HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

Manufacturer Field Safety Notices & HPRA Safety Notices

Priority 3 – Advisory

HPRA Safety Notice: SN2016(01) **Issue Date: 08 January 2016**

ISSUE

The HPRA would like to highlight the importance of manufacturer field safety notices (FSNs) in relation to medical device safety issues.

FSNs issued by manufacturers are generally the first communication issued to healthcare professionals and medical device users when a safety issue arises with a medical device. FSNs contain important safety information relating to medical devices. Healthcare professionals and medical device users should read and follow, as appropriate, the advice provided in manufacturer FSNs.

HPRA safety notices are only issued for a small percentage of the overall FSNs distributed in Ireland. HPRA safety notices are normally issued after the manufacturer's FSN has been circulated to the Irish market and are intended to supplement the manufacturer's FSN.

ACTION OR RECOMMENDATIONS

1. Healthcare professionals and medical device users are encouraged to familiarise themselves with FSNs and HPRA safety notices and to follow the advice provided in both communications, as appropriate.

2. Systems / structures should be in place to ensure that the FSN reaches the appropriate healthcare professionals and medical device users.

3. Healthcare professionals and medical device users should acknowledge receipt of the FSN.

4. Healthcare professionals and medical device users should cooperate with the manufacturer to ensure the action is carried out, as appropriate.

5. The HPRA recommends that healthcare professionals and medical device users regularly review the listing of manufacturer FSNs relating to actions impacting the Irish market, which is published on the HPRA website www.hpra.ie each month.

TARGET GROUPS

All medical device users

BACKGROUND

A key part of the medical device vigilance system is the dissemination of information, which may be used to prevent recurrence of an 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 – FSNs
- Communications that are circulated by a regulatory agency – safety notice

Manufacturer Field Safety Notices (FSNs)

A FSN is the communication format that a manufacturer must use to communicate safety related issues to 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 and/or the follow up of patients, users or others (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).

Device modifications are quite broad reaching and can include:

- permanent or temporary changes to the labelling or instructions for use;
- software upgrades following the identification of a fault in the software version already in the field, regardless of whether the software update is being implemented by customers, field service engineers or by remote access;
- modification to the clinical management of patients/samples to address a risk of death or serious deterioration in state of health related specifically to the characteristics of the device.

The European guidelines on a medical devices vigilance system (MEDDEV 2.12/1) give clear instructions on the format to be used by manufacturers when issuing a FSN.

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 the manufacturer requests the recipient to return. This form can request acknowledgment of receipt of the letter and further details regarding the number of affected devices, etc.

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

HPRA Safety Notices

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. In practice, HPRA safety notices are only issued for a small percentage of the overall FSNs distributed in Ireland. The recipient of the safety communication should ensure that the communication reaches the most appropriate personnel within their organisation. The recipient should also ensure that the issue outlined in the notice is considered, the risks assessed and the appropriate / recommended actions are completed.

The HPRA circulates safety notices in many instances. Some examples are included below:

- To highlight a serious public health issue.
- To draw attention to field safety corrective actions which, following a HPRA risk assessment, are deemed to be related to medium or high risk safety issues.
- To highlight an issue that has already been communicated by a manufacturer via a field safety notice but where the manufacturer has indicated to the HPRA that they have experienced difficulty reaching all customers or obtaining feedback from all customers.
- To highlight an issue when either the device manufacturer or distributor to the Irish market no longer exists. For example, where the manufacturer has gone into liquidation or where the manufacturer is not known e.g. counterfeit devices.
- To communicate concerning trends identified by the HPRA in relation to particular product families.
- To communicate safety concerns identified by the HPRA in monitoring vigilance issues e.g. equipment management issues and traceability issues.

Safety notices are published on the HPRA website www.hpra.ie and are circulated, at the time of publication, to healthcare professionals who have subscribed to the HPRA mailing list. The HPRA also circulates, via email, a listing of HPRA safety notices at the end of each calendar month.

HPRA CONTACT INFORMATION

For all **queries** relating to this safety notice, please contact the HPRA using the following contact details:

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