Periodic safety update reports (PSUR):

Periodic safety update reports are the reports updated by Marketing authorization holders and submitted to the authorities during post authorization phase on regular time periods to evaluate the benefits and risks of the product.

A PSUR is a comprehensive picture of the safety of the approved medicinal products.

PBRER- Periodic Benefit risk evaluation reports are referred to as PSUR since implementation in Europe via GVP module VII.

Preparation of the PSUR be done at the following intervals:

* PSURs covering interval period up to 12 months has to submit within 70 calendar days.
* PSURs covering intervals in excess of 12 months has to submit within 90 calendar days.
* If an authority requests to submit the PSUR, the timelines will be specified or else, the document has to be submitted within 90 calendar days.

Its MAH responsibility to submit the PSUR for their own products.

After the approval for marketing of a product, it very important to evaluate the safety, efficacy and effectiveness of the product. A complete benefit-risk analysis will be done for the product during the reporting interval of the product.

Precisely PSUR “comprehensive, concise and critical analysis of the Benefit Risk balance of the medicinal product, taking into account new or emerging information in the context of cumulative information on risks and benefits”.

The PSUR also referred as Periodic Benefit Risk Evaluation Report.

The date of the first marketing approval for the medicinal product in any country in the world is the International Birth date (IBD). Data lock point is the date designated for the cut off data which will be based on the IBD.

**EURD list- European union reference dates.**

This is a living document which states that, the document can be updated when ever considered necessary by the PRAC, CHMP or CMDh in response to the emergence of relevant new safety information and newly authorized substances from MAH.

EURD list is legally binded related to the frequency of submission of PSURs.

The List is available freely in EMA website.

The MAH prepares a single PSUR for all its products containing same active substance.

The practical aspects of writing a PSUR:

1. Any changes to reference safety information due to safety reasons during the reporting interval period.
2. Update from PSUR assessment in the any region.
3. Update related to the product information, recommended dosages.
4. Population exposure:

* Exposure data will be mentioned as patients/year.
* Exposure variations in different populations (pediatric/elderly/pregnant) and different geographical regions.
* Discrepancies of exposure data from one PSUR to another will be checked and if any variation should be justified.

1. Data in summary tabulations:

The specific reactions are mentioned with number of events related to the reaction.

The adverse events are compared with the safety profile the product and will be updated if any variations identified.

1. Information from safety trilas:

Any emerging efficacy and safety finding during the reporting interval will be mentioned.

1. Literature search information:

MAH will perform the literature articles which will have impact of benefit and risk analysis of the product and explained in this section.

1. Late breaking information:

The information which alters the benefit and risk profile of the product is collected, during the preparation of the PSUR is considered in this section and explained in the document where needed.

1. Over view of signals:

* New signal
* Ongoing signal
* Closed signal

The overview should be presented in the following tabular format according to GVP Module VII (European module)

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Signal term | Date  detected | Status ongoing or closed | Date closed for closed signals | Source of signal | Reason for evaluation and summary of key data | Method of signal evaluation | Action taken or planned |
|  |  |  |  |  |  |  |  |

The event to be monitored as per the PSUR assessment will be mentioned along with the signals.

1. Evaluation of risks and characterization of risks will be updated.
2. Important risk
3. Potential risk
4. Missing information
5. Signal evaluation:

Detailed description of the signals is explained:

1. Medical significance of the signal
2. The information which supports the evaluation and conclusions of the signal
3. Any important emerging safety issue information and any safety information (if any) from clinical trials are explained.
4. The non-serious Adverse reactions which have significant and potential impact on medication adherence are also explained.
5. Evaluation of risk and new information:

The new information relevant to previous known risks during the interval period are discussed considering that there won’t be duplication of the information explained in the signals.

There will be a special attention to the important potential risks whether there is any new information or data available to confirm the risks, considering the known and cumulative information.

1. Benefit-risk analysis evaluation:

During the initial Marketing of the drug the benefit evaluation of the product will be confirmed positive.

The discussion of the risks whether the new information provided had changed any already recognized important risk or identified new risks are explained.

Lack of efficacy is also take care in the respective sections of the PSUR which impacts the safety profile of the product.

Although PSURs have the appropriate regulatory scope to restrict/suspend/revoke a MA based on safety grounds, a need for wider engagement in a rigorous scientific analysis might be more appropriate via an alternative procedure (e.g. referral).

PSUR is submitted to the repository in the Europe and further assessment will be carried out by PRAC through PSUR assessment report for further necessary regulatory action.

For PSUR submission there will be Fee to be submitted.