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.

Ay-AllA	Ay-NIA	Ay-IPGT	Un-NIUM	Si-NIS	Ho-NIH
Code of Peripheral Centre		ADR Number / Year			

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

Patient Initials:		Pa	atient Record Number
Place of Birth	IPD / OPD		(PRN)
Address:		Age:	
Village / Town:		Sex:	Male / Female / Others
Post / Via:			
District / State:			
Diagnosis:	Constitution and Tempera	ment:	
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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)
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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	Manufacturer /		Form / Route of	Form (Pouto of Date of	Reason	Any unwanted occurrences	
of the drug	Batch no.	Dose	administration	Starting	Starting Stopped / Continued		

7. List of other drugs used by the patient during the period of one month:

Name	Manufacturer /		Form / Route of	Date of		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. Reactio		n abated after dr	ug stopped	or dose reduced:
	Reactior	Reaction reappeared after re administration of drug:		
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 / Any others (please specify)
Name:
Address:
Telephone / E - mail:

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

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			

<u>Score:</u> > 9 = Certain;

5-8 = Probable; 1-4 = Possible;

0 = Unlikely

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

Signature Program Coordinator