IRISH MEDICINES BOARD

news LETTER

MEDICAL DEVICES

APRIL 2011 Vol. 1 No. 31

IRISH MEDICINES BOARD, KEVIN O'MALLEY HOUSE, EARLSFORT CENTRE, EARLSFORT TERRACE, DUBLIN 2 TEL: 01 676 4971 FAX: 01 634 4033 EMAIL: MEDICALDEVICES@IMB.IE

Letter from the Editor

Welcome to the first edition of the medical devices newsletter for 2011.

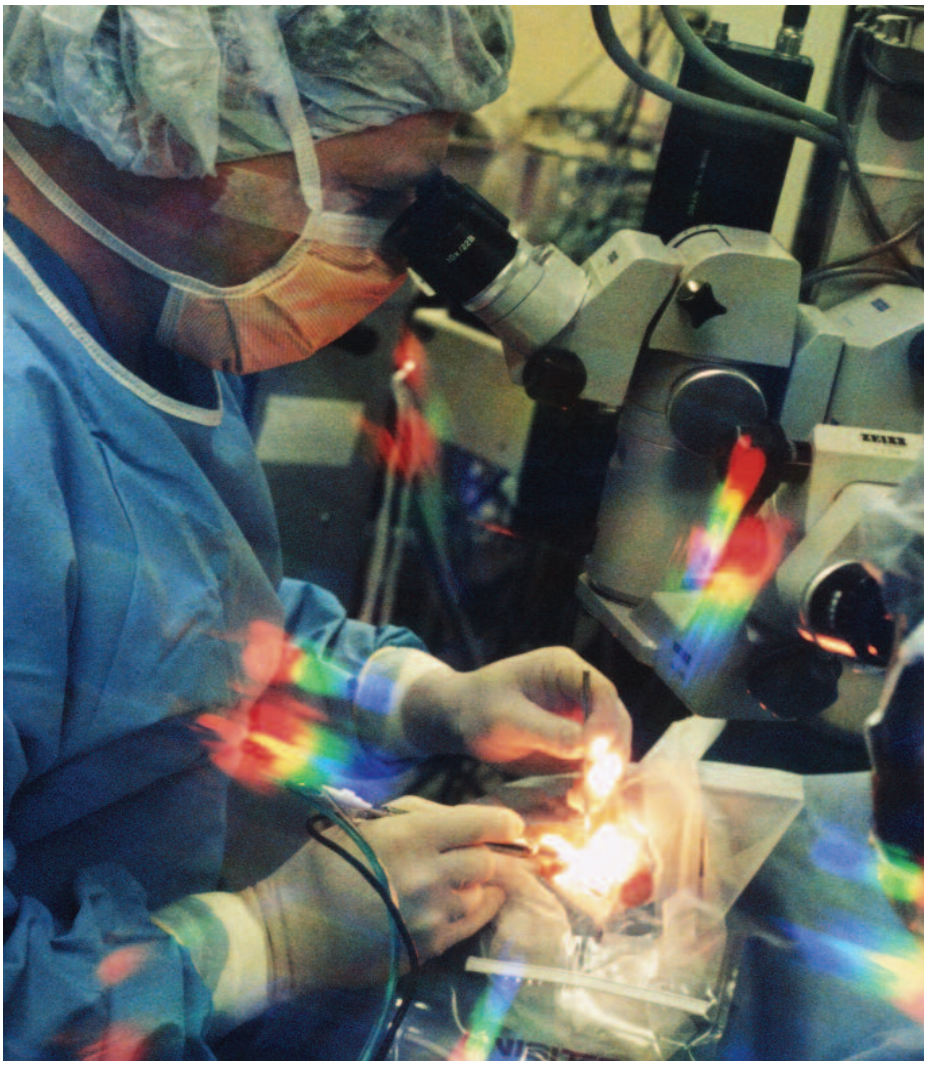
This year looks to be another busy and interesting year for medical devices.

In this edition of the newsletter we feature articles on the recently published IMB Safety Notice relating to counterfeit medical devices, on the circulation of Medical Device Alerts, and placing on the market of medical devices.

We are also pleased to feature an article provided by the Health and Safety Authority to remind us of the EU ban on placing measuring devices containing mercury on the market which came into effect in April 2009.

Updates on European meetings attended by the IMB are also provided.

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.



CONTENTS

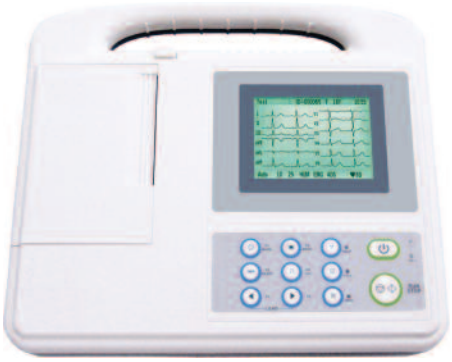
Counterfeit Safety Notice

A new safety notice has been published on the IMB's website, www.imb.ie, to highlight that in recent years there has been increased global activity in relation to the production and supply of counterfeit / illegal medical devices.

The safety notice is intended to provide advice for healthcare professionals, members of the public, distributors and medical device manufacturers in relation to counterfeit medical devices, which are not in conformity with the essential requirements of the medical devices legislation. As a result, members of the public or healthcare professionals may inadvertently use counterfeit and other medical devices that should not be on the Irish market. The safety and quality of counterfeit medical devices cannot be guaranteed as they may not be manufactured to the required standards or conform to the requirements of the medical devices legislation. Therefore counterfeit medical devices pose a risk to public health and safety.

The counterfeit products that have been identified to date do not suggest that there is a particular focus on any specific categories of medical devices. Low cost, over the counter products such as condoms and injection needles and more complex products used by specialist healthcare professionals, such as surgical meshes and contact lenses have been the subject of counterfeiting.

The consequences of using counterfeit products can vary. In some instances the user may suffer direct harm or in the case of a diagnostic medical device, the use of counterfeit



product may result in the patient not being diagnosed or treated appropriately.

Counterfeit medical devices may enter the supply chain at any point. The counterfeit product may be supplied to a distributor, wholesaler or directly to a hospital or a retail outlet. In some cases, counterfeit medical devices may be available for purchase over the internet. The source of these counterfeit medical devices is often difficult to trace. The chances of counterfeit devices reaching the end user increase when a weakness or poor governance has occurred in one or several parts of the supply chain.

With increasing financial pressures, users of medical devices are keen to seek the best value for money and as a result, consumers may now be exploring new routes of acquiring medical devices. Access to global markets, global suppliers at trade fairs and the internet has increased the accessibility and range of products available to the consumer. However, vigilance is required to ensure that the medical device that is being offered / purchased is a genuine CE-marked product from the authentic manufacturer, which complies with the EU medical devices legislative requirements.

While many genuine medical devices are available for purchase online, a large number of internet sites are unauthorised, unregulated and may offer non-compliant products. Buying medical devices online may appear to be an attractive alternative due to the perceived convenience, lower price and the privacy afforded to individuals, however, the potential risk to users who purchase medical devices over the internet may be relatively high.

The IMB recommends that the information within SN2011(02) is reviewed carefully by all relevant stakeholders. If you suspect that you may have purchased a counterfeit medical device or you suspect that counterfeit medical devices are available for sale in Ireland, please contact the IMB at enforcement@imb.ie.

Medical Device Alerts

The Irish Medicines Board (IMB) has routinely circulated Medical Device Alerts (MDAs), issued by the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom, to the Irish market. The IMB also distributes a monthly summary listing of all IMB Safety Notices and MDAs published within the previous calendar month to the members of the IMB vigilance and compliance mailing list.

Following a review of IMB practices, the IMB intends to cease the routine circulation of MDAs to the Irish market from 1st April 2011. The IMB will continue to distribute a monthly summary listing of IMB Safety Notices and MHRA MDAs, published within the previous calendar month, to the members of the IMB vigilance and compliance mailing list and as part of this summary listing will now provide a link to the MDA location on the MHRA website. Should users wish to receive notification of MDAs as they are released by the MHRA, they may do so through online registration via the MHRA website.

In order to ensure that this information is circulated appropriately, it is important that the contact details in the IMB vigilance and complaints mailing list are current and accurate. The IMB requests that you advise of any changes to email addresses. Contact details can be changed or reviewed by sending an email to vigilance@imb.ie or by calling the Medical Devices Vigilance and Compliance section on 01 6764971.

EU ban on measuring devices containing mercury

From 3rd April 2009 the placing on the market of certain measuring devices containing mercury has been banned under chemical legislation, REACH.

BAN ON FEVER THERMOMETERS

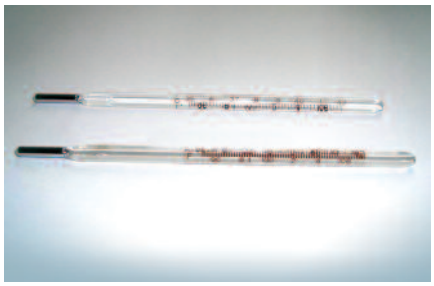
It is not permitted to supply or make mercury-containing fever thermometers available to the Irish or EU market, whether for payment of free of charge. This includes fever thermometers supplied or made available to:

- Members of the general public e.g. via pharmacies or supermarkets and
- Professionals e.g. medical and veterinary practitioners and
- Industrial sectors.

BAN ON OTHER MEASURING DEVICES

It is prohibited to place other mercury-containing measuring devices intended for sale to the general public on the market. Such devices include manometers, barometers, sphygmomanometers and thermometers other than fever thermometers.

This ban only applies to those devices supplied to members of the general public via outlets such as pharmacies and supermarkets. Supply of mercury containing measuring devices (other than fever thermometers) to professionals (e.g. medical and veterinary practitioners) and industrial sectors can continue under the current restriction.



There is one exception to this rule, measuring devices more than 50 years old on 3rd October 2007 are permitted to be placed on the market.

The entry into force of the restriction on barometers (other than those more than 50 years old on 3rd October 2007) came into effect on the 3rd October 2009.

NON-COMPLIANT STOCK

If Irish importers, recipients and/or suppliers have non-compliant devices in stock, these cannot be placed on the market. Contact could be made with the suppliers of these devices requesting that this old stock is taken back. Every effort should be made to ensure that mercury does not get into the general hazardous waste stream.

LEGISLATION

Details of the full restriction can be found at entry no. 18a in Regulation (EC) No. 552/2009, the amended Annex XVII to the REACH Regulation.

It should be noted that the European Chemicals Agency are currently reviewing a proposal to extend the restriction to include certain mercury-containing measuring devices in healthcare and other professional and industrial uses. For further information, please see the ECHA website.

If you have any questions on the above please contact the Health and Safety Authority. Email: REACHRight@hsa.ie.

Placing on the Market of Medical Devices

In November 2010 the European Commission published an interpretative document in relation to placing medical devices on the European market. The document aims to explain the situations when medical devices can be considered as being placed on the market and discuss the implications for the importation of medical devices.

The Medical Devices Directive, 93/42/EEC defines "placing on the market" as "*the first making available in return for payment or free of charge of a device other than a device intended for clinical investigation, with a view to distribution and/or use on the Community market, regardless of whether it is new or fully refurbished*". There are similar definitions in the *In-Vitro* Diagnostics Medical Devices Directive 98/79/EC, the Active Implantable Medical Devices Directive 90/385/EEC and Regulation (EC) No 765/2008 relating to market surveillance of products.

According to the European Commission's interpretation, a medical device is considered to have been placed on the market in the following circumstances:

- The medical device has been made available on the Community market when it has entered the distribution chain. The termination of manufacture of a medical device alone does not constitute placing on the market.
- The medical device has undergone a transfer from the stage of manufacture with a view to distribution or use. This transfer may be a physical hand-over of the product or a transfer of ownership. A transfer (which involves the sale, leasing, gifting, renting or hiring of a medical device) takes place from the manufacturer to a distributor (including the manufacturer's own distribution chain) or to an end user.
- Following transfer of ownership of the medical device (e.g. to a distributor or end-user) but the device is stored by the manufacturer in its warehouse on behalf of the new owner.

continued on following page

continued from previous page

- The medical device was acquired by a professional user in a third country and brought in to the EU for use within the context of his/her professional activity having been put in to service.

The document further clarifies that a medical device has not been placed on the market in the following circumstances:

- The medical device is in the stocks of the manufacturer (or authorised representative) and has not yet been made available for distribution or use
- The medical device is merely put in the manufacturer's warehouse with no transfer of ownership of the product.

- The medical device has not been granted release for free circulation by customs, or has been placed under another customs procedure or is in a free zone.
- The medical device was acquired by a private person in a third country and brought in to the EU for his/her own personal use.

In relation to medical devices that have been imported the following points must be noted:

- Imported products must be released for free circulation in the internal market by customs before they can be considered as being placed on the market. Such medical devices must also be compliant with the Medical Devices Directives.
- In some circumstances the placing on the market of an imported device does not coincide with its release for free circulation where the product has not yet been transferred from the stage of manufacture to distribution. This may occur where an authority requires the importer to take action to bring a product into compliance or where a product is transferred to a manufacturer's warehouse but not made available.

The interpretive document is available at

http://ec.europa.eu/consumers/sectors/medical-devices/files/guide-stds directives/placing_on_the_market_en.pdf

The Irish Medicines Board at the BT Young Scientists Exhibition

Thousands of students from all over Ireland recently visited the Irish Medicines Board's exhibition stand at the BT Young Scientist & Technology Exhibition 2011. The exhibition, which took place from Tuesday 11th to Saturday 15th of January in the RDS, welcomed huge numbers of visiting students, teachers, parents and members of the general public.

The IMB stand focused on building awareness of the significant role the IMB plays in protecting public and animal health. In particular, the important issue of medical devices and medicines safety was highlighted. The stand also focused on the many interesting career opportunities that are available in the life sciences sector.

Examples of the interactive medical device games from the BT Young Scientists Exhibition

A broad range of medical devices, including coronary stents, various artificial joints, diagnostic test kits, infusion devices and defibrillators, were on display. The IMB also created a special interactive game to highlight the widespread use of medical devices. The game allowed students to test their knowledge of a range devices and the circumstance in which those devices might be used.

In addition, a large number of IMB staff members were on hand to explain how medical devices can greatly improve the quality of life of those who use them. They also explained to visitors to the stand how the IMB monitors the safety of medical devices available on the Irish market and through the IMB's regulatory activities ensuring the protection and enhancement of public health.

Regulatory Update

VIGILANCE

A two day meeting of the Medical Device Vigilance Expert Group was held in March. One day of the meeting involved regulators only and the second day included representations from other stakeholders. Discussion at the meeting included the recast of the medical devices directive, the implementation of MEDDEV 2.12-1 rev 6, the Coordinating Competent Authority, the XML electronic report form, Eudamed, the classification of the FSCAs and the NCAR exchange process. Considerable progress was made in relation to the proposed revision of the MEDEV 2.12-1 rev 6 to include additional clarity for IVDs and IVF/ ART products.

UDI

The Unique Device Identification (UDI) Working Group met in January. The goal of the group is to establish a European UDI System to improve patient safety by enhancing the identification of devices, especially for adverse events and to facilitate traceability of devices in the event of a field safety corrective action. The work which has been done at the GHTF level in the UDI *Ad hoc* WG will serve as a foundation for the European initiative.

In January's meeting the UDI *Ad hoc* Working group discussed the draft document "GHTF Draft Proposal for a draft guidance on Unique Device Identification (UDI) System for Medical Devices" with representatives from a number of industry, hospital associations and patient groups (including COCIR, CED, EUCOMED, HOPE, AIM, AESGP, EFORT, PGEU, EDMA, FIDE). The aim of the meeting was to give the different groups an overview of the UDI developments and to open the debate at an EU Level.

Comments were provided relating to application of UDI for specific device types such as own brand labelled devices, custom made devices, parallel trading; location of UDI (outer or inner packaging) ; application of UDI at manufacturer, distributor and hospital level and capital costs for implementing system at hospital level (i.e. scanners)

WORKING GROUP ON QUALIFICATION AND CLASSIFICATION OF SOFTWARE

The Working Group on Qualification and Classification of Software met in both February and March to discuss the software guidance document. The purpose of this document is to define the criteria for the qualification of standalone software used in a healthcare environment as a medical device and the application of the classification criteria to such software.

Discussion focused on the qualification criteria for software under both the General Medical Device and *In Vitro* Diagnostic Medical device Directives. As an aid to manufacturers in qualifying their software products decisions trees, for both the IVD and GMD Directives, are to be included. Additionally, illustrative examples of qualification and classification for software commonly used in healthcare environments, such as patient record and telemedicine systems may be included in an annex to the guidance document. The text of the document is nearing completion and is planned to be discussed further at the next Borderline and Classification working group for endorsement.

COMPLIANCE AND ENFORCEMENT (COEN) WORKING GROUP

A meeting of the COEN Working Group was held in Brussels on Monday 11th January 2011. Updates were provided by a number of Member States on specific market surveillance projects and various issues of mutual interest. Discussion took place on parallel import and its implications for Member States. Progress was made on the market surveillance FAQ guide to ensure consistent application of the medical device legislation across Member States. The next meeting of the COEN group will be held in May 2011.

AD-HOC WORKING GROUP MEETING ON BORDERLINE CASES

In the September 2009 meeting of the medical devices expert group on borderline and classification it was agreed that an *ad-hoc* group comprising of medicinal product and medical device experts form various national Competent Authorities meet to discuss specific cases of borderline products (drug or device) such as those products which act chemically or are ingested. The first meeting of this group, hosted by the European Commission (COM) was held at the beginning of March and include representatives from the European Medicines Agency and several medical device and medicinal product Competent Authorities. The aim of the groups is to produce a guidance document for specific products on how they should be classified and regulated.

EUDAMED

Two meetings of the EUDAMED working group were held on consecutive days in the latter half of March. The first meeting related to the IT implications and testing issues experienced by Competent Authorities in preparation for the upcoming use of EUDAMED2 from 1st May 2011. The second meeting focused on the boarder use of EUDAMED with Member States presenting their national plans relating to the upload of registration, notified body certificate, vigilance and clinical investigation data. The next meeting of the working group is scheduled for Octo-

continued on following page

ber 2011, however an interim meeting following the launch of EUDAMED2 may be also be held if required.

NOTIFIED BODY OPERATIONS GROUP (NBOG)

The Notified Body Operations Group (NBOG) met in February in Brussels. Currently the NBOG Best Practice Guidance on issuance of certificates by notified bodies (NB) is undergoing significant revision, the major aspect being the level of detail which is present for class IIa and IIb medical devices on a quality system certificate. While the majority of Member States have participated in the peer review programme for designating/competent authorities conducting NB audits, NBOG are seeking to enhance participation in this essential scheme. This approach helps to ensure a harmonised approach is taken by MS on NB management. At the meeting key debates took place on in house competence requirements for NB, in particular in relation to clinical expertise. In addition, there was also a significant discussion on criteria for impartiality, confidentiality and legal status requirements for NB.

CIE WORKING GROUP

The Clinical Investigation & Evaluation (CIE) Working Group met in Brussels and finalised its proposal to the COM on clinical aspects of the Directives which could be considered during the recast.

The CIE working group is also working on revising the guidance on post-market clinical follow up to include a section on the role of the NB in PMCF.

The CIE is working closely with colleagues in the medicines unit in the COM to provide comments on discussion documents for best regulation of drug-device combination product investigations.

COMPETENT AUTHORITY MEETING

The Competent Authority for Medical Device (CAMD) meeting took place in Budapest hosted by the Hungarian Presidency. During the strategic session, the CAMD agreed the revision of the best practice for the CAMD and revisions to this document to allow for better delineation from the newly established CMC. In addition an update was provided on the activities, decisions and work programme of the CMC. During the technical/legislative sections, a significant debate took place on the COM proposals to include aesthetic implants with no clinical purpose in the Medical Device Directive as part of the recast. The COM provided an update on the IVD recast questionnaire responses, of which there were 183. The responses indicated general agreement on risk-based classification for IVDs, maintenance of the Common Technical Specifications (CTS), regulation of in house testing to an appropriate level(possibly accreditation to a laboratory standard), further requirements for direct to consumer and point of care testing and better definition and criteria for clinical evidence for IVDs.

CENTRAL MANAGEMENT COMMITTEE

The newly established Central Management Committee (CMC) for medical devices held its second meeting in Budapest at the invitation of the Hungarian Presidency. Procedures, operational issues and templates for documentation were discussed and agreed. In addition 3 decisions were made in relation to borderline/classification, NB best practice and device labelling. Details of these decisions will be published soon on www.cmc-md.eu.

New work items include setting designation criteria for Notified Bodies, developing an enhanced and better coordinated designation process, standardisation of certificate and declaration of conformity content and improving the readability of instructions for use. Ireland has been appointed to lead on developing NB designation criteria and to propose a system for enhanced coordination and harmonisation of designation of NB.

HIGH LEVEL CONFERENCE ON MEDICAL DEVICES

A high level conference took place on March 22nd on 'Exploring Innovative Healthcare – The role of medical technology innovation and regulation'. The objectives of this conference was to discuss how innovation and research can be fostered, health ageing enabled and the medical devices regulatory system enhanced and adapted to meet future needs. Pat O'Mahony, Chief Executive of the IMB made a key note address on 'Coordination needs, system resourcing'. The conference is available to view on the web and the conclusion of the Chair document is available for download at http://ec.europa.eu/consumers/sectors/medical-devices/files/exploratory_process/hlc_en.pdf .

IVD TECHNICAL GROUP

The IVD technical group meeting planned for March 2011 was deferred until Q3 2011.

IRISH MEDICINES BOARD

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

IRISH MEDICINES BOARD, KEVIN O'MALLEY HOUSE, EARLSFORT CENTRE, EARLSFORT TERRACE, DUBLIN 2
tel: +353 1 6764971 fax: +353 1 6344033 email: medicaldevices@imb.ie: http://www.imb.ie