Reporting Form for Suspected Adverse Reactions National Pharmacovigilance Program for ASU & H Drugs

Note:

Personal information will be kept confidential.

All suspected reactions are to be reported with relevant details.

ADR Number / Year
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1. Patient / consumer identification (please complete or tick boxes below as appropriate)

Patient Initials:		Patien	t Record Number (PRN)
Place of Birth	IPD / OPD		
Address		Age	:
Village / Town		Sex:	Male / Female / Others
Post / Via			
District / State			
Diagnosis:	Constitution and Temperame	ent:	

2. Description of the suspected Adverse Reactions

Date and time of initial observation	
Description of reaction	

3. Whether the patient is suffering with any chronic disorders?

Hepatic Renal Cardiac Diabetes Any Others (Specify, if others)

- 4. Addictions, if any? If yes, please specify:
- 5. H/O previous allergies / Drug reactions, if any: If yes, please specify:
- 6. List of all ASU & H drugs used by the patient during the period of one month:

Name of the	Manufact		Form / Route of	Date of		Reason	Any
drug	urer / Batch no.	Dose	administration	Starting	Stopped / Continued	for use	unwanted occurrences

7. List	7. List of other drugs used by the patient during the period of one month:					
Name	Manufacturer /	_	Form / Route of	Date of	Reason	Any

Name	Manufacturer /		Form / Route of	Date of		Form / Pouts of Date of Posses	Reason	Any
of the drug	Batch no.	Dose	administration	Starting	Stopped / Continued	for use	unwanted occurrences	

8. Details of the drug suspected to cause ADR:

- a. Name of the drug:
- b. Manufacturing date and Expiry date (if available):
- c. Remaining pack / label (if available):
- d. Consumed orally along with (water / milk / honey / or any other)
- e. Whether any dietary precautions have been prescribed? If yes, please specify:
- f. Whether the drug is consumed under medical supervision or used as self medication.
- g. Any other relevant information associated with drug use:

9. Management provided / taken for suspected adverse reaction

10. Please indicate outcome of the suspected adverse reaction (tick appropriate)

Recovered:	Not	Unknown:	Fatal:	If Fatal	
	recovered:			Date of death:	
Severe: Yes / No. Reaction ab		abated after drug	stopped or d	ose reduced:	
		· ·			
	Reaction reappeared after re administration of drug:			tion of drug:	
Was the patient admir	Was the patient admitted to hospital? If yes,				
give name and address of hospital					

11. Any abnormal findings of relevant laboratory investigations related to the episode done pre and post episode of ADR:

12. Particulars of ADR Reporter:

Please tick: Patient / Attendant / Nurse / Doctor /	/ Pharmacist / Health worker / Drug Manufacturer
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Any others (please specify)	
Name:	
Address:	
Telephone / E - mail:	

The ADR Probability Scale

(Program Coordinator has to fill this scale)

	Questions	Yes	No	Don't Know
1	Are there previous conclusive reports on the reactions?	+1	0	0
2	Did the ADR appear after the suspected drug was administered?	+2	-1	0
3	Did the ADR improve when the drug was discontinued a specific antagonist was administered?	+1	0	0
4	Did the adverse reaction reappear when the drug was re-administered?	+2	-1	0
5	Are there alternatives causes that could solely have caused the ADR?	-1	+2	0
6	Was the drug detected in the blood (or other fluids) in a concentration known to be toxic?	+1	0	0
7	Was the reaction more severe when the dose was increased, or less severe when the dose was decreased?	+1	0	0
8	Did the patient have a similar reaction to the same or similar drugs in any previous exposure?	+1	0	0
9	Was the adverse event confirmed by objective evidence?	+1	0	0
	Total Score			

Score: > 9 = Certain; 5-8 = Probable; 1-4 = Possible; 0 = Unlikely

(Reporter should fill the below by placing ✓ mark at appropriate place relevant to the reporting condition)

The Suspected Adverse Event	Grade - 1 (Mild)	
-	Grade - 2 (Moderate)	
	Grade - 3 (Severe)	
	Grade - 4 (Threatening)	
The Suspected Adverse Event	Serious	
-	Non-Serious	
The Suspected Adverse Event is	Physician	
due to	Patient	
	Drug	
	Other factors* (Explain other factors)	

Signature of the reporter:

Date:

Please send the completed form to: The centre from where the form is received or to

The Coordinator, National Pharmacovigilance Coordination Centre (NPvCC)

All India Institute of Ayurveda (AIIA), Mathura Road, Gautam Puri,

Sarita Vihar, New Delhi - 110 076

E-mail: pharmacovigilanceayush@gmail.com, ayush-pharmavig@aiia.gov.in

Signature Program Coordinator