swissmedic

Guidance document
Information of PSUR PBRER submission HMP

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List of contents

1 Terms, definitions, abbreviations

CCDS	*Company Core Data Sheet*
CD	*Calendar days*
DLP	*Data lock point*
eCTD	*Electronic Common Technical Document (ICH)*
eDok	*Electronic format for submissions to Swissmedic*
EU-SmPC	*European Summary of Product Characteristics*
HMP	*human medicinal product*
IBD	*International birth date*
ICH	*International Conference of Harmonisation*
ICH E2C (R2)	*ICH Tripartite Guideline on PBRER*
PBRER	*Periodic Benefit-Risk Evaluation Report*
PSUR	*Periodic Safety Update Report*
RMP	*Risk Management Plan*
TPA	*Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (Therapeutic Products Act; SR 812.21)*
TPO	*Ordinance of 21 September 2018 on Therapeutic Products (Therapeutic Products Ordinance; SR 812.212.21)*

2 Introduction

Swissmedic uses this guidance document first and foremost as a resource for applying the legal provisions in a uniform and equitable manner. For applicants, the guidance document is intended to clarify the specific requirements that must be fulfilled so that corresponding applications can be processed as quickly and efficiently as possible.

3 Objective

The guidance document describes the requirements pertaining to the submission of PSURs/PBRERs and explains the formal and regulatory aspects.

4 Scope

This guidance document applies to the submission of PSURs/PBRERs for human medicinal products within the Safety of Medicines department.

5 Procedure

5.1 General

According to Art. 60 TPO, marketing authorisation holders for a medicinal product with a new active substance or with a biosimilar must periodically and spontaneously submit an updated report on the safety and risk-benefit profile of this medicinal product to Swissmedic for a period of 4 years from the date of authorisation. The observation period covered by the PSUR/PBRER must include the date of the official decision and cover an interrupted period of at least 4 years following the official decision.
If the authorisation is extended after the PSUR obligation has expired, Swissmedic may impose as a condition (Art. 16 para. 1 TPA) that the obligation to submit a PSUR is extended beyond 4 years or reimposed.
The end date of the PSUR obligation is communicated to the MAH with the respective decision.
The 4-year PSUR submission obligation also applies to vaccines, with the exception of seasonal influenza vaccines, for which the obligation to submit PSURs every year applies indefinitely.

5.2 Time limits

As a rule, the PSUR/PBRER is submitted once a year. It is possible to modify the submission cycle (e.g. submission every 6 months, submission every 2 years). This requires notification to Swissmedic with brief justification.
Swissmedic will contact the MAH only if the modified submission cycle is not acceptable.
. Otherwise, the request will be considered to have been accepted, see section 5.5 Enquiries.
As a general rule, only one PSUR/PBRER document will be accepted per application.
Submission of the PBRER / PSUR should occur within 90 CD following the DLP / IBD.

5.3 Format

The format of the reports must comply with the ICH E2C (R2) Guideline. Among other things, this guideline requires a summary tabulation of any adverse reactions. This table should show the total numbers of the most important types of cases such as cases with fatal outcome, serious cases, serious unknown cases, and cases with confirmed causality.
These tables should be submitted separately as an annex if they are not included in the report.
Other formats may be accepted by prior agreement.

5.4 Documentation

The following must be enclosed with the report: the completed PSUR/PBRER form, CCDS, EU-SmPC, tabular comparison of the current Swiss Information for healthcare professionals with the EU SmPC. For national authorisations at least chapters 4.1 to 4.9 should be submitted in German, French or English. Additional information may be submitted and mentioned in the covering letter. In connection with PSUR/PBRER submissions, RMP updates may be submitted. An RMP update has to be submitted if new findings require changes to the safety concerns, to pharmacovigilance activities or to risk-mitigation measures (see Guidance document “RMP ICH E2E Information submission” HMP).
The documentation may be submitted as an eCTD or eDOK via the Swissmedic eGov portal.
If a PSUR is submitted as part of an authorisation application (e.g. for extended authorisation or change to the product information), this must be noted in the cover letter.

5.5 Enquiries

For further / general enquiries regarding the PSUR/PBRER regarding the PSUR submission please contact riskmanagement@swissmedic.ch

6 Miscellaneous

New national or international safety signals must be reported to Swissmedic on an ad hoc basis without delay (Art. 59 TPA / Arts. 61 and 62 TPO).

Change history

Version	Change	sig
2.1	New layout, no content adjustments to the previous version.	dei
2.0	Section 5.2: Additions regarding PSUR submission (only 1 PSUR/PBRER document per submission, 1x6 months or 1x12 months). Section 5.4: Additions regarding submission of RMP updates Section 5.5 No application will be necessary for modifications to the PSUR cycle in future. A notification to Risk Management is sufficient.	er
1.0	Implementation of HMV IV	er