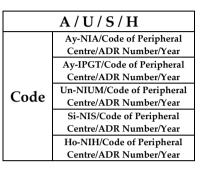
PHARMACOVIGILANCE OF AYURVEDA, SIDDHA, UNANI and HOMOEOPATHY (ASU & H) DRUGS

Reporting Form for Suspected Adverse Reactions

Note:

- i. Personal information of the consumers / patients / ADR reporter's will be kept confidential.
- ii. All suspected reactions are to be reported with relevant details.
- iii. All completed forms are to be submitted to the program coordinator of nearby centre.



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

Name		Patient	t Record Number
Place of Birth	IPD / OPD		(PRN)
Address		Age:	
Village / Town		Sex:	Male / Female
Post / Via			
District / State			
Diagnosis:	Constitution and Tempera	ament:	

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

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	Manufacturer /		Form / Route of	Da	ate of	Reason	Any unwanted
the drug	Batch no.	Dose	administration	Starting	Stopped / Continued	for use	occurrences

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

Name of the drug	Manufacturer / Batch no.	Dose	Form / Route of administration	Da Starting	ate of Stopped / Continued	Reason for use	Any 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. Rea		abated after dr	ug stopped	or dose reduced:	
Reaction reappeared after re administration of drug:					
Was the patient admitted to hospital? If					
yes, give name and a	address of ho	spital			

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 / 1	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 Centre All India Institute of Ayurveda, Sarita Vihar, New Delhi - 110 076 Email: <u>pharmacovigilanceayush@gmail.com</u>

The ADR Probability 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 =	= Unlike	ely