EUROPEAN COMMISSION
DG Competition

Case M.7919 - SANOFI / BOEHRINGER INGELHEIM CONSUMER HEALTHCARE BUSINESS

Only the English text is available and authentic.

REGULATION (EC) No 139/2004
MERGER PROCEDURE

Article 6(1)(b) in conjunction with Art 6(2)
Date: 04/08/2016

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EUROPEAN COMMISSION

Brussels, 04/08/2016
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In the published version of this decision, some information has been omitted pursuant to Article 17(2) of Council Regulation (EC) No 139/2004 concerning non-disclosure of business secrets and other confidential information. The omissions are shown thus […]. Where possible the information omitted has been replaced by ranges of figures or a general description.

PUBLIC VERSION

MERGER PROCEDURE

To the notifying party:

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

Subject: **Case M.7919 – Sanofi / Boehringer Ingelheim Consumer Healthcare Business**
Commission decision pursuant to Article 6(1)(b) in conjunction with Article 6(2) of Council Regulation No 139/2004[1] and Article 57 of the Agreement on the European Economic Area[2]

(1) On 15 June 2016, the European Commission received a notification of a proposed concentration pursuant to Article 4 of Council Regulation (EC) No 139/2004 by which Sanofi S.A. ("Sanofi", France), hereinafter "the Notifying Party", intends to acquire within the meaning of Article 3(1)(b) of the Merger Regulation sole control over Boehringer Ingelheim Consumer Healthcare business ("BI CHC", Germany), by way of purchase of shares and assets (the "Transaction"). Sanofi and BI CHC are collectively referred to as "the Parties".

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

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

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I. THE PARTIES

(2) **Sanofi** is a global pharmaceutical company active in research, development, manufacturing and sale of healthcare products. It is organized around three principal activities: (i) pharmaceuticals, (ii) human vaccines and (iii) animal health. Within pharmaceuticals, Sanofi specialises in diabetes, rare diseases and multiple sclerosis, oncology and other pharmaceutical products, including both prescription (or "Rx") and over-the-counter ("OTC") products.

(3) **BI CHC** is part of **Boehringer Ingelheim International GmbH** ("BI") which is an independent, family-owned company headquartered in Germany. BI CHC is active worldwide in the research, development, manufacturing and marketing of human medicines, and is focused mostly on gastro-intestinal treatments, cough and cold products, vitamins and well-being products, as well as pain and mobility medicines, sold OTC.

II. THE OPERATION

(4) Pursuant to an Exclusive Negotiation Agreement signed by Sanofi and BI on the 15 December 2015, Sanofi and BI engaged in an asset swap through which the full ownership over BI's CHC business will be transferred to Sanofi in exchange for Sanofi's animal health business.[3] BI will transfer all business assets exclusively related to its CHC business to Sanofi via an asset sale. In addition, Sanofi will acquire two BI's subsidiaries dedicated to the CHC business of BI via a share deal.

(5) The Transaction therefore amounts to an acquisition of sole control via purchase of assets and shares in a pre-existing business and constitutes a concentration within the meaning of Article 3(1)(b) of the Merger Regulation.

III. THE EU DIMENSION

(6) The undertakings concerned have a combined aggregate world-wide turnover of more than EUR 5 000 million[4] (Sanofi: EUR 37 056 million; BI CHC: EUR […] million). Each of them has an EU-wide turnover in excess of EUR 250 million (Sanofi: EUR […] million; BI CHC: EUR […] million), but neither achieves 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 Merger Regulation.

IV. RELEVANT MARKETS AND COMPETITIVE ASSESSMENT

IV.1. Overall context

(8) The activities of Sanofi and BI overlap predominately in the production and marketing of finished dosed pharmaceuticals ("FDPs") (section IV.2), primarily sold OTC in five therapeutic areas (gastro-intestinal treatments, cough and cold, pain and mobility, cardiac stimulants, vitamins and well-being). In addition, both Parties are involved in

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3 The acquisition by BI of Sanofi's animal health business is subject to a separate concentration M.7917 BI/Sanofi animal health business.

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

activities in relation to production and supply of APIs (section IV.4), and out-licensing (section IV.5).

IV.2. Finished Dose Pharmaceuticals

IV.2.1. General approach to the product market definition

(9) When defining relevant markets in past decisions dealing with pharmaceutical products, the Commission based its assessment on the following general approach:[5]

(10) The Commission noted that medicines may be subdivided into therapeutic classes by reference to the "Anatomical Therapeutic Classification" (ATC), devised by the European Pharmaceutical Marketing Research Association (EphMRA) and maintained by EphMRA and Intercontinental Medical Statistics (IMS).[6]

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

(12) 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.[7] In particular in relation to originator and generic medicines, the Commission has considered in previous decision plausible product markets at the ATC4 level, at a level of a molecule or a group of molecules that are considered interchangeable so as to exercise competitive pressure on one another. However, it should be borne in mind that the overlap in therapeutic uses does not necessarily imply any particular economic substitution patterns between products.[8]

(13) In a number of previous cases, pharmaceutical products were further subdivided into various segments on the basis of a variety of criteria, and in particular demand-related criteria.

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5 See for example M.6969 Valeant Pharmaceuticals International/Bausch & Lomb Holdings, M.5778 Novartis/Alcon, and M.5865 Teva/Ratiopharm.

6 See for example M.6969 Valeant Pharmaceuticals International/Bausch & Lomb Holdings, M.5865 Teva/Ratiopharm, and M.5295 Teva/Barr.

7 OJ C 372, 9.12.1997, p. 5–13.

8 See for example M.7480 Actavis/Allergan; M.7279 Mylan/Abbott EPD-DM; M.7276 GlaxoSmithKline/Novartis vaccines business (excl. influenza)/Novartis Consumer Health business; M.7275 Novartis/GlaxoSmithKline Oncology Business and M.5253 Sanofi-Aventis/Zentiva.

(14) First, the Commission has in the past[9] defined separate markets for medicines which can be dispensed only against a prescription and those which can be sold OTC. Medical indications, side effects, regulatory framework, distribution and marketing tend to differ between these drug categories, even if the active ingredients may sometimes be identical.

(15) OTC products may be advertised to the public at large. Prescribers do not need to intervene in the purchase of these products. In most cases, consumers choose OTC pharmaceuticals themselves, possibly following a guidance of a pharmacist, 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.[10]

(16) Notwithstanding such differences, it has been outlined in previous decisions[11] that in certain cases, products which are available OTC are still reimbursable if bought on prescription. 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.[12]

(17) Second, as the Commission has acknowledged in its previous decisions,[13] medicines, including within a specified molecule, can also be differentiated, in line with the European regulatory framework for medicines for human use, by their galenic form, i.e. dosage, pharmaceutical form and route of administration which may limit their substitutability.[14] The Commission has looked at this "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.

(18) In conclusion, the Commission's approach to market definition has been guided in the past pharmaceutical cases in particular by reference to ATC classes and active ingredients, the distinction prescribed versus OTC medicines, and different galenic forms.

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9 See for example M.6969 Valeant Pharmaceuticals International/Bausch & Lomb Holdings, M.5778 Novartis/Alcon, M.5865 Teva/Ratiopharm, and M.5295 Teva/Barr.

10 See M.5953 Reckitt Benckiser/SSL.

11 See for example M.5778 Novartis/Alcon, M.5253 Sanofi-Aventis/Zentiva, and M.3751 Novartis/Hexal.

12 See M.7645 Mylan/Perrigo of 29 July 2015, M.5778 Novartis/Alcon.

13 See for example M.5778 Novartis/Alcon, M.5865 Teva/Ratiopharm, and M.5253 Sanofi-Aventis/Zentiva.

14 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.

IV.2.2. Approach to the product market definition in the Decision

(19) Given that in the present case the markets concerned by the Transaction relate almost exclusively to OTC drugs, there are, in view of the above, some factors for the Commission to consider and weigh in its assessment that are of particular importance as compared to cases focusing mainly on prescribed medicines.

(20) First, the Commission noted in previous decisions that in contrast to prescribed medicines ("Rx"), OTC products may be advertised to the public at large as a result of which brands play a comparatively more significant role in the OTC industry, and advertising is a key feature in these markets.[15] The results of the market investigation confirm the importance of brands in this context.[16]

(21) Second, in making purchasing decisions, consumers seem to predominately rely, aside from the brand, on therapeutic/labelled indication, format and price.[17] Given that the OTC medicines are sold to patients without a prescription, the pharmacist is often the one helping the consumers to make these decisions.

(22) The Commission also found in the present case that the therapeutic indication and the brand, as well as (to a certain extent) the price seem generally to be the most influential factors for consumers to make the purchasing decisions for OTC medicines.

(23) It follows from the above and the results of the market investigation that the active ingredient appears to play a much more subordinated role, unless it is equivalent to a specific therapeutic/labelled indication, than in prescribed medicines markets. Therefore, the ATC and active ingredient based approach to market definition has significant limitations in an OTC context. Nonetheless this approach still provides a valuable first approximation to capture the competitive dynamic on the OTC markets that are being assessed in this case.

(24) Finally, the market investigation in the present case has also shown, for some of the products considered in this case, that different routes of administration and the pharmaceutical form of a medicine may in some cases influence the preferences of consumers or be targeted to specific consumers groups (e.g. children), and are therefore not (fully) interchangeable.[18] Where this was found to be the case, the Commission has taken account of this factor in the competitive assessment.

(25) In view of the above, the Commission has thus attributed particularly high value to aspects such as brand recognition, labelled indication and price in its assessment of the Transaction, including in defining the relevant product markets. This is reflected throughout the present decision ("the Decision").

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15 See for example M.7276 Glaxo Smith Kline / Novartis Vaccines Business (excl. Influenza) / Novartis Consumer Health Business.

16 See in particular replies to questions 6, 15, 22, 33, 42, 53, 60, 66, 73, 80, 96, 103, 111, 119, 125, 140, 152, 158, 164, 170 of Questionnaire Q1 to competitors. See also non-confidential minutes of a call with a competitor on 24 June 2016.

17 See in particular replies to questions 6, 15, 22, 33, 42, 53, 60, 66, 73, 80, 96, 103, 111, 119, 125, 140, 152, 158, 164, 170 of Questionnaire Q1 to competitors.

18 For instance, 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.2.3. Relevant geographic market

(26) The Commission has previously defined the geographic markets for pharmaceutical products as being national in scope.

(27) The Notifying Party agrees with the previous practice of the Commission and indicated that pharmaceutical markets are national in scope. This is the case in particular due to differences in administrative procedures or purchasing policies in various Member States as well as far-reaching differences in terms of brand and package size strategies as well as distribution systems.

(28) 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.

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

IV.2.4. Product-specific assessment

IV.2.4.1. Market investigation

(30) The Commission conducted a far reaching market investigation in this case. In total, the Commission sent more than 700 questionnaires to competitors and pharmacies throughout the EEA. In addition to this, the Commission conducted several conference calls with various market participants, including leading medical specialists in the relevant therapeutic areas (key opinion leaders, "KOL(s)") and pharmacies.

(31) The Commission also analysed the information provided by the Parties, including internal documents.

(32) The findings in the Decision are based on the overall assessment of all available evidence.

IV.2.4.2. Methodology used in the assessment of affected markets

(33) In the sections concerning the competitive assessment below the Commission provides a detailed and individual assessment of affected markets in each of the five main therapeutic areas where the Parties' activities overlap, namely gastro-intestinal treatments, cough and cold, pain and mobility, cardiac stimulants, vitamins and well-being.

(34) In line with the past decisions, given the large number of affected markets in pharmaceutical mergers (numerous products 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 it focused its analysis in a first instance.

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

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

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

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

- **Group 1 "plus"**:[19] 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.[20]

(36) Therefore, as a starting point, the Commission considered in detail all plausible Group 1 markets. However, as in contrast to prescription markets the pricing of OTC products is generally not regulated in the EEA Member States, a company's ability to increase prices is chiefly a function of the degree of its market power. In addition, given that, as already explained above, the ATC based market definition and the corresponding classification in groups may not accurately reflect the competitive interaction of drugs in OTC markets, the Commission also analysed in detail a number of plausible markets that were characterised as Group 2 or 3, or other combinations thereof, if there were reasons to consider that the Parties could attain market power as a result of the transaction.

(37) In most of these plausible Group 2 and Group 3 affected markets, all available evidence including the results of the market investigation lead the Commission to consider that competition concerns are unlikely. In line with previous decisions,[21] most of these markets are not considered in detail individually in the following sections, but by groups of markets.

(38) Finally, the Transaction does not give rise to marketed-to-pipeline or pipeline-to-pipeline overlaps since […]. Pipelines were thus being analysed as part of marketed-to-marketed overlaps, but are not discussed further in the Decision as they do not have a decisive bearing on the competitive assessment.

IV.3. Assessment of the markets by therapeutic area

IV.3.1. COUGH AND COLD

IV.3.1.1.a. Topical nasal preparations (R1A)

Product market definition

(39) Both Parties market a large number of topical nasal preparations (ATC3 class R1A) in the EEA. These products are used for the local treatment of nasal congestion (e.g. sympathomimetics) or for prophylaxis and treatment of allergic rhinitis (e.g. corticosteroids, cromoglicate preparations). Most of the products are nasal drops, nasal sprays or nasal inhalants.

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19 See M.5778 Novartis/Alcon, para 25.

20 No Group 1 "plus" overlaps were identified in this case.

21 See for example M.7379 Mylan/Abbott EPD-DM.

(40) The ATC3 class R1A is further subdivided into several ATC4 classes on the basis of the drug's mode of action and composition as follows: R1A1 (Nasal corticosteroids without anti-infectives), R1A3 (Nasal corticosteroids with anti-infectives), R1A4 (Nasal anti-infectives without corticosteroids), R1A6 (Nasalantiallergic agents) and R1A7 (Nasal decongestants). All other topical nasal preparations are classified under ATC4 class R1A9.

(41) In previous decisions, the Commission considered but ultimately left open plausible market definitions based on ATC3 class R1A, on the basis of one ATC4 class, a combination of ATC 4 classes (R1A1 and R1A6) as well as a combination of several ATC3 classes (R1A, R6A, R1B and R3J).[22]

(42) Moreover, as regards the distinction between OTC and prescribed products, the Commission considered in one previous decision, with reference to the treatment of allergic rhinitis, that OTC and prescription products do not compete with each other.[23]

(43) In the assessment of the Transaction, the Commission also contemplated segmentations of the relevant product market(s) by galenic form and active ingredient (for Oxymetazoline).

(44) First, concerning galenic form, this is unlikely to be a relevant factor given that all products concerned are marketed as topical nasal preparations, and therefore in the same galenic form.

(45) Second, the market investigation provided clear indications that, in line with the considerations above in paragraphs (19) and following, defining product market on the basis of active ingredient would not be appropriate in this case. Indeed, as indicated above as of paragraph (25), brand, indication and price are more important factors motivating a consumer's purchasing decision than the active ingredient in a given nasal preparation. Similarly, market participants confirmed that there is a wide range of molecules with the same or similar efficacy as Oxymetazoline that could be and are used by patients, such as phenylephrine, xylormetazoline or tramazoline.[24]

(46) In any event, the definition of the relevant product market in relation to treatments belonging to ATC3 class R1A can be left open for the purposes of the Decision as the Transaction does not raise serious doubts as to its compatibility with the internal market under any of the plausible product market definitions in this area.

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22 See M.7276 GlaxoSmithKline/Novartis, M.5502 Merck/Schering-Plough and M.3354 Sanofi-Synthelabo/Aventis.

23 See M.5502 Merck/Schering-Plough.

24 See replies to questions 111 to 114 of Questionnaire Q1 to competitors.

Competitive assessment

(47) On the basis of the plausible market definitions set out in the previous section, the Transaction gives rise to two Group 1 affected markets,[25] in Belgium and Italy.

Belgium – nasal decongestants (R1A7)

(48) On a plausible relevant market for nasal decongestants (R1A7) available OTC in Belgium, the Parties market the following topical nasal preparations: Rhinatiol (Sanofi) and Rhinospray (BI CHC).

(49) As a result of the Transaction, the Parties would attain a combined market share of [30-40]%, measured in value on the basis of figures for 2015, with an increment of [10-20]%. Novartis would be the second largest competitor, with a market share of [30-40]%, followed by Merck ([10-20]%). In addition, there are a large number of other competitors active on this market, including large pharmaceutical manufacturers such as Johnson & Johnson, Stada, Takeda and Procter & Gamble.

(50) While the results of the market investigation indicate that both Parties' products enjoy high brand recognition and are supported by advertising campaigns,[26] the products do not seem to be particularly close competitors. For example, none of the pharmacies responding to the market investigation mentioned Rhinospray as a possible alternative to Rhinatiol.[27] This may be because the indications of these products differ, with Rhinospray being recommended for patients over 16 years, and for symptoms including throat inflammation, whereas Rhinatiol can be taken as of 6 years of age including for allergic rhinitis and sinusitis.[28]

(51) In view of the above, in particular the still moderate market shares, the large number of competitors and the fact that the Parties' products do not compete closely, the Commission considers that the Transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to any plausible market for nasal preparations in Belgium of which Rhinatiol and Rhinospray form part.

Italy – nasal antiallergic agents (R1A6)

(52) On the plausible relevant market for nasal antiallergic agents (R1A6) available OTC in Italy, the Parties market the following products: Intal and Tilade (Sanofi) and Rinogutt Antiall (BI CHC).

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25 Technically, a plausibly affected market also arises in Spain (R1A chlophrenamine based products). Similarly, on a number of plausible relevant markets (R1A+R1B, Rx; R1A, Rx; R1A1+R1A6, OTC+Rx or Rx and R1A1, Rx) of which the Parties following topical nasal preparation products Azmacort (Sanofi) and Dexa Rhinospray (BI CHC) form part, potential technically affected Group 1 markets arise in Greece.

However, given that the Sanofi products that caused the overlaps have been withdrawn from the market, these markets are not considered in more detail in the Decision.

26 See replies to questions 3 and 6 of Questionnaire Q10 to pharmacies in Belgium.

27 See replies to question 8 of Questionnaire Q10 to pharmacies in Belgium.

28 See Form CO, table 231 on pages 510-511.

(53) As a result of the Transaction, the Parties would attain a combined market share of [30-40]%, measured in value ([30-40]% in volume)[29] on the basis of figures for 2015, with an increment of [5-10]%. GSK would be the second largest competitor, with a market share of [20-30]%, followed by Teofarma ([20-30]%), and Johnson & Johnson ([10-20]%). The Parties' market shares have increased by [0-5]% over the last 3 years.

(54) The results of the market investigation indicate that the Parties' products do not seem to be particularly close competitors. First, in terms of price, the Parties' products have a different positioning whereby Sanofi's products are twice as expensive as BI's Rinogutt Antiall. Second, the pharmacies responding to the market investigation mentioned other products than Intal and Tilade as closest substitutes to Rinogutt Antiall and vice versa.[30] Finally, the Parties' products have slightly different modes of action (fast vs slow onset of action).[31]

(55) Moreover, the results of the market investigation indicate that GSK with its product Azelvin is the market leader in the Italian nasal antiallergic agents market, and has the strongest brand,[32] whereas other pharmacies submitted that even following the Transaction, at least two stronger brands than those of the Parties will continue to be present on this market.[33]

(56) In view of the above, the Commission considers that the Transaction does not give rise to serious doubts as to its compatibility with the internal market in any plausible market for nasal antiallergic agents in Italy of which Intal, Tilade and Rinogutt Antiall form part.

Other countries in which (Group 2 and Group 3) affected markets arise

(57) On the basis of the plausible market definitions set out above in paragraphs (39) to (46), the Transaction gives rise to plausibly affected Group 3 markets in the following countries:[34]

i. *Bulgaria (R1A7)*

ii. *Hungary (R1A7, R1A, R1A+R1B, R1A+R1B+R6A+R3J)*

iii. *Luxembourg (R1A7, R1A, R1A+R1B, R1A+R1B+R6A+R3J), and*

iv. *Slovakia (R1A7, R1A, R1A+R1B, R1A+R1B+R6A+R3J)*

(58) On these markets the combined market share of the Parties are moderate to low (at or below [20-30]% in all plausible markets). In all these markets a number of strong competitors are active, with a wide portfolio of products and brands, such as Johnson

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29 Due to the slightly higher market shares measured in volume, this is considered a plausible Group 1 market for the purposes of the Decision.

30 See replies to questions 18 and 20 of Questionnaire Q2 to pharmacies in Italy.

31 See Form CO, table 233 on pages 516-517.

32 See replies to questions 22.1 and 22.2 of Questionnaire Q2 to pharmacies in Italy.

33 See replies to question 25 of Questionnaire Q2 to pharmacies in Italy.

34 In addition, overlaps but no affected markets arise in Austria, Denmark, Finland, Germany, Ireland, Norway, Romania, Sweden and the UK.

& Johnson, GSK, Klosterfrau, Merck and Novartis, with market shares of mostly between 10-20%.

(59) Moreover, the market investigation did not reveal any concerns in relation to these markets.[35]

(60) 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 the plausible markets referred to in paragraph (39) to (46).

IV.3.1.1.b. Throat preparations (R2A)

Product market definition

(61) Both Parties market a number of throat preparations (ATC3 class R2A) in the EEA.

(62) These products are used for the local treatment of minor infections of mouth and throat.

(63) The ATC3 class R2A is not further subdivided into ATC4 classes.

(64) In previous decisions, the Commission considered but ultimately left open narrower market definitions based on ATC3 class R2A, but excluding menthol and eucalyptus only products from the relevant market.[36]

(65) In any event, the definition of the relevant product market in relation to treatments belonging to ATC class R2A can be left open as the Transaction does not give rise to serious doubts as to its compatibility with the internal market under any of the plausible product market definitions in this area.

Competitive assessment

(66) The Transaction gives rise to a Group 3 affected market in France[37] in relation to R2A, excluding menthol and eucalyptus only products, where the Parties market the following products: Rhinatiol mx, Ordomedine and Maxilase (Sanofi), and Frubienzym and Lysopaine NF (BI CHC).

(67) As a result of the Transaction, the Parties would attain a combined market share of [30-40]%, measured in value based on 2015 figures ([30-40]% in volume), with an increment of [10-20]%. Reckit Benckisser would be the second largest competitor, with a market share of [20-30]%, followed by Recordati ([5-10]%), and Pierre Fabre ([5-10]%). Market shares have been stable over the past 3 years, with the Parties' share increasing slightly by [0-5]%.

(68) The results of the market investigation indicate that among the Parties' products, it is in particular the combination of Maxilase and Lysopain that warrants careful scrutiny,

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35 See in particular Questionnaire Q1 to competitors, Questionnaire Q6 to pharmacies in Luxembourg, Questionnaire Q9 to pharmacies in Slovakia, and Questionnaire Q11 to pharmacies in Hungary.

36 See M.5953 Reckitt Benckiser/SSL.

37 In addition, overlaps but no affected markets arise in Belgium, Italy and Luxembourg.

as they both enjoy very high brand recognition and were described, in the course of the market investigation, as must-have throat preparations products by pharmacies.[38]

(69) However, the market investigation indicated that these products do not seem to be close competitors as they treat largely different conditions. This is because Lysopaine, similarly to Reckitt's market leader Strepsils and Pierre Fabre's Drill, is taken for common sore throat whereas Maxilase is recommended to patients with mild fever which may also have a sore throat. Accordingly, Maxilase has been described as a product akin to paracetamol-based medicines,[39] which cannot be considered as an alternative to solely sore throat treating products such as Lysopaine.

(70) In addition, the market investigation did not reveal concerns in relation to throat preparations in France.[40]

(71) In view of the above, the Commission considers that the Transaction does not give rise to serious doubts as to its compatibility with the internal market in any plausible market for throat preparations in France of which Rhinatiol mx, Ordomedine, Maxilase, Frubienzym and Lysopaine NF form part.

IV.3.1.1.c. Cough (and cold) preparations (R5)

Product market definition

(72) Both Parties market a large number of cough and cold preparations (ATC2 class R5) in the EEA, most of which are available OTC and some only under prescription.

(73) The ATC2 class R5 is subdivided into four ATC3 classes, including ATC3 class R5A, which comprises cold preparations without anti-infectives, R5B, which comprises cough and cold preparations with anti-infectives, R5C, which corresponds to expectorants and R5D, which includes all antitussives.

(74) The R5A, R5B and R5C ATC3 classes are not further subdivided into ATC4 classes whereas the ATC3 class R5D is further subdivided into two ATC4 classes, namely R5D1 including all plain antitussives and R5D2 including combinations with expectorants, such as antihistamines, ephedrine and herbal tinctures.

(75) In previous decisions, relating in particular to (multi-symptom) products for cold and flu, the Commission considered combinations of several ATC3 and ATC4 classes (R5A combined with either R1A7 or with R1A7 and R1A9).[41] It also contemplated broader market definitions combining R5A with R4A (chest rubs), R1B (systemic nasal preparations), R1A7 and R1A9, but ultimately left the market definition open.[42]

(76) Given that the focus in the present case lies on (chesty/wet) cough treatments (i.e. single symptom treatments for cough), and that the Parties' products predominately

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38 See Questionnaire Q3 to pharmacies in France.

39 See non-confidential minutes of a call with a pharmacist, 1 July 2016.

40 See Questionnaire Q3 to pharmacies in France and Questionnaire Q1 to competitors.

41 See M.7276 GlaxoSmithKline/Novartis Consumer Health Care.

42 See M.4007 Reckitt Benckiser/Boots Healthcare International and M.4314 Johnson & Johnson/Pfizer Consumer Healthcare.

overlap in ATC3 class R5C (expectorants), both in the Rx and OTC space, the Commission has assessed in particular plausible market definitions pertaining to this class.

(77) In relation to the R5C class, the Commission has contemplated in the past broader markets including products from ATC3 classes R5A, R5C and R5D,[43] while it found more recently that expectorants (R5C) and antitussives (R5D) are likely to be part of different product markets as "*expectorants loosen the mucus and, by producing cough, are meant to allow better coughing up of mucus. In contrast, antitussives suppress cough and are indicated in the cases of bothersome cough, especially during night-time. Therefore, a dry, hacking cough would require an antitussive while a productive cough would require an expectorant"*.[44]

(78) In line with the considerations above in paragraphs (19) and following, the market investigation in this case suggested that the key factor to delineate the relevant market in this space is the (therapeutic) indication, namely dry and wet/chesty cough. In this context one market participant explained that *"We are looking first at the therapeutic indication to differentiate products for dry cough or for loose cough. Depending on the type of cough, products are not the same"*.[45] Similarly, another market participant noted that "*due to clear positioning of products, consumers' as well as doctors' and pharmacists' awareness of cough types [wet/chesty and dry] is nowadays rather high*".[46] In general, respondents to the market investigation have clearly distinguished dry from wet cough products.[47]

(79) In view of the above, a broad distinction between expectorants (R5C) and antitussives (R5D) seems appropriate.

(80) In addition, within ATC3 class R5C, specifically in Ireland, the results of the market investigation indicate that a number of (prescribed) products falling into this ATC3 class treat predominately cystic fibrosis patients, whereas others (including the Parties' products) intend to facilitate the release of excessive and/or viscous mucus, which can be associated with acute or chronic bronchitis (including chronic obstructive pulmonary disease, "COPD").[48] Therefore, these types of medicines treat different diseases and target different patient groups. Moreover, products treating cystic fibrosis tend to be significantly more expensive than those for wet cough/bronchitis. For example, the leading cystic fibrosis product in Ireland is almost ten times more expensive than Mucodyne, the Sanofi product in the ATC3 class R5C in Ireland (BI's product Bisolvon, being even cheaper).

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43 See M.4314 Johnson & Johnson/Pfizer Consumer Healthcare.

44 See M.1878 Pfizer/Warner Lambert, recitals 40-41, and M.6705, Procter & Gamble/Teva Pharmaceutic, M.5865 Teva/Ratiopharm.

45 See replies to question 125 of Questionnaire Q 1 to competitors. See also replies to question 126, and the explanation of one competitor that the "*the market is split into dry cough… and productive cough".*

46 See replies to question 125 of Questionnaire Q 1 to competitors.

47 See in particular replies to Questionnaire Q1 to competitors, Questionnaires Q2, Q 4, Q5, Q6, Q8 and Q10 to pharmacies; see also non-confidential minutes of a call with a pharmacist, 5 July 2016.

48 See non-confidential minutes of a call with a KOL, 18 July 2016; see also replies to question 90 of Questionnaire Q 1 to competitors.

(81) Finally, the Commission also assessed whether it would be appropriate to define, within the R5C and the R5D plausible markets, narrower markets based on the molecules ambroxol and dextromethorphan.

(82) The results of the market investigation indicate that doing so would not suitably reflect the competitive interaction between cough products in ATC classes R5C and R5D. For both molecules under investigation, there are a number of alternatives with equal or similar indication and efficacy,[49] and market participants submit that the active ingredient plays at most a subordinate role in consumer's purchasing decisions.[50] It is thus an element that will be taken into account in the competitive assessment.

(83) In addition to the above considerations pertaining to therapeutic/labelled indications, the Commission also considered whether a distinction between OTC and prescribed products would be appropriate, in particular as regards products group in ATC3 class R5C.

(84) The results of the market investigation indicate that, in line with what was explained for most product markets for medicines in paragraphs (15) to (16), OTC and prescribed R5C products exert no competitive pressure on each other, given that practically no market participant mentioned prescribed products when asked about alternatives to a given OTC chesty/wet cough product of the Parties.[51] Moreover, the Notifying Party submits that the markets should be divided into OTC and Rx, a delineation that is also consistent with the Parties internal documents that clearly distinguish between these two markets. For example, one of the Parties' internal documents describes […],[52] whereas another - "understanding the purchase path – cough and cold area" – […][53] and a third one describing the competitive landscape for cough products available against prescription […].[54]

(85) In addition, the Commission considered previously a market segmentation based on galenic form.[55] In this respect, the market investigation in the present case has been inconclusive. While a number of market participants considered the galenic form to be an important factor (in particular for oral liquid ordinary, which according to one competitor is the preferred route of treatment and obtains best patient compliance),[56] others explained that this would be more a matter of personal preference, and of inferior importance in a consumers' purchasing decision.[57] In any event, this can be

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49 For ambroxol, see in particular replies to question 127 of Questionnaire Q 1 to competitors, and question 8 and 12 of Questionnaire Q8 to pharmacies in Romenia. For dextromethorphan, see in particular replies to question 128 of Questionnaire Q 1 to competitors.

50 See replies to question 12 and 125 of Questionnaire Q 1 to competitors.

51 See in particular Questionnaire Q1 to competitors, Questionnaires Q2, Q 4, Q5, Q6, Q8, Q10 to pharmacies; see also non-confidential minutes of a call with a pharmacist, 5 July 2016.

52 See […]

53 See […]BI's internal documents, Understanding the purchase path – cough and cold area, 28 January 2015.

54 See […]

55 M.6705, Procter & Gamble/Teva Pharmaceutic.

56 See for example replies to question 5 of Questionnaire Q6 to pharmacies in Luxembourg,

57 See for example non-confidential minutes of a call with a pharmacist, 5 July 2016.

left open as it has no decisive impact on the competitive assessment, and can also be taken into account in establishing the closeness of competition between two or several products.

(86) In view of the above, the Commission defines for the purposes of the Decision, the following relevant markets: (i) R5C (chesty, wet cough) products available OTC; (ii) R5D (dry, irritating cough) products available OTC; (iii) R5C (chesty, wet cough) products available against prescription, excluding medicines for the treatment of cystic fibrosis. Whether a segmentation of those markets by galenic form would be appropriate can be left open as it has no decisive impact on the competitive assessment, and can also be taken into account in competitive assessment.

Competitive assessment

(87) The Transaction gives rise to Group 1 affected markets in chesty/wet cough treatments in Greece, Ireland and Luxembourg.

Greece – chesty/wet cough treatments available OTC (R5C)

(88) On the market for chesty/wet cough treatments available OTC (R5C) in Greece, the Parties market Mucorhinatiol (Sanofi), Mucosolvan and Bisolvon (BI CHC).

(89) As a result of the Transaction, the Parties would attain a combined market share of [90-100]%, measured in value based on 2015 figures ([80-90]% in volume), with an increment of [5-10]%. Remaining competitors have all market shares of [0-5]% or below. Were the market defined at the level of galenic forms, the market shares for the dominating form (oral liquid ordinary) would fundamentally remain the same.

(90) The results of the market investigation indicate that Bisolvon and Mucosolvan, and to a significant but lesser degree also Mucorhinatiol, enjoy high brand recognition in Greece, with Bisolvon being described as a must-have product and the clear market leader.[58] In addition, the Parties' products also seem to be competing closely, market participants having identified in particular BI CHC's Bisolvon and Sanofi's Mucorhinatiol as close substitutes.[59] In the galenic form in which the Parties' products overlap – oral liquid ordinary- Bisolvon, the market leader, is the most expensive product, with a price of EUR 7.32, whereas Sanofi's Mucorhinatiol is similarly priced as other branded competitors (EUR 5.38-5.43). The Transaction would thus result in the elimination of the challenger product with the highest market share that appears to have competed in particular on price.

(91) In view of the above, the Commission considers that the Transaction gives rise to serious doubts as to its compatibility with the internal market in the market for chesty/wet cough treatments available OTC (R5C) in Greece as it strengthens a dominant position and eliminates close competitors.

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58 See replies to question 8 of Questionnaire Q5 to pharmacies in Greece.

59 See replies to question 6 of Questionnaire Q5 to pharmacies in Greece.

Ireland – chesty/wet cough treatments available Rx (R5C)

(92) On the market for prescribed chesty/wet cough treatments falling under ATC3 class R5C excluding cystic fibrosis products in Ireland, the Parties market Mucodyne (Sanofi) and Bisolovon (BI CHC).

(93) The Parties' combined market shares reach [40-50]%, measured in value based on 2015 figures ([80-90]% in volume), with an increment of [10-20]% in value and [0-5]% in volume. The two remaining competitors have market shares in value/volume of [20-40]/[0-5]% (Pari, Mucoclear) and [20-30]/[10-20]% (Galen, Erdotin).

(94) As concerns Pari's Mucoclear, the market investigation provided indications that this product is also targeted at cystic fibrosis in view of its high price (above EUR 100) and galenic form (lung). The foregoing is consistent with Pari's limited volume based market share (significantly below [0-5]%), indicating that it is used by a small group of patients with very special needs. It follows that Pari's Mucoclear is at the very best a distant competitor to other, including Parties' products in this category.

(95) As for the Parties' remaining rival – Erdotin – it also seems to be a distant competitor, given that it aims at treating patients with a slightly different indication, namely acute exacerbations associated with chronic bronchitis. Moreover, it seems to enjoy comparatively lower brand recognition than Parties' products.[60]

(96) In view of the above, the Commission considers that the Transaction gives rise to serious doubts as to its compatibility with the internal market in the market for prescribed chesty/wet cough treatments falling under ATC3 class R5C excluding cystic fibrosis products in Ireland as it eliminates closest competitors in an already concentrated market.

Luxembourg - chesty/wet cough treatments available OTC (R5C)

(97) On the market for chesty/wet cough treatments available OTC (R5C) in Luxembourg, the Parties market Mucorhinatiol (Sanofi), as well as Mucosolvan and Bisolovon (BI CHC). A Group 1 affected market would only arise if the relevant market were defined at the level of the galenic form (oral liquid ordinary).

(98) In this case, as a result of the Transaction, the Parties would attain a combined market share of [40-50]%, measured in value based on 2015 figures ([30-40]% in volume), with an increment of [10-20]% ([5-10]% in volume). The key competitors are Teva ([10-20]%), Klosterfrau ([10-20]%) and Qualiphar ([5-10]%), but there is also a large number of other competitors, with market shares between [0-5]% including large pharmaceutical manufacturers such as Novartis and Johnson & Johnson.

(99) As regards brand recognition, Sanofi's Rhinatiol seems to be the market leader, whereas BI CHC's products are less well established and on a comparable level to those of Klosterfrau and Qualiphar.[61]

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60 See replies to question 91 of Questionnaire Q 1 to competitors

61 See replies to question 7 of Questionnaire Q6 to pharmacies in Luxembourg; see also non-confidential minutes of a call with a pharmacist 5 July 2016.

(100) In terms of closeness of competition between the Parties' products, the market investigation has not been entirely conclusive, but it appears that Siroxyl (Klosterfrau) is closer to Sanofi's Mucorhinatiol than BI CHC's products, and Toularynx (Qualiphar) to BI CHC's Bisolvon, including due to the same active ingredient (carbocisteine and dextromethorphan, respectively).[62]

(101) Moreover, market participants confirmed that while most products are sold in the galenic form oral liquid ordinary, other galenic forms are also present and are equally recommended by pharmacists and bought by patients.[63] Therefore, even if one were to define separate markets delineated by galenic form, products from outside the market would exercise a competitive constraint.

(102) In addition, the market investigation did not reveal concerns in relation to R5C OTC products in Luxembourg.[64]

(103) In view of the above, the Commission considers that the Transaction does not give rise to serious doubts as to its compatibility with the internal market in any plausible market in chesty/wet cough treatments available OTC (R5C) in Luxembourg of which Mucorhinatiol as well as Mucosolvan and Bisolovon form part.

Other countries in which (Group 2 and Group 3) affected markets arise

(104) On the basis of the plausible market definitions set out above in paragraph (86), the Transaction gives rise to additional plausibly affected Group 3 markets in the following countries:[65]

i. *Belgium (R5D1, OTC; R5A+R1A, OTC; R5A+R1A7, OTC; R5A+R4A+R1B+R1A7, OTC & OTC+Rx);*

ii. *Czech Republic (R5C, OTC; R5D1, OTC+Rx; R5A+R1A7, OTC R5A+R1A, OTC+Rx & OTC; R5A+R4A+R1B+R1A7, OTC & OTC+Rx);*

iii. *France (R5C, OTC; R5A+R4A+R1B+R1A7, OTC+Rx);*

iv. *Hungary (R5A+R1A7, OTC; R5A+R4A+R1B+R1A7, OTC);*

v. *Italy (R5C, OTC, oral liquid ordinary; R5A, OTC; R5D, OTC+Rx & OTC, oral liquid ordinary; R5A+R4A, OTC+Rx & OTC; R5A+R1B, OTC+Rx & OTC)*[66]

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62 See non-confidential minutes of a call with a pharmacist, 5 July 2016, and replies to question 87 of Questionnaire Q 1 to competitors as well as replies to question 6 of Questionnaire Q6 to pharmacies in Luxembourg.

63 See non-confidential minutes of a call with a pharmacist, 5 July 2016

64 See replies to questions 11-13 of Questionnaire Q6 to pharmacies in Luxembourg; see also non-confidential minutes of a call with a pharmacist, 5 July 2016, and replies to question 89 of Questionnaire Q 1 to competitors

65 In addition, overlaps but no affected markets arise in Bulgaria, Denmark Finland, Germany, Lativa, Lithuania, Spain, Sweden and the UK.

66 In addition, there is a plausibly affected paracetamol based R5A market in Italy. Aside from the fact that the market investigation did not reveal any concerns in relation to this market, and the low probability that it would be appropriate to define a relevant market based on paracetamol-based

vi. *Netherlands (R5A, OTC; R5A+R4A, OTC; R5A+R1A, OTC; R5A+R1B, OTC)*

vii. *Romania (R5C, OTC, oral liquid ordinary);*

viii. *Slovakia (R5C, OTC, oral liquid ordinary; R5C, OTC; R5D1, OTC+Rx; R5A+R1A7, OTC; R5A+R4A+R1B+R1A7, OTC & OTC+Rx; R5A+R1A, OTC+Rx & OTC)*

ix. *Portugal (R5C, OTC, oral liquid ordinary, R5D1, OTC; R5D, OTC, oral liquid ordinary)*

(105) On these markets the combined market share of the Parties are moderate to low (in most of the above plausible markets below [10-20]%, and only twice exceeding [30-40]% (([30-40]%). In all these markets a number of strong competitors are active (3 at the very least), with a wide portfolio of products and brands offered by significant suppliers such as Johnson & Johnson, GSK, Teva, Menarini, Klosterfrau, Qualiphar, Recordati, Pierre Fabre, Merck, Krka and Novartis.

(106) Moreover, the market investigation did not reveal any concerns in relation to these markets.[67]

(107) 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 the plausible markets referred to in paragraph (86).

IV.3.2. PAIN AND MOBILITY[68]

IV.3.2.1.a. Non-narcotics and anti-pyretics (N2B)

Product market definition

(108) Sanofi markets a large number of non-narcotics and anti-pyretics (ATC3 class N2B), which are used to treat pain in the EEA, including in France, Austria and the Czech Republic where plausible affected markets arise.

(109) The ATC3 class N2B is further subdivided into two ATC4 classes as follows: N2B1 (Prescription-bound non-narcotics and anti-pyretics) and N2B2 (Non-prescription-bound non-narcotics and anti-pyretics).

(110) In previous decisions, the Commission contemplated narrower markets based on a distinction between paediatric and adult treatments,[69] as well as segmentation between

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products in this space, market shares have decreased from [30-40] % to [20-30]% over the past 3 years, and the increment is insignificant ([0-5]%). As a result, this plausible market is not considered further in the Decision.

67 See in particular Questionnaire Q1 to competitors, Questionnaire Q 2 to pharmacies in Italy, Questionnaire Q3 to pharmacies in France, Questionnaire Q4 to pharmacies in the Czech Republic, Questionnaire Q8 to pharmacies in Romania, Questionnaire Q9 to pharmacies in Slovakia, and Questionnaire Q11 to pharmacies in Hungary.

68 In addition to the markets assessed in the remainder of this section, overlaps but no affected markets arise in ATC3 class M2A in Germany, Romania and Portugal.

OTC and prescribed products.[70] Moreover, the Commission previously considered molecule based market, notably for tramadol, and a distinction by galenic form between oral liquid, solid and parenteral form.[71] In all these previous decisions, the market definition was ultimately left open.

(111) The Notifying Party submits that the relevant market should be defined at N2B level, including both prescribed and OTC products, in particular in view of the fact that the OTC segments of the N2B space is comparatively small.

(112) However, the results of the market investigation in this case indicate that it may be appropriate to define narrower markets within the N2B field, reflecting the different levels of pain intensity on the one hand and subdivided into prescription and OTC market on the other. In this context one market participant explained that "*Products are mainly divided into 2 sub-segments based on pain intensity (low and medium). […] Codeine products can play on 2 sub-segments: OTC and prescription*".

(113) This characterisation of the relevant market is also mirrored by […] which divide the pain management field in level 1 and level 2 medicines (depending on the severity of pain), with the latter being segmented into an Rx (i.e. prescribed) and OTC part. As to the OTC/Rx distinction, […] OTC and prescription markets are seen as two distinct pillars, for different patients or patient needs, and demanding a different distribution and advertising strategy.[72]

(114) Pharmacies responding to the market investigation also clearly distinguished between prescribed and OTC products, for instance by only mentioning OTC products when asked about substitutes to a given OTC medicine of the Parties.[73]

(115) In view of the above, the Commission considers that it is appropriate to distinguish, for the purposes of the Decision, OTC from prescribed pain management treatments.

(116) As for a distinction by the severity of the pain experienced, there are also strong indications that within the OTC pain management space separate markets exist for different levels of pain. This is clearly evidenced in Sanofi internal documents referring to a […].

Graph 1: Overview of level 2 pain management space (in France)

[…]

Source: Notifying Party

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69 See M.7276 GlaxoSmithKline/Novartis Consumer Health Care.

70 See M.5253 Sanofi-Aventis/Zentiva.

71 See M.5865 Teva/Ratiopharm.

72 See […]

73 See replies to questions 35 and 35.1 of Questionnaire Q 3 to pharmacies in France. See also non-confidential minutes of a call with a pharmacist, 8 July 2016. Competitors answered similarly, see replies to questions 139 and 143 of Questionnaire Q1 to competitors.

(117) Moreover, this distinction is consistent with WHO pain categories, according to which analgesics are classified into to three different pain categories: Category I (milder to moderate pain), Category II (moderate to severe pain); Category III (severe pain).

(118) The results of the market investigation also provide indications that level two products are recommended to patients by pharmacists "*when anti-pyretics like paracetamol and ibuprofen are not efficient*".[74]

(119) Specifically, the level two pain management products comprise codeine-based products, and also tramadol and lamaline based medicines, though those are not available OTC.

(120) For the purposes of the Decision, the Commission therefore considers that it is appropriate to define a relevant market for level 2 OTC non-narcotics and anti-pyretics.

Competitive assessment

(121) Against this background, the Transaction gives rise to one Group 1 affected market in France, and one Group 2 affected market in the Czech Republic.

France

(122) On the market for level 2 OTC non-narcotics and anti-pyretics in France, Sanofi markets Codoliprane and Doliprane Codeine, and BI CHC is present with Prontalgine.

(123) As a result of the Transaction, the Parties would attain a combined market share of [70-80]%, measured in value based on 2015 figures ([70-80]% in volume), with an increment of [30-40]%. The remaining competitors have market shares of [5-10]% (Migralgine by Johnson & Johnson), [5-10]% (Klipal, Pierre Fabre), [0-5]% (Aurobindo, Gruenenthal)

(124) Sanofi internal documents estimate the Parties' market share to be even higher ([…]%).[75]

(125) The Notifying Party submits that the Parties' products are not close competitors in particular in terms of price. Specifically, Prontalgine (EUR 5.5) is marketed at the higher end price, along with Migralgine (EUR 5.5) whereas Codoliprane (EUR 2.1) and Doliprane Codeine (EUR 3.95) are marketed in the lower end prices, along with Klipal (EUR 2.59). Moreover, the Notifying Party submits that Codoliprane, even though it is an OTC product, can be partly (65%) reimbursed when bought on prescription. Because of this partial reimbursement when prescribed, its price is regulated in France, which, according to Sanofi would limit its ability to increase the price post-merger.

(126) As for closeness of competition, the Commission notes that in the OTC space, as explained above in paragraph (25), the most important factors for a consumer's purchase decision are brand recognition and therapeutic indication. As for the brand recognition, the market investigation provided clear indications that Codoliprane and

74 See replies to question 32 to pharmacies in France

75 See Sanofi's internal documents […],

Prontalgine are by far the best known products, so called flagships in this class, which also evidenced by their close to symmetrical market shares.[76] As regards indication, the market investigation revealed that the "*principal competitor of Prontalgine is Codoliprane*"[77] despite the fact that in addition to codeine, Prontalgine (similarly to Migralgine) also contains caffeine.[78]

(127) As concerns Sanofi's argument that its product Codoliprane is price regulated, the Commission notes that Sanofi recently launched a new pure OTC product in this space (Doliprane codeine) which was clearly designed to compete head-on with Prontalgine (and Migralgine). Indeed, according to a Sanofi's internal document […]. In addition, while Doliprane Codeine has at this stage limited market share, it is likely that, absent the transaction, its position would continue to increase as it can build on France's most established brand in the pain management space and trust and recognition in pharmacists and patient communities while being available at a lower price point.[79] In this context it is also noted that post-merger the merged entity may have an incentive to withdraw Doliprane Codeine from the market so that the sales of the more expensive Prontalgine are not cannibalized.

(128) Finally, a large majority of market participants expressed concerns in relation to odeine based pain killers in France arguing the merger is putting together the two strongest brands and the lack of sufficient alternatives on this market post Transaction.[80]

(129) In view of the above, the Commission considers that the Transaction gives rise to serious doubts as to its compatibility with the internal market on the market for level 2 OTC non-narcotics and anti-pyretics in France as it would eliminate closest competitors.

Czech Republic

(130) Plausible Group 2 affected markets arise if the relevant market were defined either at the level of the galenic form (N2B, oral solid ordinary, OTC only), or at molecule level (N2B, paracetamol, OTC).

(131) In both constellations, Sanofi would have a high but slightly decreasing market share of [40-50]-[40-50]% by value, based on 2015 figures. Nevertheless, the increment in market share arising from the Transaction would be very small ([0-5]%). Moreover, at

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76 See non-confidential minutes of a call with a pharmacist on 1 July, explaining that " *le principal concurrent au produit de BI à savoir Prontalgine, le leader du marché en France, est le produit de Sanofi CoDoliprane. Si certains génériques sont également disponibles sur ce marché, tels que Codeine/para de Mylan ou Paracetamol codéiné de Servier, ceux-ci sont beaucoup moins reconnus tant en raison de leur efficacité, qui reste à prouver, que de la perception qu'en ont les patients". See also* See replies to question 35.1-4 to pharmacies in France, and replies to question 140 of Questionnaire Q1 to competitors.

77 See replies to question 35.1-4 to pharmacies in France, and replies to question 139 and 143 of Questionnaire Q1 to competitors.

78 See non-confidential minutes of a call with a pharmacist on 8 July 2016.

79 See Sanofi's internal documents, Doliprane – apporter une réponse au choix d'antalogie en OTC, slide 18.

80 See replies to question 36 to pharmacies in France.

least three competitors remain on these plausible market(s), with market shares between [5-10]% and [20-30]% which exceed by far those of BI CHC.

(132) In addition, the market investigation did not reveal any concerns in relation to these markets.[81]

(133) In view of the above, the Commission concludes that the Transaction does not give rise to serious doubts as to the compatibility of the Transaction with the internal markets in relation to any plausible market in the Czech Republic of which the Parties' products classified in the ATC3 class N2B form part.

IV.3.3. GASTRO-INTESTINAL TREATEMENTS

IV.3.3.1. Antacids, antiflatulents and antiulcerants (A2)

Product market definition

(134) Both Parties sell a number of products in the EEA used to treat gastric ulcer, heartburn, reflux and bloating, both OTC and on prescription, which are classified under the ATC class A2.

(135) The ATC class A2 is subdivided into two ATC3 classes, namely A2A (antacids, antiflatulents and carminatives) and A2B (antiulcerants).

(136) As to the A2A class, in previous decisions, the Commission contemplated narrower markets distinguishing antacids from antiflatulents and carminatives,[82] antacids for infants and adults[83] as well as OTC and prescribed products,[84] but ultimately left the product market definition open.

(137) As to the A2B class, in previous decisions, the Commission considered a distinction between H2 antagonists (A2B1) and Proton Pump Inhibitors (PPI, A2B2)[85] as well as narrower molecule based markets.[86] In the more recent cases, 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.[87]

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81 See in particular Questionnaire Q1 to competitors, Questionnaire Q6 to pharmacies in Luxembourg, Questionnaire Q9 to pharmacies in Slovakia, and Questionnaire Q11 to pharmacies in Hungary.

82 See M.5253 Sanofi Aventis/Zentiva, M.7276 GlaxoSmithKline/Novartis.

83 See M.5953 Reckitt Benckiser/SSL.

84 See M.5953 Reckitt Benckiser/SSL.

85 See M.4418, Nycomed Group/Altana Pharma, M.7379 Mylan/Abbott EDP-DM.

86 See M.6258 Teva/Cephalon, M.6613 Watson/Actavis.

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

(138) The Notifying Party submits that the relevant market should comprise the ATC 3 class A2A and should include only products available OTC. As regards antiulcerants, the Notifying Party submits that the relevant market should comprise the ATC3 class A2B, without the need to distinguish between OTC and Rx products. The Notifying Party considers that this is a specific feature of the A2B market since a significant amount of antiulcerants is sold in the EEA under prescription only.

(139) In line with the Commission's precedents, the market investigation provided indications that a distinction should be made between H2 antagonists (A2B1) and Proton Pump Inhibitors (PPI, A2B2). As explained by one market participant: *"[X] does not view PPIs as in direct competition with other antiulcerants, such as antacids or H2 antagonists*".[88]

(140) As to the potential distinction of markets by molecule within PPIs, the results of the market investigation as well as the evolution of the market shares over the last two years indicate that amongst various PPIs pharmacists and patients substitute these OTC products across molecules with the same therapeutic/labelled indications. A PPI newly introduced to the OTC market by Pfizer (based on *esomeprazole*) managed to gain shares from other PPIs based on other molecules (such as *pantoprazole* or *omeprazole*). Therefore, the Commission considers that a distinction by molecule, such as *pantoprazole* where both Parties are active, from other PPIs (i.e. other drugs included in the A2B2 class) would not be relevant in relation to these OTC products, since *pantoprazole*-based products would not have specific therapeutic/labelled indications.[89]

(141) In any event, the definition of the relevant product market in relation to treatments belonging to ATC 3 classes A2A and A2B can be left open for the purpose of the Decision as the Transaction does not raise serious doubts as to its compatibility with the internal market under any of the plausible product market definitions in this area.

Competitive assessment

(142) The Transaction gives rise to one Group 1 affected market in Italy. There is no Group 2 or Group 3 overlap for any plausible market in this area in any other Member State.

Italy

(143) In antacids, antiflatulents and antiulcerants, the Transaction gives rise to a Group 1 affected market under different plausible product market definitions, all concerning only products available OTC namely all antacids, antiflatulents and carminatives as well as antiulcerants (A2A+A2B) sold OTC, all antiulcerants (A2B) sold OTC, proton pump inhibitors (A2B2) sold OTC and *pantoprazole* based products sold OTC.

(144) Sanofi markets Inipomp/Maalox Reflusso (*pantoprazol*e-based A2B2 drug), and three products which belong to A2A class: Maalox (with *aluminium, magnesium*), Neutrose (including *calcium, kaolin* and *magnesium*) and Maalox Plus (based on *aluminium, magnesium* and *simethicone*). BI CHC markets in Italy Buscopan Reflusso (*pantoprazole*-based A2B2 drug) and Buscopan Antiacido (*ranitidine*-based A2B drug). All these products are sold OTC.

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88 See replies to question XX Questionnaire Q1 to competitors.

89 See replies to question 6 to Questionnaire Q2 to pharmacies in Italy.

(145) As a result of the Transaction on the market comprising all A2A and A2B products the Parties will achieve a market share of [30-40]%, in value, with a [0-5]% increment coming from BI CHC ([40-50]% in volume, with [0-5]% increment coming from BI CHC). Main competitors include Reckitt Benckiser with [10-20]% market share, Johnson & Johnson with [10-20]% market share, Pfizer with [5-10]% and a number of other suppliers with share of [5-10]% or less including Bruno Farmaceutico, Antonetto, Menarini, Sella, GSK and Bayer. During the last three years both Parties have lost some market share, mainly to Reckitt Benckiser and Pfizer.

(146) On the market comprising A2B products only (OTC) the Parties will achieve a market share of [40-50]% in value ([20-30]% by Sanofi and [10-20]% coming from BI CHC).[90] The remaining competitors include Pfizer ([20-30]%), Menarini ([10-20]%), GlaxoSmithKlein ([5-10]%) and Teva ([5-10]%) as well as other established suppliers such as Novartis and Bayer with less significant presence on the market. On the market for A2B drugs the Parties lost [10-20] percentage points in last three years (from combined [50-60]% market share in 2013). This was the result of Pfizer's successful introduction to the OTC market of its proton pump inhibitor, Nexium, based on *esomeprazole*. Pfizer managed to build its position from no OTC sales in 2013 to [20-30]% share on the market for all antiulcerants sold OTC in 2015.

(147) As regards the market comprising proton pump inhibitors only (A2B2 products) available OTC, the Parties' combined market share will amount to [40-50]% in value (with the increment of [10-20]% coming from BI CHC), the second largest supplier being Pfizer with [30-40]%, followed by GSK with [10-20]%, Teva with [5-10]% and Bayer and Novartis with [0-5]% and [0-5]% respectively. For the same reasons related to the entry of Pfizer, in the last years the Parties have been losing market shares on the market for proton pump inhibitors from combined [50-60]% in 2013 to [40-50]% in 2015.

(148) For completeness the Commission notes that as regards the *pantoprazole*-based products, the Parties' combined market share will reach [60-70]% with the increment of [10-20]% coming from BI CHC. The remaining suppliers include GSK having [10-20]% market share, Teva with [10-20]% share and Novartis with [0-5]%. However, as specified above, in line with the Commission past decisions and as confirmed by the results of the market investigation, the Commission considers that the relevant market should rather comprise all proton pump inhibitors irrespective of the underlying molecule.

(149) As regards brand recognition, Sanofi's Maalox seems to be the market leader on the larger market comprising antacids, antiflatulents and antiulcerants while BI CHC's Buscopan Reflusso seems to be well known but not to the same extent, rather on a comparable level to the brands of Pfizer, GSK/Novartis and Bayer.[91]

(150) According to the results of the market investigation, Parties' products do not seem to be closest competitors. In this context one market participant explained that "*Buscopan Reflusso and Buscopan Antacido have a systemic mechanism of action, Maalox and Maalox Plus have a topical anti-acid activity on the gastric mucosa, so*

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90 Market shares data measured in volume are broadly the same.

91 See replies to question 5 and question 8 of Questionnaire Q2 to pharmacies in Italy and replies to question 8 of Questionnaire Q1 to competitors.

they are different products and, in some cases, they can be used in combined therapy".[92] On the other hand, it appears that Gaviscon, a product offered by Reckit Benckiser is perceived as closer substitute to Maalox: "*Maalox and Gaviscon are closer competitors to one another, than either is to the Buscopan products*". "*Buscopan's Reflusso is (…) not in direct competition with Maalox. Buscopan Anti-Acido is more likely to be viewed as a substitute to Maalox, although it has a different mechanism of action*"; *"Gaviscon is similar to Maalox/Maalox Plus, so is different from Buscopan (antispasmodic) and Buscopna Reflusso/ Buscopan Antiacido"*.[93] When indicating the closest substitutes to Sanofi's Inipomp (Maalox Reflusso) the respondents to the market investigation tend to perceive Nexium offered by Pfizer or Eugastrol offered by Teva as closer than Buscopan Reflusso.[94]

(151) As regards prices, Sanofi's products, in particular Maalox Reflusso, are reported to be more expensive (together with the product offered by Pfizer) while BI CHC's Buscopan Reflusso is cheaper (comparable rather to the drugs offered by GSK/Novartis, Bayer and Teva).[95]

(152) In addition, the market investigation did not reveal any concerns in this market in Italy. [96]

(153) In view of the above, the Commission considers that the Transaction does not give rise to serious doubts as to its compatibility with the internal market in any plausible market for antacids, antiflatulents and antiulcerants in Italy of which Inipomp/Maalox Reflusso, Maalox, Neutrose, Maalox Plus, Buscopan Reflusso and Buscopan Antiacido form part.

IV.3.3.2. Antispasmodics (A3A)

Product market definition

(154) The ATC3 class A3A comprises plain antispasmodics and anticholinergics which are used for treatment of various gastro-intestinal disorders, abdominal pain, cramping and discomfort, also, but not necessarily related to irritable bowel syndrome. 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.

(155) 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.[97]

(156) More recently,[98] the Commission found that the relevant market should be defined at the molecule level, at least as concerns *mebeverine*. The market investigation in that

92 See replies to question 9.1 of questionnaire Q1 to competitors.

93 See replies to question 9.1 and 9.2 of questionnaire Q1 to competitors.

94 See replies to question 11.1 of questionnaire Q1 to competitors.

95 See replies to question 5 of Questionnaire Q2 to pharmacies in Italy.

96 See replies to question 11 of Questionnaire Q1 to competitors and to questions 32 and 33 of Questionnaire Q1 to pharmacies in Italy.

97 See M.5253 Sanofi-Aventis/Zentiva

98 See M.7379 Mylan/Abbott EPD-DM

case 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.[99] The Commission did not consider that a distinction based on the galenic form of the products concerned would be justified.[100]

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

(158) The Notifying Party noted that in the present case there is no overlap between Sanofi and BI CHC at molecule level and provided market shares for the markets comprising all the antispasmodics as well as plausible segments taking into account the distinctions based on the galenic form or their Rx/OTC status.

(159) The market investigation revealed that on the markets where overlaps in antispasmodics arise, various antispasmodics based on various molecules compete with each other. This is also confirmed by the internal documents of the Parties.

(160) As to the distinction between prescribed and OTC products, the Commission notes that the Parties are usually present within both categories of products (Rx and OTC) and the Commission's assessment is not altered regardless of this distinction. Similarly, the market investigation did not provide any indications that the market for antispasmodics should be segmented according to the route of administration and form of a medicine, although these factors shall be taken into account in the assessment of the closeness of competition between various antispasmodics.

(161) In view of the above, the Commission defines for the purposes of the Decision, the relevant market in relation to antispasmodics at the level of ATC3 class: A3A. Whether a segmentation of this market depending on the OTC/Rx status or by galenic form would be appropriate can be left open as it has no decisive impact on the competitive assessment, and can also be taken into account in competitive assessment.

Competitive assessment

(162) On the basis of the plausible market definitions set out in the previous section, the Transaction gives rise to Group 1 affected markets in antispasmodics in the Czech Republic, Estonia], Hungary, Latvia, Poland, Romania and Slovakia.[101]

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99 See M.7379 Mylan/Abbott EPD-DM, para 214.

100 See M.7370 Mylan/Abbott, para 22 and the following.

101 Due to a mistake in the IMS data base, limited sales of Sanofi's product are reported in Belgium leading to a potentially affected market for antispasmodics in this country. The Parties submitted evidence that this product was withdrawn from the market in 1995 and thus there is no overlap in Belgium on the market for antispasmodics.

Czech Republic

(163) In antispasmodics in Czech Republic, the Transaction gives rise to one Group 1 market comprising all antispasmodics sold on prescription.

(164) In Czech Republic Sanofi markets NoSpa (*drotaverine*, in the form of tablets) and Spasmopan SNFI (*codeine, fenpiverinium, paracetamol and pitofenone*, in the form of suppositories) and BI CHC markets Buscopan (*scopolamine butyl hydroxide*, in the form of tablets). All these products are sold on prescription only.

(165) The Parties' combined market share amounts to [50-60]% in value with an increment of [20-30]% coming from BI CHC (in volume the combined market share amounts to [60-70]% with the increment of [20-30]%). The competitors include Mylan with [30-40]% market share in value ([20-40]% in volume), Liplats 2000 with [5-10]% market share ([10-20]% in volume) and Menarini with [0-5]% market share ([0-5]% in volume).

(166) As regards the closeness of competition and brand recognition the market investigation revealed that both NoSpa and Buscopan are very strong, well-recognised brands in the Czech Republic. NoSpa is a clear market leader and Buscopan is the number 2 product. These two products are generally perceived as interchangeable for most indications although NoSpa seems to have a wider spectrum of indications. In particular both drugs include urogenital indication, which competing products, in particular Mylan's Duspatalin do not have.[102]

(167) In view of the above, the Commission considers that the Transaction gives rise to serious doubts as to its compatibility with the internal market in the market for antispasmodics (A3A) in Czech Republic.

Estonia

(168) In antispasmodics in Estonia, the Transaction gives rise to one Group 2 market comprising all antispasmodics irrespective of their galenic form or OTC/Rx status. On the market for antispasmodics in Estonia Sanofi markets NoSpa (*drotaverine*) and BI CHC markets Buscopan (*scopolamine butyl hydroxide*).

(169) As a result of the Transaction on the market comprising all antispasmodics in Estonia irrespective of their galenic form or OTC/Rx distinction the Parties would achieve a combined market share of [80-90]% in value ([80-90]% in volume) with the increment in value of [0-5]% brought by BI CHC.

(170) The increment deriving from the Transaction would exceed one percent, and thus Group 1 affected market in Estonia would arise, only if the market was segmented according to the galenic form of products, for the market for antispasmodics in parenteral form, in this case ampoules. Under this market definition the Transaction is a merger to monopoly with a small increment brought by BI CHC. As explained in the section regarding the product market definition, there is no evidence that the market for antispasmodics should be segmented according to the galenic form of the drugs available. However, the fact that no other supplier offers antispasmodics in the form

102 See replies to questions 23 and 25.1 of Questionnaire Q1 to competitors.

of ampoules except the Parties indicates that at least in this respect the Parties are the closest competitors present on the market for antispasmodics in Estonia.

(171) The Commission notes that NoSpa is a clear market leader in Estonia. More importantly, Buscopan and NoSpa are the only antispasmodics offered in the form of ampoules. Buscopan is a less important product than NoSpa, but it is the only alternative supplier to NoSpa that generated sales over EUR [1 000-2 000][103] over the last three years and it has already generated sales in 2016.

(172) In view of the above, the Commission considers that the Transaction gives rise to serious doubts as to its compatibility with the internal market in the market for antispasmodics (A3A) in Estonia.

Hungary

(173) In antispasmodics in Hungary the Transaction gives rise to three Group 1 affected markets: all antispasmodics (irrespective of their OTC/Rx status), antispasmodics offered OTC and antispasmodics sold on prescription only. On these markets Sanofi markets Drotaverine-Chinoi (*drotaverine*, in the form of tablets sold OTC) and NoSpa (*drotaverine*). BI CHC markets Buscopan (*scopolamine butyl hydroxide*). Both NoSpa and Buscopan are sold in two forms: tablets are sold OTC and oral liquids sold on prescription only.

(174) As a result of the Transaction, on the market comprising all antispasmodics irrespective of the galenic form or OTC/Rx distinction, the Parties will achieve a combined market share of [70-80]% in value with an increment of [5-10]% brought by BI CHC (in volume the combined market share amounts to [80-90]% with the increment of [5-10]%). Competitors include Mylan with a market share of [10-20]% ([5-10]% in volume), and Takeda and Servier with [0-5]% market share each. In general, the market shares have remained almost unchanged over the last three years.

(175) The market investigation revealed that Sanofi's NoSpa is a clear market leader with a very well-known, well-established brand in Hungary, Drotaverine Chinoi is the second best brand and Buscopan is the third best known brand. As explained by one of the respondents to the market investigation *"NoSpa has high awareness and might be considered more modern than Buscopan due to the higher investment. But both products have high reputation among the consumers"*.[104] In addition, Sanofi's Drotaverine-Chinoi is identified by market participants as having the advantage of benefiting from co-payment in Hungary, which means that it is partly reimbursed.[105]

(176) The results of the market investigation suggest that NoSpa and Buscopan are each other's closest competitors having multiple indications, including urogenital, which competing products (and in particular Mylan's Duspatalin) do not have. As regards the prices of antispasmodics in Hungary, the market investigation revealed that Sanofi's NoSpa and BI CHC's Buscopan are priced at similar level, Sanofi's Drotaverine Chinoi is slightly cheaper, while other products on the market, notably

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103 In the last three years, the other players active with ampules (Atropine and Papaverine products) did not reach the EUR [0-1 000] sales threshold; the size of the relevant market in Estonia amounts to approximately EUR [3 000-5 000].

104 See replies to questions 7, 8, 9.1 and 34 to Questionnaire Q11 to pharmacies in Hungary.

105 See replies to question 9.1 to Questionnaire Q11 to pharmacies in Hungary.

Mylan's Duspatal is more expensive.[106]As a result the Transaction combines the two cheapest drugs on the market.

(177) Finally, some market participants raised concerns in view of the fact that the Parties' products are among a few OTC antispasmodics present in Hungary.[107]

(178) In view of the above the Commission considers that the Transaction gives rise to serious doubts as to its compatibility with the internal market in the market for antispasmodics (A3A) in Hungary.

Latvia

(179) In antispasmodics in Latvia the Transaction gives rise to two Group 1 affected markets: all antispasmodics irrespective of their OTC/Rx status and antispasmodics available OTC. In Latvia Sanofi markets NoSpa (*drotaverine*, in the form of tablets sold OTC and on prescription and in the form of a liquid on prescription only). BI CHC markets Buscopan (*scopolamine butyl hydroxide*, in the form of tablets or suppositories, both sold OTC).

(180) As a result of the Transaction, on the market comprising all antispasmodics irrespective of their galenic form or the OTC/Rx distinction, in Latvia the Parties will achieve a market share of [80-90]% in value with an increment of [0-5]% brought by BI CHC (in volume the combined market share amounts to [90-100]% with the increment of [0-5]%). There would be only two competitors remaining: Mylan with [5-10]% market share in value ([0-5]% in volume) and Meda with [5-10]% market share ([0-5]% in volume). In fact Mylan has recently acquired Meda,[108] so in fact there will be only one competitor left. More importantly the products of Mylan and Meda are not available OTC. This means that on the plausible market of antispasmodics sold OTC the Transaction would be a merger to monopoly.

(181) The market investigation confirmed that NoSpa is a clear market leader in Latvia. While Buscopan is much smaller, it is the only alternative available OTC.[109] Based on the market investigation, NoSpa and Buscopan seem to be each other's closest competitors having multiple indications, including urogenital, which competing products (and in particular Mylan's Duspatalin) do not have. As for prices, NoSpa appears to be the cheapest of the products concerned, while Buscopan is reported to be more expensive.

(182) In view of the above, the Commission considers that the Transaction gives rise to serious doubts as to its compatibility with the internal market in the market for antispasmodics (A3A) in Latvia.

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106 See replies to question 34 to Questionnaire Q1 to competitors.

107 See replies to question 11-11.4 to Questionnaire Q11 to pharmacies in Hungary and replies to questions 38.1 and 39 to Questionnaire Q1 to competitors.

108 See M.7975 Mylan/Meda.

109 See replies to question 10 to questionnaire Q12 to pharmacies in Latvia.

Poland

(183) In antispasmodics in Poland the Transaction gives rise to two Group 1 affected markets: all antispasmodics irrespective of their OTC/Rx status and antispasmodics available OTC. In Poland Sanofi markets NoSpa (*drotaverine*, in the form of tablets available OTC and on prescription and in the form of a liquid sold on prescription only) and Scopolamine (*scopolamine*, in the form of a liquid, on prescription only). BI CHC markets Buscopan in the form of tablets available OTC.

(184) As a result of the Transaction on the market comprising all the antispasmodics irrespective of galenic form or the OTC/Rx distinction, in Poland the Parties will achieve a combined market share of [60-70]% in value with the increment of [0-5]% brought by BI CHC (in volume the combined market share amounts to [70-80]% with the increment of [0-5]%). There would be a few competitors present: Mylan with [10-20]% in value ([5-10]% in volume) and several other suppliers none of them exceeding [5-10]% market share.

(185) On the market comprising antispasmodics available OTC the combined market share reaches [90-100]%: Sanofi [90-100]% and BI CHC [5-10]% (measured by volume the results are almost the same). On that market post-Transaction there would remain only two competitors present with small market shares: Polpharma (with a [0-5]% market share measured by volume and negligible market share measured by value) and Galenus (with a [0-5]% market share measured by value and negligible share by volume).

(186) The market investigation revealed that Sanofi's NoSpa is a clear market leader. One of competitors indicated that NoSpa has a very strong position in Poland strengthened by large scale marketing campaigns targeting end-customers. Buscopan apparently is also well known: Buscopan is smaller but is the only sizeable competitors having more than [5-10]% market share on the OTC segment. The results of the market investigation suggest that NoSpa and Buscopan are each other's closest competitors having multiple indications, including urogenital, which competing products (and in particular Mylan's Duspatalin) do not have.[110] Furthermore, some market participants raised concerns in view of the fact that the Parties' products are among a few OTC antispasmodics present in Poland and NoSpa has already a very strong position.[111]

(187) In view of the above, the Commission considers that the Transaction gives rise to serious doubts as to its compatibility with the internal market in the market for antispasmodics (A3A) in Poland.

Romania

(188) In antispasmodics in Romania the Transaction gives rise to a Group 2 affected market. In Romania Sanofi markets NoSpa and BI CHC markets Buscopan.

(189) A Group 1 affected market would arise in Romania only on the theoretical market limited to antispasmodics in the form of a tablet sold OTC, while as indicated above, in the section regarding product market definition, there is no evidence which would

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110 See replies to question 33 and 38.2 to Questionnaire Q1 to competitors.

111 See replies to question 11.1 to Questionnaire Q7 to pharmacies in Poland and to question 39 to Questionnaire Q1 to competitors.

justify segmenting the antispasmodics market according to the galenic form of the drugs.

(190) As regards the market comprising all the antispasmodics irrespective of the galenic form and irrespective of OTC/Rx distinction, in result of the Transaction the Parties would achieve the combined market share of [50-60]% with a small increment of [0-5]% coming from BI CHC (in volume [50-60]% with the increment of [0-5]%). The remaining competitors include Menarini with the market share of [10-20]% in value ([5-10]% in volume), Mylan with the market share of [10-20]% in value ([10-20]% in volume) and Takeda and Antibiotice with respectively [5-10]% and [5-10]% market share in volume and below [5-10]% in value.

(191) Finally, on the narrowest plausible market comprising all antispasmodics irrespective of their galenic form but limited to products available OTC the Parties combined market share measured in value would reach [80-90]% with the increment of [0-5]% brought by BI CHC (in volume the combined market share would amount to [70-80]% with the increment of [0-5]%). Competitors include Antibiotice and Takeda with respectively [5-10]% and [5-10]% market share in volume and less than [5-10]% each in value.

(192) Respondents to the market investigation indicated that there are many alternatives to NoSpa available, other than Buscopan, offered by Antibiotice, Biofarm or Labormed.[112] NoSpa is the clear market leader, also in terms of brand recognition, while the second best products would seem to be Scobutil offered by Takeda or Spaverin offered by Antibiotice; based on the results of the market investigation Buscopan does not seem to be well known in Romania.[113]

(193) In view of the above, the Commission considers that the Transaction does not give rise to serious doubts as to its compatibility with the internal market on the market for antispasmodics or any of its plausible segments in Romania.

Slovakia

(194) In Slovakia the Parties market the following antispasmodics: Sanofi markets Bentyl (*dicyclomine*, it is sold on prescription only, and is in the form of suppositories) and NoSpa (*drotaverine*); BI CHC markets Buscopan (*scopolamine butyl hydroxide*). Both NoSpa and Buscopan are offered in the form of tablets or liquids; tablets are available OTC while liquids are available OTC or on prescription.

(195) As a result of the Transaction on the market comprising all antispasmodics in Slovakia irrespective of their galenic form or OTC/Rx distinction, the Parties' combined market share would reach [80-90]% in value with the increment of [20-30]% brought by BI CHC ([80-90]% in volume with the increment of [20-30]%). There would remain only two competitors: Mylan with [10-20]% in value ([10-20]% in volume) and Liplats 2000 with [0-5]% market share in value and in volume. Moreover, the Transaction is a merger to monopoly on the market comprising antispasmodics sold OTC with the increment of [10-20]% brought by BI CHC.

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112 See replies to questions 3 to Questionnaire Q8 to pharmacies in Romania.

113 See replies to question 8 to Questionnaire Q8 to pharmacies in Romania.

(196) Market investigation revealed that Sanofi's NoSpa is a clear market leader and that Buscopan is also a well-established brand, number 2 antispasmodic in Slovakia and the only alternative available OTC. As explained by one of the pharmacists: "*regarding OTC drugs, NoSpa and Buscopan are top-sellers in this field. It is hard to say, which one is the leader"*.[114] As already mentioned, the market investigation revealed that, NoSpa and Buscopan are each other's closest competitors having multiple indications, including urogenital, which competing products (and in particular Mylan's Duspatalin) do not have.

(197) As to the closeness of competition and specifically the price levels of antispasmodics in Slovakia internal documents of the Parties indicate that NoSpa and Buscopan have a very similar price per pack (just above EUR 4 each). In addition, the main remaining competitor Mylan markets Duspatalin which is reimbursed.

(198) Furthermore, in reaction to the market investigation some market participants raised concerns in view of the fact that the Parties' products are the only antispasmodics in Slovakia available OTC.[115]

(199) In view of the above, the Commission considers that the Transaction gives rise to serious doubts as to its compatibility with the internal market in the market for antispasmodics (A3A) in Slovakia.

Other countries in which (Group 2 and Group 3) affected markets arise

(200) On the basis of the plausible market definitions set out above in paragraph (161), in addition to affected markets described above, the Transaction gives rise to plausibly affected Group 2 and Group 3 markets comprising antispasmodics in the following countries:

i. Bulgaria A3A (irrespective of OTC/Rx status, OTC only)

ii. Italy A3A(irrespective of OTC/Rx status, OTC only)

iii. UK A3A (irrespective of OTC/Rx status, Rx only)

(201) On these markets in some cases the combined market shares of the Parties are high (in Bulgaria reaching [50-60]% for all A3A drugs available OTC or in the UK reaching at maximum [50-60]% for all A3A Rx drugs), but the increment deriving from the Transaction is negligible (at most reaching [0-5]% market share) in all plausible markets. In Italy the combined market share is very high ([80-90]% for all A3A drugs available OTC) but Sanofi's market share is close to [0-5]% and in reality Sanofi's only product on this market has never been marketed by Sanofi in Italy. In all these markets a number of strong competitors are active, with a wide portfolio of products and brands, such as Sopharma or Scharper, Mylan and Menarini (in Bulgaria and Italy) and Mylan, Allergan and Johnson & Johnson in the UK.

(202) Moreover, the market investigation did not reveal any concerns in relation to these markets.[116]

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114 See replies to questions 7, 8 to Questionnaire Q9 to pharmacies in Slovakia.

115 See replies to questions 10 and 11 to Questionnaire Q9 to pharmacies in Slovakia.

(203) 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 the plausible markets referred to in paragraph (200).

IV.3.3.3. Drugs for constipation (A6A)

Product market definition

(204) 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).

(205) In previous cases the Commission considered that all laxatives constitute one relevant market.[117] 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.[118]

(206) 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 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 on the basis of galenic form or the Rx/OTC distinction.[119]

(207) The Notifying Party submits that the relevant market should be defined at ATC4 level and should include OTC products only.

(208) The results of the market investigation do not indicate that the drugs for constipation should be defined by molecule or at the ATC4 level, as drugs with are based on various molecules and belong to various ATC4 levels within the A6A class are being used as alternatives.[120] Some market participants note that certain galenic forms (e.g. suppositories) would be more suitable for certain patients (e.g. children, elderly people) or certain situations (e.g. acute constipation; when immediate effect is required). The Commission considers that these elements would not warrant defining distinct product markets depending on the galenic form or the potential length of treatment, but these elements shall be taken into account in the competitive assessment.

(209) Based on the results of the market investigation for the purpose of the assessment of the present case the Commission considers that the relevant market as regards drugs for constipation should be defined at the ATC3 level (all A6A drugs). The

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116 See in particular Questionnaire Q1 to competitors.

117 COMP/M.3853 Solvay/Fournier of 18 July 2005, paragraphs 16-23.

118 See M.6280 Procter&Gamble/Teva, para 19.

119 See M.7379 Mylan / Abbott EPD-DM, para 203.

120 See replies to question29.1 to Questionnaire Q1 to competitors.

Commission considers that for the purpose of this case the distinction between OTC and prescribed products can be left open, since almost all the products concerned are sold OTC. Similarly, the distinction according to the galenic form (tablets, liquids, suppositories) can be left open. The latter, however, is taken into account in the assessment of closeness of competition between the Parties' products.

Competitive assessment

Czech Republic

(210) On the market for drugs for constipation in Czech Republic the Transaction leads to two Group 1 affected markets: all drugs for constipation irrespective of their OTC/Rx status and all drugs for constipation available OTC. In Czech Republic Sanofi markets Glycerini (based on *glycerol*) in the form of suppositories. BI CHC markets Dulcolax (based on *bicasodyl*, in the form of tablets or suppositories) and Guttalax (*sodium picosulfate*, in the form of tablets or oral liquids). All the Parties' products are sold OTC.

(211) As a result of the Transaction, on the market comprising all drugs for constipation irrespective of their galenic form or Rx/OTC status, the Parties' combined market share in Czech Republic would reach [40-50]% in value (Sanofi [10-20]% and BI CHC [20-30]%) and [40-50]% in volume (Sanofi [20-30]% and BI CHC [20-30]%). The remaining competitors include Stada with the market share of [10-20]% in value and [10-20]% in volume and several suppliers with market shares below [10-20]%: Mylan [5-10]% in value ([5-10]% in volume), Biomedica [5-10]% in value ([5-10]% in volume) and Ferrer, Krka, Valeant, Teva, Novartis – none of them exceeding the market share of [5-10]%. The market share data have remained relatively stable over the last three years. Furthermore, as regards the market comprising drugs for constipation limited to OTC products only, the market shares of the Parties and their competitors are very similar.

(212) The market investigation revealed that BI's Guttalax and Sanofi's Glycerini are both very strong brands in Czech Republic.[121] Both products have very strong brand recognition, efficacy and similar therapeutic indications (acute constipation versus short-term treatment of constipation). The market investigation revealed that in terms of efficacy, only the Parties' products and the products of Stada, based on *bisacodyl* have "high" efficacy, while other products would be considered to be of "medium" efficacy.[122] Another product by Stada, Lactulose Stadax and product offered by Mylan, Duphalac, are both based on a different molecule, *lactulose*. The respondents to the market investigation indicated that *lactulose*-based products seem to be less efficacious, while for example BI CHC's products (based on *bisacodyl* or *picosulfuric acid*) would be more efficacious while used also for chronic constipation.[123]

(213) Furthermore, market participants note that Glycerini offered by Sanofi and Dulcolax by BI CHC, are the only products to treat constipation available in the form of suppositories (topical external form), which would address specific groups of patients (e.g. children or elderly people, persons with sensitive digestive tract or difficulties to

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121 See replies to question 18 to Questionnaire Q4 to pharmacies in Czech Republic.

122 See replies to question 27 to Questionnaire Q1 to competitors.

123 See replies to question 27 to Questionnaire Q1 to competitors.

swallow) and situations (quick action, acute intermittent constipation).[124] As explained in section regarding the product market definition the Commission considers, based on the results of the market investigation, that there is no evidence that the market should be segmented according to the galenic form of products, however the fact that the Parties are the only suppliers of the specific galenic form, in this case suppositories, indicates that at least in this respect the Parties are the closest competitors on the market concerned.

(214) As to competitors' products the market investigation revealed that Stada's product based on *bisacodyl* (Stadalax) tends to be slightly cheaper than the Parties' products but its brand does not enjoy the same level of brand recognition as the Parties' products.[125]

(215) In view of the above, the Commission considers that the Transaction gives rise to serious doubts as to its compatibility with the internal market in the market for drugs for constipation (A6A) in Czech Republic.

Slovakia

(216) As regards drugs for constipation in Slovakia the Transaction leads to one Group 1 affected market, comprising all drugs for constipation available OTC. In Slovakia Sanofi markets Glycerini in the form of suppositories. BI CHC markets Guttalax (based on *sodium picosulphate*, in the form of oral liquid) and Dulcolax (based on *bicasodyl* and *sennoside*, in the form of tablets or suppositories). All the Parties' products are sold OTC.

(217) As a result of the Transaction on the market comprising all drugs for constipation available OTC the Parties' combined market share will reach [40-50]% in value with the increment of [0-5]% brought by Sanofi ([30-40]% in volume, with the increment of [0-5]%). In this market numerous competitors will remain present: Galvex with the market share of [10-20]% in value ([10-20]% in volume), Valeant Pharma with [10-20]% market share in value ([10-20]% in volume), Leros with [0-5]% market share in value, but [10-20]% in volume as well as Krewel, Teva, Mylan and others. Over the last three years Sanofi's market share was stable and remained at the level of [0-5]% while BI CHC's market share increased since 2013 by [5-10] percentage points in value and [0-5] points in volume.

(218) According to market participants Sanofi's Glycerini and BI CHC's Guttalax are both very efficacious, but only Guttalax is a well-known recognised brand in Slovakia. Furthermore, it appears that the Parties' products in Slovakia are not the closest substitutes: Glycerinin seems to compete more with the product of Galves while BI's Dulcolax rather with another *bicasodyl*-based product offered by Krka.[126]

(219) In view of the above, the Commission considers that the Transaction does not give rise to serious doubts as to its compatibility with the internal market on the market for drugs for constipation or any of its plausible segments in Slovakia.

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124 See replied to question 26 to Questionnaire Q1 to competitors.

125 See replies to question 27 to Questionnaire Q1 to competitors.

126 See replies to questions 28 and 29.2 to Questionnaire Q1 to competitors.

Germany

(220) As regards drugs for constipation in Germany, on the basis of the plausible market definitions set out above in paragraph (209), the Transaction does not give rise to a Group 1 affected market in Germany, but only to a Group 3 affected market. On this market Sanofi markets Bisacodyl SNFI, Glycerol SNFI and Laxative SNFI. BI CHC markets Dulcolax, dulcolax M Balance and Guttalax.

(221) As the result of the Transaction the combined market share of the Parties on the market comprising all drugs for constipation in Germany (both OTC and Rx) would reach [20-30] % in value and [10-20]% in volume with a negligible increment brought by Sanofi. The situation is very similar on the market limited to OTC products only.

(222) A Group 1 affected market would arise in Germany only on the following theoretical markets:

i. the market defined at the ATC4 level comprising stimulant laxatives (A6A2 products) with the combined market share of [70-80]% in value and the increment of [0-5]% brought by Sanoif (in volume the combined market share would amount to [40-50]% with the increment of [0-5]%) and

ii. the market defined by molecule for *bicasodyl*-based anti-constipation drugs with the combined market share of [80-90]% with the increment of [0-5]% brough by Sanofi measured by value (in volume the combined market share would amount to [50-60]% with the increment of [5-10]% brought by Sanofi).

(223) The market investigation, however, did not support such a segmentation of the market since market participants indicated that drugs for constipation from various ATC4 classes compete with each other and *bisacodyl*-based drugs can be substituted by other molecules, e.g. *macrogols*, *picosulfuric acid, senna* or *lactulose*.[127]

(224) The results of the market investigation suggest that BI CHC's Dulcolax is among the leading drugs for constipation in Germany; amongst top two pharmacists also mention Movicol (by Norgine), product offered by Ratiopharm or Macrogol Hexam; Sanofi's products do not seem to be perceived as very strong in Germany ("*very low brand recognition*"). None of the respondents to the market investigation expects that the Transaction would have any impact on the market for drugs for constipation in Germany.[128]

(225) In view of the above, the Commission considers that the Transaction does not give rise to serious doubts as to its compatibility with the internal market on the market for drugs for constipation or any of its plausible segments in Germany.

Hungary

(226) As regards drugs for constipation in Hungary, on the basis of the plausible market definitions set out above in paragraph (209), the Transaction does not give rise to a Group 1 affected market in Hungary, but only to a Group 3 affected market. On this

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127 See replies to questions 44 and 46 of Questionnaire Q1 to competitors.

128 See replies to questions 8-11 of Questionnaire Q13 to pharmacists in Germany.

market Sanofi markets Codylax and BI CHC markets Dulcolax and Guttalax. All the Parties' products are sold OTC.

(227) A Group 1 affected market would arise in Hungary only on the following theoretical markets:

i. the market defined at the ATC4 level comprising stimulant laxatives (A6A2 products) with the combined market share of [50-60]% and the increment of [0-5]% coming from Sanofi (measured by value), and

ii. the market defined by molecule for *bicasodyl*-based anti-constipation drugs with the combined market share of [40-50]% and the increment of [0-5]% brought by Sanofi.

(228) The market investigation, however, did not support such a segmentation of the market since market participants indicated that drugs for constipation from various ATC4 classes compete with each other and *bisacodyl*-based drugs can be substituted by other molecules, e.g. *macrogols*, *picosulfuric acid*, *senna* or *lactulose*.[129]

(229) Thus, as a result of the Transaction, on the market for drugs for constipation as defined in paragraph (209) above irrespective of galenic form or OTC/Rx distinction the combined market share of the Parties is moderate and amounts to [30-40]% with the increment of [0-5]% coming from Sanofi. Market shares measured by volume as well as market shares for the market comprising OTC products only are at very similar level. Main competitors include Teva with market share exceeding [30-40]%, Fresenius with approximately [10-50]% share and Valeant Pharma with [5-10]% market share.

(230) In view of the above, the Commission considers that the Transaction does not give rise to serious doubts as to its compatibility with the internal market on the market for drugs for constipation or any of its plausible segments in Hungary.

Other countries in which (Group 2 and Group 3) affected markets arise

(231) On the basis of the plausible market definitions set out above in paragraph (209), the Transaction does not give rise to any additional affected markets which would fall into Group 2 or Group 3 category. In addition to the affected markets assessed above, overlaps arise in Belgium, France, Italy and the Netherlands, however, none of them leading to an affected market.

IV.3.4. CARDIAC STIMULANTS AND VARICOSE THERAPIES

IV.3.4.1.a. Cardiac stimulants excluding cardiac glycosides (C1C)

Product market definition

(232) Sanofi markets a large number of cardiac stimulants (ATC3 class C1C), which are used to treat hypotension in the EEA. Within the ATC3 class C1C, Sanofi markets Arterenol (norepinephrine), Suprarenin (epinephrine), Heptamyl (heptaminol) and

129 See replies to questions 44 and 46 of Questionnaire Q1 to competitors.

Phenylephrine SNFI (phenylephrine) used in the treatment of low blood pressure and orthostatic hypotension. BI CHC markets Effortril (etilefrine) and Effortril Plus (dihydroergotamine etilefrine). Effortril, Phenylephrine SNFI, Heptamyl are marketed as OTC in some countries and Rx in others. Arterenol and Suprarenin are marketed as Rx product in all countries.

(233) The ATC3 class C1C is further subdivided into two ATC4 classes as follows: C1C1 (Cardiac stimulants excluding dopaminergic agents) and C1C2 (Cardiac dopaminergic agents).

(234) In previous decisions, the Commission contemplated a market definition at ATC 3 level and left the product market definition open.[130] The distinction between OTC and prescription products has not yet been considered by the Commission specifically in relation to the ATC3 class C1C.

(235) The results of the market investigation indicate that it may be appropriate to define the relevant market at ATC 3 level C1C. In particular, the pharmacies confirmed that there are no specific circumstances where they will recommend specifically cardiac stimulants which belong to ATC 4 class C1C1 (products which do not contain dopaminergic agents) for the treatment of orthostatic low blood pressure.[131]

(236) In addition, in line with what was explained for most product markets for medicines as explained above in paragraphs (14) and (15), market participants, including key opinion leaders confirmed that within the ATC 3 class C1C, OTC and prescription products are not substitutable since they are intended for different patient needs. Prescribed products in this area are used in hospitals, including during surgery and re-animation, whereas OTC products, such as Effortil (in drop forms and in the formulation available OTC), are used to counter low blood pressure, in otherwise healthy patients, and are recommend for example for tourists that expose themselves to unsual heat or sun[132]. This implies that Rx and OTC products do not compete.[133]

(237) In view of the above, the Commission considers, for the purposes of the Decision, that there is a relevant market that is at most as wide as ATC 3 level C1C cardiac stimulants excluding glycosides segmented into Rx and OTC markets. In addition, for completeness the Commission will also analyse plausible further segmentations within these markets based on a galenic form. In any event, the precise product market definition relating to ATC 3 level C1C cardiac stimulants excluding glycosides can be left open for the purposes of the Decision, as no serious doubts as to the compatibility of the Transaction with the internal market arise under any plausible market definition in this area.

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130 See M.5253, Sanofi-Aventis/Zentiva, M.3354, Sanofi-Synthelabo/Aventis.

131 See replies to question 20 of Questionnaire Q 3 to pharmacies in France.

132 http://effortil.de/NuetzlicheTipps/Reisezeit/

133 See replies to questions 4 and 5 of Questionnaire Q14 to pharmacies in in Austria and non-confidential e-mails from KOLs received on 22 and 23 June 2016.

Competitive assessment

(238) The Transaction leads to Group 1 affected markets in cardiac stimulants in Austria and in France.[134]

Austria

(239) In Austria, Sanofi markets Suprarenin and Arterenol Rx only. BI markets Effortril Rx and OTC.

(240) The Parties' combined market share for prescription products in volume is [40-50]% with an increment of [10-20]% which has decreased substantially in the past three years. In value, the Parties' combined market share would reach only [5-10]% indicating Parties' products are cheaper than competitors'.

(241) The Transaction does not lead to an overlap regarding the OTC products because only one of them, Effortril, is available OTC, whereas all other products are sold only under prescription.

(242) If the market were further segmented based on a galenic form, the Parties combined market share would be [90-100]% in volume with an increment of [0-5]% regarding the oral liquid ordinary form.

(243) The market investigation revealed, however, that even though the Parties' products are both cardiac stimulants and belong to the same ATC3 class, they do not compete closely, if at all, as they have different indications and are used in different circumstances. Suprarenin and Arterenol commercialised by Sanofi are used for re-animation and in emergency medicine (this also being the reason for them to sold on prescription only), whereas Effortil is used to counter low blood pressure, including for example when tourists are exposed to unusual heat in tropical countries.[135] Indeed, no respondent to the market investigation indicated Suprarenin or Arterenol as an alternative to Effortil.[136]

(244) Lastly, the market investigation did not reveal concerns in relation to cardiac stimulants in Austria.[137]

(245) 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 the plausible markets for to cardiac stimulants in Austria of which the Parties' products from part.

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134 IMS reports sale for Heptamyl in the last three years, all market participants confirmed that the product is not available in Belgium and accordingly the Transaction does not lead to an overlap and an affected market in Belgium.

135 Non-confidential minutes of a call with KOL, on 22 June 2016.

136 See replies to question 7 of Questionnaire Q14 to pharmacies in in Austria.

137 See replies to question 10 of Questionnaire Q14 to pharmacies in Austrian and replies to question 156 of Questionnaire Q1 to competitors, as well as non-mails from KOLs received on 22 and 23 June 2016.

France

(246) In France, Sanofi markets Heptamyl, available OTC, whereas BI markets Effortil available OTC and Rx. Accordingly, the Transaction leads to a horizontal overlap at OTC level only. On this plausible Group 2 affected markets, the Parties' combined market share is [40-50]% with an increment of [0-5]% in value and [80-90]% with an increment of [0-5]% in volume.

(247) If the market is further segmented per galenic form, the Parties' combined market share results into Group 1 market only regarding the oral solid ordinary form, where the Parties combined market share is [70-80]% in volume with an increment of [0-5]%. The market share has been stable in the last three years. Sanofi's main competitors appear to be 3 Chenes ([5-10]%) and Meda ([0-5]%). In addition, there are at least 6 companies having a market share higher than the increment.

(248) The market investigation confirmed that Heptamyl of Sanofi has strong brand recognition, whereas Effortil is not a very well-known brand in France. Market participants indicated that the closest competitor of Sanofi on this market is Meda commercialising Carlyten.[138]

(249) Finally, the market investigation did not reveal any concerns in relation to cardiac stimulants in France.[139]

(250) 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 the plausible markets for to cardiac stimulants in France of which the Parties' products from part.

IV.3.4.1.b. Topical varicose therapies (ATC 3 class C5B) and systemic varicose therapies (ATC 3 class C5C)

ATC 3 class C5B

(251) As a topical treatment (ATC 3 class C5B) Sanofi offers Calciprine (*heparin*) in the form of ampules and syringes, and Pesta (*heparin*) in the form of an ointment, gel and cream. Both products are used to treat deep vein thrombosis. BI CHC offers Antistax (*vitis viniera*) used to treat chronic venous insufficiency in the form of gel and cream.

Product market definition

(252) The Commission has previously analysed the market for topical varicose therapy at ATC 3 level C5B and considered a segmentation of the market into OTC and Rx segments.[140]

(253) In any event, the definition of the relevant product market in relation to treatments belonging to ATC class C5B can be left open as the Transaction does not give rise to

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138 See replies to question 17 of Questionnaire Q3 to pharmacies in France, replies to question 167 of Questionnaire Q1 to competitors.

139 See replies to question 22 pharmacies in France, and replies to question 168 of Questionnaire Q1 to competitors.

140 See M.3354 Sanofi-Synthelabo/Aventis, para 77.

serious doubts as to its compatibility with the internal market under any of the plausible product market definitions in this area.

Competitive assessment

(254) The Transaction does not lead to a Group 1 affected market. The only plausible affected market is a Group 3 market in Germany (C5B OTC, or OTC+Rx) where the combined share of the Parties is [20-30]% with an increment of [0-5]%. The main competitors include Novartis with a [20-30]% market share and Teva with [20-30]% for the overall C5B market measured by value.

(255) Given the moderate combined market shares in these markets, the small increment and the presence of significant competitors, the Commission considers that the Transaction does not give rise to serious doubts as to its compatibility with the internal market in any plausible market for topical varicose therapy in Germany of which the Parties' products form part.

ATC 3 class C5C

Product market definition

(256) The Commission has previously assessed the systemic varicose therapy at ATC 3 level C5C and at molecule level, where it found a separate market for products based on *troxerutin*.[141]

(257) The market investigation did not support a narrower product market definition in this case for *vitis viniera* extract. Pharmacies indicated that *diosmine* based products and *ginkgo biloba* based products have the same indication as *vitis viniera* based product as regards blood circulation.[142] The Commission therefore concludes that the market should not be further analysed based on this segmentation.

(258) Beyond that, the definition of the relevant product market in relation to treatments belonging to ATC class C5C can be left open as the Transaction does not give rise to serious doubts as to its compatibility with the internal market under any of the plausible product market definitions in this area.

Competitive assessment

(259) The Transaction would lead to Group 1 affected market in the Czech Republic and in Slovakia if the market were segmented into an OTC and Rx part.

(260) In both countries, the Parties would attain a relatively high market share ([50-60]% in Slovakia and [30-40]% in the Czech Republic by value), but the increment is negligible (practically [0-5]% in both Member States), and there are several significant competitors active in both markets, including Teva and Novartis.

(261) Given the minuscule increment, and the presence of significant competitors, the Commission considers that the Transaction does not give rise to serious doubts as to

141 See M.5865 Teva/Ratiopharm para 383.

142 See reply to questions 23, 24, 25 questionnaire to Pharmacies (France).

its compatibility with the internal market in any plausible market for systemic varicose therapy in the Czech Republic or Slovakia of which the Parties' products form part.

VITAMINS

IV.3.4.1.c. Multivitamins with minerals (A11A) and 04A

(262) The Transaction leads to a horizontal overlap in the area of multi-vitamin products where Sanofi markets large array of multivitamins under the brand name of Calibrum and BI markets Pharmaton.

Product market definition

(263) The Commission has previously analysed a market for multi-vitamins at ATC 3 A11A (multi-vitamins with minerals) and A11B (multi-vitamins without minerals). Each of these classes is further subdivided in several ATC 4 classes.

(264) The Commission previously assessed the product market based on ATC 3 and ATC 4 level, but also on the basis of OTC 2 and OTC 3 level. The Commission has further considered segmentation based on the galenic form of the multi-vitamins.[143]

(265) In the case at hand, the Commission tested in the market investigation the degree of competition between multi-vitamins on one hand and a mono vitamin and minerals on the other containing the same active ingredient. In particular, the Commission tested whether Pharmaton of BI competes with the following mono-vitamins and minerals offered by Sanofi: Ascorbic acid, calcium, vitamin B12 (cyanocobalamin), vitamins A and D (ergocalciferol), iron ferrous, magnesium.

(266) Both customers and competitors confirmed that the market should not be defined based on this criteria due to lack of demand side substitutability. Neither customer nor competitors consider that multi-vitamins compete with a mono-vitamin or minerals.[144] The Commission therefore concludes that the market should not be further analysed based on this segmentation.

(267) Beyond that, the definition of the relevant product market in relation to multivitamins can be left open as the Transaction does not give rise to serious doubts as to its compatibility with the internal market under any of the plausible product market definitions in this area.

Competitive assessment

(268) The Transaction leads to Group 3 affected markets at OTC 2 level 04A and OTC 3 level 04A1, further narrowed down by the galenic form segmentation. The Group 3 countries are Spain ([30-40]% with an increment of [0-5]%) at OTC 3 04A1 Caps/Tabs and Slovakia ([20-30]% with an increment of [0-5]%) at OTC 2 04A Caps/Tabs.

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143 See M.6162 Pfizer/Ferrosan Cunsumer –Healthcare Business, paras 13-14.

144 See replies to questions 53, 60, 62 of Competitors' questionnaire and pharmacies questionnaire for Czech Republic and Slovakia (questions 23, 24, 25 26), France (questions 3, 5) and Poland and Ireland.

(269) Given the moderate combined market shares and the small increment, the Commission considers that the Transaction does not give rise to serious doubts as to its compatibility with the internal market in any plausible market for multivitamins therapy in Spain and Slovakia of which the Parties' products form part.

OTHER THERAPEUTIC AREAS IN WHICH THE PARTIES' ACTIVIES GIVE RISE TO POTENTIALLY AFFECTED MARKETS

Wound Healing agents (D3A)

(270) The Commission has previously assessed wound healing agents products at the ATC3 level (D3A).[145] No additional alternative market definitions, in particular as regards the galenic form, were contemplated in the Commission's previous decisions.

(271) In any event, the definition of the relevant product market can be left open for the purposes of the Decision as the Transaction does not raise serious doubts as to its compatibility with the internal market under any of the plausible product market definition considered in the preceding paragraph, given that the only affected market would arise if the market were segmented by galenic form is in France (ointments), where the Parties would attain a combined market share of [20-30]%, with an increment of [0-5]%.

*Benign prostatic hypertrophy products (*G4C)

(272) In the ATC3 class G4C, the Commission has previously assessed benign prostatic hypertrophy products at a molecule level, for pygeum africanum-based products[146] and tamsolusin-based products,[147] and sometimes at a wider level – ATC3 or ATC4 level.[148]As regards OTC and prescription drugs, the Commission considered that they belong to separate markets.[149]

(273) In any event, the definition of the relevant product market in relation to benign prostatic hypertrophy products can be left open as the Transaction does not give rise to serious doubts as to its compatibility with the internal market under any of the plausible product market definitions in this area.

(274) An affected Group 3 market arises in UK on the hypothetical market based on ATC4 class G4C2 OTC+Rx segmentation. On this market, the combined market share of the Parties is moderate ([20-30]% in value and [10-20]% in volume). Moreover, the increment of BI is [0-5]% in volume, and very low in value ([0-5]%).

(275) In view of the above, the Commission considers that the Transaction does not give rise to serious doubts as to its compatibility with the internal market in any plausible

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145 See M.3354 Sanofi-Synthelabo/Aventis, para 23 and Case M.457 – La Roche/Syntex, para 35.

146 See M.7379 Mylan/Abbott, paras 430-432.

147 See M.6613 Watson/Actavis, para 19.

148 See M.5865 Teva/Ratiopharm, para 136.

149 See M.5253 Sanofi-Aventis/Zentiva, para 120.

market for benign prostatic hypertrophy products in the UK of which the Parties' products form part.

Anti-migraine preparations (N2C)

(276) The Commission has previously assessed the anti-migraine preparations at both ATC3 level (N2C) and a broad market based on ICD code 346[150] which included medicines such as non-narcotic analgesics, narcotic analgesics, antiemetics. The Commission further considered segmentation between OTC and prescription products.[151] A distinction based on galenic form does not seem relevant, as most of the products classified in ATC3 class N2C are marketed in oral solid ordinary form.

(277) In any event, the definition of the relevant product market in relation to anti-migraine preparations products can be left open as the Transaction does not give rise to serious doubts as to its compatibility with the internal market under any of the plausible product market definitions in this area.

(278) A plausibly affected Group 3 market arises in Germany on the hypothetical market based on ATC3 class N2C prescription and OTC. On this market, the increment of Sanofi is at most [0-5]% both in value and volume, and the combined market share of the Parties is moderate ([30-40]% in volume, [10-20]% in value). Moreover, at least 3 main competitors remain on this plausible market such as Johnson & Johnson, GSK and Novartis.

(279) As a result of the above, the Commission considers that the Transaction does not give rise to serious doubts as to its compatibility with the internal market in any plausible market for anti-migraine preparations in Germany of which the Parties' products form part.

IV.4. Active pharmaceutical ingredients

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

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

(282) With respect to the horizontal analysis, there are no overlaps between the Parties' activities. BI CHC is not active in this segment,[152] and Sanofi a comparatively minor player […].

(283) In addition, there are no actual vertical relationships between Sanofi and BI CHC since none of the APIs manufactured by Sanofi is used by BI CHC in the downstream FDPs, and vice versa. The transaction however gives rise to four potential vertical

150 See M.555 Glaxo/Wellcome, para 24.

151 See M.555 Glaxo/Wellcome, para 8.

152 BI has some very limited activities, with total sales of below EUR […] million in 2015.

links due to the upstream API manufacturing by Sanofi and downstream activities of BI CHC in FDPs.

(284) Of those potential vertical links, two result in potentially affected markets.

(285) First, in the upstream API market for codeine Sanofi has a market share of approximately [20-30]%, and BI CHC a market share of approximately [30-40]% (volume and value) on the downstream R5D OTC market in Norway. However, in view of the fact that there more than 10 codeine manufacturers active on the upstream market (including 7 suppliers in the EEA), and the limited market shares of Sanofi, input foreclosure could not be successfully implemented by the Parties. In the same vein, customer foreclosure is not conceivable given BI CHC's limited share in the overall demand for codeine.

(286) Second, in the upstream API market for metamizole sodium, Sanofi has a market share of approximately [5-10]%, and BI CHC a market share of approximately [30-40]% (volume and value) on the downstream A3D Rx market in Spain. However, in view of the fact that there at least for metamizole sodium active on the upstream market (including two other suppliers in the EEA), and the limited market shares of Sanofi, input foreclosure is unlikely to be successfully implemented by the Parties. Customer foreclosure, on the other hand is not conceivable given BI CHC's limited share in the overall demand for metamizole sodium (less than [0-5]%).

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

IV.5. Outlicensing

(288) Outlicensing in the pharmaceutical industry refers to a licensor licensing to a licensee rights to use a dossier to obtain a marketing authorisation for a product in one or more countries. 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 [20-30]%.

(289) Based on the preceding paragraph, the Transaction results in two affected markets, in Belgium and the Netherlands.

(290) As for Belgium, the outlicensing agreement with respect to […] and therefore will not be discussed further in the Decision.[153]

(291) In the Netherlands, the Parties' and licensee's combined market share in the markets for R5D (dry cough) (both OTC and Rx) amount to at most [20-30]% (the Parties combined market share representing less than [5-10]%). In addition, there are four sizable competitors active on this market, with market shares between 10 and 20%.

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

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153 See […]

V. PROPOSED COMMITMENTS

(293) In order to render the concentration compatible with the internal market, the Parties have modified the notified concentration by entering into the following commitments ("the Commitments"), which the Notifying Party submitted on 13 July 2016. The final version of the Commitments including the adaptations made following the results of the market test was submitted on 27 July 2016. These Committments are annexed to this Decision and form an integral part thereof.

Description of the Commitments

(294) The Notifying Party offered to divest the local business on the product markets where serious doubts were identified following the phase I market investigation to one or more suitable third party purchasers ("the Purchasers").

(295) The businesses to be divested (hereafter referred to as "the Divestment Businesses") include the following businesses of Sanofi and BI CHC:

- Sanofi's Suppositoria Glycerini in the Czech Republic
- Sanofi's Mucothiol in Greece
- Sanofi's Mucodyne in Ireland
- BI's Prontalgine in France
- BI's Buscopan in the Czech Republic, Estonia, Hungary, Latvia, Poland and Slovakia.

(296) The Divestment Businesses are structured as an asset carve-out; no legal entity is to be divested. Specifically, the businesses to be divested include all assets and staff that contribute to the current operation or are necessary to ensure the viability and competitiveness of the Divestment Businesses:

- all tangible and intangible assets (including a royalty free license for all relevant intellectual property rights) including notably a full transfer of the brands in the relevant countries;
- all licenses, permits and authorisations issued by any governmental organisation for the benefit of the Divestment Businesses, in particular the transfer of the marketing authorisation in the relevant countries;
- all contracts, leases, commitments (including on the supply of raw materials and distribution) and customer orders of the Divestment Businesses; all customer credit and other records of the Divestment Businesses;
- at the option of the Purchaser, the Personnel, including notably key personnel for the marketing of the products/brands;
- the benefit for a period of up to 2 years after Closing (extendable twice by one year), on a reasonable cost basis, of a transitory non-exclusive manufacturing and/or supply agreement relating to the existing forms of

product in the country of the Divestment Businesses, and/or reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of the relevant Divestiture Business, as detailed in the Schedules;

- the benefit of a transitional distribution arrangement related to the Divestment Business lasting until the relevant marketing authorisation is transferred into the name of the Purchaser on a reasonable cost-plus basis which determination is overseen by the Monitoring Trustee.

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

(298) The Commitments also include specific Purchaser requirements in particular the need for the Purchaser(s) to be an established (OTC) pharmaceutical products supplier and to have an existing footprint in the relevant countries.

VI. ASSESSMENT OF THE PROPOSED COMMITMENTS

(299) The Commission analysed the suitability of the Commitments to remedy the serious doubts that arise as a result of the Transaction against the standards set out in the Commission Notice on Remedies.[154]

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

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

(301) As set out in the Commission Notice on Remedies, commitments have to eliminate the Commission's serious doubts entirely, they have to be comprehensive and effective from all points of view and they must be capable of being implemented effectively within a short period of time, as the conditions of competition on the market will not be maintained until the commitments have been fulfilled.[155]

(302) In assessing whether or not commitments will restore effective competition, the Commission considers their type, scale and scope by reference to the structure and the particular characteristics of the market in which the Commission has identified serious doubts as to the compatibility of the notified concentration with the internal market.[156]

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

155 Commission Notice on Remedies, paragraph 9.

156 Commission Notice on Remedies, paragraph 12.

(303) Divestiture commitments are the best way to eliminate serious doubts resulting from horizontal overlaps of the merging parties' activities.[157] Other commitments (such as licensing) may be suitable to resolve serious doubts if those commitments are equivalent to divestitures in their effects. The divested activities must consist of a 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.[158]

(304) The business to be divested must include all the assets which contribute to its current operation or which are necessary to ensure its viability and competitiveness and all personnel which are currently employed or which are necessary to ensure the business' viability and competitiveness. Personnel and assets which are currently shared between the business to be divested and other businesses of the parties, but which contribute to the operation of the business or which are necessary to ensure its viability and competitiveness, must also be included.[159] Otherwise, the viability and competitiveness of the business to be divested would be endangered.

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

(306) Even though normally the divestiture of an existing viable stand-alone business is required, the Commission, taking into account the principle of proportionality, may also consider the divestiture of businesses which have existing strong links or are partially integrated with businesses retained by the parties and therefore need to be 'carved out' in those respects.[160] Commitments including a carve-out of a business can only be accepted by the Commission if it can be certain that, at least at the time when the business is transferred to the purchaser, a viable business on a stand-alone basis will be divested and the risks for the viability and competitiveness caused by the carve-out will thereby be reduced to a minimum.[161]

VI.1.1. Scope of the Commitments

(307) In order to assess the suitability of the Commitments to remove serious doubts in this case, the Commission launched a market test on 14 July 2016.

(308) The market test of the Commitments, which was addressed to competitors, was generally positive and confirmed that the Commitments are suitable to eliminate the competition concerns identified by the Commission. In particular, almost all respondents considered that, subject to them being divested to suitable Purchasers, the Divestment Businesses include all the necessary assets to successfully market the products in the markets where the Commission identified competition concerns and to

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157 Commission Notice on Remedies, paragraph 17.

158 Commission Notice on Remedies, paragraph 23.

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

160 Commission Notice on Remedies, paragraph 35

161 Commission Notice on Remedies, paragraph 36

subsequently compete effectively with the merged entity on these markets.[162] Specifically regarding the brands included in the Divestment Businesses, an overwhelming majority of respondents consider that the brands included in the portfolio are sufficient to remove the overlaps for the markets for which the Commission raises serious doubts.[163]

(309) Responses to the market test emphasise the importance of a Purchaser being able to hire personnel having expertise and knowledge about the characteristic of the brand and the market in a given country. This possibility is included in the Commitments for all the Divestment Businesses.[164]

VI.1.2. Viability and likelihood of effectiveness of the Commitments in practice

(310) The results of the market test of the Commitments indicate that the Divestment Businesses will be viable and competitive, so that Purchaser can compete effectively with the merged entity on a lasting basis.[165] Nevertheless, some respondents suggested that only an established player in the OTC pharmaceuticals field having the necessary geographic footprint can operate the Divestment Business in a viable and competitive manner.[166] This observation is further analysed in the Purchaser's criteria section.

VI.1.3. Ability of the Commitments to be implemented in practice

(311) A vast majority of the respondents to the market test confirmed that the Commitments do not entail specific implementation risk. Nevertheless, some of them pointed out that transitional supply agreements should cover the entire duration for obtaining all regulatory requirements and performing technical adaptations; this period may exceptionally be longer than 2 years, accordingly the agreement should be extendable.[167]

(312) Sanofi has revised the Commitments on this point, the final version of which entails the possibility to prolong these supply agreements by one year, up to a maximum of another two years in total.

VI.2. Purchaser criteria

(313) Besides the standard criteria for a suitable purchaser contained in section D of the Commitments, the results of the market test indicate the need for a suitable Purchaser to be an established OTC branded products supplier in order to be an effective competitor of Sanofi/BI CHC in the relevant markets.[168] The purchaser should also have an established footprint in the relevant countries.[169]

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162 See replies to question 2 of Questionnaire R1

163 See replies to question 3 of Questionnaire R1

164 See replies to question 4 of Questionnaire R1

165 See replies to question 5 of Questionnaire R1

166 See replies to question 5 of Questionnaire R1

167 See replies to questions 7, 7.1, 7.2 and 8 of Questionnaire R1

168 See replies to question 9 of Questionnaire R1

169 See replies to question 9 and 11 of Questionnaire R1

(314) This is because, according to the results of the market test companies marketing OTC pharmaceutical products tend to compete using their entire portfolio rather than on a single product basis. In addition, there are economies of scale associated with the entire 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.[170] For example a competitor emphasised that *"Market entry of a new player is risky and would need a very high investment."*[171]

(315) In addition, the respondents to the market test almost unanimously confirmed that a suitable Purchaser needs to have an existing distribution and sales footprint in the affected markets in order to guarantee a successful and prompt commercialisation of the divested products. [172] For example one competitor pointed out that *"If the purchaser is not active in any of the concerned countries, the sales of the divested brand will be stopped in that country, i.e. the purchase will lead to a deterioration of the divested brand."*[173]

(316) On the other hand, the market test confirmed that it is not particularly important that Purchaser has a presence in the therapeutic area of the individual Divestment Businesses in the relevant countries.[174]

VI.3. Interest in the Commitments

(317) The market test revealed overall that the assets included in the Divestment Businesses are attractive.[175] In addition, a sizable number of potentially suitable Purchasers expressed interest in acquiring the Divestment Businesses as a result of which the Commission concludes that the Commitments are likely to be implemented in practice within a short period of time.

VI.4. Conclusion on the Commitments

(318) The Commitments are suitable and sufficient to remedy the serious doubts raised by the Transaction in relation to the 10 markets where serious doubts were identified, namely: Antispasmodics OTC products (A3A) in the Czech Republic, Estonia, Hungary, Latvia, Poland and Slovakia; Anti-constipation (A6A) in the Czech Republic; Chesty cough (R5C, OTC) in Greece; Chesty cough (R5C, Rx) Ireland; and level 2 non-narcotics and anti-pyretics (OTC) in France.

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170 See replies to question 9.1 and 10 of Questionnaire R1

171 See replies to question 9 of Questionnaire R1

172 See replies to question 11 of Questionnaire R1

173 See replies to question 11.1 of Questionnaire R1

174 See replies to question 12 of Questionnaire R1

175 See replies to question 14 of Questionnaire R1

(319) This is because on the basis of the results of the market test, 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.

(320) Moreover, the results of market test indicate that the Commitments are comprehensive and effective from all points of view, and are capable of being implemented effectively within a short period of time.

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

VII. CONDITIONS AND OBLIGATIONS

(322) 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.

(323) 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.

(324) 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.

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

VIII. CONCLUSION

(326) For the above reasons, the Commission has decided not to oppose the notified operation as modified by the Commitments and to declare it compatible with the internal market and with the functioning of the EEA Agreement, subject to full compliance with the conditions in Sections B (including the Schedules) of the Commitments annexed to the present Decision and with the obligations contained in the other sections of the 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)
Vera JOUROVÁ
Member of the Commission

Case No COMP/M.7919

COMMITMENTS TO THE EUROPEAN COMMISSION PURSUANT TO ARTICLE 8(2) OF REGULATION (EC) NO 139/2004

Sanofi

Boehringer Ingelheim's Consumer Healthcare business

27 July 2016

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CASE NO. COMP/M.7919 – Sanofi / Boehringer Consumer Healthcare Business

Commitments to the European Commission

Pursuant to Article 6(2), of Council Regulation (EC) No. 139/2004 (the "**Merger Regulation**"), Sanofi ("**Sanofi**") hereby enters into the following Commitments (the "**Commitments**") vis-à-vis the European Commission (the "**Commission**") with a view to rendering the acquisition of the Consumer Healthcare business of the Boehringer Ingelheim group of companies ("**BI**"), ("**BI's CHC**", together with Sanofi, the "**Parties**") (the "**CHC Transaction**") compatible with the internal market and the functioning of the EEA Agreement.

This text shall be interpreted in the light of the Commission's decision pursuant to Article 6(1)(b) of the Merger Regulation of the Merger Regulation to declare the CHC Transaction 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 the light of the Merger Regulation, and by reference to the Commission Notice on remedies acceptable under Council Regulation (EC) No 139/2004 and under the Commission Regulation (EC) No 802/2004 (the "**Remedies Notice**").

The Schedules form an integral part of the Commitments.

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 the 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 Businesses as indicated in Section B, paragraph 6 (a), (b) and (c) and described more in detail in the Schedules.

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

Closing Period: the period of **[Confidential]** from the approval of the Purchaser and the terms of sale by the Commission or, if the closing of the CHC Transaction takes place after that period, the period until closing of the CHC Transaction.

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 Businesses: the business or businesses as defined in Section B, paragraph 5, and in the Schedules which Sanofi commits to divest.

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

Effective Date: the date of adoption of the Decision.

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

Hold Separate Manager(s): one or several persons appointed by Sanofi for the Divestment Businesses to manage the day-to-day business under the supervision of the Monitoring Trustee.

Key Personnel: all personnel necessary to maintain the viability and competitiveness of the Divestment Businesses, as listed in the Schedules, including the Hold Separate Manager(s), as identified upon consultation of the Monitoring Trustee.

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

Parties: Sanofi and BI

Personnel: all staff currently employed by the Divestment Businesses, including brand and marketing managers and staff seconded to the Divestment Businesses, shared personnel as well as the additional personnel listed in the Schedules.

Purchaser: the entity approved by the Commission as acquirer of all or part of the Divestment Businesses 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.

Schedules: the schedules to these Commitments describing more in detail the Divestment Businesses.

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

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

Section B. The commitment to divest and the Divestment Businesses

Commitment to divest

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

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

(a) by the end of the Trustee Divestiture Period, Sanofi or the Divesture Trustee has entered into one or more final binding sale and purchase agreements and the Commission approves the proposed Purchaser(s) and the terms of sale as being consistent with the Commitments in accordance with the procedure described in paragraph 17;

(b) if the Closing of the sale of the Divesture Business to the Purchasers takes place within the Closing Period; and

(c) transitional agreements (if applicable) have been completed.

4. In order to maintain the structural effect of the Commitments, Sanofi shall, for a period of 10 years after Closing, not acquire, whether directly or indirectly, the possibility of exercising influence (as defined in paragraph 43 of the Remedies Notice, footnote 3) over the whole or part of the Divestment Businesses, unless, following the submission of a reasoned request from Sanofi showing good cause and accompanied by a report from the Monitoring Trustee (as provided in paragraph 42 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 Businesses is no longer necessary to render the proposed concentration compatible with the internal market.

Structure and definition of the Divestment Businesses

5. The Divestment Businesses consists of the following businesses:

- Sanofi's Suppositoria Glycerini business in Czech Republic;
- Sanofi's Mucothiol business in Greece;
- Sanofi's Mucodyne business in Ireland;
- BI's Prontalgine business in France;
- BI's Buscopan in business in Czech Republic;
- BI's Buscopan in business in Estonia;
- BI's Buscopan in business in Hungary;
- BI's Buscopan in business in Latvia;
- BI's Buscopan in business in Poland; and
- BI's Buscopan in business in Slovakia;

hereafter referred to as the "Divestment Businesses".

6. The legal and functional structure of the Divestment Businesses as operated to date is described in the Schedules. The Divestment Businesses, described in more detail in the Schedules, includes all assets and staff that contribute to the current operation or are necessary to ensure the viability and competitiveness of the Divestment Businesses, in particular:

(a) all tangible and intangible assets (including intellectual property rights);

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

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

(d) the Personnel.

7. In addition, the transaction relating to the divestment of the Divestment Businesses will include the benefit, for a transitional period of up to two years after Closing of transitory agreements, as detailed in the Schedules, unless otherwise agreed with the Purchaser. Such transitory agreement could be extended for two additional periods of one year, as reasonably

justified by the Purchaser under the oversight of Monitoring Trustee. Strict firewall procedures will be adopted so as to ensure that any competitively sensitive information related to, or arising from such supply arrangements (for example, product roadmaps) will not be shared with, or passed on to, anyone outside the identified Sanofi's teams.

Section C. Related Commitments

Preservation of viability, marketability and competitiveness

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

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

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

(c) to take all reasonable steps, or procure that all reasonable steps are being taken, including appropriate incentive schemes (based on industry practice), to encourage all Key Personnel to remain with the Divestment Businesses, and not to solicit or move any Personnel to Sanofi remaining business. Where, nevertheless, individual members of the Key Personnel exceptionally leave the Divestment Businesses, Sanofi shall provide a reasoned proposal to replace the person or persons concerned to the Commission and the Monitoring Trustee. Sanofi must be able to demonstrate to the Commission that the replacement is well suited to carry out the functions exercised by those individual members of the Key Personnel. The replacement shall take place under the supervision of the Monitoring Trustee, who shall report to the Commission.

Hold-separate obligations

9. Sanofi commits, from the Effective Date until Closing regarding the Divestment Businesses which are owned by Sanofi, or from the date of the closing of the CHC Transaction until Closing regarding Divestment Businesses which are owned by BI, to keep the Divestment Businesses separate from the businesses it is retaining and to ensure that unless explicitly permitted under these Commitments:

(a) management and staff of the businesses retained by Sanofi have no involvement in the Divestment Businesses;

(b) the Key Personnel and Personnel of the Divestment Businesses have no involvement in any business retained by Sanofi and do not report to any individual outside the Divestment Businesses.

10. Until Closing, Sanofi shall assist the Monitoring Trustee in ensuring that each of the Divestment Businesses is managed as a distinct and saleable entity separate from the businesses which Sanofi is retaining. Immediately after the adoption of the Decision, Sanofi shall, upon consultation of the Commission and the Monitoring Trustee, appoint one or several Hold Separate Manager(s). The Hold Separate Manager(s) shall manage each of the Divestment Businesses independently and in the best interest of the business with a view to

ensuring its continued economic viability, marketability and competitiveness and its independence from the businesses retained by Sanofi. The Hold Separate Manager(s) shall closely cooperate with and report to the Monitoring Trustee and, if applicable, the Divestiture Trustee. Any replacement of the Hold Separate Manager(s) shall be subject to the procedure laid down in paragraph 8(c) of these Commitments. The Commission may, after having heard Sanofi, require Sanofi to replace the Hold Separate Manager(s).

Ring-fencing

11. Sanofi shall implement, or procure to implement, all necessary measures to ensure that it does not, after the Effective Date until Closing regarding the Divestment Businesses which are owned by Sanofi, or after the date of the closing of the CHC Transaction until Closing regarding the Divestment Businesses which are owned by BI, obtain any Confidential Information relating to the Divestment Businesses and that any such Confidential Information obtained by Sanofi before the Effective Date will be eliminated and not be used by Sanofi. In particular, the participation of the Divestment Businesses in any central information technology network shall be severed to the extent possible, without compromising the viability of the Divestment Businesses. Sanofi may obtain or keep information relating to the Divestment Businesses which is reasonably necessary for the divestiture of the Divestment Businesses or the disclosure of which to Sanofi is required by law.

Non-solicitation clause

12. The Parties undertake, subject to customary limitations, not to solicit, and to procure that Affiliated Undertakings do not solicit, the Key Personnel transferred with the Divestment Businesses for a period of two years after Closing.

Due diligence

13. In order to enable potential Purchasers to carry out a reasonable due diligence of the Divestment Businesses, Sanofi shall, subject to customary confidentiality assurances and dependent on the stage of the divestiture process:

(a) provide to potential purchasers sufficient information as regards the Divestment Businesses;

(b) provide to potential purchasers sufficient information relating to the Personnel and allow them reasonable access to the Personnel.

Reporting

14. Sanofi shall submit written reports in English on potential Purchasers of the Divestment Businesses and developments in the negotiations with such potential Purchasers to the Commission and the Monitoring Trustee no later than 10 business days after the end of every month following the Effective Date (or otherwise at the Commission's request). Sanofi shall submit a list of all potential Purchasers having expressed interest in acquiring the Divestment Businesses to the Commission at each and every stage of the divestiture process, as well as a copy of all the offers made by potential Purchasers within five days of their receipt.

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

Section D. The Purchaser

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

(a) The Purchaser(s) shall be independent of and unconnected to Sanofi and its/their Affiliated Undertakings (this being assessed having regard to the situation following the divestiture).

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

(c) The acquisition of the Divestment Businesses by the Purchaser(s) 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(s) must reasonably be expected to obtain all necessary approvals from the relevant regulatory authorities for the acquisition of the Divestment Businesses;

(d) The Purchaser(s) shall have existing market presence in the field of branded OTC pharmaceutical products and have a local footprint including sales and distribution network in each country concerned by the Divestment Businesses.

For Mucodyne, the Purchaser shall have existing market presence in the field of pharmaceutical products in Ireland and have a local footprint including sales and distribution network.

17. The final binding sale and purchase agreement (as well as ancillary agreements) relating to the divestment of the Divestment Businesses shall be conditional on the Commission's approval. When Sanofi 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. Sanofi must be able to demonstrate to the Commission that the Purchaser fulfils the Purchaser Criteria and that the Divestment Businesses 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 Businesses 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 Businesses 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 Businesses after the sale, taking account of the proposed purchaser.

Section E. Trustee

I. Appointment procedure

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

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

20. The Trustee shall:

(a) at the time of appointment, be independent of Sanofi and its Affiliated Undertakings;

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

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

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

Proposal by Sanofi

22. No later than two weeks after the Effective Date, Sanofi shall submit the name or names of one or more natural or legal persons whom Sanofi 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, Sanofi shall submit a list of one or more persons whom Sanofi 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 in paragraph 20 and shall include:

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

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

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

Approval or rejection by the Commission

23. The Commission shall have the discretion to approve or reject the proposed Trustee(s) and to approve the proposed mandate subject to any modifications it deems necessary for the Trustee to fulfil its obligations. If only one name is approved, Sanofi 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, Sanofi shall be free to choose the Trustee to be appointed from among the names approved. The Trustee shall be appointed within one week of the Commission's approval, in accordance with the mandate approved by the Commission.

New proposal by the Sanofi

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

Trustee Nominated by the Commission

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

II. Functions of the Trustee

26. The Trustee shall assume its specified duties and obligations in order to ensure compliance with the Commitments. The Commission may, on its own initiative or at the request of the Trustee or Sanofi, give any orders or instructions to the Trustee in order to ensure compliance with the conditions and obligations attached to the Decision.

Duties and obligations of the Monitoring Trustee

27. The monitoring Trustee shall:

(i) propose in its first report to the Commission a detailed work plan describing how it intends to monitor compliance with the obligations and conditions attached to the Decision.

(ii) oversee, in close co-operation with the Hold Separate Manager(s), the on-going management of the Divestment Businesses with a view to ensuring its continued economic viability, marketability and competitiveness and monitor compliance by Sanofi with the conditions and obligations attached to the Decision. To that end the Monitoring Trustee shall:

(a) monitor the preservation of the economic viability, marketability and competitiveness of the Divestment Businesses, and the keeping separate of the Divestment Businesses from the business retained by the Parties, in accordance with paragraphs 8 and 9 of these Commitments;

(b) supervise the management of the Divestment Businesses 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 Sanofi does not after the Effective Date obtain any Confidential Information relating to the Divestment Businesses,

– in particular strive for the severing of the Divestment Businesses' participation in a central information technology network to the extent possible, without compromising the viability of the Divestment Businesses,

– make sure that any Confidential Information relating to the Divestment Businesses obtained by Sanofi before the Effective Date is eliminated and will not be used by Sanofi and

– decide whether such information may be disclosed to or kept by Sanofi as the disclosure is reasonably necessary to allow Sanofi 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 Businesses and Sanofi or Affiliated Undertakings;

(iii) propose to Sanofi such measures as the Monitoring Trustee considers necessary to ensure Sanofi's compliance with the conditions and obligations attached to the Decision, in particular the maintenance of the full economic viability, marketability or competitiveness of the Divestment Businesses, the holding separate of the Divestment Businesses and the non-disclosure of competitively sensitive information;

(iv) 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, potential Purchasers receive sufficient and correct information relating to the Divestment

Businesses and the Personnel in particular by reviewing, if available, the data room documentation, the information memorandum and the due diligence process;, and

(v) 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 Sanofi 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 Businesses 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 Sanofi a non-confidential copy at the same time, if it concludes on reasonable grounds that Sanofi is failing to comply with these Commitments;

(ix) within one week after receipt of the documented proposal referred to in paragraph 17 of these Commitments, submit to the Commission, sending Sanofi a non-confidential copy at the same time, a reasoned opinion as to the suitability and independence of the proposed Purchaser(s) and the viability of the Divestment Businesses after the Sale and as to whether the Divestment Businesses 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 Businesses without one or more Assets or not all of the Personnel affects the viability of the Divestment Businesses after the sale, taking account of the proposed Purchaser(s);

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

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

Duties and obligations of the Divestiture Trustee

29. Within the Trustee Divestiture Period, the Divestiture Trustee shall sell at no minimum price the Divestment Businesses 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 16 and 17 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 Sanofi, subject to Sanofi unconditional obligation to divest at no minimum price in the Trustee Divestiture Period.

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

III. Duties and obligations of the Parties

31. Sanofi shall provide and shall cause its advisors to provide the Trustee with all such co-operation, assistance and information as the Trustee may reasonably require to perform its tasks. The Trustee shall have full and complete access to any of Sanofi's or the Divestment Businesses' books, records, documents, management or other personnel, facilities, sites and technical information necessary for fulfilling its duties under the Commitments and Sanofi and the Divestment Businesses shall provide the Trustee upon request with copies of any document. Sanofi and the Divestment Businesses shall make available to the Trustee one or more offices on their premises and shall be available for meetings in order to provide the Trustee with all information necessary for the performance of its tasks.

32. Sanofi shall provide the Monitoring Trustee with all managerial and administrative support that it may reasonably request on behalf of the management of the Divestment Businesses. This shall include all administrative support functions relating to the Divestment Businesses which are currently carried out at headquarters level. Sanofi shall provide and shall cause its advisors to provide the Monitoring Trustee, on request, with the information submitted to potential Purchasers, in particular give the Monitoring Trustee access to the data room documentation and all other information granted to potential Purchasers in the due diligence procedure. Sanofi shall inform the Monitoring Trustee on possible Purchasers, submit lists of potential Purchasers at each stage of the selection process, including the offers made by potential Purchasers at those stages, and keep the Monitoring Trustee informed of all developments in the divestiture process.

33. Sanofi 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, Sanofi shall cause the documents required for effecting the sale and the Closing to be duly executed.

34. Sanofi shall indemnify the Trustee and its employees and agents (each an "**Indemnified Party**") and hold each Indemnified Party harmless against, and hereby agrees that an Indemnified Party shall have no liability to Sanofi for, any liabilities arising out of the performance of the Trustee's duties under the Commitments, except to the extent that such liabilities result from the wilful default, recklessness, gross negligence or bad faith of the Trustee, its employees, agents or advisors.

35. At the expense of Sanofi, the Trustee may appoint advisors (in particular for corporate finance or legal advice), subject to Sanofi'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 Sanofi refuse to approve the advisors proposed by the Trustee the Commission may approve the appointment of such advisors instead, after having heard Sanofi. Only the Trustee shall be entitled to issue instructions to the advisors. Paragraph 34 of these Commitments shall apply mutatis mutandis. In the Trustee Divestiture Period, the Divestiture Trustee may use advisors who served Sanofi during the Divestiture Period if the Divestiture Trustee considers this in the best interest of an expedient sale.

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

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

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

IV. Replacement, discharge and reappointment of the Trustee

39. If the Trustee ceases to perform its functions under the Commitments or for any other good cause, including the exposure of the Trustee to a Conflict of Interest:

(d) the Commission may, after hearing the Trustee and Sanofi require Sanofi to replace the Trustee; or

(e) Sanofi may, with the prior approval of the Commission, replace the Trustee.

40. If the Trustee is removed according to paragraph 39 of these Commitments, the Trustee may be required to continue in its function until a new Trustee is in place to whom the Trustee has effected a full hand over of all relevant information. The new Trustee shall be appointed in accordance with the procedure referred to in paragraphs 18-26 of these Commitments.

41. Unless removed according to paragraph 39 of these Commitments, the Trustee shall cease to act as Trustee only after the Commission has discharged it from its duties after all the Commitments with which the Trustee has been entrusted have been implemented. However, the Commission may at any time require the reappointment of the Monitoring Trustee if it subsequently appears that the relevant remedies might not have been fully and properly implemented.

Section F The review clause

42. The Commission may extend the time periods foreseen in the Commitments in response to a request from Sanofi or, in appropriate cases, on its own initiative. Where Sanofi 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 Sanofi. Only in exceptional circumstances shall Sanofi be entitled to request an extension within the last month of any period.

43. The Commission may further, in response to a reasoned request from the Notifying 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 Sanofi. The request shall not have the effect of suspending the application of the undertaking and, in particular, of suspending the expiry of any time period in which the undertaking has to be complied with.

Section G. Entry into force

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

[Signed]

duly authorised for and on behalf of Sanofi

Schedule 1

Product: Sanofi's Suppositoria Glycerini
Territory: Czech Republic

1. The Divestment Business consists of Sanofi's rights, title and interests in Suppositoria Glycerini in Czech Republic (marketed under the name Suppositoria Glycerini) including the right to develop, manufacture and use Suppositoria Glycerini with a view to its sale and marketing in any form and for any indication whatsoever in Czech Republic. Suppositoria Glycerini is used for the treatment of constipation. For the avoidance of doubt, this Divestment Business does not include any rights to sell Suppositoria Glycerini outside of Czech Republic but it includes all products under the name Suppositoria Glycerini marketed in Czech Republic, so that there will be no brand split.

2. The Divestment Businesses includes:

   a. the sale of existing Suppositoria Glycerini product inventory, sales and promotional material in Czech Republic, as far as available;
   b. all Suppositoria Glycerini-related contracts, commitments and customer records meaning customers credit records, customer invoices, purchase orders and contact details, for the last five years to the extent available, whilst only the information related to Suppositoria Glycerini specifically will be provided;
   c. the transfer of the marketing authorisation for Suppositoria Glycerini in Czech Republic including all relevant dossiers, as well as the information contained in the relevant full registration dossier(s), relating to the current and/or pending marketing authorisations available to Sanofi;
   d. an irrevocable, assignable, sub-licensable, and royalty free license for all relevant intellectual property rights (including all relevant logos and national registration of any related intellectual property right), data, books, records, packaging, trade dress and effective arrangements for the transfer of all know-how to the extent that these are related to the development, manufacture, use of Divestment Businesses with a view to its sale in Czech Republic, including in particular the information contained in the registration dossier.
   e. the transfer of any agreement for the supply of raw materials, the manufacture of the Divestment Businesses and/or the distribution of the Divestment Businesses, if any; and
   f. the free access (i.e. free opt-in), to future product development improvements (i.e. life-cycle management developments) existing at the date of the Closing in relation to Suppositoria Glycerini, to the extent that these developments are launched by Sanofi in the territory retained by it within three years from such date.

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

3. From the Effective Date, Sanofi commits to not register the Suppositoria Glycerini brand nor to oppose any future registration of the Suppositoria Glycerini brand name by the Purchaser.

4. Sanofi commits to continue the lifecycle management of the Suppositoria Glycerini branded products in the Czech Republic until the Closing.

5. 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 Suppositoria Glycerini in Czech Republic, Sanofi 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 Suppositoria Glycerini in Czech Republic.

6. At the option of the Purchaser, Sanofi shall enter into a transitory non-exclusive manufacturing and/or supply agreement relating to the existing forms of product in Czech Republic for up to two

years. Such transitory agreement could be extended for two additional periods of one year, as reasonably justified by the Purchaser under the oversight of Monitoring Trustee.

7. Such transitory arrangement shall include appropriate provisions designed to ensure the continued supply by Sanofi to the Purchaser at cost. It shall not contain provisions requiring the delivery of minimum supply volumes or batches.

8. At the option of the Purchaser, and to the extent required by law in Czech Republic, Sanofi will enter into a transitional distribution arrangement related to the Divestment Businesses lasting until the relevant marketing authorisation is transferred into the name of the Purchaser at cost which determination is overseen by the Monitoring Trustee.

9. Sanofi will transfer all historical information (orders, price, etc.) concerning its relationship regarding Suppositoria Glycerini in Czech Republic with API supplier **[Confidential]** to the Purchaser in accordance with applicable law and its pre-existing contractual obligations vis a vis **[Confidential]**. Sanofi commits to make its reasonable best efforts to ensure that the Purchaser can continue the existing relationship with **[Confidential]** with respect to Czech Republic.

10. Sanofi commits to make its reasonable best efforts to cooperate with the Purchaser to effectuate the transfer of the Divestment Businesses and to undertake all regulatory changes at Sanofi's cost (including the update of the dossier) that would be required as a result of such transfer.

11. At the option of the Purchaser, Sanofi shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of Suppositoria Glycerini in Czech Republic for a period of up to two years (extendable for one year under the supervision of the Monitoring Trustee) 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 Sanofi provides technical assistance to the Purchaser expeditiously.

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

13. The Divestment Businesses shall not include, in particular:

    a. Any manufacturing facility;
    b. Raw materials;
    c. Any research and development, clinical data and studies or intellectual property relating to Suppositoria Glycerini after Closing;
    d. All marketing authorizations currently held by the Parties outside of Czech Republic for Suppositoria Glycerini;
    e. The right to use the information contained in the registration dossiers underlying the marketing authorization(s) that are transferred as part of the Divestment Businesses to obtain marketing authorizations outside of Czech Republic;
    f. The "Sanofi" name or the name of any Sanofi subsidiaries;
    g. Monies owed to the Parties by customers for the purchase of Suppositoria Glycerini, and monies owed by the Parties to suppliers for materials used in the production of Suppositoria Glycerini.

14. If there is any asset or personnel which is not be covered by paragraph 2 of this Schedule but which is both used (exclusively or not) in the Divestment Businesses and necessary for the continued

viability and competitiveness of the Divestment Businesses, that asset or adequate substitute will be offered to the Purchaser.

Schedule 2

Product: Sanofi's Mucothiol
Territory: Greece

1. The Divestment Business consists of Sanofi's rights, title and interests in Mucothiol in Greece (marketed under the name Mucothiol) including the right to develop, manufacture and use Mucothiol with a view to its sale and marketing in any form and for any indication whatsoever in Greece. Mucothiol is used for the treatment of sore throat and cough. For the avoidance of doubt, this Divestment Business does not include any rights to sell Mucothiol outside of Greece but it includes all products under the name Mucothiol marketed in Greece, so that there will be no brand split.

2. The Divestment Businesses includes:

   a. the sale of existing Mucothiol product inventory, sales and promotional material in Greece, as far as available;
   b. all Mucothiol-related contracts, commitments and customer records meaning customers credit records, customer invoices, purchase orders and contact details, for the last five years to the extent available, whilst only the information related to Mucothiol specifically will be provided;
   c. the transfer of the marketing authorisation for Mucothiol in Greece including all relevant dossiers, as well as the information contained in the relevant full registration dossier(s), relating to the current and/or pending marketing authorisations available to Sanofi;
   d. the full transfer of the national trademark related to the product “Mucothiol” in Greece;
   e. an irrevocable, assignable, sub-licensable, and royalty free license for all other relevant intellectual property rights (including all relevant logos and national registration of any related intellectual property right), data, books, records, packaging, trade dress and effective arrangements for the transfer of all know-how to the extent that these are related to the development, manufacture, use of Divestment Businesses with a view to its sale in Greece, including in particular the information contained in the registration dossier;
   f. the transfer of any agreement for the supply of raw materials, the manufacture of the Divestment Businesses and/or the distribution of the Divestment Businesses, if any; and
   g. the free access (i.e. free opt-in), to future product development improvements (i.e. life-cycle management developments) existing at the date of the Closing in relation to Mucothiol, to the extent that these developments are launched by Sanofi in the territory retained by it within three years from such date.

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

3. From the Effective Date, Sanofi commits to not register any product under the Mucothiol brand in Greece for any other indication.

4. Sanofi commits to continue the lifecycle management of the Mucothiol branded products in Greece until the Closing.

5. If and to the extent that the know-how listed in paragraph 2 (e) above of this Schedule is not exclusively related to, and not exclusively used in respect of, the manufacture, use and sale of Mucothiol in Greece, Sanofi 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 Mucothiol in Greece.

6. At the option of the Purchaser, Sanofi shall enter into a transitory non-exclusive manufacturing and/or supply agreement relating to the existing forms of product in Greece for up to two years. Such transitory agreement could be extended for two additional periods of one year, as reasonably justified by the Purchaser under the oversight of Monitoring Trustee.

7. Such transitory arrangement shall include appropriate provisions designed to ensure the continued supply by Sanofi to the Purchaser at cost. It shall not contain provisions requiring the delivery of minimum supply volumes or batches.

8. At the option of the Purchaser, and to the extent required by law in Greece, Sanofi will enter into a transitional distribution arrangement related to the Divestment Businesses lasting until the relevant marketing authorisation is transferred into the name of the Purchaser at cost which determination is overseen by the Monitoring Trustee.

9. Sanofi will transfer all historical information (orders, price, etc.) concerning its relationship regarding Mucothiol in Greece with API suppliers **[Confidential]** to the Purchaser in accordance with applicable law and its pre-existing contractual obligations vis a vis **[Confidential]**. Sanofi commits to make its reasonable best efforts to ensure that the Purchaser can continue the existing relationships with **[Confidential]** with respect to Greece.

10. Sanofi commits to make its reasonable best efforts to cooperate with the Purchaser to effectuate the transfer of the Divestment Businesses and to undertake all regulatory changes at Sanofi's cost (including the update of the dossier) that would be required as a result of such transfer.

11. At the option of the Purchaser, Sanofi shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of Mucothiol in Greece for a period of up to two years (extendable for one year under the supervision of the Monitoring Trustee) 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 Sanofi provides technical assistance to the Purchaser expeditiously.

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

13. The Divestment Businesses shall not include, in particular:

    a. Any manufacturing facility;
    b. Raw materials;
    c. Any research and development, clinical data and studies or intellectual property relating to Mucothiol after Closing;
    d. All marketing authorizations currently held by the Parties outside of Greece for Mucothiol;
    e. The right to use the information contained in the registration dossiers underlying the marketing authorization(s) that are transferred as part of the Divestment Businesses to obtain marketing authorizations outside of Greece;
    f. The "Sanofi" name or the name of any Sanofi subsidiaries;
    g. Monies owed to the Parties by customers for the purchase of Mucothiol, and monies owed by the Parties to suppliers for materials used in the production of Mucothiol.

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

Schedule 3

Product: BI's Buscopan
Territory: Czech Republic

1. The Divestment Business consists of Sanofi's rights[1], title and interests in Buscopan in Czech Republic (marketed under the name Buscopan) including the right to develop, manufacture and use Buscopan with a view to its sale and marketing in any form and for any indication whatsoever in Czech Republic. Buscopan is used for the treatment of abdominal cramping, pain and discomfort. For the avoidance of doubt, this Divestment Business does not include any rights to sell Buscopan outside of Czech Republic[2] but it includes all products under the name Buscopan marketed in Czech Republic, so that there will be no brand split.

2. The Divestment Businesses includes:

   a. the sale of existing Buscopan product inventory, sales and promotional material in Czech Republic, as far as available;
   b. all Buscopan-related contracts, commitments and customer records meaning customers credit records, customer invoices, purchase orders and contact details, for the last five years to the extent available, whilst only the information related to Buscopan specifically will be provided;
   c. the transfer of the marketing authorisation for Buscopan in Czech Republic including all relevant dossiers, as well as the information contained in the relevant full registration dossier(s), relating to the current and/or pending marketing authorisations available to Sanofi;
   d. the full transfer of the Czech Republic part of the community trademark registration “Buscopan”;
   e. an irrevocable, assignable, sub-licensable, and royalty free license for all other relevant intellectual property rights (including all relevant logos and national registration of any related intellectual property right), data, books, records, packaging, trade dress and effective arrangements for the transfer of all know-how to the extent that these are related to the development, manufacture, use of Divestment Businesses with a view to its sale in Czech Republic, including in particular the information contained in the registration dossier;
   f. the transfer of any agreement for the supply of raw materials, the manufacture of the Divestment Businesses and/or the distribution of the Divestment Businesses, if any; and
   g. the free access (i.e. free opt-in), to future product development improvements (i.e. life-cycle management developments) existing at the date of the Closing in relation to Buscopan, to the extent that these developments are launched by Sanofi in the territory retained by it within three years from such date.

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

3. From the Effective Date, Sanofi commits to not register any product under the Buscopan brand in Czech Republic for any other indication.

4. Sanofi commits to continue the lifecycle management of the Buscopan branded products in the Czech Republic until the Closing.

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1 To be acquired after the closing of the CHC Transaction.

2 Except for Estonia, Hungary, Latvia, Poland and Slovakia as described in the other Schedules to the Commitments.

5. If and to the extent that the know-how listed in paragraph 2 (e) above of this Schedule is not exclusively related to, and not exclusively used in respect of, the manufacture, use and sale of Buscopan in Czech Republic, Sanofi 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 Buscopan in Czech Republic.

6. At the option of the Purchaser, Sanofi shall enter into a transitory non-exclusive manufacturing and/or supply agreement relating to the existing forms of product in Czech Republic for up to two years. Such transitory agreement could be extended for two additional periods of one year, as reasonably justified by the Purchaser under the oversight of Monitoring Trustee.

7. Such transitory arrangement shall include appropriate provisions designed to ensure the continued supply by Sanofi to the Purchaser at cost. It shall not contain provisions requiring the delivery of minimum supply volumes or batches.

8. At the option of the Purchaser, and to the extent required by law in Czech Republic, Sanofi will enter into a transitional distribution arrangement related to the Divestment Businesses lasting until the relevant marketing authorisation is transferred into the name of the Purchaser at cost which determination is overseen by the Monitoring Trustee.

9. Sanofi will transfer all historical information (orders, price, etc.) concerning the relationship regarding Buscopan in Czech Republic with manufacturer **[Confidential]**. to the Purchaser in accordance with applicable law and its pre-existing contractual obligations vis à vis **[Confidential]**. Sanofi commits to make its reasonable best efforts to ensure that the Purchaser can continue the existing relationship with **[Confidential]** with respect to Czech Republic.

10. Sanofi commits to make its reasonable best efforts to cooperate with the Purchaser to effectuate the transfer of the Divestment Businesses and to undertake all regulatory changes at Sanofi's cost (including the update of the dossier) that would be required as a result of such transfer.

11. At the option of the Purchaser, Sanofi shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of Buscopan in Czech Republic for a period of up to two years (extendable for one year under the supervision of the Monitoring Trustee) 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 Sanofi provides technical assistance to the Purchaser expeditiously.

12. The Purchaser will be given an option (to be exercised within one year after signing the relevant Transfer Agreement) to hire one or more Key Personnel[3] and Personnel if any, subject to applicable local employment legislation, who would reasonably be considered necessary to maintain the viability, marketability and competitiveness of this Divestment Businesses to be supervised by the Monitoring Trustee.

13. The Divestment Businesses shall not include, in particular:

    a. Any manufacturing facility;
    b. Raw materials;
    c. Any research and development, clinical data and studies or intellectual property relating to Buscopan after Closing;

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[3] Should all Buscopan products as listed in the Divestment Businesses be divested as one package, there could be one Key Personnel for such entire package.

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

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

Schedule 4

Product: BI's Buscopan
Territory: Estonia

1. The Divestment Business consists of Sanofi's rights[4], title and interests in Buscopan in Estonia (marketed under the name Buscopan) including the right to develop, manufacture and use Buscopan with a view to its sale and marketing in any form and for any indication whatsoever in Estonia. Buscopan is used for the treatment of abdominal cramping, pain and discomfort. For the avoidance of doubt, this Divestment Business does not include any rights to sell Buscopan outside of Estonia[5] but it includes all products under the name Buscopan marketed in Estonia, so that there will be no brand split.

2. The Divestment Businesses includes:

   a. the sale of existing Buscopan product inventory, sales and promotional material in Estonia, as far as available;
   b. all Buscopan-related contracts, commitments and customer records meaning customers credit records, customer invoices, purchase orders and contact details, for the last five years to the extent available, whilst only the information related to Buscopan specifically will be provided;
   c. the transfer of the marketing authorisation for Buscopan in Estonia including all relevant dossiers, as well as the information contained in the relevant full registration dossier(s), relating to the current and/or pending marketing authorisations available to Sanofi;
   d. the full transfer of the national trademark related to the product “Buscopan” in Estonia;
   e. an irrevocable, assignable, sub-licensable, and royalty free license for all other relevant intellectual property rights (including all relevant logos and national registration of any related intellectual property right), data, books, records, packaging, trade dress and effective arrangements for the transfer of all know-how to the extent that these are related to the development, manufacture, use of Divestment Businesses with a view to its sale in Estonia, including in particular the information contained in the registration dossier;
   f. the transfer of any agreement for the supply of raw materials, the manufacture of the Divestment Businesses and/or the distribution of the Divestment Businesses, if any; and
   g. the free access (i.e. free opt-in), to future product development improvements (i.e. life-cycle management developments) existing at the date of the Closing in relation to Buscopan, to the extent that these developments are launched by Sanofi in the territory retained by it within three years from such date.

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

3. From the Effective Date, Sanofi commits to not register any product under the Buscopan brand in Estonia for any other indication.

4. Sanofi commits to continue the lifecycle management of the Buscopan branded products in Estonia until the Closing.

5. If and to the extent that the know-how listed in paragraph 2 (e) above of this Schedule is not exclusively related to, and not exclusively used in respect of, the manufacture, use and sale of

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4 To be acquired after the closing of the CHC Transaction.

5 Except for Czech Republic, Hungary, Latvia, Poland and Slovakia as described in the other Schedules to the Commitments.

Buscopan in Estonia, Sanofi 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 Buscopan in Estonia.

6. At the option of the Purchaser, Sanofi shall enter into a transitory non-exclusive manufacturing and/or supply agreement relating to the existing forms of product in Estonia for up to two years. Such transitory agreement could be extended for two additional periods of one year, as reasonably justified by the Purchaser under the oversight of Monitoring Trustee.

7. Such transitory arrangement shall include appropriate provisions designed to ensure the continued supply by Sanofi to the Purchaser at cost. It shall not contain provisions requiring the delivery of minimum supply volumes or batches.

8. At the option of the Purchaser, and to the extent required by law in Estonia, Sanofi will enter into a transitional distribution arrangement related to the Divestment Businesses lasting until the relevant marketing authorisation is transferred into the name of the Purchaser at cost which determination is overseen by the Monitoring Trustee.

9. Sanofi will transfer all historical information (orders, price, etc.) concerning the relationship regarding Buscopan in Estonia with manufacturer **[Confidential]**. to the Purchaser in accordance with applicable law and its pre-existing contractual obligations vis à vis **[Confidential]**. Sanofi commits to make its reasonable best efforts to ensure that the Purchaser can continue the existing relationship with **[Confidential]** with respect to Estonia.

10. Sanofi will transfer all historical information (orders, price, etc.) concerning its relationship regarding Buscopan in Estonia with manufacturer **[Confidential]** to the Purchaser in accordance with applicable law and its pre-existing contractual obligations vis à vis **[Confidential]** Sanofi commits to make its reasonable best efforts to ensure that the Purchaser can continue the existing relationship with **[Confidential]** with respect to Estonia.

11. Sanofi commits to make its reasonable best efforts to cooperate with the Purchaser to effectuate the transfer of the Divestment Businesses and to undertake all regulatory changes at Sanofi's cost (including the update of the dossier) that would be required as a result of such transfer.

12. At the option of the Purchaser, Sanofi shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of Buscopan in Estonia for a period of up to two years (extendable for one year under the supervision of the Monitoring Trustee) 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 Sanofi provides technical assistance to the Purchaser expeditiously.

13. The Purchaser will be given an option (to be exercised within one year after signing the relevant Transfer Agreement) to hire one or more Key Personnel[6] and Personnel if any, subject to applicable local employment legislation, who would reasonably be considered necessary to maintain the viability, marketability and competitiveness of this Divestment Businesses to be supervised by the Monitoring Trustee.

14. The Divestment Businesses shall not include, in particular:

    a. Any manufacturing facility;

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[6] Should all Buscopan products as listed in the Divestment Businesses be divested as one package, there could be one Key Personnel for such entire package.

b. Raw materials;
c. Any research and development, clinical data and studies or intellectual property relating to Buscopan after Closing;
d. All marketing authorizations currently held by the Parties outside of Estonia for Buscopan;
e. The right to use the information contained in the registration dossiers underlying the marketing authorization(s) that are transferred as part of the Divestment Businesses to obtain marketing authorizations outside of Estonia;
f. The "Sanofi" name or the name of any Sanofi subsidiaries;
g. Monies owed to the Parties by customers for the purchase of Buscopan, and monies owed by the Parties to suppliers for materials used in the production of Buscopan.

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

Schedule 5

Product: BI's Buscopan
Territory: Hungary

1. The Divestment Business consists of Sanofi's rights[7], title and interests in Buscopan in Hungary (marketed under the name Buscopan) including the right to develop, manufacture and use Buscopan with a view to its sale and marketing in any form and for any indication whatsoever in Hungary. Buscopan is used for the treatment of abdominal cramping, pain and discomfort. For the avoidance of doubt, this Divestment Business does not include any rights to sell Buscopan outside of Hungary[8] but it includes all products under the name Buscopan marketed in Hungary, so that there will be no brand split.

2. The Divestment Businesses includes:

   a. the sale of existing Buscopan product inventory, sales and promotional material in Hungary, as far as available;
   b. all Buscopan-related contracts, commitments and customer records meaning customers credit records, customer invoices, purchase orders and contact details, for the last five years to the extent available, whilst only the information related to Buscopan specifically will be provided;
   c. the transfer of the marketing authorisation for Buscopan in Hungary including all relevant dossiers, as well as the information contained in the relevant full registration dossier(s), relating to the current and/or pending marketing authorisations available to Sanofi;
   d. the full transfer of the Hungary part of the community trademark registration “Buscopan”;
   e. an irrevocable, assignable, sub-licensable, and royalty free license for all other relevant intellectual property rights (including all relevant logos and national registration of any related intellectual property right), data, books, records, packaging, trade dress and effective arrangements for the transfer of all know-how to the extent that these are related to the development, manufacture, use of Divestment Businesses with a view to its sale in Hungary, including in particular the information contained in the registration dossier;
   f. the transfer of any agreement for the supply of raw materials, the manufacture of the Divestment Businesses and/or the distribution of the Divestment Businesses, if any; and
   g. the free access (i.e. free opt-in), to future product development improvements (i.e. life-cycle management developments) existing at the date of the Closing in relation to Buscopan, to the extent that these developments are launched by Sanofi in the territory retained by it within three years from such date.

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

3. From the Effective Date, Sanofi commits to not register any product under the Buscopan brand in Hungary for any other indication.

4. Sanofi commits to continue the lifecycle management of the Buscopan branded products in Hungary until the Closing.

5. If and to the extent that the know-how listed in paragraph 2 (e) above of this Schedule is not exclusively related to, and not exclusively used in respect of, the manufacture, use and sale of

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7 To be acquired after the closing of the CHC Transaction.

8 Except for Czech Republic, Estonia, Latvia, Poland and Slovakia as described in the other Schedules to the Commitments.

Buscopan in Hungary, Sanofi 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 Buscopan in Hungary.

6. At the option of the Purchaser, Sanofi shall enter into a transitory non-exclusive manufacturing and/or supply agreement relating to the existing forms of product in Hungary for up to two years. Such transitory agreement could be extended for two additional periods of one year, as reasonably justified by the Purchaser under the oversight of Monitoring Trustee.

7. Such transitory arrangement shall include appropriate provisions designed to ensure the continued supply by Sanofi to the Purchaser at cost. It shall not contain provisions requiring the delivery of minimum supply volumes or batches.

8. At the option of the Purchaser, and to the extent required by law in Hungary, Sanofi will enter into a transitional distribution arrangement related to the Divestment Businesses lasting until the relevant marketing authorisation is transferred into the name of the Purchaser at cost which determination is overseen by the Monitoring Trustee.

9. Sanofi will transfer all historical information (orders, price, etc.) concerning the relationship regarding Buscopan in Hungary with manufacturer **[Confidential]** to the Purchaser in accordance with applicable law and its pre-existing contractual obligations vis à vis **[Confidential]** Sanofi commits to make its reasonable best efforts to ensure that the Purchaser can continue the existing relationship with **[Confidential]** with respect to Hungary.

10. Sanofi commits to make its reasonable best efforts to cooperate with the Purchaser to effectuate the transfer of the Divestment Businesses and to undertake all regulatory changes at Sanofi's cost (including the update of the dossier) that would be required as a result of such transfer.

11. At the option of the Purchaser, Sanofi shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of Buscopan in Hungary for a period of up to two years (extendable for one year under the supervision of the Monitoring Trustee) 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 Sanofi provides technical assistance to the Purchaser expeditiously.

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

13. The Divestment Businesses shall not include, in particular:

    a. Any manufacturing facility;
    b. Raw materials;
    c. Any research and development, clinical data and studies or intellectual property relating to Buscopan after Closing;
    d. All marketing authorizations currently held by the Parties outside of Hungary for Buscopan;

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9 Should all Buscopan products as listed in the Divestment Businesses be divested as one package, there could be one Key Personnel for such entire package.

e. The right to use the information contained in the registration dossiers underlying the marketing authorization(s) that are transferred as part of the Divestment Businesses to obtain marketing authorizations outside of Hungary;
f. The "Sanofi" name or the name of any Sanofi subsidiaries;
g. Monies owed to the Parties by customers for the purchase of Buscopan, and monies owed by the Parties to suppliers for materials used in the production of Buscopan.

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

Schedule 6

Product: BI's Buscopan
Territory: Latvia

1. The Divestment Business consists of Sanofi's rights[10], title and interests in Buscopan in Latvia (marketed under the name Buscopan) including the right to develop, manufacture and use Buscopan with a view to its sale and marketing in any form and for any indication whatsoever in Latvia. Buscopan is used for the treatment of abdominal cramping, pain and discomfort. For the avoidance of doubt, this Divestment Business does not include any rights to sell Buscopan outside of Latvia[11] but it includes all products under the name Buscopan marketed in Latvia, so that there will be no brand split.

2. The Divestment Businesses includes:

   a. the sale of existing Buscopan product inventory, sales and promotional material in Latvia, as far as available;
   b. all Buscopan-related contracts, commitments and customer records meaning customers credit records, customer invoices, purchase orders and contact details, for the last five years to the extent available, whilst only the information related to Buscopan specifically will be provided;
   c. the transfer of the marketing authorisation for Buscopan in Latvia including all relevant dossiers, as well as the information contained in the relevant full registration dossier(s), relating to the current and/or pending marketing authorisations available to Sanofi;
   d. the full transfer of the Latvia part of the community trademark registration “Buscopan”;
   e. an irrevocable, assignable, sub-licensable, and royalty free license for all other relevant intellectual property rights (including all relevant logos and national registration of any related intellectual property right), data, books, records, packaging, trade dress and effective arrangements for the transfer of all know-how to the extent that these are related to the development, manufacture, use of Divestment Businesses with a view to its sale in Latvia, including in particular the information contained in the registration dossier;
   f. the transfer of any agreement for the supply of raw materials, the manufacture of the Divestment Businesses and/or the distribution of the Divestment Businesses, if any; and
   g. the free access (i.e. free opt-in), to future product development improvements (i.e. life-cycle management developments) existing at the date of the Closing in relation to Buscopan, to the extent that these developments are launched by Sanofi in the territory retained by it within three years from such date.

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

3. From the Effective Date, Sanofi commits to not register any product under the Buscopan brand in Latvia for any other indication.

4. Sanofi commits to continue the lifecycle management of the Buscopan branded products in Latvia until the Closing.

5. If and to the extent that the know-how listed in paragraph 2 (e) above of this Schedule is not exclusively related to, and not exclusively used in respect of, the manufacture, use and sale of

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10 To be acquired after the closing of the CHC Transaction.

11 Except for Czech Republic, Estonia, Hungary, Poland and Slovakia as described in the other Schedules to the Commitments.

Buscopan in Latvia, Sanofi 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 Buscopan in Latvia.

6. At the option of the Purchaser, Sanofi shall enter into a transitory non-exclusive manufacturing and/or supply agreement relating to the existing forms of product in Latvia for up to two years. Such transitory agreement could be extended for two additional periods of one year, as reasonably justified by the Purchaser under the oversight of Monitoring Trustee.

7. Such transitory arrangement shall include appropriate provisions designed to ensure the continued supply by Sanofi to the Purchaser at cost. It shall not contain provisions requiring the delivery of minimum supply volumes or batches.

8. At the option of the Purchaser, and to the extent required by law in Latvia, Sanofi will enter into a transitional distribution arrangement related to the Divestment Businesses lasting until the relevant marketing authorisation is transferred into the name of the Purchaser at cost which determination is overseen by the Monitoring Trustee.

9. Sanofi will transfer all historical information (orders, price, etc.) concerning the relationship regarding Buscopan in Latvia with manufacturer **[Confidential]** to the Purchaser in accordance with applicable law and its pre-existing obligations vis à vis **[Confidential]**. Sanofi commits to make its reasonable best efforts to ensure that the Purchaser can continue the existing relationship with **[Confidential]** with respect to Latvia.

10. Sanofi will transfer all historical information (orders, price, etc.) concerning its relationship regarding Buscopan in Latvia with manufacturer **[Confidential]** to the Purchaser in accordance with applicable law and its pre-existing obligations vis à vis **[Confidential]**. Sanofi commits to make its reasonable best efforts to ensure that the Purchaser can continue the existing relationship with **[Confidential]** with respect to Latvia.

11. Sanofi commits to make its reasonable best efforts to cooperate with the Purchaser to effectuate the transfer of the Divestment Businesses and to undertake all regulatory changes at Sanofi's cost (including the update of the dossier) that would be required as a result of such transfer.

12. At the option of the Purchaser, Sanofi shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of Buscopan in Latvia for a period of up to two years (extendable for one year under the supervision of the Monitoring Trustee) 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 Sanofi provides technical assistance to the Purchaser expeditiously.

13. The Purchaser will be given an option (to be exercised within one year after signing the relevant Transfer Agreement) to hire one or more Key Personnel[12] and Personnel if any, subject to applicable local employment legislation, who would reasonably be considered necessary to maintain the viability, marketability and competitiveness of this Divestment Businesses to be supervised by the Monitoring Trustee.

14. The Divestment Businesses shall not include, in particular:

    a. Any manufacturing facility;

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[12] Should all Buscopan products as listed in the Divestment Businesses be divested as one package, there could be one Key Personnel for such entire package.

b. Raw materials;
c. Any research and development, clinical data and studies or intellectual property relating to Buscopan after Closing;
d. All marketing authorizations currently held by the Parties outside of Latvia for Buscopan;
e. The right to use the information contained in the registration dossiers underlying the marketing authorization(s) that are transferred as part of the Divestment Businesses to obtain marketing authorizations outside of Latvia;
f. The "Sanofi" name or the name of any Sanofi subsidiaries;
g. Monies owed to the Parties by customers for the purchase of Buscopan, and monies owed by the Parties to suppliers for materials used in the production of Buscopan.

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

Schedule 7

Product: BI's Buscopan
Territory: Poland

1. The Divestment Business consists of Sanofi's rights[13], title and interests in Buscopan in Poland (marketed under the name Buscopan) including the right to develop, manufacture and use Buscopan with a view to its sale and marketing in any form and for any indication whatsoever in Poland. Buscopan is used for the treatment of abdominal cramping, pain and discomfort. For the avoidance of doubt, this Divestment Business does not include any rights to sell Buscopan outside of Poland[14] but it includes all products under the name Buscopan marketed in Poland, so that there will be no brand split.

2. The Divestment Businesses includes:

   a. the sale of existing Buscopan product inventory, sales and promotional material in Poland, as far as available;
   b. all Buscopan-related contracts, commitments and customer records meaning customers credit records, customer invoices, purchase orders and contact details, for the last five years to the extent available, whilst only the information related to Buscopan specifically will be provided;
   c. the transfer of the marketing authorisation for Buscopan in Poland including all relevant dossiers, as well as the information contained in the relevant full registration dossier(s), relating to the current and/or pending marketing authorisations available to Sanofi;
   d. the full transfer of the national trademark related to the product “Buscopan” in Poland;
   e. an irrevocable, assignable, sub-licensable, and royalty free license for all other relevant intellectual property rights (including all relevant logos and national registration of any related intellectual property right), data, books, records, packaging, trade dress and effective arrangements for the transfer of all know-how to the extent that these are related to the development, manufacture, use of Divestment Businesses with a view to its sale in Poland, including in particular the information contained in the registration dossier;
   f. the transfer of any agreement for the supply of raw materials, the manufacture of the Divestment Businesses and/or the distribution of the Divestment Businesses, if any; and
   g. the free access (i.e. free opt-in), to future product development improvements (i.e. life-cycle management developments) existing at the date of the Closing in relation to Buscopan, to the extent that these developments are launched by Sanofi in the territory retained by it within three years from such date.

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

3. From the Effective Date, Sanofi commits to not register any product under the Buscopan brand in Poland for any other indication.

4. Sanofi commits to continue the lifecycle management of the Buscopan branded products in Poland until the Closing.

5. If and to the extent that the know-how listed in paragraph 2 (e) above of this Schedule is not exclusively related to, and not exclusively used in respect of, the manufacture, use and sale of

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13 To be acquired after the closing of the CHC Transaction.

14 Except for Czech Republic, Estonia, Hungary, Latvia and Slovakia as described in the other Schedules to the Commitments.

Buscopan in Poland, Sanofi 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 Buscopan in Poland.

6. At the option of the Purchaser, Sanofi shall enter into a transitory non-exclusive manufacturing and/or supply agreement relating to the existing forms of product in Poland for up to two years. Such transitory agreement could be extended for two additional periods of one year, as reasonably justified by the Purchaser under the oversight of Monitoring Trustee.

7. Such transitory arrangement shall include appropriate provisions designed to ensure the continued supply by Sanofi to the Purchaser at cost. It shall not contain provisions requiring the delivery of minimum supply volumes or batches.

8. At the option of the Purchaser, and to the extent required by law in Poland, Sanofi will enter into a transitional distribution arrangement related to the Divestment Businesses lasting until the relevant marketing authorisation is transferred into the name of the Purchaser at cost which determination is overseen by the Monitoring Trustee.

9. Sanofi will transfer all historical information (orders, price, etc.) concerning the relationship regarding Buscopan in Poland with manufacturer **[Confidential]** to the Purchaser in accordance with applicable law and its pre-existing obligations vis à vis **[Confidential]**. Sanofi commits to make its reasonable best efforts to ensure that the Purchaser can continue the existing relationship with **[Confidential]** with respect to Poland.

10. Sanofi will transfer all historical information (orders, price, etc.) concerning its relationship regarding Buscopan in Poland with manufacturer **[Confidential]** to the Purchaser in accordance with applicable law and its pre-existing obligations vis à vis **[Confidential]**. Sanofi commits to make its reasonable best efforts to ensure that the Purchaser can continue the existing relationship with **[Confidential]** with respect to Poland.

11. Sanofi commits to make its reasonable best efforts to cooperate with the Purchaser to effectuate the transfer of the Divestment Businesses and to undertake all regulatory changes at Sanofi's cost (including the update of the dossier) that would be required as a result of such transfer.

12. At the option of the Purchaser, Sanofi shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of Buscopan in Poland for a period of up to two years (extendable for one year under the supervision of the Monitoring Trustee) 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 Sanofi provides technical assistance to the Purchaser expeditiously.

13. The Purchaser will be given an option (to be exercised within one year after signing the relevant Transfer Agreement) to hire one or more Key Personnel[15] and Personnel if any, subject to applicable local employment legislation, who would reasonably be considered necessary to maintain the viability, marketability and competitiveness of this Divestment Businesses to be supervised by the Monitoring Trustee.

14. The Divestment Businesses shall not include, in particular:

    a. Any manufacturing facility;

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[15] Should all Buscopan products as listed in the Divestment Businesses be divested as one package, there could be one Key Personnel for such entire package.

b. Raw materials;
c. Any research and development, clinical data and studies or intellectual property relating to Buscopan after Closing;
d. All marketing authorizations currently held by the Parties outside of Poland for Buscopan;
e. The right to use the information contained in the registration dossiers underlying the marketing authorization(s) that are transferred as part of the Divestment Businesses to obtain marketing authorizations outside of Poland;
f. The "Sanofi" name or the name of any Sanofi subsidiaries;
g. Monies owed to the Parties by customers for the purchase of Buscopan, and monies owed by the Parties to suppliers for materials used in the production of Buscopan.

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

Schedule 8

Product: BI's Buscopan
Territory: Slovakia

1. The Divestment Business consists of Sanofi's rights[16], title and interests in Buscopan in Slovakia (marketed under the name Buscopan) including the right to develop, manufacture and use Buscopan with a view to its sale and marketing in any form and for any indication whatsoever in Slovakia. Buscopan is used for the treatment of abdominal cramping, pain and discomfort. For the avoidance of doubt, this Divestment Business does not include any rights to sell Buscopan outside of Slovakia[17] but it includes all products under the name Buscopan marketed in Slovakia, so that there will be no brand split.

2. The Divestment Businesses includes:

   a. the sale of existing Buscopan product inventory, sales and promotional material in Slovakia, as far as available;
   b. all Buscopan-related contracts, commitments and customer records meaning customers credit records, customer invoices, purchase orders and contact details, for the last five years to the extent available, whilst only the information related to Buscopan specifically will be provided;
   c. the transfer of the marketing authorisation for Buscopan in Slovakia including all relevant dossiers, as well as the information contained in the relevant full registration dossier(s), relating to the current and/or pending marketing authorisations available to Sanofi;
   d. the full transfer of the Slovakia part of the community trademark registration “Buscopan”;
   e. an irrevocable, assignable, sub-licensable, and royalty free license for all other relevant intellectual property rights (including all relevant logos and national registration of any related intellectual property right), data, books, records, packaging, trade dress and effective arrangements for the transfer of all know-how to the extent that these are related to the development, manufacture, use of Divestment Businesses with a view to its sale in Slovakia, including in particular the information contained in the registration dossier;
   f. the transfer of any agreement for the supply of raw materials, the manufacture of the Divestment Businesses and/or the distribution of the Divestment Businesses, if any; and
   g. the free access (i.e. free opt-in), to future product development improvements (i.e. life-cycle management developments) existing at the date of the Closing in relation to Buscopan, to the extent that these developments are launched by Sanofi in the territory retained by it within three years from such date.

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

3. From the Effective Date, Sanofi commits to not register any product under the Buscopan brand in Slovakia for any other indication.

4. Sanofi commits to continue the lifecycle management of the Buscopan branded products in Slovakia until the Closing.

5. If and to the extent that the know-how listed in paragraph 2 (e) above of this Schedule is not exclusively related to, and not exclusively used in respect of, the manufacture, use and sale of

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16 To be acquired after the closing of the CHC Transaction.

17 Except for Czech Republic, Estonia, Hungary, Latvia and Poland as described in the other Schedules to the Commitments.

Buscopan in Slovakia, Sanofi 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 Buscopan in Slovakia.

6. At the option of the Purchaser, Sanofi shall enter into a transitory non-exclusive manufacturing and/or supply agreement relating to the existing forms of product in Slovakia for up to two years. Such transitory agreement could be extended for two additional periods of one year, as reasonably justified by the Purchaser under the oversight of Monitoring Trustee.

7. Such transitory arrangement shall include appropriate provisions designed to ensure the continued supply by Sanofi to the Purchaser at cost. It shall not contain provisions requiring the delivery of minimum supply volumes or batches.

8. At the option of the Purchaser, and to the extent required by law in Slovakia, Sanofi will enter into a transitional distribution arrangement related to the Divestment Businesses lasting until the relevant marketing authorisation is transferred into the name of the Purchaser at cost which determination is overseen by the Monitoring Trustee.

9. Sanofi will transfer all historical information (orders, price, etc.) concerning the relationship regarding Buscopan in Slovakia with manufacturer **[Confidential]** to the Purchaser in accordance with applicable law and its pre-existing contractual obligations vis à vis **[Confidential]**. Sanofi commits to make its reasonable best efforts to ensure that the Purchaser can continue the existing relationship with **[Confidential]** with respect to Slovakia.

10. Sanofi commits to make its reasonable best efforts to cooperate with the Purchaser to effectuate the transfer of the Divestment Businesses and to undertake all regulatory changes at Sanofi's cost (including the update of the dossier) that would be required as a result of such transfer.

11. At the option of the Purchaser, Sanofi shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of Buscopan in Slovakia for a period of up to two years (extendable for one year under the supervision of the Monitoring Trustee) 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 Sanofi provides technical assistance to the Purchaser expeditiously.

12. The Purchaser will be given an option (to be exercised within one year after signing the relevant Transfer Agreement) to hire one or more Key Personnel[18] and Personnel if any, subject to applicable local employment legislation, who would reasonably be considered necessary to maintain the viability, marketability and competitiveness of this Divestment Businesses to be supervised by the Monitoring Trustee.

13. The Divestment Businesses shall not include, in particular:

    a. Any manufacturing facility;
    b. Raw materials;
    c. Any research and development, clinical data and studies or intellectual property relating to Buscopan after Closing;
    d. All marketing authorizations currently held by the Parties outside of Slovakia for Buscopan;

[18] Should all Buscopan products as listed in the Divestment Businesses be divested as one package, there could be one Key Personnel for such entire package.

e. The right to use the information contained in the registration dossiers underlying the marketing authorization(s) that are transferred as part of the Divestment Businesses to obtain marketing authorizations outside of Slovakia;
f. The "Sanofi" name or the name of any Sanofi subsidiaries;
g. Monies owed to the Parties by customers for the purchase of Buscopan, and monies owed by the Parties to suppliers for materials used in the production of Buscopan.

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

Schedule 9

Product: Sanofi's Mucodyne
Territory: Ireland

1. The Divestment Business consists of Sanofi's rights, title and interests in Mucodyne in Ireland (marketed under the name Mucodyne) including the right to develop, manufacture and use Mucodyne with a view to its sale and marketing in any form and for any indication whatsoever in Ireland. Mucodyne is used for the treatment of wet cough. For the avoidance of doubt, this Divestment Business does not include any rights to sell Mucodyne outside of Ireland but it includes all products under the name Mucodyne marketed in Ireland, so that there will be no brand split.

2. The Divestment Businesses includes:

   a. the sale of existing Mucodyne product inventory, sales and promotional material in Ireland, as far as available;
   b. all Mucodyne-related contracts, commitments and customer records meaning customers credit records, customer invoices, purchase orders and contact details, for the last five years to the extent available, whilst only the information related to Mucodyne specifically will be provided;
   c. the transfer of the marketing authorisation for Mucodyne in Ireland including all relevant dossiers, as well as the information contained in the relevant full registration dossier(s), relating to the current and/or pending marketing authorisations available to Sanofi;
   d. the full transfer of the national trademark related to the product “Mucodyne” in Ireland;
   e. an irrevocable, assignable, sub-licensable, and royalty free license for all other relevant intellectual property rights (including all relevant logos and national registration of any related intellectual property right), data, books, records, packaging, trade dress and effective arrangements for the transfer of all know-how to the extent that these are related to the development, manufacture, use of Divestment Businesses with a view to its sale in Ireland, including in particular the information contained in the registration dossier;
   f. the transfer of any agreement for the supply of raw materials, the manufacture of the Divestment Businesses and/or the distribution of the Divestment Businesses, if any; and
   g. the free access (i.e. free opt-in), to future product development improvements (i.e. life-cycle management developments) existing at the date of the Closing in relation to Mucodyne, to the extent that these developments are launched by Sanofi in the territory retained by it within three years from such date.

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

3. From the Effective Date, Sanofi commits to not register any product under the Mucodyne brand in Ireland for any other indication.

4. Sanofi commits to continue the lifecycle management of the Mucodyne branded products in Ireland until the Closing.

5. If and to the extent that the know-how listed in paragraph 2 (e) above of this Schedule is not exclusively related to, and not exclusively used in respect of, the manufacture, use and sale of Mucodyne in Ireland, Sanofi 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 Mucodyne in Ireland.

6. At the option of the Purchaser, Sanofi 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 agreement could be extended for two additional periods of one year, as reasonably justified by the Purchaser under the oversight of Monitoring Trustee.

7. Such transitory arrangement shall include appropriate provisions designed to ensure the continued supply by Sanofi to the Purchaser. It shall not contain provisions requiring the delivery of minimum supply volumes or batches.

8. At the option of the Purchaser, and to the extent required by law in Ireland, Sanofi will enter into a transitional distribution arrangement related to the Divestment Businesses lasting until the relevant marketing authorisation is transferred into the name of the Purchaser at cost which determination is overseen by the Monitoring Trustee.

9. Sanofi will transfer all historical information (orders, price, etc.) concerning its relationship regarding Mucodyne in Ireland with API supplier **[Confidential]** to the Purchaser in accordance with applicable law. Sanofi commits to make its best efforts to ensure that the Purchaser can continue the existing relationship with **[Confidential]** with respect to Ireland.

10. Sanofi will transfer all historical information (orders, price, etc.) concerning its relationship regarding Mucodyne in Ireland with manufacturer **[Confidential]** to the Purchaser in accordance with applicable law. Sanofi commits to make its best efforts to ensure that the Purchaser can continue the existing relationship with **[Confidential]** with respect to Ireland.

11. Sanofi commits to make its reasonable best efforts to cooperate with the Purchaser to effectuate the transfer of the Divestment Businesses and to undertake all regulatory changes at Sanofi's cost (including the update of the dossier) that would be required as a result of such transfer.

12. At the option of the Purchaser, Sanofi shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of Buscopan in Slovakia for a period of up to two years (extendable for one year under the supervision of the Monitoring Trustee) 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 Sanofi provides technical assistance to the Purchaser expeditiously.

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

14. The Divestment Businesses shall not include:

    a. Any manufacturing facility;
    b. Raw materials;
    c. Any research and development, clinical data and studies or intellectual property relating to Mucodyne after Closing;
    d. All marketing authorizations currently held by the Parties outside of Ireland for Mucodyne;
    e. The right to use the information contained in the registration dossiers underlying the marketing authorization(s) that are transferred as part of the Divestment Businesses to obtain marketing authorizations outside of Ireland;
    f. The "Sanofi" name or the name of any Sanofi subsidiaries;
    g. Monies owed to the Parties by customers for the purchase of Mucodyne, and monies owed by the Parties to suppliers for materials used in the production of Mucodyne.

15. If there is any asset or personnel which is not be covered by paragraph 2 of this Schedule but which is both used (exclusively or not) in the Divestment Businesses and necessary for the continued

viability and competitiveness of the Divestment Businesses, that asset or adequate substitute will be offered to the Purchaser.

Schedule 10

Product: BI's Prontalgine
Territory: France

1. The Divestment Business consists of Sanofi's rights[19], title and interests in Prontalgine in France (marketed under the name Prontalgine) including the right to develop, manufacture and use Prontalgine with a view to its sale and marketing in any form and for any indication whatsoever in France. Prontalgine is used for the treatment of moderate to severe symptomatic pain. For the avoidance of doubt, this Divestment Businesses does not include any rights to sell Prontalgine outside of France but it includes all products under the name Prontalgine marketed in France, so that there will be no brand split.

2. The Divestment Businesses includes:

   a. the sale of existing Prontalgine product inventory, sales and promotional material in France, as far as available;
   b. all Prontalgine-related contracts, commitments and customer records meaning customers credit records, customer invoices, purchase orders and contact details, for the last five years to the extent available, whilst only the information related to Prontalgine specifically will be provided;
   c. the transfer of the marketing authorisation for Prontalgine in France including all relevant dossiers, as well as the information contained in the relevant full registration dossier(s), relating to the current and/or pending marketing authorisations available to Sanofi;
   d. the full transfer of the national trademark related to the product “Prontalgine” in France;
   e. an irrevocable, assignable, sub-licensable, and royalty free license for all other relevant intellectual property rights (including all relevant logos and national registration of any related intellectual property right), data, books, records, packaging, trade dress and effective arrangements for the transfer of all know-how to the extent that these are related to the development, manufacture, use of Divestment Businesses with a view to its sale in France, including in particular the information contained in the registration dossier;
   f. the transfer of any agreement for the supply of raw materials, the manufacture of the Divestment Businesses and/or the distribution of the Divestment Businesses, if any; and
   g. the free access (i.e. free opt-in), to future product development improvements (i.e. life-cycle management developments) existing at the date of the Closing in relation to Mucodyne, to the extent that these developments are launched by Sanofi in the territory retained by it within three years from such date.

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

3. From the Effective Date, Sanofi commits to not register any product under the Prontalgine brand in France for any other indication.

4. Sanofi commits to continue the lifecycle management of the Prontalgine branded products in the France until the Closing.

5. If and to the extent that the know-how listed in paragraph 2 (e) above of this Schedule is not exclusively related to, and not exclusively used in respect of, the manufacture, use and sale of Prontalgine in France, Sanofi shall have the right to retain the ownership of such asset and shall

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19 To be acquired after the closing of the CHC Transaction.

grant to the Purchaser at no additional charge an exclusive and perpetual right to use such asset for the manufacture, use and sale of Prontalgine in France.

6. At the option of the Purchaser, Sanofi shall enter into a transitory non-exclusive manufacturing and/or supply agreement relating to the existing forms of product in France for up to two years. Such transitory agreement could be extended for two additional periods of one year, as reasonably justified by the Purchaser under the oversight of Monitoring Trustee.

7. Such transitory arrangement shall include appropriate provisions designed to ensure the continued supply by Sanofi to the Purchaser. It shall not contain provisions requiring the delivery of minimum supply volumes or batches.

8. At the option of the Purchaser, and to the extent required by law in France, Sanofi will enter into a transitional distribution arrangement related to the Divestment Businesses lasting until the relevant marketing authorisation is transferred into the name of the Purchaser at cost which determination is overseen by the Monitoring Trustee.

9. Sanofi will transfer all historical information (orders, price, etc.) concerning the relationship regarding Prontalgine in France with manufacturer **[Confidential]** to the Purchaser in accordance with applicable law. Sanofi commits to make its best efforts to ensure that the Purchaser can continue the existing relationship with **[Confidential]** with respect to France.

10. Sanofi commits to make its reasonable best efforts to cooperate with the Purchaser to effectuate the transfer of the Divestment Businesses and to undertake all regulatory changes at Sanofi's cost (including the update of the dossier) that would be required as a result of such transfer.

11. At the option of the Purchaser, Sanofi shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of Buscopan in Slovakia for a period of up to two years (extendable for one year under the supervision of the Monitoring Trustee) 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 Sanofi provides technical assistance to the Purchaser expeditiously.

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

13. The Divestment Businesses shall not include:

    a. Any manufacturing facility;
    b. Raw materials;
    c. Any research and development, clinical data and studies or intellectual property relating to Prontalgine after Closing;
    d. All marketing authorizations currently held by the Parties outside of France for Prontalgine;
    e. The right to use the information contained in the registration dossiers underlying the marketing authorization(s) that are transferred as part of the Divestment Businesses to obtain marketing authorizations outside of France;
    f. The "Sanofi" name or the name of any Sanofi subsidiaries;
    g. Monies owed to the Parties by customers for the purchase of Prontalgine, and monies owed by the Parties to suppliers for materials used in the production of Prontalgine.

14. If there is any asset or personnel which is not be covered by paragraph 2 of this Schedule but which is both used (exclusively or not) in the Divestment Businesses and necessary for the continued

viability and competitiveness of the Divestment Businesses, that asset or adequate substitute will be offered to the Purchaser.