IRISH MEDICINES BOARD

MEDICAL DEVICE

SAFETY NOTICE

Medical Devices Recommended by Healthcare Institutions for Use in a Community Setting

IMB Safety Notice: SN2007(06)

MANUFACTURER / SUPPLIER

Various

TARGET GROUPS

This safety notice is primarily aimed at those responsible for prescribing, distributing or placing medical devices for use in the community. While this document aims to highlight some key recommendations in relation to this issue it is recognised that some may be difficult to action at present.

Hospital Consultants
Non-Consultant Hospital Doctors
Chief Executive Officers of Hospitals
General Practitioners
Risk Managers
Public Health Nurses
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

SAFETY NOTICE

Health Service Executive
Primary, Community & Continuing Care
Clinical Engineers
Laboratory Managers

ISSUE

The use of medical devices in a community setting continues to increase. This provides many benefits and new treatment options but results in new types of risks and challenges in ensuring medical devices are both prescribed and used appropriately, effectively and safely in the community.

BACKGROUND

This notice focuses on medical devices that are prescribed or arranged by healthcare professionals (doctors, nurses, occupational therapists, physiotherapists etc.) for use by patients or their carers in a community setting.

Medical devices used in the community have become more sophisticated and complex with such devices ranging from dentures and hearing aids through glucometers, nebulisers to more complex infusion pumps and continuous positive airway pressure (CPAP) units. This includes many custom made devices and assistive technology devices. While this increased sophistication allows more scope to treat a greater variety of medical conditions in the community setting it also results in more complex risks and safety issues. The experience of the Irish Medicines Board in undertaking its role of post-market surveillance of medical devices suggests that medical devices may be frequently 'lost to follow up' with inadequate systems in place to trace devices and monitor their ongoing effective operation and management. It is crucial that such medical devices are suitable for use in non-hospital environments and that the benefits gained from using devices in a community setting outweigh any resultant risks.

The potential for serious adverse incidents associated with medical devices in the community due to device malfunction or misuse may be a cause for concern and highlights key safety and management issues.

Points to note include:

1. The need for appropriate device maintenance and servicing
2. The need for device traceability in the event of an identified device problem / fault and any necessary field corrective action
3. The need for appropriate training in device usage
4. The requirement for appropriate device storage and usage conditions
5. The need for clear governance structures to oversee community devices at a local level

S A F E T Y

NOTICE

ACTION OR RECOMMENDATIONS

<u>Section 1</u>: Actions and Recommendations for Healthcare Staff and Prescribers providing Medical Devices through the Irish Healthcare System e.g. HSE, Voluntary Hospitals, Private Hospitals, etc:

- Medical devices that are prescribed / provided for use into the community should be suitable for use in that setting and by the proposed lay user.

- Users of medical devices in the community and their carers (if applicable) should be fully aware of the instructions for the safe and effective use of their device. This is of particular importance if there is any concern about the user's ability to use the device or understand the instructions for use e.g. declining cognitive function;

- When necessary, appropriate training should be directed to users and other designated individuals e.g. family members, carers etc, to ensure correct and safe device use. This would be particularly relevant for more complex medical devices such as infusion pumps and CPAP units. Training should be provided by appropriately qualified individuals with refresher courses / updates offered when applicable. Records should be kept of all user training courses provided;

- Medical devices should be stored and used in suitable environmental conditions and according to manufacturer recommendations. The user must be able to provide suitable and secure storage conditions for devices to ensure optimal performance and prevent device misuse;

- An adequate system should be in place to ensure routine maintenance and regular servicing in accordance with the manufacturer's recommended schedule. Maintenance, servicing and repair should be undertaken by authorised and suitably qualified individuals.

- Specific individuals should be identified at each local community level whose responsibility is to ensure routine device maintenance is performed and records are kept of device servicing and repair.

- Individuals responsible for the placement / provision of medical devices to the community setting should maintain up-to-date systems to ensure that devices are readily <u>traceable</u> in the event of a device corrective action or product recall occurring.

- Device user, distributors and manufacturers should cooperate fully and develop quality traceability systems. Devices users are strongly encouraged to complete any relevant warranty cards and participate in any device registration schemes.

S A F E T Y

NOTICE

- Consumable components e.g. glucose test strips, necessary for continued use of the device and / or any relevant ancillary equipment should be prescribed/ supplied along with the device and be readily available when replacements are required. Consumables / ancillary equipment should also be used, stored and maintained as appropriate;

- Devices distributed to multiple consecutive patients must be appropriately cleaned, decontaminated, sterilised and serviced, as applicable, prior to distribution to the next patient. Appropriate device user records should be updated accordingly to ensure continued traceability. A device traceability system could have alert levels set to indicate when a specific device is reaching the end of its intended service life;

- Devices for use in the community setting on an ongoing basis should have regular risk assessments performed to determine if an individual device should be kept in service, particularly if the device is used beyond its intended service life. This is of particular relevance for devices distributed to multiple consecutive patients.

- Individuals should be identified at each specific location in which a device is placed with overall responsibility for each device and examining any adverse incidents that result from device use.

- When a device is deemed to have reached the end of its service life it should be disposed of safely and responsibly. Records should be updated accordingly when a device has been disposed of. Advice and recommendations for appropriate device disposal should be sought from the device manufacturer.

- Adverse incidents in which actual or possible injury or harm resulted from the use of a medical device should be reported to the device manufacturer who is legally obliged to inform the Medical Devices Department of the Irish Medicines Board. Device users are strongly recommended to report problems encountered with medical devices to the device manufacturer and also to the Irish Medicines Board.

SAFETY NOTICE

<u>Section 2</u>: Actions and Recommendations for Healthcare Staff and Prescribers 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;

- Individuals should ensure that the medical device that they purchase carries a CE mark for the appropriate intended use. All medical devices must be CE marked as this is an indication that the device conforms with the requirements of the European medical device regulations;

- Individuals should be strongly advised not to consider purchase of medical devices making medical claims which do not carry a medical device CE mark;

- Device users should ensure that they are provided with instructions for use of the device, if applicable. All potential users, including carers, should be fully aware of these instructions for safe, effective and optimal device use. Appropriate training, if required, should be sought either from the device supplier or from any appropriately accredited institution;

- Individuals should be made aware of the importance of ensuring routine device maintenance and regular servicing is undertaken to maintain optimal device performance. This should be sought from an appropriately qualified source;

- Users should be advised to maintain an adequate supply of consumable components necessary for the use of the device and / or any relevant ancillary equipment which should be kept in the proximity of the device;

- Users should be aware of who to contact in the event of problems or failure of their device;

- Individuals should be advised to dispose of their device appropriately and responsibly. Records should be updated accordingly when a device has been disposed of. Advice and recommendations for appropriate device disposal should be sought from the device manufacturer.

- Adverse incidents in which actual or possible injury or harm resulted from the use of a medical device should be reported to the Medical Devices Department of the Irish Medicines Board. Device users are strongly recommended to report problems encountered with medical devices to the device manufacturer and to the Irish Medicines Board.

SAFETY NOTICE

REPORTING OF ADVERSE INCIDENTS

All adverse incidents relating to a medical device should be reported to the Medical Devices Department at the Irish Medicines Board.

Adverse incidents may be reported via our **on-line vigilance reporting system,** which can be accessed on the IMB website www.imb.ie, or by completing a **Medical Device Adverse Incident User Report Form,** which is available on request from the IMB or may be downloaded from the IMB website.

ENQUIRIES

If you have any enquiries, you may contact the Medical Devices Department at:

Irish Medicines Board
Medical Devices Department
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
Fax: +353-1-6344033
Email: medicaldevices@imb.ie
Website: www.imb.ie

SAFETY NOTICE

Appendix 1: Further Reading

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

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

IMB Newsletter May 2004 Vol.1. No. 8: Medical Devices in a Community Setting

Medical Devices Directive 93/42/EEC

Active Implantable Medical Devices Directive (90/385/EEC)

SAFETY NOTICE