OFFICE OF FAIR TRADING

Completed acquisition by Alliance Medical Limited of the assets of IBA Molecular UK Limited used to manufacture Fluorodeoxyglucose 18f

ME/6322/13

The OFT's decision on reference under section 22(1) given on 24 March 2014. Full text of decision published 6 June 2014.

Please note that the square brackets indicate figures or text which have been deleted or replaced in ranges at the request of the parties or third parties for reasons of commercial confidentiality.

PARTIES

1. Alliance Medical Limited ('**Alliance**') is a European provider of Diagnostic Imaging Services. In the UK, Alliance provides three types of patient scanning services: magnetic resonance imaging ('**MRI**'), computed tomography ('**CT**') and positron emission tomography-computed tomography ('**PET-CT**'). It also produces and sells medical radioactive tracers using isotopes. Its wholly owned subsidiary Erigal Limited ('**Erigal**') owns and operates three radiopharmaceutical units ('**RPU**') in the UK where isotopes are produced using cyclotrons. Alliance/Erigal's RPUs are based in Keele (Staffordshire), Preston (Lancashire) and Sutton (Surrey).

2. The target of this acquisition is the manufacturing assets for the production of ^{18}F-fluorodeoxyglucose ('**FDG-18**')[1] in the UK formerly controlled by IBA Molecular UK Limited ('**IBA**') ('**the Target**'). IBA is controlled by SK Capital, a private equity firm which acquired a majority shareholding in IBA in April 2012. The Target comprised two RPUs that are capable of producing FDG-18 (based at Guildford, Surrey; and Dinnington, Yorkshire), eight employees and contracts with five customers. The UK revenue of the Target in the financial year ending March 2012 was £2.1 million.

[1] FDG-18 is a tracer (also known as a biomarker) injected into patients primarily when undergoing a PET-CT scan for the diagnosis of certain types of cancer. FDG for PET-CT is commonly used for cancer staging and follow-up, evaluation of myocardial viability or sarcoidosis and assessment of neurological conditions including epilepsy and dementia. FDG for PET-CT can also be used to assess some infections.

TRANSACTION

3. Alliance Medical Molecular Imaging Limited, a subsidiary of Alliance, acquired the Target on 16 September 2013 ('**the Transaction**').

4. The consideration payable for the Transaction was [✂].

JURISDICTION

5. As a result of the merger, Alliance and the Target (the '**Parties**') have ceased to be distinct. The OFT believes that the combination of assets, contracts, employees and activities forming the Target constitute an enterprise for the purposes of Part 3 of the Enterprise Act 2002 (the Act).

6. Prior to the merger, the Parties overlapped in the manufacture and supply of FDG-18. Alliance submits that in the south of Great Britain, they account for a share of supply of [30-40] per cent (following a one per cent increment).[2, 3] Consequently, the OFT considers that the share of supply test in Section 23(3) of the Act is satisfied. As a result, the OFT believes that it is or may be the case that a relevant merger situation has been created.

7. The Transaction completed on 16 September 2013. The statutory deadline for the OFT to announce its decision in this case was subsequently suspended, and now expires on 6 April 2014. Its administrative deadline expires on 21 March 2014. The OFT was not notified of the Transaction and launched the case on its own initiative.

SECTORAL BACKGROUND

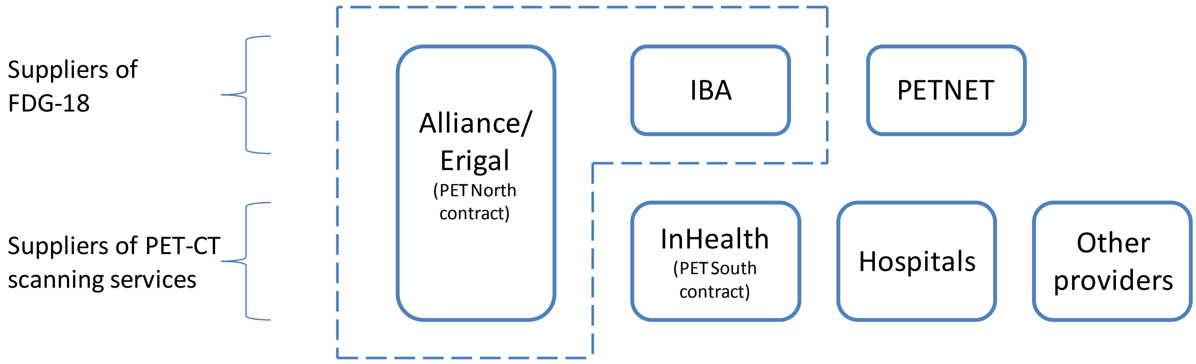
8. FDG-18 is radioactive tracer used in PET-CT scanning services. The suppliers of FDG-18 and PET-CT scanning services are presented in the schematic below.

[2] This estimated share of supply is based on the volume of doses of FDG-18 supplied by commercial licensed FDG-18 suppliers to third parties primarily in the geographic area covered by the PET-CT Scheme of the South Region (the PET-CT South contract). This is a Service Agreement previously run by the Department of Health (now run by NHS England) effective from 2008 to 2015 to ensure the provision of PET-CT scanning services. The geographic area extends from Nottingham to Plymouth and includes PET-CT scanning facilities in London, Brighton, Cambridge, Coventry, Guildford, Oxford, Sutton, Portsmouth and some mobile scans operated by InHealth. It also includes supplies to the PET-CT scanning facilities to Cardiff & Vale University Health Board.

[3] As outlined below, the OFT considers the parties' share of supply to be significantly higher than this at 50 per cent (with a 25 per cent increment), based on the volume of doses of FDG-18 and including both internal self-supply from Erigal to Alliance and long-term contracts between Erigal and those hospitals where Erigal's production facilities are based.

9. The suppliers of FDG-18 to third party providers of PET-CT scanning services are the Parties and Siemens PETNET Solutions Inc[4] ('**PETNET**'). Some hospitals produce their own FDG-18 for their own research and clinical use.

10. Alliance is vertically integrated offering PET-CT scanning services and self-supplying its FDG-18 requirements from its sites in Keele, Preston and Sutton. It also supplies third parties FDG-18 from these sites.



11. InHealth supplies PET-CT scanning services, primarily in the south of Great Britain[5], as does other providers such as Cobalt. Other providers of PET-CT scanning services are NHS and private hospitals which own and operate PET-CT scans at their premises.

12. Hospitals in England can either contract out the provision of PET-CT scanning services with third party suppliers of PET-CT scanning services, enter into long-term contracts (often for a term of 10 years), or be part of the national PET-CT block contracts ('**NHS PET-CT block contracts**') managed by NHS England and currently held by Alliance (NHS PET-CT North Contract) and InHealth (NHS PET-CT South Contract).[6] NHS Scotland, NHS Wales and NHS Northern Ireland have similar schemes.

[4] PETNET is a wholly owned subsidiary of Siemens AG. Another companies controlled by Siemens manufacture and supply PET-CT scans in multiple countries, including the UK.
[5] InHealth is for example the current provider for the NHS PET-CT South Contract. See footnote 2 above.
[6] At present NHS England is publicly consulting on the appropriate framework for the forthcoming NHS PET-CT block contracts which are due to be tendered in the next few months and implemented from April 2015. See further at https://www.supply2health.nhs.uk/Results.aspx?k=PET-CT

FRAME OF REFERENCE

Product scope

Types of isotopes

13. Prior to the merger, the parties overlapped in the manufacture and supply of licensed FDG-18 for PET-CT diagnostic services (licensed commercial supply of FDG-18 for diagnostic PET-CT).[7]

14. Alliance and IBA also overlap in the supply of contract manufacturing of isotopes for use in PET-CT scanning when imaging brains of adult patients being evaluated for Alzheimer's disease, as well as other causes of cognitive impairment ('**Alzheimer's tracers**'). As with FDG-18, these radiopharmaceuticals contain the isotope fluorine-18 (which is produced in cyclotrons in RPUs).

15. Production of these tracers has either already started or will start by the end of 2014 and so the arrangements to supply these tracers have already been determined. While there was no production overlap between the Parties pre-merger,[8] the OFT considers that the parties represented alternatives for license holders in the supply of contract manufacturing arrangements – illustrated by one license holder choosing to source such contract manufacturing from IBA[9] and another from Erigal (and the other from PETNET) – and therefore overlapped. The OFT has therefore considered whether FDG-18 and Alzheimer's tracers form part of the same product market.

16. Alliance submits, and the OFT's market testing has corroborated, that there are no substitutable products to FDG-18 for its applications in PET-CT scans. The OFT understands that, similarly, there are no substitutable products for Alzheimer's tracers for their intended clinical use in PET-CT scanning.

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[7] Erigal is also currently active in the supply of two other radioisotopes, ^{18}F-Choline and ^{18}F-Sodium Fluoride, which the Parties submitted the Target never produced, although the Target did (and the vendor continues) to resell quantities of the latter, produced by Erigal. The parties submitted that the market size of this tracer worth around £[✂] and the OFT notes that even Erigal produces only very small quantities of these tracers ([✂] doses of choline and [✂] doses of sodium fluoride in FY2011). In the absence of any material overlap, the OFT has focused its assessment on the supply of FDG-18 and has not considered these other isotopes further.

[8] The Parties submitted there are three pharmaceutical companies developing drugs in this area, Eli Lilly, GE and Piramal, each of which requires a different tracer (Florbetapir, Flutemetamol and Florbetaben, respectively), which are currently (or will be) supplied through multi-country toll arrangements and in the UK by PETNET, Erigal and IBA, respectively. [✂]

[9] Post-merger this will be produced by Alliance.

17. In the absence of evidence supporting demand-side substitution, the OFT has considered the extent to which these products may be aggregated on the basis of supply-side arguments.[10]

18. The OFT notes that the supply of FDG-18 and the supply of the other Alzheimer's tracers are very different. Producers of FDG-18 sell direct to third parties so they must hold a Marketing Authorisation ('**MA**') for their products[11] and a Manufacturer's/importer's ('**MIA**') licence for each of their production facilities. In contrast, in the case of Alzheimer's tracers, the Parties act merely as contract manufacturers. Alliance and the Target will not be selling Alzheimer's tracers direct to third parties. This means that they are not required to hold an MA. The pharmaceutical company holds the MA licence. The Parties still need an MIA licence for each production site.

19. As a result of the materially different competitive conditions in the manufacture and supply of FDG-18 and Alzheimer's tracers as described above, the OFT has taken a cautious approach and assessed FDG-18 and Alzheimer's tracers separately.

18 F-fluorodeoxyglucose ('FDG-18')

20. The OFT has considered the extent to which the licensed commercial supply of FDG-18 is the relevant product market in which to assess the merger. Specifically, there are a number of ways in which the product market may be split, which are considered in turn:

- commercial and non-commercial supply
- primary and back-up supply
- self-supply to PET-CT suppliers
- long-term supply contracts.

Commercial and non-commercial supply

21. FDG-18 is regulated as a radioactive medicine and is produced in cyclotrons located in RPUs. RPUs are licensed by the Medicines and Healthcare products

[10] The OFT considers that the boundaries of the relevant product market are generally determined by reference to demand side substitution. There are circumstances where the OFT may aggregate several narrow relevant markets into a broader one on the basis of considerations about the response of suppliers to changes in prices, specifically: where firms have the ability and incentive quickly to shift capacity between different products; and the conditions of competition between firms are the same for each product. See *Merger Assessment Guidelines, a joint publication by the Competition Commission and the Office of Fair Trading*, September 2002 (*Merger Assessment Guidelines*), paragraph 5.2.17.
[11] Alliance/Erigal's FDG-18 product is branded ERtracER™ and the brand name of PETNET is MetaTrace FDG.

Regulatory Agency ('**MHRA**') [12] to supply tracers for PET-CT imaging. As outlined above, those producers of FDG-18 supplying to third parties (that is outside their own organisation) must hold an MA licence for a given product and an MIA licence for each of their production facilities. In this decision, products holding an MA licence are described as '**commercial tracers**'.

22. In the case of cyclotrons that do not have an MA, tracers can be supplied for individual patients under a Marketing Special ('**MS**') licence. This is the licensing mechanism used by research institutes for trial scans. Non-commercial RPUs use this mechanism to supply their on-site scanners and do not supply to any third party outside their own organisations.

23. Tracers produced under an MS license cannot be advertised and cannot be supplied if an equivalent MA licensed product is available.

24. Eight NHS hospitals providing PET-CT scan services in Great Britain also operate their own cyclotrons.[13] These hospitals produce FDG-18 and self-supply all, or a part of, their own FDG-18 requirements. None of the NHS hospitals that produce FDG-18 for their own use have the necessary licenses to sell FDG-18 commercially.[14] This prevents them from supplying to third parties. These hospitals have stressed that their focus is on the production of FDG-18 for research purposes and/or in-house clinical diagnosis without contemplating supply to third parties. Some of the hospitals have explained that having considered previously the 'commercial' supply to third parties, the idea was rejected primarily due to licensing costs, additional set-up and equipment requirements, logistics set-up and the different focus of their activities.

25. The OFT has not received any evidence supporting the view that non-commercial production forms part of the same frame of reference as commercial production of FDG-18. In contrast, the evidence available to the OFT shows that non-commercial suppliers of FDG-18 would not switch to commercial production in the event of a price rise.[15]

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[12] The Medicines and Health care products Regulatory Agency is an executive agency of the Department of Health responsible for ensuring that medicines and medical devices work and are acceptably safe.

[13] In addition, four hospitals have long-term arrangements with Alliance/Erigal or PETNET by which these FDG providers install and operate a cyclotron onsite, from which they supply that hospital under a long term contract and are able to supply from that site to third parties. The extent to which supply under such long-term agreements, including these latter four operations, is considered part of the relevant market is considered below.

[14] The OFT understands that currently the only holders of Marketing Authorisation licences for FDG-18 are Erigal, IBA, Siemens PETNET Solutions Inc, the latter a wholly owned subsidiary of Siemens AG and GE Healthcare Limited (at its site in Amersham).

[15] Self-supply by potential or actual customers of the merger firms will be generally included in the relevant market if the ability of customers to choose to self-supply (rather than procuring from a third

Primary and back-up supply

26. Cyclotrons are subject to outages for either planned maintenance or due to unplanned failures. These outages represent a minimal proportion of the overall production (less than 5 per cent in 2013). However, they can cause serious inconvenience 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.

27. There are three types of back-up arrangement in practice:

- self back-up where a supplier uses another of its own cyclotrons for back-up
- formal back-up arrangements with other FDG-18 producers. This involves contracts entitling the purchaser to supplies of FDG-18 from other producers
- spot back-up arrangements when an outage leads to a request for short term supplies from one supplier to another

28. The OFT notes that customers of FDG-18 require their suppliers to organise back-up themselves and do not contract separately for primary and back-up supplies. In effect, this means that customers do not need to multi-source FDG-18 to ensure security of supply but rely entirely on their primary supplier to ensure such security. Customers are generally unconcerned by the exact process through which security is provided.

29. From a customer perspective (that is the provider of PET-CT scanning services), therefore, there is no independent demand for primary and back-up supply of FDG-18: primary and back-up supply form a package with the customer purchasing both together. The customer chooses a supplier of FDG-18 on the basis of a range of factors, in particular price and surety of supply. Both can be impacted by the back-up options of the supplier but this affects only the attractiveness of the bundle (or 'system') of primary and back-up supplies.[16] The customer pays a single price per dose under a contract with its supplier, irrespective of whether that dose is obtained by the supplier from its

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party) affects the profitability of a price rise by a hypothetical monopolists. For details of the OFT's approach to self-supply. See *Merger Assessment Guidelines*, paragraph 5.2.20.

[16] In this context, from a supplier's perspective, back-up supply may be considered an input to the sale of the 'bundle', which may be sourced internally or externally.

own production facilities or a competing supplier.[17] As a result, the OFT considers primary and back-up supply together.

30. As stated, since back-up arrangements may be a factor in the competitive strength of the FDG-18 suppliers, the OFT has considered this in its competitive assessment.

Self-supply to PET-CT suppliers

31. Alliance submits that its policy is to self-supply FDG-18 to maintain security of supply and that there is no likelihood of it purchasing FDG-18 from third parties.

32. As some firms purchase FDG-18 from an independent third party supplier, while others meet their own requirements, the OFT has considered the extent to which production of FDG-18 used for self-supply by Alliance/Erigal should be included in the relevant market. In such circumstances, generally the OFT considers captive production by the firms involved will be included in the relevant market if it can be demonstrated that it would be profitable for a supplier (in this case Alliance/Erigal) to forgo its use and supply into the merchant market in response to a price rise.[18, 19]

33. The OFT notes that the majority of Alliance's self-supply relates to its NHS PET North block contract. This is a tendered process followed by the award of the contract by (then, the Department of Health and currently) NHS England. In light of this, the OFT notes that:

- there is no certainty at present as to the configuration of the contracts for the new national NHS PET-CT block contracts, due to begin in 2015. For example, this could be in the form of one or multiple contracts relating to several geographic areas.

- regardless of the number and form of the tenders or contracts, Alliance may not retain its current volumes (if it does not win). Then, Alliance/Erigal may be expected to compete to supply FDG-18 to the merchant market (so as to maintain cyclotron utilisation rates).[20] Corroborating this, for example, one

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[17] See *Merger Assessment Guidelines*, paragraph 5.2.20 for an outline of the OFT's approach to secondary products.

[18] A small but significant non-transitory increase in price (SSNIP). See *Merger Assessment Guidelines*, paragraph 5.2.11

[19] The OFT's approach to self-supply is outlined in detail in the *Mergers Assessment Guidelines*, paragraph 5.2.20. Self-supply may be considered part of the relevant market when it would be profitable for a supplier to forgo its use and sell into the merchant market in response to a SSNIP.

[20] In assessing the incentive to supply to the merchant market, the OFT notes that the high fixed costs of supplying FDG-18 provides an incentive to utilise available capacity so that Alliance/Erigal may be expected to pursue high levels of utilisation regardless of its success level in the forthcoming award of NHS PET-CT block contracts.

third party suggested to the OFT that should Alliance/Erigal not retain the PET North contract, that Alliance/Erigal would be expected to compete fiercely for third party supplies.

34. Given the above, the OFT considers that the so-called self-supply from Erigal to Alliance (and now the Target) should be included as part of the relevant market for the purpose of assessing the effects of the merger on the supply of FDG-18.

Long-term contracts

35. Alliance characterises supply of FDG-18 under long-term exclusive contracts, where the supplier's production facilities are based on-site at the hospital, as not part of the 'contestable market'. There are four long-term contracts this relates to:

- Alliance/Erigal's contract with the Royal Marsden Hospital NHS Foundation Trust [21]
- Alliance/Erigal's contract with Lancashire Teaching Hospitals NHS Foundation Trust (whose principal location is the Royal Preston Hospital)[22]
- PETNET's contract with Nottingham City Hospital, and
- PETNET's contract with Mount Vernon

36. In relation to Erigal's contracts, the OFT has considered the extent to which Erigal's capacity at those production facilities is in the relevant market and thus was potentially competing with the Target pre-merger. The OFT notes that Erigal supplies (and competes to supply) third parties from these sites and that only a small proportion of its capacity at these sites is used to provide the on-site hospitals under long-term contracts.

37. Another consideration with regard to long-term contracts is the extent to which the Target was competing with Erigal for these particular customers, which the OFT does not consider appropriate to assess as part of the market definition. Nevertheless it notes that such contracts may be subject to competition within the next few years.[23]

38. Based on the above, the OFT believes that the volumes of these long-term contracts do not affect the extent to which Erigal was using this capacity to

[21] This supply agreement was entered by Erigal Limited on 14 July 2008 ('the **Royal Marsden Hospital contract**')
[22] This supply agreement was entered by Erigal Limited and dated 4 April 2007 ('**the Royal Preston contract**').
[23] [✂].

compete to supply third parties and, in any event, it should be deemed to be, in principle, part of the relevant market.

Geographic scope

39. Alliance submits that it is instructive to split the supply of FDG-18 geographically into the North and South of Great Britain since this division reflects industry usage and the approach of the Department of Health when it commissioned its contracts for the purchase of PET-CT scanning services in England into NHS PET-North and PET-South block contracts.[24]

40. As explained above,[25] there is no certainty about the scope of the future NHS PET-CT block contracts. A third party explained to the OFT that the national tender originally framed the NHS PET-CT block contracts in three lots and that this fluidity indicates that there is no particular necessity that the contracts be divided in the way that they are. It adds that no PET-CT provider could reasonably expect that the NHS PET-CT block contracts would necessarily continue to be split in the same way in future.

41. FDG-18 has a half-life[26] of 110 minutes. This limits the distance over which it can be transported. There are regulatory restrictions and clinical guidance on the volume of FDG-18 that patients can receive. There are also regulations on the length of time after production that the FDG-18 can be administered[27] and, according to Alliance, a four hour maximum delivery range.[28]

42. Alliance submits that 'whilst deliveries of up to four 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 two hours.'[29] Manufacturing sites delivering close to four hours' drive time away will have to deliver greater volumes of FDG-18 to meet the required levels of radioactivity (due to FDG-18's half-life) than those sites where most customers are based within a two-hour drive time.

43. The OFT notes that the market operates by suppliers delivering to customers. The OFT has therefore analysed the data Alliance submitted on drive times to customers below before then going on to consider the extent to which discrimination by customer group may allow for targeted merger effects and

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[24] Commissioning for the supply of PET-CT scanning services in England was taken over by NHS England (as special commissioner) from April 2014.
[25] See paragraphs 33.
[26] The length of time in which levels of radioactivity drop by 50 per cent.
[27] The OFT understands that the shelf-life of FDG-18 is between 10 and 12 hours.
[28] See further slides by the Society of Nuclear Medicine and Nuclear Imaging, July 2012, slide 1 at: http://interactive.snm.org/docs/PET_PROS/FDG_K_Zukotynski.pdf
[29] See Alliance's submission to the OFT of 24 January 2014, paragraph 46.

require a separate assessment.

44. Alliance provided drive times for 24 customers, four of whom multi-source their supply from two providers. Of the total of 28 suppliers that currently have an FDG-18 supply contract: 78 per cent (22) of those customers procure their FDG-18 within less than 110 minutes from the RPU; 11 per cent (3) of those customers from between 110 and 120 minutes from the RPU; and the remaining 11 per cent (3) of those customers from an RPU located more than 120 minutes drive-time away.

45. This analysis indicates that the majority of customers (almost 90 per cent) are served by suppliers that are within a two hour drive time, or one half-life of FDG-18.[30]

46. This analysis may allow for the determination of effective catchment areas around each supplier's sites to determine overlaps and competition within each catchment. However, the OFT is aware of the ability of the Parties in this case, and firms active in this industry generally, to price discriminate between customers. For example the OFT has noted that prices vary substantially among customers. This can be the result of bilateral negotiations between FDG-18 suppliers and PET-CT scanning service providers. As a result, the effects of the merger on competition to supply a targeted group of customers may differ from its effects on other groups of customers.[31] In particular, the ability to discriminate based on customer location (for example, due to the availability of substitutes or alternative suppliers in particular locations), means that the OFT may define the geographic scope based on customer location with suppliers in the market being those firms that sell to customers in that region.[32]

47. This is consistent with Alliance's own assessment of its alternative suppliers in the event that it would be required to switch its procurement from Erigal (prior to acquiring full control of Erigal).[33] It shows that Alliance considered different alternatives for each site from where it supplies PET-CT scanning services.

48. The OFT considers that such an approach – assessing separate customer groups that may be affected by the merger in different ways – is appropriate in this case, and so the OFT examines the potential differential impact of the merger on different customer groups as part of the competitive assessment. In

[30] Drive times to customers in Scotland are significantly longer than 110 minutes. The OFT notes that these relate to back-up supplies only and that there is no alternative supplier within a shorter drive time. [✂]
[31] For an overview of the OFT's approach to price discrimination and customer segmentation see *Mergers Assessment Guidelines*, paragraph 5.2.29.
[32] This may occur when suppliers deliver products to customer locations, as is the case here.
[33] Alliance's submission to the OFT of 24 January 2014, Annex 17. Presentation titled *Alternative FDG suppliers to Erigal*, *July 2012*, slide 5.

practice, this assessment splits Great Britain into four broad geographic areas, each grouping those customers within that region with similar supply alternatives. In assessing those alternatives, the OFT has taken account of the customers' primary and back-up options.

49. The first is a geographic area reflecting a two-hour drive time from the sites around London (that is, Alliance's site at Marsden, the Target's Guildford site and PETNET's Mount Vernon site). The customers in this area can be supplied by the same range of suppliers (that is, Alliance, the Target and PETNET), and the back-up options for suppliers are the same across this area. That is, PETNET can self back-up and Alliance/Erigal can self back up in the event of planned cyclotron maintenance. The Target must back-up via other supplier. For this area, the OFT assessment will be on the loss of actual competition due to the merger. For the purposes of this decision this area is known as the **South.**

50. The second area is between two and four- hour drive time north from sites around London. Customers in this region have the same supplier and these have similar back up options: Alliance/Erigal and PETNET can self back-up, and the Target could potentially supply from its mothballed site in Dinnington and self back-up. For this area, the assessment will be on the loss of potential competition due to the merger. For the purposes of this decision this area is known as the **North**.

51. The third geographic area is beyond four hours north of sites around London and in England. Customers in this area differ in their supply options from the second group because PETNET would not be able to self back up due to the distance from its site in the London area, and the same would be true of potential supplies from the Target. The competitive strength of these suppliers may therefore be different in this area compared to the second area, though the OFT's competitive assessment will also focus on the loss of potential competition due to the merger. For the purposes of this decision this area is known as the **Far North**.

52. The fourth geographic area is **Scotland.** For customers in this area, their potential suppliers are Alliance (from its Keele and Preston sites) and the Target's Dinnington site. Again, the OFT competitive assessment will focus on the loss of potential competition for these customers.

53. In summary, the relevant geographic markets are:

- the South: a two-hour drive time from the production sites around London
- the North: two-hour drive time from the production sites around London and

four hours north of production sites around London

- the Far North: beyond four hours north of sites around London and in England, and
- Scotland.

Alzheimer's tracers

54. The contracts for manufacture of Alzheimer's tracers are between the manufacturers and the pharmaceutical companies. These are on a multi-country basis. However, the OFT does not consider that this means that a multi-country frame of reference is appropriate. It is probative that despite having a global agreement with IBA Molecular (the vendor), after the Transaction Piramal entered into a toll manufacturing agreement with Alliance because IBA was unable to fulfil the UK part of the contract.[34] This evidence indicates that the market is at most national.

55. Given that those tracers contain fluorine-18 and so have the same half-life as FDG-18, the distance from supplier site to the end customer may be a key factor of competition because of its impact on the cost of supply. Indeed, [✂] which its contractor Alliance does have.

56. The OFT notes the uncertainties in the competitive landscape for Alzheimer's tracers, and, given that the geographic scope does not affect its competitive assessment, the OFT does not need to conclude on the scope of the geographic market for Alzheimer's tracers.

Positron emission tomography-computed tomography (PET-CT)

Product scope

57. Alliance is vertically integrated supplying FDG-18 and also providing PET-CT scanning services to hospitals.[35] The Target has no activities in PET-CT scanning but does supply FDG-18 and could supply other isotopes in the foreseeable future as an input to PET-CT scanning. While there is no horizontal overlap between the Parties, there is a vertical supply arrangement. The OFT has considered the relevant product scope for PET-CT scanning to assess these non-horizontal issues.

58. As stated above (see paragraphs 11 and 12 above), PET-CT scanning services

[34] Alliance submission of 24 January 2014
[35] PET-CT scanning is a medical imaging technique that produces pictures of the body's internal structures. It has oncological and non-oncological applications. See *Evidence-based indications for*

are supplied in different contexts. They can be supplied directly by NHS (and very few private) hospitals which own and operate one or more PET-CT scans at their sites; by an outsourced third party provider at a NHS hospital site, often under a long-term contract; and those commissioned in block at a national level by NHS England.[36]

59. The OFT's market testing suggests that there is no directly substitutable services to PET-CT scanning services in circumstances which match the clinical aims for the use of that service, with the choice of a PET-CT scan being clinically-led. As a result, the OFT does not currently consider demand-side substitution warrants widening the product scope beyond that of PET-CT scans.

Geographic scope

60. Alliance submits that the geographic market for the provision of PET-CT scanning services to hospitals is at least national because any supplier in the UK or abroad with the relevant technical skills would be a credible bidder.

61. The OFT understands that approximately 20 per cent of all PET-CT scans are delivered by mobile units. InHealth and Alliance are the only two providers of mobile PET-CT services with four and three scanners currently operating in the UK respectively. The regular transport of the scanners in tight set timeframes restricts the area over which scanning providers can offer services.

62. The OFT considers that the supply of PET-CT scan services has national, regional and local characteristics. From the perspective of patients, the supply of PET-CT scanning services is local or regional in scope. Suppliers are subject to national regulations and prices are informed by national tariffs (which might also contain local variations). Negotiations between suppliers of PET-CT scanning services and NHS England (as special commissioners procuring these services for certain areas), individual trusts, foundation trusts or research centres might refer to the provision of services at national, regional or local level.

63. Alliance/Erigal is primarily active in England and, to a lesser extent, Wales. The OFT understands that the competitive framework in Scotland is substantially

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the use of PET-CT in the UK 2013 produced by the Royal College of Physicians. It is available at: www.rcr.ac.uk/docs/radiology/pdf/2013_PETCT_RCP_RCR.pdf

[36] In England, the provision of PET-CT scanning services is a specialised service commissioned by NHS England. At present, there are two major contracts for the supply of PET-CT, relating to supply in the north and south of England (the 'PET-North contract' and the 'PET-South contract' respectively). Alliance is the contracted provider of PET-CT services in the North of England. InHealth is the appointed provider in the south of England.

different as Scottish hospitals primarily self-supply and the Parties only provide some small back-up supply. In Wales, Alliance/Erigal supplies some doses of FDG-18 to Cardiff where the Target supplies the necessary doses one day a week. Alliance submits that neither merging party is active in Northern Ireland. As a result the OFT focuses its analysis below in England.

64. The OFT notes the uncertainties in the competitive landscape for PET-CT given that the contracts commissioned in block in England are due to be renewed in 2015, possibly with a different scope, and, given that the geographic scope does not affect its competitive assessment, the OFT does not need to conclude on the scope of the geographic market for the supply of PET-CT scanning services.[37]

Conclusion on the frame of reference

65. The OFT has assessed the effects of the merger on the following product frames of reference in its competitive assessment:

- Manufacture and supply of primary supply of FDG-18 by operators with a license to supply to providers of PET-CT scanning services (licensed commercial FGD-18 providers) considering the differential impact of the merger on different customers in different areas (South, North, Far North and Scotland).

- Manufacture of Alzheimer's tracers, whilst not needing to conclude on the geographic scope

- Supply of PET-CT scanning services, whilst not needing to conclude on the geographic scope

COUNTERFACTUAL

Introduction

66. The OFT considers the effect of the merger compared with the most competitive counterfactual providing always that it considers that situation to be a realistic prospect.[38] In practice, the OFT often adopts the pre-merger situation as the most competitive realistic counterfactual against which to assess the

[37] In effect, the OFT's assessment of the PET-CT market is to determine the extent to which Alliance may be able to foreclose downstream competitors and who those competitors may be. The OFT has necessarily framed its analysis of the potential for vertical issues to arise in relation to the existing contracts. This same assessment, however, applies to any future contract configuration and the downstream rivals that Alliance faces as a result of those contract arrangements. From this perspective, the exact geographic scope is not considered material to the competitive assessment.
[38] *Merger Assessment Guidelines*, paragraph 4.3.5.

impact of the merger.[39] However, the OFT will assess the merger against an alternative counterfactual where, based on the evidence available to it, the OFT considers that the prospect of prevailing conditions continuing is not realistic.

67. In the current case, the submission by Alliance on the counterfactual is twofold. First, it argues that, absent this merger, the exit of the Target from the market was inevitable. Second, that should the OFT not conclude that the Target was an 'exiting firm', the counterfactual should be that the Target was a weak competitor with no prospect of improvement. This would mean that the Target would be unlikely to gain any new businesses. Consequently, in Alliance's view, the merger makes no difference. The two actual competitors for the supply of FDG-18 would be Alliance and PETNET, with and without the merger.

68. The extent to which the Target was a weaker competitor is considered as part of the competitive assessment. The extent to which an 'exiting firm' scenario applies in this case is considered below.

Exiting firm

69. In forming a view on an exiting firm scenario, the OFT will consider: [40]

    a. whether the firm would have exited (through failure or otherwise[41]); and if so

    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 exit.

Would the Target have exited the market?

70. For the OFT to accept an exiting firm argument, it would need (on the basis of compelling evidence) to believe that it was inevitable that the firm would exit the market.[42] In this case, the OFT has sought information from Alliance, the vendors and other relevant third parties (Department of Health, NHS England, MHRA, other competitors, customers and possible purchasers) on the pre-merger situation of the Target and any future plans or strategy.

Alliance's submission and other evidence

[39] *Merger Assessment Guidelines*, paragraph 4.3.5.
[40] *Merger Assessment Guidelines*, paragraph 4.3.8.
[41] The *Merger Assessment Guidelines* recognise that 'exit may also be for' [reasons other than a 'failing firm'], 'for example because the selling firm's corporate strategy has changed' (paragraph 4.3.9).
[42] *Merger Assessment Guidelines*, paragraph 4.3.10.

71. Alliance points to three main events and facts to support its view that the Target would have exited the market regardless of this merger: (i) mothballing the plant of IBA at Dinnington; and (ii) the weak position of its plant at Guildford; and (iii) the negative financial forecast of the Target with no possibility to turn the business around.

72. Alliance submits that given the financial situation of the Target, the Target sought some financial support from the Department of Health to continue operating the sites. It has not been possible for the OFT to corroborate whether the Target sought financial support from the Department of Health.[43]

73. The vendor told the OFT that it estimated that the Target had lost between [✄] in 2012. It also briefly notes that to the best of SK Capital's knowledge the Dinnington site was [✄] and was mothballed in and around October 2010.'[44] In the same response, the vendor notes that ['a business case was not looked at to reactivate [the Target's site at] [✄].'[45]

74. As to the negotiations between the vendor and Alliance with regard to this merger, the vendor explains that Alliance made an offer that allowed IBA to exit its FDG-18 business in the UK. It also notes that no formal sale process was conducted [✄].[46] The senior management of SK Capital told the OFT that it was not aware of any other party who had been interested in acquiring the Target or some of its assets.

Review of Alliance's submission and other evidence on this issue

75. In its assessment, the OFT must believe on the basis of compelling evidence that the Target's exit from the UK supply of FDG-18 would have happened inevitably in the absence of the merger. In this context, the OFT acknowledges the Target's negative EBITDA and the loss of two contracts in Manchester, apparently as a result of its earlier commercial decision to mothball its Dinnington site.

76. Having discussed this matter with the vendor, the OFT believes that it made the strategic decision to exit the supply of FDG-18 in the UK following Alliance's offer for the Target.

77. The OFT also notes that:

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[43] The OFT understands that there have been some discussions between officials at the Department of Health and representatives of all commercial FDG-18 providers in the UK on the robustness of the forecasts for growth in the supply of FDG-18 in the UK used by all providers. This does not apply exclusively to the Target.

[44] [✄]

[45] [✄]

[46] [✄]

- the vendor identified the Target as a 'potential candidate for restructuring' soon after its acquisition from IBA. The vendor has explained that given the size of the UK business related to the supply of commercial licenced FDG-18 relative to the overall business of IBA, 'limited consideration was given to the restructuring during the early stages post-acquisition**.**'

- it has not received any significant documentary evidence corroborating the strategic exit.

- the only representations in this regard have been made orally by the vendor to the OFT. Such oral representations carry some evidentiary weight in the OFT's decision.

- no third parties were aware the Target may have exited the supply of FDG-18

78. SK Capital explained to the OFT that it did not considered any re-structuring alternatives [✂]. This argument, while very plausible, does not meet the necessary evidentiary criteria for the OFT to accept that the merger was inevitable for the purpose of accepting Alliance's 'exiting firm' counterfactual argument. Alliance's stated future plans and other third parties' views on possibilities for the Target's production sites suggest that, at least, there was some scope for re-structuring of the business without the merger.

79. In light of the above, the OFT does not believe that it was inevitable that the Target would have exited in the absence of this merger. In particular, given the lack of an assessment of other possible restructuring alternatives. As such criteria (a) of the exiting firm scenario as outlined above is not considered to be met. For completeness only, the OFT has gone on to consider the extent to which the second criteria ((b) above) is met.

Any alternative purchaser?

Alliance's and IBA's submissions

80. Very late in the process, the OFT was made aware by a third party of a possible alternative purchaser for at least one of the sites. The OFT confirmed that such interest and some preliminary due diligence had taken place prior to the acquisition by SK Capital of IBA. Had the possible alternative purchaser acquired one or both of the Target's sites, such acquisition would have in principle raised substantially less competition concerns than this merger. Given the above conclusion on whether the Target would have exited, it was not necessary to assess in detail and conclude on this point.

SUBSTANTIVE ANALYSIS

81. The OFT has assessed the following theories of harm.

Horizontal unilateral effects through the loss of actual and potential competition in the supply and manufacture of FDG-18 and other tracers

82. The OFT has assessed the extent to which the merger may give rise to a substantial lessening of competition ('**SLC**') via the ability of the merged entity to unilaterally exercise market power in the manufacture and supply of FDG-18 and other tracers used for Alzheimer's diagnosis, as a result of the loss of competition between Alliance/Erigal and the Target, leading to effects such as higher prices, and/or reduction in service quality (such as reduced reliability of supply or worsening of delivery times).

83. The OFT has examined the potential for the merger to give rise to a loss of actual competition between Alliance/Erigal and the Target where they currently compete against each other. It has also assessed the loss of potential competition between the Parties where they do not currently have active production facilities. In that area, an inactive production facility may nevertheless represent an actual or perceived constraint to the other supplier with an active facility.

Vertical effects in the supply of FDG-18 to PET-CT scanning service providers

84. Alliance’s presence in both the upstream supply of FDG-18, through Erigal and now the Target, and downstream supply of PET-CT scanning, through Alliance, may provide it with the ability and incentive to undermine the competitiveness of downstream rivals so as to increase its own presence in the downstream supply of PET-CT and reduce the downstream competitive constraints faced ('**input foreclosure**').

85. In the short and medium term, such a foreclosure strategy could undermine the competitiveness of rival PET-CT scanning service providers either within an existing contractual arrangement encouraging termination of this contract, which Alliance would then be in a strong position to win, or damaging the reputation and credibility of a competing downstream supplier sufficiently to harm its competitive position in forthcoming tender awards, increasing the likelihood that Alliance would win such contracts. The effect, should it arise, would be to allow Alliance to increase its presence in the supply of PET-CT scanning services.

86. The merger effect may therefore be to create an additional incentive for unilateral effects (and certain strategies) to arise in the supply of FDG-18 as Alliance's presence downstream may increase the gains of any price increase

or supply disruption through business being diverted to Alliance downstream.

87. In the long-term, Alliance's increased presence in the supply of PET-CT scanning services and a preference for self-supplying its FDG-18 supplies could potentially also undermine PETNET, who, due to a diminished customer base, may not be able to achieve sufficient economies of scale to be viable. Through such marginalisation of PETNET, such a strategy may reduce the competitive constraints on Alliance upstream. The OFT has also therefore considered the extent to which such customer foreclosure may arise ('**customer foreclosure**').

UNILATERAL EFFECTS

Supply of FDG-18

88. The OFT has assessed the effect of the loss of pre-merger rivalry between the Parties resulting from this merger and, ultimately, whether this merger can give rise to a realistic prospect of an SLC. This could result from the merged entity enhancing its ability to exercise market power unilaterally in the manufacture and supply of FDG-18. Such unilateral actions could result in higher prices, and/or reduction in service quality, beyond what it had been able to do in the absence of this merger.

89. In assessing the effects of the merger, the OFT has considered the extent of competition between the Parties pre-merger, and assessed its potential impact on prices and service quality. The OFT has assessed the loss of current competition in the South area and the loss of potential competition in the North, Far North and Scotland areas are considered.

Existing competition

Shares of supply

90. The OFT has estimated shares of supply for the area in which there was actual competition between the Parties pre-merger, the South (as defined above).

91. The OFT notes that the Parties own two out of four cyclotrons which are currently supplying FDG-18 to third parties (that is, 50 per cent share), and PETNET owns the other two cyclotrons (that is, 50 per cent share).

92. The estimated market shares are set out below and show the Parties to have a combined share, based on the OFT's best estimate and including self-supply and long-term contracts, of [50-60] per cent (with a [15-25] per cent increment). Only one other provider, PETNET, is active with a [40-50] per cent share of supply. The OFT has calculated based on the data submitted by Alliance and other third parties that the share of supply within two hours of the southern sites

is as follows:

	Alliance	PETNET	Target	TOTAL	Total value*
Number of doses including self-supply and long-term contracts	[✂]	[✂]	[✂]	[✂]	[✂]
Shares of supply including self-supply (per cent)and long-term contracts	[20-30]	[40-50]	[15-25]		

Source: OFT analysis based on data submitted by Alliance

Figures based on Alliance data, plus King's submission on volumes. The above estimates include Alliance Birmingham and Nottingham (both around two hours from southern sites according to Google Maps).

*Value calculated using an indicative weighted average price in Great Britain of £[✂] per dose, as submitted by Alliance

93. Alliance submits that an analysis of historic market shares and an analysis of the outcomes of older bids is relatively uninformative about current competitive dynamics. The OFT acknowledges that due to the length and size of the contracts, and the bidding process, shares of supply may not accurately reflect the competitive constraints that suppliers exert on each other in the supply of FDG-18.

94. Nevertheless, the OFT considers that the shares of supply presented above do illustrate the relatively few suppliers active in the supply of FDG-18, provide probative information on the relative supply volumes of those suppliers active and provide an indication of the relative competitive position of those suppliers active. The OFT considers these shares of supply raise prima facie competition concerns for the supply of FDG-18 in the South.

95. The OFT has, however, gone on to consider evidence of the extent to which the Parties were competing against each other prior to the merger in the South to determine the loss of existing competition resulting from the merger. It has also considered the strength of competition from other providers of FDG-18.

Extent of existing competition

Bid analysis

96. Alliance told the OFT the outcome of 10 contract awards that took place between January 2011 and January 2014. In addition, the OFT has added two further contracts it has been made aware of through market testing. These are for Cobalt (starting in January 2011) and Barts Health NHS Trust (Barts) (starting in May 2011).

97. As to existing competition, the OFT has focused its assessment on bids to

contracts supplied in the South. Seven of the 12 contracts reviewed were for customers in this area.[47]

98. In Alliance's views, these awards show that:

- The Target did not win any of the contracts

- PETNET won all of the contracts in the South with one exception: King's College University Hospital NHS Foundation Trust awarded its contract to Alliance/Erigal.

99. The OFT considers that the bidding data shows that the Target has been competing for contracts against Erigal and PETNET in the South during the past three years and has been successful as outright winner on two occasions, and as joint supplier on a third. Based on overall bidding data, contracts are often re-awarded to incumbents and so success by the Target in retaining contracts for which it was the incumbent should not be dismissed.

100. The OFT also notes from this bid information that there is generally little switching that takes place in the sector with a strong incumbency advantage on renewal of contracts Alliance itself submits that the high weighting on distance in award criteria suggests that customers are relatively price insensitive. The OFT considers that when customers are insensitive to changes in the price of the merger firms' products, unilateral effects are more likely because any price rise will not lead to many lost sales, making the price rise less costly.[48] Alliance estimates that the direct contribution margin in the its supply of FDG-18 to third parties is [60-70] per cent.

Third party views

101. Most customers located in the South who responded to the OFT's questionnaire were concerned. They were concerned that the merger reduces the number of suppliers available and it could lead to less surety of supply. Customers told the OFT that immediately prior to the merger, they still considered the Target to be a credible alternative. They did not perceive the Target as a weaker competitor because it could not offer self back-up (as opposed to, for example, PETNET). Customers in general have not expressed a preference for selfback-up rather than back-up arrangements organised with another supplier. In fact, there are examples where contracts have been won without self back-up arrangements and there were some customers in the

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[47] These are London Private Hospital (December 2012), London Private Hospital (2013), Brighton University Hospital (2013), Consortium of Hospitals (2013), King's College Hospital (October 2013), Barts NHS Trust (2011) and Cobalt (2011).
[48] See *Merger Assessment Guidelines*, paragraph 5.4.9 (c).

South who specifically told the OFT their preference is multi-sourcing from two different suppliers. Those third parties did not raise any issues in terms of the reliability of the service offered which could have prevented the Target from gaining new contracts in the foreseeable future.

102. The OFT believes that the above bid data and other evidence suggest that the Target and Erigal were actively competing against each other in the South, customers generally viewed the Target as a reliable supplier and that the Target was not a significantly weakened competitive force but instead would likely continue to act as a competitive constraint going forward, in the absence of the merger. The OFT also notes that, contrary to Alliance's submission, the evidence suggests that suppliers that are unable to self back-up are competitive and able to win business against a supplier that can self back-up.

103. Prior to the merger, customers in the South could be supplied by the Target, Erigal and PETNET. The merger therefore results in a reduction from three to two credible suppliers for customers in the South. In light of its findings on this point, the OFT has gone on to consider evidence on the extent of the constraint from other suppliers in the South.

Constraint from other suppliers

104. Post-merger Alliance will face only a single competing supplier of licensed commercial FDG-18, PETNET. PETNET is the largest commercial supplier in the South, partly as a result of it being the primary supplier of FDG-18 to InHealth, which operates the PET-South block contract. Evidence points to PETNET acting as a strong competitor to Alliance/Erigal and the Target pre-merger and continuing to do so to Alliance post-merger.

105. In relation to PETNET, Alliance submits, and the OFT's market testing has corroborated, that one of the factors determining a customer's purchasing choice is security of supply of licensed commercial FDG-18 due to its use in PET-CT scanning.[49] Security of supply has two aspects: to ensure that the primary supply arrives in time and ensure that if there is a failure by which it cannot arrive in time, an alternative (or back up) dose arrives in its place.

106. Capacity constraints may make unilateral effects more likely to occur as a result of the merger through a reduction in the weight that can be attached to the constraint exerted by competitors that are capacity constrained, if competing suppliers do not have the capacity to meet demand from some customers who would like to switch in response to a price rise. The evidence before the OFT

[49] PET-CT scanning providers can receive financial penalties for failing to scan, and, ultimately patient outcomes may be affected.

suggests that PETNET is not currently capacity constrained.

107. The OFT has gone on to consider other evidence pointing to possible effects arising from the merger.

Evidence on possible effects

108. The OFT notes that there are indications of potential price rises post-merger in Alliance/Erigal's internal documents:

- the OFT notes that in preparing its internal documents considering the Transaction, [✂].[50]
- Alliance forecasted a [✂][51]
- there are other references to [✂].[52]
- [✂].

109. Alliance submits that the internal documents should take account of the context in which they were written and placed alongside other documents, in particular noting that some assumptions were not based on detailed analysis or sensitivity tested. The OFT acknowledges that internal documents should be placed in context and significant weight should not be placed on limited and selected excerpts from these. Nevertheless, in this case, the OFT considers this evidence supports the OFT's unilateral effects assessment resulting from the loss of competition in the South and underscores its conclusions.

110. The OFT also notes the differential pricing of contracts before and after Erigal facing the Target in competition: Alliance/Erigal's current price to Manchester Christie is [✂] per cent higher than the Target's price to this customer when Dinnington was open.

111. Taken together, in the round, the evidence before the OFT suggests that the merger may result in a realistic prospect of a substantial lessening of competition in the manufacturing and supply of FDG-18 to customers in the South.

Potential competition

112. Unilateral effects may also arise from the elimination of potential competition

[50] See Alliance's submission to the OFT of 24 January 2014, Annex 18, *The FDG Acquisition Paper,* tab titled *IBA*, row 3.
[51] See Alliance's submission to the OFT of 24 January 2014
[52]See Alliance's submission to the OFT of 24 January 2014, Annex Q.1, slides titled *FD Meeting, October 2013* sub ref. 3

where the removal of a potential entrant could lessen competition by weakening the competitive constraint on an incumbent supplier. In this case, the OFT's focus of concerns is on the loss of 'actual potential competition' in the form of supply from the Target's Dinnington site. Such actual potential competition is a constraint only if and when entry occurs. The most likely potential competitors are those which could enter without incurring significant sunk costs and are likely to incur those necessary costs to enter the market within a relatively short period of time, though the OFT's assessment in any case will take account of the particular aspects of the market in question.[53] [54]

113. The Target's mothballed site in Dinnington could be reactivated and serve customers in the North, Far North of England and Scotland, competing with the Alliance/Erigal's sites at Keele and Preston. As such, the Dinnington site could be viewed as a potential competitor for supply to customers in these areas.

114. Alliance submits that to reactivate Dinnington as a commercial producer of FDG-18 would take around 12-18 months, which is supported by the due diligence work undertaken prior to the Transaction. In order to reactivate Dinnington:

- equipment would need to be replaced, which Alliance estimates to be around £[✄]
- revalidation of the MHRA license would be needed, which Alliance estimates would require around 6 months of operating the site as if commercially producing, including staff on site. The cost of this is estimated at around £[✄]
- SK Capital (the Target's former owners) told the OFT that to the best of UK management's knowledge and using high level assumptions, their estimate was that reactivation would take 18 to 24 months and require an investment of more than [✄].

115. An email submitted by Alliance following a meeting with IBA (prior to the merger) during Alliance's consideration of supply options, states that IBA told Alliance that Dinnington would take 15 months to begin supply. [55]

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[53] A merger may also give rise to 'perceived potential competition' where a firm which is not in the market, but which nevertheless imposes an existing constraint because of the threat that it would enter if existing firms in the market raised their prices is removed. This constraint may arise even though the OFT does not believe that entry would actually occur. In this case, the OFT has no evidence to suggest that the Target was providing a competitive constraint in the Midlands or North areas on the basis of supplies from the mothballed Dinnington site and so has not considered perceived potential competition further.
[54] *Merger Assessment Guidelines*, paragraphs 5.4.13 to 5.4.18.
[55] See Alliance's submission to the OFT of 24 January 2014, Annex 14.

116. The OFT has received mixed views from the vendor on its willingness to reactivate the site. While senior managers of the Target told the OFT that they had no intention of reopening the site, local managers of the Target indicated to Alliance that they would consider reactivating the site, contingent on being able to supply sufficient volumes to make it commercially viable. Indeed, the OFT understands from another third party that some provisional conversations took place between that third party and the Target about the potential for reactivation and to source from the site.

117. Given the indication from the vendor that they may consider reopening the site if it had sufficient volumes, the OFT has examined estimates of available volumes and compared these to estimates of the efficient scale of production at the facility. Alliance has provided the following estimates for break-even doses for Dinnington:[56]

- If Dinnington were to compete with average national prices, it would need to sell around [✄] doses per annum to break even post reactivation.

- If Dinnington were to compete with average Northern prices, it would need to sell around [✄] doses per annum to break even post reactivation.

118. Alliance submits that this is more volume than is currently tendered by offsite third parties in the North and Far North of England.

119. Having assessed all the available evidence on this point, the OFT considers that the volume available to win through tenders by customers that could potentially be supplied by the Dinnington site, even allowing for the 12 months Alliance estimates is required to reactivate Dinnington, is greater than Alliance's estimated break-even volume. This is assuming that volumes demanded stay constant, whilst the OFT notes that growth in volumes is anticipated by some third parties.[57] From this the OFT can infer that the volumes available to supply are not a barrier to Dinnington being reactivated.

120. However, Alliance submits that given the costs of entry and fixed costs of cyclotron operation, Dinnington would not be reactivated without guaranteed volumes and only two customers could provide such sufficient volumes in advance - Alliance and InHealth. The OFT notes that the scope of the NHS

[56] See Alliance's submission to the OFT of 24 January 2014, Annex 27.

[57] For example, growth [✄] in an Erigal strategic review in 2012 (Alliance's submission to the OFT of 24 January 2014, Annex 18). As part of its market inquires, the OFT has learnt that there is a framework agreement currently at the tender stage (due to be decided in March), which covers a range of radiopharmaceuticals and lasts 5 years. This includes Barts and Leeds for their FDG-18, but also 16 other Foundation Trusts (plus further LLPs), who would be able to procure FDG-18 under this contract during its duration. The volume of this contract is, therefore, difficult to forecast but may be larger than current volumes.

PET-CT block contracts are currently uncertain and may be subject to reconfiguration. This may present opportunities for players other than Alliance and InHealth to bid and win some of these contracts. This may provide scope for Dinnington to receive guaranteed volumes from PET-CT scanning providers other than Alliance and InHealth. However, if the framework for the future national block contract (or contracts) is in the same form and won by Alliance, this would reduce the available volume in anticipated tenders to below a break-even volume.

121. Whilst the OFT considers that therefore, in theory Dinnington could win the guaranteed volumes to break-even from reactivating Dinnington, Alliance submits that the time needed for reactivation and the timing of award of contract will present a coordination problem: contracts are usually awarded shortly before supplies commence and it would take between 12 to18 months for the site to be reactivated.

122. Set against this, several sources suggest that the reactivation of Dinnington is likely:

- the email note by Alliance of the meeting with IBA, states that IBA would have been interested in supplying AM and that IBA would reopen Dinnington if they had firm orders.[58]

- a headline comment from the PwC due diligence report states:

  'The PwC view:

  The business enjoys significant market share in a market which demonstrates potential for significant growth. It is well placed to capitalise on this growth, with vacant capacity to install a further cyclotron at both sites and to return Dinnington to productivity although c.£[✂]m of capex is required to do this.'

- Credo (a strategy consultancy) states in Erigal's strategic review in 2012 that:

  > 'Capacity constraints could lead to new or reopened RPUs. This is believed to be unlikely for GE, but probable for IBA'. Credo put the likelihood of IBA reopening Dinnington or extending its London site as 'high' in its modelling.

123. The OFT considers that, should the Dinnington site have been reactivated in the absence of the merger, such reactivation would have had a material effect

[58] Alliance's submission to the OFT of 24 January 2014, Annex 14.

on competition. In the North are, Erigal (with two sites) competes against PETNET with one (in Nottingham).

Conclusion on potential competition

124. The evidence sets out above is mixed. While there are some indications that the reactivation of the Dinnington site may have been possible, it is not clear that it would be a realistic prospect that this would happen. However, in light of the OFT's finding in relation to actual competition, the OFT has not found it necessary to conclude on the extent to which the merger gives rise to a loss of potential competition.

Alzhiemer's tracers

125. Alliance and IBA both have contracts for the manufacture of tracers for the diagnosis of Alzheimer. A manufacturer requires a licensed production site[59] at the right location to compete with other possible providers. Distance from the production site affects the cost of supply and consequently the competitiveness of a given manufacturer.

126. At present, Alliance/Erigal has a contract to manufacture for GE ending in [✂]. IBA has a global agreement with Piramal. By selling the IBA UK assets, it became unable to fulfil the UK part of that contract and as result, Alliance has entered into a toll manufacturing agreement with Piramal. The agreement ends in [✂].The contract arrangements for the production of those tracers have a fixed price of production for the tracer.

127. Given the features of the toll manufacturing contracts, including fixed prices for several years, the impact of the merger will be more noted in the medium term when the existing contracts end. The OFT considers that manufacturers have incentives to maintain high utilisation levels of cyclotrons due to the high fixed costs of operation, and so also to be active in a market with growth potential.

128. Third parties estimate the market will grow from the current estimated 300 to around 12,000 doses a year in 2018.

129. Given its finding in the loss of actual competition in the manufacture and supply of FDG-18, the OFT does not need to conclude on the impact of the merger on the supply of tracers for the diagnosis of Alzheimer.

Vertical effects

130. The OFT notes that its current horizontal concerns in the supply of licensed

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[59] It requires an MIA licence. See paragraph 18 above.

commercial FDG-18, as well as other isotopes as outlined above, may be exacerbated by potential vertical effects. The OFT notes that merger specific vertical effects will only be present in the South area in which the OFT has found horizontal unilateral effects concerns in its assessment above. The OFT has therefore focused its vertical effects assessment on this area.

131. The OFT notes that FDG-18 is a critical input to PET-CT scanning for cancer diagnosis, as no alternative tracers are available for the same clinical aims. Alliance's presence in both the upstream supply of FDG-18 and downstream supply of PET-CT scanning services may provide Alliance with the incentive and ability to undermine the competitiveness of its rivals so as to increase its own presence in the downstream market and reduce the competitive constraints it faces from rivals sufficiently to raise competition concerns (that is input foreclosure). This could be through increases in the price of FDG-18 to competitors so as to raise their costs, making competitors less competitive in bids for contracts, through Alliance disrupting primary or back-up supply to competing downstream providers or totally refusing to supply primary or back-up supply of FDG-18.

132. If Alliance was to be successful in this strategy, such that it gains business downstream at the expense of competing PET-CT suppliers, its ability to 'self-supply' this additional business downstream may reduce the customers that PETNET can supply. If the supply of PETNET is reduced sufficiently through such a strategy, PETNET may be marginalised such that it can no longer achieve the economies of scale necessary to remain a strong competitor in the supply of FDG-18. As a result, contingent on the input foreclosure outlined above, the merger may also give rise, over time, to customer foreclosure, further exacerbating both the loss of competition, and the incentive of Alliance to deteriorate the competitive offering, in the supply of FDG-18.[60] The OFT considers the potential for total and partial input and customer foreclosure in turn below.[61] The OFT is usually more concerned about the effect of total rather than partial foreclosure in a market. This is because the potential gains (and therefore incentives) of implementing a successful total foreclosure strategy in the medium to long term are often higher than those obtained following a partial foreclosure strategy since, if successful, total foreclosure will reduce the set of competitors (rather than increasing their costs and ultimately reducing their

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[60] This is in addition to the potential for Alliance to weaken PETNET as a competitor in the short-term for supply to those affected customer groups by disrupting or refusing back-up supply to them, although, as outlined above, the ability of PETNET to self back-up in the South area means that this effect, should it be possible, may be limited.

[61] In practice, the analysis of the three elements (ability, incentive and effect) often overlap and many of factors affect more than one of those elements. Also the assessment of ability and incentive is often similar when assessing partial and total foreclosure. The evaluation of ability in cases of total input foreclosure also requires an assessment of how easily the merged entity can commit not to re-enter the input market. See *Merger Assessment Guidelines*, paragraph 5.6.13, first bullet point.

competitiveness).

133. The OFT received concerns relating to vertical effects from several third parties given Alliance's presence in the downstream PET-CT market. In their view, the merger increases Alliance/Erigal's ability and incentives to increase the price or disrupting the supply of FDG-18 to rivals (or give itself some preferential treatment in case of unplanned cyclotron failures). Another concern relates to Alliance's access to commercially sensitive information regarding other downstream customers. This arguably would give Alliance a distinctive advantage in forthcoming commercial tenders.

134. In relation to each of these, as highlighted above, the OFT notes that the timing of this merger is significant. At present NHS England is assessing the framework to decide the future of the two largest contracts for the provision of PET-CT scanning services (NHS PET-CT North and NHS PET-CT South) to be renewed 31 March 2015.[62] The form of the tender is yet unclear. It could have the same geographic scope as now (that is a North-South division of England), or include several contracts covering smaller geographic areas. The scope and extent of the new contracts might have an impact on the array of interested bidders.

135. The OFT typically frames analysis of non-horizontal effects by references to: the Parties' ability and incentive to foreclose, and the effect of such a strategy on competition. The OFT utilises this framework below for each of the possible foreclosure mechanisms described above.

Input foreclosure

Alliance's overall view on input foreclosure

136. In its view, Alliance has no incentive or ability to pursue a strategy of refusing to supply licensed commercial FDG-18 to rival suppliers of PET-CT scanning services or otherwise seeking to marginalise such suppliers (whether by raising prices or reducing delivery reliability) because:

- customers would switch their FDG-18 supplies to PETNET

- Alliance is almost entirely dependent on the NHS for sales of FDG-18 and PET-CT scanning services. NHS England, Commissioners, NHS Trust and NHS Foundation Trusts, would react promptly by increasing NHS hospitals' self-supply of FDG-18 if such a foreclosure action would endanger the provision of PET-CT scanning services

[62] See further at https://www.supply2health.nhs.uk/Results.aspx?k=PET-CT

- the main independent providers of PET-CT scanning services aside Alliance, these are InHealth and Cobalt would have taken up Alliance's offer to enter into long-term supply agreements for the provision of FDG-18 instead of refusing such an offer if they would have been concerned about lack of supply

- any price rises (if at all possible) would be so minimal that competing suppliers of PET-CT scanning services in the downstream market would be able to absorb them without necessarily becoming uncompetitive

- competitors at both the upstream and the downstream markets can react strategically to protect their commercial interests if they believe that this merger realistically harms their competitiveness and threatens their business opportunities

- there is no information on new business opportunities which is not known to all those involved in the sector. Any concerns on possible leaks of commercially sensitive information on new contracts, tenders or other arrangements under discussion between PET-CT scan service providers and hospitals are not founded against the commercial reality of this sector

Ability to implement an input foreclosure strategy

Alliance submission

137. Alliance assesses the possible impact on downstream rivals' PET-CT scanning prices given an indicative FDG-18 price rise. Alliance assumes that FDG-18 accounts for [20-30] to [40-50] per cent of the direct marginal costs of supplying a PET-CT scan and, assuming a price rise of FDG-18 of 20 per cent (for illustrative purposes only), this would equates to an increase in costs of between [✂] per cent. Taking costs to represent around [✂] per cent of the price of a scan, as estimated from Alliance data, and assuming full pass through of cost increases, this equates to a price increase of a PET-CT scan of around [✂] per cent.

138. Alliance submits that rivals would opt not to pass through the full extent of any input price increases, especially in the context of an increasingly competitive rival in the PET-CT scanning market post-merger in Alliance, and any effect would take several years to feed through to rivals, as many contracts agree a fixed price.

139. Alliance also assesses the possible impact on downstream rivals following a degradation of quality (such as a disruption or a refusal to supply) and noted that this would not be possible as contracts can easily be designed to

incentivise high quality service delivery and any degradation of quality would clearly be visible to the wider market, causing reputational damage to Alliance/Erigal.[63]

OFT's assessment

140. The OFT considers the following factors are important to a firm's ability to engage in input foreclosure: a) the extent to which rival manufacturers can avoid a price increase by switching away from this input; b) the cost of the input relative to all costs of the final product; c) pass through of cost increases.[64] The OFT's assessment is framed by these factors below. These factors can be viewed analogously for partial input foreclosure via a price increase or a degradation in quality through disrupting supply, and total foreclosure, and so these foreclosure mechanisms are considered together below.[65]

a) Availability of alternatives

141. The availability of alternatives is key to the ability of a firm to implement any input foreclosure strategy. If downstream rivals can turn to many substitutes for the input, the merged firm will be less able to harm rivals than if there were few alternative providers of the input.

142. The vertically integrated firm resulting from the merger must have a significant degree of market power in the upstream market for input foreclosure to be a concern. In this regard, the OFT notes Alliance's post-merger share of supply of FDG-18 in the South area is estimated to be [50-60] per cent. Alliance will own two out of four cyclotrons which are currently supplying licensed commercial FDG-18 to third parties with only one other upstream rival supplier. These market share estimates indicate that *prima facie* Alliance may have a sufficient degree of market power in this market post-merger to give them the ability to pursue such a strategy. The OFT has therefore gone on to consider evidence on the constraint from other suppliers, the importance of the licensed commercial FDG-18 to PET-CT, and the ability of downstream rivals to absorb any deterioration in the FDG-18 offering by Alliance.

143. Downstream rivals may be able to avoid any harm through an input foreclosure strategy implemented by Alliance if rivals are able to source their supplies from

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[63] Further, attempts to marginalise downstream rivals by restricting back-up supply to their FGD-18 supplier would, according to Alliance, be limited by mutual reliance on back-up supplies through reciprocal arrangements. The OFT notes that in the South area, this effect may be limited anyway as PETNET can, and ususally does in practise, self back-up.

[64] See *Merger Assessment Guidelines*, paragraph 5.6.10.

[65] The evaluation of ability in cases of total input foreclosure also requires to assess how easily the merged entity can commit not to re-enter the input market. See *Merger Assessment Guidelines*, paragraph 5.6.13, first bullet point. This is assessed in paragraph 154 below.

alternative suppliers. The OFT considers that Alliance's ability to foreclose downstream rivals will be enhanced by the limited number of upstream alternative suppliers as PETNET is the only alternative upstream supplier. However, PETNET submit that it is [✂].

144. Whilst PETNET remains a strong competitor – with two of four cyclotrons in the South area and a [40-50] per cent share of supply– the OFT has concerns that post-merger PETNET, [✂], is not sufficient to enable downstream rivals to avoid being harmed through switching to PETNET post-merger[66, 67]

145. Further, customers that demand to multi-source their FDG-18 supplies for security of supply reasons will be faced with no alternative but to seek supplies from Alliance as well as PETNET post-merger.

b) The cost of the input as a proportion of total costs

146. The OFT considers that, all else being equal, the higher the proportion of all costs accounted for by the cost of the input, the greater the ability of Alliance to harm its rivals ability to compete through raising its costs.

147. Alliance has provided estimates of costs per site. [68] The OFT notes that, on average from 2011 to 2013, FDG-18 accounts for [✂] per cent of Alliance's costs of supplying each PET-CT scanning services[69], which indicates the high importance of FDG-18 to downstream suppliers.

148. In practice, the OFT notes that the cost of the input relative to total costs generally serves only as a proxy for the importance of that input in the supply of the downstream product. In this context, third parties have indicated that FDG-18 is a crucial input (and in particular, the security of supply of FDG-18 such an important component) to PET-CT supply, irrespective of the proportion of costs it makes up, stating that there are no alternatives to achieve the same clinical aims for its use in PET-CT scanning.

149. The OFT further notes that total cost of inputs relative to the price of the

[66] The OFT notes also that PETNET may have an incentive to accommodate any price rise by Alliance (or other deterioration in Alliance's competitive offering) and increase its price in response to the increased demand. Any such accommodation would likely result in a lower price rise for downstream rivals (that is, the pricing response of PETNET would be less than any initial price rise by Alliance) but may still lead to the harm of rivals.

[67] Any resultant price increases may, in certain circumstances, encourage entry. However, in this case, as discussed in the section on entry and expansion below, the OFT considers that this may not be the case here as potential entrants would not expect prices pre-entry to be maintained post-entry due to competitors being able to adjust their prices at each tender round.

[68] Alliance's submission to the OFT of 24 January 2014, Annex Q26(ii)

[69] Alliance submits that the costs of a PET-CT scan consist of: reporting fees, FDG-18, their other direct costs (that is, in a number of sites Alliance performs other scanning services (such as MRI or CT), and salaries.

downstream product is an important consideration for the ability of a firm to engage in a foreclosure strategy, as it can provide an indication as to whether price increases can be absorbed by downstream rivals. This is considered below.

c) Pass-through of cost increases

150. The pass-through of cost increases is a key factor in determining the ability to foreclose: if higher prices of FDG-18 could be absorbed by rivals, then it is unlikely that an attempted foreclosure strategy would impact the rivals' competitiveness.[70] According to Alliance, the direct marginal costs of scanning account for around [20-30] to [40-50] per cent of the price of a scan.[71] Alliance submitted an indicative analysis suggesting that a 20 per cent price increase (by way of illustration) in the supply of FDG-18 to a downstream rival could result in an increase in PET-CT prices of [✂] per cent, assuming full pass through.

151. The OFT acknowledges that this analysis indicates that increases in the price of FDG-18 will have limited impact on the overall price of PET-CT scans, but that this may still be sufficient to undermine the competitiveness of rivals in the absence of pass through.

152. The OFT considers that downstream suppliers may have limited ability to pass through costs, especially in the short term where contracts for PET-CT are set for several years at fixed prices (with adjustments for inflation).

153. Further, at a national level, Monitor has responsibility for setting national tariffs for PET-CT, which are based on cost estimates from each NHS Trust and Foundation Trust from two years earlier. As a result, the set-up of the tariff suggests that changes in cost now could influence the level of the tariff with a two year lag, although the extent to which a downstream supplier could influence these tariffs to reflect their own higher costs may be limited. The OFT notes, however, that there are circumstances where national tariffs can be deviated from by Clinical Commissioning Groups in commissioning services, which may provide scope for costs to be passed through.

Ability to commit not to re-enter the supply of FDG-18 to rivals to implement a total foreclosure strategy

154. As stated in the *Merger Assessment Guidelines*, '[i]n evaluating the ability of the merged firm to engage in total input foreclosure, [the OFT and the CC] may

[70] This may also apply to quality degradation where steps may be taken, at a cost to the downstream rival, to prevent such quality degradation.
[71] Alliance response to the OFT's Issues Paper.

consider how easily the merged firm can commit not to re-enter the input market'.[72] In this sector, downstream rivals need to have certainty as to their supply of FDG-18 during the life of the PET-CT scanning service contracts, which can last several years.[73] The ability of Alliance/Erigal to reverse an early decision not to supply a rival will depend on the circumstances of each contract and the possible customer involved.

Conclusion on ability to foreclose

155. On partial foreclosure, given the evidence above on the limited availability of alternative FDG-18 suppliers, the importance of FDG-18 as an input to PET-CT supply and its high proportion of overall costs of a PET-CT scan, and the possibility of limited pass through of these costs to the customer, the OFT considers that Alliance may have the ability to engage in input partial foreclosure.

156. With regard to input total foreclosure, the OFT believes that Alliance's ability to commit not to supply FDG-18 may depend on its ability to achieve economies of scale at its production sites. Below the minimum economies of scale, Alliance may become uncompetitive against other FDG-18 and PET-CT providers. Therefore its ability to engage in total foreclosure would be diminished.

Incentive to implement a partial input foreclosure strategy

Alliance submission

157. Alliance submits that it would not have sufficient incentive to adopt a partial input foreclosure strategy given the visibility of this behavior to the wider market, so that customers would be reluctant to switch to a provider who had behaved in such a way. Therefore, Alliance submits, it could not expect to offset any loss in FDG-18 margin with growth in its PET-CT business.

158. It also submits an indicative analysis suggesting that a 20 per cent price increase (by way of illustration) in the supply of FDG-18 to a downstream rival could result in switching of [0-5] to [5-10] per cent to Alliance.[74] In Alliance's

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[72] Ibid, paragraph 5.6.13.
[73] The length of the contracts for the procurement of FDG-18 varies from one or two years to ten years.
[74] This indicative analysis is based on a number of assumptions. If an illustrative 20 per cent price increase resulted in an increase in the price of a PET-CT scan of [✂] per cent, based on Alliance's analysis as outlined above, using the Lerner index (which relates price, marginal cost and the price elasticity of demand facing a profit maximising firm) this suggests an own price demand elasticity of around 1.7. Such a demand elasticity suggests that a [✂] per cent increase in the price of rival PET-CT scanning services would cause around [✂] per cent of volumes to switch to Alliance, assuming diversion to Alliance of 100 per cent. Alliance also submits that such price differentials are marginal at

view, this is unlikely, to induce market exit by downstream rivals. However, Alliance acknowledges that in practice, switching could not occur at these volumes, as contracts are lumpy.

159. Alliance submits that it would not be able to degrade the quality of FDG-18 supply through disrupted supply to competitors as such quality degradation would be clearly visible to the wider market causing Alliance reputational damage and the extent to which downstream rivals could be harmed.[75]

OFT assessment

160. The OFT notes, first, that [✄]

161. It may be more profitable for Alliance to disrupt supply[76] of FDG-18 to downstream competitors and gain additional business downstream as a result. The incentive to adopt a foreclosure strategy depends on whether the gains in downstream profits outweigh the loss in upstream profits from sales foregone.[77] In assessing the incentive to engage in a partial foreclosure strategy of disrupting supply, the OFT notes that PET-CT scans have to be rescheduled in the event of no FDG-18 supply. As a result, the OFT considers that reduced sales from disruptive supply may be limited. Any reduced volumes and upstream losses will therefore only result from those volumes that switch from Alliance to PETNET (in the absence of other alternatives).

162. The benefits downstream as a result of disrupting supply would derive from damage to rivals' reputations. Alliance may be able to either: (i) disrupt or refuse to supply provision such that it damages the reputation and credibility of downstream rivals and they have a lower likelihood of winning a contract against Alliance as a result; or (ii) at the time of entering bids customers are aware of the diminished ability of downstream rivals to provide secure supply of FDG-18.

163. Alliance submits that its incentive to engage in such a strategy would be

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the point of PET-CT contracts coming to market and the switching is contained to only a portion of the market (due to self-supply of PET-CT by the NHS).

[75] Alliance also highlighted, as outlined above, that contracts can be designed to incentivise high quality service delivery which is maintained for the contract's duration.

[76] The OFT has primarily examined a foreclosure strategy of disrupting supply, as this has been the greater concern raised by third parties but also goes on to briefly consider the incentive to raise price to downstream rivals. A price rise and disrupting supply are considered separately for analytical clarity. Clearly, in practice, different strategies may be pursued simultaneously.

[77] A basic comparison of margins upstream and downstream suggests the Alliance would have an incentive to engage in foreclosure strategies: Alliance's average margin on FDG-18 is [20-30] per cent, whilst its average margin in PET-CT is [50-60] per cent. So if Alliance can undermine rivals so that it wins more PET-CT contracts, it will receive double the margin it would have received through supplying a rival FDG-18.

dampened by the potential for it to incur reputational damage, with such damage ultimately leading to it not being seen favourably by customers for downstream contracts. However, downstream rivals submit that customers purchase an end-to-end service and would be intolerant of problems with a PET-CT provider's supply chain. Therefore, at contract award, customers would rather choose the supplier with the reliable supply chain, irrespective of what the cause of the less secure supply was. This suggests that the impact of a foreclosure strategy would be to damage the reputation and credibility of the foreclosed PET-CT suppliers, far more than Alliance.

164. The OFT considers that Alliance's submission on volumes that would switch to Alliance as a result of a price increase to rivals, or an analogous degradation of quality of supply, of around [0-5] to [5-10] per cent to be an underestimate of the potential volume which would switch to Alliance.[78]

Conclusion on incentive to implement a partial foreclosure strategy

165. The OFT considers that the losses from such a partial foreclosure strategy to Alliance may be minimal whereas the gains, particularly in the medium to long-term, have the potential to be more significant. However the OFT had limited evidence on Alliance/Erigal's incentive to foreclosure and given its findings with regard to unilateral horizontal effects, it does not need to conclude on this point.

166. Nevertheless, the OFT considers that the indicative increases in PET-CT prices due to a price increase in FDG-18 suggest that it is unlikely that increases in the price of FDG-18 by Alliance to downstream rivals would be effective in undermining the competitiveness of these downstream rivals.

Effect of any partial input foreclosure strategy

167. Alliance and InHealth are the largest commercial providers of PET-CT scans in the UK. Alliance's figures suggest that Alliance has a [25-35] per cent share of PET-CT scans in the UK and InHealth has a [15-25] per cent share. It is clear that InHealth plays a significant role in the downstream market, such that foreclosure of this firm may result in significant harm to effective competition.

168. The OFT considers that disruption to supplies may have a greater impact on the competitiveness of downstream rivals than FDG-18 price increases, due to the financial penalties rivals may face and damage to reputation.

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[78] Given that suppliers compete via tenders in this market, it is not clear that customer elasticity is well modelled by the Lerner index. This may be particularly the case for damage to reputation, for which customers may have a much more elastic response than reflected in price cost margins. Further, a rival would not lose marginal volumes, but rather the existence of tenders suggests that bulk volumes would transfer to Alliance.

Incentive to implement a total input foreclosure strategy

Alliance submission

169. Alliance submits that a total input foreclosure strategy would be highly risky because the reputational damage from pursuing such a strategy would be even more severe to Alliance than a partial foreclosure strategy, since such behaviour would be even more visible to the wider market and the NHS would be likely to respond. Alliance submits that such a response by the NHS may be to take PET-CT scanning in-house, which would not return to third party provision in the future.

170. Alliance also submits that there are no instances of it engaging in such practices in the past.

OFT assessment

171. Refusal to supply FDG-18 to downstream rivals would have the effect of reducing the set of suppliers available to downstream rivals. This may in turn reduce competition in the upstream market.

172. As discussed above with respect to partial input foreclosure, the OFT has doubts that the impact of a foreclosure strategy would be to damage Alliance's reputation to a greater extent than that of its rivals.

173. In assessing Alliance/Erigal's incentive to engage in total input foreclosure, the OFT has considered the extent to which Alliance can commit not to re-enter the input market and therefore make its refusal to supply credible.

174. The OFT notes that at the point of bidding for the national PET-CT contracts, scanning providers must provide details of their FDG-18 supply arrangements. However, the OFT considers that it is unlikely that Alliance/Erigal could commit not to supply FDG-18 for the following reason: Alliance may not retain its current volumes (if it does not win the PET-CT block contracts). Then, Alliance/Erigal may have an incentive to supply FDG-18 to the merchant market (so as to maintain cyclotron utilisation rates). In assessing the incentive to supply to the merchant market, the OFT notes that the high fixed costs of supplying FDG-18 provides an incentive to utilise available capacity so that Alliance/Erigal may be expected to pursue high levels of utilisation.

175. In addition, the OFT believes that it does have sufficient evidence to conclude that Alliance would definitively have the ability to commit not to supply other downstream rivals under any circumstances. As a result, the OFT must conclude that it is unlikely that Alliance could undertake such a non-supply commitment.

Customer foreclosure

176. The OFT has also considered whether, post-merger, Alliance would have the ability and incentive to engage in customer foreclosure.

177. Customer foreclosure can arise when an upstream supplier is sufficiently dependent on a downstream customer(s) for its 'route to market' that the removal of such customers means that its economies of scale are reduced. If economies of scale are reduced sufficiently, the competitive constraint exerted by this upstream rival may be reduced (due to its higher costs) or it may have to exit supply of the upstream product. This reduction of competition upstream may allow Alliance/Erigal to deteriorate their competitive offering upstream.

178. In this context, should Alliance manage to foreclose downstream rivals, it can bring supply of FDG-18 to this new expanded business in-house. The effect would be to reduce PETNET's business. In the long-term, through Alliance's increased presence in PET-CT and self-supplying its FDG-18 supplies, this could undermine PETNET, who, due to a diminished customer base, would not be able to achieve the sufficient economies of scale to be viable.

179. Given the conclusion outlined above in relation to horizontal unilateral effects, and that no conclusion has been made in respect of input foreclosure, on which customer foreclosure is contingent, the OFT does not consider it necessary to conclude on the potential for competition concerns to arise through customer foreclosure.

Conclusion on vertical effects

180. In light of the OFT's conclusion at the horizontal level, the OFT has not found it necessary to conclude on the possible vertical effects of this merger.

COUNTERVAILING BUYER POWER

181. In some circumstances, an individual customer may be able to use its negotiating strength to limit the ability of a merged firm to raise prices. The OFT refers to this as countervailing buyer power.[79] The OFT considers that a customer's negotiating strength will be stronger if it can easily switch its demand away from the supplier.

182. In this case, the OFT considers the limited alternative suppliers available to customers, limits the extent to which a customer can switch its demand away from any supplier and thus limits the scope for countervailing buyer power. The OFT notes this is likely to be exacerbated by the requirement by customers for

[79] *Merger Assessment Guidelines*, paragraphs 5.9.1-5.9.3.

back-up supply. The removal of one of the few available alternatives reduces any threat of switching, in particular for a group of customers for which contracting with their main competitor in the downstream market might not be a suitable alternative.

183. Alliance submits that buyer power is exerted by three sources: hospitals and research centres threatening to switch to self-supply; the NHS's central buyer power; and the formation of joint procurement groups.

184. With regard to individual hospitals, Alliance submits hospitals that invest in their own cyclotron are lost from third party supply for the operational life of the cyclotron, which is 25 years.'[80] It names two examples, Edinburgh and Glasgow which have installed their own cyclotrons 'because they required sufficient volumes to make self-supply viable and they were not willing to accept Alliance/Erigal's best price for supply.'[81] It adds that hospitals are aware of the costs of operating a cyclotron and those costs operate as a '*silent bidder*' in any competitive tender requesting prices for third party supply. Alliance also notes that onsite self-supply saves transport costs thereby exerting some extra pressure on third party off-site suppliers.

185. In relation to self-supply, the OFT considers self-supply may be a constraint on prices during the tendering process if the customer can choose to self-supply instead of appointing a third party in that tender period or self-supply can begin in the following tender period.

186. Due to the long timescales (at least 2 years) and considerable costs (estimated to be at least £[✄] million) involved in investing in a cyclotron (without including any building work), the OFT is of the view that self-supply through investment in a cyclotron is a weak constraint during a tender process.[82] The OFT considers this under the Entry and Expansion section below.

187. In relation to countervailing buyer from NHS's central buyer power and/or joint purchasing arrangements among several private and/or NHS hospitals, Alliance has submitted an example of an occasion when the Department of Health (formerly responsible for commissioning the provision of PET-CT scanning services) appears to have reviewed and approved the specific terms of the sub-contract for the supply of FGD-18 between Alliance and Erigal and sought successfully to reduce the price payable by comparing with the price set out in the NHS PET-South block contract.

188. The OFT has also gathered evidence on joint purchasing consortiums

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[80] Alliance's submission to the OFT of 24 January 2014, paragraph 122.
[81] *Ibid*.
[82] Alliance's submission to the OFT of 24 January 2014.

negotiating a framework price and conditions for the provision of FDG-18 for a combination of several NHS and private hospitals.

189. The Competition Commission (CC) has noted in the past that whilst it might be theoretically possible for the NHS to exercise some countervailing influence because of its scale and status, effective countervailing buyer power has not always materialised.[83] The OFT notes that in past cases, both the OFT and the CC have been reluctant to accept that buyer power countervailed an expected substantial lessening of competition unless there is compelling evidence showing the improved conditions customers have enjoyed as a result of such buyer power.

190. The OFT notes that the most recently built cyclotrons (including those Alliance listed) are located in areas on the edge or beyond four hours' drive-time from existing production sites. In addition, third parties have told the OFT that they install cyclotrons primarily for research purposes and, to a lesser extent, self-supply. Therefore, cyclotrons have not thus far been invested in to discipline FDG-18 suppliers. As noted above, provision to other organisations has distinct licensing requirements involving some additional costs and time.

191. As to the existing joint procurement schemes, the OFT has not seen evidence pointing to the exercise of any material countervailing buyer power through price negotiations. The reduction in the number of possible providers would appear to reduce any pre-merger buyer power.

192. In conclusion, the OFT believes that the evidence presented to the OFT does not support countervailing buyer power mitigating any competitive harm arising from the merger.

ENTRY AND EXPANSION

193. Entry or expansion of existing firms can mitigate the initial effect of the merger on competition, and in some cases may mean that there is no substantial lessening of competition. In assessing whether entry or expansion might prevent a substantial lessening of competition, the OFT considers whether such entry or expansion would be timely, likely and sufficient.[84]

194. Alliance submits that the eight hospitals and three research institutions which own their own cyclotrons for self-supply are potential entrants to third party supply.

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[83] See Drager Medical AG & Co KGAA and Hillenbrand Industries Inc , a report on the proposed acquisition of certain assets representing the Air-shields business of Hillenbrand Industries Inc, May 2004,paragraph 8.29.
[84] *Merger Assessment Guidelines*, paragraphs 5.8.1 to 5.8.3.

195. The OFT is not aware of any alternative producer of FDG-18 for which entry would be likely, timely and sufficient to restore the level of competition lost as a result of the merger. Alliance provides Edinburgh and Glasgow as examples of investing in their own cyclotron. It submits that both installed their own cyclotrons because they required sufficient volumes to make self-supply viable and they were not willing to accept Alliance's best price for supply. However, the evidence collected by the OFT suggests that investment in cyclotrons is generally for clinical research purposes rather than clinical diagnosis.

196. Alliance submits that Cardiff University School of Medicine (Cardiff) has considered entry in to third party supplies. The OFT understands that Cardiff is conducting research and [✂]

197. Indeed the OFT notes that none of the hospitals that operate their own cyclotron indicated that they would begin commercial supply of FDG-18 to third parties, even in the event of a price rise.[85]

198. In Alliance's internal documents, the OFT notes that one of the fundamental objectives of Alliance's Isotope strategy is to 'create high barriers to entry', with the following details:

- Create long-term sticky customer relationships and contracts
- Lead-time for new cyclotron of between two and three years (or longer for entirely new entrant)
- [✂]

199. In light of the above uncertainties the OFT cannot conclude that entry or expansion would be likely, timely and sufficient to mitigate or prevent any substantial lessening of competition.

[85] Self-supply may be considered part of the relevant market when it would be profitable for such a supplier to forgo its use and sell into the merchant market in response to a small but significant non-transitory increase in price (SSNIP). For details of the OFT's approach to self-supply see *Merger Assessment Guidelines*, paragraph 5.2.20.

EFFICIENCIES

200. While mergers can harm competition, they can also give rise to efficiencies. Efficiencies arising from the merger may enhance rivalry, with the result that the merger does not give rise to a substantial lessening of competition[86] or efficiencies can be taken into account in the form of relevant customer benefits.[87] In order to prevent an SLC that would otherwise result from the merger, merger parties must provide compelling evidence that any alleged efficiencies will be timely, likely, sufficient and merger-specific.[88]

Alliance's submission

201. Alliance submits that the merger will give rise to a number of rivalry-enhancing efficiencies, including, as a result of being able to self-back-up in the South area:

- The operational and coordination efficiencies of having primary and back-up supply under the control of a single firm;
- Demand-side efficiencies resulting from primary and back-up supply, as economic complements, produced and sold by a single supplier.

202. Alliance submits that each of these efficiencies will enable it to compete more strongly with PETNET in the supply of FDG in the South area. Alliance submits that this benefit might apply as PET-CT providers require primary and back-up provision of FDG-18. Consistent with this, Alliance has stated that one of the reasons for this merger is that it will strengthen competition in the provision of FDG-18 in the South of England. Whilst customers do not mind how back-up is provided, according to Alliance, many place significant weight in their award criteria on the quality of back-up arrangements.[89]This enhanced competition should ultimately benefits the providers of PET-CT scanning services and consequently patients and the NHS which procure those services.

203. Specifically, Alliance submits that such efficiencies will be two-fold. First, there will be operational and coordination efficiencies of having primary and back-up under the control of a single firm. This is due to the ability to anticipate potential unplanned interruptions and supply these internally whereas a supplier will only

[86] *Merger Assessment Guidelines*, Section 5.7.

[87] *Mergers – Exceptions to the duty to refer and undertakings in lieu of reference guidance*, OFT, December 2010.

[88] *Merger Assessment Guidelines*, Section 5.7.4.

[89] Alliance provided one example of an Award Notice (for the Christie in Manchester), which included scoring against criteria that included expected delivery delays for planned and unplanned production disruptions.

be able to source back-up supplies from another supplier for unplanned interruptions where that supplier has, for some reason, produced more than was required for its own customers. Alliance submit that self back-up allows for communication through the night by advising other plants of potential problems rather than waiting until they materialise and a greater willingness to undertake additional production to cover the shortfall. Further, if one of the cyclotrons is down for a lengthy period the owner can reorganise production to maintain supply and it is unrealistic to expect a third party to be willing or able to cover this.

204. Second, Alliance submits there would also be efficiencies resulting from a single supplier producing and selling primary and back-up supply together as these are economic complements. Such demand-side efficiencies are likely to be material, according to Alliance, due to the removal of a high variable profit margin for FDG supply.[90]

205. In addition, Alliance submits that the merger will increase rivalry for PET-CT scanning contracts through the elimination of double marginalisation in the South area (as a result of additional supplies from the Target). The ability of Alliance to now self back-up and the integration of the Target with Alliance's downstream activities will result in a more competitive Alliance PET-CT scanning offering in the South.[91]

OFT's assessment

206. For the OFT to consider that efficiencies will enhance rivalry so that the merger does not result in a substantial lessening of competition, the evidence in support of these must be compelling. Efficiencies are difficult for the OFT to verify and quantify as most of the information concerning efficiencies is held by the merging parties. Given this difficulty, such efficiency claims must be supported by detailed and verifiable evidence of the likelihood and sufficiency of any efficiencies, and the timescales in which they would be achieved, such that they would prevent a substantial lessening of competition from arising, having regard to the effect on rivalry that would otherwise result from the merger. Further, the efficiencies must be a direct consequence of the merger and be unlikely to arise absent the merger (that is, they must be merger specific).[92]

207. These evidential demands reflect the OFT's status as a first-phase review

[90] Alliance uses a direct contribution margin of [60-70] per cent, based on the sale of FDG to third parties, as opposed to the variable profit margin on back-up supplies.
[91] Alliance submits that eliminating a [60-70] per cent FDG-18 contribution margin would facilitate a [5-15] per cent reduction in PET-CT price (or equivalent improvement in quality).
[92] *Mergers Assessment Guidelines*, paragraph 5.7.4 *ff.*

body. The OFT notes that the stronger the magnitude of competition concerns and greater the likelihood of concerns arising, the greater and more likely any efficiency or benefit claims must be to overcome such concerns.

208. With respect to Alliance's submission on the [✂] efficiencies that the merger will give rise to, the OFT notes that it has neither sufficiently detailed nor verifiable evidence on the magnitude and likelihood of these alleged efficiencies. The OFT considers, based on third party evidence, that such efficiencies are likely to be limited. First, the evidence does not point to material benefits arising from [✂]

209. [✂]

210. Further, the OFT notes the evidence from the assessment of horizontal unilateral effects above – including the shares of supply of Erigal and the Target in the South area,[✂]. As a result, it is not clear that, even if such efficiencies were to be material, that they would enhance rivalry to any material degree.

211. Finally, [✂] Given this context, it is not clear the extent to which the efficiencies outlined may be merger-specific.

212. On Alliance's submission on demand-side efficiencies, [✂]

213. In any event, the OFT does not consider that any such efficiency could be characterised by the removal of a [✂] per cent contribution margin. The estimated variable profit margin for the supply of FDG-18 is estimated to be around [30-40] per cent and that of the supply of PET-CT scanning services around [60-70] per cent. [✂]

214. The OFT has assessed the above submissions against the evidence presented to it and the above criteria. In this case, the OFT acknowledges that [✂]. However, based on the data available to the OFT, it cannot conclude on whether those efficiencies would be sufficient to outweigh the identified competition concern. This is not least because the magnitude of such efficiency as compared to other less anti-competitive alternatives (such as contractual arrangements) remains unclear.

ASSESSMENT

215. Prior to the merger, Alliance and the Target overlapped in the manufacture and supply of licensed commercial FDG-18 for PET-CT scanning services. Alliance submits and the OFT's market testing has concurred that there is no directly substitutable tracers. For this product, the relevant geographic are: (i) the South (a two-hour drive time from the production sites around London); (ii) the North (two-hour drive time from the production sites around London and four hours north of production sites around London);(iii) the Far North (beyond four hours north of sites around London and in England), and (iv) Scotland.

216. As a result of the materially different competitive conditions in the manufacture and supply of licensed commercial FDG-18 and Alzheimer's tracers, the OFT has taken a cautious approach and assessed these two different tracers separately. The OFT has not needed to conclude on the scope of the geographic market for Alzheimer's tracers.

217. Alliance is vertically integrated supplying licensed commercial FDG-18 and also providing PET-CT scanning services to hospitals.[93] The Target has no activities in PET-CT scanning but does supply FDG-18 and could supply other tracers in the foreseeable future as an input to PET-CT scanning. While there is no horizontal overlap between the Parties, there is a vertical supply arrangement. The OFT's market testing suggests that there is no directly substitutable services to PET-CT in circumstances which match the clinical aims for the use of that service, with the choice of a PET-CT scan being clinically-led. As a result, the OFT does not currently consider demand-side substitution warrants widening the product scope beyond that of PET-CT scans.

218. The OFT considers that the supply of PET-CT scan services has national, regional and local characteristics. From the perspective of patients, the supply of PET-CT scanning services is local or regional in scope. Suppliers are subject to national regulations and prices are informed by national tariffs (which might also contain local variations). Negotiations between suppliers of PET-CT scanning services and NHS England, individual trusts, foundation trusts or research centres might refer to the provision of services at national, regional or local level. The OFT notes the uncertainties in the competitive landscape for the supply of PET-CT scanning services given that the contracts commissioned in block in England are due to be renewed in 2015, possibly with a different scope. Given that the geographic scope does not affect its competitive assessment, the OFT does not need to conclude on the scope of the

[93] PET-CT scanning is a medical imaging technique that produces pictures of the body's internal structures. It has oncological and non-oncological applications. See *Evidence-based indications for the use of PET-CT in the UK 2013* produced by the Royal College of Physicians. It is available at: http://www.rcr.ac.uk/docs/radiology/pdf/2013_PETCT_RCP_RCR.pdf

geographic market for the supply of PET-CT scanning services.

219. In summary, The OFT has assessed the effects of the merger on the following product frames of reference in its competitive assessment:

- Manufacture and supply of primary supply of FDG-18 by operators with a license to supply to providers of PET-CT scanning services (licensed commercial FGD-18 providers) considering the differential impact of the merger on different customers in different areas (South, North, Far North and Scotland).

- Manufacture of Alzheimer's isotopes, whilst not needing to conclude on the geographic scope.

- Supply of PET-CT scanning services, whilst not needing to conclude on the geographic scope.

220. The OFT does not believe that it was inevitable that the Target would have exited in the absence of this merger. In particular, given the lack of an assessment of other possible restructuring alternatives. As such the first criterion of the exiting firm scenario is not considered to be met.

221. The OFT has assessed unilateral horizontal and vertical competition concerns. At horizontal level, it has assessed the impact of the loss of existing and potential competition between the Parties. As to vertical competition concerns, The OFT has considered the extent to which the merger changes Alliance's ability and incentives to totally and/or partially foreclose its rivals downstream and the effect that such actions would have on the relevant markets.

222. At horizontal level, the evidence before the OFT suggests that the merger gives rise to the realistic prospect of a substantial lessening of competition in the manufacturing and supply of FDG-18 to customers in the South due to the loss of the existing competition between the Parties.

223. On potential competition, the evidence sets out in this decision is mixed. While there are some indications that the reactivation of the Dinnington site may have been possible, it is not clear that it would be a realistic prospect that this would happen. However, in light of the OFT's finding in relation to existing competition at horizontal level, the OFT has not found it necessary to conclude on the extent to which the merger could give rise to the realistic prospect of a substantial lessening of competition as a result of a loss of potential competition in the North.

224. Equally, given its finding in the loss of existing competition in the manufacture and supply of licensed commercial FDG-18, the OFT does not need to

conclude on the impact of the merger on the supply of Alzheimer's. Also, in light of the OFT's conclusion at the horizontal level, the OFT has not found it necessary to conclude on the possible vertical effects of this merger.

225. As to buyer power, the OFT believes that the evidence presented to it is not sufficient to support that countervailing buyer power would mitigate any competitive harm arising from the merger. Similarly, the OFT cannot conclude that entry or expansion would be likely, timely and sufficient to mitigate or prevent any substantial lessening of competition.

226. On possible efficiencies, the OFT, cannot conclude on whether those efficiencies presented by Alliance would be sufficient to outweigh the identified competition concern. This is not least because the magnitude of such efficiency as compared to other less anti-competitive alternatives (such as contractual arrangements) remains unclear. [✂]

227. Consequently, the OFT believes that it is or may be the case that the merger has resulted or may be expected to result in a substantial lessening of competition within a market or markets in the United Kingdom.

EXCEPTIONS TO THE DUTY TO REFER

228. The OFT's duty to refer under section 22(1) of the Act is subject to the application of certain discretionary exceptions, including the relevant customer benefits exception under section 22(2)(b) of the Act and the markets of insufficient importance or 'de minimis' exception under section 22(2)(a).[94]

Relevant customer benefits

229. Alliance submits that the merger gives rise to three strands of benefits:

a) [✂]

b) [✂]

c) [✂]

230. Generally, for the OFT to consider applying its discretionary exception to the duty to refer in relation to relevant customer benefits (RCBs), as defined in section 30 of the Act, the benefits must outweigh the substantial lessening of competition concerned and any adverse effects from it. The benefits must also be clear and the evidence in support of them must be compelling. The merging parties must be able to produce detailed and verifiable evidence of the RCBs

[94] *Exceptions to the duty to refer and undertakings in lieu of reference guidance*, OFT1122, December 2010.

that allows the OFT to assess both the magnitude of the RCBs and the probability of them occurring. The OFT sets the magnitude and probability of the RCBs against the scale and probability of the identified anti-competitive effects.[95] It must also be clear that the benefits were unlikely to have occurred without the merger (section 30(1)(b) of the Act).

231. Below the OFT has considered the benefits referred to above under b) and c). Given the OFT's conclusions on the merger's impact on the supply of FDG-18 as set out earlier in this decision, the OFT considers that it is not clear that the merger will lead to an increase in competition in the [✄]

Improved security of supply of FDG-18 and PET-CT scanning services

232. Alliance submits that one of the benefits of this merger is to improve the [✄] This will benefit FDG-18 customers by providing them with an economically sustainable source of large volumes of FDG-18 which they can rely on in making long-term plans. Alliance submits that this in turn will improve reliability of Alliance's PET-CT scanning services and benefit hospitals purchasing those services and patients using them.

233. Alliance supports its submission [✄].

234. However, [✄]

235. The evidence obtained by the OFT does not suggest that [✄]is necessary to win PET-CT scanning contracts (as set out in the competitive assessment section above). Further, the OFT does not consider that, absent the merger, the Target would have inevitably exited the market (as set out in the counterfactual section above).

236. The OFT does not therefore consider that it has compelling evidence that the merger will result in benefits from [✄] that outweigh the SLC the OFT has found nor that any benefit were unlikely to have occurred without the merger.

[✄]

237. [✄]

238. [✄]

239. [✄]

240. [✄]

95 *Exceptions to the duty to refer and undertakings in lieu of reference guidance*, paragraphs 4.9-10.

- [✄]

241. [✄]

242. [✄]

243. [✄]

'De minimis' exception

244. The OFT has found a realistic prospect of a substantial lessening of competition in the market for the provision of licensed commercial FDG-18 to NHS and private hospitals in the South. The oFT believes that the annual value of the market is less than £10 million. The OFT has therefore considered whether it should apply the 'de minimis' exception to the duty to refer.

Availability of undertakings in lieu

245. The OFT generally will not apply the 'de minimis' exception where clear-cut undertakings in lieu of reference could be offered by the parties to resolve the competition concerns identified. The OFT's judgment in this respect is an 'in principle' one that does not depend on any actual offer of undertakings in lieu.[96] In any event, the existence of any such offer is unknown to the decision maker at the time of his or her decision as to whether undertakings in lieu are in principle available.

246. The OFT considered whether there a clear-cut undertaking in lieu could be available in this case. This would typically be the case where the part of the transaction that raises concerns can be divested through a structural undertaking in lieu. In the present case, the only structural undertaking in lieu open to Alliance to resolve the SLC would be to divest the Target's site in Guildford. However, given that the Target's only other site, in Dinnington, is mothballed, the OFT considers that the Guildford site is such an integral part of the merger that a divestment of this site would be tantamount to prohibiting the merger altogether and would therefore not be suitable for an undertaking in lieu.[97]

247. The OFT also considered whether some commitments as to Alliance's future conduct could resolve the identified competition concerns. However, given the OFT’s previous experience of implementing behavioural undertakings and its role as a Phase 1 review body, the OFT is generally unlikely to consider that behavioural undertakings are sufficiently clear-cut to address competition

[96] *Exceptions to the duty to refer and undertakings in lieu of reference guidance*, paragraphs 2.18-2.27.
[97] *Exceptions to the duty to refer and undertakings in lieu of reference guidance*, paragraph 2.25.

concerns.[98] In this case, the OFT does not believe that there could be behavioural undertakings that would meet the 'clear-cut' standard, and it has therefore not included these in its 'in principle' assessment.[99]

248. On the basis that the OFT believes there is no clear-cut undertaking in lieu available, the OFT has proceeded to examine whether to exercise its 'de minimis' exception in this case.

Application of the 'de minimis' exception

249. When determining whether it should apply the 'de minimis' exception, the OFT assesses the expected customer harm from the merger, in particular whether the expected merger impact is expected materially to outweigh the public costs of a reference to the Competition Commission. The main factors that the OFT considers in determining the expected customer harm are the following:[100]

- the size of the market
- the strength of the OFT's concern (that is, its view on the likelihood that the substantial lessening of competition will occur)
- the magnitude of competition lost by the merger
- the durability of the merger's impact
- any wider implications, including the merger's potential replicability and rationale

250. The OFT has considered each of the above factors in determining whether to exercise its discretion to apply the 'de minimis' exception in this case.

Market size

251. The market in which the OFT has found a realistic prospect of an SLC is the provision of FDG-18 [to NHS and private hospitals] in the South area. The aggregated size of this market, as estimated by Alliance, amounts to £[5-10] million.[101] Hence, the annual value of the market is below the £10 million benchmark above which the OFT would not generally apply the 'de minimis'

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[98] *Exceptions to the duty to refer and undertakings in lieu of reference guidance*, paragraph 5.42.
[99] *Exceptions to the duty to refer and undertakings in lieu of reference guidance*, OFT1122, December 2010, paragraph 2.27.
[100] *Exceptions to the duty to refer and undertakings in lieu of reference guidance*, section 2.
[101] The OFT notes that, as set out above, it has not concluded on possible competition concerns in other markets. If the OFT had found a realistic prospect of an SLC in some or all of these markets, these should have been included for the purposes of the 'de minimis' assessment. However, this would not affect the OFT's assessment, since in that situation the aggregated size of the markets concerned would rise above £10 million and the 'de minimis' exception would not apply.

exception, but it is above the £3 million benchmark below which a reference to the Competition Commission would generally not be justified.[102]

252. The OFT also notes that its investigation showed that the ize of the market may grow in the foreseeable future.

Strength of the OFT's concerns

253. The OFT's belief is that there is a realistic prospect that the Transaction results in a substantial lessening of competition, but it does not consider, based on the evidence set out in the competitive assessment above, that this is more likely than not (that is, the OFT's level of belief is on the 'may be the case' standard rather than on the 'is the case' standard).

Magnitude of competition lost

254. The Transaction will effectively result in a reduction from three to two in the number of providers of FDG-18 to customers rather than the creation of a monopoly. The OFT considers that the lumpy nature of demand in the market means that the impact of the merger on some contracts will be several years away.

255. However, the OFT has also taken account of the fact that the likely detriment of the reduction in competition will be suffered by the NHS and therefore, indirectly, patients. The OFT notes that a significant number of third parties, including NHS organisations, were concerned about the merger's impact on future prices and supply disruption.

Durability

256. The evidence available to the OFT and set out at the counterfactual section above indicates that, although it did not consider it appropriate to apply an alternative counterfactual to the pre-merger conditions, the vendor of the Target's may not have kept the Target in operation in the medium term.

257. However, the OFT also notes that barriers to entry are high in this market, as set out above. Further, the lumpy nature of demand means that the merger's impact on contracts that are tendered in the near future will last for those contracts' full duration.

Replicability and rationale

258. Generally, the potentially 'replicable' quality of particular 'de minimis' decisions means that the exercise of the OFT's discretion in one case could cumulatively

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[102] *Exceptions to the duty to refer and undertakings in lieu of reference guidance*, paragraph 2.15.

lead to aggregate customer harm, because consistency of treatment may require that this discretion is also applied in future cases in the same sector where competitive conditions are comparable.[103] In this case, the OFT notes that, given the particular features of this market, there is little scope for similar future similar cases.

259. The OFT may also have regard to the economic rationale behind a merger. In this case, as noted above, the OFT has taken into account that the evidence indicates that Alliance's rationale was, at least in part, [✂] that may have resulted in some benefits to the NHS, rather than (solely) the acquisition of market power.

Conclusion on the 'de minimis' exception

260. The OFT considers that on balance, taking all factors set out above into account, it is not appropriate to exercise its discretion to apply the 'de minimis' exception in this case.

DECISION

261. This merger will therefore **be referred** to the Competition Commission pursuant to section 22(1) of the Act.

Chris Walters
Chief Economist and decision maker
Office of Fair Trading
24 March 2014

[103] *Exceptions to the duty to refer and undertakings in lieu of reference guidance*, paragraph 2.42.