Alliance Medical/ IBA Molecular

Provisional findings report

Notified: 10 July 2014

The Competition and Markets Authority has excluded from this published version of the provisional findings report information which the Inquiry Group considers should be excluded having regard to the three considerations set out in section 244 of the Enterprise Act 2002 (specified information: considerations relevant to disclosure). The omissions are indicated by [✂]. Some numbers have been replaced by a range. These are shown in square brackets.

Contents

Page

Appendices

Summary

1. On 24 March 2014, the Office of Fair Trading (OFT) referred to the Competition Commission[1] (CC) under section 22 of the Enterprise Act 2002 (the Act) the completed acquisition by Alliance Medical Group Limited (Alliance) of the assets of IBA Molecular UK Limited (IBA Molecular UK) used to produce 18F-fluorodeoxyglucose (FDG-18) in the UK, as well as related rights and activities (the IBA operation). We are required to publish our report by 7 September 2014.

2. Alliance is a private company that was formed in 1989. It provides diagnostic imaging services, including positron emission tomography – computed tomography (PET-CT) scanning services to hospitals and clinics in the UK, the Republic of Ireland, Italy, Spain, the Netherlands and Scandinavia. Its main customers in the UK are NHS bodies in England. It does not provide PET-CT scanning services in Scotland, Wales or Northern Ireland. Its recently-acquired subsidiary, Erigal Limited (Erigal), manufactures FDG-18. In the year ended March 2013, Alliance generated a total revenue of £218.6 million and EBITDA of £43.8 million.

3. IBA SA is a Belgian company listed on the Euronext stock exchange. It is focused on the development and production of cancer diagnostic products and treatment equipment. In early 2012, IBA SA and a private investment firm, SK Capital Partners LP (SK Capital), created a jointly-owned new company, IBA Pharma SA (IBA Molecular), derived from IBA SA's radiopharmaceutical division, in which IBA SA retained a 40% shareholding. IBA Molecular has operations across Europe. IBA Molecular UK's PET business division (referred to as IBA's PET business) had been producing and supplying FDG-18 in England. In year ended December 2012, IBA Molecular UK generated a turnover of £5 million.

4. FDG-18 is a radioactive tracer (or radiopharmaceutical), which is used in the process of PET-CT scanning. PET-CT scans themselves are used predominantly for the diagnosis of cancers. The production of FDG-18 involves a cyclotron, which can be used to produce other radiopharmaceuticals, including 18F-Choline (FEC) and 18F-Sodium Fluoride (NaF), both of which are also used for the diagnostic of cancers. The level of radioactivity, thus the effectiveness of FDG-18, FEC and NaF doses declines over a short period of time, and transport costs are significant. Consequently, there are restrictions on the distance over which they can be transported.

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[1] On 1 April 2014 the functions of the CC in relation to the reference were transferred to the Competition and Markets Authority (CMA).

5. PET-CT scans are either carried out by hospitals (mainly NHS) or by third parties under contract. There are four third parties offering such services in England: Alliance, InHealth Group Limited (InHealth), Cobalt Unit Appeal Fund (Cobalt) and the Paul Strickland Scanner Centre.

6. Prior to the acquisition, Erigal, which became a fully-owned subsidiary of Alliance in August 2013 (having been 50% owned by it previously), produced FDG-18 at three radiopharmaceutical units (RPUs) in England: Sutton, Preston and Keele. It also produced small quantities of NaF and FEC. IBA's PET business produced FDG-18 at one RPU in Guildford and owned a cyclotron at a site in Dinnington (near Sheffield), which had not been active since 2010. There is only one other commercial supplier of FDG-18 in Great Britain: PETNET Solutions Inc (PETNET), a subsidiary of Siemens Medical Solutions USA Inc (Siemens), which also manufactures cyclotrons and PET-CT scanners. GE Healthcare Limited (a division of the General Electric Company (GE)) stopped supplying FDG-18 commercially at its Amersham RPU in 2009. Eight hospitals and three research institutions also operate cyclotrons in which they produce FDG-18 and other radiopharmaceuticals for their own use.

7. The economics of FDG-18 production are characterised by high fixed costs, significant economies of scale at site level and low variable costs. In addition, cyclotrons are subject to regular outages (whether planned or unplanned) and back-up arrangements are required by customers to ensure continuity of supply during such outages. Group-level economies of scale are thus derived from an ability to provide internal back-up supplies, in addition to shared head office costs. Demand for FDG-18 has been driven by the Department of Health which published a framework for the development of PET-CT scanning services in England in 2005 (the 2005 framework), following which the NHS tendered for the provision of such services under two contracts (the block contracts), each worth around £13 million and about 11,600 scans per year. These contracts represent approximately 50% of PET-CT scans carried out annually in England. The 2005 framework was followed by a substantial expansion of FDG-18 production capacity in the three years from 2007 to 2009, whilst over the same period prices experienced a steep downward trend. Subsequently two facilities, at Dinnington and Amersham (both of which opened in 2007), were withdrawn from FDG-18 production. Although the decline in FDG-18 prices has been significantly less pronounced since then, some operators have told us that the production of FDG-18 on a stand-alone basis is not a profitable activity. Although volumes are expected to continue to grow, largely in line with growth in the number of PET-CT scans performed, prices are not expected to rise in the short to medium term. The operators of cyclotrons who responded to our inquiry consider the production of new

pharmaceuticals to be a key opportunity. In addition to FEC and NaF, the development of radiopharmaceuticals for the diagnosis of Alzheimer's disease (known as Alzheimer's tracers) is expected to improve the economics of the industry in the long term.

8. It is against this background that we assessed the impact of the transaction between Alliance and IBA Molecular UK that was completed on 16 September 2013. This transaction involved the acquisition by Alliance of IBA's PET business's two RPUs, business records, supplier and customer contracts and transfer of eight employees and we were satisfied that it had created a relevant merger situation under the Act.

9. We first identified the relevant economic markets within which to carry out our assessment. We noted that the radiopharmaceuticals supplied by the parties are targeted at specific clinical uses and are therefore not substitutable from a demand-side perspective. Having considered a number of issues, including whether the economic market should include potential supplies of FDG-18 by hospitals to other hospitals; whether primary and back-up supplies of FDG-18 are in the same market; and whether the supplies of FDG-18 by Erigal to Alliance's PET-CT scanning operations are in the same market as supplies to non-affiliated customers, we provisionally decided that the relevant product market included the primary and back-up commercial supply of FDG-18, ie all supplies of FDG-18 by Erigal, IBA's PET business and PETNET. On the basis of the evidence available to us, we were not able to conclude whether FEC, NaF and FDG-18 were in the same product market. We provisionally concluded that FDG-18 and Alzheimer's tracers were in different product markets. Given that there are restrictions on how far FDG-18 can be transported; that prices are negotiated; and that arbitrage across customer locations is not possible due to the perishability of FDG-18, we provisionally concluded that the competitive effects of the merger in the relevant product markets should be assessed locally and centred around customer locations.

10. We then considered what was most likely to have happened to IBA's PET business if the transaction had not taken place (the counterfactual).

11. Our analysis and the evidence received from IBA Molecular showed that IBA's PET business had been consistently loss making since it started producing FDG-18 in 2007 and that financial losses would have significantly worsened in 2013 as a result of the loss of a substantial contract. We noted that demand for FDG-18 was growing and that the other two producers of FDG-18 were able to return a profit but also that IBA's PET business suffered from a weak competitive position: it operated only one site, which made it entirely dependent on its competitors for back-up supplies; it did not have a presence in other parts of the supply chain; it had not won a contract for several years

and the closure of the Dinnington site raised uncertainty about IBA Molecular's commitment to the supply of FDG-18; and while there were few opportunities to win new contracts, it was vulnerable to the loss of any one of its few contracts, which were all due to expire soon. Before the creation of IBA Molecular, IBA SA had been willing to support losses in its UK business for a number of years because of its view of the long-term opportunities associated with the development of new radiopharmaceuticals. However, IBA Molecular's majority shareholder had different strategic objectives and did not consider it worthwhile continuing to incur the losses that arose from operating the Guildford RPU. Given these objectives and our analysis of the economics of the industry, we provisionally concluded that SK Capital would have sought to exit the production of FDG-18 as soon as possible. We considered that it was likely that this would have occurred before the NHS procurement process for PET-CT scanning services (to replace the two NHS block contracts) started in spring 2014.

12. Next we considered whether, absent the transaction, the IBA operation would have been acquired by an alternative purchaser. SK Capital did not run an auction process and negotiated the transaction with Alliance on a confidential basis. No other potential buyer approached either SK Capital or IBA Molecular to express an interest either in the Dinnington site since its closure in 2010 or the Guildford site. We sought evidence from a number of parties we had identified as potential purchasers, and provisionally concluded that it was unlikely that the IBA operation would have found an alternative purchaser due to the difficulties associated with improving the performance of the business, which was at a structural disadvantage and had never returned a profit. We noted that a scenario under which PETNET acquired the IBA operation was unlikely to produce a better outcome for competition than the merger under consideration.

13. We therefore provisionally concluded that had Alliance not bought the IBA operation, the most likely outcome was that:

    (a) IBA Molecular UK would have ceased to supply FDG-18 and would have exited the market; and

    (b) there would not have been an alternative purchaser that would have produced a better outcome for competition.

14. We analysed what would have happened to the sales of IBA's PET business if it had ceased to operate. It had been serving five key customers, the contract for one of which had expired. We examined these customers' contracts (noting that none of these contracts could have been novated to a new supplier without the customer's consent) and the criteria the customers had

applied in selecting suppliers previously. We also considered what had happened to customers under similar circumstances previously. We complemented this qualitative evaluation with an analysis of distances and drive-times between these customers and the sites of the suppliers that would have remained following the closure of the Guildford RPU. This analysis showed that on the basis of distance and drive-time only, PETNET would have been a strong competitor for the contracts of the customers currently served from the Guildford RPU in the event that it had ceased to supply FDG-18. We recognised that other factors would have influenced the process by which customer sales would have been redistributed between suppliers, and could not therefore conclude precisely how sales would have been redistributed between the two suppliers. We could not, however, satisfy ourselves that the majority of sales would have switched to Alliance under the counterfactual (as in the merger scenario).

15. We therefore considered how the competitive process following the transaction differed from the competitive process under the counterfactual (ie in the situation where the Guildford RPU had exited the market). We considered that under both scenarios customer contracts that had not been previously served from Guildford would be competed for by two suppliers, and therefore with regard to these customers we did not expect that the transaction would have any adverse effect on the competitive process.

16. For customers who had previously been served from Guildford, we considered that, provided that the RPU continues to be used for the production of FDG-18 (and in contrast to the counterfactual situation), customers will be able to continue to be supplied from that site, which they would only do if it were the most attractive option.

17. We also considered whether the transaction might be giving Alliance an incumbency advantage which would either hinder customers' ability to switch to their best option or that would reduce the value of their options. We found that to the extent that there were any incumbency advantages, they would not have either of these effects, ie customers would be able to switch suppliers in response to better offers.

18. In the course of our inquiry, we received representations from InHealth, expressing concerns that the transaction would enable Alliance to take advantage of its presence in both the supply of FDG-18 and PET-CT scanning services, which would have an adverse effect on InHealth's business and ultimately customers. We provisionally concluded that, given that under the counterfactual scenario we expected that IBA's PET business would have exited the market, the concerns expressed by InHealth were not an effect of the transaction.

19. We therefore provisionally concluded that the transaction was unlikely to lead to a substantial lessening of competition within any market or markets in the UK.

Provisional findings

1. The reference

1.1 On 24 March 2014, the OFT referred to the CC under section 22 of the Act the completed acquisition by Alliance of the assets of IBA Molecular UK used to produce FDG-18 in the UK, as well as related rights and activities (the IBA operation). In these provisional findings we refer to Alliance and the IBA operation as the parties.

1.2 On 1 April 2014 the functions of the CC in relation to the reference were transferred to the CMA, under Part 3 of the Enterprise and Regulatory Reform Act 2013 and the Enterprise and Regulatory Reform Act 2013 (Commencement No. 6, Transitional Provisions and Savings) Order 2014.

1.3 The CMA must decide:

(a) whether a relevant merger situation has been created; and

(b) if so, whether the creation of that situation has resulted, or may be expected to result, in a substantial lessening of competition (SLC) within any market or markets in the UK for goods or services.[2]

1.4 Our terms of reference are in Appendix A. We are required to publish our final report by 7 September 2014.

1.5 This document, together with its appendices, constitutes our provisional findings, published and notified to Alliance in line with the CMA's Rules of Procedure.[3] Further information relevant to this inquiry, including non-confidential versions of submissions received from Alliance and third parties, as well as summaries of evidence received in oral hearings, can be found on our website.

2. The companies and the industry in which they operate

Alliance and its operations

2.1 Alliance is a private company that was formed in 1989. The business is owned by a combination of management and financial institutions, with M&G, the investment arm of the Prudential, owning [✂]% of the company. Its principal activity is the provision of diagnostic imaging services, including

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[2] The Act, section 35. The assessment is carried out by comparing the post-merger situation with what the competitive situation would have been, absent the transaction (also called the counterfactual).
[3] *CMA 17*, Rule 11.

magnetic resonance imaging (MRI), computed tomography (CT) and PET-CT scanning services,[4] to hospitals and clinics in the UK, the Republic of Ireland, Italy, Spain, the Netherlands and Scandinavia. Its UK subsidiary, Alliance Medical Limited (AML), operates over [✂] static imaging sites and over [✂] mobile scanners offering MRI, CT, PET-CT, X-ray, ultrasound and DEXA imaging services[5] in the UK. [✂][6] of these static sites and [✂][7] of the mobile scanners provide PET-CT imaging. Alliance's main customers in the UK are NHS bodies in England; it does not provide PET-CT scanning services in Scotland, Wales or Northern Ireland.

2.2 In 2013, Alliance generated total revenues of £218.6 million, EBITDA of £43.8 million, and EBIT of £[✂] million across all its operations. In the UK, AML generated revenues of £[✂] million,[8] EBITDA of £[✂] million, and EBIT of £[✂] million (before reorganisation costs). It carried out around [✂] PET-CT scans in England in 2012.

2.3 In the three-year period to 31 March 2013, Alliance's business suffered from falling sales and operating profits with its EBIT margin[9] declining from [✂] to [✂]% in 2013. The UK business has experienced a more variable performance, with revenues declining in FY12 before growing again in FY13. Operating profit margins (EBIT) have grown from [✂] to [✂]% between FY11 and FY13 (excluding exceptional costs), as shown in Table 1 below.

TABLE 1 **AML, summary financial information**

£'000

	Years ended 31 March		
	FY11	*FY12*	*FY13*
Revenue	[✂]	[✂]	[✂]
EBITDA	[✂]	[✂]	[✂]
EBIT*	[✂]	[✂]	[✂]
	[✂]	[✂]	[✂]

Source: AML Management Accounts, FY11 to FY13.

*EBIT figures are quoted on a 'pre-exceptionals' basis.

[4] Other medical diagnosis technologies used by Alliance include: dual-energy X-ray absorpotiometry (Dexa), X-ray and ultrasound scanning. The only diagnostics technology used by Alliance that is relevant to our inquiry is PET-CT scanning.
[5] Static sites are permanently installed in a hospital or clinic. Mobile sites are installed in a 'trailer' and moved from site to site as required and can therefore be used to serve multiple hospitals.
[6] We note that the static scanner at Castle Hill Hospital has been made operational only recently (2014).
[7] We note that the [✂] mobile scanners serve eight locations: Freeman Hospital, James Cook Hospital, Bradford Royal Infirmary, Priory Hospital, St George Hospital, Spire Bristol Hospital, Clatterbridge Hospital and Broadgreen Hospital.
[8] Alliance's largest single market is Italy, in which it generated revenues of just over £100 million in FY13, with each of the Republic of Ireland, Spain and Scandinavia (including the Netherlands) accounting for revenues of around £12–£13 million.
[9] As the business incurs significant ongoing capital expenditure as scanning equipment is replaced, the key operating margin for the diagnostic imaging services is EBIT (rather than EBITDA).

2.4 In 2002, AML established a 50/50 joint venture with M2i Holdings (M2i), Erigal, which manufactured radiopharmaceuticals,[10] a key input of medical scans that are carried out either by hospitals or third party providers such as Alliance. It primarily produced a radiopharmaceutical called FDG-18 at three RPUs in England (located in Keele, Preston and Sutton) and at one RPU located in Dublin. Erigal commissioned and licensed the Keele site in 2005, with Preston opening in 2008 and Sutton in 2009.[11]

2.5 In September and December 2012, Erigal breached the covenants in its loans as a result of 'a significant tightening of covenants towards the end of the existing facility', which was due to expire formally on 31 March 2013. As a result, it entered into negotiations with its bank (RBS) regarding an extension to its existing financing facilities, as well as engaging in discussions with its shareholders (Alliance and M2i) in parallel to put together a proposal to demerge the business. Under this proposal, Alliance would take full ownership of the UK part of the business, whilst the Irish operation would be taken on by M2i with an agreed amount of Erigal's debt apportioned to each part of the demerged business. The transaction was completed in August 2013.

2.6 Unlike AML, Erigal achieved significant revenue growth in the three years to 31 March 2013 and maintained its EBITDA margin at around [✂]% (its EBIT margin was around [✂]%). This is shown in Table 2.

TABLE 2 **Erigal summary financial information (UK and Ireland combined results)**

£'000

	Years ended 31 March		
	FY11	*FY12*	*FY13*
Revenue	[✂]	[✂]	[✂]
Gross profit	[✂]	[✂]	[✂]
EBITDA	[✂]	[✂]	[✂]
	[✂]	[✂]	[✂]
EBIT	[✂]	[✂]	[✂]
	[✂]	[✂]	[✂]

Source: Erigal Management Accounts, March 2012 and 2013.

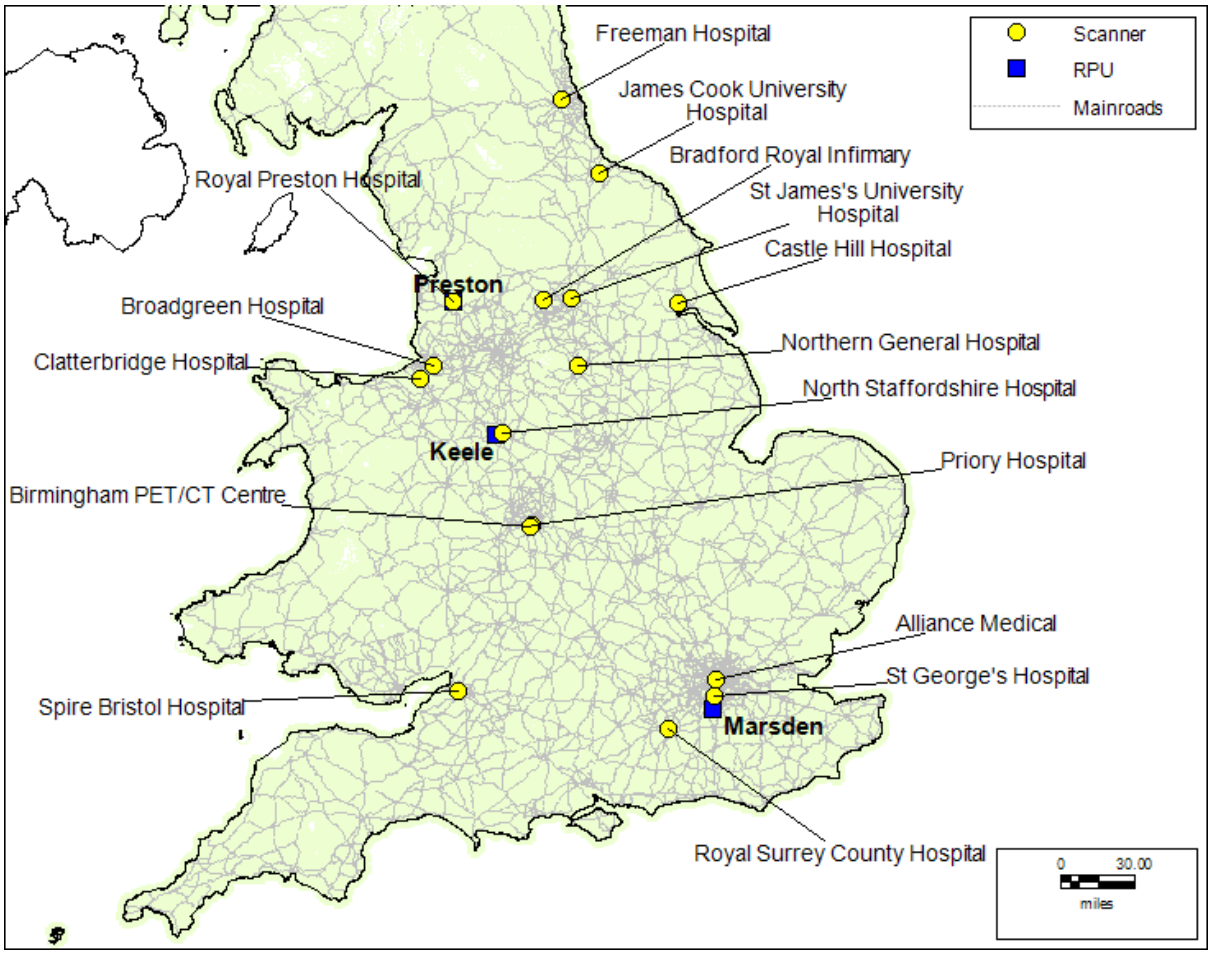
Note: Summary financial information includes Irish operations that were not acquired by Alliance.

2.7 Figure 1 shows both the UK PET-CT scanning operations of Alliance and (England-based) RPUs of Erigal prior to the transaction.

[10] Drugs that contain radioactive materials called radioisotopes. Depending on the drug and how it is given, these materials travel to various parts of the body to facilitate imaging, treat cancer or relieve its symptoms. They put out radiation, mostly in the form of alpha and beta particles that target the affected areas. They are most often used in small amounts for imaging tests, but larger doses can be used to deliver radiation: American Cancer Society Radiation Therapy Principles.
[11] Alliance Radiopharmaceuticals Locations.

FIGURE 1

Location of the PET-CT scanning operations of Alliance and the RPUs of Erigal (UK only)



Source: CMA analysis.

2.8 In 2013, Erigal delivered approximately [✂] doses of FDG-18 from its three UK sites to a range of PET-CT scanning centres, including those operated by Alliance and a number of third parties.[12] As shown in Figure 2, approximately [✂] of Erigal's UK sales of FDG-18 were to Alliance's PET-CT scanning business in 2013. Other key customers included the Royal Marsden Hospital (Sutton) and the Christie NHS Foundation Trust (Manchester) as well as IBA's Guildford site, to which Erigal provided back-up.

[12] [✂]

FIGURE 2

Breakdown of Erigal's customer base for FDG-18, 2013

[✂]

Source: Alliance.

IBA and its operations

2.9 IBA[13] SA is a Belgian company listed on the Euronext stock exchange. It is focused on the development and production of cancer diagnostic products and treatment equipment, as well as the provision of radiopharmaceuticals and radiotherapy services.[14] It has operations across Europe and the USA and generated a turnover of €213 million in 2013.

2.10 In early 2012, IBA SA and a private investment firm, SK Capital, created a jointly-owned new company, IBA Pharma SA, derived from IBA SA's radiopharmaceutical division. IBA SA retained a 40% stake in the business, with SK Capital holding the remaining 60%. IBA Pharma SA trades as IBA Molecular. Prior to the transaction, its UK subsidiary, IBA Molecular UK, comprised two lines of business:

(a) the PET business, comprising two RPUs located at Dinnington in Yorkshire and Guildford in Surrey, and specialising in the production of FDG-18 and other radiopharmaceuticals for use in PET-CT scans carried out by hospitals or independent providers of PET-CT scanning services; and

(b) the SPECT[15] business which distributes a range of radiopharmaceuticals that are produced by IBA Molecular in France and are used for SPECT scans.

2.11 In this report, we use the term 'IBA's PET business' for IBA Molecular UK's FDG-18 activities prior to the acquisition.

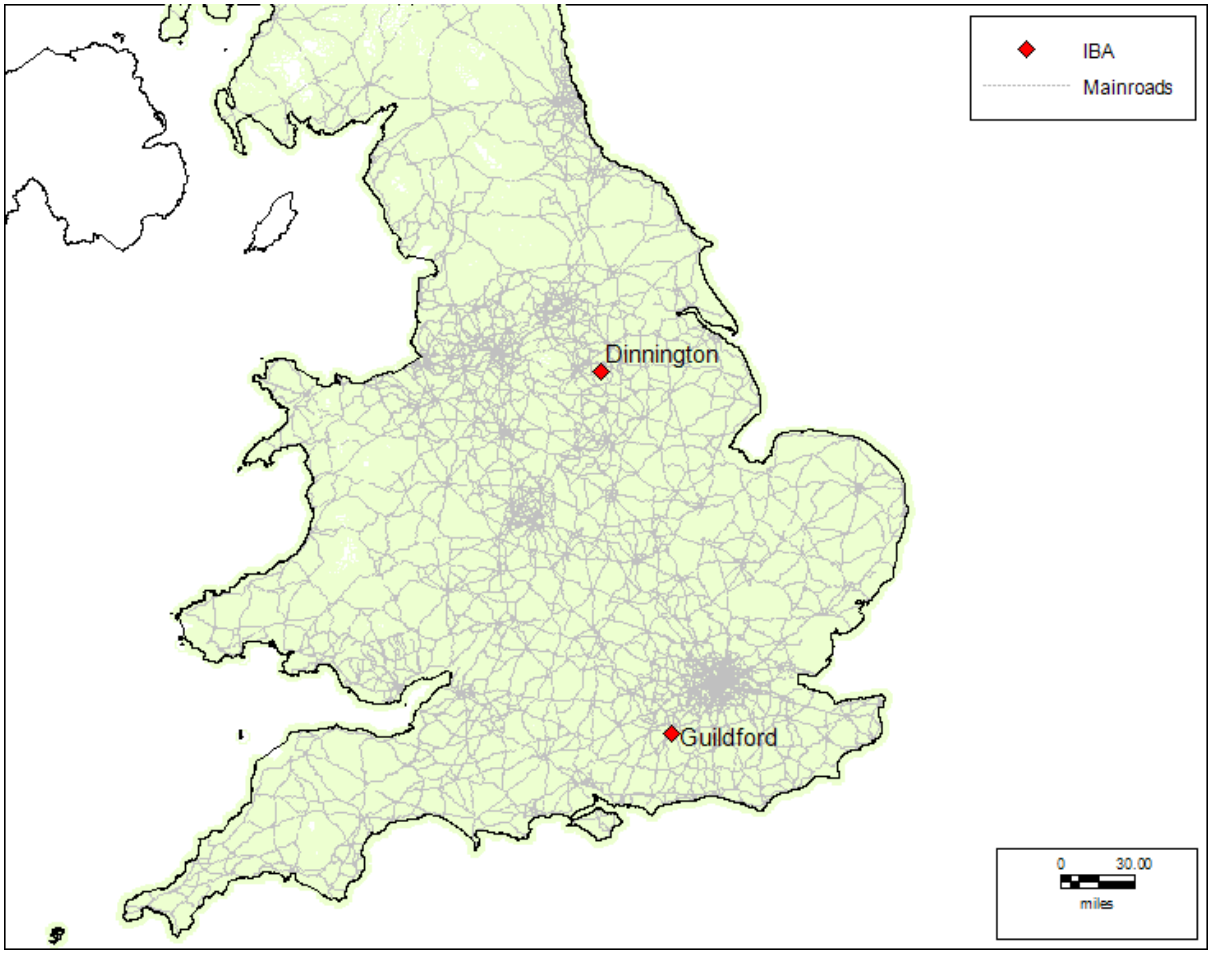
2.12 IBA Molecular UK opened its first site in Dinnington in August 2007. Its Guildford site was opened in February 2008, obtaining a full market authorisation[16] for the commercial supply of FDG-18 in May 2009. In October

[13] IBA stands for Ion Beam Applications.
[14] IBA SA both develops equipment for the production of radiopharmaceuticals and radiotherapy and provides consulting services to firms that acquire this equipment.
[15] Stands for single photon emission computed tomography.
[16] See paragraph 2.38 and Appendix D for more details on how the production of FDG-18 is regulated.

2010, the Dinnington site was mothballed[17] and whilst the majority of the equipment[18] remained on site, some was moved to provide spare parts for the Guildford site which has continued in operation. Figure 3 shows the location of the two sites.

FIGURE 3

Location of IBA's PET business's RPUs



Source: CMA analysis.

2.13 In year ended December 2012, IBA Molecular UK generated a turnover of £5.0 million and EBITDA losses of £[✂]. The revenue of IBA's PET business was £[✂] million and its EBITDA losses were £[✂]. Although IBA's PET business had experienced some growth in 2012, this was followed by the loss in June 2013 of a £[✂] contract to serve the Christie NHS Foundation Trust in

[17] The ceasing of production at an RPU. Reactivating a mothballed RPU takes between 18-24 months and involves considerable costs. In the context of the radiopharmaceutical industry, mothballing can be akin to exit. Mothballed RPUs still require regular inspections and maintenance, although some equipment may be removed from the site for use elsewhere.
[18] In particular the cyclotron. See paragraph 2.36 and Appendix C for a description of the FDG-18 production process and key equipment required.

Manchester.[19] More information on the financial performance of IBA's PET business can be found in Appendix B.

2.14 In 2012, Guildford produced approximately [✂] doses of FDG-18 for six main customers (and some smaller customers).

TABLE 3 **Number of FDG-18 doses supplied by IBA's PET business, by customer**

Customer	*2012*	*2013 (to September)*
Cambridge University Hospitals NHS Foundation Trust	[✂]	[✂]
Cobalt	[✂]	[✂]
Oxford University Hospitals NHS Trust	[✂]	[✂]
InHealth	[✂]	[✂]
Barts Health NHS Trust	[✂]	[✂]
Christie NHS Foundation Trust	[✂]	[✂]
Others	[✂]	[✂]
Total	[✂]	[✂]

Source: IBA Molecular.

Note: Transaction data submitted by IBA Molecular shows that in September 2013 Guildford also supplied small amounts of FDG to the following customers: Cancer Research UK, Central Manchester University Hospital, Clinical Imaging, Hammersmith Hospital NHS Trust, HCA International, Lister InHealth, Lodestone Patient Care, Royal Liverpool University Hospital, Royal Marsden NHS Foundation Trust, School of Medicine at Cardiff University, St Thomas' Hospital, Sussex Nuffield Hospital. [✂] doses were also delivered to the Royal Free Hospital.

Other industry players

2.15 Given the activities of the parties to the merger and possible merger effects that we have considered (see paragraph 6.2), this section provides a brief overview of industry participants involved either or both in the production of FDG-18 (and other relevant radiopharmaceuticals) and the provision of PET-CT scanning services.

PETNET

2.16 PETNET, a wholly-owned subsidiary of Siemens Medical Solutions USA Inc[20] (Siemens), manufactures and supplies products related to PET-CT scans, including equipment (in particular, cyclotrons and PET-CT scanners), FDG-18 and other radiopharmaceuticals, in a number of countries including the UK.[21] In Continental Europe PETNET supplies FDG-18 in France and Spain.[22]

2.17 In the UK, PETNET produces FDG-18 and other radiopharmaceuticals at its facilities at Nottingham City Hospital and Mount Vernon Hospital in Northwood

[19] The gross margin on the Christie contract was estimated to be approximately [✂]%, such that £[✂] of sales would have resulted in a net contribution to profits of around £[✂]. Therefore, the loss of the Christie contract would have reduced the EBITDA of the business by around £[✂] on an ongoing basis.
[20] A subsidiary of Siemens AG.
[21] PETNET Solutions Molecular Imaging.
[22] PETNET Brochure.

(north London), which it sells both to purchasers of Siemens scanners (which are sold by Siemens itself, rather than PETNET in the UK) and to customers who use scanners made by other manufacturers. It also provides ongoing maintenance and support to purchasers of Siemens scanners.

2.18 Approximately [✂]% of PETNET's UK revenue comes from sales of FDG-18. [✂]. It produced around [✂] FDG-18 doses in 2013.

2.19 Neither PETNET nor Siemens is currently involved in the provision of PET-CT scanning services.

GE Healthcare

2.20 GE Healthcare is a subsidiary of the General Electric Company. GE Healthcare is headquartered in the UK (Amersham)[23] and manufactures and supplies PET-CT scanners in the UK. It also has three cyclotrons in the UK, although currently only one of these is active. GE had previously supplied FDG-18 in the UK but it stopped in autumn 2009, when it began focusing on supplying less common radiopharmaceuticals based on Fluorine 18 radio-labelled compounds to research facilities. GE Healthcare supplies FDG-18 in Italy and Germany and PET-CT scanners throughout Continental Europe.[24]

2.21 GE Healthcare does not currently supply PET-CT scanning services.

Third party providers of PET-CT scanning services: InHealth, Cobalt and Paul Strickland Scanner Centre

InHealth

2.22 InHealth is a private company[25] which provides a range of diagnostic services (including MRI, CT and PET-CT scanning services) and managed patient services to NHS trusts.[26] It also supplies these services in the Republic of Ireland. InHealth provides fully integrated managed radiology services to [✂] NHS Trusts in the UK. In the financial year ended 30 September 2013, InHealth's turnover across all its operations in the UK and Ireland was £[✂].[27]

2.23 InHealth operates two static (Portsmouth and Nottingham) and [✂] mobile PET-CT scanners and performed [✂] PET-CT scans in 2013.

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[23] GE Healthcare History.
[24] 'PET & Molecular Imaging Europe 2010', Report by Medical Options, March 2011.
[25] InHealth Company Structure.
[26] Includes Foundation Trusts.
[27] InHealth's Statutory Accounts note that its revenue relates 'substantially' to its activities in the UK. No break-down is provided between revenues generated in the UK and the Republic of Ireland.

2.24 InHealth does not currently manufacture radiopharmaceuticals or scanning equipment.

Cobalt Unit Appeal Fund

2.25 The Cobalt Unit Appeal Fund (Cobalt) is a medical charity that provides diagnostic imaging services to the NHS and independent sector and funds and participates in research using PET-CT scanning, supporting local oncology services and providing training to healthcare professionals.

2.26 Cobalt operates a single static PET-CT scanner at the Cobalt Imaging Centre in Cheltenham. In FY13, it generated turnover of approximately £[✂] from PET-CT, [✂]. It performed around [✂] PET-CT scans in 2013.

2.27 Cobalt does not currently produce radiotracers or scanning equipment.

Paul Strickland Scanner Centre

2.28 The Paul Strickland Scanner Centre is a medical charity based at the Mount Vernon hospital (north London), with two static PET-CT scanners. In 2013, it provided around [✂] PET-CT scans to patients referred to it by 44 different hospitals.

Hospitals and research institutions

2.29 It is estimated by Alliance that 30 NHS Trusts provide PET-CT scanning in-house, having invested in one or several scanners and using NHS radiologists and other clinical staff to scan patients and interpret the results of the scans.

2.30 Eight of the NHS Trusts that provide PET-CT scanning in-house also produce their own FDG-18 using in-house cyclotrons or are provided with FDG-18 from cyclotrons operated by related universities. They are Edinburgh, Glasgow, Aberdeen, Newcastle, Cardiff, Guy's and St Thomas', UCL Hospitals and Birmingham.[28] There are also three research institutions that currently produce FDG-18 for their own research use: Imanova Limited, Wolfson Brain Imaging Centre (Cambridge) (WBIC) and Wolfson Molecular Imaging Centre (Manchester) (WMIC).

2.31 A small number of private hospitals, including HCA Wellington, Bupa Cromwell Hospital and the London Clinic, also carry out PET-CT scans in-house.

[28] This includes local universities (Birmingham University, Cardiff University, Edinburgh University and Newcastle University) that produce isotopes for their own use and for associated hospitals.

History of the industry and market trends

2.32 As explained in paragraphs 2.4 and 2.12, the parties' UK FDG-18 production units are all situated in England. In addition, although there were material volumes of FDG-18 supplied from England into Scotland in the past, this is not the case any more. The four hospitals in Scotland that offer PET-CT scanning services do so in-house and three of them produce FDG-18 for their own use, while the last one (Dundee) purchases small amounts of FDG-18 from Erigal's Preston RPU ([✂] doses in 2013). In Wales, only Cardiff hospital offers PET-CT scanning services and it produces FDG-18 for its own use.[29]

2.33 We have therefore primarily focused our analysis of the industry on England. Where appropriate, we make references to specific hospitals located in Scotland and Wales, to the extent that they may have an impact on the competitive constraints exerted by or on commercial suppliers for PET-CT scanning services and/or FDG-18.

Introduction

Product and service characteristics

2.34 PET-CT scans combine two types of scanning technology (a CT scan and a PET scan) and are used to diagnose a range of medical conditions, but predominantly for diagnostic purposes for a broad range of cancers. They can also be used to identify whether a cancer can be treated, how to treat it and whether cancer is responding to treatment. PET-CT scans can be provided using either a static or a mobile scanner. The former is permanently installed in a hospital or clinic, while the latter is installed in a 'trailer' and moved from site to site. More information on the technology used and the differences between statics and mobile scanners is provided in Appendix C.

2.35 FDG-18 is a glucose analogue with the positron-emitting radioactive isotope fluorine-18 substituted for the normal hydroxyl group in the glucose molecule. It is taken up by the high-glucose-using cells, such as the brain and kidney, as well as cancer cells. The positron emissions of the FDG-18 are detected by the PET scanner, which, in combination with the anatomical image created by the CT scanner, allows for precise and accurate anatomical localisation of biochemical activity in the body. There are a number of other radiopharma-ceuticals that can also be used with PET-CT scanning technology, all of which are also based on the fluorine-18 isotope. They include 18F-Choline (FEC)

[29] [✂] and Edinburgh obtain their back-up supplies from Erigal in Preston. They both told us that they did not have any alternative. [✂] does not have a back-up supplier, as it is located too far from other cyclotrons. Cardiff University received back-up supplies both from Erigal and IBA's PET business.

and 18F-Sodium Fluoride (NaF),[30] which are also used in the diagnosis of cancer.

2.36 Fluorine-18 isotopes are manufactured using a cyclotron,[31] and then combined with a variety of different substances to make the relevant radiopharmaceuticals, before being packaged and distributed to the PET-CT scanning centres. Due to the radioactivity of fluorine-18, cyclotrons need to be installed in concrete bunkers with walls of at least 2 metres of thickness. Their operation, maintenance and eventual decommissioning is also subject to a range of regulations.

2.37 More information on the F-18 radiopharmaceutical manufacturing process and equipment involved is provided in Appendix C.

2.38 The production of FDG-18 for medical use is subject to extensive regulation. The regulatory framework is described in Appendix D. The main relevant regulatory body is the Medicines and Healthcare products Regulatory Agency (MHRA). It is responsible for awarding licences to FDG-18 production facilities and for monitoring their compliance with the legal requirements set in the licence. To supply FDG-18 commercially, a producer needs a Manufacturer's and Importer's Authorisation (MIA) and a Marketing Authorisation (MA).[32] Different licences are required if the production of FDG-18 is intended for clinical trials or if it is intended for self-supply, ie hospitals (see paragraph 2.30) require a different licence from commercial suppliers. This is explained in Appendix D. We examine the implications of the licensing regime on the scope of the product market in Section 4.

2.39 The fluorine-18 isotope starts to decay from the point at which it leaves the cyclotron. FDG-18 has a half-life[33] of 110 minutes, which, together with clinical restrictions prohibiting the injection of more than 5 ml of solution containing FDG-18 into patients, means that FDG-18 must be used within 8 hours of being synthesised. Furthermore, a PET-CT scanning centre must use all FDG-18 contained within a single vial[34] within 4 hours of opening the vial. This short lifespan means that:

(a) Hospitals are unable to store FDG-18, instead requiring delivery of the radioisotope on a (very) regular basis. PET-CT scanning centres that

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[30] Prior to the transaction, Alliance produced both of these radiopharmaceuticals, namely [✂] doses of FEC and [✂] doses of NaF in 2013 (up to December 2013), but IBA supplied only [✂] doses of NaF, as back-up supplies (up to September 2013). We therefore focus this section on FDG-18 and only refer to FEC and NaF to a limited extent where it is necessary to draw distinctions between the products.
[31] Throughout this report, the term cyclotron refers specifically to cyclotrons that are used to produce radioisotopes for medical use.
[32] Each medicine requires a separate MA. See: MHRA website.
[33] The length of time in which levels of radioactivity drop by 50%. See Appendix C, Figure 4.
[34] Container used to transport FDG-18, which has a capacity of up to eight doses.

seek to scan patients in both morning and afternoon sessions will generally require two deliveries per day of FDG-18, one in the early morning and one around midday.

(b) The distance over which FDG-18 can be transported is limited.

2.40 FDG-18 is transported by specialist couriers, and therefore the cost of transport can be significant. Alliance estimated the cost of transport to be approximately £[✂] per mile[35] for each delivery, with a delivery containing up to eight doses, depending on the needs of the diagnostic centre. This compares with a current average selling price per dose of around £130 to £165.[36] In addition, as the tracer decays over time, a greater volume of the product must be supplied in order to produce the same number of doses for a hospital that is located further away from the RPU. In contrast, where the RPU is located on the same site as a hospital, these transport costs are avoided and there is minimal decay of the tracer between the point at which it is produced and the time of delivery. As a result, by itself, proximity to a hospital will give an FDG-18 producer a cost advantage in terms of supplying the hospital. PETNET highlighted that the theoretical capacity of its Nottingham site was lower than that of its Mount Vernon site because the customer base was more dispersed in the north of England such that the FDG-18 produced at Nottingham decayed to a greater extent during transport and therefore, on average, a greater volume needed to be delivered to each customer to achieve the same number of doses.

Economics of production

2.41 We received estimates of the cost of building an RPU and obtaining the necessary MHRA authorisations of between £4 million and £6 million: Alliance estimated that it would cost around £[✂] million for the construction of an RPU, although this figure did not include the cost of purchasing land/sites or of obtaining the MHRA authorisations.[37] PETNET estimated that the total cost of constructing a new RPU and obtaining the necessary MHRA authorisations would be between £[✂] million and £[✂] million. AAA[38] estimated that the cost of building an RPU on a greenfield site would be approximately €[✂] million, including the necessary authorisations, although AAA has not previously built such a site in the UK.

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[35] We have calculated an average transport cost of £1.9 per mile on the basis of transport cost data from the parties. We note that transport costs per mile vary substantially, therefore our calculation provides only a broad estimate.
[36] Appendix B sets out the average selling prices per dose achieved by IBA's PET business and Erigal.
[37] We note that the cost of these authorisations largely comprises those incurred in testing and validating the site and its production processes rather than direct fees related to the authorisations.
[38] A producer of radiopharmaceuticals in several European countries.

2.42 All three UK FDG-18 producers (Erigal, IBA Molecular UK and PETNET) indicated that, at site level, there were significant economies of scale in the production of FDG-18, with relatively high fixed costs and low variable costs. The effect of this can be seen in Erigal's financial results. For example, we have calculated that in FY13 Erigal's fully variable costs (direct costs of sales) accounted for approximately [✂]% of its total revenue, with semi-variable costs (ie labour and the maintenance of plant and equipment[39]) accounting for a further [✂]% of revenue. Hence, each additional £100 of sales contributes between £[✂] and £[✂] to operating profits, depending on the extent to which additional labour and equipment maintenance/replacement costs are incurred as a result of increased output.

2.43 Figure 4 illustrates the effect of site-level economies of scale on profitability at different production levels: our analysis shows costs and revenues, based on the FY13 financial results, ie actual revenues and costs incurred, for Erigal's Keele site.[40] This analysis assumes that labour and maintenance costs, as well as overheads, are broadly fixed for levels of production between [✂] and [✂] doses, ie up to [✂] firings per day. It excludes capital expenditure and/or depreciation expense.[41] The chart shows that site-level profits increase rapidly with additional doses once the break-even level of volume has been reached. For example, increasing the volume of doses sold from [✂] to [✂], ie by [✂]%, increases site-level profits by almost [✂]% (assuming constant prices[42]).

2.44 Our analysis of data provided by Alliance shows that, in addition to economies of scale at the level of an RPU, there are also group-level economies of scale arising from shared head office costs and the ability to provide internal back-up supply. When only site-level costs are taken into account, break-even for the Keele site is around [✂] doses, whereas if this site had to support the full head office costs of the Erigal business, it would need to sell approximately [✂] doses in order to break even. As the number of sites managed by a single head office increases, the break-even level of doses per site declines from around [✂] towards [✂] doses and the firm's profitability increases. This is shown in Figure 4, where the two sets of cost lines show site-level costs (lower lines) and site-level costs plus total group overhead (upper lines).[43]

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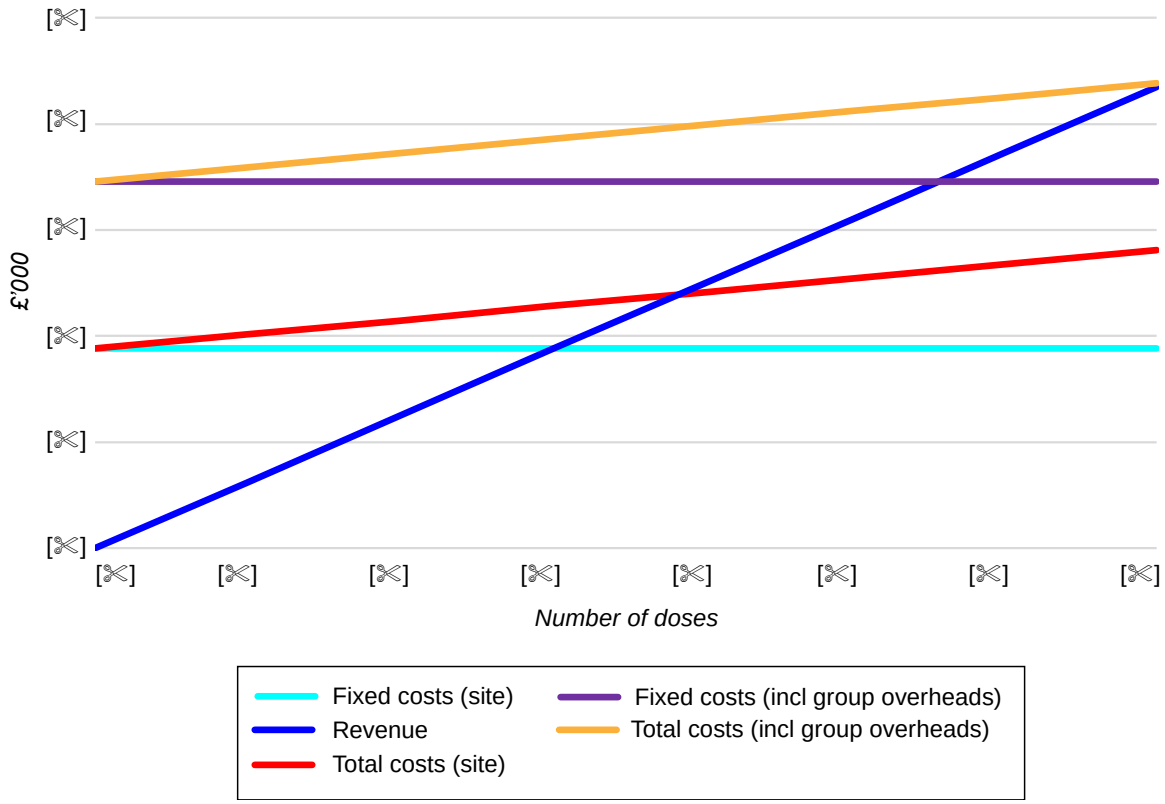
[39] We include total group capital expenditure in this maintenance cost.
[40] We selected the Keele site for this analysis as being broadly representative of Erigal's England-based RPUs.
[41] Information on capital expenditure by site was not available. However, total capital expenditure across four sites was £[✂] in FY13, which suggests an average site-level cost of around £[✂].
[42] This includes the assumption that prices are constant net of transport costs, ie transport costs are fully passed through to customers.
[43] In this latter case, all group overheads are allocated to a single site. As the number of sites managed under head office increases, the upper cost lines would decline towards the lower ones for each site within the group.

2.45 The impact of these economies of scale can be seen in the financial performance of IBA's PET business. IBA Molecular UK told us that its Guildford site was still (marginally) loss-making at around [✂] doses per year. We noted that this site *(a)* was achieving lower unit prices than Erigal's Keele site (about £[✂] per dose, compared with £[✂] for Keele) and *(b)* incurred material expense in sourcing back-up from Erigal under the 'Madrid agreement' (which is described in paragraph 2.76). As a stand-alone site (in England), it was not able to provide internal back-up and therefore sourced this externally.

FIGURE 4

CMA analysis of Erigal costs and revenues (Keele site), FY 2013



Source: Erigal financial information and CMA analysis.

2.46 FDG-18 is produced in batches, with each batch the result of a 'firing' of a cyclotron. The productive capacity of an RPU depends largely on the number of firings undertaken per day and the number of days per week the cyclotron is used. In addition, Alliance indicated that the type of synthesis unit used could influence the yield generated from each firing. Alliance told us that at current levels of yield (ie [✂]%),[44] and based on two firings per day, operating five days per week, 50 weeks per year, a cyclotron could produce approximately [✂] doses per year. PETNET told us that it typically ran [✂] FDG

[44] Alliance told us that the yield (ie proportion of the theoretical total output actually produced) achieved from a firing depended on a range of factors, including the type of synthesis unit used.

firings per day and then [✂] to produce different radiopharmaceuticals, such as NaF or Choline as demand required. IBA Molecular UK told us that its Guildford site operated [✂]firings per day (producing almost exclusively FDG-18 with most days having [✂] firings [✂])[45] and produced FDG-18 on Saturday for one of its customers. It estimated that the capacity of the Guildford site was between [✂] and [✂] (delivered) doses per year. As set out in detail in Appendix F, on the basis of this evidence, we considered that a commercial producer could sustainably operate three firings per day, five days per week and 50 weeks per year, which indicates that the six commercial cyclotrons in the UK have a total production capacity of around [120,000–130,000] (delivered) doses per year, based on the current pattern of supply from RPUs to diagnostic centres.[46] In theory, operating on the basis of four firings per day and six or seven days per week, this capacity could be increased by 30% or more. However, at the current time PET-CT scanning centres generally do not operate the evening or weekend sessions which would be required to accommodate four firings per day or weekend production.

2.47 Cyclotrons are subject to outages for either planned maintenance or due to unplanned failures. These outages represent a small proportion of the overall production (less than 5% in 2013). However, unplanned outages can cause significant disruption to patients through missed or delayed scans, and trigger a financial penalty for the provider of the PET-CT scanning service. Consequently, customers of FDG-18 require that 'back-up' arrangements are in place (that is, an alternative source of supply of FDG-18). This ensures continuity and security of supply. There are three types of back-up arrangement:

(a) self-back-up where a supplier uses another of its own cyclotrons for back-up;

(b) formal back-up arrangements with other FDG-18 producers – this involves contracts entitling the purchaser to supplies of FDG-18 from other producers; and

(c) spot back-up arrangements when an outage leads to a request for short-term supplies from one supplier to another.

[45] Only a small number of florbetaben batches (not more than ten) would have been manufactured in a given year for research and development purposes.
[46] As set out in more detail in Appendix F, the capacity, in terms of delivered doses, of an RPU depends on the geographic distribution of its customers. If customers are relatively close to the RPU, it will have a greater productive capacity than if they are further away due to the radioactive decay of the product during delivery.

2.48 Purchasers of FDG-18 generally require their suppliers to organise back-up themselves and do not contract separately for primary and back-up supplies. Some PET-CT scanning providers, such as [✂] and Central Manchester University Hospitals Foundation Trust,[47] have a dual-sourcing strategy for the primary supply of FDG-18.

Development of the industry

2.49 Cyclotrons were first installed in universities and teaching hospitals,[48] the first one being installed at Hammersmith Hospital in the 1960s. PET-CT scanning is a relatively new technology which was first used commercially in 2000.[49] The first commercial cyclotron to become operational was at PETNET's Mount Vernon RPU (in Northwood), which became operational in 2002.

2.50 In October 2005, the Department of Health published a framework for the development of PET services in England (the 2005 framework).[50] By then, there were 13 PET-CT scanning facilities[51] in England, two of which were owned privately, and six NHS PET-CT scanning facilities were under development. There were seven operational cyclotrons and a further six under development. The report identified that provision should be made for around 40,000 scans per year across England and that a throughput of 2,000 to 2,500 scans per year for individual scanners was a reasonable assumption. The report also estimated that a total of around six cyclotron facilities might, theoretically, be sufficient to cover the clinical requirements of England, if appropriately located (ie in optimum locations relative to PET-CT scanning centres) and that consideration should be given to the establishment of cyclotron services functioning on commercial principles to supply several PET scanning facilities.

2.51 In order to realise the strategy set out in the 2005 framework, the NHS tendered for the provision of PET-CT scanning services in July 2006. Two five-year contracts (which were later extended for a further two years to 31 March 2015) commenced in April 2008:

(a) The PET-North contract, awarded to Alliance, currently provides for four static scanning facilities and five mobile units. As at 2012/13, the contract was estimated by NHS England to be delivering 11,609 PET-CT scans and to have an annual value of £13 million.

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[47] This Trust includes the Manchester Royal Infirmary hospital.
[48] The term includes university hospitals.
[49] Source: Siemens website.
[50] Department of Health PET Framework.
[51] Two of which were PET facilities in the process of being replaced by PET-CT facilities.

(b) The PET-South contract, awarded to InHealth, currently provides for one static facility and 12 mobile units. As at 2012/13, the contract was estimated by NHS England to be delivering 11,619 scans and to have an annual value of £13.3 million.

2.52 The 2005 framework document was followed by the expansion of FDG-18 supply by the commercial sector. Between 2006/07 and 2009/10, the number of cyclotrons supplying FDG-18 commercially increased from two to eight, with GE Healthcare, IBA Molecular UK, PETNET and Erigal all investing in new facilities.

2.53 However, Alliance and IBA Molecular UK told us that the firms had anticipated more rapid growth in PET-CT scanning and, therefore, forecast higher demand for FDG-18 than had actually materialised.

2.54 The period of expansion of FDG-18 production capacity was followed by a period of contraction, with GE Healthcare refocusing its Amersham-based cyclotron on the production of fluorine-18 isotopes for research purposes in 2009[52] and IBA Molecular UK mothballing its Dinnington site in 2010, following the loss of a significant contract in Glasgow and in light of limited business development opportunities in the North of England. The number of cyclotrons producing FDG-18 commercially has remained stable, at six, since then.

TABLE 4 **Details of commercial cyclotrons operating in England**

Company	*Location of site*	*Year of opening*	*Current status*
PETNET	Mount Vernon	2001/02	Operational
Erigal	Keele	2005	Operational
PETNET	Nottingham	2007	Operational
IBA Molecular UK	Dinnington	2007	Mothballed
GE Healthcare	Amersham	2007	Used for other purposes
Erigal	Preston	2008	Operational
Erigal	Sutton	2009	Operational
IBA Molecular UK	Guildford	2008	Operational

Source: PETNET, Alliance, IBA Molecular and GE Healthcare company information.

2.55 Price levels and price trends have been consistent with a situation of excess capacity in an industry characterised by high fixed costs. IBA told us that prices were significantly lower than had been anticipated and much lower than elsewhere in Europe.[53] This view was echoed by Erigal in a strategy document [✂]. Cobalt told us that the market for FDG had plateaued and the price had gone as low as it possibly could. In the past it had been as high at £370 per dose and £[✂] was as low as it had ever gone. Cobalt believed that there

[52] GE Healthcare still holds an FDG marketing authorisation as it has other tracers in production, [✂].
[53] IBA Molecular UK told us that its initial business plan had been based on a price of £[✂] per dose, whereas by 2013 it was achieving a price of £[✂] per dose.

might be a small increase in the future. Figure 5 shows that prices more than halved since 2007, with a sharp decline between 2007 and 2010, followed by a stabilisation of prices.

FIGURE 5

Estimated FDG-18 dose prices

[✂]

Source: PETNET (2014 budget). Average selling price per delivered dose.

2.56 [✂] highlighted that prices in Great Britain were significantly below the levels achieved in the Republic of Ireland where there was a single commercial cyclotron in operation. [✂] A Medical Options report noted that the mean cost of FDG-18 across Europe was €[✂] per dose in 2012.[54] However, both AAA and IBA indicated that prices were declining across much of Europe. AAA noted that it was aware of a cyclotron operating in Paris that was achieving prices of €[✂] per dose, which AAA considered to be an unsustainably low price.

Supply and demand balance in England at the time of the acquisition

2.57 At the time of the acquisition, there had been significant growth in demand for FDG-18 for PET-CT scanning. Table 5 shows the FDG-18 doses supplied by the three commercial suppliers over time.

TABLE 5 **Production of FDG-18, by supplier**

Delivered doses

Supplier	*2008*	*2009*	*2010*	*2011*	*2012*	*2013*
Erigal	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]
IBA's PET business	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]
PETNET	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]
Total	-	-	-	[60,000–70,000]	[70,000–80,000]	[70,000–80,000]

Source: Data provided by the parties and CMA calculation.

Note: The Dinnington cyclotron closed in November 2010. IBA data from 2011 includes only deliveries from Guildford. Data per calendar year. IBA data for 2013 is until September 2013. PETNET and Alliance data is until December 2013.

2.58 As set out in paragraph 2.46, the six operational commercial cyclotrons in the UK have a total production capacity of approximately [120,000–130,000] doses per year on the basis of operating three firings per day, five days per week. At this level of production, the industry is characterised by significant spare capacity.

[54] Medical Options, 2013.

2.59 In addition to the commercial cyclotrons, there are 12 cyclotrons owned and operated by NHS Trusts (and/or universities) in the UK (see paragraph 2.30), ten of which are full-scale cyclotrons, with two being 'desktop' facilities.[55] In theory, ten of these cyclotrons have a similar capacity (each) to those run by the commercial operators. However, there are three factors which currently limit the impact of this additional capacity on competition:

(a) These cyclotrons are not currently able to supply FDG-18 outside the NHS Trust which operates them, as they do not hold a marketing authorisation (MA), which is necessary to supply FDG-18 commercially (see Appendix D, paragraphs 5 and 6).

(b) It is unclear whether the NHS Trusts are prepared to maintain third party commercial delivery schedules given their primary requirement to use the cyclotrons for research purposes.[56]

(c) Many of these cyclotrons are located a significant distance from the majority of PET-CT scanning centres in the UK, for example three of them are in Scotland (Aberdeen, Glasgow and Edinburgh).

2.60 In spite of the rapid growth in demand, the rate of PET-CT scanning per head of population in the UK remains at around half the average for EU countries.

2.61 Medical Options[57] noted that as of 2013 there had been growth in the use of other tracers, particularly FEC where available. It estimated that around 15 sites used FEC on a regular basis.

2.62 Both Erigal and PETNET produce small quantities of FEC and NaF, while IBA's Guildford site did not produce either but procured doses from other suppliers as needed.

Future developments

2.63 According to Medical Options, there is no reason to believe that the UK will change from a low number of PET-CT scans per head to a high number of PET-CT scans per head, but nevertheless it anticipates that the number of scans would grow at an annual rate of 11% in the period to 2017. InHealth told us that the PET-CT scanning market had grown by around 10% over the last three years. It expected the overall growth in radiology services to

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[55] 'Desktop' cyclotrons are smaller and less powerful than ordinary cyclotrons and, consequently, they have a lower productive capacity, of around 2,000 doses per year. Aberdeen and Newcastle have installed desktop cyclotrons.
[56] This is discussed further in paragraph 4.14.
[57] A market research company specialising in pharmaceuticals and medical devices and equipment. See *PET & Molecular Imaging Europe*, 2013.

continue at around 10% year on year in light of the population increase, the ageing of the population and the application of PET-CT scanning to conditions other than cancer, such as Alzheimer's diagnosis. A 10% increase in the number of scans needed not necessarily lead to a 10% increase in the number of FDG doses required. Improvements in technology and clinical developments in other European countries had led to dose reductions, but for these practices to be introduced here would require cooperation between equipment manufacturers and the clinical community.[58] Alliance told us that increasing cancer prevalence, greater acceptance and applications of PET-CT scans and increasing private sector ownership of PET-CT technology suggested that EU volumes would continue to grow at around [✂]% per year, with UK growth outpacing the European average due to the UK's current lower levels of usage of PET-CT scanning. Alliance highlighted that UK growth was likely to be supported by a focus from the NHS to increase PET-CT availability and suggested that a growth rate of between [✂] and [✂]% per year may apply. IBA Molecular estimated that the market for FDG-18 would be around [✂] doses in 2014 and [✂] doses in 2015. PETNET estimated that the total market for FDG-18 would be around [✂] doses in 2014 and [✂] doses in 2015.

2.64 On the basis that demand for FDG-18 is forecast to grow at around 10% per year, we consider that the industry may experience capacity constraints within the next five years. In addition, we consider that the distribution of productive capacity, and demand for other radiopharmaceuticals, may mean that new investment will be needed in certain areas before all cyclotrons are fully utilised. For example, [✂].

2.65 The FDG-18 producers have expressed varying views on the likely development of the price of FDG-18 over the next few years. PETNET predicted that prices were likely to decline slightly in 2014/15 and then remain broadly stable, while Alliance noted that capacity constraints could result in upward pressure on prices.

2.66 Several operators highlighted the development of new radiotracers and therapeutic radioisotopes[59] as a key opportunity for the industry. AAA told us that it did not consider the production of FDG-18 to be a profitable activity on a stand-alone basis but only in conjunction with the production of new tracers and therapeutic radioisotopes which offered higher margins than FDG-18. AAA highlighted that its main commercial focus was on the production and distribution of these isotopes. IEL (a subsidiary of AAA) suggested that FDG-

[58] InHealth hearing summary.
[59] These are radioisotopes that are used to treat rather than just diagnose cancers.

18 would decline in relative importance over the next ten years as new tracers were developed which targeted specific cancer types. However, it noted that by producing FDG-18, operators could build distribution channels which could then be used for these higher-margin products.

2.67 Alliance identified growth in demand for FEC and tracers for the treatment of dementia (known as Alzheimer's tracers), as well as technetium, as opportunities for increasing output and thereby profitability over the next few years. The status of these developments is as follows:

(a) Diagnostic tests for Alzheimer's are being developed by three pharmaceutical companies, each using a different tracer: GE Healthcare is using flutemetamol, Eli Lilly is using florbetapir and Piramal is using florbetaben. Each one of them has subcontracted the production of their chosen tracer in the UK: GE Healthcare has appointed Erigal, Eli Lilly has appointed PETNET and Piramal has appointed IBA Molecular UK.[60]

(b) The mostly commonly-used radioisotope is technetium-99, which has a half-life of 6 hours and is detected with a gamma camera (rather than a PET scanner). Approximately 500,000 to 600,000 doses of technetium are used each year in the UK for the imaging of bones, blood and other organs. These volumes are currently sourced from a small number of nuclear reactors worldwide, including the Chalk River nuclear reactor in Canada. However, this reactor is due to close in the second half of 2016, with a potential global shortage of molybdenum (from which technetium is produced) as a result.[61] Several alternative potential sources of technetium are being considered, one of which is to use (more powerful) cyclotrons to produce technetium (directly).[62]

2.68 The prices paid for certain non-FDG tracers [✂]

The supply chain and procurement

The supply chain

2.69 As explained in paragraphs 2.22 to 2.31, there are three types of providers of PET-CT scanning services: NHS Trusts, private hospitals and independent providers (of which there are currently four: Alliance, Cobalt, InHealth and the Paul Strickland Centre[63]). The independent providers offer their services

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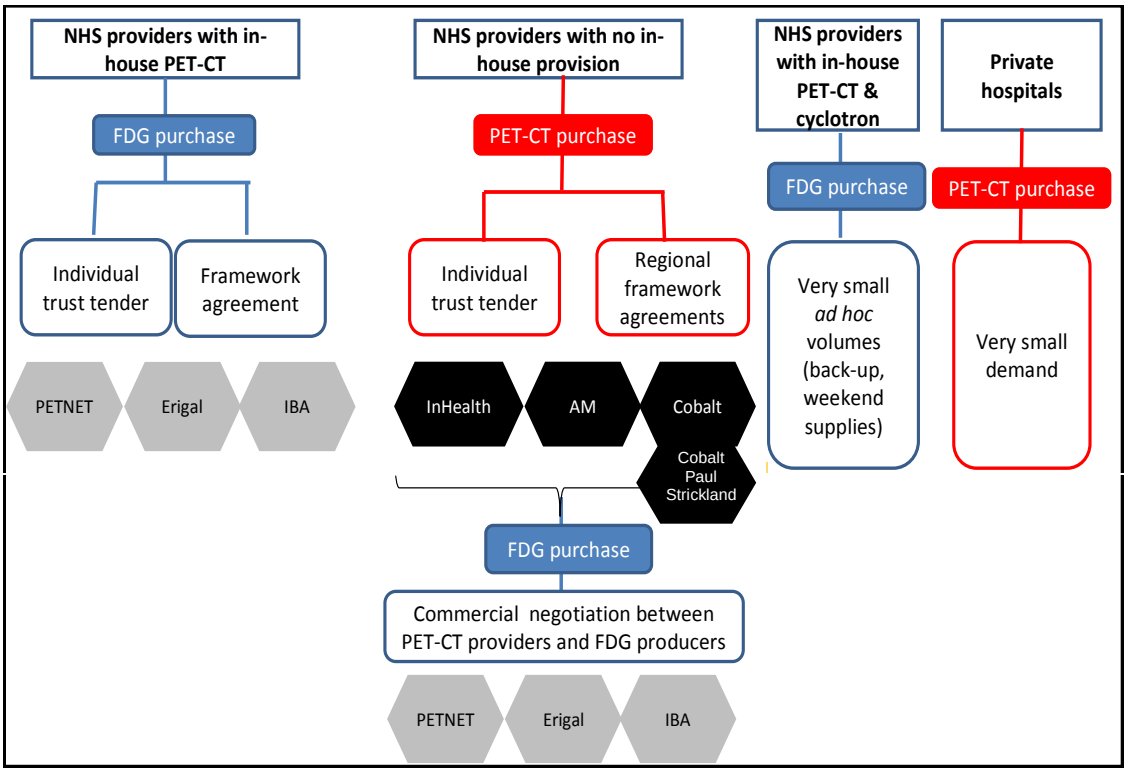
[60] [✂]
[61] OECD Report.
[62] Physics World.
The Paul Strickland Centre is located on the same site as one of PETNET's RPUs (Mount Vernon hospital) and sources all its FDG-18 from PETNET.

either under the umbrella of the two NHS contracts (PET-North and PET-South) or under contracts with individual NHS Trusts (or regional groups of NHS Trusts). The private hospitals offer PET-CT scanning services directly to their patients, who fund treatment themselves or through a private medical insurance policy. The suppliers of PET-CT scanning services (whether hospitals or independent providers) in turn either source supplies of FDG-18 from a third party (Erigal, the IBA operation or PETNET) or from their own cyclotron or cyclotron owned by an affiliated organisation (which in the case of hospitals may be a co-located university/research centre and in the case of Alliance is Erigal).

2.70 Figure 6 summarises the above relationships.

FIGURE 6

Supply arrangements for PET-CT scanning services and FDG-18



Source: Adapted from chart provided by Alliance.
Note: AM = Alliance.

2.71 Of the suppliers of FDG-18, IBA's PET business was the only one that had no links with operations at other levels in the supply chain. Erigal was owned by a supplier of PET-CT scanning services, while PETNET was owned by a supplier of PET-CT scanning equipment and cyclotrons.

Contractual arrangements

2.72 The PET-North and PET-South contracts ran for an initial period of five years and were extended for another two years to March 2015. NHS England is currently re-procuring PET-CT supplies for a substantial part of England[64] for the next ten years (as explained in Appendix E, paragraphs 25 to 30), which are intended to be for a duration of ten years. The duration of other PET-CT scanning contracts on which we have information varies from 3.5 years to 10 years. We understand that such contracts do not include any requirements relating to FDG-18.

2.73 The supply of FDG-18 to hospitals is carried out under a range of contractual arrangements, of which there are three main categories:

(a) two- to three-year contracts awarded by individual hospitals or other third party suppliers of PET-CT scanning services;[65]

(b) framework agreements, setting out the terms and conditions under which specific purchases can be made throughout the term of the agreement (where buying groups run tenders on behalf of groups of hospitals, eg the framework run by HTE), which tend to be for a similar duration to contracts entered into with individual hospitals; and

(c) long-term exclusive agreements between an operator of a cyclotron and the hospital at which the cyclotron was built. There are four of these agreements – between Alliance and the hospitals at its Sutton and Preston sites and between PETNET and the hospitals at its Mount Vernon and Nottingham sites.[66] Under such contracts, the hospital buys all its supplies from the co-located supplier but the supplier is able to sell some of its production to other hospitals.

2.74 Contracts for the supply of FDG-18, whether between commercial providers of PET-CT scanning or NHS Trusts, and the FDG-18 manufacturers tend to specify the price per dose, delivery costs and quality/reliability requirements but they do not contain volume commitments.[67]

2.75 [✂][68]

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[64] Excluding the London area.
[65] CMA assessment based on contracts submitted by Alliance Medical.
[66] CMA assessment of the contracts submitted by Alliance Medical.
[67] In some cases, a schedule of prices is set out depending on the quantity of FDG purchased over the course of a year.
[68] [✂]

2.76 As explained in paragraph 2.47, there are three different types of back-up arrangements. In particular, following the closure of Dinnington, IBA Molecular UK put in place a formal reciprocal back-up agreement (referred to as the Madrid Agreement) with Erigal, which included the following provisions (among others):

(a) IBA Molecular UK could call on Erigal to supply up to [✂]% of its customer requirements; and

(b) if IBA Molecular UK did call for back-up supply for an individual customer but did not take the full [✂]% of the volume, it had to pay Erigal [✂].

Approaches to procurement

2.77 Due to the relatively small number of NHS contracts (once Trusts which self-supply FDG-18 are excluded) and the multi-year nature of many of the agreements, there is a relatively small number of contracts tendered each year. The information provided by Alliance showed that there had been ten tenders in the four years to December 2013.

2.78 Tenders for FDG-18 contracts by NHS Trusts usually follow formal public procurement procedures,[69] with clear criteria given for the awarding of the contracts. However, there are no standard criteria or weightings, with different customers weighting the various criteria differently. These criteria include price and reliability as a minimum, with other factors taken into account to a greater or lesser extent. In the tender documents we were able to review, price was accorded a weight of between 33 and 55%. None of the tender documents we saw suggested a preference for a specific type of back-up arrangement (ie self-back-up or third party back-up). More information on the tender documents we reviewed is provided in Appendix F.

2.79 Cobalt and InHealth seek quotes from suppliers on a less structured basis. Cobalt told us that it held an initial meeting with suppliers in which it outlined its requirements, and then obtained formal quotes. Its assessment took account of the price quoted, number of manufacturing sites, location of manufacturing sites, back-up agreements with other providers, the ability to provide new tracers and the willingness to work with Cobalt to support the development of its PET/CT scanning services, which was generally achieved

[69] Public procurement processes for FDG-18 contracts (including framework agreements) above relevant financial thresholds and awarded by NHS hospitals or NHS buying groups are governed by the Public Contracts Regulations 2006. The current threshold is £111,676. The Public Contracts Regulations 2006 govern the stages of the procurement process, including the publication of a contract notice in the *Official Journal of the European Union*, the submission of tenders, evaluation of bids and the award decision. This is with a view to public procurements complying with the principles of transparency, proportionality, equal treatment and non-discrimination. Contracts are awarded on the basis of the lowest price offered or the most economically advantageous tender.

through educational programmes with referring clinicians. It told us that suppliers were then selected on the basis of cost, back-up and reliability.

2.80 InHealth told us that reliability of FDG-18 supply was a key criterion in tenders for both providers of FDG-18 to NHS hospitals which operated their own in-house PET-CT services and in tenders for third parties to provide outsourced PET-CT services to NHS hospitals. It highlighted that, although there was no direct legal requirement to contract with two FDG-18 suppliers, it considered that there was a practical need to do so in order to reduce the risk of back-up arrangements failing. [✂]

3. The merger and relevant merger situation

Outline of the merger situation

3.1 Alliance first approached IBA Molecular UK in July 2012 to enquire about the possibility of obtaining supplies of FDG-18 from the Dinnington site. This was motivated by Alliance's concerns regarding the financial situation of Erigal (see paragraph 2.5). Alliance told us that IBA Molecular UK confirmed that it could supply from Dinnington, but only if it received committed orders, which Alliance was not prepared to offer. Alliance told us that by December 2012 it had become concerned about IBA Molecular UK's commitment to FDG-18 production and started negotiating a deal that would involve Alliance acquiring IBA's PET business in return for Alliance switching its FDG-18 purchases in Europe to IBA Molecular. Although issues relating to Erigal were resolved, Alliance decided that the proposed deal with IBA Molecular UK was still strategically desirable and signed a Business and Asset Sales Agreement on 24 June 2013.

3.2 Under the Business and Asset Sale Agreement, IBA Molecular UK sold the following assets for a purchase price of €[✂] million (or £[✂] million), [✂]:

(a) IBA Molecular UK's two RPUs (at Guildford and Dinnington), including the cyclotrons and other fixed equipment;

(b) business records;

(c) certain supply contracts; and

(d) four customer contracts for the supply of FDG-18.[70]

[70] (1) Barts and London NHS Trust, (2) Cambridge University Hospitals NHS Foundation Trust, (3) Cobalt Unit Appeal Fund and (4) Oxford University Hospitals NHS Trust. We understand that a fifth contract, with InHealth, expired shortly prior to the transaction. However, supply arrangements were continued through the Guildford

In addition, eight employees were transferred with the business. We refer to this acquisition package as the IBA operation.

3.3 Alliance and IBA molecular completed the transaction on 16 September 2013.

3.4 On the same date as the completion of the sale of the IBA operation to Alliance,[71] IBA Molecular and Alliance also entered into a [✂] framework supply agreement for the former to have exclusive rights to supply the latter (and its affiliates) in Italy, Spain and Germany with FDG-18.[72] [✂][73]

3.5 [✂][74]

3.6 SK Capital told us that while the two agreements were signed at the same time, the terms in each case were effectively arm's length [✂].

Rationale for the merger

3.7 Alliance told us that there were two key elements to its strategic rationale for acquiring the IBA operation:

(a) to ensure a secure supply of FDG-18 for its PET-CT scanners, thereby enhancing its competitiveness in both the supply of FDG-18 and of PET-CT scans; and

(b) [✂].[75]

3.8 Regarding the first rationale, it noted that the supply of FDG-18 was financially unattractive and that the industry suffered from overcapacity. It also explained that operators of PET-CT scanners placed significant weight on reliability of supply when choosing a supplier of FDG-18. It argued that the ability to rely on one's own facilities to provide back-up doses in cases of outages was important and a differentiating factor in winning contracts. The acquisition of the Guildford RPU, in combination with its existing Sutton site, would therefore give it a competitive advantage as supplier of FDG-18, but also as a supplier of PET-CT scanning services.

RPU site. We therefore consider arrangements with InHealth as part of the 'IBA operation'. Although the customer contracts were part of the assets sold to Alliance, the customers were not bound to accept supply from Alliance and were able to renegotiate these agreements if they wished to do so, since the transaction was not a share transfer. Under the Business and Asset Purchase Agreement, the parties were under an obligation to use reasonable endeavours to novate the contracts. We understand that the [✂].

[71] We note that Alliance acted through its newly-created and wholly-owned subsidiary Alliance Medical Molecular Imaging Limited. The framework supply agreement was signed on 16 September 2013.

[72] Alliance initial submission, paragraphs 1–4.

[73] The agreement included provisions regulating how these prices would change over the course of the supply agreement in response to changes in costs etc.

[74] Alliance initial submission, paragraphs 113–121.

[75] ibid, paragraphs 6–15 & Annex 2.

3.9 Internal Alliance documents provided supporting evidence for its stated strategic rationale, highlighting the risks (in terms of surety of supply) associated with the potential exit of IBA Molecular UK from the supply of FDG-18, as well as the potential for incremental profit if Alliance were able to win the PET-South contract from InHealth, as a result of acquiring the IBA operation.

3.10 We noted, however, that while some internal documents identified security of FDG-18 supply as a rationale, the acquisition of the IBA operation could result in Alliance winning PET-CT business away from InHealth for other reasons. We also noted that PETNET was able to provide back-up for its customers in the South (some of which are part of InHealth's PET-South contract, whilst other hospitals in the South purchase directly from it) from its Nottingham site which is only 30 minutes closer to London than Erigal's Keele facility. PETNET also expressed the view that, based on its experience of distributing FDG-18 within Great Britain, Erigal should be able to provide the same level of back-up in the South from this (Keele) site as PETNET did from its Nottingham site.

3.11 In addition, we found that a strategy document prepared shortly after agreeing the transaction with IBA Molecular (and prior to completion) noted that [✂]. In another document, the IBA operation acquisition was expected to provide opportunities for '[✂]'.

3.12 [✂]

3.13 As cyclotrons produce radioactive material, they must be housed in concrete bunkers with 2-metre-thick walls. [✂][76,77]

3.14 [✂][78]

3.15 [✂][79]

3.16 [✂][80]

3.17 SK Capital told us that it viewed the transaction as a means of facilitating the disposal of an unprofitable business, [✂]. It emphasised that the UK PET business was very small in the context of its overall business and it continued to lose money despite several commercial initiatives to improve performance

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[76] [✂]
[77] [✂]
[78] Alliance initial submission, Annex 2, paragraph 29.
[79] [✂]
[80] [✂]

and, therefore, SK Capital did not consider that it was worth investing significant additional management time in seeking to improve its performance. SK Capital, in its June 2013 overview of the transaction for board approval, assessed the overall benefits of the transaction and supply agreement, which were expected to translate into €[✂][81] upon closing of the sale and an estimated €[✂] benefit for IBA Molecular per year.

Jurisdiction

3.18 Under section 35 of the Act and our terms of reference (see Appendix A), we are required to report on whether a relevant merger situation has been created.[82]

3.19 The concept of a relevant merger situation has two principal elements set out in section 23 of the Act, namely that the transaction structure is one which involves two or more 'enterprises ceasing to be distinct' and that either the 'turnover test' or the 'share of supply test' is satisfied.

Enterprises ceasing to be distinct

3.20 The Act defines an 'enterprise' as 'the activities or part of the activities of a business'.[83] The CMA's Merger Assessment Guidelines (the Guidelines)[84] state that in making a judgement as to whether or not the activities of a business, or part of a business, constitute an enterprise under the Act, the CMA will have regard to the substance of the arrangement under consideration, rather than merely its legal form. An enterprise may comprise any number of components, most commonly including the assets and records needed to carry on the business, together with the benefit of existing contracts and/or goodwill. In some cases, the transfer of physical assets alone may be sufficient to constitute an enterprise, for example where the facilities or site transferred enable a particular business activity to be continued. The basis on which the CMA decides whether the business or assets constitute an 'enterprise' may vary from case to case depending on, for example, the industry in question. The transfer of customer records and the application of the TUPE Regulations can be important in assessing whether an enterprise has been transferred.[85]

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[81] [✂]
[82] If so, we are required to then consider whether the creation of that situation has resulted, or may be expected to result, in a substantial lessening of competition in any market or markets in the UK for goods or services (see paragraph 1.3).
[83] Section 129(1) of the Act.
[84] *CC2*, paragraphs 4.6–4.8.
[85] Transfer of Undertakings (Protection of Employment) Regulations 2006 (SI 2006/246). The effect of this is that employee contracts take effect as if originally made with the purchaser.

3.21 The sales package sold by IBA Molecular UK to Alliance is described in paragraph 3.2 and comprised operational facilities, certain supply contracts, employees and customer contracts. Under the Business and Asset Sale Agreement, the IBA operation was transferred by way of a 'going concern' and by way of 'relevant transfer' for the purpose of TUPE regulations.

3.22 Taking these elements together, we are satisfied that the combination of assets transferred enables the business activity, namely the manufacture and supply of FDG-18, to be carried on and therefore constitutes an 'enterprise' for the purposes of the Act.

3.23 The concept of 'ceasing to be distinct' is described in section 26 of the Act. This provides that any two enterprises cease to be distinct if they are brought under common ownership or common control.[86] This remains true regardless of whether or not the business to which either of them formerly belonged continues to be carried on under the same or different ownership or control.

3.24 The transaction brought under the common ownership of Alliance two enterprises which were previously separate.

3.25 We are satisfied that Alliance and the IBA operation have ceased to be distinct as a result of the transaction described in paragraphs 3.2 and 3.3.

Turnover test/share of supply test

3.26 The turnover test is satisfied where the value of the turnover in the UK of the 'enterprise being taken over exceeds' £70 million.[87] The turnover for the IBA operation for the financial year ending March 2012 was £[✂] million, so the turnover test is not met. We therefore considered the share of supply test.

3.27 The share of supply test is satisfied where, as a result of enterprises ceasing to be distinct, at least one-quarter of goods or services of any description which are supplied in the UK, or in a substantial part of the UK, are supplied either by or to one and the same person.[88] The merger must result in an *increase* in share of supply of goods or services of a particular description and the resulting share must be 25% or more.

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[86] 'Control' is not limited to the acquisition of outright voting control but may include situations falling short of outright voting control. Section 26 of the Act distinguishes three levels of interest (in ascending order): (i) material influence; (ii) de facto control; and (iii) a controlling interest (also known as 'de jure', or 'legal' control). Since the circumstances of the present case fall within 'common ownership', we have not considered the issue of 'control' further.
[87] Section 23 of the Act.
[88] Section 23(3) & (4) of the Act.

3.28 The concept of goods or services of ‘any description’ is very broad. The CMA is able to measure shares of supply by reference to such criterion (whether value, cost, price, quantity, capacity, number of workers employed or some other criterion, of whatever nature), or such combination of criteria as the CMA considers appropriate.[89] The Act gives the CMA discretion to consider forms of supply separately or in combination (whether as a whole or taken in groups) and to consider whether transactions differ as to their nature, their parties, their terms or the surrounding circumstances.[90] In each case, the criteria are to be such as the CMA considers appropriate in the circumstances of the case.[91] The description of goods or services identified for the purposes of the jurisdictional test does not have to correspond with the economic market definition adopted for the purposes of the determining the competition test.

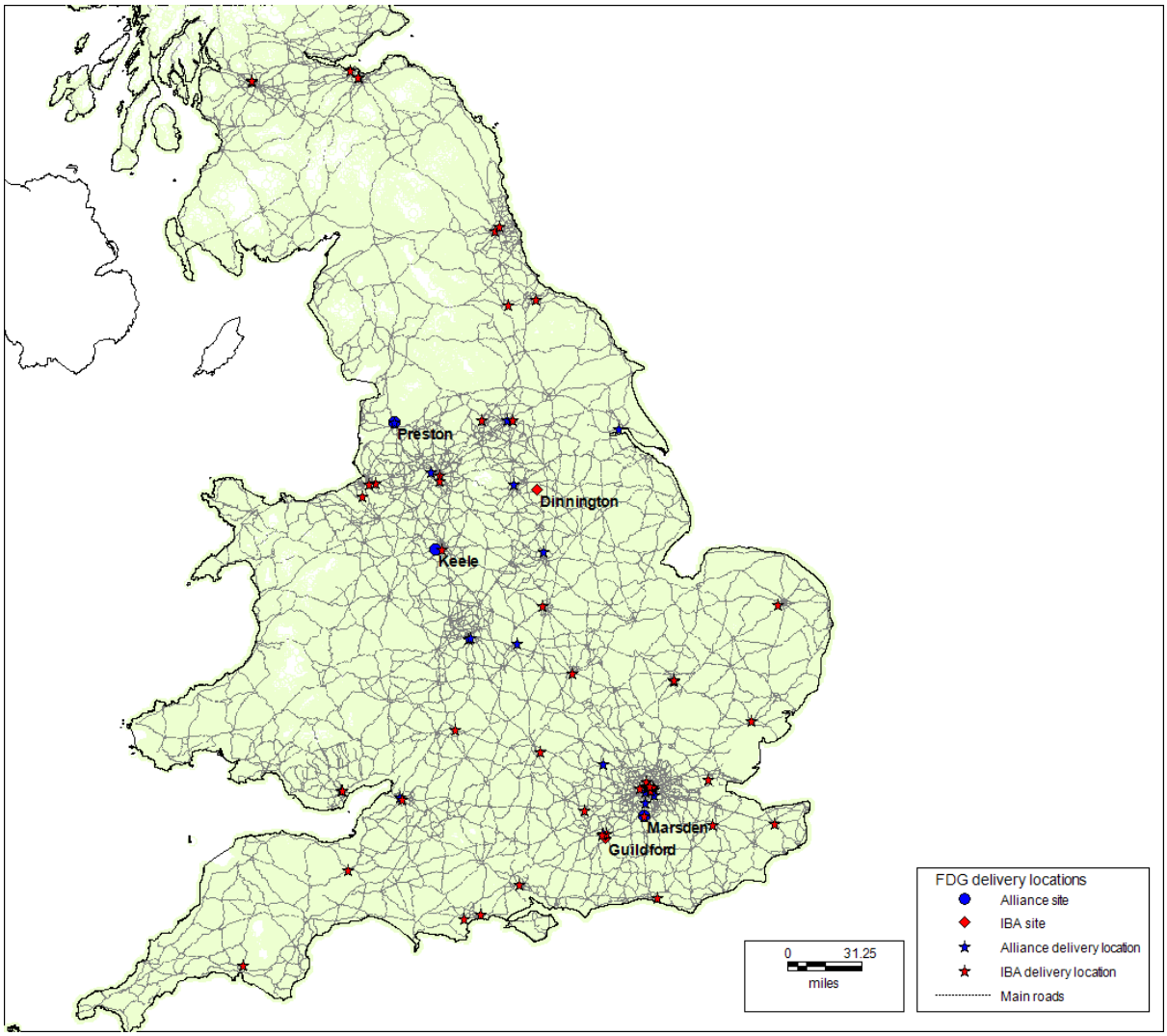
3.29 The relevant point in time for calculation of the share of supply is immediately before the reference is made.[92]

3.30 In applying the share of supply test, we considered whether it was satisfied on a national basis or in a ‘substantial part of the UK’. Prior to the acquisition, the parties overlapped in the manufacture and supply of FDG-18 and their RPUs were all located in England (as shown in Figure 7).

[89] Section 23(5) of the Act.
[90] Section 23(6) & (7) of the Act.
[91] Section 23(8) of the Act.
[92] Section 23(9) of the Act.

FIGURE 7

IBA and Alliance FDG-18 delivery locations, 2013



Source: Data provided by the parties.

3.31 Both parties supplied negligible back-up volumes of FDG-18 into Wales. As noted in paragraph 2.32, although both parties had historically supplied FDG-18 to PET-CT scanning suppliers in Scotland, this was not the case at the time of the reference, and only Erigal was supplying FDG-18 to Edinburgh, Glasgow and Dundee. Furthermore, since the mothballing of Dinnington in 2010, the IBA operation was not capable of supplying FDG-18 into Scotland due to the half-life of FDG-18 (see paragraph 2.39). We therefore considered that the share of supply test should be applied in England and that this constitutes a 'substantial part of the UK'.

3.32 We also considered whether the self-supply of FDG-18 by hospitals and whether the sales of FDG-18 from Erigal to Alliance's downstream PET-CT scanning operation should be included in the calculation of the share of

supply. We noted that hospitals' supplies were not carried out on a commercial basis, while those of Erigal were done under a supply agreement which defined commercial terms (including price commitments) that were akin to the types of agreement that governed other sales made to other customers. We therefore considered that Erigal's sales to Alliance's downstream operation should be included in the share of supply calculation, but hospitals' self-supplies should not.

3.33 Our calculations showed that prior to the transaction, Alliance had a share of commercial supplies of FDG-18 in England of [40–50]% and that the increment resulting from the transaction was [20–30]%. We therefore considered that the share of supply test was met.[93]

Conclusions on relevant merger situation

3.34 We therefore provisionally conclude that the jurisdiction test under the Act is satisfied and a relevant merger situation has been created.

4. Market definition

4.1 In this section, we set out our views on the relevant economic markets in which we have assessed the effects of the merger.

4.2 The purpose of market definition is to provide a framework for the CMA's analysis of the competitive effects of the merger. The CMA's aim when identifying the relevant market is to include the most relevant constraints on the behaviour of the merging firms. Market definition is a useful tool, but not an end in itself, and identifying the relevant market involves an element of judgement. The boundaries of the market do not determine the outcome of the CMA's analysis of the competitive effects of the merger in any mechanistic way. In assessing whether a merger may give rise to an SLC the CMA may take into account constraints outside the relevant market, segmentation within the relevant market, or other ways in which some constraints are more important than others.

4.3 Alliance submitted that the merger should be analysed in the following product and geographic markets:[94]

(a) The primary supply of FDG-18 to third parties under competitively tendered contracts. This may include potential supplies from the eight

[93] We also calculated the parties' share of supply on other bases that could plausibly be adopted (ie including Wales and Scotland; and/or including self-supply of FDG-18 by hospitals) and found that the share of supply test would still be met on any of these scenarios.
[94] Summarised from Alliance submission.

universities/hospitals and three research institutions with their own cyclotrons and/or GE Healthcare. It considered that geographically, the market should be split between the South and the North of Great Britain.

(b) The back-up supply of FDG-18 to third parties. It said that for supplies made in response to planned outages, the geographic scope of the market was the same as for primary supplies, whilst for unplanned outages, FDG-18 was generally sourced over quite short distances.

(c) The build and operation of a cyclotron on a customer's site in return for a long-term exclusive supply contract. It considered that the market was at least national and probably wider.

(d) The supply on a subcontract basis of Alzheimer's tracers to the developers of such diagnostic tests. It considered that the geographic market was at widest national.

4.4 InHealth submitted that:[95]

(a) The market for FDG-18 was distinct from the market for other tracers.

(b) The self-supply of FDG-18 by NHS hospitals was not in the same market as Alliance, since NHS self-supply of FDG-18 did not provide a competitive constraint on Alliance/IBA's ability to set prices for FDG-18.

(c) Commercial volumes of FDG-18 supplied under long-term contracts, even on an exclusive base, were in the same market as the parties if the provider of radiopharmaceuticals held an MA.

(d) Back-up supply was not part of the same market as primary supply. There was perhaps a secondary market for back-up supply and this might be internal or external.

(e) Erigal's supply of FDG-18 to its downstream operations (ie self-supply) was in the same market as the supply of FDG-18 to other customers.

(f) The four-lot structure of the upcoming PET-CT national contracts (see paragraph 2.72 and Appendix E, paragraphs 25 to 30) was a more relevant set of geographic markets to consider than the split between the North and South regions.

4.5 PETNET told us that it considered Erigal's self-supply to Alliance's PET-CT scanning operations as part of the market but PETNET was likely to be

[95] InHealth response to issues statement.

excluded at the moment. It also told us that it considered the geographic scope of the addressable market for FDG-18 to be England rather than the UK because the Scottish sites were too far from PETNET's facilities to be feasible in terms of supply. In relation to NHS in-house cyclotrons, PETNET told us that these facilities would continue to self-supply and it was not concerned they would start to supply FDG-18 commercially to third parties.

4.6 IBA Molecular UK told us that there was no evidence of the NHS owners of cyclotrons seeking a full MA, but that if they did secure a full authorisation by the MHRA, then they would be a competitor because they would be in a position to fulfil the needs of the UK market. IBA Molecular UK also told us that the geographic scope of the market for back-up supply was less geographically sensitive and that therefore the market was potentially bigger than that for primary supply.

4.7 We first assess the relevant product market before discussing the appropriate approach to defining the boundaries of the geographic market.

Product market

4.8 Our assessment of the relevant product market starts with the supply of products in which both merging parties are active.[96] Prior to the transaction the parties were active in the following areas:

(a) Alliance and IBA's PET business both manufactured and supplied FDG-18.

(b) Alliance manufactured and supplied other radiopharmaceuticals including NaF and FEC. IBA Molecular UK's Guildford site did not produce NaF but procured doses from suppliers as needed. IBA's Dinnington site had produced NaF before ceasing operations in 2010.[97]

4.9 The parties are also expected to be involved in the future production and supply of new tracers under toll manufacturing contracts that will be targeted at Alzheimer's disease (see paragraph 2.67*(a)*).

4.10 In relation to the commercial supply of FDG-18 we considered the following issues:

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[96] As explained in paragraph 6.2*(c)*, at the outset of the inquiry, we identified the possibility that the merger might lead to competition concerns in the supply of PET-CT scanning services. However, because of our provisional findings on the appropriate counterfactual, we did not need to take a view on the market to which PET-CT scanning services belong in order to reach a view on the vertical effects arising from the merger (see paragraph 6.30). We therefore do not consider what market PET-CT scanning services belong to.
[97] Alliance told us that IBA did not produce 18F-Choline or 18F-Sodium Fluoride [✂]. (See footnote 32 of Alliance initial submission.)

(a) whether potential supplies of FDG-18 by universities/hospitals that own a cyclotron (see paragraph 2.30) are in the same market as current supplies by commercial suppliers;

(b) whether potential supplies of FDG-18 by GE Healthcare should be included in the same market as current supplies by commercial suppliers;

(c) whether the primary supplies of FDG-18 and back-up supplies of FDG-18 (see paragraphs 2.47 and 2.48) are in the same market;

(d) whether the supply of FDG-18 under long-term exclusive contracts is in the same market as FDG-18 supplied under other types of agreements (see paragraph 2.73); and

(e) whether the supplies of FDG-18 by Erigal to Alliance's PET-CT scanning operations are in the same market as the supplies of FDG-18 to non-affiliated customers.

4.11 We also examined whether FDG-18 was in the same product market as other types of F-18 radiopharmaceuticals (FEC, NaF and Alzheimer's tracers), taking account of both demand-side and supply-side considerations.

4.12 We set out our reasoning and provisional findings on each of these issues in paragraphs 4.13 to 4.24.

4.13 In relation to paragraph 4.10*(a)*, Alliance told us that Cardiff Hospital was willing to market FDG-18 to NHS hospitals and independent scanning providers within a 3-hour radius from Cardiff. Alliance argued that Cardiff had already invested in a cyclotron and was incurring operating costs in producing FDG-18 for its own use. Alliance noted that any third party business won by Cardiff would therefore make a contribution to covering the costs of Cardiff's operations since the variable costs of additional production within a batch were low. Alliance noted that the main barrier to entry was that Cardiff would need to obtain a variation to the licences issued by the MHRA to permit commercial supplies, and Alliance argued that there was no reason why the MHRA would refuse to grant such a consent given that third parties were authorised to supply FDG.[98]

4.14 We noted that hospitals that currently operate a cyclotron for their own use would need to apply for an MA to be able to supply FDG-18 commercially (see Appendix D). The evidence we have received from hospitals and third

[98] Alliance initial submission. See also Cardiff University website.

parties other than Alliance[99] showed that obtaining an MA was considered a lengthy and costly process.[100] In addition, PETNET doubted that commercial supply was compatible with hospitals' working practices. Hospitals who responded to the OFT's market questionnaire and to ours told us that they had no plan to start supplying FDG-18 commercially, the cost of doing so being a key reason for this position.[101] The reluctance of hospitals to use their cyclotrons commercially was reiterated by Imaging Equipment Limited, which had unsuccessfully approached hospitals, including Cardiff, with a view to operating their cyclotrons commercially on their behalf.

4.15 We therefore provisionally concluded that potential supplies of FDG-18 by hospitals/universities are not in the same product market as the current supply of FDG-18 by commercial suppliers.

4.16 In relation to paragraph 4.10*(b)*, GE Healthcare told us that [✂] it had an MA to produce FDG-18. It also told us that in order to start producing FDG-18 [✂]. We therefore provisionally concluded that potential supplies of FDG-18 by GE Healthcare are not in the same product market as the current supplies of FDG-18 by commercial suppliers.

4.17 In relation to paragraph 4.10*(c)*, we noted that security of supply, to which back-up arrangements contribute, is important to buyers of FDG-18 (see paragraphs 2.78 to 2.80), but that, on the basis of the evidence we received, there are no instances of customers holding separate tenders for the procurement of their primary and back-up supplies.[102] This is supported by InHealth's submissions.[103] We further noted that any supplier of a radiopharmaceutical can make the product available as primary or back-up supply and, indeed, back-up supplies are frequently sourced from surplus production and only sometimes an additional batch is required to be produced.[104] We also noted that customers pay a contracted price for the products they receive and that the price paid by a customer does not vary depending on whether the supplies are sourced as primary or back-up supplies.

4.18 We therefore provisionally concluded that primary and back-up supplies of FDG-18 are in the same product market.

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[99] Alliance argued that a full commercial licence would be obtained in about three months.
[100] See Appendix D, paragraphs 15–21
[101] This includes responses from Aberdeen, Birmingham University, Cardiff University, Edinburgh University, NHS Greater Glasgow and Clyde, Guy's and St Thomas', Newcastle and Imanova.
[102] We note that some customers only purchase back-up supply in the event that they self-supply their primary FDG-18.
[103] InHealth response to issues statement, paragraph 3.18.
[104] Alliance initial submission, footnote 50.

4.19 In relation to paragraph 4.10*(d)*, ie whether the supply of FDG-18 under long-term exclusive contracts is in the same market as FDG-18 supplied under other types of agreements, there are four instances of commercial suppliers of FDG-18 setting up an on-site RPU at a hospital in exchange for a long-term contract (see paragraph 2.73*(c)*). We noted that some of these contracts will expire in the next few years.[105] We also noted that the competitive process for the award of long-term contracts would be likely to be similar (ie to involve a similar tender process and attract similar types of competitors) whether or not they are due to expire in the short or medium term.

4.20 As such, we provisionally concluded that it is appropriate to include all such contracts in the relevant product market. Whilst we have included all contracts in the product market, in the analysis of the competitive effects of the merger we would take account of the specific characteristics of each such contract and how they impact on competition between FDG-18 suppliers, to the extent that it is necessary to do so.

4.21 In relation to paragraph 4.10*(e)*, we noted that the majority ([✂]%[106] in 2013) of Erigal's sales of FDG-18 are to Alliance's PET-CT scanning services operation. We considered whether such sales were 'captive',[107] and noted that a substantial proportion of Alliance's PET-CT scanning services (about [✂]%) was associated with the NHS PET-North contract. PET-CT scanning services to NHS-England are the subject of an ongoing NHS tender process (see paragraph 2.72 and Appendix E, paragraphs 25 to 30). We noted that during this process, both the PET-CT scanning services and supplies of FDG-18 to support these services would be contestable.[108] More generally we noted that, when PET-CT scanning services providers made provision for the supply of FDG-18 (either internally, if they are vertically integrated, or externally using third parties), this was in anticipation of a tender for PET-CT scanning services, ie at a point at which the underlying scanning contracts and the related FDG-18 supply were contestable.

4.22 We therefore provisionally concluded that the sales of FDG-18 by Erigal to Alliance's PET-CT scanning services operation were not 'captive' and therefore belonged in the same product market as the sales of FDG-18 to non-affiliated customers.

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[105] For example, [✂].
[106] Calculated by the CMA using transaction data provided by Alliance. The calculation excludes negative and zero volumes and volumes of products tagged as 'Vials'.
[107] By 'captive', we refer to the production of an input by a company for its own (or group company) use. Rather than purchasing or selling the input to or from outside sources, the company 'captures' its own production and supply.
[108] This is supported by Alliance submission, footnote 36.

4.23 In relation to paragraph 4.11, we noted that each F-18 radiopharmaceutical (including FDG-18, FEC and NaF) is intended for a specific clinical use and as such, is not easily substitutable (see Appendix C, Table 1). Because all three products are made in RPUs, using isotopes manufactured in cyclotrons, we considered whether they could be substitutable from a supply-side perspective. The evidence we received on the ability to switch production between these pharmaceuticals is set out in Appendix C, paragraphs 20 to 24. It shows that putting in place the facilities required to synthesise a new type of F-18 radiopharmaceutical involves relatively low levels of investment (between £100,000 and £200,000) and can be done in less than 12 months. However, we considered it possible that the supply of FEC and NaF was subject to different conditions of competition: the products were supplied by different sets of competitors and the procurement processes of some purchasers may not be the same for each of these products.[109] On the basis of the evidence available to us, we were not able to conclude whether FEC, NaF and FDG-18 were all in the same market. We noted that, to the extent that the parties were potential competitors to each other in the supply of FEC and NaF, had they become actual competitors, the structure of the market in which competition would have taken place would have been the same as for the supply of FDG-18. Therefore our competitive assessment would not have been affected by our definition of the product market.

4.24 As set out in paragraph 2.67*(a)*, Alzheimer's tracers are still in the early stages of development, and there is little public information on competitors' products, and no information is currently available on the demand-side or supply-side substitutability of Alzheimer's tracers. Neither PETNET nor Alliance was able to comment on the substitutability of the three Alzheimer's tracers (either from a supply-side or demand-side perspective),[110] although they are all targeted at the same clinical use (but a different clinical use from FDG-18). In terms of supply-side substitution, PETNET told us that it required [✂]-worth of new equipment to introduce one such tracer, Florbetapir, and that this required 18 months of development at Nottingham and a further six months of development at Mount Vernon. We therefore considered that the costs and time required to begin the production of Alzheimer's tracers were significant in terms of supply-side substitution. We also noted that Alzheimer's tracers were produced under toll agreements with pharmaceutical companies and were therefore subject to competitive conditions that differ substantially from those surrounding FDG-18.

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[109] Alliance told us that the contracts for these products were often negotiated as they rarely reached the value thresholds for EU public procurement. However, [✂].
[110] Alzheimer's tracers are produced using specific synthesis units but little is known about their supply-side characteristics given that they are still in development.

4.25 We therefore provisionally concluded that the supplies of FDG-18 and Alzheimer's tracers were in different product markets.

Geographic market

FDG-18, FEC and NaF

4.26 As explained in paragraph 2.39, FDG-18 is a perishable product that needs to be used within 8 hours of being synthesised. In addition, transport costs can be a significant component of the delivered cost of the product (see paragraph 2.40). Together these two factors impose limits on how far FDG-18 can be commercially delivered. The same issues apply to FEC and NaF. Alliance told us that whilst deliveries of up to 4 hours are technically possible (and may be made for back-up purposes in cases of absolute necessity), suppliers become progressively and quickly uncompetitive when drive-times exceed 2 hours. The view that customers tend to be within a 2-hour catchment area of cyclotrons was supported by three third parties (BNMS, Cobalt and Royal Surrey Hospital).

4.27 We calculated that about [✂] and [✂]% of Alliance's primary supplies of FDG in 2012 and 2013, respectively, were delivered within a 2-hour drive-time from the site where they were produced.[111] [✂] the primary supplies delivered outside the 2-hour drive-time in 2013 were delivered within a 3-hour drive-time. The furthest delivery was at Bradford Royal Infirmary, located about 4.5 hours away from the Marsden site.[112] The results of our analysis were therefore consistent with what Alliance told us, as set out above (paragraph 4.26).

4.28 As explained in the Guidelines, in cases where prices are negotiated individually with customers, the CMA may define separate relevant geographic markets by customer location and not by supplier location, when suppliers can price discriminate on the basis of customer location.[113]

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[111] We could not calculate the drive-time distances for the following delivery locations: IBA and Broadgreen Hospital, due to data issues, eg missing data. PETNET did not provide transaction data and as such we could not calculate these figures. We calculated that IBA delivered about [✂] and [✂]% of its FDG primary supply within 2 hours' drive-time in 2012 and 2013 respectively. We note that these figures are broadly in line with those calculated for Alliance. However, IBA's figures need to be interpreted with caution because: *(a)* we could not include volumes delivered to InHealth, which account for about [✂]% of IBA's volume each year; *(b)* volumes delivered to Dinnington's customers that were served by Guildford, following Dinnington's closure, are included.
[112] We calculated that about [✂]% of back-up supply provided in 2013 was delivered within 2 hours' drive-time from the supplier. [✂] of the back-up supply delivered outside the 2-hour drive-time was delivered within 3 hours. The furthest back-up supply was provided to the University of Edinburgh, which is located 3.3 hours away from the Preston site.
[113] *CC2*, paragraph 5.2.27.

4.29 As explained in paragraphs 2.73 to 2.80, FDG-18 is supplied to customers under contracts which are either individually negotiated or tendered, allowing for price discrimination by customers, and FDG-18 is delivered to the customers, who incur the cost of transport. In addition, arbitrage across customer locations is not possible due to the perishability of FDG-18. We therefore provisionally considered that the market should be assessed locally and centred around customer locations, and therefore do not conclude on geographic market definition. Our analysis of the competitive effects of the merger consequently took account of the distances and journey times between each relevant customer and producers of FDG-18.[114]

Alzheimer's tracers

4.30 Because of the limited amount of publicly available information on Alzheimer's tracers and of the fact that these products are yet to be supplied on a commercial basis in the UK, there are difficulties in defining the geographic market for them. We noted that their half-life was similar to that of FDG-18.[115] In any event, because of our provisional findings on the counterfactual (see paragraph 5.79), we provisionally concluded that it is unnecessary to reach a view on the scope of the geographic market for these products.

Conclusions

4.31 We provisionally concluded that:

(a) Potential commercial supplies of FDG-18 by hospitals/universities or GE Healthcare are not in the same product market as the commercial supply of FDG-18. Primary and back-up supplies of FDG-18 are in the same product market.

(b) It is appropriate to include FDG-18 supplies under long-term exclusive arrangements in the same market as FDG-18 supplies under other types of contracts.

(c) The sales of FDG-18 by Erigal to Alliance's PET-CT scanning services operation belong to the same product market as the sales of FDG-18 to non-affiliated customers.

(d) The supplies of FDG-18 and Alzheimer's tracers are in different product markets.

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[114] We did not need to carry out similar analysis of the competitive effects of the merger for FEC of NaF, as IBA Molecular's PET Business did not have separate contracts for these products prior to the merger.
[115] Flutemetamol's half-life is 105–110 minutes.

4.32 On the basis of the evidence available to us, we were not able to conclude whether FEC, NaF and FDG-18 are in the same product market.

4.33 We provisionally concluded that the competitive effects of the merger in the relevant product markets should be assessed locally and centred around customer locations.

5. Counterfactual

5.1 Before we analyse the effects of the acquisition, we need to assess what we expect would have been the competitive situation in the absence of the transaction. This is called the 'counterfactual'.[116] It provides the scenario against which the expected effects of the acquisition are assessed. In carrying out this assessment, the CMA may consider several possible scenarios, one of which may be the continuation of the pre-merger situation. The CMA will typically incorporate into the counterfactual only those aspects of scenarios that appear likely on the basis of the facts available to it and the extent of its ability to foresee future developments.[117]

Introduction

5.2 Alliance submitted that the relevant counterfactual in this case was a situation in which the Dinnington RPU remained mothballed and the Guildford RPU would have also exited the market. In addition, Alliance put forward the view that even if the Guildford site had not exited the market, it had already become an ineffective competitor in the South of England and was becoming progressively weaker, such that a counterfactual in which it did not formally exit the market would effectively be based on competition between two firms.[118]

5.3 In the case of the Dinnington RPU, Alliance considered that it would not make economic sense for its owner to reopen the plant for the production of FDG-18 due to:

(a) The limited size of the contestable market in the North of England, compared with the volumes required for the plant to break even. Alliance highlighted that there were approximately [✂] doses which Dinnington could, in theory, serve in the North (excluding the PET-North contract) compared with a break-even volume of [✂], assuming that the site was able to achieve the average price per dose currently charged in the North

[116] *CC2*, paragraph 4.3.1.
[117] *CC2*, paragraph 4.3.6.
[118] Alliance initial submission, paragraph 21.

of England. Alliance noted further that it was unlikely that Dinnington would win all of the potential contestable contracts against Erigal, a stronger local competitor.

(b) The need for the Dinnington site to be operational in order to win contracts, combined with the unwillingness of IBA to reopen the site without already having 'firm orders' to support it. This put the site in a 'chicken and egg' situation that prevented its reopening.

(c) The time required to reopen the Dinnington site, which IBA Molecular UK had told Alliance would be 15 months, which meant that Dinnington could not be reopened in time to serve the new NHS block contracts for the North of England. These volumes would be sufficient to allow the site to operate profitably but the new contracts would commence in April 2015 and a PET-CT scanning business would need to have a secure source of FDG-18 supply arranged at the point of bidding for the contract (which would take place in the next few months).[119]

5.4 In the case of Guildford, Alliance submitted that:

(a) Following the closure of the Dinnington site, IBA Molecular UK's competitiveness in the supply of FDG-18 had declined significantly as a result of having no internal back-up supply. Alliance argued that this made it difficult for IBA Molecular UK to win FDG-18 contracts, since the award criteria typically allocate 60 to 80% to security of supply and service issues. Alliance stated that as a result, IBA Molecular UK had failed to win any new contracts since 2010, even at low prices.[120]

(b) In order to provide back-up in the absence of a second cyclotron, IBA Molecular UK entered into the 'Madrid' agreement with Erigal which was costly, with IBA Molecular UK paying Erigal approximately £[✂] per year since the closure of Dinnington.[121]

(c) IBA Molecular UK's financial weakness called into question its long-term commitment to the UK market, deterring customers from buying from IBA.[122]

[119] ibid, paragraphs 75 & 76.
[120] ibid, paragraphs 21 & 95.
[121] ibid, paragraph 78.
[122] ibid, paragraph 81.

(d) IBA Molecular UK did not invest sufficiently in maintaining the Guildford plant as a result of its financial position, which put it at risk of being closed by the MHRA.[123]

5.5 In light of the financial performance of IBA's PET business, Alliance suggested that its shareholders' losses would be minimised by ceasing operations at the site and incurring ongoing mothballing costs of around £[✂] per year, in order to avoid ongoing cash losses of over £[✂] million per year.[124] Alliance told us that formally closing the site would incur nuclear decommissioning costs, which were far larger than mothballing costs, and a decision to mothball rather than decommission a site did not imply that the owner was seeking to preserve the ability to reopen the plant in the future.[125]

5.6 Alliance told us that relatively few contracts were expected in the next three years, other than the FDG-18 supply for the replacement contracts to the existing NHS block contracts (PET-North and PET-South) and that it was not, therefore, likely that IBA Molecular UK would have been able to turn its business around.[126]

5.7 Alliance told us that it believed it would have made no business sense for a purchaser to buy the IBA operation at any price unless it had synergies arising from existing FDG-18 production or PET-CT scanning operations.[127]

5.8 No other parties made formal submissions on the counterfactual to the transaction. However, IBA Molecular UK told us that in the absence of the merger, it would have mothballed the Guildford site. In addition, it noted that no consideration was given to reopening the Dinnington site for production of FDG-18 subsequent to its closure in 2010. However, IBA Molecular UK did consider making the site available as a radiopharmacy for SPECT products but there was no concrete interest from any potential partners for such a project.

5.9 SK Capital submitted that it would not have sought either to restructure the UK PET business or to support the Guildford site in the longer term. It explained that it would have mothballed the site in order to reduce the annual operating losses but it would not have fully dismantled the site because doing so would have resulted in significant nuclear decommissioning costs.

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[123] ibid, paragraph 82.
[124] ibid, paragraph 87. We consider ongoing mothballing costs further at paragraph 5.36*(b)*.
[125] ibid, paragraph 70.
[126] ibid, paragraph 89.
[127] ibid, paragraphs 123–126.

5.10 InHealth told us that IBA's PET business was part of a large, well-established and publicly listed company[128] that was committed to FDG-18 supply. In addition, the tendering of the new NHS block contracts would provide an opportunity for material changes in the marketplace. Therefore, provided IBA's PET business was not 'bankrupt', InHealth considered that it would have been preferable for IBA's PET business to remain in operation during the 2014 tenders and see what business it might capture. InHealth told us that in the event that it could address the quality issues that had been experienced around the time of the merger, it would have been prepared to consider entering into a strategic support arrangement with IBA's PET business [✂],[129] at least in the short term, to see if IBA Molecular UK could restore its position in the market. It suggested that volumes could have been increased relatively quickly and given the high-fixed-cost nature of the business, this would have improved margins. It noted that IBA's PET business owners had made little effort to market the business and believed that had they done so, there may have been interest from various parties. It further argued that had IBA's PET business been allowed to fail, it seemed likely that its sales to its existing customers would be split between Alliance and PETNET.[130]

5.11 As explained in the Guidelines, in reaching a decision on the counterfactual, the CMA attaches significant weight to contemporaneous documents and available evidence supporting any claims that the merger under consideration was the only possible merger.[131] In this case, we requested relevant contemporaneous documents from all interested parties that we were aware of and received no contemporaneous documents relevant to any potential counterfactual.

Analysis

5.12 In light of the submissions from the parties, our analysis focused on considering whether IBA's PET business would have exited the market. As explained in the Guidelines, in forming a view on the exiting firm scenario, the CMA considers:

(a) whether the firm would have exited (through failure or otherwise); and, if so

[128] IBA SA is listed in Belgium and is a 40% shareholder in IBA Molecular.
[129] Hearing summary, response to issues statement.
[130] InHealth response to issues statement, section 4.
[131] Paragraphs 4.3.14 & 4.3.17.

(b) whether there would have been an alternative purchaser for the firm or its assets to the acquirer under consideration; and

(c) what would have happened to the sales of the firm in the event of its exit.[132]

5.13 We consider each element of the test in turn.

How likely was the IBA operation to continue operating in the near future?

Financial performance and ability to restructure the business

5.14 We first considered the historic financial performance of IBA's PET business and whether the business was sustainable on a stand-alone basis. Appendix B sets out key financial information on the business. It shows that it made losses in both 2011 and 2012. It also had negative cash flows in both years. IBA further told us that its business had been loss making since it had started producing FDG-18 in 2007. IBA told us that in order to return a profit in 2013 [✂] and to win [✂] contracts that were being [✂]. However, at the time of the transaction, it had failed to win the King's College contract and had lost its existing Christie contract which had accounted for £[✂] in 2012, which represented around [✂]% of its turnover. The Royal Free contract was also awarded to another supplier (although this was following the acquisition) In addition, towards the end of 2013, InHealth switched [✂] of the volumes it previously sourced from IBA's PET business to PETNET, due to reliability issues experienced in September 2013 (around the time the acquisition was completed).[133] The combined impact of these losses of volumes would have reduced IBA's PET business's EBITDA by a further £[✂].[134]

5.15 Consequently, we considered that it was more likely than not that IBA's PET business would have continued to make losses in 2013 absent any action being taken and that those losses would have been larger than in the previous two years. [✂].

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[132] *CC2*, paragraph 4.3.8.
[133] InHealth had reduced the volumes of FDG-18 that it bought from IBA's PET business as the result of production failures in September 2013, which forced it to reschedule scans at the sites supplied by IBA's PET business. When production failed, back-up was provided by PETNET which was then asked to supply these volumes instead of IBA's PET business. [✂].
[134] The PwC Due Diligence report commissioned by Alliance estimated that in 2012 the Christie contract generated £[✂] of revenue, with a gross margin of [✂]%, and the InHealth contract generated £[✂] with a gross margin of [✂]%. The loss of the Christie contract would reduce gross profits (and therefore EBITDA) by around £[✂], while the loss of two-thirds of the InHealth volume would reduce gross profits/EBITDA by around £[✂].

5.16 We therefore provisionally concluded that IBA's PET business had not been sustainable on a stand-alone basis, and noted that it had previously been supported by its parent company, IBA Molecular, for strategic reasons.

5.17 We next considered whether IBA Molecular UK would have been able to improve the profitability of IBA's PET business.

5.18 IBA Molecular stated that it had sought over several years to improve the financial performance of IBA's PET business but that it had been unsuccessful. It also told us that IBA Molecular had been a late entrant to the UK market and that this had put it in a weaker position in terms of winning the high-volume NHS block supply contracts than its competitors. As a result of the level and downward trend in prices (see paragraph 2.55), as well as the limited number of upcoming contracts it could contest, IBA Molecular did not see any means by which the profitability of the business could be improved materially. IBA Molecular further believed that the economics of the industry (including pricing policies driven by the need to fill spare capacity – see paragraphs 2.42 to 2.45) were such that the total profits earned by the three suppliers (Erigal, PETNET and IBA's PET business) from producing FDG-18 in England were likely to be close to zero, if not negative.

5.19 Following SK Capital's acquisition of IBA Molecular, it had sought to improve the profitability of the business by adopting a policy of 'cost-plus' pricing, and had not been able to win new contracts. SK Capital told us that given the relatively small size of IBA's PET business in the context of the overall IBA Molecular business, limited consideration was given to restructuring it during the early stages following SK Capital's acquisition of IBA Molecular. We requested internal documents discussing IBA Molecular UK's attempts at restructuring IBA's PET business but were informed that there were no such documents.

5.20 We noted that the other two suppliers of FDG-18 (Erigal and PETNET) were both profitable (see Appendix B). We also noted that demand had been growing and was expected by industry observers to continue growing at a rate of 11% per year in the medium term (see paragraph 2.63). Alliance's PET Strategy document highlighted that the growth in demand for FDG-18 and other radiopharmaceuticals, together with the reduction in spare capacity, could result in increased prices and improved profitability in the longer term. In this context, we considered carefully the extent to which IBA's PET business would have been able to improve its performance.

5.21 First, we considered the potential for IBA's PET business to return to operating two RPUs in England. We noted that it would have cost IBA Molecular UK around [£500,000–£1 million] to reactivate the Dinnington site and taken

18 to 24 months. We reasoned that IBA Molecular UK would only have incurred this cost if it believed that it could sell a sufficient volume of FDG-18 at a price that allowed it to make a reasonable return on this [✂] investment.

5.22 InHealth told us that [✂].

5.23 We noted that Dinnington had been closed for a considerable period of time and considered that the prospect of its reopening was speculative: it relied on either InHealth or another PET-CT scanning provider (excluding Alliance)[135] winning an NHS block contract in the North of England – as the other available contracts in the North of England contained insufficient volumes – and on the assumption that the contract would be sufficiently large, and at a price level, so as to enable Dinnington to operate profitably. It also relied on either InHealth or the alternative PET-CT scanning provider being prepared to guarantee the full volumes of the contract to the Dinnington site rather than sourcing some or all of the volumes from either Erigal or PETNET's RPUs in the North. We noted that there were few other contract opportunities open to the Dinnington site.

5.24 We observed that InHealth had previously sought to split its primary FDG-18 requirements between IBA's PET business and PETNET, rather than relying on a single provider. [✂]. We considered that it was unlikely that InHealth would be prepared to change its approach fundamentally. In addition, we noted that the time required for the Dinnington site to be reactivated would have meant that it could not be operational by April 2015, when the new NHS block contracts are due to commence. We considered that this undermined the credibility of the site as a potential supplier to PET-CT scanning providers and therefore that the possibility that the Dinnington site would reopen under IBA Molecular's ownership was remote.

5.25 Next, we examined the prospects for improving IBA Molecular UK's profit-ability as a single-site operator. We considered that while it was, at least theoretically, possible that the IBA Molecular management team could have improved the performance of the Guildford site by increasing sales volumes, increasing prices and/or reducing costs, practically it faced a number of challenges in seeking to do so.

5.26 First, we considered that increasing Guildford's sales volumes from its 2012 level would have been difficult because:

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[135] Alliance has a policy of sourcing all its FDG-18 from Erigal and hence it is unlikely that if Alliance won such a contract, it would source FDG-18 from IBA.

(a) There was a relatively small number of (new) contracts tendered each year (see paragraph 2.77).

(b) The Guildford site had a poor track record of winning new contracts.[136]

(c) The Guildford site had experienced some difficulties in maintaining existing contracts, arising from reliability issues in the case of the InHealth contract.[137]

(d) The site was utilising around 80% of its total capacity in 2012, which placed a limit on expanding output above the 2012 levels.[138]

5.27 In addition, when taking into account gross margins and the costs of back-up supply (which would have increased with volumes under the terms of the 'Madrid' agreement (see paragraph 2.76)), additional revenues would have made a contribution of approximately [✂] to [✂]% to operating profits. As a result, even if IBA Molecular had been able to grow volumes by 10 to 20%, it would have only reached approximately break-even at its 2012 price levels.

5.28 Also, in order to become profitable, therefore, IBA Molecular would have needed to increase its prices or reduce its cost base:

(a) Prices. As its existing contracts were fixed price, it would have needed to raise prices through winning new contracts (or renewing existing ones) at higher price levels. We consider that there is substantial uncertainty over whether this would have been possible in a market where prices had declined steadily in recent years, [✂] (see Figure 5) and where the IBA operation itself (post-acquisition) had to lower prices to InHealth in order to regain volume it had been supplying previously. In addition, we noted that, as a 'pure play' FDG manufacturer (see paragraph 2.71), IBA's PET business was not able to differentiate its offering other than on price, whereas PETNET was able to combine supplies of FDG-18 with other products or services. For example, Cobalt told us that [✂].

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[136] The Guildford site had not won any new contract since 2010. We note that this lack of success may have resulted from a number of factors. Alliance suggested that it was the result of IBA's PET business being unable to offer internal back-up, and of question marks over IBA Molecular UK's long-term commitment to supplying FDG-18 in GB.

[137] The Guildford site lost the Christie contract from mid-2013 onwards and suffered a reduction in InHealth volumes as a result of reliability issues in September 2013. In spite of these reliability issues, we considered that the evidence we received from the MHRA did not support the contention that the Guildford site suffered from underinvestment, with the issues recorded relating to operational deficiencies that were observable by the MHRA in November 2013 (ie after the acquisition of the IBA operation by Alliance).

[138] This figure does not take into account the losses of the Christie and InHealth volumes. It is based on the assumption that the Guildford site's capacity was around [✂] doses per year, which would equate to around [✂] firings per day.

(b) *Costs.* We noted that a key difference in the costs incurred by IBA's PET business and Erigal related to the Madrid agreement, which IBA Molecular UK entered into following the closure of the Dinnington site. We reasoned that IBA would have had limited opportunity to reduce this cost materially and thereby improve its profitability as the terms of the agreement had been freely negotiated between IBA Molecular UK and Erigal and reflected IBA Molecular UK's position in the market at the time.

5.29 Based on the assessment above, we provisionally found that improving the financial performance of IBA's PET business to the extent that its owners were able to earn a reasonable return would have been challenging, particularly in the short term, and would have required significant commitment on the part of its shareholders, potentially to bear several more years of losses.

Commitment of IBA Molecular shareholders to FDG-18 production in the UK

5.30 IBA's PET business had operated at a loss since the opening of its first cyclotron in 2007. In 2010, IBA Molecular UK decided to close the Dinnington site as it did not see a commercial opportunity to make it profitable given the shortage of contestable volumes of FDG-18 in the North of England. However, at this time, IBA Molecular made a conscious decision to continue to support the Guildford site, despite the fact that it was loss-making, as part of a broader global strategy. This strategy was to have a manufacturing and distribution presence in a number of markets for both its existing radiopharmaceuticals and in order to win contracts to produce and distribute new radiopharmaceuticals based on F-18, such as those for Alzheimer's, on behalf of other pharmaceutical companies which did not have their own manufacturing and distribution network. IBA Molecular saw a competitive advantage in being able to offer these companies a single partner for a large number of countries, allowing them to avoid negotiating a separate agreement for each country. IBA Molecular explained that despite the longer than expected development period for the new products, it wished (in 2010) to retain a UK presence and, as a result, was prepared to continue to support a loss-making UK business over a number of years.

5.31 IBA Molecular explained that this approach, however, changed when SK Capital acquired the business, noting that its new majority shareholder's priorities as a private equity company were different from those of IBA SA, which was a research company. IBA Molecular told us that SK Capital sought to cut losses wherever it could and it identified Guildford as a loss-making site:

> For SK Capital, as an exercise in what you might call pure number crunching, it was a very hard-nosed approach … it was a relatively straightforward economic decision given their own obligations to their investors to essentially make money, and if you cannot make money, make sure that you are not losing money … So they did a very numerical decision in terms of deciding that they would withdraw from the business ….

5.32 [✂]

5.33 SK Capital submitted that it would not have sought either to restructure the UK PET business or to support the Guildford site in the longer term. It explained that it would have 'mothballed' the site in order to reduce the annual operating losses but it would not have fully dismantled the site because doing so would have resulted in significant nuclear decommissioning costs, which it estimated to be approximately [£500,000–£1 million]. Given SK Capital's investment horizon, it noted that it would not have made sense to incur these costs. SK Capital and IBA Molecular told us that they did not consider alternative options for the site because SK Capital had received an offer from Alliance which it considered to be attractive.

5.34 IBA Molecular told us that the business had previously mothballed other sites in its network, including Dinnington (UK), [✂].

5.35 IBA Molecular explained that once a site has been mothballed it requires between 18 and 24 months to reactivate it as the owner needs to go through the full licensing and authorisation process again. In effect, this means re-installing every item of equipment, the full cleaning of the site and the testing of the production processes for the stability of outputs. IBA Molecular told us that it had never reactivated a site that had been mothballed.

5.36 We reasoned that, in the absence of the merger or the acquisition of IBA's PET business by another party, SK Capital would have chosen to cease to operate the Guildford site if it considered that the costs it incurred from doing so were lower than those that it would have incurred from continuing to manufacture and distribute FDG-18 from the site. We therefore compared the likely costs of either decommissioning or mothballing the Guildford site[139] with the expected free cash flow losses from continuing to operate it:

(a) The one-off decommissioning costs for the site would have been [£500,000–£1 million] (see paragraph 5.33). We assumed that, if the site

[139] We asked IBA if it had considered converting the site for other uses, particularly as a radiopharmacy. In particular, it would not have converted it to the production of Tc-99m, as its SPECT business distributed Tc-99m produced in Saclay in France, and it would not have wished to compete with its existing production channel.

were decommissioned, IBA Molecular UK would have been able to assign or sell the lease to avoid the ongoing rent and rates on the site.

(b) As Guildford was a leased site, if it had been mothballed rather than decommissioned, IBA Molecular UK would have continued to incur annual rent, rates and maintenance costs of about £[✂] per year.[140]

(c) In 2012, the free cash flow losses of IBA's PET business had been £[✂].

5.37 As the ongoing costs of maintaining the site in a mothballed state (£[✂]) would have exceeded the cash losses of continuing to operate the site (about £[✂] in FY12), this suggests that the performance of the operation would have needed to deteriorate in FY13 (and subsequent years) for IBA Molecular/SK Capital to withdraw from FDG-18 production through mothballing. We also noted that, given SK Capital's relatively short time horizon (two to three years), it would also have been reluctant to incur the one-off [£500,000 – to £1 million] decommissioning costs rather than the ongoing cash losses of around £[✂] per year.

5.38 However, as explained in paragraph 5.14, performance deteriorated further in 2013 with the loss of the Christie contract and significantly reduced volumes demanded by InHealth. The scale of this deterioration is illustrated by the results of the IBA operation in the first seven months following the transaction: it lost £[✂] at the EBITDA level, which equates to an annual loss of around £[✂].

5.39 We considered that losses of this scale, in combination with the challenging outlook for the business (set out in paragraphs 5.26 to 5.29), would have made exit from FDG-18 production in the UK a rational decision for SK Capital in 2013. We thought that it was not clear whether SK Capital would have preferred to exit via mothballing or via decommissioning the site but that these two means of exit were substantially equivalent in competitive terms given the time frame required to reactivate a mothballed site.

5.40 We provisionally found that, given SK Capital's strategic aim to improve the profitability of the overall IBA Molecular business in the short term and the risks (in terms of increasing losses) associated with keeping the Guildford RPU in operation, the most likely situation absent the merger and absent an alternative purchaser was that it would exit the production of FDG-18 in the UK, either through mothballing or decommissioning, as soon as possible. In light of IBA Molecular's submission that this decision would have been taken

[140] This £[✂] figure comprises £[✂] costs of maintaining a mothballed site, which was Alliance's estimate of the cost of keeping the (freehold) Dinnington site, and £[✂] of ongoing rent and rates, which we assumed that any owner to a mothballed site would be obliged to continue paying.

within two or three months of the transaction (see paragraph 5.32) and our analysis of the deterioration of the business, we considered that it was likely that this would have occurred before the NHS procurement process for PET-CT scanning services started in spring 2014.

5.41 We therefore considered next whether there could have been an alternative purchaser for the IBA operation.

Would the IBA operation have been acquired by an alternative purchaser?

5.42 The events leading up to the merger are described in paragraphs 3.1 and 3.2. SK Capital did not run an auction process or seek an alternative purchaser. In addition, no potential purchasers approached either SK Capital or IBA Molecular to express an interest in the Dinnington site in the period since 2010 when it was mothballed. There was therefore limited evidence available to us on the attractiveness of the business to other potential purchasers. We first considered whether other FDG-18 suppliers may have been potential purchasers. We then considered whether other UK PET-CT scanning suppliers may have purchased the business, before briefly examining other categories of potential purchasers.

Other FDG-18 suppliers

- *PETNET*

5.43 First, we considered whether PETNET would have had an interest in purchasing IBA's PET business (or some part thereof). PETNET told us that it had not considered acquiring the business and would have been interested in finding out more about it, had it been approached by IBA Molecular. In considering such a transaction, it would have been sensitive to the impact of consolidation in the industry, and the potential competition implications that might result from it (including the expectation that such a deal would have been investigated by the CMA). It also speculated that the Guildford site may not have been an attractive alternative to expanding its Mount Vernon site.[141] This suggested to us that PETNET was unlikely to have been a potential acquirer of IBA Molecular's UK PET business.

5.44 In addition to PETNET's stated lack of interest in acquiring IBA's PET business, we considered that the purchase of IBA's PET business by PETNET would have been likely to raise similar competition concerns to the existing merger, with the number of operators in the industry reduced from three to

[141] PETNET hearing summary, 15 May 2014.

two, with one of the existing operators gaining a market share of [50–60]% of the total commercial supply in England. Our Guidance highlights that, in considering alternative potential purchasers, we take into account those potential alternative purchasers 'whose acquisition of the firm as a going concern, or of its assets, would produce a better outcome for competition than the merger under consideration'.[142] We reasoned that this was unlikely to be the case in the scenario where PETNET acquired the IBA operation.

- *European producers of FDG-18*

5.45 AAA told us that it had considered purchasing Erigal in 2008, but having reviewed its accounts, had concluded that it could not be made profitable, in part because Erigal's initial investment had been too large. It had re-examined the situation in 2012/13 but had been unable to progress discussions with Alliance. AAA had not approached IBA Molecular, as it did not believe that it would be interested in selling its business to a European competitor. AAA also told us that it wanted to enter the UK by acquiring an existing, and ideally profitable, business along with a knowledgeable management team. It noted that it was expanding on a number of fronts and was not able to devote its own management time to expansion in a new country. We concluded from this that, at the time of the merger, it was unlikely that AAA would have been in a position to acquire the IBA operation.

5.46 We noted that in principle there were other European suppliers of FDG-18, which may have been interested in establishing operations in the UK. However, we have not seen any evidence in support of this hypothesis and, as explained in paragraphs 2.55 and 2.56, the economics of FDG-18 supply in the UK are challenging. Further AAA told us that while it did not know what FDG-18 prices were currently being achieved in the UK, it understood that demand and prices were both low, the latter due to the fact that the NHS bundled FDG-18 into the price of PET-CT scans. AAA further commented that FDG-18 prices across Europe were under pressure and becoming unsustainable: it had recently rejected an opportunity to buy a cyclotron producing FDG-18 in Spain as the business was unprofitable at a price of €80 per dose.

5.47 Whilst we could not exclude the possibility that a European supplier of FDG-18 might have considered purchasing the IBA operation if it had been marketed, we noted that the ongoing losses of IBA's PET business since its inception and recent track record would have made it a high-risk investment opportunity in the context of a market that has failed to live up to growth expectations in the past. In addition, we observed that an overseas purchaser

[142] *CC2*, paragraph 4.3.16.

would also have had to put in place a local management structure for the business which would have added to the overhead cost base of the business on an ongoing basis.

5.48 We therefore considered it unlikely that a European supplier of FDG-18 would have purchased IBA's PET business.

UK third party suppliers of PET-CT scanning services

- *Cobalt*

5.49 Cobalt told us that it had briefly considered whether it wished to operate its own cyclotron for research purposes but that the size of the investment, both in terms of capital equipment and obtaining the necessary licences, was too large for it. Cobalt told us that even if it had been approached by IBA Molecular, it would not have had any interest in acquiring either of IBA's RPUs. On this basis, we do not consider that Cobalt would have been a likely purchaser of either of IBA's sites.

- *InHealth*

5.50 InHealth told us that it valued having a choice of suppliers for FDG-18 and the [✂]. It submitted that there was a practical need for PET-CT scanning providers to dual-source FDG-18 in order to ensure security of supply via back-up arrangements. [✂] In addition, InHealth told us that it [✂].

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5.51 InHealth stated that it had considered cyclotron operation at various stages, starting in 2002 when it explored an FDG-18 cyclotron Joint Venture with [✂], as well as in 2004 and in 2005/06, in relation to its provision of PET-CT scanning services to [✂], respectively. However, InHealth explained that, in each case, it had concluded either that [✂] .

5.52 InHealth told us that it had not been aware of the financial position of IBA's PET business, in particular, and that it did not have visibility, in general, of the economics of producing and distributing FDG-18 on a commercial basis. InHealth was aware that prices had fallen in recent years but did not have an opinion regarding the sustainability of current price levels. [✂]

5.53 InHealth submitted that SK Capital did not market the business and that, if it had been approached, it would have considered the acquisition in the same way it would review any other potential acquisition. In addition . InHealth emphasised that it had the funds, capability and resources to consider appropriate acquisitions. It highlighted that InHealth had grown via a number of acquisitions of diagnostic scanning businesses and that it generally was in

the process of evaluating a number of opportunities at any one time. In addition, [✂]. It stated that it would have considered providing such support to IBA's PET business if it had been aware of its financial difficulties. InHealth also told us that it had switched volumes from IBA's PET business to PETNET [✂]

5.54 We note that InHealth perceived a value in maintaining diversity in its supply base and that this may have provided a rationale for either acquiring IBA's PET business or for providing some form of financial support, [✂]. We also noted that InHealth had the financial ability to make an acquisition of this size. However, we observed that InHealth did not have a detailed knowledge of the FDG-18 industry, in general, or the financial position of IBA's PET business in particular. In addition, [✂].

5.55 In this context, we considered it unlikely that InHealth would have placed sufficient value on maintaining IBA's PET business as a supplier to assume responsibility for operating the business itself and funding its ongoing cash losses, particularly when it did not yet know the outcome of the NHS block contract procurement process and when it had the option of sourcing FDG-18 from PETNET which was both cheaper and more reliable than the IBA operation. By acquiring the business, InHealth would have gained a strong incentive to move volumes to the Guildford site and away from PETNET which would, most likely, have resulted in PETNET renegotiating the terms of its contract with InHealth.

5.56 We therefore provisionally decided that InHealth would not have been a likely purchaser of the IBA operation in the situation where SK Capital chose to close the Guildford RPU.

5.57 Although it was possible that InHealth would have been willing to provide some financial support to IBA's PET business in the short term, it was not able to provide sufficient information on this scenario to convince us that this support would have been sufficient to persuade SK Capital to continue to operate the Guildford site, particularly as it was clear from SK Capital's representations to us that it was not prepared to allocate significant management time to what it regarded as a small part of its business.

Other types of potential purchasers

5.58 We considered whether NHS Trusts may have been interested in purchasing the IBA operation. We noted that where hospitals have built and operate a cyclotron, one reason for doing so has been to be able to use the cyclotrons

to carry out research on-site.[143] The OFT and our survey of hospitals also showed that NHS Trusts that own cyclotrons have no interest in producing FDG-18 commercially, citing the regulatory costs of doing so as the reason for their position. None of the hospitals we talked to intended to install a cyclotron and those who had contemplated doing so stated that the quantities they needed to meet their needs would not justify the investment. In addition, both Alliance and PETNET highlighted the difficulties faced by NHS Trusts in adopting the working practices that were necessary for the commercial supply of radiopharmaceuticals. We also noted that no NHS Trust had previously purchased an off-site cyclotron and that proximity was very important when producing isotopes for research purposes as certain of them had very short half-lives. We therefore considered that it was unlikely that an NHS Trust would have purchased the IBA operation, and more so given the ongoing losses that the business had experienced.

5.59 Given the ongoing losses suffered by the IBA operation, the apparent lack of restructuring opportunities, the underlying economics of FDG-18 supply and SK Capital's unwillingness to operate a formal sale process, we also considered it unlikely that financial investors, or any other firms looking to run the IBA operation as a stand-alone business, would have purchased the IBA operation.

Provisional conclusions on first two limbs of the exiting firm test

5.60 We have assessed the evidence available to us, including the economic context within which the sale of the IBA operation was carried out, in reaching a view on the most likely counterfactual. In particular, we noted that:

(a) The UK PET business had never been profitable, its record in winning and keeping customers over recent years was poor, its losses had increased, and it had appeared to be in a weaker competitive position than the other two suppliers going forward.

(b) FDG-18 production is characterised by high fixed costs, a small number of tender opportunities and currently a significant amount of spare capacity.

(c) Although the capacity situation is expected to tighten over the next few years, as demand continues to grow, prices are not expected (by PETNET) to increase over the period in which the owner of IBA's PET

[143] For example, both Glasgow and Aberdeen cited the provision of FDG-18 locally as a motivating factor. Glasgow also stated its intention to use the RPU to produce other radiotracers for clinical research purposes.

business would have had to decide whether to continue to support the business.

(d) Although losses in IBA's PET business had been supported by IBA Molecular for many years, its new shareholders' decisions (SK Capital's) were not driven by the same strategic objectives, and we noted the views expressed by several industry participants that profitability could not be reached on the basis of FDG-18 alone and that it would take a number of years for the commercial supply of other types of F-18 radiopharmaceuticals to develop.

(e) IBA Molecular UK's Dinnington site has been mothballed for a number of years and other RPUs have been mothballed in Europe by IBA Molecular. IBA Molecular told us that it had never reopened a mothballed site.

5.61 The available evidence indicated that the most likely scenario was that SK Capital would exit the production of FDG-18 in the UK as soon as possible due to the ongoing (and growing) losses of the business, either by mothballing or decommissioning, which were substantially equivalent in competitive terms given the time frame required to reactivate a mothballed site. The IBA operation was unlikely to have found an alternative purchaser due to the difficulties associated with improving the financial performance of the business, which was at a structural disadvantage in the market arising from manufacturing only a single product at a single site.

5.62 We therefore provisionally concluded that the most likely counterfactual scenario was that the IBA operation would have exited the market and that there was no likely alternative purchaser that would have produced a better outcome for competition.

What would have happened to the sales of the firm in the event of its exit?

5.63 We next considered what would have happened to the sales of the IBA operation. The Guidelines state that if the sales were likely to have been dispersed across several firms, the merger may have a significant impact on competition. If, on the other hand, the majority of the sales were expected to have switched to the acquiring firm, the merger may have little effect on competition.[144]

5.64 As a starting point, we noted that the IBA operation's sales could only have dispersed to either Alliance's Erigal subsidiary or PETNET. We considered how sales may have been distributed between these two firms by examining:

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[144] *CC2*, paragraph 4.3.18.

(a) IBA's existing customer contracts, *(b)* parties' views and precedents and *(c)* distances and drive-times.

The customers of IBA's PET business

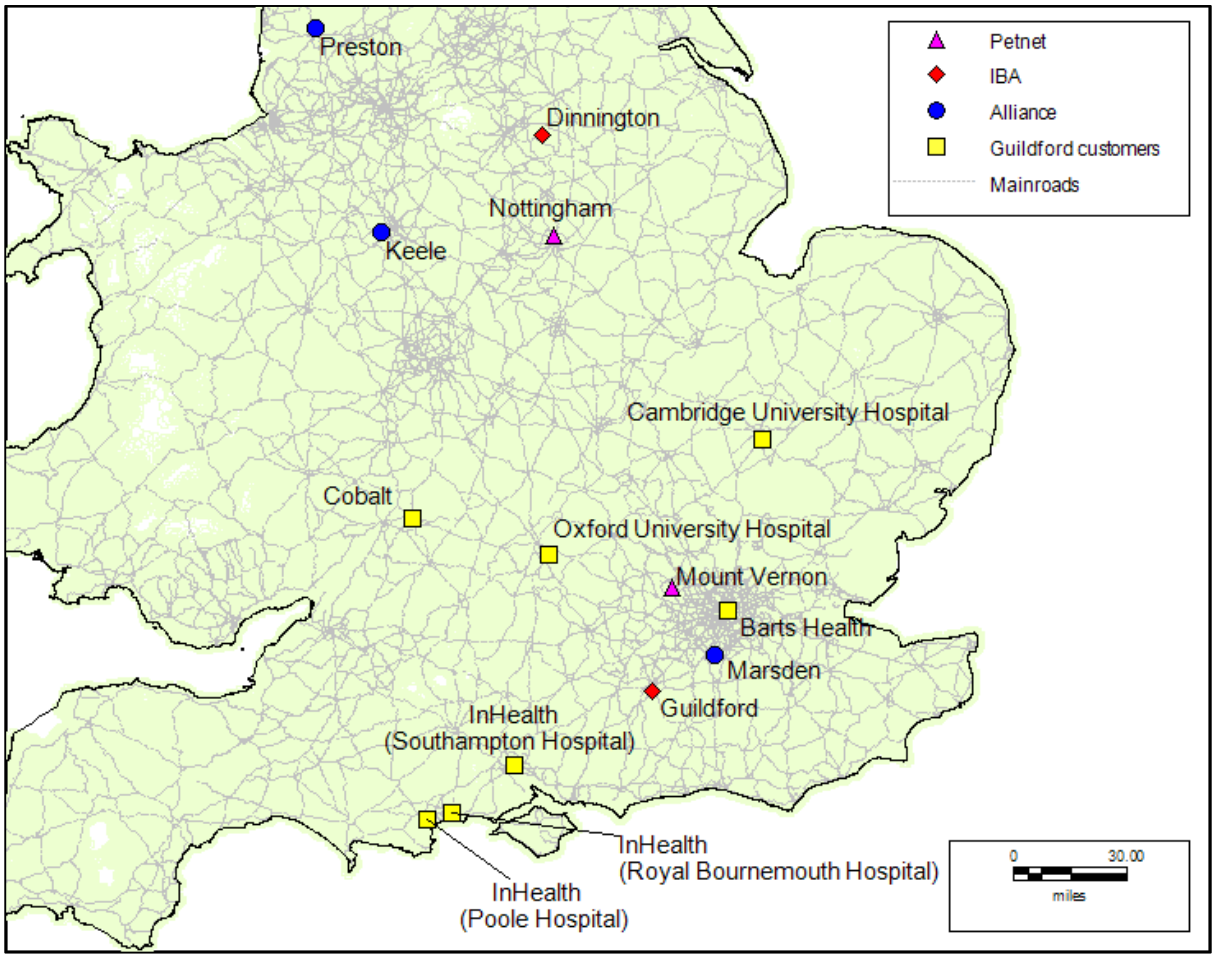
5.65 IBA's PET business had five customer contracts,[145] supplied from its Guildford site, that were part of the acquisition, one of which had expired but continued to be served (see paragraph 3.2):[146] InHealth, Cobalt, Oxford University Hospitals NHS Trust,[147] Cambridge University Hospitals NHS Foundation Trust and Barts Health NHS Trust. At the time of the merger, the Guildford RPU supplied FDG-18 to [✂] InHealth [✂] PET-CT scanning units located at the Royal Bournemouth Hospital, Poole Hospital and Southampton General Hospital. In addition, Guildford supplied InHealth's Kent sites, which were switched to PETNET in November 2013 [✂]. The volumes sold to each of these customers are shown in Table 3.

5.66 Figure 8 shows the locations of these five customers and of the RPUs of Alliance, IBA and PETNET.

[145] See Table 3.
[146] [✂]
[147] IBA supplied to Oxford University Hospitals NHS Trust as part of a framework agreement it has with Health Trust Europe (HTE), a buying group of which Oxford University Hospitals NHS Trust is a member.

FIGURE 8

Guildford customer locations



Source: CMA analysis.

Parties' views and precedents

5.67 IBA Molecular UK told us that if Guildford had been mothballed, it would have entered into conversations with Alliance and PETNET to ensure that continuity of service to customers was maintained. The approach to mothballing varied, but it would have been necessary to address each customer's contracts individually, as their terms varied, to understand how to address IBA Molecular UK's existing contract obligations. However, IBA Molecular UK had not undertaken this process since Alliance had shown interest in purchasing the assets before the mothballing of Guildford was seriously considered.

5.68 IBA Molecular told us that when Dinnington was mothballed the contracts supplied by Dinnington were taken over by a number of suppliers. The contract with Newcastle was novated to PETNET, the contract with Edinburgh was novated to Erigal and the contract with the Christie NHS Foundation Trust was novated to IBA's Guildford site. IBA Molecular considered the

Christie NHS Foundation Trust a key customer as it was the second largest cancer centre in Great Britain and it was important to maintain its position.

5.69 GE Healthcare told the OFT that when it exited the commercial provision of FDG in 2009, it novated all its existing contracts to IBA's PET business. It told us that it consulted a number of companies and considered their ability to fulfil its obligations. It then weighed up the responses objectively before selecting IBA's PET business, which produced the strongest bid. PETNET told GE Healthcare that it was not interested in taking over the contracts.

Approach to the analysis

5.70 We first examined the contracts of the five customers[148] and noted that these contracts could not have been novated to a new supplier without the consent of those customers. We therefore considered the factors that would have been likely to be relevant in the process that would have led to the transfer of the contracts to the remaining suppliers. Given the perishability of the product, transport costs and weight attached to price by customers, it follows that distances and drive-time would be important factors that could be measured.

5.71 We therefore conducted an analysis of distances and drive-times (both peak and off-peak)[149] between the Guildford customers and their potential suppliers.[150] The full analysis is provided in Appendix G. This analysis is intended to capture the local nature of competition. Both distances and drive-times affect the price aspects of bids, with closer suppliers facing lower transport costs, giving them a competitive advantage. We recognise that, while price is important, a significant part of a supplier's bid is made up of non-price factors.[151] We nevertheless consider that our analysis of distances and drive-times gives insights into the competition over Guildford's customers.

5.72 The analysis in Appendix G shows that in 79% of the tenders that took place in 2011 to 2014, the winning bidder is the closest supplier in terms of distance and/or drive-time. Given this relationship between the winning bid and distance and drive-time, the absence of a large amount of bidding data and the backward-looking nature of bidding data, we consider it informative to analyse distances and drive-times. We note that, in line with this approach,

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[148] One of the contracts (with InHealth) expired shortly before the acquisition but supply arrangements remained in place.
[149] We set in Appendix G, Annex 1 how we have taken into account in our analysis the fact that a supplier's site may not be the closest against all three criteria. See Appendix G, Annex 1, paragraphs 1–3.
[150] We examined the transport costs of Alliance and PETNET. We found no statistically significant difference between these transport costs and as such we have not used transport costs in our analysis.
[151] In particular, the tenders run by HTE (Oxford) and Barts Health give price a weighting of 50 and 40% respectively, with the remaining weights given to non-price factors.

Alliance and InHealth have provided their own analyses of drive-times.[152] In addition to our distance and drive-time analysis, we also examined for each customer data on past bidding behaviour of the suppliers if available.

5.73 We further examined how much spare capacity both PETNET and Erigal had and whether they would be able to serve any or all the customers previously served from the Guildford RPU. To the extent possible, we took account of the allocation of spare capacity between their different sites in our assessment. [✂], we also considered the possibility that Erigal and PETNET might have to supply any additional customers from their Keele and Nottingham sites respectively, as part of our analysis of drive-time and distances.

5.74 For each Guildford customer, we established which of Alliance's two sites was the closest to the customer and which of PETNET's two sites was the closest to the customer. In the main, these closest sites are Sutton and Mount Vernon respectively. However, to the extent that suppliers are unable to supply from their closest sites (eg due to capacity constraints), they may have to supply from their second closest site. We therefore analysed distances and drive-times between customers and the two suppliers' closest and second closest sites. In the main, the second closest sites are Keele and Nottingham for Alliance and PETNET respectively. We noted that for all Guildford customers except Cobalt, a supplier's closest site was significantly closer than the other supplier's second closest site. As a result, if Alliance supplied the customers from its second closest site, it would be at a competitive disadvantage vis-à-vis PETNET unless PETNET also supplied from its second closest site and vice versa.

5.75 Based on our analysis of distances, drive-times and past competitive behaviour, we provisionally found that:

(a) For Barts Health NHS Trust,[153] Oxford University Hospitals and Cambridge University Hospitals, PETNET was a strong competitor, provided it was able to supply from its Mount Vernon RPU. If PETNET supplied from Nottingham, it was a strong competitor provided that Alliance supplied from Keele.

(b) Similarly PETNET would have been a strong competitor in relation to the InHealth contract if it could serve the additional locations from its Mount Vernon site. We note that in this case PETNET's distances and drive-times are similar to those of Alliance for three of the five InHealth locations. For the other two locations, which are Kent & Canterbury and

[152] See Alliance initial submission, Table 2, and InHealth response to issues statement, Table 1.
[153] [✂]

the Maidstone Hospital, we note that these have been temporarily transferred from IBA's PET business to PETNET in the past. If PETNET supplied from Nottingham, it would have been a strong competitor for all five sites provided that Alliance supplied from Keele. We noted that on the one hand InHealth had reservations about purchasing FDG-18 from Alliance, but on the other it preferred to purchase from more than one supplier.

(c) PETNET has bid aggressively for the Cobalt contract and its distance and drive-times are similar to those of Alliance, regardless of the site from which it supplies. We note that Cobalt switched to PETNET in April 2014.

5.76 Given that our analysis suggested that PETNET was a strong competitor for the Guildford customers in the event that Guildford ceased to supply FDG-18, we considered whether it had enough spare capacity to be able to supply them. Our analysis of spare capacity, which is set out in Appendix G, Annex 3, suggests that [✂].

5.77 On the basis of the evidence set out in paragraphs 5.75 and 5.76, we cannot exclude the possibility that had the Guildford RPU ceased to supply FDG-18, some of its customers would have transferred their purchases of FDG-18 to PETNET.

Provisional conclusions of third limb of exiting firm test

5.78 The above analysis showed that it was possible that some of the contracts currently served from the Guildford RPU would have moved to PETNET (although we recognised that there were other factors that would have influenced the outcome of the process by which customer sales would have been redistributed between suppliers). Therefore we did not reach an expectation that the majority of the sales would have switched to the acquiring firm under the counterfactual (as against the merger situation).

Provisional conclusions on counterfactual

5.79 Based on the assessment above, we provisionally concluded that:

(a) the most likely scenario was that the IBA operation would have exited the market;

(b) there was no likely alternative potential purchaser which would result in a better outcome for competition; and

(c) it was possible that some of the contracts currently served from the Guildford RPU would have moved to PETNET. Therefore we did not

reach an expectation that the majority of the sales would have switched to the acquiring firm under the counterfactual.

6. Assessment of the competitive effects of the merger

Introduction and theories of harm

6.1 In this section we examine the effects of the merger compared with the counterfactual situation, as described in paragraph 5.78.

6.2 In our statement of issues,[154] we identified three ways in which the transaction could give rise to an SLC:

(a) *Theory of harm 1: loss of actual competition*. The concern under this theory of harm is that Alliance would have the ability to increase prices or lower the quality of service (possibly through reduced reliability) in the supply of FDG-18 to providers of PET-CT scanning services, because in bidding for contracts it would face competition from one fewer competitor.

(b) *Theory of harm 2: loss of potential competition.* The merger may result in the loss of potential competition if, prior to the merger, the behaviour of either party was influenced by the threat of the other expanding and entering into direct competition with it or if plans were afoot that could have been expected to result in direct competition in a product and/or geographic market in which the parties did not previously compete.

(c) *Theory of harm 3: vertical effects.* The concern under this theory of harm is that Alliance's presence in both the upstream supply of FDG-18 and downstream supply of PET-CT scanning services may provide it with the ability and incentive to undermine the competitiveness of downstream rivals in order to increase its own presence in the downstream supply (also known as 'input foreclosure'), which may in turn result in the weakening and exit of its competitor in the upstream market (also known as 'customer foreclosure').

Loss of actual competition

6.3 Under the counterfactual, FDG-18 contracts for customers that were not previously served by the Guildford RPU would be competed for by Erigal and PETNET. This would also be the case following the merger and therefore we do not expect that the merger may lead to an SLC in relation to these

[154] Alliance IBA Inquiry Issues Statement.

customers and focus our analysis on the customers who sourced their FDG-18 from Guildford prior to the merger.

6.4 We considered two possible effects arising from the merger compared with the counterfactual situation: in terms of options available to customers following the merger; and with regard to any incumbency advantage that Alliance may derive from the merger.

Options available to customers following the merger

6.5 Following the merger, Alliance could make the decision to use the Guildford site for FDG-18 production or for other purposes. It told us [that its plan was to retain the same amount of capacity for FDG-18 production:] it [✂]. We note that if this is not the case in practice, then the post-merger situation will be similar to the counterfactual scenario. Our analysis therefore focuses on a situation in which the Guildford RPU continues to produce FDG-18.

6.6 As explained in paragraph 3.2, the transaction was structured as an asset purchase and therefore customer contracts were not transferred to Alliance automatically but needed to be formally novated.[155] This process requires the consent of all parties involved, including the customer. Similarly, had IBA Molecular UK taken its Guildford RPU out of the market, customers could not have been forced to transfer their purchases to a supplier of IBA Molecular UK's choosing (since IBA Molecular UK would have been unable to perform the contract).[156]

6.7 However, following the merger, existing Guildford customers still have the option to continue to be supplied from the site, whereas under the counter-factual they would not, as the site would have ceased to operate. A customer would only choose the option to stay with Guildford if it is the most attractive option available.

6.8 It may also be the case that other customers may attach some value to the fact that in future tenders they may be able to source FDG-18 from one additional site, compared with the counterfactual scenario.

Consideration of any incumbency advantage that Alliance may derive from the merger

6.9 In this section, we consider whether the merger would give Alliance an incumbency advantage, thus inhibiting customers who are currently served

[155] [✂]
[156] What happened under similar circumstances in the past is discussed in paragraphs 5.68 & 5.69.

from the Guildford site from switching to PETNET and consequently allowing Alliance to charge higher prices or offer a worse service.

6.10 An incumbency advantage can, in principle, lead to competition concerns if:

(a) it hinders customers from switching to their best options; or

(b) it reduces the value of the best option faced by customers.

6.11 As already discussed in paragraphs 6.6 and 6.7, the merger does not hinder customers from switching to their best option. Further, we note that under the counterfactual, existing supply arrangements would be disrupted, as FDG-18 would need to be sourced from other sites, whereas following the merger, customers have the option to maintain their current supply arrangements, which may mean that the post-merger situation may be more attractive to customers than the counterfactual situation. As noted in paragraph 6.5, if Alliance does not use Guildford to produce FDG-18, then the post-merger situation will be similar to the counterfactual scenario and customers will not have the option to maintain their current supply arrangements.

6.12 We considered two possible sources of incumbency advantages:

(a) *Customer–supplier relationships*. HTE told us that there was no advantage through incumbency as the framework process was completely neutral. However, if a hospital (and in particular its clinicians) had a good relationship with a supplier at a local level, then this might result in the purchase of greater volumes from that supplier over another. We consider that, to the extent that such relationships reflect trust based on successful past collaboration, it may be in a customer's best interest to stay with the current supplier. Where this is not the case, it is not clear to us how existing relationships could prevent customers from pursuing their best options. Cobalt told us that it was satisfied with IBA's PET business's past performance. When it began experiencing reliability issues under the ownership of Alliance and these were not dealt with to its satisfaction, Cobalt took this into account when reviewing supplier options and moved its purchases to PETNET. In line with this, we consider that existing relationships do not make it less attractive (in an absolute sense) to pursue other options but rather they make it more attractive to stay with the existing supplier, provided that they reflect the quality of service provided by the existing supplier. We would expect such relationships to transfer from IBA's PET business to Alliance only to the extent that the

merger transfers also the underlying reputation and quality of service.[157] We do not consider that this decreases the value of PETNET's offering or the ability of customers to switch to PETNET. Further, we consider that the extent to which relationships are transferred to Alliance as a result of the merger is limited given that none of IBA's PET business's management was transferred.

(b) *Customer inertia.* Cobalt told us that it did not always go out to tender if it was content with its existing supplier. InHealth told us that switching behaviour in the FDG-18 market tended to be clustered around periods when longer-term, higher-volume contracts became available, as now, in the lead-up to the commissioning of PET-CT scanning services by NHS England.[158] This may reflect search costs (ie an unwillingness to go out to tender) or incomplete information.[159] This type of incumbency advantage reflects the fact that the merger may allow Guildford customers to avoid incurring switching costs to the extent that it maintains existing supply arrangements. In contrast, under the counterfactual scenario the Guildford customers have no choice but to incur switching costs. We therefore consider that incumbency advantages related to customer inertia are reflective of the merger improving Alliance's offering as opposed to reducing the value of PETNET's offering or hindering customers from switching to PETNET.

6.13 In addition, there are a number of reasons why the scope of any incumbency advantage relating to Guildford customers may be limited:

(a) PETNET is also an incumbent supplier of InHealth.

(b) Cobalt switched to PETNET (after the merger), [✂], which implies that any existing incumbency advantage that Alliance might have derived from its acquisition of the IBA operation was overcome by Cobalt and PETNET.

(c) As explained in paragraph 2.78, NHS Trusts tend to carry out formal tender processes for the award of FDG-18 contracts and for larger-value contracts are subject to public procurement rules.[160] As shown in Appendix E, Tables 9 and 10, both Barts Health and HTE used what

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[157] For example, if a given customer has a preference for working with a specific IBA employee, this relationship will only be transferred to Alliance if the employee is also transferred. In this case, the fact that this employee is now with Alliance increases the value of Alliance's offering for that customer (as opposed to making PETNET's offering less attractive or making it impossible for the customer to switch to PETNET, should it choose to do so).
[158] InHealth response to issues statement, paragraph 5.10.
[159] For example, a customer may prefer working with an incumbent supplier if it is better able to assess the reliability of the incumbent than that of other suppliers – eg as a result of a better availability of KPIs for the incumbent supplier. By working with the incumbent, a risk-averse customer can avoid the risk of getting supplies from a supplier it is less able to assess.
[160] See Appendix E, paragraph 23.

appear to us to be objective criteria for their assessment, although we recognise that how the scores for non-price criteria were arrived at is not fully transparent.

Provisional conclusions

6.14 Given that customers are able to switch supplier both in the post-merger situation and under the counterfactual scenario, the difference between the two situations is that in the post-merger situation there is one additional site involved in the production of FDG-18, which gives rise to an additional supply option. We would expect customers to choose this only if they consider it beneficial. For those Guildford customers wishing to retain their existing supply, they are only able to do so in the post-merger situation.

6.15 To the extent that incumbency advantages exist, they are likely to be beneficial to consumers (see paragraph 6.12). Notwithstanding this, we consider that there are some limits to the scope of incumbency advantages in this context (see paragraph 6.13). We have not found any evidence to suggest that incumbency advantages play a significant role.

6.16 We therefore provisionally concluded that the merger was unlikely to give rise to competitive concerns with regard to the loss of actual competition.

Loss of potential competition

6.17 As explained in paragraph 5.24, we did not expect that the Dinnington RPU would reopen under the counterfactual and there is therefore no loss of potential competition arising from this possibility.

6.18 With regard to the Guildford RPU, the arguments that we set out in paragraphs 6.3 to 6.8 also apply to whether the merger may have resulted from the loss of potential competition, ie there would not be any concern resulting from the merger, and to the extent that the Guildford site is used to manufacture new types of radiopharmaceuticals, there may be a benefit arising from the fact that the merger potentially preserves the option for customers to source such products from one additional site.[161]

6.19 We therefore provisionally concluded that the merger was unlikely to give rise to competitive concerns with regard to the loss of potential competition.

[161] Alliance told us that, by selling its UK FDG assets, IBA Molecular was unable to fulfil the UK part of its contract with Piramal for the supply of the Alzheimer's tracer florbetaben. As the new owner of IBA's UK assets, Alliance entered into a subcontract with IBA Molecular for the supply of florbetaben.

Vertical effects

6.20 InHealth and (to a lesser extent) Cobalt argued that the merger gave rise to vertical effects that would be adverse to their businesses and ultimately to customers. Their views hinged on three key themes:

(a) Alliance becomes a necessary supplier of FDG-18 to PET-CT scanning suppliers;

(b) Alliance's own PET-CT scanning operations compete with those of InHealth and Cobalt; and

(c) the NHS procurement of new block contracts provides an opportunity to Alliance to take advantage of its presence in both the supply of FDG-18 and PET-CT scanning services.

6.21 We first set out these arguments before assessing them.

Arguments put forward by InHealth and Cobalt

Alliance as a necessary supplier of FDG-18

6.22 InHealth currently obtains FDG-18 from PETNET and the IBA operation. It told us that it preferred having [✂] of FDG as this ensured the reliability of back-up supplies. [✂]

6.23 InHealth told us that it reduced the volumes it purchased from IBA's PET business as a result of reliability issues, choosing to source these from PETNET instead, but that it had recently restored these volumes to the IBA operation.[162] [✂]

6.24 [✂]

6.25 InHealth further told us that, by removing the third independent supplier in the South, Alliance made itself an essential supplier of back-up to InHealth or to PETNET.[163] InHealth told the OFT that, as a result of the merger, since no provider of PET-CT scanning services could allow itself to be reliant on a single provider of FDG-18, each supplier could be sure that all customers would be obliged to rely on obtaining FDG-18 from it, whether directly as a contracted customer or through resilience arrangements between FDG-18 suppliers.[164]

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[162] InHealth moreover told us [✂].
[163] InHealth response to issues statement, paragraph 7.4.
[164] InHealth initial submission, paragraph 1.10.2.

Effects related to Alliance as a vertically integrated supplier

6.26 InHealth made a number of points related to the fact that Alliance was a competitor of InHealth in the provision of PET-CT scanning services:

(a) InHealth told us that it was concerned that [✂].[165]

(b) [✂][166,167] It mentioned the possibility of a 'quality (reliability)-based foreclosure strategy', and that its most significant concern in relation to foreclosure was that the reliability of supplies to its PET-CT scanning operations would reduce following the merger.[168] [✂]

(c) InHealth told us that it would prefer not to [✂].[169]

Issues specific to the procurement of the NHS block contracts for PET-CT scanning services

6.27 InHealth told us that it had [✂] (described in Appendix E, Table 4).

6.28 InHealth said that customers of PET-CT scanning services were indifferent about how their suppliers arranged for security of supply, and that customers were merely concerned with whether or not the scan happened on the right day.

6.29 [✂]

Assessment

6.30 Given our view that IBA Molecular UK would have either mothballed or decommissioned its Guildford site under the counterfactual, we considered that none of the points made above (in paragraphs 6.20 to 6.29) were merger specific (ie in both the counterfactual situation and following the merger situation, the IBA operation will not be an independent supplier of FDG-18), and that the merger is therefore unlikely to give rise to vertical effects. Indeed, we consider that any vertical effects in the supply of FDG-18 would have been a product of horizontal effects in the supply of FDG-18. The fact that we have

[165] Similarly, Cobalt noted that, should there be production issues, Alliance might well favour its operational sites as opposed to Cobalt.
[166] InHealth response to issues statement, paragraph 7.5.
[167] ibid, paragraph 7.6.
[168] Cobalt told us that IBA's PET business had provided a good service to Cobalt in the past four years, but that it had experienced non-supply and late deliveries of FDG-18 in March/April 2014.
[169] [✂], Cobalt told us that, if it were to contract with Alliance for the supply of FDG-18, Alliance would be advantaged by market data from Cobalt on the number of scans, etc, and that this may drive PET-CT scanning service providers to purchase FDG-18 from PETNET, which might respond by raising prices.

not found vertical effects is therefore consistent with the fact that we have not found any horizontal effects.

6.31 We therefore provisionally concluded that the merger was unlikely to give rise to competitive concerns as a result of vertical effects.

6.32 For completeness, we provide additional commentary on the arguments made by InHealth and Cobalt in the following paragraphs.

Alliance as a necessary supplier of FDG-18

6.33 We note InHealth's preference to obtain its FDG-18 from [✂]. However, we consider that other business models are available to InHealth. Indeed other customers of FDG-18, including InHealth's competitor Cobalt, source their FDG-18 from only one supplier, leaving it to the supplier to organise adequate back-up arrangements. Whilst we recognise that InHealth is a much larger customer (of FDG-18) than Cobalt and that this may make it harder for InHealth to rely on one FDG-18 supplier, we think this is still a feasible option for InHealth. In particular, were InHealth to source all of its supplies from PETNET, we consider that PETNET could largely back itself up from Nottingham.[170]

6.34 We acknowledge that sourcing FDG-18 from two suppliers appears to have allowed InHealth to exercise a degree of bargaining power vis-à-vis FDG-18 suppliers in the past by giving it the ability to switch volumes between FDG-18 suppliers in response to price and/or quality issues. However, we do not consider that sourcing from only one supplier would substantially affect InHealth's bargaining power, as it could continue to play one FDG-18 supplier against another at the time when prices are set (eg in the form of a tender).

6.35 As noted above, InHealth argued that, by removing the third independent supplier in the South, Alliance made itself an essential supplier of back-up to InHealth or to PETNET. As noted above, in our view, IBA's PET business would not be an independent supplier in either the merger or counterfactual scenario. We have discussed the role of Alliance as an essential back-up supplier in paragraphs 6.22 to 6.25.

[170] PETNET considered that, across both of its RPUs, its unplanned outages affected less than 1% of its supply. In particular, PETNET told us that the reliability of each of its sites was in the high 90% range and that, across both of its sites, it was above 99.5%. See PETNET hearing summary, paragraph 25.

Effects related to Alliance as a vertically integrated supplier

6.36 Regarding concerns that *(a)* Alliance would prioritise FDG-18 for its own internal use, *(b)* Alliance would seek to foreclose rival scanning providers and *(c)* the role of Alliance as a supplier of FDG-18 to other scanning providers would give Alliance [✂], we note the following:[171]

(a) As argued above, we do not consider it necessary for commercial providers of PET-CT scans (ie InHealth and Cobalt) to source their FDG-18 from Alliance. In particular, should they choose to source their FDG-18 from PETNET, PETNET could back itself up.

(b) PETNET on the one hand and InHealth and Cobalt on the other have a joint incentive to eliminate double marginalisation[172] in order to enhance their ability to compete with Alliance in the provision of PET-CT scanning. This would be in PETNET's interest in order to protect the demand for its FDG-18.

(c) PETNET told us that it placed importance on the functioning of the FDG-18 market, as FDG-18 was a necessary input for scanning equipment [✂].[173] This suggests that PETNET has a long-term incentive to keep its FDG-18 prices low so as to promote demand for scanning equipment including its own.

(d) Regarding any effects Alliance's vertical integration may have regarding foreclosure [✂], to the extent that this was to make the outcome of NHS PET-CT scanning tenders less competitive, this might prompt some NHS trusts to purchase their own scanners, thus reducing the size of the PET-CT scanning market to which Alliance can supply. Alliance told us that [✂]% of FDG-18 requirements from commercial providers were for hospitals with in-house scanners. We note that a number of hospitals told us that they had considered getting a PET-CT scanner in the past. Estimates for the cost and time to obtain a scanner vary but are centred around £1.5 million and 6 to 12 months respectively.[174] In line with this, a

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[171] We focus on InHealth and Cobalt, noting that NHS trusts with their own PET-CT scanners which purchase FDG-18 will not be affected by *(b)* or *(c)* as they do not tender for PET-CT scanning business. [✂], we consider that the ability of NHS trusts to switch to PETNET is unaffected by the merger given our view that IBA Molecular UK would have mothballed or decommissioned its Guildford site under the counterfactual.

[172] Double marginalisation (or double mark-up) occurs when a firm charges a mark-up on input costs and the input costs already reflect a mark-up charged by the supplier of the input, leading to a mark-up on a mark-up.

[173] [✂].

[174] The following are the costs and time requirements estimated by various hospitals: [✂] – a minimum of £1.5 million and 12 months, [✂] – did not provide a cost estimate but submitted that it would take 6 to 12 months, [✂] – £1.5 million and 4 to 6 months, [✂]) – £1–1.5 million depending on CT slices plus associated building costs and 9 to 18 months, [✂] – £1.5–£2 million and 3 to 6 months, and [✂] – £1.5 million, with additional capital costs in the region of £1 million for the building and ancillary equipment, and 12 months.

number of hospitals suggested that volumes had to be sufficient to install a scanner, and some hospitals suggested that this might (in addition to outsourcing) be achievable through partnerships (in conjunction with other trusts) to share the capital costs.[175] This suggests that there are likely to be a number of marginal NHS trusts that are likely to purchase their own scanners in the case of a material deterioration of service quality or material price increase in the provision of third-party PET-CT scanning services. While trusts acquiring their own scanners would continue to have Alliance as a potential supplier of FDG-18, Alliance would cease to have foreclosure incentives as the trusts would cover scanning for their patients as opposed to competing for patients with Alliance as do InHealth and Cobalt.[176]

(e) Noting that the supply of PET-CT scanning services is 'more significant commercially' than the supply of FDG-18, to the extent that InHealth and Cobalt absorb any FDG-18 price increases, this would not affect patients or the NHS as end-users of PET-CT scanning.

Issues specific to the procurement of the NHS block contracts

6.37 [✂] We have addressed this argument above.

6.38 [✂]

6.39 We note that both InHealth and Cobalt have experienced reliability issues with the IBA operation. However, in the case of InHealth we note that these issues began prior to the merger, and in the case of Cobalt we note that Cobalt was able to switch to PETNET. We therefore do not consider that these events amount to evidence of the implementation of a 'quality (reliability)-based foreclosure strategy'.

7. Provisional findings

7.1 We provisionally conclude that the merger has not resulted and may not be expected to result in an SLC within any market in the UK.

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[175] [✂] told us that 'partnership working' would give it an 'opportunity to share the capital costs associated with set-up', [✂] told us that its decision to get a scanner would depend on the availability of capital monies and 'suitable partnership arrangements' and [✂] told us that it would consider installing a scanner 'in conjunction with other Trusts'.
[176] [✂]