2019

Draft

C

10.1.2020

Table of Contents

1. Introduction

The Periodic safety update report (PSUR) is a post-market surveillance documents that is generated utilizing vigilance and Post-Market Clinical Follow-up (PMCF) data. The PSUR is a standalone, comprehensive report that is prepared by the manufacturer of the medical devices at least at defined time points during the port-market phase. The manufacturer of the medical device is responsible for compiling the PSUR for his devices.

A PSUR can include an individual device or multiple devices. Where multiple devices are included, they are linked by the CE certificate. The PSUR should only relate to devices that have been certified by one Notified Body.

The main objective of a PSUR is to present a comprehensive, concise and critical analysis of the benefit risk balance of the medical device considering new or emerging information in the context of cumulative information on risks and benefits. It summarises data gathered during the post market phase, including the results of studies carried out, observed vigilance incidents and other datasets used in Post Market Surveillance (PMS) actions with this medical device.

The legal requirements for PSURs are established in REGULATION (EU) 2017/745 Article 86. The required content of PSURs is based on requirements outlined in Annex III and Annex XIV part B (MDR 2017/745).

This guideline provides guidance on the preparation and submission of PSURs. This guidance document is a consensus document that was developed by the EU Commission, member states, Industry and Notified Bodies.

2. Structures and processes

Who should prepare PSUR?

The Medical device Regulations REGULATION (EU) 2017/745 Article 86 requires Manufacturers of Class III, Class IIb and Class IIa medical devices to prepare the PSUR.

The manufacturer is responsible for the PSUR however other economic operators - Authorised Representatives, Distributors, Importers must assist the manufacturer in contributing for gathering the necessary information.

Article 122 of the Regulation also obliges Manufacturers that have placed devices on the market under the Medical Devices Directive to prepare a PSUR.

It should be limited to legacy devices still placed on the market during the "grace period".

Other devices are subject to vigilance, but a PSUR cannot be requested.

We must realize that otherwise, it would imply we initiate PSUR for very old devices not placed on the market for years already...

Timelines for PSUR preparation

The requirement to prepare the PSUR start at the date of the application of the MDR.

The first PSUR should be prepared one or two (class IIa devices) year following the certification of the device under the MDR. The preparation of PSURs should continue throughout the lifetime of the device. The lifetime of the device as indicated by the manufacturer in the device technical documentation (Annex II). The preparation of PSURs should continue throughout the lifetime of the device even in the case where the certificate for the device may be withdrawn.

For devices which are legally placed on the market under MDD/AIMDD/IVDD and still have a valid certificate after May 26, 2020 a PSUR is required latest one year or two years, based on product classification, after date of the application of the MDR.

(*Which period of time?)*Manufacturers of class IIb and III devices shall updated the PSUR at least annually and manufacturers of class IIa devices shall update the PSUR when necessary and at least every two years.

The Manufacture should complete the PSUR report on the required dated, or no later than 120 days exceeding this date. When required, The prompt submission of the report will allow the Notified Bodies to conduct their evaluation within a three-month period and when necessary the manufacturer have the time to update the PSUR.

Format of the PSUR

As the PSUR should be a single stand–alone document for the reporting interval, based on cumulative data, summary bridging reports and addendum reports will not be accepted. The PSUR shall be based on all available data and shall focus on new information which has emerged since the data lock point of the last PSUR.

t is recognised that the format of PSUR is depending on whether it should be submitted to Eudamed or not. The level of detail provided in certain sections of the PSUR should depend on the device class and known or emerging important information on the medical device's benefits and risks. The extent of the information provided may vary for example according to the length of the marketing history or clinical experience with healthcare.

PSURs submitted to Eudamed consist of two principal elements: the PSUR FORM and the PSUR DOCUMENT. The PSUR FORM details information regarding the manufacturer, NB, device and the management of the PSUR process (appendix 1). The contents of PSUR DOCUMENT is described in the section 3 and should include interval as well as cumulative data. The content of the PSUR DOCUMENT is related to the post market data, its analysis and conclusions in point of view of the benefit-risk balance.

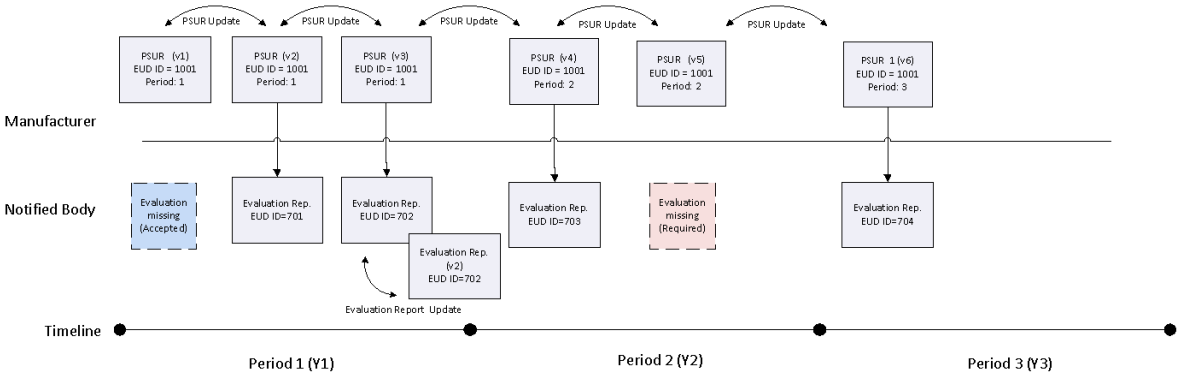
The PSURs not submitted to Eudamed consist solely of the PSUR DOCUMENT. To ensure the PSUR is a standalone document the required data should be added on the beginning of the PSUR DOCUMENT.

When required, In addition to the manufacturers PSUR the Notified Body NB's evaluation report also consists of two principal elements like the PSUR: the NB Evaluation form (appendix 2) and NB Evaluation document.

PSUR process

PSURs are part of the device technical documentation or part of the custom-made device documentation.

The PSUR process consists of repeated cycles, called PSUR periods. The duration of one *PSUR period* is same as the duration of the certificate i.e. a new certificate will start a new PSUR period. The PSUR periods are separated from each other by ID number. Each PSUR period is divided into *PSUR reporting periods*. *PSUR reporting periods* are separated by PSUR Period number and dates. The first PSUR reporting period is Period One, the second is Period Two, etc. The PSUR reporting period closes when the timeline stated in article 86 and 81 i.e. one or two years is reached. Within one PSUR reporting period several updates can be prepared. The updated versions are separated by the version number (V1, V2 etc.).



The PSUR ID number is generated by Eudamed or given by the manufacture. In Eudamed the above-mentioned documents are connected to each other by the manufacturer's Single Registration Number and PSUR process data.

The manufacturer should submit the PSUR regarding class IIb and III devices directly via email to their Notified Body and when request to the Competent Authority.

There might be exceptional scenarios where a Notified body or a competent authority may request the preparation of separate PSURs, for instance, where the evaluation of a serious public health issue is ongoing.

Who shall review the PSUR

NB should annually review and evaluate PSURs regarding class III and implantable device. During the surveillance audits NB should review and evaluate a sample of PSURs regarding the other device classes i.e. class IIa and class IIb non-implantable devices. The evaluation should happen annually or every two-year depending on the device class. The document Guidance on sampling of MDR Class IIa / Class IIb and IVDR Class B / Class C devices for the assessment of the technical documentation should be utilize through sampling.

Class III and implantable devices evaluation report shall be made available to competent authorities (CA) via email.

The NB evaluation report and PSUR are connected by PSUR running number and the date of the reporting period The NB Evaluation reports are separate from each other by the ID number. The evaluation report ID changes from report to report. Finally, NB adds the categorized outcome of the evaluation on the NB Evaluation form and to the PSUR form.

The Notified Body should then, following their assessment, circulate the PSUR and their assessment to the responsible CA.

The competent authorities may also request and review PSURs as part of their vigilance investigations, clinical trial reviews and market surveillance activities. The results of their evaluation will be/ will not be added to the database.

The PSUR process follow-up

To ensure the manufacturer fulfil the obligations to prepare PSUR according to the regulation the NB should evaluate at minimum 10 % of the PSUR FORMs during the surveillance audits.

3 PSUR document

The PSUR document includes information related to the data gathered during the PSUR reporting year or years and the conclusions made by the analysis of the data throughout PSUR period *(The idea in the current guidance document is that the data is presented yearly (two years) but the analysis are made by the certificate period. Needs discussion whether it is better to use one/two year period for both actions.)*. The PSUR should include the following 6 sections: An Executive Summary, Estimated volume of sales, population, and usage frequency of the devices, Overview of Post Market Surveillance data, Evaluation of post-market data, The assessment of the benefit-risk ratio. Guidance on what should be included in each of these sections is outlined below:

3.1. Executive Summary

The manufacturer should briefly outline the main results and provide background information in support of the current PSUR so that the PSUR "stands alone". It should also place the current PSUR in perspective relative to previous PSURs and in context with other post-market surveillance system documents, such as Risk management Plan and Report, PMCF Plan and Report, and the Clinical Evaluation Plan and Report.

3.2 Estimated volume of sales, population, and usage frequency of the devices

This section of the PSUR should provide a clear picture of the usage of the device including volume of sales, patient population and usage frequency.

3.2.1 Volume of sales

The PSUR shall provide an accurate estimate of the number of devices sold. The devices should be grouped by basic UDI-DI level. For devices placed on the market without a Basic UDI-DI and custom-made devices the number of sold devices should be grouped based on the model of device.

The number of devices provided should be based on the worldwide volumes of sales and should be broken down to the volume of sales in EEA + CH + TR and Worldwide.

Details of the total number of the devices sold during the preceding 4 years should be provided as well as the number of devices that remain on the market and are within their expected lifetime. This number should be broken down to reflect the various sizes, models and system components of the device. Where applicable and where possible, an estimate of the number of devices remaining in use in Europe should be included.

Depending on the product type, the number of products placed on the market can be reporting using one of the following issues:

- Total number of devices placed on the market or put into service
- Number of implanted devices
- Number of units distributed within a defined period
- Devices on the market, based on: Devices placed on the market or put into service
- Number of tests diagnostic tests on patients or patient samples performed
- Number of episodes of use (for reusable devices)
- Active installed base
- Other (describe)

Consistent methods for calculating the distribution or implant numbers should be used throughout the PSUR. If a change in the method is required, both the method and calculation should be provided in the PSUR introducing the change, and any significant differences between the results using the two methods should be highlighted. However, the change of the method could not materialize during the PSUR period.

Table 1. Worldwide volumes of sales (reported by EEA + CH + TR and World)

Device name					
	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					
World					

Comment : It will be cumbersome to recalculate the number of sales on periods depending on the PSUR date.

Sales data are available in the companies based on fixed periods and not moving annual total.

We suggest to use the preceeding full years (as in the MIR form) and to recalculate on an annual basis only the period N in order to get consistent data.

3.2.2 Characteristics of the population using the device

This sub-section should provide an estimate of the size and other characteristics of the population using the device (Treated populations, more than users. But, type of users may also be important

). Where post-market use of the device has occurred in special populations, information regarding cumulative device distribution numbers or number of patients having implants and the method of calculation should be provided. Populations to be considered for discussion might include

- elderly population
- paediatric population
- pregnant or lactating women

- patients with hepatic and/or renal impairment;
- patients with other relevant co-morbidity
- patients with disease severity different from that studied in clinical studies
- Off label use

Table 2. Size and characteristic of population (include if available)

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 (%)

3.2.3. Special considerations regarding implants

This sub-section should provide estimates of the size and nature of the population with the implanted medical device *(and annex XVI devices)*. An overall estimate of the time that the devices have been implanted should be provided as well as the time to the expected lifetime of the device. Depending upon the implant, other variables may be relevant, such as life cycle of the implanted product, etc.

Table?

3. 3 Overview of Post Market Surveillance data

This sub-section should provide a summary of the data obtained in the current PSUR reporting period. It may include information from the PMS plan and PMCF data. Analysis or conclusions based on the summary tables should not be provided in this section instead they should be provided in the following section 3.4 "Evaluation of the post market data".

3.3.1 Post Market Clinical Follow-up Studies and post market performance follow-up studies

In this sub- section a list of any completed and ongoing PMCF studies worldwide should be provided. It should also detail the latest enrolment numbers. Do not report the clinical investigations.

Table 3. List of the PMCF studies

Name or code of the study	Completed (Yes/No)	Name of study countries	Number of study sites	N of patients enrolled and the target number		N of serious incidents	Serious incident rate (%)	N of deaths

For each study listed above more detailed information is required. Including a cumulative summary table of reportable incidents from ongoing PMCF studies. The table should include only the ten most common serious incidents where the leading code is the device problem code and where the incidents occurred in EEA + CH + TR.

Table 4. Type and number of serious incidents occurred within PMCF studies

Name or code of the study						
Device name						
Problem code	Health Effect	Investigation Finding	N of incidents	Number of incidents by Region		Incident rate (%)
				WW		
				EEA+CH+TR		
				WW		
				EEA+CH+TR		

3.3.2 Vigilance data outside clinical studies and post market performance follow-up studies

This sub-section should provide the worldwide data for all serious incidents not included in clinical studies. The serious incidents and incidents (non-serious incidents) are reported in separate tables. The tables should be structured using Basic UDI-DI. For devices without Basic UDI-DI the tables should be structured according to the way the number of sales is reported i.e. based on the model of device.

Tables five and six should include all serious incidents that occurred within the PSUR reporting period (PSUR period and PSUR reporting period is related to the duration of the certificate. Needs conversation). Table five is for the high-volume sales of device and the table six for the low-volume sales of devices. The low volume sales of devices should be reported in a separate table since one PSUR reporting period might be too short to identify serious incidents.

The data relating to serious incidents should be broken down by the IMDRF codes and by region the serious incident occurred. The IMDRF codes used in reporting are: the device problem code, health effect and investigation finding codes. The leading code should be the device problem code for serious incidents occurred in EEA + CH + TR.

Table 5. Serious incidents by the IMDRF codes and EEA + CH + TR and World

Device name						
Problem code	Health Effect	Investigation Finding	N of serious incidents during PSUR reporting period	Number of serious incidents by Region		Incident rate (%)
				WW		
				EEA+CH+TR		
				WW		
				EEA+CH+TR		

For the low-volume devices the recommended time period for data is 4 year, but it could be defined by the manufacturer based on the number of devices sold. Similarly for high-volume devices the leading code should be the device problem code for serious incidents occurred in EEA + CH + TR.

Table 6. Serious incidents over preceding XX years for lower volume devices.

Device name						
Problem code	Health Effect	Investigation Finding	N of serious incidents during xxx years	Number of serious incidents by Region		Incident rate (%)
				WW		
				EEA+CH+TR		
				WW		
				EEA+CH+TR		

The data relating to incidents (non-serious) should include both those incidents that manufacturer has categorised a as trend report and incidents not included in a trend report. Of the latter, the ten most common incidents should be reported. The data should be broken indicating the device problem code and region where the incident occurred.

Table 7. Incidents during PSUR reporting period by device problem code and region

Device Problem Code	Health Effect	Included in trend report (Y/N)	N of incidents during PSUR reporting period	Number of incidents by Region		Incident Rate (%)
				WW		
				EEA+CH+TR		
				WW		
				EEA+CH+TR		

Comment for "Health Effect" : For one product problem code we may have multiple health effects.

3.3.3 Preventive and corrective actions taken for safety reasons

This sub-section should include a description of safety related preventive and corrective actions that have been taken during the PSUR reporting period. It should include all worldwide action that may have an impact on CE-marked devices. All actions including those that have been initiated by the manufacturer (and/or authorised representative, importer, distributor), notified body or competent authorities should be included.

For each action, the date when it was taken, Manufacturer's reference number, a brief description of the reason for action and status at the time of the PSUR (i.e. initial, follow-up, final) should be included. Field safety corrective actions (FSCA) and other actions taken for the safety reasons should be reported separately (see below).

Preventive and corrective actions that have been taken for safety reasons and that have not led to a FSCA should be considered under the following headings:

- Design changes implemented/on-going
- Significant process/manufacturing changes

- Changes to labelling/IFU
- Plans for new studies to address safety concerns including new post-marketing study requirement(s) imposed by competent authorities.
- Other preventive or corrective actions.

Table 8. FSCA during the PSUR reporting period and the status of the FSCA

Device name					
Type of action	Starting Date	Staus of the FSCA	Mnfr. Reference number	Rationale and description of action taken	Impacted regions

Table 9. Actions taken for safety reasons outside the FSCA

Type of action	Starting Date	Staus of the action	Rationale and description of action taken	Impacted regions

3.3.4 Other data source used in PSUR

This sub-section should include a list of all other data sources considered during the PSUR reporting period such as, relevant specialist or technical literature, databases and/or registers, customers surveys, feedbacks and complaints provided by users, distributors and importers and publicly available information about similar medical devices. Data from other sources such as compassionate use, or custom-made devices should also be included.

Literature searches for the PSUR should be wider than the involved medical device as they should also include data dealing with the same type of device (same or different manufacturer).

Table 10. Other data sources

Data source	A relevant specifier (N of complaints, devices)

3.4. Evaluation of post-market data

This sub-section should provide a summary of the clinically significant performance and safety findings identified during the PSUR period (i.e. certificate validity period). It should, where possible include information that supports or refutes previously identified safety concerns as well as evidence relating to

new safety signals. Information relating to use errors or device combinations should also be considered for inclusion.

Each dataset should be analysed individually, and a summary of the overall findings /results should be made. The evaluation should be done in relation to the known and possible new side-effects and in accordance with the previously defined thresholds (Annex I, section 3).

3.4.1 Evaluation of the Post Market Clinical Follow-up Studies and post market performance follow-up studies

This sub-section should provide a brief summary of clinically significant performance and safety findings identified from clinical post-market studies within the PSUR period. The results of the PMCF studies should be reported for both ongoing and completed studies. Findings from completed studies should be evaluated against each other and the possible conflicting results should be considered and reflected. The findings should be reported preferably in a table so that historical information can be easily examined.

Table 11. The results of the PMCF studies

Study name	Finding	Previously known (Y/N)	Prevalence		Contradictory (Y/N)
			Estimated	Observed	

3.4.2 Evaluation of the vigilance data arising from outside post market clinical studies and post market performance follow-up studies

This sub-section should provide analysis and conclusions drawn from the vigilance data (serious incidents, non-serious incidents, use error, or device compatibility issues) summary tables in section 3.2 in relation to the vigilance data gathered during the PSUR period. The analysis should be made in relation to the region (EEA + CH+ TR and worldwide) and when necessary assess the possible differences.

The data should be analysed using the IMDRF investigation finding codes the IMDRF investigation finding codes and should reflect the change over time including the cumulative incident rate. In cases the investigation finding code is undetermined the clarification for it should be included.

Table 12. Vigilance data by Investigation finding code and region

Investigation finding code	Cumulative Serious Incident rate (%)		Number of Serious Incidents PSUR Reporting period (N)		N – 12 months (N2)		N2-12 months (N3)		N3-12 months (N4)	
	WW		WW		WW		WW		WW	
	EEA＋CH ＋TR		EEA ＋CH＋TR		EEA ＋CH＋TR		EEA＋CH ＋TR		EA＋CH ＋TR	
	WW		WW		WW		WW		WW	

	EEA＋CH＋TR		EEA＋CH＋TR		EEA＋CH＋TR		EEA＋CH＋TR		EEA＋CH＋TR	

Note for new safety data relating to the use of a number of device combinations it is important to summarize the important safety findings e.g. valve-in-valve transcatheter procedure, modular hip replacement procedure. The data can be used to evaluate the compatibility of devices.

3.4.3 Evaluation of the preventive and corrective actions taken for safety reasons

This sub-section should provide the analysis and conclusions drawn from the summary tables in section 3.3 in relation to the data gathered during the PSUR period. A conclusion of the effectiveness of any corrective/preventive actions should be detailed and any changes in type of the corrective/preventive actions should be evaluated. Any deviations from the defined actions should be explained and an explanation outlining whether identical corrective or preventive actions are taken repeatedly.

3.4.4 Evaluation of the other data source used in PSUR

This sub-section should include an assessment of any clinically significant safety information that has been obtained from the data sources listed in table 10 within PSUR period. Assessment from other sources, such as compassionate use, or custom-made devices should also be included.

Table 10. Other data sources

Data source	A relevant specifier (N of complaints, devices)

3.4.5 Summary of the findings

This section should include a list of the most important findings, the key observation from the evaluation of the complete datasets. In addition, the evaluation should highlight the strengths and limitations of the data used.

3.5. The assessment of the benefit-risk ratio

Risk is defined in the MDR as the combination of the probability of occurrence of harm and the severity of that harm. Harm is defined in the standard ISO 14971as physical injury or damage to the health of people, or damage to property or the environment. Therefore, the term ‘risk’ includes both clinical and non-clinical harm.

Benefit-risk evaluation should be carried out throughout the lifecycle of the medical device to promote and protect public health and to enhance patient safety through effective risk minimisation. The integrated benefit-risk evaluation should be performed for all intended uses. (E.g technical documentation, IFU, labelling, etc)

For the purpose of lifecycle benefit-risk management, it is necessary to continually evaluate the risks and benefits of a medical device / IVD in everyday use and long-term use in the post-market phase. A different Benefit-risk balance may emerge as vigilance data reveals further information about safety. The manufacturer should therefore continually evaluate the benefit risk balance of the products for those populations and environments where it is in use. This structured evaluation should be undertaken in the

context of ongoing medical device vigilance and risk management (article 10) to facilitate optimisation of the benefit risk balance through effective risk minimisation.

The ten most common risks should be presented in a table including the prevalence of the risk and the changes on them. In addition, the significant benefits to the patients should be reported in a table including the assessment of acceptability by the patient group.

Comment : " …in a table including…" Which number? Is it a free designed table for the manufacturer or is a table included in this document?. It is not clear.

"…the changes of them…" Do we mean it should be presented whether each risk is unchanged, increased or decreased?

3.5.1 Baseline safety and performance information

This sub-section summarizes information which demonstrates the achieved safety and performance of the device recorded prior to the PSUR Period and outlined in the device risk management file. This information should relate to the intended use(s) of the device.

This sub-section should also include the baseline benefit information. For devices with multiple intended uses, populations, and/or routes of administration, the benefit should, when relevant, be characterized separately for each different use.

In particular, the expected rates for critical risks should be detailed, to enable conclusions to be drawn over whether the risks presented by the device during the PSUR reporting period remain acceptable when compared against the benefits it provides.

3.5.2 Update on characterization of risks

This sub-section should detail and characterize potential new risks identified in the data within PSUR period. The risks should be characterized according to the principles defined in the standard ISO 14971. Findings obtained from the evaluation of the post-market data, regardless whether the data has resulted in the identification of a signal, trend or any form of corrective action (including FSCA) should be used to update the risk assessment for the device.

Depending on the type of device involved, the following factors should be considered during the risk assessment process:

- The number of cases (numerator) and precision of estimate, taking into account the source of the data;
- The extent and/or duration of use (denominator) expressed as numbers of devices, patients, patient-time, etc., and precision of estimate;
- The frequency (computed from numerator and denominator);
- The impact on the individual patient (effects on symptoms, quality or quantity of life, reversibility);
- The public health impact;
- The risks related to a specific population;
- Any patient factor relevant to risk (e.g. age, relevant co-morbidity, disease severity)
- The strength of evidence and its uncertainties, including analysis of conflicting evidence, if applicable.

3.5.2.1 Detected Signals

Comment : Do we need methodology or only results received by the signal detection methods?

This section should describe the manufacturer's overall principles and methodology for identification of safety related signals, including trigger levels and their justifications (see baseline information section above).

Safety related signals should be described/detailed in an overview (list) with manufacturer reference number and NCA reference number (where available for reported adverse trends) for each identified signal.

Signals should be classified as:

- New signals identified (since last PSUR reporting period), date of identification, evaluation incomplete
- New signals identified (since last PSUR reporting period), date of identification, evaluation completed, conclusion incl. date of conclusion
- Signals followed up since the last PSUR
- Re-opened signals, date and reason for re-opening

For each signal, the following information should be provided:

- Description of the issue
- Potential risks or an assessment of the significance of the signal, classified according to acceptability.
- Any plans for further investigation / evaluation of the signal
- Any actions or plans of action, or justification of why no action is taken/planned

3.5.3 Effectiveness of risk reduction actions

This sub-section shall contain the results of the assessment of the effectiveness of risk reduction activities that have been undertaken as a result of the benefit-risk assessment during the PSUR reporting period. Information relating to the effectiveness and/or limitations of any specific risk reduction should be summarized.

Details of the particular effectiveness of risk reduction activities in all countries and regions are of particular interest. Information may be summarized by region, if applicable and relevant.

3.5.4 Update on characterization of benefits

This sub-section should include the new benefit information that has become available during the PSUR reporting period. A brief summary of any new positive benefit information that has an impact on the risk profile during the reporting interval should be provided.

This sub-section should provide a concise but critical evaluation of the strengths and limitations of the evidence on performance, considering the following if available

- a brief description of the strength of evidence of benefit, considering comparator(s), statistical rigor, methodological strengths and deficiencies, and consistency of findings across studies;
- clinical impact
- generalisability of benefit across the indicated patient population (e.g. information that demonstrates lack of benefit in a sub-population);
- duration of benefit;
- a determination of the extent to which performance findings from clinical studies are generalisable to patient populations treated in medical practice.

3.5.5. Update to Benefit- Risk Determination

The conclusions of the benefit-risk determination should include but not limited to:

- Whether new and unexpected risks, including off-label or misuse, were identified during the various post-market surveillance activities in any relevant European Member State
- Whether the rate of any residual risks or undesirable side-effects exceeded the predefined specific thresholds in any relevant European Member State
- Whether the benefit-risk profile remains positive for the various claims in the intended target populations and approved medical indications
- Whether the overall benefit-risk profile is acceptable when compared to the current knowledge/state of the art in the medical fields concerned

Table 12. Observed risks and benefits

Risk	Previously known (Y/N)	Incidence in PSUR reporting period	Incidence in PSUR Period	Threshold	Effect to Benefit risk ratio (Y/N)
Benefits					

4. PSUR evaluation by Notified Body

This sub-section of the PSUR summarizes the information regarding the NB evaluation. The aim of this evaluation is to analyse whether the conclusions regrading benefit risk ratio are justified from the point of view of the gathered data and its utilization. The NB has the authority to accept or reject the PSUR or request the manufacturer to update the PSUR.

4.1 PSUR Evaluation regarding class IIII and implantable devices

The class III and implantable device PSUR should be evaluated yearly and submitted in Eudamed.

4.2 PSUR Evaluation regarding class IIb and class IIa devices

The PSUR regarding the class IIb and Class IIa device should be evaluated as a part of the technical documentation based on sampling.