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: 23.12.2016

EUROPEAN COMMISSION

Brussels, 23.12.2016
C(2016) 9030 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 Where possible the information omitted has been replaced by ranges of figures or a general description.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 IE-UK Divestment Business following your letter of 19 October 2016, complemented on 24 October 2016 and 10 November 2016, the Trustee's opinion of 14 December 2016

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 the Merger Regulation,[1] 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 a substantial part of Allergan Generics' business in the United Kingdom ("UK") and Ireland ("IE-UK Divestment Businesses") to a single purchaser. The IE-UK Divestment

[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.

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Businesses is defined more specifically in Section B paragraphs 22 to 28 of the Commitments and Schedules E-1 to E-II and F-1 to F-2. More specifically, pursuant to paragraphs 21 to 28, the IE-UK Divestments Businesses include:

a. All Allergan Generics marketed products listed in Schedule E-I ("IE Marketed Divested Products") and Schedule F-I ("UK Marketed Divested Products") together with, for each of those products, the assets listed in Schedule G-I, and all Allergan Generics' pipeline products listed in Schedule E-II ("IE Pipeline Divested Products") and Schedule F-II ("UK Pipeline Divested Products"), together with, for each of those pipeline products, the assets described in Schedule G-II(1),

b. The personnel of Allergan Generics' business listed in Schedule E-III and Schedule F-III ("IE-UK Personnel"),

c. Allergan livery (pack design and artwork) in the UK and Ireland, and a licensing agreement, for a period of three years, on the Actavis brand,

d. A best effort obligation to transfer (i) the agreements between Allergan and wholesalers and logistics companies, (ii) the contracts for the supply of Active Pharmaceutical Ingredients (API) or excipients relating to the manufacturing of the IE-UK Divested Products, (iii) the private label agreement between Allergan and Almus in the UK and (iv) Allergan's UK Emergency Medicines Buffer Stock Tender Agreement,

e. Allergan Generics' Accumulator scheme in Ireland and the Accumulator scheme, Partner Pricing scheme and Allergan Buying Group Scheme in the UK,

f. All the intellectual property rights, marketing materials, databases and IT infrastructures, including websites, dedicated exclusively to the Allergan Generics' discount schemes in the UK and Ireland, as well as an arrangement to access the relevant IT infrastructure which would not be exclusively dedicated to Allergan Generics' discount schemes, until such date when the purchaser is able to set up its own infrastructure, and

g. Allergan Generics' manufacturing site located in Barnstaple ("Barnstaple Manufacturing Facility").

3. On 11 April 2016, after approval of the Commission, Teva appointed Duff&Phelps as the Monitoring Trustee (the "Trustee") under the terms of the Commitments.

4. On 25 October 2016, Teva submitted a request to modify the Commitments (the "Modification Request").[2] In relation to the IE-UK Divestment Businesses, Teva requested to remove 11 molecules from the list of 122 pipeline molecules to be divested (Schedules E-II and F-II) either because (i) Allergan Generics never had a pipeline project, (ii) Allergan Generics' pipeline project was cancelled for non-merger related reasons (in the normal course of business) before the Decision or

[2] The Commitments provide that "*the Commission may further, in response to a reasoned request from the Parties showing good cause waive, modify or substitute, in exceptional circumstances, one or more of the undertakings in the Commitments*" (paragraph 73).

(iii) Allergan Generics' pipeline projects development or in-licensing failed. Teva also requested to waive the supply arrangement and related supply assistance in relation to one other pipeline molecule in the UK for which it failed to secure a supply source. By the present Decision, the Commission does not take any position as to whether this Modification Request can be wholly or partly granted.

5. By letter of 19 October 2016, the Parties proposed Accord Healthcare Ltd ("Accord", UK), a subsidiary of Intas Pharmaceuticals Ltd ("Intas", India) for approval by the Commission as purchaser of the IE-UK Divestment Businesses and submitted the proposed Sale and Purchase Agreement together with a number of ancillary agreements dated 5 October 2016 ("Agreement dated 5 October 2016"). The Agreement dated 5 October 2016 and its amendments dated 13 December 2016 are referred to as the "Proposed Agreements".

6. On 24 October 2016, Teva submitted an analysis of the overlaps between the IE-UK Divestment Businesses and Intas' activities to complement its reasoned proposal.

7. On 25 October 2016, the Commission services of the Directorate General for Competition sent some questions to Teva in relation to the overlaps between the IE-UK Divestment Businesses and Intas' activities, to which Teva replied on 10 November 2016.

8. On 7 November 2016, the Trustee submitted an assessment of Intas' suitability as a purchaser and, in particular, indicated that Intas fulfils the criteria of the purchaser requirements in section E of the Commitments. On 10 December 2016, the Trustee complemented its assessment of Intas' suitability, with an analysis of the Proposed Agreements, and concluded that the Divestment Business would be sold in a manner consistent with the Commitments. The final version of the Trustee's reasoned opinion was provided on 14 December 2016.

II. ASSESSMENT OF THE PROPOSAL

9. 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 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.

10. 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

11. Intas is a pharmaceutical group founded in 1976 and headquartered in India. The group is active worldwide in the manufacturing, marketing, distribution and sale of finished dose pharmaceuticals, active pharmaceuticals ingredients ("API"), medical appliances and medical devices. Intas sells products in more than 70 countries and has 12 manufacturing sites worldwide, of which 6 currently have obtained European Good Manufacturing Practice (EU GMP) certification.

12. Accord is a wholly owned subsidiary of Intas, headquartered in the UK. Its presence in the UK goes back over a decade. Intas (*via* Accord) is active in the retail and hospital segments of the generic pharmaceuticals market, with a portfolio of 162 molecules in the UK and 108 molecules in Ireland. Intas owns two manufacturing sites in the UK (in Haverhill and Newcastle), of which one currently has EU GMP certification.

(a) Independence

13. 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 is no cross memberships in the management boards of the two companies.

14. Teva and Intas have the following commercial relationships: (a) Teva purchased finished dose products from Intas, for a total amount of USD [amount] million (less than [amount]% of Intas' revenues for FY 2016), (b) Intas purchases APIs from Teva, for approximately USD [amount] million in FY 2016 (also less than [amount]% of Intas' revenues) and (c) Intas' subsidiary, Astron, performs quality testing and product release services to Teva, generating GBP [amount] in FY 2016 (compared to Astron's revenues in the financial year 2015/2016 of GBP [amount]).

15. 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

16. Intas intends to finance the transaction (the consideration to Teva will amount to approximately GBP [amount]) with loan facilities up to GBP [amount] which have been secured and are to be provided by a consortium of banks.

17. Intas reported revenues of GBP [amount] for the year ending March 31, 2016 (FY 2016). This represents an increase of [amount]% compared to FY 2015. In terms of profitability, the EBITDA margin showed an increase from [amount]% in FY 2014 to [amount]% in FY 2016, which results in an increase in EBITDA (in absolute terms) of approximately [amount]% between FY 2014 and FY 2016. Intas had a Net Debt/EBITDA ratio of [amount] in 2015 (which was reduced even further to [amount] in 2016) and, as illustrated in the preceding paragraph, has access to committed loan facilities significantly in excess of the amount required for the Transaction.

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

(c) Expertise

19. Intas is a vertically integrated pharmaceutical company engaged in the manufacturing, marketing, distribution and sale of finished pharmaceutical and APIs worldwide. Its operations include in-house API production, research and development ("R&D"), regulatory, manufacturing, quality, supply chain, marketing and sales and pharmacovigilance functions.

20. In terms of R&D, Intas invests on average [amount]% of its revenues. Next to generics, the company focuses on novel and added value products. Intas' R&D personnel is composed of approximately [amount] staff.

21. In terms of manufacturing and technology transfer capabilities, Intas has a long lasting experience of manufacturing around the world and supplying into Europe. Intas' network is composed of 12 manufacturing sites, of which 6 have EU GMP approvals. Intas has 4,000 manufacturing employees, with significant technical transfer experience. Intas has extensive experience regarding technical transfers from external organizations into Intas-owned facilities or external contract manufacturing sites.

22. In Europe, Intas products are sold in around 30 countries, with 220 molecules registered, [amount] under registration and [amount] under development. Intas has a track record of successful approvals by regulatory agencies in Europe. According to IMS data, Intas is the number 17 generic pharmaceutical company on a pan European basis. Intas is aiming at entering the top 10 by 2020.

23. The UK was the first non-Indian market which Intas entered, and is the home of Accord's European headquarters. The UK is Accord's third largest market worldwide by turnover and second by staff numbers, and Accord is already among the 10 most important generic companies nationally.

24. In view of the above, the Commission considers that Intas is an established pharmaceutical company having the proven expertise to maintain and develop the IE-UK Divestment Businesses.

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

25. As part of the sale, Intas is acquiring the plant in Barnstaple, which currently manufactures [80-100] molecules (which account for almost all molecules currently manufactured at Barnstaple), representing GBP [amount] in revenues.[3] In addition, [160-180] molecules (GBP [amount] in revenues) are manufactured by third party contract manufacturers, whose contracts will be transferred to Intas. Intas will therefore have the ability and incentives to become independent with respect to the manufacture of [70-80]% (in number of molecules and in revenues) of the IE-UK Divestment Businesses as of the closing of the transaction.

26. As for the other molecules included in the IE-UK Divestment Businesses, Intas plans to transfer the production from Teva's site(s) to Barnstaple or to other Intas sites in the next three to five years as foreseen in the Commitments. This transfer

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3 All revenues figures in paragraphs 26-28 are for the period January to August 2016.

concerns [90-100] molecules (GBP [amount] in revenues). Intas has a dedicated experienced team to perform the transfers. Based on Intas' estimate, for [90-100]% of the technology transfers required, it has the capabilities in house so that the products will be transferred to Barnstaple or other site(s) of Intas. For the remaining [amount]%, Intas will reach out to third party contract manufacturers. The Monitoring Trustee also notes that Intas has the incentives to perform this process as soon as possible, since being fully in control of all the manufacturing provides it with numerous upsides such as cost competiveness, better market responsiveness, improved service levels and a simplified supply chain.

27. In addition, Teva and Intas have entered into discussions to plan manufacturing transfer projects from Barnstaple to Teva site(s) for molecules outside of the scope of the IE-UK Divestment Businesses ([0-10]molecules) and molecules within the scope of the IE-UK Divestment Businesses but sold by Teva outside the United Kingdom and Ireland. This transfer represents [50-60]molecules (GBP [amount] in revenues), and [amount]% of the Barnstaple plant's revenues. Intas mentions that it is essential to the Barnstaple plant's viability and competitiveness to offset the volume that will be lost as Teva transfers production out. In view of this, Intas argues there is an additional strong incentive to transfer production into Barnstaple where possible and as quickly as possible. Out of the [90-100]molecules for which a transfer from Teva's site(s) will be undertaken, [70-80]molecules (GBP [amount] in revenues) will be transfered to Barnstaple, which will offset the revenue loss of transfers out of Barnstaple. Taking into account these parallel transfers in Barnstaple, and the other elements above, the manufacturing plant in Barnstaple is likely to remain viable over time. The Trustee shares this conclusion.

28. In view of the above, Intas will have the ability and incentives to become independent with respect to the manufacturing of the Divested Products.

(e) Ability and incentive to maintain and develop the IE-UK Divestment Businesses

29. The acquisition of the IE-UK Divestment Businesses fits to Intas' plan to expand its activities in the European pharmaceutical retail market and to complement its developed hospital business.

30. As part of the transaction, Intas is acquiring Allergan Generics' manufacturing plant in Barnstaple, UK. According to Intas, this plant and its dedicated UK and Ireland supply chain will add strategic elements to its current manufacturing network with a close to market service orientation for oral products in the UK and Ireland. The company will be able to react faster to market dynamics and volatilities. Furthermore, it would allow a stronger customer focus, being able to package to market specific delivery, which is considered by Intas to be one of the success factors of the IE-UK Divestment Businesses. Intas currently operates one manufacturing site in Haverhill and a European test and release laboratory in London, and has recently invested to reinstate a facility in Newcastle. However, Intas' Haverhill plant is mainly used for […], while Intas' Newcastle plant specialises in […]. These plants are therefore complementary to Barnstaple's capabilities.

31. Intas is also acquiring Allergan Generics' full commercial organization in the UK and Ireland, including management and sale force. The (management) team is encouraged to continue the Divestment Businesses' strategy going forward. As per Intas, one of the most attractive elements of the IE-UK Divestment Businesses is

the fact that Allergan Generics runs loyalty direct-to-pharmacies schemes,[4] which is part of the Divestment Business. Intas' portfolio in the UK and Ireland is also largely complementary to this scheme. Indeed, post-acquisition, Intas will broaden the scope of its portfolio from [number] to [number] molecules in the UK and from [number] to [number] in Ireland. The discount scheme will contain [number] of the [number] largest pharmaceutical products (which compares to 850 out of 1,000 for Teva's own scheme). The transaction will strengthen Intas' presence in the retail channel from a current [30-40]% coverage to [60-70]% post-Closing. Intas will also be able to maintain the IE-UK Divestment Businesses marketability and competitiveness over time with the pipeline products included in the sale as well as its own pipeline products over the next 3 years.

32. As to Intas' financial projections, the Trustee carried out an analysis of the viability of the IE-UK Divestment Businesses globally and more granularly of the individual products concerned. The Trustee concluded that Intas' projections are achievable and that its incentives to maintain and develop the IE-UK Divestment Businesses are clearly laid out. For the vast majority of the molecules, Intas' projections show a clear incentive to continue marketing the products. Although a limited number of molecules may not be well performing over time (which is normal in the product life cycle that characterises the generics industry), Intas will have the incentives to continue marketing as many products as possible for the continuity of its attractive discount schemes, which according to Intas is a key factor of success of the business. In addition, the Monitoring Trustee considers that each of these molecules is interesting for Intas going forward also because of (at least) one of the following reasons: Intas expects an improvement in its margin over time through optimisation of its manufacturing network; the molecule is needed to keep the attractiveness of the scheme and/or the molecule generates volume and therefore economies of scale in Intas' manufacturing plants.

33. In view of the above, based on the information available, the Commission considers that Intas will have the ability and incentive to maintain and develop the IE-UK Divestment Businesses as a viable and active competitive force in competition with Teva and other competitors.

(f) Absence of *prima facie* competition problems

34. In its reasoned proposal, Teva made an analysis of the overlaps between Intas and the IE-UK Divestment Businesses in the UK and Ireland. This analysis was performed at molecule and galenic forms levels, covering the overlaps between (a) on-market vs on-market products, (b) pipeline versus on-market products and (c) pipeline vs pipeline products. Teva provided the sales figures of Intas and the IE-UK Divestment Businesses in value and volume in 2015 for all overlaps.

35. Based on these data, Teva identified 5 molecules (all on market vs on market overlaps) for which there could be competitive concerns, in view of the combined market share of Intas and the IE-UK Divestment Business, the increment of market share and/or the number of remaining competitors. The Commission reviewed the data provided by Teva and after reviewing additional clarifications provided by

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4 See e.g. paragraphs 314-315 of the Decision.

Teva, agreed that prima facie competition concerns may arise in relation to the five molecules identified.

36. Under the Proposed Agreements, these molecules are carved out from the sale.

37. Pursuant to paragraph 46 of the Commitments, "*the Commission may approve the sale of the Divestment Businesses without one or more Assets or parts of the Personnel, or by substituting one or more Assets or parts of the Personnel, if this does not affect the viability and competitiveness of the Divestment Businesses after the sale, taking into account the proposed purchaser(s).*"

38. In the Decision, among the five molecules concerned, the Commission identified serious doubts as to the compatibility of the transaction with the internal market for one molecule (*doxorubicin* in Ireland). The other four molecules were part of the Commitments so as to solve the Commission's serious doubts in the markets for the wholesale of generics in the UK and Ireland.

39. Teva argues that, to the extent Intas already has a significant coverage in the UK and Ireland, the five molecules carved out do not in any way affect the viability and competitiveness of the Divestment Business and are not necessary to solve the Commission's serious doubts in relation to the markets for the wholesale of generics in the UK and Ireland. In particular, Teva submits that the combined entity (Intas and the IE-UK Divestment Businesses) will reach a wider coverage in terms of number of molecules, sales and margins than the full IE-UK Divestment Businesses. However, to solve the serious doubts identified at molecule level for *doxorubicin* in Ireland, Teva commits to divest this molecule in Ireland to another purchaser.

40. The Monitoring Trustee explained that, on the basis of information available, these molecules represent only [0-5]% of the revenues of the Irish and [0-5]% of the UK operations of the IE-UK Divestment Businesses. Therefore the Monitoring Trustee concludes that the absence of these molecules would not affect the viability and competitiveness of the Divestment Businesses. In addition, the Monitoring Trustee indicates that none of these molecules are manufactured in Barnstaple, so that there is no impact on the manufacturing plant' viability.

41. As spelled out in the Decision, the assets included in the IE-UK Divestment Businesses should enable the purchaser to replicate the direct-to-pharmacy model of Allergan Generics, such as the Accumulator Scheme, and benefit from similar economies of scale and scope as each party pre-merger. In light of Intas' current coverage in the UK and Ireland, and the fact that it is already supplying the above-mentioned five molecules in the UK and Ireland, the Commission concludes that their exclusion does not affect the viability and competitiveness of the IE-UK Divestment Businesses and addresses the Commission serious doubts identified in the Decision provided that Teva will sell *doxorubicin* in Ireland to another purchaser.

42. After exclusion of the five above-mentioned molecules, the Commission considers that the acquisition by Intas of the IE-UK Divestment Business does not raise *prima facie* competitive concerns.

43. 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 Intas by a competent competition

authority under applicable merger control rules. Based on the information available, the acquisition by Intas of the IE-UK Divestment Business does not trigger mandatory notification requirements, but reaches the thresholds of the voluntary notification to the UK Competition and Market Authority.

III. ASSESSMENT OF THE PROPOSED AGREEMENTS

44. 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.

45. The Trustee concluded that the IE-UK Divestment Businesses are sold in a manner consistent with the Commitments, and made a number of observations.

46. First, as explained above, some of the molecules listed in the Commitments are not included in the Proposed Agreements:

    a. In relation to the molecules possibly raising *prima facie* competitive concerns, as explained above, the Commission concludes that their exclusion is in line with paragraph 46 of the Commitments, provided that Teva will sell *doxorubicin* in Ireland to another purchaser.

    b. In relation to the molecules covered by Teva's Modification Request, Teva agreed to divest all the existing assets of the pipeline products if the Commission was not to grant, wholly or partly, its Modification Request. Whether these assets are ultimately divested or not does not diminish the overall viability of the IE-UK Divestment Businesses.

47. In view of the above, the Commission agrees with the exclusion and/or substitution of these assets, in line with paragraph 46 of the Commitments.

48. Second, some of the assets included in the Commitments do not have specific references in the Proposed Agreements.

49. However, as explained by the Trustee in its report, even if the assets are not specifically mentioned in the Proposed Agreements, they are owned by Actavis UK whose shares are sold to Intas as part of the Proposed Agreements. This is the case, for instance for the Almus private label contract in the UK. Moreover, the business activities and assets generated in the normal course of business by the divested assets and personnel post-signing of the Commitments, during the hold separate period, are also part of Actavis UK. In this regard the Commission notes that pursuant to the Proposed Agreements, Intas will retain additional pipeline products developed by the HSM team after the signing of the Commitments.

50. Third, the Trustee raised one element of on-going discussion between the Parties on the interpretation of the Proposed Agreements in relation to Teva's ability to continue out-licensing dossiers for molecules included in the IE-UK Divestment Businesses. Pursuant to Schedule G-I, for all marketed products, Teva should divest among other assets the marketing authorization and registration dossier. Pursuant to paragraph 5 of the Commitments, to ensure the structural effects of the Commitments, Teva should not for a period of 10 years acquire the possibility of exercising influence over the whole or part of the Divestment Businesses.

51. The Commission therefore considers that, since the Proposed Agreements comprise all the assets listed in Schedule G-I and prevent Teva from re-applying for a marketing authorization based on the divested dossier, the Proposed Agreements are in line with the Commitments.

52. Finally, the Proposed Agreements provide that in case of conflicts between their provisions and the provisions of the Commitments, including the interpretation thereof, the latter should prevail.

53. In view of the above and information available, the Commission concludes that the Divestment Business is being sold in a manner consistent with the Commitments.

IV. CONCLUSION

54. On the basis of the above assessment, the Commission approves Intas as a suitable purchaser of the IE-UK Divestment Businesses for the above-mentioned reasons, subject to Teva divesting *doxorubicin* and its related assets in Ireland to another purchaser.

55. 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.

56. 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 its Commitments.

57. 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