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

Decision on acceptance of undertakings in lieu of reference

ME/7073/23

The Competition and Markets Authority's decision to accept undertakings in lieu of reference under section 73(2) of the Enterprise Act 2002 given on 12 August 2024. Full text of the decision published on 27 August 2024.

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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 11 April 2024, the Parties offered undertakings in lieu of reference to the CMA for the purposes of section 73(2) of the Act (the **UILs**). On 18 April 2024, the CMA gave notice to the Parties, pursuant to section 73A(2)(b) of the Act, 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 Parties' offer (the **UIL Provisional Acceptance Decision**)

4. The text of the SLC Decision and the UILs Provisional Acceptance Decision are available on the CMA webpages.[1]

THE UNDERTAKINGS OFFERED

5. As set out in the SLC Decision, the CMA found a realistic prospect of an SLC as a result of horizontal unilateral effects arising from the (i) loss of competition in the supply of systemic hormone replacement therapy (**HRT**) in relation to menopausal symptoms, and (ii) loss of future competition in the supply of dydrogesterone, in the UK.

6. As set out in the UIL Provisional Acceptance Decision, to address the SLCs identified by the CMA, the Parties offered undertakings to divest the rights to commercialise Femoston and Duphaston products in the UK. 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

[1] See Theramex/European Rights to Viatris' Femoston and Duphaston products - GOV.UK (www.gov.uk)

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 trademarks 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 the manufacturer of Femoston and Duphaston in the UK;

(v) the partial assignment of the finished goods manufacturing and supply agreement (**MSA**) with the manufacturer of Femoston in the UK; under the terms of the agreement, the nominated buyer would benefit from certain protections 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 from the manufacturer that currently supplies Duphaston 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**).

7. The text of the undertakings is available on the CMA webpages (the **Proposed Undertakings**).[2]

8. The Parties have also offered to enter into an agreement for the sale and purchase of the Divestment Package with an upfront buyer before the CMA finally accepts the Proposed Undertakings (the **Upfront Buyer Condition**). The Parties have proposed Exeltis UK Limited (**Exeltis**), a subsidiary of Insud Pharma, S.L. (**Insud Pharma**) as the upfront buyer. On 9 and 12 August 2024, Theramex, Viatris and Exeltis entered into agreements for the Divestment Package (the **Agreements**), conditional on acceptance by the CMA of the Proposed Undertakings, including approval of Exeltis as the buyer of the Divestment Package. The Agreements' terms and conditions were approved by the CMA prior to signing.

CONSULTATION

9. On 24 June 2024, pursuant to paragraph 2(1) of Schedule 10 to the Act, the CMA published the UILs, inviting interested parties to give their views on the UILs. The relevant text from the consultation is set out at Annex 1 of this decision.[3] For the reasons set out in the consultation, the CMA's preliminary view was that the UILs would resolve the SLC identified in the SLC Decision in a clear-cut manner, ie without giving rise to material doubts about the overall effectiveness of the UILs or concerns about their implementation.[4]

10. The CMA received no submissions during the consultation period to change its preliminary view that the UILs would be acceptable (and has not otherwise become aware of any information that might cause a change in this view).

11. The CMA therefore considers that the UILs offered by the Parties are clear-cut and appropriate to remedy, mitigate or prevent the competition concerns identified in the SLC Decision and that Exeltis is a suitable purchaser of the Divestment Package.

[2] See Theramex/European Rights to Viatris' Femoston and Duphaston products - GOV.UK (www.gov.uk).
[3] The full consultation text was published on Theramex/European Rights to Viatris' Femoston and Duphaston products - GOV.UK (www.gov.uk).
[4] Merger remedies, (**CMA87**), December 2018, Chapter 3, in particular paragraphs 3.27, 3.28 and 3.30.

DECISION

12. For the reasons set out above, the CMA considers that the UILs provided by the Parties are as comprehensive a solution as is reasonable and practicable and remedy, mitigate or prevent the SLC identified in the SLC Decision and any adverse effects resulting from it. The CMA has therefore decided to accept the UILs offered by the Parties pursuant to section 73 of the Act. The Merger will therefore not be referred for a phase 2 investigation.

13. The UILs, which have been signed by the Parties and will be published on the CMA webpages, will come into effect from the date of this decision.

Sorcha O'Carroll
Competition and Markets Authority
12 August 2024

ANNEX 1

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

NOTICE UNDER PARAGRAPH 2(1) OF SCHEDULE 10 TO THE ENTERPRISE ACT 2002 (THE ACT) – CONSULTATION ON PROPOSED UNDERTAKINGS IN LIEU OF REFERENCE PURSUANT TO SECTION 73 OF THE ACT.

ME/7073/23

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. On 11 April 2024, the Parties offered undertakings in lieu of reference to the CMA for the purposes of section 73(2) of the Act.

5. On 18 April 2024, the CMA gave notice to the Parties, pursuant to section 73A(2)(b) of the Act, 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 Parties' offer (the **UIL Provisional Acceptance Decision**).

THE UNDERTAKINGS OFFERED

6. As set out in the SLC Decision, the CMA found a realistic prospect of an SLC as a result of horizontal unilateral effects arising from the (i) loss of existing competition in the supply of systemic hormone replacement therapy (**HRT**) in relation to menopausal symptoms, and (ii) loss of future competition in the supply of dydrogesterone, in the UK.

7. As set out in the UIL Provisional Acceptance Decision, to address the SLCs identified by the CMA, the Parties have offered undertakings to divest the rights to commercialise Femoston and Duphaston products in the UK. 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 trademarks 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 the manufacturer of Femoston and Duphaston in the UK;

      (v) the partial assignment of the finished goods manufacturing and supply agreement (**MSA**) with the manufacturer of Femoston in the UK; under the terms of the agreement, the nominated buyer would benefit from certain protections 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 from the manufacturer that currently supplies Duphaston 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**). The text of the undertakings is available on the CMA webpages (the **Proposed Undertakings**).[1]

8. The Parties have also offered to enter into an agreement for the sale and purchase of the Divestment Package with an upfront buyer before the CMA finally accepts the Proposed Undertakings (**the Upfront Buyer Condition**). The Parties have proposed Exeltis UK Limited (**Exeltis**), a subsidiary of Insud Pharma, S.L. (**Insud Pharma**) as the upfront buyer. The agreement with Exeltis will be conditional on acceptance by the CMA of the Proposed Undertakings, including approval of Exeltis as the buyer of the Divestment Package.

CMA ASSESSMENT

9. The CMA currently considers that, subject to responses to the consultation required by Schedule 10 of the Act, the Proposed Undertakings will resolve the SLCs identified in the SLC Decision in a clear-cut manner, i.e. the CMA currently does not have material doubts about the overall effectiveness of the Proposed Undertakings or concerns about their implementation.[2]

10. This is because the Proposed Undertakings involve Viatris divesting the UK Rights, and both Parties providing the buyer with the assets, data and documents it needs to commercialise Femoston and Duphaston in the UK. The Proposed Undertakings also involve the Parties supporting the buyer's application for marketing authorisation for Duphaston.

11. With respect to Femoston, the Proposed Undertakings will enable the buyer to exert a competitive constraint on Theramex in the supply of systemic HRT, which would have otherwise been lost following the Merger. With respect to Duphaston, the Proposed Undertakings will ensure that (i) the buyer has the ability to compete in future in the supply of dydrogesterone in the UK, and (ii) Theramex retains its pre-Merger incentives to launch a generic version of dydrogesterone, in partnership with a third party or otherwise, in the UK.

12. The Divestment Package includes all the assets, data, documents and support needed to commercialise Femoston and Duphaston in the UK. Each of these assets, documents and data are capable of being transferred to an upfront buyer. Moreover, the Divestment Package includes a commitment from both Parties to provide the support the buyer needs in order to relaunch Duphaston in the UK.

13. The CMA notes that, while the UK Rights form part of a broader European rights package at present, the Divestment Package does not include any non-UK Rights. In addition, the Divestment Package does not include any Viatris or Theramex staff members. However, the CMA considers that the Upfront Buyer Condition mitigates the resulting composition risks (and related purchaser risk), as the CMA would accept the Proposed Undertakings only if the Parties have entered into an agreement with a nominated buyer that the CMA considers to be suitable in order to ensure that the Divestment Package, as operated by such buyer, can replace the competitive constraint that would otherwise be lost as a result of the Merger.

14. For the CMA to consider a nominated buyer to be suitable, it would need to demonstrate that it can achieve economies of scale, and that it has the staff, expertise, experience and resources needed to commercialise Femoston and Duphaston in the UK. With regards to Femoston, this means being able to become at least as competitive a supplier of Femoston as Viatris currently is. With regards to Duphaston, this means being able to relaunch Duphaston in the UK as promptly as possible. For reasons explained below, the CMA currently considers that Exeltis, the Parties' nominated buyer for the Divestment Package, is suitable.

15. The CMA also considers that the Proposed Undertakings would be capable of ready implementation, because the UK Rights would be transferred immediately upon completion. Moreover, the evidence available to the CMA indicates that Exeltis would have sufficient staff, resources, experience and expertise to enable the Divestment Package to operate as a competitor to Theramex.

Suitability of the proposed purchaser

16. In approving a purchaser, the CMA's starting position is that it must be confident without undertaking a detailed investigation that the proposed purchaser will restore pre-merger levels of competition. The CMA therefore seeks to ensure that:

(a) The acquisition by the proposed purchaser must remedy, mitigate or prevent the SLC concerned and any adverse effect resulting from it, achieving as comprehensive a solution as is reasonable and practicable.

(b) The proposed purchaser should be independent from and have no significant connection to the merger parties that may compromise the purchaser's incentives to compete with the merged entity (e.g. an equity interest, common significant shareholders, shared directors, reciprocal trading relationships or continuing financial assistance). It may also be appropriate to consider links between the purchaser and other market players.

(c) The purchaser must have sufficient capability, including access to appropriate financial resources, expertise (including managerial, operational and technical capability) and assets to enable the divested business to be an effective competitor in the market. This access should be sufficient to enable the divestiture package to continue to develop as an effective competitor.

(d) The CMA will wish to satisfy itself that the purchaser has an appropriate business plan and objectives for competing in the relevant market(s), and that the purchaser has the incentive and intention to maintain and operate the divested business as part of a viable and active business in competition with the merged entity and other competitors in the relevant market.

17. Divestiture to the purchaser should not create a realistic prospect of further competition or regulatory concerns.[3]

Exeltis

18. Subject to the responses to this consultation, and having regard in particular to the criteria set out in paragraph 16 above, the CMA currently considers Exeltis to be a suitable purchaser of the Divestment Package for the following reasons:

(a) The CMA currently considers that Exeltis' acquisition of the Divestment Package would remedy, mitigate or prevent the SLCs, and any adverse effect resulting from them, achieving as comprehensive solution as is reasonable and practicable. This is because Exeltis would have the resources, expertise, experience and staff to (i) sustain the supply of Femoston in the UK, and (ii) promptly relaunch Duphaston in the UK.

(b) The evidence available to the CMA indicates that Exeltis is independent from the Parties and has no significant connections to the Parties that may compromise its incentives to compete against Theramex if it were to acquire the Divestment Package.

(c) Exeltis' recent acquisitions of HRT drugs from Viatris, as well as its launch of Gepretix in the UK in 2023, indicate to the CMA that it is committed to

growing its presence in this sector. In addition, the evidence available to the CMA indicates that Exeltis has the staff members necessary to successfully commercialise both Femoston and Duphaston in the UK. The CMA therefore currently considers that Exeltis has the intention and resources to compete effectively in the supply of systemic HRT and dydrogesterone in the UK.

(d) The CMA notes that Insud Pharma, Exeltis' parent company, is a well-established pharmaceutical company. In particular, Insud Pharma's Chemo subsidiary is a major supplier of hormones to manufacturers. This indicates to the CMA that Insud Pharma already has considerable expertise across the supply chain for hormone-based pharmaceutical products.

(e) The CMA currently considers that Insud Pharma would be capable of manufacturing Femoston and Duphaston in-house in the event that the current manufacturer of these drugs ceased to be a viable supplier. The CMA also currently considers that there are other manufacturers who would be able to manufacture both drugs in the event that their current manufacturer ceased to be a viable supplier.

19. The CMA currently considers that the acquisition of the Divestment Package by Exeltis would not create a realistic prospect of further competition concerns. Exeltis supplies two HRT products in the UK: Elleste and Gepretix. The CMA currently considers that any loss of competition arising from adding Viatris' Femoston and Duphaston to Exeltis' portfolio would be limited and would be sufficiently offset by the constraint posed by alternative systemic HRT suppliers, such as Theramex and Besins Healthcare.[4] In relation to Duphaston specifically, the CMA has found that generic dydrogesterone products would be the closest competitors to Duphaston whilst micronised progesterone products, such as Gepretix, would pose only a weak out of market constraint. Accordingly, the CMA currently considers that the acquisition of the Divestment Package by Exeltis would not create a realistic prospect of an SLC.[5]

PROPOSED DECISION AND NEXT STEPS

20. For the reasons set out above, the CMA currently considers that the Proposed Undertakings and the purchase of the Divestment Package by Exeltis are, in the circumstances of this case, appropriate to remedy, mitigate or prevent the competition concerns identified in the SLC Decision and form as comprehensive a solution to these concerns as is reasonable and practicable.

21. The CMA therefore gives notice that it proposes to accept the Proposed Undertakings in lieu of a reference of the Merger for a phase 2 investigation. The text of the proposed undertaking is available on the CMA's web page.[6]

22. Before reaching a decision as to whether to accept the Proposed Undertakings, the CMA invites interested parties to make their views known to it. The CMA will have regard to any representations made in response to this consultation and may make modifications to the Proposed Undertakings as a result. If the CMA considers that any representation necessitates any material change to the Proposed Undertakings, the CMA will give notice of the proposed modifications and publish a further consultation.[7]

23. Representations should be made in writing to the CMA and be addressed to:

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Deadline for comments: Monday 8 July 2024