IRISH MEDICINES BOARD

news LETTER

MEDICAL DEVICES

APRIL 2009 Vol. 1 No. 25

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Letter from the Editor

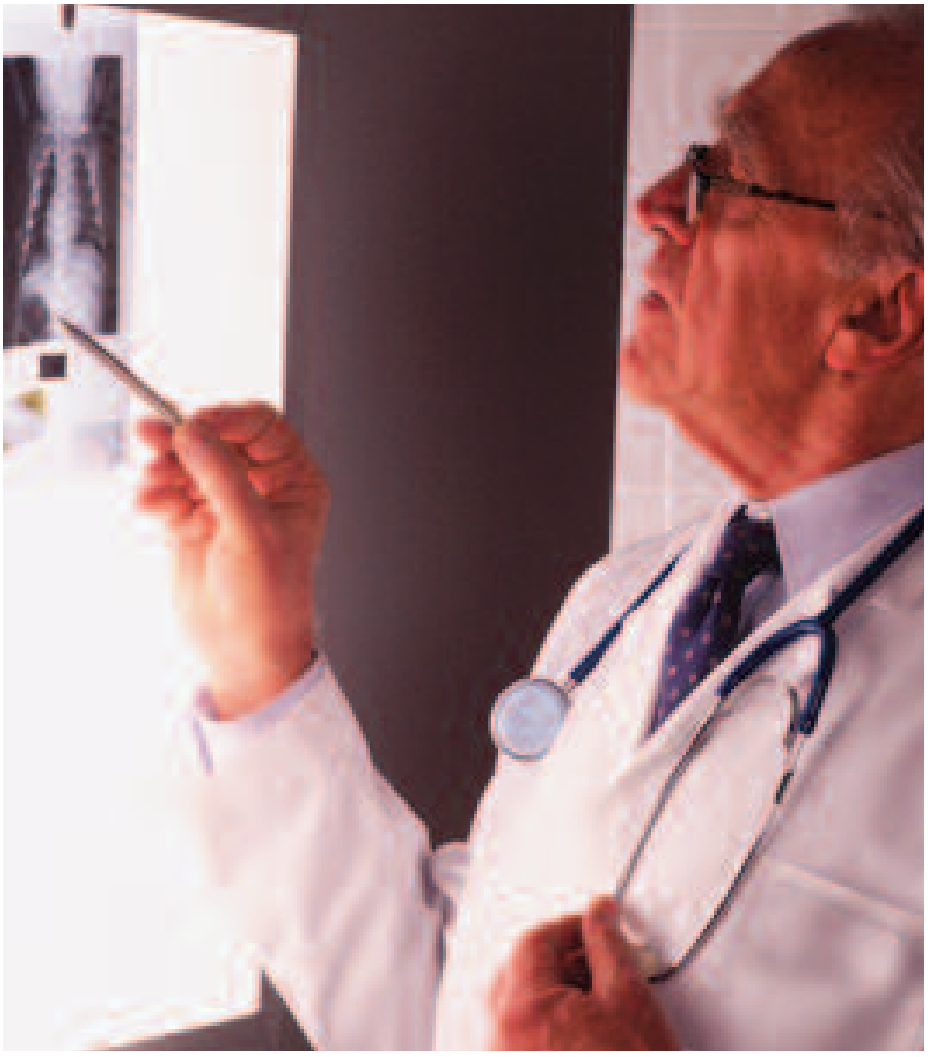
Welcome to the first edition of the medical devices newsletter of 2009

This year promises to be another interesting and busy year for medical devices.

In this edition of the newsletter, we provide an overview of the new structure of the IMB for safety, licensing and registration of human medicines and medical devices.

We also feature articles on various projects which the IMB have been working on such as the development of a series of medical device brochures for the general public, the European pilot for vigilance reporting and the guidelines for point of care testing (POCT) in the primary care setting.

As always readers are encouraged to provide feedback particularly in relation to articles that may be of interest by contacting us at medicaldevices@imb.ie.



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European Pilot for Electronic Reporting of Incidents

The IMB are participating in a European pilot for electronic reporting of incidents for medical devices.

An electronic form was developed by the BfArM, Germany to assist manufacturers and Competent Authorities. At the MDEG Vigilance Working Group in September 2008, it was agreed that a pilot for electronic reporting of incidents would take place for the first six months of 2009. Four European countries are participating in the pilot - Ireland (IMB), Germany (BfArM), France (AFSSAPS) and the United Kingdom (MHRA). The pilot program is undertaken to evaluate electronic submission of adverse events fulfilling the reporting criteria of the Medical Device Directive that are further substantiated in MEDDEV 2.12/1 rev. 5. The intention is to establish an electronic exchange of information in order to avoid paper exchange.

The IMB are looking for volunteers from all over Europe and in particular Irish manufacturers to take part in this pilot, starting from the 2nd January 2009 until the 30th June 2009. Following an incident, manufacturers are requested to complete a manufacturer's incident report form in a XML / PDF format and submit it to the participating Competent Authorities by email for review and follow-up. All reports submitted to the IMB should be emailed to vigilance@imb.ie. The pilot will involve 'live' data and 'dummy' reports will not be included as part of the pilot. All participants will require Acrobat Professional version 8 installed on their PC. Further information on this pilot is available on the IMB website.

If you have any further questions about this pilot, please contact Sinead Carty at vigilance@imb.ie or Kevin Horan at kevin.horan@imb.ie.

Frequently Asked Questions (FAQ) – Available On-line

A new addition to the medical device homepage on the IMB website is an updated FAQ section where a list of the most frequently asked questions received by the IMB, along with the answers, has been compiled. The FAQs have been categorised into their section and function. For example;

Pre-market; registration:

- Who is required to register with the IMB?
- How do I register medical devices with the IMB?

Post-market; vigilance:

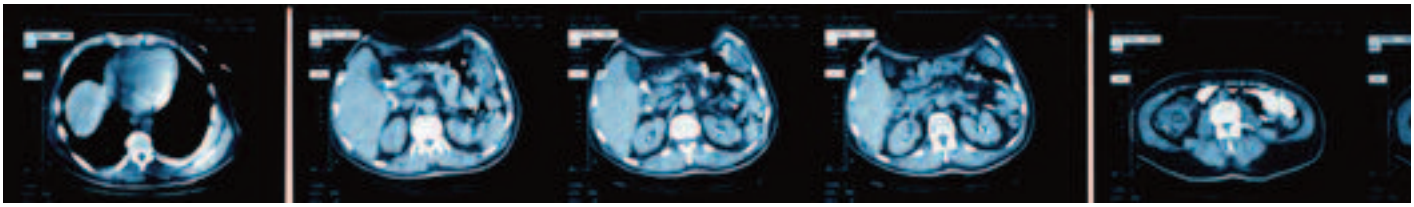
- What are the criteria for incidents relating to medical devices to be reported by manufacturers to Competent Authorities?
- What is the timescale for the initial reporting of an incident relating to a medical device?

If you have a question regarding medical devices, we would encourage you to first consult the FAQ section of the website. However, if you cannot find a FAQ response that answers your query, please feel free to send any questions to medicaldevices @imb.ie.

The medical device section of the IMB website may be accessed via http://www.imb.ie/EN/Medical-Devices.aspx.

Point of Care Guidelines

The guidelines for point of care testing (POCT) in the primary care setting are currently at an advanced stage. The aim of this document is to provide guidance to primary care settings on the implementation and management of a POCT service with a specific focus on the safe use of point of care (POC) tests. It is intended to provide recommendations for best practice for POCT in the primary care setting to ensure accurate and reliable patient results. The final text of these guidelines was discussed at a working group meeting involving the relevant stakeholders on the 4th March 2009. The guidelines will be reviewed at the May meeting of the Advisory Committee for Medical Devices with a view to being published in the coming months.



The European Commission publish the

RECAST OF THE MEDICAL DEVICES DIRECTIVES – SUMMARY OF RESPONSES TO THE PUBLIC CONSULTATION

The public consultation on the 'Recast of the Medical Devices Directives' was announced in a press release on 8 May 2008. On the same day, a questionnaire and background information was made available online on the medical devices section of the European Commission website.

Stakeholders (authorities, industry, notified bodies, healthcare professionals and patient groups) were informed by e-mail about the launch of the public consultation. The official deadline for comments was the 2nd July 2008.

The Commission received 200 responses to the public consultation. The principal contributor was industry (federations and individual companies, mainly manufacturers of medical devices) with 92 responses. Healthcare professionals and academics submitted 33 responses. Regulatory authorities submitted 27 responses (19 of which were from the EU/EFTA Member States' competent authorities, 4 from GHTF members, 2 from regional authorities, 1 from NBOG and 1 from another Ministry of a Member State). Notified Bodies (including NB-Med and Team-NB) submitted 18 responses. Other contributions came from patients and consumers (8), consultants and medical devices experts (7), standardisation bodies (7), health insurance and social security schemes (4) and others (4)." Four of these responses came from Ireland.

Generally, most respondents confirmed that the current legal framework for medical devices left some room for improvement to strengthen the regulatory system.

There was broad support for the view that some weaknesses which the Commission had highlighted in the questionnaire (e.g. inconsistent oversight of notified bodies, no uniform level of expertise in notified bodies, lack of regulation of certain products) needed to be addressed. Also, further elements of centralisation were considered useful, although the suggestion to expand the role of the European Medicines Agency

(EMEA) to include medical devices was rejected by a majority of respondents.

As regards the timing, by far the majority of respondents (in particular those from the Member States and industry) considered the exercise to be premature. They pointed to the recent revision of Directives 90/385/EEC and 93/42/EEC, to be implemented by 21 March 2010, and the adoption of the new legal framework for the Marketing of Products which was due to take effect as of 1 January 2010. It was argued that it would be advisable to wait for these changes to be implemented, in order to better assess the need for further adjustments. There was also some criticism of the timing of the launch of the public consultation (May 2008), which had left many stakeholders confused as regards its possible impact on the transposition of Directive 2007/47/EC, which was due on 21 December 2008.

The rejection of a larger role for EMEA by the vast majority of respondents was mainly based on the fear that the involvement of EMEA would represent a move towards the adoption of a pharmaceuticals-like regulation for medical devices.

The full report can be accessed at http://ec.europa.eu/enterprise/medical_devices/consult_recast_2008_en.htm

Some other key outcomes arising from the questionnaire were:

- Whether the framework should remain as Directives or Regulations, there was no clear response. The transformation of the current Directive into a Regulation would require a lot of resources and whether this would be of benefit is debatable.
- There was large support to look at strengthening the functioning of Notified Bodies oversight and market surveillance. Current framework was considered to be the most appropriate one.
- Implications of the changes to the New Approach should be considered at next recast.
- There may be a need for a pool of expertise to advise Member States and the Commission regarding specific/scientific topics
- For products that have a cosmetic purpose, the term quasi medical device was rejected. The majority said there needed to be regulation for safety of these products. For those products that have also a medical device element, cosmetic contact lenses, fillers etc, it was suggested that these should be regulated under the Medical Device Directive (MDD).
- If devices with cosmetic purpose were to be considered to be a medical device, an update to the MDD would be required. With regards to whether non-viable medical devices are to be included, respondents were divided between whether advanced therapy regula-

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tions or the MDD was the more appropriate regulatory pathway.

- Regarding *in-vitro* diagnostic medical devices (IVDs), there was unanimous support for classification in line with the GHTF document and the revision of the IVD Directive.
- On the question of keeping IVDs separate from the other medical devices directives, there were pros and cons, the majority supported keeping it separate, others said that there was sufficient similarity and feasibility to merge keeping specificities of the IVD Directive.
- A 'Supra Directive Borderline Classification' group covering many sectors was suggested

Regulatory Update

NOTIFIED BODY OPERATIONS GROUP (NBOG)

NBOG met in November 2008 and January 2009. Several guidance documents were discussed and finalised included the NBOG Best Practice Guides entitled 'Guideline for Designating Authorities to Define the Notification Scope of a Notified Body Conducting Medical Devices Assessments', 'Role of Notified Bodies in the Medical Device Vigilance System' and the 'Guidance on Design Dossier Report Content'. In addition, further agreements were reached on the peer review system for designating authorities regarding surveillance audit of a Notified Body. Draft documents discussed included guidance on Notified Body assessment and audit of suppliers / subcontractors and guidance for designating authorities on reviewing Notified Body assessments of clinical evaluations. NBOG has also set up a website (www.nbog.eu) from which these and other documents can be downloaded.

MEDICAL DEVICE EXPERT GROUP (MDEG)

The MDEG in December was split into two days. The first day was a closed meeting of Competent Authorities only and the second day was the open MDEG plenary session.

The main items discussed were:

- The transposition of revision of Directive 2007/47/EC on medical devices, in particular there were concerns regarding the period of the validity of certificates.
- The reactivation of the software task force, in particular in the light of the implications of the revised definition of a medical device under 2007/47/EC, interconnectivity and health informatics.
- E-labelling (use of IFUs in an electronic manner). It was recommended to restrict it initially to implantable and fixed installed devices only. This will be submitted to comotology procedure in 2009.

The following papers were endorsed:

- MEDDEV 2.7-2 Medical Device Directives - Guidelines for Competent Authorities in making assessment of clinical investigation notifications
- Guidelines on Clinical Evaluation of coronary stents
- MEDDEV on Committees and working groups.

Updates on working groups and GHTF were also given.

CLASSIFICATION & BORDERLINE WORKING GROUP

The Classification & Borderline Working Group met in December 2008. In addition to the specific classification issues, discussions took place again on the revision of MEDDEV 2.3/1 on demarcation between medical devices and other products. Several drafting subgroups were also established to begin work on revising the main classification MEDDEV 2.4/1 and to develop guidance on the classification of combination advanced therapy products and devices containing herbal components.

COMPLIANCE AND ENFORCEMENT WORKING GROUP (COEN)

The COEN meeting in January was attended by eighteen Member States and the European Commission where items discussed included the work programme of COEN for 2009, the impact of the new approach legislation and the draft guidance on the use of legal tools for market surveillance.

Further discussion was held on the update to the guidance notes for manufacturers of class I medical devices and to the guidance note for manufacturers of custom-made medical devices in line with the changes agreed in 2007/47/EC. There was also a review of protocols for specific coordinated market surveillance projects and specific cases of concern for Member States. The European Commission gave an update on the questionnaire on the recast of medical devices legislation.

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VIGILANCE EXPERT WORKING GROUP

A one day meeting of the expert group on vigilance was held on 21st January 2009. The meeting was attended by regulators only. Topics discussed included the MEDDEV implementation issue, the pilot on electronic reporting, the NCAR National Competent Authority Report exchange programme, and the NBOG draft guide 'Notified Bodies and the Vigilance System'. Several specific vigilance cases were also discussed in detail.

CLINICAL INVESTIGATION & EVALUATION WORKING GROUP

This group met for the first time in January. This permanent working group is to replace the Clinical Evaluation Task Force (CETF) which completed its original terms of reference last year. The working group has developed a large work programme including revision of the MEDDEV 2.7/1 on clinical evaluation, systems for clinical investigation adverse event reporting, development of the clinical module of the EUDAMED system and developing guidance for Notified Bodies on clinical evaluation.

23RD MEETING OF COMPETENT AUTHORITIES

The 23rd Meeting of Competent Authorities for medical devices took place in Prague on the 24th and 25th February 2009. The key focus of the meeting was on the transposition of Directive 2007/47/EC and proposed recast of Medical Device Directives.

Discussions took place regarding the progress by Member States in achieving the transposition of the new Directive 2007/47/EC into national legislation. A small group was created and given the task of providing solutions to reduce implementation issues encountered by each European Member State.

The European Commission is continuing to work on the future recast of the medical device directives and will be consulting with member states in this regard. Items discussed in the context of the recast included:

- the possible merging of the IVD Directive with the other medical device directives,
- the applicability of the medical device directives to products such as cosmetic wrinkle fillers,
- the future role of the statistical verification procedure in conformity assessment
- enhanced market surveillance tools and
- the management of counterfeit medical devices.

The benefits of issuing a guidance document on so-called 'Own-Brand-Labellers' and updating the MEDDEVs were also discussed.

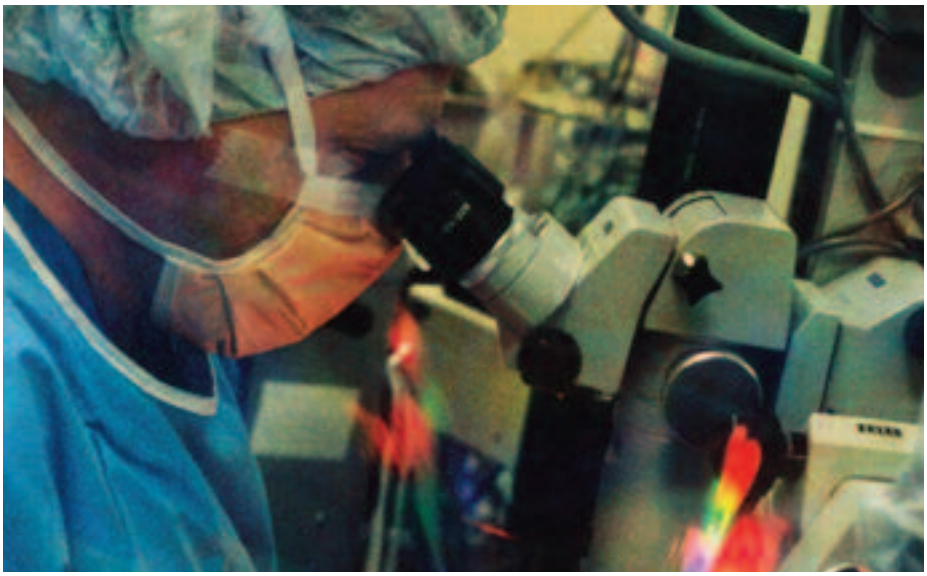
IVD TECHNICAL GROUP

Two IVD Technical Group meetings have been held in recent months. The first was held on the 20th November 2008 and the other on the 18th March 2009.

The trilateral post market surveillance operation being undertaken by the UK, Irish and French Competent Authorities in relation to the blood glucose meter (BGM) project was discussed at the IVD Technical group meetings. This coordinated action comprises a desk review involving an assessment of the 'user manual' for the meter and of the 'instructions for use' for the associated reagents (strips or electrodes) with a focus on issues relating to maltose interference and units of measurement. The protocol was endorsed by the COEN on the 13th January 2009 and approved at the Competent Authority meeting in Prague on the 24th - 26th February 2009. Manufacturers will be contacted in the coming weeks with a view to initiating the review of the associated documentation in the June timeframe.

Progress continues to be made in relation to drafting the common technical specifications (CTS) for blood based IVDs for vCJD. The subgroup met on the 10th February 2009 and will meet again on the 27th April 2009 with a view to finalising the CTS and the accompanying guidance document. It is envisaged that the CTS will be updated as scientific knowledge develops in this area.

The recast of the Medical Devices Directives, in particular the IVD Directive 98/79/EC was also discussed. The results of the public consultation identified a large support for the revision of the IVD Directive. The responses also underlined the need to retain a separate directive for IVDs. Other issues raised were the lack of regulation of 'in house' tests and diagnostic services and the need for specific requirements for genetic or predictive tests. Concern was also expressed that adoption of a risk-based classification, according the GHTF model, would subject more IVDs to a conformity assessment procedure involving a Notified Body.



Medical Device Brochures

The Irish Medicines Board has developed a series of medical device brochures for the general public, which will be distributed over the coming months.

The IMB identified the need to provide information to the general public in order to increase awareness of important safety considerations associated with the use of medical devices. The aim of the brochures is to highlight the main medical device safety issues and provide general information on the purchasing and use of medical devices and specific information on devices such as contact lenses, blood glucose meters and implantable medical devices.

There are six topics covered in this first series of brochures.

Three general brochures:
- Medical Devices in the Home
- Buying Medical Devices for Personal Use
- Buying Medical Devices Online

Three specific brochures:
- Safety Tips for Contact Lens Wearers
- Safety Tips for Blood Glucose Meters
- Implantable Medical Devices

The IMB consulted with a wide range of stakeholders including healthcare professionals, professional bodies, medical device manufacturers, distributors and patient support groups and received very useful suggestions on the brochure content.

The general brochures cover topics including information on the CE mark, device details which need to be documented and kept, correct maintenance and storage of devices and things to consider when purchasing a medical device over the internet. The specific brochures cover topics including the necessity to use the correct test strips for your glucose meter, correct use and storage of contact lenses and contact lens solution and the risk of electromagnetic interference with active implantable devices. All the brochures give information on the role of the user in reporting adverse incidents which may occur during use of their device.

The brochures are to be circulated by both post and email and will also be available on the medical devices section of the IMB website at www.imb.ie. The brochures will be sent to pharmacies, hospital clinics, professional groups, patient support groups, primary care clinics, general practices and public libraries. The general brochures will be displayed in pharmacies and public libraries and the specific brochures will be displayed at the appropriate hospital clinics. This mix of distribution options is aimed at achieving the goal to meet the various target audiences. The brochures will be published later this year. Once published, brochures can be requested by post or email from the IMB and can be downloaded from the IMB website www.imb.ie.

Committee for Advanced Therapies

The Committee for Advanced Therapies (CAT) was established at the European Medicines Agency (EMEA) in London in January 2009 arising from the Advanced Therapy Regulation (EC) No. 1394/2007 which came into force at the end of December 2008. Advanced therapies include cell therapy products, gene therapy products and tissue engineered products. Advanced therapy medicinal products may, in some instances, be combined with medical devices e.g. scaffolds, which will require assessment by a Notified Body. The Committee's composition as defined in the Regulation includes experts from many scientific, clinical and regulatory disciplines including medical devices, tissue engineering, gene therapy, cell therapy, biotechnology, surgery, pharmacovigilance, risk management and ethics. In addition, the committee includes several representatives of patients associations.

The IMB's Advanced Therapies Steering Group held a preliminary information workshop in February to identify key experts and stakeholders working in this area and to exchange information on the regulatory system and the operations of the CAT at the EMEA.

IMB Medical Device Newsletters

To date, the IMB have been circulating hard copies of the medical device newsletters by post. It is proposed that from 2010, the newsletter will be circulated by email only. This newsletter will also be available to download from the IMB website at www.imb.ie.

If you would like to continue receiving copies of the newsletter by email, please send your contact details along with your email address to medicaldevices@imb.ie or you can register for medical device updates on the IMB website at http://www.imb.ie/subscribe.aspx.

New IMB Structure

On March 23rd 2009 the Irish Medicines Board launched its new structure for safety, licensing and registration of human medicines and medical devices. The introduction of a new dedicated safety department reflects the Boards commitment to safety management across the organisation.

The new structure has been in development for approximately twelve months and is the result of a comprehensive consultation process involving a wide range of external stakeholders, including both the pharmaceutical and medical device industries.

New arrangements see the introduction of a Human Products Safety Monitoring Department and a Human Products Authorisation & Registration Department. These two new departments replace the Human Medicines Licensing and Medical Devices Departments.

We are pleased to announce that Ms. Ann O'Connor is the new Director of Human Products Authorisation & Registration and Dr. Joan Gilvarry is the new Director of Human Products Safety Monitoring. For the remainder of 2009, Ms. Ann O'Connor will continue to lead on medical device issues.

Ms. Maria Carleton has taken on the role of Planning & Regulatory Affairs Manager within the new Human Products Authorisation & Registration Department, while her colleague Ms. Mairead Finucane (Medical Device Auditor) has joined the Compliance Department. Dr. Niall MacAleenan and his pre-market team have moved into the Human Products Authorisation & Registration Department while Ms. Anne Tobin and her vigilance & compliance team are now part of the new Human Products Safety Monitoring Department.

A new role of 'Information & Education Officer' will reside within the Safety Monitoring Department. The responsibilities of this role include the development of education programmes for healthcare professionals, industry stakeholders and the public on product safety and related issues. It will also aim to provide an authoritative safety information resource to the public and healthcare professionals.

The registration of medical device manufacturers; clinical investigation of non CE marked devices; classification of medical devices and the monitoring of notified bodies for medical devices will be handled via the clinical assessment team managed by Dr. Niall MacAleenan, within the new Human Products Authorisation & Registration Department.

A number of other changes will be introduced over the coming months, notably in the customer service and case management teams. A further update will be provided as these changes are implemented.

Medical devices stakeholders should continue to use their existing email contacts with the IMB at **medical devices@imb.ie** and to check the IMB website regularly for updates **http://www.imb.ie/EN/Medical-Devices.aspx**.

Figure 1: Human Products – Authorisation & Registration Departmental Structure

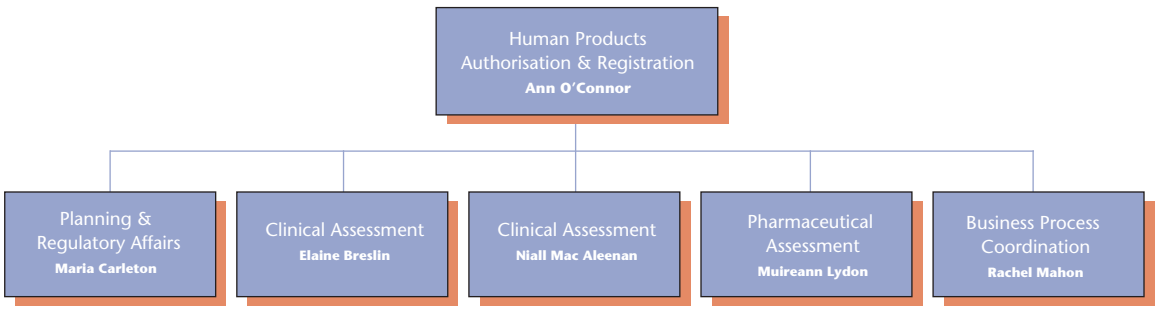
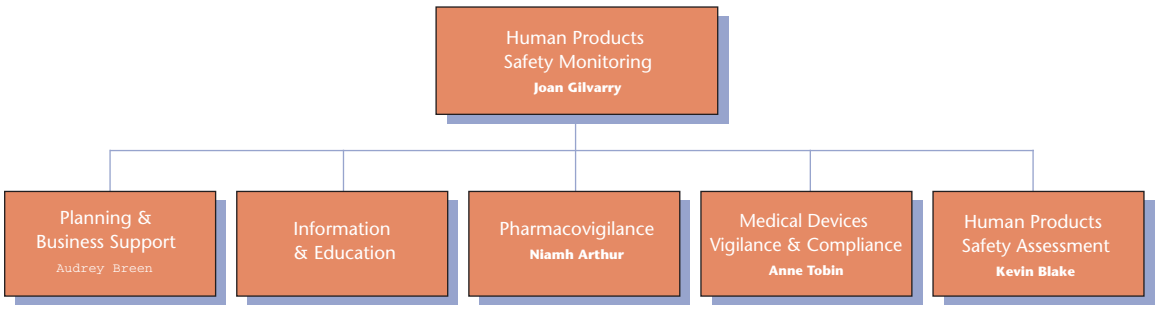


Figure 2: Human Products - Safety Monitoring Departmental Structure



Upcoming Events

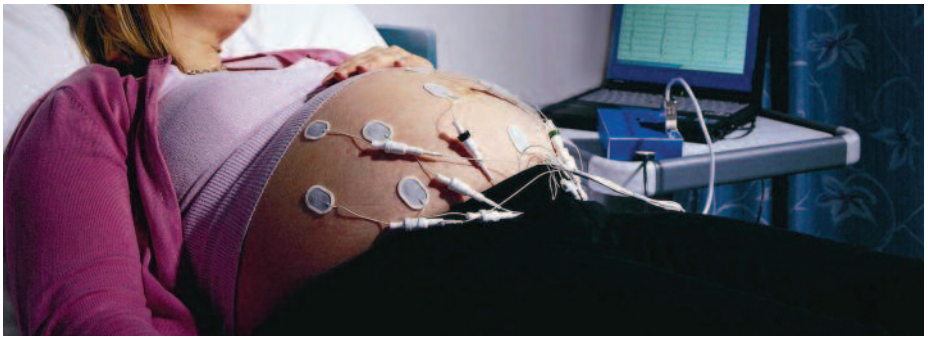
The Engineers Ireland annual conference will take place over two days in the Tullamore Court Hotel, Tullamore, Co. Offaly on April 23rd and 24th 2009. Dr. Alan Ahearne, Special Adviser to the Minister for Finance will provide the opening address at the conference. If you are interested in attending the conference, further information may be found at www.engineersireland.ie or by emailing annualconference2009@engineersireland.ie.

The annual conference of the Association of Occupational Therapists of Ireland (AOTI) will once again be held in the Lyrath Estate, Kilkenny from Wednesday 29th April 2009 to Friday 1st May 2009. The AOTI Conference will take place in conjunction with the 5-th meeting of the COTEC delegates. The theme for this year's conference will be "Occupational Therapists – Visible and Valued". Further details of how to register for the conference may be found at www.aoti.ie.

Update on the transposition of Directive 2007/47/EC

On 21 September 2007, the European Commission published an amendment to the Medical Device Directives 93/42/EC and 90/385/EEC. The new Directive 2007/47/EC introduces substantial changes to the previous text. The IMB held an information day in November 2007 focusing on the requirements of 2007/47/EC. Each Member State is responsible for transposing the text of the directive into their own national law. The transposition of 2007/47/EC into Irish law has recently been completed resulting in two new Statutory Instruments: S.I. 109 European Communities (Active Implantable Medical Devices) (Amendment) Regulations 2009 and S.I. 110 European communities (Medical devices) (Amendment) Regulations 2009. The Statutory Instruments are available on the website of the Department of Health and Children at: http://www.dohc.ie/legislation/statutory_instruments/pdf/si20090 109.pdf?direct=1 and http://www.dohc.ie/legislation/statutory_instruments/pdf/si20090110.pdf?direct=1

The requirements of 2007/47/EC and associated statutory instruments must be applied from 21st March 2010.



Staff Update

Cathal Brennan

Cathal has taken up the position of Scientific Officer in the post-market evaluation section. Prior to joining the IMB, Cathal worked as a research and development engineer in the medical device industry. Cathal's academic qualifications include a degree in Science of Materials and a M.Sc. in Bioengineering from Trinity College, Dublin.

Áine-Marie O'Hanlon

Áine-Marie has taken up the position of Scientific Officer in the post market evaluation section. Aine-Marie's academic qualifications include a BSc in Industrial Microbiology from University College Dublin and an MSc in Biomedical Science from University of Ulster, Coleraine. Prior to joining the IMB, Áine-Marie was employed in the National Virus Reference Laboratory, Dublin, and has extensive experience in diagnostic virology and *in-vitro* diagnostic medical devices. Áine-Marie is also a member of the Academy of Medical Laboratory Science.

John McElhinney

John has taken up the position of Scientific Officer for class I/IIa products in the post market evaluation section. John's academic qualifications include a B.Sc. (Applied Sciences) DIT, Kevin Street and a M.Sc. (Agric), UCD. Prior to joining the IMB, John worked as Quality Manager in a cosmetics company, and has worked in both the pharmaceutical and food industries.

Bulletin of the Medical Devices Department is designed by Ashfield Press Publishing Services for

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