DETERMINATION OF MERGER NOTIFICATION M/15/026 -

BAXTER HEALTHCARE/FANNIN COMPOUNDING

Dated 21 October 2015

Introduction

1. On 9 June 2015, in accordance with section 18(1) of the Competition Act 2002, as amended[1] (the "Act"), the Competition and Consumer Protection Commission (the "Commission") received a notification of a proposed transaction whereby Baxter Healthcare Limited ("Baxter") would acquire sole control of certain assets pertaining to the medical aseptic compounding business ("the Target Assets") of Fannin Limited ("Fannin"). The proposed transaction is an asset acquisition under section 16(1)(c) of the Act.

The Undertakings Involved

Baxter

2. Baxter is incorporated in the United Kingdom and is ultimately controlled by Baxter International Inc. Baxter International Inc. provides a broad portfolio of essential renal and hospital products, including: home, acute and in-centre dialysis; sterile IV solutions; infusion systems and devices; parenteral nutrition; biosurgery products and anaesthetics; and pharmacy automation, software and services.

3. In the State, Baxter supplies medical products and compounded medicines to customers, mainly hospitals. Baxter manufactures compounded medicines in its manufacturing facility in Deansgrange Business Park, Co. Dublin. Baxter also manufactures compounded medicines in three facilities in the United Kingdom.

4. For the financial year ending 31 December 2014, Baxter International Inc.'s worldwide turnover was €16.7 billion, of which €[…] was generated in the State.

The Vendor - Fannin

5. Fannin, incorporated in the State, is a provider of medical devices, medicines, diagnostic products and related services to the healthcare sector in the State. Fannin is a subsidiary of DCC Vital Limited ("DCC Vital").

6. DCC Vital supplies third party and own-branded pharmaceutical, medical, surgical and laboratory products in the United Kingdom and in the State. DCC Vital is controlled by DCC plc ("DCC"), an international sales, marketing, distribution and business support services group which has four divisions:

   - DCC Energy – sales of oil and liquefied petroleum gas;
   - DCC Technology – sales of technology products;
   - DCC Environmental – sales of waste management and resource recovery services; and

[1] It should be noted that the Competition and Consumer Protection Act 2014 made a number of important amendments to the merger review regime set out in the Competition Act 2002.

- DCC Healthcare – sales of pharmaceuticals, medical devices and outsourced services.

7. Each of DCC's four divisions is active in the State. DCC Vital and its subsidiary Fannin are part of the DCC Healthcare division.

8. For the financial year ending 31 March 2015, DCC's worldwide turnover was €14.3 billion, of which €717 million was generated in the State.

The Target Assets

9. The Target Assets comprise those assets of Fannin which are used exclusively in the manufacture and supply of aseptically prepared compounded medicines ("Fannin Compounding"). Fannin Compounding, a business division of Fannin, manufactures and supplies compounded medicines to hospitals in the State. Fannin Compounding has been trading since 2004 when it was first awarded a manufacturing licence by the Irish Medicines Board (now the Health Products Regulatory Authority ("HPRA")). Fannin Compounding operates out of a manufacturing facility in Sandyford Industrial Estate in Co. Dublin which was built in 2004 and expanded in 2009. This facility incorporates the following:

- Warehousing space, including a temperature controlled stock area;
- Preparation areas;
- Operational cleanrooms (one each for the product categories of chemotherapy, nutrition and antibiotics) with ten isolators;
- Final check and packing area;
- Quality control area;
- Dispatch area;
- An unused cleanroom; and
- Two unused laminar air flow rooms.

10. As part of the proposed transaction, Baxter also plans to acquire Fannin Compounding's customer list, product price list, product specifications and details of its supplier arrangements.

11. For the financial year ending 31 March 2015, the Target Assets' worldwide turnover was €[…], all of which was generated in the State.

Rationale for the Proposed Transaction

12. The parties state in the notification:

> "Baxter's compounding facility at Deansgrange Business Park, Co. Dublin is currently supported by Baxter's compounding facilities in

> the UK. Approximately 20% of the compounding that Baxter supplies to customers based in the State is originally carried out in the UK. Acquiring Fannin's current facility provides Baxter Healthcare with the opportunity to upgrade its current compounding facilities by ultimately relocating its operations from Deansgrange to Sandyford. Baxter intends that following completion of the proposed transaction, its Irish compounding operations will have sufficient capacity to serve all of Baxter's compounding customers in the State and additional capacity to serve as support for Baxter's UK compounding facilities. An alternative for Baxter to the acquisition of the Target Assets is to carry out expansion works at its existing Deansgrange facility. However, such works would be complicated by the lay-out of the Deansgrange facility. The Sandyford facility offers good accessibility and a skilled work force in addition to increased floor space. The acquisition of the Target Assets will ensure that the Sandyford facility continues to serve its customer base. It is Baxter's intention to cease compounding operations at the Deansgrange site after the lease expires in 2016. DCC's compounding facility has suffered historical and continuing financial losses and in January 2015, it appointed PWC to find a suitable purchaser for the Target Assets pursuant to a bid process. Baxter was the only entity that submitted an acceptable bid. The divestiture will enable DCC Vital to focus on its core pharma and medical devices activities in Britain and Ireland."

Preliminary Investigation ("Phase 1")

Contacts with the Undertakings Involved

13. On 17 July 2015, the Commission served a Requirement for Further Information on each of Baxter and DCC pursuant to section 20(2) of the Act. This automatically suspended the procedure for the Commission's Phase 1 assessment.

14. Upon receipt of the responses to the Requirements for Further Information, the "appropriate date" (as defined in section 19(6)(b) of the Act) became 4 September 2015.[2]

15. On 27 July 2015, the Commission met with Fannin to discuss the likely competitive impact of the proposed transaction. On 28 July 2015, Fannin made a submission to the Commission concerning its medical aseptic compounding business in the State and the relevant counterfactual (i.e., the likely state of competition if the proposed acquisition were not to take place).[3]

16. During the Phase 1 investigation, the Commission requested and received, on an on-going basis, further information and clarifications from the notifying parties.

[2] The "appropriate date" is the date from which the time limits for making both Phase 1 and Phase 2 determinations begin to run.
[3] The relevant counterfactual is discussed in detail below.

Third Party Submissions

17. No third party submission was received by the Commission during the Phase 1 investigation.

Market Enquiries

18. During the Phase 1 investigation, the Commission drew up questionnaires to be answered by various third parties, including:

- the Health Service Executive ("HSE");
- 17 hospital customers of Baxter and Fannin Compounding.[4] Seven of these 17 hospitals were identified from lists provided to the Commission in the notification by Baxter and Fannin of their top 5 customers (for compounded medicines) in the State;
- three competitors of Baxter and Fannin Compounding active in the supply of compounded medicines to customers in the State. Two of these three competitors were identified from a list provided to the Commission in the notification of the parties' top 5 competitors in the State;
- HPRA; and
- the National Cancer Control Programme ("NCCP").

19. The Commission received a full response from all third parties and, in each case, followed up with telephone calls to explore the responses in greater detail.

Phase 1 Determination

20. Having considered all the available information in its possession at the time, the Commission was unable to form the view at the conclusion of the Phase 1 investigation that the result of the proposed acquisition would not be to substantially lessen competition in any market for goods or services in the State.

21. On 3 September 2015, the Commission determined, in accordance with section 21(2)(b) of the Act, to carry out a full investigation under section 22 of the Act.

Full Investigation ("Phase 2")

Third Party Submissions

22. No third party submission was received by the Commission during the Phase 2 investigation.

[4] This includes 14 public hospitals and three private hospitals.

Market Enquiries

23. During the Phase 2 investigation, the Commission continued the process, initiated during Phase 1, of seeking the views of various third parties, including customers and competitors of the merging parties. The Commission also drew up a questionnaire to be answered by four suppliers of compounded medicines located in the United Kingdom. The Commission received full responses from all four suppliers.

Expert Accountancy Advice

24. The Commission engaged the services of Grant Thornton to carry out a detailed examination of the annual management account information and financial forecasts of Fannin Compounding for the period 2013-2016. On 15 October 2015, the Commission received a written report from Grant Thornton. The findings are reported in detail below.

Contacts with the Undertakings Involved

25. During the Phase 2 investigation, the Commission requested and received, on an on-going basis, further information and clarifications from the notifying parties. On 15 September 2015, in accordance with section 9 of the Commission's Guidelines for Merger Analysis[5], Fannin made a submission to the Commission setting out its view that Fannin Compounding and its associated assets were likely to exit the market if the proposed acquisition by Baxter was prohibited by the Commission. This is commonly referred to as the 'failing firm/division defence' since it provides a defence to an acquisition that would otherwise lead to a substantial lessening of competition.

26. On 2 October 2015, the Commission informed the parties of its intention to issue an assessment[6] on 28 October 2015 setting out its serious concerns about the likely competitive impact of the proposed transaction. The Commission met with the parties on 5 October 2015 to discuss these concerns. On 12 October 2015, Fannin made a supplemental submission to the Commission concerning its failing division defence.

Industry Background – Medical Compounding

27. Medical compounding is the preparation of prescribed medicines for individual patients under aseptic (i.e., free from contamination caused by harmful bacteria and viruses) conditions. Compounding involves individual pharmaceutical products being mixed together in the exact strength and dosage required by the patient (as prescribed by a medical consultant) before being inserted into medical devices such as syringes, intravenous bags, and infusion pumps. Compounded medicines can be grouped into the following five broad treatment categories:

- chemotherapy;
- antimicrobials (e.g., antibiotics, antivirals and antifungals);

[5] See http://www.ccpc.ie/sites/default/files/CCPC%20Merger%20Guidelines_1.pdf

[6] The furnishing of an assessment to the parties is provided for in paragraph 3.8 of the Commission's Procedures for the Review of Mergers and Acquisitions (dated 31 October 2014).

- adult total parenteral nutrition ("TPN");
- neo-natal/paediatric TPN; and
- pain relief.

The Manufacture of Compounded Medicines In-house by Hospitals

28. Many hospitals in the State compound medicines in-house in the hospital pharmacy. In order to compound medicines in-house, hospitals require an aseptic compounding facility, comprising isolator technology (in which the individual pharmaceutical products are mixed together by hand) in a clean room environment, and qualified and trained pharmacists and technicians.[7] Given the highly sensitive nature of the end product and the toxic nature of some of the pharmaceutical ingredients used to manufacture compounded chemotherapy medicines (which account for the majority of medicines compounded in-house by hospitals[8]), there are stringent regulations set down by HPRA for medical compounding to ensure the safety of both employees and the end product.

29. According to information provided to the Commission by the NCCP, there are 26 public hospitals in the State that offer chemotherapy treatments to patients, of which 17 compound chemotherapy medicines in-house in an aseptic compounding facility. The remaining nine public hospitals have no aseptic compounding facility and therefore purchase compounded chemotherapy medicines from external commercial suppliers. The Commission understands that there are at least three private hospitals in the State which have no aseptic compounding facility and therefore also purchase compounded chemotherapy medicines externally.[9]

30. HPRA informed the Commission that a hospital does not require a licence to compound medicines in-house. Hospitals do, however, need a licence to supply compounded medicines to other hospitals in the State. HPRA informed the Commission that no hospital in the State currently holds a licence to supply compounded medicines to other hospitals.

31. Many of the hospitals that currently have an aseptic compounding facility indicated to the Commission a strong preference for manufacturing compounded medicines in-house rather than sourcing them from commercial suppliers. There are two main reasons for this preference.

32. First, some compounded medicines are very expensive and it is cheaper to compound them in-house rather than purchasing from commercial suppliers. A number of hospitals indicated to the Commission that they prefer to source low-value, high-volume compounded chemotherapy medicines externally rather than manufacturing them in-house.

[7] A manufacturer currently active in the commercial supply of compounded medicines in the State expressed the view to the Commission that staff in a medical compounding facility are "expensive [and] need a significant amount of training" and that the work is "very labour intensive [and] demands high levels of concentration and precision."

[8] The Commission understands that neither adult TPN nor neo-natal/paediatric TPN are compounded in-house by any hospital in the State.

[9] See also paragraph 65 below.

33. Second, in-house compounding by hospitals provides more flexibility and certainty for clinicians rather than using external suppliers. This is primarily because of the way in which compounded chemotherapy medicine dosages are calculated by clinicians in the State. In the case of chemotherapy treatment in the State, dosages of compounded medicines are calculated by clinicians on a "patient-specific" basis, meaning that the dose is prepared and labelled specifically for that patient. The dose is calculated based on the patient's Body Surface Area which is itself calculated from measured height and weight.[10] The fact that compounded chemotherapy medicines are prescribed on a patient-specific basis in the State means that flexibility is important for clinicians when deciding the precise dosage of compounded medicine to administer to the patient.[11]

34. Hospitals who compound medicines in-house also purchase supplies of compounded medicines from external commercial suppliers. In the case of compounded chemotherapy medicines, the proportion compounded in-house varies from hospital to hospital but, on average, it is around 80%.[12] The NCCP expressed the view to the Commission that hospitals who compound medicines in-house tend to increase the amount of compounded medicines purchased externally when there are peaks in treatment activity or when there are staff shortages.[13]

<u>The Commercial Manufacture and Supply of Compounded Medicines</u>

35. In order to manufacture and supply compounded medicines commercially, a supplier requires a licence from HPRA. This is known as a manufacturer's/importer's authorisation ("MIA").[14] There are stringent manufacturing practice requirements related to the granting and retention of an MIA. HPRA informed the Commission that in order for a commercial supplier of compounded medicines to obtain and retain an MIA, it must meet the conditions as specified in the MIA and be subject to routine inspections to demonstrate ongoing compliance at a frequency determined by risk assessment.[15] An existing MIA can be varied, suspended or revoked by HPRA if the specified conditions are not met by the commercial supplier. HPRA informed the

[10] This method of calculating dosages is in contrast to "Dose-Banding" which is a system whereby doses of compounded chemotherapy medicines that fall within defined ranges or bands are rounded up or down to predetermined doses. The maximum variation up or down is 5% or less. Pre-filled syringes or infusions are then used to administer the dose. Dose-banding is increasingly prevalent in the United Kingdom. The feasibility of importing dose-banded compounded chemotherapy medicines is considered in detail below.

[11] For example, a cancer patient generally undergoes a blood test before treatment in order to determine the precise dosage of compounded chemotherapy medicine to be administered. The clinician may decide to change the level of the prescribed dosage depending on the results of the blood test (e.g., a low red blood cell count might lead to a reduction in the level of the prescribed dosage). When this occurs, the clinician will inform the hospital pharmacy of the new prescribed dosage of compounded chemotherapy medicine to be administered and this will then be prepared in-house, ready to be administered to the patient later on the same day. If, however, the hospital has no aseptic compounding facility, the hospital pharmacist will have to source the new prescribed dosage of compounded chemotherapy medicine externally which may result in the treatment being delayed if, as is likely to be the case, the compounded medicine cannot be delivered on the same day.

[12] Of the 17 hospitals contacted by the Commission, eight compound chemotherapy medicines in-house. The proportion of each hospital's total compounded chemotherapy medicine requirement in 2014 that was manufactured in-house was as follows: 80%, 90%, 98%, 80%, 96%, 93%, 78%, and 98%.

[13] This view was also expressed by a number of hospitals. One hospital noted that when a pharmacist or technician leaves his/her position, it can take some time to (a) find a suitable replacement, and (b) train the replacement. In the interim period, the hospital may have to purchase a greater proportion of supplies of compounded medicines from commercial suppliers.

[14] A separate MIA is not required to manufacture and supply different types of compounded medicines. HPRA informed the Commission that a supplier's ability to manufacture different types of compounded medicines is evaluated during inspections.

[15] A manufacturer active in the commercial supply of compounded medicines in the State expressed the view to the Commission that "there is a considerable amount of ongoing maintenance required in a [compounding] unit in order to meet the ongoing inspections from HPRA."

Commission that it takes approximately 90 days to grant an MIA following receipt of a valid application.

36. As with the in-house manufacture of compounded medicines in hospitals, a commercial supplier requires an aseptic compounding facility, comprising isolator technology in a clean room environment, and qualified and trained pharmacists and technicians. As noted above, there are stringent regulations set down by HPRA for medical compounding to ensure the safety of both employees and the end product. One competitor active in the supply of compounded medicines in the State informed the Commission that compounded parenteral nutritional medicines (adult or neo-natal/paediatric) cannot be manufactured in the same clean room as compounded chemotherapy medicines or compounded antibiotics because of the toxic nature of the latter medicines. This competitor also informed the Commission that compounded paediatric TPN medicines cannot be mixed in the same clean room as adult TPN medicines. Commercial suppliers (and hospitals who compound in-house) therefore require separate clean rooms to manufacture different types of compounded medicines.[16]

Competitive Analysis

37. There is a horizontal overlap between Baxter and Fannin Compounding in the State with respect to the commercial supply of compounded chemotherapy medicines and the commercial supply of compounded antibiotic medicines.[17]

Relevant Product and Geographic Market

Views of the Undertakings Involved

38. The notification states the following:

> "The parties consider that the relevant product and geographic market is for supply of aseptic compounding services across the island of Ireland and the UK…while compounded products are used in a variety of patient treatments such as chemotherapy, pain relief and antibiotics, similar or identical processes, skills and equipment are used for each type of compounding. In addition, common distribution systems are used. The parties thus consider that the relevant product market is the supply of aseptic compounding services."

Views of the Commission

[16] This may explain why hospitals do not compound adult TPN or neo-natal/paediatric TPN in-house and instead purchase these medicines from commercial suppliers.

[17] There is no horizontal overlap between the parties in the State with respect to the commercial supply of compounded adult TPN medicines, compounded neo-natal/paediatric TPN medicines, or compounded pain relief medicines since Fannin Compounding is not active in the supply of compounded adult TPN medicines and Baxter is not active in the supply of the latter two compounded medicines.

39. As noted above, compounded medicines can be grouped into five broad treatment categories: chemotherapy; antibiotics; adult TPN; neo-natal/paediatric TPN; and pain relief.

40. Given that each of these five types of compounded medicine are used by clinicians to treat specific medical conditions, the Commission considers that, from a demand-side perspective, it is likely that the commercial supply of each of these five types of compounded medicine occupies a distinct and separate product market. For example, it would not be clinically feasible for a cancer patient to switch from using compounded chemotherapy medicines to using compounded antibiotic medicines in response to a 5-10% price rise by a hypothetical monopoly supplier of compounded chemotherapy medicines.

41. The Commission, however, does not need to come to a definitive view on the precise relevant product market since its conclusion on the competitive impact of the proposed transaction will be unaffected whether the precise relevant product market is narrow (e.g., the commercial supply of compounded chemotherapy medicines) or broader to encompass the commercial supply of all types of compounded medicines. In order, however, to determine whether the proposed transaction might result in a substantial lessening of competition, the Commission assessed its impact by reference to the narrowest possible relevant product markets, namely:

- the commercial supply of compounded antibiotic medicines; and
- the commercial supply of compounded chemotherapy medicines.

42. Similarly, the Commission does not need to come to a definitive view on the precise relevant geographic market since its conclusion on the competitive impact of the proposed transaction will be unaffected whether the precise relevant geographic market is national or wider than the State. In order, however, to determine whether the proposed transaction might result in a substantial lessening of competition, the Commission assessed its impact by reference to the narrowest possible relevant geographic market, namely the State.[18]

43. In conclusion, for the purpose of its competitive assessment, the Commission examined the competitive impact of the proposed transaction in the following two markets:

- the commercial supply of compounded antibiotic medicines in the State; and
- the commercial supply of compounded chemotherapy medicines in the State.

44. Below, the Commission sets out in detail its assessment of the competitive impact of the proposed transaction in each of the two markets listed above.

The Commercial Supply of Compounded Antibiotic Medicines in the State

[18] The Commission is not aware of any evidence to suggest that there are regional geographic markets within the State for the commercial supply of compounded medicines.

45. There is a horizontal overlap between Baxter and Fannin Compounding for the commercial supply of compounded antibiotic medicines in the State.

46. The HSE established a contract for an Out-patient Parenteral Antimicrobial Therapy ("OPAT") service in January 2013 to support the delivery of a national service for the administration of intravenous compounded antibiotic medicines in a non-inpatient setting either in the patient's home or in a community infusion centre. The purpose of OPAT is to enable the treatment of patients requiring intravenous compounded antibiotic medicines in their homes rather than in a hospital setting. The 2013 OPAT contract, which was won by Fannin Compounding following a tender process, expired in January 2015 and the HSE awarded the new OPAT contract to Baxter.

47. By way of background, Fannin provided the following information to the Commission concerning the supply of compounded antibiotic medicines in the State:

> "The proportion of patients requiring IV [intravenous] antibiotics that receive treatment in the home is a small proportion (approximately 15%) of the total number of patients requiring IV antibiotics. Of the patients treated at home, approximately 50% receive compounded product (all outsourced) with the other 50% receiving non-compounded reconstituted or off-the-shelf antibiotics. Of the 85% of patients receiving IV antibiotics in the hospital, Fannin does not know how much of the medicine is compounded, but believes that most would be non-compounded reconstituted product."

48. A number of hospitals, including those with no aseptic compounding facility, confirmed to the Commission that antibiotic medicines are prepared in-house at ward-level by nurses.[19] The proposed transaction, therefore, has little competitive impact on the supply of compounded antibiotic medicines to hospitals in the State since most hospitals prepare antibiotics at ward-level without the need for an aseptic compounding facility or the need to purchase supplies from a commercial supplier such as Baxter or Fannin Compounding.

49. With respect to the supply of compounded antibiotic medicines to patients in the home (which, according to Fannin, accounts for only 15% of the total number of patients requiring intravenous antibiotics), the most recent OPAT contract was awarded by the HSE to Baxter in January 2015. The duration of this contract is three years with the option for a further two-year extension. While it is the case that, assuming no new entry, the HSE will only have one supplier if and when it comes to tender for the next OPAT contract, the HSE informed the Commission that the current OPAT contract fixes the price of compounded antibiotic medicines to patients in the home for at least the next three years. […][20]

[19] This is not an option for compounded chemotherapy medicines due to the toxic nature of some of the pharmaceutical ingredients.
[20] […]

50. In conclusion, the Commission considers that the proposed transaction raises no competition concerns for the commercial supply of compounded antibiotic medicines in the State.

The Commercial Supply of Compounded Chemotherapy Medicines in the State

Market Structure

51. Paragraph 3.1 of the Authority's "*Guidelines for Merger Analysis*" states the following:

> "A central element in assessing the competitive impact of a merger is identifying its effect on market structure."

52. Market structure can be characterised by the number and size distribution of firms. The initial impact of any merger or acquisition is felt on market structure as two firms pre-acquisition become one firm post-acquisition.

53. There are two commercial suppliers of compounded chemotherapy medicines to hospitals currently active in the State: Baxter and Fannin Compounding. Following the proposed transaction, Baxter will be the sole commercial supplier of compounded chemotherapy medicines in the State.

54. Table 1 below presents share data over the period 2011-2014 for the commercial supply of compounded chemotherapy medicines to hospitals in the State. The total size of the compounded chemotherapy segment was €[…] in 2014 and total sales were stable between 2011 and 2013 but declined significantly between 2013 and 2014.

Table 1: The Supply of Compounded Chemotherapy Medicines, by Value (€) %, 2011-2014, the State

	2011	2012	2013	2014
Baxter	[55-60]%	[60-65]%	[65-70]%	[65-70]%
Fannin Compounding	[40-45]%	[30-35]%	[30-35]%	[30-35]%
Total (€, millions)	[…]	[…]	[…]	[…]

Source: Turnover information provided by the Parties

55. It is significant that Fannin Compounding's share of the supply of compounded chemotherapy medicines in the State declined from [40-45]% in 2011 to [30-35]% in 2014. Information provided to the Commission by DCC indicates that Fannin Compounding's total turnover generated from the supply of compounded chemotherapy medicines in the State declined from €[…] in 2011 to €[…] in 2014. This represents a [30-35]% decline in turnover generated by Fannin Compounding from the supply of compounded chemotherapy medicines over this period.

56. When asked to explain Fannin Compounding's sharp decline in turnover generated from the commercial supply of compounded chemotherapy medicines in the State, DCC provided the following explanation to the Commission:

> "[It was] as a result of two overlapping factors: (1) Individual hospitals' strategies - approximately […]% of the decline was

> attributable to a number of hospitals changing or reverting to in-house compounding. In particular, Cork University Hospital, Mercy Hospital Cork and The Beacon Hospital (Dublin), who together comprise approximately […]% of the decline in Fannin's turnover arising from hospitals changing to in-house supply, expressly sought to limit the outsourcing of chemotherapy compounding. In the case of Cork University Hospital and Mercy Hospital Cork, the extent of prior outsourcing was partly attributable to maternity leave of key staff in the relevant hospital pharmacies. Most of this decline took place in the second half of 2012 and the first half of 2013."
>
> "(2) Individual hospitals' responses to Fannin's focus on the new national OPAT (antibiotics) contract and the existing national TPN[21] (nutrition) contract - the other […]% of the decline was caused by a number of hospitals reacting to Fannin's prioritisation of the OPAT and TPN contracts. The OPAT contract was a catalyst for a significant number of operational issues in Fannin's compounding facility. To deal with these issues, Fannin reduced its capability (primarily in terms of personnel) and service levels in the compounding of chemotherapy products. A number of hospitals (in particular the Hermitage Medical Clinic (Dublin) and Kerry General (Tralee), which together comprise over […]% of the decline in Fannin's turnover arising from hospitals' reactions to Fannin's focus on TPN and OPAT), changed to a dual-supplier strategy (i.e., sourcing from both Fannin and Baxter) as a result of these issues. The bulk of this change took place in the second half of 2013 and the first half of 2014."

57. Fannin Compounding's financial and operational difficulties in recent years are discussed in greater detail below in the Commission's assessment of the failing division defence put forward by the parties.

Competitive Effects Analysis

58. In this section, the Commission examines the competitive effects of the proposed transaction in the commercial supply of compounded chemotherapy medicines in the State.

Views of the Undertakings Involved

59. The notification by the parties states the following:

[21] The HSE had awarded the contract for the supply of compounded neo-natal/paediatric Total Parenteral Nutrition ("TPN") to a consortium of Fresenius Kabi and Fannin Compounding with the latter providing the compounding element of this contract. Fannin Compounding is the sole manufacturer of compounded neo-natal/paediatric TPN in the State. This contract expired on 30 September 2015.

> "The customer base for compounded medicines in the State is made up of the HSE, public and private hospitals. Hospitals did not traditionally outsource their compounding activities and as a result many have their own onsite compounding facilities. Outsourcing of compounding services has arisen over time primarily as a result of fluctuations in demand and seasonal factors such as hospital pharmacist staff being on maternity or annual leave or public sector headcount restrictions. The parties estimate that approximately 70-80% of pharmaceutical compounding in the State is performed in-house by hospitals."
>
> "The strong countervailing buyer power exercised by hospitals imposes a significant competitive constraint and will continue to do so after the proposed transaction. The demand for compounding services by commercial providers is dependent primarily on the decision of hospitals to outsource or indeed, 'insource'."
>
> "In respect of compounding services provided to private hospitals, health insurers such as VHI and Laya Healthcare also exercise countervailing buyer power as they dictate the maximum price they will pay for compounded products."
>
> "The parties understand that further to the planned restructuring of HSE hospitals, public hospitals with on-site compounding pharmacies may start, subject to obtaining appropriate licences from HPRA, supplying compounding services to hospitals that do not have on-site facilities, possibly through public-private partnerships."
>
> "For pharmaceutical companies and entities already providing compounding services in the UK or elsewhere, there are relatively low barriers to entry."

60. In a submission to the Commission entitled "Additional Information in relation to buyer power for compounding services" dated 5 August 2015, Baxter expressed the following views:

> "The vast majority of pharmaceutical compounding for chemotherapy products is performed in-house by hospital pharmacies with the remainder outsourced to external suppliers. As indicated in the merger notification, the largest demand for compounded services in the State is for chemotherapy treatment and typically just 20% of compounded chemotherapy products are outsourced. Hospital pharmacies typically

carry out approximately 80% of the total value of compounding services for chemotherapy in the State."

"The ability of hospitals to choose to self-supply compounded chemotherapy products in the State would impact on the profitability of a price rise by the merged entity. A substantial degree of outsourced compounded chemotherapy business moved from Baxter to in-hospital production in the last 12-18 months. Given the budget overruns in the Irish health sector and the need to cut costs, hospital pharmacists are sensitive to price changes and a price rise is likely to lead to significant lost sales as customers switch to self-supply."

"The merged entity's client base will be almost exclusively comprised of hospitals. Currently, procurement is carried out at hospital level for compounded chemotherapy products although such procurement could be centralised at any time given the recent move towards centralised public procurement in the HSE and the State…It is likely that hospitals and the HSE will continue to seek to minimise the outsourcing of compounded chemotherapy products, particularly as the demand for such products rises with the forecasted increase in cancer rates. It is also a possibility that the outsourcing of chemotherapy products by public customers could be discontinued altogether; for instance the HSE/NCCP may decide to allocate further capital investment for compounding units or steps could be taken to allow hospital pharmacies to supply compounding services to other hospitals (e.g. amongst the new Hospital Groups)."

"It is notable that St. James's Hospital has taken the decision not to proceed with establishing a compounding unit through a joint venture with a commercial operator and instead to build a compounding unit at a cost of €1.4 million. This unit will meet all of the compounding needs at St James's Hospital, which Baxter understands are estimated at approximately 30,000 units per annum."

"If the HSE or hospitals are not satisfied with the level of service or price they obtain from outsourcing compounded products, they have a clear incentive to seek alternatives given the budgetary constraints on hospitals and the HSE. Baxter considers that the pressure on its customers to minimise spend is a constraint on its ability to raise prices."

"While certain of Baxter's customers (e.g. smaller hospitals) may not currently have the space or resources

> to self-supply, Baxter's prices for compounded chemotherapy products are fully transparent to the NCCP and to the HSE. This level of transparency will continue to constrain Baxter's ability to raise prices post-merger. Price increases could incentivise the NCCP and the HSE to centralise procurement or develop more innovative procurement practices to leverage buyer power throughout the public health sector. It could also result in the development of shared services for compounding activities amongst the new Hospital Groups."
>
> "It is clear that internal compounding is currently the preferred supply method in Irish hospitals for chemotherapy products and that only high volume inexpensive chemotherapy products are outsourced to commercial providers. Hospitals that are large national cancer centres with patients with complex cancers on complex therapies tend to compound the higher value/lower volume products themselves and only outsource the lower value/higher volume products. Patients on less complex therapies and lower complexity drugs tend to be treated in their nearest regional hospital. Such hospitals also tend to outsource lower value, higher volume chemotherapy products. Regional hospitals generally have the lowest level of in-house compounding capability, although many have some."

61. Similar views concerning countervailing buyer power were expressed by Baxter in a submission to the Commission dated 24 September 2015.

Views of the Commission

62. Assessing the competitive effects of the proposed transaction requires the identification of any relevant theories of harm (i.e., how the proposed transaction could result in a substantial lessening of competition) and an analysis of those theories of harm through an evaluation of the available evidence.

63. The applicable theory of harm on which the Commission's investigation focused in the present case was unilateral effects which, as explained in paragraph 4.8 of the Commission's "*Guidelines for Merger Analysis"*, occur when "a merger results in the merged entity having the ability and the incentive to raise prices at its own initiative and without coordinating with its competitors."

64. The Commission was concerned that the proposed acquisition of Fannin Compounding would enable Baxter to unilaterally raise the price of its compounded chemotherapy medicines post-transaction. This view is based on the following evidence:

Views of Hospitals

65. The NCCP informed the Commission that there are 26 public hospitals in the State that offer chemotherapy treatments to patients, of which 17 compound chemotherapy medicines in-house in an aseptic compounding facility. The remaining nine public hospitals have no aseptic compounding facility and therefore purchase compounded chemotherapy medicines from Baxter and/or Fannin Compounding. The NCCP also informed the Commission that there are approximately six or seven private hospitals in the State that offer chemotherapy treatments to patients. The Commission contacted three private hospitals, none of which have an aseptic compounding facility.

66. The NCCP informed the Commission that based on 2012 volume (units) data, 20% of the total volume of compounded chemotherapy medicines consumed by all public hospitals in the State was purchased from commercial suppliers (i.e., Baxter and Fannin Compounding) with the other 80% compounded in-house by public hospitals who have an aseptic compounding facility.[22]

67. In order to assess the likely competitive impact of the proposed transaction, the Commission drew up a detailed questionnaire to be answered by 17 hospital customers of Baxter and Fannin Compounding. Of these 17 hospitals, 14 are public hospitals (of which five have an aseptic compounding facility) and three are private hospitals (all three do not have an aseptic compounding facility). The Commission received a full response from all hospitals and in each case followed up with telephone calls to explore the responses in greater detail. In addition, the Commission sent supplementary questions to each of the 17 hospitals as the investigation progressed. The Commission received a full response to all supplementary questions from all hospitals.

68. All 17 hospitals expressed three broad concerns about the likely impact of the proposed transaction:

    a) The price of compounded chemotherapy medicines may increase post-transaction since the competition that currently exists between Baxter and Fannin Compounding will disappear post-transaction leaving one remaining commercial supplier;

    b) Security of supply may be endangered if Baxter closes down one of the two existing aseptic compounding facilities post-transaction and decides to operate out of one aseptic manufacturing facility.[23] There is a concern amongst hospitals about access to supplies of compounded chemotherapy medicines post-transaction in the event of a sudden and unexpected reduction in capacity at the Baxter compounding facility (e.g., if an isolator broke down);[24] and

[22] In an internal document entitled "Project Dora Information Memorandum" dated February 2015, which was provided to the Commission by DCC in response to the Commission's Requirement for Further Information issued on 17 July 2015, Fannin estimates that around 78% of the total volume of compounded chemotherapy medicines used in public hospitals in the State is compounded in-house by public hospitals with the remaining 22% purchased from commercial suppliers. Fannin estimates that 69% of the total volume of compounded chemotherapy medicines used in private hospitals is compounded in-house by private hospitals with the remainder purchased from commercial suppliers.

[23] As described above, Baxter currently operates out of an aseptic manufacturing facility in Deansgrange while Fannin Compounding operates a compounding facility in Sandyford, Co. Dublin.

[24] The concern raised by hospitals about security of supply is outside the scope of the Commission's substantial lessening of competition test as set out in the Act.

c) Baxter, as the sole commercial supplier in the State post-transaction, may not have the capacity to supply all hospitals in the State with compounded medicines.

69. Each hospital was asked by the Commission how it would react in the event of a price rise by Baxter for compounded chemotherapy medicines post-transaction. Significantly, the response to this question by hospitals who have a compounding facility is different to the response given by hospitals who have no compounding facility.

70. Public hospitals with no compounding facility expressed the view that any price rise post-transaction will most likely have to be absorbed since Baxter will be the sole commercial supplier of compounded chemotherapy medicines in the State. Private hospitals with no compounding facility expressed the view that any price rise by Baxter post-transaction might lead to a reduction in the number of chemotherapy services offered to patients.

71. In contrast, some public hospitals who have a compounding facility informed the Commission that a price rise by Baxter post-transaction might lead to an increase in the in-house production of compounded chemotherapy medicines. For example, one hospital expressed the following view:

> "It would try to compound as much medicine in-house as possible; a price increase would act as an incentive…to try to reduce its dependency on external compounded medicine suppliers."

72. One hospital expressed the view that:

> "It has the option to move all of its chemotherapy compounding in-house and thus avoid any price increases by Baxter."

73. One hospital, in response to a question concerning the feasibility of switching its compounding requirements entirely in-house, expressed the following view:

> "It would be feasible depending on staffing levels and capacity, there is no type [of chemotherapy medicine] that we cannot compound in-house."

74. Most hospitals with an aseptic compounding facility compound a high proportion of their total compounded chemotherapy medicine requirement in-house. As noted above, of the 17 hospitals contacted by the Commission, eight compound chemotherapy medicines in-house. The proportion of each of these eight hospital's total compounded chemotherapy medicine requirement in 2014 that was manufactured in-house was as follows: 80%, 90%, 98%, 80%, 96%, 93%, 78%, and 98%.

75. The Commission considers that hospitals (both public and private) who compound chemotherapy medicines in-house will likely have the ability to resist any attempt by Baxter to increase its prices post-transaction by threatening to increase the proportion of chemotherapy medicine compounded in-house. While most hospitals who

compound in-house indicated to the Commission that it is not feasible to move the production of compounded chemotherapy medicines entirely in-house[25] (thereby completely removing the need to buy from commercial suppliers), the fact that hospitals can threaten to increase in-house production is likely to deter any price rise post-transaction by Baxter.

76. The Commission, however, is concerned about whether hospitals with no aseptic compounding facility (both public and private) have the ability to resist a price rise by Baxter for its compounded chemotherapy medicines post-transaction. Unlike hospitals that compound in-house, hospitals with no aseptic compounding facility cannot threaten to increase in-house production in response to a price rise.[26] To determine whether hospitals with no aseptic compounding facility are likely to have the ability to credibly resist a price rise by Baxter post-transaction, the Commission considered the following three factors that may prevent a substantial lessening in competition in the commercial supply of compounded chemotherapy medicines in the State:

- Market Entry;
- Importation; and
- Countervailing Buyer Power.

Market Entry

77. Paragraph 6.4 of the Authority's "*Guidelines for Merger Analysis"* state that for market entry to be a constraint on the ability of the merged entity to raise prices post-merger, it must be timely, likely and sufficient.

78. The parties state the following in the notification:

> "For pharmaceutical companies and entities already providing compounding services in the UK or elsewhere, there are relatively low barriers to entry…The parties consider that pharmaceutical companies are well placed to supply compounded medicines in Ireland either because: (a) they have existing compounding facilities in the UK or elsewhere; or (b) they have pharmaceutical manufacturing facilities in Ireland that could be adapted for provision of compounding services."

79. Baxter's response dated 24 July 2015 to the Commission's Requirement for Further Information issued on 17 July 2015, however, contains the following statement:

[25] One hospital that compounds chemotherapy medicines in-house expressed the view to the Commission that it is important for a hospital to have the option of sourcing compounded chemotherapy medicines externally as a contingency back-up. This hospital stated that due to staff turnover and the time it can take to find and train suitable replacement staff, there may be periods where a hospital has to purchase more compounded chemotherapy medicines externally than would normally be the case.

[26] As will be discussed in detail below, building a new aseptic compounding facility is expensive and it would take between 12 to 24 months for such a unit to be fully operational. Furthermore, funding would need to be made available to hospitals by the HSE and the latter indicated to the Commission that it "has no current plans to do this."

> "Compounded chemotherapy is a complex and highly specialized activity with just Fannin Compounding, Baxter and the acute hospitals providing compounded chemotherapy medicines in the State…There has been no successful or unsuccessful entrant to the market place…Baxter understands that […] conducted a cross EU study into the compounding market but decided against entering it, possibly due to the complex nature of the activity and the low margins by comparison to other activities of pharmaceutical companies."

80. The Commission's view is that entry into the supply of compounded chemotherapy medicines in the State is difficult. This was confirmed by information provided to the Commission by competitors of Baxter currently active in the supply of compounded adult TPN medicines to customers in the State.[27]

81. Supplier 1 of compounded adult TPN medicines in the State[28] expressed the following view to the Commission:

> "The opportunity to enter the compounded market is very difficult, expensive and would take a long time. The decision to build a unit has a number of complexities, the first decision is to find a suitable site, get planning permission and build the unit. The size, cost and complexity of the unit will depend on the types and volumes of products that will be compounded in the unit. There are significant infrastructural and cost considerations associated with the different types of compounding. Once built the unit will require approval by HPRA. The process of getting HPRA approval is time consuming and the standards are continuously changing and becoming more demanding. The staffing of the unit is also a major challenge as there is a lack of suitably qualified and experienced staff. Suitable staff are difficult to recruit, expensive, and need a significant amount of training…There is a considerable amount of ongoing maintenance required in a unit in order to meet the ongoing inspections from HPRA...There were no attempts to enter the Irish compounding market in the past 3 years."

82. Supplier 1 informed the Commission that it has no plans to start supplying compounded chemotherapy medicines in the State.

83. Supplier 2 of compounded adult TPN medicines in the State[29] expressed the following view to the Commission:

[27] Fannin Compounding does not supply compounded adult TPN medicines in the State.

[28] This supplier does not operate an aseptic compounding facility in the State nor does it supply compounded chemotherapy medicines to customers in the State. […]

[29] This supplier operates an aseptic compounding facility […] but it does not supply compounded chemotherapy medicines to customers in the State.

> "To enter the compounded pharmaceutical market is very difficult. It is highly regulated and to set up a manufacturing facility requires a significant up-front investment in buildings, facilities and equipment, personnel and training in order to manufacture the product. The timeframe to have the unit operative is typically one year during which time no products can be sold and therefore no income [can be generated]. This can be longer depending on experience. In addition, the personnel required to operate the unit will be highly qualified and salaries are high. It is not economic to build and set up a speculative facility and to make such a commitment requires a guaranteed income stream by way of a contract or an awarded tender. There have been no new entrants to the market."

84. In a follow-up telephone call, Supplier 2 provided the following information to the Commission concerning its aseptic compounding facility […]:

> "This facility took approximately two years to become fully operational (including the time needed to get regulatory approval from the Health Products Regulatory Authority) and it cost over €2 million…[I]n order to compound neo-natal/paediatric TPN medicines, chemotherapy medicines or antibiotics, Supplier 2 would need to build separate clean rooms and air handling systems since chemotherapy medicines and antibiotics are toxic medicines and thus cannot be mixed in the same clean room as nutritional medicines. Furthermore, neo-natal/paediatric TPN medicines cannot be mixed in the same clean room as adult TPN medicines. It would cost approximately €1 million to build a separate clean room and it would take around 1 year to get it fully operational."

85. Supplier 2 informed the Commission that it has no plans to start supplying compounded chemotherapy medicines in the State.

86. Given these views and the fact that there is no recent history of new entry[30] into the supply of compounded chemotherapy medicines in the State, the Commission considers that entry is unlikely to be either timely or likely such that it would be able to constrain Baxter from raising the price of compounded chemotherapy medicines post-transaction.

Importation

[30] The Commission understands that since Fannin Compounding commenced business activities in 2004, no new supplier has entered the compounded chemotherapy medicine segment in the State.

87. The Commission considered whether hospitals (in particular, hospitals with no aseptic compounding facility) could credibly threaten to import compounded chemotherapy medicines in response to a price rise by Baxter.

88. In a submission to the Commission dated 27 August 2015, Baxter stated that it is not aware of any compounded chemotherapy medicines currently being imported by hospitals either directly or through a supplier. This was confirmed to the Commission in its discussions with seventeen hospitals about the likely impact of the proposed transaction.

89. In a submission to the Commission dated 1 September 2015, Baxter expressed the following view:

> "It is feasible to import both patient-specific doses and dose-banded products. However, it would generally be more commercially viable to import larger volumes such as dose-banded products. […] Chemotherapy compounded products are particularly suitable for importation given the high volumes. In addition, most routine chemotherapy day cases are planned and scheduled ahead which means that there is a good lead time for importation. Importation would be subject to validation of impact of transport on product stability although importing dose-banded products from the United Kingdom is more likely to be feasible given the familiarity that United Kingdom facilities have with dose-banding and the fact that dose-banded products generally have a longer shelf life."

90. As described above, dose-banding is a system whereby doses of compounded chemotherapy medicines that fall within defined ranges or bands are rounded up or down to predetermined doses. In contrast, patient-specific dosages of compounded chemotherapy medicines are specifically prepared and labelled for a patient based on his/her Body Surface Area which is itself calculated from measured height and weight.

The Feasibility of Importing Dose-Banded Compounded Chemotherapy Medicines

91. In a submission to the Commission dated 27 August 2015, Baxter informed the Commission that:

> "Dose banding has been increasingly adopted in the United Kingdom in the last decade and is widely established and encouraged as a matter of policy within the National Health Service...A significant proportion (over […]% of volume) of compounded product produced by Baxter in the United Kingdom is now dose banded."

92. HPRA informed the Commission that there are no regulatory obstacles to a hospital importing compounded chemotherapy medicines (dose-banded or patient-specific).

93. All 17 hospitals contacted by the Commission stated that they have never used (or imported) dose-banded compounded chemotherapy medicines because clinicians in the State currently only prescribe patient-specific doses of compounded chemotherapy medicines.

94. The NCCP expressed the following view to the Commission regarding the likelihood and possible timing of any switch to using dose-banded compounded chemotherapy medicines in the State:

> "Detailed discussions with clinicians will be required before there is any agreement to introduce dose-banding in the State…it is not possible to put a timeframe on this but changing to dose-banding is a change in practice and it could be a lengthy process."

95. The HSE expressed the following view to the Commission about dose-banding:

> "Does-banding is a potential alternative to patient-specific compounded chemotherapy medicines but the decision as to whether to switch to dose-banded medicines is a decision for clinicians. It is unlikely that dose-banding will be introduced in the next two years."

96. The Commission considers that hospitals will not have the ability post-transaction to credibly threaten to import dose-banded compounded chemotherapy medicines in response to a price rise by Baxter because dose-banded medicines are not currently prescribed by clinicians and there is little prospect of this changing over the next two years.

The Feasibility of Importing Patient-Specific Compounded Chemotherapy Medicines

97. The Commission also considered whether hospitals could credibly threaten to import patient-specific compounded chemotherapy medicines in response to a price rise by Baxter.

98. In order to assess the feasibility of importing patient-specific compounded chemotherapy medicines, the Commission drew up a questionnaire to be answered by four suppliers of compounded medicines located in the United Kingdom. The Commission received a full response from all four suppliers.

99. None of these four suppliers has ever supplied patient-specific compounded chemotherapy medicines to hospitals in the State.

100. One supplier expressed the following view to the Commission when asked about whether there are any obstacles to exporting patient-specific compounded chemotherapy medicines to hospitals in the State:

> "No obstacles other than the degree of organisation required within the hospital concerning prescription writing in a timely manner and hence ordering would need to be tightly

> controlled. There are not many chemotherapy medicines that have 48 hours or less as a shelf life when compounded. However, there are some and these would probably be unfeasible to import."

101. One supplier expressed the following view to the Commission:

> "Product stability [i.e., expiry] is the primary limiting factor on what compounded chemotherapy medicines could be exported."

102. All 17 hospitals contacted by the Commission expressed concerns about the feasibility of importing patient-specific compounded chemotherapy medicines. It is instructive to consider in detail the responses of some of these hospitals.

103. One public hospital (with no compounding facility) expressed the following view:

> "[Compounded medicines] with short expiries [are unfeasible to import]. I have a larger concern regarding importation. The lead times would be increased, if we have patient cancellations or deteriorations we can often call off the compounding. If the compounding is occurring further afield, this flexibility will be lost as the transportation times will shorten the window available to call off/delay. The importation of compounded products could also be unfeasible if the time/temperature/hazardous chemical requirements lead to much more costly delivery charges. Compounded chemotherapy requiring refrigeration has to be cold chain delivered – this can require the use of bulky insulated boxes and this would result in expensive freight costs."

104. One public hospital (with no compounding facility) expressed the following view:

> "The organisation of product supply from two suppliers within Ireland is complex enough - the logistics of introducing a supplier from outside of Ireland would certainly add significant additional complexity. Any product which has a shelf life of 72 hrs or less [is unfeasible to import]. Depending on the logistics of the supply arrangements, it could possibly be products with a 7 day or less expiry that would not be feasible to import. Another issue to consider is that from our current suppliers within Ireland all of our products are supplied to us labelled specifically for the patient they are to be administered to. If importing product from the UK, I don't know if it would be feasible or not to have them labelled for individual patients."

105. One public hospital (with no compounding facility) expressed the following view:

> "Some compounded chemotherapy medicines have a shelf life of 24 hours once manufactured and hence would be unfeasible to import. Importation may be feasible in cases where the shelf life would be long enough. However, in cases where the shelf life is long enough, the lead time for ordering is too great. Chemotherapy patients frequently have their treatment cancelled, switched or have their dose altered at short notice. Once Baxter and Fannin are not experiencing capacity issues, we can usually obtain compounded chemotherapy medicines at 48 hours notice but the lead time from the United Kingdom would be at least 96 hours. In excess of 50% of compounded chemotherapy medicines require refrigeration. Unless an expensive cold chain delivery system was put in place, refrigerated chemotherapy would take even longer to deliver as it could not be dispatched over a weekend from the manufacturer in the United Kingdom to the hospital."

106. One public hospital (with no compounding facility) expressed the following view:

> "It would not be feasible to import any patient-specific compounded chemotherapy medicines due to logistics and the narrow time interval between confirming chemotherapy medicine orders and treating patients. This is a very vulnerable patient group and any delays in delivery of treatment could have very serious consequences. Patients are routinely reviewed the day prior to treatment and a decision is made regarding patients' eligibility for treatment. If patients are deemed eligible for treatment, individual doses are confirmed at this stage. It is challenging at times for the Dublin-based commercial compounding units to meet this need so having to import patient-specific compounded chemotherapy medicines for these patients would not be feasible. At times, emergency (same day) treatment has to be administered and this is currently facilitated by the Dublin-based compounding units but may not be possible if the compounded chemotherapy medicine had to be imported. In addition, some compounded chemotherapy medicines have extremely short expiry dates and therefore it wouldn't be feasible to import these medicines."

107. One private hospital (with no compounding facility) expressed the following view:

> "Compounded chemotherapy medicines with short expiry times such as 24 hours would probably not be feasible, depending on how long the importation takes. Also, we have had delays in the past with non-compounded medications coming from England with reasons such as weather being cited. If there was a delay, the patient would not receive

> their treatment and the compounded chemotherapy medicine would expire and need to be discarded."

108. One public hospital (with a compounding facility) expressed the following view:

> "We use patient-specific compounded chemotherapy doses. If the patient's white cell or platelet counts are low, it may be necessary to delay treatment by a few days to allow recovery, or it may be decided to reduce the dose. These last-minute changes would result in considerable waste if we were importing compounded chemotherapy doses because the lead times simply would not confer the required flexibility. Certainly one could argue that a United Kingdom-based compounding unit located near an airport might be able to deliver doses to an Irish hospital located near an airport, but given that these compounded chemotherapy medicines may have refrigeration requirements and given that special precautions are needed for handling because of their nature, one would expect that the cost of such air freight would be considerable."

109. The NCCP expressed the following view to the Commission regarding the feasibility of importing patient-specific compounded chemotherapy medicines:

> "It is unlikely that importing compounded medicines is a feasible option for hospitals for two reasons. First, some chemotherapy medicines have short stability which means importing isn't feasible. This is particularly the case for the newer chemotherapy drugs which are protein-based. Second, the dosages for some compounded chemotherapy medicines are patient-specific and will depend on the results of the blood test taken by the patient on the morning of treatment. There is a tight turnaround time as a result which means importing will not be feasible."

110. The Commission considers that hospitals are unlikely to have the ability to credibly threaten to import patient-specific compounded chemotherapy medicines in response to a price rise by Baxter post-transaction. There are two main reasons for this view.

111. First, it is not feasible for hospitals to import compounded chemotherapy medicines with an expiry date of less than 48 hours.[31] Such compounded chemotherapy medicines are unlikely to be delivered to a hospital in advance of the expiry date and thus could not be administered to the patient.

112. Second, it is clear from the views expressed to the Commission by hospitals that the patient-specific nature of dosage calculation by clinicians in the State makes the importation of patient-specific compounded chemotherapy medicines unfeasible.

[31] For hospitals not located near an airport, it may not even be feasible to import compounded chemotherapy medicines with an expiry date less than 72 hours.

Since the precise dosage of compounded chemotherapy medicine to be administered to a patient can sometimes be altered at short notice by a clinician depending on the medical condition of the patient, hospitals have a strong preference for using suppliers who operate a flexible ordering system which can respond to clinicians' prescription changes at short notice.[32] Such flexibility is unlikely to be forthcoming from suppliers located in the United Kingdom as indicated by the following view expressed by one such supplier to the Commission: "ordering [by hospitals in the State] would need to be tightly controlled."

Countervailing Buyer Power

113. The parties raised, and the Commission examined, the possibility that the existence of countervailing buyer power among hospitals and/or the HSE could act as a deterrent to Baxter raising the price of compounded chemotherapy medicines post-transaction. The Commission's "*Guidelines for Merger Analysis"* state in paragraph 7.1:

> "In some circumstances, a customer may possess sufficient negotiating strength to enable it to constrain the ability of a supplier or suppliers to harm competition."

Do Hospitals have the Ability to Exert Effective Countervailing Buyer Power?

114. The Commission considers that hospitals who compound chemotherapy medicines in-house are likely to have the ability to resist any attempt by Baxter to increase its prices post-transaction by threatening to increase the proportion of chemotherapy medicine compounded in-house. This does not mean, however, that the proposed transaction will not lead to a substantial lessening in competition in the commercial supply of compounded chemotherapy medicines in the State. The Commission's "*Guidelines for Merger Analysis"* state in paragraph 7.4:

> "In a market where some but not all buyers possess significant countervailing buyer power, a merger may still result in increased prices (or other competitive harm) for those customers with little or no countervailing buyer power. For example, it may be that only large customers have the ability to exert countervailing buyer power and protect themselves from competitive harm. Small customers may not have sufficient negotiating strength to successfully exert countervailing buyer power."

115. The Commission considers that hospitals (public and private) with no aseptic compounding facility are unlikely to have the ability post-transaction to prevent Baxter, which would be the sole remaining commercial supplier of compounded chemotherapy medicines active in the State post-transaction, from raising its prices. As detailed above, hospitals are unlikely to have the option of threatening to import compounded chemotherapy medicines in response to a price rise by Baxter post-transaction.

[32] Whether this preference for only using patient-specific dosages (as distinct from a combination of patient-specific and dose-banded medicines) is the most efficient means of supplying compounded chemotherapy medicines to patients in the State is a separate question outside the scope of the Commission's review of the proposed transaction, which must be based on evidence of current practice or likely near-term changes in such practice.

Furthermore, given the high cost of building an aseptic compounding facility,[33] non-compounding hospitals are unlikely to be able to credibly threaten to switch to the in-house production of compounded chemotherapy medicines in response to a price rise by Baxter post-transaction.[34]

116. The Commission considered whether the countervailing buyer power possessed by hospitals who compound chemotherapy medicines in-house may help to prevent Baxter raising its prices to hospitals who do not have an aseptic compounding facility. There are, in theory, two ways in which this might occur:

- Hospitals who compound chemotherapy medicines in-house might start supplying non-compounding hospitals with compounded chemotherapy medicines; and,

- Non-compounding public hospitals might start sending some of their cancer patients to compounding public hospitals for treatment.[35]

117. As noted above, each hospital negotiates with Baxter and Fannin Compounding on a bilateral basis for supplies of compounded chemotherapy medicines. The Commission's "*Guidelines for Merger Analysis"* state in paragraph 7.6:

> "…in markets where there are individual negotiations between suppliers and customers, the countervailing buyer power possessed by one or more customers will not typically protect other customers from any anti-competitive effects that may arise post-merger."

118. The Commission considers that the buyer power possessed by compounding hospitals is unlikely to protect non-compounding hospitals in the State by preventing Baxter from raising the price that it charges to such non-compounding hospitals for compounded chemotherapy medicines.

119. With regards to the possibility of compounding hospitals supplying non-compounding hospitals with chemotherapy medicines, each public hospital with an aseptic compounding facility contacted by the Commission indicated that they have no intention or wish to start supplying compounded chemotherapy medicines to other public hospitals in the State. Some compounding public hospitals expressed the view to the Commission that, with rising demand for chemotherapy treatments[36] (partly as a result of an ageing population) increasing the volume of compounded chemotherapy medicines required by each hospital, it is becoming more challenging to meet their own

[33] As noted above, one supplier of compounded adult TPN medicines in the State expressed the view to the Commission that "It would cost approximately €1 million to build a separate clean room and it would take around 1 year to get it fully operational."

[34] A number of non-compounding hospitals informed the Commission that it would not be economically feasible to build an aseptic compounding facility because they do not use a sufficient volume of compounded chemotherapy medicines on an annual basis to justify the level of investment required.

[35] This is unlikely to be an option for non-compounding private hospitals. However, a price rise by Baxter for compounded chemotherapy medicines post-transaction might lead to private hospitals reducing the number of cancer treatment services offered (as suggested to the Commission by two private hospitals) which would mean some cancer patients who would have been treated in private hospitals switching to public hospitals for treatment. Thus, such cancer patients might, in theory, be sent by non-compounding public hospitals to compounding public hospitals for treatment.

[36] An internal document dated February 2015 provided to the Commission by Baxter contains the following statement: "Cancer rates & chemotherapy treatments are set to double by 2030...demand for chemotherapy is only now beginning to rise."

requirements for compounded chemotherapy medicines without having to also supply other hospitals.[37] In order to start supplying compounded chemotherapy medicines to other hospitals in the State, a hospital would need to acquire a licence from HPRA which would entail an onerous regulatory burden in terms of ongoing compliance with the conditions of the licence.[38] This was confirmed by the HSE who expressed the view to the Commission that "there would be a high regulatory burden on compounding hospitals to meet the strict regulations set down by HPRA." The HSE also expressed the view to the Commission that it is their preference "for hospitals to rely more on supply from third parties and focus more on caring for patients."

120. With regards to the possibility of non-compounding public hospitals sending cancer patients to compounding public hospitals for treatment in response to a price rise by Baxter post-transaction, there are three reasons why the Commission considers this to be unfeasible.

121. First, as noted above, most compounding public hospitals in the State do not have sufficient capacity in their aseptic compounding units to compound the volumes of chemotherapy medicines required to treat, in addition to their own cancer patients, cancer patients sent from non-compounding hospitals.

122. Second, compounding public hospitals in the State are unlikely to have sufficient spare capacity and resources to treat, in addition to their own cancer patients, cancer patients sent from non-compounding hospitals. The HSE expressed the view to the Commission that such a move "while possible in theory, in practice it would not be desirable as it would put huge strain on compounding hospitals."

123. Third, the HSE expressed the view to the Commission that sending cancer patients from non-compounding hospitals to compounding hospitals would involve some patients travelling long distances for treatment, which is not desirable.

124. In conclusion, the Commission considers that hospitals (public and private) with no aseptic compounding facility are unlikely to have the ability to exercise effective countervailing buyer power post-transaction to prevent Baxter from raising the price of its compounded chemotherapy medicines.

Does the HSE have the Ability to Exert Effective Countervailing Buyer Power?

125. Although each hospital negotiates with Baxter and Fannin Compounding on a bilateral basis for supplies of compounded chemotherapy medicines, each public hospital's budget is controlled by the HSE.[39] The Commission assessed the possibility, as argued

[37] Furthermore, most compounding hospitals in the State would not have the in-house capacity, absent significant investment to either expand existing aseptic compounding units or to build new and bigger compounding units, to start engaging in the commercial supply of compounded chemotherapy medicines to other hospitals in the State. This is highlighted by the fact that, to the best of the Commission's knowledge, no compounding hospital in the State currently relies 100% on the in-house production of compounded chemotherapy medicines.

[38] Only one public hospital in the State (St. James's Hospital) has ever acquired a licence from HPRA to engage in the commercial supply of compounded chemotherapy medicines and St. James's Hospital indicated to the Commission that it gave up this licence approximately ten years ago and it has no plans to acquire a new licence in the future.

[39] The HSE provided the following information to the Commission: "The Acute Services section of the HSE has responsibility for funding all 48 public hospitals in the State. There are seven hospital groups which are divisions within the HSE and each hospital group has a monthly performance meeting during which any cost pressures (e.g., a price rise) that affect the budget of a hospital are flagged."

by the parties, that the HSE might intervene on behalf of public hospitals in response to a price rise by Baxter post-transaction for compounded chemotherapy medicines.

126. There are, in theory, a number of ways in which the HSE might be able to exert countervailing buyer power in response to a price rise by Baxter post-transaction. These include the following:

- The HSE could fund the expansion of existing compounding units in public hospitals and the obtaining of licences from HPRA to enable public hospitals with compounding facilities to supply non-compounding public hospitals with compounded chemotherapy medicines. The HSE could also fund the building of new aseptic compounding facilities in non-compounding public hospitals;

- The HSE could switch to centralised procurement and develop a tender process for the supply of compounded chemotherapy medicines to public hospitals in the State.

127. These two theoretical possibilities are now considered in turn.

128. With respect to the possibility of the HSE investing in compounding capacity in public hospitals, […] in the HSE, expressed the following view to the Commission in a telephone call:

> "The HSE could look at the option of investing in compounding capacity in public hospitals. This would not, however, be the first preference of the HSE and the HSE has no current plans to do this…if the HSE saw a percentage price increase of double digits by Baxter post-transaction for compounded chemotherapy medicines, it would start to consider the option of increasing capacity in existing aseptic compounding facilities in public hospitals in the State."

129. With respect to the possibility of the HSE facilitating public hospitals obtaining licenses from HPRA to enable them to start supplying compounded chemotherapy medicines to non-compounding public hospitals, […] expressed the following view to the Commission in a telephone call:

> "This is not likely to happen because there would be a high regulatory burden on compounding hospitals to meet the strict regulations set down by HPRA. Also, the HSE's preference in general is for hospitals to rely more on supply from third parties and focus more on caring for patients."

130. Given the HSE's views, the Commission does not consider that the HSE will exert countervailing buyer power post-transaction by funding the expansion of compounding capacity in public hospitals in the State.

131. With respect to the theoretical possibility of the HSE switching to centralised procurement for the supply of compounded chemotherapy medicines to public

hospitals in the State, […] expressed the view to the Commission that while this is an "option" for the HSE, it has no plans to do this in the near future.

132. While it is the case that the HSE has recent experience in procuring compounded medicines on a centralised basis on behalf of public hospitals,[40] any future tender for the supply of compounded chemotherapy medicines to public hospitals in the State will see the HSE negotiating with only one supplier: Baxter.[41]

133. […] in the HSE, informed the Commission in a telephone call that the HSE currently purchases a number of different medical products from Baxter and therefore has regular negotiations with Baxter about prices. This raises the question as to whether the HSE might have the ability to use its negotiations with Baxter in other product categories as leverage in any possible future negotiations with Baxter for the supply of compounded chemotherapy medicines to public hospitals.

134. The Commission does not consider that the HSE will have the ability to exert effective countervailing buyer power against Baxter by leveraging its negotiations with Baxter in other product categories. Given that the total size (by value) of the market for the commercial supply of compounded chemotherapy medicines in the State in 2014 ([…]) was more than the HSE's total combined spend with Baxter across all other product categories in 2014 (€[…][42]), the Commission does not consider that the HSE would have the ability to resist a price rise by Baxter post-transaction for compounded chemotherapy medicines by threatening to reduce its purchases from Baxter in other product categories.

135. In conclusion, taking all the available evidence into account, in particular the views of the HSE, the Commission considers that hospitals (public and private) with no aseptic compounding facility are unlikely to have the ability to exercise effective countervailing buyer power post-transaction to prevent Baxter from raising the price of compounded chemotherapy medicines. Furthermore, the Commission also considers that the HSE is unlikely to have the ability to exert effective countervailing buyer power by intervening on behalf of public hospitals with no aseptic compounding facility in response to a price rise by Baxter.

Conclusion on Unilateral Effects

136. Based on its assessment of the evidence (as set out above), the Commission was concerned that the proposed acquisition of Fannin Compounding might provide Baxter with the incentive and ability to unilaterally increase the price of compounded chemotherapy medicines thereby causing a substantial lessening of competition. This view is based on the following conclusions:

[40] For example, the HSE currently procures compounded neo-natal/paediatric TPN medicines from a consortium of Fresenius Kabi and Fannin Compounding with the latter supplying the compounded medicine. This contract expired on 30 September 2015 and the HSE informed the Commission that it intends to run a tender process for a new contract.

[41] As described in detail above, the Commission considers that new market entry is unlikely over the next two years and it is unlikely to be feasible for hospitals to import compounded chemotherapy medicines.

[42] […]

- Post-transaction, Baxter would be the sole commercial supplier of compounded chemotherapy medicines to public and private hospitals in the State;

- It is unlikely that new market entry would be either timely or likely such that it would be able to constrain Baxter from raising the price of its compounded chemotherapy medicines post-transaction;

- It is unlikely that hospitals would have the ability to credibly threaten to import compounded chemotherapy medicines in response to a price rise by Baxter post-transaction; and

- It is unlikely that hospitals with no aseptic compounding facility would have the ability to exercise effective countervailing buyer power post-transaction to prevent Baxter from raising the price of its compounded chemotherapy medicines. The Commission also considers that the HSE would be unlikely to have the ability to exert effective countervailing buyer power by intervening on behalf of public hospitals with no aseptic compounding facility in response to a price rise by Baxter.

The Counterfactual

137. Identifying the relevant counterfactual – i.e., the likely state of competition in the relevant market in the absence of Baxter acquiring Fannin Compounding - is an important step that provides a reference point or point of comparison when assessing the likely competitive impact of the proposed transaction.

138. The Commission's "*Guidelines for Merger Analysis"* state in paragraph 1.14:

> "Identifying the relevant counterfactual is forward-looking and necessarily involves judgement on the part of the parties and the Commission. Usually the situation prior to the merger or acquisition will be the relevant counterfactual. However, this may not always be the case…One particular example where the pre-merger situation would not be the relevant counterfactual is where one [or] more of the parties to a merger is a "failing firm."

Failing Division Defence[43]

139. The failing firm/division argument is a defence based on a counterfactual where the target firm and its assets exit the market. It provides a defence to a merger that would otherwise lead to a substantial lessening of competition.

140. The Commission's "*Guidelines for Merger Analysis"* state in paragraph 9.5:

> "The Commission's failing firm test has four elements – all of which must be met. (a) The firm must be unable to meet its financial obligations in the near future. (b) There must be no

[43] As noted above, Fannin Compounding is a division of Fannin.

> viable prospect of reorganising the business through the process of receivership, examinership or otherwise. (c) The assets of the failing firm would exit the relevant market in the absence of a merger transaction. (d) There is no credible less anti-competitive alternative outcome than the merger in question."

141. In addition, paragraph 9.11 of the Commission's guidelines states:

> "The failing division argument (i.e., where the productive assets of part of a firm would exit the market but for a merger) is essentially analogous to the failing firm argument. However, a high level of scrutiny can be anticipated in testing a failing division argument given the potential unavailability [and] ambiguity in division-specific information."

142. As noted in paragraph 9.6 of the Commission's guidelines, the onus rests with the merging parties to demonstrate that the firm meets the failing firm/division test by providing objective and detailed evidence to substantiate its argument. Fannin made a submission on 28 July 2015 to the Commission concerning the relevant counterfactual in which it expressed the view that "Fannin Compounding meets the failing division test." This submission, however, did not provide an in-depth analysis, supported by detailed evidence, of each of the four elements of the failing division defence set out above.

143. On 15 September 2015, after meeting with the Commission and in accordance with section 9 of the Commission's Guidelines for Merger Analysis, Fannin made a further submission to the Commission setting out a failing division defence. On 12 October 2015, Fannin made a supplemental submission to the Commission providing additional evidence regarding its view that Fannin Compounding was a failing division.

144. The following section details the parties' views on the relevant counterfactual and Fannin's failing division defence.

Views of the Undertakings Involved

145. With respect to the relevant counterfactual, the notification by the parties states the following:

> "Baxter considers that in light of the Target Assets' historical and continuing losses exacerbated by the recent loss of OPAT [44] activity, the relevant counterfactual to its acquisition of the Target Assets is that the assets will exit the market. In the absence of Baxter acquiring the Target Assets, Baxter would not have the capacity to meet the requirements of Fannin's existing customers and,

[44] See paragraph 46 above for a description of the HSE's OPAT contract.

> accordingly, the capacity provided by the Target Assets would be lost to the market."

146. In its submission to the Commission dated 28 July 2015 concerning the counterfactual, Fannin expressed the following views:

> "The relevant counterfactual to the acquisition of Fannin by Baxter is the closure of Fannin and the exit of Fannin's assets from the market. DCC/Fannin consider the acquisition of Fannin Compounding by Baxter to be a good outcome for the provision of healthcare services in Ireland as it sustains capacity for important patient-specific compounding services (including capacity which could potentially be used to service the needs of the OPAT program). If the Proposed Transaction does not proceed (and Fannin Compounding's assets thus exit the market), Baxter would not have sufficient capacity at its compounding facility in Dublin to meet the demand from Fannin's current customers. The exit of the target assets from the market will have negative consequences for the health system, hospitals and patients due to capacity constraints in the market."

147. In its submission to the Commission dated 15 September 2015, Fannin set out the following failing division defence:

> "**The division must be unable to meet its financial obligations in the near future** - there is no prospect of returning the Target Assets to profitability within DCC. In light of the relevant ongoing and likely future losses, DCC/Fannin concluded that the Target Assets are not sustainable within DCC. In January 2015, Fannin's board resolved to "*exit the compounding business by end of September 2015 and that the immediate preferred option for the Company [Fannin] is to find a buyer for the business in the interim*"...The Target Assets have continued to record consistent and significant operating losses…These losses total €[…] to the end of August 2015. This clearly shows the financial distress of the Target Assets. Accordingly, the question of whether the Target Assets will be able to support Fannin's financial obligations after the end of September 2015 is moot given that the business will close in the absence of a sale to Baxter."
>
> "**No viable prospect of reorganising the business through the process of receivership, examinership or otherwise** - The timelines involved in the process of receivership, examinership or some other form of restructuring would extend considerably beyond the end

> of September 2015. Given the further investment required in the business and the significant ongoing losses, DCC/Fannin considers that there is no prospect of returning the business to profitability through the process of receivership, examinership or otherwise. For various reasons, neither examinership, receivership nor any other form of business restructuring (e.g., liquidation) was considered appropriate by Fannin's board at the time the decision was made to sell the compounding business. Although the Target Assets are considered by Fannin to constitute a standalone entity, they are not a separate company. Furthermore, Fannin has not given any of the Target Assets as security, and its other divisions continue to trade well and are not in distress. Therefore, neither examinership, receivership nor liquidation of the Target Assets was appropriate in the circumstances."
>
> "**The assets of the failing division would exit the relevant market in the absence of a merger transaction -** The Target Assets are not mobile and it is not possible to sell same on a piecemeal basis…If the proposed transaction does not complete, and given the significant ongoing losses being incurred, the Target Assets will exit the market as soon as possible after the end of September 2015."
>
> "**There is no credible less anti-competitive alternative outcome than the merger in question -** In January 2015, Fannin appointed PwC to advise on and manage a sale process...DCC and PwC identified Baxter Healthcare and Fresenius Kabi [as potential purchasers]… B Braun, a manufacturer of adult TPN in the Irish market, was also considered but in view of […], B Braun was not approached by PwC…In March 2015, Baxter confirmed its interest to PwC. However, Fresenius Kabi stated it was not interested in acquiring the Target Assets, due to the high level of continuing financial losses. Baxter is thus the only viable buyer of the Target Assets… The parties thus believe that there is no credible less anti-competitive alternative than the proposed transaction."

148. In the same submission to the Commission dated 15 September 2015, Fannin also expressed the following view concerning the possibility of consumer harm arising from the closure of Fannin Compounding:

> "The closure of the Target Assets would negatively affect customers and patients specifically through a significant reduction of current capacity. In particular, an exit of the Target Assets is likely to result in: (a) certain products and services (such as patient-specific parenteral nutrition) no

> longer being available to clinicians and their patients; (b) a reduced product range (particularly in chemotherapy) being available to clinicians; (c) insufficient capacity in the State to meet the requirements of strategically important programmes such as OPAT; and (d) increased prices given the lack of capacity in the market and the need to source capacity regardless of cost."

149. In a supplemental submission to the Commission dated 12 October 2015, Fannin provided additional arguments for three of the four elements of the failing division defence:

> "**The division must be unable to meet its financial obligations in the near future** - The Target Assets have continued to record consistent and significant operating losses in each of the first six months of the current financial year (i.e. year end 31 March 2016). These losses now total €[…] to the end of September 2015. The Target Assets' current loss-making performance is unsustainable. DCC/Fannin has no rational choice but to exit this business for this reason allied to their strategic focus on other activities…Unless the assets are sold to Baxter Healthcare, DCC intends to close Fannin Compounding. This business thus will not be able to meet its financial obligations without the support of DCC."
>
> "**The assets of the failing division would exit the relevant market in the absence of a merger transaction -** The development of a compounding facility is a complex task. As soon as the Target Assets leave the market, it will be very difficult (and commercially unattractive) to replace the relevant productive capacity."
>
> "**There is no credible less anti-competitive alternative outcome than the merger in question -** In addition to the considerations which PwC highlighted with regard to B Braun, Fannin itself (as a participant in the market for paediatric nutrition) expressed reservations regarding B Braun as a potential buyer… […]. B Braun had therefore no obvious rational incentive to acquire Fannin Compounding…The Parties thus believe that B Braun (or any other third party) was (and is) objectively not a credible buyer for the Target Assets. Baxter Healthcare is the only viable purchaser of the Target Assets."

Views of the Commission

150. As set out above, the Commission considers that the proposed transaction will lead to a substantial lessening of competition in the commercial supply of compounded chemotherapy medicines in the State. If, however, the competitive structure in the

commercial supply of compounded chemotherapy medicines in the State is likely to deteriorate to the same or a greater extent in the absence of the proposed transaction, there is no basis for prohibiting the proposed transaction.[45] In this instance, a question arises as to whether, as argued by the parties, Fannin Compounding is a failing division within Fannin and whether the assets of Fannin Compounding will exit the relevant market in the near future.

151. Each of the four elements of the Commission's failing division test are now considered in turn.

<u>The division must be unable to meet its financial obligations in the near future</u>

152. Fannin Compounding is a division of Fannin which in turn is ultimately owned by DCC. A strict interpretation of this element of the failing division test would focus solely on whether DCC has the ability to continue supporting Fannin Compounding without jeopardising its financial survival. The Commission considers, however, that a more sensible approach, in the context of the relevant counterfactual, is to assess whether DCC has both the ability and incentive to meet Fannin Compounding's financial obligations in the near future.[46]

153. The Commission considers that DCC will have the ability to ensure that Fannin Compounding meets all its financial obligations in the near future. This was confirmed to the Commission by Grant Thornton who, during the Phase 2 review period, carried out, on behalf of the Commission, a detailed examination of the annual management account information and financial forecasts and budgets of Fannin Compounding for the period 2013-2016. Grant Thornton concluded that all of Fannin Compounding's liabilities will be met by DCC. The Commission also considers that there is no prospect of DCC, which generated worldwide turnover of €14.3 billion for the financial year ending 31 March 2015, being financially imperilled by continuing to meet Fannin Compounding's financial obligations in the near future.

154. As well as assessing ability, the Commission also assessed whether DCC has the incentive to keep Fannin Compounding in operation. Based on all the available evidence, the Commission considers that the continued operation of Fannin Compounding would be more costly for DCC than its closure.

155. In its report to the Commission dated 15 October 2015, Grant Thornton made the following assessment of the recent financial performance of Fannin Compounding:

> "Fannin Compounding has recorded operating losses in FY14 [financial year ended 31 March 2014] and FY15 respectively and this trend was budgeted to continue into FY16…we understand the principal reasons for historical and continuing losses include: increased regulatory oversight and requirements driving increased operating costs; the OPAT contract did not contribute positively to

[45] A similar argument was made by the European Commission in Section 7.3 of its decision in COMP/M.6360 – Nynas/Shell/Harburg Refinery.

[46] This approach is in line with that of the European Commission – see Section 7.3 of its decision in COMP/M.6360 – Nynas/Shell/Harburg Refinery.

> the extent envisaged when Fannin Compounding tendered for this contract; inability to achieve economies of scale due to business activity levels; increased operating costs associated with a business that experiences high employee attrition rates due to the stressful nature of the work…notwithstanding significant cost reductions budgeted in FY16, management has been unable to arrest the losses in the business due to high costs associated with complying with regulatory requirements."
>
> "During the six month period ended 30 September 2015, Fannin Compounding recorded a negative EBITDA of €[…] which was €[…] or […]% behind budget. Fannin Compounding has significantly underperformed against budget during the year-to-date period. Declining sales levels, the loss of OPAT gross margin, inability to achieve budgeted gross margin, the termination of the paediatric contract coupled with significant employee attrition, increased regulatory requirements (which meant Fannin Compounding was unable to realise staff cost savings post-OPAT) were the principal drivers leading to the greater than expected negative performance."
>
> "DCC perceive Fannin Compounding to be a high risk operation which is unable to generate the requisite returns on capital employed. Allied to this, Fannin Compounding operates in a challenging industry and is subject to many operational and commercial risks coupled with a rigorous regulatory environment. These factors as well as the loss of the OPAT contract have resulted in the decision to exit this business. We believe that this is not an unreasonable decision to take from a plc perspective."

156. Fannin Compounding contributed positively to Fannin up until the financial year ended 31 March 2013.[47] In January 2013, the HSE awarded the OPAT contract (for the provision of compounded antibiotics to patients in the home) to Fannin Compounding. In a submission to the Commission dated 28 July 2015, Fannin described the negative impact of the OPAT contract on Fannin Compounding:

> "For various unforeseen reasons (including variable demand patterns requiring higher levels of staff than envisaged and inadequate pricing) this activity proved to be an operational and financial disaster for both Fannin Compounding and its partner, TCP Homecare [a logistics services provider]. In the first 9 months of operation (the OPAT Contract essentially commenced in April 2013),

[47] Fannin Compounding made a pre-tax profit of €[…] for the financial year ended 31 March 2013.

> Fannin Compounding suffered a direct financial loss of €[…]. On foot of a request for a price increase from Fannin Compounding, the HSE engaged Grant Thornton to verify the direct loss from OPAT. Grant Thornton verified the losses from OPAT."
>
> "The difficulties with OPAT absorbed resources within Fannin Compounding with many negative collateral consequences including the inability to satisfy demand for its oncology services, requirements for additional staff in other areas, operational issues, problems with staff morale, and higher staff turnover, all of which exacerbated the losses. Since April 2013, Fannin Compounding has suffered financial losses of circa €[…]. Fannin Compounding's operational issues have continued, and following an unsuccessful tender for the new HSE OPAT contract [this contract was awarded to Baxter in January 2015], Fannin Compounding's financial losses have worsened, particularly in light of the fixed nature of much of Fannin Compounding's cost base."

157. Fannin Compounding made pre-tax losses in the financial years ended 31 March 2014 and 31 March 2015. During the six month period ended 30 September 2015, Fannin Compounding made a pre-tax loss of €[…]. In its report to the Commission, Grant Thornton states that "business activity and standard margins were significantly behind budget during this [six month] period." Grant Thornton also states that Fannin Compounding's tendering for the new HSE OPAT contract at significantly higher pricing[48] "was the cornerstone of its plan to return Fannin Compounding to breakeven." The HSE awarded 100% of the new OPAT contract to Baxter in January 2015.[49]

158. The operational difficulties experienced by Fannin Compounding following the commencement of the OPAT contract in January 2013 were confirmed by […] in the HSE, who expressed the following views in a telephone call to the Commission:

> "Fannin Compounding's service was less than satisfactory with occasional missed deadlines for the delivery of medicines [under the OPAT contract]. Fannin Compounding had advised [the HSE] that there were quality control issues with its facility and there was a lot of churn in staff which meant that Fannin Compounding was hiring new staff with little experience. This was negatively affecting Fannin Compounding's service quality."

[48] Fannin informed the Commission that the prices at which it bid for the new OPAT contract were more than 40% higher than for the first OPAT contract.

[49] Fannin informed the Commission that it tendered for only two thirds of the new OPAT contract as "it believed that two compounding facilities were required to provide the capacity needed to meet the growth in patient numbers, and also as a contingency in the event of downtime at one of the facilities."

159. […] also expressed the following view in writing to the Commission about Fannin Compounding when asked about the likely competitive impact of the proposed transaction:

> "The HSE has been aware for some time that significant investment in equipment and staffing would be required by Fannin Compounding in order to maintain its compounding service as a viable business. It is more likely that the appropriate investment will be forthcoming due to their incorporation into Baxter Healthcare…Fannin Compounding has been struggling since it lost the OPAT contract in January 2015 and, as a result, it has been struggling to sustain the other parts of its compounding business."

160. The operational difficulties experienced by Fannin Compounding following the commencement of the OPAT contract in January 2013 had a negative impact on its turnover in the commercial supply of compounded chemotherapy medicines to hospitals in the State (it declined by approximately [30-35]% between 2011 and 2014).[50] In a submission to Commission dated 13 August 2015, Fannin stated that there were two reasons for this decline, one of which was:

> "The other […]% of the decline [in turnover generated from the commercial supply of compounded chemotherapy medicines] was caused by a number of hospitals reacting to Fannin's prioritisation of the OPAT and TPN contracts. As noted previously, the OPAT contract was a catalyst for a significant number of operational issues in Fannin's compounding facility. To deal with these issues, Fannin reduced its capability (primarily in terms of personnel) and service levels in the compounding of chemotherapy products. A number of hospitals changed to a dual-supplier strategy (i.e., sourcing from both Fannin and Baxter) as a result of these issues. The bulk of this change took place in the second half of 2013 and the first half of 2014."

161. Fannin Compounding has been loss-making since 2013. Based on all the available evidence, including the expert opinion of Grant Thornton, the Commission is persuaded by the argument made by DCC that there is no prospect of returning Fannin Compounding to profitability in the near future. It is therefore economically rational for DCC to shut down Fannin Compounding in the absence of the proposed transaction.

162. DCC/Fannin's decision to exit the compounding business is also in line with the fact that medical compounding manufacturers have recently exited the compounding business in other countries. Fresenius Kabi, a commercial supplier of compounded adult TPN

[50] Notwithstanding these operational difficulties, only one hospital, out of the 17 contacted by the Commission, expressed concerns to the Commission about the quality and reliability of the service provided by Fannin Compounding in recent years for the commercial supply of compounded chemotherapy medicines. This hospital stated that there have been occasions when Fannin Compounding has been unable to fulfil an order due to capacity issues.

medicines in the State, informed the Commission that it has closed oncology compounding units in Germany and Australia in recent years because the price of generic pharmaceutical drugs has been declining which has resulted in lower margins for compounded chemotherapy medicines.[51]

163. The Commission has therefore concluded that DCC does not have the incentive to keep Fannin Compounding operating and ensure that it meets all its financial obligations in the near future.

<u>There must be no viable prospect of reorganising the business through the process of receivership, examinership or otherwise</u>

164. In its report to the Commission dated 15 October 2015, Grant Thornton made the following assessment of the possibility of reorganising Fannin Compounding through the process of receivership, examinership or otherwise:

> "We do not believe that receivership is a relevant mechanism to restructure Fannin Compounding for a variety of reasons including, inter alia, the following: (a) We understand that no guarantees or debentures have been provided to third-parties by Fannin Compounding; (b) Fannin Compounding's debts are guaranteed by its ultimate parent and therefore the business is able to meet all of its debts as they fall due. Were it a standalone entity without the support of its ultimate parent, it would be unable to do so indefinitely; (c) Fannin Compounding has recorded significant losses over the last two years and year to date. The reorganisation of its balance sheet would not result in a material improvement in trading performance. In effect, Fannin Compounding's issue is that it is carrying on insufficient levels of business to cover its necessary fixed cost base and is not related to its balance sheet position."

> "We do not believe that examinership is a relevant mechanism to restructure Fannin Compounding for a variety of reasons including, inter alia, the following: (a) This mechanism is more relevant where a company is overly indebted and its balance sheet needs to be right sized – this is not the key issue with Fannin Compounding; (b) Fannin Compounding's trade and assets are not within a standalone company; (c) Additional investment in Fannin Compounding is unlikely to result in an improvement in its trading performance given the limited contract-based market it is operating in; (d) Given that HSE demand is a key market driver, it is unlikely that new investment in Fannin Compounding would return it to profitability in the short term. (e) Again, Fannin

[51] As will be discussed in detail below, this was one of the reasons why Fresenius Kabi decided not to buy Fannin Compounding.

> Compounding has recorded significant losses over the last two years and year to date. The reorganisation of its balance sheet would not result in a material improvement in trading performance. In effect, Fannin Compounding's issue is that it is carrying on insufficient levels of business to cover its necessary fixed cost base and is not related to its balance sheet position."
>
> "It is important to note that insolvency mechanisms (e.g., receivership, liquidation, examinership) generally tend to be value destructive and are considered as a last resort to restructure legacy liabilities. In limited circumstances such procedures result in enhanced earnings - we believe however this would not be the case in respect of Fannin Compounding."

165. Based on the expert opinion of Grant Thornton, the Commission considers that there is no viable prospect of reorganising Fannin Compounding through the process of receivership, examinership or otherwise.

<u>The assets of the failing firm would exit the relevant market in the absence of a merger transaction</u>

166. Internal documentation provided to the Commission clearly indicates that DCC has been considering the possibility of exiting the compounding business for some time. For example, a number of DCC internal documents dated August 2014 indicate that DCC first began in August 2014 to consider the options of either divesting or closing Fannin Compounding in light of its ongoing financial losses. In January 2015, DCC prepared a budget for Fannin Compounding which, despite a planned restructuring of Fannin Compounding, showed a budgeted loss of almost €[…] for the financial year ended 31 March 2016.

167. A formal decision to exit the compounding business was made by DCC in March 2015. A DCC internal document entitled "Fannin Limited – Board Minutes Extract" dated 23 March 2015 contains the following statement:

> "The optimum scenario is for the Company [Fannin Limited] to exit the [compounding] business and now seek a trade buyer to take over the enterprise…Following detailed discussion, and after careful consideration, the meeting unanimously resolved (and the chairman so declared), that the Company exit the compounding business by end of September 2015 and that the immediate preferred option for the Company is to find a buyer for the business in the interim."

168. The Commission has therefore concluded that it is highly likely that Fannin Compounding will close in the absence of the proposed transaction and that the assets will exit the relevant market if not acquired by Baxter.

There is no credible less anti-competitive alternative outcome than the merger in question

169. Based on all the available evidence, the Commission considers that Baxter is the only credible alternative purchaser of Fannin Compounding.

170. In January 2015, Fannin appointed PwC to advise on and manage a sale process for Fannin Compounding. DCC/Fannin and PwC identified Baxter and Fresenius Kabi as the parties most likely to be interested in acquiring Fannin Compounding. In March 2015, Baxter confirmed its interest to PwC.

171. Fresenius Kabi, a commercial supplier of compounded adult TPN medicines in the State, does not have a compounding facility in the State.[52] Mr. Gerry O'Connor, General Manager of Fresenius Kabi, confirmed to the Commission that Fresenius Kabi examined the financial accounts of Fannin Compounding in early 2015 after being approached by DCC and PwC. In a telephone call, Mr. O'Connor provided the following explanation to the Commission as to why Fresenius Kabi decided not to buy Fannin Compounding:

> "Fresenius Kabi discovered that Fannin Compounding would require a lot of investment to upgrade its facilities and the staffing costs were very high. The costs involved would have been a drain on Fresenius Kabi's financial resources."

172. In a follow-up telephone call with the Commission, Mr. O'Connor provided further details as to why Fresenius Kabi decided not to buy Fannin Compounding:

> "There is a high regulatory burden from HPRA for compounding companies and that this would mean high staffing levels to meet this regulatory burden which would mean high costs. In addition to the high regulatory burden, there is the cost of providing a 7-day service to hospitals which would also mean high costs. Furthermore, Fresenius-Kabi has been closing oncology compounding units around the world in recent years (e.g., Germany and Australia) because the price of generic pharmaceutical drugs has been declining which means that the fee for compounding chemotherapy medicines has been falling. Hospitals do not want to pay a price premium for compounded medicines. For all these reasons, Fresenius Kabi decided not to buy Fannin Compounding."

173. The Commission therefore considers that Fresenius Kabi is not a credible alternative purchaser of Fannin Compounding.

174. The Commission considered whether there are any other credible alternative purchasers of Fannin Compounding that were not approached by DCC/Fannin and PwC. An undated internal document provided to the Commission by DCC states in relation to

[52] […]

the possibility of divesting Fannin Compounding that there are a "limited population of buyers." In addition to Baxter and Fresenius Kabi, this internal document lists B. Braun Medical Limited ("B. Braun") and the HSE as potential buyers.[53]

175. The Commission assessed in detail whether B. Braun might be a credible alternative purchaser of Fannin Compounding. B. Braun is a commercial supplier of compounded adult TPN medicines to hospitals in the State and it operates a compounding facility in Longford.

176. B. Braun was not approached by PwC regarding the sale of Fannin Compounding. PwC provided the following explanation to DCC as to why B. Braun was not considered by PwC to be a credible purchaser of Fannin Compounding:[54]

> "1. It was well documented that B. Braun had exited the Paediatric TPN sector…We considered that B. Braun was and remain unlikely to have a genuine interest in re-entering this market…2. We note that B. Braun have a "Central Admixture Pharmacy Services" or CAPS facility in Longford for the production of TPN bags for adults…we inferred from this that Fannin Compounding, which requires significant investment, would be unlikely to be attractive to B. Braun. 3. From a high level review of B. Braun's activities in Ireland, there is no reference to the provision of products or services in the area of oncology…4. We reviewed publicly available information regarding acquisition transactions completed by B. Braun and its German parent company and subsidiaries for the last five years. Out of five acquisitions identified, we did not identify any acquisition in the area of compounding…we reasonably concluded with [DCC] that B. Braun had no rational economic incentive to acquire [Fannin Compounding]."

177. In e-mail correspondence, B. Braun informed the Commission that it was not approached by PwC or DCC concerning the sale of Fannin Compounding. When asked whether B. Braun was interested in acquiring Fannin Compounding, B. Braun provided the following response to the Commission: "If we had been approached, we would have assessed it like any other opportunity relative to our business."

178. In a telephone call, Mr. Leo Halpenny, Director of B. Braun, informed the Commission that it would have been interested in acquiring Fannin Compounding if it had been approached by DCC. By way of background, Mr. Halpenny informed the Commission that B. Braun has, in recent years, […] with the intention of manufacturing compounded neo-natal/paediatric TPN and possibly compounded chemotherapy medicines. Mr. Halpenny informed the Commission, however, that B. Braun has never carried out any formal assessment of the feasibility of […]. The Commission requested and received

[53] At no point during the Commission's review of the proposed transaction did the HSE indicate to the Commission that it had any interest in acquiring Fannin Compounding.

[54] PwC explained the selection process in a letter to DCC dated 12 October 2015. A copy of this letter was provided to the Commission by DCC on the same day.

internal documentation from B. Braun concerning any plans or proposals (formal or otherwise) to commence supplying compounded neo-natal/paediatric TPN and/or compounded chemotherapy medicines in the State but there was no evidence of any interest in either (a) acquiring Fannin Compounding, or (b) […].

179. In a hearing under oath, Mr. Halpenny informed the Commission that B. Braun has no current plans to start supplying compounded chemotherapy medicines to customers in the State. Mr. Halpenny stated that B. Braun has never formally assessed the feasibility of either (a) acquiring Fannin Compounding, or (b) […]. Mr. Halpenny also expressed the view to the Commission, when informed of Fannin Compounding's recent poor financial performance, that this fact would have made Fannin Compounding a less attractive investment option to B. Braun.

180. Based on the information and views provided by B. Braun, the Commission has concluded that B. Braun is not a credible alternative purchaser of Fannin Compounding.

181. Based on all the available evidence, the Commission considers that Baxter is most likely the only undertaking that is seriously interested in acquiring Fannin Compounding. No other undertaking is likely to have the ability and incentive to acquire Fannin Compounding in the absence of the proposed transaction.[55] As a result, the Commission has concluded that there is no credible less anti-competitive alternative outcome to the proposed transaction.

Conclusion on Failing Division Defence

182. The Commission considers that Fannin Compounding, based on all the available evidence, satisfies each condition of the failing division test. As a result, the most likely outcome that can reasonably be predicted in the absence of the proposed transaction is that DCC/Fannin would close Fannin Compounding and its assets would exit the relevant market.

183. The Commission also considers that there are credible reasons to believe that the competitive structure in the commercial supply of compounded chemotherapy medicines in the State is likely to deteriorate to an even greater extent in the absence of the proposed transaction. The Commission considers that in the absence of the proposed transaction, there would be a relatively significant reduction in supply capacity in the State for compounded medicines, which is likely to lead to an increase in prices.

184. The impact of reduced supply capacity in the State in the absence of the proposed transaction would depend on the availability and costs of alternative sources of supply of compounded medicines. The Commission considers that in the absence of the proposed transaction, imports would be needed in order to meet the supply shortfall due to the closure of Fannin Compounding. The supply shortfall and the likely

[55] The Commission considers that for an alternative purchaser of Fannin Compounding to be deemed credible, it would most likely need to have experience in medical compounding, especially because of the onerous regulatory burden involved. The Commission therefore considers that pharmaceutical undertakings with no experience in medical compounding would not be credible alternative purchasers of Fannin Compounding.

consequent need to import compounded medicines would likely lead to a price increase.

185. In its response dated 24 July 2015 to the Commission's Requirement for Further Information issued on 17 July 2015, Baxter provided the following information to the Commission concerning the current capacity utilisation rate in its compounding facility in Deansgrange, Co. Dublin:

> "The Deansgrange facility currently has capacity for […] per annum. Based on current regulatory requirements, current staff, operating hours and equipment, the facility is operating at […]. […] In the absence of the proposed transaction, it would take approximately 24 months for Baxter to substantially increase its capacity by building a new unit."

186. Given that Baxter is currently operating at […], in the absence of the proposed transaction, the supply shortfall for compounded chemotherapy medicines caused by the closure of Fannin Compounding would likely mean that some hospitals with no aseptic compounding facility would have to import compounded chemotherapy medicines which would likely lead to an even greater price increase than would likely occur as a result of the proposed transaction.[56]

187. In the case of compounded neo-natal/paediatric TPN medicines, Fannin Compounding is currently the sole commercial supplier in the State.[57] As noted above, the HSE awarded a contract for the supply of compounded neo-natal/paediatric TPN to a consortium of Fresenius Kabi and Fannin Compounding with the latter providing the compounding element of this contract. This contract expired on 30 September 2015.[58] Absent the proposed transaction, the HSE would have to import compounded neo-natal/paediatric TPN medicines to replace the supply lost due to the closure of Fannin Compounding which would likely lead to a price increase.[59]

188. In conclusion, since the competitive structure in the commercial supply of compounded chemotherapy medicines in the State is likely to deteriorate to at least the same extent (and, possibly, to an even greater extent) in the absence of the proposed transaction, there is no basis for prohibiting the proposed transaction.

Conclusion

[56] As described in detail above, hospitals with an aseptic compounding facility may have the option of increasing the in-house production of compounded chemotherapy medicines if they have the spare capacity to do so.

[57] The Commission understands that no hospital in the State currently compounds neo-natal/paediatric TPN medicines in-house.

[58] Fannin agreed to supply compounded neo-natal/paediatric TPN medicines to the HSE for the month of October 2015. The HSE expressed concerns in writing to the Commission in October 2015 about the logistical and clinical implications for children's hospitals in the State if Fannin Compounding were to cease operations in the near future. The Commission notes, however, that the HSE's concerns are mainly the by-product of awarding a contract for the supply of compounded neo-natal/paediatric TPN medicines to a monopoly supplier, i.e., Fannin Compounding.

[59] In a letter to the Commission dated 13 October 2015, DCC stated the following: "Other than the Fannin Compounding facility, there is no compounding facility within the State which can manufacture paediatric TPN. Hence, the HSE will need to put in place a supply chain to import paediatric TPN products from the UK."

189. In light of its analysis as set out in this determination, the Commission has determined that the proposed transaction will not substantially lessen competition in any market for goods or services in the State.

Ancillary Restraints

190. The Share Purchase Agreement between the parties to the proposed transaction contains a number of restrictive obligations on Fannin. These include non-compete and non-solicitation clauses. None of these restrictive obligations exceeds the maximum duration acceptable to the Commission.[60] The Commission considers these restrictions to be directly related and necessary to the implementation of the proposed transaction.

[60] In this respect, the Commission follows the approach adopted by the EU Commission in paragraphs 20 and 26 of its "Commission Notice on restrictions directly related and necessary to concentrations" (2005). For more information see http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52005XC0305(02)&from=EN

Determination

The Competition and Consumer Protection Commission, in accordance with section 22(3)(a) of the Competition Act 2002, has determined that, in its opinion, the result of the proposed transaction whereby Baxter Healthcare Limited would acquire sole control of certain assets pertaining to the medical aseptic compounding business of Fannin Limited will not be to substantially lessen competition in any market for goods or services in the State, and, accordingly, that the acquisition may be put into effect.

For the Competition and Consumer Protection Commission

Isolde Goggin
Chairperson
Competition and Consumer Protection Commission