**Reporting of recalls or of other safety measures (FSCA)**

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Definition: Recalls or other safety measures in accordance with the Swiss Medical Devices Ordinance[1] (Art. 15c MepV) are understood as safety measures. The term Field Safety Corrective Action (FSCA) used in the European Guidelines MEDDEV 2.12-1 corresponds to the term "safety measure" used in the MepV. jkkhjk

# 1 Purpose of this information sheet

This document describes the safety measures that have to be reported to Swissmedic, the Swiss Agency for Therapeutic Products, mandatorily, and how a report should be handled. A form is made available by Swissmedic that facilitates the submission of complete reports and avoids time being spent as a result of queries related to the reports.

# 2 Scope and legal basis

The information in this information sheet is based on national law and European guidelines:

- Articles 14, 15c to 15e MepV describe the mandatory requirements regarding reporting and providing information concerning to safety measures.
- The European vigilance guidelines for medical devices MEDDEV 2.12-1 permit the uniform use and implementation of a surveillance and reporting system for medical devices within Europe[2]. These guidelines are also recognised and applied in Switzerland. Those placing medical devices on the market should therefore take them into consideration.

It is mandatory for those first placing medical devices on the market to report safety measures that concern medical devices to Swissmedic in the following cases (Art. 15c, MepV):

- If the medical device is on the Swiss market or
- If the manufacturer or its authorised EU agent has its registered offices in Switzerland, and the medical device is on the market in EU Member States, EFTA countries or in Turkey.

# 3 What are safety measures?

A safety measure is a measure determined by the manufacturer for one of the products it has placed on the market in order to reduce the risk of a direct or an indirect threat to, and / or an effect on, health in connection with a medical device.
A safety measure can be:

- A physical recall
- An exchange
- A modification to the product or to the instructions for use
- Information for users in order to reduce the risk of a possible health threat

Examples of problems that lead to a safety measure being taken:

- Packaging error (mismatch, incorrect labelling, etc.)
- Sterility problem (e.g. caused by manufacturing, transport)
- Manufacturing error
- Software error
- Safety-relevant findings discovered during post-market surveillance

Every person placing a medical device on the market must forward information on pending safety measures to the users concerned and if appropriate to patients, in an appropriate manner[3]. This is usually realized in form of a Field Safety Notice [FSN]. A FSN should contain the elements stated in MEDDEV 2.12-1, paragraph 5.4.4.2 (Content of the Field Safety Notice).

[1] Medical Devices Ordinance (MepV; SR 812.213), www.admin.ch/ch/d/sr/812_213
[2] The Guidelines are based on Directive 90/385/EEC on active implantable medical devices, Directive 93/42/EEC on medical devices and Directive 98/79/EC on in vitro diagnostic devices
[3] Arts. 14 and 15d, MepV



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It should be noted that the FSN for users constitutes part of the safety measure, even when additional measures are also foreseen.
Example: A software update is necessary. The FSN provides information on problems and necessary measures that can be taken by users in order to avoid these problems for the time being. A definitive solution via a software update may only be available later.
If recalls or exchanges of medical devices do not take place for reasons of safety, these need not be reported to Swissmedic.

## 4 When is a measure a safety measure?

Measures should be considered as safety measures when they are intended to avoid or prevent the occurrence of serious incidents in connection with a medical device. All safety measures must be reported to Swissmedic without any delay.
The EN ISO 14971 standard (Medical devices – use of a risk management system) describes the methodology for assessing whether or not a safety measure is necessary. In case of doubt, the decision should be in favour of carrying out a safety measure.

## 5 Why must safety measures be reported to Swissmedic?

Swissmedic is legally mandated to carry out surveillance, and to ensure that therapeutic products are of high quality, safe and effective (Therapeutic Products Act, TPA [HMG; SR 812.21]). When a safety measure is reported, the Agency assesses whether the risk can be adequately reduced by the measures defined by the manufacturer, and monitors the implementation of these measures by the persons placing the product on the market.

## 6 Who should report safety measures to Swissmedic?

Products are often made available by independent distributors and not by the legal manufacturers in the countries concerned. There are two possibilities:

- The safety measures are reported to the competent authorities in each country by the corresponding distributor.
- The safety measure is reported centrally, by the manufacturer or its authorised representative in the EU, to the authorities of all countries affected.

The firm is free to choose which of the two possibilities it prefers. There should be a binding contract between the manufacturer and the distributor that states which of them is responsible for reporting to the authorities. In the absence of such binding rules, the responsibility for submitting the report to Swissmedic is that of the person first placing the product on the market.

## 7 When must safety measures be reported?

The safety measure must be reported to Swissmedic **immediately**, and at the latest when sending recommendations regarding measures to the customers and to the intermediaries affected.
In order to avoid corrections to the measures being necessary, e.g. if the content of a safety measure or of an FSN is insufficient, contacting Swissmedic at an early stage is recommended. Ideally, a report should be submitted to the Agency as early as when the draft FSN is available.

## 8 How should safety measures be reported?

Swissmedic provides a reporting form. It can be downloaded from the website at
http://www.swissmedic.ch/produktbereiche/00450/index.html?lang=en
(>Materiovigilance). Reports may be submitted in one of Switzerland's official languages or in English using the Swissmedic form, or on any form with the same content (notably the European report form provided in MEDDEV 2.12-1). The points listed in the checklist shown in section 10 below and the information requested in the form are the critical components of a report. To submit reports, please use only the following e-mail address: materiovigilance@swissmedic.ch.
It should be noted that, like other Federal authorities, Swissmedic can only receive attachments of up to 4 MB. Larger files may be transmitted to Swissmedic via the following FTP server:
https://www.webftp.admin.ch/de/transfer



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# 9 What does Swissmedic do upon receiving the report?

*Evaluation of the measure*
Swissmedic's evaluation concerns whether the investigations carried out and the planned safety measures are sufficient to assess the threat correctly and to protect patients, users or third parties against life-threatening incidents or those that can seriously affect their health. Swissmedic also examines whether the time frame for the implementation of the measure is appropriate. Another critical factor is whether sufficient instructions have been provided and whether the communication is appropriate with regard to reaching all those affected (distributors, end users, medical professionals' associations or other professional organisations, users, etc.).

*Information for users (FSN)*
The person placing the product on the market is responsible for disseminating the information to customers and users. Like other authorities, Swissmedic also publishes FSNs for medical devices on the Internet: http://www.swissmedic.ch/rueckrufe_medizinprodukte/index.html?lang=en
If Swissmedic considers additional investigations and measures to be necessary, the Agency will inform the person placing the product on the market that these must be carried out. Swissmedic may also disseminate its own recommended measures and decides on the media to be used for the purpose. Usually, Swissmedic selects information channels that permit sufficiently rapid dissemination and a sufficient degree of coverage of the target groups, yet with the least possible public exposure. Swissmedic may send its own recommendations to users, for example in the following cases:

- If the measures recommended by the person placing the product on the market have shortcomings or could be misunderstood.
- If the dissemination of the information by the person placing the product on the market is not sufficiently wide, and a larger range of users must be informed of the measures.

In such cases, Swissmedic may for example also provide information to users, medical professionals' associations, other professional organisations, contact persons in hospitals, or the general public.


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a) *Exchange with other authorities (Art. 15e, MepV)*
Cantons: Swissmedic informs the Cantonal authorities of safety measures. Swissmedic may also provide information on isolated incidents, and particularly following deaths or public health hazards.

b) *Foreign authorities:*
For safety measures that affect Swiss manufacturers or authorised EU representatives with registered offices in Switzerland, Switzerland usually plays the role of the coordinating authority. Swissmedic informs foreign authorities in accordance with the requirements of the European Directives on medical devices and MEDDEV 2.12-1. Information on the case from the viewpoint of the authorities takes place by means of a National Competent Authority Report (NCAR). Usually, the firm affected is given the opportunity to comment on the NCAR before Swissmedic sends it on to other authorities. The NCAR is then sent by Swissmedic to the European Commission and to affected countries with which Switzerland has a state contract. This notably includes EU Member States, EFTA countries, Turkey, and if certain non-European states are affected by a security measure, to the Secretariat of the Global Harmonisation Task Force (GHTF) countries.
In order to avoid subsequent corrections, a draft of the FSN should, if possible, be forwarded to Swissmedic at an early stage, and preferably at least 48 hours before being sent to customers, users, or other persons involved. In urgent cases, e.g. if a large number of persons are at risk (serious public health threat), a shorter time frame should be chosen.

c) If necessary, Swissmedic may send information on an incident to those foreign authorities stated in b) above.

**Independently of the NCAR, it is also mandatory for the persons placing the product on the market to inform all foreign authorities affected on their own initiative!**

<u>Monitoring of the implementation of safety measures</u>
Swissmedic monitors the execution and implementation of safety measures by the person placing the product on the market. A final report must be drawn up and submitted to Swissmedic (Art. 15c, para. 3 MepV).



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# 10 Checklist for a safety measure

This checklist is intended to provide assistance and to facilitate the completion of the corresponding form. It mentions only the most important information that must be submitted together with the report. The list is not exhaustive and is not legally binding.

**General aspects**

☐ Complete the official FSCA report form in full. If any information is not yet available, please state when Swissmedic will receive it.

**Information on the firm**

☐ Manufacturer
☐ Authorised EU representative
☐ Distributor in Switzerland

**Information on the medical device**

☐ Trade name
☐ Nomenclature code (if possible, GMDN code), product classification
☐ Conformity assessment body / notified body
☐ Lot no., serial no., software version (if applicable)

**Description of the safety measure**

☐ Reason for the measure
☐ Root cause (if already known) / risk analysis
☐ Description of the safety measure
☐ Information letter to customers
(attach 1 copy for each language used, if possible in PDF format)
**G** ☐ **F** ☐ **I** ☐ **E** ☐
☐ List of customers and the number of products concerned
☐ Estimated time frame
☐ Time at which next report / final report will be sent

**Swiss manufacturers and authorised EU representatives with registered offices in Switzerland**

For an NCAR (National Competent Authority Report) Swissmedic also requires the following information:

☐ List of **all** countries affected
☐ Information letter to customers, or draft letter
☐ How was the problem discovered? → Clear, precise description of the problem
☐ Result of the root cause analysis if available or completed
☐ If appropriate, how many incidents are known to have taken place, in which countries?

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## Change history

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