1 Objective

This information sheet describes the function and tasks of the Materiovigilance Contact and is designed to serve as a guide for hospitals in implementing the legal requirements.

2 Legal basis

The Therapeutic Products Act requires professional users to report incidents[1] involving therapeutic products to Swissmedic (Art. 59, para. 3 HMG, SR 812.21). For medical devices (this also includes in-vitro diagnostic products (IVD)) this reporting requirement is explicitly regulated in the Medical Devices Ordinance (Art. 15, para. 2 MepV, SR 812.213).

Moreover, Art. 15 para. 4 MepV requires hospitals to set up an internal reporting system in accordance with the principles of quality assurance and to appoint a suitable qualified person (Materiovigilance Contact Person) with medical or technical training to assume responsibility for this reporting requirement. This contact person must be registered with Swissmedic.

3 Which hospitals are affected?

A Materiovigilance Contact Person is stipulated for all hospitals, including university, district, regional, cantonal or private hospitals. Depending on the size or complexity of a particular hospital, it may be advantageous to appoint several contact persons and assign these to different areas of responsibility. Thus, for example, a contact person might be appointed with responsibility for a particular organisational unit. Alternatively, several hospitals can also designate a shared contact person, which may be appropriate e.g. for smaller hospitals or a hospital group.
Other healthcare facilities such as old people's and nursing homes, emergency services, community nursing organisations, laboratories, medical practices, etc., do not need to appoint a Materiovigilance Contact Person. However, as in hospitals, the employees in such facilities must also report incidents involving medical devices to Swissmedic. Therefore, it may be beneficial for such organisations to designate a contact person and register this person with Swissmedic. Healthcare professionals also have the option of submitting reports to Swissmedic via a professional association.

4 What is the purpose of a Materiovigilance Contact Person?

- **Communication**: The Materiovigilance Contact Person acts as a liaison for employees in the hospital who encounter problems with medical devices. He or she provides an interface for the sharing of information between Swissmedic and the hospital about risks arising from medical devices. The hospital can also set up processes to ensure that the contact person receives announcements about safety measures and recalls directly from the manufacturer or downloads these from the Swissmedic website.
- **Filtering function**: Not all events with medical devices that occur daily in a hospital need to be reported but merely a relatively small proportion of these, i.e. incidents that are considered to be serious. On the basis of their experience, Materiovigilance Contact Persons can perform an important filtering function by excluding those incidents that are not subject to the reporting requirement for medical devices.
- **Anonymisation:** Reporting an incident in which one is directly involved can be unpleasant. Since Swissmedic investigates the quality of the medical device rather than the competence of the user, it does not need to know who was involved in an incident. The contact person can preserve the anonymity of the user in relation to Swissmedic while, at the same time, ensuring that further inquiries are possible.

5 What are the tasks of the Materiovigilance Contact Person?

- Collect reports of incidents within the hospital

[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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- Triage incidents on the basis of defined criteria (subject to reporting requirement or not)
- Complete those incidents that must be reported and forward them to Swissmedic via the report form.
- Inform internal hospital departments about the manufacturer's investigation results.
- Forward information about identified problems (e.g. warnings) within the hospital.

The basis for the work of the contact person is an open error culture in the hospital and an internal reporting system that enables incidents to be identified quickly. If quality assurance measures for dealing with errors already exist in the hospital, the contact person should act as a central interface in this context.

6 What requirements apply to the Materiovigilance Contact Person?

An incident involving a medical device usually throws up both medical and technical issues (What complications have occurred? What defect has occurred?). The Materiovigilance Contact Person should 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. The contact person should:

- be accepted by the professional users of medical devices
- possess sufficient medical expertise for describing observed complications
- possess sufficient technical expertise for describing technical problems
- be interested in quality assurance aspects
- be familiar with the materiovigilance system in the hospital

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 Materiovigilance-Kontaktpersonen an Swissmedic melden

Materiovigilance Contact Persons must be registered with Swissmedic as soon as they are appointed. A corresponding registration form can be found on the Swissmedic website and should be completed in full and sent to the following Swissmedic e-mail address: materiovigilance@swissmedic.ch
Any changes to the details on the registration form (e.g. new e-mail address or new phone number) must be reported to Swissmedic immediately. Please ensure that, if person-specific e-mail addresses are stated, the flow of information is maintained in the event of absences.

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_002e_MB)**	**wis**
05	**01.12.14**		**First inclusion in QM**	**wic**

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