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MEDICAL DEVICE

Post-Market Surveillance and Vigilance

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1. European Medical Device Post-Market Surveillance

Competent Authorities in Europe are more structured and organized to operate on a European-wide level and they have intensified cross-border cooperation among themselves. As such, Competent Authorities have the ability to inspect the market and determine whether manufacturers have correctly affixed the CE marking to their devices and meet their regulatory obligations.

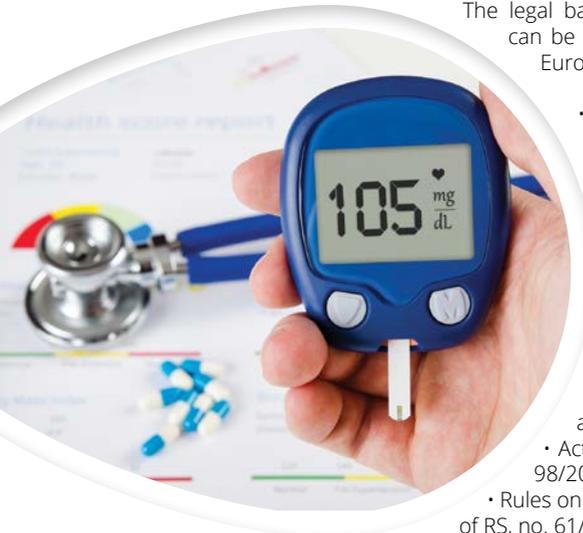
Over the last several years, there have been more inspections throughout the EEA, including random checks and on-site inspections at manufacturers and/or their Authorized Representatives. Most notably, Competent Authorities pay specific attention to manufacturers of self-declared devices, which do not need the intervention of a Third Party (Notified Body).

Both Competent Authorities and Notified Bodies are placing more emphasis on ensuring that manufacturers have implemented and maintain a post-market surveillance system. The concept of post-market surveillance is not only embraced by the New Approach Directives but also by the ISO Quality Management and Risk Management Standards.



The legal basis for post-market surveillance and vigilance can be found in the relevant sections of the following European Directives:

- Active Implantable Medical Devices Directive (AIMDD 90/385/EEC - Article 8 and Annexes II, IV, V)
- Medical Devices Directive (MDD 93/42/EEC - Article 10 and Annexes II, IV, V, VI, VII)
- In-Vitro Diagnostics Devices Directive (IVDD 98/79/EC - Article 11 and Annexes III, IV, VI)
- In addition, the quality management standards, ISO 9001:2015 & ISO 13485:2013, as well as the risk management standard ISO 14971, also include requirements for medical device manufacturers to conduct post-market activities.
- Act on medical devices (Official Gazette of RS, no. 98/2009; hereinafter ZMedPri)
- Rules on medical device vigilance system (Official Gazette of RS, no. 61/10)



In brief, medical device post-market surveillance is not only regulatory-driven, but should also be considered as a good business practice. It helps the manufacturer to understand the performance of the device once placed on the market, and provides continuous feedback that enables manufacturers to maintain a high standard of product quality and consumer satisfaction. It also helps to minimize exposure arising from incidents through effective warning and product recall processes and procedures.

Post-market activities can be divided in two categories:

- Proactive – Post-Market Surveillance
- Reactive - Vigilance

These are further described as follows: According to the Global Harmonization Task Force, Post-Market Surveillance is defined as: “the pro-active collection of information on quality, safety or performance of Medical Devices after they have been placed on the market.”

Conversely, Vigilance refers to incidents that can occur with medical devices and in-vitro diagnostic medical devices, when they do not perform as intended, thereby leading in the worst case to injury or death. The medical device directives require timely, coordinated action and provision of information between the manufacturer and the Member States’ national authorities in relation to (near) incidents that are related to the device.

The purpose of medical device vigilance is to: protect the health and safety of persons within the EEA; evaluate incidents to prevent recurrence; determine the effectiveness of corrective actions and preventive actions; and monitor and learn from experience.

The European Commission had published a guideline which lays out the requirements of the reporting system for medical devices and In-Vitro Diagnostic medical devices. The Commission Guidelines on Medical Device System (MEDDEV) cover the following items:

- Explanation of the use of the reporting system
- Guidance on what types of incidents should be reported, including timescales for (near) incident reporting and recalls
- Format for the initial and final reports to be compiled by the manufacturer for review by the Competent Authorities
- Actions taken by Competent Authorities, including what types of incidents are communicated to Member States and to the Commission in Competent Authorities Reports

The Vigilance MEDDEV is regarded by the Competent Authorities and by most in the device industry as an excellent guideline. However, there remain some challenges with regard to communications among the Manufacturer-Authorized Representative-Distributor, and also among the respective Member States’ Competent Authorities.

2. Parties Involved in the medical device post-market surveillance system

The onus of post-market surveillance for medical devices is assigned to Competent Authorities, Custom Officials, Notified Bodies, Manufacturers, Authorized Representatives, Importers/Distributors, and Users. In addition, External Quality Assessment Schemes is one mechanism to carry out post-market surveillance by maintaining and improving the analytical quality and medical appropriateness of clinical laboratory data.

In order to ensure that medical device and IVD post-market surveillance is carried out and conducted effectively, all parties involved must understand and be aware of their responsibilities and liabilities in this regard. The effectiveness of the system can be determined and inspected by Notified Bodies and Competent Authorities.

2.1 Competent Authorities

Market surveillance is mandated under the New Approach Directives, including the IVDD, and is enforced to ensure that the provisions of the directive are complied with throughout the EEA. EU Member States must appoint authorities to be responsible for market surveillance. For IVD post-market surveillance, these authorities, also known as Competent Authorities, are usually the national Ministries of Health, which were before the New Approach also responsible for the monitoring of medical products on the market. Competent Authorities are also responsible for taking the appropriate steps to ensure that any information brought to their attention regarding adverse incidents is recorded and evaluated.

In case of an incident or random audit, the Competent Authority may require access to the manufacturer's Declaration of Conformity and Technical File/Dossier. The manufacturer, his Authorized Representative or importer, must be able to provide the Technical File/Dossier upon request to the Competent Authority. If the product is found to be non-compliant, corrective action will depend on and be appropriate to the level of non-compliance.

It should be noted that the Competent Authority will hold accountable the person (in most cases, the manufacturer) who was responsible for affixing the CE marking to a non-compliant product. Others who are responsible for the non-compliance of the product will be held accountable as well. Penalties, which may include draconian sanctions such as imprisonment, are determined by national law.

Competent Authorities are able to monitor products placed on the market by either of the following means:

- reviewing product claims,
- evaluating and investigating reported complaints,
- auditing Notified Bodies,
- exchanging information among Competent Authorities,
- visiting commercial, industrial and storage premises on a regular basis,
- visiting work places and other premises where products are put into service and used,
- organizing random inspections,
- acquiring samples of products and subjecting them to examination and testing,
- disclosure of all necessary (technical) information.



3. Medical Device Vigilance Reporting in Europe

The European Medical Devices Directive (93/42/EEC) states that medical device manufacturers are legally required to report adverse incidents and Field Safety Corrective Actions (FSCAs) to Competent Authorities. However, the “when, what and to whom” aspect of EU incident reporting often confuses regulatory professionals.

The European Commission's Guidance document MEDDEV 2.12/1 offers manufacturers valuable information on terminology, timelines and other vigilance reporting requirements. Companies that fail to correctly report incidents could face severe financial penalties or criminal sentences. Ignorance is not an acceptable excuse for not reporting incidents, so manufacturers Regulatory Affairs responsible persons need to be proactive.

3.1. When are EU vigilance reports required?

The term “vigilance report” encompasses Incident Reports and Field Safety Corrective Action (FSCA) reports. According to MEDDEV 2.12/1, an incident report must be filed if a device malfunction, deterioration in device performance, inadequate instructions or inadequate labeling results in death, serious injury, or may lead to death or serious deterioration in state of health if it were to recur. The incident must be reported to the Competent Authority (CA) of the member state where the incident occurred.

If a manufacturer takes an action to reduce the risk of death or serious deterioration in health, such as a recall, a Field Safety Corrective Action (FSCA) report must be distributed to Competent Authorities in the member states where the device is being marketed.

A FSCA report must also be distributed in the member state where the manufacturer or Authorized Representative is located, if the manufacturer is located outside of the EEA. A Field Safety Notice (FSN) must also be distributed to consumers in these member states.

3.2. Trend Reporting

Manufacturers of devices classified in class IIb and III shall report any statistically significant increase in the frequency or severity of incidents that are not serious incidents, or of expected undesirable side-effects that have a significant impact on the risk-benefit analysis and which have led or may lead to unacceptable risks to the health or safety of patients, users or other persons when weighed against the intended benefits. The significant increase shall be established in comparison to the foreseeable frequency or severity of such incidents or expected undesirable side-effects in respect of the device, or category or group of devices, in question during a specific time period as established in the manufacturer's conformity assessment.



3.3. EU Medical Device Vigilance Reporting Process

Shown below are the basic steps to reporting an incident in Europe (Reference MEDDEV 2.12/1 to determine the correct reporting timeline, which will depend on the severity of the incident.):

1. Inform appropriate Competent Authorities that an incident has occurred.
2. Respond to questions from Competent Authorities regarding devices involved, time on the market and design changes.
3. Determine if a Field Safety Corrective Action (FSCA) and Field Safety Notice (FSN) are necessary and report to appropriate Competent Authorities.
4. Submit a Final Incident or FSCA Report to Competent Authorities.
5. Add vigilance reports, along with any correspondence with Competent Authorities to your ISO 13485 or other quality system records.
6. Inform your Notified Body of any incidents or FSCAs unless your device is Class 1 self-certified.
7. Update your Technical File and reassess your Clinical Evaluation.

A woman with long brown hair is holding a white rectangular sign in front of her face. The sign has the text 'WHAT? HOW? WE KNOW!' written on it in bold, black, sans-serif font. The woman's hands are visible on the left and right sides of the sign. The background is white with a large, light blue, cloud-like shape behind the woman's head.

**WHAT?
HOW?
WE KNOW!**

4. Why choose ADAX to assist with EU vigilance reporting?

If we act as your Representative, we can submit incident reports to Competent Authorities on your behalf.

Our in-depth knowledge of the European medical device market ensures that your vigilance procedures will always be up-to-date.

Our experienced consultants can help determine whether incidents are reportable and can ensure that final incident reports are completed on time. We can support you in compiling the Field Safety Corrective Action (FSCA) and Field Safety Notice (FSN).

We have experience assisting manufacturers with post-market surveillance, Periodic safety reports, CE Marking and other regulatory consulting services.

The logo for ADAX is rendered in a blue, cursive script font. The letters are lowercase and highly stylized, with the 'a' and 'd' having large loops, and the 'x' having a long, sweeping tail that extends to the right.

Add EXCELLENCE to your Medical Device with our KNOW-HOW!



Medical Device Technical File

Clinical Investigation

Clinical Evaluation

Post-Market Surveillance and Vigilance

Medical Device CE Marking

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We tailor our services to your specific need!

Adax International d.o.o. | Telephone: +386 (0) 597 10 255,
Email: info@adax.si | www.adax.si