1 FAQs

1. What is an incident[1]?
    a. The use of medical devices can lead to undesirable events or side effects in the same way that medicinal products can have side effects.
    b. The law defines an event involving a medical device as an incident. This can be impaired functioning, for example, or a change in characteristics, incorrect labelling or instructions for use that have resulted or could have resulted in death or serious impairment of the health of patients, users or third-parties.
    c. In this context it is not important whether this incident is somebody's "fault".
    d. Examples:
        i. Revision of a prosthetic hip joint, for example as a result of pain, loosening or a broken shaft
        ii. Failure of the brake on a rollator in spite of regular maintenance
        iii. Detachment of a tube from an infusion set in the absence of evident force having been exerted on the site of the tear

2. Who is responsible for reporting an incident involving a medical device?
    a. The law states that incidents involving a medical device that occur in Switzerland must be reported to Swissmedic both by the healthcare professional and by the person responsible for placing the device on the market (i.e. the manufacturer or his European representative or distributor). Incidents that occur in another country must be reported to the competent authority in that country.
    b. As a patient you can report an incident yourself, but whenever possible you should discuss this report with the doctor treating you to see if he or she has already submitted a report.

3. Why are reports of incidents important?
    a. It is necessary for the manufacturer and the supervisory authority to be informed promptly on all incidents to ensure that the safety of medical devices is monitored correctly.
    b. Reports are the only way of identifying certain malfunctions and preventing them from happening again.
    c. A statistical risk analysis is carried out when each report is submitted so that possible trends or impairments of the functioning of a device can be identified.

4. Whom should I contact if I have a problem with a medical device?
    a. Please always first contact the doctor treating you, or if you are in any doubt obtain a second opinion from another doctor or a doctor whom you trust. He or she can discuss the next steps with you. Healthcare professionals are required by law to report incidents to Swissmedic.
    b. If you are unsure whether your doctor has reported your incident to Swissmedic, please ask him or her first. If you are in any doubt, you can send a report to Swissmedic yourself.
    c. You should also notify the manufacturer of any problems you experience with your medical device.

5. What information do I receive as a patient when I submit a report to Swissmedic?
    a. We will confirm receipt of your report and allocate a case number to your case.

[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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b. Please note that an incident does not necessarily mean that a product must be taken off the market or be replaced.
c. The data protection legislation and our obligation to maintain confidentiality prevent us from giving you information about any further details that we may have requested from the manufacturer in order to investigate the case. (see also section 4 of the Therapeutic Products Act, HMG, SR 812.21)

6. Product liability – whom can I contact?
   a. Please note that product liability and the limitation period applicable to this are not the responsibility of Swissmedic and we are consequently unable to provide any binding information on this subject. However, we should point out that general information on product liability and the limitation period is not contained in the Medical Devices Ordinance (MepV) or in the Therapeutic Products Act (HMG) but in the following legal texts:
      i. Federal Act on Product Safety: http://www.admin.ch/opc/de/classified-compilation/20081129/
      ii. Federal Act on Product Liability: http://www.admin.ch/opc/de/classified-compilation/19930205/
      iii. e.g. in Article 9 Limitation period: http://www.admin.ch/opc/de/classified-compilation/19930205/index.html#a9 and Article 10 Forfeiture http://www.admin.ch/opc/de/classified-compilation/19930205/index.html#a10
      iv. Federal Act on the Amendment of the Swiss Civil Code (Part Five: Code of Obligations) http://www.admin.ch/opc/en/classified-compilation/19110009/
      v. e.g. in Article 60: http://www.admin.ch/opc/en/classified-compilation/19110009/index.html#a60. It should be noted that the period does not begin until the party which caused the damage has been identified.
   b. We recommend you to consult a lawyer or a patient advocacy organisation on this matter.

7. Who decides whether my doctor has made a mistake?
   a. Swissmedic is not responsible for clarifying this point.
   b. The legal mandate of Swissmedic is to monitor product safety.
   c. We recommend you consult a lawyer or a patient advocacy organisation on this matter.

8. What happens to a report?
   a. We first analyse every report to establish the following (this list is not exhaustive):
      i. What happened?
      ii. What was the cause?
      iii. How great is the risk of this incident being repeated?
      iv. What risks are posed by the medical device potentially having malfunctioned?
   b. In addition to analysing the specific case, we monitor the manufacturer to see whether he takes any measures that are necessary to ensure that the safety of the product is always in line with current scientific findings. All reports on individual cases are analysed and evaluated to assess the effectiveness of measures.
   c. By following up individual cases Swissmedic can identify trends and assess the balance of benefit and risk associated with a medical device in order to protect collective interests.
   d. A report does not necessarily have to lead to a product being withdrawn from the market or similar. An individual case rarely leads directly to a withdrawal or modification etc. of a product. This does not usually happen until a certain number of incidents have occurred or a trend emerges.

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9. Who decides which costs for treatment with a certain medical device are borne by the health insurance provider?
    a. Swissmedic is not responsible for defining who bears costs.
    b. You can find information about this at the FOPH (Federal Office of Public Health).
    c. An overview of the costs for certain medical devices that are covered by health insurance providers can be found in the List of Aids and Devices (MiGeL).

Change history

Version	Valid and binding from	Description, comment (by author)	Author's initials
1.1	01.08.2019	Correction of internet links in paragraph 9 New method for version	bul
04	**09.03.2017**	**New QM ident (old ident: MU101_30_006e_MB)**	**wis**
03	**01.05.2016**	**Change in the way user reports are processed. A final report is no longer issued in response to patient reports. Addition to the effect that manufacturer should be informed.**	**bul**
02	22.04.2015	Correction of internet links in paragraph 6	bul
01	**01.02.2015**	**New issue**	**bul**

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