EUROPEAN COMMISSION

DG Competition

# *Case M. 7559 – Pfizer / Hospira*

Only the English text is available and authentic.

## REGULATION (EC) No 139/2004

## MERGER PROCEDURE

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Purchaser approval - Art. 6(1)(b) in conjunction with 6(2)

Date: 31.05.2016

EUROPEAN COMMISSION

Brussels, 31.05.2016
C(2016) 3441 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 Where possible the information omitted has been replaced by ranges of figures or a general description.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

MERGER PROCEDURE

IMPLEMENTATION OF COMMITMENTS

**To the notifying party**:

Dear Sir/Madam,

**Subject:** **Case M.7559 – Pfizer / Hospira**
**Approval of Hikma Farmacêutica (Portugal) S.A. as purchaser of Sterile Injectables Divestment Businesses following your letter of 8 March 2016 and the Trustee's opinion of 14 April 2016**

## I. FACTS AND PROCEDURE

1. By decision of 4 August 2015 ("the Decision") based on Article 6(1)b in connection with Article 6(2) of Council Regulation (EEC) No 139/2004 of 20 January 2004 on the control of concentrations between undertakings,[1] the Commission declared the operation by which the undertaking Pfizer Inc. ("Pfizer", United States), acquired sole control of the whole of the undertaking Hospira Inc. ("Hospira", United States) (the "Transaction") compatible with the internal market and with the EEA Agreement, subject to full compliance with the conditions and obligations laid down in the commitments annexed to the Decision (the "Commitments").

2. In particular, the Commitments provide that Pfizer will divest, amongst others, the rights, title and interests, including the right to develop, manufacture and use, in the following molecules in the following countries:

    a. Pfizer's rights to *carboplatin* in Belgium and *vancomycin* in Ireland;

[1] OJ L 24, 29.1.2004, p. 1-22 ("the Merger Regulation").

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b. Hospira's rights to *cytarabine* in Belgium, Italy, Portugal and Sweden; to *epirubicin* in Austria, Belgium, Italy, the Netherlands and Spain; to *irinotecan* in Belgium, the Czech Republic and Italy; and to *voriconazole* in the EEA.

3. These businesses will together be referred to as the "Sterile Injectables Divestment Businesses".

4. In line with Section B and Schedules 2 to 7 of the Commitments, the Sterile Injectables Divestment Businesses include in particular product inventories, sales and promotional materials existing at the time of divestment; related contracts, customer records, tender information etc.; current and pending marketing authorisations including all relevant dossiers, licenses for all relevant intellectual property rights; trademarks and, at the option of the purchaser, transitional manufacturing or supply agreements and transitional distribution agreements.

5. By letter of 8 March 2016, the Parties proposed Hikma Farmacêutica (Portugal) S.A. ("Hikma") for approval by the Commission as purchaser of Sterile Injectables Divestment Businesses and submitted the proposed Asset Purchase and Licence Agreement and related ancillary agreements (the "Proposed Agreements").

6. On 14 April 2016, the Monitoring Trustee, CompetitionRx, member of Mazars group of companies (the "Trustee"), submitted its reasoned opinion on Hikma's suitability as a purchaser of the Sterile Injectables Divestment Businesses and, in particular, indicated that Hikma fulfils the criteria set out in Section D of the Commitments. In this reasoned opinion, the Trustee also indicated that, on the basis of the Proposed Agreements, the Sterile Injectables Divestment Businesses would be sold in a manner consistent with the Commitments.

## II. ASSESSMENT OF THE PROPOSAL

7. As set out in Section D of the Commitments, in order to be approved by the Commission, the purchaser of the Sterile Injectables Divestment Businesses must fulfil the following criteria:

   a. the purchaser shall be independent of, and unconnected to, Pfizer and its affiliated undertakings (this being assessed having regard to the situation following the divestiture);

   b. the purchaser shall have the financial resources, proven expertise and incentive to develop the Sterile Injectables Divestment Businesses as a viable and active competitive force in competition with Pfizer and other competitors;

   c. the acquisition of the Sterile Injectables Divestment Businesses by the purchaser must neither be likely to create, in light of the information available to the Commission, *prima facie* competition concerns nor give rise to a risk that the implementation of the Commitments will be delayed. In particular, the purchaser must reasonably be expected to obtain all necessary approvals from the relevant regulatory authorities for the acquisition of the Sterile Injectables Divestment Businesses.

8. This section provides a short description of the purchaser, as well as the Commission's assessment of its suitability in view of these criteria.

**Description of the purchaser**

9. Hikma is active in the development, manufacturing and marketing of branded and non-branded generics with around 7 000 employees worldwide and operations in more than 50 countries. It has 27 manufacturing facilities in 11 different countries. It is a quoted company with listings on the London Stock Exchange and Nasdaq Dubai. Hikma's current market value is USD 6.3 billion.

10. Hikma has a historic focus in Middle East and North Africa (46% of 2015 sales) and in the US (48% of 2015 sales), while 6% of its sales were generated in Europe.

11. In 2015, approximately half of Hikma's revenues were made in the injectables business. Hikma is active in the manufacturing and marketing of injectables and operates manufacturing facilities in the United States, Portugal, Germany and Italy. Hikma's portfolio of injectables covers various therapeutic categories including oncology, anti-infectives, pain management, anaesthetic and central nervous system.

**Independence from Pfizer**

12. There are no cross-shareholdings between Pfizer and Hikma, and no shareholders hold more than 5% of both Pfizer and Hikma's stock.

13. Furthermore, Hikma and Pfizer do not share any executive or non-executive directors and there are no joint ventures or entities in which both Hikma and Pfizer maintain a shared interest.

14. Finally, the existing commercial relationships between Hikma and Pfizer[2] are not material and have been concluded in the ordinary course of business and at arms-length.

15. In light of the above, the Commission considers that Hikma is independent of and unconnected to Pfizer.

**Financial resources, proven expertise and incentive to maintain and develop the Sterile Injectables Divestment Businesses as a viable and active competitor**

16. In 2015, Hikma realised sales worth USD 1.44 billion. The company's net debt amounts to less than 10% of the market value of the company's equity. While European sales of injectables constitute only […]% of Hikma's injectables sales, in 2015 they exceeded USD […] million.

17. The company's balance sheet shows shareholders' equity of approximately USD 1.4 billion and nearly USD 0.6 billion of cash (following a successful bond issue in 2015) giving a net debt of USD 135 million, less than 10% of shareholders' funds.

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2 […].

18. The purchase price for the Sterile Injectables Divestment Businesses is […]. The Sterile Injectables Divestment Businesses consist of a portfolio of five marketed generic compounds and one product to be launched (*voriconazole*). Hikma already manufactures and sells four out of the five marketed products (except for *cytarabine*[…]. Hikma has a direct commercialisation presence in six countries, as well as partnerships and distribution agreements in the remaining three countries in which the Sterile Injectables Divestment Businesses are currently present.

19. Hikma envisaged a cost of USD […] for the process of obtaining the regulatory approvals and has earmarked an additional EUR […] for transitional services and manufacturing transfer costs. The overall cost for the purchase and pursuit of the Sterile Injectables Divestment Businesses is small for a company the size of Hikma.

20. The injectables business is Hikma's largest business area, representing 49% of the group's revenue. Through organic growth and acquisitions, namely of Baxter's MultiSource Injectables in 2011 and of Bedford Laboratories assets in 2014, Hikma achieved the broadest portfolio of generic injectable products in the US market and acquired injectables R&D capabilities. This also shows that Hikma has a strong track record in technology transfer processes.

21. The Sterile Injectables Divestment Businesses will strengthen Hikma's sterile injectables portfolio and its offering in Europe; it will provide it with access to new customers in target European markets, while […]. The acquired business will […].

22. As noted by the Trustee, Hikma estimates that […]. These savings are likely to increase the profitability for all the products concerned and allow Hikma to become a strong competitor […].

23. In light of the above, the Commission considers that Hikma has the financial resources, proven expertise and incentive to maintain and develop the Sterile Injectables Divestment Businesses as a viable and active competitive force in competition with Pfizer and competitors on the market.

**Absence of *prima facie* competition concerns**

24. Hikma sells *carboplatin*, *epirubicin*, *irinotecan* and *vancomycin* in the EEA but is not active in the Member States covered by the Sterile Injectables Divestment Businesses. Hikma is also not active in the markets for *voriconazole* and *cytarabine*. This means that there are no relevant overlaps between Hikma's current activities and the Sterile Injectables Divestment Businesses.

25. Consequently, no *prima facie* competition concerns arise in the EEA.

26. This *prima facie* assessment is exclusively based on the information provided by Pfizer and Hikma, and does not prejudge the conclusion stemming from a deeper enquiry if and when this proposed concentration is notified to a competition authority, including the Commission.

## III. ASSESSMENT OF THE PROPOSED AGREEMENTS

27. Pfizer signed a final binding version of the Asset Purchase and Licence Agreement ("APLA") with Hikma on 4 March 2016. The APLA was amended on 19 May 2016.

28. The Trustee has reviewed the Proposed Agreements, including the APLA as well as the agreed forms of the Transitional Service Agreement ("TSA"), Transitional Manufacturing and Technology Transfer Agreement ("TMTTA") and Trademark Assignment Agreement. The Trustee believes that they fulfil the condition of the Commitments to transfer the Sterile Injectables Divestment Businesses to a suitable purchaser. However, it highlighted in particular the following variations compared to the Commitments:

    a. […];

    b. […];

    c. […].

29. The Commission considers that these variations are not liable to impact the viability and competitiveness of the business:

    a. […], the Commission notes that Hikma will acquire inventories of the marketed products sufficient to cover demand in each territory for a […]. Hikma expects that […] it will have completed the technology transfer of the four molecules it already manufactures (*carboplatin*, *epirubicin*, *irinotecan* and *vancomycin),* thus the risk of supply disruption is minimal. As regards *cytarabine* and *voriconazole,* Hikma expects to complete the transfer process […]. Taking into account the APLA provisions which allow for demand forecasts including a safety stock margin and the indemnity provisions against losses incurred by Hikma as a result of supply failures, the Commission considers that […] will not affect the viability and competitiveness of the Sterile Injectables Divestment Businesses.

    b. Hikma's payment obligations under the TMTTA relate to the payment of the supply prices of the products delivered and technology transfer costs […], the Commission considers that […] is not liable to impact the viability of the Sterile Injectables Divestment Businesses.

    c. […]. In the first case the modifications would be mandatory for Pfizer, and in the second case […].

30. Based on the above, the Commission concludes that the Sterile Injectables Divestment Businesses are being sold in a manner consistent with the Commitments.

## IV. CONCLUSION

31. On the basis of the above assessment, the Commission approves Hikma as a suitable purchaser of the Sterile Injectables Divestment Businesses. The Commission further concludes that the Sterile Injectables Divestment Businesses are being sold in a manner consistent with the Commitments.

32. This decision only constitutes approval of the proposed purchaser identified herein and of the Proposed Agreements. This decision does not constitute a confirmation that Pfizer has complied with the Commitments.

33. This decision is based on Section D of the Commitments attached to the Commission Decision of 4 August 2015.

*For the Commission*

*(Signed)*

*Johannes LAITENBERGER*
*Director-General*