SIEMENS

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Inquiry Manager
Project Resource Group
Competition and Markets Authority
Victoria House
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London WC1B 4AD

24th April 2014

Re: Completed acquisition by Alliance Medical Molecular Imaging Limited of the assets of IBA Molecular UK Limited

Following your invitation for PETNET Solutions to comment on the acquisition of IBA by Alliance, we are pleased to provide the following commentary.

As a general observation, we recognise the value to the market of open competition, and it is already evident that the FDG market in England enjoys competitive supply as a result of this competitive dynamic.

This rationalisation of the UK market would result in Siemens' PETNET operation being the only operator that is truly independent, insomuch as Siemens does not also provide any clinical PET service, (albeit Siemens does supply the scanning hardware). Alliance Medical does provide clinical PET services in competition with some other operators such as InHealth and Cobalt.

FDG production is not without its challenges and, occasionally, an overnight production run may fail to yield product. Suppliers have traditionally drawn upon reciprocal supply arrangements to ensure continuity of supply or alternatively the actual consumers have maintained supply relationships with multiple suppliers. Nevertheless, when there is a reduced supply as a result of production failure, the demand for dose may exceed the availability.

Whilst we have an excellent record with respect to supply availability, should we be unable to fulfil demand as a result of production issues, our customers may depend on receiving FDG production from Alliance Medical in order to avoid the cancelation of patient scans. Since 90% of FDG is used in the field of Oncology, timely diagnostic scanning is key and is firmly embedded in patient's treatment plans. Cancelled or delayed scans can, therefore, lead to resultant delays in therapeutic interventions.

I can confirm that we were not aware of IBA's intention to divest its UK PET operation until after the sale to Alliance had been announced and, therefore, did not consider an acquisition.

We are pleased to provide the following information on our UK operation.

We currently operate two FDG production facilities, the details of which are listed here together with the different PET radiopharmaceuticals we manufacture:

PETNET Solutions

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1. **Mount Vernon Hospital, Northwood, Middlesex**

FDG

AmyVid

Sodium Fluoride

Fluoromethylcholine

2. **City Hospital, Nottingham**

FDG

AmyVid

Fluorothymidine

In order to produce FDG for commercial distribution and meet the strict MHRA criteria for licencing, the following equipment is needed as a minimum:

- Cyclotron
- GMP grade Clean Room
- Dispensing Isolator
- Radiochemistry Synthesis Modules
- Fully equipped QC Lab including HPLC, GC and other analytical equipment

The investment required to build a facility and then equip it with the above is very significant as is the time required to build, install, commission and qualify such a facility.

With respect to the FDG licencing process, on the assumption that one had already made the investment in a cyclotron and clean room manufacturing facility of the requisite standard, the process of obtaining a licence to sell FDG commercially would involve making an application to the MHRA (Medicines and Healthcare products Regulatory Agency) for a Marketing Authorisation (MA). The process of preparation, application submission and inspection takes between 6 and 9 months to conclude. Once a licence is granted there is an ongoing program of re-inspection, typically every two years, in order for licences to be retained.

The production capacity of a cyclotron facility is impacted by a number of variables. By far the most impactful is that of distance to customer. Since FDG is labelled with a short-lived isotope (18-F) which has a radioactive half-life of 110 minutes, proximity to customers is key. Ideally the customer base should be within a two hour journey time of the cyclotron and certainly no more than four hours away. It is generally uneconomical and too inefficient to distribute beyond that.

From our two locations we can supply FDG to just about every PET scanner location in England. Our current customer base extends from Newcastle in the north east to Plymouth in the south west. Given the half-life issue previously described, we do not supply FDG to Scotland (or Northern Ireland) as the journey times would be too great.

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If PETNET has a rare production delay or failure at either of our sites, we have a Standard Operating Procedure in place to transfer the production of the affected customer orders to our other production site. For example, a production problem at Mount Vernon will result in the affected doses being manufactured and shipped from Nottingham instead until the issue at Mount Vernon is resolved. In the vast majority of cases these situations are resolved and normal production resumed either the same day or by the next working day.

I trust that this information will be of assistance in your deliberations and would thank you again for affording us the opportunity to contribute.

Yours sincerely

Ian Brown

Operations Manager

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