STANDARD OPERATING PROCEDURE	
Department: Pharmacovigilance	**URS No.:**
Title: Risk Management Plan	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1. OBJECTIVE:

To lay down a Procedure for the Risk Management Plan (RMP): Preparation and Submission.

2. SCOPE:

This SOP is applicable to …….

3. RESPONSIBILITY:

3.1. Pharmacovigilance Department:

Preparation of this SOP, prepare the RMP, update the RMP Tracker / RMP log. Distribution, Retrieval and Destruction of this SOP.

3.2. Drug Regulatory Affairs Department:

To provide required product data to PV and submit the completed RMP to the respective Health Authority/ Regulatory Agency.

3.3. Pharmacovigilance Officer In-charge(PvOI):

Review, Approval RMP, Training and effective implementation of this SOP.

4. ACCOUNTABILITY:

PvOI

5. PROCEDURES:

5.1. RM PREQUIREMENTS:

5.1.1. RMP is a dynamic, stand-alone document which should be updated throughout the life cycle of the pharmaceutical products. The RMP of every product shall be approved by the regulatory authority and should be updated as and when required (for new safety concern or regulatory recommendation).

5.1.2. An RMP or an update, as applicable, may need to be submitted at any time during a product's life-cycle, i.e. during both the pre- and post-authorisation phases.

- For all new marketing applications of any regulatory authority, the risk management plan describing the risk management system shall be submitted, together with a summary thereof.
- Situations, in addition, where an RMP or RMP update will normally be expected include:
  - With an application involving a significant change to an existing marketing authorisation:
    - New dosage form;
    - New route of administration;
    - New manufacturing process of a biotechnologically-derived product;
    - Paediatric indication;
    - Other significant change in indication;
  - A significant change in indication is change of authorised indication(s) of a medicinal product where the new treatment target population differs materially from the one for which the medicinal product was previously

authorised. This includes (but is not limited to): a new disease area, a new age group (e.g. paediatric indication) or a move from severe disease to a less severely affected population. It may also include a move from 2nd line or other therapy or for an oncology product a change to the concomitant medication specified in the indication.

- At the request of the Agency or national regulatory authority when there is a concern on a risk affecting the risk-benefit balance.
- With a PSUR for single authorised medicinal product, when the changes to the RMP are a direct result of the data presented in the PSUR.
- With a submission of final study results impacting the RMP.

5.2. RMP REQUEST:

5.2.1. Representative of respective regulatory affairs department shall send an email request to corporate Pharmacovigilance department for RMP preparation along with minimum data required to prepare the RMP as requested in Data Checklist (Refer Annexure I- Data Checklist).

5.2.2. Representative of Pharmacovigilance Department shall update the details in the RMP tracker immediately after receiving the RMP request (Refer Annexure II- RMP tracker/RMP log)

5.3. RMP PREPARATION:

According to RMP request, RMP data lock point shall be considered.

5.3.1. Data lock point (DLP) shall be calculated as follows:

- In case of dossier submission for new product approval, the last date of preceding month shall be considered as DLP and the period from the IBD to DLP shall be considered to prepare the RMP. (If the RMP request has received on 15th of October, last date of September month shall be considered as DLP).
- In case of product renewal, the date when Pharmacovigilance Department receives request for RMP preparation shall be considered as the DLP and period from the DLP of the previous RMP to till the date of request shall be considered to prepare the RMP.

5.3.2. The Pharmacovigilance Department shall prepare the RMP following local regulatory authority recommended format.

5.3.3. Public assessment reports, SPC/PI and the data entered in the electronic safety database shall be referred for safety information.

5.4. RMP REVIEW AND SIGNATURE:

5.4.1. Prepared RMP shall be reviewed by PvOI/Quality Reviewer for its quality, accuracy and completeness as appropriate.

5.4.2. RMPs shall be signed by PvOI before its final submission to the regulatory authorities.

5.5. RMP SUBMISSION:

5.5.1. The PvOI shall share the final RMP with the concerned person of DRA department to review their relevant

sections and for final submission.

5.5.2. The RMP tracker/log (Annexure-II) shall be updated with the submission details immediately after sharing the RMP with DRA department.

6. DISTRIBUTION:

Not Applicable

7. REFERENCES:

Not Applicable

8. ABBREVIATIONS:

ADR	Adverse Drug Reaction
CIOMS	Council for International Organizations of Medical Sciences
DLP	Data Lock Point
DRA	Drug Regulatory Affairs
IBD	International Birth Date
ICSR	Individual Case Safety Report
LPO	Local Pharmacovigilance Officer
MAH	Marketing Authorization Holder
PSUR	Periodic Safety Update Report
PV	Pharmacovigilance Department
PvOI	Pharmacovigilance Officer In-Charge
RMP	Risk Management Plan
SOP	Standard Operating Procedure

9. ANNEXURES

S.No.	Title	Annexure No.	Format No.
1.	Data Checklist	I	
2.	RMP Tracker/RMG log	II	

10. REVISION HISTORY:

Revision No.	Effective Date	Reason for change	CC No.
00		New SOP	Nil

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ANNEXURE I
DATA CHECKLIST

S. No	Product details		Attachments
1.	Brand Name		
2.	Active Substance		
3.	ATC code		
4.	Date and country of first authorization Worldwide		
5.	Date and country of first launch worldwide		
6.	Date and country of first authorization in <name of country>		
7.	Date and country of first launch in <name of country>		
8.	Strength		
9.	SPC/Package Insert/PIL of innovator		
10.	SPC/ Package Insert/PIL (proposed)		
11.	Summary of clinical study report (if available)		
12.	Clinical and non-clinical data (if available)		

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ANNEXURE II
RMP TRACKER/RMG LOG

S. No	Product Name	Country of Submission	Date of Submission	Prepared By (Sign & Date)