EUROPEAN COMMISSION
DG Competition

Case M.8675 - CVC / TEVA'S WOMEN'S HEALTH BUSINESS

Only the English text is available and authentic.

REGULATION (EC) No 139/2004
MERGER PROCEDURE

Article 6(1)(b) NON-OPPOSITION
Date: 20/12/2017

In electronic form on the EUR-Lex website under document number 32017M8675

EUROPEAN COMMISSION

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 Where possible the information omitted has been replaced by ranges of figures or a general description.

Brussels, 20.12.2017
C(2017) 9103 final

PUBLIC VERSION

To the notifying party:

Subject: **Case M.8675 – CVC / TEVA'S WOMEN'S HEALTH BUSINESS**
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 16 November 2017, the Commission received notification of a proposed concentration pursuant to Article 4 of Council Regulation (EC) 139/2004 involving the acquisition of sole control of Teva's International Women's Health Business worldwide, excluding the US, ("Target Business") by CVC Capital Partners SICAV-FIS S.A. (together with its subsidiaries and affiliates, "CVC Group") within the meaning of Article 3(1)(b) of Council Regulation (EC) No 139/2004 by way of purchase of assets[3]. The CVC Group and the Target Business are collectively referred to as "the Parties".

1. THE PARTIES

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

– The CVC Group manages and provides advice to investment funds and platforms. CVC is not directly active in markets related to the activities of the Target Business.

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 396, 23.11.2017, p. 17.

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However, the following CVC Funds' Portfolio Companies are active in horizontally related markets[4]:

- Alvogen is a global, privately owned pharmaceutical company whose product portfolio consists of a broad range of molecules 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.

– The Target Business is active in the marketing and wholesale of women's health pharmaceutical products related to fertility, contraception, menopause and osteoporosis. The Target Business includes equipment, goodwill, permits and regulatory registrations, intellectual property assets, employee contracts, business contracts, benefit plans, domain names, specific websites and inventory that relate to Teva's international (i.e. ex US) women's health product portfolio.

2. THE OPERATION

(3) On 17 September 2017, the Parties entered into an asset purchase agreement according to which Teva agreed to sell the Target Business other than the French part. Regarding the French part it is subject to a separate irrevocable offer which is binding on the Parties and thus constitutes part of the Transaction.

(4) Therefore, the Transaction involves the acquisition of sole control of Teva's International Women's Health 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 worldwide turnover of more than EUR 2,500 million[5]; in each of at least three Member States (France, Italy and Spain), the combined aggregate turnover of all the undertakings concerned is more than EUR 100 million; in each of the above three Member States the aggregate turnover of each of the two undertakings concerned is more than EUR 25 million; the aggregate Community-wide turnover of each of at the two undertakings concerned is more than EUR 100 million, and none of the Parties achieves more than two-thirds of its Community-wide turnover within one and the same Member State.

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4 With regard to potential vertical links, one of CVC Funds' Portfolio Companies, Elsan, is a private hospital operator in France. Elsan is, however, not a meaningful actual or potential customer in any of the markets in which the Target Business is active, [having spent a de-minimis amount on Target Business products]in [period]. Also, the Target Business is not significantly active in the hospital segment in France (annual sales of <EUR [0-5]m and a share well below [0-5]%). Hence, any links between Elsan and the Target business are immaterial for the present case and are not analysed

5 Turnover calculated in accordance with Article 5 of the Merger Regulation.

(6) The notified operation therefore has an EU dimension by virtue of Article 1(3) of the Merger Regulation.

4. COMPETITIVE ASSESSMENT

4.1. Identification of affected markets

(7) As a preliminary remark, it is recalled that for cases in the pharmaceutical sector, the Commission has applied a system of filters aimed at determining the group of markets where concerns are most likely and on which its focused its analysis.[6]

(8) 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).

(9) Thus, applying this methodology, the present Transaction gives rise to 8 affected markets (see Table 1 and section 4.3): 4 in Italy, 2 in Lithuania, 1 in Croatia and 1 in Romania.

Table 1 - Affected Markets

Member State	**Affected market for:**	**Group Classification**		
		Group 1 markets	**Group 2 markets**	**Group 3 markets**
Croatia	Bone Calcium Regulators			1
Italy	Risedronic Acid	2		
Italy	Drospirenone, Ethinylestradiol			2
Lithuania	Bone Calcium Regulators		1	
Lithuania	Bisphosphonates for osteoporosis and related disorders		1	
Romania	Bisphosphonates for osteoporosis and related disorders			1

6 See M.7746 - Teva / Allergan Generics; M.7645 - Mylan/ Perrigo; M.7379 – Mylan/Abbott EPD-DM

4.2. Market definition of the affected markets

4.2.1. General approach to product market definition for pharmaceutical products

ATC classification

(10) In previous decisions[7] 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)[8]. 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.

(11) 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.

(12) In previous decisions, the Commission has referred to the ATC3 level as the starting point for defining the relevant product market. In a number of cases, however, the Commission found that the ATC3 level classification did not provide the appropriate market definition within the meaning of the Commission Notice on Definition of the Relevant Market[9]. Thus, where appropriate and based on the factual evidence collected during the market investigation, the Commission defined the relevant product market at the level of the molecule[10].

Originator pharmaceuticals and generic pharmaceuticals

(13) As regards genericised products[11], the Commission has taken the view that the molecule level (or possibly group of molecules considered interchangeable) is the most plausible starting point for the product market definition, given that generic pharmaceutical companies typically produce copies of originator drugs [12] and thus it can be considered that a generic molecule is the closest substitute to the originator

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

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

9 OJ C 372, 9.12.1997, p. 5.

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

11 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 quality and purity and is biologically equivalent to the originator drug. See M.5253 – Sanofi-Aventis/Zentiva.

12 See for example 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.

medicinal product based on the same molecule or API[13]. As set out in the Commission's horizontal merger guidelines[14], the higher the degree of substitutability between the merging firms' products, the more likely it is that the merging firms will raise prices significantly[15].

(14) A potential distinction between generic and proprietary medicines was considered by the Commission. For example, in a previous case[16] the Commission made a distinction between originator and generic medicinal products stating that there is a separate market for the wholesale of generic medicines as compared to the wholesale of proprietary medicines[17]. In other cases[18], however, 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 proprietary medicine.

Other distinctions

(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, 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.

4.2.2. Product market definition in the present case

(16) The affected markets in the present case are identified based on the molecule level as well as at ATC3 and ATC4 level.

(17) Given the characteristics of the products involved in the present case (mature genericised medicinal products), the Commission takes the molecule level as the most plausible starting point for the product market definition. Where there is no overlap at molecule level, the Commission takes the ATC3 or ATC4 level as a starting point reference to assess therapeutic and economic substitutability across molecules. In the present case the exact ATC level and the question whether ATC3 need to be further segmented to ATC4 can be left open as the Transaction does not raise doubts as to its compatibility with the internal market irrespective of the precise market definition.

(18) Regarding a potential distinction between originator and generic products during the market investigation in the present case the respondents did not point out specificities other than brand recognition and price that differentiate the originator

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

14 Horizontal Merger Guidelines, para 28

15 See M.5253 – Sanofi-Aventis/Zentiva

16 See M. 7746 - Teva/Allergan Generics

17 A distinction of a wholesale market is not relevant for the present case.

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

products from the generic products[19]. In this regard, even if brand loyalty to the originator medicine may play a role in limiting switching in certain instances, competition takes place between originator and generic providers[20]. Therefore, for the purposes of the competitive assessment of the Transaction, the Commission considers that in relation to the overlapping molecules the product market includes both generic and originator versions in relation to the overlapping molecules.

(19) Also, a segmentation by pharmaceutical form in the present case is not necessary as in the affected markets the molecules are only sold in one NFC1 and therefore the NFC1 overlap is not in addition to the overlap at the molecule level.

4.2.3. Geographic market definition

(20) As regards the geographic market definition, the Notifying Party has submitted an overview of the overlapping activities on a country-by country basis. The Commission has consistently held that the market for finished pharmaceutical products[21] is national in scope[22]. 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 system; and (v) because competition between pharmaceutical companies generally takes place at national level[23].

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

4.3. Competitive assessment

General approach to the competitive assessment

(22) In the present case, a number of affected markets were identified as a result of the Transaction based on the ATC3 level and, where the ATC3 category is further subdivided, on the ATC4 level, as well as on the molecule level.

(23) According to data provided by the Parties for the years 2014, 2015 and 2016, the Transaction gives rise to the following affected markets:

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19 Replies to question 8 of questionnaire Q1 – Competitors and replies to question 6 of questionnaire Q2 – Customers.

20 See for example M.5865 - TEVA/ RATIOPHARM

21 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). All products in the present case concern finished dose pharmaceuticals.

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

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

Table 2 Levels of overlaps and market shares on the affected markets

Member State	Level of overlap	Overlap Market	Year	CVC[25]	Target	Combined[26]	Group classification and year[24]
Croatia	ATC3	M5B[27] by volume	2014	[0-5]	[20-30]	[20-30]	Group 3 (2014[28])
			2015	[0-5]	[10-20]	[10-20]	
			2016	[0-5]	[10-20]	[10-20]	
Italy	Molecule	Drospirenone, Ethinylestradiol – (G3A[29]) by volume	2014	[5-10]	[10-20]	[20-30]	Group 3 (2016)
			2015	[5-10]	[10-20]	[20-30]	
			2016	[5-10]	[10-20]	[20-30]	
Italy	Molecule NFC1	Drospirenone, Ethinylestradiol (NFC1 A) (G3A) *		See note *	See note *	See note *	Group 3 (2016)
Italy	Molecule	Risedronic Acid[30] – (M5B) by value	2014	[0-5]	[60-70]	[60-70]	Group 1 (2016)
			2015	[0-5]	[50-60]	[60-70]	
			2016	[0-5]	[50-60]	[50-60]	
		Risedronic Acid – (M5B) by volume	2014	[0-5]	[50-60]	[50-60]	Group 1 (2016)
			2015	[0-5]	[40-50]	[40-50]	
			2016	[0-5]	[30-40]	[40-50]	
Italy	Molecule NFC1	Risedronic Acid (NFC1 A) (M5B) *		See note *	See note *	See note *	Group 1 (2016)
Lithuania	ATC3	M5B by volume	2014	-	[30-40]	[30-40]	Group 2 (2016)
			2015	<[0-5]	[30-40]	[30-40]	
			2016	<[0-5]	[40-50]	[40-50]	
Lithuania	ATC4	M5B3[31] by volume	2014	-	[50-60]	[50-60]	Group 2 (2016)
			2015	<[0-5]	[50-60]	[50-60]	
			2016	[0-5]	[50-60]	[50-60]	
Romania	ATC4	M5B3 by value	2014	[0-5]	[5-10]	[10-20]	Group 3 (2016)
			2015	[0-5]	[10-20]	[10-20]	
			2016	<[0-5]	[20-30]	[20-30]	

Source: Form CO submitted on 16 November 2017.
*Note: * these molecule are only sold in one NFC1, and therefore the NFC1 overlap is not in addition to the overlap at the molecule level.*

[24] Note that if a product market falls under Group 1 definition in 2014, Group 2 definition in 2015 and Group 3 definition in 2016, it is identified overall to fall under Group 1 with the Group Classification year being 2014.

[25] CVC stands in Table1 for CVC Funds' Portfolio Companies

[26] Due to rounding, some totals in the tables may not correspond with the sum of the separate figures.

[27] M5B is an ATC 3 class which relates to Bone Calcium Regulators. See recital (27)

[28] The market was not affected in 2015 and 2016.

[29] A combination at molecular level of estrogen (ethinyl estradiol) and a progestin (drospirenone) used to prevent pregnancy, treat premenstrual dysphoric disorder or moderate acne.

[30] The ATC3 class to which the molecule Risedronic Acid belongs is M5B and it is indicated in brackets.

[31] M5B3 is an ATC4 class which relates to bisphosphonates for osteoporosis and related disorders. See recital (45)

(24) Regarding the Group 3 markets, the Parties have provided information according to which there are many competitors remaining in the market. Moreover, most of these competitors have market shares above the increment brought by the transaction.

(25) Therefore, in line with previous Commission practice, the remainder of the Decision deals with the markets that fall within Group 1 and 2 – the market for Risedronic Acid (M5B) in Italy, M5B Bone Calcium Regulators in Lithuania and M5B3 Bisphosphonates for osteoporosis and related disorders in Lithuania.

Risedronic Acid (M5B) – Italy

(26) In Italy the proposed transaction results in an affected market (Group 1, 2016) at molecule level[32] – i.e. Risedronic Acid (M5B)[33].

(27) M5B concerns Bone Calcium Regulators. Risedronic acid is a bisphosphonate used to strengthen bone, treat or prevent osteoporosis, and treat Paget's disease of bone at molecular level. Osteoporosis is a skeletal disorder characterized by low bone mass and deterioration of bone tissue, with a consequent increase in bone fragility and susceptibility to fracture[34]. Paget's disease is a disease involving bone destruction and re-growth that causes deformity[35].

(28) The overlap on the Risedronic Acid market in Italy is between Teva's Risedronic Acid products (brand names Actonel and Optinate) and DOC Generici's Risedronic Acid product (brand name Risedronato Doc).

(29) Teva's Risedronic Acid products Actonel and Optinate were acquired in the context of the 2016 Teva/Allergan transaction[36]. They are originator products but they are no longer patent protected and their market exclusivity expired in 2011. DOC Generici's Risedronic Acid product Risedronato Doc is a generic product and was launched in 2011.

(30) The market shares of the Parties and their main competitors are presented in the Table 3 below.

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32 M5B was considered in previous Commission cases. In M. 5253 Sanofi-Aventis / Zentiva the Commission took the view that in that case it would be inappropriate to define the relevant market at the molecule level, it finally left it open. In M.5555 – Novartis/Ebewe the product market definition was left open after considering segmentation at ATC3 level M5B, ATC4 class M5B4, molecule level or ATC4 combined.

33 The molecule is sold under a single NFC1. Therefore, for the purposes of the present case no separate assessment is necessary as the NFCI overlap is not in addition to the overlap at the molecule level.

34 EMA guideline on the evaluation of new medicinal products in the Treatment of primary osteoporosis, http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003406.pdf

35 CHMP Pharmacovigilance Working Party monthly report on safety concerns, guidelines and general matters, July 2012, http://www.ema.europa.eu/docs/en_GB/document_library/Report/2012/07/WC500130391.pdf

36 M.7746 – Teva/Allergan Generics. As part of that transaction, Teva committed to divest its own generic Risedronic Acid product to generic company Intas. The product is currently held separate from Teva, and the transfer to Intas is imminent.

Table 3 – The Parties' and main competitors' market shares of sales of Risedronic Acid (in value and in volume)[37]

Company	2014 Share of Sales (in value)	2015 Share of Sales (in value)	2016 Share of Sales (in value)	2014 Share of Sales (in volume)	2015 Share of Sales (in volume)	2016 Share of Sales (in volume)
CVC Funds' Portfolio Companies	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Target Business	[60-70]%	[50-60]%	[50-60]%	[50-60]%	[40-50]%	[30-40]%
Combined	**[60-70]%**	**[60-70]%**	**[50-60]%**	**[50-60]%**	**[40-50]%**	**[40-50]%**
Fenix Pharma	[10-20]%	[10-20]%	[10-20]%	[10-20]%	[10-20]%	[10-20]%
Formerly Teva (see footnote 36)	[5-10]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%	[10-20]%
Prospa	[0-5]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%
Novartis	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[5-10]%
Mylan	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[5-10]%
Stada	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Caber	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Ems	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Genetic	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%

(31) The Notifying Party submits that the increment due to Doc Generici is very limited (around [0-5]% in value and in volume) and thus the proposed transaction does not materially change the competitive landscape.

(32) In relation to the market shares of the Parties and their competitors, the Notifying Party also notes that the target Business' presence has been significantly and steadily decreasing over the last years, going from [60-70]% in 2014 to [50-60]% in 2016 in value, and from [50-60]% in 2014 to [30-40]% in 2016 in volume. Furthermore, the Notifying Party points out that throughout this period other competitors have increased their position and the merged entity will be facing active and increasing generic competition from more than 15 companies, among which more than five already have a market share above 5% in volume against three in 2014.

(33) Also, according to the Notifying Party, the way the Target Business and Doc Generici compete between them is identical to the way they each compete with any other supplier of Risedronic Acid.

(34) The Commission notes that the Transaction will lead to a merger of the market player with the largest market share [50-60]% by value and [30-40]% in 2016 by volume and one of the many generic companies on the Italian market for Risedronic Acid with a market share of [0-5]% and [0-5]% by value and in volume respectively, resulting to a combined market share of [50-60]% and [40-50]% in value and in volume respectively.

[37] Data is provided by the Parties in the Form CO.

(35) The market evolution shows that numerous generic products entered the market in 2011 when the Teva owned products Actonel and Optinate lost market exclusivity. Currently, the market for Risedronic Acid products in Italy is largely genericised with around 15 companies offering Risedronic Acid products. Teva's share, though still high, has been substantially decreasing in the last several years. Thus, even though the Transaction may result in the loss of one of the generic competitors to the originator product, the merged entity will still be facing active generic competition, among which six companies currently have a higher market share than the increment brought by the transaction (Doc Generici), both in terms of volume and of value. Indeed, the increment due to DOC Generici is limited to around [0-5]% in value and volume.

(36) The market investigation also tested the closeness of the competition between the Parties. The market participants did not point out particular advantages of the originator products in comparison with generic products[38]. Also, according to them there is no differentiation among generic products and they are all the same[39]. The closest competitors of DOC Generici are the other generic suppliers, while Teva's products, as demonstrated by the market investigation, are differentiated by all of the generic products, in terms of brand recognition[40] and price.

(37) Regarding the prices, generic companies like DOC Generici sell their products at a price below the originator's one. According to the information provided by the Notifying Party the prices of reimbursed generics like Risedronic Acid are regulated in Italy by the Italian Medicines Agency (Agenzia Italiana del Farmaco) and are the result of mandatory price cuts from the price of the originator product. Conversely, the price of the originator product is not regulated. Thus, as submitted by the Notifying Party, all generic suppliers sell their products at the same (regulated) price, while the originator's product is not regulated and its price remains significantly higher than any generic competitor. The market investigation did not show other reasons apart from brand loyalty and doctors' preferences[41] which justify the ability to maintain this higher price by Teva (the originator) in comparison with the generic products, including DOC Generici's[42].

(38) The market investigation also tested whether even though the market is genericised, market entry could be hindered by any significant barriers as well as whether there is a sufficient number of alternative suppliers and how easy and quickly it is for the customers to switch suppliers. The respondents did not point out any such barriers to entry[43]. Furthermore, the customers considered that the number of alternative supplies is sufficient[44]. Customers did not raise concerns for changing suppliers for Risedronic Acid and stated it is easy to change between them. As regards the duration of the contracts, customers mentioned that in most of the cases they last for

38 Replies to question 8 of questionnaire Q1 – Competitors.

39 Replies to question 7 of questionnaire Q2 - Customers.

40 Replies to question 6 of questionnaire Q2 – Customers.

41 Replies to question 6 of questionnaire Q2 – Customers.

42 As pointed out in recital (14) above, for the purposes of the present case the price differentiation does not justify further subsegmentaion of the market into market for originator and for generic products.

43 Replies to question 3 of questionnaire Q1 – Competitors.

44 Replies to question 4 of questionnaire Q2 – Customers.

one year, thus showing that in a relative short period of time customers could have the possibility of switching their suppliers.

(39) Based of the above, the Commission concludes that the Proposed Transaction does not materially change the competitive landscape (also because the Parties are not close competitors) and consequently does not raise serious doubts as to its compatibility with the internal market in relation to Risedronic Acid (M5B) market in Italy.

(40) In addition to the marketed products, giving rise to the overlap and the affected market at Risedronic Acid, Teva has developed a gastroresistent formulation of Risedronic Acid (Actonel GR) which has been authorised through the decentralised procedure in Italy but is not yet marketed. This gastroresitent formulation aims to relieve the patients from the burden of fasting 30 minutes […]* taking their pill, even though it is taken once per week only.

(41) The market investigation did not indicate that this gastroresistent formulation has other benefits in addition to the convenience of non-fasting and/or targets a different patient population, which differentiate it from the currently marketed Risedronic Acid products in Italy. In any case, irrespective of whether the Teva's Actonel GR and the DOC Generici's Risedronic are substitutable and competing with each other, it is unlikely that the merged entity will have any incentive to suspend or delay the marketing of the already authorised Actonel GR, which will be an originator product not facing generic competition, for the sake of potentially maximising the profits of DOC Generici's Risedronic Acid, which is a generic product already facing strong competition and occupying a market share of only around [0-5] %.

(42) It can therefore be concluded that the Transaction does not raise serious doubts, regarding this gastroresistent formulation of Risedronic Acid in Italy.

M5B Bone Calcium Regulators[45] *- Lithuania*

(43) With respect to Lithuania there is one Group 2 (2016) affected market at ATC3 level only if the shares are considered according to the sales in volume. No affected market arises if the market shares according to the value of the sales are taken into consideration.

(44) The affected market at MB5 results from the overlap between Teva and Alvogen activities. The market shares of the Parties and their main competitors on the M5B market are presented in Table 4 below.

Table 4 The Parties' and main competitors' share of sales of M5B (Rx) in Lithuania

* Should read: after.

45 As explained above, M5B class includes Bone Calcium Regulators. Bone Calcium Regulators are predominantly used to treat osteoporosis, which is a disease of bone that leads to an increased risk of fracture, but can also be used for other indications such as oncology.

Competitor	2014 Share of Sales (in value)	2015 Share of Sales (in value)	2016 Share of Sales (in value)	2014 Share of Sales (in volume)	2015 Share of Sales (in volume)	2016 Share of Sales (in volume)
CVC Funds' Portfolio Companies	-	-	<[0-5]%	-	<[0-5]%	<[0-5]%
Target Business	[5-10]%	[5-10]%	[5-10]%	[30-40]%	[30-40]%	[40-50]%
Combined	**[5-10]%**	**[5-10]%**	**[5-10]%**	**[30-40]%**	**[30-40]%**	**[40-50]%**
Servier	[5-10]%	[0-5]%	[0-5]%	[30-40]%	[20-30]%	[10-20]%
Sanofi	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[5-10]%	[5-10]%
Polpharma	[0-5]%	[0-5]%	[0-5]%	[5-10]%	[5-10]%	[5-10]%
Merck & Co	[0-5]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%
Adamed	[0-5]%	[0-5]%	[0-5]%	[5-10]%	[5-10]%	[5-10]%
Roche	[20-30]%	[10-20]%	[10-20]%	[5-10]%	[5-10]%	[0-5]%
Teva[46]	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Amgen	[20-30]%	[30-40]%	[40-50]%	[0-5]%	[0-5]%	[0-5]%
Gedeon Richter	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Chiesi	[0-5]%	[5-10]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Novartis	[10-20]%	[10-20]%	[5-10]%	[0-5]%	[0-5]%	[0-5]%
Medac	[0-5]%	[0-5]%	[0-5]%	<[0-5]%	[0-5]%	[0-5]%

M5B3 Bisphosphonates for osteoporosis and related disorders - Lithuania

(45) If the M5B market is further subdivided, the Proposed Transaction gives rise to one Group 2 (2016) affected market at ATC4 level with respect to M5B3. The ATC4 class M5B3 relates to bisphosphonates for osteoporosis and related disorders, including products indicated and used mainly for osteoporosis and Paget's disease. For example, those containing alendronic acid, etidronic acid, ibandronic acid, risedronic acid, zoledronic acid, when indicated for these conditions. Combinations of bisphosphonates with calcium, calcitriol or colecalciferol are also classified here.

(46) The market shares of the Parties and their main competitors on the M5B3 market are presented in Table 5 below.

46 Teva is active on the M5B market with the molecules Ibandronic Acid and Zoledronic Acid, which are not in the scope of the Transaction and are therefore not part of the Target Business.

Table 5 The Parties' and main competitors' share of sales of M5B3 (Rx) in Lithuania

Competitor	2014 Share of Sales (in value)	2015 Share of Sales (in value)	2016 Share of Sales (in value)	2014 Share of Sales (in volume)	2015 Share of Sales (in volume)	2016 Share of Sales (in volume)
CVC Funds' Portfolio Companies	-	-	[0-5]%	-	<[0-5]%	[0-5]%
Target Business	[5-10]%	[10-20]%	[10-20]%	[50-60]%	[50-60]%	[50-60]%
Combined	**[5-10] %**	**[10-20]%**	**[10-20]%**	**[50-60]%**	**[50-60]%**	**[50-60]%**
Sanofi	[0-5]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%	[5-10]%
Polpharma	[0-5]%	[0-5]%	[0-5]%	[5-10]%	[5-10]%	[5-10]%
Merck & Co	[5-10]%	[10-20]%	[10-20]%	[5-10]%	[5-10]%	[5-10]%
Adamed	[0-5]%	[0-5]%	[0-5]%	[5-10]%	[5-10]%	[5-10]%
Roche	[40-50]%	[30-40]%	[20-30]%	[5-10]%	[5-10]%	[5-10]%
Teva[47]	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Gedeon Richter	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Novartis	[20-30]%	[20-30]%	[20-30]%	[0-5]%	[0-5]%	[0-5]%

(47) The competitive assessment of the Proposed Transaction does not materially change under either segmentation, i.e. M5B or M5B3.

(48) The Parties submit that their combined market shares post-transaction would increase by [0-5]% in volume and in value and that the merged entity will continue to face competition from numerous companies.

(49) The Commission notes that at M5B and M5B3levels the data from the sales in the last three years shows that an affected market arises only if sales data are considered in volume (not in value) and only in 2015 and 2016 (and not in 2014). Both at ATC3 and ATC4 level, the Parties are not close competitors. Post-transaction the Parties' combined market share will increase by less than [0-5]% in volume and in value. Thus, the Transaction does not materially change the competitive landscape. Moreover, the market is product differentiated and is largely genericised. The Merged entity will continue to face competition from more than 10 companies at ATC3 and from 8 at ATC4, five of which have a market share in value and in volume near or above [5-10]%.

(50) Based on the above, Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market in relation to either M5B or M5B3 in Lithuania.

[47] Teva is active on the M5B3 market with the molecules Ibandronic Acid and Zoledronic Acid, which are not in the scope of the Transaction and are therefore not part of the Target Business.

5. CONCLUSION

(51) For the above reasons, the European Commission has decided not to oppose the notified operation and to declare it compatible with the internal market and with 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