1 What is the aim of this information sheet?

This document describes the requirements that have to be met in respect of incident[1] reports by the person first placing a medical device on the market. Professionals who become aware of incidents during the use of medical devices are also required to report such incidents. This is described in the information sheet *Materiovigilance – User reports*.
This information sheet was prepared by Swissmedic, the Swiss Agency for Therapeutic Products, and is intended for the person first placing a medical device on the market. The applicable medical device provisions should be summarised and presented in simple, understandable language and in a form that can be used directly in practice. The legal provisions apply in all cases.
For ease of readability, this document does not specify both sexes. The content always applies to both sexes.

2 Terms, definitions, abbreviations

Placing on the market: the distribution and dispensing of therapeutic products (Art. 4, para. d of HMG, Therapeutic Products Act)

Person first placing a medical device on the market: The person who is the first to provide a medical device in Switzerland, either free of charge or subject to payment (Art. 3, para. 2 of MepV, Medical Devices Ordinance), is deemed to be the person first placing the device on the market. These persons are the manufacturers (those who affix the CE label) and their European representatives. **Accordingly, anyone who imports medical devices and issues them in Switzerland to intermediaries, dispensing outlets or patients is also deemed to be the person first placing the device on the market**.

Person who continues to place devices on the market: e.g. dispensing outlets (wholesaler, retailer) or intermediaries

3 Legal basis

Reports of incidents with medical devices are regulated in the Therapeutic Products Act (HMG, SR 812.21) and the Medical Devices Ordinance (MepV, 812.213). The requirements of the three European Directives 90/385/EEC, 93/42/EEC and 98/79/EC have been implemented in Swiss legislation.

The person first placing a medical device on the market is required to organise and implement **self-surveillance** (Art. 14 MepV). They must report incidents to the competent authorities (Art. 15 MepV), i.e. **all incidents in Switzerland** must be reported to Swissmedic regardless of whether the person first placing a medical device on the market is based in Switzerland. The reporting process for incidents, as described in this information sheet, applies to all medical devices of all classes.
According to MepV the person who places a device on the market for the first time must ensure that the incidents are reported to Swissmedic. In practice, the reports can be submitted by the manufacturer, even if located in a foreign country, by its European representative or by the Swiss distributor.
Swissmedic advises Swiss importers (e.g. distributors, pharmacies, medical practices, etc.) **to conclude contractual agreements with the suppliers and/or manufacturers** which regulate the responsibilities in respect of product surveillance (Section 5 MepV: Product surveillance system, reporting of incidents and safety measures).

Anyone who **continues to place devices on the market** (wholesaler, retailer, etc.) is required to collect complaints concerning the devices and experience relating to their use and efficacy and to

[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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forward these to the person who placed the device on the market for the first time (Art. 14, para. 4 MepV, Art. 15d).

4 How to report

Switzerland is integrated in the European system through Bilateral Agreements. Accordingly, Switzerland has also taken an active part in consultations between the various interested parties (authorities, European Commission, industry) on the drafting and extension of European guidelines for a medical device surveillance and report system (MEDDEV 2.12/1). These guidelines therefore also apply in Switzerland.
The document MEDDEV 2.12/1 provides a detailed description of the procedure to be followed for an incident. The document also contains several examples designed to facilitate the interpretation of the term "incident". The document can be downloaded from the European Commission website:
http://ec.europa.eu/growth/sectors/medical-devices/guidance_en
Reports can be submitted in English or in one of the official languages. The corresponding form can be found either on the European Commission website or on the Swissmedic website under "Medical devices".

5 When to report

If the incident evidently constitutes, or has the potential to constitute, a serious and imminent threat to the **life or health of a large number of persons** (serious public health threat), the report must be submitted **within 2 calendar days** after its awareness.
The report must be submitted within **10 calendar days** if the incident has resulted, or could have resulted, in death or an unanticipated serious deterioration in state of health, and no later than **30 calendar days** following the date of awareness of all other incidents;

6 Reporting procedure

The Inital Report should be submitted to Swissmedic by the reporting deadline. This report contains all the information that is available at this point concerning:

- the incident,
- the device concerned,
- the consequences for the patient.

The First Report must also:

- state whether immediate actions are planned,
- provide a rough description of the scheduled investigation (e.g. whether and, if so, how the device is to be analysed),
- provide a rough timetable for the scheduled investigation,
- state the approximate date of the Final Report.

An Interim Report must be submitted to Swissmedic if the original actions are changed as a result of the investigation or if the date of the Final Report is deferred; this interim report should contain all the currently available results of the investigations.
The Final Report must contain all the information that was not yet available at the time of the First Report. In particular, this must include:

- the results of the investigation,
- the conclusions,
- any scheduled corrective actions and the rough timetable for their implementation.

Evaluation by Swissmedic
Swissmedic systematically compiles reports as they are received, evaluates them and then decides whether further actions are needed. For First Reports, Swissmedic pays particular attention to the evaluation of immediate actions (are such actions necessary, planned, appropriate?) and the proposed investigation (is this necessary, appropriate?). For Final Reports, the evaluation focuses on the results of the investigation and the conclusions of the manufacturer. If Swissmedic has concluded its evaluation and if all the required documents have been received, the author of the report receives

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written confirmation of the conclusion of this case by Swissmedic. However, this does not rule out the possibility of subsequent investigations should new information become available.

6.1 Trend Reports

The modalities for Trend Reports are described in a separate Swissmedic information sheet (*Periodic Summary Reports and Trend Reports for medical devices in Switzerland*).
If a marked increase in the rate of incidents or customer complaints is observed, the person first placing a medical device on the market must report this, and any implemented actions, to Swissmedic in a Trend Report. A corresponding form can be found on the European Commission website.

6.2 Summary Reports

The modalities for Summary Reports are described in a separate Swissmedic information sheet (Periodic Summary Reports and Trend Reports for medical devices in Switzerland).
Summary Reports can be authorised by Swissmedic on request if the cause of the error is known or if, after the implementation of recalls and other safety actions, defective devices continue to be placed on the market.

6.3 Devices in connection with clinical trials

If CE-labelled medical devices are used according to their intended purpose in clinical trials (Post Market Clinical Follow-Up studies, see also the European guidelines MEDDEV **2.12/2**), incidents are reported in accordance with this information sheet.
By contrast, a separate information sheet "BW101_50_002e_MB Clinical trials with medical devices: Authorisations and reports" provides information on reporting requirements in clinical trials with devices that are not yet CE-labelled, or for uses that are outside the scope of the intended purposes scheduled for CE-labelling.

7 What must be reported?

All incidents (as defined in Art. 3 MepV and MEDDEV 2.12/1) that occur in Switzerland must be reported to Swissmedic. These reports are mandatory for all medical devices that are already in circulation.
Recalls of devices or other safety actions relating to products already in circulation (Field Safety Corrective Actions, FSCA) and which involve Switzerland must likewise be reported to Swissmedic. An information sheet on the reporting of FSCA *"MU101_30_001e_MB Reporting of recalls or other safety actions (FSCA)"* is available on the Swissmedic website. If an incident occurs outside Switzerland, the case must be reported to the corresponding foreign authority. Swissmedic is not responsible for processing the corresponding incident report and does not need to be informed. However, if a marked increase in the expected rate of incidents occurs, even if no incident has occurred in Switzerland itself, the person first placing a medical device on the market must submit a corresponding Trend Report to Swissmedic (see section 6.1 Trend Reports).

7.1 Interpretation of the obligation to report side effects according to Para. 5.1.3.5 "EXPECTED AND FORESEEABLE SIDE EFFECTS" as per MEDDEV 2.12/1

According to the MEDDEV guidelines, Paragraph 5.1.3.5, expected and foreseeable side effects must meet the following criteria in order to be considered as not reportable. Specifically, **all** 4 criteria must be met:
- the side effect is clearly described in the product information;
- the side effect is clinically described as foreseeable and has a qualitative and quantitative predictability when the device is used and performs as intended;
- the side effect must be documented in the Device Master Record, with an appropriate Risk Assessment prior to the occurrence of the serious incident;
- the side effect must be clinically acceptable in terms of the individual patient benefit.

Incidents arising as a result of a malfunction of the device are reportable and cannot be classified as a side effect, even if these malfunctions are known.

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Examples:
- Breakage of a bone nail that has not been caused by an event (e.g. accident)
- Breakage of a Class I surgical instrument, a fragment of which is left behind in the patient's body
- Failure of a stent to unfurl

8 User reports to Swissmedic

Professional users are subject to a reporting requirement and must submit user reports to Swissmedic. Patients can also report incidents to Swissmedic. Swissmedic forwards such reports to the manufacturer or distributor. The company that receives a report from Swissmedic must treat this like any other report. The receipt via Swissmedic does not release companies from their own reporting obligations in relation to Swissmedic. On receipt of a user report, the following procedure should therefore be followed:

- The company receiving the report can forward this, per section 3, to another company in the distribution chain (manufacturer, representative, etc.), which will then investigate the case and send the Vigilance Report and further reports to Swissmedic.
- The company concerned must evaluate the event and decide whether it is a reportable incident or not.
- If the event is a reportable incident, the procedure described in section 6 must be followed. An Initial Report must be submitted to Swissmedic by the specified deadline. The Final Report is submitted on completion of the investigation.
- If the event is not classified as a reportable incident, the company must inform Swissmedic accordingly.
- Quality management systems require effective rules for informing customers in the event of complaints. Accordingly, the affected user and Swissmedic should be informed in writing of the results of the investigation of the relevant incident.
- Swissmedic will also forward user reports concerning obviously non-reportable events to the manufacturer for information purposes (complaint handling).

9 Confidentiality

Articles 61 to 64 of HMG address the confidentiality of data. The law stipulates an obligation of secrecy for Swiss federal and cantonal authorities and also rules on the exemptions from this obligation.
Swissmedic forwards data to federal or cantonal authorities which are responsible for enforcing legislation, e.g. the Federal Office of Public Health (FOPH) or cantonal authorities. Swissmedic informs the cantonal pharmacists about the results of any investigations of particularly incidents that have occurred in their canton.
In order to avoid health risks, Swissmedic can also exchange confidential data with foreign authorities (Art. 64 HMG).

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10 Contact for questions relating to the reporting requirement

Swissmedic, Swiss Agency for Therapeutic Products
Medical Devices Department
Hallerstrasse 7
CH-3012 Bern

Tel. +41 58 463 22 51, Fax +41 58 462 76 46
E-Mail: materiovigilance@swissmedic.ch

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

Change history

Version	Valid and binding as of:	New minor version	Description, comments (by author)	Author's initials
1.1		31.08.18	Change of contact address and internet links	bul
1.0	**09.03.17**		**New QM ident (old ident: MU101_30_005e_MB)**	**wis**
03	**01.05.16**		**Change in the procedure for user reports: Section 8, User reports to Swissmedic – paragraph added to explain that information on non-reportable events (complaints) will also be forwarded.**	**bul**
02	**01.09.15**		**Change to text in section 6, Evaluation by Swissmedic**	**bul**
01	**01.02.15**		**Initial issue for inclusion in the Q System Replaces the Internet version of 24.01.2006**	**bul**