STANDARD OPERATING PROCEDURE	
Department: Pharmacovigilance	**URS No.:**
Title: Pharmacovigilance System Master File (PVMF)	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1. OBJECTIVE:

This Standard Operating Procedure (SOP) provides general guidance on all topics and processes involved in preparation and maintenance of a Pharmacovigilance System Master File (PvMF).

2. SCOPE:

This SOP is applicable to …….

3. RESPONSIBILITY:

3.1. General Management (GM):

The General Management is responsible for overall PV process.

3.2. Pharmacovigilance Officer In-charge(PvOI):

The PvOI of …… would be responsible for ensuring and verifying that information contained in the PvMF is accurate and up-to-date reflection of the PV system and therefore approves initial as well as any updated final version of PvMF in writing.

The PvOI coordinates timely provision of all valid data, material and information necessary to update and maintain the PvMF and its annexes within the defined timelines.

3.3. Third Party

A third party e.g. client/vendor may be assigned to take over responsibilities for specific processes described in the related documents.

4. ACCOUNTABILITY:

PvOI

5. PROCEDURES:

5.1. Requirements regarding PV system and PvMF

The PvMF describes the Pharmacovigilance (PV) system for one or more medicinal products of Marketing Authorisation Holder (MAH) and documents compliance with the regulatory requirements. PvMF also contributes to appropriate planning and conduct of audits by MAH, fulfillment of supervisory responsibilities of the Pharmacovigilance Officer In-charge (PvOI) and inspections or other verification of compliance by regulatory authority. PvMF provides an overview of the PV system, which may be requested and assessed by regulatory authority during Marketing Authorisation Application (MAA) or post-authorisation.

The summary of PV system could be included in the application for marketing authorization (MA).

The PvMF is not part of MA dossier and is maintained independently from MA. It should be permanently available for inspection and should be provided to the regulatory authority, if requested. The PvMF file shall be located at the MAH's organization in India where the main PV activities of MAHs are performed.

At the time of initial MAA applicants are required to have in place a description of PV system that records system and functioning at time of granting of MA and placing of product on the market. During evaluation of a MAA, applicant may be requested to provide a copy of PvMF for review

The PvMF has to describe the PV system in place at the current time. Information about elements of the system to be implemented in future may be included, but these should be clearly described as planned rather than established or current.

5.2. Preparation of PvMF

5.2.1.Retrieval of data and information

Prior to PvMF preparation, meeting will be conducted internally in order to gather all required data and information from the respective departments. The PvOI/manager defines timelines for delivery of data and information for PvMF generation. The PvOI/manager may also assign the tracking of relevant information as well as filing of documents to staff

5.2.2.PvMF preparation and review

The nominated staff/PvOI is responsible for authoring PvMF and PvOI functions as a document owner.

The format and content of PvMF follows the below table of contents. The information should be presented concisely and when no information is available, this should be stated, accordingly.

Table of contents of the PvMF core document:

1. PvOI
2. Pharmacovigilance Organizational structure
3. Sources of safety data
4. PV Processes
5. PV system performance
6. Annexes to the PvMF

Annexes to the PvMF: Annex A: The PvOI

- Curriculum Vitae of the PvOI
- Job Description of the PvOI
- Statement on Backup Procedures of the PvOI
- List of tasks that have been delegated by the PvOI

  Annex B: The Organizational Structure of the MAH
- List of PV contracts and agreements

  Annex C: Sources of safety Data
- List of sites where PV activities are undertaken as well as delegation of activities to third parties

  Annex D: Computerized systems and Databases

  Annex E: Lists of procedural documents
- Procedural documents of MAH
- Procedural documents of PV service providers

  Annex F: PV System Performance

- Timeliness of expedited Individual Case Safety Report (ICSR) reporting within the last 12 months
- ICSR quality
- Timeliness of Periodic safety update report (PSUR)submission
- Timeliness of safety variations submitted in the last two years
- Monitoring of risk management plan activities/measures
- Monitoring of other PV obligations or conditions of a MA

Annex G: Quality System

- Audit schedules
- Completed audits for a period of a rolling five year cycle

Annex H: Products

- List(s) of products covered by the PV system
- Notes concerning the MAH (per product)

Annex I: Document and Record Control

- Logbook and documentation of changes of the content of the PvMF

5.2.3. Creation and submission of a summary of the PV system

If agreed with the PvOI, author is responsible for creation of a summary of the PV system that has to be included in the MAA. lt shall include the following elements:

- Proof that the applicant has at his disposal PvOI
- Location where the PvOI resides and carries out his/her tasks
- Contact Details of the PvOI
- Location and number of PvMF
- Statement to PvMF that applicant has necessary means to fulfill the tasks and responsibilities listed in Pharmacovigilance Guidance Document for MAHs.

5.2.4. PvMF Review

The author will send final draft to PvOI, manager and other stakeholders (if any) for review. After finalisation of the review step(s) author adapts the PvMF according to comments and forwards final PvMF back to PvOI.

5.3. Maintenance of PvMF

PvMF is a 'living document' reflecting current status of PV system with MAH. To obtain currentness of PvMF stipulated in a regular update, timely reference of applicable guidance is mandatory.

Timely input from several functions is crucial for keeping PvMF up to date. For each section and annex a contributing department will be determined for delivery of all relevant information to the PvOI.

5.3.1. Update of structures and processes related to main body of PvMF

The relevant sections of PvMF will be regularly updated (e.g. annually, semi-annually). A triggered ad hoc update may also be necessary in case of significant changes (e.g. PvOI change) or if the PvMF is requested by regulatory authority.

The PvOI /author is responsible for maintaining main body of PvMF. During regular updates an assigned member of project team will check if the information is update to date and implement any changes, if necessary. The author then requests the approval of changes from PvOI. After approval changes are implemented and all changes need to be documented.

5.3.2. Update of the Annexes of the PvMF

The annexes of PvMF document a broad range of PV activities including PV performance indicators. The annexes of PvMF will be updated on regular intervals.

5.4. Filing and Archiving of the PvMF and Annexes

PvMF shall be located either at the site where main PV activities are performed, irrespective of format (paper-based or as an electronic file). All changes to PvMF must be recorded, such that history of changes is available.

All changes to main body of the PvMF as well as to the annexes of the PvMF need to be detailed in PvMF. The different versions of PvMF and annexes should be archived with PvOI.

5.5. Access to the PvMF and Annexes

The respective PvOI and Deputy PvOI have unlimited access to the current versions of PvMF including all annexes. Read access to PvMF and its annexes is limited to the project team members.

6. DISTRIBUTION:

Not Applicable

7. REFERENCES:

Not Applicable

8. ABBREVIATIONS:

GM	General Management
ICSR	Individual Case Safety Report
MA	Marketing Authorization
MAA	Marketing Authorization Application
MAH	Marketing Authorization Holder
NA	Not Applicable
PSUR	Periodic Safety Update Report
PV	Pharmacovigilance
PvMF	Pharmacovigilance System Master File

9. ANNEXURE :

Not Applicable

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10. REVISION HISTORY:

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