

**ACQUISITION BY THERAMEX OF THE EUROPEAN RIGHTS TO VIATRIS'  
FEMOSTON AND DUPHASTON PRODUCTS**

**Undertakings given by Theramex and Viatris to the Competition  
and Markets Authority pursuant to section 73 of the Enterprise Act  
2002**

**Whereas:**

- (a) Theramex HQ UK Limited (**Theramex**) anticipated the acquisition of the rights to Viatris Inc's (**Viatris**) Femoston and Duphaston products (the **Rights**) on 20 August 2023 by way of an asset purchase agreement, and as varied in the Letter Agreement executed by Theramex and Viatris dated 30 October 2023 (the **APA** and holistically, the **Anticipated Transaction**) such that Theramex and the Rights would cease to be distinct for the purposes of the Enterprise Act 2002 (the **Act**);
- (b) Under section 33(1) of the Act the Competition and Markets Authority (**CMA**) has a duty to refer a relevant merger situation for a Phase 2 investigation where it believes that it is or may be the case that the creation of that merger situation has resulted or may be expected to result in a substantial lessening of competition within any market or markets in the UK for goods or services;
- (c) Under section 73 of the Act the CMA may, instead of making such a reference and for the purpose of remedying, mitigating or preventing the substantial lessening of competition concerned or any adverse effect which has or may have resulted from it or may be expected to result from it, accept undertakings to take such action as it considers appropriate, from such of the parties concerned as it considers appropriate. In particular, the CMA shall have regard to the need to achieve as comprehensive a solution as is reasonable and practicable to the substantial lessening of competition and any adverse effects resulting from it;
- (d) As set out in the CMA's decision of 4 April 2024 (the **Decision**), the CMA believes that, in the absence of appropriate undertakings, it would be under a duty to refer the Anticipated Transaction for a Phase 2 investigation;

- (e) The CMA considers that the undertakings given below by Theramex and Viatris (together, the **Parties** and each a **Party**) are appropriate to remedy, mitigate or prevent the substantial lessening of competition, or any adverse effect which has or may have resulted from the Anticipated Transaction, or may be expected to result from it, as specified in the Decision;
- (f) Prior to the acceptance of these undertakings by the CMA, Viatris entered into a legally binding agreement of 12 August 2024 to divest to a Proposed Purchaser a package containing the assets reasonably required for the Proposed Purchaser to (i) commercialise Femoston in the UK and (ii) re-apply for a marketing authorisation in the UK with a view to attempting to subsequently commercialise Duphaston in the UK (the **Assets**) on terms agreed by the Parties and approved by the CMA. The full list of the Assets, which will be transferred to the Proposed Purchaser, is provided at **Annex 1**.
- (g) This agreement was conditional on formal CMA approval of the Proposed Purchaser and acceptance by the CMA of these undertakings. This agreement includes a warranty that the Proposed Purchaser has the financial resources, expertise (including the managerial, operational and technical capability), incentive and intention (insofar as it is deemed commercially viable) to (i) maintain and operate the Assets with respect to Femoston as part of a viable and active business in competition with Theramex and other competitors in the supply of systemic hormone replacement therapy (**HRT**) and (ii) attempt to launch Duphaston in the UK; and
- (h) The CMA made an Initial Enforcement Order applying to CEP V Investment 25 S.à.r.l., CIM Europe S.à.r.l., Galaxy Acquisitions S.à.r.l., PAI Partners S.à.r.l. and Theramex, and Viatris on 20 November 2023 in respect of the Anticipated Transaction pursuant to section 72 of the Act for the purposes of preventing pre-emptive action, as varied on 20 November 2023, 26 March 2024 and 4 April 2024. Pursuant to section 72(6)(b) of the Act, this Initial Enforcement Order ceases to be in force on the acceptance by the CMA of the undertakings given below by the Parties.

NOW THEREFORE the Parties hereby give to the CMA the following undertakings for the purpose of remedying, mitigating or preventing the substantial lessening of competition, or any adverse effect which has or may have resulted from it or may be expected to result from it.

## **1 EFFECTIVE DATE OF THE UNDERTAKINGS**

- 1.1 These undertakings shall take effect from the date that, having been signed by the Parties, they are accepted by the CMA (subject to Viatris having entered

into a legal binding agreement to divest the Assets to a Proposed Purchaser on terms accepted by Viatris and as approved by the CMA).

## **2 DIVESTMENT OF THE ASSETS**

2.1 Viatris shall ensure that the completion of the divestment of the Assets to the Proposed Purchaser contemplated by the agreement referred to in recital (f) of these undertakings takes place on the later of:

- (a) within a period not exceeding one month from the date these undertakings take effect; or
- (b) within a period not exceeding 10 Working Days after any necessary mandatory / suspensory regulatory approvals have been obtained.

2.2 In the event that, having entered into a legally binding agreement with the Proposed Purchaser, Viatris fails to complete the divestment of the Assets in accordance with paragraph 2.1 above, the CMA may, whether or not initiating the Trustee Functions as set out in paragraph 5 below, require Viatris to divest the Assets at no minimum price to a purchaser or purchasers approved by the CMA.

2.3 Without prejudice to the generality of paragraph 2.1 above, the Parties shall take the following measures to the extent they may be necessary in the opinion of the CMA to effect the sale of the Assets in accordance with the provisions of these undertakings:

- (a) the transfer or vesting of all UK assets, rights, liabilities or obligations (including without prejudice any contracts, licences, authorisations, permits or consents) within scope of the Assets;
- (b) any other transfer of interests that will take effect with the sale;
- (c) the adjustment of contracts, whether by discharge or reduction or assignment of any liability or obligation or otherwise;
- (d) with respect to Femoston, the transfer of Viatris' existing inventory in the UK and the right to order future inventory in the UK;
- (e) with respect to Duphaston, Theramex to, at the Proposed Purchaser's election, enter into arrangements for the manufacture and supply of Duphaston which can be immediately assigned to the Proposed Purchaser; and
- (f) with respect to Duphaston, Theramex to support the Proposed Purchaser throughout the regulatory approval process for Duphaston in

the UK to the extent this is reasonably requested by the Proposed Purchaser; and

- (g) if requested by the Proposed Purchaser, the provision of any regulatory information held by Theramex in a chosen European Member State to support any application by the Proposed Purchaser for a marketing authorisation via the international recognition procedure, together with a commitment to keep the Proposed Purchaser informed of any necessary changes affecting the marketing authorisation.

2.4 Viatris shall ensure that the agreement entered into for the purposes of paragraph 2.1 above includes a warranty that the Proposed Purchaser has the financial resources, expertise (including the managerial, operational and technical capability), incentive and intention (insofar as deemed commercially viable) to (i) maintain and operate the Assets with respect to Femoston as part of a viable and active business in competition with Theramex and other competitors in the supply of systemic HRT in the UK, and (ii) attempt to launch Duphaston in the UK.

2.5 In the event that, having entered into a legally binding agreement with the Proposed Purchaser, Viatris fails to divest the Assets in accordance with paragraphs 2.1, 2.2, 2.3 and 2.4 above, the CMA may, whether or not initiating the Trustee Functions as set out in paragraph 5 below, require Viatris to divest the Assets as a going concern at no minimum price to a purchaser approved by the CMA.

### **3 APPROVAL OF PURCHASER AND TERMS OF DIVESTMENT**

3.1 For the purposes of the CMA approving a Proposed Purchaser and the terms of the divestment of the Assets in accordance with these undertakings, the Parties shall, save as required or permitted by the CMA, satisfy the CMA that:

- (a) the acquisition by the Proposed Purchaser of the Assets, on the terms set out above, remedies, mitigates or prevents the substantial lessening of competition concerned or any adverse effect which has or may have resulted from it, or may be expected to result from it, in particular having regard to the need to achieve as comprehensive a solution as is reasonable and practicable to the substantial lessening of competition and any adverse effects resulting from it;
- (b) the Proposed Purchaser is independent of and unconnected to Theramex and the Group of Interconnected Bodies Corporate to which Theramex belongs and any Associated Person or Affiliate of Theramex or such Group of Interconnected Bodies Corporate;

- (c) the Proposed Purchaser has the financial resources, expertise (including the managerial, operational and technical capability) incentive and intention (insofar as deemed commercially viable) to (i) maintain and operate the Assets with respect to Femoston as a viable and active business in competition with Theramex and other competitors in the supply of systemic HRT in the UK from the date of completion of the divestment of the Assets and (ii) attempt to launch Duphaston in the UK;
- (d) the Proposed Purchaser is equipped to obtain all necessary approvals, licences and consents from any regulatory or other authority; and
- (e) the acquisition by the Proposed Purchaser of the Assets does not create a realistic prospect of a substantial lessening of competition within any market or markets in the UK.

3.2 The CMA may require the Parties to provide it with such information and documentation as it may reasonably require to satisfy the CMA that the Proposed Purchaser will fulfil the requirements in paragraph 3.1 above.

#### **4 APPOINTMENT OF A TRUSTEE**

4.1 The provisions of paragraph 4.2 to paragraph 4.7 below shall apply only as long as the Parties have not satisfied, or where the CMA has reasonable grounds for believing that the Parties will not satisfy, all or any part of the obligation to divest the Assets in accordance with paragraph 2 above.

4.2 Within 5 Working Days of the CMA notifying the Parties in writing that it must do so, the Parties shall propose to the CMA for approval:

- (a) the names of at least two individuals to exercise the Trustee Functions; and
- (b) the full terms of a mandate in accordance with which the Trustee shall carry out the Trustee Functions.

4.3 The Parties and/or any individuals nominated pursuant to paragraph 4.2 shall satisfy the CMA that, save as required or permitted by the CMA:

- (a) such nominated individuals have the necessary qualifications to carry out their mandates, and are employees or partners of an investment bank, retail bank, commercial property agent, building society or law firm or accountancy firm with an established reputation either nationwide or in a substantial part of the UK or in another EU member state;

- (b) such nominated individuals are each independent of the Parties and of the Group of Interconnected Bodies Corporate to which the Parties belongs and of any Associated Person or Affiliate of the Parties or of such Group of Interconnected Bodies Corporate and of any Proposed Purchaser of the Assets to be sold pursuant to these undertakings, and, in the reasonable opinion of the Parties, are appropriate to be appointed as Trustee; and
- (c) such nominated individuals neither are, nor are likely to become, exposed, either directly or indirectly, to a conflict of interest that impairs or may be likely to impair their objectivity or independence in discharging the Trustee Functions.

4.4 Within 2 Working Days of the CMA approving, at its discretion, one or more of the persons nominated by the Parties and their proposed mandates pursuant to paragraph 4.2 above, and subject to any modifications the CMA deems necessary for the Trustee to carry out the Trustee Functions, the Parties shall use their best endeavours to appoint from the persons so approved one person to carry out the Trustee Functions in accordance with the mandate approved by the CMA pursuant to paragraph 4.2 above.

4.5 In the event that:

- (a) the Parties fail to propose any person or persons in accordance with paragraph 4.2 above; or
- (b) none of the persons proposed by the Parties pursuant to paragraph 4.2 are approved by the CMA; or
- (c) the Parties are unable for any reason to appoint within the time limit stipulated in paragraph 4.4 above any such person following approval by the CMA,

the Parties shall use their best endeavours to appoint from persons nominated by the CMA one person to carry out the Trustee Functions on the terms of a mandate approved by the CMA. The Parties shall use their best endeavours to make such appointment within 5 Working Days of receiving the nominations from the CMA.

4.6 The appointment of the Trustee pursuant to paragraph 4.4 or paragraph 4.5 above shall be irrevocable unless:

- (a) a conflict of interest that impairs or may be likely to impair the objectivity or independence of the Trustee in discharging the Trustee Functions arises;

- (b) the Trustee ceases to perform the Trustee Functions; or
- (c) the CMA is otherwise satisfied that there is good cause for the appointment to be terminated in advance of the satisfactory fulfilment of the Trustee Functions.

4.7 In the event that the appointment of the Trustee is terminated in accordance with paragraph 4.6 above, the Parties shall, if requested to do so in writing by the CMA, use their best endeavours to appoint from persons nominated by the CMA one person to carry out the Trustee Functions in accordance with such mandate as is approved by the CMA. The Parties shall use their best endeavours to make such appointment within seven Working Days of receiving the nominations from the CMA. Where required by the CMA, the outgoing Trustee shall continue as Trustee until a new Trustee is in place and a full handover of all relevant information has taken place.

## **5 THE MANDATE**

5.1 The terms of the mandate proposed by the Parties pursuant to paragraph 4.2 above shall, as a minimum, contain all provisions necessary to enable the Trustee to carry out the Trustee Functions including, without limitation to the generality of this paragraph:

- (a) an exclusive, irrevocable mandate to sell all assets within scope of the Assets as required by paragraph 6.1 below to a purchaser as directed or approved in writing in advance by the CMA at no minimum price and on such reasonable terms and conditions as the Trustee considers appropriate to effect an expedient sale;
- (b) a mandate to take any other steps necessary for, or incidental to, the Trustee's mandate under sub-paragraph (a) above;
- (c) a comprehensive power of attorney to the Trustee (including the authority to grant sub-powers of attorney to the Trustee's officers, employees and agents) to enable it to take all steps necessary or appropriate to effect the sale of the Assets;
- (d) a mandate to comply with any orders and/or directions given by the CMA; and
- (e) a mandate to appoint at the Parties' expense such advisers as the CMA and/or the Trustee reasonably considers necessary or appropriate in connection with the performance of the Trustee Functions.

## **6 FUNCTIONS OF TRUSTEE**

- 6.1 The Trustee shall seek to procure, within such period as may be specified in writing by the CMA, the completion of the sale of all assets within scope of the Assets at no minimum price, to a purchaser or purchasers approved by the CMA in accordance with paragraph 6.3 below.
- 6.2 Without prejudice to the generality of paragraph 6.1 above, the Trustee shall take the following measures in relation to the Assets to the extent to which such measures may be necessary to effect the divestment of the Assets in accordance with the provisions of these undertakings:
- (a) the transfer or vesting of all UK assets, rights, liabilities or obligations (including without prejudice any contracts, licences, authorisations, permits or consents) within scope of the Assets;
  - (b) any other transfer of interests that will take effect with the sale;
  - (c) the adjustment of contracts, whether by discharge or reduction or assignment of any liability or obligation or otherwise;
  - (d) with respect to Femoston, the transfer of Viatrix' existing inventory in the UK and the right to order future inventory in the UK;
  - (e) with respect to Duphaston, Theramex to, at the Proposed Purchaser's election, enter into arrangements for the manufacture and supply of Duphaston which will be immediately assigned to the Purchaser; and
  - (f) with respect to Duphaston, Theramex to support the Proposed Purchaser throughout the regulatory approval process for Duphaston in the UK to the extent this is reasonably requested by the Proposed Purchaser; and
  - (g) if requested by the Proposed Purchaser, the provision of any regulatory information held by Theramex in a chosen European Member State to support any application by the Proposed Purchaser for a marketing authorisation via the international recognition procedure, together with a commitment to keep the Proposed Purchaser informed of any necessary changes affecting the marketing authorisation.
- 6.3 The Trustee shall not sell or permit the divestment of the Assets to a Proposed Purchaser unless it has been directed to do so by the CMA or has obtained the CMA's prior written approval in respect of the identity of that Proposed Purchaser. The Trustee shall notify the CMA of the identity of a Proposed Purchaser as soon as reasonably practicable prior to the signing of a legally



enforceable agreement and in any event at least 20 Working Days in advance of the proposed completion of the proposed sale and purchase agreement in question.

- 6.4 Pending the divestment of the Assets pursuant to paragraph 6.1 above, the Trustee shall monitor the Parties' compliance with their obligations under paragraph 7.1 and paragraph 7.2 below and shall promptly take such measures as it considers necessary to ensure such compliance, as well as reporting in writing to the CMA, if the Trustee concludes on reasonable grounds that the Parties are failing or will fail to comply with such obligations.
- 6.5 The Trustee may give written directions to the Parties to take such steps as may be specified or described in the directions for the purpose of securing the Parties' compliance with its obligations under these undertakings or enabling the Trustee to carry out the Trustee Functions. The Trustee may not require the Parties to:
- (a) offer any reverse premium or similar inducement to a purchaser; or
  - (b) accept any actual or contingent liability towards a purchaser or otherwise in connection with the divestment of the Assets which would be unusual in scope, duration or financially, having regard to the price and usual market practice in relation to similar disposals.
- 6.6 The Trustee shall, as soon as reasonably practicable, comply at all times with any reasonable instructions or written directions made by the CMA for the purposes of carrying out or securing compliance with the undertakings (or any matter incidental thereto) and shall provide to the CMA such information and reports in relation to the carrying out of the Trustee Functions as the CMA may require. The Trustee shall promptly report in writing to the CMA if the Trustee concludes on reasonable grounds that the Parties are failing or will fail to comply with any of its obligations under these undertakings.
- 6.7 For the purpose of fulfilling the Trustee Functions, the Trustee shall not be bound by instructions of the Parties nor shall the Trustee Functions be extended or varied in any way by the Parties save with the prior express written consent of the CMA.

## **7 OBLIGATIONS OF THE PARTIES FOLLOWING APPOINTMENT OF TRUSTEE**

- 7.1 The Parties shall not give any instruction or request to the Trustee which conflicts with the Trustee Functions.
- 7.2 The Parties shall take all such steps as are reasonably necessary to enable the Trustee to carry out the Trustee Functions, including but not limited to:
- (a) complying with such written directions as the Trustee may from time to time give pursuant to paragraph 6.6 above; and
  - (b) providing the Trustee with all such assistance and information as it may reasonably require in carrying out the Trustee Functions.

## **8 REMUNERATION OF TRUSTEE**

- 8.1 The Parties shall pay the Trustee a reasonable remuneration for the services it provides in carrying out the Trustee Functions, and shall pay the Trustee in a way that does not impede the independent and effective fulfilment of the Trustee Functions, which shall be set out in the Trustee's mandate referred to in paragraph 5 above.

## **9 INTERIM ACTION**

- 9.1 Pending the completion of the divestment of the Assets to the satisfaction of the CMA in accordance with the provisions of these undertakings, save as otherwise agreed in advance in writing by the CMA, the Parties shall minimise as far as possible any risk of loss of competitive potential of the Assets and in particular ensure that:
- (a) the business associated with the Assets is carried on separately from the Theramex Business and the Assets' separate sales or brand identity is maintained;
  - (b) the Assets and the Theramex Business are each maintained and sufficient resources are made available for the development of the Assets and the Theramex Business, on the basis of their respective pre-Anticipated Transaction business plans;
  - (c) except in the ordinary course of business, no substantive changes are made to the organisational structure of, or the management responsibilities with respect to the business associated with the Assets or the Theramex Business;

- (d) nature, description, range and quality of goods that make up the Assets and that are supplied in the UK by each of the Parties is maintained and preserved;
- (e) except in the ordinary course of business for the separate operation of the Assets and the Theramex Business:
  - (i) all of the Assets and the assets of the Theramex Business are maintained and preserved, including facilities and goodwill;
  - (ii) none of the Assets or the Assets of the Theramex Business are disposed of; and
  - (iii) no interest in the Assets or the assets of the Theramex Business is created or disposed of;
- (f) there is no integration of the information technology used by Viatris in connection with the Assets and the Theramex Business, and, to the extent relevant, the software and hardware platforms used in connection with the Assets shall remain essentially unchanged, except for routine changes and maintenance;
- (g) the customer and supplier lists pertaining to the Assets and those pertaining to the Theramex Business shall be operated and updated separately and any negotiations with any existing or potential customers and suppliers in relation to the Assets will be carried out by Viatris alone and for the avoidance of doubt, Theramex will not negotiate on behalf of the Assets or enter into any joint agreements with respect to the Assets;
- (h) all existing contracts pertaining to the Assets continue to be serviced by Viatris and those relating to the Theramex Business continue to be serviced by the business to which they were awarded;
- (i) no changes are made to Key Staff of the Parties, without the CMA's permission; and
- (j) no Confidential Information relating to either of the Assets or the Theramex Business shall pass, directly or indirectly, from Viatris (or any of its employees, directors, agents or affiliates) to Theramex (or any of its employees, directors, agents or affiliates), or vice versa, except where strictly necessary in the ordinary course of business (for example, where required for compliance with external regulatory and/or accounting obligations) or any steps necessary in order for the Parties to comply with these undertakings, including the transfer of information necessary for the divestment process, provided that, upon divestment of the Assets,

any records or copies (electronic or otherwise) of Confidential Information held by Theramex in relation to the Assets shall be returned to the relevant business and any copies destroyed (except as may be necessary for the purposes of compliance with the obligations above).

9.2 At all times, the Parties will actively keep the CMA informed of any material developments relating to the Assets, which includes, but is not limited to:

- (a) details of Key Staff who leave the Parties;
- (b) any interruption of the Theramex Business or any interruption affecting the Assets (including without limitation aspects of procurement, production, logistics and sales) that has prevented the Parties from operating in the ordinary course of business for more than 24 hours; and
- (c) all substantial customer volumes lost in relation to the Assets; and
- (d) substantial changes in the Parties' contractual arrangements or relationships with key suppliers.

## **10 CONTINUED SEPARATION**

10.1 Except with the prior written consent of the CMA, for a period of 10 years following the divestment of the Assets pursuant to these undertakings, Theramex, or any member of the Group of Interconnected bodies Corporate to which Theramex belongs:

- (a) shall not, directly or indirectly, hold, acquire, re-acquire or use:
  - (i) an Interest in the Assets; or
  - (ii) any Interest in any company carrying on or having Control of the Assets (other than any investments made in the ordinary course of the operation of any of the employee benefit and pension schemes of Theramex or of any members of the Group of Interconnected Bodies Corporate to which Theramex belongs of not more than three per cent in aggregate of the issued equity share capital in any such company, whose shares are listed or dealt with on any recognised investment exchange, which carries no more than three per cent of the voting Assets exercisable at meetings of such company); or
  - (iii) other than in the normal course of business, any of the Assets;
- (b) shall procure that no employee or director of Theramex or any member of the Group of Interconnected Bodies Corporate to which Theramex

belongs for as long as they are an employee or director of Theramex or any member of the Group of Interconnected Bodies Corporate to which Theramex belongs holds or is nominated to any directorship or managerial position in the Assets or directorship or managerial position in any company or other undertaking carrying on or having control of the Assets without the CMA's prior written consent;

- (c) shall not participate in the formulation of, or (other than in the ordinary course of business) influence or attempt to influence, the policy of the Assets or any company or other undertaking carrying on or having control of the Assets; and
- (d) shall not enter into or carry out any agreement or arrangement with any person, if the carrying out of the agreement or arrangement is intended to result or will result in any Associated Person or Affiliate of Theramex or of any member of the Group of Interconnected Bodies Corporate to which Theramex belongs directly or indirectly acquiring the Assets or doing any of the things listed in sub-paragraphs 10.1(a), 10.1(b) and 10.1(c) above.

## **11 COMPLIANCE**

11.1 The Parties shall comply promptly with such written directions as the CMA may from time to time give:

- (a) to take such steps as may be specified or described in the directions for the purpose of carrying out or securing compliance with these undertakings; or
- (b) to do or refrain from doing anything so specified or described which it might be required by these undertakings to do or to refrain from doing.

11.2 The Parties shall co-operate fully with the CMA when the CMA is:

- (a) monitoring compliance with the provisions of these undertakings; and
- (b) investigating potential breaches of the provisions of these undertakings.

11.3 The Parties shall procure that any member of the same Group of Interconnected Bodies Corporate as the Parties complies with these undertakings as if it had given them and actions and omissions of the members of the same Group of Interconnected Bodies Corporate as the Parties shall be attributed to the relevant Party for the purposes of these undertakings.

- 11.4 Where any Affiliate of the Parties is not a member of the same Group of Interconnected Bodies Corporate as the relevant Party, such Party shall use its best endeavours to procure that any such Affiliate shall comply with these undertakings as if it had given them.

## **12 PROVISION OF INFORMATION**

- 12.1 The Parties shall furnish promptly to the CMA such information as the CMA considers necessary in relation to or in connection with the implementation and/or enforcement of and/or the compliance with these undertakings, including for the avoidance of doubt, any Confidential Information.

## **13 EXTENSION OF TIME LIMITS**

- 13.1 The CMA may, in response to a written request from the Parties, or otherwise at its own discretion, grant an extension to any time period referred to in these undertakings.

## **14 SERVICE**

- 14.1 Theramex hereby authorises Linklaters LLP, whose address for service is One Silk St, London EC2Y 8HQ, to accept service on its behalf of all documents connected with these undertakings (including any document of any kind which falls to be served on or sent to Theramex, or any of its Subsidiaries in connection with any proceedings in Courts in the UK, orders, requests, notifications or other communications connected with these undertakings).
- 14.2 Viatris hereby authorises Slaughter and May, whose address for service is One Bunhill Row, London EC1Y 8YY, to accept service on its behalf of all documents connected with these undertakings (including any document of any kind which falls to be served on or sent to Viatris, or any of its Subsidiaries in connection with any proceedings in Courts in the UK, orders, requests, notifications or other communications connected with these undertakings).
- 14.3 Unless Theramex informs the CMA in writing that Linklaters LLP has ceased to have authority to accept and acknowledge service on its or any of its Subsidiaries' behalf, any document, order, request, notification or other communication shall be validly served on Theramex if it is served on Linklaters LLP; and service shall be deemed to have been acknowledged by Theramex if it is acknowledged by Linklaters LLP or such other nominee.
- 14.4 Unless Viatris informs the CMA in writing that Slaughter and May has ceased to have authority to accept and acknowledge service on its or any of its Subsidiaries' behalf, any document, order, request, notification or other

communication shall be validly served on Viatris if it is served on Slaughter and May ; and service shall be deemed to have been acknowledged by Viatris if it is acknowledged by Slaughter and May or such other nominee.

- 14.5 Paragraph 14.3 above have effect irrespective of whether, as between Theramex and Linklaters LLP or other nominees, Linklaters LLP or other nominees has or continues to have any authority to accept and acknowledge service on Theramex' or any of its respective Subsidiaries' behalf.
- 14.6 Paragraph 14.4 above have effect irrespective of whether, as between Viatris and Slaughter and May or other nominees, Slaughter and May or other nominees has or continues to have any authority to accept and acknowledge service on Viatris' or any of its respective Subsidiaries' behalf.
- 14.7 No failure or mistake by either of Linklaters LLP or Slaughter and May or other nominees (including a failure to notify either of Theramex or Viatris of the service of any document, order, request, notification or other communication) shall invalidate any action taken in respect of these undertakings including any proceedings or judgment.
- 14.8 Any communication from the Parties to the CMA under these undertakings shall be addressed to Manager, Market and Mergers Remedies Monitoring, Competition and Markets Authority, The Cabot, 25 Cabot Square, London, E14 4QZ or such other person or address as the CMA may direct in writing.

## **15 EFFECT OF INVALIDITY**

- 15.1 Should any provision of these undertakings be contrary to law or invalid for any reason, the Parties undertake to continue to observe the remaining provisions.

## **16 GOVERNING LAW**

- 16.1 The Parties recognise and acknowledge that these undertakings shall be governed and construed in all respects in accordance with English law.
- 16.2 In the event that a dispute arises concerning these undertakings, the Parties undertake to submit to the courts of England and Wales.

## **17 TERMINATION**

- 17.1 The Parties recognise and acknowledge that these undertakings shall be in force until such time as they are varied, released or superseded under the Act.

17.2 The Parties recognise and acknowledge that the variation, release or supersession of these undertakings shall not affect the validity and enforceability of any rights or obligations that arose prior to such variation, release or supersession.

## 18 INTERPRETATION

18.1 The Interpretation Act 1978 shall apply to these undertakings as it does to Acts of Parliament.

18.2 References in these undertakings to any English law term for any legal status, interest, concept or thing shall in respect of any jurisdiction other than England and Wales be deemed to include what most nearly approximates in that jurisdiction to the English law term.

18.3 In these undertakings the word "including" shall mean including without limitation or prejudice to the generality of any description, definition, term or phrase preceding that word and the word "include" and its derivatives shall be construed accordingly.

18.4 For the purposes of these undertakings:

**“the Act”** means the Enterprise Act 2002;

**“Affiliate”** a person is an affiliate of another person if they or their respective enterprises would be regarded as being under common control for the purposes of section 26 of the Act;

**“the Anticipated Transaction”** means the transaction by which Theramex and the Rights would cease to be distinct within the meaning of section 23 of the Act;

**“Assets”** means the assets listed in Annex 1;

**“Associated Person”** means a person or persons associated with the Parties within the meaning of section 127(4) of the Act and includes any Subsidiary of such a person or persons;

**“business”** has the meaning given by section 129(1) and (3) of the Act;

**“CMA”** means the Competition and Markets Authority or any successor body;

**“Confidential Information”** means any business secrets, know-how, commercially sensitive information, intellectual property or any other information of a confidential or proprietary nature;



**“Control”** shall be construed in accordance with section 26 of the Act, and in the case of a body corporate, a person shall be deemed to Control it if he holds, or has an interest in, shares of that body corporate amounting to 10 per cent or more of its issued share capital or carrying an entitlement to vote at meetings of that body corporate of 10 per cent or more of the total number of votes which may be cast at such meetings;

**“Decision”** means the CMA’s decision under section 33 of the Act dated 4 April 2023 in connection with the Anticipated Transaction;

**“enterprise”** has the meaning given in section 129(1) of the Act;

**“Group of Interconnected Bodies Corporate”** has the meaning given in section 129(2) of the Act; references to a Group of Interconnected Bodies Corporate shall be to the Group of Interconnected Bodies Corporate as constituted from time to time;

**“Interest”** includes shares, an interest in shares and any other interest carrying an entitlement to vote at shareholders’ meetings but does not include a contract to acquire shares in the future; and for this purpose "an interest in shares" includes an entitlement by a person other than the registered holder, to exercise any right conferred by the holding of these shares or an entitlement to Control the exercise of such right;

**“Key Staff”** means staff in positions of executive or managerial responsibility and/or whose performance affects the viability of the Assets or Theramex’s Business, as the case may be;

**“Parties”** means both Theramex and Viatris, each being a **“Party”**;

**“Proposed Purchaser”** means Exeltis UK Limited (08412660), C/O BDO LLP, Two Snowhill, 7th Floor, Birmingham, UK, B4 6GA;

**“ROW Transaction”** means the acquisition of the certain rights to commercialise Femoston and Duphaston in the EEA, Switzerland, [✂];

**“Subsidiary”** shall be construed in accordance with section 1159 of the Companies Act 2006 (as amended), unless otherwise stated;

**“Theramex Business”** means the business of Theramex and its subsidiaries carried on as at the date of these undertakings;

**“UK”** means the United Kingdom of Great Britain and Northern Ireland;

**“Working Day”** means any day of the week other than a Saturday or a Sunday or any day that is a public holiday in England and Wales ;

“**Theramex**” means Theramex HQ UK Limited (10944626), 50 Broadway, 5th Floor, London, UK, SW1H 0BL; and

“**Viatriis**” means Viatriis, Inc., 1000 Mylan Boulevard, Canonsburg, PA 15317, United States;

unless the context requires otherwise, the singular shall include the plural and vice versa.

**FOR AND ON BEHALF OF THERAMEX**

Signature

Name

Title

Date

**FOR AND ON BEHALF OF VIATRIS**

Signature

Name

Title

Date

**DATE ACCEPTED BY THE CMA: Signed by Theramex and Viatriis and accepted by the CMA on 12 August 2024**

# Annex 1

Below is a complete list of the Assets which will be transferred from the Parties to the Proposed Purchaser.

- 1 With respect to Femoston:
  - 1.1 the UK marketing authorisation for Femoston;
  - 1.2 partial assignment for the UK of two agreements with [X]: (i) the finished goods manufacturing and supply agreement (**MSA**); and (ii) the joint products agreement (**JPA**);
  - 1.3 the existing inventory of Viatris of Femoston in the UK and, by virtue of the assignment outlined in paragraph 1.2 above, the right to order future inventory of Femoston;
  - 1.4 a commitment from Viatris to use reasonable best efforts to transfer all of the currently existing and effective customer contracts for Femoston in the UK to the Proposed Purchaser;
  - 1.5 all registered trade marks and unregistered IP which is specific to the UK;
  - 1.6 any relevant Femoston UK price approvals;
  - 1.7 all business records, regulatory information, and clinical data, which are Viatris' possession, custody or control and which are reasonably required for the Proposed Purchaser to operate Femoston in the UK; and
  - 1.8 any relevant broader clinical data or safety information within the Parties' possession, custody or control which is not jurisdiction-specific and is not exclusive, but may be reasonably required for the Proposed Purchaser to operate Femoston in the UK and which will be made available to the Proposed Purchaser in a timely manner (and in any case, within a maximum of five business days); and
  - 1.9 in the event that (i) [X] no longer manufactures Femoston; and (ii) instead, the formulation to manufacture Femoston is transferred by [X] to either Party, the applicable Party or Parties receiving such formulation commit(s) to use reasonable endeavours to transfer (to the extent transferable) to the Proposed Purchaser the formulation to manufacture Femoston.
- 2 With respect to Duphaston:

- 2.1 all assets that would have been transferred to Theramex as part of the Anticipated Transaction to allow Theramex to acquire the rights to supply Duphaston in the UK, including:
- (a) any regulatory information and clinical data that it acquired from Viatrix as part of the ROW Transaction (and which is therefore in its possession, custody and control), including Modules 2 to 5 and any information/documentation requested by the Proposed Purchaser from a reference country module 1 to assist in creating the UK-specific module 1; and
  - (b) all business records, regulatory information, and clinical data, which are in the Parties' possession, custody or control and which are reasonably required for the Proposed Purchaser to operate Duphaston in the UK;
- in each case to be made available to the Proposed Purchaser in a timely manner (and in any case, within a maximum of five business days).
- 2.2 partial assignment for the UK of the JPA;
- 2.3 any information within Theramex's possession, custody or control with respect to the price of Duphaston in other jurisdictions as may be reasonably requested by the Proposed Purchaser to facilitate discussions with the Department of Health and Social Care regarding the price of Duphaston in UK;
- 2.4 a commitment from Theramex to use all reasonable endeavours to facilitate the Proposed Purchaser's extension of the MSA to Duphaston in the UK including the choice to enter into an arrangement for the manufacture and supply of Duphaston destined for the UK at the Proposed Purchaser's election, whereby Theramex will procure the manufacture and supply of Duphaston destined for the UK under the MSA [X] as [X] supplies Duphaston to [X] in the ex-UK jurisdictions, which Theramex will assign to the Proposed Purchaser immediately upon entering into the agreement with [X];
- 2.5 purchaser protections, beyond those available under the MSA, to ensure that the Proposed Purchaser would not be disadvantaged in the event of any supply shortages;
- 2.6 the provision of support from Theramex to the Proposed Purchaser throughout the regulatory approval process for Duphaston in the UK to the extent this is reasonably requested by the Proposed Purchaser; and
- 2.7 any additional information within the Parties' possession, custody or control that would support the re-launch and/or which the Proposed Purchaser

considers to be relevant to obtaining a marketing authorisation in the UK including:

- (a) where the Proposed Purchaser is using the international recognition procedure (**IRP**), a marketing authorisation of the Proposed Purchaser's selection on which its application for a UK marketing authorisation will be based (the **Reference Approval**);
- (b) where the Proposed Purchaser is using the IRP, all necessary existing regulatory materials with respect to the Reference Approval (including dossier, clinical trial, safety and patient data) within Theramex's possession, custody or control and submitted as part of the approval procedures;
- (c) where the Proposed Purchaser is using the IRP, information relating to changes to the Referenced Approval throughout the lifecycle of the UK marketing authorisation for Duphaston; and
- (d) any relevant broader clinical data or safety information which is not jurisdiction-specific and is not exclusive, but may be reasonably required to secure a UK marketing authorisation for Duphaston;

in each case to be made available to the Proposed Purchaser in a timely manner (and in any case, within a maximum of five business days); and

2.8 in the event that (i) [X] no longer manufactures Duphaston; and (ii) instead, the formulation to manufacture Duphaston is transferred by [X] to either Party, the applicable Party or Parties receiving such formulation commit(s) to use reasonable endeavours to transfer (to the extent transferable) to the Proposed Purchaser the formulation to manufacture Duphaston.