



# PMS from pain to potential:

*more than just ticking a  
box*



**IMed** Consultancy

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# MANAGEMENT SUMMARY

*Among the updated requirements of new EU Medical Device Regulation 2017/745 (EU MDR) and EU In Vitro Diagnostics Regulation 2017/746 (EU IVDR) is the need for more extensive and rigorous Post Market Surveillance (PMS) to better safeguard patient safety. This renewed focus is reflected in other regulatory updates in different geographies, notably the UK with its new PMS Statutory Instrument (SI). The onus on the medical device manufacturer and on their ecosystems is thus significantly expanded but this new requirement should not be seen only as a duty, a box that needs to be ticked to achieve compliance, rather medical device manufacturers should embrace PMS for its strategic business potential.*

*Specifically, PMS is key to monitoring the safety and performance of a medical device throughout its lifecycle, helping businesses avoid costly remediation and brand damage but it can also support companies in achieving commercial advantage in a number of ways: by opening up to opportunities in geographies with similar requirements, identify new uses, user demographics and more.*

*The friction caused by the burden of documentation can also be significantly reduced with efficient mapping, making PMS a far more useful tool than initially imagined.*

# INTRODUCTION

Although by no means a new requirement, one of the areas more significantly altered by the introduction of the new EU MDR 2017/745 and EU IVDR 2017/746 concerns PMS. With the aim of improving safety for patients both regulations state that PMS should cover:

***“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 for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions.”.[1]***

Manufacturers must, therefore, provide clear and comprehensive, periodically updated information on the safety and use of their products, including labelling, design, technical features, composition, packaging, and instructions for assembly, installation, use and maintenance.

The objective of the new PMS requirements is to provide additional assurances to Notified Bodies and Regulators that patient safety is the top priority. More thorough, ongoing PMS that spans the entire lifecycle of the product, should help identify emerging risk early, before it creates serious harm to patients. If, for example, a device that typically receives three reports in two months suddenly receives six in a week, it is crucial to be able to rapidly understand what has gone wrong: is it an issue with a batch? Has the device been distributed to a different demographic? Is there an issue with transportation and distribution?

Weaknesses in design can be raised through a structured feedback loop that involves the whole supply chain as well as healthcare providers and patients. While some of the issues identified may be serious, others may simply be design improvements that eventually make the device far more user friendly and not necessarily safer. These are also important to improve patient outcomes. Finally, gathering more extensive data is key to substantiating claims, carrying out effective performance evaluations, and potentially also to exploring new claims.

PMS can thus have a triple role of protecting patient safety, helping gain competitive advantage and protecting the business from damage.

# PROTECTING PATIENTS CAN BE A FRICTIONLESS PROCESS

PMS is often seen as an expensive necessity that takes away resources and contributes only in so far as it allows a business to say they have ticked a specific regulatory box. In reality, a well-planned and consistently managed cyclical process can save time and money. Forward thinking and thorough planning can help achieve huge efficiencies. For example, scheduling your PMS, Post-Market Clinical Follow-Up (PMCF), Periodic Safety Update Reporting (PSUR) and Summary of Safety & Clinical Performance (SSCP) reporting at a time in the year that does not coincide with significant other activities such as Approved Body (AR)/Notified Body Audits (NB), for example, will ensure staff have some freedom to complete those tasks without creating bottlenecks elsewhere.

It is also possible to avoid duplicating literature searches, if PMS is scheduled in close succession to Clinical Evaluation Reporting (CER) or Performance Evaluation Reporting (PER). Literature searches for PMS can thus feed into your CER/PER. If these are carried out in a relatively quiet time for the businesses, and can thus be completed within a matter of weeks, the searches will be timely and need not be repeated, saving reiterations of lengthy searches multiple times. If there is nothing to update in between processes, risk management will document that the review has been completed contemporaneously. If these aspects follow in sequence, they are very well placed to feed into KPIs/Metrics and be presented to top management at a quality meeting. Getting these processes into a cycle ensures that all this information will then be ready for your UK AB or EU NB before reverting back to the next stage in the cycle. Of course, searches and reviews may be required with greater frequency, depending on the innovation and particular technology.

# LITERATURE SEARCHES AND AI

More and more businesses are looking to ease the burden of literature searches by leveraging AI. In fact, sources should cover not just the device but also components. As some are increasingly technological this becomes a thoroughly complex, specialist task. If implemented correctly, it is possible to improve speed and accuracy as well as save money, but errors and so-called AI “hallucinations” could lead to considerable problems down the line. It is therefore important to be aware of limitations in this process. AI does not in the short term replace the important input from Expert Authors and Evaluators who will at the very least need to review any AI output, but it can take away some of the burden of repetitive tasks.

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## COMPETITIVE ADVANTAGE: MULTIPLE MARKETS

Different jurisdictions take a differing approach to PMS. The EU has taken the lead in driving a greater focus on patient safety with its new EU MDR and EU IVDR, but other jurisdictions are also shifting their focus to more demonstrable safety, albeit with different regulatory approaches. For a portfolio spanning multiple jurisdictions, it is possible to streamline top level PMS efforts by analysing what is required by each market and leveraging potential cross over of standards and country-specific laws to develop a centralised PMS framework.

Literature reviews or other elements of reporting that are applicable to more than one geography can be repurposed ensuring that no duplication of efforts occurs. This centralised oversight is essential to the feedback loop and must allow for global sources of data to be mapped. Digital tools can also be deployed to manage and store global PMS data. For a global PMS system, it is recommended to validate and use advanced analytics, use AI and employ dashboard and visualisation tools for real-time monitoring. It is also 'mission critical' to ensure internal coordination and communication. Finally, it's imperative that data privacy (GDPR and HIPAA, for example) and language aspects (localization and translations) are considered within a global PMS system. Businesses should also not overlook cross jurisdiction requirements such as cyber-security.

There is one notable caveat, however; where devices are placed on multiple markets, territorial requirements must be addressed directly. It will be important to demonstrate that local laws have been considered and are being followed. One key way of doing this is by taking special care over definition changes. For instance, the UK definitions of 'preventive action', 'incident' and 'serious incident' differ from those outlined by the EU MDR and EU IVDR. Specifically, the UK definition of 'preventive action' includes a wider range of actions to 'reduce a risk posed by a device', regardless of whether a non-conformity has been detected.

Similarly, the critical definitions of 'incident' and 'serious incident' differ in EU and UK interpretation. In the UK an incident covers the EU regulatory definition but extends to further elements such as 'side-effects' impacting not just individuals, but patient management and public health negatively. Importantly, the UK definition of 'incident' for diagnostics is particularly complex as it includes 'erroneous results', regardless of whether they drive a decision resulting in harm to a patient or not and not taking into account the permitted tolerances for the device.

At the same time, the UK definition of ‘serious incident’ as a ‘serious deterioration of any person's state of health’ is slightly different to the EU one, and covers life-threatening illness or injury, permanent impairment of a body structure or body function, hospitalisation or prolongation of hospitalisation, medical treatment, chronic disease, and foetal distress or foetal death. This expansion of what is covered by seemingly identical terms highlights how critical it is that businesses are aware of these subtleties when setting out to leverage their existing PMS corpus across different geographies.

Another linguistic subtlety to consider relates to the term State of the Art (SOTA), a key element of PMS, that is often incorrectly used. When it is a noun it describes the position within a given landscape, when used as a compound adjective (State-of-the-art) it describes the most technologically advanced or leader in a field.

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## UK PMS

In addition to the EU, another market where PMS is about to gain increasing importance is the UK. The new UK PMS Statutory Instrument (SI) is expected to enter into force in Summer 2025,[2] with the MHRA already working on guidance to support the implementation of the new requirements.

These new UK PMS obligations closely resemble those already established in the EU MDR and the EU IVDR, albeit with some key differences such as those previously highlighted. In addition to these point examples, following the International Medical Device Regulators Forum (IMDRF) indications, the UK features more prescriptive data collection and requirements to hold higher safety standards.

Reports for devices placed on the market or put into service in Great Britain must be reported on the Manufacturer's On-line Reporting Environment (MORE) Portal to the UK Sovereign Regulator (MHRA). If the Manufacturer is not located in the UK, the responsibility falls to the designated UK Representative Person (UKRP) to act on behalf of the manufacturer.

The MHRA may also notify a manufacturer (or their designated UKRP) of any known risk or safety concern, then the manufacturer must investigate and report back to the MHRA on the outcomes of their investigation and any Corrective Action and Preventive Action (CAPA).

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## PROTECTING YOUR BUSINESS: NEW EU DIRECTIVE ON LIABILITY FOR DEFECTIVE PRODUCTS

It is also critical that businesses planning and establishing their PMS processes are aware of the new EU Directive on Liability for Defective Products. On October 10th, 2024, the Council of the EU adopted the new [EU Directive on Liability for Defective Products](#) (PLD), which will repeal the existing EU Product Liability Directive. The New PLD represents the first substantial change in the EU product liability landscape over a 40-year period. As a Directive, this framework can be transposed into national law.

This new Directive aims to address modern technological advancements and bolster consumer protection and, effective December 2026, the legislation seeks to harmonise liability standards across the EU, compelling pharmaceutical and medical device companies to revise their product-related practices.

More specifically, the update is intended to simplify the burden of proof required on the claimant, who would normally have to prove that the product was defective and that its fault was cause for the damage. Now, instead, the court can presume the device is defective, even in technically complex cases, shifting the onus onto the manufacturer to prove that the device is safe.[3] In addition to these changes, the new directive extends liability to 25 years in exceptional cases when symptoms are slow to emerge. A sturdy body of proof, gathered over years of PMS is going to prove key to helping ensure that businesses are able to defend themselves.

The new rule also stipulates that manufacturers must ensure their documentation accurately reflects the safety and performance of their products and does not solely rely on warnings to mitigate risks. In addition to this, manufacturers are legally required to consider the reasonably foreseeable use of their products, including misuse that is not unreasonable under the circumstances. Regulatory documentation should therefore address potential misuse which is typically identified during PMS and offer guidance for safe use. Regular, efficient PMS will also help capture off label use or unforeseen misuse and ensure that the manufacturer provides updates to readability, contraindications and warnings as and when required.

It is therefore critical to ensure contractual agreements with actors that address PMS clauses, and that reporting is consistently being fed in during ongoing supplier evaluations as businesses may be called upon to demonstrate that they are meeting requirements.

# 3PL DISTRIBUTORS

One often overlooked area for PMS tends to be supply chain. The manufacturer has the obligation to report on their device's performance in the real world but too often they fail to put into contract with their suppliers the need for support to perform these reporting duties efficiently. Checking customer feedback and complaints and how they are dealt with, for example, is key to ensuring that reporting is effective.

Importers, distributors, and authorised representative have legal requirements concerning reporting, such as the obligation to cooperate to achieve an appropriate level of traceability of devices. Importers have “the responsibility to inform manufacturers and their authorised representatives in the event of complaints. They should also keep a register of complaints, non-conforming devices, recalls and withdrawals, and escalate non-compliance to authorities if they suspect that a device has been falsified or that there is a serious risk to health. Importers are also required to cooperate with authorities and provide samples or grant access to the devices.” [4]

Similarly, “An authorised representative will have to cooperate with authorities on preventive and corrective actions, and inform the manufacturer immediately about complaints and authorities' requests for samples of devices. The authorised representative will be liable for defective devices together with the manufacturer, if the manufacturer has not complied with its obligations under the Regulations and is not located in the EU (MDR/IVDR Article 11(5))”, [5] while distributors “should also keep a register of complaints, non-conforming devices, recalls and withdrawals”. [6]

While these requirements are clearly laid out by law, the same cannot be said about 3PL distributors. The latter are often overlooked by manufacturers and yet they are the ones who may be delivering the product to hospitals, care homes or directly into the hands of users. It is thus critical that manufacturers include contractual obligations to support them in case of recall but also to report complaints and other feedback they receive directly.

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## HOLD TO YOUR PROMISES

One key pitfall that far too many medical device manufacturers drop themselves into is committing with Notified Bodies to proactively canvas patients for feedback. While this is a requirement in the world of pharmaceuticals, it is not for medical devices and often businesses simply do not get round to carrying out this additional part of PMS. Unfortunately, however, if they have included it in their statements this will lead to a self-created non-conformity.

The PMS approach taken should be well planned ahead, considering whether it is manageable, applicable to the product, the technological areas it covers and its intended use. While you should not dismiss sales feedback and other potential sources of PMS data such as social media, message boards and forums, committing to actively contacting users is a much more time-consuming task.

# CONCLUSION

The evolution of Post Market Surveillance (PMS) under the EU MDR and EU IVDR demonstrates that compliance is no longer just about fulfilling regulatory obligations; it is a strategic opportunity. By adopting a comprehensive, well-structured approach to PMS, manufacturers can not only ensure patient safety but also unlock competitive advantage, streamline operations, and enhance product development. Efficient PMS cycles, when properly scheduled and integrated with other regulatory processes, save time and resources, minimizing duplication of effort and ensuring that valuable insights are captured and utilized effectively. Leveraging advanced tools like AI, while carefully managing their limitations, further enhances the efficiency and accuracy of PMS activities.

As regulations continue to evolve, including the forthcoming UK PMS Statutory Instrument and the new EU Directive on Liability for Defective Products, robust PMS processes are indispensable for medical device manufacturers. These frameworks emphasize the need for meticulous documentation, proactive risk management, and collaboration across supply chains. Businesses that align their strategies with these requirements will not only achieve compliance but also fortify their market position by delivering safer, more reliable products. By embedding PMS as a core component of their quality and operational systems, manufacturers can safeguard their brand reputation, foster innovation, and meet the expectations of a more demanding global regulatory environment.

# REFERENCES

[1] EU MDR, Article 2 (60), EU IVDR, Article 2 (63)

[2] [Press release: Statutory Instrument laid in Parliament sets out first steps in delivering Medical Device Regulatory Reform and strengthening patient safety, Gov.UK, 22nd October 2024](#)

[3] [Defective products: revamped rules to better protect consumers from damages, EU Parliament, 12th March 2024](#)

[4] [EU Factsheet, Authorised Representatives, Importers and Distributors of medical devices and in vitro diagnostic medical devices](#)

[5] [EU Factsheet, Authorised Representatives, Importers and Distributors of medical devices and in vitro diagnostic medical devices](#)

[6] [EU Factsheet, Authorised Representatives, Importers and Distributors of medical devices and in vitro diagnostic medical devices](#)

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