FINAL DOCUMENT

Global Harmonization Task Force

Title: Medical Devices: Post Market Surveillance: Content of Field Safety Notices

Authoring Group: GHTF SG2

Endorsed by: The Global Harmonization Task Force

Date: 1 May 2006

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The document herein was produced by the Global Harmonization Task Force, a voluntary group of representatives from medical device regulatory agencies and the regulated industry. The document is intended to provide non-binding guidance for use in the regulation of medical devices, and has been subject to consultation throughout its development.

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Preface

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Introduction

Manufacturers or their representatives may sometimes need to undertake corrective or preventative action in relation to their medical devices. These include safety related field corrective actions taken by the manufacturer to reduce the risk of harm to patients, operators or others and/or to minimise the re-occurrence of the event.

1.0 Scope

This document identifies elements that should and should not be included in safety related notifications issued by the medical device manufacturer or its representative.

This document does not cover the distribution method or any requirements for communications to relevant Competent Authorities prior to publication of the safety related notifications.

2.0 References

No references

3.0 Definitions

Field Safety Corrective Action

A field safety corrective action (FSCA) 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.

In assessing the need of the FSCA the manufacturer is advised to use the methodology described in the harmonised standard EN ISO 14971.

This may include:

the return of a medical device to the manufacturer or its representative;
device modification [1];
device exchange;
device destruction;
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given by manufacturer regarding the use of the device (e.g. where the device is no longer on the market or has been withdrawn but could still possibly be in use e.g. implants)

Device modifications may include:

retrofit in accordance with the manufacturer's modification or design change;
permanent or temporary changes to the labelling or instructions for use;
software upgrades including those carried out be remote access;
modification to the clinical management of patients to address a risk of serious injury or death related specifically to the characteristics of the device. For example:

[1] Note: device modifications may need to be approved by the NCA or third parties.

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.
For any diagnostic device (e.g. IVD, imaging equipment or devices) the retesting of affected patients, samples or the review of previous results.
Advice on a change in the way the device is used (e.g. IVDS manufacturer advises revised quality control procedure -use of third party controls or more frequent calibration).

Field Safety Notice

A communication sent out by a manufacturer or its representative to the device users in relation to a Field Safety Corrective Action.

4.0 Content of the Field Safety Notice

The Field Safety Notice should be sent in the official language of the recipient. If the manufacturer or its representative wishes to use another language, a consultation of the competent authority of the recipient is recommended to avoid re-sending requested by the competent authority.

The manufacturer or its representative should use common layout techniques to highlight the most important parts of the letter and to have a clearly arranged notice.

The Field Safety Notice itself should include the following items

- A clear title like "Urgent Safety Notice" on the notice itself, the envelope if sent by mail and the subject line if sent by email or fax
- The intended Audience: clear statement about the intended recipient of the notice.
- Concise description of subject device, model/batch/serial number
- A factual statement explaining the reasons for the FSCA, including description of the problem
- A clear description of the hazards associated with the specific failure of the device and, where appropriate, the likelihood of occurrence, being mindful of the intended audience
- The recommended action(s) to be taken by the recipient of the Field Safety Notice including any action(s) recommended for people that have previously used or been treated by affected devices
- Where appropriate, include time frames by which the action(s) should be taken by the manufacturer and user.
- Designated contact point for the recipient of the Field Safety Notice to use to obtain further information.

The notice may contain a request to inform customers/ or patients who received the product. If relevant, a request for the details of any affected devices that have been transferred to other organisations or have been destroyed to be given to the manufacturer so that follow up can take place and for a copy of the FSN to be passed on to the organisation to which the device has been transferred.

If relevant, a request that the recipient of the advisory notice alerts other organisations to which incorrect test results from the use of the devices have been sent. For example the failure of diagnostic tests.

Manufacturers using a unique reference number to identify the FSCA should include this in the FSN; otherwise include a date (e.g. YYYY/MM/DD).

The Field Safety Notice should NOT include any:

- comments and descriptions that downplay the level of risk
- any information that is intended to promote a manufacturer or their product's market visibility for the purposes of sales and marketing

NOTE: manufacturer or product identifiers that enable or enhance product identification for the purposes of a field safety notice are not considered to be promotional material.