EN

Case No COMP/M.6969 - VALEANT PHARMACEUTICALS INTERNATIONAL/ BAUSCH & LOMB HOLDINGS

Only the English text is available and authentic.

REGULATION (EC) No 139/2004
MERGER PROCEDURE

Article 6(1)(b) NON-OPPOSITION
Date: 05/08/2013

In electronic form on the EUR-Lex website under document number 32013M6969

Office for Publications of the European Union
L-2985 Luxembourg

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 Where possible the information omitted has been replaced by ranges of figures or a general description.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, 5.8.2013
C(2013) 5231 final

PUBLIC VERSION

MERGER PROCEDURE

Dear Sir/Madam,

Subject: **Case No COMP/M.6969 – Valeant Pharmaceuticals International/ Bausch & Lomb Holdings**
Commission decision pursuant to Article 6(1)(b) of Council Regulation No 139/2004[1]

(1) On 1 July 2013, the European Commission received notification of a proposed concentration pursuant to Article 4 of Council Regulation (EC) No 139/2004 by which the undertaking Valeant Pharmaceuticals International, Inc. ("Valeant", Canada), hereinafter "the Notifying Party", indirectly acquires sole control over the undertaking Bausch & Lomb Holdings Incorporated ("Bausch & Lomb", United States)[2], by way of purchase of shares ("the Transaction"). Valeant and Bausch & Lomb are collectively referred to as "the Parties".

1. THE PARTIES AND THE OPERATION

(2) Valeant is a publicly-held company established in Canada that develops, manufactures and markets a broad range of pharmaceutical products mainly in the areas of neurology, dermatology and branded generics.

(3) Bausch & Lomb is a global eye health company offering branded and generic ophthalmic pharmaceuticals, nutritional products, contact lenses and lens care solutions, as well as products used in cataract, vitreo-retinal, refractive and other ophthalmic surgical procedures.

(4) The Transaction concerns the acquisition of 100% of the share capital of Bausch & Lomb by Valeant. A special purpose vehicle indirectly owned by

---

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 Publication in the Official Journal of the European Union No C 196, 9.7.2013, p. 3.

Valeant will be merged with and into Bausch & Lomb. As a result Bausch & Lomb will become an indirect, wholly owned subsidiary of Valeant.

(5) The Transaction constitutes a concentration within the meaning of Article 3(1)(b) of the Merger Regulation.

2. EU DIMENSION

(6) The undertakings concerned have a combined aggregate world-wide turnover of more than EUR 5 000 million[3] (Valeant: EUR 2 854 million, Bausch & Lomb: EUR 2 364 million). Each of them has an EU-wide turnover in excess of EUR 250 million (Valeant: EUR […] million, Bausch & Lomb: EUR […] million) and they do not achieve more than two-thirds of their aggregate EU-wide turnover within one and the same Member State.

(7) The Transaction therefore has an EU dimension within the meaning of Article 1(2) of the Merger Regulation.

3. COMPETITIVE ASSESSMENT

3.1. Product market definition

(8) The Parties' activities overlap in the area of: (i) ophthalmic pharmaceuticals; (ii) consumer vision care products; and (iii) ophthalmic surgical products.

(9) The Transaction will also lead to vertical links in relation to the contract manufacturing of pharmaceuticals and consumer vision products. However, as Bausch & Lomb's share in the provision of contract manufacturing services is below 5% at both EEA and worldwide level, and in the absence of any concerns relating to contract manufacturing raised by respondents to the market investigation, these vertical links will not be further discussed in the present Decision.

Commission's approach to product market definition as regards ophthalmic pharmaceuticals and consumer vision care products

ATC classification

(10) In previous decisions concerning the pharmaceutical sector, the Commission has applied the ATC (Anatomical Therapeutic Chemical) classification devised for marketing purposes by EphMRA (European Pharmaceutical Marketing Association) as a basis for product market definition.[4] The EphMRA classification consists of four levels and is regularly updated. The third level, referred to as ATC3, allows medicines to be grouped in most cases according to their therapeutic indications, that is to say their intended use, and is generally taken as the starting point for market definition in the Commission's analysis of concentrations.

(11) The Commission has also considered that it may be appropriate to carry out analyses at other ATC levels, or across ATC classes, if specific circumstances

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

4 See Commission Decision of 9 August 2010 in Case COMP/M.5778, para 9.

indicate that ATC3 is not the most appropriate level for defining the relevant product market. ATC4 has been frequently considered as a possible alternative product market definition and leads to further subdivision of the product market with reference to therapeutic or more frequently pharmacological criteria such as molecule class.[5]

OTC versus prescribed products

(12) The Commission has in the past defined separate markets for prescribed/non-prescribed (over-the-counter or OTC) pharmaceuticals because medical indications (as well as side effects), the legal framework, marketing and distribution tend to differ between these categories.[6]

(13) On the basis of these precedents, the Commission adopts the same approach in this case. Moreover, as the Notifying Party points out, all pharmaceutical products affected by the Transaction are available on a prescription-only basis while all consumer vision products affected by the Transaction are sold OTC, so the distinction does not change the assessment of the affected markets.

Originator versus generic drugs

(14) The Commission has considered that originator drugs and their generic copies belong to the same relevant product market, as generics can effectively substitute originator drugs after patent expiry, especially if the regulatory system encourages switching. When assessing the competitive situation in a given product market, the Commission takes into account the fact that an originator drug is exposed to generic competition.[7]

(15) On the basis of these precedents, the Commission adopts the same approach in this case.

Galenic forms

(16) In previous decisions,[8] the Commission noted that medicines can also be differentiated by their "galenic form", namely dosage, pharmaceutical form and route of administration, which may limit their substitutability.

(17) In the case at hand, the Commission will take into consideration possible segmentations according to the galenic form, where relevant.

Pipeline products

(18) A complete assessment of the competitive situation also requires an examination of potential competition from pipeline products. In line with previous decisions, the

---

5 See Commission Decision of 27 May 2005 in Case COMP/M.3751, para 2; Commission Decision of 19 December 2008 in Case COMP/M.5295, para 18; Commission Decision of 4 December 2009 in Case COMP/M.5253, para 15; Commission Decision of 9 August 2010 in Case COMP/M.5778, para 10; Commission Decision of 3 August 2010 in Case COMP/M.5865, para 12.

6 Commission Decision of 27 May 2005 in Case COMP/ M.3751, para 13.

7 Commission Decision of 27 May 2005 in Case COMP/ M.3751, para 15.

8 Commission Decision of 4 December 2009 in Case COMP/M.5253, Commission Decision of 9 August 2010 in Case COMP/M.5778, para 16.

Commission considers that a pipeline product is at a sufficiently advanced stage of development to be considered as a possible competitive constraint when it reaches clinical trials (Phase III).[9]

3.1.1. Ophthalmic pharmaceuticals

(19) Both Parties are active in the field of ophthalmological anti-infective and anti-inflammatory products and miotics and anti-glaucoma preparations. Ophthalmological anti-infective and anti-inflammatory products are split into four ATC3 classes: (1) ophthalmological anti-infectives (ATC3 class S1A); (2) ophthalmological corticosteroids (ATC3 class S1B); (3) ophthalmological anti-inflammatory and anti-infective combinations containing corticosteroids (ATC3 class S1C); and (4) ophthalmological non-steroidal anti-inflammatories (ATC3 class S1R). Miotics and anti-glaucoma preparations belong to ATC3 class S1E.

(20) Valeant sells *Neomycinum* (ATC3 class S1A), *Cortineff* (ATC3 class S1B) and *Oxycort A* (ATC3 class S1C), whilst Bausch & Lomb sells *Floxal* (ATC3 class S1A), *Lotemax* (ATC3 class S1B) and *Dexamytrex* (ATC3 class S1C). As regards ATC3 class S1R only Bausch & Lomb sells *Indocollyre*, a product belonging to this class. In miotics and anti-glaucoma preparations (ATC3 class S1E), Valeant sells *Luxfer*, *Oftidor*, *Timlatan* and *Latalux* and Bausch & Lomb sells *Arutimol*, *Carteolol*, *Pilocarpine* and *Clonidyne*.

(21) In addition, Bausch & Lomb sells *Vividrin*, *Berberil* and *Muro-128*, three products belonging to ATC3 class S1G ocular anti-allergics, decongestants and antiseptics. Valeant does not sell any product belonging to class S1G.

(22) In previous decisions, the Commission indicated that for ophthalmological anti-infectives (S1A) and ophthalmological corticosteroids (S1B), the appropriate level of market definition is ATC3.[10] According to the EphMRA classification, classes S1A and S1B are not further subdivided at ATC4. Nevertheless, the Commission has also considered in the past alternative market definitions for the following ATC combinations: S1B with S1C1 (ophthalmological anti-inflammatory and anti-infective combinations containing corticosteroids), S1A with S1C1[11] and S1B; S1B with S1G; and S1C with S1R, although ultimately the market definition was left open.[12]

(23) The Notifying Party argues that the market should be wider than ATC3 and that the distinction between the S1A and the S1B classes and between S1A on the one hand, and S1B and S1C on the other hand, is not justified. The S1A class comprises anti-infectives and the S1B and S1C1 classes comprise ophthalmological corticosteroids and anti-infective combinations. While eye infections are generally treated with anti-infectives, inflammations are generally treated with

---

9 Commission Decision of 3 August 2010 in Case COMP/M.5865, para 426.

10 Commission Decision of 9 August 2010 in Case COMP/M.5778.

11 According to Commission precedents (see Commission Decision of 9 August 2010 in Case COMP/M.5778) the S1C class was further subdivided into three ATC4 classes (S1C1, S1C2 and S1C9), depending on inflammatory ingredient, although ultimately the product market definition was left open.

12 Commission Decision of 9 August 2010 in Case COMP/M.5778.

corticosteroids. However, inflammation may be caused by an infection so there is a degree of substitutability between these three classes. The Notifying Party argues that at the very least, the relevant market should be defined as comprising the S1B and S1C1 classes, which both include anti-inflammatory corticosteroids. However, the Notifying Party has provided market shares on the basis of the narrowest ATC3 and ATC4 classifications as well as on various ATC3 / ATC4 permutations.

(24) The results of the market investigation in the present case are not conclusive as regards the definition of the relevant product market. Competitors confirmed that, from the supply side perspective, all of the above combinations are plausible, showing no clear support for a particular market definition.[13] From the demand side, customers' replies were even less conclusive.[14] As a consequence, for the purpose of the present decision, the Commission has analysed the impact of the Transaction under all possible market definitions mentioned in paragraph 22 above

(25) In addition, one respondent to the market investigation indicated that it might be appropriate to consider segmenting ophthalmic pharmaceuticals according to their galenic form. Such segmentation might be relevant in the case at hand only for products in ATC3 classes S1A and S1C, where various galenic forms can be found and the Parties have overlapping activities within the same galenic form.

(26) It appears, however, that such a distinction between ointments and eye drops relates mainly to the presentational form. As submitted by the Notifying Party, ointments and eye drops are substitutable products, administered in the same way and that the choice between the two forms is generally based on the physician's or patient's preference. Moreover, most pharmaceutical products in S1A and S1C classes in the Member State where the Parties' activities overlap to the greatest extent (Poland) are marketed both as ointments and as drops and they are competing with each other.

(27) Indeed, the market investigation confirmed that competitors provide various eye drops and ointments with the same therapeutic use as substitutable products[15] and that customers perceive ointments and eye drops to be within the same ATC class as competing substitutable products.[16] Therefore, in the case at hand, a segmentation of the ATC classes into narrower markets based on the galenic form is not justified.

---

13 Replies to question n° 7 to Questionnaire (Q2) - pharmaceutical products and consumer vision products – Competitors. 33% of respondents indicated each of the ATC 3 classes (S1A, S1B and S1C) to be a separate market. The other two definitions (classes S1B and S1C1 together and classes S1A, S1B and S1C1 together) were supported by 20% of respondents each and the remaining respondents suggested yet other combinations for defining the relevant market.

14 Replies to question n° 6 to Questionnaire (Q1) - pharmaceutical products and consumer vision products – Customers. 23% of respondents considered appropriate to look at each ATC3 class S1A, S1B, S1C separately, 15% expressed preference for a market definition comprising ATC3 class S1B and ATC4 class S1C1, 31% for market definition comprising ATC3 class S1B and S1G, 15% for market definition comprising ATC3 classes S1A, S1B and ATC4 class S1C1 and 15% for market definition comprising ATC3 classes S1C and S1R.

15 Replies to questions n° 18 and 19 to Questionnaire (Q2) - pharmaceutical products and consumer vision products – Competitors.

16 Replies to questions n° 17 and 18 to Questionnaire (Q1) - pharmaceutical products and consumer vision products – Consumers.

(28) In the present case, the exact product market definition can be left open as the Transaction does not give rise to serious doubts as to its compatibility with the internal market on any of the possible market segments.

3.1.2. Consumer vision care products

(29) Regarding vision care products, the Parties are active in: (i) ocular lubricants and artificial tears and ophthalmic preparations (ATC3 class S1K); and (ii) eye tonics and vitamins (ATC3 class S1M).

a) Ocular lubricants, artificial tears and ophthalmic preparations (S1K)

(30) Both Parties are active in the field of ocular lubricants, artificial tears and ophthalmic preparations. Ocular lubricants and artificial tears are ophthalmic preparations (solutions, gels or ointments) used for the symptomatic relief of eye dryness. They do not contain active pharmaceutical ingredients, thus the distinction between originator and generic products or the categorisation at ATC 4 level is not necessary.

(31) Valeant sells *Oftipan*, an OTC artificial tears product, and *Lacrisert,* a topical ophthalmic protectant and lubricant. Bausch & Lomb sells *Vidisic,* a synthetic polymer used to relieve dryness and irritation, *Artelac*, a hypromellose solution used to extend the lubricant time presence on the cornea, and *Vidisept,* a demulcent which forms a protective layer retaining moisture on the surface of the eye.

(32) In a previous decision[17] the Commission considered ATC3 class S1K (ocular lubricants and artificial tears) as the relevant product market and indicated that the differences between the products within this category do not justify the definition of narrower markets. The Notifying Party agrees with this market definition.

(33) The replies to the market investigation have confirmed that ATC3 class S1K should be regarded as the relevant product market. The results indicate that Valeant's product *Oftipan* and Bausch & Lomb's products *Visidic*, *Artelac* and *Visisept* have no special characteristics, as they have similar form and composition to other products in ATC3 class S1K.[18]

b) Eye tonics and eye vitamins (S1M)

(34) As regards eye tonics and eye vitamins, Valeant sells eye vitamin brands *Bioluteina*, *Bioluteina Total* and *Visilea* whilst Bausch & Lomb sells the *Ocuvite* eye vitamin brand. None of the Parties sells eye tonics.

(35) The Commission has considered in the past ATC3 class S1M as a relevant market without further segmentation, leaving open the question whether tonics and ocular vitamins are part of the same market.[19] The ATC3 class S1M concerns ocular vitamins and eye tonics which are qualified as food supplements or food for special

---

17 Case COMP/M.5778 *Novartis/Alcon*, para. 219.

18 Replies to questions n° 37, 38 and 39 to Questionnaire (Q2) - pharmaceutical products and consumer vision products - Competitors; and replies to questions n° 28, 29, 30 to questionnaire (Q1) - pharmaceutical products and consumer vision products - Customers.

19 Commission Decision of 9 August 2010 in Case COMP/M.5778, paras 221 and 275.

medical purposes depending on the relevant national legislation. According to the EphMRA classification, the S1M class is not further subdivided at ATC4 level.

(36) The Notifying Party agrees that ATC3 class S1M should be considered as the relevant product market.

(37) The market investigation largely confirmed that it would not be appropriate to divide the product market further according to specific vitamins and minerals as most of the products have identical or similar composition. The eye vitamins offered by Valeant and Bausch & Lomb have no special characteristics compared to other products in the S1M class and they are substitutable with other similar products on the market.[20]

(38) In the present case, the exact product market definition can be left open as the Transaction does not raise serious doubts as to its compatibility with the internal market under any possible market definition.

3.1.3. Ophthalmic surgical products

(39) According to the Notifying Party, the scope of ophthalmic surgical products can be best described by reference to the main forms of intraocular surgery, which include vitreo-retinal surgery, cataract surgery and refractive surgery.

(40) The Commission has to date not defined the market for ophthalmic surgical products.

(41) Valeant does not provide ophthalmic surgical products related to the above types of intraocular surgery. However, in April 2013, Valeant acquired certain assets relating to the medical devices and food supplements business of Croma-Pharma GmbH and the entire share capital of certain subsidiaries of Croma.[21] The Croma business acquired by Valeant sells ophthalmic surgical products in Bulgaria, Cyprus, the Czech Republic, Hungary, Latvia, Romania, Slovakia and Slovenia.[22] For the purposes of this Decision, those assets acquired by Valeant from Croma will be hereinafter collectively referred to as "Croma".

(42) As regards Bausch & Lomb, it sells ophthalmic surgical products predominantly in France, Germany, Italy, Spain and the United Kingdom.

(43) The Notifying Party claims that all ophthalmic surgical devices, solutions and instruments constitute a single product market, although it also submitted data related to five narrower market segments: ophthalmic medical devices, viscoelastic solutions, vitreo-retinal products, disposables and intraocular lenses.

(44) The Notifying Party argues that there is no generally accepted categorisation of ophthalmic surgical products (for example, a staining solution can be considered

---

20 Replies to questions n° 40, 41 and 42 to Questionnaire (Q2) - pharmaceutical products and consumer vision products – Poland- Competitors.

21 Croma-Pharma Polska Sp. zo.o. (Warsaw, Poland), and Croma Romania SR (Cluj-Napoca, Romania), Newco (Poland).

22 In other EEA countries, mainly in Western Europe, Croma-Pharma GmbH continues to exist as an autonomous entity.

either as a disposable or as a surgical device; balanced salt solutions may also either be qualified as disposables or vitreo-retinal products). Furthermore, according to the Notifying Party, there is substantial supply side substitutability, since suppliers sell various categories of products. Moreover, tenders and reimbursement procedures tend to extend to all products in a given procedure and are not generally limited or specific to individual products.

(45) In addition, the Notifying Party submits that in a typical vitreo-retinal or cataract surgery a surgeon uses various ophthalmic products, including surgical instruments, devices and disposables.

(46) The market investigation in this case was inconclusive as regards the exact product market definition. The majority of competitors supply only a few categories of surgical products.[23] Moreover, from the demand-side perspective the market investigation was inconclusive as regards purchasing patterns of the different products.[24]

(47) For the purposes of the present case, the exact product market definition can be left open, since the Transaction does not raise serious doubts as to its compatibility with the internal market under any of the possible product market definitions.

3.2. Geographic market definition

3.2.1. Ophthalmic pharmaceuticals

(48) In previous decisions,[25] the Commission considered that the relevant geographic market for finished dose pharmaceutical products was national in scope, *inter alia* on the basis of different national regulatory frameworks, authorisation procedures, and reimbursement systems. The Notifying Party agrees with this view and provided data on a national basis.

(49) The market investigation in this case has confirmed that this is still the case and that competition between pharmaceutical products generally takes place at national level.

(50) In the present case, the exact geographic market definition can be left open since the Transaction does not raise serious doubts as to its compatibility with the internal market with respect to ophthalmic pharmaceuticals under any of the possible geographic markets.

---

23 Replies to question n° 8 to Questionnaire (Q3) - Ophthalmic surgical products – EEA - Customers.

24 Replies to question n° 6 to Questionnaire (Q3) - Ophthalmic surgical products – EEA - Customers.

25 For pharmaceutical products see Commission Decision of 27 May 2005 in Case COMP/ M.3751, paras 4 and 5; Commission Decision of 19 December 2008 in Case COMP/M.5295, para 19; Commission Decision of 4 February 2009 in Case COMP/M.5253, paras 28-30. For consumer products, see, e.g., Commission Decision of 15 July 2005 in Case COMP/M.3732 *Procter&Gamble/Gilette*, para 17.

3.2.2. Consumer vision care products

(51) In previous decisions, the Commission considered that the relevant geographic market for consumer products was national.[26]

(52) The Notifying Party agrees with these findings and accordingly presented market shares on a national basis.

(53) The market investigation in this case confirmed that the market for S1K and S1M is likely to be national both from the supply and the demand perspective.[27]

(54) In the present case, the exact geographic market definition can be left open since the Transaction does not raise serious doubts as to its compatibility with the internal market under any of the possible geographic markets.

3.2.3. Ophthalmic surgical products

(55) The Notifying Party argues that the relevant geographic market is at least EEA-wide and possibly global in scope for the following main reasons: (i) the products concerned are generally marketed under the same brand name throughout the EEA; (ii) transport costs are relatively low; (iii) the marketing approval for all surgical products is subject to the same procedure in all Member States; (iv) purchases are made through EEA-wide tenders; and (v) there are no national regulatory barriers to entry.

(56) The Commission has not previously assessed relevant geographic markets for ophthalmic surgical products. Moreover, in previous decisions concerning surgical products, the Commission left open the question of whether markets for surgical products are national or EEA-wide.[28] By contrast, in a number of recent decisions regarding medical devices the Commission considered that medical devices markets are national mainly due to the fact that local presence plays an important factor and the existence of differences in the market structure from one country to another linked to reimbursement systems and purchasing patterns.[29]

(57) The results of the market investigation in this case were inconclusive as regards the precise geographic market definition. Competitors' replies to the market investigation suggest that from the supply-side, regulatory approvals required and marketing authorisation could be the same for the entire EEA.[30] By contrast, their replies as regards differences in prices and obligation to fulfil formalities with national health systems in order to be able to sell the product in a given Member

---

26 For pharmaceutical products see Commission Decision of 27 May 2005 in Case COMP/M.3751, paras 4 and 5; Commission Decision of 19 December 2008 in Case COMP/M.5295, para 19; Commission Decision of 4 February 2009 in Case COMP/M.5253, paras 28-30. For consumer products, see, e.g., Commission Decision of 15 July 2005 in Case COMP/M.3732, para 17.

27 Replies to questions n° 44 and 45 to Questionnaire (Q2) - pharmaceutical products and consumer vision products – Poland - Competitors; and replies to question n° 32 to Questionnaire (Q1) - pharmaceutical products and consumer vision products - Costumers.

28 Commission Decision of 27 March 2007 in case COMP/M.4579.

29 Commission Decision of 3 November 2011 in Case COMP/M.6266, Commission Decision of 22 April 2005 in Case COMP/M.3687.

30 Replies to question n° 13 to Questionnaire (Q4) - Ophthalmic surgical products – Competitors.

State were inconclusive.[31] All responding competitors also considered a local sales force mandatory in order to achieve a reasonable share of sales in a certain Member State.[32]

(58) From the demand side, while most customers purchase nationally, some customers buy ophthalmic surgical products from suppliers located in other countries than the one in which they are located[33], in some cases due to the fact that there is no local production available for their specific needs.[34] As regards the need to have a local presence, answers were split almost equally between customers who do require and customers who do not require a local presence of the supplier of the ophthalmic surgical products.[35]

(59) In light of the above, the effects of the Transaction will be analysed at both EEA and national level.

3.3. Competitive assessment

(60) In previous cases regarding pharmaceutical markets and medical devices,[36] the Commission has focused its investigation on markets where the Parties achieved a combined share of over 35% with an increment of over 1%. Such markets are referred to as "Group 1 markets". Furthermore the Commission distinguished between "Group 2 markets", where the Parties achieved a combined market share of over 35% and an increment below 1% and "Group 3 markets", in which the Parties achieved a combined market share below 35%. The same methodology has been followed in the present case.

(61) As regards ophthalmic pharmaceuticals, depending on the market definition retained, the Transaction may result in horizontally affected product markets in Poland, Lithuania and the Czech Republic. More precisely, in Poland, the Parties' activities overlap in the following ATC3 classes: S1A (ophthalmological anti-infectives), S1B (ophthalmological corticosteroids), S1C (ophthalmological anti-inflammatory and anti-infective combinations) and S1E (miotics and anti-glaucoma preparations). Outside Poland, the overlaps create affected markets in Czech Republic and in Lithuania, in both cases with relation to miotics and anti-glaucoma preparations (S1E class).

(62) More specifically, the Transaction gives rise to three possible Group 1 markets (in S1B, in S1B combined with S1C1 and in S1B combined with S1A and S1C1) and three Group 3 markets (in S1A, in S1C and in S1C combined with S1R) in Poland in the field of ophthalmic pharmaceuticals. Furthermore, the Transaction also gives rise to a Group 3 market in S1E in Lithuania. The table below presents the market

---

31 Replies to question n° 13 to Questionnaire (Q4) - Ophthalmic surgical products – Competitors.

32 Replies to question n° 15 to Questionnaire (Q4) - Ophthalmic surgical products – Competitors.

33 Replies to question n° 15 to Questionnaire (Q3) - Customers – Ophthalmic surgical products – EEA.

34 Replies to questions n° 13 and 14 to Questionnaire (Q3) - Customers – Ophthalmic surgical products – EEA.

35 Replies to question n° 12 to Questionnaire (Q3) - Customers – Ophthalmic surgical products – EEA.

36 Commission Decision of 19 December 2008 in Case COMP/M.5295; Commission Decision of 3 November 2011 in Case COMP/M.6266.

shares of the Parties in terms of value and volume in all the possible markets affected by the Transaction, based on 2012 data.[37]

Table 1. Affected markets in ophthalmic pharmaceutical products:

Country/ ATC3 class	Value			Volume		
	Valeant	B&L	Combined	Valeant	B&L	Combined
Lithuania						
S1E	[0-5]%	[0-5]%	[5-10]%	[5-10]%	[5-10]%	[10-20]%
Poland						
S1A	[10-20]%	[10-20]%	[30-40]%	[5-10]%	[10-20]%	10-20]%
S1B	[10-20]%	[40-50]%	[60-70]%	[10-20]%	[20-30]%	[40-50]%
S1C	[10-20]%	[10-20]%	[30-40]%	[5-10]%	[10-20]%	[10-20]%
S1B+S1C1	[10-20]%	[20-30]%	[40-50]%	[10-20]%	[10-20]%	[20-30]%
S1A+S1B+S1C1	[10-20]%	[20-30]%	[30-40]%	[5-10]%	[10-20]%	[20-30]%
S1C+S1R	[10-20]%	[10-20]%	[20-30]%	[0-5]%	[5-10]%	[10-20]%

Source: Form CO

(63) As to consumer vision care, although affected markets arise as regards ATC3 class S1M (ocular vitamins and eye tonics) in Poland and ATC3 class S1K (ocular lubricants, artificial tears and ophthalmic preparations) in both the Netherlands and in Poland, there are no Group 1 markets. The proposed transaction would lead to one Group 3 market in Poland: eye vitamins and tonics (ATC3 class S1M with a combined market share of [20-30]%) and one Group 2 market in the Netherlands with respect to ocular lubricants, artificial tears and ophthalmic preparations (combined market share of [40-50]% with an increment of less than [0-5]%).

(64) As regards ophthalmic surgical products, depending on the market definition retained, the Transaction may result in three possible Group 3 markets: viscoelastic solutions in Slovenia (with a combined market share of [10-20]% and an increment of [5-10]%), vitreo-retinal products in Bulgaria (with a combined market share of [10-20]% and an increment of less than [0-5]%) and intraocular lenses in Slovenia (a combined market share of [10-20]% and an increment of less than [0-5]%).

(65) In the present case, in all Group 2 and Group 3 markets other competitors will continue to be present and exert competitive pressure on the Parties including Polpharma, Novartis/Alcon, Allergan, Theva and Théa. Furthermore, none of the respondents to the market investigation raised any issues as regards the Group 2 or

37 The Parties also submitted data on market shares in accordance with the weight of active ingredient; this measurement, however, does not seem to properly reflect the relative position of competing products. In the past, the Commission has relied on sales values to assess the competitive structure and impact of a transaction unless specific circumstances indicated volume data to be particularly relevant, in particular in markets involving generic products (see Commission Decision of 9 August 2010 in Case COMP/M.5778, para 28).

3 markets. Furthermore, in previous cases,[38] the Commission concluded that Group 2 or Group 3 markets do not raise serious doubts as to the compatibility of a transaction with the internal market. In light of the above, serious doubts can also be excluded in the present case and these Group 2 and Group 3 markets will not be further discussed in this decision.

a) Plain corticosteroids and all corticosteroid combinations with the exception of corticosteroid/anti-infective combinations (S1B class)

(66) The Polish market of ophthalmological corticosteroids products belonging to ATC3 class S1B represented approximately EUR 2.28 million in 2012, which corresponds to around 3% of the Polish market for ophthalmological products.

(67) The Parties' combined market share in 2012 in this potential market amounted to [60-70]% with an increment of [10-20]% in terms of value. In terms of volume the combined market share of the Parties in 2012 was [40-50]% with an increment of [10-20]%.

(68) Although they reached a combined 2012 market share of [60-70]% in value and nearly [40-50]% in volume, the Notifying Party submits that the products offered by the Parties in this class are not close substitutes due to differences concerning therapeutic indication and effects.

(69) In previous decisions,[39] the Commission noted that it had generally relied on sales values to assess the competitive structure and impact of the transactions unless specific circumstances indicated volume data to be particularly relevant, as would be the case in markets involving generic products. In the case at hand, the Parties note that Poland's overall pharmaceutical industry is characterised by a high penetration of generic products (which account for 85% of volume and 66% of value of total pharmaceutical sales). Consequently, calculating market shares based on value has some limitations, especially when there are important price differences. According to the Notifying Party, the S1B class product offered by Bausch & Lomb (*Lotemax*) is 10 times more expensive than the S1B class product offered by Valeant (*Cortineff*). As value data may therefore overestimate the market position of Bausch & Lomb, the Commission has also taken into account volume data in this case.

(70) The table below shows the market shares of the Parties and their competitors in terms of value and volume for ATC class S1B.

38 Commission Decision of 26 April 2004 in Case COMP/M.3354; Commission Decision of 8 July 2005 in Case COMP/M.3751; Commission Decision of 11 November 2008 in Case COMP/M.5295; Commission Decision of 3 August 2010 in Case COMP/M.5865.

39 Commission Decision of 9 August 2010 in Case COMP/M.5778*;* Commission Decision of 4 February 2009 in Case COMP/M.5253.

(71) Table 2. Market shares of competitors on the Polish market in S1B class pharmaceuticals.

S1B class	Value	Volume
Valeant	[10-20]%	[10-20]%
Bausch & Lomb	[40-50]%	[20-30]%
Combined market	**[60-70]%**	**[40-50]%**
Polpharma	[10-20]%	[40-50]%
Novartis/Alcon	[5-10]%	[5-10]%
Théa	[5-10]%	[0-5]

Source: Form CO

(72) As shown in the table, at least three significant competitors able to exercise competitive pressure over the merged entity will remain present in the market post-merger. These are Polpharma (with a 2012 market share of 19.4% in value and 47.2% in volume), Novartis/Alcon (with a 2012 market share of 9.7% in value and 7.9% in volume) and Théa (with a 2012 market share of 7.9% in value and 1.6% in volume). Polpharma is the local incumbent in Poland and one of the largest Polish drug manufacturers. Novartis/Alcon is a global leader in eye care, ophthalmic pharmaceuticals and vision care products whilst Théa laboratories is an independent ophthalmologic group with a strong footprint in the Polish market. In addition, there are other smaller competitors active on the Polish market including Allergan, Inpharm and Delfarma, as well as a number of other marketing authorisation holders including Pabianickie Zakłady Farmaceutyczne Polfa, Warszawskie Zakłady Farmaceutyczne Polfa, Blau Farma and Tarchomińskie Zakłady Farmaceutyczne Polfa that could rapidly start marketing S1B class pharmaceuticals in Poland.

(73) The market investigation in this case has confirmed the differences between *Lotemax* and *Cortineff* with approximately half of the Parties' competitors and the majority of customers stating that they do not consider these two products to be substitutes.[40]

(74) Customers indicate that Polpharma's product in this category, *Dexamethason*, and Novartis/Alcon's products *Flarex* and *Flucon* are substitutes for Valeant's *Cortineff* and that these products are closer competitors to *Cortineff* than Bausch & Lomb's *Lotemax*. As for *Lotemax*, customers consider that *Cortineff* could be a substitute as well as other products available on the market, such as *Dexamethasone* and *Prednisolone* offered by Polpharma, *Flarex* offered by Novartis/Alcon and *Dexafree* by Théa. As regards competitors, their replies are in line with the customers' view that the Parties' products in ATC3 class S1B do not compete closely with each other.

(75) In light of the above, the Transaction does not raise serious doubts as to its compatibility with the internal market as regards a possible market encompassing the products grouped in ATC3 class S1B in Poland.

---

40 Replies to questions n° 14 to Questionnaire (Q2) - pharmaceutical products and consumer vision products – Poland - Competitors and replies to question n° 13 to Questionnaire (Q1) - pharmaceutical products and consumer vision products - Costumers.

b) Anti-inflammatory corticosteroids belonging to ATC3 classes S1B and S1C1

(76) In this hypothetical market comprising anti-inflammatory corticosteroids belonging to ATC3/ATC4 classes S1B and S1C1, the Parties' combined 2012 market share in value amounted to [40-50]% with an increment of [10-20]%. In terms of volume, the combined 2012 market share of the Parties amounted to [20-30]%, with an increment of [10-20]%. Post-merger, strong competitors will remain active, in particular Novartis/Alcon with a 2012 market share exceeding 40% both in terms of value and volume.

Table 3. Market shares of competitors on the Polish market in the combined S1B and S1C1 classes of pharmaceuticals.

S1B+S1C1	Value	Volume
Valeant	[10-20]%	[10-20]%
Bausch & Lomb	[20-30]%	[10-20]%
Combined market	**[40-50]%**	**[20-30]%**
Novartis	[40-50]%	[40-50]%
Polpharma	[5-10]%	[10-20]%
Inpharm	[0-5]%	[0-5]%

Source: CO Form

(77) On this basis, the Commission concludes that the proposed Transaction does not raise serious doubts as to its compatibility with the internal market with regard to the hypothetical market comprising products in ATC3 classes S1B and S1C in Poland.

c) Various ophthalmological anti-infective and anti-inflammatory products belonging to ATC3 classes S1A, S1B and S1C1

(78) In the hypothetical market comprising various ophthalmological anti-infective and anti-inflammatory products belonging to ATC3/ATC4 classes S1A, S1B and S1C1 the combined 2012 market share of the Parties in value was [30-40]%, with an increment of [10-20]%.

(79) In terms of volume, the Parties' combined 2012 market share was lower ([20-30]%). Strong competitors will remain present on the market post-merger, namely Novartis/Alcon (with a 2012 market share of [20-30]% in value and [20-30]% in volume), Polpharma (with a 2012 market share of [10-20]% in value and [30-40]% in volume) and Santen (with a 2012 market share of [5-10]% in value and [0-5]% in volume).

Table 4. Market shares of competitors on the Polish market in the combined S1A, S1B and S1C1 classes of pharmaceuticals.

S1A+S1B+S1C1	Value	Volume
Valeant	[10-20]%	[5-10]%
Bausch & Lomb	[20-30]%	[10-20]%
Combined market	**[30-40]%**	**[20-30]%**
Novartis	[20-30]%	[20-30]%
Polpharma	[10-20]%	[30-40]%
Santen	[5-10]%	[0-5]%

Source: CO Form

(80) Taking into account the relatively moderate combined market share of the merging Parties (i.e. just above the Group 2 ceiling for the combined 2012 market share in

terms of value and only [20-30]% in terms of volume), and because there will remain strong competitors present on this market, namely the global player Novartis/Alcon and the Polish incumbent Polpharma, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market with regard to the hypothetical market in Poland comprising the products included in ATC3/ATC4 classes S1A, S1B and S1C.

d) Pipeline products

(81) Taking into account the pipeline products of the Parties currently in phase III of clinical trials, the Transaction will result in an overlap with relation to miotics and anti-glaucoma preparations (S1E class) between a pipeline product of Valeant and the existing products of the Parties in ATC3 class S1E in the following countries: Bulgaria, the Czech Republic, Hungary, Latvia, Lithuania, Poland, Romania and Slovakia.

(82) In all these countries, the combined 2012 market shares of the Parties were low (not exceeding [10-20]%, except for Lithuania and the Czech Republic where the 2012 market shares in volume were [10-20]% and [10-20]% respectively). Furthermore, the Notifying Party estimates that the sales potential in the first years of sale of the new product will not exceed [0-5]% of the total value of the market in any of these countries.

(83) In view of the above and since the market investigation in this case did not reveal any concerns with regard to the combination of the existing products of the Parties with their pipeline products, serious doubts as to the compatibility of the Transaction with the internal market with regards to pipeline products may be excluded.

4. CONCLUSION

(84) 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.

For the Commission
(signed)
Günther OETTINGER
Member of the Commission