



EUROPEAN COMMISSION

DG Competition

Case M.7746 - TEVA / ALLERGAN GENERICS

Only the English text is available and authentic.

**REGULATION (EC) No 139/2004
MERCER PROCEDURE**

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

Date: 13.11.2017



EUROPEAN COMMISSION

Brussels, 13.11.2017
C(2017) 7682

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 Where possible the information omitted has been replaced by ranges of figures or a general description.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 Icelandic Divestment Business following your letter of 1 December 2016, complemented on 7 August 2017 and the Trustee’s opinion of 27 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) of Council Regulation (EC) No 139/2004 (“the Merger Regulation”), 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, Teva committed to divest to a single purchaser the existing Teva business in Iceland (the “*IS Divestment Business*”), which comprises all the Teva products listed in Schedule D-I of the Commitments (the “*IS Divested Marketed Products*”), together with, for each of those products, the assets described in Schedule G-I of the Commitments.
3. The IS Divestment Business also includes all Teva pipeline products listed in Schedule D-II of the Commitments (the “*IS Divested Pipeline Products*”), and,

¹ OJ L 24, 29.1.2004, p.1.

for each of those pipeline products, the assets described in Schedule G-II(1) of the Commitments to the extent any such assets exist and are owned by Teva. Schedule G-II covers all pipeline molecules of Teva in Iceland, as well as Allergan Generic Business' pipeline product for Rasagiline in Iceland.

4. The IS Divestment Business finally includes the Ratiopharm livery (pack design and artwork) in Iceland. For a period of three years after Closing and under the supervision of the Monitoring Trustee, Teva committed to grant the Purchaser a licensing agreement on the Ratiopharm brand for the products included in the IS Divestment Business.
5. At the option of the Purchaser, Teva committed to a best effort obligation to obtain the transfer of its existing distribution agreement with Lyfis.
6. The table below contains an overview of all on-market and pipeline products included in the IS Divestment Business².

INN Name	Schedule
Acetylsalicylic acid	Schedule D-I
Aciclovir	Schedule D-I
Alfuzosin HCl	Schedule D-I
Allopurinol	Schedule D-I
Amiloride HCl/HCTZ	Schedule D-I
Amorolfine HCl	Schedule D-I
Amoxicillin	Schedule D-I
Amoxicillin, Clavulanic Acid	Schedule D-I
Anastrozole	Schedule D-I
Aripiprazole	Schedule D-I
Atorvastatin Calcium	Schedule D-I
Betahistine Dihydrochloride	Schedule D-I
Bisoprolol Fumarate	Schedule D-I
Cerivedilol	Schedule D-I
Cetirizine	Schedule D-I
Clarithromycin	Schedule D-I
Cromoglycate Sodium	Schedule D-I
Cyproterone Acetate/Ethinylestradiol	Schedule D-I
Desloratadine	Schedule D-I
Desogestrel	Schedule D-I
Desogestrel/Ethinylestradiol	Schedule D-I
Dexpanthenol (Medical device)	Part of Teva's business in Iceland ³
Diclofenac	Schedule D-I

² The following molecules were mentioned in the Commitments for Iceland but are not part of the final Icelandic Divestment Business because they were included by mistake as they are not generics but originator products; [...], [...] and [...] (i.e. Teva's [...] product, the Allergan product for [...] is included in the Icelandic Divestment Business).

³ As provided at paragraph 16 of the Commitments, the Icelandic Divestment Business includes Teva's existing business in Iceland. As such, it includes both the products specifically listed in the Commitments as well as additional products that legacy Teva has in Iceland.

Diltiazem HCl	Schedule D-I
Duloxetine HCl	Schedule D-I
Enalapril, Hydrochlorothiazide	Schedule D-I
Felodipine	Schedule D-I
Fentanyl	Schedule D-I
Fluconazole	Schedule D-I
Fluoxetine	Schedule D-I
Fluticasone Propionate	Schedule D-I
Gabapentin	Schedule D-I
Ibuprofen	Schedules D-I and [...]
Ibuprofen Lysine	Part of Teva's business in Iceland
Isotretinoin	Schedule D-I
Ketoconazole	Schedule D-I
Lactic Acid, Lactobacillus acidophilus (Medical device)	Part of Teva's business in Iceland
Lactic Acid, Sodium Hyaluronate (Medical device)	Part of Teva's business in Iceland
Lamotrigine	Schedule D-I
Lansoprazole	Schedule D-I
Levetiracetam	Schedule D-I
Losartan Potassium	Schedule D-I
Memantine HCl	Schedule D-I
Metoprolol Succinate	Schedule D-I
Metoprolol Tartrate	Schedule D-I
Moclobemide	Schedule D-I
Montelukast Sodium	Schedule D-I
Mycophenolate	Schedules D-I and [...]
Neem extract (Medical device)	Part of Teva's business in Iceland
Omeprazole	Schedule D-I
Oxycodone	Schedule D-I
Paracetamol	Schedule D-I
Pioglitazone	Schedule D-I
Quetiapine Fumarate	Schedule D-I
Ramipril	Schedule D-I
Rizatriptan Benzoate	Schedule D-I
Sesame oil (Medical device)	Part of Teva's business in Iceland
Sodium Chloride (Medical device)	Part of Teva's business in Iceland
Valsartan	Schedule D-I
Valsartan/HCTZ	Schedule D-I
Xylometazoline HCl	Schedule D-I
[...]	Schedule D-II
[...]	Schedule D-II
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7. On 4 November 2016, Teva signed an Asset and Purchase Agreement ("APA") and related agreements, which were amended notably on 12 May 2017 and 27 July 2017 (the "**Proposed Agreements**"), regarding the acquisition of the IS Divestment Business by Alvogen Lux Holdings S.a.r.l ("**Alvogen**" or the "**Purchaser**"; together with Teva the "Parties") through its wholly owned subsidiary Alvogen Iceland ehf. ("**Alvogen Iceland**").
8. By letter of 1 December 2016, complemented on 7 August 2017 Teva proposed Alvogen for approval by the Commission as purchaser of the IS Divestment Business and submitted the Proposed Agreements.
9. On 15 March 2017, the Icelandic Competition Authority ("ICA") sent a letter to the Commission, indicating its preliminary view that it had jurisdiction to request a notification of the transaction from the Alvogen.
10. On 20 April 2017, Teva submitted to the Commission a request for an extension of the First Divestiture Period foreseen in the Commitments for the divestiture of the IS Divestment Businesses. The Commission granted such extension until 28 July 2017. On 12 May 2017, Alvogen and Teva entered into a Deed of Variation to the APA.
11. On 23 May 2017, Alvogen notified the transaction to the ICA. On 26 July 2017, Alvogen and the ICA executed a Settlement Agreement, whereby Alvogen undertook to allow Teva to continue to supply Lyfis with the Divested Products to enable Lyfis to continue distribution until 30 December 2017. The signing of this Settlement Agreement put an end to the ICA's investigation of this transaction. On 27 July 2017, Alvogen and Teva entered into another Deed of Variation to the APA.

12. On 27 October 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 it fulfils the purchaser criteria in Section E of the Commitments. In this opinion, the Trustee also indicated that, on the basis of the Proposed Agreements, the IS Divestment Business would be sold in a manner consistent with the Commitments.

II. ASSESSMENT OF THE PROPOSAL

13. As set out in Section E of the Commitments, the Purchaser must fulfil the following criteria:
 - 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 ability to serve the Iceland market from another EEA country, and shall have an efficient channel to market the Divested Products into Iceland;
 - 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,
14. This section provides a short description of the Purchaser, as well as an assessment of its suitability in view of the above-mentioned criteria.

Description of the Purchaser

15. 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.
16. Alvogen is currently engaged in product development, contract manufacturing and research, 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.
17. Alvogen, through its subsidiary Alvogen Iceland, is the second largest generics company operating on the Icelandic market. The company's presence in Iceland is based on its acquisition of Portfarma ehf., an Icelandic generics company, in 2014.

Assessment of the purchaser criteria

(a) Independence from Teva

18. 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 and none of the large shareholders has invested in both Teva and Alvogen.
19. 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 Medis⁴ with estimated total sales of EUR [...] in 2016.
 - 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.
20. These agreements account for less than [0-5]% of Alvogen's global sales and less than [0-5]% of Alvogen's sales in Europe. These business agreements therefore do not impede the Parties' independence regarding the transaction.
21. 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

22. Alvogen reported revenues of approximately 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.
23. 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.
24. In view of the above, the Commission considers that Alvogen has the financial resources to maintain and develop the IS Divestment Business.

⁴ Medis is a subsidiary of Teva and is responsible for Teva's outlicensing operations.

(c) Proven expertise

25. 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. The company has a full presence in Iceland with local sales and marketing teams as well as the necessary infrastructure in place.
26. In its Reasoned Proposal, Teva explained that it will complete all R&D studies before transferring the divested products to Alvogen. The Trustee however noted that in case certain follow-up studies were required post-Closing, Alvogen is well positioned to do so based on its R&D expertise. Alvogen has thus invested more than [5-10]% of its revenues on R&D in FY 2016. Alvogen has furthermore three R&D centres in the world, supported by a global clinical operations team.
27. As for Alvogen's technology transfer capabilities, the company has an experienced technical services team in Malta. This team is specialized in technical due diligence and the execution of product transfers and is capable of performing 8 to 12 transfers a year. Furthermore Alvogen indicated that it has extended its technical services team to five stand-alone teams over the last months.
28. Regarding the registration of marketing authorisations, Alvogen indicated that it has ample experience with registering medicines, including in Iceland.
29. Alvogen also has a long lasting experience in manufacturing around the world. Alvogen has thus explained that it intends to transfer 56 products to its own production facilities as a consequence of the acquisition of both the IS Divestment Business as well as the Central Eastern Europe Divestment Business⁵. These products will be transferred mainly to Romania and to a lesser extent to the United States and Taiwan. In Romania, Alvogen has acquired additional land to support a further capacity expansion. The facilities in Taiwan and the United States will be made available in order to deal with excess demand and special requirements.
30. Alvogen explained that it is incentivised to perform the technology transfers given that it expects to be able to manufacture the products at lower costs than Teva currently does.
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 independent from Teva with respect to the manufacturing of the Divested Products. The Commission also considers that Alvogen is an established generic company already active in the EEA which has the ability to serve the Icelandic market from another EEA country and has an efficient channel to market the Divested Products into Iceland.

⁵ This acquisition has been approved by the European Commission on 17 October 2017.

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

32. The acquisition of the IS Divestment Business fits into Alvogen's plans to expand its activities in this country.
33. Alvogen already has a multi-lingual packs strategy that allows it to justify minimum order quantities for Iceland. In particular, Alvogen has common packs for Iceland with Bulgaria, Croatia and Romania. In this respect, Alvogen was granted "internationalisation rights" as part of the Transaction, which will enable it to sell the Divested Products in other markets and thus fully leverage on this multi-lingual packs strategy. Alvogen has compiled an international roll out plan for these products.
34. Alvogen has provided aggregated financial projections for the IS Divestment Business. The Trustee carried out an analysis of these projections and concluded that in general Alvogen's business plan for the Divestment Business in Iceland is based on reasonable assumptions and that the viability of the IS Divestment Business is dependent on a successful implementation of the roll out plan.
35. Given the projected volumes and margins and the relatively large size in terms of financials of the roll out plan vis-à-vis the Icelandic operations, the Trustee considers that the roll out plan will provide sufficient support to the IS Divestment Business.
36. The Trustee considers it to be reasonable that Alvogen will be able to grow sales in line with historical market growth given Alvogen's proven expertise in the generic pharmaceutical industry, its already existing and dense sales and marketing/distribution network in Iceland, its experience in terms of working with local distributions in Iceland and its allocated resources to develop the IS Divestment Business going forward. The Trustee furthermore assessed that Alvogen's projected expenses of the IS Divestment Business are sufficiently supported.
37. In view of the above, the Commission considers that Alvogen will have the incentive to maintain and develop the IS Divestment Business as well as each of the Divested Products as a viable and active competitor.

(e) Absence of prima facie competition problems

38. As mentioned above, the acquisition of the IS Divestment Business by Alvogen was authorised by the ICA on 26 July 2017. The transfer of the IS Divestment Business is not subject to any other regulatory authorisation, except the approval by the Commission.
39. In its reasoned proposal, Teva made an analysis of the horizontal overlaps between Alvogen and the IS Divestment Business. This analysis was performed at molecule and NFC1 form levels. Teva's on-market to on-market analysis led to 6 overlaps, while its on-market-to-pipeline analysis led to 4 overlaps and its pipeline-to-pipeline analysis led to 2 overlaps.
40. As a preliminary point the Commission notes that, according to the ICA, in Iceland the pricing of the products is regulated and each product cannot be priced higher than the average price of the same product in each of the Nordic countries. This

regulatory arrangement reflects the specificity of the Icelandic market, which is very small in size and typically not served by a large number of competitors: in many instances there are only one or two generic companies providing a product.

41. The on-market to on-market overlaps concern Fluconazole, Ibuprofen, Levetiracetam, Losartan, Menantine and Rizatriptan N2C. Concerning Ibuprofen and Levetiracetam, the Trustee noted that none of the 2016 combined revenue and volume market shares of these products exceed 20%. Additionally, there are currently a sufficient number of competitors for these products.
42. As for Fluconazole, Alvogen would face strong competition post-transaction from Teva (ex-Allergan) which would be of a comparable size. Concerning Losartan, Teva (ex-Allergan) would remain the market leader, Alvogen would also face competition from Merck and Valeant. As for Menantine, Alvogen would face competition from Williams & Halls, which would be of a comparable size, and to a lesser extent from H Lundbeck. As for Rizatriptan N2C, post-transaction Alvogen would face competition from Merck, which is the market leader by far.
43. The on-market to pipeline overlaps concern [...] and [...]. The Monitoring Trustee noted that none of the 2016 combined revenue and volume market shares of these products exceed 20%. Additionally, there are currently a sufficient number of competitors for these products (five for [...] and three for the other products).
44. Finally, the pipeline-to-pipeline overlaps concern [...] and [...]. For both products, there is currently only one competitor active on the market. However, the Trustee noted that there are three potential competitors that either have marketing authorisations or pipeline products.⁶
45. In view of the limited combined market share of Alvogen and the IS Divestment Business for the on-market to pipeline overlaps (below 20%) as well as the presence of strong and numerous competitors, the Commission concludes that no *prima facie* competitive concerns arise for these overlaps. Additionally, considering the number of potential competitors for the pipeline-to-pipeline overlaps⁷, the Commission concludes that no *prima facie* competitive concerns arise for these overlaps.
46. Concerning vertical links, the ICA found that the transaction, as initially contemplated, may have resulted in competition concerns to the extent that it may potentially have led to a foreclosure of Lyfis from the distribution market for generic pharmaceutical products in Iceland. Alvogen therefore committed, on 12 May 2017, to allow Teva to continue to supply Lyfis with the Divested Products until 30 December 2017. This was considered necessary to help Lyfis adjust to the loss of this significant supply arrangement and sufficient to counteract the potential loss of competition in the distribution market.
47. In view of this commitment, no *prima facie* competitive concern arises from the vertical links.

⁶ Namely Krka, Teva and Zentiva.

⁷ Three, namely Krka, Teva and Zentiva.

Conclusion on the purchaser criteria

48. 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

49. 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 Commission during the sale process has been implemented in the Proposed Agreements.
50. 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 IS Divestment Business is sold in a manner consistent with the Commitments.
51. 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 IS Divestment Business is being sold in a manner consistent with the Commitments.

IV.CONCLUSION

52. On the basis of the above assessment, the Commission approves Alvogen as a suitable purchaser of the IS Divestment Business.
53. On the basis of the Proposed Agreements, the Commission further concludes that the IS Divestment Business is being sold in a manner consistent with the Commitments.
54. This decision only constitutes approval of the proposed purchaser identified herein and of the Proposed Agreements. This decision does not constitute a confirmation that Teva has complied with the Commitments.

For the Commission

(Signed)
Johannes LAITENBERGER
Director-General