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

3. Sex M F

4. Weight ______ Kgs

B. Suspected Adverse Reaction

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

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

7. Describe reaction of problem

12. Relevant tests/laboratory data with 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/yyy)_____
- ◊ Life threatening
- ◊ Hospitalization-initial or prolonged
- ◊ Disability
- ◊ Congenitial anomaly
- ◊ Required intervention to prevent permanent impairment/damage
- ◊ Other ()specify

15. Outcomes

- ◊ Fatal
- ◊ Continuing
- ◊ Recovering
- ◊ Recovered
- ◊ Unknown
- ◊ 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	Reduced 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)