Postmarketing surveillance (**PMS**), also known as **post market surveillance**, is the practice of monitoring the safety of a pharmaceutical drug or medical device after it has been released on the market and is an important part of the science of pharmacovigilance. Since drugs and medical devices are approved on the basis of clinical trials, which involve relatively small numbers of people who have been selected for this purpose – meaning that they normally do not have other medical conditions which may exist in the general population – postmarketing surveillance can further refine, or confirm or deny, the safety of a drug or device after it is used in the general population by large numbers of people who have a wide variety of medical conditions.

Postmarketing surveillance uses a number of approaches to monitor drug and device safety, including spontaneous reporting databases, prescription event monitoring, electronic health records, patient registries, and record linkage between health databases. These data are reviewed to highlight potential safety concerns in a process known as data mining.

National implementation

Canada

Health Canada is the regulatory body which approves drugs, and it has a division called "Marketed Health Products Directorate" (MHPD) which coordinates Canadian postmarketing surveillance.

European Union

The guidance document "MEDDEV 2.12-1 rev 8" offers a comprehensive guidance on best practice for *medical device post-market surveillance* (materiovigilance). The concept of *post market surveillance* is linked to the concepts of *vigilance* and *market surveillance*. A manufacturer of medical devices is required to report incidents (serious adverse events) to the national competent authority of the member state the company resides in. The Medical Device Regulation (EU) 2017/745 (MDR) provides in §2 the following definition of post-market surveillance:

‘post-market surveillance’ means 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;

Further requirements on PMS are given in §83 of the MDR; §84 details PMS Plan requirements and references Section 1.1 of Annex III of the MDR; §85 details the PMS report, while §86 describes the contents of the Periodic Safety Update Report (PSUR).Similar provisions on Post-Market Surveillance are found in the European regulation on in vitro diagnostic medical devices (IVDR).

The MDCG Guideline 2023-3 "Questions and Answers on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745 on medical devices" provides further clarification on the topic.

United Kingdom

The Medicines and Healthcare products Regulatory Agency (MHRA) and the Commission on Human Medicines (CHM) jointly operate the Yellow Card Scheme, which was one of the first examples of a pharmacovigilance scheme, aimed at mitigating adverse drug reactions (ADRs).

United States

Postmarketing surveillance is overseen by the Food and Drug Administration (FDA), which operates a system of passive surveillance called MedWatch, to which doctors or the general public can voluntarily report adverse reactions to drugs and medical devices. The FDA also conducts active surveillance of certain regulated products. For example, the FDA may monitor safety and effectiveness of medical devices through either a Post-Approval Study or through a 522 Postmarket Surveillance Study. With respect to regulation, two terms are defined: Postmarketing requirements are studies and clinical trials that sponsors are required to conduct and postmarketing commitments are studies or clinical trials that a sponsor has agreed to conduct, but that are not required by a statue or regulation.

The Post-Market Surveillance requirements

Post-Market Surveillance comprises four elements, with duties that a device manufacturer placing on the EU market must fulfil to comply with the Regulation.

- **A Post-Market Surveillance System** as per Article 83 MDR & Article 78 IVDR. This is defined as the system through which a manufacturer obtains relevant information on the quality, performance and safety of a device they have placed on the market, with measures proportionate to the risk class and type of the device and forming a vital part of their QMS. This data should be used, among others, to:
    - Update the benefit-risk determination set in the risk management;
    - Update the design and manufacture information;
    - Update the clinical evaluation;
    - Identify the needs for preventive, corrective or field safety corrective actions;
- **A Post-Market Surveillance Plan** as per Article 84 MDR & Article 79 IVDR, according to the requirements set by Annex III of the Regulation.
- **A Post-Market Surveillance Report** (PMSR) as per Article 85 MDR & Article 80 IVDR, in cases of Class I devices. This report needs to summarize the data obtained from the abovementioned Post-Market Surveillance Plan.
- **A Periodic Safety Update Report (PSUR)** as per Article 86 MDR & Article 81 IVDR**,** in cases of class IIa, IIb and III devices. Equally to the PMSR, the PSUR must be compiled for each device as a result of the implementation of the Post Market Surveillance Plan.

Only when all of the above elements are present can a manufacturer claim they are MDR compliant with Post-Market Surveillance and that they indeed have a system that gathers and filters information related to the quality, performance and safety of their device.

The Vigilance requirements

As previously determined, vigilance relates to the steps a manufacturer has to take in case of any incidents involving their devices, the way they report them and the field safety corrective action measures they have to take in response.

A series of factors play a role in the way in which Vigilance is performed, both by the manufacturer and the Competent Authorities and Commission:

- Reporting of serious incidents and field safety corrective actions and their communication to the Competent Authorities in different scenarios (Article 87 MDR & Article 82 IVDR), as well as their analysis (Article 89 MDR & Article 84 IVDR).
- Reporting potential trends regarding the frequency and severity of incidents concerning the devices placed in the market (Article 88 MDR & Article 83 IVDR).

The Commission analyzes all the collected Vigilance data is analyzed with the collaboration of the Member States as a way to determine any previously unforeseen risks (Article 90 MDR & Article 85 IVDR). This is done through an electronic system through which Vigilance and Post-Market Surveillance data is gathered and through which the Commission and the Member States ensure the fulfillment of the above requirements.

Vigilance vs PMS or Vigilance & PMS? A symbiotic relationship

As observed through the explanation of the context and characteristics of these terms, it quickly becomes apparent they are meant to be complementary to each other. One would not properly fulfil its scope without the other.

Post-Market Surveillance without Vigilance would have merely been delegated to gathering information, adverse or otherwise, without a system in place to report and act when the safety of consumers is at stake.

Vigilance without Post-Market Surveillance would simply not function, as no system would exist to gather and filter information that could imply a serious incident and necessitate field safety corrective action. Nor would the Commission and Competent Authorities be able to observe any specific trends with devices on the market and succeed in averting future incidents.

The role of Obelis on Vigilance and PMS

Obelis, as European Authorized Representative, requires detailed files on PMS and Vigilance as part of the general QMS documentation needed for the MDR compliance procedures. Comprehensive relevant files ensure that the clients are compliant with MDR 2017/745 and IVDR 2017/746 and that they will continue monitoring their devices placed in the EU market. Additionally, through their Agreement with Obelis, manufacturers must provide any copies of manufacturer incident reports that were submitted to the authorities, as well as any communication that followed as a result. Consequently, a safer environment for consumers is created, or in case of incidents, a swift reporting to the Authorities is ensured, followed by actions to rectify the problems.