IRISH MEDICINES BOARD

Notice Information: - Advisory
31 March 2014

Part 1. Product Information

a)	Title:	New Format of IMB Safety Notices. Priority 3 - Advisory
b)	Product Name/Type:	New Format of IMB Safety Notices. Priority 3 - Advisory
c)	Reference:	SN2014(16)
d)	Manufacturer/Supplier:	N/A

Part 2. Target Audience

a)	Target Audience:	All medical device users.

Part 3. Problem/Issue

a)	Problem/Issue:	Based on feedback received from our stakeholder communications questionnaire and discussions with various interested bodies, the IMB has revised the format of medical device safety notices.

Part 4. Background Information

a)	Background Information:	A key part of the medical device vigilance system is the dissemination of information, which may be used to prevent recurrence of the incident or to alleviate the consequences of such incidents. The aim of IMB safety notices is to advise the user of the device, whether that is at home, in a hospital or in a community setting, of important information regarding the safe use of their medical device. The IMB 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 an IMB 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 IMB 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 IMB in relation to particular product families. • To communicate safety concerns identified by the IMB in monitoring vigilance issues e.g. equipment management issues and traceability issues. Due to the varying nature of these safety notices, the IMB intends to pri

prioritise these communications. A traffic light system of red, amber and green will be used to aid in dissemination of safety information. The proposed system is risk based and is outlined in a table in the PDF version of this Safety Notice below.

All safety notices will be assigned a priority number (1-3) and will be categorised as outlined in the table (see PDF version of this Safety Notice below for table). The examples included in the third column of the table are not an exhaustive list.

For the coming months the new format safety notices will continue to be placed on the IMB website under the 'Advisory' notice type. The priority will be indicated on the safety notice heading. The IMB website will be updated in the coming months.

The new format will also provide information on the target audience, the background to the issue and details of the recommended actions.

In practice, IMB 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.

In some instances, the recipient of the notice may not be the most appropriate person to deal with the issue, therefore a well defined, effective mechanism for managing the communications is necessary. Some organisations, hospitals and the community care setting have found that it is very beneficial to have one designated medical device vigilance contact, a local medical device vigilance team that meet to assess the issues that arise, local medical device vigilance procedures and a database to support the management of such communications. Such structures and defined responsibilities and processes help to ensure that the communications are dealt with in a timely manner.

Another key element of the vigilance system is user reporting. The IMB

currently operates a voluntary system whereby a user, healthcare professional or any other person who identifies a medical device safety issue can report it to the IMB. The IMB 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 this to the IMB.

Safety notices will be published on the IMB website (www.imb.ie) and will continue to be circulated, at the time of publication, to healthcare professionals who have subscribed to the IMB mailing list. The IMB will also circulate, via email, a listing of IMB safety notices at the end of each calendar month.

The IMB will no longer circulate MHRA medical device alerts (MDAs). Medical device users can continue to receive MDAs by registering with the MHRA website.

Part 5. Action to be taken

a) Action to be taken:

Medical device users are encouraged to familiarise themselves with the new safety notice format. Where appropriate, the IMB will endeavour to include a picture to assist users in identifying the affected medical devices and understanding the issue.

Part 6. Enquiries

a) All enquiries should be made to:

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

Irish Medicines Board

Human Products Monitoring

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

Please click here to view a PDF version of this Safety Notice