Anticipated acquisition by Actavis UK Limited of Auden Mckenzie Holdings Ltd

ME/6513/15

The CMA's decision on reference under section 33(1) of the Enterprise Act 2002 given on 21 May 2015. Full text of the decision published on 30 June 2015.

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.

SUMMARY

1. Actavis UK Limited (**Actavis**) has agreed to acquire Auden Mckenzie Holdings Ltd (**Auden Mckenzie**) (the **Merger**). Actavis and Auden Mckenzie are together referred to as the **Parties**.[1]

2. The Competition and Markets Authority (**CMA**) considers that the Parties will cease to be distinct as a result of the Merger, that the turnover 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 overlap in the development and supply of branded and unbranded generic pharmaceuticals in the UK. On a cautious basis, the CMA has assessed the impact of the Merger on the supply in the UK of:

   (a) generic pharmaceuticals supplied by the Parties of the same molecule, in the same strength and galenic form[2]; and

   (b) generic pharmaceuticals supplied by the Parties based on the same molecule, but in different strengths and/or galenic forms.

4. In relation to the overlaps where the Parties supply products of the same molecule, strength and galenic form, Actavis acts a reseller of third parties'

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[1] Following the decision of the European Commission (**EC**) on Actavis' proposed acquisition of Allergan on 16 March 2015, in this document the term 'Parties' includes Allergan. See paragraph 19 below.
[2] Galenic form is a term that refers to a combination of features in all medicines comprising their pharmaceutical form and route of administration.

products. In these cases, the CMA found that the Parties' combined shares of supply are generally low, the incremental increases in shares of supply brought about by the Merger are generally low, and that there are other resellers besides Actavis in respect of each of these overlaps. No third party raised any concerns in relation to these products.

5. The CMA investigated three overlaps where the Parties supply products of the same molecule but in different strengths and/or galenic forms. In relation to Paracetamol and Dihydrocodeine Tartrate combination tablets, Phenytoin 100mg capsules/tablets and the molecule Dexamethasone, the CMA found that the Parties' products do not compete closely. Furthermore, no third party raised any concerns in relation to any of these products.

6. The CMA's merger investigation also ruled out concerns relating to pipeline products, concerns relating to generic pharmaceuticals of different molecules used to treat the same therapeutic condition, and concerns relating to a limited vertical overlap that exists between the Parties.

7. The CMA therefore considers that the Merger does not give rise to a realistic prospect of a substantial lessening of competition (**SLC**) as a result of horizontal unilateral or vertical effects.

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

ASSESSMENT

Parties

9. **Actavis** is indirectly a wholly-owned subsidiary of Actavis plc, a global pharmaceutical company that develops, manufactures and distributes generic and branded pharmaceuticals.

10. **Auden Mckenzie** is a UK-based company focused on the development and licensing of generic medicines, primarily in the UK. Auden Mckenzie does not have its own in-house manufacturing capacity, and uses third parties to manufacture its products. The turnover of Auden Mckenzie in 2014 was around £[✂] worldwide and around £[✂] in the UK.

Transaction

11. On 23 January 2015, Actavis entered into a share purchase agreement with the owners of Auden Mckenzie. Under this agreement, Actavis will acquire

100% of the shares in Auden Mckenzie. Actavis will thereby acquire sole control of Auden Mckenzie.

Jurisdiction

12. As a result of the Merger, the enterprises of Actavis and Auden Mckenzie will cease to be distinct.

13. As the UK turnover of Auden Mckenzie exceeds £70 million, the turnover test in section 23(1)(b) of the Act is satisfied.

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 31 March 2015 and the statutory 40 working day deadline for a decision is therefore 29 May 2015.

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 considers 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.[3]

17. The Parties submitted that the appropriate counterfactual is the sale of Auden Mckenzie, as the current shareholders wished to exit their shareholding for personal reasons. It said that, had negotiations with Actavis not progressed, Auden Mckenzie would have sought another buyer capable of entering into a transaction on similar terms.

18. Although it is realistic that, in the absence of the Merger, Auden McKenzie might have been sold to another party, it is not clear that this would have presented a more or less competitive situation than the pre-merger situation

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[3] *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).

as the identity of any likely buyer is highly speculative. Therefore, the CMA has used the pre-merger condition of Auden McKenzie in its counterfactual. The CMA received no evidence from the Parties to persuade it to adopt an alternative counterfactual, and no third party put forward arguments in this respect.

19. In November 2014, Actavis announced its intention to acquire sole control of Allergan Inc. (**Allergan**), a US pharmaceutical company, whose UK business generated a revenue of €[✂] in 2013.[4] The transaction was notified to the EC on 9 February 2015 and subsequently cleared on 16 March 2015.[5]

20. The CMA takes parallel transactions, such as Actavis' planned acquisition of Allergan, into account in its competitive assessment of a merger by considering whether the merger gives rise to a realistic prospect of an SLC whether or not the parallel transaction proceeds, unless the parallel transaction can be clearly ruled out as too speculative.[6] The CMA considers that the Allergan acquisition is not speculative in view of the public announcement of this acquisition and the EC clearance. Therefore, the CMA has assessed the Merger against the conditions of competition that would exist following completion of Actavis' acquisition of Allergan. It was not necessary for the CMA also to assess the Merger against a counterfactual in which the Allergan acquisition did not complete, since that counterfactual could not give rise to any additional competition concerns.

Background

21. Both Parties are active in the supply of generic pharmaceuticals in the UK. Generic pharmaceuticals are copies of originator pharmaceuticals[7] (ie the product that first came to market), which can be marketed once the originator product is no longer protected by patents or other rights. Once the patent for an originator drug expires, or is due to expire, the Secretariat of the British Pharmacopoeia[8] will publish a monograph for the product in question which sets the standard that a generic version of the originator product must meet.

22. All generic drugs are copies of specific branded originator drugs. A generic drug developer seeking to commercialise a generic version of an originator drug will require authorisation from the Medicines and Healthcare products

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[4] See Table 1 of the Form CO submitted to the EC on 9 February 2015.
[5] EC (March 2015), *COMP/M.7480 – Actavis/Allergan*.
[6] *Merger Assessment Guidelines*, paragraph 4.3.26.
[7] See EC (August 2010), *COMP/M.5865 – Teva/Ratiopharm*, paragraph 12, for example.
[8] The British Pharmacopoeia provides authoritative official standards for pharmaceutical substances and medicinal products.

Regulatory Agency (**MHRA**), an executive agency of the Department of Health.[9]

23. Branded generic pharmaceuticals are sold under a brand name that is different from the name of the branded originator product. Unbranded generic pharmaceuticals are sold under the name of the molecule that forms the pharmaceutical's active ingredient. The Parties are both active in branded and unbranded generic pharmaceuticals.

Product categories

24. The Parties told the CMA that pharmaceuticals for human use are classified as:

    (a) prescription-only medicines (**POM**), which are pharmaceuticals that can only be dispensed under a prescription made by a clinician;

    (b) pharmacy medicines (**P**), which are pharmaceuticals that can be sold without a prescription, but only in pharmacies; and

    (c) General Sale List medicines (**GSL**),[10] which are pharmaceuticals that can be sold in outlets other than pharmacies. Where a pharmaceutical is dispensed under a prescription, a pharmacist must supply the pharmaceutical specified, in terms of the molecule, galenic form and strength.

25. Pharmaceuticals can be prescribed using the unbranded, generic name of the product, whereby the pharmacist may supply any product (whether originator or generic, branded or unbranded) meeting the specification on the prescription. Alternatively, prescriptions can state a brand name (for example, Nurofen in relation to Ibuprofen), in which case the pharmacist must supply that exact branded drug. In all cases, if the exact item prescribed is not available, an amended prescription is required from the prescriber.[11] Therefore, it is the clinician writing the prescription who determines what molecule, strength and galenic form of pharmaceutical is used for each patient.

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[9] The Parties told the CMA that, in order for a Marketing Authorisation (**MA**) to be issued, a generic drug must meet the conditions referred to in Directive 2001/83/EC on the Community Code relating to medicinal products for human use.
[10] The Parties told the CMA that the term 'over-the-counter' (**OTC**) is used interchangeably with the term GSL.
[11] The British National Formulary (**BNF**), a guidance document used by clinicians and published by the British Medical Association and the Royal Pharmaceutical Society, advises that pharmaceuticals should be prescribed using the generic product name as 'this will enable any suitable product to be dispensed, thereby saving delay to the patient and sometimes expense to the health service'. BNF (April 2015), *Guidance on prescribing: General guidance*.

Pricing schemes for prescription pharmaceuticals

26. The Parties told the CMA that the prices of prescription pharmaceuticals dispensed under an NHS prescription are subject to price regulation schemes, and that the prices at which branded originator and branded generic drugs are sold to the NHS are constrained by the voluntary Pharmaceutical Price Regulation Scheme (**PPRS**). They said that the PPRS does not regulate prices directly, but serves as an overall limit to the prices that can be charged,[12] and that the PPRS requires companies to seek authorisation from the Department of Health for price increases.

27. The Parties said that the prices of unbranded generic drugs sold to the NHS are subject to direct regulation via the government Drug Tariff, which sets the prices that the government is prepared to reimburse pharmacists for pharmaceuticals dispensed. The Parties said that prices will only be reimbursed up to the tariff limit and that the scheme prices are based on information gathered from manufacturers on the volumes and prices of products sold, plus information from the NHS on dispensing volumes.[13]

Regulatory authorisations

28. An MA issued by the MHRA is required by the developer of any originator or generic pharmaceutical in order to place the product on the market. The Parties told the CMA that an MA can be transferred to another party by application to the issuing authority and that, in relation to distribution activities, it is possible to deal in POM and P classified pharmaceuticals under a wholesaler-dealer's licence without an MA. They said that this type of licence does not permit any activities other than moving, buying and selling through the licensed channels.

Frame of reference

29. The CMA considers that 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

[12] Department of Health (December 2013), *Pharmaceutical Price Regulation Scheme 2014*.
[13] NHS (2015), Drug tariff.

important than others. The CMA will take these factors into account in its competitive assessment.[14]

Product scope

Approach to product scope

30. 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).[15]

31. The Parties overlap in the supply of current and pipeline generic pharmaceuticals. They submitted that the appropriate frame of reference is at the molecule, galenic form and strength level.

32. The CMA considered the extent to which customers (or clinicians acting on their behalf) are likely to substitute between generic pharmaceuticals of the same molecule but in different strengths and/or galenic forms, as well as between generic pharmaceuticals of different molecules, to treat a specific medical condition. The CMA also considered whether originator and generic pharmaceuticals should form part of the same frame of reference.

Segmentation by intended use, dosage strength and galenic form

33. In previous decisions in this sector,[16] the CMA, its predecessor the Office of Fair Trading (**OFT**), and the EC have all used the 'Anatomical Therapeutic Chemical' classification (**ATC**), developed and maintained by the European Pharmaceutical Market Research Association (**EphMRA**), as a starting point for defining the product scope. The ATC has a hierarchical structure organised in 16 categories, each comprising up to four levels.

34. The third level of the ATC hierarchy (**ATC3**) groups together pharmaceuticals based on their therapeutic indications, ie their intended use.[17]

35. The CMA, the OFT and the EC have previously departed from the ATC3 level in their merger investigations where third parties indicated that another product scope was more appropriate.

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[14] *Merger Assessment Guidelines*, paragraph 5.2.2.
[15] *Merger Assessment Guidelines*, paragraph 5.2.7.
[16] See for example, *Teva/Ratiopharm*; EC (19 December 2008), M.5295 *Teva/Barr*; EC (4 February 2009), M.5253 *Sanofi-Aventis/Zentiva*; EC (13 October 2011). M.6258 *Teva/Cephalon*; EC (5 October 2012), M.6613 *Watson/Actavis*; OFT (10 February 2014), ME/6331/13 *Shire/Viropharma*; and CMA (9 March 2015), ME/6500/14 *Perrigo Company/Omega Pharma Invest*.
[17] See footnote 16.

36. For example, in *Teva/Ratiopharm*, the EC noted that the ATC3 level rarely appeared to comprise the correct range of products for analysing competition. The EC noted that its investigation indicated that, at least for POM products, demand for medicinal products based on pharmaceutical molecules was specific to the molecule in question and its galenic form. It stated that the parties in that case competed, principally, for sales of products based on the originator molecule and only to a limited extent for sales of products based on other molecules.[18] It also said that, in some instances, a group of molecules could be considered interchangeable, but generally not at a level wider than the ATC4 category.[19,20] In *Teva/Barr* and *Sanofi-Aventis/Zentiva*, the EC noted that competition primarily takes place between drugs based on the same molecule.[21]

37. The CMA sought third-party views on whether the products of Actavis and Auden Mckenzie based on different molecules could be considered to be clinical substitutes for each other. The CMA received responses from the Department for Health, two pharmacists and two NHS Clinical Commissioning Groups (**CCGs**). In general, respondents said that the products of these two companies of different molecules were not substitutable. However, one respondent indicated that, in one instance, some products of different molecules within a specific ATC3 category could be considered to be clinical substitutes. This respondent, a CCG, told the CMA that there may be a degree of demand-side substitutability between different molecules supplied by the Parties within ATC3 category N6A9 – Antidepressants and Mood Stabilisers. The CCG said that Actavis' product range within this category included all the newer antidepressants, such as Citalopram and Fluoxetine, and that Auden Mckenzie's portfolio included Nortriptyline and Tranylcypromine, which tended to be used less frequently and when other options had been exhausted. In this one instance, it appeared that there could be a degree of demand-side substitutability between the Parties' products comprising these different molecules.

38. The other third parties that provided responses gave no indication that the Parties' products in this ATC3 category, or in any of the other ATC3 categories where the Parties overlap, were substitutable.

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[18] Paragraph 13.
[19] Paragraph 14.
[20] The ATC4 level categorises the pharmaceuticals in ATC3 categories into therapeutic sub-groups. For example, the ATC3 category P1D – Anti-malarials is subdivided into two ATC4 categories: P1D1 – Single ingredient anti-malarials and P1D2 – Multi ingredient anti-malarials.
[21] Paragraphs 17 and 18, respectively.

39. In *Teva/Ratiopharm*, the EC looked at galenic form with reference to the first letter of the EphMRA New Form Codes (**NFC**),[22,23] noting that the first letter generally differentiated products on the basis of (i) systemic and topical effect; (ii) route of administration;[24] and (iii) whether it was long-acting.[25] In that case, the EC found that products designed for different routes of administration are, in general, not interchangeable.

40. In the same case, the EC noted that the development of a new galenic form of an existing generic medicine typically takes a significant amount of time, suggesting that different galenic forms of a medicine cannot be considered to lie within the same relevant market on the basis of supply-side substitutability.[26]

41. In the present case, those competitors which responded to the CMA's merger investigation generally confirmed this to be the case.

42. 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. In *Teva/Ratiopharm*, the EC said that it may be the case that pharmaceuticals of different dosages are designed to serve the needs of different patient groups and therefore may not be interchangeable.[27] It said that the correct market definition needed to consider possible distinctions on the basis of dosage.[28]

43. On the basis of the precedents referred to above, there appears generally to be limited demand-side substitutability between generic pharmaceuticals of different molecules within the same ATC3 category. Moreover, some of the precedents (see paragraph 42) indicate that there may be only limited demand-side substitutability between generic pharmaceuticals based on the same molecule, but in different galenic forms and/or strengths.

44. Taking into account the submissions of the Parties and third parties and the relevant precedents discussed above, the CMA has, on a cautious basis, assessed the Merger in relation to a frame of reference for the supply of generic pharmaceuticals supplied by the Parties based on: (i) the same

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[22] Paragraph 16.
[23] The NFC is a coding structure designed to maintain uniformity in the classification of the forms of pharmaceuticals. Each product is assigned a three letter code. See EphMRA (January 2013), *New Form Code Classification Guidelines*.
[24] For example, oral, nasal, topical or ophthalmic administration.
[25] That is, products designed to release the dosage of the active ingredient over a longer period of time than an 'ordinary' product.
[26] Paragraph 18.
[27] Paragraph 17.
[28] Paragraph 20.

molecule, strength and galenic form; and (ii) the same molecule, but different strengths and/or galenic forms. The CMA has used this frame of reference in its assessment of both current and pipeline overlaps.

45. For the purposes of this decision, it has not been necessary for the CMA to conclude on the precise boundaries of the product frame of reference in relation to the supply of generic pharmaceuticals supplied by the Parties, eg whether the market should be defined on the narrow basis of molecule, strength and galenic form, or on the basis of another, wider, delineation, as no concerns arise on any plausible delineation.

46. As set out below, the CMA has identified product overlaps between the Parties' generic pharmaceutical products on both a narrow basis, considering molecule, strength and galenic form (Group 1 overlaps), and on a wider basis, considering different strengths and galenic forms of the same molecule (Group 2 overlaps).

47. To the extent that the evidence available to the CMA indicated that certain generic pharmaceuticals supplied by the Parties of different molecules within the same ATC3 category could be demand-side substitutes for one another (see paragraph 37), the CMA has assessed the Merger within a frame of reference for the supply of these pharmaceuticals defined at the wider ATC3 category level (Group 3 overlaps).

Originator pharmaceuticals, branded generic pharmaceuticals and unbranded generic pharmaceuticals

48. The Parties submitted that competition takes place between the originator and the generic versions of pharmaceuticals and that both originator and generic products should therefore be included within the same frame of reference.

49. In *Teva/Ratiopharm*, the EC stated that generic pharmaceuticals are, in general, less expensive versions of originator drugs.[29] It stated that generic pharmaceuticals are specifically designed to compete with originator products and normally represent the closest substitute to them. In the same case, the EC did not identify separate product markets for branded and unbranded generic pharmaceuticals. The EC took into account in its competitive assessment the effect of brand loyalty[30] as well as any price premium that a branded generic product may command (relative to an unbranded product).[31]

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[29] Paragraph 25.
[30] Including loyalty to originator products or to branded generic products.
[31] Paragraph 27. In *Sanofi-Aventis/Zentiva,* the EC also noted that 'generics are in general less expensive versions of the originator drugs'. See also EC (2008), M.3751 *Novartis/Hexal*.

In *Perrigo/Omega*, the CMA included own-label and branded products within the same frame of reference.[32]

50. Taking into account the Parties' submissions and the precedents referred to above, the CMA has assessed the Merger in relation to a frame of reference which includes both branded and unbranded pharmaceuticals, and originator pharmaceuticals. However, the CMA notes that, as originator products may command a price premium relative to their generic counterparts, they may represent a weaker competitor. In addition, brand loyalty may limit switching. These factors are taken into account in the CMA's competitive assessment.

POM, P and GSL pharmaceuticals

51. In precedent cases, GSL (or over-the-counter (**OTC**)) pharmaceuticals have typically been considered as a separate product market from POM pharmaceuticals.[33] In *Reckitt Benckiser/Combe*[34] the OFT cited differences between OTC and prescription medicines in terms of the medical indications they treat, their side effects, the relevant legal frameworks, and their distribution channels and marketing, despite products sometimes being of the same molecule.

52. The Parties said that, in some cases, only one regulatory status (ie POM, P or GSL) is possible for all forms of the product but, in other cases, there can be a range of possible regulatory statuses, depending upon various factors, eg pack size.[35]

53. All the Parties current products considered in the competitive assessment below are POM products. However, for pipeline products it is not clear which regulatory status will be assigned. Nevertheless, in the case of each pipeline product where the CMA has carried out a competitive assessment, the BNF states that they are POM pharmaceuticals. For this reason, the CMA believes that the distinction between POM, P and GSL products is not significant in this case as no concerns arise on any plausible basis.[36] It is therefore not

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[32] Paragraph 37.
[33] See *Teva/Barr*, paragraph 13; *Teva/Ratiopharm*, paragraphs 22-24; and *Sanofi-Aventis/Zentiva* paragraphs 21-24.
[34] OFT (30 November 2010), ME/4703/109, paragraph 10.
[35] For example, in the case of Paracetamol 500mg, pack sizes above 32 tablets will always be POM products, pack sizes of 17-32 tablets can be sold as P products and pack sizes of up to 16 can be sold in any outlet as a GSL product.
[36] In the case of only one product covered in the CMA's competitive assessment is this distinction relevant: Paracetamol/Dihydrocodeine, where the Parties both supply POM products but where some third parties products may be sold without a prescription. However, in that instance, it is without reference to the products of third parties that the CMA reaches its conclusion that the Merger does not give rise to competition concerns.

necessary for the CMA to conclude on whether any distinctions are required in this respect.

Geographic scope

54. The Parties submitted that the geographic markets for the current overlapping products are national and that for pipeline products are no narrower than EEA-wide.

55. In previous decisions involving mergers between companies supplying generic pharmaceuticals, the CMA, the OFT and the EC have all found that the relevant geographic markets for finished products are national. In relation to pipeline products, given that the underlying research and development activity is typically global, the EC and the OFT have defined markets as being at least EEA-wide or possibly worldwide. However, in *Teva/Ratiopharm*, the EC noted that, even though the product development process may have eventually led to product launches in several or many countries, the effect of an elimination of potential competition needed to be considered at national level.[37]

56. The CMA received no third party responses to suggest that the effect of the Merger should be assessed within an alternative geographic frame of reference.

57. In relation to products currently marketed by the Parties, the CMA has therefore assessed the Merger within a geographic frame of reference that is national in scope.

58. In relation to pipeline products, the CMA has considered whether the Merger may result in a loss of competition arising if and when the Parties' products are supplied in the UK. The CMA also notes that the regulatory approval process is run by the MHRA, a national regulator. For these reasons, the CMA has also, on a cautious basis, assessed the effects of the Merger in relation to pipeline products within a national frame of reference.

Conclusion on frame of reference

59. As set out above, the CMA has assessed the impact of the merger on the supply of current and pipeline generic pharmaceuticals based on: (i) the same molecule, strength and galenic form; and (ii) the same molecule, but different strengths and/or galenic forms. To the extent that the evidence available to the CMA indicated that certain generic pharmaceuticals supplied by the

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[37] Paragraph 423.

Parties based on different molecules within the same ATC3 category could be demand-side substitutes, the CMA has also assessed the Merger within a frame of reference for the supply of these pharmaceuticals defined at the wider ATC4 category level.

60. The CMA has assessed the impact of the Merger on the basis of a national geographic scope.

Competitive assessment

Horizontal unilateral effects

61. 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.[38] Horizontal unilateral effects are more likely when the merger parties are close competitors.

62. The CMA assessed whether it is or may be the case that the Merger has resulted, or may be expected to result, in:

    (a) an SLC in the supply of pharmaceuticals currently sold by the Parties;

    (b) an SLC in the future supply of pharmaceuticals currently in both of the Parties' pipelines; and

    (c) an SLC in the future supply of pharmaceuticals currently in one of the Parties' pipelines and currently sold by the other party.

Overlaps in products currently sold by both of the Parties

63. The CMA used as a starting point for the identification of the product overlaps the ATC3 category classification (see paragraph 33). It identified 21 overlaps at this level.

64. The CMA then considered overlaps at the molecule, strength and galenic form level and found four overlaps (Group 1), and at the molecular level but not the strength and/or galenic form level and found three overlaps (Group 2).

[38] *Merger Assessment Guidelines*, from paragraph 5.4.1.

65. The Group 1 overlap products are: (i) Lormetazepam 0.5mg and 1mg tablets; (ii) Piroxicam 0.5% gel; (iii) Pethidine 50mg tablets; and (iv) Betamethasone 0.1% ointment.[39]

66. The 'Group 2' overlap products are: (i) Paracetamol and Dihydrocodeine Tartrate (tablets); (ii) Phenytoin Sodium (100mg capsules/tablets); and (iii) Dexamethasone (at the molecular level).

67. The CMA found that in 15 ATC3 categories the Parties do not overlap at the molecule level, but overlap at other levels (eg the ATC3 or ATC4 level). In light of the responses received from third parties (see paragraph 37), the CMA could not rule out the possibility of some demand-side substitutability between the Parties products within the ATC3 category N6A – *Antidepressants and Mood Stabilisers*, so the CMA also carried out a competitive assessment of this overlap (Group 3).

Pipeline overlaps

68. The Parties have several products in their pipelines that give rise to additional horizontal overlaps (Pipeline Overlap Products).

69. Several overlaps arise between products that, for both parties, are still in the development process. The Parties identified the following products where they are each developing the same molecule, strength and galenic form: (i) [✂]; (ii) [✂]; (iii) [✂]; (iv) [✂]; and (v) [✂].

70. In addition, overlaps arise between products that Auden Mckenzie is currently selling and that Actavis has in its pipeline: [✂].[40]

Group 1 overlaps

Shares of supply

71. The Parties submitted shares of supply at the molecule, strength and galenic form level based on sales for 2014, by both volume and value, for each of the Group 1 overlaps. These are presented in Table 1 below.

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[39] The parties overlap also in the supply of Prednisolone 25mg tablets. However, the Parties said that Auden Mckenzie acquired the MA for this product when it acquired NRIM in 2014 and it has made no sales since then. Moreover, Actavis has made no sales of Prednisolone 25mg tablets in the last 5 years. The CMA therefore does not give further consideration to Prednisolone 25mg tablets.

[40] The Parties identified other overlaps between products currently sold by Actavis and in the pipeline of Auden Mckenzie but stated that, for these products, Actavis' current shares of supply at the narrowest level were always less than 35%. No third party raised any concern about any of these products. On this basis, the CMA has not considered these overlaps further.

72. The CMA notes that the share of supply analysis is based on IMS Health (**IMS**)[41] data, which uses retail sales figures. This means that the data shows, for example, sales made by wholesalers to retailers, but it does not provide information on the identity of the relevant upstream suppliers and MA holders.

73. The Parties told the CMA that generic companies selling unbranded products are often reported in IMS data in a category entitled 'Lab unknown', meaning that sales cannot be attributed to a particular company.[42] As this category may include sales made by Actavis or Auden Mckenzie, the Parties calculated their own shares of supply on the basis of their actual sales,[43] as estimated by the British Generic Manufacturers' Association.[44]

Table 1: Group 1 overlaps – the Parties' shares of supply

%

Product	*Value share*			*Volume share*		
	Actavis	*Auden Mckenzie*	*Combined*	*Actavis*	*Auden Mckenzie*	*Combined*
Lormetazepam 0.5mg tablets	[0–10]	[0–10]	[0–10]	[0–10]	[0–10]	[10–20]
Lormetazepam 1mg tablets	[0–10]	[10–20]	[10–20]	[0–10]	[20–30]	[20–30]
Piroxicam 0.5% gel	[0–10]	[0–10]	[0–10]	[0–10]	[0–10]	[0–10]
Pethidine 50mg tablets	[0–10]	[0–10]	[0–10]	[0–10]	[0–10]	[0–10]
Betamethasone 0.1% ointment	[0–10]	[0–10]	[0–10]	[0–10]	[0–10]	[0–10]

Source: the Parties, based on IMS, BGMA and actual sales data.

Parties' views on the Group 1 overlaps

74. The Parties said that Actavis does not hold an MA in respect of any of the Group 1 overlaps, which meant that these overlaps were less significant. The Parties said that Actavis is one of a number of resellers of these products, which are purchased from the MA holder and resold under the livery of the MA holder. Consequently, the Parties said that the MA holders can appoint alternative resellers.

75. The MA holder for Lormetazepam is Genus; for Piroxicam and Betamethasone it is Manx Healthcare; and for Pethidine it is Martindale.

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[41] IMS is a company that provides data to clients in the healthcare sectors.
[42] The 'Lab unknown' issue was noted in *Watson/Actavis*, which states: 'IMS data for the UK lists generic players under a joint category "Lab Unknown/Unbranded" and therefore does not permit the identification of individual company shares of supply for each of the affected markets.'
[43] From 1 January 2014 to 28 October 2014, extrapolated to a 12-month basis.
[44] The CMA also notes that the IMS figures use reimbursed prices as a basis for estimates of value data. Although Actavis' shares of supply by value were calculated on the basis of reimbursed prices, Auden Mckenzie used ex-factory prices (adjusted for a [✂] margin) as reimbursed prices were not available. For these reasons, the CMA interprets the share of supply figures with some caution.

Third party views on the Group 1 overlaps

- *Lormetazepam 0.5mg and 1mg tablets*

76. A wholesaler told the CMA that it was currently purchasing Lormetazepam from Auden Mckenzie [✂]. It said that, as Actavis does not produce Lormetazepam products itself, it does not offer this product to its wholesale customers but only to its pharmacy customers. It therefore considered that the Parties did not compete in the supply of this product. It made the same point in relation to each of the Group 1 products.

77. Another wholesaler told the CMA that it is currently purchasing unbranded Lormetazepam products from Auden Mckenzie [✂] and that if Auden Mckenzie were to increase its price by 5%, it would switch to Genus or gain supply through parallel imports.[45]

78. [✂] told the CMA that if Actavis were to increase its price by 5%, it would switch to the cheapest alternative supplier. It listed Mylan, Thornton & Ross and Genus as alternatives. An independent pharmacy chain gave the same view.

79. A pharmaceutical company listed three other competitors active in these products: Teva, Genus and Mylan. [✂].

- *Piroxicam 0.5% gel*

80. A pharmaceutical company told the CMA that the main suppliers of unbranded Piroxicam 0.5% gel are, in order of importance, Teva, Dr Reddy's and Waymade.

81. A wholesaler said that, if Auden Mckenzie were to increase its price by 5%, it would switch to Manx Healthcare.

82. Another wholesaler told the CMA that it is currently purchasing unbranded Piroxicam from [✂] and that if Actavis were to increase its price by 5%, it would switch to the cheapest alternative supplier. An independent pharmacy chain expressed the same view.

[45] The Parties said that parallel importers are companies that re-package pharmaceuticals originally purchased elsewhere in the European Economic Area for import and sale in the UK. A licence is required for such re-packaging.

- *Pethidine 50mg tablets*

83. A wholesaler said that it is currently purchasing unbranded Pethidine from Auden Mckenzie and that if Auden Mckenzie were to increase its price by 5%, it would not know to which supplier to switch. However, it said that it had never tested in the market whether there are other suppliers that could offer this product. It said that it would not accept a price increase unless all the other suppliers were to increase their prices as well.

84. Another wholesaler told the CMA that Auden Mckenzie and Actavis do not compete in the supply of this product and that if Auden Mckenzie were to increase its price by 5%, it would switch to Martindale.

85. [✂] told the CMA that it currently purchases this unbranded product from Actavis, Auden Mckenzie and Martindale. It said that if Actavis or Auden Mckenzie were to increase its price by 5%, it would switch to the cheapest alternative supplier. An independent pharmacy chain said the same.

- *Betamethasone 0.1% ointment*

86. A pharmaceutical company said that the main suppliers of unbranded Betamethasone are, in order of importance, Actavis, Manx and Teva. It said that the main suppliers of branded product are, in order of importance, GlaxoSmithKline, Auden Mckenzie and MSD[46].

87. [✂]. In both cases it said that if Actavis/Auden Mckenzie (respectively) were to increase prices by 5%, it would switch to the cheapest alternative provider. An independent pharmacy chain that purchases unbranded Betamethasone told the CMA that, in the event of such a price rise, it would do the same.

CMA assessment and conclusion on Group 1 overlaps

88. The CMA notes that the Merger would not give rise to a reduction in the number of MA holders in respect of any of the Group 1 overlap products. Further, in relation to each of the Group 1 overlaps, the CMA notes that:

    (i) the Parties' combined shares of supply are generally very low and are not higher than [20–30]% in any instance, whether considered on a volume or value basis;

[46] MSD is known as Merck in the USA and Canada.

(ii) the incremental increases in shares of supply brought about by the Merger are generally low and not higher than [0–10]% in any instance;[47]

(iii) there are other resellers besides Actavis in respect of each of the Group 1 overlaps; and

(iv) none of the third parties that replied to the CMA's merger investigation raised any concerns in relation to any of the Group 1 overlaps.

89. On the basis of the above evidence, 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 relation to the supply of each of the Group 1 overlap products in the UK.

Group 2 overlaps

Paracetamol and Dihydrocodeine Tartrate combination tablets

90. The Parties told the CMA that Paracetamol and Dihydrocodeine Tartrate is a combination of two painkillers used in the treatment of mild to moderate pain. Actavis supplies 10/500mg tablets whereas Auden Mckenzie offers 20/500mg and 30/500mg tablets. The Parties each hold MAs for their respective products. Therefore, to the extent that the different strengths of this product may be prescribed interchangeably by clinicians, the Merger may bring about a reduction in the number of suppliers that hold an MA and, consequently, the number of companies that supply these products.

91. The Parties told the CMA that their products are not interchangeable and, consequently, do not compete with each other. They said that Actavis' product is prescribed for relatively moderate pain whereas Auden Mckenzie's product is prescribed for more severe pain. Moreover, the combined nature of the product, with Paracetamol and Dihydrocodeine Tartrate, means that the different strengths are not interchangeable in practice.[48]

92. A national pharmacy chain that replied to the CMA's merger investigation said that the Parties' products are generally not substitutable for each other and that they are prescribed in such a manner that patients move progressively from lower to higher doses. Amending the administration instructions for these

[47] [✂], calculated on both value and volume bases.
[48] The Parties submitted that a patient prescribed the 20/500mg product could not be given two 10/500mg tablets, as this would result in a dose of 20/1000mg, not 20/500mg.

products (eg ‘take half of a 20/500mg tablet, rather than a whole 10/500mg tablet’) would not be appropriate, as doing so would risk the patient receiving an incorrect dose.

93. An independent pharmacy told the CMA that the Parties’ products could not be prescribed interchangeably.

94. On the basis of this evidence, the CMA believes that the extent of competition between these products is very limited and, for this reason, the Merger does not give rise to a realistic prospect of an SLC as a result of horizontal unilateral effects in the supply of Paracetamol and Dihydrocodeine Tartrate combinations (10/500mg, 20/500mg and 30/500mg tablets) in the UK.

Phenytoin Sodium 100mg

95. Phenytoin is a pharmaceutical product used in the treatment of epilepsy. The Parties both currently sell Phenytoin Sodium in doses of 100mg, with Auden Mckenzie offering its product in capsule form and Actavis in tablet form.

96. The Parties told the CMA that Actavis does not hold an MA for Phenytoin but, as for the Group 1 products, it acts as a reseller of a product for which another company (Milpharm) holds the MA. Actavis resells the product under a Milpharm livery. Therefore, the Merger would not have an impact on the number of companies that hold MAs for Phenytoin Sodium 100mg.

97. The Parties also told the CMA that demand-side substitutability between their products is limited because it is recognised by clinicians that there can be an increased risk of seizures in patients as a result of switching between different manufacturers' products, even when those products have the same molecule, galenic form and strength. The Parties told the CMA that, consequently, the MHRA has advised doctors to maintain patients on a specific manufacturer’s product.

98. A national pharmacy chain told the CMA that Phenytoin capsules and tablets are not generally interchangeable and that this is outlined in the guidance published by the MHRA in July 2013.[49]

99. On the basis of this evidence, the CMA believes that the extent of competition between these products is very limited and, for this reason, the Merger does not give rise to a realistic prospect of an SLC as a result of horizontal

[49] The CMA examined the relevant MHRA guidance, which states that, in respect of Phenytoin, ‘specific measures are necessary to ensure consistent supply of a particular product (which could be either a branded product or a specified manufacturer’s generic product)’. See MHRA (July 2013), *Formulation switching of antiepileptic drugs*.

unilateral effects in the supply of Phenytoin Sodium 100mg (tablets and capsules) in the UK.

Dexamethasone

100. Dexamethasone is a corticosteroid used to treat certain endocrine and non-endocrine disorders. The Parties told the CMA that Actavis does not hold an MA for Dexamethasone. Actavis acts as a reseller on behalf of the MA holder, Perrigo, offering a 10mg/5ml and a 2mg/5ml oral solution, whereas Auden Mckenzie holds an MA for 0.5mg and 2mg tablets. Therefore, the Merger would not have an impact on the number of companies that hold MAs for Dexamethasone. The Parties provided a list of competitors that hold an MA for each of the strengths and galenic forms of Dexamethasone supplied by the Parties, showing five companies holding MAs.[50]

101. The Parties provided share of supply data on Dexamethasone, based on sales in 2014. Auden Mckenzie achieved a share of supply of [30–40]% by value and [10–20]% by volume. Actavis, however, has only recently started to supply this product on behalf of Perrigo and, for this reason, its sales in 2014 were very small, amounting to only £[✂], representing a share of supply close to zero.

102. The Parties also said that demand-side substitutability between the Parties products was limited by the fact that they were of different galenic forms.

103. On the basis of this evidence, the CMA believes that the extent of competition between these products is very limited and, for this reason, that the Merger does not give rise to a realistic prospect of an SLC as a result of horizontal unilateral effects in the supply of Dexamethasone (10mg/5ml and 2mg/5ml oral solution as well as 0.5mg and 2mg tablets) in the UK.

Group 3 overlaps – Products sold by the Parties within the ATC3 category N6A

104. The CMA has considered the impact of the Merger on the products sold by the Parties within the ATC3 category N6A – *Antidepressants and Mood Stabilisers*.

105. The Parties provided shares of supply at the molecule level for each of their products within this ATC3 category, as shown in Table 2.

[50] Aspen, Focus Pharmaceuticals, Lexon, Martindale and Rosemont Pharmaceuticals.

Table 2: The Parties' shares of supply at the molecule level in N6A (2014)

%

Molecule	*Party*	*Share of supply (volume)*	*Share of supply (value)*
Amitriptyline	Actavis	[60–70]	[60–70]
Citalopram	Actavis	[0–10]	[0–10]
Clomipramine*	Actavis	[0–10]	[0–10]
Dosulepin*	Actavis	[0–10]	[0–10]
Escitalopram	Actavis	[0–10]	[0–10]
Fluoxetine	Actavis	[0–10]	[0–10]
Imipramine	Actavis	[60–70]	[60–70]
Lofepramine	Actavis	[30–40]	[30–40]
Mirtazapine	Actavis	[40–50]	[30–40]
Nortriptyline†	Auden Mckenzie	[30–40]	[30–40]
Paroxetine	Actavis	[0–10]	[0–10]
Sertraline	Actavis	[10–20]	[0–10]
Tranylcypromine	Auden Mckenzie	[10–20]	[20–30]
Trazodone	Actavis	[0–10]	[0–10]
Venlafaxine	Actavis	[0–10]	[0–10]

Source: the Parties.
*Actavis has made no sales of Clomipramine since Q1 2014 and no sales of Dosulepin in 2014. The Parties said that Actavis is no longer active in Fluvoxamine and made no sales in 2014.
†Auden Mckenzie's sales of Notriptyline includes sales made by NRIM Ltd, which Auden Mckenzie acquired in 2014.

106. The CMA notes that Actavis has high shares of supply of [60–70]% and [60–70]% in Amitriptyline and Imipramine, respectively, and significant shares of supply of [30–40]% and [40–50]% in Lofepramine and Mirtazapine, respectively. Actavis' shares of supply in the other molecules supplied in this ATC3 category are low ([0–10]%). Auden Mckenzie's shares of supply of the two molecules it supplies in this ATC3 category, Nortriptyline and Tranylcypromine, are [10–20]% and [30–40]% respectively.

107. The CMA notes that, although Actavis may have a degree of pre-Merger market power in some of the molecules within this ATC3 category, as demonstrated by some high shares of supply, Auden's pre-Merger shares of supply in Nortriptyline and Tranylcypromine indicate that there are strong remaining constraints on the merged entity in the supply of these two molecules.[51] Therefore, even if the Parties' products based on different molecules are to some extent substitutable on the demand side, the CMA believes that the impact of the Merger would be limited.

108. To further test this conclusion, the CMA also analysed the Parties' shares of supply in the ATC4 category N6A9 – Antidepressants, all others.[52] The CMA notes that this ATC4 category includes all of the molecules in respect of which Actavis has higher shares of supply (Amitriptyline, Imipramine, Lofepramine and Mirtazapine) and both of Auden Mckenzie's molecules (Nortriptyline and

[51] In respect of Nortriptyline, the CMA notes that Medreich plc and King Pharmaceuticals currently hold MAs for these products and that, in 2014, parallel import licences were granted by the MHRA to two suppliers. In respect of Tranylcypromine, Amdipharm currently supplies products based on this molecule and the MHRA issued parallel import licences to three suppliers in 2014.
[52] This ATC4 category is a subdivision of the ATC3 category N6A - Antidepressants and Mood Stabilisers.

Tranylcypromine). Table 3 presents the Parties' shares of supply pre- and post-Merger at the ATC4 level.

Table 3: Actavis and Auden Mckenzie's shares of supply - ATC4 category N6A9 – Antidepressants, all others, by volume and value (2014)

%

ATC4 category	*Actavis shares (volume)*	*Actavis share of supply (value)*	*Auden Mckenzie share of supply (volume)*	*Auden Mckenzie share of supply (value)*	*Combined share of supply (volume)*	*Combined share of supply (value)*
N6A9 – Anti-depressants, all others	[50–60]	[20–30]	[0–10]	[0–10]	[50–60]	[20–30]

Source: the Parties

109. The CMA notes that the Parties' combined share of supply is around [50–60]% by volume and [20–30]% by value. However, the CMA also notes that the increment in share of supply brought about by the Merger is low: [0–10]% by volume and [0–10]% by value.

110. On the basis of the evidence set out above, the CMA believes that, even if there was a degree of demand-side substitution between all Actavis and Auden Mckenzie's molecules within the ATC3 category N6A, there is no realistic prospect that the Merger will increase the merged entity's market power. In particular, although Actavis has significant pre-Merger shares of supply in some of the molecules, there are strong remaining constraints on Auden Mckenzie in respect of the molecules it supplies. Furthermore, considering the ATC4 category N6A9, which includes all of the molecules in respect of which Actavis has high shares of supply and both molecules supplied by Auden Mckenzie, the increment brought about by the Merger is small. The CMA therefore believes that the Merger does not give rise to a realistic prospect of an SLC as a result of horizontal unilateral effects in the supply of the Parties' products within the ATC3 category N6A – Antidepressants and Mood Stabilisers in the UK.

Pipeline Overlap Products

111. The CMA considered whether the Merger would lead to the loss of potential competition[53] between the Parties in relation to the Pipeline Overlap Products.

[53] See *Merger Assessment Guidelines*, paragraph 5.4.14.

Product development timescales

112. The Parties told the CMA that it typically takes [✂] to develop a generic drug and a further [✂] to obtain the requisite regulatory approvals. They said that a pipeline project would typically be regarded as certain to progress to market once a stable formulation had been identified and a successful biostudy had been undertaken.

113. The Parties said that, although the likelihood of drop out should be assessed on a project-by-project basis given the differing complexity of products, overall around [✂]% to [✂]% of products are stopped or delayed during the pipeline stages.

114. The Parties told the CMA that the different stages of the development of a new product are as follows:

(a) **Stage Zero**. During this phase, which is estimated to take [✂], the project is defined and the business case approved. The Parties estimated that between [✂]% and [✂]% of projects at this stage drop out of the development process for reasons related to [✂].

(b) **Stage One**. During this phase, which is estimated to take [✂], the material is sourced, the formulation and process design take place and the analytical method is developed. The Parties estimated that this phase costs between £[✂] and £[✂], depending on the complexity of the process.[54] The Parties estimated that about [✂]% of projects drop out of the development process at this stage due to [✂].

(c) **Stage Two**. During this phase, which is estimated to take [✂], the product is transferred to the manufacturing site and stability and bioequivalence tests are run. The Parties estimated that the average cost of this phase is between £[✂] and £[✂]. The Parties estimated that between [✂]% and [✂]% of projects drop out at this stage of the development process for reasons related to [✂].

(d) **Stage Three**. During this phase, which is estimated to take [✂], the application process to the relevant regulatory authority takes place. The Parties estimated that the average cost of this phase is approximately £[✂] to £[✂]. The Parties estimated that less than [✂]% of projects drop out of the development process at this stage.

(e) **Stage Four**. This is the launch stage.

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[54] This figure excludes the costs of developing the active pharmaceutical ingredient (**API**).

115. The Parties told the CMA that the Pipeline Overlap Products are at the stages of development shown in Table 4.

Table 4: Development stages of the Pipeline Overlap Products

Product	*Actavis stage of development*	*Auden Mckenzie stage of development*
[✂]	Stage 3	Stage 0
[✂]	Stage 3	Stage 0
[✂]	Stage 2	Stage 1
[✂]	Stage 2	Stage 2
[✂]	Stage 2	Stage 2
[✂]	Stage 2	-
[✂]	-	Stage 2
[✂]	Stage 2	Stage 1
[✂]	Stage 2	Stage 1

Source: the Parties.

[✂] and [✂]

116. [✂] is a product used in the treatment of [✂]. Actavis said that it plans to introduce [these] product[s] in 2015. However, Auden Mckenzie told the CMA that its pipeline project is at the very initial stage of API sourcing, and it has not yet reached any development agreement.[55] It said that it envisaged the introduction [✂] towards the end of 2017.

117. The Parties identified [✂] current MA holders for [✂] products, [✂] of which currently supply [✂]. [✂] sells the originator product and [✂] sells a generic. There are no competitors currently holding an MA for [✂]. The CMA notes that the originator competitor active in the supply of [✂] ([✂]) may be a somewhat weaker competitor than the generic competitor ([✂]) given the potential price premium of originator pharmaceuticals (see paragraphs 49 and 50).

118. The Parties also said that there are [✂] other generic competitors[56] holding MAs for pharmaceuticals of the same molecule and galenic form but in different strengths.

119. The CMA notes that, as Auden Mckenzie's products are at a very early stage in the development, its entry is quite highly speculative. Moreover, there are [✂] current suppliers of precisely the product in development by the Parties (though one is the originator), and several competitors holding MAs for [✂] products of the same galenic form (though of different strengths). On the basis of this evidence, the CMA believes that the Merger does not give rise to

[55] The API is the substance which has the target therapeutic effect on the body.
[56] [✂]

a realistic prospect of an SLC as a result of horizontal unilateral effects in the future supply of [✂] in the UK.

[✂]

120. [✂] is used in the treatment of [✂]. Actavis told the CMA that it expects to file the necessary regulatory documentation with the MHRA in order to apply for an MA in [✂] 2015. However, Auden Mckenzie said that its development product had failed stability tests and, therefore, the previously intended launch date for this product of mid-2017 was expected to slip considerably. Auden McKenzie said that it was now uncertain whether the product would ever reach the launching stage.

121. The Parties identified [✂] current MA holders for this product: [✂] which currently supply [✂]. [57] [✂] sells the originator product and [✂] sells a generic version. [✂] and [✂] supply [✂] products of the same galenic form as the Parties' pipeline products but of different strengths. As above, the CMA notes that the originator competitor active in the supply of [✂] ([✂]) may be a somewhat weaker competitor than the generic competitor ([✂]).

122. The CMA notes that, as, independent of the Merger, Auden Mckenzie's pipeline product has failed stability tests, its entry is quite highly speculative. Moreover, there are [✂] current suppliers of precisely the product in development by the Parties (though one is the originator), and competitors holding MAs for [✂] products of the same galenic form (though of different strengths). On the basis of this evidence, 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 the future supply of [✂] in the UK.

[✂] and [✂]

123. [✂] is used in the treatment of [✂]. The Parties told the CMA that both Actavis and Auden Mckenzie envisage the introduction of [✂] in 2016.

124. The Parties identified [✂] MA holders currently supplying generic [✂],[✂] and [✂] MA holders currently supplying generic [✂], [✂].

125. The CMA received information from [✂].

126. The CMA notes that there are currently [✂] suppliers holding MAs for [✂] and [✂] suppliers holding MAs for the [✂] version. The CMA further notes that [✂]. On the basis of this evidence, the CMA believes that the Merger

[57] [✂] also supplies the originator pharmaceutical.

does not give rise to a realistic prospect of an SLC as a result of horizontal unilateral effects in the future supply of [✂] and [✂] in the UK.

[✂]

127. [✂] is used in the [✂] and in the [✂]. The Parties told the CMA that they have been developing different galenic forms: Actavis intends to launch a [✂] in 2016, whereas Auden Mckenzie's pipeline product is a [✂]. However, Auden Mckenzie also told the CMA that, independent of the Merger, its pipeline product had failed clinical trials, was on hold and under review, and there was currently no expected launch date.

128. The Parties identified [✂] MA holders currently supplying [✂]: [✂].

129. [✂][58]

130. The CMA received information from [✂].

131. The CMA notes that that there are [✂] current suppliers of [✂]. Moreover, as, independent of the Merger, Auden Mckenzie's pipeline product has failed clinical trials, its entry is quite highly speculative. On the basis of this evidence, 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 the future supply of [✂] in the UK.

[✂] and [✂]

132. [✂] is used in the treatment of [✂]. The Parties told the CMA that both Actavis and Auden Mckenzie had been developing [✂] this product.[59] Actavis told the CMA that it expects to launch its products in 2016. Auden Mckenzie told the CMA that, independent of the Merger, its products had failed stability tests and that it was now highly uncertain whether it would succeed in developing these products for the anticipated launch date of the second quarter of 2017 or at all.

133. The CMA notes that in an internal presentation, Actavis states that [✂].[60]

134. The Parties identified [✂] currently supplying [✂], which sells the [✂]. There are currently [✂] MA holders for [✂] and [✂] generic suppliers for [✂].

135. The CMA received evidence from [✂].

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[58] [✂]
[59] Actavis is also developing [✂].
[60] See [✂].

136. Unlike the other pipeline overlap products, the CMA notes that there are currently [✂] MA holders for one of the products in development by the Parties ([✂]) and [✂] generic suppliers for [✂]. [✂]. Therefore, the CMA considered these pipeline products carefully. The CMA notes that, since, independent of the Merger, Auden Mckenzie's pipeline product has failed stability tests, its entry is quite highly speculative. Moreover, even if it does enter, it will not happen for at least two years. Over this timeframe, the competitive landscape may have changed. The CMA notes in particular the time it takes to develop and launch generic pharmaceuticals and the lack of information available to the CMA about the potential development of [✂] products by other generic pharmaceutical suppliers. In addition, the CMA notes that there is [✂] of one of the products in development by the Parties (though this [✂]). Overall, on the basis of this evidence, 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 the future supply of [✂] in the UK.

[✂] and [✂]

137. Auden Mckenzie sells [✂]. Actavis said that, in May 2014, it had taken 'the first steps' towards the development of the same products, but that this project had not been a management priority and, independent of the Merger, no further steps had been taken.

138. The Parties provided information on which suppliers currently hold MAs for [✂].

139. The CMA received evidence from [✂].

140. The CMA notes that Actavis is at a very early stage in the development of these products, indicating that its entry is highly speculative. [✂]. On the basis of this evidence, 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 the future supply of [✂] in the UK.

Conclusion on horizontal unilateral effects

141. 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 relation to the supply of:

(a) the Group 1 overlap products in the UK;

(b) the Group 2 overlap products in the UK;

(c) the Group 3 overlap products in the UK; and

(d) the Pipeline Overlap Products in the UK.

Vertical effects

142. Vertical effects may arise when a merger involves firms at different levels of the supply chain, for example a merger between an upstream supplier and a downstream customer.

143. The CMA's approach to assessing vertical theories of harm is to analyse: *(a)* the ability of the merged entity to foreclose competitors; *(b)* the incentive of it to do so; and *(c)* the overall effect of the strategy on competition.[61]

144. The CMA has considered whether the merged firm's presence in both the supply of pharmaceuticals to wholesalers and its wholesale supply to independent pharmacies and national and regional pharmacy chains may give rise to input foreclosure. The CMA has considered this in respect of:

(a) Mometasone Fuorate 0.1% topical applications, where Auden McKenzie supplies the product to, amongst others, Actavis for distribution; and

(b) the Group 1 overlap products.

145. The CMA has also considered whether the Merger could give rise to an SLC through customer foreclosure in respect of the Group 1 products.

146. The CMA has dismissed potential concerns over foreclosure in relation to the Group 2 or Group 3 overlap products as the Parties are selling products not based on the same molecule, strength and galenic form and the extent of competition between the Parties' products is very limited. The CMA therefore believes that there is no realistic prospect that incentives to foreclose will arise following the merger.

Input foreclosure

Mometasone Fuorate 0.1% topical applications

- *Parties' views*

147. Mometasone Furoate 0.1% topical applications (creams and ointments) are used in the treatment of psoriasis and dermatitis. The Parties said that Auden Mckenzie holds an MA for this product but does not supply it directly to pharmacies and only supplies it to wholesalers and distributors. One of Auden

[61] *Merger Assessment Guidelines*, paragraph 5.6.6.

Mckenzie's customers is Actavis. Actavis does not hold an MA for this product and only acts as a reseller of Auden Mckenzie's product.

148. The Parties provided shares of supply for this product on both a value and volume basis as shown in Table 5.

Table 5: Mometasone Furoate 0.1% topical applications – the Parties' shares of supply

%

Product	*Value share*			*Volume share*		
	Actavis	*Auden Mckenzie*	*Combined*	*Actavis*	*Auden Mckenzie*	*Combined*
Mometasone Fuorate 0.1% topical applications	[0–10]	[0–10]	[0–10]	[0–10]	[10–20]	[10–20]

Source: the PartiesThe Parties identified several MA holders currently supplying Mometasone Furoate 0.1% topical applications.[62]

149. The Parties submitted that, as their shares of supply are low both by volume and value, and given that the increment in the share of supply brought about by the Merger is minimal, the Merger does not give rise to any competition concerns in respect of this product.

- *Third party views*

150. A wholesaler that purchases Mometasone Fuorate 0.1% topical applications from Auden Mckenzie told the CMA that, if the merged entity were to increase the price of this product by 5%, or stop supplying, it would invite tenders and appoint an alternative supplier on the basis of price and product availability.

151. Another wholesaler currently supplied by Auden Mckenzie told the CMA that it also purchased Mometasone Fuorate 0.1% topical applications from [✂]. It said that the Parties did not compete in the supply of this product.

152. A competitor told the CMA that the main suppliers of Mometasone Fuorate 0.1% topical applications are, in order of importance, Mylan, Teva, Auden Mckenzie and Actavis.[63] Another competitor said that Actavis and Auden Mckenzie do compete to some extent, but that there are several other competitors active in the supply of this product.

[62] These are, for Mometasone Fuorate 0.1% cream: Almirall; B&S Healthcare; Glenmark Pharmaceuticals; Kosei Pharma; S&M Medical; Star Pharmaceuticals and Swinghope; and for Mometasone Fuorate 0.1% ointment: Almirall, B&S Healthcare, Generics (UK), Glenmark Pharmaceuticals, S&M Medical, Star Pharmaceuticals and Swinghope.
[63] The competitor told us that these companies supply the unbranded generic versions of the product.

- *CMA assessment and conclusion*

153. The CMA notes Auden Mckenzie's low share of supply of Mometasone Furoate 0.1% and the significant number of suppliers holding MAs for this product. It further notes that no third party expressed concerns in relation to input foreclosure of this product. On the basis of this evidence, the CMA believes that the merged entity would not have the ability to engage in input foreclosure as a result of the Merger.[64] The CMA therefore believes that the Merger does not give rise to a realistic prospect of an SLC through input foreclosure in the supply of Mometasone Fuorate 0.1% topical applications in the UK.

The Group 1 overlap products

154. As explained in the horizontal effects section above, Auden Mckenzie holds an MA for each of the Group 1 overlap products, whereas Actavis does not hold an MA but acts as a reseller for other pharmaceutical companies' products. Auden Mckenzie supplies its Group 1 overlap products to a number of wholesalers, but not to Actavis.

155. The CMA notes that the combined shares of supply of the Parties in respect of the Group 1 overlap products are generally very low, whether considered on a volume or value basis (see paragraph 88). However, given the caveats explained in paragraphs 72-73, the CMA understands that these shares of supply may not take into account sales made by Auden Mckenzie to other wholesalers.

156. The CMA notes that there are other suppliers which hold MAs for these products, which they could supply to wholesalers and retailers.[65] The CMA received no evidence from the companies whose products are resold by Actavis to suggest the use of exclusive agreements between wholesalers and pharmaceutical companies.

157. Given that Auden Mckenzie's shares of supply in the Group 1 overlap products are generally low (ranging from [0–10]% to [20–30]%, see Table 1) and the number of competitors active in the upstream supply of these products, the CMA believes that the merged entity would not have the ability to foreclose downstream wholesalers through input foreclosure. The CMA

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[64] Having concluded that the merged entity would not gain the ability to engage in input foreclosure as a result of the Merger, it has not been necessary to consider the incentive of the merged entity to engage in such a strategy, nor the effect that such a strategy would have on competition.
[65] These are, in respect of Lormetazepam 0.5mg tablets: Generics (UK), Genus and Winthrop; in respect of Lormetazepam 1mg tablets: Generics (UK), Genus, Winthrop, Doncaster Pharmaceuticals and Waymade; in respect of Piroxicam 0.5% gel: Manx Healthcare, Pzifer and Aptil Pharma; in respect of Pethidine 50mg tablets: Martindale; and in respect of Betamethasone 0.1% topical applications: Manx Healthcare.

also notes that no third parties expressed concerns in relation to input foreclosure of these products.

158. However, given that there is only one competitor active upstream in the supply of Pethidine 50mg tablets and in the supply of Betamethasone 0.1% topical applications, the CMA considered these products more closely and assessed whether the merged firm would have the incentive to engage in a foreclosure strategy.

159. Such an incentive would arise to the extent that the merged firm is able to more than offset the revenue lost through reduced sales to third party wholesalers with increased revenue through its direct sales. The low shares of supply that Actavis has at the retail level suggest that there are other competitors that account for a significant proportion of sales at the retail level which could, consequently, capture significant proportions of diverted sales. For this reason the CMA believes that the merged firm would not have the incentive to foreclose in relation to these products.

160. The CMA therefore believes that the Merger does not give rise to a realistic prospect of an SLC through input foreclosure in the supply of the Group 1 overlap products in the UK.

Customer foreclosure

Group 1 overlap products

161. Auden Mckenzie is active in the supply of these products, holding an MA for each product, and currently supplies independent pharmacies and national/regional pharmacy chains directly or through wholesalers. Actavis does not hold an MA for the Group 1 overlap products but acts as a reseller for other pharmaceutical companies (see paragraph 74).

162. As set out in Table 1 above, Actavis' shares of supply in the Group 1 overlap products are low, ranging from [0–10]% to [0–10]% by value, with a similar range by volume.

- *Third party views*

163. The CMA sought views from the pharmaceutical companies that currently use Actavis as a reseller. [✂].

- *CMA assessment and conclusion*

164. The CMA believes that, given Actavis' low shares of supply in the distribution of the Group 1 overlap products as a wholesaler, the merged entity would not have the ability to foreclose its upstream rivals through customer foreclosure.[66] The CMA further notes that none of the suppliers whose products are resold by Actavis raised any concerns in relation to customer foreclosure.

165. On the basis of this evidence, the CMA believes that the Merger does not give rise to a realistic prospect of an SLC through customer foreclosure in the supply of the Group 1 overlap products in the UK.

Barriers to entry and expansion

166. 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 substantial lessening of competition. In assessing whether entry or expansion might prevent an SLC, the CMA considers whether such entry or expansion would be timely, likely and sufficient.[67]

167. The Parties submitted that barriers to entry and expansion in the UK generic pharmaceutical markets are low. They highlighted the relatively rapid entry and growth of Auden Mckenzie, stating that this demonstrates that it is possible for a new entrant to enter the market and achieve growth within a limited time period.[68] The Parties said that new entrants can outsource manufacturing and distribution at relatively low cost.

168. Competitors to the Parties told the CMA that the time and costs involved in expanding into the production of different strengths or galenic forms of molecules already produced would depend on the type of product in question. Competitors estimated that the time needed to bring such products to market varied between two and four years, with cost estimates ranging between £0.5 and £1 million. These competitors generally indicated that the time and costs involved in expanding to produce products of molecules not currently produced would not be materially different from those involved in expanding

[66] Having concluded that the merged entity would not gain the ability to engage in customer foreclosure as a result of the Merger, it has not been necessary to consider the incentive of the merged entity to engage in such a strategy, nor the effect that such a strategy would have on competition.
[67] *Merger Assessment Guidelines*, from paragraph 5.8.1.
[68] Auden Mckenzie launched 28 products in the UK between 2001 and 2004, and a further 15 products between 2005 and 2009.

into the production of different strengths or galenic forms of molecules already produced.

169. 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.

Third party views

170. The CMA contacted customers and competitors of the Parties. One competitor pharmaceutical company told the CMA that Actavis offers pricing schemes through which pharmacies can enjoy quantity rebates if they meet certain quantity targets set by Actavis. The competitor expressed concerns in relation to the Merger on the basis that the expansion of Actavis' portfolio through the Merger would exacerbate this situation. The CMA notes that the Merger does not raise customer or input foreclosure concerns (see paragraphs 160 and 165). In particular, the evidence showed that pharmaceutical companies can use alternative routes to market, wholesalers have access to alternative sources of the products, and there are no exclusive agreements between wholesalers and pharmaceutical companies. This evidence indicates that Actavis or other wholesalers could expand their product offerings through contracting with third-party suppliers. The CMA notes that, pre-Merger, Actavis was sourcing a considerable proportion of its product catalogue from third-party suppliers. Taking the above considerations into account and noting that the Merger does not lead to a significant increase in market power in any of the overlap products, the CMA believes that the Merger will not have a significant impact on the merged entity's ability to offer such quantity discounts relative to the pre-Merger situation. For these reasons, the CMA believes that the Merger does not give rise to a realistic prospect of an SLC in this respect.

171. The CMA has also been in contact with the Department of Health, NHS CCGs and the MHRA during this merger investigation.

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

Decision

173. 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 United Kingdom.

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

Andrew Wright
Director, Mergers
Competition and Markets Authority
21 May 2015