Vigilance Reporting and Monitoring (For EU Market):

REPORTING FORMS:

The following forms for vigilance reporting can be used as per annex provided in MEDDEV 2.12/1 Rev 8:

Sl. No.	Forms	We are prepared / We are not prepared
1.	Report form for manufacturers to the national competent authority	
2.	Report form for field safety corrective action	
3.	Template for a Field Safety Notice	
4.	Manufacturer's periodic summary report form	
5.	Manufacturer's trend report form	
6.	National competent authority report format	

Form may be downloaded from: https://ec.europa.eu/docsroom/documents/32305/attachments/1/translations

POST MARKET MONITORING AND COMPLIANCE:

The relevant national Competent Authorities are responsible for follow-up and monitoring of any investigation being carried out by an organization, which may include these aspects:

a) course (direction the investigation is taking)
b) conduct (how the investigation is being carried out)
c) progress (how quickly the investigation is being carried out)
d) outcome (whether the results of device analysis are satisfactory)

TRENDS REPORTING:

Trend reports on identifying a significant increase or trend of events or incidents that are usually excluded from individual reporting.

Sl. No.	Activity	Remarks
1.	A report will be made available to the relevant National Competent Authority	
2.	Organization should have suitable systems in place for proactive scrutiny of trends in complaints and incidents occurring with their devices	
3.	A trend report to the National Competent Authority where the organization or its authorized representative has its registered place of business will be made where there is a significant increase in the rate of: • already reported incidents • incidents that are usually exempt from reporting • events that are usually not reportable irrespective of whether periodic summary reporting has been agreed.	

4.	Trend Reporting form provided in Annex 7 "Manufacturer's trend report form"; Report Form Manufacturer's Trend Report Medical Devices Vigilance System (MEDDEV 2.12/1 rev 8) can be used.	
5.	Vigilance reporting will be feedback for risk management and clinical evaluation report.	

REPORTING TIME SCALE:

The time from the manufacturer first being informed of the incidence to the relevant Competent Authority receiving notification would be as per Article 87 of MDR 2017/745.

Sl. No.	Issue	Reporting time frame	Remarks
1.	Serious Incidents (after causal relationship is established/ reasonably possible)	Not later than 15 days	
2.	Serious public health threat	Immediately/ not later than 2 Days	
3.	Event of Death/ unanticipated serious deterioration in a person's state of health (after causal relationship is established/ reasonably possible)	Not later than 10 days	
4.	In case of urgency where FSCA needs to be undertaken immediately	Report in advance of the FSCA being undertaken	

NOTE: As per guidelines given in **MEDDEV 2.12-1 rev.8 Vigilance Jan 2013; Guidelines on a Medical Devices Vigilance System**, upon receiving reports of incidence, it will be recorded in customer complaint record. Adverse events and Field Safety Corrective Actions (FSCA) should be reported as per **Article 92 (5) & (7) of MDR 2017/745** to the respective National Competent Authority of EEA.

Reference:

1. MEDDEV 2.12-1 rev.8 Vigilance Jan 2013; Guidelines on a Medical Devices Vigilance System
2. 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.
3. ISO 13485:2016 (E) – Medical Devices – Quality Management systems – requirements for regulatory purposes; Clause 8.2.3 Reporting to regulatory authorities.

DISCLAIMER: This document neither creates nor confers any rights towards any person or organization and does not enforce to abide by the content. It is only intended to support organization(s) or individual(s) referring this document to understand the vigilance system and its reporting in EU market. The simple usage does not automatically imply fulfilment of any regulation. Please refer the applicable guidance for complete detail.

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