WHITEPAPER

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Periodic Safety Update Report (PSUR) for Medical Devices

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Periodic Safety Update Report (PSUR) for Medical Devices

PSUR focuses on safety which needs to be updated timely, with investigation, observation and further studiesto provide balance of risk-benefit profile of a product.

PSUR summarizes outcome of the post-marketing surveillance activities relating to safety and performance of device, setting out conclusions on the indicators followed and on significant events found. These events may be already identified and already followed up, they may also be new risks or benefits ultimately not achieved.

Surveillance objectives depend on the results of design, development, risk management and clinical evaluation activities, PSUR hence aims to demonstrate that the benefit/risk ratio remains favorable during marketing phase.

Contents of the PSUR

General information

PSUR should be self-supporting and therefore contain information necessary to understand the context:

- Identification and contact of manufacturer/ authorized representative.
- Identification and general information about device (or group, or category) and its intended use, including indications and patient exposure.
- Information on volumeof devices sold and in service, number of users, frequency of use in order to estimate the probability of risks occurring.
- Information on period of surveillance that has elapsed: start date, end date and justification for surveillance period (longer or shorter depending on the risks and uncertainties).

History of changes

All changes that may impact safety or performance relating to a device or an accessory, and the intended use are summarized and justified.

These changes may also relate to technical documentation i.e. any significant changes to risk analysis or clinical evaluation not already discussed in the report should be explained as well.

Surveillance results (including clinical follow-up)

PSUR takes up main objectives defined in the PMS along with what's performing and the results obtained.

Post-Market Clinical Follow-up (PMCF) is also taken into account detailing the results and status of ongoing clinical studies, as defined in PMCF plan and the clinical development plan. Data confirming (or not) the claimed benefits are detailed.

Actions (CAPAs) impacting safety or performance implemented during the PMS period are summarized, justified and results outlined.

New information regarding safety, e.g. from watch on equivalent devices or from literature is summarized and its consideration is identified, justified if not.

Vigilance results

Alerts, incidents (serious and non-serious), adverse reactions, withdrawals are summarized and estimated number, frequency of occurrence and health effects. Actions including FSCAs implemented are explained.

Impact on the risk analysis is summarized specifying the risks already identified and new risks detected during incidents.

Trend analysis

Any trends, detected in PMS or vigilance, are presented as well as conclusions drawn and actions decided.

Trends mainly concern the probability of occurrence and severity of residual risks, when they occur sufficiently often to allow this analysis. The idea is to detect a possible increase, to launch adequate preventive actions, or a decrease, sign of the effectiveness of the control of the risks.

Trends can also be regional, especially if there are discrepancies between the EU and other regions.
Identification and verification of signals.

Information arising from one or multiple sources, including observations and experiments, which suggests a new potentially causal association, or a new aspect of a known association between an intervention and an event or set of related events, either adverse or beneficial, that is judged to be of sufficient likelihood to justify verificatory action.

It is therefore a matter of detecting and verifying the relevance of new information or patterns (unfolding of events) observed in the field and likely to affect benefit/risk ratio. (Example: a signal relating to an intended out-of-field use that remains to be confirmed).

Benefit/risk analysis

New risks are identified and estimated, modified (or unmet) risks and benefits are re-estimated and the acceptability of benefit/risk ratio is reassessed.

A statement is made as to the evolution of the B/R ratio since the previous surveillance period.

PSUR conclusion

PSUR conclusion summarizes impact on the estimation of key risks and benefits which impact the benefit/risk ratio as well as any emerging risks, and changes in the context particularly in relation to use of the device. Remaining uncertainties are outlined as well. Actions decided at the end of the PMS period are listed and the planning of the next surveillance will take into account the PSUR findings.

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