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TEEMAT

Incident reporting ensures the safety of medical devices

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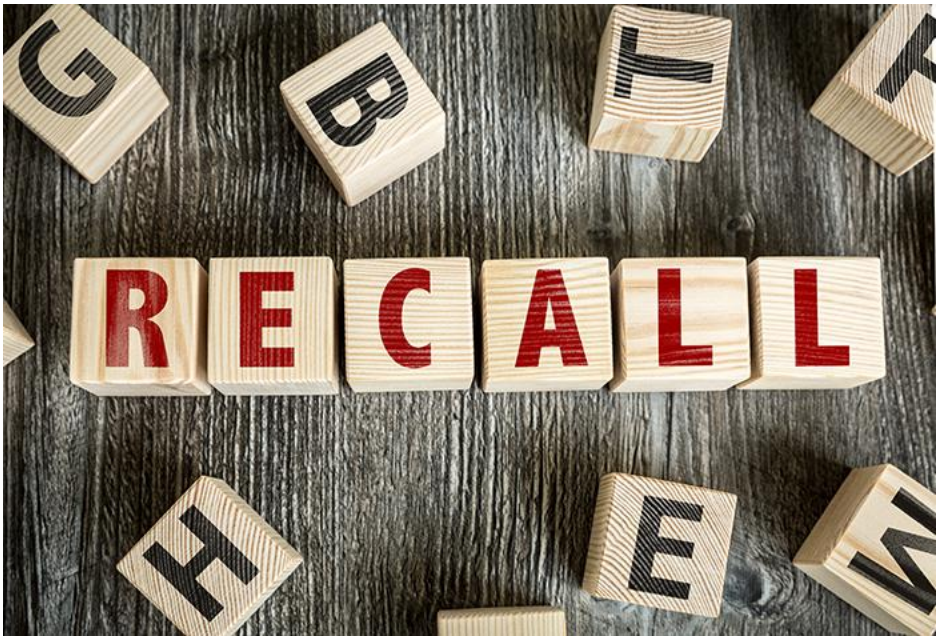

Adverse reaction reports provide important information about the safety of medicines. Incident reports serve the same purpose for medical devices. There are also some differences: submitting an incident report is a legal obligation for professional users.

“Suspected malfunction of an insulin pen, causing a rapid increase in the patient’s blood glucose levels. Suspicion that the insulin pen piston got stuck at times.”

“The ePrescription section of the patient information system did not function properly after an update, and it was necessary to use paper prescription forms.”

“The customer was using a crutch to stand up from a wheelchair when the forearm support section of the crutch broke. The patient fell down, hit their head and broke their hip.”

The examples above are real descriptions of incidents related to medical devices. The incident reporting procedure plays a key role in ensuring the safety of medical devices. The purpose is to provide the device manufacturer and Finnish Medicines Agency Fimea, as the supervisory authority, information about an unexpected event related to the device.

Incident reports give the manufacturer important information how its device performs in normal use. Based on that information, the manufacturer can further develop the medical devices or remove them from use if necessary.

The incident reporting procedure applies to all medical devices. Some medical devices are easy to identify, such as infusion pumps, ventilators or analysers used in laboratories Some products may be slightly more difficult to identify as medical devices. These include wound dressings, orthodontic appliances, various types of software, or tissue storage solutions.

Even the possibility of damage is a requirement to file a report

Professional users are obliged by law (719/2021) to report any incidents. A professional user is defined in the Medical Devices Act. For example, they include social and health care organisations, blood service and tissue facilities, and health care professionals who use a medical device in the context of professional activities or dispense them to patients. The act also specifies other professional users in more detail.

> *Damage doesn't have to occur. Situations that could have endangered a person's health must also be reported.*

Reporting an adverse incident always requires two simultaneous events: the health of a person is endangered and a problem related to a medical device. Harm doesn't have to occur. Situations that could possibly have endangered a person's health must also be reported.

A medical device problem can be associated with the device's features, undesirable side effects, deviation from performance or an error, inadequate labelling, or inadequate or incorrect instructions for use.

Medicine and device – similarities and differences

Professional users make adverse incident reports using the form found on the Fimea website. Key information in the report include the person reporting the event, unique data identifying the device and a description of the observed device problem and its consequences for the patient, user or other person.

> *Submitting an incident report is a legal obligation for professional users.*

Information about incidents that occur in Finland is compiled nationally by Fimea. The investigation and assessment of the incidents is done in cooperation with EU member states under the direction of the European Commission. Submitting an incident report is a legal obligation for professional users. It is also possible for citizens, but this is voluntary.

The corresponding procedure for medicines is a report on adverse reaction. This differs from an incident report in that filing an adverse reaction report is voluntary for everyone (Table 1). In addition to the medicine involved, an adverse reaction report identifies the patient to whom the damage was occured so that the reported incidents can be clearly identified.

An adverse reaction report related to a medicine can be made by a health care professional or a medicine user. These reports are also compiled nationally by Fimea. The work to detect and assess possible new adverse reactions is done in cooperation with EU member states.

In the case of drug-device combinations, the user should file an incident report about the device and an adverse reaction report about the medicine.

Table 1. Comparison of the key principles of the adverse reaction reporting system for medicines and the incident reporting system for medical devices.

	Report on adverse reaction for a medicine	**Incident report for a medical device**
Reporting to the authorities	Voluntary (can also be reported to the marketing authorisation holder)	Mandatory
Compiled in the EU database	Yes	Yes
Analysis at EU level	Yes	No (starting after completion of the Eudamed adverse incident module, estimated 2024)
Health care professional / professional user	Possible	Obligation

	Report on adverse reaction for a medicine	Incident report for a medical device
Layperson	Possible	Possible starting in 2022
Key data element	Patient, person reporting the event, adverse reaction and medicine/vaccine	Device, device problem, consequences for the patient or other person

Voluntary adverse event reports within an organisation can also be used as a procedure to ensure quality and safety. These can be submitted anonymously, and they are only used internally within the organisation.

Users must be informed of corrective actions

The manufacturer is obliged to investigate the cause of an incident and report the incident to the supervisory authority, which is Fimea in Finland. The MIR (Manufacturer incident report) form published by the European Commission is used for reporting. The form is available on the Fimea website.

In conjunction with its investigation, the manufacturer must assess the implementation of possible corrective actions. Safety notices are used to inform users of the actions that have been initiated. For example, last August a manufacturer initiated a recall after noticing that use of a contaminated ultrasound gel caused infections in patients.

Fimea's task is to evaluate the actions taken by the manufacturer. If necessary, Fimea can launch an independent investigation.

Further information

Medical Devices Act 719/2021 (Finlex.fi website, in Finnish)

Medical Devices Act 719/2021 (Finlex.fi website, translation in English)

Information about the adverse incident reporting procedure for a professional user (in Finnish, to be published in English)

Information about the adverse incident reporting procedure for a manufacturer (in Finnish, to be published in English)

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