1. OVERVIEW OF THE CMA'S DECISION

1. The Competition and Markets Authority (**CMA**) has found that the acquisition by Theramex HQ UK Limited (**Theramex**) of the European Rights to Viatris Inc's (**Viatris**) Femoston and Duphaston Products (the **Rights**), gives rise to a realistic prospect of a substantial lessening of competition (**SLC**) as a result of horizontal unilateral effects arising from the loss of existing competition in the supply of systemic hormone replacement therapy (**HRT**) in relation to menopausal symptoms and loss of future competition in the supply of dydrogesterone in the UK.

2. On 20 August 2023, Theramex entered into an Asset Purchase Agreement (**APA**) with Viatris to acquire the Rights in the UK, the EEA, Switzerland and certain other European countries. The CMA refers to this acquisition as the **Merger**. Theramex and the Rights are together referred to as the **Parties** and, for statements relating to the future, the **Merged Entity**.

3. As the CMA has found that the Merger gives rise to a realistic prospect of an SLC, the Parties have until 11 April 2024 to offer undertakings in lieu of a reference (**UILs**) to the CMA that will remedy the competition concerns identified. If no such undertakings are offered, then the CMA will refer the Merger for a phase 2 investigation pursuant to sections 33(1) and 34ZA(2) of the Enterprise Act 2002 (the **Act**).

Who are the businesses and what products/services do they provide?

4. Theramex is a global women's health pharmaceutical company headquartered in London. Its portfolio includes various HRT products, which treat a range of the symptoms of menopause.

5. Viatris is a global pharmaceutical and healthcare corporation headquartered in Pennsylvania.

6. The CMA focused its assessment on systemic HRT products as this is where the Parties overlap. Systemic HRT is the most commonly used treatment for managing menopausal symptoms, such as hot flushes, joint pain, anxiety and mood swings. The main component of HRT is the hormone oestrogen. Patients who have had a hysterectomy take oestrogen-only HRT, while those who have not had a hysterectomy also take progestogen to protect the lining of the womb from the effect of oestrogen. HRT treatments can be combined (ie contain both oestrogen and progestogen) or separate and, in the case of combined treatments, may deliver progestogen either

continuously or sequentially, depending on the patient's needs. HRT treatments can be taken orally as pills or applied transdermally by means of a patch, gel or spray: the choice will depend on the patient's medical needs and personal preferences.

7. The products which are the subject of the Merger are Viatris' Femoston and Duphaston. Femoston is a combined oral treatment containing oestrogen and progestogen (based on the dydrogesterone molecule) which is available in two forms, continuous (**Femoston Conti**) and sequential (referred to here as **Femoston Sequi**), both of which are available in the UK. Femoston Sequi and Femoston Conti are referred to together as **Femoston**. **Duphaston** is an oral progestogen (based on the dydrogesterone molecule) which is widely used in mainland Europe but does not currently have marketing authorisation in the UK.

Why did the CMA review this merger?

8. The CMA's primary duty is to seek to promote competition for the benefit of consumers. It has a duty to investigate mergers that could raise competition concerns in the UK, provided it has jurisdiction to do so.

9. Theramex and the Rights are both active in the supply of systemic HRT products in the UK, with a combined share of supply of [40-50]% and an increment of [5-10]% by value. The CMA has jurisdiction to review a merger where the share of supply test is met (requiring that the Parties together supply at least 25% of a particular good or service supplied in the UK, and there is an increment to the share of supply). On the basis of the Parties' shares of supply of systemic HRT products, the CMA considers that the share of supply test is met.

What evidence did the CMA look at?

10. In assessing the Merger, the CMA considered a wide range of evidence in the round.

11. The CMA received several submissions and responses to information requests from the Parties. The CMA gathered information about the rationale for the Merger, the Parties' existing products and Theramex's plans to introduce new products in the UK. The CMA also examined the Parties' own internal documents, which show how they run their business and how they view their rivals in the ordinary course of business.

12. The CMA spoke to and gathered evidence from other companies and organisations to understand better how HRT is prescribed in the UK, the

competitive landscape and their views on the impact of the Merger. In particular, the CMA received evidence from menopause specialist clinicians, relevant regulatory health agencies, public bodies as well as Integrated Care Boards and equivalent bodies and other pharmaceutical companies active in the UK market for systemic HRT.

What did the evidence tell the CMA…

…about what would have happened had the Merger not taken place?

13. In order to determine the impact that the Merger could have on competition, the CMA considered what would have happened had the Merger not taken place. This is known as the counterfactual.

14. In this case, the CMA found that, absent the Merger:

    (a) In the case of Femoston Sequi and Femoston Conti, there is evidence that another purchaser would carry on supplying these products in the UK; and

    (b) In the case of Duphaston, there is evidence that another purchaser would have acquired the rights to supply this product in the UK, while Theramex would have gone on to launch a generic version of dydrogesterone in partnership with a third party.

…about the effects on competition of the Merger?

15. The CMA looked at how the Merger could affect competition in (i) the supply of systemic HRT in the UK; and (ii) the supply of dydrogesterone in the UK.

Theory of harm 1: horizontal unilateral effects arising from the loss of competition in the supply of systemic HRT in the UK

16. The CMA considered whether the combination of Theramex and the Rights might be expected to lessen competition substantially in the supply of systemic HRT in the UK. Theramex has the largest market share in systemic HRT in the UK. The UK market for systemic HRT is highly concentrated: the two largest players have around [70-80%] of sales. The effect of the Merger would be to increase Theramex's share by [5-10]%, a significant increase in a concentrated market, and substantially to remove one of the few other material competitive constraints. The CMA found that the constraint imposed by other HRT suppliers is limited. In addition, while patient needs may differ and HRT products are differentiated, the CMA found that products owned by Theramex closely compete with the products being acquired. This includes

Theramex's Bijuve, a combined continuous oral product that competes closely with Femoston Conti. The CMA therefore found that the Merger gives rise to a realistic prospect of an SLC as a result of horizontal unilateral effects arising from the loss of competition in the supply of systemic HRT in the UK.

Theory of harm 2: loss of future competition in the supply of dydrogesterone

17. Unilateral effects may also result in a loss of future competition in relation to the supply of dydrogesterone, a progestogen-only product, in the UK. As explained above, the Rights include the rights to Duphaston, a dydrogesterone product currently marketed in Europe but not in the UK. The CMA found that there is demand for a dydrogesterone product in the UK and that an alternative purchaser of the Rights would have been likely to launch Duphaston in the UK. In addition, as explained above, the CMA found evidence that Theramex was likely to launch a generic dydrogesterone product in the UK, absent the Merger. In that scenario, the owner of Duphaston and Theramex would have been expected to compete with respect to the supply of dydrogesterone.

18. On this basis, the CMA found that absent the Merger, there may have been greater competition to enter or expand dydrogesterone products in the UK market, and more new products may have been introduced. The CMA therefore found that the Merger gives rise to a realistic prospect of an SLC in relation to loss of future competition in the supply of dydrogesterone in the UK.

What happens next?

19. As a result of these concerns, the CMA believes the Merger gives rise to a realistic prospect of SLCs as a result of horizontal unilateral effects arising from the loss of existing competition in the supply of systemic HRT and loss of future competition in the supply of dydrogesterone. The Parties have until 11 April 2024 to offer an undertaking which might be accepted by the CMA to address the SLCs. If no such undertaking is offered, or the CMA decides that any undertaking offered is insufficient to remedy its concerns to the phase 1 standard, then the CMA will refer the Merger for an in-depth phase 2 investigation pursuant to sections 33(1) and 34ZA(2) of the Act.