IRISH MEDICINES BOARD
SAFETY NOTICE

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Effective Traceability of Medical Devices

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MANUFACTURER/SUPPLIER

General medical device (GMD), active implantable medical devices (AIMD) and *in-vitro* diagnostic medical device (IVD) manufacturers and/or suppliers

TARGET GROUPS

This safety notice has been written as a guide for medical device manufacturers, distributors, purchasing managers, prescribers and users of medical devices in hospital, community and home settings including:

Hospital Consultants
Non-Consultant Hospital Doctors
Chief Executive Officers of Hospitals
General Practitioners
Risk Managers
Equipment Managers
Public Health Nurses
Theatre Managers
Community Practice Nurses / Clinical Nurse Specialists / Advanced Nurse Practitioners
Occupational Therapists
Dentists & Dental Suppliers
Palliative Care Services
Physiotherapists
Pharmacists
Medical Device Manufacturers
Distributors of Medical Devices
Community Care Services
Appliances Officers
Secondary Care Services
Diabetes Clinics / Outpatients
Respiratory Clinics / Outpatients
Providers of assistive technologies e.g. Central Remedial Clinic / National Rehabilitation Hospital
Health Service Executive
Primary, Community & Continuing Care
Clinical Engineers
Laboratory Managers

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ISSUE

The traceability of medical devices plays an important role in enhancing patient and user safety. Through effective traceability medical devices can be identified and located to allow actions that may be required to reduce the safety risks to patients and users to be carried out in a timely manner.

BACKGROUND

The IMB, as competent authority for medical devices on the Irish market, receives notification of field safety corrective actions (FSCAs) carried out on the Irish market through its medical device vigilance system. An FSCA is an action taken by a manufacturer to reduce the safety risk related to the use of a medical device on the market. An example of such an action is the recall of a medical device from the market for safety reasons. These field safety corrective actions require that devices affected by a particular issue that have been distributed to users on the Irish market are identified and located to allow the action to be carried out. The IMB has observed how the effectiveness of FSCAs can be hampered through poor traceability of devices.

UNDERSTANDING TRACEABILITY

A good traceability system requires an understanding of the intended use and lifecycle of all the medical devices within the system. Traceability of a medical device refers to the ability to fully trace a device through its entire lifecycle, from when it is manufactured through to end of life. Traceability is required for all medical devices, whether consumable devices, implants or medical equipment and whether they are used within the hospital/health clinic or prescribed to users for use in their homes.

Manufacturers are obliged to have a traceability system in place throughout the manufacturing process to meet the requirements of the Medical Device Directive MDD 93/42/EC, Active Implantable Directive AIMD 90/385/EC and the *In Vitro* diagnostic medical devices directive IVDD 98/79/EC. The medical devices must continue to be traceable after they leave the manufacturing facility to allow them to be located and accounted for at all times. Manufacturers, distributors, medical staff, care givers and patients play a role in achieving this.

To understand the role that each group plays it is important to understand the paths through which different medical devices can reach a patient or medical practitioner. The most common route is for the medical device to be supplied to a hospital or health clinic via a distributor. The patient is supplied with the prescribed medical device when they present to the hospital or health clinic.

Medical devices, such as blood glucose meters, infusion pumps and continuous positive airway pressure (CPAP) units, are used in the community setting. Blood glucose meters can be supplied to a patient through their blood clinic or can be sourced directly by a patient at a local pharmacy.

Manufacturers and distributors also supply medical devices directly to users through the internet and retail outlets.

UNDERSTANDING THE LIFECYCLE OF A MEDICAL DEVICE

It is essential that the intended use of a medical device is understood to ensure that traceability of the device is maintained throughout its entire lifecycle. Single use and consumable medical devices are discarded after use while implantable devices continue to be used after the implant procedure has been performed and the patient is discharged from the hospital. Some medical devices are comprised of reusable components and consumable components, with each component having a different

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lifecycle. For example a clinical chemistry analyser that would be managed through a laboratory's equipment management system also uses consumable reaction vessels, which have their own batch specific information. Medical equipment, such as diagnostic and infusion equipment are used until the equipment is decommissioned and taken out of service. *In-vitro* diagnostic medical devices such as blood glucose meters are often prescribed for patients for home use. Consumable medical devices such as medical sutures can be used so frequently that the risks associated with them can be forgotten, such as issues with the sterility of the sutures. A prescriber of assistive technology should understand that when the equipment leaves their facility with the patient the traceability must continue.

IMB RECOMMENDATIONS

The IMB is distributing this Safety Notice to highlight the importance of traceability of medical devices and to identify some of the safety issues that may occur as a consequence of poor traceability of medical devices.

Effective traceability measures should be implemented by all groups involved in the manufacture, distribution, prescription, servicing, re-processing and use of medical devices. A risk based approach can be used in determining the level of traceability applicable for different medical devices. For example, it might be determined that low risk consumable devices such as non-sterile dressings will only be tracked to pharmacy level as it would be difficult to track such products beyond that point and the risk benefit in tracking the product further may be very low. Applying the same approach, high risk devices such as active implantable devices would need to be tracked to patient level. The following questions can be used to assess the effectiveness of your traceability system or to assess your understanding of the importance of traceability of medical devices:

1. Is it clear what the intended use of the medical device is, who will use it and for how long?

2. Is there a system in place to record the information needed to identify and locate the medical device?

3. Is there a designated person who is responsible for maintaining the information in the system and keeping the information within the system up to date?

4. Is there a system in place to record all relevant information needed to allow an investigation to be carried out should an incident occur which involves a device?

The IMB provides, in Appendix I of this Safety Notice, some general recommendations for ensuring good traceability of medical devices as well as some specific recommendations for medical devices in a hospital or community setting and for distributors and users of medical devices.

Appendix II of this Safety Notice provides sample case studies of issues that can arise with different medical devices as a result of poor traceability.

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APPENDIX I RECOMMENDATIONS

GENERAL RECOMMENDATIONS

There are a number of policy and guidance documents available that provide recommendations for medical equipment management which are listed in the Referenced Documents section of this Safety Notice.

Healthcare staff, prescribers and patients are strongly recommended to:

- record the relevant contact (manufacturer/distributor/medical staff) in the event of issues with the device
- complete and return all warranty and/or registration cards supplied with medical devices
- inform the relevant contact of any changes to patient/device information
- participate in any device registration scheme/ asset register in place for the medical device
- report problems encountered with medical devices to the device manufacturer and also to the Irish Medicines Board.

Ensure that all medical devices carry a CE mark* for the appropriate intended use and are purchased from a reputable supplier who can provide the relevant support and traceability.

Ensure all 'Acknowledgment Forms' are returned to the manufacturer or distributor when field safety corrective actions are being carried out, even in cases where the FSCA does not impact the hospital directly

**Per Article 4 of Medical Device Directive MDD 93/42/EC and Active Implantable Directive AIMD 90/385/EC, medical devices intended for clinical investigation and custom-made devices are not required to bear the CE marking. Similarly, per Article 16 of the In Vitro diagnostic medical devices directive IVD Directive 98/79/EC, devices other than devices for performance evaluation must bear the CE marking of conformity.*

RECOMMENDATIONS SPECIFIC TO DEVICES IN A HOSPITAL SETTING

The IMB recommends the implementation of a comprehensive medical device and equipment management system (e.g. computerised database) in all hospitals to capture all aspects pertaining to the device lifecycle.

The system should be applicable to all medical devices, whether they are consumables or implants used within the hospital setting only or used by a patient after they have been discharged from the hospital, for example coagulation monitors, pacemakers or assistive technology. The system should include consumable medical devices such as blood collection tubes, surgical swabs and syringes and must be capable of providing a complete audit trail.

Individuals should be identified at each specific location in which a device is placed and assigned the responsibility for keeping device related information up to date.

Where a patient leaves the hospital setting with a medical device the responsible personnel should ensure that all relevant information relating to the patient and the specific devices (e.g. blood glucose meters, implants, pumps, CPAP devices) are added to the database prior to patient discharge.

The system should include a record of all implanted medical devices with the information required to identify specific devices implanted in patients.

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Individuals responsible for the placement / provision of medical devices in the hospital setting should maintain the system with up-to-date information:

- Device specific information including individual identification number, lot number, manufacturer contact details, instructions for use, maintenance log and schedule
- User/patient information
- Location of the device
- Distributor information and contact details

A procedure should be in place to provide guidance on the information that should be recorded when an incident involving a medical device occurs. This is essential to allow a timely and thorough investigation to be carried out. The information should include:

- the name and contact details of the user of the device at the time of the incident;
- the lot or batch number of the device
- full details of the incident, including patient outcome
- the date the incident occurred
- the location of the device. It is advised that any device involved in an incident should be placed into quarantine to allow analysis of the device as part of the investigation.

RECOMMENDATIONS SPECIFIC TO DEVICES IN A COMMUNITY SETTING

The IMB recommends the implementation of a computerised system for tracking of all medical devices in use in a community setting. This should also include devices used for Point of Care Testing in Primary and Community Care settings.

Individuals should be identified who have overall responsibility for keeping device related information up to date.

Where a patient leaves the community setting with a medical device (e.g. blood glucose meters, insulin pumps, CPAP devices) the responsible personnel should ensure that all relevant information relating to the patient and the specific devices are added to the database system prior to patient discharge. The information recorded should include:

- Device specific information including individual identification number, lot number, manufacturer contact details, instructions for use, maintenance log and schedule
- User/patient information
- Location of the device
- Distributor information and contact details

Patients should be made aware of any consumable components that are used with or as an accessory to the medical equipment they are being prescribed. They should be instructed to record relevant information (batch number, part number) of the consumable components, in addition to medical equipment information, when reporting incidents relating to use of their devices.

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- the name and contact details of the user of the device at the time of the incident;
- the lot or batch number of the device

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- full details of the incident, including patient outcome
- the date the incident occurred
- the location of the device. It is advised that any device involved in an incident should be placed into quarantine to allow analysis of the device as part of the investigation.

Where healthcare staff and prescribers are asked for advice from the public on private purchase of medical devices directly from medical device suppliers/distributors, individuals should be advised to choose a reputable supplier who can provide the relevant follow up and traceability.

RECOMMENDATIONS SPECIFIC TO MEDICAL DEVICE DISTRIBUTORS

The IMB recommends the implementation of a computerised system for tracking of all medical devices purchased by distributors.

The system should contain up-to-date information including:

- Device specific information such as individual identification number, lot/batch number and manufacturer contact details on receipt of devices
- Customer information and contact details and batch specific location of devices

The IMB recommends distributors of medical devices to familiarise themselves with the legislation governing the medical devices, in particular the section relating to vigilance reporting of incidents. Distributors should familiarise themselves with the guidance document "Guidelines on a medical device vigilance system" MEDDEV 2.12-1 rev6.

Ensure a complaint and incident reporting policy is included in the contract with the manufacturer. A policy covering responsibility for carrying out field safety corrective actions should also be agreed.

If purchasing medical devices from a non European-based manufacturer check that there is an authorised representative within the European Community identified for the devices.

Refer to IMB Newsletter No 24 – December 2008 for additional information on the role of distributors of medical devices.

RECOMMENDATIONS SPECIFIC TO PATIENTS AND DIRECT USERS

Ensure that the appropriate personnel (healthcare facility/distributor/manufacturer) are notified of changes to contact details so that the most up to date information is available should a field safety corrective action occur.

When directly supplied with medical devices (e.g. via the internet) individuals should ensure that all medical devices carry a CE mark for the appropriate intended use and are purchased from a reputable supplier who can provide the relevant support and traceability.

Patients should be aware of any consumable components that are used with or as accessory to the medical equipment they are prescribed. They should record relevant information (batch number, part number) of the consumable components, in addition to medical equipment information, when reporting incidents relating to use of their devices.

Refer to IMB brochures "Buying medical devices for personal use", "Medical devices in the home" and "Buying medical devices online" for additional advice.

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APPENDIX II CASE STUDIES

SINGLE-USE, DISPOSABLE SURGICAL SWABS

SCENARIO:
During a surgical procedure a nurse noticed a defect with a number of surgical swabs that may compromise sterility of the swabs. The manufacturer identified an issue with multiple batches of swabs and initiated a recall of specific batches.

OUTCOME:
The manufacturer and distributor did not maintain batch specific records and could not locate the batches that were required to be recalled. A general notification was distributed to all potentially affected centres. The hospitals reported that the swabs were distributed to numerous departments within the hospital and they could not locate the affected swabs or verify if the affected lots had been used.

AUTOMATED EXTERNAL DEFIBRILLATORS (AED)

SCENARIO:
AEDs are distributed widely to community centres, sports facilities, community halls and libraries to allow a rapid response to sudden cardiac arrests. The manufacturer of a particular AED device discovered that their devices needed a modification to one of its components to ensure proper functioning of the device.

OUTCOME:
The distributor of the device did not have direct contact details for the responsible personnel at the centres where the devices were distributed. The community centres could not verify where the devices were located within their facilities and did not have adequate records of the maintenance performed on the devices to determine if their devices were affected by the FSCA.

ORTHOPAEDIC IMPLANTS

SCENARIO:
The manufacturer of an orthopaedic implant discovered that various lots of the device were not manufactured to specification. The defect could lead to premature failure of the device when implanted. The affected lots were distributed to numerous hospitals and implanted in a number of patients. The manufacturer issued a field safety notifice (FSN) instructing a recall of the affected devices in stock and recommending review of patients who may have been implanted with an affected device.

OUTCOME:
The manufacturer was unable to identify the location of all affected products. The distributor did not maintain records of where specific lots of the device were distributed. The hospital where the devices were implanted did not keep records of the specific lot number of the device implanted into each patient.

PATIENT HOISTS

SCENARIO:
Patient hoists are used for repositioning or transporting immobilised patients. A manufacturer discovered that the controls of a particular hoist needed to be replaced to prevent uncontrolled movement of the device. The manufacturer sent an advisory letter to their distributor to instruct all users of the device to contact the manufacturer to arrange a modification of the affected devices.

OUTCOME:
The manufacturer and distributor contacted the centres where the devices had been supplied and were informed that the devices had been distributed to different centres

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and to patients' homes. Records of the final location of the device were incomplete. No responses were received from a number of patients supplied with the device. The manufacturer was unable to perform the necessary safety related upgrades to all affected devices.

REFERENCED DOCUMENTS

IMB Safety Notice SN2003(08) Equipment Management: Guidance for the Maintenance and Timely Replacements of Medical Equipment

IMB Safety Notice SN2003(09) Equipment Management: Some Basic Principles of Equipment Management

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

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

IMB Safety Notice SN2009(11) Automated External Defibrillator (AED)/ Public Access Defibrillator (PAD)

IMB Medical Device brochures:

- Buying medical devices for personal use
- Medical devices in the home
- Buying medical devices online

IMB Newsletter December 2008 No 24: Medical Devices and the Distributor

IMB Newsletter May 2004 No 8: Medical Devices in a Community Setting

The Health Service Executives' "Medical Devices/Equipment Management Policy" document (Document Reference Number OQR030)

The Health Service Executives' "Medical Devices/Equipment Management, Compliance with the HSE's Medical Devices Equipment Management Standard, Guidance for Service Areas" document (Document Reference Number OQR031)

Statutory Instrument No 252 of 1994, European Communities (Medical Devices) Regulations, 1994

Statutory Instrument No 253 of 1994, European Communities (Active Implantable Medical Devices) Regulations, 1994

Statutory Instrument No 304 of 2001, European Communities (*In Vitro* Medical Devices) Regulations, 2001

Statutory Instrument No 478 of 2002, European Communities (Medical Ionising Radiation Protection) Regulations, 2002

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ENQUIRIES

All adverse incidents relating to a medical device should be reported to the:

Irish Medicines Board
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2
Telephone: +353-1-6764971
Fax: +353-1-6344033
E-mail: vigilance@imb.ie
Website: www.imb.ie