Contents

Change history

Version	Valid and binding as of	Description, comments	Author's initials
1.0	**01.01.2019**	**Updating and alignment to the HMV IV revision**	**er**

1 Abbreviations

CCDS	*Company Core Data Sheet*
CD	Calendar days
eCTD	*Electronic Common Technical Document (ICH)*
eDok	Electronic format for submissions to Swissmedic
EU-SmPC	*European Summary of Product Characteristics*
GVP Module VII	*Guideline on Good Pharmacovigilance Practices on PSUR (Rev 1)*
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

The guidance document explains the submission obligations and formats regarding PSUR / PBRER.

3 Objective

This Guidance document is intended for administrative entities and therefore does not establish immediate rights and obligations on the part of individuals. Through this Guidance document, Swissmedic is ensuring transparency for applicants and other interested parties regarding the rules and processes with applicants. The conditions referred to in this Guidance document ensure consistency, transparency and efficiency.

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

4 Other valid documents

Document ID
ICH E2C (R2)
Guideline on good pharmacovigilance practices (GVP) Module VII – Periodic safety update report

5 Procedure

5.1 General

According to Art. 60 TPO, holders of authorisation 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 4 years after authorisation. The observation period covered by the PSUR/PBRER must include the date of the official decision and continue without any gaps for at least 4 years after the official decision.
Where the authorisation is extended after the PSUR obligation has expired, Swissmedic may – subject to a condition (Art. 16 para. 1 TPA) – extend the 4-year period stated in Art. 60 TPO or define a new one.
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 is submitted once a year. The period between submissions can be modified in response to a justified request. No *Bridging Reports*
The time periods apply according to ICH E2C (R2):
PBRER/PSUR covering 6 or 12 months: within 70 CD
PBRER/PSUR covering more than 12 months: within 90 CD

5.3 Format

The format of the reports must comply with the ICH E2C (R2) Guideline. Among other things, this format provides for the inclusion of a table listing any adverse reactions. This table should show the totals for the principal types of cases, such as fatal outcome, serious, *serious and serious unknown, and all 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: a covering letter, 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 in France, Germany and the UK at least chapters 4.1 to 4.9 and – if the RMP was updated since the last submission – the new RMP version.
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 submission (e.g. for extended authorisation or change to the product information), this must be noted in the covering letter.

5.5 Enquiries

Any enquiries should be sent to 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).

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