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PROPOSED DOCUMENT

Global Harmonization Task Force

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

Authoring Group: Study Group 2 of the Global Harmonization Task Force

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Preface

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.

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;
- 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given by manufacturer regarding the use of the device (e.g. where the device is no longer on the market or has been withdrawn but could still possibly be in use e.g. implants)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:
    - 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 in relation with 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”,
- The intended Audience: clear statement about the intended recipient of the notice.
- Concise description of subject device, model/batch/serial number
- A statement explaining the reasons for the SFCA, 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.
- A summary of the results and conclusions of the manufacturer’s investigation
- The recommended action(s) to be taken by the recipient of the Field Safety Notice
- 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 or to pass on the letter to other organisations (if appropriate since the manufacturer has no direct access to them).

The Field Safety Notice should NOT include any:

- comments and descriptions that downplay the level of risk
- advertisements.