1 Objective

This information sheet describes the purpose of user reports in relation to materiovigilance and is designed to serve as a guide for users in implementing the legal requirements.

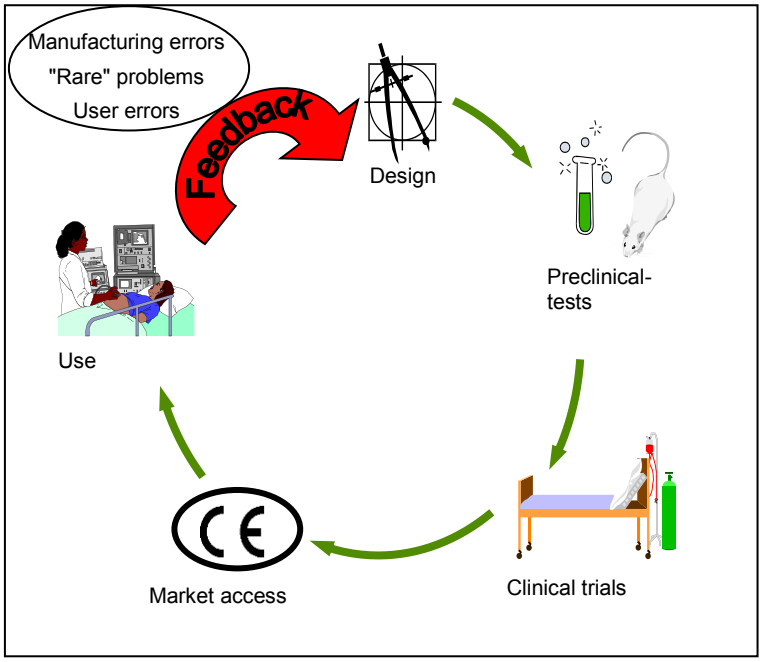
2 Legal basis

The Therapeutic Products Act requires professional users to report incidents[1] involving therapeutic products to Swissmedic (Art. 59, para. 3 HMG, SR 812.21). For medical devices (this also includes in-vitro diagnostic products (IVD)) this reporting requirement is explicitly regulated in the Medical Devices Ordinance (Art. 15, para. 2 MepV, SR 812.213).

3 Who is affected?

Anyone who uses a medical device in connection with their work or who uses a medical device on other people or for diagnosis. The reporting requirement therefore affects doctors, dentists, therapists, paramedics, nurses, laboratory personnel, technicians and other professionals. The professional who becomes aware of the incident during the use of a medical device is responsible for reporting that incident. This person must report the incident to Swissmedic either directly or via a Materiovigilance Contact Person in the hospital or a professional association.

4 Why is reporting necessary?



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.

[1] Official wording as used in 93/42/EEC concerning medical devices, 98/79/EC on in vitro diagnostic medical devices, 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices: *Incident* used as translation of "schwerwiegendes Vorkommnis", *Event* used as translation of "Vorkommnis"

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- *Prevention:* The main purpose of a report is to prevent further incidents. The reporting of an 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. The reporting of an incident in Zurich, for example, can lead to a modification of devices in Basel or Geneva and thus prevent the same problem from occurring in these locations as well.
- *Centralisation:* The reporting of incidents to Swissmedic allows information to be recorded centrally. Swissmedic can compare reports from users across Switzerland, request further investigations by the manufacturer or analyse the relevant issue with other European authorities and thus disclose a problem quicker than would otherwise be possible for an individual user. Swissmedic can also ensure that any required corrective actions are implemented quickly for all affected users.
- *Providing support:* In its role as a monitoring authority Swissmedic is in a different negotiating position in respect of the manufacturer compared to the individual user. Swissmedic can, for example, arrange further investigations and measures.

5 Reporting: What and how?

Professional users of medical devices must report incidents to Swissmedic either directly or via a Materiovigilance Contact Person or a professional association. Incidents are those which lead, or could have led, to death or to a deterioration in the health of patients, users or others, as well as incidents that require medical or surgical intervention.
The term *incident* is likewise defined in Art.3, para. 1.d of MepV (SR 812.213).

5.1 Details to be reported for an incident

- *Where:* Address of a contact person in the relevant healthcare facility.
- *What:* Description of the device (brand name, model, lot / serial number, UDI code (if known), manufacturer and supplier of the device). If possible, the device concerned should not be disposed of as it may be needed for further analysis by the manufacturer. If this is not possible due to a prevailing risk of infection, all the details of the device should be noted. On the basis of model and lot numbers, the manufacturer can check its production documentation and, if available, any retained samples from the same batch.
- *Why:* Description of the incident and its health consequences.

Swissmedic provides a simple report form on its website (www.swissmedic.ch/md-materiovigilance-user). A decision-making guide for vigilance reports can also be found at the same address.

5.2 Who do I report to?

Reports of incidents should be forwarded directly to Swissmedic. Users of medical devices who work in a hospital should submit their reports via the designated Materiovigilance Contact Person in their hospital. This allows any users involved in an incident to remain anonymous in relation to Swissmedic if they so wish. Professionals also have the option of submitting reports via a professional association, which then forwards the report to Swissmedic. In this case, please check that the report has been forwarded to Swissmedic.
In all cases, please ensure that all the necessary details of the incident and the device involved are available.
Please note that you should also inform the manufacturer of both serious and non-reportable incidents so that the manufacturer can fulfil its obligation to monitor products that have been placed on the market.

6 What happens with a report?

When submitting a report to Swissmedic, users are requested to inform the supplier or manufacturer of the device at the same time. The latter must immediately investigate the causes of the incident. If necessary, the supplier or manufacturer will also implement measures for preventing further incidents or limiting their consequences.

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6.1 Investigation of the incident

In order to establish the causes of a problem, the relevant device and any accessories must be investigated. Therefore, the user should, wherever possible, retain all accessories and packaging in addition to the device itself. The investigation is usually carried out by the manufacturer, since it possesses the knowledge, methods and equipment required for carrying out these analyses quickly. Depending on the individual case, the user, Swissmedic or other official bodies can also instruct the manufacturer not for the time being to carry out any destructive tests. If they so desire, users may also insist that the device be returned to them on completion of the investigation. Users are not usually directly involved in the investigation. On completion of the investigation, the manufacturer should inform the user of the results and conclusions, provided the manufacturer has the user's contact details.
Swissmedic will monitor the manufacturer's investigation and initiate further action if appropriate.

6.2 Analysis of the report at Swissmedic

Swissmedic ensures that the manufacturer adequately investigates the problems reported with its device and implements any required corrective actions for ensuring that the safety of the product is always adapted to the latest scientific and technological findings.
Incoming individual reports are subjected to a risk analysis at Swissmedic, and a trend analysis is performed with the aid of Swissmedic's own database. Individual reports on their own are rarely convincing as evidence. If a suspected trend emerges from the analysis, this suspicion is further investigated. Risk-reducing measures are required only in those cases where a trend is confirmed. The higher the prevailing risk, e.g. a problem that is difficult to identify or that is only identified at a late stage, serious deterioration in the patient or a high number of exposed individuals, the earlier measures should be taken and the more far-reaching these measures should be.

6.3 Examples of corrective actions

- Device recalls
- The dissemination of warnings
- Modifications of devices on site
- Changes to the design, labelling or instructions for use
- Adaptations in the manufacturing process for future devices.

6.4 Publication

Since September 2005 Swissmedic has published a list of notified recalls and other safety actions concerning devices in Switzerland on its website at www.swissmedic.ch/md-fsca-en. This list provides identifying details of the devices and letters sent to customers by the manufacturer/distributor.

7 Data protection and obligation of secrecy

7.1 Legislation

- Federal Act on Data Protection (DSG), SR 235.1
- Therapeutic Products Act (HMG), SR 812.21: Section 4: Obligation of secrecy and disclosure of data

7.2 Information in relation to data protection and obligation of secrecy

Please note that, as a result of data protection requirements and the obligation of secrecy, Swissmedic may not provide the reporting individual with any information relating to ongoing procedures on the following points:

- Number of reports in Switzerland or worldwide
- What investigations are being carried out by the company?
- What investigations are being carried out by other authorities?
- What investigations are being carried out by the Notified Body?
- What actions are planned or have already been implemented?

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The therapeutic product authorities deal with facts in which the owner of the information (in this case e.g. the manufacturer) has an interest worthy of protection and which may be entrusted to Swissmedic only on condition that it is not made public. The general principle therefore applies that all data collected on the basis of legislation relating to therapeutic products is not publicly available, but should be treated in confidence. The disclosure of data (e.g. manufacturing or commercial secrets) may cause the company concerned to suffer financial loss.

Therefore, Swissmedic will only provide the reporting individual with a confirmation of receipt, without disclosing any details of the status and analysis of the case. This information should be requested from the manufacturer or the person who received your report (e.g. supplier).

8 Medicinal products, blood products: pharmacovigilance, haemovigilance

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

9 Contact for questions relating to the reporting requirement

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Further information on medical devices can be found at www.swissmedic.ch/md

Change history

Version	Valid and binding as of:	New minor version	Description, comments (by author)	Author’s initials
1.1		31.08.2018	Change of contact address and internet links	bul
1.0	**09.03.2017**		**New QM ident (old ident: MU101_30_004e_MB)**	**wis**
02	**01.05.2016**		**Section 5.2: Note inserted that incidents should also be reported to the manufacturer.** **Section 6.2: Note inserted that the manufacturer should provide feedback to the user, provided the manufacturer has the user's contact details.** **Section 7.2: Information inserted that Swissmedic will now only send users a confirmation of receipt.**	**bul**
01	**01.12.2014**		**Initial issue for inclusion in the Q System** **Replaces the Internet version of 24.01.2006**	**bul**