

Letter from the Editor

Welcome to the first edition of the medical devices newsletter of 2008.

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

In this edition of the newsletter we have a feature article on the procurement of medical equipment in hospitals. Mr. Peter Grainger, Principal Clinical Engineer / Physicist at Naas General Hospital, shares with us the experiences of his procurement team which should provide some useful information for those involved in the area.

We have received a number of queries recently on the registration process. In this issue, we seek to provide clarification on some of the more common questions in relation to the registration process for medical devices with the IMB.

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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Own Brand Labelling of Medical Devices

Under the medical devices legislation, a manufacturer is defined as the 'person who is responsible for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party'.

It must be noted that the definition of manufacturer also extends to "own brand labelling" (also often referred to as "private labelling") of medical devices.

To clarify this point, an 'own brand labeller' is the person who places the product on the market under his own name or trademark and is therefore the manufacturer (as defined) for the purposes of the legislation. The 'own brand labeller' may not be the person who actually designed, manufactured, packaged or labelled the product but nevertheless the regulatory responsibility rests with him alone if he is responsible for placing the product on the market. An own brand labeller must:

- (a) Ensure that the appropriate conformity assessment procedure is correctly followed by him and any sub-contractor involved;
- (b) If appropriate, lodge and application with a Notified Body; of if the medical devices are class I / general category IVD's ensures they are appropriately registered with the Competent Authority;
- (c) Make available to the Competent Authority and the Notified Body that is involved for CE marking, appropriate documentation necessary for them to fulfil their respective responsibilities;
- (d) Make a declaration of conformity for the products concerned, and retains them for future reference by the Competent Authority;
- (e) Register his organisation and devices with the Competent Authority where he is located
- (f) Ensure that the CE marking of conformity is properly applied;
- (g) Ensure that post-marketing obligations such as vigilance are implemented.

In general, where any of the manufacturer's responsibilities are subcontracted to another party contractual arrangements should ensure that the

subcontractors meet the obligations of the legislation.

A distributor whose name appears on the packaging, labels or instructions for use is not considered to be an 'own brand labeller' or a manufacturer if it is clear that the product is being placed on the market under the actual manufacturer's own name / or that of the authorised representative.

The legislation imposes obligations on manufacturers with respect to:

- (a) Post production monitoring, and
- (b) The reporting of adverse incidents, and any malfunction or deterioration, which might lead to an adverse incident, to the Competent Authority.

Manufacturers, including own brand labellers, should be familiar with their legislative obligations regarding use of the CE mark. All obligations to report to the Competent Authority should be taken seriously. The consequences of not reporting incidents involving products for which there may be several own brand labellers

could be particularly serious. The IMB considers that it is the responsibility of the own brand labeller to ensure that incidents or potential incidents with a medical device that is being placed on the market under his name should also be notified to the 'actual manufacturer' of the medical device. It is also the responsibility of the 'actual manufacturer' of the medical device, if he is aware of a particular issue with his medical devices, to ensure that own brand labellers are informed of the issue so that the appropriate corrective action can be implemented in the interest of public health.

Further information in relation to the subject of own brand labelling may be found in a recently published European Commission interpretative document regarding own brand labelling in the context of the Medical Device Directives. This document is available on the European Commission website at:

http://ec.europa.eu/enterprise/medical_devices/guide-stds/interpretative_documents_en.htm





Promotion and Advertising of Medical Devices

All medical devices on the market in Ireland should be CE marked in line with the relevant Directives, 93/42/EEC for general medical devices, 90/385/EEC for active implantable medical devices and 98/79/EC for in-vitro diagnostic medical devices and the correlating Statutory Instruments S.I. No. 252 of 1994, S.I. No. 253 of 1994 and S.I. No. 304 of 2001 as amended.

Article 19(6) of S.I.252 of 1994 entitled 'Prohibition on placing on the market or putting into service' states that.

(6) Nothing in subarticles (1) or (2) shall prevent the showing at a trade fair, exhibition, demonstration or similar event of a device which does not comply with the relevant essential requirements or which does not bear the CE marking provided that a notice is prominently displayed at the event, so as to be readi-

ly visible to a prospective purchaser, indicating that the device

- (a) does not comply with those requirements or does not bear that mark; and*
- (b) may not be placed on the market or put into service until it complies with the requirements of the Directive.*

It should be noted under S.I. No. 252 of 1994 that the definition of intended purpose states:

'intended purpose' means, in relation to a device, the use for which it is intended according to the data supplied by the manufacturer on the labelling, and in any instructions and any promotional materials relating to it.

The definition of placing on the

market in S.I. No. 252 of 1994 states that:

'placing on the market' means, in relation to a device, the first making available, whether in return for payment or free of charge, of a new or fully refurbished device other than a device intended for clinical investigation, with a view to distribution, use, or both, in the Community.

Taking all of this into account, any medical device that is CE marked may be placed on the Irish market, either for a monetary fee or free of charge. While there is no specific legislative control over advertising, any promotional material supplied with a medical device should only contain information substantiated by documentation as part of the conformity assessment route to CE marking.

Cosmetics Project

In October 2007, a cosmetics project officer was appointed to the Medical Devices Department of the IMB to determine the legislative obligations and responsibilities of the IMB assuming the role of Competent Authority for cosmetics in Ireland. This has involved close interaction with the current Competent Authority, the Department of Health and Children and other stakeholders. The activities of the European Council Working Group on cosmetics are being closely monitored as a recast of the cosmetics directive is proposed for adoption which aims to strengthen the legislation in a number of key areas including definitions, good manufacturing practice and post market surveillance. The IMB has attended, as an observer, a number of European meetings relating to cosmetics including the Standing Committee on Cosmetic Products, the Working Group on Cosmetic Products, and the Platform of European Market Surveillance Authorities in Cosmetics (PEMSAC). A report outlining the implications of the IMB assuming this role is currently under preparation.





IMB Medical Device Registration Requirements

Who is required to register with the Irish Medicines Board (IMB)

In general, legal manufacturers of medical devices or their authorised representatives based in Ireland are obliged to register with the IMB if they are manufacturing class 1, custom made or in-vitro diagnostic medical devices in Ireland, or if they are carrying out own brand labelling in Ireland for the purpose of placing on the market.

1. In-vitro diagnostic (IVD) medical devices:

Registration is required if you:

- Manufacture IVDs and place them on the market under your own name or trading name(s)
- Manufacture IVDs for performance evaluation and make them available under your own name, or trading name(s)
- Are the Authorised Representative of a manufacturer based in Ireland who does not have a registered place of business in Europe;

Please note that as per Article 10 of Directive 98/79/EC, notification should also be made to the Competent Authorities of each Member State concerned by the placing of IVDs on the market.

2. General medical devices (GMDs):

Registration is required with the IMB if you:

- Manufacture class 1 or custom made devices and place them on the market under your own name, or trading name(s);
- Fully refurbish class I devices, or label one or more ready made devices, with a view to placing them on the market under your own name;
- Place devices bearing the CE marking on the market, under your own name in a system or a

procedure pack within their intended purpose and within the limits of uses specified by their original manufacturer

- Sterilise, for the purpose of placing on the market under your own name, systems or procedure packs or other CE marked medical devices designed by the manufacturers to be sterilised before use;
- Are the authorised representative of a manufacturer who does not have a registered place of business in the Community, or if you import and place on the market for a manufacturer who has no authorised representative in the Community, devices within the above listed categories.

How do I become a European authorised representative?

In order to become the authorised representative for a manufacturer you should first obtain a letter of designation from the manufacturer. Following this you may proceed to register your company as an authorised representative within the meaning of the legislation. This letter of designation should accompany your registration application.

How do I register with the IMB and how much does it cost?

If your organisation meets any of the above mentioned criteria, an application to register your organisation must be made. There are two means by which you can apply; manually or electronically. Manual registration requires you to download either the general medical device or in-vitro diagnostic medical device form from the publications section of www.imb.ie. The completed form must be accompanied by the relevant fee and signed declaration of conformity. Currently manual registration costs €146 and up to 10 devices



can be registered at one time. Any amendments to the register thereafter, such as change of contact details, withdrawal of a device or organisation can also be made on these forms and currently incurs a cost of €146. Once registration has been fully processed a unique registration number is assigned to the organisation and the device. You will then receive a registration confirmation letter and registered device details report.

Electronic registration can be made on-line at www.imb.ie. Once you have completed the necessary fields you will be asked to print off and sign the terms and conditions. This and the relevant organisation registration fee, currently €125, must be sent to the IMB for completion of the registration process. When your registration has been processed you will receive a unique username and password to access the IMB extranet at <https://access.medicaldevices.ie/home/login.asp>. Once you have accessed your organisation's registration homepage you may edit certain organisation details, add, edit, or withdraw devices and control users. An annual verification fee, based on the number of employees in your organisation, is payable for user of the on-line system: the current rates are €146 for up to 5 employees, €366 for between 6-20 employees, €732 for between 21-100 employees, and €1,568 for over 100 employees.

References

Guidance Note 2: Guidance Note for the Registration of Persons Responsible for Placing Devices on the Market in accordance with Directive 93/42/EEC and S.I. No. 252 of 1994.

Guidance Note 3: Guidance Note for the Registration of Persons Responsible for Placing In-vitro Diagnostic Medical Devices on the Market in accordance with Directive 98/79/EC and S.I. No. 304 of 2001.

Guidance Note 17: Instructions for Use of the On-Line Registration System for Medical Devices.



Medical Equipment Procurement Committee – Naas General Hospital

The safety notice from the Irish Medicines Board (IMB), SN2003(09) Equipment Management

– Some Basic Principle of Equipment Management makes three fundamental introductory points in relation to understanding the need for an appropriate medical equipment policy and governance within a hospital.

These are:

1. “Medical equipment management is a very important topic encompassing many areas including the choice of the device, purchase, commissioning, training, storage, repair and service, and replacement of the medical device.
2. Poor equipment management in organisations that use medical devices can either lead to or result in undesirable effects e.g. adverse incidents or near incidents or delayed implementation of corrective actions.
3. To ensure effective management of medical equipment in a healthcare setting a well-structured coordinated multidisciplinary approach is required.”

It was important therefore that Naas General Hospital (NGH) had a clearly defined and well-structured approach to the purchase and commissioning of medical equipment.

In May 2006, in accordance with the IMB Safety Notice – The Procurement and Commissioning of Medical Equipment for Hospitals (SN2006 (03)), NGH established a Medical Equipment Procurement Committee (MEPC).

The initial focus of this committee was on ‘high-end’ medical equipment, including laboratory equipment, and not on the purchase of routine consumable medical devices, implantable medical devices, or drugs.

The role of the medical equipment procurement committee is now established to manage the purchasing and commissioning, and associated issues, of all medical equipment within the hospital at an organisational level.

TERMS OF REFERENCE

The Committee’s ‘Terms of Reference’ are to:

1. Develop/establish and/or identify an organisation wide policy for the procurement and commissioning of medical equipment. This will ensure that a consistent approach is adopted for the acquisition of all medical equipment for the hospital.
2. Identify the methods by which medical equipment is brought into the hospital and develop appropriate policies for each method identified. (for example, loan equipment, donations, company lease, etc).
3. Develop an organisation wide mechanism for identifying medical equipment needs and a method of outlining the equipment requirement e.g. formal business case with relevant supporting documentation.
4. Develop/identify the medical equipment needs of new consultants or services being brought on line.
5. Develop medical device replacement lists for medical equipment
6. Flag to the hospital the impact associated with the introduction of a new medical device, e.g. the impact on staffing levels, hospital structure, associated consumable costs, etc.
7. Develop and identify the risk management strategies associated with the introduction of a new item of medical equipment into the hospital, and associated care.
8. Appraise the uniformity of medical equipment and the implications of uniformity.
9. Develop control policies for the use of hospital medical devices ‘off site’.
10. Develop a Medical Device Technology Assessment Policy.
11. Develop policies in regard to purchasing reusable invasive medical devices (RIMDs).



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Members of Naas General Hospital's Medical Equipment Procurement Committee: Left to Right, Ms. Ann O Shea, General Services Manager; Mr. Paul Anderson, Maintenance Manager; Mr. Pat Flynn, Laboratory Manager; Mr. Jonathan Kidd, Senior Clinical Engineer/Physicist; Mr. Peter Grainger, Chairperson & Principal Clinical Engineer/Physicist, Ms. Theresa Dixon CNM2 ICU.



Other Members: Mr. Bernard McKeon, Purchasing Officer; Ms. Margaret Scott, Finance; Ms. Margaret Tobin, Hospital Accountant; Ms. Loretta Jenkins, Quality and Risk Officer, Ms. Lisa Hanrahan, Superintendent Radiographer; Ms. Michelle Atkinson, ICT Coordinator; Ms. Breda Dreelan, Clinical Placement Coordinator; Ms. Fiona Conway, Infection Control, Dr. Nadir Al Mane, Anaesthetics.

COMMITTEE COMPOSITION

The Medical Equipment Procurement Committee is multidisciplinary in nature and includes representation from nursing, medical and surgical teams, clinical engineering, hospital management, finance, purchasing, technical services, infection control, the quality and risk office, laboratories, radiology, and information technology. Other relevant personal are seconded on to the committee to meet needs as they arise. The committee meets on a monthly basis.

INITIAL TASK – STANDARDISED & TRACEABLE PURCHASING POLICY

Hospital staff conveyed to our committee that they felt one of the more important aspects of any hospital purchasing policy was: that the procurement requisition process was traceable by them at every stage.

In addition to traceability other policy objectives defined by the committee were:

- to provide NGH with a clearly defined and well-structured approach to the procurement of medical equipment.
- to implement the current Health Service Executive procurement policies, for the purpose of planning for and purchasing of medical equipment.
- to implement IMB guidelines for the procurement of medical

- equipment for hospitals;
- to comply with national and European legislation where applicable to the selection and safe use of medical equipment.
- to ensure that NGH has access to the best medical equipment technology available, and is enabled and assisted to utilise such medical technology in a safe and efficient manner.

This policy and associated procedures are applicable to all departments, department managers, heads of service, and individuals who identify a need to acquire medical equipment as a capital expenditure item. Needs may be identified as follows:

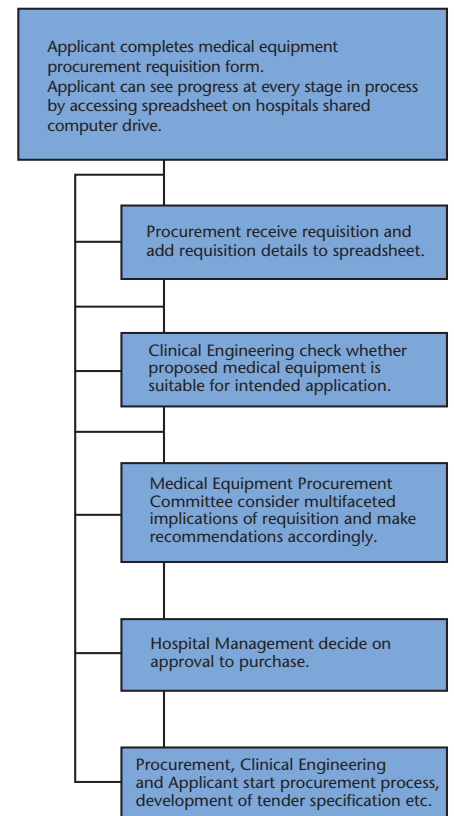
1. via user initiative (individual items)
2. via planning for new services
3. via capital planning (new replacement equipment)

The traceability element is ensured in the following way. The medical procurement policy and the medical procurement requisition form are available to all on the hospital's shared computer drive. The applicant fills out the requisition, including the business case, and drops the completed form back in the hospital's shared drive in a specified folder. This folder is monitored daily by clinical engineering and procurement.

Also in the shared folder is a spreadsheet with associated date stamp fields that outlines each stage

of the requisition process up to purchase and commissioning. This spreadsheet is populated and updated at every stage by Purchasing. All staff can view this spreadsheet at any time, and so know where in the system their requisition is.

The stages of medical equipment requisition are simplified in this illustration:



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We have found this process to work well, and the traceability element to be very informative to all.

SUB GROUP WORK

The Medical Equipment Procurement Committee has set up a number of sub groups with relevant representation to develop specific policies and procedures. Some of these ongoing work item policies are:

- A Control Policy for medical equipment being used off site, for example holter monitors, 24hr non-invasive blood pressure monitors, nebulisers, crutches etc. (The recent publication of IMB Safety Notice SN2007(0X) "Medical Devices Recommended by Healthcare Institutions for Use in a Community Setting" will greatly assist in this regard).
- A Clinical Service Development Policy so that the hospital can consider medical equipment implications in advance of new consultants taking up office; or expansion of clinical services.
- An Evidence of Medical Equipment Training Policy for staff so they can demonstrate competency in use of medical equipment prior to use.
- A Medical Equipment Donation Policy for items being donated to the hospital.
- Sales representative visitors; and trialling of medical Equipment.

These sub groups are task dependent and once the initial policy is approved they will only need to convene in future years to recycle versions of policy adapted.

MEDICAL CONSUMABLES AND ACCESSORIES SUB GROUP

One sub group which we established after the development of our procurement policy is the Medical Consumables and Accessories Sub Group. We found that medical equipment procurement and life cycle support could not be holistically considered without taking into

account associated consumables and accessories that are used with the medical equipment and devices. Again this is a multidisciplinary group, which meets once a month.

This sub group considers such issues as those outlined below.

Product Change:

A pro forma document and policy has been developed and implemented so that should any member of staff wish to change or introduce a new medical consumable or accessory a governed protocol has to be followed. This protocol considers: risk associated with diversity of product within the hospital, significantly financial implications (value for money), patient /staff safety and quality care for our patients, and also patient benefit. It is the responsibility of this sub group to review each proposal to ensure new/alternative products are appropriate.

Equipment Not Owned by Hospital:

Some items of medical equipment are used within hospitals but not owned by the hospital. The supplying company "give" the equipment to the hospital conditional on the hospital's usage of specified quantities and types of consumables and accessories. We found significant legislative and insurance matters associated with this practise that need to be teased out in every instance.

Medical Equipment Education

The Medical Equipment Procurement Committee is also involved in ongoing education and training sessions in relation to medical equipment procurement. It has developed an information pamphlet for staff that outlines how to go about developing a business case and the requisition process associated with purchasing an item of medical equipment. This leaflet is given out to all staff during staff induction sessions. The role, policies and processes associated with the Medical Equipment Procurement Committee have also been outlined at presentations to Nursing, Medical Board, Allied Health Professionals and Heads of Service meetings.

Recently members of the IMB

post market evaluation section, Ms. Andrea Hanson and Ms. Orla Keane, hosted a Medical Device Educational Seminar for staff in NGH. Some of the topics covered were: definition of a medical device (technical and layman's); classes of medical devices; IMB vigilance / incident reporting system; and reusable invasive medical devices as outlined by the Medical Device Directive. The educational seminar was attended by over 60 staff from all departments with evaluation forms indicating that the seminar was very informative, met the needs of staff, and was very successful in clarifying medical equipment and device understanding.

Conclusion

The Medical Equipment Procurement Committee and associated sub group is active and vibrant, and key to its dynamism is its across-the-board multidisciplinary nature. NGH has found the work of this committee to be invaluable in meeting with common norms, best practice, and many hospital accreditation needs with respect to medical equipment procurement and life cycle management. More importantly, it has set policies of governance for medical equipment that ultimately will be utilised to ensure best possible patient care and benefit. The specific medical equipment related 'safety notices' from the IMB have also been invaluable.

*Written by: Mr. Peter Grainger
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Procurement Committee
Principal Clinical Engineer / Physicist
Naas General Hospital*

References

IMB Safety Notice SN2006(03) – The Procurement and Commissioning of Medical Equipment for Hospitals

IMB Safety Notice SN2003(09) – Equipment Management – Some Basic Principle of Equipment Management

IMB Safety Notice SN2007(06) – Medical Devices Recommended by Healthcare Institutions for Use in a Community Setting



Regulatory Update

Unique device identifiers (UDI) for medical devices were discussed at a European Commission meeting in January. FDA proposals were considered. The FDA proposal relates to the development of a UDI to serial or lot number level to reduce medical errors and improve traceability among other issues. A UDI database is also proposed. The European Commission and the European medical industries are in favour of the proposal. The concept was further discussed at the GHTF and at the Competent Authority meeting in Slovenia. A task force will be established in Europe in relation to further development of the concept of unique device identifiers.

A meeting of the Clinical Evaluation Task Force (CETF) took place in January. The major topic of discussion was the CETF's guideline on clinical investigations involving coronary stents. The current draft has been posted for consultation on the European Commission's website at http://ec.europa.eu/enterprise/medical_devices/questionnaires/comments_coronary_stent.htm. Any comments should be submitted before the 22nd April 2008.

A meeting of the Notified Bodies Operations Group (NBOG) also took place in January. An extensive work program was tabled including development of several guidance documents relating to current and future notified body activities following the publication of the amendment to the MDD (2007/47/EC).

The 21st Meeting of Competent Authorities (CA's) for Medical Devices took place under the European presidency of Slovenia in February. CAs discussed the practical implications relating to implementation of Directive 2007/47/EC. The interface of the Medical Devices Directives with other legislation and the need for further clarification concerning interpretation of definitions was pointed out. The consequence of the revision of the horizontal New Approach Directives for the medical

devices sector, with particular reference to the designation and supervision of Notified Bodies (NB) and market surveillance, was discussed. It was agreed that a critical analysis of the changes, particularly in relation to market surveillance should be carried out by a task force of the Compliance and Enforcement Working group (COEN). The CA meeting adopted a revised market surveillance communication protocol and rationales for agreeing new work items for the COEN Working Group. A procedure on how to improve the working arrangements between current working groups was discussed and a format agreed. The need for information and best practice exchange between CAs was highlighted. The meeting endorsed the future work programme of the COEN and renewed its commitment to the work of the Notified Body Operations Group (NBOG). Preliminary information on the study on distribution channels and Member States experience concerning counterfeit medical devices were presented. CAs emphasised the need to permanently monitor and contribute to the development of new and emerging medical technologies in the light of the existing legal and regulatory framework.

The first meeting of the e-labelling ad-hoc group to consider the issues involved in implementing alternative forms of labeling and instructions for use for general medical devices took place in Brussels in March. Key topics covered were the current provisions for e-labelling within the medical devices legislation, known international positions on e-labelling and risk management. These topics will be further considered by the ad-hoc group later in the year.



Staff Update

The Medical Devices Department is delighted to announce that *Mr. Bryan Byrne*, *Dr. Pauline Bowe* and *Mr. James O'Callaghan* joined the medical devices team.

Bryan Byrne takes up the position of administrator for the class I / IIa product unit within the post market evaluation section.

Dr Pauline Bowe takes up the position of medical assessor. Pauline graduated in medicine from the Royal College of Surgeons Ireland. Prior to joining the IMB, she gained broad medical experience in general practice and travelled the world working as a ships doctor.

James O'Callaghan takes up the position of product manager for the class I / IIa unit in the post market evaluation section and his primary responsibilities will be to manage the performance of the Class I/IIa Group and to ensure that the response to all post market issues that arise in relation to these devices are managed effectively and efficiently. James's academic qualifications include a degree in Mechanical Engineering from UCD and a Diploma in Applied Project Management from UCC. He has over 10 years experience working on new product introductions in the medical device and pharmaceutical fields and has an in depth knowledge of medical device design and manufacture and the required quality systems to support these activities.

