IRISH MEDICINES BOARD

MEDICAL DEVICES
newsLETTER

NOVEMBER 2005 Vol. 1 No. 14

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 final edition of the medical devices newsletter for 2005.

In this final edition of the medical devices newsletter for 2005, we will be providing updates on work that was carried out during the year, both in Ireland and Europe.

An article relating to standards highlights and reminds us all of the importance of standards and the crucial role that we all play in the development of new standards.

Other articles include the restructuring of EU Commission, DG Enterprise, an update on the progress of the task force that is dedicated to reviewing the MED DEV on vigilance and feedback on the information day that was held by the IMB in September 2005 for the health services. At this information day, a guidance document on the 'Manufacture of Medical Devices within Healthcare Institutions' was launched.

As always we welcome feedback or suggestions for specific topics you would like to see addressed in future newsletters. If you feel you have an article you wish to contribute to the newsletter, please contact us at **medicaldevices@imb.ie**.

CONTENTS

Guidance Note for Medical Device Manufacturers regarding Auditing by the Irish Medicines Board to the Medical Device Regulations

The Irish Medicines Board (IMB) will shortly be issuing a new guidance note relating to post market surveillance auditing of medical device manufacturers. This is following a period of consultation with the Irish Medical Devices Association (IMDA) and members of the medical device manufacturing industry regarding the content of the guidance note.

As the Competent Authority for medical devices in the Republic of Ireland, the IMB may conduct post market surveillance in relation to:

(1) Products manufactured by Irish based manufacturers and
(2) Those placed on the Irish market.

This post market surveillance activity forms part of the review of manufacturers compliance to the EU Directives and related Irish legislation by the IMB.

The IMB has an obligation to ensure that manufacturers of medical devices comply with the medical device legislation in the Republic of Ireland. Where compliance with the legislation is an issue, appropriate action may be necessary in order to the protect public health.

Post market surveillance is carried out by either:

(a) Proactive surveillance

(b) Reactive surveillance

Proactive surveillance is carried out dependant on what the IMB deems appropriate e.g. targeted audits in relation to a specific category of medical device. Reactive surveillance occurs as a result of a specific market issue, which requires market follow up in the interest of public health.

Post market surveillance work can take place by way of audit. The aim of an audit is to ensure that the medical device manufacturer is complying with the minimum relevant requirements of the medical device legislation.

If a post market surveillance audit is deemed necessary by the IMB, the IMB will contact the medical device manufacturer to arrange the date, time and duration of the audit. In the case of a proactive audit, the manufacturer will be given notice prior to the audit. As reactive audits generally arise from a public health issue, the IMB is obliged to investigate an issue by whatever method is appropriate. A reactive audit of a manufacturing site may be deemed in some cases to be necessary. In such a case, a request to audit the premises of the manufacturer may be made. In such a case, the audit may need to take place immediately. The date of the visit will only be changed in exceptional circumstances.

Once agreed a confirmation letter will be sent to the medical device manufacturer specifying the date and time agreed for the post market surveillance audit and a list of the areas the audit will cover. The manufacturer may be requested to supply some information in advance of the audit in order to facilitate the process.

During the audit, the IMB authorised officer will take note of any areas of concern and discuss these as they arise.

At the end of the audit, a close out meeting will be held with the manufacturer where the findings of the audit will be presented and any non-compliance to the medical device legislation will be raised. At this meeting, the non-compliances will be documented and discussed and a timeframe for close out of these non-compliances will be agreed with the medical device manufacturer.

Once satisfactory responses have been received, the IMB will issue a letter to the medical device manufacturer to that effect. Where satisfactory responses have not been received and / or where breaches of the legislation have taken place, further action may be taken by the IMB as outlined in the legislation.

Further details regarding the auditing guidance note will be available this December on the IMB website **www.medicaldevices.ie**.

New Structure of the EU Commission

As many stakeholders may be aware, a number of staff changes have occurred at the EU Commission, DG Enterprise in relation to medical devices over the last year. Below is a summary of the staff and their functions:

Name	Function
Ms. Georgette Lalis	*Director for Consumer Goods*
Mr. Abraao Carvalho	*Head of Unit*
Mr. Antonio Lacerda de Queiroz	*Head of Sector*
Mrs. Isabelle Demade	*BSE / TSE, MDEG Vigilance - GHTF Study Group II, WEEE, Environmental Impact, MRA's*
Mr. John Brennan	*Medical Device Directive Review Process, IVDs, NBOG, GHTF Study Group I, Notified Body's Contact*
Mrs. Sharon Frank	*Enlargement, MSOG, Borderline Products, Safety Issues, Classification, Standards (CEN, CENELEC)*
Mr. Paolo Catalani	*Assistance, CIRCA Forums, Web Editing*
Mrs. Sarah Onians	*Secretariat*

Standards … Who Needs Them?

Standards have been around since the building of the pyramids and before.

Indeed, we take them for granted in almost every sphere of our lives, when we rely on consistency and performance.

No-where is this more evident or critical than in our demand for fully functioning and consistent medical devices. It is for this reason that standards for medical devices have become the cornerstone of the present regulatory environment.

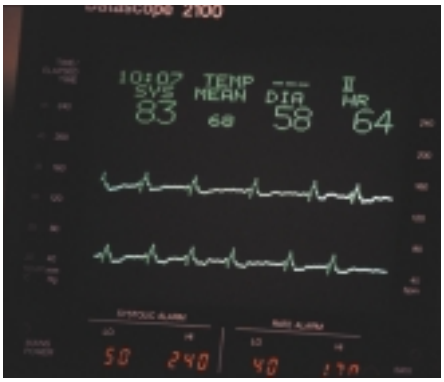
But, you may ask, who writes the standards? Where do they come from? How does it all fit together? Is it possible that I can influence the content of standards?

These are very pertinent questions, and here are some answers.

Standards are written by standards bodies. There are hundreds of these worldwide. Some deal with specific subject areas, some are multi-centered. In Ireland, the government has established the National Standards Authority of Ireland (NSAI) as the semi-state body with authority and responsibility for drafting and implementing standards in Ireland.

The NSAI do not work in isolation from the rest of the world. They are Ireland's representative on many international bodies, including ISO and CEN, the two biggest alliances of standards makers.

ISO is a global network of national standards institutes from 146 countries working in partnership with international organisations, governments, industry, business and consumer representatives. It's core structure revolves around over 200 Technical Committees (TCs), focussed on subjects as diverse as masonry, surgical instruments, packaging, etc. Each committee invites representation from member countries. The work of drafting or revising standards is usually carried out at sub-committee or task group level. Each member can have representation at this stage. This is the stage when the words are put on paper and much discussion ensues, before consensus is reached. Finally, all pre-standards are submitted for formal vote by committee members, before adoption as a standard. Committees, and their sub-committees, meet from time to time to carry out this work, but much of the work is also carried out electronically,



by e-mail and internet access. The final product is what we know as an ISO standard, e.g. ISO 14971.

CEN is the European Committee for Standardisation and was founded in 1961 by the national standards bodies in the European Economic Community and EFTA countries. It works in a similar manner to ISO, having over 300 Technical Committees. As you might expect, the scope of these committees are, in many cases, similar to that of the corresponding ISO Committee.

So, you may ask, is there a lot of overlap and duplication of resources? There could have been, were it not for an agreement called the Vienna Agreement.

The Vienna Agreement is a mechanism, whereby ISO and CEN agree to share access and information about each other's work programmes. Briefly, this agreement ensures that all standards developed, whether under CEN lead or ISO lead, are mutually visible and each body has an opportunity to contribute to the content. The aim of this is to ensure global harmonisation and removal of trade barriers.

But why should Europe need unique standards? The answer to this lies in what is commonly known as the 'New Approach' Directives. In an effort to rapidly remove the trade barriers that existed within the EU, the EU Commission produced a series of Product Directives, based on what became known as the 'New Approach'. We are all familiar with some of these Directives, e.g. Machinery Directive, Toy Directive, Medical Devices Directives, etc. These Directives are all transposed into the national laws of each Member State. They require their products to carry the CE mark to demonstrate compliance with the essential requirements of the relevant Directive. One very convenient way to demonstrate compliance with the essential requirements is to show compliance to relevant standards that have been aligned, or 'harmonised' with specific essential requirements. These 'harmonised standards' each contain a separate Annex Z that maps the alignment of the standard to the relevant essential requirements of the particular Directive. In this way, transparency of requirements can be achieved across the frontiers of the EU. It is the role of CEN to write and publish these standards. It is the role of the national standards bodies, such as NSAI to adopt these European Norms, known as ENs, as Irish standards.

Finally, you may wonder, do you have any say in this? Apart from trying to comply with standards, can you influence the content of standards? Well here's how it works…

The NSAI has established a number of National Mirror Committees who 'mirror' or follow the proceedings of the corresponding CEN and ISO Technical Committees. These committees are called consultative committees, because they seek consultation and input from many sources in order to formulate the 'Irish voting position' on developing standards. Each Standards Consultative Committee is composed of representatives of users, manufacturers, academics, governments and regulatory bodies. The work of the committee is supported by the input of panels of 'experts' drawn from these sectors. While the Standards Consultative Committees tend to meet throughout the year, the input of the 'experts' is mainly through electronic access to documents and websites.

One such Committee is the Healthcare Standards Consultative Commit-

continued on following page

continued from previous page

tee, known as the HCSC. The HCSC works in the following manner:

CEN / ISO TCxxx produces a document for review

↓

NSAI / HCSC adopts it as a 'Project' and posts it on NSAI Livelink website. The Livelink site allows experts to view the document, post their comments and review the comments of others

↓

NSAI / HCSC reviews the conclusions and votes accordingly

↓

CEN / ISO TCxxx collates the votes and comments and takes responsive action

Currently, HCSC follows twelve main subjects or interests. These are further broken down into specific fields of interest. These fields can be aligned with the relevant CEN and ISO TCs.

If you are interested in becoming involved as an 'expert' in a particular field(s), then please contact the Technical Secretary of HCSC, Chrissie Keane by email at **chrissie.keane@nsai.ie**.

Written by:
MS. CHRISSIE KEANE

Standards Development
National Standards Authority of Ireland (NSAI)
Dublin Road
Athlone
Co. Westmeath

Fax: +353-906-472034
E-mail: chrissie.keane@nsai.ie

Information Day to Launch the Guidance Document on the 'Manufacture of Medical Devices within Healthcare Institutions'

The Irish Medicines Board (IMB) held a successful conference targeted at Ireland's healthcare professionals on Tuesday 6th September 2005 in the Robert Smith Lecture Theatre, Trinity Centre for Health Sciences, St. James's Hospital Campus, James's Street, Dublin 8. The event, was attended by over 130 healthcare professionals working in hospitals throughout Ireland.

A guidance document on the 'Manufacture of Medical Devices within Healthcare Institutions' was launched at this event. This document has been written by the IMB to help clarify whether the activities carried out in or by healthcare establishments and other related organisations are covered by the provisions of medical devices legislation in Ireland.

Mr. Pat McGrath, Chairperson of the interim Health Information and Quality Authority (iHIQA) opened the meeting at St. James's Hospital. Pat O'Mahony, Chief Executive of the IMB, Mr. John O'Brien, Chief Executive of St. James's Hospital and Mr. Wilf Higgins, Chairman of the Advisory Committee for Medical Devices of the Department of Health & Children (DOH&C) all chaired sessions at this event.

Presentations were made on the following topics:

- Introduction to the Medical Devices Department of the IMB – *presented by Ann O'Connor*
- Are you a Manufacturer? – *presented by Mairead Finucane*
- Meeting the Legislative Requirements – *presented by Mairead Finucane*
- IMB Post Market Surveillance Auditing – *presented by Maria Carleton*
- Vigilance System / DATH's Pilot – *presented by Dr. Jan Guerin*

There were also two case studies presented:

- Case Study 1: Splints – *presented by Daniel Smyth*
- Case Study 2: Theatre Packs – *presented by Ann O'Connor*

If you would like a copy of the guidance document on the 'Manufacture of Medical Devices within Healthcare Institutions' please email **medical devices@imb.ie**, and copies will be sent to you. The guidance document can also be downloaded from the medical devices website **www.medical devices.ie.**

Ms. Ann O'Connor, Medical Devices Director and Mr. Wilf Higgins, Chairman of the IMB Advisory Committee for Medical Devices at the recent launch of the Guidance Document on the Manufacture of Medical Devices within Healthcare Institutions

HOSPITAL ISSUES

Revision of the Guidelines on a Medical Device Vigilance System (MEDDEV 2.12 –1 rev 4)

In 2004 following consultation with the Member States and industry, the European Commission decided to start discussions on the review of its Guidelines on a Medical Device Vigilance System (MEDDEV 2.12 –1 rev 4). The review was implemented in order to incorporate experience gained since this document was last reviewed in April 2001 and to support the enlargement of the European Union.

A task force reporting to the EU Commission's Medical Device Expert Group on Vigilance (MDEG Vigilance) was established comprising of members from Competent Authorities (Denmark, France, Finland, Germany, Ireland, Norway, Portugal, Sweden and the United Kingdom), the EU Commission, various industry groups, the European Association of Authorised Representatives and NB-Med (the Notified Body forum). The review process started in the middle of 2004.

Some of the key changes that have been proposed include:

- A new definition of a 'Field Safety Corrective Action' to replace the no longer existing European recall definition.

  A "field safety corrective action" taken by a manufacturer to prevent or reduce the risk of death or serious deterioration in the state of health associated with the use of a medical device.

  These may include:
  - the return of a medical device to the supplier
  - device modification
  - device exchange
  - device destruction
  - retrofit by purchaser of manufacturer's modification or design change
  - advice given by manufacturer regarding the use of the device (e.g. where the device is no longer on the market or has been withdrawn but could still possibly be in use e.g. implants)

- The reporting criteria for a reportable event now include:
  - a significant increase in the duration of a surgical procedure
  - a condition that requires hospitalisation or significant prolongation of existing hospitalisation
  - any unnecessary treatment or medical intervention taken as a consequence of an incorrect diagnostic result when used within manufacturer instructions for use
  - foetal distress, foetal death or any congenital abnormality or birth defects

- The time lines for reporting have been further clarified:
  - Adverse events that result in unanticipated death or unanticipated serious injury or represent a serious public health threat must be reported immediately by the manufacturer.
  - All other reportable events must be reported as soon as possible by the manufacturer, but not later than 30-elapsed calendar days following the date of awareness of the event.

For purposes of adverse event reporting, immediately means without any delay that could not be justified, but not later than 10 elapsed calendar days following the date of awareness of the event. Serious public health threat is any event type, which results in imminent risk of death, serious injury, or serious illness that may require prompt remedial action.

- The introduction of the concept of 'summary reporting' and 'trend reporting'.
- Involvement of the Notified Bodies in the vigilance process

Once the document is completed and agreed by the task force and MDEG Vigilance, it will be forwarded to the Medical Device Expert Group (MDEG) for endorsement. It is anticipated that the completed document will be presented to the MDEG in the first quarter of 2006.

Staff Update

In September, JOSEPH GALLAGHER, Vigilance Officer left the medical devices team. Any vigilance queries should be addressed to Andrea Hanson or the medical devices general e-mail address medical devices@imb.ie.

The Medical Devices Department is delighted to announce that KAREN LORD and DEIRDRE MORGAN joined the medical devices team in August 2005 and September 2005 respectively. They have both taken up positions as Medical Devices Administrators.

Karen will be working mainly with certificates of free sale and the compliance and auditing team and Deirdre will be working mainly with the vigilance team.

Revisions in the Definition of a Medicinal Product

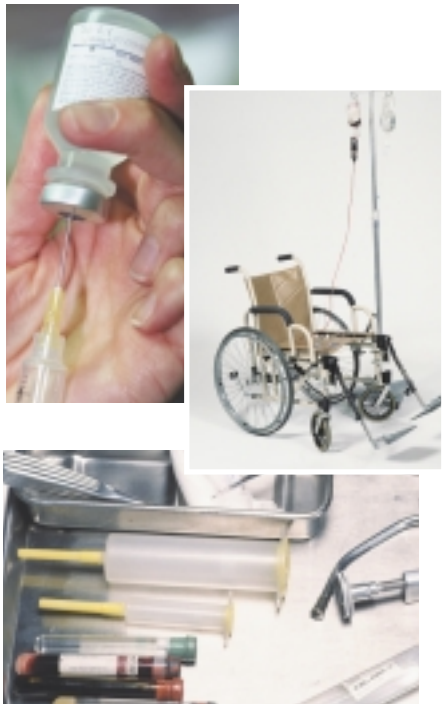
The medicinal products legislation has been updated over the past number of months resulting in a change to the definition of a medicinal product, which may have implications for product classification. It is important that the medical devices sector understands the new definition of a medicinal product and some of the clauses, which may have an impact on which legislation applies to healthcare products.

It should be noted that Article 1 of Directive 2004/27/EC makes changes to the definition of a medicinal product, as currently given in Article 1 (2) of EC Directive 2001/83/EC. The new definition states that to be considered a medicine the product must be

(i) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or

(ii) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

A new provision has been added to Article 2 of the medicines legislation.



Article 2.2 of Directive 2001/83/EC as amended now states that:

'In cases of doubt, where, taking into account all its characteristics, a product may fall within the definition of a 'medicinal product' and within the definition of a product covered by other Community legislation the provisions of this Directive shall apply'.

Taken together, these provisions are intended to ensure that where doubt exists over whether a product those on the 'borderline' between, for example, medicines and medical devices, medicines and cosmetics, medicines and food supplements, etc, the stricter medicines regulatory regime should apply.

While the impact on conventional medicinal products and medical devices is not expected to be extensive, it is important to be aware of such changes. There may however be some products on the borderline between medical products and medical devices which will need to be re-categorised following the implementation of the revised legislation.

These changes are due to be made effective from the beginning of November 2005. The IMB guideline, "What is a Medicinal Product" is consequently under revision to reflect these and other changes arising from updates to the legislation. This will also include the clearer statement in Article 2.2 of European Council Directive 2004/27/EC that where there is any doubt in regard to products which may fall on the borderline between medicinal and other legislative categories, that the medicines legislation takes priority.

It is recommended that stakeholders in the medical device sector obtain a copy of the IMB guideline, "What is a Medicinal Product", once it is available on the IMB website www.imb.ie for reference purposes.

GUIDANCE NOTES

Guidance Note Update

Guidance Note	Issue Date
Guidance Note 23: *Manufacture of Medical Devices within Healthcare Institutions*	***New Publication*** *September 2005*
Guidance Note *Guidance Note for Medical Device Manufacturers regarding Auditing by the Irish Medicines Board to the Medical Device Regulations*	***Expected Publication*** *December 2005*