SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

CDSCO

Central Drugs Standard Control Organization

Directorate General of Health Services,
Ministry of Health & Family Welfare, Government of India,
Nirman Bhawan. New Delhi - 110011
www.cdsco.nic.in

For VOLUNTARY reporting of Adverse Drug Reactions by health care professionals

Report #

To be filled in by Pharmacovigillance centres receiving the form.

A. Patient information

1. Patient identifier initials _____ In confidence

2. Age at time of event: or _____ Date of Birth:

3. Sex: ☐ M ☐ F

4. Weight_____ Kgs

B. Suspected Adverse Reaction

5. Date of reaction started (dd/mm/yy):

6. Date of recovery (dd/mm/yy):

7. Describe reaction or problem

12. Relevant tests/ laboratory data, including dates

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/yy)_____
- ☐ Life threatening
- ☐ Hospitalization-initial or prolonged
- ☐ Disability
- ☐ Congenital anomaly
- ☐ Required intervention to prevent permanent impairment/ damage
- ☐ Other (specify)_____

15. Outcomes

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

C. Suspected medication(s)

Sl. No.	8. Name (brand and / or generic name)	Manufac-turer (If known)	Batch No. / Lot No. (If known)	Exp. Date (If known)	Dose used	Route used	Frequency	Therapy dates (if unknown, give duration)		Reason for Use or 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 products and therapy dates including self medication and herbal remedies (exclude those used to treat reaction)

D. Reporter (see confidentiality section in first page)

16. Name and Professional Address: _____

_____

_____

Pin code: _____ E-mail: _____

Cell No. / Tel. No. with STD Code: _____

Speciality: _____ Signature:

17. Occupation

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

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 although 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:**
  - After completing, please return this form to the same Pharmacovigilance centre from where you received.
  - A list of countrywide Pharmacovigilance Centres is available at: www.cdsco.nic.in

- **What happens to the submitted information:**
  - Information provided in this form is handled in strict confidence. Peripheral Pharmacovigilance Centres will forward this form to the Regional Pharmacovigilance Centres, where the causality analysis is carried out and the information is forwarded to the Zonal Pharmacovigilance Centres. Finally the data is statistically analysed and forwarded to the Global Pharmacovigilance Database managed by WHO Uppsala Monitoring Center in Sweden.
  - Data is periodically reviewed by the National Pharmacovigilance Advisory Committee constituted by the Ministry of Health and Family Welfare. The Committee is entrusted with responsibility to review the data and suggest any interventions that may be required.

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ATTENTION

HEALTH CARE PROFESSIONALS

Your 5 Minutes Can Help Us Ensure Safer Medications

Please return this form to:

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.