

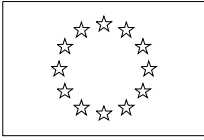
***Case No COMP/M.1403 -
ASTRA / ZENECA***

Only the English text is available and authentic.

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

Article 6(1)(b) NON-OPPOSITION
Date: 26/02/1999

*Also available in the CELEX database
Document No 399M1403*



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 26.02.1999.

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 Where possible the information omitted has been replaced by ranges of figures or a general description.

PUBLIC VERSION

MERGER PROCEDURE
ARTICLE 6(1)(b) DECISION

To the notifying parties

Dear Sirs,

Subject: Case No IV/M.1403 – ASTRA/ZENECA

Notification of 15 January 1999 pursuant to Article 4 of Council Regulation No 4064/89

1. On 15.01.1999, the Commission received a notification of a proposed concentration pursuant to Article 4 of Council Regulation (EEC) No 4064/89, as amended by Council Regulation (EEC) No 1310/97, by which the undertakings Astra AB (Astra) and Zeneca Group Plc (Zeneca) enter into a “merger of equals”, effected through a public bid by Zeneca for all shares in Astra within the meaning of Article 3(1)(b) of the Council Regulation.
2. On 08.02.1999, Astra and Zeneca submitted a proposal for modification of the operation in accordance with the terms of Article 6(2) of the Council Regulation. As a consequence, the deadline for the adoption of a decision under Article 6(1), was extended to six weeks in accordance with Article 10(2), second sub-paragraph, of the Council Regulation.

I. THE PARTIES

3. Astra and Zeneca are active in the research, production and sales of ethical pharmaceutical products. In addition Astra manufactures certain medical devices, whereas Zeneca has a major agricultural chemicals and speciality chemicals business. According to the notification, there are no overlaps in these latter areas.

II. THE OPERATION

4. The proposed transaction is a “merger of equals”, effected by means of a public bid made on 20.01.1999 by the UK company Zeneca for all shares in the Swedish company Astra. After the concentration Zeneca will change name to AstraZeneca and the management posts will be shared equally between the parties. The new company will have its primary listing on the London Stock Exchange (with secondary listings in Stockholm and New York), and its shares will be held to 46.5% by the present Astra shareholders and to 53.5% by the present Zeneca shareholders.

III. CONCENTRATION

5. On completion of the public bid, Zeneca will acquire sole control over Astra. The notified concentration therefore constitutes a concentration within the meaning of Article 3(1)(b) of the Council Regulation. It constitutes a co-operation case under the EEA Agreement, pursuant to Article 57 of that Agreement, and thus the case is to be assessed by the Commission in co-operation with the EFTA Surveillance Authority, in accordance with Article 58 and Protocol 24 of the EEA Agreement.

IV. COMMUNITY DIMENSION

6. The undertakings concerned have a combined aggregate world-wide turnover of more than EUR 5 billion¹. Each of them have a Community-wide turnover in excess of EUR 250 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.

V. COMPETITIVE ASSESSMENT

1. Relevant product markets

Introduction

7. The Commission has on many occasions dealt with the definition of the relevant market in the case of pharmaceutical products and has established a number of principles in its previous decisions.² In those decisions, it noted that medicines may be subdivided into therapeutic classes by reference to the "Anatomical Therapeutic Classification" (ATC), which is recognised and used by the World Health Organisation (WHO). This classification allows medicines to be grouped together by reference to their composition and their therapeutic properties. The third level of the ATC classification 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. However, it may be appropriate to carry out analyses at other levels of the ATC classification.

¹ 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.

² See for example IV/M.950 Hoffmann-La Roche/Boehringer Mannheim of 4 February 1998.

8. For some pharmaceutical products an analysis may also be made according to the classification drawn up by the European Pharmaceutical Marketing Research Association (EphMRA)³ which underlies the data collected by Intercontinental Medical Statistics (IMS). In the present case, the parties have used the EphMRA classification with regard to the asthma treatment sector. In this field, the classification employed in the ATC system of the WHO classifies the products at the third level partly by mode of delivery (i.e. administration is by inhalant or by other forms of systemic use) whereas the third level of the EphMRA classification classifies the products by their therapeutic indications. At the EphMRA fourth level the products are subdivided into products which are inhaled and products which are not inhaled. In general, the market investigation has confirmed the parties' claim that the third level of the EphMRA classification is more appropriate than the third level of the ATC classification for grouping anti-asthma products addressing the same therapeutic need and thus grouping substitutable products instead of grouping products which are administered in the same way.
9. Medicines may, moreover, be subdivided into various segments on the basis of a variety of criteria, and in particular demand-related criteria. A possible distinction is that between medicines, which can be issued only on prescription and those, which can be sold over the counter. A further distinction is that between medicines, which are refunded in whole or in part by sickness insurance schemes and those, which are not reimbursed. These segments partly overlap. Most medicines issued only on prescription are reimbursed, whereas most of those, which may be sold over the counter, are not reimbursed. Furthermore, the allocation of a medicine to a particular segment is not permanent. It is based instead on decisions by the authorities, which may lead to changes between segments.
10. The parties generally agree that in most cases it is appropriate to base the market definition on the third level of the ATC classification since the third level products generally serve the same treatment purpose and are not interchangeable with products from other classes. The parties have identified affected product markets mainly in the hypertension area: plain and combined betablockers (C7A/B), plain and combined calcium antagonists (C8A/B) and plain and combined ACE inhibitors (C9A/B); as well as nitrates and nitrites (C1E) which are used in the cardiovascular sector. The Commission has also examined the markets for general (N1A) and local (N1B) anaesthetics. With regard to anti-asthma products no affected market arises at the third level of the EphMRA classification. The Commission has nevertheless examined the impact of the concentration on the second level of the EphMRA classification (R3), as well as the question whether a distinction had to be made between long-acting prophylactic anti-asthmatics and short-term symptomatic anti-asthmatics.

Hypertension medicines

11. As regards hypertension medicines, the parties are however of the opinion that the products classified under the various ATC-3 classifications do not constitute separate product markets, but should be considered at a level which aggregates a number of ATC-2 classifications. This group would include not only plain and combined betablockers (C7A/B), plain and combined calcium antagonists (C8A/B) and plain and combined ACE

³ The EphMRA classification has already been used by the Commission in previous cases. See for example IV/M.737 Ciba-Geigy/Sandoz of 17 July 1996.

inhibitors (C9A/B), but also plain and combined angiotensin inhibitors (C9C/D). The parties base their view on the fact that all products in those classes are used for the treatment of hypertension.

12. The Commission has previously examined the substitutability between various hypertension medicines⁴. The result of that investigation has been confirmed in the current case, as the investigation indicates that there are arguments for defining the market more narrowly than suggested by the parties. The question of market definition is complicated by the fact that each of the above-mentioned product classes are indicated *and* contraindicated by a number of conditions, relating not only to the type and severity of the hypertension problem, but also to a number of other conditions that may be present in a specific patient. Moreover, differences in medical cultures of the Member States appear to have a significant impact on the national prescription patterns. Finally, a number of the products in question exist as combination drugs which include, for example, a betablocking agent and a diuretic. The preference for such combined products appear to be significantly stronger in some Member States (primarily Germany).
13. The parties have stated that about 50% of all patients who are given hypertension drugs for the first time change their medication (within or outside the product class) after the first year to improve effectiveness or reduce side-effects. However, even if this were to be accepted on a general level, most third party responses have stressed that hypertension medication is a life-long treatment, where no change is normally done once successful treatment has been established (unless there is a change in the condition of patient). Moreover, in particular for betablockers, a switch is potentially dangerous for patient with ischaemic heart disease, as it could increase the risk of heart attack. Finally, the importance of the cost of the chosen drug is normally is a secondary concern to its functionality. However, the importance of the relative prices of two drugs is further diminished by the fact that a switch of medication in itself will produce significant costs related to re-stabilisation of the patient and possible side-effects.
14. From a functional viewpoint betablockers lower the blood pressure through reducing the heart rate and force of cardiac contraction, whereas the other classes of hypertension medicines apply different chemical means to dilate the blood vessels that become constricted in hypertension. The primary indications for treatment with betablockers include ischaemic heart disease, benign essential tremor, thyrotoxicosis, recurrent migraine, arrhythmia (disorder in the heart rhythm) and portal hypertension. Betablockers have proven more effective in the treatment of patients of caucasian race, as well as for younger patients with stress induced hypertension. On the other hand the use of betablockers is contraindicated for patients with bronchospasm (asthma), depression, diabetes, heart block and peripheral vascular disease. They may have to be removed due to side effects, such as nightmares, change of mood or loss of physical capacity.
15. Similarly calcium antagonists, ACE inhibitors and angiotensin inhibitors have a number of primary indications and contraindications. Calcium antagonists are indicated for patients with isolated systolic hypertension, arterial tachycardia, cyclosporin induced hypertension and renal disease. They can be given to patients with diabetes or asthma,

⁴ See IV/M.737 - Ciba-Geigy/Sandoz of 17 July 1996.

and have proven more effective in the treatment of coloured people, as well as the elderly, since they do not result in the reduction of physical capacity (cf. stress induced hypertension and betablockers). Calcium antagonists are contraindicated in cases of heart block or heart failure as well as in pregnant women. They may have to be removed due to side effects, such as oedemas, headache and dizziness. The parties have submitted that recent studies (1995) have questioned the safety of calcium antagonists, which has resulted in a trend of decreasing sales compared to betablockers and ACE inhibitors. However, the results of these studies are still disputed and the sales trends appear uncertain.

16. ACE inhibitors and angiotensin inhibitors have mainly the same indications and contraindications (except that the latter are given if the patient develops side-effects in the form of dry cough in response to the former). They are indicated for patients with diabetes, heart failure, coronaropathy, proteiuria, renal disease and asthma. They are also indicated if intolerable side-effects have occurred with betablockers and/or calcium antagonists. ACE inhibitors and angiotensin inhibitors are contraindicated for certain patients, i.e. pregnant women, angioneurotic oedema or ongoing medication with lithium, potassium supplements or non-steroidal anti-inflammatories.
17. According to information provided by the parties, treatment of hypertension patients has traditionally followed a step-by-step approach, having regard to the severity of the patient's condition. According to this approach treatment would (unless contraindicated by the above-mentioned factors) start with betablockers, and gradually be increased to calcium antagonists, ACE inhibitors and angiotensin inhibitors, if necessary. The parties have stated that this approach is gradually being abandoned, in favour of a more individualised approach, for example, as indicated in the recently published WHO guidelines. However, the information provided by the parties show that most guidelines for treatment of newly diagnosed hypertension still recommend treatment with a betablocker as the 1st line treatment.
18. In conclusion, whereas it is true that the indications and contraindications for the four classes of hypertension medicines partly overlap one another, it is nevertheless equally true that for a large proportion of hypertension patients the products in the various product classes will not be substitutable. The degree of substitutability is particularly low for patients who are already effectively medicated for their hypertension, since in those cases a switch will include risks for serious side-effects, as well as additional costs. There is also insufficient evidence to support the parties contention that the process of replacing the traditional step-by-step approach to treatment of hypertension by an individualised approach may reach a stage where all hypertension products would converge into one relevant market. It therefore cannot be excluded that a supplier with a dominant position in one of the four relevant ATC classes could exercise market power without being significantly restricted by the availability of other suppliers for the products in the three other ATC classes. For all the above reasons it is appropriate to assess the impact of the proposed concentration separately for betablockers, calcium antagonists, ACE inhibitors and angiotensin inhibitors.

Plain and combined hypertension medicines

19. Each of the four ATC-2 classes of hypertension medicines consist of two ATC-3 classes; plain and combined products. In each case the combined product contains, in addition to the main hypertensive agent of the respective class, one or more additional hypertensive agent(s). As the parties only have significant activities in plain and combined betablockers (C7A/B) and in combined calcium antagonists (C8B), it is not necessary for the purpose of this decision to assess whether plain and combined ACE inhibitors (C9A/B) and plain and combined angiotensin inhibitors (C9C/D) constitute separate markets.

Betablockers

20. The Commission has in a previous decision⁵ indicated that plain and combined betablockers might be treated as a single market. One of the main reasons for this finding was the existence of indications that the prescription of combined betablockers was in decline, and, consequently, that such products were being replaced by a corresponding combined dosage of plain betablockers and the other active ingredient. However, on the basis of figures provided by Astra and Zeneca this development appears to no longer be present on the market. Although the figures provided by the parties vary significantly between the Member States, they include clear indications that their combination products have a stronger development than their plain products. It is therefore appropriate to assess in detail whether plain and combined betablockers (C7A/B) should be considered to constitute separate markets.
21. Combined betablockers consist of a betablocking agent and a diuretic. Although medical cultures appear to vary between the Member States, many third parties have stated that combination products play a significant role in aiding patient compliance with their medication (easier to take one pill instead of several, the fixed dosage reduces the risk of the patient inadvertently taking the wrong level of the respective components). The parties' marketing material for their combination products also stress these advantages.
22. A characteristic of combined betablockers is that they are not recommended by clinical guidelines as 1st line treatment of hypertension. Instead, they are given to patients for which a betablocker continues to be the preferred therapeutic choice, but where a plain betablocker has proved insufficient to control the blood pressure. Combination betablockers are thus normally seen as 2nd line treatment. Moreover, if a patient has received combined betablockers, it appears that the medication is virtually never reversed to a plain betablocker.
23. Combined betablockers are a significantly smaller class of pharmaceuticals than their plain counterparts (according to the notification, the relationship is 1/6). This appears to have had as an effect that generic competition for combination products is virtually in-existent (although there are no blocking patents for either component). As the parties consider the existence of generic competition to be one of the key drivers of competition in pharmaceutical markets, this would appear to be a significant difference between plain and combined products, and may in combination with the parties' strong

⁵ See IV/M.737 - Ciba-Geigy/Sandoz of 17 July 1996.

position also in plain betablockers explain the below described diverging development of these two types of products.

24. Reimbursement prices are in most Member States set through a system of reference to prevailing price levels for similar drugs in other Member States. Over time, the introduction of generic products in a number of countries may therefore also have an impact on the price level in states where generics are not available. On the other hand, even if generics are available in one Member State, price levels may not decrease, as comparisons continue to be made with the situation in a number of countries where no generics are present. The effect of the absence of generics for combined betablockers can be seen from the fact that, at least in certain Member States, national price control mechanisms has had a significantly greater impact on the plain versions than on the combination products. Thus, the combined betablockers of the parties are up to twice as expensive as the plain versions in Germany and Italy. Significant price differences also exist in the Netherlands (>30%) and in Austria (>15%). In particular, it should be noted that the prices for combined betablockers significantly exceed the total price for the “free combination” of the respective ingredient (i.e. the betablocking agent and the diuretic).
25. Thus, from the supply point of view, there are significant differences between the situation in plain and combined betablockers. Whereas the parties, in most Member States, will face competition from a large number of branded and generic producers of the plain versions, there are very few alternative suppliers of the combined product.
26. The varying medical cultures in the Member States is another factor which indicates that plain and combined betablockers should be seen as separate markets. The statistics provided by the parties show that the plain products are widely prescribed in all Member States. Combined betablockers, however, are virtually not prescribed at all in Sweden, Norway or France, but are widely used in Germany, the UK and Italy (which correspond to [40-50%, 20-30% and 10-20%] respectively of total EEA consumption).
27. As can be seen from the above, Germany is by far the largest consumer of combined betablockers, which is explained by the existence of a clear clinical preference for these products. For the purposes of market definition it is therefore of particular importance that prices for the combined products in Germany historically have not been restricted by relative price changes in relation to the plain version of the product.
28. In conclusion, a combined betablocker cannot be substituted by a plain betablocker; Furthermore, although it is true that a combined betablocker is clinically substitutable to the “free combination” of equivalent doses of the respective components, the available information indicates that the possibility to prescribe a “free combination” of plain betablockers and diuretics have not restricted the development where combined betablockers are significantly more expensive than the combination of the respective ingredients. It therefore cannot be excluded that a supplier with a dominant position in combined betablockers could exercise market power without being significantly restricted by the availability of other suppliers for the respective components.
29. For all the above reasons it is appropriate to assess the impact of the proposed concentration separately for plain and combined betablockers.

Calcium antagonists

30. The relationship between plain and combined calcium antagonists (C8A/B) is both similar and dissimilar to that described above for betablockers.
31. Combined calcium antagonists consist of a calcium antagonist agent and a betablocking agent (and possibly also a diuretic). They are also indicated to increase patient compliance and are usually not given as 1st line treatment of hypertension. Furthermore, combined calcium antagonists account for an even smaller proportion of the overall prescription of calcium antagonists (1/25). Finally, also for these products, generic competition for combination products is virtually in-existent.
32. However, although IMS treats combined calcium antagonists as a separate ATC-3 level, WHO does not (instead the WHO include them together with various other combination products). Moreover, contrary to the situation with betablockers, a patient who is medicated with combined calcium antagonists may be reversed to a plain calcium antagonist, if the patient develops a contraindication to the betablocking agent. Another differing feature is that whereas all of Astra and Zeneca's main competitors in betablockers have developed a combination product, a number of large suppliers of plain calcium antagonists (Pfizer, Pharmacia & Upjohn and Warner Lambert) have not developed a combined calcium antagonist. Astra and Zeneca, on the other hand, are not strong in the sales of plain calcium antagonist, despite being important suppliers of the combined products.
33. More importantly, the parties have provided evidence that their combined calcium antagonists, despite being between 15-30% more expensive than the plain product in most Member States, have, ever since their introduction, been sold at a lower price than the "free combination" of the respective ingredients.
34. In conclusion, the available evidence indicates that combined calcium antagonists fulfil medical needs significantly different from those where the plain products are used, and, consequently, that they should not be seen as a single product market. However, it is not necessary to decide finally on this question, given the fact that the prices for combined calcium antagonists have been restricted by the "free combination".

Nitrates and nitrites

35. According to the parties, nitrates and nitrites (C1E) are long-established products used for providing symptomatic relief in case of an attack of angina pectoris. The active compound for those products have never been the subject of patent protection.

Anaesthetics

36. According to the parties, general (N1A) and local anaesthetics⁶ (N1B) form separate product markets by reasons of their mechanisms of action, clinical usage and separate ATC level 3 classification. The market investigation has confirmed the parties' view. Whilst general and local anaesthetics are both used to avoid the patient from feeling pain during surgical procedures, they operate in fundamentally different ways : general anaesthetics operate directly on the patient's central nervous system and achieve anaesthesia by inducing sedation, while local anaesthetics achieve pain relief by

⁶ In case IV/M. 323 Procordia/Erbamont of 29.4.1993 (point 20) the Commission has examined the market for local anaesthetics.

blocking the pain impulses from reaching the patient's central nervous system. Moreover, there is only very limited substitutability between general and local anaesthesia and where substitutability exists, the decision to use one or the other is typically determined by clinical factors. Whilst theoretically general anaesthesia could be used in all cases instead of local anaesthesia, the latter will typically be used when possible because of the greater risks involved in general anaesthesia and the fact that local anaesthesia is more patient friendly (as stress hormones are not released as they are in general anaesthesia). Local anaesthesia takes a little more planning than general anaesthesia, so that when anaesthesia needs to be induced rapidly the latter may have to be used in any event. In certain circumstances local anaesthesia cannot be used (e.g. above the uppermost thoracic vertebra), whereas in certain cases, the patient will typically want to be conscious (childbirth). Local anaesthesia also offers advantages in terms of post-surgical pain relief.

37. For the purposes of this decision general and local anaesthetics can therefore be considered as separate product markets.
38. With regard to local anaesthetics, the parties have stated that a further distinction could be drawn between longer acting local anaesthetics (used in major surgery, obstetrics and hospital analgesia) and short acting local anaesthetics (for office dental procedures and minor surgical procedures). However, for the purpose of the present case it is not necessary to decide whether the segment for longer acting local anaesthetics is to be considered as a product market, as this distinction would not materially affect the assessment of the notified concentration.

Respiratory

39. The third level of the EphMRA classification is composed of the following classes : B2-stimulants (R3A), xanthines (R3B), non-steroidal respiratory anti-inflammatories (R3C), corticoids (R3D), combinations of B2-stimulants with R3C (R3E), combinations of B2-stimulants with corticoids (R3F), anti-cholinergics – plain, and combinations with B2-stimulants (R3G), all other bronchodilators (R3H), devices for asthmatic conditions (R3I) and antileukotriene anti-asthmatics (R3J).
40. According to the parties, anti-asthma products may be very generally classified by reference to whether they are primarily for prophylactic, long-term management of the illness or for short-term symptomatic treatment, although the parties do not view this distinction as being of itself sufficient to support a separate market definition. Short-acting symptomatic treatments are aimed at reversing the broncho-constriction which results in the wheezing and breathlessness during an asthma-attack, without necessarily having any therapeutic effect on the underlying disease. Drugs used in prophylactic or long-term management may result in the patient being symptom-free for extended periods of time or having only minor symptoms that do not affect the patient's daily life.
41. The market investigation has shown that there is a clear differentiation between the objectives of therapy for these 2 types of treatment and that therefore competition occurs more within than across types. This distinction is meaningful from a medical point of view as it allows the treating physician to balance the need for primary intervention with short-acting relieving agents, with or without disease modification depending on the severity, and the appropriate addition of long-term symptom

controllers. Moreover, short-acting symptomatic drugs are used only on a needed basis whereas prophylactic and long-term drugs are taken regularly daily.

42. According to the parties, the group of anti-asthma products used for the prophylactic, long-term management of asthma should consist of the following classes : part of R3A (i. e. the long acting B2-stimulants salmeterol and formoterol), R3C, R3D and R3J as well as the combination long and short acting categories (R3E and R3F). Third parties, on the other hand, expressed doubts with regard to the inclusion of the combination products R3E and R3F in the group of anti-asthma products used for the prophylactic, long-term management of asthma. However, for the purpose of the present case, the definition of the relevant product market can be left open given that the operation does not lead to any problem of dominance in any of the alternative markets considered above.

Research & Development

43. In the pharmaceuticals industry, a full assessment of the competitive situation requires examination of the products which are not yet on the market but which are at an advanced stage of development (normally after extremely large sums of money have been invested). The potential for these products to enter into competition with other products which are either at the development stage or already on the market can be assessed only by reference to their characteristics and intended therapeutic use. In so doing, it must be borne in mind that research and development cannot as a rule be traded between pharmaceutical companies, but are rather intended primarily for the development of a company's own active substances and products. On the other hand, co-operation takes place in the research field between pharmaceutical companies and public and private research institutes and small biotechnology undertakings which, although they have the relevant know-how, do not themselves have the resources and facilities for the clinical testing that must be carried out prior to market authorisation and for the manufacture of the pharmaceuticals. The Commission has to look at R&D potential in terms of its importance for existing markets, but also for future markets.
44. In so far as research and development must be assessed in terms of its importance for future markets, the relevant product market often cannot be defined in the same clear-cut manner as in the case of existing markets. Market definition can be based on the existing ATC classes only if existing products are to be replaced. Otherwise, it must be guided primarily by the indications to which the future products are to be applied.

2. Relevant geographic markets

45. There are efforts at European standardisation as regards pharmaceutical products. The harmonisation of technical provisions within the Community and the entry into force of new registration procedures for medicines represent the completion of the program for the single market in terms of the scientific and technical requirements applying to medicines. Since the beginning of 1995, pharmaceutical companies have had the option (and indeed, in the case of biotechnology products, the obligation) of submitting an application for registration of a new medicine to the European Agency for the Evaluation of Medicinal Products, which then issues a recommendation to the Commission, whose decision is

binding on all Member States.⁷ At present, medicines can be registered in different Member States for different indications.

46. The sale of medicines is influenced by the administrative procedures or purchasing policies which the national health authorities have introduced in the Member States. Some countries exercise a direct or indirect influence on prices, and there are different levels of reimbursement by the social security system for different categories of medicines. For this reason, the prices for medicinal products may differ from one Member State to another. In addition, there are far-reaching differences in terms of brand and pack-size strategies and in distribution systems. These differences lead to national market characteristics.
47. The markets for pharmaceutical products have therefore been defined as national markets in the decisions hitherto adopted by the Commission. As indicated above, significant differences, in terms of prices, marketing and medical cultures, exist between the Member States for the products affected by the concentration. The markets affected by the concentration can thus be regarded as national.
48. To the extent that future product markets can be considered on the basis of research and development in particular areas, the said national restrictions do not have the same degree of effectiveness. A characteristic of future markets is that no products have yet been registered. Because research and development is normally global, the consideration of future markets should therefore focus on the territory of the Community at least and possibly on world-wide markets.

3. Assessment

49. The concentration does not lead to any affected markets outside the field of pharmaceuticals. Within that field, a detailed assessment is only necessary for the markets for plain and combined betablockers (C7A/B), combined calcium antagonists (C8B) and local anaesthetics (N1B), since there is no overlap between the parties' activities in other areas, or their combined market share is below 25%.
50. The main overlap of the parties' activities is in the field of drugs for the treatment of hypertension. In 1997 the total sales value for hypertension medicines in the EEA was about EUR 6 billion. The parties will have 25% of their combined pharmaceutical turnover in the field of hypertension medicines, with the bulk of those activities relating to plain and combined betablockers (C7A/B) and combined calcium antagonists (C8B).

1. Plain Betablockers ATC C7

51. In 1997 the total sales of plain betablockers in the EEA reached a value of EUR 875 million. At this aggregated level, Astra and Zeneca achieved sales of EUR [...] and EUR [...] respectively. Thus, their combined sales was EUR [...], representing [<40%] of all sales. On this level the largest competitors are Rhone-Poulenc [<20%], Merck [<10%] and Bristol Meyers Squibb (BMS) [<10%].

⁷ See Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products, O.J. NO L214.

52. Plain betablockers have been on the market since 1965, and a relatively large number of active ingredients have since then been developed by various pharmaceutical companies. According to information submitted by third parties, about 15% of all sales in 1997 of plain betablockers in the EEA was made up by generic products.
53. Both Astra and Zeneca were among the first actively to enter this field, and the active ingredients developed by them (Astra - *metoprolol* and *alprenolol*, Zeneca – *atenolol* and *propranolol*) remains the best selling substances on the market. Each of the parties sell plain betablockers under a number of trademarks in various parts of the EEA. Astra has at least 13 such trade marks, although the majority of its sales relate to the Seloken and Seloken-Zok brands (which are called Beloc and Beloc-Zoc in Austria and Germany). Zeneca has at least 8 trade marks, the main ones being Tenormin and Inderal.
54. As the patents have expired for most plain betablockers, generic alternatives exist for most products (including the parties' main substances). However, Astra has a formulation patent for a slow-release, once a day version (Seloken-Zoc) of its largest selling product (Seloken). The patented formulation of the product has captured large part of its sales in some Member States (The Nordic countries, BeNeLux and Germany), and is sold at a significant premium (generally +50%) compared to the un-patented formulation.
55. Astra and Zeneca have significant sales of plain betablockers throughout the EEA, and the concentration would result in affected markets in all Member States. However, for the majority of Member States where they jointly would become market leaders, the overlap between the parties' respective activities is relatively limited (<4%). Therefore, further analysis of the markets for plain betablockers is only necessary for Sweden, where Astra and Zeneca would achieve combined market shares (in value) of [<80% (<70% + <20%)], Norway where they will achieve [<70% (<50% + <20%)], Belgium (total of [<50% (<20% + <40%)]) and the Netherlands (total of [<50% (<40% + <10%)]).
56. The next largest competitors in Sweden would be Merck with [<20%] and SmithKline Beecham (SKB) with [<10%]. In Norway, the competitors would be BMS with [<20%] and SKB and Pharmacia Upjohn, each with [<10%]. In Belgium, the main competitors would be American Home Products (AHP), Merck and SKB with [<20%, <20% and <20%] respectively. Finally in the Netherlands, the main competitors would be OPG Group [(<20%)], Novartis [(<10%)] and Brocaef [(<10%)].
57. In addition, the parties have indicated that strong competition will remain in the form of generic products. In the pharmaceutical industry, the impact of generic competition can normally be seen in the difference between the market share of branded products expressed in value and volume terms. If the parties' market shares are measured in volume terms for the four relevant countries, the result is for Belgium and the Netherlands that their combined market share is below 40%. However, for Sweden and Norway, the impact of using volume based data is limited. Thus in Sweden the parties would still attain combined market shares of [<80% (<40% + <40%)] and in Norway they would attain [<60% (<30% + <40%)].
58. As can be seen from the above, Zeneca's position in Sweden and Norway is significantly stronger in volume terms than in value terms. This is consistent with the results of the investigation, which indicates that Zeneca has been actively promoting its

plain betablockers (Tenormin) as a competitive alternative to Astra's largest selling betablocker in those countries.

59. Moreover, the data submitted by the parties indicates that Astra's prices for plain betablockers in Sweden and Norway are higher than their prices in the other Member States (although some variation exists with different pack-sizes and strengths). Zeneca, on the other hand, has had its lowest European prices in Sweden and Norway. Prices in Belgium and the Netherlands are on the European average for both companies. Moreover, the parties have submitted evidence indicating that prices for Astra's best selling plain betablocker has decreased in Belgium and, in particular, in the Netherlands since the launch of the product. For Sweden and Norway, the price for the same product has increased over the period.
60. In conclusion, as shown above, Astra and Zeneca has a combined market share at the EEA level of [$<40\%$]. Although none of their competitors have a share exceeding 10% at this level, it is clear that there are a number of large pharmaceutical companies that are active on a significant scale in various parts of the EEA. Thus, the horizontal overlaps of significance are confined to the Swedish, Norwegian, Belgian and Dutch markets.
61. In Belgium, the merged entity will remain subject to competition from three multi-national pharmaceutical producers (AHP, Merck and SKB), each with at least 10% of the market. In addition, the parties' market shares are below 40% measured in volume, which together with the available price data indicates that the concentration will not create or strengthen a dominant position in that country.
62. In the Netherlands, the overlap between the parties is relatively small, as Zeneca only has a market share of [$<10\%$]. Furthermore, although none of the multi-national pharmaceutical producers has a market share exceeding 10%, the available price data indicates that these competitors and generic competition have resulted in a significant price decrease since the launch of the product. Thus, the concentration will not create or strengthen a dominant position for plain betablockers in the Netherlands.
63. However, for Sweden and Norway the parties would attain value based market shares of [$<80\%$] and [$<70\%$] respectively. Moreover, the market shares would be almost at the same level if measured in volume terms, which, together with the fact that Astra has been able to charge significantly higher prices than in other Member States, provides an indication that competition from other producers (including generic products) and/or imports have not significantly restricted the company's market behaviour. Nor have the parties demonstrated that their future behaviour would be significantly restricted in the future. Furthermore, there are clear indications that Zeneca, in these countries, until now has been Astra's main competitor in plain betablockers. For all of these reasons, insofar as the Swedish and Norwegian markets for plain betablockers are concerned, the proposed concentration raises serious doubts as to the compatibility with the common market and the functioning of the EEA agreement.

2. Combined betablockers C7B

64. In 1997 the total sales of combined betablockers in the EEA reached a value of EUR [...]. At this aggregated level, Astra and Zeneca achieved sales of EUR [...] and EUR [...] respectively. Thus, their combined sales were EUR [...], representing [$<60\%$] of

all sales. On this level the largest competitors are Novartis [($<20\%$)], Merck [($<10\%$)] and Hoechst [($<10\%$)].

65. As stated above, combined betablockers consist of a betablocking agent, together with a diuretic, and are given as a 2nd line treatment to patients for whom a betablocking treatment is indicated, but where this has proved insufficient. The combined betablockers have also been on the market for about 30 years. They contain the same active betablocking ingredients as the plain versions. According to information submitted by third parties, between 5-8% of all sales in 1997 of combined betablockers in the EEA was made up by generic products.
66. In the EEA, Astra markets at least 10 combined betablockers, which are based on its *metoprolol* substance, combined with one or two generic diuretic substances. Zeneca markets at least 11 combined betablockers, based on either of its two betablocking substances (*atenolol* and *propranolol*), combined with one or two generic diuretic substances. remains the best selling substances on the market. The parties' most widely sold products for Astra are Beloc Comb and Seloken Comp, and, for Zeneca, Tenoretic and Inderetic.
67. As has been described above, there are significant differences in the medical cultures of the various Member States. Combined betablockers, are virtually not prescribed at all in Sweden, Norway or France, but are widely used in Germany, the UK and Italy. Astra and Zeneca have significant sales of combined betablockers in all Member States where the products are sold (except France, where total sales are EUR [...]). There is significant overlap between the parties' activities in most Member States, and the parties' combined market shares are between [40-80]% in all countries (except Spain and the Netherlands where it would be [$<40\%$]). In three countries, Finland, Greece and Portugal, there is no overlap, but one of the parties alone has a market share between [60-100%]. Therefore, given that the parties are the two main suppliers of combined betablockers in the EEA, the effect of the concentration is largely similar in Finland, Greece and Portugal, in that it removes the most likely source of potential competition.
68. The parties' combined market share would be at least double that of the next largest competitor in Member States except Spain (where it would be 33% larger). Astra/Zeneca's market share would be more than three times that of the following competitor in Austria, Belgium, Germany, Greece, Ireland, Portugal and the UK.
69. According to the figures provided by the parties, Zeneca charges significantly higher prices for their combined betablockers in the UK, where it alone has a market share exceeding 70%, than in all other Member States (except Germany). Moreover, both Astra and Zeneca's consistently charge their highest prices for combined betablockers in Germany, where they would have combined market shares of [$<50\%$ ($<30\% + <20\%$)]. In that respect it should be noted that Germany is, by far, the largest market in Europe (47% of all sales), and has the largest number of active suppliers of all Member States.
70. It should also be noted that the downward pressure on prices from national reimbursement schemes on combined betablockers has been significantly lower than in the case of plain betablockers. This has, for example, resulted in a situation where the parties prices for combined betablockers are now about twice as expensive as the plain versions in Germany (although they were more or less at the same level 20 years ago),

and clearly exceeding the total price for the “free combination” of the betablocking and diuretic agent.

71. The parties have submitted that this is due to the fact that national authorities are less interested in revising the prices for combined betablockers, since they are a comparatively smaller class of pharmaceuticals. Whereas it is likely that part of the explanation for the diverging trends lies in the reason submitted by the parties, it nevertheless should be recognised that for a national authority to be in a position to revise prices for a needed product, a minimum degree of competition must exist from products that are considered clinically substitutable. Consequently, it is likely that the parties, following the concentration, would be in an even better position to resist such downward revisions of the prices by the authorities of the Member States. Finally, as a consequence of the system of reference pricing for reimbursement (employed by most Member States), an increase in the price levels in the Member States where the concentration leads to an overlap, may as an indirect effect increase the price levels also in other Member States.
72. In conclusion, the parties would attain market shares indicative of dominance in most Member States, and in particular in Austria, Belgium, Germany, Greece, Ireland, Portugal and the UK. Apart from the high market shares, the concerns are aggravated by figures provided by the parties, showing a considerably lower downward pressure on prices by national authorities for the products where they have historically had high market shares, the existing pricing evidence from the UK and Germany, as well as the apparent weakness of existing competition (including generic products). The proposed concentration therefore raises serious doubts as to the compatibility with the common market and the functioning of the EEA agreement also in relation to combined betablockers.

3. Combined calcium antagonists ATC C8B

73. The parties are not significant producers of plain calcium antagonists. In fact, the concentration does not create an affected market for these products in any Member States. Instead, the market leaders are Pfizer and Bayer, each with about [<30%] of EEA sales. The parties, however, have significant activities on the markets for combined calcium antagonists. These products are made up by a calcium antagonists combined with a betablocking agent (and possibly a diuretic).
74. In 1997 the total sales of combined calcium antagonists in the EEA reached a value of EUR [...]. At this aggregated level, Astra and Zeneca achieved sales of EUR [...] and EUR [...] respectively. Thus, their combined sales were EUR [...], representing [<80%] of all sales. On this level the largest competitors are Bayer [<10%], Novartis [<10%] and Procter & Gamble [<10%]. According to information submitted by third parties, there are virtually no generic products on the market.
75. In the EEA, Astra markets at least 4 combined calcium antagonists, which are based on its *metoprolol* substance, combined with either *felodipine* (Logimax and Mobloc) or *nifedipine* (Plendil and Belnif). Zeneca markets at least 3 combined betablockers, based on its *atenolol*, combined with *nifedipine* (Nif-Ten, Tenif and Tenordate).
76. As in the case of combined betablockers, there are significant differences in the medical cultures of the various Member States, and, therefore, the use of combined calcium antagonists. Accordingly the concentration only leads to an overlap in four Member

States: Belgium, Finland, France and Germany. In each of those countries there is significant overlap between the parties' activities, and combined the parties account for two thirds or more of the total sales in each country.

77. The parties have however submitted evidence that, contrary to the situation with combined betablockers, the sales of combined calcium antagonists are restricted by competition from the sale of the "free combination" of respective ingredients. This is true, even in the case of Astra's Logimax product, which is still protected by a formulation patent. Logimax is sold in Belgium, Finland, France and Germany at a price which is between 8-28% lower than the "free combination". Given that combination medication provides clinical advantages in terms of patient compliance it is not surprising that such products are attractive, in particular when they are sold at a lower price than the "free combination".
78. However, on the basis of the apparent restriction to charge a premium price for the combination products, and since the parties do not have a dominant or, in the case of plain calcium antagonists, even strong position in any of the respective ingredients of the "free combination", the concentration will not provide the parties with any market power in the sales of combined calcium antagonists. It can therefore be concluded that the proposed concentration does not raise serious doubts as to the compatibility with the common market and the functioning of the EEA agreement in relation to the sales of combined calcium antagonists.

4. Nitrates and nitrites (C1E)

79. With regard to nitrates and nitrites an affected market arises only in the UK where the combined market share will be <40% (Astra [<40%], Zeneca [<10%]). The competitors are Schwarz Pharma [<20%]), Novartis [<10%]), Merck KGAA [<10%]) and there are unbranded generics [<20%]).
80. The investigation has provided no indications that the operation will give rise to competitive concerns on the market for nitrates and nitrites in the UK.

5. Anaesthetics

Local anaesthetics (N1B)

81. In 1997 the total sales of local anaesthetics reached a value of EUR [...] in the world and EUR [...] in the EEA. At a world-wide level Astra achieved sales of EUR [...], representing [<70%] of all sales. Also in the EEA, Astra is by far the market leader with market shares of [<60%] in Germany, [<70%] in Italy and [<60%] in the UK. These are the countries where IMS collects data not only from the pharmacies but also from hospital panels. Since most anaesthetics tend to be used in hospitals, it is not possible to rely on the data obtained from pharmacies only. However, the parties consider that the position in these 3 countries is broadly representative of the position throughout the EEA. Astra's most important competitors for local anaesthetics in the EEA are Baxter International [<10%), Klosterfrau [<10%) and Rhône-Poulenc [<10%).
82. The by far most widely used longer acting local anaesthetic is Astra's *bupivacaine*, which is already long off patent. Recently Astra has introduced *ropivacaine* (Naropin), another longer acting local anaesthetic, which has less cardiac and central nervous system side-effects than *bupivacaine* and is sold at a premium price compared to

bupivacaine. Except for Astra's recent launch of *ropivacaine*, the market for local anaesthetics is characterised by a lack of introduction of new products.

83. Until 1998 Zeneca had neither actual nor potential presence on the market for local anaesthetics. However, in March 1998 Zeneca concluded an exclusive world-wide (except for Japan) agreement to license-in *Chirocaine* (*levobupivacaine*), a longer acting local anaesthetic. *Chirocaine* is a compound derived from *bupivacaine*⁸ and developed by Chiroscience PLC, a British biotech company. Chiroscience claims that *Chirocaine*, has major safety benefits compared to the original *bupivacaine*. In December 1998 regulatory approval for *Chirocaine* was granted by the Swedish MPA, which can be submitted to the other Member States for mutual recognition.
84. Prima facie Astra's high market share, the lack of introduction of new products and the absence of strong competitors gives rise to a presumption of a pre-existing dominant position. It can be concluded that the exclusive license for *Chirocaine* would strengthen the parties' position on the market for local anaesthetics (and on the segment for longer acting local anaesthetics) by removing the only likely source of competition, as it is doubtful whether the parties would be willing to launch and to support a product that will compete strongly with their existing products. The proposed concentration therefore raises serious doubts as to its compatibility with the common market and the functioning of the EEA agreement also in relation to local anaesthetics.

General anaesthetics (N1A)

85. In 1997 the total sales of general anaesthetics in the world reached a value of EUR [...]. At this aggregated level Zeneca achieved sales of EUR [...], representing [<40%] of all sales. Zeneca is the market leader (Germany [<40%], Italy [<40%] and UK [<40%]). Zeneca's most important competitors in the EEA are Abbott Laboratories [(<30%)], Roche [(<20%)] and Johnson & Johnson [(<20%)]. Astra has no presence in this market. and therefore, the market for general anaesthesia does not constitute an affected market.

5. Respiratory

86. Astra has a number of well-established anti-asthma products in R3A, R3B and R3D as well as asthma devices (R3I). Until the recent development of *Accolate*, a leucotriene receptor antagonist (LTRA), Zeneca had no anti-asthma products. According to Zeneca's sales data *Accolate* is currently available in Belgium, Denmark, Finland, Ireland, Italy, the UK and Norway. LTRA's are part of R3J and are a new class of compounds that has been recently developed for long-term treatment of mild to moderate asthma. They are distinguished from all existing anti-asthmatic products by way of their operation and are unusual in being administered orally.
87. In 1997 the total sales of anti-asthmatic products (EphMRA level 2 - R3) in the EEA reached a value of EUR [...]. At this aggregated level, Astra and Zeneca achieved sales of EUR [...] and EUR [...] respectively. Thus, their combined sales represent [<30% (<30% + <10%)] of all sales. On this level the largest competitors are Glaxo Wellcome

⁸ It is the single left isomer of *bupivacaine*, which is intended to have better side-effect characteristics.

[(<40%)], Boehringer Ingelheim [(<10%)], Novartis [(<10%)] and Rhône-Poulenc [(<10%)]. Also on a national level, the overlap between the parties will be insignificant.

88. At the third level of the EphMRA classification no overlap occurs. However, on the segment for the long-term management of asthma - where Astra holds a stronger position than on the segment for short-term management of asthma – and where the overlap occurs with Zeneca's *Accolate*, the parties will have a combined share of sales of [<30% (<30% + <10%)]⁹ on an EEA level whereas Glaxo Wellcome holds a share of sales of [<50%], the other competitors being Novartis [(<10%)] and Rhône-Poulenc [(<10%)]. On a national level the parties' share of sales in the first semester of 1998 was in all Member States - except for Sweden and Belgium - equal or <30%. In Sweden Astra's share of sales was [<40%] (Astra only, as *Accolate* is not yet available in Sweden). The strongest competitor is Glaxo Wellcome with [<40%] share of sales, followed by Cross Pharma [(<20%)] and Rhône-Poulenc [(<10%)]. In Belgium Astra had a share of sales of [<50%]¹⁰ whereas Glaxo Wellcome had [<50%], followed by Rhône-Poulenc [(<10%)] and Novartis [(<10%)]. Moreover, Zeneca's *Accolate* will face strong competition from Merck's *Singulair*, another LTRA, which has been successfully marketed in the USA and which is – according to IMS data - already sold in Denmark, Finland, Germany, Spain, Sweden and the United Kingdom. Abbott Laboratories has developed *Zyflo*, a 5-lipoxygenase inhibitor, which is also part R3J and other companies have anti-leukotrienes under development.
89. For these reasons, the operation will not give rise to any problems of dominance on any of the alternative respiratory markets (and segments) considered above.

7. Conclusion

90. On the basis of the above described circumstances, the concentration, as originally notified, gave rise to concerns about potential dominance, as set out above, and would warrant the opening of proceedings in accordance with Article 6(1)(c).

V. MODIFICATIONS TO THE PROPOSAL

91. In order to remove the concerns raised by the operation, not only in relation to the notification made to the European Commission but also following consultations with other competition authorities, Astra and Zeneca submitted on 08.02.1999 a proposal for modification of the operation in accordance with the terms of Article 6(2) of the ECMR. This proposal involved an undertaking given by Zeneca relating to its license for the long-acting local anaesthetic Chirocaine, and to remove the Commission's doubts with regard to plain and combination betablockers.
92. According to the Chirocaine commitment, Zeneca will, at the latest within [...] of the Commission's decision, agree with Chiroscience on the reversal of all arrangements relating to Chirocaine (surrender of licence, trademark, know-how etc.). In order to maintain the viability of the product, Zeneca will, during an initial [...] transitional period, continue to support the development and launch of Chirocaine. There will be

⁹ Data for the first semester of 1998.

¹⁰ Although according to Zeneca's internal sales data, *Accolate* is already sold in Belgium, Zeneca's sales of *Accolate* do not appear in the IMS data for Belgium.

“ring-fencing arrangements” to ensure that non-public information concerning the product is restricted to the Zeneca personnel involved in the project. Finally, an independent trustee will be appointed to oversee Zeneca’s adherence to the transitional arrangements, including the “ring-fencing obligations”. These measures will guarantee that the prospective launch of Chirocaine as a competing product on the markets for local anaesthetics is not jeopardised by the notified concentration. It will also remove the overlap between the parties’ activities in local anaesthetics.

93. For plain betablockers, the parties have undertaken to, within at most [...] of the Commission’s decision, grant a viable and independent third party exclusive distribution rights for Tenormin in Sweden and Norway for a period of at least 10 years. Tenormin represents more than 70% of Zeneca’s sales in those countries. An independent trustee will be appointed to report to the Commission on the price arrangements to be adopted in the distribution agreement and on the identity and characteristics of potential distributors identified by AstraZeneca.
94. For combined betablockers, the parties have undertaken to, within at most [...] of the Commission’s decision, divest Astra’s entire interest in dual combination betablockers throughout the EEA to a viable and independent third party. As AstraZeneca will retain rights to these products outside the EEA, the divestiture will be effected by the grant of an indefinite and exclusive trademark licence, granting of the necessary patent rights and a supply agreement, which will last at least as long as the patent period for *metoprolol Zok*. Once implemented, this will remove the overlap between the parties’ activities in combined betablockers. An independent trustee will be appointed to report to the Commission on the price arrangements to be adopted in the distribution agreement and on the identity and characteristics of potential purchasers identified by AstraZeneca.
95. The Commission conducted a market test to verify that the proposed undertakings were sufficient to remove the competitive concerns raised by this operation. In view of the market test certain modifications to the proposed undertakings were submitted on 18.02.1999. The final divestment proposal is set out in more detail in the text of the modification as accepted, which is annexed hereto and forms an integral part of this Decision.

VI. CONCLUSION

96. The Commission has concluded that these undertakings are sufficient to address the competition concerns raised by this concentration. Accordingly it has decided not to oppose the notified operation and to declare it compatible with the common market and with the functioning of the EEA Agreement. This decision is adopted in application of Article 6 (1)(b) of Council Regulation (EEC) No.4064/89, as amended by Regulation No.1310/97, and of Article 57 of the EEA Agreement.

For the Commission,

CASE NO. IV/M.1403

ASTRA/ZENECA

COMMITMENTS TO THE EUROPEAN COMMISSION PURSUANT TO ARTICLE 6(2) OF
COUNCIL REGULATION (EEC) No 4064/89

Pursuant to Article 6(2) of Council Regulation (EEC) No. 4064/89 (as amended) (the *Regulation*), Zeneca Group PLC for and on behalf of its affiliates, and following its merger (the *Merger*) with Astra AB (*Astra*) to be known as AstraZeneca, (*Zeneca*) hereby gives the commitments set out below to the Commission of the European Communities (the *Commission*) in order to achieve clearance of the Merger.

1. Prior to, or at the latest within [...] after, the Commission having issued a decision pursuant to Article 6 (1) (b) of the Regulation (the *Decision*) clearing the Merger, Zeneca undertakes to enter into one or more agreements to take effect immediately on their execution (the *Agreements*) with Chiroscience Group plc (*Chiroscience*) and/or its wholly-owned subsidiary, Darwin Discovery Limited (*Darwin*), and/or any of Chiroscience's or Darwin's respective affiliates providing for:

- (a) the surrender to Chiroscience and/or Darwin and/or any of Chiroscience's or Darwin's respective affiliates of Zeneca Limited's world-wide (other than Japan) exclusive licence (the *Licence*) to make, have made, use, import, sell or otherwise exploit "Chirocaine";
- (b) the reassignment of the trademark "Chirocaine" to Chiroscience and/or Darwin and/or any of Chiroscience's or Darwin's respective affiliates;
- (c) the transfer or return to Chiroscience and/or Darwin and/or any of Chiroscience's or Darwin's respective affiliates of all know-how, information and other materials that have been received or generated by Zeneca relating to the actual or proposed development, promotion or sale of "Chirocaine" in its role as licensee of "Chirocaine" (the *Information*). The Agreements will provide that:
 - (i) Chiroscience will be entitled to request copies of the Information from Zeneca as from the date of execution of the Agreements until the expiry of the Transitional Period as defined in paragraph 3(a) below;
 - (ii) Zeneca will be obliged to return or transfer to Chiroscience all Information as and when Zeneca no longer requires such Information in order to perform the arrangements set out in paragraph 3(a) below and in any event on the expiry of the Transitional Period;
 - (iii) all intellectual property rights (including rights in the Information) relating to "Chirocaine" which are generated by Zeneca in the performance of the Agreements or in connection with the performance of the arrangements set out in paragraph 3(a) below shall be transferred to Chiroscience as and when Zeneca no longer requires such rights in order to perform the arrangements set out in paragraph 3(a) below and in any event on the expiry of the Transitional Period;

- (d) the termination of the agreement between Zeneca and Chiroscience [...].
2. Zeneca undertakes to retain its minority shareholding in Chiroscience until [...] and will comply with the existing obligations agreed between Chiroscience and Zeneca in relation to any disposal of such shares after such date.
3. In connection with the Agreements, and in order to maintain and develop as fully as possible the marketability and viability of “Chirocaine”, Zeneca also undertakes to:
- (a) undertake and/or to fund arrangements for regulatory, manufacturing, commercial and clinical trials support of “Chirocaine” as may be agreed with Chiroscience for an appropriate period of time to be agreed with Chiroscience which may be either until the completion of the relevant arrangements or until the selection by Chiroscience of a new licensee for “Chirocaine” or thereafter, but which period shall be [...] from the date of the Decision or such longer period not exceeding [...] from the date of the Decision as Chiroscience may request and the Commission (based on the advice of the trustee) approves as being reasonably necessary for the completion of the relevant arrangement (the *Transitional Period*);
 - (b) introduce internal communication arrangements to ensure that no non-public information relating to “Chirocaine” (including, for the avoidance of doubt, the Information) from those Zeneca employees hitherto involved with “Chirocaine” or providing the support referred to in paragraph 3(a) above or otherwise involved in the performance of the Agreements is supplied to any other Zeneca employee or any Astra employee or any unauthorised third party other than those Zeneca employees who strictly need to know the same as agreed with Chiroscience; and
 - (c) refrain (and procure that its affiliates and subsidiaries from time to time will refrain) from using or disclosing any non-public information described in paragraph 3(b) above.
4. As soon as reasonably practicable, and in any event within [...] from the date of the execution of the Agreements, Zeneca undertakes to appoint an independent trustee acceptable to Chiroscience to monitor compliance with paragraphs 1 and 3 above. Such trustee shall be approved by the Commission and shall be mandated to monitor and advise the Commission as to the adequacy of the arrangements adopted in compliance with paragraphs 1 and 3 above, and to provide the Commission with written reports each month on the efficacy of those arrangements.

5. Completion of the transactions envisaged by the above commitments will be subject to the Commission having issued the Decision.

ZENECA GROUP PLC

Case IV/M.1403 Astra/Zeneca**Plain betablockers (C7A)**

The Commission currently has concerns in relation to Sweden and Norway. In relation to these two countries:

- (1) AstraZeneca will grant to a viable and independent third party approved for the purpose by the Commission rights to distribute, on an exclusive arm's length basis, Zeneca's leading plain betablocker product, Tenormin. The terms of the distribution agreement will be designed to make the distributor a viable competitor. Accordingly, AstraZeneca will supply the product at a price which will ensure that the third party distributor can compete effectively in the market. The third party distributor will be responsible for any price negotiations with the authorities. The initial term of the agreement will be 10 years. This term will be automatically renewable, save in the event that the Commission determines, at the request of AstraZeneca, that the third party distribution arrangement is no longer required in the light of substantial changes in market conditions.
- (2) Within [...] from adoption by the Commission of a decision under Article 6(1)(b), AstraZeneca will appoint a Trustee to report to the Commission on the suitability of the transfer price arrangements to be adopted in the distribution agreement and on the identity and characteristics of the potential distributors identified by AstraZeneca.
- (3) The arrangement will be entered into as soon as practicable following completion of the AstraZeneca merger and in any event within [...] of the date of the Commission's decision clearing the merger. AstraZeneca will report bi-monthly to the Commission on progress of the negotiations. If, at the end of the period of [...] (or such extension to that period as may be agreed with the Commission), no suitable arrangement has been concluded, AstraZeneca will grant to a Trustee an irrevocable mandate to negotiate and conclude the arrangement described at paragraph (1) of this letter.

Combination betablockers (C7B)

- (4) The parties propose to divest their interests in Astra's current range of dual combination betablockers throughout the EEA, under arrangements as described below. They will however retain the triple combination product Treloc, currently sold in Germany and Austria. The business to be divested comprises Astra's betablocker *metoprolol* sold in fixed combination with a diuretic product. The product is currently sold in Austria, Belgium, Denmark, Finland, Germany, Ireland, Italy, the Netherlands, Spain and the United Kingdom. The product is primarily sold under the Selokomb/Beloc Comp/Seloken retard plus trademarks.

- (5) The Commission will be aware that AstraZeneca retains rights to these combination products outside the Community and retains rights to the related plain betablocker products also within the Community which are sold under the proximate ‘Selo’ prefix trademarks. Accordingly, for quality control and product safety purposes, the divestiture will take the following form:
- (a) Divestiture to a viable and independent third party purchaser approved for the purpose by the Commission;
 - (b) Grant of an exclusive trademark licence under the principal trademarks currently used by Astra for the products concerned in the relevant country, for an indefinite period;
 - (c) Arrangements under which AstraZeneca will continue to supply the purchaser with the licensee’s requirements of fully formulated products produced by AstraZeneca. Pricing will be at a level designed to ensure that the purchaser will be a viable competitor in the market. These supply arrangements will be for a minimum of 6 years (which period coincides with the expiry of the patent period for the *metoprolol* Zok form included in the product in most territories). AstraZeneca will negotiate suitable arrangements to ensure the ongoing sourcing of products by the purchaser and the purchaser’s continuing ability to compete effectively in the market at the end of the supply agreement;
 - (d) In so far as necessary, AstraZeneca will grant any necessary patent rights to permit sale of the products within the EEA; and
 - (e) Within [...] from adoption by the Commission of a decision under Article 6(1)(b), AstraZeneca will appoint a Trustee to report to the Commission on the suitability of the transfer price arrangements to be adopted in the supply agreement, and on the identity and characteristics of the potential purchasers identified by AstraZeneca.
- (6) The arrangements described above will be entered into as soon as practicable following completion of the merger but in any event within [...] following Commission clearance of the merger. AstraZeneca will report to the Commission bi-monthly on the progress of the negotiations. If, at the end of the period of [...] (or such extension to that period as may be agreed with the Commission), no suitable arrangements have been concluded, AstraZeneca will grant to a Trustee an irrevocable mandate to negotiate and conclude the arrangements described at paragraphs (4) and (5) of this letter.

For Zeneca Group PLC

For Astra AB