# Anticipated acquisition by Baxter International, Inc of Hospira UK Limited's compounding business and related assets

# Decision on relevant merger situation and substantial lessening of competition

**ME/6770/18**

## SUMMARY


1. Baxter International, Inc. through its wholly-owned indirect UK subsidiary Baxter Healthcare Limited (**Baxter**) has agreed to acquire the aseptic compounding business and related assets (**Hospira**) of Hospira UK Limited (the **Merger**). Baxter and Hospira are together referred to as the **Parties**.

2. The Competition and Markets Authority (**CMA**) believes that it is or may be the case that each of Baxter and Hospira is an enterprise; that these enterprises will cease to be distinct as a result of the Merger; and that the share of supply test is met. 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 commercial supply of compounded cytotoxics and monoclonal antibodies (**MABs**) for use in chemotherapy and immunology to healthcare customers in Great Britain. The CMA has assessed the Merger in this frame of reference.

4. Baxter is also engaged in activities upstream and downstream of the supply of compounded cytotoxics and MABs. Upstream it is active in the supply of certain oncology products and IV bags, while downstream it is active as a homecare provider, administering medication to patients at home.

5. The CMA has found that, while Hospira is a competitor to Baxter in the supply of compounded cytotoxics and MABs, the constraint it exercises is not particularly significant and the Parties are not particularly close competitors. The merged entity will continue to face more significant constraints from other commercial competitors, in particular Bath ASU and ITH Pharma. The Parties

will also continue to face some additional constraint from Quantum Pharmaceutical, and to a more limited extent from Celesio, as well as from self-supply and cross-supply by healthcare customers. The CMA believes that these constraints, taken together, are sufficient to ensure that the Merger does not give rise to a realistic prospect of a substantial lessening of competition (**SLC**) as a result of horizontal unilateral effects.

6. In relation to Baxter's upstream and downstream activities, the CMA believes that the merged entity would not have the ability and/or incentive to engage in a foreclosure strategy to disadvantage competitors in the supply of compounded cytotoxics and MABs. Therefore, the CMA believes that the Merger does not give rise to an SLC as a result of vertical effects.

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

## ASSESSMENT

### Parties

8. Baxter's hospital business manufactures products used in the delivery of fluids and drugs to patients. These include IV and other sterile solutions and administration sets, premixed drugs and drug-reconstitution systems, IV nutrition products, infusion pumps and inhalation anaesthetics. It also provides products and services related to compounding, drug formulation and packaging technologies.

9. The turnover of Baxter International, Inc. in the year ending 31 December 2017 was $10,561 million (approximately £7,817 million) worldwide, of which $**[✂]** (approximately £**[✂]**) was generated in the UK.

10. Hospira is a subsidiary of Pfizer, Inc. (**Pfizer**), a global research-based biomedical and pharmaceutical company. Hospira was acquired by Pfizer in September 2015. Hospira sells generic and biosimilar drugs and medical devices. The company also manufactures and sells compounded medicines.

11. The turnover of Hospira in the year ending 30 November 2017 was approximately £**[✂]** worldwide, of which approximately £**[✂]** was generated in the UK.

### Transaction

12. Through the Merger, Baxter will acquire the aseptic compounding business carried on by Hospira, including all related assets. These assets comprise contracts, property, goodwill, intellectual property, fixtures, plant and

equipment, an ordering system, and any other related property/rights. Hospira's other businesses (generic and biosimilar drugs and medical devices) are not part of the proposed transaction. The transaction is valued at approximately £**[✂]**.[1]

## Procedure

13. The Merger was considered at a Case Review Meeting.[2]

## Jurisdiction

14. Each of Baxter and Hospira is an enterprise. As a result of the Merger, these enterprises will cease to be distinct.

15. The Parties overlap in the supply of compounded cytotoxics and MABs for chemotherapy and immunology by commercial suppliers to healthcare customers in Great Britain, with a combined share of supply by volume of 40 - 50% (increment 10 - 20%).[3] The CMA therefore believes that the share of supply test in section 23 of the Act is met.

16. The initial period for consideration of the Merger under section 34ZA(3) of the Act started on 19 October 2018 and the statutory 40 working day deadline for a decision is therefore 13 December 2018.

## Counterfactual

17. 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.[4]

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[1] Baxter will also make a subsequent payment to Hospira as consideration for Hospira inventory. The quantum of this payment will be determined following completion.
[2] See *Mergers: Guidance on the CMA's jurisdiction and procedure* (CMA2), January 2014, from paragraph 7.34.
[3] See Table 1 below.
[4] *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).

18. The Parties submitted that, absent the Merger, Hospira would have closed because Pfizer is committed to exiting the compounding market. The Parties said that Pfizer could have attempted to sell Hospira to another party but that a sale was unlikely, given a lack of potential purchasers and the losses which it would have continued to incur during the period prior to achieving a sale.

19. For the CMA to accept an exiting firm scenario, it must believe that the following conditions are met:

    a. on the basis of compelling evidence that, absent the Merger, it is inevitable that Hospira would have exited the market (limb 1);

    b. that there is no substantially less anti-competitive purchaser for the business or its assets (limb 2); and

    c. that the Merger does not represent a substantially less competitive outcome compared with what would have happened to the sales of the business in the event of its exit (limb 3).[5]

20. In line with its guidance, the CMA carefully considered:

    a. evidence of the commercial rationale for Hospira exiting the compounding market, and the decisions and actions taken by the Board and senior management towards closure of Hospira prior to agreeing a sale with Baxter; and

    b. the sales process which Pfizer undertook to dispose of Hospira.

21. The evidence available to the CMA from Pfizer's internal documents showed that there was a clear strategic and financial rationale for Pfizer to close Hospira. Hospira's compounding business did not fit Pfizer's strategic objectives. Hospira was bought as part of the wider acquisition by Pfizer of Hospira UK Ltd in September 2015, and the aseptic compounding business had always been identified by Pfizer as non-core and potentially to be divested.[6] Consistent with this, Pfizer made an attempt to sell the Hospira compounding business in 2016, but this was abandoned following initial interest and a bid of £**[✂]** from Baxter, which was subsequently rescinded[7].

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[5] *Merger Assessment Guidelines*, paragraph 4.3.14

[6] Merger Notice, Annex 12 – Pfizer Global Supply Executive Summary – Project Lantern Hospira UK Compounding Business, June 27 2016, Merger Notice, Annex 13 – Minutes of a meeting of the Board of Directors held via telephone, 4 November 2016.

[7] The CMA understands that in light of onerous supply guarantees and other obligations contained in a key Hospira supply agreement, no longer in place at the time of the most recent sale process, Baxter was at the time identified as being the only other participant in the UK compounding market in a position to take on - and provide a sufficient parental guarantee in respect of - those contractual obligations. Pfizer further explained that the reason it had entertained an offer of £**[✂]** at that point in time was because Baxter had been willing to take on this onerous supply agreement.

Pfizer's lack of strategic focus on compounding was further confirmed by some third parties.

22. Hospira's financial position had also been in decline. In 2015, the Croydon site made a loss of £**[✂]**, in 2016 it made a profit of £**[✂]**, and in 2017 it made a loss of £**[✂]**. The site is forecast to make a further loss of £**[✂]** in 2018. Although the sales process may have contributed to some of these later losses, it was clear to the CMA that Pfizer perceived the Hospira business to be loss-making. Third parties also confirmed this view. Some potential purchasers cited the poor financial performance of the business and its low margins as their principal reason for pulling out of the bidding process to buy the business.

23. However, the CMA also found evidence from internal documents indicating that closure of the site would have reputational implications for Pfizer and that Pfizer therefore preferred a sale of the business to closure.[8] At the time the Merger was in contemplation, Pfizer's internal documents are unclear as to whether, in the absence of a bid from Baxter, it would have continued in a longer sale process with other potential bidders, or would have closed the business down in the face of continued losses.[9]

24. The CMA discussed the sale process with Results Healthcare, which managed the process for Pfizer, and with potential alternative purchasers of Hospira and found some evidence that, in the absence of Baxter, there may have been an alternative purchaser for Hospira. At the point at which Pfizer decided to proceed with the sale to Baxter, it had received one alternative firm offer and two other parties also remained interested.

25. The alternative offer received by Pfizer was a **[✂]** sum which was considerably lower than that submitted by Baxter. Of the other two interested parties, one provided two indicative offers within a range where any firm offer it might make would have fallen, the latter of which implied a negative sum at the lower end of that range. The other party had been unable to make any bid by the deadline and, while it had taken significant steps internally towards putting together a bid, it would have required more time to get the necessary internal approvals for a bid.

26. Therefore, on a cautious basis, the CMA has assessed the Merger using the prevailing conditions of competition as the relevant counterfactual. Given that the CMA has found that the Merger does not give rise to a realistic prospect of

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[8] Merger Notice, Annex 19 - Pfizer Global Supply, Executive Summary, Hospira UK Compounding Business, June 2018.
[9] Merger Notice, Annex 19 - Pfizer Global Supply, Executive Summary, Hospira UK Compounding Business, June 2018.

an SLC, the CMA has not found it necessary to ultimately conclude on whether the conditions of the exiting firm counterfactual are met in this case.

## Background on aseptic compounded medicines

### *Products*

27. Compounding involves the combining, mixing or altering of a combination of pharmaceutical ingredients to create a medicine of a particular strength or dosage. The compounding process is carried out under aseptic conditions, with the resulting compounded medicines administered to patients in a range of formats, including via syringe, IV bag or infusion pump.

28. Compounded medicines can be produced either individually, in 'patient-specific' format, or as part of a batch. Patient-specific compounding allows medicines to be tailored to a patient's clinical requirements, both in terms of strength and dosage. Batch production involves the compounding of medicines in line with a pre-defined dosage, with the medicines then administered to patients on the basis that their needs fall within a band of the defined dose.

29. The shelf life of different compounded medicines can vary significantly, based on a range of factors. Some compounded medicines with lower stability attributes must be administered to patients within a few hours of being produced, whereas others remain safe and effective for use for at least 12 weeks from manufacture. For practical reasons, therefore, it is ordinarily the case that batch production is only suitable for compounded medicines with a shelf-life of more than 28 days.

30. Compounded medicines can include toxic (or cytotoxic) and non-toxic products. Toxic compounded medicines are predominantly used in chemotherapy. Evidence from both the Parties and third parties indicates that there are differences between the processes and resources required for the compounding of cytotoxics and the compounding of non-toxic medicines. Such differences arise principally due to the increased risk profile and hazardous nature of cytotoxics, which necessitates additional safety measures and protocols.

31. While each compounded medicine is a bespoke medical product, compounded medicines can be grouped into five broad treatment categories:

    a. Chemotherapy (cytotoxics and MABs);

    b. Immunology (MABs);

c. Antimicrobials (antivirals and antifungals);

d. Total parenteral nutrition (intravenous feeding); and

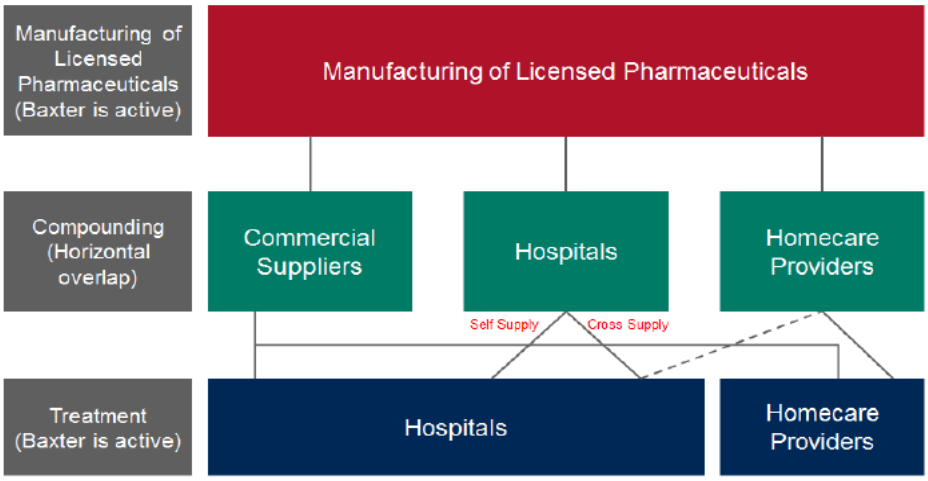
e. Pain relief.

32. Other compounded medicines, serving a variety of other treatment functions, eg antibiotics, are referred to as centralised intravenous additive services (**CIVAS**).

***Supply chain***

33. Figure 1 presents the compounding supply chain.

**Figure 1 – Compounding supply chain[10]**




34. Manufacturers of licensed pharmaceuticals supply directly to hospitals, commercial suppliers and homecare providers, and via wholesalers.

35. Customers of compounded medicines include NHS hospitals/trusts, private hospitals and providers of patient homecare services.

*Customers and contracts*

36. Contracts for the supply of compounded medicines are typically awarded on the basis of tenders. Purchases by NHS trusts are usually based on a

[10] The dashed line from homecare providers was used by the Parties to indicate that some homecare providers supply compounded medicines into hospitals, though to a less significant degree.

framework agreement that has been tendered by a regional purchasing group. Customers can purchase from one or more approved suppliers, such that being named as an approved supplier following a tender does not guarantee sales. NHS hospitals (particularly larger hospitals) can also conduct tenders directly. As part of these individual tender arrangements, hospitals can enter into co-location agreements, whereby a commercial supplier agrees to install a unit on or very near to the relevant hospital's premises with a view to supplying a significant proportion of that hospital's needs.

37. Private hospitals also typically purchase through tenders, though without the same EU/UK public procurement rules as NHS organisations.

38. Although the majority of commercial supply appears to be agreed through contracts, customers can also order ad-hoc supplies as required.

39. The CMA has found, based on evidence from the Parties and from customers and competitors, that price and technical ability/quality are particularly important to customers. While standards of quality for compounding are strictly regulated, and therefore there is little scope for differentiation in the physical product supplied, suppliers can differentiate themselves based on price and aspects of service, including their ease of ordering and customer responsiveness.

*Suppliers*

40. Many hospitals and homecare providers self-supply at least some of their compounded medicine needs using their own in-house facilities. Within the NHS, approximately 65% of all aseptic compounded medicines, excluding CIVAS, are self-supplied through in-house compounding. There are approximately 180 NHS aseptic facilities. Certain compounded medicines, with particularly short shelf-lives, are particularly well-suited to self-supply and a large proportion of self-supply is committed to this type of production.

41. Alternatively, or additionally, customers can obtain compounded medicines from commercial suppliers, such as the Parties, or from other NHS hospitals which cross-supply. 24% of NHS aseptic facilities have an MHRA 'Manufacturer Specials' licence permitting cross-supply.

42. In addition to the Parties, the other main commercial suppliers of compounded cytotoxics and MABs for chemotherapy and/or immunology to healthcare providers in the UK are Bath ASU, ITH Pharma and Quantum Pharmaceutical (**Quantum**). Celesio also supplies some compounded medicines to hospitals, but is predominantly focused on supplying homecare customers. In this Decision, the term 'commercial suppliers' is used to refer to the Parties and these competing suppliers.

### *Market trends*

*Review and reform of self-supply and cross-supply*

43. The supply of compounded medicines in the NHS has recently been the subject of two detailed reviews.

44. **Carter review on productivity in NHS hospitals (2016):**[11] A key recommendation from Lord Carter's report was to shift the balance of activity in pharmacies from essential pharmacy infrastructure services to clinical-facing roles. The review encouraged better use of NHS facilities along with commercial outsourcing. Each non-specialist acute trust in England produced a Hospital Pharmacy Transformation Plan by April 2017. Many of these plans indicated the intention to consolidate aseptic services. Several third parties told the CMA that a significant number of NHS compounding units had closed following these proposals and that third parties had generally seen this as a prompt towards greater use of outsourcing.

45. **NHSI review of capacity in aseptic compounding (2018)**:[12] The aim of this review was to enable NHS Improvement to build on the recommendations of the Carter report to gain a comprehensive understanding of the nature and location of currently available services, to inform planning for future service provision. This review identified a number of features of self-supply and cross-supply, including a significant under-utilisation of current NHS capacity. NHSI is working with the Office of the Chief Pharmacist on developing proposals to improve the efficiency and quality of self-supply and cross-supply, with the aim of making better use of existing in-house NHS facilities and reducing reliance upon commercial supply.

*Demand and capacity*

46. Customers and competitors told the CMA that the nature and extent of demand for the commercial (or outsourced) supply of compounded medicines is changing.

47. In April 2016, NHS England introduced a national dose-banded system and encouraged hospitals to standardise dosing where appropriate. Third parties indicated that, while there will always be a need to commercially source some patient-specific medicines, this system is leading to an increased demand for

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[11] Operational productivity and performance in English NHS acute hospitals: Unwarranted variations - An independent report for the Department of Health by Lord Carter of Coles, February 2016.
[12] NHSI, Pharmacy Aseptic Services Review, Summary of Key Findings 28th March 2018

batch-compounded medicines and more efficient use of compounding capacity.[13]

48. Third parties, including NHSI, also indicated that demand for outsourced compounded medicines is generally increasing, for several reasons:

    a. generally increasing patient demand linked to demographic factors;

    b. constraints in self and cross-supply, due to limitations in NHS facilities, equipment and the availability of staff, and the withdrawal of some capacity from the market as NHS facilities are de-commissioned;

    c. a perception from NHS trusts that more aseptic compounding should be outsourced and that this can be cheaper; and

    d. a general perception that there is risk associated with such production that may be better borne by commercial suppliers.

49. Third parties generally flagged concerns about the commercial capacity available in aseptic compounding, noting that there had been significant exits from the compounding of cytotoxics and MABs in recent years (eg B. Braun in 2016). However, a number of suppliers noted the opportunities provided by the increasing demand, in particular for batch compounding. Some noted that this was creating an attractive environment for potential further investment and the expansion of capacity. Some suppliers said that they had either recently invested or had plans to invest to expand capacity for this reason.

## Frame of reference

50. Market definition provides a framework for assessing the competitive effects of a merger and involves an element of judgement. The relevant market or 'frame of reference' is intended to include the most significant competitive alternatives available to the customers of the merging firms.[14] However, 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 merging parties from outside the relevant market, segmentation within the relevant market, or other reasons why some constraints are more important than others. The CMA will take these factors into account in its competitive assessment.[15]

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[13] The CMA understands that similar considerations also apply in Scotland, though there has already been a more significant and concerted move towards dose-banding in Scotland than is the case in other parts of Great Britain.

[14] *Merger Assessment Guidelines*, paragraph 5.2.1.

[15] *Merger Assessment Guidelines*, paragraph 5.2.2.

51. The Parties' activities overlap in the supply of aseptic compounding of:

    a. cytotoxics for use in chemotherapy;

    b. MABs for use in chemotherapy and immunology; and

    c. three CIVAS products: potassium chloride, desferrioxamine and ganciclovir.[16]

52. Both of the Parties supply NHS and private hospitals across the UK with compounded products. Baxter operates four compounding sites, while Hospira has a single compounding facility in Croydon (South London) [17].

53. Baxter is also active upstream and downstream of its compounding activities. Upstream it supplies:

    a. three oncology products (cyclophosphamide, ifosfamide and mitoxantrone) as well as a supporting medication, mesna. These products are all used in chemotherapy; and

    b. IV bags and related ancillary products, such as elastomeric pumps for syringes.[18]

    Downstream, it supplies homecare services, which involves the dispensing and delivery of compounded medicines to patients at home and/or giving support to administer intravenous drugs in the patient's home.[19]

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[16] The evidence available to the CMA from the Parties and third parties indicates that the appropriate frame of reference is likely to be wider than these three drugs to encompass all CIVAS products, due to evidence of strong supply side substitutability. In that context, the evidence available to the CMA indicates that that the Parties' volumes and revenues from CIVAS activities are low, and that there are a number of other suppliers, including Bath ASU, ITH, Quantum and more significant cross-supply (for example, Portsmouth and Queen's NHS Trusts). Therefore, the CMA believes that there is no realistic prospect of an SLC in relation to these products and they are not discussed further in this Decision.

[17] Until mid-2017, Hospira also operated from an older facility in Park Royal, north London, prior to its closure.

[18] The CMA considered whether this vertical relationship may lead to an SLC through vertical effects. See further below on the CMA's framework for assessing these theories of harm. The CMA believes that the merged entity is unlikely to have an ability to harm competitors downstream by increasing prices/reducing quality or otherwise restricting access to their supply of IV bags. Although Baxter has a high market share, there are alternative suppliers of IV bags. The Parties submitted that Fresenius, B. Braun and Macopharma are alternative suppliers of IV bags, and third parties named these suppliers as possible alternatives. Competition from these suppliers would prevent the Parties from increasing the prices/restricting access of IV bags sufficiently to harm downstream rivals. The CMA therefore believes that there is no realistic prospect of an SLC based on this vertical link and has not found it necessary to further consider incentives or effects. These services are therefore not discussed further in this Decision.

[19] The CMA considered whether this vertical relationship may lead to an SLC through vertical effects. See further below on the CMA's framework for assessing these theories of harm. The CMA believes that the merged entity is unlikely to have an ability to harm competitors downstream by increasing prices/reducing quality or otherwise restricting access to their homecare services. The evidence available to the CMA from the Parties and third parties indicates that Baxter's activities are limited, and Baxter does not seem to be an important customer for other compounders in the market. In addition, as Baxter's homecare services do not require chemotherapy or MABs, there is unlikely to be any merger-specific change in incentives. Finally, the CMA received no concerns

### *Compounded medicines*

*Product scope*

54. The supply of compounded medicines has been considered previously by the OFT.[20] In particular, in *Mayne/ITH*, the OFT considered the extent to which it was appropriate to distinguish by: (i) treatment category/toxicity; and (ii) route to market (ie nature of supply/suppliers). Although the OFT did not reach a conclusion, it assessed the effects of the merger both in the supply of compounded medicines overall and in the supply of cytotoxic medicines by commercial suppliers. The OFT recognised that cross-supply by hospitals and supply from homecare providers posed some competitive constraint, while in-house supply posed an additional constraint in the medium to longer term.

55. In the present case, the CMA has considered the extent to which it is appropriate to distinguish in the frame of reference between: (i) treatment category and toxicity; (ii) batch production and patient-specific production; (iii) customer type; and/or (iv) routes to market.

*Treatment category and toxicity*

56. Compounded cytotoxics are predominantly used in chemotherapy. Compounded MABs, which are predominantly (though not exclusively) non-toxic, are also used in chemotherapy, with some classifications being used for immunology. Some MABs are used both for chemotherapy and immunology.

57. The CMA has considered the appropriateness of segmenting the compounding of cytotoxics and MABs according to: (i) different treatment categories, ie MABs for immunology and MABs and cytotoxics for chemotherapy; (ii) toxicity, ie cytotoxics (including toxic MABs) and non-toxic MABs; and (iii) different treatment categories and toxicity.

58. The Parties submitted, consistent with the findings in *Mayne/ITH*, that from a demand side perspective these medicines are not substitutable. However, the Parties also submitted that, on the supply side, suppliers can switch production easily within the same treatment category and that switching production between cytotoxics and other non-toxic treatment categories (including MABs for immunology) is possible.

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about the impact of the Merger on Baxter's homecare activities. Therefore, the CMA believes there is no realistic prospect of an SLC as a result of the merged entity's vertical activities in homecare services. These services are therefore not discussed further in this Decision.

[20] ME/1169/04 Anticipated acquisition by Intercare Group plc of Eldon Laboratories Ltd, Clearance, OFT decision of 10 September 2004. ME/1643/05 Anticipated acquisition by Mayne Pharma plc of Intra-Tech Healthcare Ltd, Clearance, OFT decision of 26 April 2005

59. Competitors confirmed that there is a strong degree of supply-side substitutability between both (i) the compounding of cytotoxics and MABs; and (ii) the compounding of MABs for chemotherapy and immunology. Both customers and competitors explained that it is usual for commercial suppliers and hospitals to compound both cytotoxics for chemotherapy and MABs for chemotherapy and immunology. The CMA noted that all of the commercial suppliers of cytotoxics are also active in the compounding of MABs. Third parties, including commercial suppliers, explained that there is little or no material difference in the materials handling and other processes required for the compounding of MABs intended for the two treatment types, which supported the Parties' submission.

60. The CMA noted that some hospitals compound cytotoxics and MABs solely for use in chemotherapy. However, it did not find this to be the case generally, and all commercial suppliers compound cytotoxics and MABs for use in both chemotherapy and immunology.

61. Therefore, the CMA has not distinguished between cytotoxics and MABs, nor between use in chemotherapy and immunology, for the purposes of the product frame of reference.

62. However, the evidence available to the CMA indicated that it may not be appropriate to expand the product frame of reference beyond the compounding of cytotoxics and MABs for chemotherapy and immunology. The CMA found that there are several compounders of non-toxic medications, such as CIVAS products, who are not active in the compounding of cytotoxics or MABs. Some of these compounders cited significant supply-side costs associated with beginning to compound MABs and/or cytotoxics, whether for the treatment of chemotherapy or immunology.

63. Therefore, the CMA has assessed the impact of the Merger in the supply of compounded cytotoxics and MABs for chemotherapy and immunology. The CMA notes that its competitive assessment of the Merger would not differ were it to consider the supply of cytotoxics and MABs separately, as the conditions of competition and the constraint from other suppliers are similar.

*Batch production and patient-specific production*

64. The Parties submitted that it would not be appropriate to segment the market by reference to patient-specific and batch compounding as it is not possible to precisely delineate between the two, noting the varied definitions of batch and patient-specific compounding applied by different suppliers. Further, the Parties stated that the distinction between the two compounding formats is

becoming increasingly blurred as the NHS, a key customer of commercial suppliers, moves increasingly towards batch-production.

65. While there are demand-side differences between patient-specific and batch compounding, customers and competitors confirmed that both batch and patient-specific compounding can be undertaken at the same facility, using the same input drugs, staff and equipment. Some third parties explained that on the supply-side, there is essentially no real difference in terms of process between the compounding of patient-specific and batch medicines, bar the number of preparations compounded in a session. Third parties told the CMA that there are no significant switching costs for a supplier in alternating between batch and patient-specific compounding, with just one third party noting the need for specific labelling and barcode technology to supply batch-compounded products to hospitals.

66. Therefore, the CMA has not distinguished between patient-specific and batch-specific production for the purposes of its frame of reference. The CMA notes that its competitive assessment of the Merger would not differ were it to consider batch and patient-specific separately as the conditions of competition are similar. For this reason, the CMA has not found it necessary to conclude on the product frame of reference in relation to patient-specific and batch compounding.

*Customer type*

67. The Parties submitted that the OFT did not segment the market according to customer types in previous cases and that it would not be appropriate to do so in the present case. The Parties said that there are no meaningful differences in the parameters of competition between each customer type, in particular as there is no discernible difference in the types of compounded cytotoxics and MABs demanded by each customer type. The Parties submitted that they compete against the same set of competitors for each customer type.

68. Customers and competitors confirmed that the requirements of NHS trusts and private hospitals are largely similar and, although homecare providers may have slightly more specific or lower volume demands, their requirements are not materially different. The CMA also found that all customer types are served by the same set of commercial suppliers.

69. The CMA found that there were, in principle, no differences in the supplier set which could bid for co-location contracts, and that such contracts did not guarantee exclusivity of supply to the particular hospital. The CMA therefore considered competition for these contracts within the same frame of reference as general supply.

70. For these reasons, the CMA has not segmented its frame of reference by customer type and has assessed the Merger by reference to all healthcare customers.

*Routes to market*

71. The Parties submitted that there are four primary routes to market for compounded medicines, which should be considered together: (i) self-supply by hospitals or homecare providers; (ii) cross-supply by hospitals; (iii) commercial supply to hospitals and homecare providers; and (iv) commercial supply to hospitals by homecare providers.[21]

72. To support their view, the Parties submitted that: (i) customers deploy various sourcing strategies and are able to regularly switch between different sources of supply due to low switching costs; (ii) most hospital in-house facilities have spare capacity; and (iii) appropriately licenced hospitals supply other hospitals outside their trust area.

73. The evidence available to the CMA indicated that non-commercial suppliers are not a significant alternative for customers of the Parties as:

    a. Third parties told the CMA that, even where a hospital has some in-house supply, there is generally also a need for an outsourced or commercial supply solution. Customers that self-supply often want to source some of their demand from commercial suppliers. This can be to ensure sustainability of supply or to benefit from lower prices (due to efficiencies which may arise from the production of large batches).

    b. While a large proportion of healthcare customers (principally hospitals) self-supply to some extent, capacity constraints mean they may be unable to significantly expand this capacity. Therefore, at any point of demand, they may not be able to choose between self-supply and commercial supply. Moreover, only two of the many hospitals which said they undertake the in-house compounding of cytotoxics and/or MABs said that they would consider moving more compounding in-house following a 5% rise in the prices charged by commercial suppliers.

[21] As part of its investigation, the CMA has seen evidence that certain homecare providers source some or all of their compounding requirements in-house, and that some homecare providers are beginning to supply hospitals. However, these volumes are currently very small.

c. A significant proportion of healthcare customers are entirely reliant upon commercial supply and are unlikely to start self-supplying in response to a small but significant price rise.

d. The extent of cross-supply from other NHS trusts is currently limited and may not increase significantly in the near future, in light of difficulties in increasing the utilisation of NHS capacity, such as funding limitations and difficulties in recruiting and retaining suitably qualified personnel.

74. On the basis of this evidence, and consistent with decisional practice, the CMA has assessed the effects of the Merger in the supply of compounded cytotoxics and MABs (for both immunology and chemotherapy together) by commercial suppliers to healthcare customers, excluding both self-supply and cross-supply. However, the CMA has considered the extent of the constraint from self-supply and cross-supply in its competitive assessment.

***Oncology products for use in chemotherapy***

75. Baxter manufactures and supplies a range of oncology products, including three cytotoxic products (cyclophosphamide, ifosfamide and mitoxantrone) and a non-toxic supporting medication (mesna), each of which is used in chemotherapy treatment.

76. The Parties referred to past decisional practice in the pharmaceuticals sector, where the third Anatomical Therapeutic Chemical ('ATC') level, which groups medicines according to their therapeutic properties, has been used as a starting point for market definition. Under this classification, Baxter's oncology products fall within the following ATC3 categories:

    a. Ifosfamide (L01AA06) and cyclophosphamide (L01AA01) – antineoplastic agents, alkylating agents and nitrogen mustard analogues;

    b. Mitoxantrone (L01DB07) – antineoplastic agents, cytotoxic antibodies and related substances, and anthracyclines and related substances; and

    c. Mesna – detoxifying agents for antineoplastic treatment

    These products are referred to as the **relevant oncology products** for the purposes of this Decision.

77. For the purposes of its assessment of the Merger, the CMA has seen no reason to deviate from this approach for determining the appropriate product frame of reference for the relevant oncology products.

***Conclusion on product scope***

78. For the reasons set out above, the CMA has assessed the impact of the Merger in the following product frames of reference:

    a. the supply of compounded cytotoxics and MABs for chemotherapy and immunology by commercial suppliers to healthcare customers; and

    b. the supply of the relevant oncology products.

***Geographic scope***

*Compounded cytotoxics and MABs*

79. In *Mayne/ITH*, the OFT adopted a Great Britain-wide frame of reference on the basis that all commercial suppliers could supply the whole of Great Britain. However, it noted that some customers required rapid supply in 24 to 72 hours, due to the limited stability and shelf life of particular products, and it therefore also considered whether there might be concerns on a regional basis.

80. The Parties only overlap in Great Britain as Hospira is not active in Northern Ireland.

81. The Parties submitted that the relevant geographic frame of reference is national, or at least Great Britain, and that it would not be meaningful to focus on smaller geographic areas. This is because the location of compounding facilities does not influence customer choice to any significant degree; and because suppliers of compounded medicines serve the whole of Great Britain from different parts of the country, using dedicated couriers capable of delivery times of less than 24 hours, when required.

82. Customers and competitors confirmed this view. Some customers indicated that a commercial supplier's close proximity to a customer is desirable, or in some instances necessary, due to the very short shelf lives of certain compounded medicines, but third parties generally indicated that all commercial suppliers have the ability to deliver medicines anywhere in Great Britain within 24 hours, when necessary. Baxter is currently the only commercial supplier with more than one compounding facility in Great Britain, having four sites located in different areas of the country: London, Oxford, Thetford and Stockport. Three of these are co-location sites, each serving the needs of a particular NHS hospital. Bath ASU is located in the south west of England, ITH Pharma and Hospira are located in the London area and Quantum is located in the north east of England.

83. On the basis of this evidence, the CMA has assessed the impact of the Merger in the supply of compounded cytotoxics and MABs in Great Britain. The CMA has taken into account any differences in the geographic focus of suppliers in its competitive assessment.

*Oncology products*

84. The Parties submitted that, consistent with decisional practice, the appropriate frame of reference in which to assess the effect of the Merger is the supply of the relevant oncology products is the UK.

85. The CMA found no evidence to contradict the reasoning provided by the Parties.

86. For this reason, the CMA has assessed the impact of the Merger in the supply of the relevant oncology products in the UK.

### *Conclusion on frame of reference*

87. For the reasons set out above, the CMA has assessed the impact of the Merger in the following frames of reference:

    a. the supply of compounded cytotoxics and MABs for chemotherapy and immunology by commercial suppliers to healthcare customers in Great Britain (in the remainder of this Decision, this is referred to as the supply of compounded cytotoxics and MABs); and

    b. the supply of the relevant oncology products in the UK.

## Competitive assessment

### *Horizontal unilateral effects*

88. 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 to degrade quality on its own and without needing to coordinate with its rivals.[22] Horizontal unilateral effects are more likely when the merging parties are close competitors.

89. The CMA assessed whether it is or may be the case that the Merger has resulted, or may be expected to result, in an SLC in relation to horizontal unilateral effects in the supply of compounded cytotoxics and MABs for

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

chemotherapy and immunology by commercial suppliers to healthcare customers in Great Britain.

*Shares of supply*

90. Based on information provided by the Parties and third parties, the CMA has estimated the adjusted shares of supply of cytotoxics and MABs by volume,[23] as set out in Table 1 below.

**Table 1: Shares of supply of compounded cytotoxics and MABs**

| | Volume | Share (%) |
|---|---|---|
| **Baxter *** | **[✂]** | 20-30% |
| **Hospira**** | **[✂]** | 10-20% |
| **Combined** | **[✂]** | 40-50% |
| **Bath ASU** | **[✂]** | 30-40% |
| **ITH Pharma** | **[✂]** | 20-30% |
| **Quantum** | **[✂]** | 0-5% |
| **Total** | **[✂]** | 100 |
| **Celesio***** | **[✂]** | 0-5% |
| **NHS Cross-supply****** | **[✂]** | 0-5% |

Source: Parties and third parties.

*Adjusted to reflect Baxter's new contract with **[✂]**: the proportion of **[✂]**'s 2017 volumes awarded to Baxter have been added to Baxter's actual 2017 sales (using Annex 88 of the Merger Notice). The CMA has not excluded Baxter's volumes from co-location customer contracts because, as noted in the frame of reference discussion, it does not consider it appropriate to consider these customers separately.

**Hospira lost **[✂]** as a customer in 2018. Previously, **[✂]** had been a significant customer which accounted for **[✂]**% of its revenue. This table therefore uses Hospira's projected 2018 volumes as set out in the Merger Notice.

*** Celesio is a healthcare customer which predominantly self-supplies compounded cytotoxics and MABs but also commercially supplies some volumes to other healthcare customers. Its commercial supply volumes are very limited and predominantly homecare customer focused. As such the CMA has presented its shares separately.

**** Based on NHSI evidence received as part of its 2018 review of aseptic compounding, which was not an exhaustive review of all cross-supply options. While technically outside the CMA's frame of reference, the CMA has included it here for ease of comparison.

91. These shares indicate that:

    a. The Parties are currently the second and fourth largest commercial suppliers of cytotoxics and MABs and, after the Merger, the merged entity would be the largest supplier by volume.

[23] Compounding is normally charged on the basis of cost pass-through for the molecular inputs combined with a service charge. The costs of required molecular inputs vary greatly. Therefore, reporting shares on a revenue basis would be distorted by the value of the inputs compounded by each company. The CMA believes that volume is likely to be a more informative proxy for competitive strength.

b. There are four other commercial suppliers. Two of these will continue to have significant positions relative to the merged entity.

92. The Parties submitted that market shares are not an appropriate indicator of market power, given that sales are made in bidding markets characterised by formal tender procedures. The CMA acknowledges that it is important to take account of the nature of the market when interpreting shares of supply. The CMA has considered the extent to which the Parties compete with each other and other suppliers in further detail below.

*Closeness of competition*

93. The Parties acknowledged that Hospira was a credible competitor to Baxter, with some historical strengths, but submitted that Baxter competed more closely with other suppliers, in particular Bath ASU. The Parties presented tender data to support their views. The Parties noted that Hospira had recently lost some important contracts, including its largest contract with **[✂]**.

94. The Parties recognised that uncertainty regarding Hospira's future, especially over the period in which Pfizer had been attempting to sell the business, may have contributed to some of Hospira's recent customer losses. However, the Parties submitted that this did not imply the constraint on Baxter from Hospira was understated in its recent competitive interactions. They said that Hospira's constraint had diminished and would continue to diminish due to changes in the market, such as the increase in batch production where, although Hospira was active, it was less focused than ITH and Bath ASU.

95. The CMA considered the closeness of the Parties' offerings, and whether Hospira's recent competitive interactions may understate its potential constraint (ie under different ownership). The CMA considered: (i) third party views; (ii) internal documents; and (iii) tender data provided by the Parties.

*Third parties and internal documents*

96. Third parties named the Parties among the main commercial suppliers of cytotoxics and MABs. The majority of respondents said that the Parties compete closely and/or provide a similar offering. Several third parties told the CMA that Hospira's service levels are well-regarded and that its site is a well-managed and effective facility. A number of third parties noted that Hospira's Ascura ordering system was particularly helpful, which made Hospira's offering attractive.

97. The CMA found these views to be consistent with some of Baxter's internal documents.[24] For example, documents prepared for Baxter senior management for the purposes of deciding whether to make a non-binding offer for Hospira consistently describe the Hospira site as high quality, referring to it being: "**[✂]**" and a "**[✂]**". One of these documents states that: "**[✂]**".[25]

98. However, many third parties noted that all the main commercial suppliers of cytotoxics and MABs provide a similar service. Moreover, some third parties (including some competitors or potential competitors which had themselves considered acquiring Hospira) noted that the Hospira site was not particularly attractive as it was nearing the end of its life and would require significant investment in the near future. Some noted that, in its current form, only Baxter could make best use of the site as it had essentially been built to Baxter's specifications and blueprint, due to the involvement of a former Baxter employee in its design.

*Tender data*

99. Baxter bid in all tenders in which Hospira bid (**[✂]** in total); however, there were only **[✂]** instances in which it was the only other bidder, with Bath ASU bidding in all **[✂]** of the other contracts and ITH bidding in a significant number of them (**[✂]** of the **[✂]** tenders). Hospira bid in around a third of the tenders in which Baxter bid (**[✂]** in total), with other suppliers, in particular Bath ASU, bidding far more frequently. In general, Hospira was significantly less successful than Baxter and Bath ASU in winning on a tender in which Baxter also bid (**[✂]**% success rate compared with Bath's **[✂]**% and Baxter's **[✂]**%).[26]

100. The CMA considers that this tender data shows that Bath ASU is the strongest competitor to Baxter, with ITH also being a stronger constraint on Baxter than Hospira. The tender data also shows that Baxter was a strong competitor to Hospira but that Bath ASU and ITH Pharma were also competing closely.

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[24] The CMA also received some internal documents from Hospira which refer to market conditions and the competitive landscape. The CMA relied on these where relevant but in general found that they did not contain any detailed commentary or that they were somewhat dated and did not appear to represent more recent market features.

[25] Annex 078 (180122 Project Lantern Final Shared), page 5. This business case document was prepared by **[✂]**, on 22 January 2018. The document was presented to senior management to ensure alignment on whether to proceed with the non-binding offer.

[26] This is based on the 'lines' ie product lines awarded in any given tender.

*Conclusion on closeness of competition*

101. The CMA believes that, while Hospira is a competitor to Baxter in the supply of compounded cytotoxics and MABs, its constraint is not particularly significant and the Parties are not particularly close competitors. The merged entity will continue to face more significant constraints from other commercial competitors, in particular Bath ASU and ITH Pharma. The evidence available to the CMA also does not indicate that Hospira's constraint is substantially understated in its recent competitive interactions. While Hospira has advantages in its offering (eg its Ascura ordering system), its compounding facilities are older than those of some of its competitors and have some limitations. The CMA also notes that Hospira's financial problems to some extent pre-date Pfizer's acquisition of the business.

*Competitive constraints*

102. Unilateral effects are more likely where customers have little choice of alternative supplier. The CMA has therefore assessed whether there are alternative suppliers which would continue to impose an effective competitive constraint on the merged entity. The CMA has considered the constraint from (i) commercial suppliers; (ii) cross-supply; and (iii) self-supply, based on evidence from the Parties' submissions, third party evidence and tender data provided by the Parties.

*Commercial suppliers*

103. The Parties face four rival commercial suppliers in the relevant frame of reference: Bath ASU, ITH Pharma, Quantum and Celesio.

*Bath ASU*

104. Bath ASU is a large supplier, located in Bath, supplying both patient-specific and batch compounded cytotoxics and MABs across Great Britain. Third parties frequently identified Bath ASU as an alternative and significant supplier. Based on tender data received from the Parties, Bath ASU bid in almost all tenders in which Baxter bid, and appears to have been successful in those tenders approximately as often as Baxter (and far more often than Hospira). Consistent with this evidence, Bath ASU is identified in the Parties' internal documents as a large supplier with a particularly aggressive competitive strategy. The documents also note that Bath ASU has recently significantly expanded its production capacity.[27] The CMA notes that **[✂]**.

[27] See for example, Annex 007, Baxter's Pharmacy Services Business Plan for 2018

*ITH Pharma*

105. ITH Pharma is based in north west London and supplies patient-specific and batch compounding across Great Britain. The Parties submitted that ITH Pharma is an aggressive competitor and has expanded rapidly, since launching its compounding business in 2008.

106. Third parties consistently identified ITH Pharma as a significant alternative commercial supplier to the Parties, though less frequently than Bath ASU. The Parties' tender data suggested that ITH Pharma bid against Baxter more often than Hospira and that it was successful in more instances than Hospira. Consistent with this evidence, Baxter's Pharmacy Services Business Plan for 2018 acknowledges ITH Pharma as an active competitor with strong facilities and good technology, and high levels of customer service.

*Quantum*

107. Quantum is based in the north east of England and supplies patient-specific and batch compounded medicines across Great Britain. As a smaller business than the four leading compounders (ie the Parties, Bath ASU and ITH Pharma), it is generally focused on smaller batches or patient-specific medicines. It has grown organically and initially sought to build relationships with customers located nearby, though its reach has since extended to nationwide.

108. Third party responses indicated that, consistent with its share of supply, Quantum is currently a much smaller supplier of cytotoxics and MABs than the four main commercial suppliers. Only a minority of respondents mentioned Quantum as an alternative to the Parties. In addition, some customers in the midlands and southern England indicated that Quantum's location, being more geographically distant, made it a less attractive supply alternative. Quantum did not feature significantly in the tender data available to the CMA from the Parties or third parties.

109. However, some third party evidence indicated that **[✂].**

*Celesio*

110. Celesio's compounding activities in relation to cytotoxics and MABs are primarily focused on self-supply to its homecare business. As indicated in Table 1, its commercial supplies to other healthcare providers are very limited. No third parties identified Celesio as an alternative supplier to the Parties and the Parties' internal documents do not refer to it. However, the Parties submitted that Celesio is likely to impose a material constraint in the near

future as it has a significant presence in pharmaceuticals, with established customer relationships, and **[✂]**.

*Conclusion on commercial suppliers*

111. The evidence available to the CMA indicates that the Parties will continue to face significant constraints from Bath ASU and ITH Pharma, who have been competing more strongly with Baxter than has Hospira. The Parties will also continue to face some additional constraint from Quantum and to a significantly more limited extent from Celesio.

*Cross-supply*

112. The Parties submitted that, irrespective of the inclusion or exclusion of self-supply and cross-supply from the frame of reference, the CMA should consider the constraint posed by the NHS. The Parties submitted that this constraint was significant as:

    a. the NHS had a significant installed base of capacity and the level of cross-supply was material;

    b. significant work was being done to improve the efficiency and capacity of the NHS' installed facilities, which meant that NHS customers would have more ability to flex between internal supply and commercial outsourcing; and

    c. commercial suppliers would not typically have access to information on how much a given healthcare customer could self-supply, and this would act as a constraint to their commercial plans, particularly for ad-hoc work.

113. The CMA received some evidence that NHS cross-supply may provide a certain level of constraint on the Parties:

    a. NHSI's report on aseptic compounding in the UK noted that there is a significant flow of compounded medicines between NHS sites.[28] While the dataset available to NHSI as part of its market review in 2018 was not exhaustive, the evidence indicated that approximately 5-10% of outsourced chemotherapy products are cross-supplied by other healthcare providers.

[28] NHSI, Pharmacy Aseptic Services Review, Summary of Key Findings 28th March 2018, page 16.

b. 24% of approximately 180 NHS units in England have a 'Manufacturer Specials' licence to enable cross-supply;[29]

c. NHSI's report indicates that a number of other NHS sites are looking to apply for licences.[30]

d. A presentation given by NHSI to commercial compounders, based on its review, indicated that there are a significant number of good quality NHS aseptic units which may currently be underutilised. [31]

e. Some NHS trusts indicated they had preliminary plans to expand in-house capacity and were conscious of the need to use this capacity to help other hospitals by engaging to a greater extent in cross-supply.

114. However, the CMA also found that the constraint from cross-supply by healthcare providers (including NHS trusts and homecare providers) is limited:

a. The overall volume of cross-supply is low. Portsmouth Hospitals NHS Trust is one of the few hospitals which supplies cytotoxics and MABs to other hospitals. Third party evidence indicated that it was one of the largest NHS cross-suppliers, but the volumes it supplied were only around 0-5% of the combined volumes of all commercial suppliers.

b. NHSI's review noted that parts of southern England, the midlands and east of England did not have any supply relationships between NHS trusts as there was a lack of licensed facilities in these geographical areas.[32]

c. Customers and competitors told the CMA that some NHS trusts only supplied to a single other hospital.

d. Evidence from tender data indicated that NHS trusts rarely bid in supply tenders.

115. Evidence from commercial suppliers consistently indicated that cross-supply was not considered a significant competitive constraint. One commercial supplier noted that cross-supply (and self-supply) may be better suited to serving a specific need, eg patient-specific products with short shelf-lives, though these can be less of a focus for commercial suppliers. Others suggested that, while some NHS trusts may bid to cross-supply, they cannot

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[29] NHSI, Pharmacy Aseptic Services Review, Summary of Key Findings 28th March 2018, page 15.
[30] NHSI, Pharmacy Aseptic Services Review, Summary of Key Findings 28th March 2018, page 16
[31] The Future of Pharmacy Aseptic Services in England, Commercial Compounders Meeting, 12 October 2018, slide 2: "219 pieces of equipment not in use (167 in good condition)"
[32] NHSI, Pharmacy Aseptic Services Review, Summary of Key Findings 28th March 2018, page 16

currently compete with commercial suppliers on volumes nor terms of service. The findings in NHSI's review confirmed some of these perceptions, and the Parties' internal documents are also consistent with this view. Baxter identified NHS cross-supply alongside its commercial competitors in its Pharmacy Services Business Plan 2018, though its commentary highlighted several limitations in the strength of this constraint, in particular in terms of capacity and capability.[33]

116. Evidence from third parties (including NHSI) suggests that the capacity available within the NHS for cross-supply is limited and is unlikely to increase significantly in the short term; as this would require significant co-ordinated reform and additional funding. While some action is underway, this is still at a relatively early stage.

*Self-supply*

117. The CMA found that healthcare customers self-supply the majority of their requirements. Evidence from third parties and from NHSI's review indicated that for much of a customer's supply needs, either in-house production or outsourcing could be used. Moreover, the CMA found that many self-supplying healthcare providers had some spare capacity, at least some of the time. Therefore, commercial suppliers are constrained to some extent by many customers' alternative option to self-supply. The CMA found some evidence of NHS trusts increasing the amount they self-supply in response to poor service from commercial suppliers.

118. However, the evidence available to the CMA indicated that the constraint from self-supply is limited for several reasons:

    a. As noted above (see paragraph 44), in-house capacity is currently declining. Many NHS hospitals told the CMA that they are subject to acute in-house capacity constraints, which means that they regularly need to procure a proportion of their supply from commercial suppliers. Some hospitals noted that they had recently closed their in-house compounding units. Several hospitals told the CMA that more NHS in-house compounding facilities are closing than are opening. The CMA noted that, in one area, 38% of compounding units were planning to close.

[33] Annex 007, Baxter's Pharmacy Services Business Plan for 2018

b. Due to both the contraction of in-house supply and an increase in demand for cytotoxics and MABs (see paragraph 48), demand for outsourced supply is increasing.

c. Several NHS hospitals told the CMA that securing additional investment in compounding facilities is costly, difficult and can be very time consuming, due to the complexities involved in raising the capital investment, finding a suitable site and procuring adequate staffing for an expanded or newly opened facility. On the whole, NHS hospitals said that the level of their compounding volume requirements, and budgetary and staff constraints, meant that the expansion, introduction or resumption of in-house compounding was unlikely.

*Conclusion on cross-supply and self-supply*

119. Cross-supply and self-supply currently provide some degree of constraint on commercial suppliers but, for the reasons set out above, this constraint is limited and is not likely to increase significantly in the foreseeable future.

*Conclusion on horizontal unilateral effects*

120. For the reasons set out above, the CMA believes that, while Hospira is a competitor to Baxter in the supply of compounded cytotoxics and MABs, its constraint is not particularly significant, nor are the Parties particularly close competitors. The merged entity will continue to face more significant constraints from other commercial competitors, in particular Bath ASU and ITH Pharma. The merged entity will also continue to face some additional constraint from Quantum, and to a more limited extent from Celesio, as well as from self-supply and cross-supply by healthcare customers. The CMA believes that these constraints, taken together, are sufficient to ensure 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 compounded cytotoxics and MABs for chemotherapy and immunology by commercial suppliers to healthcare customers in Great Britain.

***Vertical effects***

121. 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 or a downstream competitor of the supplier's customers. Vertical mergers may be competitively benign or even efficiency-enhancing, but in certain circumstances can weaken rivalry, for example when they result in foreclosure of the merged firm's competitors. The CMA only regards such foreclosure to be anticompetitive where it results in an SLC in

the foreclosed market(s), not merely where it disadvantages one or more competitors.

122. In the present case, Baxter supplies certain inputs into compounded cytotoxic medicines in the UK, specifically the relevant oncology products (cyclophosphamide, ifosfamide, mitoxantrone and mesna). The CMA has considered whether, as a result of the Merger, Baxter may foreclose downstream rivals in the compounding of medicine using these inputs. This may be total foreclosure of downstream rivals (refusing to supply), or partial foreclosure (degrading the offering to downstream rivals in terms of price, quality or other aspects of supply). Foreclosure would make it harder for rival compounders to compete, or self-supplying hospitals to self-supply, which may lead to customers switching their purchase of compounded medicines to the merged entity.

123. The CMA's approach to assessing vertical theories of harm is to analyse (i) the ability of the merged entity to foreclose competitors, (ii) the incentive of it to do so, and (iii) the overall effect of the strategy on competition.[34]

*Ability*

124. For cyclophosphamide and mitoxantrone, while there are alternative suppliers available, Baxter has market shares of 80 - 90% and 60 - 70% respectively. For the other two oncology products, no alternatives are currently available to UK customers.

125. The Parties submitted that they would not be able to directly target commercial competitors with a price increase post-Merger, as these competitors would be able to purchase through wholesalers. Wholesalers account for over **[✂]**% of Baxter's sales of the relevant oncology products.

126. The CMA acknowledges that the role of wholesalers is likely to prevent the Parties from being able to pursue a strategy whereby they target commercial competitors exclusively. However, this would not prevent the Parties from pursuing a strategy of targeting both commercial competitors and NHS hospitals (ie with a view to increasing the proportion of those hospitals' demand for compounded cytotoxics which it is preferable for them to outsource).

127. The CMA therefore believes that the Parties may have some post-Merger ability to harm competitors in the supply of compounded medicines by

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

increasing prices (or else reducing quality of service, for example in delivery times) for the relevant oncology products.

*Incentive*

128. The CMA has therefore considered whether a foreclosure strategy would be profitable for the Parties, ie whether the profit gained in the downstream supply of compounded cytotoxics would outweigh the lost profit in the supply of the relevant oncology products. As a result of its analysis, the CMA believes that a number of factors limit the Parties' incentive to foreclose:

    a. Baxter's margins for the upstream relevant oncology products are significantly higher than its downstream margins for cytotoxic compounding. Therefore, a foreclosure strategy is unlikely to be profitable.

    b. The merger does not change Baxter's ability to carry out such a strategy. It would only increase the incentive to do so if Baxter were able to recoup significantly more downstream sales as a result of the merger. Given the CMA's conclusions on horizontal effects, the CMA believes that the Merger is unlikely to increase significantly Baxter's incentives to foreclose its rivals.

129. Given these conclusions, the CMA has not found it necessary to consider the effects of a possible foreclosure strategy.

*Conclusion on vertical effects*

130. For 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 vertical effects in the supply of the relevant oncology products.

***Barriers to entry and expansion***

131. Entry, or the 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.[35]

132. In the present case, 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.

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

## Decision

133. 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.

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

**Andrea Gomes da Silva**
**Executive Director, Markets and Mergers Directorate**
**Competition and Markets Authority**
**13 December 2018**