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WHO MODEL RMP ASSESSMENT STANDARD OPERATION PROCEDURE (SOP)

31 OCTOBER 2025

Name of Procedure	Management and review of Risk Management Plan (RMP)
Document Number	
Prepared by	
Authorised by	
Effective date	

1. OBJECTIVE

The purpose of this Standard Operating Procedure (SOP) is to provide clear instructions for staff responsible for reviewing and managing Risk Management Plans (RMPs). It outlines the process for assessing RMPs and implementing assessment outcomes. The SOP also details the procedures for receiving, administratively processing and evaluating RMPs.

2. SCOPE

The scope of this Procedure includes Risk Management Plans (RMPs) submitted by Market Authorisation Holders (MAHs), RMPs approved by a reference organization, e.g. WHO-Listed Authority (WLA) or elaborated in the context of WHO Pre-Qualification (PQ) as well as other RMP-relevant documents used as alternative whenever these are not accessible or not approved by reference organizations. The Procedure may be used for initial application for Market Authorisation (MA), new submission/change in RMP, as well as MA renewal.

3. CROSS-REFERENCES

The WHO Model Risk Management Plan Assessment Guidelines (Annex 1) and Assessment Template (Annex 2) are used in assessing the RMP described in this SOP. (Add any other references here.)

4. DEFINITIONS

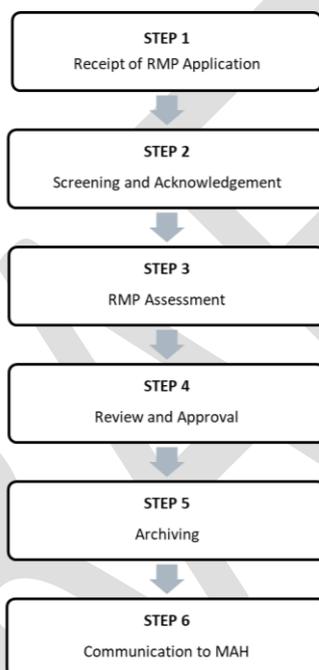
RMP	Risk Management Plan
WLA	WHO-Listed Authority
PSUR	Periodic Safety Update Report
MAH	Marketing Authorization Holder

5. RESPONSIBILITIES

The Head of the Registration Unit is responsible for maintaining and overseeing this SOP. RMP reviewers are responsible for ensuring that the procedures and related documents, including the RMP Assessment Guidelines and Templates, are kept up to date.

Head of the Registration Unit	<ul style="list-style-type: none"> • Designate technical officers to review an RMP. • Approve the RMP assessment report and confirm if any regulatory actions need to be taken. • Maintain this SOP
Head of the Pharmacovigilance Unit	<ul style="list-style-type: none"> • Designate technical officers to review an RMP. • Provide feedback on the RMP assessment report
RMP Reviewer	<ul style="list-style-type: none"> • Review the RMP documents and submit the RMP Assessment Report for internal discussion and approval
RMP Coordinator	<ul style="list-style-type: none"> • Archive and maintain the RMP tracking sheet

6. HIGH LEVEL FLOW CHART



7. PROCESS

7.1. Submission of RMP Documents

The Marketing Authorization Holder (MAH) shall submit Risk Management Plan (RMP) documents electronically to **[Name of NRA]** as part of the marketing authorization application.

- The submission must follow the NRA's prescribed electronic format and include all relevant modules, appendices, and supporting data.
- The MAH may also submit an RMP when newly requested by the NRA, or updated or revised RMPs post-authorization when new safety information becomes available or upon request by the NRA.

7.2. Screening and Acknowledgement of Receipt

The RMP Coordinator is responsible for screening all incoming RMP submissions to ensure completeness and compliance with the required format.

- Incomplete or non-compliant submissions shall be returned to the MAH for correction.
- Upon confirming receipt of a complete dossier, the RMP Coordinator shall issue an acknowledgement letter or email to the MAH, confirming successful submission and recording the date of receipt.

7.3. Tracking and Assignment Timeline

The RMP Coordinator shall record and monitor the timeline for review.

- The expected review due date must be clearly indicated on the cover page or tracking form of the RMP application.
- This tracking ensures timely allocation, review, and reporting in accordance with the internal performance standards or SOP timelines.

7.4. Allocation of Reviewers

The RMP Coordinator shall forward the validated RMP dossier to [Name of the responsible MA or PV unit] for reviewer assignment.

- Allocation shall consider expertise, workload balance, and product type (e.g., vaccine, biologic, generic, new chemical entity).
- The RMP Coordinator maintains a log of reviewer assignments for accountability and traceability.

7.5. Review and Assessment

The designated RMP reviewers shall assess the RMP following the RMP Assessment Guidelines and Templates.

- The assessment should cover the Safety Specification, Pharmacovigilance Plan, and Risk Minimization Plan, as applicable focusing on non-routine methods and measures.
- Reviewers shall prepare and submit an **RMP Assessment Report** to the Head of their Unit within the defined review period.

7.6. Finalization of Assessment Report

The **Head of the [Pharmacovigilance Unit or Registration Unit]** shall consolidate reviewer inputs and finalize the RMP Assessment Report.

- The finalized report shall then be submitted to the **Head of the [Pharmacovigilance Unit or Registration Unit]** for review, final conclusions, and regulatory recommendations (e.g., approval, request for revision, or rejection).

7.7. Archiving Final Report

The RMP Coordinator is responsible for maintaining proper documentation and archiving the final approved assessment report and all related correspondence in both electronic and physical formats according to the **[Name of the NRA]**'s document retention policy.

7.8. Communication to the MAH

The RMP Coordinator shall issue an **official communication** to the MAH on the outcome of the RMP assessment.

- The RMP Coordinator communicates with the MAH if there are any queries to clarify.
- The letter shall clearly outline any risk management commitments, follow-up actions, or conditions imposed as part of the marketing authorization.
- The RMP Coordinator ensures that all communications are logged and stored for future reference.

7.9. Implementation of Additional Pharmacovigilance Activities

If deemed necessary, the Head of the Pharmacovigilance Unit shall initiate or coordinate additional pharmacovigilance activities to further monitor, evaluate, or mitigate identified risks.

- Such activities may include enhanced adverse event monitoring, targeted post-authorization studies (PASS), or risk-minimization interventions.
- Outcomes of these activities shall be documented and integrated into ongoing pharmacovigilance and regulatory decision-making processes.

8. RECORDS

The RMP Coordinate is responsible for archiving and maintains the RMP tracking sheet. (The detailed instructions should be included here.)

9. REVISION HISTORY

For conducting any of the steps described in this Procedure, the designated Pharmacovigilance Officer (PVO) is expected to refer to the Guideline (Annex 1).

Version	Reason for revision	Author	Approved by	Date issued
0.1	New document			

ANNEX 1

WHO Model Risk Management Plan Assessment Guidelines

ANNEX 2

WHO Model RMP Assessment Template

ANNEX 3

Timelines for RMP Assessment

DRAFT