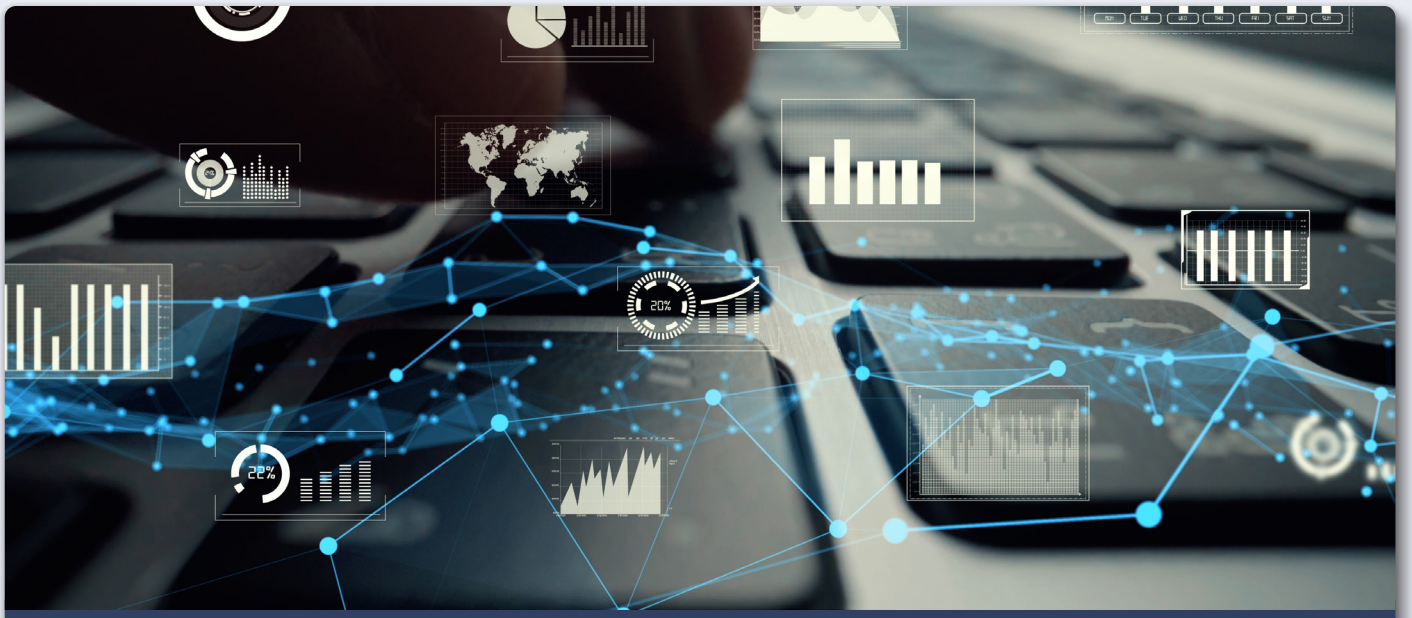
GMED LNE GROUP Newsletter

N°14 | MARCH 2024

Version Française

# PERIODIC SAFETY UPDATE REPORTS FOR DEVICES: REQUIREMENTS AND FEEDBACK



The Periodic Safety Update Report or PSUR for devices[1] is a new requirement that stems from Article 86 of the Regulation (UE) 2017/745 (MDR), implemented by regulators in order to strengthen their surveillance. According to Section 1 of Chapter VII of the MDR, each device manufacturer shall plan, establish, document, implement, maintain, and update a Post-Market Surveillance (PMS) system. This process should be part of the quality management system, appropriately to the type of device and proportionately to the risk class.

Article 84 of the MDR stipulates that manufacturers should document this PMS in a Post-Market Surveillance Plan (PMSP) and disclose the results of this surveillance in a specific report.

For class I devices, this report is called "Post-Market Surveillance Report" while for class IIa or higher this report is called "Periodic Safety Update Report" or PSUR. The new PSUR requirements include more data than the PMS report that manufacturers were used to have under the medical devices directive.

The PSUR is meant to summarize the results and conclusions of the analysis of the PMS data that has been gathered, resulting from the activities detailed in the PMSP, in order to demonstrate that the benefit/risk ratio remains favorable after the marketing of the device.

In addition, any rationale and description of any preventive and corrective actions taken for safety reasons should be included.

[1] *MDR Article 1(4): For the purposes of this regulation, medical devices, accessories for medical devices, and products listed in Annex XVI to which this regulation applies pursuant to paragraph 2 shall hereinafter be referred to as 'devices'.*

## A REMINDER OF REGULATORY REQUIREMENTS REGARDING PSUR

The introduction of the PSUR under the MDR requires a more consistent, standardized, and systematic review of all PMS data by devices manufacturers.

The frequency of report updates and transmission depending on the classes are described in the table below:

| Device risk class | Type of report | Update frequency | Shared with | | |
|---|---|---|---|---|---|
| | | | Authority upon request | NB | EUDAMED |
| **Class I** | PMS Report | As needed | ✓ | | |
| **Class IIa** | PSUR | As needed, at least every two years | ✓ | ✓ | |
| **Class IIb non-implantable** | PSUR | As needed, at least once a year | ✓ | ✓ | |
| **Class III and implantable** | PSUR | As needed, at least once a year<br>As needed, at least every two years (class IIa implantable) | ✓ | ✓ | ✓ |

For class III devices or implantable devices, manufacturers shall submit PSURs by means of EUDAMED to the notified body (NB) involved in the conformity assessment. Until EUDAMED is fully functional, manufacturers should deliver the PSUR to the relevant NB by appropriate means such as email.

## B WHAT'S INCLUDED IN A PSUR?

The PSUR shall be a stand-alone document and therefore it can be assessed independently from the supporting documentation. It shall also be presented in a clear, organized, readily searchable, and unambiguous manner.

In December 2022, the Medical Device Coordination Group (MDCG) released guidelines MDCG 2022-21 guidance, intended to help manufacturers implement the legal requirements of Article 86 and Annex III.

The document lists the post-market data to be included in a PSUR, as well as a proposed report template. MDCG 2022-21 guidance contains two annexes; Annex I which describes the PSUR template with information on what should be included in each section, and Annex II which presents suggestions for the data presentation in tabular form.

At the bare minimum, PSUR should include:
- An executive summary;
- Post-market surveillance information including the main findings of the PMCF;
- Vigilance data
- A description of CAPAs and their rationale;
- Any trends;
- Detected information about the sales;
- An estimate of the user population and usage frequency;
- A safety conlusion and benefit-risk analysis.

Devices manufacturers must prepare a PSUR for each device, and where relevant, for each category or group of devices. The notion of grouping within a PSUR is detailed in the MDCG 2022-21 guidance and therefore allows the manufacturers to include several devices within the scope of its report. In that case, the manufacturer has to justify the relevance of the grouping.

To facilitate the readability and understanding of the PSUR, it is recommended to adopt a PSUR scope consistent with what is claimed in the clinical evaluation. This will allow the manufacturer to strengthen the technical documentation consistency.

## C DATA COLLECTION PERIOD AND TIMELINE

The MDCG 2022-21 guidance provides some elements that allow the manufacturer to establish a PSUR schedule, to define the data collection periods, and the rules for the updates.

The starting dates[2] are:
- The date of application of the MDR, i.e., May 26, 2021, for "legacy devices";
- The date of certification under the MDR for newly certified devices.

In the event of a change in the starting dates or durations allocated to the collection of PMS data, the manufacturer is asked to inform the NB, in particular for class III devices and implantable devices.

*[2] If available, for the first PSUR, the data analysis should include historical data collected through the PMS activities conducted prior to date of application or MDR device certification date.*

Control of the PSUR schedule is essential to ensure continuity in the collection of PMS data and compliance with the MDR requirements.

This is also required when a "legacy device" becomes certified under the MDR.

NB have recommended a specific additional duration for the establishment and the submission of the PSUR after the end of the data collection period, to enable an efficient PSUR back-and-forth system for class III and implantable devices with the manufacturers.

## D OBSERVATIONS AND FINDINGS

Despite the provision of this information, eagerly awaited by all stakeholders, the implementation of this new requirement reveals some areas for improvement to enable compliance of the PSUR with the requirements of Regulation (EU) 2017/745.

In order to raise awareness among device manufacturers and better prepare and submit PSURs, GMED has drawn up a list of the most recurring pitfalls:

- Incomplete PMS data;
- Dates and calendar issues (collective date, timeframe, delayed submission);
- Management of groups of devices with the same PSUR without any rationale or justification;
- Content does not meet the minimum requirements of Article 86.

The PSUR is a summary of the results, analysis, and conclusions of the PMS data collected over a defined period of time. As such, the NB will ensure the completeness of the report by comparing it to other elements of the technical documentation.

To avoid the risk of omission, the manufacturer ensures that all PMS data are covered and should also mention the types of data for which it there is no reporting over the period.

Here are some examples of inconsistencies encountered during PSURs assessment:

- The manufacturer does not report cases of vigilance in its PSUR report even though the NB received vigilance reports over the covered period;
- The manufacturer does not provide information on the characteristics of the population using the device;
- The manufacturer does not present historical data for its device even though its device was placed on the market long before May, 2021.

## Conclusion

The European Commission has significantly increased the requirements for devices surveillance, with many new demands being placed on manufacturers.

To summarize, the PSUR is a periodic report required by the MDR for all Class IIa and above devices throughout the lifetime of the device.
PSUR should be written and updated at the end of each PMS period; two years for Class IIa, one year for Class IIb and Class III.

The PSUR shall be updated and communicated to the NB via EUDAMED when it would be functional or by appropriate means in the meantime. The submission frequency should be every 12 months for Class III and IIb implantable devices, or 24 months for Class IIa implantable.

A PSUR is meant to provide an overview of information, not to be a complete duplicate of all the PMS report information. Article 86 requires a summary of the main PMCF findings to be included in the PSUR, as it is an important part of the report.

In order to ensure consistency and continuity of the data collection, the MDCG 2022-21 guidance proposes several scenarios for the data collection period and submission depending on the device's class but also its regulatory status (i.e., whether it's a new device certified under the MDR or a "legacy device").

# To go further

### TRAININGS FOR AMERICA REGION

**Post Market Surveillance and Vigilance - New Requirements under the European Medical Device Regulations**
8-hour training session | April 04, 2024 | Virtual classroom

→ CHECK OUT THE PROGRAM

**The Clinical Evaluation Requirements (CER) under the EU MDR 2017/745**
8-hour training session | April 09-10, 2024 | Virtual classroom

→ CHECK OUT THE PROGRAM

### TRAININGS FOR OTHER REGIONS

**Apply the requirements of the European Regulation 2017/745 on medical devices**
SA56 | 2-day training session | On demand

**Meet regulatory requirements for post-market surveillance and vigilance**
SA45 | 1-day training session | On demand

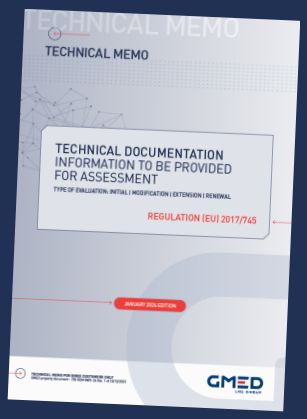
**Compile technical documentation in compliance with Regulation (EU) 2017/745**
SA57 | 2-day training session | On demand

→ CONTACT GMED TRAINING CENTER

### TECHNICAL MEMO

**Technical Documentation - Information to be provided for assessment – Regulation (EU) 2017/745**

[ONLY FOR GMED CUSTOMERS]




GMED teams are mobilized to support you in applying the procedures of the European Medical Device Regulation (MDR), with the visibility and predictability you expect from your notified body and in accordance with the applicable requirements. The GMED technical memo contains information related to the format and content of the technical documentation to be provided for the assessment of a device under the MDR.

→ REQUEST THE TECHNICAL MEMO FROM YOUR CERTIFICATION PROJECT MANAGER

## Newsletter

**Do not miss the latest updates of the Medical Device Industry**

Subscribe

© ByMoka • Photo : iStock

→ HEADQUARTERS

GMED SAS
1 rue Gaston Boissier
75015 PARIS • FRANCE
+33 (0)1 40 43 37 00
info@lne-gmed.com

→ FRENCH REGIONAL OFFICE

GMED SAS
19 D rue de la Télématique
42000 SAINT-ETIENNE • FRANCE
+33 (0)4 77 10 11 11

→ NORTH AMERICAN SUBSIDIARY

GMED NORTH AMERICA, INC
2600 Tower Oaks Boulevard - Suite 500
ROCKVILLE, MD 20852 • USA
+1 (301) 495 0477
request@lne-gmed.com