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POST-MARKET SURVEILLANCE OF DEVICES

The Post-Market Surveillance (PMS) system is an essential process for ensuring the safety and effectiveness of medical devices placed on the market.

Integrated into the manufacturer's quality management system, PMS is based on Articles 10.10 of Regulation (EU) 2017/745 (MDR) and 10.9 of Regulation (EU) 2017/746 (IVDR).

This process has been significantly strengthened since the MDR and IVDR came into force, introducing more regulations and requirements for manufacturers and increased oversight by competent authorities and Notified Bodies (NBs).

A METHODS AND TYPES OF PMS DATA

The post-marketing surveillance system is based on the following elements:

A data collection system

(type of data, periodicity, means)

Analytical methods for evaluating and analyzing the data collected

Definition of indicators and thresholds

Establishment of communication methods

(with customers, competent authorities, notified bodies, EUDAMED)

Establishment of resolution methods

(for implementing actions, CAPA system, incident notification, market actions)

Traceability

(allowing devices authentication on the market)

This process is implemented as follows:
- Establishment of surveillance plans: the manufacturer defines a PMS plan incorporating a PMCF[1]/PMPF[2] plan, in which he describes and documents the strategy for collecting, recording, and analyzing PMS data.
- Establishment of reporting: depending on the risk class of the device, the manufacturer draws up a PMS report or a Periodic Safety Update Report (or PSUR, detailed below), including, where applicable, a PMCF/PMPF report, in which it summarizes the results obtained by following the strategy defined in the Surveillance plan.

The PMS system collects two types of data:
- "Proactive" data: the results of all activities defined and implemented by the manufacturer to collect information on his device;
- "Reactive" data: data that are available and extracted from the flow of information going passively back to the manufacturer.

The methodology and data analysis tools set out in the device's post-market surveillance plan enable the manufacturer to carry out an analysis of the data collected. The manufacturer is then able to detect statistical signals and trends in relation to PMS data.

That information is then used to improve the product, restore compliance, and/or communicate with the competent authorities.

EXAMPLES OF PMS DATA TYPES	
PROACTIVE DATA	**REACTIVE DATA**
• User feedback (customer surveys, expert opinions); • Data from literature; • PMCF/PMPF data (registers, studies).	• Audit/inspection data; • Quality management system data (NC, CAPA/FSCA, risk management); • Data from complaints/incidents (including vigilance).

B INCREASED VIGILANCE UNDER MDR AND IVDR

Vigilance under the regulations sets new requirements for all players, especially NBs.

Vigilance reports must be communicated to the competent authorities, as well as to NBs. This communication to NBs, introduced by the regulations, makes it possible to verify the impact of incidents on the validity of certificates issued, even under one of the directives.

These vigilance reports include the following:
- Manufacturer Incident Report (MIR);
- Periodic Safety Report (PSR);
- Trend Report (TR);
- Field Safety Corrective Action (FSCA);
- Field Safety Notice (FSN).

Access to notifications of vigilance cases for devices placed on the market enables the NB to make the link with the information collected by other surveillance means (audits and assessments) and to activate, if necessary, additional surveillance measures such as additional or unannounced audits or a documentary review. In the most critical cases, the validity of the certificate may be called into question. The NB is empowered to restrict, suspend, or withdraw the certificate concerned.

The addition of the notified body as a recipient of vigilance reports helps to limit the risk to the patient and the user, thanks to the control and monitoring actions taken on the manufacturer by the NB.

C PSUR AND PMS REPORTS

The manufacturer draws up reports summarizing all the data collection activity and the conclusions of the data analysis over a given period, through a PMS report or a PSUR, depending on the risk class of the device concerned.

NB also monitors this activity by assessing the PSUR for class III devices, implantable devices and class D devices. During audits for non-implantable class IIa and IIb devices, NB ensures that the PSUR is available and updated according to the frequencies defined in the Regulations. PMS reports for class I and A or B devices are updated when necessary and may also be reviewed by the NB during an audit, to ensure as a minimum that the PMS system is effective, and that the various PMS plans have been properly implemented.

[1] PMCF: Post-Marketing Clinical Follow-up
[2] PMPF: Post-Market Performance Follow-Up

The updating of the above-mentioned reports enables a periodic reassessment of the device's benefit/risk balance, based on the real-life performance of the device, while considering the state-of-the-art development. This exercise enables the manufacturer to confirm the safety and performance of its device, and the NB to maintain certification if the conclusions of the assessment are satisfying.

NB monitoring of PMS data is carried out by:
- Continuous monitoring through analysis of incident vigilance reports;
- Periodic monitoring through PSUR assessment, audits or technical documentation assessment.

Guides and support documents

In order to support and guide manufacturers in setting up and maintaining a strong post-market surveillance system that complies with regulatory requirements, the Medical Device Coordination Group (MDCG) has published several guides:
- MDCG 2022-21 Guidance on Periodic Safety Update Report (PSUR) according to Regulation (EU) 2017/745;
- MDCG 2023-3 Questions and Answers on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745 on medical devices;
- A series of guides for reporting incidents involving certain types of devices: MDCG 2024-1-X Device Specific Vigilance Guidance (DSVG) (i.e.Cardiac ablation, Coronary stents, Cardiac implantable electronic devices, Breast implants).

A document recently published:
- A new MIR form template, version 7.3.1, published in May, 2025.

A series of documents is also in preparation at the European level on the following topics:
- A transposition of existing guides for Regulation (EU) 2017/746;
- A MDCG guide on Trend Reporting.

GMED encourages manufacturers to rely on these documents to define and build their post-market surveillance system. GMED also points out that Notified Bodies must take these guides into account in their conformity assessment activities[3], and that manufacturers must therefore put in place resources at least equivalent to the MDCG recommendations.

D MONITORING BY THE NOTIFIED BODY

The NB carries out surveillance of PMS data through audit activities, evaluation of technical documentation and analysis of vigilance reports.

In order to raise manufacturers' awareness and help them implement a more solid post-market surveillance system, GMED shares the main elements identified during surveillance activities that do not enable manufacturers to comply fully with regulations.

During surveillance audits, GMED's main findings are as follows:
1. **Lack of control over vigilance notification procedures** (who to notify, how and when);
2. **PMS data collected and analyzed do not enrich other critical processes** and are not used to update technical documentation (i.e. risk management file or clinical evaluation report);
3. **Lack of data exploitation, particularly of data related to a type of incident already identified.** The expected and predefined incidence for an identified incident typology is not confronted with the incidence observed on post-marketing data.

When evaluating technical documentation, GMED highlights the following points:
1. **A lack of control over the methodology applied in terms of PMS data analysis.** The manufacturer is responsible for developing and implementing an appropriate methodology;
2. **Linked to the previous point, a lack of exploitation of data from devices on the market,** which constitutes an obstacle to improve device quality and safety.

In analyzing the vigilance reports, GMED made the following observations:
1. **Incomplete MIR forms,** particularly in the sections dedicated to investigations carried out by manufacturers;
2. **The use of IMDRF codes Appendix F,** describing the impact of the incident on the health of the patient/user, inconsistent with the description of the incident documented in the MIR;
3. **A lack of information on whether action needs to be taken** after the manufacturer has completed the investigation.

[3] MDR/IVDR Annex VII § 4.5.1

Conclusion

The implementation of post-market surveillance by the medical device manufacturer achieves a triple objective:

1. **To confirm the safety and performance data defined during the design and development phase of the medical device;**
2. **Continuously update the technical documentation;**
3. **Obtain new clinical or performance data to resolve uncertainties identified during the clinical or performance evaluation of the medical device/in vitro diagnostic medical device.**

The introduction of the NB into the circuit of recipients of notifications of vigilance reports, and the periodic evaluation of PSURs, allow permanent and immediate access to PMS data, to serious incidents involving devices placed on the market.

The NB is then able to :

- Verify that manufacturers are meeting the incident management requirements set out in the regulations;
- Ensure that PMS data does not call into question the conformity of medical devices with regulations, and the validity of certifications issued.

The post-market surveillance activity implemented by the manufacturer, controlled by the NB and monitored by the competent authorities, ensures that patients and users have access to safe, high-performance products that comply with regulations.

To go further

TRAININGS FOR AMERICA REGION

Post Market Surveillance and Vigilance
1-day training session | Virtual classroom & In-Person Training
→ CHECK OUT THE PROGRAM

European Medical Device Regulation (EU) 2017/745
2-day training session | Virtual classroom
→ CHECK OUT THE PROGRAM

European in Vitro Diagnostic Device Regulation (EU) 2017/746
2-day training session | Virtual classroom
→ CHECK OUT THE PROGRAM

Biocompatibility of Medical Devices
3 half-day training session | Virtual classroom
→ CHECK OUT THE PROGRAM

TRAININGS FOR OTHER REGIONS

Meet regulatory requirements for post-market surveillance and vigilance
SA45 | 1-day | Virtual classroom
→ CONTACT GMED TRAINING CENTER

Understand the regulatory requirements for clinical evaluation to choose the right route
SA65 | 1-day | Virtual classroom
→ CONTACT GMED TRAINING CENTER

Adapt your quality management system to ISO 13485 v2016
SA19 | 2-day | Virtual classroom
→ CONTACT GMED TRAINING CENTER

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