Guidance document
FSCA economic operators

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1 Terms, definitions, abbreviations

1.1 Abbreviations

FOPH	Federal Office of Public Health
FSCA	Field Safety Corrective Action
FSN	Field Safety Notice
IvDO	Ordinance of 4 May 2022 on In Vitro Diagnostic Medical Devices (SR 812.219)
IVDR	Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU
MDR	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No. 178/2002 and Regulation (EC) No. 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
MedDO	Medical Devices Ordinance of 1 July 2020 (SR 812.213)

TPA Therapeutic Products Act of 15 December 2000 (SR 812.21)

1.2 Terms, definitions

Device: In this guidance document, the term "device" refers to medical devices and other devices according to Art. 1 MedDO and in vitro diagnostic medical devices and the associated accessories according to Art. 1 para. 1 IvDO. Where provisions apply only to specific devices or device groups in an ordinance (MedDO or IvDO), this is explicitly stated.

Field safety corrective action: A field safety corrective action (FSCA) means a corrective action taken for technical or medical reasons[1] to prevent or reduce the risk of a serious incident[2].

Manufacturer[3]: Any natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark; this definition is subject to the clarifying explanations and exceptions in Art. 16 para. 1 and 2 MDR and Art. 16 para. 1 and 2 IVDR.

System and procedure pack producer: System and procedure pack producer (SPPP) refers to the natural or legal person that assembles a system or procedure pack[4].

Authorised representative[5]*: Any natural or legal person domiciled in Switzerland who has received and accepted a written mandate from a manufacturer located in another country to act on the manufacturer's behalf in relation to specified tasks with regard to the latter's obligations under this Ordinance.

Economic operator[6]: manufacturer, authorised representative, importer or distributor and the person referred to in Art. 22 para. 1 and 3 MDR (SPPP).

[1] Art. 4 para. 2 MedDO in conjunction with Art. 2 no. 65 MDR and Art. 4 para. 2 IvDO in conjunction with Art.2 no. 68 IVDR
[2] Art. 4 para. 2 MedDO in conjunction with Art. 2 no. 68 MDR and Art. 4 para. 2 IvDO in conjunction with Art.2 no. 71 IVDR
[3] Art. 4 para. 1 let. f MedDO and Art. 4 para. 1 let. e IvDO
[4] Art. 11 MedDO in conjunction with Art. 22 MDR
[5] Art. 4 para. 1 let. g MedDO and Art. 4 para. 1 let. f IvDO
* Based on the Customs Treaty between Liechtenstein and Switzerland, the following applies:
Manufacturers domiciled in Switzerland do not have to appoint an authorised representative to place their medical devices on the market in Switzerland. By the same token, manufacturers domiciled in Switzerland also do not have to appoint an authorised representative to place their devices on the market in Liechtenstein. Switzerland and Lichtenstein are therefore considered to be a single region. A manufacturer outside of this region must therefore appoint an authorised representative in either Switzerland or Liechtenstein before placing their device on the market in Switzerland and/or Liechtenstein.
[6] Art. 4 para. 1 let. j MedDO and Art. 4 para. 1 let i IvDO

2 Introduction

If problems arise with devices, systems or procedure packs supplied in Switzerland or Liechtenstein under Customs Treaty law that require corrective actions, the manufacturer or SPPP or their authorised representative is responsible for ensuring that information about implemented field safety corrective actions is immediately brought to the attention of the users of the relevant device by means of a Field Safety Notice. The manufacturer or SPPP also has a statutory duty to inform Swissmedic, the Swiss Agency for Therapeutic Products.**

3 Objective

This document describes when a field safety corrective action must be reported to Swissmedic and the corresponding report procedure.

4 Legal basis

The legal requirements governing field safety corrective actions are set out in the following pieces of legislation:

- Art. 59 TPA describes the reporting obligations for therapeutic products
- Art. 66 MedDO and Art. 59 IvDO describe the obligations to report and to provide information about field safety corrective actions
- Art. 87 MDR and Art. 84 IVDR set out the requirements for reporting field safety corrective actions.

5 What is an FSCA?

A field safety corrective action (FSCA) means a corrective action taken by the manufacturer or SPPP in order to reduce the risk of a direct or indirect hazard and/or risk to health associated with a device that it has placed on the market.

Possible FSCAs include:

- a physical recall
- a replacement
- a modification of the device or its instructions for use
- information provided to users to reduce the risk of a possible health risk

Examples of problems that lead to an FSCA:

- packaging errors (mismatch, incorrect labelling, etc.)
- sterility problem (e.g. arising from manufacturing, transport)
- manufacturing errors
- software errors
- safety-related findings discovered during post-market surveillance

Every manufacturer or SPPP is required to forward information on FSCAs to be implemented to the users concerned and, if applicable, to patients[7]. This usually involves sending a Field Safety Notice

** Owing to the EEA Agreement and the Swiss-Liechtenstein Customs Treaty, two jurisdictions apply in parallel to medical devices in Liechtenstein (parallel marketability). Medical devices can be placed on the market in Liechtenstein either on the basis of EU-MDR or the MedDO. See LI website, under Marktzugang (market access)).
Swissmedic is responsible for processing safety corrective actions for devices supplied under Customs Treaty law in Liechtenstein (Customs Treaty between Switzerland and Liechtenstein, concluded on 29 March 1923, SR

(FSN). Templates for FSNs and the confirmation form are available on the European Commission website.
The templates are intended to assist manufacturers or SPPPs in producing good-quality customer letters that contain all the necessary information.

Actions are then considered to be FSCAs if they are designed to reduce or prevent the risk of serious incidents involving a device. All FSCAs involving products placed on the Swiss and/or Liechtenstein market under Customs Treaty law must be reported to Swissmedic without undue delay[8]. ***

5.1 Responsibilities

Manufacturers and SPPPs are obliged to report FSCAs involving products placed on the Swiss and/or Liechtenstein market under Customs Treaty law to Swissmedic[9].
For manufacturers and SPPPs who are not based in Switzerland or Liechtenstein, the authorised representative assumes responsibility for reporting[10]. In this case, the report can be submitted by the manufacturer, the SPPP or the authorised representative.

Swissmedic is responsible for monitoring the safety of therapeutic products[11]. When a FSCA is reported, Swissmedic checks whether the risk can be adequately reduced by the actions specified by the manufacturer or the SPPP and monitors the implementation of these actions.

5.2 Electronic submission

FSCAs must be reported using the form published by Swissmedic. This form can be downloaded from the Swissmedic website (www.swissmedic.ch/md-materiovigilance-manufacturers (Field Safety Corrective Action (FSCA) section)). All reports of FSCAs must be submitted to Swissmedic in electronic, machine-readable format using this form[12]. Reports may be submitted in one of the official Swiss languages or in English. All mandatory fields must be completed. The completed report form, the field safety notice (FSN), customer list and any other documentation should be sent to the following e-mail address: materiovigilance@swissmedic.ch. Please also note the requirements in section 7.2 FSN Publication.
Swissmedic will contact you by e-mail if it has any additional questions about an FSCA.

0.631.112.514, most recently revised by the announcement of 18 October 2022 on changes to the Annexes to the Customs Treaty.
2022.280 | Lilex - law database of the Principality of Liechtenstein)
[7] Art. 66 para. 2 MedDO in conjunction with Art. 89 para. 8 MDR and Art. 59 para. 2 IvDO in conjunction with Art. 84 para. 8 IVDR
[8] Art. 66 para. 1 let. b MedDO and Art. 59 para. 1 let. b IvDO
*** Swissmedic is responsible for processing FSCAs for devices supplied in Liechtenstein under Customs Treaty law. Swissmedic must therefore be notified of the FSCAs for devices that were placed on the market under Customs Treaty Law.
[9] Art. 66 para. 1 MedDO and Art. 59 para. 1 IvDO
[10] Art. 66 para. 2bis MedDO and Art. 59 para 3 IvDO
[11] Art. 58 para. 3 TPA
[12] Art. 66 para. 5 MedDO and Art. 59 para 5 IvDO.

5.3 Time frame

FSCAs must be reported to Swissmedic without undue delay[13]. Once the manufacturer or SPPP has decided that an FSCA is necessary, that action should be instigated and reported to Swissmedic within an appropriate time frame for the risk in question.
Except in urgent cases, the draft of the FSN must be submitted to the responsible competent authority so that it can then issue any comments[14].
Draft FSNs that have already been submitted to an authority in the EU or EEA for comment in response to this legal requirement do not also have to be submitted to Swissmedic for prior review. Swissmedic reserves the right to demand modifications to FSCAs at any time.

6 Tasks of Swissmedic

6.1 Evaluation of actions

Swissmedic determines whether the FSCAs planned or already instigated by the manufacturer or SPPP are sufficient to reduce or prevent the risk posed by the device in question[15]. Swissmedic also checks whether the time frame for their implementation is appropriate. In this context, it is also crucial to ensure that adequate instructions are issued and to establish whether the notice is suitable for reaching all those affected (distributors, end customers, medical associations or professional associations, users, etc.).

6.2 FSN publication

The manufacturer or SPPP is responsible for distributing the information to customers and users[16]. It is important as a matter of course to select information channels that will ensure adequate target group coverage and speed of dissemination. Apart from exceptional cases, Swissmedic also publishes FSNs that concern devices on the Swiss and/or Lichtenstein market **** on its website: https://fsca.swissmedic.ch/mep/

The following should be observed for documents to be submitted for publication by Swissmedic:

- Only one (1) machine-readable PDF document should be submitted per language.
- The document must include the following elements:
  - FSN explaining the facts
  - Form for confirmation of receipt of the FSN by the customers (if no such form is provided for this purpose, an explanation of how follow-up of the FSCA will be ensured is expected)
  - Other attachments such as product or batch lists (if necessary)

The manufacturer or SPPP or its authorised representative is responsible for the content (accuracy, completeness and data protection). The FSN must not contain any information that would conflict with

[13] Art. 66 para. 2 MedDO in conjunction with Art. 87 para. 8 MDR and Art. 59 para 2 IvDO in conjunction with Art. 82 para. 8 IVDR
[14] Art. 66 MedDO in conjunction with Art. 89 para. 8 MDR and Art. 59 IvDO in conjunction with Art. 84 para. 8 IVDR
[15] Art. 66 MedDO in conjunction with Art. 89 para. 3 MDR and Art. 59 IvDO in conjunction with Art. 84 para. 3 IVDR
[16] Art. 66 para. 2 MedDO in conjunction with Art. 89 para. 8 MDR and Art. 59 para 2 IvDO in conjunction with Art. 84 para. 8 IVDR
**** The following applies to devices on the Liechtenstein market: Swissmedic is only responsible for devices placed on the Liechtenstein market under Customs Treaty law (SR 0.631.112.514) and as a consequence only publishes the FSNs in these cases.

data protection provisions in the event of publication. Particularly sensitive personal data should be removed or, if they are absolutely essential, anonymised before publication.

If Swissmedic is of the opinion that additional investigations and actions are necessary, it will instruct the manufacturer or SPPP or its authorised representative accordingly. Swissmedic can also send its own recommendations to users, for example in the following cases:

- The manufacturer's or SPPP's recommended actions are incomplete or unclear.
- The distribution of the information by the manufacturer or SPPP is inadequate, and a larger group of users should be informed about the actions.

In such cases, Swissmedic can additionally inform e.g. users, medical associations, other professional associations, contact persons in hospitals or the public.

6.3 Exchange with other authorities

6.3.1 National authorities

If necessary, Swissmedic can inform the cantons or the FOPH about FSCAs, particularly if there is a risk to public health[17].

6.3.2 Foreign authorities

In individual cases, Swissmedic may share confidential data with foreign authorities, for example when doing so could avert serious health risks[18].

6.4 Monitoring the execution of FSCAs

The execution and implementation of FSCAs is monitored by Swissmedic. The conclusion of the FSCA should be reported to Swissmedic using the form for FSCAs published by Swissmedic[19].

Manufacturers are responsible for users being made aware of FSCAs. Swissmedic therefore expects manufacturers to confirm that all affected customers have received the information and/or the actions have been implemented for all devices concerned. If the manufacturer does not receive feedback from the end customer/user, Swissmedic expects the customer to be contacted/reminded at least three (3) times after the FSN has been sent. If fewer than three (3) reminders are sent, risk-based justification must be provided.

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[20]. 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)[21].

[17] Art. 63 para. 1 TPA
[18] Art. 64 TPA
[19] Art. 66 para. 2 MedDO in conjunction with Art. 89 MDR and Art. 66 para. 5 MedDO and Art. 59 para. 2 IvDO in conjunction with Art. 84 IVDR and Art. 59 para. 5 IvDO
[20] Art. 62 TPA
[21] Art. 61 ff. TPA

Change history

Version	Change	sig
3.0	- Amendment due to revision of Customs Treaty with Liechtenstein - Additional information on Swissmedic's requriements regarding the manufacturer's process for reminding recipients of the FSN.	wru
2.0	Amendments due to entry into force of IvDO.	dra
1.0	Doc newly created owing to revision of MD regulatory provisions; old doc ID: MU510_00_007e_MB	dra