

ALLIANCE/IBA MERGER INQUIRY

Summary of a hearing with the British Nuclear Medicine Society held on 22 April 2014

Background

1. The British Nuclear Medicine Society (BNMS) said that in the 1990s there had only been a few centres that could offer PET-only services and then PET-CT services had developed in the early 2000s to allow improved imaging.
2. Initially PET was limited to a few academic institutions with links to hospitals that had had cyclotrons and produced FDG18, with the world's first being Hammersmith Hospital in the 1960s. From there they then went into additional hospitals and university settings.
3. PETNET launched its first cyclotron around 15 years ago in the London area and then it was only PETNET and various academic institutions that produced FDG18. PET-CT scans were then rolled out gradually to other areas. In 2002/03 the Royal Colleges of Physicians and Radiologists came together to design a national strategy for PET-CT scanning and they recommended the use of mobile sites because it was impossible to move from fixed operations in a few hospitals to providing fixed sites nationwide.
4. The Government decided that funding PET scans should be a national priority and that it would be more appropriate to use external suppliers rather than it being done by the NHS. Hence the independent sector supplied mobile services and FDG was supplied directly from industry, hospital-based or academic cyclotrons.
5. With time the number of hospital sites with fixed PET-CT services and on-site cyclotrons for FDG production for local use had increased. The independent sector supplied approximately 50 to 55% of PET-CT services including FDG. Two contractors – InHealth and Alliance – provided the PET services in the south and north respectively.
6. As Alliance and InHealth increased their business, Erigal (another producer of FDG) set up two sites in Preston and Keele and PETNET expanded and opened a site in Nottingham. IBA then entered the market with a cyclotron at Guildford and then in Sheffield at Dinnington. GE had a facility at Amersham

but never established an FDG supply into the UK market. Rationalisation then occurred with Siemens taking over PETNET and Alliance taking over Erigal.

7. BNMS said that recently the market had developed considerably. Ten years ago there had been a few indications for cancer scanning. The recently published evidence-based guidelines now numbered in excess of 20 indications for PET-CT in the UK. (www.rcplondon.ac.uk/sites/default/files/pet-ct_guidelines_2013.pdf) At one time the UK had among the lowest use of PET-CT services, but now it was somewhere in the middle.
8. PET-CT scanners were mostly based in major cities, principally in cancer centres and all of them needed a regular supply of FDG.

Market definition

9. BNMS said that 20 years ago there had only been one or two hospitals with cyclotrons, but now it estimated that there were around 20 cyclotrons throughout the UK and Ireland.
10. Currently around 55,000 scans were done a year in the UK. Half of these were done by the independent sector using both fixed and mobile sites.
11. There had been a trend towards increased use of PET-CT for diagnosis and treatment planning: PET scans accounted for around 10% of the global radiopharmaceutical market in 2010. The forecast was for this to be around 17% in 2017. Therefore BNMS believed that the capability to produce FDG would be crucial to the growth of the PET scan market.
12. BNMS stated that there was no minimum size for a hospital in order for it to have PET-CT scanning facilities, but that 90% of the PET-CT market was for cancer services and around 90% of cancer services were found in larger hospital centres due to the need to concentrate expertise and resources at these centres.
13. Whilst the CT scanning services market had increased, FDG production had been rationalised. BNMS believed that this was because the independent sector's estimations about the growth of the PET scan market had not materialised as fast as it had predicted.

Licensing

14. In order to sell any medicine a product licence was needed and these were only available to commercial suppliers. All licensed products had to be fully compliant with MHRA regulations and the cost of obtaining and maintaining a licence was high. Every manufacturer applying for a licence also needed to go

through a centralised European application process and it took a long time to submit all the papers to get the product licensed.

15. While FDG was produced by academia and hospitals, in England hospitals would not consider supplying outside their Trust boundaries as they would need a licence.

Procurement

16. The original contract for PET-CT scans had been set up by the Department of Health in order to ensure an equitable share out of the market. This had then been overtaken by the PET north and PET south contracts which were managed within the NHS.
17. Procurement for PET-CT contracts had recently been advertised as the contracts were due to end in March 2015. However, procurement for FDG was different to PET-CT services.
18. Trusts used NHS procurement hubs to buy FDG as coming together gave them increased buyer power. In the past hospitals had tendered individually, but a move had been made towards hubs because hospital procurement departments felt that hubs were better placed to deal with the OJEU tenders and as hubs were often private companies, the number of people working in hospital procurement/supply departments had decreased.
19. BNMS noted that within the contracts, the amount of FDG, and how it would be delivered, was not specified.
20. On the whole fixed sites were less likely to be managed by independent providers than the NHS itself but there seemed to be a trend by both Alliance and InHealth to use existing facilities at NHS trusts so that they could decrease their capital costs. Often there was an agreement between NHS trusts and Alliance/InHealth for a rental or payback scheme and sometimes Alliance/InHealth used NHS staff.

Competition

21. Failure rates for cyclotrons seemed to have increased over the last few years and BNMS believed that this was possibly due to the fact that they were operating under increased stress. They were being required to produce more FDG and therefore there was less time allocated for equipment maintenance. Often little faults would add up and then the cyclotron could be out of operation for a day while people were trying to find the cause of the problem.

22. Competing companies often agreed to back each other up in case of cyclotron failure. As it took 8 hours to get a cyclotron up and running, it was not possible to have one on standby and economically it was too expensive for companies to have two sites with one acting as a back-up. Therefore the NHS expected that there would be a small number of days when a cyclotron would go offline, but it was usually easy to switch to a different supplier if necessary. However, geography and logistics were key aspects of a viable back-up as FDG had a half-life of 110 minutes.
23. BNMS was concerned that now there were only two manufacturers of FDG. It believed that one of the criteria for awarding a contract was to get those tendering to show a printout of the number of days that their cyclotron had failed over the last three years. With only two suppliers, BNMS was concerned that it would be harder to use one as a back-up to the other.

The merger

24. BNMS was concerned that Alliance never used to produce FDG, but it had now moved into supplying the market having already got a national PET-CT contract. As Alliance was now a supplier and an end user, BNMS feared a monopoly situation that would threaten FDG services.
25. BNMS believed there could be efficiencies from vertical integration, but with the closure of Dinnington it was concerned that there was less potential backup and that the rationalisation may be problematic if there were failures at existing sites. However, it said that there could be savings made and this would be beneficial to patients.

New entry

26. BNMS stated that hospital trusts could not sponsor entry into the market as they were too small. Any entry sponsorship would need to be at a national level.
27. One or two larger NHS institutions might band together to put in a bid to supply PET-CT services, but such instances were few and far between.

Technetium

28. The short-lived ^{99m}Tc Technetium (obtained from a ^{99}Mo generator) was currently supplied from outside the UK as there was no reactor production of Molybdenum (the parent molecule of Technetium) within the UK shores. Because of the closure of research reactors producing Molybdenum there would be a shortage from 2016 to 2020. It might be possible to produce

Technetium in cyclotrons but industrial partners would be needed for this. It was currently being investigated in Canada, but they had already invested C\$100 million in the last five years and they had only just started producing suitable quantities for distribution. This form of ^{99m}Tc Technetium had yet to gain regulatory approval.

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