



EUROPEAN COMMISSION  
DG Competition

***Case M.7975 - MYLAN / MEDA***

Only the English text is available and authentic.

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

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Article 6(1)(b) in conjunction with Art 6(2)  
Date: 20/07/2016

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## EUROPEAN COMMISSION

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 Where possible the information omitted has been replaced by ranges of figures or a general description.

Brussels, 20.07.2016  
C(2016) 4873 final

PUBLIC VERSION

MERGER PROCEDURE

**To the notifying party:**

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

**Subject: Case M.7975 – MYLAN / MEDA  
Commission decision pursuant to Article 6(1)(b) in conjunction with  
Article 6(2) of Council Regulation No 139/2004<sup>1</sup> and Article 57 of the  
Agreement on the European Economic Area<sup>2</sup>**

- (1) On 1 June 2016, the European Commission received the notification of a proposed concentration pursuant to Article 4 of the Merger Regulation by which the undertaking Mylan N.V. (“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 Meda AB (“Meda”, Sweden) by way of purchase of shares (together the “Parties”).<sup>3</sup>

### **I. THE PARTIES**

- (2) **Mylan** is a global pharmaceutical company which develops, licenses, manufactures, markets and distributes generic, branded generic and specialty pharmaceuticals, mainly prescription (“Rx”) pharmaceuticals. Mylan offers a large portfolio of generics (more than 1400) and branded pharmaceuticals and is active in approximately 165 countries. Mylan is also active in research and development (“R&D”) and is vertically-integrated in manufacturing of some active pharmaceutical ingredients

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<sup>1</sup> 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.

<sup>2</sup> OJ L1, 3.1.1994, p. 3 (“the EEA Agreement”).

<sup>3</sup> Publication in the Official Journal of the European Union No C 207, 10.6.2016, p. 15.

("API"). It has overall than 50 facilities around the world. Additionally, Mylan has a specialty business in the U.S. that is focused on respiratory and allergy therapies.

- (3) **Meda** is an international speciality pharmaceutical company that manufactures and distributes prescription and non-prescription i.e. over-the-counter ("OTC") pharmaceuticals. Meda's three key therapeutic areas – respiratory, dermatology and pain and inflammation – account for around 50% of Meda's sales. Meda's main focus is not on in-house development, but on sales, marketing and development of existing products.

## **II. THE OPERATION**

- (4) Pursuant to the business transfer agreement, Meda will be merged with and into Mylan. Mylan's shareholders will hold around 95% of the outstanding new Mylan ordinary shares on a fully diluted base. The outstanding 5% of shares of the new Mylan will be held by the current shareholders of Meda. (hereinafter, the "Transaction")
- (5) The Transaction thus constitutes an acquisition of sole control by Mylan over Meda 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<sup>4</sup> (Mylan: EUR 8.7 billion; Meda: EUR 2.1 billion). Each of them has an EU-wide turnover in excess of EUR 250 million (Mylan: EUR [...]; Meda: EUR [...]), but each does not achieve more than two-thirds of its aggregate EU-wide turnover within one and the same Member State.
- (7) The notified operation therefore has a Union dimension pursuant to Article 1(2) of the Merger Regulation.

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

### **Overall context**

- (8) The rationale of the Transaction is for Mylan to further develop its presence in the OTC segment and benefit from Meda's established sales force and infrastructure, in particular in Europe. The transaction will also expand and diversify Mylan's portfolio by adding a number of complementary products, namely in the allergy/respiratory, dermatology and pain areas.
- (9) In the area of finished dose pharmaceuticals ("FDPs") the combination of activities of Mylan and Meda gives rise to a large number of horizontally affected markets in different therapeutic areas, in particular alimentary tract and metabolism and cardiovascular system. In addition, both Parties develop certain pipeline products, including some that overlap with the other Party's marketed FDPs. Finally, both Parties are active in the production and sales of APIs, contract manufacturing of FDPs and FDP outlicensing.

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

## IV.1. Finished Dose Pharmaceuticals

### IV.1.1. Market definition

#### *Analysis based on ATC classification*

- (10) In previous decisions dealing with the marketing of pharmaceutical products,<sup>5</sup> the Commission has applied the Anatomical Therapeutic Classification ("ATC"), devised by the European Pharmaceutical Marketing Research Association ("EphMRA") and maintained by EphMRA and Intercontinental Medical Statistics ("IMS")<sup>6</sup> as a basis for the assessment of the relevant market definition.
- (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 main anatomical groups. The second level (ATC2) represents 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). 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. Finally, the level of the chemical substance is the so-called molecule level. 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 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.<sup>7</sup> The overlap in therapeutic uses does not necessarily imply any particular economic substitution patterns between products.

#### *Originator pharmaceuticals and generic pharmaceuticals*

- (12) 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

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<sup>5</sup> 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.

<sup>6</sup> 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.

<sup>7</sup> COMP/M.7645 Mylan/Perrigo of 29 July 2015, COMP M.7379 Mylan/Abbott EPD-DM of 28 January 2015, 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.

composition in terms of active substance and the same pharmaceutical form and is bioequivalent to the originator drug.

- (13) In previous cases,<sup>8</sup> 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.<sup>9</sup>
- (14) 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.

*Prescription drugs v. Over-the-counter (“OTC”) drugs*

- (15) 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<sup>10</sup> 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.
- (16) 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.<sup>11</sup>
- (17) Notwithstanding such differences, it has been outlined in previous decisions<sup>12</sup> that in certain cases, products which are available OTC are still reimbursable if bought on prescription.

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<sup>8</sup> See for example COMP/M.5865 Teva/Ratiopharm of 3 August 2010, and COMP/M.5295 Teva/Barr of 19 December 2008.

<sup>9</sup> COMP/M.5253 Sanofi-Aventis/Zentiva of 4 February 2009.

<sup>10</sup> 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.

<sup>11</sup> COMP/M.5953 Reckitt Benckiser/SSL of 25 October 2010.

<sup>12</sup> 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.

- (18) 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.<sup>13</sup>
- (19) 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.

#### *Galenic form*

- (20) As the Commission has acknowledged in its previous decisions,<sup>14</sup> medicines are differentiated not only by their active ingredient(s), but also, in particular, as recognized by the European regulatory framework for medicines for human use, by their dosage, pharmaceutical form and route of administration and this may limit their substitutability.<sup>15</sup>
- (21) 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.
- (22) 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 form of certain drugs (such as patches), which are the preferred form for certain patients (such as elderly people) to reduce the daily intake of pills.

#### *IV.1.2. Relevant geographic market*

- (23) 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.
- (24) 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.1.3. Product-specific assessment*

- (25) The Commission conducted a far reaching market investigation in this case. In total, the Commission sent more than 600 questionnaires to five different categories of

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<sup>13</sup> COMP/M.7645 Mylan/Perrigo of 29 July 2015, COMP/M.5778 Novartis/Alcon of 9 August 2010.

<sup>14</sup> 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.

<sup>15</sup> 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.

market participants: prescribers, competitors, wholesalers, distributors and pharmacies. In addition to this, the Commission conducted more than 15 conference calls with various market participants, including the leading medical specialists in the relevant areas (“key opinion leaders”).

- (26) The Commission also analysed the information provided by the Parties, including a considerable number of internal documents.
- (27) The findings in this decision are based on the overall assessment of all available evidence.

*Methodology used in the assessment of affected markets*

- (28) 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 therapeutic areas where the Parties' activities overlap.
- (29) 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.
- (30) Specifically, the markets were grouped in four groups:
- **Group 1:** where the Parties' combined market share exceeds 35% AND the increment exceeds 1%.
  - **Group 1 “plus”:**<sup>16</sup> 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.
  - **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%<sup>17</sup> and 35%.

- (31) 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. In total, 203 Group 1 overlaps were examined, namely 54 at the molecule level, 16 at the ATC4 level, 120 at the ATC3 level, 11 at the Vaughan Williams level and 1 overlap at the indications level for an OTC market, such as gynaecological antiseptics.

- (32) 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

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<sup>16</sup> See COMP/M.5778 Novartis/Alcon of 9 August 2010, paragraph 25.

<sup>17</sup> 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.

three different alternative levels: (i) at the narrowest market definition, i.e. the molecule, (ii) at a combination of interchangeable molecules within the same ATC4 or ATC3 class, and finally (iii) at the broader ATC4 or ATC3 level.

- (33) Besides, 60 Group 2 and 208 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.

#### *Assessment of the markets by therapeutic area*

### **CARDIO AREA**

- (34) 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 in relation to the molecules/group of molecules set out below.

#### IV.1.3.1. Vaughan Williams Class I-C (propafenone and flecainide) (C1B)

##### Product market definition

- (35) In the C1B class (antiarrhythmic agents), Mylan mostly markets propafenone and, in certain EEA countries, also markets flecainide and/or amiodarone,<sup>18</sup> while Meda markets flecainide-based branded products. These drugs all belong to the ATC3 class C1B, which comprises 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).
- (36) The Commission has previously considered whether the ATC3 class C1B was appropriate to define the product market for this type of products and has concluded that the Vaughan-Williams classification, rather than the ATC classification, is more appropriate.<sup>19</sup>
- (37) The Vaughan-Williams classification system was developed 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 (Sodium Channel Blockers): includes the main molecules that affect the conduction velocity (i.e. the speed with which an electrical impulse can be transmitted through excitable tissue). This Class is further subdivided into three sub-classes, based on the way that the antiarrhythmic agent belonging to this

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<sup>18</sup> In the UK, Mylan also markets Disopyramide, named after its active ingredient.

<sup>19</sup> See COMP M.3354 Sanofi-Synthelabo/Aventis of 26 April 2004, paragraph 40, and COMP/M.1397 Sanofi/Synthelabo of 17 May 1999, paragraph 34 and Case M. 7379 Mylan/Abbott EPD-DM of 28 January 2015.



class affect the effective refractory period ("ERP"), namely I-A (sodium channel blockers that increase the ERP), I-B (sodium channel blockers decreasing ERP) and I-C (sodium channel blockers having no effect on the ERP);

- ii. Class II (Beta-blockers): includes beta blockers (anti-hypertensives that act by way of beta-adrenergic blocking) for the treatment of hypertension;
  - iii. Class III (Potassium Channel Blockers): 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.
- (38) In previous cases,<sup>20</sup> in line with this classification, the Commission considered that Classes I (containing propafenone and flecainide) and III (containing amiodarone) may not be substitutable, but ultimately left the exact market definition open.
- (39) The Parties' products overlap in relation to Class I and more specifically Class I-C of the Vaughan Williams classification, where Meda markets Tambocor (flecainide)<sup>21</sup> and Mylan markets Rythmonorm (propafenone) and flecainide-based generics in certain EEA countries.

*Notifying Party's submission*

- (40) The Notifying Party submits that the market should be defined at molecule level.
- (41) First, the Notifying Party claims that the Vaughan Williams classification should be regarded as mere classification instrument that does not entirely correspond to the various anti arrhythmic agents' indicated specific mode of action.
- (42) More generally, the Notifying Party submits that elements that characterize antiarrhythmic agents advocate in favour of a market definition at molecule level, in particular: (i) their differentiated and critical safety profiles, (ii) a narrow therapeutic index, (iii) the fact that these products are experience goods and thus depend on each specific patient's reaction to the drug, and (iv) the seriousness of the condition which provides a high threshold for switching when a therapy is effective.
- (43) With specific reference to the Vaughan Williams Class I-C, the Notifying Party submits that, while propafenone and flecainide have indications that are to a large extent similar,<sup>22</sup> they present certain differences in terms of use and effect and that products based on the same molecule constrain each other to a higher extent than products based on different molecules.

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<sup>20</sup> See COMP/M.3354 Sanofi-Synthelabo/Aventis of 26 April 2004, paragraph 40.

<sup>21</sup> Meda's product is also marketed with other brand names in certain EEA countries.

<sup>22</sup> When referring to Rythmonorm and Tambocor, the Notifying Party states that "*their indications are to a large degree similar*" (Form CO, paragraph 567).

### *Commission's assessment*

- (44) The market investigation generally confirmed the Commission's findings in previous cases that the products for the treatment of arrhythmia, disorders of cardiac rhythm and tachycardia should be classified according to the Vaughan-Williams classification and that this classification is still widely recognized as the appropriate classification in medical practice.
- (45) The Commission acknowledges that products based on the same molecule are typically closer substitutes than products based on different molecules. However, this does not mean that, in certain circumstances, products based on different molecules with an equivalent therapeutic profile may competitively constrain one another. In these instances, the prescriber would typically choose between different molecules based on his/her assessment of therapeutic efficacy, preference and experience, before even considering a generic version of the chosen molecule. This appears to be the case with molecules belonging to Vaughan Williams Class I-C, namely flecainide and propafenone.
- (46) Indeed, the market investigation provided clear indications that propafenone and flecainide constrain each other and are closely substitutable.
- (47) In particular, according to key opinion leaders that responded during the market investigation, flecainide and propafenone are both used for the treatment of supraventricular arrhythmias, in particular for the prevention of atrial fibrillation. Flecainide and propafenone have a similar percentage of efficacy and comparable side effects. These two drugs are both contraindicated in patients with heart failure due to their pro-arrhythmic effects and are used in the same line treatment (third line).<sup>23</sup>
- (48) The market investigation revealed that the choice between these two drugs mainly depends on the preference and experience of the prescriber, rather than on differences in the therapeutic indications of the two drugs and that it is possible to use propafenone and flecainide interchangeably at the very least for new patients.<sup>24</sup>
- (49) The Parties' internal documents also provide indications of the interchangeability and competitive interaction between these two molecules. For example, a Meda internal document concerning the Italian market clearly refers to the possibility to substitute propafenone with flecainide-based products in all patients that are candidates for a treatment with drugs classified under the Vaughan Williams Class I-C.<sup>25</sup>
- (50) The market investigation also confirmed that propafenone and flecainide are generally not substitutable with drugs belonging to other Vaughan Williams classes. For example, amiodarone (Class III) is generally considered as a more effective drug and used as a first line treatment by some doctors, but can lead to specific side effects,

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<sup>23</sup> According to a Portuguese KOL, "*there are no other antiarrhythmic drugs (other than flecainide and propafenone) that can be used as third line treatment). The alternative, in case of failure of these last resort drugs, is to proceed with an invasive treatment (surgery).*" See non-confidential minutes of conference call held on 19 May 2016.

<sup>24</sup> According to an Italian doctor: "*if one fails, you can use the other*". See non-confidential minutes of conference call with Italian doctor held on 20 May 2016.

<sup>25</sup> Meda internal document titled [*Internal document concerning substitutability of flecainide-based products*].

such as hypothyroidism or hyperthyroidism. In addition, drugs belonging to other Vaughan Williams class I sub-classes (i.e. I-A and I-B) are either not marketed or even forbidden in some EEA countries (for example, lidocaine is forbidden in Italy) or are used for different indications.

- (51) On the basis of the considerations above, and for the purposes of this decision, the Commission considers that the relevant product market in relation to drugs treating arrhythmias, and in particular propafenone and flecainide (Class I-C) should be defined according to the Vaughan-Williams classification.

#### Competitive assessment

- (52) On the basis of the market definition set out above, the Transaction gives rise to Group 1 affected markets in Belgium, Denmark, Estonia, France, Ireland, Italy, Luxembourg, Portugal, Spain, Sweden and the UK.

#### Belgium

- (53) In the Vaughan-Williams Class I-C, the Parties market the following molecules: Mylan markets propafenone under the brand name Rytmonorm and a flecainide-based generic and Meda markets flecainide under the brand names of Tambocor and Apocard Retard.
- (54) The Parties' combined market share reaches [90-100]% (value) and [90-100]% (volume) with an increment brought by Mylan of [10-20]% (value) and [20-30]% (volume). Only competitors with a very limited market share (below [5-10]%) will remain in the market post-merger with a flecainide-based generic, namely Stada ([0-5]%), Novartis ([0-5]%) and Teva ([0-5]%).
- (55) Generic penetration in Belgium - that has only concerned flecainide, since no propafenone-based generic product is currently present on the Belgian market - has not led to significant changes in the market. Meda's Tambocor (originator) is the only flecainide-based branded product in Belgium and has maintained, and even increased, its already strong position (Meda's shares went from [80-90]% (value) and [60-70]% (volume) in 2013 to [80-90]% (value) and [60-70]% (volume) in 2015), despite the entry of generic products that, on the contrary, have not managed to gain market share and continue to hold only a very limited presence in the market. Furthermore, the Transaction would eliminate competition between the market leader Meda and one of the few generic products that are currently competing on the market (Mylan's flecainide).
- (56) In addition, the possibility of INN prescription has been introduced in Belgium, but it is not mandatory. Physicians can still prescribe branded pharmaceutical products can thus block generic substitution (which is not allowed at pharmacy level in Belgium). The strong position of the Parties' branded products on the market (in particular of Meda's Tambocor & Apocard Retard) constitutes evidence that doctors still prefer prescribing the brand.

#### Conclusion

- (57) Based on the above, the Commission concludes that serious doubts arise as regards the compatibility of the Transaction with the internal market in relation to the products belonging to the Vaughan-Williams Class I-C in Belgium.

### Denmark

- (58) In the Vaughan-Williams Class I-C, the Parties market the following molecules: Mylan markets propafenone under the brand name Rytmonorm and Meda markets flecainide under the brand name of Tambocor.
- (59) The Parties' combined market share reaches [40-50]% (value) and [20-30]% (volume), with an increment brought by Meda of [10-20]% (value) and [5-10]% (volume). The Parties will continue to face competition from Allergan,<sup>26</sup> with a market share of [30-40]% (value) and [30-40]% (volume), Novartis with a market share of [10-20]% (value) and [10-20]% (volume) and Orifarm with a market share of [5-10]% in value and [5-10]% in volume. In addition, parallel importer 2Care4 is present with a market share of [0-5]% in value and [5-10]% in volume.
- (60) Several characteristics of the Danish market need to be taken into consideration when assessing the impact of the Transaction.
- (61) First, procurement procedures for these products are characterised by the use of tenders which occur frequently and typically exert downward pressure on pricing.
- (62) Second, as also confirmed by the market investigation in this case parallel importers form a significant competitive constraint (especially in terms of pricing) and will continue to constrain the merged entity. This is particularly due to the frequency in which tenders are organized, which facilitates the participation of parallel importers despite their general lack of ability to secure long-term supply.
- (63) Finally, the regulatory framework in Denmark will further constrain the ability of the merged entity to raise prices. As regards reimbursed products (such as the Parties' products), pharmaceutical suppliers have to report their pharmacy purchasing prices on a bi-weekly basis to the DKMA,<sup>27</sup> which then calculates the pharmacy retail price using a fixed mark up.
- (64) The market investigation did not reveal any concerns in relation to the Vaughan Williams Class I-C market in Denmark.

### Conclusion

- (65) Based on the above considerations, the Commission 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 I-C in Denmark.

### Estonia

- (66) In the Vaughan-Williams Class I-C, the Parties market the following molecules: Mylan markets propafenone under the brand name of Rytmonorm and Meda markets flecainide under the brand name of Tambocor.

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<sup>26</sup> Allergan was acquired by Teva. The transaction received clearance from the Commission on 10 March 2016. See [http://europa.eu/rapid/press-release\\_IP-16-727\\_en.htm](http://europa.eu/rapid/press-release_IP-16-727_en.htm).

<sup>27</sup> Danish Medicines Agency.

- (67) Based on the information provided by the Parties in the Form CO, the Parties' combined market shares amount to [50-60]% (value) and [30-40]% (volume), with an increment of [5-10]% (value) and [0-5]% (volume) brought by Meda. The only competitor remaining in the market with a propafenone-based product would be Pro Med with a share (estimated by the Parties on the basis of IMS data) of [40-50]% (value) and [60-70]% (volume).
- (68) Post-Transaction, only two competitors (the merged entity and Pro Med) would remain on the market. In this context, the market investigation revealed that Pro Med's market shares in IMS may be overestimated as according to ProMed, its sales of this product in Estonia are not substantial.

#### Conclusion

- (69) Based on the above considerations, the Commission concludes that serious doubts arise as regards the compatibility of the Transaction with the internal market in relation to the products belonging to the Vaughan-Williams Class I-C in Estonia.

#### France

- (70) In the Vaughan Williams Class I-C, the Parties compete with the following products: Mylan markets propafenone under the brand name Rythmol and a flecainide-based generic; Meda markets flecainide under the name Flecaïne.
- (71) The Parties' combined market share reaches [50-60]% (value) and [40-50]% (volume), with an increment brought by Mylan of [10-20]% (value) and [10-20]% (volume). The Parties face competition from other strong suppliers, including Servier, with a share of [20-30]% in value and [30-40]% in volume, Teva, with a share of [5-10]% in value and [10-20]% in volume and Sanofi, having a share of [5-10]% in value and [5-10]% in volume. In addition, four other suppliers are active in the market with a share between [0-5]%.
- (72) The market share developments of the past three years demonstrate that, in France, generic competition does exert a significant level of competitive pressure in the market. Specifically, the originator of flecainide in France, Meda, has seen its market share decrease since the entry of generics from [80-90]% (value) and [70-80]% (volume) in 2013 to [40-50]% (value) and [30-40]% (volume) in 2015 at Vaughan Williams I-C level. This nearly [50-60]% loss of market share was captured by Sanofi, Teva and, particularly Servier that entered the market for flecainide-based generics recently. In 2013, these suppliers had a share of less than [0-5]%.
- (73) In addition, in France, there is a strict regulatory framework that constrains pharmaceutical suppliers in terms of price setting at all levels of the value chain. In France, the maximum ex-factory prices of reimbursed prescription products (such as the Parties') are fixed while wholesale and pharmacy margins are regulated. In addition, the price decreases of all drugs, including originators are paced by the entry of generics. As a consequence the ability of pharmaceutical companies to increase prices for these drugs is limited.<sup>28</sup>

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<sup>28</sup> See COMP/M.7379 Mylan/Abbott EPD-DM of 28 January 2015, footnote 24.

- (74) Finally, the market investigation did not reveal any concerns in relation to the Vaughan Williams Class I-C market in France.

#### Conclusion

- (75) Based on the above considerations, the Commission 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 I-C in France, as the Parties will continue to face a number of credible competitors post-merger, generic suppliers will continue to exert competitive pressure on the merged entity and the French regulatory framework impedes the merged entity to freely increase prices.

#### Ireland

- (76) In the Vaughan Williams Class I-C, the Parties compete with the following products: Mylan markets propafenone under the brand name Arythmol and a flecainide-based generic; Meda markets flecainide under the brand names Tambocor and Apocard.
- (77) The Parties' combined market share reaches [90-100]% (value) and [90-100]% (volume) with an increment brought by Mylan of [10-20]% (value) and [20-30]% (volume). Only one competitor (Intas) will remain on the market with a propafenone-based generic.
- (78) In addition to being the strongest competitors at Vaughan Williams Class I-C level, the Parties also overlap at molecule level (flecainide) and are each other's close competitors in this regard. The Commission has, in fact, previously recognized<sup>29</sup> that competing products based on the same molecule are typically closer substitutes than products based on different molecules, even if they belong to the same Vaughan-Williams class.
- (79) The merger would eliminate competition between the market leader and ex-originator, Meda, and the only flecainide-based generic (Mylan). Based on the market share data submitted by the Parties Mylan appears to have been significantly constraining Meda's strong position in Ireland by taking away its market share. Indeed, Mylan's share in flecainide has increased from [0-5]% (value) and [0-5]% (volume) in 2013 to [5-10]% (value and volume) in 2015.

#### Conclusion

- (80) Based on the above considerations, the Commission concludes that serious doubts arise as regards the compatibility of the Transaction with the internal market in relation to the products belonging to the Vaughan-Williams Class I-C) in Ireland, as the Transaction would strengthen the dominant position of the merged entity on this market, amount to a three-to-two merger with only one competitor (with a nearly insignificant market share) on the market remaining and eliminate the only credible generic alternative (Mylan's Flecainide).

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<sup>29</sup> See COMP/M.7379 Mylan/Abbott EPD-DM of 28 January 2015.

*Italy*

- (81) In the Vaughan Williams Class I-C, the Parties compete with the following products: Mylan markets propafenone under the brand name of Rythmonorm and Meda markets flecainide under the brand name of Almarytm.
- (82) The Parties' combined market share amounts to [80-90]% (value) and [70-80]% (volume) with a significant increment in value brought by Mylan amounting to [30-40]% and a significant increment in volume brought by Meda of [30-40]%. Other suppliers are present in the market with generic products (flecainide-based and/or propafenone-based), including Novartis ([5-10]%) and other players with smaller shares (below [5-10]%), including Teva, Bruno Farmaceutici (that entered at the beginning of 2015), Doc Generici.
- (83) The Parties' products are the only branded products in the market and have historically held a significant market share.
- (84) The Notifying Party argues that the market share of generic products grows rapidly and that generic products are increasingly constraining the Parties. The Notifying Party further submits that the total market for flecainide has grown significantly between 2013 and 2016: [20-30]% (value) and [30-40]% (volume) and that new entrants (such as Bruno Farmaceutici) have taken the most advantage of this growth, while Meda has not managed to profit from the growth of the market in the same manner as its competitors and even lost market share should the market growth be taken into account (from 2015).
- (85) The Commission considers that a series of factors should be taken into account when assessing the incremental competitive pressure of generics in the market and the possible causes of the alleged proportional decrease in Meda's position. First, the increase in market size for flecainide at least partially coincided with a decrease in the market size of propafenone. This is evidenced by the data submitted by the Notifying Party,<sup>30</sup> as well as by the Parties' internal documents (see below). In addition, the most recent (April 2015 – April 2016) monthly market data for flecainide submitted by the Notifying Party evidences that Teva's market share sharply decreased going from [5-10]% in April 2015 to [0-5]% in April 2016. As a consequence, it cannot be ruled out that the increase in market share of Bruno Farmaceutici and other flecainide generics (Doc Generici and Novartis) is linked to Teva's sharp decrease in the last year rather than to it taking share from Meda.
- (86) Consequently, the Commission cannot conclude that the alleged proportionally more limited growth of Meda in the market can be exclusively attributed to the competitive pressure exercised by generics (and in particular by the growth of Bruno Farmaceutici) on Meda as the Notifying Party appears to suggest.
- (87) The Parties' internal documents provide further evidence both of the correlation between flecainide and propafenone and on the degree of competitive pressure that generics exercise on brands in Italy.

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<sup>30</sup> See Notifying Party's supplementary submission dated 7 July 2016.

- (88) For instance, the slide below extracted from Mylan's internal presentation [...] <sup>31</sup> shows that the increase in sale of Meda's flecainide-based Almarytm appears to be strictly correlated to the decrease in sales of Mylan's propafenone-based Rytmonorm. In addition, the slide below shows that the growth of flecainide-based generics is proportionally much less significant than the growth of Almarytm, that, besides, Mylan defines as [...].

Image 1 - Market size and evolution: Rytmonorm

[...]

- (89) Similarly, an internal document of Meda concerning the Italian market confirms that despite the entry of generics Meda's Almarytm maintains a positive trend. <sup>32</sup>
- (90) Furthermore, the market investigation provided evidence that doctors tend to prescribe the branded goods, as opposed to generics.
- (91) The market investigation indicated that while Italian pharmacies are required by the Italian regulatory system to offer a generic alternative, patients prefer the medicines prescribed by the doctors. <sup>33</sup> This was also confirmed by the Parties' competitors during the market investigation. An Italian generic competitor stated that: "[...] *the generic market in Italy is relatively young and therefore originators still hold a high market share in most therapeutic classes*" and that the still high share of Rytmonorm and Almarytm is "*not surprising*" as "*many consumers are willing to pay the price difference with the generic and stay with the originator*" <sup>34</sup>. Similarly, it was explained that "*Italians like brands and are prepared to pay the price difference and continue with the originator.*" <sup>35</sup> According to another market player, "*the Italian market differs from the other European markets in that there is very little substitution for branded prescriptions. This is even more so in niche segments such as the CIB class as is demonstrated by the fact that Almarytm, Rytmonorm and Cordarone remain market leaders of the class.*" <sup>36</sup>

### Conclusion

- (92) Based on the above considerations, the Commission concludes that serious doubts arise as regards the compatibility of the Transaction with the internal market in relation to the products belonging to the Vaughan-Williams Class I-C in Italy, as the Transaction would strengthen the dominant position of the Parties, in a market where brands remain strong and generics have not so far demonstrated to be able to exercise a significant competitive constraint.

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<sup>31</sup> Annex 18 (c) submitted in response of Question 31 of RFI 1, page 5.

<sup>32</sup> [Meda internal document concerning Almarytm and the Italian market] Response to RFI 1).

<sup>33</sup> See response to Q 9 – Questionnaire to pharmacies in Italy, question 17.

<sup>34</sup> See responses to Q 12 – Questionnaire to competitors, question 70.

<sup>35</sup> See responses to Q 12 – Questionnaire to competitors, Question 71.

<sup>36</sup> See responses to Q 12 – Questionnaire to competitors, Question 70.



### Luxembourg

- (93) In the Vaughan Williams I-C class, the Parties compete with the following products: Mylan markets propafenone under the brand name of Rytmonorm; Meda markets flecainide under the brand names of Tambocor and Apocard Retard.
- (94) The Parties' combined market shares amount to [90-100]% (value and volume) with an increment brought by Mylan of [5-10]% (value) and [10-20]% (volume). The only competitor remaining in the market would be Novartis with a flecainide-based generic and a market share of approximately [0-5]%.
- (95) The competitive pressure of generics in the Luxembourgish market is nearly insignificant. This is further evidenced by the constant growth of Meda's market shares (from [80-90]% (value) in 2013 to [90-100]% (value) in 2015) and the inability of Novartis to gain a meaningful presence in the market with a competing generic based on the same molecule, despite the possibility for physicians to prescribe by INN in Luxembourg.

### Conclusion

- (96) Based on the above considerations, the Commission concludes that serious doubts arise as regards the compatibility of the Transaction with the internal market in relation to the products belonging to the Vaughan-Williams Class I-C in Luxembourg, as the Transaction would strengthen the dominant position of Meda in this market and amount to a three-to-two transaction with only one remaining competitor.

### Portugal

- (97) In the Vaughan Williams I-C class, the Parties compete with the following products: Mylan markets propafenone under the brand name of Rytmonorm; Meda markets flecainide under the brand name of Apocard.
- (98) The Parties' combined market share amounts to [90-100]% (in both value and volume), with an increment brought by Meda of [20-30]% (value) and [10-20]% (volume). No other pharmaceutical supplier will be active in the market.
- (99) In addition, the market investigation provided evidence that, despite the loss of exclusivity flecainide-based and propafenone-based products in Portugal (Meda and Mylan were the respective originators), Portugal has not experienced to date entry by generic suppliers. As a result, the Parties are the only competitors in this area in Portugal.

### Conclusion

- (100) Based on the above considerations, the Commission concludes that serious doubts arise as regards the compatibility of the Transaction with the internal market in relation to the products belonging to the Vaughan-Williams Class I-C in Portugal, as the Transaction would lead to a merger to monopoly between the only two products in this class in Portugal.

## Spain

- (101) In the Vaughan Williams I-C class, the Parties compete with the following products: Mylan markets propafenone under the brand name of Rytmonorm; Meda markets flecainide under the brand name of Apocard.
- (102) The Parties' combined market share reaches [90-100]% (value) and [90-100]% (volume), with an increment brought by Myan of [5-10]% (value) and [10-20]% (volume).
- (103) The Notifying Party argues that, following the loss of exclusivity of Meda's originator product in 2015, three generic pharmaceutical suppliers entered the market, namely Normon, Apotex and Invent Farma and that these suppliers are rapidly gaining market shares.
- (104) However, the data provided by the Notifying Party shows a very limited penetration of generic products in the Spanish market. After one year from the entry (i.e. in May 2016), the combined market share of the three new entrants amounted only to [0-5]%. While it is true that the presence of these companies has increased, especially if only new patients are considered, this growth does not appear to have translated into a decrease in Meda's sales and has not substantially eroded Meda's leading position on the Spanish market.
- (105) The limited competitive pressure exercised by generics in the Spanish market was also confirmed by the market investigation. In this context one market player noted that *"The Spanish market is similar to the Italian one in that there is very little substitution for branded prescriptions. This is even more so in niche segment such as the C1B class."*<sup>37</sup>
- (106) Furthermore, and importantly, flecainide has been included in the list of non-substitutable drugs by the Spanish regulator as a result of which generic substitution is expressly blocked at pharmacy level. This seems to be corroborated by the Parties' internal documents suggesting that generics substitution for flecanide-based products can even be dangerous in some instances.<sup>38</sup> It follows that the choice to prescribe a branded product or a generic depends solely on the physicians. The data (the level of market share of branded products) and the market investigation suggest that they prefer prescribing the branded products.

## Conclusion

- (107) Based on the above considerations, the Commission concludes that serious doubts arise as regards the compatibility of the Transaction with the internal market in relation to the products belonging to the Vaughan-Williams Class I-C in Spain.

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<sup>37</sup> See response to Q 12 – Questionnaire to competitors, question 94.

<sup>38</sup> See Meda internal document on Apocard submitted in response to Question 31 of Commission's RFI 1 (Annex 18 (f)), according to which substitution of Apocard with flecainide-based generics can lead to inefficacy or to severe adverse effects: [...].

### Sweden

- (108) In the Vaughan Williams Class I-C, the Parties market the following products: Mylan markets propafenone under the brand name Rythmonorm and Meda markets flecainide under the brand name of Tambocor.
- (109) The Parties' combined market shares amount to [40-50]% (value) and [40-50]% (volume), with an increment brought by Mylan of [0-5]% (value) and [0-5]% (volume). Two competitors will remain in the market, namely parallel importer 2Care4 ([30-40]% in value and [30-40]% in volume), Orifarm ([10-20]% in value and [10-20]% in volume) and Medartuum ([0-5]% in value and volume).
- (110) Several characteristics of the Swedish market need to be taken into consideration when assessing the impact of the Transaction.
- (111) In Sweden, the pharmacy purchase price and the pharmacy margin are set by TLV,<sup>39</sup> thereby effectively determining a fixed national pharmacy retail price. In addition, the pricing for products in the reimbursement system is set through government tenders. These tenders occur every month and only the winner will be reimbursed in Sweden which has a downward pressure on pricing. In such a system, high market shares are not necessarily indicative of the Parties' ability to affect the conditions of sale pre- or post-merger.
- (112) In addition, the market investigation confirmed that parallel importers exert a significant competitive constraint (especially in terms of pricing) and will continue to constrain the merged entity. This is particularly due to the high frequency in which tenders are organized in Sweden which facilitates the participation of parallel importers despite their general lack of ability to secure long-term supply. As a consequence, parallel importers can exert a pricing constraint in Sweden.<sup>40</sup>
- (113) Finally, it is noted that the market investigation did not reveal any concerns in relation to the Vaughan Williams Class I-C market in Sweden.

### Conclusion

- (114) Based on the above considerations, the Commission 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 I-C in Sweden.

### UK

- (115) In the Vaughan Williams Class I-C, the Parties compete with the following products: Mylan markets propafenone under the brand name of Arythmol and a generic flecainide and Meda offers flecainide under the brand name of Tambocor.
- (116) Based on the information provided by the Parties, their combined share in the UK amounts to [40-50]% (value and volume), with an increment brought by Mylan

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<sup>39</sup> Tandvårds- och läkemedelsförmånsverket, i.e. the Swedish Dental and Pharmaceutical Agency.

<sup>40</sup> See COMP/M.7379 Mylan/Abbott EPD-DM of 28 January 2015.

of [10-20]% (value) and [5-10]% (volume). The two main competitors of the Parties are Actavis (Teva) and Aurobindo.<sup>41</sup>

- (117) However, the market investigation revealed that Aurobindo's sales in the IMS database are substantially overestimated and its share in the Vaughan Williams I-C is likely below 5%. It follows that, post-merger, there will be only one credible competitor, Actavis (Teva).
- (118) In addition to being the strongest competitors at Vaughan Williams Class I-C level, the Parties also overlap at molecule level (flecainide) and are each other's close competitors in this regard. The Commission has, in fact, previously recognized<sup>42</sup> that 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.<sup>43</sup>
- (119) Furthermore, the UK regulatory system provides for free pricing whereby the price is a function of competition in the market.<sup>44</sup> In particular, there are no regulatory price ceilings. Generics prices are freely determined by pharmaceutical suppliers in accordance with market forces. Consequently, the regulatory system would not prevent the merged entity from raising prices.
- (120) The market investigation provided evidence that the prices of these products (and in particular of flecainide-based products) have been already increasing since 2013.<sup>45</sup> In this context, the market investigation also indicated that the UK market has been experiencing shortages of flecainide that led to substantial increases in the prices of the products based on this molecule (including of the Parties' products). In particular, a UK pharmacy stated that "*There has been a shortage of Mylan's Amiodarone, Flecainide and Disopyramide. [...] In a short period of acute shortage of Flecainide, we were forced to use Meda's Tambocor as the only item available.*"<sup>46</sup> The same pharmacy stated that, the price for Flecainide has increased considerably as "*there is very little generic competition for this molecule*".<sup>47</sup> The data provided by the Notifying Party indeed appear to show an increase in the price of Meda's Tambocor 100mg since a shortage of Mylan's 100 mg Flecainide started.<sup>48</sup>
- (121) The Commission, taking all the above considerations into account, concludes that the Transaction gives rise to serious doubts as to its compatibility with the internal market in relation to the products belonging to the Vaughan-Williams Class I-C in the UK.

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41 The Notifying Party did not provide market share data for its competitors on the market based on the fact that IMS data is not available for the UK.

42 See COMP/M.7379 Mylan/Abbott EPD-DM of 28 January 2015.

43 See COMP/M.7379 Mylan/Abbott EPD-DM of 28 January 2015.

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

45 See response to Q.8 – Questionnaire to Pharmacies in the United Kingdom, Q. 12.1.

46 See response to Q.8 – Questionnaire to Pharmacies in the United Kingdom, Q. 11.

47 See response to Q.8 – Questionnaire to Pharmacies in the United Kingdom, Q.12.1.

48 See response to Commission RFI 3 dated 27 May 2016, question 3.

#### IV.1.3.2. C1C – Cardiac stimulants (excluding cardiac glycosides)

##### Product market definition

- (122) The C1C class includes products indicated for hypotension, chiefly sympathomimetic agents, excluding those sympathomimetic agents with predominant bronchodilatory effects that are used in the treatment of asthma and similar conditions. This class is further divided in two ATC4 classes, namely C1C1 (cardiac stimulants excluding dopaminergic agents and C1C2 containing cardiac dopaminergic agents.
- (123) In previous decisions,<sup>49</sup> the Commission left the exact market definition for this ATC3 class open.

##### *Notifying Party's submission*

- (124) The Notifying Party submits that, in this case, it is not necessary for the Commission to reach a conclusion on the exact market definition, as no competition concerns arise because the Parties' products have different indications, target different patient groups and do not compete with each other.

##### *Commission's assessment*

- (125) As it will be further explained below, the market investigation indicated that products belonging to this class are generally very heterogeneous and sometimes used for completely different indications, even if they contain the same active ingredient. This is the case of the Parties' competing products in the EEA countries where Group 1 affected markets arise as a result of the Transaction.
- (126) In any event, for the purposes of the present case, the exact market definition can be left open, as no serious doubts arise under any plausible alternative market definition.

##### Competitive assessment

- (127) Group 1 affected markets in relation to this category arise in Belgium and Iceland.

##### Belgium

- (128) In Belgium, Mylan competes in the C1C class with a dobutamine-based product, Dobutrex and Meda offers Epipen® with epinephrine as an active ingredient.

##### *Notifying Party's submission*

- (129) The Notifying Party submits that the Parties' products are used for completely different indications. Specifically, while Dobutrex is prescribed to help increase the cardiac output in a failing heart due to heart disease or cardiac surgery, Meda's product is an auto-injector device used to manage potentially life threatening anaphylactic reactions to allergens.

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<sup>49</sup> See COMP/M.4418 Nycomed Group/Altana Pharma of 13 December 2006 and Case M.5253 Sanofi-Aventis/Zentiva of 4 February 2009, See COMP/M.7379 Mylan/Abbott EPD-DM of 28 January 2015.

### *Commission's assessment*

- (130) The market investigation confirmed that Mylan's Dobutrex and Meda's Epipen® are used for completely different indications and therefore do not compete with each other.<sup>50</sup> The market investigation did not reveal any concerns in relation to the C1C ATC3 class.

### Conclusion

- (131) Based on the above considerations, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to products belonging to the C1C ATC3 class in Belgium.

### Iceland

- (132) In Iceland, Mylan markets two C1C products, namely Efedrin (with ephedrine hydrochloride ("HCL") as its active ingredient) and Adrenalin (with epinephrine/Adrenalin tartrat as its active ingredient). Meda, is active with its epinephrine/adrenalin tartrat-based product Epipen®.<sup>51</sup>
- (133) The Notifying Party submits that the Parties' products do not compete with each other as they are used for completely different indications.
- (134) The market investigation confirmed that the Parties' products, despite being classified under the same ATC3 class or, in the case of Mylan's Adrenalin and Meda's Epipen®, even containing the same active ingredient, do not compete on the Icelandic market. Indeed, with specific reference to Mylan's Adrenalin and Meda's Epipen®, which are based on the same molecule (epinephrine or Adrenalin tartrat) and have the same galenic form (F- Parenteral ordinary), the market investigation confirmed that these two products *"are used for different clinical situations and cannot be exchanged."*<sup>52</sup> In particular, while Epipen® is used to manage severe anaphylactic (allergic) reactions and is self-administered by the patient through an auto-injector, Mylan's Adrenalin is an injectable solution used in emergency situations (i.e., it is not self-administered by the patient) in a hospital setting in case of cardiac arrest, bronchial asthma and hypersensitivity reactions.
- (135) Likewise, the market investigation further confirmed the Notifying Party's claim that Meda's Epipen® and Mylan's Efedrin do not compete with each other and are used for completely different indications. Meda's Epipen® is an auto-injector that is used to manage severe anaphylactic reactions. On the contrary, Mylan's Efedrin is an injectable solution indicated for the reduction of hypotension during spinal anaesthesia.
- (136) More generally, the market investigation did not reveal any concerns in relation to the C1C category in Iceland.

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<sup>50</sup> See non-confidential minutes of conference call with Belgian doctor, dated 19 May 2016.

<sup>51</sup> Meda also offers Epipen Junior in Iceland.

<sup>52</sup> See response of Icelandic doctor to Commission's questionnaire to Icelandic KOLs.

## Conclusion

- (137) Based on the above considerations, the Commission considers 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 C1C ATC3 class in Iceland.

### IV.1.3.3. C1E – Nitrites and Nitrates

#### Product market definition

- (138) The ATC3 class C1E includes all nitrites and analogous products and combinations indicated for the treatment of angina pectoris, which is the most common symptom of ischemic heart disease and is characterised as chest pain which results from a situation of insufficient blood flow through one or more coronary arteries, due to the narrowing of blood vessels that lead to a lack of oxygen in the heart. These products, by opening the blood vessels, allow the oxygen to reach the heart.
- (139) In a past case,<sup>53</sup> the Commission's investigation focused on the market for nitrates and nitrites in the UK, but left the exact product market definition open. In another past case, the Commission examined the market for nitroglycerin in Portugal, but ultimately left the exact product market definition open.<sup>54</sup>

#### *Notifying Party's submission*

- (140) The Notifying Party submits that the market should be defined by distinguishing between short-acting nitrates used for the short term control of angina pectoris,<sup>55</sup> which provide immediate symptoms relief in connection with attacks of angina and long-acting nitrates used for the long-term treatment of angina pectoris, which are suitable for maintenance therapy.<sup>56</sup> The Notifying Party also argues that long-acting nitrates and other anti-anginal drugs (falling within the C1D ATC3 category) belong to the same relevant market as they are also used for the long-term treatment of angina pectoris.

#### *Commission's assessment*

- (141) While the market investigation provided indications that a distinction may exist between short-acting nitrates, which are used in acute situations to immediately resolve the pain when patients have an attack and long-acting nitrates that are used as a maintenance therapy for this type of disease, it did not confirm the Parties' claim that other agents (e.g. ivabradine) belonging to other ATC3 classes (as claimed by the Parties) are substitutable with other nitrites and nitrates that are used for the long-term treatment of angina pectoris. In this context one Belgian doctor stated that "*Ivabradine is not in competition with nitrates.*"

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<sup>53</sup> Case M.1403 Astra/Zeneca of 26 February 1999, paragraphs 79 and 80.

<sup>54</sup> Case M.7559 Pfizer/Hospira of 4 August 2015, paragraphs 222-224.

<sup>55</sup> Nitroglycerin sublingual tablets and spray, isosorbide dinitrate sublingual tablets and spray and nitroglycerin & isosorbide dinitrate (intravenous infusions).

<sup>56</sup> Isosorbide dinitrate (tablets), isosorbide mononitrate (tablets) and nitroglycerin (patches).

- (142) The market investigation, however, revealed that, within the C1E category, and more specifically within nitrates that are used for the long-term treatment of angina pectoris, Nitroglycerin in the form of patches should be singled out.
- (143) Nitroglycerin patches generally cover a longer period of efficacy than pills and, with their slow release, cover from 12 up to 16 hours and can be used either during the day or at night. Patches allow the decrease of oral intake of pills and, for this reason, they are often the preferred alternative in patients (especially elderly patients) that have difficulties in swallowing and/or are on too many oral medications. In addition, some patients (and this appears to be quite common) develop headaches with the oral formulations and can therefore be prescribed only patches. Furthermore, doctors consider that observance can be better monitored with patches<sup>57</sup>.
- (144) Based on the above, the Commission considers that nitroglycerin patches are likely to constitute a distinct product market. However, the precise market definition may be left open in this case because no serious doubts arise as to the compatibility of the transaction with the internal market in relation to C1E ATC3 class, irrespective of the exact product market definition.

#### Competitive assessment

- (145) Against the above background, the transaction gives rise to a series of Group 1 affected markets in nitroglycerin patches, namely in Belgium, France, Italy and Luxembourg. Another Group 1 affected market at the narrowest molecule level (isosorbide mononitrate) arises in Portugal. In addition, although the Parties' activities do not overlap at molecule level, Group 1 affected markets arise in Denmark and Sweden at the ATC3 level.

#### Belgium

- (146) In Belgium, the Parties only market nitroglycerin patches: Mylan markets Trinipatch and Meda markets Minitran.
- (147) The Parties' combined market share in nitroglycerin patches amounts to [70-80]% (value) and [60-70]% (volume), with an increment brought by Mylan of [10-20]% (value) and [10-20]% (volume). Based on the information provided by the Parties in the Form CO, three competitors will remain post-merger, namely Novartis ([10-20]%), Takeda ([5-10]%) and Merck ([0-5]%).
- (148) The market investigation revealed, however, that Takeda decided to discontinue the commercialization of its product and is currently only selling out the remaining stock.<sup>58</sup>
- (149) More importantly, Mylan sells its patches (Trinipatch) under an exclusive distribution agreement [...that will be terminated].<sup>59</sup> [...] .<sup>60</sup>During the market investigation,<sup>61</sup>

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<sup>57</sup> See responses to Commission's questionnaire to Belgian C1E KOLs.

<sup>58</sup> See response to Q 12 – Questionnaire to competitors, question 114.

<sup>59</sup> The MA is held by Mylan EPD sprl and is a national MA (both for Luxembourg and Belgium). However, termination of the distribution agreement [...] leads to the retransfer of the MA to [...] or an appointed third party.

<sup>60</sup> See Form RM, submitted by the Notifying Party on 29 June 2016, paras.284-289.



[...it was confirmed that Mylan (pre and post-merger) will not be in a position to renew this contract and distribute Trinipach in Belgium and/all Luxembourg] [...].

### Conclusion

- (150) Based on the above considerations, and in particular on the fact that Mylan will not be in a position to distribute Trinipatch nitroglycerin patches in Belgium [...], the Commission concludes that no serious doubts arise with respect to nitroglycerin patches (and more in general with respect to the C1E ATC3 class) in Belgium.

### France

- (151) In France, the Parties only market the nitroglycerin patches: Mylan markets Trinitrine and Meda markets Discotrine.
- (152) The Parties' combined share in nitroglycerin patches amounts to [60-70]% (value) and [60-70]% (volume), with an increment brought by Mylan of [20-30]% in value and [20-30]% in volume. Other suppliers will remain in the market post-merger, including Novartis, with a share of [10-20]% (value) and [10-20]% (volume), Walgreens Boots with a share of [10-20]% in value and [5-10]% in volume, Pierre Fabre ([5-10]% in value and [5-10]% in volume) and Recordati, with a share of [5-10]% in value and [5-10]% in volume.
- (153) It is noted that, in France, one of the Parties' competitors, Recordati, is active with its nitroglycerin patches only on the basis of a license and supply agreement with Meda. On the basis of this agreement Meda has granted Recordati the [...] right to promote, sell and distribute nitroglycerin patches in France.<sup>62</sup> Meda has also granted Recordati [...] license as to the trademarks associated with the products. The agreement with Recordati was signed in 2002 and is valid until [...]. The agreement will [...].<sup>63</sup> Therefore, Recordati's position in the market is to a large extent dependent on Meda.
- (154) With the exception of Mylan's products, the prices of the other nitroglycerin patches in France are identical as they were all on the market in 1994 when nitroglycerin patches became reimbursed and, for this reason, all received the same price and reimbursement rate from the HAS (*Haute Autorité de Santé*).<sup>64</sup> Mylan's product is slightly cheaper. This is due to the fact that Mylan entered the market only in 2001 and obtained reimbursement status from the HAS in 2003<sup>65</sup>, while all the other

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<sup>61</sup> Conference call with [...] on 8 July 2016. [...].

<sup>62</sup> On the basis of the agreement, Meda withholds the right [...]. Under the agreement, the MA holder is Recordati, [...].

<sup>63</sup> See Parties' supplementary submission dated 3 July 2016.

<sup>64</sup> See Parties' supplementary submission dated 3 July 2016.

<sup>65</sup> Based on the information provided by the Notifying Party in its supplementary submission dated 3 July 2016, when it entered the market, Mylan's Trinitrine was classified as having a substantial ACB, but [...]. As a result, the reimbursement was set at 65%, however in order to be reimbursed Mylan's product price was required to be lower than that of the other nitroglycerin patches. The CEPS (Comité Économique des Produits de Santé) determines that products that have no clinical improvement compared to available treatments can only be reimbursed if the price is lower than those of the available alternatives. Consequently, the price granted by CEPS to Mylan was lower than the other Nitroglycerin products.

products were longer in the market thus received the same price and reimbursement rate.

(155) In addition, in France, there is a strict regulatory framework that generally constrains pharmaceutical suppliers in terms of price setting at all levels of the value chain. In France, the maximum ex-factory prices of reimbursed prescription products (such as the Parties') are fixed, while wholesale and pharmacy margins are regulated. In addition, the price decreases of all drugs, including originators are paced by the entry of generics. As a consequence the ability of pharmaceutical companies to increase prices for these drugs is limited.<sup>66</sup>

(156) Based on the above considerations, the Commission concludes that the transaction does not raise doubts as to its compatibility with the internal market in relation to nitroglycerin patches in France.

### Italy

(157) In Italy, the Parties market the following products: Mylan markets nitroglycerin patches under the brand name of Nitrocor as well as Isosorbide MN named after its active ingredient and Meda markets nitroglycerin patches under the brand names of Epinitril, Minitran and Venitran.

(158) The Parties' combined market share of nitroglycerin patches (narrowest possible level and only product in relation to which the Parties' activities overlap) only amounts to [30-40]% (value) and [30-40]% (volume), with an increment brought by Mylan of [0-5]% (value) and [5-10]% (volume). Numerous competitors will remain post-merger, namely Doc Generici ([10-20]% in value and [10-20]% in volume), Ucb ([10-20]% in value and [10-20]% in volume), Novartis ([10-20]% in value and [10-20]% in volume), Daiichi Sankyo ([5-10]% in value and [5-10]% in volume) and Chiesi ([5-10]% in value and [5-10]% in volume).

(159) It is noted that [...competitor with a market share of 5-10%] is active with its nitroglycerin patches only on the basis of a distribution agreement with Meda concluded in 2012. Therefore, [this competitor's] position in the market is to a large extent dependent on Meda.

(160) The market investigation did not reveal any concerns in relation to nitroglycerin patches or any other product in the C1E category in Italy.

### Conclusion

(161) Based on the above considerations, the Commission concludes that the Transaction does not raise doubts as to its compatibility with the internal market in relation to nitroglycerin patches in Italy.

### Luxembourg

(162) In Luxembourg, the Parties only market nitroglycerin patches: Mylan markets Trinipatch and Meda markets Minitran.

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<sup>66</sup> See COMP/M.7379 Mylan/Abbott EPD-DM of 28 January 2015, footnote 24.

- (163) The Parties' combined market share in nitroglycerin patches (narrowest possible level and only product marketed by the Parties in the class) amounts to [40-50]% (value) and [40-50]% (volume), with an increment brought by Mylan of [20-30]% (value) and [10-20]% (volume). Only one competitor will remain in the market, namely Ucb,<sup>67</sup> with a share of [50-60]% (value) and [50-60]% (volume).
- (164) Similarly to Belgium, Mylan is active in Luxembourg on the basis of its distribution agreement [...] which is being terminated.

#### Conclusion

- (165) Based on the above considerations, and in particular on the fact that Mylan will not be in a position to distribute Trinipatch nitroglycerin patches in Luxembourg [...] the Commission concludes that no serious doubts arise with respect to nitroglycerin patches (and more in general with respect to the C1E ATC3 class) in Luxembourg.

#### Portugal

- (166) In Portugal, the Parties market the following products: Mylan markets Mononitrato de Isossorbido, and Meda markets Isoket based on isosorbide dinitrate, Monoket based on isosorbide mononitrate and Epinitril (nitroglycerin patches).
- (167) At the narrowest possible level, (molecule level: isosorbide mononitrate), the Parties' combined market share amounts to [60-70]% (value) and [60-70]% (volume), with an increment brought by Mylan of [20-30]% (value) and [20-30]% (volume). Several competitors will remain post-merger, namely Astrazeneca with a share of [20-30]% in value and [10-20]% in volume, Pharmakern with a share of [5-10]% in value and [5-10]% in volume and Ferraz Lynce, with a share of [5-10]% in value and [5-10]% in volume.
- (168) The combined market shares of the Parties at any other possible level are moderate and other strong competitors, including Astrazeneca, Merck and Novartis will remain in the market.<sup>68</sup>
- (169) The market investigation did not reveal any concerns in relation to C1E market in Portugal.

#### Conclusion

- (170) Based on the above considerations, the Commission concludes that no serious doubts arise with respect to isosorbide mononitrate (and more in general with respect to the C1E ATC3 class) in Portugal

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<sup>67</sup> On 4 February 2016, Merus Labs International Inc. ("Merus Labs") announced that it had completed the acquisition of rights to, amongst others, Deponit (Ucb's product) in Europe (and in Luxembourg) from Ucb.

<sup>68</sup> It is noted that [...] has a license and supply agreement with Meda in relation to nitroglycerin patches in Portugal.

### Denmark

- (171) In Denmark, the Parties market the following products: Mylan markets Fem-Mono Retard with isosorbide mononitrate as the active ingredient and Meda markets Glytrin based on nitroglycerin and Discotrine (nitroglycerin patches).
- (172) The Parties' activities do not overlap at molecule level. At ATC3 level, the combined market share of the Parties amounts to [20-30]% (value) and [40-50]% (volume), with an increment brought by Mylan of [10-20]% (value) and [10-20]% (volume). Strong and well-established suppliers will remain on the market, including Astrazeneca with a market share of [30-40]% in value and [20-30]% in volume, Novartis with a market share of [10-20]% in value and [5-10]% in volume, Orion with a market share of [10-20]% in value and [5-10]% in volume. If only long-acting nitrates are considered, the combined market shares would be even lower ([10-20]% in value and [20-30]% in volume). Strong competitors will remain on the market, including Astrazeneca with a share of [40-50]% in value and [40-50]% in volume, Novartis, with a share of [20-30]% in value and [10-20]% in volume and Orion, with a share of [10-20]% in value and [10-20]% in volume). The combined market shares are therefore moderate and other well-established suppliers will remain on the market.
- (173) In addition, several characteristics of the Danish market need to be taken into consideration when assessing the impact of the Transaction.
- (174) First, procurement procedures for these products are characterised by the use of tenders which occur frequently and typically exert downward pressure on pricing.
- (175) Second, as also confirmed by the market investigation in this case parallel importers form a significant competitive constraint (especially in terms of pricing) and will continue to constrain the merged entity. This is particularly due to the frequency in which tenders are organized, which facilitates the participation of parallel importers despite their general lack of ability to secure long-term supply.
- (176) Finally, the regulatory framework in Denmark will further constrain the ability of the merged entity to raise prices. As regards reimbursed products (such as the Parties' products), pharmaceutical suppliers have to report their pharmacy purchasing prices on a bi-weekly basis to the DKMA,<sup>69</sup> which then calculates the pharmacy retail price using a fixed mark up.
- (177) The market investigation did not reveal any concerns in relation to the C1E ATC class in Denmark.

### Conclusion

- (178) Based on the above considerations, the Commission concludes that the Transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to products belonging to the C1E ATC3 class in Denmark, irrespective of the market definition.

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<sup>69</sup> Danish Medicines Agency.

## Sweden

- (179) In Sweden, the Parties market the following products: Mylan markets Isosorbide MN, and Meda markets Sorbangil based on isosorbide dinitrate, Nitroglycerin and Glirtin based on nitroglycerin and Minitran (nitroglycerin patches).
- (180) The Parties' activities do not overlap at molecule level. At ATC3 level, the combined market share of the Parties is [10-20]% (value) and [30-40]% (volume), with an increment brought by Mylan of [5-10]% (value) and [5-10]% (volume). If only long-acting nitrates are considered, the combined market shares would be even lower ([10-20]% in value and [10-20]% in volume). Several other competitors will remain on the market, including Astrazeneca, Medivir, Pharmpole and Deyco.
- (181) In addition, several characteristics of the Swedish market need to be taken into consideration when assessing the impact of the Transaction.
- (182) In Sweden, the pharmacy purchase price and the pharmacy margin are set by TLV,<sup>70</sup> thereby effectively determining a fixed national pharmacy retail price. In addition, the pricing for products in the reimbursement system is set through government tenders. These tenders occur every month and only the winner will be reimbursed in Sweden. In such a system, high market shares are not necessarily indicative of the Parties' ability to affect the conditions of sale pre- or post-merger.
- (183) In addition, the market investigation confirmed that parallel importers form a significant competitive threat that constrain (especially in terms of pricing) and will continue to constrain the merged entity. This is particularly due to the high frequency in which tenders are organized in Sweden (on a monthly basis) which 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.<sup>71</sup>
- (184) The market investigation did not reveal any concerns in relation to the C1E class in Sweden.

## Conclusion

- (185) Based on the above considerations, the Commission concludes that the Transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to products belonging to the C1E ATC3 class in Sweden, irrespective of the market definition.

### IV.1.3.4. C7B – Beta-Blocking agents, combinations

#### Product market definition

- (186) The ATC3 class C7B is comprised of beta-blockers combined with other drugs. Beta-blockers lower the blood pressure by reducing the heart rate and force of cardiac contraction, whereas the other classes of hypertension medicines apply different chemical means to dilate the blood vessels that become constricted in hypertension.

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<sup>70</sup> Tandvårds- och läkemedelsförmånsverket, i.e. the Swedish Dental and Pharmaceutical Agency.

<sup>71</sup> See COMP/M.7379 Mylan/Abbott EPD-DM of 28 January 2015.

- (187) In *Astra/Zeneca*,<sup>72</sup> the Commission concluded that a combined betablocker (C7B) cannot be substituted by a plain betablocker (C7A).

*Notifying Party's submission*

- (188) The Notifying Party submits that the market should be defined at ATC3 level or at a combination of both C7A and C7B level.
- (189) In any event, for the purpose of this decision, the exact product market definition can be left open, as no serious doubts arise in relation to C7A class under any plausible market definition.

Competitive assessment

- (190) A Group 1 affected market would arise only at ATC3 level in Ireland.

Ireland

- (191) In Ireland, Mylan markets Atenic, with atenolol/chloralidone as its active ingredient, which is indicated for the treatment of essential hypertension in patients whose blood pressure is not adequately controlled on atenolol or chlortalidone alone and Meda's markets Prestim based on bendroflumethiziade/timolol, which is indicated for the treatment of mild to moderate hypertension.
- (192) At the only level in which a Group 1 affected market arises, i.e. ATC3 level, the combined market shares of the Parties are moderate ([20-30]% in value and [30-40]% in volume), with an increment brought by Meda amounting to [0-5]% in value and [0-5]% in volume. In addition, strong well-established competitors, including Menarini ([40-50]% in value and [30-40]% in volume), AstraZeneca ([20-30]% in value and [20-30]% in volume) and Novartis ([5-10]% in value and [5-10]% in volume) will remain in the market post-transaction.
- (193) The market investigation did not reveal any concerns in relation to the products belonging to the C7A class in Ireland.

Conclusion

- (194) Based on the above considerations, the Commission concludes that the Transaction, irrespective of the market definition, does not give rise to serious doubts as to its compatibility with the internal market in relation to the products belonging to the C78 category in Ireland.

IV.1.3.5. Nicardipine (Italy), Lercanidipine and Diltiazem (Portugal) (C8A)

Product market definition

- (195) Both Mylan and Meda market calcium channel blockers nicardipine and nifedipine<sup>73</sup> in Italy and lercanidipine and diltiazem in Portugal. These molecules belong to the ATC3 class C8A which is comprised of plain calcium antagonists that are primarily

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<sup>72</sup> See COMP/M.1403 Astra/Zeneca of 26 February 1999.

<sup>73</sup> The Parties both market nifedipine based products. However, the combined market shares ([5-10]% in value and [10-20]% in volume) do not reach the Group 1 market threshold.

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 diltiazem.

- (196) In previous decisions,<sup>74</sup> the Commission concluded that combining multiple ATC2 classes consisting of numerous hypertension drugs would be too wide for market definition purposes. The Commission has also assessed ATC3 class C8A and concluded that DHPs and non-DHPs belong to the same market. It also found that various types of antihypertensive drugs including beta blockers, calcium antagonists, ACE inhibitors form separate markets.<sup>75</sup> In *Mylan/Abbott EPD-DM*, the Commission considered whether the market should be defined at molecule level (diltiazem and verapamil), but ultimately left the market definition open.<sup>76</sup>

*Notifying Party's submission*

- (197) The Notifying Party submits that the market should include all products characterized under the C8A ATC3 class and possibly be defined even more widely to include the fixed combination products falling under ATC3 classes C9B3 (Ace Inhibitors/calcium channel blockers) and C9D3 (sartans/calcium channel blockers), as products belonging to these ATC3 classes are, in the Notifying Party's view, exercising increasing competitive pressure on the molecules belonging to the C8A category.

*Commission's assessment*

- (198) The market investigation confirmed the Commission's finding in *Mylan/Abbott EPD-DM*<sup>77</sup> that there are several molecules that share mechanism of action and indications with diltiazem and nifedipine, such as amlodipine, felodipine, gallopamil, nifedipine, and which can therefore in some cases and for some patients be prescribed alternatively by physicians. This partial overlap in therapeutic uses does not however imply any particular economic substitution patterns across calcium antagonist drugs.
- (199) Mylan has developed and commercialises 8 calcium antagonist products based on different molecules (amlodipine; manidipine; nifedipine; diltiazem; felodipine; lercanidipine; nifedipine; and verapamil) in Italy and 5 calcium antagonist products (amlodipine; diltiazem; felodipine; lercanidipine and verapamil) in Portugal. Meda markets several calcium antagonist products based on different molecules (for example in Italy, Meda markets 3 calcium antagonist products based on nifedipine, nifedipine and lercanidipine respectively). 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.

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<sup>74</sup> See COMP/M.1403 Astra/Zeneca of 26 February 1999, and COMP/M.1878 Pfizer/Warner-Lambert of 22 May 2000.

<sup>75</sup> See COMP/M.1878 Pfizer/Warner-Lambert of 22 May 2000, paragraphs 23-25.

<sup>76</sup> See COMP/M.7379 Mylan/Abbott EPD/DM of 28 January 2015, paragraph 85.

<sup>77</sup> See COMP/M.7379 Mylan/Abbott EPD/DM of 28 January 2015.

(200) Moreover, as previously recognized by the Commission, competing products based on the same molecule are typically closer substitutes than products based on different molecules.<sup>78</sup>

(201) For these reasons, the Commission assessed the impact of the Transaction on the basis of the narrowest molecule-based market definition.

#### Competitive assessment

(202) On the basis of the narrowest plausible molecule-based market definition, the proposed transaction gives rise to one Group 1 affected markets for nicardipine in Italy, one Group 1 affected market in relation to lercandipine in Portugal and one Group 1 affected market in relation to diltiazem in Portugal.

#### Italy

(203) In Italy, the Parties market the following nicardipine-based products: Mylan markets Nicardipine, and Meda markets Bionicard.

(204) At the narrowest possible level (molecule level: nicardipine)<sup>79</sup> the Parties' combined market shares is [80-90]% (value) and [80-90]% (volume), with an increment brought by Meda of [20-30]% (value) and [20-30]% (volume). Post-merger, Italfarmaco will remain on the market with a share of [10-20]% (value) and [10-20]% (volume). The market investigation confirmed that other competitors will also remain on the market with competing products, namely Officina Farmaceutica Fiorentina, Merck, Francia Farmaceutici and Grunental.

(205) The market investigation provided indications that the prescription of products based on nicardipine is not very common in Italy (other molecules such as amoldipine, nifedipine, barnidipine, lacidipine, lercanidipine are more commonly prescribed).

(206) This is confirmed by the small size of the market which has been sharply declining from EUR 412 743 in 2013 to EUR 203 531 in 2015.

(207) The market investigation did not reveal any concerns with respect to nicardipine in Italy.

#### Conclusion

(208) Based on the above considerations, the Commission concludes that the transaction, irrespective of the market definition, does not raise serious doubts as to its compatibility with the internal market in relation to nicardipine in Italy.

#### Portugal (lercanidipine)

(209) In Portugal, the Parties market the following lercanidipine-based products: Mylan markets Lercanidipina and Meda markets Zanicor.

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<sup>78</sup> See COMP/M.7379 Mylan/Abbott EPD/DM of 28 January 2015.

<sup>79</sup> The Parties also both market nifedipine based products in Italy. However, the combined market shares ([5-10]% in value and [10-20]% in volume) do not reach the Group 1 market threshold.



- (210) At the narrowest possible level (molecule level: lercanidipine) level, the Parties' combined market share is [30-40]% in value and [20-30]% in volume, with an increment brought by Mylan of [10-20]% in value and [10-20]% in volume. Well-established competitors will continue to be active post-merger, including Teva, with a share of [20-30]% in value and [20-30]% in volume, Recordati, with a share of [10-20]% in value and [10-20]% in volume and Novartis, with a share of [5-10]% in value and [5-10]% in volume.
- (211) The market investigation did not reveal any concern with respect to lercanidipine in Italy.

#### Conclusion

- (212) Based on the above considerations, the Commission concludes that the transaction does not raise serious doubts as to its compatibility with the internal market in relation to lercanidipine in Portugal.

#### Portugal (diltiazem)

- (213) In Portugal, the Parties market the following diltiazem based products: Mylan markets Diltiazem and a branded diltiazem Dilfar and Meda markets Etizem and Herbesser.
- (214) At the narrowest possible level (molecule level: diltiazem), the Parties' combined market share is [70-80]% (value) and [80-90]% (volume), with a significant increment brought by Mylan of [20-30]% (value) and [30-40]% (volume). Only one competitor (Sanofi) would remain in the market with a significant share ([20-30]% in value and [10-20]% in volume). While Novartis and Grupo Tecnimede are also present, their share is negligent: not exceeding [0-5]%.
- (215) In *Mylan/Abbott EPD-DM*, the Commission excluded serious doubts in relation to this market on the basis that the market leader Rottapharm Madaus would remain on the market and constrain the merged entity.<sup>80</sup> However, since then, Meda acquired Rottapharm Madaus and has consequently become the market leader in Portugal with a share of [40-50]%.<sup>81</sup> Mylan is now acquiring that market leader.

#### Conclusion

- (216) Based on the above considerations, the Commission concludes that the Transaction gives rise to serious doubts as to its compatibility with the internal market in relation to the supply of diltiazem in Portugal.

### IV.1.3.6. Benazepril (France) (C9A)

#### Product market definition

- (217) Both Mylan and Meda market benazepril, which is an anti-hypertension product. Benazepril is an ACE inhibitor used primarily in treatment of hypertension, congestive heart failure, and heart attacks, and also in preventing the renal and retinal complications of diabetes. It belongs to the ATC3 class C9A which is comprised of

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<sup>80</sup> See COMP/M.7379 Mylan/Abbott EPD/DM, of 28 January 2015, paragraph 101.

<sup>81</sup> See <http://www.meda.se/investors/rottapharm-acquisition/>.

plain ACE inhibitors that are primarily used for the treatment of high blood pressure and congestive heart failure.

- (218) In its investigation into 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.<sup>82</sup> In its latest merger decision dealing with ACE-inhibitors, the Commission analysed the transaction at the narrowest possible level (molecule level: tandolapril), but ultimately left the market definition open. In previous merger decisions, the Commission left the product market definition open in relation to ACE inhibitors.<sup>83</sup>

#### *Notifying Party's submission*

- (219) 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.

#### *Commission's assessment*

- (220) In *Mylan/Abbott EPD-DM*, the Commission found 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 benazepril is even the only ACE inhibitor that can be used. Indeed, the overlap in some indications does not imply substitution patterns across ACE inhibitors.<sup>84</sup>
- (221) Mylan has developed and commercialises several ACE inhibitors based on different molecules in parallel. 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.
- (222) In any event, the product market definition in relation to benazepril can be left open in this case as no serious doubts arise in relation to benazepril irrespective of the market definition.

#### Competitive assessment

- (223) On the basis of the narrowest molecule-based market definition, the proposed Transaction gives rise to one Group 1 affected market in France.

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<sup>82</sup> See COMP/39612 Perindopril (Servier) case, press release from July 9, 2014 ([http://europa.eu/rapid/press-release\\_IP-14-799\\_en.htm](http://europa.eu/rapid/press-release_IP-14-799_en.htm)).

<sup>83</sup> See COMP/M.1403 Astra/Zeneca of 26 February 1999, paragraph 18, COMP/M.1878 Pfizer/Warner-Lambert of 22 May 2000, paragraph 24, COMP/M.2517 Bristol Myers Squibb/Du Pont of 9 August 2001, paragraph 14; COMP/M.3354 Sanofi-Synthelabo/Aventis of 26 April 2004, paragraph 82.

<sup>84</sup> See COMP/M.7379 Mylan/Abbott EPD/DM of 28 January 2015, paragraph 116.

### France

- (224) The Parties market the following benazepril-based products: Meda markets Briem and Cibacen and Mylan markets Benazepril.
- (225) At the narrowest possible level (molecule level: benazepril), the Parties' combined market share is [50-60]% (value) and [50-60]% (volume), with an increment brought by Mylan of [10-20]% in value and [10-20]% in volume. Well-established competitors will remain in the market post-merger, namely Stada, with a share of [10-20]% in value and [20-30]% in volume, Teva, with a share of [10-20]% in value and [10-20]% in volume and Aurobindo, with a share of [5-10]% in value and [5-10]% in volume.
- (226) In addition, in France, there is a strict regulatory framework that constrains pharmaceutical suppliers in terms of price setting at all levels of the value chain. In France, the maximum ex-factory prices of reimbursed prescription products (such as the Parties') are fixed while wholesale and pharmacy margins are regulated. In addition, the price decreases of all drugs, including originators are paced by the entry of generics. As a consequence the ability of pharmaceutical companies to increase prices for these drugs is limited.<sup>85</sup>
- (227) The market investigation did not reveal any concerns in relation to benazepril in France.

### Conclusion

- (228) Based on the above considerations, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to benazepril in France.

#### IV.1.3.7. Other Group 2 and Group 3 markets in the cardio therapeutic area

- (229) 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 Czech Republic, France, Germany, Lithuania, Norway, Slovenia, the Netherlands, Poland and in the UK;*
  - *ATC3 class C1C in Austria, Belgium, Germany, France and in Norway;*
  - *ATC3 class C4A in France;*
  - *ATC3 class C7A in France;*
  - *ATC3 class C7B in France;*
  - *ATC3 class C8A in Portugal and Spain;*
  - *ATC3 class C9A in France; and*
  - *ATC3 class C1E in Italy, Luxembourg and Norway.*

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<sup>85</sup> See COMP/M.7379 Mylan /Abbott EPD-DM of 28 January 2015, footnote 24.

- (230) Within these ATC classes several galenic forms are marketed and give rise to technically affected markets. However, the market investigation did not provide sufficient evidence that the product markets should be defined on the basis of the galenic form (except for nitroglycerin patches as explained above) or on whether the drug is sold against a prescription or OTC.
- (231) On all of these markets the combined market share of the Parties are moderate to low and / or the increment is below [0-5]%. 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 Sanofi, Pfizer, Aguettant, Teva, Fresenius, Sirton Pharm, Pro Med, Novartis, Life Medical.
- (232) The market investigation did not provide any indication that competition issues would arise in these markets. Based on the above considerations, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to any of these markets.

### **ALIMENTARY TRACT AND METABOLISM**

- (233) 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 (antiulcerants), cramps and spasm of the stomach, intestines and bladder, irritable bowel syndrome and constipation. Both Parties are present in these therapeutic areas with several marketed products, which belong to various ATC3 classes, as described in detail below.

#### IV.1.3.8. Ranitidine (A2B)

##### Product market definition

- (234) The A2B class, antiulcerants, encompasses a variety of drugs used to treat a range of common disorders 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. omeprazole-based products).
- (235) 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).<sup>86</sup> In the most recent case, the market investigation regarding ranitidine indicated that there seems to be one-way substitutability of H2 antagonists (including ranitidine) by acid pump inhibitors, and therefore for the assessment of H2 antagonists and ranitidine in particular, the relevant product market was considered to be wider than the molecule, but narrower than the ATC3 class, likely comprising ATC4 classes A2B1 and A2B2.<sup>87</sup>

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<sup>86</sup> See COMP/M.1846 Glaxo Wellcome/Smithkline Beecham of 8 May 2000 and COMP/M.3354 Sanofi-Synthelabo/Aventis of 26 April 2004.

<sup>87</sup> See Case M.7379 Mylan/Abbott EPD-DM of 28 January 2015.

- (236) 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.

*Notifying Party's submission*

- (237) The Notifying Party supports a market definition comprising ATC4 classes A2B1 and A2B2, which would include both H2 antagonists (such as *ranitidine*) as well as proton pump inhibitors (for example *omeprazole*, *pantoprazole*).

*Commission's assessment*

- (238) For the purposes of the present case, it can be left open whether the relevant product market for antiulcerants and for ranitidine in particular should be defined at the molecule level, ATC4 level (H2 antagonists) or should comprise both A2B1 and A2B2 classes (H2 antagonists and proton pump inhibitors) since no serious doubts arise under any plausible market definition.

Competitive assessment

- (239) In the A2B class Group 1 affected markets arise only in Sweden.

Sweden

- (240) In Sweden Mylan markets several antiulcerants: ranitidine, which is an H2 antagonist (A2B1 class) and three proton pump inhibitors (A2B2 class) namely omeprazole-based products (Asimax and Omeprazole) and lansoprazole- and pantoprazole-based products (both named after their respective active ingredient). Meda markets in Sweden only one antiulcerant, ranitidine, under the name Inside.
- (241) On the market combining A2B1 and A2B2 antiulcerants (i.e. H2 antagonists and proton pump inhibitors), the Parties' combined market share is very small: [0-5]% by value and [0-5]% by volume. At the narrowest level, the market for *ranitidine*, the Parties' combined market share is [20-30]% by value (Mylan [5-10]%, Meda [20-30]%) and [30-40]% by volume (Mylan [10-20]%, Meda [10-20]%). Post-merger a number of strong competitors would remain in the market, including the market leader GSK, holding a market share of [30-40]% (value) and [20-30]% (volume), as well as Novartis with a market share of [10-20]% (value) and [20-30]% (volume), Allergan with a market share of [10-20]% (value) and [10-20]% (volume) and Orifarm with a market share of [5-10]% (value) and [5-10]% (volume).
- (242) A Group 1 affected market would arise if the market were defined at the molecule level and was further limited to only OTC products. Under this market definition the combined market share is [30-40]% (value) and [40-50]% volume, with the increment brought by Meda of [0-5]% (value) and [5-10]% (volume). Strong and well-established competitors would remain active on the market, including GSK, with market share of [40-50]% (value) and [30-40]% (volume), Orifarm, Evolan and three competitors with a market share between [0-5]%, including Novartis and Allergan.
- (243) The market investigation did not reveal any concerns in relation to A2B class in Sweden and ranitidine in particular.
- (244) In addition, several characteristics of the Swedish market need to be taken into consideration when assessing the impact of the Transaction.

- (245) In Sweden, the pharmacy purchase price and the pharmacy margin are set by TLV,<sup>88</sup> thereby effectively determining a fixed national pharmacy retail price. In addition, the pricing for products in the reimbursement system is set through government tenders. These tenders occur every month and only the winner will be reimbursed in Sweden. In such a system, high market shares are not necessarily indicative of the Parties' ability to affect the conditions of sale pre- or post-merger.
- (246) In addition, the market investigation confirmed that parallel importers form a significant competitive threat that constrain (especially in terms of pricing) and will continue to constrain the merged entity. This is particularly due to the high frequency in which tenders are organized in Sweden (on a monthly basis) which 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 Sweden.<sup>89</sup>

### Conclusion

- (247) Based on the above considerations, the Commission concludes that the Transaction does raise serious doubts as to its compatibility with the internal market in relation to A2B class in Sweden and ranitidine in particular.

#### IV.1.3.9. Plain antispasmodics and anticholinergics (A3A)

##### Product market definition

- (248) The A3A class covers all plain synthetic and natural antispasmodic and anticholinergic drugs, which are used to relieve cramps and spasms of the stomach, intestines and bladder.
- (249) In past decisions the Commission adopted a market definition approach based on the ATC3 level. The Commission also identified a possible distinction between the OTC and prescription segments.<sup>90</sup>
- (250) More recently,<sup>91</sup> the Commission found that the relevant market should be defined at the molecule level, at least as concerns mebeverine. The market investigation revealed that mebeverine is unlikely to be fully replaceable in the treatment of its main indications, in particular irritable bowel syndrome (IBS), as it has a longer action which is unique compared to other molecules on the market and contrary to alternative products it provides a long term retarded effect, thus is particularly useful in chronic conditions.<sup>92</sup> In addition, some of the alternative products tend to cause greater side effects than mebeverine.
- (251) In the same decision the Commission assessed the market for pinaverium bromide, which also belongs to the same class of antispasmodics and anticholinergics. With regard to this molecule, the Commission found that pinaverium bromide has no

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<sup>88</sup> Tandvårds- och läkemedelsförmånsverket, i.e. the Swedish Dental and Pharmaceutical Agency.

<sup>89</sup> See COMP/M.7379 Mylan/Abbott EPD-DM of 28 January 2015.

<sup>90</sup> COMP/M.5253 Sanofi-Aventis/Zentiva of 4 February 2009.

<sup>91</sup> COMP/M.7379 Mylan/Abbott EPD-DM of 28 January 2015.

<sup>92</sup> COMP/M.7379 Mylan/Abbott EPD-DM of 28 January 2015, paragraph 214.

specificities when compared to other antispasmodics and anticholinergics available, with the exception of mebeverine, which, as described above constitutes a separate product market.

*Notifying Party's submission*

- (252) The Notifying Party submits that the relevant market as regards antispasmodics and anticholinergics should be defined at the molecule level.

*Commission's assessment*

- (253) For the purpose of this case, the Commission considers that mebeverine constitutes a distinct product market. As regards the remaining molecules in the class it can be left open whether the relevant product market encompasses all the antispasmodics and anticholinergics except for mebeverine, or whether each of the molecules concerned constitutes a distinct product market, since no serious doubts arise under any plausible alternative market definition in relation to antispasmodics and anticholinergics.

Competitive assessment

- (254) On the basis of the market definition set out above, no affected market arise in the area of antispasmodic and anticholinergic drugs.

IV.1.3.10. Metoclopramide (France) (A3F)

Product market definition

- (255) Gastroprokinetics are used for dyspepsia and gastro-oesophageal reflux; they enhance gastrointestinal mobility by increasing the frequency of the contractions in the small intestine or by making them stronger. In previous cases the Commission concluded that gastroprokinetics should not be considered as part of the product market together with anti-emetics and anti-nauseants (ATC3 class A4A).<sup>93</sup> More recently, the Commission assessed the market for metoclopramide at the molecule level.<sup>94</sup>

*Notifying Party's submission*

- (256) The Notifying Party submits that within gastroprokinetics, benzamides, such as *metoclopramide*, are all substitutable for the treatment of nausea or vomiting.

*Commission's assessment*

- (257) In any event, for the purpose of this case, it can be left open whether the relevant market should be defined at the ATC3 level, at more granular level or at molecule level, since no serious doubts arise under any plausible market definition.

Competitive assessment

- (258) In the A3F class, Group 1 affected markets arise in relation to metoclopramide in France.

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<sup>93</sup> COMP/M.1846 Glaxo Wellcome/Smithkline Beecham of 8 May 2000.

<sup>94</sup> COMP/M.1846 Glaxo Wellcome/Smithkline Beecham of 8 May 2000, paragraphs 16-23.

## France

- (259) In France, Mylan markets three gastroprokinetics, each named after their active ingredient: Domperidone, Metoclopramide and Trimubutine. Domperidone and Metoclopramide are indicated to relieve nausea and vomiting, while Trimubutine is used to treat irritable bowel syndrome, by slowing down or normalizing the abnormal movements of the bowel. Meda's only gastroprokinetic in France is Anausin, based on *metoclopramide*.
- (260) A Group 1 market arises only at the molecule level. The Parties' combined market share is however moderate: [30-40]% by value (Mylan [30-40]% and Meda [0-5]%) and [40-50]% by volume (Mylan [40-50]% and Meda [0-5]%). Post-merger a number of strong competitors will remain present, including Sanofi with a market share of [30-40]% by value and [20-30]% by volume, Techni Pharma holding a market share of [10-20]% by value and [5-10]% by volume and Novartis with a market share of [10-20]% by value and [10-20]% by volume.
- (261) Finally, the Commission notes that metoclopramide is reimbursed in France and, therefore a strict regulatory framework concerning pricing and reimbursement of prescription medicines applies. As a consequence the ability of pharmaceutical companies to increase prices for these drugs is generally limited.<sup>95</sup>
- (262) The market investigation did not reveal any concerns in relation to the A3F class in France.

## Conclusion

- (263) Based on the above considerations, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to metoclopramide in France.

### IV.1.3.11. Hepatic protectors and lipotropics (A5B)

#### Product market definition

- (264) The A5B class covers various products indicated for treatment of acute and chronic liver disease. In past decisions, the Commission considered that all hepatic protectors and lipotropics constitute one relevant market.<sup>96</sup> In another case the Commission considered that all products which belong to the A5B class constitute one product market irrespective of Rx/OTC distinction, since the conditions of acute or chronic liver disease are inappropriate for self-medication.<sup>97</sup>

#### *Notifying Party's submission*

- (265) The Notifying Party supports a market definition comprising all products belonging to A5B class without further segmentation on the basis of the galenic form or their availability (Rx or OTC), with the exception of Belgium and Luxembourg. The Notifying Party submits that in Belgium and Luxembourg the market should be

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<sup>95</sup> COMP/M.7379 Mylan/Abbott EPD-DM of 28 January 2015, footnote 24.

<sup>96</sup> Case IV/M.950 Hoffmann La Roche/Boehringer Mannheim of 4 February 1998.

<sup>97</sup> COMP/M.5253 Sanofi-Aventis/Zentiva of 4 February 2009.



defined at molecule level, since the products offered by the Parties in these countries have completely different indications. Lactulose-based product offered by Mylan can be used in the treatment of hepatic encephalopathy, which is the occurrence of confusion, altered levels of consciousness and coma due to liver failure caused by accumulation of toxic substances. Conversely, the product offered by Meda, Legalon, based on silymarin, is indicated to support healthy liver function and is used in the treatment of liver diseases, especially liver steatosis (fat accumulation in the liver), for the supportive therapy of chronic inflammatory liver diseases and liver cirrhosis (a slowly progressing disease in which healthy liver tissue is replaced with scar tissue).

#### *Commission's assessment*

- (266) The market investigation confirmed the Notifying Party's claims as to the different indications of lactulose and silymarin. The prescribers clarified that lactulose (apart from its usage as a laxative) is indeed prescribed for the treatment of hepatic encephalopathy, which is a complication of a liver disease, for example the chronic liver cirrhosis. This means, however, that lactulose is not treating the underlying cause of the problem, namely the liver disease as such and thus, usually is used in parallel to other treatments. As for silymarin, the practitioners first underlined that they do not prescribe it. They clarified that silymarin is believed to improve liver performance, it is sold over the counter, but there is no scientific evidence that it is an effective treatment for liver disease.
- (267) The market investigation also revealed that another molecule offered by one of the Parties for the treatment of liver conditions, adementionine, has yet another role. This product is prescribed for the treatment of intrahepatic cholestasis, the condition that impairs the release of bile from liver cells, which impairs the liver function. Prescribers explained that in clinical routine adementionine would be administered in the form of an oral tablet; in acute situations, like poisoning with mushrooms, an injection of adementionine would be administered.
- (268) The Commission concludes, based on the results of the market investigation, that for the purpose of this case, each of the molecules concerned used for treatment of various liver-related diseases, namely lactulose, silymarin and adementionine, should be considered as a distinct product market.

#### Competitive assessment

- (269) On the basis of the market definition set out above, the Transaction does not lead to any overlaps in the area of hepatic protectors and lipotropics.

#### IV.1.3.12. Drugs for constipation (lactulose) (A6A)

##### Product market definition

- (270) The A6A class encompasses a variety of drugs prescribed and available OTC, used for the treatment of constipation. They are divided depending on their laxative action into ATC4 classes: faecal softening laxatives (A6A1), stimulant laxatives (A6A2), bulk-forming laxatives (A6A3), enemas (A6A4), osmotic laxatives with (A6A7) and without electrolytes (A6A6).

- (271) In previous cases the Commission considered that all laxatives constitute one relevant market.<sup>98</sup> Similarly, in another case where drugs for constipation were analysed 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 question whether the market should be defined at the ATC4 or ATC3 level.<sup>99</sup>
- (272) In a more recent case, the Commission analysed overlaps in one of the laxatives, namely lactulose, which is categorised under the A6A6 class of osmotic laxatives without electrolytes. In that case, the Commission found that lactulose is a relatively old molecule and that there exist newer and more effective products treating the same conditions, for example macrogol. On that basis the Commission concluded that other molecules may be substitutable to lactulose and thus the relevant product market for lactulose should be defined at least as comprising other products in the ATC4 class A6A6 without further segmenting the market in the basis of galenic form or the Rx/OTC distinction.<sup>100</sup>

*Notifying Party's submission*

- (273) The Notifying Party submits that in view of the fact that all laxatives are known to be comparable in ease of use, the relevant market should be defined at the ATC3 level, without a further segmentation on the basis of the galenic form or the Rx/OTC distinction. The Notifying Party provided internal documents demonstrating that the Parties consider competitors from other ATC4 classes (e.g. A6A2 and A6A4 classes) to be their main competitors.

*Commission's assessment*

- (274) For the purposes of this case the product market definition regarding lactulose as well as any drugs for the treatment of constipation can be left open as no serious doubts arise in relation to lactulose and any other drugs for the treatment of constipation.

Competitive assessment

- (275) In the A6A class Group 1 affected markets arise in Ireland, Norway, Portugal, Spain and Sweden.

Ireland

- (276) In Ireland, Mylan markets Colofac, lactulose-based drug for the treatment of constipation, classified under A6A6 class. Mylan is the originator of lactulose. Meda markets Molaxole, which includes macrogol(s)/potassium/sodium as the active ingredient and is classified under A6A7 class. Therefore at the ATC4 level and also at the molecule level the Transaction does not lead to any overlaps in Ireland.
- (277) At the overall A6A level (all drugs for the treatment of constipation) the Transaction does not lead to a Group 1 affected market in Ireland (the combined market shares by value or volume are below 30%).

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<sup>98</sup> COMP/M.3853 Solvay/Fournier of 18 July 2005, paragraphs 16-23.

<sup>99</sup> COMP/M.6280 Procter&Gamble/Teva of 30 September 2011, paragraph 19.

<sup>100</sup> COMP/M.7379 Mylan/Abbott EPD-DM of 28 January 2015, paragraph 203.

- (278) Thus the Parties' combined market share is moderate, and post-Transaction a number of strong competitors will remain present, in particular the market leader Norgine with the market share of [40-50]% by value and [10-20]% by volume, as well as Wockhardt with the market share of [10-20]% by value and [30-40]% by volume.

#### Conclusion

- (279) Based on the above considerations, the Commission concludes that irrespective of the precise product market definition the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to drugs for the treatment of constipation in Ireland.

#### Norway

- (280) In Norway, Mylan markets Duphalac, lactulose-based drug for the treatment of constipation, classified under A6A6 class. Mylan is the originator of lactulose. In Norway, Meda markets Moxalole with macrogol(s)/potassium/sodium as the active ingredient, classified under A6A7 class and two other products: Vi Sibliin and Lunelax, both with plantago ovata as the active ingredient, classified under A6A3 class. Therefore, at the ATC4 level and also at the molecule level the Transaction does not lead to any overlaps in Norway.
- (281) At the overall A6A level (all drugs for the treatment of constipation) the Transaction leads to a Group 1 affected market in Norway only when measured by volume of sales. The combined market share of the Parties amounts to [10-20]% by value (Mylan [10-20]% and Meda [5-10]%) and to [50-60]% by volume (Mylan [40-50]% and Meda [10-20]%).
- (282) On a market comprising all drugs for constipation available OTC (irrespective of their galenic form), the Parties' combined market share amounts to [20-30]% by value (Mylan [10-20]% and Meda [5-10]%) and to [60-70]% by volume (Mylan [40-50]% and Meda [10-20]%). The Commission notes that the very big discrepancy between the market shares measured by value of sales and by volume of sales is due to the fact that Mylan's product, Duphalac is very cheap, much cheaper than other products in the class. This has also been confirmed by the results of the market investigation. A number of competitors will remain present: Boehringer Ingelheim with a market share of [10-20]% by value and [20-30]% by volume, three other players (J&J, Ferring and AS Produksjonslab) with a market share above 10% each by value and less than 5% by volume and Novartis with a market share of [5-10]% by value and [5-10]% by volume.
- (283) The market investigation revealed that Duphalac by Mylan is indeed a very strong brand in Norway, but its closest competing products are lactulose generics, not the products offered by Meda. Furthermore, competitors present on the Norwegian market, when asked about the leading drugs for the treatment of constipation in Norway mentioned various products: most often Movicol offered by Norgine, Duphalac by Mylan, but also Microlax offered by J&J and Klyx (by Ferring). None of the respondents to the market investigation considered that products offered by Meda are closely competing with Mylan's Duphalac.

### Conclusion

- (284) Based on the above considerations, the Commission concludes the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to drugs for the treatment of constipation in Norway.

### Portugal

- (285) In Portugal, Mylan markets Duphalac, lactulose-based drug for the treatment of constipation, classified under A6A6 class. Mylan is the originator of lactulose. Meda markets several products based on macrogol(s)/potassium/sodium, plantago ovata, plantago ovata in combination with senna and gelatin glycerol as the respective active ingredients, and they are classified under various ATC4 classes (A6A2, A6A3, A6A4 and A6A7) class. Therefore at the ATC4 level and also at the molecule level the Transaction does not lead to any overlaps in Portugal.
- (286) At the overall A6A level (all drugs for the treatment of constipation) the Transaction leads to a Group 1 affected market in Portugal only by volume: the combined market share amount to [10-20]% by value (Mylan [0-5]% and Meda [10-20]%) and [40-50]% by volume (Mylan [40-50]% and Meda [0-5]%). Numerous competitors will remain present with market shares above 10% by value (Recordati [10-20]%, Ferraz Lynce with [10-20]%, Boehringer Ingelheim with [10-20]% and Norgine with [10-20]% market share).
- (287) The market investigation did not reveal any concerns in relation to the A6A class in Portugal.

### Conclusion

- (288) Based on the above considerations, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to drugs for the treatment of constipation in Portugal.

### Spain

- (289) In Spain, Mylan markets Duphalac, a lactulose-based drug for the treatment of constipation, classified under A6A6 class. Mylan is the originator of lactulose. Meda markets Molaxole, which includes macrogol(s)/potassium/sodium as the active ingredient, Cenat (with guma guar and plantago ovata), Hodernal (with paraffin oil), Plantaben and Plantago Ovata Madaus (plantago oavata) and Agiolax (with plantago oavata and senna as active ingredients). Therefore at the ATC4 level and also at the molecule level the Transaction does not lead to any overlaps in Spain.
- (290) At the overall A6A level (all drugs for the treatment of constipation) the Parties' combined market share in Spain amounts to [20-30]% by value (Mylan [10-20]% and Meda [10-20]%) and [50-60]% by volume (Mylan [30-40]% and Meda [20-30]%). Post-merger several strong competitors will remain present including J&J with the market share of [10-20]% by value, Recordati ([10-20]%), Norgine ([10-20]%) as well as Boehringer Ingelheim and Lainco with a market share exceeding 5% each.
- (291) The combined market shares on the hypothetical market comprising all drugs for constipation sold on prescription would reach [30-40]% by value (Mylan [30-40]% and Meda [5-10]%) and [70-80]% by volume (Mylan [70-80]% and Meda [5-10]%). In this case, the combined market share is high only by volume, since Mylan's

product is particularly inexpensive; furthermore the increment stemming from the transaction is relatively small. Very high market share of prescribed Duphalac in Spain is due to the fact that contrary to the situation in other Member States, in Spain Duphalac is not available OTC.

### Conclusion

- (292) Based on the above considerations, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to drugs for the treatment of constipation in Spain.

### Sweden

- (293) In Sweden, Mylan markets Duphalac, lactulose-based drug for the treatment of constipation, classified under A6A class. Mylan is the originator of lactulose. Meda's A6A products in Sweden are Lactulose, Moxalole, Lunelax and Resulax with lactulose, macrogol(s)/potassium/sodium, plantago ovata and sorbitol as the respective active ingredients.
- (294) At the overall A6A level (all drugs for the treatment of constipation) the Parties' combined market share in Sweden amounts to [30-40]% by value (Mylan [10-20]% and Meda [20-30]%) and [40-50]% by volume (Mylan [10-20]% and Meda [30-40]%). Post-merger several competitors will remain present including Norgine ([10-20]%), J&J ([10-20]%), Ferring ([10-20]%), Boeringer Ingelheim ([5-10]%), Galen ([5-10]%), Allergan ([5-10]%) and Novartis ([5-10]%).
- (295) At the narrowest possible level (molecule: lactulose), the Parties' combined market share in Sweden amounts to [50-60]% in value and [50-60]% in volume., with an increment brought by Mylan of [5-10]% (value) and [5-10]% (volume). The current market leader Allergan<sup>101</sup> will remain on the market to constrain the merged entity with a market share of [40-50]% (value) and [50-60]% (volume). In any event, as mentioned above and as stated in *Mylan/Abbott EPD-DM*, the relevant product market for lactulose should be defined at least as comprising other products in the ATC4 class A6A6 without further segmenting the market in the basis of galenic form or the Rx/OTC distinction.<sup>102</sup>
- (296) In addition, several characteristics of the Swedish market need to be taken into consideration when assessing the impact of the Transaction.
- (297) In Sweden, the pharmacy purchase price and the pharmacy margin are set by TLV, thereby effectively determining a fixed national pharmacy retail price. In addition, the pricing for products in the reimbursement system is set through government tenders. These tenders occur every month and only the winner will be reimbursed in Sweden. In such a system, high market shares are not necessarily indicative of the Parties' ability to affect the conditions of sale pre- or post-merger.
- (298) In addition, the market investigation confirmed that parallel importers form a significant competitive threat that constrain (especially in terms of pricing) and will continue to constrain the merged entity. This is particularly due to the high frequency

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<sup>101</sup> Allergan was recently acquired by Teva.

<sup>102</sup> COMP/M.7379 Mylan/Abbott EPD-DM of 28 January 2015, paragraph 203.

in which tenders are organized in Sweden (on a monthly basis) which 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 Sweden.

- (299) The market investigation did not reveal any concerns in relation to the A6A class in Sweden.

#### Conclusion

- (300) Based on the above considerations, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to drugs for the treatment of constipation in Sweden.

#### IV.1.3.13. Multivitamins without minerals for paediatric use (A11B)

##### Product market definition

- (301) The ATC3 class A11B class comprises all multivitamin combinations that do not contain minerals; they are usually used in prevention of diet deficiencies, as well as for strength and immunity enhancement. The class is segmented in four ATC4 segments based on the target group: A11B1 contains prenatal multivitamins, A11B2 – paediatric multivitamins, A11B3 – geriatric and A11B4 – other multivitamins without minerals.
- (302) In Teva/Barr, the Commission considered the market for multivitamins without minerals in Poland. The market investigation in that case indicated that the market should be defined at the ATC3 level.<sup>103</sup>

##### *Notifying Party's submission*

- (303) The Notifying Party submits that the relevant market should include all multivitamins without minerals for children included in ATC 4 class A11B2 including both products sold directly to pharmacies, as well as products sold in the mass market (e.g. supermarkets and drug stores). The Notifying Party notes that the distinction based on the galenic form is not relevant for product market definition purposes as all multivitamins for children concerned are marketed in liquid form.

##### Competitive assessment

- (304) In the A11B class, Group 1 affected markets arise in Portugal.

##### Portugal

- (305) In Portugal, Mylan markets Vi-Dailin with ascorbic acid, cyanocobalamin, ergocalciferol, nicotinamide, retinol, riboflavin and thiamine as active ingredients. Mylan is the originator of this molecule combination. Vi-Dailin is used to treat or prevent vitamin deficiencies in children and it is sold OTC in pharmacies. Meda markets Dagravit 8, which includes ascorbic acid, colecalciferol, nicotinamide, pantothenic acid, pyridoxine, retinol, riboflavin and thiamine as active ingredients. It is also used to prevent and treat vitamin deficiencies in children. Both products are OTC products available only in pharmacies.

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<sup>103</sup> COMP/M.5295 Teva/Barr of 19 December 2008.

- (306) The market investigation provided indications that, with specific reference to multivitamins products for paediatric use (and more specifically for products suitable for infants below one year of age), products that are sold on the mass market (e.g. supermarkets, drug stores) do not exercise a competitive constraint on the products sold in pharmacies as those products cannot typically be dispensed to infants below one year of age.<sup>104</sup> Indeed, Farmodietica's product Absorvit Infantil sold in the mass market and suitable only for children above 3 years of age is only a distant competitor to Parties' products whose brands Vi Dailin and Dagravit 8 seem to have strong brand recognition in the pharmacy market.
- (307) On the OTC market for multivitamins for children sold in pharmacies the combined market shares of the Parties amount to [80-90]% in value and [90-100]% in volume with an increment brought by Meda [10-20]% in value and [20-30]% in volume. The only remaining competitor would be Bayer having market share of [10-20]% by value and less than 5% in volume.
- (308) As the market share data indicates, Bayer's product seems to be more expensive than the Parties' products thus having in practice insignificant presence in volume. As a result, the Transaction would reduce the number of competitors from 3-to-2 combining the two cheapest products in a free price setting OTC environment.

#### Conclusion

- (309) Based on the above considerations, the Commission concludes that serious doubts arise as regards the compatibility of the Transaction with the internal market in relation to multivitamins without minerals in Portugal.

#### IV.1.3.14. A11C - Vitamin A and D, including combinations of the two

##### Product market definition

- (310) The A11C class comprises all vitamins A and D including combinations of the two, as well as products containing halibut or cod liver oil. The class is segmented into three ATC4 levels: A11C1 containing vitamin A (also in combination with vitamin E), A11C2 containing vitamin D and A11C3 with combinations of vitamin A and vitamin D.
- (311) In past decisions, the Commission considered the market for vitamins A and D, in particular products based on alfacalcidol and on colecalciferol, and ultimately left open as to whether these two products constitute separate product markets or the whole ATC3 class (A11C) should be considered as one relevant product market.
- (312) In any event, the exact product market definition can be left open because the Transaction does not give rise to serious doubts as to its compatibility with the internal market under any plausible market definition.

##### Competitive assessment

- (313) In the A11C class, Group 1 affected markets arise in France.

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<sup>104</sup> See response to Q. 12 – Questionnaire to competitors, question 55.

### France

- (314) In France, Mylan markets Vitamin D3 with colecalciferol as its active ingredient. Colecalciferol is one of the five forms of vitamin D and is used to prevent rickets in infants and young children, as food supplement in case of inadequate nutrition or lack of sun and for pregnant and nursing women. Mylan markets Zyma D and Zymaduo with colecalciferol and colecalciferol/fluorine as their respective active ingredient. Colecalciferol/fluorine is indicated for the prevention of tooth decay and rickets in infants between 0-18 months. All the Parties' products are offered in oral liquid form and all are reimbursed in France.
- (315) At the ATC3 level, the combined market share amounts to [20-30]% by value (Mylan [0-5]% and Meda [20-30]%) and [30-40]% by volume (Mylan [0-5]% and Meda [30-40]%). Strong competitors remain present, including the market leader Crinex, with markets share of [30-40]% by value and [20-30]% by volume, Leo Pharma holding the market share of [10-20]% by value and [20-30]% by volume and D B Pharma with around [5-10]% share (by value and by volume).
- (316) On a plausible product market encompassing products including colecalciferol, i.e. including products with colecalciferol and combinations of colecalciferol with fluorine the Parties' combined market share amounts to [40-50]% by value (Mylan [0-5]% and Meda [30-40]%) and to [60-70]% by volume (Mylan [0-5]% and Meda [50-60]%).
- (317) Even in this worst case scenario, the increment stemming from Mylan is rather small and post-merger four competitors will remain present. They include Crinex, the market leader holding the market share of [40-50]% (by value) and [30-40]% by volume, Servier with [5-10]% share in value and [5-10]% in volume and Novartis with the share of [0-5]% in value and [0-5]% in volume.
- (318) The market investigation did not reveal any concerns in relation to the A11C class in France.

### Conclusion

- (319) Based on the above considerations, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to colecalciferol and its combinations in France.

#### IV.1.3.15. Other Group 2 and Group 3 markets in the area of alimentary tract and metabolism

- (320) In addition to the Group 1 markets analysed above, there is a number of Group 2 and Group 3 affected markets in the area of alimentary tract and metabolism, specifically:
- *ATC3 class A2B in Sweden;*
  - *ATC3 class A3A in Belgium, Italy and the UK;*
  - *ATC3 class A3F in France;*
  - *ATC3 class A4A in Italy;*
  - *ATC3 class A5B in Germany;*



- *ATC3 class A6A in Austria, Bulgaria, France, Germany, Ireland, Latvia, Lithuania and Luxembourg;*
  - *ATC3 class A10J in Sweden;*
  - *ATC3 class A11C in France; and*
  - *ATC3 class A13A in France.*
- (321) 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.
- (322) On these markets the combined market share of the Parties are moderate to low and / or the increment is below [0-5]%. 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 Pfizer, Sanofi, Novartis, Teva, GlaxoSmithKline, Bayer, AstraZeneca and Takeda.
- (323) The market investigation did not reveal any concerns in relation to Group 2 and Group 3 markets in the area of alimentary tract and metabolism.
- (324) Based on the above considerations, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to any of these markets.

## **DERMATOLOGICALS**

- (325) This therapeutic area includes products that are agents applied directly to the skin for treatment of various kinds of skin conditions. More particularly, the relevant products in this therapeutic area for the purposes of the proposed Transaction are (i) topical viral infection products, categorized in the ATC 3 class D6D, which are products principally used for a wide and distinct variety of viral infections, from the treatment of cold sores (herpes simplex labialis) to the treatment of genital warts and (ii) antiseptics and disinfectants, categorized in the ATC 3 class D8A, which covers all dermatological antiseptic preparations for human use, including soaps and shampoos with antiseptic/disinfectant properties.

### IV.1.3.16. Topical Viral Infection Products (D6D)

#### Product market definition

- (326) The products categorized in ATC 3 class D6D are used for a wide and distinct variety of viral infections, from the treatment of cold sores (herpes simplex labialis) to the treatment of genital warts. The ATC 3 class is further segmented into ATC 4 classes D6D1, which contains topical antivirals, and D6D9, which contains other topical products used for symptomatic treatment of viral infections.
- (327) Mylan markets Aciclovir, which is indicated for treatment of herpes simplex virus ("HSV" or also known as cold sore) infections of the skin and mucous membranes including initial and recurrent genital herpes. Meda's product is Aldara (imiquimod). Meda is the originator of imiquimod which is an immune response modifier for the treatment of different forms of non-melanoma skin cancer such as small areas of

actinic keratosis and superficial basal cell carcinoma (the most frequent skin tumor that rarely metastasizes), and external genital warts in men and women, an infection caused by the human papilloma virus some subtypes of which are associated with cervical cancer.

- (328) In previous decisions, the Commission considered that the ATC 3 level is appropriate for the assessment of topical viral infection products.<sup>105</sup> In its decision *Novartis/Hexal*, the Commission considered a separate market for OTC and Rx products.<sup>106</sup>
- (329) In a more recent case *Glaxosmithkline/Novartis Vaccines Business (Excl. Influenza)/Novartis Consumer Health Business*, the Commission limited its market analysis of D6D products to topical antivirals used for the treatment of cold sores, excluding products that are indicated for the treatment of warts.<sup>107</sup>
- (330) The Notifying Party submits that the market should be defined at ATC 3 level thereby considering the products' indication with a further subdivision between the virus/disease targeted by the products.
- (331) For the purpose of the present case, the precise market definition can be left open, since no serious doubts arise under any plausible market definition in relation to topical viral infection products.

#### Competitive assessment

- (332) In the D6D ATC class, the Transaction gives rise to two Group 1 markets, namely in France and Italy.

#### France

- (333) The Parties market two different molecules in France, namely Aciclovir (Mylan) and Imiquimod (Meda). The Parties combined market share in ATC 3 class D6D limited to prescription products ("Rx") is [60-70]% in value and [30-40]% in volume. The increment comes from Mylan with [5-10]% in value and [20-30]% in volume. The size of the entire French topical virus infection products market (ATC 3 class D6D) is around EUR 24.6 million in 2015 and has been declining from EUR 29 million in 2013.
- (334) The indications of Parties' products are different based on the summary product characteristics ("SPC"). Specifically, Mylan's Aciclovir is indicated for the treatment of genital infection with the herpes simplex virus (HSV), whereas Meda's Aldara (imiquimod) is used to treat different forms of skin cancer and genital warts. Therefore, the Parties' products are not indicated for the same group of patients and are not substitutable.

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<sup>105</sup> COMP M.1846 Glaxo Wellcome/Smithkline Beecham of 8 May 2000, paragraph. 31; COMP M.3751 Novartis/Hexal of 27 May 2005, page 7.

<sup>106</sup> COMP M.3751 Novartis/Hexal of 27 May 2005, paragraph 3.

<sup>107</sup> COMP M.7276 Glaxosmithkline/Novartis Vaccines Business (Excl. Influenza)/Novartis Consumer Health Business of 28 January 2015, paragraph 197.

- (335) In addition, the Parties' products have a different mode of action and different clinical and safety profiles. Finally, the Parties' products belong to two different ATC 4 classes: while Mylan's product falls under ATC 4 class D6D1 (topical antivirals), Meda's product is categorized under the category D6D9 (other topical products used in viral infections) which indicates that aciclovir and imiquimod are not each other's closest competitors.
- (336) In any event, the Parties' products face competition, at the molecule level, from several competitors, such as Servier ([5-10]%), Teva ([0-5]%), GSK ([0-5]%), Stada ([0-5]%), Novartis ([0-5]%), and numerous other competitors with market shares below [0-5]%.
- (337) The market investigation did not reveal any concerns in relation to the D6D class in France.

### Conclusion

- (338) Based on the above considerations, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to topical viral infection products in France.

### Italy

- (339) The Parties market two different molecules in Italy, namely Aciclovir (Mylan) and Imiquimod (Meda). The Parties combined market share in ATC 3 class D6D limited to prescription products ("Rx") is [30-40]% in value and [20-30]% in volume. The increment in value comes from Mylan with [10-20]%, the increment in volume comes from Meda ([5-10]%). The size of the entire Italian topical virus infection products market (ATC 3 class D6D) is around EUR 21.2 million in 2015 and has been increasing slightly from EUR 20.3 million in 2013.
- (340) As can be derived from the summary of product characteristics ("SPC") of the Parties' products for Italy, Mylan's aciclovir is indicated for the treatment of genital infection with the herpes simplex virus (HSV), whereas Meda's Aldara (imiquimod) is used to treat different forms of skin cancer and genital warts. Imiquimod has a different mode of action than aciclovir. Therefore, the Parties' products are not indicated for the same group of patients and are not substitutable.
- (341) In addition, the Parties' products have a different mode of action and different clinical and safety profiles. Finally, the Parties' products belong to two different ATC 4 classes: while Mylan's product falls under ATC 4 class D6D1 (topical antivirals), Meda's product is categorized under the category D6D9 (other topical products used in viral infections) which indicates that acyclovir and imiquimod are not each other's closest competitors.
- (342) In any event, the Parties' products face competition, at the molecule level, from several competitors, such as Teva ([10-20]%), Stada ([10-20]%), IfC ([10-20]%), GSK ([5-10]%), Doc Generici ([5-10]%) and numerous other competitors with market shares below 5%.
- (343) The market investigation did not reveal any concerns in relation to the D6D class in Italy.

### Conclusion

- (344) Based on the above considerations, the Commission concludes that the Transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to topical viral infection products in Italy.

#### IV.1.3.17. Antiseptics and disinfectants (D8A)

##### Product market definition

- (345) The ATC 3 class D8A comprises all dermatological antiseptic preparations for human use, including soaps and shampoos with antiseptic/disinfectant properties. Excluded from ATC 3 class D8A are wound healing agents (D3A), topical antibacterials (D6A), topical viral infection products (D6D), combinations of corticosteroids with antibacterials (D7B), anti-acne preparations (D10A) and ectoparasiticides (P3). ATC 3 class D8A is further segmented into two ATC 4 classes: one that covers all antiseptics and disinfectants, excluding hand products (D8A1) and one that covers hand antiseptics and disinfectants (D8A2).
- (346) Mylan markets two products, namely Hexamidine and Povidone-Iodine, both named after their respective active pharmaceutical ingredients. Meda's product is Betadine, which has povidone-iodine as the active ingredient. Betadine has been on the market for more than 50 years and is sold in OTC and Rx versions.
- (347) In previous decisions, the Commission analysed the market for antiseptics and disinfectants at the ATC 3 level.<sup>108</sup> In its decision *Reckitt Benckiser/Boots Healthcare International*, the Commission left open whether also some D3A products belong to the same market as D8A products.<sup>109</sup>
- (348) The Parties support a market definition at the level of ATC 3 class D8A as all antiseptic agents are more or less equally effective, comparable in ease of use and indicated for the same kinds of treatment.
- (349) For the purpose of the present case, the exact product market definition can be left open, as irrespective of the precise product market definition the Transaction raises serious doubts in relation to the povidone-iodine market in France where the Parties are each other's closest competitors.

##### Competitive assessment

- (350) In the D8A ATC3 class, the Transaction gives rise to one Group 1 market, at the molecule level, namely povidone-iodine in France.

##### France

- (351) In France, Mylan markets hexamidine and a generic povidone-iodine, while Meda markets Betadine, a branded product based on povidone-iodine. The size of the entire

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<sup>108</sup> COMP M.1378 Hoechst/Rhône-Poulenc of 9 August 1999, paragraph 55; COMP M.3354 Sanofi-Synthélabo/Aventis of 26 April 2004, paragraph 23.

<sup>109</sup> COMP M.4007 Reckitt Benckiser/Boots Healthcare International of 6 January 2006, paragraph 24 *et seq.*

French antiseptics and disinfectant products market (ATC 3 class D8A) is around EUR 113.3 million in 2015 and has been declining from EUR 117.5 million in 2013.

- (352) The Parties' combined market share at the molecule level, regardless whether limited to OTC or Rx versions is [90-100]%. Betadine is the clear market leader in France in this segment ([90-100]% market share) and enjoys strong brand recognition. Mylan is the only generic product directly competing at a molecule level with Betadine. The Parties themselves confirm that the two povidone-iodine products are each other closest competitors and that no other supplier offers a povidone-iodine based antiseptic and disinfectant agent in France.
- (353) Mylan's generic product is ca. [30-40]% cheaper than Meda's Betadine (based on the pharmacy prices for 125 ml, dosage 0.1). Since 2013, Mylan's sales of povidone-iodine in its Rx version have tripled in value and volume and its market share has over three years increased from [0-5]% to [0-5]%. Indeed, as confirmed by the Parties, Meda has lost [0-5]% market share in terms of value and [5-10]% in terms of volume from 2013 to 2015, while Mylan has gained [0-5]% in value and [5-10]% in volume in the same period.
- (354) As regards the OTC version, Mylan's sales have also increased albeit less strikingly, namely rising from [5-10]% to [5-10]% in volume. This slower increase appears to be caused by patients continuously preferring Meda's well-known Betadine branded product.
- (355) Therefore, following the Transaction, the merged entity would have an incentive to discontinue the generic povidone-iodine product and/or to increase its prices in particular as regards the OTC version, which is not price-regulated in France, without facing any direct competitive constraint at the molecule level.
- (356) The market investigation revealed concerns in relation to povidone-iodine based products in France. The competitor Pierre Fabre states that Betadine seems to be preferred by prescribers and patients<sup>110</sup> and Stada considers that patients are not willing to change.<sup>111</sup>

### Conclusion

- (357) Based on the above considerations, the Commission concludes that serious doubts arise as regards the compatibility of the Transaction with the internal market in relation to povidone-iodine in France, where the Parties are close and only competitors.

#### IV.1.3.18. Other Group 2 and Group 3 markets in the dermatological products area

- (358) In addition to the Group 1 market analysed above, there are two Group 3 affected markets in the dermatologicals products area, specifically:

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<sup>110</sup> See response of a Competitor to questionnaire Q12-Competitors, question 142.

<sup>111</sup> See response of a Competitor to questionnaire Q12-Competitors, question 143.

- *ATC 3 class D6D in Italy and Spain.*
- (359) 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.
- (360) On these markets the combined market share of the Parties are moderate to low and / or the increment is below [0-5]%. 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 Bial, Grupo Indokern, GSK, Ifc, Perrigo, Stada and Teva.
- (361) 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.

### **GENITO-URINARY SYSTEM AND SEX HORMONES**

- (362) This therapeutic area includes products that are agents for gynaecological, sexual (e.g. contraceptives) and hormone therapy applications. In particular, the relevant products in this therapeutic area for the purposes of the proposed Transaction are (i) gynaecological antiseptics, categorized in the ATC 3 class G1D (gynaecological antiseptics), (ii) substances used for hormone replacement therapies for oestrogen insufficiencies and menopause, categorized in the ATC 3 class G3C (oestrogens) and (iii) progestogens for the treatment of dysmenorrhoea, endometriosis, infertility, irregular menstrual cycles and pre-menstrual syndrome, categorized in ATC 3 class G3D (progestogens, excluding G3A, G3F). The Parties are both active in these three ATC 3 classes.

#### IV.1.3.19. Gynaecological Antiseptics (G1D)

##### Product market definition

- (363) The ATC 3 class G1D includes gynaecological antiseptics products.
- (364) In this class, Mylan markets its product Lindemil (aluminium and potassium / benzalkonium chloride). Lindemil is a vaginal wash that is used as a disinfectant of the external vaginal area which is indicated to treat the symptoms associated with vaginal infections. Meda's product is Betadine Vaginal (povidone-iodine) which is a rinse-off medicated cleansing solution for the treatment of mild to moderate vaginal infections and for cleaning the vaginal area.
- (365) Both Lindemil and Betadine-Vagina are sold OTC. OTC products may be advertised to the public at large and physicians do not need to intervene in the purchase of these products. In most cases, consumers choose OTC products themselves and purchases are not reimbursed. Therefore the product markets for OTC products are typically based on indication rather than on individual products or molecules as pharmacists recommend various products based on their indication profile and price.

- (366) In line with this, the Notifying Party submits that the relevant product market for gynaecological antiseptics is broader than the ATC 3 class G1D and should include all products that are used as a disinfectant of the external vaginal area and that are indicated to treat the symptoms associated with vaginal infections. This would specifically include products belonging to other ATC 3 classes including other gynaecological products.
- (367) The results of the market investigation indeed suggest that several products from ATC 3 classes G1D, G2X and D8A are used interchangeably as effective treatment for patients suffering of vaginal infections. Indeed, according to market investigation respondents, neither Lindemil nor Betadine Vaginal are unique and several substitutable options are available, such as Rosalgin (belonging to ATC 3 class G2X), Melagyn by Gynea Laboratorios (KernPharma) and Cristalmina (chlorhexidine, categorized in ATC 3 class D8A) by Laboratorios Salvat. The market investigation also indicated that the Parties' products are rather old and have numerous side-effects. Physicians therefore prefer to prescribe improved, better alternative products, such as Melagyn.
- (368) It therefore follows that in view of the OTC nature of the products, the market for vaginal disinfectants is most likely wider than ATC 3 class G1D encompassing all disinfectants adapted to treat vaginal infections. However, the exact product market definition can be left open for the purpose of the present case, since no serious doubts arise under any plausible alternative market definition in relation to vaginal disinfectants.

#### Competitive assessment

- (369) In the G1D class, the Transaction gives rise to one Group 1 market, namely Spain.

#### Spain

- (370) The Parties market two different molecules in Spain. Mylan sells aluminium and potassium / benazlkonium chloride under the brand name Lindemil, whereas Meda markets povidone-iodine under the brand name Betadine Vaginal. The products of both Parties are sold OTC.
- (371) The Parties' products do not overlap at molecule level. While the Parties' combined market share at ATC 3 class G1D would reach [90-100]%, as already explained above, G1D class is not the relevant market definition for vaginal disinfectants as many other OTC branded products such as Rosalgin, Melagyn or Cristalmina compete with the Parties' products. Indeed, [...] considers [...] Betadine Vaginal in Spain to be in competition with several products from different ATC3 classes, namely Ginejuvent, Rosalgin and Lindemil.
- (372) In a product market consisting of Mylan's Lindemil, Meda's Betadine Vaginal and Rosalgin (Angelini) and Cristalmina (Salvat), the combined market share of the Parties is [10-20]% in value and <[0-5]% in volume. The size of this market is EUR 9 million, having grown from EUR 8% in 2013. Cristalmina ([60-70]% in value and [90-100]% in volume) and Rosalgin ([20-30]% in value, <5% in volume) achieve significant sales.
- (373) Since 2013, Cristalmina has been the cheapest product on this product market. The average public pharmacy prices of Cristalmina, Rosalgin, Lindemil Betadine Vaginal and Ginejuvent have developed uniformly for the last four years and their relative

price position to each other, with Cristalmina being the cheapest and Rosalgin being the most expensive product has not changed since then.

- (374) In addition, the market investigation did not raise any concerns in relation to gynaecological antiseptics in Spain.

#### Conclusion

- (375) Based on the above considerations, the Commission concludes that the Transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to gynaecological antiseptics in Spain.

#### IV.1.3.20. Oestrogens (G3C)

##### Product market definition

- (376) The ATC 3 class G3C comprises all substances used for hormone replacement therapy for oestrogen insufficiencies and menopause. In addition, all products containing a selective oestrogen receptor modulator ("SERM") in combination with an oestrogen and indicated for the short-term treatment of menopausal symptoms together with the prevention of osteoporosis are also categorized in ATC 3 class G3C. There are no further ATC 4 class segments.
- (377) The Parties supply products based on the same molecule, estradiol, which belongs to this ATC 3 class. Mylan markets its product under the brand name Zumenon (estradiol) and Meda's products are branded Dermestril (estradiol) and Elleste Solo (estradiol).
- (378) The Notifying Party submits that the appropriate market definition should include ATC 3 classes G3C (oestrogens), G3E (androgens) and G3F (oestrogen/progestogen combinations). Products classified under these three ATC3 classes are all used for hormone replacement therapy ("HRT") for oestrogen insufficiencies and menopause. HRT aims to replace oestrogens and relieve the symptoms in post-menopausal women.
- (379) The Commission previously considered the ATC3 class G3F in *Solvay/Fournier*.<sup>112</sup> In that case the Commission assessed the market at multiple ATC 3 levels, including the classes G3C, G3E and G3F. However, the Commission ultimately left open the exact market definition.
- (380) The respondents to the market investigation in this case suggest that estradiol is not unique and can be substituted with other oestrogens categorized in ATC 3 class G3C, while this is not possible with products classified in ATC3 classes G3F or G3E, which contain combination products, for instance with progestogens. Estradiol is usually not prescribed in a combination therapy. Moreover, all the progestogen combination products are very different from estradiol and the oestrogen products of ATC3 class G3C.
- (381) As regards the different galenic forms, the market investigation provided indications that oestrogen tablets and patches may be part of different markets, or at the very least

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<sup>112</sup> COMP M.3853 Solvay/Fournier of 18 July 2005 paragraph 27.



are not close substitutes. This is because they do have different side effects and are indicated for different patient groups.

- (382) In this context, the Parties explain that oestrogens are usually administered in oral form (tablets), as they are easy to use. But a treatment via the oral route requires the patient to take higher dosages, because 90% of the administered dose is inactivated due to metabolization. Oestrogens stimulate the production of triglycerides (a type of fat). Higher levels of plasma triglycerides are associated with cardiovascular diseases. Therefore, it is advised to treat patients having elevated level of triglycerides with oestrogens in other forms than oral tablets. Similarly, patients suffering from lactose intolerance are generally not to be treated with oral solid forms, as lactose is used as excipient for the oestrogen preparations. For these two types of patients oestrogen patches are a useful alternative to oral solid tablets to avoid unwanted side-effects.
- (383) Based on the above, a market definition limited to oestrogen products classified in ATC3 class G3C appears likely. However, for the purposes of the present case, it can be left open how the relevant product market for oestrogens should be defined, since no serious doubts arise under any plausible alternative market definition in relation to oestrogens.

#### Competitive assessment

- (384) In the G3C class, the Transaction gives rise to two Group 1 markets, namely Portugal and the UK.

#### Portugal

- (385) Both Mylan and Meda market a product based on estradiol. Mylan supplies its branded product Zumenon, in the galenic form of oral solid ordinary tablets. Meda offers Dermestril, an estradiol product in the galenic form of patches. The Parties' combined market share at molecule level is [40-50]% in value and volume. The size of the Portuguese oestrogen based products market (ATC 3 class G3C) is around EUR 478 000 in 2015.
- (386) The Notifying Party submits that they are not each other's closest competitors in the G3C market, as they market a different galenic form. As can be derived from the results of the market investigation, oestrogen tablets and patches are used by different sub-groups of patients given the different side-effects. When considering the different galenic forms, Mylan's estradiol tablets have a market share of [30-40]% in Portugal and are competing with Esteve's estradiol tablets ([30-40]%) and Puig's estradiol tablets (also [30-40]% market share). Meda is the market leader in Portugal with its estradiol patches with a market share of [50-60]%. It faces competition from Novartis ([20-30]%), Bayer ([10-20]%) and Teva ([10-20]%), all of which also market estradiol patches in Portugal.
- (387) Moreover, the market investigation did not reveal any concerns in relation to oestrogens in Portugal.

#### Conclusion

- (388) 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 oestrogens in Portugal.

## UK

- (389) Both Mylan and Meda market products based on estradiol. Mylan supplies its branded product Zumenon, only in the galenic form of oral solid ordinary tablets. Meda offers two estradiol products in the UK. Both are branded Elleste Solo. Meda supplies Elleste Solo as oral solid ordinary tablets as well as patches. The size of the British oestrogen products market (ATC 3 class G3C) is around EUR 4.5 million in 2015.
- (390) The Parties' highest combined market share at the molecule level, limited to the galenic form oral solid ordinary tablets, is [50-60]% in value ([20-30]% in volume). The increment comes from Mylan with [5-10]% in value ([0-5]% in volume). Post-merger, the Parties will be constrained by several competitors, which are active on the market with a tablet product. In particular, Novartis markets its branded product Merimono, Bayer sells Progynova, resource Medical offers Bedol and Kyowa Hakko Kirin markets Adgyn on this market.
- (391) In addition, as the market shares illustrate, the Parties' products are amongst the most expensive ones on the market, translating in low volume based market share. This, in the context of free pricing in the UK where competition takes place primarily on price, means that should the merged entity attempt to further increase the prices, their volume based market share would become even smaller as there are numerous cheaper alternative products available on the market.
- (392) Finally, the market investigation did not reveal any concerns in relation to the oestrogens in the UK.

## Conclusion

- (393) Based on the above considerations, the Commission concludes that the Transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to oestrogens in the United Kingdom.

### IV.1.3.21. Progestogens, excluding G3A, G3F (G3D)

#### Product market definition

- (394) The ATC 3 class G3D encompasses progestogen replacement products which are used for the treatment of dysmenorrhea, menorrhagia, endometriosis, infertility, menopause, PMS, puerperal depression and breast cancer. This ATC 3 class is not further segmented in ATC 4 classes.
- (395) The Parties supply products based on two different molecules. Mylan markets dydrogesterone under the brand name Duphaston while Meda sells progesterone which is branded Utrogestan.
- (396) The Notifying Party submits that the appropriate market definition is ATC3 class G3D, as the products categorized in this class can generally be prescribed for the same indications.

- (397) The Commission has previously assessed the market for progestogens in its decision *Monsanto/Pharmacia & Upjohn*, where the market investigation indicated that the ATC3 level is appropriate for assessing the market.<sup>113</sup>
- (398) The respondents to the market investigation in this case suggested that products based on different molecules and categorized in ATC3 class G3D, such as levonorgestrel,<sup>114</sup> medroxyprogesterone<sup>115</sup> and progesterone<sup>116</sup> compete with the Parties' molecules dydrogesterone and progesterone. It follows that the appropriate market definition for progestogens is most likely wider than molecule, possibly encompassing the entire ATC3 class G3D.

#### Competitive assessment

- (399) In the G3D class, the Transaction gives rise to one Group 1 market, namely Austria.

#### Austria

- (400) Mylan supplies its branded product Duphaston (dydrogesterone) and Meda sells Utrogestan (progesterone). The size of the Austrian progestogen-based products market (ATC 3 class G3D) is around EUR 1.8 million in 2015.
- (401) The Parties' combined market share at the ATC3 level limited to the galenic form oral solid ordinary tablets is [70-80]%. Mylan's product is the market leader with a market share of [40-50]%. Meda is a strong number 2 with a market share of [30-40]%. Exeltis, the number 3, which markets a branded generic under the name Arefam, has a market share of [10-20]% and Merck & Co's market share is [5-10]%.
- (402) Based on the market investigation, the Parties' products seem to be close competitors. In particular, Parties' brands Duphaston and Utrestogan benefit from strong brand recognition amongst the Austrian prescribers community, despite the availability of cheaper generic products, such as Arefam by Exeltis. This seems to be confirmed by the data indicating that generic penetration is limited, reaching only 15%. The rest of the market is dominated by branded, originator products. This, together with the fact that in Austria, physicians are not allowed to prescribe pharmaceutical products by INN and pharmacists are not allowed to substitute prescribed brands for generic products, limits the competitive constraint effect of generics in Austria.

#### Conclusion

- (403) Based on the above considerations, the Commission concludes that the Transaction gives rise to serious doubts as to its compatibility with the internal market in relation to progestogens in Austria.

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<sup>113</sup> COMP M.1835 Monsanto/Pharmacia & Upjohn of 30 March 2000, paragraph 23.

<sup>114</sup> See responses of two Competitors to questionnaire Q12-Competitors, question 170.

<sup>115</sup> See response of a Competitor to questionnaire Q12-Competitors, question 170.

<sup>116</sup> See response of a Competitor to questionnaire Q12-Competitors, question 170.

#### IV.1.3.22. Urinary Incontinence Products (G4D)

##### Product market definition

- (404) The ATC 3 class G4D comprises urinary incontinence products. It is further subdivided into two ATC4 classes depending on the underlying substance of the products. ATC 4 class G4D4 contains urinary incontinence products (e.g. oxybutynin-based products) and ATC 4 Class G4D8 contains products of herbal or animal origin, as well as homeopathic products.
- (405) The Parties market products based on two different molecules. Mylan supplies the branded product Driptane and the non-branded product Oxybutynin, both based on oxybutynin. Meda sells a branded product Ceris which has trospium as active pharmaceutical ingredient.
- (406) The Notifying Party submits that the relevant product market should be broader than the molecule encompassing the products belonging to ATC 3 class G4D.
- (407) The Commission assessed ATC3 class G4D products in *Mylan/Abbott EPD-DM*. The Commission's market investigation in that case focused on the molecule oxybutynin and suggested that there are more modern alternatives available to oxybutynin, which cause fewer side effects. Therefore, the Commission concluded that the relevant product market in relation to oxybutynin-based products should be wider than the molecule level, but narrower than the ATC 3 class, likely comprising the two ATC 4 classes G4D4 and G4D8.<sup>117</sup>
- (408) The results of the market investigation in this case also suggest that not all molecules of ATC 3 class G4D can be used interchangeably for all patient groups. As regards the Parties' products, trospium has a very good safety profile for elder patients, while oxybutynin is not indicated for elder patients due to side-effects. However, neither oxybutynin nor trospium are unique as physicians have other molecules at hand, such as solfenacine, darifenacine or fesoterodine.
- (409) Based on the above, and in line with its conclusion in *Mylan/Abbott EPD-DM*, the Commission considers that the relevant product market is likely narrower than the ATC 3 class G4D, but possibly wider than the molecule level. However, for the purpose of the present case, the exact product market definition can be left open, since no serious doubts arise under any plausible alternative market definition in relation to urinary incontinence products.

##### Competitive assessment

- (410) In the G4D class two Group 1 markets arise, namely France and Italy.

##### France

- (411) Mylan's products in France are Driptane and Oxybutynin (both based on oxybutynin) and Meda supplies its branded product Ceris (trospium), of which it is the originator. The size of the entire French urinary incontinence products market (ATC 3 class

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<sup>117</sup> COMP M.7379 Mylan/Abbott EPD-DM of 28 January 2015, paragraph 444.

G4D) is around EUR 62 million in 2015 and has been growing from EUR 51 million in 2013.

(412) The Parties' combined market share on ATC 3 level limited to the Rx version and the galenic form oral solid ordinary tablets is [30-40]% in volume and [10-20]% in value. The increment is coming from Mylan ([0-5]% in value, [10-20]% in volume). Based on the results of the market investigation, the Parties' products are not each other's closest competitors as trospium has a very good safety profile for elder patients, while oxybutynin is not indicated for elder patients due to side-effects.

(413) In addition, post-merger, the Parties will continue to face competition, including on molecule level from competitors, such as Astellas Pharma ([30-40]% in volume), Servier ([5-10]% in volume) and Sanofi, Teva, Novartis, Stada and Majorelle (<5% in volume).

#### Conclusion

(414) Based on the above considerations, the Commission concludes that the Transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to urinary incontinence products in France.

#### Italy

(415) Mylan's product in Italy is Oxybutynin (named after its active pharmaceutical ingredient). Meda markets two branded products based on two different molecules, Urivesc (trospium) and Cistalgan (flavoxate/ propyphenazone) and is the originator of both. The size of the Italian urinary incontinence products market (ATC 3 class G4D) is around EUR 20 million in 2015 and has been growing from EUR 18 million in 2013.

(416) The Parties' combined market share at the ATC3 level limited to the galenic form oral solid ordinary tablets is [50-60]% in volume and [20-30]% in value. The increment comes from Mylan in value terms, [5-10]% and from Meda in volume terms, [20-30]%. Based on the results of the market investigation, the Parties' products are not each other's closest competitors as trospium has a very good safety profile for elder patients, while oxybutynin is not indicated for elder patients due to side-effects.

(417) In addition, post-merger, the Parties will continue to face competition, including on molecule level, from competitors, such as Stada ([10-20]% in volume), Astellas Pharma ([10-20]% in volume), Sanofi ([5-10]% in volume), Pfizer ([0-5]% in volume) and four other competitors with market shares below [0-5]%.

#### Conclusion

(418) Based on the above considerations, the Commission concludes that the Transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to urinary incontinence products in Italy.

IV.1.3.23. Other Group 2 and Group 3 markets in the genito-urinary system and sex hormones therapeutic area

(419) In addition to the Group 1 markets analysed above, there is a number of Group 2 and Group 3 affected markets in the genito-urinary system and sex hormones area, specifically:

- *ATC 3 class G1D in France;*
- *ATC 3 class G3C in Sweden and the United Kingdom;*
- *ATC 3 class G4E in Sweden, Czech Republic and Spain;*
- *ATC 3 class G4C in Belgium;*
- *ATC 3 class G4D in Bulgaria, Poland and France;*
- *ATC 3 class G3A in Germany;*
- *ATC 3 class G3F in Austria and Ireland; and*
- *ATC 3 class G3D in Italy.*

(420) 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 [0-5]%.

(421) 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 Abacus Medicine, Allergan, Astellas Pharma, Bayer, Boiron, Chemo, Concordia, Eli Lilly, Gedeon Richter, GSK, Ibsa, Italfarmaco, Johnson & Johnson, Johnson & Johnson, Medochemie, Merck & Co, Merck KGaA, Montavit, Novartis, Novo Nordisk, Orifarm, Orion, Paranova, Pharmachim, Pharmacons, Pfizer, Sanofi, Stada, Teva and Zambon.

(422) 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.

### **GENERAL ANTI-INFECTIVES SYSTEMIC**

(423) This therapeutic area comprises anti-infective agents. In particular, the relevant products in this therapeutic area for the purposes of the proposed Transaction are (i) broad-spectrum penicillins, categorized in the ATC3 class J1C and (ii) macrolides and similar types, categorized in the ATC3 class J1F. The Parties are both active in these two ATC 3 classes.

#### IV.1.3.24. Broad spectrum penicillins (J1C)

(424) Broad spectrum penicillins are systemic antibacterials of penicillin derivatives either plain or in combination with other anti-infectives. They are categorized in the ATC 3 class J1C, which is further segmented into two ATC 4 classes that cover oral broad spectrum penicillins (J1C1) and injectable broad spectrum penicillins (J1C2).

(425) Mylan supplies products based on amoxicillin, amoxicillin/clavulanic acid and piperacillin/tazobactam. Meda markets amoxicillin and bacampicillin based products.

##### *Notifying Party's submission*

(426) The Notifying Party submits that the relevant market encompasses the entire ATC 3 class J1C.

##### *The Commission's assessment*

(427) In its previous decisions *Glaxo Wellcome/Smithkline Beecham* and *Sanofi Synthélabo/Aventis*, the Commission considered that the appropriate market definition for J1C products is based on the ATC 3 level.<sup>118</sup> In *GlaxoWellcome/SmithKline*, the Commission's market test indicated that broad-spectrum penicillins (J1C), cephalosporins (J1D), macrolides (J1F) and fluoroquinolones (J1G) are all used as first line treatment for common infections, namely the largest indication of community acquired pneumonia.

(428) In its decision *Pfizer/Wyeth*, the Commission left the market definition open.<sup>119</sup>

(429) The results of the market investigation in the case at hand suggest that in relation to amoxicillin specifically the market should be defined at molecule level, in particular, because no oral beta lactam antibiotics except amoxicillin have good effect on penicillin non susceptible pneumococci.<sup>120</sup> A key opinion leader confirmed that other broad spectrum penicillins are to a large extent used for a different spectrum of indications."<sup>121</sup> Similarly, another respondent explained that "*amoxicillin is unique as molecule and a substitution would lead to increased side effects for the patients and in a wider sense, increase the problem of antibacterial resistance through the use of other broader spectrum penicillins.*"<sup>122</sup>

(430) Based on the above, for the purposes of this decision, the Commission concludes that the relevant product market for broad spectrum penicillins, and amoxicillin in particular, should be defined at the molecule level.

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<sup>118</sup> COMP Case M.1846 *Glaxo Wellcome/Smithkline Beecham* of 8 May 2000, paragraph 49; COMP Case M.3354 *Sanofi Synthélabo/Aventis* of 26 April 2004, paragraph 87 *et seq.*

<sup>119</sup> COMP/M.5476 *Pfizer/Wyeth* of 17 July 2009.

<sup>120</sup> Non-confidential minutes of a conference call with Swedish doctor, held on 23 May 2016.

<sup>121</sup> Non-confidential minutes of a conference call with Swedish doctor, held on 8 June 2016.

<sup>122</sup> Non-confidential minutes of a conference call with Swedish doctor, held on 8 June 2016.

### Competitive assessment

- (431) In the J1C class, the Transaction gives rise to three Group 1 affected markets, namely in Italy, Norway and Sweden.

#### Italy

- (432) Mylan's products in Italy are Amoxicillina, Amoxicillina/ Acido Clavulinico, Bacampicillina and Piperacillina/Tazobactam, all of which are named after their active ingredients (namely amoxicillin, amoxicillin/clavulanic acid, bacampicillin and piperacillin/tazobactam). Meda markets a generic product based on amoxicillin and a branded product Bacacil, based on bacampicillin of which it is the originator.
- (433) The Parties' combined market shares at the molecule level for amoxicilline are too small to give rise to a group 1 market. The Parties' combined market shares for the molecule bacampicillin are [80-90]%. However, Mylan stopped the supply of its bacampicillin product in January 2016, because the product was [...]. For Mylan to re-enter this market, [...] which is unlikely for a drug that was genericized in 2000 and is now a mature generic market.
- (434) Respondents to the market investigation confirmed that Mylan's bacampicillin product is no longer available on the Italian market, while other generics such as Stada ([10-20]%), Angelini ([0-5]%) and K24 pharma will continue to be active.

#### Conclusion

- (435) Based on the above considerations, the Commission concludes that the Transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to bacampicillin in Italy.

#### Norway

- (436) Mylan's product in Norway is Amoxicillin, named after its active pharmaceutical ingredient. Meda supplies Imacillin, which is also based on amoxicillin.
- (437) The Parties' combined market share is [90-100]% in value and [90-100]% in volume. The increment is coming from Meda, [40-50]% in value and [20-30]% in volume. The only other competitor at molecule level is Novartis with a market share of [0-5]% in value and [0-5]% in volume.
- (438) The market investigation revealed concerns in relation to amoxicillin in Norway as the market is already very concentrated – only three players – while the current three suppliers are the only ones having access to the market as there seem to be no marketing authorisations (dossiers) available on the market which would enable a competitor to enter the Norwegian market with an amoxicillin product in the short term. As a result a new entry is particularly unlikely. This is confirmed by the Parties indicating that besides them and Novartis there is no other supplier holding an active marketing authorisation.
- (439) The Notifying Party submitted that pharmaceutical suppliers in Norway are constrained by a group of concentrated buyers. Three large pharmacy chains which are vertically integrated with large wholesalers control a large part of the wholesale and retail market in Norway. Therefore, these three groups have a countervailing buyer-power limiting the ability of the merged entity to exercise market power post-



merger. However, the market investigation confirmed that such buyer power could only be exercised if there are available options in the market. Post-merger will be significantly reduced.

### Conclusion

- (440) Based on the above, the Commission concludes that serious doubts arise as regards the compatibility of the Transaction with the internal market in relation to amoxicillin in Norway

### Sweden

- (441) Mylan's products in Sweden are Amoxicillin and Piperacillin/Tazobactam, both named after their active ingredients. Meda supplies Amimox and Imacillin, both with amoxicillin as the active pharmaceutical ingredient; Spektramox, with amoxicillin/clavulanic acid as its active ingredient and Doktacillin, based on ampicillin.
- (442) The Parties' combined market share at the molecule level is [70-80]% in value and [40-50]% in volume. The increment comes from Mylan with [0-5]% in value and [10-20]% in volume. There are two competitors at molecule level, namely Novartis ([20-30]% in value, [40-50]% in volume) and Aurobindo (>5% in value and [10-20]% in volume).
- (443) The respondents to the market investigation confirm that competition in Sweden is price-driven, because "*all molecules included are subject to prescription [...] and are subject to government tenders [...] where the lowest price wins. For the products sold through pharmacies, the government has a monthly tender for each molecule/strength/form/pack size where the available product with the lowest price wins.*"<sup>123</sup> Moreover, "*Sweden is a price-driven market and thus we assume there is no company/trade name preference.*"<sup>124</sup> As another competitor puts it, "*[...] the majority of the usage is decided by a model whereby the lowest price of the month is being sold at the pharmacy level.*"<sup>125</sup>
- (444) In Sweden, the pharmacy purchase price and the pharmacy margin are set by the TLV,<sup>126</sup> thereby effectively determining a fixed national pharmacy retail price. In addition, the pricing for products in the reimbursement system is set through government tenders. These tenders occur every month and only the winner will be reimbursed in Sweden which has a downward pressure on pricing. In such a system, high market shares are not necessarily indicative of the Parties' ability to affect the conditions of sale pre- or post-merger.

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<sup>123</sup> See response of a competitor to Q12- Questionnaire to Competitors, question 213.

<sup>124</sup> See response of a competitor to Q12- Questionnaire to Competitors, question 216.

<sup>125</sup> See response of a competitor to Q12- Questionnaire to competitors, question 216.

<sup>126</sup> Tandvårds- och läkemedelsförmånsverket, i.e. the Swedish Dental and Pharmaceutical Agency.

## Conclusion

- (445) Based on the above considerations, the Commission concludes that the Transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to amoxicillin in Sweden.

### IV.1.3.25. Macrolides and similar types (J1F)

- (446) Macrolide antibiotics are used for a range of indications, including lower and upper respiratory tract infections, infections of skin and soft tissue, severe acne and certain STDs. These pharmaceuticals form a subcategory of anti-bacterials generally reserved for those specific bacteria resistant to penicillin, as well as for patients hypersensitive to penicillin. All macrolides are variations of the well-known molecule erythromycin. Macrolides are categorized in ATC 3 class J1F; there is no further subdivision into ATC 4 classes.
- (447) Mylan supplies products based on clarithromycin. Meda markets the molecule erythromycin.
- (448) In previous decisions, where macrolides were assessed, the Commission considered the ATC3 class J1F as the appropriate definition of the relevant product market.<sup>127</sup> However, in one case where the Commission examined more particularly the molecule azithromycin, the market investigation provided evidence in favour of defining the market at the molecule level although the market definition was ultimately left open.<sup>128</sup> In *Mylan/Abbott EPD-DM*, the Commission concluded that the relevant market is not as wide as the entire ATC 3 class J1F, but wider than the molecule level and the market should at least comprise of clarithromycin and azithromycin.<sup>129</sup>

#### *Notifying Party's view*

- (449) The Notifying Party submits that the market should be defined in accordance with the conclusion of the Commission in *Mylan/Abbott EPD-DM*.

#### *Commission's assessment*

- (450) The respondents to the market investigation suggest that clarithromycin and erythromycin are not substitutable with each other. When comparing both molecules, a respondent stated that "*Clarithromycin is a drug with unique indications [...] clarithromycin is however the preferred drug due to less side-effects and should replace erythromycin.*"<sup>130</sup> Moreover, clarithromycin has significantly lesser side-effects (e.g. diarrhoea) than erythromycin.

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<sup>127</sup> COMP/M.3354 Sanofi-Synthelabo/Aventis of 26 April 2004 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.

<sup>128</sup> COMP/M.5865 Teva/Ratiopharm of 3 August 2010, paragraph 186.

<sup>129</sup> COMP/M.7379 Mylan/Abbott EPD-DM of 28 January 2015, paragraph 254.

<sup>130</sup> See response of Norwegian doctor to questionnaire to KOL (J1C).

- (451) Based on the above, the Commission concludes that the relevant product market for macrolides and similar types, and clarithromycin and erythromycin in particular, should be defined at the molecule level.

#### Competitive assessment

- (452) On the basis of the market definition set out above, no affected market arises in the area of macrolides and similar types of products.

#### IV.1.3.26. Other Group 2 and Group 3 markets in the general anti-infectives systemic therapeutic area

- (453) In addition to the Group 1 markets analysed above, there are two Group 3 affected markets in the general anti-infectives systemic area, specifically:

- *ATC 3 class J1A in the United Kingdom;*
- *ATC 3 class J2A in France.*

- (454) 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.

- (455) On these markets the combined market share of the Parties are moderate to low and / or the increment is below [0-5]%. 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 Alternova, Concordia, Orifarm, Merck & Co, Novartis, Pfizer and Servier.

- (456) The market investigation did not provide any indication that competition issues would arise in these markets. 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.

#### **ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS**

- (457) This therapeutic area comprises preparations used in the treatment of malignant neoplastic diseases, and immune-modulating agents. In particular, the relevant products in this therapeutic area for the purposes of the proposed Transaction are cytostatic hormones, categorized in the ATC 3 class L2A.

#### IV.1.3.27. Cytostatic Hormones (L2A)

- (458) Cytostatic hormones, which belong to ATC 3 class L2A, are hormones that have the ability to prevent the growth and proliferation of cells and are often used to treat cancer. The ATC 3 class is further subdivided into four ATC4 classes: L2A1 containing cytostatic oestrogens, L2A2 containing cytostatic progestogens, L2A3 containing cytostatic gonadotropin-releasing hormone analogues and L2A9, containing other cytostatic hormones.

- (459) In this ATC 3 class both Mylan and Meda supply products based on the molecule megestrol.

- (460) The Notifying Party submits that in view of the general characteristics of megestrol products, the market should be defined at a level wider than ATC 3 class L2A. Since megestrol is currently used for the treatment of the Anorexia-Cachexia Syndrome ("ACS"), the appropriate market definition should include all molecules indicated for the treatment of ACS, regardless of the corresponding ATC codes.
- (461) There are no Commission precedents analysing specifically products belonging to ATC 3 class L2A.
- (462) The results of the market investigation in this case suggest that "*Megefren (megestrol) and Borea (megestrol) are cytostatic hormones which are used for the treatment of breast and endometrial cancer. Today, megestrol is mostly prescribed for cancer and AIDS-associated hyporexia/cachexia.*"<sup>131</sup> Megestrol has unique characteristics: "*Megestrol as molecule has a very specific and unique role for appetite stimulation in patients suffering from cancer and is not substitutable. Megestrol-based drugs are the first line of treatment for anorexia in the context of palliative care.*"<sup>132</sup>
- (463) On the basis of the above, the market for cytostatic hormones should be assessed at molecule level.

#### Competitive assessment

- (464) In the L2A class, the proposed Transaction gives rise to one Group 1 market, namely in Spain.

#### Spain

- (465) Mylan markets its branded product Megefren which is based on megestrol while Meda sells Borea, also based on megestrol.
- (466) The Parties' combined market shares at molecule level are [70-80]% in value and [70-80]% in volume, the increment coming from Mylan with [10-20]% in value and volume, the remainder of the market is Sobi's product Maygace. At the molecule level limited to the galenic form of oral liquid ordinary, the combined market shares of the Parties are [50-60]% in value and [50-60]% in volume. Finally, at the molecule level limited to the galenic form of oral solid ordinary tablets, the Parties achieve a combined market share of [90-100]%.
- (467) Meda's product Borea is the clear market leader with Mylan being a strong number two. The Parties indicate that the third supplier on the market, Sobi, holds a significant market share of [20-30]% in value and [20-30]% in volume.
- (468) However, contrary to the Parties' statement the market investigation revealed that Sobi's market share is in the range of 5-10% and that the Parties are each other's closest competitors. This is because, first, Sobi only offers one galenic form, namely oral liquid ordinary, whereas the Parties offer two different galenic forms, oral solid ordinary tablets and oral liquid ordinary. Second, Sobi's Maygace is limited to the treatment of anorexia-cachexia for AIDS or advanced oncology patients, while both Parties' products Megefren and Borea also have a breast and endometrial cancer

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<sup>131</sup> Non-confidential minutes of a conference call with Spanish KOL held on 2 June 2016.

<sup>132</sup> Non-confidential minutes of a conference call with Spanish KOL, dated 21 June 2016.

indication. Finally, one market participant explained that Parties' brand recognition is particularly strong *"Megefren and Borea are very known brands as they work well and are more modern than other competitors."*<sup>133</sup>

### Conclusion

(469) Based on the above, the Commission concludes that serious doubts arise as regards the compatibility of the Transaction with the internal market in relation to megestrol in Spain.

#### IV.1.3.28. Other Group 2 and Group 3 markets in the antineoplastic and immunomodulating agents therapeutic area

(470) In addition to the Group 1 markets analysed above, there are two Group 3 affected market in the antineoplastic and immunomodulating agents area, specifically:

- *ATC 3 class L1D in France; and*
- *ATC 3 class L1B in France.*

(471) 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.

(472) On these markets the combined market share of the Parties are moderate to low and / or the increment is below [0-5]%. 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 Intas, Novartis, Pfizer, Sanofi and Teva.

(473) 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.

### **MUSCOLOSKELETAL SYSTEM**

(474) This therapeutic area comprises peripherally, centrally and directly acting muscle relaxants as well as drugs used for the treatment of bone diseases and other drugs for disorders of the musculoskeletal system. In particular, the relevant products in this therapeutic area for the purposes of the proposed Transaction are (i) non-steroidal anti-rheumatics, categorized in the ATC 3 class M1A and (ii) centrally acting muscle relaxants, categorized in the ATC 3 class M3B. The Parties are both active in these two ATC 3 classes.

#### IV.1.3.29. Non-steroidal anti-rheumatics (M1A)

(475) Non-steroidal anti-rheumatics are categorized in the ATC 3 class M1A, which covers non-hormonal anti-inflammatory products for systemic treatment of musculoskeletal inflammation. The ATC 3 M1A class is further divided into three ATC 4 classes

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<sup>133</sup> See response of a competitor to questionnaire Q12- Questionnaire to Competitors, question 234.

depending on the mode of action and the type of molecules: anti-rheumatics, non-steroidal plain (M1A1) and combination products (M1A2) and products that are highly specific to the COX-2 enzyme (M1A3).

- (476) Mylan supplies products based on celecoxib, diclofenac, indomethacin, meloxicam, naproxen, ibuprofen, piroxicam and nabumetone. Meda markets products based on the molecule nabumetone.
- (477) The Notifying Party submits that the appropriate market definition for this market is the ATC 4 level, namely class M1A1, because their M1A1-classified products are substitutable with other propionic acid derivatives in this ATC 4 class.
- (478) In the present case, Group 1 affected markets only arise at molecule level (nabumetone) in the Netherlands and the UK.
- (479) The Commission previously recognized that competing products based on the same molecule are typically closer substitutes than products based on different molecules.<sup>134</sup>
- (480) The Commission therefore assessed the impact of the Transaction on the basis of the narrowest molecule-based market definition.

#### Competitive assessment

- (481) As noted above, in the M1A class, the Transaction gives rise to two Group 1 markets, namely the Netherlands and the United Kingdom.

#### The Netherlands

- (482) Mylan is active with a large number of different products on the Dutch market namely Diclofenac, Ibuprofen, Brufen, Indometacin, Meloxicam, Nabumetone, Naproxen, Piroxicam, Flurbiprofen and Celecoxib, all named after their active ingredients. Meda supplies Mebutan, which is based on nabumetone. The Parties combined market share at the molecule level (nabumetone) is [60-70]%.
- (483) The market for nabumetone in the Netherlands is very small, amounting to EUR 181 000 of sales in 2015 and declining from EUR 219 000 in 2013. While Meda is the market leader [50-60]% market share, Mylan's market share is small ([0-5]%) and thus the increment minimal.
- (484) Post-merger, the Parties will continue to face competition from Teva ([10-20]%), Novartis ([10-20]%), Aurobindo ([10-20]%) and Stada, all supplying nabumetone based products. The market investigation provided indications that due to frequent wholesaler and health insurance tenders the Dutch market is very competitive and dominated by generic products.
- (485) Finally, the market investigation did not raise concerns in relation to non-steroidal anti-rheumatics in general or any of the molecules in ATC 3 class M1A in particular in the Netherlands.

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<sup>134</sup> See COMP/M.7379 Mylan/Abbott EPD/DM of 28 January 2015.

### Conclusion

- (486) 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 non-steroidal anti-rheumatics in the Netherlands.

### United Kingdom

- (487) Mylan is active with a large number of different products belonging to the M1A1 class on the British market, namely Celecoxib, Etolyn, Flurbiprofen, Ibuprofen Lysine FC, Meloxicam, Nabumetone, Piroxicam and Sulindac, all named after their active ingredients. Meda markets its branded products Relifex with nabumetone as the active pharmaceutical ingredient, Mobiflex, with Tenoxicam as the active pharmaceutical ingredient, and Eccoxolac based on etodolac. The size of the British nabumetone products market at molecule level is around EUR 742 000 in 2015 and has been growing slightly from EUR 707 000 in 2013.
- (488) At the narrowest possible level (molecule level), the Parties overlap in relation to nabumetone where Mylan sells a generic product while Meda sells the branded ex-originator product Reliflex. The Parties' combined market shares are [60-70]% in value and [80-90]% in volume.
- (489) Contrary to what the Notifying Party indicated in the Form CO, the market investigation revealed that there are only three suppliers of nabumetone products in the UK, namely the Parties and one other supplier, Actavis.
- (490) Actavis' product is however the most expensive product in the market, second most expensive being Meda's branded product Reliflex while Mylan's generic is the cheapest. This is also clearly evidenced in market shares where the Parties' combined market share in value is significantly lower to their market share in volume reaching [80-90]%.
- (491) In addition, there is evidence that a recent shortage of Mylan's generic product led to a price increase of Meda's branded product Reliflex in the range of 5-8%.
- (492) It follows that the combination of the two cheapest products in a market where only three competitors compete would necessarily lead to price increases. In this context the market investigation revealed concerns that the combination of the two best-selling nabumetone products in the UK would have an impact on prices.
- (493) This is to be seen in the context of regulatory framework in the UK, where, unlike in other EEA countries, the prices for pharmaceutical products are not regulated and price is a function of competition in the market.

### Conclusion

- (494) Based on the above, including the results of the market investigation, the Commission concludes that serious doubts arise as regards to the compatibility of the Transaction with the internal market in relation to nabumetone in the UK.

#### IV.1.3.30. Centrally Acting Muscle Relaxants (M3B)

- (495) Centrally acting muscle relaxants, which are categorized in the ATC 3 class M3B, comprises products with various indications ranging from the treatment of nightly leg cramps to the treatment of musculoskeletal spasms as well as spasticity in a variety of severe neurological conditions such as Amyotrophic Lateral Sclerosis ("ALS"). The ATC 3 class M3B is not further segmented into ATC 4 classes.
- (496) Mylan supplies products based on baclofen and Meda markets products based on hydroquinin.
- (497) In line with the Commission's findings in its previous decisions,<sup>135</sup> the Notifying Party supports further segmentation of the ATC 3 class M3B market into baclofen-based products, indicated for treatment of spasticity of cerebral origin, and non-baclofen-based products, indicated for treatment of other diseases.
- (498) In past decisions the Commission considered that the relevant product market for centrally acting muscle relaxants should be defined at ATC3 level M3B.<sup>136</sup> In *Teva/Cephalon*, the Commission considered a possible M3B market excluding baclofen-based products, but ultimately left the exact market definition open.<sup>137</sup>
- (499) For the purpose of the present case, the precise market definition can be left open, since no serious doubts arise under any plausible alternative market definition.

#### Competitive assessment

- (500) In the M3B class, the proposed Transaction gives rise to two Group 1 affected markets, namely the Netherlands and Iceland.

#### The Netherlands

- (501) The Parties market two different molecules in the Netherlands. Mylan's product is Baclofen, named after its active pharmaceutical ingredient. Meda supplies a branded product called Inhibin, based on the molecule hydroquinine. The size of the Dutch centrally acting muscle relaxant products market (ATC 3 class M3B) is around EUR 2.8 million in 2015.
- (502) The Parties' combined market share in ATC 3 class M3B is [30-40]% in value and [30-40]% in volume, with an increment of Mylan ([0-5]% in value and [5-6]% in volume). However, should the market be subdivided into baclofen based products and non-baclofen based products, there would be no overlap. Based on the summary of product characteristics ("SPC") of the Parties' products in the Netherlands, the Parties' products seem to have different indications. Indeed, Mylan's baclofen product is indicated for the treatment of relief of severe neurological disorders, such as spasticity of voluntary muscle resulting from disorders such as multiple sclerosis, ALS and

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<sup>135</sup> COMP Case M.3751 Novartis/Hexal of 27 May 2005, page 12 and COMP Case M.6258 Teva/Cephalon of 13 October 2011, paragraph 60 *et seq.*

<sup>136</sup> COMP Case M.6258 – Teva/Cephalon of 13 October 2011, paragraph 60 *et seq.*; COMP Case M.3354 Sanofi-Synthelabo/Aventis of 26 April 2004, paragraph 95 *et seq.*; COMP Case M.1397 Sanofi/Synthelabo of 17 May 1999, paragraph 63.

<sup>137</sup> COMP Case M.6258 Teva/Cephalon of 13 October 2011, paragraph 63.



other spinal lesions, whereas Meda's Inhibin (hydroquinine) is used to treat nightly muscle cramps in the legs.

- (503) In addition, Mylan's product is reimbursed in the Netherlands and only available via prescription, while Meda's product is sold OTC and not reimbursed. Therefore, the Parties' products are not indicated for the same group of patients and are neither substitutable nor each other's close competitors.
- (504) In any event, the Parties' products face competition, including at the level of the molecule baclofen, from several competitors, such as Novartis ([20-30]% market share), Teva ([20-30]%) and Aurobindo ([10-20]% market share) and the Dutch market is based on tenders.

#### Conclusion

- (505) The Commission, taking into consideration all of the above, concludes that the Transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to centrally acting muscle relaxants products in the Netherlands.

#### Iceland

- (506) The Parties market two different molecules in Iceland. Mylan's product is Baclofen, named after its active pharmaceutical ingredient. Meda supplies a branded product called Norgesic, based on the molecules orphenadrine and paracetamol. The size of the Icelandic centrally acting muscle relaxant products market (ATC 3 class M3B) is around EUR 19 million in 2015 and has been declining from EUR 22 million in 2013.
- (507) The Parties' combined market share in ATC 3 class M3B is [50-60]%. However, should the market be subdivided into baclofen based products and non-baclofen based products, there would be no overlap. Indeed, based on the summary of product characteristics ("SPC") of the Parties' products for Iceland, Mylan's baclofen product is indicated for the treatment of relief of severe neurological disorders, such as spasticity of voluntary muscle resulting from disorders such as multiple sclerosis, ALS and other spinal lesions, whereas Meda's Norgesic (orphenadrine/paracetamol) is used to treat stiffness, pain and discomfort caused by strains, sprains or other muscle injuries. Therefore, the Parties' products are not indicated for the same group of patients and are neither substitutable nor each other's close competitors.
- (508) In any event, the Parties' products face competition, from Novartis ([40-50]%), which sells a baclofen-based product.

#### Conclusion

- (509) The Commission, taking into consideration all of the above, concludes that the Transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to centrally acting muscle relaxants products in Iceland.

IV.1.3.31. Other Group 2 and Group 3 markets in the musculoskeletal system therapeutic area

- (510) In addition to the Group 1 markets analysed above, there is a number of Group 2 and Group 3 affected markets in the musculoskeletal system area, specifically:
- *ATC 3 class M1A in Belgium, France, Italy, Luxembourg, Portugal, Romania and Sweden;*
  - *ATC 3 class M3B in Finland and in Sweden; and*
  - *ATC 3 class M5X in Germany, Latvia, Portugal, Slovakia.*
- (511) 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 [0-5]%.
- (512) 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 Abiogen Pharma, Alfasigma, Allergan, Almirall, Angelini, Alternova, Baldacci, Bial, Bluepharma, Boehringer Ingelheim, Bluefish, Chiesi, Croma Pharma, CSP Benelux, Esteve, Expanscience, Fidia, Generis Pharma, Grupo Tecnimed, Gruenthal, GSK, Heel, Ibsa, Italfarmaco, Mediolanum, Merck & Co, Medarduum, Medivir, Novartis, Orifarm, Orion, Pfizer, Pierre Fabre, Sanofi, Servier, Stada, Takeda, Teva, Therabel and Zambon.
- (513) 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.

**NERVOUS SYSTEM**

- (514) This therapeutic area comprises a wide variety of drugs used for the treatment of the nervous system. In particular, the relevant products in this therapeutic area for the purposes of the proposed Transaction are (i) hypnotics/sedatives, categorized in ATC 3 class N5B and (ii) anti-depressants and mood-stabilizers, categorized in ATC 3 class N6A. The Parties are both active in these ATC 3 classes.

IV.1.3.32. Hypnotics / Sedatives (N5B)

- (515) The ATC 3 class N5B comprises hypnotics / sedatives, which are used for the treatment of insomnia. The N5B class is further subdivided into several ATC 4 classes, which distinguish non-barbiturates (N5B1, N5B2), barbiturates (N5B3, N5B4) and herbal hypnotics/sedatives (N5B5).
- (516) The Parties' products are categorized in this ATC 3 class. Mylan supplies products based on zolpidem, zopiclone, lormetazepam and flunitrazepam. Meda markets products which are based on the molecules flurazepam, nitrazepam, zaleplon, zolpidem, zopiclone, lormetazepam, phenobarbital and promethazine/thiourea.

- (517) The Notifying Party submit that the appropriate market definition should comprise products at the combined ATC 4 level, including both N5B1 and N5B2 products.
- (518) In previous decisions, the Commission assessed the market on the basis of the ATC 3 class N5B.<sup>138</sup> A possible sub-segmentation, along benzodiazepines and non-benzodiazepines, was left open by the Commission.<sup>139</sup> In *Sanofi-Aventis/Zentiva*<sup>140</sup> the Commission excluded barbiturates from the relevant market, due to their highly addictive character, which lead to their replacement in clinical guidelines. In *Sanofi-Aventis/Zentiva*, the Commission concluded that the assessment *de facto* corresponds to an analysis of the ATC 4 classes N5B1 and N5B2.<sup>141</sup>
- (519) For the purpose of the present case, it can be left open how the relevant product market for hypnotics / sedatives should be defined, since no serious doubts arise under any plausible alternative market definition.

#### Competitive assessment

- (520) In the N5B class, the proposed Transaction gives rise to three Group 1 markets, namely Ireland, Luxembourg and Sweden.

#### Ireland

- (521) The Parties market several different molecules in Ireland. Mylan supplies Zoldem and Zimoclone with zolpidem and zopiclone as the respective active pharmaceutical ingredients. Meda is active with several products based on flurazepam, nitrazepam, zaleplon and zopiclone as the respective active pharmaceutical ingredients.
- (522) At molecule level, the Parties overlap in relation to zopiclone. The size of the Irish zopiclone products market (ATC 4 class N5B1-molecule) is around EUR 2.8 million in 2015 and has been declining from EUR 3.6 million in 2013.
- (523) The Parties' combined share at molecule level is [40-50]% while other strong competitors namely Stada ([30-40]%), Teva ([10-20]%) and Wockhardt ([10-20]%) will remain to be present.
- (524) The market investigation did not reveal any concerns in relation to products in the ATC3 class N5B in Ireland.

#### Conclusion

- (525) The Commission, taking into consideration all of the above, concludes that the Transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to hypnotics / sedatives products in Ireland.

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<sup>138</sup> COMP M.1397 Sanofi/Synthélabo of 17 May 1999, paragraph 35, COMP M.3354 Sanofi-Synthélabo/Aventis of 26 April 2004, paragraph 111 and 112.

<sup>139</sup> COMP M.3751 Novartis/Hexal of 27 May 2005, page 14.

<sup>140</sup> COMP M.5253 Sanofi-Aventis/Zentiva of 4 February 2009, paragraph 159 *et seq.*

<sup>141</sup> COMP M.5253 Sanofi-Aventis/Zentiva of 4 February 2009, paragraph 165.

### Luxembourg

- (526) The Parties market several different molecules in Luxembourg. Mylan markets Lormetazepam, named after its active pharmaceutical ingredients. Meda sells several products based on nitrazepam, zopiclone and lormetazepam as the respective active pharmaceutical ingredients.
- (527) The Parties overlap in relation to the molecule lormetazepam. While the combined market share of the Parties is [70-80]% in value and in volume, the increment coming from Mylan, is very small reaching [0-5]% in value and [0-5]% in volume. The size of the lormetazepam products market at molecule level in Luxembourg is small, amounting to around EUR 426 000 in 2015.
- (528) Post-merger, the Parties will face several competitors at molecule level, namely Bayer ([10-20]%), Stada ([10-20]%) as well as Novartis and Takeda (each with a market share <5% but larger than Mylan).
- (529) The market investigation did not reveal any concerns in relation to products in the N5B class in Luxembourg.

### Conclusion

- (530) The Commission, taking into consideration all of the above, concludes that the Transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to hypnotics / sedatives products in Luxembourg.

### Sweden

- (531) The Parties market several different molecules in Sweden. Mylan supplies Flunitrazepam, Zolpidem and Zopiclone, all named after their respective active pharmaceutical ingredients. Meda markets several products based on nitrazepam, phenobarbital, promethazine/thiourea, zaleplon, zolpidem and zopiclone as the respective active pharmaceutical ingredients.
- (532) The Parties overlap in relation to two molecules, namely zolpidem and zopiclone. The combined market share on molecule level for zolpidem is below the threshold for a group 1 market.
- (533) The size of the Swedish zopiclone products market at molecule level is around EUR 3.4 million in 2015. The Parties' combined market share in relation to zopiclone is [60-70]% with an increment of less than [0-5]%, as Mylan's sales in 2015 are very small (13 400 units) compared to Meda's sales (60 million units). Several other competitors, namely Pilum Pharma ([20-30]%) and Stada ([5-10]%) as well as Allergan and Jubilant Pharm (each with a market share <5%), whose market shares are all larger than Mylan's increment will continue to be present.
- (534) Due to the regulatory framework in Sweden, all molecules, including hypnotics / sedatives, are subject to government tenders, where the product with the lowest price wins. Products sold through pharmacies are subject to monthly tenders for each molecule, strength, form and pack size.
- (535) As stated in *Mylan/Abbott EPD-DM*, tenders are used to appoint preferred suppliers on the basis of a competitive process based on price competition. In such a system,

high market shares for zopiclone are not necessarily indicative of the Parties' ability to affect the conditions of sale pre- or post-merger.<sup>142</sup>

- (536) The market investigation did not reveal any concerns in relation to products in the N5B class in Sweden.

#### Conclusion

- (537) The Commission, taking into consideration all of the above, concludes that the Transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to hypnotics / sedatives products in Sweden.

#### IV.1.3.33. Anti-Depressants and Mood Stabilizers (N6A)

- (538) The ATC 3 class N6A comprises substances used for the treatment of depression and mood stabilization. The N6A class is further subdivided in several ATC 4 classes with different modes of actions such as herbal antidepressants (N6A2), mood stabilizers (N6A3), selective serotonin re-uptake inhibitors ("SSRIs") antidepressants (N6A4), serotonin-noradrenaline re-uptake inhibitors ("SNRIs") antidepressants (N6A5) and other antidepressants (N6A9).

- (539) Mylan sells products based on citalopram, duloxetine, escitalopram, fluoxetine, fluvoxamine, mirtazapine, paroxetine, sertraline, trazodone, venlafaxine and moclobemide. Meda supplies products which are based on the molecule moclobemide.

- (540) The Notifying Party submits that their moclobemide-based products compete with products within the N6A9 class. The Parties further emphasize that certain molecules from other ATC 4 categories (SSRIs and SNRIs) may be regarded as interchangeable with moclobemide-based anti-depressants.

- (541) 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 ATC 3 class, the ATC 3 class excluding certain ATC 4 classes or the ATC 4 class N6A9.<sup>143</sup> In a subsequent case, the Commission analysed several molecules on potentially narrower markets, while leaving the market definition ultimately open.<sup>144</sup> In *Teva/Ratiopharm*, the Commission noted that moclobemide is an old molecule being largely replaced by newer alternatives.<sup>145</sup>

- (542) For the purpose of the present case, it can be left open how the relevant product market for anti-depressants and mood stabilizers should be defined, since no serious doubts arise under any plausible alternative market definition.

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<sup>142</sup> COMP Case M.7379 Mylan/Abbott EPD-DM of 28 January 2015, paragraph 97.

<sup>143</sup> COMP/M.5295 Teva/Barr of 19 December 2008, paragraph 164.

<sup>144</sup> COMP/M.5865 Teva/Ratiopharm of 3 August 2010, paragraphs 302 *et seq.*

<sup>145</sup> COMP M.5865 Teva/Ratiopharm of 3 August 2010, paragraph 317.

### Competitive assessment

(543) In the N6A class, the Transaction gives rise to one Group 1 market, namely Belgium.

#### Belgium

(544) The Parties market several different molecules in Belgium. Mylan markets one branded product, Floxyfral (fluvoxamine) as well as Citalopram, Duloxetine, Escitalopram, Fluoxetine, Mirtazapine, Paroxetine, Sertraline, Trazodone, Venlafaxine and Moclobemide, all named after their respective active pharmaceutical ingredients. Meda is active with one product branded Aurorix, with moclobemide as the active pharmaceutical ingredient.

(545) The Parties overlap in relation to molecule moclobemide. The market for moclobemide in Belgium is very small, amounting to EUR 121 000 in 2015 and declining from EUR 147 000 in 2013.

(546) The combined market share of the Parties is [50-60]% with Mylan's increment of [5-10]%.

(547) Post-merger, the Parties would face Novartis as competitor at the molecule level with a market share of [40-50]% (value) and [50-60]% (volume). As mentioned above, moclobemide is an old molecule, which is replaced by newer alternatives. This is also indicated through the [20-30]% decrease in market value during the last three years in Belgium.

(548) Despite the fact that the Transaction would result in a 3 to 2 market situation post-merger, 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 which would be difficult to justify in relation to an old molecule.

### Conclusion

(549) Based on the above considerations, the Commission concludes that the Transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to anti-depressants and mood stabilizers products in Belgium.

#### IV.1.3.34. Other Group 2 and Group 3 markets in the nervous system therapeutic area

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

- *ATC 3 class N7X in France, Italy, the Netherlands, Norway and the United Kingdom;*
- *ATC 3 class N5A in Belgium;*
- *ATC 3 class N5B in Belgium, Greece, Ireland, Sweden and Luxembourg;*
- *ATC 3 class N2B in Belgium, France, Portugal, the Netherlands and Spain; and*

– *ATC 3 class N2A in the Netherlands.*

- (551) 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.
- (552) On these markets the combined market share of the Parties are moderate to low and / or the increment is below [0-5]%. 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 Allergan, Almirall, Aurobindo, Bene Chemie, Biogen, Biomarin Pharma, BMS, Chiesi, Cinfa, Eli Lilly, Eumedica, Expanscience, Ferrer, Fidia, Fisher Pharma, Flynn Pharma, Fresenius, Gruenthal, Grupo Indokern, Ifet, Johnson & Johnson, Juvise, Kiron Pharma, Kyowa Hakko Kirin, Lane Group, Level, Lundbeck, Menarini, Merck & Co, Mundipharma, Neurim Pharma, Novartis, Orifarm, Pfizer, Pilum Pharma, Sanofi, Servier, SMB, Stada, Sun Pharma, Therabel, Teva, Trenker, UCB, Wockhardt and Zambon.
- (553) 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.

## **RESPIRATORY SYSTEM**

- (554) This therapeutic area comprises a large number of preparations used for the treatment of diseases of the respiratory system, such as colds or flu. In particular, the relevant products in this therapeutic area for the purposes of the proposed Transaction are expectorants, categorized in the ATC 3 class R5C.

### IV.1.3.35. Expectorants (R5C)

- (555) The ATC 3 class R5C comprises expectorant-based cough preparations with secretolytic or secretomotoric activity indicated for treatment of colds and influenza. This ATC 3 class is not further segmented into ATC4 classes.
- (556) Mylan sells products based on acetylcysteine. Meda supplies products which are based on the molecules diphenhydramine and acetylcysteine.
- (557) The Notifying Party submits that all R5C products have the same intended use and mode of action and compete with each other. Therefore the most appropriate market definition should cover all R5C products.
- (558) In preceding decisions, the Commission found the ATC 3 class R5C to be the relevant product market.<sup>146</sup>
- (559) For the purpose of the present case, it can be left open how the relevant product market for expectorants drugs should be defined, since no serious doubts arise under any plausible alternative market definition.

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<sup>146</sup> COMP M.6705 Procter & Gamble/Teva Pharmaceuticals OTC II of 9 November 2012, paragraph 19 and COMP M.5865 Teva/Ratiopharm of 3 August 2010, paragraphs 359 and 360.

### Competitive assessment

- (560) On the basis of the market definition set out above, the proposed Transaction gives rise to two Group 1 affected markets, namely Sweden and Iceland.

#### Sweden

- (561) Mylan supplies Acetylcystein, named after its active pharmaceutical ingredient. Meda also sells Acetylcystein, named after its active ingredient, and a branded product called Desentol, with diphenhydramine as the active ingredient. The size of the Swedish acetylcysteine products market at molecule level is EUR 2.9 million in 2015 and has been declining from EUR 3.3 million in 2013.
- (562) The Parties' highest combined market share at the level of the molecule acetylcysteine is [50-60]% while several competitors namely Novartis ([20-30]%), Alternova ([10-20]%) and Teva ([5-10]%) are active.
- (563) Due to regulation in Sweden, all molecules, including expectorants, are subject to government tenders, where the product with the lowest price wins. Products sold through pharmacies are subject to monthly tenders for each molecule, strength, form and pack size.
- (564) As stated in *Mylan/Abbott EPD-DM*, tenders are used to appoint preferred suppliers on the basis of a competitive process based on price competition. In such a system, high market shares for acetylcysteine are not necessarily indicative of the Parties' ability to affect the conditions of sale pre- or post-merger.<sup>147</sup>

#### Conclusion

- (565) Based on the above considerations, the Commission concludes that the Transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to expectorant products in Sweden.

#### Iceland

- (566) Mylan supplies Acetylcystein, named after its active pharmaceutical ingredient. Meda is present on the Icelandic market with its branded product Mucomyst which is based on acetylcysteine as its active pharmaceutical ingredient.
- (567) However, the Parties' products are not close competitors. Indeed, while Mylan's acetylcysteine is an effervescent product which is available OTC, Meda's product Mucomyst is a solution used for administration via nebulizer for patients who cannot take a different galenic form. Mucomyst is only sold through the hospital channel in Iceland. In addition, Meda's mucomyst has no marketing authorization in Iceland. It is imported to Iceland on the basis of a special license regime. This implies that the physician has to obtain prior approval from the Icelandic Medicines Agency before mucomyst is imported.
- (568) The Notifying Party submits that Mylan does not produce acetylcysteine solution for use in a nebulizer. As regards Iceland in particular, Meda may neither provide any marketing support nor any other promotion for its product. Meda can neither

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<sup>147</sup> COMP Case M.7379 Mylan/Abbott EPD-DM of 28 January 2015.paragraph 97.



influence how many orders are placed nor the price of its product in Iceland. The Notifying Party further submits that Sandoz (Novartis) received a marketing authorization for acetylcysteine products (Mucolysin) in Iceland in 2015.

- (569) The Icelandic Medicines Agency ("IMA") as respondent to the market investigation confirmed that mucomyst has no marketing authorization in Iceland and is imported on individual basis following an individual medical approval (named-patient use). The IMA also confirmed that Mylan's effervescent acetylcysteine and Meda's mucomyst are indicated for different patient groups and do not overlap. Furthermore, the IMA stated that Sandoz (Novartis) has begun to supply Iceland with an effervescent acetylcysteine in spring 2016.

#### Conclusion

- (570) Based on the above considerations, the Commission concludes that the Transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to expectorant products in Iceland.

#### IV.1.3.36. Other Group 2 and Group 3 markets in the respiratory system therapeutic area

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

- *ATC 3 class R5C in Sweden; and*
- *ATC 3 class R3D in the Netherlands.*

- (572) 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.

- (573) On these markets the combined market share of the Parties are moderate to low and / or the increment is below [0-5]%. 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 AstraZeneca, Medivir and Novartis.

- (574) The market investigation did not provide any indication that competition issues would arise in these markets.

- (575) Based on the above considerations, 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.

#### **OTHER THERAPEUTIC AREAS**

#### IV.1.3.37. Group 2 and group 3 markets in other therapeutic classes

- (576) In addition to the Group 1,2 and 3 markets analysed above, there is a number of Group 2 and Group 3 affected markets in other therapeutical areas than the ones analysed above, specifically:

- *ATC 3 class SIG in the United Kingdom;*

- *ATC 3 class S1E in Belgium;*
  - *ATC 3 class T2C in Italy; and*
  - *ATC 3 class V3X in Austria.*
- (577) 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.
- (578) On these markets the combined market share of the Parties are moderate to low and / or the increment is below [0-5]%. 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 Angelini, Artsana, Baxen Italia, Bioforce, Church & Dwight, Corman, Federpharma, Klosterfrau, Kwizda, Novartis, Pfizer, Pietrasanta Pharma, Safety and Sanamed,
- (579) The market investigation did not provide any indication that competition issues would arise in these markets. Based on the above considerations, 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.2. Pipeline products**

- (580) Pipeline products are those products which are not yet on the market but which are at an advanced stage of development. Once pipeline products in a sufficiently advanced stage of development are identified, the Commission assesses whether such pipeline products can compete with products that are already present on existing markets ("pipeline-to-marketed" competition) and/or with other pipeline products ("pipeline-to-pipeline" competition).
- (581) 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.<sup>148</sup>
- (582) The Notifying Party submits that Mylan and Meda have different strategies as regards pipeline products. Meda's pipeline products are acquired or in-licensed and mainly focus on well-known active ingredients and improving the characteristics of existing products while Mylan invests in research and development of new products.

##### *IV.2.1. Pipeline-To-Pipeline*

- (583) The Parties have one pipeline-to-pipeline overlap. Specifically, both Parties have generic pipeline products in the market for [...].
- (584) However, based on the market investigation, the Parties' pipeline [...] products are based on different molecules, and in the countries where both parties intend to launch

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<sup>148</sup> COMP/M.6258 Teva/Cephalon of 13 October 2011, paragraphs 81 and 129, and COMP/M.6613 Watson/Actavis of 5 October 2012, paragraphs 110-111.

their [...] products, there are several strong well-established generic companies active with the molecule the Parties intend to launch and/or in view of the recent loss of exclusivity of the originator product, several other generic suppliers are likely to launch a generic version.

#### *IV.2.2. Pipeline-To-Marketed*

- (585) Both Parties have pipeline products that overlap with a marketed product of the other party.
- (586) The Notifying Party has identified in the Form CO five 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 five relevant pipeline products of the Parties are the following:
- (587) Mylan has [Confidential information about Mylan's pipeline products]. Meda, on the other hand, has [Confidential information about Meda's pipeline products].
- (588) The market investigation did not reveal any concerns in relation to pipeline products and indicated 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 under the appropriate market definition no overlap would occur and that a number of strong competing pharmaceutical companies will remain active in these markets.
- (589) Based on the above considerations, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to the Parties' pipeline products.

### **IV.3. Active pharmaceutical ingredients**

- (590) An Active Pharmaceutical Ingredient ("API") is the substance in a FDP that is pharmaceutically active and is suspended in excipients (that is, inert substances taking the form, for instance, of a tablet or a solution), for the purposes of administration.
- (591) Both Parties are active in the production of APIs for pharmaceutical products.

#### *IV.3.1. Market definition*

##### *IV.3.1.1. Product market definition*

- (592) In the past, the Commission considered that APIs constitute separate markets that are upstream to the markets for marketing FDPs and that each individual API potentially constitutes a separate product market, whilst noting that it was not excluded that certain APIs may be substitutable with each other for all, or for a range of, applications.<sup>149</sup>
- (593) In view of the fact that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to the API markets under any

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<sup>149</sup> See M.7645 Mylan/Perrigo of 29 July 2015; M.6258 Teva/Cephalon of 13 October 2011.

plausible market definition, the exact scope of the product market can be left open for the purposes of the competitive assessment of the Transaction.

#### IV.3.1.2. Geographic market definition

- (594) In the past, the Commission considered that API markets are, from a geographic perspective, at least EEA-wide and possibly global in scope.<sup>150</sup>
- (595) In view of the fact that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to the API markets under any plausible market definition, the exact scope of the geographic market can be left open for the purposes of the competitive assessment of the Transaction.

#### IV.3.2. *Competitive assessment*

- (596) In line with the Commission's previous practice,<sup>151</sup> the Notifying Party identified one vertically affected market. Specifically, Mylan holds more than 5% in the aciclovir API market while Meda holds a market share in excess of 30% at the downstream FDP market defined at the molecule level and, at the upstream level,
- (597) In particular, Meda commercializes an aciclovir product in Norway and Sweden. In both countries Meda's market share exceeds the threshold of 30% at the molecule level. The amount of aciclovir used in FDPs in both Norway and Sweden accounts for less than [0-5]% of the EEA and worldwide upstream API markets.
- (598) Mylan does not have a significant upstream market power in relation to acyclovir API as a result of which input foreclosure is unlikely.<sup>152</sup> Similarly, as concerns customer foreclosure, it is noted that (1) API volumes sold for the purpose of manufacturing the FDP in the relevant countries are very small compared to the corresponding total worldwide volume for the API and (2) since suppliers of APIs are active globally, it is unlikely that losing one customer in Norway and Sweden would have any impact on their activity.
- (599) Finally, the market investigation did not reveal any concerns in relation to any vertical links stemming from this Transaction.
- (600) Based on the above considerations, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to any vertical links between APIs and FDPs.

#### IV.4. **Contract manufacturing**

- (601) 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. The contract manufacturing process may or may not include the provision of the final packaging of the product. In

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<sup>150</sup> See M.7645 Mylan/Perrigo of 29 July 2015; M.6258 Teva/Cephalon of 13 October 2011.

<sup>151</sup> See M.7645 Mylan/Perrigo of 29 July 2015.

<sup>152</sup> Mylan's aciclovir market share is [20-30]% on a worldwide basis and [20-30]% if the market would be defined at the EEA level.

its previous decisions, the Commission found that the geographic market for contract manufacturing to be worldwide or at least EEA-wide.<sup>153</sup>

- (602) Both Mylan and Meda have contract manufacturing activities. None of the Parties is a major player in contract manufacturing activities given their low estimated market shares in various segments. Furthermore, a sufficient number of suppliers providing contract manufacturing services are likely to remain post-merger.
- (603) The market investigation did not reveal any concerns in relation to contract manufacturing activities.
- (604) Based on the above considerations, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to the Parties' contract manufacturing activities.

#### **IV.5. Outlicensing**

- (605) 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%.
- (606) Both Parties outlicense dossiers to third parties. While several 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 fact that strong competitors will remain active post-merger on the downstream market; and (ii) ample alternative sources of supply.
- (607) The market investigation did not reveal any concerns in relation to outlicensing activities.
- (608) Based on the above considerations, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to the Parties' outlicensing activities.

### **V. COMMITMENTS**

#### **V.1. Framework for the assessment of the Commitments**

- (609) Where a notified concentration raises serious doubts as to its compatibility with the internal market, the parties may undertake to modify the concentration so as to remove the grounds for the serious doubts identified by the Commission. Pursuant to Article 6(2) of the Merger Regulation, where the Commission finds that, following modification by the undertakings concerned, a notified concentration no longer raises serious doubts, it shall declare the concentration compatible with the internal market pursuant to Article 6(1)(b) of the Merger Regulation.

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<sup>153</sup> COMP/M.5953 Reckitt Benckiser/SSL of 25 October 2010, paragraph 64, and COMP/M.6613 Watson/Actavis of 5 October 2012, paragraph 124.

- (610) As set out in the Commission's Remedies Notice<sup>154</sup>, the commitments have to eliminate the competition concerns entirely, and have to be comprehensive and effective from all points of view.<sup>155</sup>
- (611) In assessing whether commitments will maintain effective competition, the Commission considers all relevant factors, including the type, scale and scope of the proposed commitments with reference to the structure and the particular characteristics of the market in which the Transaction is likely to significantly impede effective competition, including the position of the Parties and other participants on the market.<sup>156</sup>
- (612) In order for the commitments to comply with those principles, they must be capable of being implemented effectively within a short period of time. Concerning the form of acceptable commitments, the Merger Regulation gives discretion to the Commission as long as the commitments meet the required standards. Structural commitments will meet the conditions set out above only in so far as the Commission is able to conclude with the requisite degree of certainty, at the time of its Decision, that it will be possible to implement them and that it will be likely that the new commercial structures resulting from them will be sufficiently workable and lasting to ensure that effective competition will be maintained.<sup>157</sup> Divestiture commitments are normally the best way to eliminate competition concerns resulting from horizontal overlaps.
- (613) The divested activities must consist of a 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. The business 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.<sup>158</sup>
- (614) The intended effect of the divestiture will only be achieved if and once the business is transferred to a suitable purchaser in whose hands it will become an active competitive force in the market. The potential of a business to attract a suitable purchaser is an important element of the Commission's assessment of the appropriateness of the proposed commitment.<sup>159</sup>
- (615) It is against this background that the Commission analysed the proposed commitments in this case.

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<sup>154</sup> Commission Notice on remedies acceptable under Council Regulation (EC) No 139/2004 and under Commission Regulation (EC) No 802/2004 (OJ C 267, 22.10.2008, p. 1-27), the "Remedies Notice".

<sup>155</sup> Remedies Notice, paragraphs 9 and 61.

<sup>156</sup> Remedies Notice, paragraph 12.

<sup>157</sup> Remedies Notice, paragraph 10.

<sup>158</sup> Remedies Notice, paragraph 23-25.

<sup>159</sup> Remedies Notice, paragraph 47.

## V.2. Commitments submitted by the Parties

- (616) In order to render the concentration compatible with the internal market, the Parties have modified the notified concentration by entering into the following Commitments pursuant to Article 6(2) of the Merger Regulation, which the Notifying Party submitted on 29 June 2016 (the "Initial Commitments"). The Commission market tested the Initial Commitments in order to assess whether they are sufficient and suitable to remedy the serious doubts identified above. The Commitments were subsequently modified on 11 July 2016, to exclude certain divestment businesses in relation to which the Commission had in the meantime dispelled concerns on the basis of supplementary information provided by the Notifying Party.<sup>160</sup> The final version of the Commitments including the adaptations made following the results of the market test was submitted on 12 July 2016.
- (617) Specifically, Mylan offered to divest its or Meda's 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").
- (618) The businesses to be divested (hereafter referred to as "the Divestment Businesses") include the following:
- (i) Mylan's propafenone business in Belgium;
  - (ii) Mylan's propafenone business in Luxembourg;
  - (i) Mylan's flecainide business in Belgium;
  - (ii) Mylan's propafenone business in Ireland;
  - (iii) Mylan's flecainide business in Ireland;
  - (iv) Mylan's propafenone business in Italy;
  - (v) Mylan's propafenone business in Spain;
  - (vi) Meda's flecainide business in Portugal;
  - (vii) Meda's flecainide business in the United Kingdom;
  - (viii) Meda's flecainide business in Estonia;
  - (ix) Mylan's povidone-iodine business in France;
  - (x) Mylan's diltiazem (Dilfar & Diltiazem) business in Portugal;
  - (xi) Meda's Dagravit 8 business in Portugal;
  - (xii) Meda's progesterone business in Austria;
  - (xiii) Meda's amoxicillin business in Norway;

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<sup>160</sup> See section IV.2.3.2.c concerning nitroglycerin patches in France, Belgium and Luxembourg.

- (xiv) Mylan's megestrol business in Spain; and
  - (xv) Mylan's nabumetone business in the United Kingdom.
- (619) 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. 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);
  - ii. all licences, permits and authorizations issued by any governmental organisation;
  - iii. all contracts, commitments and customer orders of the Divestment Business; all customer, credit and other records;
  - iv. all advertising, marketing, sales, publicity and presentational materials related to the Divestment Business;
  - v. the full transfer of the brand as relevant;
  - vi. if such contract exists, a best efforts obligation to obtain the assignment of existing contract manufacturing contracts and/or awarded tender contracts and/or the active pharmaceutical ingredient ("API") supply contracts and/or any other relevant contract currently in place, in particular where the assignment of these contracts is subject to third party consent;
  - vii. the benefit for a period of up to two years after Closing (i) 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 Member State of the Divestment Business (such transitory arrangement(s) shall include appropriate provisions to ensure the continued supply of the product to the Purchaser, including prioritization of the supply to the Purchaser in case of shortages); and/or (ii) at a reasonable cost reimbursement to be agreed with the Purchaser and overseen by the Monitoring Trustee of reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of the relevant Divestiture Business;
  - viii. an option for the Purchaser to hire one or more Personnel (subject to applicable local employment legislation) 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.
- (620) In addition, Mylan has entered into related commitments, *inter alia* regarding the separation of the Divestment Businesses from their retained businesses, the preservation of the economic viability, marketability and competitiveness of the Divestment Businesses, including the appointment of a monitoring trustee and, if necessary, a divestiture trustee.



- (621) The Commitments also include specific Purchaser requirements in particular the need for the Purchaser(s) to have an existing marketing and distribution footprint that includes generic pharmaceuticals in the relevant countries.

## **VI. ASSESSMENT OF THE PROPOSED COMMITMENTS**

- (622) The Commission analysed the suitability of the Commitments to remedy serious doubts in this case against the standard set out in the Commission Remedies Notice. In its assessment, the Commission relied *inter alia* on the results of the market test launched on 30 June 2016.

### **VI.1. Suitability for removing serious doubts**

- (623) The results of the market test of the Commitments were 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.

- (624) In particular, the Commitments consist of businesses which include in particular marketing authorisations issued by national health authorities and provide the access to the national pharmaceutical product markets where competition concerns were identified.

- (625) Since it is a common practice in the pharmaceutical sector to cooperate with third-party producers of APIs or FDPs, 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/Meda 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.

- (626) 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**

- (627) Besides the standard criteria for a suitable purchaser contained in section D of the Commitments, the results of the market test confirmed the need for a suitable Purchaser(s) to be an established player in the business of marketing generic pharmaceutical products. This is because, according to the market test, companies marketing generic pharmaceutical products tend to compete using their entire portfolio or a subset of products 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.

(628) The market test also confirmed that a suitable Purchaser needs to have an existing and strong distribution and sales footprint in the relevant countries in order to guarantee a successful and prompt commercialisation of the divested products.

### **VI.3. Interest in the Commitments**

(629) The market test revealed an interest of a sufficient number of potentially suitable Purchasers. The Commission therefore considers that the Commitments are likely to be implemented in practice within a short period of time.

### **VI.4. Conclusion on the Commitments**

(630) 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.

(631) The Commitments address the competition concerns identified in the present decision as they remove the overlap between Mylan and Meda in all problematic markets and provide grounds for a new player to emerge.

(632) In particular, the Commitments are suitable and sufficient to remedy the serious doubts raised by the Transaction in relation to the 15 markets where serious doubts were identified, namely:

- i. Vaughan Williams Class I-C (propafenone and flecainide) in Belgium, Estonia, Ireland, Italy, Luxembourg, Portugal, Spain and the United Kingdom.
- ii. Povidone-iodine in France;
- iii. Diltiazem in Portugal;
- iv. Multivitamins without minerals for paediatric use (Dagravit 8) in Portugal;
- v. Progestones in Austria;
- vi. Amoxicillin in Norway;
- vii. Megestrol in Spain; and
- viii. Nabumetone in the United Kingdom.

(633) 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.

(634) 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.

### **VI.5. Conditions and obligations**

(635) 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.

- (636) 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 6(3)(b) of the Merger Regulation. The undertakings concerned may also be subject to fines and periodic penalty payments under Articles 14(2)(d) and 15(1)(c) of the Merger Regulation.
- (637) 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.
- (638) The full text of the final Commitments is annexed to the present Decision and forms an integral part thereof.

## **VII. CONCLUSION**

- (639) 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 Section B (including the Schedules) 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*

**Case COMP/M.7975 – MYLAN/MEDA**

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**COMMITMENTS**

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## COMMITMENTS TO THE EUROPEAN COMMISSION

Pursuant to Article 6(2) of Council Regulation (EC) No 139/2004 (the "**Merger Regulation**"), Mylan N.V. ("**Mylan**") hereby enter 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 Meda AB (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**").

## SECTION A – DEFINITIONS

- (1) For the purpose of the Commitments, the following terms shall have the following meaning:

**Affiliated Undertakings:** undertakings controlled by the Parties and/or by the ultimate parents of the Parties, whereby the notion of control shall be interpreted pursuant to Article 3 of the Merger Regulation and in 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, paragraph 6 (a), (b) and (c) 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 [...] months 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.

**Divestment Business:** the business or businesses as defined in Section B and in the Schedule which Mylan commits to divest.

**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.

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

**First Divestiture Period:** the period of [...] months 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.

**Meda:** Meda AB is a public limited liability company organized under the laws of Sweden, with its corporate seat in Stockholm, Sweden. Its corporate identity number at the Swedish Companies Registrations office (*Bolagsverket*) is (556427-2812).

**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:** Mylan N.V. a private limited liability company organized and existing under the laws of the Netherlands, with its corporate seat in Amsterdam, the Netherlands and

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registered at the Dutch chamber of commerce (*Kamer van Koophandel*) under number 61036137.

**Parties:** Mylan and Meda.

**Personnel:** the staff that could be reasonably considered necessary to maintain the viability, marketability and competitiveness of the Divestment Business.

**Purchaser:** the entity 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 17 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.

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

**Trustee Divestiture Period:** the period of [...] months 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 Business by the end of the Trustee Divestiture Period as a going concern to a purchaser and on terms of sale approved by the Commission in accordance with the procedure described in paragraph 18 of these Commitments. To carry out the divestiture, Mylan commits to find a purchaser/purchasers 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 30 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 18; and
  - (b) the Closing of the sale of the Divestment Business 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
  - (5)



the whole or part of the Divestment Business, unless, following the submission of a reasoned request from the Mylan showing good cause and accompanied by a report from the Monitoring Trustee (as provided in paragraph 44 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 propafenone business in Belgium;
  - (ii) Mylan's propafenone business in Luxembourg;
  - (iii) Mylan's flecainide business in Belgium;
  - (iv) Mylan's propafenone business in Ireland;
  - (v) Mylan's flecainide business in Ireland;
  - (vi) Mylan's propafenone business in Italy;
  - (vii) Mylan's propafenone business in Spain;
  - (viii) Meda's flecainide business in Portugal;
  - (ix) Meda's flecainide business in the United Kingdom;
  - (x) Meda's flecainide business in Estonia;
  - (xi) Mylan's povidone-iodine business in France;
  - (xii) Mylan's diltiazem (Dilfar & Diltiazem) business in Portugal;
  - (xiii) Meda's Dagravit 8 business in Portugal;
  - (xiv) Meda's progesterone business in Austria;
  - (xv) Meda's amoxicillin business in Norway;
  - (xvi) Mylan's megestrol business in Spain;
  - (xvii) Mylan's nabumetone business in the United Kingdom.
- (6) Each of these Divestment Businesses, described in more detail in the Schedules, shall include to the extent specific to the relevant Divestment Business, 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,
- (6)

- marketability and competitiveness of the Divestment Business);
- (b) all licences, permits and authorizations 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) <sup>1</sup> to obtain the assignment of existing contract manufacturing contracts and/or awarded tender contracts and/or the active pharmaceutical ingredient ("**API**") supply contracts and/or any other relevant contract currently in place, in particular where the assignment of these contracts is subject to third party consent;
  - (g) the benefit for a period of up to 2 years after Closing (i) on a reasonable cost-plus basis to be agreed with the Purchaser and overseen by the Monitoring Trustee in accordance with paragraph (28)(iii), of a non-exclusive and transitory manufacturing or supply arrangement relating to the existing forms of product in the Member State of the Divestment Business (such transitory arrangement(s) shall include appropriate provisions to ensure the continued supply of the product to the Purchaser, including prioritization of the supply to the Purchaser in case of shortages); and/or (ii) at a reasonable cost reimbursement to be agreed with the Purchaser and overseen by the Monitoring Trustee in accordance with paragraph (28)(iii), of 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.

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<sup>1</sup> 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).

## **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 minimize 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;
  - (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 Meda business as will be transferred to Mylan after the Effective Date. Mylan also commits to ensure that the Personnel of the Divestment Business – including the Hold Separate Manager – will have no involvement in the Meda business as will be transferred to Mylan after the Effective Date. Mylan likewise commits to ensure that the personnel of the Meda business will be transferred to Mylan after the Effective Date will have no involvement in the Divestment Business.
- (10) Until closing, Mylan shall assist the Monitoring Trustee in ensuring that the Divestment Business is managed separately from the Meda business 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 Meda business 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 obtain commercially sensitive and/or product specific confidential information relating to the Meda business as will be
- (8)

transferred to Mylan after the Effective Date.

- (12) Mylan shall implement, or procure to implement, all necessary measures to ensure that its personnel that manages the Meda business as will be transferred to Mylan after the Effective Date shall not obtain commercially sensitive and/or product specific confidential information relating to the Divestment Businesses.

Non-Solicitation clause

- (13) 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 according to paragraph 6(g) for a period of 24 months after Closing.

Due diligence

- (14) In order to enable potential purchasers to carry out a reasonable due diligence of the Divestment Business, Mylan shall, subject to customary confidentiality assurances and subject to confidentiality obligations vis-à-vis third parties 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 and allow them reasonable access to the Personnel.

Reporting

- (15) 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.
- (16) 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**

- (17) 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
- (9)

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 that includes generic pharmaceuticals 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.
- (18) 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 parts of the Personnel, or by substituting one or more Assets or parts of the Personnel with one or more different assets or different personnel, 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**

- (19) 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.
- (20) 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.
- (21) 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
- (10)

sufficient relevant experience as an investment banker or consultant or auditor;  
and

- (iii) neither have nor become exposed to a Conflict of Interest.
- (22) The Trustee shall be remunerated by the 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*

- (23) No later than two weeks after the Effective Date, Mylan shall submit the name or names of one 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 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*

- (24) 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*

- (25) 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 (19) and (24) of these Commitments.

*Trustee nominated by the Commission*

- (26) 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

- (27) 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*

- (28) 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 business retained by the Parties, in accordance with paragraphs 8 and 9 of these Commitments;
    - (b) supervise the management of the Divestment Business as a distinct and saleable entity, in accordance with paragraph 10 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 Divestment Business,
      - in particular strive for the severing of the Divestment Business' participation in a central information technology network to the extent possible, without compromising the viability of the Divestment Business,
      - 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 and the allocation of Personnel between the Divestment Business and Mylan or Affiliated Undertakings;
- (iii) oversee the determination of the reasonable cost-plus basis for the transitory manufacturing or supply arrangements and/or reasonable cost reimbursement for technical assistance that Mylan will offer to the Purchaser (see paragraph (6)(g) 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 and the nondisclosure 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 reasonable 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 18 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.
- (29) 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*

- (30) 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 (15) and (16) 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.
- (31) In the Trustee Divestiture Period (or otherwise at the Commission's request), the Divestiture Trustee shall provide the Commission with a comprehensive monthly report written in English on the progress of the divestiture process. Such reports shall be submitted within 15 days after the end of every month with a simultaneous copy to the Monitoring Trustee and a non-confidential copy to the Parties.

### III. Duties and obligations of the Parties

- (32) Mylan shall provide and shall cause its advisors to provide the Trustee with all such cooperation, assistance and information as the Trustee may reasonably require to perform its tasks. The Trustee shall have full and complete access to any of Mylan's or the Divestment Business' books, records, 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.
- (33) 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
- (14)

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.

- (34) 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.
- (35) 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.
- (36) At the expense of Mylan, the Trustee may appoint advisors (in particular for corporate finance or legal advice), 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 35 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.
- (37) 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*.
- (38) 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.
- (39) 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

- (40) 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.
- (41) If the Trustee is removed according to paragraph 40 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 19-26 of these Commitments.
- (42) Unless removed according to paragraph 40 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**

- (43) 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 Mylan. Only in exceptional circumstances shall Mylan be entitled to request an extension within the last month of any period.
- (44) 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**

- (45) The Commitments shall take effect upon the date of adoption of the Decision.

*[signature]* duly authorized for and on behalf of Mylan

## **Product: Mylan's propafenone products**

### **Territory: Belgium**

- (1) The Divestment Business consists of Mylan's rights, title and interests in propafenone in Belgium (currently marketed under the name Rytmonorm) including the right to develop, manufacture and use propafenone with a view to its sale and marketing in any form in Belgium. Propafenone is no longer under exclusivity and is used for several indications (i) life-threatening ventricular tachycardia; (ii) non-sustained ventricular tachycardia, when other treatments have proved ineffective; (iii) AV-nodal tachycardia, when beta-blockers and calcium channel blockers have proved ineffective; (iv) Wolff-Parkinson-White Syndrome and similar conditions; and (v) paroxysmal atrial fibrillation and atrial flutter. For the avoidance of doubt, this Divestment Business does not include any rights to sell propafenone outside of Belgium.
- (2) The Divestment Business includes:
  - (a) the sale of existing propafenone finished product inventory,<sup>2</sup> sales and promotional material in Belgium to the extent available;
  - (b) all propafenone-related contracts, commitments, and customer records, meaning customer credit records, customer invoices, purchase orders and contact details, whilst only the information related to propafenone specifically will be provided;<sup>3</sup>
  - (c) the transfer of the marketing authorization for propafenone in Belgium 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 authorizations available to Mylan;
  - (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 the Divestment Business with a view to its sale in Belgium, including in particular the information in the registration dossier; and
  - (e) subject to consent of the licensor ([...]), full transfer of the trademark "Rytmonorm" related to propafenone in Belgium or a sub-license to use that trademark for the Divestment Business, subject to the terms and conditions, Mylan's rights and obligations, and any other restriction under the sub-license.

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<sup>2</sup> Where it concerns the transfer of inventory bearing the [...] trademark or trade dress, Mylan will make its best efforts to obtain [...] consent.

<sup>3</sup> Mylan will include all customer lists and records since 2011 in the Divestment Business.

The items referred to under (a) - (e) are hereinafter collectively referred to as "**Assets of the Divestment Business**".<sup>4</sup>

- (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 propafenone in Belgium, 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 propafenone in Belgium.
- (4) Mylan will transfer all historical information (orders, price, etc.) concerning its relationship, if applicable, regarding propafenone in Belgium with contract manufacturers [...] and [...] and its API supplier [...] to the Purchaser in accordance with applicable law. Mylan commits to make its best efforts to facilitate the assignment to the Purchaser of the supply agreements it has in place concerning the Divestment Business, subject to the consent of the respective parties.
- (5) Mylan shall make its best effort to obtain written consent of the licensor for the transfer, licensing or sub-licensing of the trademark "Rytmonorm" relating to propafenone in Belgium.
- (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. Until transfer of the Divestment Business, Mylan will bear the costs for updates to maintain the current registration of the dossier of the Divestment Business. In addition, Mylan will bear the dossier preparation and regulatory filing costs for all the updates of the dossier triggered by the transfer of the Divestment Business to the Purchaser.
- (7) 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.
- (8) 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 propafenone after Closing;

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<sup>4</sup> For the avoidance of doubt, the Divestment Business is transferred subject to any contractual obligations or restrictions applicable thereto in favor of third parties, including those as to development, manufacture, distribution, marketing and sale.

- (d) all marketing authorizations currently held by the Parties outside of Belgium for propafenone;
  - (e) any other asset not part of the Divestment Business or which is used in relation to a business of the Parties other than the Divestment Business;
  - (f) the "Mylan" name, Mylan trademark and Mylan trade dress or the name, trademark and trade dress of any Mylan subsidiaries;<sup>5</sup> and
  - (g) monies owed to the Parties by customers for the purchase of propafenone, and monies owed by the Parties to suppliers for materials used in the production of propafenone.
- (9) If there is any asset or personnel which is not 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 personnel or adequate substitute will be offered to the Purchaser.

\* \* \* \* \*

**Product: Mylan's propafenone products**

**Territory: Luxembourg**

- (1) The Divestment Business consists of Mylan's rights, title and interests in propafenone in Luxembourg (currently marketed under the name Rytmonorm) including the right to develop, manufacture and use propafenone with a view to its sale and marketing in any form in Luxembourg. Propafenone is no longer under exclusivity and is used for several indications (i) life-threatening ventricular tachycardia; (ii) non-sustained ventricular tachycardia, when other treatments have proved ineffective; (iii) AV-nodal tachycardia, when beta-blockers and calcium channel blockers have proved ineffective; (iv) Wolff-Parkinson-White Syndrome and similar conditions; and (v) paroxysmal atrial fibrillation and atrial flutter. For the avoidance of doubt, this Divestment Business does not include any rights to sell propafenone outside of Luxembourg.
- (2) The Divestment Business includes:
  - (a) the sale of existing propafenone finished product inventory,<sup>6</sup> sales and promotional material in Luxembourg to the extent available;

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<sup>5</sup> With the exception of the sale of inventory existing at Closing and sold to the Purchaser.

<sup>6</sup> Where it concerns the transfer of inventory bearing the [...] trademark or trade dress, Mylan will make its best efforts to obtain [...] consent.

- (b) all propafenone-related contracts, commitments, and customer records, meaning customer credit records, customer invoices, purchase orders and contact details, whilst only the information related to propafenone specifically will be provided;<sup>7</sup>
- (c) the transfer of the marketing authorization for propafenone in Luxembourg 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 authorizations available to Mylan;
- (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 the Divestment Business with a view to its sale in Luxembourg, including in particular the information in the registration dossier; and
- (e) subject to consent of the licensor ([...]), full transfer of the trademark "Rytmonorm" related to propafenone in Luxembourg or a sub-license to use that trademark for the Divestment Business, subject to the terms and conditions, Mylan's rights and obligations, and any other restriction under the sub-license.

The items referred to under (a) - (e) are hereinafter collectively referred to as "**Assets of the Divestment Business**".<sup>8</sup>

- (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 propafenone in Luxembourg, 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 propafenone in Luxembourg.
- (4) Mylan will transfer all historical information (orders, price, etc.) concerning its relationship, if applicable, regarding propafenone in Luxembourg with contract manufacturers [...] and [...] and its API supplier [...] to the Purchaser in accordance with applicable law. Mylan commits to make its best efforts to facilitate the assignment to the Purchaser of the supply agreements it has in place concerning the Divestment Business, subject to the consent of the respective parties.
- (5) Mylan shall make its best effort to obtain written consent of the licensor for the transfer, licensing or sub-licensing of the trademark "Rytmonorm" relating to propafenone in Luxembourg.

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<sup>7</sup> Mylan will include all customer lists and records since 2011 in the Divestment Business.

<sup>8</sup> For the avoidance of doubt, the Divestment Business is transferred subject to any contractual obligations or restrictions applicable thereto in favor of third parties, including those as to development, manufacture, distribution, marketing and sale.

- (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. Until transfer of the Divestment Business, Mylan will bear the costs for updates to maintain the current registration of the dossier of the Divestment Business. In addition, Mylan will bear the dossier preparation and regulatory filing costs for all the updates of the dossier triggered by the transfer of the Divestment Business to the Purchaser.
- (7) 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.
- (8) 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 propafenone after Closing;
  - (d) all marketing authorizations currently held by the Parties outside of Luxembourg for propafenone;
  - (e) any other asset not part of the Divestment Business or which is used in relation to a business of the Parties other than the Divestment Business;
  - (f) the "Mylan" name, Mylan trademark and Mylan trade dress or the name, trademark and trade dress of any Mylan subsidiaries;<sup>9</sup> and
  - (g) monies owed to the Parties by customers for the purchase of propafenone, and monies owed by the Parties to suppliers for materials used in the production of propafenone.
- (9) If there is any asset or personnel which is not 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 personnel or adequate substitute will be offered to the Purchaser.

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<sup>9</sup> With the exception of the sale of inventory existing at Closing and sold to the Purchaser.



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**Product: Mylan's flecainide products**

**Territory: Belgium**

- (1) The Divestment Business consists of Mylan's rights, title and interests in flecainide in Belgium (currently marketed under the name Flecaïnide) including the right to develop, manufacture and use flecainide with a view to its sale and marketing in any form in Belgium. Flecainide is no longer under exclusivity and is used for several indications (i) life-threatening ventricular tachycardia; (ii) non-sustained ventricular tachycardia, when other treatments have proved ineffective; (iii) AV-nodal tachycardia, when beta-blockers and calcium channel blockers have proved ineffective; (iv) Wolff-Parkinson-White Syndrome and similar conditions; and (v) paroxysmal atrial fibrillation and atrial flutter. For the avoidance of doubt, this Divestment Business does not include any rights to sell flecainide outside of Belgium.
  
- (2) The Divestment Business includes:
  - (a) the sale of existing flecainide finished product inventory, sales and promotional material in Belgium, as far as available;
  - (b) all flecainide-related contracts, commitments and customer records, meaning customers credit records, customer invoices, purchase orders and contact details, whilst only the information related to flecainide specifically will be provided;<sup>10</sup>
  - (c) the transfer of the marketing authorization for Mylan's flecainide in Belgium including the relevant dossiers, as well as the information contained in the relevant full registration dossier(s), relating to the current and/or pending marketing authorizations 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 Belgium, including in particular the information contained in the registration dossier.

The items referred to under (a) - (d) are 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 flecainide in Belgium, 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 flecainide in Belgium.

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<sup>10</sup> Mylan will include all customer lists and records since 2011 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 Belgium 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 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. Until transfer of the Divestment Business, Mylan will bear the costs for updates to maintain the current registration of the dossier of the Divestment Business. In addition, Mylan will bear the dossier preparation and regulatory filing costs for all the updates of the dossier triggered by the transfer of the Divestment Business to the Purchaser.
- (6) At the option of the Purchaser, Mylan shall provide reasonable technical assistance at a reasonable cost reimbursement to the Purchaser to assume responsibility for the manufacture, sale and marketing of flecainide in Belgium 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.
- (7) 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.
- (8) 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 flecainide after Closing;
  - (d) all marketing authorizations currently held by the Parties outside of Belgium for flecainide;
  - (e) any other asset not part of the Divestment Business or which is used in relation to a business of the Parties other than the Divestment Business;
  - (f) the "Mylan" name, Mylan trademark and Mylan trade dress or the name, trademark and trade dress of any Mylan subsidiaries;<sup>11</sup> and
  - (g) monies owed to the Parties by customers for the purchase of flecainide, and

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<sup>11</sup> With the exception of the sale of inventory existing at Closing and sold to the Purchaser.

monies owed by the Parties to suppliers for materials used in the production of flecainide.

- (9) If there is any asset or personnel which is not 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 personnel or adequate substitute will be offered to the Purchaser.

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**Product: Mylan's propafenone products**

**Territory: Ireland**

- (1) The Divestment Business consists of Mylan's rights, title and interests in propafenone in Ireland (currently marketed under the name Arythmol) including the right to develop, manufacture and use propafenone with a view to its sale and marketing in any form in Ireland. Propafenone is no longer under exclusivity and is used for several indications (i) life-threatening ventricular tachycardia; (ii) non-sustained ventricular tachycardia, when other treatments have proved ineffective; (iii) AV-nodal tachycardia, when beta-blockers and calcium channel blockers have proved ineffective; (iv) Wolff-Parkinson-White Syndrome and similar conditions; and (v) paroxysmal atrial fibrillation and atrial flutter. For the avoidance of doubt, this Divestment Business does not include any rights to sell propafenone outside of Ireland.
- (2) The Divestment Business includes:
- (a) the sale of existing propafenone finished product inventory,<sup>12</sup> sales and promotional material in Ireland to the extent available;
  - (b) all propafenone-related contracts, commitments, and customer records regarding the propafenone product in Ireland, meaning customer credit records, customer invoices, purchase orders and contact details, whilst only the information related to propafenone specifically will be provided;<sup>13</sup>
  - (c) the transfer of the marketing authorization for propafenone 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 authorizations available to Mylan;

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<sup>12</sup> Where it concerns the transfer of inventory bearing the [...] trademark or trade dress, Mylan will make its best efforts to obtain [...] consent.

<sup>13</sup> Mylan will include all customer lists and records since 2011 in the Divestment Business.

- (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 the Divestment Business with a view to its sale in Ireland, including in particular the information in the registration dossier; and
- (e) subject to consent of the licensor (Mr. [...]), full transfer of the trademark "Arythmol" related to propafenone in Ireland or a sub-license to use that trademark for the Divestment Business, subject to the terms and conditions, Mylan's rights and obligations, and any other restriction under the sub-license.

The items referred to under (a) - (e) are hereinafter collectively referred to as "**Assets of the Divestment Business**").<sup>14</sup>

- (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 propafenone in Ireland, 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 propafenone in Ireland.
- (4) Mylan will transfer all historical information (orders, price, etc.) concerning its relationship, if applicable, regarding propafenone in Ireland with contract manufacturers [...] and [...] and its API supplier [...] to the Purchaser in accordance with applicable law. Mylan commits to make its best efforts to facilitate the assignment to the Purchaser of the supply agreements it has in place concerning the Divestment Business, subject to the consent of the respective parties.
- (5) Mylan shall make its best effort to obtain written consent of the licensor for the transfer, licensing or sub-licensing of the trademark " Arythmol" relating to propafenone in Ireland.
- (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. Until transfer of the Divestment Business, Mylan will bear the costs for updates to maintain the current registration of the dossier of the Divestment Business. In addition, Mylan will bear the dossier preparation and regulatory filing costs for all the updates of the dossier triggered by the transfer of the Divestment Business to the Purchaser.
- (7) 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

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<sup>14</sup> For the avoidance of doubt, the Divestment Business is transferred subject to any contractual obligations or restrictions applicable thereto in favor of third parties, including those as to development, manufacture, distribution, marketing and sale.

by the Monitoring Trustee.

- (8) 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 propafenone after Closing;
  - (d) all marketing authorizations currently held by the Parties outside of Ireland for propafenone;
  - (e) any other asset not part of the Divestment Business or which is used in relation to a business of the Parties other than the Divestment Business;
  - (f) the "Mylan" name, Mylan trademark and Mylan trade dress or the name, trademark and trade dress of any Mylan subsidiaries;<sup>15</sup> and
  - (g) monies owed to the Parties by customers for the purchase of propafenone, and monies owed by the Parties to suppliers for materials used in the production of propafenone.
- (9) If there is any asset or Personnel which is not 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 personnel or adequate substitute will be offered to the Purchaser.

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**Product: Mylan's flecainide products**  
**Territory: Ireland**

- (1) The Divestment Business consists of Mylan's rights, title and interests in flecainide in Ireland (currently marketed under the name Flecainide) including the right to develop, manufacture and use flecainide with a view to its sale and marketing in any form in Ireland. Flecainide is no longer under exclusivity and is used for several indications (i) life-threatening ventricular tachycardia; (ii) non-sustained ventricular tachycardia, when other treatments have proved ineffective; (iii) AV-nodal tachycardia, when beta-blockers and calcium channel blockers have proved ineffective; (iv) Wolff-Parkinson-White Syndrome and similar conditions; and (v) paroxysmal atrial fibrillation and atrial flutter. For the avoidance of doubt, this Divestment Business does not include any rights to sell flecainide

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<sup>15</sup> With the exception of the sale of inventory existing at Closing and sold to the Purchaser.

outside of Ireland.

- (2) The Divestment Business includes:
- (a) the sale of existing flecainide finished product inventory, sales and promotional material in Ireland, as far as available;
  - (b) all flecainide-related contracts, commitments and customer records, meaning customers credit records, customer invoices, purchase orders and contact details, whilst only the information related to flecainide specifically will be provided;<sup>16</sup>
  - (c) the transfer of the marketing authorization for Mylan's flecainide in Ireland including the relevant dossiers, as well as the information contained in the relevant full registration dossier(s), relating to the current and/or pending marketing authorizations 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 Ireland, including in particular the information contained in the registration dossier.

The items referred to under (a) - (d) are 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 flecainide in Ireland, 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 flecainide in Ireland.
- (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 Ireland 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 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. Until transfer of the Divestment Business, Mylan will bear the costs for updates to maintain the current registration of the dossier of the Divestment Business. In addition, Mylan will bear the dossier preparation and regulatory filing costs for all the updates of the dossier triggered by the transfer of the Divestment Business to the Purchaser.
- (6) At the option of the Purchaser, Mylan shall provide reasonable technical assistance at a

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<sup>16</sup> Mylan will include all customer lists and records since 2011 in the Divestment Business.

reasonable cost reimbursement to the Purchaser to assume responsibility for the manufacture, sale and marketing of flecainide 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.

- (7) 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.
- (8) 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 flecainide after Closing;
  - (d) all marketing authorizations currently held by the Parties outside of Ireland for flecainide;
  - (e) any other asset not part of the Divestment Business or which is used in relation to a business of the Parties other than the Divestment Business.
  - (f) the "Mylan" name, Mylan trademark and Mylan trade dress or the name, trademark and trade dress of any Mylan subsidiaries;<sup>17</sup>and
  - (g) monies owed to the Parties by customers for the purchase of flecainide, and monies owed by the Parties to suppliers for materials used in the production of flecainide.
- (9) If there is any asset or personnel which is not 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 personnel or adequate substitute will be offered to the Purchaser.

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<sup>17</sup> With the exception of the sale of inventory existing at Closing and sold to the Purchaser.

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**Product: Mylan's propafenone products**

**Territory: Italy**

- (1) The Divestment Business consists of Mylan's rights, title and interests of propafenone in Italy (currently marketed under the name Rytmonorm) including the right to develop, manufacture and use propafenone with a view to its sale and marketing in any form in Italy. Propafenone is no longer under exclusivity and is used for several indications (i) life-threatening ventricular tachycardia; (ii) non-sustained ventricular tachycardia, when other treatments have proved ineffective; (iii) AV-nodal tachycardia, when beta-blockers and calcium channel blockers have proved ineffective; (iv) Wolff-Parkinson-White Syndrome and similar conditions; and (v) paroxysmal atrial fibrillation and atrial flutter. For the avoidance of doubt, this Divestment Business does not include any rights to sell propafenone outside of Italy.
- (2) The Divestment Business includes:
  - (a) the sale of existing propafenone finished product inventory,<sup>18</sup> sales and promotional material in Italy to the extent available;
  - (b) all propafenone-related contracts, commitments, and customer records regarding the propafenone product in Italy, meaning customer credit records, customer invoices, purchase orders and contact details, whilst only the information related to propafenone specifically will be provided;<sup>19</sup>
  - (c) the transfer of the marketing authorization for propafenone 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 authorizations available to Mylan;
  - (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 the Divestment Business with a view to its sale in Italy, including in particular the information in the registration dossier; and
  - (e) subject to consent of the licensor ([...]), full transfer of the trademark "Rytmonorm" related to propafenone in Italy or a sub-license to use that

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<sup>18</sup> Where it concerns the transfer of inventory bearing the [...] trademark or trade dress, Mylan will make its best efforts to obtain [...] consent.

<sup>19</sup> Mylan will include all customer lists and records since 2011 in the Divestment Business.



trademark for the Divestment Business, subject to the terms and conditions, Mylan's rights and obligations, and any other restriction under the sub-license.

The items referred to under (a) - (e) hereinafter collectively referred to as "**Assets of the Divestment Business**".<sup>20</sup>

- (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 propafenone in Italy, 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 propafenone in Italy.
- (4) Mylan will transfer all historical information (orders, price, etc.) concerning its relationship, if applicable, regarding propafenone in Italy with contract manufacturers [...] and [...] and its API supplier [...] to the Purchaser in accordance with applicable law. Mylan commits to make its best efforts to facilitate the assignment to the Purchaser of the supply agreements it has in place concerning the Divestment Business, subject to the consent of the respective parties.
- (5) Mylan shall make its best effort to obtain written consent of the licensor for the transfer, licensing or sub-licensing of the trademark "Rytmonorm" relating to propafenone in Italy.
- (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. Until transfer of the Divestment Business, Mylan will bear the costs for updates to maintain the current registration of the dossier of the Divestment Business. In addition, Mylan will bear the dossier preparation and regulatory filing costs for all the updates of the dossier triggered by the transfer of the Divestment Business to the Purchaser.
- (7) 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.
- (8) In relation to the existing tender contracts, Mylan commits to make its best efforts to suggest the Purchaser of the Divestment Business to the relevant tender authorities as the new supplier of the product for the remainder of the tender duration.
- (9) Mylan commits to continue its participation in tenders for the Divestment Business up until Closing. If Mylan were to win any tenders pertaining to propafenone in Italy before Closing, Mylan commits to make its best efforts to suggest the Purchaser of the Divestment Business to the relevant tender authorities as the new supplier of the product for the

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<sup>20</sup> For the avoidance of doubt, the Divestment Business is transferred subject to any contractual obligations or restrictions applicable thereto in favor of third parties, including those as to development, manufacture, distribution, marketing and sale.

remainder of the tender duration.

- (10) At the option of the Purchaser, and in case any of the tender contracting entities would decide not to accept the Purchaser as the new supplier with respect to the existing tender contract, Mylan will enter into a transitional dual distributorship arrangement related to the Divestment Business lasting until the relevant marketing authorization 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.
- (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 propafenone after Closing;
  - (d) all marketing authorizations currently held by the Parties outside of Italy for propafenone;
  - (e) any other asset not part of the Divestment Business or which is used in relation to a business of the Parties other than the Divestment Business;
  - (f) the "Mylan" name, Mylan trademark and Mylan trade dress or the name, trademark and trade dress of any Mylan subsidiaries;<sup>21</sup> and
  - (g) monies owed to the Parties by customers for the purchase of propafenone, and monies owed by the Parties to suppliers for materials used in the production of propafenone.
- (12) If there is any asset or personnel which is not 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 personnel or adequate substitute will be offered to the Purchaser.

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<sup>21</sup> With the exception of the sale of the inventory existing at Closing and sold to the Purchaser.

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**Product: Mylan's propafenone products**

**Territory: Spain**

- (1) The Divestment Business consists of Mylan's rights, title and interests in propafenone in Spain (currently marketed under the name Rytmonorm) including the right to develop, manufacture and use propafenone with a view to its sale and marketing in any form in Spain. Propafenone is no longer under exclusivity and is used for several indications (i) life-threatening ventricular tachycardia; (ii) non-sustained ventricular tachycardia, when other treatments have proved ineffective; (iii) AV-nodal tachycardia, when beta-blockers and calcium channel blockers have proved ineffective; (iv) Wolff-Parkinson-White Syndrome and similar conditions; and (v) paroxysmal atrial fibrillation and atrial flutter. For the avoidance of doubt, this Divestment Business does not include any rights to sell propafenone outside of Spain.
- (2) The Divestment Business includes:
  - (a) the sale of existing propafenone finished product inventory,<sup>22</sup> sales and promotional material in Spain to the extent available;
  - (b) all propafenone-related contracts, commitments, and customer records regarding the propafenone product in Spain, meaning customer credit records, customer invoices, purchase orders and contact details, whilst only the information related to propafenone specifically will be provided;<sup>23</sup>
  - (c) the transfer of the marketing authorization for propafenone in Spain 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 authorizations available to Mylan;
  - (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 the Divestment Business with a view to its sale in Spain, including in particular the information in the registration dossier;

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<sup>22</sup> Where it concerns the transfer of inventory bearing the [...] trademark or trade dress, Mylan will make its best efforts to obtain [...] consent.

<sup>23</sup> Mylan will include all customer lists and records since 2011 in the Divestment Business.

- (e) subject to consent of the licensor ([...]), full transfer of the trademark "Rytmonorm" related to propafenone in Spain or a sub-license to use that trademark for the Divestment Business, subject to the terms and conditions, Mylan's rights and obligations, and any other restriction under the sub-license.

The items referred to under (a) - (e) are hereinafter collectively referred to as "**Assets of the Divestment Business**".<sup>24</sup>

- (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 propafenone in Spain, 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 propafenone in Spain.
- (4) Mylan will transfer all historical information (orders, price, etc.) concerning its relationship, if applicable, regarding propafenone in Ireland with contract manufacturers [...] and [...] and its API supplier [...] to the Purchaser in accordance with applicable law. Mylan commits to make its best efforts to facilitate the assignment to the Purchaser of the supply agreements it has in place concerning the Divestment Business, subject to the consent of the respective parties..
- (5) Mylan shall make its best effort to obtain written consent of the licensor for the transfer, licensing or sub-licensing of the trademark "Rytmonorm" relating to propafenone in Spain.
- (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. Until transfer of the Divestment Business, Mylan will bear the costs for updates to maintain the current registration of the dossier of the Divestment Business. In addition, Mylan will bear the dossier preparation and regulatory filing costs for all the updates of the dossier triggered by the transfer of the Divestment Business to the Purchaser.
- (7) 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.
- (8) The Divestment Business shall not include:
  - (a) any manufacturing facility;
  - (b) raw materials;

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<sup>24</sup> For the avoidance of doubt, the Divestment Business is transferred subject to any contractual obligations or restrictions applicable thereto in favor of third parties, including those as to development, manufacture, distribution, marketing and sale.

- (c) any research and development, clinical data and studies or intellectual property relating to propafenone after Closing;
  - (d) all marketing authorizations currently held by the Parties outside of Spain for propafenone;
  - (e) any other asset not part of the Divestment Business or which is used in relation to a business of the Parties other than the Divestment Business;
  - (f) the "Mylan" name, Mylan trademark and Mylan trade dress or the name, trademark and trade dress of any Mylan subsidiaries;<sup>25</sup> and
  - (g) monies owed to the Parties by customers for the purchase of propafenone, and monies owed by the Parties to suppliers for materials used in the production of propafenone.
- (9) If there is any asset or personnel which is not 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 personnel or adequate substitute will be offered to the Purchaser.

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**Product: Meda's flecainide products**

**Territory: Portugal**

- (1) The Divestment Business consists of Meda's rights, title and interests of flecainide in Portugal (currently marketed under the name Apocard) including the right to develop, manufacture and use flecainide with a view to its sale and marketing in any form in Portugal. Flecainide is no longer under exclusivity and is used for several indications (i) life-threatening ventricular tachycardia; (ii) non-sustained ventricular tachycardia, when other treatments have proved ineffective; (iii) AV-nodal tachycardia, when beta-blockers and calcium channel blockers have proved ineffective; (iv) Wolff-Parkinson-White Syndrome and similar conditions; and (v) paroxysmal atrial fibrillation and atrial flutter. For the avoidance of doubt, this Divestment Business does not include any rights to sell flecainide outside of Portugal.
- (2) The Divestment Business includes:
- (a) the sale of existing flecainide finished product inventory, sales and promotional material in Portugal, as far as available;
  - (b) all flecainide-related contracts, commitments and customer records meaning

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<sup>25</sup> With the exception of the sale of inventory existing at Closing and sold to the Purchaser.

customers credit records, customer invoices, purchase orders and contact details, whilst only the information related to flecainide specifically will be provided;<sup>26</sup>

- (c) the transfer of the marketing authorization for Meda's flecainide in Portugal including the relevant dossiers, as well as the information contained in the relevant full registration dossier(s), relating to the current and/or pending marketing authorizations available to Meda;
- (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 Portugal, including in particular the information contained in the registration dossier; and
- (e) full transfer of the designation Portugal of the international trademark "Apocard" related to flecainide in Portugal.

The items referred to under (a) - (e) are 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 flecainide in Portugal, 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 flecainide in Portugal.
- (4) Meda will transfer all historical information (orders, price, etc.) concerning its relationship regarding flecainide in Portugal with [...] and [...] to the Purchaser in accordance with applicable law. Mylan commits to make its best efforts to facilitate the assignment to the Purchaser of the supply agreements it has in place concerning the Divestment Business, subject to the consent of the respective parties.
- (5) Mylan will transfer all historical information (orders; price; etc.) concerning its relationship with the [...] regarding the tender contract for flecainide in Portugal. Mylan commits to make its best efforts to support the Purchaser to obtain [...] consent for the transfer the tender contract.
- (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. Until transfer of the Divestment Business, Mylan will bear the costs for updates to maintain the current registration of the dossier of the Divestment Business. In addition, Mylan will bear the dossier preparation and regulatory filing costs for all the updates of the dossier triggered by the transfer of the Divestment Business to the Purchaser.
- (7) In relation to the existing tender contracts or contracts awarded before Closing, Mylan

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<sup>26</sup> Meda will include all customer lists and records since 2011 in the Divestment Business.

commits to make its best efforts to transfer the tender contracts to the Purchaser of the Divestment Business for the remainder of the tender duration.

- (8) 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.
- (9) The Divestment Business shall not include:
- (a) any manufacturing facility;
  - (b) raw materials;
  - (c) any research and development, clinical data and studies or intellectual property relating to flecainide after Closing;
  - (d) all marketing authorizations currently held by the Parties outside of Portugal for flecainide;
  - (e) any other asset not part of the Divestment Business or which is used in relation to a business of the Parties other than the Divestment Business;
  - (f) the "Meda" name, Meda trademark and Meda trade dress or the name, trademark and trade dress of any Meda subsidiaries;<sup>27</sup> and
  - (g) monies owed to the Parties by customers for the purchase of flecainide, and monies owed by the Parties to suppliers for materials used in the production of flecainide.
- (10) If there is any asset or personnel which is not 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 personnel or adequate substitute will be offered to the Purchaser.

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**Product: Meda's flecainide products**

**Territory: United Kingdom**

- (1) The Divestment Business consists of Meda's rights, title and interests of flecainide in the United Kingdom (currently marketed under the name Tambocor) including the right to

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<sup>27</sup> With the exception of the sale of the inventory existing at Closing and sold to the Purchaser.

develop, manufacture and use flecainide with a view to its sale and marketing in any form in the United Kingdom. Flecainide is no longer under exclusivity and is used for several indications (i) life-threatening ventricular tachycardia; (ii) non-sustained ventricular tachycardia, when other treatments have proved ineffective; (iii) AV-nodal tachycardia, when beta-blockers and calcium channel blockers have proved ineffective; (iv) Wolff-Parkinson-White Syndrome and similar conditions; and (v) paroxysmal atrial fibrillation and atrial flutter. For the avoidance of doubt, this Divestment Business does not include any rights to sell flecainide outside of the United Kingdom.

- (2) The Divestment Business includes:
- (a) the sale of existing flecainide finished product inventory, sales and promotional material in the United Kingdom, as far as available;
  - (b) all flecainide-related contracts, commitments and customer records meaning customers credit records, customer invoices, purchase orders and contact details, whilst only the information related to flecainide specifically will be provided;<sup>28</sup>
  - (c) the transfer of the marketing authorization for Meda's flecainide in the United Kingdom including the relevant dossiers, as well as the information contained in the relevant full registration dossier(s), relating to the current and/or pending marketing authorizations available to Meda;
  - (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 United Kingdom, including in particular the information contained in the registration dossier; and
  - (e) full transfer of the national trademark "Tambocor" related to flecainide in the UK.

The items referred to under (a) - (e) are 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 flecainide in the United Kingdom, 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 flecainide in the United Kingdom.
- (4) Meda will transfer all historical information (orders, price, etc.) concerning its relationship regarding flecainide in the United Kingdom with [...] and [...] to the Purchaser in accordance with applicable law. Mylan commits to make its best efforts to facilitate the assignment to the Purchaser of the supply agreements it has in place concerning the

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<sup>28</sup>

Meda will include all customer lists and records since 2011 in the Divestment Business.



Divestment Business, subject to the consent of the respective parties.

- (5) 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. Until transfer of the Divestment Business, Mylan will bear the costs for updates to maintain the current registration of the dossier of the Divestment Business. In addition, Mylan will bear the dossier preparation and regulatory filing costs for all the updates of the dossier triggered by the transfer of the Divestment Business to the Purchaser.
- (6) 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.
- (7) 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 flecainide after Closing;
  - (d) all marketing authorizations currently held by the Parties outside of the United Kingdom for flecainide;
  - (e) any other asset not part of the Divestment Business or which is used in relation to a business of the Parties other than the Divestment Business;
  - (f) the "Meda" name, Meda trademark and Meda trade dress or the name, trademark and trade dress of any Meda subsidiaries;<sup>29</sup> and
  - (g) monies owed to the Parties by customers for the purchase of flecainide, and monies owed by the Parties to suppliers for materials used in the production of flecainide.
- (8) If there is any asset or personnel which is not 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 personnel or adequate substitute will be offered to the Purchaser.

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<sup>29</sup> With the exception of the sale of the inventory existing at Closing and sold to the Purchaser.

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**Product: Meda's flecainide products**

**Territory: Estonia**

- (1) The Divestment Business consists of Meda's rights, title and interests of flecainide in Estonia (currently marketed under the name Tambocor) including the right to develop, manufacture and use flecainide with a view to its sale and marketing in any form in Estonia. Flecainide is no longer under exclusivity and is used for several indications (i) life-threatening ventricular tachycardia; (ii) non-sustained ventricular tachycardia, when other treatments have proved ineffective; (iii) AV-nodal tachycardia, when beta-blockers and calcium channel blockers have proved ineffective; (iv) Wolff-Parkinson-White Syndrome and similar conditions; and (v) paroxysmal atrial fibrillation and atrial flutter. For the avoidance of doubt, this Divestment Business does not include any rights to sell flecainide outside of Estonia.
- (2) The Divestment Business includes:
  - (a) the sale of existing flecainide finished product inventory, sales and promotional material in Estonia, as far as available
  - (b) all flecainide-related contracts, commitments and customer records meaning customers credit records, customer invoices, purchase orders and contact details, whilst only the information related to flecainide specifically will be provided;<sup>30</sup>
  - (c) the transfer of the marketing authorization for Meda's flecainide in Estonia including the relevant dossiers, as well as the information contained in the relevant full registration dossier(s), relating to the current and/or pending marketing authorizations available to Meda;
  - (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 Estonia, including in particular the information contained in the registration dossier; and

The items referred to under (a) - (d) are 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 flecainide in Estonia, 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

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<sup>30</sup>

Mylan will include all customer lists and records since 2011 in the Divestment Business.

such asset for the manufacture, use and sale of flecainide in Estonia.

- (4) Mylan commits neither to register the Tambocor brand in Estonia nor to oppose the future registration of Tambocor brand name by the Purchaser in Estonia. The Purchaser will have the right to use the Tambocor brand in Estonia.
- (5) Mylan will transfer all historical information (orders, price, etc.) concerning its relationship regarding flecainide in Estonia with [...] and [...] to the Purchaser in accordance with applicable law. Mylan commits to make its best efforts to facilitate the assignment to the Purchaser of the supply agreements it has in place concerning the Divestment Business, subject to the consent of the respective parties.
- (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. Until transfer of the Divestment Business, Mylan will bear the costs for updates to maintain the current registration of the dossier of the Divestment Business. In addition, Mylan will bear the dossier preparation and regulatory filing costs for all the updates of the dossier triggered by the transfer of the Divestment Business to the Purchaser.
- (7) 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.
- (8) 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 flecainide after Closing;
  - (d) all marketing authorizations currently held by the Parties outside of Estonia for flecainide;
  - (e) any other asset not part of the Divestment Business or which is used in relation to a business of the Parties other than the Divestment Business;
  - (f) the "Meda" name, Meda trademark and Meda trade dress or the name, trademark and trade dress of any Meda subsidiaries;<sup>31</sup> and
  - (g) monies owed to the Parties by customers for the purchase of flecainide, and monies owed by the Parties to suppliers for materials used in the production of

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<sup>31</sup> With the exception of the sale of the inventory existing at Closing and sold to the Purchaser.

flecainide.

- (9) If there is any asset or personnel which is not 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 personnel or adequate substitute will be offered to the Purchaser.

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**Product: Mylan's povidone-iodine products**

**Territory: France**

- (1) The Divestment Business consists of Mylan's rights, title and interests of povidone-iodine in France (currently marketed under the name Povidone-Iodee) including the right to develop, manufacture and use povidone-iodine with a view to its sale and marketing in any form in France. Povidone-iodine is no longer under exclusivity and is indicated for treatment of small wounds and infections. For the avoidance of doubt, this Divestment Business does not include any rights to sell povidone-iodine outside of France.
- (2) The Divestment Business includes:
- (a) the sale of existing povidone-iodine finished product inventory, sales and promotional material in France, as far as available;
  - (b) all povidone-iodine-related contracts, commitments and customer records meaning customers credit records, customer invoices, purchase orders and contact details, whilst only the information related to povidone-iodine specifically will be provided;<sup>32</sup>
  - (c) subject to the consent of the licensor, the transfer of the marketing authorization for povidone-iodine in France including the relevant dossiers, as well as the information contained in the relevant full registration dossier(s), relating to the current and/or pending marketing authorizations 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 France, including in particular the information contained in the registration dossier.

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

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<sup>32</sup> Mylan will include all customer lists and records since 2011 in 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 povidone-iodine in France, 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 povidone-iodine in France.
- (4) Mylan will transfer all historical information (orders, price, etc.) concerning its relationship regarding povidone-iodine in France with contract manufacturer [...] to the Purchaser in accordance with applicable law. Mylan commits to make its best efforts to facilitate the assignment to Purchaser of the supply agreement it has in place concerning the Divestment Business, subject to the consent of [...].
- (5) 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. Until transfer of the Divestment Business, Mylan will bear the costs for updates to maintain the current registration of the dossier of the Divestment Business. In addition, Mylan will bear the dossier preparation and regulatory filing costs for all the updates of the dossier triggered by the transfer of the Divestment Business to the Purchaser.
- (6) 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.
- (7) 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 povidone-iodine after Closing;
  - (d) all marketing authorizations currently held by the Parties outside of France for povidone-iodine;
  - (e) any other asset not part of the Divestment Business or which is used in relation to a business of the Parties other than the Divestment Business;
  - (f) the "Mylan" name, Mylan trademark and Mylan trade dress or the name, trademark and trade dress of any Mylan subsidiaries;<sup>33</sup> and
  - (g) monies owed to the Parties by customers for the purchase of povidone-iodine, and monies owed by the Parties to suppliers for materials used in the production of

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<sup>33</sup> With exception of the sale of inventory existing at Closing and sold to the Purchaser.

povidone-iodine.

- (8) If there is any asset or personnel which is not 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 personnel or adequate substitute will be offered to the Purchaser.

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**Product: Mylan's diltiazem products**

**Territory: Portugal**

- (1) The Divestment Business consists of Mylan's rights, title and interests in diltiazem in Portugal (marketed under the name Dilfar<sup>34</sup>) including the right to develop, manufacture and use diltiazem with a view to its sale and marketing in any form in Portugal. Diltiazem is no longer under exclusivity and is used for the prevention angina. For the avoidance of doubt, this Divestment Business does not include any rights to sell diltiazem outside of Portugal.
- (2) The Divestment Business includes:
- (a) the sale of existing diltiazem finished product inventory,<sup>35</sup> sales and promotional material in Portugal, as far as available;
  - (b) all diltiazem-related contracts, commitments and customer records meaning customers credit records, customer invoices, purchase orders and contact details, whilst only the information related to diltiazem specifically will be provided;<sup>36</sup>
  - (c) the transfer of the license and distribution agreement with [...], subject to the prior consent of the licensor;<sup>37</sup>
  - (d) the transfer of the marketing authorization for Mylan's diltiazem in Portugal including the license to the dossier, subject to the prior consent of the licensor; and

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<sup>34</sup> The product is currently not marketed due to the absence of a manufacturer.

<sup>35</sup> Where it concerns the transfer of inventory bearing the [...] trademark or trade dress, Mylan will make its best efforts to obtain [...] consent.

<sup>36</sup> Mylan will include all customer lists and records since 2011 in the Divestment Business.

<sup>37</sup> The agreement with [...] covers 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 manufacture, use, registration and sale of the divestment business in Portugal, including in particular the information in the registration dossier.

- (e) full transfer of the national trademark related to diltiazem "Dilfar".

The items referred to under (a) - (e) are hereinafter collectively referred to as "**Assets of the Divestment Business**".<sup>38</sup>

- (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 diltiazem in Portugal, 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 diltiazem in Portugal.
- (4) Mylan will transfer all historical information (orders, price, etc.) concerning its relationship regarding diltiazem in Portugal with the licensor [...] to the Purchaser in accordance with applicable law. Mylan commits to make its best efforts to obtain [...] consent to assign to the Purchaser the full contract in relation to its right concerning Diltiazem.
- (5) If negotiations for a manufacturing contract between Mylan and any third party would be concluded prior to the transfer of the Divestment Business, Mylan commits to make its best efforts to facilitate the assignment of the manufacturing agreement (with said third party) concerning Dilfar in Portugal to the Purchaser. Any negotiations related to said agreement after the Effective date will be conducted by the hold-separate-manager.
- (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) 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.
- (8) 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 diltiazem after Closing;
  - (d) all marketing authorizations currently held by the Parties outside of Portugal for diltiazem;

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<sup>38</sup> For the avoidance of doubt, the Divestment Business is transferred subject to any contractual obligations or restrictions applicable thereto in favor of third parties, including those as to development, manufacture, distribution, marketing and sale.

- (e) any other asset not part of the Divestment Business or which is used in relation to a business of the Parties other than the Divestment Business;
  - (f) the "Mylan" name, Mylan trademark and Mylan trade dress or the name, trademark and trade dress of any Mylan subsidiaries;<sup>39</sup> and
  - (g) monies owed to the Parties by customers for the purchase of diltiazem, and monies owed by the Parties to suppliers for materials used in the production of diltiazem.
- (9) If there is any asset or personnel which is not 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 personnel or adequate substitute will be offered to the Purchaser.

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**Product: Mylan's diltiazem products**

**Territory: Portugal**

- (1) The Divestment Business consists of Mylan's rights, title and interests in diltiazem in Portugal (currently marketed under the name Diltiazem) including the right to develop, manufacture and use diltiazem with a view to its sale and marketing in any form in Portugal. Diltiazem is no longer under exclusivity and is used to prevent angina. For the avoidance of doubt, this Divestment Business does not include any rights to sell Diltiazem outside of Portugal.
- (2) The Divestment Business includes:
  - (a) the sale of existing diltiazem finished product inventory, sales and promotional material in Portugal to the extent available;
  - (b) all diltiazem-related contracts, commitments, and customer records, meaning customer credit records, customer invoices, purchase orders and contact details, whilst only the information related to diltiazem specifically will be provided;<sup>40</sup>
  - (c) the transfer of the license and distribution agreement with [...], subject to the prior consent of the licensor;<sup>41</sup> and

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<sup>39</sup> With the exception of the sale of inventory existing at Closing and sold to the Purchaser.

<sup>40</sup> Mylan will include all customer lists and records since 2011 in the Divestment Business.

<sup>41</sup> The agreement with [...] covers 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



- (d) the transfer of the marketing authorization for Mylan's diltiazem in Portugal including the license to the dossier, subject to the prior consent of the licensor.

The 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 diltiazem in Portugal, 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 diltiazem in Portugal.
- (4) Mylan will transfer all historical information (orders, price, etc.) concerning its relationship regarding diltiazem in Portugal with the licensor [...] to the Purchaser in accordance with applicable law. Mylan commits to make its best efforts to obtain [...] consent to assign to the Purchaser the full contract in relation to its right concerning Diltiazem.
- (5) Mylan will transfer all historical information (orders, price, etc.) concerning its relationship regarding diltiazem in Portugal with the contract manufacturer [...] to the Purchaser in accordance with applicable law. Mylan commits to make its best efforts to obtain [...] consent to assign to the Purchaser the full contract in relation to its right concerning Diltiazem.
- (6) Mylan will transfer all historical information (orders, price, etc.) concerning its relationship with [...] regarding the packaging and relieve activities for diltiazem in Portugal. Mylan commits to make its best efforts to support the Purchaser to obtain [...] consent for the transfer the tender contract.
- (7) Mylan will transfer all historical information (orders, price, etc.) concerning its relationship with [...] regarding the tender contract for diltiazem in Portugal. Mylan commits to make its best efforts to support the Purchaser to obtain [...] consent for the transfer the tender contract.
- (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) Mylan commits to continue its participation in tenders for the Divestment Business up until Closing. If Mylan were to win any tenders pertaining to diltiazem before Closing, Mylan commits to make its best efforts to facilitate the assignment of the relationship or the contract in line with the provisions contained in this Schedule concerning existing tender contracts.

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manufacture, use, registration and sale of the divestment business in Portugal, including in particular the information in the registration dossier.

- (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 diltiazem after Closing;
  - (d) all marketing authorizations currently held by the Parties outside of Portugal for diltiazem;
  - (e) any other asset not part of the Divestment Business or which is used in relation to a business of the Parties other than the Divestment Business;
  - (f) the "Mylan" name, Mylan trademark and Mylan trade dress or the name, trademark and trade dress of any Mylan subsidiaries;<sup>42</sup> and
  - (g) monies owed to the Parties by customers for the purchase of diltiazem, and monies owed by the Parties to suppliers for materials used in the production of diltiazem.
- (12) If there is any asset or personnel which is not 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 personnel or adequate substitute will be offered to the Purchaser.

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**Product: Meda's Dagravit 8 products**

**Territory: Portugal**

- (1) The Divestment Business consists of Meda's rights, title and interests in ascorbic acid/ colecalciferol/ nicotinamide/ pantothenic acid/ pyridoxine/ retinol/ riboflavin/ thiamine in Portugal (currently marketed under the name Dagravit 8) including the right to develop, manufacture and Dagravit 8 with a view to its sale and marketing in any form in Portugal. Dagravit 8 is no longer under exclusivity and is used for the prevention and treatment of

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<sup>42</sup> With the exception of the sale of inventory existing at Closing and sold to the Purchaser.

vitamin deficiencies in children. For the avoidance of doubt, this Divestment Business does not include any rights to sell Dagravit 8 outside of Portugal.

- (2) The Divestment Business includes:
- (a) the sale of existing Dagravit 8 finished product inventory, sales and promotional material in Portugal, as far as available;
  - (b) all Dagravit 8-related contracts, commitments and customer records meaning customers credit records, customer invoices, purchase orders and contact details, whilst only the information related to Dagravit 8 specifically will be provided;<sup>43</sup>
  - (c) the transfer of the marketing authorization for Meda's Dagravit 8 in Portugal including the relevant dossiers, as well as the information contained in the relevant full registration dossier(s), relating to the current and/or pending marketing authorizations available to Mylan;
  - (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 Portugal, including in particular the information contained in the registration dossier; and
  - (e) full transfer of the national trademark "Dagravit 8" in Portugal.

The items referred to under (a) - (e) 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 Dagravit 8 in Portugal, 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 Dagravit 8 in Portugal.
- (4) Mylan will transfer all historical information (orders, price, etc.) concerning its relationship regarding Dagravit 8 in Portugal with Contract manufacturer [...] to the Purchaser in accordance with applicable law. Mylan commits to make its best efforts to facilitate the assignment to Purchaser of the supply agreement it has in place concerning the Divestment Business, subject to the consent of [...].
- (5) Mylan will transfer all historical information (orders; price; etc.) concerning its relationship with [...] regarding the tender contract for Dagravit 8 in Portugal. Mylan commits to make its best efforts to support the Purchaser to obtain [...] consent for the transfer the tender contract.
- (6) Mylan commits to make its best efforts to cooperate with the Purchaser to effectuate the

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<sup>43</sup> Mylan will include all customer lists and records since 2011 in the Divestment Business.

transfer of the Divestment Business and to undertake all regulatory changes that would be required as a result of such transfer. Until transfer of the Divestment Business, Mylan will bear the costs for updates to maintain the current registration of the dossier of the Divestment Business. In addition, Mylan will bear the dossier preparation and regulatory filing costs for all the updates of the dossier triggered by the transfer of the Divestment Business to the Purchaser.

- (7) Mylan commits to continue its participation in tenders for the Divestment Business up until Closing. If Mylan were to win any tenders pertaining to Dagravit 8 before Closing, Mylan commits to make its best efforts to facilitate the assignment of the relationship or the contract in line with the provisions contained in this Schedule concerning existing tender contracts.
- (8) 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.
- (9) The Divestment Business shall not include:
  - (a) any manufacturing facility;
  - (b) raw materials;
  - (c) any research and development, clinical data and studies or intellectual property relating to Dagravit 8 after Closing;
  - (d) all marketing authorizations currently held by the Parties outside of Portugal for Dagravit 8;
  - (e) any other asset not part of the Divestment Business or which is used in relation to a business of the Parties other than the Divestment Business;
  - (f) the "Meda" name, Meda trademark and Meda trade dress or the name, trademark and trade dress of any Meda subsidiaries;<sup>44</sup> and
  - (g) monies owed to the Parties by customers for the purchase of Dagravit 8, and monies owed by the Parties to suppliers for materials used in the production of Dagravit 8.
- (10) If there is any asset or personnel which is not 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 personnel or adequate substitute will be offered to the Purchaser.

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<sup>44</sup> With the exception of the sale of inventory existing at Closing and sold to the Purchaser.

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**Product: Meda's progesterone products**

**Territory: Austria**

- (1) The Divestment Business consists of Meda's rights, title and interests in progesterone in Austria (currently marketed under the name Utrogestan) including the right to develop, manufacture and use progesterone with a view to its sale and marketing in any form in Austria. Progesterone is no longer under exclusivity and is used for a variety of disorders related to a progesterone deficit. For the avoidance of doubt, this Divestment Business does not include any rights to sell progesterone outside of Austria.
  
- (2) The Divestment Business includes:
  - (a) the sale of existing progesterone finished product inventory, sales and promotional material in Austria to the extent available;
  - (b) all progesterone-related contracts, commitments, and customer records, meaning customer credit records, customer invoices, purchase orders and contact details, whilst only the information related to progesterone specifically will be provided;  
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  - (c) the transfer of the license and distribution agreement with [...], subject to the prior consent of the licensor<sup>46</sup>;
  - (d) the transfer of the marketing authorization for Meda's progesterone in Austria including the license to the dossier, subject to the prior written consent of the licensor; and
  - (e) subject to consent of the licensor ([...]), full transfer of the trademark "Utrogestan" related to progesterone in Austria or a sub-license to use that trademark for the Divestment Business, subject to the terms and conditions, Mylan's rights and obligations, and any other restriction under the sub-license.

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

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<sup>45</sup> Mylan will include all customer lists and records since 2011 in the Divestment Business.

<sup>46</sup> The agreement with [...] covers 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 manufacture, use, registration and sale of the divestment business in Austria, including in particular the information in the registration dossier.

- (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 progesterone in Austria, 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 progesterone in Austria.
- (4) Mylan will transfer all historical information (orders, price, etc.) concerning its relationship regarding progesterone in Austria with the licensor ([...]) to the Purchaser in accordance with applicable law. Mylan commits to make its best efforts to obtain the licensor' consent to assign to the Purchaser the full contract in relation to its right concerning Utrogestan in Austria.
- (5) Mylan will transfer all historical information (orders, price, etc.) concerning its relationship regarding progesterone in Austria with contract manufacturer [...] to the Purchaser in accordance with applicable law. Mylan commits to make its best efforts to obtain [...] consent to assign to the Purchaser the full contract in relation to its right concerning Utrogestan.
- (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) 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.
- (8) 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 progesterone after Closing;
  - (d) all marketing authorizations currently held by the Parties outside of Austria for progesterone;
  - (e) any other asset not part of the Divestment Business or which is used in relation to a business of the Parties other than the Divestment Business;
  - (f) the "Meda" name, Meda trademark and Meda trade dress or the name, trademark and trade dress of any Meda subsidiaries;<sup>47</sup> and

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<sup>47</sup> With the exception of the sale of inventory existing at Closing and sold to the Purchaser.

- (g) monies owed to the Parties by customers for the purchase of progesterone, and monies owed by the Parties to suppliers for materials used in the production of progesterone.
- (9) If there is any asset or personnel which is not 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 personnel or adequate substitute will be offered to the Purchaser.

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**Product: Meda's amoxicillin products**

**Territory: Norway**

- (1) The Divestment Business consists of Meda's rights, title and interests in amoxicillin in Norway (currently marketed under the name Imacillin) including the right to develop, manufacture and use amoxicillin with a view to its sale and marketing in any form in Norway. Amoxicillin is no longer under exclusivity and is indicated for treatment of a wide variety of bacterial infections including skin infections, streptococcal pharyngitis, pneumonia, Salmonella infections and Lyme disease. For the avoidance of doubt, this Divestment Business does not include any rights to sell Amoxicillin outside of Norway.
- (2) The Divestment Business includes:
  - (a) the sale of existing amoxicillin finished product inventory, sales and promotional material in Norway, as far as available;
  - (b) all amoxicillin-related contracts, commitments and customer records meaning customers credit records, customer invoices, purchase orders and contact details, whilst only the information related to amoxicillin specifically will be provided;<sup>48</sup>
  - (c) the transfer of the marketing authorization for Meda's amoxicillin in Norway including the relevant dossiers, as well as the information contained in the relevant full registration dossier(s), relating to the current and/or pending marketing authorizations available to Mylan;
  - (d) an irrevocable, assignable, sub-licensable, and royalty-free license for all relevant intellectual property rights including the "Imacillin" 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 Norway, including in particular the information contained in the registration dossier; and

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<sup>48</sup> Mylan will include all customer lists and records since 2011 in the Divestment Business.

- (e) full transfer of the national trademark "Imacillin" related to amoxicillin in Norway.

The items referred to under (a) - (e) are 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 amoxicillin in Norway, 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 amoxicillin in Norway.
- (4) Mylan will transfer all information concerning its imminent relationship regarding amoxicillin in Norway with contract manufacturer [...], with which it is currently finalizing the negotiations of a new manufacturing agreement, to the Purchaser in accordance with applicable law.
- (5) If negotiations for a contract between Meda and [...] would be concluded prior to the transfer of the Divestment Business, Mylan commits to make its best efforts to facilitate the assignment of the manufacturing agreement (with [...]) concerning amoxicillin in Norway to the Purchaser, subject to consent from [...]. Any negotiations related to said agreement after the Effective Date will be conducted by the Hold Separate Manager. If the agreement with [...] has not been concluded before the transfer of the Divestment Business, Mylan commits to provide the Purchaser with documents concerning the negotiation history (such as draft agreements and offers, etc.).
- (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. Until transfer of the Divestment Business, Mylan will bear the costs for updates to maintain the current registration of the dossier of the Divestment Business. In addition, Mylan will bear the dossier preparation and regulatory filing costs for all the updates of the dossier triggered by the transfer of the Divestment Business to the Purchaser.
- (7) 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.
- (8) 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 amoxicillin after Closing;
  - (d) all marketing authorizations currently held by the Parties outside of Norway for



amoxicillin;

- (e) any other asset not part of the Divestment Business or which is used in relation to a business of the Parties other than the Divestment Business;
  - (f) the "Meda" name, Meda trademark and Meda trade dress or the name, trademark and trade dress of any Meda subsidiaries;<sup>49</sup> and
  - (g) monies owed to the Parties by customers for the purchase of amoxicillin, and monies owed by the Parties to suppliers for materials used in the production of amoxicillin.
- (9) If there is any asset or personnel which is not 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 personnel adequate substitute will be offered to the Purchaser.

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**Product: Mylan's megestrol products**

**Territory: Spain**

- (1) The Divestment Business consists of Mylan's rights, title and interests in megestrol in Spain (currently marketed under the name Megefren) including the right to develop, manufacture and use megestrol with a view to its sale and marketing in any form in Spain. Megestrol is no longer under exclusivity and is mainly used for the treatment of anorexia and, to a lesser extent, for the treatment of advanced breast cancer and endometrial cancer. For the avoidance of doubt, this Divestment Business does not include any rights to sell megestrol outside of Spain.
- (2) The Divestment Business includes:
  - (a) the sale of existing megestrol finished product inventory, sales and promotional material in Spain, as far as available;
  - (b) all megestrol-related contracts, commitments and customer records meaning customers credit records, customer invoices, purchase orders and contact details, whilst only the information related to megestrol specifically will be provided;<sup>50</sup>
  - (c) the transfer of the marketing authorization for Mylan's megestrol in Spain including the relevant dossiers, as well as the information contained in the

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<sup>49</sup> With exception of the sale of inventory existing at Closing and sold to the Purchaser.

<sup>50</sup> Mylan will include all customer lists and records since 2011 in the Divestment Business.

relevant full registration dossier(s), relating to the current and/or pending marketing authorizations available to Mylan;

- (d) an irrevocable, assignable, sub-licensable, and royalty-free license for all relevant intellectual property rights including the "Megefren" 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 Spain, including in particular the information contained in the registration dossier; and
- (e) full transfer of the national trademark "Megefren" related to megestrol in Spain.

The items referred to under (a) - (e) are 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 megestrol in Spain, 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 megestrol in Spain.
- (4) Mylan will transfer all historical information (order, price, etc.) concerning its relationship regarding megestrol in Spain with contract manufacturer [...] to the Purchaser in accordance with applicable law. Mylan commits to make its best efforts to facilitate the assignment to Purchaser of the supply agreement it has in place concerning the Divestment Business, subject to the consent of [...].
- (5) 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. Until transfer of the Divestment Business, Mylan will bear the costs for updates to maintain the current registration of the dossier of the Divestment Business. In addition, Mylan will bear the dossier preparation and regulatory filing costs for all the updates of the dossier triggered by the transfer of the Divestment Business to the Purchaser.
- (6) 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.
- (7) 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 megestrol after Closing;

- (d) all marketing authorizations currently held by the Parties outside of Spain for megestrol;
  - (e) any asset not part of the Divestment Business or which is used in relation to a business of the Parties other than the Divestment Business;
  - (f) the "Mylan" name, Mylan trademark and Mylan trade dress or the name, trademark and trade dress of any Mylan subsidiaries;<sup>51</sup> and
  - (g) monies owed to the Parties by customers for the purchase of megestrol, and monies owed by the Parties to suppliers for materials used in the production of megestrol.
- (8) If there is any asset or personnel which is not 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 personnel or adequate substitute will be offered to the Purchaser.

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**Product: Mylan's nabumetone products**

**Territory: United Kingdom**

- (1) The Divestment Business consists of Mylan's rights, title and interests in nabumetone in the United Kingdom (currently marketed under the name Nabumetone) including the right to develop, manufacture and use nabumetone with a view to its sale and marketing in any form in the United Kingdom. Nabumetone is no longer under exclusivity and is used in the treatment of osteoarthritis and rheumatoid arthritis requiring anti-inflammatory and analgesic treatment. For the avoidance of doubt, this Divestment Business does not include any rights to sell nabumetone outside of the United Kingdom.
- (2) The Divestment Business includes:
  - (a) the sale of existing nabumetone finished product inventory, sales and promotional material in the United Kingdom, as far as available;
  - (b) all nabumetone-related contracts, commitments and customer records meaning customers credit records, customer invoices, purchase orders and contact details, whilst only the information related to nabumetone specifically will be provided;<sup>52</sup>
  - (c) the transfer of the marketing authorization for Mylan's nabumetone in the United

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<sup>51</sup> With the exception of the sale of inventory existing at Closing and sold to the Purchaser.

<sup>52</sup> Mylan will include all customer lists and records since 2011 in the Divestment Business.

Kingdom including the relevant dossiers, as well as the information contained in the relevant full registration dossier(s), relating to the current and/or pending marketing authorizations 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 United Kingdom, including in particular the information contained in the registration dossier.

The items referred to under (a) - (d) are 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 nabumetone in the United Kingdom, 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 nabumetone in the United Kingdom.
  - (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 United Kingdom 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 will transfer all historical information (orders, price, etc.) concerning its relationship regarding nabumetone in the United Kingdom with API supplier [...], supplied through intermediate [...], to the Purchaser in accordance with applicable law. Mylan commits to make its best efforts to support the Purchaser to enter into a direct supply agreement with [...] and [...] with respect to the United Kingdom. Mylan commits to make its best efforts to facilitate the assignment to Purchaser of the supply agreements it has in place concerning the Divestment Business, subject to the consent of the respective parties.
  - (6) Mylan will transfer all historical information (orders; price; etc.) concerning its relationship with [...] regarding the tender contracts for Nabumetone in the UK. Mylan commits to make its best efforts to support the Purchaser to obtain [...] consent for the transfer the tender contract.
  - (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. Until transfer of the Divestment Business, Mylan will bear the costs for updates to maintain the current registration of the dossier of the Divestment Business. In addition, Mylan will bear the dossier preparation and regulatory filing costs for all the updates of the dossier triggered by the transfer of the Divestment Business to the Purchaser.
  - (8) Mylan commits to continue its participation in tenders for the Divestment Business up until Closing. If Mylan were to win any tenders pertaining to Nabumetone before Closing, Mylan
- (57)

commits to make its best efforts to facilitate the assignment of the relationship or the contract in line with the provisions contained in this Schedule concerning existing tender contracts.

- (9) At the option of the Purchaser, Mylan shall provide reasonable technical assistance at a reasonable cost reimbursement to the Purchaser to assume responsibility for the manufacture, sale and marketing of nabumetone in the United Kingdom 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 nabumetone after Closing;
  - (d) all marketing authorizations currently held by the Parties outside of the United Kingdom for nabumetone;
  - (e) any asset not part of the Divestment Business or which is used in relation to a business of the Parties other than the Divestment Business;
  - (f) the "Mylan" name, Mylan trademark and Mylan trade dress or the name, trademark and trade dress of any Mylan subsidiaries;<sup>53</sup> and
  - (g) monies owed to the Parties by customers for the purchase of nabumetone, and monies owed by the Parties to suppliers for materials used in the production of nabumetone.
- (12) If there is any asset or personnel which is not 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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<sup>53</sup> With the exception of the sale of inventory existing at Closing and sold to the Purchaser.