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WHITEPAPER

PSUR Requirements and Process

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The PSUR is a summary of the results of post-market surveillance activities as well as the conclusions that manufacturers have drawn from those results. If the manufacturer has taken any corrective or preventive actions (CAPAs), a description and rationale for the actions must also be included in this report.

The Periodic Safety Update Report is part of a device's technical documentation, and it has to be updated throughout the device's lifecycle. The PSUR is initially submitted to a Notified Body during the device's conformity assessment audit, but from then on it must be updated either annually or biennially.

Requirements:

Article 86 (Periodic Safety Update Report)

Manufacturers of class IIa, class IIb and class III devices shall prepare a periodic safety update report ('PSUR') for each device and where relevant for each category or group of devices summarizing the results and conclusions of the analyses of the post-market surveillance data and description of any preventive and corrective actions taken.

Article 86 should not be considered alone when in view of the PSUR and its impact, there are other requirements that are to be considered.

Article 83 (Post-market surveillance system of the manufacturer)

For each device, manufacturers shall plan, establish, document, implement, maintain and update a post-market surveillance system in a manner that is proportionate to the risk class and appropriate for the type of device. That system shall be an integral part of the manufacturer's quality management system.

The post-market surveillance system shall be suited to actively and systematically gathering, recording and analyzing relevant data on the quality, performance and safety of a device throughout its entire lifetime, and to drawing the necessary conclusions and to determining, implementing and monitoring any preventive and corrective actions.

If in the course of the post-market surveillance, a need for preventive or corrective action or both is identified, the manufacturer shall implement the appropriate measures and inform the competent authorities concerned and, where applicable, the notified body. Where a serious incident is identified or a field safety corrective action is implemented, it shall be reported.

Article 84 (Post-market surveillance plan)

The post-market surveillance system shall be on a post-market surveillance plan. For devices other than custom-made devices, the post-market surveillance plan shall be part of the technical documentation.

The post-market surveillance plan shall address the collection and utilization of available information, in particular:

- Information concerning serious incidents, including information from 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, databases and/or registers;
- Information, including feedbacks and complaints, provided by users, distributors and importers; and
- Publicly available information about similar medical devices.

Article 87 Vigilance (Reporting of serious incidents and field safety corrective actions)

Manufacturers of devices made available on the Union market, other than investigational devices, shall report, to the relevant competent authorities, the following:

- Any serious incident involving devices made available on the Union market, except expected side-effects which are clearly documented in the product information and quantified in the technical documentation and are subject to trend reporting;
- Any field safety corrective action in respect of devices made available on the Union market, including any field safety corrective action undertaken in a third country in relation to a device which is also legally made available on the Union market, if the reason for the field safety corrective action is not limited to the device made available in the third country.

Article 88 (Trend Reporting)

Manufacturers shall report, by means of the electronic system, any statistically significant increase in the frequency or severity of incidents that are not serious incidents or that are expected undesirable side-effects that could have a significant impact on the benefit-risk analysis and which have led or may lead to risks to the health or safety of patients, users or other persons that are unacceptable when weighed against the intended benefits. The significant increase shall be established in comparison to the foreseeable frequency or severity of such incidents in respect of the device, or category or group of devices, in question during a specific period as specified in the technical documentation and product information.

Article 89 (Analysis of serious incidents and field safety corrective actions)

Following the reporting of a serious incident pursuant to Article 87(1), the manufacturer shall, perform the necessary investigations in relation to the serious incident and the devices concerned without delay. This shall include a risk assessment of the incident and field safety corrective action.

Member States shall take the necessary steps to ensure that any information regarding a serious incident that has occurred within their territory, or a field safety corrective action that has been or is to be undertaken within their territory, and that is brought to their knowledge is evaluated centrally at national level by their competent authority, if possible together with the manufacturer, and, where relevant, the notified body concerned.

The competent authority shall evaluate the risks arising from the reported serious incident and evaluate any related field safety corrective actions, taking into account the protection of public health and criteria such as causality, detectability and probability of recurrence of the problem, frequency of use of the device, probability of occurrence of direct or indirect harm, the severity of that harm, the clinical benefit of the device, intended and potential users, and population affected. The competent authority shall also evaluate the adequacy of the field safety corrective action envisaged or undertaken by the manufacturer and the need for, and kind of, any other corrective action.

Upon request by the national competent authority, manufacturers shall provide all documents necessary for the risk assessment.

Annex III (Technical Documentation On Post-Market Surveillance):

The technical documentation on post-market surveillance to be drawn up by the manufacturer in accordance with Articles 83 to 86 shall be presented in a clear, organised, readily searchable and unambiguous manner.

Figure 1: Requirements of PSUR

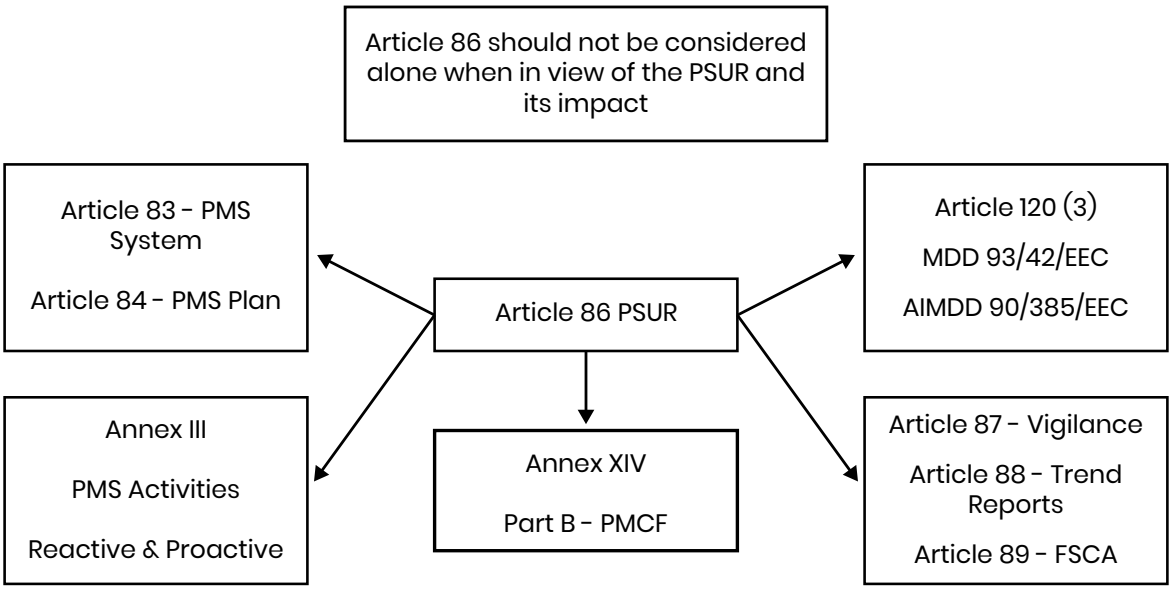
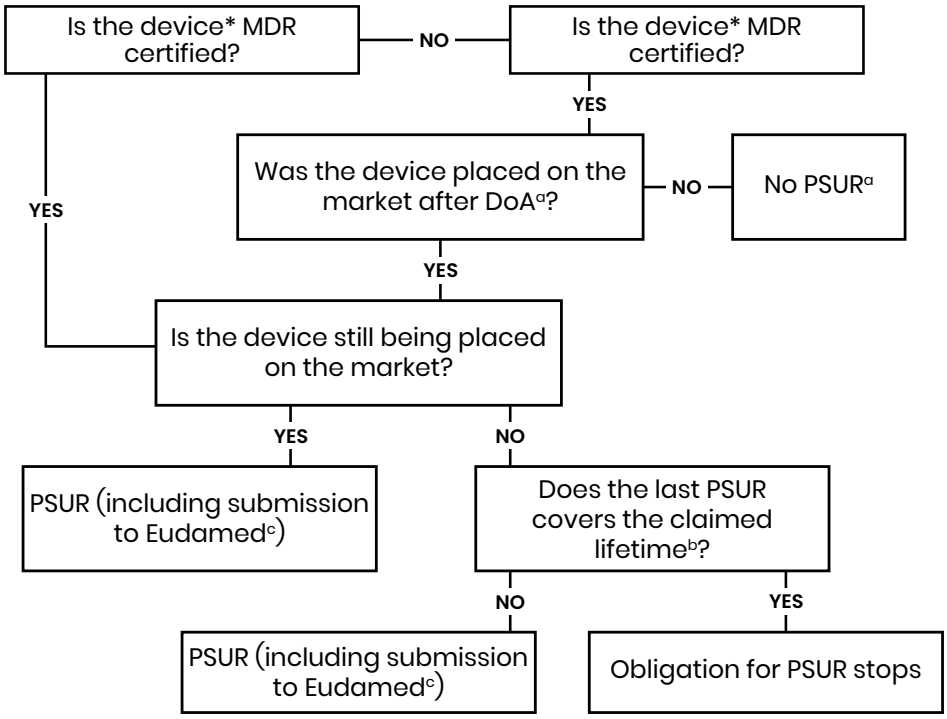


Figure 2: Workflow for assessment of PSUR requirement



An overview of contents to be included in the PSUR:

1. Description of the devices included in the PSUR
2. The post-market surveillance data (Complaints, Customer Survey/ Market Feedback)
3. The conclusions of your benefit-risk analysis
4. A description of any CAPAs and the rationale behind them and Vigilance information
5. The findings of Post Market Clinical Follow-up
6. The device's sales volume and an estimate of the user population
7. The frequency of the device's usage (if practical)
8. An Analysis and Summary

PSUR Preparation and Issuance:

1. Data Collection, issuance timeline, submission and schedule of PSURs:
The data collection period should start at the device MDR certification date. If the device is not MDR-certified, the data collection period starts at MDR Date of Application.

2. PSUR preparation and issuance timeline
It refers to the period required for the manufacturer to prepare and submit or make available the PSUR after the end of the data collection period.

3. PSUR submission / issuance
Depending on the class of the device and in accordance with Article 86(2), the manufacturer should either submit the PSUR to the Notified Body via EUDAMED or make it available to the Notified Body involved in the conformity assessment.

4. Schedule for PSUR updates
The schedule is the generated cycle for (i) the start and the end of the data collection period covered by each PSUR and (ii) preparing and submitting the PSUR or making it available after the end of the data collection period.

Table 1: Depending on the type of device and its classification, you will need to compile either a PMSR or a PSUR

Type	Classification	PMSR/ PSUR	Submission Protocol	Update Frequency
Medical device (MDR)	Class I	PMSR	Upon Request	As Necessary
	Class IIa	PSUR	During Conformity Assessment for Notified Body review	Every Two years
	Class IIb (Non Implantable)	PSUR	During Conformity Assessment for Notified Body review	Annually
	Class IIa (implantable)	PSUR	Via EUDAMED for Notified Body review	Annually
	Class III	PSUR	Via EUDAMED for Notified Body review	Annually
IVD	Class A, B	PMSR	Upon Request	As Necessary
	Class C	PSUR	During Conformity Assessment for Notified Body review	Annually
	Class D	PSUR	During Conformity Assessment for Notified Body review	Annually

Grouping of Devices:

1. The manufacturer should justify the grouping of the devices in one PSUR.
2. The justification could be based on the benefits to report multiple devices in one PSUR or alternatively the disadvantages to report each device in separate PSURs.
3. In case the group of devices is changed, a justification for the change should be provided. The manufacturer should also provide the PSUR reference number of the PSUR where the data of the removed device(s) are reported.
4. The manufacturer should define the "leading device" according to which the PSUR schedule is determined.
5. The PSUR reference number is attached to the "leading device" and should remain unchanged for the PSUR updates, provided the "leading device" within the grouped devices has remained the same.

Contents to be included in the PSUR:

1. **Description of the devices included in the PSUR**
   - Details to be included:
     a) Device Name
     b) Legal Manufacturer Name and Address
     c) Notified Body and Organization Number
     d) Reporting period to be covered
     e) Basic UDI – DI
     f) EMDN/ GMDN Code for the specific device
     g) Classification of the device
     h) Date on which the device is being CE Marked
     i) The Intended Purpose
     j) Indications and Contraindications
     k) Status of the device in the market (whether the device is placed in the market or the marketed device is still in the market or discontinued, if any FSCA initiated)
     l) Target patient population

2. **Volume of Sales**
   - Number of sales for the device during the reporting period.

3. **Size and other characteristics of the population using the device**
   - Include the patient exposure of the device.
   - Estimate the number of patients exposed, as the sales numbers alone do not necessarily reflect the number of uses of the device (usage frequency).

4. **Post-Market Surveillance: Vigilance and CAPA information**
   - Information concerning Serious Incidents (Article 87, Annex III MDR)
   - Information from Trend Reporting (Article 88, Annex III MDR, non-serious incidents and expected undesirable side effects)
   - Information from Field Safety Corrective Actions (FSCA) (Article 87, Annex II MDR)
   - Preventive and / or Corrective Actions (CAPA) (Article 83.4 and Article 86 MDR)

5. **Post-Market Surveillance: Information including general Post-Market Clinical Follow-up (PMCF) information**
   - Feedbacks and complaints from users, distributors and importers
   - Scientific Literature Review of relevant specialist or technical literature
   - Public Databases and /or Registry Data
   - Publicly Available Information about Similar Medical Devices

6. **Specific Post-Market Clinical Follow-Up (PMCF) Information**
   - A summary of the findings generated from the analysis of specific PMCF activities performed by the manufacturer is to be included.

7. **Summary and Conclusions**
   - Validity of the collected data
   - Overall conclusions from the analysis of the collected data
   - Actions taken by the manufacturer

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