EN

Case No COMP/M.5502 - MERCK/ SCHERING-PLOUGH

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REGULATION (EC) No 139/2004 MERGER PROCEDURE

Article 6(1)(b) NON-OPPOSITION
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COMMISSION OF THE EUROPEAN COMMUNITIES

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PUBLIC VERSION

MERGER PROCEDURE
ARTICLE 6(1)(b) DECISION

To the Notifying party:

Dear Sir/Madam,

Subject: **Case No COMP/M.5502 – MERCK/ SCHERING-PLOUGH**
Notification of 18 September 2009 pursuant to Article 4 of Council Regulation No 139/2004

1. On 18 September 2009 the Commission received a notification of a proposed concentration pursuant to Article 4 of Council Regulation (EC) No 139/2004[1] by which the undertaking Merck & Co. Inc. ("Merck", US) acquires sole control over the undertaking Schering-Plough Corporation ("Schering-Plough", US) within the meaning of Article 3(1)(b) of the Council Regulation by way of purchase of shares.

2. The Commission has concluded that the notified operation falls within the scope of the Merger Regulation. Having finalised its first-phase market investigation, the Commission concluded that the notified operation does not raise serious doubts as to its compatibility with the common market and the EEA Agreement.

1. THE PARTIES

3. Merck is a global research-driven pharmaceutical company that discovers, develops, manufactures and markets a broad range of innovative human health products.

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

4. Schering-Plough is global science-based healthcare company active in three business segments: human health prescription pharmaceuticals, animal health and over-the-counter consumer healthcare.

2. CONCENTRATION

5. Merck intends to acquire Schering-Plough in a cash-and-stock transaction. Although the Parties signed a "Merger Agreement" the transaction leads to an acquisition of control by Merck over Schering-Plough. Existing Merck shareholders will own approximately 68% of the combined company. Schering-Plough will be renamed Merck. The transaction constitutes a concentration within the meaning of Article 3(1)(b) of the Merger Regulation.

6. Prior to the notification of the present transaction, Merck sold its 50% share in Merial, a joint venture through which Merck was active in the animal health sector, to Sanofi-Aventis (Commission decision of 16 September 2009 in case COMP/M.5614).

3. COMMUNITY DIMENSION

7. The undertakings concerned have a combined aggregate world-wide turnover of more than EUR 5 billion[2] (Merck: EUR […] million, Schering-Plough: EUR […] million). Each of them has a Community-wide turnover in excess of EUR […] million (Merck: EUR […] million, Schering-Plough: EUR […] million), but they do not achieve more than two-thirds of their aggregate Community-wide turnover within one and the same Member State.

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

[2] Turnover calculated in accordance with Article 5(1) of the Merger Regulation and the Commission Consolidated Jurisdictional Notice (OJ C95, 16.04.2008, p.1).

4. COMPETITIVE ASSESSMENT

4.1. Introduction

9. The notified operation concerns a large number of markets in the field of human health. The Parties' activities are complementary to a relatively large extent, but substantial horizontal overlaps arise in several areas such as asthma treatments, treatment of allergic rhinitis, systemic antifungal treatments, anti-depressants, plain corticosteroids and rheumatoid arthritis.

10. The Commission has also analysed a number of future markets where (1) either of the Parties has an existing product and the other has a pipeline product in an advanced stage of development[3] and (2) where both Parties have pipeline products in advanced stages[4]. None of these potential overlaps in future markets would give rise to competition concerns. The information provided by the Parties allowed the conclusion that no competition concerns arise in this respect. Also third parties did not indicate that the transaction could have a negative impact on any of those therapeutic areas. With regard to overlaps in pipeline products, there are no overlaps in any therapeutic area where both Parties have pipeline products that have reached "Phase III" (extensive clinical trials) or a further advanced stage of development. Therefore, in the present case there are no competition concerns with regard to pipeline products.

4.2 Relevant Product Markets

ATC classification

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

12. However, it is appropriate to carry out analyses also at other ATC levels, or a mixture thereof, if the circumstances of a case show that sufficiently strong competitive constraints faced by the undertakings involved are situated at another level and there are indications that ATC3 class does not lead to a correct market definition.[5] The Commission has previously departed from the ATC3 class in

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3 Antithrombotic agents, Hepatitis C Virus treatments, HIV/AIDS treatments, anti-emetics, oncology treatments (sarcoma, […]).

4 Treatments of […], […], schizophrenia, chronic obstructive pulmonary disease, and oncology treatments (colorectal cancer).

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

cases where the market investigation indicated that another market definition was more appropriate, for example the ATC4 class or medicines based on the same active pharmaceutical ingredient (molecule level) [6].

Prescription pharmaceuticals and over-the-counter pharmaceuticals

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

14. In the present case, the market investigation has largely confirmed that, for the treatment areas where this was relevant, i.e. allergic rhinitis, OTC and prescription pharmaceuticals constitute separate product markets.

Originator pharmaceuticals and generic pharmaceuticals

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

4.3 Relevant Geographic Markets

16. The Commission has previously defined the geographic markets for pharmaceutical products as being national in scope.[9] The market investigation has

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

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

8 Cases COMP/M.5253 – *Sanofi-Aventis/Zentiva*, decision of 4 February 2009; COMP/M.5295 – *Teva/Barr*, decision of 19 December 2008; COMP/M.3751 – *Novartis/Hexal*, decision of 27 May 2005.

9 Cases COMP/M.5253 – Sanofi-Aventis/Zentiva; COMP/M.5295 – Teva/Barr; COMP/M.3751 – Novartis/Hexal.

confirmed that this is still the case. Competition between research pharmaceutical firms still predominantly takes place at a national level and the same approach is appropriate for generic pharmaceutical firms.

4.4 Affected markets

17. As in previous human health cases, the Parties were required to group all affected human pharmaceuticals markets in three categories. These groupings are:

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

18. The Commission has focused its investigation in particular on affected markets falling into category 1 ("Group 1 markets"). This decision summarises the outcome of the market investigation in all Group 1 markets taking into account the Parties' pipeline products at an advanced stage of development.

19. Referring to previous Commission decisions[10], the Parties have identified 26 horizontally affected Group 1 markets (on six possible relevant product markets). Furthermore, there are a number of Group 2 and Group 3 markets. The market investigation has focused on Group 1 markets but has also covered potential competition concerns in Group 2 and Group 3 markets.

20. For all other markets where the Parties' activities overlap and their joint market shares do not exceed 35% under any plausible market definition and/or where the increment is below 1%, competition concerns may be excluded. The information provided by the Parties allowed the preliminary conclusion that no competition concerns arise. Also third Parties did not indicate that the transaction could have a negative impact on any of those markets. It may therefore be concluded that the transaction does not raise serious doubts as to its compatibility with the Common market and the EEA-agreement (hereafter referred to as "serious doubts").[11]

21. The proposed transaction does not result in any affected markets in animal health area, given that Merck sold its 50% share in Merial, a joint venture through which Merck was active in the animal health sector, to Sanofi-Aventis, so that there are no overlaps in the field of animal health.

22. It is noted that Sanofi-Aventis holds a call option to combine the Intervet/Schering-Plough Animal Health business with Merial to form an animal health joint venture owned equally by Merck/Schering-Plough and Sanofi-

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[10] Cases COMP/M.3354 – *Sanofi-Synthelabo/Aventis*, decision of 26 April 2004; COMP/M.3751 – *Novartis/Hexal*, decision of 27 May 2005; COMP/M.5295 – *Teva/Barr*, decision of 19 December 2008.

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

Aventis. Sanofi-Aventis has this call-option for approximately 3 months from the closing of the present transaction and its exercise may trigger a separate concentration.

23. In the present case, the Commission has analysed the licensing and supply agreements that survive the termination of the Merial joint venture (Termination Agreement in connection with Master Merial JV agreement).[12] The Parties have modified the provisions relating to certain Merck's rights over the implementation of products by Merial. After review, there are no indications that Merck will have the possibility to influence the commercial behaviour of Merial.

4.5 Markets with horizontal overlaps

Asthma treatments

Market definition

24. Anti-asthma products are classified in ATC2 class R3 (anti-asthma and COPD products). This group includes all preparations indicated for bronchial asthma and chronic obstructive pulmonary disease ("COPD"). There are indications that for asthma treatment the individual ATC3 classes are not appropriate to define the relevant market. In previous decisions,[13] the Commission indicated that products for asthma treatments can be categorised into long-term (prophylaxis) and short-term (symptomatic) treatment products. In these previous cases, the Commission has left open whether the segment for long-term asthma treatment products consists of ATC3 classes R3A (B2-stimulants, i.e. long acting B2 stimulants salmeterol and formoterol, hereinafter "LABAs"), R3D (corticoids hereinafter "ICSs"), R3C (non-steroidal respiratory anti-inflammatories), R3J (anti-leukotriene anti-asthmatics, hereinafter "LATRAs") and R3B (xanthines, i.e. theophylline), or whether the combination categories R3E (combinations of e.g. LABAs with non-steroidal respiratory anti-inflammatories) and R3F (combinations of B2 stimulants with corticoids) should also be included.

25. According to the Parties, since the Commission's last decision, fixed-dose combinations of ICS and LABA products have become the mainstay treatment for chronic asthma in Europe. Therefore, in their view, the market for the long-term treatment of asthma should include the combinations of long-acting B2 stimulants and corticoids grouped in ATC3 class R3F (combinations of long-acting B2-stimulants with corticoids, hereafter "ICS/LABA fixed-dose combination products").[14]

26. The respondents to the market investigation broadly confirmed this view of the Parties as regards the definition of the relevant product market, indicating that fixed-dose combination products classified in ATC3 class R3F (ICS/LABA fixed-

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12 i.e. […].

13 Cases COMP/M.1403 – *Astra/Zeneca*, decision of 26 February 1999, para.41; COMP/M.1846 – *Glaxo Wellcome / Smithkline Beecham*, decision of 8 May 2000, para.164.

14 The Parties did not take into account competitors' sales of products in ATC3 class R3E class (the Parties do not sell these products), because such sales are marginal and only concern Germany and Spain, where the Parties activities do not result in any affected markets.

dose combination products) should be included in the market definition. Most competitors replied that also the fixed-dose combination products, classified in ATC3 class R3E (combinations LABAs with non-steroidal respiratory anti-inflammatories) should be included in the market for the long-term treatment of asthma. According to the replies to the market investigation, ICS/LABA fixed-dose combination products are increasingly prescribed as first line therapies and, according to some respondents, they represent 20-50% of all prescriptions.

27. The Parties state that a possible distinction could be drawn between products typically used for first-line long-term treatment of astma (i.e. ICSs) and other long-term asthma products, which are generally used as second-line treatment. According to the Parties, in daily practice, ICS/LABA fixed-dose combination products are increasingly prescribed in Europe as a first-line treatment for chronic athma instead of singe entity ICS products. The results of the market investigation did not clearly indicate whether a distinction should be drawn between single-entity ICS which are typically used for first-line long-term asthma treatment and other long-term asthma products, which are generally used as second-line treatment.

28. For the purpose of the present case the market definition may be left open, as serious doubts do not arise under any alternative market definition.

Assessment

29. Merck produces and markets Singulair (*montelukast*), an oral LATRA used for long-term treatment of asthma and classified in ATC3 class R3J. Merck's patent protection in the EEA will expire between 2011-2014. According to the Parties, Krka has launched a generic product version of Singulair under the name Monkasta (*montelukast*) in Slovenia as well as recently in Finland, Bulgaria and Poland.

30. Schering-Plough sells Asmanex Twisthaler (*mometasone furoate*) ("Asmanex"), a single entity ICS, indicated for long-term treatment of asthma and belonging to ATC3 class R3D.[15] Within the EEA, Asmanex is available only in Denmark, Germany, Greece, Iceland, Ireland, Slovenia, Sweden and the United Kingdom. Schering-Plough's patent protection in the EEA will expire between 2018-2020.

31. In addition, Schering-Plough is developing an ICS/LABA fixed-dose combination product (*mometasone and formoterol*), which is at a regulatory approval stage and is expected to be launched in […]. It would be classified in ATC3 class R3F. A number of other pipeline products of the Parties have not yet reached Phase III of development.[16]

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15 Schering-Plough also sells a short-acting beta-blocker (SABA) Proventil HFA and Foradil Aeroliser (LABA, licences from Novartis) outside the EEA.

16 E.g. Schering-Plough's research on the possibility of obtaining a paediatric indication for its ICS/LABA pipeline product is at Phase II. Merck is developing a combination product, currently only in Phase II, that will combine *montelucast* (LATRA) and a generic version of […] (ICS).

32. Only under a market definition for the long-term treatment of asthma excluding ICS/LABA fixed-dose combination products grouped in ATC3 class R3F, the proposed transaction would amount to a Group 1 market in Slovenia with a combined market share of [50-60]% ([40-50]% for Merck, [10-20]% for Schering-Plough, [20-30]% for GSK, [5-10]% for Krka (generic version of Merck's Singulair, launched in Slovenia in 2007), and [5-10]% for Altana Pharma).

33. Under any other alternative market definition there would be no Group 1 or Group 2 market in any Member State. At the individual ATC3 class level, the Parties' products do not overlap, as they belong to different ATC3 categories. The overlap of the Parties' activities occurs in the segment for long-term asthma treatments, which consists of products belonging to several ATC3 classes. According to the market definition proposed by the Parties (i.e. including ICS/LABA fixed-dose combination products grouped in ATC3 class R3F), combining the Parties' activities would result in two Group 3 affected markets, each below 25%.

34. Given that only under a market definition for the long-term treatment of asthma excluding ICS/LABA fixed-dose combination products grouped in ATC3 class R3F, the proposed transaction would amount to a Group 1 market in Slovenia, only this market is further assessed. In all other markets, competition concerns may be excluded.

35. According to the Parties, in *Slovenia* all sales of Singulair as well as all sales of Asmanex are made to wholesalers which then distribute to pharmacies and hospitals. Singulair is reimbursed according to the Slovenian Reimbursement Regulations and covered by mandatory and additional voluntary insurance. Asmanex is subject to pricing control and reimbursement regimes in Slovenia. The prices for the daily dose of the Parties' products range on the same level.

36. According to a study provided by the Parties, ICSs are the most effective anti-inflammatory drugs available for long-term asthma treatment. However, some asthma patients are not well-controlled on ICS therapy alone and require the addition of a LABA product for their treatment. Since the Commission's decisions mentioned above, ICS/LABA fixed-dose combination products have entered the market.

37. In relation to asthma treatments in Slovenia, the market investigation has indicated a number of factors which contribute to the conclusion that competition problems may be excluded. The market investigation confirmed the view of the Parties, that Merck's Singulair is not a close competitor of Schering-Plough's Asmanex. As regards the closest competing products of Singulair, the market investigation confirmed the Parties view that Krka's generic version of Singulair (LATRA) product Monkasta (*montekulast*) is the closest competing product of Singulair. The respondents to the market investigation consider that further close competitors of Singulair are ICS/LABA fixed-dose combination product Symbicort (AstraZeneca) and the LATRA product Accolate (AstraZeneca). Schering-Plough's Asmanex closest competitors are other ICS products, in particular Flixotide (GSK) and Alvesco (Nycomed) as well as ICS/LABA fixed-dose combination products.

38. The market investigation has furthermore confirmed that the prices for products for the treatment of asthma in Slovenia are regulated by the government. It was also broadly confirmed that the entry of further innovative and generic products (single-entity as well as combination products) is expected in the near future. The replies to the market investigation indicated that competitors have a number of innovative and generic pipeline products, namely ICS/LABA fixed-dose combination products, in advanced stages.

39. Taking these considerations into account and given that there are several other single-entity ICS and single-entity LATRA products available and that the generic version of Singulair, which was launched in 2007, already gained a market share of [5-10]%, even under a narrow market definition the transaction would not give rise to serious doubts as to its compatibility with the common market with regard to long-term asthma treatment in Slovenia.

Allergic rhinitis treatment

Market definition

40. Both Parties have products for the treatment of allergic rhinitis. Allergic rhinitis is the inflammation of the mucous membrane of the nasal passages caused by an allergic reaction. There is no known cure for allergic rhinitis, the treatment focuses largely on the alleviation of symptoms after exposure to an allergen. The traditional treatments consist of anti-histamines, nasal corticosteroids and systemic nasal preparations.

41. Merck manufactures and markets the asthma product Singulair which also has an indication for the treatment of allergic rhinitis in asthma patients in most of the EEA countries. Singulair belongs to the ATC3 class R3J (anti-leukotriene anti-asthmatics).

42. Schering-Plough manufactures and markets several allergic rhinitis products[17] which belong to different ATC3 classes (ATC3 class R1A, ATC3 class R1B and ATC3 class R6A). Schering-Plough has no products in the ATC3 class R3J. Schering-Plough's allergic rhinitis products are not indicated for asthma.

43. According to the Parties, there are four different groups of products for the treatment of allergic rhinitis which correspond closely to the existing ATC classification. The four groups of treatments are nasal corticosteroids (belonging to ATC3 class R1A[18]), systemic nasal preparations (ATC3 class R1B), systemic anti-histamines (ATC3 class R6A) and anti-leukotrienes ("LATRA") (ATC3 class R3J). Regarding the onset

[17] These products are Nasonex (R1A), Drixine/Afrin/Respir/Nasoarox (R1A), Disophrol/ Constipal/ Disofrol (R1B), Claritin (R6A), Clarinex/Aerius (R6A), Trimeton (R6A) and Polaramine (R6A).

[18] Within the ATC3 class R1A only three sub-categories, namely ATC4 classes R1A1 + R1A6 + R1A7 are taken into account. Other ATC4 subcategories are no longer in use or do not treat allergic rhinitis. Schering-Plough's nasal corticosteroids belong to these ATC4 classes (R1A1, R1A6, R1A7).

of action, the mode of administration and the therapeutic use, the four treatments differ to some extent.[19]

44. In several former cases the Commission examined the market for allergic rhinitis treatment. The Commission considered separate markets at ATC3 level for systemic anti-histamines (R6A)[20], topical nasal preparations (R1A), and systemic nasal preparations (R1B)[21] but did not reach a conclusion on the market definition. In case COMP.M.3571 - Novartis/Hexal, the Commission considered the merging Parties' argument that the R6A market should be sub-divided into two separate product markets, one for non-sedative antihistamines and one for sedative antihistamines. However, the market investigation did not confirm this possible sub-division. Again, the Commission left the precise market definition open since it did not affect the competitive assessment.

45. The Parties argue that regarding allergic rhinitis treatments a market definition on ATC3 level would be appropriate, whereby each ATC3 class constitutes a seperate market. On the basis of the market definition proposed by the Parties' no product overlap exists. There would only be an overlap should some of the above treatment groups be considered substitutable.

46. The market investigation in the present case generally confirmed the market delineation on the basis of separate ATC3 classes as the products have different modes of action, indications and forms of administration. Doctors confirmed that Singulair is essentially seen as an asthma treatment and not an allergic rhinitis treatment. This is supported by a larger number of national prescription guidelines issued by European health authorities. In addition, professional associations do not endorse the use of Singulair as an allergic rhinitis treatment.[22]

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[19] For example, nasal corticosteroids (ATC4 classes R1A1, R1A6 and R1A7) are anti-inflammatory treatments and are effective at remedying nasal congestion, discharge and dripping and are administered as a nasal spray. Systemic nasal preparations are also anti-inflammatory effective at remedying nasal congestion but also ocular itching and tearing, while anti-histamines (ATC3 class R6A) act as histamine antagonist and serve to inhibit the release or action of histamine and therefore seek to treat the symptoms of allergic rhinitis at the source. Anti-histamines are administered orally and are considered the mainstay treatment of allergic rhinitis. Anti-leukotrienes (leukotrienes receptor antagonist, so-called "LATRA") are anti-inflammatory treatments and active in the upper airways and lungs with limited effect on the nasal mucosa. They are administered orally.

[20] Recent decisions include: Cases COMP/M.5253 - *Sanofi-Aventis/Zentiva*, decision of 4 February 2009, para. 171; COMP/M.5295 - *Teva/Barr*, decision of 19 December 2008, para. 172; COMP.M3751 - *Novartis/Hexal*, decision of 27 May 2005.

[21] In *Pfizer/Warner-Lambert*, Case COMP/M. 1878, decision of 22 May 2000 the Commission considered whether there where separate markets for R1A and R1B but did not reach a definite conclusion. See also case COMP.M 3354 - *Sanofi-Synthelabo/ aventis*, para. 23.

[22] See for example guidelines by the Dutch Association of General Practitioners, the Norwegian Medical Product Agency, the Swedish Medical Product Agency, the British NHS, Danish Association of the Pharmaceuticals Industry, the Estonian Association of Immunologists and Allergists, the Estonian Pulmonary Doctors' Association, the Spanish *InformaciónTerapéutica del Sistema Nacional de Salud: Rinitis alérgica*, the French Otolaryngological, the Agenzia Italiana del Farmaco, the General Practitioners Association of Lithuania, the Finnish Respiratory Society, the Finnish Paediatric Society and the Finnish Society of Clinical Physiology, the College of Pulmonologists in Hungary, the Bulgarian Rhinologic Society, etc. According to the Parties, these guidelines e.g. either do not recommend or do not mention the use of Singulair or anti-leukotrienes for the treatment of allergic

However, on the other hand, in a number of countries Singulair has a separate indication for allergic rhinitis and the market investigation showed that, to a minor extent, Singulair is used as treatment for allergic rhinitis.

47. Regarding the question if OTC and prescription treatments for allergic rhinitis belong to different product markets, the market investigation confirmed that OTC and prescription drugs in the treatment of allergic rhinitis do not compete with each other and are not close enough substitutes to be considered in the same market.[23]

48. The exact market definition may be left open in this case since the notified transaction will not lead to serious doubts in any of the affected countries, regardless of the market definition considered.

Assessment

Introduction

49. In line with previous practice, the Commission has primarily relied on the value of sales recorded by IMS, and provided by the Parties, as a measure of market share. However, calculating market shares based on value has certain limitations, in particular when considering Singulair as it can be significantly differentiated from the other allergic rhinitis treatments, not least because it has significantly higher prices than the traditional allergic rhinitis treatment products when considering cost per day of treatment. The market investigation has confirmed in this context that a very significant number of players consider volume alongside value as a relevant parameter in assessing market positions in the allergic rhinitis treatment area. Shares based on value in the vast majority of cases differ very significantly from market shares based on volume, so that in many instances, Group 1 markets based on value would not be considered as such in volume.

50. On the basis of a market definition which comprises all allergic rhinitis treatments, i.e. all four ATC3 classes referred to in recital 43, the Commission has identified twelve potential Group 1 markets (i.e., 35% market share or more, with an increment of 1% or more) on the basis of market share in value: Austria, Finland, France, Hungary, Iceland, Ireland, Lithuania, Norway, Portugal, Romania, Slovenia and Sweden.

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rhinitis, or state that there is no or not enough evidence to support that Singulair (or anti-leukotrienes) are effective for the treatment of allergic rhinitis.

[23] Although the market investigation also confirmed that OTC drugs might still act, in this field, and to a certain extent, as a competitive constraint on prescription drugs.

Table 1: Market comprising all Allergic Rhinitis Treatments in value sales, 2008 (ATC3 Classes R1A[24] + R1B + R6A + R3J (sales attributed to allergic rhinitis only[25]))

MEMBER STATES	MERCK (%)	SP (%)	TOTAL (%)	THREE LARGEST COMPETITORS
Austria	[0-5]%	[40-50]%	[50-60]%	UCB ([20-30]%), Novartis (Generic) ([5-10]%), AstraZeneca ([5-10]%)
Finland	[0-5]%	[30-40]%	[30-40]%	GSK ([20-30]%), UCB ([10-20]%), Almirall ([5-10]%)
France	[0-5]%	[40-50]%	[40-50]%	UCB ([10-20]%), Sanofi-aventis (Generic) ([10-20]%), Almirall ([5-10]%)
Hungary	[0-5]%	[30-40]%	[40-50]%	UCB ([20-30]%), Novartis (Generic) ([5-10]%), AstraZeneca ([5-10]%)
Iceland	[0-5]%	[30-40]%	[30-40]%	Sanofi-Aventis ([20-30]%), GSK ([10-20]%), Actavis ([5-10]%)[26]
Ireland	[0-5]%	[30-40]%	[30-40]%	GSK ([20-30]%), UCB ([20-30]%), Sanofi-aventis ([5-10]%)
Lithuania	[0-5]%	[30-40]%	[30-40]%	UCB ([10-20]%), Novartis ([10-20]%), Sandoz ([10-20]%)
Norway	[0-5]%	[30-40]%	[40-50]%	Sanofi-aventis ([10-20]%), UCB (7%), Almirall ([5-10]%)
Portugal	[0-5]%	[30-40]%	[40-50]%	UCB ([20-30]%), Almirall ([5-10]%), AstraZeneca ([5-10]%)
Romania	[0-5]%	[40-50]%	[40-50]%	UCB ([20-30]%), Novartis ([5-10]%), Thea ([5-10]%)[27]
Slovenia	[0-5]%	[50-60]%	[50-60]%	UCB ([10-20]%), GSK ([10-20]%), Krka (Generic) ([5-10]%)
Sweden	[0-5]%	[30-40]%	[30-40]%	Orifarm (Generic) ([10-20]%), Sanofi-aventis (Generic) ([5-10]%), Teva (Generic) ([5-10]%)

Source: IMS and the Parties

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24 Within the ATC3 class R1A only three sub-categories, namely ATC4 classes R1A1 + R1A6 + R1A7 are taken into account. Other ATC4 subcategories are no longer in use or do not treat allergic rhinitis.

25 In calculating the Merck's market share of Singulair the notifying party calculates, based on IMS ICD data that tracks prescriptions of a panel of participating physicians in 19 EEA Member States, that [0-5]% of Singulair sales in the EEA account for the treatment of allergic rhinitis. In certain countries (Bulgaria, Lithuania, Romania and Slovenia) no such data was collected, therefore when calculating market shares for allergic rhinitis, a conservative [5-10]% estimate of Singulair sales attributable to allergic rhinitis treatments was used. The market investigation did not provide any evidence that might lead to the consideration that this would be incorrect or unreasonable.

26 For Iceland, the Parties relied on a local database (IDM), the Icelandic official price list for pharmaceutical products, and their best estimates of Prescription/OTC breakdowns to obtain their market share estimates. Market shares for the competitors do not take such breakdown into consideration.

27 For Romania, Merck has not been able to obtain from IMS data on OTC and prescription sales, so the data provided on this table for Merck and Schering-Plough's market shares are estimates based upon prescription / OTC breakdown with the IMS data. Market shares for the three largest competitors use IMS data, and therefore are for a market that includes both OTC and prescription sales.

51. On the basis of a narrower market definition which includes only anti-histamines (R6A) and anti-leukotrienes (R3J)[28], i.e., excluding nasal preparations (R1A and R1B), the market shares of the Parties range between [30-40]% and [50-60]% and there would be thirteen Group 1 markets. Under this narrow market definition Finland, Hungary, Iceland, Norway would not fall under Group 1 markets. On the other hand, Bulgaria, Greece, Luxembourg, The Netherlands and Poland would be considered to fall under the Group 1 market category.

Table 2: The Parties' and Largest Competitors' 2008 Share of Sales of Allergic Rhinitis Treatments [29]
(ATC3 Classes R6A + R3J (sales attributed to allergic rhinitis only))

MEMBER STATES	MERCK (%)	SP (%)	TOTAL (%)	THREE LARGEST COMPETITORS
Austria	[0-5]%	[40-50]%	[40-50]%	UCB ([20-30]%), Novartis (Generic) ([10-20]%), Genericon (Generic) ([5-10]%)
Bulgaria	[0-5]%	[30-40]%	[30-40]%	UCB ([40-50]%), Actavis ([5-10]%), Novartis ([5-10]%)
France	[0-5]%	[40-50]%	[50-60]%	UCB ([20-30]%), Almirall ([10-20]%), Sanofi-aventis (Generic) ([5-10]%)
Greece	[0-5]%	[30-40]%	[30-40]%	UCB ([40-50]%), Olvos Science ([5-10]%), Novis ([5-10]%),
Ireland	[5-10]%	[30-40]%	[30-40]%	UCB ([50-60]%), Wockhardt (Generic) ([5-10]%), Mylan (Generic) ([5-10]%)
Lithuania	[5-10]%	[30-40]%	[30-40]%	UCB ([20-30]%), Novartis (Generic) ([10-20]%), Sandoz ([10-20]%)
Luxembourg	[5-10]%	[30-40]%	[40-50]%	UCB ([40-50]%), Sanofi-aventis ([10-20]%), Novartis (Generic) ([5-10]%)
Netherlands	[0-5]%	[30-40]%	[40-50]%	UCB ([30-40]%), Sanofi-aventis ([5-10]%), Mylan (Generic) ([5-10]%)
Poland	[5-10]%	[30-40]%	[30-40]%	UCB ([20-30]%), Sanofi-Aventis ([10-20]%), Sanitas Lith ([5-10]%)
Portugal	[5-10]%	[30-40]%	[30-40]%	UCB ([20-30]%), Almirall ([10-20]%), Bial ([5-10]%)
Romania	[0-5]%	[50-60]%	[50-60]%	UCB ([20-30]%), Novartis (Generic) ([10-20]%), Sanofi-aventis ([5-10]%)
Slovenia	[0-5]%	[40-50]%	[40-50]%	UCB ([20-30]%), Krka (Generic) ([10-20]%), Sanofi-aventis ([5-10]%)
Sweden	[0-5]%	[50-60]%	[50-60]%	Sanofi-aventis (Generic) ([10-20]%), Almirall ([10-20]%), Novartis (Generic) ([10-20]%)

Source: IMS data provided by the notifying Party, except for Slovenia, where PharMIS data was used.

52. Whilst these are Group 1 market shares and overall market shares are relatively high, Merck's sales of Singulair for allergic rhinitis treatments are relatively small

[28] In the remainder of this assessment of allergic rhinitis treatments the market definition covering the ATC3 classes R6A and R3J will be referred to as the narrow market definition, while the market covering the ATC classes R1A + R1B + R6A + R3J will be referred to as the wide market definition. Within the ATC3 class R1A only three sub-categories, namely ATC4 classes R1A1 + R1A6 + R1A7 are taken into account. Other ATC4 subcategories are no longer in use or do not treat allergic rhinitis.

[29] See above footnote 25.

so that the increments are also quite limited[30]. Considering volume, the market share increment by Singulair would in all Member States listed in the Tables 1 and 2, be below [0-5]%.

53. Furthermore, according to the Parties their products are not close substitutes and Singulair cannot be properly characterized as an allergic rhinitis treatment in the EEA. The market investigation clearly confirmed that Singulair is not the closest competitor to Schering-Plough's allergic rhinitis products and vice versa. Instead, the market investigation confirmed that close competitors to the respective Schering-Plough's products are anti-histamines, nasal corticosteroids and systemic nasal preparations by other competitors, such as UCB's Zyrtec and Xyzal, GSK's Flixonase, Almirall's Kestine (Ebastel), Sanofi-aventis' Telfast/Allegra, Novartis' Fenistil, amongst other products. Doctors confirmed that Singulair is mainly seen as an asthma treatment and not an allergic rhinitis treatment, as they tend to prescribe Singulair mainly for co-morbid asthma patients and do not, or only to a limited extent, prescribe Singulair for patients who only suffer from allergic rhinitis. The investigation also largely confirmed the Parties' claim that Singulair is best viewed as complementary to Schering-Plough's allergic rhinitis treatments, with a few respondents considering that these may be used when anti-histamines and nasal corticosteroids have not proved to be effective in a particular case.

54. The fact that Singulair is priced significantly higher ([…]) than Schering-Plough's products for allergic rhinitis, supports the statement made by the notifying Party that it is not priced as an allergic rhinitis treatment product but as an asthma product. Furthermore, in all Member states but one, Singulair is either not reimbursed for allergic rhinitis at all or it is only reimbursed for allergic rhinitis in asthma patients. The market investigation showed that these significant price differences are considered as an additional important factor for not considering Singulair as a close competitor to the other allergic rhinitis treatments.

55. In most Member States, with the exception of Bulgaria, Czech Republic, Lithuania, Norway, Romania, Slovakia and Slovenia, Singulair is only indicated for allergic rhinitis in asthma patients. Even in those Member States where Singulair has a separate indication for allergic rhinitis, the notifying Party stated (and provided documentary marketing evidence) that it does not market Singulair as an allergic rhinitis treatment product. Indeed, the market investigation also confirmed that off-label usage of Singulair for the treatment of allergic rhinitis has no commercial significance in any of the investigated countries.

56. On the other hand, it is unlikely that Singulair may be in future be repositioned and marketed by Merck as an allergic rhinitis product. In effect, the commercial window for such a change is narrow as, on the one hand, patent expiry dates for Singulair in most of the EEA countries are mostly due during 2012[31], and on the

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30 Singulair was launched in the EEA in 1997.

31 In some countries Singulair does not enjoy patent protection for its compound (Belgium, Bulgaria, Estonia, Iceland, Lithuania, Malta, Poland), whilst patent protection will cease by August 2012 in another 18 EEA members. Singulair will lose the patent protection for its formulation throughout the EEA by October 2012.

other hand, to obtain marketing authorisation for the rest of the EEA and eventually reimbursement status for allergic rhinitis would require at least some months. The latter, would most probably, according to the notifying Party, require a significantly lower pricing of Singulair – as it is currently priced as an asthma medicine. The Parties have also argued that the repositioning of Singulair would constitute a further hurdle, as it might place Singulair's traditional therapeutic positioning as an asthma product at risk.

57. Finally, according to the notifying Party, both Merck and Schering-Plough have no Phase III pipeline products for allergic rhinitis treatment.

Assessment of individual countries

58. In *Austria*, the combined market share of the Parties would be [50-60]% on the basis of the wide market definition covering all allergic rhinitis treatments[32] and [40-50]% on the basis of the narrow market definition covering the ATC3 classes R6A and R3J, with Merck contributing an increment of [0-5]% and [0-5]% respectively. The Parties face competition from strong competitors, such as UCB ([20-30]%), Novartis ([10-20]%) and Genericon ([0-5]%), all with anti-histamine products.[33] Although Singulair has an indication for allergic rhinitis in asthma patients, it is not reimbursed for the treatment of allergic rhinitis at all, i.e. neither for asthmatic nor for non-asthmatic patients. On the other hand, Schering-Plough's products Nasonex and Clarinex/Aerius are reimbursable for allergic rhinitis patients. As Singulair is significantly more costly than two of the most important Schering-Plough's products: Nasonex (a corticosteroid) and Clarinex/Aerius (an anti-histamine) (regarding the cost per day of treatment Singulair is about […] more expensive than Aerius and about […] more expensive than Nasonex), doctors and patients have little or no incentive to use Singulair for the treatment of allergic rhinitis. In addition, UCB, Novartis and Astra Zeneca supply allergic rhinitis products which are closer competitors to Schering-Plough's products than Singulair and a number of other competitors, such as Genericon, Ratiopharma, Apomedica, supply generic versions of anti-histamines (ATC3 class R6A) and nasal preparations (ATC4 class R1A7 and R1A6).

59. In *Bulgaria,* the combined market share of the Parties on the basis of the narrow market definition would be [30-40]%, with Merck contributing an increment of [0-5]%. The Parties will face competition from a number of strong competitors such as UCB ([40-50]%), Actavis ([5-10]%) and Novartis ([0-5]%). Singulair is not reimbursed at all in Bulgaria for the treatment of allergic rhinitis (both in asthma patients and in other patients). Even though it has a separate indication for seasonal allergic rhinitis in non-asthma patients, this indication is not reimbursed. As Singulair is […] more expensive than Schering-Plough's Nasonex and […] more expensive than Aerius, two of the most important Schering-Plough's prescription allergic rhinitis products, doctors and patients have little or no incentive to use Singulair for the treatment of allergic rhinitis. In any event, UCB,

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32 I.e. ATC classes R1A1 + R1A6 + R1A7 + R1B + R6A + R3J. See also above footnote 24.

33 Under the wide market definition the market shares of the largest competitors are UCB ([20-30]%), Novartis (generics) ([5-10]%) and AstraZeneca ([5-10]%).

Actavis and Novartis supply anti-histamines (UCB's Xyzal, Actavis' Clemastin, Novartis' Cetrizin) that are close competitors to Schering-Plough's product Aerius. The marketing plans provided by the Parties for Bulgaria show that Singulair is promoted as an asthma drug and not as an allergic rhinitis product for non-asthmatic patients. Furthermore, generic versions of Singulair were launched by Teva and Krka in 2009. According to the Parties these generic products have the same indications as Singulair.

60. In *Finland*, the combined market share of the Parties would be [30-40]% on the basis of the wide market definition covering all allergic rhinitis treatments, with Merck contributing an increment of [0-5]%. Competitors such as GSK ([20-30]%), UCB ([10-20]%) and Almirall ([5-10]%) and a number of other competitors, such as Orion, Ratiopharm, and Teva supply generic versions of anti-histamines (ATC3 class R6A) and nasal preparations (ATC4 classes R1A7, R1A1 and R1A6). Singulair has an indication for allergic rhinitis in asthma patients and only that indication is reimbursed. Schering-Plough's main allergic rhinitis products Nasonex and Aerius are reimbursable. As the price for Singulair exceeds the prices of two of the most important Schering-Plough's prescription allergic rhinitis products by approximately […] for Aerius and […] for Nasonex, Singulair cannot be considered a relevant source of competition in allergic rhinitis in Finland. Even if was to be considered that Singulair is an effective substitute product for allergic rhinitis treatment, the market investigation showed that both customers and competitors do not regard Singulair to be a close competitor to Schering-Plough's allergic rhinitis treatments.

61. In *France*, the combined market share of the Parties would be [40-50]% on the basis of the wide market definition and [50-60]% on the basis of the narrower market definition (ATC3 classes R6A + R3J). Merck would contribute a minor increment of [0-5]% and [0-5]% respectively. The combined entity will continue to face competition from a number of companies, including UCB ([20-30]%), Sanofi-Aventis (generic) ([5-10]%) and Almirall ([10-20]%)[34]. A number of generic versions of anti-histamines that have been identified by the market investigation as being close competitors to Schering-Plough's allergic rhinitis products are also being sold. Singulair has an indication for allergic rhinitis in asthma patients and is reimbursed as an allergic rhinitis treatment only for those patients. Schering-Plough's main allergic rhinitis products are reimbursable. Again, the daily cost of treatment using Singulair is more than […] higher than the daily cost of treatment using Schering-Plough's product Nasonex and more than […] higher for Aerius (two of the most important Schering-Plough products in allergic rhinitis) which makes it difficult to consider Singulair a relevant source of competition in the allergic rhinitis treatments.

62. In *Greece*, the combined market share of the Parties would be [30-40]% on the basis of the narrow market definition (ATC3 classes R6A + R3J) with Merck contributing an increment of [0-5]%. The Parties face competition from UCB ([40-50]%), Olvos Science/Galenica ([5-10]%) and Novis ([5-10]%). Merck's Singulair is only indicated and reimbursed for allergic rhinitis in asthma patients. Schering-Plough's main allergic rhinitis products (Aerius and Nasonex) are

[34] Under the wide market definition the market shares of the largest competitors are UCB ([10-20]%), Sanofi-aventis ([10-20]%) and Almirall ([5-10]%).

reimbursable. As Singulair is significantly more expensive than Schering-Plough's products (Singulair is about […] more expensive than Schering-Plough's Nasonex and […] more expensive than Schering-Plough's Aerius), it cannot be considered a relevant source of competition in the allergic rhinitis treatments.

63. In *Hungary*, the combined market share of the Parties would be [40-50]% on the basis of the wide market definition with Merck contributing an increment of [0-5]%. The Parties face competition from UCB ([20-30]%), Novartis (generic) ([5-10]%), Astra Zeneca ([5-10]%). Merck's Singulair is only indicated and reimbursed for allergic rhinitis in asthma patients. Schering-Plough's main allergic rhinitis products are reimbursable. The prescription guidelines issued by the ministry of Health in Hungary also limit the recommended use of LATRA to the treatment of allergic rhinitis in asthma patients only. Therefore the Parties' products cannot be seen as each others closest competitors. Generic versions of anti-histamines are available e.g. from Novartis and Servier, generic versions of corticosteroids are available e.g. from Teva, Novartis and Orion. As Singulair is significantly more expensive than Schering-Plough's products (Singulair is about […] more expensive than Schering-Plough's Nasonex and […] more expensive than Schering-Plough's Aerius), it cannot be considered a relevant source of competition in the allergic rhinitis treatments.

64. In *Iceland*, the combined market share on the basis of the wide market definition would be [30-40]% with Merck contributing an increment of [0-5]%[35]. The Parties face competition from competitors such as Sanofi-Aventis ([20-30]%), GSK ([10-20]%), Actavis ([5-10]%). Singulair is not indicated nor reimbursed for allergic rhinitis in non-asthma patients. Moreover, Singulair does not enjoy patent protection for its compound and several generic versions of anti-histamines are available in the market representing already significant sales in the marketplace. Actavis' Loritin (an anti-histamine) on its own represents [5-10]% on the basis of the wide market definition and [20-30]% on the basis of the narrow market. As Singulair is significantly more expensive than Schering-Plough's products (Singulair is about […] more expensive than Schering-Plough's Nasonex and […] more expensive than Aerius), it cannot be considered a relevant source of competition in the allergic rhinitis treatment.

65. In *Ireland*, the proposed transaction would lead to a combined market share of [30-40]% on the basis of the wide market definition with an increment of [0-5]% by Merck. On the basis of the narrow market definition the combined market share would be [30-40]% with an increment of [5-10]%. The Parties will continue to face a number of strong competitors, such as UCB ([50-60]%), and several generics hold the remaining shares (Wockhardt [0-5]%, Mylan [0-5]% and Helsinn Corp [0-5]%)[36]. Moreover, a generic competitor (Teva) is understood to be in the process of developing and registering generic versions of Singulair in Ireland but the product has not yet been launched. Singulair is only indicated and reimbursed for the treatment of allergic rhinitis in asthma patients. Also, Singulair is substantially more costly than two of the most important Schering-Plough's

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35 Market share data is based on the local data base IMD, the Icelandic official list for pharmaceutical products, since no IMS data was available.

36 Under the wide market definition the market shares of these competitors are GSK ([20-30]%), UCB ([20-30]%), Sanofi ([5-10]%) and Teva ([0-5]%).

prescription allergic rhinitis medicines and daily treatment costs exceed the daily treatments costs of Schering-Plough' allergic rhinitis products (it is […] more costly than Nasonex and […] more costly than Aerius). Even if was to be considered that Singulair is an effective substitute for allergic rhinitis treatment products, the market investigation showed that both customers and competitors do not regard the Parties' products as close competitors.

66. In *Lithuania*, the combined market share of the Parties on the basis of the wide market definition would be [30-40]% and [30-40]% on the basis of the narrow market definition, with Merck contributing [0-5]% and [5-10]% respectively[37]. The Parties face competition from UCB ([20-30]%), Novartis (generics) ([10-20]%) and Sandoz ([10-20]%)[38]. Marketing plans show that Singulair is promoted as an asthma drug and not as allergic rhinitis product, which was confirmed during the market investigation. Singulair has a separate indication for allergic rhinitis in non-asthmatic patients. It is not reimbursed at all, i.e., neither for allergic rhinitis patients with asthma nor without. Daily treatment cost shows that Singulair is substantially more costly and […] the cost of Schering-Plough's Aerius and is […] more expensive than Nasonex.

67. In *Luxembourg*, the combined market share on the basis of the narrow market definition, would be [40-50]%[39] with an increment of [5-10]% by Merck. The Parties face competition from UCB ([40-50]%), Sanofi-aventis ([01-20]%) and Novartis (generic) ([5-10]%). Moreover, in 2009 a generic competitor (Teva) has registered a generic version of Singulair (*montelukast*) but it has not yet launched it. Singulair is only indicated for the treatment of allergic rhinitis in asthma patients and not reimbursed at all for the treatment of allergic rhinitis both in asthma patients and non-asthma patients. Also, daily treatment cost using Singulair exceeds the daily treatment cost of two of the most important Schering-Plough' prescription allergic rhinitis products (Singulair is […] more expensive than Nasonex and […] more expensive than Aerius). Finally, the market investigation confirmed that Merck's and Schering-Plough's respective products are not in direct competition.

68. In the *Netherlands*, the combined market share on the basis of the narrow market definition would be [40-50]% with Merck contributing an increment of [0-5]%[40]. The Parties will face competition from UCB ([30-40]%) and Sanofi-aventis ([5-10]%) and Mylan (generics) ([0-5]%) whose products closely compete with Schering-Plough's products. Moreover, three companies are understood to be in the process of development and registration of generic versions of Singulair in the Netherlands. Singulair is only indicated and reimbursed for the treatment of allergic rhinitis in asthma patients. Schering-Plough's main allergic rhinitis

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37 Merck's market share of Singulair is based on [5-10]% of sales of Singulair accounting for the treatment of allergic rhinits.

38 Under the wide market definition the market shares of the largest competitors are UCB ([10-20]%), Novartis ([10-20]%) and Sandoz ([10-20]%).

39 The market share of Singulair for allergic rhinitis is based on the hypothetical [5-10]% sales of Singulair's sales, since no distinguished data exists between asthma and allergic rhinitis sales of Singulair.

40 On the basis of the wide market definition the combined market share will be [30-40]%.

products are reimbursable. Singulair is substantially more costly than two of the most important Schering-Plough' allergic rhinitis prescription products and daily treatment costs exceed the daily treatments costs of Schering-Plough' allergic rhinitis products […] (Singulair is […] more expensive than Nasonex and […] more expensive than Aerius).

69. In *Norway*, the combined market share of the Parties would be [40-50]% on the basis of the wide market definition with Merck contributing an increment of [0-5]%[41]. In any event, the combined entity will continue to face competition from a number of companies, including from Sanofi-Aventis ([10-20]%), UCB ([5-10]%), Almirall ([5-10]%), Astra Zeneca ([5-10]%), Farmagon ([5-10]%), GSK ([5-10]%) and further companies with generic products Biophausia ([0-5]%) and Novartis ([0-5]%) - all of which supply allergic rhinitis treatments that have been identified by the market investigation as being close competitors to Schering-Plough's allergic rhinitis products. Although Singulair has a separate indication for allergic rhinitis, it is not reimbursed at all. Singulair is also substantially more costly than Schering-Plough's allergic rhinitis medicines. According to IMS data provided by the Parties, Singulair daily treatment costs in Norway exceed the daily treatment costs of two of the most important Schering-Plough's prescription allergic rhinitis products […] (Singulair is […] more expensive than Nasonex and […] more expensive than Aerius). However, even if was to be considered that Singulair is an effective substitute product for allergic rhinitis treatment products the market investigation revealed that both customers and competitors do not regard Singulair to be a close competitor to Schering-Plough's allergic rhinitis treatment. Therefore, Singulair cannot be considered a relevant source of competition in allergic rhinitis.

70. In *Poland,* the Parties' combined market share on the basis of the narrow market definition would be [30-40]% with Merck adding an increment of [0-5]%. The Parties face a number of competitors such as UCB ([20-30]%), Sanofi-Aventis ([10-20]%), Sanitas Lith ([5-10]%), Warszawa ZF Polfa (generics) ([5-10]%) and other generic competitors. Singulair is only indicated and reimbursed for the treatment of allergic rhinitis in asthma patients and is substantially more costly than two of the most important Schering-Plough's allergic rhinitis products - Singulair is […] more expensive than Nasonex and Aerius respectively. The market investigation points out that the Parties are not each others closest competitors since UCB and Sanofi-Aventis, which both supply anti-histamines, are close competitors to Schering-Plough' Aerius and Claritin. In addition, a number of companies, such as Krka, have also already launched generic versions of Singulair.

71. In *Portugal,* the market share of the Parties on the basis of the wide market definition would be [40-50]% with Merck contributing an increment of [0-5]% and [30-40]% on the basis of the narrower market definition with a [5-10]% increment by Merck. The Parties will continue to face competitors, such as UCB ([20-30]%), Almirall ([10-20]%) and Bial ([5-10]%)[42], all of which supply

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41 The narrow market definition, excluding nasal preparations, would lead to a combined market share of [30-40]%.

42 Under the wide market definition the largest competitors are UCB ([20-30]%), Almirall ([5-10]%) and AstraZeneca ([5-10]%).

allergic rhinitis treatments that have been identified by the market investigation as being close competitors to Schering-Plough's allergic rhinitis products. Merck's Singulair is only indicated and reimbursed for the treatment of allergic rhinitis in asthma patients and not for the treatment of allergic rhinitis in non-asthma patients. Schering-Plough's main allergic rhinitis products, on the other hand, are reimbursable. Singulair is substantially more costly than two of the most important Schering-Plough's prescription allergic rhinitis medicines. According to IMS data provided by the notifying Party, Singulair daily treatment costs in Portugal exceed the daily treatment costs of Schering-Plough's allergic rhinitis products […] with Singulair being almost […] more expensive than Nasonex and […] more expensive than Aerius.

72. In *Romania,* the combined market share of the Parties would be [40-50]% on the basis of the wide market definition and [50-60]% on the basis of the narrow market definition. These shares include a contribution of Merck of [0-5]% and [0-5]% respectively. The Parties will continue to face competition from UCB ([20-30]%), Novartis (generic) ([10-20]%) and Sanofi-Aventis ([5-10]%)[43] who have much closer competing products to Schering-Plough's allergic rhinitis products, according to the majority of respondents in the market investigation. Indeed, although Singulair has a separate indication, Merck´s Singulair is not reimbursed at all for allergic rhinitis in both asthma patients and non-asthma patients. On the other hand, two of Schering-Plough's most important products Nasonex and Clarinex/Aerius are subject to reimbursement[44]. According to the data provided by Merck, Singulair is also substantially more expensive in daily treatment cost terms – approximately […] more than Aerius and […] more than Nasonex - in comparison to the main competitor products in allergic rhinitis. Further, the notifying Party has clearly stated that it has not marketed Singulair as an allergic rhinitis product, since it launched the product.

73. In *Slovenia,* the combined market share of the Parties on the basis of a wide market definition would be [50-60]% and [40-50]% on the narrower delineation with Merck contributing an increment of [0-5]% and [0-5]% respectively. The Parties face competition from UCB ([20-30]%), Krka (generic) ([10-20]%) and Sanofi-aventis ([5-10]%)[45]. There is a generic version of Singulair (sold by Krka) that also has an indication for allergic rhinitis in both asthma and non-asthma patients. According to the Parties and the market investigation, the closest competitors of Schering-Plough's allergic rhinitis products are those with similar therapeutic characteristics, i.e., other nasal corticosteroids and anti-histamines, including GSK's Flixonase and Avamys, Lek's Tafen (generic budesonide), UCB's Xyzal and Zyrtec, Sanofi-Aventis' Telfast/Allegra, and Krka's Letizen (cetirizine). Indeed, although Singulair has a separate indication for seasonal allergic rhinitis, Singulair is only reimbursed for the treatment of allergic rhinitis

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43 Under the wide market definition the largest competitors are UCB ([20-30]%), Novartis (generics) ([5-10]%) and Thea (generics) ([5-10]%).

44 The majority of the competitors active in Romania do agree with the Parties' statement that the fact that Singulair is not reimbursed for allergic rhinitis in asthma patients means that it is not really a substitute for anti-histamines and nasal preparations in Romania.

45 Under the wide market definition the largest competitors are UCB ([10-20]%), GSK ([10-20]%) and Krka (generic) ([5-10]%).

in asthma patients in Slovenia. On the other hand, according to Merck, nasal corticosteroids and anti-histamines enjoy 100% reimbursement for allergic rhinitis treatment. Additionally, data provided by the notifying Party regarding the relative cost of treatment of allergic rhinitis, show that Singulair is more than […] more expensive than Schering-Plough's Nasonex and […] more than Aerius, two of the most important Schering-Plough products in the allergic rhinitis area. The other allergic rhinitis treatments have very similar price levels. Finally, marketing plans for Singulair on the Slovenian market show that Singulair is promoted as an asthma product which can also be prescribed in asthma patients with allergic rhinitis. This is consistent with the overall market plans for Singulair. Singulair is not put forward as an allergic rhinitis medicine only but as an add-on or complementary product for allergic rhinitis in asthma patients.

74. In *Sweden,* the combined market shares of the Parties under the wide market definition would be [30-40]% and [50-60]% under the narrow market definition with Merck contributing an increment of [0-5]% and [0-5]% respectively. The Parties continue to face competition from a number of competitors, such as Sanofi-Aventis (generic) ([10-20]%), Almirall ([10-20]%) and Novartis (generic) ([10-20]%)[46], all of which supply allergic rhinitis treatments that have been identified by the market investigation as being close competitors to Schering-Plough's allergic rhinitis products. Merck's Singulair is only indicated and reimbursed for the treatment of allergic rhinitis in asthma patients and not for the treatment of allergic rhinitis in non-asthma patients. However, the Swedish Medical Product Agency does not endorse the use of Singulair in allergic rhinitis as it considers there not to be enough evidence to support its effectiveness to treat this condition. Singulair is also substantially more costly than Schering-Plough's allergic rhinitis medicines. According to IMS data provided by the notifying Party, Singulair daily treatment costs exceed the daily treatment costs of two of the most important Schering-Plough's prescription products Nasonex by […] and Aerius by […]. Furthermore, one of the main competitor products to Aerius is Almirall's Kestine, an anti-histamine which according to the notifying Party has substantial volumes being sold over the counter and exerts additional competitive pressure.

75. In conclusion and taking into account that Merck's product is not a close competitor to Schering-Plough's products and has minor sales as allergic rhinitis treatment, the transaction does not give rise to serious doubts as to its compatibility with the common market with regard to allergic rhinitis treatments in the countries assessed above.

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46 Under the wide market definition the largest competitors are Oripharm (generic) ([10-20]%), Sanofi (generic) ([5-10]%) and Teva (generic) ([5-10]%).

Systemic Anti-fungal treatments

Market definition

76. Systemic fungal infections are infections that are not limited to a localized area of the body but affect one or more body systems. The Parties maintain that at least three main groups of systemic anti-fungal medicines can be distinguished: *echinocandins*, *azoles* and *polyenes*. These all belong to the ATC3 class J2A (Systemic Agents for Fungal Infection), that is not further subdivided into ATC4 classes.

77. In previous decisions the Commission left the market definition for anti-fungal treatments open without considering a possible segmentation of the ATC3 class J2A[47].

78. According to the Parties, within systemic anti-fungal agents, a basic distinction can be drawn between products for the treatment of mild infection (such as Schering-Plough's Noxafil) and products for the treatment of moderately severe and severe infections (such as Merck's Cancidas). Furthermore each of these groups can be further subdivided based on the specific fungal infections.

79. The respondents to the market investigation broadly confirmed the view of the Parties, indicating that the above-mentioned groups of anti-fungal agents cannot always be seen as substitutable as they have different indications, spectrum of activity, formulations, side effects and price[48].

80. The market investigation however does not unanimously indicate that a narrow market definition for products treating severe infections would be more appropriate than a broad market definition covering all products classified in J2A. This is mainly due to the complexity of this therapeutic area where the same fungi can cause mild and severe infections, depending, for instance, on the immune status of the infected individual.

81. For the purpose of the present case the market definition can be left open, as serious doubts do not arise under any alternative market definition.

Assessment

82. Both Parties are present in the market for systemic anti-fungal treatments. Merck produces and sell Cancidas (*caspofungin*), whereas Schering-Plough sells Noxafil (*posaconazole*). According to the Parties, their products are not substitutes and are better seen as complements since Cancidas is administered intravenously and is used as initial therapy in invasive Candida infections, and in empirical therapy for presumed fungal infections in febrile, neutropenic patients, whereas Noxafil is

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47 Cases COMP/M.5295 – *Teva/Barr*, decision of 19 December 2008, paras. 168 and 173; COMP/M.3493 – *Yamanouchi/Fujisawa*, decision of 18 August 2004, paras. 6 and 17.

48 According to some respondents, for example, polyenes are fungicidal and exert activity across a broad spectrum of yeasts and moulds, whereas echinocandins and azoles are fungistatic and have limited range of activity.

orally administered and is used in prophylaxis of invasive fungal infections, in Aspergillus infections and in other mould infections.

83. The majority of the respondents confirmed that Cancidas is prescribed for the anti-fungal treatment of seriously ill patients who require stronger treatments, while Noxafil is indicated for prophilaxis of invasive aspergillus and candida infections, indicating that the Parties' products cannot be seen as each other's closest competitors.

84. Only if the transaction were to be assessed on the basis of systemic anti-fungal treatments belonging to ATC3 level class JA2, Group 1 markets would occur in the following countries: Denmark, Finland, Norway, Slovenia and Sweden.

Table 3: Systemic Anti-fungal Treatments (ATC3 class J2A)

MEMBER STATES	MERCK (%)	SP (%)	TOTAL (%)	LARGEST COMPETITORS
Denmark	[40-50]%	[0-5]%	[40-50]%	Pfizer ([20-30]%), Gilead ([20-30]%), Stada ([0-5]%), Orifarm ([0-5]%),
Finland	[40-50]%	[0-5]%	[40-50]%	Pfizer ([20-30]%), Ratiopharm ([0-5]%), Orifarm ([10-20]%), Gilead ([0-5]%), Johnson&Johnson ([5-10]%)
Norway	[40-50]%	[0-5]%	[40-50]%	Pfizer ([20-30]%), Orifarm ([10-20]%), Actavis ([5-10]%)
Slovenia	[30-40]%	[5-10]%	[40-50]%	Pfizer ([20-30]%), Gilead ([10-20]%), Krka ([5-10]%), Janssen Cilag ([5-10]%)
Sweden	[30-40]%	[5-10]%	[30-40]%	Pfizer ([20-30]%), Gilead ([10-20]%), Novartis ([5-10]%), Nycomed ([0-5]%), Krka ([0-5]%)

85. In all Group 1 markets the Parties will have less than [40-50]% market share with increments ranging between [0-5]% and [5-10]%. The Parties will also face competition from established players, such as Pfizer, which has a portfolio of three anti-fungal drugs, Gilead, Novartis and a number of generic producers, mainly with generic versions of the competitors' products (such as Teva, Stada, Krka, Nycomed, Orifarm). The relevant markets are also characterised by a dynamic nature thanks to a number of new products by existing players or new entrants (for example Astella's product has recently been launched in the majority of the EEA Member States[49]).

86. In the light of the above, the Commission concludes that the merger does not raise serious doubts in the markets for systemic anti-fungal treatments in Denmark, Finland, Norway, Slovenia and Sweden.

[49] Astella's Mycamine is an *echinocandin* and has been mentioned in the market investigation as a close competitor to Merck's Cancidas.

Anti-depressant medications

87. Both Parties are active in the production and marketing of drugs used for the treatment of major depressive disorders. Such drugs are classified in the ATC3 category N6A (Anti-depressants and Mood stabilisers). The poducts sold by the Parties are heterocyclic anti-depresants belonging to ATC 4 category N6A9 (all other anti-depressants).

88. Merck manufactures and markets a tricyclic anti-depressant Tryptizole (*amitriptyline*) which is no longer under patent protection.

89. Schering-Plough manufactures and markets two tetracyclic anti-depressants, namely Remeron (*mitrazapine*) and Tolvon (*mianserin*). The patents for both drugs have expired.

90. The Parties products overlap on ATC3, ATC4 category levels and on a hypothetical segment comprising all heterocyclic antidepressants. There is no overlap on a molecule level.

Market Definition

91. Anti-depressant medications are classified in ATC3 class N6A (Anti-depressants and Mood Stabilisers). In previous decisions,[50] the Commission has left open whether the market ought to be defined on the basis of (1) ATC3 class N6A, (2) ATC3 class excluding ATC4 classes N6A2 (herbal) and N6A3 (indication for bipolar disorders), (3) on ATC4 class level, e.g. N6A9 (all other anti-depressants) or (4) at another level. Furthermore, in its previous decision the Commission has considered that differences between drugs as to their mechanism of action might not be decisive when indentifying separate product markets.

92. In view of the Parties, the market for anti-depressant medications comprises all the products in ATC3 category N6A. Although replies to the market investigation were mixed in this respect, the market definition can be left open as the transaction does not raise serious doubts under any alternative market definition.

Assessment

93. Only on ATC4 class N6A9 level, the Parties activities would result in Group 1 markets, namely in Spain and Sweden. Under any other alternative segmentation the Parties' combined market shares would not exceed 15%.

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[50] Cases COMP/M.5476 - *Pfizer/Wyeth*, decision of 17 July 2009, paras.73-77; COMP/M.5295 - *Teva/Barr*, decision of 19 December 2000, para.164; COMP/M.1878 - *Pfizer/Warner-Lambert*, decision of 22 May 2000, para.29.

Table 4: Anti-depressant Medications (ATC 4 class N6A9)

MEMBER STATES	MERCK (%)	SP (%)	TOTAL (%)	THREE LARGEST COMPETITORS
Spain	[0-5]%	[30-40]%	[30-40]%	Esteve (*Vastat*, *mitrazapine* generics) ([20-30]%), Angelini ([10-20]%), Sigma Tau ([5-10]%)
Sweden	[5-10]%	[20-30]%	[30-40]%	Krka (*mitrazapine* generics) ([10-20]%), Mylan (including *mitrazapine* and *mianserin* generics) ([10-20]%), Teva (*mitrazapine* generics) ([5-10]%), Pfizer ([5-10]%)

94. In relation to both markets, it should be considered that the market value of Tolvon (*miansierin*) and Tryptizole (*amitriptyline*) is significantly lower compared to the sales of Remeron (*mitrazapine*): *Remeron* accounts for [20-30]-[30-40]% of the market, *Tryptizol* for [0-5]-[5-10]%, and *Tolvon* for [0-5]-[5-10]% in Spain and Sweden.

95. In relation to the *Spanish* market for anti-depressants at ATC4 category N6A9, there are a number of established competitors: Esteve with a generic *mitrazapine* product Vastat accounting for [20-30]%, Angelini ([10-20]%), and Sigma Tau ([5-10]%). There are at least 12 generic producers of *mitrazapine* in Spain[51] and one generic producer of *amitriptyline* (Aldo Union).

96. In *Sweden* there are also a number of established competitors: Krka ([10-20]%), Mylan ([10-20]%), Teva ([5-10]%), Pfizer ([5-10]%). There are 10 generic *mitrazapine* producers in Sweden[52] and one generic producer of *mianserin* (Mylan). In addition, Lundbek is licenced to market Merck's *amitriptyline* in Sweden.

97. According to the market investigation, the majority of the competitors do not regard the Parties' products as each other's closest substitites. For ATC4 category N6A9 level, respondents indicated a number of other competing products, including both originator and generic alternatives[53].

98. In the light of the above, the Commission concludes that the merger does not raise serious doubts in the markets for anti-depressant medications in Spain and Sweden.

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51 Esteve, Stada, Teva, Alter, Novartis, Mylan, Ratiopharm, Biomedica Foscama, Cinfa, Normon, Combino Pharm, Sanofi-Aventis.

52 Krka, Teva, Actavis, Mylan, Ratiopharm, Novartis, Orion, Nycomed Pharma, Arrow Generiques and Stada.

53 e.g. for Remeron *mitrazapine* generics, for Tryptizole *amitriptyline*, *nortriptyline*, *clomipramine, trazadone, maprotiline* (Spain)*, mitrazapine* products, and for Tolvon *mianserin* generic (in Sweden), *trazadone, clomipramine*, *mitrazapine, amitriptyline, reboxetine* products.

Plain Corticosteroids

Market definition

99. Plain corticosteroids include all systemic products containing one or more corticosteroid, without any other active ingredient. They are commonly used to treat a wider range of inflammations and are available on prescription only. Plain corticosteroids are classified in ATC3 class H2A. This ATC3 class is subdivided into the ATC4 classes H2A1 (injectable corticosteroids, plain), H2A2 (oral corticosteroids, plain) and H2A3 (other systemic corticosteroids, plain).

100. The Parties have submitted in line with previous Commission decisions, that the relevant product market is the ATC3 level category H2A[54].

101. For the purpose of the present case the market definition might be left open, as serious doubts do not arise under any alternative market definition.

Assessment

102. Under a market definition for plain corticosteroids grouped in ATC3 class H2A, the proposed transaction would amount to a Group 1 market in Austria with a combined market share of [30-40]% ([0-5]% for Merck, [30-40]% for Schering-Plough, [20-30]% for Merck KGAA, [10-20]% for Sanofi-Aventis, and [10-20]% for Dermapharm).

103. Under any other alternative market definition there would be no Group 1 or Group 2 market in any Member State. Based on ATC4 class H2A1, there is no overlap between the Parties products, as Merck does not sell injectable corticosteroids. Based on ATC4 class H2A2, the Parties' activities overlap only in three Member States but in none of them the combined market share exceeds 15%.

104. Merck sells Hydrocortone (*hydrocortisone*), an oral plain corticosteroid in five Member States.[55] This product is used to treat many different conditions. It was launched in Europe in 1952 and is off-patent. In 2008, Merck sold its UK Hydrocortone business to Auden McKenzie […].

105. Schering-Plough markets four plain corticosteroids in the EEA, Celestone (*betamethasone*), Meticorten (*prednisone*), Diadreson (*prednisolone*) and Oradexon (*dexamenthasone*) which all belong to the ATC3 class H2A. All these products are off-patent. Only Celestone and Meticorten are sold in the same Member States where Merck sells Hydrocortone. Celestone is to a large extent sold in the EEA in an injectable version belonging to ATC4 class H2A1. In Austria, Celestone is only sold in an injectable form. Meticorten is an oral corticosteroid belonging to ATC4 class H2A2. Within the EEA, Meticorten is only sold in Portugal.

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54 See cases COMP/M.2922-Pfizer/Pharmacia, decision of 27 February 2003, para 47; COMP/M.1835-Monsanto/Pharmacia&Upjohn, decision of 30 March 2000, paras 24, 25.

55 Austria, Ireland, Lithuania, Norway and Portugal.

106. As regards the Group 1 market in *Austria*, the Parties' products are not closest competitors. Merck markets an oral corticosteroid belonging to a different ATC4 class than Schering-Plough's product which is sold only as an injectable version. It can be assumed that closest competitors are the products within the same ATC4 class. The market share added by Merck will be very small. The market is mature with products being off-patent and none of the Parties has any R&D projects with regard to plain corticosteroids. There are a number of strong competitors with remarkable market shares. Furthermore, […].

107. Taking these consideration into account and given that there are several other competitors the transaction would not give rise to serious doubts with regard to plain corticosteroids in Austria.

Rheumatoid Arthritis

Market definition

108. Rheumatoid arthritis is an auto-immune disease that causes chronic inflammation and stiffening of the joints. Pharmacological treatments of rheumatoid arthritis include symptomatic treatments and disease modifying drugs that inhibit or halt long-term joint damage.

109. In the area of rheumatoid arthritis Merck produces and markets Arcoxia (*etoricoxib*), belonging to ATC3 class M1A (Anti-rheumatics, non-steroidal). Schering-Plough produces and markets Celestone (*betamethason*e), ATC3 class H2A (Systemic corticosteroids, plain), and Remicade (*infliximab*), ATC3 class L4A (Immunosuppressive agents), the first being a plain corticosteroid also indicated for rheumatoid arthritis, and the second a disease modifying anti-rheumatic drug. In addition Schering-Plough has a pipeline product in the regulatory approval phase, Simponi (*golimubab*), a TNF alpha inhibitor[56]. With the exception of Celestone, the Parties' products are patent protected

110. According to the Parties, these products are rather complements than substitutes in the treatment of rheumatoid arthritis as they differ substantially in therapeutic indication, mode of administration, treatment setting and side effect. The respondents to the market investigation confirmed the view of the Parties, indicating that in this therapeutic area it is possible to distinguish between products for the treatment of the underlying cause of the disease, such as disease modifying anti-rheumatic drugs (DMARDs) and TNF-alpha inhibitors, and products for the relief of pain (symptomatic treatments) such as non-steroidal, anti-inflammatory drugs (NSAIDs) and corticosteroids.

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

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[56] A so-called TNF-alpha inhibitor is a disease modifying anti-rheumatic drug (DMARD) that targets the underlying cause of the disease.

Assessment

112. The Parties sell medications that have an indication, *inter alia*, in the rheumatoid arthritis area. At ATC3 level there is no overlap as the Parties' products belong to different ATC3 classes: Merck's Arcoxia belongs to ATC3 class M1A, whereas Schering-Plough's Celestone and Remicade are in ATC3 classes H2A and L4A respectively.

113. The market investigation indicated that the Parties' products cannot be seen as substitutes but rather as complementary, due to their different mode of action and to the fact that DMARDs like Remicade and Simponi are intended to treat the underlying cause of the disease whereas COX-2 inhibitors like Arcoxia are primarily pain medications, which deal with the symptoms of the disease rather than the underlying cause. Moreover, according to the results of the market investigation, Schering-Plough's pipeline product, Simponi, is a much closer substitute to Schering-Plough's Remicade rather than Merck's Arcoxia. Therefore, the market investigation clearly shows that the Parties' products are most likely part of different relevant markets and are in any case not the closest competitors.

114. If the transaction were to be assessed on the basis of a market delineation encompassing the ATC3 classes M1A, H2A (*betamethasone*) and L4A, Group 1 markets would occur in *Belgium*, [40-50]% ([0-5]% Merck and [40-50]% Schering-Plough, [10-20]% Novartis, [10-20]% Astellas, [5-10]% Roche), and in *the Netherlands*, [40-50]% ([0-5]% Merck, [30-40]% Schering-Plough, [5-10]% Celgene Corp, [5-10]% Novartis, [5-10]% Atellas).

115. However, the Parties submit that these shares overestimate the proportion of their products' sales made for the purpose of rheumatoid arthritis since IMS sales data for a particular ATC class include sales of those products for all their therapeutic indications, whereas based on internal information, only [0-5]% of total EEA Arcoxia sales, [0-5]% of total EEA Celestone sales and [20-30]% of total EEA Remicade sales are made for the purpose of rheumatoid arthritis[57].

116. In the light of the above considerations, it can be concluded that the merger does not raise serious doubts in the market for rheumatoid arthritis treatments in Belgium and the Netherlands.

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[57] Arcoxia is indicated for symptomatic relief of osteoarthritis, rheumatoid arthritis, and the pain signs of inflammation associated with acute gouty arthritis. In June 2009, Arcoxia received a further approved indication for the treatment of anckylosing spondylitis. Remicade is indicated for rheumatoid arthritis, adult and paedriatic Crohn's disease, ulcerative colitis, ankylosing spondylitis, psoriatic arthritis, and psoriasis. Celestone is indicated for allergies, dermatologic diseases, endocrine disorders, primary and secondary adrenocortical insufficiency, gastrointestinal diseases, hematologic disorders, renal diseases, ophthalmic diseases, respiratory diseases, rheumatic disorders, neoplastic diseases, and nervous system.

5. CONCLUSION

117. For the above reasons, the Commission has decided not to oppose the notified operation and to declare it compatible with the common market and with the EEA Agreement. This decision is adopted in application of Article 6(1)(b) of Council Regulation (EC) No 139/2004.

For the Commission
(signed)
Meglena Kuneva,
Member of the Commission