Periodic Safety Update Report (PSUR)

This report describes product-specific post-market surveillance activity output as outlined in the Post-Market Surveillance Plan.

General information

Manufacturer Name and Address:
Product Name:
Unique Device Identification (UDI):
Product Version:
Surveillance Period:
PSUR Reference Number:
PSUR Version Number:
Notified Body name and organization number:

Device information

Classification:
Date of the first DoC:
Date first made available:
Device status (on the market/recalled/...):
Intended Purpose:
Indications:
Contraindications:
Target populations:
Device trade name(s):

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1. Summary

Note: Highlight which issues around the safety and performance of your device you identified and whether the benefit-risk ratio changes. Give a status update on the issues identified in the last PSUR (if applicable).

2. Impact on Clinical Evaluation: Benefit and Performance

Are the claims made for expected benefits and performance being met?

( ) Yes ( ) No

If not, reasons for deviation:

3. Impact on Risk Management: Risks and Benefits Determination

The medical device is safe and the risks correspond to the assumptions in the risk management file:

( ) Yes ( ) No

If not, describe new risks that have been identified:

Do the clinical benefits of the device outweigh the risks?

( ) Yes ( ) No

If not, reasons for deviation:

4. Results of Post-Market Surveillance Activities

Market Data

Describe sales volume of the device, e.g. amount of users, their demography, and, where practicable, the usage frequency of the device. Compare the actual patient population to the expected usage with regards to over- or under-representation of a patient group.

Summary of Incidents and Problems

Describe incidents that happened with your device and actions taken (e.g. adverse event reports to authorities, field safety notices to customers, field safety actions). Group them by geography, population or any other parameter that makes sense if there are multiple.

Observed undesirable side effects

Describe incidents that happened with your device and actions taken.

Title	Date	Hazard in Risk Table	Expected Frequency / Severity	Assessment

List of CAPAs

The following CAPAs resulted from post-market surveillance activities during product lifetime and the following CAPAs were initiated during this surveillance period:

Summary of Customer Complaints and Problems

Overall Feedback Assessment:

- According to the device's post-market surveillance plan, the overall feedback and complaint rate can be deemed acceptable if (. . .)
- Feedback data showed (. . .)

  Note: Summarize the number of customer complaints, predominant subjects of feedback and whether there was anything of importance regarding safety. More specifically, take into account:

  - Is the overall complaint rate deemed acceptable and if so, why?
  - Based on feedback, have any trends been analyzed and have any corrective measures been taken? What is the status of such actions?
  - Has PMS data been compared to occurrence probabilities from risk management?

Copy this table for every relevant feedback issue that you have analyzed

Subject
Feedback Source
Date
Root Cause
Assessment

SOUP Issues

Describe anything of relevance you found when going through issue trackers of your SOUP. Also describe whether this leads to any changes, e.g. you could have updated the SOUP to a newer version (and then updated that entry in the SOUP list), or you identified new risks which should be added to the risk table.

The SOUP List has been updated.

(Describe significant changes, e.g., new risks, if applicable)

Post-Market Data of Similar Products

Note: copy the sections below for every database that you looked into.

BfArM Database(s) Short description of database:

Search keywords: (Insert keywords)

Subject	Description and Date	Assessment	Applicable (Yes / No)

FDA Database(s) Short description of database:

Search keywords: (Insert keywords)

Subject	Description and Date	Assessment	Applicable (Yes / No)

Summary of Post-Market Clinical Follow-Up Findings

Post-Market Clinical Follow-Up activities were performed following the manufacturer's process for clinical evaluation.

Main Findings of Post-Market Clinical Follow-Up Activities:

Describe the main findings that were derived from your post-market clinical follow-up.

Status of Post-Market Clinical Follow-Up Activities:

Describe or list here which PMCF activities are planned, were adjusted or completed. Include evidence that the post-market surveillance activities are meeting their objectives. Reference the location of the original data and the analysis performed.

State of Research and Development

Market Information on Similar Devices

Note: Describe any relevant information on similar devices in the market, e.g. clinical studies that started with outcomes that may be applicable to our device.

Copy this table for every issue that you evaluated.

Query
Results (incl. date)
Applicable?
Assessment

Scientific Literature

Note: This chapter should analyze other publications applicable to our product if not considered already as part of the post-market clinical follow-up.

Copy this section for every issue that you evaluated.

Short description of database: Search keywords: (Insert keywords)

ID / Title	Description (incl. date)	Assessment	Applicable (Yes / No)

General Updates of Standards and Legislation

List legislation and standards which were updated in the meantime. E.g. there could be a new version of ISO 13485 which could be relevant for your company.

5. Trend Analysis

Describe trends that you identified according to the metrics and threshold values that were specified in your post-market surveillance plan.

For example: during the surveillance period, we received several customer complaints related to product feature XYZ. Malfunctioning of this software component led to XYZ cases of minor injury which was not anticipated. Therefore, we initiated action to do XYZ (ideally, refer here to the listed CAPAs in section 1 above).

Copy this table for every issue that you evaluated.

Hazard
Date / Time Span
Occurrence acc. to Observation
Probability acc. to risk table
Assessment and Actions Taken

Updated Post-Market Surveillance Plan

List updates to Post-Market Surveillance Plan, if applicable.

6. Summary and Conclusions

Validity of the collected data

Is the data collected sufficient and representative to draw conclusions?
Is an impact assessment of the benefit-risk ratio possible?

Overall conclusions

Have all benefits been met? Have new benefits/risks been identified? How does that change the benefit-risk profile?

Actions taken by the manufacturer

Describe all actions that have been initiated as a part of the PMS data collection or resulting from the findings in this report.
