MD REGULATORY DIGEST

FOCUS ON

POST-MARKET SURVEILLANCE

PMS SYSTEM

For each device, manufacturers shall establish a post-market surveillance system ('**PMS sytem**'). That system shall be an integral part of the manufacturer's **quality management system** and shall be based on a post-market surveillance plan ('**PMS plan**').

The requirements of the post-market surveillance plan are set out in Annex III.1.1. That PMS plan shall be part of the **technical documentation**.

Mainly, the PMS system shall be a **proactive process** and shall be **constantly updated**. (Art. 83 & 84)

REPORTS

The nature and period of the reports that the manufacturer shall provide depend on the class of the device.

Manufacturers of class I devices shall prepare a **post-market surveillance report**, and manufacturers of class IIa, class IIb and class III devices shall prepare a periodic safety update report ('**PSUR**') for each device.

Those reports shall summarise the **results and conclusions** of the analyses of the post-market surveillance data gathered as a result of the PMS plan. (Art. 85 & 86)

VIGILANCE

Manufacturers shall report to the relevant competent authorities **any serious incident** and **any field safety corrective action**.

The reports shall be submitted through **Eudamed**, and the period for the reporting shall take account of the severity of the incident:

- in the event of a **serious public health threat**, the report shall be provided immediately, and not later than **2 days** after the manufacturer becomes aware of that threat;

- in the event of **death** or an **unanticipated serious deterioration in a person's state of health**, the report shall be provided immediately, and not later than **10 days** after the manufacturer becomes aware of the serious incident;

- in other cases, the report shall be provided immediately, and not later than **15 days** after the manufacturer becomes aware of the incident.

Where necessary to ensure timely reporting, the manufacturer may submit an **initial report that is incomplete** followed up by a complete report. (Art. 87)

LATEST NEWS

European Commission

European Commission:

UDI and device data sets to provide in EUDAMED published (Device, Other Device Data, System or Procedure Pack).

03/05/2019

https://ec.europa.eu/docsroom/documents/35241?locale=en

EUDAMED UDI Device Data Dictionary published.

03/05/2019

https://ec.europa.eu/docsroom/documents/35243?locale=en

List of member state competent authority TSE/BSE contact points published.

06/05/2019

https://ec.europa.eu/docsroom/documents/35261?locale=en

Version 2 of Guidance on BASIC UDI-DI and changes to UDI-DI published.

08/05/2019

https://ec.europa.eu/docsroom/documents/35382?locale=en