EUROPEAN COMMISSION
DG Competition

Case M.9044 - CVC / RECORDATI

Only the English text is available and authentic.

REGULATION (EC) No 139/2004
MERGER PROCEDURE

Article 6(1)(b) NON-OPPOSITION
Date: 04/12/2018

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EUROPEAN COMMISSION

Brussels, 04.12.2018
C(2018)8437 final

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 Where possible the information omitted has been replaced by ranges of figures or a general description.

PUBLIC VERSION

To the notifying party:

Subject: **Case M.9044 – CVC / RECORDATI**
Commission decision pursuant to Article 6(1)(b) of Council Regulation No 139/2004[1] and Article 57 of the Agreement on the European Economic Area[2]

Dear Sir or Madam,

(1) On 26 October 2018, the European Commission received notification of a proposed concentration pursuant to Article 4 of the Merger Regulation by which CVC Capital Partners SICAV-FIS S.A. ("CVC") acquires within the meaning of Article 3(1)(b) of the Merger Regulation sole control of Recordati SpA (”Recordati” or the "Target") by way of purchase of shares ("the Transaction"). CVC and Recordati are referred to hereinafter as the Parties and CVC as the Notifying Party.[3]

1. THE PARTIES

(2) The primary business activities of the undertakings concerned are:

– […]* manages and provides advice to investment funds and platforms. The following portfolio companies are active in markets horizontally or vertically related to the Target's activities:

[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] Publication in the Official Journal of the European Union No C 400, 6.11.2018, p. 15.

* Should read: “the CVC network”

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- Alvogen is a global pharmaceutical company whose product portfolio consists of a broad range of generic, branded, and biosimilar products for use in oncology, cardiology, respiratory, neurology and gastroenterology treatments. Alvogen currently has commercial operations in 35 countries across North America, Central and Eastern Europe and Asia Pacific.

- DOC Generici is a generic pharmaceutical company in Italy focused on developing and manufacturing cardiovascular, gastroenterology & metabolic and neurology products.

- Elsan is a French private healthcare business, operating more than 35 health clinics primarily focused on medicine, surgery and obstetrics.

- Metropolitan is a Greek private hospital.

– Recordati develops and markets branded and generic drugs for the treatment of hypertension and other cardiovascular disorders, disorders of the lower urinary tract as well as drugs for treatment of rare diseases such as metabolic deficiencies of a genetic nature.

2. THE OPERATION

(3) On 29 June 2018, the Parties entered into a share purchase agreement according to which CVC acquires through special purpose vehicles a controlling shareholding of approximately 51.8% in the Target. None of the other shareholders besides CVC will have any veto right over the strategic decisions of the Target, including decisions regarding the Target's annual budget, business plan or appointment of senior management.

(4) Therefore, the Transaction involves the acquisition of sole control of Recordati by CVC within the meaning of Article 3(1)(b) of the Merger Regulation.

3. EU DIMENSION

(5) The undertakings concerned have a combined aggregate world-wide turnover of more than EUR 5 000 million[4] (CVC: EUR […] million; Recordati: EUR […] million). Each of them has an EU-wide turnover in excess of EUR 250 million (CVC: EUR […] million; Recordati: EUR […] million). The Parties do not achieve more than two-thirds of their Community-wide turnover within one and the same Member State.

(6) The notified operation therefore has an EU dimension by virtue of Article 1(2) of the Merger Regulation.

[4] 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).

4. COMPETITIVE ASSESSMENT

4.1 Market definitions

(7) The Transaction gives rise to horizontal overlaps in relation to several finished dose pharmaceuticals ("FDPs") marketed by both Parties.[5] […]* also develops pipeline products that overlap with FDPs marketed by […]**. Finally, the Transaction also gives rise to potential vertical links between Recordati's activities on the markets for FDPs (upstream markets) and the provision of hospital services by CVC […]*** portfolio companies (downstream markets).

4.1.1 Finished dose pharmaceutical products ("FDP")

Product market definition

(8) In previous decisions[6] concerning the pharmaceutical sector, the Commission has noted that pharmaceutical products may be classified into therapeutic classes by reference to the Anatomical Therapeutic Classification (ATC)[7]. This classification has the advantage of being developed and maintained for commercial use and providing ready access to statistics. It is based on finished dose pharmaceutical products and their approved indications in the various countries, which may in many cases vary from one country to another.

(9) In the EphMRA ATC system, medicines are classified into groups at four different levels. In the first and broadest level (ATC1), medicinal products are divided into the 16 main anatomical groups. The second level (ATC2) represents either a pharmacological or therapeutic group. The third level (ATC3) further groups medicinal products by their specific therapeutic indications, i.e. their intended use. The ATC4 level is the most detailed one (not available for all ATC3) and refers for instance to the mode of action (e.g. distinction of some ATC3 classes into topical and systemic depending on their way of action) or any other subdivision of the group. Finally, the level of the chemical substance is the so-called molecule level (ATC5).

(10) In previous decisions, the Commission has referred to the ATC3 level as the starting point for defining the relevant product market. The Commission found however that the ATC3 level classification did in many cases not provide the appropriate market definition within the meaning of the Commission Notice on Definition of the Relevant Market[8]. Thus, where appropriate and based on the

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[5] Finished dose pharmaceuticals are essentially pharmaceutical products in the form in which they are marketed for use, typically involving a mixture of active drug components and nondrug components (excipients), along with other non-reusable material that may not be considered either ingredient or packaging (such as a capsule shell, for example).

[6] M.7746 – *Teva/Allergan Generics*; M.7559 – *Pfizer/Hospira*; M.7379 – *Mylan/Abbott EPD-DM*; M.6613 – *Watson/Actavis.*

[7] The ATC classification devised by the European Pharmaceutical Marketing Research Association ("EphMRA") and maintained by EphMRA and Intercontinental Medical Statistics ("IMS").

[8] OJ C 372, 9.12.1997, p. 5.

* Should read: "CVC Funds portfolio companies"

** Should read: "the Target"

*** Should read: "Funds"

factual evidence collected during the market investigation, the Commission defined the relevant product market at the level of the molecule[9].

(11) As regards genericised products, for which the originator drug lost market exclusivity and competes with generic drugs, the Commission has taken the view that the molecule level is the most plausible starting point for the product market definition, given that generic pharmaceutical companies typically produce copies of originator drugs[10] and thus it can be considered that a generic molecule is the closest substitute to the originator medicinal product based on the same molecule or API[11]. As set out in the Commission's Horizontal Merger Guidelines[12], the higher the degree of substitutability between the merging firms' products, the more likely it is that the merging firms will raise prices significantly[13].

(12) As regards a potential distinction between generic and originator medicines, in previous decisions[14], the Commission set out that where the market is genericised, originator drugs and generics could be considered to be close substitutes for a given indication and a product market may be defined as including both the generic and the originator medicine.

(13) In the present case, in line with the previous practice, the Commission takes the molecule level as the most plausible starting point for the product market definition.

(14) Regarding a potential distinction between originator and generic products, during the market investigation in the present case the respondents indicated that brand recognition and price differentiate originator products from the generic products based on the same molecule[15]. In this regard, brand loyalty to the originator medicine may play a role in limiting the number of customers switching away from the originator drug in certain instances, and thus limiting the competition that takes place between originator and generic providers[16]. However, such dynamics are typical of differentiated products within a product market where brand recognition and marketing can influence customers' decision between substitutable products. Therefore, for the purposes of the competitive assessment

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9 See for example M.7559 – *Pfizer/Hospira* and M.5253 – *Sanofi-Aventis/Zentiva*.

10 Generics are in general less expensive versions of the originator drugs. In regulatory approval procedures, a generic drug manufacturer has to demonstrate that the generic version of the originator drug has identical composition in active substances, same strength and pharmaceutical form; and is biologically equivalent to the originator drug. See for example M.5253 – *Sanofi-Aventis/Zentiva* and M.5295 – *Teva/Barr*. Note however that there may still be small differences, such as in inactive ingredients, which may lead in certain, probably relatively uncommon cases, to the drugs being non-equivalent from a medical standpoint.

11 See M. 7746 - *Teva/Allergan Generics*; M.7559 – *Pfizer Hospira*; M.7379 – *Mylan/Abbott EPD-DM*; M.6613 – *Watson/Actavis.*

12 Guidelines on the assessment of horizontal mergers under the Council Regulation on the control of concentrations between undertakings ("Horizontal Merger Guidelines"), OJ C 31, 5.2.2004, p. 5, para 28.

13 See M.5253 – *Sanofi-Aventis/Zentiva.*

14 See M. 4418 - *Nycomed Group/Altana Pharma* and M.3751 - *Novartis/Hexal.*

15 See Section 4.2.1.2 below.

16 See for example M.5865 - *TEVA/ RATIOPHARM.*

of the Transaction, the Commission considers that in relation to the overlapping molecules the product market includes both generic and originator versions.[17]

(15) In addition, medicines are differentiated not only by their active ingredient(s), but also, as recognised by the European regulatory framework for medicines for human use[18], by their dosage, pharmaceutical form and route of administration, which may limit their substitutability. The Commission looked in the past at the pharmaceutical form or "galenic" form with reference to the first letter of the typology of form codes ("New Form Code 1", or "NFC1"), for the purposes of defining the relevant product market.

(16) The market investigation in the present case has shown, for some of the molecules considered, that different routes of administration and the pharmaceutical forms of a medicine may have limited substitutability[19]. In any event, the question of whether the relevant markets should be further subdivided according to the galenic form can be left open for the purpose of this decision as the competitive assessment of individual markets would not change irrespective of galenic form concerned. [20]

Geographic market definition

(17) As regards the geographic market definition, the Notifying Party has submitted an overview of the overlapping molecules on a country-by-country basis. The Commission has consistently held that the market for finished pharmaceutical products is national in scope[21]. This conclusion has been reached because of (i) varying regulatory controls for pharmaceutical products; (ii) perceived differences in price setting and purchasing patterns/reimbursement by Member States; (iii) differences in national clinical guidelines, medical views and patient preferences; (iv) differences in brand, pack size and distribution systems; and (v) because competition between pharmaceutical companies generally takes place at national level[22].

(18) There is no reason to depart from the previous practice in the present case.

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17 In any event, in the present case, a potential distinction between generic and originator medicines would significantly reduce the overlaps between the activities of the Parties since, in most cases, the overlaps result from the combination of the Target's originator product and CVC's generic product. Therefore, should the market be defined at originator or generic level, the Parties' activities would not overlap (subject to one exception, *i.e.* aciclovir in Italy – see Section 4.2.1.2).

18 The European regulatory framework for human medicines sets standards to ensure a high level of public health protection and the quality, safety and efficacy of authorised medicines and to promote the functioning of the internal market. It is based on the principle that a medicinal product requires a marketing authorisation by the competent authorities before being placed on the market.

19 See replies to questions 11, 38, 65, 74 of questionnaire Q2 to customers in Italy and questions 6, 22, 42 of questionnaire Q1 to competitors.

20 See below recital 31.

21 See for example M. 7746 - *Teva/Allergan Generics* and M.7559 – *Pfizer/Hospira.*

22 See for example M.6705 *Procter&Gamble/Teva Pharmaceuticals OTC II* and M.6280 *P&G/Teva OTC Business.*

4.1.2 Pipeline generic pharmaceuticals

Product market definition

(19) Following the same approach as for FDPs and in line with past decisions,[23] the Commission takes the molecule level as the most plausible relevant market for pipeline generic pharmaceuticals, considering that a pipeline generic molecule is typically the closest substitute to the other generic medicinal product based on the same molecule. There is no reason to depart from the previous practice in the present case.

Geographic market definition

(20) For pipeline products, the Commission previously considered that the geographic scope of the relevant market is at least EEA-wide.[24] There is no reason to depart from the previous practice in the present case.

4.1.3 Hospital services

Product market definition

(21) The Commission has analysed the market for the provision of hospital services in a number of decisions, distinguishing between inpatient (acute) hospital procedures conducted in hospitals and outpatient (ambulatory) procedures conducted in hospitals.[25] The Commission has also examined whether a distinction between different specialist medical departments should be made[26], ultimately leaving open the exact definition. Furthermore, the Commission has considered whether a distinction between private (or independent) hospitals and public hospitals could be appropriate although the exact delineation largely depended on the specificities of the case and the national market in question.[27] For example, a separate market for private acute general hospitals was defined for the UK because on the UK market the demand for such services was different from the demand for public acute general hospitals.[28]

Geographic market definition

(22) As to the geographical definition, in prior decisions the Commission indicated that the market for private hospitals was not broader than national in scope.[29] Ultimately, it was left open whether the market is national, regional or local in scope.[30]

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23 See M.7645 – *Mylan / Perrigo*; M.7559 – *Pfizer / Hospira*; M.7379 - *Mylan/ Abbott EPD-DM.*

24 See M.7645 – *Mylan / Perrigo*; M.7559 – *Pfizer / Hospira*; M.7379 - *Mylan/ Abbott EPD-DM.*

25 M.8146 – *Carlyle/Schön Family/Schön Klinik.*

26 M.8146 – *Carlyle/Schön Family/Schön Klinik.*

27 M.4010 – *Fresenius/Helios.*

28 M.4367 – *APW/ Nordic Capital/ APSA/ Capio.*

29 M. 4229 *APHL/L&R/Netcare General Healthcare Group*; M.4788 *Rozier/BHS.*

30 M.4010 – *Fresenius/Helios.*

Conclusion

(23) The precise product and geographic market definition can be left open […]*, as no serious doubts would arise in relation to the compatibility of the Transaction with the internal market under all plausible market definitions.

4.2 Competitive assessment

4.2.1. Horizontal overlaps

4.2.1.1. Introduction

Finished dose pharmaceutical products

(24) In its decisional practice, the Commission has applied a system of filters aimed at determining the group of markets where concerns are most likely and on which […]** focused its analysis.[31]

(25) Based on this filter, pharmaceutical markets are analysed according to three categories:

- Group 1: where the Parties' combined market share exceeds 35% and the increment exceeds 1%;
- Group 1+: either (a) the Parties' combined market share is below 35%, but only one other competitor remains on the market, or (b) the Parties' combined market share exceeds 35% and the increment is below 1% but the Party with the small increment is a recent entrant.
- Group 2: where the Parties' combined market share exceeds 35% but the increment is less than 1% (and the Party with the small increment is not a recent entrant);
- Group 3: The Parties' combined market share is between 20% and 35% (and more than one competitor remains on the market).

(26) Thus, applying this methodology, the present Transaction gives rise at molecule level to the affected markets as presented in Table 1.

Table 1 – Summary of Affected Markets at molecule level

Member State	Affected market	Group Classification
Iceland	Metoprolol - C7A	Group 1 (2017)
Italy	Lercanidipine - C8A	Group 1 (2017)
Italy	Lercanidipine and enalapril	Group 1+ (2018)
Italy	Rupatadine - R6A	Group 1 (2017)
Italy	Aciclovir - J5B	Group 1 (2017)
Italy	Ketorolac - N2B	Group 1 (2017)

[31] See M.7746 - *Teva / Allergan Generics*; M.7645 - *Mylan/ Perrigo*; M.7379 – *Mylan/Abbott EPD-DM.*

* Should read: " "

** Should read: "it"

Member State	Affected market	Group Classification
Italy	Domperidone - A3F	Group 1 (2017)
Italy	Metoprolol - C7A	Group 1 (2017)
Italy	Bisoprolol - C7A	Group 3 (2017)
France	Calcium, Colecalciferol - A12A	Group 3 (2017)
Romania	Metoprolol - C7A	Group 1 (2017)
Spain	Calcium, Colecalciferol - A12A	Group 3 (2015)

(27) The Transaction does not lead to Group 2 affected markets. Regarding the Group 3 markets, many competitors remain in the market. Moreover, most of these competitors have market shares above the increment brought by the Transaction:[32]

- *in the market for the supply C7A bisoprolol in Italy*, the Parties have a combined market share of [30-40]% in value in 2017 ([20-30]% in volume) and would face, post-Transaction, nine competitors, with value and volume market shares similar to or higher than the increment brought by the Transaction (*i.e.* [0-5]%) including notably Daiichi Sankyo [10-20]-[20-30]%), Novartis ([10-20]-[20-30]%), Dompe ([10-20]%), Mylan ([0-5]-[5-10]%), Stada ([0-5]%), *etc.*;

- *in the market for the supply A12A Calcium*, Colecalciferol in France, the Parties have a combined market share of [20-30]% in value in 2017 ([20-30]% in volume) and would face, post-Transaction, 11 competitors, with value and volume market shares similar to or higher than the increment brought by the Transaction (*i.e.* [0-5]%) including notably Aurobindo ([20-30]%), Mayoly-Spindler ([10-20]%), Pfizer ([10-20]%), Expaniance ([5-10]%), Innothera ([5-10]%), *etc.*;

- *in the market for the supply A12A Calcium, Colecalciferol in Spain*, over the last three years, the Parties' activities overlapped only in 2015, with a combined market share of [20-30]% in value ([20-30]% in volume); post-Transaction, the Parties would face at least eight competitors, with 2017 value and volume market shares higher than the increment brought by the Transaction (*i.e.* [0-5]%) including Italfarmaco ([30-40]%), Takeda ([20-30]%), Alter ([5-10]%-[10-20]%), GlaxoSmithKline ([5-10]%), Rovi ([0-5]%), *etc*.

(28) Therefore, the Transaction does not raise serious doubts as to it compatibility with the internal market in respect of the Group 3 markets. The Commission will in the remainder of the Decision deal with the markets that fall within Group 1 and Group1+.[33]

[32] See Form CO, Annex 17.

[33] See M.7746 – *Teva/Allergan Generics*.

Pipeline generic pharmaceuticals

(29) When assessing pipeline competition, the Commission has previously focused on instances where one party is planning to enter a market with a new product within a period of two years and the other party (or the parties combined) has a market share of 35% or more on any possible market where the pipeline products and existing products overlap[34]. The Notifying Party agrees with the above approach.

(30) There is no reason to depart from the previous practice in the present case.

4.2.1.2. Finished dose pharmaceutical products

(31) The Parties' market shares of sales of overlapping molecules in the affected Group 1 markets are presented in Table 2, which provides market shares at molecule level. As explained in Section 4.1.1, the markets can be potentially further divided depending on the galenic forms. In the present case, for most markets concerned, the Parties' activities do not overlap at galenic form level. Moreover, if the Commission were to look at galenic form level, market shares in the markets where the Parties' activities overlap at galenic form level (*i.e.* domperidone in Italy, ketorolac in Italy, rupatadine in Italy, metoprolol in Italy and Iceland) would not materially differ from the molecule level (including all galenic forms). Moreover, market participants indicated that the competitive dynamics in the overlapping galenic forms do not materially differ from the molecule level.[35] Therefore, unless otherwise specified, in Section 4.2.1, the Commission's findings at molecule level also apply to the potential markets for galenic forms where the Parties' activities overlap.

Table 2 –Market shares[36] of sales of overlapping molecules in the affected markets (Groups 1 and 1+)(in value and in volume)

Member State	Year	CVC		RECORDATI		Combined		Total market size (€'000s)	Competitors with market shares >5% (in value and volume)
		value	*volume*	*value*	*volume*	*value*	*volume*		
ACICLOVIR - J5B (Antivirals, Other)									
Italy	***2017***	[5-10]%	[10-20]%	[30-40]%	[0-5]%	**[40-50]%**	**[10-20]%**	[...]	Stada – [10-20]%; [10-20]% Mylan – [10-20]%; [10-20]% Fidia – [5-10]%; [10-20]% Teva – [5-10]%; [10-20]% Glaxo SmithKl – [5-10]%; [5-10]% Novartis – [5-10]%; [5-10]%

[34] See e.g. M.7559 – *Pfizer/Hospira*, M.6258 – *Teva/Cephalon* and M.6613 – *Watson/Actavis*.

[35] See e.g. replies to questions 7.1, 13..1, 16.1, 22.1, 34.1, 38 of questionnaire Q1 to competitors; questions 12.1, 13, 14, 20.1, 22.1, 24, 28.1 of questionnaire Q2 to customers Italy, questions 9, 12.1, 13, 20.1, 22.1 of questionnaire Q3 to customers in Iceland; and questions 11.1, 13, 14, 19.1 of questionnaires Q4 to customers in Romania.

[36] The figures are rounded. Therefore, the combined market shares may have up to 1% deviation from sum up of the individual shares.

Member State	Year	CVC		RECORDATI		Combined		Total market size (€'000s)	Competitors with market shares >5% (in value and volume)
		value	*volume*	*value*	*volume*	*value*	*volume*		
	2016	[5-10]%	[10-20]%	[30-40]%	[0-5]%	**[40-50]%**	**[10-20]%**	[...]	Stada – [10-20]%; [10-20]% Mylan – [5-10]%; [10-20]% Fidia – [5-10]%; [10-20]% Teva – [5-10]%; [10-20]% Glaxo SmithKl – [10-20]%; [5-10]%
	2015	[5-10]%	[10-20]%	[20-30]%	[0-5]%	**[30-40]%**	**[10-20]%**	[...]	Stada – [10-20]%; [10-20]% Mylan – [5-10]%; [10-20]% Fidia – [5-10]%; [10-20]% Teva – [5-10]%; [10-20]% Glaxo SmithKl – [10-20]%; [5-10]%
DOMPERIDONE - A3F (Gastroprokinetics)									
Italy	***2017***	[0-5]%	[0-5]%	[50-60]%	[50-60]%	**[50-60]%**	**[60-70]%**	[...]	Johnson & Johnson – [10-20]%; [10-20]% Stada – [10-20]%; [5-10]% Teva – [5-10]%; [5-10]% Mylan – [0-5]%; [5-10]%
	2016	[0-5]%	[0-5]%	[50-60]%	[50-60]%	**[50-60]%**	**[60-70]%**	[...]	Johnson & Johnson – [10-20]%; [10-20]% Stada – [10-20]%; [5-10]% Teva – [5-10]%; [5-10]% Mylan – [0-5]%; [5-10]%
	2015	[0-5]%	[0-5]%	[50-60]%	[50-60]%	**[60-70]%**	**[60-70]%**	[...]	Johnson & Johnson – [10-20]%; [10-20]% Stada – [5-10]%; [5-10]% Teva – [5-10]%; [5-10]% Mylan – [0-5]%; [5-10]%
KETOROLAC - N2B (Non-narcotic Analgesics)									
Italy	***2017***	[0-5]%	[0-5]%	[80-90]%	[80-90]%	**[80-90]%**	**[80-90]%**	[...]	Mylan – [5-10]%; [10-20]%
	2016	[0-5]%	[0-5]%	[80-90]%	[80-90]%	**[80-90]%**	**[80-90]%**	[...]	Mylan – [0-5]%; [5-10]%
	2015	[0-5]%	[0-5]%	[80-90]%	[80-90]%	**[80-90]%**	**[80-90]%**	[...]	Mylan – [0-5]%; [0-5]%
LERCANIDIPINE - C8A (Calcium Antagonist Plain)									
Italy	***2017***	[5-10]%	[10-20]%	[60-70]%	[50-60]%	**[70-80]%**	**[60-70]%**	[...]	Mylan – [5-10]%; [10-20]% Polifarma Benesser – [5-10]%; [5-10]%
	2016	[5-10]%	[10-20]%	[60-70]%	[50-60]%	**[70-80]%**	**[60-70]%**	[...]	Mylan – [5-10]%; [10-20]% Polifarma Benesser – [5-10]%; [5-10]%

Member State	Year	CVC		RECORDATI		Combined		Total market size (€'000s)	Competitors with market shares >5% (in value and volume)
		value	*volume*	*value*	*volume*	*value*	*volume*		
	2015	[5-10]%	[10-20]%	[60-70]%	[50-60]%	**[70-80]%**	**[60-70]%**	[...]	Mylan – [5-10]%; [10-20]% Polifarma Benesser – [5-10]%; [5-10]%
LERCANIDIPINE AND ENALAPRIL									
Italy	***H1 2018***	[0-5]%	[0-5]%	[60-70]%	[60-70]%	**[60-70]%**	**[60-70]%**	[...]	Italfarmaco – [20-30]%; [10-20]% Polifarma Benesser – [10-20]%; [10-20]% Teva – [5-10]%; [5-10]%
	2017	-	-	[60-70]%	[60-70]%	**[60-70]%**	**[60-70]%**	[...]	Italfarmaco – [20-30]%; [20-30]% Polifarma Benesser – [10-20]%; [10-20]% Teva – [5-10]%; [0-5]%
	2016	-	-	[60-70]%	[60-70]%	**[60-70]%**	**[60-70]%**	[...]	Italfarmaco [10-20]%; [10-20]% Polifarma Benesser – [10-20]%; [10-20]%
	2015	-	-	[60-70]%	[60-70]%	**[60-70]%**	**[60-70]%**	[...]	Italfarmaco – [10-20]%; [10-20]% Polifarma Benesser – [10-20]%; [10-20]%
RUPATADINE - R6A (Antihistamines Systemic)									
Italy	***2017***	[0-5]%	[0-5]%	[30-40]%	[30-40]%	**[40-50]%**	**[40-50]%**	[...]	Mylan – [50-60]%; [50-60]%
	2016	-	-	[40-50]%	[40-50]%	**[40-50]%**	**[40-50]%**	[...]	Mylan – [50-60]%; [50-60]%
	2015	-	-	[40-50]%	[40-50]%	**[40-50]%**	**[40-50]%**	[...]	Mylan – [50-60]%; [50-60]%
METOPROLOL - C7A (Beta Blocking Agents, Plain)									
Italy	***2017***	[5-10]%	[10-20]%	[30-40]%	[20-30]%	**[30-40]%**	**[30-40]%**	[...]	Daiichi Sankyo – [30-40]%, [20-30]% Novartis – [10-20]%; [10-20]% Stada – [10-20]%; [10-20]%
	2016	[5-10]%	[10-20]%	[30-40]%	[20-30]%	**[30-40]%**	**[30-40]%**	[...]	Daiichi Sankyo – [30-40]%; [20-30]% Novartis – [10-20]%; [10-20]% Stada – [10-20]%; [10-20]%
	2015	[5-10]%	[5-10]%	[30-40]%	[20-30]%	**[30-40]%**	**[30-40]%**	[...]	Daiichi Sankyo – [40-50]%; [30-40]% Novartis – [10-20]%; [10-20]% Stada – [10-20]%; [10-20]%
Iceland	***2017***	[20-30]%	[30-40]%	[40-50]%	[30-40]%	**[70-80]%**	**[60-70]%**	[...]	Artasan Ehf – [10-20]%; [20-30]% Lyfis Ehf – [5-10]%; [5-10]%
	2016	[40-50]%	[40-50]%	[40-50]%	[20-30]%	**[80-90]%**	**[70-80]%**	[...]	Artasan Ehf – [10-20]%; [20-30]%

Member State	Year	CVC		RECORDATI		Combined		Total market size (€'000s)	Competitors with market shares >5% (in value and volume)
		value	*volume*	*value*	*volume*	*value*	*volume*		
	2015	[40-50]%	[50-60]%	[40-50]%	[30-40]%	**[80-90]%**	**[80-90]%**	[...]	Artasan Ehf – [5-10]%; [10-20]%
Romania	***2017***	[10-20]%	[20-30]%	[50-60]%	[30-40]%	**[70-80]%**	**[60-70]%**	[...]	Sun Pharma – [10-20]%; [10-20]% Servier – [5-10]%; [10-20]% Novartis – [5-10]%; [5-10]%
	2016	[10-20]%	[20-30]%	[50-60]%	[30-40]%	**[60-70]%**	**[50-60]%**	[...]	Sun Pharma – [10-20]%; [20-30]% Servier – [5-10]%; [10-20]%; Novartis – [5-10]%; [5-10]%
	2015	[10-20]%;	[30-40]%	[50-60]%	[20-30]%	**[70-80]%**	**[60-70]%**	[...]	Sun Pharma – [10-20]%; [10-20]% Servier – [5-10]%; [10-20]% Novartis – [5-10]%; [5-10]%

Source: Form CO

Aciclovir - Italy

(32) Aciclovir is an antiviral drug. It is used for the treatment of herpes simplex virus infections, chickenpox and shingles. The overlap concerns the J5B aciclovir which has systemic administration, in both oral and injectable forms, and which is different from D6D aciclovir for topical administration

(33) The overlap on the J5B aciclovir market in Italy is between Recordati's generic product (Aciclovir Recordati) and DOC Generici's generic product (Aciclovir DOC).

(34) The Commission considers that concerning the market for aciclovir in Italy[37], the Transaction does not raise serious doubts as to it compatibility with the internal market for the following reasons.

(35) First, the Transaction gives rise to an affected market only in relation to the value of the sales (with a [40-50]% combined market share in 2017), while in volume, the Parties' combined market share remains much lower ([10-20]%) and does not lead to an affected market. According to the Parties, the IMS data used for the market share estimates overstate the amount of sales by value of the products sold to hospitals (including all of the Target's injectable aciclovir), which explains the apparent discrepancy between the Target's market share by value ([30-40]%) and by volume ([0-5]%). This is corroborated by the fact that actual sales of the Target in 2017 for injectable aciclovir are about […]% of the amount reported in the IMS data used for the market share estimates. It follows that the Parties' [40-50]% combined value market share is likely overstated. Moreover, the increment brought by the Transaction is small in volume ([0-5]%) and moderate in value ([5-10%]).

[37] At galenic form level, the Parties' activities do not overlap on this market.

(36) Second, post-Transaction, the Parties will continue to face competition from numerous players: six other sellers of aciclovir have shares of supply of over 5% in value in Italy and two of them (Stada and Mylan) have value shares equal to or higher than the combined Parties.[38]

(37) Third, at molecule level, the Parties' products do not seem to be close substitutes. There are three different galenic forms for J5B aciclovir: class A (oral solid ordinary), class D (oral liquid ordinary) and class F (parenteral ordinary). The Parties' activities overlap with none of them in Italy. They supply different galenic forms, with modes of administration that are entirely different (oral *vs.* injectable), under different channels: DOC Generici (CVC) sells orally-administered products (NFC1 A and D classes) to wholesalers and pharmacies, while the Target sells injectable products (NFC1 F class) to hospitals.

(38) As regards pricing and reimbursement of medicinal products in Italy, as indicated by the Notifying Party, the Italian National Healthcare System reimburses the lowest price among the prices of off-patent medicinal products with interchangeable active ingredients, the same pharmaceutical form, same method of administration, same number of units and same unit dosage. Any difference from this reference price is paid by patients if they refuse an interchangeable generic alternative and/or their doctor prescribes a pharmaceutical product with a price higher than the reference price and specifically provides that this product cannot be substituted with other products. Thus, the reimbursement system provides incentives to the generic suppliers to price their products similarly, unless they are successful in differentiating them in terms of package size, dosage, *etc*.[39]

(39) Based on the above considerations, in particular the fact that the Parties are not close competitors and that the overlap is moderate, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to the supply of J5B aciclovir in Italy irrespective of whether the market is subdivided by galenic form.

Domperidone – Italy

(40) Domperidone is a blocker of dopamine receptors. It is used for the treatment of nausea and vomiting.

(41) The overlap on the domperidone market in Italy is between Recordati's originator product (Peridon) and DOC Generici's generic product (Domperidone DOC).

(42) The Notifying Party submits that despite the high combined market shares of the Parties for domperidone, the increment arising from DOC Generici is minimal and the Transaction does not materially change the competitive landscape.

[38] See Form CO, Annex 17.

[39] See Form CO, Annex 20.

(43) The Commission considers that concerning the market for domperidone in Italy and its potential sub-segments[40], the Transaction does not raise serious doubts as to it compatibility with the internal market for the following reasons.

(44) First, the overlap is limited. The Parties' high combined market share in the Domperidone market in Italy primarily reflects the strong market position of Recordati's originator product. DOC Generici's sales are very limited ([…] k€ in 2017). As a result, the increment brought by the Transaction is modest ([0-5]%both in value and volume).

(45) Second, the domperidone market in Italy is largely genericised and there are more than 15 companies active on the market (both at molecule and NFC1 A levels), of which 4 have market shares larger than the increment brought by DOC Generici (namely Johnson & Johnson, Stada, Teva, and Mylan). Some offer originator products (namely Johnson & Johnson's Motilium), but most supply generic versions. Both customers and competitors consider that the market is competitive due to the large number of alternative suppliers.[41] In fact, most customers multisource and have between 4 and more than 10 different suppliers. For the vast majority of them, switching suppliers is relatively easy.[42]

(46) Third, the market investigation indicated that the Parties are not close competitors, as DOC Generici's generic domperidone competes more closely with multiple other generics of the same medicine than with Recordati's originator domperidone. In particular; price and brand recognition are considered as key parameters of competition by most respondents and Recordati's originator product is differentiated from generics due to its established brand and a certain degree of customer loyalty.[43] Conversely, no specific competitive advantage was identified for DOC Generici's generic domperidone, which is described as being comparable to the other generic products.[44] According to a generic competitor, "*the brand market and generic one have market dynamic completely different*".[45] Also, price competition appears greater between generics than it is between generics and Recordati's originator domperidone. According to the national pricing and reimbursement rules, explained above, patients are reimbursed only up to the amount of the cheapest generic version. If they choose to buy the more expensive originators, they pay the price difference. Due to this feature, price competition on the domperidone market takes place more intensely between the different generic supplies, which are numerous and will continue to exert competitive pressure on the merged entity.

(47) Fourth, there are three different galenic forms for A3F domperidone: class A (oral solid ordinary), class D (oral liquid ordinary), and class H (rectal systemic). The market investigation suggests that, at molecule level, due to the difference in

[40] On this market, the Parties' activities overlap both at molecule and galenic form levels.

[41] Replies to question 12 of questionnaire Q2 to customers in Italy and question 7 of questionnaire Q1 to competitors.

[42] Replies to questions 8, 18, and 20 of questionnaire Q2 to customers in Italy.

[43] Replies to questions 13 to 16 of questionnaire Q2 to customers in Italy and questions 8 to 11 of questionnaire Q1 to competitors.

[44] Replies to question 16 of questionnaire Q2 to customers in Italy and question 11 of questionnaire Q1 to competitors.

[45] See Aristo Pharma's non-confidential reply to question 13 of questionnaire Q1 to competitors.

galenic form, the Parties are not close competitors: (i) the replies of the market participants show that substitutability between the three galenic forms may be somewhat limited[46] and (ii) DOC Generici's products fall within the NFC1 A class and the Target's products fall within classes A, D and H; in other words, the Parties overlap only with respect to one galenic form.

(48) Finally, the Commission notes that all informative respondents consider that the impact of the Transaction will be "*neutral*" on the domperidone market in Italy. A large number of customers indicated that there will remain sufficient alternative sources of supply post-Transaction regardless of the galenic form. The customers that took the opposite view mostly complained about the lack of alternatives to Recordati in relation to galenic forms for which the Parties' activities do not overlap.[47]

(49) Based on the above considerations, in particular the fact that the Parties are not close competitors and that the overlap is limited, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to the supply of domperidone in Italy irrespective of whether the market is subdivided by galenic form.

Ketorolac - Italy

(50) Ketorolac is a pyrrolizine carboxylic acid derivative. It is used as an analgesic.

(51) The overlap on the ketorolac market in Italy is between Recordati's originator products (Toradol) and DOC Generici's generic product (Ketorolac DOC).

(52) The Notifying Party submits that the increment arising from DOC Generici is minimal and the Transaction does not materially change the competitive landscape.

(53) The Commission considers that concerning the market for ketorolac in Italy and its potential sub-segments[48], the Transaction does not raise serious doubts as to it compatibility with the internal market for the following reasons.

(54) First, the overlap is limited. Similarly to domperidone, the Parties' high combined market share on the ketorolac market in Italy primarily reflects the strong market position of Recordati's originator product. DOC Generici's sales of ketorolac are very limited ([…] k€ in 2017). As a result, the increment of the Transaction is modest [0-5]% in value and [0-5]% in volume.

(55) Second, the ketorolac market is largely genericised, with a large number of competitors. Post-Transaction, there would remain no less than 10 other suppliers, including several players with market share larger than the increment brought by

[46] Replies to question 11 of questionnaire Q2 to customers in Italy and question 6 of questionnaire Q1 to competitors.

[47] Replies to questions 21-22 of questionnaire Q2 to customers in Italy and question 13 of questionnaire Q1 to competitors.

[48] On this market, the Parties' activities overlap both at molecule and galenic form levels.

DOC Generici (such as Mylan and So.Se.Pharma) and one alternative originator product (namely Atnahs Pharma's Lixidol). The Commission also notes that, over the past three years, Mylan's market share has significantly increased (+[5-10]% in value and +[5-10]% in volume in 2017 compared to 2015), while the Parties' combined share has decreased (-[0-5]%in value and -[0-5]% in volume in 2017 compared to 2015). In fact, most market participants consider that the ketorolac market is rather competitive.[49] The market investigation also shows that most customers multisource, with up to 10 different suppliers, and a large number of them indicated that switching is relatively easy.[50]

(56) Third, the market investigation indicated that the Parties are not close competitors, as DOC Generici's generic ketorolac competes more closely with multiple other generics of the same medicine than with Recordati's originator product. Price and brand recognitions are among the key parameters of competition for both customers and competitors. Recordati's originator product is differentiated from generics due to its established brand and a certain degree of customer loyalty. Conversely, no specific competitive advantage was identified for DOC Generici's products.[51] Also, competition appears greater between generics than it is between generics and Recordati's originator ketorolac due the national pricing and reimbursement rules, according to which patients are reimbursed only up to the amount of the cheapest generic version. If they choose to buy the more expensive originator, they pay the price difference. Due to this feature, price competition on the ketorolac market takes place more intensely between the different generic supplies,[52] which are numerous and will continue to exert competitive pressure on the merged entity.

(57) Fourth, there are three different galenic forms for ketorolac: class A (oral solid ordinary), class D (oral liquid ordinary) and class F (parenteral ordinary). Recordati offers the three galenic forms, contrary to DOC Generici, which offers only classes D and F. This product portfolio difference further limits the degree of closeness of competition between the Parties at molecule level.[53]

(58) Finally, all informative respondents (both customers and competitors) consider that the impact of the Transaction will be "*neutral*" on the ketorolac market in Italy regardless of the galenic form.[54]

(59) Based on the above considerations, in particular the fact that the Parties are not close competitors and that the overlap is limited, the Commission considers that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to the supply of ketorolac in Italy irrespective of whether the market is subdivided by galenic form.

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49 Replies to question 28 of questionnaire Q2 to customers in Italy.

50 Replies to questions 24, 34, and 36 of questionnaire Q2 to customers in Italy.

51 Replies to questions 28 to 32 of questionnaire Q2 to customers in Italy and questions 16 to 20 of questionnaire Q1 to competitors.

52 See Form CO, Annex 20.

53 Replies to question 27 of questionnaire Q2 to customers in Italy and question 15 of questionnaire Q1 to competitors.

54 Replies to question 38 of questionnaire Q2 to customers in Italy and question 22 of questionnaire Q1 to competitors.

Lercanidipine – Italy

(60) Lercanidipine is an antihypertensive drug. It is used for the treatment of mild to moderate hypertension.

(61) The overlap on the lercanidipine market in Italy is between Recordati's originator products (Lercadip and Zanedip) and DOC Generici's generic products (Lercanidipina DOC).

(62) The Notifying Party claims that lercanidipine is demonstrably substitutable with several other calcium channel blockers (CCBs). In particular, it submitted that […]. Doctors in Italy contacted in the context of the market investigation explained that both lercanidipine and amlodipine belong to dihydropiridine CCBs. Dihydropiridine CCBs are among the most effective antihypertensive agents. Amlodipine shares similar effects with lercanidipine. However, considering that neither the Notifying Party nor the market investigation produced conclusive evidence that the CCBs were not only therapeutic substitutes, but were actual, economic substitutes, the Commission cannot exclude that the product market is limited to lercanidipine. Therefore, the subsequent assessment takes into account the candidate market for medicines with lercanidipine as the active ingredient.

(63) The Notifying Party also submits that despite the relatively high combined market shares of the Parties for lercanidipine in Italy, the Transaction does not raise competition concerns on the grounds that (i) the Parties are not close competitors (originator *vs.* generic), (ii) the Target's market share has steadily declined since its loss of exclusivity in 2010, (iii) the Parties face a large number of competitors, and (iv) the Italian price regulation is strict favouring price competition to the benefit of generic competitors.

(64) The Commission considers that concerning the market for lercanidipine in Italy[55], the Transaction does not raise serious doubts as to it compatibility with the internal market for the following reasons.

(65) First, the overlap is moderate, with a [5-10]% increment in value ([10-20]% in volume) brought by DOC Generici. The Parties' high combined market share on the lercanidipine market in Italy primarily reflects the strong market position of Recordati's originator product.

(66) Second, the market is largely genericised and there are more than 10 companies active on the market, including Mylan, which has a higher market share than DOC Generici ([5-10]% in value and [10-20]% in volume in 2017), as well as many other credible players, such as Polifarma, Novartis, Stada, and Teva. Post-Transaction, the new entity will face both competing originator products (Polifarma's Cardiovasc) and generic products. In fact, most market participants consider that the lercanidipine market is competitive due to the larger number of suppliers.[56] For instance, a competitor indicated that the market is "*very competitive because of takeover of generics […] the generics' market shares*

[55] The segmentation based on the galenic forms is not relevant on lercanidipine market where there is only one galenic form.

[56] Replies to question 27 of questionnaire Q2 to customers in Italy and question 15 of questionnaire Q1 to competitors.

increase every year"[57], which is corroborated by the Parties' market share estimates. The market investigation also showed that most customers (including both wholesalers and pharmacies) multisource and have between 4 and more than 10 different suppliers. For a large number of them, switching is relatively easy.[58]

(67) Third, despite relatively high market shares of Recordati for its originator lercanidipine, the Parties are not close competitors, as DOC Generici's generic lercanidipine competes more closely with multiple other generics of the same medicine.

(68) In the first place, the price, brand recognition and reliability of supply are considered as key parameters of competition by both customers and competitors. Recordati's originator product is differentiated from generics due to its established brand and a certain degree of customer loyalty. No specific competitive advantage was identified for DOC Generici's generic lercanidipine.[59] For instance, a competitor stated that: "*Lercadip and Zanedip [i.e. Recordati's brand products] are well known brands prescribed by physicians since years. Lercarnidipine DOC (as for the other generic products) is not differentiated but has a lower price*".[60] This has allowed Recordati to retain a significant market share despite the presence of several generics at significantly lower prices.

(69) In the second place, price competition is more intense between generics than it is between generics and Recordati's originator lercanidipine. According to the national pricing and reimbursement rules, explained in recital 38, patients are reimbursed only up to the amount of the cheapest generic version and they pay the price difference if they choose to buy the more expensive competing product. Due to this feature, price competition on the lercanidipine market takes place more intensely between the different generic […]*, which are numerous and will continue to exert competitive pressure on the merged entity. Accordingly, the evolution of prices, volume and value shares does not suggest intense competition between originator and generic products after the initial period of genericisation around the generic entry in 2010, when a significant part of demand for lercanidipine shifted to generic products. [61]

(70) Finally, the Commission notes that all informative respondents consider that the impact of the Transaction will be "*neutral*" on the lercanidipine market in Italy. Moreover, 80% of the customers indicated that there will remain sufficient alternative sources of supply post-Transaction.[62]

(71) Based on the above considerations, in particular the fact that the Parties are not close competitors and that the overlap is moderate, the Commission concludes

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[57] See Polifarma's non-confidential reply to question 25 of questionnaire Q1 to competitors.

[58] Replies to question 27 of questionnaire Q2 to customers in Italy and question 15 of questionnaire Q1 to competitors.

[59] Replies to questions 44 to 47 of questionnaire Q2 to customers in Italy and questions 26 to 29 of questionnaire Q1 to competitors.

[60] Sandoz (Novartis)'s non-confidential reply to question 28 of questionnaire Q1 to competitors.

[61] See notably Form CO, Annex 20.

[62] Replies to questions 52 and 53 of questionnaire Q2 to customers in Italy and question 31 of questionnaire Q1 to competitors.

* Should read: "suppliers"

that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to the supply of lercanidipine in Italy.

Fixed combination lercanidipine and enalapril - Italy

(72) The molecular combination lercanidipine and enalapril (C9B – ACE inhibitors, combinations) is a combination hypertension therapy of lercanidipine (a calcium channel blocker) and enalapril (an ACE inhibitor).

(73) The overlap on the fixed combination lercanidipine and enalapril market in Italy is between Recordati's originator product (Zanipril) and DOC Generici's generic product (Enalapr/Lercan Doc).

(74) The Commission considers that concerning the market for lercanidipine and enalapril in Italy[63], the Transaction does not raise serious doubts as to its compatibility with the internal market for the following reasons.

(75) First, DOC Generici only began selling its generic version of this Recordati-originated product in 2018[64] and the increment brought by the Transaction is very limited (below 0.5% in both value and volume). The Parties' high combined market share on the lercanidipine market in Italy primarily reflects the strong market position of Recordati's originator product.

(76) Second, there are five other competitors offering this molecule combination. Two companies market originator products (with market shares of respectively [10-20]% and [10-20]% in value in 2017) and three sell a generic version (one with a market share of [5-10]% in value in 2017).[65]

(77) Third, Recordati's and DOC Generici's respective originator products and generic products are not close competitors. This is notably illustrated by the significant price differentials between Recordati's originator product, on the one hand, and the generics products, on the other hand (+[50-60%]).[66]

(78) Based on the above, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to the supply of lercanidipine and enalapril in Italy.

Rupatadine - Italy

(79) Rupatadine is a dual histamine H1 receptor. It is used as an anti-allergenic.

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63 The segmentation based on the galenic forms is not relevant on this market where there is only one galenic form.

64 See Form CO, footnote 31.

65 See the Notifying Party's reply to RFI 4, question 2.

66 See the Notifying Party's reply to RFI 4, question 2.

(80) The overlap on the rupatadine market in Italy is between Recordati's originator products (Rupafin) and DOC Generici's generic product (Rupatadina DOC).

(81) The Notifying Party submits that the increment arising from DOC Generici is minimal and the Transaction does not materially change the competitive landscape.

(82) The Commission considers that concerning the market for rupatadine in Italy and its potential sub-segments[67], the Transaction does not raise serious doubts as to it compatibility with the internal market for the following reasons.

(83) First, the overlap is limited. The increment brought by DOC Generici on the rupatadine market in 2017 is [0-5]% in value and [0-5]% in volume. The Parties' substantial combined market share ([40-50]%) primarily reflects the market position of Recordati's originator product.

(84) Second, the Parties face several credible competitors, including the market leader, Mylan, which offers on the rupatadine market both originator products (Pafinur) and generic products (Rupatina Myl PH). Mylan's market share of [50-60]% in value and [50-60]% in volume in 2017 is higher than the combined share of the Parties. Moreover, following the recent expiry of patent protection and market exclusivity in 2017, besides DOC Generici, two other credible generic competitors entered the Italian rupatadine market, namely Teva and Stada. In fact, most customers multisource and have between 4 and 5 different suppliers. For the vast majority of them, switching suppliers is relatively easy.[68]

(85) Third, the market investigation indicated that the Parties are not close competitors, as DOC Generici's generic rupatadine competes more closely with the three other generics of the same medicine than with Recordati's originator rupatadine. Price and brand recognitions are considered as key parameters of competition by both customers and competitors and Recordati's originator product is differentiated from generics due to its established brand and a certain degree of customer loyalty. Conversely, no specific competitive advantage was identified for DOC Generici's generic rupatadine.[69] Also, price competition appears greater between generics than it is between generics and Recordati's originator rupatadine. As previously explained, under the national regulation, patients are reimbursed only up to the amount of the cheapest generic version. If they choose to buy the more expensive originators, they pay the price difference. Due to this feature, price competition on the rupatadine market takes place more intensely between the different generic suppliers, which will continue to exert competitive pressure on the merged entity.[70]

(86) Fourth, the market investigation suggests that, due to the difference in galenic form, the Parties are not close competitors at molecule level. There are two different galenic forms for rupatadine, i.e. class A (oral solid ordinary) and class D (oral liquid ordinary), and the Parties overlap only with respect to one galenic

[67] On this market, the Parties' activities overlap both at molecule and galenic form levels.

[68] Replies to questions 71, 81, and 83 of questionnaire Q2 to customers in Italy.

[69] Replies to questions 76 to 79 of questionnaire Q2 to customers in Italy and questions 44 to 47 of questionnaire Q1 to competitors.

[70] See Form CO, Annex 20.

form: DOC Generici's products fall within the NFC1 A class and the Target's products fall within classes A and D. The replies of the market participants show that substitutability between the […]* galenic forms may be somewhat limited.[71]

(87) Finally, the Commission notes that all informative respondents consider that the impact of the Transaction will be "*neutral*" on the rupatadine market in Italy regardless of the galenic form. In particular, half of the customers indicated that there will remain sufficient alternative sources of supply post-Transaction regardless of the galenic form. The customers that took the opposite view mostly complained about the lack of alternatives to Recordati in relation to galenic forms for which the Parties' activities do not overlap (NFC1 D class).[72]

(88) Based on the above considerations, in particular the fact that the overlap is marginal and that the Parties are not close competitors, the Commission considers that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to the supply of rupatadine in Italy irrespective of whether the market is subdivided by galenic form.

Metoprolol – Italy

(89) […]** is a cardioselective β1-adrenergic blocking agent. It is used for the treatment of acute myocardial infarction, heart failure, angina pectoris and mild to moderate hypertension.

(90) The overlap on the metoprolol market in Italy is between Recordati's originator product (Seloken) and DOC Generici's generic product (Metoprololo Doc). Seloken is an originator product that Recordati sources from AstraZeneca. Seloken was first put on the market in Italy in 1978, but Recordati acquired the rights to sell it in 2017.[73] DOC Generici's metoprolol product is a generic product and was launched in 2003.

(91) The Notifying Party submits that the combined market share in value and in volume is not particularly high and barely surpasses the Group 1 threshold of 35%. The Notifying Party also notes that the merged entity will continue to face strong competition from numerous generic distributors.

(92) The Commission considers that concerning the market for metoprolol in Italy and its potential sub-segments[74], the Transaction does not raise serious doubts as to its compatibility with the internal market for the following reasons.

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[71] Replies to question 74 of questionnaire Q2 to customers in Italy and question 42 of questionnaire Q1 to competitors.

[72] Replies to questions 84 and 85 of questionnaire Q2 to customers in Italy and question 49 of questionnaire Q1 to competitors.

[73] Recordati acquired the rights to sell AstraZeneca's metoprolol in Italy but also in other of EEA countries, including Iceland and Romania, where the Transaction gives rise to affected markets.

[74] On this market, the Parties' activities overlap both at molecule and galenic form levels.

* Should read: "two"

** Should read: "Metoprolol"

(93) First, the overlap in the Italian metoprolol market is moderate. Recordati is the second largest player, with a market share of [30-40]% by value and [20-30]% by volume (in 2017), while DOC Generici is one of the several generic companies, with a moderate market share of [5-10]% and [10-20]% by value and in volume respectively. Post-Transaction, the new entity would have a combined market share of around [30-40]% in value and volume.

(94) Second, the market for metoprolol in Italy is largely genericised, with several suppliers, and perceived as competitive by most market participants.[75] The market evolution shows that several generic companies have entered the market since the originator products lost market exclusivity. Currently, besides the Parties, there are five competing generic products and one originator product (namely Daiichi Sankyo's Lopresor). Thus, even though the Transaction may result in the loss of one generic competitor, the merged entity will still be facing active originator and generic competition. In particular, post-Transaction, Daiichi Sankyo, which is perceived by market participants as the top supplier thanks notably to its well-known brand,[76] would remain the market leader in terms of value (with a [30-40]% market share in 2017). The Parties will also face two other players, *i.e.* Novartis, and Stada, with market shares higher than DOC Generici (above [10-20]% both in value and volume).

(95) Moreover, the market investigation tested whether a sufficient number of alternative suppliers exists and how easy and quickly customers can switch suppliers. All responding customers indicated that they purchase metoprolol from several suppliers.[77] Most customers also pointed out that the number of alternative supplies would remain sufficient post-Transaction regardless of the galenic form.[78]

(96) Third, the market investigation indicated that the Parties are not close competitors, as DOC Generici's generic metoprolol competes more closely with the other generics of the same medicine than with Recordati's originator Seloken. In particular, price and brand recognition are considered as key parameters of competition by most respondents and Recordati's originator product is differentiated from generics due to its established brand and a certain degree of customer loyalty.[79] The market investigation did not point out other differences between the originator and the generic product over and above brand recognition and price[80]. A customer indicated that the choice of metoprolol products is between the generics and originator products[81] and that the difference between originator and generics is that the latter's price list is lower.[82] Also, price competition appears greater between generics than it is between generics and originator products. As previously explained in relation to other markets, under

[75] Replies to question 34 questionnaire Q1 – Competitor and Replies to question 59 of questionnaire Q2 – Customers - Italy.

[76] Replies to question 36 questionnaire Q1 – Competitors.

[77] Replies to question 65 of questionnaire Q2 – Customers - Italy

[78] Replies to question 68 of questionnaire Q2 – Customers - Italy.

[79] Replies to question 37 questionnaire Q1 – Competitors.

[80] Replies to question 37 questionnaire Q1 – Competitors.

[81] Replies to question 63 of questionnaire Q2 – Customers - Italy.

[82] Replies to question 59.1 of questionnaire Q2 – Customers - Italy

the national regulation, only the lowest price among the prices of off-patent medicinal products is reimbursed and if patients choose to buy more expensive originator products, they must pay the price difference. Due to this feature, price competition on the Italian metoprolol market takes place more intensely between the different generic suppliers, which are numerous and will continue to exert competitive pressure on the merged entity.

(97) Fourth, the market investigation suggests that, due to the difference in galenic form, the Parties are not close competitors at molecule level. There are three different galenic forms for metoprolol: class A (oral solid ordinary), […]* B (oral solid long acting), and class F (parenteral ordinary). In Italy, the Parties' activities overlap only with respect to one of them: DOC Generici's products fall within the NFC1 A class and Recordati's products fall within classes A, B and F. The replies to the market investigation are not conclusive to the extent to which different galenic forms are substitutable[83]. Regarding the parenteral metoprolol, it is unlikely that the merged entity will have any incentive to suspend or delay its supply to customers in Italy for the sake of potentially maximising the profits of the other forms, which are already facing significant competition.

(98) Finally, the Commission notes that all informative respondents consider that the impact of the Transaction will be "*neutral*" on the metoprolol market in Italy regardless of the galenic form.[84]

(99) Based on the above considerations, in particular the fact that the overlap is moderated and that the Parties are not close competitors, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to the supply of metoprolol in Italy irrespective of whether the market is subdivided by galenic form.

Metoprolol – Iceland

(100) In Iceland the Transaction will combine an originator product to be marketed by Recordati (Seloken) and Alvogen's generic metoprolol products (Metoprolol Succinate Teva and Metoprolol Tartrate Teva).

(101) Earlier in 2018, Alvogen began distributing Teva's generic metoprolol-based products in Iceland, which was previously distributed by Medical Limited (a Lyfis subsidiary) on behalf of Ratiopharm (a Teva subsidiary). This followed Alvogen's acquisition of a portfolio of products from Teva as a consequence of divestment commitments in case M.7746 - *Teva/Allergan Generics*[85]. The acquisition agreement included provision for transfer of the marketing authorisation for metoprolol in Iceland from Ratiopharm to Alvogen.

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[83] Replies to question 58 of questionnaire Q2 – Customers - Italy.

[84] Replies to question 69 of questionnaire Q2 – Customers – Italy and question 40 of questionnaire Q1 - Competitors.

[85] Case M.7746 — Teva/Allergan Generics

* Should read: “class”

(102) As regards Recordati, it acquired the rights to sell AstraZeneca's metoprolol-based products in Iceland in 2017. […]

(103) The Parties claim that in Iceland there is currently no overlap, as Recordati's sales will begin in […]. Nevertheless, based on the historical sales figures achieved by the previous distributor of AstraZeneca's and Teva's metoprolol in Iceland, the Parties' combined market share is between [60-70]% (in volume) and [70-80]% (in value) in 2017.

(104) The Commission considers that, concerning the metoprolol market in Iceland and its potential sub-segments[86], the Transaction does not raise serious doubts as to its compatibility with the internal market for the following reasons.

(105) First, despite the small size of the metoprolol market in Iceland (EUR […] in 2017), the Parties face several generic competitors active, namely Artasan Ehf ([10-20]% in value and [20-30]% in volume), followed by Lyfis Ehf ([5-10]% in value and [5-10]% in volume) and Icepharma Hf ([0-5]% in value and [0-5]% in volume). Pharmacies consider that the number of alternative metoprolol suppliers would be sufficient post-Transaction.[87] Moreover, according to most responding pharmacies, it is easy to switch suppliers of metoprolol.[88] It was notably pointed out that suppliers provide a next-day-delivery on workdays making it easy and not long to switch.[89]

(106) Second, the market investigation showed that the Parties are not close competitors, as Alvogen's generic metoprolol competes more closely with multiple other generics of the same medicine than with the Recordati's originator Seloken. This is corroborated by several elements.

(107) In the first place, the market investigation indicated that Recordati's originator product is differentiated from generics due to its established brand and a certain degree of customer loyalty. The respondents pointed out brand recognition as a particular advantage of the originator product in comparison with generic products. This is in line with the Notifying Party's claims that consumers easily switch between generics but are more reluctant to switch away from the originator drug. A customer indicated that many people choose the original brand-name product over the generic version only because they dislike generic medicines.[90]

(108) In the second place, as shown in Table 2 above, the Parties' combined market share has significantly decreased over the past three years (-[10-20]% in value and -[20-30]% in volume in 2017 compared to 2015). This is mainly due to the declining market shares of Alvogen's generic product (-[10-20]% in value and -[20-30]% in volume over the 2015-2017 period) to the benefit of several generic competitors. For example, in the last three years the Parties' largest competitor Artasan Ehf more than doubled its market presence (+[10-20]% in value and +[10-20]% in volume in 2017 compared to 2015). At the same time, the previous

86 On this market, the Parties' activities overlap both at molecule and galenic form levels.

87 Replies to question 21 and 21.1 of questionnaire Q3 – Customers – Iceland.

88 Replies to question 20 of questionnaire Q3 – Customers – Iceland.

89 A reply to question 20.1 of questionnaire Q3 – Customers – Iceland

90 A reply to question 21.1 of questionnaire Q3 – Customers – Iceland.

distributor of AstraZeneca's originator product retained a market share in the range [40-50]% in value and [30-40]% in volume, without attracting market shares from the account of Alvogen's generic products. This evolution shows that generic products primarily compete with each other and there is little competitive interaction between generic products on the one hand and the originator drug Seloken on the other.

(109) This is also illustrated by KRKA Slovenia's recent entry to the Icelandic metoprolol market. In July 2017, KRKA Slovenia began selling Bloxazoc (its generic metoprolol product) through a local distributor, Lyfis. KRKA Slovenia was a successful entrant, reaching a market share of [5-10]% in 2017 and [10-20]% in 2018 (year to August). Bloxazoc gained volumes from competing generic suppliers (including Alvogen's predecessor), rather than attracting sales from Seloken. Whenever Bloxazoc's share increased, other generic products' shares of supply decreased. Correspondingly, whenever Bloxazoc's share of supply decreased, other generic products' share of supply increased. In contrast, Seloken's share remained relatively stable during the period, suggesting it was not affected by generic developments.

(110) In the third place, the significant price differentials between the originator product, on the one hand, and the generics products, on the other hand, provide additional evidence of the fact that the Parties' respective metoprolol products do not compete closely in Iceland. In fact, in Iceland, the price difference between the originator Seloken and the generic drugs, which varies depending on the strengths/formulations of the products sold, can be very significant (see Table 3 below).

Table 3 – Illustrations of price differences between originator and generic metoprolol in Iceland

Reference price code	Package	Seloken's average price (2017)	Price difference compared to the most expensive generic product
V0054	200 mg - extended-release tablets	[…]	**+[20-40]%**
V0050	25 mg - extended-release tablets	[…]	**+[80-100]%**
V0049	100 mg - extended-release tablets	[…]	**+[30-50]%**
V0048	50 mg - extended-release tablets	[…]	**+[40-60]%**

Source: RBB analysis of IDM data. Prices refer to weighted average annual prices per unit.

(111) Finally, the Commission found that Recordati's originator products are already priced at the maximum permissible level under the Icelandic regulatory regime. At national level, the maximum prices of metoprolol-based products are determined by the Icelandic Medicine Pricing and Reimbursement Committee on a monthly basis. The committee's monthly medicinal product list includes reimbursements, wholesale prices and retail prices. Pharmacies are required by law to ask customers if they want a cheaper alternative if the medicine prescribed by the doctor is not the cheapest available.[91] It follows that the Transaction is unlikely to give rise to price increases. This is endorsed by market participants, which do not expect price changes post-Transaction.[92] For instance, a respondent

[91] A reply to question 13 of questionnaire Q3 – Customers – Iceland.

[92] A reply to question 22.1 of questionnaire Q3 – Customers – Iceland.

stated that "*the price will not lower because both products are very strong and they will probably not increase because of competition (for metoprolol succinat Teva) and because of governmental price roof (Seloken Zoc)*".[93]

(112) Based on the above considerations, , the Commission concludes that the Transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to the supply of metoprolol in Iceland irrespective of whether the market is subdivided by galenic form.

Metoprolol – Romania

(113) The overlap on the metoprolol market in Romania is between an originator product (Betaloc and Betaloc ZOK), supplied by Recordati, and Alvogen's generic product (Alvogen LPH). Recordati acquired the rights to sell Betaloc and Betaloc ZOK (AstraZeneca's metoprolol-based products) in 2017. Recordati has already started supplying metoprolol in Romania but […].

(114) With respect to the supply of metoprolol in Romania, the Notifying Party points out that some interchangeable use of metoprolol and bisoprolol has been noted in the literature and claims that the merged entity will be constrained by competing molecules, even if they do not belong to the same relevant product market. However, considering that neither the Notifying Party nor the market investigation produced conclusive evidence that the metoprolol and bisoprolol were not only potential therapeutic substitutes, but were actual, economic substitutes, the Commission cannot exclude that the competitive constraints are limited to metoprolol products. Therefore, the subsequent assessment takes into account the candidate market for medicines with metoprolol as the active ingredient.

(115) The Notifying Party also claims that despite the combined market shares of the Parties (respectively [70-80]% in value and [60-70]% in volume in 2017), the Transaction is unlikely to have a material impact on competition because the merged entity would combine an originator drug with a generic drug, with the remaining generic suppliers being a source of competitive pressure on the market.

(116) The Commission considers that concerning the market for metoprolol in Romania,[94] the Transaction does not raise serious doubts as to its compatibility with the internal market for the following reasons.

(117) First, the market for metoprolol in Romania is highly competitive. The Commission notes that the Romanian metoprolol market, which decreased in value from EUR […] million in 2015 to EUR […] million in 2017, is largely genericised. The market investigation indicated that metoprolol is an old molecule and there are multiple generic companies on the market.[95] In this regard, the Transaction leads to a merger of one of the originator suppliers with one of the

[93] A reply to question 21.1 of questionnaire Q3 – Customers – Iceland.

[94] At galenic form level, the Parties' activities do not overlap on this market.

[95] A reply to question 68 of questionnaire Q1 – Competitors.

many generic companies. Post-Transaction, 10 competitors will supply metoprolol-based products, one of which (Servier) offers another originator product. The three larger competitors have market shares in value respectively of [10-20]%, [5-10]% and [5-10]%. The largest of these, Sun Pharma commands a higher market share in value ([10-20]%) than Alvogen. Seven additional smaller competitors will also remain active on the market. The market investigation showed that they exert sufficient competitive pressure on the Parties and most customers consider that the number of alternatives suppliers would remain sufficient post-Transaction.[96]

(118) Furthermore, the Commission notes that the new entity will also face competitive constraints from potential competitors that could enter the market within a short time frame. This applies in particular to Slavia, a generic provider, which has a marketing authorization for metoprolol in Romania and could therefore enter the market segment at any time. The Parties also submit that a number of firms that either (i) have supplied metoprolol in Romania in the past (such as Arena Group, Fabiol, Incdcf, Laropharm, Medico Uno, and Teva) or (ii) are selling metoprolol in neighbouring geographic markets (Bulgaria, Croatia, Czech Republic, Hungary, Poland, Slovakia, Slovenia) (such as Dipharm, Biofarm, Bioton Group, Cefarm.Lab) are likely to have the relevant expertise to (re-)enter the Romanian metoprolol market within a short timeframe.

(119) Customers rated the market conditions for the supply of metoprolol in Romania as competitive.[97] In their view many and significant players are present on the market, which "insures price competition for the molecule".[98] A customer states that "*the prices are really low and there are a lot of suppliers and discounts to make a product more desirable that the one produced by the competition*".[99] Competitors described the metoprolol market as "*a crowded market*",[100] particularly in relation to the oral solid ordinary form.

(120) Pharmacies multisource metoprolol from several suppliers.[101] The typical duration of the contracts is one year, with a possibility for extension.[102] showing that they can be changed fairly quickly. The fact that pharmacies can negotiate discounts[103] demonstrates that they can exert pressure on the suppliers and further intensify competition.

(121) Second, the Parties's respective metoprolol products are not close substitutes.

(122) In the first place, the market investigation suggests that, due to the difference in galenic form, the Parties' products are not close therapeutic substitutes. Alvogen's products fall within the NFC1 A class (oral solid ordinary) and the Recordati's products fall within classes B (oral solid long acting) and F (parenteral ordinary).

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96 Replies to question 20 of questionnaire Q4 to customers in Romania.

97 Replies to question 11 of questionnaire Q4 – Customers – Romania.

98 Replies to question 11.1 of questionnaire Q4 – Customers – Romania.

99 Replies to question 11.1 of questionnaire Q4 – Customers – Romania.

100 A reply q 65.1 Q1

101 Replies to q 7 Q4 – Customers - Romania

102 Replies to question 8 of questionnaire Q4 – Customers – Romania.

103 Replies to question 9.1 of questionnaire Q4 – Customers – Romania.

In other words, the Parties' galenic forms do not overlap. Though not conclusive, the replies of the market participants show that substitutability between the different galenic forms may be somewhat limited. On the one hand, some pharmacists explained that the ordinary and the long-acting forms can be considered similar products, as they are prescribed alternatively for the same diagnosis[104], and there is a large base of patients who have long-term treatment.[105] On the other hand, the choice of galenic form is made by the physicians, after which the pharmacists cannot automatically substitute it with another form but must dispense the prescribed pharmaceutical form.[106] Furthermore, due […]* an entirely different mode of administration, the parenteral form of metoprolol is an even more remote substitute, suitable only for very specific patient populations.

(123) In the second place, the respondents pointed out brand recognition as a particular advantage of the originator product in comparison with generic products.[107]

(124) In the third place, although customers are price sensitive, there appears to be more limited price competition between Recordati's originator product and other metoprolol products, whether generic or originator (Servier). Both suppliers and customers affirmed that Romanian customers are very sensitive to prices and that price is therefore one of the main factors for customers' choice of metoprolol suppliers.[108] High price competition is driven by generic penetration due to a high number of generic companies.[109] These observations appear to be particularly relevant for competitive dynamics between generic metoprolol (including Servier's originator product), but do not explain the fact that Recordati's originator metoprolol enjoys a considerable price premium over other metoprolol products[110] while maintaining a significant market share.

(125) Limited price pressure on Recordati can be explained by brand recognition, as well as the limited therapeutic differentiation (not all generics, including Alvogen, supply the long acting galenic form). According to the pharmacies responding to the investigation, customers' choice is to a larger extend determined by branding[111], as certain patients specifically ask for a certain product or brand.[112]

(126) Finally, the Commission found that Recordati's originator products (Betaloc) are already priced at the maximum permissible level under the national regulatory regime. Pursuant to Romania's pharmaceutical regulatory pricing regime, there are three different reference prices set for each given product – the manufacturer's price, wholesale price and retail price. General practice for originators is to price at the maximum permissible level for all three prices. Betaloc, the Target's originator product in Romania, is already priced at the maximum retail price

[104] A reply to question 10 of questionnaire Q4 – Customers – Romania.
[105] A reply to question 10 of questionnaire Q4 – Customers – Romania.
[106] Replies to question 11 of questionnaire Q4 – Customers – Romania.
[107] Replies q 69 Q1 and Replies to question 14 of questionnaire Q4 – Customers – Romania.
[108] A reply to question 66 of questionnaire Q1 – Competitors.
[109] A reply to question 8 of questionnaire Q1 – Competitors.
[110] In Romania generic providers can set prices only up to 35% below the price of the originator drug.
[111] A reply to question 14 of questionnaire Q4 – Customers – Romania.
[112] A reply to question 10 of questionnaire Q4 – Customers – Romania.

* Should read: "to"

permitted under Romanian regulation. It follows that the Transaction is unlikely to give rise to price increases: Recordati's originator is already at the maximum level, while Alvogen's generic products face a high price competition from other generics.

(127) Based on the above considerations, the Commission concludes that the Transaction does not give rise to serious doubts as to its compatibility with the internal market in relation to the supply of metoprolol in Romania.

4.2.1.3. Pipeline generic pharmaceuticals

(128) In accordance with the past practice[113], the Commission identified the marketed-to-product overlaps between the Parties' marketed and pipeline products, as presented in Table 4 below

Table 4 – Pipeline-to-marketed affected markets

Molecule	Marketed Product				Party developing the pipeline
	Party marketing it	Market share[114]	EEA Member State with market shares > 35%	Total market size (2017) (€'000s)	
[…]	Recordati	[80-90]%	Italy	[…]	DOC Generici
[…]	Recordati	[90-100]%	Czech Republic	[…]	DOC Generici
			Estonia	[…]	
			Greece	[…]	
			Ireland	[…]	
			Latvia	[…]	
			Lithuania	[…]	
			Poland	[…]	
			Romania	[…]	
			Slovakia	[…]	
		[90-100]%	Germany	[…]	
		[60-70]%	France	[…]	
		[70-80]%	Italy	[…]	
		[50-60]%	Portugal	[…]	
		[40-50]%	Spain	[…]	

[…]

(129) […].

(130) As regards […], Italy is the only EEA Member State where Target's market share is above 35%: Recordati's market shares in Italy in 2017 for […] were [80-90]% both in value and in volume.[115]

[113] See e.g. M.7559 – *Pfizer/Hospira*, M.6258 – *Teva/Cephalon* and M.6613 – *Watson/Actavis*.

[114] Market shares in value and volumes do not differ.

(131) The Notifying Party claims that should the merged entity not enter the […] market with generics, it would not be able to have a market offering for those customers that consider switching to lower priced generics. In other words, the merged entity would forego attracting part of the demand by not entering the market, thus decreasing its profitability.

(132) The Notifying Party indicated that it intends to commercialise its generic product once the regulatory procedure is completed.

(133) The market investigation showed that several other […]-based products are currently undergoing authorisation procedures, which has been confirmed by the Agenza Italiana del Farmaco. Consequently, once on the market these products will exert competitive pressure on the merged entity's originator product even if the merged entity were to discontinue or delay the development of its generic product in an attempt to preserve its marketed originator product sales.

(134) Thus, in the light of the above, the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to the development of […]-based generic pharmaceuticals in the EEA.

[…]

(135) […]

(136) In relation to […], Recordati holds [90-100]% of the market in Czech Republic, Estonia, Greece, Ireland, Latvia, Lithuania, Poland, Romania and Slovakia. In Germany, France, Italy, Portugal and Spain the Target's share of sales is above 35%.

(137) In relation to […], and similarly to […], the Notifying Party claims that should the merged entity not enter the […] market with generics, it would not be able to have a market offering for those customers that consider switching to lower priced generics. In other words, the merged entity would forego attracting part of the demand by not entering the market, thus decreasing its profitability. The Notifying Party also indicated that it intends to commercialise its generic product once the regulatory procedure is completed.

(138) The […] market at both the EEA and in a number of Member States is not yet genericised as Recordati's product is still patent protected in many member States. Generic products are, however, under development. The Notifying Party indicated and the Commission notes that it has submitted a marketing authorisation application for a generic version of its originator […] product under the centralised procedure. Furthermore, as is generally observed in the pharmaceutical industry towards the expiry of patent and market exclusivity, the market investigation showed that several companies are developing […]-based products.[116] Consequently, once on the market these products will exert competitive pressure on the merged entity's originator product even if the merged

[115] Apart from Italy, the other EEA Member State where the Recordati is active with […] is Portugal, where its 2017 share of sales in value was [0-5]% ([0-5]% in volume).

[116] See replies to question 74.2 of questionnaire Q1 to competitors.

entity were to discontinue or delay the development of its generic product in an attempt to preserve its marketed originator product sales.

(139) Thus, in the light of the above, the Transaction does not raise serious doubts as to its compatibility with the internal market with respect to development of the […]-based generic pharmaceuticals in the EEA.

4.2.2. Vertical links

(140) The Transaction creates some potential vertical links between Recordati's activities on the market for finished dose pharmaceutical products (upstream markets) and the provision of hospital services by CVC Fund Portfolio Companies (downstream markets). Potential vertical links between the Parties were considered in each geographic market where Recordati and relevant CVC Funds' Portfolio Companies are active. Vertically affected markets arise in France and in Greece.

France (Elsan and Recordati)

(141) Downstream, the market share of Elsan, a CVC Fund Portfolio Company active in the French private hospitals market, does not exceed 30% under any plausible market definition.[117]

(142) Upstream, Recordati sells a number of products to French hospitals and holds a monopoly for the supply of methadone, phosphoneuros, citrafleet, recholan, logimax, otofa, adiazine, nordaz, urispas, basdene, abufene, and hexaspray. For four other products – urorec, seloken, polydexa and ery, Recordati's market shares in France are above 30%.

(143) The Notifying Party explained that the monopoly position is due to historical reasons – either no other competitor has decided to develop and market a competing product based on the same molecule or competitors have decided it was not commercially interesting to maintain these products in the market. There are, however, no intellectual property constraints which would prevent an interested third party from procuring Active Pharmaceutical Ingredients (APIs) and manufacturing and selling originator or generic products based on the molecules, subject to obtaining the required marketing authorisations and other permits.

(144) Further, the Commission notes that Recordati currently does not supply any of the molecules referred to in recital […]* to Elsan and will not have any incentive to provide its products on an exclusive basis only to Elsan for the future, as it is hardly thinkable that the merged entity would be able to divert patients to a specific hospital chain by refusing supply of medicines to other hospitals. It would therefore run against the merged entity's commercial interests to attempt refusing supplies to Elsan's competitors. In addition, except for methadone (2017 sales of EUR […]), Recordati's sales to hospital are negligible (well below EUR

[117] See the Notifying Party's reply to RFI3 question 7.b.

* Should read: "(142)"

0.5 million per molecule). Based on these considerations, the Commission considers it unlikely that the Parties will have ability to implement foreclosure strategies in respect of the molecules.

Greece (Metropolitan and Recordati)

(145) Downstream, Metropolitan's market share slightly exceeds 30% only in one plausible market, *i.e.* the Greek private general hospital market ([30-40]%).[118] Upstream, even though Recordati generates some sales to the hospital network in Greece, its market shares do not exceed 30% under any plausible product market definition. Taking into account also that Metropolitan's purchases from the Target are negligible, the Commission considers that the Transaction does not give rise to risks of input or customer foreclosure.

Conclusion

(146) Based on the foregoing considerations of the vertical links, the Commission considers that the Transaction does not raise serious doubts as to its compatibility with the internal market and the EEA Agreement.

5. CONCLUSION

(147) For the above reasons, the Commission has decided not to oppose the notified operation and to declare it compatible with the internal market and with the functioning of the EEA Agreement. This decision is adopted in application of Article 6(1)(b) of the Merger Regulation and Article 57 of the EEA Agreement.

For the Commission

(Signed)
Margrethe VESTAGER
Member of the Commission

[118] See the Notifying Party's reply to RFI3 question 7.b. Metropolitan's market share estimates include the Hygiea Group, which is currently in the process of being acquired by Metropolitan.