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Periodic Safety Update Report (PSUR) − a report prepared by the MAH describing the worldwide safety experience with a medicine at a defined time after its authorization.

International birth date (IBD) − the date of first Marketing Authorization (MA) for a company's new medicinal product (MP) containing the active substance in any country in the world; date on which the first RA granted MA of a new drug.

For other terms and definitions refer to the SOP-QA-003 «Pharmacovigilance Glossary».

V. PROCEDURE

A. General Specification

1. PSUR's structure

A PSUR is a pharmacovigilance document intended to provide the evaluation of the risk-benefit ratio of a MP at defined time points during the post-authorization phase.

A single PSUR is prepared for all MPs containing the same active substance or the same combination of active substances for all approved indications.

The PSUR should contain the following sections:

1. **Title page including signature of a person responsible for PSUR preparation**
2. **Executive Summary**
3. **Table of Contents**
4. **Introduction**
5. **Worldwide MA status**
6. **Actions taken in the reporting interval for safety reasons**
7. **Changes to reference safety information**
8. **Estimated Exposure**
   - Cumulative subject exposure in clinical trials
   - Cumulative patient exposure from marketing experience
9. **Data in summary tabulations**
   - Reference information
   - Cumulative summary tabulations of serious adverse events from clinical trials
   - Cumulative summary tabulations from post-marketing data sources
10. **Summaries of significant findings from clinical trials during the reporting interval**
    - Completed clinical trial
    - Ongoing clinical trials
    - Long-term follow-up
    - Other therapeutic use of MP
    - New safety data related to fixed combination therapies
11. **Findings from non-interventional studies**
12. **Information from other clinical trials and sources**
13. **Non-clinical Data**
14. **Literature**
15. **Other periodic safety reports**
16. **Lack of efficacy in controlled clinical trials**

PERIODIC SAFETY UPDATE REPORT
for

ACTIVE SUBSTANCE(S): <INN>
ATC CODE(S): <Code(s)>

MEDICINAL PRODUCTS COVERED:

[Pharmaceutical form, dosage, Marketing authorization holder, Marketing authorization number, date of issue]

INTERNATIONAL BIRTH DATE (IBD): <Date>

INTERVAL COVERED BY THIS REPORT
From <date> to <date (i.e. data lock point)>
DATE OF THIS REPORT:
<Date>

OTHER INFORMATION:
<Other identifying or clarifying information if necessary>
MARKETING AUTHORISATION HOLDER'S NAME AND ADDRESS:
<Name>
<Address>
<E-mail address> (contact person for the PSUR procedure)
NAME AND CONTACT DETAILS OF THE QPPV:
<Name>
<Address>
<Telephone number>
<Fax number>
<E-mail address>
SIGNATURE (QPPV or designated person):

<Country>, YYYY

TO REGULATORY AUTHORITIES

2. WORLDWIDE MARKETING AUTHORISATION STATUS

In the section it is necessary to briefly provide information on date of the first authorization worldwide, indications(s) & authorized dose(s), and Since when &where authorized.

No	Finding	Checklist-2. Worldwide marketing authorisation status	Comments
1	CR	No data on drug authorization	
2	CR	Data on authorization of all drugs with the same INN, including those that do not belong to the MAH, are presented	
3	MI	The numbers of authorization certificates are not listed in the section	
4	MI	The section does not specify the dates of primary authorizations in the States	
5	MI	The section does not indicate approved indications for use in countries of authorization or no indication of differences in the indications section.	
6	MI	The section does not include authorized forms of release and dosage in the countries of authorization.	
7	MI	If the table with the authorization data is voluminous, it is not put into a separate annex.	