Contents

1 Terms, definitions, abbreviations 1
1.1 Terms, definitions 1
1.2 Abbreviations 2
2 Aim of this information sheet 2
3 Scope and legal basis 2
4 What is an FSCA? 2
5 Reporting an FSCA 3
5.1 Responsibilities 3
5.2 Electronic submission 3
5.3 Time frame 3
6 Tasks of Swissmedic 3
6.1 Evaluation of actions 3
6.2 FSN publication 4
6.3 Exchange with other authorities 4
6.3.1 National authorities 4
6.3.2 Foreign authorities 4
6.4 Monitoring the execution of field safety corrective actions 4
7 Data protection 5

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1 Terms, definitions, abbreviations

1.1 Terms, definitions

Recalls or other safety measures in accordance with the Swiss Medical Devices Ordinance[1] (Art. 15c MedDO) 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 concerning the device that is on the market used in the MedDO.

[1] Medical Devices Ordinance (MedDO; SR 812.213), www.admin.ch/ch/d/sr/812_213

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1.2 Abbreviations

FSCA	Field Safety Corrective Action
FSN	Field Safety Notice
NCAR	National Competent Authority Report

2 Aim 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.

3 Scope and legal basis

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

- Articles 14, 15c to 15e MedDO 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 first placing medical devices on the market should therefore take them into consideration as well as persons who continue to place devices on the market.

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, MedDO):

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

4 What is an FSCA?

A safety measure is a measure taken for products 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 FSN. Templates for FSNs and the confirmation form are available on the European Commission website under "Guidance MEDDEVs" in section 2.12 "Post-Market Surveillance":
https://ec.europa.eu/health/md_sector/current_directives_en

[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, MedDO

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The templates are intended to assist manufacturers in producing good-quality customer letters that contain all the necessary information.

Actions are then considered to be field safety corrective actions if they are designed to reduce or prevent the risk of serious incidents involving a medical device. All FSCAs concerning devices on the Swiss market and/or whose manufacturer / European authorised representative has their registered office in Switzerland must be reported immediately to Swissmedic.

5 Reporting an FSCA

5.1 Responsibilities

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.

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.

5.2 Electronic submission

Swissmedic provides the report form used in the EU (from MEDDEV 2.12-1) as a template. It is available online at www.swissmedic.ch/md-materiovigilance-manufacturers (section Field Safety Corrective Action (FSCA)). Reports may be submitted in one of the official Swiss languages or in English. The completed report form, the FSN and any other documentation should be sent to the following e-mail address: materiovigilance@swissmedic.ch.

5.3 Time frame

The FSCA must be reported to Swissmedic without delay, and at the latest when the FSN is sent to the relevant customers and intermediaries. 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.

6 Tasks of Swissmedic

6.1 Evaluation of actions

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

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appropriate with regard to reaching all those affected (distributors, end users, medical professionals' associations or other professional organisations, users, etc.).

6.2 FSN publication

The manufacturer is responsible for distributing the information to customers and users. Apart from exceptional cases, Swissmedic publishes FSNs that concern devices on the Swiss market on the internet: https://fsca.swissmedic.ch/mep/
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.

6.3 Exchange with other authorities

6.3.1 National authorities

If necessary, Swissmedic can inform the cantons or the FOPH about field safety corrective actions, particularly if there is a risk to public health.[4]

6.3.2 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. Swissmedic then sends the NCAR to the European Commission and all contracting states (EU member states, EFTA countries and Turkey).
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.
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!

6.4 Monitoring the execution of field safety corrective actions

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.[5]

[4] Art. 15e MedDO.
[5] Art. 15c para. 3 MedDO

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7 Data protection

If there is an overriding legitimate interest in preserving the secrecy of the data collected in accordance with the Therapeutic Products Act, Swissmedic must treat such data as confidential[6]. The processing and disclosure of data (including in other countries) are based on the requirements of Section 4 of the Therapeutic Products Act (Obligation of Secrecy and Data Processing)[7].

[6] Art. 62 TPA
[7] Art. 61 ff. TPA

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