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***Case No COMP/M.5253 -
SANOFI-AVENTIS /
ZENTIVA***

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

Article 6(2) in conjunction with 6(2)
NON-OPPOSITION
Date: 04/02/2009

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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 04.02.2009

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In the published version of this decision, some information has been omitted pursuant to Article 17(2) of Council Regulation (EC) No 139/2004 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 Where possible the information omitted has been replaced by ranges of figures or a general description.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
in conjunction with ARTICLE 6(2)

To the Notifying Party:

Dear Sir/Madam,

**Subject: Case No COMP/M.5253 - SANOFI-AVENTIS/ ZENTIVA
Notification of 5 September 2008, as amended by additional submission of
5 December 2008, pursuant to Article 4 of Council Regulation
No 139/2004¹**

1. On 5 September 2008, the Commission received a notification of a proposed concentration pursuant to Article 4 of Council Regulation (EC) No 139/2004 (the "EC Merger Regulation" or "ECMR") by which the undertaking Sanofi-Aventis Europe ("Sanofi-Aventis", France, or the "Notifying Party") acquires within the meaning of Article 3(1)(b) of the Council Regulation control of the whole of the undertaking Zentiva N.V. ("Zentiva", The Netherlands²), collectively "the Parties", by way of purchase of shares via a voluntary public offer. Prior to notifying the transaction, Sanofi-Aventis held 24.88% of the issued share capital and voting rights of Zentiva.
2. On 2 October 2008, the Commission wrote to the Notifying Party on the basis of Article 5(2) of Commission Regulation 802/2004 (the "Implementing Regulation")³ declaring that the original notification had been incomplete.

¹ OJ L 24, 29.1.2004 p. 1.

² Zentiva is a company incorporated in the Netherlands, with its operational headquarters and primary stock listing in Prague, Czech Republic.

³ OJ L 133, 30.4.2004, p.1.

3. On 5 December 2008, the Commission received a further submission from Sanofi-Aventis completing the original submission. In accordance with Article 5(2) of the Implementing Regulation, the notification therefore became effective only from that date.

I. THE PARTIES

4. Sanofi-Aventis is a global pharmaceutical group engaged in the research, development, manufacture and marketing of healthcare products. The business of Sanofi-Aventis includes two main activities (i.) pharmaceuticals and (ii.) human vaccines. In the pharmaceutical sector Sanofi-Aventis specialises in six therapeutic areas: thrombosis, cardiovascular, metabolic disorders, oncology, central nervous systems and internal medicine. Sanofi-Aventis is therefore primarily an innovator pharmaceutical company and it is active throughout the EU and globally.
5. Zentiva is a pharmaceutical group active in the Central and Eastern Europe region focused on the development, manufacturing and marketing of branded generic pharmaceutical products. Zentiva focuses on the treatment of cardiovascular diseases, pain, diseases of the central nervous system, alimentary and genito-urinary tract diseases and inflammatory conditions. In total, the company is active in nine EU Member States, in all of which Sanofi-Aventis is also active, namely Bulgaria, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Romania and the Slovak Republic (the "Affected Countries").

II. CONCENTRATION

6. Sanofi-Aventis, through its subsidiary Sanofi-Aventis Europe, published a voluntary public bid for all the issued ordinary shares and global depository shares of Zentiva on 11 July 2008. This operation would constitute an acquisition of sole control.
7. On 22 September 2008, Sanofi-Aventis increased its offer price in return for a commitment on the part of Zentiva's management to recommend the bid to shareholders.
8. Sanofi-Aventis' offer – which has not lapsed - is conditional *inter alia* upon merger clearance by the Commission.
9. The transaction therefore constitutes a concentration within the meaning of Article 3(1)(b) of the Merger Regulation

III. COMMUNITY DIMENSION

10. The transaction has a Community dimension pursuant to article 1(2) of the Merger Regulation. The parties have a combined aggregate worldwide turnover in excess of EUR 5,000 million (Sanofi-Aventis EUR 28,052 million, Zentiva EUR 600 million) and a Community-wide turnover in excess of EUR 250 million (Sanofi-Aventis [...], Zentiva

[...]).⁴ Neither of the parties realises more than two-thirds of its Community-wide turnover in one and the same Member State.

11. The notified operation therefore has a Community dimension within the meaning of Article 1(2) of the EC Merger Regulation.

IV. RELEVANT MARKETS AND COMPETITIVE ASSESSMENT

IV.1. RELEVANT MARKETS

IV.1.1. INTRODUCTORY REMARKS

IV.1.1.1. Analysis based on ATC classification

12. In previous cases the Commission has taken as a starting point for market definition purposes the Anatomical Therapeutic Chemical ("ATC") division of medicines by therapeutic use devised by the European Pharmaceutical Marketing Research Association ("EphMRA") and maintained by EphMRA and Intercontinental Medical Statistics ("IMS")⁵.
13. This classification has the advantage of being developed and maintained for commercial use and providing ready access to statistics. It is based on finished dose pharmaceutical products and their approved indications in the various countries, which may in many cases vary from one country to another.
14. Notwithstanding approved use, it may also be that, in practice, certain molecules are almost exclusively used for only one, or for a smaller subset, of all the approved uses. The Parties have argued this in certain cases detailed below⁶.
15. The EphMRA classification consists of four levels and is regularly updated. The third level, referred to as ATC3, allows medicines to be grouped in most cases according to their therapeutic indications, i.e. their intended use, and is generally taken as the starting point for market definition in Commission's analyses⁷. However, it may be appropriate

⁴ Turnover calculated in accordance with Article 5(1) of the Merger Regulation and the Commission Notice on the calculation of turnover, OJ C66, 2.3.1998, p. 25.

⁵ It should be noted, for the avoidance of confusion, that the EphMRA ATC classification, whilst very similar to the ATC classification maintained by the World Health Organization (WHO), is not exactly the same as the latter. The WHO classification uses similar categories but is based on active ingredients and serves a scientific, rather than commercial, purpose. Thus, a given active ingredient is classified in only one place in the WHO classification, whereas products based on it may be classified in more than one class of the IMS classification, depending on formulation and approved use in a given country.

⁶ It is also possible for a medicine to be used for non-approved indications at the discretion of the prescribing physician, so-called "off label" use. The use of OTC products may also sometimes vary from those recorded in the IMS classification.

⁷ In some cases, the ATC3 level already constitutes a pharmacological rather than therapeutic grouping, as for instance in category J1 antibiotics.

to carry out analyses at other levels, or across classes, if specific circumstances indicate that the ATC3 level is not the most appropriate for the purposes of market definition.

16. In this case, the ATC4 level has been frequently considered as a possible alternative market definition. This level constitutes a further subdivision which may be based on therapeutic or more frequently pharmacological criteria such as molecule class, formulation or mode of action⁸.

IV.1.1.2. Analysis at molecular level

17. Where appropriate, the Commission has also considered competition at the more detailed, molecule level⁹. This has proven particularly relevant in the present case given that generic pharmaceutical companies typically produce copies of originator drugs which therefore can normally be viewed as the closest substitute to those drugs.¹⁰ As set out in the Commission's horizontal merger guidelines, the higher the degree of substitutability between the merging firms' products, the more likely it is that the merging firms will raise prices significantly¹¹.
18. The market investigation in the present case indicates that it is only in a minority of cases that products based on alternative active pharmaceutical ingredients (APIs), i.e. alternative molecules, can be considered as perfect substitutes for each other. The role of the molecule level in the market analysis is particularly important in those cases where (i.) doctors may, or are even required to, prescribe medicines using the international non-proprietary name (INN) of the molecule rather than by brand name (ii.) reimbursement is based on the price of a generic version of the originator medicine and (iii.) pharmacies may, or are required to, offer the patient the opportunity to substitute an originator medicine with a generic equivalent¹².
19. Therefore, a merger may cause a significant loss of competition even if the originator drug has a relatively modest market share at ATC3 or even ATC4 level. Such loss of competition may occur, in particular, in cases where the producer of an originator drug acquires an important, or even the sole, producer of its generic equivalent on the market.
20. It should, of course, be noted that even in cases where the molecule is the same, the formulation of two medicines may differ in terms of dosage strength, mode of delivery,

⁸ See <http://www.ephmra.org/pdf/AC%20booklet%20Who%20we%20are%202008.pdf>

⁹ Sometimes the ATC4 level may only consist of a single molecule, in which case the analysis at ATC4 level and molecule level become identical.

¹⁰ See Case No COMP M.5295 – Teva/Barr, Decision of 19 December 2008. Note however that there may still be small differences, such as in inactive ingredients, which may lead in certain, probably relatively uncommon cases, to the drugs being non-equivalent from a medical standpoint.

¹¹ Horizontal Merger Guidelines, para 28

¹² The market investigation indicated that such a requirement never extends to medicines based on an alternative API to the one prescribed by the patient's physician.

adjuvants and inactive ingredients. With the exception of the inactive ingredients, these differences may, and in prescription markets typically would, limit substitutability to a certain extent. This applies especially in cases where substitution would need to take place at the initiative of the pharmacist or patient.

IV.1.1.3. Prescription pharmaceuticals and over-the-counter pharmaceuticals

21. In numerous cases in the past, the Commission has defined separate relevant product markets within the same ATC3 category for pharmaceuticals available without prescription (over-the-counter, "OTC") and pharmaceuticals available only on prescription, because medical indications (including possible side-effects), legal framework, marketing and distribution all tend to differ between the two categories of medicines, even when the active ingredients are identical¹³. Doctors do not directly play a role in the purchase of OTC pharmaceuticals and in most cases consumers bear the full cost. Prescription pharmaceuticals are prescribed by a doctor and part of the patient's purchase price is reimbursed by the public health-care system. Marketing of prescription pharmaceuticals is therefore targeted at the prescribers and not the patients¹⁴.
22. It has been noted in previous decisions, however, that, in certain cases, products which are available OTC are still reimbursable if bought on prescription¹⁵. In the present case it has been confirmed that this is sometimes the case, albeit in a minority of instances and under defined conditions (for example for certain patients only such as children or pregnant/breastfeeding women).
23. Moreover, it may happen in certain markets that some variants of a drug with the same brand name are classified as OTC, whilst others are classified as prescription-only, depending on the package size, dosage or galenic form.¹⁶
24. Therefore, the Commission has, where necessary, tested the appropriateness of the OTC/prescription distinction in its assessment on a case-by-case basis below.

¹³ Cases COMP/M.3751 *Novartis/Hexal*, decision of 27 May 2005; COMP/M.3544 *Bayer Healthcare/Roche*, decision of 19 November 2004; M.3394 *Johnson and Johnson/J&J MSD Europe*, decision of 29 March 2004.

¹⁴ In certain cases, the OTC/prescription distinction corresponds also to a distinction at ATC4 level.

¹⁵ Cf. *Novartis/Hexal*, op cit.

¹⁶ It should also be noted that certain methodological difficulties have arisen in the present case as regards the distinction between OTC and prescription pharmaceuticals in the IMS data provided by the Parties. These difficulties are often related to the dual status (OTC and prescription) of certain medicines but may also occur because certain strengths or pack sizes of a given brand are only available on prescription, whilst others are available OTC or have a dual status. Sometimes this distinction is not fully reflected in the data provided by the parties. As a result, certain estimates of market share made below may be subject to a degree of uncertainty, which however, unless specifically discussed, is understood not to be of such an extent as to invalidate the competitive assessment.

IV.1.1.4. Originator pharmaceuticals and generic pharmaceuticals

25. Generics are in general less expensive versions of the originator drugs. In regulatory approval procedures, a generic drug manufacturer has to demonstrate that the generic version of the originator drug has identical quality and purity and is biologically equivalent to the originator drug.
26. In the present case, the market investigation has often suggested that there may be differences in the demand for originator versus generic drugs, even when they are bioequivalent. However, it has not suggested that this phenomenon was so extensive as to place the two types of drugs in separate markets. Indeed, generic versions of originator medicines are specifically designed to compete with those medicines and normally represent the closest substitute to them.
27. In the present case, the interaction between originator medicines and generics does, however, need to be specifically analyzed in relation to potential and incipient competition from generics owing to the particular profile of Zentiva as an important provider of generics, in particular in the Czech and Slovak Republics and in Romania.

IV.1.2. FINISHED DOSE PHARMACEUTICALS

IV.1.2.1. RELEVANT GEOGRAPHIC MARKETS

28. In previous decisions, the Commission has held that the relevant geographic markets for finished pharmaceutical products were national¹⁷.
29. The market investigation has confirmed that this is still the case. Even if certain wholesalers may source products internationally, demand and prices for pharmaceuticals vary substantially from one country to another.
30. Owing to sometimes quite significant differences between countries as to the structure of individual pharmaceutical markets, it is important to stress at the outset that the definition of the relevant product market may, accordingly, vary from one country to another. Where this is the case for the countries considered in the present decision and this difference is relevant to the analysis, it is noted below.

IV.1.2.2. RELEVANT PRODUCT MARKETS

Introduction

31. In the definition of relevant product markets below, an extended discussion is provided for all product markets in which the market investigation indicated that possible serious doubts needed to be considered, including, but not limited to, all products in which the

¹⁷ See e.g. cases *Novartis/Hexal*, op cit.; COMP/M.5295 *Teva/Barr*, decision of 19 December 2008.

Parties have a combined market share of 35% or more in at least one country and an increment of at least 1%. This calculation has been applied on the ATC3 level in any case, as well as at more detailed levels where the market investigation suggested that the correct market definition might be found at those levels. A number of markets which raised specific issues have been discussed even where these thresholds were not met.

32. The remaining affected product markets in the sense of the Horizontal Guidelines are listed under "other markets" at the end of this section where market definition precedents are mentioned in footnotes.
33. As the position of the Parties on the relevant markets in certain countries sometimes needs to be considered in order to determine whether or not the market definition may be left open, the relevant geographical overlap in their activities is referred to in such instances, but not systematically.

A2A Antiacids, Antiflatulants, Carminatives

34. Antacids, antiflatulents and carminatives belong to the ATC3 class A2A. These drugs are used for the treatment of mild digestive disorders, often for self-medication. This is therefore essentially an OTC) market, although some products may also be reimbursable when bought on prescription.
35. The Parties have argued that the appropriate market definition is the ATC3 class A2A as a whole. In previous decisions the Commission has considered that antiacids, antiflatulants and carminatives may constitute a relevant product market.¹⁸ However, there are also grounds to consider antacids separately from antiflatulants and carminatives, given that stomach acidity is a distinct condition from intestinal gas.
36. The transaction results in one affected market in Romania. Most competitors of the Parties active in this market in Romania and one wholesaler considered that the ATC3 level might be appropriate for the purpose of defining the relevant product market. One competitor stated that there are also products from other ATC3 classes which can be used to treat the same conditions (namely Antibiotice's Gastroben¹⁹ product). However, the sales of this product are marginal in the geographic market where the Parties' activities overlap so the possible exclusion or inclusion of this drug will not affect the overall competitive assessment.
37. For the purpose of this decision, however the exact market definition may be left open since the transaction leads to serious doubts as to its compatibility with the common market in Romania regardless of the exact market definition.

¹⁸ Cases COMP/M.1878 *Pfizer/Warner-Lambert*, decision of 22 May 2000 and COMP/M.1378 *Hoechst/Rhône Poulenc*, decision of 9 August 1999.

¹⁹ For the purposes of this decision, note that branded medicines are always written with an initial capital letter whereas molecules (except at the start of a sentence) are written with small letters.

A3A Plain antispasmodics and anticholinergics

38. Antispasmodics and anticholinergics belong to the ATC3 class A3A. These products are used to relieve cramps or spasms in particular of the digestive system. This class consists of products sold both OTC and on prescription. The Parties' products are typically sold in both OTC and prescription-only formulations. The ATC3 category A3A is not subdivided further into ATC4 classes. The ATC3 category A3A therefore includes all products for these indications.
39. Sanofi-Aventis submits that the ATC 3 category is the most relevant approach, even though in some cases the products might not be entirely substitutable.
40. The Commission has not previously assessed the relevant market for these products.
41. Most of the Parties' competitors in the countries affected, and most wholesalers, confirmed the ATC3 approach but subject to a possible distinction between OTC and prescription products.
42. For the purposes of this decision, the question whether a distinction should be made between OTC and prescription products may, however, be left open, since, regardless of the exact market definition, the transaction leads to serious doubts as to its compatibility with the common market in Romania and Hungary whereas it does not lead to serious doubts in other affected countries.

A4A Antiemetics and antinauseants

43. Products in this category are mainly used to prevent or relieve nausea and vomiting.
44. According to the Parties, the ATC3 class A4A comprises two subgroups of products: (i.) products used to relieve nausea and vomiting due to banal causes and (ii.) products mainly used in preventing and controlling vomiting as a side effect of chemotherapy. The Parties claim that, due to their indications and price, these two subgroups should be viewed as constituting distinct relevant product markets. The first subgroup comprises products including antihistamines, anticholinergics and herbal products, indicated in motion sickness, dizziness and vomiting of more common aetiology. These products are significantly cheaper and are in many cases available OTC.
45. Regardless of the exact product market definition, the notified transaction leads to an affected market in Bulgaria. Most competitors confirmed that this product market should be subdivided as argued by the Parties. Furthermore, most competitors confirmed that the possibilities to switch between the two product segments are limited.
46. The exact market definition may, however, be left open in this case, since the notified transaction would not result in serious doubts in Bulgaria, regardless of the market definition considered.

A5B Hepatic protectors and lipotropics

47. Hepatic protectors and lipotropics belong to the ATC3 class A5B. These products are used for adjuvant treatment in all forms of acute and chronic liver disease.
48. The Parties suggested that the appropriate market definition was the ATC3 class A5B.
49. In two previous decisions the Commission considered that hepatic protectors and lipotropics may constitute a relevant product market without explicitly considering a split between OTC and prescription products.²⁰
50. In the present instance, the notified transaction would result in affected markets in the Czech Republic, Romania and the Slovak Republic.
51. The replies of competitors and wholesalers suggest that it would be inappropriate in this instance to make a distinction between OTC and prescription products in the Czech and Slovak Republics.
52. Certain competitors stated that although some A5B products are available OTC in those countries, these same products are reimbursable when bought on prescription.
53. It is therefore likely that all products in this category might belong to a single relevant product market, due to the fact that the conditions of acute or chronic liver disease are indications which are inappropriate for self-medication and since in certain cases the OTC products are reimbursable when bought on prescription.
54. For the purposes of this decision, the Commission concludes that the relevant product market in the Slovak Republic respectively consists of all products classified in the ATC3 category A5B, without distinguishing between OTC and prescription products. For the Czech Republic the market definition can be left open, since both Parties' products are only available on prescription. The Parties' market share in a market only containing the prescription products in this category would therefore be even higher. In the case of Romania this question can also be left open, since the transaction does not give rise to serious doubts, regardless of the market definition considered.

A7A Intestinal anti-infective antidiarrhoeals

55. Intestinal anti-infective antidiarrhoeals belong to the ATC3 class A7A. These products are used for disinfection and stabilisation of the intestinal microflora and for treatment of acute diarrhoeal diseases. In a previous decision, the Commission considered that intestinal anti-infective antidiarrhoeals may constitute a relevant product market.²¹
56. The only competitor confirmed that the relevant product market should be defined on the basis of the ATC3 class.

²⁰ Cases COMP/M.1835 – Monsanto/Pharmacia & Upjohn, decision of 30 March 2000, paras 15, 16 and 52; IV/M.950 – Hoffmann La Roche/Boehringer Mannheim, decision of 4 February 1998, para 11.

²¹ Case COMP/M.1878 – Pfizer/Warner Lambert, decision of 22 May 2000, para 18.

57. In the present case, the notified transaction would lead to an affected market in the Czech Republic.
58. A7A products are available OTC but are reimbursable if bought on prescription. Moreover, the market investigation suggested that OTC and prescription medicines may in some instances be more closely related in the Czech Republic than in some other countries owing to the need for the patient to pay a nominal fixed fee on prescription medicines²².
59. Therefore it cannot be ruled out that in this case, as argued by the Parties, the OTC and prescription products in the ATC3 category A7A would belong to the same market in the Czech Republic.

A10B Oral antidiabetics

60. Oral antidiabetics comprise drugs used in diabetes treatment for Type 2 diabetes. These products are mainly used for reducing blood sugar levels in diabetes patients.
61. Referring to a previous decision, where the Commission considered that oral antidiabetics constituted a relevant product market,²³ the Parties submit that the appropriate market definition is the ATC3 class A10B.
62. According to the Parties, the products of Sanofi-Aventis and Zentiva are both based on the same molecule, glimepiride.
63. Glimeperide is an antidiabetic in the sulfonylurea class, A10B1²⁴. Sulfonylureas, as also glinides, work by stimulating beta-cells to release insulin²⁵.
64. According to one competitor, glimepiride, as well as glitazones (A10B4) and DPP4 inhibitors (A10B6) are all used as second-line treatment to metformin which, however, also belongs to the ATC3 class A10B, and more specifically to the class of biguanides

²² This is more likely to be the case for relatively more inexpensive medicines with similar medicines available in both categories and which are not used by the patient over a prolonged period of time, since in such instances the patient may also consider the financial cost and possible inconvenience of a visit to the doctor, and is therefore less likely to be motivated to do so merely due to the difference in the net price payable on the pharmaceutical products concerned.

²³ Case COMP/M.1846 – Glaxo Wellcome/SmithKline Becham, Commission decision of 8 May 2000, para 150 and 208.

²⁴ It should be noted that in the 2009 nomenclature, EphMRA has effectively upgraded what had been the ATC4 subdivisions until then, into ATC3 groups in their own right which become classes A10H through A10S. In this decision the Commission uses the earlier nomenclature but the change of nomenclature has no effect on the competition assessment.

²⁵ See <http://www.diabetesmonitor.com/su.htm>; <http://www.diabetes.org/type-2-diabetes/oral-medications.jsp> (both retrieved on 30 January 2009). The glinides were classified in A10B9 (other oral antidiabetics) until the 2009 nomenclature change (see below) when they received their own ATC3 category.

(A10B2). The Parties also acknowledge that metformin is the first-line treatment²⁶. It therefore might be appropriate to define a relevant market consisting of all products except metformin (or except A10B2 in general).

65. There are a number of molecules in the A10B1 category, including, in addition to glimeperide, chlorpropamide, glibenclamide, glibornuride, gliclazide, tolbutamide, glipizide, gliquidone, glyclopyramide, acetohexamide and tolazamide. All of these except chlorpropamide, tolbutamide, acetohexamide and tolazamide are considered to be second-generation sulfonylureas with fewer side effects, and the first generation drugs are largely absent or have insignificant market shares in the affected countries.
66. The exact market definition may be left open in this case, since the notified transaction would not result in serious doubts regardless of the market definition considered.

A12C Other Mineral Supplements

67. This A12C category groups together products that are indicated in the treatment of deficiencies in mineral elements such as magnesium, potassium and sodium.
68. The Parties suggested in the notification that the appropriate market definition was the ATC3 class A12C.
69. Although the Commission has, in the past, looked at this class as a whole²⁷ it might appear to be justified to break it down to the level of the mineral supplement in question. However, this is not material in any case, since almost the whole category in the affected countries is constituted by magnesium supplements.
70. The exact market definition may, however, be left open in this case, since the notified transaction would not result in serious doubts regardless of the market definition considered.

B1B Heparins

71. Heparins are injectable anticoagulants and belong to the ATC3 class B1B. The ATC4 category B1B1 includes injectable high molecular weight (unfractionated) heparin (hereafter referred to as "UFH") whereas the ATC4 category B1B2 includes the newer generation of injectable low molecular weight (fractionated) heparins (hereafter referred to as "LMWH")²⁸.

²⁶ Reply to the questions of the Commission of 18 September 2008

²⁷ Case COMP/M.737 – *Ciba-Geigy/Sandoz*, decision of 17 July 1996.

²⁸ The ATC3 category includes two additional ATC4 categories, B1B3 and B1B9, which are not relevant in the present case as discussed below.

72. UFH and LMWHs are both used to prevent blood-clotting and therefore to prevent or treat acute thromboembolic disorders.²⁹ Heparins are biological substances and are obtained from the lung, intestines, etc., of vertebrates, most commonly pigs or cows. LMWHs are derived from UFHs by a process of splitting.
73. According to the Parties, UFH and LMWHs have a common set of indications. However, their efficacy and safety are different. UFHs are associated with a higher risk of thrombopenia induced by heparin. LMWHs, the second generation heparins, are considered more efficient, safer and easier to use. According to the Parties, LMWHs are now used in most instances in the Czech Republic and Slovak Republic. UFH is still used in some cases for specific indication/administration modes, where LMWHs are contra-indicated (for example, for patients with renal dysfunctions).
74. The Commission has previously considered UFH and LMWHs to belong to the same product market. In *Sanofi-Synthelabo/Aventis*, the Commission accepted the argument put forward by Sanofi-Synthelabo that the ATC3 level was the appropriate basis for defining the market for heparins³⁰.
75. While in the present case the Parties have followed the Commission's previous approach as a starting point in their market analysis and considered the relevant market as comprising ATC4 categories B1B1 and B1B2 together, they stressed the differences between these two products. Besides the differences in efficacy and use, the Parties argued that there were significant price differences between the two products. As a consequence, the two types of heparins are purchased separately in the Czech Republic and Slovak Republic through different procedures. Whereas more expensive LMWHs are purchased through tenders, lower value UFHs are purchased on an order basis with a maximum price set by the state. The Parties also pointed to the obsolescence of UFH and the shrinking demand for this product. They argued that due to these facts, UFH and LMWHs were in fact not competitively related.
76. The Parties' activities overlap in the Czech Republic and Slovak Republic. Since it is only UFH (B1B1) and LMWHs (B1B2) that are marketed in these countries within the B1B ATC3 category, it is not necessary to conclude on whether the relevant market includes B1B3 or B1B9 heparins. The market investigation therefore only focused on whether UFH and LMWHs belong to the same product market or not.
77. The market investigation confirmed that UFH and LMWHs have largely common indications, although UFH has a wider range of applications. Notwithstanding the commonality of applications, the market investigation also confirmed that LMWHs are safer to use and are more efficient. Whereas UFH can only be administered as an infusion in hospitals requiring constant monitoring, LMWHs can also be used in outpatient care. The market investigation confirmed that, due to their safety and efficacy of use, LMWHs are clinicians' preferred choice of heparin in many cases. On the other hand, respondents also considered that, taking into account both therapeutic and cost

²⁹ Heparins are also used as a coating for certain medical and diagnostics devices, such as catheters for example. The ATC4 group B1B3 regroups heparins used for such purposes.

³⁰ Case COMP/M.3353 *Sanofi-Synthelabo/Aventis*, decision of 26 April 2004.

effectiveness considerations, UFH can still often be an effective substitute to LMWHs in a hospital setting in the two countries and that the lower price of UFH may still favour its use in clinical practice under certain circumstances.

78. Despite the creation of new opportunities for outpatient use due to the introduction of LMWHs, the hospital segment represents over 80% of the total market for BIB in both countries³¹. Furthermore, the market investigation also indicated that significant discounts on LMWHs were provided only to hospitals.
79. The Parties confirmed to this effect that LMWHs were marketed to hospitals through a separate channel and stated that [...].
80. Given that the hospital segment is a separate and substantial segment of the heparin market and the fact that the overlap in the use of UFH and LMWHs is limited to hospitals, the Commission assessed the potential competitive impact of the transaction in the hospital segment separately.
81. The market investigation confirmed the price difference between UFH and LMWHs. It should be noted, however, that the therapeutically equivalent dosage of UFH and LMWHs is also significantly different³². In particular, the average maintenance dose per day (the quantity of the drug needed to treat an adult patient for one day) requires 10 000 international units³³ of UFHs whereas it only requires 2000 international units of Sanofi-Aventis's LMWH³⁴. IMS price data does not take into account differences in the daily defined dose. The value of sales concerning the use of heparins in the hospital segment provided by IMS also does not take into account discounts provided to hospitals, which are usually higher for newer drugs produced by originator companies compared to older ones where a generic market is already developed. Therefore, IMS data is likely to overestimate the price difference between LMWHs and UFH. The market investigation also indicated that taking into account hospital discounts on LMWHs and the differences in dosage and efficacy, the price of the two types of heparins would be more comparable, at least in the Czech Republic. In light of the above, notwithstanding the price difference between UFHs and LMWHs, it cannot be concluded that this price difference in itself would clearly place UFHs and LMWHs in separate markets.
82. In light of the different dosage requirements and pricing which underlie sales figures, the Commission requested the Parties to restate market shares based on a volume indicator that would reflect the actual use of the two types of heparins in hospitals and

³¹ Figure in volume (days of treatment) based on first three quarters of 2008

³² The so-called "daily defined dose" or DDD.

³³ International Units (IUs) are a standard measure of quantity (mass or volume, as appropriate) of an active substance, based on its biological effect. The quantity (ml or mg) corresponding to 1 IU is defined by the WHO for each substance. This is distinct from IMS standard units (SUs) which are defined in terms of the smallest available "commercial" unit in which the product is physically produced and marketed (e.g. number of tablets, syringes, etc.)

³⁴ Comparative indicators from the World Health Organisation submitted by the Parties

would allow for a comparison between UFH and LMWH use. The Parties suggested using "days of treatment", which is a comparative "volume" indicator that accounts for different dosage requirements as described in the previous paragraph. The "days of treatment" indicator is calculated by dividing all the international units sold in a given year by the daily defined dosage for the molecule in question. Even if not taking into account discounts, this measure would serve as a useful addition to sales values in terms of providing an overview of the market structure and competitive dynamics in the hospital segment in the B1B category. Therefore, *in addition* to sales value, this indicator was also used for the competitive assessment.

83. In the present case, it is however not necessary to conclude whether UFH and LMWHs belong to the same relevant product market or whether the hospital segment constitutes a separate relevant product market as competition concerns do not arise regardless of the market definition considered.

B1C Platelet aggregation inhibitors

84. The ATC3 category B1C comprises platelet aggregation inhibitors, which are used in primary and secondary prevention of thrombotic cerebrovascular or cardiovascular disease. Antiplatelet drugs prevent the formation of blood clots by preventing platelets (a type of blood cell) from aggregating. Platelet aggregation is beneficial for the healing of external wounds for example. However, platelets can also aggregate when injury to a blood vessel occurs and this may lead to or aggravate serious cardiovascular conditions (heart attacks and strokes). Platelet aggregation inhibitors are used to prevent such conditions.
85. Whereas heparins and antiplatelet drugs both prevent the formation of clots, there are important differences between the two ATC3 groups. Heparins interfere with blood clotting by blocking the activity of thrombin (a coagulation protein). Antiplatelet (B1C) drugs on the other hand target platelets. Platelet aggregation inhibitors are also different insofar as they are effective in arterial circulation.
86. The B1C category includes products which have platelet aggregation inhibition as their main indication (e.g. clopidogrel, the active ingredient contained in Sanofi-Aventis' innovator drug, Plavix) as well as products where platelet aggregation inhibition is only indicated for a specific dosage/presentation (e.g. acetylsalicylic acid – the active ingredient of aspirine – which is contained in Zentiva's products). Since 2000, the ATC3 group has been subdivided into six ATC4 subcategories. The three categories relevant for the Parties' products are: (i.) B1C1 (cyclo-oxygenase inhibitors) comprising mainly low dosage acetylsalicylic acid (hereafter referred to as ASA), (ii.) B1C2 (adenosine diphosphate receptor antagonists) comprising mainly clopidogrel and also its predecessor ticlopidine and (iii.) B1C4 (platelet cAMP enhancing).
87. Zentiva supplies B1C1 ASA in the Czech and Slovak Republic, and, to a much lesser extent, dipyridamole (another type of antiplatelet drug) in Romania. Sanofi-Aventis supplies mostly clopidogrel in these countries under the brand name Plavix and to a lesser extent ticlopidine (Ticlid).

88. Plavix is a "blockbuster" drug for which patent protection has recently expired in the three countries concerned.
89. The main focus of the market investigation in terms of market definition was therefore whether or not ASA and clopidogrel belong to the same relevant product market.
90. In previous decisions³⁵ – adopted prior to the ATC4 subdivision – the Commission made a distinction between first line B1C drugs (ASA, dipyridamole) and second line B1C drugs (at the time ticlopidine, the predecessor of clopidogrel). The market investigation in *Sanofi/Synthélabo* indicated that ticlopidine was a more potent drug only used in cases where ASA was ineffective or in cases where the patient was intolerant to ASA. ASA accounted for the bulk of the use of B1C drugs and was the only choice in primary prevention (i.e. treatment before a significant cardiac event occurs).
91. In the present case, the Parties proposed to retain this distinction. Concerning the market of platelet aggregation inhibitors used in the prevention of cardiovascular disease, ASA remains, according to the parties, the antiplatelet of choice for primary prevention, for treatment in acute stroke and in long-term secondary prevention of cardiovascular disease. Clopidogrel is generally considered an alternative on the basis of ASA intolerance and for higher grade stages of the disease and is, therefore, second-line to ASA. As indicated, clopidogrel is used differently for the treatment of Acute Coronary Syndrome (ACS), where guidelines recommend the combined use of ASA and clopidogrel for a specific duration, followed by ASA monotherapy.
92. Consequently, Sanofi-Aventis proposed that the segmentation used in the two earlier cases was still the most appropriate way of defining the relevant product markets. First-line treatments concern mainly ASA (ATC4 category B1C1) and, less often, dipyridamole (ATC4 category B1C4), whereas second-line treatments include mainly clopidogrel as well as ticlopidine (B1C2) and some combinations of platelet aggregation inhibitors (mainly the combination of ASA and dipyridamole, B1C5). Notwithstanding the fact that the Parties agree that clopidogrel could be used as a first-line treatment in certain cases (ie ASA intolerance or for ACS), they argue that this accounts for a minor part of first-line treatment use of antiplatelet drugs and does not create opportunities for direct competition with ASA.
93. In order to assess further whether the use of clopidogrel is indeed limited to cases where ASA is not a therapeutic alternative, the main differences in the uses of these products within the relevant countries (Czech and Slovak Republics) are considered in more detail below.
94. Firstly, it should be noted that ASA and clopidogrel exhibit a number of important differences. ASA is a well-known, widely genericised drug that has been in use for a very long time. Besides the platelet aggregation inhibition indication, it has a variety of other indications depending on the dosage. Clopidogrel, on the other hand, is a relatively recent drug with a very specific indication for platelet aggregation inhibition. It is

³⁵ Cases COMP/M.1543 *Sanofi/Synthélabo*, decision of 28 July 1999; case COMP/M.1835 *Monsanto/Pharmacia & Upjohn*, decision of 16 February 2000.

therefore a more potent drug for this specific indication. The two molecules have different modes of action and different chemical and pharmacological properties. Similarly, dypiridamole has a different mode of action, is already genericised and widely available. It appears that the use of dypiridamole is rather limited and that it is mainly used in combination with ASA.

95. Secondly, the differences between ASA and dypiridamole, on the one hand, and clopidogrel, on the other, are reflected in the price difference between the two products. According to the information provided by the Parties, in the Czech Republic and the Slovak Republic the price of Plavix is about 100 times the price of ASA. The Parties further argue that the magnitude of the price difference between clopidogrel and dypiridamole in Romania is comparable. With the expiry of patents, Sanofi-Aventis expects significant generic entry for clopidogrel, in particular given its significance in terms of cashflow in Sanofi-Aventis' current portfolio. However, based on Sanofi-Aventis' internal analysis carried out in anticipation of the patent expiry on Plavix, the price effects of genericisation, though significant, will not bring down prices of clopidogrel to a level which would be comparable to ASA in the foreseeable future.
96. Thirdly, whether motivated by medical considerations, price considerations or both, prescription and reimbursement of clopidogrel is much more restrictive in the Czech Republic and Slovakia than that of ASA. The restriction applies for both the type of physician that may prescribe the drug and the indications for which the drug may be reimbursed.
97. According to information provided by the Parties, high dosage ASA is available OTC in the Czech Republic. However, the low dosage ASA, which is used as an antiplatelet drug, has prescription status. In principle any physician can prescribe ASA for any of its approved indications. Clopidogrel on the other hand is only available on prescription and it can only be prescribed by specialised doctors (internist, cardiologist or neurologist) for a limited number of specific indications. Despite the fact that there are several approved indications for clopidogrel, it is only reimbursed for Acute Coronary Syndrome ("ACS"), where it is used in combination with ASA. The other indications of Plavix (secondary prevention of myocardial infarction, stroke and peripheric artherial disease) are not reimbursed, whereas they are reimbursed for Zentiva's ASA product, Anopyrin. The Parties calculated based on IMS data that the combination of ASA with clopidogrel is used in approximately 3-4% of all ASA prescriptions for cardiological (B1C) indications).
98. In the Slovak Republic, B1C1 ASA has a dual status, i.e. it is available OTC but reimbursed when prescribed by a physician. Again, there are no specific restrictions on prescription. Clopidogrel, on the other hand, can only be prescribed by a specialist (internist, cardiologist, angiologist, vascular surgeon or neurologist) for a limited number of applications. Clopidogrel may be used in combination with ASA for ACS (accounting for 1-2% of all cardiological prescriptions of ASA according to the calculations of the parties based on IMS). In secondary prevention of stroke, the use of Plavix is limited to cases where other antiplatelet treatments (including ASA) have failed. Regarding the treatment of peripheral arterial disease, clopidogrel is an alternative to ASA only in serious cases accounting for less than 2% of all B1C1 and B1C2 prescriptions as estimated by the Parties. Due to these prescription and indication

limitations, Sanofi-Aventis argues that ASA and clopidogrel are not even potentially interchangeable.

99. The Parties argue that also in Romania, the national guidelines limit the use of clopidogrel to second-line treatments or combination with ASA. Based on the information received from the Romanian National Medicines Agency there also appear to be restrictions on the use of clopidogrel that appear consistent with it being used as a second-line treatment. At the same time dipyridamole appears to be a first-line product.
100. The market investigation in the present case has largely confirmed that ASA and dipyridamole were first-line treatments. Based on the market investigation it appears that, by default, clopidogrel (Plavix) is considered to be a second-line treatment. However, there are also some indications that in certain cases clopidogrel would be used as a first-line treatment (e.g. secondary prevention of stroke, non-ST elevation ACS and for the management of ST segment elevation myocardial infarction). Furthermore, there are also indications of significant price differences, which play a role in the choice between the two drugs.
101. The possibility that clopidogrel could be used as a first-line treatment in certain cases does not *per se* contradict the first/second line division outlined in *Sanofi/Synthélabo* or the arguments put forward by the Parties. As outlined above, the limited use of ticlopidine as a first-line treatment was also recognised by that decision and the Parties admit that clopidogrel is used as a first-line treatment in certain cases. It also transpires from the present market investigation that the application of clopidogrel (or its predecessor ticlopidine) as a first-line treatment seem to be restricted to specific cases. There were indications that second line products would be used more for serious indications and/or in combination with first line products (e.g. clopidogrel with ASA). This is consistent with the information provided by the Parties.
102. Based on the above it therefore appears that due to a mixture of medical and economic reasons, the national regulatory environment in the Czech Republic, Slovak Republic and Romania places restrictions on the use of clopidogrel that significantly limit the substitution between ASA and dipyridamole on the one hand and clopidogrel on the other. Considering also the differences between the two molecules in terms of their history, mode of action and range of applications, for the purposes of the present case it may be correct to conclude that the ATC3 level is not the relevant market. However, the market definition can be left open as the merger does not raise serious doubts regardless of the market definition.

C4A Cerebral and peripheral vasodilators

103. The ATC3 category C4A includes all products used to improve cerebral or peripheral arterial circulation. According to the Notifying Party, the evidence of clinical efficacy for products belonging to this category has been questioned, which has resulted in diverging usage and reimbursement schemes in different Member States.

104. In previous cases, the Commission has stated that the ATC3 category C4A could constitute a relevant product market.³⁶ The Notifying Party considers that this ATC3 category is appropriate for market definition purposes.
105. In the present case, the market investigation indicated that in certain cases it may be appropriate to define separate relevant product markets for products available OTC and products available on prescription respectively. With one exception – Estonia - the potential distinction between OTC and prescription products would have no impact on the competitive analysis, because all products in the C4A category in the Czech Republic and the Slovak Republic are available only on prescription³⁷.
106. In Estonia, the C4A category includes products based on ginkgo biloba³⁸. In this country, sales of products based on ginkgo biloba are primarily driven by direct-to-consumer advertising as opposed to prescriptions by physicians. The Commission therefore considers that - in the specific case of Estonia - it is appropriate to exclude products available OTC from the relevant product market. Therefore, the relevant product market in Estonia ought to be confined to all products belonging to the ATC3 group C4A available on prescription.

C7A Beta-blocking agents, plain

107. The ATC 3 category C7A includes all plain beta-blocking agents. Substances in this group are used for the treatment of a number of heart diseases, in particular to prevent angina pectoris attacks and to treat heart insufficiency, high blood pressure and heart arrhythmia. Products in this class are only available on prescription.
108. The Notifying Party maintains that the ATC3 class C7A is appropriate for market definition purposes.
109. Beta-blockers (beta-adrenoceptor antagonists) are drugs that bind to beta-adrenoceptors and thereby block the binding of norepinephrine and epinephrine to these receptors. Beta-blockers are therefore sympatholytic drugs. The first generation of beta-blockers were non-selective, meaning that they blocked both beta 1 and beta 2 adrenoceptors. Second generation, beta-blockers are more cardioselective in the sense

³⁶ See cases COMP/M.4402 *UCB/Schwartz Pharma*, decision of 21 November 2006; *Novartis/Hexal*, op cit; COMP/M.457 *American Home Products/Monsanto*, decision of 20 June 1994.

³⁷ Reply by Sanofi-Aventis of 23 September 2008 to Commission request for information.

³⁸ Ginkgo biloba is a unique species of tree with no close living relatives. Extracts of Ginkgo leaves contain flavonoid glycosides and terpenoids. Ginkgo has many alleged nootropic properties and is mainly used as a memory and concentration enhancer and an anti-vertigo agent. According to some studies, in a few cases, Ginkgo can significantly improve attention in healthy individuals. However, studies differ about its efficacy.

that they are relatively selective for beta 1 adrenoceptors. The Commission market investigation indicates that selective beta-blockers are substitutable to a great extent. The narrowest conceivable market definition would be to define a separate product market for selective beta-blockers. However, selective beta-blockers have replaced non-selective beta-blockers to a great extent. In the Czech Republic, the selective beta-blocker segment accounted for more than 80% of total sales in 2007.³⁹ All the Parties' products (except one with a marginal market share) are selective beta-blockers. Consequently, defining a narrower relevant product market based on selective beta-blockers only would not affect the competitive analysis. In the present case, the Commission will therefore confine its analysis of the impact of the merger in Czech Republic to the ATC3 level.

D1A Dermatological Antifungals

110. Dermatological antifungals are mainly used for the treatment of skin infections caused by fungus. According to the Parties, this category ought to be divided further at the ATC4 level into (i.) topical dermatological antifungals (ATC4 class D1A1), (ii.) systemic dermatological antifungals (ATC4 class D1A2) and (iii.) Topical scalp antifungals (ATC4 class D1A3), since there is limited substitutability between products in each of these three classes.
111. The Parties maintain that the appropriate market definition in this case is the ATC4 class D1A1, in which they overlap in the Czech and Slovak Republics.
112. In previous decisions,⁴⁰ the Commission examined the relevant product market at the ATC4 level but finally left the product market definition open.
113. The market investigation did not clearly confirm the Parties' approach. Although a majority of Parties' competitors stated that topical antifungals may be substituted with systemic and scalp antifungals, a minority stated that this type of substitution never occurs. It therefore appears that there is a certain degree of demand-side substitutability. However, there are very significant price differences and it would appear that a systemic antifungal carries greater risks of side effects and therefore would not be used in a number of cases where a topical antifungal suffices to treat the patient's condition.
114. The exact market definition may, however, be left open in this case, since the notified transaction would not result in serious doubts regardless of the market definition considered.

³⁹ According to the Notification, the selective beta-blockers segment accounted for between 82% and 94% of total beta-blocker sales in the Czech Republic in 2007. It was not possible to calculate the exact share on the basis of the information provided by the Notifying Party because the market share breakdown included a category denoted "Other competitors" which accounted for [10-20]% of total sales and it is not known to the Commission what portion of "other sales" should be allocated to selective and non-selective beta-blockers respectively.

⁴⁰ See e.g. Case COMP/M.4341 *Johnson&Johnson/Pfizer*, decision of 11 December 2005.

G4C Benign Prostatic Hypertrophy Products

115. The ATC4 category G4C comprises products used for the treatment of benign prostatic hypertrophy (BPH), which is a condition characterised by a modification of prostate volume affecting the male urinary function.
116. The ATC3 category G4C is subdivided into two ATC4 categories. G4C1 includes products exclusively for BPH, such as alfuzosin, dutasteride, finasteride, and tamsulosin, whereas products of herbal or animal origin and homeopathic products are classified in G4C8. Products containing mepartricine, serenoa repens or pygeum africanum are classified in G4C8 if indicated for BPH. G4C8 also includes herbal products for improving prostatic health more generally.
117. The Parties submit that the relevant market should include all G4C products, including the molecule doxazosin, which they argue is mainly indicated for BPH although it may also be prescribed as a treatment for hypertension and is included in a separate ATC3 category in some countries for this reason.
118. According to the Parties, finasteride (or dutasteride) in combination with either alpha-blockers or herbal products is administered to patients with enlarged prostates. This is the case mostly for patients with moderate to severe symptoms. The main indication for finasteride (or dutasteride) is the reduction of the prostate's size. In the case of mild to moderate symptoms, either herbal products or alpha-blockers can also be used alone, without combination with finasteride (or dutasteride), both types of products acting as muscle relaxants. Combination treatments with finasteride (or dutasteride) and either alpha-blockers or herbal products can, however, sometimes be prescribed for patients with milder symptoms or a high prostate specific antigen (PSA)⁴¹
119. According to the Parties' best estimates, mild cases represent about 20% of all cases, moderate cases about 50-60%; and severe cases about 20%.
120. The market investigation confirmed that doxazosin had an indication for BPH. Upon further investigation, however, it appeared that some BPH products of natural origin (in the category G4C8) were available OTC where G4C1 drugs were only available on prescription. This was the case in particular in Estonia, where the transaction would lead to combined market shares above 35% with a significant increment. The market investigation supported the presumption that OTC and prescription drugs belong to separate markets in the present case. Therefore the Commission concludes that a distinction should be made for the purposes of the assessment between prescription and OTC products within the G4C category in Estonia and that these form separate relevant markets. For the remaining countries, this can be left open as the transaction does not lead to serious doubts regardless of the market definition considered.

⁴¹ A protein produced by the cells of the prostate gland.

J1G Fluoro-Quinolones

121. The ATC3 category J1G, comprises fluoro-quinolones. Fluoro-quinolones are synthetic broad-spectrum antibiotics. There are a relatively wide range of molecules belonging to this spectrum, which can be divided into older and newer generation molecules based on their antibacterial spectrum (generally wider for new generation drugs). Older generation molecules include ciprofloxacin, enoxacin, lomefloxacin, nadifloxacin, norfloxacin, ofloxacin, pefloxacin and rufloxacin. Newer generation molecules include e.g. balofloxacin, gatifloxacin, grepafloxacin, levofloxacin, moxifloxacin, pazufloxacin, sparfloxacin and tosufloxacin.
122. In the case of fluoro-quinolones, the sub-division of the ATC3 class is not based on any specific subset of indications but on the galenic form of the drugs. As a result, the same molecule could be classified in either of the two ATC4 categories, J1G1 (oral fluoro-quinolones) and J1G2 (injectable fluoro-quinolones)
123. In *Glaxo Wellcome/Smithkline Beecham*⁴² the Commission investigated a number of antibiotics markets in the ATC2 class J1, including J1C, J1D, J1F and J1G. For these classes, the Commission considered the possible distinction between place and mode of usage, in particular between hospital use (mainly injectable fluoroquinolones) and community use (oral fluoroquinolones). The market investigation in that case indicated that, for price reasons, hospitals tended to switch from injectable to oral treatment as soon as possible. The J1G market in that case, in which the parties' overlap was marginal, was finally assessed at the ATC3 level.
124. In the present case, the Parties' activities overlap significantly and the merger would lead to substantial market shares. The Commission therefore investigated the potential separation based on galenic forms in more depth. As it is in the injectable form that Parties would have higher market shares in the Czech Republic and the Slovak Republic, the focus of the investigation was the competitive constraint exercised by the oral formulation segment on the injectable formulation segment.
125. The Parties suggest following the ATC3 market definition for J1G markets. Whereas, in some cases, injectable forms of fluoro-quinolones represent the only possible mode of administration, the parties argued that in other cases they are only used for reasons of convenience (for example for patients in hospitals who are already receiving infusions for other reasons). Furthermore, the Parties argued that the first criterion of choice remains the medical benefits associated with a specific molecule and that the formulation was of secondary importance.
126. The market investigation confirmed that hospitals have a distinct demand for injectable fluoroquinolones. The market investigation also indicated that substitution of injectable fluoro-quinolones by oral ones is limited. In particular, respondents indicated that in terms of therapeutic efficacy and cost effectiveness, injectable fluoroquinolones can sometimes be effectively substituted by oral fluoroquinolones. The market

⁴² Case COMP/M.1846 *Glaxo Wellcome/Smithkline Beecham*, decision of 20 March 2000.

investigation confirmed that injectable fluoro-quinolones are the only option in case of severe conditions where a high concentration formulation was needed and/or oral forms cannot be administered (e.g. patients in serious conditions who are otherwise unable to take oral forms). The market investigation also confirmed that in other cases injectable forms are preferred for their convenience of use but the Commission found no compelling evidence regarding the relative frequency of the use of injectable fluoroquinolones for one or other reason, nor on the readiness of clinicians to switch to oral forms in the latter case. In other words, the extent of the overlap in medical substitutability (preferred use situation) may or may not be sufficient to have a significant effect on competitive conditions in the J1G2 segment. Furthermore, even in such a case, preferences may be too strongly rooted, creating significant barriers to switching from injectable to oral formulations.

127. The Parties also put forward arguments concerning supply-side substitutability. Notwithstanding the fact that the manufacturing of antibiotics requires dedicated facilities, the Parties argued that the technology involved is standardised. Injectable and oral forms of fluoro-quinolones could therefore in principle be manufactured within the same facility, although their manufacturing processes only have one or two steps in common. Furthermore, the Parties emphasised the fact that most players are present in the fluoroquinolones market with both injectable and oral formulations and that the companies which market injectable formulations were not specialised "injectable" manufacturers. In addition to their own product offering, the Parties pointed to other competitors in the relevant geographic markets, such as KRKA, Cipla, and Novartis. As also pointed out by the Parties, there are pharmaceutical companies present in J1G markets that have a wide presence across different ATC3 and even ATC2 categories. These companies are therefore likely to have the required resources to supply both formulations.
128. Whereas a separate market authorisation is needed for different formulations of the same molecule and the production processes are also quite different, the market investigation indicated a tendency for the more significant competitors to supply both formulations. Nevertheless, some competitors may also specialise in either form for commercial reasons or because they lack the necessary production facilities (the size of the oral formulation segment in the two countries in question is larger than the injectable segment). Therefore, it is plausible that barriers to entry between different formulations of the same molecule are lower than between different molecules.
129. Due to the limitations in substituting injectable by oral forms of fluoroquinolones and since immediate supply-side substitution is unlikely it cannot be excluded that the two formulations belong to two separate product markets. However, depending on the relative importance of "preferred use" situations as opposed to "necessary use" situations in hospitals and the extent of barriers of switching in situations of medical substitutability on the one hand and on the extent of barriers to entry between different formulations of the same molecule on the other, it may be the case that J1G1 and J1G2 would rather be two separate segments of the same relevant market.
130. However, it is not necessary to conclude on the exact market definition in this case as the transaction does not lead to serious doubts even on the narrower market segmentation.

J4A Tuberculosis

131. The ATC3 category J4A comprises all specific tubercular preparations as well as streptomycin and dihydrostreptomycin. This category is used for the treatment of tuberculosis in combination with other anti-tuberculosis treatment. The three main objectives of essential tuberculosis drugs are: bactericidal activities, sterilisation activities and the prevention of resistance to treatment. Existing drugs are prescribed in combination with other drugs in order to optimise the achievement of these three objectives.
132. The European Commission has not previously defined the scope of the relevant product market for J4A. While the Parties consider that the J4A category groups all essential treatments of tuberculosis together, this ATC3 class contains a group of largely complementary products, rather than competitive ones. This is because strict protocols require the use of a combination or chemotherapy of two or more products in the treatment of tuberculosis. One product used alone would not be sufficient to cure the disease and would create a high risk of resistance to treatments and, consequently, to the loss of any opportunity to prevent the progression of the disease.
133. The market investigation largely confirmed that drugs belonging to this category are used in combination and that the Parties' products were complementary, rather than in direct competition. Furthermore, in one previous decision⁴³ it was shown that the relevant market for drugs used by hospitals for serious illnesses in many cases may be the molecule rather than the ATC3 group. As tuberculosis is a serious disease with a strong public health priority, this is also likely to apply here. Since the incidence of tuberculosis is not high in the relevant countries, these markets are very small markets (below 100.000 € in the Czech Republic and the Slovak Republic).
134. Having established that the Parties' products are complementary, it follows that they belong to different relevant markets within the overall J4A category and that therefore there is no overlap.

M1A Antirheumatics, non-steroidal

135. The ATC 3 category M1A comprises drugs prescribed against various arthroarthritic diseases such as back pain, joint disorders, osteoarthritis and arthropathies. The Notifying Party submits that the ATC3 category M1A is appropriate for purposes of market definition.
136. In *Monsanto/Pharmacia & Upjohn*, the Commission stated that the ATC3 category M1A would be appropriate for market definition purposes.⁴⁴ The market investigation in this case has not indicated that deviating from the ATC3 approach would be called for.

⁴³ Case COMP/M.5295 *Teva/Barr* Commission decision of 19 December 2008

⁴⁴ Case COMP/M.1838 *Monsanto/ Pharmacia & Upjohn*, Commission decision of 20 March 2000.

137. The exact definition of the relevant product market can, however, be left open in this case, since the notified transaction would not give rise to serious doubts regardless of the market definition considered.

M5B Bone calcium regulators

138. The ATC3 category M5B contains drugs predominantly prescribed against osteoporosis. Other indications for drugs belonging to this class are Paget's disease, oncology and osteolytic malignancies with or without hypercalcemia. The Notifying Party submits that the ATC3 category M5B is appropriate for purposes of market definition.

139. Pharmaceuticals in this class are further divided at ATC4 level into M5B3, which consists of products based on molecules in the class of bisphosphonates and used in the treatment of osteoporosis; M5B4 which consists of products used in oncology; and M5B9, which consists of all non-bisphosphonate drugs similarly used to treat osteoporosis.

140. In the present case, the Parties overlap in M5B3 and provide products based on the same molecule, namely risedronic acid.

141. The Commission has interviewed two of Sanofi-Aventis' and Zentiva's main competitors to investigate the degree of substitutability between the main osteoporosis drugs available in the Affected Countries.

142. The first competitor contacted stated that bisphosphonates are the mainstay of osteoporosis treatment and that all bisphosphonates are interchangeable. The two first-generation drugs, Sanofi-Aventis' Actonel and Merck & Co's Fosamax, are substitutable for most indications. Currently, most bisphosphonates have to be taken once per week, with the exception of Hoffman-La Roche's Bonviva (also known as Boniva) which is ingested once per month. According to this respondent, monthly ingestion is not necessarily a competitive advantage compared to drugs requiring to be taken weekly, because patients more frequently forget to take the drug if only taken once per month.⁴⁵

143. The second competitor contacted confirmed the view that all bisphosphonates are substitutable to a large extent. To compete with Hoffman-La Roche's product Bonviva, Sanofi-Aventis has developed a variant of Actonel that only needs to be taken twice per month.⁴⁶

144. The Commission has further analyzed economic evidence on the extent of substitutability between the various bisphosphonates, the results of which confirm the evidence above, namely that there is a high degree of substitution between all bisphosphonates and therefore that it would be inappropriate to define the relevant

⁴⁵ Minutes of telephone conference on 14 October 2008.

⁴⁶ Minutes of telephone conference, 29 October 2008.

market at the molecule level (i.e. it would be inappropriate to define a separate relevant market for drugs based on risedronic acid due to the very high degree of substitutability between this molecule and other bisphosphonates).

145. Having established that the relevant market is not to be defined in this case at the molecule level, it can further be left open whether the relevant market should be defined as M5B as a whole or limited to a market based on bisphosphonates only, since on either alternative market definition, serious doubts do not arise.

N2B Non-narcotic analgesics and antipyretics

146. Analgesics are drugs which attenuate pain, whilst antipyretics reduce fever. In the IMS classification these drugs are grouped in a single class owing to the fact that most molecules have both properties.
147. Certain drugs have, in addition to analgesic and antipyretic properties, also anti-inflammatory properties. In the IMS classification, anti-inflammatory analgesics used for both musculo-skeletal conditions and analgesia are, in principle, classified in M1A⁴⁷. In the affected markets, moreover, ibuprofen and metamizole, notwithstanding their anti-inflammatory properties, appear frequently classified in N2B or in both groups.
148. In its decision in *Hoechst/Rhône-Poulenc*⁴⁸, the Commission considered whether the N2B market should be further divided according to the category of pain treated, but concluded that this was not necessary in that case. In that case, market participants suggested, however, that the distinction between OTC and prescription products was a relevant distinction for the purposes of defining the relevant product market.
149. In the present case, the Parties have submitted that the market should be defined at the level of ATC3 class N2B, without a further distinction between prescription and OTC products.
150. The market investigation, by contrast, has suggested that the OTC/prescription distinction is a relevant one in all of the countries concerned by the proposed transaction⁴⁹.
151. In certain cases, including Hungary, the IMS data provides a direct division between prescription products (N2B1) and OTC products (N2B2). However, for the remaining affected countries this is not the case and in this case dual status products have been counted twice by the Parties for the purposes of calculating the relevant market shares.

⁴⁷ There are also two molecules which are classified by IMS in N2B, although in the WHO classification, they are classified as M1A: mefenamic acid and ketorolac. These molecules do not appear to generate any significant turnover in any of the affected countries and may therefore be ignored.

⁴⁸ *Hoechst/Rhône-Poulenc*, op cit..

⁴⁹ This distinction was also made in a decision by the competition authority in the Slovak Republic, decision No 2003/FH/3/1/179 *Zentiva/Slovakopharma* of 11 August 2003.

152. In the current case, having established the distinction between OTC and prescription markets, it is not necessarily to conclude as to any possible further subdivision of the N2B market, as serious doubts do not arise regardless of the market definition considered.

N3A Anti-epileptics

153. Products in this class are mainly for use in the prevention of epileptic seizures. Some are also used to treat bipolar disorder and non-epileptic convulsions.

154. In its decisions in *Sanofi-Synthelabo/Aventis*⁵⁰ and *UCB/Schwarz Pharma*⁵¹, the Commission considered a potential distinction in this market between (i.) products approved for the treatment of partial seizures and those approved for the treatment of generalised seizures; and (ii.) products indicated for use as monotherapy and those approved for use as an adjunctive therapy only. However, the Commission left the exact product market definition open.

155. The exact market definition may also be left open in this case, since the notified transaction would not result in serious doubts regardless of the market definition considered.

N5A Anti-psychotics

156. Products in this category are mainly used to treat psychosis, which is typified by schizophrenia and mania. Antipsychotics may also be used in mood disorder (e.g. bipolar disorder) even when no signs of psychosis are present.

157. In its decision in *Sanofi-Synthelabo/Aventis*⁵², the Commission considered whether the ATC3 category N5A should be subdivided into conventional (N5A9) and atypical (N5A1) anti-psychotics. The Commission also considered whether the latter class should be further subdivided based on specific therapeutic indications of the drugs in question. However, the Commission finally left both questions open.

158. The exact market definition may also be left open in this case, since the notified transaction would not result in serious doubts regardless of the market definition considered.

⁵⁰ *Sanofi-Synthelabo/Aventis*, op cit.

⁵¹ *UCB/Schwarz Pharma*, op cit.

⁵² *Sanofi-Synthelabo/Aventis*, op cit

N5B Sedatives and hypnotics

159. The N5B class of sedatives and hypnotics covers drugs which focus on inducing or maintaining sleep.
160. The Commission analysed this class of medicines in its *Sanofi/Synthelabo*⁵³ and *Sanofi-Synthelabo/Aventis*⁵⁴ decisions. In *Novartis/Hexal*⁵⁵, prescription products were considered separately. In the latter case, it was also considered whether the market should be divided between benzodiazepines and non-benzodiazepines, because of the potentially addictive nature of the former, but this was left open.
161. In the present case, the market investigation indicated that this class frequently includes OTC products, some of which are aggressively promoted, based on naturally occurring compounds such as herbal extracts, the medical efficacy of which is either unproven, or which are typically used to treat less severe instances of insomnia. Moreover, these OTC products are classified at ATC4 level in a separate category, N5B5.
162. According to the Parties, the objectives of inducing and maintaining sleep are somewhat distinct, address different patient groups, and correspond to different molecules. Nonetheless, the market investigation did not suggest there was a need to distinguish between these roles for the purposes of the present case, in particular because the distinct problem of maintaining sleep represents only a small part of the overall market and because benzodiazepines have both indications.
163. In any case, the need for such a further division – whether between inducing and maintaining sleep or between benzodiazepines and non-benzodiazepines – can be left open for the purposes of the present decision, since, in all cases where the transaction leads to serious doubts, such doubts also arise on a narrower market definition.
164. The market investigation has indicated, however, that barbiturates, which are still used quite widely in some of the affected countries as hypnotics and sedatives – in particular in Romania and Bulgaria – should be given a special treatment owing to their highly addictive character which has led to their being progressively replaced in clinical guidelines by other types of drugs. This is, moreover, once again underlined by their categorization under a separate heading at ATC4 level, namely N5B3 (plain) and N5B4 (combinations). Where relevant, barbiturates have accordingly been excluded by the Commission from the relevant market considered.
165. The assessment below is therefore based on the N5B (prescription) market as a whole, excluding barbiturates. Since the Parties do not, except in Romania, market products containing barbiturates in the N5B category, this exclusion in other cases results in an increase in market share which is mostly marginal, and has only been

⁵³ Case No COMP/M.1397, *Sanofi/Synthelabo*, op cit..

⁵⁴ *Sanofi-Synthelabo/Aventis*, op cit.

⁵⁵ *Novartis/Hexal*, op cit.

analyzed specifically in those instances where this affects the existence of serious doubts as to the compatibility of the operation with the common market. This analysis therefore corresponds essentially to an analysis of categories N5B1 and N5B2 only, and taken together.

N7X subset – Products for the symptomatic treatment of myasthenia

166. The IMS category N7X covers all central nervous system drugs not covered elsewhere in the typology. These drugs therefore do not necessarily have therapeutic links.
167. In the present case, the Parties overlap in respect of acetylcholinesterase inhibitors, which are used in the symptomatic treatment of myasthenia gravis. The Parties propose this as a market definition.
168. The Parties note that other treatments of myasthenia, such as corticosteroids and azathioprine (an immunosuppressant), belong to different markets and are included under different headings of the EphMRA and WHO typologies.
169. The market investigation has confirmed this approach in the affected national markets.
170. The assessment below is therefore based on a relevant market consisting of a subset of N7X, namely acetylcholinesterase inhibitors used in the symptomatic treatment of myasthenia gravis.

R6A Systemic antihistamines

171. Systemic antihistamines are indicated in the treatment of allergic rhinitis and urticaria.
172. The Parties note that the distinction between sedative and non-sedative antihistamines proposed by the notifying parties in *Novartis/Hexal* was not supported by the market investigation in that case.⁵⁶
173. The market investigation in the present case also gave no grounds to consider that first-generation sedative and second-generation non-sedative antihistamines constituted distinct product markets. It was, however, indicated that the sedative property was in most cases undesirable and hence that this older generation of medicines was increasingly in limited use.
174. The market investigation also indicated that products based on the molecule fexofenadine, in which the Parties overlap in certain countries, should not be considered as a separate relevant market. Products based on this molecule are substitutable with

⁵⁶ *Novartis/Hexal*, op cit.

other second-generation antihistamines based on different molecules. For the purposes of the present decision, it can therefore be excluded that the molecule level is the correct market definition.

175. Having established that the correct market definition is not to be found at the molecule level, the exact market definition may be left open in this case, since the notified transaction would not result in serious doubts regardless of the market definition considered.

Other markets⁵⁷

176. The Parties' activities also overlap in the following ATC product classes where the Parties' combined market share at ATC3 level (and/or on the basis of an alternative market definition if such a market definition has previously been considered by the Commission) in one or more of the affected countries is greater than 15%. In all of these cases, the Parties proposed to treat the market at the ATC3 level, at which level either the combined market share is less than 35% and/or the increment is less than 1%. The market investigation in these cases has not suggested alternative market definitions for these markets other than to the extent noted in the corresponding footnotes:

- a. A2B Anti-ulcerants⁵⁸
- b. B3A, Haematinics, iron and all combinations⁵⁹
- c. C1B, Anti-arrhythmics⁶⁰
- d. C1C, Cardiac stimulants, excluding cardiac glycosides,⁶¹

⁵⁷ This section exclusively lists markets for which the filter criteria were met in *all* of the affected countries. The other affected product markets are discussed individually above.

⁵⁸ In case COMP/M.4418 *Nycomed Group/Altana Pharma*, decision of 13 December 2006, the Commission assessed this market at the ATC4 level. In the present case, the Parties overlap only in the ATC4 category A2B2 Proton Pump Inhibitors, but the increment is marginal on either level. No competition concerns arise irrespective of the market definition.

⁵⁹ In Case No COMP/M.2312 *Abbott/BASF*, decision of 22 February 2001, the Commission defined the relevant product market for haematinics, iron and all combinations as corresponding to the ATC3 class B3A. In *UCB/Schwarz*, op cit, most respondents to the market investigation agreed with this market definition but a few respondents stated that the market could possibly be broken down further following the ATC4 classification. The market definition was left open. In the present case, competition concerns do not arise on either market definition.

⁶⁰ In *Sanofi-Synthelabo*, op cit, the Commission stated that the ATC3 class could constitute a relevant product market but finally left this open.

⁶¹ The Commission has not previously discussed the appropriateness of defining the ATC3 category C1C as a relevant product market. However, in *Nycomed Group/Altana Pharma*, op cit, the Commission excluded competition concerns in this market without further investigation because market shares based on ATC3

- e. C8A, Calcium antagonists, plain⁶²
- f. C9A, ACE inhibitors, plain⁶³
- g. C9B, ACE inhibitors, combinations⁶⁴
- h. C9C, Angiotensin-II antagonists, plain⁶⁵
- i. C9D Angiotensin-II antagonists, combinations⁶⁶
- j. C10A Cholesterol and triglyceride regulating preparations,⁶⁷
- k. D7A, Plain topical corticosteroids⁶⁸
- l. G1A, Trichomonacides⁶⁹
- m. J1F, Macrolides and Similar Types⁷⁰
- n. N5C, Tranquillizers⁷¹

and ATC4 levels were both unproblematic. In the present case, competition concerns do not arise on either market definition.

- ⁶² In *Pfizer/Warner-Lambert*, op cit, the Commission defined the relevant market at the ATC3 level.
- ⁶³ In *Sanofi-Synthelabo/Aventis*, op cit, the Commission considered whether C9A and C9B constitute separate relevant product markets or whether they should be grouped together in one market. The Commission left the market definition open. In the present case, no competition concerns arise on either market definition.
- ⁶⁴ In *Sanofi-Synthelabo/Aventis*, the Commission considered whether C9A and C9B constitute separate relevant product markets or whether they should be grouped together in one market. The Commission left the market definition open. In the present case, no competition concerns arise on either market definition.
- ⁶⁵ The Commission has previously considered C9A category in case COMP/M.1403 *Astra/Zeneca*, decision of 26 February 1999, *Pfizer/Warner-Lambert*, op cit and case COMP/M.2922 *Pfizer/Pharmacia*, decision of 27 February 2003, but has left the exact scope of this market open. In the present case, no competition concerns arise at the AT3 level. There is no overlap at molecule level.
- ⁶⁶ The Commission has previously considered C9D category in *Astra/Zeneca*, op cit, *Pfizer/Warner-Lambert*, op cit, and *Pfizer/Pharmacia*, op cit, but has left the exact scope of this market open. In the present case, no competition concerns arise at the AT3 level. There is no overlap at molecule level.
- ⁶⁷ In *Pfizer/Warner-Lambert*, op cit, the Commission carried out its competitive analysis at the ATC3 level.
- ⁶⁸ The Commission assessed this market on the basis of the ATC3 class in case COMP/M.457 *La Roche/Syntex*, decision of 20 June 1994; case COMP/M.500 *American Home Products/American Cyanamid*, decision of 19 September 1994; case *Sanofi-Synthelabo/Aventis*, op cit.
- ⁶⁹ In *Monsanto/Pharmacia & Upjohn*, op cit, the Commission took the ATC3 level as the basis of assessment.
- ⁷⁰ In *Sanofi-Synthelabo/Aventis*, op cit, the Commission analysed this market and considered that the relevant market corresponded to the ATC3 category J1F.

o. N6A Anti-Depressants and Mood Stabilizers⁷²

177. For all of these markets, the Parties proposed that the ATC3 level was the relevant product market definition. With the exception of certain cases referred to in the footnotes to the previous paragraph, which have been individually considered by the Commission in its assessment, the market investigation has not suggested that there was a need in this instance to explicitly consider any of the remaining markets on another basis than the ATC3 level for the purposes of assessing the proposed transaction.
178. In the present case the market definition for all of these markets can, however, be left open, as the transaction does not give rise to serious doubts regardless of the market definition considered

IV.1.3. ACTIVE PHARMACEUTICAL INGREDIENTS

IV.1.3.1. RELEVANT PRODUCT MARKETS

179. In previous decisions the Commission has considered that APIs form separate markets which are upstream of the markets of the finished pharmaceutical products.⁷³ The market investigation in this case has confirmed this approach.
180. The Commission has looked at each individual API as potentially constituting a relevant market by itself. However, it cannot be excluded that certain APIs may be substitutable with each other for all, or for a range of, applications.
181. In the present case, the market definition can be left open in all but one case, since in all other cases no competition concerns arise, even on the narrowest possible market definition, i.e. on the basis of considering the individual API as the relevant market.
182. The single case where the Commission needed to investigate further the market definition related to the API ethylmorphine.
183. According to the Notifying Party, ethylmorphine is mainly used as an ingredient for anti-tussive products (ATC3 class R5D), which represent about [90-100]% of its applications.
184. Employing IMS data, the Notifying Party estimates that ethylmorphine is present only in [0-5]% of finished anti-tussive products. The Parties argued that there is a

⁷¹ The Commission has not previously defined this market

⁷² In *Novartis/Hexal*, op cit, the Commission analysed this market at the ATC3 level but subdivided it into one segment for OTC products and a separate segment for prescription products. In the present case, such a division does not affect the competitive analysis.

⁷³ See for instance *Johnson & Johnson/Johnson & Johnson MSD Europe*, op cit, *Novartis/Hexal*, op cit and *Teva/Barr*, op cit.

variety of alternative APIs used in the production of anti-tussive products, such as codeine, butiramate or dextromethorphan, most often included in multi-ingredient compositions. These products can, in the Parties' view, easily replace the ethylmorphine-based products, in particular because anti-tussive products are mainly OTC products for which customer loyalty is based on brand image more than on the composition of the products.

185. The market investigation confirmed the Notifying Party's views as stated above in relation to ethylmorphine. It can thus be concluded that ethylmorphine belongs to a wider market of inputs used in anti-tussive preparations. Since ethylmorphine represents only a very small percentage of these substitutable inputs, it is unnecessary to conclude on the precise market definition, since, having established that at least some of the alternative APIs mentioned by the Parties belong to the same market, no competition concerns arise on this market regardless of its exact definition.

IV.1.3.2. RELEVANT GEOGRAPHIC MARKET

186. The Commission has previously considered that the markets for the provision of APIs are wider than the markets for finished dose pharmaceuticals and possibly worldwide. The market investigation in this case has confirmed that the relevant geographic market is likely to be worldwide in scope. However, having established that these markets are wider than national in scope, the exact scope of geographic market can be left open as serious doubts do not arise either the basis of an EEA-wide market, or a worldwide market.

IV.1.4. CONTRACT MANUFACTURING

IV.1.4.1. RELEVANT PRODUCT MARKET

187. Contract manufacturing of finished dose pharmaceuticals (contract manufacturing) consists in the manufacturing under contract, on behalf of third party pharmaceutical companies, of finished pharmaceutical products, which may or may not include final packaging. This third party then goes on to market the finished products under its own label or brands. This definition excludes the manufacturing of active pharmaceutical ingredients, since such ingredients are not typically manufactured on a contract basis and typically may be procured from a wide variety of sources.
188. In its previous decisions, the Commission has not defined the contract manufacturing market. Its market investigation in the current case indicated that there were, as argued by the Parties, certain core technologies in contract manufacturing which were widely available and corresponded to the most common pharmaceutical forms. Certain other technologies, on the other hand, are more specialized. From both the demand and supply side, these technologies are not substitutable. However, most of the core technologies are offered by most of the undertakings active in the contract manufacturing business either as their core business or as an adjunct to their captive production activities.

189. It follows that a number of contract manufacturing markets could be defined, corresponding in each case to the pharmaceutical form which is manufactured and also in some cases the conditions of manufacture (types of API involved in the process, toxicity, sterile environment etc).
190. In the present case, however, the precise market definition can be left open since, regardless of the market definition considered, the transaction does not lead to any horizontally affected markets or to serious doubts on any downstream markets for finished products⁷⁴.

IV.1.4.2. RELEVANT GEOGRAPHIC MARKET

191. In relation to the relevant geographic market, there was a strong degree of consensus in the market investigation that this was a worldwide market, notwithstanding the need for EU certification of manufacturing processes.
192. For the purposes of the present decision, it can, however, be left open whether this market is EEA-wide or worldwide, since the relevant geographic scope of the market, at least for the products considered in this decision, is clearly at least EEA-wide and, given this, the transaction does not lead to serious doubts as to its compatibility with the common market regardless of the exact geographic market definition considered.

IV.1.5. **POTENTIAL COMPETITION**

IV.1.5.1. RELEVANT PRODUCT MARKETS

193. The present case raised issues of potential competition of two kinds.
194. Firstly, the Commission considered the consequences of the transaction for products in which Sanofi-Aventis had an important position in an originator molecule and Zentiva had a generic equivalent of this molecule in its pipeline, or a generic equivalent of another molecule with the same therapeutic indications and therefore within the same relevant product market ("pipeline competition"). As it was very likely that these products would eventually be brought to market, this competition therefore would materialize in the future with a high probability. For such products, it was necessary to ascertain whether the removal of the future constraint posed by the Zentiva pipeline product to the market position of Sanofi-Aventis would lead to serious doubts as to the compatibility of the transaction with the common market.
195. Secondly, the Commission also considered the more general question of whether the change of control over Zentiva would lead to less generic competition in the future in any of the Affected Countries, both for molecules whose patents were held by Sanofi-Aventis itself, and for other originator molecules marketed by other pharmaceutical companies ("generic competition"). In respect of Sanofi-Aventis' own molecules, this

⁷⁴ In certain instances, serious doubts arise in some of the downstream markets which are vertically affected in the present case owing to the existence of a contract manufacturing relationship. However, in all such cases these doubts would also arise in the absence of the vertical relationship.

includes, but is not limited to, the possibility that Sanofi-Aventis might, through Zentiva, introduce its own generic version of the molecule (a so-called "authorized generic") which might impact on the subsequent competitive process.

IV.1.5.2. RELEVANT GEOGRAPHIC MARKET

196. As finished pharmaceutical products are marketed within national markets based sometimes on national authorizations and invariably on national prescription and reimbursement guidelines, it follows that all actual competition is national in scope. Nonetheless, up to a certain point in the development process the steps involved are not specific to a given country but reflect a process which occurs on a multinational basis and may eventually lead to product launches in more than one country.
197. Notwithstanding this, the effect of an elimination of potential competition still needs to be considered at national level, since it may well be asymmetric given the differing presence of the constraining undertaking, in this case of Zentiva, in different countries.
198. [...] Therefore it can be concluded that the transaction might only have an effect in terms of potential competition in the countries where Zentiva is present today, i.e. the Affected Countries.
199. For the purposes of the present decision, issues relating to potential competition therefore have to be considered on a national basis for each of the affected countries.

IV.2. COMPETITIVE ASSESSMENT

IV.2.1. Overview

200. Whilst Sanofi-Aventis is primarily an innovator pharmaceutical company active throughout the EU and globally, Zentiva is a regional player in branded generics which is particularly strong in its historical home markets of the Czech Republic and the Slovak Republic and also has a strong position in Romania acquired through acquisition. In the Czech Republic and Slovakia, it is the most important pharmaceutical company both by value and volume of sales.
201. The case therefore raised a certain number of issues related to the specific market position of Zentiva on its home markets, as well as to the position of generic medicines, and more specifically branded generics, on those markets.
202. For the purposes of this decision it is also necessary to bear in mind that pharmaceutical markets may display certain rigidities as regards both pricing and entry.
203. These issues are considered below both in relation to the competitive assessment and to the analysis of the commitments submitted.

IV.2.2. Introductory remarks

IV.2.2.1. Calculation and interpretation of market shares

204. In line with previous practice, the Commission has primarily relied on the value of sales recorded by IMS as a measure of market share. Calculating market shares on the basis of value has the advantage of allowing easy aggregation of products which may be based on different active ingredients, different quantities of which may be required to achieve the same therapeutic outcome.
205. However, calculating market shares based on value has certain limitations in pharmaceuticals markets, because Zentiva, like other generic producers, often charges prices which may be significantly lower than those of Sanofi-Aventis and other producers of original drugs. In such cases, shares based on value may sometimes differ significantly from market shares based on volume (measured as the quantity of individual APIs sold or normalized to some measure of therapeutic value such as days of treatment⁷⁵).
206. Market shares based on value may therefore underestimate Zentiva's "patient market share" in cases where Zentiva has a large share of the generic part of the market which is large in volume terms relative to Sanofi-Aventis' share. In the contrary case, they may overestimate this share.
207. Within the limitations of its phase one investigation in this case, the Commission has not systematically carried out its analysis on another basis than value of sales, but it has nonetheless considered the likely qualitative impact of such an alternative calculation of market shares in instances where *prima facie* competition concerns would arise.
208. As a general rule, the market investigation has shown that it is likely that the quantity or patient market share would be higher than the share based on value in all markets which are imperfectly genericised (that is to say, in which originator molecules continue to play an important role and to command a premium relative to generic equivalents) in the Czech and Slovak republics and, depending on the market, in Romania.
209. The Commission cites market shares according to IMS data, corrected where necessary, for 2007 unless otherwise stated; however, it has considered data for the three years 2005 through 2007 in its analysis and, in certain cases, also more recent data. Where this leads to a modification to the assessment it has been cited in the relevant sections below.

IV.2.2.2. Barriers to entry in generics markets

210. The regulated nature of pharmaceutical markets influences the likelihood and time needed for entry. As regards the likelihood of entry, it is not possible to determine the

⁷⁵ See the discussion of the B1B market above.

related effects in the abstract, since the ability to charge a supracompetitive price which is not paid by the final consumer may attract entry, whilst tight price regulation may limit margins to the extent that entry is no longer attractive.

211. According to the Parties, barriers to market entry are lower for generics than for innovator drugs. For generics, R&D aims at ensuring that a finished product is bioequivalent to the innovator drug. The development of a generic drug typically takes from eight months up to four and a half years. It should however be noted that generics producers usually start the development work well before the innovator drug's patent expires.
212. Marketing authorisations for generic products must be obtained from national authorities in the Member State where the products will be marketed. In the European Union, a company that wishes to bring a medicine – innovator or generic – to the market may also submit a single application to the EMEA for a marketing authorisation (licence) that is valid simultaneously in all EU Member States (and the EEA-countries Iceland, Liechtenstein and Norway). This is called the "centralised (or "Community") authorisation procedure", and is mandatory for certain types of medicines and optional for others. The precise scope is set out in Regulation (EC) No 726/2004.⁷⁶ In respect of reimbursement ceilings, the procedures are always national.
213. The Commission market investigation indicated in this case, and in its earlier *Teva/Barr*⁷⁷ decision, that the investment required to establish generic bioequivalence, to obtain a marketing authorisation, to build up an operation, to register for reimbursement, to get reimbursement approval, to promote and organize the distribution of a generic drug are the main entry barriers. Furthermore, a generic company needs to have credibility in the national market and local knowledge. To enter a national market with a generic drug therefore takes at least one to two years and may take significantly longer in many cases.
214. These elements indicate that there are significant barriers to entry in the affected countries for new generic products. Compared to innovator drugs, generic entry requires lower but still significant investments to obtain market authorisations and, in particular, to build up a marketing and distribution organisation. Reimbursement rules can also constitute barriers to entry. The development of a generic drug takes at least ten months. Once the development of the drug has been finalised, a certain time is required for the administrative procedure. Development and administrative procedure adds up to more than one year and it might take several years depending on the product. This means in general that the strategic decision to enter national markets with a certain generic drug must be taken well in advance of actual entry. The precise dynamics depend on the product and country in question.
215. It was also pointed out during the market investigation in the present case that the generic pharmaceutical industry is subject to economies of scale and scope. Because of

⁷⁶ Regulation (EC) No 726/2004 of The European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, OJ L 136/1, 30.04.2004.

⁷⁷ *Teva/Barr*, op cit.

the need for national labelling, distribution and authorizations, entry into new geographies implies a sunk investment which could not be recuperated on very small volumes of business.

216. It follows that entry can only be considered to constrain the market position of the Parties post-merger if there is positive proof of its likelihood within a short period.

IV.2.3. Horizontal effects

IV.2.3.1. FINISHED DOSE PHARMACEUTICALS

Introduction

217. In this section, the Commission makes a detailed assessment of all those product markets and geographies in which possible competition concerns were identified during the market investigation.

218. For many markets and geographies, the parties' joint market shares do not exceed 35% on any of the alternative market definitions considered (including at molecule level where it has not been excluded that this is the relevant market definition), and/or the increment is below 1% on any of these alternative market definitions. As in previous Commission decisions, these markets are dealt with "en masse" unless particular situations were identified which required a more detailed discussion. For these markets reference is therefore made to the final subsection of this section (paragraph 487).

219. For the avoidance of doubt, it should be noted that the Parties may overlap for a given product market in certain geographies which are not individually discussed here, but which fall within the scope of the general conclusion of the absence of serious doubts covered by that paragraph. The geographies explicitly considered below may therefore not include all affected geographical markets for the products in question.

220. A certain number of product markets are considered only in the market definition section above and do not appear individually in this assessment section at all. In such a case, the discussion of the market definition was necessary in order to establish that the thresholds indeed applied which would permit the Commission to exclude serious doubts in all affected geographic markets. Having established this to be the case, an individual assessment of these markets was again not required. Such markets therefore fall within the scope of the conclusion in paragraph 487 for all affected geographic markets for the product in question.

A2A Antiacids, Antiflatulents, Carminatives

Romania

221. In Romania the combined market share of the parties in 2007 based on ATC3 class amounted to [60-70]% (Sanofi-Aventis: [10-20]%, Zentiva: [50-60]%). The largest

competitors were Pfizer ([10-20]%) and Menarini ([10-20]%). All other competitors had market shares below 5%.

222. The market has grown in size since 2005. The combined market shares of the Parties decreased slightly as well as those of other competitors while Menarini's market share increased from [0-5]% in 2005. According to the Parties, their market shares continued to decrease in 2008. For the period January-May 2008, the Parties' joint market share was [50-60]%.
223. At the ATC4 level, the Parties' products in Romania are both preparations in class A2A1. Sanofi-Aventis' product is Maalox, whilst Zentiva's market share is almost entirely attributable to its Dicarbocalm product, although it also has a second product with no sales in 2007, namely Carbo Medicinalis.
224. The Parties acknowledge that their products are in direct competition. This has also been confirmed by the Commission's market investigation.
225. Taking into account the high, albeit somewhat declining, combined market share, the fact that the Parties currently represent the most and second most significant competitors on the market, the much lower market shares of the Parties' competitors and the fact that the Parties' products are direct competitors and possibly each other's closest competitor, as well as the existing barriers to entry referred to in section IV.2.2.2, it can be concluded that serious doubts arise in respect of the A2A market in Romania.

A3A Plain antispasmodics and anticholinergics

Romania

226. In Romania the combined market share of the parties in 2007 amounted to [60-70]% (Sanofi-Aventis: [50-60]%, Zentiva: [10-20]%). The largest competitors were Berlin Chemie ([10-20]%) and Solvay Pharma ([10-20]%). All other competitors had market shares of 5% or below. The market has grown since 2005. The combined market shares of the Parties decreased slightly while those of Berlin Chemie and Slovac increased slightly since 2005.
227. According to the Parties, their products are in direct competition. This was confirmed by the market investigation. Sanofi-Aventis' product No-Spa is based on the molecule drotaverine, whereas Zentiva's product Scobutil ([5-10]% share) is based on butylscopolamine bromide, a belladonna derivative.
228. Both products have injectable formulations, which are prescription-only, and oral ones which are OTC. Given that injections are administered by physicians and in hospital settings, it can be assumed that the great majority of sales by value relate for both products to the oral formulation and therefore to the OTC market.
229. Taking into account the high, albeit somewhat declining, combined market share, the much lower market shares of the Parties' competitors, the fact that the Parties' products are direct competitors as well as the barriers to entry referred to in section IV.2.2.2, it can be concluded that serious doubts as to the compatibility of the transaction with the

common market arise in respect of the A3A market in Romania, regardless of whether this market is further subdivided between OTC and prescription markets.

Hungary

230. In Hungary, the combined market share of the parties in 2007 amounted to [70-80]% (Sanofi-Aventis: [60-70]%, Zentiva: [5-10]%). The largest competitor was Solvay Pharma ([10-20]%). All other competitors had market shares of below 5%. The market declined since 2005. The combined market shares of the Parties as well as those of their competitors were rather stable since 2005.
231. According to the Parties their products are in direct competition. This was confirmed by the market investigation. Sanofi-Aventis' product No-Spa is based on the molecule drotaverine, whereas Zentiva's product is based on papaverine, which is structurally and pharmacologically close to drotaverine with similar activities and indications.
232. Both products have injectable formulations, which are prescription-only, and oral ones which are OTC. Given that injections are administered by physicians and in hospital settings, it can be assumed that the great majority of sales by value relate for both products to the oral formulation and therefore to the OTC market.
233. Taking into account the high combined market share and the much lower market shares of the Parties' competitors and the fact that the Parties' products are direct competitors as well as the barriers to entry referred to in section IV.2.2.2, it can be concluded that serious doubts arise in respect of the A3A market in Hungary, regardless of whether this market is further subdivided between OTC and prescription markets..

Slovak Republic

234. In Slovak Republic the combined market share of the parties in 2007 amounted to [50-60]% (Sanofi-Aventis: [40-50]%, Zentiva: [5-10]%). The largest competitors were Solvay Pharma ([30-40]%) and Boehringer Ingelheim ([10-20]%). All other competitors had market shares of below 5%. The market size has grown only marginally by value since 2005. The combined market shares of the Parties increased slightly while those of their competitors decreased slightly (Solvay, Boehringer Ingelheim) over this period.
235. Zentiva's product Spasmopan is a suppository based on a combination of paracetamol, codeine phosphate, pitofenone and fempiverinium.
236. According to the Parties their products to some extent target different patient populations: No-Spa is administered by oral tablets and parenteral ampoules while Spasmopan is administered by rectal suppositories for acute home care vomiting patients who are not able to swallow tablets. The Parties suggested, however, that these products nonetheless belong to the same market.
237. The Commission's market test confirmed that the products of Sanofi-Aventis and Zentiva are not the closest competitors to each other, since the closest substitute to the Sanofi-Aventis product was considered to be Duspatalin (Solvay).
238. There are no indications that a possible subdivision of the market into OTC and prescription markets would alter this competitive analysis.

239. Taking into account the existence of two significant competitors and a number of smaller ones, and the relatively limited increment in a product which, in this case, is clearly not the closest substitute to Sanofi-Aventis' product, it can be concluded that serious doubts do not arise in respect of the A3A market in the Slovak Republic, or in the possible OTC and prescription submarkets.

Czech Republic

240. In the Czech Republic, the combined market share of the parties in 2007 amounted to [40-50]% (Sanofi-Aventis: [30-40]%, Zentiva: [5-10]%). The largest competitors were Solvay Pharma ([20-30]%) and Boehringer Ingelheim ([10-20]%). There are some other competitors with market shares of below 10%. The market size grew since 2005. The combined market shares of the Parties decreased rather strongly while those of Solvay have been increasing strong and those of Boehringer Ingelheim decreased slightly since 2005. There are no indications that a possible subdivision of the market into OTC and prescription markets would alter this competitive analysis.

241. The situation in the Czech Republic is similar to that in the Slovak Republic, with identical products from the Parties. The Commission's market test confirmed that the products of Sanofi-Aventis and Zentiva are not the closest competitors to each other, since the closest substitute to the Sanofi-Aventis product was considered to be Duspatalin (Solvay). Moreover, fempiverinium and pitofenone are not considered therapeutic alternatives to drotaverine in the Czech cluster system referred to above.

242. An analogical analysis therefore applies in this case and it can be concluded that serious doubts do not arise in respect of the A3A market in Czech Republic, or in the possible OTC and prescription submarkets.

A4A Antiemetics and antinauseants

Bulgaria

243. In Bulgaria the combined market share of the parties in the ATC3 class A4A in 2007 amounted to [30-40]% (Sanofi-Aventis: [10-20]%, Zentiva: [20-30]%). The largest competitors were GSK ([30-40]%), Roche ([10-20]%) and Heel ([10-20]%). There are further competitors with market shares below 10%.

244. Sanofi-Aventis' product Anzement ([10-20]% of the ATC3 category) belongs to the subgroup of products indicated against chemotherapy side effects and its main competitors for this indication are GSK's product Zofran ([30-40]%) and Roche's product Kytril ([10-20]%).

245. Zentiva's product Medrin ([20-30]%) belongs to the product subgroup indicated against vomiting caused by more common causes. Other companies with products in this subgroup are Heel with Vomitusheel ([10-20]%), Actavis with Dimenhydrinat ([5-10]%) and Novartis with Vomacur ([0-5]%). Sanofi-Aventis does not market any drug classified in this subgroup.

246. It follows that the relatively limited combined market share is further mitigated by the fact that the Parties' products are, even if they were considered to belong to the same relevant market, clearly not each other's closest substitute. Moreover, there are at least two competitors, one with a higher market share than the Parties. At ATC4 level, the Parties' products are in different classes and are based on different molecules.
247. It therefore follows that serious doubts do not arise in respect of the A4A market in Bulgaria or any alternative subdivision thereof.

A5B Hepatic protectors and lipotropics

Czech Republic

248. In the Czech Republic the combined market share of the parties in 2007 amounted to [70-80]% (Sanofi-Aventis: [40-50]%, Zentiva: [20-30]%). The largest competitors were Ratiopharm ([10-20]%) and Woerwag ([5-10]%). All other competitors have market shares of below 5%.
249. According to the Parties their products are in direct competition notwithstanding that they belong to different ATC4 groups. In Czech Republic both products are prescription products with nearly similar indications (adjuvant therapies). The market investigation did not indicate a different view.
250. Taking into account the high combined market share, the fact that the transaction combines the players with the two largest market shares, the much lower market shares of the Parties' competitors and the fact that the Parties recognize that their products are in direct competition as well as the existing barriers to entry referred to in section IV.2.2.2, it can be concluded that serious doubts as to the compatibility of the transaction with the common market arise in respect of the A5B market in the Czech Republic.

Slovak Republic

251. In the Slovak Republic, the combined market share of the parties in 2007 amounted to [70-80]% (Sanofi-Aventis: [30-40]%, Zentiva: [30-40]%). Sanofi-Aventis' product Essentiale is an OTC product while Zentiva's Flavobion is a prescription product. The only competitor is Woerwag ([20-30]%).
252. According to the Parties, their products are not in direct competition, since in the Slovak Republic, Zentiva's Flavobion is a prescription product and is therefore subject to price regulation, while Sanofi-Aventis' Essentiale is an OTC-product and not subject to price regulation. However the Parties accept that both products belong to the same market and should be considered as therapeutical alternatives.
253. Even though one Party's product is sold OTC while the other Party's is sold only on prescription, it has to be taken into account in this case that also the products sold OTC are reimbursable. This was confirmed by the market investigation.

254. Taking into account the high combined market share, the fact that the transaction combines the players with the two largest market shares with only one competitor remaining, and the much lower market shares of the Parties' only competitor as well as the existing barriers to entry referred to in section IV.2.2.2, it can be concluded that serious doubts arise as to the compatibility with the common market in respect of the A5B market in the Slovak Republic

A7A Intestinal anti-infective antidiarrhoeals

Czech Republic

255. Based on the ATC3 class the combined market share of the Parties amounted to 90% in 2007 (Sanofi-Aventis: [10-20]%, Zentiva: [70-80]%). Sanofi-Aventis' product Ercefuryl is a prescription product while Zentiva's Endiaron is an OTC product. The only other competitor in this class is Medicom ([10-20]%). The market size has grown since 2005 and the market shares of the Parties and their competitor have remained stable.

256. According to the Parties, their products are in direct competition.

257. According to the only competitor, Zentiva's closest competitor as well as Sanofi-Aventis' closest competitor would be the third competitor's product Nomix.

258. Taking into account the high combined market share, the fact that the transaction combines the players with the two largest market share with only one competitor remaining, and the much lower market shares of the Parties' only competitor as well as the barriers to entry referred in section IV.2.2.2, it can be concluded that serious doubts arise as to the compatibility of the transaction with the Common market in respect of the A7A market in the Czech Republic.

A10B Oral antidiabetics

Poland

259. Based on the ATC3 approach, Sanofi-Aventis had a market share of [10-20]% in 2007 while Zentiva's market share was below 1% with the recently launched product Amyx, which is a generic version of the Sanofi-Aventis product Amaryl (glimepiride). As Zentiva's product was recently launched and is a generic equivalent of the Sanofi-Aventis product, the Commission deemed it necessary to examine this market more closely.

260. The products of the competitors Teva, Menarini, Polpharma and Merck, all containing the molecule metformin, account for [20-30]% of the A10B market⁷⁸. The

⁷⁸ Metformin is a biguanide antidiabetic, in class A10J of the 2009 nomenclature

Parties' market shares would rise to [20-30]% in an alternative market without products based on metformin.

261. The Parties' products belong to the same ATC4 class, A10B1, consisting of sulfonylurea antidiabetics⁷⁹. Their combined market share at ATC4 level would be [20-30]% (Sanofi-Aventis [20-30]%, Zentiva [0-5]%).
262. According to the Parties, there are many competitors in Poland with a generic version of Amaryl: Teva (Glimteva), Menarini (Oltar), Polopharm (Glibetic) and some others with market shares below 5%.
263. Given the relatively low combined market shares on any of the alternative market definitions, the small increment and the number of competitors with the same molecule as Sanofi-Aventis, serious doubts do not arise as to the compatibility of the transaction with the common market in respect of the A10B market in Poland.

Romania

264. Sanofi-Aventis had a market share of [10-20]% at ATC3 level in 2007, while Zentiva's market share was 1% with the recently launched product Amyx, a generic version of the Sanofi-Aventis product Amaryl (glimepiride)⁸⁰. As this product was recently launched and is a generic equivalent of the Sanofi-Aventis product, the Commission deemed it necessary to examine this market more closely.
265. The Menarini product based on the molecule metformin, accounted for [20-30]% of the A10B market in 2007. The Parties' joint market share would rise to [10-20]% in an alternative market without products based on metformin.
266. The Parties active products belong to the same ATC4 class, A10B1. Their combined market share at ATC4 level would be [30-40]% (Sanofi-Aventis [30-40]%, Zentiva [0-5]%).
267. In Romania there are a number of competitors with a generic version of Amaryl, including Servier (Glemid).
268. Given the relatively low combined market share, and the small increment even at ATC4 level, as well as the number of competitors, including several with the same molecule, serious doubts do not arise as to the compatibility of the transaction with the common market in respect of the A10B market in Romania.

Czech Republic

269. Sanofi-Aventis had a market share of [5-10]% at ATC3 level in 2007, including the product Metfirex which is based on metformin ([0-5]%), while Zentiva's market share

⁷⁹ Corresponding to A10H in the 2009 nomenclature. This class is not further subdivided at ATC4 level.

⁸⁰ Zentiva has or had three other products in A10B in Romania, but the sales of all these other products was zero in 2007 and negligible in earlier years. They are hence disregarded in the remainder of the analysis.

was [0-5]% with the recently launched product Amyx and four further products based on different molecules, two of them based on metformin.

270. The products by Sanofi-Aventis, Zentiva, Menarini, GSK, Merck and Ratiopharm containing the molecule metformin account for [40-50]% of the market. The Parties' market share in a market without products based on metformin would rise to [10-20]%. The Parties' combined market share for the products containing metformin would be below [5-10]%. One of Zentiva's metformin products (Langerin) entered the market recently.
271. Those of the Parties' products which are not based on metformin all belong to the same ATC4 category, A10B1 (sulfonylurea). Their combined market share at the ATC4 level would be [20-30]% (Sanofi-Aventis [10-20]%, Zentiva [0-5]%).
272. In the Czech Republic there are many competitors with a generic version of Amaryl: Menarini (Oltar), Servier (Glemid), Ratiopharm (Glimepirid Rat), TEVA (Glimepirid Teva) and several other companies with market shares below 5%.
273. Given the low combined market shares, the small increment and the number of competitors, serious doubts do not arise as to the compatibility of the transaction with the common market in respect of the A10B market in the Czech Republic.

Slovak Republic

274. Sanofi-Aventis had a market share of [5-10]% at ATC3 level in 2007, while Zentiva's market share was [0-5]% with the recently launched product Amyx and four further products based on different molecules, two of them based on metformin.
275. The products by Zentiva, Menarini, and Merck KGAA containing the molecule metformin account for [40-50]% of the market. The Parties' joint market share would rise to 11% in an alternative market without products based on metformin. In the Slovak Republic, Sanofi-Aventis has no product in this class based on metformin.
276. The Parties overlap at the ATC4 level only in class A10B1, at which level their combined market share would be approximately [10-20]% (Sanofi-Aventis [5-10]%, Zentiva [0-5]%).
277. In the Slovak Republic there are many competitors with a generic version of Amaryl: Menarini (Oltar), Servier (Glemid) and some others with market shares below 5%.
278. Given the low combined market shares, the small increment and the number of competitors, serious doubts do not arise as to the compatibility of the transaction with the common market in respect of the A10B market in the Slovak Republic.

Hungary

279. In Hungary, in 2007 Sanofi-Aventis had a market share of 5% at ATC3 level, while Zentiva's market share was [0-5]%.

280. The products by GSK, Merck KGAA, Menarini and Novartis containing the molecule metformin account for [30-40]% of total sales. The Parties market share in a market without products based on metformin would rise to [10-20]%.
281. The Parties' products all belong to the same ATC4 class, A10B1, with the exception of Zentiva's product Adebit (buformin), which is a biguanide and, as such, in the same group as metformin. Their combined market share at ATC4 level would be [10-20]% (Sanofi-Aventis [10-20]%, Zentiva [0-5]%).
282. In Hungary there are many competitors with a generic version of Amaryl: Menarini (Sintecal), Novartis (Glimepirid) and some others with market shares below 5%.
283. Given the low combined market shares, the small increment and the substantial number of competitors active in this market, serious doubts do not arise in respect of the A10B market in Hungary.

A12C Other Mineral Supplements

Romania

284. The combined market share of the parties in 2007 would amount to [40-50]% (Sanofi-Aventis: [30-40]%, Zentiva: [0-5]%). All the parties' products are OTC products that contain magnesium. The largest competitors were Biofarm ([20-30]%) and Woerwag ([10-20]%). All other competitors had market shares of 5% or below.
285. One competitor stated that Zentiva's closest competitor was Sanofi-Aventis with the product Magne B6. Zentiva originally also indicated that [...].
286. The Romanian National Medicines Agency stated that Sanofi-Aventis Magne B6 and Zentiva's Glutamag B6 are substitutable oral products. The same Agency indicated that Sicovit Magnesium (1% of the market) is not a medicinal product, but probably a food supplement.
287. Even if the Glutamag product were to be considered as the closest substitute to Sanofi-Aventis' product, the increment by Zentiva would be very limited. Its combined market share, which is constant since 2005, is [0-5]%, and would be only [0-5]% if Sicovit Magnesium were excluded. The analysis would not change if the market were to be defined at the level of the mineral supplement as most of these supplements contain magnesium.
288. According to the Parties the market share of Sanofi-Aventis has decreased from [50-60]% in 2005 to [30-40]% in 2007. There are several competitors with increasing market shares like Biofarm with [20-30]% ([20-30]% in 2005) and Woerwag with [10-20]% ([5-10]% in 2005), both of which offer close substitutes, particularly Biofarm which also offers magnesium in combination with vitamin B6.
289. It can thus be concluded that serious doubts do not arise as to the compatibility of the notified transaction with the common market in the A10C market in Romania.

B1B Heparins

Introduction

290. The Parties' activities overlap in the Czech Republic and the Slovak Republic. Whereas Zentiva solely supplies old generation heparin (UFH) belonging to the ATC3 category B1B1 and Sanofi-Aventis solely supplies a new generation heparin (LMWH) belonging to the ATC4 category B1B2, the overlap in their activities only occurs at the ATC3 level B1B. In both countries only B1B1 and B1B2 heparins are marketed, hence their combined sales account for the entire B1B ATC3 market. The competitive assessment will concentrate on the hospital segment which, as mentioned above, represents [80-90]% of the total B1B market in both countries and was the only segment in which concerns might have arisen, given that UFH is not used in outpatient contexts.

Czech Republic

291. In the overall B1B market, the Parties have a combined market share of [50-60]% in the Czech Republic based on the value of sales in 2007 (Sanofi-Aventis [40-50]% and Zentiva [5-10]%). GSK would be the Parties' most significant competitor with [30-40]%, followed by Pfizer ([5-10]%) and two other competitors with smaller market shares (Menarini [0-5]% and Novartis [0-5]%). The total value of the B1B market was EUR [...] in 2007 with UFH accounting for only [5-10]%. While the LMWH segment has grown by over 10%, the size of the UFH segment (in sales value) has not changed significantly between 2005 and 2007. The closest competitor in terms of size and product to Sanofi-Aventis appears to be GSK (LMWH). Furthermore, the market investigation indicated that in the Czech Republic there is strong competition among LMWHs.

292. Looking at the hospital segment based on sales value, the competitive situation appears to be similar as market shares are not materially different. This notwithstanding, the comparative volume indicators (days of treatment) in the hospital segment show a decline in the *actual use* of UFHs.

293. The share of UFH within the hospital segment has shown a steady decline in terms of actual use (measured as days of treatment), falling from [20-30]% in 2005 to only [10-20]% in 2008. This is also accompanied by an absolute decline in volume sales. On the other hand, the use of LMWHs (measured as days of treatment) increased both in absolute and in relative terms.

294. Expressed in days of treatment, the combined market share of the Parties in the hospital segment in the Czech Republic would be [50-60]% (Sanofi-Aventis [30-40]% and Zentiva [10-20]%) based on 2007 figures. However, Zentiva's market share has shown a steady decline, in line with the general trend in the UFH market (Zentiva's market share was [10-20]% on average in the first three quarters of 2008). There remain two significant LMWH competitors GSK ([30-40]%) and Pfizer ([10-20]%). In 2007 Novartis had [0-5]% of the market with its UFH product which it relaunched in the same year following the redesign of packaging.

295. Given the fact that the Parties are not each other's closest competitors, and that the main competitive constraint on Sanofi-Aventis comes from other LMWH manufacturers, in particular GSK, and given the declining trends in the actual use (days of treatment) of Zentiva's UFH products and UFH products in general it can therefore be concluded that the transaction does not lead to serious doubts, whether on the hospital segment or, a fortiori, in the overall market for heparins in the Czech Republic.

Slovak Republic

296. In the overall B1B market, the Parties have a combined market share of [40-50]% in the Slovak Republic based on value of sales in 2007 (Sanofi-Aventis [40-50]% and Zentiva [0-5]%). GSK would remain the market leader with [40-50]%. Other competitors include Pfizer ([5-10]%) and three competitors with marginal sales of [0-5]% or less (Novartis, Abbott and Menarini). The total value of the market was EUR [...] in 2007 with UFH accounting for only [0-5]% of the entire market in 2007. While the overall sales of LMWHs doubled between 2005 and 2007, overall UFH sales dropped by around [10-20]%. The closest competitor in terms of size and product to Sanofi-Aventis appears to be GSK (LMWH).

297. In the hospital segment, the Parties have a lower combined market share by sales value of [40-50]% (Sanofi-Aventis [30-40]% and Zentiva [0-5]%). GSK accounts for [50-60]% of the hospital segment.

298. The decline of UFH is particularly pronounced in the Slovak Republic where, based on use (days of treatment) the share of UFH dropped from [20-30]% in 2005 to only [10-20]% through the third quarter of 2008. The market investigation confirmed that this market has been shrinking and that this trend is expected to continue in the future. On the other hand, the use of LMWHs increased both in absolute and in relative terms.

299. Expressed in days of treatment, the combined market share of the Parties in the hospital segment in Slovakia was [40-50]% (Sanofi-Aventis [30-40]% and Zentiva [10-20]%) in 2007. However, Zentiva's market share has shown a steep decline from 2005 to 2008 (from [20-30]% in 2005 to [5-10]% in the first three quarters of 2008). The parties would continue to face strong competition from other LMWH suppliers, especially the present market leader, GSK, which had [40-50]% of the market in 2007.

300. In light of the fact that the Parties are not each other's closest competitors and that the main competitive constraint on Sanofi-Aventis appears to stem from other LMWH manufacturers, which belong to the same ATC4 category, in particular the market leader GSK, and given the declining trends in the actual use (days of treatment) of Zentiva's UFH product and UFH products in general, it can be concluded that the transaction is not likely to raise competition concerns in the market for heparins in the Slovak Republic, whether on the hospital segment or, a fortiori, in the overall market for heparins in the Slovak Republic.

B1C Platelet aggregation inhibitors

Czech Republic

301. Based on either an ATC4 approach or a first/second line approach the transaction would only lead to a minor overlap in the Czech Republic, where Zentiva has a strong presence with a traditional ASA product, Anopyrin, and Sanofi-Aventis has a niche ASA based product, Kardegic. Kardegic is only marketed in an injectable form used only in an acute phase (acute ischemic attack) as the initial dose, especially when oral administration is not possible. It is used sometimes by emergency services.
302. Based on a first line/second line treatment division, the transaction would give rise to combined market share of [70-80]% of B1C drugs used as a first-line treatment, but with a marginal increment of [0-5]% due to Sanofi-Aventis. (Zentiva's sales in 2007 were [...], whereas Sanofi-Aventis had sales of only [...]) Other competitors include Pflieger ([10-20]%), Pfizer ([5-10]%) and Boehringer Ingelheim ([0-5]%). Given the marginal increment and the very specific application of Kardegic, the transaction is unlikely to lead to anticompetitive effects. Based on the B1C1 ATC4 market, the 2007 sales of the parties would together account for [60-70]% of the market, again with a marginal increment of [0-5]% due to Sanofi-Aventis.
303. On the basis of an ATC3 market definition, the Parties would have a combined market share of [30-40]% (Sanofi-Aventis [10-20]%, Zentiva [10-20]%). Given the differences between their products, which are not each other's closest substitute, it is therefore unlikely competition concerns would arise even if the ATC3 level were retained as the relevant product market.
304. Furthermore, Plavix is a blockbuster drug of Sanofi-Aventis, for which the patent has only recently expired. Sanofi-Aventis expects significant generic entry for clopidogrel as of [...]. Given these specific circumstances, and upon further investigation, the Commission has in its assessment taken into account the effect of potential generic entry as this is a concrete and major development in the market that is expected to take place in the near future and is likely to have lasting consequences. It is therefore likely that the competitive pressure on the merged entity will get stronger with generic entry. Based on the above the transaction does not raise serious doubts in the B1C segment in the Czech Republic, irrespective of whether the market is defined as ATC3, ATC4 or based on the distinction between first line/second line treatments.

Slovak Republic

305. The Parties' activities would only overlap at the ATC3 level. The Parties would reach a combined market share of [50-60]% (Sanofi-Aventis [40-50]%, Zentiva [10-20]%). In light of the differences outlined above, the parties do not appear to be the closest competitors. Since Zentiva's product, ASA can be considered as a first line product and Sanofi-Aventis' products (Plavix and Ticlid) are second-line products, they do not appear to be close competitors. Other competitors include Servier ([10-20]%) and Ratiopharm ([5-10]%) with their ticlopidine-based products and Boehringer Ingelheim with an ASA-dipyridamole combination product. Bayer seems to have entered the market in 2007 with an ASA product although their sales in that year were marginal.

306. Furthermore, Plavix is a blockbuster drug of Sanofi-Aventis, for which the patent has only recently expired. Sanofi-Aventis expects significant generic entry for clopidogrel as of [...]. Given these specific circumstances, and upon further investigation, the Commission has in its assessment taken into account the effect of potential generic entry as this is a concrete and major development in the market that is expected to take place in the near future and is likely to have lasting consequences. It is therefore likely that the competitive pressure on the merged entity will get stronger with generic entry. Based on the above the transaction does not raise serious doubts in the B1C segment in Slovakia irrespective of whether the market is defined as ATC3, ATC4 or based on the distinction between first line/second line treatment.

Romania

307. The Parties' activities would only overlap at the ATC3 level. The Parties would reach a combined market share of [50-60]%, with an increment of less than [0-5]% due to Zentiva. Other competitors include Ranbaxy ([20-30]%), Schiapparelli ([5-10]%), Servier ([0-5]%) and a number of other smaller players with 1% or less each. Since Zentiva's product, dypiridamole, can be considered as a first line product and Sanofi-Aventis' products (mainly Plavix and to a lesser extent Ticlid) are second-line products, they do not appear to be close competitors. The market investigation mostly indicated Servier's product to be the closest competitor to Sanofi Aventis' products as it is based on ticlopidine.

308. Furthermore, Plavix is a blockbuster drug of Sanofi_Aventis, for which the patent has only recently expired. Sanofi-Aventis expects significant generic entry for clopidogrel in [...]. Given these specific circumstances, and upon further investigation, the Commission has in its assessment taken into account the effect of potential generic entry as this is a concrete and major development in the market that is expected to take place in the near future and is likely to have lasting consequences. It is therefore likely that the competitive pressure on the merged entity will get stronger with generic entry.

309. Based on the above the transaction does not raise serious doubts in the B1C segment in Romania irrespective of whether the market is defined as ATC3, ATC4 or based on the distinction between first line/second line treatment.

C4A Cerebral and peripheral vasotherapeutics

Czech Republic

310. After the merger, the Parties would have a joint market share at ATC3 level of [40-50]% (Zentiva [30-40]% and Sanofi-Aventis [10-20]%).

311. Sanofi-Aventis markets one product in the Czech Republic, namely Trental (pentoxifylline). During 2005-2007, Trental's market share has remained stable at approximately [10-20]%.

312. Zentiva markets four products in the Czech Republic, namely Enelbin (naftidrofuryl, market share [20-30]%), Agapurin (pentoxifylline, market share [10-20]%), Xanidil (xantinol nicotinate, market share [0-5]%), Dilceren (nimodipine, market share [0-5]%).

During 2005-2007, Enelbin's market share has increased somewhat, Agapurin's market share has declined significantly and the sales of Xanidil have remained marginal at approximately [0-5]%.

313. According to the Notifying Party, Sanofi-Aventis' and Zentiva's products are in direct competition with each other. None of the Parties' products are covered by patent protection.
314. Sanofi-Aventis launched its product Trental based on pentoxifylline in 1994. Pentoxifylline improves blood flow through blood vessels and therefore helps with blood circulation in the arms and legs. The drug is a central and peripheral vasodilator mainly prescribed to patients with intermittent claudication resulting from chronic occlusive arterial disease of the limb. Zentiva's drug Agapurin is a generic version of Sanofi-Aventis originator drug. It can be concluded that for a substantial part of market demand ([20-30]%), the Parties are each other's closest competitors.
315. At the molecular level, there is one additional competitor with a significant market share, namely Ratiopharm, which markets the drug Pentomer (pentoxifylline) with a market share of [5-10]%.
316. Naftidrofuryl is a drug used for treatment of the management of peripheral and cerebral vascular disorders. It is claimed to enhance cellular oxidative capacity and to be a spasmolytic. Zentiva's drug Enelbin is the best-selling product by far in this market, accounting for [20-30]% of total sales. The Notifying Party considers that Zentiva's Enelbin is in direct competition with Sanofi-Aventis' Trental.
317. The second largest competitor in the market is Novartis with a market share of [20-30]% in 2007, i.e. a market share less than half of the Parties' joint market share. It should also be noted that the vast majority of Novartis' sales in the Czech Republic are generated by the product Gingio (Ginkgo Biloba). As noted above in the market definition section, Ginkgo biloba is a herbal drug the efficacy of which has been questioned in some studies.⁸¹ Ginkgo Biloba has alleged positive effects on memory and is used as a concentration enhancer. Novartis main product can therefore not be considered as a close substitute to the products marketed by the parties.
318. In addition to Novartis, there are three additional competitors with moderate market shares; (i.) Ibsen, a company that markets the product Tanakan (Ginkgo Biloba, [5-10]%) which – as stated above - cannot be considered a close substitute to the drugs marketed by Sanofi-Aventis and Zentiva, (ii.) Teva, (total market share [5-10]%) which markets three drugs with marginal market shares based on different molecules than Sanofi-Aventis' and Zentiva's drugs and Ratiopharm ([5-10]%) whose main product is Pentomer (pentoxifylline, market share slightly below [5-10]%).
319. Finally there is a "tail end" of competitors with marginal market shares (all below [0-5]%), some of which market drugs based on the same molecules as the products marketed by the Parties.

⁸¹ In certain Member States, Ginkgo biloba-based drugs are not classified as pharmaceuticals.

320. Considering the circumstances described above - in particular the fact that (i.) Sanofi-Aventis/Zentiva would account for half of the sales in Czech market, (ii.) the Parties' products are close substitutes, (iii.) the largest competitor Novartis has a market share that is less than half of the merged firm's (iv.) Novartis markets a product which is not a close substitute to the Parties' products and (v.) the "tail end" of small and marginal competitors cannot be expected to significantly constrain the competitive behaviour of the merged entity - the Commission concludes that serious doubts arise as regards the C4A market in the Czech Republic.

Estonia

321. As stated in the market definition section above, the Notifying Party has agreed – after a thorough review of the market dynamics – that it is appropriate to exclude Ginkgo biloba-based products and other OTC-products from the relevant product market in the specific case of Estonia.

322. On the basis of a product market consisting only of drugs available on prescription, Sanofi-Aventis/Zentiva would obtain a joint market share of [60-70]% at ATC3 level (Sanofi-Aventis [50-60]%, Zentiva [10-20]%).

323. Sanofi-Aventis markets one product in Estonia, namely Trental (pentoxifylline). During 2005-2007, Trental's market share in Estonia increased substantially from [40-50]% in 2005 to [50-60]% in 2007.

324. Zentiva markets one product in Estonia, namely Enelbin Zent (naftidrofuryl, market share [10-20]%). Enelbin Zent's market share has almost doubled in one year ([5-10]% in 2006 and [10-20]% in 2007). Zentiva also holds a market authorisation in Estonia for Agapurin (pentoxifylline) but the company generated no sales of Agapurin in 2006 and 2007.

325. According to the Notifying Party, Sanofi-Aventis' and Zentiva's products are in direct competition with each other. None of the Parties' products are in protected by patent rights.

326. There is one substantial competitor to the Parties, namely Johnson & Johnson, which markets the product Stugeron (cinnarizine) with a market share of [20-30]%. However, Stugeron's market share in Estonia has declined steeply during 2005-2007, from [40-50]% in 2005 to [20-30]% in 2007.

327. Cinnarizine is an anti-histaminic drug which is mainly used for the control of vomiting due to motion sickness. Cinnarizine was first synthesized by Janssen Pharmaceutica in 1955. Cinnarizine could be also viewed as a nootropic drug because of its vasorelaxating abilities (due to calcium channel blockage), which happen mostly in the brain. It is also effectively combined with other nootropics, primarily piracetam in such combination each drug potentiate the other in boosting brain oxygen supply.

328. Due to the limited overlap in indications between Stugeron and the two products marketed by the Parties and the fact that Stugeron is outdated, Stugeron cannot be considered a close substitute to Trental and Enelbin Zent.

329. Finally, there are two competitors with moderate and marginal market shares, i.e. Lannacher which markets the drug Vasonit (pentoxifylline, market share [0-5]%) and Krka which markets the drug Pentilin (pentoxifylline, market share [0-5]%).
330. Considering the circumstances described above - in particular the fact that (i.) Sanofi-Aventis/Zentiva would account for [60-70] of the sales in the Estonian market, (ii.) both Sanofi-Aventis and Zentiva have increased their market shares substantially between 2005 and 2007, (iii.) Johnson & Johnson is the only competitor with a significant market share ([20-30]%), (iv.) Johnson & Johnson's product is based on a very old molecule which is not a close substitute to the Parties' products (v.) the two smaller competitors Lannacher and Krka cannot be expected to significantly constrain the competitive behaviour of the merged firm - the Commission concludes that serious doubts arise as regards the C4A prescription market in Estonia.

Slovak Republic

331. After the merger, the Parties would have a joint market share of [40-50]% (Zentiva [20-30]% and Sanofi-Aventis [10-20]%).
332. Sanofi-Aventis markets one product in the Slovak Republic, namely Trental (pentoxifylline). During 2005-2007, Trental's market share has remained relatively stable.
333. Zentiva markets three products in the Slovak Republic, Agapurin (pentoxifylline, market share [20-30]%), Dilceren (nimodipine, market share [0-5]%) and Xanidil (xantinol nicotinate, market share less than [0-5]%). During 2005-2007, Agapurin's market share has remained relatively stable at approximately [20-30]% while sales of Dilceren remained marginal at approximately [0-5]%.
334. Since Zentiva's main product Agapurin is a generic version of Sanofi-Aventis' product Trental, the Parties are each other's closest competitors. None of the Parties' products are covered by patent protection. There are no other competitors marketing products based on pentoxifylline in the Slovak Republic with substantial market shares.⁸²
335. The second largest competitor in the market is Stada which markets the drug Enelbin (naftidrofuryl, market share [20-30]%). Additional competitors are Schwabe which markets the product Tebokan (ginkgo biloba, market share [10-20]%), Ibsen which markets the product Tanakan (ginkgo biloba, market share [5-10]%) and Novartis which markets the products Gingium (ginkgo biloba, market share [5-10]%) and Cinnarizin Sandoz (cinnarizine, market share [0-5]%). Finally, there is a "tail end" of smaller competitors with market shares less than [0-5]%.
336. It should be noted that a substantial part of competitors' sales ([20-30]% in total) are generated by ginkgo biloba-based products. As stated above in the market definition

⁸² Stada markets a pentoxifylline-based product in the Slovak Republic but sales are negligible ([...] in 2007).

section, these products cannot be regarded as close substitutes to the Parties' products and may be part of a separate market.

337. Considering the circumstances described above - in particular the fact that (i.) Sanofi-Aventis/Zentiva would account for more than [40-50]% of total sales in the Slovak Republic, (ii.) the Parties' products are each other's closest substitutes, (iii.) the second largest competitor has a market share that is less than half than the merged firm's (iv.) a substantial part of competitors' sales are generated by herbal products which are not close substitutes to the Parties' products and (v.) the "tail end" of small and marginal competitors cannot be expected to significantly constrain the competitive behaviour of the merged entity - the Commission concludes that serious doubts arise as regards the C4A market in the Slovak Republic.

C7A Beta-blocking agents, plain

Czech Republic

338. After the merger, the Parties' would have a joint market share at ATC3 level of [50-60]% (Sanofi-Aventis [30-40]%, Zentiva [20-30]%).

339. Sanofi-Aventis markets two products in the Czech Republic, namely Lokren (betaxolol, market share [20-30]%) which was launched in 1992 and Sectral (acebutolol, market share [5-10]%). During 2005-2007 the market shares of Lokren and Sectral remained stable at approximately [20-30]% and [5-10]% respectively.

340. Zentiva markets six products in the Czech Republic. The company's main products are Vasocardin (metoprolol, market share [5-10]%) launched in 1991, Betaxa (betaxolol, market share [5-10]%) launched in 2004 and Tenoloc (celiprolol, [0-5]%). In addition, Zentiva markets three products with marginal sales (market shares [0-5]% or less).⁸³ The market shares for Vasocardin, Betaxa and Tenoloc have remained relatively stable at approximately [10-20]%, [5-10]% and [0-5]% respectively during 2005-2007.

341. One of Zentiva's main products, Betaxa, is the closest competitor to Sanofi-Aventis' main product Lokren, since they are based on the same molecule. No other competitor with a significant market share markets a product based on betaxolol in the Czech Republic.

342. The Notifying Party submits that all Sanofi-Aventis' and Zentiva's products in this category have a common indication for the treatment of arterial hypertension and prophylactic treatment of stable exertional angina pectoris. None of these products are patent protected.

343. The second largest competitor in the market is Astra-Zeneca with a total market share of [20-30]%. Astra-Zeneca markets three products in the Czech Republic, namely Betaloc (metoprolol, market share [10-20]%, Betaloc Zok (metoprolol succinate, market share [0-5]%) and Tenormin (atenolol, market share [0-5]%) and Betaloc Zok

⁸³ These products are Atram, Sandonorm and Trimepranol.

(metoprolol succinate, market share [0-5]%). Astra-Zeneca's market share has remained relatively stable at approximately [20-30]% during 2005-2007.

344. There is another competitor with a significant market share, namely Merck KGAA with a total market share of [5-10]%. Merck KGAA markets two products in the Czech Republic; Concor (bisoprolol, market share [0-5]%) and Concor COR (bisoprolol, market share [0-5]%). In addition, there is a "tail end" of competitors with marginal market shares ([0-5]% or less).
345. Considering the circumstances above - in particular the fact that (i.) the Parties would account for more than half the sales in the market, (ii.) the Parties' products would be each other's closest competitors for a substantial part of market demand (Lokren and Betaxa together account for [30-40]% of total sales); (iii.) the merged entity would have a market share which is twice as high as the largest competitor Astra-Zeneca (iv.) none of Astra-Zeneca's products are based on the same molecule as Lokren and Betaxa and (v.) the "tail end" of small and marginal competitors cannot be expected to constrain the competitive behaviour of the merged entity the Commission concludes that serious doubts arise as regards the C7A market in the Czech Republic.

G4C Benign Prostatic Hypertrophy Products

346. The transaction would lead to a combined market share of [40-50]% (Sanofi [20-30]%, Zentiva [10-20]%) in the G4C category in Estonia, combining the current first and second players. In a prescription-only market, the transaction would lead to a significantly higher combined market share of [60-70]% (Sanofi [30-40]% and Zentiva [20-30]%). Krka would be far behind in second place with [10-20]% followed by Astellas Pharma ([0-10]%), GSK ([5-10]%), Pfizer ([5-10]%) and some smaller players with [0-5]% or less (Merck and Co, Gedeon Richter, Novartis and Menarini). The merger would combine the two largest competitors, with a post-merger combined market share of over five times the closest competitor.
347. It should also be noted that the merged entity would have, with the exception of dutasteride, a full range of BPH products in its portfolio. The market investigation also indicated Zentiva's products Zoxon and Fokusin to be close competitors to Sanofi-Aventis' product, Alfuzosin
348. Based on the above, the transaction raises serious doubts on the market for prescription G4C products in Estonia.

J1G Fluoroquinolones

Czech Republic

349. In the Czech Republic, the Parties would have a combined market share of [40-50]% (Sanofi-Aventis [0-5]%, Zentiva [40-50]%) of the J1G market. Other competitors include Krka ([20-30]%), Cipla ([10-20]%), Medochemie ([10-20]%), Novartis ([0-5]%) and Interchemia ([5-10]%). Zentiva supplies ciprofloxacin ([20-30]% of the J1G

market) and ofloxacin ([10-20]%). In 2007 Sanofi-Aventis mostly supplied levofloxacin⁸⁴. There are other competitors supplying both ciprofloxacin (Krka [5-10]%, Cipla [10-20]%, Promed [0-5]% and Teva, Barr and Fresenius with less than [0-5]% each) as well as ofloxacin (Interchemia, [5-10]%).

350. Due to the relatively small increment due to Sanofi-Aventis and the presence of a number of competitors which are closer to Zentiva in terms of their size and product offering, it can be concluded that the merger would not lead to serious doubts in the J1G market in the Czech Republic if the ATC3 level were retained as the correct product market definition.

351. In the J1G1 segment (oral fluoro-quinolones), the Parties would not reach a combined market share that would be indicative of a significant increase in market power. The Parties would have a combined market share of only [20-30]%, with only a [0-5]% increment due to Sanofi-Aventis. They would continue to face strong competition from a sufficient number of significant competitors. In the Czech Republic, competitors would include Krka ([20-30]%), Medochemie ([20-30]%), Cipla ([5-10]%), Interchemia ([5-10]%) and Novartis ([0-5]%). The sales of the main competitors include drugs based on the same molecules as Zentiva's products and there are some smaller players as well.

352. Based on the above, it can be concluded that the proposed transaction does not raise serious doubts in the J1G1 segment of the fluoro-quinolone market in the Czech Republic.

353. In the J1G2 segment (injectable fluoroquinolones), the Parties would achieve a combined market share of [60-70]% (Sanofi-Aventis [5-10]%, Zentiva [60-70]%). High combined market shares arise as a result of Zentiva's strong position in this segment prior to the proposed merger. In the Czech Republic, as also in Slovakia, this strong position comes from sales of the old generation fluoro-quinolone ciprofloxacin. In 2007, this molecule accounted for over [90-100]% of Zentiva's J1G2 sales in the Czech Republic⁸⁵. Sanofi-Aventis only sells a drug based on levofloxacin, a new generation molecule.

354. The closest competitors to Zentiva in the J1G2 segment are competitors which are close competitors also in the J1G1 segment, suggesting a degree of supply-side synergies between the two segments. In the Czech Republic, Cipla and Krka are both present with injectable forms of ciprofloxacin-based drugs and achieve [10-20]% and [10-20]% respectively. Novartis' sales of another old generation drug, pefloxacin, account for [0-5]% and there is a smaller player, Fresenius, also present with a ciprofloxacin-based product.

355. It should further be noted that the market investigation did not identify substantial barriers to expansion in this segment. Injectable fluoroquinolones are used and bought

⁸⁴ Sanofi-Aventis had marginal sales of ofloxacin giving rise to only [0-5]% market share.

⁸⁵ The remainder of Zentiva's sales are due to another drug based on an old generation fluoroquinolone, ofloxacin.

by hospitals, which are knowledgeable buyers with direct budgetary constraints. The market investigation indicated price to be a strong constraint for hospitals in their purchases of injectable fluoro-quinolones. Price appears to be a primary consideration for hospitals and branding has, if any, only a secondary importance. Given their presence in the overall J1G market, alternative suppliers appear to be well-known and reputable. Any attempt by the merged entity to raise prices may therefore be unprofitable due to hospitals switching to alternative suppliers of products which are bioequivalent to those of Zentiva. Furthermore, the potential entry of other significant players from the J1G1 segment (for example Medochemie) may also serve as a deterrent given the apparent supply-side synergies. In fact, it was mainly commercial considerations that were indicated to the Commission as considerations that would play a role in a decision to enter from the oral fluoro-quinolone segment.

356. In light of the fact that these competitors have a product offering that is closer to Zentiva's than is Sanofi-Aventis' product, and achieve market shares that are comparable or significantly higher than Sanofi-Aventis, the lack of substantial barriers to expansion and the potential entry of close competitors in the oral segment, and given that competition within a given class of fluoroquinolones (old vs new generation), and particularly for a given molecule, appears to be primarily on price, it is unlikely that the merged entity would have an increased ability post-merger to significantly impede effective competition even if the J1G2 segment were to be identified as a separate relevant market.

357. Based on the above, it can be concluded that the proposed transaction, does not raise serious doubts in the J1G2 segment of the fluoroquinolone market in the Czech Republic.

Slovak Republic

358. In the Slovak Republic the parties would have a combined market share of [30-40]% (Sanofi-Aventis [5-10]%, Zentiva [30-40]%) of the J1G market. Other competitors include Krka ([20-30]%), Cipla ([10-20]%), Medochemie ([10-20]%), Novartis ([5-10]%) and Interchemia [0-5]%. Zentiva supplies mostly ciprofloxacin ([20-30]% of the J1G market) and to a lesser extent ofloxacin ([0-5]%). In 2007 Sanofi-Aventis supplied both levofloxacin ([0-5]%) and ofloxacin ([0-5]%). There are other competitors supplying both ciprofloxacin (Krka [5-10]%, Cipla [10-20]%, Promed [0-5]% and Teva, Barr and Fresenius with less than [0-5]% each) and ofloxacin (Medochemie [0-5]% Interchemia [0-5]%).
359. The Parties' combined market share is just above [30-40]% and the merged entity will continue to face strong competition from a number of competitors, which have a similar product offering to Zentiva. The transaction therefore does not lead to serious doubts in the J1G market if it were to be considered the relevant market definition in this case.
360. In the J1G1 segment (oral fluoro-quinolones) the Parties would not reach a combined market share that would be indicative of market strength in the Slovak Republic. The Parties would reach a combined market share of only [20-30]% with a [5-10]% increment due to Sanofi-Aventis. They would continue to face strong competition from a sufficient number of significant competitors. In the Slovak Republic, the main competitors are largely the same as in the Czech Republic, KRKA ([20-30]%), Cipla ([10-20]%), Medochemie ([10-20]%), Novartis ([10-20]%), Interchemia ([0-5]%). As in the Czech Republic, the sales of the main competitors include drugs based on the same molecules as Zentiva's products and there are some smaller players as well.
361. Based on the above, the proposed transaction does not raise serious doubts in the J1G1 segment of the fluoro-quinolone market of the Slovak Republic.
362. In the J1G2 segment (injectable fluoroquinolones), the Parties would achieve a combined market share of [70-80]% (Sanofi-Aventis [0-5]%, Zentiva [70-80]%). As in the Czech Republic, high combined market shares arise as a result of Zentiva's strong position in this segment prior to the proposed merger. As in the Czech Republic this strong position comes from the sale of the old generation fluoro-quinolone ciprofloxacin. This molecule accounts for Zentiva's entire J1G2 sales in 2007 in Slovakia. Sanofi-Aventis only sells a drug based on levofloxacin, a new generation molecule.
363. As in the Czech Republic, the closest competitors to Zentiva in the J1G2 segment are competitors which are close competitors also in the J1G1 segment, suggesting again a degree of supply-side synergies between the two segments. In Slovakia Krka's and Cipla's ciprofloxacin-based drugs account for [5-10]% and [0-5]% of the market respectively and there is another ciprofloxacin supplier, Hikma Pharma with [5-10]%. Novartis' pefloxacin-based product has [10-20]% of the market.
364. The statements made regarding barriers to expansion and barriers to entry in para 355 are also valid for the Slovak Republic. Therefore, in light of the fact that

competitors have a product offering that is closer to Zentiva's than Sanofi-Aventis' product and achieve market shares that are comparable or significantly higher than Sanofi-Aventis, the lack of substantial barriers to expansion and the potential entry of close competitors already active in the oral segment, and given that competition within a given class of fluoroquinolones (old vs new generation), and particularly for a given molecule, appears to be primarily on price, it is unlikely that the merged entity would have an increased ability post-merger to significantly impede effective competition in the J1G2 segment of the J1G market even if it were to be considered to constitute a distinct relevant product market.

365. The proposed transaction, therefore, does not raise serious doubts in the J1G2 segment in the Slovak Republic.

M1A Antirheumatics, non-steroidal

Czech Republic

366. In the Czech Republic, the Parties would have a joint market share of [40-50]% at the ATC3 level (Sanofi-Aventis [0-5]%, Zentiva [40-50]%).

367. Sanofi-Aventis markets three products in the Czech Republic, namely Monoflam (diclofenac), Profenid (ketoprofen) and Meloxiwin (meloxicam). Sanofi-Aventis' market share has remained stable at approximately [0-5]% during 2005-2007.

368. Zentiva markets five products in the Czech Republic, namely Ibalgin (ibuprofen, market share [20-30]%), Coxtral (nimesulide, market share [10-20]%), Recoxa (meloxicam, market share [0-5]%), Dolmina (diclofenac, market share [0-5]%) and Surgam (tiaprofenic acid, market share [0-5]%). Zentiva's market share has increased marginally during 2005-2007 (from [40-50]% in 2005 to [40-50]% in 2007).

369. The Parties are each other's closest competitors for products based on diclofenac. However, both products are of marginal importance on the Czech market with a joint market share of approximately [5-10]%. Sanofi-Aventis does not market any drug based on the same molecule as Zentiva's main drug Ibalgin, nor any drug based on the same molecule as Zentiva's second most important product Coxtral.

370. According to the Parties, the Czech M1A market is completely open to generic competition.

371. The largest competitors to the Parties are Apotex (market share [10-20]%), Medicom (market share [5-10]%), Menarini (market share [5-10]%) and four other competitors with market shares between [0-5]%. In addition, there is a "tail end" of competitors with marginal market shares (accounting for [10-20]% of sales in total).

372. Considering the circumstances above – in particular the fact that (i.) Sanofi-Aventis' presence in the Czech market is marginal with a total market share of [0-5]% across three products, (ii.) there are seven competitors with higher market shares than Sanofi-Aventis and (iii.) the addition of Sanofi-Aventis' marginal market share to Zentiva's market share will not affect competitive conditions in a generalised market with more

than 30 suppliers in total – the Commission concludes that the notified transaction does not give rise to serious doubts as regards the M1A market in the Czech Republic. This conclusion would not change if alternative market definitions were considered.

M5B Bone calcium regulators

Lithuania

373. In Lithuania, the Parties would have a joint market share of [30-40]% at the ATC3 level (Sanofi-Aventis [30-40]%, Zentiva [0-5]%, based on sales in 2007).
374. Sanofi-Aventis markets one product in Lithuania, namely Actonel (risedronic acid) and Zentiva launched a generic version of this drug, Risendros, in late 2007 (Zentiva's market share for 2007 amounted to [0-5]%). Actonel's market share has decreased somewhat, from [40-50]% in 2006 to [30-40]% in 2007. During the course of the investigation, the Notifying Party submitted sales figures for the first half of 2008, which indicate that Sanofi-Aventis' sales decreased substantially to [20-30]% and Zentiva's sales increased to [0-5]%. It should be noted that Zentiva has captured only a limited portion of Zentiva's market share loss, which means that the Parties' joint market share decreased from [30-40]% in 2007 to [30-40]% in the first half of 2008. According to the Notifying Party, neither drug is patent protected in Lithuania.
375. Due to the minimal overlap at the end of 2007 between the Parties' products, the M5B market in Lithuania did not appear to give rise to *prima facie* competition concerns. However, certain respondents to the Commission's market investigation expressed potential concerns that the notified transaction would remove the closest competitor to the largest player in the Lithuanian market. The Commission therefore investigated this market further in order to exclude that the competitive effect of Zentiva's entry might in due course be larger than the currently available figures suggested.
376. Risedronic acid is a bisphosphonate used to strengthen bone, treat or prevent osteoporosis, and treat Paget's disease of bone. It is produced and marketed by Procter & Gamble and Sanofi-Aventis.
377. After the merger, the largest competitor in Lithuania at the ATC3 level would be Merck & Co with a total market share of [30-40]%. The company markets two products in Lithuania, Fosamax Plus D (alendronic acid and vitamin D, market share [20-30]%) and Fosamax (alendronic acid, market share [5-10]%).
378. Alendronic acid is also a bisphosphonate drug used for osteoporosis and several other bone diseases. It is marketed alone as well as in combination with vitamin D.⁸⁶

⁸⁶ [...].

379. The second largest competitor to the Parties in Lithuania at ATC3 level would be Servier with a market share of [20-30]%. Servier markets the product Protelos (strontium ranelate), a non-bisphosphonate.
380. Strontium ranelate, a strontium(II) salt of ranelic acid, is a medication for treatment of osteoporosis. This molecule is unusual in the sense that it both increases deposition of new bone osteoblasts and reduces the resorption of bone by osteoclasts. It is therefore promoted as a "dual action bone agent" (DABA). Strontium ranelate is the only antiosteoporotic agent which both increases bone formation and reduces bone resorption, resulting in a rebalance of bone turnover in favor of bone formation. The main indication for strontium ranelate is the same as for bisphosphonates, namely the treatment of osteoporosis in post-menopausal women to reduce the risk of vertebral and hip fractures.
381. There is another competitor with a significant market share, namely GSK with a market share of [5-10]%. GSK markets the product Bonviva (ibandronic acid) in Lithuania.
382. Ibandronic acid is another bisphosphonate drug used in the prevention and treatment of osteoporosis. This molecule is indicated for the treatment and prevention of osteoporosis in post-menopausal women. It may also be used to treat hypercalcemia (elevated blood calcium levels). Bonviva is the first oral bisphosphonate approved for the treatment of postmenopausal osteoporosis that only needs to be taken once per month.⁸⁷
383. Finally, there is a "tail end" of smaller competitors active in Lithuania with market shares of [0-5]% or less.
384. The Parties argue that the proposed transaction would not cause competition concerns in the Lithuanian ATC3 market for the following reasons: (i.) the market is growing substantially with a [20-30]% sales increase in 2007 compared to the year before; (ii.) neither of the Parties' products is patent protected; (iii.) the Parties' main competitors are large, multinational companies with substantial market shares in Lithuania (Merck & Co [30-40]%, Servier [20-30]%); (iv.) there are two distinct generations of drugs in the market, Sanofi-Aventis' Actonel and Merck & Co's Fosamax whose patent protections have expired on the one hand and Servier's Protelos (launched in 2005) and GSK's Bonviva (launched in 2006) which still benefit from patent protection; (v.) due to the fact that Sanofi-Aventis' drug is exposed to both generic competition and competition from other second generation osteoporosis drugs, Sanofi-Aventis' market share may be expected to decline further in the near future; and (vi.) the marginal increment brought to date by the addition of Zentiva's Risendros sales does not change the competitive structure in the M5B market in Lithuania.
385. The Commission's market investigation has confirmed several of the arguments submitted by the Notifying Party, in particular the high degree of demand-side substitutability between the main competitors' bisphosphonate products in Lithuania (Sanofi-Aventis' Actonel, Zentiva's Risendros, Merck & CO's Fosamax and GSK's

⁸⁷ Source: "Roche from A to Z", p. 105, as published on the Roche web-site (www.roche.com).

Bonviva). In addition, the market investigation indicated that in addition to Zentiva's generic version of Actonel there are several other generic drugs based on risendronic acid for which market authorisations have been granted or are pending in other Member States. These market authorisations, once granted, may be extended to other Member States in the short term, including Lithuania, if post-merger price increases would make entry more attractive. Finally, the market investigation indicated that Protelos (strontium ranelate) – though not a bisphosphonate - is similar and largely substitutable to bisphosphonates.⁸⁸

386. Having ruled out the possibility of defining the relevant product market at molecule level (i.e. the hypothesis that drugs based on risedronic acid would belong to a relevant product market which is separate from other bisphosphonates), the narrowest feasible market definition would be an relevant product market limited to bisphosphonates, corresponding to the ATC4 classes M5B3 and M5B4. In such a hypothetical bisphosphonates-only market, Sanofi-Aventis' market share in 2007 would be [40-50]% and Zentiva's market share would remain marginal at [0-5]%. During the course of the investigation, the Parties have subsequently provided figures for the first half of 2008, which indicate that Sanofi-Aventis' market share has decreased significantly to [30-40]% and Zentiva has captured a market share of [0-5]%.⁸⁹ Due to the marginal overlap and the presence in the market of several competitors marketing products that are very close substitutes to Sanofi-Aventis' Actonel as well as [...], the notified transaction does not cause competitive concerns on an alternative bisphosphonates-only market.

387. For these reasons, the Commission concludes that the notified transaction would not give rise to serious doubts as regards the M5B market in Lithuania. This conclusion would not change if the relevant product market was limited to drugs based on bisphosphonates only..

N2B Non-narcotic analgesics and anti-pyretics

Slovak Republic

388. Post merger the Parties would have a [60-70]% share of the prescription market (Zentiva [40-50]%, Sanofi-Aventis [10-20]%).

389. Sanofi-Aventis' product Novalgine (metamizole sodium), with a stable market share of [10-20]%, belongs to the class of pyrazolones and is a drug which also has anti-inflammatory properties in addition to being a powerful painkiller and fever reducer.

390. Metamizole is an old molecule that was freely available worldwide until the 1970s, when it was discovered that the drug carries a small risk of causing agranulocytosis - a very dangerous and potentially fatal condition. Although controversy remains regarding

⁸⁸ See e.g. minutes from a telephone interview with a competitor on 29 October 2009.

⁸⁹ Sanofi-Aventis reply of 19 September 2008 to Commission request for information.

the level of risk, several national medical authorities have banned metamizole either totally or have restricted it to be available only on prescription.

391. Sanofi-Aventis' product Quarelin, which has a [0-5]% market share, is a combination of metamizole and drotaverine. Drotaverine is an antispasmodic drug and a selective inhibitor of phosphodiesterase 4 which also gives it anti-inflammatory properties.
392. Zentiva's Tralgit (a slow release form of tramadol) is indicated in the treatment of acute and chronic, moderately severe to severe pain, including pain resulting from painful diagnostic, therapeutic or surgical interventions and malignant diseases. It is available in a wide variety of formulations. Tralgit and Tralgit SR represent [30-40]% of the prescription market. Tramadol is an opiate.
393. The other significant Zentiva product, with a market share of [10-20]%, is Analgon, a combination of acetylsalicylic acid (ASA) with phenobarbital, a barbiturate. Barbiturates are derivatives of barbituric acid which act as central nervous system depressants, and have a wide spectrum of effects, from mild sedation to anesthesia. They are also effective as anxiolytics and hypnotics and as anticonvulsants. They have addiction potential, both physical and psychological. Phenobarbital is one of the oldest antiepileptic drugs and is still widely used worldwide. It has also sedative and hypnotic properties. For both indications, it is in general no longer recommended as a first-line medication, due to its safety profile and risk of overdose, however its use may vary from one country to another.
394. Sanofi-Aventis is the only provider of products based on metamizole in this ATC class in Slovakia, whilst Zentiva is the only provider of a product based on Phenobarbital. There are, by contrast, numerous products in this class based on tramadol.
395. The other molecules in this class are ibuprofen, paracetamol and ASA, all of which Zentiva has in its portfolio. These products are available OTC, but may also in some cases be reimbursed if bought on prescription, notably when used paediatrically. These three molecules are used to treat less severe pain.
396. The position on this market appears to be rather specific, with a limited degree of substitutability between, in particular, Zentiva's main Tralgit product and the other products which the Parties have on the market. There is no competition at molecule level in respect of these other products, whilst there remains significant competition in respect of tramadol. Moreover, the scope of substitution between the Parties' non-tramadol products themselves also appears to be limited due to the specific properties of metamizole and phenobarbital respectively which imply that tramadol or another prescription analgesic will already be the drug of choice in all instances where it is satisfactory given the patient's condition, and that the availability and price of products based on metamizole or phenobarbital will have no appreciable influence on their use in conditions where tramadol might be prescribed.
397. It can therefore be concluded that, notwithstanding the fact that, if measured at ATC3 level, market shares would appear to be high, the transaction will not result in any additional market power for the Parties in respect of any of the products which they will have in their portfolio post-merger.

398. Accordingly, it can be concluded that the transaction does not give rise to serious doubts as to its compatibility with the common market in respect of the N2B prescription market in Slovakia.

399. The Parties do not overlap on the OTC market.

Hungary

400. Post merger the Parties would have a [60-70]% share of the prescription market. However, the increment is only of [0-5]%.

401. Sanofi-Aventis' product Algopyrin (metamizole sodium) accounts for [50-60]% of the total market, whilst Quarelin (discussed above) represents a further [10-20]%. Novopyrin (dextropropoxyphene in combination with paracetamol) has a [0-5]% share.

402. The Zentiva products in this market – Tramadol and Demagonil – account for a minor increment in market share ([0-5]%). Tramadol is widely genericized. Moreover, Zentiva has no particular advantages on the Hungarian market where it is only recently present. Demagonil is a combination of allobarbitol, a barbiturate, with aminophenazone, a drug from the same class of molecules as metamizole, i.e. pyrazolones. As such it could be a close substitute to Sanofi-Aventis' products. However, there is an alternative product on the market including prophyphenazone, a similar molecule, namely Saridon from Bayer. The sales of Demagonil have been declining.

403. Accordingly, the transaction does not give rise to serious doubts as to its compatibility with the common market in respect of the N2B prescription market in Hungary.

404. The OTC N2B market is also technically affected in Hungary with a combined share of [30-40]% (Sanofi-Aventis [20-30]%, Zentiva [5-10]%).

405. Zentiva's product Rubophen is based on paracetamol, a product for which there are a number of competitors on the market, including Glaxosmithkline's Panadol product which has a comparable market share. Sanofi's product Algoflex is based on ibuprofen, and faces two other important competitors, Reckitt Benckiser and Wyeth, each with [5-10]% of the ATC3 OTC class. Almost all the remainder of the market is attributable to Bayer with products based on acetylsalicylic acid ([30-40]%).

406. The market investigation has demonstrated that there is a high degree of substitutability between the OTC products within this class and that barriers to entry are lower than in prescription markets although building a successful brand may require some investment. Since the final customer internalizes the full cost of his or her purchase, price elasticity may also be expected to be greater in OTC markets.

407. There are, accordingly, no grounds for serious doubts as regards the compatibility of the transaction with the common market in respect of the N2B OTC market in Hungary.

Czech Republic

408. Post merger the Parties would have a [40-50]% share of the prescription market (Sanofi-Aventis [0-5]%, Zentiva [40-50]%). It should also be considered that Zentiva currently manufactures one product which has a dual status for Herbacos-Biofarma, namely Acylpyrin (acetylsalicylic acid, [5-10]% share if entirely attributed to the prescription category). However, there remain a large number of competitors and Zentiva does not offer a generic version of Sanofi-Aventis' only product, Novalgin (metamizole).
409. As already stated above, metamizole-based analgesics also have fever-reducing (antipyretic) and anti-inflammatory properties and have been waning in popularity worldwide owing to the risk of side effects, namely agranulocytosis. Sales of this product have been largely stable in the Czech market in recent years, as has the market itself.
410. Zentiva does market a drug including metamizole, in combination with fempiverinium hydroxide and pitofenone in category A3D in the Czech Republic (antispasmodic/analgesic combinations). It also has a drug based on metamizole alone in N2B in Romania (see below).
411. Zentiva's product Ibalgin (ibuprofen), with a [0-5]% market share in this market, which like Novalgin also has anti-inflammatory properties, is also categorized in M1A, with the vast majority of sales attributed to that category ([...]€ compared to [...]€).
412. Zentiva's main products in the category are Tralgit (tramadol, [10-20]%) and Paralen (paracetamol, [10-20]%). Since the latter has dual prescription/OTC status, a part of the market share should probably be attributed to the prescription market, thereby lowering the combined market share.
413. Ibuprofen, tramadol and paracetamol are all marketed by a number of other competitors.
414. It follows that the indications of the Parties' main products in this market appear to be somewhat distinct and substitutable only to a limited degree. Moreover, the small increment in market share at ATC3 level due to Sanofi-Aventis' Novalgin product in this case is unlikely to give rise to important portfolio effects within the market and there remain many competitors.
415. The transaction therefore does not give rise to serious doubts as to its compatibility with the common market in the N2B prescription market in the Czech Republic.
416. The Parties do not overlap on the OTC market.

Romania

417. Post merger the Parties, based on the figures provided, would have a [50-60]% share of the prescription market. The increment in this market is due to Sanofi-Aventis' Quarelin product and represents [0-5]%.

418. In this market, the product Quarelin is partly in competition with the market leader, Zentiva's Algocalmin (a product marketed by Zentiva only in Romania): both are metamizole formulations, but Quarelin also has drotaverine, an antispasmodic. In fact, Quarelin is even classified by IMS for Romania in ATC3 category A3D. Moreover Algocalmin is dual-status, and therefore also available OTC.
419. In this market there is also a vertical relationship, [...]. One other product on the Romanian prescription market contains metamizole, but has a very small market share. The remainder of the market is constituted by a number of undertakings offering products based on ibuprofen and tramadol, with acetylsalicylic acid being purely an OTC product.
420. Sanofi-Aventis does not market Novalgine (metamizole) in Romania.
421. Notwithstanding the presence of only one other prescription product based on metamizole there are, in Romania, numerous formulations of metamizole available OTC. In fact, the Zentiva Algocalmin product, which accounts for [40-50]% of the segment as reported by the Parties, is available in two formulations: 500mg tablets, which are available OTC, and an injectable solution, which is a prescription product. It can, accordingly, be deduced that the vast majority of sales should in fact be attributed to the OTC category.
422. It may therefore be concluded that the transaction does not raise serious doubts as to its compatibility with the common market in the N2B prescription market in Romania.
423. There is also an increment of [0-5]% and a combined market share of [40-50]% on the OTC market viewed separately (but counting, as indicated above, Algocalmin twice). This can be deemed immaterial.
424. It may therefore also be concluded that the transaction does not raise serious doubts as to its compatibility with the common market in the N2B OTC market in Romania.

N3A Anti-epileptics

Romania

425. The transaction only leads to an affected market in Romania, due to the addition of Zentiva's [0-5]% market share with its Fenobarbital product to the [20-30]% share represented by Sanofi-Aventis' Depakine (valproic acid).
426. Although these shares and the corresponding HHIs⁹⁰ are below the relevant thresholds for serious doubts contained in the Commission's Guidelines on the assessment of horizontal mergers, the Commission nonetheless took a closer look at this market due to possible interactions with the N5B prescription market in Romania.

⁹⁰ [...] with a delta of [...].

427. Valproic acid is indicated for generalized epileptic seizures such as tonic-clonic seizures (grand mal), absences (petit mal), myoclonic seizures and atonic seizures, as well as partial (focal) seizures. It is further indicated in the treatment of manic episodes, and the maintenance and prophylactic treatment of bipolar disease in patients not responding to or not tolerating lithium.
428. Phenobarbital is one of the oldest antiepileptic drugs and is still widely used worldwide. It has also sedative and hypnotic properties. For both indications, it is in general no longer recommended as a first-line medication, due to its safety profile and risk of overdose. However, its use may vary from one country to another.
429. Zentiva's Extraveral product, although classified in Romania in N5B (WHO classification N05CB02), also contains phenobarbital together with valerian, a mild hypnotic agent of herbal origin. However, the dosage per tablet is only 20mg, whereas the drugs marketed in the N3A class have much higher dosages, namely 100 or 200mg.
430. [...]
431. Accordingly the limited increment in market share, relatively low combined market share post-merger, and specificities of the Zentiva product all allow the Commission to conclude that serious doubts as to the compatibility of the notified transaction with the common market do not arise in respect of the N3A market in Romania.[...]

N5A Anti-psychotics

Czech Republic

432. At the ATC3 level in the Czech Republic, the parties would have a combined market share of [10-20]% (Sanofi-Aventis [10-20]%, Zentiva [0-5]%).
433. Although below the relevant thresholds for serious doubts contained in the Commission's Guidelines on the assessment of horizontal mergers⁹¹, the Commission nonetheless took a closer look at this market due to certain uncertainties as to the correct market definition.
434. The Sanofi-Aventis products in this market together with their market share are Solian (amisulpride, [5-10]%), Tiapridal (tiapride, [5-10]%), Deniban (amisulpride, [0-5]%), Dogmatil (sulpiride,[0-5]%) and Winperid (risperidone, sales almost zero)
435. The Zentiva products are Rispen (risperidone, [0-5]%), Tiapra (tiapride, [0-5]%) and Chlorprothixen (chlorprothixene, [0-5]%). Zentiva also has marketing authorizations, but no sales, for two further products, Perfenazin (perphenazine) and Thioridazin (thioridazine).
436. The Parties therefore overlap at the molecule level notably in respect of risperidone and tiapride.

⁹¹ The post-merger HHI is [...] with a delta of [...].

437. There are numerous other versions of risperidone available on the Czech market. In respect of tiapride, however, the only other competitor is Ratiopharm, with a market share of [0-5]%.
438. Tiapride is a conventional antipsychotic similar to sulpiride, versions of which are provided also by Novartis and Pro-Med. It is a benzamide derivative with a highly selective antagonistic effect on striatal adenylyate cyclase-independent dopamine-2 receptors.
439. The market investigation has not suggested that this drug, which represents a very small part of the overall category, has any specific characteristics which would substantially limit its substitutability with other drugs in the class, or at least with other atypical antipsychotics.
440. In the light of this, and of the availability of an alternative generic supplier for tiapride, serious doubts as to the compatibility of the notified transaction with the common market do not arise in respect of the N5A market in the Czech Republic.

Romania

441. At the ATC3 level in Romania, the parties would have a combined market share of [10-20]% (Sanofi-Aventis [10-20]%, Zentiva [0-5]%)⁹².
442. Sanofi-Aventis has three products in this market: Solian (amisulpride, [10-20]%), Tiapridal (tiapride, [0-5]%) and Eglonyl (sulpiride, [0-5]%). Zentiva has only one product, Risperin (risperidone), with a [0-5]% market share. There is therefore no overlap at the molecule level.
443. Risperidone and amisulpride are both atypical antiepileptics. However, they have differing modes of action, making them imperfect substitutes. Moreover, the most important atypical antiepileptic in Romania by far is Eli Lilly's Zyprexa (olanzapine), with [30-40]% of the ATC3 class.
444. In the light of this and of the limited combined market shares, serious doubts as to the compatibility of the notified transaction with the common market do not arise in respect of the N5A market in Romania.

N5B Sedatives and hypnotics (prescription)

Czech Republic

445. After the merger the Parties would have an [80-90]% share of the N5B prescription market (Sanofi-Aventis: [40-50]%; Zentiva: [30-40]%).
446. Barbiturates are almost absent from this category in the Czech Republic.

⁹² The post-merger HHI is [...] with a delta of [...].

447. If the market were restricted to non-benzodiazepines, to drugs focused on inducing sleep, or to zolpidem itself, these shares would be higher still since the overlap is almost entirely in respect of zolpidem, and the only other molecule present to a significant extent is a benzodiazepine, midazolam (Roche).
448. In this market Sanofi-Aventis only markets Stilnox and almost the entire Zentiva market share is generated by sales of Hypnogen, Zentiva's generic version of Stilnox. Ratiopharm and Krka also have generic versions of Stilnox, with [5-10]% and [0-5]% of the ATC3 prescription market respectively, and there are a couple of other competitors who also have the zolpidem molecule but have insignificant market shares.
449. The Hypnogen brand, which has been marketed since 1999, is itself well known in the market.
450. Notwithstanding the presence of generic versions of zolpidem in the Czech Republic over a long period, Sanofi-Aventis' originator version of the drug remains market leader. The proposed transaction would therefore lead to very high market shares and the elimination of the most important competitor for a drug based on the same molecule. The competitive constraint exercised by other generic versions of Stilnox is further limited by the strength of the Hypnogen brand.
451. Accordingly, serious doubts arise in respect of the N5B (prescription) market in the Czech Republic.

Slovak Republic

452. After the merger the Parties would have a [70-80]% share of the overall N5B prescription market (Sanofi-Aventis [20-30]%, Zentiva [50-60]%).
453. Barbiturates are scarcely present in this market in Slovakia.
454. Zopiclone represents [10-20]% of the segment and is provided only by Zentiva.
455. The overlap is due to Sanofi-Aventis' Stilnox product which has a [20-30]% market share and directly competes with Zentiva's generic equivalent, Hypnogen, which has a [30-40]% market share. There are two other versions of zolpidem on the market, offered by Novartis and Mylan ([0-5]% and [5-10]% respectively).
456. The only other molecule with a significant presence on the market is a benzodiazepine derivative, cinolazepam (Gerot) with [10-20]%. Therefore, if the market were restricted to non-benzodiazepines, to drugs focused on inducing sleep, or to zolpidem itself, the combined market shares would be higher still
457. Notwithstanding the presence of generic versions of zolpidem in the Slovak Republic over a long period, Zentiva's version is the clear market leader closely followed by Sanofi-Aventis' originator version, with two other competitors having only limited market shares. The proposed transaction would therefore lead to very high market shares and the elimination of the most important competitor for a drug based on the same molecule, as well as a limitation in the number of suppliers of zolpidem from four to three. The competitive constraint exercised by other generic versions of Stilnox is further limited by the strength of the Hypnogen brand.

458. Accordingly, serious doubts arise in respect of the N5B (prescription) market in the Slovak Republic.

Estonia

459. After the merger, the Parties would have a [60-70]% share of the overall N5B prescription market (Sanofi-Aventis [50-60]%, Zentiva [5-10]%).

460. About 5% of the market thus stated is due to barbiturates. As this does not make a material difference to the assessment, the market shares stated below are not corrected to exclude barbiturates.

461. The overlap is due to Zentiva's Hypnogen product which has a [5-10]% market share and is the generic equivalent of Sanofi-Aventis' Stilnox, with an [5-10]% market share.

462. There is one additional generic version of Stilnox available in Estonia, provided by Novartis with an insignificant market share. Zentiva's product is therefore clearly the closest competitor to Stilnox and has achieved brand recognition in the market.

463. Almost all other products on the market are benzodiazepines, with the exception of a generic version of zopiclone by Grindex which achieves [10-20]% share of the segment. There is one other version of zopiclone which achieves insignificant sales.

464. Therefore, if the market were restricted to non-benzodiazepines, to drugs focused on inducing sleep, or to zolpidem itself, the combined market shares would be higher still (close to [90-100]% in the latter case).

465. The proposed transaction would therefore lead to very high market shares and the elimination of the most important competitor to Sanofi-Aventis for a drug based on the same molecule, as well as a limitation in the number of suppliers of zolpidem from three to two.

466. Accordingly, serious doubts arise as to the compatibility of the notified transaction with the common market in respect of the N5B (prescription) market in Estonia.

Romania

467. After the merger, the Parties would have a [70-80]% share of the overall N5B prescription market (Sanofi-Aventis [20-30]%, Zentiva [50-60]%).

468. In Romania, however, the market situation is very specific since Zentiva's main product, Extraveral ([40-50]%), contains phenobarbital as well as Valerian, a herbal product. It is therefore very differently situated compared to zolpidem and zopiclone used in Sanofi-Aventis' products Stilnox and Imovane, and in Zentiva's Hypnogen which is also present in Romania. Zentiva's second product, Distonocalm, also contains phenobarbital.

469. As stated in the discussion of the relevant market above, first-line use of phenobarbital is no longer recommended practice but the two Zentiva products nonetheless represents over half ([50-60]%) of the N5B prescription market and are the only significant barbiturate-based products in this class in Romania.

470. It also appears that Extraveral, whilst categorized in this ATC class, is in fact used in part for distinct applications given its sedative and anticonvulsant properties. These include nervous hyperexcitability, arterial hypertension and hyperthyroidism.
471. It moreover appears that Distonocalm in Romania is used for neurovegetative dystonia. It is, in fact, classified in WHO category C7N according to the usage of the national drug agency.
472. Exclusion of Extraveral and Distonocalm, i.e. of all barbiturates, from the relevant market results in a combined share for the Parties post-merger of [40-50]% (Zentiva [0-5]%, Sanofi-Aventis [30-40]%)⁹³.
473. The only significant issue to consider in Romania is, therefore, the [0-5]% increment on the non-barbiturate market due to Hypnogen, the generic version of Sanofi-Aventis' Stilnox (zolpidem), which has a [20-30]% share of the non-barbiturate market, the remainder being due to Imovane (zopiclone).
474. In this regard, it should be observed that there are several generic versions of zolpidem available on the Romanian market, and that Zentiva is not the most important generic supplier, with [0-5]% of the non-barbiturate market compared to [5-10]% for Novartis, [0-5]% for Gedeon Richter and [0-5]% for Labormed.
475. The remainder of the market is essentially constituted by benzodiazepines and Glaxosmithkline's Calmogen product ([10-20]% of the market excluding barbiturates), the indications of which are not focused on sleep. It follows that if the market were restricted further to non-benzodiazepines, to drugs focused on sleep, or to zolpidem itself, the combined market shares would be larger, but the increment due to Zentiva would remain relatively limited, with three other competitors for the molecule.
476. It can therefore be concluded that serious doubts do not arise as to the compatibility of the transaction with the common market in the N5B prescription market in Romania.

Bulgaria

477. After the merger, the Parties would have a [40-50]% share of the ATC3 prescription market including barbiturates (Sanofi-Aventis [0-5]%, Zentiva [30-40]%). Excluding barbiturates, however, the combined market share is [60-70]%, with Sanofi-Aventis's Stilnox product then accounting for a [5-10]% increment in market share⁹⁴.
478. The bulk of this market ([50-60]% excluding barbiturates) is constituted by sales of Zentiva's Zopiclone, a generic version of Sanofi-Aventis' Imovane which it does not market in Bulgaria.

⁹³ The recalculation of the market to exclude barbiturates includes 5% of the ATC3 prescription class attributed non-specifically to "others" in the data available to the Commission.

⁹⁴ In this latter calculation, Mentha Arvensis has also been excluded, where the Parties stated they were unsure as to the prescription status, but which appears to be clearly a herbal product whose sedative properties must be considered as milder than those of the typical prescription medicines.

479. Zentiva's Hypnogen, which is a generic version of Stilnox, has been in the Bulgarian market since 2005, but has achieved very limited sales. There do not appear to be any other generic alternatives to Stilnox in Bulgaria at present, but both Pliva and Krka have obtained marketing authorizations.
480. The other relevant products on the market are either benzodiazepines or bromine.
481. It follows that if the market were limited to non-benzodiazepines, market shares would be higher still. If the market were limited to zolpidem itself, then the market would be almost monopolized by Sanofi-Aventis' Stilnox product, with elimination of the only competitor for this molecule, albeit one which has hitherto achieved only very limited sales.
482. The most relevant result of the transaction in Bulgaria is therefore the addition of the market shares of the two currently only significant providers of zopiclone and zolpidem and the elimination of the only competitor for zolpidem.
483. According to the Parties, the two molecules have a slightly different mode of action: zopiclone is focused on maintaining sleep whereas zolpidem is focused on inducing sleep. However, they both belong to the latest generation of non-benzodiazepine hypnotics with similar action to benzodiazepines on the production of gamma-aminobutyric acid (GABA), which is the chief inhibitory neurotransmitter in the human central nervous system. In this class they represent essentially all prescriptions in Bulgaria.
484. Both the high market shares and the relative closeness of these two molecules must therefore lead to the conclusion that there exist serious doubts on the N5B non-barbiturate prescription market in Bulgaria.

N7X subset - acetylcholinesterase inhibitors used to treat myasthenia gravis

Czech Republic

485. The Parties combined share in the market analyzed in this way amounts to [10-20]%, behind the major suppliers Valeant Pharma ([50-60]%) and Nycomed ([20-30]%). Moreover, Sanitas, with a [5-10]% market share, also provides a generic version of the same molecule offered by Zentiva, neostigmine ([10-20]%). The addition of Sanofi-Aventis' [0-5]% market share for its product Mytelase, which is based on a different active ingredient, therefore does not give rise to concerns.
486. It can therefore be concluded that serious doubts do not arise in the market of acetylcholinesterase inhibitors used to treat myasthenia gravis in the Czech Republic.

Other markets for finished dose pharmaceuticals

487. For all other markets where the parties' activities overlap and their joint market shares do not exceed 35% on any of the alternative market definitions considered

(including at molecule level where it has not been excluded that this is the relevant market definition), and/or where the increment is below 1% on any of these alternative market definitions, competition concerns may be excluded. Third parties did not indicate that competition would be significantly impeded on these markets and the Commission's analysis supports this view.

IV.2.3.2. ACTIVE PHARMACEUTICAL INGREDIENTS (APIs)

488. Both Parties are active in the production of APIs. They produce APIs principally for their own use but sell them also to third parties. Sanofi-Aventis' sales of APIs to third parties in 2007 amounted to [...] which represents about [0-5]% of Sanofi-Aventis' total turnover. Zentiva's sales of APIs to third parties in 2007 amounted to [...] which represents about [0-5]% of Zentiva's total turnover.

Assessment

489. Seven APIs are manufactured by each of the Parties and also sold to third parties. These APIs, which belong to the family of opioids, are narcotics and controlled by the International Narcotic Control Board, a department of the United Nations. These drugs are sold on a worldwide basis. According to the Notifying Parties there are specific regulations for such APIs in France, Spain, UK, USA and Japan. In France, the Sanofi-Aventis' affiliate Francopia is the only authorised producer and distributor for these APIs. Given these specific regulations, Sanofi-Aventis submits that the jurisdictions listed above should be excluded for the purpose of the calculation of narcotic drugs APIs on the free market. Therefore the Parties calculated Sanofi-Aventis' sales to third parties excluding France.

490. On a worldwide basis the combined market share of the Parties is below 35% in six out of seven cases in which they both sell to third parties: codein phosphate, dihydrocodeine, pethidin, methadone, morphine and ocycodone. Only for the API ethylmorphine the combined market share of the Parties exceeds 35%. There are no indications that on an EEA wide basis the market shares differ significantly.

Codeine phosphate

491. In 2007 the Parties' estimated their combined market share to approximately [20-30]% (Sanofi-Aventis [10-20]%, Zentiva [5-10]%). If Sanofi-Aventis total production of this API is referred to the worldwide production, its market share would amount to [20-30]%. Competitors in this market are Mallinedrodt, Noramco, MacFarlan Smith, GSK, Weifa, Alealiber, Tasmanian Alkaloids and Alkaloida.

Dihydrocodeine

492. In 2007 the Parties' estimated their combined market share to approximately [10-20]% (Sanofi-Aventis [10-20]%, Zentiva [5-10]%). Sanofi-Aventis does currently not produce the API dihydrocodeine but purchases it from other producers. Significant competitors in this market are Salars and MacFarlan Smith.

Pethidin

493. In 2007 the Parties' estimated their combined market share to approximately [30-40]% (Sanofi-Aventis [5-10]%, Zentiva [20-30]%). Sanofi-Aventis did not produce the API pethidin in 2006 but purchases it from other producers because demand is low and has been declining in recent years. There are several producers of pethidin, including some based in the USA, representing about 50% of the worldwide production, Spain and China, each representing about 10% of the worldwide production and UK, representing about 5% of the worldwide production.

Methadone

494. In 2007 the Parties' estimated their combined market share to approximately [10-20]% (Sanofi-Aventis below [0-5]%, Zentiva [10-20]%). Sanofi-Aventis does currently not produce the API methadone but purchases it from two other producers.

Morphine

495. In 2007 the Parties' estimated their combined market share to approximately [10-20]% (Sanofi-Aventis [0-5]%, Zentiva [10-20]%). If Sanofi-Aventis total production of this API is referred to the worldwide production, its market share would amount to [0-5]%.
5

Oxycodone

496. In 2007 the Parties' estimated their combined market share to approximately [10-20]% (Sanofi-Aventis [10-20]%, Zentiva [0-5]%). If Sanofi-Aventis total production of this API is referred to the worldwide production, its market share would amount to less than [0-5]%.
6

Ethylmorphine

497. In 2007 the Parties' estimated their combined market share in ethylmorphine to be approximately [80-90]% (Sanofi-Aventis [70-80]%, Zentiva [5-10]%).
7

498. The Parties explain the presence of Sanofi-Aventis in this market by the regulatory obligation to supply opiate derivatives (such as ethylmorphine) in France. Sanofi-

Aventis states that it is not actively marketing this API and that its continuing presence in this market is due to the necessity to comply with its current supply obligations. The total sales made by Sanofi-Aventis on this API represented less than [...] in 2006.

499. As stated above, the Commission's market investigation concluded that ethylmorphine belonged to a wider market of APIs used as an input in antitussive preparations.

500. The Parties would have no ability to foreclose access of downstream competitors to ethylmorphine, given that this API accounts only for about [0-5]% of finished anti-tussive products and is fully or very largely substitutable with alternatives. Due to the minor presence of the Parties in the downstream market for anti-tussive products based on ethylmorphine there would also be no customer foreclosure.

501. It can therefore be concluded that serious doubts do not arise in the market for inputs in antitussive preparations, regardless of how this market is precisely defined.

APIs produced by both Parties but only sold to third parties by Zentiva

502. Furthermore three APIs are manufactured by each of the Parties but are not sold to third parties by Sanofi-Aventis: [...], [...] and [...]. Sanofi-Aventis produces these APIs exclusively for its own consumption as well as the consumption of [...], under an alliance agreement.

503. Given that Sanofi-Aventis does not produce these APIs for the sale to third parties and that there are a number of competitors for each of these APIs, competition concerns do not arise.

504. For these reasons, the Commission concludes that the notified transaction does not raise any competition concerns as regards of horizontal overlaps for APIs.

IV.2.3.3. PIPELINE AND GENERIC COMPETITION

505. The Commission looked at several possible issues in relation to pipeline and generic competition raised, or potentially raised, by the transaction.

506. Firstly, the Commission considered the possible impact of the merged entity adopting an "authorised generics" strategy whereby Sanofi-Aventis would use Zentiva to introduce the first generic version of one of its own originator drugs.

507. The market investigation suggested that this strategy, if adopted, was unlikely to be merger-specific. Moreover, its effect on the market would vary in function of national regulations and was only likely to be sizeable in cases where such regulation specifically provides for a premium to the first generic entrant. Even in such cases, whilst there may be a negative effect on competitors, any effect on consumer welfare is ambiguous. Moreover, were problems to arise, they could be addressed by adapting the regulations in question.

508. Secondly, the Commission considered all instances where Zentiva already has a generic version of a Sanofi-Aventis drug in its pipeline, regardless of whether Sanofi-Aventis might, as a result of the merger, decide to cancel this product or launch it as an authorized generic.
509. Some instances of this kind are analyzed individually above due to the specific issues identified. In all other cases, the Commission was able to exclude serious doubts. This was principally due to the large number of alternative well-established competitors planning to launch the same molecule and likely to have similar commercial success.
510. The econometric analysis and other evidence referred to below in the section on incumbency advantages (IV.2.5) also confirmed that competition concerns could be excluded in this respect, since it demonstrated that Zentiva did not exercise a unique competitive constraint on Sanofi-Aventis in any of the Affected Countries as compared to other generic producers.

IV.2.4. Vertical and conglomerate effects

IV.2.4.1. ACTIVE PHARMACEUTICAL INGREDIENTS (APIs)

511. Since APIs are important inputs to finished dose pharmaceuticals and both Sanofi-Aventis and Zentiva produce APIs and sell them to third parties (the merchant market), the proposed transaction gives rise to a number of vertically affected markets, i.e. markets where Sanofi-Aventis produces the API and Zentiva is active in the downstream market where the API is used or vice versa.
512. When identifying vertically affected markets which may give rise to serious doubts, the Commission has focused on vertical relationships where:
- (i.) either party has a market share of more than 30% in an upstream API-market and the other party has a market share of more than 5% in an ATC3 class containing that particular API, or
 - (ii.) either party has a market share of more than 25% in a downstream ATC3 class and the other party has market share of more than 5% of a corresponding upstream API-market.⁹⁵

Assessment

513. The Parties have identified two downstream vertically affected market where Sanofi-Aventis' market share exceeds 30% in the upstream API market and Zentiva has a market share of more than 5% in a corresponding downstream ATC3 class. Moreover, the Parties have identified five downstream vertically affected markets where Zentiva

⁹⁵ As is the case for horizontally affected markets, the Commission has used the ATC3 class as a starting point for the demarcation of the downstream product market for finished dose pharmaceuticals.

might have a market share of more than 30% in an upstream API market and Sanofi-Aventis has a market share of more than 5% in a corresponding downstream ATC3 class. Finally, there are five upstream vertically affected markets where Zentiva has a market share of more than 25% in a downstream ATC3 class and Sanofi-Aventis has a market share of more than 5% in a corresponding upstream API market. In total, this results in 12 vertically affected markets.

514. The Parties argue that the notified operation will neither give rise to competition concerns as the API markets are very competitive markets with numerous suppliers in addition to the Parties. Due to the limited upstream market share of Sanofi-Aventis, the limited presence of Zentiva in downstream markets and vice versa and the presence of numerous competitors offering these APIs, the transaction will not lead so any significant impediment to the risk of vertical foreclosure.

515. As regards the downstream vertically affected markets the Commission considers that the merged entity would in all likelihood lack the ability to engage in input foreclosure because even if the merged entity would stop supplying its customers or supply them on less favourable terms it would not affect the markets in which the merged entity is active at the downstream level as the customers could switch to another supplier of these APIs.

516. As regards the upstream vertically affected markets the Commission considers that the notified operation is unlikely to raise competition concerns because the upstream markets for the provision of APIs are likely to be worldwide whereas the downstream markets for finished dose pharmaceuticals are national. This means that even if the merged entity holds a large share of a given national pharmaceutical market, this share would represent only a fraction of the total worldwide demand for the APIs concerned. Consequently, even if the merged firm would try to foreclose a competing API producer, it would still have numerous alternatives to sell the API in other parts of the world.

517. No respondent to the Commission market investigation has indicated that the notified operation would lead to any vertical competition concerns. As also identified in a recent Commission decision,⁹⁶ moderate entry barriers for existing API suppliers, the frequent use of dual sourcing for APIs, the current spare capacity in the API-industry and increasing competition from producers in China and India makes any vertical foreclosure strategy unlikely to succeed.

518. For these reasons, the Commission concludes that the notified transaction does not lead to serious doubts as regards vertical foreclosure in relation to APIs.

IV.2.4.2. CONTRACT MANUFACTURING

519. In respect of contract manufacturing, the transaction leads to ten vertically affected markets in which the Parties are present with a combined share of over 25% in the downstream market including the share of the competitor(s) for which Zentiva

⁹⁶ COMP/M.5295 – Teva/Barr, Decision of 19 December 2008.

manufactures. Seven of these markets arise in the Affected Countries and a further three in other EU Member States. In all cases, the relationship involves Zentiva in a contract manufacturing relationship for a competitor of Sanofi-Aventis, or of both Parties, in the downstream market.

520. The vertically affected markets in the Affected Countries are the following: [...].
521. Since in all of these markets both Sanofi-Aventis and Zentiva are present directly, the vertical relationship in these markets results from the fact that, in addition, Zentiva manufactures on behalf of a competitor.
522. In [three cases], the transaction would remain below the threshold for serious doubts regardless of the market definition considered, even if the contract manufacturing customer of the Parties were to be considered not to act independently from them on the market. Therefore in line with the general approach outlined above, no individual assessment of these markets is required⁹⁷.
523. In [the remaining four cases][...].
524. [...].
525. It should also be noted that the antitrust status of such a supply agreement is not assessed in the present decision, and is not and cannot be affected by the assessment made by the Commission of the present transaction under the ECMR.
526. In [...].
527. In [...].
528. In [...], the product manufactured by Zentiva is available OTC. It therefore belongs to a different market to the one on which the Parties' activities overlap and competition on that market, from which Sanofi-Aventis is absent, is unaffected by the present transaction.
529. In [...], the product manufactured by Zentiva has a dual status OTC/prescription and thus partly competes with the Parties' products. However, even if all turnover of this product were hypothetically attributed to the prescription market on which the Parties overlap, the effect would be minimal and unable to change the Commission's analysis as given above.
530. The remaining three vertically affected markets are [...]. On these markets Zentiva is not present directly, but it manufactures for a competitor of Sanofi-Aventis. The Commission has therefore to determine whether this relationship might affect competition on the markets in question.
531. In principle, a number of considerations might be relevant to this assessment, such as the degree of exclusivity of the relationship, the risk and cost of any leakage of

⁹⁷ For a discussion of the G4C market see the market definition section above. For a discussion of the C9A market, see the relevant footnote in the market definition section covering "other markets".

sensitive information to competitors, change of control provisions and the effective possibility to change provider, the period in which such a change could be effected, and the degree of lock-in contained in the contracts. In the present case, however, it is unnecessary to analyze this in greater detail since competition concerns would not arise even if the competitor in question were to be viewed as fully commercially dependent on the merged entity post-merger.

532. In [...], Zentiva manufactures [...] product for a company present in [...] with a small share of the overall [...] market (below 5%). The company owns the relevant registration dossiers and sources the API itself and Zentiva's manufacturing according to the parties is based on a standard [...] technology.
533. Zentiva's supply represents only a fraction of the customer's demand for these type of products suggesting that the customer has recourse to other sources. [...]. Therefore, there appear to be sufficient alternatives for supply. A change of production facilities and/or contract manufacturing suppliers does not appear to be uncommon in the industry. In this case, the fact that the customer owns the relevant registration files, sources the API itself and [...] would facilitate this process. Therefore the merged entity would unlikely be able to foreclose access to inputs on a lasting basis. It should be noted that the customer in question has been contacted during the market investigation but did not raise concerns.
534. In any event, given the fact that Sanofi-Aventis discontinued marketing [...] in [...], the customer's and Sanofi-Aventis' activities only overlap in the wider [...] market, where Sanofi-Aventis is a major player ([...]) but the customer's presence is not significant (<5%). The potential gain of an input foreclosure strategy for Sanofi-Aventis is not apparent given the limited sales by the customer and the presence of other suppliers of [...], which are closer substitutes to the customer's products than Sanofi-Aventis' [...] product. The merged entity would therefore not likely have the incentive to engage in any input foreclosure strategy.
535. The market shares of the competitors for which Zentiva manufactures in [...] and [...] are very small (well below 1%) and serious doubts may therefore also be excluded in relation to these markets.
536. Finally, the contract manufacturing market itself is also technically a vertically affected market, but since the downstream pharmaceuticals for which the Parties manufacture collectively represent only a small fraction of total pharmaceutical production for sale in the EU, no concerns arise as to possible foreclosure on this basis.
537. In conclusion, the vertical relationships which result from contract manufacturing in the present case do not lead to serious doubts as to the compatibility of the transaction with the common market.

IV.2.5. POSSIBLE INCUMBENCY ADVANTAGES

538. Some responses in the market investigation suggested that Zentiva is a generic firm with a particularly strong position in the Czech Republic and the Slovak Republic due to

incumbent advantages. Such a position could potentially not be replicated by other generic firms.

539. This argument was relevant to the Commission's assessment in two ways. Firstly, it needed to be excluded that Zentiva's position was so particular that the removal of it as a potential competitor to Sanofi-Aventis might result in later or less aggressive generic entry in respect of Sanofi-Aventis' molecules in the Czech and Slovak republics in the future, even in respect of molecules where Zentiva did not yet have a product in its pipeline. Secondly, it needed to be assessed whether the competitive constraint currently provided by Zentiva could not be replicated by a purchaser of divested assets in those markets where the Commission has found serious concerns. Although this latter aspect is relevant to the assessment of the proposed commitments carried out below, for reasons of convenience both issues are discussed here as the potential concern related to incumbency is similar if not identical in both cases⁹⁸.

540. In order to address these potential concerns, two parallel approaches were adopted, consisting of an extensive site visit in Prague and Bratislava and an econometric analysis. The goal was to verify whether Zentiva as a generic firm has a particularly strong position in the Czech Republic and the Slovak Republic due to incumbency advantages. If they exist, incumbency advantages would be extremely difficult to replicate for other generic firms. Therefore, the merger could potentially have strong anticompetitive effects in geographic markets where such advantages occur.

541. All relevant stakeholders interviewed by the Commission, namely Ministries of Health, drug control agencies, health insurance companies and (for the Czech Republic) pharmacists confirmed that the position of Zentiva, whilst strong, was not unique, and particularly that it was not a stronger competitor than other generic companies in respect of new product introduction. [...] This perception was also in line with financial figures and explanations of its legacy position by Zentiva itself during the visit at its premises.

542. In addition, the market investigation indicated that first-mover advantages may be particularly strong in certain generic markets. In markets where patent expiry of a Sanofi-Aventis drug is imminent, Sanofi-Aventis may be able to take advantage of this by releasing "authorised" generic versions of its own drugs through Zentiva. This scenario is most likely to occur in countries where Zentiva already has a substantial market presence. However, it is possible that this could arise in respect of all EEA countries. The reduced ability for independent generic producers to compete effectively with generic versions of Sanofi-Aventis drugs could reduce the potential scope of offering of generic producers and the attractiveness of the generic market as a whole.

543. In order to address the concerns about future competition in markets where Zentiva has products in the pipeline, a data request was made to Sanofi-Aventis. The data gathered included sales, prices and advertisement expenditure for the years 1996-2008 in all geographic markets in which a Sanofi-Aventis faced the entry of a generic producer at the molecule level between 1998 and 2010 in ten countries (Czech Republic,

⁹⁸ Potentially these concerns could be different, as Zentiva might be differently placed in respect of competing with existing products and introducing new ones. In practice, the analysis applies, however, to both cases.

Slovak Republic, Romania, Hungary, Estonia, Greece, Germany, France, United Kingdom and Portugal). The data request covered Sanofi-Aventis and Zentiva and their competitors at the ATC3 and ATC4 levels in these countries.

544. A simple descriptive analysis of the data revealed that in the Czech Republic, Zentiva was the first firm to launch a generic version in seven out of eleven markets where Sanofi-Aventis' patents expired. In the Slovak Republic, this was the case in six out of seventeen occurrences. In Romania, Zentiva was never the first producer to launch a generic version. These descriptive findings supported the hypothesis that Zentiva has particularly strong market positions in the Czech Republic and in the Slovak Republic.
545. Focusing on Sanofi-Aventis products, the Commission performed an econometric analysis in order to test the hypothesis of whether, as compared to an average generic producer, Zentiva exercises a stronger competitive constraint on Sanofi-Aventis. This hypothesis was tested with respect to (i.) Sanofi-Aventis market shares and (ii.) Sanofi-Aventis' ex-manufacturer prices (considering the retail and the hospital segments separately). The analysis was first carried out for each of the three countries of potential concern (Czech Republic, Slovak Republic and Romania) and then on the data set resulting from the pooling of these countries. Finally, the regressions were run with the pooled data-set containing data from the eight countries at Commission's disposal.
546. The econometric analysis took the form of a reduced-form regression for those markets where Sanofi-Aventis faced generic entry. The regression controlled for the evolution over time of the different markets, for the entry of other generic producers as well as for the specificities of the different APIs. The latter control was implemented using fixed effects at the molecule level. Finally, both static and dynamic specifications were tested.
547. The Commission found no significant evidence that Zentiva should be regarded as a special competitor for Sanofi-Aventis, either when it enters as the first "independent" generic or, when it enters at a later stage. The results of the analysis therefore suggest that the competitive constraint exerted by Zentiva on Sanofi-Aventis is not stronger than that exercised by an average generic competitor. This conclusion is convergent with what emerged from the site visit.
548. Accordingly, the Commission was able to conclude that Zentiva, at the time of the proposed transaction, no longer constituted a unique competitor (regardless of whether this was the case in the past) whose market performance and/or new product launch capabilities could not be matched by other generic pharmaceutical companies. On the contrary, it appears that several such companies are [...] as well placed as Zentiva to introduce and market generic products in Zentiva's historical home markets. Whilst in individual markets Zentiva's position needs to be, and has been, separately assessed, concerns related specifically to incumbency can therefore be excluded insofar as they relate to new product introduction or to the viability of remedies.

IV.2.6. CONCLUSION – SERIOUS DOUBTS

549. For the reasons set out above, the Commission concludes that the notified operation gives rise to serious doubts as regards the compatibility with the common market and the EEA-agreement for the following markets for the provision of finished dose pharmaceuticals:

- i. A2A - Antiacids, antifatulants, carminatives in Romania;
- ii. A3A – Plain antispasmodics and anticholinergics in Romania;
- iii. A3A - Plain antispasmodics and anticholinergics in Hungary;
- iv. A5B – Hepatic protectors and lipotropics in the Czech Republic;
- v. A5B – Hepatic protectors and lipotropics in the Slovak Republic;
- vi. A7A – Intestinal anti-infective antidiarrhoeals in the Czech Republic;
- vii. C4A – Cerebral and peripheral vasolidators in the Czech Republic;
- viii. C4A prescription market – Cerebral and peripheral vasolidators in Estonia;
- ix. C4A – Cerebral and peripheral vasolidators in the Slovak Republic;
- x. C7A – Beta-blocking agents, plain, in the Czech Republic;
- xi. G4C prescription market – Benign Prostatic Hypertrophy Products in Estonia;
- xii. N5B prescription market – Sedatives and hypnotics in the Czech Republic;
- xiii. N5B prescription market – Sedatives and hypnotics in the Slovak Republic.
- xiv. N5B prescription market – Sedatives and hypnotics in Estonia;
- xv. N5B prescription market (excluding barbiturates) in Bulgaria.

V. MODIFICATIONS TO THE PROPOSED OPERATION

V.1. Description of the commitments

550. In order to remove the serious doubts resulting from the proposed transaction, Sanofi- Aventis formally submitted commitments to the Commission on 14 January 2009. Following the market test, the commitments were modified on 2 February 2009.

551. Sanofi-Aventis commits to divest:

- i. Sanofi-Aventis' Maalox™ (A2A) business in Romania;

- ii. Zentiva's Scobutil™ and Sulfat de Atropina (A3A) businesses in Romania;
- iii. Zentiva's Papaverinium HCL (A3A) business in Hungary;
- iv. Zentiva's Flavobion™ (A5B) business in the Czech Republic;
- v. Zentiva's Flavobion™ (A5B) business in the Slovak Republic;
- vi. Sanofi-Aventis' Ercefuryl™ (A7A) business in the Czech Republic;
- vii. Sanofi-Aventis' Trental™ (C4A) business in the Czech Republic;
- viii. Sanofi-Aventis' Trental™ (C4A prescription market) business in Estonia;
- ix. Sanofi-Aventis' Trental™ (C4A) business in the Slovak Republic;
- x. Zentiva's Vasocardin™, Betaxa™ and Tenoloc™ (C7A) businesses in the Czech Republic;
- xi. Zentiva's Fokusin™, Penester™ and Zoxon™ (G4C) businesses in Estonia;
- xii. Zentiva's Hypnogen™ (N5B prescription market) business in the Czech Republic;
- xiii. Zentiva's Hypnogen™ (N5B prescription market) business in the Slovak Republic.
- xiv. Zentiva's Hypnogen™ (N5B prescription market) business in Estonia;
- xv. Zentiva's Zopiclon (N5B1/N5B2) business in Bulgaria;

552. The businesses to be divested include: (i.) all tangible and intangible assets (including IPRs), (ii.) all licenses, permits and authorizations, (iii.) all contracts, leases, commitments and customer orders, all customer, credit and all other records, (iv.) all advertising, marketing, sales, publicity and presentational materials, (v.) best efforts to obtain the assignment of manufacturing arrangement and/or API supply arrangement and/or licensing agreement entered into by one of the Parties, (vi.) an option of a manufacturing or supply agreement for a period of up to 2 year, (vii.) an option to hire Personnel to maintain the viability of the divestment business, (viii.) at the option of the purchaser, a best effort to obtain the assignment of the outsourced promotional agreement entered into by Zentiva, and (ix.) an option to be granted free access to future product development improvements related to the divestment business.

V.2. Assessment of the modified commitments

553. The market test of the commitments was positive overall. Some issues were raised concerning the transitional supply arrangements. Although most respondents considered the two-year duration of the transitional supply agreement as sufficient, a number of respondents considered this period as insufficient for a potential buyer. For this reason, the Notifying Party was requested to extend the duration of the transitional supply agreement to a period of three years. In order to ensure a smooth transfer of the production of the divestment businesses, the Commission requested that a provision be

added that the Purchasers of the divestment businesses should have the capacity to take over production of the products concerned, either themselves or via third parties independent from the Parties.

554. In addition, a right-of-first-refusal clause was added to the commitments. The objective of this clause is to avoid that the Notifying Party sells the divestment businesses to an artificially large number of Purchasers to weaken post-merger competition.

555. After the amendments outlined above, the Commission considers that the commitments fully removes the Commission's serious doubts about the proposed transaction's compatibility with the common market and the EEA agreement.

556. In order to ensure that Sanofi-Aventis complies with these commitments, the Commission attaches conditions and obligations to this decision. The commitments set out in Sections B, C and D and Schedules I to XV of the commitments annexed to the present decision constitute conditions, since only by fulfilling them may the structural change on the relevant markets be achieved so as to eliminate the serious doubts identified by the Commission. The other commitments constitute obligations, since they concern the implementing steps necessary to achieve the structural change intended to eliminate the serious doubts identified by the Commission.

VI. CONCLUSION

557. The Commission has concluded that the remedies submitted by the Notifying Party are sufficient to remove the serious doubts raised by the concentration. Accordingly, subject to the full compliance with the conditions set out in Sections B, C and D and Schedules I to XV of the Commitments submitted by the Notifying Party on 2 February 2009 and with the obligations set out in the other Sections of the Commitments, the Commission has decided not to oppose the notified operation and to declare it compatible with the common market and with the EEA Agreement. This decision is adopted in application of Article 6(1)(b) and Article 6(2) of Council Regulation (EC) No 139/2004.

558. The detailed text of the commitments is annexed to this decision. The full text of the annexed commitments forms an integral part of this decision.

For the Commission
(signed)
Neelie KROES
Member of the Commission

Case M.5253 – Sanofi-Aventis/Zentiva

COMMITMENTS TO THE EUROPEAN COMMISSION

Pursuant to Article 6(2) of Council Regulation (EC) No. 139/2004 as amended (the "**Merger Regulation**"), Sanofi-Aventis hereby provides the following commitments (the "**Commitments**") in order to enable the European Commission (the "**Commission**") to declare the acquisition of sole control over Zentiva N.V. ("**Zentiva**") 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. For the avoidance of doubt, the Commitments shall cease to have effect if Sanofi-Aventis demonstrates to the satisfaction of the Commission that it has abandoned its offer for Zentiva.

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 light of the Merger Regulation, and by reference to the Commission Notice on remedies acceptable under Council Regulation (EC) No 139/2004 and under Commission Regulation (EC) No 802/2004.

Section A. Definitions

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

Affiliated Undertakings: undertakings controlled 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 Consolidated Jurisdictional Notice under Council Regulation (EC) No 139/2004 on the control of concentrations between undertakings.

Closing: the transfer of the legal title of each of the Divestment Businesses to the Purchaser.

Divestment Business: each of the businesses, as set out in paragraph 4 and defined in the 15 attached Schedules, that Sanofi-Aventis commits to divest.

Divestiture Trustee: one or more natural or legal person(s), independent from the Parties, who is approved by the Commission and appointed by Sanofi-Aventis and who has received from Sanofi-Aventis the exclusive Trustee Mandate to sell the Divestment Businesses to a Purchaser [...].

Effective Date: the date of adoption of the Decision.

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

Hold Separate Manager(s): the person appointed by Sanofi-Aventis, on a non-exclusive basis, for the Divestment Businesses to manage the day-to-day business under the supervision of the Monitoring Trustee pending their sale.

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

Offer Completion Date: the date on which the title to the Zentiva securities to be acquired by Sanofi-Aventis Europe S.A. pursuant to its offer for Zentiva passes to the acquirer.

Parties: Sanofi-Aventis and Zentiva.

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

Purchaser: the entity or each of the entities approved by the Commission as acquirer(s) of one or more of the Divestment Businesses in accordance with the criteria set out in Section D.

Sanofi-Aventis: Sanofi-Aventis, incorporated under the laws of France, with its registered office in Paris, France and registered with the Commercial/Company Register at Paris under number B395030844.

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

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

Zentiva: Zentiva N.V., a company incorporated under the laws of the Netherlands, with its registered office in Amsterdam, the Netherlands and registered with the Trade Register of the Chamber of Commerce of Amsterdam under number 33302572.

Section B. The Divestment Businesses

Commitment to divest

1. In order to restore effective competition, Sanofi-Aventis commits to divest, or procure the divestiture of each of the Divestment Businesses 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 14. To carry out the divestiture, Sanofi-Aventis commits to find a purchaser and to enter into a final binding sale and purchase agreement for the sale of one or more of the Divestment Businesses within the First Divestiture Period. If Sanofi-Aventis has not entered into such an agreement at the end of the First Divestiture Period, Sanofi-Aventis shall grant the Divestiture Trustee an exclusive mandate to sell the Divestment Businesses in accordance with the procedure described in paragraph 23 in the Trustee Divestiture Period.
2. Sanofi-Aventis shall be deemed to have complied with this commitment if, for each of the Divestment Businesses: (i) by the end of the Trustee Divestiture Period, Sanofi-Aventis has entered into a final binding sale and purchase agreement for the Divestment Business; (ii) the Commission approves the Purchaser and the terms in accordance with the procedure described in paragraph 14; and (iii) Closing takes place within a period not exceeding [...] after the approval of the Purchaser and the terms of sale by the Commission.

3. In order to maintain the structural effect of the Commitments, the Parties shall, for a period of 10 years after the Effective Date, not acquire direct or indirect influence over the whole or part of any of the Divestment Businesses without the Commission's prior consent, unless the Commission has previously found that the structure of the market has changed to such an extent that the absence of influence over the Divestment Businesses is no longer necessary to render the proposed concentration compatible with the common market.

Structure and definition of the Divestment Businesses

4. The Divestment Businesses consist of:
- i. Sanofi-Aventis' Maalox™ (A2A) business in Romania;
 - ii. Sanofi-Aventis' Ercefuryl™ (A7A) business in the Czech Republic;
 - iii. Sanofi-Aventis' Trental™ (C4A) business in the Czech Republic;
 - iv. Sanofi-Aventis' Trental™ (C4A Rx) business in Estonia;
 - v. Sanofi-Aventis' Trental™ (C4A) business in the Slovak Republic;
 - vi. Zentiva's Papaverinium HCL (A3A) business in Hungary;
 - vii. Zentiva's Scobutil™ and Sulfat de Aptropina (A3A) businesses in Romania (as a single package);
 - viii. Zentiva's Flavobion™ (A5B) business in the Czech Republic;
 - ix. Zentiva's Flavobion™ (A5B) business in the Slovak Republic;
 - x. Zentiva's Vasocardin™, Betaxa™ and Tenoloc™ (C7A) businesses in the Czech Republic (as a single package);
 - xi. Zentiva's Fokusin™, Penester™ and Zoxon™ (G4C) businesses in Estonia (as a single package);
 - xii. Zentiva's Zopiclon (N5B1/N5B2) business in Bulgaria;
 - xiii. Zentiva's Hypnogen™ (N5B Rx) business in the Czech Republic;
 - xiv. Zentiva's Hypnogen™ (N5B Rx) business in Estonia;
 - xv. Zentiva's Hypnogen™ (N5B Rx) business in the Slovak Republic.

Each of these Divestment Businesses, as described in more detail in the Schedules, shall include, as applicable:

- (a) all tangible and intangible assets (including intellectual property rights, such as the Divestment Business trademarks and know-how, where applicable), which contribute to the current operation and are necessary to ensure the viability, marketability and competitiveness of the Divestment Business;
- (b) all licences, permits and authorisations issued by any governmental organisation for the benefit of the Divestment Business, including the

marketing authorisation for each of the Divestment Businesses and related registration files and documentation of clinical studies;

- (c) all contracts, leases, commitments and customer orders, all customer, credit and other records related to the Divestment Business;
- (d) all advertising, marketing, sales, publicity and presentational materials related to the Divestment Business, as applicable (items referred to under (a)-(d) hereinafter collectively referred to as "**Assets**"); and
- (e) if such contract exists, a best effort obligation to obtain the assignment of the manufacturing arrangement entered into by one of the Parties and/or the active pharmaceutical ingredient ("**API**") supply arrangement entered into by one of the Parties and/or the licensing agreement by virtue of which a Party is entitled to sell a specified product in a particular Member State;
- (f) the benefit for a period of up to 3 years after Closing, on a reasonable cost-plus basis to be agreed with the Purchaser, of an exclusive and transitory manufacturing or supply arrangement relating to the existing forms of product in the Member State of the Divestment Business, and/or reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of the relevant Divestment Business, as detailed in the Schedules;
- (g) in relation to the Divestment Businesses composed of non-promoted products and set out in Schedules [...], an option for the Purchaser to hire one or more Personnel, who work for the relevant Divestment Business and could assume a product management role in relation to the relevant Divestment Business(es), and who would reasonably be considered necessary to maintain the viability, marketability and competitiveness of that Divestment Business;
- (h) in relation to the Divestment Businesses composed of promoted products and set out in Schedules [...], an option for the Purchaser to hire one or more Personnel of the Divestment Business employed in the relevant Business Unit and who would reasonably be considered necessary to maintain the viability, marketability and competitiveness of that Divestment Business. Details of the relevant Business Units are set out in these specified individual Divestment Business Schedules;
- (i) in relation to the Divestment Business set out in Schedule [...] for which promotional activities are outsourced, and at the option of the Purchaser, a best effort obligation to obtain the assignment of the outsourced promotional agreement [...].
- (j) At the option of the Purchaser, an option to be granted free access (i.e. free opt-in) to future product development improvements (i.e. galenical and packaging developments) in relation to the Divestment Business in any territory retained by the Parties for a period of five years should any such product improvements be undertaken by the Parties.

Section C. Related commitments

Preservation of Viability, Marketability and Competitiveness

5. From the Effective Date until Closing, the Parties shall preserve the economic viability, marketability and competitiveness of the Divestment Businesses, in a manner consistent with Sanofi-Aventis' or Zentiva's, as the case may be, past practice and 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, the Parties undertake:
 - (a) not to carry out any act upon its own authority that might have a significant adverse impact on the value, management or competitiveness of the Divestment Businesses or that might alter the nature and scope of activity, or the commercial strategy or the investment policy of the Divestment Businesses;
 - (b) to make available sufficient resources for the commercial development of the Divestment Businesses, on the basis and continuation of the existing business plans and to maintain the marketing and sales efforts devoted to the Divestment Businesses at their current level. In particular, the Parties commit to maintain the level of promotional efforts and marketing expenditures for the Divestment Businesses referred to at paragraph 4(h) above at the same level as at the Effective Date and not to increase such level of promotional efforts and marketing expenditures for retained businesses directly competing with such Divestment Businesses until Closing.

Hold-separate obligations of Parties

6. The Parties commit, from the Effective Date until Closing, to the maximum extent possible, to keep the Divestment Businesses separate from the businesses Sanofi-Aventis is retaining and to ensure that Personnel of the Divestment Businesses – including the Hold Separate Manager – has no involvement in any business retained and vice versa. In particular, the Parties commit that the Divestment Businesses referred to at paragraph 4(h) above will be kept separate from retained businesses directly competing with such Divestment Businesses and the business units promoting them will not be integrated until Closing.
7. Until Closing, Sanofi-Aventis shall assist the Monitoring Trustee in ensuring that, as far as possible, each Divestment Business is managed as a distinct and saleable entity separate from the businesses retained by the Parties. Sanofi-Aventis shall appoint a Hold Separate Manager who shall be responsible for the management of the Divestment Businesses, under the supervision of the Monitoring Trustee. The Hold Separate Manager shall manage the relevant Divestment Businesses as far as practicable independently and in the best interest of the business with a view to ensuring their continued economic viability, marketability and competitiveness and their independence from the businesses retained by the Parties.

Ring-fencing

8. Without prejudice to the commitment set out in paragraph 5 above, Sanofi-Aventis 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. Sanofi-Aventis may obtain business secrets, know-how or information relating to the Divestment Businesses in order to comply with obligations entered into in accordance with these Commitments or which is otherwise reasonably necessary to allow Sanofi-Aventis to carry out the divestiture of the Divestment Businesses or whose disclosure to Sanofi-Aventis and/or Zentiva is required by law.

Non-compete and non-solicitation clause

9. The Parties undertake:
- (i) in the territory in which a Divestment Business is divested:
 - (a) not to launch, and to procure that Affiliated Undertakings do not launch, any new branded or unbranded generic version of the product(s) comprising that Divestment Business for a period of [...] after Closing (for the avoidance of doubt, it is understood and agreed that the Parties may continue to market all products other than the one(s) composing that Divestment Business that they were already marketing at the date of the Decision); and
 - (b) not to start supplying, and to procure that Affiliated Undertakings do not start supplying, the product(s) comprising that Divestment Business to any third party marketing or planning to market such product(s) in that territory for a period of [...] after Closing (for the avoidance of doubt, it is understood and agreed that the Parties may continue to supply the product(s) comprising that Divestment Business to all third parties to whom they were already supplying at the date of the Decision); and
 - (ii) subject to customary limitations, not to solicit, and to procure that Affiliated Undertakings do not solicit, the Personnel transferred with any Divestment Business for a period of [...] after Closing.

Due Diligence

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

Reporting

11. Sanofi-Aventis shall submit written reports in English 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 10 days after the end of every month following the Offer Completion Date (or otherwise at the Commission's request).
12. The Parties shall inform the Commission and the Monitoring Trustee on the preparation of the data room documentation and the due diligence procedure and shall submit a copy of an information memorandum, if any, to the Commission and the Monitoring Trustee before sending the memorandum out to potential purchasers.

Section D. The Purchaser

13. In order to ensure the immediate restoration of effective competition, the Purchaser of any Divestment Business, in order to be approved by the Commission must:
 - (a) be independent of and unconnected to the Parties;
 - (b) have the financial resources, proven expertise and incentive to maintain and develop the Divestment Business as a viable and active competitive force in competition with the Parties and other competitors, including the capacity to transfer manufacturing production of the Divestment Business products to the Purchaser's own facility or to a third-party manufacturer independent from the Parties;
 - (c) be an existing or potential competitor in the generic pharmaceutical industry with current activities, entry or expansion plans in: (a) the Central or Eastern European region; or (b) in the therapeutic area concerned within the EEA;
 - (d) neither be likely to create, in the light of the information available to the Commission, *prima facie* competition concerns nor give rise to a risk that the implementation of the Commitments will be delayed, and must, in particular, reasonably be expected to obtain all necessary approvals from the relevant regulatory authorities for the acquisition of the Divestment Business (the before-mentioned criteria for the purchaser hereafter the "**Purchaser Requirements**").
14. The final binding sale and purchase agreements for the Divestment Businesses shall be conditional on the Commission's approval. When Sanofi-Aventis has reached an agreement with a proposed purchaser, it shall submit a fully documented and reasoned proposal, including a copy of the final agreement(s), to the Commission and the Monitoring Trustee. For each of the Divestment Businesses, Sanofi-Aventis must be able to demonstrate to the Commission that the purchaser meets the Purchaser Requirements and that the Divestment Business is being sold in a manner consistent with the Commitments. For the approval, the Commission shall verify that the proposed purchaser fulfils the Purchaser Requirements and that the Divestment Business is being sold in a manner consistent with the Commitments. The Commission may approve the sale of the Divestment Business without one or more Assets if this does not affect the viability, marketability and competitiveness of the Divestment Business after the sale, taking account of the proposed purchaser.

Sanofi-Aventis will inform all potential Purchasers that the proposed purchase of only a single Divestment Business, which is composed of a product that is being divested in

more than one Member State, will be subject to a right of first refusal as follows. Before concluding a binding sale and purchase agreement for a single Divestment Business at a given price, on an individual basis rather than as part of a package of more than one Divestment Businesses, any Purchaser of the same product in another relevant Member State, with whom Sanofi-Aventis has already entered into a final binding sale and purchase agreement, shall be offered the option to make a bid for the individual Divestment Business concerned. The Monitoring Trustee shall inform the Purchaser(s) concerned of the main terms and conditions of the non-binding offer (without disclosing the name of the offeror) and of the existence of another bidder (if any), and invite them to submit a bid for at least the same price within 5 business days. In the case where only one bid is submitted, the Divestment Business shall be sold, subject to the Commission's agreement, to the Purchaser of the same product in another relevant Member State if the proposed price matches or exceeds the price previously offered by the former proposed purchaser. In the case where two bids are submitted, the Divestment Business shall be sold, subject to the Commission's agreement, to the Purchaser of the same product in another relevant Member State proposing the highest price.

Section E. Trustee

I. Appointment Procedure

15. Sanofi-Aventis shall appoint a Monitoring Trustee to carry out the functions specified in the Commitments for a Monitoring Trustee. If, for one or more of the Divestment Businesses, (i) Sanofi-Aventis has not entered into a binding sale and purchase agreement [...] before the end of the First Divestiture Period or (ii) the Commission has rejected a purchaser proposed by Sanofi-Aventis at that time or thereafter, Sanofi-Aventis shall, in accordance with the procedure and timetable set out in paragraphs 17 and 18, 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 expiry of the First Divestiture Period.
16. The Trustee shall be independent of the Parties, possess the necessary qualifications to carry out its mandate, for example as an investment bank or consultant or auditor, and shall neither have nor become exposed to a conflict of interest. The Trustee shall be remunerated by 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 sale value of the Divestment Businesses, the fee shall also be linked to a divestiture within the Trustee Divestiture Period.

Proposal by Sanofi-Aventis

17. No later than [...] after the Effective Date, Sanofi-Aventis shall submit a list of one or more persons whom Sanofi-Aventis proposes to appoint as the Monitoring Trustee to the Commission for approval. No later than [...] before the end of the First Divestiture

Period, Sanofi-Aventis shall submit a list of one or more persons whom Sanofi-Aventis 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 16 and shall include:

- (a) the full terms of the proposed mandate, which shall include all provisions necessary to enable the Trustee to fulfil its duties under these Commitments;
- (b) the outline of a work plan which describes how the Trustee intends to carry out its assigned tasks;
- (c) an indication whether the proposed Trustee is to act as both Monitoring Trustee and Divestiture Trustee or whether different trustees are proposed for the two functions.

Approval or rejection by the Commission

18. The Commission shall have the discretion to approve or reject the proposed Trustee(s) and to approve the proposed mandate subject to any modifications it deems necessary for the Trustee to fulfil its obligations. If only one name is approved, Sanofi-Aventis shall appoint or cause to be appointed, the individual or institution concerned as Trustee, in accordance with the mandate approved by the Commission. If more than one name is approved, Sanofi-Aventis shall be free to choose the Trustee to be appointed from among the names approved. The Trustee shall be appointed within [...] of the Commission's approval, in accordance with the mandate approved by the Commission.

New proposal by Sanofi-Aventis

19. If all the proposed Trustees are rejected, Sanofi-Aventis shall submit the names of at least two more individuals or institutions within [...] of being informed of the rejection, in accordance with the requirements and the procedure set out in paragraphs 15 to 18.

Trustee nominated by the Commission

20. If all further proposed Trustees are rejected by the Commission, the Commission shall nominate a Trustee, whom Sanofi-Aventis shall appoint, or cause to be appointed, in accordance with a trustee mandate approved by the Commission.

II Functions of the Trustee

21. 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 Sanofi-Aventis, give any orders or instructions to the Trustee in order to ensure compliance with the conditions and obligations attached to the Decision.

Duties and obligations of the Monitoring Trustee

22. 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 their continued economic viability, marketability and competitiveness and monitor compliance by Sanofi-Aventis 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 business retained by the Parties, in accordance with paragraphs 5 to 7 of the Commitments;
 - (ii) supervise the management of the Divestment Businesses as a distinct and saleable entities, in accordance with paragraph 7 of the Commitments;
 - (iii) (i) in consultation with Sanofi-Aventis and without compromising the viability of the Divestment Businesses, determine all necessary measures to ensure, as far as practicable, that the part of the business of Sanofi-Aventis or Zentiva, as the case may be, which does not concern the Divestment Businesses, from as early as practicable following the Offer Completion Date and in any event after the date which is two weeks following the Offer Completion Date, does not obtain from within Sanofi-Aventis or Zentiva any business secrets, know-how, commercial information, or any other information of a confidential or proprietary nature relating to the Divestment Businesses, and (ii) decide whether such information may be disclosed to Sanofi-Aventis on the basis that the disclosure is reasonably necessary to allow Sanofi-Aventis to carry out the divestiture of the Divestment Businesses or the disclosure of which to Sanofi-Aventis and/or Zentiva is required by law;
 - (iv) monitor the splitting of assets between the Divestment Businesses and Sanofi-Aventis, Zentiva 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 Sanofi-Aventis such measures as the Monitoring Trustee considers necessary to ensure Sanofi-Aventis'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 purchasers, with a view to identifying an appropriate number of purchasers able to maintain the viability, marketability

and competitiveness of the Divestment Businesses, as well as the progress of the divestiture process and verify that, dependent on the stage of the divestiture process, potential purchasers receive sufficient information relating to the Divestment Businesses in particular by reviewing, if available, the data room documentation, the information memorandum, if any, and the due diligence process;

- (f) provide to the Commission, sending Sanofi-Aventis a non-confidential copy at the same time, a written report within 15 days after the end of every month. The report shall cover the operation and management of the Divestment Businesses so that the Commission can assess whether they are held in a manner consistent with the Commitments and the progress of the divestiture process as well as potential purchasers. In addition to these reports, the Monitoring Trustee shall promptly report in writing to the Commission, sending Sanofi-Aventis a non-confidential copy at the same time, if it concludes on reasonable grounds that Sanofi-Aventis is failing to comply with these Commitments;
- (g) within [...] after receipt of the documented proposal referred to in paragraph 14, submit to the Commission a reasoned opinion: (i) as to the suitability and independence of the proposed purchaser and the viability of the Divestment Businesses after the sale (including an assessment by the Trustee of the current activities, entry or expansion plans of the potential purchaser in the affected markets related to the Divestment Business(es)); and (ii) as to whether the Divestment Businesses are sold in a manner consistent with the conditions and obligations attached to the Decision, in particular, if relevant, whether the sale of any of the Divestment Businesses without one or more Assets affects the viability of that Divestment Business after the sale, taking account of the proposed purchaser.

Duties and obligations of the Divestiture Trustee

- 23. Within the Trustee Divestiture Period, the Divestiture Trustee shall sell [...] the Divestment Businesses to a purchaser, provided that the Commission has approved both the purchaser and the final binding sale and purchase agreement in accordance with the procedure laid down in paragraph 14. The Divestiture Trustee shall include in the sale and purchase agreement such terms and conditions as it considers appropriate for an expedient sale in the Trustee Divestiture Period. In particular, the Divestiture Trustee may include in the sale and purchase agreement such customary representations and warranties and indemnities as are reasonably required to effect the sale. The Divestiture Trustee shall protect the legitimate financial interests of Sanofi-Aventis, subject to the Parties' unconditional obligation to divest [...] in the Trustee Divestiture Period.
- 24. In the Trustee Divestiture Period (or otherwise at the Commission's request), the Divestiture Trustee shall provide the Commission with a comprehensive monthly report written in English on the progress of the divestiture process. Such reports shall be submitted within 15 days after the end of every month with a simultaneous copy to the Monitoring Trustee and a non-confidential copy to the Parties.

III Duties and obligations of the Parties

25. Sanofi-Aventis shall provide and shall cause its advisors to provide the Trustee with all such cooperation, assistance and information as the Trustee may reasonably require to perform its tasks. The Trustee shall have full and complete access to any of the Parties' or the Divestment Businesses' books, records, documents, management or other personnel, facilities, sites and technical information necessary for fulfilling its duties under the Commitments and the Parties shall provide the Trustee upon request with copies of any document. Similarly, the Trustee shall have full and complete access to any of the Parties' dossiers and technical information necessary for fulfilling its duties under the Commitments and the Parties shall provide the Trustee upon request with copies of any document. The Parties shall make available to the Trustee one or more offices on their premises and shall be available for meetings in order to provide the Trustee with all information necessary for the performance of its tasks.
26. Sanofi-Aventis shall provide the Monitoring Trustee with all managerial and administrative support that it may reasonably request on behalf of the management of the Divestment Businesses. This shall include all administrative support functions relating to the Divestment Businesses which are currently carried out at headquarters level. Sanofi-Aventis shall provide and shall cause its advisors to provide the Monitoring Trustee, on request, with the information submitted to potential purchasers, in particular give the Monitoring Trustee access to the data room documentation and all other information granted to potential purchasers in the due diligence procedure. Sanofi-Aventis shall inform the Monitoring Trustee on possible purchasers, submit a list of potential purchasers, and keep the Monitoring Trustee informed of all developments in the divestiture process.
27. Sanofi-Aventis shall grant or procure Affiliated Undertakings to grant comprehensive powers of attorney, duly executed, to the Divestiture Trustee upon expiry of the First Divestiture Period to effect the sale, the Closing and all actions and declarations which the Divestiture Trustee considers necessary or appropriate to achieve the sale and the Closing, including the appointment of advisors to assist with the sale process. Upon request of the Divestiture Trustee, Sanofi-Aventis shall cause the documents required for effecting the sale and the Closing to be duly executed.
28. Sanofi-Aventis shall indemnify the Trustee and its employees and agents (each an "*Indemnified Party*") and hold each Indemnified Party harmless against, and hereby agrees that an Indemnified Party shall have no liability to Sanofi-Aventis 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.
29. At the expense of Sanofi-Aventis, the Trustee may appoint advisors (in particular for corporate finance or legal advice), subject to Sanofi-Aventis' 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 Sanofi-Aventis refuse to approve the advisors proposed by the Trustee the Commission may approve the appointment of such advisors instead, after having heard Sanofi-Aventis. Only the Trustee shall be entitled to issue instructions to the advisors. Paragraph 28 shall apply mutatis mutandis. In the Trustee Divestiture Period, the Divestiture Trustee may use advisors who served Sanofi-Aventis during the

Divestiture Period if the Divestiture Trustee considers this in the best interest of an expedient sale.

IV. Replacement, discharge and reappointment of the Trustee

30. If the Trustee ceases to perform its functions under the Commitments or for any other good cause, including the exposure of the Trustee to a conflict of interest:
- (a) the Commission may, after hearing the Trustee, require Sanofi-Aventis to replace the Trustee; or
 - (b) Sanofi-Aventis, with the prior approval of the Commission, may replace the Trustee.
31. If the Trustee is removed according to paragraph 30, 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 15 to 20.
32. Beside the removal according to paragraph 30, the Trustee shall cease to act as Trustee only after the Commission has discharged it from its duties after all the Commitments with which the Trustee has been entrusted have been implemented. However, the Commission may at any time require the reappointment of the Monitoring Trustee if it subsequently appears that the relevant remedies might not have been fully and properly implemented.

Section F. The Review Clause

33. The Commission may, where appropriate, in response to a request from Sanofi-Aventis showing good cause and accompanied by a report from the Monitoring Trustee:
- (i) Grant an extension of the time periods foreseen in the Commitments, or
 - (ii) Waive, modify or substitute, in exceptional circumstances, one or more of the undertakings in these Commitments.

Where Sanofi-Aventis seeks an extension of a time period, it shall submit a request to the Commission no later than [...] before the expiry of that period, showing good cause. Only in exceptional circumstances shall Sanofi-Aventis be entitled to request an extension within [...] of any period.

.....

duly authorised for and on behalf of

Sanofi-Aventis

SCHEDULE i

Product: Maalox™ (A2A)

Territory: Romania

1. This Divestment Business consists of Sanofi-Aventis' (or an Affiliated Undertaking's) rights, title and interests in its product consisting in a combination of aluminium and magnesium in Romania (currently marketed under the brand name Maalox™) including the right to develop, manufacture and use Maalox™ with a view to its sale and marketing in any form and for any indication whatsoever in Romania. For the avoidance of doubt, this Divestment Business does not include any rights to sell Maalox™ outside of Romania.
2. The Divestment Business includes:
 - (a) the transfer of the national marketing authorisation for Maalox™ in Romania held by Theraplix/Sanofi-Aventis France, including the transfer of all relevant dossiers relating to the marketing authorisation, to the extent available to the current marketing authorisation holder;
 - (b) an irrevocable, exclusive (including vis-à-vis the Parties), assignable, sub-licensable, and royalty free licence to use the Maalox™ trademark in Romania held by Aventisub II, Inc.. (national trademark Nr 19147 and valid until April 2012);
 - (c) transfer of all licences, permits and authorisations issued by any governmental organisation related to the Divestment Business;
 - (d) assignment of all know-how related to the presentation forms of the Divestment Business that are currently marketed in Romania and which is used for the manufacture, use and/or sale of the Divestment Business at Closing, to the extent owned by Sanofi-Aventis;
 - (e) assignment of all contracts, leases, commitments and customer orders, all customer, credit and other records;⁹⁹
 - (f) transfer of (i) books, records and files relating to the prosecution and maintenance of the trademark, to the extent such trademark is assigned pursuant to sub-paragraph (c) above; (ii) all records of customers and suppliers, price lists, catalogues and mailing lists; and (iii) all advertising, marketing, sales, publicity and presentational materials; and
 - (g) sale of existing product inventory at the date of Closing in Romania (items referred to under (a)-(g) hereinafter collectively referred to as "*Assets of the Divestment Business*").

⁹⁹ Sanofi-Aventis is currently negotiating ten non-exclusive annual sales and purchasing agreements with wholesalers that cover Maalox™ and other Sanofi-Aventis products in Romania.

3. If and to the extent that the know-how listed in paragraph 2(d) above of this Schedule is not exclusively related to, and not exclusively used in respect of, the manufacture, use and sale of the Divestment Business in Romania, the Parties shall have the right to retain the ownership of such asset and shall grant to the Purchaser at no additional charge an exclusive and perpetual right to use such asset for the manufacture, use and sale of the Divestment Business in Romania.
4. At the option of the Purchaser, the Parties shall enter into a transitory exclusive manufacturing and/or supply arrangement related to the Divestment Business for the finished and packaged forms of Maalox™ in Romania existing and marketed by Sanofi-Aventis at Closing on a reasonable cost-plus basis, for a period of up to three years. Such transitory arrangement shall include appropriate provisions designed to ensure the continuous supply by the Parties to the Purchaser. It shall not contain provision requiring the delivery of minimum supply volumes or batches.
5. At the option of the Purchaser and to the extent required by law in Romania the Parties will enter into a transitional distribution arrangement related to the Divestment Business lasting until the relevant marketing authorisation is transferred into the name of the Purchaser on a reasonable cost-plus basis.
6. The Parties commit to make their best efforts to cooperate with the Purchaser for the transfer of the manufacture, sale and marketing of the Divestment Business and to undertake all regulatory changes that would be required as a result of such transfer.
7. At the option of the Purchaser, the Parties shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of the Divestment Business in Romania for a period of up to three years on a reasonable cost plus basis to be agreed with the Purchaser.
8. The transitional technical assistance agreement referred to above shall include appropriate provisions to ensure that the Parties provides technical assistance to the Purchaser expeditiously. The Parties shall carry out the technical assistance for the technology transfer in accordance with good industry practice including as regards the timing and responsiveness with which this assistance is provided through the different stages of the transfer.
9. The Parties commit to submit to the Commission, every 6 months as of Closing, a report on the progress made in relation to the transfer of the production to the facilities designated by the Purchaser. A copy of this report will be sent to the Monitoring Trustee.
10. At the option of the Purchaser, the Parties will make their best efforts to enable the Purchaser to obtain the supply of the aluminium and magnesium APIs manufactured by Sanofi-Aventis' current supplier on terms comparable to those offered to Sanofi-Aventis.
11. At the option of the Purchaser, the Parties agree to provide free access (i.e. free opt-in) to future product development improvements (i.e. galenical and packaging developments) in relation to the Divestment Business in any territory retained by the Parties for a period of five years should any such product improvements be undertaken by the Parties.
12. The Purchaser will be given an option to hire one or more Personnel, [...] who would reasonably be considered necessary to maintain the viability, marketability and competitiveness of this Divestment Business.

SCHEDULE ii

Product: Ercefuryl™ (A7A)

Territory: Czech Republic

1. This Divestment Business consists of Sanofi-Aventis' (or an Affiliated Undertaking's) rights, title and interests in its nifuroxazide product in the Czech Republic (currently marketed under the brand name Ercefuryl™) including the right to develop, manufacture and use Ercefuryl™ with a view to its sale and marketing in any form and for any indication whatsoever in the Czech Republic. For the avoidance of doubt, this Divestment Business does not include any rights to sell Ercefuryl™ outside of the Czech Republic.
2. The Divestment Business includes:
 - (a) the transfer of the marketing authorisation for Ercefuryl™ in the Czech Republic held by Laboratoires Synthélabo, including the transfer of all relevant dossiers relating to the marketing authorisation, to the extent available to the current marketing authorisation holder;
 - (b) an irrevocable, exclusive (including vis-à-vis the Parties), assignable, sub-licensable, and royalty free licence to use the Ercefuryl™ trademark in the Czech Republic, held by Sanofi-Aventis (IR Nr 266659 and valid until March 2013);
 - (c) transfer of all licences, permits and authorisations issued by any governmental organisation related to the Divestment Business;
 - (d) assignment of all know-how related to the presentation forms of the Divestment Business that are currently marketed in the Czech Republic and which is used for the manufacture, use and/or sale of the Divestment Business at Closing, to the extent owned by Sanofi-Aventis;
 - (e) assignment of all contracts, leases, commitments and customer orders, all customer, credit and other records;
 - (f) transfer of (i) books, records and files relating to the prosecution and maintenance of the trademark, to the extent such trademark is assigned pursuant to sub-paragraph (c) above; (ii) all records of customers and suppliers, price lists, catalogues and mailing lists; and (iii) all advertising, marketing, sales, publicity and presentational materials; and
 - (g) sale of existing product inventory at the date of Closing in the Czech Republic (items referred to under (a)-(g) hereinafter collectively referred to as "***Assets of the Divestment Business***").
3. If and to the extent that the know-how listed in paragraph 2(d) above of this Schedule is not exclusively related to, and not exclusively used in respect of, the manufacture, use and sale of the Divestment Business in the Czech Republic, the Parties shall have the right to retain the ownership of such asset and shall grant to the Purchaser at no additional charge an

exclusive and perpetual right to use such asset for the manufacture, use and sale of the Divestment Business in the Czech Republic.

4. At the option of the Purchaser, the Parties shall enter into a transitory exclusive manufacturing and/or supply arrangement related to the Divestment Business for the finished and packaged forms of Ercefuryl™ in the Czech Republic existing and marketed by Sanofi-Aventis at Closing on a reasonable cost-plus basis, for a period of up to three years. Such transitory arrangement shall include appropriate provisions designed to ensure the continuous supply by the Parties to the Purchaser. It shall not contain provision requiring the delivery of minimum supply volumes or batches.
5. At the option of the Purchaser and to the extent required by law in the Czech Republic the Parties will enter into a transitional distribution arrangement related to the Divestment Business lasting until the relevant marketing authorisation is transferred into the name of the Purchaser on a reasonable cost-plus basis.
6. The Parties commit to make their best efforts to cooperate with the Purchaser for the transfer of the manufacture, sale and marketing of the Divestment Business and to undertake all regulatory changes that would be required as a result of such transfer.
7. At the option of the Purchaser, the Parties shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of the Divestment Business in the Czech Republic for a period of up to three years on a reasonable cost plus basis to be agreed with the Purchaser.
8. The transitional technical assistance agreement referred to above shall include appropriate provisions to ensure that the Parties provides technical assistance to the Purchaser expeditiously. The Parties shall carry out the technical assistance for the technology transfer in accordance with good industry practice including as regards the timing and responsiveness with which this assistance is provided through the different stages of the transfer.
9. The Parties commit to submit to the Commission, every 6 months as of Closing, a report on the progress made in relation to the transfer of the production to the facilities designated by the Purchaser. A copy of this report will be sent to the Monitoring Trustee.
10. At the option of the Purchaser, the Parties shall enter into a transitory non-exclusive API supply agreement for the supply of the nifuroxazide API manufactured by Sanofi-Aventis' affiliate on a cost-plus basis, for a period of up to three years.
11. At the option of the Purchaser, the Parties agree to provide free access (i.e. free opt-in) to future product development improvements (i.e. galenical and packaging developments) in relation to the Divestment Business in any territory retained by the Parties for a period of five years should any such product improvements be undertaken by the Parties.
12. The Purchaser will be given an option to hire one or more Personnel, [...] who would reasonably be considered necessary to maintain the viability, marketability and competitiveness of this Divestment Business.

SCHEDULE iii

Product: Trental™ (C4A)

Territory: Czech Republic

1. This Divestment Business consists of Sanofi-Aventis' (or an Affiliated Undertaking's) rights, title and interests in its pentoxifylline product in the Czech Republic (currently marketed under the brand name Trental™) including the right to develop, manufacture and use Trental™ with a view to its sale and marketing in any form and for any indication whatsoever in the Czech Republic. For the avoidance of doubt, this Divestment Business does not include any rights to sell Trental™ outside of the Czech Republic.

2. The Divestment Business includes:
 - (a) the transfer of the marketing authorisation for Trental™ in the Czech Republic held by Sanofi-Aventis SRO, including the transfer of all relevant dossiers relating to the marketing authorisation, to the extent available to the current marketing authorisation holder;
 - (b) an irrevocable, exclusive (including vis-à-vis the Parties), assignable, sub-licensable, and royalty free licence to use the Trental™ trademark in the Czech Republic held by Sanofi-Aventis Deutschland GmbH (IR Nr 264457 and valid until January 2013);
 - (c) transfer of all licences, permits and authorisations issued by any governmental organisation related to the Divestment Business;
 - (d) assignment of all know-how related to the presentation forms of the Divestment Business that are currently marketed in the Czech Republic and which is used for the manufacture, use and/or sale of the Divestment Business at Closing, to the extent owned by Sanofi-Aventis;
 - (e) assignment of all contracts, leases, commitments and customer orders, all customer, credit and other records;
 - (f) transfer of (i) books, records and files relating to the prosecution and maintenance of the trademark, to the extent such trademark is assigned pursuant to sub-paragraph (c) above; (ii) all records of customers and suppliers, price lists, catalogues and mailing lists; and (iii) all advertising, marketing, sales, publicity and presentational materials; and
 - (g) sale of existing product inventory at the date of Closing in the Czech Republic (items referred to under (a)-(g) hereinafter collectively referred to as "***Assets of the Divestment Business***").

3. If and to the extent that the know-how listed in paragraph 2(d) above of this Schedule is not exclusively related to, and not exclusively used in respect of, the manufacture, use and sale of the Divestment Business in the Czech Republic, the Parties shall have the right to retain the ownership of such asset and shall grant to the Purchaser at no additional charge an

exclusive and perpetual right to use such asset for the manufacture, use and sale of the Divestment Business in the Czech Republic.

4. At the option of the Purchaser, the Parties shall enter into a transitory exclusive manufacturing and/or supply arrangement related to the Divestment Business for the finished and packaged forms of Trental™ in the Czech Republic existing and marketed by Sanofi-Aventis at Closing on a reasonable cost-plus basis, for a period of up to three years. Such transitory arrangement shall include appropriate provisions designed to ensure the continuous supply by the Parties to the Purchaser. It shall not contain provision requiring the delivery of minimum supply volumes or batches.
5. At the option of the Purchaser and to the extent required by law in the Czech Republic the Parties will enter into a transitional distribution arrangement related to the Divestment Business lasting until the relevant marketing authorisation is transferred into the name of the Purchaser on a reasonable cost-plus basis.
6. The Parties commit to make their best efforts to cooperate with the Purchaser for the transfer of the manufacture, sale and marketing of the Divestment Business and to undertake all regulatory changes that would be required as a result of such transfer.
7. At the option of the Purchaser, the Parties shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of the Divestment Business in the Czech Republic for a period of up to three years on a reasonable cost plus basis to be agreed with the Purchaser.
8. The transitional technical assistance agreement referred to above shall include appropriate provisions to ensure that the Parties provides technical assistance to the Purchaser expeditiously. The Parties shall carry out the technical assistance for the technology transfer in accordance with good industry practice including as regards the timing and responsiveness with which this assistance is provided through the different stages of the transfer.
9. The Parties commit to submit to the Commission, every 6 months as of Closing, a report on the progress made in relation to the transfer of the production to the facilities designated by the Purchaser. A copy of this report will be sent to the Monitoring Trustee.
10. At the option of the Purchaser, the Parties will make their best efforts to enable the Purchaser to obtain the supply of the pentoxifylline API manufactured by Sanofi-Aventis' current supplier on terms comparable to those offered to Sanofi-Aventis.
11. At the option of the Purchaser, the Parties agree to provide free access (i.e. free opt-in) to future product development improvements (i.e. galenical and packaging developments) in relation to the Divestment Business in any territory retained by the Parties for a period of five years should any such product improvements be undertaken by the Parties.
12. The Purchaser will be given an option to hire one or more Personnel, [...] who would reasonably be considered necessary to maintain the viability, marketability and competitiveness of this Divestment Business.

SCHEDULE iv

Product: Trental™ (C4A Rx)

Territory: Estonia

1. This Divestment Business consists of Sanofi-Aventis' (or an Affiliated Undertaking's) rights, title and interests in its pentoxifylline product in Estonia (currently marketed under the brand name Trental™) including the right to develop, manufacture and use Trental™ with a view to its sale and marketing in any form and for any indication whatsoever in Estonia. For the avoidance of doubt, this Divestment Business does not include any rights to sell Trental™ outside of Estonia.

2. The Divestment Business includes:
 - (a) the transfer of the national marketing authorisation for Trental™ in Estonia held by Sanofi-Aventis Estonia OU, including the transfer of all relevant dossiers relating to the marketing authorisation, to the extent available to the current marketing authorisation holder;
 - (b) an irrevocable, exclusive (including vis-à-vis the Parties), assignable, sub-licensable, and royalty free licence to use the Trental™ trademark in Estonia held by Sanofi-Aventis Deutschland GmbH (national trademark Nr 19013 and valid until April 2016);
 - (c) transfer of all licences, permits and authorisations issued by any governmental organisation related to the Divestment Business;
 - (d) assignment of all know-how related to the presentation forms of the Divestment Business that are currently marketed in Estonia and which is used for the manufacture, use and/or sale of the Divestment Business at Closing, to the extent owned by Sanofi-Aventis;
 - (e) assignment of all contracts, leases, commitments and customer orders, all customer, credit and other records;
 - (f) transfer of (i) books, records and files relating to the prosecution and maintenance of the trademark, to the extent such trademark is assigned pursuant to sub-paragraph (c) above; (ii) all records of customers and suppliers, price lists, catalogues and mailing lists; and (iii) all advertising, marketing, sales, publicity and presentational materials; and
 - (g) sale of existing product inventory at the date of Closing in Estonia (items referred to under (a)-(g) hereinafter collectively referred to as "*Assets of the Divestment Business*").

3. If and to the extent that the know-how listed in paragraph 2(d) above of this Schedule is not exclusively related to, and not exclusively used in respect of, the manufacture, use and sale of the Divestment Business in Estonia, the Parties shall have the right to retain the ownership of such asset and shall grant to the Purchaser at no additional charge an exclusive

and perpetual right to use such asset for the manufacture, use and sale of the Divestment Business in Estonia.

4. At the option of the Purchaser, the Parties shall enter into a transitory exclusive manufacturing and/or supply arrangement related to the Divestment Business for the finished and packaged forms of Trental™ in Estonia existing and marketed by Sanofi-Aventis at Closing on a reasonable cost-plus basis, for a period of up to three years. Such transitory arrangement shall include appropriate provisions designed to ensure the continuous supply by the Parties to the Purchaser. It shall not contain provision requiring the delivery of minimum supply volumes or batches.
5. At the option of the Purchaser and to the extent required by law in Estonia the Parties will enter into a transitional distribution arrangement related to the Divestment Business lasting until the relevant marketing authorisation is transferred into the name of the Purchaser on a reasonable cost-plus basis.
6. The Parties commit to make their best efforts to cooperate with the Purchaser for the transfer of the manufacture, sale and marketing of the Divestment Business and to undertake all regulatory changes that would be required as a result of such transfer.
7. At the option of the Purchaser, the Parties shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of the Divestment Business in Estonia for a period of up to three years on a reasonable cost plus basis to be agreed with the Purchaser.
8. The transitional technical assistance agreement referred to above shall include appropriate provisions to ensure that the Parties provides technical assistance to the Purchaser expeditiously. The Parties shall carry out the technical assistance for the technology transfer in accordance with good industry practice including as regards the timing and responsiveness with which this assistance is provided through the different stages of the transfer.
9. The Parties commit to submit to the Commission, every 6 months as of Closing, a report on the progress made in relation to the transfer of the production to the facilities designated by the Purchaser. A copy of this report will be sent to the Monitoring Trustee.
10. At the option of the Purchaser, the Parties will make their best efforts to enable the Purchaser to obtain the supply of the pentoxifylline API manufactured by Sanofi-Aventis' current supplier on terms comparable to those offered to Sanofi-Aventis.
11. At the option of the Purchaser, the Parties agree to provide free access (i.e. free opt-in) to future product development improvements (i.e. galenical and packaging developments) in relation to the Divestment Business in any territory retained by the Parties for a period of five years should any such product improvements be undertaken by the Parties.
12. The Purchaser will be given an option to hire one or more Personnel, [...] who would reasonably be considered necessary to maintain the viability, marketability and competitiveness of this Divestment Business.

SCHEDULE v**Product: Trental™ (C4A)****Territory: Slovak Republic**

1. This Divestment Business consists of Sanofi-Aventis' (or an Affiliated Undertaking's) rights, title and interests in its pentoxifylline product in the Slovak Republic (currently marketed under the brand name Trental™) including the right to develop, manufacture and use Trental™ with a view to its sale and marketing in any form and for any indication whatsoever in the Slovak Republic. For the avoidance of doubt, this Divestment Business does not include any rights to sell Trental™ outside of the Slovak Republic.
2. The Divestment Business includes:
 - (a) the transfer of the marketing authorisation for Trental™ in the Slovak Republic held by Sanofi-Aventis Slovakia SRO, including the transfer of all relevant dossiers relating to the marketing authorisation, to the extent available to the current marketing authorisation holder;
 - (b) an irrevocable, exclusive (including vis-à-vis the Parties), assignable, sub-licensable, and royalty free licence to use the Trental™ trademark in the Slovak Republic held by Sanofi-Aventis Deutschland GmbH (IR Nr 264457 and valid until January 2013).;
 - (c) transfer of all licences, permits and authorisations issued by any governmental organisation related to the Divestment Business;
 - (d) assignment of all know-how related to the presentation forms of the Divestment Business that are currently marketed in the Slovak Republic and which is used for the manufacture, use and/or sale of the Divestment Business at Closing, to the extent owned by Sanofi-Aventis;
 - (e) assignment of all contracts, leases, commitments and customer orders, all customer, credit and other records;
 - (f) transfer of (i) books, records and files relating to the prosecution and maintenance of the trademark, to the extent such trademark is assigned pursuant to sub-paragraph (c) above; (ii) all records of customers and suppliers, price lists, catalogues and mailing lists; and (iii) all advertising, marketing, sales, publicity and presentational materials; and
 - (g) sale of existing product inventory at the date of Closing in the Slovak Republic (items referred to under (a)-(g) hereinafter collectively referred to as "**Assets of the Divestment Business**").
3. If and to the extent that the know-how listed in paragraph 2(d) above of this Schedule is not exclusively related to, and not exclusively used in respect of, the manufacture, use and sale of the Divestment Business in the Slovak Republic, the Parties shall have the right to retain the ownership of such asset and shall grant to the Purchaser at no additional charge an

exclusive and perpetual right to use such asset for the manufacture, use and sale of the Divestment Business in the Slovak Republic.

4. At the option of the Purchaser, the Parties shall enter into a transitory exclusive manufacturing and/or supply arrangement related to the Divestment Business for the finished and packaged forms of Trental™ in the Slovak Republic existing and marketed by Sanofi-Aventis at Closing on a reasonable cost-plus basis, for a period of up to three years. Such transitory arrangement shall include appropriate provisions designed to ensure the continuous supply by the Parties to the Purchaser. It shall not contain provision requiring the delivery of minimum supply volumes or batches.
5. At the option of the Purchaser and to the extent required by law in the Slovak Republic the Parties will enter into a transitional distribution arrangement related to the Divestment Business lasting until the relevant marketing authorisation is transferred into the name of the Purchaser on a reasonable cost-plus basis.
6. The Parties commit to make their best efforts to cooperate with the Purchaser for the transfer of the manufacture, sale and marketing of the Divestment Business and to undertake all regulatory changes that would be required as a result of such transfer.
7. At the option of the Purchaser, the Parties shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of the Divestment Business in the Slovak Republic for a period of up to three years on a reasonable cost plus basis to be agreed with the Purchaser.
8. The transitional technical assistance agreement referred to above shall include appropriate provisions to ensure that the Parties provides technical assistance to the Purchaser expeditiously. The Parties shall carry out the technical assistance for the technology transfer in accordance with good industry practice including as regards the timing and responsiveness with which this assistance is provided through the different stages of the transfer.
9. The Parties commit to submit to the Commission, every 6 months as of Closing, a report on the progress made in relation to the transfer of the production to the facilities designated by the Purchaser. A copy of this report will be sent to the Monitoring Trustee.
10. At the option of the Purchaser, the Parties will make their best efforts to enable the Purchaser to obtain the supply of the pentoxifylline API manufactured by Sanofi-Aventis' current supplier on terms comparable to those offered to Sanofi-Aventis.
11. At the option of the Purchaser, the Parties agree to provide free access (i.e. free opt-in) to future product development improvements (i.e. galenical and packaging developments) in relation to the Divestment Business in any territory retained by the Parties for a period of five years should any such product improvements be undertaken by the Parties.
12. The Purchaser will be given an option to hire one or more Personnel, [...] who would reasonably be considered necessary to maintain the viability, marketability and competitiveness of this Divestment Business.

SCHEDULE vi

Product: Papaverinium HCL (A3A)

Territory: Hungary

1. This Divestment Business consists of Zentiva's (or an Affiliated Undertaking's) rights, title and interests in its papaverinium product in Hungary (currently marketed under the brand name Papaverinium HCL) including the right to develop, manufacture and use Papaverinium HCL with a view to its sale and marketing in any form and for any indication whatsoever in Hungary. For the avoidance of doubt, this Divestment Business does not include any rights to sell Papaverinium HCL outside of Hungary.
2. The Divestment Business includes:
 - (a) the transfer of the marketing authorisation for Papaverinium HCL in Hungary held by Zentiva Hungary Ltd, including the transfer of all relevant dossiers relating to the marketing authorisation, to the extent available to the current marketing authorisation holder;
 - (b) transfer of all licences, permits and authorisations issued by any governmental organisation related to the Divestment Business;
 - (c) assignment of all know-how related to the presentation forms of the Divestment Business that are currently marketed in Hungary and which is used for the manufacture, use and/or sale of the Divestment Business at Closing, to the extent owned by Zentiva;
 - (d) assignment of all contracts, leases, commitments and customer orders, all customer, credit and other records;
 - (e) transfer of (i) all records of customers and suppliers, price lists, catalogues and mailing lists; and (ii) all advertising, marketing, sales, publicity and presentational materials; and
 - (f) sale of existing product inventory at the date of Closing in Hungary (items referred to under (a)-(f) hereinafter collectively referred to as "**Assets of the Divestment Business**").
3. If and to the extent that the know-how listed in paragraph 2(c) above of this Schedule is not exclusively related to, and not exclusively used in respect of, the manufacture, use and sale of the Divestment Business in Hungary, the Parties shall have the right to retain the ownership of such asset and shall grant to the Purchaser at no additional charge an exclusive and perpetual right to use such asset for the manufacture, use and sale of the Divestment Business in Hungary.
4. At the option of the Purchaser, the Parties shall enter into a transitory exclusive manufacturing and/or supply arrangement related to the Divestment Business for the finished and packaged forms of Papaverinium HCL in Hungary existing and marketed by Zentiva at Closing on a reasonable cost-plus basis, for a period of up to three years. Such transitory arrangement shall include appropriate provisions designed to ensure the

continuous supply by the Parties to the Purchaser. It shall not contain provision requiring the delivery of minimum supply volumes or batches.

5. At the option of the Purchaser and to the extent required by law in Hungary the Parties will enter into a transitional distribution arrangement related to the Divestment Business lasting until the relevant marketing authorisation is transferred into the name of the Purchaser on a reasonable cost-plus basis.
6. The Parties commit to make their best efforts to cooperate with the Purchaser for the transfer of the manufacture, sale and marketing of the Divestment Business and to undertake all regulatory changes that would be required as a result of such transfer.
7. At the option of the Purchaser, the Parties shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of the Divestment Business in Hungary for a period of up to three years on a reasonable cost plus basis to be agreed with the Purchaser.
8. The transitional technical assistance agreement referred to above shall include appropriate provisions to ensure that the Parties provides technical assistance to the Purchaser expeditiously. The Parties shall carry out the technical assistance for the technology transfer in accordance with good industry practice including as regards the timing and responsiveness with which this assistance is provided through the different stages of the transfer.
9. The Parties commit to submit to the Commission, every 6 months as of Closing, a report on the progress made in relation to the transfer of the production to the facilities designated by the Purchaser. A copy of this report will be sent to the Monitoring Trustee.
10. At the option of the Purchaser, the Parties will make their best efforts to enable the Purchaser to obtain the supply of the papaverinium API manufactured by Zentiva's current supplier on terms comparable to those offered to Zentiva.
11. At the option of the Purchaser, the Parties agree to provide free access (i.e. free opt-in) to future product development improvements (i.e. galenical and packaging developments) in relation to the Divestment Business in any territory retained by the Parties for a period of five years should any such product improvements be undertaken by the Parties.
12. The Purchaser will be given an option to hire one or more Personnel, [...] who would reasonably be considered necessary to maintain the viability, marketability and competitiveness of this Divestment Business.

SCHEDULE vii

Products: Scobutil™ and Sulfat de Atropina¹⁰⁰ (A3A)

Territory: Romania

1. This Divestment Business consists of Zentiva's (or an Affiliated Undertaking's) rights, title and interests in a single package comprising both (a) its butylscopolammonii bromidum product in Romania (currently marketed under the brand name Scobutil™) and (b) its atropine product in Romania (currently marketed under the brand name Sulfat de Atropina), including the right to develop, manufacture and use Scobutil™ and Sulfat de Atropina with a view to their sale and marketing in any form and for any indication whatsoever in Romania. For the avoidance of doubt, this Divestment Business does not include any rights to sell Scobutil™ and/or Sulfat de Atropina outside of Romania.

2. The Divestment Business includes:
 - A. **Scobutil™**
 - (a) the transfer of the marketing authorisation for Scobutil™ in Romania held by Zentiva SA, including the transfer of all relevant dossiers relating to the marketing authorisation, to the extent available to the current marketing authorisation holder;
 - (b) an irrevocable, exclusive (including vis-à-vis the Parties), assignable, sub-licensable, and royalty free licence to use the Scobutil™ trademark in Romania held by Zentiva S.A. (national trademark Nr 015092 and valid until October 2017);
 - (c) transfer of all licences, permits and authorisations issued by any governmental organisation related to the Divestment Business;
 - (d) assignment of all know-how related to the presentation forms of the Divestment Business that are currently marketed in Romania and which is used for the manufacture, use and/or sale of the Divestment Business at Closing, to the extent owned by Zentiva;
 - (e) assignment of all contracts, leases, commitments and customer orders, all customer, credit and other records;
 - (f) transfer of (i) books, records and files relating to the prosecution and maintenance of the trademark, to the extent such trademark is assigned pursuant to sub-paragraph (c) above; (ii) all records of customers and suppliers, price lists, catalogues and mailing lists; and (iii) all advertising, marketing, sales, publicity and presentational materials; and
 - (g) sale of existing product inventory at the date of Closing in Romania.

¹⁰⁰ Note that there is no trademark for Sulfat de Atropina, so there is no trademark assignment provision in this schedule for this product.

B. Sulfat de Atropina

- (a) the transfer of the marketing authorisation for Sulfat de Atropina in Romania held by Zentiva SA, including the transfer of all relevant dossiers relating to the marketing authorisation, to the extent available to the current marketing authorisation holder;
 - (b) transfer of all licences, permits and authorisations issued by any governmental organisation related to the Divestment Business;
 - (c) assignment of all know-how related to the presentation forms of the Divestment Business that are currently marketed in Romania and which is used for the manufacture, use and/or sale of the Divestment Business at Closing, to the extent owned by Zentiva;
 - (d) assignment of all contracts, leases, commitments and customer orders, all customer, credit and other records;
 - (e) transfer of (i) all records of customers and suppliers, price lists, catalogues and mailing lists; and (ii) all advertising, marketing, sales, publicity and presentational materials; and
 - (f) sale of existing product inventory at the date of Closing in Romania (items referred to under 2A(a)-(f) and 2B(a)-(f) hereinafter collectively referred to as "***Assets of the Divestment Business***").
3. If and to the extent that the know-how listed in paragraph 2A(d) and 2B(c) above of this Schedule is not exclusively related to, and not exclusively used in respect of, the manufacture, use and sale of the Divestment Business in Romania, the Parties shall have the right to retain the ownership of such assets and shall grant to the Purchaser at no additional charge an exclusive and perpetual right to use such assets for the manufacture, use and sale of the Divestment Business in Romania.
 4. At the option of the Purchaser, the Parties shall enter into a transitory exclusive manufacturing and/or supply arrangement related to the Divestment Business for the finished and packaged forms of Scobutil™ and/or Sulfat de Atropina in Romania existing and marketed by Zentiva at Closing on a reasonable cost-plus basis, for a period of up to three years. Such transitory arrangement shall include appropriate provisions designed to ensure the continuous supply by the Parties to the Purchaser. It shall not contain provision requiring the delivery of minimum supply volumes or batches.
 5. At the option of the Purchaser and to the extent required by law in Romania the Parties will enter into a transitional distribution arrangement related to the Divestment Business lasting until the relevant marketing authorisations are transferred into the name of the Purchaser on a reasonable cost-plus basis.
 6. The Parties commit to make their best efforts to cooperate with the Purchaser for the transfer of the manufacture, sale and marketing of the Divestment Business and to undertake all regulatory changes that would be required as a result of such transfer.
 7. At the option of the Purchaser, the Parties shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of the Divestment Business in Romania for a period of up to three years on a reasonable cost plus basis to be agreed with the Purchaser.
 8. The transitional technical assistance agreement referred to above shall include appropriate provisions to ensure that the Parties provides technical assistance to the Purchaser

expeditiously. The Parties shall carry out the technical assistance for the technology transfer in accordance with good industry practice including as regards the timing and responsiveness with which this assistance is provided through the different stages of the transfer.

9. The Parties commit to submit to the Commission, every 6 months as of Closing, a report on the progress made in relation to the transfer of the production to the facilities designated by the Purchaser. A copy of this report will be sent to the Monitoring Trustee.
10. At the option of the Purchaser, the Parties will make their best efforts to enable the Purchaser to obtain the supply of the butylscopolammonil bromidum and atropine APIs manufactured by Zentiva's current supplier on terms comparable to those offered to Zentiva.
11. At the option of the Purchaser, the Parties agree to provide free access (i.e. free opt-in) to future product development improvements (i.e. galenical and packaging developments) in relation to the Divestment Business in any territory retained by the Parties for a period of five years should any such product improvements be undertaken by the Parties.
12. The Purchaser will be given an option to hire one or more Personnel, [...] who would reasonably be considered necessary to maintain the viability, marketability and competitiveness of this Divestment Business.

SCHEDULE viii

Product: Flavobion™ (A5B)

Territory: Czech Republic

1. This Divestment Business consists of Zentiva's (or an Affiliated Undertaking's) rights, title and interests in its silymarin product in the Czech Republic (currently marketed under the brand name Flavobion™) including the right to develop, manufacture and use Flavobion™ with a view to its sale and marketing in any form and for any indication whatsoever in the Czech Republic. For the avoidance of doubt, this Divestment Business does not include any rights to sell Flavobion™ outside of the Czech Republic.
2. The Divestment Business includes:
 - (a) the transfer of the marketing authorisation for Flavobion™ in the Czech Republic held by Zentiva a.s., including the transfer of all relevant dossiers relating to the marketing authorisation, to the extent available to the current marketing authorisation holder;
 - (b) an irrevocable, exclusive (including vis-à-vis the Parties), assignable, sub-licensable, and royalty free licence to use the Flavobion™ trademark in the Czech Republic held by Zentiva a.s. (national trademark Nr CZ100162 and valid until April 2014);
 - (c) transfer of all licences, permits and authorisations issued by any governmental organisation related to the Divestment Business;
 - (d) assignment of all know-how related to the presentation forms of the Divestment Business that are currently marketed in the Czech Republic and which is used for the manufacture, use and/or sale of the Divestment Business at Closing, to the extent owned by Zentiva;
 - (e) assignment of all contracts, leases, commitments and customer orders, all customer, credit and other records;
 - (f) transfer of (i) books, records and files relating to the prosecution and maintenance of the trademark, to the extent such trademark is assigned pursuant to sub-paragraph (c) above; (ii) all records of customers and suppliers, price lists, catalogues and mailing lists; and (iii) all advertising, marketing, sales, publicity and presentational materials; and
 - (g) sale of existing product inventory at the date of Closing in the Czech Republic (items referred to under (a)-(g) hereinafter collectively referred to as "***Assets of the Divestment Business***").
3. If and to the extent that the know-how listed in paragraph 2(d) above of this Schedule is not exclusively related to, and not exclusively used in respect of, the manufacture, use and sale of the Divestment Business in the Czech Republic, the Parties shall have the right to retain the ownership of such asset and shall grant to the Purchaser at no additional charge an exclusive and perpetual right to use such asset for the manufacture, use and sale of the Divestment Business in the Czech Republic.

4. At the option of the Purchaser, the Parties shall enter into a transitory exclusive manufacturing and/or supply arrangement related to the Divestment Business for the finished and packaged forms of Flavobion™ in the Czech Republic existing and marketed by Zentiva at Closing on a reasonable cost-plus basis, for a period of up to three years. Such transitory arrangement shall include appropriate provisions designed to ensure the continuous supply by the Parties to the Purchaser. It shall not contain provision requiring the delivery of minimum supply volumes or batches.
5. At the option of the Purchaser and to the extent required by law in the Czech Republic the Parties will enter into a transitional distribution arrangement related to the Divestment Business lasting until the relevant marketing authorisation is transferred into the name of the Purchaser on a reasonable cost-plus basis.
6. The Parties commit to make their best efforts to cooperate with the Purchaser for the transfer of the manufacture, sale and marketing of the Divestment Business and to undertake all regulatory changes that would be required as a result of such transfer.
7. At the option of the Purchaser, the Parties shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of the Divestment Business in the Czech Republic for a period of up to three years on a reasonable cost plus basis to be agreed with the Purchaser.
8. The transitional technical assistance agreement referred to above shall include appropriate provisions to ensure that the Parties provides technical assistance to the Purchaser expeditiously. The Parties shall carry out the technical assistance for the technology transfer in accordance with good industry practice including as regards the timing and responsiveness with which this assistance is provided through the different stages of the transfer.
9. The Parties commit to submit to the Commission, every 6 months as of Closing, a report on the progress made in relation to the transfer of the production to the facilities designated by the Purchaser. A copy of this report will be sent to the Monitoring Trustee.
10. At the option of the Purchaser, the Parties will make their best efforts to enable the Purchaser to obtain the supply of the silymarin API manufactured by Zentiva's current supplier on terms comparable to those offered to Zentiva.
11. At the option of the Purchaser, the Parties agree to provide free access (i.e. free opt-in) to future product development improvements (i.e. galenical and packaging developments) in relation to the Divestment Business in any territory retained by the Parties for a period of five years should any such product improvements be undertaken by the Parties.
12. The Purchaser will be given an option to hire one or more Personnel, [...]who would reasonably be considered necessary to maintain the viability, marketability and competitiveness of this Divestment Business.

SCHEDULE ix

Product: Flavobion™

Territory: Slovak Republic (A5B)

1. This Divestment Business consists of Zentiva's (or an Affiliated Undertaking's) rights, title and interests in its silymarin product in the Slovak Republic (currently marketed under the brand name Flavobion™) including the right to develop, manufacture and use Flavobion™ with a view to its sale and marketing in any form and for any indication whatsoever in the Slovak Republic. For the avoidance of doubt, this Divestment Business does not include any rights to sell Flavobion™ outside of the Slovak Republic.
2. The Divestment Business includes:
 - (a) the transfer of the marketing authorisation for Flavobion™ in the Slovak Republic held by Zentiva a.s., including the transfer of all relevant dossiers relating to the marketing authorisation, to the extent available to the current marketing authorisation holder;
 - (b) an irrevocable, exclusive (including vis-à-vis the Parties), assignable, sub-licensable, and royalty free licence to use the Flavobion™ trademark in the Slovak Republic held by Zentiva a.s. (national trademark Nr 100162 and valid until April 2014);
 - (c) transfer of all licences, permits and authorisations issued by any governmental organisation related to the Divestment Business;
 - (d) assignment of all know-how related to the presentation forms of the Divestment Business that are currently marketed in the Slovak Republic and which is used for the manufacture, use and/or sale of the Divestment Business at Closing, to the extent owned by Zentiva;
 - (e) assignment of all contracts, leases, commitments and customer orders, all customer, credit and other records;
 - (f) transfer of (i) books, records and files relating to the prosecution and maintenance of the trademark, to the extent such trademark is assigned pursuant to sub-paragraph (c) above; (ii) all records of customers and suppliers, price lists, catalogues and mailing lists; and (iii) all advertising, marketing, sales, publicity and presentational materials; and
 - (g) sale of existing product inventory at the date of Closing in the Slovak Republic (items referred to under (a)-(g) hereinafter collectively referred to as "***Assets of the Divestment Business***").
3. If and to the extent that the know-how listed in paragraph 2(d) above of this Schedule is not exclusively related to, and not exclusively used in respect of, the manufacture, use and sale of the Divestment Business in the Slovak Republic, the Parties shall have the right to retain the ownership of such asset and shall grant to the Purchaser at no additional charge an exclusive and perpetual right to use such asset for the manufacture, use and sale of the Divestment Business in the Slovak Republic.

4. At the option of the Purchaser, the Parties shall enter into a transitory exclusive manufacturing and/or supply arrangement related to the Divestment Business for the finished and packaged forms of Flavobion™ in the Slovak Republic existing and marketed by Zentiva at Closing on a reasonable cost-plus basis, for a period of up to three years. Such transitory arrangement shall include appropriate provisions designed to ensure the continuous supply by the Parties to the Purchaser. It shall not contain provision requiring the delivery of minimum supply volumes or batches.
5. At the option of the Purchaser and to the extent required by law in the Slovak Republic the Parties will enter into a transitional distribution arrangement related to the Divestment Business lasting until the relevant marketing authorisation is transferred into the name of the Purchaser on a reasonable cost-plus basis.
6. The Parties commit to make their best efforts to cooperate with the Purchaser for the transfer of the manufacture, sale and marketing of the Divestment Business and to undertake all regulatory changes that would be required as a result of such transfer.
7. At the option of the Purchaser, the Parties shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of the Divestment Business in the Slovak Republic for a period of up to three years on a reasonable cost plus basis to be agreed with the Purchaser.
8. The transitional technical assistance agreement referred to above shall include appropriate provisions to ensure that the Parties provides technical assistance to the Purchaser expeditiously. The Parties shall carry out the technical assistance for the technology transfer in accordance with good industry practice including as regards the timing and responsiveness with which this assistance is provided through the different stages of the transfer.
9. The Parties commit to submit to the Commission, every 6 months as of Closing, a report on the progress made in relation to the transfer of the production to the facilities designated by the Purchaser. A copy of this report will be sent to the Monitoring Trustee.
10. At the option of the Purchaser, the Parties will make their best efforts to enable the Purchaser to obtain the supply of the silymarin API manufactured by Zentiva's current supplier on terms comparable to those offered to Zentiva.
11. At the option of the Purchaser, the Parties agree to provide free access (i.e. free opt-in) to future product development improvements (i.e. galenical and packaging developments) in relation to the Divestment Business in any territory retained by the Parties for a period of five years should any such product improvements be undertaken by the Parties.
12. The Purchaser will be given an option to hire one or more Personnel, [...]d who would reasonably be considered necessary to maintain the viability, marketability and competitiveness of this Divestment Business.

SCHEDULE x

Products: Vasocardin™, Betaxa™ and Tenoloc™ (C7A)

Territory: Czech Republic

1. This Divestment Business consists of Zentiva's (or an Affiliated Undertaking's) rights, title and interests in a single package comprising each of (a) its metoprolol product in the Czech Republic (currently marketed under the brand name Vasocardin™); (b) its betaxolol product in the Czech Republic (currently marketed under the brand name Betaxa™); and (c) its celiprolol product in the Czech Republic, including the right to develop, manufacture and use Vasocardin™, Betaxa™ and Tenoloc™ with a view to their sale and marketing in any form and for any indication whatsoever in the Czech Republic. For the avoidance of doubt, this Divestment Business does not include any rights to sell Vasocardin™, Betaxa™ and/or Tenoloc™ outside of the Czech Republic.
2. The Divestment Business includes:
 - A. Vasocardin™**
 - (a) the transfer of the marketing authorisation for Vasocardin™ in the Czech Republic held by Zentiva a.s., including the transfer of all relevant dossiers relating to the marketing authorisation, to the extent available to the current marketing authorisation holder;
 - (b) an irrevocable, exclusive (including vis-à-vis the Parties), assignable, sub-licensable, and royalty free licence to use the Vasocardin™ trademark in the Czech Republic, held by Zentiva a.s. (national trademark CZ 100370 and valid until January 2009);
 - (c) transfer of all licences, permits and authorisations issued by any governmental organisation related to the Divestment Business;
 - (d) assignment of all know-how related to the presentation forms of the Divestment Business that are currently marketed in the Czech Republic and which is used for the manufacture, use and/or sale of the Divestment Business at Closing, to the extent owned by Zentiva;
 - (e) assignment of all contracts, leases, commitments and customer orders, all customer, credit and other records;
 - (f) transfer of (i) books, records and files relating to the prosecution and maintenance of the trademark, to the extent such trademark is assigned pursuant to sub-paragraph (c) above; (ii) all records of customers and suppliers, price lists, catalogues and mailing lists; and (iii) all advertising, marketing, sales, publicity and presentational materials; and
 - (g) sale of existing product inventory at the date of Closing in the Czech Republic.
 - B. Betaxa™**
 - (a) the transfer of the marketing authorisation for Betaxa™ in the Czech Republic held by Zentiva a.s., including the transfer of all relevant dossiers relating to the marketing authorisation, to the extent available to the current marketing authorisation holder;

- (b) an irrevocable, exclusive (including vis-à-vis the Parties), assignable, sub-licensable, and royalty free licence to use the Betaxa™ trademark in the Czech Republic, held by Zentiva a.s. (national trademark CZ 263875 and valid until January 2012);
- (c) transfer of all licences, permits and authorisations issued by any governmental organisation related to the Divestment Business;
- (d) assignment of all know-how related to the presentation forms of the Divestment Business that are currently marketed in the Czech Republic and which is used for the manufacture, use and/or sale of the Divestment Business at Closing, to the extent owned by Zentiva;
- (e) assignment of all contracts, leases, commitments and customer orders, all customer, credit and other records;
- (f) transfer of (i) books, records and files relating to the prosecution and maintenance of the trademark, to the extent such trademark is assigned pursuant to sub-paragraph (c) above; (ii) all records of customers and suppliers, price lists, catalogues and mailing lists; and (iii) all advertising, marketing, sales, publicity and presentational materials; and
- (g) sale of existing product inventory at the date of Closing in the Czech Republic.

C. Tenoloc™

- (a) the transfer of the marketing authorisation for Tenoloc™ in the Czech Republic held by Zentiva a.s., including the transfer of all relevant dossiers relating to the marketing authorisation, to the extent available to the current marketing authorisation holder;
 - (b) an irrevocable, exclusive (including vis-à-vis the Parties), assignable, sub-licensable, and royalty free licence to use the Tenoloc™ trademark in the Czech Republic held by Zentiva a.s. (national trademark CZ 226451 and valid until February 2010);
 - (c) transfer of all licences, permits and authorisations issued by any governmental organisation related to the Divestment Business;
 - (d) assignment of all know-how related to the presentation forms of the Divestment Business that are currently marketed in the Czech Republic and which is used for the manufacture, use and/or sale of the Divestment Business at Closing, to the extent owned by Zentiva;
 - (e) assignment of all contracts, leases, commitments and customer orders, all customer, credit and other records;
 - (f) transfer of (i) books, records and files relating to the prosecution and maintenance of the trademark, to the extent such trademark is assigned pursuant to sub-paragraph (c) above; (ii) all records of customers and suppliers, price lists, catalogues and mailing lists; and (iii) all advertising, marketing, sales, publicity and presentational materials; and
 - (g) sale of existing product inventory, sales and promotional material at the date of Closing in the Czech Republic, as applicable (items referred to under 2A(a)-(g), 2B(a)-(g) and 2C(a)-(g) hereinafter collectively referred to as "*Assets of the Divestment Business*").
3. If and to the extent that the know-how listed in paragraph 2A(d), 2B(d) and 2C(d) above of this Schedule are not exclusively related to, and not exclusively used in respect of, the manufacture, use and sale of the Divestment Business in the Czech Republic, the Parties

shall have the right to retain the ownership of such assets and shall grant to the Purchaser at no additional charge an exclusive and perpetual right to use such assets for the manufacture, use and sale of the Divestment Business in the Czech Republic.

4. At the option of the Purchaser, the Parties shall enter into a transitory exclusive manufacturing and/or supply arrangement related to the Divestment Business for the finished and packaged forms of Vasocardin™, Betaxa™ and/or Tenoloc™ in the Czech Republic existing and marketed by Zentiva at Closing on a reasonable cost-plus basis, for a period of up to three years. Such transitory arrangement shall include appropriate provisions designed to ensure the continuous supply by the Parties to the Purchaser. It shall not contain provision requiring the delivery of minimum supply volumes or batches.
5. At the option of the Purchaser and to the extent required by law in the Czech Republic the Parties will enter into a transitional distribution arrangement related to the Divestment Business lasting until the relevant marketing authorisations are transferred into the name of the Purchaser on a reasonable cost-plus basis.
6. The Parties commit to make their best efforts to cooperate with the Purchaser for the transfer of the manufacture, sale and marketing of the Divestment Business and to undertake all regulatory changes that would be required as a result of such transfer.
7. At the option of the Purchaser, the Parties shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of the Divestment Business in the Czech Republic for a period of up to three years on a reasonable cost plus basis to be agreed with the Purchaser.
8. The transitional technical assistance agreement referred to above shall include appropriate provisions to ensure that the Parties provides technical assistance to the Purchaser expeditiously. The Parties shall carry out the technical assistance for the technology transfer in accordance with good industry practice including as regards the timing and responsiveness with which this assistance is provided through the different stages of the transfer.
9. The Parties commit to submit to the Commission, every 6 months as of Closing, a report on the progress made in relation to the transfer of the production to the facilities designated by the Purchaser. A copy of this report will be sent to the Monitoring Trustee.
10. At the option of the Purchaser, the Parties shall enter into a transitory non-exclusive API supply agreement for the supply of the celiprolol API manufactured by Zentiva's affiliate on a cost-plus basis, for a period of up to three years.
11. At the option of the Purchaser, the Parties will make their best efforts to enable the Purchaser to obtain the supply of the metoprolol, betaxolol and celiprolol APIs manufactured by Zentiva's current supplier on terms comparable to those offered to Zentiva.
12. At the option of the Purchaser, the Parties agree to provide free access (i.e. free opt-in) to future product development improvements (i.e. galenical and packaging developments) in relation to the Divestment Business in any territory retained by the Parties for a period of five years should any such product improvements be undertaken by the Parties.

13. The Purchaser will be given an option to hire one or more Personnel in relation to Tenoloc™, who work for this Divestment Business and who could assume a product management role in relation to this Divestment Business, and who would reasonably be considered necessary to maintain the viability, marketability and competitiveness of this Divestment Business.
14. [...]

SCHEDULE xi**Product: Fokusin™, Penester™ and Zoxon™ (G4C)****Territory: Estonia**

1. This Divestment Business consists of Zentiva's (or an Affiliated Undertaking's) rights, title and interests in a single package comprising each of (a) its tamsulosin product in Estonia (currently marketed under the brand name Fokusin™); (b) its finasteride product in Estonia (currently marketed under the brand name Penester™); and (c) its doxazosin product in Estonia (currently marketed under the brand name Zoxon™) including the right to develop, manufacture and use Fokusin™, Penester™ and Zoxon™ with a view to its sale and marketing in any form and for any indication whatsoever in Estonia. For the avoidance of doubt, this Divestment Business does not include any rights to sell Fokusin™, Penester™ and/or Zoxon™ outside of Estonia.
2. The Divestment Business includes:
 - A. **Fokusin™**
 - (a) the transfer of the marketing authorisation for Fokusin™ in Estonia held by Zentiva a.s., including the transfer of all relevant dossiers relating to the marketing authorisation, to the extent available to the current marketing authorisation holder;
 - (b) an irrevocable, exclusive (including vis-à-vis the Parties), assignable, sub-licensable, and royalty free licence to use the Fokusin™ trademark in Estonia held by Zentiva a.s. (international trademark 789064 and valid until July 2012);
 - (c) transfer of all licences, permits and authorisations issued by any governmental organisation related to the Divestment Business;
 - (d) assignment of all know-how related to the presentation forms of the Divestment Business that are currently marketed in Estonia and which is used for the manufacture, use and/or sale of the Divestment Business at Closing, to the extent owned by Zentiva;
 - (e) assignment of all contracts, leases, commitments and customer orders, all customer, credit and other records;
 - (f) transfer of (i) books, records and files relating to the prosecution and maintenance of the trademark, to the extent such trademark is assigned pursuant to sub-paragraph (c) above; (ii) all records of customers and suppliers, price lists, catalogues and mailing lists; and (iii) all advertising, marketing, sales, publicity and presentational materials; and
 - (g) sale of existing product inventory at the date of Closing in Estonia.

B. Penester™

- (a) the transfer of the marketing authorisation for Penester™ in Estonia held by Zentiva a.s., including the transfer of all relevant dossiers relating to the marketing authorisation, to the extent available to the current marketing authorisation holder;
- (b) an irrevocable, exclusive (including vis-à-vis the Parties), assignable, sub-licensable, and royalty free licence to use the Penester™ trademark in Estonia held by Zentiva a.s. (international trademark 702437 and valid until September 2018);
- (c) transfer of all licences, permits and authorisations issued by any governmental organisation related to the Divestment Business;
- (d) assignment of all know-how related to the presentation forms of the Divestment Business that are currently marketed in Estonia and which is used for the manufacture, use and/or sale of the Divestment Business at Closing, to the extent owned by Zentiva;
- (e) assignment of all contracts, leases, commitments and customer orders, all customer, credit and other records;
- (f) transfer of (i) books, records and files relating to the prosecution and maintenance of the trademark, to the extent such trademark is assigned pursuant to sub-paragraph (c) above; (ii) all records of customers and suppliers, price lists, catalogues and mailing lists; and (iii) all advertising, marketing, sales, publicity and presentational materials; and
- (g) sale of existing product inventory at the date of Closing in Estonia.

C. Zoxon™

- (a) the transfer of the marketing authorisation for Zoxon™ in Estonia held by Zentiva a.s., including the transfer of all relevant dossiers relating to the marketing authorisation, to the extent available to the current marketing authorisation holder;
- (b) an irrevocable, exclusive (including vis-à-vis the Parties), assignable, sub-licensable, and royalty free licence to use the Zoxon™ trademark in Estonia held by Zentiva a.s. (international trademark 668242 and valid until December 2016);
- (c) transfer of all licences, permits and authorisations issued by any governmental organisation related to the Divestment Business;
- (d) assignment of all know-how related to the presentation forms of the Divestment Business that are currently marketed in Estonia and which is used for the manufacture, use and/or sale of the Divestment Business at Closing, to the extent owned by Zentiva;
- (e) assignment of all contracts, leases, commitments and customer orders, all customer, credit and other records;
- (f) transfer of (i) books, records and files relating to the prosecution and maintenance of the trademark, to the extent such trademark is assigned pursuant to sub-paragraph (c) above; (ii) all records of customers and suppliers, price lists, catalogues and mailing

- lists; and (iii) all advertising, marketing, sales, publicity and presentational materials; and
- (g) sale of existing product inventory at the date of Closing in Estonia (items referred to under 2A(a)-(g), 2B(a)-(g) and 2C(a)-(g) hereinafter collectively referred to as "***Assets of the Divestment Business***").
3. If and to the extent that the know-how listed in paragraph 2A(d), 2B(d) and 2C(d) above of this Schedule is not exclusively related to, and not exclusively used in respect of, the manufacture, use and sale of the Divestment Business in Estonia, the Parties shall have the right to retain the ownership of such asset and shall grant to the Purchaser at no additional charge an exclusive and perpetual right to use such asset for the manufacture, use and sale of the Divestment Business in Estonia.
 4. At the option of the Purchaser, the Parties shall enter into a transitory exclusive manufacturing and/or supply arrangement related to the Divestment Business for the finished and packaged forms of Fokusin™ Penester™ and/or Zoxon™ in Estonia existing and marketed by Zentiva at Closing on a reasonable cost-plus basis, for a period of up to three years. Such transitory arrangement shall include appropriate provisions designed to ensure the continuous supply by the Parties to the Purchaser. It shall not contain provision requiring the delivery of minimum supply volumes or batches.
 5. At the option of the Purchaser and to the extent required by law in Estonia the Parties will enter into a transitional distribution arrangement related to the Divestment Business lasting until the relevant marketing authorisation is transferred into the name of the Purchaser on a reasonable cost-plus basis.
 6. The Parties commit to make their best efforts to cooperate with the Purchaser for the transfer of the manufacture, sale and marketing of the Divestment Business and to undertake all regulatory changes that would be required as a result of such transfer.
 7. At the option of the Purchaser, the Parties shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of the Divestment Business in Estonia for a period of up to three years on a reasonable cost plus basis to be agreed with the Purchaser.
 8. The transitional technical assistance agreement referred to above shall include appropriate provisions to ensure that the Parties provides technical assistance to the Purchaser expeditiously. The Parties shall carry out the technical assistance for the technology transfer in accordance with good industry practice including as regards the timing and responsiveness with which this assistance is provided through the different stages of the transfer.
 9. The Parties commit to submit to the Commission, every 6 months as of Closing, a report on the progress made in relation to the transfer of the production to the facilities designated by the Purchaser. A copy of this report will be sent to the Monitoring Trustee.
 10. At the option of the Purchaser, the Parties shall enter into a transitory non-exclusive API supply agreement for the supply of the doxazosin and tamsulosin APIs manufactured by Zentiva's affiliate on a cost-plus basis, for a period of up to three years.
 11. At the option of the Purchaser, the Parties will make their best efforts to enable the Purchaser to obtain the supply of the finasteride API manufactured by Zentiva's current supplier on terms comparable to those offered to Zentiva.

12. At the option of the Purchaser, the Parties agree to provide free access (i.e. free opt-in) to future product development improvements (i.e. galenical and packaging developments) in relation to the Divestment Business in any territory retained by the Parties for a period of five years should any such product improvements be undertaken by the Parties.
13. The Purchaser will be given an option to hire one or more Personnel, [...] who would reasonably be considered necessary to maintain the viability, marketability and competitiveness of this Divestment Business.

SCHEDULE xii

Product: Zopiclon

Territory: Bulgaria (N5B1/N5B2)

1. This Divestment Business consists of Zentiva's (or an Affiliated Undertaking's) rights, title and interests in its zopiclone product in Bulgaria (currently marketed under the brand name Zopiclon™) including the right to develop, manufacture and use Zopiclon™ with a view to its sale and marketing in any form and for any indication whatsoever in Bulgaria. For the avoidance of doubt, this Divestment Business does not include any rights to sell Zopiclon™ outside of Bulgaria.
2. The Divestment Business includes:
 - (a) the transfer of the marketing authorisation for Zopiclon in Bulgaria, held by Zentiva a.s., including the transfer of all relevant dossiers relating to the marketing authorisation, to the extent available to the current marketing authorisation holder;
 - (b) transfer of all licences, permits and authorisations issued by any governmental organisation related to the Divestment Business;
 - (c) assignment of all know-how related to the presentation forms of the Divestment Business that are currently marketed in Bulgaria and which is used for the manufacture, use and/or sale of the Divestment Business at Closing, to the extent owned by Zentiva;
 - (d) assignment of all contracts, leases, commitments and customer orders, all customer, credit and other records;
 - (e) transfer of (i) all records of customers and suppliers, price lists, catalogues and mailing lists; and (ii) all advertising, marketing, sales, publicity and presentational materials; and
 - (f) sale of existing product inventory at the date of Closing in Bulgaria (items referred to under (a)-(f) hereinafter collectively referred to as "*Assets of the Divestment Business*").
3. If and to the extent that the know-how listed in paragraph 2(c) above of this Schedule is not exclusively related to, and not exclusively used in respect of, the manufacture, use and sale of the Divestment Business in Bulgaria, the Parties shall have the right to retain the ownership of such asset and shall grant to the Purchaser at no additional charge an exclusive and perpetual right to use such asset for the manufacture, use and sale of the Divestment Business in Bulgaria.
4. At the option of the Purchaser, the Parties shall enter into a transitory exclusive manufacturing and/or supply arrangement related to the Divestment Business for the finished and packaged forms of Zopiclon™ in Bulgaria existing and marketed by Zentiva at Closing on a reasonable cost-plus basis, for a period of up to three years. Such transitory arrangement shall include appropriate provisions designed to ensure the continuous supply by the Parties to the Purchaser. It shall not contain provision requiring the delivery of minimum supply volumes or batches.

5. At the option of the Purchaser and to the extent required by law in Bulgaria the Parties will enter into a transitional distribution arrangement related to the Divestment Business lasting until the relevant marketing authorisation is transferred into the name of the Purchaser on a reasonable cost-plus basis.
6. The Parties commit to make their best efforts to cooperate with the Purchaser for the transfer of the manufacture, sale and marketing of the Divestment Business and to undertake all regulatory changes that would be required as a result of such transfer.
7. At the option of the Purchaser, the Parties shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of the Divestment Business in Bulgaria for a period of up to three years on a reasonable cost plus basis to be agreed with the Purchaser.
8. The transitional technical assistance agreement referred to above shall include appropriate provisions to ensure that the Parties provides technical assistance to the Purchaser expeditiously. The Parties shall carry out the technical assistance for the technology transfer in accordance with good industry practice including as regards the timing and responsiveness with which this assistance is provided through the different stages of the transfer.
9. The Parties commit to submit to the Commission, every 6 months as of Closing, a report on the progress made in relation to the transfer of the production to the facilities designated by the Purchaser. A copy of this report will be sent to the Monitoring Trustee.
10. At the option of the Purchaser, the Parties will make their best efforts to enable the Purchaser to obtain the supply of the zopiclon API manufactured by Zentiva's current supplier on terms comparable to those offered to Zentiva.
11. At the option of the Purchaser, the Parties agree to provide free access (i.e. free opt-in) to future product development improvements (i.e. galenical and packaging developments) in relation to the Divestment Business in any territory retained by the Parties for a period of five years should any such product improvements be undertaken by the Parties.
12. The Purchaser will be given an option to hire one or more Personnel, [...] who would reasonably be considered necessary to maintain the viability, marketability and competitiveness of this Divestment Business.

SCHEDULE xiii**Product: Hypnogen™ (N5B Rx)****Territory: Czech Republic**

1. This Divestment Business consists of Zentiva's (or an Affiliated Undertaking's) rights, title and interests in its zolpidem product in the Czech Republic (currently marketed under the brand name Hypnogen™) including the right to develop, manufacture and use Hypnogen™ with a view to its sale and marketing in any form and for any indication whatsoever in the Czech Republic. For the avoidance of doubt, this Divestment Business does not include any rights to sell Hypnogen™ outside of the Czech Republic.
2. The Divestment Business includes:
 - (a) the transfer of the marketing authorisation for Hypnogen™ in the Czech Republic, held by Zentiva a.s., including the transfer of all relevant dossiers relating to the marketing authorisation, to the extent available to the current marketing authorisation holder;
 - (b) an irrevocable, exclusive (including vis-à-vis the Parties), assignable, sub-licensable, and royalty free licence to use the Hypnogen™ trademark in the Czech Republic held by Zentiva a.s. (national trademark CZ 99572 and valid until September 2009);
 - (c) transfer of all licences, permits and authorisations issued by any governmental organisation related to the Divestment Business;
 - (d) assignment of all know-how related to the presentation forms of the Divestment Business that are currently marketed in the Czech Republic and which is used for the manufacture, use and/or sale of the Divestment Business at Closing, to the extent owned by Zentiva;
 - (e) assignment of all contracts, leases, commitments and customer orders, all customer, credit and other records;
 - (f) transfer of (i) books, records and files relating to the prosecution and maintenance of the trademark, to the extent such trademark is assigned pursuant to sub-paragraph (c) above; (ii) all records of customers and suppliers, price lists, catalogues and mailing lists; and (iii) all advertising, marketing, sales, publicity and presentational materials; and
 - (g) sale of existing product inventory at the date of Closing in the Czech Republic (items referred to under (a)-(g) hereinafter collectively referred to as "***Assets of the Divestment Business***").
3. If and to the extent that the know-how listed in paragraph 2(d) above of this Schedule is not exclusively related to, and not exclusively used in respect of, the manufacture, use and sale of the Divestment Business in the Czech Republic, the Parties shall have the right to retain the ownership of such asset and shall grant to the Purchaser at no additional charge an exclusive and perpetual right to use such asset for the manufacture, use and sale of the Divestment Business in the Czech Republic.

4. At the option of the Purchaser, the Parties shall enter into a transitory exclusive manufacturing and/or supply arrangement related to the Divestment Business for the finished and packaged forms of Hypnogen™ in the Czech Republic existing and marketed by Zentiva at Closing on a reasonable cost-plus basis, for a period of up to three years. Such transitory arrangement shall include appropriate provisions designed to ensure the continuous supply by the Parties to the Purchaser. It shall not contain provision requiring the delivery of minimum supply volumes or batches.
5. At the option of the Purchaser and to the extent required by law in the Czech Republic the Parties will enter into a transitional distribution arrangement related to the Divestment Business lasting until the relevant marketing authorisation is transferred into the name of the Purchaser on a reasonable cost-plus basis.
6. The Parties commit to make their best efforts to cooperate with the Purchaser for the transfer of the manufacture, sale and marketing of the Divestment Business and to undertake all regulatory changes that would be required as a result of such transfer.
7. At the option of the Purchaser, the Parties shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of the Divestment Business in the Czech Republic for a period of up to three years on a reasonable cost plus basis to be agreed with the Purchaser.
8. The transitional technical assistance agreement referred to above shall include appropriate provisions to ensure that the Parties provides technical assistance to the Purchaser expeditiously. The Parties shall carry out the technical assistance for the technology transfer in accordance with good industry practice including as regards the timing and responsiveness with which this assistance is provided through the different stages of the transfer.
9. The Parties commit to submit to the Commission, every 6 months as of Closing, a report on the progress made in relation to the transfer of the production to the facilities designated by the Purchaser. A copy of this report will be sent to the Monitoring Trustee.
10. At the option of the Purchaser, the Parties will make their best efforts to enable the Purchaser to obtain the supply of the zolpidem API manufactured by Zentiva's current supplier on terms comparable to those offered to Zentiva.
11. At the option of the Purchaser, the Parties agree to provide free access (i.e. free opt-in) to future product development improvements (i.e. galenical and packaging developments) in relation to the Divestment Business in any territory retained by the Parties for a period of five years should any such product improvements be undertaken by the Parties.
12. The Purchaser will be given an option to hire one or more Personnel [...] who would reasonably be considered necessary to maintain the viability, marketability and competitiveness of the Divestment Business.

SCHEDULE xiv

Product: Hypnogen™ (N5B Rx)

Territory: Estonia

1. This Divestment Business consists of Zentiva's (or an Affiliated Undertaking's) rights, title and interests in its zolpidem product in Estonia (currently marketed under the brand name Hypnogen™) including the right to develop, manufacture and use Hypnogen™ with a view to its sale and marketing in any form and for any indication whatsoever in Estonia. For the avoidance of doubt, this Divestment Business does not include any rights to sell Hypnogen™ outside of Estonia.
2. The Divestment Business includes:
 - (a) the transfer of the marketing authorisation for Hypnogen™ in Estonia held by Zentiva a.s., including the transfer of all relevant dossiers relating to the marketing authorisation, to the extent available to the current marketing authorisation holder;
 - (b) an irrevocable, exclusive (including vis-à-vis the Parties), assignable, sub-licensable, and royalty free licence to use the Hypnogen™ trademark in Estonia held by Zentiva a.s. (national trademark EE 30191 and valid until February 2010);
 - (c) transfer of all licences, permits and authorisations issued by any governmental organisation related to the Divestment Business;
 - (d) assignment of all know-how related to the presentation forms of the Divestment Business that are currently marketed in Estonia and which is used for the manufacture, use and/or sale of the Divestment Business at Closing, to the extent owned by Zentiva;
 - (e) assignment of all contracts, leases, commitments and customer orders, all customer, credit and other records;
 - (f) transfer of (i) books, records and files relating to the prosecution and maintenance of the trademark, to the extent such trademark is assigned pursuant to sub-paragraph (c) above; (ii) all records of customers and suppliers, price lists, catalogues and mailing lists; and (iii) all advertising, marketing, sales, publicity and presentational materials; and
 - (g) sale of existing product inventory at the date of Closing in Estonia (items referred to under (a)-(g) hereinafter collectively referred to as "**Assets of the Divestment Business**").
3. If and to the extent that the know-how listed in paragraph 2(d) above of this Schedule is not exclusively related to, and not exclusively used in respect of, the manufacture, use and sale of the Divestment Business in Estonia, the Parties shall have the right to retain the ownership of such asset and shall grant to the Purchaser at no additional charge an exclusive and perpetual right to use such asset for the manufacture, use and sale of the Divestment Business in Estonia.
4. At the option of the Purchaser, the Parties shall enter into a transitory exclusive manufacturing and/or supply arrangement related to the Divestment Business for the finished and packaged

forms of Hypnogen™ in Estonia existing and marketed by Zentiva at Closing on a reasonable cost-plus basis, for a period of up to three years. Such transitory arrangement shall include appropriate provisions designed to ensure the continuous supply by the Parties to the Purchaser. It shall not contain provision requiring the delivery of minimum supply volumes or batches.

5. At the option of the Purchaser and to the extent required by law in Estonia the Parties will enter into a transitional distribution arrangement related to the Divestment Business lasting until the relevant marketing authorisation is transferred into the name of the Purchaser on a reasonable cost-plus basis.
6. The Parties commit to make their best efforts to cooperate with the Purchaser for the transfer of the manufacture, sale and marketing of the Divestment Business and to undertake all regulatory changes that would be required as a result of such transfer.
7. At the option of the Purchaser, the Parties shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of the Divestment Business in Estonia for a period of up to three years on a reasonable cost plus basis to be agreed with the Purchaser.
8. The transitional technical assistance agreement referred to above shall include appropriate provisions to ensure that the Parties provides technical assistance to the Purchaser expeditiously. The Parties shall carry out the technical assistance for the technology transfer in accordance with good industry practice including as regards the timing and responsiveness with which this assistance is provided through the different stages of the transfer.
9. The Parties commit to submit to the Commission, every 6 months as of Closing, a report on the progress made in relation to the transfer of the production to the facilities designated by the Purchaser. A copy of this report will be sent to the Monitoring Trustee.
10. At the option of the Purchaser, the Parties will make their best efforts to enable the Purchaser to obtain the supply of the zolpidem API manufactured by Zentiva's current supplier on terms comparable to those offered to Zentiva.
11. At the option of the Purchaser, the Parties agree to provide free access (i.e. free opt-in) to future product development improvements (i.e. galenical and packaging developments) in relation to the Divestment Business in any territory retained by the Parties for a period of five years should any such product improvements be undertaken by the Parties.
12. The Purchaser will be given an option to hire one or more Personnel, [...] who would reasonably be considered necessary to maintain the viability, marketability and competitiveness of this Divestment Business.

SCHEDULE xv

Product: Hypnogen™ (N5B Rx)

Territory: Slovak Republic

1. This Divestment Business consists of Zentiva's (or an Affiliated Undertaking's) rights, title and interests in its zolpidem product in the Slovak Republic (currently marketed under the brand name Hypnogen™) including the right to develop, manufacture and use Hypnogen™ with a view to its sale and marketing in any form and for any indication whatsoever in the Slovak Republic. For the avoidance of doubt, this Divestment Business does not include any rights to sell Hypnogen™ outside of the Slovak Republic.
2. The Divestment Business includes:
 - (a) the transfer of the marketing authorisation for Hypnogen™ in the Slovak Republic held by Zentiva a.s., including the transfer of all relevant dossiers relating to the marketing authorisation, to the extent available to the current marketing authorisation holder;
 - (b) an irrevocable, exclusive (including vis-à-vis the Parties), assignable, sub-licensable, and royalty free licence to use the Hypnogen™ trademark in the Slovak Republic held by Zentiva a.s. (national trademark Nr 99572 and valid until September 2009);
 - (c) transfer of all licences, permits and authorisations issued by any governmental organisation related to the Divestment Business;
 - (d) assignment of all know-how related to the presentation forms of the Divestment Business that are currently marketed in the Slovak Republic and which is used for the manufacture, use and/or sale of the Divestment Business at Closing, to the extent owned by Zentiva;
 - (e) assignment of all contracts, leases, commitments and customer orders, all customer, credit and other records;
 - (f) transfer of (i) books, records and files relating to the prosecution and maintenance of the trademark, to the extent such trademark is assigned pursuant to sub-paragraph (c) above; (ii) all records of customers and suppliers, price lists, catalogues and mailing lists; and (iii) all advertising, marketing, sales, publicity and presentational materials; and
 - (g) sale of existing product inventory at the date of Closing in the Slovak Republic (items referred to under (a)-(g) hereinafter collectively referred to as "***Assets of the Divestment Business***").
3. If and to the extent that the know-how listed in paragraph 2(d) above of this Schedule is not exclusively related to, and not exclusively used in respect of, the manufacture, use and sale of the Divestment Business in the Slovak Republic, the Parties shall have the right to retain the ownership of such asset and shall grant to the Purchaser at no additional charge an exclusive and perpetual right to use such asset for the manufacture, use and sale of the Divestment Business in the Slovak Republic.

4. At the option of the Purchaser, the Parties shall enter into a transitory exclusive manufacturing and/or supply arrangement related to the Divestment Business for the finished and packaged forms of Hypnogen™ in the Slovak Republic existing and marketed by Zentiva at Closing on a reasonable cost-plus basis, for a period of up to three years. Such transitory arrangement shall include appropriate provisions designed to ensure the continuous supply by the Parties to the Purchaser. It shall not contain provision requiring the delivery of minimum supply volumes or batches.
5. At the option of the Purchaser and to the extent required by law in the Slovak Republic the Parties will enter into a transitional distribution arrangement related to the Divestment Business lasting until the relevant marketing authorisation is transferred into the name of the Purchaser on a reasonable cost-plus basis.
6. The Parties commit to make their best efforts to cooperate with the Purchaser for the transfer of the manufacture, sale and marketing of the Divestment Business and to undertake all regulatory changes that would be required as a result of such transfer.
7. At the option of the Purchaser, the Parties shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of the Divestment Business in the Slovak Republic for a period of up to three years on a reasonable cost plus basis to be agreed with the Purchaser.
8. The transitional technical assistance agreement referred to above shall include appropriate provisions to ensure that the Parties provides technical assistance to the Purchaser expeditiously. The Parties shall carry out the technical assistance for the technology transfer in accordance with good industry practice including as regards the timing and responsiveness with which this assistance is provided through the different stages of the transfer.
9. The Parties commit to submit to the Commission, every 6 months as of Closing, a report on the progress made in relation to the transfer of the production to the facilities designated by the Purchaser. A copy of this report will be sent to the Monitoring Trustee.
10. At the option of the Purchaser, the Parties will make their best efforts to enable the Purchaser to obtain the supply of the zolpidem API manufactured by Zentiva's current supplier on terms comparable to those offered to Zentiva.
11. At the option of the Purchaser, the Parties agree to provide free access (i.e. free opt-in) to future product development improvements (i.e. galenical and packaging developments) in relation to the Divestment Business in any territory retained by the Parties for a period of five years should any such product improvements be undertaken by the Parties.
12. The Purchaser will be given an option to hire one or more Personnel [...] who would reasonably be considered necessary to maintain the viability, marketability and competitiveness of the Divestment Business.