	INDIAN PHARMACOPOEIA COMMISSION **National Coordination Centre-Pharmacovigilance Programme of India**			
	STANDARD OPERATING PROCEDURE		**Page No.**	**1 of 4**
			SOP No.	**IPC/PvPI/MIS/001**
	Section	PvPI Helpline (MIS)	**Revision No.**	**03**
	Effective Date	03/05/2016	**Review Date**	02/05/2019
Title: SOP for receiving ADR from Healthcare Professionals and Consumers through PvPI Helpline				

1.0 OBJECTIVE

1.1 To lay down a procedure for receiving ADR through Helpline.

2.0 SCOPE

2.1 This SOP shall be applicable to Personnel working at NCC.

3.0 RESPONSIBILITY

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

3.2 All the Officers and Section In charge shall ensure that this SOP has been reflected in the sections.

3.3 Quality Manager/Technical Manager shall ensure overall implementation of this SOP.

4.0 ACCONTABILITY

4.1 Officer In charge – Pharmacovigilance Programme of India

5.0 PROCEDURE

5.1 The designated personnel at NCC need to attend all the calls received via PvPI helpline **(18001803024).**

Note: The call received via helpline could be either to report ADR or to enquire about ADR reporting. The personnel have to respond accordingly.

5.2 If a caller is enquiring about ADR reporting, assist the caller on ADR reporting, monitoring and how, where and whom to report. Also give a brief overview of PvPI-mission and objectives.

	Name	Designation	Signature	Date
Prepared by	Prabhakar Mishra	Tech. Associate		22/04/2016
Reviewed by	Dr. Rafeed Thota	S.A		25/04/2016
Approved by	Dr. Kalaiselvan	PSO		26/04/2016

5.3 If a call is for reporting ADR, the personnel have to collect reporter's information. Note down the reporter's name, type of reporter (healthcare professional, non-healthcare professional or patient), reporter's address and contact details.

Note: Collect all the information on Suspected Adverse Drug Reaction Reporting Form / Medicines Side Effect Reporting Form (For Consumers) as per SOP.

5.4 The personnel have to collect information on patient initial, age at the onset of event and sex.

5.5 Write down the reaction as it is describe by the reporter. If the reporter is a healthcare professional, request the reporter for a specific reaction term. Also confirm the date on which the reaction was observed (date of event occurred is mandatory).

5.6 Provide each option for the seriousness criteria to the reporter and if a reaction found to be serious tick (✓) the appropriate option.

5.7 Collect the information on the suspected medicine from the reporter (name of the drug is mandatory). If possible, collect information regarding manufacturer details, batch no., dose, route, frequency and date of therapy.

5.8 The personnel also have to collect information on whether the drug was stopped, continued or dose reduced and subsequently ask for outcome of the reaction whether it was recovered, recovering or not recovered.

5.9 Collect information on concomitant drugs (if any) and laboratory data supporting the reaction occurrence.

5.10 In addition to this, ask the reporter for any previous history of reaction with same or different drug(s) to the patient.

5.11 The personnel shall ask for any pre-existing medical condition (allergies, smoking, alcohol use, co-morbidities etc.) to the patient.

5.12 The personnel shall ask for additional information (if any).

5.13 After collecting the information, assist the reporter on how to report an ADR in future. Provide the details of the nearest AMC to the reporter.

Note: Always send a feedback message to the reporter after collecting ADR.

5.14 Collected information shall be filled in ADR reporting form and a scanned copy with e-mail shall be forwarded to the nearest AMC depending upon the location of the reporter for further follow up and verification of the report, within three working days.

Note: If the reporter is a Healthcare Professional then collected ADR shall enter in VigiFlow at NCC.

5.15 The Coordinator/Technical Associate at the respective AMC shall call to the reporter for follow-up and validation of the report within five working days after receiving ADR at AMC.

5.16 The Coordinator/Technical Associate shall also have to enter the details into VigiFlow software and send Report ID with a confirmation e-mail to NCC after validating and performing the causality assessment.

Note: The Coordinator/Technical Associate must enter the report in the VigiFlow irrespective of the relationship between the suspected drug and reaction.

5.17 The Personnel entering the report into VigiFlow must indicate in the report title as (HELPLINE) for the reports received via PvPI helpline.

e.g. Gum hyperplasia : Phenytoin (HELPLINE)

	Name	Designation	Signature	Date
Prepared by	Prabhakar Mishra	Tech. Associate		22/04/2016
Reviewed by	Dr. Rahul Thota	SA		25/04/2016
Approved by	Dr. Kalaiselvan	PSO		26/4/2016

6.0 SAFETY AND PRECAUTION (IF ANY)

6.1 Do not use 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 REFRENCES : In-house

8.0 ABBREVIATION

ADR	:	Adverse Drug Reaction
SOP	:	Standard Operating Procedure
NCC	:	National Coordination Centre
AMC	:	Adverse Drug Reaction Monitoring Centre
PvPI	:	Pharmacovigilance Programme of India

9.0 ANNEXURE : Nil

	Name	Designation	Signature	Date
Prepared by	Prabhakar Mishra	Tech. Associate		22/04/2016
Reviewed by	Dr. Rafat Jyoti	S.O		25/04/2016
Approved by	Dr. Kalaiselvan	PIO		26/04/2016