Anticipated acquisition by LEO Pharma A/S of certain assets of Astellas Pharma Inc

Decision on relevant merger situation and substantial lessening of competition

ME/6581-15

Please note that [✂] indicates figures or text which have been deleted or replaced in ranges at the request of the parties for reasons of commercial confidentiality.

The CMA's decision on reference under section 33(1) of the Enterprise Act 2002 given on 11 March 2016. Full text of the decision published on 5 April 2016.

SUMMARY

1. LEO Pharma A/S (**LEO**) has agreed to acquire a portfolio of dermatological pharmaceutical products and associated assets of Astellas Pharma Inc (**Astellas**) (the **Target Business**) (the **Merger**). LEO and the Target Business are together referred to as the **Parties**.

2. The Competition and Markets Authority (**CMA**) believes that it is or may be the case that the Parties will cease to be distinct as a result of the Merger, that the share of supply test is met and that accordingly arrangements are in progress or in contemplation which, if carried into effect, will result in the creation of a relevant merger situation.

3. The Parties both supply a number of dermatological pharmaceutical products in the United Kingdom (**UK**). The CMA assessed whether the Merger will result in a realistic prospect of a substantial lessening of competition (**SLC**) as a result of horizontal unilateral effects in the following possible product frames of reference in which the Parties' products overlap:

   (a) the supply of products in the Anatomical Therapeutic Chemical (**ATC**) 3 D5X category (other nonsteroidal products for inflammatory skin disorders);

(b) the supply of products with a similar composition (in this case, dermatological products containing hydrocortisone) but in different ATC3 categories; and

(c) the supply of products prescribed for the same therapeutic indication (in this case, topical psoriasis products and topical eczema products) but in different ATC3 categories.

4. The CMA did not find it necessary to conclude on the appropriate product frames of reference in this case since, as set out below, no competition concerns arise in any of the possible frames of reference identified. In terms of geographic scope, the CMA assessed the effect of the Merger in the UK.

5. The evidence available to the CMA from third parties and internal documents indicate that the Parties' dermatological products are not considered to be the closest alternatives to each other. Some third parties did not consider the Parties' dermatological products to be alternatives at all. Third parties also identified various substitute products to those of the Parties and no third party raised any concerns in relation to any of the overlap products. More specifically:

(a) in relation to the supply of products in the D5X category, the CMA found that the Parties' products are not close substitutes as they are used to treat different skin conditions. Additionally, there will remain several competitors post-Merger to constrain the merged entity;

(b) in relation to the supply of dermatological products containing hydrocortisone, the CMA found that the increment in the combined share of supply due to the Merger is very small (around [0–5]%). The CMA also found that the Parties' products are not close substitutes and that there will remain several competitors post-Merger to constrain the merged entity; and

(c) in relation to the supply of:

(i) topical psoriasis products, the increment in the combined share of supply due to the Merger is very small (less than [0–5]%), indicating that the competitive impact of the Merger will be negligible; and

(ii) topical eczema products, the CMA found that the Parties' respective products do not compete closely and there will remain several competitors post-Merger to constrain the merged entity.

6. On the basis of this evidence, the CMA believes that there is no realistic prospect of the Merger resulting in an SLC as a result of horizontal unilateral effects within a market or markets in the UK.

7. The Merger will therefore **not be referred** under section 33(1) of the Enterprise Act 2002 (the **Act**).

ASSESSMENT

Parties

8. LEO is a multinational Danish pharmaceutical company, wholly owned by The LEO Foundation. LEO develops, manufactures and markets dermatological products. In 2014, LEO's portfolio of products for skin diseases included solutions for the treatment of psoriasis, actinic keratosis, infected eczema and other skin infections. The turnover of LEO in 2014 was around £862 million worldwide and around £[✂] in the UK.

9. Astellas is a Japanese pharmaceutical company which focuses on products in six therapeutic areas: urology, oncology, immunology (including transplantation), nephrology, neuroscience and dermatology. The Target Business consists of the following dermatological pharmaceutical products and related assets (including trademarks, patents, marketing authorisations and know-how): Protopic, Condyline, Fonx Range, Lipobase Range, Locobase Repair, Locoid Range, Pimafucort Range, Pimafucin Range, Mildison, Synalar Range, Zineryt, Veltin, Deflatop, Verel, Ciclopoli and Conotrane. The turnover of the Target Business in 2015 was around £[✂] worldwide and around £[✂] in the UK.

Transaction

10. On 11 November 2015, LEO and Astellas entered into an asset purchase agreement under which LEO agreed to purchase the Target Business from Astellas.

11. The Parties informed the CMA that the Merger is also the subject of review by competition authorities in Germany, Poland, Portugal, Spain and Ukraine.

Jurisdiction

12. As a result of the Merger, the enterprises of LEO and the Target Business will cease to be distinct.

13. The Parties overlap in the supply of dermatological pharmaceutical products. In particular, the Parties both supply products in the UK which are classified within the ATC3 category D5X (the ATC classification system is discussed in greater detail at paragraphs 22 and 23 below). The Parties' combined share of supply in the D5X category is approximately [30–40]%, with an increment of approximately [5–10]% (as shown in Table 2 below). The CMA therefore believes that the share of supply test in section 23 of the Act is met.

14. The CMA therefore believes that it is or may be the case that arrangements are in progress or in contemplation which, if carried into effect, will result in the creation of a relevant merger situation.

15. The initial period for consideration of the Merger under section 34ZA(3) of the Act started on 25 January 2016. The statutory 40 working day deadline for a decision is therefore 18 March 2016.[1]

Counterfactual

16. The CMA assesses a merger's impact relative to the situation that would prevail absent the merger (ie the counterfactual). For anticipated mergers, the CMA generally adopts the prevailing conditions of competition as the counterfactual against which to assess the impact of the merger. However, the CMA will assess the merger against an alternative counterfactual where, based on the evidence available to it, it believes that, in the absence of the merger, the prospect of these conditions continuing is not realistic, or there is a realistic prospect of a counterfactual that is more competitive than these conditions.[2]

17. The CMA noted that the Target Business has two products (Pimafucort and Deflatop) which it supplies in Germany but which are currently not supplied in the UK. If these products were supplied in the UK, they would overlap in some of the product frames of reference with LEO's products. However, the CMA saw no reason to believe that these products would be supplied into the UK in the foreseeable future in the absence of the Merger, and no third party raised any concerns in relation to these products. Therefore, the CMA has not considered these products further.

18. As there is no evidence supporting a different counterfactual, and the Parties and third parties have not put forward arguments in this respect, the CMA

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[1] See *Mergers: Guidance on the CMA's jurisdiction and procedure* (CMA2), January 2014, from paragraph 7.34.
[2] *Merger Assessment Guidelines* (OFT1254/CC2), September 2010, from paragraph 4.3.5. The *Merger Assessment Guidelines* have been adopted by the CMA (see *Mergers: Guidance on the CMA's jurisdiction and procedure* (CMA2), January 2014, Annex D).

believes the prevailing conditions of competition to be the relevant counterfactual.

Frame of reference

19. Market definition provides a framework for assessing the competitive effects of a merger and involves an element of judgement. The boundaries of the market do not determine the outcome of the analysis of the competitive effects of the merger, as it is recognised that there can be constraints on merger parties from outside the relevant market, segmentation within the relevant market, or other ways in which some constraints are more important than others. The CMA will take these factors into account in its competitive assessment.[3]

Product scope

20. The relevant product market is identified primarily by considering demand-side substitution, ie the response of customers to an increase in the price of the merging parties' products (or one of them).[4]

21. The Parties submitted that the Target Business and LEO overlap in the manufacturing and supply of dermatological pharmaceutical products. They told the CMA that all of the Parties' products currently sold in the UK are prescription-only medicines (**POM**) used for the treatment of psoriasis and eczema.

22. In previous decisions in the pharmaceutical sector,[5] the CMA (including its predecessors) and the European Commission (**EC**) have all used the ATC classification, developed and maintained by the European Pharmaceutical Market Research Association (**EphMRA**), as a starting point for defining the product scope.

23. The ATC has a hierarchical structure organised in 16 categories, each comprising up to four levels. The third level of the EphMRA ATC classification (**ATC3**), which groups together pharmaceuticals based on their therapeutic indications (ie their intended use) has generally been used as a starting point for defining product scopes.

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[3] *Merger Assessment Guidelines*, paragraph 5.2.2.
[4] *Merger Assessment Guidelines*, paragraph 5.2.7.
[5] See for example, M.5295 *Teva/Barr*, EC, 19 December 2008; M.5253 *Sanofi-Aventis/ Zentiva*, EC, 4 February 2009; M.5865 *Teva/Ratiopharm*, EC, 3 August 2010; M.6258 *Teva/Cephalon*, EC, 13 October 2011 and; M.6613 *Watson/Actavis*, EC, 5 October 2012; ME/6331/13 *Shire/Viropharma*, OFT, 10 February 2014; ME/6500/14 *Perrigo Company/Omega Pharma Invest*, CMA, 9 March 2015; and ME/6513/15 *Actavis/Auden*, CMA, 21 May 2015.

24. In the present case, the CMA has assessed the impact of the Merger in relation to a frame of reference based on the ATC3 category, but has also considered other possible frames of reference.

25. The CMA and EC have previously departed from the ATC3 level when evidence has indicated that a narrower or wider product scope is more appropriate, for example using the fourth level of the classification or including (or excluding) medicines irrespective of their ATC classification. For example, in *Teva/Ratiopharm*, the EC's investigation indicated that, at least for POMs, demand for medicinal products based on pharmaceutical molecules was specific to the molecule in question and its galenic form.[6] In *Teva/Barr* and *Sanofi-Aventis/Zentiva*, the EC noted that competition primarily takes place between drugs based on the same molecule. In *Sanofi-Aventis/Zentiva*, the EC noted that, even in cases where the molecule is the same, the formulation of two medicines may differ in terms of dosage strength and, in prescription markets, this would typically limit substitutability.

26. In *Actavis/Auden McKenzie*, the CMA found that there is generally limited demand-side substitutability between generic pharmaceuticals of different molecules within the same ATC3 category, and noted that precedents in the sector indicate that there may be limited demand-side substitutability between generic pharmaceuticals based on the same molecule but in different galenic forms and/or strengths.[7] Accordingly, the CMA assessed the impact of the merger in relation to a frame of reference for the supply of generic pharmaceuticals supplied by the merging parties based on: (i) the same molecule, strength and galenic form; and (ii) the same molecule, but different strengths and/or galenic forms.

27. In the present case, and on a cautious basis, the CMA has assessed the impact of the Merger in relation to a frame of reference for the supply of products with a similar composition (ie dermatological products containing hydrocortisone). This is a conservative approach because, if the frame of reference was based on the same molecule, strength and galenic form, the Parties products would not overlap.

28. The Parties submitted that the ATC3 categorisation does not reflect the market for dermatological pharmaceutical products. They said that the dermatological ATC3 categories are both over and under-inclusive in that, in respect of certain indications (eg eczema), competition occurs across ATC3 categories, while in respect of other indications (eg psoriasis), not all products

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[6] Galenic form is a term that refers to a combination of features in all medicines comprising their pharmaceutical form and route of administration.
[7] ME/6513/15 *Actavis/Auden*, CMA, 21 May 2015; paragraph 43.

captured by the relevant ATC3 category are substitutable. Hence, the Parties supported a frame of reference based on the product's therapeutic indication.

29. The CMA spoke to a number of third parties to understand the extent to which they consider the Parties' products to be substitutable and to understand whether using the ATC3 category is an appropriate frame of reference. All respondents took the same approach as the Parties and assessed the substitutability of the Parties' products based on what indication the products are prescribed for (rather than based on products which are in the same ATC3 category).

30. Accordingly, the CMA also assessed the impact of the Merger in relation to a frame of reference based on therapeutic indication in the following distinct segments in which the Parties' products overlap: (i) the supply of topical psoriasis products; and (ii) the supply of topical eczema products.

31. In summary, the CMA has, on a cautious basis, assessed the impact of the Merger using the following possible frames of reference:

    (a) the supply of products in the same ATC3 category (in this case, the D5X category);

    (b) the supply of products with a similar composition (in this case, dermatological products containing hydrocortisone) but in different ATC3 categories; and

    (c) the supply of products prescribed for the same therapeutic indication (in this case, topical psoriasis products and topical eczema products) but in different ATC3 categories.

32. The CMA has not found it necessary to conclude on the appropriate product frames of reference in this case, since, as set out below, no competition concerns arise in any of the possible frames of reference.

Geographic scope

33. The Parties submitted that the market for finished pharmaceutical products should be assessed on the basis of a national geographic scope, as the following aspects typically vary from country to country:

    (a) the authorisation procedures for pharmaceutical products;

    (b) price setting and reimbursement scheme mechanisms;

    (c) marketing strategy, brands and pack sizes;

(d) distribution channels; and

(e) national clinical guidelines, medical views and preference.

34. In previous decisions[8] involving mergers between companies supplying finished pharmaceuticals, the CMA has found that the relevant geographic markets for finished products are national.

35. The CMA did not find any evidence to suggest that a departure from the geographic frame of reference in previous cases was necessary. The CMA has therefore considered the impact of the Merger in the UK.

Conclusion on frame of reference

36. For the reasons set out above, the CMA has considered the impact of the Merger in the following possible product frames of reference in which the Parties' products overlap:

(a) the supply of products in the same ATC3 category (in this case, the D5X category);

(b) the supply of products with a similar composition (in this case, dermatological products containing hydrocortisone) but in different ATC3 categories; and

(c) the supply of products prescribed for the same therapeutic indication (in this case, topical psoriasis products and topical eczema products) but in different ATC3 categories.

37. In terms of geographic scope, the CMA has assessed the effect of the Merger in the UK.

Competitive assessment

Horizontal unilateral effects

38. Horizontal unilateral effects may arise when one firm merges with a competitor that previously provided a competitive constraint, allowing the merged firm profitably to raise prices or degrade quality on its own and without needing to coordinate with its rivals.[9] Horizontal unilateral effects are more likely when the merger parties are close competitors. The CMA assessed whether it is or may be the case that the Merger has resulted, or

[8] See footnote 6.
[9] *Merger Assessment Guidelines*, from paragraph 5.4.1.

may be expected to result, in an SLC in relation to unilateral horizontal effects in the supply of dermatological pharmaceutical products in the UK.

39. The CMA considered a range of evidence in conducting its competitive assessment of the Merger, including shares of supply, internal documents provided by the Parties and third party views. The CMA used this evidence to assess both the closeness of competition between the Parties and the extent of the competitive constraints exerted by alternative suppliers that would remain post-Merger.

Overlaps in products currently sold by both of the Parties

40. Based on the frames of reference set out above, the CMA identified the following overlaps:

    (a) ATC3 category: Both LEO's Picato product (indicated for the treatment of actinic keratosis) and the Target Business's Protopic product (indicated for the treatment of eczema) fall within the D5X category (Other nonsteroidal products for inflammatory skin disorders).

    (b) Products with a similar composition: Both LEO's Fucidin H product (used for the short-term treatment of infected eczema) and the Target Business's Locoid and Mildison products (both used for the long-term treatment of non-infected eczema) are dermatological products containing hydrocortisone, but are in different ATC3 categories.

    (c) Products prescribed for the same therapeutic indication: Both LEO's Dovobet and Dovonex products and the Target Business's Locoid and Mildison products are indicated for the treatment of psoriasis, but are in different ATC3 categories; and both LEO's Fucibet and Fucidin H products and the Target Business's Protopic, Locoid, and Mildison products are indicated for the treatment of eczema.

41. These overlaps are summarised in Table 1.

Table 1: Overlap areas between LEO's and the Target Business's products

Frame of reference		LEO's product	Target Business's product
ATC3 category: D5X		Picato	Protopic
Products with similar composition (containing hydrocortisone)		Fucidin H	Locoid
			Mildison
Products prescribed for the same therapeutic indication	Treatment of psoriasis	Dovobet	Locoid
		Dovonex	Mildison
	Treatment of eczema	Fucidin H	Locoid
		Fucibet	Mildison
			Protopic

Source: The Parties.

Supply of products in ATC3 D5X category

Share of supply

42. The Parties submitted shares of supply, by both volume and value, for their products falling within the D5X category, as shown in Table 2.[10]

[10] The share data provided by the Parties is based on the volume and value data reported by IMS Health (**IMS**) for the period 1 October 2014 to 30 September 2015. The Parties consider that IMS is the most reliable source of UK sales data for prescription dermatological products, but that IMS data is likely to under-report the value and volume of sales attributable to unbranded generic products as these are often reported by IMS in a category entitled 'Lab unknown'. According to the Parties, as a result, IMS data tend to under-represent the market position held by generic competitors and overstate the market position of suppliers of branded/originator products (eg LEO and the Target Business).

Table 2: Shares by value and by volume for the supply of D5X products in the UK

		Volume		Value	
Manufacturer	**Product**	**Units ('000s)**	**Market share**	**Value (£'000s)**	**Market share**
LEO	Picato	[✂]	[5–10]%	[✂]	[5–10]%
Target Business	Protopic	[✂]	[40–50]%	[✂]	[30–40]%
Combined		[✂]	*[50–60]%*	[✂]	*[30–40]%*
Almirall	Solaraze	[✂]	[30–40]%	[✂]	[40–50]%
GSK	Toctino	[✂]	[0–5]%	[✂]	[10–20]%
Meda Pharmaceuticals	Elidel	[✂]	[5–10]%	[✂]	[5–10]%
Basilea Pharma	Toctino BS	[✂]	[0–5]%	[✂]	[0–5]%
Sinclair IS Pharma	Atopiclair	[✂]	[0–5]%	[✂]	[0–5]%
DDD Group	Soleve	[✂]	[0–5]%	[✂]	[0–5]%
Other	Zinc Salicylic	[✂]	[0–5]%	[✂]	[0–5]%
Total		**5,418**	**100%**	**203,367**	**100%**

Source: The Parties (for the period 1 October 2014 to 30 September 2015).

43. The table shows that the Parties are the second and fourth largest suppliers of D5X products by value in the UK. Post-Merger, LEO would remain the second largest supplier of D5X products. It would have around [30–40]% share of supply by value, with an increment of around [5–10]% arising from the Merger.

44. The CMA notes that Almirall would remain the largest supplier of D5X products with a [40–50]% share of supply by value, and that the top four providers would account for around [90–100]% share of supply of D5X products in the UK.

Parties' views

45. The Parties submitted that their products, Picato and Protopic, are not substitutes given the differences in active ingredient and conditions they treat:

(a) Picato contains the active ingredient, ingenol mebutate, and is indicated for the treatment of actinic keratosis; while

(b) Protopic contains the active ingredient, tacrolimus monohydrate, and is indicated for the treatment of eczema.

46. The Parties told the CMA that the ATC3 D5X category does not provide an appropriate basis on which to define the market as the D5X category is a catch-all category that encompasses all nonsteroidal products for inflammatory skin disorders other than those falling within categories D5A (topical anti-psoriasis products) and D5B (systemic anti-psoriasis products). Thus, products that fall within the D5X category are indicated for treating a

broad range of conditions and are based on a wide array of different molecules.

47. The Parties submitted that Picato and Protopic are not the closest competitor products within the D5X category. They said that, of the products within the D5X category, Picato competes most closely with Solaraze, which is the leading actinic keratosis drug, whereas Protopic's closest competitor is Elidel, which is a topical non-steroidal treatment for eczema.

Internal documents

48. LEO provided internal documents to the CMA showing an extensive assessment of the anticipated acquisition of the Target Business. In the internal documents assessing the strategic fit of the Target Business's products with LEO's dermatological portfolio,[11] Protopic is not compared with Picato[12] which suggests that LEO believed there was little or no competitive interaction between these two products.

49. Similarly, in LEO's [✂],[13] the closest competitor products to Picato are stated to be: [✂]. Protopic is not included in this analysis.

50. In the internal document assessing the competitive environment of Astellas' dermatological portfolio,[14] Picato is not identified as a competitor product to Protopic. Instead, [✂] is identified as the closest competitor product. The report identifies additional competitors to include topical corticosteroids and oral corticosteroids such as [✂].

Third party views

51. Responses from customers and competitors to the CMA's investigation indicate that Picato and Protopic are not close substitutes. Most respondents told the CMA that the products do not treat the same skin condition and, as such, are not substitutes.

52. Most respondents said that the closest competitor product to Picato is Solaraze and the closest competitor product to Protopic is Elidel (both Solaraze and Elidel are within the D5X category). Other respondents named

[11] Attachment 13 to the Merger Notice – [✂] and Attachment 15 to the Merger Notice – [✂].
[12] Rather, it is compared to Fucidin H.
[13] Attachment 22 to the Merger Notice [✂].
[14] Attachment 19 to the Merger Notice [✂].

products which are not within the D5X category as substitutes for Picato and Protopic.[15]

53. The Medicines and Healthcare products Regulatory Authority (**MHRA**) and the Department of Health (**DoH**) told the CMA that Picato and Protopic do not treat the same skin condition and are not substitutes, with both identifying Elidel as the closest competitor product to Protopic.

CMA assessment

54. While the Parties' combined share of supply of D5X products in the UK post-Merger is significant, at around [50–60]%, the CMA believes, on the basis of the evidence set out above, that the Parties' products in this ATC3 category do not compete closely and, therefore, the competition that would be lost as a result of the Merger would be minimal. Additionally, there will remain several competitors post-Merger to constrain the merged entity.

55. The CMA therefore believes that the Merger does not give rise to a realistic prospect of an SLC in the supply of products in the ATC3 D5X category in the UK.

Supply of dermatological products containing hydrocortisone

Share of supply

56. The Parties submitted shares of supply, by both volume and value, for dermatological products containing hydrocortisone, as shown in Table 3.[16]

[15] Third parties identified Le Desowen (Galderma) and Efficort (Galderma) as close substitutes for Protopic; and Efudix (Meda Pharmaceuticals), Zyclara (Meda Pharmaceuticals), Actikerall (Almirall), Metvix (Galderma) and Silkis (Galderma) as close substitutes for Picato.
[16] The share data provided by the Parties is based on the volume and value data reported by IMS Health (IMS) for the period 1 October 2014 to 30 September 2015 (see footnote 10).

Table 3: Shares by value and volume for the supply of hydrocortisone products in the UK

		Volume		Value	
Manufacturer	**Product**	**Units ('000s)**	**Market share**	**Value (£'000s)**	**Market share**
LEO	Fucidin H	[✂]	[5–10]%	[✂]	[10–20]%
Target Business	Locoid	[✂]	[0–5]%	[✂]	[0–5]%
	Mildison	[✂]	[0–5]%	[✂]	[0–5]%
Combined		[✂]	*[10–20]%*	[✂]	*[10–20]%*
Other Generics	Hydrocortisone	[✂]	[40–50]%	[✂]	[30–40]%
Johnson & Johnson	Daktacort	[✂]	[20–30]%	[✂]	[20–30]%
Bayer	Canesten	[✂]	[10–20]%	[✂]	[10–20]%
Alliance Pharma	Multiple	[✂]	[5–10]%	[✂]	[5–10]%
Other	Other	[✂]	[0–5]%	[✂]	[0–5]%
Reckitt Benckiser	HC 45 Cream	[✂]	[0–5]%	[✂]	[0–5]%
Total		**9,574**	**100%**	**26,402**	**100%**

Source: The Parties (for the period 1 October 2014 to 30 September 2015).

57. The table shows that three companies – LEO, Johnson & Johnson and Bayer – currently have a combined share of supply of hydrocortisone products in the UK of around [50–60]% by value. Post-Merger, LEO would remain the second largest supplier with around [10–20]% share of supply by value, with a small increment of around [0–5]% arising from the Merger. Johnson & Johnson would remain the largest supplier of hydrocortisone products in the UK with a share of supply of [20–30]% by value. The table also shows that there are a large number of generic products available, accounting for at least [30–40]% share of supply by value, as well as products from other smaller providers.

Parties' views

58. The Parties submitted that their products which contain hydrocortisone (ie Fucidin H, Locoid, and Mildison) do not compete closely for two main reasons:

(a) Mildison and Locoid (products of the Target Business) are both single agent products (ie they only contain hydrocortisone) while LEO's Fucidin H is a combination product containing both hydrocortisone acetate and fusidic acid (an antibiotic) and, as such, they would not be prescribed interchangeably;[17]

[17] As noted in the Ephmra Anatomical Classification Guidelines 2016 (Introduction), a plain (or single agent) product can contain one or more active ingredients of a similar type, eg a topical steroid containing one or two corticosteroids; however, when another active ingredient is added, eg an anti-infective agent, it becomes a combination product.

(b) Mildison and Locoid are used for the long-term treatment of non-infected eczema, while Fucidin H is typically used for the short-term treatment of infected eczema.[18]

59. The Parties also told the CMA that there are a significant number of branded and generic products sold in the UK which contain hydrocortisone (including in combination with other active ingredients), as shown in Table 3.

Internal documents

60. In the internal document assessing the strategic fit of the Target Business's products with LEO's dermatological portfolio,[19] Locoid is compared to Fucidin H and described as being complementary for the treatment of infected eczema (ie LEO will be able to provide a complete portfolio covering non-steroidal maintenance therapy with acute treatment for infected eczema and non-infected eczema as well as medical skin care). Mildison is not included in the assessment, which suggests that LEO did not consider this product to be overlapping or complementary.

61. In the internal document assessing the competitive environment of Astellas' dermatological portfolio,[20] Locoid and/or Mildison are not identified as competitor products to Fucidin H.

Third party views

62. All respondents to the CMA's investigation said that Fucidin H is not substitutable with either Locoid or Mildison.

63. Some respondents told the CMA that, although the products treat the same skin condition, Locoid and Mildison are used for different types or severities of the condition compared with Fucidin H. Other respondents told the CMA that Locoid and Mildison are not used for treating the same skin condition as Fucidin H.

64. The MHRA told the CMA that Fucidin H, Locoid and Mildison are used to treat the same skin condition, but are used for different forms, stages or levels of severity of the condition, and, as such, are not substitutes. The DoH told the CMA that these products are not substitutes based on their indications for

[18] Once the infection has cleared, treatment of the underling condition resumes (usually) with a single agent product.
[19] Attachment 13 to the Merger Notice – [✂] and Attachment 15 to the Merger Notice – [✂].
[20] Attachment 19 to the Merger Notice – [✂].

use. The National Institute for Health and Care Excellence (**NICE**) said that there is a wide range of competing alternatives for Fucidin H.

CMA assessment

65. On the basis of the evidence set out above (in particular, the Parties' relatively low combined shares of supply and the small increment; evidence demonstrating that the Parties' products do not compete closely; and the presence of several competitors supplying dermatological products containing hydrocortisone), the CMA believes that the Merger does not give rise to a realistic prospect of an SLC in the supply of dermatological products containing hydrocortisone in the UK.

Supply of topical psoriasis and eczema products

(a) Topical psoriasis products

- *Share of supply*

66. The Parties submitted shares of supply, by both volume and value, for topical products used for treating psoriasis, as shown in Table 4.[21]

[21] The share data provided by the Parties is based on the volume and value data reported by IMS Health (IMS) for the period 1 October 2014 to 30 September 2015 (see footnote 10). Certain adjustments were made to the underlying IMS data: the Parties adjusted the data using Cegedim Strategic Data (which is based on prescription data contained in the computer systems of prescribing doctors) to reflect better the volume and value of Locoid and Mildison sales that were prescribed for the treatment of psoriasis (both are more commonly prescribed to treat eczema).

Table 4: Shares by value and volume for the supply of topical psoriasis products in the UK

		Volume		Value	
Manufacturer	**Product**	**Units ('000s)**	**Market share**	**Value (£'000s)**	**Market share**
LEO	Dovobet	[✂]	[20–30]%	[✂]	[60–70]%
	Dovonex	[✂]	[10–20]%	[✂]	[5–10]%
Target Business	Locoid	[✂]	[0–5]%	[✂]	[0–5]%
	Mildison	[✂]	[0–5]%	[✂]	[0–5]%
Combined		[✂]	*[40–50]%*	[✂]	*[60–70]%*
Other Generics	Steroids	[✂]	[20–30]%	[✂]	[5–10]%
Other Generics	Calcipotriol	[✂]	[0–5]%	[✂]	[5–10]%
Other	Other D5A	[✂]	[5–10]%	[✂]	[0–5]%
Dermal Laboratories	Capasal	[✂]	[5–10]%	[✂]	[0–5]%
Johnson & Johnson	T Gel	[✂]	[5–10]%	[✂]	[0–5]%
Allergan	Exorex	[✂]	[0–5]%	[✂]	[0–5]%
Galderma / Nestle	Silkis	[✂]	[0–5]%	[✂]	[0–5]%
Perrigo	Alphosyl	[✂]	[0–5]%	[✂]	[0–5]%
Total		**5,734**	**100%**	**74,965**	**100%**

Source: The Parties (for the period 1 October 2014 to 30 September 2015).

67. The table shows that LEO is the largest supplier of products that treat topical psoriasis with around [60–70]% share of supply based on value. By contrast, the Target Business has a negligible share of supply of less than [0–5]%. The table also shows that there are several generic and branded products available.

- *Parties' views*

68. The Parties told the CMA that Dovonex and Dovobet are each other's closest competitor, with Silkis (Galderma) also competing closely.

69. The Parties submitted that Locoid and Mildison do not compete closely with Dovobet and Dovonex because Locoid and Mildison contain low potency steroids as their active ingredients while Dovonex is a non-steroidal product which has a vitamin D analogue as its active ingredient and Dovobet is a combination product which contains a potent steroid. The Parties said that, because of these differences, the products would not be prescribed interchangeably.

70. The Parties also submitted that the combined topical psoriasis portfolio of LEO and the Target Business will face constraints from other types of treatment outside the market (ie phototherapy, systemic products and biologics), as well as competition from the generic manufacturers of calcipotriol.

- *Internal documents*

71. In the internal document assessing the strategic fit of the Target Business's products with LEO's dermatological portfolio,[22] Locoid is compared with Dovobet, but it is stated that there is only very limited overlap on the basis that the main therapy for mild psoriasis is steroid-based. Mildison is not compared to Dovobet and neither Locoid nor Mildison are compared with Dovonex, which suggests that LEO did not consider these products to be overlapping or complementary.

72. In the internal document assessing the competitive environment of Astellas' dermatological portfolio,[23] neither Locoid nor Mildison are identified as competitors of Dovonex and/or Dovobet.

- *Third party views*

73. Most respondents to the CMA's investigation said that neither Dovobet nor Dovonex are substitutable with either Locoid or Mildison. However, two competitors told the CMA that Dovobet is substitutable with Locoid, and one of those competitors also said that Dovonex is substitutable with Locoid.

74. Respondents differed in their reasoning why the products are not substitutable. Some respondents told the CMA that, although the products treat the same skin condition, Locoid and Mildison are used for different types or severities of the condition compared with Dovobet and Dovonex. Other respondents told the CMA that Locoid and Mildison are not used for treating the same skin condition as Dovobet and Dovonex.

75. The MHRA told the CMA that these products treat the same skin condition, but are used for different forms, stages or levels of severity of the condition, and, as such, are not substitutes. NICE said that Dovobet, Locoid and Mildison are all used for short-term treatment of topical psoriasis, but that they are used for different levels of severity of the condition.

- *CMA assessment*

76. On the basis of the evidence set out above (in particular, the very small increment in the Parties' combined share of supply as a result of the Merger (less than [0–5]%); and the majority of respondents indicating and explaining why the Parties' respective products are not substitutable), the CMA believes

[22] Attachment 13 to the Merger Notice – [✂] and Attachment 15 to the Merger Notice – [✂].
[23] Attachment 19 to the Merger Notice – [✂].

that the Merger does not give rise to a realistic prospect of an SLC in the supply of topical psoriasis products in the UK.

(b) Topical eczema products

- *Share of supply*

77. The Parties submitted shares of supply, by both volume and value, for topical products used for treating eczema, as shown in Table 5.[24]

Table 5: Shares by value and volume for the supply of topical eczema products in the UK

		Volume		Value	
Manufacturer	**Product**	**Units ('000s)**	**Market share**	**Value (£'000s)**	**Market share**
LEO	Fucibet	[✂]	[5–10]%	[✂]	[5–10]%
	Fucidin H	[✂]	[0–5]%	[✂]	[0–5]%
Target Business	Protopic	[✂]	[0–5]%	[✂]	[5–10]%
	Locoid	[✂]	[0–5]%	[✂]	[0–5]%
	Mildison	[✂]	[0–5]%	[✂]	[0–5]%
Combined		[✂]	*[10–20]%*	[✂]	*[10–20]%*
Other	Other D7A/D7B	[✂]	[30–40]%	[✂]	[30–40]%
Other Generics	Betamethasone	[✂]	[5–10]%	[✂]	[10–20]%
Other Generics	Hydrocortisone	[✂]	[10–20]%	[✂]	[5–10]%
Merck Sharp & Dohme	Elocon	[✂]	[0–5]%	[✂]	[5–10]%
Johnson & Johnson	Daktacort	[✂]	[10–20]%	[✂]	[5–10]%
GSK	Betnovate	[✂]	[5–10]%	[✂]	[5–10]%
Bayer	Canesten HC	[✂]	[5–10]%	[✂]	[0–5]%
Merck Sharp & Dohme	Diprosalic	[✂]	[0–5]%	[✂]	[0–5]%
Meda Pharmaceuticals	Elidel	[✂]	[0–5]%	[✂]	[0–5]%
Total		**21,836**	**100%**	**101,320**	**100%**

Source: The Parties.

78. The table shows that shares of supply are fairly evenly distributed among a large number of competitors, and that there are several generic and branded products available. The three largest providers – LEO, the Target Business, and Merck Sharp & Dohme – have a combined share of supply of around [20–30]% based on value. LEO is the largest supplier with a share of supply of around [10–20]% followed by Merck Sharp & Dohme and the Target Business, which have shares of supply around [5–10]% and [5–10]% respectively.

[24] The share data provided by the Parties is based on the volume and value data reported by IMS Health (IMS) for the period 1 October 2014 to 30 September 2015 (see footnote 10).

79. Post-Merger, LEO would provide around [10–20]% of topical eczema products in the UK, with an increment of [5–10]% by value arising from the Merger.

- *Parties' views*

80. The Parties submitted that their products do not compete closely, for the following reasons:

(a) Fucidin H and Fucibet are combination products containing fusidic acid (an antibiotic) and are typically used for the short-term treatment of infected eczema; and

(b) Protopic, Locoid, and Mildison are used for the long-term treatment of non-infected eczema and to treat flare-ups/clinical inflammation (ie to combat the primary condition).

81. The Parties submitted that Protopic is a topical calcineurin inhibitor which, unlike topical steroids/corticosteroids (ie Fucidin H and Fucibet), does not cause skin thinning, pigment changes, blood vessel formation or loss of response with prolonged use. The Parties said that, when Astellas released the product in the UK, it specifically marketed the product for cases where topical corticosteroids are either ineffective or unsuitable.

- *Internal documents*

82. In the internal document assessing the strategic fit of the Target Business's products with LEO's dermatological portfolio,[25] Protopic and Locoid are compared to Fucidin H and described as complementary to LEO's product portfolio for the treatment of infected eczema. Mildison and Fucibet are not included in the assessment which suggests that LEO did not consider these products to be overlapping or complementary.

83. In the internal document assessing the competitive environment of Astellas' dermatological portfolio,[26] neither Protopic, Locoid nor Mildison are identified as competitors of Fucidin H or Fucibet.

- *Third party views*

84. Most respondents to the CMA's investigation said that neither Fucibet nor Fucidin H are substitutable with any of the Target Business's topical eczema products (Locoid, Mildison and/or Protopic). Two competitors stated that

[25] Attachment 13 to the Merger Notice – [✂] and Attachment 15 to the Merger Notice – [✂].
[26] Attachment 19 to the Merger Notice – [✂].

Locoid and Protopic are substitutable with Fucibet as they treat the same skin condition. However, the MHRA told the CMA that, while these products are used to treat the same skin condition, they are used for different forms, stages or levels of severity of the condition and, as such, are not substitutes. NICE said that there is a wide range of competing alternatives to Fucidin H and Fucibet.

85. Respondents who believed that the Parties' respective products are not substitutable differed in their reasons why. Some respondents told the CMA that, although the products treat the same skin condition, Locoid, Mildison and Protopic are used for different types or severities of the condition compared to Dovobet and Dovonex. Other respondents told the CMA that Locoid and Mildison are not used for treating the same skin condition as Fucibet and Fucidin H.

- *CMA assessment*

86. On the basis of the evidence set out above (in particular, the Parties' modest combined share of supply; the views of the majority of third parties and internal documents which indicate that the Parties' respective products do not compete closely; and the presence of several competitors supplying products for the topical treatment of eczema), the CMA believes that the Merger does not give rise to a realistic prospect of an SLC in the supply of topical treatments for eczema in the UK.

Conclusion on horizontal unilateral effects

87. For all the reasons set out above, the CMA believes that the Merger does not give rise to a realistic prospect of an SLC as a result of horizontal unilateral effects in any market in the UK.

Barriers to entry and expansion

88. Entry, or expansion of existing firms, can mitigate the initial effect of a merger on competition, and in some cases may mean that there is no SLC. In assessing whether entry or expansion might prevent an SLC, the CMA considers whether such entry or expansion would be timely, likely and sufficient.[27]

89. However, the CMA has not had to conclude on barriers to entry or expansion as the Merger does not give rise to competition concerns on any basis.

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[27] *Merger Assessment Guidelines*, from paragraph 5.8.1.

Third party views

90. The CMA contacted customers and competitors of the Parties and received seven responses from customers and nine responses from competitors. The CMA also contacted the DoH, NICE and the MHRA. Although some third parties said that some of the Parties' products were substitutable (as set out above), no third party raised any concerns about the Merger.

91. Third party comments have been taken into account where appropriate in the competitive assessment above.

Decision

92. Consequently, the CMA does not believe that it is or may be the case that the Merger may be expected to result in an SLC within a market or markets in the UK.

93. The Merger will therefore **not be referred** under section 33(1) of the Act.

Andrew Wright
Director, Mergers
Competition and Markets Authority
11 March 2016