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: 28.03.2017

EUROPEAN COMMISSION

Brussels, 28.3.2017
C(2017) 2183

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 Where possible the information omitted has been replaced by ranges of figures or a general description.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 Aurobindo as purchaser of Divestment Business following your letter of 13 January 2017 and the Trustee's opinion of 13 March 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 Commission declared the operation by which Teva Pharmaceuticals Industries Limited ("Teva") acquires 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. During the sale process of the Other Countries On-Market Overlaps Divestment Businesses, Teva defined six baskets of divested products to be sold to one or several purchasers based mainly on geographic criteria. One of the baskets contained *calcium carbonate* and *calcium carbonate, colecalciferol* in France ("the

Commission européenne, DG COMP MERGER REGISTRY, 1049 Bruxelles, BELGIQUE
Europese Commissie, DG COMP MERGER REGISTRY, 1049 Brussel, BELGIË

Tel: +32 229-91111. Fax: +32 229-64301. E-mail: COMP-MERGER-REGISTRY@ec.europa.eu

"***Divested Products***")[1] as well as the related Orocal brand (the "***Divestment Business***").

4. On 24 November 2016, a subsidiary of Teva, Teva Pharmaceuticals Europe B.V., and a subsidiary of Aurobindo Pharma Group ("***Aurobindo***"), Arrow Generiques S.A.S, signed a Sale and Purchase Agreement and related agreements in relation to the sale of the Divestment Business ("SPA") which was amended on 23 March 2017 (the "***Proposed Agreements***"). Aurobindo agreed to pay Teva EUR [amount] for the Divestment Business.

5. By letter of 13 January 2017, Teva proposed Aurobindo for approval by the Commission as purchaser of the Divestment Business and submitted the SPA.

6. On 13 March 2017, the monitoring trustee (Duff & Phelps, hereinafter referred to as the "the Trustee") has submitted an opinion regarding Aurobindo's suitability as a purchaser and, in particular, has indicated that in the Trustee's view it fulfils the criteria of the purchaser requirements in section E of the Commitments attached to the Decision. In this opinion, the Trustee also indicated that, on the basis of the Proposed Agreement, the Divestment Business would be sold in a manner consistent with the Commitments.

II. ASSESSMENT OF THE PROPOSAL

7. As set out in section E of the Commitments, the Purchaser of Other Countries Overlap Divestment Businesses, such as the Divestment Business, must fulfil the following criteria:

    a. The Purchaser shall be independent of and unconnected to Teva,

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

    c. The acquisition of the Divestment Businesses 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,

    d. 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,

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

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[1] In France, the products to be divested (Schedule A, Commitments) include: *calcium carbonate*; *calcium carbonate, colecalciferol* and *risedronic acid. Calcium carbonate* and *calcium carbonate, colecalciferol* are part of one basket and are analysed in this decision, while *risedronic acid* in France is part of a separate basket which comprises *risedronic acid* in several EEA countries (Belgium, Croatia, Estonia, Finland, France, Germany, Italy, the Netherlands, Portugal, Spain, Sweden and Greece) as well as EEA pipeline products.

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

Description of the purchaser

9. Founded in 1986 and headquartered in India, Aurobindo is a pharmaceutical company active worldwide involved in all aspects of generic drugs, and more particularly the development, manufacturing and marketing of oral and injectable generic formulations and active pharmaceuticals ingredients ("***APIs***"). Aurobindo has over 15,000 employees and generates sales in 150 countries across the globe.

10. In France, where the Divested Products are marketed, Aurobindo operates through Arrow France, which it acquired in April 2014. Aurobindo has 180 employees in this country, and is among the top 6 generic pharmaceutical companies in the retail market. Aurobindo's portfolio covers a large number of therapeutic areas and, in particular, already includes products indicated for the treatment of osteoporosis, such as *alendronic acid* and *risedronic acid*.

(a) Independence

11. In its reasoned proposal, Teva submitted that neither Aurobindo nor, to the best of Teva's knowledge, any of its shareholders[2] have any connections to the Teva group. In its reasoned opinion, the Trustee identified two common shareholders. However, none of these shareholders holds a material stake (ownership stake of more than 5%) in Teva or Aurobindo so they are not able to exercise any material influence on either Teva's or Aurobindo's strategic decisions.

12. Moreover, there are no cross memberships in the management boards of the two groups, nor any joint ventures or alliances between them.

13. As to business relationships, Teva and Aurobindo are party to commercial agreements that were, for the greatest part, established in the context of Aurobindo's acquisition of Actavis' Western Europe Operations in 2014.[3]

14. More specifically, Actavis and Aurobindo concluded transitional agreements at the time, including a License and Supply Agreement signed on 1 April 2014 ("LSA"). Pursuant to the LSA, Actavis' marketing authorizations would be transferred to Aurobindo and the latter would purchase the products from Medis (Allergan's out licencing unit) until March 2019 (unless Aurobindo notifies Medis of its intention to finalise a manufacturing transfer of some of the products before that date). For some of these products (approximately 10% of Aurobindo's purchases), Teva committed to extend the duration of supply until March 2020 under one of its Commitments attached to the Decision.[4]

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2 This analysis was based on a list of major Aurobindo shareholders available on Aurobindo's website at the following URL: http://www.aurobindo.com/investor-relations/investors/shareholding-pattern.

3 Aurobindo acquired Allergan Generics' businesses in France, Italy, Spain, Portugal, Belgium, Germany and the Netherlands.

4 Pursuant paragraph 33 of the Commitments, for the molecules listed in Schedule C-II, Teva and Allergan commit that Medis will maintain its relationship with Aurobindo on terms equivalent to

15. In 2015, Aurobindo purchased products for EUR [amount] from Medis. These purchases can be divided as follows:

    a. EUR [amount] million of purchases relate to products for which manufacturing will be transferred to Aurobindo by the end of [date] (EUR [amount] million) or [date] (EUR [amount] million) and the marketing authorizations will be meanwhile granted to Aurobindo,

    b. EUR [amount] million of purchases relate to products for which manufacturing will be transferred to Aurobindo's facilities [confidential information on Aurobindo Technology transfer plans]. In this regard, the vast majority of the marketing authorizations to Aurobindo are [confidential information on Aurobindo Technology marketing authorisation transfer plans].

    c. EUR [amount] million of purchases relate to products for which the transfer of the manufacturing [confidential information on Aurobindo Technology transfer plans],

    d. EUR [amount] million of purchases relate to products for which Aurobindo [confidential information on Aurobindo Technology sourcing strategy], and

    e. EUR [amount] million of purchases relate to products for which Aurobindo [confidential information on Aurobindo Technology sourcing strategy].

16. Based on the Monitoring Trustee's estimates, Aurobindo purchases currently less than [10-20]% ([10-20]%) of its global 2016 Costs of Goods (COGS) from Medis. However, after Aurobindo's transitional arrangement with Medis comes to an end, this proportion will be reduced to [0-5]% of its worldwide COGS.

17. In addition, Aurobindo made local purchases of finished dose products from Teva in France, the Netherlands and Belgium, amounting to approximately EUR [amount] million. This amounts to a very limited proportion ([0-5]%) of Aurobindo's global 2016 COGS.

18. Finally, Aurobindo is a party to a number of commercial arrangements, such as out-licensing arrangements, with Teva (including ex-Allergan) which purchased EUR [amount] million from Aurobindo in 2015. These purchases account for a very limited portion of Aurobindo's worldwide turnover (less than [amount]%).

19. In light of the above, the Commission considers that the business relationships between Teva and Aurobindo do not affect Aurobindo's independence since its purchases from Teva represented less than [10-20]% of its global COGS and this proportion will substantially decrease and become immaterial over the next years.

20. The Commission concludes that Aurobindo is independent from and unconnected to Teva for the purpose of operating the Divestment Business.

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those that currently apply to those molecules for a duration of 4 years as of the Effective Date and assist Aurobindo for the corresponding technology transfers.

(b) Financial resources

21. Aurobindo generated EUR 1.9 billion worth of revenues and EUR 444 million worth of EBITDA worldwide for the fiscal year (FY) ending March 2016. The company employs more than 15,000 professionals, from over 30 countries, across various divisions (Research & Development, Manufacturing, Quality assurance, Marketing, Supply chain, Commercial and HRD).

22. The Commission concludes that Aurobindo can easily finance the purchase price of [amount] for the acquisition of the Divestment Business from Teva through its own resources and/or its capacity to access external finance. Equally, Aurobindo has all the necessary resources to subsequently operate and further grow the Divestment Business.

(c) Generic company already active in the EEA

23. Aurobindo initially entered the EEA generic markets with acquisitions of Milpharm in the United Kingdom in 2006 and Pharmacin in the Netherlands in 2007. Through the acquisition of the Western European generic operations of Actavis in 2014, Aurobindo acquired both extensive additional product lines, including over 1,250 dossier license rights and over 350 INNs, and distribution and hospital sales networks in Germany, France, Italy, Spain, the Netherlands, Belgium and Portugal.

24. In 2016, Aurobindo achieved net sales of EUR 505 million in Europe. Aurobindo is currently amongst the top 15 generic companies by sales in Europe. It has operations in nine EEA countries with 1,352 products currently marketed, [amount] planned launches in the next two years. It has 566 employees in the EEA, including sales force and support infrastructure.

25. The Commission concludes that Aurobindo is a generic company already active in the EEA.

(d) Expertise

26. As indicated above, Aurobindo is an established generic company with distribution and sales capabilities around the EEA and in France in particular.

27. Aurobindo has the required regulatory experience to ensure the transfer of the Divestment Business. In the context of its acquisition of Actavis Western European Operations in 2014, Aurobindo had already successfully transferred [amount] marketing authorizations, representing [80-90]% of transferrable marketing authorizations in this transaction.

28. In terms of its safety and quality record, Aurobindo has a successful track record of pharmacovigilance inspections with no critical findings in last five years. Its extensive network of local pharmacovigilance support in place in each EU country ensures compliance with pharmacovigilance legislation. Aurobindo also has procedures for product recalls to address safety concerns.

29. The Commission concludes that Aurobindo has the required expertise to operate successfully the Divestment Business.

(e) Ability and incentives to become independent with respect to the manufacturing of the Divested Products

30. With respect to the manufacturing of the Divested Products, Aurobindo will benefit from the existing agreements with AJC Pharma, Takeda and Laboratoires Macors which manufacture the Divested Products. Those three companies are unconnected to Teva. Aurobindo also has the ability to manufacture the Divested Products in its own manufacturing network, [70-80]% of its portfolio being currently vertically integrated.

31. The Commission concludes that Aurobindo will have the ability and incentives to become independent from Teva in a timely manner with respect to the manufacturing of the Divested Products.

(f) Ability and incentives to maintain and develop each of the Divested Products

32. The Monitoring Trustee indicated that this Transaction fits Aurobindo's strategy to pursue merger and acquisition opportunities that fill the gap in its existing portfolio and help to expand its presence in premium regulated European geographies like France. In particular, it will help the company to achieve a bigger scale in France while using its existing operations, and therefore rationalize economies of scale.

33. In addition, as part of the Transaction, Teva is granting Aurobindo the right to develop the Orocal brand beyond the scope of the Divested Products, and to use it for any other calcium product indicated for the treatment of osteoporosis.

34. The Monitoring Trustee analysed Aurobindo's business plan with respect to the Divested Businesses (overall and at standard keeping unit (SKU) levels) for the next five years under both a realistic and conservative scenario. The Monitoring Trustee concluded that Aurobindo's projections were reasonable and that the envisaged expenses will be relatively easily recovered under the two scenarios, making the Divestment Business and each Divested Product attractive.

35. In light of the above, Aurobindo will have the ability and incentives to maintain and develop each of the Divested Products.

(g) Absence of prima facie competition problems

36. The transfer of the Divestment Business is not subject to any regulatory authorization, except the approval of the Commission.

37. In addition, there is no overlap at molecule or galenic form level between the Divested Products and Aurobindo's existing and pipeline portfolio in France. Aurobindo only has complementary osteoporosis products in its portfolio, with a limited market position at molecule level.

38. The Commission concludes that no prima facie competition concerns exist for the Transaction. 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 Divestment Business by a competent competition authority under applicable merger control rules if applicable.

III. ASSESSMENT OF THE PROPOSED AGREEMENTS

39. As to the compliance of the Proposed Agreements with the Commitments, the Trustee reviewed the tracker provided by Teva and stated that the Commitments are fully reflected in the Proposed Agreements.

40. The Commission therefore concludes that the Divestment Business is being sold in a manner consistent with the Commitments.

IV. CONCLUSION

41. On the basis of the above assessment, the Commission approves Aurobindo as a suitable purchaser for the above-mentioned reasons.

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

43. 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 its Commitments.

44. This decision is based on paragraphs 8 and 9 of the Commitments attached to the Commission Decision of 10 March 2016.

For the Commission

(Signed)

Johannes LAITENBERGER
Director-General