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Change history

Version	Valid and binding as of	Description, comments (by author)	Author's initials
1.0	26.05.2021	Doc newly created owing to revision of MD regulatory provisions; old doc ID: MU510_00_001e_MB	wic

1 Terms, definitions, abbreviations

FSCA: Field Safety Corrective Action
CIRS: Critical Incident Reporting System

2 Objective

This document is intended to give hospitals, and particularly the vigilance contact persons for medical devices, an overview of the development steps that a medical device undergoes until it is placed on the market and its post-market surveillance, focusing on the contribution made by the hospitals to this monitoring process. It explains the requirements applicable to the reporting system in a hospital and the role played by the vigilance contact person.
The definition of a serious incident and the reporting time limits are not addressed in this document. You can find this information in the guidance document "WL_MDV_Incident report user".

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3 Introduction to medical devices

The Therapeutic Products Act[1] (TPA) defines medical devices in Art. 4 para. 1 letter b as follows: Products, including instruments, apparatus, appliances, in vitro diagnostics, software, implants, reagents, materials and other goods or substances which are intended to have, or are presented as having, a medical use and which do not achieve their principal intended action by pharmacological, immunological or metabolic means.
There are wide variety of medical devices, ranging from wheelchairs, patient beds, contact lenses, dental prostheses, sphygmomanometers, blood glucose meters, pregnancy tests, laboratory analysers, infusion pumps, hip implants, cardiac pacemakers and artificial heart valves to surgical robots, x-ray machines, surgical equipment and patient monitoring systems.
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, 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[2] (MedDO).

The lifecycle of a medical device can roughly be divided into 3 phases.

1st phase

During the **development phase** a manufacturer produces various prototypes. These prototypes first undergo technical testing, e.g. in the laboratory. But these laboratory tests are not usually sufficient for proving that the medical device can also be used safely and is effective. Therefore, clinical trials are often conducted during the development phase with "precursors" or "prototypes" of medical devices that may only be used within the clinical trial. Manufacturers of medical devices are required to collect and evaluate any adverse events with consequences for the patients or product defects that are noted during clinical trials. To this end, patients/subjects are closely monitored during the clinical trial in order to detect and prevent any risks as soon as possible.

[1] Federal Act on Medicinal Products and Medical Devices (TPA, SR 812.21)
[2] Medical Devices Ordinance, 1 July 2020 (MedDO, SR 812.21)

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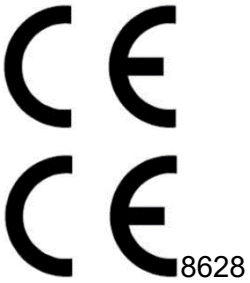
2nd phase

If, during the product development phase, the manufacturer is able to prove, by recording scientific data, that its medical device can be used sufficiently safely and effectively, the **market launch** phase can start.

In contrast with a medicinal product, a medical device is not authorised by Swissmedic. Rather, the manufacturer is responsible for conformity with the legal requirements and for ensuring that a medical device undergoes a conformity assessment procedure. Once this assessment procedure has been successfully completed, the medical device receives a declaration of conformity. For medical devices associated with a higher risk (e.g. infusion sets, implants, x-ray machines, HIV test), an independent conformity assessment body must also be consulted. Following a successful assessment, this body issues a certificate of conformity for the medical device concerned. The visible result of a completed conformity assessment procedure is the CE mark (with or without numbers) on the medical device. With this mark, medical devices can be placed on the market within the EU (European Union) or EEA (European Economic Area), but also in Switzerland.



3rd phase

If a medical device is available on the market, it may be freely used accordingly for its intended purpose. But this also means that its use is no longer as strictly monitored as it is in clinical trials. Nevertheless, the manufacturer is also required in this phase – known as the **market surveillance phase** – to continue monitoring the medical devices such that it is able to react immediately when an increased or new risk is discovered. This includes the systematic collection and evaluation of serious incidents and other feedback from the market and, if necessary, taking corresponding measures for minimising unacceptable risks. This system for monitoring risks connected with the use of medical devices is termed the **materiovigilance system**.

4 The vigilance system

Vigilance refers to a system for monitoring risks connected with the use of therapeutic products. Therapeutic products can be medicinal products, medical devices or blood and blood components. Accordingly, a distinction is made between:

Pharmacovigilance: Monitoring the risks of adverse reactions connected with the use of medicinal products.

Haemovigilance: Monitoring the risks connected with the provision of blood and blood components, from the donor to the recipient

Materiovigilance: Monitoring the risks connected with the use of medical devices.

This basically involves the collection and analysis of incidents that have resulted – or that could have resulted – in a serious risk to the health of individuals or in death, so that risks are identified and any risk minimisation measures are taken as soon as possible. Such serious incidents with medical devices can include:

- Early revision surgery for a knee implant, e.g. due to loosening of the implant
- A patient dies and there is reason to believe that the defibrillator implanted in the patient was not functioning correctly
- An infusion pump delivers much more than the programmed quantity. No alarm is triggered and an overdose scenario occurs.

4.1 Materiovigilance – the roles

The cooperation of all those involved is needed for the materiovigilance system to function correctly:

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- Manufacturers 
- Swissmedic swissmedic
- Users of medical devices (hospitals) 

The manufacturer of medical devices is responsible for ensuring that its products can be used safely and effectively. For example, the manufacturer must systematically collect and analyse all feedback and incidents that come to its knowledge and take any required measures. The manufacturer is required by law to report all serious incidents in Switzerland to Swissmedic. If the manufacturer takes measures to minimise risks – e.g. due to serious incidents – it must also report these measures to Swissmedic. Risk-reducing, preventive measures (known as Field Safety Corrective Actions or FSCAs), for example a product recall, must be reported to Swissmedic even if these actions were not based on a serious incident.

Swissmedic collects and reviews reports on serious incidents, analyses the risks associated with the incidents, evaluates the investigation planned by the manufacturer and the results and, if necessary, orders additional actions. The FSCAs are published and updated by Swissmedic on its website. Once a week, an e-mail listing the newly published actions is sent to all vigilance contact persons for medical devices in hospitals (Swissmedic – New recalls).

Hospitals as users of medical devices use the medical devices and are therefore usually the first to notice possible problems or risks in the form of incidents. Users report the incidents to the manufacturer or supplier for analysis. If the users are healthcare professionals (e.g. doctors in hospitals), they are legally required to report serious incidents both to the supplier and to Swissmedic.

If those involved fulfil their obligations, then Swissmedic receives the report of a given serious incident twice, once from the manufacturer and once from the hospital. The law incorporates this duplication in the system deliberately in order to ensure that incidents are reported and that any required measures can be taken as soon as possible.

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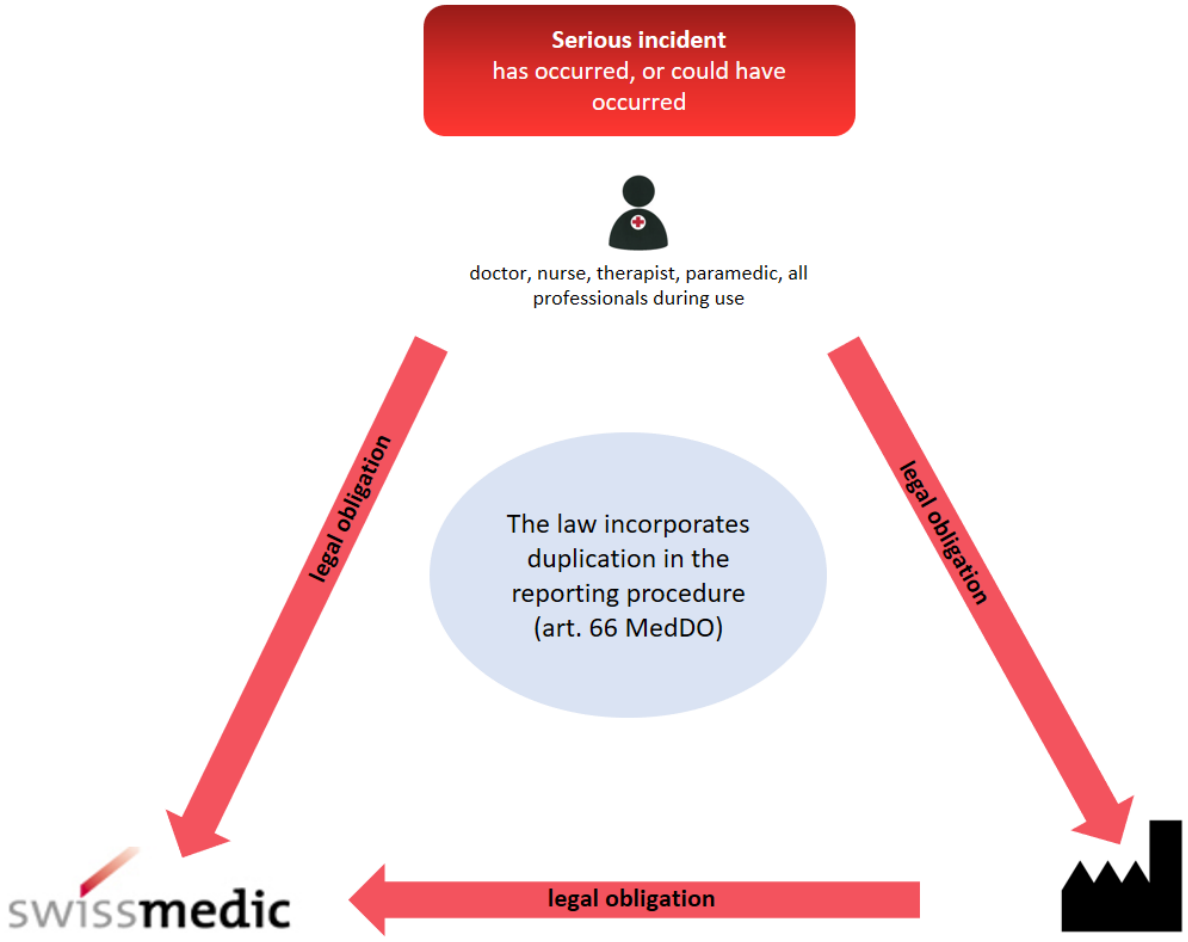

4.2 Reporting system in the hospital

A hospital is a healthcare facility in which inpatient treatments for illnesses, medical rehabilitation or medical measures for cosmetic purposes are provided by medical or nursing interventions.[3] According to art. 67 MedDO, hospitals are required to set up a reporting system as part of an established quality management system. What does this mean?

Serious incidents with medical devices can basically occur wherever medical devices are used. If such incidents occur in a hospital, they usually come to the attention of healthcare professionals, e.g. doctors, therapists, paramedics or nurses. All healthcare professionals are legally required to report serious incidents.[4] Anyone who fails to comply with this reporting obligation is liable to a fine.[5] The hospital must define and document the details of the reporting process according to the principles of its quality assurance system. For example, many hospitals have a Vigilance Manager in every department who collects – and possibly pre-sorts – the reports and then forwards them to a defined vigilance contact person for medical devices in the hospital.[6] The vigilance contact person for medical devices must report a serious incident to Swissmedic using the official report form. In other hospitals, the report is entered in an electronic system (e.g. CIRS) directly by any healthcare professional who notices an incident. Via this electronic system the reports then reach the vigilance contact person for medical devices, who carries out the final sorting and decides which incidents actually need to be

[3] Art. 3 para. 1 letter k Medical Devices Ordinance, 1 July 2020 (MedDO, SR 812.21)
[4] Art. 66 para.4 Medical Devices Ordinance, 1 July 2020 (MedDO, SR 812.21)
[5] Art. 87 para. 1 letter c Federal Act on Medicinal Products and Medical Devices (TPA, SR 812.21)
[6] Art. 67 para. 2 Medical Devices Ordinance, 1 July 2020 (MedDO, SR 812.21)

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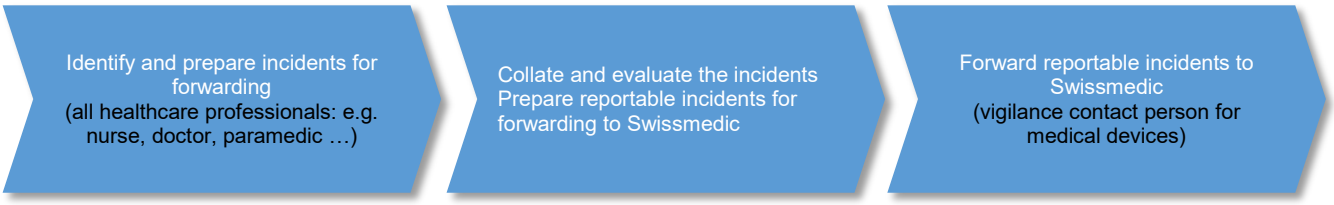
forwarded to Swissmedic. But this process only works if the individuals who use the medical devices notice incidents, realise that these must be reported and process them correctly.



The following is stipulated by law:

- who is responsible for identifying and initial forwarding (all healthcare professionals)
- who is responsible for the final forwarding of the reportable incidents to Swissmedic (contact persons)
- that this vigilance contact person for medical devices should be officially notified to Swissmedic (hospital)
- that all reports should be forwarded to Swissmedic in accordance with the requirements published on the Swissmedic website
- that a reporting system must be defined and practised as part of an established quality management system (hospital)
- that all documents produced in connection with the quality management system must be archived for at least 15 years (hospital)

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The following, among other things, should be defined in the reporting process:

- Areas of competence and responsibilities (incl. deputising arrangements)
- Definitions, e.g. of a serious incident
- Procedure, e.g. how the information about an incident passes from the location where the incident occurred to the vigilance contact person for medical devices
- Criteria for deciding whether a reportable incident is involved
- Where/how the decisions are documented
- Reporting time limits
- How it can be ensured that all individuals concerned know, at a given time, who is responsible for which part of the process

The guidance document "WL_MDV_Incident report user" provides information on how a serious incident is defined, how it must be reported to Swissmedic and what time limits must be observed.

4.3 The vigilance contact person for medical devices

Hospitals are legally required to designate a suitable qualified person with medical or technical training to assume responsibility for the requirement to report to Swissmedic.[7]
Since the vigilance contact person for medical devices acts in an official capacity in relation to Swissmedic, the vigilance contact person must also be officially notified to Swissmedic.[8] Swissmedic must also be informed of any changes in the contact details or personnel change. The corresponding form for notifying the vigilance contact person for medical devices can be found on the Swissmedic website www.swissmedic.ch/md-materiovigilance-user.

A vigilance contact person for medical devices has the following tasks:

- Act as the contact, both within the hospital and for Swissmedic, to answer questions concerning vigilance for medical devices
- Collate all incident reports within a hospital
- Sort the incidents according to the criteria defined in the process and decide which need to be reported and forwarded to Swissmedic.
- For these reportable incidents, the vigilance contact person completes the form provided by Swissmedic and forwards it to Swissmedic.
- If necessary, disseminate new, relevant information from Swissmedic, e.g. the weekly e-mail with the list of field safety corrective actions, within the hospital.

Requirements applicable to the vigilance contact person for medical devices:
An incident involving a medical device usually throws up both medical and technical issues (What complications have occurred or might occur? What defect has occurred?). The vigilance contact person should therefore possess sufficient expertise in both medical and technical areas. Swissmedic deliberately refrains from stating specific requirements for the professional qualification of contact persons. This is intended to give the hospital the greatest possible flexibility in designating the corresponding function. When designating a contact person the hospital should ensure that he/she

- is accepted by the professional users of medical devices
- possesses sufficient medical expertise for describing complications
- possesses sufficient technical expertise for describing technical problems
- be interested in quality assurance aspects.

All the necessary skills can be acquired through both training and experience. The hospital is responsible for preparing and/or training the contact persons so that they are able to carry out their tasks.

[7] Art. 67 para. 2 Medical Devices Ordinance, 1 July 2020 (MedDO, SR 812.21)
[8] Art. 67 para. 2 Medical Devices Ordinance, 1 July 2020 (MedDO, SR 812.21)

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The role of the vigilance contact person for medical devices means that other healthcare professionals are able to report serious incidents to Swissmedic **anonymously**. The vigilance contact person can therefore preserve the anonymity of the user in relation to Swissmedic while, at the same time, ensuring that further inquiries are possible.

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