BNMS RADIOPHARMACY SUMMIT

Notes of meeting held in London on 9th February 2009

Present: Dr Gill Vivian President
Prof Alan Perkins Hon Secretary
Ms Claire Greaves Professional & Education Standards Committee
Dr Maria Palmer Radiopharmacy Group

Mr Paul Maltby UK Radiopharmacy Group
Dr Tom Nunan ARSAC, National Imaging Board (“NIB”)
Prof Adil Al-Nahhas European Association of Nuclear Medicine
Ms Wendy Waddington Institute of Physics & Engineering NM Special Interest Group
Mr Mike Woodhall MHRA, Senior GMP Inspector
Mr Graham Matthews MHRA
Mr James Taylor Health & Safety Executive (“HSE”)

Mr David Baker Covidien, UK Nuclear Medicine Manager
Mr Nico Beukman Covidien, Area Vice President Imaging
UK, SA, Benelux and Norden
Mr Harrie Buurlage Covidien, Director of Manufacturing
Mr Peter Dobson Diagnostic Imaging
Prof Dewi Lewis GE Healthcare, Head of Physics
Ms Zillah Moore GE Healthcare
Mr Alejandro Otero GE Healthcare, GM for Europe, Middle East & Africa
Mr Mike Yon IBA, General Manager
Ms Amanda Williams IBA
Ms Smaragda Progiou Qados
Ms Beverley Wallace Nuclear Medicine Industry Association

Apologies: Dr E Denton (NIB), Mr S Ebdon-Jackson (HPA), Mr I Chell (DH), M Nettleton, P Snelson, C Temple (HSE)

Prof Perkins presented a summary of the production methods and the logistical problems with reactor operations and distribution. This included the reactor failures of the past 18 months and the proposed production schedule for 2009 (see attached presentation).

Current Molybdenum position
Covidien – Mr Buurlage reported that the High Flux Reactor in Petten, Holland was very close to restarting. They were waiting for five Dutch Government ministers to sign off. However, this would not resolve future problems where it was likely that only two reactors would govern 90% of worldwide scans.
Covidien were currently defining a strategy with a company whereby they would no longer be dependent on research reactors but have a dedicated Molybdenum machine to ensure 50% supplies for the US market and thereafter the European market but this was a long-term project. In his opinion the short-term solution was to forecast patient planning four weeks ahead when shortages were known.

Dr Vivian asked what was the strategy for reinvestment in light of increasing costs of Molybdenum production. She was concerned that tariffs in the UK were fixed two – three years ago.

Mr Buurlage noted that unfortunately a High Flux Reactor depended upon US finance and therefore a significant proportion was exported to the US market; they had future plans to connect to low risk uranium but this required substantial R&D costs. The cost of Molybdenum would rise significantly in the future. (Long term 2015 –2016; new technologies 10 – 15 years.)

GE Healthcare – Mr Otero explained:
Long-term – they were studying 2 – 3 different solutions; short term the situation was extremely fragile. He anticipated two – three years of shortage. The price of Molybdenum supplies had increased significantly and he highlighted the fact that technetium was currently subsidized by companies in the market and this will stop. It was a loss leader and therefore uneconomic. Prof Lewis noted that the cost base for generating supplies was unrealistic; ageing reactor profile of research reactors shut down by the age of 35 except SAFARI in South Africa

IBA – Mr Yon echoed the previous comments on Molybdenum pricing and also the need to forecast demand; fifteen days ahead then best guess information back from users.

Diagnostic Imaging – Mr Dobson felt one solution would be improved software capabilities enabling reduced imaging times or reduced amount of activity used.

MHRA – Mr Matthews stated that the import of unlicensed medicines into the UK, which would normally take 28 days from notification to import, can be waived in emergencies and can be turned around in 10 days. He said it was a requirement of the license holder to inform MHRA of any interruption of supplies.

UK Radiopharmacy Group – Mr Maltby reported that there was limited scope for equitably sharing supplies between radiopharmacies as close proximity no longer existed; it was not realistic to travel 30 – 40 miles not least because of time constraints.

BNMS Radiopharmacy Group – with a timescale shortage of 2 – 5 years, Dr Palmer felt that a radical change would have to take place and nuclear medicine departments would have to operate 24 hours a day.
EANM – Prof Al-Nahhas reported that the EANM were actively lobbying the European Parliament and in discussions with APES and other Societies. A meeting of 38 European delegates would be taking place in Vienna on 15th March where this issue would be discussed.

HSE – Mr Taylor highlighted the importance of risk assessment e.g. if technetium generators were getting more dosage than was being used, then justification would have to be made.

**Clinical recommendations**
Dr Vivien reported on the clinical perspective of reduced supplies and outcomes from working Groups 4 and 5 of the OECD meeting held in Paris in January (see attached presentation).

**Other radiopharmaceutical issues**
Mr Maltby expressed concern that in the last few years a range of products had been withdrawn for clinical use and usually without consultation. Some products were unique to the UK and with less than 12 months notice this did not help with services for clinical colleagues. Trying to import unlicensed products was only half the story; consultation between industry and the nuclear medicine community was vital. Was there any scope to bring back suspended licensed products? Of the nine products that had gone during the year four had no alternative product.

*Mr Otero agreed that dialogue was key between both communities and hoped this would improve in the future; although products had to be commercially viable, he noted the last 3 / 4 product withdrawals were due to the inability to source raw materials.*

Mr Dobson – short term availability - failed QA; because of 28 day rule of licensed product How could this be overcome?

*MHRA - Mr Woodhall stated that notifications did not have a time limit; important to ensure dialogue between MHRA, license holder and manufacturer.*

**Action:**
UK Radiopharmacy Group to write a statement of clarification with MHRA and make available to clinicians when shortages will occur on how to make requests in order to keep products.

Mr Matthews – method is to use importer who has license to state clinical risk and why it must be fast-tracked. Dr Vivian felt it would be useful to have clarification when and how fast-track system can be considered.

**Action:** set up a forum or communication between UK Radiopharmacy Group, manufacturers and distributors to include scheduling times and other issues.

3.30 Prof Al-Nahhas and Dr Palmer left the meeting.
Mr Dobson – when would UK Radiopharmacy Group handbook be updated as it listed products with out of date licenses? Paul Maltby stated that with only six people in the UK Group the handbook was likely to be withdrawn.

**Current position**

Dr Vivian - Molybdenum supply in hospitals was variable and dependent upon the supplier; short notice of generator capacity limits planning clinical activity. SHA data collection on behalf of DH in November 2008 35% - 75% expected Molybdenum delivery; many hospitals have an independent radiopharmacy. Across UK less than 700 patients were waiting for nuclear medicine procedures; no data available yet available to look at disruptions. Dr Nunan – 18 week waiting data had no relationship on clinical contingency planning. No UK co-ordination; planning required.

Covidien – encourage utilization through different scheduling of procedures; centralized radiopharmacies appeared to fare better because of this e.g. UCLH.

Mr Maltby – 7 hospitals in region with two radiopharmacists; profile patients rather than large amount on demand. At Bourneville meeting majority work in regional radiopharmacies; percentage in UK 50:50. 220 major sites only 120 radiopharmacists. Both systems fared equally.

Covidien – David Baker – Petten allocation for UK was equally distributed. Sometimes only a few places, e.g. Liverpool can react to taking additional Molybdenum and therefore surplus was wasted. Mr. Baker wondered if it were at all feasible for radiopharmacies to be more flexible to supplies.

Dr Vivian – more clinical leadership required; clinicians look at a week ahead; staffing issues – is that a model that would work? Ms Moore – a week’s notice for production could be done ad hoc. Covidien - 24 hours lead-time; pool system.

Dr Nunan – order less if you can find a customer that will take more.

Mr Baker – NM usually operates a 9 – 5 day with some variations; need to reconsider extended days and down time when shortages were known. Maximise period when Molybdenum was available; they have 2/3 weeks notice.

Mr Burrlage – In the next five years there will be shortage problems and it would be wise to plan for the future.

Imaging technology – Beverley Wallace – software solutions can reduce dose or time; contact NHS Supply chain to put software into procurement.
Dr Nunan – Steve Ebdon-Jackson discussed with Erika Denton would DH sponsor some work; can BNMS help with it?

Prof Perkins – lack of evidence, may be IPEM/BNMS multi-site software study; talk to Mr Ebdon-Jackson.

Dr Vivian – medium term solution reduce moly dose requirement to patient; less radiation exposure

Wrap up and Actions
It was agreed that the BNMS could play an essential role in ensuring the flow of information to the clinical users and in ensuring that best use is made when supplies are limited. This would be done by carrying out the following.

- Establishing working groups to disseminate information
- Ask radiopharmacists to look at option proposals for delivering different methods of the radiopharmacy service
- Understanding the demands on radiopharmacies at regional or national level then feedback to the production process would be helpful.
- MHRA – would be as flexible as possible with shortages and understanding market conditions would enable them to be as flexible
- Look at ordering generators on a forecast basis (next BNMS survey would be a good way to identify needs)
- BNMS Website – give end user alternative radiopharmaceuticals they might use;
- Considering contingency planning through National Imaging Board
- No national co-ordination for optimizing service delivery – find a common way for allocating scarce resources.
- Work with DH Radiation Division and HPA
- Work with ARSAC re dose reduction,
- Accepting that this is a long term crisis and therefore staff accordingly for an expensive and scarce resource.
- The meeting information would be shared with Canadians
- At BNMS meeting in April ask clinicians to look at lessons we can learn and ask senior manufacturers to keep us informed as well; by June plan to come up with recommendations.
- A moly session would be taking place in Manchester.
- The BNMS would engage with EANM meetings taking place in Vienna and Barcelona and at the SNM in Toronto.
- The BNMS will feedback formally to DH and NIB.
- Would manufacturers and suppliers inform the BNMS of any issues of confidentiality.