Version 1.4

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For **VOLUNTARY** reporting of ADRs 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

PvPI Helpline (Toll Free) :1800-180-3024 (9:00 AM to 5:30 PM, Monday-Friday)

Initial Case ❑ ____ Follow-up Case ❑ ____

FOR AMC / NCC USE ONLY

Reg. No. / IPD No. / OPD No. / CR No. :

AMC Report No. :

Worldwide Unique No. :

A. PATIENT INFORMATION *

1. Patient Initials:

2. Age or date of birth:

3. Gender: M ☐ F ☐ Other ☐

4. Weight (in Kg.)

B. SUSPECTED ADVERSE REACTION *

5. Event / Reaction start date (dd/mm/yyyy)

6. Event / Reaction stop date (dd/mm/yyyy)

7. Describe Event/Reaction management with details , if any

12. Relevant investigations with dates :

13. Relevant medical / medication history (e.g. allergies, pregnancy, addiction, hepatic, renal dysfunction etc.)

14. Seriousness of the reaction : No ☐ if Yes ☐ (*please tick anyone*)

☐ Death (dd/mm/yyyy) ☐ Congenital-anomaly

☐ Life threatening ☐ Disability

☐ Hospitalization-Initial/Prolonged ☐ Other Medically important

15. Outcome:

☐ 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.	Expiry Date (if known)	Dose	Route	Frequency	Therapy Dates		Indication	Causality Assessment
								Date Started	Date Stopped		
i											
ii											
iii											
iv#											

9. Action taken after reaction (*please tick*)

S. No. as per C	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown
i						
ii						
iii						
iv						

10. Reaction reappeared after reintroduction of suspected medication (*please tick*)

Yes	No	Effect unknown	Dose (if re-introduced)

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	Route	Frequency (OD, BD, etc.)	Therapy Dates		Indication
					Date Started	Date Stopped	
i							
ii							
iii#							

Additional Information :

D. REPORTER DETAILS *

16. Name & Address : _____

_____

Pin : _____ Email : _____

Contact No- : _____

Occupation : _____ Signature : _____

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

Signature and Name of Receiving Personnel :

Confidentiality : The patient's identity is held in strict confidence and protected to the fullest extent. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction. Submission of an ADR report does not have any legal implication on the reporter.

\# Use separate page for more information

* Mandatory Fields for suspected ADR Reporting Form

ADVICE ABOUT REPORTING

A. What to report?

All adverse events should be reported

Report non-serious, known or unknown, frequent or rare adverse drug reactions due to Medicines, Vaccines & Herbal Products.

Report every 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
- Report intervention to prevent permanent impairment or damage

NOTE : Serious/Adverse Event following immunization can also be reported in Serious AEFI case Notification Form available on http://www.ipc.gov.in

B. Who can report?

All healthcare professionals (Clinicians, Dentists, Pharmacists and Nurse etc.) can report adverse drug reactions

C. Where to report?

Duly filled in Suspected Adverse Drug Reaction Reporting Form can be sent to the nearest Adverse Drug Reaction Monitoring Centre (AMC) or directly to the National Coordination Centre (NCC) for PvPI.

Call on Helpline (Toll Free) 1800 180 3024 to report ADRs or directly mail this filled form to pvpi.ipc@gov.in

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-PvPI 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 Signal Review Panel of PvPI reviews the data and suggests any interventions that may be required.

E. Mandatory fields for suspected ADR Reporting Form (*)

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

For Adverse Drug Reaction Reporting Tools

- **E-mail : pvpi.ipc@gov.in**
- **PvPI Helpline (Toll Free) : 1800 180 3024** (9:00 AM to 5:30 PM, Monday-Friday)
- **ADR Mobile App : "ADRPvPI"**