MDCG GUIDANCE ON PERIODIC SAFETY UPDATE REPORT (PSUR) ACCORDING TO REGULATION 2017/745 (Medical Devices Regulation)

This guidance document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. The MDCG is composed of representatives of all Member States and it is chaired by a representative of the European Commission.

This guidance document is not legally binding. It was prepared following contribution from national competent authorities, industry and relevant stakeholders and it should therefore be recognized as best practice. The guidance also intends to promote and support a harmonized approach with respect to the implementation of the PSUR requirements for manufacturers and notified bodies.

Part I: What is PSUR and how to elaborate it

1 Introduction and general aspects

The Periodic Safety Update Report (PSUR) is a new type of report that has been introduced in Article 86[1] the Medical Device Regulation (MDR) 2017/745. The introduction of the PSUR under the MDR requires a more consistent, standardized and systematic review of all Post Market Surveillance (PMS) data (including Vigilance) by medical device manufacturers.

The PSUR summarizes the results and conclusions of the analysis of the post-market surveillance data gathered as a result of the activities detailed in the Post-Market Surveillance Plan (PMSP), referred to in Article 84, together with a rationale and description of any preventive and corrective actions taken for safety reasons. It also summaries the list of corrective actions and preventive actions (CAPAs) to be provided to the relevant competent Authorities for information as laid down in Article 83(4).

This guidance document details the information to be included in the content of the PSUR, based on the MDR requirements. It also explains how this information should be consolidated and evaluated by the manufacturer in the context of its post-market surveillance activities.

This guidance is applicable to all manufacturers of medical devices which have been certified under the MDR or under MDD 93/42/EEC and AIMDD 90/385/EEC (see section 3.1). Manufacturers of class I devices do not have to prepare the PSUR; instead they have to prepare a Post-Market Surveillance Reports (PMSR) as detailed in Article 85. This guidance, although not covering PMSR, may provide useful suggestions on how information can be presented. .

[1] All references to Articles in this guidance should be understood as reference to Medical Device Regulation (MDR) 2017/745 unless otherwise stipulated.

This guidance also informs manufacturers of the operational processes, review and evaluation of the PSUR by notified bodies and details the requirements and responsibilities for the notified body's activities in the evaluation of the PSUR (see section 5).

For the sake of clarity and to provide flexibility for the different type of products, the date referred to with the wording "product certification date" used in this guidance should be understood as one of the follows:

- Date of issuance of the EU type-examination certificate for Annex X devices OR
- Date of issuance of the EU technical documentation assessment certificate for Annex IX (including chapter II) devices
- The date of signing the Declaration of Conformity for Annex IX (Chapters I & III) devices OR
- date of the issuance of the statement required in Annex XIII, section 1 for custom-made devices.

1.1 Structure of the guidance

This guidance is composed of two parts and Annexes:

- Part I: General concepts and rules applicable to the PSUR including those elements relating to the notified body evaluation of the PSUR.
- Part II: Rules related to the PSURs and the evaluation reports to be submitted in EUDAMED.
- Annexes.

1.2 Place of the PSUR in the Post-Market Surveillance system

The process associated to PSUR reporting should be linked to the Post Market Surveillance Plan, the Risk Management Plan, the PMCF Plan and the Clinical Evaluation Plan as appropriate.

As illustrated by image 1, post market surveillance data should feed into the risk management process in order to identify and determine whether there has been any change in the safety or performance profile of the medical device(s).

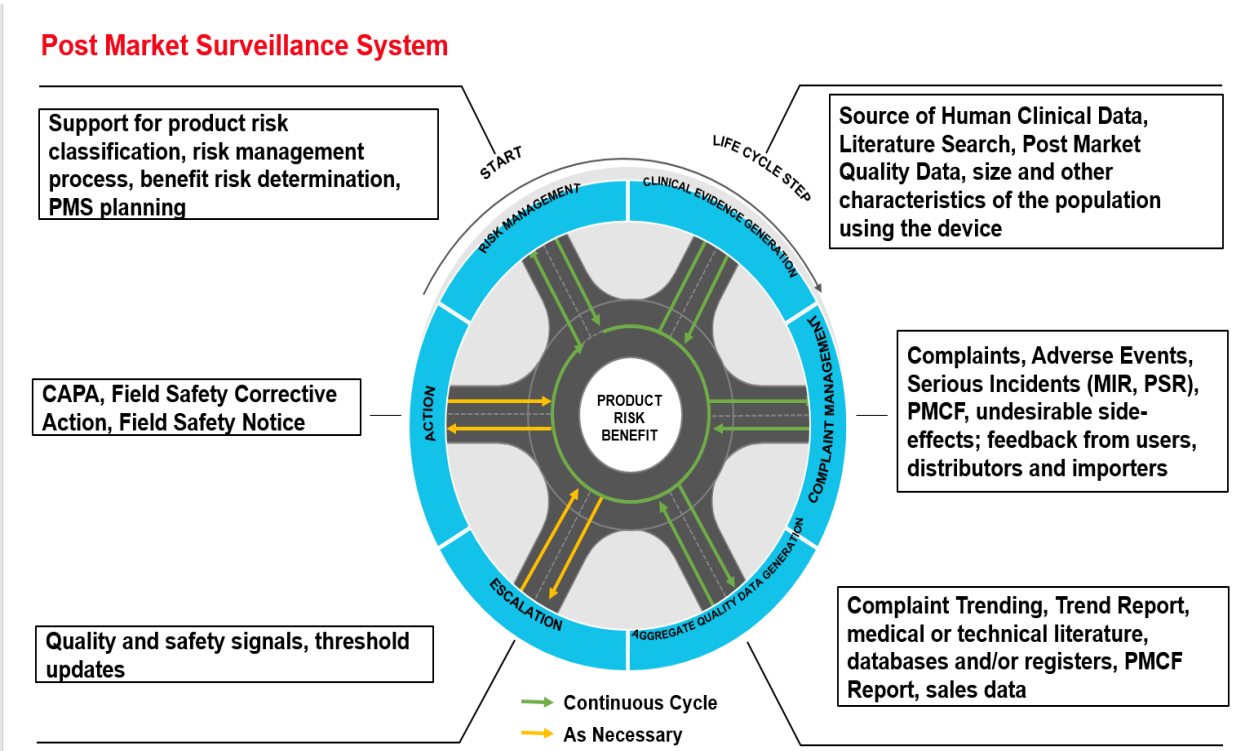


Image 1: Data source feeds to be used for the generation of the Reports

Within the context of the PMS system, the role of the PSUR is to provide a comprehensive analysis of the PMS activities of the manufacturer and summarize the results of the benefits and the risks of the device and their possible evolution during the period considered by the PSUR. The PSUR should demonstrate evidence of effective and well-integrated Risk Management, Clinical Evaluation and Post-Market Surveillance Processes.

While image 1 details the different data that feed into the PMS system, image 2 is an interactive representation of all the Reports required by MDR in the Post Market Surveillance area. The PSUR should be linked to the Risk Management Plan, the Post-Market Clinical Follow-up (PMCF) Plan and the Clinical Evaluation Report (CER) as appropriate.

It aims at visualizing the place of PSUR in relation to other reports; typically the output of data collected within the specified plans (PMS, PMCF, Clinical Evaluation, Risk management). The Plans themselves detail the requirements of each of the individual Systems (Post Market Surveillance System, Risk Management System) .

All the reports mandated by the Regulation are to be part of the Technical Documentation which is described in Annexes II and III of the MDR and in Annex XIII for Custom Made Devices (CMD).

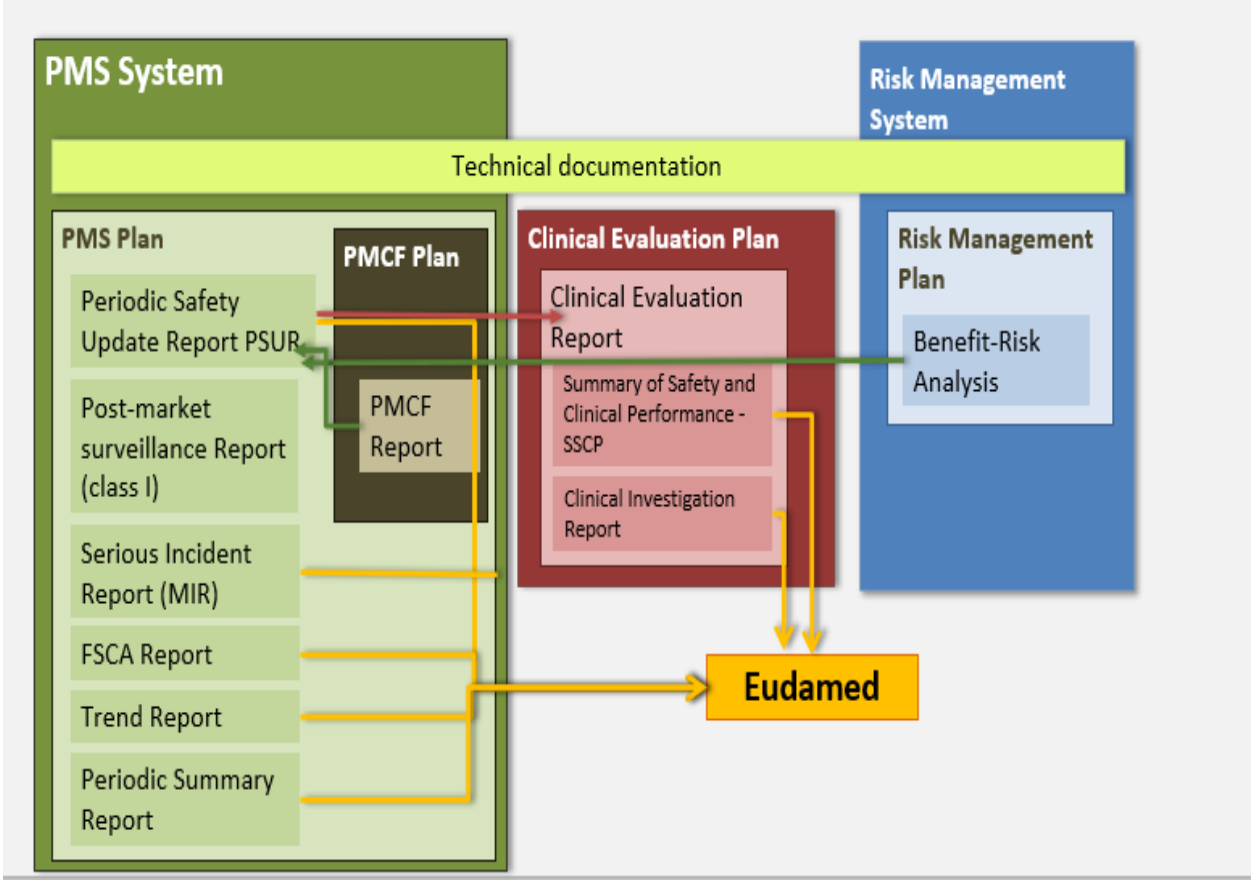


Image 2: PMS reports generated under the MDR

The graphic representation illustrates the place of the PSUR in the PMS plan / system and its links and interactions with the other Plans (PMCF, Clinical evaluation and Risk Management). It does not intend to represent the links between the different plans and systems for all types of devices.

1.3 It also highlights those reports that have to be submitted to EUDAMED (such as PSUR, MIR SSCP…). PSUR actors

1.3.1 Manufacturers

The manufacturer is responsible for preparing and updating the PSURs and making it part of the technical documentation as specified in Annexes II and III of the MDR. However other economic operators (authorised representatives, distributors, importers) must assist the manufacturer in contributing for gathering the necessary information. All PSURs shall be available to the notified body involved in the conformity assessment and, upon request, to competent authorities.

He should also submit the PSURs - or making PSURs available to the NB involved in the conformity assessment depending to the device class:

- For class III devices or implantable devices, manufacturers shall submit PSURs by electronic system (EUDAMED) to the notified body involved in the conformity assessment who shall review the report and add its evaluation to the electronic system. The evaluation by the notify body shall be made available to competent authorities through EUDAMED.
- For IIa and IIb not implantable devices, manufacturers shall make PSURs available to the notified body involved in the conformity assessment and, upon request, to competent authorities.

1.3.2 Notified Bodies

The notified bodies are responsible for evaluating each PSUR for class III devices and implantable devices of class IIa and IIb, producing an evaluation report for each PSUR and their uploading in EUDAMED.

For non implantable devices of class IIa and IIb, the PSURs are made available to the notified bodies involved in the conformity assessment (see section 5).

1.3.3 National competent authorities

The national competent authorities may also request and review the PSURs as part of their vigilance investigations, clinical trial reviews and market surveillance activities. For PSURs which need to be uploaded in Eudamed, the competent authorities have access to PSURs directly.

1.4 PSUR objectives

1.4.1 For manufacturers

The main objective of a PSUR is to present a comprehensive, concise and critical analysis of the PMS data relating to a device or a device group, thus allowing the identification of any possible changes to the benefit/risk profile of the medical device(s), considering new or emerging information in the context of cumulative information on benefits and risks.

This analysis should summarize the data gathered during the post market phase including the results of the Post-Market Clinical Follow-up (PMCF) studies carried out, observed incidents and other datasets used in Post Market Surveillance (PMS) actions with the medical device.

- **Evaluation of benefit/risk profile**

Manufacturers must present this information to identify any safety and performance concerns, through both reactive and proactive PMS data collection. When concerns have been identified this

gathered information will be used to reevaluate the benefit/risk profile and the state of the art of the medical device(s).

Where there is evidence of an adverse change to the benefit/risk profile of the medical device(s), this information should be evaluated and considered in line within the clinical evaluation and it should be determined whether the profile of the device has been negatively impacted. In the event of such circumstances, there should be clear consideration and evaluation as to whether the medical device remains safe and effective.

In line with the objectives of the MDR, the PSUR must provide transparency of all Post Market Surveillance data to the Notified Body responsible of the conformity assessment of the device and to Competent Authorities.

The PSUR report should demonstrate that the manufacturer has had an active role during the post-market phase by systematically and actively gathering information from post-market experience with its devices in order to update their technical documentation.

Relevant data and information gathered through post-market surveillance, as well as experience gained from safety related implemented preventive and/or corrective actions, should be used to update any relevant part of technical documentation, such as those relating to risk assessment and clinical evaluation,. The PSUR is a summary of all those actions.

- **Reporting of preventive or corrective actions under Article 83(4)**

If a preventive or corrective action is directly related to a serious incident, the description should be part of the related Vigilance reports (e.g. MIR or FSCA) to be reported by manufacturers in a systematic way and also to be covered by the PSUR, including a summary of these reports.

When in the course of the post-market surveillance, a need for Corrective Actions or Preventive Actions (CAPAs) as defined in Article 83(4) first sentence is identified, the manufacturer shall implement the appropriate measures and inform the competent authorities concerned and, where applicable, the notified body.

Nevertheless the scope of the various types of CAPAs to be reported to the competent authorities and where applicable to the notified bodies, is not limited to safety issues. These CAPAs are related to:

- Product already placed on the market (new models, new releases, new versions are excluded as long as they have not been placed on the market), and
- Issues that might have a direct impact on product and that might impact product safety, performance or quality, and
- Evaluation of benefits/risks as described in Annex III, point 1.1 (a) of MDR, i.e. 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.

A summary of all the above CAPAs should be reported or made available to the Competent Authorities through the PSUR (see table n°9 in Annex VI of this guidance).

Note: It excludes quality management system related CAPA's, unless they could have a direct impact on product safety, performance or quality.

1.4.2 For notified bodies

The PSUR is also intended, where relevant, for review or evaluation by the notified body which issues the certificate of conformity: the information provided within the PSUR should allow the notified body to assess the validity for the data presented and consider their impact, if any, on the certification that it has provided. The notified body should, where necessary, consider all appropriate action(s) in the event there are unacceptable changes to the benefit/risk profile of the medical device(s).

The review or evaluation to be performed by the notified bodies according to the device classes are detailed in section 5.

2 PSUR content and output

Per Annex III of the MDR, the PSUR is part of the technical documentation on post-market surveillance to be drawn up by the manufacturer in accordance with Articles 83 to 86 and shall be presented in a clear, organised, readily searchable and unambiguous manner and shall include in particular the elements described in Annex II of this guidance.

Therefore, the content of the PSUR is aligned to the corresponding device's PMS plan (PMSP), which through the years can be changed by the manufacturer based on experience gained: a new device compared to a well-established device on the market for many years with abundant literature, clinical, and post market data, are likely to have different PMS plans. Information from earlier PMS, PSUR, PMCF will feed the PMS plan.

In case there are no design changes to the devices initially placed on the market, the PSUR must at least include: data regarding product complaints, reporting of serious incidents, FSCA and Trend reports and relevant data from literature research.

2.1 Grouping of devices

Device should be understood by default as the device(s) associated with one Basic UDI-DI. The PSUR may reference multiple Basic UDI-DIs, however a justification should always be provided by the manufacturer for grouping of devices within the PSUR.

(To develop a text for grouping of legacy devices without basic UDI-DI) Due to the involvement of only one Notified Body for the review or evaluation of a PSUR, the grouping of devices within one PSUR is only possible for devices for which the conformity assessment has been carried out by the same notified body.

There are different scenario depending on the fact when the devices covered by one PSUR are intended or not to be combined together to achieve a common intended medical purpose.

- When they have been combined together by the manufacturer for above purpose, the notified body made a single assessment of the clinical evaluation produced for the combined devices and a single assessment of the unique or multiple related technical documentation(s): these devices can therefore been grouped within one PSUR.
- When they have not been combined together for above purpose, it depends whether the equivalence of the devices to be grouped within one PSUR can be demonstrated or not by the manufacturer.
  - If this equivalence can be demonstrated/established, then the notified body can perform several assessments of the corresponding technical documentations.
  - It this equivalence cannot be demonstrated/established, then the grouping may be possible, on case by case basis, to be prior agreed between the manufacturer and its notified body.

These different scenario for the grouping of devices are illustrated in image 3 below:

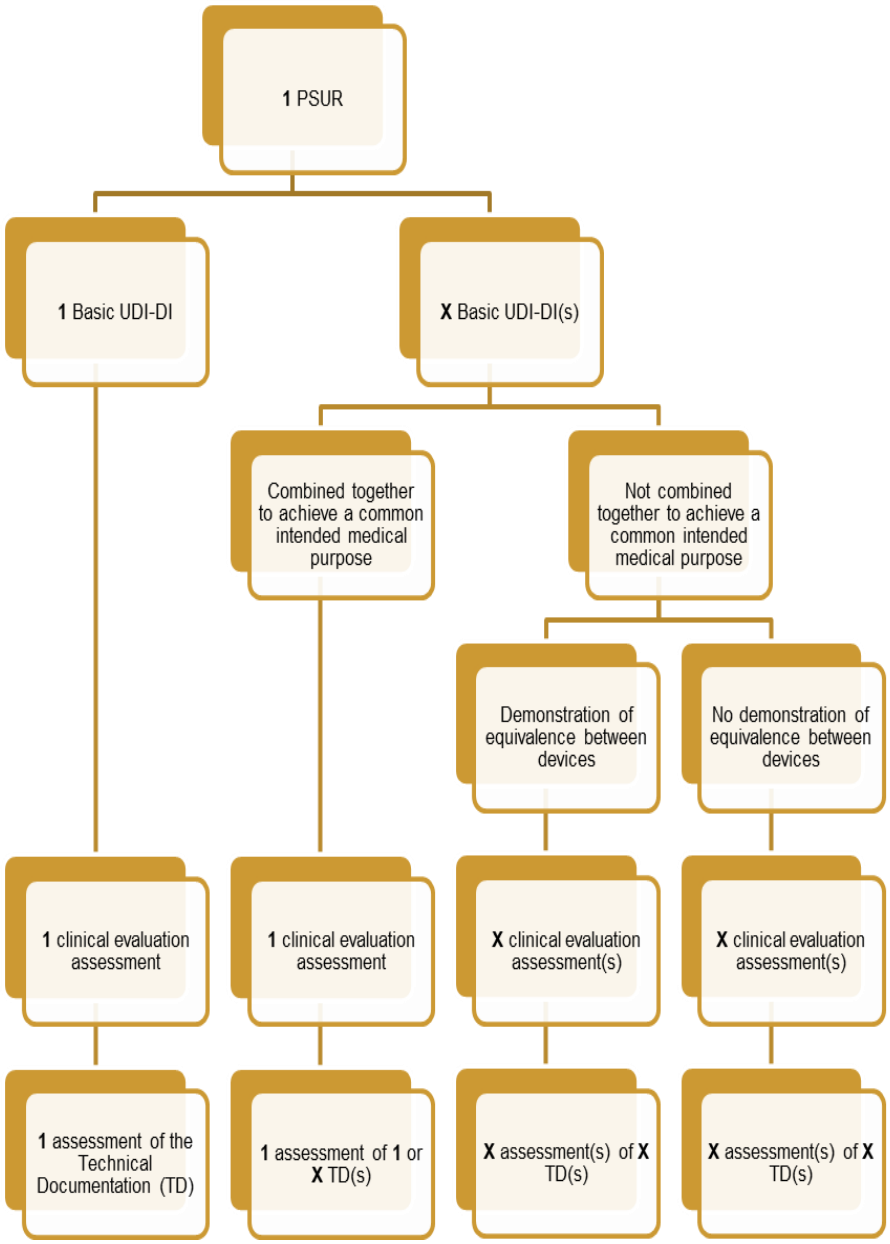


Image 3: *possibilities of grouping several Basic UDI-DIs within the same PSUR*

In case a PSUR includes several Basic-UDI-DIs the data should be clearly stratified so that it is easy to figure out how each device performed independently. The first PSUR and the reporting frequency should be linked to the higher class device.

In the case that a device is on the market with successive certificates of different NBs; a cross reference should be added in the PSUR. Cross reference must include the PSUR identification

number, the latest version number and the involved NB and when applicable the conclusions of the latest reviewed PSUR of that NB.

However, in all cases, one Basic-UDI-DI can only be linked to one PSUR for Eudamed purposes. For accessories applicable to use with multiple other devices, one PSUR is needed / recommended for the general accessory: in that PSUR justification for use with multiple main devices must be demonstrated. Cross links with main devices PSUR would be necessary. The first PSUR and the reporting frequency should be linked to the main device not to the accessories.

2.2 Type of data and information covered

The PSUR should be a "self-standing" document providing a general overview of all PMS activities and data for the device and a comprehensive executive summary on safety and performance data.

The aim of the PSUR is not to duplicate all data and reports generated by the PMS Plan: it should summarize all results and conclusions generated after the implementation of PMSP.
The manufacturer need to specify the relevant information and section of the different reports and provide a summary of the data collected, their evaluation and conclusion as well as the actions taken where appropriate.

In cases the device is not placed on market anymore, the PSUR must at least include reactive data regarding product complaints reporting of serious incidents FSCA and Trend reports as documented in the system used to record the data and relevant data from literature research and relevant databases. (to add sentence referring to Annex II of this guidance)

The "other" devices linked to a main device may be accessories, but also medical device on their own and used as accessories (e.g. orthopedic screws).

Accessories that are considered devices per Article 1.4 may require a PSUR. The current best practice is that multi-use accessories are documented in a single Technical Documentation and assessed for conformity separately according to their risk class which results in a single certificate. Since the performance of the accessory is related to the main device, there are two options to prepare the PSUR for the multi-use accessory:

- PSUR contains the full set of data isolated for the Accessory in various applications.
- PSUR for the Accessory contain only links to the corresponding documents of the main devices where such Accessory is used. The documents do not contain actual data, but a number of links to the data.

2.3 PSUR output

The PSUR should establish:

- the results and conclusions of the analyses of the post-market surveillance data generated by the PMS Plan mainly:
  — 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;
  — publicly available information about similar medical devices.
- the conclusions of the benefit/risk determination
- the main findings of the PMCF;
- the volume of sales of the device and an estimate evaluation of the size and other characteristics of the population using the device and, where practicable, the usage frequency of the device.

2.4 PSUR structure

In view of facilitating consistency and readiness for notified bodies and competent Authorities between the PSURs of the same manufacturer and between manufacturers, it is recommended that, to the extent possible, the same structure is followed for the drafting of all PSUR reports regardless of the device class. The recommended structure is provided in Annex II of this guidance.

3 Scope and length of the PSUR requirement

3.1 Devices in the scope of PSUR requirement

Article 86 requires manufacturers of class III, class IIb and class IIa devices to "prepare a Periodic Safety Update Report (PSUR) for each device and where relevant, for each category or group of devices".

- **MDR compliant devices**
  - Class IIa, class IIb and class III devices, including Annex XVI devices of these classes certified according to the requirements of the MDR placed on the market/put into service either before or after the MDR Date of Application, 26 May 2021 (DoA).
  - Custom-made devices complying with the requirements of the MDR.

The PSUR shall be part of the documentation referred to in Section 2 of Annex XIII of MDR to move to section on PSUR content).

- **Legacy devices**[2]
  - Devices with a valid certificate issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC which are continued being placed on the market or put into service after the MDR Date of Application (DoA), 26 May 2021.

In case of the stopping the placing on the market after DoA for MDR and legacy devices, the frequency for issuing the PSUR remains the same as for devices with a valid certificate unless the manufacturer has ceased its business or went bankrupt: no PSUR can be issue in that case.

3.2 Devices outside the scope of PSUR requirement

- Class I devices.

- Devices which are placed on the market under the MDD/AIMDD before the MDR Date of Application (DoA) and which do not continue to be placed on the market after DoA (so called "old devices") are not covered by the MDR, thus the obligation of the PSUR does not apply to them. The manufacturer must continue to perform the PMS activities.

Image 4 : Workflow for assessment of PSUR obligation

- PSUR requirement and device lifetimeA PSUR is required throughout the lifetime of the device which is defined and declared by the manufacturer (to keep)The lifetime of a medical device is defined in the technical documentation. (to keep) ~~For specific types of devices, minimum periods are defined by the MDR.~~
  Note: The PSUR is required for the device lifetime plus the shelf-life where relevant.
- When the device is no longer placed on the market, a PSUR remains required by the competent authorities despite it is not anymore evaluated by a Notified Body. In this case the competent authorities should be notified by the manufacturer or its authorized representative. The frequency for issuing the PSUR during the period after the device is no longer placed on the market is the same than during the period with a valid certificate.

- A PSUR is no longer required only when the device is not placed on the market anymore[3] and the period of the lifetime of the device has been covered by the last PSUR. When a PSUR becomes no longer mandatory, vigilance and surveillance system still need to remain in place in all cases.

[2] Regulation (EU) 2017/745 Article 120 (3) lays down that the requirements of this Regulation relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices shall apply in place of the corresponding requirements in those Directives

[3] for example: a medical device with a lifetime of 20 years and for which after 5 years, the manufacturer stops producing and is not renewing the certificate. The manufacturer should prepare a PSUR until 20 years is covered in the PSUR's, thus for another 15 Years.

A workflow to determine whether a PSUR is required or not is provided with image 4:

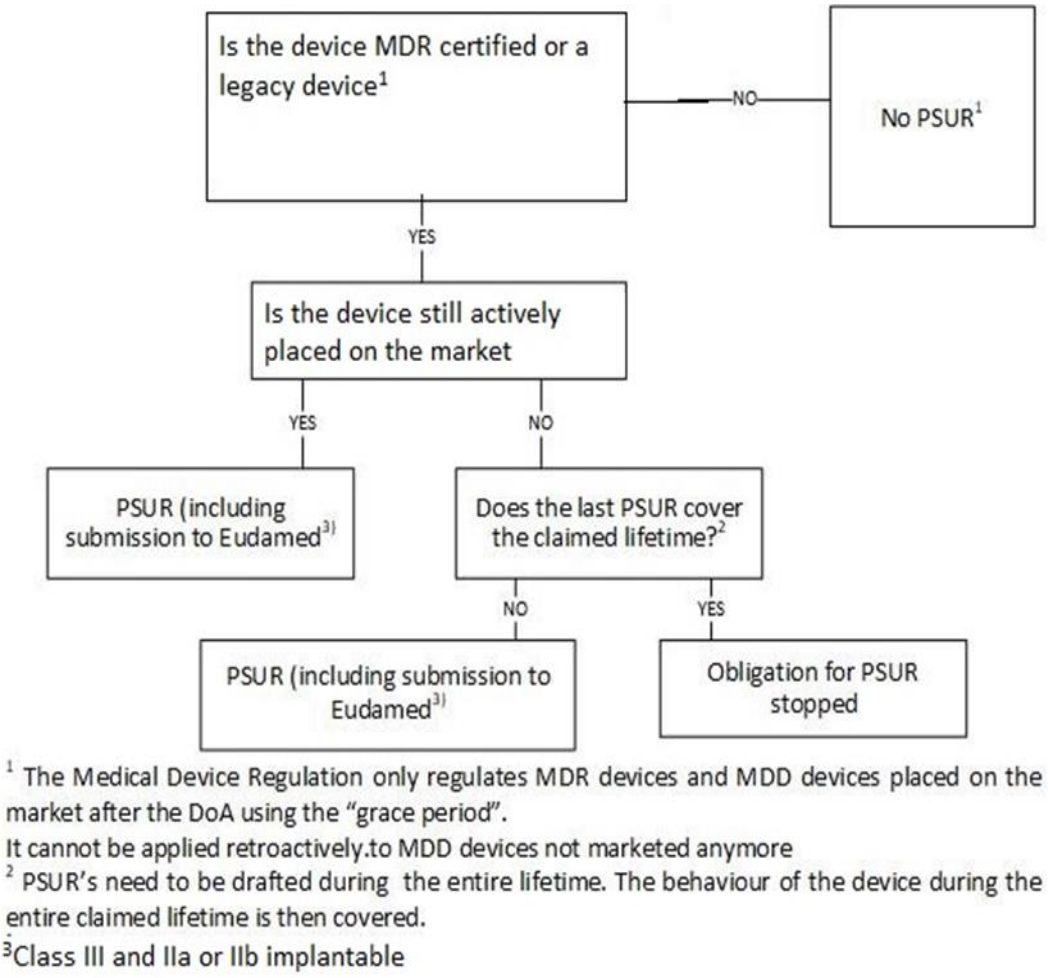


Image 4 : Workflow for assessment of PSUR obligation (to reexamine footnote 1)

3.3 Requirements for 1st and subsequent PSUR issuing

The requirement to issue a PSUR applies from the MDR date of entry into application (DoA) except for MDR compliant devices which have been certified before DoA where it applies from the date device has been MDR certified or Declaration of conformity (DoC) has been signed.

3.3.1 For legacy devices

For MDD/AIMDD devices, the first PSUR is based on the MDD/AIMDD device classification and is required counting from MDR DoA, at the latest one year or two years (based on product

classification) from the certificate or declaration of conformity anniversary date which occurs after MDR DoA.

The annual or(each second year) (two yearly) submission is to be understood as follow: the initial PSUR for the MDD devices has to be submitted at the anniversary date or at the latest during the required calendar* year in an agreed cadence with the Notified Body (latest Dec 31st 2022 for annual or 2023 for biannual submission as applicable).

Any subsequent annual (biannual) report will be required at the anniversary date of the initial submission. When the first PSUR is not covering an exact period of 12 of 24 months, the second PSUR must to be able to compare information over an even time. Even if an initial period deviates from the 1 or 2 year period, the subsequent PSUR must compare the results with the previous 12 or 24 months.

3.3.2 For MDR compliant devices

- **Device is MDR certified prior to MDR Date of Application**

The first PSUR should be prepared within one (class IIb and III) or two (class IIa devices) year(s) following the first "product certification date" of the device under the MDR.

- **Device becomes MDR certified at or post Date of Application and an initial PSUR has already been issued for the MDD compliant device. (to be updated in section 5)**

When a device becomes certified under the MDR regulation, the initial PSUR cadence established under the MDD regime will continue. The PSUR for the newly MDR-certified device will be issued at the anniversary date of the original PSUR submission.

- **Device becomes MDR certified post Date of Application and an initial PSUR has not yet been issued for the MDD compliant device**

When a new device becomes certified for the first time under the MDR the PSUR will be issued at the anniversary date of the MDR certification or issuance of DoC (custom-made devices and Annex IX devices).

When a device becomes re-certified under the MDR, and no PSUR was issued by the time of certification (e.g. the MDR certification occurs within the first (second) year after DoA), the PSUR will be issued at the anniversary date of the MDR certification or issuance ofDoC.

N.B. the timelines for the issuing of the PSUR by the manufacturer and for the evaluation of the PSUR by the notified body are described in section 5.

3.4 Frequency for PSUR updating

- manufacturers of **class IIb[4] and class III devices** shall update the PSUR at least annually. That PSUR shall be part of the technical documentation as specified in Annexes II and III of MDR except for custom-made devices for which it should be part of the documentation referred to in Section 2 of Annex XIII of the MDR.(repetition)

- manufacturers of **class IIa devices** shall update the PSUR when necessary and at least every two years. That PSUR shall, be part of the technical documentation as specified in Annexes II and III of MDR, except for custom-made devices for which it should be part of the documentation referred to in Section 2 of Annex XIII of the MDR.
- Manufacturers of legacy devices shall follow the rules corresponding to the class on the valid MDD certificate.

In case of a grouping of devices for the purpose of PSUR, manufacturer has to select a leading device which will drive the cadence of the PSUR submission.

4 Timelines for data collection and PSUR issuing

4.1 Data collection period

- **For the first PSUR (to be updated)**

The data collected and analyzed should cover the collecting period starting at the latest from:

1. New MDR devices, never certified under MDD/AIMD before

The collection period starts at the MDR device certification date for devices certified prior or after the Date of Application.

2. MDD/AIMD devices becoming MDR before DoA

The collection period starts at the MDR device certification date.

3. Legacy devices (not becoming MDR certified)

The collection period starts from the DoA.

As consequence, the first collection period may be different from 12 or 24 months (To be revised)

4. Legacy devices becoming MDR after the DoA (to reflect according new text in section 3)
    a. A PSUR has been issued for the legacy device at the date of MDR certification (To be revised to keep synchronization with MDR).

The data collection period used for the legacy device will continue without change.

    b. No PSUR has been issued at the date of MDR certification

[4] For manufacturers of "devices listed in Article 52(4) (e.g. sutures, dental fillings, etc) and referred to as "Well Established Technology" devices, a PSURs shall be uploaded in Eudamed annually, as required per Article 86 (2).

The collection period starts at the Date of MDR device certification

With regards to legacy devices (context 3) and MDD/AIMD devices (context 2 and 4) that have become MDR certified, the data analysis should be supported by the device's historical data collected through the Post Market Surveillance activities as they were conducted prior to Date of Application or MDR Device Certification date. As consequence the data related to period of times prior DoA may be in a different format/structure as the MDR ones and could be limited to a summary.

The information from these previous reports, for example main adverse events, and incidents, FSCA in progress, PMCF data available) should be used and integrated in the analysis to support the Benefit Risk assessment of the device.

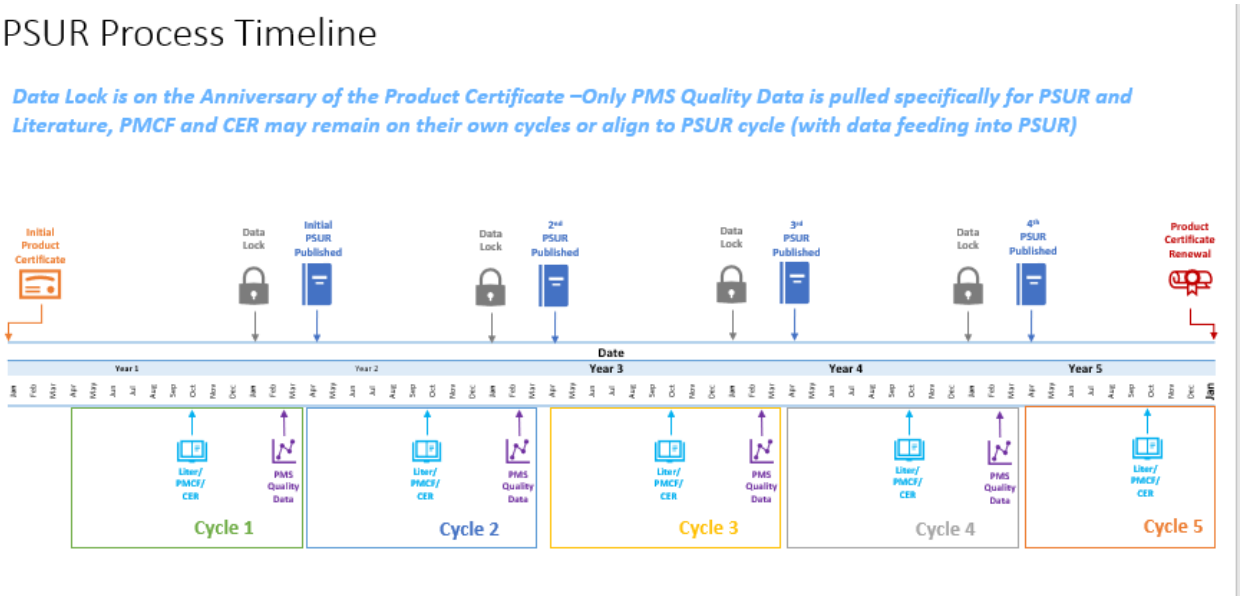
In all cases, the end of collection period (one or two years) will correspond to the anniversary of the device certification date. (To be revised. To compare between sections 3, 4 and 5).

- **For the following PSURs (to be updated)**

The annually / each second year updated PSUR should include at least 12 month post-market data from "product certification date" and the PSUR updated every two year must include at least 24 month post-market data. The data collection periods should be contiguous to avoid any overlapping of loopholes (see figure 6).

4.2 Timeline for PSUR submission by the manufacturer

- Timeline for PSUR submission in Eudamed for Class III or classes IIa and IIb implantable devices (see section 5.1.1)
- Timeline for PSUR submission to Notify Body for non implantable classes IIa and IIb (see section 5
- Timeline for submission of revised PSUR if required by the Notify Body (to be developed in section 5.6).



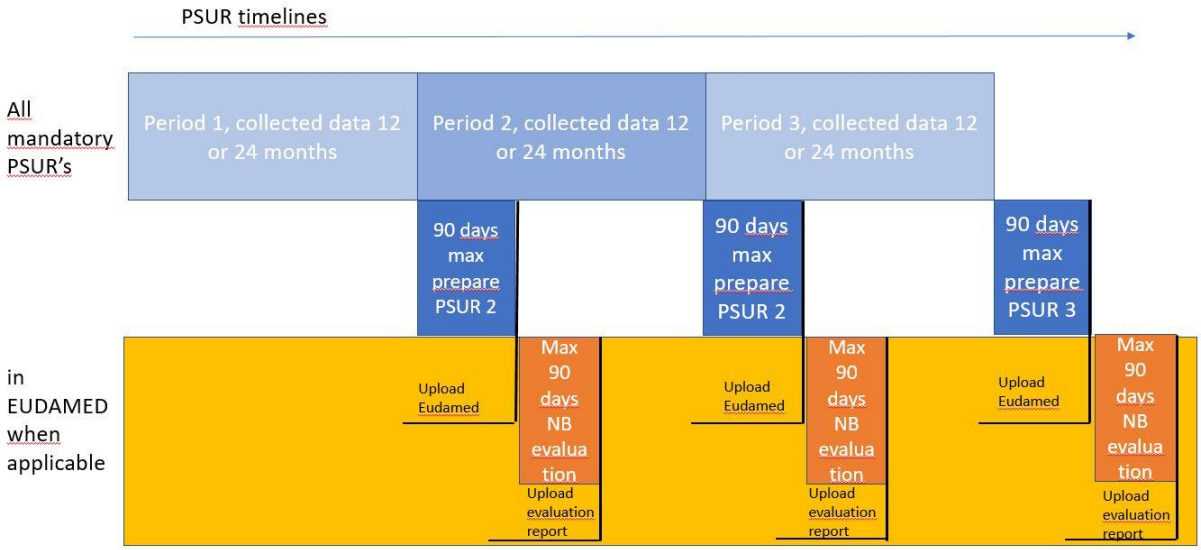


Image 5 timelines for data collection, PSUR submission in Eudamed and PSUR evaluation

5 Notified Body Evaluation

The aim of the Notified Body evaluation is to analyze whether the manufacturer's conclusions regarding benefit/risk ratio are justified from the point of view of the gathered data and the manufacturer's analysis.

The purpose of this chapter is to highlight the notified bodies responsibilities in relation to the PSUR and the relevant classifications of devices, along with any possible actions that may be required by the notified body. The chapter also provides information on the required timelines of the notified body.

This chapter also considers legacy device PSUR(s) in relation to notified body assessment and considerations specifically to certification and recertification activities.

5.1 The different PSUR evaluation obligations for notified bodies

5.1.1. Class III and Implantable Devices - via EUDAMED

Article 86(2) of MDR stipulates that manufacturers must submit PSURs in EUDAMED for class III and implantable devices to allow for notified body review. The notified body's evaluation of the PSUR must be uploaded in EUDAMED and will be made available to the competent authorities.

The PSUR should be uploaded to EUDAMED by the manufacturer and the notified body should provide conclusions of its evaluation of the PSUR within EUDAMED within 90 days.

Implantable Well-Established Technologies (WET) Article 52 (4)) of MDR – via EUDAMED

- The PSUR should be uploaded to EUDAMED by the manufacturer while the notified body should provide conclusions of its evaluation of the PSUR within EUDAMED during the notified body surveillance (assessment of the technical documentation in line with the sampling plan) and the recertification activities. The allowance for this is given due to the fact they are well established technologies i.e.
    - relatively simple, common and stable designs with little evolution;
    - their generic device group has well-known safety and has not been associated with safety issues in the past
    - well-known clinical performance characteristics and their generic device group are standard of care devices where there is little evolution in indications and the state of the art;
    - a long history on the market.

5.1.2. Classes IIa/IIb Non-Implantable Devices - outside of EUDAMED

For non-implantable class IIa and non-implantable class IIb devices, in accordance with Article 86 (3), PSURs should be made available to the notified body for review during surveillance (assessment of the technical documentation in line with the sampling plan) and recertification activities.

The detailed rules for PSUR first availability and recurring preparation, for PSUR submission and evaluation or review for the various classes of devices either certified under the MDR or the MDD / AIMDD are presented in Annex IV of this guidance.

5.2 Notified Body Evaluation Timeline

When the PSUR is submitted by the manufacturer in accordance with Article 86 (2). For class III and implantable devices, the notified body shall complete its evaluation of the PSUR no later than 90 days after the date the manufacturer has uploaded the PSUR to Eudamed.

In exceptional circumstances, as described in section 5.8 of this guidance, the notified body may require additional time to perform the evaluation. In these circumstances the notified body shall upload to Eudamed no later than the 90th day, a statement explaining the reasons for the need of additional time. The notified body shall have a further 90 days to evaluate the PSUR.

The notified body may request after its evaluation of the PSUR that for the next upload per the timing cycle identified in Article 86(2), that further detailed information/data is required in the PSUR from the manufacturer to improve the quality of the PSUR.

5.3 An assessment of the Data Presented in the PSUR (for PSURs submitted in EUDAMED)

The Notified Body shall verify that the manufacturer has carried out the completeness check of the PSUR and that the information is clearly indicated as available in the document (or if applicable a justification indicating the reason of the lack of information).

Bilaterally, the Notified Body may ask the manufacturer to provide missing information in order to carry out its assessment of the PSUR for this reporting period. It may also request corrective actions which should be reflected in the PSUR of the next reporting period.

Then the Notified Body shall provide it conclusions of the evaluation of the data provided in the PSUR and document whether the conclusions of the benefit-risk determination drawn by the manufacturer are traceable.

Notified Body Conclusions of the Evaluation of the PSUR:

- If the Notified Body agrees with the Manufacturer that the data presented confirm no adverse impact to the benefit/risk ratio of the device(s), the Notified Body shall provide a confirmatory statement of its conclusion.

- If the Notified Body concludes as part of its evaluation that the data presented confirms an adverse impact to the benefit/risk ratio of the device(s), the Notified Body will request a corrective action plan from the manufacturer. In addition, the Notified Body may perform an assessment of the appropriate technical documentation of the device(s) and possibly of any actions listed in section 5.8 of this guidance (see below). This process will require a reassessment of the benefit/risk ratio of the device(s). For class III and Implantable devices, at the time the notified body has completed its assessment, it will provide its evaluation to EUDAMED along with a statement detailing the actions it has taken.

- If the notified body identifies a non-conformity in the data presented within the PSUR, any corrective action requested should be reflected in the NB PSUR evaluation report of this period and in the PSUR of the next reporting period.

5.4 Surveillance Activities (as Part of Technical Documentation (TD) sampling)[5]

Class IIa/IIb Non-Implantable Devices (subject to TD sampling):

The PSUR should be evaluated during the evaluation of the technical documentation and in accordance with frequency defined in the sampling plan, throughout the period of validity of the certificate (with the exception of the technical documentation sampled during the initial assessment, see below).

The PSUR should be evaluated as an integral part of the technical documentation and the results of this evaluation are indicated in the evaluation report of the technical documentation.

If the notified body identifies a non-conformity in the data presented within the PSUR, any corrective action requested should be reflected in the evaluation report of the technical documentation making reference to the PSUR.

Implantable Well-Established Technologies (WET Article 52 (4)) of MDR (Subject to TD Sampling):

PSURs will be uploaded to EUDAMED by the manufacturer in alignment with the frequency laid down in Article 86 (2) for specifically those devices listed in Article 52(4), but will be evaluated as part of sampling by the notified body.

In this case, the PSUR will be evaluated during the evaluation of the technical documentation as defined in the sampling plan, throughout the period of validity of the certificate. The conclusions of this evaluation are uploaded to EUDAMED within 90 days after the review of sampling the technical documentation has been completed.

As part of the management of the vigilance data collected by the Notified Body and the potential impact of this data on the certification granted, the Notified body may also modify and adapt the sampling plan.

5.5 PSUR Evaluation by the notified body as part of Initial MDR certification and MDR recertification processes – Timing cycles

Initial MDR certification of MD not previously been placed on the market under MDD/AIMDD

In these cases, a PSUR cannot be presented at initial certification because there has been no post-market surveillance data collection performed.

[5] *MDCG 2019-13 Guidance on sampling of MDR Class IIa / Class IIb and IVDR Class B / Class C devices for the assessment of the technical documentation*

However, the provisions made within the quality management system for establishing the PSURs should be verified during the evaluation of the technical documentation (systematic or by sampling) and during the audits.

Initial MDR Certification of Legacy Devices

For these devices, there may have been previous submissions of PSUR(s) to EUDAMED or the notified body as outlined in Article 86 (2) and (3). PSUR(s) previously completed will be required during the initial certification process, if at least one PSUR has been issued within the transition period (post-DoA), manufacturers should use data from the previous PSUR(s) submitted to EUDAMED or the notified body to support the initial certification.

Recertification of MDR Certificates

As post market surveillance information has been collected and previously presented, then the PSUR should be reviewed in the assessment of recertification of a device.

Timing cycle

The timing cycle of the PSUR uploaded to EUDAMED by the manufacturer and evaluation by the notified body as defined in Article 86 (1) and (2) of MDR remains unchanged until the MDR certification is granted.

Once the MDR certificate is approved by the notified body then the timing cycle is reset and the PSUR is provided as defined in Article 86 (1) and (2). For manufacturers which continue to hold both an MDD/AIMDD and MDR Certificate, it is permissible for the manufacturer to provide all information of the same device certified both under MDR and MDD/AIMDD in a single PSUR. The single PSUR must distinguish the data between the same device placed on the market under MDD/AIMDD and MDR.

In the case of a MDR recertification, the timing cycle remains unchanged.

5.6 PSUR Evaluation by the notified body as part of the assessment of changes (according to Annex IX (4.10) and Annex X (5.2) of MDR)

The PSUR shall be updated at least once a year or once every 2 years depending on the risk class but there may be certain circumstances where modifications are made that may require updating the document earlier. This is the case with changes that could affect conformity with the general safety and performance requirements or with the conditions prescribed for use of the device (according to Annex IX (4.10) and Annex X (5.2) of MDR).

The notified body shall assess the planned changes and decide whether the planned changes require a new conformity assessment.

Post market surveillance data generated from the new device should be presented alongside data from the previous device generation in the same PSUR to allow the notified body to perform its evaluation of the impact of the changes.

In exceptional circumstances, the notified body may request that the data is presented in a separate PSUR at time of the conformity assessment (an example would include where modifications to a device are significant that equivalence to a previous generation of device can longer be claimed and results in a new Basic UDI-DI). The justification for this request will be documented in the evaluation report of the first PSUR.

In the case of a legacy device, if the change planned by the manufacturer is a significant change in design and intended purpose according to Article 120 (3) of MDR, the updated technical documentation will be reassessed as part of initial certification under MDR.

5.7 PSUR(s) Submission period to Notified Body

5.7.1 Devices certified under MDR

Class III and implantable devices (subject to EUDAMED submission)

The end of collecting data period of the PSUR for Class III or implantable devices should be aligned to the anniversary date of the issued MDR certificate (under which the product is placed on the market), and the manufacturer has an additional 90 days for preparing and submitting the PSUR:

- Each year after MDR Certificate Anniversary Date, for class III and IIb implantable devices
- Every 2 years after MDR Certificate Anniversary Date per agreed cadence with the notified body, for class IIa implantable devices

Class IIb and IIa non-implantable devices (outside EUDAMED)

For these devices, the PSUR is not submitted to the notified body but it should be made available to the notified body (Article 86 (3)). The manufacturer in agreement with the notified body may provide its PSUR to align with surveillance activities.

The end of collecting data period of the PSUR for class IIb or IIa non-implantable devices should be aligned to the anniversary date of the issued MDR certificate (under which the product is placed on the market), and the manufacturer has an additional 180 days for preparing and making the PSUR available to the notify body:

- Each year after MDR Certificate Anniversary Date, for class IIb non-implantable devices
- Every 2 years after MDR Certificate Anniversary Date per agreed cadence with the notified body, for class IIa non-implantable devices

5.7.2 Class III and IIb Implantable devices certified under MDD & AIMDD (Legacy Devices)

Notified bodies may request the first PSURs of Class III and Class IIb Implantable legacy devices to be uploaded in a timely manner to avoid a peak every 12 months after 26th May 2021.

The end of collecting data period of the first PSUR for Class III or Class IIb implantable legacy devices should be aligned to the anniversary date of the original first issued CE certificate and the manufacturer has an additional 90 days for preparing and submitting the PSUR:

- For devices certified with an anniversary date of original first issue between 27th November and 26th May, that aligns in the time period of 27th November 2021 and 26th May 2022
- For devices certified with an anniversary date of original first issue between 27th May and 26th November, that aligns in the time period of 27th May 2022 and 26th November 2022

It is accepted that for the first PSURs of legacy devices provided before November 26th 2022, will not have the required 12 months of data set, however all subsequent PSURs will need to provide 12 months of data.

The manufacturer may on agreement from the notified body provide its first PSUR, earlier than the dates described above.

The preparation and submission of the PSUR for the next reporting period should be aligned to the first PSUR submission date.

5.7.3 Class IIa Implantable Devices certified under MDD/AIMDD (Legacy Devices)

Notified bodies may request the first PSURs of class IIa implantable legacy devices in a timely manner to avoid a peak 24 months after 26th May 2021.

The end of data collecting period of the first PSUR for Class IIa implantable legacy devices should be aligned to the anniversary date of the original first issued CE certificate and the manufacturer has an additional 90 days for preparing and submitting the PSUR:

- For devices certified with an anniversary date of original first issue between 27th November and 26th May, that aligns in the time period of 27th November 2022 and 26th May 2023.
- For devices certified with an anniversary date of original first issue between 27th May and 26th November, that aligns in the time period of 27th May 2023 and 26th November 2023.

It is accepted that for the first PSURs of legacy devices provided before November 26th 2023, will not have the required 24 months data set, however all subsequent PSURs will provide 24 months of data.

The manufacturer may on agreement from the notified body provide its first PSUR, earlier than the dates described above.

The preparation and submission of the PSUR for the next reporting period should be aligned to the first PSUR submission date.

5.7.4 Legacy Devices & Full Quality Assurance Certificates

Class IIb and Class IIa Implantable (Subject to EUDAMED submission)

PSURs for legacy devices listed on a quality assurance certificate that are subject to Article 86(2) of MDR shall be uploaded to Eudamed by the manufacturer for evaluation by the notified body.

The end of collecting data period of the PSUR should be aligned to the anniversary date of the certificate under which the first product is placed on the market. The dates listed for CE certificate in section 5.7.2 and 5.7.3 will apply.

The manufacturer may on agreement from the notified body provide its first PSUR, earlier than the dates described above.
The preparation and submission of the PSUR for the next reporting period should be aligned to the first PSUR submission date.

Class IIb and Class IIa Non-Implantable (Outside of EUDAMED)

For these devices, the PSUR is not submitted to the notified body but it should be made available to the notified body (Article 86 (3) of MDR). The manufacturer in agreement with the notified body may provide its PSUR to align with surveillance activities.

The end of collecting data period of the PSUR should be aligned to the anniversary date of the certificate under which the first product is placed on the market and the manufacturer has an additional 180 days for preparing and making the PSUR available to the notify body. The dates listed for CE certificate in section 5.7.2 and 5.7.3 will apply.

The preparation and availability of the PSUR for the next reporting period should be aligned to the date of the first PSUR availability.

5.8 Actions to be taken by the Notified Body (according to Annex VII (4.10) of MDR)

When the notified body evaluates the PSUR and considers that the device does not conclude a favorable benefit / risk ratio, compatible with a high level of protection of health and safety and taking into account the generally acknowledged state of the art, the notified body may decide to consider any the following options, but not limited to:

- Ask the manufacturer to provide a scientific based justification, details or additional documents in order to verify that the device still complies with the requirements of the Regulations.
- Ask the manufacturer to justify why the post-market surveillance plan, including the PMCF plan, is still deemed adequate,

- To perform extraordinary surveillance measures, such as document reviews, short-notice or unannounced audits and/or product testing
- To increase the frequency of surveillance audits,
- To decide whether specific conditions or provisions need to be defined for the certification,
- To suspend or reduce the scope of the certificate(s)
- To take any other relevant measure(s).

As a last resort, there may also be the decision to withdraw the certification.

Part II: Rules applicable for PSURs to be submitted in EUDAMED

6 Completeness check of the PSUR Report

The PSUR report should include the different sections outlined in this guidance. The completeness check should demonstrate that the relevant data sets and information detailed in this guidance have been covered by PSUR.

It has to be systematically performed[6] by the manufacturers for PSURs for class III and implantable devices before submission in Eudamed. This systematic review is required to ensure that all the relevant data and information necessary for evaluation by the notified bodies are provided in a structured way. If there are data set and information requirements laid down by this guidance which are not applicable, manufacturers should provide a justification within the completeness check itself for not including them.

The completeness check form to be filled up by the manufacturers is provided in Annex I of this guidance. It has to be inserted at the top of the PSUR report.

If the lack of completeness of the PSUR prevents the notified body to be able to perform an evaluation, the notified body may request a revised PSUR from the manufacturer (see section 5).

7 PSUR format

The PSUR format is composed of two elements: the PSUR form and the PSUR REPORT.

PSUR format = PSUR FORM + PSUR REPORT

- The PSUR REPORT is a PDF file that the manufacturer should upload in Eudamed for class III devices or for implantable devices.

- The PSUR form is a form which has to be filled up by the manufacturer and uploaded in Eudamed together with the PSUR report.

[6] This completeness check by the manufacturer is also recommended for the PSURs which are not submitted in Eudamed.

7.1 PSUR Form

The PSUR form contains all the relevant administrative data as well as data to identify and distinguish between different PSURs for the same device. It also provides, where relevant, the data necessary for the registration of the PSUR in Eudamed.

For those PSUR forms submitted to EUDAMED, certain fields are automatically populated from that database into the form by the system (e.g. NB, Manufacturer, Single Registration Number (SRN)). Those fields that are not be automatically populated or for those medical devices whose PSUR are not submitted thought/via EUDAMED, the fields should be completed manually.

The manufacturer should fill in the PSUR identification and process related information. The manufacturer creates a PSUR reference number which will remain the same as long as the device identification information (Basic anniversary

-DI(s), Eudamed DI) is unchanged. The PSUR process related information separates the different PSURs from each other and are PSUR data collection period and PSUR version number.

The manufacturer upload the PSUR document into Eudamed and finally submits the PSUR form into Eudamed. Eudamed provides the submission date and calculates the prerequisite times. Finally and Eudamed send notification to notified body. Outside Eudamed the manufacturer should fill in all required information.

Those fields that are not be automatically populated or for those medical devices whose PSUR are not submitted thought/via EUDAMED, the fields should be completed manually.

The PSUR form is available on the Commission website for downloading (insert link) and in Eudamed when it becomes available. The PSUR form is also provided in Annex VI of this guidance.

7.2 Notified Body Evaluation Format

For those PSURS the Notified Body's Evaluation report is required the NB Evalution report is composed of two elements: the PSUR Evaluation Report Form and the Evaluation Report.

NB Evaluation Format = NB Evaluation FORM + NB Evaluation REPORT

The Notify Body Evaluation Report is a PDF file that should be attached to the NB Evaluation Form.

The Notify Body Evaluation form is available on the Commission website for downloading (insert link) and in Eudamed when it becomes available. The PSUR form is also provided in Annex VI of this guidance.

8 Period before Eudamed entry in function

For the time period before EUDAMED becomes fully functional, alternative methods for notifying the PSUR and the Notified Body evaluation are defined in the MDCG Guidance (reference n°) on harmonized administrative practices and alternative technical solutions.

9 ANNEXES

9.1 ANNEX I: COMPLETENESS CHECK FORM

Completeness check performed by the manufacturer prior to submission of its PSUR in Eudamed)

The purpose of the completeness check is to ensure that the manufacturer has verified that its PSURs for class III and implantable devices which need to be submitted to Eudamed for notified body evaluation do provide all the required information for evaluation by the notified bodies and competent authorities. This review needs to be performed in accordance with the PSUR guidance. If some types of data have not been reported or considered in its PSUR, the manufacturer should then provide a short justification for not having done it.
The purpose of the completeness check is to ensure that PSURs are of the sufficient quality for evaluation by the Notified Bodies and Competent Authorities.

Manufacturers shall confirm that the data sets for each of the listed sections within the PSUR are present and where the data is not present, the manufacturer should duly justify its absence.

The outcome of the completeness check below should be inserted in the first page of the PSUR.

Information Required	**Check ✓**	**Justification if information /data are not present**
Executive Summary - Statement of benefit/risk impact		
Description of the Devices covered by the PSUR and their Intended Uses		
Rationale for Grouping of Devices		
Presentation of the Data and Their Evaluation - Volume of sales - Characteristics of the population using the device(s)		
Post Market Surveillance (PMS) Data - Vigilance Data Including Possible Detected Signals - Preventive or Corrective Actions (Article 83.4)		

- Preventive and Corrective Actions for Safety Reasons and Evaluation (Article 87) - Signal Identification		
Post Market Clinical Follow-up (PMCF) Data		
Shared Data within PMS and PMCF - Feedback and Complaints from Market - Marketing Activities and Usability Surveys - Systematic Literature Research - Public Registry Data - Publicly Available Information about Similar Medical Devices. - Other Data Sources		
Summary of the Findings Received from the Collected Data		
The Conclusions of the Benefit-Risk Determination by Manufacturer -Conclusion Related to the Risks -Conclusions Related to the Benefits -Update to Benefit-Risk Profile		
Conclusions of the PSUR Report		
Conclusions on any effects on the PMS plan		

774

775

9.2 ANNEX II: TEMPLATE FOR THE PSUR REPORT

a) **Executive Summary**

- The executive summary should include background information related to the benefit risk profile of the device so that the PSUR "stands alone", information related to actions required by NB and also provide the main results of the current PSUR.
    - The background information is gathered prior to the current PSUR and may include, for example, the achieved safety and performance of the device, information related to intended benefits achieved or not and description of the essential changes detected such as new risks or emergence trends in the earlier PSURs.
    - A brief description of the actions NB requested on the basis of the previous PSUR
    - The main results of the current PSUR includes a clear and bold statement declaring whether the benefit risk ratio has been impacted, negatively or positively, based on the information reported within the current PSUR. The statement could be a simple expression for example, "*PSUR **have not** impacted the 'benefit risk* or *PSUR **have** impacted the 'benefit risk.* This statement should be declared after the conclusions of the PSUR have been completed.

b) **Description of the Devices Covered By the PSUR and Their Intended Uses**

- Provide a number and an overview of the devices covered by the PSUR broken down by the Basic UDI-DI(s) and explain any device changes within each Basic UDI-DI compared to the previous PSUR.
- In cases where the PSUR covers multiple Basic UDI-DIs explain whether all grouped devices are main devices, the device and its accessories or including only accessories used with different devices
- Device trade name(s) (this include all trade names the device may have on the market in different Member States) and Medical device nomenclature. When nomenclature is unavailable, device model number may be used. With the CMD use the name of the device group.
- Class of device
- Year when the first certificate (CE) was issued covering the device
- Broken down by the Basic UDI-DI status of the device(s) included into the PSUR by device: on the market, no longer placed on the market, recalled, field safety corrective action initiated
- Broken down by the Basic UDI-DI the intended purpose of the device(s) included into the PSUR and any indications, contraindications and target populations
- A description of the device, including a reference to previous generation(s) or variants if such exist, and a description of the differences, as well as, where relevant, a description of any accessories, other devices and products, which are intended to be used in combination with the device
- Information on any residual risks and any undesirable effects, warnings and precautions

c) **Justification of the grouping of devices if applicable**

- In cases where the PSUR includes more than one Basic UDI-DI or model of the MDD, AIMDD devices or custom-made devices describe the justification to group the devices in one PSUR.
- The justification could be based on the benefits to report multiple devices in one PSUR or alternatively weaknesses to report each device in separate PSURs.
- In any case, take into account that the PSUR must remain comprehensible.

- Once the manufacturer decides and justifies the grouping of devices in the previous PSURs, the next PSURs must include the same Basic UDI-DI(s) or model of the MDD, AIMDD devices or custom-made devices .

The requirement to form a new Basic UDI-DI necessitate a new PSUR

d) **Presentation of the Data and Their Evaluation**

General information related to the data presentation and evaluation is described in Annex III and examples of used tables in Annex V of this guidance .The basis for the required datasets are in Articles 86 and 83, Annex III and XIV of the MDR (Section 3. PSUR content and structure). The data collection time is defined in Section 4.3 and the presented and evaluated data comprises data from the four/two last data collection periods. The data is presented and evaluated both annually or biennial and four-year summary data.

The presented data consists of proactively and reactively collected data based on the PMS and PMCF plans. If the collected datasets are partially overlapping, then it is allowed to only present a summary information on the PSUR if the data is described and conclusions presented in other obligatory reports. However, the PSUR data collection times should be considered.

The main principle is that the data presented and evaluated are generated after the application of MDR. The data accumulates year by year so that the first PSUR comprises data collected within the first data collection period and the fourth/second PSUR comprises all the required data. Historical data should also be presented for legacy devices when possible. The presented data when possible, should be reported according to this guidance document.

1. Volume of Sales

- Provide an accurate information of the number of devices sold and the possible changes on it. The data should be presented by year to year (Table 1).
- Provide further information on the volume of sales in respect to the various sizes, models and configurations of the device.
- Indicate to what criteria the number of devices on the market is provided
  - Devices placed on the market or put into service
  - Units distributed within each time period
  - Number of episodes of use (for reusable devices)
  - Active installed base
  - Units distributed from the date of declaration of conformity/CE mark approval to the end date of each time period
  - Number of devices implanted
  - Other -describe

2. Characteristics of the Population using the Device(s)

The data related to the characteristics of the patient population shall be reported on the extent, which is possible for the manufacturer. If the detailed information applies only to one or a few countries, it shall be reported.

- Describe the observed usage of the device in different patient populations and when available compare it to the expected usage and identify the possible over-represented or under-represented patient groups.

- Regarding implantable devices describe the size and nature of the patient population with the implanted medical device and proportion of the patient group using the implant in comparison to the population.
- Consider the off-label use as a whole and in specific patient or disease groups.
- Describe the possible changes in patient groups using the device during the last four years, on a year to year basis.
- When applicable evaluate the effect of the detected changes to findings obtained previously and in the current PSUR.
- Estimate the generalizability of the results

3. Post Market Surveillance (PMS) Data

PMS specific data consists of data related to the serious incidents, trend reports, CAPAs and FSCAs.

- **Vigilance Data Including Possible Detected Signals**
  - The serious incidents (article 87) and trend reports (article 88) should be reported separately
  - The data relating to serious incidents should contain all occurred incidents and data relating to the trend reports should contain all prepared trend reports.
  - <u>Serious Incidents</u>
    - Firstly, provide a list of the most frequent serious incidents by IMDRF device problem code by year to year. Organize the list in descending order so that the first one listed is the most common device problem type occurred in EEA+TR+CH within current reporting period. (Table 3)
      - For the low volume device use four years summary data and organize the list by IMDRF Problem code so that the first one is the most common device problem code occurred in EEA+TR+CH (table 4)
    - Secondly, provide a list of investigation findings by IMDRF investigation finding code by year to year. Organize the list in descending order so that the first entry is the most common investigation finding occurred in EU+TR+CH within current reporting period. (Table 5)
    - Thirdly, provide a list of the health impacts by IMDRF health impact code. Use the 4-year summary data and split the data by the IMDRF Investigation conclusion code caused the health impact. Organize the list in descending order so that the first entry is the most common health impact occurred in EEA+TR+CH within current reporting period. (Table 6)
  - <u>Trend Reports</u>
    - <u>The data related to the trend reports will be updated after the MDR based Vigilance Guidance is finalized. So far, the text and tables related to the trend reports should be considered as examples.</u>
    - Firstly, provide a list of trend reports by IMDRF device problem code by year to year. Organize the list in descending order so that the first one is the most common device problem type occurred in EEA+TR+CH within the current reporting period. Report also the basis for the trend report i.e. incident or side effect. (Table 7)
    - Secondly, provide a list of the health impacts by IMDRF health impact code. Use the 4-year summary data and split the data by the IMDRF Investigation conclusion code caused the health impact. Organize the list in descending order so that the

first entry is the most common health impact occurred in EU+TR+CH within current reporting period. (Table 8)

- **Preventive or Corrective Actions (Article 83.4)**
  - Provide a list of preventive and corrective actions (CAPA), detected on the basis of PMS plan , which have a direct impact on product safety, performance or quality and identified thorough execution from the collection of information as described in Annex III point 1(a). The list should not include quality management system related CAPA's, unless they could have a direct impact on product safety, performance or quality
  - Provide following information by CAPA: the type of action, starting day and status of the action, reference number, method to detect the requirement to release a CAPA and the action taken, the root cause, Impacted regions and proportion of CAPA's that indicated a FSCA (Table 9).
  - The analysis should identify the results of actions and whether there are deviations from the defined actions, the identified actions should be listed, and the deviation should be justified.
  - In cases where identical CAPAs are repeated provide an explanation.

- **Preventive and Corrective Actions for Safety Reasons and Evaluation (Article 87)**

  FSCAs will be reported according to the current FSCA forms until Eudamed is functional. When Eudamed is functional and the data collection related to the FSCA reports is updated then this part of PSUR will be also updated.

  - Provide a list of FSCAs performed including following information: manufacturer's reference number, the date of initiation, a brief description of the reason for action, status at the time of the PSUR (i.e. initial, follow-up, final) and information whether a Field Safety Notice has been issued.
  - The analysis should identify whether there are deviations from the defined actions, when identified those actions should be listed and justify the deviation.
  - When identical FSCAs are performed repeatedly they should be justified.
  - Clarification for the prolonged duration of the corrective actions shall be provided.

- **Signal Identification**
  - Provide a list of new signals detected in current PSUR, previously detected signals and their status (switch to risk, eliminated, still monitoring) and re-opened signals and reason(s) for re-opening.
  - For each signal, evaluate the significance of it and describe plans for further evaluation of it and if no action is planned justify it.

4. Post Market Clinical Follow-up (PMCF) Data

This section shall include the main findings of data generated from the output of PMCF activities performed by the manufacturer. This section is not limited to PMCF studies and should include other activities conducted by the manufacturer, these may include but not limited to; manufacturer device registries, surveys, and real world evidence analyses.

A summary of PMCF data should be presented for each activity, including ongoing, completed or terminated in the data collection period. The summary should give consideration on the progress of the activity and any new information identified in relation to the data set period. In particular consideration should be given to;

- Name & Type of PMCF Activity,
- Start date of PMCF Activity, and planned end date of PMCF activity,
- Number of total enrolled participants Vs number of planned participants per PMCF plan,
- Number of total enrolled sites Vs number of planned sites per PMCF plan,
- Any new risks or direct patient harm identified from PMCF activities,
- Any study protocol deviations or issues identified hindering the conduct of PMCF activity
- Any change in relation to state of the art identified from PMCF activity

Manufacturers may refer to the PMCF Evaluation Report to allow for a comprehensive assessment of the PMCF activities, however sufficient detail within the PSUR should be made available to allow an adequate evaluation to be made.

5. Shared Data within PMS and PMCF

The shared data consists of other datasets not mentioned above and are generated from post market activities (Annex III and XIV of the MDR). Sections below should be completed in alignment with the PMS and PMCF plans.

A list should be provided of all other data sources collected in the post market phase in the data collection period including current data collection period. Safety and performance data generated from these activities should be used also for comparison to other devices with same intended purpose

- Feedback and Complaints from Market
  - All Feedback and complaints, generated by users, distributors and importers should be considered in this section. The 10 highest groups of complaints shall be presented within this section of the PSUR with the following considerations;
  - Title and brief description of complaint
  - Number of complaints (Including %)
  - Information whether the group of complaints has initiated a CAPA

- Literature Research
  - Provide a list of completed literature searches conducted within the data collection period including following information: name of the literature search, indication for the literature search, search terms, used data sources, proportion of the accepted publications, number of patients and findings.
  - For detailed information around literature searches conducted and results generated, the manufacturer may refer to the technical documentation.

- Public Registry Data

  Provide a list of all registries reviewed including the following information: the name or registry reference, type of registry (Prospective or Retrospective data collection),

- Provide a list of findings in comparison to the devices with same intended use and justify any identified differences. Provide information about any new risks identified from this data set.

- Publicly Available Information about Similar Medical Devices.

  - Additional publicly available information may include information identified from other manufacturers of similar medical devices, (e.g. results of a manufacturer's PMCF study made publicly available in the manufacturer's Summary of Safety and Clinical Performance (SSCP) Report).

  - The type and location of this information should be provided, and where possible a comparison of the devices with same intended purpose should be evaluated with any possible differences in safety and performance reported.

- Other Data Sources
  - The other used data sources could be for example real-world data from electronic health records, digital health-monitoring devices, complaints, and other feedback from health care professionals.
  - Provide a list of the used data sources and findings with specific reference to safety and performance.

g) **Summary of the Findings Received from the Collected Data**

Manufacturers should consider the following elements when preparing the summary:

- An overview of the data; its coverage, quality, possible deficiencies and bias.
- That the summary is based on all used datasets and evaluate whether the findings obtained are consistent within the used datasets.
- A list of the possibly detected deviations, to describe the previously unknown risks, side effects and benefit not achieved as intended. Consider each deviation.
- The strengths and limitations of the data and analysis used.
- Comparison to the available information of other devices with the same intended use, state of art and consider the possible differences in safety and performance of the device.

h) The Conclusions of the Benefit-Risk Determination by Manufacturer

Provide a conclusion of the output of the activities where the benefit risk balance is adversely impacted

<u>Conclusion Related to the Risks</u>

- Areas to consider includes potential new risks by patient groups, device sizes, accessories used, region and previously established risks which prevalence or seriousness has increased.
- Conclusion should also consider the detected new risks in relation to the seriousness, potential impact and duration.
- Evaluate the clinical significance of the new detected risks and changed risks.

- Summarized information by region, patient groups and device sizes or models if applicable and relevant.
- Provide a conclusion of the risk reduction activities and the effectiveness of them.
    - A list of the risk reduction activities performed in cases where there are new risks identified, and the prevalence or seriousness of a known risk has increased.
    - The effectiveness of risk reduction activities should be evaluated and where actions have not be taken provide justification.

Conclusion Related to the Benefits

- Provide a list of the new detected benefits and benefits not gained by patient groups, device sizes, accessories and region.
- Regarding the detected new benefits and benefits not gained, evaluate the clinical significance and duration of them.
- Describe the effect of the benefits not gained to the acceptability of the usages of the device.
- Summarized information by region, patient groups and device sizes or models if applicable and relevant.

Update to Benefit-Risk Profile

- Provide a summary of the benefit risk update and justify the actions you have or have not taken.

i) Conclusions of the PSUR Report

- Provide a statement declaring whether the benefit risk ratio has been negatively impacted based on the information reported within the current PSUR and add the conclusion statement in Executive Summary section
- Identify specific points that should be considered in the next PSUR.

j) Conclusions of any Effects on the PMS Plan

- Describe how the current PSUR will effect to the further PMS Plan
- Provide a list of the updated documents and describe the updated content.
- Describe the essential changes on the PMS plan.

9.3 ANNEX III: General Information Related to the Data Reporting and Their Evaluation

A. How Data Should be Reported

- Each dataset collected within the PMS Plan should be presented and analysed individually and finally provide a summary of the all used datasets including the PMCF data highlighting the strengths and weaknesses of the used data.

- Each individual data should be split by Basic UDI-DI or model of the device if the Basic UDI-DI does not exist.

- When the devices within a Basic UDI-DI(s) is changed significantly, then necessary to report separately the data with former and later combination of devices.

- Whether the device design changes has been implemented split the data to enable the comparison between the different device variants;

- The data should be split also by region when applicable. The used region is EEA, CH, TR, and worldwide. Worldwide data includes data from EEA, CH and TR.

- Each PSUR should contain data gathered over the last four years except PSURs, which data collection periods do not cover four year data;

- Depending on the detail, the data is used as a 4-year summary data, when the 4-year data is available or a yearly data.

- Data reported by year to year:

    - Class III and Class IIb: Reporting Day+ preceding 12 months (N); N – 12 months (N2); N2-12 months (N3); N3-12 months (N4)
    - Class IIa: Reporting Day+ preceding 24 months (N); N – 24 months (N2)

- Report the data by the International Medical Device Regulators Forum (IMDRF) codes when the content of the data facilitates it:

    - Level 2 terms are satisfactory to enable the grouping of cases.
    - When the level 2 terms are not available use the level 1 terms.
    - The used codes are:
        - Device problem code (Annex A)
        - Health impact code (Annex F)
        - Investigation finding code (Annex C)

- Investigation Conclusion code (Annex D),

B. How Data Should be Evaluated

- Findings from all used datasets should be evaluated against each other with consideration and reflect the possible conflicting results.
- Evaluate the results in viewpoint of the different patient populations, size and model of the device, device combination or variants. When applicable evaluate the findings in relation to the state of the art.
- Evaluate the data in relation to the thresholds concerning known risks and side effects and benefits intended to gain.
- Identify the possible unknown signals, positive or negative.
- The long-term findings should be evaluated against the recent findings to ensure that they are stable.
- Where applicable use the IMDRF terminologies for Categorized Adverse Event Reporting in the analysis. Identify factors that support or refute previously identified safety and performance concerns as well as evidence relating to new safety signals and previously unknown benefits and benefits not achieved.
- Whether the device is used as a combination of devices the analysis should identify the role of the target device in comparison to other devices or accessories.
- Compare the performance and safety of the device to other devices with the same intended use.
- For detecting signals describe overall principles and methodology including trigger levels and their justifications and the method used to detect signals.

9.4 Annex IV - First availability and recurring preparation of PSUR

Devices certified under MDR

Devices certified under MDR

	Class III and IIb implantable medical devices	**Class IIb implantable WET (Limited to devices listed in Article 52 (4))**	**Class IIb not-implantable medical devices**	**Class IIa implantable medical devices**	**Class IIa not-implantable medical devices**	**Custom-made devices**
Frequency	Yearly	Yearly	Yearly	Every 2 years	Every 2 years	
PSUR uploaded to Eudamed	**Yes**	**Yes**	No	**Yes**	No	No
PSUR (first) availability	One year after the MDR certification of the device. (+ 90 days preparation by manufacturer) in accordance with Eudamed rules	One year after the MDR certification of the device or Quality System (FQA) (+ 90 days preparation by manufacturer) in accordance with Eudamed rules	One year after the MDR certification of the device or Quality System (FQA) (+ 90 days preparation by manufacturer)	2 years after the MDR certification of the device or Quality System (FQA) in agreed cadence with NB. (+ 90 days preparation by manufacturer) in accordance with Eudamed rules	2 years after the MDR certification of the device or Quality System (FQA) in agreed cadence with NB (+ 90 days preparation by manufacturer)	For class III implantable devices the PSUR shall be updated in the same schedule following the classes schedule and shared with authorities upon request For the rest of the devices: upon request.
PSUR recurring preparation and availability	Each year after MDR Certificate Anniversary Date. (+ 90 days preparation by manufacturer)	Each year after MDR Certificate Anniversary Date. (+ 90 days preparation by manufacturer)	Each year after MDR Certificate Anniversary Date. (+ 90 days preparation by manufacturer)	Every 2 years after MDR Certificate Anniversary Date per agreed cadence with NB. (+ 90 days preparation by manufacturer)	Every 2 years after MDR Certificate Anniversary Date per agreed cadence with NB. (+ 90 days preparation by manufacturer)	
Notified body evaluation	**Yes** (+ 90 days after submission to EUDAMED by manufacturer)	**Yes** (as part of NB TF Sampling Plan)	Evaluation not required, only making it available. Notified bodies will be assessing this following a sampling plan.	**Yes**(+ 90 days after submission to EUDAMED by manufacturer)	Evaluation not required, only making it available. Notified bodies will be assessing this following a sampling plan.	Evaluation not required, only making it available

Competent Authorities	Made available through Eudamed	Made available through Eudamed	Made available upon request	Made available through Eudamed	Made available upon request	Made available upon request
In Technical Documentation	Yes, as specified in Annexes II and III	Yes, as specified in Annexes II and III	Yes, as specified in Annexes II and III	Yes, as specified in Annexes II and III	Yes, as specified in Annexes II and III	Part of documentation referred in Section 2 of Annex XIII

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1140 **Legacy Devices certified under MDD/AIMDD**

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	Class III and IIb implantable medical devices placed on the market after DoA (26 May 2021) with valid MDD/AIMDD certificate	**Class IIb WET implantable medical devices placed on the market after DoA (26 May 2021) with valid MDD/AIMDD certificate**	**Class IIb not-implantable medical devices placed on the market after DoA (26 May 2021) with valid MDD certificate**	**Class IIa implantable medical devices placed on the market after DoA (26 May 2021) with valid MDD certificate**	**Class IIa not-implantable medical devices placed on the market after DoA (26 May 2021) with valid MDD certificate**
Frequency	Yearly	Yearly	Yearly	Every 2 years	Every 2 years
PSUR uploaded to Eudamed	**Yes**	**Yes**	No	**Yes**	No
PSUR (first) availability	For first CE certificate issued between 27th November and 26th May, that aligns in the time period of 27th November 2021 and 26th May 2022. For first certificate issued between 27th May and 26th November, that aligns in the time period of 27th May 2022 and 26th November 2022.	For first CE certificate or FQA issued between 27th November and 26th May, that aligns in the time period of 27th November 2021 and 26th May 2022. For first certificate issued between 27th May and 26th November, that aligns in the time period of 27th May 2022 and 26th November 2022.	For first CE certificate or FQA issued between 27th November and 26th May, that aligns in the time period of 27th November 2021 and 26th May 2022. For first certificate issued between 27th May and 26th November, that aligns in the time period of 27th May 2022 and 26th November 2022	For first CE certificate or FQA issued between 27th November and 26th May, that aligns in the time period of 27th November 2022 and 26th May 2023. For first CE certificate or FQA issued between 27th May and 26th November, that aligns in the time period of 27th May 2023 and 26th November 2023	For first CE certificate or FQA issued between 27th November and 26th May, that aligns in the time period of 27th November 2022 and 26th May 2023. For first CE certificate or FQA issued between 27th May and 26th November, that aligns in the time period of 27th May 2023 and 26th November 2023

	(+ 90 days preparation by manufacturer) in accordance with Eudamed rules	(+ 90 days preparation by manufacturer) in accordance with Eudamed rules	(+ 180 days preparation by manufacturer)	(+ 90 days preparation by manufacturer) in accordance with Eudamed rules	(+ 180 days preparation by manufacturer)
PSUR recurring preparation and availability	One year after the first PSUR is submitted per above. If device holds MDD/AIMDD certificate and MDR certificate, reporting may occur only in MDR certificate PSUR. (+ 90 days preparation by manufacturer)	One year after the first PSUR is submitted per above. If device holds MDD/AIMDD certificate and MDR certificate, reporting may occur only in MDR certificate PSUR. (+ 90 days preparation by manufacturer)	One year after the first PSUR is submitted per above. If device holds MDD/AIMDD certificate and MDR certificate, reporting may occur only in MDR certificate PSUR. (+ 90 days preparation by manufacturer)	2 years after the first PSUR is submitted per above. If device is certified under MDD/AIMDD certificate and MDR certificate, reporting may occur only in MDR certificate PSUR. (+ 90 days preparation by manufacturer)	2 years after the first PSUR is submitted per above. If device is certified under MDD/AIMDD certificate and MDR certificate, reporting may occur only in MDR certificate PSUR. (+ 90 days preparation by manufacturer)
Notified body evaluation	**Yes**(+ 90 days after submission to EUDAMED by manufacturer)	**Yes** (as part of NB TF Sampling Plan)	Evaluation not required, only making it available. Notified bodies will be assessing this following a sampling plan.	**Yes**(+ 90 days after submission to EUDAMED by manufacturer)	Evaluation not required, only making it available. Notified bodies will be assessing this following a sampling plan.
Competent Authorities	Made available through Eudamed	Made available through Eudamed	Made available upon request	Made available through Eudamed	Made available upon request
In Technical Documentation	Yes, as specified in Annexes II and III	Yes, as specified in Annexes II and III	Yes, as specified in Annexes II and III	Yes, as specified in Annexes II and III	Yes, as specified in Annexes II and III

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9.5 ANNEX V: GUIDANCE FOR TEMPLATES FOR REPORTING OF DATA

Table 1. Volumes of sales* by region

Basic UDI-DI/ Legacy device name or model					
	Total Number of devices in expected lifetime	Reporting Day+ preceding 12 months (N)	N – 12 months (N2)	N2-12 months (N3)	N3-12 months (N4)
EEA+CH+TR					
WW					

* Indicate to what criteria the number of devices on the market is provided

Table 2. Size and characteristic of population

Basic UDI-DI/ Legacy device name or model					
Estimated size of the patient population	Estimated number of patients using the device	Proportion of elderly (%)	Proportion of paediatric patients (%)	Proportion of specify (%)	Proportion of specify (%)

Table 3. Incident rate (%)* of the serious incidents by IMDRF Problem Code

Basic UDI-DI/Legacy Device name or model					
IMDRF problem code by region		Reporting Day+ preceding 12 months (N)	N – 12 months (N2)	N2-12 months (N3)	N3-12 months (N4)
EEA+CH+TR					
WW					
EEA+CH+TR					
WW					

*The denominator is compatible to the number of devices in table 1

Table 4. Incident rate (%) of the Serious incidents over preceding 4 years* by IMDRF Problem Code for lower volume devices

IMDRF problem code by region		N of serious incidents	Incident rate **
EEA+CH+TR			
WW			
EEA+CH+TR			
WW			

*Use the data gathered until 4-year data is reached

** The denominator is compatible to the number of devices in table 1

Table 5. Incident rate (%)* of the Serious Incidents by Investigation finding code, region and time

Basic UDI-DI/Legacy Device name or model					
IMDRF Investigation finding code by region		Reporting Day+ preceding 12 months (N)	N – 12 months (N2)	N2-12 months (N3)	N3-12 months (N4)
EEA+CH+TR					
WW					
EEA+CH+TR					
WW					

* The denominator is compatible to the number of devices in table 1

Table 6. Health Effects by Investigation Conclusion code in last 4-years

BASIC UDI-DI/Legacy Device name or model					
IMDRF Health Effect code by region		Investigation conclusion code $_1$ %	Investigation conclusion code$_2$ %	Investigation conclusioncode$_3$ %	Investigation conclusion code$_4$ %
EEA+CH+TR					
WW					
EEA+CH+TR					
WW					

Table 7. Incident rate (%) of incidents and expected side-effects reported on the trend reports by the IMDRF Problem Code

BASIC UDI-DI/Legacy Device name or model					
IMDRF problem code by region		Date the trend detected	Trigger for the trend	Observed Incident rate	Basis for the report**
EEA+CH+TR*					
WW					
EEA+CH+TR					
WW					

*****provide a list of affected countries in EU

** I = incident, S= expected side effect

Table 8. Health Effects by Investigation Conclusion code in last 4-years detected within trend reports

BASIC UDI-DI/Legacy Device name or model						
IMDRF Health Effect code by region		N of trend reports	Investigation conclusion code $_1$ %	Investigation conclusion code$_2$ %	Investigation conclusioncode$_3$ %	Investigation conclusion code$_4$ %
EEA+CH+TR						
WW						
EEA+CH+TR						
WW						

Table 9. CAPA taken in current reporting period and open cases

BASIC UDI-DI/Legacy Device name or model							
Type of action	Starting Date	Status of the CAPA	Mnfr. Reference number	Rationale and description of action taken	Impacted regions	Root cause	FSCA issued (Y/N)

Table 10. FSCA and the status of the FSCA in current reporting period and open FSCAs issues formerly*

BASIC UDI-DI/Device name or model					
Type of action	Starting Date	Status of the FSCA	Mnfr. Reference number	Rationale and description of action taken	Impacted regions

* Will be further developed when the new FSCA form is in use.

Table 11. Other data sources

Type of data	Number of patients involved	A relevant specifier (N of complaints, devices)

Table 12. Observed new risks and benefits and benefits not achieved

Type of phenomena (R,B,No B)*	Name of the Risk/Benefit/ Benefit not achieved	Prevalence in current PSUR	Acceptance measure	Change to Benefit risk ratio (Y/N)

*R=risk, B= benefit, No B= Intended benefit not achieved

9.6 ANNEX VI : PSUR FORM and NB EVALATION FORM

Periodic Safety Update Report by Manufacturer

1	**Manufacturer information**		
a	Manufacturer SRN		
b	Manufacturer organisation name		
c	Contact's first name	**d**	Contact's last name
e	Email	**f**	Phone
g	Country		
h	Street	i	Street number
j	Address complement	k	PO Box
l	City name	m	Postal code
4	**Corresponding Competent Authority**		
a	Name of national competent authority (NCA)		
b	EUDAMED number of NCA		
4	**Medical Device Information**		
a	Basic UDI (s)-		
b	Eudamed DI (s)		
c	Custom Made Device Model		
d	Well Established Technology Y/N		
2	**PSUR Submission in Eudamed**		
a	Date of submission YYYY MM DD	Scheduled date YYYY MM DD	Timeliness Days
b	PSUR Reference number		

c	Data collection period YYYY MM DD - YYYY MM DD		
d	Version Number		
3	**Notified Body**		
a	NB organisation name and number		
b	Contact's first name	**c**	Contact's last name
4	Upload the PSUR document (including the completeness check document)		

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PSUR Evaluation Report by Notified Body

1	**NB Information**		
a	NB Organization Number		
b	NB Organization Name		
c	Contact's first name	**d**	Contact's last name
e	Email	**f**	Phone
g	Country		
h	Street	**i**	Street number
j	Address complement	**k**	PO Box
l	City name	**m**	Postal code
2	Designating Authority of the NB		
a	Name of national competent authority (NCA)		
b	EUDAMED number of NCA		
3	**Identification of the PSUR**		
a	Manufacturer's Single registration number		
b	Manufacturer's name		
d	PSUR Reference number		
e	Time period of the PSUR report		

	YYYY MM DD - YYYY MM DD
f	PSUR Version Number
g	Certificate number(s)
4	**Identification of the Evaluation Report**
a	Date of submission YYYY MM DD Scheduled date YYYY MM DD NB Evaluation Timeliness ☐
b	Evaluation report reference number
c	Duration of the whole process Days
5	**PSUR resolution**
	☐ WET, no evaluation report for current PSUR ☐ Accepted ☐ Rejected ☐ Actions requested by the Notify Body
6	Upload the PSUR Evaluation Report

9.7 Annex VII: TERMINOLOGY

Benefit-risk determination: the analysis of all assessments of benefit and risk of possible relevance for the use of the device for the intended purpose, when used in accordance with the intended purpose given by the manufacturer. MDR Article 2(24).

Equivalent medical devices: Devices in which clinical, technical and biological characteristics defined in Annex XIV part A shall be similar to the extent that there would be no clinically significant difference in the safety and clinical performance of the device. MDR Annex XIV part A, section 3.

Making available in the market: means any supply of a device, other than an investigational device, for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge. MDR Article 2(27)

OLD DEVICES; MDD devices, not placed on the market after 26 May 2021)

PERIODIC SAFETY UPDATE REPORT (PSUR): 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 summarising the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan referred to in Article 84 together with a rationale and description of any preventive and corrective actions taken. MDR Article 86. The PSUR (REPORT) is composed of two elements: the PSUR FORM and the PSUR DOCUMENT.

PSUR FORM: Template that contains all the relevant administrative data requested in the PSUR. This FORM details information regarding the medical device, manufacturer, NB and the management of the PSUR process.

PSUR DOCUMENT: Single stand-alone document for the reporting PSUR interval that will be always attached as a PDF to the PSUR FORM and contains the data, tables and summarises the results and conclusions for the analyses of the post-market surveillance data.

Placing on the market: means the first making available of a device, other than an investigational device, on the Union market. MDR Article 2(28)

Post-market surveillance (PMS) means all activities carried out by manufacturers in cooperation with other economic operators to institute and keep up to date a systematic procedure to proactively collect and review experience gained from devices they place on the market, make available on the market or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions. MDR Article 2(60).

Putting into service: means the stage at which a device, other than an investigational device, has been made available to the final user as being ready for use on the Union market for the first time for its intended purpose. MDR Article 2(29).

Serious public health threat: means an event which could result in imminent risk of death, serious deterioration in a person´s state of health, or serious illness, that may require prompt remedial action, and that may cause significant morbidity or mortality in humans, or that is unusual or unexpected for the given place and time. MDR Article 2(66).

Similar medical devices: devices belonging to the same generic device group. The MDR defines this as a set of devices having the same or similar intended purposes or a commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics. MDCG 2020-6. (MDR 2 (7))

Legacy devices: Devices with a valid certificate issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC which are continued being placed on the market or put into service after the MDR Date of Application (DoA), 26 May 2021.