

 	INDIAN PHARMACOPOEIA COMMISSION National Coordination Centre - Pharmacovigilance Programme of India		MASTER COPY Sign: [Signature] Dt: 08/11/2016	CONTROLLED COPY Sign: [Signature] Dt: 08/11/2016
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	Division	Quality Assurance	Revision No.	00
Effective Date	15/11/2016	Review Date	14/11/2019	
Title: SOP for functioning of Working Group				

1.0 OBJECTIVE

To lay down the procedure for functioning of Working Group.

2.0 SCOPE

This SOP shall be applicable for operational aspects of the Working Group under Pharmacovigilance Programme of India.

3.0 RESPONSIBILITY

- 3.1 All members of the Working Group shall be responsible for the implementation of this SOP.
- 3.2 Technical Secretariat/ Member Secretary shall be responsible for coordination with Working Group.
- 3.3 Quality Manager/Technical Manager shall ensure overall implementation of this SOP.

4.0 ACCOUNTABILITY

Officer-in-charge Pharmacovigilance Programme of India

5.0 PROCEDURE

- 5.1 The Working Group shall function under the aegis of IPC, NCC-PvPI. The working Group shall perform the following activities:

	Name	Designation	Signature	Date
Prepared by	Dr. Rajesh Thakur	S.A	[Signature]	04/11/16
Reviewed by	Dr. Pawan K. Saini	S.O.	[Signature]	07/11/16
Approved by	Dr. Kalisharan	P.S.O	[Signature]	08/11/16

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- 5.1.1 To function as policy making body for the implementation of new effective plan for the PvPI.
- 5.1.2 To advice and approve the strategies to increase the reach of PvPI across the Country.
- 5.1.3 To advice and approve the strategies to promote and create awareness amongst stakeholders about the ADR Reporting.
- 5.1.4 To advice and approve the strategies to establish national/international linkages with healthcare institution and Health Care Professionals.
- 5.1.5 To revise and approve Suspected ADR Reporting form and Guidance document.
- 5.1.6 To consider and approve recommendations of PvPI-Core Training panel, Signal Review Panel, Quality Review Panel.
- 5.1.7 To consider and opine on any issue related to PvPI which has been brought to its notice.

5.2 Quorum of Working Group

- 5.2.1 Minimum four members shall be required to complete a quorum.
- 5.2.2 The maximum number of member in working group shall be 12.

5.3 Constitution of the Working Group

5.3.1 Working Group shall be multi disciplinary panel, constituted by DCG(I) w.r.t Government of India notification with representation of the following:

- Regulator
- Pharmacologist
- Pharmacist
- Clinicians

	Name	Designation	Signature	Date
Prepared by	Dr. Pooja Mehta	S-A	[Signature]	07/11/16
Reviewed by	Dr. Pawan K. Saini	S.O.	[Signature]	07/11/16
Approved by	Dr. Kalu Selvan	PO	[Signature]	8/11/16



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5.3.2 In addition to the above members included in this group, the chairman may co-opt two to three outside experts, whenever felt necessary.

5.4 Decision Making

5.4.1 Decision shall be reached on a majority vote of the Working Group members, provided a quorum has been met.

5.5 Schedule of Meetings

5.5.1 The Working Group shall meet twice in a year.

5.5.2 In order to fix a meeting date, a mutual consensus will be obtained from the members.

5.5.3 All members shall sign a confidentiality disclosure agreement form before the start of first Working Group meeting.

5.5.5 If the member is unable to attend the meeting then he/she shall give reason for not attending the meeting in writing.

5.5.6 The Member Secretary shall be responsible to intimate the members along with meeting details preferably 21 days in advance.

5.5.7 The NCC-PvPI shall maintain records of all its meeting, correspondence and other proceedings for minimum period of five years.

5.6 Communication of meeting outcomes

5.6.1 Member Secretary shall draft the minutes of meeting in consultation with the chairperson and shall circulate to all members of the Working Group for comments.

	Name	Designation	Signature	Date
Prepared by	Dr. Pooja Tripathi	S.A	[Signature]	04/11/16
Reviewed by	Dr. Pawan K. Saini	S.O.	[Signature]	07/11/16
Approved by	Dr. Kalisekharan	PSO	[Signature]	8/11/16



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- 5.6.2 The members shall offer their comments (if any) within 5 working days.
- 5.6.3 The final minutes of meeting shall be approved by Secretary-cum-Scientific Director and the same shall be circulated to all members of Working Group.

6.0 SAFETY AND PRECAUTION

- 6.1 Do not use any SOP if it is not signed and issued by QA Personnel or the authorized signatories.
- 6.2 Do not use adhesive tape or whitener on SOP.
- 6.3 Do not share the SOP information outside the organization.

7.0 REFERENCES: In house

8.0 ABBREVIATIONS

- IPC : Indian Pharmacopoeia Commission
NCC : National Coordination Centre
PvPI : Pharmacovigilance Programme of India

9.0 ANNEXURE: Not applicable

	Name	Designation	Signature	Date
Prepared by	Dr. Pradeep Tripathi	S.A	[Signature]	07/11/16
Reviewed by	Dr. Pawan K. Saini	S.O.	[Signature]	07/11/16
Approved by	Dr. K. G. L. S. V. R. N.	P.S.O	[Signature]	8/11/16