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Change history

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1 Introduction

The Therapeutic Products Act[1] requires professional users to report serious incidents involving therapeutic products to Swissmedic (Art. 59, para. 3 TPA). For medical devices[2], this reporting obligation is explicitly regulated in the Swiss Medical Devices Ordinance (Art. 66 para. 4 MedDO).

2 Objective

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

3 Who must report?

Anyone who uses a medical device in connection with their work or who uses a medical device on other people or for diagnosis is subject to the reporting obligation. The reporting requirement therefore affects doctors, dentists, therapists, paramedics, nurses and other professionals. The professional who becomes aware of the serious incident during the use of a medical device is responsible for reporting that incident.[3] This person must report the serious incident to either directly to Swissmedic or via a vigilance contact person for medical devices in the hospital and to the supplier.[4]

[1] Federal Act on Medicinal Products and Medical Devices (TPA, SR 812.21)
[2] The term "medical devices" covers all the products defined in Art. 1 para. 1 MedDO. Consequently, this guidance document also applies to groups of products without an intended medical purpose as per Annex I MedDO (Annex XVI MDR).
[3] Art. 59 para. 3 Federal Act on Medicinal Products and Medical Devices (TPA, SR 812.21)
[4] Art. 66 para. 4 Medical Devices Ordinance, July 1st, 2020 (MedDO, SR 812.21)

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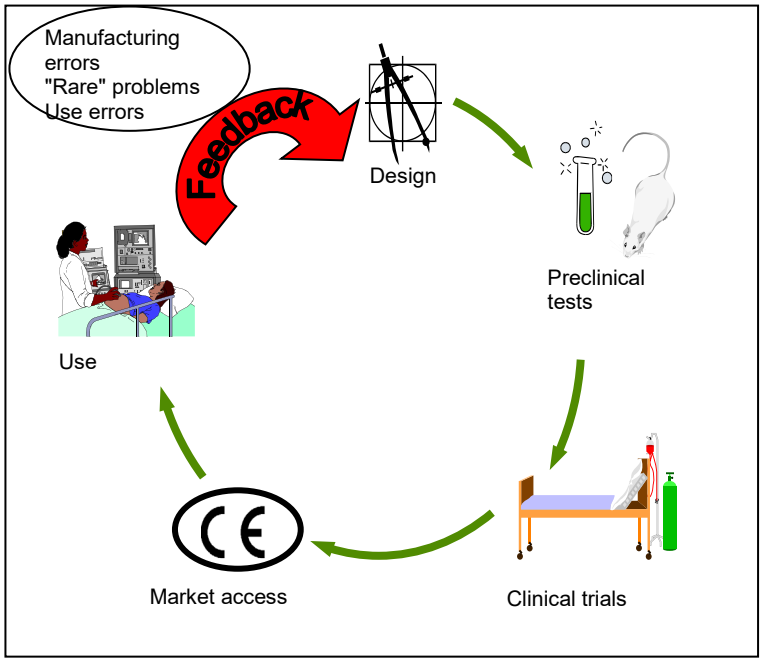
4 Why report?



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 medical 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.
Although the safety of a medical device is checked before being placed on the market, e.g. in technical tests, preclinical and clinical studies, or by a performance evaluation process, 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.
Prevention*:* The main purpose of a report is to prevent further incidents. 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, where necessary.

5 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 and any undesirable side effect.[5]
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:[6]

- 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:

[5] Art. 4 para. 2 Medical Devices Ordinance, July 1st, 2020 (MedDO, SR 812.21) in conjunction with Art. 2 point 64 Regulation (EU) 2017/745 on medical devices (MDR)
[6] Art. 4 para. 2 Medical Devices Ordinance, July 1st, 2020 (MedDO, SR 812.21) in conjunction with Art. 2 point 65 Regulation (EU) 2017/745 on medical devices (MDR)

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- A guide wire breaks during a transcatheter heart valve replacement. The medical 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 medical 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 medical 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).

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.

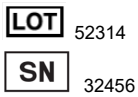
6 Reporting a serious incident to Swissmedic

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
		Lot number Serial number
		UDI (Unique Device Identification) Code (if it exists). See Chapter 8.

- An accurate and concise description of the serious incident

- We would point out that, if possible, the medical device concerned should not be disposed of but should be made available to the manufacturer. Otherwise, the manufacturer will not be able to analyse the device. The manufacturer 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.

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7 Reporting a serious incident to the supplier

To ensure that manufacturers are able to analyse incidents, healthcare professionals are legally obliged to report serious incidents with medical devices to the corresponding manufacturers or suppliers.[7] The manufacturer must immediately investigate the cause of the incident and, if necessary, take actions designed to prevent further incidents or limit their impact.

8 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 medical device is placed on the market, the manufacturer must assign a product identifier (UDI) to the device. The UDI must appear on the device's label and any additional levels of packaging.
The UDI is being introduced in phases in line with the transitional periods defined in Regulation (EU) 2017/745 on medical devices[8].
The UDI system will simplify the traceability of medical 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.

9 Requirements for hospitals concerning UDI

For Class III implantable devices, healthcare institutions must determine and record (preferably electronically) the UDIs of devices that they have procured and dispensed[9].
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.

10 Reporting timelines

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

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 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, monitors its analyses and reviews the investigation results and the conclusions.
- Any field safety corrective actions (FSCAs) concerning Switzerland 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.

[7] Art. 66 para. 4 Medical Devices Ordinance, July 1st, 2020 (MedDO, SR 812.21)
[8] Art. 123 Regulation (EU) 2017/745 on medical devices (MDR)
[9] Art. 65 Medical Devices Ordinance, July 1st, 2020 (MedDO, SR 812.21)
[10] Art. 66 para. 4 Medical Devices Ordinance, July 1st, 2020 (MedDO, SR 812.21) in conjunction with Art. 87 Regulation (EU) 2017/745 on medical devices (MDR)

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- Swissmedic conducts inspections in hospitals in the context of vigilance relating to medical 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 or the person who received your report (e.g. distributor).

12 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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