

***Case No COMP/M.5865 -  
TEVA/ RATIOPHARM***

Only the English text is available and authentic.

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

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Article 6(1)(b) in conjunction with Art 6(2)  
Date: 03/08/2010

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## COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 3.8.2010  
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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 Where possible the information omitted has been replaced by ranges of figures or a general description.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 combination with ARTICLE  
6(2)

### **To the Notifying Party:**

Dear Sir/Madam,

**Subject: Case No COMP/M.5865 – TEVA/ RATIOPHARM  
Notification of 14 June 2010 pursuant to Article 4 of Council Regulation  
No 139/2004<sup>1</sup>**

1. On 14 June 2010, the Commission received a notification of a proposed concentration pursuant to Article 4 of Council Regulation (EC) No 139/2004 (the "EU Merger Regulation" or "EUMR") by which the undertaking Teva Pharmaceutical Industries Limited ("Teva", Israel) acquires within the meaning of Article 3(1)(b) of the EUMR control of the whole of the undertakings Merckle GmbH, CT Arzneimittel GmbH and AbZ-Pharma GmbH (collectively the "Merckle/Ratiopharm group" or "Ratiopharm", Germany) by way of purchase of shares.

### **I. THE PARTIES**

2. Teva is an international pharmaceutical company headquartered in Israel which is involved in the development, production and marketing of generic and proprietary pharmaceutical products as well as biopharmaceuticals and active pharmaceutical ingredients (APIs).
3. Ratiopharm is an international pharmaceutical company headquartered in Germany which is involved in the development, production and marketing of generic pharmaceutical products and biopharmaceuticals. Unlike Teva, it does not develop and market any

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<sup>1</sup> OJ L 24, 29.1.2004 p. 1.

innovative pharmaceuticals nor is it involved in the sale of APIs on the free market, although it does produce them for its own use.

## **II. CONCENTRATION**

4. The Parties have entered into a Share Purchase Agreement by virtue of which Teva, through its subsidiary Teva Health GmbH will acquire the entire shares of Merckle GmbH ("Merckle"), CT Arzneimittel GmbH ("CT") and AbZ-Pharma GmbH ("AbZ") which indirectly or indirectly control all the operational entities of Ratiopharm.
5. The transaction therefore constitutes an acquisition of sole control of Ratiopharm by Teva and constitutes a concentration in the sense of Article 3(1)(b) of the EUMR.

## **III. EU DIMENSION**

6. The undertakings concerned have a combined aggregate world-wide turnover of more than EUR 5 billion<sup>2</sup> (Teva EUR 9 965 million, Ratiopharm EUR 1 663 million). Each of them has a EU-wide turnover in excess of EUR 250 million (Teva: EUR [...] million; Ratiopharm: EUR [...] million), but they do not achieve more than two-thirds of their aggregate EU-wide turnover within one and the same Member State. The notified operation therefore has an EU dimension within the meaning of Article 1(2) of the Regulation.

## **IV. RELEVANT MARKETS AND COMPETITIVE ASSESSMENT**

### **IV.1. OVERALL CONTEXT OF THE CONCENTRATION**

7. The notified transaction will result in a generic player in finished pharmaceuticals which will be the largest such player in the EEA, with about [10-20]% of total generic sales, in an overall generic landscape which remains relatively fragmented. The combined firm will also be the leading player in a number of Member States, although some of these markets have to date relatively limited overall generic penetration. The overall picture in the most affected member states according to material developed by the Parties is as follows (by overall value of generic sales in the country in question):

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<sup>2</sup> Turnover calculated in accordance with Article 5(1) of the Merger Regulation and the Commission Consolidated Jurisdictional Notice (OJ C95, 16.04.2008, p1).

	<b>Teva</b>	<b>Ratio</b>	<b>Market position post-merger</b>
<b>Netherlands<sup>3</sup></b>	Approx. 29%	Approx. 11%	#1 with 40%
<b>Germany</b>	[0-5]%	[10-20]%	#2 after Novartis ([20-30]%)
<b>France</b>	[10-20]%	[5-10]%	#3 after Mylan ([30-40]%) and Biogaran ([20-30]%)
<b>Italy</b>	[20-30]%	[10-20]%	#1 (Teva already #1 pre-merger)
<b>Spain</b>	[10-20]%	[10-20]%	#1 (from Teva #2 behind Cinfa, 20%)
<b>Portugal</b>	[5-10]%	[10-20]%	#1 with [10-20]%
<b>Finland</b>	[0-5]%	[20-30]%	#2 with [20-30]%
<b>Austria</b>	-	[20-30]%	#1

8. The transaction will most significantly increase the overall strength of the Parties in the Netherlands, where Teva, which was already the largest provider of generics pre-merger, acquires the third-largest player, resulting in an overall share of generic turnover estimated by third-party sources at around 40-45% (see further below).
9. In addition to the analysis of individual product markets below, the market investigation therefore focused on the overall impact of the concentration on generic competition in the various affected countries, with particular attention to issues such as distribution power, range discounts and the value of the corporate brand, as well as the specificities of how generic products are prescribed, dispensed and reimbursed in the various countries concerned.

## **IV.2. FINISHED DOSE PHARMACEUTICALS**

### **IV.2.1. INTRODUCTORY REMARKS ON MARKET DEFINITION**

#### IV.2.1.1. Analysis based on ATC classification

10. In previous cases the Commission has taken as a starting point for market definition purposes the Anatomical Therapeutic Chemical ("ATC") division of medicines by

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<sup>3</sup> The source for the Dutch figures is Stichting Farmaceutische Kentallen (SFK), "Grote Verschuivingen in Generiek", 11 March 2010, see [http://www.sfk.nl/publicaties/farmacie\\_in\\_cijfers/2010/2010-10.html](http://www.sfk.nl/publicaties/farmacie_in_cijfers/2010/2010-10.html). For all other countries, the source is internal information prepared by the Parties.

therapeutic use devised by the European Pharmaceutical Marketing Research Association ("EphMRA") and maintained by EphMRA and Intercontinental Medical Statistics ("IMS").<sup>4</sup>

11. 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 some cases vary from one country to another.
12. The EphMRA classification consists of four levels and is regularly updated. In older cases involving originator pharmaceutical companies, the third level, referred to as ATC3, which allows medicines to be grouped in most cases according to their therapeutic indications, i.e. their intended use, has generally been taken as the starting point for market definition in the Commission's analyses. However, in recent cases involving generic companies the Commission, based on its market investigation, has tended to identify competition issues – where such issues arose – more often at the molecule level, at the ATC4 level,<sup>5</sup> or on the basis of a group of molecules.<sup>6</sup> This is because generic pharmaceutical companies typically produce copies of originator drugs which therefore can normally be viewed as the closest substitute to those drugs.<sup>7</sup> 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 significantly.<sup>8</sup>
13. For all those products which were specifically investigated in the market investigation, the ATC3 level rarely appeared to be the correct range of products for analyzing competition. In the genericised pharmaceutical markets concerned by the notified transaction, the Parties achieved significant market shares, in a large majority of cases, only when such markets were looked at at the molecule level. In most cases, responses to the market investigation, whether from competitors, customers, insurers or national authorities, indicated that demand for medicinal products based on established and well-known pharmaceutical molecules is specific to the molecule in question (and its galenic form, see below), at least for prescription products and products for hospital use. The Parties compete, principally, for sales of products based on the originator molecule (i.e. the product which was first to

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<sup>4</sup> 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.

<sup>5</sup> The ATC4 level constitutes a further subdivision which may be based on therapeutic or more frequently pharmacological criteria such as molecule class, formulation or mode of action.

<sup>6</sup> See Case COMP/M.5253 Sanofi-Aventis/Zentiva, Commission decision of 4 February 2009, further cited as *Sanofi-Aventis/Zentiva...* and Case COMP/M.5295 Teva/Barr, decision of 19 December 2008, further cited as *Teva/Barr*.

<sup>7</sup> See *Teva/Barr* and *Sanofi-Aventis/Zentiva*, recital 17. Note however that there may still be small differences, such as in inactive ingredients, which may lead in certain, relatively uncommon cases, to the drugs being non-equivalent from a medical standpoint.

<sup>8</sup> Horizontal Merger Guidelines, para 28

market and benefited from patent protection which has now expired, as well as an originator brand name), and only to a limited extent against products based on other molecules.

14. In a certain number of cases, however, a group of molecules can be considered interchangeable for a wide range of applications and the relevant market in this case should be defined on the basis of all molecules which are so interchangeable. Such a definition may in principle coincide with the ATC3 or even a higher level, but more commonly it is not wider than ATC4 and may be confined to a subset of molecules within the ATC4 class.
15. Independently of the market definition, the present decision is nonetheless organized by ATC3 class where possible, for ease of reference and comparison with earlier decisions.

#### IV.2.1.2. Galenic form

16. As already noted in *Sanofi-Aventis/Zentiva*, medicines are differentiated not only by their active ingredient(s), but also, in particular, as recognized by the European regulatory framework for medicines for human use, by their dosage, pharmaceutical form and route of administration and this may limit their substitutability<sup>9</sup>. This combination of features is loosely referred to for the purposes of the present decision as "galenic form". For the purposes of this decision, the Commission has looked at "galenic form" with reference to the first letter of the typology of form codes (the so-called "New Form Code" or NFC) used by IMS/EphMRA<sup>10</sup>. In general, the first letter differentiates between forms for systemic and topical effect, site of application, and also between long-acting and ordinary forms.
17. Although numerous variations in the form of medicines exist, and therefore the notion of "galenic form" is not without ambiguity, the market investigation in the present case has shown that, for the products considered in this case, different routes of administration of a medicine are, in general, designed to serve the needs of different patient groups and are therefore not interchangeable. This may also be the case of the dosage and of the pharmaceutical form, especially in pediatrics, although some forms, especially those which may distinguish OTC medicines (such as orally dissolving tablets, effervescent forms etc), frequently present purely convenience rather than medical benefits, and may therefore be competitively related.
18. On the supply side, the market investigation has shown that the development of a new galenic form of an existing generic medicine typically takes a significant amount of time, estimated at two to three years or even more in some cases<sup>11</sup>. This consideration suggests that different galenic forms of a medicine cannot be considered to lie within the same relevant market purely on the basis of supply-side substitutability, since such

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<sup>9</sup> See recital 20 of the decision and Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67), as amended by various subsequent acts.

<sup>10</sup> See <http://www.ephmra.org/pdf/NFCVersion2010Guidelines.pdf>.

<sup>11</sup> Certain galenic forms may also require specific know-how and manufacturing facilities to produce; this was cited in the market investigation in particular in relation to sterile forms, slow release forms and patches.

substitutability is only taken into account when defining markets in those situations where its effects are equivalent to those of demand substitution in terms of effectiveness and immediacy<sup>12</sup>. For the distinctions considered in the present Decision, supply-side substitution can therefore be excluded<sup>13</sup>.

19. Although it is possible that in the OTC market there is a degree of substitutability between different preparations, certain common galenic forms were seen in the context of this case to be, in general, not substitutable. In the present case, the most relevant distinctions of this type to be drawn are between oral syrups (commonly used for patients who are unable to swallow tablets, in particular pediatric patients), rectal forms (also known as suppositories, also often used for pediatric patients but also for patients at risk of vomiting and in instances where the pharmacokinetic profile of the medicine is improved by bypassing the stomach), and injectable or parenteral forms<sup>14</sup>. Although this needs to be confirmed for individual products on a case-by-case basis, it was generally found that these forms are not substitutable either on the demand or the supply side.
20. It follows that the correct market definition needs to consider possible distinctions on the basis of pharmaceutical form, dosage and route of administration and is likely more often than not to draw such a distinction at least in the broad instances mentioned above.
21. The route of administration and pharmaceutical form is sometimes, but not always, reflected in the ATC product categorization in addition to being identified by the NFC. For a single galenic form (or possibly a small group of closely related galenic forms), the market definition has been approached in the present case by the Commission normally on the basis of looking first at the active ingredient and only then at the galenic form, since affected markets typically arose on the basis of a possible molecule market definition. There is nonetheless no reason in principle to exclude that the correct market definition may consider a single galenic form, but refer to a group of molecules where it can be established that they are freely interchangeable for a substantial part of their use. This has been looked at by the Commission systematically on the basis of ATC3 and ATC4 categories, and additionally using other groupings on a case-by-case basis, as described below.

#### IV.2.1.3. Prescription pharmaceuticals and over-the-counter pharmaceuticals

22. In numerous cases in the past, the Commission has defined separate relevant product markets for pharmaceuticals available without prescription (over-the-counter, "OTC") and pharmaceuticals available only on prescription, because medical indications (including possible side-effects), the legal framework, marketing, distribution and rules on reimbursement all tend to differ between the two categories of medicines, even when

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<sup>12</sup> Commission Notice on the definition of relevant market for the purposes of Community competition law, OJ C 372 of 9 December 1997, paragraph 20.

<sup>13</sup> These conclusions apply, at least, to the high-level distinctions recognized in the first letter of the NFC code. The market investigation did not focus on the time it would take to introduce more minor variations to a medicine.

<sup>14</sup> Cf. Case No COMP/M.5476 Pfizer/Wyeth, Commission Decision of 17 July 2009, dealing with animal health, recitals 122, 292, 324, 339 and *passim*.

the active ingredients are identical<sup>15</sup>. Doctors do not directly play a role in the purchase of OTC pharmaceuticals, whereas pharmacists can suggest other (substitutable) products, 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 or directly paid by health insurers. Marketing of prescription pharmaceuticals, if it takes place, is targeted at the prescribers and not the patients. Moreover, it may happen in certain markets that some variants of a drug with the same active ingredient or brand name are classified as OTC, whilst others are classified as prescription-only, depending on the package size, dosage or galenic form<sup>16</sup>.

23. In certain instances in previous decisions, it has nonetheless been observed that prescription and OTC markets may be more closely related, in particular due to the added inconvenience for a patient to visit a doctor in order to obtain a prescription for drugs which are available OTC and which treat more routine conditions<sup>17</sup>. In this case, the price of the OTC medicine may be a factor determining whether or not the patient simply purchases this medicine at his or her own expense or visits a doctor in order to obtain a prescription for a reimbursable alternative.
24. In the present case such a relationship between OTC and prescription markets has been looked at in the market investigation wherever it was alleged by the Parties. However, it has not been found to lead to a single market in any product across the two segments. In the remainder of this decision, they are therefore treated as separate product markets. Such a conclusion is limited to the circumstances of the case at hand.

#### IV.2.1.4. Originator pharmaceuticals and generic pharmaceuticals

25. Generics are in general less expensive versions of 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 bioequivalent to the originator drug.
26. In previous cases, 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<sup>18</sup>.
27. As the present case involves a merger between two primarily generic companies, affected markets arise, particularly at the molecule level, only in instances where generic medicines overall, and more specifically those of the Parties, have succeeded in

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<sup>15</sup> *Sanofi-Aventis/Zentiva*, recitals 21-24; 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.

<sup>16</sup> In other countries, however, the use of the same brand name for prescription and OTC medicines is not allowed.

<sup>17</sup> *Sanofi-Aventis/Zentiva*, recital 22.

<sup>18</sup> *Sanofi-Aventis/Zentiva*, recitals 25-26.



capturing a significant share of demand from the originator. For this reason, it may thus be taken as a starting point that competition takes place between originator and generic providers, even if brand loyalty to the originator medicine (and/or in some cases to a branded generic) may play a role in limiting switching in certain instances. In certain instances, Teva also has originator medicines for which Ratiopharm is a generic competitor, and this will be noted where relevant in the assessment below.

#### IV.2.1.5. Biosimilars vs small molecule traditional generics

28. Biological medicinal products are medicines whose active substance is made by or derived from living organisms (e.g. immunological products and medicines derived from human blood and plasma). Biosimilars aim to mimic the original patented biopharmaceutical molecule with an identical therapeutic mechanism and clinical attributes and can be described as "generic" versions of originator biopharmaceuticals, but, unlike for small molecule generics, they are not exact copies of the originator drug. Making an exact copy is impossible as biopharmaceuticals are based on either mammalian or microbial cell cultures and the active ingredient is never exactly the same as the biological originator product. This is a fundamental difference between biosimilars and small molecule generics, which are also referred to as synthetic generics since they can be synthesized by chemical processes.
29. The development of biosimilars requires considerably longer lead times than synthetic generics (it may take six to eight years from development to marketing) and high upfront investments (significantly more than those required for the development of generic pharmaceuticals). There is a higher risk of failure of research and development (R&D).<sup>19</sup> The development and manufacturing of biosimilars also requires specific biotech know-how and facilities. The R&D process is more similar to the R&D of originator than of synthetic generic drugs. For example, as opposed to non-biotech generics, it requires clinical trials.
30. The biosimilar segment of pharmaceutical markets is relatively new. The first biosimilars – growth hormones – were launched in Europe in 2006 following the adoption of regulatory guidance on the approval of biosimilar products at the EU level<sup>20</sup>.
31. The Commission has previously considered biosimilars in the *Lonza / Teva / JV* Decision<sup>21</sup>. The focus of that case, however, was the upstream contract manufacturing market and the market definition was not concluded for any downstream market.
32. Both parties are active in the development, manufacturing and commercialisation of biosimilars. Due to the fact that the biosimilar market is very new, however, the existing overlap between the parties is limited to one product, filgrastim.

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<sup>19</sup> See: Case COMP/M.5479 - *Lonza /Teva/ JV*, Commission Decision of 14 May 2009.

<sup>20</sup> European Medicines Agency Guideline CHMP/437/04 of 30 October 2005, see <http://www.emea.europa.eu/pdfs/human/biosimilar/043704en.pdf>.

<sup>21</sup> Case No COMP/M.5479 - *Lonza /Teva/ JV*, op. cit.

#### IV.2.1.6. Discontinued products

33. In the present case, a number of instances arose, several of which were signalled late in the procedure, of products [...] which Ratiopharm had decided to discontinue [...] already before the decision to merge their activities.
34. In certain cases the marketing authorization for the relevant product had been withdrawn at the initiative of the relevant Party but in many cases it was still valid.
35. Insofar as the decision to exit those product markets can be said to be reversible, and stocks may continue to suffice for a number of months or even in some cases several years, the Commission has asked the Parties to provide documentary evidence of the decision to exit and to explain the business grounds on which it was taken. In the event that such business grounds appeared uncertain or open to change in the relevant counterfactual, that is absent the merger, on a conservative basis the Commission has taken the view that sales of the product might have continued or been resumed – in particular in the event of a price rise – and therefore that it needed to assess on a case-by-case basis whether or not the merger led to the elimination of a competitive constraint<sup>22</sup>. In other cases, where the Parties have provided solid justification of the decision to exit the relevant market based for example, on the lack of profitability of a product relative to the size of the market, the Commission has taken the discontinuation of these products as the relevant counterfactual.
36. A particularly important instance of product discontinuation in the present case results from the decision of Ratiopharm in February 2009 (made public on 6 April 2009) to close its production facility at Zaandam and to supply the Dutch market from other facilities. The Parties have explained that, following this decision, Ratiopharm performed an analysis on all products manufactured at Zaandam, and based on factors such as [...], determined a list of products to be withdrawn from the Dutch market, which was later approved by the management board. Ratiopharm stopped manufacturing these products at Zaandam in December 2009, and the manufacturing facility was closed. Its sales in the Netherlands since then consist only of product that is already in inventory. <sup>23</sup>[...]
37. This situation concerned a number of products for which the Commission services raised during the procedure the likelihood of serious doubts, received remedies and went on to market-test these remedies, namely capsicum, hydroxytoluic acid, imipramine, cortisone, methyldopa and riboflavin in the Netherlands<sup>24</sup>.
38. As regards products manufactured at Ratiopharm's Zaandam facility, the Commission has accepted the view put forward by the Parties that the discontinuation of such products was an autonomous and definitive business decision by Ratiopharm and that manufacturing was unlikely to resume, whether from Ratiopharm's own remaining facilities or by having recourse to a third party contract manufacturer, even in the event

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<sup>22</sup> See for example citalopram in Norway, discussed starting at recital 320 below and moclobemide in the UK, at recital 326.

<sup>23</sup> [...].

<sup>24</sup> The marketing authorisations for these products are still valid, except for capsicum for which the authorisation has already been cancelled. [...].

of any plausible increase in the price, [...] As a result, Ratiopharm's decision to exit the relevant markets constitutes the relevant counterfactual, and overlaps in these markets do not arise. For other products which were not manufactured at Zaandam where the Parties argued that products had been discontinued, this has been analyzed on a case-by-case basis (see footnote 22).

#### IV.2.1.7. Data provided by the Parties and possible market definition considered

39. In addition to any views expressed by the Parties as to the appropriate relevant market definition, the Commission asked the Parties to provide data and systematically considered all possible market definitions based on ATC3 and ATC4 levels, and, within the ATC4 level, on individual active ingredients (molecule level<sup>25</sup>), taking into consideration the pharmaceutical form and route of administration where relevant.
40. This approach may, however, also group together different forms of a given medicine, which, as discussed above (see section IV.2.1.2), are generally not interchangeable. In many cases, this is not a problem either because the ATC product classification itself operates a distinction based on galenic form, or because only one galenic form of a medicine is available. The market investigation nonetheless revealed a number of instances in which this approach resulted in inappropriately grouping together different galenic forms, sometimes with the effect of misstating the Parties' market shares in the relevant market substantially.
41. In such instances, where the Commission could conclude that different galenic forms were unlikely to be substitutable to a significant degree, it has considered each of these possible market definitions based equally on a primary distinction between galenic forms using the NFC (see recital 16 above). Where the Parties' activities, even if they result in an overlap at ATC3, ATC4 or molecule level, do not overlap at the level of the NFC, and the NFC relates to galenic forms of the kind which can in general be presumed not to be substitutable, the Commission has been able to conclude that no horizontal overlap arises. Instances of this kind are, however, individually discussed in the market definition section of the decision.
42. The Commission has also systematically considered all market definitions discussed and not excluded in earlier cases and asked the Parties to provide data on this basis also.
43. In previous cases, the Commission has focused the market investigation for finished pharmaceuticals by looking in more detail in the first instance at markets where the Parties achieved a combined share of over 35% and the increment in the share was of over 1%. Such markets are referred to as "Group 1 markets". In the context of this Decision, the Commission has systematically considered all possible Group 1 markets on any alternative market definition in order to verify whether or not this threshold might be met and, if it was, whether serious doubts arose.
44. In the sections below dealing with the definition of the relevant product markets, a number of Group 1 markets are not individually described for the reason that, on full examination of those markets, no concerns arise regardless of any of these alternative market definitions. The reasons for this are set out at recital 386 below where these

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<sup>25</sup> Occasionally a combination of active ingredients is used in a single product. Overlaps based on this combination have been considered and where necessary the market definition is discussed further below.

markets are also listed. In all of these cases, as well as for all non-Group 1 markets, the analysis is the same regardless of the exact product market definition and it can be left open.

45. It should also be noted that the analysis which is included in the individual market definition sections below relates exclusively, unless otherwise stated, to those national markets in which Group 1 markets potentially arose in this case based on some possible market definition. The national markets concerned are those which figure in the assessment section following each market definition, as well as those listed at recital 386.
46. In previous Decisions, finished pharmaceutical markets with a combined share of over 35% but an increment of 1% or less have been referred to as "Group 2" markets, and markets with a combined share in the range of 15% to 35% as "Group 3" markets. Unless specific issues in such markets were raised during the market investigation, markets which fell within these categories for all possible market definitions have not been considered in detail individually and they fall within the general conclusions of no serious doubts set out at recital 391 below.
47. As a result of sometimes quite significant differences between countries as to the structure of individual pharmaceutical markets, the definition of the relevant product market may sometimes 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.2.2. INTRODUCTORY REMARKS ON ASSESSMENT CRITERIA AND METHODOLOGY AND ON GENERAL CONCLUSIONS OF THE MARKET INVESTIGATION**

##### IV.2.2.1. Conduct of the market investigation

48. As has been its practice in previous cases such as *Sanofi-Aventis/Zentiva* and *Teva/Barr*, the Commission in the current case sent extensive questionnaires to the vast majority of the Parties' competitors for all potential Group 1 markets, covering both general and product-specific issues<sup>26</sup>. It further consulted a large selection of wholesalers and hospital clients as well as all significant health insurance bodies and authorities in the Group 1 affected countries (i.e. those countries with at least one Group 1 affected market). Individual questions were followed up with respondents where necessary. The Commission's conclusions in the present case therefore rest on a wide consultation of all of the relevant market actors.

##### IV.2.2.2. Calculation and interpretation of market shares

49. In previous cases, 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

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<sup>26</sup> A reply to these questionnaires is required from undertakings under Article 11(1) of the ECMR. National authorities and agencies were also extremely helpful in providing information and replies to the Commission's questionnaires.

active ingredients, different quantities of which may be required to achieve the same therapeutic outcome.

50. However, as noted in previous decisions, calculating market shares based on value may have certain limitations in genericised pharmaceuticals markets, because generic producers often charge prices which may be significantly lower than those of originators<sup>27</sup>. Branded generics may also be able to command a price premium relative to non-branded ones, in particular where generic substitution of the brand does not systematically apply in pharmacies and prescriptions are not necessarily based on the international non-proprietary name (INN) of the active ingredient(s) concerned. In such cases, shares based on value may sometimes differ significantly from market shares based on volume. For molecule markets, volume shares can easily be assessed based on weight of active ingredient. For markets consisting of a number of molecules, a volume market share would need to be calculated normalized to some measure of therapeutic value such as days of treatment. The Parties have pointed, nonetheless, to certain, in their view, inadequacies of the latter measure. Although in previous cases the Commission has sometimes cited data based on days of treatment<sup>28</sup> or so-called "international units"<sup>29</sup>, the fact that the vast majority of potentially affected markets in the present case arise at the molecule level means that it has not been necessary to take a view on volume measures for multi-molecule markets in the context of this case, and such measures are in general not cited in the assessment below, although where available and potentially relevant to the assessment the Commission has considered them.
51. In the context of the present case, the Commission has systematically requested data based on weight of active ingredient for molecule markets, as well as on standard units, but waived the requirement systematically to provide days of treatment data. In the assessment below, market shares for molecule markets are provided where possible on both a value and volume basis. For an initial screening of possible wider-than-molecule markets, the Commission has nonetheless generally relied on the value of sales.
52. It should be further noted that the indication of market shares by volume may only make sense when markets are looked at on the basis of dosage and/or galenic form. Although, as discussed, distinctions of this type are often relevant also for market definition purposes and have been considered in the assessment, their relevance is not necessarily systematically the case and where it is not, neither measure taken alone is fully satisfactory.
53. The Commission cites market shares according to IMS data, corrected where necessary, and for the year 2009 unless otherwise stated; however, it has considered data for the three years from 2007-2009 in its analysis and, in certain cases, also more recent data.

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<sup>27</sup> *Sanofi-Aventis/Zentiva*, recitals 205 and 206. It should be noted that where multiple dosages or galenic forms are included in a possible market definition, value and volume market shares may also diverge significantly. In the present case, this tended to indicate that the market definition considered was not appropriate.

<sup>28</sup> See *Sanofi-Aventis/Zentiva*, recitals 82, 292-294, 298-299.

<sup>29</sup> See *Sanofi-Aventis/Zentiva*, recital 81.

Where this leads to a modification to the assessment it has been cited in the relevant sections below.

#### IV.2.2.3. Market Entry

54. The market investigation in the present case also paid particular attention to the circumstances under which potential entry in a particular product by a rival generic company might constitute a constraint on the competitive behaviour of the Parties<sup>30</sup>.
55. In its earlier *Sanofi-Aventis/Zentiva* decision, the Commission discussed barriers to entry for generic pharmaceutical products to be developed *ex novo*, and concluded that in such an instance, barriers to entry could be high owing to the degree of investment required and the time it would take before bringing such a new product to market. This has been confirmed also in the circumstances of the present case as regards the introduction of products based on a different form or route of administration to an existing product (see section IV.2.1.2).
56. Competitors consulted during the market investigation in the present case nonetheless overwhelmingly confirmed that, under certain conditions, entry was feasible within a short period of time, typically within a year. More specifically, entry could be considered practicable in most cases within a short period if all of the following criteria were met: (i) the competitor already had the same pharmaceutical form and dosage of the target product in another market within the EEA, and especially in neighboring markets to the target market; (ii) the competitor already had a significant base of generic operations with a number of products in the target market, belonging to the same or closely related therapeutic areas; and (iii) the competitor had no specific economic disincentive to introduce the product, such as a risk of cannibalizing existing sales of another product. Although these conditions may seem restrictive, they were seen in the circumstances of the present case to occur quite often and therefore to be relevant for the competitive analysis.
57. Competitors further indicated that whether entry actually would occur also depended, of course, on whether it would be profitable. As was already confirmed in *Sanofi-Aventis/Zentiva* and *Teva/Barr*<sup>31</sup>, entry was therefore less likely in small markets which naturally could support only a limited number of players, in declining and legacy markets, in markets where the Parties had an existing cost advantage (or would acquire a cost advantage as a result of the transaction) which competitors could not match, and in markets where pricing regulations imposed additional pricing discounts on later generic entrants. This type of consideration was frequently cited by competitors in certain markets as a reason why they would be unlikely to enter with the product in question.

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<sup>30</sup> In a number of instances, actual planned entry was identified or competitors confirmed that they would enter a market if prices were to rise. For reasons of confidentiality, these specific instances cannot be cited in this decision, but in any case they do not need to be relied on to support the conclusion of an absence of serious doubts where this is the conclusion that the Commission has come to.

<sup>31</sup> *Sanofi-Aventis/Zentiva*, recitals 213-215.

#### IV.2.2.4. Economies of scope

58. Replies to the market investigation, particularly from competitors, underlined the importance – already noted in *Sanofi-Aventis/Zentiva* – for many generic companies to achieve a wide portfolio of medicines in order to benefit from economies of scope<sup>32</sup>. To a varying extent in function of various criteria such as overall generic penetration, the position of the company concerned, and any legal restrictions, economies of scope may also make it possible to apply a strategy of range discounts which, all other things being equal, tends to favour the larger players on the market. Many market respondents anticipated that this was a factor favouring consolidation in the sector.
59. Factors cited in support of the importance of economies of scope on the supply side were efficiencies in the use of marketing and sales resources and in logistics, whilst on the demand side it was said to result from administrative efficiencies in the ordering process of wholesalers and of other purchasing collectives, in inventory management (since smaller amounts needed to be held in inventory from a supplier with which orders were frequent), and in the desire to leverage countervailing buyer power.
60. The provision of a given product across a range of geographies also gives rise to economies of scale. However, for the vast majority of products considered, a number of providers of the product exist at EEA level and the Parties do not achieve, as a result of the transaction, a significant increment at EEA level. Indeed, there were very few markets which were affected in more than one or two Member States, indicating that, with a few exceptions, overall generic consolidation in the EEA remains limited, even at the level of individual products.
61. As regards specifically the Netherlands, the inability of smaller competitors to match the range of products of the Parties and therefore achieve similar economies of scope was considered a barrier to entry by a significant number of competitors, even though the minimum scope required was not clear and the possibility of profitably occupying a niche position on the market appeared to remain open in a number of cases. The specific position of the Parties on the Dutch market has been discussed in more detail below (recitals 70-76).

#### IV.2.2.5. Price competition and pricing regulations

62. As similarly noted in previous decisions<sup>33</sup>, for the purposes of assessing competition in pharmaceutical markets it is also necessary to bear in mind that such markets may display certain rigidities as regards both pricing and entry.
63. In the market investigation, the Commission specifically asked about the ability of the Parties to determine prices of existing products post-merger in the light of pricing and reimbursement regulations. At a general level, there was a good deal of consensus on the part of all market participants that this ability was in many cases subject to a number of constraints.

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<sup>32</sup> See recital 215.

<sup>33</sup> *Sanofi-Aventis/Zentiva*, recital 202.

64. As regards OTC products, it was generally considered that the Parties could freely determine prices to wholesalers, which in turn might lead to a variation in the retail price, although the maximum retail price of some OTC medicines is regulated in certain countries.
65. For prescription medicines, quite a number of factors were cited in support of the view that prices in all the affected countries for many medicines in mature generic markets were upwardly inflexible or could only be increased with difficulty. Reference pricing systems, relatively long-term contracts, and negotiations on the price with one or a few powerful players all supported this view. In such mature markets, there are frequently a number of generic entrants or potential generic entrants and discounts from the originator price are expected and even sometimes prescribed, and in any case a condition for commercial success.
66. For hospital drugs, but also for prescription drugs generally in certain countries, the use of tendering by public authorities and/or insurers ("bidding markets") was another factor cited in support of the view that generic firms would not easily be able to raise prices, although the conclusion in this respect was less unanimous, with some respondents claiming that three or four competitors were required to achieve competitive prices.
67. It follows that, at moderate concentration levels, the existence of pricing constraints is one factor allowing the Commission to conclude that smaller competitors may act as a sufficient constraining influence<sup>34</sup>. Such a consideration supports the conclusion of no serious doubts in a number of places in this Decision, and in particular in the cases dealt with at recital 386 below.
68. Nonetheless, at very high concentration levels for a particular product and/or in the presence of additional features of the market structure, the relevance of pricing regulations and tendering as a sufficient competitive constraint cannot, on the basis of the market investigation, be concluded with confidence. Thus, many respondents to the market investigation, when they did believe that price increases for prescription medicines were possible, specifically cited the eventuality of very high market shares at product level in support of this possibility. It should also be noted that, if authorities or insurers are unable to constrain prices, at doctor and patient level there is likely, for all but more routine medications, to be an absence of price sensitivity due in particular to the fact that patients do not directly bear the costs.
69. Finally, it should in any case be borne in mind that the existence of a price ceiling does not exclude that the relevant counterfactual in the absence of the merger would have been continuing price decreases. Many national markets have, indeed, shown very significant decreases in the prices of common generic medicines over recent years, a trend which relies on sufficient competition in the market. The Commission in its assessment has therefore relied also on the basic economics of generic competition, namely, for unbranded generics, the fact that the goods involved are non-differentiated (and therefore competitors compete on price).

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<sup>34</sup> cf. para. 17 of the Horizontal Merger Guidelines, OJ C 31 of 5 February 2004, p.5.



#### IV.2.2.6. Specific situation in the Netherlands

70. The Dutch pharmaceutical market may be considered to show a high degree of generic penetration. Generic pharmaceuticals represented 57% of all prescriptions in 2009, and during the same year the average price of generic medicines decreased by 22%<sup>35</sup>.
71. As indicated in the table at recital 7 above, third party figures for the second half of 2009 estimate the share of generic sales by value of the Parties at around 40%. Teva's share of around 29% has declined from around 33% in first half of 2007. Ratiopharm's share peaked at around 18% in second half of 2008 but over the following twelve months has declined significantly<sup>36</sup>. As no clear trend can be determined, an estimate of shares in the range of 40-45% for generics seems to be justified.
72. Sandoz (Novartis' generic subsidiary) has, over this period, consistently occupied the second position. On the latest figures for second half of 2009, it would appear that both Actavis and Apothecon/Mylan have overtaken Ratiopharm and that therefore it would have recently slipped from third to fifth place<sup>37</sup>. This notwithstanding, Teva's existing position as market leader will be considerably reinforced as a result of the notified transaction.
73. The overall market structure post-transaction on a view limited to the generic segment and using the SFK figures for second half of 2009 would look approximately as follows:

Teva/Ratiopharm	40%
Sandoz (Novartis)	20%
Mylan/Apothecon	14%
Actavis	12%
Centrafarm (Stada)	4%
Others	12%

74. Specific concerns as to the overall strength of the combined firm (leaving aside comments on biosimilars, see below, and for individual products) were raised by a few customers in the Netherlands. Some respondents drew the Commission's attention to the competitive advantage for a generic company to offer a wide range of products and the effect of range discounts on the behaviour of distributors and pharmacies (see further section IV.2.2.4 above). In the longer run, respondents both in the Netherlands and in some other countries expected further consolidation of the generic industry due to these economic features of the industry.

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<sup>35</sup> By value, the share would nevertheless be considerably lower; combining IMS and SFK figures it can be estimated at around 17%.

<sup>36</sup> Source: SFK.

<sup>37</sup> Source: SFK.

75. A minority also pointed out, however, that preference policies of insurers in the Netherlands (essentially, choosing the cheapest price for a given drug independently of range discounts) allowed, at present, some niche players to maintain a market position which might otherwise be more difficult<sup>38</sup>. This preference policy applies to a range of the most common generic medicines, but not to all medicines<sup>39</sup>.
76. Although overall concerns as a result of the merger do not arise (see section IV.7 below), as will be seen below the market investigation has nonetheless found competition concerns in a number of individual product markets in the Netherlands which, in a number of instances, result from or are reinforced by considerations of the economies of scope in-country and of scale in production available to the Parties post-merger. Such instances are indicated in the discussion of the relevant markets in the next section. The Parties have submitted remedies for these markets and, as will be seen in the remedy section of this Decision, the combined strength of the two firms in the Netherlands has needed to be given due weight in the design of these remedies.

#### IV.2.2.7. Structure of the Decision

77. For many markets and geographies, the parties' joint market shares do not exceed 35% on any of the alternative market definitions considered, and/or the increment is below 1% on any of these alternative market definitions (non-Group 1 markets, see recital 43 above). As in previous Commission decisions, these markets are dealt with "en bloc" unless particular situations were identified which required a more detailed discussion. For these markets reference is therefore made to recital 391 below.
78. In the context of the present case, involving a merger of two largely generic companies providing unbranded generic pharmaceuticals and with, generally speaking, sufficient generic competitors remaining on the market, the Commission is also able, in the vast majority of cases, as a result of the market investigation to exclude serious doubts for those products where at least three generic competitors would remain on the national market in question, each of them with at least 5% market share and with an existing substantial presence in the country concerned in terms of a portfolio of products in the same or related therapeutic areas. In such instances, there are good reasons to conclude that the Parties would be unlikely to be in a position, post-merger, to increase prices over the long term without one or more of these competitors responding by increasing output (except in certain instances as a possible result of the increased economies of

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<sup>38</sup> See also the SFK article cited above. The legal requirement for wholesalers to carry all approved products marketed in the country may also be mentioned as a factor enabling entry.

<sup>39</sup> The preference policy has been progressively developed by the largest Dutch health insurers and works at molecule level. Thus insurer Univé VGZ IZA Trias, for example, has applied since 1 July 2005, together with six other insurers, such a policy for cholesterol-lowering medicines based on simvastatin and pravastatin and for stomach antacids based on omeprazol. From 1 July 2008 this insurer unilaterally extended the policy to products based on alendronic acid, alfuzosine, amlodipine, captopril, ciprofloxacin, citalopram, caritromycine, codeine, enalapril, ethinylestradiol-levonorgestrel, finasteride, fluoxetine, fluvoxamine, fosinopril, gliclazide, glimepiride, ibuprofen, lansoprazol, lisinopril, metformine, metoprolol, mirtazapine, ondansetron, paroxetine, perindopril, quinapril, ramipril, ranitidine, risperidon, sertraline, sumatriptan, tamsulosine and tolbutamide. As of 1 June 2009 it was further extended to amoxicillin, amoxicillin/clavulanic acid, bicalutamide, diclofenac, fentanyl, fluticasone, naproxen, oxycodone, pantoprazol, ropinirol, sotalol and venlafaxine. Of the markets with serious doubts in the Netherlands in this decision, only ibuprofen and fentanyl are covered by the policy. See <http://www.medicalfacts.nl/2009/06/02/preferentiebeleid-meest-gestelde-vragen-en-antwoorden/>.

scope and scale from which the Parties would benefit in the Netherlands). Third parties have not raised substantiated concerns in respect of any of these markets. All of these product markets have been individually assessed but the results are summarised together at recital 386 below due to the common reasoning which applies in all such cases.

79. It is important to note that the approach followed by the Commission for presenting its conclusions in relation to such markets represents simply a shorthand for describing, *ex-post*, the assessment of a large number of markets (over one hundred molecule/country combinations) where the same reasoning and conclusions apply.
80. In the relevant assessment sections below, the Commission provides a detailed and individual assessment of: (1) all those Group 1 product markets and geographies in which possible competition concerns were identified during the market investigation and where such concerns could not be eliminated based on general features of the market and the competitive environment, but where additional factors needed to be considered; and (2) all markets where serious doubts arise.
81. For the avoidance of doubt, it should be noted that Group 1 markets may arise, for a given product market, in certain geographies which fall within the scope of the general conclusion of the absence of serious doubts covered by recital 386 as well as in other geographies which require a more extended discussion. In such instances the situation in the latter countries is discussed individually, while for the remaining countries the conclusions of recital 386 apply.
82. In other cases, a certain number of product markets require a discussion from the standpoint of market definition in order to establish certain features of the relevant product market but, once this has been done, the relevant conclusions as to the absence of serious doubts presented at recitals 386 or 391 apply. In such instances, an assessment of individual geographies is not presented in the text.

#### **IV.2.3. RELEVANT GEOGRAPHIC MARKETS**

83. In previous decisions, the Commission has held that the relevant geographic markets for finished pharmaceutical products were national<sup>40</sup>. The market investigation in the present case supports the view that competition for such products essentially takes place at a national level, due in particular to national approval procedures and reimbursement schemes. Differences in national clinical guidelines and medical views and preferences may also play a role in certain instances.

#### **IV.2.4. RELEVANT PRODUCT MARKETS**

##### **A5A – Cholagogues and choleretics – OTC**

###### *Market definition*

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<sup>40</sup> See e.g. Case No COMP/M.3751 - Novartis/Hexal, Commission Decision of 27 May 2005, hereafter cited as *Novartis/Hexal*, recitals 4 and 5; *Teva/Barr*, recital 19.

84. The A5A category contains drugs for bile therapy and lipotropics in combination. Both Parties are active in the ATC 4 class A5A1. The A5A class includes products indicated as cholagogues and choleretics.
85. The Commission has previously assessed this market at the ATC 4 level,<sup>41</sup> at which level the Parties achieve a [50-60]% market share by value in Hungary. There is only one other competitor at this level, Rowa Wagner, which accounts for the remaining [40-50]%.
86. However, the Parties argue that this level is not appropriate for the assessment of pharmaceuticals in this class in Hungary because the products belonging to the same ATC 4 class are not fully substitutable.
87. Teva is present in this class in Hungary with Cholagol, a product containing a number of active ingredients of vegetable origin such as: curcuma longa, frangula alnus, menthol, and salicylic acid. Most of the ingredients have a stimulating effect on production and secretion of bile. In addition Cholagol moderates spasms of the smooth muscles of the biliary tracts and has an anti-inflammatory effect and a slightly laxative effect. The product is used as adjuvant therapy in case of cholelithiasis, chronic cholecystitis, conditions after surgery on biliary tract with symptoms of dyspepsia, dyspeptic troubles during chronic hepatopathies.
88. The product of Ratiopharm belonging to the same ATC 4 class in Hungary is called Bilobene and it consists of different ingredients than Cholagol, i.e. fumaria officinalis. The product is used to regulate bile and, according to the Parties, has a distinct medical use compared to Cholagol. Bilobene is used for treatment of spasms of the gallbladder and of the biliary tract and in general it is used for shorter treatment than Cholagol.
89. Therefore the Parties products are based on different ingredients. What is more, these products exist in different galenic forms on the market: while Cholagol is present on the market in oral liquid ordinary form (drops), Bilobene exists in oral solid ordinary (tablets).
90. The responses to the market investigation indicate that the products of the Parties are used for different purposes and could be substitutable, if at all, only to a very limited degree.<sup>42</sup> The market investigation indicated also that Cholagol, contrary to Bilobene is, reimbursed at a 100% rate for socially disadvantaged persons, whereas Bilobene is not reimbursable. The product of Rowa Wagner, Rowachol, is partly substitutable to Cholagol but not to Bilobene as it is indicated for treatment of liver complaints and conditions such as cholecystics and gall stones.
91. It follows that the Parties' products belong to separate relevant product markets and, accordingly, no overlap arises.

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<sup>41</sup> Case IV/M.0072 – Sanofi/Sterling drugs, decision of 10 June 1991.

<sup>42</sup> According to the Hungarian National Institute of Pharmacy Cholagol can rarely be effectively substituted with Bilobene as these products have only one overlapping indication – dyspepsia. If necessary Cholagol can substitute Bilobene for dyspepsia however, the two products contain different active substances.

## A11D – Vitamin B1 and combinations

### *Market definition*

92. The A11D class contains vitamin B1 pharmaceuticals and their combinations with other vitamins (e.g. plain vitamin B1, vitamin B1 combinations with vitamin B6 and / or vitamin B12). The Parties argued that the market should be defined based on the ATC3 level. The Commission has previously analysed the market at the ATC3 level<sup>43</sup> but in *Teva/Barr* also took into consideration in its analysis the molecule level, although it found no indications that this should be the relevant market definition.
93. The A11D class is further subdivided into ATC 4 classes. The Parties overlap in the following classes: A11D3 and A11D4. The Parties manufacture and sell thiamine (vitamin B1) and pyridoxine thiamine (vitamin B1 in combination with vitamin B6) belonging to this class. These molecules can be used to treat deficiency of vitamin B1 (or vitamin B1 and vitamin B6 respectively) or, in the OTC segment, as a general food supplement and for self-medication.
94. Thiamine (vitamin B1) is a medicinal product which could be used to treat or mitigate a specific condition of deficiency of vitamin B1 which could subsequently lead to serious diseases, such as beri-beri.
95. Pyridoxine thiamine is a combination of thiamine with vitamin B6.
96. The Parties argue that in most instances plain thiamine is likely to be prescribed in very similar conditions as the combination of thiamine with pyridoxine (vitamin B6), especially in the OTC segment. The market investigation also indicates that pyridoxine thiamine and thiamine are used for the same conditions/deficiencies.
97. Serious doubts arise irrespective of the market definition in the Netherlands; whereas in Germany, under all alternative market definitions serious doubts can be excluded. Therefore there is no need to decide on the exact market definition in this case.

### *Germany*

98. In Germany the Parties overlap at the OTC segment of the A11D class. The Parties have market shares of [10-20]% in this class (increment of [0-5]% due to Teva). At the ATC 4 levels, the combined market shares are also below 35%.<sup>44</sup> High market shares for Germany arise only at molecule level, namely for pyridoxine thiamine ([30-40]%, increment [0-5]% due to Teva) and thiamine ([50-60]%, increment [0-5]% due to Teva). However, competitors exist for these molecules in Germany; for pyridoxine thiamine: Abbott ([20-30]%, Sanofi – Aventis [5-10]% and Stada [5-10]%) and for thiamine: Merck KGAA [20-30]%, Hevert [5-10]% and Pascoe [5-10]%.
99. The increment due to the transaction is very low and in each class there exist a number of competitors. What is more, the market investigation indicated that the molecule level

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<sup>43</sup> See for instance case IV/M.950 Hoffmann - La Roche / Boehringer Mannheim, Commission Decision of 4 February 1998.

<sup>44</sup> The combined market shares for A11D4 class where pyridoxine thiamine belongs are [20-30]% (OTC) and for A11D3 class where thiamine belongs the market shares of the Parties are below 15%.

is not the appropriate level for the assessment of pharmaceuticals belonging to this group in Germany, and that it therefore it is more likely that the market is wider than the molecule. The Parties' market shares are below 35% for both ATC 4 and ATC 3 classes.

100. The Commission therefore concludes that no serious doubts arise with respect to this market in Germany.

#### *The Netherlands*

101. In the Netherlands the Parties are both present in this class with the molecule thiamine. The Parties have combined 100% market shares at ATC3, ATC4 and molecule level for pharmaceuticals sold OTC (with [10-20]% increment due to Ratiopharm).

102. If one considers the overall market of pharmaceuticals OTC (over-the-counter) and Rx (prescription) in the A11D class, the Parties will obtain a combined market share of [90-100]% post-transaction with 2 small competitors remaining for the products belonging to another ATC4 class, A11D4.<sup>45</sup> These competitors are Medcor ([0-5]%) and Merck KGAA ([5-10]%) with Cyanocobalamin Pyriodoxine Thiamine sold Rx in different galenic form to the Parties' products. The competitors' products are in the form of parenteral ordinary while the Parties overlap only at the OTC level, where they are both active in oral solid ordinary form.

103. Therefore, the transaction results in a merger to monopoly irrespective of the level at which the market would be assessed in the A11D class in the Netherlands.

104. It results from the above that the transaction will lead to serious doubts irrespective of the market definition.

### **A11G – Ascorbic acid (Vitamin C)**

#### *Market definition*

105. The A11G class contains vitamin C including combinations with minerals. The A11G class is subdivided into two ATC 4 categories: A11G1 which consists of plain vitamin C, including vitamin C salts and A11G2 where vitamin C combinations belong. The Parties submitted that all the products belonging to the A11G class have the same therapeutic properties and that the relevant market should be defined with reference to the ATC 3 class A11G.

106. However, the exact market definition in relation to A11G can be left open since the transaction leads to serious doubts irrespective of the market definition in this class in the Netherlands.

#### *Netherlands*

107. Post transaction, in the A11G class in the Netherlands, the Parties will achieve a combined market share in the OTC segment of [70-80]% (increment [30-40]% due to

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<sup>45</sup> The Parties do not overlap on the Rx products, where only Teva is active.

Teva) with only one other important competitor of [20-30]% (Stada)<sup>46</sup> and another minor competitor Will Pharma (with a product in oral long lasting form and a market share of [0-5]%).<sup>47 48</sup>[...]

108. All products sold in the Netherlands in this class belong to the ATC4 class A11G1 (plain vitamin C) and are based on the same molecule (ascorbic acid). The Parties' combined market shares at ATC4 and molecule level are the same as at the ATC3 level.
109. The market investigation confirmed that, in addition to the very high combined market position of the Parties on the vitamin C OTC market, both Parties and their main competitor offer products in the same galenic form - oral solid ordinary. Post-transaction, Teva and Ratiopharm combined would be the only player for 500 mg tablets and Stada would be the only significant remaining competitor.
110. It results from the above that the transaction will lead to serious doubts irrespective of the market definition.

## **A11X – Other vitamins**

### *Market definition*

111. The A11X class consists of the vitamins not belonging to any other class (it should be noted that the ATC3 classes ending in "X" are a residual class of miscellaneous molecules and therefore this is not a likely market definition).
112. The A11X class is subdivided into four categories. The A11X2 category consists of plain vitamin B6, also known as pyridoxine. The A11X9 contains of other vitamins not belonging to any other class and includes molecules such as panthotenic acid, riboflavine, para-aminobenzoic acid etc.
113. The Parties overlap in the Netherlands in two molecules, namely: riboflavin (which is sold only OTC) and pyridoxine (both Rx and OTC). In the *Teva/Barr* decision the Commission found that these molecules, although belonging to the same ATC 3 class, are not substitutable and therefore constituted separate product markets.
114. Pyridoxine is a plain molecule B6 and is used as a food supplement as well as in cases of deficiencies of this molecule. Riboflavin – i.e. vitamin B2 - is also used as a food supplement and in case of vitamin B2 deficiencies, e.g. severe depletion of vitamin B2 that can escalate to a disease known as ariboflavinosis.
115. In the *Teva/Barr* decision, the Commission concluded that drugs based on riboflavin and pyridoxine constituted separate relevant product markets. The market investigation in the present case confirmed that products based on these different molecules, i.e.

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<sup>46</sup> If both Rx and OTC products were taken into account, the Parties would achieve [60-70]% market share combined.

<sup>47</sup> [...].

<sup>48</sup> [...].

pyridoxine and riboflavin are used for different purposes and cannot be considered substitutes. More particularly the market investigation confirmed lack of substitutability of riboflavin with other molecules belonging to the same ATC3 class.

#### *Pyridoxine, Netherlands*

116. In the A11X2 class the Parties achieve a combined market share of [90-100]% due to their presence in this class with the molecule pyridoxine (in the Netherlands all the products belonging to A11X2 class are pyridoxine-based).
117. However, the Parties overlap only on the Rx segment of pyridoxine and not on the OTC segment. The Rx segment of pyridoxine constitutes only 9% of the overall pyridoxine market in the Netherlands. The Parties would achieve a combined market share of [80-90]% on this market (with one competitor remaining, i.e. Stada at [10-20]%). However, the Parties' products are in different galenic form.
118. Ratiopharm's product is in oral solid ordinary form (tablets) whereas Teva's product is in parenteral form (injections). Their unit price also differs significantly: while the price per unit for parenteral ordinary (Teva) is 1,38 EUR, for oral solid ordinary form (Ratiopharm) it is 0,02 EUR. Due to the different routes of administration of these products and the large difference in price, the substitutability of these two forms can be excluded.
119. Taking into account the small part of the overall molecule market where the Parties' overlap as well as different galenic forms in which these products exist on the market and the existence of one competitor, the transaction will not lead to serious doubts with regard to the market of pyridoxine in the Netherlands.

#### *Riboflavin, Netherlands*

120. With respect to pharmaceuticals based on riboflavin, the Parties' combined market shares post transaction would amount to [90-100]% based on the A11X9 ATC4 class and more particularly on the molecule level, riboflavin ([90-100]%, increment of [20-30]% due to Ratiopharm).<sup>49</sup>
121. However, during the market investigation, the Parties claimed that Ratiopharm has discontinued its riboflavin-based products (Riboflavine-RAT). Ratiopharm stopped producing riboflavin in December 2009 [...]. In light of this, and consistent with the general approach to this issue as outlined above, it is concluded that the transaction does not raise serious doubts.

### **B3X – Anti-anaemic products, including folic acid**

#### *Market definition*

122. The class B3X includes prescription folic and folinic acid preparations for treatment of anaemia when it is based on a folic acid insufficiency, as well as OTC folic acid used for self-medication and as a nutritional supplement. It also includes prescription

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<sup>49</sup> The ATC4 based market shares are the same as the molecule based market shares.



products based on calcium folinate which are specifically indicated in anaemia induced by chemotherapy. A Group 1 market arises only in the Netherlands.

123. The market investigation has confirmed that, for the Netherlands, the OTC and prescription markets should be treated separately, and that products based on calcium folinate within the prescription segment should be excluded from the relevant prescription market due to their different use.
124. Folinic acid products are also classified, when they have additional indications, in class V3D which covers detoxifying agents for anti-neoplastic treatment. This market was looked at in Teva/Barr, where the Commission concluded that calcium folinate constituted a separate relevant market within the class<sup>50</sup>.
125. It follows that relevant product markets arise in the Netherlands for OTC folic acid and prescription folic acid. The inclusion or otherwise of folinic acid in the relevant market definition can be left open, as there is no significant competitor on the market with this molecule.
126. For the OTC segment, serious doubts do not arise since the conclusions starting at recital 386 below apply to this segment.

#### *Folic acid – prescription segment – Netherlands*

127. The Parties achieve a combined share of [60-70]% by value and [60-70]% by volume in the prescription segment of folic acid. There is only one other competitor (Actavis with [30-40]%), and the Ratiopharm increment at [10-20]% is significant.
128. In view of the degree of market concentration as a result of the merger and the elimination of an important competitor, as well as in view of the Parties' overall strength in the Netherlands post-merger, serious doubts arise in the folic acid (B3X) prescription market in the Netherlands.
129. The Parties have offered to divest Ratiopharm's product.

## **C2A – Anti-hypertensives, plain**

### *Market definition*

130. The C2A class includes a group of substances used primarily for the treatment of hypertension. It comprises plain antihypertensives and combinations other than those with diuretics. Products which are mainly centrally-acting are included in the ATC4 class C2A1, while products which are mainly peripherally-acting are included in the ATC4 class C2A2.
131. In view of high combined market shares for these molecules, the market investigation looked more closely at the cases of methyl dopa, prazosin and terazosin.

### *Methyl dopa*

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<sup>50</sup> Recitals 39 to 42.

132. Methyldopa is an anti-hypertensive belonging to the group of centrally-acting antihypertensives (C2A1) with specific indications in pregnancy-induced hypertension and for which the Parties achieved high pro forma market shares in the Netherlands. The molecule is available in the Netherlands only in oral solid form.

133. Although a certain number of indications pointed in the direction of the molecule as the relevant market in view of the specificity of its applications, the market definition can nonetheless be left open for this molecule, as serious doubts do not arise.

#### *Prazosin*

134. Prazosin contains a piperazinyloquinazoline nucleus and is a potent and selective alpha-1 receptor antagonist. It is used to reduce blood pressure by blocking alpha-1 receptors in the arterioles and veins. One of the main indications for this molecule is benign prostatic hypertrophy (BPH).

135. The market investigation in Germany confirms the Parties' view that the molecule is not the relevant market for the assessment of this transaction, as at least a number of molecules belonging to the same ATC4 class (for example doxazosin and terazosin) are substitutable for prazosin by virtue of their indication for BPH, mode of action and side effects, and switching would be anticipated in the event that prices were to rise. Moreover some respondents to the market investigation suggested that prazosin-based products may also be substitutable to some products classified in a different ATC3 class, G4C, which are also indicated for BPH.

136. On the basis of the results of the market investigation, the market definition based on molecule level can therefore be excluded for the purpose of this decision. It can, however, be left open whether the ATC3, ATC4 or only the two or three molecules taken together (prazosin and doxazosin and/or terazosin) would constitute a relevant product market as the transaction would not lead to serious doubts under any of these market definitions.

#### *Terazosin*

137. The Parties stated that terazosin is a selective alpha 1 antagonist, which may be used for the symptomatic relief of BPH. The Parties argue that a number of other alpha 1 blockers are available on the UK market, which would otherwise be a Group 1 market if defined at the level of the molecule. Alternatives, in the Parties' view, would include alfuzosin, doxazosin, indoramin, prazosin, tamsulosin and terazosin) and therefore they argued that the market should be defined at a level wider than the molecule.

138. As mentioned above for prazosin, the market investigation confirms the Parties' view that the molecule is not the relevant market for the assessment of this transaction, as at least a number of molecules belonging to the same ATC4 class (for example doxazosin and prazosin) are substitutable for terazosin by virtue of their indication for BPH, mode of action and side effects, and switching would be anticipated in the event that prices were to rise. Moreover some respondents to the market investigation suggested that terazosin-based products may be substitutable to some products classified in a different ATC3 class, G4C, which are indicated for BPH.

#### *Assessment*

##### *C2A1 – methyldopa – Netherlands*

139. The Parties would achieve a combined market share of [40-50]% in the C2A1 class and [60-70]% in the molecule methyldopa (increment of [10-20]% due to Ratiopharm). There would remain post-merger two other generic providers, Novartis ([10-20]%) and Stada ([20-30]%). These are both significant competitors in the Netherlands.
140. However, it has been established that Ratiopharm had already decided to exit this market before the merger in the context described in recital 36 above. As a result, pursuant to the approach described there and although the Parties initially offered a remedy for this market, serious doubts can be excluded on the basis of there being no overlap on the relevant counterfactual.

#### *C2A2 - prazosin - Germany*

141. In Germany the Parties achieve a combined market share of less than 15% in the C2A class, [20-30]% in the C2A1 class, [20-30]% based on the combination of the molecules prazosin and doxazosin, and [20-30]% based on the combination of the three molecules. A number of credible competitors will remain in Germany for both molecules, such as Dexxon and Eurimpharm for prazosin and Novartis, Mylan, Pfizer and Stada for doxazosin.
142. It can therefore be concluded that serious doubts do not arise as regards the relevant market including prazosin in Germany, regardless of the exact definition of this market.

#### *C2A2 - terazosin - UK*

143. In the UK the Parties achieve a combined market share of [10-20]% in the C2A class, [10-20]% in the C2A2 class, whereas no affected market arise based on the combination of the molecules terazosin, prazosin and doxazosin.
144. It can therefore be concluded that serious doubts do not arise as regards the relevant market which includes terazosin in the UK, regardless of the exact definition of this market.

### **C3A – Diuretics**

#### *Market definition*

145. The C3A class consists of diuretics, which are medicines that elevate the rate of urination and are prescribed to treat hypertension as well as more severe conditions such as heart failure, cirrhosis of the liver and certain kidney disorders.
146. The market investigation considered more specifically the case of hydrochlorothiazide (HCT), which is a first line diuretic drug of the thiazide (C3A3) class that acts by inhibiting the kidneys' ability to retain water.
147. The market investigation showed that the thiazide diuretics have specific indications which make them not substitutable in terms of demand with other diuretics from the C3A class and in particular with loop diuretics (C3A2).
148. Group C3A5 consists of thiazide diuretics in combination with potassium-sparing agents. Potassium-sparing diuretics are generally used in combination with other diuretic drugs that would otherwise tend to lower potassium levels in the body to

potentially dangerously low levels. The market investigation did not allow the Commission to form a firm view as to whether or not the combination products should be included in the relevant market for thiazide diuretics. Potassium-sparing diuretics are also available on a standalone basis in the Netherlands and are then classified in C3A1.

149. In any case, a clear majority of competitors including all of those present in the affected market viewed competition to take place at the level of the molecule HCT.
150. Accordingly, a relevant market arises in the Netherlands which is no wider in scope than the ATC4 classes C3A3 and C3A5 taken together, but likely to be limited to HCT.
151. It can nonetheless be left open whether HCT constitutes a separate relevant market as, independently of this, serious doubts arise also on the alternative market definitions in the absence of a remedy for HCT and are addressed by the remedy outlined below.

*Thiazide diuretics (C3A3) – hydrochlorothiazide – Netherlands*

152. The Parties have a combined market share of [70-80]% by value and [60-70]% by volume in HCT and of [70-80]% by value at ATC4 level, i.e. for all plain thiazide diuretics. Considering classes C3A3 and C3A5 together, the combined market share by value would be [60-70]%. C3A3 products in the Netherlands are available only in oral solid form.
153. By value, competitors in HCT are Novartis ([10-20]%), Actavis ([5-10]%), Mylan ([0-5]%) and Stada ([0-5]%).
154. The bulk of the Parties' shares in either C3A3 or C3A3+C3A5 are constituted by HCT, respectively [80-90]% and [70-80]%. Within the C3A3 class, the Parties also overlap in chlortalidone, spironolactone and indapamide. Within C3A5, they overlap in hydrochlorothiazide in combination with the potassium-sparing diuretic amiloride, but with a minimum increment due to Ratiopharm and there are several other competitors with this combination.
155. It follows that the Parties are close competitors on any of the alternative market definitions and that the merger would eliminate an important competitive constraint in particular for monotherapy HCT. Therefore, in combination with the specific position of the Parties on the Dutch market post-merger discussed at recital 61 above, serious doubts arise on the Dutch market for thiazide diuretics, whether or not as combination therapy or limited to HCT.
156. The Parties have offered to divest Ratiopharm's HCT product, thereby eliminating the entire overlap in monotherapy HCT. At ATC4 level, the remaining increment due to Ratiopharm would be only [0-5]% and on the basis of the two ATC4 classes in combination it would be [0-5]%.

## H2A – Systemic corticosteroids

### *Market definition*

157. The market investigation showed that oral (H2A2) and injectable (H2A1) corticosteroids serve distinct patient groups and fall within separate product markets. The Parties overlap in oral formulations only, i.e. H2A2.
158. Within the overall group of oral corticosteroids, the Parties' combined market shares were indicative of potential concerns only in relation to cortisone, hydrocortisone and dexamethasone. Accordingly, it is only necessary to consider the correct market definition in relation to these three molecules.
159. As regards the molecule level, the market investigation indicated that oral cortisone has a reduced range of applications and for all of these is substitutable with certain other molecules from the same ATC4 class, in particular with hydrocortisone. Accordingly, it may be that the molecule level definition is not the correct market definition for this molecule. This can nonetheless be left open as serious doubts for cortisone do not arise.
160. [...], at a late stage of the proceedings, significant overlaps in oral dexamethasone and oral hydrocortisone in the Netherlands [were identified]. Accordingly, the substitutability of these molecules with other molecules has not been able to be market tested.
161. Nonetheless the Parties have noted, and publicly available sources have confirmed, that these corticosteroids have very different glucocorticoid potency profiles, as well as durations of action. The Parties note that the potency of dexamethasone is approximately 5-7 times that of prednisolone, 20-30 times that of naturally-occurring hydrocortisone, and 25-35 times that of cortisone. Dexamethasone is thus, in their view, only prescribed for short-term treatments, as it is unsafe for long-term use.
162. For this reason, the Parties acknowledge that dexamethasone and hydrocortisone may not be considered as fully interchangeable with each other or with other corticosteroids, and would therefore belong to separate product markets.
163. Whilst the Commission has not been able to establish possible substitutability between cortisone and hydrocortisone, it notes that cortisone, although significantly less expensive (EUR [...] versus EUR [...] per standard unit), is in uncommon use. In any case, this can be left open as regardless of whether ordinary cortisone were part of the same market, serious doubts would arise.
164. There are therefore sufficient grounds to consider that dexamethasone and hydrocortisone (or hydrocortisone together with cortisone) constitute distinct relevant markets. The Commission is not able to conclude this with certainty, however, since the Parties' views have not been contrasted with third Parties and the characteristics of the remaining products in the market have not been investigated. Under such circumstances, in its earlier *Pfizer/Wyeth* Decision the Commission considered that the relevant market could nonetheless be defined on the basis of the available objective elements even if

there remained some doubts due to the inability to carry out a full consultation of the market for the product in question<sup>51</sup>.

165. The assessment is therefore carried out on the basis of separate relevant markets for oral dexamethasone and oral hydrocortisone in the Netherlands.

*Oral corticosteroids (H2A2) – cortisone, hydrocortisone and dexamethasone – Netherlands*

166. The transaction involves a merger to monopoly at the molecule level for oral cortisone and high combined market shares for oral dexamethasone ([90-100]%) and oral hydrocortisone ([60-70]%), as well as significant overlaps in oral prednisolone ([60-70]%) and oral prednisone ([50-60]%). At the overall ATC4 level, the Parties achieve a combined market share of [60-70]%.

167. The Parties have indicated at a late stage in the proceedings that Ratiopharm had in fact withdrawn its oral cortisone product prior to the merger being announced. Pursuant to the approach described in recital 36 above, on the basis of the relevant counterfactual, no overlap occurs in respect of oral cortisone.

168. For both oral dexamethasone and oral hydrocortisone, the only remaining competitor is Stada ([5-10]% and [30-40]% respectively). For dexamethasone, the Parties are each others' closest competitors whilst for hydrocortisone the increment is also significant, at [10-20]% (Ratiopharm). Considering also the overall strength of the Parties in the Netherlands post-merger, it follows that serious doubts arise for oral dexamethasone. Similarly, regardless of whether or not oral cortisone is included in the relevant market, serious doubts arise for oral hydrocortisone.

169. For the oral forms of prednisolone, which is by far the most prescribed molecule in the class, and prednisone, and for the ATC4 class as a whole, serious doubts do not arise for the reasons set out at recital 386 below.

170. Teva has offered to divest Ratiopharm's oral dexamethasone and hydrocortisone products, thereby removing the overlap in these molecules.

### **H3B – Anti Thyroid Preparations**

*Market definition*

171. An affected market would arise in the Netherlands in the event that the market were defined with reference to the single molecule propylthiouracil.

172. The market investigation suggested that propylthiouracil may be substitutable with a certain number of other molecules, to which switching would be anticipated in the event that prices were to rise, and in particular with methylthiouracil and benzylthiouracil. However, neither of these closely related molecules appears to be available in the Netherlands.

173. The only product in the H3B class in the Netherlands sold by a company other than the Parties is thiamizole (also known as methimazole). According to the Parties, thiamizole is generally considered as a first-line therapy, whilst propylthiouracil is

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<sup>51</sup> Pfizer/Wyeth, recital 403.

generally considered as second-line drug therapy, except in patients who are allergic to or intolerant of thiamizole. This is because propylthiouracil and thiamizole do not have the same safety profile. Consequently, the Parties accept that propylthiouracil and thiamizole cannot be considered as fully interchangeable and would therefore belong to separate product markets.

174. The market investigation produced no further evidence on the substitutability or otherwise of propylthiouracil and thiamizole, but the view of the Parties is nonetheless fully consistent with the medical literature available to the Commission. According to such literature, severe liver injury and acute liver failure, in some cases fatal, have been reported in patients treated with propylthiouracil and therefore it is recommended that propylthiouracil should be reserved for patients who can not tolerate thiamizole.
175. Because of the risk of fetal abnormalities associated with thiamizole, propylthiouracil may, on the other hand, be the treatment of choice when an antithyroid drug is indicated during or just prior to the first trimester of pregnancy.
176. It follows that thiamizole and propylthiouracil belong to separate relevant product markets, at least in the Netherlands.

#### *Propylthiouracil - Netherlands*

177. As indicated, the transaction results in a merger to monopoly for the molecule (Teva [50-60]%, Ratiopharm [40-50]%). In view of the limited turnover within the market and the combined position of the Parties on the Dutch market post-merger, new entry can also be considered unlikely to be very attractive.
178. Accordingly, serious doubts arise on the Dutch market for propylthiouracil.
179. The Parties have offered to divest Ratiopharm's product.

### **J1F – Macrolides and similar types**

#### *Market definition*

180. Macrolides are systemic antibacterials within the overall J1 class. According to the Parties, all J1 drugs can be used to treat a wide variety of infections and many infections can be treated by a wide variety of J1 products. Certain J1 products require dedicated production facilities, in particular J1C penicillin, J1D, J1H penicillin and J1P, but others do not. For the purposes of the present decision it is unnecessary to conclude on the overall market definition and the substitutability of these various products. Topical antibiotic creams (D6A) and gynaecological antibacterials (G1C) are excluded from this category in IMS.
181. Due to the degree of overlaps, the market investigation in the present case looked in more detail at two systemic antibacterial agents, erythromycin in Hungary and azithromycin in a number of countries.

#### *Erythromycin*

182. Erythromycin is a macrolide antibiotic that has an antimicrobial spectrum similar to or slightly wider than that of penicillin. The market investigation has shown that this molecule only has residual uses in Hungary, and has largely been replaced by other

macrolide antibiotics, all of which are derivatives of erythromycin. The replacement of erythromycin is explained by its sensitivity to acid in the stomach, which makes its oral administration inefficient.

183. The market investigation has suggested that erythromycin is normally substitutable by other macrolide antibiotics, which have similar efficacy (although the precise scope of action varies from one molecule to another). Such substitution would be likely if its price were to rise. Accordingly, it might be incorrect to define a relevant market at the level of the molecule.
184. Nonetheless, this issue can be left open since the Parties do not overlap, but are rather complementary, in terms of galenic form. Teva's product is an oral liquid destined for use in pediatrics, whilst Ratiopharm's is an oral solid form. The market investigation has confirmed that these formulations serve clearly distinct patient groups and therefore are distinct in terms of demand and it follows that no affected market arises.

#### *Azithromycin*

185. Azithromycin is derived from erythromycin and is one of the world's best-selling antibiotics. Azithromycin is used to treat or prevent certain bacterial infections, most often those causing middle ear infections, tonsillitis, throat infections, laryngitis, bronchitis, pneumonia, Typhoid, and sinusitis. In recent years, it has primarily been used to prevent bacterial infections in infants and those with weaker immune systems. It is also effective against certain urinary tract infections and venereal diseases, such as non-gonococcal urethritis, chlamydia, gonorrhoea and cervicitis. Teva markets the originator drug, Sumamed, in the Member States in Central and Eastern Europe, the rights to which it acquired from Pliva as part of the Barr acquisition cleared by the Commission in 2008.
186. A certain number of arguments were raised in the market investigation in favour of the molecule (in combination with the galenic form) as a relevant market definition, although this cannot be concluded with certainty as a degree of substitution with other macrolides (with the exception of oral erythromycin), and possibly with other systemic antibacterials, would appear to exist. It was, however, noted that clinical guidelines often specify in individual countries which systemic antibacterials are to be preferred for which infections in order to manage issues of the emergence of resistant bacterial strains. The market definition can, however, be left open since in any case serious doubts do not arise.

#### *Assessment*<sup>52</sup>

##### *Azithromycin – ordinary solid form – Hungary*

187. In Hungary, the Parties achieve a combined market share of [60-70]% by value and [40-50]% by volume but the increment due to Ratiopharm is limited – less than [0-5]% on either measure - and has been declining while Sandoz and Krka have been gaining market share (respectively [20-30]% and [5-10]%, from [10-20]% and [0-5]% in 2007). Formal barriers to entry for some qualified companies established on the Hungarian

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<sup>52</sup> For azithromycin in Latvia, Lithuania and Estonia, it emerged during the procedure that the Ratiopharm product had already been sold to a competitor and therefore the Parties did not overlap.



market may also be considered to be low, such that entry by these players would not be unduly difficult if the price were to rise as a result of the transaction.

188. As a result, the competitive constraint exercised on the Teva originator product by the Ratiopharm generic alternative may be considered to be limited and serious doubts do not arise.

*Azithromycin – ordinary solid form – Denmark*

189. In Denmark, Pfizer was historically the market leader with the originator product (licensed by Pliva under the terms of an agreement which has now lapsed), but its share has declined significantly due to generic entry and is now only [10-20]%. The Parties' combined market share is [40-50]%, whilst Sandoz (Novartis) is the market leader with [40-50]%. There are no other significant competitors.
190. The market investigation has nonetheless confirmed that competition concerns in relation to this product do not arise. Of particular relevance are the low barriers to entry for generic companies established on the local market and which have this product in their portfolio elsewhere. Such companies could complete a product registration in Denmark quite quickly and thus constitute credible potential entrants.

**J4A – Tuberculosis**

*Market definition*

191. 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.
192. The Commission considered this market in Sanofi-Aventis/Zentiva and noted that it 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<sup>53</sup>.
193. The Parties overlap in the single molecule isoniazid administered on a standalone basis. Isoniazid is one of four drugs used in combination during the first two months of therapy to treat tuberculosis. Following this initial phase, a further four months of treatment is given in combination with rifampicin. Because resistance would otherwise quickly develop, isoniazid is never used on its own.
194. The Parties overlap in standalone isoniazid. There is also a product containing isoniazid in combination with rifampicin provided by Sanofi-Aventis in the Netherlands

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<sup>53</sup> Recitals 131-134.

which, for the reasons given above would seem to be equivalent and hence part of the same market. This can, however, be left open since it does not affect the conclusion of serious doubts.

195. The market investigation has therefore confirmed that a relevant market arises in the Netherlands for products containing isoniazid, whether or not in combination with other antitubercular drugs.

*Isoniazid (and combinations) – Netherlands*

196. The Parties would achieve a combined market share of [90-100]% in the Netherlands in isoniazid administered in isolation. Including combination therapies and based on quantity of the active ingredient isoniazid administered, the Parties would achieve a combined market share of [80-90]%. Moreover, given the small size of the relevant market, it is unlikely that new entry would be attractive.

197. It was suggested during the market investigation that the public health nature of the concern related to tuberculosis needs to be taken into account in considering the pricing and availability of such products and that the State would be able to act, if necessary, to obtain supplies on a cross-border basis. This idea, however, remains speculative and unproven and the Parties have not been able to substantiate it to the necessary standard of proof.

198. Accordingly, serious doubts arise for products based on isoniazid in the Netherlands, whether or not in combination with other antitubercular drugs.

199. The Parties have offered to divest Ratiopharm's product.

**L1X - All other anti-neoplastics**

*Market definition*

200. The ATC3 category L1X combines all other antineoplastics. The ATC4 category L1X2 - Platinum compounds includes drugs based on carboplatin, oxaliplatin and cisplatin.

201. Platinum compounds are chemotherapy drugs used in the treatment of a number of different cancers. Their usefulness derives from the property of platinum to inhibit cell division thereby inhibiting the growth of tumours. The first platinum based drug to be developed for the treatment of cancer is cisplatin. Carboplatin is a second generation platinum compound and oxaliplatin is third generation. The therapeutic indications of platinum based products have been extended over time in view of new clinical trials and additional indications may still be added. Cisplatin and carboplatin are more mature products than oxaliplatin. They are currently indicated for the treatment of a greater number of cancers than oxaliplatin<sup>54</sup>, which is indicated mainly for colon cancer.

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<sup>54</sup> Cisplatin: Metastatic ovarian carcinoma, Advanced bladder carcinoma, Metastatic testicular cancer, Small cell carcinoma of the lung, Squamous cell carcinoma of the oesophagus. Carboplatin: Ovarian cancer, Small cell lung cancer, Head and neck cancer.

202. The Commission previously examined oncology drugs, including drugs in the L1X category and found the ATC3 level market definition not to be appropriate.<sup>55</sup> While the market investigation in the present case also did not indicate the ATC3 category to be appropriate, this question does not have to be decided given that the transaction does not give rise to affected markets under this definition.
203. The Commission has also previously investigated platinum compounds, and, in particular carboplatin and cisplatin in *Teva/Barr*.<sup>56</sup> In that decision the relevant market definition for carboplatin and cisplatin was considered to be the molecule. This was based on the finding that indications for carboplatin and cisplatin were only partially overlapping. Furthermore, there was a general indication from hospitals (the main customers for these drugs) that in the case of drugs used in the treatment of serious illnesses, switching between molecules would be limited.<sup>57</sup>
204. In other cases involving oncology drugs<sup>58</sup>, the Commission considered the possibility of defining the market based on the type and stage of cancer. Those cases, however, involved originator drugs, where generic competition and molecular overlaps were less relevant. Furthermore, platinum compounds are used in a number of different cancers and they are not differentiated according to the type and stage of cancer they are used in (e.g. in terms of packaging, dosage, formulation or galenic form).
205. The parties concur with the molecule-level market definition followed in *Teva/Barr*.
206. The market investigation did not give a clear indication on whether platinum compounds can frequently and effectively substitute for each other. Whether the correct product market definition is the molecule or the ATC4 level can in any event be left open as the transaction does not raise serious doubts on either of these levels. The market investigation did not indicate frequent and effective substitution of platinum compounds with any other products than other platinum compounds. An alternative market definition, for example based on the type and stage of cancer, will therefore not be considered in the present case.
207. All platinum compounds in the markets concerned are administered in parenteral form. Oxaliplatin is available in both ready-to-use form and in powder form (which needs some preparation before use). Whether this particular distinction is relevant for market definition purposes can be left open as the parties do not overlap to this effect (Teva has a ready-to-use product, while Ratiopharm has a powder-based product).
208. All platinum compounds are prescription only.

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<sup>55</sup> *Teva/Barr, Pfizer/Wyeth*, COMP/M.3354 – Sanofi-Synthélabo/Aventis, Commission Decision of 26 April 2004.

<sup>56</sup> *Teva/Barr*, recitals 48 and 56.

<sup>57</sup> *Teva/Barr*, recital 17.

<sup>58</sup> *Sanofi-Synthélabo/Aventis* – colorectal cancer (recitals 55-58); *Pfizer-Wyeth* - Metastatic renal cell carcinoma (recitals 21-26).

209. For the purposes of the present case the market definition can be left open insofar as the distinction between the molecular, ATC4 and ATC3 level is concerned. The market investigation did not indicate the need to consider any other alternative product markets.

*Platinum compounds (L1X2) – oxaliplatin - Hungary*

210. The transaction would lead to one Group 1 market in Hungary at the ATC4 level (L1X2, all platinum compounds).

211. In Hungary the parties would have a combined market share of [30-40]% (Teva [20-30]%, Ratiopharm [5-10]%) if all platinum compounds were to be considered to belong to the same relevant product market (equivalent to the ATC4 category of L1X2). Ratiopharm only sells oxaliplatin, while Teva sells all three platinum compounds. Competitors include the originator of oxaliplatin, Sanofi-Aventis ([20-30]%) and a number of generics: Hospira ([20-30]%), Novartis (including Ebewe) and a tail end of smaller competitors including Gedeon Richter (a significant regional competitor), Merck KGA and Medac. These smaller competitors all entered in the course of 2009 with their oxaliplatin products.

212. In terms of closeness of competition, the molecular overlap between the parties is limited to oxaliplatin. All competitors sell oxaliplatin and the transaction does not give rise to a Group 1 market at the molecule level. Sanofi, Hospira and Fresenius Kabi have the same ready-to-use oxaliplatin product as Teva, while others have the powder-based product of Ratiopharm. The parties are not therefore the closest competitors in this respect. Furthermore, based on market presence, Hospira and Novartis seem to be a closer competitor to Teva than Ratiopharm.

213. The Parties' competitors were confirmed by the market investigation to be credible competitors that would constrain the merged entity. In addition, Fresenius Kabi and Egis in particular have also been mentioned as credible alternatives for oxaliplatin as well. The market investigation indicated expansion to be possible and likely to occur in case of an attempted price increase by the merged entity. The market investigation did not indicate either Teva or Ratiopharm to have any products to be of significantly better quality or significantly more efficient than other products.

214. Based on the i) relatively modest combined market shares of the parties ii) the presence of several credible competitors and possibilities of expansion; and iii) the fact that the parties are not the closest competitors the transaction is unlikely to lead to competition concerns for the possible market of both platinum compounds and of oxaliplatin in Hungary.

## **L2B – Cytostatic hormone antagonists**

*Market definition*

215. The L2B ATC3 class contains hormone-related drugs used mainly in the treatment of cancers. These drugs are mainly indicated for the treatment of cancers that have a link to the hormonal system, for example breast and prostate cancer. This is because certain organs that are often the primary sites of tumour growth are dependent upon hormones for their growth, function etc. Carcinomas arising from these organs often retain some of the hormonal responsiveness of their normal counterparts for varying periods of time.

216. The ATC3 class is divided into four ATC4 categories. The relevant ATC4 categories for the present case are L2B1 (Cytostatic anti-oestrogens) and L2B2 (cytostatic anti-androgens).
217. In the present case significant combined market shares and overlaps (Group 1 markets) arise in L2B1 and L2B2 at the ATC4 level and in bicalutamide (L2B2), flutamide (L2B2) and tamoxifen (L2B1) at the molecule level.
218. Although the use of these products is of course determined by a number of factors, as a general rule, anti-androgens and other hormone inhibitors (L2B1) are used for the treatment of prostate cancer, while anti-oestrogens and hormone inhibitors (L2B2) are used for the treatment of breast cancer.
219. More specifically, tamoxifen-based (L2B1) products are indicated for the treatment of breast cancer (and treatment of ovulatory infertility in women) while antiandrogenic bicalutamide and flutamide based products (L2B2) are indicated for the treatment of prostate cancer. Due to this fundamental difference in indications and the fact that they target different hormones, substitution between these ATC4 categories is unlikely.
220. The Commission has previously examined one drug in the ATC3 class, tamoxifen (L2B1)<sup>59</sup>. The Commission considered the molecule level to be the appropriate market definition due to the same reasons as in the case of carboplatin and cisplatin (see analysis in recital 203). The Commission did not consider market definition for other products in the wider ATC4 and ATC3 class.
221. The Parties concur with the molecular market definition adopted in *Teva/Barr* for tamoxifen and propose the same approach for the other L2B products due to their highly specialised nature.
222. All L2B drugs are prescription only. Furthermore, bicalutamide, tamoxifen and flutamide are sold in oral solid ordinary form only and this is also the case for L2B1 drugs and for the most part of L2B2 as well. A distinction based on prescription status and on galenic forms will therefore not be considered further.
223. Based on the market investigation it is not possible to draw conclusions on the substitutability of each of tamoxifen, bicalutamide and flutamide with each other and/or with other products. However, as the transaction does not raise competition concerns either at the ATC4 or the molecule level, the market definition can be left open.
224. The competitive assessment for all possible L3A markets falls within the overall framework set out at recital 386 below.

### **L3A - Immunostimulating agents excluding interferons**

225. The ATC3 class L3A comprises immunostimulating agents excluding interferons. It is sub-divided into two ATC4 categories. The ATC4 category L3A1 includes colony-stimulating factors. Colony-stimulating factors are used to stimulate the formation of blood cells, in particular white blood cells. They have a mode of action specific to this

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<sup>59</sup> *Teva/Barr*.

group of products. L3A9 includes all other immunostimulating agents in this ATC3 class.

226. The parties sell only two products in this ATC3 class. Both parties sell filgrastim, a biosimilar drug. Filgrastim is classified in the ATC4 category L3A1. The Parties do not overlap in the L3A9 segment, but Teva has an originator product in this segment used for the treatment of multiple sclerosis (MS). The brand name of the drug is Copaxone and the active ingredient is glatiramer acetate.
227. Notwithstanding that all L3A products have an action on the immune system, the Parties submit that filgrastim and glatiramer acetate have completely different indications and do not therefore belong to the same relevant market. The market investigation confirmed this. Consequently, the ATC3 level is not considered relevant for market definition purposes. Possible alternative markets relevant for the parties' L3A products are therefore considered below.

#### *Multiple Sclerosis*

228. In *Novartis/Chiron* the Commission examined markets relating to the treatment of multiple sclerosis<sup>60</sup>. Disease-modifying agents addressing the immunological causes of MS were considered to belong to a separate product market than products that relieve only the symptoms of MS. It was found in that case that there were a wide array of products from different ATC3 classes that can treat the symptoms.
229. As mentioned above, Teva sells Copaxone, a disease-modifying drug indicated for the reduction of the frequency of relapses. Ratiopharm's only product that can be used in the treatment of MS is prednisone, which is a synthetic corticosteroid. It may be used to relieve the symptoms of MS in acute attacks. It has a wide range of other uses as well, e.g. in certain auto-immune and inflammatory diseases, various kidney diseases, cancer treatments etc. The market investigation also supported the Parties' view that these products have different indications. For this reason, possible markets for MS treatments do not need to be considered further.

#### *L3A1 - Filgrastim / pegfilgrastim*

230. As mentioned above, the Parties overlap in the supply of biosimilar filgrastim (see para 28 for the description of biosimilars). This is the only biosimilar on market where the parties overlap. Filgrastim is a granulocyte colony stimulating factor (hereafter referred to as GCSF): it stimulates the production of the most important type of white blood cell when the level of this type of cell in the blood is abnormally low<sup>61</sup>. Filgrastim is applied in severe conditions. These include acute situations, where the condition is induced by chemotherapy or bone marrow transplants. However, filgrastim is also applied in severe chronic conditions (related to e.g. HIV infections).
231. The market investigation indicated that filgrastim is substitutable with lenograstim. Both drugs are GCSFs. They have the same indications and comparable efficacy and safety profiles.

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<sup>60</sup> Case COMP/M.4049 *Novartis/Chiron*, Commission Decision of 6 February 2006.

<sup>61</sup> This condition is called neutropaenia after the name of the relevant white blood cells (neutrophils).

232. Filgrastim and lenograstim are both short-acting agents. There is also a long- acting version on the market, namely pegfilgrastim. Long-acting filgrastim was developed as a second-generation product to short-acting filgrastim. It replaces multiple doses of short-acting filgrastim with one injection per chemotherapy treatment cycle.
233. It appears that from a medical point of view pegfilgrastim can effectively substitute filgrastim in a significant proportion of cases where the latter can be applied. However, there appears to be a significant minority of cases (e.g. the treatment of myeloid malignancies) where substitution is for the moment not possible.

#### *Competitive assessment*

234. The originator drug of filgrastim and pegfilgrastim is Neupogen and Neulasta respectively. Both are commercialised by Amgen. Pegfilgrastim and lenograstim are still patent protected. Filgrastim is no longer patent protected and biosimilar versions are already on the market in the EEA.
235. The Parties codeveloped filgrastim (the original agreement was made between Ratiopharm and a company that was subsequently acquired by Teva). Based on the terms of the agreement, each party has exclusive rights to commercialise the product. Initially, Ratiopharm had exclusive rights to commercialise the products in [list of countries]. However, following a period of [...],- Teva can start to distribute the product in such country through its own sales.
236. The Parties' filgrastim products were approved in the EEA in 2008. After the initial period of exclusivity, Teva is, as of 2010, free to commercialise its own product in [...] Teva's product (TevGrastim) has already been launched in Lithuania, Latvia, Estonia, Belgium, Bulgaria, Greece, France, Norway, Portugal, Romania, Spain, United Kingdom, Hungary, Italy, the Netherlands, and Slovakia. [...]
237. Besides the originator Amgen, Ratiopharm and Teva, there is one other biosimilar filgrastim product on the market in the EEA, the version of the generic subsidiary of Novartis (Sandoz), which was launched recently, after Ratiopharm's products (the Novartis product was approved in February 2009). Besides those, another credible competitor recently received marketing authorization for its filgrastim product (Nivestim).
238. The transaction gives rise to only one affected market in the UK, where the combined market share of the parties would be [20-30]% with a [5-10]% increment contributed by Teva. Amgen is still the market leader with [70-80]%. [5-10]% of the market is attributed in IMS to other generics (IMS lists these under a joint generic category without further allocating sales). The Parties consider that these sales are by Novartis, Hospira or both. In all other countries where Teva has launched their product, the originator still had most of the market in 2009. In those markets where Ratiopharm is present and Teva has recently entered<sup>62</sup>, Ratiopharm does not have high market shares<sup>63</sup>.

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<sup>62</sup> France, Hungary, Italy, Netherlands, Romania, Slovakia, Spain and Norway

<sup>63</sup> Ratiopharm's market share is the highest in these markets in Slovakia ([20-30]%), where Amgen has [70-80]% and Novartis has already entered in 2009. Ratiopharm's market share is less than [0-5]% in

239. In view of recent and/or potential entry by the Parties and competitors, the market investigation also focussed on the potential competitive pressure stemming from the Parties and competitors. The market investigation indicated to this effect that Amgen and two other generics, Novartis and a new entrant, would be credible alternatives for filgrastim.
240. Furthermore, independent third party reports<sup>64</sup> also indicate filgrastim pipelines of two other generic companies to be in an advanced stage of development.
241. In addition, it should be noted that notwithstanding the independent commercialisation of filgrastim, Ratiopharm relies on Teva for the supply of [...]. The merger does not therefore lead to significantly increased concentration at the production level for filgrastim. Competition between the parties would therefore likely have been focussed at the marketing and distribution level in the absence of the merger.
242. Besides filgrastim, both Parties also have a long-acting version of filgrastim in the pipeline. The originator version of this drug (also by Amgen) is still patent protected. The Parties are developing this product independently of each other. According to the Parties, neither of these products are biosimilars, rather they are innovative drugs. Teva's product in particular is not developed following the biosimilar regulatory pathway. It appears to use a specific technology (albumin fusion) to achieve the long acting mode of action. Ratiopharm also appears to be using a specific technology (glycoPEGylation) to transform filgrastim into a long-acting product. Both Parties plan to launch pegfilgrastim in the course of [...]. Furthermore, as indicated above, pegfilgrastim is likely to be constrained also, for some indications, by short-acting versions of filgrastim.
243. In light of the above, competition concerns do not arise due to i) the strong presence of originator products in this market ii) the pre-merger links between the parties for the development and manufacturing of filgrastim; iii) the fact that both parties are recent entrants with Teva being a very recent and, in some countries, only potential (though likely) entrant; and iv) the presence of other credible recent and/or potential entrants.

#### **L4B and L4X – Immunosuppressants<sup>65</sup>**

##### *Market definition*

244. Immunosuppressive agents are substances used to prevent the production of antibodies and are used at different stages of therapy against organ transplant rejection but also for a number of other indications such as other autoimmune diseases like rheumatoid arthritis.
245. Prior to 2010, the L4A ATC3 class comprised all immunosuppressants. Following a modification in 2010 in the classification, there are now two separate ATC3 classes for

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Italy and the Netherlands (the only other competitor in both countries is the originator product sold directly by Amgen or by parallel importers). Ratiopharm has market shares between 5% and 15% in France, Hungary, Norway and Spain. Ratiopharm is generally the number 1 generic in these markets. As of 2010, Novartis appears also to be present in France, Italy, the Netherlands, Slovakia and Spain.

<sup>64</sup> Visiongain: Biosimilars and Follow-on Biologics – The Global Outlook 2009-2024.

<sup>65</sup> 2010 classification.



the former L4A class, namely L2B (Anti TNF products) and L4X (other immunosuppressants). This division follows the distinction between immunosuppressants used in the treatment of rejection in organ transplants (L4X) and immunosuppressants used for other indications, e.g. multiple sclerosis, rheumatoid arthritis, Crohn's disease, psoriasis etc (L4B).

246. This distinction has been recognised in previous Commission decisions. The Commission considered L4A markets in its previous decisions in the *Novartis/Hexal* and *Novartis/Chiron* cases, but left the exact market definition open. In these decisions the Commission considered products used for the treatment of rejection of organ transplants and identified possible further markets for these products below the ATC3 level<sup>66</sup>.
247. All immunosuppressants are prescription products. They are predominantly sold in oral solid forms in the countries where the Parties overlap. Where they are sold both in parenteral ordinary and oral solid/liquid forms, this does not affect the competitive assessment in the present case.
248. The market definition in the present case can be left open as the transaction does not give rise to competition concerns under any possible market definition mentioned above.
249. The competitive assessment for azathioprine in the Netherlands, which is the only possible Group 1 L4B/L4X market, falls within the overall framework set out at recital 386 below.

## **M1A – Antirheumatics, non-steroidal**

### *Market definition*

250. The ATC 3 category M1A comprises drugs prescribed against various arthroarthritic diseases such as back pain, joint disorders, osteoarthritis and arthropathies.
251. The market investigation in the present case focused on ibuprofen (M1A1), for which the Parties achieve a very high combined market share in the Netherlands for the rectal systemic form for high-dosage prescriptions. This fact came to light only late in the investigation.
252. The market investigation which was carried out in relation to other molecules in the class for which such overlaps were identified nonetheless suggested that ibuprofen is only imperfectly substitutable with other medicines in the class. Although on purely medical grounds it cannot be excluded that there is a greater degree of substitutability, ibuprofen is a familiar medicine with prescribing physicians and likely to continue to be prescribed in similar quantities even if the price were to increase by 5-10%.
253. The product information leaflet for the Parties' products indicates itself explicitly that the high-dosage rectal form of ibuprofen is not recommended where the oral form can be used, because of possible local effects upon insertion. It is therefore used only

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<sup>66</sup> Primary, accompanying/adjuvante and induction immunosuppressants.

when the oral form cannot be used, for instance because of a risk of vomiting, and, as such, is not substitutable with it.

254. The Parties have acknowledged that the rectal form of ibuprofen may therefore belong to a separate relevant market.

255. The available information therefore points clearly towards a separate relevant market for rectal ibuprofen. However, the Commission is not able completely to exclude the existence of a degree of substitutability between the high-dosage rectal form of ibuprofen and other products, since this has not been tested with third Parties and the characteristics of the remaining products in the market have not been investigated. Under such circumstances, as already noted above for H2A, in its earlier *Pfizer/Wyeth* Decision the Commission considered that the relevant market could nonetheless be defined on the basis of available objective elements even if there remained some doubts due to the inability to carry out a full consultation of the market for the product in question<sup>67</sup>.

256. The assessment is therefore carried out on the basis of a distinct relevant market for rectal systemic high-dosage prescription ibuprofen in the Netherlands

#### *Ibuprofen (rectal form) – Netherlands*

257. For the high-dosage rectal systemic form of ibuprofen, the Parties achieve a [90-100]% combined market share, with only Apotex remaining as a competitor. Given, moreover, the small size of the market, new entry may not be attractive.

258. Considering also the overall strength of the Parties in the Netherlands post-merger, serious doubts arise for rectal ibuprofen in the Netherlands

259. The Parties have offered to divest Ratiopharm's product.

### **M4A – Anti-Gout preparations**

#### *Market definition*

260. The M4A class contains two main molecules, colchicine and allopurinol. Colchicine is used for acute gout attacks, whereas allopurinol is used to treat chronic gout.

261. The market investigation has therefore confirmed the relevance of the molecule level for colchicine as a market definition in the Netherlands. For the other countries where affected markets arise, the market definition can be left open as serious doubts do not arise.

#### *Colchicine – Netherlands*

262. The Parties achieve a combined share of [70-80]% for the molecule. There would remain post-merger two other generics in the market, Mylan ([10-20]%) and Actavis ([5-10]%).

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<sup>67</sup> *Pfizer/Wyeth*, recital 403.

263. This reduced level of remaining competition, coupled with the distribution strength of the Parties in the Netherlands post-merger as indicated in section IV.1, leads to the conclusion that serious doubts arise in respect of colchicine in the Netherlands.
264. The Parties have offered to divest Ratiopharm's product.

## **N2A - Narcotics**

### *Market definition*

265. Narcotics are powerful analgesics, classified as such in accordance with legal definitions in each country.
266. Within the N2A class, fentanyl is a powerful synthetic opiate analgesic similar to but more potent than morphine. It is typically used to treat patients with severe pain, or to manage pain after surgery. It is also sometimes used to treat people with chronic pain who are physically tolerant to opiates. The market investigation has indicated that fentanyl is not substitutable from a demand perspective with other molecules due to its specific analgesic profile.
267. The galenic form of fentanyl predominantly used is of slow-release patches. The market investigation has suggested that the market might be defined more narrowly still, at the level of this galenic form, to which the products of both Parties belong. However, this can be left open as on either market definition, serious doubts arise.
268. Accordingly a relevant market arises in the Netherlands for fentanyl or more specifically for slow-release fentanyl administered by patches. Remaining issues of market definition in the N2A class can be left open as regardless thereof, serious doubts in other markets do not arise.

### *Fentanyl – Netherlands*

269. The Parties achieve a combined share of [30-40]% in the molecule fentanyl in the Netherlands, rising to [50-60]% by weight. There is one significant other competitor, the originator Johnson and Johnson (J&J). Sandoz ([10-20]% by value) and Actavis ([0-5]% by value) are also present in the market.
270. The galenic form predominantly used is of slow-release patches. On the basis of a definition of the market on galenic form, the combined market share of the Parties by value would be at least [40-50]%, with [30-40]% for J&J<sup>68</sup>.
271. [...] Ratiopharm has grown its market share very significantly in recent years, from [5-10]% by value on fentanyl overall in 2007 to [20-30]% in 2009, and in 2009 sold more of the product than Teva (which achieved [10-20]% by value). It therefore constitutes clearly the most important independent competitive force in the market for this form of fentanyl.

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<sup>68</sup> The exact market share depends on the galenic form of the products of some minor competitors, which the Commission was not able to verify within the timeframe of its investigation.

272. As a result, the merger would eliminate the most important competitive force in the Dutch market for fentanyl/slow-release fentanyl. It follows that serious doubts arise.
273. The Parties have offered to divest Ratiopharm's product.

## **N2B – Non-narcotic analgesics and antipyretics**

### *Market definition*

274. 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.
275. Certain drugs have, in addition to analgesic and antipyretic properties, anti-inflammatory properties. In the IMS classification, anti-inflammatory analgesics used for both musculo-skeletal conditions and analgesia are, in principle, classified in M1A.
276. In its decision in *Hoechst/Rhône-Poulenc*<sup>69</sup>, 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.
277. In *Sanofi-Aventis/Zentiva*, the market investigation suggested that the OTC/prescription distinction was a relevant one in all of the countries concerned by that transaction<sup>70</sup>, and further left the market definition open.
278. In the current case, the Parties overlap in a variety of molecules, but notably at the level of the molecule tramadol in Hungary. The market definition has shown that the indications of tramadol are specific in the treatment of moderate to severe pain such that it is not readily substitutable with other molecules for most patients. Accordingly, a relevant market for products based on tramadol in Hungary can be identified.
279. The market investigation further considered the division of this molecule by galenic form, and in particular the oral solid ordinary, oral liquid and parenteral forms in which the Parties have an even higher combined market share. Whilst in principle these are likely to constitute separate relevant markets, however, this can be left open in the context of the present case as in any event serious doubts arise.
280. It is not necessary to conclude as to any other possible subdivisions of the N2B market, as, in all other cases, serious doubts do not arise regardless of the market definition considered.

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<sup>69</sup> Case IV/M.1378 Hoechst/Rhône-Poulenc, Commission Decision of 9 August 1999.

<sup>70</sup> Recital 150.

## *Tramadol – Hungary*

281. Considering all galenic forms of tramadol, the Parties would achieve a combined market share of [60-70]% by value, with a couple of small competitors and one big one, Novartis ([20-30]%). Based on galenic form, these market shares are significantly higher still (oral solid ordinary: [80-90]% with a Ratiopharm increment of [30-40]%; oral liquid [90-100]% with a Ratiopharm increment of [5-10]%; parenteral ordinary [90-100]%, with a Ratiopharm increment of [30-40]%).
282. This market structure appears to be in part explained by the originator and branded nature of the Teva product, Contramal, which is a market leader for all galenic forms. Overall, Novartis achieves the highest generic turnover in the molecule, but mainly in the long-acting oral form (where Zentiva is also present). For all other galenic forms, it is clear that the Parties are each other's closest competitors.
283. As indicated in the earlier *Sanofi-Aventis/Zentiva* decision, 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.<sup>71</sup>
284. The market investigation has confirmed that the transaction is likely to remove the incentive for Teva to promote Ratiopharm's generic version of Contramal given the importance of this generic competitor and the premium positioning of its own originator product. It follows that serious doubts arise in a market for tramadol in Hungary, regardless of further subdivisions by galenic form.
285. The Parties have offered to divest the marketing authorization for the Ratiopharm products.

## **N3A – Anti-epileptics**

### *Market definition*

286. 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.
287. In its decisions in *Sanofi-Synthélabo/Aventis* and *UCB/Schwarz Pharma*<sup>72</sup>, 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.
288. The market investigation in the present case focused on the molecule gapapentin and was inconclusive as to whether or not the relevant market should be defined at this level, with a number of respondents arguing that clinicians would not switch patients who were stable on the drug, with one respondent suggesting that this would even apply to

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<sup>71</sup> Recital 20.

<sup>72</sup> Case No COMP/M.4402 - UCB/Schwarz Pharma, Commission Decision of 21 November 2006.

switching from the originator to a generic version. On the other hand, it was also suggested that other drugs acting on the GABA pathway might be considered substitutes, at least at the moment of initial prescription.

289. 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.

290. The competitive assessment for all possible Group 1 markets for N3A falls within the overall framework set out at recital 386 below.

## **N5A – Anti-psychotics**

### *Market definition*

291. 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.

292. In its decision in *Sanofi-Synthélabo/Aventis*, 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.

293. 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.

294. The competitive assessment for all possible Group 1 markets for N5A falls within the overall framework set out at recital 386 below.

## **N5B – Hypnotics/Sedatives**

### *Market definition*

295. The market investigation in the present case focused on the specific case of phenobarbital in the Netherlands, and of barbiturates more generally, of which phenobarbital is the only molecule marketed in the Netherlands.

296. Phenobarbital is a highly addictive old-generation sedative drug. In its Decision in *Sanofi-Aventis/Zentiva*, the Commission noted that barbiturates formed part of a separate market from other hypnotics and sedatives due to their addictive character.

297. The market investigation in the present case has confirmed that phenobarbital it is only prescribed in restricted circumstances in the Netherlands, including sometimes in palliative care.

298. Accordingly, a separate market arises for barbiturates. It can be left open whether the correct market definition is at the molecule or ATC4 level since there is only one molecule in the ATC4 class in the Netherlands.

### *Barbiturates (N5B3) – phenobarbital - Netherlands*

299. The transaction results in a merger to monopoly based either on the molecule or ATC4 class. Given, moreover, the small size of the market, new entry may not be attractive.
300. Considering also the specific position of the Parties in the Netherlands post-merger, it can be concluded that serious doubts arise for phenobarbital in the Netherlands.
301. The Parties have offered to divest the marketing authorization for the Ratiopharm product.

### **N6A – antidepressants and mood stabilizers**

#### ***Market definitions***

302. The N6A class is further subdivided in the EphMRA classification between herbal antidepressants (N6A1), mood stabilizers (N6A3), SSRI antidepressants (N6A4), SNRI antidepressants (N6A5) and other antidepressants (N6A9).
303. The market investigation looked more closely at the case of imipramine, mianserin and lithium in the Netherlands, moclobemide in the UK and citalopram in Norway.

#### *Imipramine*

304. Imipramine (N6A9) is a tricyclic antidepressant (TCA) of the dibenzazepine group mainly used in the treatment of major depression and enuresis (inability to control urination).
305. In recent times, TCAs have been largely replaced in clinical use in most parts of the world by newer antidepressants such as the selective serotonin reuptake inhibitors (SSRIs) and serotonin-norepinephrine reuptake inhibitors (SNRIs), among others, though they are still sometimes prescribed for certain indications. The progressive replacement of these molecules has been confirmed for the Netherlands by the market investigation.
306. Imipramine is the only dibenzazepine TCA available in the Netherlands and therefore the analysis is the same at the level of all dibenzazepine TCAs.
307. The market investigation has not indicated unambiguously whether or not either imipramine itself, or dibenzazepine TCAs more generally, constitute a relevant product market. It therefore remains open whether or not the market should be defined at this level.

#### *Mianserin*

308. Mianserin (N6A9) is a psychoactive drug of the tetracyclic antidepressant (TeCA) which is classified as a noradrenergic and specific serotonergic antidepressant (NaSSA) and has antidepressant, anxiolytic, hypnotic, antiemetic, orexigenic, and antihistamine effects. In most markets it has been phased out in favor of its analogue and successor mirtazapine.

309. The market investigation has confirmed that the use of mianserin is now marginal in the Netherlands and that if the price were to rise, switching towards the newer drug would be expected to take place. Due to the importance of the competitive constraint from the newer mirtazapine, it can thus be excluded that a relevant market arises for mianserin in the Netherlands.

#### *Lithium*

310. [...] the overlap in oral solid ordinary lithium in the Netherlands [was identified] only at a late stage of the procedure. A preliminary survey of the medical literature suggests to the Commission that lithium occupies a specific position within the class which is unlikely to be substitutable with other molecules.

311. Lithium would not give rise to a Group 1 market if also slow-release oral forms were included in the relevant market. The Parties initially suggested that such an approach would be appropriate, but subsequently acknowledged that, whilst maintaining that short-acting and long-acting forms of the same molecule are generally interchangeable, this may not be the case for lithium-based products. The lack of substitutability would result from the very high toxicity of the product, as a result of which when lithium is prescribed to new patients and treatment has not yet stabilized, general practitioners need to closely monitor lithium dosage by taking frequent blood tests. As it is considerably more difficult to monitor the dosage of the long-acting form, general practitioners, in the view of the Parties, generally do not prescribe the long-acting form to new patients and choose the short-acting form instead. As a result, there is a specific demand for the short-acting form which would not be materially affected by a change in relative price.

312. These views expressed by the Parties correspond with the insistence noted by the Commission in the medical literature on the importance of carefully monitoring and controlling lithium serum levels for some patients, and so appear to be reasonable *a priori*.

313. The available information therefore points clearly towards a separate relevant market for immediate-release lithium. Nonetheless, the Commission is not able completely to exclude substitutability at either the molecule or galenic form level, since it has not been possible in the framework of the phase one procedure to carry out a full market investigation for this product due to the overlap having been identified only at a late stage.

314. Under such circumstances, as already noted above for H2A and M1A, in its earlier *Pfizer/Wyeth* Decision the Commission considered that the relevant market could nonetheless be defined on the basis of available objective elements even if there remained some doubts due to the inability to carry out a full consultation of the market for the product in question<sup>73</sup>.

315. The assessment is therefore carried out on the basis of a distinct market for immediate-release lithium in the Netherlands.

#### *Moclobemide*

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<sup>73</sup> *Pfizer/Wyeth*, recital 403.



316. Moclobemide (N6A9) is a reversible inhibitor of monoamine oxidase A (RIMA). It acts on serotonin, norepinephrine (noradrenaline), and dopamine.
317. Prescriptions of the molecule in the UK are very limited and the market investigation has shown that it is largely replaced by newer alternatives, to which, in the event of a price rise, switching would be likely to occur.

#### *Citalopram*

318. Citalopram is an SSRI originally developed by Lundbeck. The market investigation has shown that the appropriate market definition was likely to be at the molecule level, in particular because the molecule is well-established and familiar to both patients and doctors. Generic citalopram clearly targets prescriptions of the originator and is not targeted at the replacement of other originator molecules. However, the exact market definition can nonetheless be left open for the purposes of the present decision.

#### *Conclusion on N6A antidepressants*

319. In conclusion, with the exception of mianserin and lithium in the Netherlands and moclobemide in the UK, all other market definitions in respect of this class can be left open for the purposes of the present decision, as serious doubts do not arise for such products, regardless of the market definition.

#### *Assessment*

##### *N6A – antidepressants – N6A4 – citalopram – Norway*

320. If the molecule were considered the relevant market, the Parties would achieve a combined market share of [50-60]% and would be the only generic competitor actively on the market (a few others have dormant marketing authorizations). The rest of the market is represented by the originator product, directly marketed by the originator, Lundbeck ([20-30]%) and parallel imported by Farmagon. By weight, the Parties achieve [80-90]%. This disparity is explained, according to the Parties, by the fact that generic citalopram is significantly cheaper in Norway than the originator version. The existence of such a price differential is evidence that there remains considerable brand loyalty to the originator version.
321. The Parties have, however, indicated and provided evidence from internal documents that Ratiopharm had already decided to withdraw its product, [...]
322. This notwithstanding, it could not be excluded that the existence of a marketing authorization (MA), and the presence on the market of Ratiopharm, continued to exercise a competitive constraint on Teva in the absence of the merger which would no longer exist subsequently.
323. At the same time, the presence on the market of two competitors (Actavis and Novartis) with dormant MAs suggests that at this point in time, these other competitors might play a similar role to Ratiopharm<sup>74</sup> and that divestment of the MA would not alter the competitive situation because it is primarily explained by a competitive advantage which Teva already had in this market prior to the merger [...]

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<sup>74</sup> [...].

324. In light of the above, it can therefore be concluded that serious doubts do not arise on the Norwegian market for citalopram.

*N6A9 – moclobemide – UK*

325. If the molecule were to be considered the relevant market, the Parties would achieve a combined market share of [50-60]% by value (Teva [50-60]%, Ratiopharm [5-10]%) and [70-80]% by weight (Teva [60-70]%, Ratiopharm [5-10]%). There is one significant other competitor, Meda, with [30-40]% market by value, and Sandoz is also present with [5-10]%. Several other competitors have an MA and a low level of sales.

326. The Parties have indicated and provided evidence from internal documents that Teva had previously decided to exit the market for moclobemide in the UK, [...] On the relevant counterfactual, therefore, Ratiopharm would remain on the market but there would be competition for the share given up by Teva. Owing to the fact that Ratiopharm's initial market share was anyway very low, there can be no presumption that Teva's ability to reenter the market, if any, constitutes a competitive constraint specifically on Ratiopharm, the removal of which could lead to an impediment to competition, since any of the other competitors would be similarly placed to compete.

327. It follows that serious doubts do not arise on the UK market for moclobemide.

*N6A9 – imipramine – Netherlands*

328. The Parties achieve a combined market share of [70-80]% at the molecule level and there is only one other competitor, Stada. Imipramine is the only dibenzozapine TCA available in the Netherlands and therefore the analysis is the same at the level of all dibenzozapine TCAs.

329. The Parties have in any case indicated that Ratiopharm's sales of this product to date in 2010 have been minimal ([...]€ of turnover only) and that it has discontinued production in the circumstances referred to in recital 36 above.

330. It follows that on the basis of the relevant counterfactual there is no overlap and serious doubts do not arise.

*N6A9 – lithium – oral solid ordinary form – Netherlands*

331. The notified transaction results in a merger to monopoly in short-acting oral lithium in the Netherlands. If the slow-release oral form were to be considered part of the same market, the Parties would achieve a combined market share of [20-30]% by volume with two other large competitors (Norgine [40-50]%, Sanofi-Aventis [20-30]%). Even on this basis, they would be each others' closest competitor.

332. Given moreover the small size of the market, as a result of which new entry is unlikely to be attractive, and the combined strength of the Parties overall in the Netherlands as a result of the transaction, it follows that serious doubts arise for the oral solid ordinary form of lithium in the Netherlands.

333. The Parties have offered to divest Ratiopharm's product.

### **R3C – Non-steroidal respiratory anti-inflammatories**

#### *Market definition*

334. This group contains respiratory antihistamines and non-steroidal respiratory anti-inflammatory products. R3C1 comprises inhalants and R3C2 systemic forms.
335. In *Astra/Zeneca*<sup>75</sup>, the Commission indicated that products for asthma treatment, classified in ATC class R2, could be categorized into longterm (prophylaxis) and short-term (symptomatic) treatment products.
336. The Parties overlap for prophylaxis products in the Netherlands. For such products, the Commission has left open whether it consisted of a variety of classes namely (i) ATC 3 classes R3A (B2 stimulants, i.e. long acting B2 stimulants salmeterol and formeterol), R3D (corticoids), R3C (non-steroidals respiratory anti-inflammatories), R3J (anti-leukotriene anti-asthmatics) and R3B (xanthines, i.e. theophylline); or (ii) all of the above, plus categories R3E (combination with non-steroidals respiratory anti-inflammatories) and R3F (combinations of B2 stimulants with corticoids).<sup>76</sup> The Parties submit that this is the case. However, with the exception of ketotifen in oral liquid form as indicated below, the market definition can be left open for the purposes of the present case since, regardless of the precise market definition, serious doubts do not arise.
337. The market definition in the present case looked more specifically, however, at the case of ketotifen in the Netherlands due to the Parties' combined position in this product.
338. Although overall sales of this molecule are low relative to the class, ketotifen is important in oral liquid form for the prevention of asthma attacks in pediatric patients. The Parties have only this galenic form. The solid form is little used, but in any case not by the same patient group.
339. Although, as indicated, in previous cases the Commission has considered a market definition for asthma prophylaxis which also included other ATC3 classes within the overall R3 category, regardless of whether the market definition is based on the ATC4, ATC3 or even ATC2 class in combination with the oral liquid galenic form, serious doubts would arise. In category R3C2, only ketotifen is present in the Netherlands.
340. It follows that a relevant market exists in the Netherlands which is no wider than all oral liquid medications for the prevention of asthma attacks in pediatric patients. It can be left open whether or not there is a further need to subdivide this market since, regardless of the molecules considered to form part of this market, serious doubts arise in the Netherlands.

#### *R3C2 – ketotifen – Netherlands*

341. The Parties achieve a [60-70]% combined market share by value in the ATC4 category R3C2 for oral liquids. Actavis and Stada are also present in oral liquid

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<sup>75</sup> Case COMP/M.1403, Commission Decision of 26 February 1999.

<sup>76</sup> See Case COMP/M.5502 - Merck/Schering Plough, Commission Decision of 22 October 2009, recitals 24-28; Case COMP/M.1846 Glaxo Wellcome/Smithkline Beecham, Commission Decision of 8 May 2000, recitals 153-158; *Astra/Zeneca*, recitals 41-42.

ketotifen ([10-20]% and [10-20]% by value respectively). The market shares and market structure are not substantially different considering a market for oral liquids at ATC3 or even ATC2 level.

342. Given moreover the distribution strength of the Parties in the Netherlands post-merger, it follows that serious doubts arise on the Dutch market for oral liquid medications for the prevention of asthma attacks in pediatric patients, whether or not further limited at the ATC3, ATC4 or molecule level.

### **R3D – Corticoids – Germany (Rx) and the Netherlands**

#### *Market definition*

343. Corticoids are products used for prophylactic (i.e. preventive) and long-term management of asthma. They are required to be taken on a regular basis (i.e. daily) as part of a preventative treatment regimen.

344. The Parties submit that the molecule beclomethasone is highly substitutable with several other molecules belonging to the R3D category, such as budesonide, flunisolide, fluticasone, mometasone, prednisone, and prednisolone, in accordance with the DrugDex evaluations<sup>77</sup>. Thus the market investigation in the present case looked at the molecule beclomethasone and its alleged substitutability with other molecules.

345. Beclomethasone is used for the prophylaxis of asthma. As a nasal spray, it is also used for the treatment of rhinitis (e.g. hay fever) and sinusitis.

346. At ATC3 or ATC4 level, the combined market share of the parties in Germany is below 35% and in the Netherlands no affected market would arise. Therefore, serious doubts would not arise if ATC3 or ATC4 were the relevant product market.

347. The market investigation did not give rise to a clear consensus on the question of whether the molecule beclomethasone should be considered to be in a relevant market of its own or other molecules, in particular certain other inhaled glucocorticoid steroids, could be included in this market, with a majority of respondents indicating that beclomethasone had specific indications rendering it not substitutable, though some argued that other inhaled glucocorticoids were possible substitutes.

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<sup>77</sup> Drugdex evaluations (March, 3, 2010) indicates, inter alia that : “Short-term trials have demonstrated that budesonide is as effective as beclomethasone in the treatment of asthma”; “In a critical review, the efficacy and safety of 3 aerosolized corticosteroids available in the United States (beclomethasone dipropionate, triamcinolone acetonide, flunisolide) were compared (Johnson, 1987a). Despite differences in the specific pharmacologic effects of these agents, none appear to confer any clinically significant advantage or disadvantage over the others.” ); “ In a randomized, double-blind study of 227 patients with moderate persistent asthma, mometasone furoate was equally as effective as beclomethasone dipropionate during a 12 week study period”.” Beclomethasone dipropionate 1200 mcg daily by inhalation was as effective as oral prednisone (prednisolone equivalent) 12.5 mg daily in improving pulmonary function for 18 patients with chronic asthma in a single-blind study”; “Beclomethasone (BDP) and triamcinolone (TA) were comparable for treating asthma in adults; they were significantly more effective than placebo (Berkowitz et al, 1998).” Drugdex evaluation is a US database that provides evidence-based evaluations of drugs.

348. Given the responses to the market investigation, there appear to be sufficient grounds to make a market definition at the molecule level more likely than not. In the Netherlands, serious doubts would arise on the basis of a market defined at the molecule level. In the remaining instances, in particular in Germany, the market definition can be left open as no serious doubts arise regardless of the exact product market definition.

#### *Beclomethasone – Netherlands*

349. At molecule level, by value the Parties achieve a combined [80-90]% market share. Teva has a branded originator (Qvar) as well as a generic version which is identically priced. The branded version accounts for about [60-70%] of Teva's sales. At [0-5]% by value, the increment in the molecule share due to Ratiopharm would appear limited and it has been declining somewhat since 2007 ([0-5]%). Sandoz is the main competitor with [5-10]% and has been growing somewhat from [5-10]% in 2007.

350. Despite being the originator, Teva has grown its market share since 2007 from [70-80]% to [80-90]% in 2009 by value and therefore can be said to have a very strong position on the market.

351. The Ratiopharm inhalable product, similar to that of Novartis, is positioned as much cheaper than Teva's, at only [40-50]% of the price. For this reason, market shares by weight show Ratiopharm with [5-10]% and Novartis [10-20]%, while Teva has [70-80]% and no other competitor is above [0-5]%.

352. Beclomethasone is used for the prophylaxis of asthma. As a nasal spray, it is also used for the treatment of rhinitis (e.g. hay fever) and sinusitis. The Parties achieve a [40-50]% combined market share for this galenic form, which represents about [10-20]% by value of the overall class. Only Novartis is present as a competitor, with [50-60]%.

353. In view of the Parties' combined market share, their overall position in the Netherlands post-merger, and the elimination of a significant and much cheaper independent generic alternative to Teva's branded product, leaving only one important competitor, Novartis, on the market<sup>78</sup>, it can be concluded that serious doubts arise on the Dutch market for beclomethasone regardless of whether or not the market is subdivided by galenic form.

354. The Parties have offered to divest Ratiopharm's products based on beclomethasone in R3D in the Netherlands.

#### *Beclomethasone – Germany*

355. In Germany, if the molecule beclomethasone were considered the relevant market, the Parties would achieve a combined market share of [60-70]%.<sup>79</sup> However, there are two other big generic competitors active in this market: Chiesi ([10-20]%) and Astellas ([10-20]%) and a number of smaller competitors which will sufficiently constrain the merged entity. Furthermore, Novartis, which is the strongest generic pharmaceutical group in Germany, with approximately [40-50]% of the prescription-bound generic market, has

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<sup>78</sup> cf *Sanofi-Aventis/Zentiva*, recital 20.

<sup>79</sup> The parties' combined market share would be comparable in case of a distinction by galenic form.

considerable sales of beclomethasone-based products in the neighbouring Member States and would have the ability to increase output in the event of a price increase by the Parties.

356. According to the respondents to the Commission's market investigation, in this specific instance, the parties would be additionally constrained by the regulatory environment in Germany (in particular the existence of tenders and so-called rebate contracts between insurers and generic producers) as well as parallel imports. Lastly, the market investigation has not pointed to any competition concerns in the possible product market at the molecule level. On this basis, serious doubts can be excluded.

## **R5C – expectorants - Hungary**

### *Market definition*

357. The R5C class includes all cough preparations (in all galenic forms) with an expectorant as the main ingredient.

358. An affected market would arise on the OTC segment in Hungary if the molecule ambroxol were considered the relevant market. At the ATC3, ATC4 or broader level the combined market share of the Parties would remain well below 35%.

359. The Parties submit that all R5C products have the same use and mode of action and compete with each other. In particular, the Parties submit that ambroxol-based products compete with several other molecules belonging to the same ATC3 class, such as acetylcysteine, carbocisteine, and bromhexine.

360. The market investigation has indeed shown that other molecules are substitutable for ambroxol and accordingly for the purpose of this decision, the Commission concludes that products based on ambroxol should not be considered as a separate product market. For the rest, the exact product market definition can be left open as no serious doubts arise regardless of the precise product market definition.

## **R6A – Systemic antihistamines**

### *Market definition*

361. R6A comprises all antihistamines, plain or in combination, excluding antihistamines used in combination with decongestants, which are classified in R1B. Systemic antihistamines are indicated in the treatment of allergic rhinitis and urticaria.

362. 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.

363. The market investigation in *Sanofi-Aventis/Zentiva* 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<sup>80</sup>.

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<sup>80</sup> Recital 173.

364. The market investigation in that case also indicated that products based on the molecule fexofenadine should not be considered as a separate relevant market. Products based on that molecule were considered substitutable with other second-generation antihistamines based on different molecules. For the purposes of that decision, it could therefore be excluded that the molecule level was the correct market definition.
365. In this case, both parties manufacture loratadine-based products. This molecule can be used to treat allergies and is marketed for its non-sedating properties. When used in combination with decongestants (R1B), loratadine can help to treat colds as well as allergies, but can have potential side-effects of insomnia, nervousness, and anxiety. Its indications are seasonal allergic rhinitis and perennial allergic rhinitis as well as skin allergies including chronic urticaria.
366. An affected market would arise on the RX segment in Slovakia only if the molecule loratadine were considered the relevant market. The market investigation has nonetheless shown that other molecules, such as desloratadine and levocetirizine, are substitutable for loratadine.
367. Having established that the correct market definition is not to be found at the level of fexofenadine, 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.

### **S1F (Rx) – Mydriatics and Cycloplegics**

#### *Market definition*

368. The S1F class is a part of broader category of ophthalmologicals. The S1F class contains products used to temporarily paralyze accommodation or to dilate the pupil. This class is not divided into further ATC 4 classes. It includes molecules such as parasympatholytics, i.e. products which paralyse the parasympathetic nervous system of the pupil (e.g. atropine, cyclopentolate, homatropine, tropicamide) and sympathomimetics which mimic the effect of the sympathetic nervous system (e.g. phenylephrine, tyramine). The Parties' high market shares in this class in the Netherlands are due to their presence with the molecule atropine.
369. The Parties submit that all the S1F products perform similar functions and therefore are substitutable and that the transaction should be assessed at the level of ATC 3 class. However, the market investigation indicated that the molecule level is more appropriate for the assessment of the present operation, especially with relation to atropine in the Netherlands, where the Parties achieve very high combined market shares.
370. The market investigation indicated strong loyalty on the part of ophthalmologists to atropine in the Netherlands (which has been present for a long time on the market and is traditionally used to dilate the pupil in ophthalmological examinations). It also indicated a low likelihood to change to different molecules within the same ATC3 (e.g. tropicamide, cyclopentolate) class for dilating the pupil. In addition, the length of activity of these molecules is different and therefore atropine is used most commonly in ophthalmological examination.
371. What is more, atropine- based products can be delivered in different packages as different solutions, i.e. atropine as eye-drops based on a non-sterile solution with preservative (packed in multi-dose package) which is used for diagnostics on the one

hand and atropine as eye-drops based on a sterile packed solution without preservative (as eye-unit dose) which can be used also for surgical conditions on the other hand. For the assessment of this transaction, it can be left open whether these different solutions constitute the same product market or belong to different markets.

372. However, as explained above, in the present case it has to be concluded that the ATC 3 class S1F is not the relevant market for the assessment of the transaction and that for the purpose of this decision the market shall be assessed at the molecule level in the Netherlands, i.e. atropine.

#### *Netherlands*

373. The transaction leads to a very high combined market share of the Parties at the molecule level, i.e. on the market of atropine ([90-100]% on the molecule level with an increment of [5-10]% due to Ratiopharm) with one competitor remaining (Bausch and Lomb, [0-5]%).<sup>81</sup>

374. In the Netherlands, all atropine-based products are sold on prescription only. The Parties' product is a different formulation than the product of Bausch and Lomb, which is designed for use in surgical situations only. Therefore, the Parties would achieve a combined market share of [90-100]% if the market were to be further subdivided based on such a distinction. However, for the purpose of this decision it can be left open whether such a distinction would be appropriate for the assessment of the transaction since serious doubts arise on either market definition.

375. It results from the above that the transaction will lead to serious doubts.

#### **10B1 – Systemic antivaricose**

376. The Parties are both active in 10B1 medicaments based on troxerutin. An overlap arises only for the oral solid ordinary galenic form. Teva produces Venotrex and Ratiopharm produces Troxeratio.

377. 10B1 is an OTC category specific to a number of countries, which contains medicaments targeted at the systemic treatment of varicose veins. This category is listed in the IMS Self Medication database, which is an additional medication database, available *inter alia* in Poland, and lists a self medication market with medicinal products available without prescription (OTC) and other self medication categories (medical devices, dietetics, cosmetics and other).

378. The 10B1 category contains different molecules which are, according to the Parties, targeted at the treatment of varicose veins. It has to be noted that the pharmaceuticals targeted at the treatment of varicose veins are also listed under the Ephmra classification under C5C – products used for systemic treatment of varicose veins and recommended for the treatment of diseases of the veins. The C5C class in Poland is not affected by the current transaction.

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<sup>81</sup> Bausch and Lomb 'Minims' branded products are specifically designed for use in ocular surgery. They are packaged as single dose eye-drops containing no preservatives.



379. The market investigation confirmed that many molecules of different classes (i.e. of 10B1 as well as of C5C) could be substitutable for the treatment of varicose veins, especially when it comes to OTC products, which are usually recommended by pharmacists and therefore the degree of substitutability is higher.
380. According to the market investigation, medicines based on troxerutin constitute only a limited part of the market for varicose veins treatment. What is more, troxerutin is considered an "old generation" molecule that is currently being replaced by molecules such as diosmin; therefore the market for troxerutin-based pharmaceuticals is declining.
381. For the purpose of the assessment of this transaction, the market definition can be left open since the transaction does not lead to serious doubts under any alternative market definition.

#### *Poland*

382. If the whole 10B1 category in Poland was taken into account, the combined market share of the Parties would be relatively small ([10-20]% with an increment of [0-5]% due to Ratiopharm). There exist a number of competitors in this category such as Lek-Am with Diosminex ([30-40]%) or Pierre Fabre with Cyclo 3 Fort ([10-20]%) and Solvay with Phlebodia ([10-20]%).
383. Based on the molecule level, the Parties achieve a combined market share of [60-70]% (increment [20-30]% due to Ratiopharm) and there will still remain two competitors Synteza ([20-30]%) and Gedeon Richter ([10-20]%) for pharmaceuticals based on the same molecule.
384. The market investigation indicated that the barriers to entry are low on this market and that the remaining competitors' products are substitutable to the products of the Parties.
385. In the view of the above it can be concluded that the transaction does not lead to serious doubts regarding the 10B1 market in Poland.

#### **Markets with a combined market share in excess of 35% which nonetheless can be cleared based on sufficient generic competition**

386. For the following possible Group 1 markets, the Parties' joint market share does not lead to an excessive concentration in the market and there remain at least three generic providers with at least 5% market share each (both by value and volume), each with a substantial presence in the country concerned in terms of a portfolio of products in the same therapeutic area. The Commission has individually assessed each of these markets, but in view of the commonality of the reasoning which applies, is nonetheless able to present the conclusion that serious doubts do not arise in a summary format.

- A2B – A2B1 – cimetidine, lansoprazole (oral solid) and famotidine – Netherlands
- A3F – metoclopramide (oral solid) – Netherlands
- A6A – lactulose – Netherlands
- A7E – sulfasalazine – Netherlands
- A10H – glibenclamide and tolbutamide – Netherlands
- A10J – A10J1 – metformin – Netherlands
- B1A – acenocoumarol – Netherlands

- B1C – B1C1 – acetylsalicylic acid (low dosage) – Netherlands
- B3A – B3A1 – iron ferrous – Netherlands
- B3X – folic acid, OTC segment – Netherlands
- C3A – C3A2 – amiloride – Netherlands
- C3A – C3A5 – chlortalidone, indapramide and spironolactone – Netherlands
- C7A – acebutolol, atenolol, pindolol, pronanolol, sotalolol – Netherlands
- C7B – atenolol chlortalidone – Netherlands
- C8A – amlodipine, nifedipine, verapamil – Netherlands
- C8A – felodipine – Czech Republic, Hungary, Netherlands, Slovakia
- C8A – nifedipine – Estonia
- C9A – captopril, enalapril, fosinopril – Netherlands
- C9B – captopril and lisinopril with hydrochlorothiazide – Netherlands
- C10A – gemfibrozil – Netherlands
- C10A – simvastatin – Slovakia, Finland, Lithuania
- D1A – D1A3 – ketaconazole – Netherlands
- D6A – sulfadiazine – Netherlands
- D7B – D7B2 – hydrocortisone miconazole – Netherlands
- D10B – cyproterone ethinyl estradiol – Netherlands
- G1A – G1A1 – metronidazole (including oral solid) – Netherlands
- G4A – G4A9 – nitrofurantoin – Netherlands
- G4A – G4A9 – methionine, OTC segment - Germany
- G4C – alfuzosin – Netherlands
- G4C – G4C1 – tamsulosin – Slovakia
- H2A – H2A2 – prednisolone and prednisone – Netherlands
- J1 oral solids – Netherlands
- J1A – minocycline and doxycycline – Netherlands
- J1C – J1C1 – amoxicillin plus clavulanic acid (including oral solid) – Netherlands
- J1E – trimethoprim and sulfamethoxazole – Netherlands
- J1F – azithromycin – Czech Republic
- J1F – clindamycin and clarythromycin (oral solid) – Netherlands
- J1G – J1G1 – ciprofloxacin<sup>82</sup>, norfloxacin and ofloxacin – Netherlands
- J1H – J1H1 – flucloxacillin – Netherlands
- J2A – terbinafine and fluconazole – Netherlands<sup>83</sup>
- L2B – L2B1 – tamoxifen – Netherlands
- L2B – L2B2 – bicalutamide – Sweden
- L2B – L2B2 – flutamide – Netherlands
- L4B/L4X – azathioprine – Netherlands
- M1A – M1A1 – diclofenac, indometacin, ketoprofen, meloxicam and naproxen – Netherlands
- M3B – baclofen – Netherlands
- M4A – allopurinol – Netherlands
- M5B – M5B3 – alendronic acid – Hungary, Poland and Slovakia

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<sup>82</sup> In ciprofloxacin the fourth generic provider would have less than 5% market share, but is a credible competitor, namely Mylan.

<sup>83</sup> The same conclusion applies on the basis of a segmentation of the market for systemic antifungales between products used to treat mild, moderate and severe infections.

- N2A – morphine – Netherlands<sup>84</sup>
- N2B – N2B1 – paracetamol plus codeine – Netherlands<sup>85</sup>
- N3A – gabapentin – Netherlands, UK and Italy<sup>86</sup>
- N5B – N5B1 – flunitrazepam, lormetazepam, nitrazepam, temazepam, zolpidem and zopiclone – Netherlands<sup>87</sup>
- N5C – bromazepam, chlordiazepoxide and oxazepam – Netherlands<sup>88</sup>
- N6A – N6A9 – clomipramine, maprotiline, moclobemide, mianserin<sup>89</sup> – Netherlands
- N6A – N6A9 – moclobemide and dosulepin – UK<sup>90</sup>
- N6A – N6A9 – mianserin – Germany
- N6A – N6A4 – fluoxetine – Sweden
- N7C – cinnarizine and betahistine – Netherlands
- R6A – fexofenadine – oral solid – Netherlands<sup>91</sup>

387. In most cases, the Parties' combined market share on any possible market definition remains below 50%, though in some instances it may be 60 or 65% (either by value or volume). The market investigation in the present case has confirmed, for all of these markets, that, in the context of a merger of two largely generic companies providing unbranded generic pharmaceuticals, product market share alone was not a reliable predictor of market power for that product provided that a sufficient number of credible competitors remained in the market.

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<sup>84</sup> This conclusion also applies on the basis of the distinction between immediate and slow release forms considered in Case No COMP/M.1835 Monsanto/Pharmacia & Upjohn, Commission Decision of 30 March 2000

<sup>85</sup> This conclusion also applies on the basis of the other distinctions discussed in the relevant market definition section of this Decision

<sup>86</sup> This conclusion also applies on the basis of the other distinctions discussed in the relevant market definition section of this Decision. For Italy, there are two competitors with shares over 5% but a large number of significant players with smaller shares who can be deemed to constitute a competitive constraint. The increment due to Ratiopharm in the market is [0-5]% whereas Teva has [50-60]% of the market. In the UK, Ratiopharm had already decided to leave the market and in any case its share was marginal.

<sup>87</sup> This conclusion also applies on the basis of the other distinctions discussed in *Sanofi-Aventis/Zentiva*.

<sup>88</sup> This conclusion also applies on the basis of the distinction between benzodiazepines and non-benzodiazepines considered in *Pfizer/Wyeth*.

<sup>89</sup> The conclusion for mianserin relies on its exclusion as a relevant market as discussed in the market definition section above.

<sup>90</sup> This conclusion applies based on exclusion of the molecule as the relevant market in the UK, as discussed in the market definition section of this decision. The conclusions for all N6A markets also apply on the basis of the other distinctions discussed in that section.

<sup>91</sup> This conclusion is based on exclusion of the molecule as the relevant market in the Netherlands. The Parties would achieve a combined market share of [50-60]% for the oral solid form, with two other large competitors – Mylan [20-30]%) and Sanofi-Aventis ([20-30]%).

388. This view is supported by a large weight of evidence from competitors, distributors, authorities, insurers and institutional users such as hospitals. Third parties did not indicate that competition would be significantly impeded on any of these markets.
389. The Commission's own analysis has confirmed in each case listed above that there are serious and credible existing generic competitors, as well as in several cases possible and planned entrants, and that harm to competition is therefore unlikely. In all of these instances, there are no reasons to believe that the Parties would be in a position, post-merger, to increase prices over their long term trend without one or more of the identified credible competitors responding by increased output.
390. It follows that serious doubts do not arise for any of these possible markets.

**Other affected markets for finished dose pharmaceuticals which can be cleared based on relatively limited market shares and/or increments between the Parties**

391. For all other markets where the parties' activities overlap, competition concerns may be excluded, and in particular where one or both of the following applies:
- their joint market shares do not exceed 35% on any of the alternative market definitions considered,
  - the increment is below 1% on any of these alternative market definitions.
392. Third parties did not indicate that competition would be significantly impeded on any of these markets and the Commission's analysis supports this view.

**IV.3. ACTIVE PHARMACEUTICAL INGREDIENTS (APIs)**

**IV.3.1. RELEVANT PRODUCT MARKETS**

393. In previous decisions the Commission has considered that APIs form separate markets which are upstream of the markets of the finished pharmaceutical products.<sup>92</sup> The market investigation in the present case has confirmed this approach.
394. The Commission has looked at each individual API as potentially constituting a relevant market by itself, whilst noting that it cannot be excluded that certain APIs may be substitutable with each other for all, or for a range of, applications.
395. In the present case, the market definition can be left open in all cases, since 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.

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<sup>92</sup> See for instance Case COMP/M.3394 Johnson & Johnson/Johnson & Johnson MSD Europe, Commission Decision of 29 March 2004; *Novartis/Hexal*; *Teva/Barr*; *Sanofi-Aventis/Zentiva*, recital 179.

### IV.3.2. RELEVANT GEOGRAPHIC MARKET

396. The Commission has previously considered that markets for the provision of APIs are wider than the markets for finished dose pharmaceuticals and possibly worldwide<sup>93</sup>. 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 on the basis of an EEA-wide market, or of a worldwide market.

### IV.3.3. ASSESSMENT

397. Teva manufactures a portfolio of around [...] APIs and sells it externally to third parties whereas Ratiopharm does not sell any APIs to third parties, although it produces them for its own use. Therefore, the transaction does not give rise to any horizontally affected markets for APIs.

398. Since APIs are essential inputs to finished pharmaceuticals and Teva produces APIs and sells them to third parties (the merchant market), the proposed transaction gives rise to a number of vertically affected markets, i.e. markets where Teva produces the API and one or other (or both) of the Parties is active in the downstream market where the API is used.

399. According to Commission precedent, and notably in *Teva/Barr*<sup>94</sup>, the Parties identified vertically affected markets 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/ATC4 or molecule class containing that particular API, or (ii) either party has a market share of more than 25% in a downstream ATC3/ATC4 or molecule class and the other party has a market share of more than 5% of a corresponding upstream API-market.

#### *Assessment*

400. Using a conservative methodology, the Parties have identified 21 downstream vertically affected markets where Teva's market share may exceed 30% in the upstream API market and Ratiopharm has a market share of more than 5% in a corresponding downstream market, namely:

- Allopurinol (M4A) in Finland, France, Germany, Spain, Sweden and the Netherlands
- Bromocriptine (G2D) in Germany
- Dihydroergotamine (C4A) in Germany
- Diltiazem (C8A) in Finland, Germany and the Netherlands
- Loperamide (A7H) in Estonia, Hungary and Sweden
- Lovastatin (C10A) in Finland, Norway and Portugal
- Pravastatin (C10A) in Finland, France and Germany
- Pancuronium hydroxide (M3A) in Germany

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<sup>93</sup> *Sanofi-Aventis/Zentiva*, recital 186.

<sup>94</sup> Recital 196.

401. The Parties have in addition identified 28 upstream vertically affected markets where Ratiopharm has a market share of more than 25% in a downstream ATC3 class and Teva may have a market share of more than 5% in a corresponding upstream API market, namely:

- Aciclovir (D6D) in Germany
- Atenolol (C7A) in Germany, Lithuania, Portugal and Slovakia
- Clomifene (G3G) in Germany
- Dihydroergotamine (N2C) in Germany
- Furosemide (C3A) in Germany, the Czech Republic, Hungary and Slovakia
- Ticlopidine (B1C) in Germany and Slovakia
- Lisinopril (C9A) in Portugal, Slovakia and Norway
- Lansoprazole (A2B) in Germany, Norway and Sweden
- Indometacin (M1A) in the Czech Republic, Estonia, Germany, Latvia and Slovakia
- Verapamil (C8A) in Estonia and Latvia
- Alendronic acid (M5B) in Slovakia and Norway

402. In total, this results in 49 vertically affected markets.

403. 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 Teva, the limited presence of Ratiopharm in downstream markets and vice versa and the presence of numerous competitors offering these APIs, the transaction will not lead to any significant risk of vertical foreclosure.

404. 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.

405. 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, as already noted in *Sanofi-Aventis/Zentiva*, even if the merged entity holds a large share of a given national pharmaceutical market, this share would represent only a small fraction of the total worldwide demand for the APIs concerned. Consequently, even large shares of the merged firm on a national market for finished pharmaceuticals provide no opportunity to engage in a customer foreclosure strategy, given that any competing API producer would still be able to sell its products to its existing customers in all other parts of the world and overall demand for its products would not be significantly affected.

406. No respondent to the Commission market investigation has indicated that the notified operation would lead to any vertical competition concerns. As also identified in *Teva/Barr*, 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.

407. 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.4. CONTRACT MANUFACTURING/OUTLICENSING

408. 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<sup>95</sup>. 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.

409. In the present case, neither Party offers contract manufacturing services to third parties as such, but rather outlicenses some of its own products to third parties which then commercialize that product under their own name. Under such arrangements, the IP is owned and licensed by the manufacturer<sup>96</sup>.

410. In such instances, it needs to be assessed whether these third Parties can be considered autonomous players on the relevant market following the concentration, which might be the case if they can easily switch supplier or the terms of supply are locked in through long term contracts, or if the concentration may potentially change the incentives of the Parties to supply this competitor with the product on the pre-existing terms. In *Sanofi-Aventis/Zentiva*, the Commission noted that 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 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<sup>97</sup>.

411. In respect of contract manufacturing/outlicensing, the transaction leads to 14 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 either Party is the source of the product.

412. There are nine vertically affected markets by reason of Teva's outlicensing arrangements, namely the following:

- Ambroxol (R5C) in the Czech Republic
- Simvastatin (C10A) in the Czech Republic, Finland, Slovakia and Spain
- Cabergoline (N4A) in Germany
- Paclitaxel (L1C) in Germany
- Lansoprazole and Omeprazole (A2B) in Sweden

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<sup>95</sup> *Sanofi-Aventis/Zentiva*, recital 187.

<sup>96</sup> A number of the Parties' own products are, nonetheless, produced for them under contract by third parties.

<sup>97</sup> Recital 531.

- Calcium folinate/Leucovorin (B3X) in the Netherlands
413. There are also five vertically affected markets as a result of outlicensing arrangements by Ratiopharm, namely:
- Tramadol (N2A) in Germany
  - Beta-Acetyldigoxin (C1A) in Germany
  - Clonidine (C2A) in Germany
  - Folic acid (B3X) in Germany
  - Ambroxol (R5C) in Poland
414. In five of these fourteen cases, the transaction would remain below the threshold for serious doubts because they would not be "Group 1" markets 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 required. This is the case for cabergoline, beta-acetyldigoxin, folic acid and tramadol in Germany, and omeprazole in Sweden
415. Lansoprazole in Sweden is not an affected market at the molecule level and at any other level, the marginal share of the outlicensee is minimal (well under [0-5]%).
416. Calcium folinate/leucovorin was not provided by Ratiopharm in the Netherlands pre-merger. It may therefore be assumed that the incentives for Teva to provide the product under outlicensing arrangements are not substantially altered as a result of the merger.
417. For ambroxol, the Commission has concluded for Hungary that the molecule is not the relevant market definition (see recital 360 above), and this conclusion can be extrapolated to Poland and the Czech Republic given that the same molecules and in many cases the same players are present on the market.
418. For simvastatin in the Czech Republic and Spain, and for paclitaxel and clonidine in Germany, the Commission's conclusions at recital 386 above would apply even if the outlicensee were considered to depend commercially on the Parties. For the same molecule in Finland and Slovakia, there are at least two other significant independent competitors<sup>98</sup> and a number of smaller ones, which in addition to the fact that the relationship between the Parties and their outlicensee is not a structural one may also be considered sufficient to exclude serious doubts.
419. Furthermore, no indications have been received from third parties during the market investigation according to which any vertical issues in relation to outlicensing arrangements would arise.
420. In conclusion, the vertical relationships which result from contract manufacturing/outlicensing in the present case do not lead to serious doubts as to the compatibility of the transaction with the common market.

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<sup>98</sup> Sandoz with [10-20]% and Orion with [10-20]% in Finland, [10-20]% for others combined; Sanofi-Aventis (Zentiva) with [20-30]% and Merck with [5-10]% in Slovakia, others [0-5]%.



## IV.5. PIPELINES

421. In addition to drugs already on the market, many generic companies are, at any point in time, developing a number of pipeline drugs which are intended to compete with originators as soon as they come off-patent. While for the biggest-selling drugs (so-called "blockbusters"), there are often a number of generics prepared to enter, this cannot always be assumed for more niche products. Both Parties have pipeline products for synthetic generics, which overlap with pipeline products of the other Party or with products which that Party already has on the market. In addition, both Parties are involved in the development of pipeline biosimilar products as described in section IV.2.1.5 above.

### IV.5.1. RELEVANT GEOGRAPHIC MARKET

422. As the Commission noted in *Sanofi-Aventis/Zentiva*, since 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, the development process itself is not specific to a given country but most often occurs on a multinational basis and may eventually lead to product launches in several or many countries. For biosimilars, the EEA-wide centralized approvals process further underlines this tendency.

423. Notwithstanding this, the effect of an elimination of potential competition still needs to be considered at national level. 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.5.2. BIOSIMILARS

424. As this is a relatively new market and as most biopharmaceuticals are still under patent protection, the main issue concerning biosimilars in this case is potential competition. The parties both have a number of biosimilar pipelines, [...] <sup>99</sup>. For several of these products, due to the long lead times of development, the potential competitive impact of these products is likely to materialise only some years from now. The market investigation for such products therefore also focussed on general product generation capabilities in order to gauge any potential impact the transaction may have on the markets concerned.

#### *Biosimilar development and manufacturing*

425. According to the Parties, the first step of biosimilar development is cell line development and early cell development (which includes clone selection, development and evaluation). Once a stable cell line is constructed, it needs to be expanded to create a "cell bank". This becomes the source of cells for clinical trials and for production. Once a cell bank is created, the process moves to clinical trials. Parallel to clinical trials, preparations are made (include process development and scale-up) for production.

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<sup>99</sup> [...].

426. In previous decisions relating to originator pipelines, a pipeline was considered to be in a sufficiently advanced stage of development to be considered as a possible competitive constraint when it reached clinical trials (Phase III). As noted above, the approval of biosimilars also requires the performance of clinical trials. This notwithstanding, the development process is different to that of originator pharmaceuticals. For this reason the market investigation aimed to verify at which stage of the biosimilar development process eventual launch could be considered sufficiently certain for the pipeline to be considered a potential competitive constraint.
427. The market investigation indicated that the most difficult part of the process was to achieve the stage just before clinical trials, and, in particular, to show proof of similarity. Once the project is in a stage that it can enter clinical trials, according to the market investigation, there is a good chance of eventual launch.
428. The market investigation indicated a specific type of biopharmaceutical, monoclonal antibodies (based on mammalian cells) to be more complex than others. This means that the development of biosimilar versions of these products is also likely to be more complex.

*The Parties' pipelines and capabilities*

429. The Parties have [...] overlapping pipeline products<sup>100</sup> in varying degrees of development. [...] of these products ([...]) have reached the stage where launch is likely according to the market investigation (i.e. clinical trials)<sup>101</sup>.
430. [...]
431. The Parties also both have biosimilar versions of [...] in the pipeline<sup>102</sup> [*indications and stage of development described*]<sup>103</sup>It therefore cannot be established that the product would have been launched in a timely fashion in the absence of the merger.
432. Ratiopharm has [...] other pipeline projects [...] that reached the pre-clinical stage of development which overlap with Teva projects [*indications and stage of development described*]<sup>104</sup>. [...]<sup>105</sup>.
433. [...]<sup>106</sup>[...]<sup>107</sup>.

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<sup>100</sup> This information is confidential between the Parties.

<sup>101</sup> This information is confidential between the Parties.

<sup>102</sup> This information is confidential between the Parties.

<sup>103</sup> [...].

<sup>104</sup> This information is confidential between the Parties.

<sup>105</sup> [...].

<sup>106</sup> [...].

<sup>107</sup> [...].

434. [...] <sup>108</sup>. [...] <sup>109</sup>[...].
435. Based on the above, for [...] <sup>110</sup>, it cannot be concluded that both parties' pipelines reached the stage of development where an analysis of the competitive constraint stemming from the pipeline could be carried out with the necessary degree of confidence as regards future competition.
436. As regards the other [...] products, where the parties overlap, only one, or neither, Party has reached the stage of development where launch is considered to be more likely than not. The planned launch dates vary between [...] <sup>111</sup>.
437. The market investigation indicated that competition in biosimilars may be more difficult than in traditional generics due to higher barriers to entry: biosimilars require specific capabilities not all generic companies have. The market investigation further indicated that both parties possess the capabilities to develop more complex products. The parties also possess other important capabilities to supply biosimilars, including marketing and sales capabilities to facilitate the acceptance of biosimilar products.
438. Notwithstanding that the market investigation, including competitors and health authorities, indicated both Parties to be important existing and potential competitors in biosimilar markets, there were other generics indicated to have such capabilities. It may also be possible to some extent to overcome potential barriers to entry through outsourcing and/or partnerships, although finding credible partners may be easier for some steps of the development and manufacturing process than for others. Ratiopharm's internal documents submitted in response to Section 5.4 of the Form CO <sup>112</sup> also suggest that mid-size generics, in particular from India and/or biotechnology companies focussing on biopharmaceuticals may also enter the EEA through partnerships with generic companies with marketing and distribution capabilities in Europe. A third party report <sup>113</sup> also mentions such existing and/or potential collaborations.
439. In light of the above, serious doubts do not arise for the [...] products where one or both of the Parties' products is in an early stage of development. In these cases, at least one of the Parties' products is not at a stage which was indicated by previous decisions and the present market investigation to be at a sufficiently advanced stage to pose a concrete competitive constraint. It cannot therefore be assumed with certainty that both parties' products will reach the market in a reasonable timeframe. Furthermore, even if this were to be the case, due to the long timelines of launch, it cannot be established that there would not remain a number of competitors which could maintain sufficient competitive pressure.

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<sup>108</sup> [...].

<sup>109</sup> [...].

<sup>110</sup> This is confidential information between the Parties.

<sup>111</sup> This is confidential information between the Parties.

<sup>112</sup> [...].

<sup>113</sup> Visiongain: Biosimilars and Follow-on Biologics – The Global Outlook 2009-2024.

### IV.5.3. OTHER MOLECULES

440. As the Parties are large generic companies, they have a large pipeline portfolio with a significant number of overlapping pipelines in several countries. The investigation focussed in particular on cases where there were indications, at least for one of the Parties, that they are a significant player in the market and where competition between generics may be more relevant than competition between originator and generic. The investigation therefore focused on those cases where one Party had over 35% on some possible market definition (typically on the basis of a hypothetical definition at molecule level) and the other had a pipeline.

441. The Parties identified [...] instances in which Teva has a pipeline product in this case, namely [...] They also identified [...] instances where this applies for Ratiopharm, namely [...]

442. In the case of [...], the other Party is not present in the national market at the molecule level at all<sup>114</sup>. In all cases, there are other existing competitors with significant market shares – the molecule market share of the other Party is never more than 55%, with one exception – [...] – which requires further discussion because Teva currently has [90-100]% of the market<sup>115</sup>. For the remaining cases, in addition to existing products, which already constrain the Parties, the market investigation has established that there is also planned entry and/or potential entry (meeting the conditions set out in recital 56 above) in all markets which would have fewer than three other generics currently on the market.

[...].

443. [...].

444. [...].

445. [...].

446. [...]<sup>116</sup>.

447. [...].

448. [...].

449. Taking into consideration [...] as well as [...], the notified transaction does not raise serious doubts with regard to [...].

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<sup>114</sup> [...].

<sup>115</sup> [...].

<sup>116</sup> [...].

## IV.6. WHOLESALING OF PHARMACEUTICAL PRODUCTS FOR HUMAN USE

### IV.6.1. RELEVANT PRODUCT AND GEOGRAPHIC MARKETS

450. Teva is active in pharmaceutical wholesaling through its subsidiary Humantrade in Hungary. Although Ratiopharm is not itself involved in wholesaling, it was, prior to the transaction, under common ownership with Phoenix, which is an important wholesaler in a number of Member States.
451. In previous decisions the Commission has identified a market for the full-line wholesale of pharmaceutical products (i.e. a broad range of products encompassing pharmaceutical products available by doctor's prescription, products subject to sale by pharmacists and other pharmaceuticals as well as other products which require special storage and treatment like analgesics and highly inflammable substances)<sup>117</sup>.
452. The Commission has also stated that due to the narrowly defined legal framework in which full-line wholesalers usually operate (i.e. the obligation to obtain specific permissions and fulfil a number of legal requirements in order to be able to operate as a full-line pharmaceutical wholesaler), their activities can be distinguished from (i) the direct distribution of products by manufacturers to pharmacists (direct-line) and (ii) the activities of short-line distributors or parallel importers, who generally focus on a limited range of products<sup>118</sup>.
453. However, the Commission observed that there may exist a degree of substitutability between long and short-line wholesalers and was able to leave the market definition open<sup>119</sup>.
454. The Commission has regarded the geographic scope of the wholesale of pharmaceutical products as national due to differences in national market conditions, in particular with regard to the national registration systems, the social security systems and the different price finding systems.<sup>120</sup> In previous decisions the Commission considered that the geographic market might be narrower than national due to the emphasis placed by customers on the frequency and speed of delivery and the resulting need for wholesalers to compete on a sub-national basis and to have warehouses at regional level.<sup>121</sup>

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<sup>117</sup> Case COMP/M.2573 – A&C/Grossfarma, Commission Decision of 30 August 2001, recital 11.

<sup>118</sup> *A&C/Grossfarma*, recital 12.

<sup>119</sup> *loc.cit.*

<sup>120</sup> *A&C/Grossfarma*, recitals 14-16; Case No COMP/M.2193 - Alliance Unichem /Interpharm, Commission Decision of 7 December 2000, recital 10; Case IV/M.716 – Gehe/Lloyds, Commission Decision of 22 March 1996, recitals 10-13; Case IV/M.1058 – Unichem/Alliance Santé, Commission Decision of 22 December 1997, recital 11; case COMP/M.718 – Phoenix/Comifar, Commission Decision of 20 March 1996, recital 7.

<sup>121</sup> *A&C/Grossfarma*, recital 14; case COMP/M.2432 – Angelini/Phoenix/JV, Commission Decision of 6 July 2001.

455. In the present case, the exact product and geographic market definitions in the wholesale of pharmaceutical products sector can be left open, as the proposed transaction will not lead to competition concerns under any alternative market definition.

#### **IV.6.2. ASSESSMENT**

456. The controlling interests of the Parties in pharmaceutical wholesalers are limited to the third wholesaler in Hungary, Humantrade, which is owned by Teva and has a [10-20]% market share in Hungary.

457. This market is technically vertically affected due to the fact that there are numerous upstream markets for individual finished pharmaceutical products on which the Parties achieve a combined share of over 25%. This notwithstanding, the Parties' overall share of the Hungarian market for finished pharmaceuticals is only [5-10]%<sup>122</sup>. Based on such a limited share of both the downstream and the overall upstream markets, the Parties could not successfully engage in an input or customer foreclosure strategy. Moreover, pharmaceutical wholesalers are frequently required to carry a full range of products and in any case commercially incentivized to do so. In Hungary, there are only three large wholesalers and they all carry a full range of products. Hungaropharma has a [40-50]% market share and Phoenix [30-40]%.

458. Although Humantrade [...] [this] does not materially affect the analysis on the Hungarian market for finished pharmaceuticals either. There are no markets on which Teva's ownership interest in this wholesaler could be expected to result in material increments to the combined market share of the Parties post-merger. Although Teva's ownership of Humantrade was sometimes mentioned during the market investigation as a relevant fact to consider, no third Party indicated that such ownership would lead to specific competition concerns post-merger.

459. Although as indicated, Ratiopharm was, prior to the transaction, under common ownership with the Phoenix pharmaceutical wholesaling group, which is a significant player in a number of markets, the Parties have indicated that relations were always conducted at an arm's length basis and that there exists no agreement with Phoenix or the Merckle group relating to distribution arrangements following the transaction. It may thus be concluded that this historical relationship will not affect the market dynamics going forward.

460. It is therefore concluded that the proposed transaction does not give rise to serious doubts with regard to potential vertical issues arising in the wholesaling market.

#### **IV.7. CONGLOMERATE EFFECTS**

461. As indicated in section IV.2.2.6 above, certain concerns were raised during the market investigation as to the overall strength of the Parties in the Netherlands post-merger and the effect this might have on competition and prices. Such concerns were

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<sup>122</sup> The Parties estimate their share on a market defined to exclude all drugs remaining under patent in Hungary to be only a little higher, at [5-10]%. On a division by top-level (ATC1) category for genericised (or genericizable) drugs, it is never more than [10-20]%, with the exception of category K, hospital solutions, where Teva has [50-60]% but Ratiopharm is not present.

developed in particular by one insurer and were mentioned by a few respondents to the market test of the remedies, though these were in a clear minority, whereas a clear majority of respondents, whether competitors, customers, authorities or insurers, were of the view that no significant overall concerns on the generic pharmaceutical market in the Netherlands would arise as a result of the merger, even where concerns were raised for particular products where the Parties would achieve a high market share.

462. The Commission's guidelines on non-horizontal mergers set out that the non-horizontal aspects of mergers are generally less likely to significantly impede competition than the horizontal aspects, inter alia because of substantial scope for efficiencies<sup>123</sup>.
463. Due to the national structure of finished pharmaceutical markets, any possible conglomerate effects are also to be analyzed at national level. In any case, the Parties' overall position on any market segments which may be broader than national is sufficiently limited that such effects can be excluded.
464. The conglomerate effects of the merger are unable to give rise to direct foreclosure in the Netherlands because of the fact that the largest wholesalers all carry a full range of products. Similarly, the market structure and particularly the use of competitive tendering and guarantees by insurers of exclusivity to the successful tenderer as well as the number of remaining firms on the market are such as to allow the Commission to conclude that there are no grounds for serious concerns as regards coordination<sup>124</sup>.
465. Any effect of foreclosure would therefore need to be indirect and rely on the ability of the Parties to leverage their product scope in such a way as to incentivize the purchase of their products rather than those of competitors. In this regard, it should be noted that, although the Parties will be strong in the generic segment post-merger, by far the majority of the market by value is still made up of originator drugs, in which segment the Parties are scarcely present. In terms, therefore, of the overall value of their sales to wholesalers and, through them, to pharmacies and hospitals, they face a number of important competitors, some of whom, like Novartis, have both originator and generic divisions.
466. The market investigation did not give rise to any substantiated evidence to suggest that the Parties would have the ability to foreclose rivals. Many of the concerns raised during the market investigation, in particular by the one insurer mentioned, appear more likely to have the character of an efficiency, which may explain why the majority of respondents did not mention the scope of offering of the Parties as an overall concern, but only raised it in the context of individual products as referred to above. Thus, to the extent that economies of scope on the supply-side are passed on to customers, and on the demand-side directly benefit these customers, in the absence of risks of foreclosure, as the non-horizontal Guidelines clearly set out, competition concerns are not likely to arise<sup>125</sup>.

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<sup>123</sup> Guidelines on the assessment of non-horizontal mergers, Official Journal C 265 of 18 October 2008, recitals 7, 11 and 13.

<sup>124</sup> See paragraph 18 of the non-horizontal Guidelines cited above.

<sup>125</sup> See paragraphs 93 and following of the non-horizontal Guidelines

467. Whilst the combined strength of the Parties may, therefore, tip some purchasing decisions in their favour and result, as has been suggested, in certain of the smallest competitors being less able to remain on the market in the long-term, overall there does not appear to be a risk of a significant reduction in competition.

468. It follows that serious doubts as to an overall impediment to competition due to the range of the combined firm's products can, on the basis of replies to the market investigation and of the market structure as it stands, be excluded in the Netherlands. The market investigation indicated that there would remain sufficient competition for a large majority of finished pharmaceuticals and anticompetitive conglomerate effects as a result of the merger were, in general, not to be anticipated.

469. Given that the Parties position, and the change to it, is greatest in the Netherlands and all other national markets are similarly characterized by a number of credible competitors, it follows that conglomerate concerns can also be excluded on all other national markets.

#### **IV.8. CONCLUSION – SERIOUS DOUBTS**

470. 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. thiamine (A11D) in the Netherlands;
- ii. ascorbic acid (A11G) in the Netherlands;
- iii. folic acid (B3X) in the Netherlands;
- iv. hydrochlorothiazide (C3A3) in the Netherlands;
- v. isoniazid (J4A) in the Netherlands;
- vi. colchicine (M4A) in the Netherlands;
- vii. fentanyl (N2A) in the Netherlands;
- viii. phenobarbital (N5B3) in the Netherlands;
- ix. beclomethasone (R3D) in the Netherlands;
- x. atropine (S1F) in the Netherlands;
- xi. ketotifen (R3C2) in the Netherlands;
- xii. dexamethasone (H2A2, oral solid ordinary form only) in the Netherlands;
- xiii. hydrocortisone (H2A2, oral solid ordinary form only) in the Netherlands;
- xiv. ibuprofen (M1A, rectal systemic form only) in the Netherlands;
- xv. lithium (oral solid ordinary form only) in the Netherlands;



- xvi. propylthiouracil (H3B) in the Netherlands
- xvii. tramadol (N2B) in Hungary;

## V. MODIFICATIONS TO THE PROPOSED OPERATION

### V.1. Description of the commitments

471. In order to remove the serious doubts resulting from the proposed transaction, Teva formally submitted commitments to the Commission on 12 July 2010. These initial commitments consisted in the divestiture of several products for specific markets in and outside of the Netherlands. Following the market test, the commitments were modified on 28 July 2010 to include an alternative divestiture consisting of the divestiture of the whole Ratiopharm entity in the Netherlands (the so-called "NL ratiopharm entity", as described in more detail below).
472. The detailed text of these commitments is annexed to this Decision. The main elements of the commitments, as modified, are summarised below.
473. The Divestment Businesses consists of (a) the "Non-NL Divestment Business", and (b) either the "NL Divestment Businesses" or the whole "Ratiopharm NL entity".
474. Teva has committed, in the first divestiture period ([...] from the date of adoption of the decision), to sell the "Non-NL Divestment Business" and either the "NL Divestment Businesses" or, alternatively, the "Ratiopharm NL entity".
475. If within the first divestiture period Teva has not entered into an agreement to sell the Non-NL Divestment Business, the Divestiture Trustee will have the exclusive mandate to sell this business.
476. If Teva, within the first divestiture period, has not entered into an agreement to sell either the "NL Divestment Businesses" or the "Ratiopharm NL entity", the Divestiture Trustee will have the exclusive mandate to sell the "Ratiopharm NL entity".
477. The "Non NL Divestment Business" consists of Ratiopharm's tramadol business in Hungary.
478. The "NL Divestment Businesses" consist of the businesses for medicines based on the following molecules as active ingredients:
- i. Ratiopharm's thiamine business in the Netherlands;
  - ii. Ratiopharm's ascorbic acid business in the Netherlands;
  - iii. Ratiopharm's folic acid business in the Netherlands;
  - iv. Ratiopharm's hydrochlorothiazide business in the Netherlands;
  - v. Ratiopharm's isoniazid business in the Netherlands;
  - vi. Ratiopharm's colchicine business in the Netherlands;
  - vii. Ratiopharm's fentanyl business in the Netherlands;
  - viii. Ratiopharm's phenobarbital business in the Netherlands;
  - ix. Ratiopharm's beclomethasone business in the Netherlands;

- x. Ratiopharm's atropine business in the Netherlands;
- xi. Ratiopharm's ketotifen business in the Netherlands;
- xii. Ratiopharm's dexamethasone (oral solid ordinary form only) business in the Netherlands;
- xiii. Ratiopharm's hydrocortisone (oral solid ordinary form only) business in the Netherlands;
- xiv. Ratiopharm's ibuprofen (rectal systemic form only) business in the Netherlands;
- xv. Ratiopharm's lithium (oral solid ordinary form only) business in the Netherlands;
- xvi. Ratiopharm's propylthiouracil business in the Netherlands.

479. In the event that Teva cannot, for a reason outside its control (such as the absence of a required third party consent in case of contract manufacturing) divest one or more of the molecule businesses belonging to the "Non-NL Divestment Business" or the "NL Divestment Businesses" as listed above (together with all necessary items referred to below), Teva shall divest Teva's own molecule business based on the same molecule in the same country. This however does not preclude the possibility to divest the whole Netherlands business of Ratiopharm in the event described in recital 476.

480. The businesses to be divested include: (a) all tangible and intangible assets (including IPRs, the existing and pending marketing authorizations and the information contained in the relevant registration dossiers), (b) if applicable, all generic brands associated with the Divestment Businesses, (c) all licenses, permits and authorizations, (d) all contracts, leases, commitments and customer orders, (e) all necessary supply arrangements for the benefit of the Divestment Businesses, (f) all proprietary information associated with the production process of the Divestment Businesses, (g) reasonable technical assistance, (h) all the Personnel employed by Ratiopharm in the Netherlands and, for the "Non NL Divestment Business", an option to hire members of sales and marketing forces necessary to maintain the competitiveness of the "Non NL Divestment Business".

481. The "NL Divestment Businesses" also include, subject to any exception that might be agreed with the Purchaser and approved by the Commission, all the assets that are used for the distribution of the "NL Divestment Businesses" (hereafter the "NL Distribution Assets"). The "NL Distribution Assets" include:

- all the Personnel employed by Ratiopharm in the Netherlands as listed in Schedule B, including Personnel who are involved in marketing and sales, regulatory affairs and business development, finance and administration and technical operations<sup>126</sup>;
- the five year lease entered into by Ratiopharm for its premises in the Netherlands (with the consent of the lessor);
- all moveable property owned by Ratiopharm in the Netherlands, including but not limited to IT equipment and software;
- all logistical arrangements that are in place for the distribution of the "NL Divestment Businesses": the "NL Distribution Assets" will include the transfer of the

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<sup>126</sup> For avoidance of doubt, there is no difference between the Personnel included in the NL Distribution Assets and the Personnel mentioned in recital 480 (h).

agreement with [...] (with the consent of [...]) for the distribution of the "NL Divestment Businesses";

482. The "Ratiopharm NL entity", described in more detail in Schedule C, includes:

(a) all tangible and intangible assets (including intellectual property rights), which contribute to the current operation or are necessary to ensure the viability and competitiveness of the Ratiopharm NL entity, including in particular all the marketing authorizations used by Ratiopharm in the context of its business (including pipeline products) as well as the information contained in the relevant registration dossiers such as described in paragraph 12.a of the Commitments, and the pending applications for marketing authorizations, if any as well as all existing product inventory, sales and promotional material;

(b) at the option of the Purchaser of the "Ratiopharm NL entity", an exclusive license to use Ratiopharm's name and logo in the Netherlands for a period of two years;

(c) all licenses, permits and authorizations issued by any governmental organization for the benefit of the Ratiopharm NL entity;

(d) all contracts, leases, commitments and customer orders of the "Ratiopharm NL entity"; all customer, credit and other records of the "Ratiopharm NL entity" (items referred to under (a)-(d) hereinafter collectively referred to as "Ratiopharm NL entity's Assets");

(e) all necessary supply arrangements for the benefit of the "Ratiopharm NL entity" for the relevant products referred to in paragraph 11.2 of the Commitments, including:

- if applicable, a best efforts obligation to obtain consent to assign the contract manufacturing agreements entered into by the "Ratiopharm NL entity" for the manufacture of the relevant products referred to in paragraph 11.2 of the Commitments; and/or

- at the option of the Purchaser of the "Ratiopharm NL entity", the benefit, for a period of three years, on a reasonable cost-plus basis to be agreed with the Purchaser of Ratiopharm NL entity, of a supply arrangement for the relevant products referred to in paragraph 11.2 of the Commitments;

(f) at the option of the Purchaser of the "Ratiopharm NL entity", the benefit, for a period of three years, on a reasonable cost-plus basis to be agreed with the Purchaser of the "Ratiopharm NL entity", of all current arrangements under which Ratiopharm supply other services to the "Ratiopharm NL entity" and/or reasonable technical assistance to the Purchaser of the "Ratiopharm NL entity" to enable it to assume responsibility for the manufacture of the "Ratiopharm NL entity's" products;

(g) the "NL Distribution Assets" as defined in paragraph 12.i of the Commitments and described above in recital 481.

483. The NL Divestment Businesses and the Non NL Divestment Business is structured as an asset carve-out; no legal entity of Ratiopharm in the Netherlands is to be divested, except in the event that the whole Ratiopharm NL entity is divested.

## V.2. Assessment of the modified commitments

### *Suitability for removing the serious doubts*

484. The Commission considers that the Commitments (as modified on 28 July 2010) are suitable to remove serious doubts since they remove the entire overlap in the Parties' activities in the markets where the Commission identified competition concerns.
485. The market test has confirmed that the initial set of commitments would fully eliminate the competition concerns identified by the Commission. The market test has also confirmed that the approach of the divestiture of certain products for specific markets was acceptable in principle, but would only fully restore the competitive constraint if the purchaser met a number of conditions.
486. The market test of the commitments was generally positive. In particular the majority of respondents considered that the Divestment Businesses include all assets necessary to enter markets where the Commission identified competition concerns and subsequently compete effectively with the merged entity on these markets. Most respondents considered that the intangible assets (IPR, Marketing authorisations, permits, licences etc.) to be divested would enable a qualified purchaser to re-establish the competitive position pre-merger of Ratiopharm in these markets and that the transitional supply arrangements provided for in the Commitments will help to maintain the full economic viability and competitiveness of the divested businesses for a transitional period, which they agreed would not need to be longer than three years.
487. In addition, the respondents considered that it is likely that customers currently sourcing the divestment products from Ratiopharm will continue to source these products from the purchaser of the divestment products provided that it can offer a portfolio of products and can supply the divested products at comparable cost.
488. The market test has furthermore indicated that the divestment of Ratiopharm's personnel and other distribution assets would help a Purchaser to re-establish the competitive position pre-merger of Ratiopharm in the markets where the Commission identified competition concerns, although certain purchasers might not need all of these assets.
489. The market test has also revealed that there are a number of potential purchasers for the Divestment Businesses.

### *Viability and modifications of the initial commitments in view of the market test, "crown jewel"*

490. Based on the indications from the market test, the viability of the Divestment Businesses and its ability to compete effectively with the merged entity depends to a significant extent on the Purchaser. The respondents believed that a suitable purchaser needs to be already present in the affected countries (with an extensive sales and distribution network) and that it has to have a portfolio of products in these countries.
491. As regard the viability of the Divestment Businesses and the possibility of finding a suitable purchaser for the "NL Divestment Businesses", several respondents expressed concern whether – given the limited scope of the initial divestiture package in terms of the number of business included in it – the divestiture would be sufficient to create the conditions for effective and durable competition between the purchaser and the merged

entity in the markets where the Commission identified competition concerns. It appears from the market test that especially in the Netherlands, where the merged entity will be particularly strong, the purchaser will only be able to effectively compete with the Parties when it possesses a sufficiently broad portfolio of products.

492. In the light of the above and in particular the uncertainty of finding a suitable purchaser for the "NL Divestment Businesses", the Parties modified the Commitments to include a second alternative divestiture consisting of the divestiture of the whole "NL Ratiopharm entity" which they will be obliged to implement in case they are not able to implement the initial commitment, i.e. the divestiture of the "NL Divestment Businesses" to a suitable purchaser.

493. The Commission considers that, in the light of the answers to the market test, it can be confident that this second alternative divestiture will serve the purpose of ensuring the removal of competition concerns in the event that the initial option ("NL Divestment Businesses") were not to find one or more suitable purchasers. The alternative is significantly more extensive than the first divestiture given that, according to the parties' estimates, the "Ratiopharm NL entity" holds more than 800 marketing authorisations. The second alternative divestiture is capable of being implemented quickly (and within the timeframe foreseen for the first divestiture, i.e. the NL Divestment Businesses) since the alternative divestiture covers an existing stand-alone business. The Commission therefore considers the second alternative divestiture as a "crown jewel" commitment which provides the necessary degree of confidence that the competition concerns it has identified will be addressed by the remedies offered.

494. The initial commitments were further modified in view of the fact that, based on the Commission's ongoing market investigation, serious doubts could be excluded for the following products, all of which Ratiopharm had ceased producing prior to the decision to merge (see section IV.2.1.6 and, for certain of these products, the discussion further in the text above):

- riboflavin (A11X9) in the Netherlands;
- methyldopa (C2A1) in the Netherlands;
- cortisone (H2A2) in the Netherlands;
- imipramine (N6A9) in the Netherlands;
- capsicum (topical dermatological) in the Netherlands;
- hydroxytoluic acid (topical dermatological) in the Netherlands;
- citalopram (N6A4) in Norway.

495. These products were thus removed from the list of products included in the "NL Divestiture Businesses".

496. On the other hand, the Commission's further market investigation also revealed serious doubts with respect to one product, propylthiouracil in the Netherlands, which

had not been identified at the time of the market test<sup>127</sup>. The parties therefore included this product in the modified version of the commitments.

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

498. In order to ensure that Teva 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 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**

499. 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 of the Commitments submitted by the Notifying Party on 28 July 2010 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.

500. 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)  
Janusz Lewandowski  
Member of the Commission

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<sup>127</sup> This market is discussed above at recitals 171 and following.

## Case M. 5865 – Teva / ratiopharm

### COMMITMENTS TO THE EUROPEAN COMMISSION

Pursuant to Article 6(2), of Council Regulation (EEC) No. 139/2004 as amended (the “**Merger Regulation**”), Teva Pharmaceutical Industries Limited (“**Teva**”) hereby provide the following Commitments (the “**Commitments**”) in order to enable the European Commission (the “**Commission**”) to declare the acquisition of the Merckle/ratiopharm group (“**ratiopharm**”) (collectively the “**Parties**”), compatible with the common market and the EEA Agreement by its decision pursuant to Article 6(1)(b) of the Merger Regulation (the “**Decision**”).

The Commitments shall take effect upon the date of adoption of the Decision. This text shall be interpreted in the light of the Decision to the extent that the Commitments are attached as conditions and obligations, in the general framework of Community law, in particular in the light of the Merger Regulation, and by reference to the Commission Notice on remedies acceptable under Council Regulation (EEC) No 139/2004 and under Commission Regulation (EC) No 447/98.

#### SECTION A. DEFINITIONS

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

**Affiliated Undertakings:** undertakings controlled by the Parties and/or by the ultimate parents of the Parties, whereby the notion of control shall be interpreted pursuant to Article 3 of the Merger Regulation and in the light of the Commission Notice on the concept of concentration under Council Regulation (EEC) No 139/2004.

**ratiopharm:** the Merckle/ratiopharm group is composed of Merckle GmbH, CT Arzneimittel GmbH and AbZ Pharma GmbH and their subsidiaries. Merckle GmbH is a limited liability company organized under the laws of Germany with registered offices at Blaubeuren and registered with the Commercial Register of the Lower Court Ulm under HR B 5125. CT Arzneimittel GmbH is a limited liability company organized under the laws of Germany with registered offices at Berlin and registered with the Commercial Register of the Lower Court Charlottenburg under HR B 21928 B. AbZ Pharma GmbH is a limited liability company organized under the laws of Germany with registered offices at Blaubeuren and registered with the Commercial Register of the Lower Court at Ulm under HR 3643.

**Closing:** the transfer of the legal title of the Divestment Business to the Purchaser.

**Divestment Businesses:** (a) the Non NL Divestment Business, and (b) either the NL Divestment Businesses or the ratiopharm NL entity, as defined in the attached Schedules that Teva 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 Teva and who has received from Teva the exclusive Trustee Mandate to sell the Divestment Businesses , to one or more Purchaser(s) at no minimum price.

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

**Employees :** the Personnel as defined in Section B.

**First Divestiture Period:** the period of [confidential] from the Effective Date.

**Hold Separate Manager:** the person appointed by Teva for the Divestment Businesses to manage the day-to-day business under the supervision of the Monitoring Trustee.

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

**Non NL Divestment Business:** the Tramadol business in Hungary as defined in Section B and in section XVII of Schedule A.

**NL Divestment Businesses:** the businesses in the Netherlands as defined in Section B under paragraph 11.2 and in sections I to XVI of Schedule A.

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

**Purchaser:** the entity approved by the Commission as acquirer of the Divestment Businesses in accordance with the criteria set out in Section D.

**ratiopharm NL entity:** ratiopharm B.V. and its subsidiaries as defined in Schedule C.

**Teva:** Teva Pharmaceutical Industries Ltd. is a limited liability company, incorporated under the laws of Israel, with its registered office at 5 Basel Street Peach Tikva 49131, Israel and registered with the Israeli Company Register under number 520013954.

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

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

## **SECTION B. THE DIVESTMENT BUSINESSES**

### **Commitment to divest**

1. In order to restore effective competition, Teva commits to divest, or procure the divestiture of the Divestment Businesses by the end of the Trustee Divestiture Period in accordance with the provisions herein.



***Commitment to divest the Non NL Divestment Business***

2. To carry out the divestiture, Teva commits to find a purchaser and to enter into a final binding agreement for the sale of the Non NL Divestment Business within the First Divestiture Period.
3. If Teva has not been able to enter into such an agreement at the end of the First Divestiture Period, Teva shall grant the Divestiture Trustee an exclusive mandate to sell the Non NL Divestment Business in accordance with the procedure described in paragraph 43 in the Trustee Divestiture Period.
4. Teva shall be deemed to have complied with this commitment if, by the end of Trustee Divestiture Period, Teva has entered into a final binding sale and purchase agreement, if the Commission approves the Purchaser and the terms in accordance with the procedure described in paragraph 33, and if the Closing of the sale of the Non NL Divestment Business takes place within a period not exceeding 3 months after the approval of the Purchaser and the terms of sale by the Commission.
5. 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 the Non NL Divestment Business, unless the Commission has previously found that the structure of the market has changed to such an extent that the absence of influence over the Non NL Divestment Business is no longer necessary to render the proposed concentration compatible with the common market.

***Commitment to divest the NL Divestment Businesses, or, as an alternative, the ratiopharm NL entity***

6. To carry out the divestiture, Teva commits to find one or more purchaser(s) and to enter into one or more final binding agreement(s) for the sale of the NL Divestment Businesses within the First Divestiture Period.
7. During the First Divestiture Period, Teva can choose to divest the ratiopharm NL entity instead of the NL Divestment Businesses to remove competition concerns in the Netherlands where the Commission has found serious doubts as to the compatibility of the notified transaction with the common market. To carry out the divestiture, Teva commits to find a purchaser and to enter into a final binding agreement for the sale of the ratiopharm NL entity within the First Divestiture Period.
8. To the extent that at the end of the First Divestiture Period Teva has not entered into such agreement(s) for the sale of the NL Divestment Businesses, nor for the sale of the ratiopharm NL entity, Teva shall grant the Divestiture Trustee an exclusive mandate to sell the ratiopharm NL entity in accordance with the procedure described in paragraph 43 in the Trustee Divestiture Period.
9. Teva shall be deemed to have complied with this commitment if, by the end of Trustee Divestiture Period, Teva has entered into one or more final binding sale and purchase agreement(s) for the sale of the NL Divestment Businesses, or for the sale of the ratiopharm NL entity, if the Commission approves the Purchaser(s) and the terms in accordance with the procedure described in paragraph 33, and if the Closing of the sale of the NL Divestment Businesses, or, if applicable, the sale of the ratiopharm NL entity, takes place within a period not exceeding 3 months after the approval of the Purchaser(s) and the terms of sale by the Commission.

10. 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 the NL Divestment Businesses if these have been sold to one or more Purchaser(s), or over the whole or part of the ratiopharm NL entity if the ratiopharm NL entity has been sold instead to a Purchaser as an alternative commitment to divest, 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 NL Divestment Businesses, or, as the case may be, the ratiopharm NL entity, is no longer necessary to render the proposed concentration compatible with the common market.

### **Structure and definition of the Divestment Businesses**

11. The Divestment Businesses consists of (a) the Non NL Divestment Business, and (b) either the NL Divestment Businesses or the ratiopharm NL entity:

11.1. The Non NL Divestment Business consists of ratiopharm's tramadol business in Hungary.

11.2. The NL Divestment Businesses consist of:

- i. ratiopharm's thiamine business in the Netherlands;
  - ii. ratiopharm's ascorbic acid business in the Netherlands;
  - iii. ratiopharm's folic acid business in the Netherlands;
  - iv. ratiopharm's hydrochlorothiazide business in the Netherlands;
  - v. ratiopharm's isoniazid business in the Netherlands;
  - vi. ratiopharm's colchicines business in the Netherlands;
  - vii. ratiopharm's fentanyl business in the Netherlands;
  - viii. ratiopharm's phenobarbital business in the Netherlands;
  - ix. ratiopharm's beclometasone business in the Netherlands;
  - x. ratiopharm's atropine business in the Netherlands;
  - xi. ratiopharm's ketotifen business in the Netherlands;
  - xii. ratiopharm's dexamethasone (oral solid ordinary form only) business in the Netherlands;
  - xiii. ratiopharm's hydrocortisone (oral solid ordinary form only) business in the Netherlands;
  - xiv. ratiopharm's ibuprofen (rectal systemic form only) business in the Netherlands;
  - xv. ratiopharm's lithium (oral solid ordinary form only) business in the Netherlands;
  - xvi. ratiopharm's propylthiouracil business in the Netherlands
- 11.3. In the event that Teva cannot, for a reason outside its control (such as the absence of a required third party consent) divest one or more of the Non NL Divestment Business or NL Divestment Businesses listed above in paragraphs 11.1 or 11.2, together with all necessary items referred to in paragraph 12 below, Teva shall divest Teva's own business based on the same molecule in the same country.

12. These Non NL Divestment Business and NL Divestment Businesses are described in more detail in the attached Schedule A, section I to XVII and include:

(a) all tangible and intangible assets (including intellectual property rights), which contribute to the current operation or are necessary to ensure the viability and competitiveness of the NL Divestment Businesses and the Non NL Divestment Business; including in particular the marketing authorizations and the information contained in the relevant registration dossiers, which contain the following modules :

- Module 1: administrative information about the marketing authorizations holder, release site, mock-ups of packaging, etc.
- Module 2: high level summaries (the Quality Overall Summary, the Nonclinical Overview/Summaries and the Clinical Overview/Summaries);
- Module 3: chemical, pharmaceutical and biological documentation;
- Module 4: Nonclinical Study Reports;
- Module 5: Clinical Study Reports.

The divestment of the marketing authorizations referred to above shall include the pending applications for marketing authorizations if any.

(b) if applicable, all generic brands associated with the NL Divestment Businesses and the Non NL Divestment Business;

(c) all licenses, permits and authorizations issued by any governmental organization for the benefit of the NL Divestment Businesses, and the Non NL Divestment Business;

(d) all contracts, leases, commitments and customer orders of the NL Divestment Businesses and the Non NL Divestment Business; all customer, credit and other records of the NL Divestment Businesses and the Non NL Divestment Business (items referred to under (a)-(d) hereinafter collectively referred to as “*Assets*”);

(e) all necessary supply arrangements for the benefit of the NL Divestment Businesses, and the Non NL Divestment Business including:

- if applicable, a best efforts obligation to obtain consent to assign the contract manufacturing agreements entered into by ratiopharm for the manufacture of the product; and/or
- at the option of the Purchaser, the benefit, for a period of three years, on a reasonable cost-plus basis to be agreed with the Purchaser, of a supply arrangement for the relevant products;

(f) all proprietary information associated with the production process of the NL Divestment Businesses and the Non NL Divestment Business, for use only within the Netherlands for the NL Divestment Businesses or within Hungary for the Non NL Divestment Business;

- (g) at the option of the Purchaser, technical assistance to the Purchaser to facilitate the procurement of raw materials necessary for the manufacturing of the NL Divestment Businesses and the Non NL Divestment Business;
  - (h) at the option of the Purchaser, technical assistance to the Purchaser to assume responsibility for the sale and marketing of the NL Divestment Businesses and the Non NL Divestment Business, for such period as is required by the Purchaser to establish the NL Divestment Businesses and the Non NL Divestment Business as viable independent businesses;
  - (i) for the NL Divestment Businesses, subject to any exception that might be agreed with the Purchaser and approved by the Commission, all the assets that are used for the distribution of the NL Divestment Businesses (hereafter the “**NL Distribution Assets**”). The NL Distribution Assets include:
    - all the Personnel employed by ratiopharm in the Netherlands as listed in Schedule B, including Personnel who are involved in marketing and sales, regulatory affairs and business development, finance and administration and technical operations;
    - the five year lease entered into by ratiopharm for its premises in the Netherlands (with the consent of the lessor);
    - all moveable property owned by ratiopharm in the Netherlands, including but not limited to IT equipment and software;
    - all logistical arrangements that are in place for the distribution of the NL Divestment Businesses : the NL Distribution Assets will include the transfer of the agreement with [confidential] (with the consent of [confidential]) for the distribution of the NL Divestment Businesses;
  - (j) for the Non NL Divestment Business referred to in paragraph 11.1. above, an option for the Purchaser to hire any Personnel, and in particular members of sales and marketing forces (including seconded or shared employees), whom the Purchaser would consider necessary to maintain the viability, the value and the competitiveness of the Business, provided, however, that the Personnel hired by the Purchaser would be employees currently employed by ratiopharm (or by Teva in case of divestment of Teva’s product) in Hungary (the Personnel referred to under (i) and (j) hereinafter collectively referred to as “**the Employees**”).
13. For the avoidance of doubt, the NL Divestment Businesses and the Non NL Divestment Business shall, *inter alia*, not include:
- (a) any manufacturing facilities of the Parties;
  - (b) intellectual property which does not contribute to the current operations and/or is not necessary to ensure the viability and competitiveness of the NL Divestment Businesses and the Non NL Divestment Business;
  - (c) the ratiopharm and Teva names or logos in any form;
  - (d) books and records required to be retained pursuant to any statute, rule, regulation or ordinance, provided that a Purchaser shall obtain a copy of the same and shall be

permitted access to the original of such books and records upon reasonable request during normal business hours; and

- (e) general books of account and books of original entry that comprise the Parties' or an Affiliated Undertaking's permanent accounting or tax records.

14. The ratiopharm NL entity, described in more detail in Schedule C, includes :

- (a) all tangible and intangible assets (including intellectual property rights), which contribute to the current operation or are necessary to ensure the viability and competitiveness of the ratiopharm NL entity, including in particular the marketing authorizations as well as the information contained in the relevant registration dossiers such as described in paragraph 12.a above, and the pending applications for marketing authorizations, if any;
- (b) at the option of the Purchaser of the ratiopharm NL entity, an exclusive license to use ratiopharm's name and logo in the Netherlands for a period of two years;
- (c) all licenses, permits and authorizations issued by any governmental organization for the benefit of the ratiopharm NL entity;
- (d) all contracts, leases, commitments and customer orders of the ratiopharm NL entity; all customer, credit and other records of the ratiopharm NL entity (items referred to under (a)-(d) hereinafter collectively referred to as "*ratiopharm NL entity's Assets*");
- (e) all necessary supply arrangements for the benefit of the ratiopharm NL entity for the relevant products referred to in paragraph 11.2 above, including:
  - if applicable, a best efforts obligation to obtain consent to assign the contract manufacturing agreements entered into by the ratiopharm NL entity for the manufacture of the relevant products referred to in paragraph 11.2 above; and/or
  - at the option of the Purchaser of the ratiopharm NL entity, the benefit, for a period of three years, on a reasonable cost-plus basis to be agreed with the Purchaser of ratiopharm NL entity, of a supply arrangement for the relevant products referred to in paragraph 11.2 above;
- (f) at the option of the Purchaser of the ratiopharm NL entity, the benefit, for a period of three years, on a reasonable cost-plus basis to be agreed with the Purchaser of the ratiopharm NL entity, of all current arrangements under which ratiopharm supply other services to the ratiopharm NL entity and/or reasonable technical assistance to the Purchaser of the ratiopharm NL entity to enable it to assume responsibility for the manufacture of the ratiopharm NL entity's products;
- (g) the NL Distribution Assets as defined in paragraph 12.i above, including all the Personnel employed by ratiopharm in the Netherlands as listed in Schedule B, including Personnel who are involved in marketing and sales, regulatory affairs and business development, finance and administration and technical operations.

15. Subject to the remainder of this paragraph, the NL Divestment Businesses will be divested to a single Purchaser. Although the sale of the NL Divestment Businesses to a single Purchaser is the preferred remedy, upon consent of the Commission, Teva may divest the

NL Divestment Businesses to more than one Purchasers, provided each of them has a presence in the Netherlands and local distribution capabilities, so that the viability and competitiveness of the NL Divestment Businesses will be maintained.

16. For the avoidance of doubt, Teva may sell such other assets as it and the Purchaser may agree in the context of the sales of the Divestment Businesses.

## **SECTION C. RELATED COMMITMENTS**

### **Preservation of Viability, Marketability and Competitiveness**

17. From the Effective Date until Closing, the Parties shall preserve the economic viability, marketability and competitiveness of the Divestment Businesses, in accordance with good business practice, and shall minimize as far as possible any risk of loss of competitive potential of the Divestment Businesses.
18. In particular the Parties undertake:
  - (a) not to carry out any act upon their own authority that might have a significant adverse impact on the value, management or competitiveness of the Divestment Businesses or that might alter the nature and scope of activity, or the industrial or commercial strategy or the investment policy of the Divestment Businesses;
  - (b) to make available sufficient resources for the development of the Divestment Businesses, on the basis and continuation of the existing business plans and maintain the marketing and sales efforts devoted to the Divestment Businesses at their current level.
19. The obligation described in paragraphs 17 and 18 above shall also apply to the ratiopharm NL entity from the Effective Date until (a) the Commission approves the Purchaser(s) of the NL Divestment Businesses terms in accordance with the procedure described in paragraph 33; or (b) Closing of the sale of the ratiopharm NL entity.

### **Hold-separate obligations of Parties**

20. Teva commits, from the Effective Date until Closing, to the extent reasonably practical, to firewall the Divestment Businesses and the businesses retained by the Parties. Teva also commits to ensure that the Personnel of the Divestment Businesses - including the Hold Separate Manager - have their involvement in any businesses retained by the Parties limited and vice versa, to the extent reasonably practical and recognizing that the Personnel will inevitably have to deal with products from the businesses retained by the Parties, without compromising the viability of the Divestment Businesses or the businesses retained by the Parties.
21. Until Closing, Teva shall assist the Monitoring Trustee in ensuring that the Divestment Businesses are managed in accordance with provision 20 above. Teva 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 Divestment Businesses in the best interest of the businesses with a view to ensuring their continued economic viability, marketability and competitiveness and their

independence from the businesses retained by the Parties, to the extent reasonably possible without compromising the viability of the Divestment Businesses.

22. Teva commits to take all reasonable steps to ensure that Teva personnel involved in the transfer of the Divestment Businesses shall not use any confidential information from the Purchaser other than information strictly required to assist in the transfer of the Divestment Business concerned, and they shall disclose such information to other Teva personnel only to the extent strictly required to assist in the transfer of the Divestment Businesses concerned.
23. The hold separate obligations described in paragraphs 20 and 21 above shall also apply to the ratiopharm NL entity from the Effective Date until (a) the Commission approves the Purchaser(s) of the NL Divestment Businesses terms in accordance with the procedure described in paragraph 33; or (b) Closing of the sale of the ratiopharm NL entity.

### **Ring-Fencing**

24. Teva 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 restricted to the extent possible, without compromising the viability of the Divestment Businesses. Teva may obtain information relating to the Divestment Businesses which is reasonably necessary for the divestiture of the Divestment Businesses or whose disclosure to Teva is required by law.
25. The ring fencing obligation described in paragraph 23 above shall also apply to the ratiopharm NL entity from the Effective Date until (a) the Commission approves the Purchaser(s) of the NL Divestment Businesses terms in accordance with the procedure described in paragraph 33; or (b) Closing of the sale of the ratiopharm NL entity.

### **Personnel**

#### ***Transfer of the Employees of the NL Divestment Businesses and Non NL Divestment Business***

26. The Parties shall use their reasonable best efforts, to the extent permitted by law, to facilitate the transfer to the relevant Purchaser(s) (if possible by collective transfer) of the Employees desired by such Purchaser(s). The Parties shall provide relevant contact details for the Employees as desired by the Purchaser(s), or otherwise make the Employees available to the Purchaser(s) subject to compliance with applicable laws. Prior to Closing, the Parties shall facilitate interviews between such Personnel and the Purchaser(s), shall not discourage such Employee from participating in such interviews, and shall not interfere in employment negotiations between such Personnel and the Purchaser(s).
27. With respect to each Employee who receives an offer of employment from the Purchaser(s) (conditional on or following the Closing), the Parties shall do the following: (i) not prevent, prohibit or restrict or threaten to prevent, prohibit or restrict the Employee from being employed by the Purchaser(s), and not offer any incentive to the Employee to decline employment with the Purchaser(s); (ii) if the Employee accepts such offer of employment from the Purchaser(s), the Parties shall cooperate with the Purchaser(s) in effecting transfer of the Employee to the employ of the Purchaser(s) and the Parties shall amend or waive the relevant provisions of employment agreements, stock options and other employee benefit

arrangements of Personnel so that they do not suffer adverse consequences as a result of their negotiations with, or acceptance of an offer from, the Purchaser(s).

28. For the avoidance of doubt, the transfer obligations described in paragraphs 25 and 26 above shall not apply to the sale of the ratiopharm NL entity, as the Personnel of the ratiopharm NL entity will be transferred to the Purchaser as part of the ratiopharm NL entity.

#### ***Non-solicitation clause***

29. Each of the Parties undertakes, subject to customary limitations, that in relation to Employees who are hired by (as opposed to seconded to) the Purchaser(s), it will not solicit and will procure that its Affiliated Undertakings do not solicit, such Employees for a period of 12 months after Closing or after the date of termination of employment of such Employees by the Parties (as applicable).

#### **Due Diligence**

30. In order to enable potential purchasers to carry out a reasonable due diligence of the Divestment Businesses, Teva 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**

31. Teva 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 Effective Date (or otherwise at the Commission's request).
32. Teva 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 to the Commission and the Monitoring Trustee before sending the memorandum out to potential purchasers.

#### **SECTION D. THE PURCHASER(S)**

33. In order to ensure the immediate restoration of effective competition, the Purchaser(s), 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 Businesses as a viable and active competitive force in competition with the Parties and other competitors;
  - (c) for the NL Divestment Businesses and the Non NL Divestment Business, be a company active in the sales and marketing of pharmaceutical products in the EEA, unless otherwise approved by the Commission, and
  - (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 Businesses (the before-mentioned criteria for the purchaser(s) hereafter the “*Purchaser Requirements*”);

34. The final binding sale and purchase agreement shall be conditional on the Commission’s approval. When Teva has reached an agreement with a 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. Teva 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 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 Businesses without one or more Assets, if this does not affect the viability and competitiveness of the Divestment Businesses after the sale, taking account of the proposed purchaser(s).

## **SECTION E. TRUSTEE**

### **I. Appointment Procedure**

35. Teva shall appoint a Monitoring Trustee to carry out the functions specified in the Commitments for a Monitoring Trustee. If Teva has not entered into a binding sale and purchase agreement one month before the end of the First Divestiture Period or if the Commission has rejected a purchaser proposed by Teva at that time or thereafter, Teva shall appoint a Divestiture Trustee to carry out the functions specified in the Commitments for a Divestiture Trustee. The appointment of the Divestiture Trustee shall take effect upon the commencement of the Trustee Divestiture Period.
36. 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 fulfillment 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 the Parties***

37. No later than one week after the Effective Date, Teva shall submit a list of one or more persons whom Teva proposes to appoint as the Monitoring Trustee to the Commission for approval. No later than one month before the end of the First Divestiture Period, Teva shall submit a list of one or more persons whom Teva 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 36 and shall include:
  - (a) the full terms of the proposed mandate, which shall include all provisions necessary to enable the Trustee to fulfill 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***

38. 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 fulfill its obligations. If only one name is approved, Teva 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, Teva shall be free to choose the Trustee to be appointed from among the names approved. The Trustee shall be appointed within one week of the Commission's approval, in accordance with the mandate approved by the Commission.

***New proposal by the Parties***

39. If all the proposed Trustees are rejected, Teva shall submit the names of at least two more individuals or institutions within one week of being informed of the rejection, in accordance with the requirements and the procedure set out in paragraphs 35 and 38.

***Trustee nominated by the Commission***

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

## II. Functions of the Trustee

41. 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 Teva, 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*

42. The Monitoring Trustee shall:
- (i) propose in its first report to the Commission a detailed work plan describing how it intends to monitor compliance with the obligations and conditions attached to the Decision;
  - (ii) 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 Teva with the conditions and obligations attached to the Decision. To that end the Monitoring Trustee shall:
    - (a) 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 16 to 23 of the Commitments;
    - (b) supervise the management of the Divestment Businesses as a distinct and saleable entity, in accordance with paragraph 20 of the Commitments;
    - (c) (i) in consultation with Teva, determine all necessary measures to ensure that Teva 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 strive for the severing of the Divestment Business's participation in a central information technology network to the extent possible, without compromising the viability of the Divestment Businesses, and (ii) decide whether such information may be disclosed to Teva as the disclosure is reasonably necessary to allow Teva to carry out the divestiture or as the disclosure is required by law;
    - (d) monitor the splitting of assets between the Divestment Businesses and Teva or Affiliated Undertakings;
  - (iii) assume the other functions assigned to the Monitoring Trustee under the conditions and obligations attached to the Decision;
  - (iv) propose to Teva such measures as the Monitoring Trustee considers necessary to ensure Teva'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;

- (v) review and assess potential purchasers as well as the progress of the divestiture process and verify that, dependent on the stage of the divestiture process, (a) potential purchasers receive sufficient information relating to the Divestment Businesses and the Personnel in particular by reviewing, if available, the data room documentation, the information memorandum and the due diligence process and (b) potential purchasers are granted reasonable access to the Personnel;
- (vi) provide to the Commission, sending Teva 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 the businesses 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 Teva a non-confidential copy at the same time, if it concludes on reasonable grounds that Teva is failing to comply with these Commitments;
- (vii) within one week after receipt of the documented proposal referred to in paragraph 33, submit to the Commission a reasoned opinion as to the suitability and independence of the proposed purchaser and the viability of the Divestment Businesses and after the sale and 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 the Divestment Businesses without one or more Assets affects the viability of the Divestment Businesses after the sale, taking account of the proposed purchaser.

#### ***Duties and obligations of the Divestiture Trustee***

- 43. Within the Trustee Divestiture Period, the Divestiture Trustee shall sell at no minimum price the Non NL Divestment Business, and/or, as the case may be, the ratiopharm NL entity, to one or more purchaser(s), provided that the Commission has approved both the purchaser(s) and the final binding sale and purchase agreement(s) in accordance with the procedure laid down in paragraph 33. 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 divestment 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 Teva, subject to the Parties' unconditional obligation to divest at no minimum price in the Trustee Divestiture Period.
- 44. 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**

45. Teva 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 Teva's 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 Teva and the Divestment Businesses shall provide the Trustee upon request with copies of any document. Teva and the Divestment Businesses 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.
46. Teva 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. Teva 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. Teva 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.
47. Teva shall grant or procure Affiliated Undertakings to grant comprehensive powers of attorney, duly executed, to the Divestiture Trustee 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, Teva shall cause the documents required for effecting the sale and the Closing to be duly executed.
48. Teva 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 Teva 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 willful default, recklessness, gross negligence or bad faith of the Trustee, its employees, agents or advisors.
49. At the expense of Teva, the Trustee may appoint advisors (in particular for corporate finance or legal advice), subject to Teva's approval (this approval not to be unreasonably withheld or delayed) if the Trustee considers the appointment of such advisors necessary or appropriate for the performance of its duties and obligations under the Mandate, provided that any fees and other expenses incurred by the Trustee are reasonable. Should Teva refuse to approve the advisors proposed by the Trustee the Commission may approve the appointment of such advisors instead, after having heard Teva. Only the Trustee shall be entitled to issue instructions to the advisors. Paragraph 48 shall apply mutatis mutandis. In the Trustee Divestiture Period, the Divestiture Trustee may use advisors who served Teva 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**

50. 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 Teva to replace the Trustee; or

(b) Teva, with the prior approval of the Commission, may replace the Trustee.

51. If the Trustee is removed according to paragraph 50, 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 35 to 40.
52. Beside the removal according to paragraph 50, 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**

53. The Commission may, where appropriate, in response to a request from Teva 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.
54. Where Teva seeks an extension of a time period, it shall submit a request to the Commission no later than one month before the expiry of that period, showing good cause. Only in exceptional circumstances shall Teva be entitled to request an extension within the last month of any period.

.....

On behalf of Teva

Name:

Title:

## SCHEDULE - A

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### SCHEDULE - (I)

#### RATIOPHARM'S THIAMINE BASED PRODUCT

#### THIAMINE - THE NETHERLANDS

1. Divestment Business consists of ratiopharm's (or an Affiliated Undertaking's) rights, title and interests in Thiamine in the Netherlands (currently marketed under the brand name Thiamine-HCL-rat) including the right to develop, manufacture and use Thiamine with a view to its sale in any form and for any indication whatsoever in the Netherlands. Thiamine is indicated for the treatment or the mitigation of a specific condition or deficiency (a severe depletion of vitamin B1 can escalate to diseases such as beriberi), or as general food supplement. For the avoidance of doubt, Divestment Business does not contain any rights to sell Thiamine outside of the Netherlands.
2. Divestment Business includes:
  - (a) the sale of existing product inventory, sales and promotional material in the Netherlands;
  - (b) all contracts, leases, commitments and customer orders, all customer, credit and other records;
  - (c) the transfer of the marketing authorization for Thiamine in the Netherlands including all relevant dossiers relating to the current and/or pending marketing authorizations available to ratiopharm;
  - (d) an irrevocable, assignable, sub-licensable, and royalty free license for all relevant intellectual property rights, data, books, records and effective arrangements for the transfer of all know-how to the extent that these are related to the development, manufacture, use of Divestment Business with a view to its sale in the Netherlands; including in particular the information contained in the registration dossier, which contains the following modules:
    - Module 1: administrative information about the marketing authorization holder, release site, mock-ups of packaging, etc.
    - Module 2: high level summaries (the Quality Overall Summary, the Nonclinical Overview/Summaries and the Clinical Overview/Summaries);
    - Module 3: chemical, pharmaceutical and biological documentation;
    - Module 4: Nonclinical Study Reports;
    - Module 5: Clinical Study Reports;

(items referred to under (a)-(d) hereinafter collectively referred to as "Assets of Divestment Business").

3. Teva commits on behalf of ratiopharm to make its best efforts to obtain the assignment of the contract manufacturing agreement entered into between ratiopharm and [confidential] or at the option of the Purchaser, Teva shall enter into a supply arrangement with the Purchaser for the non-exclusive supply of Thiamine in the Netherlands, for a period of three years and on a reasonable cost plus basis to be agreed with the Purchaser.
4. The transitional supply arrangement referred to in paragraph 3 shall include appropriate provisions designed to ensure the continuous supply by Teva to the Purchaser of Thiamine in the Netherlands for a period of three years. It shall not contain any provision requiring the delivery of minimum supply volumes or batches, nor supply quantity restrictions.
5. Teva commits on behalf of ratiopharm to make its best efforts to cooperate with the Purchaser for the transfer of the production of Thiamine to the Purchaser's production facilities and undertakes to approve all regulatory changes that would be required as a result of such transfer.
6. Teva commits on behalf of ratiopharm 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 of the products to the Purchaser's facilities. A copy of this report will be sent to the Monitoring Trustee.
7. At the option of the Purchaser, Teva commits on behalf of ratiopharm to provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of Thiamine in the Netherlands, including any transitory regulatory, logistics and distribution services, for a period of 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 ratiopharm provide technical assistance to the Purchaser expeditiously. ratiopharm 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.
10. The Divestment Business shall not include:
  - (a) Any manufacturing facility;
  - (b) Raw materials;
  - (c) Any research and development, clinical data and studies or intellectual property relating to Thiamine after Closing;
  - (d) All marketing authorizations currently held by the Parties outside of the Netherlands for Thiamine;
  - (e) Monies owed to the Parties by customers for the purchase of Thiamine, and monies owed by the Parties to suppliers for materials used in the productions of Thiamine.



## SCHEDULE - (II)

### RATIOPHARM'S ASCORBIC ACID BASED PRODUCT

#### ASCORBIC ACID - THE NETHERLANDS

1. Divestment Business consists of ratiopharm's (or an Affiliated Undertaking's) rights, title and interests in Ascorbic acid in the Netherlands (currently marketed under the brand name Ascorbinezuur-rat) including the right to develop, manufacture and use Ascorbic acid with a view to its sale in any form and for any indication whatsoever in the Netherlands. Ascorbic acid is a sugar acid used for its antioxidant properties. For the avoidance of doubt, Divestment Business does not contain any rights to sell Ascorbic acid outside of the Netherlands.
  
2. Divestment Business includes:
  - (a) the sale of existing product inventory, sales and promotional material in the Netherlands;
  - (b) all contracts, leases, commitments and customer orders, all customer, credit and other records;
  - (c) the transfer of the marketing authorization for Ascorbic acid in the Netherlands including all relevant dossiers relating to the current and/or pending marketing authorizations available to ratiopharm;
  - (d) an irrevocable, assignable, sub-licensable, and royalty free license for all relevant intellectual property rights, data, books, records and effective arrangements for the transfer of all know-how to the extent that these are related to the development, manufacture, use of Divestment Business with a view to its sale in the Netherlands; including in particular the information contained in the registration dossier, which contains the following modules:
    - Module 1: administrative information about the marketing authorization holder, release site, mock-ups of packaging, etc.
    - Module 2: high level summaries (the Quality Overall Summary, the Nonclinical Overview/Summaries and the Clinical Overview/Summaries);
    - Module 3: chemical, pharmaceutical and biological documentation;
    - Module 4: Nonclinical Study Reports;
    - Module 5: Clinical Study Reports;(items referred to under (a)-(d) hereinafter collectively referred to as "Assets of Divestment Business").
  
3. Teva commits on behalf of ratiopharm to make its best efforts to obtain the assignment of the contract manufacturing agreement entered into between ratiopharm and [confidential] or at the option of the Purchaser, Teva shall enter into a supply arrangement with the Purchaser for the non-exclusive supply of Ascorbic acid in the Netherlands, for a period of three years, and on a reasonable cost plus basis to be agreed with the Purchaser.

4. The transitional supply arrangement referred to in paragraph 3 shall include appropriate provisions designed to ensure the continuous supply by Teva to the Purchaser of Ascorbic acid in the Netherlands for a period of three years. It shall not contain any provision requiring the delivery of minimum supply volumes or batches, nor supply quantity restrictions.
5. Teva commits on behalf of ratiopharm to make its best efforts to cooperate with the Purchaser for the transfer of the production of Ascorbic acid to the Purchaser's production facilities and undertakes to approve all regulatory changes that would be required as a result of such transfer.
6. Teva commits on behalf of ratiopharm 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 of the products to the Purchaser's facilities. A copy of this report will be sent to the Monitoring Trustee.
7. At the option of the Purchaser, Teva commits on behalf of ratiopharm to provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of Ascorbic acid in the Netherlands, including any transitory regulatory, logistics and distribution services, for a period of 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 ratiopharm provide technical assistance to the Purchaser expeditiously. ratiopharm 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 Divestment Business shall not include:
  - (a) Any manufacturing facility;
  - (b) Raw materials;
  - (c) Any research and development, clinical data and studies or intellectual property relating to Ascorbic acid after Closing;
  - (d) All marketing authorizations currently held by the Parties outside of the Netherlands for Ascorbic acid;
  - (e) Monies owed to the Parties by customers for the purchase of Ascorbic acid, and monies owed by the Parties to suppliers for materials used in the productions of Ascorbic acid.

## SCHEDULE - (III)

### RATIOPHARM'S FOLIC ACID BASED PRODUCT

#### FOLIC ACID - THE NETHERLANDS

1. Divestment Business consists of ratiopharm's (or an Affiliated Undertaking's) rights, title and interests in Folic Acid in the Netherlands (currently marketed under the brand name Foliumzuur-rat) including the right to develop, manufacture and use Folic Acid with a view to its sale in any form and for any indication whatsoever in the Netherlands. Folic Acid is indicated for the treatment or the mitigation of a specific condition or deficiency (a severe depletion of vitamin B9), or as general food supplement. For the avoidance of doubt, Divestment Business does not contain any rights to sell Folic Acid outside of the Netherlands.
  
2. Divestment Business includes:
  - (a) the sale of existing product inventory, sales and promotional material in the Netherlands;
  - (b) all contracts, leases, commitments and customer orders, all customer, credit and other records;
  - (c) the transfer of the marketing authorization for Folic Acid in the Netherlands including all relevant dossiers relating to the current and/or pending marketing authorizations available to ratiopharm;
  - (d) an irrevocable, assignable, sub-licensable, and royalty free license for all relevant intellectual property rights, data, books, records and effective arrangements for the transfer of all know-how to the extent that these are related to the development, manufacture, use of Divestment Business with a view to its sale in the Netherlands; including in particular the information contained in the registration dossier, which contains the following modules:
    - Module 1: administrative information about the marketing authorization holder, release site, mock-ups of packaging, etc.
    - Module 2: high level summaries (the Quality Overall Summary, the Nonclinical Overview/Summaries and the Clinical Overview/Summaries);
    - Module 3: chemical, pharmaceutical and biological documentation;
    - Module 4: Nonclinical Study Reports;
    - Module 5: Clinical Study Reports;(items referred to under (a)-(d) hereinafter collectively referred to as "Assets of Divestment Business").
  
3. Teva commits on behalf of ratiopharm to make its best efforts to obtain the assignment of the contract manufacturing agreement entered into between ratiopharm and [confidential] or at the option of the Purchaser, Teva shall enter into a supply arrangement with the Purchaser

for the non-exclusive supply of Folic Acid in the Netherlands, for a period of three years, and on a reasonable cost plus basis to be agreed with the Purchaser.

4. The transitional supply arrangement referred to in paragraph 3 shall include appropriate provisions designed to ensure the continuous supply by Teva to the Purchaser of Folic Acid in the Netherlands for a period of three years. It shall not contain any provision requiring the delivery of minimum supply volumes or batches, nor supply quantity restrictions.
5. Teva commits on behalf of ratiopharm to make its best efforts to cooperate with the Purchaser for the transfer of the production of Folic Acid to the Purchaser's production facilities and undertakes to approve all regulatory changes that would be required as a result of such transfer.
6. Teva commits on behalf of ratiopharm 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 of the products to the Purchaser's facilities. A copy of this report will be sent to the Monitoring Trustee.
7. At the option of the Purchaser, Teva commits on behalf of ratiopharm to provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of Folic Acid in the Netherlands, including any transitory regulatory, logistics and distribution services, for a period of 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 ratiopharm provide technical assistance to the Purchaser expeditiously. ratiopharm 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 Divestment Business shall not include:
  - (a) Any manufacturing facility;
  - (b) Raw materials;
  - (c) Any research and development, clinical data and studies or intellectual property relating to Folic Acid after Closing;
  - (d) All marketing authorizations currently held by the Parties outside of the Netherlands for Folic Acid;
  - (e) Monies owed to the Parties by customers for the purchase of Folic Acid, and monies owed by the Parties to suppliers for materials used in the productions of Folic Acid.

## SCHEDULE - (IV)

### RATIOPHARM'S HYDROCHLOROTHIAZIDE BASED PRODUCT

#### HYDROCHLOROTHIAZIDE - THE NETHERLANDS

1. Divestment Business consists of ratiopharm's (or an Affiliated Undertaking's) rights, title and interests in Hydrochlorothiazide in the Netherlands (currently marketed under the brand name Hydrochloroth-rat including the right to develop, manufacture and use Hydrochlorothiazide with a view to its sale in any form and for any indication whatsoever in the Netherlands. Hydrochlorothiazide is a first line diuretic drug of the thiazide class that acts by inhibiting the kidneys' ability to retain water, and reduces the volume of the blood, decreasing blood return to the heart and thus cardiac output. For the avoidance of doubt, Divestment Business does not contain any rights to sell Hydrochlorothiazide outside of the Netherlands.
2. Divestment Business includes:
  - (a) the sale of existing product inventory, sales and promotional material in the Netherlands;
  - (b) all contracts, leases, commitments and customer orders, all customer, credit and other records;
  - (c) the transfer of the marketing authorization for Hydrochlorothiazide in the Netherlands including all relevant dossiers relating to the current and/or pending marketing authorizations available to ratiopharm;
  - (d) an irrevocable, assignable, sub-licensable, and royalty free license for all relevant intellectual property rights, data, books, records and effective arrangements for the transfer of all know-how to the extent that these are related to the development, manufacture, use of Divestment Business with a view to its sale in the Netherlands; including in particular the information contained in the registration dossier, which contains the following modules:
    - Module 1: administrative information about the marketing authorization holder, release site, mock-ups of packaging, etc.
    - Module 2: high level summaries (the Quality Overall Summary, the Nonclinical Overview/Summaries and the Clinical Overview/Summaries);
    - Module 3: chemical, pharmaceutical and biological documentation;
    - Module 4: Nonclinical Study Reports;
    - Module 5: Clinical Study Reports;(items referred to under (a)-(d) hereinafter collectively referred to as "Assets of Divestment Business").
3. At the option of the Purchaser, Teva shall enter into a supply arrangement with the Purchaser for the non-exclusive supply of Hydrochlorothiazide in the Netherlands, for a period of three years , and on a reasonable cost plus basis to be agreed with the Purchaser.

4. The transitional supply arrangement referred to in paragraph 3 shall include appropriate provisions designed to ensure the continuous supply by Teva to the Purchaser of Hydrochlorothiazide in the Netherlands for a period of three years . It shall not contain any provision requiring the delivery of minimum supply volumes or batches, nor supply quantity restrictions.
5. Teva commits on behalf of ratiopharm to make its best efforts to cooperate with the Purchaser for the transfer of the production of Hydrochlorothiazide to the Purchaser's production facilities and undertakes to approve all regulatory changes that would be required as a result of such transfer.
6. Teva commits on behalf of ratiopharm 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 of the products to the Purchaser's facilities. A copy of this report will be sent to the Monitoring Trustee.
7. At the option of the Purchaser, Teva commits on behalf of ratiopharm to provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of Hydrochlorothiazide in the Netherlands, including any transitory regulatory, logistics and distribution services, for a period of 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 ratiopharm provide technical assistance to the Purchaser expeditiously. ratiopharm 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 Divestment Business shall not include:
  - (a) Any manufacturing facility;
  - (b) Raw materials;
  - (c) Any research and development, clinical data and studies or intellectual property relating to Hydrochlorothiazide after Closing;
  - (d) All marketing authorizations currently held by the Parties outside of the Netherlands for Hydrochlorothiazide;
  - (e) Monies owed to the Parties by customers for the purchase of Hydrochlorothiazide, and monies owed by the Parties to suppliers for materials used in the productions of Hydrochlorothiazide.

## SCHEDULE - (V)

### RATIOPHARM'S ISONIAZID BASED PRODUCT

#### ISONIAZID - THE NETHERLANDS

1. Divestment Business consists of ratiopharm's (or an Affiliated Undertaking's) rights, title and interests in Isoniazid in the Netherlands (currently marketed under the brand name Isoniazide-rat) including the right to develop, manufacture and use Isoniazid with a view to its sale in any form and for any indication whatsoever in the Netherlands. Isoniazid is a first-line antituberculosis medication in prevention and treatment. For the avoidance of doubt, Divestment Business does not contain any rights to sell Isoniazid outside of the Netherlands.
2. Divestment Business includes:
  - (a) the sale of existing product inventory, sales and promotional material in the Netherlands;
  - (b) all contracts, leases, commitments and customer orders, all customer, credit and other records;
  - (c) the transfer of the marketing authorization for Isoniazid in the Netherlands including all relevant dossiers relating to the current and/or pending marketing authorizations available to ratiopharm;
  - (d) an irrevocable, assignable, sub-licensable, and royalty free license for all relevant intellectual property rights, data, books, records and effective arrangements for the transfer of all know-how to the extent that these are related to the development, manufacture, use of Divestment Business with a view to its sale in the Netherlands; including in particular the information contained in the registration dossier, which contains the following modules:
    - Module 1: administrative information about the marketing authorization holder, release site, mock-ups of packaging, etc.
    - Module 2: high level summaries (the Quality Overall Summary, the Nonclinical Overview/Summaries and the Clinical Overview/Summaries);
    - Module 3: chemical, pharmaceutical and biological documentation;
    - Module 4: Nonclinical Study Reports;
    - Module 5: Clinical Study Reports;(items referred to under (a)-(d) hereinafter collectively referred to as "Assets of Divestment Business").
3. At the option of the Purchaser, Teva shall enter into a supply arrangement with the Purchaser for the non-exclusive supply of Isoniazid in the Netherlands, for a period of three years and on a reasonable cost plus basis to be agreed with the Purchaser.
4. The transitional supply arrangement referred to in paragraph 3 shall include appropriate provisions designed to ensure the continuous supply by Teva to the Purchaser of Isoniazid in

the Netherlands for a period of three years . It shall not contain any provision requiring the delivery of minimum supply volumes or batches, nor supply quantity restrictions.

5. Teva commits on behalf of ratiopharm to make its best efforts to cooperate with the Purchaser for the transfer of the production of Isoniazid to the Purchaser's production facilities and undertakes to approve all regulatory changes that would be required as a result of such transfer.
6. Teva commits on behalf of ratiopharm 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 of the products to the Purchaser's facilities. A copy of this report will be sent to the Monitoring Trustee.
7. At the option of the Purchaser, Teva commits on behalf of ratiopharm to provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of Isoniazid in the Netherlands, including any transitory regulatory, logistics and distribution services, for a period of 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 ratiopharm provide technical assistance to the Purchaser expeditiously. ratiopharm 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 Divestment Business shall not include:
  - (a) Any manufacturing facility;
  - (b) Raw materials;
  - (c) Any research and development, clinical data and studies or intellectual property relating to Isoniazid after Closing;
  - (d) All marketing authorizations currently held by the Parties outside of the Netherlands for Isoniazid;
  - (e) Monies owed to the Parties by customers for the purchase of Isoniazid, and monies owed by the Parties to suppliers for materials used in the productions of Isoniazid.



## SCHEDULE - (VI)

### RATIOPHARM'S COLCHICINE BASED PRODUCT

#### COLCHICINE - THE NETHERLANDS

1. Divestment Business consists of ratiopharm's (or an Affiliated Undertaking's) rights, title and interests in Colchicine in the Netherlands (currently marketed under the brand name Colchicine-rat) including the right to develop, manufacture and use Colchicine with a view to its sale in any form and for any indication whatsoever in the Netherlands. Colchicine is a toxic natural product and secondary metabolite which is used to treat rheumatic complaints, especially gout. For the avoidance of doubt, Divestment Business does not contain any rights to sell Colchicine outside of the Netherlands.
2. Divestment Business includes:
  - (a) the sale of existing product inventory, sales and promotional material in the Netherlands;
  - (b) all contracts, leases, commitments and customer orders, all customer, credit and other records;
  - (c) the transfer of the marketing authorization for Colchicine in the Netherlands including all relevant dossiers relating to the current and/or pending marketing authorizations available to ratiopharm;
  - (d) an irrevocable, assignable, sub-licensable, and royalty free license for all relevant intellectual property rights, data, books, records and effective arrangements for the transfer of all know-how to the extent that these are related to the development, manufacture, use of Divestment Business with a view to its sale in the Netherlands; including in particular the information contained in the registration dossier, which contains the following modules:
    - Module 1: administrative information about the marketing authorization holder, release site, mock-ups of packaging, etc.
    - Module 2: high level summaries (the Quality Overall Summary, the Nonclinical Overview/Summaries and the Clinical Overview/Summaries);
    - Module 3: chemical, pharmaceutical and biological documentation;
    - Module 4: Nonclinical Study Reports;
    - Module 5: Clinical Study Reports;(items referred to under (a)-(d) hereinafter collectively referred to as "Assets of Divestment Business").
3. At the option of the Purchaser, Teva shall enter into a supply arrangement with the Purchaser for the non-exclusive supply of Colchicine in the Netherlands, for a period of three years, and on a reasonable cost plus basis to be agreed with the Purchaser.

4. The transitional supply arrangement referred to in paragraph 3 shall include appropriate provisions designed to ensure the continuous supply by Teva to the Purchaser of Colchicine in the Netherlands for a period of three years. It shall not contain any provision requiring the delivery of minimum supply volumes or batches, nor supply quantity restrictions.
5. Teva commits on behalf of ratiopharm to make its best efforts to cooperate with the Purchaser for the transfer of the production of Colchicine to the Purchaser's production facilities and undertakes to approve all regulatory changes that would be required as a result of such transfer.
6. Teva commits on behalf of ratiopharm 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 of the products to the Purchaser's facilities. A copy of this report will be sent to the Monitoring Trustee.
7. At the option of the Purchaser, Teva commits on behalf of ratiopharm to provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of Colchicine in the Netherlands, including any transitory regulatory, logistics and distribution services, for a period of 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 ratiopharm provide technical assistance to the Purchaser expeditiously. ratiopharm 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 Divestment Business shall not include:
  - (a) Any manufacturing facility;
  - (b) Raw materials;
  - (c) Any research and development, clinical data and studies or intellectual property relating to Colchicine after Closing;
  - (d) All marketing authorizations currently held by the Parties outside of the Netherlands for Colchicine;
  - (e) Monies owed to the Parties by customers for the purchase of Colchicine, and monies owed by the Parties to suppliers for materials used in the productions of Colchicine.

## SCHEDULE - (VII)

### RATIOPHARM'S FENTANYL BASED PRODUCT

#### FENTANYL - THE NETHERLANDS

1. Divestment Business consists of ratiopharm's (or an Affiliated Undertaking's) rights, title and interests in Fentanyl in the Netherlands (currently marketed under the brand name Fentanyl MTRIX-rat) including the right to develop, manufacture and use Fentanyl with a view to its sale in any form and for any indication whatsoever in the Netherlands. Fentanyl is a drug used in medicine to relieve pain, and is also used as an adjunct to general anesthetics, and as an anesthetic for induction and maintenance. For the avoidance of doubt, Divestment Business does not contain any rights to sell Fentanyl outside of the Netherlands.
2. Divestment Business includes:
  - (a) the sale of existing product inventory, sales and promotional material in the Netherlands;
  - (b) all contracts, leases, commitments and customer orders, all customer, credit and other records;
  - (c) the transfer of the marketing authorization for Fentanyl in the Netherlands including all relevant dossiers relating to the current and/or pending marketing authorizations available to ratiopharm;
  - (d) an irrevocable, assignable, sub-licensable, and royalty free license for all relevant intellectual property rights, data, books, records and effective arrangements for the transfer of all know-how to the extent that these are related to the development, manufacture, use of Divestment Business with a view to its sale in the Netherlands; including in particular the information contained in the registration dossier, which contains the following modules:
    - Module 1: administrative information about the marketing authorization holder, release site, mock-ups of packaging, etc.
    - Module 2: high level summaries (the Quality Overall Summary, the Nonclinical Overview/Summaries and the Clinical Overview/Summaries);
    - Module 3: chemical, pharmaceutical and biological documentation;
    - Module 4: Nonclinical Study Reports;
    - Module 5: Clinical Study Reports;(items referred to under (a)-(d) hereinafter collectively referred to as "Assets of Divestment Business").
3. At the option of the Purchaser, Teva shall enter into a supply arrangement with the Purchaser for the non-exclusive supply of Fentanyl in the Netherlands, for a period of three years and on a reasonable cost plus basis to be agreed with the Purchaser.

4. The transitional supply arrangement referred to in paragraph 3 shall include appropriate provisions designed to ensure the continuous supply by Teva to the Purchaser of Fentanyl in the Netherlands for a period of three years . It shall not contain any provision requiring the delivery of minimum supply volumes or batches, nor supply quantity restrictions.
5. Teva commits on behalf of ratiopharm to make its best efforts to cooperate with the Purchaser for the transfer of the production of Fentanyl to the Purchaser's production facilities and undertakes to approve all regulatory changes that would be required as a result of such transfer.
6. Teva commits on behalf of ratiopharm 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 of the products to the Purchaser's facilities. A copy of this report will be sent to the Monitoring Trustee.
7. At the option of the Purchaser, Teva commits on behalf of ratiopharm to provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of Fentanyl in the Netherlands, including any transitory regulatory, logistics and distribution services, for a period of 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 ratiopharm provide technical assistance to the Purchaser expeditiously. ratiopharm 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 Divestment Business shall not include:
  - (a) Any manufacturing facility;
  - (b) Raw materials;
  - (c) Any research and development, clinical data and studies or intellectual property relating to Fentanyl after Closing;
  - (d) All marketing authorizations currently held by the Parties outside of the Netherlands for Fentanyl;
  - (e) Monies owed to the Parties by customers for the purchase of Fentanyl, and monies owed by the Parties to suppliers for materials used in the productions of Fentanyl.

## SCHEDULE - (VIII)

### RATIOPHARM'S PHENOBARBITAL BASED PRODUCT

#### PHENOBARBITAL - THE NETHERLANDS

1. Divestment Business consists of ratiopharm's (or an Affiliated Undertaking's) rights, title and interests in Phenobarbital in the Netherlands (currently marketed under the brand name Fenobarbital-rat) including the right to develop, manufacture and use Phenobarbital with a view to its sale in any form and for any indication whatsoever in the Netherlands. Phenobarbital is a barbiturate. A widely used anticonvulsant, it also has sedative and hypnotic properties. For the avoidance of doubt, Divestment Business does not contain any rights to sell Phenobarbital outside of the Netherlands.
2. Divestment Business includes:
  - (a) the sale of existing product inventory, sales and promotional material in the Netherlands;
  - (b) all contracts, leases, commitments and customer orders, all customer, credit and other records;
  - (c) the transfer of the marketing authorization for Phenobarbital in the Netherlands including all relevant dossiers relating to the current and/or pending marketing authorizations available to ratiopharm;
  - (d) an irrevocable, assignable, sub-licensable, and royalty free license for all relevant intellectual property rights, data, books, records and effective arrangements for the transfer of all know-how to the extent that these are related to the development, manufacture, use of Divestment Business with a view to its sale in the Netherlands; including in particular the information contained in the registration dossier, which contains the following modules:
    - Module 1: administrative information about the marketing authorization holder, release site, mock-ups of packaging, etc.
    - Module 2: high level summaries (the Quality Overall Summary, the Nonclinical Overview/Summaries and the Clinical Overview/Summaries);
    - Module 3: chemical, pharmaceutical and biological documentation;
    - Module 4: Nonclinical Study Reports;
    - Module 5: Clinical Study Reports;(items referred to under (a)-(d) hereinafter collectively referred to as "Assets of Divestment Business").
3. At the option of the Purchaser, Teva shall enter into a supply arrangement with the Purchaser for the non-exclusive supply of Phenobarbital in the Netherlands, for a period of three years , and on a reasonable cost plus basis to be agreed with the Purchaser.

4. The transitional supply arrangement referred to in paragraph 3 shall include appropriate provisions designed to ensure the continuous supply by Teva to the Purchaser of Phenobarbital in the Netherlands for a period of three years . It shall not contain any provision requiring the delivery of minimum supply volumes or batches, nor supply quantity restrictions.
5. Teva commits on behalf of ratiopharm to make its best efforts to cooperate with the Purchaser for the transfer of the production of Phenobarbital to the Purchaser's production facilities and undertakes to approve all regulatory changes that would be required as a result of such transfer.
6. Teva commits on behalf of ratiopharm 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 of the products to the Purchaser's facilities. A copy of this report will be sent to the Monitoring Trustee.
7. At the option of the Purchaser, Teva commits on behalf of ratiopharm to provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of Phenobarbital in the Netherlands, including any transitory regulatory, logistics and distribution services, for a period of 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 ratiopharm provide technical assistance to the Purchaser expeditiously. ratiopharm 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 Divestment Business shall not include:
  - (a) Any manufacturing facility;
  - (b) Raw materials;
  - (c) Any research and development, clinical data and studies or intellectual property relating to Phenobarbital after Closing;
  - (d) All marketing authorizations currently held by the Parties outside of the Netherlands for Phenobarbital;
  - (e) Monies owed to the Parties by customers for the purchase of Phenobarbital, and monies owed by the Parties to suppliers for materials used in the productions of Phenobarbital.

## SCHEDULE - (IX)

### RATIOPHARM'S BECLOMETASONE BASED PRODUCT

#### BECLOMETASONE - THE NETHERLANDS

1. Divestment Business consists of ratiopharm's (or an Affiliated Undertaking's) rights, title and interests in Beclometasone in the Netherlands (currently marketed under the brand name Beclometasone-rat) including the right to develop, manufacture and use Beclometasone with a view to its sale in any form and for any indication whatsoever in the Netherlands. Beclometasone is indicated to treat the prophylaxis of asthma, the treatment of rhinitis and sinusitis, as well as the treatment of unusually severe canker sores. For the avoidance of doubt, Divestment Business does not contain any rights to sell Beclometasone outside of the Netherlands.
2. Divestment Business includes:
  - (a) the sale of existing product inventory, sales and promotional material in the Netherlands;
  - (b) all contracts, leases, commitments and customer orders, all customer, credit and other records;
  - (c) the transfer of the marketing authorization for Beclometasone in the Netherlands including all relevant dossiers relating to the current and/or pending marketing authorizations available to ratiopharm;
  - (d) an irrevocable, assignable, sub-licensable, and royalty free license for all relevant intellectual property rights, data, books, records and effective arrangements for the transfer of all know-how to the extent that these are related to the development, manufacture, use of Divestment Business with a view to its sale in the Netherlands; including in particular the information contained in the registration dossier, which contains the following modules:
    - Module 1: administrative information about the marketing authorization holder, release site, mock-ups of packaging, etc.
    - Module 2: high level summaries (the Quality Overall Summary, the Nonclinical Overview/Summaries and the Clinical Overview/Summaries);
    - Module 3: chemical, pharmaceutical and biological documentation;
    - Module 4: Nonclinical Study Reports;
    - Module 5: Clinical Study Reports;(items referred to under (a)-(d) hereinafter collectively referred to as "Assets of Divestment Business").
3. Teva commits on behalf of ratiopharm to make its best efforts to obtain the assignment of the contract manufacturing agreement entered into between ratiopharm and [confidential] or at the option of the Purchaser, Teva shall enter into a supply arrangement with the Purchaser

for the non-exclusive supply of Beclometasone in the Netherlands, for a period of three years and on a reasonable cost plus basis to be agreed with the Purchaser.

4. The transitional supply arrangement referred to in paragraph 3 shall include appropriate provisions designed to ensure the continuous supply by Teva to the Purchaser of Beclometasone in the Netherlands for a period of three years. It shall not contain any provision requiring the delivery of minimum supply volumes or batches, nor supply quantity restrictions.
5. Teva commits on behalf of ratiopharm to make its best efforts to cooperate with the Purchaser for the transfer of the production of Beclometasone to the Purchaser's production facilities and undertakes to approve all regulatory changes that would be required as a result of such transfer.
6. Teva commits on behalf of ratiopharm 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 of the products to the Purchaser's facilities. A copy of this report will be sent to the Monitoring Trustee.
7. At the option of the Purchaser, Teva commits on behalf of ratiopharm to provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of Beclometasone in the Netherlands, including any transitory regulatory, logistics and distribution services, for a period of 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 ratiopharm provide technical assistance to the Purchaser expeditiously. ratiopharm 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 Divestment Business shall not include:
  - (a) Any manufacturing facility;
  - (b) Raw materials;
  - (c) Any research and development, clinical data and studies or intellectual property relating to Beclometasone after Closing;
  - (d) All marketing authorizations currently held by the Parties outside of the Netherlands for Beclometasone;
  - (e) Monies owed to the Parties by customers for the purchase of Beclometasone, and monies owed by the Parties to suppliers for materials used in the productions of Beclometasone.



## SCHEDULE - (X)

### RATIOPHARM'S ATROPINE BASED PRODUCT

#### ATROPINE - THE NETHERLANDS

1. Divestment Business consists of ratiopharm's (or an Affiliated Undertaking's) rights, title and interests in Atropine in the Netherlands (currently marketed under the brand name Atropinesulf-rat) including the right to develop, manufacture and use Atropine with a view to its sale in any form and for any indication whatsoever in the Netherlands. Atropine is a poisonous crystalline alkaloid extracted from the nightshade family; used as an antispasmodic and to dilate the eye pupil; also administered in large amounts as an antidote for organophosphate nerve agents or organophosphate insecticides. For the avoidance of doubt, Divestment Business does not contain any rights to sell Atropine outside of the Netherlands.
2. Divestment Business includes:
  - (a) the sale of existing product inventory, sales and promotional material in the Netherlands;
  - (b) all contracts, leases, commitments and customer orders, all customer, credit and other records;
  - (c) the transfer of the marketing authorization for Atropine in the Netherlands including all relevant dossiers relating to the current and/or pending marketing authorizations available to ratiopharm;
  - (d) an irrevocable, assignable, sub-licensable, and royalty free license for all relevant intellectual property rights, data, books, records and effective arrangements for the transfer of all know-how to the extent that these are related to the development, manufacture, use of Divestment Business with a view to its sale in the Netherlands; including in particular the information contained in the registration dossier, which contains the following modules:
    - Module 1: administrative information about the marketing authorization holder, release site, mock-ups of packaging, etc.
    - Module 2: high level summaries (the Quality Overall Summary, the Nonclinical Overview/Summaries and the Clinical Overview/Summaries);
    - Module 3: chemical, pharmaceutical and biological documentation;
    - Module 4: Nonclinical Study Reports;
    - Module 5: Clinical Study Reports;(items referred to under (a)-(d) hereinafter collectively referred to as "Assets of Divestment Business").
3. Teva commits on behalf of ratiopharm to make its best efforts to obtain the assignment of the contract manufacturing agreement entered into between ratiopharm and [confidential] or at the option of the Purchaser, Teva shall enter into a supply arrangement with the Purchaser

for the non-exclusive supply of Atropine in the Netherlands, for a period of three years and on a reasonable cost plus basis to be agreed with the Purchaser.

4. The transitional supply arrangement referred to in paragraph 3 shall include appropriate provisions designed to ensure the continuous supply by Teva to the Purchaser of Atropine in the Netherlands for a period of three years . It shall not contain any provision requiring the delivery of minimum supply volumes or batches, nor supply quantity restrictions.
5. Teva commits on behalf of ratiopharm to make its best efforts to cooperate with the Purchaser for the transfer of the production of Atropine to the Purchaser's production facilities and undertakes to approve all regulatory changes that would be required as a result of such transfer.
6. Teva commits on behalf of ratiopharm 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 of the products to the Purchaser's facilities. A copy of this report will be sent to the Monitoring Trustee.
7. At the option of the Purchaser, Teva commits on behalf of ratiopharm to provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of Atropine in the Netherlands, including any transitory regulatory, logistics and distribution services, for a period of 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 ratiopharm provide technical assistance to the Purchaser expeditiously. ratiopharm 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 Divestment Business shall not include:
  - (a) Any manufacturing facility;
  - (b) Raw materials;
  - (c) Any research and development, clinical data and studies or intellectual property relating to Atropine after Closing;
  - (d) All marketing authorizations currently held by the Parties outside of the Netherlands for Atropine;
  - (e) Monies owed to the Parties by customers for the purchase of Atropine, and monies owed by the Parties to suppliers for materials used in the productions of Atropine.

## SCHEDULE - (XI)

### RATIOPHARM'S KETOTIFEN BASED PRODUCT

#### KETOTIFEN - THE NETHERLANDS

1. Divestment Business consists of ratiopharm's (or an Affiliated Undertaking's) rights, title and interests in Ketotifen in the Netherlands (currently marketed under the brand name Ketotifen-GF) including the right to develop, manufacture and use Ketotifen with a view to its sale in any form and for any indication whatsoever in the Netherlands. Depending on its form, Ketotifen is indicated for the treatment of allergic conjunctivitis or to prevent asthma attacks. For the avoidance of doubt, Divestment Business does not contain any rights to sell Ketotifen outside of the Netherlands.
2. Divestment Business includes:
  - (a) the sale of existing product inventory, sales and promotional material in the Netherlands;
  - (b) all contracts, leases, commitments and customer orders, all customer, credit and other records;
  - (c) the transfer of the marketing authorization for Ketotifen in the Netherlands including all relevant dossiers relating to the current and/or pending marketing authorizations available to ratiopharm;
  - (d) an irrevocable, assignable, sub-licensable, and royalty free license for all relevant intellectual property rights, data, books, records and effective arrangements for the transfer of all know-how to the extent that these are related to the development, manufacture, use of Divestment Business with a view to its sale in the Netherlands; including in particular the information contained in the registration dossier, which contains the following modules:
    - Module 1: administrative information about the marketing authorization holder, release site, mock-ups of packaging, etc.
    - Module 2: high level summaries (the Quality Overall Summary, the Nonclinical Overview/Summaries and the Clinical Overview/Summaries);
    - Module 3: chemical, pharmaceutical and biological documentation;
    - Module 4: Nonclinical Study Reports;
    - Module 5: Clinical Study Reports;(items referred to under (a)-(d) hereinafter collectively referred to as "Assets of Divestment Business").
3. At the option of the Purchaser, Teva shall enter into a supply arrangement with the Purchaser for the non-exclusive supply of Ketotifen in the Netherlands, for a period of three years and on a reasonable cost plus basis to be agreed with the Purchaser.

4. The transitional supply arrangement referred to in paragraph 3 shall include appropriate provisions designed to ensure the continuous supply by Teva to the Purchaser of Ketotifen in the Netherlands for a period of three years . It shall not contain any provision requiring the delivery of minimum supply volumes or batches, nor supply quantity restrictions.
5. Teva commits on behalf of ratiopharm to make its best efforts to cooperate with the Purchaser for the transfer of the production of Ketotifen to the Purchaser's production facilities and undertakes to approve all regulatory changes that would be required as a result of such transfer.
6. Teva commits on behalf of ratiopharm 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 of the products to the Purchaser's facilities. A copy of this report will be sent to the Monitoring Trustee.
7. At the option of the Purchaser, Teva commits on behalf of ratiopharm to provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of Ketotifen in the Netherlands, including any transitory regulatory, logistics and distribution services, for a period of 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 ratiopharm provide technical assistance to the Purchaser expeditiously. ratiopharm 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 Divestment Business shall not include:
  - (a) Any manufacturing facility;
  - (b) Raw materials;
  - (c) Any research and development, clinical data and studies or intellectual property relating to Ketotifen after Closing;
  - (d) All marketing authorizations currently held by the Parties outside of the Netherlands for Ketotifen;
  - (e) Monies owed to the Parties by customers for the purchase of Ketotifen, and monies owed by the Parties to suppliers for materials used in the productions of Ketotifen.

## SCHEDULE - (XII)

### RATIOPHARM'S DEXAMETHASONE BASED PRODUCT

#### DEXAMETHASONE - THE NETHERLANDS

1. Divestment Business consists of ratiopharm's (or an Affiliated Undertaking's) rights, title and interests in Dexamethasone in the Netherlands (currently marketed under the brand name Dexamethason-rat) including the right to develop, manufacture and use Dexamethasone with a view to its sale in the oral solid ordinary form only, and for any indication whatsoever in the Netherlands. Dexamethasone is a steroid drug used as an anti-inflammatory and immunosuppressant. For the avoidance of doubt, Divestment Business does not include any of ratiopharm's (or an Affiliated Undertaking's) rights, title and interest in any form of Dexamethasone other than the oral solid ordinary form and does not contain any rights to sell Dexamethasone outside of the Netherlands.
2. Divestment Business includes:
  - (a) the sale of existing product inventory, sales and promotional material in the Netherlands;
  - (b) all contracts, leases, commitments and customer orders, all customer, credit and other records;
  - (c) the transfer of the marketing authorization for Dexamethasone in the Netherlands including all relevant dossiers relating to the current and/or pending marketing authorizations available to ratiopharm;
  - (d) an irrevocable, assignable, sub-licensable, and royalty free license for all relevant intellectual property rights, data, books, records and effective arrangements for the transfer of all know-how to the extent that these are related to the development, manufacture, use of Divestment Business with a view to its sale in the Netherlands; including in particular the information contained in the registration dossier, which contains the following modules:
    - Module 1: administrative information about the marketing authorization holder, release site, mock-ups of packaging, etc.
    - Module 2: high level summaries (the Quality Overall Summary, the Nonclinical Overview/Summaries and the Clinical Overview/Summaries);
    - Module 3: chemical, pharmaceutical and biological documentation;
    - Module 4: Nonclinical Study Reports;
    - Module 5: Clinical Study Reports;(items referred to under (a)-(d) hereinafter collectively referred to as "Assets of Divestment Business").
3. Teva commits on behalf of ratiopharm to make its best efforts to obtain the assignment of the contract manufacturing agreement entered into between ratiopharm and [confidential], or at the option of the Purchaser, Teva shall enter into a supply arrangement with the Purchaser

for the non-exclusive supply of Dexamethasone in the Netherlands, for a period of three years , and on a reasonable cost plus basis to be agreed with the Purchaser.

4. The transitional supply arrangement referred to in paragraph 3 shall include appropriate provisions designed to ensure the continuous supply by Teva to the Purchaser of Dexamethasone in the Netherlands for a period of three years . It shall not contain any provision requiring the delivery of minimum supply volumes or batches, nor supply quantity restrictions.
5. Teva commits on behalf of ratiopharm to make its best efforts to cooperate with the Purchaser for the transfer of the production of Dexamethasone to the Purchaser's production facilities and undertakes to approve all regulatory changes that would be required as a result of such transfer.
6. Teva commits on behalf of ratiopharm 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 of the products to the Purchaser's facilities. A copy of this report will be sent to the Monitoring Trustee.
7. At the option of the Purchaser, Teva commits on behalf of ratiopharm to provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of Dexamethasone in the Netherlands, including any transitory regulatory, logistics and distribution services, for a period of 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 ratiopharm provide technical assistance to the Purchaser expeditiously. ratiopharm 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 Divestment Business shall not include:
  - (a) Any manufacturing facility;
  - (b) Raw materials;
  - (c) Any research and development, clinical data and studies or intellectual property relating to Dexamethasone after Closing;
  - (d) All marketing authorizations currently held by the Parties outside of the Netherlands for Dexamethasone;
  - (e) Monies owed to the Parties by customers for the purchase of Dexamethasone, and monies owed by the Parties to suppliers for materials used in the productions of Dexamethasone.

## SCHEDULE - (XIII)

### RATIOPHARM'S HYDROCORTISONE BASED PRODUCT

#### HYDROCORTISONE - THE NETHERLANDS

1. Divestment Business consists of ratiopharm's (or an Affiliated Undertaking's) rights, title and interests in Hydrocortisone in the Netherlands (currently marketed under the brand name Hydrocortis.AC-GF) including the right to develop, manufacture and use Hydrocortisone with a view to its sale in the oral ordinary form only and for any indication whatsoever in the Netherlands. Hydrocortisone is a steroid hormone used for the treatment of diseases that are caused by an overactive immune system, such as allergies, asthma, autoimmune diseases and sepsis. For the avoidance of doubt, Divestment Business does not include any of ratiopharm's (or an Affiliated Undertaking's) rights, title and interest in any form of Hydrocortisone other than the oral solid ordinary form and does not contain any rights to sell Hydrocortisone outside of the Netherlands.
  
  2. Divestment Business includes:
    - (a) the sale of existing product inventory, sales and promotional material in the Netherlands;
    - (b) all contracts, leases, commitments and customer orders, all customer, credit and other records;
    - (c) the transfer of the marketing authorization for Hydrocortisone in the Netherlands including all relevant dossiers relating to the current and/or pending marketing authorizations available to ratiopharm;
    - (d) an irrevocable, assignable, sub-licensable, and royalty free license for all relevant intellectual property rights, data, books, records and effective arrangements for the transfer of all know-how to the extent that these are related to the development, manufacture, use of Divestment Business with a view to its sale in the Netherlands; including in particular the information contained in the registration dossier, which contains the following modules:
      - Module 1: administrative information about the marketing authorization holder, release site, mock-ups of packaging, etc.
      - Module 2: high level summaries (the Quality Overall Summary, the Nonclinical Overview/Summaries and the Clinical Overview/Summaries);
      - Module 3: chemical, pharmaceutical and biological documentation;
      - Module 4: Nonclinical Study Reports;
      - Module 5: Clinical Study Reports;
- (items referred to under (a)-(d) hereinafter collectively referred to as "Assets of Divestment Business").

3. [confidential] at the option of the Purchaser, Teva shall enter into a supply arrangement with the Purchaser for the non-exclusive supply of Hydrocortisone in the Netherlands, for a period of three years , and on a reasonable cost plus basis to be agreed with the Purchaser.
4. [confidential] the transitional supply arrangement referred to in paragraph 3 shall include appropriate provisions designed to ensure the continuous supply by Teva to the Purchaser of Hydrocortisone in the Netherlands for a period of three years . It shall not contain any provision requiring the delivery of minimum supply volumes or batches, nor supply quantity restrictions.
5. [confidential] Teva commits on behalf of ratiopharm to make its best efforts to cooperate with the Purchaser for the transfer of the production of Hydrocortisone to the Purchaser's production facilities and undertakes to approve all regulatory changes that would be required as a result of such transfer.
6. [confidential] Teva commits on behalf of ratiopharm 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 of the products to the Purchaser's facilities. A copy of this report will be sent to the Monitoring Trustee.
7. At the option of the Purchaser, Teva commits on behalf of ratiopharm to provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of Hydrocortisone in the Netherlands, including any transitory regulatory, logistics and distribution services, for a period of 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 ratiopharm provide technical assistance to the Purchaser expeditiously. ratiopharm 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 Divestment Business shall not include:
  - (a) Any manufacturing facility;
  - (b) Raw materials;
  - (c) Any research and development, clinical data and studies or intellectual property relating to Hydrocortisone after Closing;
  - (d) All marketing authorizations currently held by the Parties outside of the Netherlands for Hydrocortisone;
  - (e) Monies owed to the Parties by customers for the purchase of Hydrocortisone, and monies owed by the Parties to suppliers for materials used in the productions of Hydrocortisone.



## SCHEDULE - (XIV)

### RATIOPHARM'S IBUPROFEN BASED PRODUCT

#### IBUPROFEN - THE NETHERLANDS

1. Divestment Business consists of ratiopharm's (or an Affiliated Undertaking's) rights, title and interests in Ibuprofen in the Netherlands (currently marketed under the brand name Ibuprofen-rat) including the right to develop, manufacture and use Ibuprofen with a view to its sale in the rectal systemic form only and for any indication whatsoever in the Netherlands. Ibuprofen is a non-steroidal anti-inflammatory drug used for relief of symptoms of arthritis, primary dysmenorrhea, fever, and as an analgesic, especially where there is an inflammatory component. For the avoidance of doubt, Divestment Business does not include any of ratiopharm's (or an Affiliated Undertaking's) rights, title and interest in any form of Ibuprofen other than the rectal systemic form and does not contain any rights to sell Ibuprofen outside of the Netherlands.
  
  2. Divestment Business includes:
    - (a) the sale of existing product inventory, sales and promotional material in the Netherlands;
    - (b) all contracts, leases, commitments and customer orders, all customer, credit and other records;
    - (c) the transfer of the marketing authorization for Ibuprofen in the Netherlands including all relevant dossiers relating to the current and/or pending marketing authorizations available to ratiopharm;
    - (d) an irrevocable, assignable, sub-licensable, and royalty free license for all relevant intellectual property rights, data, books, records and effective arrangements for the transfer of all know-how to the extent that these are related to the development, manufacture, use of Divestment Business with a view to its sale in the Netherlands; including in particular the information contained in the registration dossier, which contains the following modules:
      - Module 1: administrative information about the marketing authorization holder, release site, mock-ups of packaging, etc.
      - Module 2: high level summaries (the Quality Overall Summary, the Nonclinical Overview/Summaries and the Clinical Overview/Summaries);
      - Module 3: chemical, pharmaceutical and biological documentation;
      - Module 4: Nonclinical Study Reports;
      - Module 5: Clinical Study Reports;
- (items referred to under (a)-(d) hereinafter collectively referred to as "Assets of Divestment Business").

3. At the option of the Purchaser, Teva shall enter into a supply arrangement with the Purchaser for the non-exclusive supply of Ibuprofen in the Netherlands, for a period of three years , and on a reasonable cost plus basis to be agreed with the Purchaser.
4. The transitional supply arrangement referred to in paragraph 3 shall include appropriate provisions designed to ensure the continuous supply by Teva to the Purchaser of Ibuprofen in the Netherlands for a period of three years . It shall not contain any provision requiring the delivery of minimum supply volumes or batches, nor supply quantity restrictions.
5. Teva commits on behalf of ratiopharm to make its best efforts to cooperate with the Purchaser for the transfer of the production of Ibuprofen to the Purchaser's production facilities and undertakes to approve all regulatory changes that would be required as a result of such transfer.
6. Teva commits on behalf of ratiopharm 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 of the products to the Purchaser's facilities. A copy of this report will be sent to the Monitoring Trustee.
7. At the option of the Purchaser, Teva commits on behalf of ratiopharm to provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of Ibuprofen in the Netherlands, including any transitory regulatory, logistics and distribution services, for a period of 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 ratiopharm provide technical assistance to the Purchaser expeditiously. ratiopharm 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 Divestment Business shall not include:
  - (a) Any manufacturing facility;
  - (b) Raw materials;
  - (c) Any research and development, clinical data and studies or intellectual property relating to Ibuprofen after Closing;
  - (d) All marketing authorizations currently held by the Parties outside of the Netherlands for Ibuprofen;
  - (e) Monies owed to the Parties by customers for the purchase of Ibuprofen, and monies owed by the Parties to suppliers for materials used in the productions of Ibuprofen.

## SCHEDULE - (XV)

### RATIOPHARM'S LITHIUM BASED PRODUCT

#### LITHIUM - THE NETHERLANDS

1. Divestment Business consists of ratiopharm's (or an Affiliated Undertaking's) rights, title and interests in Lithium in the Netherlands (currently marketed under the brand name LithiumCarbon-GF) including the right to develop, manufacture and use Lithium with a view to its sale in the oral solid ordinary form only and for any indication whatsoever in the Netherlands. Lithium is a mood stabilizer. For the avoidance of doubt, Divestment Business does not include any of ratiopharm's (or an Affiliated Undertaking's) rights, title and interest in any form of Lithium other than the oral solid ordinary form and does not contain any rights to sell Lithium outside of the Netherlands.
2. Divestment Business includes:
  - (a) the sale of existing product inventory, sales and promotional material in the Netherlands;
  - (b) all contracts, leases, commitments and customer orders, all customer, credit and other records;
  - (c) the transfer of the marketing authorization for Lithium in the Netherlands including all relevant dossiers relating to the current and/or pending marketing authorizations available to ratiopharm;
  - (d) an irrevocable, assignable, sub-licensable, and royalty free license for all relevant intellectual property rights, data, books, records and effective arrangements for the transfer of all know-how to the extent that these are related to the development, manufacture, use of Divestment Business with a view to its sale in the Netherlands; including in particular the information contained in the registration dossier, which contains the following modules:
    - Module 1: administrative information about the marketing authorization holder, release site, mock-ups of packaging, etc.
    - Module 2: high level summaries (the Quality Overall Summary, the Nonclinical Overview/Summaries and the Clinical Overview/Summaries);
    - Module 3: chemical, pharmaceutical and biological documentation;
    - Module 4: Nonclinical Study Reports;
    - Module 5: Clinical Study Reports;(items referred to under (a)-(d) hereinafter collectively referred to as "Assets of Divestment Business").
3. At the option of the Purchaser, Teva shall enter into a supply arrangement with the Purchaser for the non-exclusive supply of Lithium in the Netherlands, for a period of three years , and on a reasonable cost plus basis to be agreed with the Purchaser.

4. The transitional supply arrangement referred to in paragraph 3 shall include appropriate provisions designed to ensure the continuous supply by Teva to the Purchaser of Lithium in the Netherlands for a period of three years . It shall not contain any provision requiring the delivery of minimum supply volumes or batches, nor supply quantity restrictions.
5. Teva commits on behalf of ratiopharm to make its best efforts to cooperate with the Purchaser for the transfer of the production of Lithium to the Purchaser's production facilities and undertakes to approve all regulatory changes that would be required as a result of such transfer.
6. Teva commits on behalf of ratiopharm 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 of the products to the Purchaser's facilities. A copy of this report will be sent to the Monitoring Trustee.
7. At the option of the Purchaser, Teva commits on behalf of ratiopharm to provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of Lithium in the Netherlands, including any transitory regulatory, logistics and distribution services, for a period of 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 ratiopharm provide technical assistance to the Purchaser expeditiously. ratiopharm 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 Divestment Business shall not include:
  - (a) Any manufacturing facility;
  - (b) Raw materials;
  - (c) Any research and development, clinical data and studies or intellectual property relating to Lithium after Closing;
  - (d) All marketing authorizations currently held by the Parties outside of the Netherlands for Lithium;
  - (e) Monies owed to the Parties by customers for the purchase of Lithium, and monies owed by the Parties to suppliers for materials used in the productions of Lithium.

## SCHEDULE - (XVI)

### RATIOPHARM'S PROPYLTHIOURACIL BASED PRODUCT

#### PROPYLTHIOURACIL - THE NETHERLANDS

1. Divestment Business consists of ratiopharm's (or an Affiliated Undertaking's) rights, title and interests in Propylthiouracil in the Netherlands (currently marketed under the brand name Propylthiouracil-rat) including the right to develop, manufacture and use Propylthiouracil with a view to its sale in any form and for any indication whatsoever in the Netherlands. Propylthiouracil is a thioamide drug used to treat hyperthyroidism. For the avoidance of doubt, Divestment Business does not contain any rights to sell Propylthiouracil outside of the Netherlands.
2. Divestment Business includes:
  - (a) the sale of existing product inventory, sales and promotional material in the Netherlands;
  - (b) all contracts, leases, commitments and customer orders, all customer, credit and other records;
  - (c) the transfer of the marketing authorization for Propylthiouracil in the Netherlands including all relevant dossiers relating to the current and/or pending marketing authorizations available to ratiopharm;
  - (d) an irrevocable, assignable, sub-licensable, and royalty free license for all relevant intellectual property rights, data, books, records and effective arrangements for the transfer of all know-how to the extent that these are related to the development, manufacture, use of Divestment Business with a view to its sale in the Netherlands; including in particular the information contained in the registration dossier, which contains the following modules:
    - Module 1: administrative information about the marketing authorization holder, release site, mock-ups of packaging, etc.
    - Module 2: high level summaries (the Quality Overall Summary, the Nonclinical Overview/Summaries and the Clinical Overview/Summaries);
    - Module 3: chemical, pharmaceutical and biological documentation;
    - Module 4: Nonclinical Study Reports;
    - Module 5: Clinical Study Reports;(items referred to under (a)-(d) hereinafter collectively referred to as "Assets of Divestment Business").
3. Teva commits on behalf of ratiopharm to make its best efforts to obtain the assignment of the contract manufacturing agreement entered into between ratiopharm and [confidential], or at the option of the Purchaser, Teva shall enter into a supply arrangement with the Purchaser for the non-exclusive supply of Propylthiouracil in the Netherlands, for a period of three years and on a reasonable cost plus basis to be agreed with the Purchaser.

4. The transitional supply arrangement referred to in paragraph 3 shall include appropriate provisions designed to ensure the continuous supply by Teva to the Purchaser of Propylthiouracil in the Netherlands for a period of three years. It shall not contain any provision requiring the delivery of minimum supply volumes or batches, nor supply quantity restrictions.
5. Teva commits on behalf of ratiopharm to make its best efforts to cooperate with the Purchaser for the transfer of the production of Propylthiouracil to the Purchaser's production facilities and undertakes to approve all regulatory changes that would be required as a result of such transfer.
6. Teva commits on behalf of ratiopharm 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 of the products to the Purchaser's facilities. A copy of this report will be sent to the Monitoring Trustee.
7. At the option of the Purchaser, Teva commits on behalf of ratiopharm to provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of Propylthiouracil in the Netherlands, including any transitory regulatory, logistics and distribution services, for a period of 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 ratiopharm provide technical assistance to the Purchaser expeditiously. ratiopharm 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 Divestment Business shall not include:
  - (a) Any manufacturing facility;
  - (b) Raw materials;
  - (c) Any research and development, clinical data and studies or intellectual property relating to Propylthiouracil after Closing;
  - (d) All marketing authorizations currently held by the Parties outside of the Netherlands for Propylthiouracil;
  - (e) Monies owed to the Parties by customers for the purchase of Propylthiouracil, and monies owed by the Parties to suppliers for materials used in the productions of Propylthiouracil.

## SCHEDULE - (XVII)

### RATIOPHARM'S TRAMADOL BASED PRODUCT

#### TRAMADOL - HUNGARY

1. Divestment Business consists of ratiopharm's (or an Affiliated Undertaking's) rights, title and interests in Tramadol in Hungary (currently marketed under the brand name Tramado-ratioph.) including the right to develop, manufacture and use Tramadol with a view to its sale in any form and for any indication whatsoever in Hungary. Tramadol is a centrally-acting analgesic, used for treating moderate to moderately severe pain. For the avoidance of doubt, Divestment Business does not contain any rights to sell Tramadol outside of Hungary.
2. Divestment Business includes:
  - (a) the sale of existing product inventory, sales and promotional material in Hungary;
  - (b) all contracts, leases, commitments and customer orders, all customer, credit and other records;
  - (c) the transfer of the marketing authorization for Tramadol in Hungary including all relevant dossiers relating to the current and/or pending marketing authorizations available to ratiopharm;
  - (d) an irrevocable, assignable, sub-licensable, and royalty free license for all relevant intellectual property rights, data, books, records and effective arrangements for the transfer of all know-how to the extent that these are related to the development, manufacture, use of Divestment Business with a view to its sale in Hungary; including in particular the information contained in the registration dossier, which contains the following modules:
    - Module 1: administrative information about the marketing authorization holder, release site, mock-ups of packaging, etc.
    - Module 2: high level summaries (the Quality Overall Summary, the Nonclinical Overview/Summaries and the Clinical Overview/Summaries);
    - Module 3: chemical, pharmaceutical and biological documentation;
    - Module 4: Nonclinical Study Reports;
    - Module 5: Clinical Study Reports;(items referred to under (a)-(d) hereinafter collectively referred to as "Assets of Divestment Business").
3. At the option of the Purchaser, Teva shall enter into a supply arrangement with the Purchaser for the non-exclusive supply of Tramadol in Hungary, for a period of three years, and on a reasonable cost plus basis to be agreed with the Purchaser.

4. The transitional supply arrangement referred to in paragraph 3 shall include appropriate provisions designed to ensure the continuous supply by Teva to the Purchaser of Tramadol in Hungary for a period of three years . It shall not contain any provision requiring the delivery of minimum supply volumes or batches, nor supply quantity restrictions.
5. Teva commits on behalf of ratiopharm to make its best efforts to cooperate with the Purchaser for the transfer of the production of Tramadol to the Purchaser's production facilities and undertakes to approve all regulatory changes that would be required as a result of such transfer.
6. Teva commits on behalf of ratiopharm 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 of the products to the Purchaser's facilities. A copy of this report will be sent to the Monitoring Trustee.
7. At the option of the Purchaser, Teva commits on behalf of ratiopharm to provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of Tramadol in Hungary, including any transitory regulatory, logistics and distribution services, for a period of 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 ratiopharm provide technical assistance to the Purchaser expeditiously. ratiopharm 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 Purchaser will be given an option to hire the Personnel referred to under paragraph 5 of the Commitments, provided, however, that the Personnel hired by the Purchaser would be employees currently employed by ratiopharm.
10. The Divestment Business shall not include:
  - (a) Any manufacturing facility;
  - (b) Raw materials;
  - (c) Any research and development, clinical data and studies or intellectual property relating to Tramadol after Closing;
  - (d) All marketing authorizations currently held by the Parties outside of Hungary for Tramadol;
  - (e) Monies owed to the Parties by customers for the purchase of Tramadol, and monies owed by the Parties to suppliers for materials used in the productions of Tramadol.



## SCHEDULE - B

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[Confidential - list of personnel of ratiopharm in the Netherlands. This list covers a total of 24 employees, including the Managing Director and the Chief Financial Officer. 10 employees are involved in marketing and sales, 2 in regulatory affairs and business development, 4 in finance and administration and 3 in technical operations.]

## SCHEDULE - C

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### RATIOPHARM B.V. AND ITS SUBSIDIARIES (*RATIOPHARM NL ENTITY*)

1. ratiopharm B.V. (*ratiopharm NL entity*) is a legal entity which is currently a wholly owned subsidiary of ratiopharm International GmbH.
2. ratiopharm B.V.'s registered address is: Florapark 4, 2012 HK Haarlem, Netherlands. It is its only place of business. ratiopharm B.V owns three entities, Holland Pharmaceutical Supply B.V, ratiopharm Nederland B.V and Pharmetica B.V. ratiopharm B.V contains all operational sales activities. ratiopharm Nederland B.V. is the marketing authorization holder of the ratiopharm dossiers. Pharmetica B.V. holds the marketing authorizations for the drugstore products. Holland Pharmaceutical Supply B.V has no activity and no asset.
3. Following paragraph 14 of these Commitments, the ratiopharm NL entity includes all tangible and intangible assets (including intellectual property rights), which contribute to the current operation or are necessary to ensure the viability and competitiveness of the ratiopharm NL entity, including in particular:
  - (a) all existing product inventory, sales and promotional material;
  - (b) all contracts, leases, commitments and customer orders, all customer, credit and other records;
  - (c) all licenses, permits and authorizations issued by any governmental organization for the benefit of the ratiopharm NL entity, including a manufacturing license, an import license and a wholesaler license;
  - (e) the transfer of all (approximately [confidential]) marketing authorizations (authorized or submitted) used by the ratiopharm NL entity for the conduct of its business (including pipeline products) including all relevant dossiers relating to the current and/or pending marketing authorizations available to ratiopharm with a view to the sale of the products in the Netherlands;
  - (f) at the option of the Purchaser, an exclusive license to use ratiopharm's name and logo in the Netherlands for a period of two years;
  - (g) all the Personnel employed by ratiopharm in the Netherlands as listed in Schedule B, including Personnel who are involved in marketing and sales, regulatory affairs and business development, finance and administration and technical operations;
  - (h) the five year lease entered into by ratiopharm for its premises in the Netherlands;

- (i) all moveable property owned by ratiopharm in the Netherlands, including but not limited to IT equipment and software;
  - (j) all logistical arrangements that are in place for the distribution of the NL Divestment Businesses : the NL Distribution Assets will include the transfer of the agreement with [confidential] for the distribution of the products of the ratiopharm NL entity in the Netherlands.
- 4. If applicable, Teva commits on behalf of ratiopharm to make its best efforts to obtain the assignment of the contract manufacturing agreement entered into by the ratiopharm NL entity for the manufacture of the relevant products referred to in section 11.2 of the Commitments, or at the option of the Purchaser, Teva shall enter into a supply arrangement with the Purchaser for the non-exclusive supply of the relevant products referred to in section 11.2 of the Commitments in the Netherlands, for a period of three years and on a reasonable cost plus basis to be agreed with the Purchaser.
- 5. If applicable, the transitional supply arrangement referred to in paragraph 4 above shall include appropriate provisions designed to ensure the continuous supply by Teva to the Purchaser of the relevant products referred to in section 11.2 of the Commitments in the Netherlands for a period of three years. It shall not contain any provision requiring the delivery of minimum supply volumes or batches, nor supply quantity restrictions.
- 6. If applicable, Teva commits on behalf of ratiopharm to make its best efforts to cooperate with the Purchaser for the transfer of the production of the products referred to in section 11.2 of the Commitments to the Purchaser's production facilities and undertakes to approve all regulatory changes that would be required as a result of such transfer.
- 7. If applicable, Teva commits on behalf of ratiopharm 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 of the relevant products referred to in section 11.2 of the Commitments to the Purchaser's facilities. A copy of this report will be sent to the Monitoring Trustee.
- 8. At the option of the Purchaser, Teva commits on behalf of ratiopharm to provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture of the relevant products referred to in section 11.2 of the Commitments in the Netherlands, for a period of three years, on a reasonable cost plus basis to be agreed with the Purchaser.
- 9. The transitional technical assistance agreement referred to in paragraph 8 above shall include appropriate provisions to ensure that ratiopharm provide technical assistance to the Purchaser expeditiously. ratiopharm 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.