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Implementing Post-Market Surveillance (PMS) under the IVDR

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Executive Summary

Post Market Surveillance (PMS) in the European Union is not a new concept for manufacturers of in vitro diagnostic devices. PMS principles have been reflected in international standards such as ISO 13485, addressing quality management systems for medical devices, and ISO 14971, which covers risk management requirements. Prior to the In Vitro Diagnostic Medical Device Regulation (IVDR) (2017/746), the IVD Directive (IVDD) (98/79/EC) required manufacturers to maintain a systematic process for reviewing experience gained from devices once they were placed on the market.

However, the IVDR introduced significantly expanded and more prescriptive requirements for Post-Market Surveillance (PMS). Under the IVDR, PMS is no longer a passive, complaint-driven activity — it is a proactive, systematic, and continuous process embedded directly into a manufacturer's Quality Management System (QMS).

This white paper aims to provide:

- **Clear explanations** of PMS requirements by device class, including legacy devices
- **A step-by-step guide** to build, implement, and maintain a compliant PMS system under the IVDR.

It is designed for regulatory, quality, clinical, and technical teams across the IVD industry, including those managing **legacy devices** transitioning to IVDR requirements.

Understanding PMS under the IVDR

The IVDR defines PMS 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))*

Under the IVDR, manufacturers are required to plan, establish, document, implement, maintain, and continuously update a PMS system that is proportionate to the device's risk class and suitable for its intended purpose. This obligation applies to **all CE-marked IVDs**, including **legacy devices**, and spans every risk category. While PMS is universally required, the **scope of activities, types of documents, reporting expectations, and update frequency** vary by device classification.

PMS should not be viewed as an isolated activity. Instead, it should be considered a core component of the overall quality and regulatory framework, relying on multiple interconnected processes to ensure effective post-market oversight. PMS processes and documentation must address the requirements set out in **Articles 78–81**, **Annex III**, and **Annex XIII Part B**, and must be tightly integrated with related activities such as **Risk Management**, **Post-Market Performance Follow Up**

(PMPF), **Performance Evaluation**, the **Summary of Safety and Performance (SSP)**, **Corrective and Preventive Actions (CAPA)**, as well as design and manufacturing controls.

A compliant PMS system must enable manufacturers to **proactively and systematically collect, record, and analyse** all relevant data on the device's safety, performance, and quality throughout its entire lifecycle.
Insights gained from this evaluation should allow manufacturers to draw evidence-based conclusions, identify the need for preventive or corrective actions, implement appropriate measures, and monitor the effectiveness of those actions over time.

The main documents within a PMS system are:

Document	IVDR Reference	Overview
Post-Market Surveillance Plan (PMSP)	IVDR Annex III, Section 1 and IVDR articles 78, 79 and 81	For all devices, including legacy devices Outlines the methods and processes the manufacturer uses to collect and assess post-market data
Post-Market Surveillance Report (PMSR)	IVDR Article 80	For class A and class B devices, as well as legacy devices Summarises the results and conclusions drawn from PMS activities, along with any preventative or corrective actions taken
Periodic Safety Update Report (PSUR)	IVDR Article 81	For class C and class D devices PMSR content and additional elements such as the benefit–risk conclusions, PMPF findings, and sales or usage data.

Please note that these core PMS documents often interact with, or incorporate information from, a wider range of materials within the manufacturer's QMS and technical documentation, ensuring alignment across all lifecycle processes.

Which IVD Devices require PMS under IVDR?

All CE-marked IVDs – including legacy devices - are subject to PMS requirements, with **no transitional exemptions** for the PMS system obligations. The PMS system must be IVDR-compliant, and PMPF may still be expected.

However, the specific PMS documents required differ by device type and classification.

Legacy Devices

As the IVDD did not use the IVDR risk classification system (Classes A–D), the requirements specific to Class C and Class D devices—such as the Periodic Safety Update Report (PSUR) and the Summary of Safety and Performance (SSP)—do not apply **during the transitional period**.

Therefore, the required elements during the transition period are:

- PMS plan
- PMS report

While PSUR and SSP are not formally required for legacy devices under Article 110, manufacturers are expected to align their PMS activities, as far as possible, with IVDR requirements. This is particularly relevant for higher-risk devices, and manufacturers may voluntarily prepare PSURs and SSPs.
Please note, by the time the device is undergoing IVDR certification, the PMS documentation will be expected to be fully updated to include the applicable IVDR requirements.

Class A and Class B devices

Manufacturers of class A and B devices are not required to produce an updated SSP or PSUR.
Required elements:

- PMS plan
- PMS report
- PMPF plan and report (if applicable and not already included within the PMS documentation).

Class C and Class D devices

For these higher-risk categories, heightened documentation is required.
Required elements:

- PMS Plan
- PMPF Plan and Report (if applicable and not included in the PMS Plan/Report)
- Summary of Safety and Performance (SSP)
- Periodic Safety Update Report (PSUR)

Post-Market Surveillance Plan (PMSP)

At the centre of the PMS framework is the Post-Market Surveillance Plan (PMSP), outlined in Annex III, Section 1.

A robust PMSP must clearly define the categories of data to be gathered as part of ongoing surveillance activities, as well as the mechanisms and sources used to obtain them. At a minimum, the plan should address:

- Information on serious incidents, including data reported through PSURs and any field safety corrective actions.
- Records of non-serious incidents and any undesirable side effects that could influence the benefit–risk profile.
- Data derived from trend reporting, capturing changes in the frequency or severity of incidents.
- Insights sourced from scientific literature, technical databases, registries, and other relevant reference materials.
- Feedback and complaints received from users, distributors, and importers across the supply chain.
- Publicly available information on comparable medical devices, providing context for benchmarking performance and safety.

Beyond listing these data categories, the PMSP must describe a proactive, systematic, and well-structured process for collecting each type. This includes clarifying the frequency of data collection, the specific sources to be used, and the methods applied to ensure that the data captured is comprehensive enough to support meaningful comparison with other devices on the market.

Equally essential is defining how the manufacturer will assess and interpret post-market data. The PMSP must outline the analytical framework used to ensure consistent, objective evaluation and continuous monitoring of benefit–risk. This includes:

- Defined methods and analytical processes for evaluating post-market information.
- Clear indicators and threshold values used to reassess the benefit–risk profile, in alignment with IVDR Annex I, Section 3.
- Structured procedures for investigating complaints and analysing field performance, ensuring efficient root-cause investigation and escalation.
- Protocols for trend reporting, including statistical approaches for identifying significant increases in incident rates and determining appropriate observation periods.
- Communication pathways enabling effective information exchange with competent authorities, notified bodies, economic operators, and users.
- References to all supporting internal procedures that integrate with PMS activities.
- Systematic procedures to identify and initiate appropriate measures—including corrective actions—supported by effective tools to trace and identify any devices that may require such actions.

- A Post-Market Performance Follow-Up (PMPF) Plan, or a substantiated rationale for when PMPF activities are not required.

Post-Market Performance Follow-up (PMPF)

A key component explicitly required within the PMS framework is the Post-Market Performance Follow-Up (PMPF). PMPF is an ongoing, structured process designed to continuously update the device's Performance Evaluation once it is on the market. Through PMPF activities, the manufacturer proactively collects and assesses performance-related and scientific data generated during real-world use of the device in its intended purpose.

PMPF activities aim to:

- Confirm the device's safety, performance, and scientific validity throughout its expected lifecycle.
- Detect previously unknown risks, performance limitations, or contraindications.
- Identify and assess emerging risks using objective evidence.
- Ensure that the clinical evidence and benefit–risk profile remain acceptable over time.
- Detect patterns of systematic misuse.

While the PMPF Plan shares similarities with the PMS Plan, its focus is specifically aligned with Performance Evaluation requirements.

A compliant PMPF Plan must include:

- General methods and procedures, such as analysis of clinical experience, user feedback, literature reviews, and other relevant performance or scientific data sources.
- Specific methods and procedures, including ring trials, quality assurance activities, epidemiological studies, evaluation of patient or disease registries, genetic databanks, or post market clinical performance studies.
- A justified rationale for the selected methods and procedures.
- References to applicable sections of the Performance Evaluation Report and the risk management documentation.
- Clearly defined objectives that the PMPF activities aim to address.
- An assessment of performance data from equivalent or similar devices and alignment with the current state of the art.
- Reference to applicable Common Specifications, harmonized standards, and relevant PMPF guidance, where used.
- A detailed and justified schedule outlining PMPF activities, including timelines for data analysis and reporting.

The PMPF process is closely interconnected with the Performance Evaluation Plan and Report. While the initial Performance Evaluation is carried out during the pre-market phase, it must be continuously reviewed and updated throughout the device's lifecycle. Performance evaluation findings should feed into the PMPF,

and PMPF outcomes should, in turn, inform the Performance Evaluation to keep the evidence base current and comprehensive.

In certain cases, PMPF activities may not be necessary; however, a clear and well-reasoned justification must always be provided. Since the primary purpose of PMPF is to confirm ongoing safety, performance, and scientific validity, it may be considered unnecessary if these elements have already been conclusively demonstrated during Performance Evaluation and risk management activities. However, PMPF may only be omitted where the manufacturer can clearly demonstrate that:

- All risks are fully characterized and controlled,
- Performance is stable and well-established,
- No residual uncertainties remain,
- No further data are required to confirm benefit-risk acceptability.

If any uncertainties remain, if risks require further monitoring, or if device performance may evolve over time, PMPF becomes essential.

Although the IVDR places particular emphasis on proactive data-collection methods for both PMS and PMPF, manufacturers are expected to employ a balanced combination of proactive and reactive approaches. Reactive sources include serious incident reports, field safety corrective actions, and customer complaints. Proactive methods may include literature reviews, post-market performance studies, analyses of publicly available recall information, searches of IVD registries, user surveys, and monitoring of publicly accessible online channels.

The outputs of PMS activities are documented either in a PMS Report (for Class A, Class B) or a PSUR (for Class C and Class D devices). Where applicable, these reports must also incorporate the results of PMPF activities, summarised in a dedicated PMPF Evaluation Report.

Post-Market Surveillance Report (PMSR)

A PMSR is required for Class A and Class B devices. It provides a summary of the PMS data collected under the PMS Plan, including the conclusions drawn from the analysis and any preventive or corrective actions implemented. PMSRs may be created for individual devices or, where appropriate, for a category or group of devices. The report must be kept up to date and made available to the notified body or competent authority upon request.

Periodic Safety Update Report (PSUR)

A PSUR is required for Class C and Class D devices.

A PSUR must include all information normally contained in a PMSR, plus:

- Conclusions of the benefit–risk determination
- Key findings from PMPF activities
- Sales volumes, estimates of the user population, and—where feasible—the frequency of device use

PSURs may be prepared for individual devices or relevant device groups and must be updated **at least annually**.
For Class C devices, the manufacturer must make the PSUR available to the notified body involved in the conformity assessment and to competent authorities upon request.
For Class D devices, the PSUR must be submitted to the notified body, which will review it and upload its assessment and any related actions to EUDAMED.

Summary

A Practical Implementation Guide

Below is a structured approach to implementing PMS according to IVDR Articles 78–81 and Annex III.

<table>
<tr><th colspan="4">Step 1 - Establish PMS System</th></tr>
<tr><td colspan="4">A PMS system must be embedded in the QMS and aligned with:</td></tr>
<tr><td colspan="2">• Risk Management (ISO 14971)
• Performance Evaluation & PMPF
• CAPA and complaint handling processes
• Vigilance and FSCA reporting</td><td>Define:
• Roles and responsibilities
• PMS review cycles
• Communication pathways (internal & external)
• Escalation mechanisms</td><td>PMS governance must ensure feedback loops across all lifecycle processes.</td></tr>
<tr><th colspan="4">Step 2 — Develop the PMS Plan (PMSP)</th></tr>
<tr><td colspan="4">The PMS Plan is the foundational document. IVDR Annex III Section 1 specifies detailed requirements, including:</td></tr>
<tr><td>2.1 Data Sources to Collect Proactively & Reactively
The PMSP must describe how the manufacturer collects:
• Serious incidents & FSCA records
• Nonserious incidents & undesirable side effects
• Trend reporting data</td><td>2.2 Methods for Data Assessment
The PMSP must detail:
• Methods for trend analysis
• Thresholds & indicators for risk analysis updates
• Approaches for complaint and field data investigation
• Statistical tools and decision rules
• Communication processes with</td><td>2.3 Corrective Measures & Traceability
The PMSP must define procedures for:
• Triggering corrective/preventive action
• Assessing field safety corrective actions
• Identifying affected devices via traceability systems</td><td>2.4 PMPF Integration
The PMSP must reference:
• The PMPF Plan
or
• A justification when PMPF is not required</td></tr>
</table>

• Feedback from users, distributors, importers • Literature, registries, databases • Publicly available information on similar devices • PMPF outputs Each data source must include: • Method of collection • Frequency • Tools / systems used • Responsible function	Competent Authorities and Notified Bodies • Links to related procedures (CAPA, Risk Management, PMPF, PE, vigilance)		

Step 3 — Implement Post-Market Performance Follow Up (PMPF)		
PMPF is a proactive process that continuously updates performance evaluation once a device is on the market. It must assess: • Safety • Analytical performance • Clinical performance • Scientific validity	It may include: • Literature screening • Performance studies • Ring trials • Registry or databank analysis • Epidemiological studies	Where PMPF is deemed unnecessary, justification must demonstrate that device risks and performance characteristics are fully understood.

Step 4 — Produce PMS Reports and PSURs	
4.1 PMS Report (PMSR) Required for: • Class A devices • Class B devices The PMSR must summarize: • PMS data analysis • Conclusions • Any preventive or corrective actions taken Updated ***as needed*** and available to authorities on request.	**4.2 Periodic Safety Update Report (PSUR)** Required for: • Class C devices (submitted to NB upon request) • Class D devices (reviewed by NB and uploaded to EUDAMED) Includes PMSR content plus: • Benefit–risk determination • PMPF findings • Sales & usage data Must be updated **at least annually**.

Step 5 — Use PMS Outputs to Update Device Documentation
PMS data must feed into:
• Risk Management File • Performance Evaluation • Design & Manufacturing information • IFU and labelling • Summary of Safety and Performance (SSP) (for class C and class D) • CAPA • FSCA decisions This ensures the PMS system actively drives continuous improvement.