DIFFERENCE BETWEEN PSUR & PBRER

AN OVERVIEW AND ITS CONTENTS

INTRODUCTION

The Periodic Benefit-Risk Evaluation Report (PBRER) described in this guideline is intended to be a common standard for periodic benefit-risk evaluation reporting on marketed products (including approved drugs that are under further study) among the ICH regions.

Regulators from EU, Japan, and the US believe that the PBRER may be used to meet prevailing national and regional requirements for periodic safety and/or benefit-risk reports for approved medicinal products.

This guideline defines the recommended content and format of a PBRER and provides an outline of points to be considered in its preparation and submission.

MAIN DIFFERENCE

The primary objective of the PSUR was to provide a comprehensive picture of the safety of approved medicinal products with recognition that the assessment of the risk of a medicinal product is most meaningful when considered in light of its benefits, the PBERE would provide greater emphasis on benefit than the PSUR, particularly when risk estimates change importantly.

The PBRER would also provide greater emphasis on the cumulative knowledge regarding a medicinal product, while retaining a focus on new information.

WHY PBRER ?

A formal evaluation of benefit is a new feature of the PBRER; however, it is recognised that a concise discussion of benefit will usually be sufficient, unless the safety or benefit-risk profile has changed significantly during the reporting interval.

Thus, the level of detail provided in certain sections of the PBRER (e.g., evaluation of safety and efficacy data, evaluation of safety signals and benefit-risk evaluation) should be proportional to the medicinal product's known or emerging important risks and to evidence of emerging important benefits.

OVERVIEW

- **What is a Periodic Safety Update Report (PSUR)?**

Periodic safety update reports (PSURs) are Pharmacovigilance documents intended to provide an evaluation of the risk-benefit balance of a medicinal product for submission by marketing authorisation holders at defined time points during the post-authorisation phase.

GUIDANCE DOCUMENTS :

- **What is the guidance document?**

✓E2C(R2)-Periodic Benefit-Risk Evaluation Report (PBRER)

OBJECTIVE

The main objective of a PBRER is to

- present a comprehensive and critical analysis of new or emerging information on the risks of the medicinal product
- Provide benefit in approved indications, to enable an appraisal of the product's overall benefit-risk profile

The PBRER should be submitted to regulatory authorities, and will contain an evaluation of new information relevant to the medicinal product that became available to the MAH during the reporting interval, in the context of cumulative information.

OBJECTIVE

The PBRER should:

• examine whether the information obtained by the MAH during the reporting interval is in accord with previous knowledge of the medicinal product's benefit and risk profile

• summarise relevant new safety information that could have an impact on the benefit-risk profile of the medicinal product

• summarise any important new efficacy/effectiveness information that available during the reporting interval and

• any important new safety information has emerged, conducting an integrated benefit-risk evaluation for approved indications.

OBJECTIVE

The PBRER should:

- be concise and provide sufficient information to assure regulatory authorities that the MAH is adequately monitoring and evaluating the evolving risk profile of a medicinal product
- contain all pertinent new safety information discovered during the reporting interval should be discussed in the appropriate sections of the PBRER
- report urgent safety information through the appropriate mechanism
- this report is not intended to be used to provide initial notification of significant new safety information or to provide the means by which new safety concerns are detected

FORMAT AND CONTENTS

1. Introduction
2. Worldwide Marketing Approval Status
3. Actions Taken in the Reporting Period for Safety Reasons
4. Changes to Reference Safety Information
5. Estimated exposure and use patterns
6. Data in summary Tabulations
7. Summaries of significant findings from clinical trials during the reporting interval
8. Findings from non-interventional studies
9. Information from other clinical trials and sources
10. Non-clinical Data

FORMAT AND CONTENTS

11. Literature
12. Other periodic reports
13. Lack of efficacy in controlled clinical trials
14. Late-Breaking information
15. Overview of signals: new, on-going, or closed
16. Signal and risk evaluation
17. Benefit evaluation
18. Integrated benefit-risk analysis for approved indications
19. Conclusions and actions
20. Appendices to the PBRER

COMMON INTERVIEW QUESTIONS PSUR & PBRER

- What is a PSUR?
- What are the sections of PSUR?
- What is the frequency of submission?
- Why PBRER needs to be submitted?
- What is a DLP?

COMMON INTERVIEW QUESTIONS PSUR & PBRER

- What is late-breaking information?
- What is the main difference between PSUR and PBRER?
- What is a PSUR schedule?
- What is an EURD list?
- What is a PSUR repository?

What are the issues and challenges?

There are quite number issues/challenges faced during and after drafting of report:

- **Literature data & Data tabulations**
- **Collating the information**
- **Quality of the report**
- **Misinformation and misinterpretation**
- **Delivery within the timelines**

- **How to handle them?**

The trick is to start drafting of the report 3 to weeks before the data lock point to complete the report in short time at the same time deliver high quality.

WANT TO LEARN HOW TO DRAFT A FULL REPORT?

Enrol for the full training course on:

- How to perform the "benefit-risk evaluation"?
- How to draft a:
  - Single PBRER for an active substance
  - PBRERs for fixed dose combination product
- Drafting each and every section of the report in detail

For consultation and training, visit:

www.Globalplacosolutions.com

GOOD LUCK!

Thank you for downloading