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: 15.9.2017

EUROPEAN COMMISSION

Brussels, 15.9.2017
C(2017) 6328 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 Where possible the information omitted has been replaced by ranges of figures or a general description.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 Rivopharm as purchaser of the Divestment Business following your letter of 28 February 2017, complemented on 15 September 2017 and the Trustee's opinion of 15 September 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)

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

(collectively the "*On-market-to-Pipeline Divestment Businesses*") and for all 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 allocated each of the products in Schedule A, Schedule B-I and Schedule C-I and associated assets to one of six baskets to be sold to one or several purchasers based mainly on geographic criteria. The Divestment Business in the present decision includes the acquisition of Basket 1 (Nordics countries), 2 (Baltics countries) and 4 (Western Europe). The basket for Nordics countries (Basket 1) contains mainly products sold in Denmark, Finland, Sweden and Norway. The basket for Baltics countries (Basket 2) contains mainly products sold in Estonia, Latvia, and Lithuania. The basket for Western Europe (Basket 4) contains mainly products sold in Germany, Italy, the Netherlands, France and Austria.[2] The table in Annex 1 lists the products included in Baskets 1, 2 and 4 ("the Divested Products") included in the Divestment Business.

6. On 24 November 2016, Teva signed an Asset and Purchase Agreement ("APA") and related agreements which were amended on 20 January 2017 and on 13 September 2017 (the "***Proposed Agreements***") regarding the acquisition of the Divestment Business by Rivopharm S.A. ("***Rivopharm***" or the "***Purchaser***").

7. By letter of 28 February 2017, complemented on 15 September 2017, Teva proposed Rivopharm for approval by the Commission as purchaser of the Divestment Business and submitted the Proposed Agreements.

8. On 15 September 2017, the monitoring trustee (Duff & Phelps, hereinafter referred to as the "Trustee") submitted a reasoned opinion regarding Rivopharm's 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 Agreements, the Divestment Business would be sold in a manner consistent with the Commitments.

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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 Divestment Businesses also include molecules in other countries; this is the case when the molecules concerned are marketed in more than one region and had the highest sales in Nordics, Baltics and/or Western Europe.

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 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,

10. 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

11. Founded in 1961 and headquartered in Lugano, Switzerland, Rivopharm currently owns a portfolio of approximately [25-35] registered International non-proprietary names (INNs) across Europe and had revenues amounting to around EUR [35-45] million in 2016. Rivopharm currently employs 148 employees.

12. Rivopharm is primarily engaged in the development and manufacturing of generic pharmaceutical products. In 2015, Rivopharm decided to become a fully integrated pharmaceutical company with sales through Europe and beyond. Thus, while Rivopharm originally operated as a contract manufacturing organisation ("CMO"), it has increasingly developed its production of own generic products.

Assessment of the purchaser criteria

(a) Independence from Teva

13. Teva does not have any ownership stake in Rivopharm and *vice versa*. There are no cross-memberships in the management boards of the two companies. Additionally, Teva has no joint venture or alliance with Rivopharm. Furthermore, Teva and Rivopharm have not acted as counterparties in any transactions between March 2014 and March 2017.

14. With respect to commercial operations, the business agreements between Teva and Rivopharm amount to less than 7.5% of Rivopharm's revenues for the financial year 2016 (FY 2016). Additionally, these agreements relate to Rivopharm's CMO

operations, which have a lower gross margin than Rivopharm's other business operations.

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

(b) Financial resources

17. Rivopharm intends to finance the acquisition of the Divestment Business from Teva with a loan provided by its shareholders.

18. Rivopharm reported revenues of EUR [35-45] million for FY 2016. Between 2013 and 2017, Rivopharm's revenues have grown steadily. In terms of profitability, their operating income has significantly increased between 2013 and 2016. In addition there has also been an annual growth of Rivopharm's total assets between 2013 and 2016.

19. The Trustee also noted that Rivopharm presented […], which, in view of the […] realised between [date] and [date], raised questions about […]. In that context, […]. Rivopharm also explained that its main creditors are its shareholders, and that in these circumstances the provision of additional loans by shareholders is similar to the provision of equity from the point of view of assessing Rivopharm's leverage. If the financial position of Rivopharm is assessed at group level jointly with the financial position of its shareholders/creditors, it appears solid and capable of financing the acquisition and development of the Divestment Business. Based on these explanations and guarantees, the Trustee expects that Rivopharm will be able to both finance the Transaction and subsequently develop the Divestment Business.

20. The Commission shares the assessment above and considers that Rivopharm has the financial resources to maintain and develop the Divestment Business.

(c) Proven expertise

23. Rivopharm spends between EUR [2-3] million and EUR [3-4] million annually on research and development (R&D) activities.

24. Rivopharm has long-lasting experience in manufacturing, especially on manufacturing solid-oral forms. Thanks to a recent expansion, Rivopharm's manufacturing facility in Lugano (Switzerland) has a capacity of approximately [1-3] billion units per year, of which in 2016 only approximately [20-30] % was utilised. According to Rivopharm, the technology transfer due to the purchase of the Divestment Business would result in an additional manufacturing volume of [150-160] million units annually.

25. Additionally, Rivopharm indicated that it intends to enhance its manufacturing capabilities through additional investments in the near term. Rivopharm also intends to optimise its current production area and set up a new analytical laboratory. In the medium term, it also plans on acquiring new manufacturing equipment and additional chromatographic and dissolution systems.

26. Rivopharm has created a network of partners which supports the company in its development process, scale-up activities and formulation and analytical troubleshooting.

27. According to the Trustee, Rivopharm has some relevant experience with respect to all the types of technology transfer activities required to execute the integration of the Divestment Business. The European Commission concurs with this assessment.

28. As a consequence of the Divestment Business' purchase, Rivopharm plans to perform [40-60] technology transfers to either its manufacturing site (for [20-30] products) or the manufacturing sites of external CMOs (for [20-40] products).[3] For the transfers to external CMOs, Rivopharm will receive support from technology transfer employees of the external CMOs. This will reduce the workload for Rivopharm's technology transfer teams. Additionally, Rivopharm plans on setting up a dedicated technology transfer unit and therefore plans on hiring additional employees for this unit.

29. Rivopharm expects to be able to successfully perform the technology transfers within 1.5 years for a substantial part of the products transferred. In order to do so, Rivopharm intends to set up a dedicated technology transfer unit composed of [5-10] of its current employees and [10-20] additional employees Rivopharm intends to hire.

30. The Trustee noted that the timeline of 1.5 years for the technology transfer seems ambitious and that the technology transfer team is not yet operational as twelve employees still need to be hired. Following the Trustee's concerns regarding the technology transfer, Teva has agreed to the secondment of three of its employees on a full time basis and for a maximum period of 5 years to Rivopharm's technology transfer plan at Teva's reasonable costs. The secondment includes one project manager whose responsibilities will notably include identifying and agreeing contractual terms with the relevant manufacturers and overseeing the execution of any technology transfer plan.

31. The Trustee noted that, in view of Rivopharm's plans and experience as well as in view of Teva's agreement to second personnel, Rivopharm appears to have the ability to perform the full technology transfers within the timeline of the Commitments, that is three plus two years. The European Commission concurs with this assessment.

32. Concerning its sales and marketing capabilities, Rivopharm owns several legal entities located in Germany, Lithuania and the United Kingdom from which it intends to distribute the products purchased to several European countries. Rivopharm intends to hire an additional [20-40] employees spread over six European countries to its current workforce of 148 employees. Additionally, Rivopharm has conditionally signed distributor agreements with distributors in countries where (i) the Divestment Businesses generate revenues and where (ii) Rivopharm has no own presence and does not intend to obtain a presence. For instance, Rivopharm signed an agreement with GxMed Nordics for the Nordics (Denmark, Finland, Sweden and Norway). The Trustee considered that the distributors chosen, as well as their parents companies, are suitable in terms of distribution and marketing capabilities, financially able and incentivised to execute the distributor agreement with Rivopharm. The distributors and their parent companies are also sufficiently independent from Teva.

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[3] The other 90 products (SKUs) will continue to be produced by the same CMO as before the divestment.

33. The Commission shares the assessment above and considers that Rivopharm is a generic company already active in the EEA which has the incentive and ability to become independent from Teva with respect to the manufacturing of the Divested Products. The Commission also considers that based on its capabilities, experience and plans described above, Rivopharm has the expertise and ability to maintain and develop the Divestment Business as a viable and competitive force.

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

35. The acquisition by Rivopharm of the Divestment Business fits well within its strategic rationale to evolve from a CMO to a fully integrated pharmaceutical company. As part of this strategic rationale, Rivopharm opened in 2013 an office in the United Kingdom, acquired in 2016 Holsten Pharma GmbH to facilitate the marketing of its products in Germany, acquired in 2017 Sanoswiss active in the Baltics, and concluded several distribution agreements in other countries.

36. Rivopharm provided an overview of its financial projections for the Divestment Business. On an aggregated level, the net sales of the Divestment Business are expected to grow from approximately EUR [20-30] million in 2017 to EUR [30-40] million in 2021, which implies an annual growth rate of approximately [5-10]%. Additionally, Rivopharm expects gross margins and EBITDA margin to amount to approximately [70-80]% and [30-40]% during the projection period.

37. Rivopharm also provided an overview of its financial projections for the different countries in which the Divestment Business operates. In most of these countries, Rivopharm expects the Divested Products to generate satisfactory levels of profitability.

38. The Trustee notes that Rivopharm business plans seem generally ambitious. However, the Trustee considers that the Divestment Business will cover the budgeted expenses relatively easily and is therefore likely to remain sufficiently attractive for Rivopharm in the long term. The Trustee adds that based on its business plans, the incentives of Rivopharm to maintain and develop the Divestment Business and the Divested Products are sufficiently laid out.

39. The Commission shares the assessment above and considers that Rivopharm has sufficient incentives to maintain and develop the Divestment Businesses, including each of the Divested Products, as a viable and active competitor post-closing.

(e) Absence of prima facie competition problems

40. The transfer of the Divestment Business is not subject to any regulatory authorisation, except for the buyer approval by the Commission.

41. In its reasoned proposal, Teva presented an analysis of the overlaps between Rivopharm and the Divestment Business. This analysis was performed at molecule and galenic form levels. The result of this analysis is that no horizontal overlap exists. With respect to vertical overlaps, Rivopharm does not have any outlicensing activities for the molecule/country pairs which are included in the Divestment Business. However, a vertical overlap exists for *gabapentin* in Sweden as Rivopharm supplies *gabapentin* to one customer which sells the product under its own brand and livery. This vertical overlap is however unlikely to give rise to any prima facie competition concern for the following reasons. First, Rivopharm's

customer is the marketing authorisation holder and thus is the one selling this product. Second, in 2016, the combined market share of Rivopharm's product and the Divested Product was below the 30% threshold both in value (21%) and volume (14%). Third, strong competitors are present on the market, notably Teva (with a market share in value of 37%) and Novartis (with a market share in value of 22%).

41. In view of the above, the Commission concludes that prima facie competitive concerns do not arise.

42. 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 Rivopharm by a competent competition authority under applicable merger control rules.

Conclusion on the purchaser criteria

43. 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 Rivopharm meets the purchaser criteria set out in Section E of the Commitments.

III. ASSESSMENT OF THE PROPOSED AGREEMENTS

43. As to the compliance of the Proposed Agreements with the Commitments, the Trustee reviewed the tracker tables 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.

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

45. The Commission shares the assessment above and concludes that the Divestment Business is being sold in a manner consistent with the Commitments.

IV. CONCLUSION

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

49. 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.

50. 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

Annex 1 – List of Divested Products

Country	Molecule	Schedule of the Commitments
Austria	Betahistine	Schedule A
	Clarithromycin	Schedule A
	Indapamide	Schedule A
	Repaglinide	Schedule A
	Carbidopa, Entacapone Levodopa	Schedule B-II
	[…]	Schedule B-II
	[…]	Schedule B-II
	[…]	Schedule B-II
	[…]	Schedule B-II
	[…]	Schedule B-III
	Hydrochlorothiazide Losartan	Schedule C-I
Croatia	Repaglinide	Schedule C-I
Czech Republic	Fosinopril	Schedule C-I
	[…]	Schedule B-III
Denmark	Atorvastatin	Schedule A
	Epirubicin	Schedule A
	Eplerenone	Schedule A
	Felodipine	Schedule A
	Finasteride	Schedule A
	Indapamide	Schedule A
	Ipratopium Bromide Salbutamol	Schedule A
	Lansoprazole	Schedule A
	Latanoprost	Schedule A
	Lercanidipine	Schedule A
	Montelukast	Schedule A
	Moxonidine	Schedule A
	Olanzapine	Schedule A
	Orlistat	Schedule A
	Pantoprazole	Schedule A
	Repaglinide	Schedule A
	Tolterodine	Schedule A
	Zolmitriptan	Schedule A
	Capecitabine	Schedule B-I
	[…]	Schedule B-II
	Carbidopa, Entacapone Levodopa	Schedule B-II
	[…]	Schedule B-II
	[…]	Schedule B-II
	[…]	Schedule B-III
	Lercanidipine	Schedule C-I

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

Country	Molecule	Schedule of the Commitments
Estonia[4]	Azithromycin	Schedule A
	Olanzapine	Schedule A
	Sertraline	Schedule A
	Trimetazidine	Schedule A
	[…]	Schedule B-I
	[…]	Schedule B-II
Finland[5]	Bisoprolol	Schedule A
	Candesartan cilexetil Hydrochlorothiazide	Schedule A
	Cetirizine	Schedule A
	Desloratadine	Schedule A
	Diazepam	Schedule A
	Donepezil	Schedule A
	Dorzolamide	Schedule A
	Epirubicin	Schedule A
	Escitalopram	Schedule A
	Felodipine	Schedule A
	Ibandronic acid	Schedule A
	Isotretinoin	Schedule A
	Ketoconazole	Schedule A
	Letrozole	Schedule A
	Levocetirizine	Schedule A
	Loratadine	Schedule A
	Omeprazole	Schedule A
	Simvastatin	Schedule A
	Tamsulosin	Schedule A
	Tolterodine	Schedule A
	Zolpidem	Schedule A
	[…]	Schedule B-II
	[…]	Schedule B-II
	Mometasone	Schedule B-II
	[…]	Schedule B-II
	Donepezil	Schedule C-I
	[…]	Schedule B-III
France[6]	[…]	Schedule B-II
	Fluvastatin	Schedule C-I
	Fosinopril	Schedule C-I

4 The Commitments also include the following marketed molecule for Estonia, which is part of another basket that will be sold to another purchaser: Risedronic Acid (Basket 5 Risedronic Acid and EEA Pipelines).

5 The Commitments also include the following marketed molecule for Finland, which is part of another basket that will be sold to another purchaser: Risedronic Acid (Basket 5 Risedronic Acid and EEA Pipelines).

6 The Commitments also include the following marketed molecules for France, which are part of another basket that will be sold to another purchaser: Calcium, Calcium Colecalciferol (Basket 6 Orocal), Risedronic Acid (Basket 5 Risedronic Acid and EEA Pipelines).

Country	Molecule	Schedule of the Commitments
	Hydrochlorothiazide	
Germany[7]	[…]	Schedule B-II
	Finasteride	Schedule C-I
	Fluvastatin	Schedule C-I
	Fosinopril Hydrochlorothiazide	Schedule C-I
Hungary	Epirubicin	Schedule A
	Fosinopril, Hydrochlorothiazide	Schedule A
	Ambroxol	Schedule B-I
	Atorvastatin	Schedule C-I
	[…]	Schedule B-III
Italy[8]	Olanzapine	Schedule C-I
Ireland	Doxorubicin	Schedule E
Latvia[9]	Azithromycin	Schedule A
	Bicalutamide	Schedule A
	Citalopram	Schedule A
	Paclitaxel	Schedule A
	Paracetamol	Schedule A
	[…]	Schedule B-I
Lithuania[10]	Atenolol	Schedule A
	Azithromycin	Schedule A
	Bicalutamide	Schedule A
	Carbamazepine	Schedule A
	Fosinopril	Schedule A
	Mirtazapine	Schedule A
	Omeprazole	Schedule A
	[…]	Schedule B-I
Netherlands[11]	Captopril, Hydrochlorothiazide	Schedule C-I
	Famciclovir	Schedule C-I

7 The Commitments also include the following marketed molecule for Germany, which is part of another basket that will be sold to another purchaser: Risedronic Acid (Basket 5 Risedronic Acid and EEA Pipelines).

8 The Commitments also include the following marketed molecules for Italy, which is part of another basket that will be sold to another purchaser: Risedronic Acid (Basket 5 Risedronic Acid and EEA Pipelines).

9 The Commitments also include the following marketed molecules for Latvia, which are part of another basket that will be sold to another purchaser: Docetaxel, Doxorubicin, Oxaliplatin and Topotecan (Basket 3 Central Eastern Europe).

10 The Commitments also include the following market molecule for Lithuania, which is part of another basket that will be sold to another purchaser: Doxorubicin (Basket 3 Central Eastern Europe).

11 The Commitments also include the following marketed molecules for the Netherlands, which are part of another basket that will be sold to another purchaser: Risedronic Acid (Basket 5 Risedronic Acid and EEA Pipelines), and Methotrexate (Basket 6 Orocal).

Country	Molecule	Schedule of the Commitments
	Fosinopril	Schedule C-I
	Glimepiride	Schedule C-I
	Hydrochlorothiazide Lisinopril	Schedule C-I
	Ketoconazole	Schedule C-I
	Lercanidipine	Schedule C-I
	Ramipril	Schedule C-I
	Desloratadine	Schedule C-I
	Flucloxacilin	Schedule C-I
Norway	Diclofenac	Schedule A
	Escitalopram	Schedule A
	Methotrexate	Schedule B-I
	[…]	Schedule B-III
Poland	Tolterodine	Schedule A
	[…]	Schedule B-III
	[…]	Schedule B-II
Portugal	Fluvastatin	Schedule C-I
Romania	[…]	Schedule B-I
	[…]	Schedule B-II
Slovakia	Fosinopril	Schedule C-I
Slovenia	Epirubicin	Schedule A
Sweden[12]	Alfuzosin	Schedule A
	Carboplatin	Schedule A
	Diclofenac	Schedule A
	Epirubicin	Schedule A
	Felodipine	Schedule A
	Gabapentin	Schedule A
	Hydrochlorothiazide Valsartan	Schedule A
	Ipratropium Bromide Salbutamol	Schedule A
	Doxorubicin	Schedule A
	Pioglitazone	Schedule A
	Pravastatin	Schedule A
	Simvastatin	Schedule A
	Terbinafine	Schedule A
	Tolterodine	Schedule A
	Zolmitriptan	Schedule A
	[…]	Schedule B-I
	Carbidopa, Entacapone Levodopa	Schedule B-II
	[…]	Schedule B-III
	Loratadine	Schedule C-I

[12] The Commitments also include the following marketed molecules for Sweden, which are part of another basket that will be sold to another purchaser: Risedronic Acid (Basket 5 Risedronic Acid and EEA Pipelines).

Country	Molecule	Schedule of the Commitments
United Kingdom	Famciclovir	Schedule C-I
Cyprus	[…]	Schedule B-III
Malta	[…]	Schedule B-III