PMS & PSUR requirements under the European MDR

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Executive Summary

Medical device post-market surveillance (PMS) activities have already been described in the European Medical Device Directive (93/42/EEC) and are part of the Quality Management System (QMS) certification under EN ISO 13485:2016. However, resulting from various scandals such as PIP implants, PMS activities and oversight powers of Notified Bodies (NB) and Competent Authorities (CA) have been reinforced. Consequently, on May 26th, 2020, the Medical Devices Regulation (MDR) will impose new PMS requirements and supplemental reporting to NBs or CAs in proportion to the risk class and the type of device.

This whitepaper presents the new MDR requirements regarding PMS obligations and the risks resulting from their implementation in a global QMS.

Reference

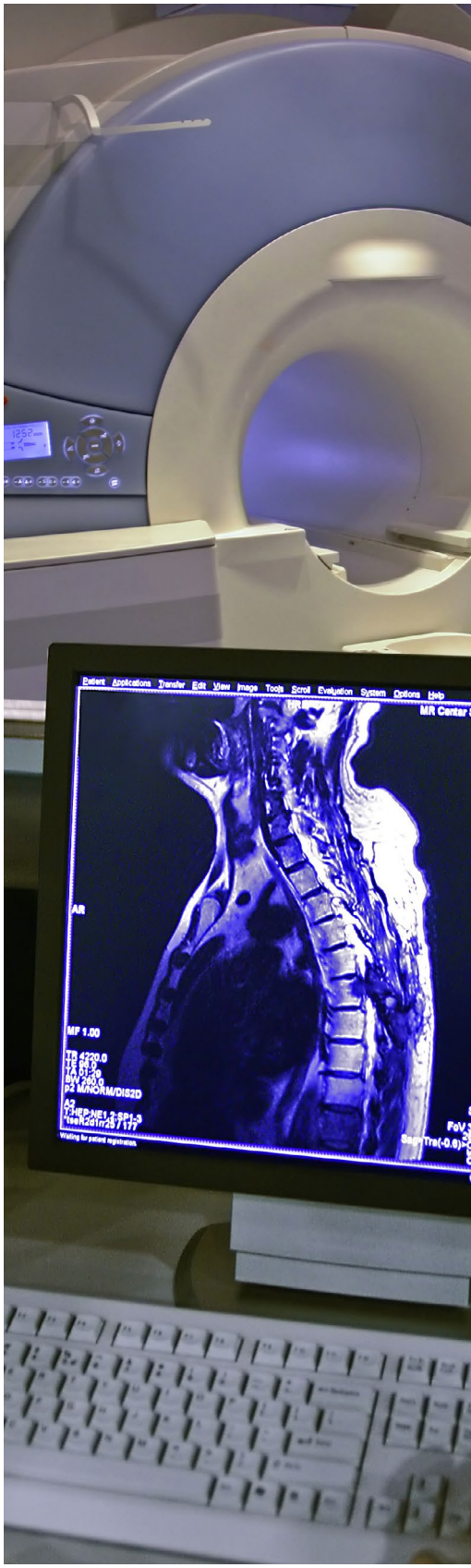
2017/745/EU (Medical Device Regulation - MDR)

- 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)

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 on May 26th, 2020.

Acronym	Meaning
B/R	Benefit / Risk Ratio
CAPA	Corrective Action and Preventive Action
CER	Clinical Evaluation Report
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



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 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
- PMS report or PSU report

The following table describes the purpose of each document, the connection with other QMS processes, and the frequency of updates and reporting requirements to 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 Post-Market Surveillance Plan (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 PMS plan, PMS report and PSU report.

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

The next table presents PMS inputs that should be collected and PMS outputs that should be analyzed to determine the continued suitability of a medical device. This must be considered in the context of the current knowledge and interpretation of the MDR, as the MDCG actively works on PMS guidance under MDR that should establish the exact expectations for a PSUR or PMSR, as well as the relationship between EUDAMED and PMS activities.

It is also highly important to be aware that PMS activities may have an impact on other QMS records (e.g., CER, IFU, risk analysis) 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 ensure consistency between data and the different records required by the MDR.

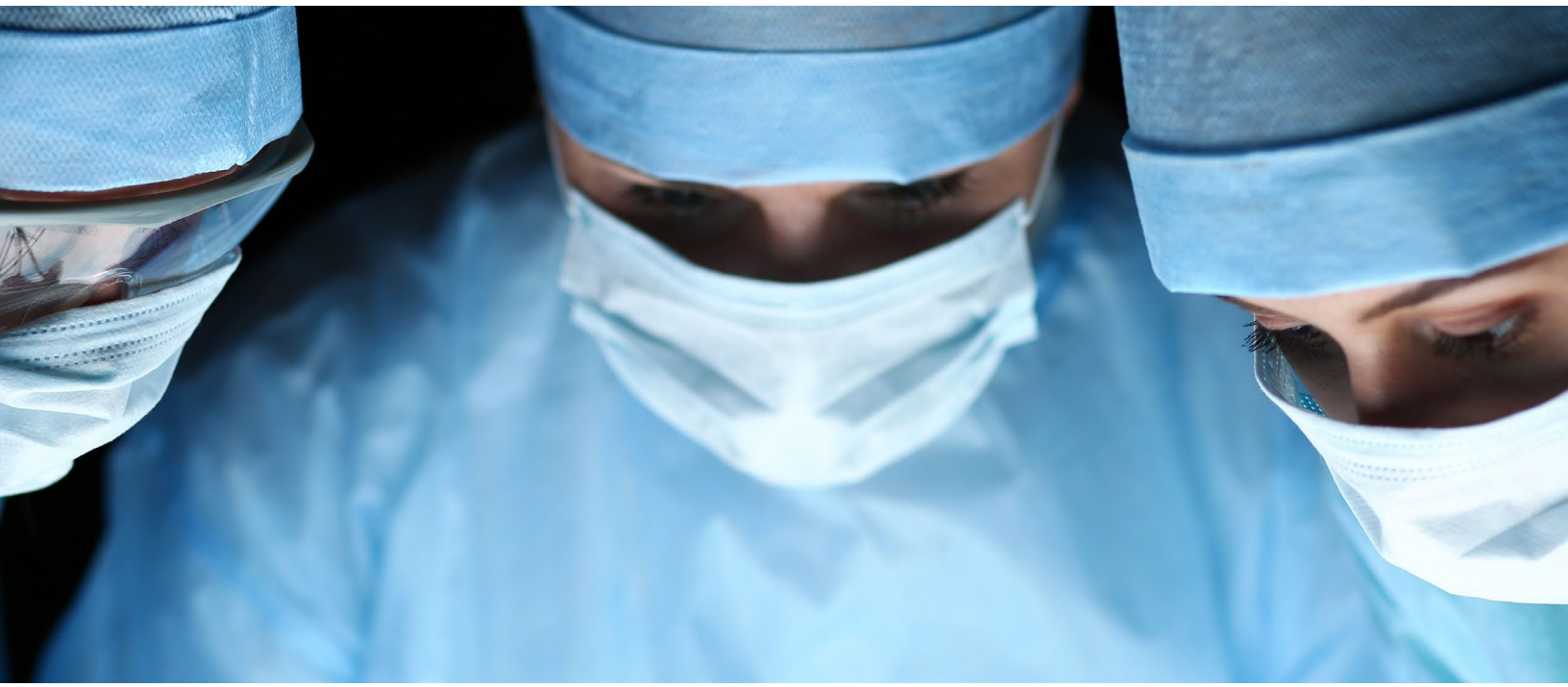
The following table summarizes the potential impact of PMS collection and analysis upon other QMS records.

PMS activities in PMS plan	Proposed inputs of data collection*	Proposed outputs of data collection*	Impact on other QMS records
Market feedback	• device experience • similar device experience (based on literature, database, register)	• number of sales • number of uses • number of patients • frequency of use • patient characteristics • complaints (type/rate) • adverse events (type/rate) • side-effects (type/rate) • FSCAs (type/rate) • results of published studies	• CER (integration of market experience) • CER (integration of similar/equivalent device experience)
Customer feedback	• user, distributor or importer feedback	• Trend of feedback per type	• None
Complaints handling vigilance	• non-serious events • serious events • undesirable side-effects • expected side-effects	• Rate of serious events, rate of non-serious event and rate of side-effects (considering sales or estimated number of use)	• Risk management file (inadequate risk estimation, new risk) • CAPA (for significant events or unexpected trend change) • Trend reporting (for trend of events or expected side-effects that may impact B/R) • CER (integration of vigilance data) • PMCF (for occurrence of significant risks) • IFU (new residual risks, undesirable side-effects)
Recall	• FSCA (FSN or recall)	• Type of event that caused the FSCA • Status of CAPAs for FSCAs	• CER (integration of vigilance data) • Risk management file (evaluation of risk associated with field safety event)
Literature / database / register review	• new articles • new events • new clinical results	• Summary of new performance data • Summary of new safety data • Summary of new data for SoA	• CER (integration of new literature and vigilance data) • PMCF (for occurrence of significant risks or confirm suitability of device) • CAPA (for significant events or unexpected trend change) • IFU (new residual risk, undesirable side-effects) • Risk management file (inadequate risk estimation, new risk)

* The proposed inputs and outputs of analysis are assumptions based on the MDR requirements that must be confirmed following the issuance of the European Commission's PSUR/PMSR template and guidance (MDCG document).

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; estimation of population size using the device; and the usage frequency in the case of reusable devices.

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.

Summary + Conclusion

The MDR is a major change from MDD 93/42/EEC in terms of providing a solid framework that ensures 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, although the exact formats of PMSR, PSUR, and PSUR submitted via Eudamed are still not available. In addition, it is anticipated that specific measurable outputs of PSUR (e.g., rate of complaints regarding the estimated number of use) will be further described for the highest device classes to efficiently compare the manufacturer data submitted in Eudamed. Such guidances should be available in the coming months via the MDCG, which assists stakeholders in implementing the MDR.

Learn more

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About the author

Alexandre Pétiard is a Senior Regulatory and Quality Consultant at Emergo by UL. With more than 10 years of experience in regulatory affairs, his expertise includes design control support, technical file preparation, clinical evaluation report, risk management file, 510(k), quality system implementation and audits, and post-market surveillance and vigilance activities. Mr. Pétiard previously held regulatory positions at Covidien, Integra LifeSciences, and Alcis.

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