SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of Adverse Drug Reactions by healthcare professionals

CDSCO
Central Drugs Standard Control Organization
Directorate General of Health Services,
Ministry of Health & Family Welfare, Government of India,
FDA Bhavan, ITO, Kotla Road, New Delhi
www.cdsco.nic.in

(AMC/ NCC Use only
AMC Report No.
Worldwide Unique no.

A. Patient Information

1.Patient Initials _____

2.Age at time of Event or date of birth

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3. Sex ☐M ☐ F

4. Weight ____Kgs

12. Relevant tests / laboratory data with dates

B .Suspected Adverse Reaction

5. Date of reaction stated (dd/mm/yyyy)

6. Date of recovery (dd/mm/yyyy)

7. Describe reaction or problem

13. Other relevant history including pre-existing medical conditions (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/ renal dysfunction etc)

14. Seriousness of the reaction

- ☐ Death (dd/mm/yyy)____
- ☐ Life threatening
- ☐ Hospitalization-initial or prolonged
- ☐ Disability
- ☐ Congenitial anomaly
- ☐ Required intervention to prevent permanent impairment / damage
- ☐ Other (specify)

15. Outcomes

- ☐ Fatal
- ☐ Recovering
- ☐ Unknown
- ☐ Continuing
- ☐ Recovered
- ☐ Other (specify)____

C.Suspected medication(s)

S.No	8. Name (brand and /or generic name)	Manufacturer (if known)	Batch No./ Lot No. (if known)	Exp. Date (if known)	Dose used	Route used	Frequency	Therapy dates (if known give duration)		Reason for use of prescribed for
								Date started	Date stopped	
i.										
ii.										
iii.										
iv.										

Sl.No As per C	9. Reaction abated after drug stopped or dose reduced					10. Reaction reappeared after reintroduction				
	Yes	No	Unknown	NA	Reduced dose	Yes	No	Unknown	NA	If reintroduced dose
i.										
ii.										
iii.										
iv.										

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

D. Reporter (see confidentiality section in first page)

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

17. Causality Assessment

18. Date of this report (dd/mm/yyyy)

ADVICE ABOUT REPORTING

- **Report adverse experiences with medications**
- **Report serious adverse reactions. A reaction is serious when the patient outcome is:**

  - death
  - life-threatening (real risk of dying)
  - hospitalization (initial or prolonged)
  - disability (significant, persistent or permanent
  - congenital anomaly
  - required intervention to prevent permanent impairment or damage

- **Report even if:**

  - You're not certain the product caused adverse reaction
  - you don't have all the details, however, point nos. **1, 5, 7, 8, 11, 15, 16 & 18** (see reverse) are essentially required.

- **Who can report:**

  - Any health care professional (Doctors including Dentists, Nurses and Pharmacists)

- **Where to report:**

  - Please return the completed form to the nearest ***Adverse drug reaction Monitoring Centre (AMC)*** or to ***National Coordinating Centre***
  - A list of nationwide AMCs is available at: http://cdsco.nic.in/pharmacovigilance.htm

- **What happens to the submitted information:**

  - Information provided in this form is handled in strict confidence. The causality assessment is carried out at Adverse Drug Reaction Monitoring Centres (AMCs) by using WHO-UMC scale. The analyzed forms are forwarded to the National Coordinating Centre through the ADR database. Finally the data is analyzed and forwarded to the Global Pharmacovigilance Database managed by WHO Uppsala Monitoring Center in Sweden.

  - The reports are periodically reviewed by the National Coordinating Centre (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 and Family Welfare. The Committee is entrusted with the responsibility to review the data and suggest any interventions that may be required.

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Pharmacovigilance Programme of India for Assuring Drug Safety

Pharmacovigilance Programme of India (PvPI)

National Coordinating Centre,
Indian Pharmacopoeia Commission
Ministry of Health & Family Welfare,
Govt. of India
Sector-23, Raj Nagar, Ghaziabad-201 002.Tel.:0120-2783400, 2783401, 2783392, FAX: 0120-2783311
E.mail: ipclab@vsnl.net

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Programme staff is not ex- pected 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**.

A. Patient Information

1. *Patient initials:* A reporter should only mention the initials of a patient instead of the full name. For e.g.: Madhu Gupta should be written as MG.
2. *Age at 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. *Sex:* A reporter must mention the gender of the patient.
4. *Weight:* The weight of the patient should be in kilograms.

B. Suspected Adverse Reaction

5. *Date of reaction started:* A reporter must report the date on which the reaction was first observed.
6. *Date of recovery:* If the reaction recovered, the date on which the reaction recovered should be reported.
7. *Describe reaction:* A reporter must briefly describe the event in terms of nature, localization etc. For example patient developed erythematous maculopapular rash over upper and lower limbs.

C. Suspected Medications

8. The details of suspected medication(s) such as the *drug name (brand or generic name), manufacturer, batch no/lot no, expiry date, dose used, route used, frequency, dates of therapy started and stopped, and indication of use* must be provided by the reporter.
9. *De-challenge details:* A reporter must report the status of de-challenge as:
    - **'Yes'**- if reaction abated or reduced after de-challenge
    - **'No'**- if reaction did not abated after de-challenge
    - **'Unknown'**- if information on de-challenge is not confirmed or not known
    - **'Not Applicable' or 'NA'**- if de-challenge is not possible as in case of anaphylaxis, life threatening events, anaesthetic drugs or where a single dose is given.
    - **'Reduced dose'**- If dose at which the reaction occurred is reduced
      Note: Also mention the reduced dose
10. *Re-challenge details:* A reporter must report the status of re-challenge as:
    - '**Yes'**- if reaction reappeared after re-challenge

- **'No'**- if reaction did not reappear after re-challenge
- **'Unknown'**- if information on re-challenge is not confirmed or not known
- **'Not Applicable' or 'NA'**- if re-challenge is not applicable as in the case of injections.
- **'Re-introduced dose'**- If the drug is reintroduced is it a reduced dose or is it the same dose at which adverse event occurred initially.

11. *Concomitant drugs:* A reporter should include all the details of concomitant drugs including self medication, OTC medication, herbal remedies with therapy dates (start and stop date.)

12. *Relevant tests/ laboratory data:* A reporter must mention any laboratory data (if available) relevant to the adverse event that occurred.

13. *Other relevant history:* A reporter must mention any relevant history pertaining to the patient including pre-existing medical conditions (e.g. allergies, pregnancy, smoking, alcohol use, hepatic/renal dysfunction).

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
- **'Life-threatening'**- if patient was at substantial risk of dying because of the adverse event
- **'Hospitalisation/prolonged'**- if the adverse event led to hospitalization or increased the hospital stay of the patient
- **'Disability'**- if the adverse event resulted in a substantial disruption of a person's ability to conduct normal life functions
- **'Congenital anomaly'**- if exposure of drug prior to conception or during pregnancy may have resulted in an adverse outcome in the child.
- **'Required intervention to prevent permanent impairment/damage'**- if medical or surgical intervention was necessary to preclude permanent impairment of a body function, or prevent permanent damage to a body structure
- **'Other'** -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. Examples include serious blood dyscrasias (blood

disorders) 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:

- **'Fatal'**- if the patient dies due to the adverse event
- **'Continuing'**- if the patient is continuing to have the symptoms of the adverse event which occurred
- **'Recovering'**- if the patient is recovering from the existing adverse event
- **'Recovered'**- if the patient has recovered from the event
- **'Unknown'**- if the outcome is not known

D. Reporter

16. *Name and Professional address:* A reporter must mention his/her name and professional address on the form. The identity of the reporter will be maintained confidential

17. *Causality assessment:* The reporter (if trained) must perform the causality assessment.

18. *Date of report:* Mention the date on which he/she reported the adverse event.

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 present. Following are the mandatory fields for a valid case report:

- Patient information: initials, age at onset of reaction, gender.
- Suspected adverse reaction: A reaction term(s), date of onset of reaction
- Suspected medication: Drug(s) name, dose, date of therapy started, indication of use, seriousness, outcome, de-challenge and re-challenge details
- Reporter: Name and address, causality assessment, date of report