Post-Market Surveillance (PMS) Plan for Medical Device Manufacturer under EU MDR

The technical documentation i.e. Post Market Surveillance Plan on PMS for medical device manufacturer in accordance with Articles 83 to 86 of the EU MDR shall address the collection and utilization of available information particularly stated below:

SL. NO.	OBLIGATION	YES	NO	COMMENT
1.	Information concerning: • Serious incidents • Information from periodic safety update report (PSUR) • Information from field safety corrective actions (FSCA)	☐	☐	
2.	Records referring to • Non-serious incidents • Data on any undesirable side-effects	☐	☐	
3.	Information from • Qualitative and quantitative data analysis • Trend reporting • Post production manufacturing data analysis	☐	☐	
4.	Relevant specialist or technical literature, Databases and/or registers	☐	☐	
5.	Information provided by users, distributors and importers which may include: • Feedbacks • Complaints • Failure • Deviations	☐	☐	
6.	Information available in • the public domain or • database about similar medical devices	☐	☐	

The post-market surveillance plan shall cover at least:

SL. NO.	OBLIGATION	YES	NO	COMMENT
1.	A proactive and systematic process to collect any information referred above. The process shall allow a correct characterization of the performance of the devices and shall also allow a comparison to be made between the devices and similar products available in the market.	☐	☐	

2.	Effective and appropriate methods, statistical tools (when applicable) and processes to assess the collected data	☐	☐	
3.	Suitable indicators and threshold values that shall be used in the continuous re-assessment of the benefit-risk analysis and of risk management	☐	☐	
4.	Effective and appropriate methods and tools (statistical tools, when applicable)) to investigate complaints and analyze market-related experience collected in the field	☐	☐	
5.	Most appropriate methods and protocols to manage the events subject to the trend report as provided for in Article 88, including the methods and protocols to be used to establish any statistically significant increase in the frequency or severity of incidents as well as the observation period	☐	☐	
6.	Methods and protocols to communicate effectively with competent authorities, notified bodies, economic operators and users	☐	☐	
7.	Reference to procedures to fulfill the manufacturers' obligations laid down in Articles 83 (PMS system), 84 (PMS Plan) and 86 (PSUR)	☐	☐	
8.	Systematic procedures to identify and initiate appropriate measures including corrective actions	☐	☐	
9.	Effective tools to trace and identify devices for which corrective actions might be necessary; and	☐	☐	
10.	A PMPF plan as referred to in Part B of Annex XIV, or a justification as to why a PMPF is not applicable	☐	☐	

Reference:

Regulation (EU) 2017/745 of the European Parliament and of the council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC; Annex III.

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