EN

Case No COMP/M.7379 - MYLAN/ ABBOTT EPD-DM

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REGULATION (EC) No 139/2004
MERGER PROCEDURE

Article 6(1)(b) in conjunction with Art 6(2)
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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 Where possible the information omitted has been replaced by ranges of figures or a general description.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

To the notifying party:

Dear Madam(s) and/or Sir(s),

Subject: **Case M.7379 – MYLAN/ ABBOTT EPD-DM**
Commission decision pursuant to Article 6(1)(b) in conjunction with Article 6(2) of Council Regulation No 139/2004[1] and Article 57 of the Agreement on the European Economic Area[2]

(1) On 28 November 2014**,** the European Commission received notification of a proposed concentration pursuant to Article 4 of the Merger Regulation by which the undertaking Mylan, Inc. ("Mylan" or "the Notifying Party", US) acquires within the meaning of Article 3(1)(b) of the Merger Regulation control of the whole of the undertaking Abbott EPD-DM ("Abbott EPD-DM", Switzerland) by way of purchase of shares.

I. THE PARTIES

(2) **Mylan** is a U.S.-based global pharmaceutical company which develops, licenses, manufactures, markets and distributes generic, branded generic and specialty pharmaceuticals. Mylan offers a broad product portfolio, including more than 1,300 marketed products, to customers in approximately 140 countries. Mylan operates a global vertically-integrated manufacturing platform, which includes more than 35

1 OJ L24, 29.1.2004, p.1 ("the Merger Regulation"). With effect from 1 December 2009, the Treaty on the Functioning of the European Union ("TFEU") has introduced certain changes, such as the replacement of "Community" by 'Union' and "common market" by "internal market". The terminology of the TFEU will be used throughout this decision.

2 OJ L1, 3.1.1994, p.3 ("the EEA Agreement").

Commission européenne, DG COMP MERGER REGISTRY, 1049 Bruxelles, BELGIQUE
Europese Commissie, DG COMP MERGER REGISTRY, 1049 Brussel, BELGIË

Tel: +32 229-91111. Fax: +32 229-64301. E-mail: COMP-MERGER-REGISTRY@ec.europa.eu.

manufacturing facilities around the world. It has extensive active pharmaceutical ingredient ("API") operations.

(3) **Abbott EPD-DM** is the Non-U.S. Developed Markets Specialty and Branded Generics Business of Abbott Laboratories. Abbott EPD-DM is focused on distributing branded ex-originator products whose patents expired.[3] Its portfolio includes approximately 100 products in different therapeutic areas. Products are sourced from both internal and third party manufacturing facilities. Internal production capabilities include plants in Europe, Canada and Japan. The proposed concentration includes the transfer of the finished dose pharmaceutical ("FDP") manufacturing facilities in France and Japan.

II. THE OPERATION

(4) Pursuant to the business transfer agreement signed on 4 November 2014, Abbott EPD-DM will be merged with and into Mylan. Mylan shareholders will hold around 78% of shares of new Mylan. The remaining 22% of shares of the new Mylan will be held by the current shareholders of Abbott EPD-DM, who will not have decisive influence over Mylan.

(5) The transaction thus constitutes an acquisition of sole control by Mylan over Abbott EPD-DM and a concentration within the meaning of Article 3(1)(b) of the Merger Regulation.

III. UNION DIMENSION

(6) The undertakings concerned have a combined aggregate world-wide turnover of more than EUR 5 000 million[4] (Mylan: EUR 5.2 billion; Abbott EPD-DM: EUR 1.6 billion). Each of them has an EU-wide turnover in excess of EUR 250 million (Mylan: EUR […]; Abbott EPD-DM: EUR […]), but each does not achieve more than two-thirds of its aggregate EU-wide turnover within one and the same Member State. The notified operation therefore has a Union dimension.

IV. RELEVANT MARKETS AND COMPETITIVE ASSESSMENT

IV.1. Overall context

(7) In contrast to precedents, the proposed transaction involves a merger between a producer of branded ex-originator drugs (Abbott EPD-DM) and a producer of generics (Mylan). Although all Abbott EPD-DM's ex-originator drugs affected by this transaction lost their exclusivity at least two years ago, Abbott EPD-DM's products remain branded and often command a price premium over their generic equivalents. Mylan, on the other hand is a typical generic supplier, selling mostly non-branded generics. Given the difference in the business model, i.e. branded v. generics, Mylan and Abbott EPD-DM focus on different distribution channels. As the originator, Abbott EPD-DM principally aims its sales efforts at prescribers. By contrast, as a

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3 In January 2013, Abbott Laboratories separated its business into two publicly traded companies: Abbott EPD-DM, focused on diversified medical products, and AbbVie, focused on research-based pharmaceuticals. Only the former, Abbott EPD-DM, is part of the proposed transaction.

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

typical generic company, Mylan mainly focuses its sales efforts on pharmacies and wholesalers.

(8) The rationale of the transaction is for Mylan to diversify its business outside of the U.S. by adding a differentiated portfolio of specialty and branded generic products, to provide entry into the over-the-counter ("OTC") market, to penetrate new markets, in particular Eastern Europe, and to enhance Mylan's reach to physicians as part of the sales channel. For the seller, Abbott Laboratories, the transaction rationale is based on its strategic decision to focus its branded generics business on emerging markets.[5]

(9) The activities of Mylan and Abbott EPD-DM overlap in five therapeutic areas (cardio-metabolic, gastro, anti-infective/respiratory, CNS/pain and women's and men's health) in the production and marketing of generic FDPs (section IV.2). In addition, both Parties develop products in their pipelines (section IV.3). Finally, both Parties are involved in activities in relation to APIs (section IV.4), contract manufacturing (section IV.5) and outlicensing (section IV.6).

IV.2. Finished Dose Pharmaceuticals

IV.2.1. General approach to the product market definition

Analysis based on ATC classification

(10) When defining relevant markets in past decisions dealing with pharmaceutical products, the Commission has established a number of principles.[6] In those decisions it noted that medicines may be subdivided into therapeutic classes by reference to the "Anatomical Therapeutic Classification" (ATC), devised by the European Pharmaceutical Marketing Research Association (EphMRA) and maintained by EphMRA and Intercontinental Medical Statistics (IMS).[7]

(11) The ATC system is a hierarchical and coded four-level system which classifies medicinal products according to their indication, therapeutic use, composition and mode of action. In the first and broadest level (ATC1), medicinal products are divided into the 16 anatomical main groups. The second level (ATC2) is either a pharmacological or therapeutic group. The third level (ATC3) further groups medicinal products by their specific therapeutic indications, i.e. their intended use (e.g. S1K - Artificial tears and ocular lubricants). Finally, the ATC4 level is the most detailed one (not available for all ATC3) and refers for instance to the mode of action (e.g. distinction of some ATC3 classes into topical and systemic depending on their way of action) or any other subdivision of the group.

(12) In its past merger decisions in the pharmaceutical sector, the Commission has referred to the third level (ATC3) as the starting point for defining the relevant

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5 Form CO, paragraphs 11-17.

6 See for example COMP/M.6969 Valeant Pharmaceuticals International/Bausch & Lomb Holdings of 5 August 2013, COMP/M.5778 Novartis/Alcon of 9 August 2010, and COMP/M.5865 Teva/ Ratiopharm of 3 August 2010.

7 See for example COMP/M.6969 Valeant Pharmaceuticals International/Bausch & Lomb Holdings of 5 August 2013, COMP/M.5865 Teva/Ratiopharm of 3 August 2010, and COMP/M.5295 Teva/Barr of 19 December 2008.

product market. However, in a number of cases, the Commission found that the ATC3 level classification did not yield the appropriate market definition within the meaning of the Commission Notice on the Definition of the Relevant Market. As a result, where appropriate and based on the factual evidence collected during the market investigation, the Commission has defined the relevant product market at the ATC4 level or at a level of molecule or a group of molecules that are considered interchangeable so as to exercise competitive pressure on one another.[8] The overlap in therapeutic uses does not necessarily imply any particular economic substitution patterns between products.

(13) In the present case, given the nature of the markets, i.e. mature genericized markets, the Commission took as a starting point the molecule level and assessed, on a case-by-case basis, whether the market should be expanded by including other molecules within the class having the same indication. In those cases in which the substitutability with other molecules was evidenced, the Commission took into account the closeness of substitution between them, while generally considering the generic molecule as being the closest substitute to the ex-originator drug based on the same molecule.

Originator pharmaceuticals and generic pharmaceuticals

(14) Generics are in general less expensive, bioequivalent versions of originator drugs. In regulatory approval procedures, a generic drug manufacturer has to demonstrate that the generic version of the originator drug has the same qualitative and quantitative composition in terms of active substance and the same pharmaceutical form and is bioequivalent to the originator drug.

(15) In previous cases,[9] the market investigation has often suggested that there may be differences in the demand for originator versus generic drugs, even when they are bioequivalent. This is the case more particularly in countries where the penetration of generics is lower and the importance of the brand is higher. On the other hand, the growing trend of regulatory pushes in some countries in favour of generics, such as for instance, mandatory substitution at the pharmacy level, mandatory INN prescription etc. increases the generic substitution. Finally, generic versions of originator medicines are specifically designed to compete with those medicines and normally represent the closest substitute to them.[10]

(16) In addition, the present case specifically concerns the combination of an ex-originator with a generic producer competing head-to-head in many markets. Therefore, in line with the precedents, the Commission considers that in relation to the overlapping molecules the product market includes both generic and originator versions.

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8 COMP/M.6969 Valeant Pharmaceuticals International/Bausch & Lomb Holdings of 5 August 2013, COMP/M.6705 Procter & Gamble/Teva Pharmaceuticals OTC II of 9 November 2012, COMP/M.6613 Watson/Actavis of 5 October 2012, and COMP/M.5865 Teva/Ratiopharm of 3 August 2010.

9 See for example COMP/M.5865 Teva/Ratiopharm of 3 August 2010, and COMP/M.5295 Teva/Barr of 19 December 2008.

10 COMP/M.5253 Sanofi-Aventis/Zentiva of 4 February 2009.

Prescription drugs v. Over-the-counter ("OTC") drugs

(17) In certain cases, pharmaceutical products may be further subdivided into various segments on the basis of a variety of criteria, and in particular demand-related criteria. The Commission has in the past[11] defined separate markets for medicines, which can be issued only on prescription and those, which can be sold over the counter (OTC). Medical indications, side effects, legal framework, distribution and marketing tend to differ between these drug categories, even if the active ingredients are sometimes identical.

(18) OTC products may be advertised to the public at large. Doctors do not need to intervene in the purchase of these products. In most cases, consumers choose OTC pharmaceuticals themselves and purchases are not reimbursed. By contrast, prescription pharmaceuticals need to be prescribed by a doctor, whose intervention is thus essential in the choice of the product. Pricing for prescription products is influenced by the public health care system, who pays (part of) the purchase price via reimbursement. Marketing, therefore, is targeted at prescribers, that is, doctors and hospitals.[12]

(19) Notwithstanding such differences, it has been outlined in previous decisions[13] that in certain cases, products which are available OTC are still reimbursable if bought on prescription.

(20) Furthermore, in some specific circumstances it may not be excluded that these products compete with each other, especially in cases where the status of the drug is not clearly limited to either OTC or prescription.[14]

(21) In the case at hand, most drugs are only prescription drugs. For those drugs that are both available on prescription and OTC, the market investigation did not provide any indications that the market should be sub-divided according to this criterion.

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11 See for example COMP/M.6969 Valeant Pharmaceuticals International/Bausch & Lomb Holdings of 5 August 2013, COMP/M.5778 Novartis/Alcon of 9 August 2010, COMP/M.5865 Teva/Ratiopharm of 3 August 2010, and COMP/M.5295 Teva/Barr of 19 December 2008.

12 COMP/M.5953 Reckitt Benckiser/SSL of 25 October 2010.

13 See for example COMP/M.5778 Novartis/Alcon of 9 August 2010, COMP/M.5253 Sanofi-Aventis/Zentiva of 4 February 2009, and COMP/M.3751 Novartis/Hexal of 27 May 2005.

14 COMP/M.5778 Novartis/Alcon of 9 August 2010.

Galenic form

(22) As the Commission has acknowledged in its previous decisions,[15] 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.[16]

(23) 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. In general, the first letter differentiates between forms for systemic and topical effect, site of application, and also between long-acting and ordinary forms.

(24) The market investigation in the present case has shown, for some of the products considered in this case, that different routes of administration and the pharmaceutical form of a medicine may be designed to serve the needs of different patient groups and are therefore not interchangeable. This was shown to be the case for the liquid form of certain drugs (such as syrups), which are mainly designed for paediatric patients.

(25) In any event, the question of whether the relevant markets should be further subdivided according to the galenic form can be left open for the purpose of this decision as competitive assessment of individual markets would not change irrespective of galenic form concerned.

IV.2.2. Relevant geographic market

(26) The Commission has previously defined the geographic markets for pharmaceutical products as being national in scope. The market investigation in this case did not provide any indications that such market definition should be revisited, in particular in view of the national regulatory and reimbursement schemes and the fact that competition between pharmaceutical firms still predominantly takes place at a national level.

(27) Therefore, for the purpose of this decision the Commission concludes that the scope of the geographic markets in relation to all assessed FDPs markets is national.

IV.2.3. Product-specific assessment

(28) The Commission conducted a far reaching market investigation in this case. In total, the Commission sent more than 800 questionnaires to five different categories of market participants: prescribers, competitors, wholesalers and distributors, pharmacies and national health authorities. In addition to this, the Commission conducted more than 30 conference calls with various market participants, including the leading medical specialists in the relevant areas ("key opinion leaders").

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15 See for example COMP/M.5778 Novartis/Alcon of 9 August 2010, COMP/M.5865 Teva/ Ratiopharm of 3 August 2010, and COMP/M.5253 Sanofi-Aventis/Zentiva 4 February 2009.

16 See 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 L311, 28.11.2001, p.67), as amended by various subsequent acts.

(29) The Commission also analysed the information provided by the Parties, including a considerable number of internal documents.

(30) The findings in this decision are based on the overall assessment of all available evidence.

IV.2.3.1. Methodology used in the assessment of affected markets

(31) In the sections concerning the competitive assessment in each affected market below, the Commission provides a detailed and individual assessment of a number of affected markets in each of the five main therapeutic areas where the Parties' activities overlap: cardio-metabolic, gastro, anti-infective/respiratory, CNS/pain and women's and men's health.

(32) In line with the past decisions, given a large number of affected markets in pharmaceutical mergers (numerous product and geographic markets), the Commission has applied a system of filters aimed at determining the group of markets where concerns are most likely and on which its focused its analysis.

(33) Specifically, the markets were grouped in four groups:

- **Group 1**: where the Parties' combined market share exceeds 35% AND the increment exceeds 1%.

- **Group 2**: where the Parties' combined market share exceeds 35% but the increment is below 1%.

- **Group 3**: where the Parties' combined market share is between 20%[17] and 35%.

- **Group 1 "plus"**:[18] there are two scenarios of non-Group 1 markets, which deserve a closer attention: (1) the combined market share is below 35% BUT only one other competitor remains on the market, and (2) the combined market share exceeds 35% and the increment is below 1% BUT the party with the small increment is a recent entrant.[19]

17 Initially, this group included markets where the combined market share ranges between 15% and 35%. However, in line with the new Notice on Simplified procedure (Commission Notice on a simplified procedure for treatment of certain concentrations under Council Regulation (EC) No 139/2004) this range was adapted to 20% to 35% to include only affected markets.

18 See COMP/M.5778 Novartis/Alcon, paragraph 25.

19 No Group 1 "plus" overlaps were identified in this case (Form CO, footnote 31).

(34) Therefore, as a starting point the Commission assessed in detail all Group 1 markets under the narrowest plausible market definition, i.e. at the molecule level. Specifically, the market investigation focused on a number of molecules belonging to these five therapeutic areas, giving rise to 68 Group 1 overlaps at the molecule level, 13 Group 1 overlaps at the ATC4 level and 26 Group 1 overlaps at the ATC3 level. A total number of 107 Group 1 overlaps were examined by the Commission.

(35) Depending on the results of the market investigation on the scope of the relevant market in relation to these molecules, the Commission assessed these markets on three different alternative levels: (i) at the narrowest market definition, i.e. the molecule, which in any case, as explained above (see paragraph (13)), was taken as the starting point of the assessment, (ii) at a combination of interchangeable molecules within the same ATC4 or ATC3 class, and finally (iii) at the broader ATC4 or ATC3 level. In some instances, in particular in relation to the markets where serious doubts arise, the market investigation provided clear indications that the markets are limited to the molecule based on the specificities of those molecules pointing to the lack of alternatives providing therapeutically equal outcome.

(36) Besides, a total of 198 Group 2 and Group 3 affected markets were also examined. Affected markets which fell within these categories have been considered within their therapeutic area. The Commission in particular assessed the competitive situation on these markets analysing the nature and the number of existing competitors. In this decision, these markets are not considered in detail individually and are covered by the general conclusions in relation to markets where no serious doubts as to the compatibility of the transaction with the internal market arise.

IV.2.3.2. Assessment of the markets by therapeutic area

CARDIO AREA

(37) This therapeutic area includes a range of drugs that are used to treat various forms of heart and blood vessel diseases and to control the various risk factors that arise from heart disease, such as hypertension, high blood lipid levels and irregular heart rhythms. Both Parties are present in this therapeutic area with numerous marketed molecules, which belong to various ATC3 classes. In particular, Group 1 overlaps were identified (at the molecule level) in relation to the molecules set out below.

IV.2.3.2.a. Propafenone and amiodarone hydrochloride (C1B)

Product market definition

(38) Abbott EPD-DM markets propafenone and Mylan markets amiodarone, two drugs that both belong to the ATC3 class C1B which comprises of all products recommended for use for irregularities with the rate or rhythm of the heartbeat (arrhythmia), disorders of cardiac rhythm and tachycardia (heart rate that exceeds the normal range).

(39) In its precedent decisions, the Commission has considered whether the ATC3 class C1B was appropriate to define the product market for this type of products. It

concluded from the results of the market investigation that applying the Vaughan-Williams classification, rather than the ATC classification is more appropriate.[20]

(40) The Vaughan-Williams classification system was developed in an attempt to classify the numerous antiarrhythmic drugs on the basis of their mechanism. This system re-classifies the drugs included in ATC3 class C1B in four different classes:

i. Class I: includes the main molecules that affect the conduction velocity (i.e. the speed with which an electrical impulse can be transmitted through excitable tissue);

ii. Class II: includes beta blockers (anti-hypertensives that act by way of beta-adrenergic blocking) for the treatment of hypertension;

iii. Class III: includes two products that slow down the ventricular repolarization and affect sodium channels: amiodarone and sotalol;

iv. Class IV: includes the calcium antagonists used for the treatment of hypertension or cardiac ischemia.

(41) Although in past cases the Commission considered that Classes I (containing propafenone) and III (containing amiodarone) may not be substitutable when used in the treatment of ventricular arrhythmias, it left the exact market definition open.[21]

(42) The Notifying Party submits that the Parties market two different molecules, propafenone and amiodarone. With regard to these two molecules, there is an overlap of the Parties' products at the level of the ATC3 class C1B, but no overlap according to the classification by Vaughan-Williams, because propafenone belongs to Vaughan-Williams Class I and amiodarone to Vaughan-Williams Class III.

(43) However, Abbott EPD-DM markets also solatol, a beta-blocking agent, which belongs to ATC3 class C7A and is used to treat arrhythmia and hypertension. Solatol belongs to Vaughan-Williams Class II and III at the same time; given that it has both beta-blockade and potassium-channel blockade effects. Accordingly, the Parties' products overlap in relation to Class III of the Vaughan-Williams classification.

(44) The market investigation provided indications that the products for the treatment of arrhythmia, disorders of cardiac rhythm and tachycardia may be classified according to the classification of Vaughan-Williams. In this context, the prescribers indicated that sotalol and amiodarone are generally substitutable to each other.

(45) Therefore, for the purposes of this decision, the Commission concludes that the relevant product market in relation to drugs treating arrhythmias, and in particular propafenone and amiodarone, should be defined according to the Vaughan-Williams classification.

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20 See COMP/M.3354 Sanofi-Synthelabo/Aventis, paragraph 40, and COMP/M.1397 Sanofi/Synthélabo, paragraph 34.

21 See COMP/M.3354 Sanofi-Synthelabo/Aventis, paragraph 40.

Competitive assessment

(46) On the basis of the market definition set out about, the proposed transaction gives rise to one Group 1 affected market, Portugal.

Portugal

(47) In Vaughan-Williams Class III, the Parties market the following molecules: Abbott EPD-DM markets solatol under the brand name Darob. Mylan markets amiodarone as branded generic Amioda.

(48) The Parties' combined market share reaches [30-40]% (value) and [30-40]% (volume) with an increment (Abbott EPD-DM) of [10-20]% (value) and [10-20]% (volume). There is a number of branded and generic competitors active, namely the market leader Sanofi having a market share of [40-50]% (in value) and [30-40]% (in volume), followed by Generis Farma with a market share of [5-10]% in value and [5-10]% in volume. In addition, Hikma Pharma is active and has a [0-5]% market share (value and volume) as well as Alter Pharma with a market share of [0-5]% (in value and volume).

(49) The size of the Portuguese market (2013) is EUR 2.9 million and has been declining from EUR 3.3 million in 2011. Sanofi as the ex-originator markets its branded product Cordarone based on amiodarone. Generis Farma and Fresenius together market three un-branded generic products based on amiodarone. Hikma Pharma and Alter Pharma each offer an amiodarone-based un-branded generic product.

(50) In addition, four competitors (BioPortugal, Bluepharma Genéricos, Labesfal Genéricos and Ibigen) hold dormant marketing authorisations for different dosages of amiodarone in the Portuguese market, which can be used to enter the market within a short period of time.

(51) Except for one Fresenius product, all drugs in the Vaughan-Williams Class III of the Parties and their main competitors in Portugal are reimbursed by the national health authorities. The Portuguese health authorities establish a maximum ex-factory price. This price is based on an international reference system considering the average wholesale price in three other EU member states which have a comparable gross domestic product to Portugal. Since wholesale and pharmacy margins are also regulated, this results therefore in a capped outpatient price at pharmacy level (public price paid by patients in the pharmacy). Price increases of pharmaceutical products are possible up to the maximum price set by the authority. In addition, each pharmaceutical company may submit an application for a price increase, which however needs to be motivated. It follows that the ability of pharmaceutical companies to increase prices for these drugs is generally limited.

(52) Moreover, competing products based on the same molecule are typically closer substitutes than products based on different molecules, even if they belong to same Vaughan-Williams class. This is due to the different clinical and safety profile of each molecule. The regulatory framework in Portugal also facilitates substitutability across products based on the same molecule at pharmacy level,[22] while substitution

22 In Portugal, INN prescribing is mandatory. When dispensing, the pharmacist must inform the patient of the most affordable medicinal product that complies with the medical prescription and which is reimbursed and available in the pharmacy.

across molecules can only happen at the level of physician's prescription. In the case at hand, the overlap is observed in products based on different molecules, which therefore are unlikely to be closest competitors.

(53) Finally, given that solatol also belongs to Williams-Vaughan Class II, it is likely to be simultaneously constrained by the competitive dynamics between products in this other class, where the Parties do not overlap.

Conclusion

(54) The Commission, taking into consideration all of the above, including the results of the market investigation, concludes that the transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to the products belonging to the Vaughan-Williams Class III in Portugal.

IV.2.3.2.b. Moxonidine (C2A)

Product market definition

(55) Both Mylan and Abbott EPD-DM sell moxonidine which belongs to the ATC3 class C2A – Antihypertensives (of non-herbal origin), plain. The C2A class includes a group of substances used primarily for the treatment of hypertension. It comprises plain antihypertensives and various fixed dose combinations other than those with diuretics. The C2A class is further subdivided into ATC4 classes whereby the class C2A1 includes products which are mainly centrally-acting (e.g. moxonidine), while products which are mainly peripherally-acting are included in the ATC4 class C2A2.

(56) Although the Commission has not dealt specifically with moxonidine in a past decision concerning antihypertensives,[23] the Commission, analysing the effects of the transaction on the molecule level in relation to three molecules namely methyldopa, prasozin and terasozin, ultimately left the exact market definition open and in particular the question of whether the relevant market should be defined on the basis of ATC3, ATC4 or even molecule level.

(57) The Notifying Party submits that its products based on moxonidine compete with other centrally-acting antihypertensives, as they have the same mode of action, serve the same patient group and the therapeutical results are similar for all centrally-acting antihypertensives. In addition, in the countries where relevant overlaps occur (see below), moxonidine and its other centrally-acting alternatives are subject to the same reimbursement rate. Therefore, Notifying Party submits that the relevant market for moxonidine would comprise all centrally-acting antihypertensives, i.e. the entire ATC4 class C2A1.

(58) Based on the results of the market investigation many hypertension conditions that are treated by moxonidine could also be treated by some other centrally-acting antihypertension drugs. However, this does not necessarily imply substitution patterns across centrally-acting antihypertension drugs.

(59) Moreover, competing products based on the same molecule are typically closer competitors than products based on different molecules, even if they belong to the

23 See COMP/M.5865 Teva/Ratiopharm, paragraph 130 et seq.

same ATC class. This is due to the fact that, despite the shared indications, different molecules still show different clinical and safety profiles. The regulatory framework also typically facilitates substitutability across products based on the same molecule at pharmacy level, while substitution across molecules can only happen at the level of physician's prescription.

(60) The degree of product differentiation between the several calcium antagonist products available in the market is sufficient to have led Mylan to develop and commercialise two centrally-acting hypertensive products based on different molecules (moxonidine and rilmenidine). This evidence suggests a degree of economic differentiation across centrally-acting hypertensives, and that having an additional centrally-acting hypertensive based on a different molecule in the firm's portfolio brings enough additional sales as to justify the sunk investment needed to develop and launch it in the first place.

(61) In any event, the exact product market definition for moxonidine can be left open for the purpose of this decision as no serious doubts arise in relation to moxonidine under any alternative market definition.

Competitive assessment

(62) On the basis of a narrowest molecule based market, the proposed transaction gives rise to three Group 1 markets, namely France, Czech Republic and Italy.

France

(63) On the molecule level, the combined market share of the Parties reaches [50-60]% (value) and [50-60]% (volume). Abbott EPD-DM's has been steadily decreasing (halved) in last years. The size of the French moxonidine market is around EUR 5.2 million in 2013 and has been declining from EUR 7.6 million in 2011.

(64) There is a number of branded and generic competitors active, namely the market leader Servier having a market share of [20-30]% (in value) and [20-30]% (in volume) with its branded generic product Moxonidine Biogaran, followed by Teva ([10-20]% in value and [20-30]% in volume), and Stada ([5-10]% in value and [5-10]% in volume). Both Servier and Teva have increased their market shares by some [5-10]% each between 2011 and 2013 and have significant marketing and distribution footprints as well as customer relationships in France. In parallel, Abbott EPD-DM has been consistently losing market share.

(65) Moxonidine is a reimbursed drug in France. The prices of all reimbursed drugs in France are regulated throughout the chain given that they are all part of the so-called positive lists for hospitals and for community pharmacies.[24] As a result, the ability of pharmaceutical companies to increase prices for these drugs is generally limited.[25]

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24 In France, there is a strict regulatory framework concerning the pricing and reimbursement of prescription medicines. Through its medical and economic assessment, the French national health authority (*Haute Autorité de Santé – HAS*) establishes whether a drug is reimbursable or not. It also eventually fixes the level of reimbursement for all drugs which are listed on the positive lists. The level of reimbursement of the drugs (as % of the price) is decided on the basis of different levels of actual benefit of the drug, such as follows: important (65% reimbursed), moderate (30% reimbursed), mild (15% reimbursed) and insufficient (no reimbursement, not listed). The French national pricing authority (*Comité Economique des Produits de Santé - CEPS*) sets the maximum prices (*ex-factory*)

(66) Finally, the market investigation did not raise concerns in relation to moxonidine in France.

Conclusion

(67) The Commission, taking into consideration all of the above, including the results of the market investigation, concludes that the transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to the moxonidine market in France.

Czech Republic

(68) On the molecule level, the combined market share of the Parties' reaches [50-60]% (value) and [40-50]% (volume) with a rather limited increment of [5-10]% (value) and [5-10]% (volume). The size of the Czech moxonidine market is around EUR 5.4 million in 2013 and has been declining from EUR 6.6 million in 2011.

(69) Abbott EPD-DM's market share has been steadily decreasing in the last years. There is a number of branded and generic competitors active, namely Stada holding a market share of [20-30]% (value) and [30-40]% (volume), Actavis with a market share of [10-20]% and Worevag with a comparable share to the increment brought by Mylan, i.e. [5-10]%. Actavis seems to be a competitor gaining significant market share from [5-10]% in 2012 when it entered to above [10-20]% in the year thereafter.

(70) Moxonidine is a reimbursed drug in the Czech Republic. Reimbursable pharmaceutical products are subject to a maximum ex-factory price and a maximum distribution margin based on external reference pricing derived from a basket of several EU countries. As a result, the ability of pharmaceutical companies to increase prices for these drugs is generally limited.

(71) Finally, the market investigation did not raise concerns in relation to moxonidine in the Czech Republic.

Conclusion

(72) The Commission, taking into consideration all of the above, including the results of the market investigation, concludes that the transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to moxonidine in the Czech Republic.

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for originator and generic medicines that are reimbursed. Medicine lines which are genericized are deemed to be submitted to further regular price reductions (so-called "*baisse de prix*"). In addition, wholesale and pharmacy margins for reimbursed products are regulated by law. It can be concluded from the specificities of the French health regulation that the ability to increase prices is limited.

25 A change of the regulated outpatient price is only possible through application to the HAS and requires either robust clinical data demonstrating a clinical value-added or by delisting the product from the reimbursement list, which would then result in free pricing. It can be concluded from the specificities of the French health regulation that the ability to increase pharmacy sales prices is limited as it is constrained by the need to apply for and achieve a positive evaluation from the HAS.

Italy

(73) On the molecule level, the combined market share of the Parties' reaches [70-80]% (value) and [70-80]% (volume) with a rather limited increment of [0-5]% (value) and [0-5]% (volume). The size of the Italian moxonidine market is around EUR 1.8 million in 2013 and has been declining from EUR 2.4 million in 2011.

(74) Abbott EPD-DM is active with its ex-originator branded product Fisiotens and its share of the market has been steadily decreasing since the loss of exclusivity. Stada is the strongest competitor holding a market share of [20-30]% (value) and [20-30]% (volume), consistently gaining share from Abbott EPD-DM in the last years. Stada's entry had a significant impact on moxonodine price which, according to the Parties' internal documents have been declining.

(75) Moxonidine is a reimbursed drug in Italy. The prices of the reimbursed drugs are set through negotiation between the relevant manufacturer and the Italian Medicines Agency ("AIFA"). The regulatory framework does not generally allow for price increases where it concerns reimbursed products. As a result, the ability of pharmaceutical companies to increase prices for these drugs is generally limited.

(76) One competitor holds a dormant marketing authorisation for three different dosages of moxonidine in Italy, which can be re-activated within a short period of time.

(77) Finally, the market investigation did not raise concerns in relation to moxonidine in Italy.

Conclusion

(78) The Commission, taking into consideration all of the above, including the results of the market investigation, concludes that the transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to moxonidine in Italy.

IV.2.3.2.c. Verapamil and Diltiazem (C8A)

Product market definition

(79) Both Mylan and Abbott EPD-DM market verapamil, which is a calcium channel blocker derived from phylalkylamine. It belongs to the ATC3 class C8A which is comprised of plain calcium antagonists that are primarily used for the treatment of high blood pressure and angina. Calcium antagonists, or calcium channel blockers, are a type of anti-hypertensives that inhibit movement of calcium ions across a cell membrane. They include dihydropyridines ("DHPs") like nifedipine and non-DHPs such as verapamil and diltiazem.

(80) The Commission has so far assessed this type of molecules twice.[26] First, it concluded that combining multiple ATC2 classes consisting of numerous hypertension drugs would be too wide for market definition purposes. In a subsequent case, the Commission assessed ATC3 class C8A and concluded that DHPs and non-DHPs compete. It also found that various types of antihypertensive

26 See COMP/M.1403 Astra/Zeneca, and COMP/M.1878 Pfizer/Warner-Lambert.

drugs including beta blockers, calcium antagonists, ACE inhibitors form separate markets.[27]

(81) The Notifying Party submits that the product market should be defined in line with the Commission's precedents as ATC3 class C8A, because DHPs and non-DHPs (such as verapamil and diltiazem) compete with one another.

(82) It can be derived from the results of the market investigation that there are several molecules that share mechanism of action and indications with verapamil, such as amlodipine, diltiazem, felodipine, gallopamil, nifedipine, and which can therefore in some cases and for some patients be prescribed alternatively by physicians. This overlap in therapeutic uses does not however imply any particular economic substitution patterns across calcium antagonist drugs. The market investigation did not provide any indications that the market in this case should be further segmented depending on the galenic form or on whether the drug is sold against a prescription or OTC.

(83) Moreover, competing products based on the same molecule are typically closer substitutes than products based on different molecules, even if they belong to same ATC class. This is due to the fact that, despite the shared indications, different molecules still show different clinical and safety profiles. The regulatory framework also typically facilitates substitutability across products based on the same molecule at pharmacy level, while substitution across molecules can only happen at the level of physician's prescription.

(84) The degree of product differentiation between the several calcium antagonist products available in the market is sufficient to have led Mylan to develop and commercialise not less than 6 calcium antagonist products based on different molecules (amlodipine; diltiazem; lercanidipine; manidipine; nifedipine and nitrendipine). This evidence suggests a degree of differentiation between calcium antagonists, and that having an additional calcium antagonist based on a different molecule in the firm's portfolio brings enough additional sales as to justify the sunk investment needed to develop and launch it in the first place. In any event, the exact product market definition for verapamil and diltiazem can be left open for the purpose of this decision as no serious doubts arise in relation to verapamil and diltiazem under any alternative market definition.

Competitive assessment

(85) On the basis of the narrowest molecule based market definition, the proposed transaction gives rise to three Group 1 affected markets for verapamil, namely in France, Ireland and Sweden, as well as one Group 1 affected market in relation to diltiazem, namely in Portugal.

France

(86) On the molecule level for verapamil, the combined market shares of the Parties reach [60-70]% (value) and [60-70]% (volume). Abbott EPD-DM's shares have been steadily decreasing in the last years. The size of the French verapamil market is around EUR 21.5 million in 2013.

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27 See COMP/M.1878 Pfizer/Warner-Lambert, paragraphs 23-25.

(87) There are a number of branded and generic competitors active, namely Teva with a market share of [10-20]% (value) and [20-30]% (volume), Servier with [5-10]% (value) and [5-10]% (volume), Stada with [5-10]% and Novartis with [0-5]%. All these four competitors have a significant marketing and distribution footprint as well as customer relations in France. Therefore, they will be in a position to exert competitive pressure on the merged entity post-merger.

(88) The prices of all drugs in the class in France are regulated throughout the chain given that they are all part of the so-called positive lists for hospital and for community pharmacies. As a result, the ability of pharmaceutical companies to increase prices for these drugs is generally limited.[28]

(89) Finally, the market investigation did not raise concerns in relation to verapamil in France.

Conclusion

(90) The Commission, taking into consideration all of the above, including the results of the market investigation, concludes that the transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to verapamil in France.

Ireland

(91) On the molecule level for verapamil, the combined market share of the Parties in Ireland reaches [60-70]% (value) and [60-70]% (volume) with the increment of Mylan being limited reaching only [0-5]% in value and [5-10]% in volume. Abbott EPD-DM is present with its branded products Isoptin and Securon, albeit its market share has been decreasing from [60-70]% in volume and [60-70]% in value in 2011. The Irish verapamil market is very small with a turnover of EUR 339,000 in 2013 and has been declining from EUR 660,000 in 2011.

(92) [Mylan's information on phasing out activities and the lack of future plans with regard to re-entering the market of verapamil in Ireland].. The degree of competitive constraint exercised by Mylan can already be considered as negligible as it does not have any prospects of re-entry in the short term.

(93) In addition, the other competitors, Novartis/Rowa/Wagner and Orion have increased their market share from [10-20]% and [5-10]% (in value) in 2011 to [20-30]% and [10-20]% in 2013 respectively.

(94) Finally, the market investigation did not raise concerns in relation to verapamil in Ireland.

Conclusion

(95) The Commission, taking into consideration all of the above, including the results of the market investigation, concludes that the transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to verapamil in Ireland.

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28 See footnotes 24 and 25 for the description of the French regulatory system.

Sweden

(96) On the molecule level for verapamil, the combined market share of the Parties in Sweden reaches [50-60]% (value) and [60-70]% (volume) going down from [90-100]% (value) and [90-100]% (volume) as a consequence of parallel imports by 2Care4 and Orifarm that reached market shares of [20-30]% and [10-20]% (value) and [10-20]% and [10-20]% (volume).

(97) Procurement procedures for verapamil in Sweden are characterised by the use of tenders which occur every month and typically exert downward pressure on pricing. Tenders are used to appoint preferred suppliers on the basis of a competitive process based on price competition. Therefore, competition takes place for the market (as opposed to "in the market"). In such a system, high market shares for verapamil are not necessarily indicative of the Parties' ability to affect the conditions of sale pre- or post-merger.

(98) Moreover, the size of the Swedish verapamil market is relatively small with a turnover of around EUR 1.28 million in 2013 and has been declining from EUR 1.45 million in 2011. In these particular circumstances, namely where tenders are frequent and the market is small, importing capacity of parallel importers may be significant. The ability of parallel importers to quote lower prices when participating in tender procedures triggers downward pressure on prices, obliging suppliers with an established local presence to undercut prices to avoid being excluded from the set of appointed preferred suppliers. The high frequency of tenders in Sweden (i.e. on a monthly basis) facilitates the participation of parallel importers despite their general lack of security of long-term supply. As a consequence, parallel importers can exert a pricing constraint in the rather unique setting observed in Sweden.

(99) Finally, the market investigation did not raise concerns in relation to verapamil in Sweden.

Conclusion

(100) The Commission, taking into consideration all of the above, including the results of the market investigation, concludes that the transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to verapamil in Sweden.

Portugal

(101) On the diltiazem molecule level, the combined market share of the Parties in Portugal reaches [20-30]% (value) and [30-40]% (volume) with an increment of [0-5]% for Abbott EPD-DM's product. The market leader is Rottapharm Madaus with a [40-50]% market share (value and volume). Sanofi has a market share of [20-30]% in value and [10-20]% in volume. The size of the Portuguese diltiazem market is around EUR 4.5 million in 2013 and has been declining from EUR 6 million in 2011.

(102) The Portuguese health authorities establish a maximum ex-factory price. This price is based on an international reference system considering the average wholesale price in three other EU Member States which have a comparable gross domestic product to Portugal. Since wholesale and pharmacy margins are also regulated, this results therefore in a capped outpatient price at pharmacy level (public price paid by patients in the pharmacy). Price increases of pharmaceutical products are possible up

to the maximum price set by the authority. In addition, each pharmaceutical company may submit an application for a price increase, which however needs to be motivated. It follows that the ability of pharmaceutical companies to increase prices for these drugs is generally limited.

(103) Finally, the market investigation did not raise concerns in relation to diltiazem in Portugal.

Conclusion

(104) The Commission, taking into consideration all of the above, including the results of the market investigation, concludes that the transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to diltiazem in Portugal.

IV.2.3.2.d. Hydrochlorothiazide/verapamil and mefruside/nifedipine (C8B1)

Product market definition

(105) The ATC3 class C8B includes calcium antagonists combined with other active ingredients. Calcium antagonists are used to treat various conditions of the heart and blood vessels including hypertension. The ATC4 class C8B1 relates to combinations of calcium antagonists with other antihypertensives and/or diuretics.

(106) The Commission has so far twice assessed this type of molecules.[29] First, it concluded that combining multiple ATC2 classes consisting of numerous hypertension drugs would be too wide for market definition purposes. In the subsequent case, the Commission assessed ATC3 class C8A and concluded that DHPs and non-DHPs compete. It also held that various types of antihypertensive drugs including beta blockers, calcium antagonists, ACE inhibitors form separate markets.[30] However, the Commission has not yet considered a product market definition for ATC4 class C8B1 combination products.

(107) The Notifying Party submits that due to the fact that it discontinued its product in ATC4 class C8B1 in mid-2013 and re-entry will not occur in the short to medium term there is no need to reach any conclusions on market definition for this segment.

(108) Mylan stopped the marketing of its product (sold under the brand name Duranifin Sali), [Mylan's information on discontinuation of its product].

(109) [Mylan's information on market share development of its product]. Therefore, Mylan sold the last batch into the market in August 2013 and it confirms that there are no stocks left. Accordingly, Mylan has no commercial incentive to-enter this market segment.

(110) Finally, Mylan's product has officially been set "AV" (i.e. sales officially terminated) in the German public price list "Lauertaxe" on 15 September 2013.

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29 See COMP/M.1403 Astra/Zeneca, and COMP/M.1878 Pfizer/Warner-Lambert.

30 See COMP/M.1878 Pfizer/Warner-Lambert, paragraphs 23-25.

Conclusion

(111) Based on the above, the Commission considers that the discontinuation of Mylan's ATC4 C8B1 product Duranifin Sali was an autonomous and definitive business decision by Mylan and that production and marketing of this product was unlikely to resume. As a result, Mylan's decision to exit the relevant markets constitutes the relevant counterfactual and therefore overlaps in these markets do not arise irrespective of the market definition.

IV.2.3.2.e. Trandolapril (C9A)

Product market definition

(112) Both Mylan and Abbott EPD-DM market trandolapril, an anti-hypertension product. Trandolapril is an angiotensin-converting-enzyme inhibitor ("ACE inhibitor"), which reduces peripheral arterial resistance by inactivating an enzyme that converts angiotensin I to the vasoconstrictor angiotensin II. It belongs to the ATC3 class C9A which is comprised of plain ACE inhibitors that are primarily used for the treatment of high blood pressure and congestive heart failure.

(113) In its latest decision dealing with ACE-inhibitors, the Commission defined the market at the molecule level. In its investigation on perindopril, an ACE inhibitor in the C9A class, the Commission concluded that no antihypertensive medicine other than the generic versions of perindopril was able to meaningfully constrain branded perindopril sales and prices.[31] In previous merger decisions, the Commission had left the product market definition open in relation to ACE inhibitors.[32]

(114) The Notifying Party submits that the product market should be defined to include at least ATC3 class C9A and possibly also ATC3 class C9B, as all ACE inhibitor drugs have comparable efficacy in terms of their blood pressure lowering ability.

(115) The market investigation indicated that although ACE inhibitors share mechanism of action and indications, they cannot always substitute each other. The market investigation provided evidence that each molecule has its specificities and that in some cases trandolapril is even the only ACE inhibitor that can be used. Indeed, the overlap in some indications does not imply substitution patterns across ACE inhibitors.

(116) Moreover, products based on the same molecule are typically closer substitutes than products based on different molecules, even if they belong to same ATC class. This is due to the fact that, despite the shared indications, different molecules still show different clinical and safety profiles. The regulatory framework also typically facilitates substitutability across products based on the same molecule at pharmacy level, while substitution across molecules can only happen at the level of physician's prescription.

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31 See COMP/39612 Perindopril (Servier) case, press release from July 9, 2014 (http://europa.eu/rapid/press-release_IP-14-799_en htm).

32 See COMP/M.1403 Astra/Zeneca, paragraph 18, COMP/M.1878 Pfizer/Warner-Lambert, paragraph 24, COMP/M.2517 Bristol Myers Squibb/Du Pont, paragraph 14, and COMP/M.3354 Sanofi-Synthelabo/Aventis, paragraph 82.

(117) The degree of product differentiation between the several calcium antagonist products available in the market is sufficient to have led both Abbott EPD-DM and Mylan to develop and commercialise several ACE inhibitors based on different molecules in parallel. Abbott EPD-DM commercialises three ACE inhibitors (cilazapril, imidapril and trandolapril), while Mylan commercialises ten different ACE inhibitors (benazepril, captopril, enalapril, fosinopril, lisinopril, perindopril, quinapril, ramipril, trandolapril and zofenopril). This evidence suggests a degree of differentiation between ACE inhibitors, and that having an additional ACE inhibitor based on a different molecule in the firm's portfolio brings enough additional sales as to justify the sunk investment needed to develop and launch it in the first place.

(118) The market investigation also indicated that trandolapril is not a widely used ACE inhibitor and its share has been declining as more modern therapies, including combination drugs, gain traction in the market.

(119) In any event, the product market definition in relation to trandolapril can be left open for the purpose of this case as no serious doubts arise in relation to trandolapril irrespective of the market definition.

Competitive assessment

(120) On the basis of the narrowest molecule based market definition, the proposed transaction gives rise to Group 1 affected markets in Poland, Czech Republic, France, Italy, Portugal and Slovakia.

Poland

(121) The combined market share of the Parties at molecule level in Poland reaches [90-100]% (value) and [90-100]% (volume) with a limited increment of less than [0-5]% (value) and [0-5]% (volume) brought by Mylan. Abbott EPD-DM is active with its branded product Gopten while Mylan sells generic. Since 2013 Actavis is also active with a share of around [5-10]% which it gained in the first year.

(122) The size of the Polish trandolapril market is rather small of around EUR 3.6 million in 2013 and has been declining from EUR 4.1 million in 2011. This seems to be in line with the finding that trandolapril is a rarely used molecule in Poland and more generally in Eastern Europe. According to the market investigation, trandolapril in Poland is typically used only as a third line of treatment, in rare situations where ramipril and perindopril would not produce satisfying effects.

(123) In addition, none of trandolapril based drugs are reimbursed in Poland, which also explains its low penetration. Although pricing of non-reimbursed drugs is free, the prices have been decreasing in Poland irrespective of the concentrated nature of the Polish trandolapril market. The rapid gain of trandolapril sales share by Actavis, compared to the decrease in Mylan's share between 2012 and 2013, suggests that Actavis currently exerts the strongest competitive pressure on Abbott EPD-DM for trandolapril in Poland. This competitive constraint will remain active post transaction.

(124) Moreover, three competitors hold dormant marketing authorisations to sell trandolapril in several dosages in the Polish market, which can be re-activated within a short period of time. One of these marketing authorisations is held by Galex, with an established presence in the Polish market through a portfolio of drugs, including several cardiologic therapies like ramipril, lisinopril and valsartan amongst others.

Galex is present with trandolapril in a number of other European markets, including Slovenia, Denmark, Czech Republic, Hungary, Slovakia, Bulgaria, Estonia, Latvia, Lithuania and Romania. Alvogen, a generic multinational company that acquired the Romanian Labormed Pharma, is the current holder of another market authorisation for trandolapril in Poland. Alvogen has a portfolio of more than 350 pharmaceutical products and an established presence in Poland as well as most Eastern and Central European Countries, including Bulgaria, Croatia, Czech Republic, Estonia, Hungary, Latvia, Lithuania and Slovakia.

(125) Finally, the market investigation did not raise concerns in relation to trandolapril in Poland.

Conclusion

(126) Taking into consideration all of the above, including the results of the market investigation and the minimal increment resulting from the transaction, the Commission, concludes that the transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to trandolapril in Poland.

Czech Republic

(127) The combined market share of the Parties at molecule level in the Czech Republic reaches [90-100]% (value) and [90-100]% (volume) with a limited increment of [0-5]% (value) and [0-5]% (volume) brought by Mylan. Abbott EPD-DM is active with its branded product Gopten while Mylan sells a generic product. Since 2013 Teva has also been active with a share of around [5-10]% which it gained in the first year.

(128) The size of the Czech trandolapril market is rather small of less than EUR 3 million in 2013 and has been declining from EUR 3.7 million in 2011. Similarly to Poland, trandorapril is a rarely used molecule in the Czech Republic, relative to other ACE inhibitors.

(129) The rapid gain of trandolapril sales share by Teva, compared to the relatively flat evolution of Mylan's share since 2011, suggests that Teva currently exerts the strongest competitive pressure on Abbott EPD-DM for trandolapril in the Czech Republic.

(130) Moreover, at least one competitor, Galex, holds a dormant marketing authorisation to sell trandolapril in several dosages in the Czech Republic, which can be re-activated within a short period of time. Galex has an established presence in the Czech market through a portfolio of drugs, including several cardiologic therapies like ramipril and valsartan. Galex is present with trandolapril in a number of other European markets, including Slovenia, Denmark, Czech Republic, Hungary, Slovakia, Bulgaria, Estonia, Latvia, Lithuania and Romania.

(131) Trandolapril-based products are reimbursed in the Czech Republic. Reimbursable pharmaceutical products are subject to a maximum ex-factory price and a maximum distribution margin based on external reference pricing derived from a basket of several EU countries. As a result, the ability of pharmaceutical companies to increase prices for these drugs is generally limited.

(132) Finally, the market investigation did not raise concerns in relation to trandolapril in the Czech Republic.

Conclusion

(133) Taking into consideration all of the above, and in particular the minimal increment resulting from the transaction, together with the rising constraint exerted by Teva and the presence of relevant potential competition, the Commission concludes that the transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to trandolapril in the Czech Republic.

France

(134) The combined market share of the Parties at molecule level in France reaches [60-70]% (both in value and volume). Abbott EPD-DM is active with its branded product Odrik while Mylan sells a generic product. Servier, Actavis and Stada are also present holding market shares of [20-30]%, [5-10]% and [0-5]% respectively. Moreover, [EPD-DM's information on lack of promotion of trandolapril in France]. Between 2011 and 2013, its market share dropped from [50-60]% to [30-40]%.

(135) The size of the French trandolapril market is limited amounting to less than EUR 6 million in 2013 and has been declining from EUR 7.3 million in 2011. In addition, given its strong network of prescribers in the cardio-metabolic area and French historical franchise, Servier is a particularly vigorous competitor in the French market consistently gaining market share. Specifically, between 2011 and 2013 Servier gained [10-20]% market share while Abbott EPD-DM lost around [10-20]% of its sales. This evidence suggests that Servier's trandolapril currently exerts the strongest competitive pressure on the merging Parties for trandolapril in France.

(136) Trandolapril-based products are reimbursed in France. The prices of all reimbursed drugs in France are regulated throughout the chain given that they are all part of the so-called positive lists for hospital and for community pharmacies. As a result, the ability of pharmaceutical companies to increase prices for these drugs is generally limited.[33]

(137) Finally, the market investigation did not raise concerns in relation to trandolapril in France.

Conclusion

(138) The Commission, taking into consideration all of the above, including the results of the market investigation, concludes that the transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to trandolapril in France.

Italy

(139) The combined market share of the Parties at molecule level in Italy reaches [90-100]%. Abbott EPD-DM is active with its branded product Gopten while Mylan sells a generic product.

(140) Two competitors hold dormant marketing authorizations for various strengths of trandolapril in Italy. One of them is Mediolanum Farmaceutici, an Italian-based

33 See footnotes 24 and 25 for the description of the French regulatory system.

company with established R&D, manufacturing and commercialisation footprint in Italy. Its portfolio of products includes other cardio-metabolic drugs, like lisinopril and ticlopidine. This makes it an experienced potential competitor in the area. The other marketing authorisation is held by Actavis, since it acquired Arrow, the previous holder. Actavis is a multinational pharmaceutical company, with an established manufacturing and commercial presence in Italy. Moreover, Actavis has recently entered the trandolapril market in other countries, like Poland, where it has been a vigorous competitor rapidly gaining market share.

(141) The size of the Italian trandolapril market is very limited amounting to EUR 409,000 in 2013 and has been declining from EUR 578,000 in 2011. Moreover, both relative market shares and unit prices for trandolapril in Italy have remained broadly stable over the last years. The latter, together with the declining size of an already very small market by size, suggests that the competitive dynamics were unlikely to deliver any further price reductions absent the proposed transaction.

(142) In addition, trandolapril is a reimbursed drug in Italy. The prices of the reimbursed drugs are set through negotiation between the relevant manufacturer and AIFA. The regulatory framework does not generally allow for price increases where it concerns reimbursed products. As a result, the ability of pharmaceutical companies to increase prices for these drugs is generally limited.

(143) Finally, the market investigation did not raise concerns in relation to trandolapril in Italy.

Conclusion

(144) The Commission, taking into consideration all of the above, including the results of the market investigation, concludes that the transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to trandolapril in Italy.

Portugal

(145) The combined market share of the Parties at molecule level in Portugal reaches [30-40]% (value) and [30-40]% (volume). Abbott EPD-DM is active with its branded product Gopten while Mylan sells a generic product. Faes and Generis Farma are also present holding significant – higher than Mylan - market shares of [40-50]% and [20-30]% respectively.

(146) The size of the Portugese trandolapril market is very limited amounting to EUR 414,000 in 2013 and has been declining from EUR 1 million in 2011. Generis Farma's market share was steadily rising since 2011 from [10-20]% to [20-30]%.

(147) The trandolapril-based products of the Parties and their competitors in Portugal are reimbursed by the national health authorities. The Portuguese health authorities establish a maximum ex-factory price. This price is based on an international reference system considering the average wholesale price in three other EU member states which have a comparable gross domestic product to Portugal. Since wholesale and pharmacy margins are also regulated, this results therefore in a capped outpatient price at pharmacy level (public price paid by patients in the pharmacy). Price increases of pharmaceutical products are possible up to the maximum price set by the authority. In addition, each pharmaceutical company may submit an application

for a price increase, which however needs to be motivated. It follows that the ability of pharmaceutical companies to increase prices for these drugs is generally limited.

(148) Finally, the market investigation did not raise concerns in relation to trandolapril in Portugal.

Conclusion

(149) The Commission, taking into consideration all of the above, including the results of the market investigation, concludes that the transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to trandolapril in Portugal.

Slovakia

(150) The combined market share of the Parties at molecule level in Slovakia reaches [80-90]% (value) and [80-90]% (volume) with a limited increment of [0-5]% (both in value and [0-5]% (volume) brought by Mylan. Abbott EPD-DM is active with its branded product Gopten while Mylan sells a generic product. Teva is also active holding a market share of [10-20]% (value) and [10-20]% (volume), as well as Actavis ([0-5]% market share in value and volume). The size of the Slovak trandolapril market is around EUR 4.5 million in 2013 and has been declining from EUR 5.4 million in 2011.

(151) The Notifying Party submits that in view of its marginal market share and [Mylan's commercial information concerning its sales of trandolapril in Slovakia], Mylan has decided to discontinue its trandolapril activities in Slovakia. Mylan's stock which is still in the market will be exhausted in the course of […].

(152) Finally, the market investigation did not raise concerns in relation to trandolapril in Slovakia.

Conclusion

(153) The Commission, taking into consideration all of the above, including the results of the market investigation, concludes that the transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to trandolapril in Slovakia.

IV.2.3.2.f. Fenofibrate (C10A)

Product market definition

(154) Fenofibrate is a broad spectrum lipid-lowering agent belonging to the ATC3 class C10A comprising various products used for a range of metabolic disorders, mainly cholesterol and trigyceride regulating preparations. They operate by reducing the amount of fats in blood.

(155) In its past decision, the Commission has considered that the market definition encompasses all cholesterol and tryglyceride regulating preparations (the ATC3 class C10A).[34]

(156) The Notifying Party submits that the product market should be defined in line with the precedent at ATC3 class C10A, as substitution takes place, for example, between fibrates (ATC4 class C10A2) and statins (ATC4 class C10A1).

(157) Based on the results of the market investigation, fenofibrate shares therapeutic indications with other agents, such as bezafibrate, ciprofibrate or fluvastatin, atorvastatin, and simvastatin. This overlap in indications does not imply any particular economic substitution patterns across angiotensin-II receptor antagonists. In addition, the market investigation did not provide any indications that the market in this case should be further segmented depending on the galenic form or on whether the drug is sold against a prescription or OTC.

(158) Moreover, competing products based on the same molecule are typically closer substitutes than products based on different molecules, even if they belong to same ATC class. This is due to the fact that, despite the shared indications, different molecules still show different clinical and safety profiles.

(159) The degree of product differentiation between the several cholesterol and tryglyceride regulating products available in the market is sufficient to have led Mylan to develop four different cholesterol and tryglyceride regulating drugs (bezafibrate, ciprofibrate, fenofibrate and gemfibrozil). This evidence suggests a degree of differentiation between cholesterol and tryglyceride regulating drugs, and that having an additional cholesterol and tryglyceride regulating drug based on a different molecule in the firm's portfolio brings enough additional sales as to justify the sunk investment needed to develop and launch it in the first place.

(160) In any event, the product market definition in relation to fenofibrate can be left open for the purpose of this case as no serious doubts arise in relation to fenofibrate irrespective of the market definition.

Competitive assessment

(161) On the basis of the narrowest molecule based market definition, the proposed transaction gives rise to three Group 1 affected markets, namely France, Germany and Belgium.

France

(162) The combined market share of the Parties at molecule level in France reaches [40-50]% (value) and [40-50]% (volume) with an increment of [20-30]% (value) and [10-20]% (volume) brought by Abbott EPD-DM. A number of other competitors are present in the market, namely Servier with a market share of [20-30]% (value) and [20-30]% (volume), Teva with [10-20]% (value) and [10-20]% (volume), as well as Novartis with [5-10]% (value) and [10-20]% (volume). All three competitors are well established firms, whose market shares increased both jointly and individually

34 See COMP/M.1878 Pfizer/Warner-Lambert, paragraph 24.

over the last years, showing that they represent a significant competitive constraint to the merging Parties.

(163) The size of the French fenofibrate market is around EUR 55 million in 2013 and has been declining from EUR 70 million in 2011.

(164) Fenofibrate-based products are reimbursed in France. The prices of all reimbursed drugs in France are regulated throughout the chain given that they are all part of the so-called positive lists for hospital and for community pharmacies. As a result, the ability of pharmaceutical companies to increase prices for these drugs is generally limited.[35]

(165) Finally, the market investigation did not raise concerns in relation to fenofibrate in France.

Conclusion

(166) The Commission, taking into consideration all of the above, including the results of the market investigation, concludes that the transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to fenofibrate in France.

Germany

(167) The combined market share of the Parties at molecule level in Germany reaches [30-40]% (value) and [20-30]% (volume) with an increment of [10-20]% (value) and [10-20]% (volume) brought by Mylan. The size of the German fenofibrate market is around EUR 9.4 million in 2013 and has been declining from EUR 12.3 million in 2011.

(168) A number of other competitors are present in the market, namely Torrent with a market share of [30-40]% (value) and [30-40]% (volume), Sanofi with [20-30]% (value) and [20-30]% (volume), Novartis with [5-10]% (value) and [5-10]% (volume), as well as Teva with [5-10]% (volume). All the competitors are well established firms. The market share of the leading competitor is higher than the combined market share of the merging Parties, while the second largest competitor has market share well above the increment resulting from the proposed transaction.

(169) Finally, the market investigation did not raise concerns in relation to fenofibrate in Germany.

Conclusion

(170) The Commission, taking into consideration all of the above, including the results of the market investigation, concludes that the transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to fenofibrate in Germany.

35 See footnotes 24 and 25 for the description of the French regulatory system.

Belgium

(171) The combined market share of the Parties at molecule level in Belgium reaches [80-90]% (value) and [70-80]% (volume) with a very low increment of [0-5]% (value) and [0-5]% (volume) brought by Mylan, which entered the market in 2003 as a first generic company. The size of the Belgian fenofibrate market is around EUR 6.6 million in 2013 and has been declining from EUR 7.2 million in 2011.

(172) Other competitors, with much higher market share than Mylan, are present in the market, namely SMB with a market share of [10-20]% (value) and [10-20]% (volume), as well as Stada with [5-10]% (value) and [5-10]% (volume). Both competitors have a well-established and stable presence in the Belgian market and have market share several times higher than the increment resulting from the proposed transaction. Therefore, the main competitive constraints to Abbott EPD-DM will remain active post-transaction.

(173) Finally, the market investigation did not raise concerns in relation to fenofibrate in Belgium.

Conclusion

(174) The Commission, taking into consideration all of the above, including the results of the market investigation, concludes that the transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to fenofibrate in Belgium.

IV.2.3.2.g. Eprosartan (C9C)

Product market definition

(175) Eprosartan belongs to the ATC3 class C9C including plain angiotensin II receptor antagonists. This group of pharmaceuticals is used to treat hypertension, diabetic nephropathy (kidney damage due to diabetes) and congestive heart failure.

(176) So far, the Commission has not assessed the molecule eprosartan specifically. With regard to anti-hypertensives, the Commission has considered in its past decisions that anti-hypertensives belonging to ATC3 classes C7A/B (plain and combined betablockers), ATC3 class C8A/B (plain and combined calcium antagonists), ATC3 class C9A/B (plain and combined ACE inhibitors) and ATC3 class C9C/D (plain and combined angiotensin II inhibitors) are not part of the same product market.[36]

(177) The Notifying Party submits that its products based on eprosartan, which fall under ATC3 class C9C compete with other angiotensin II antagonists, including candesartan, irbesartan, losartan, olmesartan, telmisartan and valsartan. In its submission, the Notifying Party relies on comparable efficacy and safety of different angiotensin II antagonists and the lack of clear clinical benefit as compared from one angiotensin II antagonist to another.

(178) Based on the results of the market investigation, eprosartan shares therapeutic indications with other angiotensin-II receptor antagonists, including losartan,

36 See COMP/M.1403 Astra/Zeneca, paragraph 18, and COMP/M.1878 Pfizer/Warner-Lambert, paragraph 24.

valsartan, candesartan and irbesartan. The overlap in indications does not imply any particular economic substitution patterns across angiotensin-II receptor antagonists.

(179) Moreover, competing products based on the same molecule are typically closer substitutes than products based on different molecules, even if they belong to the same ATC class. This is due to the fact that, despite the shared indications, different molecules still show different interactions and secondary effects. The regulatory framework also often facilitates substitutability across products based on the same molecule at pharmacy level, while substitution across molecules can only happen at the level of physician's prescription.

(180) The degree of product differentiation between the several angiotensin-II receptor antagonists available in the market is sufficient to have led Mylan to develop no less than seven different angiotensin-II receptor antagonists (candesartan cilexetil, eprosartan, irbesartan, losartan, telmisartan and valsartan). This evidence suggests a degree of differentiation between angiotensin-II receptor antagonists, and that having an additional angiotensin-II receptor antagonist based on a different molecule in the firm's portfolio brings enough additional sales as to justify the sunk investment needed to develop and launch it in the first place.

(181) In any event, the product market definition in relation to eprosartan can be left open for the purpose of this case as no serious doubts arise in relation to eprosartan irrespective of the market definition.

Competitive assessment

(182) On the basis of the narrowest molecule-based market definition, the proposed transaction gives rise to one Group 1 affected market, the Netherlands.

The Netherlands

(183) The combined market share of the Parties at molecule level in the Netherlands reaches [60-70]% (value) and [60-70]% (volume) with an increment of [10-20]% (value) and [10-20]% (volume) brought by Mylan. Abbott EPD-DM is active with its branded product Teveten while Mylan sells generic.

(184) There is a strong activity of parallel importers supplying the remaining quantities of eprosartan. In 2011 and 2012, parallel importers provided up to 70% of the overall supplies, after being appointed as preferred suppliers by regulatory authorities following the tenders organised in the framework of the "preference policy" mechanism.

(185) The size of the Dutch eprosartan molecule market is very small with a turnover of around EUR 0.89 million in 2013. The limited size of the market, as compared with Abbott EPD-DM's significant EEA-wide sales of Teveten of […] million, allows parallel importers to find sufficient sources of supply to participate in Dutch tenders. This is evidenced by the approximately 70% market share held by parallel importers in 2011 and 2012. As a consequence, parallel importers exert a pricing constraint in this rather unique setting observed in the Netherlands.

(186) Eprosartan-based products are reimbursed in the Netherlands, and the regulatory framework includes the "preference policy" mechanism that exerts strong downward pressures on pricing through tenders, significantly constraining firms' commercial behaviour. The system enables in fact the use national tenders for generic medicines

such as eprosartan to decide which suppliers are preferred on the basis of a competitive process, based on price. Given the size of the market and the frequency of the tenders, parallel importers also compete in tenders. In such a system, high market shares for generic products are not necessarily indicative of the Parties' ability to affect the conditions of sales. Benefits of competition are rather achieved through effective use of competition for the market (as opposed to competition "in the market").

(187) Finally, the market investigation did not raise concerns in relation to eprosartan in the Netherlands

Conclusion

(188) Taking into consideration all of the above, including the results of the market investigation and in particular the regulatory environment and the rather unique "preference policy" implemented in the Netherlands, the Commission concludes that the transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to eprosartan in the Netherlands.

IV.2.3.2.h. Other Group 2 and Group 3 markets in the cardio therapeutic area

(189) In addition to the Group 1 markets analysed above, there is a number of Group 2 and Group 3 affected markets in the cardio area, specifically:

- *ATC3 class C1B in Belgium, the Czech Republic, France, Italy, and the UK.*
- *ATC3 class C2A in the Czech Republic, Finland, France, Italy, Belgium, Slovakia and Spain.*
- *ATC3 class C7A in Italy*
- *ATC3 class C8A in France, Italy and Portugal*
- *ATC3 class C9A in France and Slovakia*
- *ATC3 class C9B in France*
- *ATC3 class C9C in France*
- *ATC3 class C10A in Belgium, Czech Republic, France, Germany and the UK*

(190) Within these ATC classes several galenic forms are marketed and give rise to technically affected markets. However, the market investigation did not provide any indications that the markets in this case should be further segmented depending on the galenic form or on whether the drug is sold against a prescription or OTC.

(191) On these markets the combined market share of the Parties are moderate to low and / or the increment is below 1%. In all cases there are a number of strong competitors active on these markets with a wide portfolio of products, including branded medicines but also branded and non-branded generic products, such as Servier, Sanofi, Novartis, Stada, Teva, Actavis, Pfizer, Takeda, Sigma Tau, Bristol Myers Squibb, Böhringer Ingelheim.

(192) The market investigation did not provide any indication that competition issues would arise in these markets. On this basis the Commission concludes that the transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to any of these markets.

GASTRO AREA

(193) This therapeutic area concerns products that are prescribed for gastrointestinal indications. The relevant products in this segment for the envisaged transaction are prescribed for treatment of disorders concerning the acid secretion by the stomach, obstipation and irritable bowel syndrome. Both Parties are present in this therapeutic area with several marketed products, which belong to various ATC3 classes. In particular, they compete in the relation to the molecules as set out below.

IV.2.3.2.i. Ranitidine (A2B)

Product market definition

(194) Ranitidine belongs to the ATC3 class A2B which includes antiulcerants. The anti-peptic ulcer category encompasses a variety of drugs used to treat a range of common disorders considered to be related to acid secretion by the stomach. The ATC3 class A2B is further divided into several ATC4 classes depending on the mode of action. For instance, ATC4 class A2B1 contains the H2 antagonists (e.g. ranitidine-based products) and ATC4 class A2B2 includes acid (or proton) pump inhibitors (e.g. lansoprazole-based products).

(195) In past decisions, the Commission has analysed this market both at the ATC3 (A2B – antiulcerants) and ATC4 level (A2B1 - H2 antagonists and A2B2 - acid pump inhibitors).[37] In case COMP/37.507 (AstraZeneca), the Commission defined a separate market at the ATC4 level for proton pump inhibitors which did not include H2 blockers.

(196) The Notifying Party supports a market definition at the ATC4 level leading to a relevant market for the A2B1 class of H2 antagonists, which would include molecules such as ranitidine, cimetidine, famotidine, nizatidine, and roxatidine.

(197) The market investigation indicated that various molecules within the category of H2 antagonists are substitutable and ranitidine is by no means specific. In addition, the results of the market investigation revealed that within the family of antiulcerants A2B2, acid pump inhibitors such as omeprazole, are a more recent and effective generation of products compared to H2 antagonists. Hence, acid pump inhibitors, appear to be preferred by doctors. For example, it was submitted that in France doctors prescribe acid pump inhibitors instead of H2 antagonists in more than 95% of cases. Also, switching patients who are already taking H2 antagonists to acid pump inhibitors is not problematic. Therefore, H2 antagonists appear to be substitutable by acid pump inhibitors, which seem to be more effective (although the reverse substitution may not occur).

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37 See COMP/M.1846 Glaxo Wellcome/Smithkline Beecham and COMP/M.3354 Sanofi-Synthelabo/ Aventis.

(198) Given the one-way substitutability of H2 antagonists (including ranitidine) by acid pump inhibitors, for the purposes of this case the Commission concludes that the relevant product market in relation to ranitidine-based products is wider than the molecule, but narrower than the ATC3 class, likely comprising ATC4 classes A2B1 and A2B2.

Conclusion

(199) On the basis of the market definition set out above, no Group 1 affected markets arise and the transaction does not raise serious doubts in relation to ranitidine.

IV.2.3.2.j. Lactulose (A6A)

Product market definition

(200) Lactulose belongs to the ATC3 class A6A which includes OTC and prescription products used for the treatment of constipation. ATC3 class A6A is further subdivided into several ATC4 classes on the basis of the drugs' mode of action. Lactulose-based products are categorised under the A6A6 class of osmotic laxatives without electrolytes.[38]

(201) In the past, the Commission examined all A6A products within one market.[39] Similarly, in another case where the ATC3 class A6A was considered the Commission found that products categorized in the various ATC4 classes belonging to the ATC3 class A6A are interchangeable to some degree, but it ultimately left open the market definition.[40]

(202) The results of the market investigation suggest that other molecules may be substitutable to lactulose. According to the respondents, lactulose is a relatively old molecule which had popularity in the past. Since then, newer and more effective products have appeared on the market treating the same condition, in particular Polyethylene Glycol ("PEG"), also known under the International Non-proprietary Name ("INN") macrogol, which belongs to the same ATC4 class A6A6 as lactulose. PEG products appear to have lower side effects compared to lactulose. Given their substitutability, PEG products are prescribed more often compared to lactulose based-products, for example in France. [Internal Mylan documents concerning relationship PEG/Macrogol versus lactulose.]

(203) Based on the above, for the purposes of this decision, the Commission concludes that the relevant product market for lactulose should be defined at least as comprising other products in the ATC4 class A6A6.

Competitive assessment

(204) On the basis of the market definition set out above, a Group 1 market arises in France.

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38 For instance, faecal softening laxatives (A6A1), stimulant laxatives (A6A2), bulk-forming laxatives (A6A3), enemas (A6A4), osmotic laxatives with (A6A7) or without electrolytes (A6A6; e.g. lactulose-based products).

39 COMP/M.3853 Solvay/Fournier, paragraphs 16-23.

40 COMP/M.6280 Procter&Gamble/Teva, paragraph 19.

France

(205) Both Parties market lactulose-based products in France, which are primarily sold OTC. Abbott EPD-DM markets its product under the brand name Duphalac while Mylan markets a generic lactulose product. Lactulose products are reimbursed in France. The size of the French lactulose market is around EUR 19.5 million in 2013.

(206) The Parties' combined market share at the ATC4 level is [40-50]% by value (Abbott EPD-DM: [10-20]%; Mylan: [20-30]%) and [40-50]% by volume (Abbott EPD-DM: [10-20]%; Mylan: [20-30]%).

(207) Post-merger, a number of strong competitors would remain in the market, including a market leader, Servier, with its generic lactulose product holding a market share of [20-30]% (value) and [20-30]% (volume), as well as Ipsen with a market share of [10-20]% (value) and [10-20]% volume, and Novartis with a market share of [5-10]% (value) and [10-20]% (volume).

(208) In addition, eight competitors (including Teva, Fresenius and Ranbaxy) hold dormant marketing authorisations for different dosages of lactulose in the French market, which can be used to enter the market within a short period of time.

(209) The prices of all reimbursed drugs in France are regulated throughout the chain given that they are all part of the so-called positive lists for hospital and for community pharmacies. As a result, the ability of pharmaceutical companies to increase prices for these drugs is generally limited.[41]

Conclusion

(210) Taking into consideration all of the above, including the results of the market investigation and in particular the presence of significant competitors, the Commission concludes that the transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to lactulose in France.

IV.2.3.2.k. Mebeverine (A3A)

Product market definition

(211) Mebeverine belongs to the ATC3 class A3A covering all plain synthetic and natural antispasmodics and anticholinergics which are part of the wider ATC2 class A3 covering functional gastro-intestinal disorder drugs. Amongst other things, anticholinergic or antispasmodic drugs are used to relieve cramps or spasms of the stomach, intestines and bladder.

(212) The Notifying Party submits that the relevant market for mebeverine should be defined at ATC3 level, encompassesing all plain synthetic and natural antispasmodics and anticholinergics.

(213) The Commission analysed the A3A class in the past[42] adopting a market definition approach based on the ATC3 level, although there were indications that in some

41 See footnotes 24 and 25 for the description of the French regulatory system.

42 COMP/M.5253 Sanofi-Aventis/Zentiva of 4 February 2009.

cases the products might not be entirely substitutable. The Commission also identified a possible distinction between the OTC and prescription segments.

(214) In the present case, the feedback received from respondents to the market investigation suggests that, while it may be possible to substitute mebeverine by some other products in some specific cases, mebeverine is unlikely to be fully replaceable in the treatment of its main indications, in particular irritable bowel syndrome. The results of the market investigation indicate that mebeverine has a longer action which is unique compared to other molecules on the market. Alternative products, such as Buscopan (based on butylscopolamine), are characterised by short targeted action and are usually prescribed in case of acute cramps. By contrast, mebeverine provides a long term retarded effect and is particularly useful in chronic conditions. Moreover, some of the alternative products tend to cause greater side effects than mebeverine

(215) Based on the above, for the purposes of this decision, the Commission concludes that the relevant product market for mebeverine should be defined at the molecule level.

Competitive assessment

(216) On the basis of the market definition set out above, Group 1 markets arise in relation to Germany and the UK.

Germany

(217) Abbott EPD-DM markets its product under the brand Duspatal. Mylan's generic version of mebeverine is non-branded and is marketed under the name of the active ingredient. The total size of the market in Germany in terms of sales is approximately EUR 6 million.

(218) The Parties' combined market share for mebeverine-based products in Germany at the molecule level is [60-70]% by volume (Abbott EPD-DM: [20-30]%; Mylan: [40-50]%) and [60-70]% by value (Abbott EPD-DM: [30-40]%; Mylan: [30-40]%).

(219) The only competitors to the Parties for mebeverine in Germany are parallel importers, which buy branded mebeverine-based products, in this case Abbott EPD-DM's, in other Member States and import them to Germany. According to the market investigation, the competitive constraint imposed by parallel importers in Germany is limited since they: (i) do not control the availability of product and are dependent on supply from the branded manufacturers in other countries; (ii) benchmark their pricing against the branded product (namely, Abbott EPD-DM's); and (iii) rarely participate in tenders run by insurance companies in Germany given the lack of ability of parallel importers to commit to long-term supply. The difficulties of parallel importers to ensure supply of mebeverine is explained by the relatively large size of the mebeverine market in Germany (i.e. EUR 6 million) as compared with the relatively limited source base (i.e. Abbott EPD-DM's total EAA-wide sales of mebeverine of […] million). This is in line with the evidence that the share of parallel importers in German mebeverine market is relatively limited, below 30% in the last three years.[43]

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43 Parallel importers in Germany have to comply with the 15/15 rule (paragraph 129 Deutsches Sozialgesetzbuch 5). According to this rule, imported pharmaceutical products have to be always at

(220) In addition, a large part of pharmaceuticals in the German market is sold pursuant to public tenders organised by health insurers. The Notifying Party estimates that 70% of the generic volume in the German market is tender driven. Mebeverine is also a tendered molecule albeit not for the full volume. Price undercutting between tender participants occurs in Germany in the context of the "rebate agreements" which are awarded as a result of tenders. Given the limited role played by parallel importers in tenders for mebeverine (see paragraph (219)), the transaction effectively leads a merger from two to one, which may result in increase in prices. In this context, market investigation revealed concerns about the lack of competition and the available participants in tenders for mebeverine.

(221) Furthermore, Germany operates a reference price system for pharmaceuticals. The amount of reimbursement is computed based on the reference price set by the Joint Federal Committee of Physicians and Health Funds ("GBA"). A price increase by a pharmaceutical company is possible, which could lead to a greater co-payment by patients, as well as a risk of loss of market share. For example, currently Mylan's price for mebeverine is set below the reference price and there is no co-payment for patients. Following the merger, the merged entity is likely to be able to increase its prices leading to greater co-payment by patients without the threat of losing market share given the limited remaining competition.

(222) Dormant marketing authorisations for mebeverine-based products in Germany are held only by parallel importers. Their potential entry, even if it were to occur, would have only a limited countervailing effect on the merged entity, for the reasons explained in paragraph (219).

Conclusion

(223) The Commission concludes that serious doubts arise as regards the compatibility of the transaction with the internal market in relation to mebeverine in Germany, because the transaction would create a dominant position of the merged entity on this market, in particular leading to a merger from two to one in relation to tenders for mebeverine.

The United Kingdom

(224) Abbott EPD-DM markets its mebeverine-based product under the brand Colofac in the UK. Mylan's generic version of mebeverine is non-branded and is marketed under the name of the active ingredient. The Notifying Party estimates the total size of the market in the UK in terms of sales to be approximately EUR 7 million.

(225) The Parties' combined market share for mebeverine-based products in the UK at the molecule level is [60-70]% by volume (Abbott EPD-DM: [30-40]%; Mylan: [20-30]%).[44]

(226) The only important competitor to the Parties is Teva which markets a generic mebeverine product. In 2013, Teva experienced shortages of supply due to operational and administrative reasons, which lasted for almost a year. These

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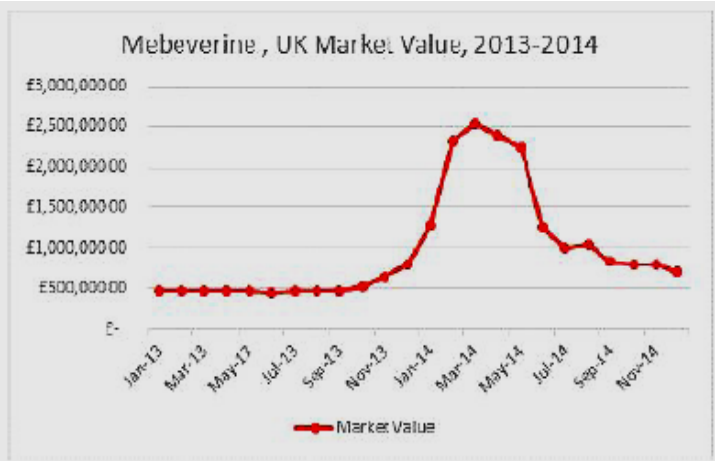
least 15% or EUR 15 cheaper than the price of the reference drug to be cost effective. See non-confidential minutes of the conference call with AOK-Bundesverband of 17 December 2014.

44 The Notifying Party was unable to provide market shares by value for the UK.

problems did not lead to any product recall from the market, but the market investigation revealed that during that time the price for mebeverine in the UK has increased substantially. This is illustrated by the following graph:

Figure 1



Source: Response to the 7th RFI of 11 December 2014, question 1b

(227) Teva confirmed that there were some price increases for mebeverine in the UK following the supply shortages it had experienced.[45]

(228) The increase of price for mebeverine during Teva's shortages provides an indication of possible effects stemming from the disappearance of one of the competitors, as would be a result of the merger.

(229) Furthermore, there are no potential competitors which could enter the mebeverine market in the UK sufficiently quickly to counter the potential negative effects of the merger.

(230) Finally, the UK regulatory system provides for free pricing whereby the price is a function of competition in the market.[46] In particular, there are no regulatory price ceilings. Generics prices are freely determined by pharmaceutical suppliers in accordance with market forces. Consequently, the merged entity would be able to raise prices, as was evidenced in a market situation with two players during Teva's shortage.

Conclusion

(231) The Commission concludes that serious doubts arise as regards the compatibility of the transaction with the internal market in relation to mebeverine in the UK, because the transaction would create a dominant position of the merged entity on this market.

45 Non-confidential minutes of a conference call with Teva, 16 December 2014, paragraph 3.

46 The reimbursement price is then set taking into account the average of prices to distributors.

IV.2.3.2.l. Pinaverium Bromide (A3A)

Product market definition

(232) Like mebeverine, pinaverium bromide belongs to the ATC3 class A3A of all plain synthetic and natural antispasmodics and anticholinergics which are part of the wider ATC2 class A3 covering functional gastro-intestinal disorder drugs. Amongst other things, anticholinergic or antispasmodic drugs are used to relieve cramps or spasms of the stomach, intestines and bladder.

(233) As mentioned in paragraph (213), in the past the Commission assessed the relevant A3A products under the ATC3 market definition approach, although there were indications that in some cases the products might not be entirely substitutable.[47]

(234) The Notifying Party submits that the appropriate market definition for pinaverium bromide is the ATC3 level, which encompasses all plain synthetic and natural antispasmodics and anticholinergics.

(235) The market investigation has not revealed any specificities of pinaverium bromide compared to other molecules within the ATC3 class, except mebeverine which, as described in section IV.2.3.2.k, constitutes a separate product market.

(236) In any event, for the purposes of the present case, it can be left open whether the relevant product market for pinaverium bromide should be defined at the ATC3 level or narrower since no serious doubts arise under any plausible alternative market definition.

France

Competitive assessment

(237) Both Parties sell their pinaverium bromide-based products in France. On the ATC3 level, no Group 1 market arises given a substantial position of competitors which excludes serious doubts.[48] However, a Group 1 market would arise if the relevant product market were defined at the molecule level. The latter conservative approach is applied in the analysis below.

(238) The size of the French market for pinaverium bromide at the molecule level is around EUR 7.1 million in 2013 and has been declining from EUR 9.2 million in 2011.

(239) The Parties' combined market share for pinaverium bromide-based products at the molecule level in France is [50-60]% by value (Abbott EPD-DM: [30-40]%; Mylan: [20-30]%) and [50-60]% by volume (Abbott EPD-DM: [20-30]%; Mylan: [20-30]%).

(240) Post-merger, a number of competitors selling generic pinaverium bromide products would remain in the market: Servier with a market share of [10-20]% (value) and

47 COMP/M.5253 Sanofi-Aventis/Zentiva of 4 February 2009..

48 At the ATC3 level A3A, the Parties combined market share in France is [5-10]% in terms of value and [5-10]% in terms of volume.

[20-30]% (volume), Novartis with a market share of [10-20]% (value) and [10-20]% (volume), Teva with a market share of [5-10]% (value) and [5-10]% (volume) and Actavis with a market share of [0-5]% (value) and [5-10]% (volume). These parties are strong competitors with substantial financial and manufacturing capabilities and market presence in France.

(241) In addition, two competitors (Teva and Arrow) hold dormant marketing authorisations to sell pinaverium bromide in the French market, which can be used to enter the market within a short period of time.

(242) Pinaverium bromide-based products are reimbursed in France. The prices of all reimbursed drugs in France are regulated throughout the chain given that they are all part of the so-called positive lists for hospital and for community pharmacies. As a result, the ability of pharmaceutical companies to increase prices for these drugs is generally limited.[49]

Conclusion

(243) The Commission, taking into consideration all of the above, including the results of the market investigation, concludes that the transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to pinaverium bromide in France.

IV.2.3.2.m. Other Group 2 and Group 3 markets in the gastro therapeutic area

(244) In addition to the Group 1 markets analysed above, there is a number of Group 2 and Group 3 affected markets in the gastro area, specifically:

- *ATC3 class A2B in France*
- *ATC3 class A3A in Germany and the UK*
- *ATC3 class A6A in France, Germany and Italy*
- *ATC3 class A9A in the Netherlands*

(245) Within these ATC classes several galenic forms are marketed and give rise to technically affected markets. However, the market investigation did not provide any indications that the markets in this case should be further segmented depending on the galenic form or on whether the drug is sold against a prescription or OTC.

(246) On these markets the combined market share of the Parties are moderate to low and / or the increment is below 1%. In all cases there is a number of strong competitors active on these markets with a wide portfolio of products, including branded medicines but also branded and non-branded generic products, such as Servier, Novartis, Teva, GlaxoSmithKline, AstraZeneca and Takeda.

(247) The market investigation did not provide any indication that competition issues would arise in these markets. On this basis the Commission concludes that the

49 See footnotes 24 and 25 for the description of the French regulatory system.

transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to any of these markets.

ANTI-INFECTIVE / RESPIRATORY AREA

(248) This therapeutic area includes products that are prescribed for the treatment of various kinds of infections, asthma and bronchitis. More particularly, the relevant products in this therapeutic area for the purposes of the proposed transaction are prescribed for the treatment of bacterial infection and infections caused by methicillin-resistant staphylococcal ("MRS") strains.

(249) Both Parties are active in this therapeutic area with marketed products belonging to the ATC3 class J1F (macrolides and similar types). The Parties compete in relation to some molecules in this therapeutic area. In particular, Group 1 overlaps were identified (at the molecule level) in relation to clarithromycin.

IV.2.3.2.n. Clarithromycin (J1F)

Product market definition

(250) Both Mylan and Abbott EPD-DM sell clarithromycin-based products. Clarithromycin is a leading macrolide anti-infective belonging to the ATC3 class J1F – Macrolides and similar types. Macrolide antibiotics are used in the treatment of several types of infections, such as lower and upper respiratory tract infections, skin infections, etc. These products are a subcategory of antibacterials generally reserved to treat those specific bacteria resistant to penicillin and for patients oversensitive to penicillin.

(251) In previous decisions where macrolides were assessed, the Commission considered the ATC3 class J1F as the appropriate definition of the relevant product market.[50] However, in one case where the Commission examined more particularly the molecule azithromycin, the market investigation raised some arguments in favour of defining the market at the molecule level although the market definition was ultimately left open.[51]

(252) According to the Notifying Party, the relevant market for clarithromycin should comprise all macrolides.

(253) While the results of the market investigation in this case indicated that the market definition at molecule level would be unduly narrow, the market investigation also confirmed that the relevant market is not as wide as the entire ATC3 class. Specifically, according to the market participants, azithromycin seems to be a close substitute to clarithromycin and in some cases it is even the preferred treatment. To a lesser extent, other macrolides such as roxithromycin and spiramycin, were also indicated to be possible alternatives to clarithromycin in some cases. One of the main reasons why the prescribers indicated that clarithromycin and azithromycin are

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50 COMP/M.3354 Sanofi-Synthelabo/Aventis, where the Commission considered defining a separate product market for drugs used for dental infections but the market division did not support making such a distinction.

51 COMP/M.5865 Teva/Ratiopharm, paragraph 186.

the closest substitutes were relatively more severe side effects (e.g. diarrhoea) of the other macrolides.

(254) On the basis of the above, the Commission concludes for the purpose of this decision that the relevant market should comprise at least clarithromycin and azithromycin, regardless of the galenic form.

Competitive assessment

(255) On the basis of the market definition set out above, the proposed transaction gives rise to a number of Group 1 affected markets, which are examined in turn below.

Italy

(256) Macrolide antibiotics are prescription drugs which are reimbursable in Italy.

(257) The relevant overlap in Italy occurs between products available in oral solid ordinary form (galenic form NFC1-A). The Parties' products marketed under this form are Abbott EPD-DM's product sold under the brand name Klacid and Mylan's generic products Azitromicina and Claritromicina. Abbott EPD-DM is the former originator of clarithromycin-based products in these markets. The size of the Italian clarithromycin market is around EUR 58 million in 2013 and has been declining from EUR 72.6 million in 2011.

(258) The Parties' combined market share at this level reaches [20-30]% (value) with an increment (Mylan) of [0-5]% (value) and [20-30]% (volume) with an increment of [0-5]% (volume).

(259) Post-merger, strong competitors remain in the market, namely the current market leader Pfizer with its azithromycin-based branded product Zithromax, holding a market share of [20-30]% (value) and [10-20]% (volume), a strong local player Menarini with a market share of [20-30]% (value) and [30-40]% (volume), Teva with a market share of [5-10]% (value) and [5-10]% (volume), Stada with a market share of [5-10]% (volume) and Novartis with a market share of [5-10]% (volume).

(260) Moreover, twenty competitors (including Pfizer) hold dormant marketing authorisations to sell clarithromycin in its various forms/formats in the Italian market, which can be re-activated within a short period of time.

Conclusion

(261) The Commission, taking into consideration all of the above, including the results of the market investigation, concludes that the transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to the macrolides clarithromycin and azithromycin in Italy.

France

(262) The only overlap at this level occurs between products available in liquid form (galenic form NFC1-D). The Parties' relevant products in liquid form are Abbott EPD-DM's product sold under the brand name Zeclar and Mylan's generic product Clarithromycin. The size of this market is around EUR 2.7 million in 2013.

(263) The Parties' combined market share reaches [20-30]% (value) and [50-60]% (volume), with an increment (Mylan) of [10-20]% (value) and [20-30]% (volume).

(264) Post-merger, strong competitors remain in the market: Pfizer with its azithromycin-based product Zithromax, which was confirmed by the market investigation to be the leading macrolide in France, with a market share of [60-70]% (value) and [20-30]% (volume) and Novartis with a market share of [5-10]% (value) and [10-20]% (volume).

(265) Moreover, three competitors (including Pfizer) hold dormant marketing authorisations to sell clarithromycin in the French market, which can be re-activated within a short period of time.

(266) The Parties' products and their competitors' products are prescription drugs which are reimbursed in France. The prices of all reimbursed drugs in France are regulated throughout the chain given that they are all part of the so-called positive lists for hospital and for community pharmacies. As a result, the ability of pharmaceutical companies to increase prices for these drugs is generally limited.[52]

Conclusion

(267) The Commission, taking into consideration all of the above, including the results of the market investigation, concludes that the transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to the macrolides clarithromycin and azithromycin in France.

Ireland

(268) Abbott EPD-DM is the former originator of the clarithromycin-based products in Ireland. The Parties' products where the relevant overlap occurs are Abbott EPD-DM's branded product Klacid and Mylan's branded generic products sold under the brands Azromax and Klariger. The size of the Irish clarithromycin market is around EUR 5 million in 2013.

(269) The Parties' combined market share reaches [30-40]% (value) and [40-50]% (volume), with an increment (Mylan) of [5-10]% (value) and [5-10]% (volume).

(270) Post-merger, a number of strong competitors remain in the market: Pfizer with its azithromycin-based product Zithromax, with a market share of [10-20]% (value) and [10-20]% (volume), Teva with a market share of [10-20]% (value) and [10-20]% volume), Stada with a market share of [10-20]% (value) and [10-20]% (volume), Novartis with a market share of [10-20]% (value) and [10-20]% (volume) and Actavis with a market share of [5-10]% (value) and [5-10]% (volume).

(271) Moreover, four competitors hold dormant marketing authorisations to sell clarithromycin in the Irish market, which can be re-activated within a short period of time.

(272) The Parties' products and most of their competitors' products[53] are prescription drugs which are reimbursed in Ireland. The ability of pharmaceutical companies to

52 See footnotes 24 and 25 for the description of the French regulatory system.

53 With the exception of Novartis' product based on clarithromycin, Clorom.

increase prices of reimbursed drugs in Ireland is very limited. The only possibility for this requires filing an application to the relevant authority motivating the reason for the price increase. The market investigation showed that historically price increases required evidence of price oppression and the National health Authority's expectation was that budget neutral modulation across a portfolio of products was the preferred methodology.

Conclusion

(273) The Commission, taking into consideration all of the above, including the results of the market investigation, concludes that the transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to the macrolides clarithromycin and azithromycin in Ireland.

Austria

(274) Abbott EPD-DM is the former originator of the clarithromycin-based products in Austria. The only overlap at this level occurs between products available in liquid form. The Parties' relevant products in liquid form are Abbott EPD-DM's branded products Klacid and Klaricid and Mylan's generic products Azithromycin and Clarithromycin. The size of the clarithromycin market in Austria is around EUR 4.8 million in 2013.

(275) The Parties' combined market share reaches [40-50]% (value) and [50-60]% (volume), with an increment (Mylan) of [0-5]% (value) and [0-5]% (volume).

(276) Post-merger, two strong competitors remain in the market: Pfizer with its product Zithromax, which the market investigation confirmed to be the leading macrolide in Austria, with a market share of [30-40]% (value) and [10-20]% (volume) and Novartis with a market share of [20-30]% (value) and [20-30]% volume.

(277) Moreover, three competitors hold dormant marketing authorisations to sell clarithromycin in the Austrian market, which can be re-activated within a short period of time.

(278) The Parties' products and their competitors' products in this segment are reimbursed in Austria. The ability of pharmaceutical companies to increase prices of reimbursed drugs in Austria is limited. The only possibility for this requires filing an application to the relevant authority motivating the reason for the price increase or delisting the product from the reimbursement list (free pricing).

Conclusion

(279) The Commission, taking into consideration all of the above, including the results of the market investigation, concludes that the transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to the macrolides clarithromycin and azithromycin in Austria.

Belgium

(280) Abbott EPD-DM is the former originator of the clarithromycin-based products in Belgium. The Parties' products where the relevant overlap occurs are Abbott EPD-

DM's products Biclar, Clarithromycine, Heliclar and Maclar and Mylan's products Azithromycin and Clarithromycin, which are reimbursed in Belgium. The size of the clarithromycin market in Belgium is around EUR 6.6 million in 2013.

(281) The Parties' combined market share reaches [30-40]% (value) and [40-50]% (volume), with an increment (Mylan) of [0-5]% (value) and [0-5]% (volume).

(282) Post-merger, three strong competitors remain in the market: Stada with a market share of [20-30]% (value) and [20-30]% (volume), Novartis with a market share of [20-30]% (value) and [10-20]% (volume) and Pfizer with a market share of [5-10]% (value) and [10-20]% (volume).

(283) Moreover, one competitor holds a dormant marketing authorisation to sell clarithromycin in the Belgian market, which can be re-activated within a short period of time.

(284) The Parties' products and Pfizer's product Zithromax are reimbursed in Belgium. Novartis and Stada's products are not reimbursed. However, this does not change the outcome of the Commission's assessment, since in Belgium the maximum ex-factory prices of all pharmaceutical products (reimbursed or not) are set by the competent authorities. The only possibility for pharmaceutical companies to increase the price of pharmaceutical products requires filing an application to the relevant authority motivating the reason for the price increase.

Conclusion

(285) The Commission, taking into consideration all of the above, including the results of the market investigation, concludes that the transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to the macrolides clarithromycin and azithromycin in Belgium.

Czech Republic

(286) Macrolide antibiotics are prescription products which are reimbursable in the Czech Republic.

(287) Abbott EPD-DM is the former originator of clarithromycin-based products in the Czech Republic. The Parties' products where the relevant overlap occurs are Abbott EPD-DM's product Klacid and Mylan's products Azithromycin and Klarithromycin. The size of the clarithromycin market in the Czech Republic is around EUR 10.4 million in 2013.

(288) The Parties' combined market share reaches [40-50]% (value) and [50-60]% (volume), with an increment (Mylan) of [0-5]% (value) and [0-5]% (volume).

(289) Post-merger, three strong competitors remain in the market: the strong local player Krka with a market share of [20-30]% (value) and [20-30]% (volume), Teva with a market share of [10-20]% (value) and [5-10]% (volume) and Novartis with a market share of [5-10]% (value).

(290) Moreover, five competitors hold a dormant marketing authorisation to sell clarithromycin in the Czech market, which can be re-activated within a short period of time.

(291) The Parties' products and their competitors' products in this segment are reimbursed in the Czech Republic. The ability of pharmaceutical companies to increase prices of reimbursed drugs in the Czech Republic is limited. Some reimbursable pharmaceutical products are subject to a maximum ex-factory price, which is the case for azithromycin-based products. The regulatory framework does not allow for price increases of these products above such limit. On the other hand, clarithromycin-based products in the Czech Republic are not subject to a price cap, which means that their prices may be increased each quarter. However, such increase is subject to an application to the relevant authority in the precedent quarter. In any case, the authorities in the Czech Republic set the maximum reimbursement amount, which pharmaceutical companies take into account when determining their prices.

Conclusion

(292) The Commission, taking into consideration all of the above, including the results of the market investigation, concludes that the transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to the macrolides clarithromycin and azithromycin in the Czech Republic.

Portugal

(293) Macrolide antibiotics are prescription products which are reimbursable in Portugal.

(294) The only relevant overlap at this level occurs between products available in liquid form. The Parties' relevant products in liquid form are Abbott EPD-DM's product Klacid and Mylan's products Azithromycin and Clarithromycin. The size of the clarithromycin market in Portugal is around EUR 5.4 million in 2013.

(295) The Parties' combined market share reaches [40-50]% (value) and [60-70]% (volume), with an increment (Mylan) of [0-5]% (value) and [0-5]% (volume).

(296) Post-merger, at least three strong competitors remain in the market: Pfizer with its azithromycin-based product Zithromax with a market share of [30-40]% (value) and [20-30]% (volume), Generis Farma with a market share of [10-20]% (value) and [10-20]% (volume) and Teva with a market share of [5-10]% (value).

(297) Moreover, eleven competitors hold a dormant marketing authorisation to sell clarithromycin in the Portuguese market, which can be re-activated within a short period of time.

(298) The Parties' products and Pfizer's products[54] are reimbursed in Portugal. The relevant authority sets the maximum public price for reimbursed drugs, which limits the ability of pharmaceutical companies to increase their prices. The only possibility to increase the price of reimbursed pharmaceutical products requires filing an application to the authority motivating the reason for the price increase.

Conclusion

(299) The Commission, taking into consideration all of the above, including the results of the market investigation, concludes that the transaction does not give rise to serious

54 With the exception of Pfizer's azithromycin-based product, Zithromax IV.

doubts as to its compatibility with the internal market in relation to the macrolides clarithromycin and azithromycin in Portugal.

IV.2.3.2.o. Other Group 2 and Group 3 markets in the anti-infective / respiratory therapeutic area

(300) In addition to the Group 1 markets analysed above, there is a number of Group 2 and Group 3 affected markets in the anti-infective / respiratory area, specifically:

- *ATC3 class J1F in Austria, Belgium, Czech Republic, France, Germany, Greece, Hungary, Italy, Ireland, the Netherlands, Portugal, Slovakia, Spain and the UK*

(301) Within these ATC classes several galenic forms are marketed and give rise to technically affected markets. However, the market investigation did not provide any indications that the markets in this case should be further segmented depending on the galenic form or on whether the drug is sold against a prescription or OTC.

(302) On these markets the combined market share of the Parties are moderate to low and / or the increment is below 1%. In all cases there is a number of strong competitors active on these markets with a wide portfolio of products, including branded medicines but also branded and non-branded generic products, such as Pfizer, Novartis, Stada, Sanofi, Servier, Teva, Estallas Pharma, Daiichi Sankyo, Menarini, Elpen, Krka Pharma.

(303) The market investigation did not provide any indication that competition issues would arise in these markets. On this basis the Commission concludes that the transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to any of these markets.

CNS / PAIN AREA

(304) This therapeutic area concerns products that are prescribed for the treatment of pain and indications relating to the central nervous system. The relevant products are prescribed for the treatment of disorders ranging from musculoskeletal inflammation to vertigo and Meniere's disease.

(305) Both Parties are active in this therapeutic area with a number of marketed products belonging to the ATC3 classes N5C (tranquilisers) M1A (anti-rheumatics, non-steroidal), N5A (anti-psychotics), N6A (antidepressants and mood stabilisers) and N7C (antivertigo products). The Parties compete in relation to a number of molecules in this therapeutic area. In particular, Group 1 overlaps were identified (at the molecule level) in relation to the molecules set out below.

IV.2.3.2.p. Delorazepam (N5C)

Product market definition

(306) Delorazepam belongs to the ATC3 class N5C-Tranquilizers. This class includes minor tranquillisers, e.g. benzodiazepines (delorazepam, lorazepam, etc.), hydroxyzine and meprobamate, used for their sedative, anxiolytic (anti-anxiety), anticonvulsant, and muscle relaxant properties.

(307) In previous decisions where the ATC3 class N5C was analysed, the Commission has not considered delorazepam specifically.[55]

(308) The Notifying Party submits that delorazepam is substitutable and competes with the other benzodiazepines categorized in the ATC3 class N5C, such as bromazepam, alprazolam and lorazepam, in view of the identical mode of action and equivalent anxiolytic therapeutic effects of all benzodiazepines. According to the Notifying Party, the closest competitor of Abbott EPD-DM's branded delorazepam-based drug EN is Pfizer with its branded originator product Xanax based on alprazolam, another benzodiazepine, and not generics based on delorazepam.

(309) The results of the market investigation indicate that delorazepam is a popular drug for treating anxiety disorders in Italy. The market investigation confirmed that there is some degree of substitutability between delorazepam and other benzodiazepines in the ATC3 class N5C. Indeed, the indications in case of which different benzodiazepines are prescribed by doctors are sometimes overlapping. Nevertheless, the market investigation also revealed that the molecule of delorazepam has certain specific characteristics, which distinguish it from other benzodiazepines.

(310) In particular, according to the responses received during the market investigation delorazepam is characterised by longer action and less sedative effect compared to other benzodiazepines and therefore is often prescribed as first line of treatment. Also, medical specialists stated that delorazepam is usually prescribed is case of general anxiety disorders, while alprazolam (Pfizer’s Xanax) is more suited for treating panic disorders. Therefore, in the view of the respondents, Abbott EPD-DM's delorazepam-based EN and Pfizer's alprazolam-based Xanax are not close competitors, unlike submitted by the Notifying Party.. The market investigation did not provide any indications that the market in this case should be further segmented depending on the galenic form or on whether the drug is sold against a prescription or OTC.

(311) Moreover, competing products based on the same molecule are typically closer substitutes than products based on different molecules, even if they belong to same ATC class. This is due to the fact that, despite the shared indications, different molecules still show different clinical and safety profiles. The regulatory framework also typically facilitates substitutability across products based on the same molecule at pharmacy level, while substitution across molecules can only happen at the level of physician's prescription.

(312) To rebut the findings of the Phase 1 market investigation in relation to the market definition, the Notifying Party submitted additional evidence. First, the Notifying Party submitted prescription data for the Italian market from the Medical Audit database developed by IMS Health. These data provide the total number of prescriptions of several benzodiazepines according to various indications collected through a panel of physicians (both general practitioners and specialists). According to the Notifying Party, these data suggest that for each of the main listed indications of delorazepam other benzodiazepines are prescribed more often. In the view of the Notifying Party, this confirms that delorazepam is not unique in its action and is substitutable by other benzodiazepines.

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55 See for example COMP/ M.5865 Teva/Ratiopharm, and COMP/M.5476 Pfizer/Wyeth.

(313) The Commission acknowledges that there is a certain degree of overlap between the indications in which delorazepam and other benzodiazepines are prescribed. Nevertheless the Commission considers that the provided prescription data does not demonstrate the absence of the specific characteristics of delorazepam which would limit its substitutability with other benzodiazepines, identified in paragraph (310). For example, in the data provided, the largest proportion of prescriptions of delorazepam (22%), as well as of other benzodiazepines, are categorised under "F419 Anxiety disorder, unspecified".[56] This category groups prescriptions for symptoms that do not clearly fit any single more specific diagnostic category. Thus, this largest category does not provide a granular enough data to allow robust conclusions on the precise indications for delorazepam as compared with other benzodiazepines. For instance, within the general F419 category, the indications for delorazepam could include symptoms which are closer to generalized anxiety disorder, while for alprazolam those closer to panic disorders, in line with the feedback received from the market investigation (see paragraph (310)). In addition, the fact that that various drugs may be prescribed for one general indication does not in itself evidence the substitutability of the drug for individual patients; if anything it demonstrates that some patients are better treated with one drug rather than the other. Overall, the Commission considers that the prescription data does not convincingly refute the findings that the molecule of delorazepam is generally used for different purposes than other benzodiazepines.

(314) Second, the Notifying Party submitted pricing and volume data in relation to delorazepam. According to these data, the prices for generic benzodiazepines, including delorazepam, remained stable in recent years. By contrast, the prices for branded benzodiazepine-based products, including Abbott EPD-DM's EN (delorazepam), Pfizer's Xanax (alprazolam) and Pfizer's Tavor (lorazepam), have increased. Overall, the Notifying Party concludes that the submitted data confirms that EN competes mainly with branded products based on other benzodiazepines, while generic benzodiazepines compete between themselves independently. The Notifying Party supports this conclusion with [internal documents which analyse a price increase for benzodiazepines].

(315) The Commission notes that some internal documents of the Notifying Party clearly suggest that Abbott EPD-DM's delorazepam-based EN is subject to competitive pressure and is losing market share to generics, and in particular to Mylan's product, rather than other benzodiazepines and Pfizer's branded products, as indicated in the graph below.

Figure 2

Source: [Third party advisor] Report – Project Air Commercial Assessment – June 10, 2014, slide 102

(316) The graph above illustrates that the market share of Abbott EPD-DM's EN declined by [0-10]%, from [60-70]% to [60-70]%, between 2010 and 2013 (first line from the top), while Mylan's share has grown by [0-10]%, from [0-10]% to [10-20]% in the

56 For delorazepam, the five highest proportions from total prescriptions of delorazepam by indication are the following: "F419 Anxiety disorder, unspecified" – 22%; "F341 Dysthymia" – 9%; "F412 Mixed anxiety and depressive disorder" – 6%; "F329 Depressive episode, unspecified" – 5%; and "F200 Paranoid schizophrenia" – 3%.

same period (second line from the top). The same slide states that […].[57] The slide does not refer to other benzodiazepines, including Pfizer's Xanax, which suggests that the main competitive constraint for Abbott EPD-DM's delorazepam-based EN comes from delorazepam-based generics rather than from other benzodiazepines.

(317) Moreover, the Commission considers that the presented pricing data and internal documents of the Notifying Party do not evidence that other branded benzodiazepines would be closer competitors to Abbott EPD-DM's branded delorazepam than would be generic delorazepam. The fact that Abbott EPD-DM follows developments on a wider benzodiazepines market does not in itself mean that the other benzodiazepines belong to the same relevant market for competition purposes. Indeed, the Notifying Party did not provide any evidence of substitution of delorazepam by other benzodiazepines in response to a price increase. To the contrary, based on the data in

(318) Figure 2 it can be inferred that Abbott EPD-DM's branded delorazepam lost share to generic delorazepam during the same period when Abbott EPD-DM was implementing price increases (see paragraph (330)).

(319) Further, the Notifying Party submitted an internal graph tracking the market shares of various benzodiazepines purportedly showing that "*[Abbott's information and assessment regarding the relationship between the developments in EPD-DM and Pfizer market shares in the benzodiazepines market in Italy]*".[58]

Figure 3

Source: Parties' response of 14 January 2015, question 5

(320) The basis of the above-mentioned conclusion is unclear. Contrary to the Notifying Party's statement, the graph above shows very limited fluctuation of the market share of Abbott EPD-DM's EN (third line from the bottom) in response to much greater fluctuations (in absolute terms and in variations of extremes) of market shares of Pfizer's Xanax and Tavor (first and second lines from the top, respectively) at least in the period from April to October. At best, this evidence cannot be considered as conclusive.

(321) Overall, and within the limits of the Phase I investigation, the Commission considers that the information presented by the Notifying Party does not disprove the indications received from medical specialists that delorazepam has specific characteristics which distinguish it from other benzodiazepines.

(322) Therefore, the Commission concludes for the purpose of this decision that the relevant product market is limited to delorazepam only.

Competitive assessment

(323) On the basis of the market definition set out above, a Group 1 market arises in Italy.

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57 [Third party advisor] Report – Project Air Commercial Assessment – June 10, 2014, slide 102.

58 The Parties' response of 14 January 2015, question 5.

Italy

(324) Both Parties market delorazepam-based products in Italy. While delorazepam was never patent-protected in Italy, Abbott EPD-DM's product was the first product to be registered in Italy containing that active ingredient. Abbott EPD-DM markets its product under the brand name EN, while Mylan markets a non-branded generic version of delorazepam. Delorazepam-based products are subject to prescription but are not reimbursed in Italy.

(325) The total size of the market for delorazepam in Italy in terms of sales is approximately EUR 40 million.

(326) The Parties' combined market share at the molecule level is [80-90]% (value) and [80-90]% (volume), with an increment (Mylan) of [5-10]% (value) and [10-20]% (volume). Abbott EPD-DM is clearly the market leader although in the last three years, its volume share has been consistently declining. As Abbott EPD-DM has been losing sales, Mylan's volume share has been growing, as illustrated by the graph in Figure 2.

(327) Also, the Parties' internal documents state in relation to Abbott EPD-DM's product EN that […]".[59] This suggests that EN is subject to a competitive constraint from Mylan's delorazepam-based product. Nevertheless, EN remains a popular product with "[information on the product contained in internal document]" for which brand loyalty is high.[60] The price for Abbott EPD-DM's product EN has been rising steadily every two years since 2005.

(328) The only sizeable competitor on the market is Teva, which markets a generic version of delorazepam. Teva holds a market share of [5-10]% (value) and [5-10]% (volume). Teva's share has remained largely stable in the last three years, in contrast with Mylan's share which has been steadily growing. During the market investigation, Teva stated that overall it considered Italy to be a difficult market in which demand has to be stimulated at the retail level which requires costs and good distribution network. Furthermore, Teva has other priority products than delorazepam in Italy. Therefore, the limited presence of Teva in delorazepam is unlikely to constrain the merged entity.

(329) There are seven dormant marketing authorisations for delorazepam held by third parties in Italy. While these marketing authorisations can be potentially used for a market entry, by itself this possibility is insufficient to rule out competition concerns, especially in view of the fact that the steady rise in the price of Abbott EPD-DM's delorazepam-based product has not triggered entry.

(330) Based on the above, the Commission considers that Abbott EPD-DM holds a dominant position on the market for delorazepam in Italy. This dominant position will be further strengthened by the addition of Mylan.

(331) Finally, the regulatory framework in Italy allows for price increases of non-reimbursed pharmaceuticals once every two years. While AIFA publishes

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59 [Third party advisor] Report – Project Air Commercial Assessment – June 10, 2014, slide 102.

60 [Third party advisor] Report – Project Air Commercial Assessment – June 10, 2014, slide 102.

recommended price increases for all non-reimbursable products in Italy, pharmaceutical companies can increase prices also beyond recommended levels.[61]

Conclusion

(332) The Commission concludes that serious doubts arise as regards the compatibility of the transaction with the internal market in relation to delorazepam in Italy, because the transaction would strengthen the dominant position which Abbott EPD-DM already holds on this market.

IV.2.3.2.q. Ibuprofen (M1A)

Product market definition

(333) Ibuprofen is a non-steroidal anti-inflammatory drug derivative of propionic acid belonging to the ATC3 class M1A (anti-rheumatics, non-steroidal) and N2B (non-narcotics and anti-pyretics). The ATC3 class M1A is further subdivided into two ATC4 classes: M1A1 (anti-rheumatics, non-steroidal plain), to which ibuprofen belongs, and M1A2 (anti-rheumatics, non-steroidal combination). It is used for reliving pain and fever as well as reducing inflammation and it can be acquired in the OTC and in the prescription segment.

(334) In a previous decision, the Commission did not consider whether the forms of ibuprofen in which the Parties are active may be substitutable with drugs based on different molecules.[62] The market investigation did not provide any indications that the market in this case should be further segmented depending on the galenic form

(335) The Notifying Party supports a market definition at the ATC4 level, comprising all propionic acid derivatives, such as ibuprofen, naproxen, fenoprofen, flurbiprofen and ketoprofen.

(336) In the case at hand, the results of the market investigation generally indicated that ibuprofen is widely substitutable by other propionic acid derivatives belonging to the same ATC4 class, and in particular by molecules naproxen and diclofenac. This is because practitioners generally considered that ibuprofen has similar therapeutic profile than other pain relieving drugs both in terms of efficacy, tolerability and side effects. The respondents also indicated that should the prices of ibuprofen go up by 5-10% they would switch to other substitutes.

(337) Therefore, the Commission concludes for the purposes of the present decision that the relevant product market for ibuprofen should be defined at least at the ATC4 level, comprising all anti-rheumatic drugs belonging to the M1A1 class, or wider. The question of whether the market should be further segmented according to the

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61 If pharmaceutical companies increase their prices above the maximum levels recommended by the AIFA, they have to provide their rationale for doing so. Moreover, the AIFA makes it public which companies have exceeded the limits suggested by the AIFA.

62 While in COMP/M.5865 Teva/Ratiopharm the Commission found strong indications for the existence of a separate market for rectal form ibuprofen (paragraph 255), the Commission was not able 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 The Parties in the present case are not active in rectal ibuprofen; their products are based on a lower-dosage oral solid ordinary form.

galenic form or prescription versus OTC can be left open for the purpose of this case as no serious doubts arise in relation to the M1A1 class irrespective of the market definition.

(338) On the basis of the above, no affected markets arise and the transaction does not raise serious doubts in relation to ibuprofen.

IV.2.3.2.r. Promazine and risperidone (N5A)

Product market definition

(339) Promazine and risperidone are two antipsychotics belonging to the ATC3 class N5A. Antipsychotics are mainly used to treat psychosis, which is typified by schizophrenia and mania. However, these two molecules belong to two different ATC4 classes: promazine is a conventional antipsychotic (ATC4 N5A1) while risperidone is an atypical antipsychotic (ATC4 N5A9). The overlap between the Parties in relation to N5A class arises only at ATC3 level.

(340) In previous decisions, the Commission considered whether conventional and atypical anti-psychotics should be considered two separate product markets, but ultimately left the question open.[63]

(341) The Notifying party supports a market definition at the ATC4 level leading to two separate product markets for conventional anti-psychotics (N5A1) and for atypical anti-psychotics (N5A9).

(342) The market investigation indicated that the two molecules are considered to be substitutable by prescribers. In any event, the product market definition in relation to promazine and risperidone can be left open for the purpose of this case as no serious doubts arise in relation to promazine and risperidone irrespective of the market definition.

Competitive assessment

(343) The proposed transaction gives rise to one Group 1 affected market at ATC3 level in Italy.

Italy

(344) The Parties' products in the N5A class are Abbott EPD-DM's branded product Talofen, with promazine as the active ingredient, and Mylan's generic product Risperidone. The former originator of risperidone-based products in Italy is J&J, while the former originator of promazine-based products is Sanofi-Aventis. The size of the market for the N5A class in Italy (2013) is around EUR 31 million.

(345) The Parties' combined market share at the ATC3 level reaches [50-60]% (value) and [30-40]% (volume), with an increment (Mylan) of [0-5]% (value) and [0-5]% (volume).

63 COMP/M.3354 Sanofi-Synthelabo/Aventis, paragraph 106, and COMP/M.5865 Teva/Ratiopharm, paragraph 293.

(346) Post-merger, strong competitors remain in the market: J&J with a market share of [10-20]% (value) and [30-40]% (volume), Otsuka with a market share of [10-20]% (value), Menarini with a market share of [5-10]% (value) and [10-20]% (volume) and Novartis with a market share of [5-10]% (value) and [5-10]% (volume).

(347) Moreover, two competitors hold dormant marketing authorisations for promazine-based products and twenty competitors hold them to sell risperidone-based products in the Italian market, which can be re-activated within a short period of time.

(348) Promazine and risperidone are prescription drugs. Mylan's product Risperidone is reimbursed in Italy, while Abbott EPD-DM's product Talofen (promazine) and their competitors' products are not. However, pricing restrictions are in place in Italy both for reimbursable and non-reimbursable medicines.

Conclusion

(349) The Commission, taking into consideration all of the above, including the results of the market investigation, concludes that the transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to anti-psychotics in Italy.

IV.2.3.2.s. Fluvoxamine and paroxetine (N6A4)

Product market definition

(350) Fluvoxamine and paroxetine belong to the ATC3 class N6A, which includes substances used in the treatment of depression and mood stabilisation. The N6A class is further subdivided into several ATC4 classes with different modes of action: herbal antidepressants (N6A1), mood stabilisers (N6A3), selective serotonin re-uptake inhibitors ("SSRIs") antidepressants (N6A4), serotonin-noradrenaline re-uptake inhibitors ("SNRIs) antidepressants (N6A5) and other antidepressants (N6A9). Both fluvoxamine and paroxetine belong to the N6A4 SSRIs antidepressants category.

(351) The Commission has assessed this segment in a number of previous decisions, but ultimately left the market definition open. Firstly, the Commission left open whether the market ought to be defined on the basis of the ATC3 class, the ATC3 class excluding certain ATC4 classes or the ATC4 class N6A9.[64] In a subsequent case, the Commission analysed several molecules on potentially narrower markets, while leaving the market definition ultimately open.[65]

(352) The Notifying Party supports a market definition at the ATC4 level, comprising all the SSRIs, due to their similar scope of action and same level of reimbursement in the affected markets.

(353) The results of the market investigation indicated that while both being SSRIs, fluvoxamine and paroxetine are not perfect substitutes as paroxetine is considered the first line of treatment while fluvoxamine would typically be used in the second line.

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64 COMP/M.5295 Teva/Barr, paragraph 164.

65 COMP/M.5865 Teva/Ratiopharm, paragraphs 302 et seq.

(354) In any event, the precise market definition in relation to fluvoxamine and paroxetine can be left open for the purpose of this case as no serious doubts arise in relation to these products irrespective of the market definition.

Competitive assessment

(355) At the molecule level, the proposed transaction gives rise to two Group 1 affected markets, namely fluvoxamine in France and paroxetine in Italy.

Fluvoxamine in France

(356) The combined market share of the Parties at molecule level in France reaches [60-70]% (value) and [60-70]% (volume) with an increment of [10-20]% (Abbott-EPD-DM). Abbott EPD-DM is active as ex-originator with several branded products: Fluoxetin (based on fluoxetine), Dumirox, Faverin, Floxyfra and; Maveral (based on fluvoxamine) and Casbol and Sereupin (based on paroxetine), while Mylan sells generic products. Several other competitors are also active, namely Teva ([10-20]%), Novartis ([10-20]%) and Stada ([5-10]%), all marketing an unbranded generic product. All these competitors have an established presence and customer relationships in France.

(357) Despite the fact that Abbott EPD-DM is the ex-originator, its market share has for the last three years been significantly smaller than Mylan's market share. Both Mylan's and Abbott EDP-DM's market shares decreased since 2011, while Novartis' market share increased steadily and Stada and Teva preserved their market shares. Accordingly, with regard to fluvoxamine, Mylan and Abbott EDP-DM appear not to be the closest competitors and competition appears to occur mainly among the generic products.

(358) The size of the French fluvoxamine market is relatively limited, amounting to less than EUR 1.5 million and has been declining from EUR 1.8 million in 2011. Fluvoxamine is a highly genericized market with Abbott EPD-DM holding less than [5-10]% market share in volume and [10-20]% in value.

(359) Two competitors hold dormant marketing authorizations for fluvoxamine in France.

(360) Fluvoxamine is a reimbursed drug in France. The prices of all reimbursed drugs in France are regulated throughout the chain given that they are all part of the so-called positive lists for hospital and for community pharmacies. As a result, the ability of pharmaceutical companies to increase prices for these drugs is generally limited.[66]

(361) In addition, the market investigation did not reveal any concerns in relation to flvoxamine market in France.

Conclusion

(362) The Commission, taking into consideration all of the above, including the results of the market investigation, concludes that the transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to fluvoxamine in France.

66 See footnotes 24 and 25 for the description of the French regulatory system.

Paroxetine in Italy

(363) The combined market share of the Parties at molecule level in Italy reaches [40-50]% (value) and [40-50]% (volume), with an increment by Mylan of [5-10]% (value) and [10-20]% (volume). Abbott EPD-DM is active with its branded product Sereupin while Mylan sells a generic product. Several other competitors, all holding a share higher than Mylan - namely Angelini ([20-30]%), Italfarmaco ([10-20]%) and GSK ([5-10]%) – are also active.

(364) The size of the Italian paroxetine market is around EUR 61.5 million in 2013.

(365) Paroxetine-based products are reimbursed in Italy. The prices of the reimbursed drugs are set through negotiation between the relevant manufacturer and AIFA. The regulatory framework does not generally allow for price increases where it concerns reimbursed products. As a result, the ability of pharmaceutical companies to increase prices for these drugs is generally limited.

(366) In addition, the market investigation did not reveal any concerns in relation to paroxetine market in Italy.

Conclusion

(367) The Commission, taking into consideration all of the above, including the results of the market investigation, concludes that the transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to paroxetine market in Italy.

IV.2.3.2.t. Betahistine (N7C)

Product market definition

(368) Betahistine belongs to the ATC3 class N7C (antivertigo products), which includes molecules betahistine, cinnarizine, acetylleucine and flunarizine when indicated for vertigo and Menière's disease. Betahistine stimulates the H1-receptors in the inner ear and acts by reducing the asymmetrical functioning of sensory vestibular organs and by increasing vestibulocochlear blood flow, which decreases symptoms of vertigo and balance disorders.

(369) The Notifying Party submits that the appropriate market definition for betahistine would comprise all the antivertigo products, i.e. the entire ATC3 class N7C.

(370) The Commission has not examined the appropriate market definition for the N7C class in the past.[67]

(371) The market investigation in this case provided indications that betahistine may be a unique molecule, not interchangeable with the other molecules within the ATC3 class N7C. In any event the market definition for betahistine can be left open for the purpose of this case as in Ireland serious doubts arise in relation to betahistine irrespective of the market definition while in other countries no serious doubts arise under any plausible market definition.

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67 In COMP/M.5865 Teva/Ratiopharm (paragraph 386), the N7C class was briefly mentioned in the list of Group 1 markets for which serious doubts did not arise.

Competitive assessment

(372) On the basis of the market definition set out above, the proposed transaction gives rise to eight Group 1 affected markets in France, Ireland, Austria, Belgium, the Czech Republic, Hungary, Portugal and the UK. Abbott EPD-DM is the former originator of betahistine-based drugs in these markets.

France

(373) The Parties' products where the relevant overlap occurs at the molecule level are Abbott EPD-DM's branded products Betahistine Biphar, Betaserc and Serc, and Mylan's generic product Betahistine. The size of the market for betahistine in France (2013) is EUR 20.6 million.

(374) The Parties' combined market share for betahistine-based products in France at the molecule level reaches [30-40]% by value (Abbott EPD-DM: [10-20]%; Mylan: [20-30]%) and [40-50]% by volume (Abbott EPD-DM: [10-20]%; Mylan: [20-30]%).

(375) Post-merger, three strong competitors remain in the French market for betahistine: Recordati with a market share of [20-30]% (value) and [10-20]% (volume), Servier with a market share of [10-20]% (value) and [10-20]% (volume) and Teva with a market share of [5-10]% (value) and [0-5]% (volume).

(376) Moreover, seven competitors hold dormant marketing authorisations to sell betahistine-based products in the French market, which can be re-activated within a short period of time.

(377) Betahistine can be acquired both at the prescription and at the OTC segment in France. The Parties' products are reimbursed if prescribed. In France, OTC products that are allowed into the reimbursement system are subject to the same pricing restrictions, if prescribed, as prescription products that are reimbursed. A price increase of reimbursed drugs is only possible through an application to the HAS and requires either robust clinical data demonstrating a clinical added-value or completely delisting the product from the reimbursement list (free pricing).

Conclusion

(378) The Commission, taking into consideration all of the above, including the results of the market investigation, concludes that the transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to betahistine in France.

Austria

(379) The Parties' products where the relevant overlap occurs at the molecule level are Abbott EPD-DM's products Betaserc, and Mylan's product Betahistine – Arca. The size of the market for betahistine in Austria (2013) is EUR 1.8 million.

(380) The Parties' combined market share for betahistine-based products in Austria at the molecule level reaches [40-50]% (value) with a [0-5]% increment (Mylan) and [40-50]% (volume) with a [0-5]% increment (Mylan).

(381) Post-merger, two strong generic players remain in the Austrian market for betahistine: Teva with a market share of [30-40]% (value) and [30-40]% (volume) and Actavis with a market share of [10-20]% (value) and [10-20]% (volume).

(382) Moreover, two competitors hold dormant marketing authorisations to sell betahistine-based products in the Austrian market, which can be re-activated within a short period of time.

(383) Betahistine is sold as a prescription drug in Austria. Mylan's product Betahistine is reimbursed in Austria, while Abbott EPD-DM's product is not. The ability of pharmaceutical companies to increase prices of reimbursed drugs in Austria is limited. The only possibility for this requires filing an application to the relevant authority motivating the reason for the price increase or delisting the product from the reimbursement list (free pricing).

Conclusion

(384) The Commission, taking into consideration all of the above, including the results of the market investigation, concludes that the transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to betahistine in Austria.

Belgium

(385) The Parties' products where the relevant overlap occurs at the molecule level are Abbott EPD-DM's branded product Betaserc and Mylan's products Betahistine and Docbetahi. The size of the market for betahistine in Belgium (2013) is EUR 6.2 million.

(386) The Parties' combined market share for betahistine-based products in Belgium at the molecule level reaches [40-50]% by value (Abbott EPD-DM: [20-30]%; Mylan: [10-20]%) and [30-40]% by volume (Abbott EPD-DM: [10-20]%; Mylan: [10-20]%).

(387) Post-merger, the market leader Stada remains in the Belgian market with a market share of [50-60]% (value) and [50-60]% (volume). Stada's betahistine-based products are not reimbursed in Belgium; the products of the Parties and their other competitors are reimbursed. However, this does not change the outcome of the Commission's assessment, since in Belgium the maximum ex-factory prices of all pharmaceutical products (reimbursed or not) are set by the competent authorities. The only possibility for pharmaceutical companies to increase the price of pharmaceutical products requires filing an application to the relevant authority motivating the reason for the price increase.

(388) Moreover, two competitors hold dormant marketing authorisations to sell betahistine-based products in the Belgian market, which can be re-activated within a short period of time.

Conclusion

(389) The Commission, taking into consideration all of the above, including the results of the market investigation, concludes that the transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to betahistine in Belgium.

The Czech Republic

(390) The Parties' products where the relevant overlap occurs at the molecule level are Abbott EPD-DM's branded product Betaserc and Mylan's generic product Betahistin. The size of the market for betahistine in the Czech Republic (2013) is EUR 3.7 million.

(391) The Parties' combined market share for betahistine-based products in the Czech Republic at the molecule level reaches [30-40]% (value) with a [0-5]% increment (Mylan) and [30-40]% (volume) with a [0-5]% increment (Mylan).

(392) Post-merger, three strong players remain in the Czech market: Actavis with a market share of [20-30]% (value) and [30-40]% (volume), Teva with a market share of [10-20]% (value) and [20-30]% (volume) and Avefarm with a market share of [5-10]% (value) and [10-20]% (volume).

(393) Moreover, three competitors hold dormant marketing authorisations to sell betahistine-based products in the Belgian market, which can be re-activated within a short period of time.

(394) Betahistine is sold as a prescription drug in the Czech Republic. The product of the Parties and their competitors are reimbursed in the Czech Republic. The ability of pharmaceutical companies to increase prices of reimbursed drugs in the Czech Republic is limited. Some reimbursable pharmaceutical products are subject to a maximum ex-factory price, in which case the regulatory framework does not allow for price increases of these products above such limit. For products that are not subject to a price cap, their prices may be increased each quarter. However, such increase is subject to an application to the relevant authority in the precedent quarter. In any case, the authorities in the Czech Republic set the maximum reimbursement amount, which pharmaceutical companies take into account when determining their prices

Conclusion

(395) The Commission, taking into consideration all of the above, including the results of the market investigation, concludes that the transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to betahistine in the Czech Republic.

Hungary

(396) The Parties' products where the relevant overlap occurs at the molecule level are Abbott EPD-DM's branded product Betaserc, and Mylan's product Betagen. The size of the market for betahistine in Hungary (2013) is EUR 5.6 million.

(397) The Parties' combined market share for betahistine-based products in Hungary at the molecule level reaches [60-70]% by value (Abbott EPD-DM: [30-40]%; Mylan: [20-30]%) and [50-60]% by volume (Abbott EPD-DM: [30-40]%, Mylan: [20-30]%).

(398) Post-merger, three strong players remain in the Hungarian market: Teva with a market share of [20-30]% (value) and [20-30]% (volume), Sager Pharma with a market share of [10-20]% (value) and [5-10]% (volume) and Actavis with a market share of [5-10]% (value) and [5-10]% (volume).

(399) Moreover, eight competitors hold dormant marketing authorisations to sell betahistine-based products in the Hungarian market, which can be re-activated within a short period of time.

(400) Betahistine is sold as a prescription drug in Hungary. Mylan's product Betagen is reimbursed in Hungary, while Abbott EPD-DM's product Betaserc and SagerPharma's product Betaverin are not. In Hungary, the regulatory framework does not allow for price increases for reimbursed products. Moreover, in Hungary, there is a bi-annual "blind-price" bidding system put in place by the reimbursement authority. As a result of this price bidding system the average price on the betahistine market has decreased by 22% in the last four years.[68]

Conclusion

(401) The Commission, taking into consideration all of the above, including the results of the market investigation, concludes that the transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to betahistine in Hungary.

Portugal

(402) The Parties' products where the relevant overlap occurs at the molecule level are Abbott EPD-DM's branded product Betaserc and Mylan's product Betahistina. The size of the market for betahistine in Portugal (2013) is EUR 9.6 million.

(403) The Parties' combined market share for betahistine-based products in Portugal at the molecule level reaches [50-60]% (value) with an increment of [0-5]% (Mylan) and [40-50]% (volume) with an increment of [0-5]% (Mylan).

(404) Post-merger, three players remain in the Portuguese market: Generis Farma with a market share of [20-30]% (value) and [30-40]% (volume), Actavis with a market share of [5-10]% (value) and [10-20]% (volume) and Aurobindo with a market share of [5-10]% by volume.

(405) Moreover, four competitors hold dormant marketing authorisations to sell betahistine-based products in the Portuguese market, which can be re-activated within a short period of time.

(406) Betahistine is sold as a prescription drug in Portugal. The products of the Parties and their competitors are reimbursed in Portugal. In Portugal, the relevant authority sets the maximum public price for reimbursed drugs, which limits the ability of pharmaceutical companies to increase their prices. The only possibility to increase the price of reimbursed pharmaceutical products requires filing an application to the authority motivating the reason for the price increase.

Conclusion

(407) The Commission, taking into consideration all of the above, including the results of the market investigation, concludes that the transaction does not give rise to serious

68 Form CO, "Overview of the regulatory landscape in the affected countries", page 54.

doubts as to its compatibility with the internal market in relation to betahistine in Portugal.

The United Kingdom

(408) Abbott EPD-DM is active in the UK with its betahistine-based branded product Serc while Mylan sells a generic Betahistine.

(409) The Parties' combined market share for betahistine-based products in the UK at the molecule level reaches [40-50]% by volume (Abbott EPD-DM: [30-40]%; Mylan: [10-20]%).

(410) Post-merger, three generic players remain in the UK market: Teva, Actavis and Sandoz.[69] Moreover, at least four competitors hold dormant marketing authorisations to sell betahistine-based products in the UK. In addition to this, the UK market has a very high rate of generic penetration, confirmed by the presence of three of the strongest generic suppliers across Europe, and Abbott EPD-DM's market share decreased by [0-10]% between years 2012 and 2013 at every plausible market definition.

(411) Abbott EPD-DM's products based on betahistine are sold in the prescription segment, while Mylan's products are sold both under prescription and OTC. In the UK, the prices of generics are determined freely by the pharmaceutical companies and therefore price increases and price decreases occur. However, the reimbursement level is set by the authorities for different categories of pharmaceutical products depending on how valuable each product is (according to their cost and how commonly they are prescribed). The market investigation revealed that in cases of shortages and in particular where there is only one supplier in the market, there are concessions and the drugs can be sold at a higher price and reimbursed at this higher level. However, in a competitive scenario such as the one at hand, in which the merged entity would face competitive constraint from three strong generic players, such possibility can be excluded.

Conclusion

(412) The Commission, taking into consideration all of the above, including the results of the market investigation, concludes that the transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to betahistine in the UK.

Ireland

(413) Abbott EPD-DM is active in Ireland with its branded product Serc while Mylan sells a branded generic Vertigon. The size of the market (2013) is EUR 1.5 million.

69 The exact market share information for the Parties' competitors in the UK is not available. As the Parties indicate in their submission (Form CO, page 433), the database IMS does not provide a complete set of data for the UK. Therefore, the Parties relied on actual sales data and internal estimations to reproduce the best market view possible.

(414) The Parties' combined market share for betahistine-based products in Ireland at the molecule level reaches [80-90]% by value (Abbott EPD-DM [60-70]%; Mylan [10-20]%) and [80-90]% by volume (Abbott EPD-DM: [60-70]%; Mylan: [10-20]%), which makes them the only sizeable players in this market. High market shares are equally reached at the broader ATC3 N7C class, where the Parties' combined market share reaches [70-80]% by value (Abbott EPD-DM: [50-60]%; Mylan: [10-20]%) and [70-80]% by volume (Abbott EPD-DM: [50-60]%; Mylan: [10-20]%).

(415) The only competitors to the Parties at the molecule level are two small players with a generic profile, namely Fannin and Accord, which entered the market in 2013. Fannin, which has taken the place of Erga Healthcare (Helsinn Corp.) by obtaining its marketing authorisation for the branded generic product "By Vertin" in August 2013, has a market share of [10-20]% (value) and [10-20]% (volume). Accord's market share is negligible (far below [0-5]%).[70] At the broader ATC3 level, the Parties' main competitor is J&J[71] with its branded product Stugeron, based on a different molecule, cinnarizine which is reimbursed in Ireland.

(416) The market investigation showed that the brand plays a very important role in this market. Indeed, the market for betahistine in Ireland is driven by prescribers acting as the ultimate gatekeepers as there is no pharmacy substitution for betahistine in Ireland. Doctors in Ireland seem to be particularly attached to brands and unwilling to switch. In this context it is noted that both Abbott EPD-DM and Mylan sell betahistine in Ireland under very strong brands, while the brands from other producers such as Fannin's product By-Vertin have only a limited take-up in the market.

(417) Only one competitor holds a dormant marketing authorisation to enter this market while his plans remain unclear. In addition, given the strong branded nature of this particular market, any potential entrant would have to create a brand and overcome the barrier stemming from the strong position of the Parties' established brands benefitting from strong prescribers' loyalty.

(418) Moreover, there are a number of additional barriers to enter this market, given that betahistine is an old molecule which would require engaging in a lengthy and costly procedure in order to update the marketing dossier. Such barriers, in combination with the small size of the market (EUR 1.5 million), strong brand of Abbott EPD-DM and the fact that there is no pharmacy substitution for this molecule in Ireland, make entry in the market very unlikely.

(419) Based on the above, the Commission considers that Abbott EPD-DM holds a dominant position on the market for betahistine in Ireland. This dominant position will be further strengthened by the addition of Mylan.

(420) Finally, the Commission considered the regulatory framework in Ireland. Betahistine is sold as a prescription drug in Ireland. The product of the Parties and their competitors are reimbursed in Ireland. The ability of pharmaceutical companies to increase prices of reimbursed drugs in Ireland is limited. The only possibility for this

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70 The market investigation revealed that there were roughly […] orders for Accord's betahistine-based products (16 mg doses) in Ireland in September 2014, as opposed to […] orders for Abbott EPD-DM's product Serc and […] for Mylan's product Vertigon (same dose).

71 J&J's market share at the broader ATC3 level is [10-20]% by value and [10-20]% by volume.

requires filing an application to the relevant authority motivating the reason for the price increase. However, the market investigation in relation to Ireland revealed that in highly concentrated markets with limited competition (as in the present case), price increases are possible and are more likely to be granted than in markets with a number of established players.

Conclusion

(421) The Commission concludes that serious doubts arise as regards the compatibility of the transaction with the internal market in relation to betahistine in Ireland, because the transaction would strengthen the dominant position which Abbott EPD-DM already holds on this market.

IV.2.3.2.u. Other Group 2 and Group 3 markets in the CNS / pain therapeutic area

(422) In addition to the Group 1 markets analysed above, there is a number of Group 2 and Group 3 affected markets in the CNS / pain area, specifically:

- *ATC3 class M1A in the Czech Republic, France, Italy, Luxembourg, the Netherlands, Portugal, Spain and Sweden*
- *ATC3 class N2B in France*
- *ATC3 class N2C in Italy*
- *ATC3 class N5C in Italy*
- *ATC3 class N6A in France, Germany and Italy*
- *ATC3 class N7C in France, Italy, Luxembourg and Poland*

(423) Within these ATC classes several galenic forms are marketed and give rise to technically affected markets. However, the market investigation did not provide any indications that the markets in this case should be further segmented depending on the galenic form or on whether the drug is sold against a prescription or OTC.

(424) On these markets the combined market share of the Parties are moderate to low and / or the increment is below 1%. In all cases there is a number of strong competitors active on these markets with a wide portfolio of products, including branded medicines but also branded and non-branded generic products, such as Sanofi, Servier, Teva, Pfizer, Novartis, Johnson & Johnson, Roche, Daiichi Sankyo, Actavis Gruenenthal, Recordati, Polifarma.

(425) The market investigation did not provide any indication that competition issues would arise in these markets. On this basis the Commission concludes that the transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to any of these markets.

WOMEN'S AND MEN'S HEALTH AREA

IV.2.3.2.v. Pygeum africanum (G4C9)

Product market definition

(426) Pygeum africanum is a product of herbal origin derived from the bark of a tree called pygeum africanum, belonging to the Prunus family. Pygeum africanum belongs to the ATC3 class G4C, which includes benign prostatic hypertrophy ("BPH") products, which treat the growth of individual prostatic stromal and epithelial cells. The ATC3 class G4C is further split in seven ATC4 classes depending on their mode of action or the origin of the products, two of which are out of use. The Parties' pygeum africanum-based products fall under class G4C9. Class G4C9 includes also other products of herbal or animal origin, as well as homeopathic products, improving prostatic health.

(427) The Notifying Party submits that the relevant product market for pygeum africanum comprises at least all products within the class G4C9, including serenoa repens.

(428) There are no Commission precedents analysing specifically pygeum africanum-based products.

(429) The results of the market investigation suggest that pygeum africanum is used as an effective treatment for patients with BPH. According to respondents, while other products, for example serenoa repens, can be prescribed for the same condition, their action is not the same since natural extracts all have their specificities. Given its natural origin, pygeum arfricanum cannot be reproduced in its exact action.

(430) Therefore, for the purposes of this decision, the Commission concludes that the relevant product market for pygeum africanum should be defined at the molecule level.

Competitive assessment

(431) On the basis of the market definition set out about, the proposed transaction gives rise to one Group 1 market, namely France.

France

(432) The Parties both market their pygeum africanum-based products in France.[72] Abbott EPD-DM sells its product under the brand name Tadenan, whereas Mylan uses a non-registered name Prunier d'Afrique. The products of both Parties are sold OTC.

(433) The total size of the market for pygeum africanum in France in terms of sales is approximately EUR 23 million.

(434) The Parties' combined market share for pygeum africanum-based products in France at the molecule level is [90-100]%, with an increment from Mylan of [0-5]% (value) and [0-5]% (volume) in 2013. While Mylan's increment was small in 2013, its market position was stronger in the preceding years, achieving up to [20-30]% (volume) in 2011.

72 The Parties have no or limited sales of pygeum africanum-based products outside of France.

(435) The decrease in Mylan's market share is explained by [Mylan's commercial information regarding the product]. Therefore, the limited market share of Mylan in 2013 does not reflect its full marketing potential and is likely to underestimate its future market position [Mylan's commercial information regarding the product].

(436) In addition, despite the relatively significant size of the market in France (EUR 23 million), there are no other competitors currently present nor does any other competitor hold a marketing authorization. This suggests that the Parties have certain advantages (e.g. access to scarce supply sources, know-how, etc.) and that entry is likely to be difficult.

(437) Based on the above, the Commission considers that Abbott EPD-DM holds a dominant position on the market for pygeum africanum in France. This dominant position will be further strengthened by the addition of Mylan.

(438) Finally, the Parties' pygeum africanum-based products are sold OTC, which means they are subject to free pricing in France. Hence, the merged entity would not face any regulatory constraints to increase prices.

Conclusion

(439) The Commission concludes that serious doubts arise as regards the compatibility of the transaction with the internal market in relation to pygeum africanum in France, because the transaction would strengthen the dominant position which Abbott EPD-DM already holds on this market.

IV.2.3.2.w. Oxybutynin (G4D)

Product market definition

(440) Oxybutynin belongs to the ATC3 class G4D which includes urinary incontinence products and is further divided in two ATC4 classes depending on the origin of the products. ATC4 class contains urinary incontinence products (e.g. oxybutynin-based products) and ATC4 Class G4D8 contains products of herbal or animal origin, as well as homeopathic products. Oxybutynin is an urinary antispasmodic that serves as anticholinergic agent that inhibits involuntary detrusor contractions.

(441) The Commission has not assessed oxybutynin or the ATC3 class G4D in its previous decisions.

(442) The Notifying Party submits that the appropriate market definition for oxybutynin should include all anticholinergics covered in class G4D, although it may potentially exclude some drugs with other modes of action also included in this class.

(443) The results of the market investigation suggest that there are more modern alternatives available to oxybutynin, which cause fewer side effects. In particular, the respondents mentioned general substitutability of oxybutynin with various anticholinergic agents belonging to the ATC3 class G4D including propiverine, trospium, tolterodine, solifenacine, trospium, darifenacine, and fesoterodine.

(444) Based on the above, for the purposes of this case the Commission concludes that the relevant product market in relation to oxybutynin-based products is wider than the molecule, but narrower than the ATC3 class, likely comprising ATC4 classes A2B1 and A2B2.

(445) Therefore, for the purposes of this decision, the Commission concludes that the relevant product market for oxybutynin should be defined at the ATC3 level. It may be left open whether some specific G4D class products are not substitutable with oxybutynin, since it will not change the assessment in the present case.

Conclusion

(446) On the basis of the market definition set out above, no Group 1 markets arise and the transaction does not raise serious doubts in relation to oxybutynin.

IV.2.3.2.x. Other Group 2 and Group 3 markets in the women's and men's health therapeutic area

(447) In addition to the Group 1 markets analysed above, there is a number of Group 2 and Group 3 affected markets in the women's and men's health area, specifically:

- *ATC3 class G3D in France*
- *ATC3 class G4C in France*
- *ATC3 class G4D in France*

(448) Within these ATC classes several galenic forms are marketed and give rise to technically affected markets. However, the market investigation did not provide any indications that the markets in this case should be further segmented depending on the galenic form or on whether the drug is sold against a prescription or OTC. On these markets the combined market share of the Parties are moderate to low and / or the increment is below 1%. In all cases there is a number of strong competitors active on these markets with a wide portfolio of products, including branded medicines but also branded and non-branded generic products, such as Teva, Servier, Sanofi, Urgo, Zambon Group, and Pierre Fabre.

(449) The market investigation did not provide any indication that competition issues would arise in these markets. On this basis the Commission concludes that the transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to any of these markets.

IV.3. Pipeline products

(450) In addition to drugs already on the market, generic companies are usually developing a number of pipeline generic drugs which are intended to compete with originators which come off-patent. In assessing pipeline competition, the Commission has previously focused on instances where one party is planning to enter a market with a new product within a period of two years and the other party (or the parties combined) has a market share of 35% or more on any possible market definition where the pipeline products and existing products overlap.[73]

(451) Both Abbott EPD-DM and Mylan invest in the development of new products. [Parties' information on pipeline products].

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73 COMP/M.6258 Teva/Cephalon, paragraphs 81 and 129, and COMP/M.6613 Watson/Actavis, paragraphs 110-111.

(452) Based on the above, the Parties have identified in the Form CO [Parties' information on pipeline products] products in a sufficiently advanced stage of development (i.e. around two years till launch) where the other Party has an existing market share of at least 35% based on all plausible market definitions and the other party is planning to enter. These [Parties' information on pipeline products] relevant pipeline products of the Parties are the following:

- [Parties' information on pipeline products];
- [Parties' information on pipeline products].

(453) The market investigation confirmed that sufficient competition is likely to remain in relation to the above-mentioned products in the relevant Member States post-merger. This is due to the fact that the relevant product markets are wider than the ones where the other Party would have a market share of at least 35% ([Parties' information on pipeline products]) and/or a number of strong competing pharmaceutical companies remaining post-merger ([Parties' information on pipeline products]).

(454) In addition to the [Parties' information on pipeline products] above-mentioned pipeline products, [Parties' information on pipeline products].

(455) Consequently, the Commission concludes that serious doubts do not arise in relation to the Parties' pipeline products.

IV.4. Active pharmaceutical ingredients

(456) An API is the substance in a drug that is pharmaceutically active, as opposed to the excipient (inert substance in which the API is suspended).

(457) APIs are produced from chemical and biological products and may be manufactured internally or sourced from external manufacturers. In past cases, the Commission considered that APIs form separate product markets upstream from the markets for FDPs. Geographically, the latter are considered to be national markets, due to national regulation, while API markets are at least EEA-wide and possible global in scope.

(458) With respect to horizontal analysis, while Mylan has extensive active pharmaceutical ingredient ("API") operations, Abbott EPD-DM is essentially not active in the production of APIs for sale to third parties (it only sells limited excess inventory). Hence, any increment to the combined market share would be limited.

(459) Also, there are no actual vertical relationships between Mylan and Abbott EPD-DM since none of the APIs manufactured by Mylan is used by Abbott EPD-DM in the downstream FDPs, and vice versa. The transaction however gives rise to several potential vertical links due to the upstream API manufacturing by Mylan and downstream activities of Abbott EPD-DM in FDPs.

(460) For all potential vertically affected links the API produced by Mylan is a different molecule than the API used by Abbott EPD-DM to produce its corresponding FDP. This suggests that the producer upstream is unlikely to successfully engage in input foreclosure and the producer downstream is unlikely to successfully engage in customer foreclosure.

(461) There is only one vertically affected link downstream where Abbott EPD-DM's competitors produce FDPs using the same API as produced by Mylan. However, this API is produced also by several other API producers. Therefore, API purchasers would have several alternative sources post-merger.

(462) Accordingly, the Commission concludes that serious doubts do not arise in relation to the Parties' API activities.

IV.5. Contract manufacturing

(463) Contract manufacturing of FDPs consists of the manufacturing under contract of FDPs on behalf of third party pharmaceutical companies. The third party then commercializes the FDPs under its own label or brand. In its previous decisions, the Commission found that the geographic market for contract manufacturing to be worldwide or at least EEA-wide.[74]

(464) Both Abbott EPD-DM and Mylan have contract manufacturing activities. All Abbott EPD-DM's contract manufacturing sales are generated by its plant in Japan and none was in the EEA. None of the Parties is a major player in contract manufacturing activities given their low estimated market shares in various segments. Sufficient alternative contract manufacturers are likely to remain post-merger.

(465) Accordingly, the Commission concludes that serious doubts do not arise in relation to the Parties' contract manufacturing activities.

IV.6. Outlicensing

(466) Outlicensing in the pharmaceutical industry refers to a licensor licensing to a licensee rights to use a dossier to obtain a marketing authorization for a product in one or more countries. Based on Commission’s practice, outlicensing may result in vertically affected markets where (i) one party is active on a downstream FDPs market, (ii) the other party is active upstream as a licensor and contract manufacturer of a downstream competitor and where (iii) the combined share of the Parties and the licensee on the downstream market are in excess of 25%.

(467) Mylan and Abbott EPD-DM are both active in the market of outlicensing market authorization dossiers to third parties. Three vertically affected markets have been identified. The Notifying Party submits that no competition concerns arise given (i) the lack of incentive for the merged entity to discontinue its licensing arrangements given the Parties' small market shares downstream; and (ii) ample alternative sources of supply. The market investigation has confirmed these statements.

(468) Accordingly, the Commission concludes that serious doubts do not arise in relation to the Parties' outlicensing activities.

V. PROPOSED COMMITMENTS

(469) In order to render the concentration compatible with the internal market, the Parties have modified the notified concentration by entering into the following Commitments, which the Notifying Party submitted on 7 January 2015. The

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74 COMP/M.5953 Reckitt Benckiser/SSL, paragraph 64, and COMP/M.6613 Watson/Actavis, paragraph 124.

Commitments were subsequently modified on 8 January 2015. The final version of the Commitments including the adaptations made following the results of the market test was submitted on 21 January 2015. These Committments are annexed to this decision and form an integral part thereof.

Description of the Commitments

(470) Specifically, Mylan offered to divest its local businesses in the product markets where serious doubts were identified following the phase I market investigation to one or more suitable third party purchasers ("the Purchasers").

(471) The businesses to be divested (hereafter referred to as "the Divestment Businesses") include the following:

- Mylan's mebeverine business in Germany;
- Mylan's mebeverine business in the United Kingdom;
- Mylan's pygeum africanum business in France;
- Mylan's betahistine business in Ireland;
- Mylan's delorazepam business in Italy.

(472) The Divestment Businesses are structured as an asset carve-out; no legal entity of Mylan is to be divested. Specifically, the businesses to be divested include the following assets:

i. the relevant marketing authorizations under which the Divestment Businesses operate, including all relevant dossiers, and without any limitation as to the use of the information contained in the dossiers;

ii. all licenses, permits and authorisations issued by any governmental organisation for the benefit of the Divestment Business;

iii. customer contacts and historical information of orders;

iv. to the extent such contracts exist, assignment of contracts or a best efforts obligation to obtain the assignment of the supply and/or customer contracts or entered into by Mylan;

v. all advertising, marketing, sales, publicity and presentational materials related to the Divestment Businesses, as applicable.

vi. the benefit for a period of up to 2 years after Closing, on a reasonable cost-plus basis to be agreed with the Purchaser and overseen by the Monitoring Trustee, of an non-exclusive and transitory manufacturing or supply arrangement relating to the existing forms of product in the country of the Divestment Business, and/or reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of the relevant Divestiture Business, as detailed in the Schedules;

vii. an option for the Purchaser to hire one or more Personnel, who work for the relevant Divestment Business and who would reasonably be considered necessary to maintain the viability, marketability and competitiveness of that

Divestment Business, to be supervised by the Monitoring Trustee. This option is to be exercised within a period of one year after signing the Transfer Agreement.

(473) In addition the undertakings concerned have entered into related commitments, *inter alia* regarding the separation of the divested businesses from their retained businesses, the preservation of the viability, marketability and competitiveness of the divested businesses, including the appointment of a monitoring trustee and, if necessary, a divestiture trustee.

(474) The Commitments also include specific Purchaser requirements in particular the need for the Purchaser(s) to have an existing footprint in the sale of generics in the relevant country.

VI. ASSESSMENT OF THE PROPOSED COMMITMENTS

(475) The Commission analysed the suitability of the Commitments to remedy serious doubts in this case against the standard set out in the Commission Notice on Remedies.[75]

VI.1. Framework for the Commission's assessment of the Commitments

(476) Where a notified concentration raises serious doubts as to its compatibility with the internal market, the parties may modify the notified concentration so as to remove the grounds for the serious doubts identified by the Commission with a view to having it declared compatible with the internal market pursuant to Article 6(1)(b) in conjunction with Article 6(2) of the Merger Regulation.

(477) As set out in the Commission Notice on Remedies, commitments have to eliminate the Commission's serious doubts entirely, they have to be comprehensive and effective from all points of view and they must be capable of being implemented effectively within a short period of time, as the conditions of competition on the market will not be maintained until the commitments have been fulfilled.[76]

(478) In assessing whether or not commitments will restore effective competition, the Commission considers their type, scale and scope by reference to the structure and the particular characteristics of the market in which the Commission has identified serious doubts as to the compatibility of the notified concentration with the internal market.[77]

(479) Divestiture commitments are the best way to eliminate serious doubts resulting from horizontal overlaps of the merging parties' activities.[78] Other commitments (such as licensing) may be suitable to resolve serious doubts if those commitments are equivalent to divestitures in their effects. The divested activities must consist of a

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75 Commission Notice on remedies acceptable under Council Regulation (EC) No 139/2004 and under Commission Regulation (EC) No 802/2004 (2008/C 267/01), (the "Commission Notice on Remedies").

76 Commission Notice on Remedies, paragraph 9.

77 Commission Notice on Remedies, paragraph 12.

78 Commission Notice on Remedies, paragraph 17.

viable business that, if operated by a suitable purchaser, can compete effectively with the merged entity on a lasting basis and that is divested as a going concern.[79]

(480) The business to be divested must include all the assets which contribute to its current operation or which are necessary to ensure its viability and competitiveness and all personnel which are currently employed or which are necessary to ensure the business' viability and competitiveness. Personnel and assets which are currently shared between the business to be divested and other businesses of the parties, but which contribute to the operation of the business or which are necessary to ensure its viability and competitiveness, must also be included.[80] Otherwise, the viability and competitiveness of the business to be divested would be endangered.

(481) Furthermore, the intended effect of the divestiture will only be achieved if and once the business is transferred to a suitable purchaser with proven relevant expertise and ability to maintain and develop the business to be divested as a viable and active competitive undertaking. This may imply some specific purchaser requirements are included in the commitments to ensure that the transferred business remains viable.

(482) Even though normally the divestiture of an existing viable stand-alone business is required, the Commission, taking into account the principle of proportionality, may also consider the divestiture of businesses which have existing strong links or are partially integrated with businesses retained by the parties and therefore need to be 'carved out' in those respects.[81] Commitments including a carve-out of a business can only be accepted by the Commission if it can be certain that, at least at the time when the business is transferred to the purchaser, a viable business on a stand-alone basis will be divested and the risks for the viability and competitiveness caused by the carve-out will thereby be reduced to a minimum.[82]

Suitability for removing serious doubts

(483) In order to assess the suitability of the Commitments to remove serious doubts in this case, the Commission launched a market test on 9 January 2015. The market test of the Commitments, which was addressed to competitors, customers and wholesalers, distributors and German Health Funds, was generally positive and confirmed that the Commitments are suitable to eliminate the competition concerns identified by the Commission. In particular, the majority of respondents considered that, subject to them being divested to suitable Purchasers, the Divestment Businesses include all the necessary assets to successfully market the specific molecules in the markets where the Commission identified competition concerns and to subsequently compete effectively with the merged entity on these markets.

(484) Specifically, the Commitments consist of businesses evolving around marketing authorisations issued by national health authorities and providing the access to the national pharmaceutical products' markets where competition concerns were

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79 Commission Notice on Remedies, paragraph 23.

80 The need for some of these assets may in some cases also depend on the nature of the Purchaser and therefore is assessed on a case-by-case basis.

81 Commission Notice on Remedies, paragraph 35.

82 Commission Notice on Remedies, paragraph 36.

identified. Given the economies of scale associated with the sale of generic products, companies are typically active in several countries. Therefore, the market test indicated that to preserve the attractiveness of the Divestment Businesses the use of information contained in the divested marketing authorisations should not be limited. The revised Commitments of 21 January 2015 do not include any limitation with regard to the scope of the use of the marketing authorisations to be divested.

(485) Since it is a common practice in the pharmaceutical sector to cooperate with third-party producers of API or FDP, the market test confirmed that it is necessary to ensure that the Purchasers have access to all third parties, such as contract manufacturers, in the same way as Mylan has had. This also holds true for all customer contracts and any other customer related information. To that end, the Commitments package includes the transfer of all such contracts and in the absence of such, a commitment of Mylan's best efforts for the transfer of the relationship.

(486) In addition, to ensure that the divested products will be swiftly marketed by the Purchaser(s) and to the extent required by the latter, the Commitments include an option to hire some of Mylan's personnel as needed.

VI.2. Purchaser criteria

(487) Besides the standard criteria for a suitable purchaser contained in section D of the Commitments, the results of the market test indicated the need for a suitable Purchaser to be an established player in the business of marketing generic pharmaceutical products.

(488) This is because, according to the market test, companies marketing generic pharmaceutical products tend to compete using their entire portfolio rather than on a single product basis. In addition, there are economies of scale associated with the entire generic supply chain. Therefore, for the divestment businesses to remain viable there is a need for the Purchaser to have the ability to swiftly include the acquired business into its own product portfolio which should have a sufficient breadth to appeal to pharmacy and wholesale customers. It follows that for the Purchaser to be able to establish a competitive position in the problematic markets, it should therefore be a company which markets a broad product portfolio, such as Mylan's.

(489) In addition, the respondents to the market test confirmed that a suitable Purchaser needs to have an existing and strong distribution and sales footprint in the affected markets in order to guarantee a successful and prompt commercialisation of the divested products.

VI.3. Interest in the Commitments

(490) The market test revealed an interest of a sufficient number of potentially suitable Purchasers as a result of what it can be concluded that the Commitments are likely to be implemented in practice.

VI.4. Conclusion on the Commitments

(491) On the basis of the above the Commission concludes that the Divestment Businesses are viable businesses and the modalities foreseen for their transfer will enable their operation by the corresponding Purchaser(s) in a competitive and viable manner.

(492) The Commitments will permit to address the competition concerns identified in the present decision as they remove the overlap between Mylan and Abbott APD-DM in problematic markets and provide grounds for a new player to emerge.

(493) In particular, the Commitments are suitable and sufficient to remedy the serious doubts raised by the transaction in relation to the five markets where serious doubts were identified, namely

i. Mebeverine in Germany,

ii. Mebeverine in the UK,

iii. Delorazepam in Italy,

iv. Betahistine in Ireland and

v. Pygeum africanum in France.

(494) Moreover, the Commitments are comprehensive and effective from all points of view, and are capable of being implemented effectively within a short period of time.

(495) The Commission therefore considers that the Commitments, as submitted including the adaptations made following the results of the market test, are sufficient to eliminate all serious doubts as to the compatibility of the transaction with the internal market and the EEA Agreement.

VII. CONDITIONS AND OBLIGATIONS

(496) Pursuant to the first sentence of the second subparagraph of Article 6(2) of the Merger Regulation, the Commission may attach to its decision conditions and obligations intended to ensure that the undertakings concerned comply with the commitments they have entered into vis-à-vis the Commission with a view to rendering the concentration compatible with the internal market.

(497) The achievement of the measure that gives rise to the structural change of the market is a condition, whereas the implementing steps which are necessary to achieve this result are generally obligations on the parties. Where a condition is not fulfilled, the Commission's decision declaring the concentration compatible with the internal market and the EEA Agreement no longer stands. Where the undertakings concerned commit a breach of an obligation, the Commission may revoke the clearance decision in accordance with Article 8(6)(b) of the Merger Regulation. The undertakings concerned may also be subject to fines and periodic penalty payments under Articles 14(2) and 15(1) of the Merger Regulation.

(498) In accordance with the basic distinction between conditions and obligations, the decision in this case is conditional on full compliance with the requirements set out in Section B of the final Commitments, which constitute conditions. The remaining requirements set out in the other Sections of the said Commitments are considered to constitute obligations.

(499) The full text of the final Commitments is annexed to this Decision as Annex I and forms an integral part thereof.

VIII. CONCLUSION

(500) For the above reasons, the Commission has decided not to oppose the notified operation as modified by the Commitments and to declare it compatible with the internal market and with the functioning of the EEA Agreement, subject to full compliance with the conditions in sections B and C of the Commitments annexed to the present decision and with the obligations contained in the other sections of the said commitments. This decision is adopted in application of Article 6(1)(b) in conjunction with Article 6(2) of the Merger Regulation and Article 57 of the EEA Agreement.

For the Commission
(Signed)
Margrethe VESTAGER
Member of the Commission

COMMITMENTS TO THE EUROPEAN COMMISSION

Pursuant to Article 6(2) of Council Regulation (EC) No 139/2004 (the "**Merger Regulation**"), New Moon B.V. ("**Mylan**") hereby enters into the following Commitments (the "**Commitments**") vis-à-vis the European Commission (the "**Commission**") with a view to rendering the acquisition of sole control by Mylan over Abbott EPD-DM (the "**Concentration**") compatible with the internal market and the functioning of the EEA Agreement.

This text shall be interpreted in light of the Commission's decision pursuant to Article 6(1)(b) of the Merger Regulation to declare the Concentration compatible with the internal market and the functioning of the EEA Agreement (the "**Decision**"), in the general framework of European Union law, in particular in light of the Merger Regulation, and by reference to the Commission Notice on remedies acceptable under Council Regulation (EC) No 139/2004 and under Commission Regulation (EC) No 802/2004 (the "**Remedies Notice**").

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Section A. Definitions

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

Abbott EPD-DM: Abbott Laboratories' Non-U.S. Developed Markets Speciality and Branded Generics Business.

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 light of the Commission Consolidated Jurisdictional Notice under Council Regulation (EC) No 139/2004 on the control of concentrations between undertakings (the "***Consolidated Jurisdictional Notice***").

Assets: the assets that contribute to the current operation or are necessary to ensure the viability and competitiveness of the Divestment Business as indicated in Section B and described more in detail in the Schedule.

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

Closing Period: the period of [*] from the approval of the Purchaser and the terms of sale by the Commission

Confidential Information: any business secrets, know-how, commercial information, or any other information of a proprietary nature that is not in the public domain.

Conflict of Interest: any conflict of interest that impairs the Trustee's objectivity and independence in discharging its duties under the Commitments.

Divestiture Trustee: one or more natural or legal person(s) who is/are approved by the Commission and appointed by Mylan and who has/have received from Mylan the exclusive Trustee Mandate to sell the Divestment Business to a Purchaser at no minimum price.

Divestment Business: the businesses as defined in Section B and in the Schedules which Mylan commits to divest.

Effective Date: the date of adoption of the Commission Decision declaring the acquisition of sole control by Mylan over Abbott EPD-DM compatible with the internal market and the functioning of the EEA Agreement.

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

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

Monitoring Trustee: one or more natural or legal person(s) who is/are approved by the Commission and appointed by Mylan, and who has/have the duty to monitor Mylan's compliance with the conditions and obligations attached to the Decision.

Mylan: New Moon B.V. a private limited liability company organized and existing under the laws of the Netherlands, with its corporate seat in Amsterdam, the Netherlands and registered at the Dutch chamber of commerce (*Kamer van Koophandel*) under number 61036137. After the closing of the acquisition of Abbott EPD-DM, New Moon B.V. will be converted to Mylan N.V. a limited liability company organized and existing under the law of the Netherlands, with its corporate seat in Amsterdam.

Parties: Mylan and Abbott EPD-DM.

Personnel: all staff currently employed by the legal entity or entities of which the Divestment Businesses form part.

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

Purchaser Criteria: the criteria laid down in paragraph 16 of these Commitments that the Purchaser must fulfil in order to be approved by the Commission.

Schedule: the schedule to these Commitments describing more in detail the Divestment Business.

Transfer Agreement: the agreement by virtue of which the Divestment Business is transferred to the Purchaser.

Trustee(s): the Monitoring Trustee and/or the Divestiture Trustee as the case may be.

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

SECTION B. THE COMMITMENT TO DIVEST AND THE DIVESTMENT BUSINESS

Commitment to divest

2. In order to maintain effective competition, Mylan commits to divest, or procure the divestiture of the Divestment Businesses by the end of the Trustee Divestiture Period to a purchaser and on terms of sale approved by the Commission in accordance with the procedure described in paragraph 17 of these Commitments. To carry out the divestiture, Mylan commits to find a purchaser and to enter into a final binding sale and purchase agreement for the sale of the Divestment Business within the First Divestiture Period. If Mylan has not entered into such an agreement at the end of the First Divestiture Period, Mylan shall grant the Divestiture Trustee an exclusive mandate to sell the Divestment Business in accordance with the procedure described in paragraph 29 in the Trustee Divestiture Period.

3. Mylan shall be deemed to have complied with this commitment if:

   (a) by the end of the Trustee Divestiture Period, Mylan or the Divestiture Trustee has entered into a final binding sale and purchase agreement and the Commission approves the proposed purchaser and the terms of sale as being consistent with the Commitments in accordance with the procedure described in paragraph 17; and

   (b) the Closing of the sale of the Divestment Businesses to the Purchaser takes place within the Closing Period.

4. In order to maintain the structural effect of the Commitments, Mylan shall, for a period of 10 years after Closing, not acquire, whether directly or indirectly, the possibility of exercising influence (as defined in paragraph 43 of the Remedies Notice, footnote 3) over the whole or part of the Divestment Business, unless, following the submission of a reasoned request from Mylan showing good cause and accompanied by a report from the Monitoring Trustee (as provided in paragraph 43 of these Commitments), the Commission finds that the structure of the market has changed to such an extent that the absence of influence over the Divestment Business is no longer necessary to render the proposed concentration compatible with the internal market.

Structure and definition of the Divestment Business

5. The Divestment Business consists of

   i. Mylan's mebeverine business in Germany;

   ii. Mylan's mebeverine business in the United Kingdom;

   iii. Mylan's pygeum africanum business in France;

   iv. Mylan's betahistine business in Ireland; and

   v. Mylan's delorazepam business in Italy.

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

   (a) all tangible and intangible assets (including intellectual property rights, which contribute to the current operation and are necessary to ensure the viability, marketability and competitiveness of the Divestment Business);

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

(c) all contracts, commitments and customer orders of the Divestment Business; all customer, credit and other records of the Divestment Business;

(d) all advertising, marketing, sales, publicity and presentational materials related to the Divestment Business, as applicable (items referred to under (a)-(d) hereinafter collectively referred to as "**Assets**");

(e) if such contract exists, a best efforts obligation
(f) [1] to obtain the assignment of the contract manufacturing arrangement entered into by Mylan and/or the active pharmaceutical ingredient ("**API**") supply arrangement entered into by Mylan;

(g) the benefit for a period of up to 2 years after Closing, on a reasonable cost-plus basis to be agreed with the Purchaser and overseen by the Monitoring Trustee in accordance with paragraph 27(iii), of an non-exclusive and transitory manufacturing or supply arrangement relating to the existing forms of product in the Member State of the Divestment Business, and/or reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of the relevant Divestiture Business, as detailed in the Schedules;

(h) in relation to the Divestment Businesses set out in the Schedules, subject to applicable local employment legislation, an option for the Purchaser to hire one or more Personnel, who work for the relevant Divestment Business and who would reasonably be considered necessary to maintain the viability, marketability and competitiveness of that Divestment Business to be supervised by the Monitoring Trustee. This option is to be exercised within a period of one year after signing the Transfer Agreement.

7. The Divestment Business is structured as an asset carve-out; no legal entity of Mylan is to be divested.

SECTION C. RELATED COMMITMENTS

Preservation of viability, marketability and competitiveness

8. From the Effective Date until Closing, Mylan shall preserve or procure the preservation of the economic viability, marketability and competitiveness of the Divestment Business, in accordance with good business practice, and shall minimise as far as possible any risk of loss of competitive potential of the Divestment Business. In particular the Parties undertake:

(a) not to carry out any action that might have a significant adverse impact on the value, management or competitiveness of the Divestment Business or that might alter the nature and scope of activity, or the industrial or commercial strategy or the investment policy of the Divestment Business;

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[1] Best efforts obligations in this context are in line with the Commission's practice in the context of pharmaceutical mergers. See, for example, the remedies accepted in case M.5253 (Sanofi-Aventis/Zentiva).

(b) to make available, or procure to make available, sufficient resources for the development of the Divestment Business, on the basis and continuation of the existing business plans.

Hold-separate obligations

9. Mylan commits, from the Effective Date until Closing, to the extent reasonably practical, to keep the Divestment Businesses separate from the EPD-DM business covering the same molecules as will be transferred to Mylan after the Effective Date. Mylan also commits to ensure that the Personnel of the Divestment Businesses – including the Hold Separate Manager – will have no involvement in the EPD-DM business covering the same molecules as will be transferred to Mylan after the Effective Date and vice versa, to the extent reasonably practical without compromising the viability of Divestment Businesses or the businesses retained by the Parties.

10. Until closing, Mylan shall assist the Monitoring Trustee in ensuring that the Divestment Business is managed separately from the EPD-DM business covering the same molecules as will be transferred to Mylan after the Effective Date. Immediately after the adoption of the Decision, Mylan shall appoint a Hold Separate Manager. The Hold Separate Manager shall manage the Divestment Business independently from the EPD-DM business covering the same molecules as will be transferred to Mylan after the Effective Date and in the best interest of the business with a view to ensuring its continued economic viability, marketability and competitiveness. The Hold Separate Manager shall closely cooperate with and report to the Monitoring Trustee and, if applicable, the Divestiture Trustee. In case of any replacement of the Hold Separate Manager, Mylan shall provide a reasoned proposal to replace the person or persons concerned to the Commission and the Monitoring Trustee. Mylan must be able to demonstrate to the Commission that the replacement is well suited to carry out the functions exercised by the Hold Separate Manager. The replacement shall take place under the supervision of the Monitoring Trustee, who shall report to the Commission. The Commission may, after having heard Mylan, require Mylan to replace the Hold Separate Manager.

Ring-fencing

11. Mylan shall implement, or procure to implement, all necessary measures to ensure that its personnel that manages the Divestment Businesses shall not, after the Effective Date and Until Closing, obtain any Confidential Information relating to the EPD-DM business covering the same molecules as will be transferred to Mylan after the Effective Date, and vice versa.

Non-solicitation clause

12. In the instance that the Purchaser exercises the option as described in paragraph 6(g), Mylan undertakes, subject to customary limitations, not to solicit, and to procure that Affiliated Undertakings do not solicit Personnel hired by (as opposed to seconded to) the Purchaser for a period of 24 months after Closing.

Due diligence

13. In order to enable potential purchasers to carry out a reasonable due diligence of the Divestment Businesses, Mylan shall, subject to customary confidentiality assurances and dependent on the stage of the divestiture process:
    (a) provide to potential purchasers sufficient information as regards the Divestment Business;
    (b) provide to potential purchasers sufficient information relating to the Personnel.

Reporting

14. Mylan shall submit written reports in English on potential purchasers of the Divestment Business 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). Mylan shall submit a list of all potential purchasers having expressed interest in acquiring the Divestment Business to the Commission at each and every stage of the divestiture process, as well as a copy of all the offers made by potential purchasers within five days of their receipt.

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

SECTION D. THE PURCHASER

16. In order to be approved by the Commission, the Purchaser must fulfil the following criteria:

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

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

    (c) The Purchaser shall have an existing marketing and distribution footprint in generics in the relevant countries in which the Divestment Business is currently active;

    (d) The acquisition of the Divestment Business by the Purchaser must neither be likely to create, in 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. In particular, the Purchaser must reasonably be expected to obtain all necessary approvals from the relevant regulatory authorities for the acquisition of the Divestment Business.

17. The final binding sale and purchase agreement (as well as ancillary agreements) relating to the divestment of the Divestment Business shall be conditional on the Commission's approval. When Mylan has reached an agreement with a purchaser, it shall submit a fully documented and reasoned proposal, including a copy of the final agreement(s), within one week to the Commission and the Monitoring Trustee. Mylan must be able to demonstrate to the Commission that the purchaser fulfils the Purchaser Criteria and that the Divestment Business is being sold in a manner consistent with the Commission's Decision and the Commitments. For the approval, the Commission shall verify that the purchaser fulfils the Purchaser Criteria and that the Divestment Business is being sold in a manner consistent with the Commitments including their objective to bring about a lasting structural change in the market. The Commission may approve the sale of the Divestment Business without one or more Assets, or by substituting one or more Assets with one or more different assets, if this does not affect the viability and competitiveness of the Divestment Business after the sale, taking account of the proposed purchaser.

SECTION E. TRUSTEE

I. Appointment procedure

18. Mylan shall appoint a Monitoring Trustee to carry out the functions specified in these Commitments for a Monitoring Trustee. Mylan commits not to close the Concentration before the appointment of a Monitoring Trustee.

19. If Mylan has not entered into a binding sale and purchase agreement regarding the Divestment Business one month before the end of the First Divestiture Period or if the Commission has rejected a purchaser proposed by Mylan at that time or thereafter, Mylan shall appoint a Divestiture Trustee. The appointment of the Divestiture Trustee shall take effect upon the commencement of the Trustee Divestiture Period.

20. The Trustee shall:

    (i) at the time of appointment, be independent of the Parties and their Affiliated Undertakings;

    (ii) possess the necessary qualifications to carry out its mandate, for example have sufficient relevant experience as an investment banker or consultant or auditor; and

    (iii) neither have nor become exposed to a Conflict of Interest.

21. The Trustee shall be remunerated by Mylan in a way that does not impede the independent and effective fulfilment of its mandate. In particular, where the remuneration package of a Divestiture Trustee includes a success premium linked to the final sale value of the Divestment Business, such success premium may only be earned if the divestiture takes place within the Trustee Divestiture Period.

Proposal by Mylan

22. No later than two weeks after the Effective Date, Mylan shall submit the names of three or more natural or legal persons whom Mylan 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 or on request by the Commission, Mylan shall submit a list of one or more persons whom Mylan proposes to appoint as Divestiture Trustee to the Commission for approval. The proposal shall contain sufficient information for the Commission to verify that the person or persons proposed as Trustee fulfil the requirements as set out above and shall include:

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

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

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

Approval or rejection by the Commission

23. The Commission shall have the discretion to approve or reject the proposed Trustee(s) and to approve the proposed mandate subject to any modifications it deems necessary for the Trustee to fulfil its obligations. If only one name is approved, Mylan shall appoint or cause to be appointed the person or persons concerned as Trustee, in accordance with the mandate approved by the Commission. If more than one name is approved, Mylan 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 Mylan

24. If all the proposed Trustees are rejected, Mylan shall submit the names of at least two more natural or legal persons within one week of being informed of the rejection, in accordance with paragraphs 18 and 23 of these Commitments.

Trustee nominated by the Commission

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

II. Functions of the Trustee

26. The Trustee shall assume its specified duties and obligations in order to ensure compliance with the Commitments. The Commission may, on its own initiative or at the request of the Trustee or Mylan, 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

27. 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, in close co-operation with the Hold Separate Manager, the on-going management of the Divestment Business with a view to ensuring its continued economic viability, marketability and competitiveness and monitor compliance by Mylan 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 Business, and the keeping separate of the Divestment Business from the EPD-DM business covering the same molecules as will be transferred to Mylan after the Effective Date, in accordance with paragraphs 9 and 10 of these Commitments;

(b) supervise the management of the Divestment Business, in accordance with paragraph 9 of these Commitments;

(c) with respect to Confidential Information:

– determine all necessary measures to ensure that Mylan does not after the Effective Date obtain any Confidential Information relating to the EPD-DM business covering the same molecules as will be transferred to Mylan after the Effective Date;
– in particular strive for the severing of the Divestment Business' participation in a central information technology network to the extent possible, without compromising the viability of the Divestment Business;
– make sure that any Confidential Information relating to the Divestment Business obtained by Mylan before the Effective Date is eliminated and will not be used by Mylan; and
– decide whether such information may be disclosed to or kept by Mylan as the disclosure is reasonably necessary to allow Mylan to carry out the divestiture or as the disclosure is required by law;

(d) monitor the splitting of assets between the Divestment Business and the Parties or Affiliated Undertakings;

(iii) oversee the determination of the reasonable cost-plus basis for the transitory manufacturing or supply arrangements that Mylan will offer to the Purchaser (see paragraph 6(f) above);

(iv) propose to Mylan such measures as the Monitoring Trustee considers necessary to ensure Mylan'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 Business, the holding separate of the Divestment Business from the EPD-DM business covering the same molecules as will be transferred to Mylan after the Effective Date 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 and correct information relating to the Divestment Business 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 sufficient access to the Personnel;

(vi) act as a contact point for any requests by third parties, in particular potential purchasers, in relation to the Commitments;

(vii) provide to the Commission, sending Mylan a non-confidential copy at the same time, a written report within 15 days after the end of every month that shall cover the operation and management of the Divestment Business as well as the splitting of assets and the allocation of Personnel so that the Commission can assess whether the business is held in a manner consistent with the Commitments and the progress of the divestiture process as well as potential purchasers;

(viii) promptly report in writing to the Commission, sending Mylan a non-confidential copy at the same time, if it concludes on reasonable grounds that Mylan is failing to comply with these Commitments;

(ix) within one week after receipt of the documented proposal referred to in paragraph 14 of these Commitments, submit to the Commission, sending Mylan a non-confidential copy at the same time, a reasoned opinion as to the suitability and independence of the proposed purchaser and the viability of the Divestment Business after the Sale and as to whether the Divestment Business is sold in a manner consistent with the conditions and obligations attached to the Decision, in particular, if relevant, whether the Sale of the Divestment Business without one or more Assets or not all of the Personnel affects the viability of the Divestment Business after the sale, taking account of the proposed purchaser;

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

28. If the Monitoring and Divestiture Trustee are not the same legal or natural persons, the Monitoring Trustee and the Divestiture Trustee shall cooperate closely with each other during and for the purpose of the preparation of the Trustee Divestiture Period in order to facilitate each other's tasks.

Duties and obligations of the Divestiture Trustee

29. Within the Trustee Divestiture Period, the Divestiture Trustee shall sell at no minimum price the Divestment Business to a purchaser, provided that the Commission has approved both the purchaser and the final binding sale and purchase agreement (and ancillary agreements) as in line with the Commission's Decision and the Commitments in accordance with paragraphs 14 and 15 of these Commitments. The Divestiture Trustee shall include in the sale and purchase agreement (as well as in any ancillary agreements) such terms and conditions as it considers appropriate for an expedient sale in the Trustee Divestiture Period. In particular, the Divestiture Trustee may include in the sale and purchase agreement such customary representations and warranties and indemnities as are reasonably required to effect the sale. The Divestiture Trustee shall protect the legitimate financial interests of Mylan, subject to the Parties' unconditional obligation to divest at no minimum price in the Trustee Divestiture Period.

30. 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 Mylan

31. Mylan shall provide and shall cause its advisors to provide the Trustee with all such co-operation, assistance and information as the Trustee may reasonably require to perform its tasks. The Trustee shall have full and complete access to any of Mylan's or the Divestment Business' books, records (including the information reasonably necessary for the Trustee's task as defined in paragraph 27(iii) above), documents, management or other personnel, facilities, sites and technical information necessary for fulfilling its duties under the Commitments and Mylan and the Divestment Business shall provide the Trustee upon request with copies of any document. Mylan and the Divestment Business 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.

32. Mylan shall provide the Monitoring Trustee with all managerial and administrative support that it may reasonably request on behalf of the management of the Divestment Business. This shall include all administrative support functions relating to the Divestment Business which are currently carried out at headquarters level. Mylan 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. Mylan shall inform the Monitoring Trustee on possible purchasers, submit lists of potential purchasers at each stage of the selection process, including the offers made by potential purchasers at those stages, and keep the Monitoring Trustee informed of all developments in the divestiture process.

33. Mylan shall grant or procure Affiliated Undertakings to grant comprehensive powers of attorney, duly executed, to the Divestiture Trustee to effect the sale (including ancillary agreements), 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, Mylan shall cause the documents required for effecting the sale and the Closing to be duly executed.

34. Mylan 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 Mylan for, any liabilities arising out of the performance of the Trustee's duties under the Commitments, except to the extent that such liabilities result from the wilful default, recklessness, gross negligence or bad faith of the Trustee, its employees, agents or advisors.

35. At the expense of Mylan, the Trustee may appoint advisors (in particular for corporate finance or legal advice, the determination of the cost plus of supply agreements or any other expert in the pharmaceutical industry reasonably necessary for the implementation of the Commitments), subject to Mylan'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 Mylan refuse to approve the advisors proposed by the Trustee the Commission may approve the appointment of such advisors instead, after having heard Mylan. Only the Trustee shall be entitled to issue instructions to the advisors. Paragraph 32 of these Commitments shall apply *mutatis mutandis*. In the Trustee Divestiture Period, the Divestiture Trustee may use advisors who served Mylan during the Divestiture Period if the Divestiture Trustee considers this in the best interest of an expedient sale.

36. Mylan agrees that the Commission may share Confidential Information proprietary to Mylan with the Trustee. The Trustee shall not disclose such information and the principles contained in Article 17 (1) and (2) of the Merger Regulation apply *mutatis mutandis*.

37. Mylan agrees that the contact details of the Monitoring Trustee are published on the website of the Commission's Directorate-General for Competition and they shall inform interested third parties, in particular any potential purchasers, of the identity and the tasks of the Monitoring Trustee.

38. For a period of 10 years from the Effective Date the Commission may request all information
from the Parties that is reasonably necessary to monitor the effective implementation of these Commitments.

IV. Replacement, discharge and reappointment of the Trustee

39. 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 and Mylan, require Mylan to replace the Trustee; or

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

40. If the Trustee is removed according to paragraph 39 of these Commitments, 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 18-25 of these Commitments.

41. Unless removed according to paragraph 39 of these Commitments, 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

42. The Commission may extend the time periods foreseen in the Commitments in response to a request from Mylan or, in appropriate cases, on its own initiative. Where Mylan requests an extension of a time period, it shall submit a reasoned request to the Commission no later than one month before the expiry of that period, showing good cause. This request shall be accompanied by a report from the Monitoring Trustee, who shall, at the same time send a non-confidential copy of the report to the Notifying Party. Only in exceptional circumstances shall Mylan be entitled to request an extension within the last month of any period.

43. The Commission may further, in response to a reasoned request from the Parties showing good cause waive, modify or substitute, in exceptional circumstances, one or more of the undertakings in these Commitments. This request shall be accompanied by a report from the Monitoring Trustee, who shall, at the same time send a non-confidential copy of the report to Mylan. The request shall not have the effect of suspending the application of the undertaking and, in particular, of suspending the expiry of any time period in which the undertaking has to be complied with.

SECTION G. ENTRY INTO FORCE

44. The Commitments shall take effect upon the date of adoption of the Decision.

[Signed]

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duly authorised for and on behalf of Mylan

SCHEDULE I

Product: Mylan's mebeverine products
Territory: Germany

1. The Divestment Business consists of Mylan's rights, title and interests in mebeverine in Germany (currently marketed under the name Mebeverine Dura) including the right to develop, manufacture and use mebeverine with a view to its sale and marketing in any form and for any indication whatsoever in Germany. Mebeverine is used for the treatment of irritable bowel syndrome and related symptoms. For the avoidance of doubt, this Divestment Business does not include any rights to sell mebeverine outside of Germany.

2. The Divestment Business includes:

(a) the sale of existing mebeverine product inventory, sales and promotional material in Germany, as far as available;

(b) all mebeverine-related contracts, commitments and customer records meaning customers credit records, customer invoices, purchase orders and contact details, whilst only the information related to mebeverine specifically will be provided;[2]

(c) the transfer of the marketing authorisation for mebeverine in Germany including all relevant dossiers, as well as the information contained in the relevant full registration dossier(s), relating to the current and/or pending marketing authorisations available to Mylan; and

(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 Germany, including in particular the information contained in the registration dossier.

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

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

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2 Mylan will include all customer lists and records since 2010 in the Divestment Business.

4. At the option of the Purchaser, Mylan shall enter into a transitory non-exclusive manufacturing and/or supply agreement relating to the existing forms of product in Germany for up to two years. Such transitory arrangement shall include appropriate provisions designed to ensure the continued supply by Mylan to the Purchaser. It shall not contain provisions requiring the delivery of minimum supply volumes or batches.

5. Mylan commits to make its best efforts to facilitate the assignment of the relevant health fund contracts to the Purchaser in as far as the contracts concern mebeverine.

6. At the option of the Purchaser, and to the extent required by law in Germany or necessary with a view to assigning or transferring the relevant contracts with the German health funds pertaining to mebeverine to the Purchaser, Mylan will enter into a transitional distribution arrangement related to the Divestment Business lasting until the relevant marketing authorisation is transferred into the name of the Purchaser on a reasonable cost-plus basis which determination is overseen by the Monitoring Trustee. Mylan commits to make its best efforts to ensure that no supply disruption will occur or any other supply issue that might lead to the termination of the contract with the relevant German health funds.

7. If Mylan were to win any tenders pertaining to mebeverine before Closing, Mylan commits to make its best efforts to facilitate the assignment of the relationship or the contract as the case may be with the relevant German health funds to the Purchaser in line with the provisions contained in this Schedule concerning existing contracts with the relevant German health funds.

8. Mylan will transfer all historical information (orders; price; etc.) concerning its relationship regarding mebeverine in Germany with API supplier [*] to the Purchaser in accordance with applicable law. Mylan commits to make its best efforts to ensure that the Purchaser can continue the existing relationship with [*] with respect to Germany.

9. Mylan commits to make its best efforts to cooperate with the Purchaser to effectuate the transfer of the Divestment Business and to undertake all regulatory changes that would be required as a result of such transfer.

10. At the option of the Purchaser, Mylan shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of mebeverine in Germany for a period of up to two years to be agreed with the Purchaser and which determination is overseen by the Monitoring Trustee. The transitional technical assistance agreement shall include appropriate provisions to ensure that Mylan provides technical assistance to the Purchaser expeditiously.

11. The Purchaser will be given an option (to be exercised within one year after signing the relevant Transfer Agreement) to hire one or more Personnel, subject to applicable local employment legislation, who would reasonably be considered necessary to maintain the viability, marketability and competitiveness of this Divestment Business to be supervised by the Monitoring Trustee.

12. 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 mebeverine after Closing;
d. All marketing authorizations currently held by the Parties outside of Germany for mebeverine;
e. The right to use the information contained in the registration dossiers underlying the marketing authorization(s) that are transferred as part of the Divestment Business to obtain marketing authorizations outside of Germany;
f. The "Mylan" name or the name of any Mylan subsidiaries;
g. Monies owed to the Parties by customers for the purchase of mebeverine, and monies owed by the Parties to suppliers for materials used in the production of mebeverine.

13. If there is any asset or personnel which is not be covered by paragraph 2 of this Schedule but which is both used (exclusively or not) in the Divestment Business and
necessary for the continued viability and competitiveness of the Divestment Business,
that asset or adequate substitute will be offered to the Purchaser.

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SCHEDULE II

Product: Mylan's mebeverine products
Territory: United Kingdom (UK)

1. The Divestment Business consists of Mylan's rights, title and interests in mebeverine in the UK (currently marketed under the name Mebeverine) including the right to develop, manufacture and use mebeverine with a view to its sale and marketing in any form and for any indication whatsoever in the UK. Mebeverine is used for the treatment of irritable bowel syndrome and related symptoms. For the avoidance of doubt, this Divestment Business does not include any rights to sell mebeverine outside of the UK.

2. The Divestment Business includes:

(a) the sale of existing mebeverine product inventory, sales and promotional material in the UK, as far as available;

(b) all mebeverine-related contracts, commitments and customer records meaning customers credit records, customer invoices, purchase orders and contact details, whilst only the information related to mebeverine specifically will be provided;[3]

(c) the transfer of the marketing authorisation for mebeverine in the UK including all relevant dossiers, as well as the information contained in the relevant full registration dossier(s), relating to the current and/or pending marketing authorisations available to Mylan; and

(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 UK, including in particular the information contained in the registration dossier.

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

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

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[3] Mylan will include all customer lists and records since 2010 in the Divestment Business.

4. At the option of the Purchaser, Mylan shall enter into a transitory non-exclusive manufacturing and/or supply agreement relating to the existing forms of product in the UK for up to two years. Such transitory arrangement shall include appropriate provisions designed to ensure the continued supply by Mylan to the Purchaser. It shall not contain provisions requiring the delivery of minimum supply volumes or batches.

5. At the option of the Purchaser and to the extent required by law in the UK, Mylan will enter into a transitional distribution arrangement related to the Divestment Business lasting until the relevant marketing authorisation is transferred into the name of the Purchaser on a reasonable cost-plus basis which determination is overseen by the Monitoring Trustee.

6. Mylan will transfer all historical information (orders; price; etc.) concerning its relationship regarding mebeverine in the UK with API supplier [*] to the Purchaser in accordance with applicable law. Mylan commits to make its best efforts to ensure that the Purchaser can continue the existing relationship with [*] with respect to mebeverine.

7. Mylan commits to make its best efforts to cooperate with the Purchaser to effectuate the transfer of the Divestment Business and to undertake all regulatory changes that would be required as a result of such transfer.

8. Mylan commits to make its best efforts to obtain the licensor's consent to assign to the Purchaser the full contract in relation to its right concerning [*]. In addition, Mylan will provide the Purchaser with all the relevant information concerning the steps taken by Mylan to obtain the aforementioned contract.

9. At the option of the Purchaser, Mylan shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of mebeverine in the UK for a period of up to two years to be agreed with the Purchaser and which determination is overseen by the Monitoring Trustee. The transitional technical assistance agreement shall include appropriate provisions to ensure that Mylan provides technical assistance to the Purchaser expeditiously.

10. The Purchaser will be given an option (to be exercised within one year after signing the relevant Transfer Agreement) to hire one or more Personnel, subject to applicable local employment legislation, who would reasonably be considered necessary to maintain the viability, marketability and competitiveness of this Divestment Business to be supervised by the Monitoring Trustee.

11. 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 mebeverine after Closing;
d. All marketing authorizations currently held by the Parties outside of the UK for mebeverine;
e. The right to use the information contained in the registration dossiers underlying the marketing authorization(s) that are transferred as part of the Divestment Business to obtain marketing authorizations outside of the UK;
f. The "Mylan" name or the name of any Mylan subsidiaries;
g. Monies owed to the Parties by customers for the purchase of mebeverine, and monies owed by the Parties to suppliers for materials used in the production of mebeverine.

12. If there is any asset or personnel which is not be covered by paragraph 2 of this Schedule but which is both used (exclusively or not) in the Divestment Business and
necessary for the continued viability and competitiveness of the Divestment Business,
that asset or adequate substitute will be offered to the Purchaser.

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SCHEDULE III

Product: Mylan's pygeum africanum products
Territory: France

1. The Divestment Business consists of Mylan's rights, title and interests in pygeum africanum in France (currently marketed under the name Prunier d'Afrique Mylan) including the right to develop, manufacture and use pygeum africanum with a view to its sale and marketing in any form and for any indication whatsoever in France. Pygeum africanum is used for the treatment benign prostatic hypertrophy. For the avoidance of doubt, this Divestment Business does not include any rights to sell pygeum africanum outside of France.

2. The Divestment Business includes:

   (a) the sale of existing pygeum africanum product inventory, sales and promotional material in France;

   (b) all pygeum africanum-related contracts, commitments and customer records meaning customers credit records, customer invoices, purchase orders and contact details, whilst only the information related to pygeum africanum specifically will be provided;[4]

   (c) the transfer of the marketing authorisation for pygeum africanum in France including all relevant dossiers, as well as the information contained in the relevant full registration dossier(s), relating to the current and/or pending marketing authorisations available to Mylan; and

   (d) an irrevocable, assignable, sub-licensable, and royalty free licence 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 pygeum africanum with a view to its sale in France; including in particular the information contained in the registration dossier.
   (items referred to under (a)-(d) hereinafter collectively referred to as "**Assets of the Divestment Business**")

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

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4 Mylan will include all customer lists and records since 2010 in the Divestment Business.

4. At the option of the Purchaser and to the extent required by law in France Mylan will enter into a transitional distribution arrangement related to pygeum africanum lasting until the relevant marketing authorisation is transferred into the name of the Purchaser on a reasonable cost-plus basis which determination is overseen by the Monitoring Trustee.

5. Mylan will transfer all historical information (orders; price; etc.) concerning its relationship on pygeum africanum in France with API supplier [*] to the Purchaser in accordance with applicable law. Mylan commits to make its best efforts to ensure that the Purchaser can continue the existing relationship with [*] with respect to pygeum africanum.

6. If such contract would be concluded before the transfer of the Divestment Business and at the option of the Purchaser, Mylan commits to make its best efforts to facilitate the assignment of the contract manufacturing agreement (with [*]) concerning pygeum africanum in France to the Purchaser. Any negotiations related to said agreement after the Closing will be conducted by the hold-separate manager.

7. If the contract manufacturing agreement with [*] has not been concluded before the transfer of the Divestment Business and at the option of the Purchaser, Mylan commits to provide the Purchaser with documents concerning the negotiation history (such as draft agreements and offers, etc).

8. Mylan commits to make its best efforts to cooperate with the Purchaser to effectuate the transfer of the Divestment Business and to undertake all regulatory changes that would be required as a result of such transfer.

9. The Purchaser will be given an option (to be exercised within one year after signing the relevant Transfer Agreement) to hire one or more Personnel, subject to applicable local employment legislation, who would reasonably be considered necessary to maintain the viability, marketability and competitiveness of this Divestment Business to be supervised by the Monitoring Trustee.

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 pygeum africanum after Closing;
    d. All marketing authorizations currently held by the Parties outside of France for pygeum africanum;
    e. The right to use the information contained in the registration dossiers underlying the marketing authorization(s) that are transferred as part of the Divestment Business to obtain marketing authorizations outside of France;

f. The "Mylan" name or the name of any Mylan subsidiaries;
g. Monies owed to the Parties by customers for the purchase of pygeum africanum, and monies owed by the Parties to suppliers for materials used in the production of pygeum africanum.

11. If there is any asset or personnel which is not be covered by paragraph 2 of this Schedule but which is both used (exclusively or not) in the Divestment Business and
necessary for the continued viability and competitiveness of the Divestment Business,
that asset or adequate substitute will be offered to the Purchaser.

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SCHEDULE IV

Product: Mylan's betahistine products
Territory: Ireland

1. The Divestment Business consists of Mylan's rights, title and interests in betahistine in Ireland (currently marketed under the brand Vertigon) including the right to develop, manufacture and use betahistine with a view to its sale and marketing in any form and for any indication whatsoever in Ireland. Betahistine is used for the treatment of vertigo and Meniere's disease. For the avoidance of doubt, this Divestment Business does not include any rights to sell betahistine outside of Ireland.

2. The Divestment Business includes:

   (a) the sale of existing betahistine product inventory, sales and promotional material in Ireland;

   (b) all betahistine-related contracts, commitments and customer records meaning customers credit records, customer invoices, purchase orders and contact details, whilst only the information related to betahistine specifically will be provided;[5]

   (c) the transfer of the marketing authorisation for betahistine in Ireland including all relevant dossiers, as well as the information contained in the relevant full registration dossier(s), relating to the current and/or pending marketing authorisations available to Mylan; and

   (d) an irrevocable, assignable, sub-licensable, and royalty free license for all relevant intellectual property rights (including the "Vertigon" brand), 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 Ireland; including in particular the information contained in the registration dossier.
   (items referred to under (a)-(d) hereinafter collectively referred to as "**Assets of the Divestment Business**").

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

4. Mylan commits not to register the Vertigon brand nor to oppose the future registration of the Vertigon brand name by the Purchaser.

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5 Mylan will include all customer lists and records since 2010 in the Divestment Business.

5. At the option of the Purchaser, Mylan shall enter into a transitory non-exclusive manufacturing and/or supply agreement relating to the existing forms of product in Ireland for up to two years. Such transitory arrangement shall include appropriate provisions designed to ensure the continued supply by the Parties to the Purchaser. It shall not contain provisions requiring the delivery of minimum supply volumes or batches.

6. At the option of the Purchaser and to the extent required by law in Ireland, Mylan will enter into a transitional distribution arrangement related to the Divestment Business lasting until the relevant marketing authorisation is transferred into the name of the Purchaser on a reasonable cost-plus basis which determination is overseen by the Monitoring Trustee

7. If such contract would be concluded before the transfer of the Divestment Business and at the option of the Purchaser, Mylan commits to make its best efforts to facilitate the assignment of the API supply agreement (with [*]) concerning betahistine in Ireland to the Purchaser. Any negotiations related to said agreements after the Closing will be conducted by the hold-separate manager.

8. If the API supply agreement with [*] concerning betahistine has not been concluded before the transfer of the Divestment Business and at the option of the Purchaser, Mylan commits to provide the Purchaser with documents concerning the negotiation history such as draft agreements and offers.

9. Mylan commits to make its best efforts to cooperate with the Purchaser to effectuate the transfer of the Divestment Business and to undertake all regulatory changes that would be required as a result of such transfer.

10. At the option of the Purchaser, Mylan shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of betahistine in Ireland for a period of up to two years to be agreed with the Purchaser and which determination is overseen by the Monitoring Trustee. The transitional technical assistance agreement shall include appropriate provisions to ensure that Mylan provides technical assistance to the Purchaser expeditiously.

11. The Purchaser will be given an option (to be exercised within one year after signing the relevant Transfer Agreement) to hire one or more Personnel, subject to applicable local employment legislation, who would reasonably be considered necessary to maintain the viability, marketability and competitiveness of this Divestment Business to be supervised by the Monitoring Trustee.

12. 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 betahistine after Closing;
d. All marketing authorizations currently held by the Parties outside of Ireland for betahistine;
e. The right to use the information contained in the registration dossiers underlying the marketing authorization(s) that are transferred as part of the Divestment Business to obtain marketing authorizations outside of Ireland;
f. The "Mylan" name or the name of any Mylan subsidiaries;
g. Monies owed to the Parties by customers for the purchase of betahistine, and monies owed by the Parties to suppliers for materials used in the production of betahistine.

13. If there is any asset or personnel which is not be covered by paragraph 2 of this Schedule but which is both used (exclusively or not) in the Divestment Business and
necessary for the continued viability and competitiveness of the Divestment Business,
that asset or adequate substitute will be offered to the Purchaser.

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SCHEDULE V

Product: Mylan's delorazepam products
Territory: Italy

1. The Divestment Business consists of Mylan's rights, title and interests in delorazepam in Italy (currently marketed under the name Delorazepam) including the right to develop, manufacture and use delorazepam with a view to its sale and marketing in any form and for any indication whatsoever in Italy. Delorazepam is used for the treatment of anxiety disorders. For the avoidance of doubt, this Divestment Business does not include any rights to sell delorazepam outside of Italy.

2. The Divestment Business includes:

   (a) the sale of existing delorazepam product inventory, sales and promotional material in Italy;

   (b) all delorazepam-related contracts, commitments and customer records meaning customers credit records, customer invoices, purchase orders and contact details, whilst only the information related to delorazepam specifically will be provided;;[6]

   (c) the transfer of the marketing authorisation for delorazepam in Italy including all relevant dossiers, as well as the information contained in the relevant full registration dossier(s), relating to the current and/or pending marketing authorisations available to Mylan; and

   (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 Italy; including in particular the information contained in the registration dossier.

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

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

4. At the option of the Purchaser and to the extent required by law in Italy, Mylan will enter into a transitional distribution arrangement related to the

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6 Mylan will include all customer lists and records since 2010 in the Divestment Business.

Divestment Business lasting until the relevant marketing authorisation is transferred into the name of the Purchaser on a reasonable cost-plus basis which determination is overseen by the Monitoring Trustee.

5. At the option of the Purchaser, Mylan commits to make its best efforts to facilitate the assignment of the contract manufacturing agreement Mylan has in place concerning delorazepam in Italy to the Purchaser.

6. Mylan commits to make its best efforts to cooperate with the Purchaser to effectuate the transfer of the Divestment Business and to undertake all regulatory changes that would be required as a result of such transfer.

7. Mylan will commit to make its best efforts to facilitate the assignment of the contract manufacturing agreement with [*] to the Purchaser.

8. [Contract Manufacturing Agreement with […].

9. If the contract manufacturing agreement with [*] concerning delorazepam has not been concluded before the transfer of the Divestment Business and at the option of the Purchaser, Mylan commits to provide the Purchaser with documents concerning the negotiation history such as draft agreements and offers.

10. The Purchaser will be given an option (to be exercised within one year after signing the relevant Transfer Agreement) to hire one or more Personnel, subject to applicable local employment legislation, who would reasonably be considered necessary to maintain the viability, marketability and competitiveness of this Divestment Business to be supervised by the Monitoring Trustee.

11. 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 delorazepam after Closing;
d. All marketing authorizations currently held by the Parties outside of Italy for delorazepam;
e. The right to use the information contained in the registration dossiers underlying the marketing authorization(s) that are transferred as part of the Divestment Business to obtain marketing authorizations outside of Italy;
f. The "Mylan" name or the name of any Mylan subsidiaries;

g. Monies owed to the Parties by customers for the purchase of delorazepam, and monies owed by the Parties to suppliers for materials used in the production of delorazepam.

12. If there is any asset or personnel which is not be covered by paragraph 2 of this Schedule but which is both used (exclusively or not) in the Divestment Business and
necessary for the continued viability and competitiveness of the Divestment Business,
that asset or adequate substitute will be offered to the Purchaser.

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Annex to the Commitments

[Divestment Business Customer Overview]