Contents

Change history

Version	Valid and binding as of:	Description, comments (by author)	Author's initials
3.1	03.05.2023	Link to Liechtenstein website corrected	wic
3.0	15.12.2022	Change due to revision of Customs Treaty with Liechtenstein	wic
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1.0	26.05.2021	Doc newly created owing to revision of MD regulatory provisions; old doc ID: MU510_00_003e_MB	wic

1 Terms, definitions, abbreviations

1.1 Abbreviations

FSCA	Field Safety Corrective Action
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)
SPPP	System and procedure pack producer
TPA	Therapeutic Products Act of 15 December 2000 (SR 812.21)

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1.2 Terms, definitions

Device In this guidance document, the term "device" refers to medical devices and other groups of products 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.

Manufacturer[1]: A 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 paras. 1 and 2 MDR and Art.16 paras. 1 and 2 IVDR.

System and procedure pack producer[2]: System and procedure pack producer refers to the natural or legal person that assembles a system or procedure pack.

2 Introduction

The TPA requires professional users in Switzerland and Liechtenstein* to report serious incidents involving therapeutic products to Swissmedic[3]. For devices, this reporting obligation is explicitly regulated in the MedDO and IvDO[4].

3 Objective

This guidance document describes the purpose of user reports in the context of vigilance relating to devices and is designed to serve as a guide for users in implementing the legal requirements.

4 Who must report?

Anyone who uses a device in connection with their work or who uses a device on other people or for diagnosis is subject to the reporting obligation. The reporting requirement therefore affects doctors, dentists, therapists, laboratory technicians, paramedics, nurses and other professionals such as beauticians. The professional who becomes aware of a serious incident[5] during the use of a device is responsible for reporting that incident[6] . This person must report the serious incident either directly to Swissmedic or via a vigilance contact person for medical devices in the hospital as well as to the supplier.[7]

* 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 [in German]). Swissmedic is responsible for processing vigilance reports for products provided under Customs Treaty law in Liechtenstein (Customs Treaty between Switzerland and Liechtenstein, concluded on 29 March 1923, SR 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)

[1] Art. 4 para. 1 let. f MedDO and Art. 4 para. 1 let. e IvDO
[2] Art. 11 MedDO in conjunction with Art. 22 MDR
[3] Art. 59 para. 3 TPA.
[4] Art. 66 para. 4 MedDO and Art. 59 para. 4 IvDO
[5] 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
[6] Art. 59 para. 3 TPA
[7] Art. 66 para. 4 MedDO and Art. 59 para. 4 IvDO

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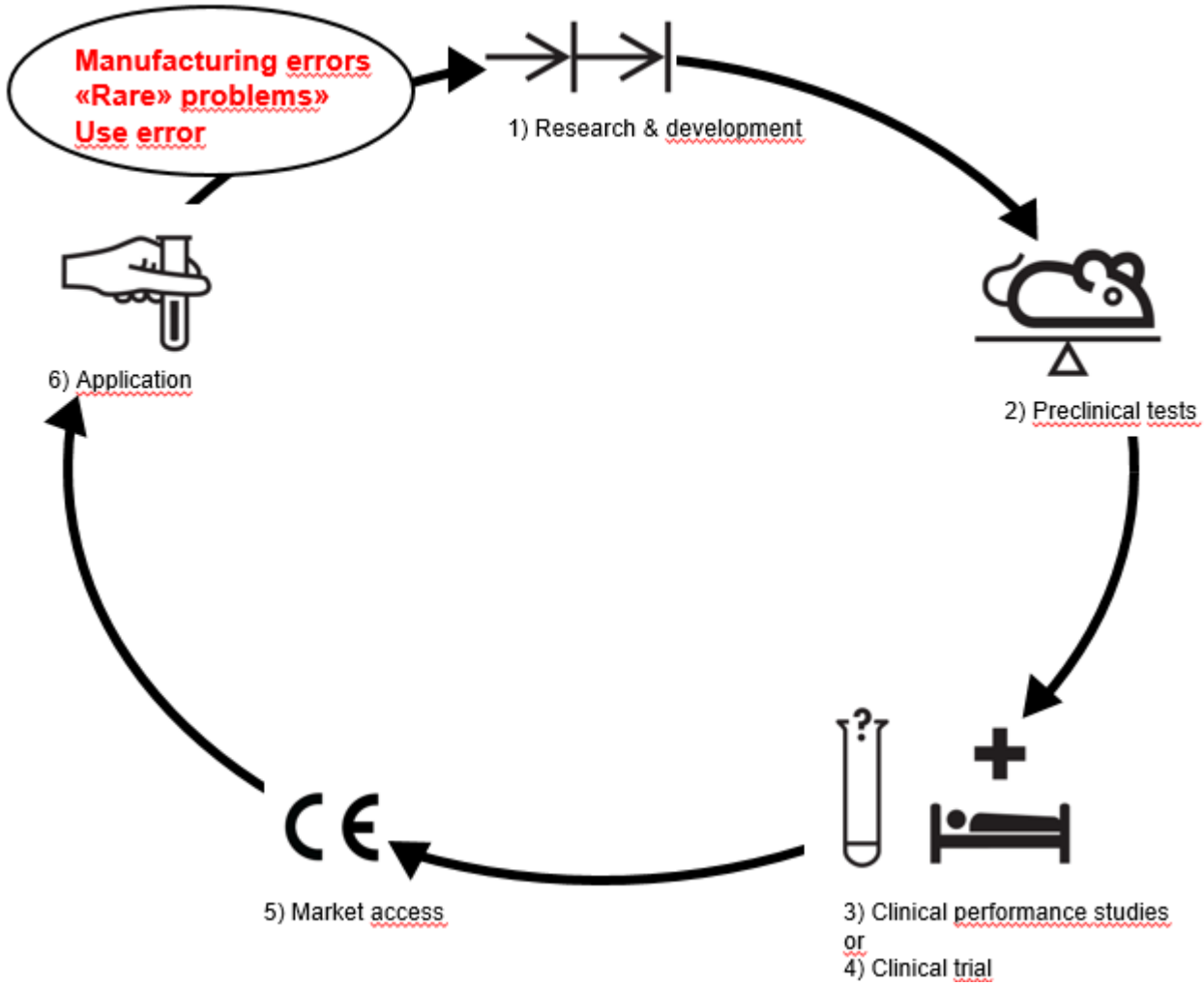
5 Why report?



The reporting system is designed to protect the health of patients and users. In particular, it aims to avoid recurrences of incidents based on problems with the design, manufacture or use of devices. The purpose of the reporting system is merely to identify technical causes of incidents. Apportioning blame is therefore not one of the aims of the reporting system.
The safety of a device is checked before being placed on the market, e.g. in technical tests, preclinical and clinical investigations and in clinical performance studies. The results of these investigations and studies are summarised in a clinical evaluation report or, in the case of devices covered by IvDO, in a performance evaluation report and clinical evidence. Nevertheless, certain problems become apparent only when the device is used on a wider scale. A system for the monitoring of devices during their use is therefore essential and is based on the active cooperation of users.
The reporting of a serious incident allows the problem to be investigated, any trends to be identified and any required corrective actions to be defined and implemented for all other affected devices in Switzerland and in Liechtenstein, where necessary.

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6 Serious incident: Definition

An incident means any malfunction or deterioration in the characteristics or performance of a device, including use errors due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer. Furthermore, the term includes undesirable side effects when applied specifically to devices covered by MedDO and any harm as a consequence of a medical decision or an action taken or not taken on the basis of information or results provided by the device when applied specifically to a device covered by IvDO[8].

An incident is classed as "serious" and therefore reportable, if at least one of the following consequences have occurred – or might occur – either directly or indirectly[9].

- The death of a patient, user or other person
- A temporary or permanent serious deterioration in a patient's, user's or other person's state of health
- A serious public health threat.

Examples of reportable incidents for devices covered by MedDO:

- A guide wire breaks during a transcatheter heart valve replacement. The device involved is the "guide wire". Since the event could have resulted in an injury to a vessel or to its occlusion, it is a serious incident.

- A patient suddenly experiences severe pain in the area of his/her hip implant. An x-ray reveals that the implant is broken and no longer correctly integrated with the bone (connection with device). Revision surgery is required (serious deterioration in the state of health).

- An elastomeric pump with a cancer therapy drug empties too quickly, although the dosage and quantity of the drug in the pump was correctly calculated (event in connection with device). Fortunately, the patient does not subsequently suffer any side effects. Nevertheless, this event is still reportable since, in a worst-case scenario, the patient could have gone into shock (it could have led to a serious deterioration in health).

Examples of reportable incidents for devices covered by IvDO:

- A patient is admitted to hospital with cardiac problems. The patient’s treatment is delayed owing to an incorrect diagnostic test result (e.g. troponin).

- A patient receives the incorrect dose of a particular medication owing to an incorrect diagnostic test result (e.g. digitoxin). In the worst-case scenario, the incorrect dosage could cause adverse reactions.

- A lab technician cuts their finger on the sharp edge of a tube containing a blood sample when opening the tube.

In case of doubt, users should always report. If you conclude that a reportable incident is not involved, this should be explained and documented in writing within the hospital.

[8] Art. 4 para. 2 MedDO in conjunction with Art. 2 no. 64 MDR and Art. 4 para. 2 IvDO in conjunction with Art. 2 no. 67 IVDR
[9] 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

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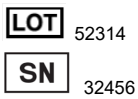
7 Reporting a serious incident to Swissmedic

If you conclude that a reportable incident is involved, please complete the whole of the form provided on the Swissmedic website.

Swissmedic website: www.swissmedic.ch/md-materiovigilance-user

You can find the required information either in the instructions for use, on the device packaging, on the device itself or on the delivery note. The following symbols may also be helpful:

- Trade name of the device,

TM	→ e.g.: Famed™	™ for Trade Mark,
©	→ e.g.: Medifire©	© for Copyright Please do not use internal hospital names/umbrella terms, but only exactly what is stated on the device or in the instructions for use.
		Name and address of the manufacturer or SPPP
		Lot number Serial number
		UDI (Unique Device Identification) Code (if it exists). See also section 9.

- An accurate and concise description of the serious incident and the serious or possibly serious consequences for the patient, user or a third party.
- We would point out that, if possible, the device concerned should not be disposed of but should be made available to the manufacturer or SPPP. Otherwise, the manufacturer or SPPP will not be able to analyse the device. The manufacturer, SPPP or supplier will usually send you details on the method and timing of return shipment. Please note that Swissmedic does not analyse any devices involved in incidents.

8 Reporting a serious incident to the supplier

To ensure that manufacturers or SPPPs are able to analyse incidents, healthcare professionals are legally obliged to report serious incidents with devices to the corresponding manufacturers, SPPPs or suppliers[10]. The manufacturer or SPPP must immediately investigate the cause of the incident and, if necessary, take actions designed to prevent further incidents or limit their impact.

9 What is a UDI?

A UDI is a sequence of numerical or alphanumerical characters issued using internationally recognised identification and coding standards which enables individual devices on the market to be identified via a unique identifier. Before a device is placed on the market, the manufacturer or SPPP must assign a product identifier (UDI) to the device. The UDI must appear on the device's label and any additional levels of packaging.

[10] Art. 66 para. 4 MedDO and Art. 59 para. 4 IvDO

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The UDI is being introduced in phases in line with the transitional periods defined for devices covered by MedDO and devices covered by IvDO[11]. Systems and procedure packs are subject to the transition period applicable to the class of system or procedure pack in question.
The UDI system will simplify the traceability of devices, significantly increase the efficacy of safety-related activities after devices have been placed on the market, and enable improved surveillance by the relevant authorities. It will also help to reduce the number of medical errors and take action against counterfeiting. Furthermore, the use of the UDI system should improve procurement and disposal policies as well as stock management at healthcare institutions.

10 Requirements for hospitals concerning UDI

For Class III implantable devices covered by MedDO or devices covered by IvDO, healthcare institutions must determine and record (preferably electronically) the UDIs of devices that they have procured and dispensed[12].
To improve the traceability of devices, recording the UDIs of all procured and dispensed products is recommended. This would enable the relevant patients to be identified more easily, for instance in the event of a recall.

11 Reporting timelines

The reporting timeline is either 2, 10 or 15 days depending on the associated risk[13].

Any serious and immediate threat to public health must be reported without delay, and at the latest within 2 days.

Serious Incidents that have resulted in the death or unanticipated serious deterioration in a person's state of health must be reported without delay, and at the latest within 10 days.

All other serious incidents must be reported without delay, and at the latest within 15 days.

[11] Art. 104 MedDO and Art. 85 IvDO
[12] Art. 65 MedDO and Art. 58 IvDO in conjunction with Art. 24 para. 11 let. a IVDR
[13] Art. 66 para. 4 MedDO in conjunction with Art. 87 MDR and Art. 59 para. 4 IvDO in conjunction with Art. 82 IVDR

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12 Tasks of Swissmedic in the context of vigilance relating to medical devices

- Swissmedic evaluates the report and identifies possible trends for serious incidents.
- If applicable, Swissmedic forwards the report to the manufacturer or SPPP, monitors its analyses and reviews the investigation results and the conclusions.
- Any field safety corrective actions (FSCAs) concerning Switzerland or Liechtenstein that are implemented as a result of incidents are published by Swissmedic on its website www.swissmedic.ch/md-fsca-en
- Once a week, Swissmedic informs all vigilance contact persons for medical devices about the newly published actions by e-mail.
- Swissmedic conducts inspections in hospitals in the context of vigilance relating to devices.
- Swissmedic does not provide information on incident reports. Therefore, Swissmedic will only provide the reporting individual with an automatic acknowledgement of receipt, without disclosing any details on the status or analysis of the case. This information should be requested from the manufacturer, SPPP or the person who received your report (e.g. distributor).

13 Incidents with medicinal products or blood products

Information on the reporting of incidents involving medicinal products, including biological and blood products, can be found on the website www.swissmedic.ch under the heading "Human medicines" → "Market surveillance" in the "Pharmacovigilance" and "Haemovigilance" sections.

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