

PMS requirements under IVDR

WHITE PAPER





Post-Market Surveillance (PMS) under the EU's In Vitro Diagnostic Medical Device Regulation (IVDR) (2017/746) is not an entirely new idea for IVD manufacturers. The requirement to have a PMS system was articulated in the IVDR's predecessor, the In Vitro Diagnostic Medical Device Directive (IVDD) (98/79/EC), as an obligation to maintain a systematic procedure to review experience gained from devices in the post-production phase (IVDD Annex III (5)). PMS requirements are also addressed in ISO 13485 (medical devices quality management systems) and ISO 14971 (medical devices risk management). However, IVDR's PMS requirements are much more precise, extensive and detailed.

What is PMS under the IVDR?

According to the IVDR, PMS is defined as *“all activities carried out **by manufacturers** in cooperation with other economic operators to institute and keep up to date a systematic procedure to proactively collect and review experience gained from devices they place on the market, make available on the market or put into service to identify any need to immediately apply any necessary corrective or preventive actions”* (IVDR Art. 2(63)). This should be clearly distinguished from “market surveillance”, which is meant as *“the activities carried out and measures taken **by public authorities** to check and ensure that devices comply with the requirements [...]”* (IVDR Art. 2(64)).

The IVDR requires manufacturers to plan, establish, document, implement, maintain and update a PMS system proportionate to the risk class and appropriate for the device type. This requirement applies to each CE-marked IVD device, including legacy devices and all risk classes. However, differences exist regarding the required scope, documents, update frequency and reporting for different devices.

Legacy devices under the IVDR – “devices referred to in the 2nd or 3rd subparagraph of Article 110(3) IVDR, which are placed on the market or put into service after 26 May 2022 (i.e. the IVDR’s date of application) and until the end of the respective transition period set out in the 2nd or 3rd subparagraph of Article 110(3), if the conditions laid down in the 1st subparagraph of Article 110(3)3 are fulfilled. Those devices can be:

- a) devices covered by a valid EC certificate issued by a notified body in accordance with Directive 98/79/EC on in vitro diagnostic medical devices (IVDD) prior to 26 May 2022; or
- b) devices for which a declaration of conformity was drawn up prior to 26 May 2022 in accordance with the IVDD and for which the conformity assessment procedure pursuant to the IVDR (contrary to the IVDD) requires the involvement of a notified body”.



MDCG 2022-8 – Regulation (EU) 2017/746 – application of IVDR requirements to ‘legacy devices’ and to devices placed on the market prior to 26 May 2022 in accordance with Directive 98/79/EC.

PMS is not a “stand-alone” system. It is crucial to understand that several aspects come together to deliver robust post-market activities. PMS must be integral to the manufacturer’s Quality Management System (QMS) and Technical Documentation. PMS processes and documentation must cover the PMS requirements described in IVDR Article 78-81, Annex III and Annex XIII Part B, and must be actively linked with other processes and documentation, including Risk Management, Post Market Performance Follow-Up, Performance Evaluation, Summary of Safety and Performance, Corrective and Preventive Actions (CAPA), design, manufacturing, etc.

The PMS system should be suited to actively and systematically gathering, recording and analyzing relevant data on the device’s quality, performance and safety throughout its lifetime. Based on this information, the manufacturer can analyze and draw the necessary conclusions, determine appropriate actions and implement and monitor any preventive and corrective measures.

It must describe a process for collecting relevant post-market data, analyzing them and using conclusions to trigger necessary activities.

The main documents describing the PMS system are:

- **Post-Market Surveillance Plan (PMSP)**, according to IVDR Annex III, Section 1 and IVDR Articles 78, 79, and 81 – for all devices, including legacy devices
- **Post-Market Surveillance Report (PMSR)**, according to IVDR Article 80 – for Class A and Class B devices, as well as legacy devices
- **Periodic Safety Update Report (PSUR)**, according to IVDR Article 81 – for Class C and Class D devices

These elements, however, are usually related to or contain many other documents of the manufacturer’s QMS and Technical Documentation.

Post-market surveillance plan (PMSP)

The requirements referring to the PMSP are thoroughly described in IVDR Annex III, Section 1. According to this, the manufacturer's PMS Plan must specify the data collection they will implement for the PMS, in particular:

- Information concerning serious incidents, including information from the PSURs and field safety corrective actions
- 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

A proactive and systematic process for collecting these data must also be described. The process should allow correct characterization of the device's performance and comparison with similar products available on the market. Detailed information must be provided on how each data type will be collected, how frequently and what sources.

Then, the PMS Plan must describe how the collected data will be assessed, covering at least the following:

- Effective and appropriate methods and processes to assess the collected data
- Suitable indicators and threshold values that should be used in the continuous reassessment of the benefit-risk analysis and the risk management, as described in IVDR Annex I Section 3
- Effective and appropriate methods and tools to investigate complaints and analyze market-related experience collected in the field
- Methods and protocols to manage the incidents subject to the trend report, including the methods and protocols to establish any statistically significant increase in the frequency or severity of incidents and the observation period
- Methods and protocols to communicate effectively with competent authorities, NBs, economic operators and users
- Reference to related procedures
- Systematic procedures to identify and initiate appropriate measures, including corrective actions
- Effective tools to trace and identify devices for which corrective actions might be necessary
- A Post-Market Performance Follow-Up (PMPF) Plan or a justification as to why a PMPF is not applicable

Post-market performance follow-up

There is another critical process addressed explicitly in the PMS Plan requirements: the PMPF.

Briefly, the PMPF is a process required to update the Performance Evaluation of the device continuously, once it is on the market.

When conducting the PMPF, the manufacturer must proactively collect and evaluate performance and relevant scientific data from the use of a device within its intended purpose to:

- Confirm the device's safety, performance and scientific validity throughout its expected lifetime
- Identify previously unknown risks or limits to performance and contra-indications
- Identify and analyze emergent risks based on factual evidence
- Ensure the continued acceptability of the clinical evidence and the benefit-risk ratio
- Identify possible systematic misuse

The PMPF Plan requirements are generally quite like those for the PMS Plan, but they mostly focus on Performance Evaluation aspects.

The PMPF plan must include at least the following:

- The general methods and procedures, such as gathering of clinical experience gained, feedback from users, screening of scientific literature and other sources of performance or scientific data
- The specific methods and procedures, such as ring trials and other quality assurance activities; epidemiological studies, evaluation of suitable patient or disease registers, genetic databanks or post-market clinical performance studies
- A rationale for the appropriateness of the methods and procedures applied
- A reference to the relevant parts of the performance evaluation report and the risk management
- The specific objectives to be addressed by the PMPF
- An evaluation of the performance data relating to equivalent or similar devices, and the current state of the art
- Reference to any relevant Common Specifications (CS), harmonized standards when used by the manufacturer and relevant guidance on the PMPF
- A detailed and adequately justified schedule for PMPF activities, such as analysis of the PMPF data and reporting

Common specifications (CS) – “a set of technical and/or clinical requirements, other than a standard, that provides a means of complying with the legal obligations applicable to a device, process or system.”

Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR), Art. 2(74)

Regulation (EU) 2022/1107 laying down common specifications for certain class D in vitro diagnostic medical devices in accordance with Regulation (EU) 2017/746



The PMPF is also closely related to the Performance Evaluation Plan and Report, including Scientific Validity, Analytical Performance and Clinical Performance. The initial Performance Evaluations are conducted in the pre-market phase but need to be continuously monitored and updated throughout the device's life cycle. The results of Performance Evaluation processes should be considered in the PMPF Plan and vice versa – the results of the PMPF are to be used to update Performance Evaluation results.

The PMPF may not be necessary for some specific devices – in this case, a clear justification must always be provided. The PMPF's main goals are to confirm the device's safety, performance and scientific validity, so the PMPF may not be needed if the safety of the device when used in clinical practice has already been completely confirmed during the performance evaluation and risk management.

However, if there are any outstanding risks or uncertainties about the device's performance when used in clinical practice or if the performance may change over time, the PMPF needs to be required.

Although proactive methods for collecting the PMS and PMPF data are emphasized in the IVDR, both proactive and reactive methods should be used. While reactive actions/data sources include information on serious incidents, the FSCA, or customers' complaints, examples of proactive activities/data sources include literature searches, post-market performance studies, published recall information, searching IVD device registries, user surveys, social media monitoring, etc.

The PMS results are provided as a PMS Report (for Class A, Class B and legacy devices) or a PSUR (for Class C and Class D devices). If applicable, both should include the results of the PMPF reported as a PMPF Evaluation Report.

Post-market surveillance report

A PMSR is required for Class A, Class B and legacy devices. It should summarize the results and conclusions of the analyses of the PMS data gathered because of the Post-Market Surveillance Plan, along with a rationale and description of any preventive and corrective actions taken.

PMSRs may be prepared for each device and, where relevant, for the appropriate category or group of devices.

The report must be updated when necessary and made available to the NB and the competent authority upon request.



Periodic safety update report

A PSUR is required for Class C and Class D devices. It does not apply to legacy devices, since the IVDD did not provide for classification of devices in A / B / C / D risk classes.

The PSUR must contain all data required in the PMS Report and, additionally:

- The conclusions of the benefit-risk determination
- The main findings of the PMPF
- The volume of sales of the device, an estimate of the size and other characteristics of the population using the device and, where practicable, the usage frequency of the device

The PSUR may be prepared for each device and, where relevant, for the relevant category or group of devices.

PSURs must be updated at least annually.

For Class C devices, the manufacturer should make the PSUR available to the NB involved in the conformity assessment and, upon request, to competent authorities.

Class D device manufacturers should submit the PSUR to the NB involved in the device's conformity assessment. The NB should review the report and upload its evaluation to the EUDAMED system with details of any action taken.

How to use results of PMS

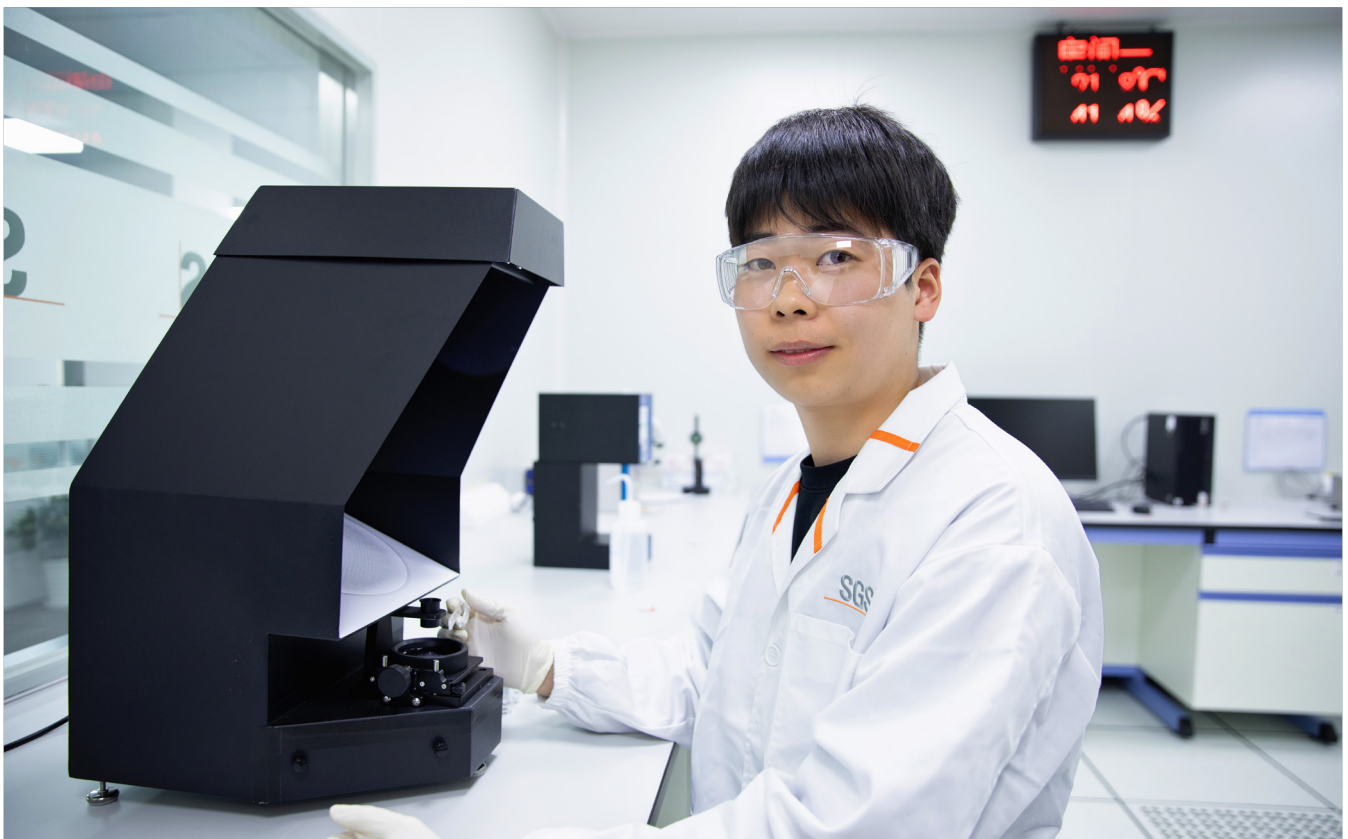
Finally, data gathered by the manufacturer's PMS system should be used to update the information relevant to the device (and sometimes to other manufacturer's devices) and improve its usability, safety and performance, in particular:

- To update the benefit-risk determination and to improve the risk management, as referred to Annex I Chapter I
- To update the design and manufacturing information, the instructions for use and labeling
- To update the Performance Evaluation
- To update the Summary of Safety and Performance, referred to in Article 29
- For identifying the need for preventive, corrective or field safety corrective action
- For identifying the options to improve the device's usability, performance and safety
- When relevant, contribute to the PMS of other devices
- To detect and report trends, according to Article 83
- To update the Technical Documentation

Which IVD devices require PMS under IVDR?

Generally, all CE-marked IVD devices, including legacy devices, are subject to the IVDR's PMS requirements. No transition periods refer to the PMS requirements under the IVDR. There are, however, some differences and exceptions:

- For legacy IVD devices, the PMS requirements specific to Class C and Class D devices under IVDR are not expected since the IVDD did not provide for the classification of devices in A / B / C / D risk classes. These requirements are an update of the Summary of Safety and Performance (SSP) and a Periodic Safety Update Report (PSUR). Obligatory elements are the PMS Plan and PMS Report
- For Class A and Class B devices, an updated SSP and PSUR are not expected. Obligatory elements are: the PMS Plan, PMS Report and Post-Market Performance Follow-Up (PMPF) Plan and Report – if appropriate and not included in PMS Plan and Report
- For Class C and Class D devices, a PMS Report is not expected. Obligatory elements are: the PMS Plan, PMPF Plan and Report – if appropriate and not included in the PMS Plan and Report – and the SSP as well as PSUR



Useful links and documents

Many documents and guidance provide more detailed information, which can be helpful when preparing PMS systems and related documents under the IVDR. Some of them are:

- [Regulation 2017/746 on in-vitro diagnostic devices \(IVDR\)](#)
- [MDCG 2022-2 - Guidance on general principles of clinical evidence for In Vitro Diagnostic medical devices \(IVDs\)](#)
- [MDCG 2022-8 - Regulation \(EU\) 2017/746 - application of IVDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2022 in accordance with Directive 98/79/EC](#)
- [MDCG 2022-9 / Rev.1 - Summary of safety and performance. Template](#)
- [MDCG 2022-21 - Guidance on Periodic Safety Update Report \(PSUR\) according to Regulation \(EU\) 2017/745 \(MDR\)](#)
- [ISO 13485:2016 – Medical devices – Quality management systems – Requirements for regulatory purposes on QMS for medical devices](#)
- [ISO 14971:2019 – Medical devices – Application of risk management to medical devices](#)
- [ISO/TR 20416:2020 – Medical devices – Post-Market Surveillance for manufacturers](#)
- [ISO 20916:2019 - Vitro diagnostic devices – Clinical performance studies using specimens on human subjects – Good study practice](#)
- [WHO Guidance on post-market and market surveillance of medical devices including IVDs](#)
- [IMDRF \(International Medical Device Regulators Forum\)](#)

Disclaimer! Check Your Situation

SGS and the author of this white paper have checked with believed to be reliable sources in their efforts to provide complete information that is generally in accordance with European Union regulations and industry standards at the time of publication. Still, readers are advised to recheck their specific situation against the law and, when needed, seek legal or regulatory advice from professionals with relevant expertise and licensure.

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