



EUROPEAN COMMISSION
DG Competition

***Case M.11383 - COOPER / VIATRIS (EUROPEAN OTC
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: 26/06/2024

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EUROPEAN COMMISSION

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PUBLIC VERSION

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 Where possible the information omitted has been replaced by ranges of figures or a general description.

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Subject: Case M.11383 – COOPER / VIATRIS (EUROPEAN OTC BUSINESS)
Commission decision pursuant to Article 6(1)(b) in conjunction with Article 6(2) of Council Regulation No 139/2004¹ and Article 57 of the Agreement on the European Economic Area²

Dear Sir or Madam,

- (1) On 3 May 2024, the European Commission received notification of a proposed concentration pursuant to Article 4 of the Merger Regulation by which Cooper Consumer Health S.A.S. (“Cooper”, France or the “Notifying Party”) will acquire within the meaning of Article 3(1)(b) of the Merger Regulation sole control over the European over-the-counter (“OTC”) business of Viatris Inc. (the “Target”, France and Italy), by way of purchase of assets (the “Transaction”).³

1. THE PARTIES

- (2) **Cooper** is a consumer healthcare company based in France. Cooper is principally active in the manufacturing and distribution of OTC consumer health and consumer self-care products. Cooper is under the sole control of CVC Capital Partners

¹ OJ L 24, 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 L 1, 3.1.1994, p. 3 (the ‘EEA Agreement’).

³ OJ C, C/ 2024/3216, 16.5.2024.

SICAV-FIS S.A (“CVC”, together with the Target the “Parties”), a private equity investment firm. In addition to Cooper, a number of CVC funds’ portfolio companies including Recordati Industria Chimica E Farmaceutica S.P.A. (“Recordati”, Italy), Hellenic Healthcare Group (“HHG”, Greece) and Disapo.de Apotheke B.V (“Disapo”, the Netherlands, a subsidiary of the Douglas Group, Germany) are also active in markets that are horizontally and vertically related to those in which the Target is active.

- (3) **The Target** is the European OTC business of Viatriis,⁴ a global healthcare company headquartered in the United States. The Target’s assets include a range of finished dose pharmaceuticals (“FDPs”)⁵ across various categories such as body care, body cleansing, intimate hygiene, food supplements, homeopathics and baby hygiene. The Target provides R&D, manufacturing and operational infrastructure support for these assets.

2. THE TRANSACTION AND THE CONCENTRATION

- (4) Pursuant to a put option agreement dated 1 October 2023 and a transaction agreement attached to it and to be entered into upon exercise of the put option, Cooper will acquire all of the issued and outstanding equity in certain legal entities holding the Target’s assets, which will confer upon Cooper sole control over the Target.
- (5) The Transaction constitutes a concentration under Article 3(1)(b) of the Merger Regulation.

3. UNION DIMENSION

- (6) The undertakings concerned have a combined aggregate world-wide turnover of more than EUR 5 000 million (CVC: EUR [...] and the Target: EUR [...])⁶. Each of them has a Union-wide turnover in excess of EUR 250 million (CVC: EUR [...] and the Target: EUR [...]), but they do not achieve more than two-thirds of their aggregate Union-wide turnover within one and the same Member State. The Transaction therefore has a Union dimension.

4. COMPETITIVE ASSESSMENT OF THE HORIZONTAL OVERLAPS

- (7) Both Parties are active in the development, manufacture, and commercialisation of FDPs, giving rise to various horizontal overlaps as discussed below in Section 4.5 of this decision.

4.1. Legal framework

- (8) Article 2 of the Merger Regulation requires the Commission to examine whether notified concentrations are compatible with the internal market, by assessing

⁴ Viatriis was formed through the merger of Mylan and Upjohn in November 2020, which was cleared by the Commission on 22 April 2020 (case M.9517 – *Mylan / Upjohn*).

⁵ FDPs are pharmaceutical products that have undergone all stages of production, including packaging in the final container and labelling.

⁶ Turnover calculated in accordance with Article 5(1) of the Merger Regulation and the Commission Consolidated Jurisdictional Notice (OJ C95, 16.4.2008, p.1).

whether they would significantly impede effective competition in the internal market or in a substantial part of it.

- (9) A merger giving rise to a significant impediment of effective competition may do so as a result of the creation or strengthening of a dominant position in the relevant market(s). Moreover, mergers in oligopolistic markets involving the elimination of the important competitive constraints that the parties previously exerted on each other, together with a reduction of competitive pressure on the remaining competitors, may also result in a significant impediment to effective competition, even in the absence of dominance.
- (10) The Commission Guidelines on the assessment of horizontal mergers under the Merger Regulation (the “Horizontal Merger Guidelines”)⁷ describe horizontal non-coordinated effects as follows: “A merger may significantly impede effective competition in a market by removing important competitive constraints on one or more sellers who consequently have increased market power. The most direct effect of the merger will be the loss of competition between the merging firms. For example, if prior to the merger one of the merging firms had raised its price, it would have lost some sales to the other merging firm. The merger removes this particular constraint. Non-merging firms in the same market can also benefit from the reduction of competitive pressure that results from the merger, since the merging firms’ price increase may switch some demand to the rival firms, which, in turn, may find it profitable to increase their prices. The reduction in these competitive constraints could lead to significant price increases in the relevant market.”⁸
- (11) The Horizontal Merger Guidelines list a number of factors which may influence whether or not significant non-coordinated effects are likely to result from a merger, such as large market shares of the merging firms, the fact that the merging firms are close competitors, the limited possibilities for customers to switch suppliers, or the fact that the merger would eliminate an important competitive force.⁹ That list of factors applies equally regardless of whether a merger would create or strengthen a dominant position, or would otherwise significantly impede effective competition due to non-coordinated effects. Furthermore, not all of these factors need to be present for significant non-coordinated effects to be likely. The list of factors, each of which is not necessarily decisive in its own right, is also not an exhaustive list.¹⁰
- (12) Finally, the Horizontal Merger Guidelines describe a number of factors, which could counteract the harmful effects of the merger on competition, including the likelihood of buyer power, the entry of new competitors on the market, and efficiencies.

4.2. Overview of the Commission practice in relation to market definition for FDPs

- (13) To define relevant product markets for FDPs, the Commission typically takes into account the Anatomical Therapeutic Classification (“ATC”) of the European

⁷ OJ C 31, 5.2.2004, p. 5.

⁸ Horizontal Merger Guidelines, paragraph 24.

⁹ Horizontal Merger Guidelines, paragraphs 27 *et seq.*

¹⁰ Horizontal Merger Guidelines, paragraphs 24-38.

Pharmaceutical Marketing Research Association, starting at ATC3 level¹¹ where products are grouped by therapeutic indications i.e. their intended use. However, the Commission has recognised that it is sometimes necessary to carry out analyses at the narrower classification level ATC4,¹² or possibly even at the molecule level.¹³ The ATC classification covers both prescription-bound (“Rx”) and OTC-sold drugs.

- (14) For OTC-sold drugs, IQVIA¹⁴ also administers the Consumer Health Classification (“CHC”). With respect to this classification, the Commission typically uses CHC3 level (often similar to ATC3) as a starting point for relevant product market definition but narrower delineations are also considered (e.g., at CHC4 level (often similar to ATC4) or by molecule).¹⁵
- (15) In some instances, the Commission has also considered wider than ATC3 or CHC3 level markets or observed that a particular ATC class is in fact not a suitable starting point for market definition.¹⁶
- (16) For FDPs, the Commission has consistently defined relevant markets at national level.¹⁷
- (17) The market investigation did not provide any indications that would require the Commission to depart from its previous decisional practice on the geographic scope of the different plausible markets for FDPs. Therefore, for the purposes of this decision, the Commission considers the geographic scope of the different plausible markets for FDPs to be national in scope.

4.3. Methodology for the identification and the assessment of affected markets

- (18) To identify the affected markets that the Transaction gives rise to in relation to FDPs, the Notifying Party has used IQVIA data.¹⁸ For those countries not covered by the IQVIA MIDAS data, namely Malta, Iceland, Liechtenstein and Cyprus, and the countries not covered in IQVIA CHC data, namely Luxembourg and Sweden, the Parties compared their sales and concluded there was no overlap between their

¹¹ The ATC3 level classification is narrower than ATC1 and ATC2 level classifications. At ATC1, drugs are divided into 16 anatomical main groups. At ATC2, drugs are divided at pharmacological or therapeutic groups.

¹² The ATC4 level classification is generally the most detailed (although not available for all ATC3 classes) and refers, for instance, to the mode of action or any other subdivision of the relevant products.

¹³ See e.g. M.10247 - *CVC / Cooper*, Decision of 22 October 2021, paragraph 7.

¹⁴ IQVIA is an American multinational company serving the combined industries of health information technology and clinical research, formerly Quintiles and IMS Health, Inc.

¹⁵ See e.g. M.10247 - *CVC / Cooper*, Decision of 22 October 2021, paragraph 7.

¹⁶ See e.g. M.7975 – *Mylan / Meda*, Decision of 20 July 2016, paragraph 219 and M.7559 – *Pfizer / Hospira*, Decision of 4 August 2015, paragraph 239.

¹⁷ See e.g. M.10247 - *CVC / Cooper*, Decision of 22 October 2021, paragraphs 41-43.

¹⁸ More specifically, the Notifying Party obtained IQVIA data from the two databases covering European pharmaceutical sales, namely: (i) the "Midas" IQVIA sales database, which covers Rx and some OTC pharmaceuticals categorised using ATC categories; and (ii) the "Consumer Health" IQVIA sales database, which covers not only OTC pharmaceuticals with drug status, but also a broader range of OTC healthcare products including nutrition, personal care and patient care categorised using CHC categories. In addition, the Notifying Party also acquired data on sales of pharmaceuticals and OTC products in Denmark from DLI (part of the Danish Pharmaceutical Industry Organisation), as the Consumer Health IQVIA license did not give access to data for Denmark.

products.¹⁹ In addition, for some of the product markets the Notifying Party has also supplemented the IQVIA data with their own market knowledge.

- (19) In accordance with the Commission's decisional practice²⁰ in respect of pharmaceutical transactions with a large number of affected markets (involving numerous product and geographic markets), the Commission has grouped the affected markets as presented below in Table 1.

Table 1: Market Categorisation in FDPs

Group Category	Description
Group 1	Parties' combined share (in volume/value) exceeds 35% and the increment exceeds 1%.
Group 1+	(i) Parties' combined share (in volume/value) <35% but only one competitor remains in the market; or (ii) Parties' combined share >35% and the increment is <1% but the party with the smaller increment is a recent entrant.
Group 2	Parties' combined share (in volume/value) >35% but the increment is <1%.
Group 3	Parties' combined share (in volume/value) is 20%-35%.

- (20) Table 2 below summarises the number of affected markets based on ATC3/CHC3, ATC4/CHC4 or molecule in each market category as presented in Table 1 above. These markets do not necessarily correspond to plausible product markets as further discussed in the relevant market definition sections.

Table 2: Summary of affected markets based on ATC/CHC classifications

ATC/CHC level	Affected markets	Group 1/1+ Markets	Group 2 Markets	Group 3 Markets
ATC3/CHC3	38	17	4	17
ATC4/CHC4	35	16	4	15
Molecule	9	5	1	3
Total	82	38	9	35

Source: Form CO, Table 1.

- (21) The Group 1/1+ affected markets based on ATC/CHC classifications are presented in Table 3 below. The Group 2 and 3 markets affected based on ATC/CHC classifications are provided in Appendix 1.

Table 3: Overview of horizontally affected markets based on ATC/CHC classifications (Group 1/1+)

Product category	Group	Country	Affected at ATC3/CHC3 level	Affected at ATC4/CHC4 level	Affected at molecule level
Antiseptics and disinfectants	1 / 1+	Belgium	✓ (D8A)		
Antiseptics and disinfectants	1 / 1+	France	✓ (D8A) ✓ (06B2) ✓ (06B3)	✓ (06B3L) ✓ (06B3O)	
Antiseptics and disinfectants	1 / 1+	Italy	✓ (06B3)	✓ (06B3L)	
Antiseptics and disinfectants	1 / 1+	Luxembourg	✓ (D8A)		
Prostate products	1 / 1+	Belgium	✓ (12F1)	✓ (12F1C)	
Tonics	1 / 1+	France	✓ (A13A) ²¹		

¹⁹ Form CO, paragraphs 92-100.

²⁰ See e.g. M.10247 - *CVC / Cooper*, Decision of 22 October 2021, paragraph 11.

²¹ A13A in France will not be a Group 1 affected market going forward as Cooper's G.C. Form product was discontinued in December 2022. Therefore, this market is not further considered in this decision.

Product category	Group	Country	Affected at ATC3/CHC3 level	Affected at ATC4/CHC4 level	Affected at molecule level
Tonics	1 / 1+	Portugal	✓ (05A1)*		
Tonics	1 / 1+	Spain			✓ (A13A2- Arginine) ²² ✓ (05A1M - Arginine) ²³
Wart/ corn removal products	1 / 1+	France	✓ (06L1)	✓ (06L1Z)	
Antiparasitic haircare products	1 / 1+	France	✓ (86H1)	✓ (86H1B)	
Drugs for constipation	1 / 1+	France		✓ (A6A9) ✓ (03C2S)	
Drugs for constipation	1 / 1+	Luxemburg		✓ (A6A6)*	
Drugs for constipation	1 / 1+	Portugal	✓ (A6A)	✓ (A6A4)	
Drugs for constipation	1 / 1+	Spain	✓ (A6A) ✓ (03C1)	✓ (A6A6)* ✓ (03C1P)	
Earwax removal products	1 / 1+	Germany	✓ (S2D)	✓ (S2D1)	
Mouthwash for halitosis	1 / 1+	Italy		✓ (87B3G)	
Topical products for joint and muscular pain	1 / 1+	Italy			✓ (M2A0 – Escin/Salicylic Acid)* ✓ (02E1O – Escin/Salicylic Acid)*
Topical products for joint and muscular pain	1 / 1+	Portugal		✓ (02E1K)	
Magnesium supplements	1 / 1+	Luxemburg	✓ (A12C)	✓ (A12C1)	✓ (A12C1 - Magnesium)
Liver disorder products, hepatic protectors and lipotropics	1 / 1+	Portugal	✓ (A5B)*		

Source: Form CO, Table 3.

Notes: *According to the Commission's assessment these markets do not constitute a plausible product market for the purposes of this case and are therefore not further discussed in the decision. Please see the relevant sections in Section 4.5. for further explanations.

- (22) The product market definitions and competitive assessment for the Group 1/1+ markets are discussed below.
- (23) The Notifying Party considers value-based market shares to be an appropriate indicator of the structure and competitive dynamics of the relevant markets and notes that where the relevant market includes multiple pack sizes, molecules and galenic forms, volume shares based on packets sold do not adequately reflect the position of the Parties and their competitors. Moreover, according to the Notifying Party there is no single volume unit that could be used to compare the sales of the

²² A13A2 (molecule level) in Spain will not be a Group 1A+ market going forward as Recordati's Sorbenor product was discontinued in July 2021. Therefore, this market is not further considered in this decision.

²³ 05MA1M (molecule level) in Spain will not be a Group 1A+ market going forward as Recordati's Sorbenor product was discontinued in July 2021. Therefore, this market is not further considered in this decision.

products concerned in any meaningful way.²⁴ However, the feedback received by market participants has been mixed, with the majority of respondents to the Commission’s market investigation arguing that both volume-based and value-based metrics should be taken into consideration to duly assess the competitive dynamics of the OTC markets.²⁵ Therefore, in its assessment, the Commission has considered market shares both based on sales value and volume in 2022. Nevertheless, as further explained in the relevant sections, the outcome of the Commission’s assessment remains the same based on both value- and volume-based market shares.

4.4. Competitive assessment of Group 2 and 3 markets

- (24) In line with the Commission’s previous decisional practice,²⁶ the product market definitions of Group 2 and 3 markets are not individually discussed in detail.
- (25) For all of the Group 2 and Group 3 markets, the market shares of the Parties are limited, significant competitors remain on the market post-Transaction that will likely sufficiently constrain the merged entity and/or the Transaction brings about only a limited increment. In addition, the market investigation did not reveal any concerns in relation to any of the Group 2 and 3 affected markets.
- (26) The Commission assessed the competitive situation on these markets analysing the nature and the number of existing competitors and considered that the Transaction does not raise serious doubts as to its compatibility with the internal market or the functioning of the EEA agreement as a result of horizontal effects in any of those markets. Consequently, in line with previous decisions,²⁷ Group 2 and Group 3 overlaps will not be assessed any further in the present decision.

4.5. Assessment of the Group 1/1+ markets

4.5.1. Drugs for constipation in Portugal, Spain and France

4.5.1.1. Product market definition

- (27) The ATC3 class A6A comprises a variety of Rx and OTC drugs used for the treatment of constipation (“laxatives”), which are divided into ATC4 categories depending on their laxative action.²⁸
- (28) Under the CHC classification, the CHC3 class 03C1 covers fibre laxatives, which is similar to the ATC4 class A6A3 bulk-forming laxatives,²⁹ and the CHC4 class 03C1P is a subsegment of this class covering fibre laxatives in powder form. The CHC3 class 03C2 on the other hand covers osmotic laxatives, which is similar to the ATC4 class A6A7 osmotic laxatives (excluding saline), and the CHC4 class

²⁴ Form CO, paragraph 104.

²⁵ See Response to Questionnaire 1 to Competitors, Question N.1-2.

²⁶ See for example e.g. M.10247 - CVC / Cooper, Decision of 22 October 2021, paragraph 14.

²⁷ See for example Commission decision M.10247 - CVC / Cooper, dated 22 October 2021, paragraph 50.

²⁸ The ATC4 classes are faecal softening laxatives (A6A1), stimulant laxatives (A6A2), bulk-forming laxatives (A6A3), enemas (A6A4), osmotic laxatives with electrolytes (A6A7) and laxatives without electrolytes (A6A6). The ATC4 class A6A9 (other drugs for constipation) consists of other drugs for constipation and combinations of laxatives not classified in A6A1-A6A7, including glycerol and effervescent suppositories.

²⁹ Form CO, paragraph 336.

03C2S is a subsegment of this class covering osmotic laxatives in the form of suppositories.

- (29) The Commission has in the past considered that the relevant market for drugs for constipation should be defined at the ATC3 (class A6A).³⁰ In other cases where drugs for constipation were analysed, the Commission similarly found that products in the ATC4 classes of A6A are interchangeable to some degree, while ultimately leaving open the questions of whether the market should be defined at the ATC4 or ATC3 level,³¹ the distinction between Rx and OTC,³² and the distinction according to galenic forms (e.g. tablets, liquids, suppositories).³³ In cases where the Commission investigated further segmentation according to individual molecule, it was found that such a distinction is not relevant.³⁴ The Commission has not previously investigated whether there is a market for constipation drugs for infants distinct from a market for constipation drugs for adults.
- (30) According to the Notifying Party the appropriate level at which to conduct the competitive assessment is the ATC3 class A6A (drugs for constipation). The Notifying Party recognises that drugs for constipation can be differentiated across different dimensions such as the mode of actions (bulk-forming, osmotic and stimulant laxatives) or based on the route of administration (oral vs rectal). However, it submits that these different dimensions should be taken into account in the competitive assessment carried out at the ATC3/CHC3-level, not as indications of the existence of separate relevant product markets.³⁵
- (31) The results of the Commission's market investigation generally suggest a degree of substitutability between all drugs for constipation, with some exceptions as described in the following.
- (32) *First*, with respect to laxatives with different modes of action (bulk-forming/fibre, osmotic or stimulant), the investigation suggests that there is a certain degree of substitutability between such laxatives. Specifically, the majority of the respondents to the market investigation consider constipation drugs to be substitutable to some degree regardless of their mode of action.³⁶ For example one competitor explained that bulk-forming, osmotic and stimulant laxatives are “*substitutable in most cases, unless there are patient intolerances or preferences and/or medical contraindications (e.g. if the type of laxative interferes with the action of another medication taken by the consumer)*”.³⁷ Another competitor also considers that: “*in general all laxatives (regardless of the mode of action or route*

³⁰ See for example M.7919 – *Sanofi/Boehringer Ingelheim Consumer Healthcare Business*, Decision of 4 August 2016, paragraphs 204-209; M.3853 – *Solvay/Fournier*, Decision of 18 July 2005, paragraphs 16 – 18.

³¹ See M.6280 – *Procter&Gambler/Teva*, Decision of 30 September 2011, paragraph 19.

³² See M.7919 – *Sanofi/Boehringer Ingelheim Consumer Healthcare Business*, Decision of 4 August 2016, paragraphs 204 – 209.

³³ *Ibid.*

³⁴ See M.7919 – *Sanofi/Boehringer Ingelheim Consumer Healthcare Business*, Decision of 4 August 2016, paragraphs 204 – 209; M.7379 - *Mylan / Abbott EPD-DM*, Decision of 28 January 2015, paragraphs 200 – 203.

³⁵ Form CO, paragraph 252 *et seq.*

³⁶ Responses to questions E.A.1, F.A.1 and H.A.1 of the questionnaire to Customers; responses to question C.A.1 of the questionnaire to Competitors.

³⁷ Response to question C.A.1 of the questionnaire to Competitors.

*of administration) compete with one another to a certain extent.”*³⁸ In relation to osmotic laxatives specifically, the Commission notes that these are included both in ATC4 class A6A6 - osmotic laxative without electrolytes and class A6A7 - osmotic laxatives with electrolytes. Nothing in the Commission’s past decisions and investigation in this case suggested that such a distinction is relevant for the purposes of defining a relevant product market, and therefore these two classes are combined to form a plausible market for all osmotic laxatives.³⁹

- (33) However, there appears to be a relatively lower level of substitutability when it comes to stimulant laxatives, as they act faster and are therefore used in more urgent situations. A competitor explains for example:⁴⁰ *“Generally, if a consumer is operating in a more preventative mode and does not require an immediate relief, it will use a bulk or an osmotic laxative (as these take a longer time to work). On the other hand, in case of an emergency, a consumer will typically opt for a stimulant laxative.”*
- (34) In any case, the question of whether laxatives with different modes of action form separate product markets may be left open as the Transaction does not give rise to concerns under any of the narrower plausible product markets for laxatives with specific forms of action.
- (35) *Second*, with respect to laxative products with different routes of administration (oral vs rectal) and in different galenic forms (e.g. liquids, capsules, suppositories), the results of the Commission’s market investigation suggest that there is a higher degree of substitutability for adult patients, but a lower degree in case of infant patients.
- (36) In relation to adult patients, the majority of the respondents to the market investigation consider that at least for some patients, laxatives with different routes of administration and with different galenic forms are substitutable, but explain that the level of substitutability may depend on the specificities of the case.⁴¹ For example, some competitors explain: *“Depending of the constipation’s severity is [sic] possible to use different kind of solutions. In that way we consider that products can be direct competitors despite, different galenic forms, or different forms of administration.”* and *“While rectal and oral laxatives may be substitutable to some degree, the choice between them depends on factors such as the speed of onset desired, convenience, effectiveness, and individual preferences.”*⁴² Respondents to the market investigation have also confirmed that bulk-forming laxatives in the form of powder are substitutable with bulk-forming laxatives in other forms (e.g. capsules).⁴³ In any case, the question of whether adult laxatives

³⁸ Non-confidential minutes from a call held with a competitor on 2 February 2024.

³⁹ As indicated in Table 3, Group 1/1+ affected markets arise in Spain and in Luxembourg based on the overlap at the A6A6 level. As described, the Commission considers A6A6 and A6A7 combined (as opposed to A6A6 alone) as an appropriate plausible product market for the purposes of this case. Spain, the Transaction gives rise to an affected market at the level of A6A6 and A6A7 combined, which is therefore further discussed in Section 4.5.1.2.2. In Luxembourg, the Transaction does not give rise to an affected market at the level of A6A6 and A6A7 combined, which is therefore not further discussed in this decision.

⁴⁰ Non-confidential minutes from a call held with a competitor on 2 February 2024.

⁴¹ Responses to questions E.A.2, E.A.4, F.A.2-F.A.5, H.A.2-H.A.5 of the questionnaire to Customers; responses to questions C.A.2, C.A.3, C.A.6 and C.A.7 of the questionnaire to Competitors.

⁴² Responses to question C.A.3 of the questionnaire to Competitors.

⁴³ Regarding potential further segmentation of bulk-forming laxatives, the majority of the respondents of the Commission’s market investigation consider bulk-forming laxatives in the form of powder to

with different routes of administration and galenic forms constitute separate product markets can be left open as the Transaction does not give rise to concerns under any of the narrower plausible product markets for adult laxatives with specific routes of administration and galenic forms.

- (37) In relation to infant patients, several respondents have indicated that the level of substitutability between laxatives with different routes of administration and even galenic forms is more limited. Specifically, rectal administration is often perceived as more convenient for infants compared to oral administration. For example, a competitor explains: *“For example, in infants constipation the preferential application shall be enemas and suppositories, and for an adult colonoscopy exam it shall be used an oral osmotic/stimulant laxative.”*⁴⁴ In addition, the market investigation results suggest that there may be certain circumstances of infant constipation in which rectal laxatives specifically in the galenic form of enemas are more suitable.⁴⁵ As a competitor has explained: *“alternatives to laxative enemas for adults and older children include rectal laxatives in other forms such as suppositories, as well as oral laxatives in some cases. However, for infants and young children, laxative enemas may be the preferred option in certain situations where other forms of laxatives are not suitable or effective”*.⁴⁶ Also, while the Notifying Party submits that there should be no distinction between enemas and other laxatives for infants, the information submitted in the Form CO similarly suggests that there are certain situations in which only enemas may be suitable: *“whilst both suppositories and enemas are laxatives administered rectally, enemas are used for urgent situations due to their anal sphincter stimulation”*.⁴⁷ Therefore, the Commission considers that there exists a plausible product market for laxative enemas suitable for infants.
- (38) In any case, the precise product market definition can be left open because the Transaction, as modified by the Final Bebegel Commitments (see Section 6.2.), does not give rise to concerns under any plausible product market definition.

4.5.1.2. Competitive assessment

4.5.1.2.1. Portugal

- (39) The Parties’ activities result in Group 1/1+ affected markets for drugs for constipation in Portugal both at the ATC3 level (A6A – drugs for constipation) and at the narrower ATC4 level (A6A4 – laxative enemas). In addition, as discussed above, there appears to be a plausible separate market for laxative enemas for infants, in which the Parties’ activities also give rise to a Group 1/1+ affected market.
- (40) Table 4 below provides an overview of the drugs for constipation provided by the Parties belonging to Group 1/1+ affected markets in Portugal.

be substitutable to some degree with bulk-forming laxatives in other forms (e.g. capsules) (responses to questions C.A.4. and C.A.5 of the questionnaire to Competitors.

⁴⁴ Responses to question C.A.3 of the questionnaire to Competitors.

⁴⁵ Response to questions C.A.3 and C.A.7 of the questionnaire to Competitors.

⁴⁶ Response to question C.A.7 of the questionnaire to Competitors.

⁴⁷ Form CO, paragraph 293-294.

Table 4: An overview of the Parties' constipation drugs belonging to Group 1/1+ affected markets in Portugal

Party	Product Name	Molecule	Mode of Action	Route of administration	Galenic form	Group 1/1+ affected market
Target	Agiolax	Plantago Ovata, Senna	Combination of a bulk forming and a stimulant laxative	Oral	Granules, powder	A6A
Target	Bebegel	Gelatin, Glycerol	Rectal gel with osmotic laxative action	Rectal	Enema	A6A, A6A4, Laxative enemas suitable for infants
Target	Duphalac	Lactulose	Osmotic laxative	Oral	Syrup, oral powder for oral solution, oral solution	A6A
Target	Molaxole	Macrogol(S), Potassium, Sodium	Osmotic laxative	Oral	Powder for oral solution	A6A
Recordati	Casenlax	Macrogol(S)	Osmotic laxative	Oral	Powder for oral solution, liquid	A6A
Recordati	Microlax	Phosphoric Acid	Lubricant laxative	Rectal	Enema	A6A, A6A4, Laxative enemas suitable for infants
Recordati	Enema Casen	Citric Acid, Dodecyl Sulfoacetic Acid	Laxative enema that softens stool	Rectal	Enema	A6A, A6A4

Source: Form CO, Table 19 and Annex 8.1-XI.

- (41) Tables 5 and 6 below provide the market shares of the Parties and their main competitors in the Group 1/1+ affected markets in Portugal for 2022, in value and in volume.

Table 5: The Parties' and competitors' market shares in Group 1/1+ affected markets for drugs for constipation in Portugal, 2022, in value

	A6A – Drugs for constipation	A6A4 – Laxative Enemas	A6A4 – Laxative Enemas for infants
Target (Duphalac, Agiolax, Molaxole, Bebegel (enema))	15.0%	22.5%	76.7%
CVC - Recordati (Casenlax, Microlax (enema), Enema Casen (enema))	25.5%	68.2%	6.6%
Combined	40.5%	90.7%	83.3%
Ferraz Lynce (Laevolac)	13.2%	-	-
Norgine (Movicol, Normacol Plus)	12.6%	-	-
Sanofi (Dulcolax, Totalaxan)	10.7%	-	-
Faes Farma (Forlax, Bekunis, Bekunis CHA 0)	5.2%	-	-
Prospa (Clyss-GO (enema))	1.9%	6.7%	-
Phytoderm (Melilax Pediatric (enema))	-	-	16.7%
Others	15.9%	2.6%	-
Total	100%	100%	100%

Source: Form CO, Annex 8.1-I and Table 27.

Table 6: The Parties' and competitors' market shares in Group 1/1+ affected markets for drugs for constipation in Portugal, 2022, in volume

	A6A – Drugs for constipation	A6A4 – Laxative Enemas	A6A4 – Laxative Enemas for infants
Target (Duphalac, Agiolax, Molaxole, Bebegel (enema))	34.1%	32.1%	86.4%
CVC - Recordati (Casenlax, Microlax (enema), Enema Casen (enema))	8.4%	63.0%	5.1%
Combined	42.5%	95.1%	91.5%
Ferraz Lynce (Laevolac)	12.7%	-	-
Norgine (Movicol, Normacol Plus)	8.6%	-	-
Sanofi (Dulcolax, Totalaxan)	10.4%	-	-
Faes Farma (Forlax, Bekunis, Bekunis CHA 0)	8.2%	-	-
Prospa (Clyss-GO (enema))	0.1%	1.8%	-
Phytoderm (Melilax pediatric (enema))	-	-	8.5%
Others	17.5%	3.2%	-
Total	100%	100%	100%

Source: Form CO, Annex 8.1-I and Table 27.

4.5.1.2.1.1. ATC3 class A6A – Drugs for constipation in Portugal

- (42) Prior to the Transaction, both Parties supply various constipation drugs in Portugal. More specifically, the Target is supplying Duphalac, Agiolax, Molaxole and Bebegel, whereas Recordati (CVC) is supplying Casenlax, Microlax and Enema Casen (see Tables 5 and 6 above). In this market, the Parties' combined market share is 40.5% in value (or 42.5% in volume), with an increment of 15.0% in value (or 8.4% in volume).
- (43) According to the Notifying Party, the Transaction will not result in any competition concerns. The Notifying Party submits that the Parties' products are not close substitutes because they are largely based on different active ingredients, have different routes of administration and modes of action and/or are indicated for different patient groups.⁴⁸
- (44) Among the Parties' products, the products with the highest shares are Recordati's Microlax (18.5% in value) and the Target's Bebegel (6.5% in value). While both of these products are administered rectally, the Notifying Party highlights that these products are not close substitutes as Bebegel is indicated for infants and breastfeeding or pregnant mothers whereas Microlax and Enema Casen are not suitable for this population (apart from Lactentes & Crianças version of Microlax, which is discussed below in the context of laxative enemas for infants).⁴⁹
- (45) According to the Notifying Party, the merged entity will also continue to face a number of strong competitors present in the A6A class including Ferraz Lynce (13.2% in value), Norgine (12.6% in value) and Sanofi (10.7% in value).
- (46) Based on the Commission's assessment the Transaction does not raise competition concerns in relation to the ATC3 class A6A in Portugal in light of the following factors.

⁴⁸ Form CO, paragraphs 315-316.

⁴⁹ Form CO, paragraph 316.

- (47) *First*, the Parties' products do not appear to be close competitors for the following reasons. Firstly, nearly all of the Parties' products are based on different active pharmaceutical ingredients ("API"s) and have different routes of administration as indicated in Table 4 above. Secondly, in cases where products have the same route of administration, they are differentiated along other characteristics. Specifically: (i) of the 3 overlapping products administered rectally, the Target's Bebegel is indicated for infants and pregnant/breastfeeding mothers whereas Microlax and Enema Casen are generally not suitable for this population (see also Section 4.5.1.2.1.3. below); and (ii) of the 4 overlapping products administered orally, all have different modes of action and/or APIs.
- (48) *Second*, the Parties will continue facing competition from a large number of competitors, including 3 competitors with a value market share of above 10%, namely Ferraz Lynce, Norgine, and Sanofi. This is also reflected in some of the responses to the market investigation. For example, a customer explained: "*There are more than 50 alternative laxative products from different brands*"⁵⁰ and a competitor: "*It is a very large market with 78 companies present, with 156 brands.*"⁵¹
- (49) *Third*, the market investigation confirmed that the overall market for constipation drugs in Portugal is and will remain competitive post-Transaction. In particular, virtually all of the respondents to the market investigation confirmed that consumers in Portugal will continue to have access to a sufficient number of alternative constipation drugs post-Transaction.⁵²
- (50) *Fourth*, the large majority of respondents to the market investigation consider that the Transaction will have a positive or neutral impact on the laxative market in Portugal.⁵³
- (51) Considering the above, the Commission does not consider that the Transaction would raise any serious doubts as to its compatibility with the internal market or the functioning of the EEA agreement as a result of the ATC3 class A6A overlap in Portugal.

4.5.1.2.1.2. ATC 4 class A6A4 – Laxative Enemas in Portugal

- (52) Prior to the Transaction both Parties supply laxative enemas in Portugal as the Target is supplying Bebegel and Recordati is supplying Microlax and Enema Casen. In this market, the Parties' combined market share is 90.7% in value (or 95.1% in volume), with an increment of 22.5% in value (or 32.1% in volume).
- (53) The Notifying Party submits that the overlap in the Parties' laxative enemas in Portugal will not result in any competition concerns because, as already described above, the Parties' products are targeting different patient groups. The Target's Bebegel is mostly used for the treatment and preparation of infants and babies (as well as breastfeeding or pregnant mothers), which is reflected in the product's

⁵⁰ Response to question F.A.7 of the questionnaire to Customers.

⁵¹ Response to question C.C.2 of the questionnaire to Competitors.

⁵² Responses to question F.A.7 of the questionnaire to Customers; and responses to question C.C.2 of the questionnaire to Competitors. Non-confidential minutes from a call held with a competitor on 2 February 2024.

⁵³ Responses to question J.3 of the questionnaire to Customers; and responses to question O.3 of the questionnaire to Competitors.

name, packaging and easy-to-use form (in a single dose cannula).⁵⁴ Recordati's Microlax and Enema Casen on the other hand are not suitable for this population (with the exception of Lactentes & Crianças version of Microlax, which represents a limited part of Microlax's overall sales).⁵⁵

- (54) Despite the high combined market shares, the Commission finds that the overlap between the Parties' products in laxative enemas in Portugal does not raise competition concerns.
- (55) *First*, as discussed above in Section 4.5.1.1, for the adult population, there appears to be substitutability between and within oral and rectal laxatives. Therefore, laxative enemas, at least for the adult population, face competitive pressure from other rectal laxatives (i.e. suppositories) as well as other oral laxatives.
- (56) *Second*, even in the narrower plausible market for laxative enemas, the Parties' products do not appear to offer close alternatives, as Bebegel on one hand is intended for infants and pregnant/breastfeeding mothers, while Microlax (apart from Microlax Lactentes & Crianças discussed in Section 4.5.1.2.1.3. below) and Enema Casen on the other are not suitable for this population. The products therefore target different patient groups and hence do not appear to be closely competing with one another.
- (57) *Third*, the above is confirmed by the results of the market investigation. In particular, when asked to list the closest alternative to Microlax and Enema Casen in Portugal, none of the responding competitors listed Bebegel.⁵⁶ In fact, the majority of the respondents listed rectal laxatives in forms other than enemas (e.g. suppositories and rectal gels), further confirming that laxative enemas, at least for the adult population, face competitive pressure from other rectal laxatives.
- (58) *Fourth*, no respondent to the market investigation has raised concerns in relation to the overlap resulting from the Transaction in laxative enemas. On the contrary, the majority of the respondents confirm that a sufficient number of alternative laxative enemas will remain available in Portugal post-Transaction.⁵⁷
- (59) *Fifth*, the large majority of respondents to the market investigation consider that the Transaction will have a positive or neutral impact on the laxative market in Portugal, with no indication that this would differ specifically in relation to laxative enemas in Portugal.⁵⁸
- (60) Considering the above, the Commission does not consider that the Transaction would raise any serious doubts as to its compatibility with the internal market or the functioning of the EEA agreement as a result of the overlap regarding laxative enemas in Portugal.

⁵⁴ Form CO, paragraph 270.

⁵⁵ Recordati estimates that the sales of Microlax Lactentes & Crianças that were EUR [...] out of total Microlax sales of EUR 3,643,088 in 2022 (Form CO, paragraph 309, footnote 165 and paragraph 322).

⁵⁶ Responses to question C.C.1 of the questionnaire to Competitors.

⁵⁷ Responses to question F.A.7 of the questionnaire to Customers; and responses to question C.C.2 of the questionnaire to Competitors. Non-confidential minutes from a call held with a competitor on 2 February 2024

⁵⁸ Responses to question J.3 of the questionnaire to Customers; and responses to question O.3 of the questionnaire to Competitors.

4.5.1.2.1.3. Laxative Enemas for infants in Portugal

- (61) Prior to the Transaction both Parties supply laxative enemas suitable for infants as the Target is supplying Bebegel and Recordati is supplying Microlax Lactentes & Crianças, which is a version of Microlax suitable for infants and breastfeeding or pregnant mothers. In this market the Parties' combined market share is 83.3% in value (or 91.5% in volume) with an increment brought by Recordati of 6.6% in value (or 5.1% in volume).
- (62) According to the Notifying Party no distinction should be made between enemas and other laxatives for infants. The Notifying Party has submitted that the substitutability between enemas and other forms of laxatives is evidenced, for example, by the fact that enemas are less commonly used in certain other EEA countries where instead other forms of laxatives are more common. The Notifying Party has stated that the market position of the laxative enemas in Portugal is not due to these products' lack of substitutability with other laxative forms, but is rather due to a particular set of circumstances and preferences in Portugal.⁵⁹
- (63) The Notifying Party submits that post-Transaction sufficient alternatives will remain available to treat infant constipation in Portugal and that laxative enemas for infants will continue to be constrained by infant laxative products in other forms.⁶⁰ In addition, the Notifying Party submits that the merged entity will face sufficient competitive constraints from potential market entrants.⁶¹
- (64) As described above the Commission considers there to be a plausible market for laxative enemas for infants. While enemas may be used less frequently in other EEA countries as submitted by the Notifying Party, the Commission notes that the relevant geographical scope of the laxative markets is national. The differences in the preferences regarding specific laxative forms show that the conditions of competition vary across different EEA countries and that in Portugal there appears to be a clear preference for infant laxatives which are in the form of enemas. Moreover, as has been described in further detail above in paragraph 37 of Section 4.5.1.1., in certain circumstances enemas do not appear to be substitutable with other forms of infant laxatives.
- (65) For the reasons set out below, the Commission considers that the Transaction raises serious doubts as to its compatibility with the internal market with respect to this plausible market for laxative enemas for infants in Portugal.
- (66) *First*, the Parties are strong providers of laxative enemas suitable for infants in Portugal. As noted above, the Parties' combined market share in the plausible market for laxative enemas for infants is high at 83.3% based on value and 91.5% based on volume, which is significantly above the presumption of dominance threshold set forth by paragraph 17 of the Horizontal Merger Guidelines. In addition, the Transaction results in a non-negligible increment of 6.6% based on value and 5.1% based on volume.
- (67) *Second*, in addition to the merged entity only Phytoderm (with its product Melilax Pediatric) would remain active in the market for laxative enemas for infants post-

⁵⁹ The Notifying Party's submission on infant laxative products in Portugal, dated 28 May 2024.

⁶⁰ Form CO, paragraphs 293-298 and 306-308.

⁶¹ Form CO, paragraphs 300-304.

Transaction, as confirmed by the market investigation. Therefore, the Transaction would reduce the number of competitors from three to two in this market. In addition, the market share of Phytoderm's Melilax Pediatric would be significantly smaller compared to that of the merged entity (16.7% in value and 8.5% in volume), and therefore Melilax Pediatric would be unlikely to sufficiently constrain the merged entity post-Transaction.

- (68) *Third*, further entry into the Portuguese infant laxative enemas market does not appear to be likely, timely and sufficient to deter or defeat any potential anti-competitive effects of the merger based on the market feedback received.
- (69) In relation to potential entry from suppliers of adult laxative enemas in Portugal, the Notifying Party explains that the process to obtain the necessary clinical data and the regulatory approvals could take up to 3.5 years.⁶² The market investigation results further confirmed that launch of a new laxative product is not a straightforward process, and its timeline and success may depend on a variety of factors.⁶³ Respondents for example explain that: *“Launching a new laxative product involves navigating multiple challenges, including chemical complexity, intellectual property considerations, regulatory requirements, and market competition. Manufacturers must invest significant resources in research and development, regulatory compliance, and marketing to successfully bring a new product to market.”* and *“Launching a new laxative product involves various factors that can influence the ease or difficulty of entry into the market. While it's true that laxatives may not face as many barriers as some other pharmaceutical products, there are still significant considerations to take into account: Chemical Complexity, Intellectual Property (IP) Rights, Regulatory Requirements, Market Competition, Consumer Perceptions and Preferences.”*⁶⁴ Such entry therefore does not appear sufficiently timely nor likely.
- (70) In relation to potential entry from suppliers providing laxative enemas for infants in other EEA countries, the Notifying Party explains that a player would require a marketing authorisation from the Portuguese Health Authority, which could take up to 3.5 years.⁶⁵ The market investigation confirm that such entry is not straightforward and not sufficiently timely. While the respondents to the market investigation explained that for products already registered in another EEA country the process for registration in Portugal is relatively easier, the necessary timeline is estimated to exceed two years. Respondents for example explained that: *“It takes sometime to get the necessary AIMs from the Portuguese authorities [sic]. It may not be possible in two years time.”* and *“In general terms, a product not (already) authorised in Portugal will take at least 3 years to obtain marketing authorisation and start the commercialization”*.⁶⁶
- (71) In addition, the market participants explain that the economic realities of the laxative market in general and laxative enemas for infants in Portugal specifically, may deter further entry into these markets. In relation to laxative enemas for infants in Portugal, in particular the relatively small total market size of this market (EUR

⁶² Notifying Party's response to RFI 4 of 27 March 2024.

⁶³ Responses to question C.B.3 of the questionnaire to Competitors.

⁶⁴ Responses to question C.B.3 of the questionnaire to Competitors.

⁶⁵ Notifying Party's response to RFI 4 of 27 March 2024.

⁶⁶ Responses to question C.C.4 of the questionnaire to Competitors.

1.7 million in 2022),⁶⁷ coupled with the Parties' strong position, means that further entry is unlikely. One respondent for example explained: *"In addition the number of competitors, market size and local regulatory requirements are also barriers in the product launch definition."*, *"Launching a new laxative product involves navigating multiple challenges, including [...] market competition."* and *"With a range of alternative laxatives and generic forms of many of the well established products in the market already, development of new IP and successful commercial launch, relying on sufficient differentiation or competitive pricing makes it very difficult."*⁶⁸

- (72) *Fourth*, the market investigation did not provide any other indication of the merged entity facing any other source of competitive pressure post-Transaction.
- (73) In light of the above considerations, taking into account the market investigation and all the evidence available to it, the Commission considers that the Transaction raises serious doubts as to its compatibility with the internal market as regards the plausible market for the supply of laxative enemas for infants in Portugal.

4.5.1.2.2. Spain

- (74) The Parties' activities result in Group 1/1+ affected markets for drugs for constipation in Spain in the following plausible markets: ATC3 class A6A – drugs for constipation, OTC3 class 03C1 – Fibre laxatives, combined ATC4 classes A6A6 and A6A7 – Osmotic laxatives (with electrolytes)⁶⁹ and a narrower OTC4 class 03C1P – Fibre laxatives in powder form.
- (75) Table 7 below provides an overview of the drugs for constipation provided by the Parties belonging to Group 1/1+ affected market in Spain.

⁶⁷ Form CO, Table 27.

⁶⁸ Responses to question C.B.3 of the questionnaire to Competitors.

⁶⁹ ATC4 class A6A6 includes osmotic laxative without electrolytes, while ATC4 class A6A7 includes osmotic laxatives with electrolytes. Given that nothing in the Commission's past decisions and investigation in this case suggested that such a distinction is relevant for the purposes of defining a relevant product market, these two classes are combined for the purposes of identifying plausible affected Group 1/1+ markets.

**Table 7: An overview of the Parties' constipation drugs belonging to
Group 1/1+ affected markets in Spain**

Party	Product Name	Molecule / API	Mode of Action	Route of administration	Galenic form	Group 1/1+ affected markets
Target	Agiocur	Plantago Ovata	Bulk forming laxative	Oral	Powder	A6A, 03C1, 03C1P
Target	Agiolax	Plantago Ovata, Senna	Combination of a bulk forming and a stimulant laxative	Oral	Powder, granules	A6A, 03C1, 03C1P
Target	Cenat	Plantago Ovata	Bulk forming laxative	Oral	Powder, granules	A6A, 03C1, 03C1P
Target	Duphalac	Lactulose	Osmotic laxative	Oral	Syrup, oral powder for oral solution, oral solution	A6A, A6A6 + A6A7
Recordati	Adulax Casen	Glycerol	Laxative enema	Rectal	Enema	A6A
Recordati	Casenfibra	Fructooligosaccharides, Maltodextrin, Vegetable Fibre	Bulk forming laxative	Oral	Powder, liquid	03C1, 03C1P
Recordati	Casenlax	Macrogol(S)	Osmotic laxative	Oral	Powder for oral solution, liquid	A6A, A6A6 + A6A7
Recordati	Contumax	Picosulfuric Acid	Stimulant laxative	Oral	Drop for oral administration	A6A
Recordati	Enema Casen	Citric Acid, Dodecyl Sulfoacetic Acid	Laxative enema	Rectal	Enema	A6A
Recordati	Rizmoic ⁷⁰	Naldemedine	The API within Rizmoic attaches and blocks receptors in the gut, through which opioid medicines cause constipation.	Oral	Tablets	A6A
Cooper	Zeninas	Aloe Barbadensis, Rhamnus Purshiana	Stimulant laxative	Oral	Tablets	A6A

Source: Form CO, Table 19 and Annex 8.1-XI.

- (76) Tables 8 and 9 below provides the market shares of the Parties and their main competitors in the Group 1/1+ affected markets in Spain for 2022, in value and in volume.

⁷⁰

Used to treat constipation caused by opioid pain relief medicines.

Table 8: The Parties' and competitors' market shares in Group 1/1+ affected markets for drugs for constipation in Spain, 2022, in value

	A6A – Drugs for constipation	A6A6 and A6A7 – Osmotic laxatives (with and without electrolytes)	03C1 – Fibre laxatives	03C1P – Fibre laxatives – Powders
Target (Duphalac, Agiocur, Agiolax, Cenat)	14.6%	20.5%	31.4%	63.6%
CVC - Recordati (Casenlax, Enema Casen, Adulax Casen, Rizmoic, Contumax, Casenfibra)	12.5%	14.7%	7.1%	6.3%
CVC – Cooper (Zeninas)	0.5%	-	-	-
Combined	27.6%	35.2%	38.5%	70.0%
Norgine (Movicol)	20.4%	44.1%	-	-
Johnson & Johnson (Microlax, Glycerol J.J.)	13.1%			
Lainco (Lactulosa Lainco, Magnesia Lainco, Foslainco, Emuliquen Laxante)	6.8%	5.2%	-	-
Cinfa (Magnesium Cinf)	3.6%	2.8%	-	-
Grupo Uriach (Fave di Fuca, Fuca Regularidad, Fuca Colon Clean and others)	4.4%	-	33.0%	-
A. Vogel (Linomed, Linoforce)	1.1%	-	8.1%	16.5%
Perrigo (Kijimea, Regulamine)	-	-	3.3%	6.6%
Others	23.0%	12.7%	17.1%	6.9%
Total	100%	100%	100%	100%

Source: Form CO, Annex 8.1-I and Annex 8.1-XIII.

Table 9: The Parties' and competitors' market shares in Group 1/1+ affected markets for drugs for constipation in Spain, 2022, in volume

	A6A – Drugs for constipation	A6A6 and A6A7 – Osmotic laxatives (with and without electrolytes)	03C1 – Fibre laxatives	03C1P – Fibre laxatives – Powders
Target (Duphalac, Agiocur, Agiolax, Cenat)	41.4%	51.2%	57.5%	87.5%
CVC – Recordati (Casenlax, Enema Casen, Adulax Casen, Rizmoic, Contumax, Casenfibra)	4.0%	7.6%	1.7%	0.8%
CVC – Cooper (Zeninas)	0.5%			
Combined	45.9%	58.8%	59.2%	88.3%
Norgine (Movicol)	9.6%	19.4%	-	-
Johnson & Johnson (Microlax, Glycerol J.J.)	3.8%			
Lainco (Lactulosa Lainco, Magnesia Lainco, Foslainco, Emuliquen Laxante)	7.1%	7.7%	-	-
Cinfa (Magnesium Cinf)	6.0%	6.0%	-	-
Grupo Uriach (Fave di Fuca, Fuca Regularidad, Fuca Colon Clean and others)	6.2%	-	26.1%	-
A. Vogel (Linomed, Linoforce)	1.2%	-	5.2%	7.9%
Perrigo (Kijimea, Regulamine)	-	-	1.1%	1.7%
Others	20.2%	8.1%	8.4%	2.1%
Total	100%	100%	100%	100%

Source: Form CO, Annex 8.1-I and Annex 8.1-XIII.

4.5.1.2.2.1. ATC3 class A6A – Drugs for constipation in Spain

- (77) Both Parties supply various constipation drugs belonging to ATC3 class A6A in Spain. More specifically, the Target supplies Duphalac, Agiocur, Agiolax, Cenat, whereas Recordati supplies Casenlax, Enema Casen, Adulax Casen, Rizmoic, Contumax, and Cooper is supplying Zeninas. In this market the Parties' combined market share is 27.6% in value (or 45.9% in volume) with an increment of 13% in value (or 4.5% in volume).

- (78) According to the Notifying Party, the Transaction will not result in any competition concerns, as the Parties' value market shares are limited, the Parties' products are not close substitutes as they are based on different APIs and have different routes of administration and modes of actions, and the merged entity will continue to face a number of strong competitors post-Transaction including Norgine, Johnson & Johnson and Lainco.
- (79) Based on the Commission's assessment the Transaction does not raise competition concerns in relation to the ATC3 class A6A in Spain in light of the following factors.
- (80) *First*, the Commission notes that the overlap in the ATC3 class A6A in Spain does not give rise to an affected Group 1/1+ market based on the value shares, as the Parties' combined value market share is limited at 27.6%. This suggests that the merged entity will have a moderate position in this market and will continue to face sufficient competitive pressure from its competitors. While the combined market share based on volume is comparatively higher at 45.9%, the increment based on volume market share remains limited at 4.5%. In any case, as explained by the Notifying Party, the volume-based market shares appear to be of less relevance in OTC markets due to the difficulties in standardising volume measures across players.
- (81) *Second*, the Parties' products do not appear to be close competitors as their products are based on different APIs and to a large extent have different modes of actions (see Table 7 above). In particular, the main Target's product in the class is an osmotic laxative Duphalac (9.5% value market share in 2022), which is based on lactulose. While Recordati's Casenlax (6.8% value market share in 2022) is also an osmotic laxative, it is based on a different API, namely macrogol. Therefore, Target's Duphalac competes more closely with Lainco's Lactulosa Lainco also based on lactulose (2.0% value market share in 2022), and Recordati's Casenlax more closely with Norgine's Movicol also based on macrogol (20.4% value market share in 2022). The Target's other products include Agiocur, Agiolax and Cenat, all of which have different mode of actions compared to Recordati's and Cooper's products. The fact that the Parties' products are not close competitors has also been confirmed by the market investigation since when asked about the closest alternatives to the individual Parties' products, virtually all the respondents listed competitors' products.⁷¹
- (82) *Third*, the Parties will continue to face competition from a large number of competitors, including Norgine (market share of 20.4% by value), Johnson & Johnson (market share of 13.1% by value) and Lainco (market share of 6.8% by value). This is confirmed by the market investigation, since virtually all respondents consider that consumers in Spain will continue to have access to a sufficient number of alternative drugs for constipation post-Transaction.⁷²

⁷¹ Responses to question H.A.6 of the questionnaire to Customers; and responses to question C.D.1 of the questionnaire to Competitors.

⁷² Responses to question H.A.3 of the questionnaire to Customers; and responses to question C.D.2 of the questionnaire to Competitors.

- (83) *Finally*, the large majority of respondents consider that the Transaction will have a positive or neutral impact on the laxative market in Spain.⁷³
- (84) In light of the above, the Commission considers that the Transaction does not raise serious doubts as to its compatibility with the internal market or the functioning of the EEA agreement as a result of the identified overlap regarding constipation drugs in Spain.

4.5.1.2.2.2. ATC4 classes A6A6 and A6A7 – Osmotic laxatives (with and without electrolytes) in Spain

- (85) Both Parties supply osmotic laxatives in Spain. More specifically, the Target is supplying Duphalac, whereas Recordati is supplying Casenlax. In this market, the Parties' combined market share is 35.2% in value (or 58.8% in volume), with an increment of 14.7% in value (or 7.6% in volume).
- (86) According to the Notifying Party, the Parties are not close competitors and will continue to face competition from a number of competitors including Norgine (44.1% in value) and Lainco (5.2% in value).⁷⁴
- (87) Based on the Commission's assessment the Transaction does not raise competition concerns in relation to the ATC4 classes A6A6 and ATC7 (osmotic laxatives with and without electrolytes)⁷⁵ in Spain in light of the following factors.
- (88) *First*, the Parties' combined value market shares are moderate at 35.2%, barely exceeding the threshold for a Group 3 affected market (see Section 4.4.), which typically do not warrant a detailed assessment as the market shares of the Parties are limited, and significant competitors that will likely sufficiently constrain the merged entity remain on the market post-Transaction. While the combined market share based on volume is higher at 58.8%, as explained by the Notifying Party, the volume-based market shares appear to be of less relevance in OTC markets due to the difficulties in standardising volume measures across players.
- (89) *Second*, as discussed in Section 4.5.1.1. above, there appears to be a certain level of substitutability between laxatives with different modes of action. Therefore, osmotic laxatives face competitive pressure at least from bulk-forming laxatives, and to some degree also from stimulant laxatives.
- (90) *Third*, even in the plausible narrower market for osmotic laxatives, the Parties' products do not appear to be close competitors. As explained above, the Target's Duphalac is based on lactulose and therefore competes more closely with Lainco's Lactulosa Lainco also based on lactulose (4.3% value market share). On the other hand, Recordati's Casenlax is based on macrogol and therefore competes more closely with Norgine's Movicol also based on macrogol (44.1% value market share) and a number of other macrogol based products available in Spain.

⁷³ Responses to questions J.3 of the questionnaire to Customers; and responses to question O.3 of the questionnaire to Competitors.

⁷⁴ Form CO, paragraph 335 and Annex 8.1-XIII.

⁷⁵ As explained in footnote 69, ATC4 class A6A6 includes osmotic laxative, excluding osmotic laxatives with electrolytes, while ATC4 class A6A7 includes osmotic laxatives with electrolytes. Given that nothing in the Commission's past decisions and investigation in this case suggested that such a distinction is relevant for the purposes of defining a relevant product market, these two classes are combined for the purposes of identifying plausible affected Group 1/1+ markets.

- (91) *Fourth*, the above is confirmed by the results of the market investigation. When asked about the closest alternatives to the individual Parties' products, virtually all the respondents listed competitors' products.⁷⁶
- (92) *Fifth*, the Parties will continue facing competition from a large number of competitors, including Norgine, which has a value market share higher than that of the merged entity (44.1%). This is confirmed by the market investigation, since virtually all respondents consider that consumers in Spain will continue to have access to a sufficient number of alternative osmotic laxatives post-Transaction.⁷⁷ One respondent for example even explained that: "*There are 20 different companies operating with Osmotic Laxatives*".⁷⁸
- (93) *Finally*, the large majority of respondents to the market investigation consider that the Transaction will have a positive or neutral impact on the laxative market in Spain, with no indication that this would differ specifically in relation to osmotic laxatives in Spain.⁷⁹
- (94) Considering the above, the Commission does not consider that the Transaction would raise any serious doubts as to its compatibility with the internal market or the functioning of the EEA agreement as a result of the overlap regarding osmotic laxatives in Spain.

4.5.1.2.2.3. CHC3 class 03C1 – Fibre laxatives and CHC4 class 03C1P – Fibre laxatives in powder form in Spain

- (95) Both Parties supply fibre laxatives (also called bulk-forming laxatives) in Spain. More specifically, the Target is supplying Agiocur, Agiolax and Cenant whereas Recordati is supplying Casenfibra, all of which also come in powder form. The Parties' combined market share is 38.5% in value (or 59.2% in volume), with an increment of 7.1% in value (or 1.7% in volume) in the market for fibre laxatives (CHC3 class 03C1) and in the market limited to products in powder form (CHC4 class 03C1P) 70.0% in value (or 88.3% in volume), with an increment of 6.3% in value (or 0.8% in volume).
- (96) According to the Notifying Party the Parties' products are not close substitutes, and will continue to face a number of competitors post-Transaction. In addition, the Notifying Party notes that the Parties have faced declining market shares in the 03C1 and 03C1P classes since 2020. Moreover, the Notifying Party does not consider sub-segmentation of the 03C1 class (fibre laxatives) by capsules or powders appropriate, as both modes of administration are oral presentations that it considers readily substitutable.⁸⁰
- (97) Based on the Commission's assessment the Transaction does not raise competition concerns in relation to the CHC3 class 03C1 (fibre laxatives) or the CHC4 class 03C1P (fibre laxatives in powder form) in Spain in light of the following factors.

⁷⁶ Responses to question H.A.6 of the questionnaire to Customers; and responses to question C.D.1 of the questionnaire to Competitors.

⁷⁷ Responses to question H.A.3 of the questionnaire to Customers; and responses to question C.D.2 of the questionnaire to Competitors.

⁷⁸ Responses to question C.D.2 of the questionnaire to Competitors.

⁷⁹ Responses to questions J.3 of the questionnaire to Customers; and responses to question O.3 of the questionnaire to Competitors.

⁸⁰ Form CO, paragraphs 335-341.

- (98) *First*, as discussed in Section 4.5.1.1 above, there appears to be a certain level of substitutability between laxatives with different modes of action. Moreover, while there may be some users that are not able to swallow capsules and need to take in powder form, for the general part of the population all galenic forms of bulk-forming laxatives appear substitutable. This is confirmed by the market investigation, as the majority of the respondents consider that bulk-forming laxatives in the form of powder are substitutable with bulk-forming laxatives in other forms (e.g. capsules).⁸¹ Therefore, bulk-forming laxatives in powder form face competitive pressure at least from other bulk-forming laxatives, which in turn face competition also from osmotic laxatives, and to some degree also from stimulant laxatives.
- (99) *Second*, even in the plausible narrower market for bulk-forming laxatives, the Parties' products do not appear to be close competitors as they are used at different stages of the treatment. In particular, the Target's Agiocur, Agiolax and Cenat are natural remedies for the short-term treatment of constipation, whereas Recordati's Casenfibra is a food supplement designed to effectively prevent constipation. Therefore, Casenfibra competes more closely with Grupo Uriach's Fuca Regularidad (7.1% by value in 2022) as it is also a food supplement, which contributes to the normal functioning of the digestive system. In contrast, the Target's products compete more closely with Grupo Uriach's Fave di Fuca (24.6%) and A. Vogel's Linomed (8.1%) as both of those products are focused on the short-term treatment of occasional constipation.
- (100) *Third*, even in the narrower plausible markets the Parties will continue facing competition from a large number of competitors. These include *inter alia* Grupo Uriach (33.0% value market share in 03C1), A. Vogel (8.1% in 03C1 and 16.5% in 03C1P) and Perrigo (3.3% in 03C1 and 6.6% in 03C1P). This is confirmed by the market investigation, since virtually all respondents consider that consumers in Spain will continue to have access to a sufficient number of alternative bulk-forming laxatives (in powder form) post-Transaction.⁸² One respondent for example even explained that: "*There are 138 companies operating in this [bulk-forming] laxatives segment*" and "*There are 34 products under the powder format.*"⁸³
- (101) *Finally*, the large majority of respondents to the market investigation consider that the Transaction will have a positive or neutral impact on the laxative market in Spain, with no indication that this would differ specifically in relation to fibre laxatives (in powder form) in Spain.⁸⁴
- (102) Considering the above, the Commission does not consider that the Transaction would raise any serious doubts as to its compatibility with the internal market or the functioning of the EEA agreement as a result of the overlap regarding fibre laxatives (in fibre form) in Spain.

⁸¹ Responses to questions C.A.4. and C.A.5 of the questionnaire to Competitors.

⁸² Responses to question H.A.3 of the questionnaire to Customers; and responses to question C.D.2 of the questionnaire to Competitors.

⁸³ Responses to question C.D.2 of the questionnaire to Competitors.

⁸⁴ Responses to questions J.3 of the questionnaire to Customers; and responses to question O.3 of the questionnaire to Competitors.

4.5.1.2.3. France

- (103) In France, the Transaction gives rise to two Group 1/1+ affected market in relation to drugs for constipation namely the ATC4 class A6A9 (other drugs for constipation) and the CHC4 class 03C2S (suppositories).
- (104) The Commission notes that the ATC4 class A6A9 (other drugs for constipation) is a catch-all category that encompasses a range of constipation drugs which do not fit into the other ATC4 classifications. As the category contains a range of disparate products the Commission does not consider this category to constitute a relevant market and this class will therefore not be further addressed in this decision.

4.5.1.2.3.1. CHC4 class 03C2S – Suppositories in France

- (105) Both Parties supply suppositories in France. More specifically, the Target is supplying Rectopanbiline whereas Cooper supplies Glycerol Cooe. In this market, the Parties' combined market share is 59.6% in value (or 56.2% in volume), with an increment of 8.7% in value (or 1.5% in volume).
- (106) According to the Notifying Party the Parties products are not close competitors as they are based on different molecules. Furthermore, the Notifying Party submits that the merged entity will continue to face a number of other competing products post-Transaction.⁸⁵
- (107) Based on the Commission's assessment the Transaction does not raise competition concerns in relation to the CHC4 class 03C2S (suppositories) in light of the following factors.
- (108) *First*, the Commission notes that the merged entity will continue facing competition post-Transaction from various competitors such as Qualiphar (market share of 25.3% in value) and Gilbert (market share of 9.1% in value). The existence of alternatives post-Transaction is also evidenced by the fact that respondents to the Commission's market investigation have identified several alternatives to the Parties products including, for example, glycerol suppositories supplied by Gilbert and Gifrer.⁸⁶
- (109) *Second*, as already described above in Section 4.5.1.1., for the adult population there appears to be greater substitutability between and within oral and rectal laxatives. Therefore, suppositories, at least for the adult population, face competitive pressure from other rectal laxatives (i.e. enemas) as well as other oral laxatives.
- (110) *Third*, while the market participants consider that Viatri's Rectopanbiline and Cooper's Glycerool Cooe offer close alternatives to one another,⁸⁷ they also confirm that the differences in molecule may matter to some patients. For example, a competitor explains that: "*because they contain different active ingredients, patients may have preferences based on non-medical criteria, such as product composition or habits of use.*"⁸⁸ In addition, when asked about the closest

⁸⁵ Form CO, paragraph 353.

⁸⁶ Responses to question D.A.8 of the questionnaire to Customers; and responses to C.E.3 of the questionnaire to Competitors.

⁸⁷ Responses to C.E.1 of the questionnaire to Competitors.

⁸⁸ Responses to C.E.2 of the questionnaire to Competitors.

alternative to Cooper's Glycerool Cooe, the majority of the respondents listed other products based on glycerine, further confirming that in this case the differences in molecules do play a role in consumers' choice.

- (111) *Finally*, the majority of respondents, consider the impact of the Transaction to be neutral on the French laxative market, with no indication that this would differ specially in relation to suppositories in France.⁸⁹
- (112) In light of the above, the Commission considers that the Transaction does not raise serious doubts as to its compatibility with the internal market or the functioning of the EEA agreement as a result of the identified overlaps regarding constipation drugs in France.

4.5.2. *Antiseptics and disinfectants in Belgium, France, Italy and Luxembourg*

4.5.2.1. Market definition

- (113) The ATC3 class D8A (Antiseptics and Disinfectants) comprises all dermatological antiseptic preparations for human use, including soaps and shampoos with antiseptic or disinfectant properties. The ATC3 class is not further divided into any ATC4 classes.
- (114) The CHC3 class 06B2 comprises products for skin disinfection while the CHC3 class 06B3 comprises products for wound disinfection, including CHC4 classes 06B3L (wound disinfection in liquid/lotion form) and 06B3O (products for wound disinfection in cream or ointment form).
- (115) The Commission has in the past defined the product market for antiseptics and disinfectants at ATC3 level D8A.⁹⁰ In some cases, it left open whether the product market also includes some D3A wound-healing agents.⁹¹
- (116) The Notifying Party submits that the relevant product market is narrower than ATC3 level or CHC4 level, but rather at molecule level – where there is no overlap between the Parties' products – in light of their differentiated nature, the fact-specific use cases and the procurement by API in the relevant jurisdictions.
- (117) The results of the Commission's market investigation generally point towards there being separate product markets for antiseptics and disinfectants based on each intended use (e.g. suitability for surgical procedures, prenatal and pediatric cases, open wounds, mucous membrane, and/or damaged skin), with fewer indications that plausible separate markets may exist based on different molecules/active ingredients.⁹²
- (118) For the purposes of this decision, the product market definition for antiseptics and disinfectants can be left open, as the Transaction does not give rise to serious

⁸⁹ Responses to questions J.3 of the questionnaire to Customers, responses to question O.3 of the questionnaire to Competitors.

⁹⁰ See cases M.1378 – *Hoechst/Rhone-Poulenc* (1999), paragraph 55 and M.3354 *Sanofi-Synthelabo/Aventis* (2004), paragraph 23.

⁹¹ See Cases M.4007 – *Reckitt Benckiser/Boots Healthcare International* (2006), paragraphs 14-26; and M.7975 – *Mylan/Meda* (2017), paragraphs 347-349.

⁹² Responses to questions C.A.1, D.B.1., E.B.1., and G.B.1. of the questionnaire to Customers; and responses to question D.A.1 of the questionnaire to Competitors.

doubts as to its compatibility with the internal market or the functioning of the EEA agreement even in the narrowest plausible market (i.e. at the molecule level).

4.5.2.2. Competitive assessment

- (119) The Target and Cooper⁹³ both supply antiseptics/disinfectants in Belgium, France, Luxembourg and Italy. The Target's Betadine is based on the molecule providone-iodine and is used to disinfect the skin before surgery and as an antiseptic for wounds. Cooper produces a number of antiseptics/disinfectants⁹⁴ that belong to the same ATC/CHC classes as Betadine but are all based on other molecules and used for skin treatment and disinfection purposes.
- (120) Table 10 and 11 below provide an overview of the Parties' market shares in affected markets for antiseptics/disinfectants in Belgium, France, Luxembourg and Italy for 2022, in value and in volume.

Table 10: The Parties' market shares in affected markets for antiseptics/disinfectants in Belgium, France, Luxembourg and Italy, 2022, in value

	Belgium	France					Luxembourg	Italy	
	D8A – Antiseptics and Disinfectants	D8A – Antiseptics and Disinfectants	06B2 – Skin Disinfection	06B3 – Wound Disinfection	06B3L – Liquids / Lotions (Topical)	06B3O – Ointments / Creams	D8A – Antiseptics and Disinfectants	06B3 – Wound Disinfection	06B3L – Liquids / Lotions (Topical)
Target	59.9%	29.2%	47.9%	10.5%	43.6%	33.0%	34.5%	31.8%	37.4%
Cooper	0.5%	23.0%	13.2%	34.8%	11.7%	21.2%	1.4%	5.3%	7.2%
Combined	60.4%	52.2%	61.1%	45.3%	55.3%	54.2%	35.9%	37.2%	44.6%
Others	39.6%	47.8%	38.9%	54.7%	44.7%	45.8%	64.1%	62.8%	55.4%
Total	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

Source: Form CO, Annex 8.1-I.

⁹³ None of the other CVC portfolio companies supply antiseptics/disinfectants in Belgium, France, Luxembourg or Italy.

⁹⁴ Cooper produces and markets the following products that give rise to Group 1 affected markets due to their overlap in certain ATC and CHC classes with Betadine: Dakin (France, Belgium, Luxembourg), Hexomedine (France), Alcool Modifié (France), Aureocyde (France) and Bialcol (Italy). See Form CO, paragraph 439.

Table 11: The Parties' market shares in affected markets for antiseptics/disinfectants in Belgium, France, Luxembourg and Italy, 2022, in volume.

	Belgium	France					Luxembourg	Italy	
	D8A – Antiseptics and Disinfectants	D8A – Antiseptics and Disinfectants	06B2 – Skin Disinfection	06B3 – Wound Disinfection	06B3L – Liquids / Lotions (Topical)	06B3O – Ointments / Creams	D8A – Antiseptics and Disinfectants	06B3 – Wound Disinfection	06B3L – Liquids / Lotions (Topical)
Target	47.6%	25.6%	48.5%	6.1%	10.1%	18.7%	22.9%	15.4%	19.2%
Cooper	1.4%	22.6%	0.1%	25.3%	35.5%	12.7%	3.0%	10.4%	13.7%
Combined	49.0%	48.2%	48.6%	31.4%	45.6%	31.3%	25.9%	25.8%	32.9%
Others	51.0%	51.8%	51.4%	68.6%	54.4%	68.7%	74.1%	74.2%	67.1%
Total	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

Source: Form CO, Annex 8.1-I.

- (121) In general, the Notifying Party argues that the Parties' overlapping antiseptics and disinfectants are not close substitutes, as they differ across a number of parameters, including their use case, range of bacterial action and active ingredient. Furthermore, they consider that the merged entity will not be able to raise prices in Belgium, France and Luxembourg post-Transaction due to national price regulation regimes of pharmaceuticals.⁹⁵
- (122) The Notifying Party also submits that the merged entity will continue to face strong competition post-Transaction,⁹⁶ and that, in any event, the competition effects of the Transaction should be assessed at molecule level as the appropriate relevant product market, where the Parties' antiseptics and disinfectants do not overlap. Moreover, in Belgium and in Luxembourg, the Transaction would not have a material impact in these markets in light of the small increments by Cooper.

4.5.2.2.1. Belgium

- (123) As indicated in 10 and 11 above, in the market for antiseptics and disinfectants (at ATC3 level D8A) in **Belgium**, the combined share of the Parties was 60.4% in value (with an increment of 0.5% by Cooper) and 49% in volume (with an increment of 1.4% by Cooper).
- (124) The Commission considers that the Transaction does not raise concerns for the following reasons.

⁹⁵ In Belgium, France and Luxembourg, the prices of pharmaceutical products are subject to national regulation and prior approval by state officials. For instance, pharmaceutical manufacturers in Belgium are required by regulation to notify and seek prior authorisation from the Federal Ministry for the Economy in Belgium for proposed price increases. See Form CO paras 457, 458, 470, 494, 495.

⁹⁶ In Belgium, 15 competitors will remain to constrain the merged entity, including two with a market share exceeding 5% (Mölnlycke Health Care and Qualiphar). In France 20 competitors will remain, including four above 5% (Bayer, Pierre Fabre, Servier and Gilbert). In Luxembourg more than 10 competitors, including five above 5% (Mölnlycke Health Care, Pierre Fabre, Schuelke, Klösterfrau, Qualiphar). In Italy more than 50 competitors will remain, including three above 5% (Angelini, Bolton Group and Dompe). According to the Notifying Party, a number of those competitors compete more closely with the Parties' products. See Form CO, paras. 455, 469, 493, 498.

- (125) *First*, the Parties' overlapping antiseptics and disinfectants are not close substitutes, as they differ across a number of parameters, including use case, range of bacterial action and active ingredient.⁹⁷ In particular, the Target's Betadine and Cooper's Dakin differ significantly in their suitability for surgical preparation, stability, application sensation, and usage contexts. In its previous assessment of the D8A class in France, the Commission concluded that Dakin and Betadine are not close competitors.⁹⁸
- (126) *Second*, whilst the market investigation results were mixed regarding the Parties' products' closeness, the vast majority of respondents consider that there will be sufficient alternatives in Belgium post-Transaction. Further, as noted above in footnote 96 the merged entity will continue to face strong competition post-Transaction.
- (127) *Third*, according to the market investigation results the impact of the Transaction in antiseptics and disinfectants in Belgium would be neutral.⁹⁹
- (128) In light of the above considerations, the Commission considers that the Transaction does not raise serious doubts as to its compatibility with the internal market or the functioning of the EEA agreement as a result of horizontal effects in the market for antiseptics and disinfectants in Belgium.

4.5.2.2.2. *France*

- (129) In **France**, the Parties' activities result in five Group 1/1+ affected markets for antiseptics and disinfectants, namely: (i) at the ATC3 level (D8A – antiseptics and disinfectants); (ii) at the CHC3 (06B2 - skin disinfection); (iii) at the CHC3 (06B3 - wound disinfection); (iv) at the CHC4 (06B3L – liquids / lotions (topical)); and (v) at the CHC4 level (06B3O – ointments / creams). At the ATC3 level (D8A) the Parties' combined market share was 52.2% in value (increment of 23%) and 48.2% in volume (increment of 22.6%), at the CHC3 level (06B2) the Parties' combined market share was 61.1% in value (increment of 13.2%) and 48.6% in volume (increment of 0.1%), at the CHC3 (06B3) the Parties' combined market share was 45.3% in value (increment of 34.8%) and 31.4% in volume (increment of 25.3%), at the CHC4 (06B3L) the Parties' combined market share was 55.3% in value (increment of 11.7%) and 45.6% in volume (increment of 35.5%) and at the CHC4 level (06B3O) the Parties' combined market share was 54.2% in value (increment of 21.2%) and 31.3% in volume (increment of 12.7%).
- (130) The Commission considers that the Transaction does not raise concerns for the following reasons.
- (131) *First*, the Parties' antiseptics and disinfectants are not close substitutes, as they differ across a number of parameters, including use case, range of bacterial action and active ingredient.¹⁰⁰ In particular, Target's Betadine is distinguished by its

⁹⁷ Dakin (Cooper) and Betadine (Target) are present in ATC3 (D8A) in Belgium. Betadine is based on the molecule povidone-iodine, while Dakin is based on the molecule sodium hypochlorite.

⁹⁸ See M.7975 – Mylan/Meda, para. 352.

⁹⁹ Responses to questions C.A.6., and J.3. of the questionnaire to Customers; and responses to D.C.4., and O.3. of the questionnaire to Competitors.

¹⁰⁰ Cooper's products active in France that compete with Betadine include Dakin (present in 06B3, 06B3L, and D8A), Hexomédine (present in 06B3, 06B3L, 06B3O, and D8A), Alcool Modifié (present in 06B3, 06B3L, and D8A), and Aureocyde (present in 06B2). Betadine is based on the

skin-coloring properties, longer-lasting antiseptic efficacy, and broader suitability for surgical use. In contrast, Cooper's Dakin, Hexomedine, Alcool Modifié differ in antiseptic effectiveness, application restrictions, and stability, while Aureocyde is categorized as a cosmetic product.

- (132) *Second*, whilst the market investigation results were mixed regarding the Parties' products' closeness, the vast majority of market investigation participants consider that there will be sufficient alternatives in France, post-Transaction. Further, as noted above, the merged entity will continue to face strong competition post-Transaction.¹⁰¹
- (133) *Third*, according to the market investigation results the impact of the Transaction in antiseptics and disinfectants in France would be neutral.¹⁰²
- (134) In light of the above considerations, the Commission considers that the Transaction does not raise serious doubts as to its compatibility with the internal market or the functioning of the EEA agreement as a result of horizontal effects in the market for antiseptics and disinfectants in France.

4.5.2.2.3. Luxembourg

- (135) In **Luxembourg**, the combined market share of the Parties was 35.9% in value (with an increment of 1.4% by Cooper) and 25.9% in volume (with an increment of 3% by Cooper).
- (136) The Commission considers that the Transaction does not raise concerns for the following reasons.
- (137) *First*, the Parties' combined value market share in the ATC3 class D8A in Luxembourg is moderate at 35.9% barely exceeding the threshold for a Group 3 affected market (see Section 4.4) which typically do not warrant a detailed assessment as the market shares of the Parties are limited and significant competitors that will likely sufficiently constrain the merged entity remain on the market post-Transaction. Additionally, the increment brought by Cooper is relatively limited at 1.4%, further indicating that the impact on the market will be moderate.
- (138) *Second*, the Parties' overlapping antiseptics and disinfectants are not close substitutes, as they differ across a number of parameters, including use case, range

molecule povidone-iodine, while Dakin is based on the molecule sodium hypochlorite, Hexomedine on molecule hexamidine, Alcool Modifié on molecule ethanol and Aureocyde on molecule hydrogen peroxide.

¹⁰¹ Post-transaction, at the D8A class in France, more than 20 competitors will remain to constrain the merged entity, include four competitors with value market shares exceeding 5% (Bayer, Pierre Fabre, Servier and Gilbert). At the 06B2 class 20 competitors will remain in the segment, including one with market shares exceeding the increment resulting from Cooper (Pierre Fabre with 30% value market shares in 2022). At the 06B3, 06B3L and 06B30 classes in France more than 40 competitors will remain to constrain the merged entity. The competitors include Servier's benzalkonium chloride chlorhexidine product (16.2% by value in 2022), Bayer's Biseptine and Dermaspraid Antiseptique (11.7% by value in 2022), and Teva's Povidone-Iodine (2.2% by value in 2022).

¹⁰² Responses to questions D.B.4., and J.3. of the questionnaire to Customers; and responses to D.D.2., and O.3. of the questionnaire to Competitors.

of bacterial action and active ingredient.¹⁰³ In particular, as noted above in paragraph 130, Target's Betadine and Cooper's Dakin differ significantly in their suitability for surgical preparation, stability, application sensation, and usage contexts.

- (139) *Third*, whilst the market investigation results were mixed regarding the Parties' products' closeness, the vast majority of market participants consider that there will be sufficient alternatives in Luxembourg, post-Transaction. Further, as noted above, the merged entity will continue to face strong competition post-Transaction.¹⁰⁴
- (140) *Fourth*, according to the market investigation results the impact of the Transaction in antiseptics and disinfectants in Luxembourg would be neutral.¹⁰⁵
- (141) In light of the above considerations, the Commission considers that the Transaction does not raise serious doubts as to its compatibility with the internal market or the functioning of the EEA agreement as a result of horizontal effects in the market for antiseptics and disinfectants in Luxembourg.

4.5.2.2.4. Italy

- (142) In **Italy**, the Parties' activities result in two Group 1/1+ affected markets for antiseptics and disinfectants, namely: (i) at the CHC3 (06B3 - wound disinfection); and (ii) at the CHC4 (06B3L – liquids / lotions (topical)). At the CH3 (06B3) level the Parties' combined market share was 37.2% in value (increment of 5.3%) and 25.8% in volume (increment of 10.4%) and at the CHC4 level (06B3L) the Parties' combined market share was 44.6% in value (increment of 7.2%) and 32.9% in volume (increment of 13.7%).
- (143) The Commission considers that the Transaction does not raise concerns for the following reasons.
- (144) *First*, the Parties' combined value market share in the ATC3 class 06B3 in Italy is moderate at 37.2% barely exceeding the threshold for a Group 3 affected market (see Section 4.4) which typically do not warrant a detailed assessment as the market shares of the Parties are limited and significant competitors that will likely sufficiently constrain the merged entity remain on the market post-Transaction. Additionally, the increment brought by Cooper is relatively limited at 5.3%, further indicating that the impact on the market will be moderate.
- (145) *Second*, the Parties' overlapping antiseptics and disinfectants are not close substitutes, as they differ across a number of parameters, including use case, range of bacterial action and active ingredient.¹⁰⁶ In particular, Target's Betadine and Cooper's Bialcol differ significantly in their formulation characteristics, with Bialcol lacking skin-coloring properties, featuring a narrower spectrum of

¹⁰³ Dakin (Cooper) and Betadine (Target) are present in ATC3 (D8A) in Luxembourg. Betadine is based on the molecule povidone-iodine, while Dakin is based on the molecule sodium hypochlorite.

¹⁰⁴ See Table 11 and Form CO, paragraph 493.

¹⁰⁵ Responses to questions E.B.6., and J.3. of the questionnaire to Customers; and responses to D.E.4., and O.3. of the questionnaire to Competitors.

¹⁰⁶ Bialcol (Cooper) and Betadine (Target) are present in CHC3 (06B3) in Italy. Betadine is based on the molecule povidone-iodine, while Bialcol is based on the molecule benzoxonium.

antimicrobial activity, requiring shorter treatment periods because of bacterial resistance and limited to use on unbroken skin.¹⁰⁷

- (146) *Third*, whilst the market investigation results were mixed regarding the Parties' products' closeness, the vast majority of market participants consider that there will be sufficient alternatives in Italy, post-Transaction. Further, as noted above, the merged entity will continue to face strong competition post-Transaction.¹⁰⁸
- (147) *Fourth*, according to the market investigation results the impact of the Transaction in antiseptics and disinfectants in Italy would be neutral.¹⁰⁹
- (148) In light of the above considerations, the Commission considers that the Transaction does not raise serious doubts as to its compatibility with the internal market or the functioning of the EEA agreement as a result of horizontal effects in the market for antiseptics and disinfectants in Italy.

4.5.3. *Liver disorder products, hepatic protectors and lipotropics in Portugal*

4.5.3.1. Product market definition

- (149) The ATC3 class A5B (liver disorder products, hepatic protectors and lipotropics) comprises all products for liver disorders such as non-alcoholic steatohepatitis, hepatic protectors and combinations, but excludes liver extracts indicated for the treatment of anaemia.
- (150) The Commission has in the past generally considered the ATC3 class A5B to be the relevant product market irrespective of Rx/OTC distinction.¹¹⁰ However, in case M.7975 – *Mylan / Meda* the Commission defined the market for liver products at molecule level.¹¹¹
- (151) According to the Notifying Party given that the Parties' products are used to treat different indications, the appropriate level at which to assess competitive dynamics is the molecule level.¹¹²
- (152) The results of the Commission's market investigation have been inconclusive as to the appropriate level of the relevant product market for liver disorder products, hepatic protectors and lipotropics.¹¹³ However, all of the respondents of the market investigation indicated that the Parties' products are not substitutable with each

¹⁰⁷ See Form CO, para. 444.

¹⁰⁸ At 06B3 in Italy, more than 50 competitors will remain, including three with over 5% market share (Angelini, Bolton Group, and Dompe). At 06B3L in Italy, Bolton Group's Citrosil (8.3% market share by value in 2022) and various benzalkonium chloride products with shares below 5% will continue to compete more closely with Bialcol due to same active ingredients.

¹⁰⁹ Responses to questions G.B.6., and J.3. of the questionnaire to Customers; and responses to D.F.4., and O.3. of the questionnaire to Competitors.

¹¹⁰ See e.g. M.5253 – *Sanofi-Aventis/Zentiva*, Decision of 4 February 2009, paragraph 54; M.1835 – *Monsanto/Pharmacia & Upjohn*, Decision of 30 March 2000, paras 15-16.

¹¹¹ See M.7975 – *Mylan/Meda*, Decision of 20 July 2016, paragraphs 266-268. In this case the Commission considered separate markets for products based on lactulose, silymarin and adementionine.

¹¹² Form CO, paragraph 420.

¹¹³ Responses to questions F.C.1 and F.C.2 of the questionnaire to Customers; responses to questions E.A.1 and E.A.2 of the questionnaire to Competitors.

other.¹¹⁴ For example one customer has explained that “Legalon and Guronsan have different end uses and Legalon purchase requires a prescription and Guronsan does not” and another that “they serve completely different purposes/end result. Guronsan is a product is a drug [sic] for detoxifying the body, while Legalon is a hepatoprotector indicated for the treatment of digestive disorders that occur in liver diseases and toxic lesions of the liver”.¹¹⁵ Therefore, the Commission finds that the Parties’ products do not belong to the same relevant product market and will not further address these products in this decision.

4.5.4. *Topical products for joint and muscular pain in Portugal*

4.5.4.1. Product market definition

- (153) The ATC3 class M2A (Topical Anti-Rheumatics and Analgesics) comprises ointments, liniments, plasters, etc. which may produce symptomatic relief in instances of joint and muscular pain, and which are based on various active ingredients. The CHC3 class 02E1 (Muscular Pain Relief Topical) is similarly comprised of products for topical muscular pain relief. Contrary to the ATC3 class, which is not further sub-divided into ATC4 classes, the CHC3 class is further broken down into CHC4 classes based on format or delivery mode such as CHC4 class 02E1O comprising of products in the form of ointments/creams and class 02E1K comprising of products in the form of patches that are neither heated nor cold. The respective ATC3 and CHC4 classes may be further broken down based on the specific molecule / molecule combination.
- (154) The Commission has in the past generally considered the relevant product market to consist of all products classified under the ATC3 class M2A and CHC3 class 02E1.¹¹⁶ In some instances, the Commission has also considered potential sub-segmentations based on molecules, but ultimately left this question open.¹¹⁷
- (155) The Notifying Party considers the ATC3/CHC3 to be the appropriate level at which to conduct the competitive assessment as it considers the products within these classes to be sufficiently interchangeable.¹¹⁸
- (156) The results of the Commission’s market investigation revealed that the vast majority of respondents (both customers and competitors) consider that the relevant product market should consist of all products for topical muscular and joint pain relief without further segmentation based on the molecules/APIs.¹¹⁹ Respondents have explained that such segmentation is not appropriate for joint and muscular pain products as the specific molecule/API is generally not considered very relevant for these products. For example, one competitor noted that for joint and muscular pain products “*the active ingredient is usually of very little concern to patients*” and another that “*patients will not differentiate between the API only*

¹¹⁴ Responses to questions F.C.3 and F.C.4 of the questionnaire to Customers; responses to questions E.B.1 and E.B.2 of the questionnaire to Competitors

¹¹⁵ Responses to question F.C.4 of the questionnaire to Customers.

¹¹⁶ See e.g. M.9274 – *Glaxosmithkline / Pfizer Consumer Healthcare Business*, Decision of 10 July 2019, paragraphs 54, 58-62; M.6705 – *Procter & Gamble/Teva Pharmaceuticals OTC II*, Decision of 9 November 2012, paragraph 16

¹¹⁷ See e.g. M.8889 – *Teva/PGT OTC Assets*, Decision of 29 June 2018, paragraphs 39 and 43.

¹¹⁸ Form CO, paragraphs 549 and 566.

¹¹⁹ Responses to questions F.D.1 and G.C.1 of the questionnaire to Customers; responses to question J.A.1 of the questionnaire to Competitors.

looking for relief [sic]”.¹²⁰ Furthermore, as alternatives to the Parties’ products, respondents have also listed various products based on different molecules/APIs hereby further indicating substitutability across products based on different molecules/APIs.¹²¹

- (157) While the majority of respondents also consider that the relevant product market should consist of all products for topical muscular and joint pain relief without further segmentation based on the form of the product (e.g. aerosol / sprays, heat / cold patches, non-heat / cold patches, liquids, ointments/creams),¹²² some respondents have indicated that it could be necessary to segment between certain product forms.¹²³
- (158) For the purposes of this decision, the Commission considers that the scope of the relevant product market in relation to the topical products for joint and muscular pain amounts to the ATC3 class M2A and CHC4 classes such as 02E1K, without further segmentation based on the molecules/APIs.¹²⁴ The question of potential segmentation based on the form of the product can be left open as the Transaction does not give rise to serious doubts as to its compatibility with the internal market or the functioning of the EEA agreements regardless of whether the competition assessment is carried out at the CHC3 level or the narrower CHC4 level.

4.5.4.2. Competitive assessment

- (159) The Parties’ activities result in one Group 1/1+ affected market in Portugal for topical products for joint and muscular pain namely the CHC4 class 02E1K (all topical muscular pain relief products in the form of patches that are neither heated nor cold), where the Parties have a combined market share of 68.5% (increment of 1.2%) in value and 78.7% (increment of 1.4%) in volume.
- (160) According to the Notifying Party this overlap will not result in any competition concerns considering the negligible increment resulting from the Transaction and the fact that the Parties products (i.e. the Target’s Doroxan and Recordati’s TransAct LAT) are not close substitutes. In addition, the Notifying Party submits that the merged entity will continue to face a number of strong competitors including Haleon’s Voltaren (16.2% based on value).¹²⁵
- (161) Based on the assessment carried out by the Commission, the Commission finds the Transaction will not result in a significant impediment to competition for topical joint and muscular relief products in Portugal.
- (162) *First*, considering that the Transaction only brings about a negligible increment (1.2% based on value and 1.4% based on volume), it is unlikely to significantly affect the competitive landscape in this market.

¹²⁰ Responses to questions J.A.2 and J.A.4 of the questionnaire to Competitors.

¹²¹ Responses to question G.C.7 of the questionnaire to customers; and responses to questions J.B.3 and J.C.2 of the questionnaire to competitors.

¹²² Responses to questions F.D.1 and G.C.1 of the questionnaire to Customers; responses to question J.A.1 of the questionnaire to Competitors.

¹²³ Responses to questions J.A.1 and J.A.2 of the questionnaire to Competitors.

¹²⁴ As indicated in table 3, a Group 1/1+ market arises in Italy only based on the overlap at the molecule level. As described, the Commission does not consider the molecule level an appropriate relevant market for the purposes of this case. Therefore, the molecule level overlaps in Italy are not further discussed in this decision.

¹²⁵ Form CO, paragraphs 567-575.

- (163) *Second*, the merged entity will continue to face competition post-Transaction. The majority of the respondents to the Commission's market investigation have indicated that a sufficient number of alternative topical muscular pain relief products remain available for customers in Portugal post-Transaction.¹²⁶ Alternatives mentioned by respondents include for example Hialeon's Voltaren and Teva's Olfen.¹²⁷
- (164) *Thirdly*, the majority of respondents have indicated that the Transaction would have a positive or neutral impact on the market for topical product for joint and muscular pain in Portugal, with no indication that this would differ specifically in relation to topical muscular pain relief products in the form of patches that are neither heated nor cold in Portugal.¹²⁸
- (165) Therefore, the Commission finds that the Transaction does not raise serious doubts as to its compatibility with the internal market or the functioning of the EEA agreement as a result of the overlap in relation to topical muscular pain relief products in the form of patches that are neither heated nor cold arising in Portugal.

4.5.5. *Magnesium supplements in Luxembourg*

4.5.5.1. Market definition

- (166) The ATC3 class A12C comprises products that are indicated for the treatment of deficiencies in mineral elements and covers all mineral supplements other than calcium and potassium. A12C is sub-divided into: (i) ATC4 A12C1 - supplements containing magnesium; and (ii) ATC4 A12C2 - minerals other than calcium, potassium or magnesium.
- (167) The Commission has in the past looked at this ATC3 A12C class as a whole¹²⁹ and also considered that a breakdown to the level of the mineral supplement in question could be justified, but it ultimately left it open as it was not material to the case in question.¹³⁰
- (168) The Notifying Party submits that the relevant product market is wider than the ATC3 A12C class, as it considers that mineral supplements containing magnesium are substitutable with magnesium-only products and therefore also include competitors from other ATC3 classes.¹³¹
- (169) The results of the market investigation were mixed. Whilst the majority of participants considered that there is demand substitutability, at least for some patients, between magnesium supplements and other mineral supplements (incl.

¹²⁶ Responses to questions F.D.1 and F.D.2 of the questionnaire to Customers and responses to questions J.C.1 and J.C.2. of the questionnaire to Competitors.

¹²⁷ Responses to question F.D.4 of the questionnaire to Customers; and responses to question J.C.2 of the questionnaire to Competitors.

¹²⁸ Responses to questions J.3 of the questionnaire to Customers; and responses to question O.3 of the questionnaire to Competitors.

¹²⁹ See Cases M.737 – *Ciba-Geigy/Sandoz*, Decision of 17 July 1996; and M.4367 *Apw/Apsa/Nordic Capital /Capio*, Decision of 16 March 2007, paragraph 27.

¹³⁰ See Case M.5253 – *Sanofi/Aventis/Zentiva*, Decision of 4 February 2009, paragraphs 69-70.

¹³¹ Other ATC3 classes such as ATC3 A11A (Multivitamins with Minerals) and A11G (Vitamin C, including Combinations with Minerals) also contain magnesium-based products that compete with the Parties' offerings.

food supplements and multivitamins) containing magnesium, only one third of respondents found that this is the case for the majority of patients.¹³²

- (170) In any event, for the purposes of this decision, the exact product market definition for magnesium supplements can be left open, since the Transaction does not give rise to serious doubts as to its compatibility with the internal market or the functioning of the EEA agreement, even under the narrowest plausible market for magnesium supplements (at ATC4 level A12C1), as assessed below.

4.5.5.2. Competitive assessment

- (171) The Target and Cooper both supply magnesium supplements in Luxembourg.¹³³ Whilst the Target's Biomagnesin product is indicated for neuromuscular disorders due to magnesium deficiency, Cooper's Mag 2's primary indication is to reduce fatigue, but can also be used for neuromuscular disorders, nervousness, irritability and mild anxiety.
- (172) In the narrower market for magnesium supplements (at ATC4 level A12C1) in Luxembourg, the combined share of the Parties was 77% in value (with an increment of 5.9% by the Target) and 79.3% in volume (with an increment of 9.2% by the Target).
- (173) The Notifying Party argues that these market shares are overstated;¹³⁴ that there are very low barriers to start supplying the Luxembourg market (from another Member State),¹³⁵ and that they will continue to face strong competition in Luxembourg.¹³⁶
- (174) The results of the Commission's market investigation indicate that the Transaction does not raise serious doubts as to its compatibility with the internal market or the functioning of the EEA agreement as a result of horizontal effects in the market for magnesium supplements in Luxembourg for the following reasons.
- (175) *First*, the market investigation confirmed that magnesium supplements compete – at least to some extent – with food supplements/multivitamins with the same indication.¹³⁷ Hence, the above market shares are overstated, and according to the Parties' best estimates, their combined share for magnesium supplements in Luxembourg, including food supplements/multivitamins with magnesium and

¹³² See Responses to question G.A.1 of the questionnaire to Competitors; responses to Question E.C.1 of the questionnaire to Customers.

¹³³ None of the other CVC portfolio companies supply magnesium supplements in Luxembourg.

¹³⁴ IQVIA's Midas data does not capture sales of competing multivitamins or food supplements containing magnesium, nor does it capture online sales in Luxembourg. According to their estimated calculations, the combined value share adjusted to account for similar magnesium-based products sold in other ATC3 classes, as well as products sold without drug status or via the e-commerce channel, would be [10-20]% in Luxembourg, with an increment of [0-5]% by the Target. See the Parties' Response of 25 March 2024 to RFI 3 Question 13.

¹³⁵ According to the Notifying Party, the barriers to entry are low, as magnesium supplements are extremely common and easily available in a variety of forms for purchase as OTC products in Luxembourg. In addition, food supplements are marketed as food products and not as pharmaceutical products and are subject to EU-wide health regulations, which make it possible for a supplier in another Member State to supply into Luxembourg.

¹³⁶ Post-Transaction, seven competitors will remain to constrain the merged entity, including two competitors (Sanofi and Cefak) with market shares exceeding 10%. The Notifying Party submits that it will also continue to face competition from distributors of multivitamins and food supplements containing magnesium.

¹³⁷ See responses to question G.B.4 of the questionnaire to Competitors.

online and drugstore sales, was [10-20]% (with an increment of [0-5]% by the Target) in Luxembourg.¹³⁸ At this level, this is not an affected market.

- (176) *Second*, the results of the market investigation indicate that neither Cooper's Mag 2 nor the Target's Biomagnesium play a particularly important role in the market for magnesium supplements in Luxembourg. Whilst the market investigation results were mixed regarding the Parties' products' closeness, the majority of market investigation participants consider that there will be sufficient alternatives in Luxembourg post-Transaction.¹³⁹
- (177) *Third*, the results of the market investigation¹⁴⁰ confirmed that players that market magnesium supplements in neighbouring countries could easily (in a short period of time and without a significant investment) start marketing magnesium supplements in Luxembourg.
- (178) *Fourth*, the majority of the market investigation respondents indicated that the Transaction would have a neutral impact on the market for magnesium supplements in Luxembourg.¹⁴¹
- (179) In light of the above considerations, the Commission considers that the Transaction does not raise serious doubts as to its compatibility with the internal market or the functioning of the EEA agreement as a result of horizontal effects in the market for magnesium supplements in Luxembourg.

4.5.6. *Prostate products in Belgium*

4.5.6.1. Market definition

- (180) The CHC3 class 12F1 comprises all OTC products for prostate conditions across different forms such as capsules, oral mixtures, teas and others. The CHC4 class 12F1C comprises those prostate products in capsule or tablet form. This class makes up 98% (by both volume and value) of the CHC3 12F1 class in Belgium.
- (181) Whilst the Commission has not previously defined the market for prostate products, the Notifying Party submits that the relevant product market is at CHC3 12F1 level, since oral mixtures compete with tablet and capsule products.
- (182) Whilst the results of the market investigation to competitors were more mixed, all customers responding to the market investigation agree that there is demand substitutability for prostate products across all forms (especially across oral forms, *e.g.* tablets and capsules), and with food supplements with the same indication.¹⁴²
- (183) In any event, for the purposes of this decision, the exact product market definition for prostate products can be left open, since the Transaction does not give rise to serious doubts as to its compatibility with the internal market or the functioning of

¹³⁸ See footnote 134 above, and the Parties' Response of 25 March 2024 to RFI 3 Question 13.

¹³⁹ See responses to questions E.C.2-6 of the questionnaire to Customers; and responses to questions G.B.1-2, G.B. 10-11 of the questionnaire to Competitors.

¹⁴⁰ See responses to question G.B.9 of the questionnaire to Competitors; and Non-Confidential Minutes of a call with a Competitor on 2 February 2024, paragraphs 11-13.

¹⁴¹ See responses to question O.3 of the questionnaire to Competitors; and responses to question J.3 of the questionnaire to Customers.

¹⁴² See responses to question H.A.1 of the questionnaire to Competitors; and responses to question C.B.1 of the questionnaire to Customers.

the EEA agreement, even under the narrowest plausible market for prostate tablets and capsules (at CHC4 level 12F1C), as assessed below.

4.5.6.2. Competitive assessment

- (184) The Target and Cooper both supply prostate products in Belgium. The Parties' products are all natural, herbal supplements and are used for urinary support or prostate care.
- (185) In the narrower market for prostate tablets and capsules (at CHC4 level 12F1C) in Belgium, the combined share of the Parties was 49.8% in value (with an increment of 1.2% by Cooper) and 44.8% in volume (with an increment of 0.7% by Cooper).
- (186) The Notifying Party submits that the Transaction will not have a material impact on either (12F1 or 12F1C) market in Belgium due to the negligible increment brought about by Cooper, and because the merged entity will continue to face strong actual competition¹⁴³ and potential competition post-Transaction.¹⁴⁴
- (187) The market investigation indicated that Cooper's Benypro competes with the Target's Prosta Urogenin, which are "*both based on the same plant extract and therefore indicated for the same treatment.*"¹⁴⁵ Whilst the results on market entry from another EEA Member State were mixed,¹⁴⁶ the market investigation conclusively confirmed that there will be sufficient alternatives in Belgium post-Transaction.¹⁴⁷
- (188) The majority of the market investigation respondents also indicated that the impact of the Transaction on this market would be neutral.¹⁴⁸
- (189) In addition, the increment brought by Cooper's Benypro is minimal (1.2% in value, 0.7% in volume).
- (190) In any event, the Notifying Party submits that this overlap is historical as Cooper's product Benypro has been discontinued, [...].¹⁴⁹
- (191) In light of the above considerations, the Commission considers that the Transaction does not raise serious doubts as to its compatibility with the internal market or the

¹⁴³ It will remain constrained by more than 30 competitors, including 2 competitors with market shares above 10% (Farmafyt and Primrose). According to the Notifying Party there are a number of products that compete more closely with the Target's product than Cooper's offerings (e.g. Vogel's Serenoa Repens, Mephar's Pro-Lutsen and Arkopharma's Arklogelules, which are based on the same API and serve the same functionality).

¹⁴⁴ The markets for food supplements are characterised by lower regulatory barriers, lead times and R&D costs than those associated with registered drugs according to the Notifying Party.

¹⁴⁵ See responses to question H.B.1 of the questionnaire to Competitors; and to question C.B.2 of the questionnaire to Customers.

¹⁴⁶ See responses to questions H.B.2-3 of the questionnaire to Competitors.

¹⁴⁷ See responses to questions H.B.4-5 of the questionnaire to Competitors; and responses to questions C.B.3-4 of the questionnaire to Customers. One competitor stated that "*there are alternatives coming up every year*" and a customer explained that "*many alternatives exist in a highly fragmented market.*"

¹⁴⁸ See responses to question O.3 of the questionnaire to Competitors; and responses to question J.3 of the questionnaire to Customers.

¹⁴⁹ [...]. See the Parties' Response to RFI 2 of 4 March 2024, paragraph 19.2. See signed statement from Cooper received on 26 March 2024.

functioning of the EEA agreement as a result of horizontal effects in the market for prostate products in Belgium.

4.5.7. *Earwax removal products in Germany*

4.5.7.1. Market definition

- (192) The ATC3 class S2D includes all ear preparations that contain neither an antibacterial nor a steroid. The ATC4 class S2D1 includes earwax removal products that contain neither an antibacterial nor a steroid.
- (193) Under the CHC classification, there is no "earwax removal" category. However, the CHC3 class 08A1 refers to "ear care" products and includes Cooper's Audispray range of products as well as Target's Otowaxol. At CHC4 level (based on form), the Parties overlap only in the CHC4 08A1D "ear care – ear drops" class.¹⁵⁰
- (194) The Notifying Party submits that the relevant product market is wider than ATC3 level. Namely, it considers that systemic homeopathic products and medical devices for manual earwax removal should also be included.
- (195) Whilst the market investigation indicated that there is demand substitutability between ear sprays and ear drops, the results were mixed regarding demand substitutability between earwax removal sprays/drops and either: (i) systemic homeopathic solutions; or (ii) manual mechanical earwax removers.¹⁵¹
- (196) On this basis, the market for earwax removal products cannot be defined as including systemic homeopathy and mechanical earwax removers and must therefore be assessed under the narrower market definition for earwax removal products (at ATC4 level S2D1).

4.5.7.2. Competitive assessment

- (197) The Target and Cooper both supply earwax removal products in Germany. Whilst both the Target's Otowaxol and Cooper's Audispray Ultra are based on the same active ingredient (docusate sodium) and used to remove excess earwax and earwax plugs, Cooper's Audispray Adult and Audispray Junior are based on purified sea water and used to prevent the formation of ear wax.
- (198) As indicated in Table 12 below, in the narrower market for earwax removal products (at ATC4 level S2D1) in Germany, the combined share of the Parties was 88.7% in value (with an increment of 28.7% by Cooper) and 89.7% in volume (with an increment of 23.9% by the Target).¹⁵²

¹⁵⁰ See case M.10247 – CVC/Cooper, paragraphs 27-31; and the Parties' Response to RFI 7 of 24 May 2024, paragraph 1.1.

¹⁵¹ See responses to question I.A.1 of the questionnaire to Competitors; and the response to question I.A.1. of the questionnaire to Customers.

¹⁵² See Table 12. Source: IQVIA. See Form CO, Tables 3 and 73. The Parties note that the higher volume share of Cooper compared to its value share and lower volume share of the Target compared to its value share is driven by the fact that IQVIA counts 0.1ml as 1 Standard Unit in this category. Given the higher ml content of Cooper's Audispray (20/25/50ml) compared to Target's Otowaxol (10ml), as well as other competitors' products, its share by SU is higher than its share by value. At **CHC3 level**, the Parties' combined market share for ear care products was 32.6% in value, and 48.3% in volume. At **CHC4 level**, the Parties' combined market share for ear drops was 38.6% in value and 26.1% in volume. See the Parties' response to RFI 7 of 24 May 2024.

- (199) These market shares are based on IQVIA data, which do not include sales via the e-commerce or physical drugstore channels in Germany. According to the Parties' best estimates, listed in Table 12 below, their combined share in this market was [50-60]% in value (with an increment of [10-20]% by Cooper) and [50-60]% in volume (with an increment of [10-20]% by the Target), if online and physical drugstore sales are included.

Table 12: Market shares by value and by volume of the (adjusted) S2D1 class in Germany, in 2022

	Product	API	Intended use	VALUE		VOLUME	
				S2D1 class	Adjusted S2D1 class ¹⁵³	S2D1 class	Adjusted S2D1 class ¹⁵⁴
Cooper	Audispray Adult	Sea water	Prevention	[20-30]%	[10-20]%	[60-70]%	[30-40]%
	Audispray Ultra	Docusate Sodium	Removal	[0-5]%	[0-5]%		[0-5]%
	Audispray Junior	Sea water, Glycerol	Prevention	[0-5]%	[0-5]%		[0-5]%
	Audibaby	Sea water	Prevention	[0-5]%	[0-5]%		[0-5]%
Target	Otowaxol	Docusate, Ethanol, Glycerol	Removal	[60-70]%	[30-40]%	[20-30]%	[10-20]%
Combined				[80-90]%	[50-60]%	[80-90]%	[50-60]%
Biobridge Europe	Axoid	Olea Europea	Removal	[0-5]%	[0-5]%	[0-5]%	[0-5]%
	Crulysin	Ethylhexylglycerol, Glycerol, Sodium	Removal		[0-5]%		[0-5]%
Silicol	Vaxol	Olea Europea	Removal	[0-5]%	[0-5]%	[0-5]%	[0-5]%
BENE Chemie	Cerustop	Paraffin Oil, Prunus Amygdalus (Dulcis), Triglycerides	Removal	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Bader/Baer	Otitex	Docusate	Removal		[0-5]%	[0-5]%	[0-5]%
Prodeco Pharma	GSE Ear Drops Free	Aesculus Hippocastanum, Citrus Paradisi, Glycerol, Ribes Nigrum	Removal		[0-5]%		[0-5]%
Others				[0-5]%	[30-40]%	[0-5]%	[30-40]%
Total				100%	100%	100%	100%

Source: Form CO; Annexes 8.1-I and 8.1-XIII; Responses to RFI 8 and to RFI 12.

- (200) The Notifying Party submits that these shares are still overstated, as the Parties will continue to face strong competition from other methods of earwax removal¹⁵⁵ and

¹⁵³ Parties' best estimates, including online and drugstore sales, assuming that drugstore sales constitute [20-30]% of the market and e-commerce sales constitute [20-30]% of the market. See the Parties' Response to RFI 8, Table 1.

¹⁵⁴ Parties' best estimates, including online and drugstore sales, assuming that drugstore sales constitute [20-30]% of the market and e-commerce sales constitute [20-30]% of the market. See the Parties' Responses to RFI 12, Table 1.

¹⁵⁵ According to the Parties, the merged entity will continue to face strong competition from other products in the market including eardrops with solvent components, homeopathic products, which are common preventive or curing treatments in Germany, as well as from medical devices for the manual removal of earwax and substitutable home remedies like salt water and olive oil. See the Parties' "Submission on earwax removal products in Germany" of 28 May 2024 and Response to RFI 8 of 31 May 2024.

potential entry from products sold in neighbouring member states.¹⁵⁶ It also argues that the Parties' products do not compete closely and are meaningfully differentiated, as most of Cooper's products are intended to prevent earwax from building and clean ears effectively, whilst the Target's Otowaxol is aimed at removing excess earwax (with the exception of Cooper's Audispray Ultra, which is also aimed at removing earwax).¹⁵⁷

- (201) For the reasons set out below, the Commission considers that the Transaction raises serious doubts as to its compatibility with the internal market with respect to the market for ear removal products in Germany.
- (202) *First*, the Parties have high combined market shares in this market, which amount to almost 90% at ATC4 level (88.7% in value and 89.7% in volume), with a non-negligible increment between 20-30%, and which amount to almost 60% according to the Parties' calculations including e-commerce and drugstore sales, with an increment of almost 20% by Cooper.
- (203) *Second*, there are no other players in the market with a share above 3.5%. Indeed, the market investigation indicated that the Target's Otowaxol and Cooper's Audispray Ultra constitute the two main brands for earwax removal in Germany. One competitor noted specifically that brand recognition is very important in this market.¹⁵⁸
- (204) *Third*, whilst the Commission was not able to test the Notifying Party's arguments regarding the closeness of competition of competition between ear wax removal products primarily aimed at earwax prevention (e.g. Audispray Adult) and products primarily aimed at earwax removal, as these arguments were submitted post-State of Play, the Commission notes that the Target's Otowaxol competes closely with Cooper's Audispray Ultra. These products are both based on docusate sodium and the market investigation respondents indicated that "*Audispray Ultra contains similar ingredients to Otowaxol and is targeted at the same ear wax removal use cases (dissolving ear wax plugs and excess ear wax)*" and another respondent stated that "*Cooper's Audispray Ultra and Viatris' Otowaxol are close competitors and have a strong position in the market for earwax removal products in Germany.*"¹⁵⁹
- (205) *Fourth*, the market investigation results however were mixed with regard to potential market entry from another EEA Member State¹⁶⁰ and whether or not sufficient alternatives will remain, indicating that there might not be sufficient earwax removal alternatives for all patients in Germany post-Transaction.¹⁶¹

¹⁵⁶ According to the Parties, they will also continue to face constraints from potential entrants from neighbouring markets, e.g. Cerustop in Austria, and Cerulyse in France, as well as from medical device products which face lower barriers to entry than drugs given they do not require marketing authorisation. See Form CO, paragraphs 606-607.

¹⁵⁷ See the Parties' "Submission on earwax removal products in Germany" of 28 May 2024 and Response to RFI 8 of 31 May 2024.

¹⁵⁸ See Minutes of a call with a competitor on 6 June 2024.

¹⁵⁹ See responses to question I.A.2 of the questionnaire to Customers; and the minutes of a call with a competitor on 6 June 2024.

¹⁶⁰ See responses to questions I.B.2-3 of the questionnaire to Competitors.

¹⁶¹ See mixed responses to questions I.B.4-5 of the questionnaire to Competitors; and response to questions I.A.3-4 of the questionnaire to Customers.

- (206) *Fifth*, around a third of respondents found that the Transaction would have a negative impact on the German market for earwax removal products, including on price and choice *e.g.* because “*in the end there will be less competitors*” and “*the Transaction will lead to an increase in prices and a reduction in consumer choice*”.¹⁶²
- (207) In light of above considerations and of all available evidence, the Commission considers that the Transaction raises serious doubts as to its compatibility with the internal market as regards earwax removal products in Germany, as the Transaction would lead to a creation or strengthening of dominance in this market.

4.5.8. Tonics in Portugal

4.5.8.1. Product market definition

- (208) Tonics refer to products for general well-being, ranging across a variety of pharmacological and therapeutic subgroups in both ATC and CHC classification systems. The CHC3 class 05A1 covers all tonics across various forms such as capsules and tablets, oral mixtures, powders and others.
- (209) The Commission has in the past generally considered the relevant market to consist of all products which fall into the ATC3 class A13A. The Commission has also considered whether the relevant market for tonics should be wider than the ATC3 class A13A including also vitamins with minerals (ATC3 category A11A) but has ultimately left this open.¹⁶³ The Commission has not previously assessed these markets under the CHC classification system.
- (210) The Notifying Party considers the CHC3 class 05A1 to be the relevant level for competition assessment.¹⁶⁴
- (211) The clear majority of respondents to the Commission’s market investigation have indicated that the Parties’ products have different end uses and do not compete with one another.¹⁶⁵ For example, one competitor has stated that the Parties’ products “*have different end uses and thus do not directly compete with each other*”¹⁶⁶ and one customer that they “*serve completely different purposes. Guronsan is a drug for detoxifying the body, while Sargenor is an energiser for physical and mental fatigue*”.¹⁶⁷ Therefore, the Commission finds that the Parties’ products do not belong to the same relevant product market and will not further address these products in this decision.

¹⁶² See responses to question O.3 of the questionnaire to Competitors; and responses to question J.3 of the questionnaire to Customer; and the Minutes of a call with a competitor on 6 June 2024.

¹⁶³ See M.4418, *Nycomed Group/Altana Pharma*, Decision of 13 December 2006, paragraphs 18-19.

¹⁶⁴ Form CO, paragraph 224.

¹⁶⁵ Responses to questions F.B.1 and F.B.2 of the questionnaire to Customers and responses to questions F.1 and F.2. of the questionnaire to Competitors.

¹⁶⁶ Response to question F.2 of the questionnaire to Competitors.

¹⁶⁷ Response to question F.B.2 of the questionnaire to Customers.

4.5.9. Mouthwash for halitosis in Italy

4.5.9.1. Product market definition

- (212) The CHC4 class 87B3G covers mouthwashes for halitosis. It is a subset of CHC3 category 87B3 which covers adult mouthwashes.
- (213) The Commission has not previously considered mouthwashes specifically for the treatment of halitosis but has in the past considered separate markets for: (i) daily-use mouthwash products; and (ii) mouth infection treatments, in particular, because of the different duration of their respective uses (daily v. short-term use), the different sales channels (grocery/retail v. pharmacies), their different indications (cosmetic v. infection treatment) and price differences.¹⁶⁸
- (214) The Notifying Party considers the CHC3 class 87B3 (adult mouthwashes) as the appropriate level for the competitive assessment as it submits that most mouthwashes would work against bad breath regardless of their primary indication.¹⁶⁹
- (215) The results of the Commission's market investigation indicate that daily-use mouthwash and mouth infection treatments belong to two separate product markets.¹⁷⁰ The results of the market investigation have been inconclusive regarding whether mouthwash products for halitosis could be substitutable with mouthwash products primarily marketed for other indications than halitosis i.e. whether the relevant market should be defined at the CHC3 or the CHC4 level.¹⁷¹
- (216) In any case, for the purposes of this case the exact product market definition for mouthwash products for halitosis can be left open since the Transaction does not give rise to serious doubts as to its compatibility with the internal market or the functioning of the EEA agreements under any plausible market definition.

4.5.9.2. Competitive assessment

- (217) The Parties' activities result in one Group 1/1+ market for mouthwash products for halitosis in Italy, namely the CHC4 class 87B3G (mouthwash for halitosis), where the Parties have a combined market share of 51.5% (increment of <5.9%) based on value and 31.9% (increment of 3.8%) based on volume.
- (218) According to the Notifying Party, the Transaction will not result in any competitive concerns regarding mouthwash products for halitosis in Italy as the Parties' products (i.e. Recordati's Dentosan and the Target's CB12) are not close substitutes, the merged entity will continue to face strong competition for example from Colgate-Palmolive's Meridol (market share of 45.3% by value and 61.5% by volume) and will be constrained by external competitive pressure by other means and products used to improve mouth hygiene and halitosis.¹⁷²

¹⁶⁸ See e.g. M.4314 – *Johnson & Johnson / Pfizer Consumer Healthcare*, paragraphs 37-39.

¹⁶⁹ Form CO, paragraph 369.

¹⁷⁰ Responses to questions G.A.1-G.A.2 of the questionnaire to Customers; and responses to questions K.A.1-K.A.2 of the questionnaire to Competitors

¹⁷¹ Responses to question G.A.3 of the questionnaire to Customers; and responses to question K.A.3 of the questionnaire to Competitors

¹⁷² From CO, paragraphs 373-378.

- (219) Based on the assessment carried out by the Commission it finds that the overlap in the CHC4 class 87B3G in Italy will not result in significant impediment to effective competition.
- (220) *First*, the Commission notes that the Parties' products do not appear to be close substitutes. Based on a segmentation between daily-use mouthwash products and mouth infection treatments, the Parties' products would fall within distinct markets as the Target's CB12 is used primarily to neutralise and prevent the substances that cause halitosis over a continuous period, but is not suitable for surgical purposes or for the treatment of infections (i.e. it would be classified within the daily-use (cosmetic) mouthwashes category), whereas Recordati's Dentosan is used for the control of plaque formation and other conditions including infections (i.e. it would be classified within the mouth infection treatments category).¹⁷³ Also, the majority of the respondents to the market investigation consider that the Parties' products are not typically substitutable with one another.¹⁷⁴
- (221) *Second*, respondents have confirmed that there will continue to be a sufficient number of alternatives for halitosis mouthwash products for consumers in Italy post-Transaction.¹⁷⁵ Respondents have identified that the merged entity will continue to face competitive pressure from products such as Meridol, Oral B, Biorepair, Listerine, Mentadent Alito Puro and Elmex..
- (222) *Third*, the majority of respondents have indicated that the Transaction would have a positive or neutral impact on the market for mouthwash for halitosis in Italy.¹⁷⁶
- (223) In light of the above considerations, the Commission finds that the Transaction does not raise serious doubts as to its compatibility with the internal market or the functioning of the EEA agreement as a result of the overlap regarding mouthwash for halitosis in Italy.

4.5.10. Wart/corn removal products in France

4.5.10.1. Product market definition

- (224) The CHC3 class 06L1 covers products used for wart and corn removal of various forms, however excluding plasters. The sub-category CHC4 class 06L1Z comprises all wart and corn removal products not in topical liquid or ointment/cream form.
- (225) The Commission has previously left open the relevant market in relation to wart/corn removal products.¹⁷⁷

¹⁷³ Form CO, paragraph 371. Several respondents to the Commission's market investigation have also explicitly confirmed differences between the Parties' products thereby further justifying their categorisation into the distinct markets (responses to questions G.A.2, G.A.4, G.A.5 of the questionnaire to Customers; and responses to questions K.B.1 and K.B.2 of the questionnaire to Competitors).

¹⁷⁴ Responses to questions G.A.2, G.A.4, G.A.5 of the questionnaire to Customers; and responses to questions K.B.1 and K.B.2 of the questionnaire to Competitors.

¹⁷⁵ Responses to questions G.A.6 and G.A.7 of the questionnaire to Customers; and responses to questions K.B.3 and K.B.4 of the questionnaire to Competitors.

¹⁷⁶ Responses to question J.3 of the questionnaire to Customers; and responses to question O.3 of the questionnaire to Competitors.

¹⁷⁷ See M.5530 – *Glaxo Smith Kline / Stiefel Laboratories*, Decision of 17 July 2009, paragraphs 29-32.

- (226) The Notifying Party does not find it appropriate to distinguish wart and corn removal products by form. According to the Notifying Party, all home therapies are alternatives regardless of their mode of action (topical acids, cryotherapy or oral form) as they treat the same indication. Therefore, the Notifying Party considers CHC3 class 06L1 as the appropriate level for the competition assessment.¹⁷⁸
- (227) The results from the Commission's market investigation were inconclusive as to the relevant product market for wart/corn removal products i.e. whether all home treatments for wart/corn removal are substitutable with each other regardless of their mode of action.¹⁷⁹ In any case, for the purposes of this decision the exact product market definition for wart/corn removal products can be left open since the Transaction does not give rise to serious doubts as to its compatibility with the internal market or the functioning of the EEA agreements under any plausible market definition.

4.5.10.2.Competitive assessment

- (228) The Parties' activities result in two Group 1/1+ affected market for wart/corn removal products in France namely: (i) the CHC3 class 06L1 (wart/corn removal excluding plasters); and (ii) its sub-category the CHC4 class 06L1Z wart/corn removals excluding plaster (other forms).
- (229) At the CHC3 level the Parties have a combined market share of 36.0% (increment of 13.3%) in value and 36.3% (increment of 3.6%) in volume and at the CHC4 level 46.8% (increment of 22.5%) in value and 55.7% (increment of 5.9%) in volume.
- (230) According to the Notifying Party, the Parties' products are differentiated, and the merged entity will continue to be constrained by numerous well-known competitors including Urgo (at the CHC3 level 17.5% and at the CHC4 level 19.4% in value), Stada (at the CHC3 level 13.4%), Pierre Fabre (at the CHC3 level 9.8%) and Perrigo (at the CHC3 level 7.9% and at the CHC4 level 22.2% in value).¹⁸⁰
- (231) The Commission finds that the Transaction does not raise competition concerns at the CHC3 level (06L1) nor at the narrower CHC4 level (06L1Z).
- (232) *First*, the Commission notes that the merged entity will continue to face competition both at the CHC3 level and at the CHC4 level from established players such as Perrigo and Urgo. Also, the majority of respondents to the Commission's market investigation have confirmed that post-Transaction there will remain sufficient alternatives for all types of wart/corn removal products for consumers in France.¹⁸¹ For example one competitor has explained that "[t]here are many brands on the market from many laboratories, and even new brands entering the market

¹⁷⁸ Form CO, paragraph 511.

¹⁷⁹ Responses to questions D.C.1-D.C.2 of the questionnaire to Customers, responses to questions L.A.1 and L.A.2 of the questionnaire to Competitors.

¹⁸⁰ Form CO, paragraph 515-521.

¹⁸¹ Responses to questions D.C.3 and D.C.4 of the questionnaire to Customers, responses to questions L.B.1 and L.B.2 of the questionnaire to Competitors.

(*ex. Poderm*)”¹⁸² with several customers also explicitly stating that there are “*a lot of alternatives*” available.¹⁸³

- (233) *Second*, the majority of respondents consider the impact of the Transaction to be neutral on the warts/corn removal product market in France.¹⁸⁴
- (234) In light of the above considerations, the Commission finds that the Transaction does not raise serious doubts as to its compatibility with the internal market or the functioning of the EEA agreement as a result of the overlap in wart/corn removal products in France.

4.5.11. *Antiparasitic haircare products in France*

4.5.11.1. Product market definition

- (235) The CHC3 class 86H1 comprises all antiparasitic products for hair, irrespective of form (sprays, lotions/liquids, creams/ointments, powders, shampoos, etc.). The narrower CHC4 class 86H1B includes only antiparasitic hair products in liquid or lotion form.
- (236) The Commission has previously left open the relevant market in relation to antiparasitic haircare products.¹⁸⁵
- (237) The Notifying Party does not consider a distinction by form appropriate, as products in whatever form (sprays, shampoos, lotions, creams, etc.) are used in a similar way (i.e. topical application) and similar effectiveness for the removal of hair parasites and therefore considers CHC3 as the appropriate relevant market.¹⁸⁶
- (238) The results of the Commission’s market investigation are inconclusive as to whether from the consumer’s perspective antiparasitic haircare products are generally substitutable with each other regardless of their form i.e. whether the market should be defined at the CHC3 or CHC 4 level.¹⁸⁷ In any case, for the purposes of this decision the exact product market definition for antiparasitic haircare products can be left open since the Transaction does not give rise to serious doubts as to its compatibility with the internal market or the functioning of the EEA agreements under any plausible market definition.

4.5.11.2. Competitive assessment

- (239) The Parties’ activities result in two Group 1/1+ affected markets for antiparasitic haircare products in France namely: (i) at the CHC3 level (86H1 – antiparasitic products for hair); and (ii) at the CHC4 level (86H1B – antiparasitic hair products in liquid or lotion form). At the CHC3 level, the Parties have a combined market share of 44.5% (increment of 1.1%) in value and 40.8% (increment of 1.4%) in

¹⁸² Response to question L.B.2 of the questionnaire to Competitors.

¹⁸³ Responses to questions D.C.4 of the questionnaire to Customers

¹⁸⁴ Responses to questions J.3 of the questionnaire to Customers, responses to question O.3 of the questionnaire to Competitors.

¹⁸⁵ See M.1878 – *Pfizer / Warner-Lambert*, Decision of 22 May 2000, paragraphs 33-34.

¹⁸⁶ Form CO, paragraph 614

¹⁸⁷ Responses to questions D.D.1 and D.D.2 of the questionnaire to Customers, responses to questions M.A.1 and M.A.2 of the questionnaire to Competitors.

volume, and at the CHC4 level of 41.8% (increment of 2.2%) in value and 40.7% (increment of 3.2%) in volume.¹⁸⁸

- (240) Based on the Commission's assessment, it considers that the Transaction does not raise competition concerns in relation to the CHC3 class 86H1 or CHC4 class 86H1B in France.
- (241) *First*, the Transaction will not result in any significant change to the market structure as the increment brought about by the Transaction is limited both at the CHC3 level (1.1% in value and 1.4% in volume) and the CHC4 level (2.2% in value and 3.2% in volume).
- (242) *Second*, the Commission notes that the merged entity will continue to face competition both at the CHC3 and the CHC4 levels post-Transaction. The results of the market investigation have confirmed that post-Transaction there will remain a sufficient number of alternatives for all types of antiparasitic haircare products.¹⁸⁹ Several respondents have explicitly stated that there are a lot of alternatives in the French market and identified several competing products including Apaisyl, Paranix, Puresentiel and Cinq sur Cinq.¹⁹⁰
- (243) *Third*, the majority of respondents consider that the impact of the Transaction on the French antiparasitic haircare product market will be neutral.¹⁹¹
- (244) In light of the above considerations, the Commission finds that the Transaction does not raise serious doubts as to its compatibility with the internal market or the functioning of the EEA agreement as a result of the overlap in antiparasitic haircare products in France.

4.5.12. Overall conclusion on horizontal effects

- (245) In light of the considerations discussed above, the Commission considers that the Transaction raises serious doubts as to its compatibility with the internal market with regard to the overlaps resulting from the Transaction in the markets for: (i) laxative enemas for infants in Portugal; and (ii) earwax removal products in Germany.

5. COMPETITIVE ASSESSMENT OF THE VERTICAL RELATIONSHIPS

- (246) In addition to the horizontal overlaps discussed above, some of CVC's portfolio companies are active in markets downstream from plausible FDP markets, giving rise to two vertically affected relationships:
- (a) FDPs – Target (upstream) / Private hospital services in Greece – CVC (downstream)

¹⁸⁸ As described the CHC4 class 86H1B is a subset of the CHC3 class 86H1 that includes only antiparasitic hair products in liquid or lotion form. Some of the Parties' products are not included in the narrower CHC4 class, which explains the lower combined market share in the narrower CHC4 class.

¹⁸⁹ Responses to questions D.D.3 and D.D.4 of the questionnaire to Customers; and responses to questions M.B.1 and M.B.2 of the questionnaire to Competitors.

¹⁹⁰ Responses to question D.D.4 of the questionnaire to Customers; and responses to question M.B.2 of the questionnaire to Competitors

¹⁹¹ Responses to questions J.3 of the questionnaire to Customers; and responses to question O.3 of the questionnaire to Competitors.

- (b) FDPs – Target (upstream) / Retail sale of health and beauty products in Germany – CVC (downstream)

5.1. Legal framework

- (247) A concentration can also entail vertical and/or conglomerate effects. The Commission Guidelines on the assessment of non-horizontal mergers under the Merger Regulation¹⁹² (the “Non-Horizontal Merger Guidelines”) distinguish between two main ways in which non-horizontal mergers may significantly impede effective competition: (a) when they give rise to input and/or customer foreclosure (non-coordinated effects); and (b) when the merger changes the nature of competition in such a way that firms that previously were not coordinating their behaviour, are now more likely to coordinate to raise prices or otherwise harm effective competition (coordinated effects).¹⁹³ The Non-Horizontal Merger Guidelines distinguish two types of foreclosure: (a) where the merger is likely to raise the costs of downstream rivals by restricting their access to an important input (input foreclosure) and (b) where the merger is likely to foreclose upstream rivals by restricting their access to a sufficient customer base (customer foreclosure).¹⁹⁴
- (248) In assessing the likelihood of an anticompetitive input foreclosure strategy, the Commission has to examine whether: (i) the merged entity would have the ability to substantially foreclose access to inputs; (ii) whether it would have the incentive to do so; and (iii) whether a foreclosure strategy would have a significant detrimental effect on competition downstream.¹⁹⁵ In assessing the likelihood of an anticompetitive customer foreclosure strategy, the Commission has to examine whether: (i) the merged entity would have the ability to foreclose access to downstream markets by reducing its purchases from upstream rivals; (ii) whether it would have the incentive to do so; and (iii) whether a foreclosure strategy would have a significant detrimental effect on consumers in the downstream market.¹⁹⁶ According to the Non-Horizontal Merger Guidelines, the Commission is unlikely to find concern in non-horizontal mergers, where the market share post-merger of the new entity in each of the markets concerned is below 30%.¹⁹⁷
- (249) The Non-Horizontal Merger Guidelines define conglomerate mergers as mergers between firms that are in a relationship which is neither horizontal (as competitors in the same relevant market) nor vertical (as suppliers or customers).¹⁹⁸

¹⁹² Commission Guidelines on the assessment of non-horizontal mergers under the Merger Regulation (OJ C 265, 18.10.2008, p. 6).

¹⁹³ Non-horizontal Merger Guidelines, paragraphs 17-19.

¹⁹⁴ Non-horizontal Merger Guidelines, paragraph 30.

¹⁹⁵ Non-horizontal Merger Guidelines, paragraph 32.

¹⁹⁶ Non-horizontal Merger Guidelines, paragraph 59.

¹⁹⁷ Non-horizontal Merger Guidelines, paragraph 25.

¹⁹⁸ Non-horizontal Merger Guidelines, paragraph 5.

5.2. Market definition

5.2.1. *FDPs*

5.2.1.1. Product market for FDPs

- (250) As explained above,¹⁹⁹ the Commission consistently considers plausible product market for FDPs based on the IQVIA datasets, at ATC3/CHC3 level; at AT4/CHC4 level; or at molecule level.
- (251) The market investigation did not provide any indications that would require the Commission to depart from its previous decisional practice with respect to the product market definition for FDPs that are vertically affected.
- (252) The precise delineation of the FDP market(s) that are vertically affected by the Transaction can be left open because no competition concerns arise under any plausible relevant market definition.

5.2.1.2. Geographical market for private hospital services

- (253) As explained above,²⁰⁰ the Commission consistently defines the different plausible markets for FDPs as national in scope.
- (254) The market investigation did not provide any indications that would require the Commission to depart from its previous decisional practice on the geographic scope of the different plausible markets for FDPs that are vertically affected.
- (255) Therefore, for the purposes of this decision, the Commission considers the geographic scope of the different plausible markets for FDPs to be national in scope.

5.2.2. *Private hospital services*

5.2.2.1. Product market for private hospital services

- (256) The Commission has previously considered a relevant product market for private hospital services which would be separate from public hospital services, depending on the specificities of the case and the national market in question.²⁰¹
- (257) In addition, the Commission has previously considered a distinction between inpatient (acute) hospital procedures conducted in hospitals and outpatient (ambulatory) procedures conducted in hospitals as well as a distinction between different specialist medical departments.²⁰²
- (258) The Notifying Party agrees that the national differences between Member States merits a case-by-case assessment. According to the Notifying Party a distinction between specialist medical departments is not relevant for the present case where the Parties are active on vertically related markets and there is no horizontal

¹⁹⁹ Section 4.2.

²⁰⁰ Section 4.2.

²⁰¹ See e.g. M.9044 – *CVC/Recordati*, Decision of 4 December 2018, paragraphs, 21 and 145.

²⁰² *Ibid*, paragraph 21.

overlap in relation to hospital services. Therefore, the Notifying Party submits that the market for private general hospital services should not be further segmented.²⁰³

- (259) The Commission's market investigation did not provide any indications that it would be appropriate for the Commission to depart from its previous decisional practice for private hospital services.
- (260) In any case, for the purposes of this case the product market definition for hospital services can be left open since the Transaction does not give rise to serious doubts as to its compatibility with the internal market or the functioning of the EEA agreement even under the narrowest plausible product market definition of private hospital services.

5.2.2.2. Geographical market for private hospital services

- (261) The Commission has in the past considered the geographical scope of the market for (private) hospital services to be national or narrower.²⁰⁴
- (262) According to the Notifying Party the geographical market should be defined as national.²⁰⁵
- (263) The Commission's market investigation did not provide any indications that it would be appropriate for the Commission to depart from its conclusion that the relevant market for general private hospital services is local in scope (i.e. Attica).²⁰⁶
- (264) In any case, for the purposes of this case, the exact geographic market definition for private hospital services can be left open since the Transaction does not give rise to serious doubts as to its compatibility with the internal market or the functioning of the EEA agreement under any plausible geographical market definition of private hospital services.

5.2.3. *Retail sale of health and beauty products*

5.2.3.1. Product market for retail sale of health and beauty products

- (265) The Commission has in the past considered a broad market for these products but acknowledged potential sub-segments.²⁰⁷
- (266) According to the Notifying Party, the most appropriate product market definition for the case at hand would be a retail mass market for health and beauty products without any further segmentation.²⁰⁸

²⁰³ Form CO, paragraphs 81-82.

²⁰⁴ See e.g. M.9044 – *CVC/Recordati*, Decision of 4 December 2018, paragraph 22.

²⁰⁵ Form CO, paragraph 83.

²⁰⁶ See e.g. M.10247 - *CVC / Ethniki*, Decision of 24 February 2022, paragraphs 42-49.

²⁰⁷ See e.g. M.7224 - *Kesko/Oriola/JV*, Decision of 10 May 2017, where the Commission evaluated sub-segments including cosmetics, body care, health foods, and baby products. In M.3732 - *AS Watson/Marionnaud*, Decision of 07 April 2005, the retail sale was segmented into luxury perfumes and mass-market health and beauty products, further distinguishing by retail type (e.g., specialty stores, supermarkets). Additionally, the Commission recognized specific segments like body care, face care, and oral care products, and considered whether online and offline sales belong to the same market.

²⁰⁸ Form CO, paragraph 91.

- (267) The Commission's market investigation did not provide any alternative market definitions for retail sale of health and beauty products. In any case, for the purposes of this case, the exact product market definition for the market for retail sale of health and beauty products can be left open since the Transaction does not give rise to serious doubts as to its compatibility with the internal market or the functioning of the EEA agreement under any plausible product market definition.

5.2.3.2. Geographical market for retail sale of health and beauty products

- (268) While local market conditions and catchment areas (10-30 minutes driving time) have also been considered, the Commission typically has defined the geographic market for the retail sale of health, beauty, and beauty products as national, influenced by uniform pricing and marketing strategies across countries.²⁰⁹
- (269) According to the Notifying Party, the most appropriate geographic market for the case at hand would be a national.²¹⁰
- (270) The Commission's market investigation did not provide any alternative market definitions for retail sale of health and beauty products. In any case, for the purposes of this case, the exact geographic market definition for retail sale of health and beauty products can be left open since the Transaction does not give rise to serious doubts as to its compatibility with the internal market or the functioning of the EEA agreement under any plausible geographical market definition of retail sale of health and beauty products.

5.3. Competitive assessment of the vertical relationships

- (271) The vertically affected markets are summarised in Table 13 below.

Table 13. Overview with vertically affected markets

Upstream market	Party active	Downstream market	Party active
FDPs	Target	Private hospital services in Greece	CVC (Hellenic Healthcare Group)
FDPs	Target	Retail sale of health and beauty products in Germany	CVC (Disapo)

5.3.1. *FDPs – Target (Upstream) / Private Hospital Services – CVC (Downstream)*

- (272) CVC is active in the downstream market for private hospital services in Greece.²¹¹ The Target offers FDPs in Greece that could be an upstream input for the operation of private hospitals downstream. The vertically linked (at the ATC3/CHC3 level) upstream and downstream markets and the Parties' shares are below.

²⁰⁹ See e.g. cases like M.7224 - Kesko/Oriola/JV and M.3732 - AS Watson/Marionnaud, where various product categories and retail types were assessed with a national scope due to factors such as product range and national advertising

²¹⁰ Form CO, paragraph 91.

²¹¹ Through the HHG which is the largest private hospital group in Greece, consisting of six hospitals: Metropolitan Hospital; Metropolitan General; Hygeia Hospital; Mitera; Leto; and Creta Interclinic. HHG provides all major procedures and treats approximately 100,000 inpatients and 1 million outpatients annually.

Table 14: Summary of vertically affected markets in Greece 2022, (shares in value)

Upstream market (Target)			Downstream market (CVC)		
Product market	Geographic market	Market share	Product market	Geographic market	Market share
ATC3 - A6A DRUGS FOR CONSTIPATION (DUPHALAC)	Greece	34.5%	Private general hospitals	Attica	40-50%
CHC3 - 03C2 OSMOTIC LAXAT (EXC SALINE) (DUPHALAC)	Greece	35.9%	Private general hospitals	Attica	40-50%
ATC3 - C10B ANTI-ATHEROMA (OMACOR)	Greece	69.1%	Private general hospitals	Attica	40-50%
CHC3 - 10F1 OMEGA-3 HEART/CIRC/LIPID (OMACOR)	Greece	54.5%	Private general hospitals	Attica	40-50%
ATC3 - D6A TOPICAL ANTIBACTERIALS (PULVO 47)	Greece	34.5%	Private general hospitals	Attica	40-50%
CHC3 - 06F3 WOUND HEALING PROD (PULVO 47)	Greece	27.8%	Private general hospitals	Attica	40-50%
CHC3 - 06L1 WART/CORN REMOV EXC PLAST (ENDWARTS) ²¹²	Greece	29.7%	Private general hospitals	Attica	40-50%

Source: Form CO.

- (273) The Notifying Party submits that the minimal sales of Duphalac, Omacor, and Pulvo 47 to HHG and its main competitors indicate that these products are not important inputs for HHG and its main competitors and has no bearing on a patient's choice of hospital as patients continue to choose hospitals that use alternative products or do not use these products for treatment. In addition, HHG's competitors have access to several alternative suppliers.
- (274) The Commission considers that the Transaction does not raise concerns for input or customer foreclosure for the following reasons.
- (275) *First*, the combined entity is unlikely to have the ability to engage in input foreclosure due to the minimal sales of FDPs from the Target to HHG and its main competitors. Particularly, the Target has sold three FDPs to private general hospitals of HHG in Greece during the period from 2020 to September 2023: Duphalac, Omacor, and Pulvo 47.²¹³ The Target's total sales of these FDPs to HHG amounted to less than EUR [...] in 2022, representing [0-5]% of the Target's sales in Greece in 2022. Further, HHG's competitors procured insignificant amounts of the relevant products during that period.²¹⁴ The negligible sales do not represent a

²¹² The Target made [...] sales of Endwarts to private hospitals in 2020, 2021, and 2022.

²¹³ The Target also sold Rheum Officinale / Salicylic Acid to HHG during the period between 2020 to September 2023 [...].

²¹⁴ In particular, Iatriko Athens Medical sales figures amounted to [...] EUR for Duphalac, [...] EUR for Omacor, and [...] EUR for Pulvo. Henry Dunant Hospital's sales figures were [...] EUR for Duphalac and [...] EUR for Pulvo, with no sales reported for Omacor. Euromedica's sales amounted to [...] EUR for Duphalac, [...] EUR for Omacor, and [...] EUR for Pulvo. Euroclinic of Athens recorded sales of [...] EUR for Duphalac and [...] EUR for Omacor, with no sales for Pulvo. St Luke's had sales of [...] EUR for Duphalac and did not report any sales for Omacor and Pulvo. In total, the

significant cost factor for the downstream services provided by HHG's competitors, nor are these products critical components or a significant source of product differentiation for the downstream services. Additionally, HHG's competitors have access to multiple alternative products.²¹⁵

- (276) *Second*, the Parties have no incentive to engage in such a foreclosure strategy due to its lack of profitability. The Target's sales of relevant products to downstream competitors of HHG are minimal, and these competitors have access to multiple alternative products, therefore, restricting input sales would not yield any significant profit from expanding market share or increasing prices downstream for the combined entity.
- (277) *Third*, the combined entity is unlikely to have the ability to engage in customer foreclosure because it would not constitute an important customer for the upstream FDP markets in Greece. In particular, HHG's purchasing share of the relevant upstream national FDP market is likely to be less than 5%.²¹⁶
- (278) *Fourth*, the combined entity has no incentive to engage in such a foreclosure strategy due to its lack of profitability. The Target's competitors have access to multiple alternative customers, therefore, the upstream division of the merged entity would not benefit from possibly higher price levels in the upstream market arising as a result of upstream rivals being foreclosed.²¹⁷
- (279) Based on the above, the Commission considers that the Transaction does not raise concerns for input or customer foreclosure.

5.3.2. *FDPs – Target (upstream) / Retail sale of health and beauty products in Germany – CVC (downstream)*

- (280) CVC, through Disapo, is active in the downstream market for retail sale of health and beauty products in Germany. The Target offers FDPs in Germany that could be an upstream input for the retail sale of health and beauty products downstream. The vertically linked (at the CHC3 level) upstream and downstream markets and the Parties' shares are below.

cumulative sales figures across these hospitals were [...] EUR for Duphalac, [...] EUR for Omacor, and [...] EUR for Pulvo. See more in Form CO, para. 146 and table 10.

²¹⁵ In Greece, there are multiple alternatives to: (a) Duphalac including Dulcolax (22.9% by value in 2022) and Forlax (4.7% by value in 2022); (b) Omacor including Galenica's Zodin Derh (14.1% by value in 2022) and Unipharma's Prolipid (13.8% share by value in 2022); and (c) Pulvo 47 including Verisfield Hy-sil (24% by value in 2022), as well as Zwitter Sylfio (3.6% by value in 2022). See more in Form CO, para. 150.

²¹⁶ Form CO, para. 144.

²¹⁷ See footnote 227.

Table 15: Summary of vertically affected markets in Germany 2022, (shares in value)

Product market	Market share	Product market	Market share
CHC3 - 85D1 INTIMATE DETERGENTS	53.1%	Retail sale of health and beauty products	<5%
CHC3 - 10F3 OTH CHOLESTEROL REGUL PRD	59.0%	Retail sale of health and beauty products	<5%
CHC3 - 82G4 AFTER EPILAT/DEPILAT PRDS	67.6%	Retail sale of health and beauty products	<5%

Source: Form CO.

- (281) The Notifying Party submits that the vertical relationship with Disapo is limited to the pharmacy retail channel and the sales of the Target's products constitute [0-5]% of Disapo's total sales. In addition to this, Disapo's downstream market share in Germany remains [0-5]% and ceasing sales to other major retailers such as Docmorris and Shop Apotheke, who account for the majority share, would not serve the interests of the merged entity.
- (282) The Commission considers that the Transaction does not raise concerns for input or customer foreclosure for the following reasons.
- (283) *First*, the combined entity is unlikely to have the ability to engage in input foreclosure. Particularly, healthcare retailers sell a vast range of products and the unavailability of a few stock keeping units would not diminish their ability to compete effectively in the market. For example, sales of the Target's products accounted for [0-5]% of Disapo's sales in 2022. In addition, the Target's sales to Disapo's main competitors are limited.²¹⁸ Specifically, Target's sales to Docmorris in 2022 amounted to EUR [...] and accounted for [0-5]% of 2022 sales by Docmorris in Germany (EUR [...]) and sales to Shop Apotheke in 2022 amounted to EUR [...] and accounted for [0-5]% of 2022 sales by Shop Apotheke in Germany (EUR [...]). As such, Docmorris and Shop Apotheke would remain effective competitors to Disapo in the hypothetical scenario in which Target ceased to supply them with its FDPs. In any event, Disapo's competitors can procure alternative products to the Target's upstream products from other companies.²¹⁹
- (284) *Second*, the Parties have no incentive to engage in such a foreclosure strategy due to its lack of profitability. The Target's sales of relevant products to downstream competitors of Disapo are minimal, therefore, restricting input sales would not yield any significant profit from expanding market share or increasing prices downstream for the combined entity.
- (285) *Third*, the combined entity is unlikely to have the ability to engage in customer foreclosure because it would not constitute an important customer for the upstream FDP markets in Germany. In particular, Disapo's market share of the relevant downstream national market is less than 5%.

²¹⁸ Form CO, footnote 104.

²¹⁹ See response in RFI 15, tables 1,2 and 3. For instance, in Germany, at the 10F3 CHC3 class available products include Symbiolact (Symbiopharm) with a value share of 7.2% and Arterin (Perrigo) with a value share of 7.1%. Similarly, at the 82G4 CHC3 class, available products include Biomed (Skin Doctors) holding a value share of 31.1%, and Australian Bodycare and Intim (Bergland Pharma) each with a value share of 0.6%. At the 85D1 CHC3 class, available products include Vagisan (Dr. Wolff) with a 29.5% value share and Deumavan (Kaymogyn) with an 8.0% value share.

(286) *Fourth*, the combined entity has no incentive to engage in such a foreclosure strategy due to its lack of profitability. Given the Disapo's limited downstream market power the Target's competitors have access to multiple alternative customers, therefore, the upstream division of the merged entity would not benefit from possibly higher price levels in the upstream market arising as a result of upstream rivals being foreclosed.

(287) Based on the above, the Commission considers that the Transaction does not raise concerns for input or customer foreclosure.

5.3.3. *Overall conclusion on vertical effects*

(288) In light of the considerations discussed in paragraphs (272) to (287), the Commission considers that the Transaction does not raise serious doubts as to its compatibility with the internal market or the functioning of the EEA agreement in terms of its competition impact on the vertical relationships identified in paragraph (271).

6. **PROPOSED COMMITMENTS**

6.1. **Framework for the assessment of the commitments**

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

(290) As set out in the Commission's Remedies Notice,²²⁰ commitments have to eliminate the competition concerns entirely, and have to be comprehensive and effective from all points of view.²²¹

(291) In the first phase of the Commission's investigation of a concentration ("Phase I"), commitments offered by the Parties can only be accepted where the competition concerns are readily identifiable and can easily be remedied. The competition concerns therefore need to be straightforward and the remedies clearcut and sufficient to clearly rule out "serious doubts" within the meaning of Article 6(1)(c) of the Merger Regulation, so that it is not necessary to enter into an in-depth ("Phase II") investigation. Where the assessment confirms that the proposed commitments remove the grounds for serious doubts on this basis, the Commission clears the concentration in Phase I.²²²

(292) In assessing whether commitments will maintain effective competition, the Commission considers all relevant factors, including the type, scale, and scope of the proposed commitments, with reference to the structure and particular

²²⁰ Commission Notice on remedies acceptable under Council Regulation (EC) No 139/2004 and under Commission Regulation (EC) No 802/2004 (OJ C 267, 22.10.2008, pages 1 to 27) ("the Remedies Notice").

²²¹ Remedies Notice, paragraphs 9 and 61.

²²² Remedies Notice, paragraph 81.

characteristics of the market in which the concentration is likely to significantly impede effective competition, including the position of the Parties and other participants on the market.²²³

- (293) In order for commitments to comply with those principles, they must be capable of being implemented effectively within a short period of time. Concerning the form of acceptable commitments, the Merger Regulation gives discretion to the Commission as long as the commitments meet the requisite standard. Structural commitments will meet the conditions set out above only in so far as the Commission is able to conclude with the requisite degree of certainty, at the time of its Decision, that it will be possible to implement them and that it will be likely that the new commercial structures resulting from them will be sufficiently workable and lasting to ensure that effective competition will be maintained.²²⁴ Divestiture commitments are normally the best way to eliminate competition concerns resulting from horizontal overlaps.
- (294) The divested activities must consist of a viable business that, if operated by a suitable purchaser, can compete effectively with the merged entity on a lasting basis and that is divested as a going concern. The business must include all the assets which contribute to its current operation or which are necessary to ensure its viability and competitiveness and all personnel which are currently employed or which are necessary to ensure the business' viability and competitiveness.²²⁵
- (295) The intended effect of the divestiture will only be achieved if and once the business is transferred to a suitable purchaser in whose hands it will become an active competitive force in the market. The potential of a business to attract a suitable purchaser is an important element of the Commission's assessment of the appropriateness of the proposed commitment.²²⁶

6.2. The Bebegel Commitments

6.2.1. Initial Bebegel Commitments

- (296) In order to render the Transaction compatible with the internal market in relation to the plausible market for laxative enemas for infants in Portugal, the Parties submitted a set of commitments under Article 6(2) of the Merger Regulation on 5 June 2024 (the "Initial Bebegel Commitments").
- (297) Under the Initial Bebegel Commitments, the Parties offered to divest the rights, title and interests in the Target's Bebegel (86.4% market share in the plausible market for laxative enemas for infants in Portugal) to a suitable purchaser (the "Bebegel Purchaser"). Specifically, the Parties committed to divest the right to develop, manufacture and use Bebegel with a view to its sale and marketing in any form in Portugal and, at the option of the Bebegel Purchaser, in France (the "Bebegel Divestment Business").
- (298) Under the Initial Bebegel Commitments, the Bebegel Divestment Business consisted of the transfer of the following assets to the Bebegel Purchaser:

²²³ Remedies Notice, paragraph 12.

²²⁴ Remedies Notice, paragraph 10.

²²⁵ Remedies Notice, paragraph 23-25

²²⁶ Remedies Notice, paragraph 47.

- (a) All tangible and intangible assets, including intellectual property rights;
 - (b) All licenses, permits and authorisations issued by any governmental organisation for the benefit of the Bebegel Divestment Business;
 - (c) All contracts, commitments and customer orders of the Bebegel Divestment Business;
 - (d) All customer, credit and other records of the Bebegel Divestment Business;
 - (e) All advertising, marketing, sales, publicity and presentational materials related to the Bebegel Divestment Business, as applicable; and
 - (f) A full transfer of any trademarks related to the Bebegel Divestment Business, and in case of a wider than national trademark, an irrevocable, assignable, sub-licensable, perpetual and royalty free license from the Bebegel Divestment Business to Cooper and/or Viatriis to use the trademark outside of Portugal and France.
- (299) Currently, Bebegel is manufactured and packaged by a third-party, [...], based on a manufacturing contract between Viatriis and [...]. Under the Initial Bebegel Commitments, the Parties will endeavour on a best-efforts basis to obtain the assignment, at the option of the Bebegel Purchaser, of the existing manufacturing contract for the Bebegel Divestment Business or, in the event that consent for the assignment cannot be obtained and at the option of the Bebegel Purchaser, the benefit of back-to-back arrangements for the supply by Cooper of the products to the Bebegel Purchaser for the duration of the relevant contract and, in any case, for no longer than three years.
- (300) Finally, under the Initial Bebegel Commitments, the Bebegel Purchaser must in addition to meeting the criteria of the Commission's model text for divestiture commitments,²²⁷ also have a sales and marketing presence in Portugal in the relevant sales channels.

6.2.2. *Market test*

- (301) The Commission market tested the Initial Bebegel Commitments in order to assess whether they are sufficient and suitable to remedy the serious doubts identified in Section 4.5.1.2.1.3. of this decision and, and whether they were sufficient to ensure the viability and competitiveness of the Bebegel Divested Business.
- (302) Virtually all respondents indicated that the Bebegel Divested Businesses, as defined under the Initial Bebegel Commitments, is a viable and competitive standalone business. In particular, respondents consider that the Bebegel Divestment Business includes all the necessary assets and agreements needed to remain a viable competitive force in the market for laxative enemas for infants in Portugal after the transfer to a suitable purchaser,²²⁸ and will likely attract suitable purchasers.²²⁹ Moreover, several respondents expressed their interest in purchasing the Bebegel Divestment Business.²³⁰

²²⁷ See https://ec.europa.eu/competition-policy/mergers/legislation/best-practices_en.

²²⁸ Responses to question C.B.1 of the Laxative remedy market test questionnaire.

²²⁹ Responses to question C.C.1 of the Laxative remedy market test questionnaire.

²³⁰ Responses to question C.C.9 of the Laxative remedy market test questionnaire.

- (303) With respect to the implementation of the Initial Bebegel Commitments, virtually all respondents agree that the scope and content of the Initial Bebegel Commitments is sufficiently clear for them to be effectively implemented,²³¹ and the majority considers that the Bebegel Purchaser would not encounter significant challenges in the transfer of the manufacturing contract for Bebegel.²³²
- (304) The majority of the respondents also consider that the Initial Bebegel Commitments would solve potential competition concerns arising from the Transaction in relation to laxative enemas for infants in Portugal.
- (305) With respect to the Bebegel Purchaser, the respondents generally agree with the identified criteria that a suitable Bebegel Purchase would need to meet, but some identified an additional criterion.²³³ Specifically, some respondents indicated that a suitable Bebegel Purchaser should in addition to having a marketing and sales presence, also have access to a distribution network in Portugal.²³⁴
- (306) Other than the additional suitable purchaser criteria mentioned in the above paragraph, the respondents of the market test did not identify any other major shortcomings in relation to the Initial Bebegel Commitments.

6.2.3. *Final Bebegel Commitments*

- (307) Following the feedback received during the market test, the Initial Commitments were refined. The Parties submitted amended commitments on 24 June 2024 (the “Final Commitments”). The Final Commitments are annexed to this decision and form an integral part thereof.
- (308) The Final Bebegel Commitments differ from the Initial Bebegel Commitments only on the following points.
- (309) *First*, in the Final Commitments, the Parties have specified that in addition to having a marketing and sales presence, the Bebegel Purchaser shall also have access to an appropriate distribution network in Portugal. In the Final Commitments the Parties have further specified that the relevant sales channels for Bebegel include wholesalers, hospitals and pharmacies.
- (310) *Second*, in the Final Bebegel Commitments it is clarified that the Parties endeavour on a best-efforts basis to obtain the assignment of the existing manufacturing contract for the Bebegel Divestment Business on substantially the same terms and conditions (including price), not just to obtain the assignment.
- (311) *Third*, in relation to the transfer of trademarks, in the Final Commitments it is added that the Bebegel Divestment Business shall include the full transfer of any trademarks related to the Bebegel Divestment Business and relating to any EU Member State or States (except, at the Purchaser's option, trademarks relating to France and French Polynesia²³⁵) in order to allow the Bebegel purchaser to enter and expand in other EU Member States.

²³¹ Responses to question C.A.1 of the Laxative remedy market test questionnaire.

²³² Responses to question C.B.5 of the Laxative remedy market test questionnaire.

²³³ Responses to question C.C.3 of the Laxative remedy market test questionnaire.

²³⁴ Responses to questions C.C.4 of the Laxative remedy market test questionnaire.

²³⁵ See above paragraph 297.

6.2.4. *The Commission's assessment of the Final Bebegel Commitments*

- (312) The Commission analysed the suitability of the Commitments to remedy serious doubts in this case against the standard set out in the Commission Remedies Notice. In its assessment, the Commission relied inter alia on the results of the market test outlined in Section 6.2.2. above.
- (313) The Final Bebegel Commitments eliminate competition concerns in a plausible market for laxative enemas for infants in Portugal where serious doubts were identified in Section 4.5.1.2.1.3. of this decision, as the Final Bebegel Commitments remove the entire overlap of the Parties in this plausible market.
- (314) This is further supported by the market test, where virtually all respondents confirmed that the Initial Bebegel Commitments were already suitable to effectively remove the competition concerns that may result from the Transaction in the market for laxative enemas in Portugal.²³⁶
- (315) In addition, the Commission considers that the amendments described in Section 6.2.3. above adequately address the shortcoming raised by market test respondents and the Commission in relation to the Initial Bebegel Commitments.
- (316) For the reasons outlined above, the commitments entered into by the undertakings concerned are sufficient to eliminate the serious doubts as to the compatibility of the transaction with the internal market in relation to the plausible market for laxative enemas for infants in Portugal.

6.3. **The Otowaxol Commitments**

6.3.1. *Initial Otowaxol Commitments*

- (317) In order to render the Transaction compatible with the internal market in relation to the plausible market for earwax removal products in Germany, the Parties submitted a set of commitments under Article 6(2) of the Merger Regulation on 5 June 2024 (the “Initial Otowaxol Commitments”).
- (318) Under the Initial Otowaxol Commitments, the Parties offered to divest the rights, title and interests in the Target’s Otowaxol (with a [60-70]% market share in a plausible market for earwax removal products in Germany) to a suitable purchaser (the “Otowaxol Purchaser”). Specifically, the Parties committed to divest the right to develop, manufacture and use Otowaxol with a view to its sale and marketing in any form in Germany and, at the option of the Otowaxol Purchaser, in Ireland (the “Initial Otowaxol Divestment Business”).
- (319) The Initial Otowaxol Divestment Business consisted of the transfer of the following assets to the Otowaxol Purchaser:
- (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 Otowaxol Divestment Business;
 - (c) all contracts, commitments and customer orders of the Otowaxol Divestment Business;

²³⁶ Responses to question C.A.3 of the Laxative remedy market test questionnaire.

- (d) all customer, credit and other records of the Otowaxol Divestment Business;
 - (e) all advertising, marketing, sales, publicity and presentational materials related to the Otowaxol Divestment Business, as applicable; and
 - (f) a full transfer of any trademarks related to the Otowaxol Divestment Business and relating to any EU Member State or States except, at the
 - (g) Purchaser's option, the trademark relating to Ireland..
- (320) Currently, Otowaxol is manufactured and packaged by a third-party, [...], based on a manufacturing contract between Viatrix and[...]. Under the Initial Otowaxol Commitments, the Parties committed, at the option of the Otowaxol Purchaser, to use its best efforts to obtain the assignment of the existing contract manufacturing contracts for Otowaxol or, in the event that consent for the assignment cannot be obtained, at the option of the Otowaxol Purchaser, the benefit of a back-to-back arrangement for the supply of Otowaxol for the duration of the relevant contract and, in any case, for no longer than three years.
- (321) Finally, under the Initial Otowaxol Commitments, the Otowaxol Purchaser must in addition to meeting the criteria of the Commission's model text for divestiture commitments,²³⁷ also have a sales and marketing presence in Germany in the relevant sales channels.

6.3.2. Market test

- (322) The Commission market tested the Initial Otowaxol Commitments in order to assess whether they are sufficient and suitable to remedy the serious doubts identified in Section 4.5.7 of this decision and, and whether they are sufficient to ensure the viability and competitiveness of the Otowaxol Divestment Business.
- (323) Overall, virtually all respondents indicated that the Otowaxol Divestment Businesses, as defined under the Initial Otowaxol Commitments, is a viable and competitive standalone business. In particular, virtually all of the respondents consider that the Otowaxol Divestment Business includes all the necessary assets and agreements needed to remain a viable competitive force in the market for earwax removal products in Germany after the transfer to a suitable purchaser (without the need for additional purchaser criteria or the transfer of personnel).²³⁸
- (324) One respondent, however, indicated the need for the Otowaxol Purchaser to have a strong and wide distribution network in Germany, in addition to its required sales and marketing presence there.²³⁹
- (325) The majority of respondents also confirmed that the option for the Otowaxol Divestment Business to include the relevant assets in Ireland increases the viability of the Otowaxol Divestment Business, *e.g* because of economies of scale and additional revenues, and because “*more volume creates a better negotiation position with potential manufacturers over time.*”²⁴⁰

²³⁷ See https://ec.europa.eu/competition-policy/mergers/legislation/best-practices_en.

²³⁸ See responses to questions C.B.1, C.C.3, C.C.5 of the Earwax remedy market test questionnaire.

²³⁹ See response to questions C.C.3-4 of the Earwax remedy market test questionnaire.

²⁴⁰ See responses to questions C.B.3-4 of the Earwax remedy market test questionnaire.

- (326) With respect to the implementation of the Initial Otowaxol Commitments, virtually all respondents agreed that the scope and content of the Initial Otowaxol Commitments is sufficiently clear for them to be effectively implemented.²⁴¹
- (327) Whilst the market test indicated that the Otowaxol Purchaser could encounter challenges in the transfer of the manufacturing contract for Otowaxol, the majority of the respondents found the proposed back-to-back supply to be an appropriate transitory alternative to allow a suitable purchaser to operate the Otowaxol Divestment Business in a viable manner until it obtains its own manufacturing arrangements.²⁴²
- (328) Virtually all respondents also considered that the Initial Otowaxol Commitments are suitable to effectively remove the competition concerns that may result from the Transaction in the market for earwax removal products in Germany²⁴³ and will likely attract suitable purchasers.²⁴⁴
- (329) In addition, several respondents have expressed potential interest in purchasing the Otowaxol Divestment business.²⁴⁵
- (330) Other than the suggested additional suitable purchaser criterion mentioned above, the respondents of the market test did not identify any other major shortcomings in relation to the Initial Otowaxol Commitments.

6.3.3. *Final Otowaxol Commitments*

- (331) Following the feedback received during the market test, the Initial Otowaxol Commitments were refined and improved. The Parties submitted amended commitments on 24 June 2024 (the “Final Otowaxol Commitments”). The Final Commitments are annexed to this decision and form an integral part thereof.
- (332) The Final Otowaxol Commitments differ from the Initial Otowaxol Commitments only on the following points.
- (333) *First*, in the Final Commitments, the Parties have specified that in addition to having a marketing and sales presence, the Otowaxol Purchaser shall also have access to an appropriate distribution network in Germany. In the Final Commitments, the Parties have further specified that the relevant sales channels for Otowaxol include wholesalers and pharmacies. *Second*, in the Final Otowaxol Commitments, the Parties have also specified that they will endeavour on a best-efforts basis to obtain the assignment of the existing manufacturing contracts for the Otowaxol Divestment Business on substantially the same terms and conditions (including price), rather than just the best efforts obligation to obtain the assignment.
- (334) *Third*, in relation to the transfer of trademarks, in the Final Commitments, the Parties have clarified that the Otowaxol Divestment Business shall include the full transfer of any trademarks related to the Otowaxol Divestment Business (including Otowaxol and Waxsol) and relating to any EU Member State or States (except, at

²⁴¹ See responses to question C.A.1 of the Earwax remedy market test questionnaire.

²⁴² See responses to questions C.B.5 to C.B.7 of the Earwax remedy market test questionnaire.

²⁴³ See responses to question C.A.3 of the Earwax remedy market test questionnaire.

²⁴⁴ See responses to question C.C.1 of the Earwax remedy market test questionnaire.

²⁴⁵ See responses to question C.C.9 of the Earwax remedy market test questionnaire.

the Purchaser's option, trademarks relating to Ireland²⁴⁶) in order to allow the Otowaxol purchaser to enter and expand in other EU Member States.

6.3.4. *The Commission's assessment of Final Otowaxol Commitments*

- (335) The Commission analysed the suitability of the Commitments to remedy serious doubts in this case against the standard set out in the Commission Remedies Notice. In its assessment, the Commission relied inter alia on the results of the market test outlined in Section 6.3.2 above.
- (336) The Final Otowaxol Commitments eliminate competition concerns in a plausible market for earwax removal products in Germany where serious doubts were identified in Section 4.5.7. of this decision, since the Final Otowaxol Commitments remove the entire overlap of the Parties in this plausible market.
- (337) This is further supported by the market test, where virtually all respondents found that the Initial Otowaxol Commitments were already suitable to effectively remove the competition concerns that may result from the Transaction in the market for earwax removal products in Germany.²⁴⁷
- (338) In addition, the Commission considers that the amendments described in Section 6.3.3 above adequately address the shortcoming raised by the market test respondents and the Commission in relation to the Initial Otowaxol Commitments.
- (339) For the reasons outlined above, the Otowaxol Commitments entered into by the Parties are sufficient to eliminate the serious doubts as to the compatibility of the Transaction with the internal market in relation to the plausible market for earwax removal products in Germany.

6.4. Conclusion

- (340) For the reasons outlined above, the Final Bebegel Commitments and the Final Otowaxol Commitments entered into by the Parties are sufficient to eliminate the serious doubts as to the compatibility of the transaction with the internal market.
- (341) The commitments in Sections B of the annexed commitments constitute conditions attached to this decision, as only through full compliance therewith can the structural changes in the relevant markets be achieved. The other commitments set out in the annexed commitments constitute obligations, as they concern the implementing steps which are necessary to achieve the modifications sought in a manner compatible with the internal market.

7. CONCLUSION

- (342) For the above reasons, the Commission has decided not to oppose the notified Transaction 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 of the commitments annexed to the present decision and with the obligations contained in the other sections of the said commitments. This decision is adopted in application of Article 6(1)(b) in

²⁴⁶ See above paragraph 318.

²⁴⁷ See responses to question C.A.3 of the Earwax remedy market test questionnaire.

conjunction with Article 6(2) of the Merger Regulation and Article 57 of the EEA Agreement.

For the Commission

(Signed)
Margrethe VESTAGER
Executive Vice-President

Appendix 1

Product category	Group	Country	Affected at ATC3 CHC3 level	Affected at ATC4/CHC4 level	Affected at molecule level
Antiseptics and disinfectants	2	France		✓ (06B2L)	
Mouth pain relief	2	Italy	✓ (02D1)	✓ (02D1Z)	
Topical Antivaricose	2	Italy	✓ (10B2)	✓ (10B2O)	
Magnesium supplements	2	Italy		✓ (04F3P)	✓ (04F3P - magnesium)
Antispasmodic+Anti chol plain	2	Portugal	✓ (A3A)		
Antidotes	2	Slovakia	✓ (V3E)		
Antifungals for nails	3	Belgium		✓ (06G2L)	
Antiseptics and disinfectants	3	France		✓ (S1G6)	
Antiseptics and disinfectants	3	Italy	✓ (D8A) ✓ (06B2)		
Wound healing	3	Netherlands	✓ (D3A)		
Antifungals for nails	3	Spain		✓ (06G2L)	
Antifungals for nails	3	Belgium	✓ (06G2)		
Sore throat remedies	3	France	✓ (R2A)		
Sore throat remedies	3	Italy	✓ (R2A)		
Adult mouthwashes	3	France	✓ (87B3)		
Topical antivirals	3	France		✓ (D6D1)	✓ (D6D1 - aciclovir)
Antiparasitic haircare products	3	France		✓ (86H1E)	
Drugs for constipation	3	Germany		✓ (A6A6) ✓ (03C2M)	
Drugs for constipation	3	Italy		✓ (A6A6)	
Drugs for constipation	3	Portugal	✓ (03C2)	✓ (A6A6)	

Product category	Group	Country	Affected at ATC3 CHC3 level	Affected at ATC4/CHC4 level	Affected at molecule level
Wart/ corn removal products	3	Germany		✓ (06L1L)	
Wart/ corn removal products	3	Portugal		✓ (06L1Z)	
Magnesium supplements	3	Italy	✓ (04F3)		
Eye antiallergics	3	Italy	✓ (07A2)	✓ (07A2N)	
Cholesterol products	3	Italy	✓ (10F3)	✓ (10F3C)	
Intimate detergents	3	Italy	✓ (85D1)		
Sore throat remedies	3	Italy		✓ (01C1A)	
Herpes Antivirals	3	Italy			✓ (J5B3 - aciclovir)
Calcium	3	Luxembourg	✓ (A12A)		✓ (A12A0 – calcium/colecalciferol)
Drugs for constipation	3	Luxembourg	✓ (A6A)		
Chest Rubs and Other Inhalants	3	Netherlands	✓ (01B3)		
Mouth pain relief	3	Portugal	✓ (02D1)	✓ (02D1Z)	
Antidotes	3	Spain	✓ (V3E)		

CASE M.11383 – COOPER / VIATRIS (EUROPEAN OTC BUSINESS)

COMMITMENTS TO THE EUROPEAN COMMISSION

Pursuant to Article 6(2) of Council Regulation (EC) No 139/2004 (the "**Merger Regulation**"), Cooper Consumer Health S.A.S. ("**Cooper**") and Viatris Inc. ("**Viатris**") hereby enter into the following Commitments (the "**Commitments**") vis-à-vis the European Commission (the "**Commission**") with a view to rendering the acquisition by Cooper of sole control of the European over-the-counter ("**OTC**") business of Viatris (the "**Proposed Transaction**") compatible with the internal market and the functioning of the EEA Agreement.

This text shall be interpreted in light of the Commission's decision pursuant to Articles 6(1)(b) and 6(2) of the Merger Regulation to declare the Proposed 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 light of the Merger Regulation, and by reference to the Commission Notice on remedies acceptable under Council Regulation (EC) No 139/2004 and under Commission Regulation (EC) No 802/2004 (the "**Remedies Notice**").

Section A. Definitions

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

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

Assets: the assets that contribute to the current operation or are necessary to ensure the viability and competitiveness of the Divestment Businesses as indicated in Section B, paragraph 6.1 (a), (b) and (c) and paragraph 6.2 (a), (b) and (c) and described more in detail in the Schedules.

Bebegel Divestment Business: the Divestment Business described in more detail in Schedule A.

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

Closings: the Bebegel Divestment Business Closing and the Otowaxol Divestment Business Closing, and "Closing" shall mean any one of the Closings, as relevant.

Closing Period: for each Divestment Business, the period of [time period] from the approval of the Purchaser and the terms of sale by the Commission for that Divestment Business.

Commission: European Commission.

Commitments: these commitments offered by the Parties to the Commission.

Completion: the closing of the Proposed 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.

Cooper: Cooper Consumer Health S.A.S.

Decision: the Commission's decision pursuant to Article 6(1)(b) and Article 6(2) of the Merger Regulation to declare the Proposed Transaction compatible with the internal market and the functioning of the EEA Agreement.

Divestment Businesses: the Bebegel Divestment Business and the Otowaxol Divestment Business, and "**Divestment Business**" shall mean any one of the Divestment Businesses, as relevant.

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

Effective Date: the date of adoption of the Decision.

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

Hold Separate Manager: the person appointed by Cooper to manage the day-to-day operations of the Divestment Businesses 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.

Merger Regulation: Council Regulation (EC) No. 139/2004.

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

Notifying Party: Cooper Consumer Health S.A.S.

OTC: Over-the-counter.

Otowaxol Divestment Business: the Divestment Business described in more detail in Schedule B.

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

Parties: Cooper and Viatris.

Personnel: the staff currently employed in relation to and required to maintain the viability of the Divestment Businesses.

Proposed Transaction: Cooper's proposed acquisition of sole control of the European OTC business of Viatris.

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

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

Remedies Notice: Commission Regulation (EC) No 802/2004.

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 [time period] from the end of the First Divestiture Period.

Viatris: Viatris Inc. a corporation incorporated under the laws of the state of Delaware, the United States of America, with its corporate seat in Delaware, the United States of America.

Section B. The commitment to divest and the Divestment Business

Commitment to divest

2. In order to maintain effective competition, the Parties commit to divest, or procure the divestiture of, the Bebegel Divestment Business and Otowaxol Divestment Business by the end of the Trustee Divestiture Period as a going concern to a Purchaser or Purchasers on terms of sale approved by the Commission in accordance with the procedure described in paragraph 17 of these Commitments.
3. To carry out the divestiture, the Parties commit to finding a Purchaser or Purchasers and to enter into a final binding sale and purchase agreement with Cooper for the sale of the Divestment Businesses within the First Divestiture Period. If Cooper has not entered into such an agreement at the end of the First Divestiture Period in relation to either Divestment Business, Cooper shall grant the Divestiture Trustee an exclusive mandate to sell the relevant Divestment Business in accordance with the procedure described in paragraph 29 in the Trustee Divestiture Period and subject to Completion.
4. The Parties shall be deemed to have complied with this commitment if:
 - (a) by the end of the Trustee Divestiture Period, Cooper or the Divestiture Trustee has entered into a final binding sale and purchase agreement(s) and the Commission approves the proposed Purchaser(s) and the terms of sale as being consistent with these Commitments in accordance with the procedure described in paragraph 17; and
 - (b) the Closings take place within the Closing Period.

Following Completion, Viartis will only remain bound by paragraphs 6, 7, 11, 36, 37, 38, 42 and 43 of these Commitments.

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

Structure and definition of the Divestment Businesses

6. The Divestment Businesses comprise the Bebegel Divestment Business and the Otowaxol Divestment Business:
 - 6.1. The legal and functional structure of the Bebegel Divestment Business as operated to date is described in Schedule A. The Bebegel Divestment Business, described in more detail in Schedule A, includes all assets and staff that contribute to

the current operation or are necessary to ensure the viability and competitiveness of the Bebegel Divestment Business, 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 Bebegel Divestment Business;
- (c) all contracts, commitments and customer orders of the Bebegel Divestment Business; all customer, credit and other records of the Bebegel Divestment Business;
- (d) all advertising, marketing, sales, publicity and presentational materials related to the Bebegel Divestment Business, as applicable; and
- (e) a full transfer of any trademarks related to the Bebegel Divestment Business and relating to any EU Member State or States except, at the Purchaser's option, trademarks relating to France and French Polynesia.

In addition, the Parties will endeavour on a best-efforts basis to obtain the assignment (at the Purchaser's option) of the existing manufacturing contracts for the Bebegel Divestment Business on substantially the same terms and conditions (including price) or, in the event that consent for the assignment cannot be obtained on substantially the same terms and conditions (including price) and, at the Purchaser's option, the benefit of back-to-back arrangements for the supply by Cooper of the products to the Purchaser for the duration of the relevant contracts and, in any case, for no longer than three years.

6.2. The legal and functional structure of the Otowaxol Divestment Business as operated to date is described in Schedule B. The Otowaxol Divestment Business, described in more detail in Schedule B, includes all assets and staff that contribute to the current operation or are necessary to ensure the viability and competitiveness of the Otowaxol Divestment Business, 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 Otowaxol Divestment Business;
- (c) all contracts, commitments and customer orders of the Otowaxol Divestment Business; all customer, credit and other records of the Otowaxol Divestment Business;
- (d) all advertising, marketing, sales, publicity and presentational materials related to the Otowaxol Divestment Business, as applicable; and
- (e) a full transfer of any trademarks related to the Otowaxol Divestment Business and relating to any EU Member State or States except, at the Purchaser's option, the trademark relating to Ireland.

In addition, the Parties will endeavour on a best-efforts basis to obtain the assignment (at the Purchaser's option) of the existing manufacturing contracts for the Otowaxol Divestment Business on substantially the same terms and conditions (including price) or, in the event that consent for the assignment cannot be obtained on substantially the same terms and conditions (including price) and, at the Purchaser's option, the benefit of back-to-back arrangements for the supply by Cooper of the products to the Purchaser for the duration of the relevant contracts and, in any case, for no longer than three years.

Section C. Related commitments

Preservation of viability, marketability and competitiveness

7. The Parties shall from the Effective Date until the Closings, preserve or procure the preservation of the economic viability, marketability and competitiveness of the Bebegel Divestment Business (including in France) and the Otowaxol Divestment Business (including in Ireland), in accordance with good business practice, and shall minimise as far as possible any risk of loss of competitive potential of the Divestment Businesses. In particular, the Parties undertake:
 - (a) not to carry out any 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; and
 - (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 the Parties' remaining business. Where, nevertheless, individual members of the Key Personnel exceptionally leave the Divestment Businesses, Cooper shall provide a reasoned proposal to replace the person or persons concerned to the Commission and the Monitoring Trustee. Cooper 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

8. Cooper commit(s), from the Effective Date until Closings, to keep the Divestment Businesses separate from the business it is retaining and to ensure that unless explicitly permitted under these Commitments: (i) management and staff of the business(es) retained by Cooper have no involvement in the Divestment Businesses; (ii) the Key Personnel and Personnel of the Divestment Businesses have no involvement in any business retained by Cooper and do not report to any individual outside the Divestment Businesses.
9. Until Closings, Cooper shall assist the Monitoring Trustee in ensuring that the Divestment Businesses are managed as a distinct and saleable businesses separate from the retained business. Immediately after the adoption of the Decision, Cooper shall appoint a Hold Separate Manager. The Hold Separate Manager shall manage the Divestment Businesses independently and in the best interest of the business with a view to ensuring their continued economic viability, marketability and competitiveness and their independence from the retained business. The Hold Separate Manager shall closely cooperate with and report to the Monitoring Trustee and, if applicable, the Divestiture Trustee. Any replacement of the Hold Separate Manager shall be subject to

the procedure laid down in paragraph 7(c) of these Commitments. The Commission may, after having heard Cooper, require Cooper to replace the Hold Separate Manager.

Ring-fencing

10. Cooper shall implement, or procure to implement, all necessary measures to ensure that it does not, after the Effective Date, obtain any Confidential Information relating to the Divestment Businesses and that any such Confidential Information obtained by Cooper before the Effective Date will be eliminated and not be used by Cooper. 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. The Parties 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 the Parties is required by law.

Non-solicitation clause

11. 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 Closings.

Due diligence

12. In order to enable potential purchasers to carry out a reasonable due diligence of the Divestment Businesses, the Parties 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; and
 - (b) provide to potential purchasers sufficient information relating to the Personnel and allow them reasonable access to the Personnel.

Reporting

13. The Parties shall submit written reports in English on potential purchasers of the Divestment Businesses and developments in the negotiations with such potential purchasers to the Commission and the Monitoring Trustee no later than 10 days after the end of every month following the Effective Date (or otherwise at the Commission's request).
14. The Parties 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 5 days of their receipt.
15. The Parties shall inform the Commission and the Monitoring Trustee on the preparation of the data room documentation and the due diligence procedure and shall submit a copy of any information memorandum to the Commission and the Monitoring Trustee before sending the memorandum out to potential purchasers.

Section D. The Purchaser

16. In order to be approved by the Commission, the Purchaser(s) must fulfil the following criteria:
- (a) The Purchaser(s) shall be independent of and unconnected to the Notifying Party and 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 relevant Divestment Business as a viable and active competitive force in competition with Cooper and other competitors;
 - (c) The acquisition of the relevant Divestment Business 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; and
 - (d) The Purchaser of the Bebegel Divestment Business must have a sales and marketing presence and access to an appropriate distribution network in Portugal in the relevant sales channels (including wholesalers, hospitals and pharmacies) and the Purchaser of the Otowaxol Divestment Business must have a sales and marketing presence and access to an appropriate distribution network in Germany in the relevant sales channels (including wholesalers and pharmacies).
17. The final binding sale and purchase agreement(s) (as well as any ancillary agreements) relating to the divestment of the Divestment Businesses shall be conditional on the Commission's approval. When Cooper 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. Cooper must be able to demonstrate to the Commission that the purchaser(s) 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. Cooper shall appoint a Monitoring Trustee to carry out the functions specified in these Commitments for a Monitoring Trustee. The Notifying Party commit(s) not to close the Proposed Transaction before the appointment of a Monitoring Trustee.

19. If Cooper has not entered into a binding sale and purchase agreement regarding either Divestment Business one month before the end of the First Divestiture Period or if the Commission has rejected a purchaser proposed by Cooper at that time or thereafter, Cooper shall appoint a Divestiture Trustee in respect of the relevant Divestment Business. 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 the Notifying Party 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 the Notifying Party in a way that does not impede the independent and effective fulfilment of its mandate. In particular, where the remuneration package of a Divestiture Trustee includes a success premium linked to the final sale value of the Divestment Business, such success premium may only be earned if the divestiture takes place within the Trustee Divestiture Period.

Proposal by Cooper

22. No later than two weeks after the Effective Date, Cooper shall submit the name or names of one or more natural or legal persons whom Cooper 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, Cooper shall submit a list of one or more persons whom Cooper 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, Cooper 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, Cooper 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 Cooper

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

Trustee nominated by the Commission

25. If all further proposed Trustees are rejected by the Commission, the Commission shall nominate a Trustee, whom Cooper 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 Cooper, give any orders or instructions to the Trustee in order to ensure compliance with the conditions and obligations attached to the Decision.

Duties and obligations of the Monitoring Trustee

27. The Monitoring Trustee shall:
- (i) propose in its first report to the Commission a detailed work plan describing how it intends to monitor compliance with the obligations and conditions attached to the Decision.
 - (ii) oversee, in close co-operation with the Hold Separate Manager, the on-going management of the relevant Divestment Business with a view to ensuring its continued economic viability, marketability and competitiveness and monitor compliance by Cooper with the conditions and obligations attached to the Decision. To that end the Monitoring Trustee shall:
 - (a) monitor the preservation of the economic viability, marketability and competitiveness of the Divestment Business, and the keeping separate of the Divestment Business from the retained business, in accordance with paragraphs 7 and 8 of these Commitments;
 - (b) supervise the management of the Divestment Business as a distinct and saleable entity, in accordance with paragraph 9 of these Commitments;
 - (c) with respect to Confidential Information:
 - determine all necessary measures to ensure that Cooper does not after the Effective Date obtain any Confidential Information relating to the Divestment Business,
 - in particular strive for the severing of the Divestment Business' participation in a central information technology network to the extent possible, without compromising the viability of the Divestment Business,
 - make sure that any Confidential Information relating to the Divestment Business obtained by Cooper before the Effective Date is eliminated and will not be used by Cooper and

- decide whether such information may be disclosed to or kept by Cooper as the disclosure is reasonably necessary to allow Cooper to carry out the divestiture or as the disclosure is required by law;
 - (d) monitor the splitting of assets and the allocation of Personnel between the Divestment Business and Cooper or its Affiliated Undertakings;
 - (iii) propose to Cooper such measures as the Monitoring Trustee considers necessary to ensure Cooper's compliance with the conditions and obligations attached to the Decision, in particular the maintenance of the full economic viability, marketability or competitiveness of the Divestment Business, the holding separate of the Divestment Business and the 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:
 - (a) potential purchasers receive sufficient and correct information relating to the Divestment Business and the Personnel in particular by reviewing, if available, the data room documentation, the information memorandum and the due diligence process, and
 - (b) potential purchasers are granted reasonable access to the Personnel;
 - (v) act as a contact point for any requests by third parties, in particular potential purchasers, in relation to the Commitments;
 - (vi) provide to the Commission, sending Cooper a non-confidential copy at the same time, a written report within 15 days after the end of every month that shall cover the operation and management of the Divestment Business as well as the splitting of assets and the allocation of Personnel so that the Commission can assess whether the business is held in a manner consistent with the Commitments and the progress of the divestiture process as well as potential purchasers;
 - (vii) promptly report in writing to the Commission, sending Cooper a non-confidential copy at the same time, if it concludes on reasonable grounds that Cooper is failing to comply with these Commitments;
 - (viii) within one week after receipt of the documented proposal referred to in paragraph 17 of these Commitments, submit to the Commission, sending Cooper a non-confidential copy at the same time, a reasoned opinion as to the suitability and independence of the proposed purchaser and the viability of the Divestment Business after the Sale and as to whether the Divestment Business is sold in a manner consistent with the conditions and obligations attached to the Decision, in particular, if relevant, whether the sale of the Divestment Business without one or more Assets or not all of the Personnel affects the viability of the Divestment Business after the sale, taking account of the proposed purchaser; and
 - (ix) 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 relevant Divestment Business to a purchaser or purchasers, provided that the Commission has approved both the purchaser(s) and the final binding sale and purchase

agreement(s) (and ancillary agreements) as in line with the 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 Cooper, subject to Cooper's 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 Cooper.

III. Duties and obligations of Cooper and Viatrix

31. The Parties 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 the Parties' or the relevant Divestment Business' books, records, documents, management or other personnel, facilities, sites and technical information necessary for fulfilling its duties under the Commitments and the Parties and the Divestment Business shall provide the Trustee upon request with copies of any document. The Parties and the Divestment Business shall make available to the Trustee one or more offices on their premises and shall be available for meetings in order to provide the Trustee with all information necessary for the performance of its tasks.
32. The Parties shall provide the Monitoring Trustee with all managerial and administrative support that it may reasonably request on behalf of the management of the Divestment Business. This shall include all administrative support functions relating to the Divestment Business which are currently carried out at headquarters level. The Parties 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. The Parties 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. Cooper 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 Closings and all actions and declarations which the Divestiture Trustee considers necessary or appropriate to achieve the sale and the Closings, including the appointment of advisors to assist with the sale process. Upon request of the Divestiture Trustee, Cooper shall cause the documents required for effecting the sale and the Closings to be duly executed.

34. Cooper 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 Cooper 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 Cooper, the Trustee may appoint advisors (in particular for corporate finance or legal advice), subject to Cooper'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 Cooper refuse to approve the advisors proposed by the Trustee the Commission may approve the appointment of such advisors instead, after having heard Cooper. 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 Cooper during the First Divestiture Period if the Divestiture Trustee considers this in the best interest of an expedient sale.
36. The Parties agree that the Commission may share Confidential Information proprietary to either of the Parties 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. The Parties agree that the contact details of the Monitoring Trustee are published on the website of the Commission's Directorate-General for Competition and they shall inform interested third parties, in particular any potential purchasers, of the identity and the tasks of the Monitoring Trustee.
38. For a period of 10 years from the Effective Date, the Commission may request all information from the Parties that is reasonably necessary to monitor the effective implementation of these Commitments.

IV. Replacement, discharge and reappointment of the Trustee

39. If the Trustee ceases to perform its functions under the Commitments or for any other good cause, including the exposure of the Trustee to a Conflict of Interest:
- (a) the Commission may, after hearing the Trustee and Cooper, require Cooper to replace the Trustee; or
 - (b) Cooper may, with the prior approval of the Commission, replace the Trustee.
40. If the Trustee is removed according to paragraph 39 of these Commitments, the Trustee may be required to continue in its function until a new Trustee is in place to whom the Trustee has effected a full hand over of all relevant information. The new Trustee shall be appointed in accordance with the procedure referred to in paragraphs 18-25 of these Commitments.

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

Section F. The review clause

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

[signed]

duly authorised for and on behalf of Viatriis Inc.

SCHEDULES

Schedule A (Bebegel)

1. The Bebegel Divestment Business consists of the rights, title and interests in Bebegel including the right to develop, manufacture and use Bebegel with a view to its sale and marketing in any form in Portugal and, at the Purchaser's option, in France. Bebegel is used to treat constipation in infants.
2. The Bebegel Divestment Business includes the transfer of all assets predominantly or exclusively used for the purposes of marketing Bebegel in Portugal and, at the Purchaser's option, in France. It includes in particular:
 - (a) existing Bebegel finished product inventory, sales and promotional material to the extent available;
 - (b) all Bebegel-related contracts, commitments, and customer records, meaning customer credit records, customer invoices, purchase orders and contact details, redacting from such material any information which is not related to Bebegel;¹
 - (c) the transfer of the marketing authorization for Bebegel in Portugal and, at the Purchaser's option, 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 authorizations available to the Parties;
 - (d) an irrevocable, assignable, sub-licensable and royalty-free license for all relevant intellectual property rights, data books, records and effective arrangements for the transfer of all know-how to the extent that these are related to the development, manufacture, use of the Bebegel Divestment Business;
 - (e) all advertising, marketing, sales, publicity and presentational materials related to the Bebegel Divestment Business, as applicable; and
 - (f) a full transfer of any trademarks related to the Bebegel Divestment Business and relating to any EU Member State or States (set out at Table 1 below) except, at the Purchaser's option, trademarks relating to France and French Polynesia.

Table 1: Trademarks for the Bebegel Divestment Business

Trademark	Country	Application #	Application Date	Registration #	Registration Date	Renewal Date	Status
BEBEGEL	Portugal	187492	09/27/1974	187492	02/10/1982	09/27/2024	Registered
BEBEGEL	France	1284471	09/19/1984	1284471	09/19/1984	09/19/2024	Registered
BEBEGEL	French Polynesia	1284471	09/19/1984	1284471	09/19/1984	09/19/2024	Registered

¹ The Parties will include customer lists and records in the Bebegel Divestment Business, but not provide any accounts receivable or payable.

3. The Parties will transfer all information (orders, price, etc.) concerning their relationship regarding Bebegel with contract manufacturer [name of contract manufacturer] to the Purchaser in accordance with applicable law. The Parties will endeavour on a best-efforts basis to obtain the assignment (at the Purchaser's option) of the existing manufacturing contracts for the Bebegel Divestment Business on substantially the same terms and conditions (including price) or, in the event that consent for the assignment cannot be obtained on substantially the same terms and conditions (including price) and, at the Purchaser's option, the benefit of back-to-back arrangements for the supply by Cooper of the products to the Purchaser for the duration of the relevant contracts and, in any case, for no longer than three years.
4. In relation to the existing tender contracts, the Parties will transfer all information (orders; price; etc.). The Parties commit to use their best efforts to support the Purchaser to obtain the hospital's consent for the transfer the tender contracts.
5. The Parties commit to use their best efforts to cooperate with the Purchaser to effectuate the transfer of the Bebegel Divestment Business and to undertake all regulatory changes that would be required as a result of such transfer. Until transfer of the Bebegel Divestment Business, Cooper will bear the costs for updates to maintain the current registration of the dossier of the Bebegel Divestment Business. In addition, Cooper will bear the dossier preparation and regulatory filing costs for all the updates of the dossier triggered by the transfer of the Bebegel Divestment Business to the Purchaser.
6. The Bebegel Divestment Business shall not include:
 - (a) any manufacturing facility;
 - (b) raw materials;
 - (c) any other asset not part of the Bebegel Divestment Business or which is used in relation to a business of the Parties other than the Bebegel Divestment Business; and
 - (d) the "Viatrix" name, Viatrix trademark and Viatrix trade dress or trade dress of any of its subsidiaries.
7. If there are any assets or personnel which are not covered by paragraph 2 of this Schedule but which are both used (exclusively or not) in the Bebegel Divestment Business and necessary for the continued viability and competitiveness of the Bebegel Divestment Business, that asset or an adequate substitute will be offered by Cooper to the Purchaser.

Schedule B (Otowaxol)

8. The Otowaxol Divestment Business consists of the rights, title and interests in Otowaxol including the right to develop, manufacture and use Otowaxol, with a view to its sale and marketing in any form in Germany and, at the Purchaser's option, in Ireland. Otowaxol is used to remove excess earwax and earwax build-up.
9. The Otowaxol Divestment Business includes the transfer of all assets predominantly or exclusively used for the purposes of marketing Otowaxol in Germany and, at the Purchaser's option, in Ireland. It includes in particular:

- (a) existing Otowaxol finished product inventory, sales and promotional material to the extent available;
 - (b) all Otowaxol-related contracts, commitments, and customer records, meaning customer credit records, customer invoices, purchase orders and contact details, redacting from such material any information which is not related to Otowaxol;²
 - (c) an irrevocable, assignable, sub-licensable and royalty-free license for all relevant intellectual property rights, data books, records and effective arrangements for the transfer of all know-how to the extent that these are related to the development, manufacture, use of the Otowaxol Divestment Business;
 - (d) all advertising, marketing, sales, publicity and presentational materials related to the Otowaxol Divestment Business, as applicable; and
 - (e) a full transfer of any trademarks related to the Otowaxol Divestment Business (including Otowaxol and Waxsol) and relating to any EU Member State or States (set out at Table 2 below) except, at the Purchaser's option, the trademark relating to Ireland.
10. The Parties will transfer all information (orders, price, etc.) concerning their relationship regarding Otowaxol with contract manufacturer [name of contract manufacturer] to the Purchaser in accordance with applicable law. The Parties will endeavour on a best-efforts basis to obtain the assignment (at the Purchaser's option) of the existing manufacturing contracts for the Otowaxol Divestment Business on substantially the same terms and conditions (including price) or, in the event that consent for the assignment cannot be obtained on substantially the same terms and conditions (including price) and, at the Purchaser's option, the benefit of back-to-back arrangements for the supply by Cooper of the products to the Purchaser for the duration of the relevant contracts and, in any case, for no longer than three years.
11. The Parties commit to use their best efforts to cooperate with the Purchaser to effectuate the transfer of the Otowaxol Divestment Business and to undertake all regulatory changes that would be required as a result of such transfer. Until transfer of the Otowaxol Divestment Business, Cooper will bear the costs for updates to maintain the current registration of the dossier of the Otowaxol Divestment Business. In addition, Cooper will bear the dossier preparation and regulatory filing costs for all the updates of the dossier triggered by the transfer of the Otowaxol Divestment Business to the Purchaser.
12. The Otowaxol Divestment Business shall not include:
- (a) any manufacturing facility;
 - (b) raw materials;
 - (c) any other asset not part of the Otowaxol Divestment Business or which is used in relation to a business of the Parties other than the Otowaxol Divestment Business; and
 - (d) the "Viatriis" name, Viatriis trademark and Viatriis trade dress or trade dress of any of its subsidiaries.

² The Parties will include customer lists and records in the Otowaxol Divestment Business, but not provide any accounts receivable or payable.

13. If there are any assets or personnel which are not covered by paragraph 9 of this Schedule but which are both used (exclusively or not) in the Otowaxol Divestment Business and necessary for the continued viability and competitiveness of the Otowaxol Divestment Business, that asset or an adequate substitute will be offered by Cooper to the Purchaser.

Table 2: Trademarks for the Otowaxol Divestment Business

Trademark	Country	Application #	Application Date	Registration #	Registration Date	Renewal Date	Status
OTOWAXOL	Germany	N15578	10/11/1977	976545	09/18/1978	10/31/2027	Registered
WAXSOL	Ireland	B72169	06/02/1967	B72169	06/02/1967	06/02/2032	Registered
OTOWAXOL	World Intellectual Property Organization (WIPO), covers Austria, Benelux, Morocco Switzerland	445517	06/18/1979	445517	06/18/1979	06/18/2029	Registered
WAXSOL	Malta	12478	02/05/1976	12478			
WAXSOL	Greece	43374	01/23/1970	43374			
WAXSOL	Benelux Office for Intellectual Property (BOIP)	0331345	03/05/1975	0331345			
WAXSOL	France	1410977	05/27/1987	1410977			
WAXSOL	WIPO, covers Austria, BOIP, Switzerland, Monaco	435287B	02/03/1978	435287B			