# SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of Adverse Drug Reactions by Healthcare Professionals

## A. PATIENT INFORMATION

<table>
<thead>
<tr>
<th>1. Patient Initials</th>
<th>2. Age at time of Event or Date of Birth</th>
<th>3. M □ F □ Other □</th>
<th>4. Weight □ Kgs</th>
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## B. SUSPECTED ADVERSE REACTION

<table>
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<tr>
<th>5. Date of reaction started (dd/mm/yyyy)</th>
<th>6. Date of recovery (dd/mm/yyyy)</th>
<th>7. Describe reaction or problem</th>
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## C. SUSPECTED MEDICATION(S)

<table>
<thead>
<tr>
<th>S.No</th>
<th>8. Name (Brand/Generic)</th>
<th>Manufacturer (if known)</th>
<th>Batch No./ Lot No.</th>
<th>Exp. Date (if known)</th>
<th>Dose used</th>
<th>Route used</th>
<th>Frequency (OD, BD etc.)</th>
<th>Therapy dates</th>
<th>Indication</th>
<th>Causality Assessment</th>
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## D. REPORTER DETAILS

<table>
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<tr>
<th>16. Name and Professional Address:</th>
<th>17. Date of this report (dd/mm/yyyy):</th>
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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.
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:

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.