IRISH MEDICINES BOARD

GUIDE TO FIELD SAFETY CORRECTIVE ACTIONS FOR MEDICAL DEVICES AND *IN-VITRO* DIAGNOSTIC MEDICAL DEVICES

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This guide does not purport to be an interpretation of the law and/or regulations and is for guidance purposes only.

CONTENTS

1. SCOPE

The Irish Medicines Board (IMB) is the Competent Authority (CA) in Ireland for medical devices. This guide outlines how to achieve an effective interface between the legal manufacturers or their authorised representatives and the IMB in the event of a field safety corrective action (FSCA) for a medical device, active implantable medical device or an *in-vitro* diagnostic medical device and associated accessories. It aims to describe what an FSCA is and clarifies the role played by the legal manufacturer or authorised representative and by the IMB in ensuring that an efficient and effective FSCA is carried out.

2. INTRODUCTION

There are three Directives and related Irish Regulations that are applicable to medical devices, active implantable medical device and in-vitro diagnostic medical devices. Under the legislation manufacturers are required to notify the CA of incidents occurring following placing of devices on the market, i.e. Article 10 of Medical Devices Directive (93/42/EEC), Article 8 of the Active Implantable Medical Devices Directive (90/385/EEC) and Article 11 of the In-vitro Diagnostics Medical Devices Directive (98/79/EC).

Regarding serious risk to the safety of patients or other users, Article 14b of Directive 93/42/EEC, Article 13 of IVD Directive 98/79/EC and Article 14 of AIMD Directive 90/385/EEC allows for necessary and justified transitional action in relation to a product or group of products, limiting the availability of such products in order to ensure that public health requirements are observed.

In addition the ‘safeguard clause’ (Article 8 of Directive 93/42/EEC, Article 8 of Directive 98/79/EC and Article 7 of AIMD Directive 90/385/EEC) may be invoked where it is considered that the medical device in question may compromise the health and safety of the patient, users or, where applicable, other persons. If the particular health monitoring measure or safeguard clause is to be used the IMB will notify the EU Commission, member states and the manufacturer giving the reasons for the decision.

3. DEFINITION OF A FIELD SAFETY CORRECTIVE ACTION AND A RECALL

According to the European Commission Guidelines on a Medical Devices Vigilance System MEDDEV 2.12-1 rev 6 the definition for a FSCA is:

“Field safety corrective action is an action taken by a manufacturer to reduce a risk of death or serious deterioration in the state of health associated with the use of a

medical device that is already placed on the market. Such actions should be notified via a field safety notice."

The FSCA may include:

- the return of a medical device to the supplier;
- device modification;
- device exchange;
- device destruction;
- retrofit by purchaser of the manufacturer's modification or design change;
- advice given by the 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).

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.

For example:

- For implantable devices it is often clinically unjustifiable to explant the device. Corrective action taking the form of special patient follow-up, irrespective of whether any affected un-implanted devices remain available for return, constitutes a FSCA.
- For any diagnostic device (e.g. IVD, imaging equipment or devices) the recall of patients for retesting or the retest or review of previous results constitutes a FSCA.
- Advice relating to a change in the way the device is used e.g. IVD manufacturer advises revised quality control procedure - use of third party controls or more frequent calibration or modification of control values for IVDs, constitutes a FSCA.

This guide uses the definition of FSCA as a synonym for **recall** as mentioned in article 10(1), paragraph 1b) of the Medical Device Directive (93/42/EEC) and article 11 *In-vitro* Diagnostic Directive (98/79/EC) since there is no harmonised definition of **recall**.

An FSCA only applies to a medical device that has already been distributed by the manufacturer. An FSCA does not arise when a manufacturer is exchanging or upgrading devices in the absence of a safety risk or when removals from the market are for purely commercial reasons.

The manufacturer should issue field safety notices (FSN) when implementing a FSCA. Copies of FSNs should be sent to the CAs of countries where they are applicable. In addition a copy of the FSN for devices in Class IIa, Class IIb, Class III and IVDs listed in Annex II or those for self testing should be forwarded to the CA in the country where the Notified Body (NB) is situated and which made the attestation which led to the CE marking being attached to the device.

4. DETERMINING THE NEED FOR A FIELD SAFETY CORRECTIVE ACTION

The manufacturer of the medical device in question takes responsibility for determining the need for an FSCA. A number of issues should be considered in determining the need for an FSCA including:

1. The hazard arising from the device shortcoming
2. The probability of the hazard occurring
3. Whether the risk outweighs any possible hazard caused by the FSCA due to its temporary / permanent removal from use, modification, exchange, retrofit or due to new advice being provided by the manufacturer.

An FSCA may be triggered by information indicating an unacceptable increase in risk. This information may arise from post-market surveillance by the manufacturer. On occasions the IMB may advise manufacturers or their authorised representatives to implement an FSCA in relation to a medical device due to a risk of serious injury or death to patients, users or others which has been brought to the attention of the IMB through incident reports or other means.

In certain cases it may be necessary to use precautionary measures in the interest of public health and restrict or prohibit products subject to particular requirements. In other cases for safety reasons it may be necessary to mandate the use of the safeguard clause to remove a medical device from the marketplace.

5. FIELD SAFETY CORRECTIVE ACTION NOTIFICATION TO THE IMB

When a manufacturer or their authorised representative decides to initiate a FSCA he should notify the CA of each Member State in which the FSCA is to be conducted. In addition, the CA of the country where the legal manufacturer / authorised representative resides should be informed.

The notification should be made before or when the FSN is being issued. Where possible, the IMB should be informed of a FSCA prior to its initiation of the action but an urgent FSCA should not be delayed pending IMB notification.

The manufacturer should use the FSCA form to notify the CA of the FSCA. When the action is associated with an incident, the manufacturer should submit the *Manufacturers Incident Report Form* and the *Field Safety Corrective Action Report Form* (using the appropriate forms outlined below).

If a manufacturer or his authorised representative is reporting an incident which has given rise to an FSCA, the incident and the field safety notification may be submitted using the *Field Safety Corrective Action Report Form* and the *Field Safety Notice* template provided in Annex 4 and Annex 5 respectively of the European Commission Guidelines on a Medical Devices Vigilance System MEDDEV 2.12-1 rev 6.

Manufacturers should also consider the notification obligations to their Notified Body and to other regulatory bodies outside of the EEA if the product has been distributed in that territory.

6. INITIAL INFORMATION TO BE PROVIDED TO THE IMB

When the need for an FSCA has been established the manufacturer should gather all relevant information on incident reports, the product and its distribution, and the action proposed. Some information may not be available immediately (e.g. distribution chains, batch size etc.). Notification to the IMB should not be delayed pending collation of these data.

The report should be made using the *Field Safety Corrective Action Report Form* and the *Field Safety Notice* template which are available on request from the IMB or may be downloaded from the IMB website. They can also be obtained in Annex 4 and Annex 5 respectively of the European Commission Guidelines on a Medical Devices Vigilance System MEDDEV 2.12-1 rev 6.

The Field Safety Corrective Action Report Form is divided into the following sections:

Part 1: Administrative information
Part 2: Information on the submitter
Part 3: Manufacturers Information
Part 4: Authorised Representatives Information
Part 5: National Contact Point Information
Part 6: Medical Device Information
Part 7: Description of the FSCA
Part 8: Comments

If the cause of the FSCA is known at the time of issuance of the FSN it should be specified. If distribution is limited, the information given above may be provided over the telephone but in all cases an FSN should be subsequently issued.

In all cases the FSN should be sent to the device user. If the name of the appropriate healthcare user is not known then the FSN should be addressed to the head of the appropriate hospital department, community medical centres and to the chief executive officer and relevant healthcare professional (e.g. pharmacy or GP) as appropriate.

An interim report should be submitted to the IMB providing an update on progress of the reconciliation of stock affected by the FSCA, together with confirmation, where practicable, that the customers have received the FSN. It should also give a progress report on the investigation to date and any corrective action which is being considered.

7. LIAISON WITH OTHER COMPETENT AUHTORITIES

When the IMB acts as the lead CA according to the European Commission Guidelines on a Medical Devices Vigilance System MEDDEV 2.12-1 rev 6, a National Competent Authority Report (NCAR) report is prepared and forwarded to all other EEA member states and the European Commission in the format detailed in Annex 6 of the guideline.

The IMB will inform manufacturers or their authorised representative of actions being taken to advise other EEA states. When an NCAR report is being prepared the manufacturer will usually be contacted and the text verified for accuracy.

8. CORRECTIVE ACTION

On completion of an FSCA the manufacturer or his authorised representative should provide details to the IMB of the proposed corrective action to prevent reoccurrence of the problem that gave rise to the FSCA.

9. WHO TO CONTACT AT THE IMB

When an FSCA is being considered, the Human Products Safety Monitoring Department of the IMB should be contacted, where possible, before initiation.

For further information and for copies of the guidance documents and vigilance forms please contact:

Human Products Safety Monitoring Department
Irish Medicines Board
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
Fax: +353-1-6344033
E-mail: vigilance@imb.ie

Information is also available from the IMB website at www.imb.ie.

APPENDIX 1 CHECKLIST OF KEY ACTIVITIES AND DECISIONS TO AID THE FSCA PROCEDURE

1. Is an FSCA needed?
2. What level of communication is needed?
3. What should users do with affected product?
4. How urgent is this? Should some early warning be provided or can it wait for the FSN
5. Is there a need for recalling or retesting of patients or review of patients results?
6. Draft FSN.
7. Is there time to consult with the IMB regarding the draft FSN?
8. Decision on best method to distribute the FSN letter.
9. What form of proof of delivery / receipt is needed?
10. Agree milestones with the IMB for the interim and final report.
11. Progress FSCA
12. Issue interim report.
13. Progress in-house corrective action to prevent recurrence of the problem.
14. Issue final report to the IMB, including validation of corrective measures.