1 FAQs

1. What is a medical device?
    a. In simplified terms, a medical device is anything that can be used for medical purposes but is not a medicinal product. Medical devices are products – including instruments, apparatus, software and other items or materials – that are intended for human medical use. Examples of medical devices range from artificial joints (implants) to wheelchairs, cardiac pacemakers, blood pressure monitor, x-ray machines, hearing aids and contact lenses.
    b. IVD (in-vitro diagnostics) form a specific group of medical devices. They are used to investigate samples obtained from the human body, such as urine and blood. Examples of in-vitro diagnostics include trisomy, pregnancy or HIV tests.
    c. A number of products that are not intended for medical use are subject to the same legislation as that for medical devices. These include coloured non-prescription contact lenses (without vision correction), hyaluronic acid for treating wrinkles, cryolipolysis devices for reducing body fat, and hair-removal lasers. For a more precise definition of the products that fall into this category, please see Annex I of the Medical Devices Ordinance (MedDO, SR 812.213).

2. What is a serious incident?
    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.
    The law defines a serious incident as an event involving a medical device that could result, or could have resulted, in the death or serious impairment of the health of patients, users or third parties. For example, such an event could involve a malfunction or a deterioration in the characteristics or performance of a product, or adverse reactions. It is of no relevance whether the serious incident is anybody's "fault".
    b. Examples:
    - Premature revision of a prosthetic hip joint, for example as a result of loosening or a broken shaft
    - Failure of the brake on a rollator, despite regular maintenance
    - Detachment of a line from an infusion set with no evidence of force having been exerted at the tear, but with severe anticipated consequences for the patient.

3. What is vigilance, and what is Swissmedic's role?
    As the Swiss authority responsible for the supervision of therapeutic products, Swissmedic systematically collects and evaluates reports of serious incidents involving medical devices that have taken place in Switzerland.
    The reporting system is designed to protect the health of patients and users. In particular, it aims to avoid recurrences of serious incidents attributable to problems that can be traced to the design, manufacture or use of medical devices.

4. Who is responsible for reporting a serious incident involving a medical device?
    a. By law, serious incidents involving a medical device that occur in Switzerland must be reported to Swissmedic by both the healthcare professional and the manufacturer. Serious incidents that occur in another country must be reported to the competent authority in that country.
    b. As a patient you can report a serious 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.

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5. Whom should I contact if I have a problem with a medical device?
    a. Please always contact the doctor who is treating you first, or, if you are in any doubt, obtain a second opinion from another doctor whom you trust. He or she can discuss the next steps with you. Healthcare professionals are required by law to report serious incidents to Swissmedic.
    b. If you are unsure whether your doctor has reported your serious 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.

6. How do I report serious incidents?
    a. There is no special form for patients. Please report serious incidents by sending an e-mail to materiovigilance@swissmedic.ch.
    b. Please make sure that your report contains details of the medical device and its manufacturer at the very least. To carry out a full analysis of the serious incident, Swissmedic and the manufacturer require the following information (if available):
        - Manufacturer's name
        - Product trade name
        - Product catalogue/model number and batch/serial number
        - Date and short description of the serious incident
        - Name of the hospital that treated you (if applicable)
    c. If the medical device in question is an implant, you can generally find this information on the implant card given to you by the doctor. If the medical device in question is a catheter, insulin pump or other product that you use yourself, the information is printed on the packaging or on the device itself.

7. Why are reports of serious incidents important?
    a. It is necessary for the manufacturer and the competent authorities to be informed promptly on all serious 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.

8. 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.
    b. Please note that a serious 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, TPA, SR 812.21)

9. How can I get more information about a medical device?
    a. The first thing to do is ask your doctor for advice
    b. If you have an implant, you will be given information on the product as well as an implant card.

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10. Product liability – whom can I contact?
    a. Please note that product liability and the associated limitation period fall outside Swissmedic's responsibility and we are consequently unable to provide any 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 (MedDO) or in the Therapeutic Products Act (TPA) but in the following legal texts:
        - Federal Act on Product Safety: https://www.fedlex.admin.ch/eli/cc/2010/347/de
        - Federal Act on Product Liability: https://www.fedlex.admin.ch/eli/cc/1993/3122_3122_3122/de
        - e.g. in Article 9 Limitation period: https://www.fedlex.admin.ch/eli/cc/1993/3122_3122_3122/de#art_9 and Article 10 Forfeiture https://www.fedlex.admin.ch/eli/cc/1993/3122_3122_3122/de#art_10
        - Federal Act on the Amendment of the Swiss Civil Code (Part Five: Code of Obligations) https://www.fedlex.admin.ch/eli/cc/27/317_321_377/en
        - e.g. in Article 60: https://www.fedlex.admin.ch/eli/cc/27/317_321_377/en#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.

11. 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.

12. What happens to a report?
    a. We first analyse every report to establish the following (this list is not exhaustive):
        - What happened?
        - What was the cause?
        - How great is the risk of this serious incident being repeated?
        - 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 serious incidents have occurred or a trend emerges.

13. What will happen to my medical device?
    a. The manufacturer must immediately investigate the causes of the serious incident. In order to establish the causes of a problem, the relevant device and any accessories have to be investigated. If possible, you should therefore retain all accessories and packaging as well as the device itself. The manufacturer will normally conduct the investigation. It will have the knowledge, methods and equipment needed to complete it quickly. As soon as the manufacturer or supplier is aware of the serious incident, it will contact you to organise the return of the product.

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14. 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

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