# Post-Market Surveillance: PMS report and PSUR

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**As the first anniversary of the MDR came and gone, so did the end of the first evaluation period for post-market surveillance. After collecting the data from post-market surveillance, it is now time to evaluate and summarise them. In the following article, Dr. Benedikt Fabry from novineon CRO describes the differences between the reports and what the main focus should be when preparing them.**

Few requirements of the MDR have made such high waves among medical device companies as the „manufacturer's post-market surveillance system" described in Chapter VII. A title that already inspires a certain awe due to its unwieldiness. In everyday use, therefore, the abbreviation PMS, has prevailed.

However, the PMS system is not a completely new requirement of the MDR, as the Medical Devices Directive 93/42/EEC (MDD) already called for a systematic procedure for evaluating experience with devices in the post-production phases (Annex II 3.1). Also, the post-market surveillance plan described in Article 84 of the MDR was already described in the Medical Devices Directive 93/42/EEC (Annex X 1.1c).

Actually new in the PMS system, however, is the requirement for regular reports summarising the results including analyses and conclusions from the data collected by the PMS system.

This is in line with the general idea of the MDR to transfer all relevant areas of the placing of medical devices on the market into systematic and comprehensible processes. The resulting sequence of plan and report is already familiar from other processes such as clinical evaluation.

## Type of reports is regulated

For risk class I devices, a post-market surveillance report (MDR Article 85), also called **PMS report**, is required.

For all other devices, a **periodic safety update report** (MDR Article 86) is required. This periodic safety update report is referred to as PSUR.

The de facto static system of the MDD is strongly dynamised by the MDR. The reports are actively requested and are subject to an explicitly defined periodicity.

The MDR not only clearly regulates which type of report has to be prepared for which product, but also how often the report has to be prepared or updated (see **table**). Both reports are to be understood as a tool for communication with the Notified Bodies and competent authorities, through which smooth communication should be made possible.

For **custom-made devices**, the PSUR is part of the technical documentation according to Annex XIII Section 2 and should therefore be integrated into it according to MDR Article 2 (3). As with other medical devices, the regular cycle and assessment of the PSUR are based on the risk class.

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| Risk class | type of report | Regular cycle | Addressee | Assessment |
|---|---|---|---|---|
| I | PMS report | If needed | Competent authority: Upon request | – |
| IIa | PSUR | If needed; at least every 2 years | Mandatory to the Notified Body & on request to the competent authority | – |
| IIb | PSUR | Yearly | Mandatory to the Notified Body & on request to the competent authority | – |
| III/ implants | PSUR | Yearly | Mandatory to the Notified Body via EUDAMED | Assessment by Notified Body; the PSUR & its assessment are forwarded to competent authority |

**Overview of the periods to be covered and addressees of the reports of the PMS system. For custom-made devices according to MDR Article 2(3), the PSUR is additionally part of the documentation according to Annex XIII Section 2.**

## PMS report or PSUR: the differences

MDR specifies that the PMS system must be appropriate to the device. Accordingly, the PMS report is to be updated only when necessary and made available to the Notified Body upon request. The content of the PMS report is also less extensive than the PSUR for devices with a higher risk class.

The PMS report summarises the data collected from the post-market surveillance. However, the main objective is to describe and justify any preventive and corrective actions resulting from the PMS data.

Based on the higher risk, the PSUR for class IIa, IIb and III products is significantly more comprehensive. In addition to the information also required for the PMS report, the PSUR must also contain the most important results of the clinical evaluation and the conclusion of the benefit-risk assessment. In addition, the sales volume of the product including (where feasible) an estimate of the number of users and / or patients and the frequency of product use.

This report shall be made available to the Notified Bodies on a regular basis for evaluation. In the case of Class III devices and implants, the PSUR and the evaluation shall additionally be forwarded to the competent authorities.

**It is important to create clear structures for information gathering and integration**

Both reports only summarise the information obtained. The definition of the PMS measures, their implementation and the evaluation are decoupled from these reports and can be found in the PMS plan.

## A uniform template

The Medical Device Coordination Group is currently working on a guidance document on the PSUR, which should facilitate a uniform reporting of the relevant information to the Notified Body and competent authority. The publication of this guide is planned for the second quarter of 2022.

The document is eagerly awaited by many parties. This is because the PSUR template may also be of interest to manufacturers of Class I devices, who do not have to forward the results of their PMS directly on a mandatory basis. They can use the template in order to build up uniform in-house documentation.

## Relevance for the clinical evaluation

The results of the PMS, the clinical data and the technical documentation, are the basis for the clinical evaluation of the product. Skilful coordination of the clinical evaluation with the preparation of the PMS report or the PSUR can save a lot of time and effort.

Especially in the case of implants and products of risk class III, certain

tasks can be synchronised through the usually annual updating of the clinical evaluation and the PSUR. This way the current information such as sales figures and complaints or the search in the databases of the authorities, can be used in all documents. The summary of results as a text block can also be used in several documents.

This may also be appropriate for class I devices, for which the clinical evaluation is updated less frequently. Again, regular documentation can facilitate subsequent work.

## Conclusion

- The PMS report and PSUR are essential parts of the PMS system, which follows the planning - implementation - report sequence often required by the MDR.
- Both documents are a means of communicating PMS results and the resulting actions with Notified Bodies and competent authorities.
- Until the MDCG guidance document concerning the PSUR is published, it is important to have a lean, highly structured document that can be read independently.
- In terms of content, the following points should be covered: Scope, product reference and data on the defined reporting period.
- By synchronising the updates of the PMS system reports and the clinical evaluation, the required working time for both documents can be reduced.