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Health and Youth Care Inspectorate
Ministry of Health, Welfare and Sport

Call to medical device manufacturers: implement an effective PMS system

The inspectorate has identified insufficient post-market surveillance (PMS) at all the manufacturers they visited

The Health and Youth Care Inspectorate (IGJ) supervises PMS at manufacturers of (in-vitro diagnostic) medical devices based in the Netherlands. PMS involves a set of coordinated activities that manufacturers must carry out to monitor and improve the safety and performance of the medical devices they sell. None of the 13 manufacturers visited by the IGJ in 2023 and 2024 met the PMS requirements as laid out by the MDR and IVDR.

For manufacturers, it is essential to have a well-functioning PMS system in place to promptly detect and resolve any potential issues. This minimises the risk of injury for users of the medical devices. Furthermore, data from a robust PMS system can lead to improvements to the medical device, offering opportunities for manufacturers

What is this about?

PMS refers to a range of activities that manufacturers must undertake in a coordinated manner to monitor the safety and performance of their devices. This process begins as soon as the product is launched and continues throughout its use. Since some products remain on the market for many years, it is crucial to ensure they still meet the required standards.

The purpose of PMS is to ensure that the manufacturer always has the most up-to-date information about their medical device. With this information, they can improve the device or its safe use if necessary, reducing the risks to individuals who come into contact with these devices. Manufacturers therefore must have an effective PMS system. The IGJ assesses whether manufacturers are conducting PMS according to the applicable regulations.

Since September 2023, the IGJ has intensified its supervision of PMS for manufacturers of (in-vitro diagnostic) medical devices based in the Netherlands. The IGJ assesses a number of manufacturers specifically on their PMS practices. For these inspections, the IGJ has developed a PMS assessment framework, which was published in September 2023. This framework has been used by inspectors to evaluate how 13 manufacturers are executing PMS and ensuring its ongoing compliance. The inspections focused primarily on micro, small, and medium-sized enterprises, covering Class I medical devices, software applications, and in-vitro diagnostics (IVDs) that are being marketed as legacy devices. Legacy devices are medical products that, after the transition period, move into a higher risk category and require certification by a notified body.

When manufacturers do not comply with legal and regulatory requirements, enforcement action is taken in accordance with the MDR/IVDR intervention policy.

A brief glossary of terms is provided at the end of this document.

Supervision and key findings

The inspections focused on the PMS requirements that manufacturers must meet according to the MDR and IVDR. The scope of the inspection was limited to evaluating the PMS plan, PMS reports, and the Periodic Safety Update Reports (PSURs) that must be prepared annually or biennially. Additionally, the IGJ examined how PMS processes were integrated with other key processes within the manufacturer's quality management system (QMS). During the inspections, the following aspects were assessed:

1. Has the manufacturer incorporated the PMS system as part of its own **quality management system (QMS)**?
2. Does the manufacturer have the **required PMS documentation**?
3. Are PMS reports or PSURs prepared at a **frequency** that is appropriate for the nature, intended use, risk profile of the medical device and specific MDR and IVDR requirements?
4. Does the manufacturer actively and systematically collect and record relevant **data** on the quality, performance and safety of the medical device throughout its lifecycle as part of PMS?
5. Is the **analysis** of the collected data structured in such a way that the manufacturer can draw conclusions about the safety and effectiveness of the specific medical device?
6. Are the **results and conclusions** from PMS used as input for systematic improvements to the medical device or for taking corrective and/or preventive actions?
7. Are the processes that interact with the PMS system **carried out** in accordance with established procedures?

The implementation of PMS was found to be inadequate at all 13 manufacturers visited in 2023 and 2024. There was little to no difference in the number and type of non-compliances between the various categories of medical devices inspected. Manufacturers perceive the PMS requirements from the MDR and IVDR to be complex.

However, the IGJ also observed that manufacturers are capable of establishing an effective PMS system when they give it the appropriate attention and priority. This was evident from follow-up inspections, where manufacturers demonstrated their ability to meet the requirements. The IGJ encourages manufacturers to take proactive steps on their own initiative. The outcomes from a well-functioning PMS system can also lead to innovative solutions or further development of the medical device. This offers manufacturers an opportunity to become leaders in the field.

The IGJ assessed 13 manufacturers against the PMS requirements of the MDR and IVDR. While this is a relatively small group, the fact that none fully complied prompted the IGJ to address the entire sector on this issue.

What are the areas of concern?

During the inspections, while assessing the PMS requirements from the MDR and IVDR, attention was also given to the broader context. This included factors such as the manufacturer's history and background, the type and risk classification of the medical device, and the market in which the manufacturer operates. This approach ensured that the PMS requirements were considered in the appropriate context for each medical device and manufacturer. The findings are summarised as follows:

- PMS is partially implemented, but the plan is not well-developed.

All manufacturers reported that they regularly gather information about their medical devices from customers or other sources.

However, this was often done in an unstructured manner. In many cases, they did not specify which information they intended to collect about the device. Furthermore, their plans or procedures often failed to indicate how they would gather data from the selected sources, or how they would analyse the collected information.

This approach raises concerns about whether manufacturers have carefully considered which information is relevant to collect regarding their medical devices. The lack of a clear pre-established plan makes the execution of PMS overly dependent on personal interpretations.

- Manufacturers have limited knowledge, skills and focus regarding the purpose of PMS.

Based on discussions and reviewed documents, it became apparent that many manufacturers equate PMS requirements with vigilance requirements. Although both processes involve the use of information about incidents involving the medical device, vigilance requirements are primarily designed to address individual cases quickly.

A PMS system, on the other hand, also uses incident data, but its primary aim is to identify trends from multiple sources and take action based on those trends to improve the overall safety of the medical device. This proactive approach helps prevent incidents in the first place.

The PMS plans examined also revealed that manufacturers were not always able to clearly explain how the system should be implemented. A significant number of manufacturers lacked sufficient knowledge about PMS, and this knowledge was not well established within their organisations. It was also unclear to some manufacturers that PMS interacts with other systems, such as the risk management system and clinical or performance evaluation.

PMS is an integrated system designed to ensure and improve the safety and effectiveness of a product, so that manufacturers can identify opportunities for improvement and prevent incidents with their medical devices. Successfully implementing PMS requires thoroughknowledge of the product, expertise in PMS, a commitment of time and resources, prioritisation, and a critical attitude. Not all manufacturers fully grasp the purpose and mindset behind PMS.

- The PMS system is not tailored to the specific type of medical device

The plans for carrying out PMS are often not tailored to a specific type of medical device but instead apply to several very different devices or are too broadly defined.

Because the PMS system is not properly customised for the specific type of medical device, it is unclear which information is relevant to collect, how it should be analysed, and how it should lead to improvements in the product where necessary. Without a well-thought-out and clear plan in place, manufacturers cannot ensure that they are gathering the correct information about the safety and quality of the product.

- Manufacturers lack a clear understanding of when action is needed based on PMS

In addition to planning how PMS information will be collected, it is also crucial for the effective operation of the PMS system that manufacturers pre-determine when the collected information should prompt action. For example, when the information should lead to design modifications, adjustments in the risk management system or updates to the clinical or performance evaluation.

Many PMS plans or underlying procedures lacked suitable indicators and threshold valuesfor the various data sources. These are pre-defined values set by the manufacturer, which, when exceeded, should trigger action. Because manufacturers have not defined these values in advance, they cannot ensure that critical information about the medical device is addressed in a timely and appropriate manner. This leaves the manufacturer unable to prevent potential issues with the medical device before an incident occurs.

Manufacturers' perspectives on PMS

During the inspections, the IGJ gained insight into how manufacturers perceive PMS and the challenges they face in implementing it correctly. The following points emerged:

- Manufacturers find the new PMS requirements in the MDR and IVDR to be complex, requiring significant effort to comply. This complexity, combined with other MDR and IVDR requirements, sometimes influences manufacturers' decisions to cease marketing medical devices after the transition periods expire.
- Cost and time are significant factors in carrying out PMS properly, particularly for smaller manufacturers with limited resources.

- Manufacturers that market devices not requiring notified body assessments often lack experience with processes such as PMS.

- Most manufacturers are aware that the MDR and IVDR requirements for PMS currently apply to products under the transitional provisions.

What does the IGJ expect from manufacturers?

The IGJ expects all manufacturers to prioritise PMS and ensure that there is sufficient knowledge of PMS within their organisation. Only with a well-functioning PMS system can manufacturers detect potential issues with their medical devices at an early stage. These issues can then be addressed before any harm occurs.

By not properly implementing PMS, manufacturers also miss out on opportunities to further develop their medical devices and potentially become leaders in their field. Outcomes from a functioning PMS system can lead to innovative solutions or further improvements (e.g., ergonomic adjustments or customer-suggested enhancements) to the device.

Two-thirds of the inspected manufacturers market legacy devices – medical devices that move to a higher risk classification after the transition periods and require certification by a notified body. The PMS systems observed by the IGJ at these companies were inadequate. This suggests that other manufacturers of legacy devices, who were not inspected, may also be failing to meet the PMS requirements of the MDR or IVDR. If manufacturers do not have their PMS systems in order on time, certification by a notified body may be delayed. This poses a risk that it could take longer for a notified body to issue a CE certificate for a medical device and manufacturers may not be able to market their devices temporarily.

What should manufacturers do? Key action points:

✓ All manufacturers, including those not inspected, should carefully review this publication and critically assess whether they meet the PMS requirements. It is important that manufacturers:
- clearly assign responsibility for PMS within their organisation and ensure this is integrated into the quality management system;
- safeguard knowledge of PMS within the organisation, and where necessary, seek external expertise to ensure they are well-equipped to execute PMS effectively;
- Seek out and use available resources for more information and guidance on PMS, such as the PMS assessment framework published by the IGJ, relevant legislation, and other resources. Additionally, manufacturers should remain alert to new European guidelines on PMS, with new PMS guidance expected in autumn 2024.

✓ We expect manufacturers to apply this to all medical devices they market.

✓ Manufacturers should recognise that a lack of knowledge about PMS may also indicate insufficient knowledge of other aspects of the MDR and IVDR. We expect them to independently evaluate whether they meet all the MDR and IVDR requirements.

✓ We ask authorised representatives to actively share this publication with manufacturers outside the EU, drawing attention to the importance of PMS.

What are the findings from the visits?

The IGJ assessed 13 manufacturers against the PMS requirements from the MDR and IVDR. Below are our findings from these visits.

The results for the different elements of the assessment framework are represented using icons. Each element corresponds to a legal requirement from the MDR and IVDR, as outlined in the published assessment framework. A green checkmark indicates that more than 75% of the manufacturers met the assessment criterion. An orange/yellow exclamation mark means that between 50% and 75% of the manufacturers met the criterion. A red cross shows that fewer than half of the manufacturers met the assessment criterion. Based on this method, the results are as follows:

✓	More than 75% of the manufacturers met the assessment criterion.
!	50 - 75% of the manufacturers met the assessment criterion.
✗	Less than 50% of the manufacturers met the assessment criterion.

1. Has the manufacturer incorporated the PMS system as part of its own quality management system (QMS)?

1. Quality management system (QMS)

#	Requirement	Result
1.1	PMS as an integral part of the QMS	✓

For the majority of manufacturers, the PMS system was an integral part of the Quality Management System (QMS).

Most manufacturers had a QMS certified to EN ISO 13485 or ISO 9001. Within these systems, there were PMS procedures that were linked to processes related to the design of the medical device, risk management and clinical or performance evaluation.

2. Does the manufacturer have the required PMS documentation?

2. Required documentation		
#	Requirement	Result
2.1	PMS plan established	!
2.2	PMS report/PSUR created	✓
2.3	Summary of PMS results	!

A little more than half of the manufacturers had a PMS plan. Where a plan was missing, manufacturers often did not clearly describe which medical device the plan pertained to. In some cases, so much information was missing from the PMS plan that the IGJ considered it to be non-existent.

The majority of manufacturers had produced a PMS report or, where applicable, a PSUR. However, the content of these reports was often insufficient. For just under half of the manufacturers visited, the PMS report lacked a summary of the results and conclusions from the analysed PMS data. The conclusions manufacturers drew following a PMS cycle were often based on the results from individual data sources. These isolated conclusions did not always lead to modifications of the medical device.

When conclusions from all PMS data sources are reviewed collectively, they can reveal visible trends that may require action by the manufacturer or present opportunities for product improvement.

3. Are PMS reports or PSURs prepared at a frequency that is appropriate for the nature, intended use, risk profile of the medical device and specific MDR and IVDR requirements?

3. Frequency		
#	Requirement	Result
3.1a	Frequency of PMS report creation	✓
3.1b	PMS report/PSUR updated	!

The MDR and IVDR specify that the PMS report should be updated when necessary. There is no mandatory frequency set for the creation of a PMS report. During inspections, the IGJ checked what manufacturers had included in their PMS plans regarding the frequency of updates, particularly how they interpreted 'when necessary. Inspectors then assessed whether manufacturers adhered to their own PMS plan regarding the frequency and criteria for updating the PMS report. This was not always the case.

Only a part of the manufacturers updated the PMS report or PSUR when they deemed it necessary.

4. Does the manufacturer actively and systematically collect and record relevant data on the quality, performance and safety of the medical device throughout its lifecycle as part of PMS?

4. Data		
#	Requirement	Result
4.3	Provisions for serious incidents	✗
4.4	Provisions for non-serious incidents	✗
4.5	Provisions for reporting trends	✗
4.6	Provisions for literature review	✗
4.7	Provisions for customer feedback	!
4.8	Provisions for similar medical devices	✗
4.2	Proactive and systematic procedures	✗
4.9	PMCF/PMPF plan	!
4.1	Appropriate data sources	✓

Data sources in the PMS plan

During inspections, the IGJ examined which data sources manufacturers used within their PMS system. Manufacturers are required to consider and document these data sources in their PMS plan.

The findings revealed that, despite the MDR and IVDR specifying the required data sources, manufacturers did not always include these in their PMS plan. For example, manufacturers often mentioned 'incidents' as a data source, but they frequently failed to distinguish between serious and non-serious incidents and adverse effects. This omission made it unclear which specific data the manufacturer was collecting about incidents.

Another observation was that many manufacturers did not tailor their PMS plan to the type of medical device they were marketing. Some used PMS plans that applied to multiple types of devices without clearly specifying which data they intended to collect for

each type. As a result, the PMS plans were too generic for the medical devices they covered.

In some cases, the IGJ also encountered PMS plans that included (non-mandatory) data sources. Manufacturers sometimes admitted that the mentioned source provided no or irrelevant information about the type of medical device in question. It was unclear why these sources were still included in the PMS plan.

Proactively and systematically collecting PMS information
Identifying relevant data sources for PMS is one aspect. Determining what information should be collected and analysed from these sources is equally crucial.

The IGJ found that more than half of the inspected manufacturers lacked a clear procedure for proactively and systematically obtaining PMS information. The PMS plans did not sufficiently describe which information should be extracted from the sources, how it would be analysed and what actions would be taken based on the analysis. Consequently, the PMS plans did not clearly define the manufacturer's concrete approach for obtaining the correct information about the medical device. Additionally, many PMS plans did not specify which employee was responsible for executing parts of the plan and when the information from the sources would be collected.

5. Is the analysis of the collected data structured in such a way that the manufacturer can draw conclusions about the safety and effectiveness of the specific medical device?

5. Analysis

#	Requirement	Result
5.1	All PMS data sources consulted	!
5.2	Thresholds defined	✗

During the inspections, the IGJ examined how closely manufacturers followed their own PMS plans and how certain outcomes triggered adjustments in other processes and/or documents. More than half of the visited manufacturers consulted the data sources listed in their PMS plan or explained why certain sources were not consulted, such as in cases where no reports had been received.

In only a few PMS plans did manufacturers describe indicators and/or thresholds that would lead to adjustments in other processes and/or documents once exceeded. As a result, the majority of manufacturers did not provide clear evidence or documentation for when certain critical safety and quality information about the medical device would lead to further action.

Defining indicators and/or thresholds to determine when action should be taken to enhance the safety and performance of the medical device is a crucial element of PMS

6. Are the results and conclusions of PMS used as input for systematic improvements to the medical device or for taking corrective and/or preventive actions?

6. Results and conclusions

#	Requirement	Result
6.1	PMS report/PSUR contains conclusions of renewed benefit-risk analysis	✗
6.2	PMS report/PSUR contains preventive/ corrective actions	✓

The IGJ investigated whether manufacturers included conclusions in their PMS report or PSUR regarding the reassessment of the benefit-risk ratio. At half of the inspected manufacturers that had prepared a PMS report or PSUR, the document did not contain conclusions about whether the collected PMS data led to a renewed benefit-risk analysis.

The findings and conclusions about risks were not linked to the benefit-risk analysis, as required by the MDR and IVDR.

When manufacturers concluded that the PMS results required action in the form of preventive and/or corrective measures, all manufacturers documented these actions in the PMS report or PSUR.

7. Are the processes that interact with the PMS system carried out in accordance with established procedures?

7. Execution

#	Requirement	Result
7.1	PMS outcomes for design/instructions for use/labelling	✓
7.2	PMS outcomes for clinical or performance evaluation	!

If PMS outcomes led to the conclusion that the design, labelling and/or instructions for use of the medical device needed to be adjusted, all manufacturers implemented these changes.

Adjustments to the clinical evaluation often occurred via the manufacturer's risk management system as a result of PMS findings.

However, not all manufacturers followed the described procedure for updating a clinical or performance evaluation based on PMS results.

What's next?

None of the visited manufacturers fully complied with the PMS requirements of the MDR or IVDR. As a result, enforcement measures have been or will be imposed on these manufacturers. These measures require the manufacturers to resolve the violations, and the inspection will follow up until the issues are addressed.

The IGJ is also calling for a broader, structural improvement of processes at manufacturers. The inspection urges manufacturers to investigate what led to the violation of MDR or IVDR and to translate this into corrective and/or preventive actions.

Additionally, the IGJ continues to raise awareness about PMS both nationally and internationally. The topic is being discussed with various parties, including those responsible for policymaking. The IGJ plans to disseminate this publication widely through multiple channels.

In addition to emphasising the importance of PMS, the IGJ will maintain its supervision of manufacturers regarding this topic and incorporate it into routine inspections. The IGJ will assess whether manufacturers have properly considered how they implement PMS and whether the system is appropriate for the type of medical device being marketed.

Moreover, the IGJ will evaluate what is needed to encourage the industry to take responsibility. A new European PMS guidance will be published soon, and IGJ inspectors will ensure that relevant parties are informed.

Glossary

Legacy devices

hese are medical devices that comply with previous regulations (the Medical Device Directive, In Vitro Diagnostic Medical Devices Directive, and Active Implantable Medical Devices Directive) and are allowed to be placed on the market under transitional provisions, subject to conditions. At the time of the inspection, no CE certificate had yet been issued by a notified body for the selected legacy devices.

Risk classes

The above-mentioned directives classify medical devices into four risk classes: I, IIa, IIb, and III, with the risk increasing from class I (lowest risk) to class III (highest risk). The intended purpose and risks associated with the medical device determine its risk class. For example, an artificial heart valve falls into risk class III, while a general hospital bed falls into class I. The higher the risk class, the more stringent the requirements that the medical device must meet.

IVDs are also classified into four risk classes: A, B, C and D, with the risk increasing from class A (lowest risk) to class D (highest risk). The intended use and associated risks of the IVD determine the risk class it falls into. For example, an HIV test falls into the highest risk class D, while a urine container falls into the lowest risk class A. The higher the risk class, the more stringent the requirements the IVD must meet.

Notified body

A notified body is a certifying authority that manufacturers must engage to verify whether their medical devices and quality management procedures comply with applicable regulations. If all requirements are met, the notified body issues a CE certificate, allowing the manufacturer to market the medical device. Once the medical device is on the market, the notified body also periodically inspects the manufacturer to ensure the device continues to meet MDR or IVDR requirements. Not all medical devices need to be reviewed by a notified body. This applies only to devices in risk classes IIa, IIb, III and IVDs in classes B, C and D, as well as class I devices and class A IVDs that are sterile or have a measuring function. Notified bodies are designated by EU member states and operate across the European market. This means that medical devices certified by a Dutch notified body can then be marketed in all Union countries. The European NANDO database lists all notified bodies designated by member states.

Company categories in this publication

- A micro-enterprise is a company with fewer than 10 employees and an annual turnover or balance sheet total not exceeding 2 million euros.
- A small enterprise is a company with fewer than 50 employees and an annual turnover or balance sheet total not exceeding 10 million euros.
- A medium-sized enterprise is a company with fewer than 250 employees and an annual turnover not exceeding 50 million euros or a balance sheet total not exceeding 43 million euros.