

22/04/2016

Sign. [Signature] Dt. 22/04/2016

INDIAN PHARMACOPOEIA COMMISSION
National Coordination Centre-Pharmacovigilance Programme of India



STANDARD OPERATING PROCEDURE

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SOP No.	IPC/PvPI/SD/001
Revision No.	01
Review Date	26/04/2019

Section	SD Section
Effective Date	27/04/2016

Title: SOP for Operational Functioning of Signal Review Panel.

1.0 OBJECTIVE

1.1 To lay down a procedure for operational functioning of Signal Review Panel.

2.0 SCOPE

2.1 This SOP shall be applicable for operational aspects of the Signal Review Panel under Pharmacovigilance Programme of India.

3.0 RESPONSIBILITY

- 3.1 All members of the quorum shall be responsible for the implementation of this SOP.
- 3.2 Signal Detection section shall be responsible for Coordination with Signal Review Panel.
- 3.3 Quality Manager/Technical Manager shall ensure overall implementation of this SOP.

4.0 ACCOUNTABILITY

4.1 Officer Incharge – Pharmacovigilance Programme of India

5.0 PROCEDURE

- 5.1 The SRP shall function under the aegis of IPC. The SRP shall perform the following activities:
 - a. Identification of the signal and its review
 - b. Confirmation of causality
 - c. Assessment of strength of the signal
 - d. Stake holders consultation
 - e. Recommendations to the regulatory authority
 - f. Follow up action (if any)
 - g. Other activities related signal management

	Name	Designation	Signature	Date
Prepared by	Dr. Piyush Rajput	Technical Associate	[Signature]	18/04/2016
Reviewed by	Dr. Prasad Kumar	SA	[Signature]	21/04/2016
Approved by	Dr. N. Kalwase	PSO	[Signature]	22/04/2016



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- h. Participation and interaction with international Pharmacovigilance forums
- i. Reference to and discussions on international Pharmacovigilance alerts and news letters
- j. Exchange of information through newsletters

5.2 Quorum of the SRP

- 5.2.1 Minimum 7 members shall constitute a quorum including at least one clinician and one pharmacologist in the SRP.
- 5.2.2 The maximum number of members in the SRP shall be 19.

5.3 Constitution of the SRP

- 5.3.1 SRP shall be a multi disciplinary committee, constituted by Government of India notification with representation of the following: Clinicians, pharmacists, medical pharmacologists, public health experts, regulatory authority representative.
- 5.3.2 The Member secretary shall be from the NCC-PvPI, IPC and co-ordinate all activities of the SRP.
- 5.3.3 The chairperson shall be nominated by the Health Secretary, Ministry of Health and Family Welfare, Government of India.
- 5.3.4 Tenure of the committee shall be 3 years. Special invitees e.g. subject experts shall be invited to attend meetings but shall not have any voting rights.

5.4 Decision making

- 5.4.1 Decision shall be reached based on a majority vote of the SRP members, provided a quorum has been met.
- 5.4.2 The chair person shall not have veto powers.

5.5 Schedule of meetings

- 5.5.1 The SRP shall meet **every 3 months** and no later than every **6 months**.
- 5.5.2 All members shall declare their conflict of interests in writing before the start of every SRP meeting.

	Name	Designation	Signature	Date
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- 5.5.3 All members shall sign a confidentiality disclosure agreement form before the start of first SRP meeting as a member.
- 5.5.4 If the members unable to attend the meeting then he/she shall give reason for not attending the meeting in writing before the start of every SRP meeting.
- 5.5.5 Alternate members shall attend in the place of absent regular members in order to meet the quorum requirements.
- 5.5.6 The venue of the SRP meeting would be decided in the previous meeting and the Member Secretary would intimate the meeting details at least **15 days** in advance.
- 5.5.7 The SRP shall maintain records of all its meetings, correspondence and other proceedings for a minimum period of **five years** in the **Signal Review Cell** at NCC.

5.6 Emergency Review Meeting

- 5.6.1 An emergency review meeting shall be convened by the NCC if required.
- 5.6.2 Member Secretary shall inform Chairperson of such a request.
- 5.6.3 A meeting of SRP shall be scheduled **within a minimum of 3 working days**.
- 5.6.4 A minimum 3 members of SRP, one of which relevant clinical expert, Member Secretary and Chairperson shall be present.
- 5.6.4 The panel mentioned above can submit a preliminary report to the NCC in the form of "Draft Report".
- 5.6.5 The Chairperson shall share the preliminary report with all members of SRP within 3 working days after submission of the preliminary report to the NCC.
- 5.6.6 The next meeting of the SRP shall be scheduled by the Chairperson **within 30 days** of the submission of preliminary report.
- 5.6.7 Final findings of the SRP shall concur or differ from the preliminary report. In either case the Chairperson shall re-submit the final report to the NCC.

5.7 Communication of the meeting outcomes

- 5.7.1 Draft version of the minutes shall be finalized by the Member Secretary in consultation with the chairperson and shall be circulated to all members of the SRP.
- 5.7.2 The members shall offer their comments within 5 working days.

	Name	Designation	Signature	Date
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6.0 SAFETY AND PRECAUTIONS

6.1 Do not use any SOP if it is not signed and issued by QA Personnel's or the authorized signatories.

6.1.1 Do not use adhesive tape or whitener on SOP.

6.1.2 Do not share the SOP information to outside the organization.

7.0 REFERENCES: In house

8.0 ABBREVIATIONS

SOP : Standard Operating Procedure
PvPI : Pharmacovigilance Programme of India
NCC : National Coordination Centre
SRP : Signal Review Panel
IPC : Indian Pharmacopoeia Commission
PSUR : Periodic Safety Update Report

9.0 ANNEXURE: Not applicable

	Name	Designation	Signature	Date
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