PMS and PSUR Requirements Under the European MDR

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Executive summary

The introduction of the post-market surveillance (PMS) requirement under the Medical Devices Regulation (MDR) requires a more consistent, standardized and systematic review of all PMS data by manufacturers.

This white paper presents up-to-date information about MDR requirements regarding PMS obligations with the publication of the MDCG 2022-21 guidance on Periodic Safety Update Report (PSUR).

Reference

2017/745/EU (Medical Device Regulation - MDR)

- Chapter VII (Post-market surveillance, vigilance and market surveillance)
  a. Article 83: Post-market surveillance system of the manufacturer
  b. Article 84: Post-market surveillance plan (PMSP)
  c. Article 85: Post-market surveillance report (PMSR)
  d. Article 86: Periodic safety update Report (PSUR)
  e. Article 92: Electronic system on vigilance and on post-market surveillance
- Annex III (Technical documentation on post-market surveillance)

MDCG 2022-21 Guidance on Periodic Safety Update Report (PSUR) according to regulation (EU) 2017/745 (MDR) – December 2022

Timeline

Regardless of whether a medical device has a valid certificate under the MDD or MDR, all manufacturers must comply with PMS requirements delineated in the MDR after the date of application of May 26, 2021. Duration requirements apply throughout the lifetime of the device. The lifetime of a device is the time period specified by the manufacturer in the device documentation during which the device is expected to remain as safe and effective as possible for use/in use.

Acronym	Meaning
AET	Adverse Event Terminology
B/R	Benefit / Risk Ratio
CAPA	Corrective Action and Preventive Action
CER	Clinical Evaluation Report
EEA	European Economic Area
EUDAMED	European Database of Medical Devices
FSCA	Field Safety Corrective Action
IFU	Instructions For Use
MDR	Medical Devices Regulation (EU MDR 2017/745)
MDCG	Medical Devices Coordination Group
NB	Notified Body
PMCF	Post-Market Clinical Follow-up
PMS	Post-Market Surveillance
PMSP	Post-Market Surveillance Plan
PMSR	Post-Market Surveillance Report
PSUR	Periodic Safety Update Report
QMS	Quality Management System
SoA	State of the Art
SSCP	Summary of Safety and Clinical Performance
TR	Turkey
XI	Northern Ireland

Post-market surveillance overview

Each medical device must be integrated into a post-market surveillance system that in turn makes up part of the manufacturer's QMS, which must be established in a manner proportionate to the risk associated with the device. The PMS system must collect and analyze the relevant data to confirm device safety and performance or initiate the CAPA.

The PMS system consists of:

- PMS procedure(s) to control the PMS activities
- PMS plan (PMSP)
- PMS report (PMSR) or PSUR

The following table describes the purpose of each document, the connection with other QMS processes, and the frequency of updates and reporting requirements to Notified Bodies (NBs) or competent authorities.

PMS activities	MDR articles	Purpose	Device class	Connection with other QMS processes	Frequency of update	Notification*
PMS plan	Art. 84	Define a proactive and systemic process to collect the PMS data to: • characterize the device performance • compare the device performance with similar devices on the market	All	• Technical documentation • Customer feedback (including complaints) • Vigilance • FSCA • PSUR • Trend reporting • CER • Risk management file • QMS's PMS procedures • CAPA • PMCF plan or rationale	When necessary	No
PMS report	Art. 85	Summary of results and conclusions resulting from PMSP including the description of CAPA taken	Class I		When necessary (frequency to justify)	No
PSUR	Art. 86	Summary of results and conclusions resulting from PMSP including: • the description of CAPA taken • conclusion of B/R • PMCF findings • Sales • Number of patient (estimate) • Usage frequency (if applicable) • Patient characteristics	Class IIa		Every two years	NB
			Class IIb		Every year	NB (other than implants) NB via EUDAMED (for implants)
			Class III		Every year	NB via EUDAMED

*PMSR and PSUR must be available to competent authorities upon request, during conformity assessment procedures, or via EUDAMED.

Post-market surveillance plan

A PMSP is part of the technical documentation required by the MDR. A PMSP includes the description of data collection and analysis and the summary of collection methods with reference to the associated QMS procedures, as well as the methods of analysis including measurable outputs. As part of the PMS system, the manufacturer must also establish procedure(s) to describe the activities of its PMSP, PMSR, and PSUR.

According to Article 84 and Annex III, the MDR requires manufacturers to consider various PMS activities, such as:

- Market feedback
- Customer feedback and complaints
- Vigilance
- FSCA
- Collection of new data from literature or databases

In December 2022, a MDCG guidance was issued on PSUR (MDCG 2022-21). The main objective of this guidance document is to assist manufacturers in implementing the requirements in Article 86 of the MDR. This guidance, although it does not include PMSR, may provide useful suggestions on how information can be presented in the PMSR but also how it should be required in the PMSP (to be prepared for all classes of devices).

As per Annex III 1.1 (a) of the MDR, the PMSP shall address the collection and utilization of available information, in particular:

- Information concerning serious incidents, including information from PSURs, and FSCA
- Records referring to non-serious incidents and data on any undesirable side effects
- Information from trend reporting
- Relevant specialist or technical literature, databases and/or registers
- Information, including feedback and complaints, provided by users, distributors and importers
- Publicly available information about similar medical devices

Both PMSR and PSUR must contain a summary considering the elements as listed above. The PSUR must specifically set out:

- The conclusions of the B/R determination
- The main findings of the PMCF
- The volume of sales of the device and an estimated evaluation of the size and other characteristics of the population using the device and, where practicable, the usage frequency of the device.

Through Annexes I to III, the MDCG 2022-21 provides more detailed information on the collection of the relevant data and their presentation and evaluation, as shown in the following table.

Elements to be present in the PMS Report and/or PSUR	Information on data collection, presentation and evaluation
Information concerning serious incidents (Art. 87, Annex III MDR)	• Serious incidents and their impact on the overall device safety should be presented. • Data should be characterized at least from three different perspectives: the device's problems, the root cause and the health effects on the person(s) affected. • A summary text regarding any new types of serious incidents which have occurred since the last report should be provided. • IMDRF Adverse Event Terminology (AET) should be used (Level 2 terms/codes). • Absolute figures and rate should be reported. • Data should be split by region (EEA + TR + XI)[1] and worldwide. • Examples of data presentation are shared in Annex II of MDCG 2022-21 (table 4 to 6).
Information from trend reporting (Art. 88, Annex III MDR, non-serious incidents and expected undesirable side effects)	• MDCG 2024-1 Guidance on the vigilance system for CE-marked devices DSVG 00 Device Specific Vigilance Guidance (DSVG) Template provides guidance on trend reporting. • The manufacturer should report to a Competent Authority any 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 B/R analysis, and which have led or may lead to risks to the health or safety of patients, users or other persons that are unacceptable when weighed against the intended benefits. Trends should be identified by the manufacturer as they can be indicative of a change in the B/R ratio. • For further information and clarification on what constitutes incidents and undesirable side effects please refer to MDCG 2023-3 "Questions and Answers on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745 on medical devices".
Information from FSCA (Art. 87, Annex II MDR)	• Summary of the FSCA should be provided and compared with previous PSURs information. • Summary should include types of actions, issuing date, scope of the FSCA, status of the FSCA at the time of the PSUR, manufacturer's reference number, a brief description of the reason for action and description of action and impacted regions. • Example of data presentation is shared in Annex II of MDCG 2022-21 (table 7).
CAPA (Art. 83.4 and Art. 86)	• The list of all CAPA should be provided. • The following information should be provided for each CAPA: the type of action, initiation date, scope of the CAPA, status of the action, manufacturer's reference number, CAPA description, the root cause (internal codes with the explanation, IMDRF terms/codes or free text), effectiveness of the CAPA. • Example of data presentation is shared in Annex II of MDCG 2022-21 (table 8).
Feedback and complaints from users, distributors and importers (general PMCF)	• All feedback and complaints not reported in the categories as above should be considered in this category. • The most common complaints should be presented with the following considerations: grouping by IMDRF AET Annex A – "Medical Device Problem" (including the term and code) or internal event codes including term, occurrence rate (including reference chosen), justification for inclusion of these groups of complaints and exclusion of those not presented • Information on whether the presented complaints have led to initiation of CAPA.
Scientific literature review of relevant specialist or technical literature (general PMCF)	• The manufacturer may refer to the technical documentation for detailed information about literature searches conducted and results generated.
Public databases and/or Registry data (general PMCF)	• A list of all registries reviewed should be provided including the name or registry reference, type of registry (prospective or retrospective data collection). • A list of findings in comparison to the devices with same intended use should be provided and any identified differences justified. Information about any new risks identified from this data set should be provided.
Publicly available information about similar medical devices (general PMCF)	• This may include information gathered from other manufacturers of similar medical devices (e.g. results of a manufacturer's specific PMCF study made publicly available in the manufacturer's Summary of Safety and Clinical Performance (SSCP), Cochrane Library or other libraries. • The type and location of this information should be provided, and when possible, a comparison of the device with same intended purpose should be evaluated with any possible differences in safety and performance reported.

1. EEA: European Economic Area; TR: Turkey; XI: Northern Ireland

Elements to be present in the PMS Report and/or PSUR	Information on data collection, presentation and evaluation
Other data sources (general PMCF)	• The other used data sources could be for example real-world data from electronic health record and digital health-monitoring devices. • A list of the used data sources should be provided in the same manner as findings with specific reference to safety and performance of the device.
Specific PMCF information (Art. 86, MDR Annex XIV, Part B, 6.2(b)	• A summary of the findings generated from the analysis of specific PMCF activities performed by the manufacturer. • This is not limited to PMCF studies and should include other specific PMCF activities conducted by the manufacturer • The manufacturer should refer to the main findings of the PMCF and, when available, to the conclusions documented in the PMCF Evaluation Report.
Volume of sales (Art. 86.1) (requirement for PSUR only)	• All the devices placed on the market should be considered. • This could be volumes of sales, units shipped, or units implanted or another suitable indicator. • Accurate information should be presented. • Method used should be consistent throughout the PSUR. • Data should be presented by year-to-year. • Further information should be provided with respect to the various sizes, models and configurations. • Criteria – the number of devices on the market provided should be indicated (devices placed on the market or put into service, number of devices implanted, number of episodes of use (for reusable devices)). • Example of data presentation is shared in Annex II of MDCG 2022-21 (table 1).
Size and other characteristics of the population using the device (Art. 86.1) (requirement for PSUR only)	• Number of devices exposed to the device should be evaluated and their characteristics. • For some devices the sales numbers do not directly correlate with the patient numbers exposed to the device. The number of patients exposed should be estimated as the sales numbers alone do not necessarily reflect the number of uses of the device (usage frequency). • The usage of the device in different patient populations should be described and, when available, compared to the expected usage and the possible over-represented or under-represented patient groups should be identified if clinically relevant and known by the manufacturer. • When possible, consideration should be given to patient demographic aspects. • When applicable, evaluate the effect of the detected changes to findings obtained previously and in the current PSUR.

It is also highly important to be aware that PMS activities may have an impact on other QMS systems and records (e.g., CER, IFU, risk management) and therefore the consistency of data between the different records has never been as critical as now. For example, PMS raw data are fully included in the CERs, which are regularly updated. Similarly, the risk analysis along with its risk estimation must be aligned with the events and rates observed in the vigilance, PMS data and CER.

In addition, various records are directly submitted to or regularly reviewed by the NB (e.g., CER, technical file). For Class IIa, IIb or III devices, the raw data contained in the PSUR must be aligned with the vigilance data as both will be submitted to NBs and via EUDAMED for Class IIb implantable or Class III devices.

Also, for implantable and Class III devices, the summary of safety and clinical performance (SSCP) that includes information on therapeutic alternatives, a summary of CER and the list of residual risks or undesirable side effects, must be submitted to the NB. The interconnection between all QMS processes and the communication between departments that produce or compile the PMS data must be reviewed carefully to confirm consistency between data and the different records required by the MDR.

Post-market surveillance report/ periodic safety update report

The PMSR or PSUR are documents that must be included in technical documentation. The PMSR is required for Class I devices and must be kept available to Competent Authorities. The PMSR must be updated regularly as defined in the related procedure. The PSUR is required for Class IIa, IIb and III devices. For implantable and Class III devices, the PSUR must be submitted via EUDAMED to the NB for review. For Class IIa and non-implantable IIb devices, the PSUR will be transferred to the NB. The PSUR must be updated at least every two years for Class IIa devices and every year for Class IIb and III devices.

The PMSR and PSUR must document the implementation of PMSP and record the results, analysis and conclusions along with the rationale and description of any CAPA taken.

In addition, the PSUR must include the conclusion of B/R resulting from the risk analysis; the PMCF findings; as well as the volume of sales; the estimation of population size using the device; and the usage frequency in the case of reusable devices.

The MDCG 2022-21 provides guidance on the requirements.

This guidance is not aimed to be retroactive. As long as a PSUR is already drawn up, or in the process of being prepared, is in compliance with Art. 86 of the MDR, it is not expected to follow this guidance.

The PSUR is expected to be a stand-alone document and should not duplicate the data but summarize the results and conclusions.

It is possible to generate a PSUR per device or for a category or group of devices at the moment a justification is provided to demonstrate the relevance of the grouping of several devices within the same PSUR. Although, it must be noted grouping under the same PSUR it is possible only for devices covered by the same NB. A leading device must be identified when it is decided to generate a PSUR for a group of devices. A leading device is defined by the highest risk class device of the group. This leading device drives the PSUR schedule in terms of data collection period, PSUR frequency, issuance timeline, and PSUR reporting through EUDAMED or not.

For MDR devices, the data collection period starts at the MDR device certification date. If not MDR-certified (for a legacy device), the data collection period starts at the MDR date of application (DoA) (May 21, 2021). So that the first PSUR may not cover an exact period of 12 or 24 months. When a legacy device becomes MDR certified, if there is no significant change (in the sense of Art. 120(“) of the MDR), the PSUR schedule is unchanged and may not be aligned on the MDR certification date. If there is a significant change, the device is considered to be a new device and the schedule will then be aligned on the new MDR certification date.

For class III and implantable devices which are MDR-certified, the PSUR must be submitted in EUDAMED. Until EUDAMED becomes functional, the manufacturer should align with their NB on the submission method. The PSUR Web Form for Manufacturer from Annex V of the MDCG 2022-21 contains all the relevant administrative data necessary for the registration of the PSUR in EUDAMED. For those PSURs submitted to EUDAMED, this PSUR form can be considered as a cover page. Then, once EUDAMED becomes functional, this information will be provided directly through the EUDAMED Web interface (certain fields will be automatically populated (NB, manufacturer, single registration number (SRN)).

In addition to the core data in the table above, the PSUR should contain a cover page, an executive summary, a description of the devices covered by the PSUR and their intended use, a justification in case of grouping and a summary of findings and conclusions.

Overall conclusions from the analysis of the collected data in the aim to determine whether the B/R profile of the device has changed or not and if relevant the specific actions taken by the manufacturer. The manufacturer should also discuss the validity of the collected data (limitations like reduced sales) and possible impact on the ability to formulate meaningful conclusions.

To maintain consistency with the data resulting from the CER, the PMS records under a PMSR or PSUR must also be carefully designed to present how device performance is achieved, and especially regarding similar devices on the market (a list of findings in comparison to the devices with same intended use should be provided and any identified differences justified (from public databases and/or registry data) and a comparison of the device with same intended purpose should be evaluated with any possible differences in safety and performance reported (from publicly available information about similar devices) (MDCG 2022-21).

Summary and conclusion

The MDR is a major change from MDD 93/42/EEC in terms of providing a solid framework that supports safe and effective use of medical devices in Europe. As part of these changes, the MDR reinforces the principles of PMS in a manner proportionate to the device risk. Consequently, for the highest classes of risk, manufacturers must actively and regularly communicate the results of their PMS activities with NBs and make that data available in the new European database (EUDAMED). For the lowest classes of risk, PMS records must remain available upon request and updated with a suitable frequency (e.g., every two years for Class IIa).

The MDR also provides a clearer view of PMS requirements, and with the publication of the MDCG 2022-21, there is now a detailed view of the expectations in terms of contents of the PSUR, contents/scope/duration/grouping/frequency/data collection period/availability/uploading to EUDAMED of the PSUR requirement. The PSUR template and data presentation examples, as provided in MDCG 2022-21, are very useful sources of information. Although Class I devices are outside the scope of this guidance, this also provides relevant suggestions to be applied to them.

Learn more

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About the author

Rachel Paul has over 13 years of experience in the medical device industry as well as international experience in high-risk device regulatory submissions and quality assurance requirements. Rachel's accomplishments include: 9 FDA 510(k) clearances; 10+ EU Technical Files/Design Dossiers; writing more than 25 Clinical Evaluation Reports; implementation of 5 quality systems to ISO 13485/CE Marking/FDA QSRs/CMDCAS; quality system gap assessment and improvements; auditing for compliance to multiple standards; conducting training to various international regulations; more than 30 global regulatory strategy analyses; and compilation and submission of numerous registration dossiers for international marketing authorization.

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