ANTICIPATED ACQUISITION BY THERAMEX HQ UK LIMITED OF THE EUROPEAN RIGHTS TO VIATRIS' FEMOSTON AND DUPHASTON PRODUCTS

Decision that undertakings might be accepted

ME/7073/23

The Competition and Markets Authority (CMA) has excluded from this published version of the decision information which the CMA considers should be excluded having regard to the three considerations set out in section 244 of the Enterprise Act 2002 (specified information: considerations relevant to disclosure). The omissions are indicated by [✂]. Some numbers have been replaced by a range, which are shown in square brackets.

1. INTRODUCTION

1. Theramex HQ UK Limited (**Theramex**) has agreed to acquire the European rights to commercialise Viatris Inc's (**Viatris**) Femoston and Duphaston products in the UK, the EEA, Switzerland and certain other European countries (the **Rights**) (the **Merger**). Theramex and Viatris are together referred to as the **Parties**.

2. On 4 April 2024, the Competition and Markets Authority (**CMA**) decided under section 33(1) of the Enterprise Act 2002 (the **Act**) that it is or may be the case that the Merger consists of arrangements that are in progress or in contemplation which, if carried into effect, will result in the creation of a relevant merger situation, and that this may be expected to result in a substantial lessening of competition (**SLC**) within a market or markets in the United Kingdom (the **SLC Decision**).

3. On the date of the SLC Decision, the CMA gave notice pursuant to section 34ZA(1)(b) of the Act to the Parties of the SLC Decision. However, the CMA did not refer the Merger for a phase 2 investigation pursuant to section 33(3)(b) on the date of the SLC Decision in order to allow the Parties the opportunity to offer undertakings to the CMA in lieu of such reference for the purposes of section 73(2) of the Act.

4. Pursuant to section 73A(1) of the Act, if a party wishes to offer undertakings for the purposes of section 73(2) of the Act, it must do so within the five working day period specified in section 73A(1)(a) of the Act. Accordingly, on 11 April 2024, the Parties offered undertakings to the CMA for the purposes of section 73(2) of the Act.

5. The CMA now gives notice, pursuant to section 73A(2)(b) of the Act, to the Parties that it considers that there are reasonable grounds for believing that the undertakings offered, or a modified version of them, might be accepted by the CMA under section 73(2) of the Act and that it is considering the offer.

2. THE UNDERTAKINGS OFFERED

6. Under section 73 of the Act, the CMA may, instead of making a reference, and for the purpose of remedying, mitigating or preventing the SLC concerned or any adverse effect which has or may have resulted from it or may be expected to result from it, accept from such of the merger parties concerned as it considers appropriate undertakings to take such action as it considers appropriate.

7. The SLC Decision found that the Merger gives rise to a realistic prospect of an SLC in relation to horizontal unilateral effects arising from (i) the loss of competition in the supply of systemic hormone replacement therapy (**HRT**) in relation to menopausal symptoms; and (ii) the loss of future competition in the supply of dydrogesterone, in the UK.

8. To address the competition concerns set out in the SLC Decision, the Parties have offered to give undertakings in lieu of a reference that will result in the divestment of the rights to commercialise Femoston and Duphaston products in the UK (the **Proposed Undertakings**). The divestment will be by way of the sale of an asset package comprising the following:

a) the Rights in the UK (**UK Rights**);

b) all UK-specific assets reasonably required for the buyer to commercialise Femoston in the UK and attempt to relaunch Duphaston in the UK, including all assets that would have been transferred to Theramex in relation to these products as part of the Merger. The assets which will be transferred include, but are not limited to:

(i) Viatris' existing inventory of Femoston in the UK;

(ii) customer contracts relating to Femoston in the UK (subject to obtaining necessary consents, which Viatris does not expect to be withheld and in any case shall use reasonable efforts to obtain);

(iii) all registered trade marks and unregistered intellectual property in respect of Femoston and Duphaston which is specific to the UK;

(iv) the partial assignment of the joint products agreement with [✂] in relation to Femoston and Duphaston in the UK;

(v) the partial assignment of the finished goods manufacturing and supply agreement with [✂] in relation to Femoston in the UK; under the terms of the agreement, [✂], on the same terms as the Parties; in relation to Duphaston, at the buyer's election, Theramex will use all reasonable endeavours to procure the manufacture and supply of Duphaston destined for the UK under the MSA [✂] as [✂] supplies Duphaston to [✂] in ex-UK jurisdictions and then assign this agreement to the buyer;

(vi) the marketing authorisation for Femoston in the UK;

(vii) the UK-specific regulatory materials for supporting the buyer to apply for a marketing authorisation for Duphaston;

c) timely access to all regulatory information and clinical data which is in the Parties' possession, custody or control which is not jurisdiction-specific, and which is reasonably required by the buyer to commercialise Femoston and attempt to relaunch Duphaston in the UK. This includes, but is not limited to, all regulatory information and clinical data which is reasonably required by the buyer to apply for marketing authorisation for Duphaston (i) by way of a standard national application for a UK marketing authorisation; and/or (ii) via

the Medicines and Healthcare products Regulatory Agency international recognition procedure;

d) support by the Parties to the buyer throughout the regulatory approval process for Duphaston in the UK to the extent this is reasonably requested by the buyer;

(together the **Divestment Package**).

9. Under the Proposed Undertakings, the Parties have also offered to enter into a purchase agreement with a buyer approved by the CMA before the CMA finally accepts the Proposed Undertakings (**Upfront Buyer Condition**).

3. THE CMA'S PROVISIONAL VIEWS

10. The CMA considers that undertakings in lieu of a reference are appropriate when they are clear-cut and capable of ready implementation. The CMA's starting point when assessing undertakings is to seek an outcome that restores competition to the level that would have prevailed absent the merger.[1] The clear-cut requirement has two dimensions. In relation to the substantive competition assessment, it means that there must not be material doubts about the overall effectiveness of the remedy. In practical terms, it means that remedies of such complexity that their implementation is not feasible within the constraints of the phase 1 timetable are unlikely to be accepted.[2]

11. The CMA believes that the Proposed Undertakings, or a modified version of them, might be acceptable as a suitable remedy to the SLC identified by the CMA, given that, for the reasons set out below, they are capable of addressing the competition concerns identified by the CMA. The CMA also believes, at this stage, that the Proposed Undertakings may be capable of ready implementation, in particular given that the Divestment Package is a business that is capable of being sold and the Parties have provided evidence that there are potential purchasers who have expressed interest in the Divestment Package. The CMA has also taken into account the following:

a) The CMA understands that the Divestment Package includes all assets, including customer contracts and manufacturing and supply agreements, required to commercialise Femoston in the UK;

b) The CMA understands that the Divestment Package includes all assets and support from the Parties required for the nominated buyer to re-launch Duphaston in the UK. Specifically, this includes assets and support needed to assist the buyer in (i) obtaining a manufacture and supply agreement with

[1] Mergers remedies (**CMA87**), December 2018, Chapter 3 (in particular paragraphs 3.27, 3.28 and 3.30).
[2] CMA87, December 2018, paragraph 3.28.

[✂], and (ii) gaining regulatory approval in the UK. The aforementioned assets and support would put the buyer in as good a position to relaunch Duphaston in the UK as the owner of Duphaston in the counterfactual scenario. Meanwhile, Theramex's incentives to develop an alternative generic dydrogesterone product in the UK will be restored, thereby returning competition to the level that would have prevailed absent the Merger.

12. While the UK Rights, including related assets and support during the regulatory approval process, form part of a broader European rights package at present, the CMA currently considers that the UK Rights and related assets and support include what is required to replace the competitive constraint that would otherwise be lost as a result of the Merger (provided the purchaser of the Divestment Package meets each of the criteria set out in paragraph 16). The CMA also understands that it is common in this industry to buy and sell rights to market a specific drug to other pharmaceutical companies within only one jurisdiction. For example, around [✂] of Theramex's products are commercialised by Theramex in only one jurisdiction.[3]

13. The CMA therefore currently believes that the Proposed Undertakings are capable of amounting to a sufficiently clear-cut and effective remedy for the CMA's competition concerns.

14. The Upfront Buyer Condition means that the CMA will only accept the Proposed Undertakings after the Parties have entered into an agreement with a nominated buyer that the CMA considers to be suitable. It also means that, before acceptance, the CMA will consult publicly on the suitability of the nominated buyer, as well as other aspects of the Proposed Undertakings. At Phase 1, the CMA will generally require an upfront buyer unless it considers that there are reasonable grounds for not doing so and, in particular, where the risk profile of the remedy does not require it.[4]

15. The CMA considers that an Upfront Buyer Condition is necessary in this case to mitigate the composition risk (and related purchaser risk) associated with the Proposed Undertakings. These risks arise from the fact that (i) the Divestment Package consists of the UK Rights only (ie without the right to commercialise Femoston and Duphaston in the other jurisdictions covered by the Rights); and (ii) there may be only a limited pool of suitable purchasers in light of the purchaser suitability criteria set out below.[5]

16. The CMA considers that due to the nature of the remedy set out in the Proposed Undertakings (comprising rights to market particular drugs plus related assets and

[3] See the Parties' Remedies Form, paragraph 58 and 59.
[4] CMA87, paragraph 5.29.
[5] CMA87, paragraphs 5.28–5.32.

support), and the fact that the concerns relating to Duphaston relate to the loss of future competition, a suitable purchaser would need to demonstrate the following:

a) That it has experience in supplying drugs in the women's healthcare space (in the UK or comparable jurisdictions), with a significant track record of supporting the introduction of new pharmaceutical products in the women's healthcare space, as well as experience in clinician education (relating to women's healthcare products).

b) That it is an established and committed player in the women's healthcare space with the ability to negotiate supply agreements on a multi-jurisdictional and single-jurisdictional basis and/or which possesses its own manufacturing capabilities.

c) That it has sufficient scale and product/service compatibility with Femoston and Duphaston to create the necessary synergies to ensure it can supply Duphaston and Femoston profitably in the UK.

d) That it has a credible business plan for successfully commercialising Femoston and relaunching Duphaston in the UK without owning the rights to those drugs in other jurisdictions.

17. The Parties submit that they will put forward to the CMA a purchaser who is able to demonstrate each of the above.

18. For these reasons, the CMA currently thinks that there are reasonable grounds for believing that the Proposed Undertakings, or a modified version of them, might be accepted by the CMA under section 73(2) of the Act.

19. The CMA's decision on whether ultimately to accept the Proposed Undertakings or refer the Merger for a phase 2 investigation will be informed by, among other things, third party views on whether the Proposed Undertakings are suitable to address the competition concerns identified by the CMA. In particular, before ultimately accepting the Proposed Undertakings, the CMA must be confident that the nominated buyer is effective and credible such that the competitive constraint provided by the UK Rights absent the Merger is replaced to a sufficient extent.

4. CONSULTATION PROCESS

20. Full details of the undertakings offered will be published in due course when the CMA consults on the undertakings offered as required by Schedule 10 of the Act.[6]

[6] CMA87, paragraph 4.27–4.28.

DECISION

21. The CMA therefore considers that there are reasonable grounds for believing that the Proposed Undertakings offered by the Parties, or a modified version of them, might be accepted by the CMA under section 73(2) of the Act. The CMA now has until 17 June 2024 pursuant to section 73A(3) of the Act to decide whether to accept the undertakings, with the possibility to extend this timeframe pursuant to section 73A(4) of the Act to 12 August 2024 if it considers that there are special reasons for doing so. If no undertakings are accepted, the CMA will refer the Merger for a phase 2 investigation pursuant to sections 33(1) and 34ZA(2) of the Act.

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Competition and Markets Authority
18 April 2024