



INDIAN PHARMACOPOEIA COMMISSION
National Coordination Centre-Pharmacovigilance Programme of India

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STANDARD OPERATING PROCEDURE

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SOP No.

IPC/PvPI/CP/002

Section

All section

Revision No.

04

Effective Date

01/09/2016

Review Date

31/08/2019

Title: SOP for Communication between PvPI and stakeholders.

1.0 OBJECTIVE

1.1 To lay down a procedure to communicate information under PvPI to stakeholders

2.0 SCOPE

2.1 This SOP shall be applicable to PvPI.

3.0 RESPONSIBILITY

3.1 The personnel engaged in the PvPI activity shall be responsible for adhering to this SOP.

3.2 Quality Manager, Technical Manager, Section-In-charge & AMC Coordinator shall ensure overall implementation of this SOP.

4.0 ACCOUNTABILITY

4.1 Officer Incharge - Pharmacovigilance Programme of India

5.0 PROCEDURE

5.1 The stakeholders of PvPI includes, AMCs including all Health Care Professionals, Pharmaceutical Industries, Patients, Consumers, National Health Programmes, CDSCO, WHO, WHO-UMC, Other regulatory agencies, Research and Development organizations etc.

5.2 Communication of PvPI Staff with AMCs

	Name	Designation	Signature	Date
Prepared by	Pranay Kumar	PVA	Pranay Kumar	24/08/2016
Reviewed by	Dr. Kawan K. Saini	Scientific officer	[Signature]	25/08/2016
Approved by	Dr. Kalai Hwar	PJO	[Signature]	26/08/2016



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The AMCs can use manual, print, electronic and digital mode of communication to create awareness on Pharmacovigilance among healthcare professionals and public with prior permission from NCC.

- 5.2 All the PvPI staff working in NCC/AMC shall require to get prior approval from competent authority to attend the workshop/training/CME/conferences on Pharmacovigilance.
- 5.3 NCC is responsible to publish/communicate any findings from NCC database to journals/media/online-web.
- 5.4 Whereas other PvPI personnel at AMCs are required to get prior approval from NCC to publish/communicate any data or matter related to PvPI.
- 5.5 Any query regarding VigiFlow database shall be forwarded to NCC and not directly to WHO-UMC.
- 5.6 All communication with WHO-HQ, WHO Country office- India shall be managed by NCC.
- 5.7 The NCC shall communicate monthly progress report of AMCs to concern stakeholders.
- 5.8 All PvPI personnel shall document a copy of each communication made at their end.
- 5.9 All publications related to Pharmacovigilance by AMC/NCC shall require to be acknowledged the technical/logistics/financial support of NCC-PvPI.
- 5.10 **Communication with other Stakeholders**
- 5.11 The Communication with other stakeholders shall be done in accordance with individual SOPs such
IPC/PvPI/NHP/001, IPC/PvPI/NHP/002, IPC/PvPI/IIP/001, IPC/PvPI/MIS/001,
IPC/PvPI/QA/010, IPC/PvPI/CP/001, IPC/PvPI/SD/002, IPC/PvPI/TE/002
- 5.12 Apart from the above SOPs communication with stakeholders shall be done with prior permission from the programme In-charge.

	Name	Designation	Signature	Date
Prepared by	Pranay Kumar	PvA	Pranay Kumar	24/08/2016
Reviewed by	Dr. Pawan K. Saini	S.O.	[Signature]	25/08/2016
Approved by	Dr. Kalishwan	PJO	[Signature]	20/08/2016



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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 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

SOP	:	Standard Operating Procedure
AMC	:	Adverse Drug Reaction Monitoring Centre
PvPI	:	Pharmacovigilance Programme of India
NCC	:	National Coordination Centre
QA	:	Quality Assurance
ADR	:	Adverse Drug Reaction
PvA	:	Pharmacovigilance Associate
WHO-HQ	:	World Health Organization-Head Quarter
UMC	:	Uppsala Monitoring Centre
CME	:	Continuing Medical Education

9.0 ANNEXURE(s): Not Applicable

	Name	Designation	Signature	Date
Prepared by	Pranay Kumar	PvA	Pranay Kumar	24/08/2016
Reviewed by	Dr. Pawan K. Saini	S.O.	MJ	25/08/2016
Approved by	Dr. Kalaiselvan	P/0	U	26/08/2016