Appendix 4: Post-market surveillance

The information below provides a snapshot of the detailed requirements for post-market surveillance documentation in Annex III of the European Regulations.

For the **complete list** of European requirements, refer to Annex III:

EU MDR Annex III Technical documentation on post-market surveillance, and Chapter VII, Articles 83-86.

EU IVDR Annex III Technical documentation on post-market surveillance, and Chapter VII, Articles 78-81.

Annex III in the European Regulations states the purpose and requirements of the post-market surveillance plan. In summary:

a. It shall address the collection and utilization of available information:

– Information concerning serious incidents, including information from periodic safety update reports (PSURs), and field safety corrective actions;

– Records referring to non-serious incidents and data on any undesirable side-effects;

– Information from trend reporting;

– Relevant specialist or technical literature, database and/or register;

– Information, including feedbacks and complaints, provided by users, distributors and importers; and

– Publicly available information about similar medical devices.

b. It shall cover at least:

– A proactive and systemic process to collection information;

– Effective and appropriate methods and processes to assess the collected data;

– Suitable indicators and threshold values that shall be used in the continuous reassessment of the benefit-risk analysis and risk management;

– Effective and appropriate methods and tools to investigate complaints and analyse market-related experience;

– Methods and protocols to manage the events subject to trend report;

– Methods and protocols to communicate effectively with competent authorities;

– Reference to procedures to fulfil the manufacturers obligations;

– Systematic procedures to identify and initiate appropriate measures;

– Effective tools to trace and identify devices that require corrective actions; and

– A PMCF plan or a justification as to why it is not applicable.

Annex III in the European Regulations also requires both a PSUR and a post-market surveillance report (PMSR), in accordance with:

- EU MDR Article 86 of (PSUR) and Article 85 (PMSR)
- EU IVDR Article 81 (PSUR) and Article 80 (PMSR)

Post Market Surveillance Report (PMSR)

Article 85 (EU MDR) and Article 80 (EU IVDR) state:

Manufacturers of class I non-IVD and Class A and B IVD devices shall prepare a post-market surveillance report summarising the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan referred to in Article 84 (EU MDR) and Article 79 (EU IVDR) together with a rationale and description of any preventive and corrective actions taken. The report shall be updated when necessary and made available to the competent authority upon request.

Periodic Safety Update report (PSUR)

Article 86 (EU MDR) and Article 81 (EU IVDR) state:

Manufacturers of class IIa, class IIb and class III devices and Class 3 and 4 IVD devices shall prepare a periodic safety update report ('PSUR') for each device and where relevant for each category or group of devices summarising the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan referred to in Article 84 (EU MDR) and Article 79 (EU IVDR) together with a rationale and description of any preventive and corrective actions taken. Throughout the lifetime of the device concerned, that PSUR shall set out:

a. the conclusions of the benefit-risk determination;

b. the main findings of the PMCF; and

c. the volume of sales of the device and an estimate evaluation of the size and other characteristics of the population using the device and, where practicable, the usage frequency of the device.

Manufacturers of Class IIb and Class III medical devices and Class 3 and 4 IVD medical devices shall update the PSUR at least annually.

That PSUR shall, except in the case of custom-made devices, be part of the technical documentation.

Manufacturers of Class IIa devices shall update the PSUR when necessary and at least every two years. That PSUR shall, except in the case of custom-made devices, be part of the technical documentation as specified in Annexes II and III.

For custom-made devices, the PSUR shall be part of the documentation.