Instructions to HCPs for Filling Suspected ADR Reporting Form

A. PATIENT INFORMATION

1. **Patient Initials:** A reporter should only mention the initials of a patient instead of the full name e.g., Ramesh Patil should be written as RP.

2. **Age at the Time of Event or Date of Birth:** A reporter must report either the date of birth or age of the patient at the time the event or reaction occurred.

3. **Gender:** A reporter should mention the gender of the patient.

4. **Weight:** A reporter should mention weight of the patient in kilograms.

B. SUSPECTED ADVERSE REACTION

5. **Event / Reaction Start Date:** A reporter must report the date on which the reaction was first observed. Dates should be usually mentioned in dd/mm/yyyy format.

6. **Event / Reaction Stop Date:** If the event or reaction stopped/recovered, the date on which it takes place should be reported.
   6(i). Onset Lag Time: Reporter should mention approximate time required for first occurrence of reaction/event/symptoms after the drug administration e.g., if drug is administered at 10.00 am and reaction/event was first observed at 11.30 am, then onset lag time should be recorded as 1 hour 30 minutes.

7. **Describe Event/Reaction with Treatment Details, if any:** A reporter must briefly describe the event in terms of nature, localization etc. e.g., patient developed erythematous maculopapular rash over upper and lower limbs.

C. SUSPECTED MEDICATION(S)

8. **Name of Medication:** The details of suspected medication(s) such as the drug name (brand or generic name), manufactured/marketed by, batch No./lot No., expiry date, dose used, route used, dosage frequency, dates of therapy started and stopped, and indication should be provided by the reporter.
   Causality Assessment: The reporter (if trained) should perform the causality assessment. Causality assessment should be done as per the 'World Health Organization – Uppsala Monitoring Center (WHO-UMC) Causality Assessment Scale'. Please refer page number 4 to get information on 'causality terms' and 'assessment criteria' used for this scale.

9. **Action Taken:** A reporter should mark (√) tick inside the relevant box/section (following are the options: drug withdrawn, dose increased, dose reduced, dose unchanged, not applicable, unknown).
    - Unknown: If information is not confirmed or not known.
    - Not Applicable/NA: In case of anaphylaxis, life threatening events, anesthetic drugs.
    - Dose Increased/Reduced: Reporter to mention the increased/reduced dose of the medication.

10. **Reaction Reappeared after Re-introduction (Re-challenge Details):** A reporter must report the status of re-introduction as:
    - Yes: If reaction reappeared after re-introduction.
    - No: If reaction did not reappear after re-introduction.
    - Unknown: If information on re-introduction is not confirmed or not known.
    - Not Applicable/NA: If re-introduction is not applicable as in the case of injections.
    - Re-introduced dose: If the drug is reintroduced, mention exact dose of the medicine. This information will be useful to understand whether dose of the medicine was reduced or unchanged or increased.

11. **Concomitant Medications** (exclude those used to treat reaction): A reporter should include all the details of concomitant drugs (brand/generic name, dose used, route used, dosage frequency, indication etc.) including self-medication, OTC medication, herbal remedies with therapy dates (start and stop date).

12. **Relevant Tests/ Laboratory Data:** If available, a reporter should mention laboratory data with dates relevant to the adverse event that occurred.

13. **Relevant Medical/Medication History:** A reporter must mention any relevant history pertaining to the patient including pre-existing medical conditions e.g., allergies, race, pregnancy, smoking, alcohol use, hepatic/renal dysfunction, post-surgery etc.

14. **Seriousness of the Reaction:** If any event is serious in nature, a reporter must select the appropriate reason for seriousness:
    - Death: If the patient died due to the adverse event. In this case, date of the death should be mentioned.
    - Disability: If the adverse event resulted in a substantial disruption of a person's ability to conduct normal life functions.
    - Life-threatening: If patient was at substantial risk of dying because of the adverse event.

- Congenital Anomaly: If exposure of drug prior to conception or during pregnancy may have resulted in an adverse outcome in the child.
- Hospitalization/Prolonged Hospital Stay: If the adverse event led to hospitalization or increased the hospital stay of the patient.
- Other Medically Important: When the event does not fit the other outcomes, but the event may put the patient at risk and may require medical or surgical intervention to prevent one of the other outcomes e.g., serious blood dyscrasias or seizures/convulsions that do not result in hospitalization, development of drug dependence or drug abuse.

15. **Outcomes:** The reporter must tick the outcome of the event as:
    - Recovered: If the patient is recovered from the event.
- Recovering: If the patient is recovering from the existing adverse event.
    - Not Recovered: If condition of the patient is not improved/recovered.
    - Fatal: If the patient dies due to the adverse event.
    - Recovered with Sequelae: Patient has recovered from the acute event, but, subsequently develop sequelae which are associated with the adverse reactions of drug therapy.
- Unknown: If the outcome is not known.

D. REPORTER DETAILS

16. **Name and Address:** On the form, a reporter/health care professional (HCP) such as Clinician, Dentist, Pharmacist, or Nurse should mention his/her name, address, qualification/occupation, and contact details along with their signature. The identity of the reporter will be kept confidential.

17. **Date of the Report:** A reporter must record the date on which the report has been generated.

NOTE: For quality reporting of ICSRs all the above mentioned fields are essential. In case of incomplete information, the reporter must take care that at least mandatory fields are reported (marked with * in the ADR form). If you need any help in this regard, you can contact to our representatives/PvOI.

Following are the mandatory fields for a valid case report:

- Patient Information: Initials, age at onset of reaction.
- Suspected Adverse Reaction: Description of the reaction (reaction terms), reaction date.
- Suspected Medication(s): Name (brand/generic) of the medication.
- Reporter Details: Name, address, contact details, qualification, and date of the report.

WHO-UMC Causality Categories / Assessment Scale

Causality Term	Assessment Criteria
Certain	• Event or laboratory test abnormality, with plausible time relationship to drug intake • Cannot be explained by disease or other drugs • Response to withdrawal plausible (pharmacologically, pathologically) • Event definitive pharmacologically or phenomenologically (i.e. an objective and specific medical disorder or a recognised pharmacological phenomenon) • Rechallenge satisfactory, if necessary
Probable / Likely	• Event or laboratory test abnormality, with reasonable time relationship to drug intake • Unlikely to be attributed to disease or other drugs • Response to withdrawal clinically reasonable • Rechallenge not required
Possible	• Event or laboratory test abnormality, with reasonable time relationship to drug intake • Could also be explained by disease or other drugs • Information on drug withdrawal may be lacking or unclear
Unlikely	• Event or laboratory test abnormality, with a time to drug intake that makes a relationship improbable (but not impossible) • Disease or other drugs provide plausible explanations
Conditional / Unclassified	• Event or laboratory test abnormality • More data for proper assessment needed, or • Additional data under examination
Unassessable / Unclassifiable	• Report suggesting an adverse reaction • Cannot be judged because information is insufficient or contradictory • Data cannot be supplemented or verified