HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

Medical Devices in the Home

Priority 3 – Advisory

HPRA Safety Notice: SN2015(02) **Issue Date: 2nd February 2015**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Various	N/A

ISSUE
Medical devices that are used in the home have become more sophisticated and complex ranging from hearing aids and nebulisers to more complex infusion pumps and continuous positive airway pressure (CPAP) units. *In vitro* diagnostic medical devices such as blood glucose meters and INR self testing devices are also routinely used. The benefits are wide-ranging; including improved quality of life and reduced cost of care. The Health Products Regulatory Authority (HPRA) recognises the importance of safe, high-quality medical devices that are capable of meeting patients' needs in the home. However, there are risks and challenges in ensuring that medical devices are both prescribed and used effectively and safely in this setting. It is fundamental that good medical device management is adhered to in order to reduce the potential for harm associated with the use of medical devices in this environment. This safety notice is aimed at those responsible in hospital and community based organisations for providing, distributing, deployment, maintenance and repair of medical devices for use in the home setting. Advice is also provided for carers and family members of medical device users in the home.

ACTION OR RECOMMENDATIONS

A) Advice for healthcare staff providing medical devices to service users in the home:

1. For effective management of medical devices in the home setting the HPRA recommends that each facility has a policy on the management of medical devices to include: acquisition, deployment, use, monitoring, maintenance, tracking decontamination and disposal.

2. Medical devices that are provided for use in the home should be suitable for use in that setting and by the proposed device user.

3. Appropriate training should be directed to device 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 hoists, 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.

4. Advise device users to alert their electricity supplier as a Priority Register exists for customers who depend on electrically powered equipment such as home dialysis machines, oxygen concentrators or artificial ventilators. Application forms for the Priority Register are available from your supplier. Further information can also be found at the following links: http://www.citizensinformation.ie/en/consumer_affairs/energy_and_water_services/electricity_services_in_ireland.html

5. A system should be in place to ensure that medical devices which require routine maintenance and regular servicing are managed 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.

6. Individuals responsible for the placement / provision of medical devices to users in the home setting should maintain up-to-date systems to ensure that devices are readily traceable in the event of a market action e.g. product recall.

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

8. Devices distributed to multiple consecutive users must be appropriately cleaned, decontaminated, sterilised and serviced, as applicable, prior to distribution to the next device user. 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.

9. Devices for use in the home setting should have regular risk assessments performed on an ongoing basis to determine if an individual device should be kept in service

and to ensure the device is not used beyond its intended service life. This is of particular relevance for devices distributed to multiple consecutive device users.

10. 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.

11. Medical devices must be CE marked as this is an indication that the device complies with the requirements of the European medical device regulations.

12. Users should be referred to the HPRA's Medical Devices Information Leaflet 'Medical Devices in the Home' for more advice on medical devices in the home: http://www.hpra.ie/docs/default-source/publications-forms/information-leaflets/hpra_medical-devices_home_web.pdf?sfvrsn=6

B) Advice for users and carers / family members of device users provided with medical devices in the home:

1. Device users should ensure that they receive and follow the instructions for use that are provided with the medical device, if applicable. Appropriate training if required, should be sought from the medical device supplier / manufacturer.

2. Refer to the user manual or instructions for use with regard to device maintenance or seek advice from the person who provided your medical device.

3. Alert your electricity supplier as a Priority Register exists for customers who depend on electrically powered equipment such as home dialysis machines, oxygen concentrators or artificial ventilators. Application forms for the Priority Register are available from your supplier.
   Further information can also be found at the following links:
   http://www.citizensinformation.ie/en/consumer_affairs/energy_and_water_services/electricity_services_in_ireland.html

4. Store and use medical devices in suitable environmental conditions and according to manufacturer recommendations to ensure optimal performance and prevent device misuse.

5. You are strongly encouraged to complete any relevant warranty cards and participate in any device registration schemes.

6. Maintain an adequate amount of consumables and / or any relevant ancillary equipment necessary for the user of the device

7. Where appropriate, ensure that the device is used within the stated shelf-life / expiry date provided by the manufacturer.

8. Be aware of who to contact in the event of problems with or failure of a device.

9. Dispose of devices appropriately and responsibly. Advice and recommendations for appropriate device disposal should be sought from the device manufacturer.

10. Return equipment when it is no longer needed / unsuitable.

C) Advice for users and carers / family members of device users purchasing medical devices in the home:

In addition to the above in part B;

11. Consult your healthcare professional to determine the medical device that is most suitable for your needs.

12. Choose a reputable supplier who can provide the relevant follow up and traceability.

13. Ensure that the medical device that you 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 complies with the requirements of the European medical device regulations.

TARGET GROUPS

Patients / device users
Carers / family members
Healthcare professionals

BACKGROUND

The potential for serious adverse incidents associated with the use of medical devices in the home due to device malfunction or misuse is a cause for concern and this safety notice aims to highlight key safety and management issues.

It is crucial that such medical devices are suitable for use in non-hospital environments and that a risk – benefit strategy is put in place to ensure that the benefits gained from using devices in a home setting outweigh any risks. The experience of the HPRA in undertaking its role in relation to market surveillance of medical devices indicates that it is not always possible to locate medical devices, with inadequate systems in place to trace devices and monitor their ongoing effective operation and management.

It is also important to ensure that individuals and organizations involved in prescribing, distributing, deployment, maintenance, repair and disposal of medical devices for home use have systems in place to confirm that medical devices are managed in a way which complies with the relevant legislation.

The HPRA advises that medical device management is crucial to ensuring safe and effective use of devices in the home setting.

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 Vigilance section of the HPRA. Device users are strongly recommended to report all adverse incidents, including user problems with a device, software failures or problems with the instructions for use, encountered with medical devices to the device manufacturer and also to the HPRA.

MANUFACTURER / DISTRIBUTOR CONTACT INFORMATION

Enquiries to the **manufacturer** should be addressed to the contact details found on the device labelling / instructions for use.

HPRA CONTACT INFORMATION

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

Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
Fax: +353-1-6344033
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie