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The Essence of EU SSCP and **EU PSUR** ?

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Disclaimer

This presentation is intended for education purpose only and do not replace the legal text of the legislations, standards or guidance documents.

Periodic Safety Update Report (PSUR) – Article 86

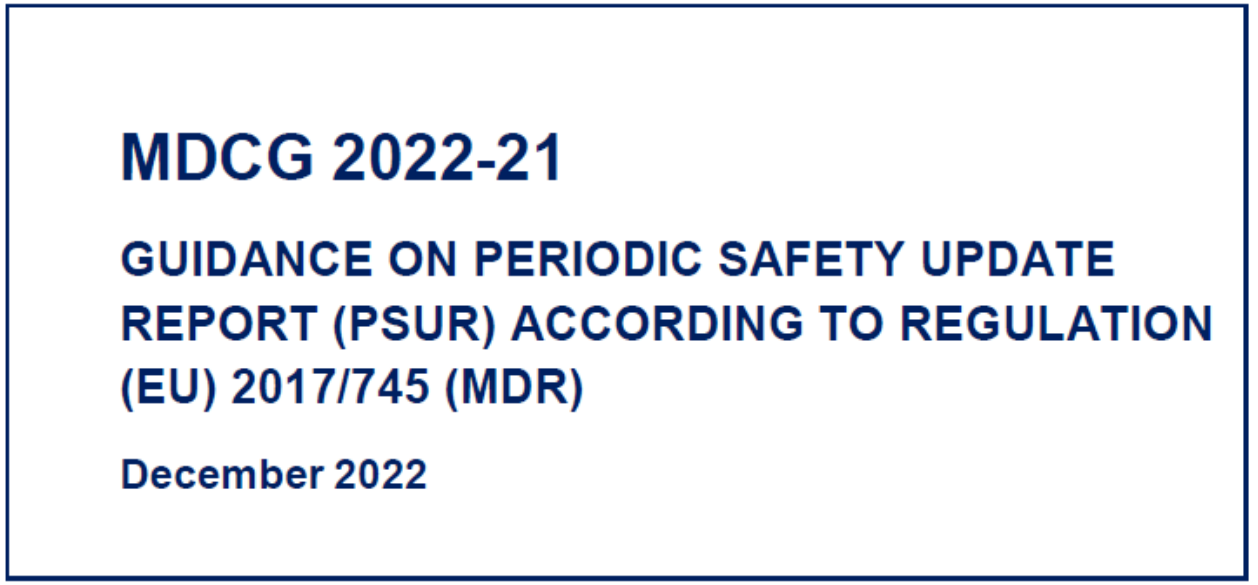
- Class IIb and III – annually
- Class IIa – biannually
- Part of the TD

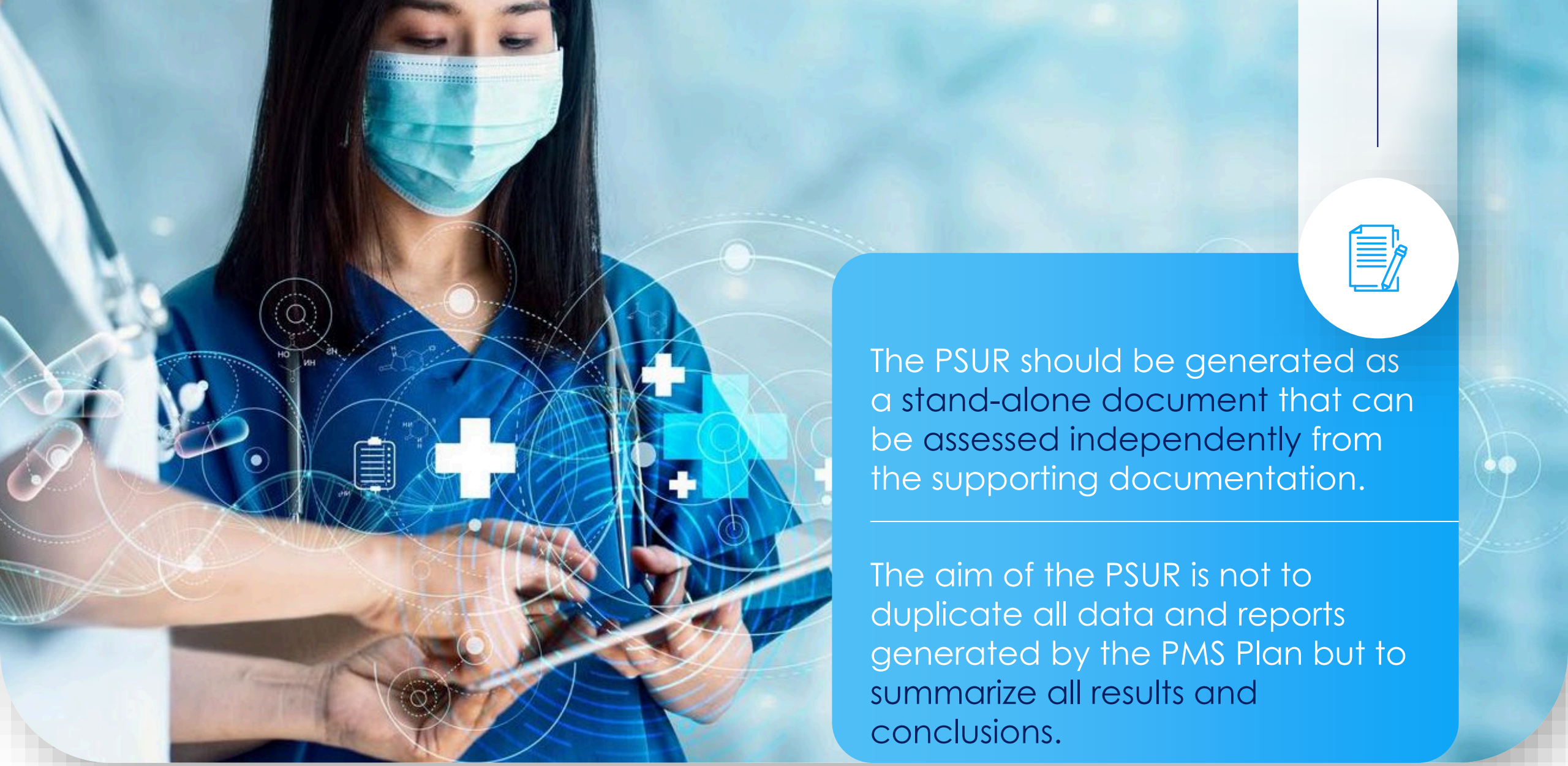
- Upload to EUDAMED
- Class III and Implants assessed by NB
- Legacy devices require a PSUR

MDCG 2022-21

01 The main objective of this guidance document is to **assist manufacturers to implement the legal requirements** laid down in Article 86 MDR.

02 However, manufacturers should have **reasonable time to adapt their quality management systems and sufficient flexibility** (as per MDCG 2022-14) when they draw up and update a PSUR as long as they can demonstrate that it is in line with Article 86 MDR.





The PSUR should be generated as a stand-alone document that can be assessed independently from the supporting documentation.

The aim of the PSUR is not to duplicate all data and reports generated by the PMS Plan but to summarize all results and conclusions.

Specific aspects

In order to prepare the summary from PSUR, the following elements should be considered:

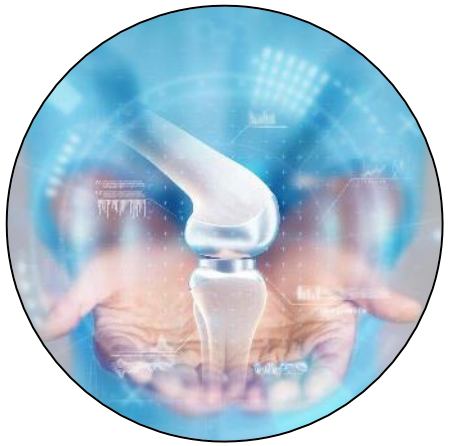
- Serious incidents and field safety corrective actions
- Non-serious incidents and data on any undesirable side-effects
- Trend reporting (Art. 88)
- Specialist or technical literature, databases and/or registers
- Information about similar medical devices

Specific aspects

Summary from PSUR

- Conclusions of the benefit-risk determination
- Findings of the PMCF
- Sales volume of the device and an estimate evaluation of the size and other characteristics of the population using the device

Determination of the end of the obligation to update the PSUR



A PSUR is no longer required to be updated when the last manufactured device of the device model has been placed on the market and the **intended lifetime of that (individual) device**; i.e. the overall lifetime of the device (model), **has been achieved**.

When a device's **certificate has expired** and the **lifetime of the device has not yet been covered** by the last PSUR, a **PSUR should continue to be made available**, upon request, to the competent authorities.

Grouping of Devices – multiple Basic UDI-DIs in one PSUR, Art. 86(1)

- The data should be presented in a clear, organized manner
- In case of a group of devices covered by the same PSUR, the manufacturer should assign a "leading device"
- In case of a change related to the "leading device" (new device model /change of the Basic UDI DI), a new PSUR should then be issued
- Grouping only feasible for the same assessing NB

Data collection period, Issuance timeline, PSUR schedule

- First PSUR might include device's historical data from PMS prior to MDR certification or DoA
- Depending on the class of the device the PSUR should be submitted to the NB via EUDAMED or make it available to the NB involved in the conformity assessment.

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** (26 May 2021).

MDCG 2022-21 Annex I and Annex II

Medical Devices

Medical Device Coordination Group Document MDCG 2022-21

ANNEXES

ANNEX I: Template for the PSUR

ANNEX II: Templates for the Presentation of Data in the PSUR

These tables are intended to provide guidance to manufacturer and are only examples. It is up to the manufacturer to present the data in the most appropriate manner depending on the nature of the data and of the device. Please read this Annex II in conjunction with Annex I when forming tables.

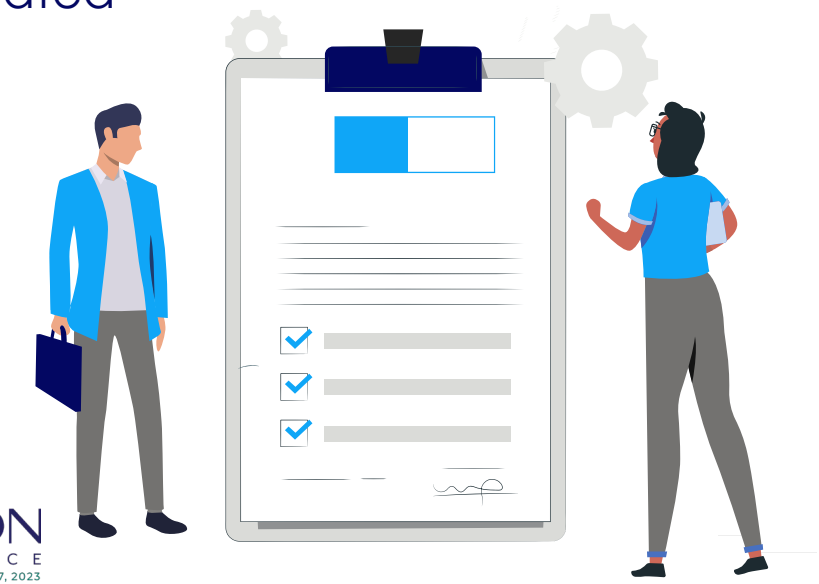
Table 1. Volume of sales* by region over time

Basic UDI-DI/ Legacy device name or model					
	Total Number of devices	Reporting Day+ preceding 12 months (N)	N – 12 months (N2)	N2-12 months (N3)	N3-12 months (N4)
EEA+TR + XI**					
Worldwide					

Validation of updates of the SSCP between certification activities

Manufacturer obligations:

1. Keep the SSCP updated
2. Prepare a PSUR
3. If PSUR contains information rendering any information in the SSCP incorrect or incomplete, SSCP shall be updated to be in line with the information in most recent PSUR
4. If SSCP has been updated, updated SSCP to be submitted to NB when submitting PSUR



Take Home Message

- ✓ PSUR dates related to certificate or DoA anniversary
- ✓ PSUR should be a stand-alone document
- ✓ Grouping of devices into one PSUR possible
- ✓ Template in MDCG 2020-21 strongly recommended
- ✓ Communicate with your NB on timelines

Thank You!

Questions?

Do you need help?

Write us now:
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