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# *Case No COMP/M.3544 - BAYER HEALTHCARE / ROCHE (OTC BUSINESS)*

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## REGULATION (EC) No 139/2004
## MERGER PROCEDURE

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Article 6(2) NON-OPPOSITION
Date: 19/11/2004

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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, **19/11/2004**

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PUBLIC VERSION

MERGER PROCEDURE
ARTICLES 6(1)(b) & 6(2)
DECISION

To the notifying party

Dear Sir/Madam,

**Subject: Case No COMP/M.3544 - BAYER HEALTHCARE / ROCHE (OTC BUSINESS)**
**Notification of 29.09.2004 pursuant to Article 4 of Council Regulation No 139/2004[1]**

1. On 29 September 2004, the Commission received a notification of a proposed concentration whereby Bayer HealthCare AG ("Bayer"), a subsidiary of Bayer AG of Germany acquires within the meaning of Article 3(1)(b) of the Council Regulation (EC) No 139/2004 ("Merger Regulation") control of the worldwide Roche OTC[2] business ("Orion", Switzerland) by way of purchase of shares and assets.

2. In the course of the proceedings, the notifying party 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 and does not raise serious doubts as to its compatibility with the common market and with the functioning of the EEA Agreement.

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1 OJ L 24, 29.1.2004 p. 1.

2 OTC : over the counter.

## Article I. THE PARTIES

3. **Bayer AG** is a diversified German group active in health care, crop science and polymer products. **Bayer Healthcare** combines the Bayer group's global healthcare activities in the fields of Animal Health, Biological Products, Consumer Care, Diagnostics and Pharmaceuticals. Its Consumer Care division is active in OTC medication and nutritional supplements.

4. **Orion** consists of the Roche Consumer Health business, the OTC operations of the Swiss company Roche Holding AG ("Roche"). After the transaction, Roche will retain its two other main operating divisions, (prescription) pharmaceuticals and diagnostics.

## Article II. THE OPERATION AND THE CONCENTRATION

5. On 16 July 2004, Bayer entered into a Share and Asset Purchase Agreement with Roche whereby Bayer intends to acquire sole control of substantially all assets of Orion, the worldwide Roche over-the-counter business, which includes assets and public registrations in about 50 countries. Roche will, as a result, substantially withdraw from the OTC pharmaceuticals business and concentrate instead on prescription drugs.

6. The notified operation confers to Bayer sole control over Orion. It therefore constitutes a concentration within the meaning of Article 3(1)(b) of the Merger Regulation.

## Article III. COMMUNITY DIMENSION

7. The undertakings concerned have a combined aggregate world-wide turnover of more than EUR 5 billion[3] (Bayer AG, € 28.566 million; Orion, € 889 million). Each of them have a Community-wide turnover in excess of EUR 250 million (Bayer AG, € […] million; Orion, € […] 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.

## Article IV. COMPETITIVE ASSESSMENT

### A. Overview

8. Following the transaction, Bayer will become the largest European player in the OTC market and the third largest worldwide, adding a number of important brands to its portfolio. Bayer's leading brands include *Aspirin, Aktren, Alka-Seltzer, Canesten and One-A-Day*, while Orion considers the following brands as its core products: *Bepanthol, Supradyn, Rennie, Aleve/ Flanax, Redoxon, Berocca, Saridon, Elevit Pronatal,* and *Vital 50+*. Roche also owns the *Aspro* brand, a non-narcotic analgesic.

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

9. The parties submit that Bayer's and Orion's product portfolios are largely complementary. Nevertheless, substantial horizontal overlap arises particularly in three therapeutic areas: antacids, antiflatulents, carminatives (ATC[4] 3 class A2A), non-narcotic analgesics (N2B), dermatological antifungals (D1A) and, technically, other urological preparations (G4B)[5]

10. According to the parties, there are only marginal overlaps in vitamin products at the ATC 3 level (in Poland and Slovenia). They do not lead to any affected markets.

11. With regards to vertical relationships, Bayer Healthcare produces some active ingredients however for its own needs only, except for one (etofenamate). Orion has no activities in the production of active ingredients. On the etofenamate market, the market share of Bayer is below 25% and Orion does not manufacture any downstream medicine using Etofenamate. Therefore the vertical relationships will not be further analysed in the present decision.

**B. Relevant product markets**

12. In previous decisions[6], 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). 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. ATC 3 can, thus, be a useful starting point when defining relevant product markets. However, as ATC is merely a statistical classification system, it is in certain cases necessary to deviate from it when defining relevant markets for competition analysis. For example, it may be necessary to analyse pharmaceutical products at a higher, lower or mixed level or to further subdivide the ATC 3 classes on the basis of demand-related criteria.

13. The Commission has also in the past[7] defined separate markets for OTC (as opposed to prescription) pharmaceuticals because medical indications (as well as side effects), legal framework, marketing and distributing tend to differ between these categories, even if the active ingredients are identical. OTC products may be advertised to the public at large. Doctors do not need to intervene in the purchase of these products. Consumers make their own choice and bear the costs of their purchase, generally leading to a higher price elasticity of demand. By contrast, prescription pharmaceuticals need to be prescribed by a doctor, whose intervention is thus essential in the choice of the product. Pricing for prescription products is influenced by the public health care system, who pays (part of) the purchase price via reimbursement. Marketing, therefore, is targeted at prescribers, that is,

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4 Anatomical Therapeutic Chemical classification

5 However, as will be outlined below, no meaningful overlap arises for purposes of competition analysis.

6 See for instance case COMP/M.3354 – Sanofi-Synthelabo/Aventis, paragraph 15

7 See case COMP/M.3394 – Johnson & Johnson/ Johnson & Johnson MSD Europe, paragraph 14-15

doctors and hospitals. "Semi-ethical" products are OTC drugs for which reimbursement can be obtained if they are purchased on prescription. In the present case, the market investigation has largely confirmed that prescription and OTC products constitute separate product markets.

14. In the present case, the parties submit that the relevant product markets for OTCs should generally be defined according to third-level Anatomical Therapeutic Chemical classification ("ATC 3"). However, for some product markets, which are further discussed below, the parties have suggested alternative market definitions.

#### 14.1.1. A2A - Antacids, Antiflatulents, Carminatives

15. The parties argue that antacids and antiflatulents belong to different markets, but H2 antagonists (which belong to a different ATC 3 category) should be added to a market for plain antacids as they have, in the parties' view, the same indications. The Commission has investigated these two (non-)substitution relationship alleged by the parties.

16. Antacids and antiflatulents are used to treat two different medical conditions and the active ingredients generally differ accordingly. Antacids are used for anti-acid treatment of conditions such as heartburn and acid-related gastric disorders as well as gastric and duodenal ulcers. By contrast, antiflatulents, such as Bayer's Lefax, are indicated for the treatment of excessive formation and accumulation of gas in the gastrointestinal tract, functional digestive complaints (e.g. sensation of fullness, premature satiation, bloating, belching and metorism) and similar symptoms. Respondents to the Commission's market investigation confirmed that the product categories treat different medical conditions and are, thus, not substitutable from a consumer perspective.

17. However, the parties point out that some products, in particular Roche's Rennie Defarin, can be used for treating both flatulence and acid indigestion, thus blurring the lines between the antacid and antiflatulent segments. This observation is reflected in some replies by competitors. Rennie Defarin contains an additional ingredient, Dimeticon-Siliciumdioxide, not present in the regular Rennie line to treat certain flatulence symptoms. Rennie and Rennie Defarin are marketed in different pack sizes and prices differ, a possible indication that Roche may be able to price discriminate between the two market segments. For example, in Germany, a pack of 36 Rennie tablets is priced at EUR […] (ex manufacturer, equivalent to […] cents/ tablet), whereas 48 Rennie Defarin cost EUR […] ([…] cents/ tablet, i.e. […] than regular Rennie), according to data supplied by the parties.

18. Hence, there are indications that antacids and antiflatulents belong to separate relevant OTC product markets. However, it is not necessary to conclude definitively on this question as it does not affect the outcome of the market investigation in the present case. The parties' product portfolios do not overlap to any significant degree in a separate market for antiflatulents in any given national market; i.e. including both antacids and antiflatulents in one and the same product market would merely widen the relevant market (and thus decrease the parties' combined market share).[8]

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[8] Overlap would arise only in Germany; however, while Bayer's Lefax (A2A2) enjoys a strong market position in this country, Roche's Rennie Defarin (A2A4) is insignificant (EUR […] sales in 2003, […]% market share). Likewise, according to the Form CO, the parties' activities do not overlap in (or with) any

19. Regarding the question whether H2 antagonists are substitutable for antacids in the OTC market, there was wide consensus among both customers and competitors covered by the market investigation that both treat the same symptoms. Whereas antacids neutralise, in one way or another, excess acids, H2 antagonists act upon the stomach's acid production process. Although they may be considered as "stronger" drugs, relative to antacids, the lower dosages authorised for OTC sale, despite their different mode of action, are indicated for similar (i.e. mild to moderate) gravities of disease.

20. In conclusion, there are strong indications that there exists a relevant OTC product market comprising antacids (ATC 4 category A2A1) and H2 antagonists (A2B1). Antiflatulents do not appear to belong to this market; however, it is not necessary to conclude definitively on this aspect for purposes of the present decision.

**20.1.2. N2B - Non-Narcotic Analgesics**

21. This ATC 3 category includes a range of medicines used to treat conditions such as headaches, fever, cold and flu symptoms and other pain conditions. The 4th level of ATC is used to differentiate prescription (N2B1) from non prescription (N2B2) pharmaceuticals and is only used in Austria, Finland, Hungary, Germany, South Africa, Sweden and Switzerland. Therefore the question about which level of ATC is a suitable delineation of the relevant product market for the N2B products amounts to distinguishing between prescription and OTC products.

22. The parties argue that the N2B which contain vitamin C should not be included in the same product market as it is mainly used as a cold and flu treatment rather than a pain treatment. The market investigation has not confirmed this approach.

23. Therefore and as discussed in paragraph 13 above , the Commission will assess the effects of this concentration on the OTC segment of the N2B market.

**23.1.3. Dermatological Antifungals**

24. The parties submit in the notification that the ATC 3 level is appropriate to define the relevant market in this area. The ATC 4 category further subdivides these treatments by application mode, distinguishing between scalp treatments, systemic (i.e. orally taken) and topical treatments. In the course of the investigation, the parties, in apparent deviation from the arguments put forward in the Form CO, argued for a much narrower market definition below ATC 4, which would largely eliminate the horizontal overlap between Bayer's and Orion's activities in this segment.

25. The Commission's market investigation confirmed that the D1A category includes a wide range of dermatological products based on different active ingredients and different delivery modes. It therefore appears more appropriate to further subdivide this category to ATC4 level in order to account for the non-substitutability of topical antifungals, systemic ones and scalp treatments. The relevant product market where the parties are active is the OTC segment of the D1A1 category, topical antifungals. However, even at ATC4 level, products are significantly differentiated. Thus, on the basis of the results of the market investigation and the arguments put forward by the parties, the Commission has partially

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other ATC 4 category in this area (A2A3 through A2A7), which contain combinations of antacids/ antiflatulents with other drugs (like Rennie Defarin).

adjusted the relevant product market, slightly deviating from the D1A1 category, to exclude individual products that clearly belong to a different product market for purposes of competition analysis.

26. Therefore, products classified in the D1A1 category, which, according to the results of the market investigation, are shampoos or other scalp treatments, have been excluded from the market for topical antifungals. Conversely, other products classified by IMS as prescription bound medicine, but which the parties and the market investigation confirmed to be available OTC in Ireland, have been included in the relevant product market. Part of this analysis is specific to Ireland, the only country where an affected market arises in this area.

27. In Ireland, the parties are currently active in this market with the following products: Canesten, which belongs to Bayer, and Caldesene and Desenex, belonging to Roche, with the latter products being marketed only in Ireland. The parties hold that Caldesene is not substitutable with Canesten or Desenex since it is used for the treatment and prevention of nappy rash, whereas Canesten and Desenex are used for the treatment of fungal infections such as athlete's foot. Furthermore they submit that Caldesene is rather comparable with topical wound healing and emollient and protective products usually classified in ATC3 categories D2A or D3A. Therefore, they hold that an appropriate market definition should exclude Caldesene.

28. However, this argument is not supported by the market investigation and it is also contradicted by information the parties have provided to the Commission. Caldesene, Canesten and Desenex are all recommended by their respective leaflets as suitable to heal antifungal infections caused either by candida fungi (such as nappy rash) or tinea fungi (such as athlete's foot).

29. Therefore, all of them appear to be part of a relevant market for topical antifungals.

#### d) G4B - Other Urological Preparations

30. The ATC 3 category for G4B is very broad, including such diverse conditions as erectile dysfunction (G4B3) and urinary incontinence (G4B4). Based on a narrower, ATC 4, market, the parties' activities do not overlap. This approach is in line with previous Commission decisions[9]. Given that Bayer's and Orion's products in the G4B area are clearly not substitutes, this market was not further investigated.

### C. Relevant geographic markets

31. 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 parties submit that the relevant geographic market for pharmaceutical products is national.

32. The results of the investigation suggest that the Commission should not deviate from its previous practice in assessing pharmaceutical markets at the national level and that the same approach is appropriate for OTC products. At this stage, despite the presence of large European wholesalers, the competition still takes place at national level.

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9 See case COMP/M.2922 - Pfizer/Pharmacia, paragraph 37-44

## D. Assessment

### a) Plain Antacids and H2 Antagonists

33. In the market for plain antacids and H2 antagonists authorised for OTC sale, affected markets (overlap and combined market share in excess of 15%) arise in Germany, Austria, the Czech Republic, Hungary and Slovenia. The following table sets out the parties' and competitors' market shares by value, according to IMS data as provided by the parties:

**Market shares plain antacids/ H2 antagonists 2003 (percent, by value)**

| **Country:** | **A** | **CZ** | **D** | **H** | **SLO** |
|---|---|---|---|---|---|
| Bayer | [10-15] | [5-10] | [20-25] | [0-5] | [40-45] |
| Orion | [45-50] | [10-15] | [10-15] | [40-45] | [0-5] |
| **Combined** | **[55-60]** | **[20-25]** | **[30-35]** | **[45-50]** | **[45-50]** |
| Pfizer | [15-20] | | [10-15] | | |
| Altana | [15-20] | | [10-15] | | |
| Merckle (Ratioph.) | [0-5] | | [0-5] | | |
| GSK | | [20-25] | [0-5] | | |
| Johnson&Johnson | | | [0-5] | | |
| Klosterfrau | | | [15-20] | | |
| Genericon | [0-5] | | | | |
| Sanofi-Aventis | | [25-30] | | [20-25] | |
| Zentiva | | [10-15] | | | |
| Promed | | [5-10] | | | |
| Valeant | | | | [15-20] | |
| Gedeon Richter | | | | [10-15] | |
| Novartis | | | | | [15-20] |
| Krka | | | | | [20-25] |
| Lekarna | | | | | [10-15] |
| Pliva | | | | | [0-5] |
| Others | [5-10] | [10-15] | [10-15] | [0-5] | [0-5] |

*Source: IMS/ MIDAS as reported by the parties*

34. In a hypothetical OTC market including also antiflatulents (A2A + H2 antagonists), the parties would have the following combined market shares (in 2003): A: [35-40]%, CZ: [10-15]%, D: [35-40]%, H: [25-30]%, SLO: [40-45]%.[10] The competitive assessment would not be affected by these alternative market definitions in any of these countries.

*Germany*

35. Bayer ("Talcid" brand) and Roche ("Rennie") have a combined market share of [30-35]% in Germany (Bayer [20-25]%, Roche [10-15]%). Klosterfrau ([15-20]%, "Maaloxan"), Pfizer ([10-15]%, "Kompensan" et al) and Altana ([10-15]%, "Riopan") all compete with products in the A2A1 category (plain antacids), although the respective formulations vary somewhat. GSK ([0-5]%, "Zantac") and Johnson & Johnson ([0-5]%, "Pepciddual", "Pepcid") compete in the OTC market with low dosage-versions of their H2 antagonists. Merckle offers both plain antacids and H2 antagonists under its Ratiopharm umbrella brand, however, its market share is low in this segment ([0-5]%).

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[10] Likewise, in a separate OTC market for plain antacids (A2A1), the parties' combined position would not be materially different from those in an antacids/ H2 antagonists market: A: [60-65]%, CZ: [25-30]%, D: [35-40]%, H:[55-60]%, SLO: [55-60]% (2003 figures).

36. Although they are designed to treat the same symptoms, products in the plain antacids/ H2 antagonists market are significantly differentiated both by formulation and branding. Most competitors offer a range of delivery options ranging from traditional tablets over chewable tablets to gel designed for ease of use and to encourage consumers to actually treat their condition (as opposed to just ignoring or "sitting out" the symptoms). Although no quantitative data is available, market research by Roche suggests that the fact that some potential customers do not treat their condition is a major concern in its marketing strategy and convincing them of the benefits of treatment constitutes an important source of growth. However, no mention is made of price as a potential incentive for greater use (and no indication of price elasticity is given).

37. The Commission has collected in its market investigation, mainly qualitative, information about the various competitors' market positioning to assess whether the notified operation, despite the relatively limited combined market share in Germany, may lead to a significant impediment to effective competition. This could be the case, for example, if the parties' products were particularly close substitutes relative to the remaining competitors. However, the market investigation has shown that this is not the case.

38. Replies by customers and competitors to the Commission's market investigation as well as pharmacists contacted by the Commission indicate that Maaloxan, Riopan and Kompensan are all considered as closer substitutes to Bayer's Talcid relative to Roche's Rennie, the latter being considered as a comparatively "simple" drug. Accordingly, Rennie appears to be marketed to a significant degree through mass consumer advertising, whereas Talcid relies more strongly on pharmacist endorsement.

39. Hence, the market investigation indicates that the parties' products are not each other's closest substitutes in the German market for plain antacids and H2 antagonists. There remain at least three close substitutes to Talcid post-merger, in addition to the Ratiopharm-family products and the H2 blockers supplied by Johnson & Johnson and GSK. It can, thus, be concluded that Bayer/ Roche's combined market share does not understate the transaction's competitive impact and that, consequently, no serious doubts with regard to the operation's compatibility with the Common Market arise in the German market.

*Austria*

40. Compared to Germany, the Austrian market for OTC pharmaceutical is significantly less developed in the plain antacids/ H2 antagonists market. In 2003, the total market was worth EUR […] in Austria, whereas in Germany, the total market size amounted to EUR […]. Even when accounting for the difference in population size[11], per capita consumption in Germany is approximately three times as high as in Austria. As a result, the horizontal overlap of the parties' activities in Austria amounts to only EUR […] sales per annum. Consequently, even a small output increase in value terms would greatly affect competitors' market shares.

41. Many OTC pharmaceuticals can be refunded by the Austrian health insurers when prescribed by a doctor, although the range of eligible products appears to differ between insurance plans. Rennie does not normally appear to be refundable, i.e. it is a "pure" OTC product.

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[11] D: 82 million, A: 8 million

42. Austria operates a system of price controls for OTC pharmaceuticals whereby the finance minister, in consultation with stakeholders from the consumer and industry sectors, can impose price caps. At present, prices in Austria are among the lowest in the EEA, according to data provided by competitors. The market investigation has found no conclusive evidence as to whether this has discouraged some suppliers from entering the Austrian OTC market. However, while Merckle (Ratiopharm) and Genericon offer H2 antagonist-based products in Austria, GSK and Johnson & Johnson with their H2 antagonist brands are absent from the Austrian OTC market.

43. Rennie, which cannot normally be refunded, is the clear market leader in the Austrian OTC market with [45-50]% market share. Together with Bayer's Talcid ([10-15]%), the combined market share amounts to [55-60]%. Altana ([15-20]%, Riopan) and Pfizer ([15-20]%, Solugastril, Antacidum Pfizer) are the principal remaining competitors. Like in Germany, they are considered by customers and competitors as close substitutes to Talcid, whereas Rennie is positioned at the more "casual" end of the market. Altana and Pfizer, thus, would be expected to capture more additional sales from Talcid, if the latter attempted to raise prices post merger, than one would anticipate from looking at market shares alone. The parties' combined market share is therefore likely to overstate the competitive impact of the merger.

44. Like GSK and Johnson & Johnson, Maalox/ Maaloxan[12] is currently not present in the Austrian OTC market, although it constitutes a close substitute to Talcid from a product point of view. Due to their presence in other pharmaceutical markets, GSK and Johnson & Johnson, in particular, already have distribution channels in place. The fact that Austria and Germany share a common language and both electronic and print media partially overlap facilitates entry further. All three companies, therefore, must be considered as potential entrants to the Austrian OTC market for plain antacids and H2 antagonists.

45. In conclusion, the specific characteristics of the Austrian plain antacids/ H2 antagonists market will prevent any significant impediment to effective competition in this case. The high combined market share overstates the transaction's competitive impact because Bayer/ Roche's products are relatively distant substitutes, two close substitutes to Bayer's Talcid will remain after the merger and three potential entrants, in addition to Ratiopharm, exist and are already active in neighbouring geographic and product markets.

*Czech Republic*

46. Bayer/ Roche's combined market shares amounts to [20-25]% post merger. Sanofi-Aventis will remain market leader with [25-30]% market share and several other competitors remain. The market investigation found no evidence that would suggest that the transaction, despite the limited combined market share, may significantly impede effective competition.

*Hungary and Slovenia*

47. In both Hungary and Slovenia the parties' competitive overlap is marginal in value terms (EUR […] and EUR […] respectively). Although the notified transaction will strengthen Bayer's market leadership in Slovenia and will see it acquire Roche's market leading

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[12] owned in Austria by Gerot, currently a prescription drug

position in Hungary, the increment in terms of market share and value is insignificant. Three significant competitors will remain in each market. Several companies producing close substitutes in terms of formulation have not yet entered the Hungarian and Slovenian plain antacids /H2 antagonists markets (e.g. Pfizer, Altana, GSK, Johnson & Johnson), but have strong operations in other geographic markets as well as neighbouring product markets. Hence, in view of the minimal competitive overlap in Hungary and Slovenia, the market investigation has found no indication that competition may be significantly impeded as a result of the notified transaction.

**b) N2B-OTC - Non-Narcotic Analgesics**

48. The parties have combined market shares (in 2003) at the N2B-OTC level in excess of [40-45]% in Portugal and Austria, and above [15-20]% in the Czech Republic ([15-20]%), Germany ([30-35]%), Hungary ([15-20]%), Italy ([30-35]%), Lithuania ([20-25]%), Luxemburg ([30-35]%), Slovenia ([35-40]%) and Spain ([30-35]%). However the investigation has confirmed that competition concerns are unlikely to arise as several competitors remain and they include either market leaders or have otherwise strong market positions. Third parties in their replies to the Commission's questionnaires have not raised any substantiated concerns on any of these markets.

*Portugal*

49. In Portugal the parties sell their products Aspirina, Aspirina C, Alka Selzer, Cafiaspirina, Saridon and Aspro. The combined market share of the parties is [40-45]% (Bayer [35-40]%, Orion [0-5]%). However the increment in market share is only [0-5]%. Other important competitors such as GlaxoSmithKline ([25-30]%), Wyeth ([5-10]%), J&J ([5-10]%) and Bristol Meyers ([0-5]%) are active on the market (all based on 2003 figures). During the market investigation competitors and customers have not revealed any competition concerns with regard to the Portugese N2B market (OTC).

*Austria*

50. In Austria the parties sell their products Aspirin, Aspirin Plus C, Asparin Akut as well as Aspro, Aspro C and Saridon. The combined shares of the parties is [50-55]% (Bayer [40-45]%, Orion [10-15]%[13]). Other competitors such as Boehringer Ingelheim ([15-20]%), Merckle ([5-10]%), Kwizda ([5-10]%) and others are active on the market. It can be concluded that the market share of the parties will approximately be three times as big as the next competitor. In addition, the market share of Bayer has increased from 2001.

51. The parties argue that among the European wholesalers, the top 3 wholesaler groups control [65-70]% of the European wholesale market and therefore there is a significant concentration of buying power. However, the views of the parties have not been confirmed by the market investigation, which indicated that for OTC products buying power of wholesalers is rather limited.

52. The market investigation revealed that among the three best alternatives *Aspro* and *Aspirin* are always mentioned. The market investigation also showed that there exist entry barriers to the OTC market for these products in the form of the high level of advertising/marketing costs relative to product value which have to be spent to be

[13] Orion's market share in Austria is equivalent to annual sales of EUR […].

recognized as a new player and there are indications that customers have a substantial level of brand loyalty to existing OTC brands. Also there are no indications that generic products play a significant role in this market. In addition some competitors have expressed concerns as to the concentrated level of the Austrian N2B OTC market as a result of the concentration which might lead to a reduction of competition.

53. Based on the above, it can be concluded that the proposed concentration raises serious doubts as to its compatibility with the common market since it may significantly impede effective competition in the common market or in a substantial part thereof by the creation of a single dominant position of the merged entity in the Austrian OTC N2B market.

**c) Topical Dermatological Antifungals in Ireland**

54. An affected market arises only in Ireland. The parties' combined market share in Ireland amounts to [65-70]% in the OTC segment of the ATC 4 level, according to the IMS data for 2003. However, as explained above, the IMS classification has been adjusted to take into account the results of the market investigation and the specific characteristics of the Irish market. Thus, some products (such as Abbott's Selsun) which, according to the market investigation are more appropriately classified as shampoos or other scalp treatments, have been excluded from the market definition, whereas another product (Johnson & Johnson's Daktarin), classified by IMS as a prescription-bound medicine, has been included in the OTC market because it is available prescription-free in Ireland. Therefore, in the relevant product market for topical antifungals for OTC sale in Ireland, the parties' combined market share is [55-60]% (Bayer [30-35]%, Roche [25-30]%). Due to the very substantial overlap, Bayer's market share will almost double as a result of the merger. The main competitors in the market are Johnson & Johnson ([10-15]%), Novartis ([5-10]%) and Boots ([5-10]%).

55. The market investigation has also confirmed that significant barriers-to-entry exist (such as the sunk costs of building a new brand).The parties' argument that the relevant market is a dynamic one, where new entrants like Novartis had easily gained a market share of almost [0-5]% in one year, from 2002 to 2003, does not appear convincing against this background, as the Novartis product in question (Lamisil) was already marketed in Ireland before 2003, as an prescription medicine.

56. The parties' very high combined market share, the significant competitive overlap and the low market shares of the remaining competitors by themselves raise serious doubts as to the transaction's compatibility with the Common Market, since it may significantly impede effective competition in the common market or in a substantial part thereof as a result of the creation of a single dominant position in the Irish OTC market for topical antifungals.

## Article V. MODIFICATIONS TO THE PROPOSED OPERATION

57. In order to remove the serious doubts resulting from the proposed transaction, the parties submitted undertakings to the Commission. 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.

58. In order to remove the serious doubts in the market for N2B Non Narcotic Analgesics in Austria, the parties have offered to divest the Aspro and Aspro C products. The parties'

combined market share on the Austrian N2B (OTC) market after the implementation of the proposed concentration and the divestment of Aspro and Aspro C will amount to approximately [40-45]% (by value). As a consequence of the divestment, nearly the whole overlap between the parties will be removed and only a minimal overlap will remain on this market as the increment in market share will be limited to only [0-5]% (market share of the product Saridon, equivalent to EUR […] annual sales). As a result, the commitments will eliminate all competition concerns with regard to the Austrian N2B (OTC) market. Should a separate divestiture limited to the Austrian market to a viable purchaser able to act as an effective competitive not be possible within […], the divestment package will be extended automatically to include […].

59. In the market for D1A1 in Ireland the parties propose to divest the marketing authorisation and trademarks for the existing formulations of Caldesene in Ireland, including the right to use the Caldesene trademark as well as the marketing authorisation and trademarks for the existing formulations of Desenex in Ireland, including the right to use the Desenex brand. The divestiture eliminates entirely the horizontal overlap between the parties' activities in Ireland. Sale of the divested assets to a viable purchaser will, thus, restore the competitive conditions prevailing pre-merger.

60. The Commission considers that the undertakings are sufficient to eliminate serious doubts as to the compatibility of the transaction with the common market. The undertakings were supported by third parties in their replies to the Commission's market test.

61. In order to ensure that Bayer complies with these undertakings, the Commission attaches conditions and obligations to this decision. The undertakings set out in sections B (as specified in schedules I, II and II) and D of the commitments annexed to the present decision constitute conditions, since only by fulfilling them may the structural change on the relevant markets be achieved. The other undertakings constitute obligations, since they concern the implementing steps necessary to achieve the structural change intended.

## Article VI. CONCLUSION

62. 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, subject to the condition of full compliance with sections B (as specified in schedules I, II and II) and D of the commitments annexed to the present decision and to the obligation of full compliance with the other sections of the said commitments. This decision is adopted in application of Article 6(1)(b) and 6(2) of Council Regulation (EC) No 139/2004.

For the Commission

***Signed,***
**Mario MONTI**
Member of the Commission

Mr. Paul Malric-Smith

European Commission

Directorate-General for Competition

Merger Registry

J-70

B-1049 Bruxelles

12 November 2004

**STRICTLY PRIVATE & CONFIDENTIAL**
**CONTAINS BUSINESS SECRETS**

**WITHOUT PREJUDICE**

**Case M.3544 - Bayer/Roche (OTC Business)**

# Commitments to the European Commission

Pursuant to article 6(2) of Council Regulation (EC) No 139/2004 (the "**Merger Regulation**"), Bayer HealthCare AG ("**Bayer HealthCare**") hereby provides the following commitments (the "**Commitments**") in order to enable the European Commission (the "**Commission**") to declare the acquisition of sole control over the Roche Consumer Health Business (the "**Orion Business**"/"**Orion**", Bayer HealthCare and Orion jointly referred to as the "**Parties**") compatible with the common market and the EEA Agreement by its decision pursuant to article 6(1)(b) of the Merger Regulation (the "**Decision**"). The Commitments shall take effect upon the date of adoption of the Decision.

This text shall be interpreted in the light of the Decision to the extent that the Commitments are attached as conditions and obligations, in the general framework of Community law, in particular in the light of the Merger Regulation, and by reference to the Commission Notice on remedies acceptable under Council Regulation (EEC) No 4064/89 and under Commission Regulation (EC) No 802/2004.

# 1 SECTION A. DEFINITIONS

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

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

**Bayer HealthCare**: Bayer HealthCare AG, 51368 Leverkusen, Germany.

**Closing**: the Divestment of a Divestment Business.

**Divestment Agreement**: the licence and/or sale and purchase agreement regarding a Divestment Business.

**Divestment Businesses**: the businesses as defined in Section B and in Schedules I, II and III that Bayer HealthCare commits to divest. For the purpose of this document, the term "**Divestment**" shall include the transfer of legal title as well as the licence, transfer or assignment of 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 natural or legal person(s), independent from the Parties, who is approved by the Commission and appointed by Bayer HealthCare and who has received from Bayer HealthCare the irrevocable and exclusive mandate to conclude a Divestment Agreement.

**Effective Date**: the date of the Decision.

**Extended First Divestiture Period**: for the purpose of Schedule I, the period of <BUSINESS SECRETS>months from the expiry of the First Divestiture Period.

**First Divestiture Period**: the period of <BUSINESS SECRETS> months from the Effective Date.

**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 natural or legal person(s), independent from the Parties and their Affiliated Undertakings, who is approved by the Commission and appointed by Bayer HealthCare, and who has the duty to monitor Bayer HealthCare's compliance with the conditions and obligations attached to the Decision.

**Orion**: the current Roche (Roche Holding AG, Grenzacherstrasse 124, 4058 Basel, Switzerland) Consumer Health Business including assets and public registrations.

**Parties**: Bayer HealthCare and Orion.

**Purchaser(s):** the entity (entities) approved by the Commission as purchaser(s) of the Divestment Businesses in accordance with the criteria set out in Section D.

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

**Trustee Divestiture Period**: the period of <BUSINESS SECRETS> months from the end of the First Divestiture Period; for the purpose of Schedule I, the period of <BUSINESS SECRETS>months from the expiry of the Extended First Divestiture Period.

## 2 SECTION B. THE DIVESTMENT BUSINESSES

2.1 In order to restore effective competition, Bayer HealthCare commits to divest, or procure the divestiture of the Divestment Business by the end of the Trustee Divestiture Period as a going concern to a purchaser and on terms of sale approved by the Commission in accordance with the procedure described in paragraph 4.2. To carry out the divestiture, Bayer HealthCare commits to find a purchaser and to enter into a final binding sale and purchase agreement for the sale of the Divestment Business within the First Divestiture Period. If Bayer HealthCare has not entered into such an agreement at the end of the First Divestiture Period, Bayer HealthCare shall grant the Divestiture Trustee an exclusive mandate to sell the Divestment Business in accordance with the procedure described in paragraph 5.2.3 in the Trustee Divestiture Period.

2.2 In order to maintain the structural effects of the Commitments, the Parties shall, for a period of ten years after the Effective Date, not acquire direct or indirect influence over the whole or part of the Divestment Business, unless the Commission has previously found that the structure of the market has changed to such an extent that the absence of influence over the Divestment Business is no longer necessary to render the proposed concentration compatible with the Common market.

2.3 Bayer HealthCare shall discharge the commitments specified in Schedules I, II and III (the "**Divestment Commitments**"). Schedules I, II and III identify all the relevant legal, factual, scientific and commercial features of the Divestment Businesses.

2.4 The Divestment Businesses, described in more detail in Schedules I, II and III, include all necessary:

(a) 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) licences, permits and authorisations issued by any governmental organisation for the benefit of the Divestment Business; and

(c) contracts, agreements, leases, commitments and understandings of the Divestment Business; all customer, credit and other records specific to the Divestment Business. (items referred to under (a)-(c) hereinafter collectively referred to as "Assets").

2.5 For the avoidance of doubt, the Divestment Businesses shall, *inter alia*, not include:

(a) intellectual property other than intellectual property forming part of the Divestment Businesses;

(a) the "Bayer" and "Roche" names and logos in any form;

(b) books and records required to be retained pursuant to any statute, rule, regulation or ordinance, provided that a Purchaser shall be permitted access to such books and records upon reasonable request during normal business hours (if necessary for the Divested Business, copies of such documents will be provided to the purchaser);

(c) general books of account and books of original entry that comprise the Parties' or an Affiliated Undertaking's permanent accounting or tax records (if necessary for the Divested Business, copies of such documents will be provided to the purchaser) ; and

(d) any authorisations, which may not be transferred by their terms or without the consent, notation, waiver or approval of a third person and for which such consent, notation, waiver or approval has not been obtained. However, Bayer HealthCare shall use its best endeavours to obtain such consent, notation, waiver or approval.

## 3 SECTION C. RELATED COMMITMENTS

3.1 Preservation of Viability, Marketability and Competitiveness

Bayer HealthCare shall use its best endeavours to preserve the economic viability, marketability and competitiveness of the Divestment Businesses from the Effective Date until Closing, in accordance with good business practice, and shall minimise as far as possible any risk of loss of competitive potential of the Divestment Businesses. In particular, Bayer HealthCare undertakes:

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

(f) *to make available sufficient resources for the development of the Divestment Businesses, on the basis and continuation of the existing business plans, until Closing.*

3.2 Hold-Separate Obligations of the Parties

3.2.1 Bayer HealthCare commits, from the Effective Date until Closing, to keep the Divestment Businesses separate from the businesses it is retaining in accordance

with the rules set up by the Monitoring Trustee in consultation with the Commission and in accordance with paragraphs 3.1 and 5.2.2.

3.2.2 Until Closing, Bayer HealthCare shall assist the Monitoring Trustee in ensuring that the Divestment Businesses are managed separately from the businesses it is retaining.

3.3 Ring-fencing

Bayer HealthCare shall implement all necessary measures to ensure that it does not after the Effective Date obtain any business secrets, know-how, commercial information, or any other information of a confidential or proprietary nature relating to the Divestment Businesses. In particular, the participation of the Divestment Businesses in a central information technology network shall be severed to the extent possible, without compromising the viability of the Divestment Businesses. Bayer HealthCare may obtain information relating to the Divestment Businesses, which is reasonably necessary for the Divestment of the Divestment Businesses or whose disclosure to Bayer HealthCare is required by law.

3.4 Due Diligence

In order to enable potential purchasers to carry out a reasonable due diligence of the Divestment Businesses, Bayer HealthCare shall, subject to customary confidentiality assurances and dependent on the stage of the Divestment process, provide to potential purchasers sufficient information as regards the Divestment Businesses.

3.5 Reporting

3.5.1 Bayer HealthCare shall submit written reports in the English language on potential purchasers of the Divestment Businesses and developments in the negotiations with such potential purchasers to the Commission and the Monitoring Trustee no later than ten (10) calendar days after the end of every month following the Effective Date (or otherwise at the Commission's request); however, where this date falls on a day, which is not a working day as defined under the Merger Regulation, such written reports will be due on the following working day as defined under the terms of the Merger Regulation.

3.5.2 Bayer HealthCare shall inform the Commission and the Monitoring Trustee on the preparation of any data room documentation, information memorandum, and the due diligence procedure and shall submit a copy of any information memorandum to the Commission and the Monitoring Trustee before sending the memorandum out to potential purchasers.

## 4 SECTION D. THE PURCHASER

4.1 The Purchaser, in order to be approved by the Commission, must:

(a) be independent of and unconnected to the Parties;

(b) have the financial resources and incentive to maintain and develop the Divestment Business as a viable and active competitive force in competition with the Parties and other competitors;

(c) neither be likely to create, in the light of the information available to the Commission, prima facie competition concerns nor give rise to a risk that the implementation of the Commitments will be delayed (the before-mentioned criteria for the licensee hereafter the "**Purchaser Requirements**").

4.2 The final binding Divestment Agreement shall be conditional on the Commission's approval. When Bayer HealthCare has reached an agreement with a purchaser, it shall submit a fully documented and reasoned proposal, including a copy of the final Divestment Agreement(s), to the Commission and the Monitoring Trustee. Bayer HealthCare must be able to demonstrate to the Commission that the purchaser meets the Purchaser Requirements and that the Divestment Businesses are being sold in a manner consistent with the Commitments. For the approval, the Commission shall verify that the purchaser fulfils the Purchaser Requirements and that the Divestment Businesses are being sold in a manner consistent with the Commitments. The Commission may approve the sale of the Divestment Business without one or more Assets or parts of the Personnel, if this does not affect the viability and competitiveness of the Divestment Business after the sale, taking account of the proposed purchaser.

## 5 SECTION E. TRUSTEE

5.1 Appointment Procedure

5.1.1 Bayer HealthCare shall appoint a Monitoring Trustee to carry out the functions specified in the Commitments for a Monitoring Trustee. If Bayer HealthCare has not entered into a binding Divestment Agreement one month before the end of the First Divestiture Period (or, for the purpose of Schedule I, before the end of the Extended Divestiture Period, as applicable) or if the Commission has rejected a purchaser proposed by Bayer HealthCare at that time or thereafter, Bayer HealthCare shall

appoint a Divestiture Trustee to carry out the functions specified in the Commitments for a Divestiture Trustee. The appointment of the Divestiture Trustee shall take effect upon the commencement of the Trustee Divestiture Period.

5.1.2 Bayer HealthCare shall appoint one or more Trustees, subject to the prior approval of the Commission as referred to in paragraphs 5.1.3 and 5.1.4. 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. In particular, where the remuneration package of a Divestiture Trustee includes a success premium linked to the final licence or sale value of the Divestment Business, the fee shall also be linked to a divestiture within the Trustee Divestiture Period.

5.1.3 Proposal by the Parties

No later than one week after the Effective Date, Bayer HealthCare shall submit a list of one or more persons whom Bayer HealthCare proposes to appoint as the Monitoring Trustee to the Commission for approval. No later than one month before the end of the First Divestiture Period, Bayer HealthCare shall submit a list of one or more persons whom Bayer HealthCare proposes to appoint as Divestiture Trustee to the Commission for approval. The proposal shall contain sufficient information for the Commission to verify that the proposed Trustee fulfils the requirements set out in paragraph 5.1.2 and shall include:

(a) the full terms of the proposed mandate, which shall include all provisions necessary to enable the Trustee to fulfil its duties under these Commitments;

(b) the outline of a work plan which describes how the Trustee intends to carry out its assigned tasks;

(c) an indication whether the proposed Trustee is to act as both Monitoring Trustee and Divestiture Trustee or whether different trustees are proposed for the two functions.

5.1.4 Approval or rejection by the Commission

The Commission shall have the discretion to approve or reject the proposed Trustee(s) and to approve the proposed mandate subject to any modifications the Commission deems necessary for the Trustee to fulfil its obligations. If only one individual or institution is approved, Bayer HealthCare 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 individual or institution is approved, Bayer HealthCare shall be free to choose the Trustee to be appointed from among the individuals or institutions approved. The Trustee shall be appointed within one week of the Commission's approval, in accordance with the mandate approved by the Commission.

5.1.5 New proposal by the Parties

If all the proposed Trustees are rejected, Bayer HealthCare shall submit the names of at least two more individuals or institutions within one week of being informed of the rejection, in accordance with the requirements and the procedure set out in paragraphs 5.1.1 to 5.1.3.

5.1.6 Trustee nominated by the Commission

If the Commission rejects all further proposed Trustees, the Commission shall nominate a Trustee, whom Bayer HealthCare shall appoint, or cause to be appointed, in accordance with a trustee mandate approved by the Commission.

5.2 Functions of the Trustee

5.2.1 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 Bayer HealthCare, give any orders or instructions to the Trustee in order to ensure compliance with the conditions and obligations attached to the Decision.

5.2.2 Duties and obligations of the Monitoring Trustee

Following its appointment, the Monitoring Trustee shall:

(a) propose in its first report to the *Commission* a detailed work plan describing how it intends to monitor compliance with the obligations and conditions attached to the Decision;

(b) oversee the on-going management of the Divestment Businesses with a view to ensuring its continued economic viability, marketability and competitiveness and monitor compliance by Bayer HealthCare with the conditions and obligations attached to the Decision. To that end the Monitoring Trustee shall:

(i) monitor the preservation of the economic viability, marketability and competitiveness of the Divestment Businesses, and the keeping separate of the Divestment Businesses from the businesses retained by the Parties, in accordance with paragraphs 3.1 and 3.2 of the Commitments;

(ii) supervise the management of the Divestment Business as a distinct and saleable entity, in accordance with paragraph 3.2.2 of the Commitments;

(iii) (1) in consultation with Bayer HealthCare, determine all necessary measures to ensure that Bayer HealthCare does not after the Effective Date obtain any business secrets, know-how, commercial information, or any other information of a confidential or proprietary nature relating to the Divestment Business, in particular strive for the severing of the Divestment Business' participation in a central information technology network to the extent possible, without compromising the viability of the Divestment Business, and (2) decide whether such information may be disclosed to Bayer HealthCare as the disclosure is reasonably necessary to allow Bayer HealthCare to carry out the divestiture or as the disclosure is required by law;

(iv) monitor any necessary splitting of assets and allocation of personnel between the Divestment Businesses and Bayer HealthCare or Affiliated Undertakings;

(c) assume the other functions assigned to the Monitoring Trustee under the conditions and obligations attached to the Decision;

(d) propose to Bayer HealthCare such measures as the Monitoring Trustee considers necessary to ensure Bayer HealthCare's compliance with the conditions and obligations attached to the Decision, in particular the maintenance of the full economic viability, marketability or competitiveness of the Divestment Businesses, the holding separate of the Divestment Businesses and the non-disclosure of competitively sensitive information;

(e) review and assess potential licensees as well as the progress of the divestiture process and verify that, dependent on the stage of the divestiture process, potential licensees receive sufficient information relating to the Divestment Businesses and in particular by reviewing, if available, the data room documentation, the information memorandum and the due diligence process;

(f) provide to the Commission, sending Bayer HealthCare a non-confidential copy at the same time, a written report within fifteen (15) calendar days after the end of

every month; however, where this date is not a working day within the meaning of the Merger Regulation, such written reports will be due on the following working day as defined under the terms of that Regulation. The report shall cover the operation and management of the Divestment Business to enable the Commission to assess whether the business is held in a manner consistent with the Commitments and the progress of the divestiture process as well as potential licensees. In addition to these reports, the Monitoring Trustee shall promptly report in writing to the Commission, sending Bayer HealthCare a non-confidential copy at the same time, if it concludes on reasonable grounds that Bayer HealthCare is failing to comply with these Commitments;

(g) within one week after receipt of the documented proposal referred to in paragraph 4.2, submit to the Commission a reasoned opinion as to the suitability and independence of the proposed Purchaser and the viability of the Divestment Business after the Divestment and as to whether the Divestment Business is sold in a manner consistent with the conditions and obligations attached to the Decision, in particular, if relevant, whether the Sale of the Divestment Business without one or more Assets or not all of the Personal affects the viability of the Divestment Business after the sale, taking account of the proposed purchaser.

5.2.3 Duties and obligations of the Divestiture Trustee

(h) Within the Trustee Divestiture Period, the Divestiture Trustee shall conclude <BUSINESS SECRETS> the Divestment Agreement as set out above with a Purchaser independent of the Parties, provided that the Commission has approved that Purchaser and the final binding Divestment Agreement in accordance with the procedure laid down in paragraph 4.2. The Divestiture Trustee shall include in the Divestment Agreement such terms and conditions as it considers appropriate for an expedient agreement. In particular, the Divestiture Trustee may include in the Divestment Agreement such provisions as are reasonably required to effect the agreement. The Divestiture Trustee shall protect the legitimate interests of Bayer HealthCare, subject to the Parties' unconditional obligation to divest <BUSINESS SECRETS> in the Trustee Divestiture Period.

(i) In the Trustee Divestiture Period (or otherwise at the Commission's request), the Divestiture Trustee shall provide the Commission with a comprehensive monthly report written in the English language on the progress of the divestiture process. Such reports shall be submitted within fifteen (15) calendar days after the end of every month with a simultaneous copy to the Monitoring Trustee and a non-confidential copy to the Parties.

5.3 Duties and obligations of the Parties

5.3.1 Bayer HealthCare shall provide and shall cause its advisors to 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. In addition, the Trustee

shall have full and complete access to any of Bayer HealthCare's or the Divestment Business' books, records, documents, personnel, facilities, sites and technical information necessary for fulfilling its duties under the Commitments. Bayer HealthCare and the Divestment Business shall make available to the Trustee offices on their premises and a representative of Bayer HealthCare shall be available for meetings in order to provide the Trustee with all information necessary for the performance of its tasks.

5.3.2 Bayer HealthCare shall provide the Monitoring Trustee with all managerial and administrative support that it may reasonably request on behalf of the management of the Divestment Business. This shall include all administrative support functions relating to the Divestment Business, which are currently carried out at headquarters level. Bayer HealthCare shall provide and shall cause its advisors to 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. Bayer HealthCare shall inform the Monitoring Trustee on potential purchasers, submit a list of potential purchasers, and keep the Monitoring Trustee informed of all developments in the Divestment process.

5.3.3 Bayer HealthCare shall grant or procure Affiliated Undertakings to grant comprehensive powers of attorney, duly executed, to the Divestiture Trustee to effect the Divestment Agreement, the Closing and all actions and declarations which the Divestiture Trustee considers necessary or appropriate to achieve the Divestment and the Closing, including the appointment of advisors to assist with the process of concluding a Divestment Agreement. Upon request of the Divestiture Trustee, Bayer HealthCare shall cause the documents required for effecting the Divestment and the Closing to be duly executed.

5.3.4 Bayer HealthCare shall indemnify the Trustee and its employees, agents or advisors (each an "**Indemnified Party**") and hold each Indemnified Party harmless against, and hereby agrees that an Indemnified Party shall have no liability to Bayer HealthCare for, any liabilities arising out of the performance of the Trustee's duties under the Commitments, except to the extent that such liabilities result from the wilful default, recklessness, gross negligence or bad faith of the Trustee, its employees, agents or advisors.

5.3.5 At the expense of Bayer HealthCare, the Trustee may appoint advisors (in particular, for corporate finance or legal advice), subject to Bayer HealthCare's approval (this approval not to be unreasonably withheld or delayed) if the Trustee considers the appointment of such advisors necessary or appropriate for the performance of its

duties and obligations under the Mandate, provided that any fees and other expenses incurred by the Trustee are reasonable. Should Bayer HealthCare refuse to approve the advisors proposed by the Trustee the Commission may approve the appointment of such advisors instead, after having heard Bayer HealthCare. Only the Trustee shall be entitled to issue instructions to the advisors. In the Trustee Divestiture Period, the Divestiture Trustee may use advisors who served Bayer HealthCare during the Divestiture Period if the Divestiture Trustee considers this in the best interest of an expedient Divestment.

5.4 Replacement, discharge and reappointment of the Trustee

5.4.1 If the Trustee ceases to perform its functions under the Commitments or for any other good cause, including the exposure of the Trustee to a conflict of interest:

(j) the Commission may, after hearing the Trustee, require Bayer HealthCare to replace the Trustee; or

(k) Bayer HealthCare, with the prior approval of the Commission, may replace the Trustee.

5.4.2 If the Trustee is removed according to paragraph 5.4.1, 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 5.1.

5.4.3 Beside the removal according to paragraph 5.4.1, the Trustee shall cease to act as Trustee only after the Commission has discharged it from its duties after all the Commitments with which the Trustee has been entrusted have been implemented. However, the Commission may at any time require the reappointment of the Monitoring Trustee if it subsequently appears that the relevant remedies might not have been fully and properly implemented.

## 6 SECTION F. THE REVIEW CLAUSE

6.1 The Commission may, where appropriate, in response to a request from Bayer HealthCare showing good cause and accompanied by a report from the Monitoring Trustee:

(a) *grant an extension of the time periods foreseen in the Commitments; or*

(b) *waive, modify or substitute, in exceptional circumstances, one or more of the undertakings in these Commitments. Where Bayer HealthCare 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 Bayer HealthCare be entitled to request an extension within the last month of any period.*

6.2 In case of a material change of circumstances, Bayer HealthCare reserves its rights under Community law to request the Commission to review the whole or any specific undertakings relating to the Commitments as set out above.

Signed in Leverkusen on 12 November 2004

For and on behalf of Bayer HealthCare AG

_____

Dr. Alexander Bey, duly authorised for and on behalf of Bayer HealthCare AG

## SCHEDULE I

### Aspro and Aspro C

1. The Commitment regarding the Divestment of Divestment Business I, as defined in this Schedule I, provides for two alternatives: The Alternative B Commitment shall only apply if the Alternative A Commitment is not implemented within the time frame set out below.

2. Bayer HealthCare commits to procure the Divestment of the Alternative A Divestment Business I by the sale, or licence, as appropriate, of the Alternative A Assets of the Divestment Business I as defined below to the Purchaser (the "**Alternative A Commitment**").

3. If the Alternative A Commitment is not implemented pursuant to paragraph 4.2 within the First Divestiture Period, Bayer HealthCare commits to procure the Divestment of the Alternative B Divestment Business I by the sale, or licence, as appropriate, of the Alternative B Assets of the Divestment Business I as defined below to the Purchaser (the "**Alternative B Commitment**"). In this case, and in deviation from Section A, the First Divestiture Period will be extended by additional <BUSINESS SECRETS> months ("**Extended First Divestiture Period**"). Accordingly, the Trustee Divestiture Period shall not begin before the expiry of the Extended First Divestiture Period amounting to an overall period of <BUSINESS SECRETS> months from the Effective Date.

4. Alternative A Divestment Business I

   (a) For the purpose of Alternative A, Divestment Business I consists of Orion's rights to sell and market in Austria the acetylsalicylic acid-based formulations (tablets, effervescent tablets, granule and powder) marketed under the trade names Aspro and Aspro C, which have already been marketed in Austria prior to the Effective Date (hereinafter referred to as "**Existing Formulations of Aspro and Aspro C**").

   (b) The Divestment Business includes, in particular:

      (i) existing inventory, sales and promotional material in Austria of the Existing Formulations of Aspro and Aspro C;

      (ii) an irrevocable, assignable and sub-licensable exclusive licence, including intellectual property rights and other know-how, to manufacture, use and sell the Existing Formulations of Aspro and

Aspro C as well as future formulations of Aspro and Aspro C developed by the Purchaser in Austria within the field of the ATC 3 category N2B;

(iii) the right to use the Aspro and the Aspro C trademarks as well as variations of the Aspro trademark in Austria;

(iv) the marketing authorisations for the Existing Formulations of Aspro and Aspro C in Austria. The respective marketing authorisations issued by the Austrian competent regulatory authority (as listed in the Annex) will be transferred to Bayer HealthCare following the completion of the proposed concentration. The duration of the process of transferring these marketing authorisations depends on the workload of the competent Austrian authority; and

(v) all relevant data, books and records on existing customers for the Existing Formulations of Aspro and Aspro C in Austria (items referred to under (i)-(v) hereinafter collectively referred to as "**Alternative A Assets of Divestment Business I**").

(c) Bayer HealthCare shall not use the trademarks Aspro and Aspro C nor any other related trademark within Austria.

(d) At the option of the Purchaser, Bayer HealthCare will enter into a supply or toll manufacture agreement with the Purchaser for the exclusive supply or the toll manufacture of the Existing Formulations of Aspro and Aspro C for sale in the Member States of the EEA. Such agreement will be entered into for a period of up to <BUSINESS SECRETS>from Closing on terms to be agreed between Bayer HealthCare and the Purchaser covering all of Bayer HealthCare's <BUSINESS SECRETS>.

5. Alternative B Divestment Business I

(a) For the purpose of Alternative B, Divestment Business I consists of Orion's rights to sell and market in the Member States of the EEA the acetylsalicylic acid-based formulations (tablets, effervescent tablets, granule and powder) marketed under the trade names Aspro and Aspro C, which have already been marketed in these Member States prior to the Effective Date (hereinafter referred to as "**Existing Formulations of Aspro and Aspro C**").

(b) The Divestment Business includes, in particular:

(vi) existing inventory, sales and promotional material of the Existing Formulations of Aspro and Aspro C in the Member States of the EEA;

(vii) an irrevocable, assignable and sub-licensable exclusive licence, including the intellectual property rights and other know-how, to manufacture, use and sell the Existing Formulations of Aspro and Aspro C as well as future formulations of Aspro and Aspro C developed by the Purchaser in the Member States of the EEA within the field of the ATC 3 category N2B;

(viii) the right to use the Aspro and the Aspro C trademarks as well as variations of the Aspro trademark in the Member States of the EEA;

(ix) the marketing authorisations for the Existing Formulations of Aspro and Aspro C in the Member States of the EEA, where such authorisations have been issued. The respective marketing authorisations issued by the competent regulatory authorities of the Member States of the EEA are set out in the **Annex** and will be transferred to Bayer HealthCare following the completion of the proposed concentration. The duration of the process of transferring these marketing authorisations depends on the workload of the competent authorities; and

(x) all relevant data, books and records on existing customers for the Existing Formulations of Aspro and Aspro C in the Member States of the EEA (items referred to under (i)-(v) hereinafter collectively referred to as "**Alternative B Assets of Divestment Business I**").

(c) Bayer HealthCare shall not use the trademarks Aspro and Aspro C nor any other related trademark within the EEA.

(d) At the option of the Purchaser, Bayer HealthCare will enter into a supply or toll manufacture agreement with the Purchaser for the exclusive supply or the toll manufacture of the Existing Formulations of Aspro and Aspro C for sale in the Member States of the EEA. Such agreement will be entered into for a period of up to <BUSINESS SECRETS>from Closing on terms to be agreed between Bayer HealthCare and the Purchaser covering all of Bayer HealthCare's <BUSINESS SECRETS>.

6. Bayer HealthCare shall be deemed to have complied with this Commitment if: (1) by the end of the First Divestiture Period, Bayer Healthcare has entered into a final

binding Divestment Agreement, if the Commission approves the Purchaser and the terms in accordance with the procedure described in paragraph 4.2 and if the Closing takes place within a period not exceeding three months after the approval of the Purchaser and the terms of the Divestment Agreement by the Commission; or (2) by the end of the Alternative B Divestiture Period, Bayer Healthcare has entered into a final binding Divestment Agreement, if the Commission approves the Purchaser and the terms in accordance with the procedure described in paragraph 4.2 and if the Closing takes place within a period not exceeding three months after the approval of the Purchaser and the terms of the Divestment Agreement by the Commission; or (3) by the end of the Trustee Divestiture Period, Bayer HealthCare has entered into a final binding Divestment Agreement, if the Commission approves the Purchaser and the terms in accordance with the procedure described in paragraph 4.2 and if the Closing takes place within a period not exceeding three months after the approval of the Purchaser and the terms of the Divestment Agreement by the Commission.

## SCHEDULE II

### Caldesene

1. Divestment Business II consists of Orion's rights, title and interest in the zinc oxide-based formulations (ointment, powder) currently marketed under the trade name Caldesene, which have already been marketed in Ireland prior to the Effective Date (hereinafter referred to as "**Existing Formulations of Caldesene**").

2. Divestment Business II includes:

   (e) existing Irish product inventory, sales and promotional material regarding the Existing Formulations of Caldesene;

   (f) the existing Caldesene trademark without geographic limitation;

   (g) the marketing authorisations for Caldesene in Ireland. The respective marketing authorisations issued by the competent Irish regulatory authority (registration numbers 050/110/1 and 050/108/1) are currently held by Roche Products Ltd., Welwyn, UK, and will be transferred to Bayer HealthCare following the completion of the proposed merger. The duration of the process of transferring these marketing authorisations depends on the workload of the competent Irish authority;

   (h) all relevant intellectual property rights, data, books, records and know-how, including customer lists and data, to the extent that these are related to the manufacture, use or sale the Existing Formulations of Caldesene in Ireland;

   (i) all rights and claims of Orion and Affiliated Undertakings against third parties relating exclusively to Divestment Business II other than such rights and claims relating to Divestment Business II as defined under paragraph 2.5 (items referred to under (e)-(i) hereinafter collectively referred to as "**Assets of Divestment Business II**").

3. Bayer HealthCare commits to procure the Divestment of Divestment Business II by the sale of the Assets of Divestment Business II to the Purchaser.

4. At the option of the Purchaser, Bayer HealthCare will enter into a supply or toll manufacture agreement with the Purchaser for the exclusive supply or the toll manufacture of the finished product consisting of the Existing Formulations of Caldesene. Such agreement will be entered into for a period of up to <BUSINESS

SECRETS> from Closing on terms to be agreed between Bayer HealthCare and the Purchaser covering all of Bayer HealthCare's <BUSINESS SECRETS>.

5. Bayer HealthCare shall be deemed to have complied with this Commitment if: (1) by the end of the First Divestiture Period, Bayer Healthcare has entered into a final binding Divestment Agreement, if the Commission approves the Purchaser and the terms in accordance with the procedure described in paragraph 4.2 and if the Closing takes place within a period not exceeding three months after the approval of the Purchaser and the terms of the Divestment Agreement by the Commission; or (2) by the end of the Trustee Divestiture Period, Bayer HealthCare has entered into a final binding Divestment Agreement, if the Commission approves the Purchaser and the terms in accordance with the procedure described in paragraph 4.2 and if the Closing takes place within a period not exceeding three months after the approval of the Purchaser and the terms of the Divestment Agreement by the Commission.

## SCHEDULE III

### Desenex

6. Divestment Business III consists of Orion's rights, title and interest in the undecylenic acid-based antifungal formulations (ointment, powder) marketed under the trade name Desenex, which have already been marketed in Ireland prior to the Effective Date (hereinafter referred to as "**Existing Formulations of Desenex**").

7. Divestment Business III includes:

   (j) existing Irish product inventory, sales and promotional material regarding the Existing Formulations of Desenex;

   (k) the existing Desenex trademark without geographic limitation;

   (l) the marketing authorisations for Desenex in Ireland. The respective marketing authorisations issued by the competent Irish regulatory authority (registration numbers 050/111/1 and 050/111/2) are currently held by Roche Products Ltd., Welwyn, UK, and will be transferred to Bayer HealthCare following the completion of the proposed concentration. The duration of the process of transferring these marketing authorisations depends on the workload of the competent Irish authority;

   (m) all relevant intellectual property rights, data, books, records and know-how, including customer lists and data, to the extent that these are related to the manufacture, use or sale the Existing Formulations of Desenex in Ireland;

   (n) all rights and claims of Orion and Affiliated Undertakings against third parties relating exclusively to Divestment Business III other than such rights and claims relating to Divestment Business III as defined under paragraph 2.5 (items referred to under (j)-(n) hereinafter collectively referred to as "**Assets of Divestment Business III**").

8. Bayer HealthCare commits to procure the Divestment of Divestment Business III by the sale of the Assets of Divestment Business III to the Purchaser.

9. At the option of the Purchaser, Bayer HealthCare will enter into a supply or toll manufacture agreement with the Purchaser for the exclusive supply or the toll manufacture of the finished product consisting of the Existing Formulations of Desenex for sale in Ireland. Such agreement will be entered into for a period of up to <BUSINESS SECRETS> from Closing on terms to be agreed between Bayer

HealthCare and the Purchaser covering all of Bayer HealthCare's <BUSINESS SECRETS>.

10. Bayer HealthCare shall be deemed to have complied with this commitment if: (1) by the end of the First Divestiture Period, Bayer Healthcare has entered into a final binding Divestment Agreement, if the Commission approves the Purchaser and the terms in accordance with the procedure described in paragraph 4.2 and if the Closing takes place within a period not exceeding three months after the approval of the Purchaser and the terms of the Divestment Agreement by the Commission; or (2) by the end of the Trustee Divestiture Period, Bayer HealthCare has entered into a final binding Divestment Agreement, if the Commission approves the Purchaser and the terms in accordance with the procedure described in paragraph 4.2 and if the Closing takes place within a period not exceeding three months after the approval of the Purchaser and the terms of the Divestment Agreement by the Commission.

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