EUROPEAN COMMISSION

DG Competition

Case M.7746 - TEVA / ALLERGAN GENERICS

Only the English text is available and authentic.

REGULATION (EC) No 139/2004

MERGER PROCEDURE

Decision on the implementation of remedies - Art. 6(1)(b) in conjunction with 6(2) - Purchaser approval

Date: 17.10.2017

EUROPEAN COMMISSION

Brussels, 17.10.2017
C(2017) 7092

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 Where possible the information omitted has been replaced by ranges of figures or a general description.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.7746 – TEVA/ALLERGAN GENERICS**
Approval of Alvogen as purchaser of the Central Eastern Europe Divestment Business following your letter of 31 January 2017, complemented on 10 October 2017, and the Trustee's opinion of 10 October 2017

Dear Sir/Madam,

I. FACTS AND PROCEDURE

1. By decision of 10 March 2016 ("the Decision") based on Article 6(1)(b) in connection with Article 6(2), the European Commission (the "Commission") declared the operation by which Teva Pharmaceuticals Industries Limited ("Teva") acquired control over the global generic pharmaceuticals business of Allergan plc ("Allergan Generics") compatible with the internal market following modifications by Teva, subject to conditions and obligations (the "Commitments").

2. In particular, the Commitments provide that Teva commits to divest either Teva or Allergan Generics' generic products listed in Schedule A, together with, for each of those products, the assets listed in Schedule G-I ("*Other Countries On-Market Overlaps Divestment Businesses*"). The Other Countries On-Market Overlaps Divestment Businesses also include any pipeline products that the Divesting Party may have for the relevant molecule in the relevant country together with, for each of those pipeline products, the assets listed in Schedule G-II(1).

3. Teva also committed to divest for all products listed in Schedule B-I either (i) the on-market product of one of either Allergan Generics or Teva, together with the assets listed in Schedule G-I or (ii) the pipeline product of either Allergan Generics or Teva in the relevant country together with the assets listed in Schedule G-II(1) (collectively the "*On-market-to-Pipeline Divestment Businesses*") and for all

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products listed in Schedule B-II either (i) the on-market product of either Allergan Generics Business or Teva, together with the assets listed in Schedule G-I or (ii) the pipeline product of one of either Allergan Generics Business or Teva in the relevant country, together with the assets listed in Schedule G-II(1) (collectively the "*National Pipeline-to-Pipeline Divestment Businesses*").

4. Finally, for all the molecules listed in Schedule C-I (together "*the Non-Aurobindo Products*"), Teva committed to divest either (i) the outlicensing business conducted by either Medis[1] or Teva for the relevant product, together with the assets listed in Schedule G-III (the "*Upstream Outlicensing Divestment Businesses*"), or (ii) the on-market business of either Teva or Allergan Generics Business in the relevant country together with the assets listed in Schedule G-I (the "*Downstream Outlicensing Divestment Businesses*") (collectively the "*Outlicensing Divestment Businesses*").

5. During the sale process, Teva defined six baskets of products to be sold to one or several purchasers based mainly on geographic criteria. The basket for Central Eastern Europe (Basket 3) contains mainly products sold in Bulgaria, Czech Republic, Croatia, Hungary, Poland, Romania and Slovakia.[2] The table below presents the molecules included in the Central Eastern Europe Divestment Business (the "Divested Products" for the purposes of this decision).

Country	**Molecule**	**Schedule of the Commitments**
Bulgaria	Alendronic Acid	Schedule A
	Azithromycin	Schedule C-I
	Betahistine	Schedule A
	Carbamazepine	Schedule A
	Carboplatin	Schedule A
	Gliclazide	Schedule A
	Levofloxacin	Schedule A
	Tizanidine HCL	Schedule A
	Valsartan	Schedule A / Schedule C-I
	Hydrochlorothiazide, Valsartan	Schedule A/ Schedule C-I
	Verapamil	Schedule A
	Zoledronic Acid	Schedule A
Czech Republic[3]	Alendronic Acid	Schedule A
	Docetaxel	Schedule A
	[…]	Schedule B-I
Croatia[4]	Docetaxel	[…] Schedule C-I

1 Founded in 1985, Medis is Teva's subsidiary. Medis is specialised in high quality generic pharmaceuticals and has a customer base in more than 140 countries.

2 The Central and Eastern Europe Divestment Business also includes molecules in other countries; this is the case when the molecules concerned are marketed in more than one region and Central and Eastern Europe is the region where it had the highest sales.

3 The Commitments also include the following marketed molecule for Czech Republic, which is part of another basket that will be sold to another purchaser: Fosinopril (Basket 4 Western Europe).

4 The Commitments also include the following marketed molecules for Croatia, which are part of other baskets that will be sold to other purchasers: Repaglinide (Basket Rivopharm), Risedronic Acid (Basket 5 Risedronic Acid and EEA Pipelines).

	Methotrexate	Schedule B-I
Cyprus	[…]	Schedule B-II
	[…]	Schedule B-II
Greece	[…]	Schedule B-II
	Granisetron	Schedule A
	[…]	Schedule B-II
	[…]	Schedule B-I
	[…]	Schedule B-II
	[…]	Schedule B-II
Hungary[5]	Atorvastatin	Schedule A
	Bisoprolol	Schedule A
	Carboplatin	Schedule A
	Docetaxel	Schedule A
	[…]	Schedule B-I
	Isotretinoin	Schedule A
	Lansoprazole	Schedule A
	Mirtazapine	Schedule C-I
	Oxaliplatin	Schedule A
	Paracetamol/Phenylephrine	Schedule B-II
	[…]	Schedule B-II
	[…]	Schedule B-I
	Tramadol	Schedule A
	Vancomycin	Schedule A
Latvia	Docetaxel	Schedule A
	Doxorubicin	Schedule A
	Oxaliplatin	Schedule A
	Topotecan	Schedule A
Lithuania	Doxorubicin	Schedule A
Malta	[…]	Schedule B-II
Poland[6]	Alendronic Acid	Schedule A
	Butamirate	Schedule B-I
	Docetaxel	Schedule A
	Fludarabine	Schedule A
Romania[7]	[…]	Schedule B-II

5 The Commitments also include the following marketed molecules for Hungary, which are part of other baskets that will be sold to other purchasers: Ambroxol (Basket 2 Baltics), Atorvastatin (Basket Rivopharm), Epirubicin (Basket 1 Nordics), Fosinopril, Hydrochlorothiazide (Basket 4 Western Europe).

6 The Commitments also include the following marketed molecules for Poland, which are part of other baskets that will be sold to other purchaser(s): Ambroxol (Basket 2 Baltics) and Tolterodine (Basket 1 Nordics).

7 The Commitments also include the following marketed molecules for Romania, which are part of other baskets that will be sold to other purchaser(s): Carbidopa, Entacapone, Levodopa (Basket 1 Nordics), Linezolid (Basket 4 Western Europe).

	Calcium Folinate	Schedule A
	Cisplatin	Schedule A
	Docetaxel	Schedule A
	Doxorubicin	Schedule A
	Etoposide	Schedule A
	Gemcitabine	Schedule A/Schedule C-I
	Granisetron	Schedule A/Schedule C-I
	Levetiracetam	Schedule A
	[…]	Schedule B-I
	[…]	Schedule B-II
	Topotecan	Schedule A
Slovakia[8]	Azithromycin	Schedule A
	Fentanyl	Schedule A
Slovenia	Carboplatin	Schedule A
	Mycophenolate Mofetil	Schedule A
	Piperacillin/Tazobactam	Schedule A
	[…]	Schedule B-II

6. These molecules, together with the divested assets, are referred to in this Decision as the "Central and Eastern Europe Divestment Business".

7. On 16 December 2016, Teva signed an Asset and Purchase Agreement ("APA") and related agreements which were amended on 5 October 2017 (the "***Proposed Agreements***") regarding the acquisition of the Central Eastern Europe Divestment Business by Alvogen Lux Holdings S.a.r.l. ("***Alvogen***" or the "***Purchaser***") through its wholly owned subsidiary Alvogen Malta Operations (Row) Limited ("Alvogen Malta").

8. By letter of 31 January 2017, complemented on 10 October 2017, Teva proposed Alvogen for approval by the Commission as purchaser of the Central and Eastern Europe Divestment Business and submitted the APA as well as the other proposed agreements.

9. On 10 October August 2017, the monitoring trustee (Duff & Phelps, hereinafter referred to as the "Trustee") submitted a reasoned opinion regarding Alvogen's suitability as a purchaser and, in particular, indicated that in the Trustee's view Alvogen fulfils the purchaser criteria set out in Section E of the Commitments attached to the Decision. In this opinion, the Trustee also indicated that, on the basis of the Proposed Agreements, the Divestment Business would be sold in a manner consistent with the Commitments.

II. ASSESSMENT OF THE PROPOSAL

10. As set out in Section E of the Commitments, the Purchaser must fulfil the following criteria:

[8] The Commitments also include the following marketed molecule for Slovakia, which is part of another basket that will be sold to another purchaser: Fosinopril (Basket 4 Western Europe).

a. The Purchaser shall be independent of and unconnected to the Notifying Party and its Affiliated Undertakings,

b. The Purchaser shall have the financial resources, proven expertise, ability and incentive to maintain and develop the Divestment Business as a viable and active competitive force in competition with Teva and other competitors,

c. The Purchaser shall be an established pharmaceutical company having the incentive and ability to become independent of the Notifying Party with respect to the manufacturing of the Divested Products.

d. The Purchaser shall be a generic company already active in the EEA, and shall have the incentive and the ability to maintain and develop each of the Divested Products.

e. The acquisition of the Divestment Business by the Purchaser must neither be likely to create, in light of the information available to the Commission, prima facie competitive concerns nor give rise to a risk that the implementation of the Commitments will be delayed,

11. This section provides a short description of the Purchaser, as well as an assessment of its suitability in view of these criteria.

Description of the Purchaser

12. Alvogen Inc, incorporated in 2008 in the United States, has in seven years developed into a full-fledged generics company with revenues of around EUR 750 million in 2016.

13. Alvogen is currently engaged in product development, contract manufacturing and research, and sales of generic and branded medicinal products, biosimilars and over the counter ("OTC") medicinal products in 35 countries, notably in North America, Central and Eastern Europe and Asia Pacific. Alvogen employs 2,300 employees worldwide, and has a portfolio of 350 marketed products.

Assessment of the purchaser criteria

(a) Independence from Teva

14. Teva does not have any ownership stake or equity connections in Alvogen and vice *versa*. Teva has no joint venture or alliances with Alvogen. There are no cross-memberships in the management boards of the two companies.

15. Teva and Alvogen's commercial relationship is limited to the following licensing agreements:

a. On-market products in Hungary: Alvogen in-licensed some products from Medis[9] with estimated total sales of EUR […] million in 2016.

9 Medis is a subsidiary of Teva and is responsible for Teva's outlicensing operations.

b. Pipeline products in Hungary: Alvogen concluded an in-licensing agreement with Medis for some pipeline products with estimated total annual sales of EUR […] million.

c. On-market products in Iceland: Alvogen in-licensed some products from Medis with estimated total sales of EUR […] in 2016.

16. These agreements account for [0-5]% of Alvogen's sales in Europe and [5-10]% of Alvogen's sales in Hungary.

17. In view of the above, the Commission considers that there are no structural links or material commercial links that could cast doubts on Alvogen's independence from Teva. Therefore, based on the information provided, the Commission considers Alvogen to be independent of and unconnected to Teva.

(b) Financial resources

18. Alvogen intends to finance the acquisition of the Central and Eastern Europe Divestment Business from Teva for approximately EUR […].

19. Alvogen reported revenues of USD 766 million for the year ending December 31, 2016 (*i.e.* FY 2016). This represents an increase of approximately [20-30]% on an annual basis compared to FY 2013. In terms of profitability, the operating income margin showed an increase from [5-10]% of revenues in FY 2013 to [10-20]% of revenues in FY 2016, which results in an increase in operating income (in absolute terms) of approximately [70-80]% on an annual basis between FY 2013 and FY 2016.

20. In addition, Alvogen's total assets grew by approximately [40-50]% on an annual basis between FY 2013 and FY 2016. This growth was fully financed with equity. Alvogen also has a sizeable cash and cash equivalents position.

21. In view of the above, the Commission considers that Alvogen has the financial resources to maintain and develop the Central Eastern Europe Divestment Business.

(c) Proven expertise

22. Alvogen organizes its operations along the following four business lines: (i) biopharmaceuticals, (ii) contract-manufacturing, (iii) OTC medicines and (iv) generics. As for the latter Alvogen has 350 on-market generic products and a significant number of development ongoing projects.

23. More specifically, in Central and Eastern Europe (*CEE*), Alvogen's product portfolio contains 204 marketed products and a significant number of pipeline products. This portfolio consists for 48% of prescription products, 20% of biosimilar products, 18% of OTC products and 14% of hospital products. Moreover, the company operates a manufacturing plant in Romania and has 769 employees in the CEE, including 39% of the employees focused on sales & marketing, 33% on manufacturing & quality and 10% on research & development ("R&D"). Alvogen does not currently have operations in the Czech Republic, Greece, Slovenia and Slovakia.

24. It its Reasoned Proposal, Teva explains it will complete all R&D studies before transferring the divested products to Alvogen. In some cases however certain

follow-up studies are required post-closing, which will be carried out by Alvogen directly. In this regard Alvogen has invested more than 8% of its revenues on R&D in 2015. Alvogen has three R&D centres in the world (including one in Romania), supported by a global clinical operations team.

25. Alvogen also possesses the necessary regulatory expertise to take over and develop the Central and Eastern Europe Divestment Business, particularly for the registration of marketing authorizations. It has regulatory support teams located in its offices in Bucharest (Romania) and Sofia (Bulgaria).

26. As for Alvogen's technology transfer capabilities, Alvogen has an experienced technical services team in Malta. This team is specialized in technical due diligence and executing product transfers and is capable of performing 8 to 12 transfers a year. Alvogen has extended its technical services team to five stand-alone teams in the last few months.

27. Against this background, 33 technology transfers are required for the Central and Eastern Europe Divestment Business. Alvogen has put forward a timeline for these technology transfers over 3 years, which is in line with its capabilities. Out of the 33 technology transfers, only 12 are related to product transfers to Alvogen's own production facilities whereas 21 products will be transferred to facilities of external CMOs. For the latter technology transfers, in line with normal market practice it can be expected that Alvogen will receive support from technology transfer employees of the external CMOs. This will reduce the workload for Alvogen's technology transfer teams.

28. Alvogen also has a long lasting experience in manufacturing around the world. Alvogen intends to transfer the production of the majority of the 12 products it will manufacture in-house to its manufacturing facility in Bucharest, Romania. However, its facilities in Taiwan and the United States will be made available to deal with excess demand and special requirements.

29. As for Alvogen's sales and marketing capabilities, Alvogen has a significant presence in the largest countries where the Central Eastern Europe Divestment Business generates revenues.[10] Indeed, Alvogen generates approximately 18% of its global sales in this region and has a sufficient number of sales and marketing employees to take over the products of the Central Eastern Europe Divestment Businesses.

30. As for the remaining countries where the Central Eastern Europe Divestment Business generates revenues[11], Alvogen has concluded distributor agreements with a number of distributors. Based on the information provided in the Trustee Reasoned Opinion, these distributors are suitable in terms of distribution and marketing capabilities and sufficiently independent from Teva. The European Commission concurs with this assessment.

31. In view of the above, the Commission considers that Alvogen is an established pharmaceutical company which has the incentive and the ability to become

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[10] Bulgaria, Croatia, Hungary, Poland and Romania.

[11] Czech Republic, Latvia, Lithuania, Greece, Slovakia and Slovenia.

independent from Teva with respect to the manufacturing of the Divested Products. The Commission also considers that Alvogen is an established generic company having the proven expertise to maintain and develop each of the products of the Central Eastern Europe Divestment Businesses as a viable and active competitive force.

(d) Incentive to maintain and develop the Divested Business as a viable and active competitor

32. The acquisition of the Central Eastern Europe Divestment Business fits into Alvogen's plans to expand its activities in this region, which is of high importance for the company. As explained above, this is reflected in the fact that Alvogen generates approximately 18% of its global sales in this region and has a significant sales and distribution network in some of the relevant countries as well as a large and cost-efficient manufacturing site in Romania.

33. Alvogen has provided aggregated financial projections for the Central Eastern Europe Divestment Business. The Trustee carried out an analysis of these projections and concluded that they are achievable and that Alvogen's incentives to maintain and develop the Central Eastern Europe Divestment Businesses are clearly laid out, for the following reasons. In general, Alvogen assumed volumes for all Divested Products to change in line with their historical performance in the last few years. In terms of price evolution, its assumptions are based on input from its local sales and marketing teams.

34. Also, Alvogen's estimation of the expenses of the Central Eastern Europe Divestment Business seems reasonable to the Trustee for the following reasons. First, Alvogen assumed that the main cost component, the cost of goods sold ("COGS") per unit, will remain equal to the historical COGS per unit as provided by Teva. Second, the main operating cost component, sales and marketing expenses, is based on Alvogen's historical experience in the Central Eastern Europe region. Third, other operational expenses are included on a (conservative) incremental basis although Alvogen expects that it can operate the Central Eastern Europe Divestment Business with its existing operations and workforce.

35. The European Commission concurs with the Trustee's assessments on these matters.

36. Besides aggregated projections, Alvogen also provided a business plan with an overview of its financial projections for each country in which the Central Eastern Europe Divestment Business operates, namely Bulgaria, the Czech Republic, Croatia, Cyprus, Greece, Hungary, Latvia, Malta, Poland, Slovakia, Slovenia, Romania and Lithuania.

37. Alvogen expects most of the Divested Products to generate acceptable levels of profitability. Each of the Divested Product is thus interesting for Alvogen as the Purchaser expects the transaction to lead to a significant reduction in the COGS, for instance either after the planned transfer of the relevant molecule to its Romanian production facility or by renegotiating supply prices. Furthermore, Alvogen aims at broadening its portfolio. Additionally, economies of scale would arise from the purchasing of the Divested Products.

38. Alvogen indicated that it intends to continue to monitor the possibility of bringing back on the market some products which have been discontinued or cancelled by

Teva (and relatedly to keep the marketing authorizations alive, where they exist), in particular after obtaining improved COGS post-technology transfer. The presence of these products in the Central Eastern Europe Divestment Business does not affect its overall viability.

39. In view of the above, the Commission considers that Alvogen will have the incentive to maintain and develop the Central Eastern Europe Divestment Businesses as well as each of the Divested Products as a viable and active competitor.

(e) Absence of prima facie competition problems

40. In its reasoned proposal, Teva made an analysis of the overlaps between Alvogen and the Central Eastern Europe Divestment Business. This analysis was performed at molecule and galenic form levels, and led to two on-market to on-market overlaps and one pipeline to on-market overlap (there are no pipeline to pipeline overlaps).

41. The on-market to on-market overlaps concern *atorvastatin* in Hungary and *granisetron* in Romania and the pipeline to on-market overlap concerns *paracetamol* in Romania.

42. Each of these markets is highly competitive. For instance *atorvastatin* in Hungary faces competition from 1A Pharma, Actavis, Aramis, Dr. Schlichtinger, ExtractumPharma, Egis, Gedeon, Glenmark Pharmaceutical, Goodwill, Pharma-Regist, Richter, Pfizer, Krka, Polpharma, Q Pharma, Ranbaxy, Pharma-Regist, Teva, Wörwag Pharma and Zentiva. *Granisetron* in Romania faces competition from Actavis, Teva, Egis, Fresenius and Dr. Reddy's, Finally, *paracetamol* in Romania faces competition from Accord Healthcare, Antibiotice, Arena, Biofarm, Bristol-Myers Squibb, Europharm, Farmex, Fabiol, Fresenius Kabi, Krka, Magistra, McNeil, Meduman, Pharmaceutical Works, Pharmex,Ozone Laboratories, Sanosan, Sintofarm, Zentiva, GlaxoSmithKline, Labormed Pharma, Panpharma, Terapia, Laropharm, TIS Farmaceutic, Novartis, Rompharm and Grünenthal.

43. Additionally, the combined market shares of Alvogen and the Central Eastern Europe Divestment Business for the on-market to on-market overlaps and of Alvogen for the on-market to pipeline overlap are limited (below 20%).

44. For these reasons, the Commission concludes that no prima facie competitive concerns arise.

45. This prima facie assessment is based on the information available for the purpose of this buyer approval and does not prejudge the competition assessment of the acquisition of the Central Eastern Europe Divestment Business by Alvogen by a competent competition authority under applicable merger control rules.

Conclusion on the purchaser criteria

46. In light of the above considerations, taking into account the reasoned opinion submitted by the Trustee, and in light of the information available to it, the Commission concludes that Alvogen meets the purchaser criteria set out in Section E of the Commitments.

III. ASSESSMENT OF THE PROPOSED AGREEMENTS

47. As to the compliance of the Proposed Agreements with the Commitments, the Trustee reviewed the trackers provided by Teva on (i) how the Commitments are reflected in the Proposed Agreements and (ii) how the guidance sought from the European Commission during the sale process has been implemented in the Proposed Agreements.

48. The Trustee made a number of observations concerning the compliance of the Proposed Agreements with the Commitments, which led to several amendments by the Parties. Following these amendments, the Trustee concluded that the Central Eastern Europe Divestment Business is sold in a manner consistent with the Commitments.

49. In light of the above considerations, taking into account the reasoned opinion submitted by the Trustee, and in light of the information available to it, the Commission concludes that the Central and Eastern Europe Divestment Business is being sold in a manner consistent with the Commitments.

IV. CONCLUSION

50. On the basis of the above assessment, the Commission approves Alvogen as a suitable purchaser of the Divestment Business.

51. On the basis of the Proposed Agreements, the Commission further concludes that the Divestment Business is being sold in a manner consistent with the Commitments.

52. This decision only constitutes approval of the proposed purchaser identified herein and of the Proposed Agreement. This decision does not constitute a confirmation that Teva has complied with the Commitments.

For the Commission

(Signed)
Johannes LAITENBERGER
Director-General