	INDIAN PHARMACOPOEIA COMMISSION National Coordination Centre-Pharmacovigilance Programme of India			
	STANDARD OPERATING PROCEDURE		Page No.	1 of 4
			SOP No.	IPC/PvPI/QA/023
	Division	Quality Assurance	Revision No.	00
	Effective Date	15/11/2016	Review Date	14/11/2019
Title: SOP for functioning of Steering Committee				

1.0 OBJECTIVE

To lay down the procedure for functioning of Steering Committee.

2.0 SCOPE

This SOP shall be applicable for operational aspects of the Steering Committee under Pharmacovigilance Programme of India.

3.0 RESPONSIBILITY

3.1 All members of the Steering Committee shall be responsible for the implementation of this SOP.

3.2 Technical Secretariat/ Member Secretary shall be responsible for coordination with Steering Committee.

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 Steering Committee shall function under the aegis of IPC, NCC-PvPI. The Steering Committee shall perform the following activities:

5.1.1 To supervise the programme.

	Name	Designation	Signature	Date
Prepared by	Dr. Prafull Thota	S.A		04/11/16
Reviewed by	Dr Pawan K. Saini	Scientific officer		07/11/16
Approved by	Dr. Kalaiselvan	PSO		8/11/16

5.1.2 To give the proper direction for expansion of the programme.

5.2 Quorum of Steering Committee

5.2.1 Minimum three members shall be required to complete a quorum.

5.2.2 The maximum number of member in Steering Committee shall be ten.

5.3 Constitution of the Steering Committee

5.3.1 Steering Committee shall be apex panel of PvPI constituted by MoHFW Government of India with representation of the following:

Drug Controller General (India)	Chairperson ex-officio
Secretary-cum-Scientific Director, Indian Pharmacopoeia Commission, Ghaziabad (U.P)	Member ex-officio
Head, Department of Pharmacology, AIIMS, New Delhi	Member ex-officio
A nominee of Director General, ICMR	Member
Assistant Director General (Expanded Programme of Immunization) [ADG(EPI) as representative of the Directorate General Health Services	Member ex-officio
Under Secretary (Drugs Control) as representative of the Ministry of Health & Family Welfare	Member ex-officio
A nominee of Vice Chancellor of Medical / Pharma University	Member

	Name	Designation	Signature	Date
Prepared by	Dr. Pradeep Dutta	S.A		04/11/16
Reviewed by	Dr Pawanki Saini	S.O.		07/11/16
Approved by	Dr Kalaiselvan	PSO		08/11/16

A nominee of the Medical Council of India	Member
A nominee of the Pharmacy Council of India	Member
Officer-In-charge (New Drugs), Central Drugs Standard Control Organisation (CDSCO)	Member-Secretary ex-officio

5.4 Decision Making

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

5.5 Schedule of Meetings

5.5.1 The Steering Committee members shall meet when required.

5.5.2 In order to schedule 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 Steering Committee meeting member.

5.5.4 The Member Secretary shall intimate the meeting details preferably 21 days in advance.

5.5.5 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

	Name	Designation	Signature	Date
Prepared by	Dr. Rajesh Thota	S.A		04/11/16
Reviewed by	Dr. Pawan K. Saini	S.O		07/11/16
Approved by	Dr. Kalaiselvan	D&S		08/11/16

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

5.6.2 The members shall offer their comments (if any) within five working days.

5.6.3 The final minutes of meeting shall be approved by the DCG(I)

6.0 SAFETY AND PRECAUTIONS

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

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

CDSCO : Central Drugs Standard Control Organisation

DCGI : Drug Controller General (India)

IPC : Indian Pharmacopoeia Commission

MoHFW : Ministry of Health and Family Welfare

NCC : National Coordination Centre

PvPI : Pharmacovigilance Programme of India

QA : Quality Assurance

9.0 ANNEXURE: Not applicable.

	Name	Designation	Signature	Date
Prepared by	Dr. Rashid Thota	S.A		04/11/16
Reviewed by	Dr. Pawan K Saini	S.O.		07/11/2016
Approved by	Dr. Kalaiselvan	PSO		08/11/2016