and of the transfer of certain rights, title and interest in assets related to the Sedatives Distribution Divestment Business to […] for distribution by […] or to a third party distributor approved by […]. At the option of […], Pfizer will use all reasonable best efforts to assist […] to find a third party distributor to ensure that the Sedatives currently distributed by Pfizer on the basis of the […] Distribution Agreement are replicated under a similar or equivalent arrangement with a third party distributor. For the avoidance of doubt, the Sedatives Distribution Divestment Business does not contain any right to sell the Sedatives outside the UK.

The Sedatives Distribution Divestment Business includes:

(a) Finished goods inventory, work in process, sales and promotional material (where available) relating to the Sedatives Distribution Divestment Business, held by Pfizer and that Pfizer is legally permitted to transfer to a Purchaser at the date of Closing;

(b) All current marketing authorisations and pending applications for marketing authorisations for the Sedatives held by Pfizer and that Pfizer is legally permitted to transfer, including all relevant dossiers relating to the current and/or pending marketing authorisations available to the Parties;

(c) Copies of all relevant clinical reports held by Pfizer and that Pfizer is legally permitted to transfer relating to the Sedatives Distribution Divestment Business existing prior to Closing;

(d) The trademarks for the Sedatives in the United Kingdom held by Pfizer and that Pfizer is legally permitted to transfer by way of an exclusive, perpetual, irrevocable license; and

(e) Copies of all relevant data, books, records, and other documents exclusively related to or necessary for the operations of the Sedatives Distribution Divestment Business held by Pfizer and that Pfizer is legally permitted to transfer, including, for example, existing customer records, sales and financial data, price lists, competitor analyses, and correspondence with third parties in the United Kingdom, provided that the Parties may redact from such copies any information that does not relate to the Sedatives Distribution Divestment Business.

At the option of […] or the third party distributor approved by […], Pfizer shall provide reasonable technical assistance to […] or the third party distributor approved by […] to assume responsibility for the sale and marketing of the Sedatives in the United Kingdom, for such period as is required by the […] or the third party approved

by […] to establish the Sedatives Distribution Divestment Business as a viable and independent business, but not exceeding twenty-four (24) calendar months from the date of Closing, and on a reasonable cost plus basis to be agreed with […] or the third party distributor.

At the option of […] or the third party distributor approved by […] and subject to applicable local employment legislation, sufficiently qualified sales and marketing personnel employed by one of the Parties will be made available, to the extent reasonably necessary for […] or the third party distributor to operate the Sedatives Distribution Divestment Business in accordance with normal market practice.

For the avoidance of doubt, the Sedatives Distribution Divestment Business shall not include any right, title and/or interest in:

(a) Any manufacturing facility;

(b) Any raw materials;

(c) All marketing authorisations or other regulatory approvals in any territory currently held by Pfizer outside the United Kingdom for the Sedatives;

(d) Any other asset not part of the Sedatives Distribution Divestment Business or which is used in relation to a business of the Parties other than the Sedatives Distribution Divestment Business; and

(e) Monies owed (including accounts receivables and unbilled accounts) to PAH by customers for the purchase of the Sedatives, and monies owed (including accounts payables and unbilled accounts) by PAH to suppliers for materials used in the production of the Sedatives at the time of Closing.

SECTION 11

TETRACYCLINE SPRAYS

The Tetracycline Sprays Distribution Divestment Business will consist of the termination of the […] Distribution Arrangement for the distribution of the […] Tetracycline Sprays in Austria, Belgium, the Czech Republic, France, Germany, Hungary, Iceland, Italy, The Netherlands, Slovakia, and the United Kingdom, as well as the transfer of certain rights, title and interest in assets related to the Tetracycline Sprays Distribution Divestment Business. At the option of […], Pfizer will use all reasonable best efforts to assist […] to find a third party distributor to ensure that the […] Tetracycline Sprays currently distributed by FD on the basis of the […] distribution arrangement are replicated under a similar or equivalent arrangement with a third party distributor.

The Tetracycline Sprays Divestment Business will consist of FD's tetracycline sprays business in Portugal, all Pfizer's reasonable best efforts to assign FD's Tetracycline Sprays Toll Manufacturing Agreement with […], and the transfer of certain rights, title and interest in assets related to the Tetracycline Sprays Divestment Business.

For the avoidance of doubt, the Tetracycline Sprays Distribution Divestment Business and the Tetracycline Sprays Divestment Business will not include any right to sell Chlortetracycline spray outside of the EEA or any right to sell Oxytetracycline spray outside of the EEA.

Pfizer intends to include the following in the Tetracycline Sprays Divestment Business and to the extent that FD does not own any of these assets, Pfizer will use all reasonable best efforts to achieve this scope of the Tetracycline Sprays Divestment Business:

(a) Finished goods inventory, work in process, sales and promotional material (where available) relating to the Tetracycline Sprays Divestment Business, held by FD and that FD is legally permitted to transfer to the purchaser at the date of Closing;

(b) All current marketing authorisations and pending applications for marketing authorisations for the Tetracycline Sprays in Portugal held by FD and that FD is legally permitted to transfer, including all relevant dossiers relating to the current and/or pending marketing authorisations available to the Parties;

(c) Copies of all relevant clinical reports held by FD and that FD is legally permitted to transfer relating to the Tetracycline Sprays Divestment Business existing prior to Closing;

(d) The *Duphacycline Spray* and/or *Nixal Spray* trademarks currently held by FD in Portugal and that FD is legally permitted to transfer by way of an exclusive, perpetual, irrevocable license; and

(e) Copies of all relevant data, books, records, and other documents exclusively related to or necessary for the operations of the Tetracycline Sprays Divestment Business held by FD and that FD is legally permitted to transfer, including, for example, existing customer records, sales and financial data, price lists, competitor analyses, and correspondence with third parties in Portugal, provided that the Parties may redact from such copies any information that does not relate to the Tetracycline Sprays Divestment Business.

At the option of the purchaser of the Tetracycline Sprays Divestment Business, Pfizer shall provide reasonable technical assistance the purchaser to assume responsibility for the sale and marketing of the Tetracycline Sprays Divestment Business, for such period as is required by the purchaser to establish the Tetracycline Sprays Divestment Business as a viable and independent business, but not exceeding twenty-four (24) calendar months from the date of Closing, and on a reasonable cost plus basis to be agreed with the Purchaser.

At the option of the Purchaser and subject to applicable local employment legislation, sufficiently qualified sales and marketing personnel employed by one of the Parties will be made available to the Purchaser, to the extent reasonably necessary for the Purchaser to operate the Tetracycline Sprays Divestment Business in accordance with normal market practice.

Pfizer intends to include the following in the Tetracycline Sprays Distribution Divestment Business and to the extent that FD does not own any of these assets, Pfizer will use all best efforts to achieve this scope of the Tetracycline Sprays Distribution Divestment Business:

(a) Finished goods inventory, work in process, sales and promotional material (where available) relating to the Tetracycline Sprays Distribution Divestment Business, held by FD and that FD is legally permitted to transfer (to […] or the third party distributor approved by […]) at the date of Closing;

(b) All current marketing authorisations and pending applications for marketing authorisations for the Tetracycline Sprays in Austria, Belgium, Czech Republic, France, Germany, Hungary, Iceland, Italy, The Netherlands, Slovakia and the United Kingdom held by FD and that FD is legally permitted to transfer, including all relevant dossiers relating to the current and/or pending marketing authorisations available to the Parties;

(c) Copies of all relevant clinical reports held by FD and that FD is legally permitted to transfer relating to the Tetracycline Sprays Distribution Divestment Business existing prior to Closing;

(d) The *Duphacycline Spray* and/or *Nixal Spray* trademarks currently held by FD in Austria, Belgium, Czech Republic, France, Germany, Hungary, Iceland, Italy, The Netherlands, Slovak Republic and the United Kingdom and that FD

is legally permitted to transfer by way of an exclusive, perpetual, irrevocable license. Pfizer will also use all reasonable best efforts to assign to […], or the third party distributor approved by […] the right to use any other Tetracycline Sprays trademark currently licensed to but not currently owned by FD in Austria, Belgium, Czech Republic, France, Germany, Hungary, Iceland, Italy, The Netherlands, Slovak Republic and the United Kingdom; and

(e) Copies of all relevant data, books, records, and other documents exclusively related to or necessary for the operations of the Tetracycline Sprays Distribution Divestment Business held by FD and that FD is legally permitted to transfer, including, for example, existing customer records, sales and financial data, price lists, competitor analyses, and correspondence with third parties in the EEA, provided that the Parties may redact from such copies any information that does not relate to the Tetracycline Sprays Distribution Divestment Business.

At the option of […] or the third party distributor appointed by […], Pfizer shall provide reasonable technical assistance to […] or the third party distributor appointed by […] to assume responsibility for the sale and marketing of the […] Tetracycline Sprays in Austria, Belgium, Czech Republic, France, Germany, Hungary, Iceland, Italy, The Netherlands, Slovakia, and the United Kingdom, for such period as is required by […] or the third party distributor appointed by […] to establish the Tetracycline Sprays Distribution Divestment Business as a viable and independent business, but not exceeding twenty-four (24) calendar months from the date of Closing, and on a reasonable cost plus basis to be agreed with […] or the third party distributor appointed by […].

At the option of the Purchaser, Pfizer shall provide reasonable technical assistance to the Purchaser to assume responsibility for the sale and marketing of the Tetracycline Sprays in Portugal for such period as is required by the Purchaser to establish the Tetracycline Sprays Divestment Business as a viable and independent business, but not exceeding twenty-four (24) calendar months from the date of Closing, and on a reasonable cost plus basis to be agreed with the Purchaser.

At the option of […] or the third party distributor appointed by […] and subject to applicable local employment legislation, sufficiently qualified sales and marketing personnel employed by one of the Parties will be made available to […] or the third party distributor appointed by […], to the extent reasonably necessary for […] or the third party distributor appointed by […] to operate the Tetracycline Sprays Distribution Divestment Business in accordance with normal market practice.

For the avoidance of doubt, neither the Tetracycline Sprays Divestment Business nor the Tetracycline Sprays Distribution Divestment Business shall include any right, title and/or interest in:

(a) Any manufacturing facility;

(b) Any raw materials, including, but not limited to, Chlortetracycline hydrochloride, Gentian Violet, and ethyl alcohol, used in the production of Chlortetracycline spray;

(c) All marketing authorisations or other regulatory approvals in any territory currently held by FD outside of the EEA for the Tetracycline Sprays;

(d) The *Aureomycin Spray* trademark currently in-licensed by FD from […];

(e) Any other asset not part of the Tetracycline Sprays Divestment Business or the Tetracycline Sprays Distribution Divestment Business which is used in relation to a business of the Parties other than the Tetracycline Sprays Divestment Business or the Tetracycline Sprays Distribution Divestment Business; and

(f) Monies owed (including accounts receivables and unbilled accounts) to FD by customers for the purchase of the Tetracycline Sprays, and monies owed (including accounts payables and unbilled accounts) by FD to suppliers of the Tetracycline Sprays at the time of Closing.

SECTION 12
CEPHALOSPORINS

The Cephalosporin Distribution Divestment Business will consist of the termination of the Distribution Agreement for the distribution of the […] Cephalosporin Product in Italy, and the transfer of certain rights, title and interest in assets related to the […] Cephalosporin Product to […] or a third party distributor appointed by […]. At the option of […], Pfizer will use all reasonable best efforts to assist […] to find a third party distributor to ensure that the […] Cephalosporin Product currently distributed by FD on the basis of the distribution agreement with […] is replicated under a similar or equivalent arrangement with a third party distributor.

The Cephalosporin Distribution Divestment Business includes:

(a) Finished goods inventory, work in process, sales and promotional materials (where available) relating to the […] Cephalosporin Product that is sold in Italy, held by FD and that FD is legally permitted to transfer at the date of Closing;

(b) Copies of all clinical reports held by FD and that FD is legally permitted to transfer relating to the […] Cephalosporin Product existing prior to Closing; and

(c) Copies of all relevant data, books, records, and other documents exclusively related to or necessary for the operations of the Cephalosporin Distribution Divestment Business in Italy held by FD and that FD is legally permitted to transfer, including, for example, existing customer records, sales and financial data, price lists, competitor analyses, and correspondence with third parties in Italy, provided that Pfizer may redact from such copies any information that does not relate to the Cephalosporin Distribution Divestment Business.[5]

At the option of […] or the third party distributor appointed by […], Pfizer shall provide reasonable technical assistance to […] or the third party distributor appointed by […] to assume responsibility for the sale and marketing the […] Cephalosporin Products in Italy, for such period as is required by […] or the third party distributor appointed by […] to establish the Cephalosporin Distribution Divestment Business as a viable and independent business, but not exceeding twenty-four (24) calendar months from the date of Closing, and on a reasonable cost plus basis to be agreed with […] or the third party distributor.

At the option of […] or the third party distributor appointed by […] and subject to applicable local employment legislation, sufficiently qualified sales and marketing personnel employed by one of the Parties will be made available, to the extent

reasonably necessary for […] or the third party distributor to operate the Cephalosporin Distribution Divestment Business in accordance with normal market practice.

For the avoidance of doubt, the Cephalosporin Distribution Divestment Business shall not include any right, title and/or interest in:

(a) Any manufacturing facilities;

(b) Any raw materials;

(c) Any marketing authorisations or other regulatory approvals for FD's […] Cephalosporin Product in any territory outside Italy;

(d) Any other asset not part of the Cephalosporin Distribution Divestment Business or which is used in relation to a business of Pfizer of FD other than the Cephalosporin Distribution Divestment Business; and

(e) Monies owed to FD by customers for the purchase of the […] Cephalosporin Product (including accounts receivables and unbilled accounts), and/or monies owed by FD to suppliers of the […] Cephalosporin Product (including accounts payables and unbilled accounts) at the time of Closing.

C: MEDICINAL FOOD ADDITIVES

SECTION 13

ORAL REHYDRATION SALTS

The ORS Divestment Business will consist of rights, title and interests, including the right to develop and improve, in the ORS Products, which have already been marketed in the EEA or a part thereof prior to the Effective Date. For the avoidance of doubt, the ORS Divestment Business does not contain any right to sell the ORS Products outside of the EEA.

The ORS Divestment Business includes:

(a) Finished goods inventory, work in process, rights to product improvements, sales and promotional material (where available) relating to the ORS Divestment Business in the EEA, held at the date of Closing;

(b) All current marketing authorisations and pending applications for marketing authorisations for the ORS Products in the EEA or a part thereof held by Pfizer, including all relevant dossiers relating to the current and/or pending marketing authorisations available to the Parties;

(c) Copies of all relevant clinical reports relating to the ORS Divestment Business existing prior to Closing;

(d) The trademarks for the ORS Products in the EEA (including those EEA countries where the ORS Products may not currently be registered) by way of an exclusive perpetual, irrevocable license;

(e) The intellectual property rights where available and necessary to give a Purchaser the non-exclusive right to manufacture the ORS Products anywhere in the world for sale solely in the EEA and the exclusive right to sell the ORS Products in the EEA by way of a perpetual, irrevocable licence. These intellectual property rights include product formulations, manufacturing know-how and other secret know-how, packaging specifications, 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 ORS Divestment Business in the EEA, including existing customer records of the ORS Divestment Business in the EEA, provided that the Parties may redact from such copies any information that does not relate to the ORS Divestment Business.

At the option of the Purchaser, Pfizer 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 ORS Products for sale 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 Pfizer or the Purchaser, this period can be extended by the Monitoring Trustee until such time that the Purchaser has established the ORS Divestment Business.

The transitional supply or toll-manufacturing arrangement referred to above shall include appropriate provisions designed to ensure the reasonable continuous supply by Pfizer to the Purchaser of any ORS Product for sale in the EEA for the duration of the arrangement.

At the option of the Purchaser, Pfizer shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of any ORS Product in the EEA, for such period as is required by the Purchaser to establish the ORS Divestment Business as a viable and independent business, but not exceeding thirty-six (36) calendar months from the date of Closing, on a reasonable cost plus basis to be agreed with the Purchaser. Under circumstances outside the control of Pfizer or the Purchaser, this period can be extended by the Monitoring Trustee until such time that the Purchaser has established the ORS Divestment Business.

At the option of the Purchaser, Pfizer shall provide reasonable technical assistance to the Purchaser to facilitate the procurement of raw materials necessary for the manufacture of any ORS Product. If the Purchaser is not able to source such raw materials, Pfizer commits to enter, at the option of the Purchaser, into back-to-back supply agreements with certain raw material suppliers and to make such raw materials available to the Purchaser on a reasonable cost plus basis to be agreed with the Purchaser, for such period as is required by the Purchaser to establish the ORS Divestment Business as a viable and independent business, but not exceeding thirty-six (36) calendar months from the date of Closing. Under circumstances outside the control of Pfizer or the Purchaser, this period can be extended by the Monitoring Trustee until such time that the Purchaser has established the ORS Divestment Business.

The scope and elements of the reasonable technical assistance referred to above will have to be negotiated with the Purchaser, as this will largely depend on the requirements of the Purchaser. Pfizer envisages that reasonable technical assistance could include one or more of the following elements: advising on technical knowledge documentation, supporting the Purchaser in acquiring specific equipment, providing staff with suitable experience and skills to assist and/or advise on technical issues, assisting in trainings for the Purchaser's staff, provide guidance on regulatory and legal aspects related to the transfer of licenses.

At the option of the Purchaser and subject to applicable local employment legislation, sufficiently qualified sales and marketing personnel employed by one of the Parties will be made available to the Purchaser, to the extent reasonably necessary for the Purchaser to operate the ORS Divestment Business in accordance with normal market practice.

For the avoidance of doubt, the ORS Divestment Business shall not include any right, title and/or interest in:

Any manufacturing facility;

(a) Raw materials, other than the raw materials in stock used to produce the ORS Products for the EEA;

(b) All marketing authorisations currently held by Pfizer outside of the EEA for the ORS Products;

(c) Any other asset not part of the ORS Divestment Business or which is used in relation to a business of the Parties other than the ORS Divestment Business; and

(d) Monies owed (including accounts receivables and unbilled accounts) to Pfizer by customers for the purchase of the ORS Products, and monies owed (including accounts payables and unbilled accounts) by Pfizer to suppliers for materials used in the production of the ORS Products at the time of Closing.

D: MANUFACTURING FACILITY

SECTION 14

SLIGO DIVESTMENT BUSINESS

Introduction

The Sligo manufacturing facility is located in the Finisklin Industrial Estate in Sligo, Ireland, and has been in operation since 1992 (the "Sligo Manufacturing Facility"). The Sligo Manufacturing Facility building is situated on a site that is 14,569 square meters, utilizing 3,252 square meters currently, with room to expand. The Sligo Manufacturing Facility currently employs [approximately 100 persons] and manufactures a range of both modified live (MLV) and inactivated veterinary vaccines.

The Sligo Manufacturing Facility's current core capabilities include bioreactor antigen manufacturing, freeze drying, media manufacturing, cell supply, and biological blending, filling, and finish. The Sligo Manufacturing Facility also has a quality control function. The Sligo Manufacturing Facility was designed specifically for veterinary vaccine manufacture to EU GMP standards. Products are finished on-site for distribution mostly to the European market.

The Sligo Manufacturing Facility currently manufactures a range of vaccines, not all of which are included in the Vaccines Divestment Business.[6] However, the Sligo Divestment Business will have the capability to manufacture all of the vaccines manufactured by the Vaccines Divestment Businesses (the "Divested Vaccines") acquired by the Purchaser following certain modifications and capital improvements set forth in more detail below, which Pfizer will commit, at the option of the Purchaser, to undertake and/or fund, to ultimately deliver the Sligo Divestment Business as a fully functional manufacturing facility capable of manufacturing all of the Divested Vaccines. The divestment of the Sligo Manufacturing Facility is at the option of the Purchaser of the Divested Vaccines

The details of the scope of the specific Vaccines Divestment Businesses are described in Sections 1-4 above. To facilitate the transfer of products (other than the Divested Vaccines) that are currently manufactured at the Sligo Manufacturing Facility out of the plant, the Purchaser of the Sligo Divestment Business will be required to provide manufacturing services to Pfizer for a transitional period after the Closing of the proposed divestment, which Pfizer expects to be approximately […] months.

Scope of the Sligo Divestment Business

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6 The following subset of the cattle vaccines are the only divested Vaccines manufactured at the Sligo Plant: Triangle 3, Triangle 4 and Triangle 4 + PKH (though the PKH antigen is made at Fort Dodge's Charles City plant and shipped to Sligo where it is combined with the Triangle 4 antigen).

The Sligo Divestment Business will consist of a transfer of ownership rights, title and interest to FD's Sligo Manufacturing Facility and certain related assets including, but not limited to the following:

(a) The existing Sligo Manufacturing Facility, which consists of the (i) property; (ii) buildings; (iii) equipment, including FD purpose-built equipment for viral vaccine manufacturing, specifically […] bio reactors used for antigen production, […] micron centrifuge used for antigen separation, and […] nominal molecular weight cut-off downstream processing concentration cartridges used for viral concentration and third party-purchased equipment for viral vaccine manufacturing, specifically multiple roller racks used for normal cell production, […] portable blend vessels, and […] filling, stoppering and capping machine; and (iv) other assets necessary for the production and testing of veterinary biological products, including vaccines, which are currently located at the Sligo Manufacturing Facility;

(b) Capital expenditures, and improvements, which Pfizer commits to undertake at the Purchaser's option after the Closing, up to $ […], necessary to enable the facility to accept and manufacture the Divested Vaccines acquired by the Purchaser of the Sligo Manufacturing Facility that are not presently manufactured, or capable of being manufactured, at the facility, including but not necessarily limited to plant expansions to add antigen capability, including fermentation, downstream processing capability, filling capability for large format bottles, and packaging capability for large format bottles;[7]

(c) The opportunity to hire the existing manufacturing, support, and administrative personnel currently employed at the Sligo Manufacturing Facility necessary for the new Purchaser to operate the plant;

(d) Subject to applicable local employment legislation, the opportunity to hire the following Key Personnel: the Plant Manager, the Production Manager, the Engineer Manager, the Technical Manager, the Maintenance Supervisor and the Quality Manager.

(e) Reasonable technical assistance for the Purchaser to operate the plant, including licenses to the manufacturing know-how necessary to manufacture the Divested Vaccines that are sold to the Purchaser of the Sligo Divestment Business;

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[7] Pfizer expects that the capital improvements to the Sligo Manufacturing Facility and the necessary regulatory and other requirements for the transfer of the last of the Divested Vaccines acquired by any Purchaser of Sligo to be complete within approximately [...] months from acquisition of the Sligo Divestment Business.

(f) Assistance and support in obtaining necessary registrations, consents, permits, or regulatory approvals or maintenance of existing registrations and approvals for the plant;

(g) Copies of all relevant data, books, records, and other documents exclusively related to or necessary for the operations of the Sligo Manufacturing Facility.

The scope and elements of the reasonable technical assistance referred to above will have to be negotiated with the Purchaser, because this will largely depend on the requirements of the Purchaser. Pfizer envisages that reasonable technical assistance could include one or more of the following elements: advice on technical knowledge documentation, support for the Purchaser in acquiring specific equipment, provide staff with suitable experience and skills to assist and/or advise on technical issues, assist in trainings for the Purchaser's staff, provide guidance on regulatory and legal aspects related to the transfer of licenses.

For the avoidance of doubt, the Sligo Divestment Business shall not include any right, title and/or interest in:

(a) any manufacturing facility other than the Sligo Manufacturing Facility;

(b) any personnel of the Parties in the EEA, other than personnel associated with the Sligo Manufacturing Facility;

(c) any product currently manufactured at the Sligo Manufacturing Facility other than any of the Divested Vaccines acquired by the Purchaser of the Sligo Divestment Business;

(d) any other assets, services, or production steps currently used or in place at the Sligo Manufacturing Facility that are not necessary to manufacture or support the Divested Vaccines that are sold to the Purchaser of the Sligo Divestment Business;

(e) raw materials, other than the raw materials in stock at the Sligo Manufacturing Facility used to produce any of the Divested Vaccines acquired by the Purchaser of the Sligo Divestment Business;

(f) any marketing authorisations or other regulatory approvals in any territory currently held by Pfizer or FD;

(g) any intellectual property, including any patents, know-how or trademarks owned or controlled by Pfizer or FD other than the license described above;

(h) any other asset not part of the Sligo Divestment Business or which is used in relation to a business of the Parties other than the Sligo Divestment Business; and

(i) monies owed (including accounts receivables and unbilled accounts) to Pfizer or FD by customers for the purchase of any of the Divested Vaccines or the Sligo Divestment Business.

SCHEDULE 2

Commitments

Case M. 5476 – Pfizer/Wyeth

Alternative Divestment Businesses

SECTION 1

COMPANION ANIMALS ORAL PENICILLIN

The CAOP Alternative Divestment Business will consist of rights, title and interests, including the right to develop and improve, in the CAOP Products, which have already been marketed by Pfizer in the Czech Republic, Italy, Slovakia, Spain and the United Kingdom. For the avoidance of doubt, the CAOP Alternative Divestment Business does not contain any right to sell the CAOP Products outside the Czech Republic, Italy, Slovakia, Spain or the United Kingdom.

The CAOP Alternative Divestment Business includes:

(a) Finished goods inventory, work in process, rights to product improvements, sales and promotional material (where available) relating to the CAOP Alternative Divestment Business in the Czech Republic, Italy, Slovakia, Spain and the United Kingdom, held at the date of Closing;

(b) All current marketing authorisations and pending applications for marketing authorisations for the CAOP Products in Czech Republic, Italy, Slovakia, Spain and the United Kingdom held by Pfizer, including all relevant dossiers relating to the current and/or pending marketing authorisations available to Pfizer;

(c) Copies of all relevant clinical reports relating to the CAOP Alternative Divestment Business existing prior to Closing;

(d) The trademarks in Czech Republic, Italy, Slovakia, Spain and the United Kingdom for the CAOP Products in Czech Republic, Italy, Slovakia, Spain and the United Kingdom by way of an exclusive, perpetual, irrevocable license;

(e) The intellectual property rights where available and necessary to give a Purchaser the non-exclusive right to manufacture the CAOP Products anywhere in the world for sale solely in the Czech Republic, Italy, Slovakia, Spain and the United Kingdom and the exclusive right to sell the CAOP Products in the Czech Republic, Italy, Slovakia, Spain and the United Kingdom by way of a perpetual, irrevocable licence. These intellectual property rights include product formulations, manufacturing know-how and other secret know-how, packaging specifications, 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 CAOP Alternative Divestment Business in the Czech Republic, Italy, Slovakia, Spain and the United Kingdom, including existing customer records of the CAOP Alternative Divestment Business the Czech Republic, Italy, Slovakia, Spain and the United Kingdom, provided that the Parties may redact from such copies any information that does not relate to the CAOP Alternative Divestment Business.

At the option of the Purchaser, Pfizer 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 CAOP Products for sale in the Czech Republic, Italy, Slovakia, Spain and the United Kingdom 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 Pfizer or the Purchaser, this period can be extended by the Monitoring Trustee until such time that the Purchaser has established the CAOP Alternative Divestment Business.

At the option of the Purchaser, Pfizer shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of any CAOP Products in the Czech Republic, Italy, Slovakia, Spain and the United Kingdom, for such period as is required by the Purchaser to establish the CAOP Alternative Divestment Business as a viable and independent business, but not exceeding 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 Pfizer or the Purchaser, this period can be extended by the Monitoring Trustee until such time that the Purchaser has established the CAOP Alternative Divestment Business.

At the option of the Purchaser, Pfizer shall provide reasonable technical assistance to the Purchaser to facilitate the procurement of raw materials necessary for the manufacture of any CAOP Products. If the Purchaser is not able to source such raw materials, Pfizer commits to enter, at the option of the Purchaser, into back-to-back supply agreements with certain raw material suppliers and to make such raw materials available to the Purchaser on a reasonable cost plus basis to be agreed with the Purchaser, for such period as is required by the Purchaser to establish the CAOP Alternative Divestment Business as a viable and independent business, but not exceeding thirty-six (36) calendar months from the date of Closing. Under circumstances outside the control of Pfizer or the Purchaser, this period can be extended by the Monitoring Trustee until such time that the Purchaser has established the CAOP Alternative Divestment Business.

The scope and elements of the reasonable technical assistance referred to above will have to be negotiated with the Purchaser, as this will largely depend on the requirements of the Purchaser. Pfizer envisages that reasonable technical assistance could include one or more of the following elements: advising on technical knowledge documentation, supporting the Purchaser in acquiring specific equipment, providing staff with suitable experience and skills

to assist and/or advise on technical issues, assisting in trainings for the Purchaser's staff, providing guidance on regulatory and legal aspects related to the transfer of licenses.

At the option of the Purchaser and subject to applicable local employment legislation, sufficiently qualified sales and marketing personnel employed by one of the Parties will be made available to the Purchaser, to the extent reasonably necessary for the Purchaser to operate the CAOP Alternative Divestment Business in accordance with normal market practice.

For the avoidance of doubt, the CAOP Alternative Divestment Business shall not include any right, title and/or interest in:

(a) Any manufacturing facility;

(b) Raw materials, other than the raw materials in stock used to produce the CAOP Products in the Czech Republic, Italy, Slovakia, Spain and the United Kingdom

(c) All marketing authorisations or other regulatory approvals in any territory currently held by Pfizer outside of the Czech Republic, Italy, Slovakia, Spain and the United Kingdom for the CAOP Products;

(d) Any other asset not part of the CAOP Alternative Divestment Business or which is used in relation to a business of the Parties other than the CAOP Alternative Divestment Business; and

(e) Monies owed (including accounts receivables and unbilled accounts) to Pfizer by customers for the purchase of the CAOP Products, and monies owed (including accounts receivables and unbilled accounts) by Pfizer to suppliers for materials used in the production of the CAOP Products.

SECTION 2

TETRACYCLINE SPRAYS

The Tetracycline Sprays Alternative Divestment Business will consist of rights, title and interests, including the right to develop and improve, in the Alternative Tetracycline Sprays, which have already been marketed in the United Kingdom and/or Portugal. For the avoidance of doubt, the Tetracycline Sprays Alternative Divestment Business does not contain any right to sell the Alternative Tetracycline Sprays outside the United Kingdom and/or Portugal.

The Tetracycline Sprays Alternative Divestment Business includes:

(a) Finished goods inventory, work in process, rights to product improvements, sales and promotional material (where available) relating to the Tetracycline Sprays Alternative Divestment Business in the United Kingdom and/or Portugal, held at the date of Closing;

(b) All current marketing authorisations and pending applications for marketing authorisations for the Alternative Tetracycline Sprays in the United Kingdom and/or Portugal and held by Pfizer, including all relevant dossiers relating to the current and/or pending marketing authorisations available to Pfizer;

(c) Copies of all relevant clinical reports relating to the Tetracycline Sprays Alternative Divestment Business existing prior to Closing;

(d) The trademarks in the United Kingdom and/or Portugal and for the Alternative Tetracycline Sprays by way of an exclusive, perpetual, irrevocable license;

(e) The intellectual property rights where available and necessary to give a Purchaser the non-exclusive right to manufacture the Alternative Tetracycline Sprays anywhere in the world for sale solely in the United Kingdom and/or Portugal and the exclusive right to sell the Alternative Tetracycline Sprays in the United Kingdom and/or Portugal by way of a perpetual, irrevocable licence. These intellectual property rights include product formulations, manufacturing know-how and other secret know-how, packaging specifications, 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 Tetracycline Sprays Alternative Divestment Business in the United Kingdom and/or Portugal, including existing customer records of the Tetracycline Sprays Alternative Divestment Business, provided that the Parties may redact from such copies any information that does not relate to the Tetracycline Sprays Alternative Divestment Business.

At the option of the Purchaser, Pfizer 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 Alternative Tetracycline Sprays for sale in the United Kingdom and/or

Portugal 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 Pfizer or the Purchaser, this period can be extended by the Monitoring Trustee until such time that the Purchaser has established the Tetracycline Sprays Alternative Divestment Business.

At the option of the Purchaser, Pfizer shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of any Alternative Tetracycline Sprays in the United Kingdom and/or Portugal for such period as is required by the Purchaser to establish the Tetracycline Sprays Alternative Divestment Business as a viable and independent business, but not exceeding 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 Pfizer or the Purchaser, this period can be extended by the Monitoring Trustee until such time that the Purchaser has established the Tetracycline Sprays Alternative Divestment Business.

At the option of the Purchaser, Pfizer shall provide reasonable technical assistance to the Purchaser to facilitate the procurement of raw materials necessary for the manufacture of any Alternative Tetracycline Sprays. If the Purchaser is not able to source such raw materials, Pfizer commits to enter, at the option of the Purchaser, into back-to-back supply agreements with certain raw material suppliers and to make such raw materials available to the Purchaser at on a reasonable cost plus basis to be agreed with the Purchaser, for such period as is required by the Purchaser to establish the Tetracycline Sprays Alternative Divestment Business as a viable and independent business, but not exceeding thirty-six (36) calendar months from the date of Closing. Under circumstances outside the control of Pfizer or the Purchaser, this period can be extended by the Monitoring Trustee until such time that the Purchaser has established the Tetracycline Sprays Alternative Divestment Business.

The scope and elements of the reasonable technical assistance referred to above will have to be negotiated with the Purchaser, as this will largely depend on the requirements of the Purchaser. Pfizer envisages that reasonable technical assistance could include one or more of the following elements: advising on technical knowledge documentation, supporting the Purchaser in acquiring specific equipment, providing staff with suitable experience and skills to assist and/or advise on technical issues, assisting in trainings for the Purchaser's staff, providing guidance on regulatory and legal aspects related to the transfer of licenses.

At the option of the Purchaser and subject to applicable local employment legislation, sufficiently qualified sales and marketing personnel employed by one of the Parties will be made available to the Purchaser, to the extent reasonably necessary for the Purchaser to operate the Tetracycline Sprays Alternative Divestment Business in accordance with normal market practice.

For the avoidance of doubt, the Tetracycline Sprays Alternative Divestment Business shall not include any right, title and/or interest in:

(a) Any manufacturing facility;

(b) Raw materials, other than the raw materials in stock used to produce the Alternative Tetracycline Sprays in the United Kingdom and/or Portugal;

(c) All marketing authorisations or other regulatory approvals in any territory currently held by Pfizer outside of the United Kingdom and Portugal for the Alternative Tetracycline Sprays;

(d) Any other asset not part of the Tetracycline Sprays Alternative Divestment Business or which is used in relation to a business of the Parties other than the Tetracycline Sprays Alternative Divestment Business; and

(e) Monies owed (including accounts receivables and unbilled accounts) to Pfizer by customers for the purchase of the Alternative Tetracycline Sprays, and monies owed (including accounts receivables and unbilled accounts) by Pfizer to suppliers for materials used in the production of the Alternative Tetracycline Sprays.

SECTION 3

AIF PA TETRACYCLINES

The AIF PA Tetracyclines Alternative Divestment Business will consist of rights, title and interests, including the right to develop and improve, in the AIF PA Tetracyclines, which have already been marketed in Finland and Italy. For the avoidance of doubt, the AIF PA Tetracyclines Alternative Divestment Business does not contain any right to sell the AIF PA Tetracyclines outside Finland and Italy.

The AIF PA Tetracyclines Alternative Divestment Business includes:

(a) Finished goods inventory, work in process, rights to product improvements, sales and promotional material (where available) relating to the AIF PA Tetracyclines Alternative Divestment Business in Finland and Italy, held at the date of Closing;

(b) All current marketing authorisations and pending applications for marketing authorisations for the AIF PA Tetracyclines in Finland and Italy held by Pfizer, including all relevant dossiers relating to the current and/or pending marketing authorisations available to Pfizer;

(c) Copies of all relevant clinical reports relating to the AIF PA Tetracyclines Alternative Divestment Business existing prior to Closing;

(d) The trademarks in Finland and Italy for the AIF PA Tetracyclines in Finland and Italy by way of an exclusive, perpetual, irrevocable license;

(e) The intellectual property rights where available and necessary to give a Purchaser the non-exclusive right to manufacture the AIF PA Tetracyclines anywhere in the world for sale solely in Finland and Italy and the exclusive right to sell the AIF PA Tetracyclines in Finland and Italy by way of a perpetual, irrevocable licence. These intellectual property rights include product formulations, manufacturing know-how and other secret know-how, packaging specifications, 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 AIF PA Tetracyclines Alternative Divestment Business in Finland and Italy, including existing customer records of the AIF PA Tetracyclines Alternative Divestment Business in Finland and Italy, provided that the Parties may redact from such copies any information that does not relate to the AIF PA Tetracyclines Alternative Divestment Business.

At the option of the Purchaser, Pfizer 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 AIF PA Tetracyclines for sale in Finland and Italy 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 Pfizer or the Purchaser, this period can be extended by the Monitoring

Trustee until such time that the Purchaser has established the AIF PA Tetracyclines Alternative Divestment Business.

At the option of the Purchaser, Pfizer shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of any AIF PA Tetracyclines in Finland and Italy for such period as is required by the Purchaser to establish the AIF PA Tetracyclines Alternative Divestment Business as a viable and independent business, but not exceeding 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 Pfizer or the Purchaser, this period can be extended by the Monitoring Trustee until such time that the Purchaser has established the AIF PA Tetracyclines Alternative Divestment Business.

At the option of the Purchaser, Pfizer shall provide reasonable technical assistance to the Purchaser to facilitate the procurement of raw materials necessary for the manufacture of any AIF PA Tetracyclines. If the Purchaser is not able to source such raw materials, Pfizer commits to enter, at the option of the Purchaser, into back-to-back supply agreements with certain raw material suppliers and to make such raw materials available to the Purchaser on a reasonable cost plus basis to be agreed with the Purchaser, for such period as is required by the Purchaser to establish the AIF PA Tetracyclines Alternative Divestment Business as a viable and independent business, but not exceeding thirty-six (36) calendar months from the date of Closing. Under circumstances outside the control of Pfizer or the Purchaser, this period can be extended by the Monitoring Trustee until such time that the Purchaser has established the AIF PA Tetracyclines Alternative Divestment Business.

The scope and elements of the reasonable technical assistance referred to above will have to be negotiated with the Purchaser, as this will largely depend on the requirements of the Purchaser. Pfizer envisages that reasonable technical assistance could include one or more of the following elements: advising on technical knowledge documentation, supporting the Purchaser in acquiring specific equipment, providing staff with suitable experience and skills to assist and/or advise on technical issues, assisting in trainings for the Purchaser's staff, providing guidance on regulatory and legal aspects related to the transfer of licenses.

At the option of the Purchaser and subject to applicable local employment legislation, sufficiently qualified sales and marketing personnel employed by one of the Parties will be made available to the Purchaser, to the extent reasonably necessary for the Purchaser to operate the AIF PA Tetracyclines Alternative Divestment Business in accordance with normal market practice.

For the avoidance of doubt, the AIF PA Tetracyclines Alternative Divestment Business shall not include any right, title and/or interest in:

(a) Any manufacturing facility;

(b) Raw materials, other than the raw materials in stock used to produce the AIF PA Tetracyclines in Finland and Italy;

(c) All marketing authorisations or other regulatory approvals in any territory currently held by Pfizer outside of Finland and Italy for the AIF PA Tetracyclines;

(d) Any other asset not part of the AIF PA Tetracyclines Alternative Divestment Business or which is used in relation to a business of the Parties other than the AIF PA Tetracyclines Alternative Divestment Business; and

(e) Monies owed (including accounts receivables and unbilled accounts) to Pfizer by customers for the purchase of the AIF PA Tetracyclines, and monies owed (including accounts receivables and unbilled accounts) by Pfizer to suppliers for materials used in the production of the AIF PA Tetracyclines.

SECTION 4

PAH CEPHALOSPORINS

The Cephalosporins Alternative Divestment Business will consist of rights, title and interests, including the right to develop and improve, in the PAH Cephalosporins, which have already been marketed in Italy. For the avoidance of doubt, the Cephalosporins Alternative Divestment Business does not contain any right to sell the PAH Cephalosporins outside of Italy

The Cephalosporins Alternative Divestment Business includes:

(a) Finished goods inventory, work in process, rights to product improvements, sales and promotional material (where available) relating to the Cephalosporins Alternative Divestment Business in Italy, held at the date of Closing;

(b) All current marketing authorisations and pending applications for marketing authorisations for the PAH Cephalosporins in Italy held by Pfizer, including all relevant dossiers relating to the current and/or pending marketing authorisations available to the Pfizer;

(c) Copies of all relevant clinical reports relating to the Cephalosporins Alternative Divestment Business existing prior to Closing;

(d) The trademarks in Italy for the PAH Cephalosporins in Italy by way of an exclusive, perpetual, irrevocable license;

(e) The intellectual property rights where available and necessary to give a Purchaser the non-exclusive right to manufacture a the PAH Cephalosporins anywhere in the world for sale solely in Italy and the exclusive right to sell the PAH Cephalosporins in Italy by way of a perpetual, irrevocable licence. These intellectual property rights include product formulations, manufacturing know-how and other secret know-how, packaging specifications, 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 Cephalosporins Alternative Divestment Business in Italy, including existing customer records of the Cephalosporins Alternative Divestment Business in Italy, provided that the Parties may redact from such copies any information that does not relate to the Cephalosporins Alternative Divestment Business.

At the option of the Purchaser, Pfizer 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 PAH Cephalosporins for sale in Italy 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

Pfizer or the Purchaser, this period can be extended by the Monitoring Trustee until such time that the Purchaser has established the Cephalosporins Alternative Divestment Business.

At the option of the Purchaser, Pfizer shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of any PAH Cephalosporins in Italy for such period as is required by the Purchaser to establish the Cephalosporins Alternative Divestment Business as a viable and independent business, but not exceeding 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 Pfizer or the Purchaser, this period can be extended by the Monitoring Trustee until such time that the Purchaser has established the Cephalosporins Alternative Divestment Business.

At the option of the Purchaser, Pfizer shall provide reasonable technical assistance to the Purchaser to facilitate the procurement of raw materials necessary for the manufacture of any PAH Cephalosporins. If the Purchaser is not able to source such raw materials, Pfizer commits to enter, at the option of the Purchaser, into back-to-back supply agreements with certain raw material suppliers and to make such raw materials available to the Purchaser on a reasonable cost plus basis to be agreed with the Purchaser, for such period as is required by the Purchaser to establish the Cephalosporins Alternative Divestment Business as a viable and independent business, but not exceeding thirty-six (36) calendar months from the date of Closing.

The scope and elements of the reasonable technical assistance referred to above will have to be negotiated with the Purchaser, as this will largely depend on the requirements of the Purchaser. Pfizer envisages that reasonable technical assistance could include one or more of the following elements: advising on technical knowledge documentation, supporting the Purchaser in acquiring specific equipment, providing staff with suitable experience and skills to assist and/or advise on technical issues, assisting in trainings for the Purchaser's staff, providing guidance on regulatory and legal aspects related to the transfer of licenses.

At the option of the Purchaser and subject to local employment legislation, sufficiently qualified sales and marketing personnel employed by one of the Parties will be made available to the Purchaser, to the extent reasonably necessary for the Purchaser to operate the Cephalosporins Alternative Divestment Business in accordance with normal market practice.

For the avoidance of doubt, the Cephalosporins Alternative Divestment Business shall not include any right, title and/or interest in:

(a) Any manufacturing facility;

(b) Raw materials, other than the raw materials in stock used to produce the PAH Cephalosporins in Italy;

(c) All marketing authorisations or other regulatory approvals in any territory currently held by Pfizer outside of Italy for the PAH Cephalosporins;

(d) Any other asset not part of the Cephalosporins Alternative Divestment Business or which is used in relation to a business of the Parties other than the Cephalosporins Alternative Divestment Business; and

(e) Monies owed (including accounts receivables and unbilled accounts) to Pfizer by customers for the purchase of the PAH Cephalosporins, and monies owed (including accounts receivables and unbilled accounts) by Pfizer to suppliers for materials used in the production of the PAH Cephalosporins.