GHWP

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Towards Medical Device Harmonization

PROPOSED DOCUMENT

Title: Definition and Classification of Field Corrective Actions, including Field Safety Corrective Actions, Recalls and Non-Safety related Field Corrective Actions

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Foreword

This GHWP Document was developed by Global Harmonization Working Party (GHWP) Work Group 4 (Post-market). GHWP is a voluntary group of representatives from medical device regulatory authorities and the medical device industry. The document is intended to provide non-binding guidance for use in the regulation of medical devices, and subject to consultation throughout its development process.

This GHWP Document shall be read in conjunction with the current laws and regulations used in member economies.

Any statements or references from external sources are used under appropriate citations as specified in the normative references and bibliography.

In this GHWP Document, the following verbal forms are used:

— “shall” indicates a requirement;

— “should” indicates a recommendation;

— “may” indicates a permission; and

— “can” indicates a possibility or a capability.

This document cancels and replaces AHWP/WG2/F002:2012, Definition and Classification of Field Corrective Actions, including Field Safety Corrective Actions, Recalls and Non Safety related Field Corrective Actions.

1 Scope

This document, developed by Work Group 4 of GHWP, provides comprehensive guidance and information on Field Safety Corrective Actions and Non-Safety related Field Corrective Actions for marketed medical devices. It outlines key concepts, definitions, and classifications that are essential for understanding and managing these actions.

2 Normative References

There are no normative references in this document.

3 Terms and Definitions

3.1 Field Corrective Action (FCA)

A Field Corrective Action is a measure implemented to address the root cause and prevent the recurrence of an undesirable situation in a marketed medical device. It may be categorized as either a Field Safety Corrective Action or a Non-Safety related Field Corrective Action.

3.2 Field Safety Corrective Action (FSCA)

A Field Safety Corrective Action (FSCA) is any remedial action, including preventive and corrective measures, taken by a manufacturer to reduce the risk of death or serious deterioration in the state of health associated with the use of a medical device. This action can include product recalls, device modifications, implant alerts, device precautions, and user warnings.

Five types of FSCA are listed below. Related examples are provided in **Annex A**.

3.2.1 Device Recall

The permanent removal from the market and / or destruction of devices, when the device has or may have a safety problem.

3.2.2 Device Modification

The repair, modification or adjustment of the device (including software update) or the label and / or instructions for use when the device has or

could cause a safety problem. The corrective action may take place at the users' or the manufacturer's premises or any other agreed upon location.

3.2.3 Implant Alert

The issuing of precautionary information about a device where the affected devices are already implanted.

3.2.4 Device Precaution

The issuing of information and precautionary measures about adverse events with a medical device where neither the root cause nor their resolution has been established but it is likely that follow up action will be necessary.

3.2.5 User Warning

The issuing of information which would warn of a potential patient safety risk that may arise from procedural or medical device use.

3.3 Non-Safety related Field Corrective Action (NSFCA)

A Non-Safety related Field Corrective Action (NSFCA) is any corrective action taken by the manufacturer for reasons other than reducing the risk of death or serious deterioration in the state of health associated with the use of a medical device.

The three types of NSFCA are listed below. Related examples are presented in **Annex B**.

3.3.1 Device Withdrawal

The removal of a product from supply and use when the medical device does not pose a safety problem.

3.3.2 Device Enhancement

The enhancement or upgrade that improves the features and performance of a medical device that is not related to safety reasons.

3.3.3 Stock Recovery

The correction or removal from supply of a device that has not been marketed or that has not left the direct control of the manufacturer.

4 Classification of FCAs

Classifications are proposed by the manufacturer to identify the level of risk posed to patients, users and others, and if the device is continued to be used. The classification of FCA can be based on a risk assessment that considers the potential impact on patient safety and clinical outcomes. It facilitates manufacturers, regulatory authorities and healthcare providers to prioritize FCA in their management plan. Proper classification ensures that the most critical issues are addressed promptly to mitigate any adverse health outcomes. The classification is divided into three classes, which are listed below, with examples provided in **Annex C**.

4.1 Class 1

A field corrective action taken by the manufacturer when death or serious deterioration in the state of health of a patient, user or other person has occured or there is a reasonable probability that exposure to or use of the violative medical device(s) can lead to death or serious deterioration in the state of health of a patient, user or other person.

4.2 Class 2

A field corrective action taken by the manufacturer when there is a reasonable probability that the exposure or use of the violative medical device(s) has or can lead to temporary illness, injury, mistreatment or deterioration of the state of health of a patient, user or other person.

4.3 Class 3

A field corrective action taken by the manufacturer when there is a reasonable probability that the exposure or use of the violative medical device will not lead to temporary illness, injury, mistreatment or deterioration of the state of health of a patient, user or other person.

Annex A

Examples of Field Safety Corrective Action (FSCA)

Type 1 – **Device Recall**

The permanent removal from the market and / or destruction of devices, when the device has or may have a safety problem.

Example 1

Following a report concerning a nurse being contaminated by a chemotherapy agent, an investigation by the manufacturer into adverse event reports about the splitting of the barrel of syringes used to inject cytotoxic chemotherapy drugs determines that the root cause was a manufacturing error and that batches manufactured between certain dates are affected. To prevent potential unintended exposure to chemotherapy or other harm caused by the use of a defective syringe, the manufacturer contacts all distributors and users who received syringes from the affected batches, requesting either their return for disposal by the manufacturer or documentation of disposal by the distributors or users. Batches outside of the range identified are not affected and can be used or supplied. **The permanent removal or destruction of the potentially faulty syringes from the market for safety reasons makes this action an FSCA Type 1.**

Example 2

The manufacturer has received reports about catheter balloons bursting during procedures to remove blood clots from patients' arteries. An investigation by the manufacturer reveals that the material and design used for these balloon catheters is the same as for those used to inflate coronary artery stents and that the medical device may not be appropriate for use in removing blood clots. The manufacturer has decided that all balloon catheters intended to be used for removal of blood clots and have this design and material must be returned to them even though this same design and material is considered to be safe when used for coronary arteries stenting. **The permanent removal of this medical device model for safety reasons makes this action a FSCA Type 1.**

Example 3

The manufacturer of an in-vitro testing device receives reports that the software error results in false positives to the test. Based on these inaccurate test results, the patients received unnecessary treatment associated with significant toxicity. Reports were also received of false negative test results, which delayed treatment until the patient became symptomatic. The manufacturer determined that a software modification will not resolve the inaccurate test results, so requested all laboratories using the device to return all units. **The permanent removal or destruction of a device for safety reasons makes this action an FSCA Type 1.**

Type 2 – Device Modification

The repair, modification, or adjustment of the device or the label and / or instructions for use when the device has or could cause a safety problem. The corrective action may take place at the users' or the manufacturer's premises or any other agreed upon location.

Example 1

Patient was misdiagnosed because images from a CT scan were mislabeled. During the investigation of the event, the manufacturer discovered that the cause was user error that could be mitigated by a software correction. A “software patch” was delivered to all users of the system with instructions for imaging technicians at the radiology centers on how to install and validate the “software patch” – users of the system were also given the option for a manufacturer’s service agent to install the service pack. **The act of providing a software patch or service upgrade for safety reasons makes this an FSCA Type 2.**

Example 2

A number of adverse events with a negative pressure wound therapy device have been reported to the manufacturer. The instructions for use were missing or did not include warnings against use of this device on patients with particular medical conditions. The manufacturer has added the additional warnings to the instructions for use and sent out a new version to all users to replace the original instructions for use. **The act of providing additions to or replacement versions of instructions for use for safety reasons, even if replaced by the user, makes this an FSCA Type 2.**

Example 3

A manufacturer received multiple reports of inadvertent activation of an insulin pump during patient movement which could result in inappropriate drug delivery. The manufacturer sent all users a protecting ring to be placed around the device activation switch, to prevent accidental activation. **Medical device replacement or changes which offer improvements to performance for safety reasons, even if replaced by the user, makes this an FSCA Type 2.**

Type 3 – Implant Alert

The issuing of precautionary information about a device where the affected devices are already implanted.

Example 1

A manufacturer discovers that certain models of a specific pacemaker may reach their end of life prematurely. The investigation finds the cause to be related to the reliability of an electrical component. The manufacturer issues an advisory to implanting surgeons and cardiologists to counsel and to follow those implanted patients at more regular intervals and only replace devices as appropriate. **The act of communicating a problem about an implantable device and providing information about patient follow up or elective device replacement makes this an FSCA Type 3.**

Example 2

An increasing number of adverse events involving surgical mesh implanted into the bladder for problems with urinary incontinence have been received by the manufacturer. The meshes have eroded into surrounding tissues and the patients continue to experience severe pain and incontinence. Due to the extent of the internal damage, it is not known if the mesh can be safely removed without further serious injury. The manufacturer issues a labelling update, notifying physicians about the situation and advising them to communicate to the patient prior to implantation regarding the increase in known adverse events and the need to monitor patients who have the mesh already implanted. **The act of communicating to physicians about potential problems with implants makes this an FSCA Type 3.**

Type 4 – Device Precaution

The issuing of information and precautionary measures about adverse events with a medical device where neither the root cause nor their resolution has been established but it is likely that follow up action will be necessary.

Example 1

The manufacturer has received reports about the failure of a particular model of anesthetic machine when operated in a certain mode. The manufacturer is still investigating this particular problem and its potential corrective actions. There are few alternative methods of delivering anesthetic available. The manufacturer decides to inform users of this problem and advise them that this mode should not be used until they have determined the solution to the problem. Once a cause and corrective solution has been found, further information will be distributed to users. Based on the progress in the investigation, the manufacturer may take additional FSCA. **Notifying users of a problem without a known resolution while continuing to investigate makes this an FSCA Type 4.**

Type 5 – User Warning

The issuing of information which would warn of a potential patient safety risk that may arise from procedural or medical device use.

Example 1

A number of adverse events with a thermal ligature sealer have been reported to the manufacturer. The investigation revealed that surgical drapes and/or patients have been burned. Further information revealed the user had placed the ligature sealer down on the drapes during the procedure. Placing the ligature sealer on the drapes is contrary to the instructions for use. A notice was sent to all known users of ligature sealers stressing the need to place the sealer in a proper holder instead of on the surgical drapes because of the potential for burns. **The act of sending out a user warning reminder to prevent a safety issue, even though there had been no medical device fault, makes this an FSCA Type 5.**

Example 2

The manufacturer has been notified of instances where an In-Vitro Diagnostic Device (IVDD) kit for HIV has been used for diagnosis instead of its intended purpose of screening. The manufacturer issued a reminder notice to pathology laboratories and

physicians that the IVDD kit was not specifically developed for a definitive diagnosis of HIV. The instructions for use state that this IVDD kit is for screening purposes only and that it should not be used as a confirmatory test. Patients may be incorrectly diagnosed and treated with drugs that have serious side effects. **Notifying the user of the medical device's limitations and usage to avoid an incorrect diagnosis makes this an FSCA Type 5.**

Annex B

Examples of Non-Safety Field Corrective Action (NSFCA)

Type 1 – **Device Withdrawal**

The removal of a medical device from supply and use when the medical device does not pose a safety problem.

Example 1

A manufacturer terminates the sale and distribution of a prepared plated media (PPM) line that tests for methicillin resistant *Staphylococcus aureus* because they recently received approval to market an automated rapid instrument system which will replace the current PPM line. This line will be exchanged or replaced by a newer version. **Because this medical device change does not raise safety issues, the event is a Non-Safety related Field Corrective Action Type 1.**

Example 2

A manufacturer decides to remove a range of wound care medical devices that are not as widely used as a similar medical device due to a business and marketing decision. Safety and liability were not factors in the decision. The medical devices are removed from the shelves and may or may not be replaced with other similar medical devices. **Medical device removal due solely to a business decision is a Non-Safety related Field Corrective Action Type 1.**

Example 3

A manufacturer decides to remove a batch of thermometer probe covers from customer's shelves because of complaints that the covers are sticking together preventing their use. The covers are removed and replaced with covers from a different batch. **Medical device removed due to a quality complaint, that would not pose a safety problem is a Non-Safety related Field Corrective Action Type 1.**

Type 2 – Device Enhancement

The enhancement or upgrade that improves the features and performance of a medical device that is not related to safety reasons.

Example 1

The manufacturer of a CT scanner has developed a software add-on that will enable the user to perform additional functions. The manufacturer sends the software add-on with updated instructions for use to the healthcare facility for their technicians to load onto the scanner or offers to send one of their technicians to the facility to load the software. **Enhancements to the functionality of medical devices where there are no improvements indicated by safety issues are Non-Safety related Field Corrective Action Type 2**.

Example 2

The manufacturer discontinues an In-Vitro Diagnostic Device (IVDD) line and replaces it with one in which controls are now supplied in a single-use only vial, offering better stability and better Quality Control. The old IVDD will still be supplied until stock depletion. **Replacement or changes to medical devices which offer improvements to performance are Non-Safety related Field Corrective Action Type 2**.

Type 3 – Stock Recovery

The correction or removal from supply of a device that has not been marketed or that has not left the direct control of the manufacturer.

Example 1

A manufacturer discovers that due to a manufacturing error on one lot, only one of the two tools is included in a surgical kit. The manufacturer adds the missing tool in the instrument trays within their own manufacturing and distribution location sites before the device is placed on the market. **Error corrections for medical devices that have not left the manufacturer's control are Non-Safety related Field Corrective Action Type 3.**

Example 2

The manufacturer has identified that incorrect power is labeled on a lot of Intraocular Lenses (IOLs). The lot is contained within the company manufacturing and distribution sites. The entire lot is quarantined by the manufacturer prior to release into the market. **Error corrections that have not left the manufacturer's control are Non-Safety related Field Corrective Action Type 3.**

Annex C

Examples of Classification of Field Corrective Actions

The initial classification of notifiable FCAs is proposed by the manufacturer based on information available which is accepted by the National Competent Authority (NCA). Should new information become available, the classification may be adjusted. When an FCA includes multiple corrective actions with different classification of risks, the actions associated with the highest level of risk takes precedence.

Class 1

A field corrective action taken by the manufacturer when death or serious deterioration in the state of health of a patient, user or other person has happened or there is a reasonable probability that exposure to or use of the medical device(s) can lead to death or serious deterioration in the state of health of a patient, user or other person.

Example 1 – Implant Alert

An increasing number of adverse events involving surgical mesh implanted into the bladder for problems with urinary incontinence have been received by the manufacturer. The meshes have eroded into surrounding tissues and the patients continue to experience severe pain and incontinence. Due to the extent of the internal damage, it is not known if the mesh can be safely removed without further serious injury. The manufacturer issues a labeling update, notifying physicians about the situation and advising them to communicate to the patient prior to implantation regarding the increase in known adverse events and the need to monitor patients who have the mesh already implanted.

Rationale: Due to the inability to remove the surgical mesh, patients have suffered or can suffer a serious deterioration in their state of health, making this a Class 1 FCA.

Example 2 – Device Modification

A manufacturer received multiple reports of inadvertent activation of an insulin pump during patient movement which could result in inappropriate drug delivery. The manufacturer sent all users a protecting ring to be placed around the device activation switch, to prevent accidental activation.

Rationale: Inappropriate drug delivery of insulin to patients can lead to death or serious deterioration of health of the patient making this a Class 1 FCA.

Class 2

A field corrective action taken by the manufacturer when there is a reasonable probability that the exposure or use of the medical device(s) has or can lead to temporary illness, injury, mistreatment or deterioration of the state of health of a patient, user or other person.

Example 1 – User Warning

A number of adverse events with a thermal ligature sealer have been reported to the manufacturer. The investigation revealed that surgical drapes and/or patients have been burned. Further information revealed the user had placed the ligature sealer down on the drapes during the procedure. Placing the ligature sealer on the drapes is contrary to the instructions for use. A notice was sent to all known users of ligature sealers stressing the need to place the sealer in a proper holder instead of on the surgical drapes because of the potential for burns.

Rationale: Due to the instructions not being followed, there is possibility of temporary injury to patients or users, making this a Class 2 FCA.

Example 2 – Device Removal

Following a report concerning a nurse being contaminated by a chemotherapy agent, an investigation by the manufacturer into adverse event reports about the splitting of the barrel of syringes used to inject cytotoxic chemotherapy drugs determines that the root cause was a manufacturing error and that batches manufactured between certain dates are affected. To prevent potential unintended exposure to chemotherapy or other harm caused by the use of a defective syringe, the manufacturer contacts all distributors and users who received syringes from the affected batches, requesting

their return for disposal by the manufacturer or documentation of disposal by the distributors or users. Batches outside of the range identified are not affected and can be used or supplied.

Rationale: The unintended exposure to cytotoxic drugs can lead to temporary injury or deterioration in state of health of patient or user making this a Class 2 FCA.

Class 3

A field corrective action taken by the manufacturer when there is a reasonable probability that the exposure or use of the medical device will not lead to temporary illness, injury, mistreatment or deterioration of the state of health of a patient, user or other person.

Example 1 – Device Enhancement

The manufacturer discontinues an In-Vitro Diagnostic Device (IVDD) line and replaces it with one in which controls are now supplied in a single-use only vial, offering better stability and better quality control. The old IVDD will still be supplied until stock depletion.

Rationale: It is unlikely that injury, illness or deterioration in the patient's health will occur as a result of continued use of the old IVDD making this a Class 3 FCA.

Example 2 – Stock Recovery

A manufacturer discovers that due to a manufacturing error on one lot, only one of the two tools is included in a surgical kit. The manufacturer adds the missing tool in the instrument trays within their own manufacturing and distribution location sites before the device is placed on the market.

Rationale: This is unlikely to cause any injury or deterioration in the state of health of the patient as the correction is being taken before the device is used making this a Class 3 FCA.

Bibliography

[1] AHWP/WG2/SADS/001: Framework for GHWP Safety Alert Dissemination System (SADS)

[2] AHWP/WG2/SADS/002: Safety Alert Dissemination System: Safety Alert Dissemination Criteria, Procedures and Form