1 Terms and definitions

1.1 Summary Reports

According to Art. 15a of the Medicinal Devices Ordinance (MedDO, SR 812.213)[1] Periodic Summary Reports (PSRs) are reports of serious incidents that are being submitted periodically in summarised form.

1.2 Trend Report

According to Art. 15b MedDO, a Trend Report provides information about a significant increase in the occurrence of events and/or serious incidents.

1.3 CAPA: Corrective and Preventive Action

CAPA is a concept within quality management. CAPA focuses on the systematic investigation of discrepancies (e.g. failure and/or deviations) and endeavours to prevent their recurrence (*corrective action*) or prevent their occurrence in the first place (*preventive action*).

1.4 Person first placing a device on the market

The "first placing on the market" applies if the device is transferred in Switzerland for the first time (Art. 3 para. 2 MedDO). Accordingly, anyone who imports medical devices and issues them in Switzerland to intermediaries, dispensing outlets or patients is deemed to be the person first placing the device on the market.

Persons who further place devices on the market must contribute towards the monitoring of the safety of the devices on the market and are therefore required to compile complaints and relevant experience concerning their use and efficacy and to forward these to the person first placing the device on the market.

2 Objective

This information sheet provides guidance on the requirements for Summary Reports and Trend Reports for medical devices in Switzerland. It describes the reporting criteria and the requirements for Periodic Summary and Trend Reports and their handling by Swissmedic.

3 Legal requirements and guidelines

The specific requirements for PSRs and Trend Reports in Switzerland are described in Articles 15a and 15b of MedDO.
The basic concepts, examples and the European procedures for PSRs and trend reports are laid down in the European document MEDDEV 2.12-1[2].
The IMDRF (International Medical Devices Regulatory Forum) (ex GHTF) document N36R7[3] provides international guidelines for establishing significant increases in the occurrence of incidents.

4 Corporate obligations in Switzerland and in the international context

4.1 Periodic Summary Reporting

Incidents that fulfil the PSR criteria can be reported by the manufacturer, its EU representative or the person first placing the device on the market in Switzerland by means of compiled PSRs. The manufacturer, its EU representative or the person first placing the device on the market must discuss the content of the PSRs with the authorities concerned and/or Swissmedic and obtain their consent to the reporting of the described incidents by means of PSRs.

[1] Medical Devices Ordinance (MedDO, SR 812.213)
[2] Guidelines on a medical devices vigilance system, MEDDEV 2.12-1
[3] GHTF/SG2/N36R7:2003, Manufacturer's Trend Reporting of Adverse Events

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PSRs may then be issued if the following criteria are fulfilled:

i) the root cause of the reportable incidents is known or
ii) defective devices are still on the market following recalls and other field safety corrective actions

4.2 Trend Reports

Trend Reports are mandatory and must be submitted to Swissmedic by the manufacturer, its EU representative or the person first placing the device on the market. Trend Reports must also be submitted to the authorities in the country in which the manufacturer or its EU representative has its registered office.

Please note the difference in this context between Swiss legislation and MEDDEV 2.12-1, which serves as a guideline for the EU, in that only the authority in the country in which the manufacturer or its EU representative has its registered office receives information in the form of Trend Reports.

5 Procedure at Swissmedic

5.1 General procedure

Swissmedic treats PSRs and Trend Reports like reports of incidents. Swissmedic expects the reporting company to submit at least an initial report and a final report, with intermediate reports depending on the situation. Swissmedic issues the reporting company with at least an acknowledgement of receipt of the initial report and a confirmation of case closure after evaluation of the final report. Swissmedic reserves the right to pose additional questions and request further information.

5.2 PSRs

For PSRs, explicit consent must be obtained from Swissmedic and from the other authorities concerning the admissibility of the company to report a particular type of incident in the form of PSRs and the specific information that must be included in the PSR.

5.3 Trend Reports

Trend Reports relate to the manufacturer's duty to monitor its devices, recognize any trends in the overall market and react in good time. Swissmedic requires a Trend Report whenever there is a significant increase in the occurrence of the following types of incidents:

i) incidents that must be reported under any circumstances
ii) incidents that are normally excluded from the reporting obligation (e.g. user error that could potentially lead to death or serious harm to health)
iii) incidents that do not need to be reported (e.g. breakage of a component of a medical device that has not, or could not have, led to death or serious harm to health)

regardless of whether Periodic Summary Reporting has been negotiated for these types of incidents.

The trigger levels for issuing a Trend Report must be specified by the company. Swissmedic recommends that the need for issuing a report is reviewed within the CAPA that has been opened for a recognized trend.
The manufacturer is responsible for ensuring that corrective actions are implemented for recognized trends.

6 Discussion

PSRs and Trend Reports concern incidents and must be submitted by companies to Swissmedic basically in the same way as reports about incidents. The subsequent processing of these reports by Swissmedic corresponds to the procedure for reports about incidents.

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Change history

Version	Valid and mandatory as of	adapted without version change	Description, remark (provided by author)	Initials, author
01	**09.03.17**		**New QM ident (old ident: MU101_30_007e_MB)**	**wis**
01	**01.05.15**		**Revision of the content of the document "Periodic Summary Reports and Trend Reports for medical devices in Switzerland"** **Inclusion in the quality management system.**	**bul**

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