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: 20.12.2017

EUROPEAN COMMISSION

Brussels, 20.12.2017
C(2017) 9072 final

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 Where possible the information omitted has been replaced by ranges of figures or a general description.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 Intas as purchaser of the Out-licensing Divestment Business following your letter of 19 October 2016, complemented on 19 December 2017, and the Trustee's opinion of 19.12.2017

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 for all molecules listed in Schedule C-I (together "*the Non-Aurobindo Products*"), 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

[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.

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or Allergan Generics Business in the relevant country together with the assets listed in Schedule G-I (the "*Downstream Outlicensing Divestment Businesses*").

3. During the sale process, Teva defined one basket of divested products comprising the Upstream Outlicensing Divestment Businesses. The following molecules, together with the assets listed in Schedule G-III are referred to as the "Out-licensing Divestment Business".

Country	Molecule	Schedule/paragraph(s) of the Commitments
Belgium	Acetylsalicylic acid	Schedule C-I
Croatia	Acetylsalicylic acid	Schedule C-I
Germany	Acetylsalicylic acid	Schedule C-I
Iceland	Acetylsalicylic acid	Schedule C-I
Ireland	Acetylsalicylic acid	Schedule C-I
Italy	Acetylsalicylic acid	Schedule C-I
Poland	Acetylsalicylic acid	Schedule C-I
Serbia	Acetylsalicylic acid	Schedule C-I
Austria	Alendronic acid	Schedule C-I
Belgium	Alendronic acid	Schedule C-I
France	Alendronic acid	Schedule C-I
Germany	Alendronic acid	Schedule C-I
Hungary	Alendronic acid	Schedule C-I
Netherlands	Alendronic acid	Schedule C-I
Poland	Alendronic acid	Schedule C-I
Portugal	Alendronic acid	Schedule C-I
Serbia	Alendronic acid	Schedule C-I
Spain	Alendronic acid	Schedule C-I
United Kingdom	Alendronic acid	Schedule C-I
n/a	Benazepril	Schedule C-I
n/a	Benazepril hydrochlorothiazide	Schedule C-I
n/a	Hydrochlorothiazide quinapril	Schedule C-I
Netherlands	Ipratropium bromide salbutamol	Schedule C-I
Italy	Lisinopril	Schedule C-I
Austria	Lisinopril	Schedule C-I
Croatia	Lisinopril	Schedule C-I
France	Lisinopril	Schedule C-I
Germany	Lisinopril	Schedule C-I
Netherlands	Lisinopril	Schedule C-I
Portugal	Lisinopril	Schedule C-I
Bulgaria	Nifedipine	Schedule C-I
Czech Republic	Oxaliplatin	Schedule C-I
Germany	Oxaliplatin	Schedule C-I
Greece	Oxaliplatin	Schedule C-I
France	Risedronic acid	Schedule C-I
Germany	Risedronic acid	Schedule C-I
Greece	Risedronic acid	Schedule C-I
Italy	Risedronic acid	Schedule C-I
Netherlands	Risedronic acid	Schedule C-I
Spain	Risedronic acid	Schedule C-I
Bulgaria	Triamterene hydrochlorothiazide	Schedule C-I

4. On 5 October 2016, Teva and Intas Pharmaceutical Ltd. ("Intas" or the "Purchaser") through its wholly owned subsidiary Accord Healthcare Ltd.

("Accord EMENA") signed an Asset Purchase Agreement and related agreements in relation to the sale of the Out-licensing Divestment Business. The Parties also signed a deed of amendment and restatement on January 10, 2017. Furthermore an additional deed of amendment and restatement and updated related transaction documents were signed in December. The above mentioned documents comprise the transaction documents ("Proposed Agreements").

5. By letter of 19 October 2016, Teva proposed Intas for approval by the Commission as purchaser of the Divestment Business and submitted the Proposed Agreements. This letter was amended on 19 December 2017.

6. On 19 December 2017, the monitoring trustee (Duff & Phelps, hereinafter referred to as the " Trustee") submitted an opinion regarding Intas' suitability as a purchaser and, in particular, 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 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 Businesses 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 company that already has outlicensing activities in the EEA.

    e. 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,

8. 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

9. Intas, founded in 1976 and headquartered in Ahmedabad, India, is engaged in the manufacturing, marketing, distribution, and sale of finished pharmaceutical formulations, active pharmaceutical ingredients ("APIs"), medical appliances, and medical devices worldwide. The company markets its products through

wholesalers, mail order pharmacies, and retail pharmaceutical chains. Intas has a presence in more than 70 countries and has 13 manufacturing sites worldwide.

10. On 23 December 2016, the Commission approved Intas as a purchaser of a substantial part of Allergan Generics' business in the United Kingdom and Ireland which was also being divested as part of the Commitments ("IE-UK Divestment Business").[2]

Assessment of the purchaser criteria

(a) Independence from Teva

11. Teva does not have any ownership stake or equity connections in Intas and *vice versa*. Teva has no joint venture or alliances with Intas. There are no cross-memberships in the management boards of the two companies. Teva and Intas have not acted as counterparties in any transaction between March 2014 to March 2017, except for the acquisition of the IE-UK Divestment Business.

12. With respect to commercial operations, Teva purchases […] from Intas […] for a total amount of EUR […]. In addition, Intas purchases APIs from Teva for approximately EUR […] based on the year ending March 31, 2017 (i.e. FY 2017). The latter revenues come from […]. These agreements amount to only [0-5]% of Intas' global revenues.

13. Also, as a result of its acquisition of the IE-UK Divestment Business, Intas concluded several agreements with Teva. However, these agreements are transitional and together accounted for less than [0-5]% ([0-5]%) of Intas' global revenues.

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

(b) Financial resources

15. Intas expects to generate revenues of more than EUR […] for FY 2017. This represents a substantial annual increase compared to FY 2014. In terms of profitability, the EBITDA margin is expected to substantially increase between FY 2014 and FY 2017.

16. In addition, Intas' total assets have grown substantially every year between FY 2014 and FY 2016**.** This growth is primarily financed […].

17. The consideration for the acquisition of the […]* Divestment Business for EUR […] thus comprises just a small part of (i) Intas' expected EBIT for FY 2017 and (ii) Intas' total book value of assets.

[2] Case M.7746 – Teva/Allergan Generics, Approval of Intas as purchaser of IE-UK Divestment Business, 23 December 2016.

18. In view of the above, the Commission considers that Intas has the financial resources to maintain and develop the Out-licensing Divestment Business.

(c) Proven expertise

19. Intas is engaged in the manufacturing, marketing, distribution and sale of finished pharmaceutical formulations, APIs, medical appliances, and medical devices on a worldwide basis. Over 2,500 Stock Keeping Units (SKUs) are currently on-market in Europe and […] launches are planned in the next […] years. Intas generated important revenues in the EMENA region[3] in 2016.

20. Intas' operations are fully vertically integrated. More in particular, its operations comprise in-house API production, research and development ("R&D"), regulatory, manufacturing, quality, supply chain, marketing and sales and pharmacovigilance functions.

21. Intas has long-lasting experience in global manufacturing and supplying into European markets. The company's entire network comprises 13 sites, 7 with European good manufacturing practice ("GMP") approvals, and several new sites scheduled for development and upgrade. Overall, Intas has several thousand manufacturing employees and produces several billion tabs on an annual basis.

22. As for Intas' EEA sites, until recently, Intas operated one primary and secondary packing site in Haverhill, United Kingdom, and a European test and release laboratory in London, United Kingdom. Furthermore, Intas has recently invested to reinstate a facility in Newcastle, United Kingdom and recently acquired a plant in Barnstaple as part of its acquisition of the IE-UK Divestment Business on January 9, 2017.

23. Following the acquisition of the Outlicensing Divestment Business, Intas will perform […] technology transfers which are scheduled between […]. When it comes to the company's technology transfer expertise, Intas has performed numerous technology transfers of products to new production facilities. In particular, Intas has extensive experience regarding technology transfers from external organizations into Intas-owned facilities.

24. As for its outlicensing activities in the EEA, Intas has been operating an outlicensing business model for approximately 12 years and has concentrated these activities in its offices in India, Barcelona (Spain), Montreal (Canada) and Melbourne (Australia). Its Barcelona office is focused on the European market and comprises front-end employees dedicated to business development, supply chain, legal, IP, regulatory affairs and artworks, to provide full assistance to Intas' outlicensing customers across Europe. In addition, back-end employees located in Intas' Indian headquarters are dedicated to providing support to the European outlicensing operations. Intas also has a Barcelona based contracted laboratory that offers testing and batch release services to its European customers.

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3 Europe, Middle East and North Africa.

* should read Outlicensing

25. Intas currently outlicenses over 100 molecules to dozens of corporate clients, and has witnessed several years of rapid growth. Despite its worldwide coverage, Intas' outlicensing operations are primarily focused on Europe where it obtains over 70% of its outlicensing revenues. In FY 2016, Intas generated almost EUR […] million in revenues with its outlicensing activities which is expected to increase as per FY 2017.

26. In view of the above, the Commission considers that Intas is an established pharmaceutical company, with outlicensing activities in the EEA, having the proven expertise to maintain and develop the Out-licensing Divestment Business and the ability to become independent of Teva with respect to the manufacturing of the Divested Products.

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

27. The acquisition of the Outlicensing Divestment Business fits into Intas' strategy of ensuring maximal market access for its product developments. To that end Intas has concluded outlicensing agreements with an extensive platform of customers (consisting of major generic companies as well as regional and local players). The Transaction will provide Intas with access to new customers.

28. The Transaction will also broaden Intas' relationship with its existing outlicensing clients. Some of these are already within the top ranking of Intas' outlicensing customers. Furthermore, Intas' experience and ongoing relationships with these customers will also ensure a smooth transition of the Outlicensing Divestment Business from Teva to Intas.

29. Intas is currently already manufacturing and commercializing some of the divested products in other countries than those included in the Outlicensing Divestment Business[4]. Nevertheless, Intas provided reasonable explanations as to why it will engage in technology transfers also for these molecules.

30. For most products, Intas has provided an overview of the revenues and gross margin per product, their revenues are assumed to […] which is mostly in line with their historical revenue growth rates and reflects the fact that these products are relatively mature.

31. The Trustee concluded that Intas' projections are achievable and that its incentives to maintain and develop the Out-licensing Divestment Business are clearly laid out. More in particular, the Trustee considers it reasonable that Intas will be able to grow the revenues of the products given its proven expertise in launching new products in Europe which it can apply to the Out-licensing Divestment Business.

32. Furthermore, the Trustee considers that the estimation of the expenses of the Out-licensing Divestment Business is sufficiently supported given that (i) the main cost component, cost of goods sold, is estimated based on Teva's current supply prices and, (ii) Intas' estimate of the operating expenses is based on the company's historical experience with outlicensing in Europe. The Trustee also notes that the

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4 Acetylsalicylic Acid, Alendronic Acid, Lisinopril and Oxaliplatin

Out-licensing Divestment Business will be able to cover these expenses relatively easily.

33. The Commission concurs with the Trustee's assessment and, in view of the above and based on the information available, the Commission considers that Intas will have the ability and incentive to maintain and develop the Out-licensing Divestment Business as a viable and active competitive force in competition with Teva and other competitors and to become independent of Teva with respect to the manufacturing of the Divested Products.

(e) Absence of prima facie competition problems

34. The transfer of the Out-licensing Divestment Business is not subject to any regulatory authorization, except from the buyer approval by the Commission.

35. The Transaction would bring about the following vertical and horizontal overlaps.

36. As for vertical overlaps, the Out-licensing Divestment Business only has sales to customers regarding molecule/country pairs for which Intas already has an on-market product for (i) *oxaliplatin* in the Czech Republic and in Germany as well as (ii) *alendronic acid* in the Netherlands. Given the limited combined market shares of Intas and the Out-licensing Divestment Business' licensees for these molecule/country pairs and the number and strength of active competitors, namely Accord Healthcare, Actavis, Ebewe, Hospira, Kabi Pharmacia, STADA, Teva, Sanofi-Aventis, Merck, Mylan, Medac, Egis, Bendalis, Omnicare, Onkovis, Haemato Pharm, Ribosepharm and Cancernova for *oxaliplatin* in the Czech Republic and in Germany as well as Mylan, Sandoz, Teva, Pharmachemie, Will, Actavis, Aurobindo, Bioeq Pharma, Bluefish, Centrafarm, Curaphar, MSD, Mibe, Osteonorm and Steovess for *alendronic acid* in the Netherlands, these overlaps would not create prima facie competition concerns.

37. As for horizontal overlaps, Intas only has outlicensing activities in the EEA for one molecule included in the Outlicensing Divestment Business, *oxaliplatin*. In view of the fact that 11 competitors, namely Fresenius Kabi, Hospira, Teva, Qilu, Sandoz, Sun Pharma, Mylan, Cadila Pharma, Pharmascience, Stragen and Medac, are active as outlicensors for *oxaliplatin*, this overlap would not create prima facie competition concerns.

38. 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 Out-licensing Divestment Business by Intas by a competent competition authority under applicable merger control rules.

Conclusion on the purchaser criteria

39. 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 Intas meets the purchaser criteria set out in Section E of the Commitments.

III. ASSESSMENT OF THE PROPOSED AGREEMENTS

40. 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.

41. 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 Outlicensing Divestment Business is sold in a manner consistent with the Commitments.

42. 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 Outlicensing Divestment Business is being sold in a manner consistent with the Commitments.

IV. CONCLUSION

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

44. 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.

45. 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.

46. This decision is based on Section B of the Commitments attached to the Commission Decision of 10 March 2016.

For the Commission

(Signed)
Johannes LAITENBERGER
Director-General