European Commission

EUDAMED

European Database on Medical Devices

Manufacturers of devices made available on the Union market **shall register** (or their Authorised Representative if specified in the mandate) **serious incident reports** (MIR), **field safety corrective action reports** (FSCA), **field safety notices** (FSN), **periodic summary reports** (PSR) and **trend reports** as vigilance reporting.

Additionally, **manufacturers shall register periodic safety update reports** (PSUR) for MDR class III devices, implantable devices and IVDR class D devices. The relevant Notified Body shall add an evaluation to the PSUR registered in EUDAMED as post-market surveillance reporting.

VIGILANCE REPORTS

Introduction of the different type of reports to submit to EUDAMED

MIR

Report of serious incidents involving devices made available on the Union market (content partially available to the public for final reportable incidents).

FSCA

Report of corrective actions taken by a manufacturer for technical or medical reasons to prevent or reduce the risk of a serious incident.

FSN

Manufacturer communication to users or customers in relation to one or several FSCA (fully available to the public).

PSR

Periodic Summary report (agreed on the content/scope and frequency between the manufacturer and the competent authority(ies)) of similar incidents with the same device(s) or device type(s) in a consolidated and periodic way, where the root cause has been identified or a field safety corrective action implemented or where the incidents are common and well documented.

Trend

Report of statistically significant increase in the frequency or severity of incidents that are not serious incidents, or that are expected undesirable side-effects that could have a significant impact on the benefit-risk analysis.

POST MARKET SURVEILLANCE

PSUR

Periodic Safety Update report summarises the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan. Manufacturers shall register a PSUR in EUDAMED for their MDR class III devices, implantable devices and IVDR class D devices at least annually (except for IIa implantable devices for which it is at least every two years).

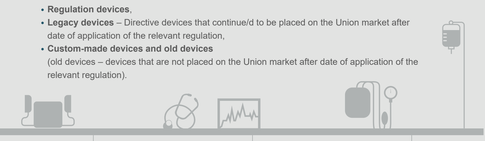
The Notified Body referenced in the PSUR, and that is involved in the conformity assessment, shall review the PSUR and add its evaluation in EUDAMED with details on any action taken.

DEVICE INFORMATION

Which devices are concerned?

MIR, FSCA, FSN, PSR and **Trend report** can be for **devices of all types of regulatory framework**:

- **Regulation devices**,
- **Legacy devices** – Directive devices that continue/d to be placed on the Union market after date of application of the relevant regulation,
- **Custom-made devices and old devices** (old devices – devices that are not placed on the Union market after date of application of the relevant regulation).



REGULATION DEVICES

LEGACY DEVICES

CUSTOM-MADE & OLD DEVICES

PRE-REQUISITE

Regulation and legacy devices shall be registered in the UDI/Device module as a pre-requisite (except for initial MIR).

For **PSR** and **Trend report**, the **device scope** can be determined either:

- at **device category/type/group(s) level** by specifying EMDN nomenclature code,
- or at **device model level** by specifying Basic UDI-DI(s)
- or at **device level** by specifying UDI-DI(s) / EUDAMED ID(s) / Trade name(s) / Catalogue / Ref number(s)
- or at **product level** by specifying UDI-PI(s) / Lot/Batch number(s) for one specific device (UDI-DI/EUDAMED ID / Trade name / Catalogue / Ref number).

DEVICE CATEFORY / TYPE / GROUP(S)

DEVICE MODEL

DEVICE

PRODUCT

PSUR to be registered in EUDAMED only concern:

Regulation devices (that are not custom-made devices) at Basic UDI-DI level, which shall be registered in UDI/Device module as a pre-requisite.

One and only one leading Basic UDI-DI that cannot change must be identified as such in each PSUR.

BASIC UDI-DI

REGULATION DEVICES

Exceptionally, during the transitional period, the PSUR may also relate to ***legacy devices*** *if the device is a combination of products for which the leading one is a regulation device identified by a Basic UDI-DI.*

DG Health and Food Safety