IRISH MEDICINES BOARD

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EDITORIAL

Letter from the Editor

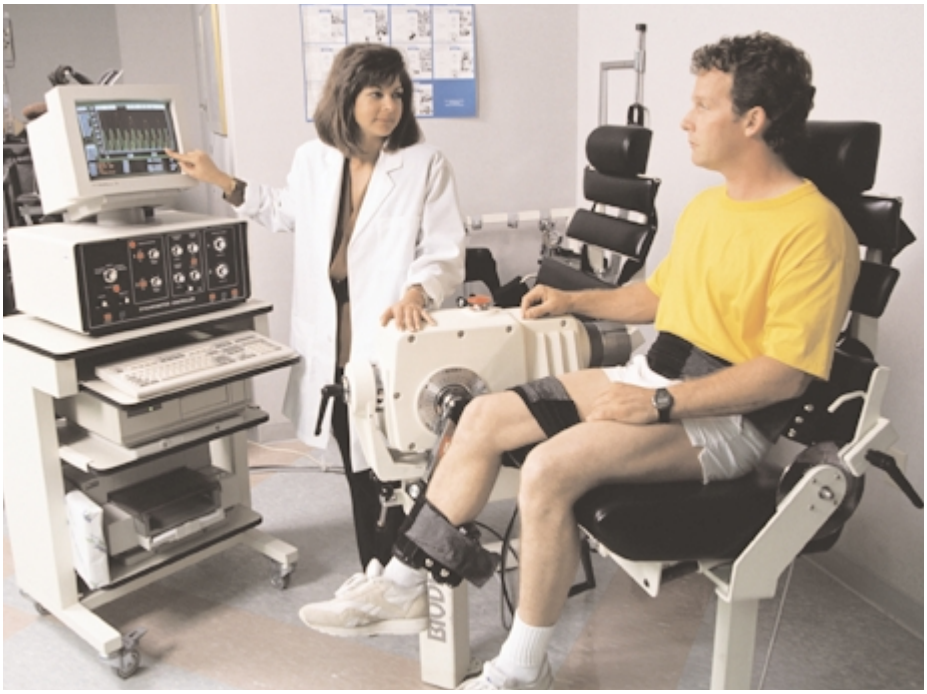
Welcome to this edition of the newsletter.

In this edition we are providing you with an overview of the review of vigilance reporting in Ireland in 2003. The trends show a 46% increase in reporting. Given that more and more patients are being managed in the community setting we have included an article on the management of medical devices in the Community setting

We are now well into our Presidency and the regulatory update provides information on the key activities taking place. Currently proposed changes to the Medical Devices Directive 93/42/EEC are being considered. Also at this stage, the Accession countries have become full members of the EU, a historic occasion.

As a follow on from our earlier articles on standards we are providing an overview of the new European standard currently being drafted by CEN and entitled EN13795 "Surgical drapes and clean air suits, used as medical devices for patients clinical staff an equipment". We are also including an overview of a draft standard under development in relation to "Software Life Cycle" which is worth noting for those that are developing software that is classified as a medical device.

As always we hope you enjoy reading this edition and welcome any feedback, comments or suggestions.



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Information Leaflet on Reporting of Adverse Incidents, for Professional Users of Medical Devices

In order to increase awareness among professional users of medical devices, the IMB has developed an information leaflet which will be distributed to professional users of devices over the coming months.

The aim of the leaflet is to (1) outline the role of the user in reporting adverse incidents during use of medical devices and (2) outline the role of the Medical Devices Department of the IMB as Competent Authority in Ireland.

This leaflet contains information for the user on the definitions of (1) a medical device (2) an *in-vitro* diagnostic medical device and (3) an adverse incident. It will give guidance on (a) when to report an incident (b) who to report to and (c) on the importance of retaining the device for analysis, etc. Contact details will be provided in the leaflet to facilitate timely reporting of incidents.

The IMB user report form which is currently available on the IMB website is available on the reverse side of the leaflet and can be photocopied for convenience. The leaflet will be gloss celluglazed for durability, the intention being that the leaflet would be available to the user in the future, if required i.e. in the general practitioner's surgery, operating theatre, hospital ward, etc.

Copies of the leaflet are also available, on request, from the Medical Devices Department of the IMB at medicaldevices@imb.ie

Off-Label Use of Medical Devices

"Off-label use" of medical devices, means use of a medical device for purposes other than those intended by the manufacturer and outside the scope and indications detailed by the manufacturer in the labelling / instructions for use (IFU).

The Medical Device Regulations state that the manufacturer of a device is responsible for establishing that a device is safe and suitable for its intended purpose. The manufacturer ensures this through compliance with the Regulations. This involves an analysis of risks that could arise during use, an assessment of relevant pre-clinical and clinical data, the preparation of appropriate instructions for use and, if necessary, specific training schemes. From such activities, manufacturers are able to verify that risks have been eliminated or minimised and are judged acceptable when weighed against the anticipated benefits to patients.

Devices that are used "off-label", i.e. outside the terms of the CE mark granted, for any indication outside that outlined in the IFU will not have undergone this level of scrutiny. The consequent lack of verification of device performance could mean that safety, suitability and effectiveness of the device may not be guaranteed. The use of a device in these circumstances could expose users and patients to unknown and therefore unacceptable risks and may have legal and ethical implications.

The responsibility for the device will change with "off-label" use. Liability for "off-label" use rests with the user, not the original manufacturer of the medical device.

Examples of potential dangers include, adverse reactions, inadequate sterilisation, insufficient mechanical strength and / or structural integrity, insufficient durability and misuse due to lack of adequate training.

It is important to ensure that as the user of the medical device that you are familiar with the instructions for use for the device including its intended purposes and that you are up to speed with any specific training related to the medical device in question.

Medical Devices in a Community Setting

When considering the management of medical equipment it is very easy to focus on the management of devices that are housed in hospital, clinic and medical centres.

The equipment that is prescribed for patient use in their homes is often forgotten, not managed, and disappears in to *"a Great Black Hole*".

As an increasing number of patients today are been discharged from hospital with more, and relatively complex medical devices, it is appropriate that appropriate equipment management procedures are in place.

The hospital or health board that purchase the medical device is ultimately responsible for the management of the device through it full life cycle from its initial purchase, commissioning, use, repair and maintenance to the final decommissioning.

Below we outline some of the many areas that need to be considered:

Device Considerations:

- Is the device suitable for home use? (have, for example, robustness, back-up systems, alarms been considered if appropriate, modifications needed, patient care and instructions)?
- Has the device been fully tested with confirmed full functionality and fitness for purpose?
- Are any accessories required, if so where to obtain these and how often?
- Can the hospital / health boards track and locate all equipment that is used by patients in their homes?

Patient / Carer :

- Has the person responsible for use of the device been identified, i.e. is it patient and/or carer?
- Does the patient / carer know the name of the device?
- Does the patient / carer know how to set up the device in the home?
- Has the patient / carer been trained in the use and functions of the device?
- Has the patient / carer been provided with written instructions specifically about the device?
- Has the patient / carer been trained in how to deal with fail-safe features, e.g. alarms?
- Has the patient / carer been trained in the care of the device?
- Does the patient / carer require accessories? If so, does the patient / carer know where to obtain these and how often?

Repair Maintenance and Return:

- Is maintenance required? If so, is the patient / carer aware and in possession of instructions about how this will be achieved?
- If relevant, does the patient / carer have a contact point in case of emergency?
- How are the device service records for the device maintained?
- Does the patient / carer know when to return the device?
- Does the patient / carer know where to return the device once treatment is complete, to whom and at what time?

Hospital Laboratory Automation Systems – Vigilance

As the Competent Authority in Ireland for In-vitro Diagnostic Medical Devices (IVD's), the IMB receives vigilance reports regarding in-vitro diagnostic medical devices from both users and manufacturers of these devices.

It has become apparent that laboratory analysers, which may have performed without incident for many years, may malfunction when integrated into a Laboratory Automation System (LAS). Although both analyser and LAS may be individually CE marked in compliance with EU Directive 98/79/EC this does not guarantee that the devices will work together without incident. Malfunctioning of the analyser may result as a result of this integration.

The hospital should ensure that the integrated system, which is to be used in the hospital laboratory, has been fully validated prior to use of the system for the analysis of patient samples.

Regulatory Update

Following on from the Medical Devices Directive review and the Commission Communication of July 2003 proposals for amendments to the Medical Devices Directive 93/42/EEC are now being considered by the Medical Devices Expert Group (MDEG). It is hoped that the final proposals will be available at the end of 2004.

Discussions have also taken place at both the MDEG and Working Group level in relation to implementation of the legislation in relation to devices utilising tissues of animal origin. It should be noted that Ireland has transposed the EU legislation by way of S.I. No. 554 of 2003. All new devices placed on the market after 30 April 2004 must meet the requirements of the new legislation and those devices currently on the market must comply by 30 September 2004.

Further discussions have taken place in relation to electronic labelling. It has been agreed that during the discussions on the proposals for amending Directive 93/42/EEC that the legal mechanism to allow for the possibility of electronic labelling will be considered. At the last MDEG it was agreed, as a starting point, electronic labelling will be allowed in parallel to the provision of the instructions for use in paper format. The topic will remain on the agenda of the MDEG for further deliberation.

Regarding reclassification of total joint replacement medical devices from class IIb to class III, the vote of the Article 7 Regulatory Committee has been postponed due to delays in translations being available for Member States. Given that there will be a need for additional translations after 01 May 2004 due to Accession countries becoming full members of the EU further delays are expected while all translations are completed.

The draft Decision on EUDAMED is almost complete. However there still remain a number of points to be clarified by the EU Commission namely the issue of copyright, who will deliver the licence and how the Maintenance Agency will be funded and operate. Work is continuing to resolve these issues

The first meeting of the Software Task Force took place in February 2004 where a work programme and scope were agreed. The scope of the Task Force will be in relation to software implications that arise from the Medical Devices Directives. Ireland has agreed to prepare a paper on "what is meant by medical device software" as a starting point for discussions.

The Task Force on the Competitiveness Study had its first meeting with the University of Sienna who were the successful candidate from the tender process. It is expected that the next meeting of this Task Force will take place when a draft document is available for comment.

The third in a series of four Workshops for Accession countries took place in Tallinn, Estonia in the second half of April. The focus was on how to apply the Directives and use of the specific MED.DEV's e.g. vigilance and classification. The workshop, which was run over two days, was very interactive and allowed for plenty of discussion and debate. Ireland as part of the TROIKA played a key role in developing the programme.

In principle it was agreed during the Italian Presidency that the Annex II and Borderline IVD Working Groups would merge. This is expected to take place following the next of the Annex II Working Group.

A number of documents are currently under preparation by the Clinical Evaluation Task Force namely "Post Market Follow Up as part of Post Market Surveillance" and a "Checklist for Competent Authorities with regard to data that needs to be reviewed for uniformity in approach to Clinical investigation application review". Specific guidelines are also being considered for certain families of medical devices e.g. coronary stents and hip implants.

Classification Fees

The number of Classification requests for medical devices received in 2003 and the 1st Quarter of 2004 have increased significantly and to allow processing in a timely and efficient manner, it has been decided to charge for review and arbitration of classification requests.

From the 01 May 2004, the IMB will be charging €156.00 for the review of classification requests for one product and €120.00 for additional products.

Staff Update

Two new staff members joined the Medical Devices Department in April 2004.

Jan Guerin *has taken up the post of* In-vitro *Diagnostic (IVD) Specialist. Jan is an Immunologist with extensive experience in Biomedical Science having worked in hospital laboratory and research environments in Ireland and Australia. She also worked as a Clinical Project Leader with the National Centre in HIV Epidemiology and Clinical Research in Sydney, where she managed clinical studies in HIV infection investigating the host genetic, immunological and therapeutic factors associated with disease pathogenesis.*

Mary Atkinson *has taken up the post of Medical Devices Administrator. Mary will be working with Andrea Hanson, Vigilance Coordinator in the vigilance section.*

Vigilance

In the year 2003, there was a marked increase in the number of vigilance reports received by the IMB.

Four hundred and forty reports in total were received, an increase of approximately 46% on 2002 and over 50% on 2001. (See Table 1)

The reports received from the Competent Authorities for medical devices in other Member States increased by 42% and from manufacturers by 45%. A continued increase in the number of user reports was evident, with a 36% increase. (See Table 2)

The majority of reports received related to valid incidents, with only three reports not fulfilling the medical device vigilance system reporting criteria as defined in European guidance. Incidents relating to Class IIa and Class IIb medical devices constituted the majority of those reports received.

TABLE 1
Number of Vigilance Reports Received during 2000 to 2003

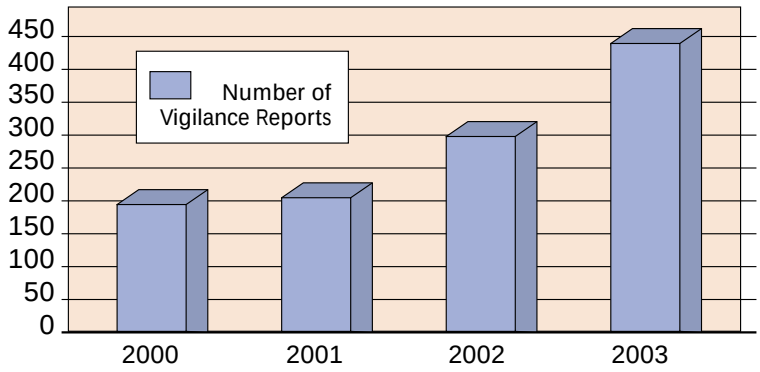
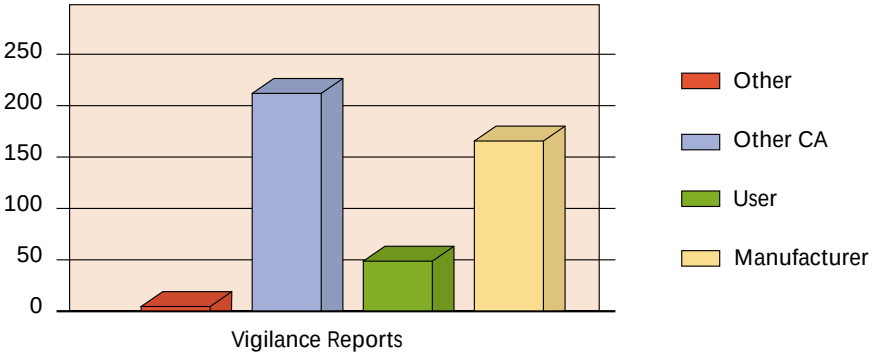


TABLE 2
Sources of the Vigilance Reports in 2003

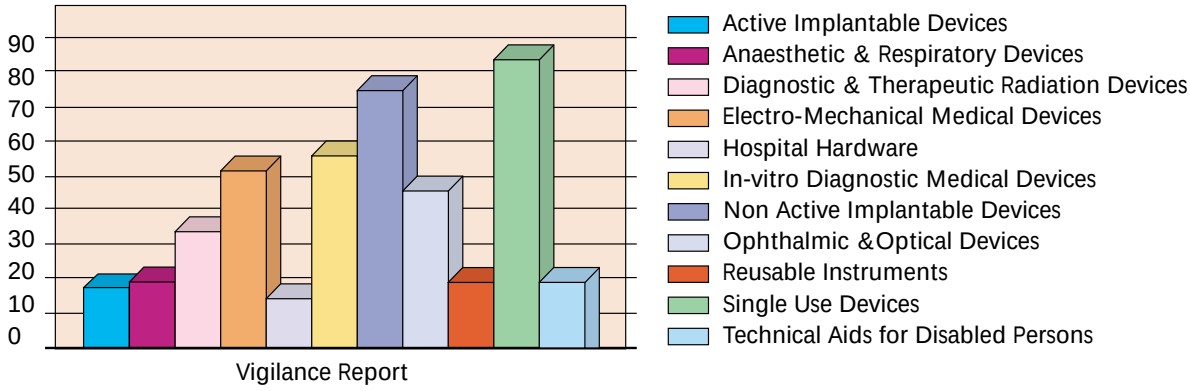


Single use devices and non-active implantable devices again presented as the product families with the more significant number of reports in 2003.

As expected in 2003 there was a significant increases in those reports relating to *in-vitro* diagnostic devices which was as expected due to the pending implementation date for the IVD Directive. (See Table 3)

Further details will be available in the 2003 IMB Annual Report.

TABLE 3
Family Groups of Devices Implicated in Vigilance Reports in 2003



The IEC/ISO 62304 "Medical Device Software – Software Life Cycle Processes"

IEC and ISO are currently preparing a new standard IEC/ISO 62304 "Medical device softwarec – Software life cycle processes" which is scheduled to be released in late 2005. This standard combines the requirements for a software life cycle model described in ISO/IEC 12207 "Information technology – Software life cycle processes", with a risk based approach according to ISO 14971 "Medical devices – Risk management – Application of risk management to medical devices".

Scope: The standard applies to the development and maintenance of medical device software.

Content: Requirements for medical device software life cycle processes, including primary life cycle development and maintenance processes, and supporting processes such as software hazard management, documentation, configuration management, verification and problem resolution are included. The proposed standard applies to software that is a stand-alone medical device and to software that is an embedded or integral part of the final device. It includes a compliance section based on whether or not the software can cause a hazard or controls risk.

As a prerequisite, the standard specifies that:

(a) quality management system according to ISO 13485 requirements and
(b) risk management system according to ISO 14971, should be in place.

Using the risk management system, the software or parts of it shall be classified according to the severity of a hazard it might contribute to:

- *Class A:* Software does not contribute to any harm
- *Class B:* Software might contribute to non-serious injury
- *Class C:* Software might contribute to death or serious injury of a patient, operator or bystander.

Depending on the software class the standard establishes requirements, which have to be fulfilled by the software life cycle model the manufacturer uses.

Surgical Gowns, Drapes and Coverings

A new European standard is currently being drafted by the European Standards Working Group (CEN/TC205/ WG14) entitled: EN 13795: 'Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment'. The plan is to publish it in five parts. Part 1 was published in November 2002: 'General requirements for manufacturers, processors and products'. Subsequent parts of the standard will outline appropriate physical test methods and the performance levels to be met.

There are many different types of reusable and disposable surgical gowns and drapes available for use in operating theatres. All those involved in using operating theatre fabrics should establish their needs and priorities based on risk so they can assess and determine the most suitable fabrics to use for all types of surgical procedure.

There are several factors to consider in determining the most appropriate textile to use in the operating theatre. Some of these could include:

- The type of surgical procedure and the assessed level of risk involved
- A priority of properties desired, for example: wet and dry bacterial barrier properties, fluid resistance, liquid absorption, strength, linting, etc
- Disposable or reusable
- Processing requirements, for example: ability to be sterilized, rinse finishes in laundry
- Cost
- Expected life

Some of these priorities may well conflict with each other. They will need to be discussed and agreed with all persons involved in using surgical gowns, drapes and coverings, e.g.:

- Surgeons
- Theatre managers and staff
- Sterile services departments
- Infection control staff
- Laundry staff

There is no legal requirement to comply with European or international standards, although meeting harmonised European standards is the easiest way to demonstrate compliance with the requirements of the Medical Devices Directive. Compliance with harmonised standards is voluntary, and manufacturers are free to choose any other technical solution that provides compliance with the Essential Requirements of the Medical Devices Directive based on the intended purpose of the product.

Copies of the standards are available to purchase on www.ili.co.uk.

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