COMPLETED ACQUISITION BY ALLIANCE MEDICAL GROUP LTD OF THE ASSETS OF IBA MOLECULAR LTD USED TO MANUFACTURE FLUORODEOXYGLUCOSE 18F

Statement of issues

28 April 2014

The reference

1. On 24 March 2014, the Office of Fair Trading (OFT) referred to the Competition Commission (CC) under section 22 of the Enterprise Act 2002 (the Act) the completed acquisition by Alliance Medical Group Limited (Alliance) of the assets of IBA Molecular UK Limited used to produce 18F-fluorodeoxyglucose (FDG-18) in the UK, as well as related rights and activities (the IBA operation). In this statement we refer to Alliance and the IBA operation as the parties.

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

3. The CMA must decide:

   - "whether a relevant merger situation has been created; and
   - if so, whether the creation of that situation has resulted, or may be expected to result, in a substantial lessening of competition (SLC) within any market or markets in the UK for goods or services" (Enterprise Act 2002)

4. In this statement, we set out the main issues we are likely to consider in reaching our decisions. This does not preclude the consideration of any other issues which may be identified during the course of our investigation.

Background

5. FDG-18 is a radioactive tracer (or radiopharmaceutical), which is used for PET-CT scans, which themselves are used predominantly for the diagnosis of cancers. FDG-18 is produced in cyclotrons, of which there are 19 in the UK, 12 of which are owned by hospitals or research institutions.[1] Cyclotrons can be used to produce other radiopharmaceuticals, including Florbetapir, Flutemetamol and Florbetaben (collectively referred to as Alzheimer's tracers, as they are used in the diagnosis of Alzheimer's disease). PET-CT scans are either carried out by hospitals (whether private or NHS) or by third parties under contract. PET-CT scanners operated by third parties can either be fixed at a given location (typically in a hospital) or be mobile (and transported in specialised units).

6. The level of radioactivity and therefore effectiveness of FDG-18 doses declines over time. This limits the distance over which they can be transported. Cyclotrons are subject to regular outages (whether planned or unplanned) and back-up arrangements are required by customers to ensure continuity of supply during such outages.

7. Prior to the acquisition, Erigal Ltd, which became a fully-owned subsidiary of Alliance in August 2013, produced FDG-18 at three sites in England: Sutton, Preston and Keele. The IBA operation produced FDG-18 at one site in Guildford and owned a cyclotron in Dinnington (near Sheffield), which had not been active since 2010. There is only one other commercial supplier of FDG-18 in Great Britain: Siemens plc under the PETNET Solutions brand (PETNET). The commercial supply of FDG-18 to third parties requires a Market Authorisation (MA) licence issued by the Medicines and Healthcare Products Regulatory Agency (MHRA). None of the hospitals or research institutions owning cyclotrons holds such a licence. We understand that GE Healthcare Limited (a division of the General Electric Company, GE) holds an MA licence but stopped supplying FDG-18 commercially in 2009.

8. Alliance also provides PET-CT scanning services. Other third party suppliers (ie other than hospitals) of such services are Cobalt (a registered charity) and InHealth Group Limited (InHealth).

9. On 16 September 2013, Alliance Medical Molecular Imaging Limited, a wholly-owned subsidiary of Alliance, completed the acquisition of the IBA operation.

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[1] At one of them, Imanova Limited operates two cyclotrons.

Market definition

10. Market definition is a useful tool, but not an end in itself, and identifying the relevant market involves an element of judgement. The boundaries of the market do not determine the outcome of the CMA's analysis of the competitive effects of the merger in any mechanistic way. In assessing whether a merger may give rise to an SLC the CMA may take into account constraints outside the relevant market, segmentation within the relevant market, or other ways in which some constraints are more important than others.[2]

11. The parties overlap in the supply of FDG-18, produced at sites located in England. They do not overlap in the production of Alzheimer's tracers in the UK, but they will shortly do in their supply to the UK under multi-country contracts with three companies developing the diagnostic tests using those tracers.

12. The evidence received by the OFT at Phase 1 showed that there were no substitutable products for the intended clinical uses of FDG-18 or of Alzheimer's tracers. Alliance agreed with this position in its initial submission to the CMA.

13. In coming to a view on the scope of the product market or markets, we will therefore focus our analysis on the following aspects of demand and supply, some of which relate to whether self-supply should be included in the product market:

    - Whether hospitals which own and operate cyclotrons for their own needs but do not currently supply to other parties should be included in the same market as commercial suppliers.

    - Whether arrangements whereby a third party builds and operates a cyclotron at its customer's site (typically a hospital) in return for a long-term exclusive supply contract are in the same market as other types of commercial arrangements.

    - Whether the primary supply of FDG-18 is in the same market as all or some of the back-up arrangements that currently exist, namely: self-back-up, where a supplier uses another of its own cyclotrons for back-up; formal back-up arrangements; and spot back-up arrangements.

    - Whether the supply of FDG-18 by Alliance to its own downstream PET-CT scanning services operation should be included in the same market as the

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

supply of FDG-18 to other providers of PET-CT scanning services or hospitals carrying out the scans themselves.

14. We will also consider the geographic scope of the market, and in this respect we note that there are restrictions on the length of time from production within which FDG-18 must be administered and that this in turn impacts on the delivery range within which it can be delivered from a given cyclotron. However, the actual distances over which products will travel in practice may depend on the nature of the contracts governing their supply and the ability of various suppliers to compete for such contracts.

15. We will also consider the definition of the markets for Alzheimer's tracers and PET-CT scanning services. With regard to the latter, our analysis will take account of the three ways in which such services are currently provided, ie: directly by a hospital that owns and operates the PET-CT scanning equipment; by a third party under a mid- to long-term contract with a given hospital or group of hospitals; by a third party to a number of hospitals under a contract centrally procured and administered by the NHS (of which there are currently two: PET-North and PET-South).

16. Our current view is that our analysis should focus on England, as neither party has facilities in Northern Ireland, Wales or Scotland and to our knowledge, the parties did not compete with each other in those areas. However, we would welcome views on whether there might be a merger effect in Northern Ireland, Wales or Scotland.

Assessment of the competitive effects of the merger

Counterfactual

17. We will assess the possible effects of the merger on competition compared with the competitive conditions in the counterfactual situation (ie the competitive situation without the merger). We will therefore consider what would have happened if the merger had not taken place, and in particular whether:

- the IBA operation would have failed or exited and if so, what would have happened to the sales of the firm in the event of its exit. In making this assessment, we will examine its financial position and ability to compete given the size of the operation (both in terms of scale and geographic scope)

- the IBA operation's previous owners would have been able and willing to reopen its Dinnington site

- whether there would have been other likely buyers for part or all of the IBA operation and whether such buyers would have led to competition concerns

18. In making our assessment, we will consider possible alternative scenarios and decide upon the appropriate counterfactual situation on the basis of the facts available to us and the extent of our ability to foresee future development.

Theories of harm

19. Theories of harm describe the possible ways in which an SLC could arise as a result of the merger and provide the framework for our analysis of the competitive effects of the merger. We have set out below the theories of harm which we intend to investigate. However, we may revise our theories of harm as our inquiry progresses. Also, the identification of a theory of harm does not preclude an SLC being identified on another basis following further work by us or the receipt of additional evidence. We welcome the views of parties on all the theories of harm set out below.

Theory of harm 1: loss of actual competition

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

21. We will assess the extent to which the parties competed with each other before the merger and the extent to which the products and services of other suppliers (whether they are within or outside the relevant market or markets) could be expected to exert a competitive constraint on Alliance following the merger. Issues and evidence which we are likely to consider include:

- the outcome of past bids, including the relative strength of bidders
- views of customers and documentary evidence on the closeness of competition between Alliance and the IBA operation
- customer switching and the threat of switching between suppliers of FDG-18
- the margins achieved by Alliance's FDG-18 operation and the IBA operation

- the extent of spare capacity at the parties' and other suppliers' FDG-18 production sites
- the difference in transport costs (and other marginal costs) of the suppliers
- the extent to which the closure of sites or other changes in supply have had an impact on prices
- rivalry-enhancing efficiencies: we will consider the argument put forward by Alliance that the merger will create a stronger competitor to InHealth and PETNET

22. In carrying out our assessment we will consider how future changes to the procurement of PET-CT scanning services by the NHS may impact on the nature of competition in the supply of FDG-18.

Theory of harm 2: loss of potential competition

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

24. Under this theory of harm, we will examine the nature of the competitive constraint that the Dinnington site could have been expected to exert on Alliance both now and in the future and the extent to which the parties could have been expected to compete in the provision of Alzheimer's tracers or other radiopharmaceuticals in the future.

Theory of harm 3: vertical effects

25. Under this theory of harm, we will consider whether Alliance's presence in both the upstream supply of FDG-18 and downstream supply of PET-CT scanning services may provide it with the ability and incentive to undermine the competitiveness of downstream rivals in order to increase its own presence in the downstream supply (also known as 'input foreclosure'), which may in turn result in the weakening and exit of its competitor in the upstream market (also known as 'customer foreclosure'). Our assessment will include us considering:

- the effect of the merger on prices at both levels in the supply chain, given the cost of production of Alliance and its rivals

- the level of spare capacity held by other suppliers of FDG-18 and their ability thus to defeat an input foreclosure strategy by Alliance

- the extent of planned and unplanned outages and effect of the merger on the ability of suppliers of FDG-18 to raise their rivals' costs through back-up supply arrangements

- the ability and incentive of upstream and downstream competitors to vertically integrate and the ability of the NHS to sponsor entry into or to supply its own FDG-18 and/or PET-CT scanning services

Theory of harm 4: coordinated effects

26. Under this theory of harm the merger may increase the ability and incentive of market participants to increase prices because it creates or strengthens the conditions under which they can coordinate. An assessment of this theory of harm would require an analysis of whether the market(s) in which the parties operate had characteristics that were conducive to coordination and whether such conditions would be significantly affected by the merger. We note that as a result of the merger, there will be two competitors of a similar size in the supply of FDG-18 and both could be dependent upon each other for back-up supplies. We also note, however, that the structure and certain characteristics of the markets in which the parties and their competitors operate may reduce their incentives and ability to coordinate.

27. At this stage in the inquiry, we do not propose to investigate this theory of harm in detail, but will consider this further in light of the evidence that we will obtain in our investigation.

Countervailing factors

28. We will consider whether there are countervailing factors which are likely to prevent or mitigate any competition concerns that we may find as a result of our analysis of the effects of the merger. In particular, we intend to consider the following:

- *Entry and expansion*: we will consider whether entry or expansion would be timely, likely and sufficient to mitigate the effects that might otherwise arise. In particular, we will investigate the ability and willingness of the 12 owners of cyclotrons who currently do not supply FDG-18 to third parties (eight hospitals; three research institutions and GE Healthcare) to do so following the merger. The owners of these cyclotrons could either supply FDG-18 commercially or they could arrange for their cyclotrons to be used by third parties to supply FDG-18.

- *Any offsetting efficiencies* (see also paragraph 21).

- *Buyer power*: we will consider the negotiating strength of hospitals (whether individually or in concert) and NHS England and their ability to sponsor entry or increase the level of self-supply. In making this assessment, we will take account of the ways in which contracts are structured and negotiated.

29. We are not aware of any other possible countervailing factors at this stage.

Possible remedies and relevant customer benefits

30. Should we conclude that the merger may be expected to result in an SLC in one or more markets, we will consider whether, and if so what, remedies might be appropriate, and will issue a further statement.

31. In any consideration of possible remedies, we will take into account whether any relevant customer benefits might be expected to arise as a result of the merger and, if so, what these benefits are likely to be and which customers would benefit.

Responses to the issues statement

32. Any party wishing to respond to this issues statement should do so in writing, by no later than 5pm on 13 May 2014. Please email Alliance.IBA@cma.gsi.gov.uk or write to:

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