**MDCG 2022-21 – Periodic Safety Update Reports (PSUR)**

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**ANNEX I: Template for the PSUR**

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

The PSUR should provide a general overview of all post-market surveillance activities and the data collected and analysed based on the PMS plan for the device. Therefore, the aim of the PSUR is not to duplicate all data and reports generated by the PMS Plan but it should summarize all results and conclusions.

The manufacturer should specify the relevant information and sections of the different reports and provide a summary of the data collected, their assessment and conclusion as well as any actions taken when appropriate. If a manufacturer decides that specific data sets are not used or deemed to be not required, the manufacturer should duly justify the absence of the data sets not included in the relevant sections of the PSUR.

It is recommended to add an executive summary in particular as regards the main relevant information related to benefits and risks and to the changes in the acceptability of the benefit-risk profile.

**PSUR cover page**

The PSUR cover page includes the relevant data to allow distinguishing between the various PSUR updates.

For those PSURs submitted to EUDAMED, the PSUR form (EUDAMED Web form, see Annex V) can be considered as a cover page. A Table of Contents should also be present for all PSURs.

The cover page should at least include the following information:

* Manufacturer information
* Medical device(s) covered by the PSUR
* Notified body name and organization number;
* PSUR reference number assigned by the manufacturer\*;
* Version number of the PSUR;  The data collection period covered by the PSUR;
* Table of contents.

**Executive summary**

When an executive summary is produced, it should provide a brief overview of the PSUR content and an overall conclusion in relation to the benefit-risk determination.

It should include the following information:

* A brief description and status of actions taken by the manufacturer based on the previous PSUR;
* A brief description and status of actions taken by the Notified Body as part of the review of the previous PSUR;
* In case the data collection period is changed by the manufacturer, a justification should be provided, and a statement should be provided whether the change affects the comparability of the results gained;
* Once the conclusions of the PSUR have been completed, the main results of the current PSUR should include a clear and bold statement declaring whether the benefit-risk profile has been impacted, negatively or positively or remains unchanged, based on the information reported within the current PSUR. The statement could be a simple expression, for example “Based on the analysis of the collected data, it is concluded that the benefit-risk profile of the device(s) has not been (or has been) adversely impacted / remains unchanged”.

**Description of the devices covered by the PSUR and their intended uses (Article 86.1)**

This section is intended to provide an overview of the devices covered by the PSUR and the possible changes to its scope. The added and removed devices should be clearly identified. The following information should be included for the devices covered by the PSUR:

* Device Classification (risk class of device) in accordance with the applicable classification rules.
* Date from one of the following: first declaration of conformity, first EC / EU Certificate issued, first date device CE-marked, first placed on the market, first put into service, if software, date first made available.
* Status of the device(s): on the market, no longer placed on the market, recalled, field safety corrective action initiated.
* The intended purpose of the device(s) as per the Instructions for Use according to Annex I, Chapter III, 23.4(b) MDR, any indications, contra-indications, and target populations.

- For MDR Devices

* The information shall be broken down by the Basic UDI-DI(s) and explain any device changes within each Basic UDI-DI compared to the previous PSUR to comprehend possible changes in results compared to the previous PSURs.
* Provide device trade name(s) associated to the corresponding Basic DI(s) and the European Medical Device Nomenclature (EMDN)

- For Legacy Devices

* The information shall be broken down by device group/family of devices
* Provide device trade name(s) (this includes all trade names the device may have on the market in different Member States) and European Medical device Nomenclature (EMDN).
* For Custom-Made Devices (MDR)
* Provide the required information by device group.

**Grouping of the Devices**

Information regarding the grouping of devices are provided in section 4 of this guidance.

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

**Volume of Sales (Article 86.1)**

* The manufacturer should consider all the devices placed on the market. This could be volumes of sales, units shipped, or units implanted or another suitable indicator. Whichever method is used should be consistent throughout the PSUR in all areas to allow for a comparison of data. Provide accurate information the number of devices sold. The data should be presented by year to year (see Annex II, Table 1).
* Provide further information on the volume of sales in respect to the various sizes, models and configurations of the device as deemed necessary.
* 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 or EC/EU mark approval to the end date of each time period;
  + Number of devices implanted;
  + Other – description/rational should be provided.

**Size and other characteristics of the population using the device (Article 86.1)**

* Evaluate how many patients have been exposed to the device and the characteristics of the exposed patient group(s).
* Estimate the number of patients exposed, as the sales numbers alone do not necessarily reflect the number of uses of the device (usage frequency). There are different scenarios as: Active devices may have a lifetime of several years with multiple uses each day, resulting in high number of patients exposed to the device (e.g. CTs). In case of implants, multiple devices may be used in one patient, e.g. several bone screws in one surgery. For other devices, the sales numbers directly correlate with the patient number exposed to the device.
* Describe the 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 if clinically relevant and known by the manufacturer.
* When possible, consideration should be given to patient demographic aspects.
* When applicable, evaluate the effect of the detected changes to findings obtained previously and in the current PSUR.

**Post-Market Surveillance: Vigilance and CAPA information**

Background information should be 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 new risks or emerging trends reported in earlier PSURs.

Vigilance data consist of information concerning serious incidents, field safety corrective actions (FSCAs) and trend reports. The data could be presented in tables, figures and/or in text format. The aim of the data presentation is to provide an accurate summary and appraisal of the Vigilance data (Article 87 and Article 88 MDR) and CAPA data (Article 83(4) and Article 86 MDR) for the reported data collection period and to compare with the same types of data from the previous PSURs.

The data should be presented by the device (Basic UDI-DI), device group (CMD) or device group/family level (legacy devices). When justified, the data can be presented for combinations of devices, for example, a device and its accessory.

1. Information concerning Serious Incidents (Article 87, Annex III MDR)

* The aim is to present the serious incidents and their impact on the overall device safety. This section should characterize the data from at least three different perspectives: the device problems, the root cause and the health effects on the person(s) affected. In addition to the data, provide a summary text regarding any new types of serious incidents which have occurred since the last report.
* Data regarding serious incidents should be reported using the IMDRF Adverse Event Terminology (AET) (link to [IMDRF](https://www.imdrf.org/documents/terminologies-categorized-adverse-event-reporting-aer-terms-terminology-and-codes) website), when available. With regard to the historical data, the usage of the IMDRF Adverse Event Terminology is not required.
* The usages of the Level 2 terms/codes are considered sufficient to enable the grouping of the serious incidents;
* Report both the codes and the terms.
* When applicable report both absolute figures and rate of the serious incidents and split the data by region (EEA+TR+XI) and worldwide.
* Examples of the data presentation are shared in Annex II of this guidance.
* The most frequent medical device problems by IMDRF Adverse Event Terminology Annex A – “Medical Device Problem”, by year to year- (see Annex II, Table 4).
* The most common investigation findings as part of the completed “cause investigation” of the serious incidents by IMDRF Adverse Event Terminology Annex C – “Investigation Findings”, (see Annex II, Table 5).
* The health impacts on the person affected as a consequence of the medical device serious incident by IMDRF Adverse Event Terminology Annex F – “Health Impact”, including the term and code. It could also be used for the 4year summary data (starting as of the device MDR certification date or the MDR date of application for legacy devices) and split the data by the IMDRF Adverse Event Terminology Annex D – “Investigation Conclusion” (including term and code). Use only the most relevant investigation conclusion terms/codes which are related to the detected health impacts. Report the most common health impacts as well as any cases resulting into death, regardless if they are included in the most common health impacts. In addition, split the data by region (see Annex II, Table 6).

1. Information from Trend Reporting (Article 88, Annex III MDR, non-serious incidents and expected undesirable side effects)

The data related to the trend reports will be detailed after the adoption of the MDCG guidance on trend reporting.

1. Information from Field Safety Corrective Actions (FSCA) (Article 87, Annex II MDR)

* Provide a summary of the FSCAs for the period of the PSUR and compare with the information from the previous PSURs.
* The summary should include the following information (*When EUDAMED will become fully functional, the information that need to be collected may change and the information presented in this section should be updated accordingly)*:
* types of actions.
* issuing date,
* scope of the FSCA,
* status of the FSCA at the time of the PSUR,
* manufacturer’s reference number,
* a brief description of the reason for action and description of action and impacted regions.

An example of the data presentation is presented in Annex II of this guidance (table 7).

1. Preventive and / or Corrective Actions (CAPA) (Article 83.4 and Article 86 MDR)

* Provide a list of all preventive and / or corrective actions (CAPA) according to Article 83(4) and to Article 86.
* The following information should be provided for each CAPA:
* the type of action,
* initiation date,
* scope of the CAPA,
* status of the action,
* manufacturer’s reference number,
* CAPA description,
* The root cause (internal codes with the explanation, IMDRF terms/codes or free text),
* effectiveness of the CAPA

An example of the data presentation is presented in Annex II of this guidance (table 8).

**Post-Market Surveillance: information including general Post-Market Clinical Follow-up (PMCF) information (Annex III and Annex XIV, Part B, 6.2(a) and (f) MDR)**

The data that should be reported in this section consist of other PMS datasets not referred to above and are generated by general methods and procedures of PMCF (Annexes III, Annex XIV Part B, 6.2 (a) and (f) MDR). The sections below should be completed in alignment with the PMS and PMCF plans.

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

1. Feedbacks and complaints from users, distributors and importers

* All feedback from users, distributors and importers and complaints not reported in the Vigilance section above should be considered in this section. The most common complaints should be presented within this section of the PSUR with the following considerations:
  + Grouping of complaints by IMDRF Adverse Event Terminology Annex A – “Medical Device Problem” (including the term and code) or internal event codes including term;
  + Occurence rate (including reference chosen);
  + Justification for inclusion of these groups of complaints and exclusion of those not presented;
  + Information whether the presented complaints have led to initiation of preventive and / or corrective actions (CAPA).

1. Scientific Literature Review of relevant specialist or technical literature

* For detailed information about literature searches conducted and results generated, the manufacturer may refer to the technical documentation.

1. Public Databases and /or 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.

1. Publicly Available Information about Similar Medical Devices

* Additional publicly available information may include information gathered from other manufacturers of similar medical devices, (e.g. results of a manufacturer’s specific PMCF study made publicly available in the manufacturer’s Summary of Safety and Clinical Performance (SSCP), Cochrane Library or other libraries);
* The type and location of this information should be provided, and when possible a comparison of the devices with same intended purpose should be evaluated with any possible differences in safety and performance reported.

1. Other Data Sources

* The other used data sources could be for example real-world data from electronic health records and digital health-monitoring devices;
* Provide a list of the used data sources and findings with specific reference to safety and performance of the device.

**Specific Post-Market Clinical Follow-up (PMCF) Information (Article 86, MDR Annex XIV, Part B, 6.2(b))**

This section should include a summary of the findings generated from the analysis of specific PMCF activities performed by the manufacturer as defined in Annex XIV, Part B, 6.2(b). This section is not limited to PMCF studies and should include other specific PMCF activities conducted by the manufacturer.

For this section, the manufacturer should refer to the main findings of the PMCF and, when available, to the conclusions documented in the PMCF Evaluation Report to allow for a comprehensive assessment of the specific PMCF activities it has performed.

**Summary of Findings and Conclusions of the PSUR**

In this section of the PSUR, the manufacturer should consider the validity of the collected data taking into consideration any deficiencies or bias, and provide a conclusion on the benefits and risks of the device from the gathered data. In the case when these data have had any impact on the overall benefit-risk determination, this should be described. The manufacturer should also outline all actions that have been taken as a result of the analysis of data collected since the last PSUR.

1. Validity of the collected data

* The manufacturer should identify any limitations to the data that have been collected, this could include for example reduced sales or usage of the device, known bias from feedback obtained or enrolment into a PMCF study.
* The manufacturer should consider whether these limitations impact the ability to formulate meaningful conclusions and whether an impact assessment of the overall benefit-risk profile is still possible.

1. Overall conclusions from the analysis of the collected data

* The manufacturer should outline any new or emerging risks identified or when common occurrences of poor performance or claimed benefits have not been achieved within the current reporting period. When there are new or emerging risks that have been identified, the manufacturer should consider any specific patient groups, device models, accessories used, geographical regions impacted, duration of risk etc. Specific information should be provided on the seriousness and the full potential clinical impact of these risks.
* The manufacturer may also describe any new benefits that have been identified from the reporting period.
* The manufacturer should formulate evidence-based conclusions to determine whether the benefit-risk profile of the device has changed or not.
* Finally, within the conclusion, the manufacturer should declare whether there has been an adverse impact on the benefit-risk profile of the device or the benefit-risk profile remains unchanged.

1. Actions taken by the manufacturer

* The manufacturer should describe any specific actions that have been taken to address any newly identified or emerging risks and occurrences of poor performance.
* The manufacturer should identify all actions initiated during the data collection period as described in Article 83 (3).