U.K. Radiopharmacy Group

NEWSLETTER
2007 Q4

IN THIS ISSUE

I would particularly like to draw your attention to the following important items in this issue:

BNMS annual meeting 2008

Next year's BNMS congress will be held in Edinburgh. The preliminary programme was distributed recently and is available on the BNMS website. One of the invited speakers is Prof Phil Blower, talking about Radiopharmaceutical Development. The meeting is later than usual, being held 12-14 May. Let's try to maintain the momentum from last year with a high level of participation in the radiopharmacy stream. The abstract deadline is 11 January.

UKRG EVENTS

Radiopharmacy Workshop 2008

The next UKRG Radiopharmacy Workshop will take place on Friday 18 January 2008 at the Beeches Management Centre, Bournville, Birmingham. Information is available on the UKRG website, but please contact paul.maltby@rlbuht.nhs.uk as the date is getting close. The morning session will contain talks on the current radiopharmacy research in the UK, both academic and practice based. Clinical aspects for new therapy will feature and the workshop will look at developing training in GMP for radiopharmacy staff, and disinfectants in the radiopharmacy. Exhibitors will include Bartec, Southern Scientific, Britec, and LabLogic. We hope to see many of you there. For those arriving Thursday evening there will be the usual curry night with off licence beverages.

Postgraduate course in radiopharmacy

The next running of the UKRG Easter course at King's College London will take place 10-13 March 2008. As in the last two years, it will be held in the Sherman Education Centre at Guy's Hospital in the historic London Bridge area. Registration packs should be available on the UKRG website or by contacting jim.ballinger@kcl.ac.uk.

UKRG INITIATIVES

Reporting of adverse events and defective products

There have been further problems with the electronic reporting system but these have now been repaired and reports can be submitted via either the UKRG or BNMS website. It is hoped that summary reports can be distributed in the near future.

Sampson's Textbook of Radiopharmacy

The authors have been contacted and most have submitted outlines of their chapters. Manuscripts are due mid 2008 with the book to be published about a year later by the Pharmaceutical Press.

Hetastarch

The sad saga of hetastarch continues. The original Hespan was discontinued in this country several years ago and most of the licensed alternatives have been found to be ineffective. We have been getting by with the Baxter product, which has now also been withdrawn, and the Torbay product, which will be discontinued shortly. The search for a suitable alternative is ongoing. Methyl cellulose, as described in the GE ^{111}In oxine leaflet, is prepared by at least one of the NHS pharmaceutical specials manufacturing units and is effective.

WORKFORCE ISSUES

Competency framework

Technical Specialist Education and Training (TSET) is working on a competency framework for pharmacy production areas. A consensus panel meeting was held on 3rd December and there were three radiopharmacy representatives in attendance. There are generic competencies in the broad areas of personnel, production, and quality assurance. It is anticipated that the radiopharmacy specific competencies would be based on the HCS NOS framework which consumed so much effort a couple of years ago and is available on the Skills for Health website.

REGULATORY ISSUES

ARSAC news

Administered activities for myocardial perfusion imaging. Following a study commissioned by ARSAC, it has been decided to increase the diagnostic reference levels for ^{99m}Tc agents for myocardial perfusion studies in order to improve the diagnostic accuracy of the test. The paper reporting that study will be out shortly in the *European Journal of Nuclear Medicine and Molecular Imaging* (Robinson CN *et al*., The relationship between administered radiopharm-aceutical activity in myocardial perfusion scintigraphy and imaging outcome). The preferred option is the two day protocol with a DRL of 800 MBq on each day. Where a one day protocol is required the DRLs are 400 and 1200 MBq.

This change presents (at least) three challenges to radiopharmacy:

- To cost of the additional kits which will be required (fewer patients per kit)
- The additional pertechnetate which will be required; cost and licensing issues for larger generators
- The higher extremity doses to those preparing the tracers.

Nuclear medicine patients and border crossings

The issue of nuclear medicine patients setting off sensitive radiation detectors at border crossings is a concern. ARSAC has been working with HM Customs (the Cyclamen Project) to agree wording in the patient appointment letter which the patient would carry if travelling abroad within a certain period of the nuclear medicine diagnostic or therapeutic procedure (7 days for ^{99m}Tc, 3 months for other diagnostic radionuclides, and longer for therapies).

The proposed text is as follows:

"It has come to our attention that there are extremely sensitive radiation detectors in place in some train stations, airports and seaports around the world. These monitors can detect extremely small quantities of radiation and it is just possible that, until the radioactivity from this test has completely left your body, you may trigger one of these detectors. In the unlikely event that this occurs, there is no reason to be concerned. Customs officials who operate these types of detectors are experienced in understanding what the detector has picked up, and after asking you a few simple questions and conducting a brief non-intrusive examination with a hand held detector, will let you pass on your way as soon as possible.

"Different countries have different procedures and some may wish to see your appointment letter as part of this process. If you are planning to travel in the near future it is recommended you carry this letter with you. Please ask a member of the department staff for advice on how long your body is likely to retain traces of the radioactivity, and therefore whether carrying your letter will be necessary."

These and other issues are discussed in the ARSAC Newsletter, available at www.arsac.org.uk.

MHRA issues

As mentioned in the last Newsletter, the MHRA has prepared an internal document which should lead to a more consistent approach to inspections of radiopharmacies by different inspectors. There is also a move to have lead inspectors for areas such as radiopharmacy, who would provide guidance to the individual inspectors. Additionally, it is the intention to send the same inspector for three visits and on the third of these the next inspector would accompany.

The MHRA also made a presentation on how to respond to inspections. The MHRA is now following up on action plans and will expect to see copies of amended SOPs, etc.

There is a new consultation document regarding the frequency of inspections, i.e. units with a good record would be inspected less frequently. The new system would make use of self inspections, which would mean more paperwork for the licensees. However, this partly depends on whether the MHRA considers radiopharmaceuticals to be high risk or not.

Health Building Note 29

The long awaited HBN 29 is now out, but just to confuse you it is called HBN 14-01: Pharmacy and radiopharmacy facilities. ISBN 978-0-11-322795-2 (August 2007).

Information technology

The National Programme for Information Technology is progressing, with one of the issues being bar coding for identification/tracking of drugs. However, radiopharmacy is not included in the first phase of adoption of this plan.

INDUSTRY NEWS

GE Healthcare withdrawing research products

GE is discontinuing its "short lived" life sciences research products, i.e. anything shorter than tritium, at the end of the year. This is not expected to affect radiopharmaceuticals.

BMS to divest imaging division

The old NEN radiopharmaceutical division, which was bought by DuPont and later by BMS, is up for sale again. The lack of a successor to Cardiolite, which is soon to come off patent, was a major factor. This is the second time that BMS has sold off a radiopharmaceutical division; first it was Squibb, one of the original radiopharmaceutical companies, along with NEN. Squibb was bought by Bracco and still makes a few kits and the $^{82}Sr/^{82}Rb$ generator for PET myocardial perfusion imaging but has not brought out any new SPECT products in years.

Molybdenum shortage

The AECL reactor at Chalk River, Ontario, which produces something like two thirds of the world's supply of ^{99}Mo (particularly for the Americas and Japan), was shut down for regulatory reasons. Such was the outcry from the nuclear medicine community in North America that the Canadian government quickly passed a law allowing AECL to resume operation for an interim period without the required safety features.

MEETING REPORTS

European nuclear medicine congress, Copenhagen

The first impression of Copenhagen was of cold winds, though that changed on Friday evening which was their equivalent of Open Buildings, where we experienced the warmth of the people as they traipsed through the City Hall, filled free concerts and art shows in churches, and thronged the pedestrianised streets.

There was a fair contingent from the UK radiopharm community and a lot of presentations from the groups of Phil Blower, Steve Mather, and Paul Marsden (the latter giving three invited talks). However, from a radiopharm point of view it was not one of the better congresses, particularly in terms of new chemistry.

There were two sessions devoted to radiopharm regulatory issues and although these had high level participation and good attendance, to my mind nothing conclusive came out in the end. On a slightly more positive note, I got the impression that Prof Jean-Noel Talbot, chair of the EMEA scientific advisory group on diagnostics, really does have an understanding of radiopharmaceuticals, which at least is a start. Another encouraging note is that Prof Liselotte Hojgaard, head of nuclear medicine and PET at the Rigshospitalet in Copenhagen, is currently chair of the European Medical Research Council (EMRC) and is raising the profile of nuclear medicine research, particularly PET/CT.

On the exhibit floor, the most exciting development I saw was a small scale auto synthesis unit which is intended for just in time unit doses of PET tracers from an ^{18}F stock solution, but can also be used for optimisation of reaction conditions. The example given was 30 labelling reactions in a half day, which would have taken weeks with a standard unit.

GE regional academic meeting

Steve Mather, Adrian Hall, and I recently attended what was billed as an invitation only GE Healthcare Regional Academic Meeting. (To be truthful, Steve was the only one of us actually invited; I pretended to be Paul and Adrian got in on Bev's ticket.) There were about 20 people from across the UK (interestingly, it was not just The Usual Suspects) and a similar number from GE. This was the first of what is (or was) planned to be a series of regional meetings: Germany, Japan, and several in America.

There was not a lot of new information, and most of it was very general. However, we did glean the following:

- The debate between PET and SPECT is still raging within GE; however, most of the oncology products will be labelled with ^{18}F. It is likely that any new SPECT products will be labelled with ^{123}I (mainly neuroreceptor ligands).
- There are two new products which they expect to be licensed in the next couple of years:
  - An RGD peptide for imaging angiogenesis. I know they were working on both ^{99m}Tc and ^{18}F versions and I don't think they explicitly stated which was to be commercialised but since it is for oncology I suspect that ^{18}F wins.

- An ^{18}F probe for amyloid in Alzheimer's disease (i.e. F-PIB). They admitted this has been delayed by about 3 years due to problems with chemistry and stability.

- They are keeping an eye on ^{68}Ga but not actively pursuing it. There was no mention of radiocopper.
- Regarding small market products where they do not have IP rights, they will not produce them but will help people make them using FastLab automation.
- Probably the biggest disappointment is that they are not developing any therapy products.
- They share our frustration with the regulatory process for clinical trials and there may be an opportunity for joint action.

UPCOMING MEETINGS

28th International Symposium on Radioactive Isotopes in Clinical Medicine and Research 9-12 January 2008, Bad Hofgastein.

14th European Symposium on Radiopharmacy and Radiopharmaceuticals 24-27 April, Skopje, Macedonia. Abstract deadline: 15 January. http://esrr08.eanm.org

British Nuclear Medicine Society 36th annual meeting 12-14 May 2008, Edinburgh. Abstract deadline: 11 January. www.bnms.org.uk

Society of Nuclear Medicine annual meeting 14-18 June, New Orleans. Abstract deadline: 10 January. www.snm.org

European nuclear medicine congress 11-15 October, Munich

UPCOMING COURSES

European Postgraduate Certificate Course in Radiopharmaceutical Chemistry and Radiopharmacy
Module 2, 4-15 February, Zurich
Module 3, 31 August, Leipzig
www.postgraduate.pharma.ethz.ch

From the Editor

Best wishes for the Christmas season to all readers. Thank you for the positive feedback which I have received. And may 2008 be even better for all of us!

www.ukrg.org.uk	*Editor:* Jim Ballinger Department of Nuclear Medicine Guy's and St Thomas' NHS Foundation Trust St Thomas Street, London, UK, SE1 9RT Phone: 020 7188 5521; Fax: 020 7188 4094 E-mail: jim.ballinger@kcl.ac.uk
Issue 2007 Q4 Published 14 December 2007	This and previous issues of the Newsletter are available from the UKRG web site and are posted in the library section at www.VirRad.org