	INDIAN PHARMACOPOEIA COMMISSION **National Coordination Centre-Pharmacovigilance Programme of India**			
	STANDARD OPERATING PROCEDURE		**Page No.**	**1 of 6**
			SOP No.	**IPC/PvPI/QA/011**
	Section	All Sections	**Revision No.**	**04**
	Effective Date	01/04/2016	**Review Date**	31/03/2019
Title:	**SOP to fill Suspected Adverse Drug Reaction Reporting Form**			

1.0 OBJECTIVE

1.1 To lay down a procedure to fill Suspected Adverse Drug Reaction Reporting Form.

2.0 SCOPE

2.1 This SOP shall be applicable to NCC and AMC under PvPI.

3.0 RESPONSIBILITY

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

3.2 All AMC's Co-ordinators who works for Pharmacovigilance Programme of India at their respective AMCs shall be responsible for adhering to this SOP.

3.3 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 Suspected ADR Reporting Form is divided into four sections – (A) Patient Information, (B) Suspected Adverse Reaction, (C) Suspected Medications and (D) Reporter details.

	Name	**Designation**	**Signature**	**Date**
Prepared by	Rishi Kumar	Tech. Associate		14/3/2016
Reviewed by	Dr. Priyadarshi	S.A		15/03/2016
Approved by	Dr. Idaleuselvan	PSO		16/03/16

5.2 In section A, write the patient initials (point no 1), age at the time of event or date of birth of the patient (point no 2), sex (point no 3) and weight (point no 4). This information should be filled completely as it is used to identify patient characteristics.

5.3 Mention the date of reaction started (point no 5) and date of reaction recovered (point no 6) in section B. If exact date is not known at least mention the month and year.

5.4 Describe the event or reaction (point no 7) in terms of its nature, localization, severity and characteristics.

5.5 In the section C, provide either the generic or brand name of suspected medication(s) (point no 8) with details of manufacturer, batch no, expiry date, dose used, route of administration, frequency, dates of drug started & stopped, indication for use and causality assessment.

Note: If a drug is not stopped at the time of reporting, write 'continued' in the space provided.

5.6 Carefully tick (✓) in the point no 9, Action Taken and point no 10, Reaction reappeared after reintroduction, for de-challenge and re-challenge status of medication respectively.

5.7 Consider the following description: **'Drug withdrawn'-** if the drug has been stopped after reaction. '**Dose increased'-** if the dose has been increased after reaction, **'Dose reduced'-** if the dose has been decreased after reaction, **'Dose not changed'-** if the dose not changed, **'Unknown'**- if information on de-challenge is not known, **'Not Applicable'**- if de-challenge is not applicable as in case of vaccines, anaesthesia or where single dose is given,

Note: In case dechallenge has not performed and the drug therapy is continued, write 'continued' in the space provide below the option date stopped (point no 8) and leave point no 9 as blank.

	Name	Designation	Signature	Date
Prepared by	Rishi Kumar	Tech. Associate		14/3/2016
Reviewed by	Dr. Pratap Sinha	S.A		15/3/2016
Approved by	Dr. Kalaiselvan	PSO		16/3/16

5.8 Consider the following description while optioning for re-challenge: **'Yes'**- if reaction reappeared after re-challenge, **'No'**- if reaction does not reappeared after re-challenge, **'Effect unknown'**- if information on re-challenge is not known, **'dose (if reintroduced)'**- if a dose is reduced on dechallenge and reintroduced to patient after dechallenge. Also mention the reintroduced dose (either same or different).

5.9 Write the details of concomitant medication(s) (point no 11) as this information is required in causal analysis of the event and to detect drug interactions.

5.10 Mention the laboratory tests and tests data with dates (if done) which support the occurrence of event or reaction (point no 12).

5.11 Write the other relevant medical history (point no 13) such as allergies, smoking, alcohol use, pregnancy, hepatic/renal dysfunction surgeries, hereditary illness etc. Any pre-existing medical conditions (e.g. hypertension, diabetes etc) should also mention in this section.

5.12 If an event is serious in nature (see definitions), tick (✓) the appropriate criteria for seriousness of the reaction (point no 14). If an event is not serious, tick (✓) the appropriate box provided.

5.13 Carefully tick (✓) the option for the outcome of the reaction (point no 15). Consider the following description while optioning for outcome: '**Fatal**'- if the patient dies due to adverse event or the ADR is associated with fatal outcome, **'Not Recovered'**- if the patient is continuing with the event occurred, **'Recovering'**- if the patient is recovering from the existing event occurred, **'Recovered'**- if the patient recovered from the event occurred, '**Recovered with sequelae'**- if the patient recuperated and retained the pathological condition resulting from previous disease or injury. **'Unknown'**- if the outcome is not known.

5.14 A reporter must mention his/her name, professional address, contact details and signature after filling the form (point no 16), Section D.

	Name	Designation	Signature	Date
Prepared by	Rishi Kumar	Tech. Associate		14/3/2016
Reviewed by	Dr. Syed Shoab	S.A		15/03/2016
Approved by	Dr. Kalaiselvan	PSO		16/03/16

5.16 Ensure all the points filled in the form are appropriate and legible and use of whitener is prohibited. In case any mistake happen in filling the sADR reporting form that may be once strike with pen and initial signature of reporter may be put on mistake.

5.17 Write patient identity (OPD or IPD registration number) number on the top (left hand side) of the Suspected ADR Reporting Form. This will help in verification/ cross-checking of the reports by coordinators of AMCs as well as representative from NCC and CDSCO for auditing AMCs.

5.18 Follow the below format to write AMC Report No: AMC name/month-year of report received at AMC/Report no. of that particular month e.g. AIIMS/Jan-2013/01

5.19 Write AMC Report No. and Worldwide Unique No. (Generated by VigiFlow) at the top right corner of Suspected ADR Reporting Form in the box provided.

Important Notes:

a) All the duly filled forms should be archived at the respective AMC at least for a period of three years after reporting to NCC.

b) Multiple ADRs suspected to be caused by same drug that are manifestation of the same problem/reaction should be recorded in the same form.

c) For multiple ADRs suspected to be cause by same drug that are not overtly related to each other, use separate forms to record them. The AMC Report No followed by subsequent increase in the report no. with respect to reporting date. For e.g. AIIMS/Jan-2013/01-a, AIIMS/Jan-2013/01-b, AIIMS/Jan-2013/01-c. Subsequently the suffixes a, b, and c can increase. All these filled ADR forms will share the same Worldwide Unique No.

d) For multiple ADRs caused by different drugs taken concomitantly by a patient, use separate forms to record them and follow the above same pattern to provide AMC Report No.

	Name	Designation	Signature	Date
Prepared by	Rishi Kumar	Tech. Associate		14/3/2016
Reviewed by	Dr. Pradeep Sharma	S.A		15/03/2016
Approved by	Dr. Kalaiselvan	PIO		16/03/16

e) Collect all the information required to be filled in the form. In case complete information is not available fill all the Essentially Required items (ERI) for a quality ICSR. In case ERI are not available make sure that the form contains all the mandatory fields.

Mandatory Fields	Essentially Required items
Patient initials, age at onset of reaction, reaction term(s), date of onset of reaction, suspected medication(s) and reporter's information.	Patient initials, age at onset of reaction, gender, reaction term(s), date of onset of reaction, suspected medication(s), dose, date of therapy started, indication of use, seriousness, outcome, drug withdrawn and rechallenge details, reporter's information and date of report, causality assessment.

Note: For a valid case report mandatory fields are the minimum requirement.

6.0 SAFETY AND PRECAUTIONS

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

6.2 Do not use adhesive tape or whitener on SOP.

6.3 Do not share the SOP information out side the organization.

	Name	Designation	Signature	Date
Prepared by	Rishi Kumar	Tech. Associate		14/3/2016
Reviewed by		S.A		15/3/2016
Approved by	Dr. Kalaiselvan	PSO		16/3/16

7.0 REFERENCES

7.1 VigiFlow user guide (https://adr.who-umc.org/userguide.pdf)

8.0 ABBREVIATIONS

SOP	:	Standard Operating Procedure
PvPI	:	Pharmacovigilance Programme of India
NCC	:	National Coordination Centre
QA	:	Quality Assurance
ADR	:	Adverse Drug Reaction
ICSRs	:	Individual Case Safety Reports
OPD	:	Out Patient Department
IPD	:	In Patient Department

9.0 ANNEXURE(s):

Annexure I : Specimen copy of ADR reporting Form

	Name	Designation	Signature	Date
Prepared by	Rishi Kumar	Tech. Associate		14/3/2016
Reviewed by	Dr. Prasad Thota	S-A		15/3/2016
Approved by	Dr. Kalaiselvan	PSO		16/3/16

INDIAN PHARMACOPOEIA COMMISSION

National Coordination Centre-Pharmacovigilance Programme of India

Annexure-1
SUSPECTED ADR REPORTING FORM

Version-1.2

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of Adverse Drug Reactions by Healthcare Professionals

INDIAN PHARMACOPOEIA COMMISSION
(National Coordination Centre-Pharmacovigilance Programme of India)
Ministry of Health & Family Welfare, Government of India
Sector-23, Raj Nagar, Ghaziabad-201002

FOR AMC/NCC USE ONLY

AMC Report No. :

Worldwide Unique No. :

Report Type ☐ Initial ☐ Follow up

A. PATIENT INFORMATION

1. Patient Initials _____
2. Age at time of Event or Date of Birth _____
3. M ☐ F ☐ Other ☐
4. Weight _____ Kgs

B. SUSPECTED ADVERSE REACTION

5. Date of reaction started (dd/mm/yyyy)
6. Date of recovery (dd/mm/yyyy)
7. Describe reaction or problem

12. Relevant tests/ laboratory data with dates

13. Relevant medical/ medication history (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/renal dysfunction etc.)

14. Seriousness of the reaction: No ☐ if Yes ☐ (please tick anyone)
- ☐ Death (dd/mm/yyyy)
- ☐ Life threatening
- ☐ Hospitalization/Prolonged
- ☐ Disability
- ☐ Congenital-anomaly
- ☐ Required intervention to Prevent permanent impairment/damage
- ☐ Other (specify)

15. Outcomes
- ☐ Recovered
- ☐ Recovering
- ☐ Not recovered
- ☐ Fatal
- ☐ Recovered with sequelae
- ☐ Unknown

C. SUSPECTED MEDICATION(S)

S.No	8. Name (Brand/Generic)	Manufacturer (if known)	Batch No. / Lot No.	Exp. Date (if known)	Dose used	Route used	Frequency (OD, BD etc.)	Therapy dates		Indication	Causality Assessment
								Date started	Date stopped		
i											
ii											
iii											
iv											

S.No as per C	9. Action Taken (please tick)						10. Reaction reappeared after reintroduction (please tick)			
	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown	Yes	No	Effect unknown	Dose (if reintroduced)
i										
ii										
iii										
iv										

11. Concomitant medical product including self-medication and herbal remedies with therapy dates (Exclude those used to treat reaction)

S.No	Name (Brand/Generic)	Dose used	Route used	Frequency (OD, BD, etc.)	Therapy dates		Indication
					Date started	Date stopped	
i							
ii							
iii							

Additional Information:

D. REPORTER DETAILS

16. Name and Professional Address: _____
_____
Pin: _____ E-mail _____
Tel. No. (with STD code) _____
Occupation: _____ Signature: _____

17. Date of this report (dd/mm/yyyy):

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Programme staff is not expected to and will not disclose the reporter's identity in response to a request from the public. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction.

	Name	Designation	Signature	Date
Prepared by	Rithi Kumar	Tech. Associate		14/3/2016
Reviewed by	Dr. Anjali Gupta	S.O		15/3/2016
Approved by	Dr. Kalaiselvan	P.S.O		16/3/16

INDIAN PHARMACOPOEIA COMMISSION

National Coordination Centre-Pharmacovigilance Programme of India

Annexure-1
SUSPECTED ADR REPORTING FORM

National Coordination Centre
Pharmacovigilance Programme of India
Ministry of Health & Family Welfare,
Government of India
Sector-23, Raj Nagar, Ghaziabad-201002
Tel.: 0120-2783400, 2783401, 2783392
Fax: 0120-2783311
www.ipc.nic.in

Pharmacovigilance Programme of India for Assuring Drug Safety

ADVICE ABOUT REPORTING

A. What to report

- Report serious adverse drug reactions. A reaction is serious when the patient outcome is:
  - Death
  - Life-threatening
  - Hospitalization (initial or prolonged)
  - Disability (significant, persistent or permanent)
  - Congenital anomaly
  - Required intervention to prevent permanent impairment or damage
- Report non-serious, known or unknown, frequent or rare adverse drug reactions due to Medicines, Vaccines and Herbal products.

B. Who can report

- All healthcare professionals (Clinicians, Dentists, Pharmacists and Nurses) can report adverse drug reactions

C. Where to report

- Duly filled Suspected Adverse Drug Reaction Reporting Form can be send to the nearest Adverse Drug Reaction Monitoring Centre (AMC) or directly to the National Coordination Centre (NCC).
- Call on Helpline (Toll Free) 1800 180 3024 to report ADRs.
- Or can directly mail this filled form to pvpi@ipcindia.net or pvpi.ipcindia@gmail.com
- A list of nationwide AMCs is available at:
  http://www.ipc.gov.in, http://www.ipc.gov.in/PvPI/pv_home.html

D. What happens to the submitted information

- Information provided in this form is handled in strict confidence. The causality assessment is carried out at AMCs by using WHO-UMC scale. The analyzed forms are forwarded to the NCC through ADR database. Finally the data is analyzed and forwarded to the Global Pharmacovigilance Database managed by WHO Uppsala Monitoring Centre in Sweden.
- The reports are periodically reviewed by the NCC-PvPI. The information generated on the basis of these reports helps in continuous assessment of the benefit-risk ratio of medicines.
- The information is submitted to the Steering committee of PvPI constituted by the Ministry of Health & Family Welfare. The Committee is entrusted with the responsibility to review the data and suggest any interventions that may be required.

E. Mandatory field for suspected ADR reporting form

- Patient initials, age at onset of reaction, reaction term(s), date of onset of reaction, suspected medication(s) and reporter information.

For ADRs Reporting Call on PvPI Helpline (Toll Free)

1800 180 3024

(9:00 AM to 5:30 PM, Working Days)

	Name	Designation	Signature	Date
Prepared by	Rishi Kumar	Tech. Assistant		14/3/2016
Reviewed by	Dr. Prafull Jain	SA		15/3/2016
Approved by	Dr. Kalaiselvan	PSO		16/3/16