



# SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of Adverse Drug Reactions by Healthcare Professionals

<b>INDIAN PHARMACOPOEIA COMMISSION</b>							<b>FOR AMC/NCC USE ONLY</b>				
(National Coordination Centre-Pharmacovigilance Programme of India) Ministry of Health & Family Welfare, Government of India Sector-23, Raj Nagar, Ghaziabad-201002							AMC Report No. _____ :				
Report Type <input type="checkbox"/> Initial <input type="checkbox"/> Follow up							Worldwide Unique No. _____ :				
<b>A. PATIENT INFORMATION</b>							12. Relevant tests/ laboratory data with dates				
1. Patient Initials _____		2. Age at time of Event or Date of Birth _____		3. M <input type="checkbox"/> F <input type="checkbox"/> Other <input type="checkbox"/>							
				4. Weight _____ Kgs							
<b>B. SUSPECTED ADVERSE REACTION</b>							13. Relevant medical/ medication history (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/renal dysfunction etc.)				
5. Date of reaction started (dd/mm/yyyy)							14. Seriousness of the reaction: No <input type="checkbox"/> if Yes <input type="checkbox"/> (please tick anyone)  <input type="checkbox"/> Death (dd/mm/yyyy) <input type="checkbox"/> Congenital-anomaly <input type="checkbox"/> Life threatening <input type="checkbox"/> Required intervention to Prevent permanent impairment/damage <input type="checkbox"/> Hospitalization/Prolonged <input type="checkbox"/> Disability <input type="checkbox"/> Other (specify) _____				
6. Date of recovery (dd/mm/yyyy)											
7. Describe reaction or problem											
							15. Outcomes  <input type="checkbox"/> Recovered <input type="checkbox"/> Recovering <input type="checkbox"/> Not recovered <input type="checkbox"/> Fatal <input type="checkbox"/> Recovered with sequelae <input type="checkbox"/> Unknown				
<b>C. SUSPECTED MEDICATION(S)</b>											
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	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unkn own	Yes	No	Effect unknown	Dose (if reintroduced)	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:							<b>D. REPORTER DETAILS</b>				
							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.

**National Coordination Centre**  
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**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](mailto:pvpi@ipcindia.net) or [pvpi.ipcindia@gmail.com](mailto: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](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)