

***Case No COMP/M.2922 -
PFIZER / PHARMACIA***

Only the English text is available and authentic.

**REGULATION (EEC) No 4064/89
MERGER PROCEDURE**

Article 6(2) NON-OPPOSITION
Date: 27/02/2003

*Also available in the CELEX database
Document No 303M2922*



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 27.02.2003

SG (2003) **D/228752**

In the published version of this decision, some information has been omitted pursuant to Article 17(2) of Council Regulation (EEC) No 4064/89 concerning non-disclosure of business secrets and other confidential information. The omissions are shown thus [...]. Where possible the information omitted has been replaced by ranges of figures or a general description.

PUBLIC VERSION

MERGER PROCEDURE
ARTICLE 6(2) DECISION

To the notifying party

Dear Sir/Madam,

**Subject: Case No COMP/M.2922 - Pfizer/Pharmacia
Notification of 25.10.2002 pursuant to Article 4 of Council Regulation
No 4064/89¹**

1. On 25.10.2002, the Commission received a notification whereby the US based pharmaceutical company Pfizer Inc. ("Pfizer") notified its intention to acquire the US-based pharmaceutical company Pharmacia Corporation ("Pharmacia") within the meaning of Art 3(1)b of the Merger Regulation.
2. Following a prior request for information, on Monday 18.11.2002, an Article 11 request for information decision was addressed to Pharmacia. This decision effectively stopped the clock of the case. The clock was re-started on 6.2.2003, after Pharmacia had submitted full information to the Commission's questions.
3. In the course of the proceedings, the parties submitted undertakings designed to eliminate competition concerns identified by the Commission, in accordance with Article 6(2) of the Merger Regulation. In the light of these modifications, the Commission has concluded that the notified operation falls within the scope of the Merger Regulation as amended and does not raise serious doubts as to its compatibility with the common market and with the functioning of the EEA Agreement..

¹ OJ L 395, 30.12.1989 p. 1; corrigendum OJ L 257 of 21.9.1990, p. 13; Regulation as last amended by Regulation (EC) No 1310/97 (OJ L 180, 9. 7. 1997, p. 1, corrigendum OJ L 40, 13.2.1998, p. 17).

I. THE PARTIES

4. Both Pfizer and Pharmacia are active in human pharmaceutical and animal healthcare products. Both companies are also active in consumer healthcare. In addition, Pharmacia is currently active in speciality businesses, including diagnostic products, fine chemicals, contract manufacturing from R&D to production of finished pharmaceutical products and biopharmaceutical activities.

II. THE OPERATION

5. The acquisition is a tax-free stock-for-stock transaction valued at \$ 60 billion. At completion of the notified transaction, Pfizer will exchange 1.4 shares of Pfizer common stock for each outstanding share of Pharmacia stock. Upon completion, Pfizer's shareholders will own approximately 77% of the combined company and Pharmacia's shareholders will own approximately 23%.
6. The acquisition will create the largest pharmaceutical company in the world. It will account for 11% of total pharmaceutical world-wide sales. Not only will Pfizer become the leading pharmaceutical company in terms of pharmaceutical sales but it will also be, with a combined R&D budget for 2002 exceeding [...] billion, by far the largest privately funded biomedical research organisation in the world.
7. Prior to the notified transaction, Pharmacia divested its remaining 84% ownership of Monsanto Co, its agricultural business, to the other shareholders of Monsanto Co.

III. CONCENTRATION

8. The operation will result in a full merger between Pfizer and Pharmacia and, therefore, is a concentration within the meaning of Article 3(1)(b) of the Merger Regulation.

IV. COMMUNITY DIMENSION

9. The undertakings concerned have a combined aggregate world-wide turnover of more than EUR 5 billion² (Pfizer: EUR 35,691 million, Pharmacia: EUR 15,442 million). Each of the undertakings have a Community-wide turnover in excess of EUR 250 million (Pfizer: EUR [...] million, Pharmacia: EUR [...] million), but they do not achieve more than two-thirds of their aggregate Community-wide turnover within one and the same Member State. The notified operation therefore has a Community dimension.

² Turnover calculated in accordance with Article 5(1) of the Merger Regulation and the Commission Notice on the calculation of turnover (OJ C66, 2.3.1998, p 25). To the extent that figures include turnover for the period before 1.1.1999, they are calculated on the basis of average ECU exchange rates and translated into EUR on a one-for-one basis.

V. COMPETITIVE ASSESSMENT

Introduction

10. The parties have horizontally overlapping activities in human pharmaceuticals, active substances and animal healthcare. In addition, there is a vertical relationship between the parties as regards hydrocortisone and hard gelatine capsules.
11. With regard to active substances, Pharmacia sells a number of active substances to third parties. Pfizer produces active substances mainly for internal consumption, with minimal sales to third parties. There is only one active substance in respect of which both parties currently conduct external sales, namely methotrexate. However, in 2000, Pfizer decided to discontinue production of methotrexate and produced one final campaign [...]. Therefore, the overlap has ceased to exist.
12. As regards vertical relationships, there are two vertically affected markets: hydrocortisone and hard gelatine capsules. As regards hydrocortisone, Pharmacia has [20-30]% market share in the EEA. However, given that Aventis and Schering are on the market with market shares around [25-35]% each, competition concerns are unlikely to arise. As regards hard gelatine capsules, there exists a vertical relationship between the parties as Pfizer supplies these products to Pharmacia.
13. In the following, human pharmaceuticals, hard gelatine capsules and animal health will be discussed in more detail.

1. Pharmaceutic specialities

A. Relevant product markets

14. Pharmaceutical products are used for the treatment of human illnesses and diseases. Prescription/ethical medicines are pharmaceutical products exclusively accessible by way of medicinal prescription and subject, for the main part, to reimbursement through social security schemes. OTC drugs are “over-the-counter” pharmaceutical products certain of which can be prescribed by a doctor and may be reimbursable through a social security scheme.
15. In its previous decisions, the Commission noted that medicines 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). It is to be noted that whilst similar in concept to the EphMRA ATC system, the classification system prepared by the World Health Organisation (WHO) differs to some extent from it. The parties have used the EphMRA ATC system as a starting point in their pharmaceutical products market definition. The ATC is hierarchical and has 16 categories (A, B, C, D, etc.) each with up to four levels. The first level (ATC 1) is the most general and the fourth level (ATC 4) the most detailed. The third level (ATC 3) allows medicines to be grouped in terms of their therapeutic indications, i.e. their intended use, and can therefore be used as an operational market definition. These groups of products generally have the same therapeutic indication and cannot be substituted by products belonging to other ATC 3 classes.

16. However, the Commission has in earlier decisions considered that the third level of the ATC is not in all cases an appropriate basis for the definition of products markets and that it may be appropriate in certain cases to carry out analyses at other levels of the ATC classification. For example, it may be necessary to combine certain groups of pharmaceutical specialities. This would be the case where certain products from different ATC classes are substitutes for the treatment of a specific illness or disease.
17. On the other hand, it may also be appropriate to apply a narrower market definition where the pharmaceutical specialities forming part of a certain ATC 3 class have clearly differing indications. In certain cases, pharmaceuticals may be further subdivided into various segments on the basis of a variety of criteria, and in particular demand-related criteria. A possible distinction is that between medicines which can be issued only on prescription and those which can be sold over the counter (OTC). Most medicines issued only on prescription are reimbursed, whereas most of those which may be sold over the counter are not. There are also other key considerations such as indications variances between prescription and OTC products, disease severity, demographic differences in consumers who refer to prescription as opposed to OTC products, driven by attitudinal differences and pricing factors. Prescription medicines and OTC products can belong to different markets, even if they are indicated in the same diseases, because the customers, the legal background, the inherent risk, the marketing and distribution may be different. The allocation of a medicine to the prescription or the OTC segment is based on decisions by the authorities, which may lead to changes between segments according to the country concerned. There are different overlaps between the prescription and OTC market depending to a large degree on the reimbursement systems of different Member States.
18. In this case, the parties have used the ATC 3 classification as a starting point in their analysis and accept this as the market definition for most product markets. However, for some product markets, which are further discussed below, the parties have suggested alternative market definitions.
19. In human pharmaceuticals, the parties have horizontally overlapping activities where the combined market shares exceed 15% in 25 ATC product categories in 112 national markets (including Norway). The aggregated sales share of the parties exceeds 40% and the increment is more than 1% ("Class 3 markets"³) in seven ATC categories and in [...] national markets. In relation to four ATC categories in [...] national markets, the parties' combined sales share is above 40% but with an increment of less than 1% ("Class 2 markets"). Finally, in 23 ATC categories and in altogether [...] national markets, the parties' combined market share remains below 40% ("Class 1 markets").
20. The investigation has confirmed that, as regards the Class 1 markets, competition concerns are unlikely to arise as competitors are either market leaders or have otherwise strong market positions. With regard to Class 2 markets, the small increment of market share (<1%) is unlikely to lead to a lasting structural change on any of these markets. Third parties in their replies to the Commission's questionnaires have not raised any substantiated concerns on any of these markets.

³ "Class 1", "Class 2" and "Class 3" markets are used by the Commission in order to group the markets according to the market shares and the increment thereof. This is for the Commission's assessment purposes only and has no bearing on and no connection with the ATC classification system.

21. For the purposes of this decision, therefore, only Class 3 markets will be examined more closely. These markets are the following: C2A Antihypertensives (of non-herbal origin) Plain, C8A Calcium Antagonist Plain, D4A Topical Antipruritics, G4B3 Erectile Dysfunction, H2A Plain Corticosteroids, J1F Macrolides & Similar Type and L1D Cytostatic Antibiotics.
22. In previous decisions in the pharmaceutical industry, the Commission has taken the view that a full assessment of the competitive position of the parties requires also an analysis of products which are not yet on the market but are at an advanced stage of development. In line with previous cases (most recently in case COMP/M.1846 - GlaxoWellcome/SmithKline Beecham) projects in a late stage of development, known as Phase III, will be examined. The parties submit that two potential pipeline overlaps exist: in Chronic Obstructive Pulmonary Disease (COPD) and Urinary Incontinence (over active bladder, OAB).
23. As regards COPD, Pfizer does not have its own product for the treatment of COPD but has an alliance with Boehringer Ingelheim to co-promote/co-market Spiriva, a product developed by Boehringer Ingelheim and which has recently been launched in a number of European countries. Pharmacia does not currently have a COPD product on the market but has entered into an alliance with Altana Pharma (Byk Gulden) with respect to Roflumilast. Roflumilast is currently in Phase [...] of development with a scheduled launch in Europe in [...]. Otherwise, the parties do not have any other COPD products.
24. The parties argue that Spiriva and Roflumilast are not competitors because *inter alia* they work using very different mechanisms of action and therefore have a different role in the treatment of COPD. Most COPD specialists contacted by the Commission agree with the parties. With regard to competing COPD products, in line with the Commission's findings in M.1846 - Glaxo Wellcome/SmithKline Beecham, the investigation has confirmed that competition on the COPD market is vigorous. The current market leader in Europe is GSK, with other large competitors including Boehringer-Ingelheim, Astra-Zeneca and Novartis. Other significant participants include Bayer, Merck, Aventis, ICOS and Schering-Plough. With regard to competing pipeline products, the investigation shows that all major pharmaceutical companies have products in the pipeline for the treatment of COPD in all phases of development.
25. Therefore, in view of the fact that the parties have currently no or only *de minimis* market positions in COPD, that the parties' pipeline products are not direct competitors, and given the existence of strong actual and potential competitors, the Commission considers that the operation as notified would not give rise to any serious competition concerns with regard to COPD markets in any Member State.
26. The parties' activities in Urinary Incontinence will be discussed in more detail below.

a) C2A Antihypertensives (of non-herbal origin) Plain

27. The parties submit that the ATC-2 class C2 includes various medicines that are used primarily for the treatment of hypertension, that is, high blood pressure. In EphMRA's ATC classification, this group is split at the ATC-3 level between antihypertensives of non-herbal origin (C2A and C2B) and antihypertensives of herbal origin (C2C and C2D). Within non-herbal antihypertensives, a further distinction is made between combination antihypertensives with diuretics (C2B), on the one hand, and plain antihypertensives and combinations other than those with diuretics (C2A), on the other hand. The parties' products are all classified in C2A, also referred to as alpha-blockers.

In addition to treating hypertension, alpha-blockers are also normally indicated for the treatment of heart failure, for urinary outflow obstruction and for obstructive and irritative symptoms associated with benign prostatic hypertrophy.

28. Other hypertension products include plain and combined calcium antagonists (C8A/C8B), plain and combined beta blockers (C7A/C7B), plain and combined ACE inhibitors (C9A/C9B), plain and combined angiotensin inhibitors (C9C/C9D) and diuretics (C3A). The Commission has previously examined the substitutability between various hypertension medicines and concluded in the case *IV/M.1403 - Astra/Zeneca* that, while the indications and contraindications for the four classes of hypertension medicines examined in that case partly overlap with one another, for a large proportion of hypertension patients the products in the various product classes are not substitutable. The Commission subsequently assessed the impact of the transaction separately for betablockers, calcium antagonists, ACE inhibitors and angiotensin inhibitors. As regards the potential substitutability of the class C2A drugs and other hypertension drugs, nothing in the present case suggests that the conclusions in *IV/M.1403 - Astra/Zeneca* would not apply also to the C2A product class. The large majority of third parties who have responded to the Commission's questionnaires submit that C2A constitutes the relevant product market.
29. Pfizer's products are Cardura and Minipress. Pharmacia sells Adesipress, Loniten and Ketensin. As regards Cardura and Adesipress, the parties submit that these drugs do not directly compete since they have different mechanisms of action and recommendations for use: Cardura is an alpha-blocker with peripheral action, while Adesipress is an alpha-blocker with central action. The results of the market investigation show, however, that Cardura and Adesipress do compete with each other. Third parties have indicated that even though Cardura and Adesipress have different mechanisms of action, a fact which has previously been attributed decisive importance by the Commission in defining separate product market, in the present case they have an identical indication (hypertension) and a similar diagnosis profile⁴. Therefore, for the purposes of this decision, the Commission considers that the two products are substitutable.

b) C8A Calcium Antagonist Plain

30. Calcium antagonists are primarily used for the treatment of high blood pressure (*hypertension*) and angina. The parties have submitted in line with the Commission's decisions in *IV/M.1403 - Astra/Zeneca* and *IV/M.1878 - Pfizer/Warner-Lambert* that the relevant product market is the ATC 3 level category C8A. Nothing in the replies of the third parties indicate that the Commission should deviate from its previous practice for the purposes of this case.

⁴ See case COMP/M.1397 - Sanofi/Synthelabo (point 30): "L'enquête de la Commission a montré que d'un point de vue médical, l'hypothèse d'un marché global pour les trois catégories précitées est inappropriée car elles ont chacune un mode d'action unique et bien identifié ... ". See also case COMP/M.1403 - Astra/Zeneca (point 36) where the Commission considered that fundamental differences in operations of pharmaceutical products argues in favour of separate product markets.

31. Pfizer sells on this market Norvasc and Pharmacia sells Cardizem. The parties submit that Norvasc and Cardizem are not substitutable. They argue that Norvasc is a DHP (dihydropyridine) and Cardizem is a non-DHP (non-dihydropyridine). Furthermore, the parties submit that the products have different particular strengths and contra-indications and tend to be prescribed for different patient profiles.
32. The Commission, however, found in the case *IV/M.1878 - Pfizer/Warner-Lambert* that DHPs and non-DHPs are largely competitive. Moreover, both Norvasc and Cardizem are indicated and prescribed for both hypertension and also angina. This has been confirmed by the market investigation also in the present case. Therefore, in line with the case *IV/M.1878 - Pfizer/Warner-Lambert* and for the purposes of this decision, the Commission considers that Norvasc and Cardizem are substitutable.

c) D4A Topical Antipruritics

33. The category antipruritics belongs to the broader ATC category D Dermatologicals. It includes topical preparations for the relief of skin irritation (itching, insect bites, eczema, etc) and may contain antihistamines, anaesthetics, or other active ingredients (but excluding corticosteroids combinations, which are classified in D7B). These products are typically non-prescription, OTC drugs.
34. The parties have submitted that the relevant product market definition for antipruritics is the ATC 3 level category D4A. The market investigation has not contested the product market definition as proposed by the parties.
35. The only affected market arises in Belgium. On this market, Pfizer sells Caladryl and Urtic. Pharmacia sells Droxyaryl. The parties have submitted that Caladryl and Droxyaryl are fundamentally different drugs as they have different active ingredients and are used for different specific pathologies. On this basis, the parties submit that Caladryl and Droxyaryl are therefore not substitutable and that, as a result, there exists no actual overlap. Moreover, the parties submit that, [...] ⁵.
36. The market investigation has confirmed the parties' claims and that Caladryl and Droxyaryl are therefore not substitutable products. Therefore, the Commission has concluded that there is no addition of market share and that no serious doubts exist as to the compatibility of the operation with the common market as regards D4A Topical Antipruritics. This product market will therefore not be discussed any further.

d) G4B3 Erectile Dysfunction,

37. Erectile dysfunction ("ED") products are used for the treatment of male impotence. The parties have submitted that the area of erectile dysfunction is one where a narrower definition, at ATC-4 level, is more accurate, and therefore more appropriate than the ATC-3 level. The relevant ATC-3 level (G4B) is very broad, referring to Other Urological Preparations. The ATC-4 classifications in this area are (i) prostatic

⁵ The production of Droxyaryl cream, the only formulation of the product that was still being produced, was [...] stopped at the end of 2002 [...]. Hence, the product will no longer be sold once the current stock is exhausted.

disease products (G4B2), (ii) erectile dysfunction products (G4B3), (iii) urinary incontinence products (G4B4) and (iv) all other urological products (G4B9)⁶.

38. The different indications of the products grouped into the above mentioned ATC-4 classifications clearly illustrate that they do not compete and hence belong in different product markets. The market investigation has confirmed that the ATC-4 level G4B3 Erectile Dysfunction is the appropriate market definition.
39. Pfizer sells Viagra, while Pharmacia sells Caverject. Pharmacia is also developing two new products for the treatment of ED.
40. Viagra operates as a PDE-5 inhibitor and is administered orally in the form of tablets. Viagra enables men with ED to respond to sexual stimulation, by increasing the blood flow to the penis. Viagra is the most extensively studied ED treatment in the world and is now marketed and sold in more than 110 countries, including all of the EEA countries.
41. Pharmacia's product, Caverject, is an older product (launched in 1994) and is applied by injection into the penis prior to sexual intercourse. According to the parties, Caverject is, from the user's perspective, difficult and painful to administer. The injection must be carried out under sterile conditions and the dose of Caverject has to be individualised for each patient under the supervision of a physician. The first injections must be given at the physician's office by medically trained personnel. Self-injection therapy by the patient can be started only after the patient is properly instructed and well-trained in the self-injection technique. The physician is advised to make a careful assessment of the patient's skills and competence with this procedure.
42. The market investigation has largely confirmed the parties' submission that Viagra and Caverject do not compete due to the radically different method of administration of Caverject. The investigation shows that Caverjet is generally used where Viagra is contra-indicated and/or does not produce results. As such, Caverject would be used as second line treatment, while a penile implant would be regarded as last resort. Moreover, the investigation shows that there are price differentials across the EEA, ranging from [5-15]% to [250-300]% depending on the different dosage strengths compared and on the different national markets. This also supports the argument that the two products do not compete.
43. Some third parties have argued that, even if not directly competing, Viagra and Caverject in the hands of the same company might give rise to competitive concerns. More particularly, it has been argued that Pfizer might attempt to divert patients who have unsuccessfully tried Viagra away from direct competitors by "directing" them towards Caverjet as second-line products. However, these claims have not been substantiated. Moreover, in view of the fact that a large number of competitors are developing drugs similar to Viagra (see further below), it appears increasingly likely that those patients who have failed on Viagra would first try some other products administered in a tablet format rather than moving directly to Caverject (or other injectable products directly competing with Caverjet).

⁶ The ATC category G4B1 is no longer being used.

44. Therefore, for the purposes of this decision and for the reasons given above, the Commission considers that Viagra and Caverject are not substitutable products. However, in view of the fact that Pharmacia has two products under development for the treatment of ED, there is a potential overlap between the parties. This will be examined in more detail below.

e) H2A Plain Corticosteroids

45. Plain corticosteroids include all systemic products containing one or more corticosteroids, without any other active ingredient. Corticosteroids are commonly used for their anti-inflammatory indications to treat a wide range of inflammations, such as asthma, rheumatoid arthritis, inflammatory bowel disease and connective tissue disorders. They are also used in the treatment of certain cancers and to prevent the rejection of organ or tissue transplants.
46. Plain corticosteroid products may exist in different forms: oral corticosteroids are mostly used for the treatment of small, moderate or chronic diseases and injections are used in more severe cases where treatment needs are quick, direct and in high doses. Injectables are mainly administered in hospital for either acutely ill patients suffering from a drop in blood pressure or due to their inability to absorb oral steroids. Corticosteroids are available on prescription only.
47. The parties have submitted in line with the Commission's decisions in case COMP/M.1835 - *Monstanto/Pharmacia & Upjohn* that the relevant product market is the ATC 3 level category H2A. This market definition has been largely confirmed by the market investigation.
48. Pfizer has one product in this category, Deltacortril, which is available only in oral form. Pharmacia's principal product in this category is sold in oral form under the trademark Medrol and in injectable form under the trade marks Solu-Medrol, Depo-Medrol and Depo-Medrol+Lidoca. Pharmacia also sells an injectable hydrocortisone under the trademark Solu-Cortef. The parties' products are all off patent.
49. The parties submit that in Belgium, which is the only affected market, Medrol is mainly prescribed for asthma disorders and COPD, whereas Deltacortril is mainly prescribed for various forms of arthritis. It is not however necessary to decide whether the two products belong to the same relevant product market, because regardless of the market definition considered, the operation would not give rise to serious doubts.

f) J1F Macrolides & Similar Type

50. Antibiotics are antibacterial agents that inhibit the growth of certain micro-organisms. Systemic antibiotics (J1) are classes of semi-synthetically or fully synthetically prepared antibiotics, which followed the development of penicillin into second and third generation products.
51. The J1F category "Macrolides and similar types" refers to systemic macrolides. The parties submit that, in common with certain other antibiotics, such as broad-spectrum penicillins (J1C), cephalosporins (J1D) and fluoroquinolones (J1G), macrolides are usually used as second line treatment for a range of common infections, including throat infection, bronchitis, urinary tract infection, ear infection, sinusitis and pneumonia. The parties submit that, in the EEA, by far the most common of these

infections are respiratory tract infections (70%), followed by urinary tract infections (8%) and skin/soft tissue infections (8%).

52. The Commission has examined macrolides in a number of previous cases. In case IV/M.1378 - *Hoechst/Rhône-Poulenc* the Commission concluded that the JIF ATC 3 class, with the exception of Rodogyl, which is an anti-infective exclusively targeted to dental infections, was sufficiently homogeneous to constitute the relevant market. In case COMP/M.1846 - *GlaxoWellcome/SmithKline Beecham*, the Commission concluded that, although different antibiotics within the ATC second level may be interchangeable to a certain extent, they are not completely substitutable. Therefore, the Commission considered the ATC third level as the most appropriate market definition and carried out the assessment at this level, so as to examine the narrowest possible market.
53. Two products in the JIF class are relevant for the assessment of this case: Pfizer's Zithromax and Pharmacia's Dalacin C. Zithromax is an oral antibiotic used for the treatment of various mild to moderate infections (such as bronchitis, pneumonia, pharyngitis, sinusitis and skin infections). According to the parties, its main sales are in relation to upper and lower respiratory infections. Zithromax is also used in gynaecological infections with chlamydia trachomatis. It is a relatively new product and remains subject to patent protection in Europe.
54. Dalacin C is an older, off-patent product. It is available in solution, in capsules and in suspension form. The parties submit that Dalacin C is primarily used for skin and soft tissue infections and recurrent pharyngotonsillitis. It may also be used for certain respiratory tract infections and certain gynaecological infections.
55. The parties submit that, with regard to Finland and Sweden which are the affected markets, Zithromax and Dalacin C do not directly compete with each other as they are largely used for different indications. More particularly, the parties submit that the vast majority of Zithromax prescriptions are for respiratory infections, with very few prescriptions for skin and tissue related infections. In contrast, the majority of Dalacin C prescriptions in the same national markets are for skin and tissue related infections, with very few prescriptions for respiratory infections.
56. Doctors, national regulatory bodies (The Social Insurance Institution of Finland ("KELA") and SRGA⁷ in Sweden) and competitors in both Finland and Sweden, have confirmed the parties' submission that Zithromax and Dalacin C are indeed prescribed for different pathologies. More particularly, the investigation shows that Zithromax is prescribed for respiratory tract infections and urogenital infections, such as chlamydia trachomatis. Dalacin C is mostly used in difficult Staphylococcus aureus-infections such as skin, soft tissue and bone infections, and anaerobic infections.
57. On the basis of the foregoing and for the purposes of this decision, the Commission considers that the parties' products are not substitutable. Therefore, the Commission has concluded that there is no addition of market share and that no serious doubts exist as to the compatibility of the operation with the common market as regards JIF Macrolides. This product market will therefore not be discussed any further

⁷ The Swedish Reference Group for Antibiotics ("SRGA"), organised by the Swedish Association of Medicine and the Swedish Institute for Infectious Disease Control

g) L1D Cytostatic Antibiotics

58. The L1D class of products is used to slow or stop the replication of bacteria to allow the body to deal with infection as part of the treatment of various cancers.
59. The only overlap market is Germany. On this market, Pfizer sells Bleomycin and Pharmacia Farmorubicin, Adriblastina, Zavedos and Daunoblastina. The parties have submitted that their products have largely different indications and as such are not in direct competition with each other. The sole exception according to the parties is Pfizer's Bleomycin and Pharmacia's Adriblastina, which are both approved for the treatment of morbus hodgkin and non-hodgkin lymphoma cancers.
60. For the purposes of this decision, the exact market definition can be left open since regardless of the market definition considered, the transaction as notified would not give rise to serious competition concerns.

h) Urinary Incontinence (G4B4)

61. As discussed above (see G4B3 Erectile Dysfunction), the ATC-3 level (G4B) is very broad as it refers to Other Urological Preparations. The ATC-4 classifications in this area are (i) prostatic disease products (G4B2), (ii) erectile dysfunction products (G4B3), (iii) urinary incontinence products (G4B4) and (iv) all other urological products (G4B9). The different indications of the products grouped into the above mentioned ATC-4 classifications clearly illustrate that they do not compete and hence belong in different product markets. The parties have submitted that the correct product market to assess products developed for over active bladder (OAB) is the G4B4 category. This has been confirmed by the market investigation.

B. Relevant geographic markets

62. The Commission has previously defined the geographic markets for pharmaceutical products as being national in scope, despite the trend towards standardisation at a European level. The sale of medicines is influenced by the administrative procedures or purchasing policies which the national health authorities have introduced in Member States. Some countries exercise a direct or indirect influence on prices, and there are different levels of reimbursement by the social security system for different categories of medicines. For this reason, the prices for medicinal products may differ from one Member State to another. In addition, there are far reaching differences in terms of brand and pack-size strategies and in distribution systems. These differences lead to national market characteristics.
63. The results of the investigation do not suggest that the Commission should deviate from its previous practice in assessing pharmaceutical markets at the national level. Therefore, the markets for pharmaceutical specialities affected by the concentration will be regarded as national.
64. With regard to future products, to the extent that products not yet on the market must be taken into account on the basis of research and development in particular areas, national administrative procedures and regulations do not have the same degree of effectiveness as for existing pharmaceuticals. Normally, a characteristic of such products is that they have not yet been registered. Because research and development is normally global, the consideration of future markets should therefore at least focus on the territory of the EEA and, possibly, on world-wide markets.

C. Assessment

a) C2A Antihypertensives (of non-herbal origin) Plain

65. There are two Class 3 affected markets: Italy and the Netherlands. As regards **Italy**, the parties' combined market share is [60-70]% (Pfizer [55-65]%, Pharmacia [<10]%). The parties' combined share of sales in Italy derives primarily from Pfizer's sales of Cardura, which constitutes the whole of Pfizer's market share on this market. Cardura came off patent in April 2002. Pharmacia is present mainly with Adesipress and has a share of [<10]%. Adesipress is off patent. The market share of Pharmacia's other product, Loniten, is *de minimis* [<5]%).
66. The evolution of the market shares shows that Pfizer has increased its market share slightly from [55-65]% to [55-65]% and that the market share of Adesipress has been declining from [<10]% in 2000 to the present [<10]%. According to the parties, the product is off-patent and not heavily promoted. The largest competitors on this market are Boehringer-Ingelheim ([10-20]%) and Italfranco ([5-15]%), the latter of which has been increasing its market share slightly with its product Dedralen. There are also a large number of other smaller competitors on the market.
67. The Commission considers that the operation would not lead to competition concerns on the market. First, given the market positions of Boehringer-Ingelheim and Italfranco, the Commission does not consider that the operation is removing a main competitor from the market. Second, the Commission notes that Pharmacia's product Adesipress is off patent, its market share is relatively small and has been declining over the years and that, at the same time, competitors such as Italfranco and Errekappa, have been able to steadily increase their market share. Therefore, for these reasons, the Commission considers that the market share increment to Pfizer's strong position is not sufficient to give rise to competition concerns on this market. Third parties in their replies to the Commission's questionnaires have confirmed that the market will remain competitive after the merger and have not raised any competition concerns.
68. Therefore, on the basis of the foregoing, the Commission considers that the operation does not raise serious doubts as to its compatibility with the common market in the market for C2A Antihypertensives (of non-herbal origin) Plain in Italy
69. With regard to the **Netherlands**, the parties' combined market position would be [60-70]%, with a relatively large increment of market share (Pfizer [40-50]%, Pharmacia [20-30]%). Pfizer sells on this market primarily Cardura, which came off patent in April 2002. Pfizer's market share increased in 2001 (from [45-55]% to [45-55]%) but decreased again in 2002 to [40-50]%. Pfizer's Minipress accounts currently for [<5]% of the market but has been recently withdrawn.
70. Pharmacia's market share is derived mainly from the sales of Ketensin. Ketensin is a [...] product that Pharmacia promotes on its behalf in The Netherlands. Ketensin came off patent in 2000. The sales of Ketensin have slightly decreased from [20-30]% in 2000 to [15-25]% in 2002. Pharmacia's Loniten, which is off-patent, has only [<5]% of the market.
71. The parties have submitted that the largest competitor on this market is OPG, which has increased its market share from [<5]% in 2000 to [5-15]% in 2002. The rest of the market is very fragmented, with the remaining competitors having market shares between 1 and 5%.

72. The parties submit that due to generic competition, the operation would not lead to the creation or strengthening of a dominant position. As noted above, Ketensin has been off-patent since 2000 and the patent on the basic compound of Cardura expired in April 2002. The parties expect generic versions of Cardura to be launched shortly. To this effect, the parties submit that generic versions have been registered by Pharmachemie, Multipharma, Genthon, Centrafarm and Hexal.
73. While third parties have confirmed that generic competition exists in the pharmaceutical markets in the Netherlands and that some generic versions of Cardura are about to be launched on the Dutch C2A market, the Commission considers it unlikely that generic versions of Cardura will be able to offset the market power resulting from the operation in the foreseeable future. First, Pharmacia's Ketensin has been the strongest competitor on this market and, via the operation, Pfizer will acquire the strongest competitor and the closest substitute. In this respect, the Commission notes that although Ketensin has been off-patent since 2000, it has lost only [<5] percentage points of its market share on a relatively stable total market. Neither the parties nor any third parties have indicated that generic versions of Ketensin exist or are about to be launched on the Dutch market. Second, the Commission notes that Pfizer has introduced a long acting version of Cardura in 1999 (Cardura XL), which enjoys process patent protection until 2009. Cardura XL has replaced effectively the earlier version of Cardura, the market share of which has steadily decreased and accounts now only for [<5] % of the products sold by Pfizer. Neither the parties nor any third parties have indicated that generic versions of Cardura XL are to be launched on the market in the near future. Cardura XL is therefore likely to help Pfizer to defend its market position also in the future. Third, there are no indications, neither from the parties nor from third parties, that any other competing products will be launched on the market. Fourth, with regard to [...], this company has submitted in its reply to the Commission's questionnaires that it acts as an exclusive distributor for the parties' products. Therefore, it cannot be regarded as a direct competitor to the new entity.
74. Therefore, on the basis of the foregoing, the Commission considers that the operation raises serious doubts as to its compatibility with the common market in the market for C2A Antihypertensives (of non-herbal origin) Plain in the Netherlands.

b) C8A Calcium Antagonist Plain

75. **Norway** is the only Class 3 affected market, where the parties would attain a combined market share of [$65-75$] % (Pfizer [$60-70$] %, Pharmacia [<10] %). The market share derives mainly from Pfizer's product Norvasc, which is under patent protection until 2007. Pfizer has increased its market presence by almost [<10] percentage points for the past three years ([$50-60$] % in 2000). Pharmacia's market shares derives almost entirely from Cardizem, which Pharmacia markets in Norway pursuant to a licence agreement with Tanabe. Cardizem is based on diltiazem hydrochloride, which has been off-patent for several years. The other two Pharmacia products, Diltiazem and Nifedipine, have [<5] % of the market each. These market shares have not changed for the past three years.
76. As to the question, whether the addition of Pharmacia's product would further strengthen this position, the Commission has taken note of the fact that the market share of Pharmacia's product Cardizem has declined steadily from [$5-15$] % in 2000 to [<10] % in 2002 due to a decreasing price. At the same time, one of the main competitors, AstraZeneca, has increased the market share of its product Plendil by

[<10] percentage points, from [<5]% to [<10]%. The active substance of Plendil (felodipine) is under patent protection until 2003 and there is a process patent protection until 2007 for Plendil. Other competitors include most importantly Bayer, who has [<10]% of the market with its hypertension product Adalat.

77. The doctors consulted by the Commission consider a number of products - including importantly Bayer's Adalat and AstraZeneca's Plendil - to be the most effective substitutes to Pfizer's Norvasc. The investigation therefore shows that the operation would not remove the closest competitor from the market. None of the third parties contacted by the Commission have raised concerns on this market. In view of this and given the declining market share of Pharmacia's product and the market position of the main competitors Bayer and AstraZeneca, the Commission considers that no competition concerns would arise in the market for Calcium Antagonist Plain (C8A) in Norway.

c) G4B3 Erectile Dysfunction

78. Pfizer attains very high market shares throughout the EEA with its product Viagra. These market shares range from [65-75]% in France to [85-95]% in Luxembourg. There is a limited number of existing products available for the treatment of erectile dysfunction: in June 2001, Abbott Laboratories ("Abbott") launched in Europe a new orally administered product, named Uprima, which is based on the active substance apomorphine. Uprima is available throughout the EEA and Abbott's market shares range between [<5]% and [<10]%. Third parties have indicated, however, that this product has serious side effects, such as severe nausea, and is not expected to challenge the market position of Viagra. Schwarz Pharma AG ("Schwarz") sells Viridal/Edex (an intracavernosal injectable product) in France, Germany, Italy and the UK with market shares ranging from [<5]% to [<10]%. Schwarz's has not been able to increase its market position to any appreciable extent in any EU country. Vivus sells, in a limited number of EEA markets, Muse, a product administered through an intraurethral pellet, with market shares ranging from [<5] and [<10]%.
79. There is a potential overlap between Pfizer and Pharmacia, since Pharmacia is developing two new products for the treatment of ED. Pharmacia is developing an apomorphine for inhalation in co-operation with Nasteck. It is in [...] Phase [...] development. The investigation suggests that the new route of administration of this apomorphine based product could solve some of the side-effects of the current apomorphine-based product Uprima. Pharmacia has also a selective agonist for dopamine D2 receptor (oral) in [...] Phase [...] development. Both products must be considered to represent a viable, potential alternative to Viagra due to their non-invasive route of administration (one is an oral tablet, the other a nasal spray) and because they treat the same physical condition (ED). According to third parties, both products stand a good chance of eventually reaching the market. Although these products are only in Phase [...] of development, the Commission considers that they need to be taken into account in the assessment given Pfizer's existing strong market position and the patent litigation, which could affect negatively all major actual and potential competitors (see further below).
80. Following Viagra's unprecedented success, a number of competitors are developing products for the treatment of ED. Like Viagra, a large number of products being developed are PDE-5 inhibitors. Bayer has developed vardenafil (brand name Levitra), which is to be promoted with GlaxoSmithKline ("GSK"). On 22 November 2002

Bayer/GSK received a positive opinion from the European Committee for Proprietary Medicinal Products for vardenafil and the European marketing authorisation appears likely to be granted shortly. The launch is foreseen in Europe in the first half of 2003. Eli Lilly and ICOS have jointly developed tadalafil (brand name Cialis). On 14 November 2002 Eli Lilly/ICOS received their marketing approval in the EU and announced that the product will be launched in the first half of 2003. In addition to Bayer/GSK and Eli Lilly/ICOS, 10 other competitors are developing PDE-5 inhibitors for the treatment of ED⁸.

81. The investigation shows that the PDE-5 inhibitors under development would be direct competitors to Viagra. In addition, a number of them are expected to have an increasing pharmacological selectivity, in other words, an increased level of efficacy and, potentially, a more optimal safety profile than Viagra.
82. A number of competitors are developing non-PDE-5 inhibitors for the treatment of ED. These companies include Schering-Plough Corporation, Zonagen, Nitromed, Orion, Palatin Technologies Watson, Speracor, Abbott, Britannia Pharma, MacroChem, NexMed and Vibragen. The Commission's investigation has shown that these products are being developed with the purpose of competing directly with PDE5 inhibitors. However, the Commission notes that, differently from PDE5, most of the non-PDE5 being researched by the above mentioned companies are in their relatively early phase of development [...]. It has also to be underlined that, as mentioned above, Pharmacia is also developing two non-PDE5 products.
83. According to the parties, no competition concerns would arise from the transaction since Viagra and Caverject do not compete. Moreover, the parties argue that because of the presence of newly entered competitors and the expected launch of further competitive products in a growing market, the transaction does not give rise to any serious doubts as to its compatibility with the common market. In this respect, the parties argue that Viagra's market shares are declining, owing to both actual and potential competition.
84. While the Commission agrees that Caverject cannot be considered as an effective substitute for Viagra due to its radically different method of administration, the Commission must take into account the potential future overlap between Pfizer's existing product and Pharmacia's pipeline products. With regard to Pfizer's market shares, the development has been very stable and the existing competitors are not expected to seriously challenge Pfizer's high market shares. As a matter of fact, the investigation has dismissed the claim that Viagra faces, at this stage, competition from other products. Viagra is indeed perceived in many markets and in many instances as the only non-injectable product available for the treatment of ED. This is underpinned by the fact that, in some cases the second best selling product, after Viagra, is Caverjet. On the basis of the conclusion that Viagra and Caverjet do not directly compete, owing to their different method of administration and the perception of Caverjet as a last resort treatment, this seems to clearly indicate that Viagra faces very little competitive constraints from other non-injectable products. As concerns Viagra's competing pipeline products, the Commission notes that Pfizer has claimed broad patents

⁸ These companies are Vivus Inc, Schering-Plough Corporation, Merck Patent GmH, Ortho-McNeil Pharmaceutical Inc., Mochida Pharmaceutical Co.Ltd, Synthelabo, Eisai Co. Ltd, Fujisawa Pharmaceutical Co. Ltd., Tanabe Seiyaku Co. Ltd., and Bristol-Myers Squibb Company.

covering PDE-5 inhibitors in the EEA and in the US, which could affect negatively the future competition of other PDE-5 inhibitors.

85. With regard to patents concerning PDE-5 inhibitors, Pfizer has recently won a very broad "method of use" patent coverage for PDE-5 inhibitors in the US, which is valid until 2017. Pfizer has subsequently commenced patent litigation proceedings against Bayer/GSK's and Eli Lilly/Icos' PDE-5 inhibitors.
86. Pfizer's European patent, which relates to Viagra and its field of use claim⁹, has been held invalid by way of interim decision by the European Patent Office (EPO) in October 2001. Pfizer has, however, appealed the interim measure and the final decision is pending. The same patent has also been the subject of litigation in the United Kingdom, where Pfizer has lost its case both in first instance and on appeal. This decision is final¹⁰.
87. The parties have claimed that [...]. While third parties have expressed confidence that the PDE-5 inhibitor patent will be held invalid also on appeal, the outcome of the issue is not certain. However, the situation is different in the US, and most third parties have expressed serious concern that the US patent will have negative spill-over effects - both financial and in terms of product perception - in Europe, should Pfizer prevail in the US.
88. The ongoing patent litigation against recently launched and about-to-be-launched competing PDE-5 inhibitors risks making Viagra the only product available in this category. Under the worst case scenario, should the patent be held valid both in the US and in Europe, Viagra would be the only PDE-5 inhibitor on the market.
89. Even if Pfizer's PDE-5 inhibitor patent were to be upheld only in the USA, there is likely to be a negative spill-over effect on the EEA market. Third parties which are developing PDE-5 inhibitors have argued that Pfizer's victory in the US courts might by itself damage Pfizer's competitors also in the EEA by reducing their profitability and thus forcing them to retrench to some extent their strategic plans in the EEA. It has also been argued that an extensive patent coverage in the US would reduce the marketing effect of the new products in the EEA, due to the fact that the US market accounts for more than 50% of the ED market: successful launch in the US acts as a marketing boost world-wide, including the EEA markets. Moreover, third parties have argued that Pfizer's patent victory in the US would discourage or delay further research on PDE-5 inhibitors in general, because a market excluding the US would be too small to justify such investments in R&D. Finally, third parties have claimed that, regardless of its final outcome both in Europe and in the USA, the pending patent litigation could also create uncertainty among physicians and a negative presumption among customers about the effectiveness and the future availability of competing PDE-5 products, hence possibly strengthening Viagra's market position.
90. With regard to the non-PDE-5 inhibitors currently under development by competitors and by Pharmacia, the Commission notes that these pipeline products would not be

⁹ Patent No. 0702555

¹⁰ High Court-Chancery Division-Patents Court, Case No. HC 1999 No. 01110, 59 BMLR 123; Supreme Court of Judicature Court of Appeal (Civil Division), Case No. A3/2000/3811, [2002] EWCA Civ 02, [2002] 1 All ER 842, [2002] 1 WLR 2253.

subject to the above discussed patent litigation. Hence, in case of Pfizer's patent victory, non-PDE5 products would constitute the main source of competitive constraints on Viagra. Moreover, although the market power of the new entity relies largely on the leading product Viagra, its overall market position would be reinforced by the two pipeline products. In addition, the Commission notes that most of the companies developing these products are relatively smaller than the new entity and would have to face the incumbent firm with a paramount market position. Furthermore, only one company (Abbott) has any prior experience on the ED markets. On the contrary, in view of the fact that the new entity is the leading expert in ED, has the know-how and the necessary financial resources, the Commission considers that it is the new entity rather than any of the competitors who has the greatest potential and stand the greatest chance to successfully launch a non-PDE-5 inhibitor on the market.

91. Therefore, in the light of the above and given in particular Pfizer's present high market shares, the uncertainty about the patent litigation relating to competing PDE-5 products and the addition to Pfizer of Pharmacia's two pipeline products, the Commission has concluded that the combination of these factors gives rise to serious doubts as to the compatibility of the operation with the common market with regard to G4B3 Erectile Dysfunction in all Member States and Norway.

d) H2A Plain Corticosteroids

92. The only Class 3 market occurs in **Belgium**, where Pharmacia has [70-80]% of the market (with the Medrol-products representing most of Pharmacia's sales in Belgium) and Pfizer [<5]%. Pfizer's market share has decreased from [<5]% in 1999. Competitors are relatively small with only one larger competitor, Schering Plough, on the market with [10-20]% market share. The parties submit that the transaction will not affect Pharmacia's position in Belgium, given Pfizer's minimal local presence and the fact that Pfizer's share has remained stable over the last three years.
93. Although Pharmacia is a very significant player on the H2A Belgian market, the market share added by Pfizer's sales in Belgium will be very small. The parties submit that Pfizer's product Deltacortril has not been promoted in Belgium for a number of years. On the basis of the investigation, the Commission considers that the addition of Pfizer's product does not give rise to serious concerns on this market, given the very small increment of market share and the fact that the increment comes from an off-patent product. This assessment would not be materially affected if injectable and oral corticosteroids were to be considered separately, due to the small increment of market share.
94. Therefore, on the basis of the foregoing, the Commission considers that the operation does not raise serious doubts as to its compatibility with the common market in the market for plain corticosteroids (H2A) in Belgium.

e) L1D Cytostatic Antibiotics

95. The parties' combined market shares of total cytostatic antibiotic sales in Germany amounts to [40-50]%. Pfizer's Bleomycin accounts for only [<5]% of sales compared to a combined [40-50]% for Pharmacia's products (Farmorubicin [25-35]%, Adriblastina [<10]%, Zavedos [<10]% and Daunoblastina [<5]%). The parties claim that there are no significant competition concerns since the products do not compete directly, the transaction represents only a [<5]% increment attributable to Pfizer's Bleomycin [...], and there remains effective competition from a number of competitors.

96. Pfizer's Bleomycin is a generic product sold by Pfizer in Germany under license and Pfizer has confirmed that [...]. In light of the minimal increase in the parties' combined market share following the transaction, and [...], this transaction is not likely to result in a serious reduction of competition regardless of the market definition.

f) Urinary Incontinence (G4B4)

97. Urinary incontinence products (G4B4) include preparations indicated for urinary incontinence. Urinary incontinence refers to the involuntary loss of urine due to an over active bladder resulting from involuntary contractions of the bladder muscle and/or stress incontinence due to increased abdominal pressure and weak support muscles.
98. Pharmacia sells Detrusitol, a product to treat OAB. Pharmacia has relatively high market shares with its existing product, ranging from [35-45]% to almost [90-100]% in most Member States¹¹. Only in France and Italy Sanofi-Synthelabo has been able to hold a relatively large market share ([55-65]% in France - where Detrusitol is currently not reimbursed - and [25-35]% in Italy) and in Portugal Madaus has a leading market share ([40-50]%). However, in all Member States except in France and Portugal, the market share of Pharmacia has rapidly increased while the sales of the competitors have decreased. Pharmacia has increased its market position most significantly in the UK, within 6 months from [35-45]% to the present [60-70]%.
99. Pfizer has a compound, Darifenacin, in Phase [...] development. Both Detrusitol and Darifenacin have the same indication and mechanism of action. Both products block muscarinic receptors and thereby reduce the frequency and intensity of involuntary bladder contractions. All third parties contacted by the Commission have confirmed that Detrusitol and Darifenacin are substitutable products.
100. Some competitors are developing pipeline products for the treatment of OAB: Schwarz Pharma has a compound, Fesoterodine, under Phase [...] development. Also AstraZeneca has a compound in Phase [...] development. However, given the present strong position of Pharmacia and the fact that Darifenacin is already in Phase [...] development, it is unlikely that competitors will be able to challenge the market position of the new entity in the near future, in particular as neither company is currently present on the market. A large number of third parties have expressed serious concerns over the combination of Pharmacia's existing strong market position and Pfizer's pipeline product.
101. For the foregoing reasons, in view of the present strong market position of Pharmacia throughout the common market, given the fact that Pharmacia's market share has been increasing rapidly while the competitors' market positions have been deteriorating in all Member States except in France and in Portugal and the fact that Pfizer is about to launch a new product in this area, the Commission concludes that the operation as notified would give rise to serious doubts as to the compatibility of the operation with

¹¹ Austria [40-50]%, Belgium [30-40]%, Denmark [90-100]%, Finland [65-75]%, France [<10]%, Germany [35-45]%, Greece [80-90]%, Ireland [75-85]%, Italy [50-60]%, Luxembourg [50-60]%, the Netherlands [60-70]%, Norway [90-100]%, Portugal [5-15]%, Spain [40-50]%, Sweden [90-100]%, United Kingdom [60-70]%

the common market in urinary incontinence products (G4B4) in all EU Member States, with the exception of France and Portugal, and in Norway.

2. Vertically affected markets: Hard Gelatine Capsules

102. 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.
103. The parties submit that all major suppliers of hard gelatine capsules operate on a world-wide basis. The market investigation has confirmed that the geographic scope of this market is at least EEA wide, if not world-wide.
104. For the purposes of this decision, the exact definition of the product market can be left open, since regardless of the product market considered, no competition concerns would arise. Similarly, the exact geographic market definition can be left open, as the operation is will not adversely affect competition in this market even under the narrowest market definition considered.
105. Pfizer produces and sells hard gelatine capsules through its subsidiary Capsugel. Pfizer's market share in the EEA is [60-70]% and the main competitors are RP Scherer ([<10]%), Shionogi Qualicaps ([10-20]%) and Roxlor (approximately [<10]%). Pharmacia does not manufacture or supply hard gelatine capsules. However, it purchases from Pfizer approximately [90-100]% of its global capsule requirements ([...] billion capsules, valued at US\$ [...] million), which represents approximately [<10]% of Pfizer's total capsules sales (2001 figures). No hard gelatine capsule purchases are made by any Pharmacia company in the EEA.
106. The parties submit that there is no risk of foreclosure of the market because Pharmacia represents a minor source of demand for Pfizer. Pharmacia is already sourcing almost all its hard gelatine capsules from Pfizer. If Pharmacia were to transfer all its sourcing to Pfizer, this would have no appreciable effect on the availability of hard gelatine capsules in the EEA. Third parties in their replies to the Commission's enquiries have confirmed that the transaction is unlikely to lead to the foreclosure of the market upstream or downstream.
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 as notified would not give rise to serious competition concerns.

3. Animal Healthcare

Introduction

108. The transaction affects the production, distribution and sale of animal healthcare products.
109. In 2001, Pfizer had animal health sales globally of US\$ [...] million (approx. Euro [...] million), accounting for approximately [5-15]% of global sales of animal health products. Pharmacia's animal health business had sales in 2001 of US\$ [...] million (approx. Euro [...] million), accounting for approximately [<10]% of global sales of animal health products. The parties' animal health business combined would account for approximately [10-20]% of global sales, just ahead of Merial, which has

approximately [10-20]% of global sales, and closely followed by a large number of significant players with shares between [<10]% and [5-15]%, including Intervet (Akzo Nobel), Fort Dodge (Wyeth), SPAH (Schering Plough), Bayer and Elanco (Eli Lilly).

110. The parties submit that they have few overlaps in the animal health sector, due mainly to differing focuses. Pfizer's significant activity in the supply of vaccines is not shared by Pharmacia, and there are no overlaps in this area. Furthermore, Pfizer has recently divested its feed additives business, while Pharmacia remains active in this area.
111. Animal health products can be divided into three core areas, namely (i) medicinal food additives, (ii) biologicals and (iii) pharmaceuticals. In addition, there are two further product categories, considered to be part of animal health in the widest sense: (i) nutritional feed additives and (ii) hygiene products.
112. The parties have submitted that they only have overlapping activities in the area of veterinary pharmaceuticals. The market investigation has not contested this claim. In the following, veterinary pharmaceuticals will be discussed in more detail.

Veterinary Pharmaceuticals

A. Relevant product market

113. This segment is the largest one among animal health products. It comprises a wide variety of active ingredients for the prevention or treatment of a large range of infectious diseases, parasitical infestations, endocrine disorders, metabolic diseases, inflammatory symptoms, etc.
114. In its previous decisions¹², the Commission has segmented the broad area of veterinary pharmaceuticals into: a) parasiticides, b) antimicrobials, c) endocrine treatments, d) anti-inflammatories and analgesics, e) performance enhancers and others. The market investigation has confirmed that this segmentation is generally used by the animal health industry.
115. In addition, Commission's previous decisions have indicated that the segmentation of the veterinary pharmaceuticals business can be based on a combination of some or all of the following criteria: the disease treatment indication, the route of administration, the animal species indication, the active substance included, the stage in an animal's reproductive cycle, etc.
116. The parties have not contested the validity of this segmentation as a basis for the analysis. Nevertheless, the parties have stressed that defining the market in veterinary pharmaceuticals is a complex issue, because substitutability between different products may vary between different clinical situations and between consumers (animal owners, advised by veterinary surgeons). This allegedly makes it difficult to offer any simple generalisation. Moreover the parties underlined that substitution and competitive interaction occur to an appreciable degree across the boundaries of categories defined on the basis of any or all of the above criteria.

¹² See in particular Case No COMP/M.1681, *Akzo Nobel/Hoechst Roussel Vet*, Decision of 22 November 1999.

B. Relevant geographic market

117. In past decisions the Commission has held that the geographic market in the animal health sector has a national scope¹³. The parties have not contested this geographic market definition. Consequently, the geographical markets for the animal health markets affected by the concentration will be considered as national in scope.

C. Competitive assessment

118. The parties submit that the only broad areas of overlap, with combined market shares exceeding 15%, occurs in veterinary pharmaceuticals in the field of (i) antimicrobials (also referred to as anti-infectives); (ii) anti-inflammatories; and (iii) analgesics.
119. As to antimicrobials, overlaps occur in products used in the treatment of topical mastitis. Within this category, the parties produce and sell products for the treatment of dry cow mastitis and lactating cow mastitis. An overlap also occurs in the markets for oral antibiotics, companion animals, penicillin. As to (ii) anti-inflammatories and (iii) analgesics, according to the market definition by the parties overlaps occur in the market for injectable corticosteroids for use in acute conditions.
120. Antimicrobials, anti-inflammatories and analgesics will be examined more closely in the following.

1. Antimicrobials

121. Antimicrobials pharmaceuticals include antibacterials and antibiotics. They are used both for food animals and for pets to treat diseases of bacterial, mycoplasmal or fungal origin. The antimicrobials sector consists of a large number of products, that differ mainly as to a) their route of administration (injection, oral administration, topical application on the skin or in the ear, eye, udder or uterus) and b) their active ingredient (specific chemical molecule or group of antibiotic drugs).
122. Antimicrobials are therefore generally divided into various subcategories of products depending on: a) the route of administration: injectable products, products for oral administration and products for topical administration (such as mastitis and endometritis treatments); b) their active substance: in this respect, the parties state that the main categories for these active substances are sulphanomides, penicillins, cephalosporins, tetracyclines, macrolides, quinolones, aminoglycosides, phenicals and fluoroquinolones and novobiocin.
123. As mentioned above, there are antimicrobials overlaps in a) products used in the treatment of topical mastitis and b) in the markets for oral antibiotics, companion animals, penicillin.

Topical mastitis treatment

¹³ See Case No IV/M.737, *Ciba-Geigy/Sandoz*, Decision of 17 July 1996; Case No IV/M.885, *Merck/Rhône-Poulenc/Merial*, Decision of 2 February 1997; and Case No COMP/M.1681, *Akzo Nobel/Hoechst Roussel Vet*, Decision of 22 November 1999.

124. Mastitis is an inflammation of the mammary gland. In the dairy cow, mastitis is nearly always caused by micro-organisms, usually bacteria, that invade the udder, multiply and produce inflammatory toxins. Mastitis treatments are thus administered to eliminate the bacteria inside the udder of a cow which cause an acute or chronic inflammation of the udder. The infection is treated by using anti-infective compounds to kill the bacteria which cause the disease. Topical mastitis treatments are administered through a specific injector tube that is inserted in the teat canal and emptied into the udder.
125. There are two different types of mastitis infection. Acute mastitis most commonly occurs during the lactation period. The treatment of acute cases requires daily repeated administration of quick and short acting therapeutic formulations (“lactating cow products”). Chronic udder infections (or sub-clinical mastitis) are less clearly noticed than acute mastitis and merely cause an increased number of white blood cells in the milk, without any obvious clinical symptoms. Sub-clinical mastitis is typically treated during the 60 days of the year when the cow is not milked, with routine preventive (single) administration of one injector at the start of the dry period.
126. The parties have submitted in line with the Commission's decisions in Case No COMP/M.1681, *Akzo Nobel/Hoechst Roussel Vet*, that the sector of mastitis treatment should be divided in two markets: lactating cow products and dry cow products. These two markets should be further divided according to the active substance used. The active substance at stake would be different kinds of antibiotics (sulphanomides, penicillins, cephalosporins, tetracyclines, macrolides, quinolones, aminoglycosides, phenicals and fluoroquinolones). Although some third parties indicated alternative definitions of the market (old molecules / new molecules or broad/narrow spectrum products) the Commission considers that there are no strong reasons to deviate from its previous practice for the purposes of this case.

a) Topical mastitis, dry cow – penicillin antibiotics

127. The only class 3 (i.e. with combined market shares exceeding 40% and increment higher than 1%) affected market occurs in the United Kingdom. There were potentially class 3 affected markets in both Germany and Ireland as well, but these are no longer affected. In Germany Pharmacia had prior to the transaction already taken the decision that [...]. In Ireland Pharmacia's product had no sales in 2001 and hence there is no overlap.
128. On the UK market the parties would attain a combined market share of [50-60]%. Pharmacia's product, Tetraclox Dry Cow, accounts for [<5]% share of sales of all dry cow mastitis penicillin products. The Pfizer products (Orbenin DC and Orbenin Extra DC) between them account for approximately [45-55]% of all penicillin class dry cow mastitis products sold. The Parties' products face competition from Norbrook, with a share of approximately [25-35]% and from Fort Dodge, whose products account for [5-15]% of the dry cow mastitis penicillin class. The parties' products are all off-patent, and there are numerous generic competitors (such as the Norbrook and Fort Dodge products mentioned).
129. Despite the parties high combined market share, when taking into account the relative small increment of market share, the competitive restraints exercised by the presence of strong competitors, the competition from generic products, the stable market shares of the parties, the Commission does not consider that the operation as notified would give

rise to serious doubts as to the compatibility with the common market on the market for penicillin class products for the treatment of dry cow mastitis in the UK.

b) Topical mastitis, lactating cow – penicillin antibiotics

130. The only overlap occurs in Germany where Pfizer has [10-20]% with its product *Ampiclox LC* in 2001, while Pharmacia's product *Eumacid* had less than [<5]% share of sales of all lactating cow mastitis penicillin products. Both products are off-patent. A number of competitors exist on the German market for these products, including the market leaders, Merial, which is estimated to have a share of sales of approximately [20-30]%, and Virbac, which holds an approximate share of [20-30]%. Bayer's products together account for around [10-20]% share of the market.
131. The operation will thus leave the market position almost unchanged because of the small increment of market share. Furthermore the new entity will face strong competitors. Therefore the operation does not give rise serious doubts as to the compatibility with the common market on the market for penicillin class products for the treatment of lactating cow mastitis in Germany.

Oral Antibiotics for Companion Animals-Penicillin

A. Relevant product market

132. Oral antibiotics for companion animals are used to treat different infections (e.g. soft tissue infections, dental infections, urinary tract infections and respiratory disease). The parties have analysed the sector of oral antibiotics for companion animals on the basis of a definition of the relevant market established per class of antibiotics, i.e. on the basis of the active substances contained therein (e.g. Penicillin).
133. However, alternative market definitions were suggested by the market investigation, possibly as wide as to encompass a number of classes of antibiotics for companion animals. Some respondents indicated that a market definition based on intended use or indication would be more appropriate. Others suggested classifying products into a) narrow spectrum and b) broad spectrum antibiotics. It was also suggested that a market definition based on intended use or indications could be examined on the basis of "old molecules" and "new generation molecules" categories. It appears that all alternative market definitions would hinge upon/lead to cross-class substitutability.
134. Within this alternative framework, it was suggested to the Commission that Pharmacia's product *Antirobe* (brand-named *Cleorobe* in Germany) was directly substitutable to Pfizer's *Synulox*. *Antirobe* belongs to the *Macrolides* class of antibiotics, which – for certain intended uses or indications – overlaps with *Synulox*, which belongs to the *Penicillin* class. To further its understanding of this sector and clarify which market definition would more appropriately reflect market reality the Commission launched a specific market investigation. At the same time the parties were requested to provide information and to comment on the alternative market definitions suggested.
135. The number of alternatives proposed by the market investigation indicates that a certain degree of substitutability between products in different classes is likely to exist. However, products of the same class normally tend to be perceived as closest substitutes. The Commission believes that the limited overlaps in indications highlighted by the market investigation in this case, although not sufficient to

completely exclude that some products from one class may be considered substitutes for certain products of another class, did not provide evidence of the existence of strong competitive constraints between any two classes of antibiotics, and in particular between the penicillin class and other classes.

136. In particular, in the framework of alternative cross-class market definitions, the Commission focussed on possible patterns of substitutability between Antirobe and Synulox, as third parties indicated that Antirobe could be a substitute to Synulox. It was found that the two products are substitutable only in a limited number of instances. As a matter of fact, while Antirobe has a limited number of indications (mainly dental and skin infections in dogs and cats) Synulox is a broad spectrum antimicrobial and has more than 15 indications for a number of species (cattle, pigs, dogs and cats). However, even for the few overlapping indications, Antirobe is usually not considered as a first line product, due to its higher price. Moreover, the veterinarian/customer will need both antibiotics to be able to face all possible situations and meet different “patients” needs. Similar considerations are also valid for other products, belonging to classes of antibiotics other than macrolides, for which limited overlaps in indications were mentioned by third parties¹⁴.
137. In view of the foregoing, the Commission considers that, for the purpose of this decision, there is not sufficient evidence in support of the inclusion of products from different classes of antibiotics into the relevant product market. The relevant product market is thus considered to be oral antibiotics for companion animals-penicillins.

Assessment

138. The only overlap occurs in Germany for penicillin based products. Pfizer holds a share in this market of [70-80]%, while Pharmacia’s share is [<10]%. One of Pfizer’s product *Synulox* ([65-75]% of total sales) is an amoxicillin based penicillin indicated for a wide range of diseases in cats and dogs including deep and superficial pyodermas, soft tissue infections, dental infections, urinary tract infections, respiratory disease and enteritis. Pfizer also sells *Clamoxyl* ([<5]% of total sales). The latter product is also based on amoxicillin, and its main indications are for localised infections, alimentary tract infections, urogenital tract infections, secondary bacterial infections and generalised infections. Pharmacia’s product *Parkemoxin* ([<10]% of total sales) is an amoxicillin based penicillin indicated for use in dogs and cats. It is indicated for lung and airway infections, gastro-intestinal infections, urinary tract infections, localised infections and secondary infections. The product is off-patent. Both Synulox and Parkemoxin are used in the treatment of both gram-positive and gram-negative bacteria sensitive to amoxicillin.
139. There have been no significant changes of the above mentioned market shares for the past three years. The largest competitors on the market are CEVA, with around [<10]% share of the market, and Vetoquinol with two products holding a combined market share of [<10]%.
140. The parties submission that Synulox and Parkemoxin are not each other’s closest competitors, as Synulox is perceived as a product for use in more challenging

¹⁴ For instance Bayer’s Baytril and Marbocyl’s Vetoquinol were mentioned by third parties as having an overlap with Synulox for the treatment of prostatic infections.

infections, or where a vet wishes to combat a range of possible infections at the same time, has not been confirmed by the market investigation. Although the products do not have completely overlapping indications, they are to a large extent substitutable.

141. The market investigation did confirm that a number of generic products are also marketed, although market data as regards their market shares are not available. Therefore market shares in this sector, like in most animal health markets, do not accurately reflect the real size of the market for the penicillin class of oral antibiotics for companion animals. The investigation did not, however, shed any light on the actual “weight” of these unlisted generic products. Furthermore, the market investigation also confirmed that competitive restraints exerted by other classes of antibiotics do, to some extent, exist.
142. In spite of the uncertainty and the analytical difficulties of the assessment of the possible competitive pressure stemming both from products belonging to other classes and from generic products, the Commission nevertheless has considered that, owing to a very high combined market share, amounting to approximately [75-85]%, and the elimination of Pharmacia as a close competitor, it can be concluded that serious doubts exist with regard to this market as to the compatibility of the operation with the common market and the EEA Agreement.

2. Anti-inflammatory and analgesic products

143. Following the Commission’s previous approaches to market definition in animal healthcare pharmaceuticals, the parties have analysed the transaction at the levels of non-steroidal anti-inflammatory drugs (“NSAIDs”) on the one hand and steroids on the other, further sub-dividing the segments by relevant factors such as the route of administration, and the species for which a particular formulation is intended.
144. The conclusion of this analysis has led to the identification of overlaps for orally administered NSAIDs for horses in the UK¹⁵ and injectable corticosteroids¹⁶ in Belgium and in the Netherlands. The first, however, does not give rise to an affected market since the parties’ combined share in the UK, the only country where the overlap occurs, does not exceed [5-15]%.
145. Corticosteroids act on the immune system by blocking the production of substances that trigger inflammatory actions, such as prostaglandins. However, they also impede the function of white blood cells which destroy foreign bodies and help the proper functioning of the immune system.
146. The parties have submitted that while a sub-division of the market by species or size of animal does not reflect market reality, a distinction can be drawn, on the basis of their different setting of prescription indication¹⁷, between: a) injectable corticosteroids prescribed for use in chronic conditions and b) injectable corticosteroids prescribed for use in acute conditions. The parties submitted that the a) and b) would generally not be

¹⁵ Pfizer sells Rimadyl granule sand Pharmacia sells Apirel

¹⁶ Pfizer sells Cortexilar; Pharmacia sells Predef 2x, Solu-Delta-Cortef

¹⁷ Especially in companion animals, the administration of an injection is usually only carried out by a trained veterinarian. Chronic conditions are therefore generally treated through the use of long-acting injections (to minimise visits to a veterinarian’s surgery) or orally administered treatments (which can be administered by the owner), while acute conditions are normally treated through short-acting injections.

viewed as substitutable. This claim was not contested by the market investigation. At any rate the exact market definition can, for the purpose of this case, be left open as no competition concern arises regardless of any possible alternative market definition.

147. Pfizer is not active in the treatment of chronic conditions through corticosteroids. Therefore no overlap stems from the operation in this specific area.
148. As regards injectable corticosteroids for use in acute conditions, the operation will bring about overlaps in Belgium and The Netherlands. In The Netherlands, there is no affected market, as the combined share of sales of the parties is below 15%.
149. An affected market occurs in Belgium for injectable steroids used in acute conditions, as the combined share of sales of the Pharmacia products would total [10-20]% of the market, with Pfizer's Cortexilar adding an increment of only [<5]%. Eurovet's Rapidexon is the market leader, with [30-40]% of the market, and the company has an overall share of sales of [35-45]% when one also considers its generic prednisolone injection product. All Pfizer's and Pharmacia's products are off-patent.
150. On the basis of the foregoing, the Commission has concluded that no serious doubts exist as to the compatibility of the operation with the common market for anti-inflammatory and analgesic products in Belgium.

VI. MODIFICATIONS TO THE PROPOSED OPERATION

151. In order to remove the serious doubts resulting from the proposed transaction, the parties offered the Commission undertakings. The detailed text of these undertakings is annexed to this decision. The full text of the annexed undertakings forms an integral part of this decision.
152. In the market for G4B4 Urinary Incontinence Products, the parties propose to divest the Phase [...] compound Darifenacin world-wide. The proposed undertaking will remove the entire overlap between Pharmacia and Pfizer in this market.
153. In the market for G4B3 Erectile Dysfunction Products, the parties propose to transfer/divest Pharmacia's two products in development: Pharmacia will transfer the rights to develop and commercialise the Apomorphine hydrochloride nasal spray for human sexual dysfunction to Nastech Pharmaceutical Company, Inc. ("Nastech") and will provide financial and technical assistance to Nastech to preserve the viability of the project. In addition, Pharmacia will divest the rights to develop and commercialise the selective agonist for the dopamine D2 receptor [...] for the treatment of human sexual dysfunction.
154. The proposed undertakings will remove the overlap between Pfizer's and Pharmacia's existing and pipeline products and will facilitate new entry into a highly concentrated market.
155. In the market for C2A Antihypertensives (of Non-Herbal Origin) Plain in the Netherlands, the parties propose that Pharmacia will discontinue selling Ketensin and transfer any relevant rights or assets to the original licensor or one or more designated third parties. In view of the very small market share (<1%) of the parties' other products, this would effectively eliminate the overlap between the parties.

156. With regard to animal healthcare, in the Oral Penicillin Antibiotics for Companion Animals in Germany, the parties propose to divest Pharmacia's product Parkemoxin. This will eliminate the overlap between the parties.
157. The Commission considers that the undertakings are sufficient to eliminate serious doubts as to the compatibility of the transaction with the common market. These commitments will solve competition concerns both by eliminating the overlap between the parties in this market and facilitating new entry to the market. The undertakings have also been supported by third parties in their replies to the Commission's market test.

VII. CONCLUSION

158. The Commission concludes that the undertakings submitted by the parties are sufficient to address the competition concerns raised by this concentration. Accordingly, subject to the full compliance with the commitment submitted by the notifying parties, the Commission has decided not to oppose the notified operation and to declare it compatible with the common market and with the EEA Agreement. This decision is adopted in application of Article 6(2) of Council Regulation (EEC) No 4064/89.

For the Commission

Mario MONTI
Member of the Commission
(signed)

Case No COMP/M.2922 - Pfizer Inc./Pharmacia Corporation Commitments to the European Commission

Pursuant to Article 6(2) of Council Regulation (EEC) No. 4064/89 as amended (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 Pharmacia Corporation (“Pharmacia”) by Pfizer (together the “Parties”) compatible with the common market and the EEA Agreement by its decision pursuant to Article 6(1)(b) of Council Regulation (EEC) No 4064/89 (the “Merger Regulation”) (the “Decision”).

Any term used in this text, unless otherwise defined, or unless the context indicates otherwise, shall be interpreted in the light of the Commission Notice on remedies acceptable under the Merger Regulation and under Commission Regulation (EC) No 447/98.

SECTION A. DEFINITIONS

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

Affiliated Undertakings: undertakings under the control of the Parties, whereby the notion of control shall be interpreted pursuant to Article 3 Merger Regulation and in the light of the Commission Notice on the concept of concentration under Council Regulation (EEC) No 4064/89.

Closing: the Divestment of a Divestment Business.

Commission Standard Trustee Mandate: the Commission’s recommended model trustee mandate in the case of commitments accepted under the Merger Regulation.

Divestment Businesses: the businesses as defined in Section B and more particularly delineated in Schedules I to V (each respective business described in Schedules I to V herein referred to as a "Divestment Business"). For the purposes of this document the term "Divestment" shall include: the transfer and/or the discontinuation of the right to commercialise Third Party Products distributed under licence or distribution agreements; and/or the licence, transfer or assignment of all rights currently held by the Parties; and/or the transfer of supply or other related agreements as necessary and appropriate.

Divestiture Trustee: one or more than one natural or legal person, independent from the Parties, who is approved by the Commission and appointed by Pfizer and who has received from Pfizer the irrevocable and exclusive mandate to conduct the Divestment of one or more Divestment Businesses at no minimum price.

Effective Date: unless specified otherwise, the first business day after the satisfaction or waiver (subject to the applicable law) of the conditions set forth in Article VI and the termination rights set forth in Article VII of the Agreement and Plan of Merger dated as of July 13, 2002 among Pfizer Inc., Pilsner Acquisition Sub Corp. and Pharmacia Corporation which will bring about the acquisition of Pharmacia by Pfizer.

Extended Divestiture Period: the period from the date of expiry of the First Divestiture Period within which the Divestiture Trustee shall have an irrevocable and exclusive mandate from Pfizer to conduct the Divestment of one or more Divestment Businesses at no minimum price.

First Divestiture Period: the period within which Pfizer may conduct the Divestment of the Divestment Businesses before providing a mandate to the Divestiture Trustee.

Intellectual Property Rights: intellectual property rights forming part of a Divestment Business and relating to the research, development, manufacture, sale or use of a Divestment Business product and where relevant its active substances, existing and new formulations and combinations with other active substances, including but not limited to, existing and pending patents, trademarks, copyright, trade secrets, research materials, technical information, inventions, test data, know-how, product efficacy and safety data.

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

Pfizer: Pfizer is incorporated under the laws of the State of Delaware, USA with its registered office at 235 East 42nd Street, New York, New York 10017, USA.

Pharmacia: Pharmacia is incorporated under the laws of the State of Delaware, USA with its registered office at 100 Route 206, North Peapack, New Jersey, 07977, USA.

Purchaser: an entity approved by the Commission as acquiror of Divestment Business I, III or V in accordance with the criteria set out in Section E.

Retained Businesses: all of the businesses not forming part of the Divestment Businesses and retained by Pfizer following Closing.

Territory: world-wide unless otherwise specified in Schedules I to V.

Third Party Products: Products sold by Pharmacia under licence or distribution agreements described in Schedule II.

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

SECTION B. THE DIVESTMENT BUSINESSES

Commitment to Divest

1. Pfizer shall discharge the commitments more particularly described in Schedules I to V as specified below (the "Divestment Commitments"). Pfizer warrants that the Divestment Businesses include all the relevant legal, factual, scientific, commercial and other features of the Divestment Businesses necessary for the viability, marketability and competitiveness of the Divestment Businesses; unless expressly excluded in Schedules I to V.
2. The Divestment Businesses, described in more detail in Schedules I to V, include:
 - (a) all necessary rights to tangible and intangible assets (including Intellectual Property Rights), be it by transfer or licensing, which contribute to the current operation or may be necessary to ensure the viability and competitiveness of the Divestment Business;
 - (b) all necessary licences, permits and authorisations issued by any governmental organisation for the benefit of the Divestment Business;
 - (c) all necessary contracts, agreements, leases, commitments and understandings of the Divestment Business; all customer, credit and other records specific to the Divestment Business; and
 - (d) a commitment by Pfizer to offer the Purchaser the opportunity to seek to hire all personnel predominantly relating to the Divestment Businesses (including seconded staff and shared personnel) necessary for the development of and for the effective Divestment and for the preservation of the viability, marketability, competitiveness and development of the Divestment Businesses.
3. For the avoidance of doubt, the Divestment Businesses shall, *inter alia*, not include:
 - (a) intellectual property other than intellectual property predominantly relating to the Divestment Businesses;
 - (b) the "Pfizer" and "Pharmacia" name and logo in any form;
 - (c) books and records required to be retained pursuant to any statute, rule, regulation or ordinance, provided that a Purchaser shall obtain a copy of the same and shall be permitted access to the original of such books and records upon reasonable request during normal business hours; and
 - (d) general books of account and books of original entry that comprise the Parties' or an Affiliated Undertaking's permanent accounting or tax records.
4. Should Pfizer not be able to comply with the above-mentioned Divestment Commitments due to the fact that any authorisations may not be transferred by their terms or without the consent, novation, waiver or approval of a third person and for which such consent, novation, waiver or approval has not been obtained, Pfizer shall invoke the Review Clause

below, with a view to modifying the Divestment Commitment(s) so as to remedy otherwise the competition concerns identified in the Decision.

SECTION C. RELATED COMMITMENTS

Preservation of Viability, Marketability and Competitiveness

5. Pfizer undertakes to preserve the full economic viability, marketability and competitiveness of the Divestment Businesses to the extent possible and reasonably practicable from the date of the Decision until Closing, in accordance with past commercial practice, and to reduce to the minimum any risk of loss of competitive potential of the Divestment Businesses. In particular, until Closing, Pfizer undertakes not to carry out any act upon its own authority that would foreseeably have a significant adverse impact on the economic value or the competitiveness of the Divestment Businesses. Furthermore, Pfizer undertakes, to the extent possible and reasonably practicable, to take any positive action required to avoid any foreseeable and significant adverse impact on the economic value or the competitiveness of the Divestment Businesses. Sufficient resources shall be made available for the development of the Divestment Businesses, on the basis and continuation of the existing business plans, until Closing.

Hold-Separate Obligations of Parties

6. Pfizer commits, from the date of the Decision, to keep the Divestment Businesses separate, to the extent possible, reasonably practicable and subject to paragraph 5, from the businesses it is retaining.
7. Prior to Closing, Pfizer shall assist the Monitoring Trustee, to the extent possible and reasonably practicable, in ensuring that the Divestment Businesses are managed as saleable entities separate from the businesses it is retaining.

Ring-Fencing

8. Pfizer shall, to the extent possible and reasonably practicable, implement all necessary measures to ensure that the Parties do not, after the date of the Decision, obtain any business secrets, know-how, commercial information, or any other information of a confidential or proprietary nature relating to the Divestment Businesses, with the exception of information which is reasonably necessary for the Divestment of the Divestment Businesses or whose disclosure is required by law.

Non-Assertion of Retained Patents

9. Pfizer commits to abstain from any use of existing and pending patents world-wide related to its Retained Businesses as well as any future patents obtained by Pfizer world-wide following its acquisition of Pharmacia to the extent that this would prevent the Purchaser of the Divestment Businesses from developing, producing, or using the Divestment Businesses world-wide, or selling the medicinal products containing the active substances (whether or not in combination with other active substances) forming part of the Divestment Businesses in the Territory. Pfizer shall require its successors in title, licensees and assigns to do the same. For the avoidance of doubt, nothing herein shall prevent Pfizer from enforcing its rights in respect of a combination of an active substance forming part of the Divestment

Business with an active substance not forming part of the Divestment Business, where the latter active substance is the cause of the infringement of Pfizer's rights.

10. Pfizer may require the Purchaser to commit to abstain from any use of existing and pending patents world-wide related to the Divestment Businesses as well as any future patents obtained by the Purchaser world-wide following its acquisition of the Divestment Businesses to the extent that this would prevent Pfizer from developing, producing, or using the Retained Businesses world-wide or selling the medicinal products containing the active substances (whether or not in combination with other active substances) forming part of the Retained Businesses. Purchaser shall require its successors in title, licensees and assigns to do the same. For the avoidance of doubt, nothing herein shall prevent the Purchaser from enforcing its rights in respect of a combination of an active substance forming part of the Divestment Business with an active substance not forming part of the Divestment Business, where the former active substance is the cause of the infringement of the Purchaser's rights.

SECTION D. THE DIVESTITURE PROCEDURE

The First Divestiture Period

11. Pfizer undertakes to enter into any necessary agreements to discharge the Divestment Commitments within [...] from the Effective Date.

The Extended Divestiture Period

12. Should Pfizer be unable to enter into binding agreements to discharge the Divestment Commitments in the First Divestiture Period, the First Divestiture Period shall be extended by [...] from the date of the expiry of the First Divestiture Period. Pfizer undertakes to give the Divestiture Trustee an irrevocable and exclusive mandate to discharge the Divestment Commitments within the Extended Divestiture Period at no minimum price.

Closing

13. Pfizer shall be deemed to have complied with this undertaking if, within a period not exceeding [...] from the Effective Date, it has entered into a legally binding agreement in accordance with paragraphs 16 to 18 and that any Closing takes place no later than [...] after the conclusion of such arrangements.

Reporting

14. Pfizer shall submit written reports in English on the progress on the discharge of the Divestment Commitments, potential Purchasers and developments in the negotiations with such potential Purchasers to the Commission and the Monitoring Trustee no later than 10 calendar days after the end of every month following the Effective Date (or otherwise at the Commission's request).
15. Pfizer shall inform the Commission and the Monitoring Trustee on the preparation of any data room documentation, information memorandum and due diligence procedure arranged by Pfizer. Before sending out any information memorandum prepared by Pfizer for a

Divestment to potential Purchasers, Pfizer shall submit a copy of the draft to the Commission and the Monitoring Trustee so that the Commission can verify the information memorandum's consistency with the terms of the Commitments.

SECTION E. THE PURCHASER

16. Pfizer undertakes to ensure that a Purchaser shall be independent of and unconnected to the Parties, have the financial resources, proven expertise and incentive, as appropriate to the nature of the Divestment Business, to maintain and/or develop a Divestment Business as a viable and active competitive force in competition with Pfizer and other competitors. Pfizer must be able to demonstrate to the Commission that the Divestment of a Divestment Business occurs in a manner consistent with these Commitments. In order to maintain the structural effect of any or all of these Commitments, Pfizer shall not subsequently acquire direct or indirect influence over the whole or part 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 Businesses is no longer necessary to render the proposed concentration compatible with the common market.
17. When Pfizer has reached or is about to reach an agreement to achieve the Divestment of a Divestment Business to a Purchaser, it shall submit a fully documented and reasoned proposal, including a copy of any relevant agreement, to the Commission and the Monitoring Trustee. The proposal shall enable the Commission to verify that the requirements set out in paragraph 16 with regard to a Purchaser are fulfilled and that the Divestment of a Divestment Business occurs in a manner consistent with the conditions and obligations attached to the Decision.
18. Any final binding agreement with a Purchaser, shall be conditional on the Commission's approval. The verification that the Divestment of the Divestment Business is being achieved in a manner consistent with the conditions and obligations attached to the Decision shall include the Commission's expeditious approval of a Purchaser and of the final binding agreement.

SECTION F. TRUSTEE

I. Appointment Procedure

19. Pfizer shall appoint one or more Trustees, subject to the prior approval of the Commission as referred to in paragraph 20. 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 be nor become exposed to a conflict of interest. The Trustee shall be remunerated by the Parties in a way that does not impede the independent and effective fulfilment of its mandate.

Proposal by Pfizer

20. Pfizer shall propose a list of Trustees and the full terms of their mandates for the Commission's approval no later than [...] after the date of the Decision in the case of the Monitoring Trustee and no later than [...] before the end of the First Divestiture Period in that of the Divestiture Trustee. The proposal shall contain sufficient information for the

Commission to verify that the Trustee fulfils the requirements set out in paragraph 19 and the outline of a work plan in which the Trustee describes how it intends to carry out the tasks assigned to it under the conditions and obligations attached to the Decision. Pfizer shall indicate to the Commission whether the proposed Trustees are to act as both Monitoring Trustee and Divestiture Trustee or whether different trustees are proposed for the two functions. The mandate submitted for approval shall be drawn up taking due account of the Commission Standard Trustee Mandate and shall include all provisions necessary to enable the Trustee to fulfil its duties under these Commitments.

Approval or rejection by the Commission

21. The Commission shall have the discretion to approve or reject the proposed Trustee(s) and to approve the proposed mandate subject to any modifications it deems necessary for the Trustee to fulfil its obligations. If only one name is approved, 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 [...] of the Commission's approval, in accordance with the mandate approved by the Commission.

New proposal by Pfizer

22. If all the proposed Trustees are rejected, Pfizer shall submit the names of at least two more individuals or institutions within [...] of being informed of the rejection, in accordance with the requirements set out in paragraph 19 for approval in accordance with paragraph 21.

Trustee nominated by the Commission

23. 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.

II. Functions of the Trustee

24. 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

25. Following its appointment, 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, in particular those referred to in paragraphs 5 to 10;
 - (ii) monitor compliance by the Parties with the conditions and obligations attached to the Decision;

- (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 the Parties' compliance with the conditions and obligations attached to the Decision;
- (v) review and assess potential Purchasers as well as the progress of the Divestment process and verify that potential Purchasers receive sufficient information;
- (vi) provide to the Commission, sending Pfizer a non-confidential copy at the same time, a written report within 15 calendar days after the end of every month. The report shall cover the operation and management of the Divestment Businesses so that the Commission can assess whether the business is held in a manner consistent with the Commitments and the progress of the Divestment 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 the Parties are failing to comply with any of the conditions or obligations under these Commitments;
- (vii) once Pfizer has proposed to the Commission a Purchaser or Purchasers, within [...] after receipt of the proposal, assess the independence and suitability of the proposed Purchasers and give its opinion to the Commission as to whether the Divestment Businesses are being sold in a manner consistent with the conditions and obligations attached to the Decision.

Duties and obligations of the Divestiture Trustee

- 26. Within the Extended Divestiture Period, the Divestiture Trustee shall discharge the Divestment Commitments at no minimum price, subject where applicable to the procedures laid down in paragraphs 14 to 16. The Divestiture Trustee shall include in a Divestment agreement such terms and conditions as it considers appropriate for an expedient Divestment. In particular, the Divestiture Trustee may include in the agreement such customary representations and warranties and indemnities as are reasonably required to effect the Divestment.
- 27. Following the expiration of the First 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 Divestment process. Such reports shall be submitted within 15 calendar days after the end of every month. The Monitoring Trustee and Pfizer shall be provided a simultaneous non-confidential copy of these reports.

III. Duties and obligations of the Parties

- 28. Pfizer shall provide the Trustee with all such assistance and information, including copies of all relevant documents, as the Trustee may reasonably require to perform its tasks. The Trustee shall have full and complete access to any of the Parties' books, records, documents, personnel, facilities, sites and technical information necessary for fulfilling its duties under the Commitments. Pfizer shall make available to the Trustee one or more than one offices on

its premises and shall be available for meetings in order to provide the Trustee with all information necessary for the performance of its tasks.

29. Pfizer shall provide the Monitoring Trustee with all managerial and administrative support that it may reasonably request. Pfizer shall provide the Monitoring Trustee, on request, with access to the information submitted to potential Purchasers, in particular to any data room documentation and all other information granted to potential Purchasers in the due diligence procedure. Pfizer shall inform the Monitoring Trustee on identifying possible Purchasers, submit a list of potential Purchasers and inform it of development in the Divestment process. Pfizer shall inform the Trustee about meetings with potential Purchasers and where possible grant the Trustee access to such meetings.
30. Pfizer shall grant comprehensive powers of attorney, duly executed, to the Divestiture Trustee for a Divestment, a Closing and all actions and declarations which the Divestiture Trustee considers reasonably necessary or appropriate to discharge the Commitments, including the appointment of advisors to assist with the Divestment process. Upon request of the Divestiture Trustee, Pfizer shall cause the documents required for effecting any Divestment and any Closing to be duly executed.
31. At the expense of Pfizer, the Trustee may appoint advisors (in particular for corporate finance or legal advice), incurring reasonable fees and other expenses, subject to Pfizer's approval (this approval not to be unreasonably withheld) if the Trustee considers the advisors reasonably necessary or appropriate for the performance of its duties. Should Pfizer refuse to approve the advisors proposed by the Trustee the Commission may approve the appointment of such advisors instead. Only the Trustee shall be entitled to issue instructions to the advisors. In the Extended Divestiture Period, the Divestiture Trustee may use advisors who served Pfizer during the First Divestiture Period if the Divestiture Trustee considers this in the best interest of an expedient Divestment.

IV. Replacement, Discharge and Reappointment of the Trustee

32. The Commission may, after hearing the Trustee, order Pfizer to remove the Trustee if the Trustee has not acted in accordance with the Commitments or for any other good cause.
33. The Trustee may also be removed by Pfizer with the prior approval of the Commission and after the Commission has heard the Trustee if the Trustee has not acted in accordance with the Commitments or for any other good cause.
34. 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 19-23.
35. The Trustee shall cease to act as Trustee only after the Commission has discharged it from its duties, following a request from the Trustee or Pfizer after all the Commitments with which the Trustee has been entrusted have been fulfilled. 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 fulfilled.

SECTION G. THE REVIEW CLAUSE

36. 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 Divestiture Period, or
 - (ii) Allow the transfer of the Divestment Businesses, without one or more assets, or
 - (iii) Waive or modify, in exceptional circumstances, one or more of the conditions and obligations in the Commitments.

Where Pfizer seeks an extension of a time period, it shall submit a request to the Commission no later than one month before the expiry of that period, showing good cause. Only in exceptional circumstances shall Pfizer be entitled to request an extension within the last month of any period.

Date:

Signature:

duly authorised for and on behalf of Pfizer Inc.

SCHEDULE I

Parkemoxin

- A. Divestment Business I consists of Pharmacia's rights, title and interests in Parkemoxin in Germany including the right to develop, manufacture and use Parkemoxin anywhere in the world with a view to its sale in any form and for any indication whatsoever in Germany. Parkemoxin is the Pharmacia oral companion animal penicillin-based (amoxicillin trihydrat) tablet. For the avoidance of doubt, Divestment Business I does not contain any rights to sell Parkemoxin outside Germany.
- B. Divestment Business I includes:
- (a) existing German product inventory, sales and promotional material;
 - (b) the rights to use the Parkemoxin trademark¹ in Germany;
 - (c) the marketing authorisation for Parkemoxin in Germany (registration number 6187493.00.00);
 - (d) all relevant intellectual property rights, data, books, records and effective arrangements for the transfer of all know-how to the extent that these are related to the development, manufacture, use of Divestment Business I anywhere in the world with a view to its sale in Germany (items referred to under (a)-(e) hereinafter collectively referred to as "Assets of Divestment Business I"). In order to assist Purchaser to assume responsibility for Divestment Business I, Pfizer will provide, if necessary, at a cost equal to Pfizer's cost, technical assistance, for an appropriate period of time as the Parties may agree..
- C. Pfizer commits to procure the Divestment of Divestment Business I by the outright sale, or the grant of an irrevocable, assignable, sub-licensable exclusive licence, as appropriate, of the Assets of Divestment Business I to the Purchaser.
- D. Pharmacia has a toll manufacturing agreement with [...] under which [...] sources the raw materials, manufactures in finished form, packages and sends Parkemoxin to Pharmacia (the "Toll Manufacturing Agreement"²). If requested by Purchaser, Pfizer will use reasonable best efforts to procure that [...] enters into a toll manufacturing agreement with the Purchaser on terms substantially similar to the Toll Manufacturing Agreement. Otherwise, Pfizer commits to supply the Purchaser with all its requirements of Parkemoxin, at a cost equal to Pfizer's cost, for an appropriate period of time as the Parties may agree.

¹ The Parkemoxin trademark is owned by the Pfizer subsidiary Parke-Davis GmbH under German Registration No. 1170554.

² [...].

SCHEDULE II

Ketensin

- A. Divestment Business II consists of the distribution rights and obligations of Pharmacia granted pursuant to a distribution agreement dated [...] between [...] and Pharmacia relating to the product Ketensin (ketenserin tartrate) in the Netherlands (the "Distribution Agreement").
- [...]
- B. The Divestment Business II includes:
- (a) existing product inventory, sales and promotional material in the Netherlands;
 - (b) the trademark Ketensin (no 01451901) and any other intellectual property rights;
 - (c) all relevant data, material files, reports, plans and operating records, customer lists and contracts as well as any know-how, information, customer lists and other materials related to Divestment Business II. In order to assist Purchaser to assume responsibility for Divestment Business II, Pfizer will provide, if necessary, at a cost equal to Pfizer's cost, technical assistance, for an appropriate period of time as the Parties may agree;
 - (d) the marketing authorisation held by Pharmacia B.V. in relation to Ketensin (items referred to under (a)-(d) hereinafter collectively referred to as "Assets of Divestment Business II").
- C. Pfizer commits to procure the Divestment of Divestment Business II by termination of the Distribution Agreement.
- D. If requested by [...], Pfizer will procure the transfer of the Assets of Divestment Business III to [...] or its designated distributor.
- E. Pharmacia has a toll manufacturing agreement with [...] for production of the product. If requested by [...], Pfizer will use reasonable best efforts to procure that [...] will enter into a supply agreement with [...] or its designated distributor on terms substantially similar to Pharmacia's current toll manufacturing agreement. Otherwise, Pfizer commits to supply [...] with all its requirements of the product, at a cost equal to Pfizer's cost, for an appropriate period of time as the Parties may agree.

SCHEDULE III

Darifenacin

- A. Divestment Business III consists of Pfizer's rights, title and interests in and to the assets and rights in the compound Darifenacin, a muscarinic M3 receptor subtype antagonist, presently undergoing [...] clinical trials for the treatment of the symptoms of overactive bladder, described chemically as [...].
- B. Divestment Business III includes:
- (a) all patents and patent applications world-wide forming part of and predominantly relating to Divestment Business III;
 - (b) all trademark registrations and applications covering the ENABLEX mark, and related domain names and all other intellectual property owned by Pfizer predominantly relating to Divestment Business III;
 - (c) all rights of Pfizer in relevant IND and similar regulatory filings, licences and permits predominantly related to the performance of clinical trials relevant to Divestment Business III;
 - (d) all relevant data, in particular, all material files, reports, plans and operating records and correspondence in Pfizer's possession predominantly related to Divestment Business III;
 - (e) know-how, including ideas, inventions, data, instructions, processes, formulas, formulation information, validations, package specifications, chemical specifications, chemical and finished goods analytical test methods, stability data, all testing data, product specifications, information with respect to expert opinion and information (whether or not patented or patentable), technology and other intellectual property (including patents and any pending patent applications), owned by Pfizer or Affiliated Undertakings or under which Pfizer or Affiliated Undertakings have the right to transfer or grant sub-licences, all of the foregoing only to the extent predominantly related to the development, manufacture, use or sale of Divestment Business III, including, without limitation, all biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, clinical, safety, manufacturing and quality control data and information related thereto, all correspondence with the Food and Drug Agency ("FDA") or other regulatory authority specifically relating to Divestment Business III and all other documents pertaining to communications with the FDA or other regulatory authority (including, but not limited to, minutes of any FDA communications regarding Divestment Business III and applications for any regulatory approval of Divestment Business III, if any);
 - (f) all rights and claims of Pfizer and Affiliated Undertakings against third parties predominantly relating to Divestment Business III, choate or inchoate, known or unknown, contingent or otherwise, (items referred to under (a)-(f) hereinafter collectively referred to as "Assets of Divestment Business III").

- C. Pfizer commits to procure the Divestment of Divestment Business III by the outright sale of the Assets of Divestment Business III to a Purchaser. Any tangible and intangible assets shared between Divestment Business III and any Retained Businesses, are included in Divestment Business III insofar as they relate predominantly to Darifenacin, subject to Pfizer receiving a licence back or access insofar as these are necessary for its Retained Businesses. Insofar as such assets do not relate predominantly to Darifenacin, but are necessary for the operation of Divestment Business III, a licence and/or access to such assets shall be included in the Divestment Business, insofar as they are necessary for use in the Divestment Businesses.
- D. In order to assist a Purchaser to assume responsibility for ongoing clinical and pre-clinical studies and, if applicable, for preparation of the NDA or other regulatory filings, Pfizer will provide, if necessary, at a cost to such Purchaser equal to the cost to Pfizer of providing such technical assistance, technical assistance to such Purchaser for an appropriate period of time as the Parties may agree. In addition, contract-manufacturing services will be provided, if necessary, at a cost equal to Pfizer's cost to such Purchaser for an appropriate period of time as the Parties may agree.
- E. "Fall –back" remedy

In the event that Pfizer's rights relating to Darifenacin, as described in A, B,C and D, cannot be transferred to a Purchaser approved by the Commission within [...] Pfizer, within an additional period of [...], commits to [...].

SCHEDULE IV

Apomorphine nasal spray

- A. Divestment Business IV consists of Pharmacia's rights to develop and commercialise apomorphine nasal spray for the prevention, treatment, diagnosis or control of human sexual dysfunction on a world-wide basis and Pharmacia's exclusive world-wide licence to Nastech's patents and patent applications directed to formulations of apomorphine nasal spray for sexual dysfunction. Apomorphine nasal spray is a non-specific dopamine agonist administered intra-nasally. Pharmacia is developing apomorphine nasal spray for the treatment of human sexual dysfunction pursuant to an Agreement between Pharmacia and Nastech Pharmaceutical Company, Inc. ("Nastech") (the "Nastech Agreement").
- B. Divestment Business IV is described fully in an Agreement made between Pharmacia and Nastech dated 24 January 2003 (the "Divestiture Agreement")³, and includes:
- (a) Pharmacia's rights to develop and commercialise the formulations of the intranasal apomorphine product that have been the subject of clinical trials conducted by Nastech prior to the 24th January 2003, including formulations that differ from such product only as to the quantity or concentration of its active ingredient or inactive ingredients, for the prevention, treatment, diagnosis or control of human sexual dysfunction (the "Current Collaboration Product");
 - (b) Pharmacia's inventory of clinical supplies of the packaged formulation of apomorphine nasal spray;
 - (c) All relevant data generated throughout the term of the Nastech Agreement, including all material technical, preclinical, clinical and marketing files, reports, plans, and records in the possession or control of Pharmacia or Affiliated Undertakings immediately prior to the closing of the Pharmacia-Pfizer merger which is related to the development or commercialisation of the Current Collaboration Product;
 - (d) Exclusive, world-wide, irrevocable licence rights (including the right to sublicense) pertaining to patents (including pending patent applications) and know-how that, immediately prior to the closing of the Pfizer-Pharmacia merger, are owned by Pharmacia or Affiliated Undertakings or under which Pharmacia or Affiliated Undertakings have the right to transfer or grant sublicenses, to the extent that such patents or know-how are related to the development, manufacture, use, importation or sale of the Current Collaboration Product for the prevention, treatment, diagnosis or control of human sexual dysfunction;
 - (e) Exclusive, world-wide, royalty-free, irrevocable license rights (including the right to sublicense) pertaining to any patents (including pending patent applications) claiming any invention or discovery that is conceived or reduced to practice

³ In the event of discrepancy between the description of Divestment Business IV provided herein and the Divestiture Agreement, the latter shall prevail.

pursuant to the Natestch Agreement and is owned by Pharmacia or Affiliated Undertakings or under which Pharmacia or Affiliated Undertakings have the right to transfer or grant sublicenses, to the extent that such patents are related to the research, development, manufacture, use, importation or sale of any intranasal apomorphine products for the prevention, treatment, diagnosis or control of human sexual dysfunction; and

- (f) All regulatory filings and approvals including investigative new drug applications in the United States (if any) relating to the Current Collaboration Product.
- C. At the Effective Date, Pfizer shall, in substitution for Pharmacia, proceed to the Closing of Divestment Business IV pursuant to the terms and provisions of the Divestiture Agreement.

SCHEDULE V

[...]

- A. Divestment Business V consists of all of Pharmacia's rights to develop and commercialise [...] for the treatment of male erectile dysfunction and female sexual dysfunction[...] is a selective agonist for the dopamine D2 receptor being developed by Pharmacia. Divestment Business V shall not include any rights in relation to the use of [...] for any indication other than human male erectile dysfunction or female sexual dysfunction.
- B. Divestment Business V includes:
- (a) the inventory of tablet formulation of [...] for clinical studies; inventory of [...] drug substance (the pre-cursor to the tablet formulation of [...]);
 - (b) irrevocable assignable, sub-licensable exclusive licences for the indication of treating human male erectile dysfunction and female sexual dysfunction with [...], of the following intellectual property rights: [...];
 - (c) clinical trial applications with respect to the use of [...] to treat human male erectile dysfunction and female sexual dysfunction obtained for the following countries: [...]; and
 - (d) the right to use, within the field of use of human male erectile dysfunction and/or female sexual dysfunction, clinical study reports and animal toxicology reports relating to [...], reports and documents relating to the process for the development and manufacture of the formulation. For the avoidance of doubt, Pfizer shall retain the right to use these reports for any indication other than human male erectile dysfunction or female sexual dysfunction.
- C. Pfizer commits to procure the Divestment of Divestment Business V by an irrevocable, assignable, sub-licensable exclusive licence of Pharmacia's rights to develop and commercialise [...] for the treatment of human male erectile dysfunction and female sexual dysfunction.
- D. At the request of any licensee, Pfizer will use reasonable best efforts to procure that [...] provides a supply of compound [...] to the licensee on terms substantially similar to Pharmacia's current supply arrangement. Otherwise, Pfizer commits to supply Purchaser with all its requirements of the compound [...] at a cost equal to Pfizer's cost for an appropriate period of time as the parties may agree.
- E. "Fall-back" remedy
- In the event that Pfizer's rights relating to [...], as described in A, B, C and D, cannot be transferred to a Purchaser approved by the Commission within [...], Pfizer, within an additional period of [...], commits to [...].