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INDIAN PHARMACOPOEIA COMMISSION  
National Coordination Centre, Pharmacovigilance Programme of India  
Sign: \_\_\_\_\_ Date: 23/06/2016

STANDARD OPERATING PROCEDURE

Page No.

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SOP No.

IPC/PvPI/CP/001

Section

Communication & Publication

Revision No.

00

Effective Date

01/07/2016

Review Date

30/06/2019

Title: SOP for drafting, publication, distribution and control of Resource Materials of PvPI

**1.0 OBJECTIVE**

- 1.1 To lay down the procedure for drafting, publication, distribution and control of Resource Materials of Pharmacovigilance Programme of India.
- 1.2 This SOP describes written instructions, Format, Initiation, Review, Approval, Implementation, Distribution and Control of Resource Materials.

**2.0 SCOPE**

- 2.1 This SOP shall be applicable to the Communication & Publication section of Pharmacovigilance Programme of India.

**3.0 RESPONSIBILITY**

- 3.1 The personnel engaged in the Publication of Resource Materials shall be responsible for adhering to this SOP.
- 3.2 All the Officers and Section-Incharge shall ensure that this SOP has been reflected in the particular section of NCC.
- 3.3 Quality-Manager/Technical-Manager shall ensure overall implementation of this SOP.

**4.0 ACCOUNTABILITY**

- 4.1 Officer Incharge - Pharmacovigilance Programme of India

	Name	Designation	Signature	Date
Prepared by	Pranay Kumar	PvA	<i>Pranay Kumar</i>	21/06/2016
Reviewed by	Dr. Pawan K. Saini	Scientific Officer	<i>[Signature]</i>	22/06/2016
Approved by	Dr. Kalaiselvan	PSO	<i>[Signature]</i>	23/06/2016



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**5.0 PROCEDURE**

- 5.1 The Resource Materials of PvPI shall include PvPI Newsletter, Guidance Document, Performance/Annual Report, Pamphlets, Posters, Stickers, Brochures, Position Paper, Leaflets etc.
- 5.2 Resource materials shall be published by NCC-PvPI as on when required and the whole process of designing, printing, and distribution shall be done within one month time after the final draft approval by the competent authority.
- 5.3 The draft of the newsletter shall be prepared by capturing all the events and updates of PvPI during the specified quarter in a single word file on or before the completion of the quarter and shall be reviewed by the communication team followed by concerned officers and editorial team, advisory board of PvPI newsletter for any suggestion and correction and shall be forwarded to the director for approval and then communicated to the printer for designing and printing.
- 5.4 The e-version (soft copy) of the news letter shall be distributed to all the AMCs, partners and stakeholders of PvPI quarterly after the publication. A hard copy of the Newsletter shall be provided to AMCs & the stakeholders of PvPI on request or as required and a stock register of the same shall be maintained.
- 5.5 The draft of guidance document shall include the various chapters to ensure the good pharmacovigilance practices and shall be reviewed by the concerned experts for their suggestion and comments. All the justified comments shall be

	Name	Designation	Signature	Date
Prepared by	Pranay Kumar	PvA	<i>Pranay Kumar</i>	21/06/2016
Reviewed by	Dr. Pawan K. Saini	S.O.	<i>P.K. Saini</i>	22/06/2016
Approved by	Dr. Kaluisehen	PSO	<i>Kaluisehen</i>	23/06/2016

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included in the final copy and shall be forwarded for designing and printing after the approval from the director.

5.6 The Performance Report shall be published at the end of financial year. The process of drafting shall be completed on or before the end of every financial year. The draft shall capture all the events and updates of PvPI during the specified year and shall be reviewed by the concerned experts. The whole process of designing, printing and distribution shall be done within three months of time after the draft approved by competent authority.

5.7 The content of the Posters, Stickers, Leaflets, Brochures, Position papers shall be prepared as or when required drafted by the communication team as instructed and finalized by the officer incharge PvPI whenever required. The designing and printing shall be done within one month after preparation of final content.

5.8 Copy of resource materials shall be distributed to the AMCs, partners, stakeholders of PvPI on request. The dispatch details shall be mention in the stock register.

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 signatories.

6.2 Do not use adhesive tape or whitener on SOP.

6.3 Do not share the SOP information outside the organization.

	Name	Designation	Signature	Date
Prepared by	Pranay Kumar	PvA	Pranay Kumar	21/06/2016
Reviewed by	Dr. Pawan K. Saini	S.O.	[Signature]	22/06/2016
Approved by	Dr. Kalishwan	PSO	[Signature]	23/06/2016

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**7.0 REFERENCES :** In-house

### 8.0 ABBREVIATIONS

IPC	:	Indian Pharmacopoeia Commission
PvPI	:	Pharmacovigilance Programme of India
NCC	:	National Coordination Centre
AMCs	:	Adverse drug reaction monitoring centres
SOP	:	Standard operating procedure

**9.0 ANNEXURE(s):** Not Applicable

	Name	Designation	Signature	Date
Prepared by	Pranay Kumar	PA	Pranay Kumar	21/06/2016
Reviewed by	Dr. Pawan K. Saini	S.O.	[Signature]	22/06/2016
Approved by	Dr. Kalaidaswan	MO	[Signature]	23/06/2016