HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Medical Device Vigilance
Competent Authority Perspective

Introduction

Medical devices and *in-vitro* diagnostic (IVD) medical devices are of increasing importance to public health and the provision of medical care. It is essential that the regulatory system creates a framework for safe, effective and innovative medical devices including IVD medical devices.

The vigilance system achieves its objectives in several ways:

- manufacturers and users submitting vigilance reports (incidents and field safety corrective actions) to the relevant competent authorities (the HPRA in Ireland);
- the evaluation of reports by the competent authorities;
- the dissemination of information, which may be used to prevent recurrence of the incident, or to alleviate the consequences of such incidents, in cases when it is necessary to do so;
- by the device being updated, modified or taken off the market in cases when it is necessary to do so.

Further guidance on the vigilance system may be found in the 'European Guidelines on a Medical Devices Vigilance System (MEDDEV 2.12/1)[1]'. This and related guidance may be found on the European Commission website www.ec.europa.eu.

The European medical device vigilance system was set up under the medical device directives (93/42/EEC, 90/385/EEC, and 98/79/EC) to minimise risks to the safety of patients, users and others. The Directives include requirements for medical device manufacturers to report certain types of events to the competent authority (CA). In Ireland the Health Products Regulatory Authority (HPRA) is the competent authority for medical devices.

Reporting

There is a mandatory requirement for manufacturers to report vigilance issues in line with the European Guidelines on a Medical Devices Vigilance System (MEDDEV 2.12/1[1]). Manufacturers are required to implement a systematic procedure to review experience gained from devices and ensure that any risks or problems associated with the use of their device are identified at an early stage and are reported to competent authorities so that appropriate action is taken.

In relation to user reporting, the HPRA currently operates a voluntary system whereby a user, healthcare professional or any other person who identifies a medical device safety issue can report it

1. Guidelines on a Medical Devices Vigilance System MEDDEV 2.12-1
http://ec.europa.eu/health/medical-devices/documents/guidelines/index_en.htm

to the HPRA. The HPRA strongly encourages healthcare professionals and members of the public who have encountered a safety issue with a medical device that they have used to report the issue. Increased levels of reporting from healthcare professionals and other device users may help in the early detection of adverse trends or safety issues.

Dissemination of Information

A key part of the medical device vigilance system is the dissemination of information, which aims to prevent recurrence of the incident or to alleviate the consequences of such incidents. Medical device safety communications that are circulated to healthcare professionals and medical device 'users' may be divided into two main groups:

- Communications that are circulated by the manufacturer or their local agent – field safety notice (FSN).
- Communications that are circulated by a regulatory agency.

A FSN is the communication format that a manufacturer must use to communicate such safety related issues to the customers and/or users of the device. Examples of those actions that can be communicated via a FSN include:

- the return of a medical device to the supplier (recall);
- device modification;
- device exchange;
- device destruction;
- retrofit by purchaser of manufacturer's modification or design change;
- advice given by manufacturer regarding the use of the device (e.g. where the device is no longer on the market or has been withdrawn but could still possibly be in use e.g. implants or change in analytical sensitivity or specificity for diagnostic devices)

This is quite broad reaching as a device modification can include:

- permanent or temporary changes to the labelling or instructions for use;
- software upgrades including those carried out by remote access;
- modification to the clinical management of patients to address a risk of death or serious deterioration in state of health related specifically to the characteristics of the device.

The guidelines state that the FSN should be on a company letterhead, be written in the language(s) accepted by the national competent authority(s) and include the following:

- A clear title, with 'Urgent FIELD SAFETY NOTICE' followed by the commercial name of the affected product, an identifier (e.g. date) and the type of action.
- Specific details to enable the affected product to be easily identified e.g. type of device, model name and number, batch/lot or serial numbers of affected devices and part or order number.
- A factual statement explaining the reasons for the action, including description of the device deficiency or malfunction, clarification of the potential hazard associated with the continued use of the device and the associated risk to the patient, user or other person and any possible risks to patients associated with previous use of affected devices.
- Advice on actions to be taken by the user. Include as appropriate:
    - identifying and quarantining the device,

  - method of recovery, disposal or modification of device
  - recommended review of patients previous results or patient follow up, e.g. implants, IVD.
  - timelines.
- A request to pass the field safety notice to all those who need to be aware of it within the organisation and to maintain awareness over an appropriate defined period.
- If relevant, a request for the details of any affected devices that have been transferred to other organisations, to be given to the manufacturer and for a copy of the field safety notice to be passed on to the organisation to which the device has been transferred.
- If relevant, a request that the recipient of the field safety notice alerts other organisations to which incorrect test results from the use of the devices have been sent. For example failure of diagnostic tests.
- Confirmation that the relevant national competent authorities have been advised of the field safety corrective action.
- Any comments and descriptions that attempt to
  - serve to play down the level of risk in an inappropriate manner
  - advertise products or services

  should be omitted.
- Contact point for customers how and when to reach the designated person. An acknowledgment form for the receiver might also be included (especially useful for manufacturer's control purposes).

The manufacturer can send the FSN by post, email, fax or in some instances may hand deliver the notice. The manufacturer may address the FSN to the healthcare professionals impacted by the issues outlined in the communication e.g. theatre staff, clinical engineering, lab managers, specific clinical specialities or in some instances where the devices are used by multiple departments the manufacturer may address the notice to the CEO, the risk manager or the procurement department.

The manufacturer often includes an acknowledgement form / fax back form with the FSN which he requests the recipient to return. This form can request acknowledgment of the receipt of the letter and further details regarding the numbers of affected devices etc.

A monthly listing of field safety notices relating to actions that have impacted the Irish market is published on the HPRA website www.hpra.ie.

The HPRA also communicates with healthcare professionals and medical device 'users' in many different formats:

- Safety notices
- Information leaflets
- Surveys
- Targeted letters
- Information days
- Journal articles
- Newsletters
- Presentations at conferences
- Information notices

HPRA safety notices are considered a key tool for communicating important medical device issues. The aim of HPRA safety notices is to advise the user of the device, whether at home, in a hospital or in a community setting, of important information regarding the safe use of their medical device.

Further details on the format of a HPRA safety notice can be found in the HPRA Safety Notice SN2014(16): New Format of HPRA Safety Notices.