SMBT Sevabhavi Trust's
SMBT AYURVED COLLEGE AND HOSPITAL
Nandihills, Dhamangaon-Gholi, Tal. Igatpuri, Nashik-422403 Ph. (02553) 282341
Email : principal.ayurved@smbt.edu.in | smbtayurved@gmail.com | www.smbt.edu.in

Date: 15/02/2021

Mechanism of collection, analysis and reporting of adverse drug reactions

(Standard Operation Procedures)

Title:

Mechanism of collection, analysis and reporting of adverse drug reactions

Tenure of the committee:

The committee shall be reconstituted every year.

Scope of the committee:

The committee shall meet quarterly in a year. The committee shall be responsible for planning, implementing and monitoring of various activities of the Pharmacovigilance committee. They will also work as mentors and facilitators.

Purpose:

To generate awareness about Adverse Drug Reactions (ADRs) amongst all health care providers (doctors, consultants, nurses, pharmacists, post graduate & undergraduate students, service providers, etc) of S.M.BT. Ayurved College and Hospital, Dhamangaon to identify ADR occurring in patients admitted to S.M.B.T. Ayurved Hospital and report the same to the appropriate authorities.

S.M.B.T. Ayurved College Dhamangaon

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Roles and Responsibilities of committee:

Chairman:

The chairman will chair and conduct all meetings and will function as administrative head of the committee.

Coordinator:

The convener shall be responsible for arranging meetings and conducting activities with help of member secretary. He/She will have following responsibilities:

1. To arrange for the meetings, write minutes, circulate and document the same

2. To collect ADR reports from member secretory (Co-chairperson)

3. To report collected ADRs to Peripheral Pharmacovigilance Center i.e. Raja Ramdeo Anandilal Podar (RRAP) at https://www.ayushsuraksha.com/suspected-adverse reactions/(Center code: Ay/NIA/002) in first week of every month

4. To report all serious adverse reactions to the Peripheral Pharmacovigilance Center within 24 Hrs.

5. To liaison with healthcare professionals in order to inculcate / foster the culture of ADR reporting

5. To organize the awareness generation programs for reporting ADR related to ASU and H drugs

6. To organize and attend training programs/ interactive meetings for interns, P.G students, nursing staff and teaching faculty members in the institute.

Member Secretary (Co-chairperson):

The member secretary will play the pivotal role and shall undertake following activities to help the task of the convener (Co-ordinator):

1. Prepare agenda of the meetings and send in advance to members
2. Collect ADR reports from S.M.B.T Ayurved Hospital
3. Carry out causality assessment.
4. He/she will also chair the meetings in absence of the chairman.

Members:

Members will primarily work as subject experts and will also do the mentoring of junior/young faculty/resident doctors/ students in the area of ADR. They will collect information of ADR observed in OPD/IPD of Department to the member secretory. They will give suggestions for better and effective functioning of the committee and shall work as facilitators.

Procedure:

What to Report?

- All suspected drug related adverse events, including those suspected to have been caused by ASU drugs alone or along with any other drugs. All adverse reactions suspected to have been caused by interaction with any other drugs or food incompatibilities should be reported.
- The reporting of seemingly insignificant or common adverse reactions would be important since it may highlight a widespread prescribing problem.

- Reactions to any other drugs which are suspected of significantly affecting a patients management, including reactions suspected of causing:

  1. Death
  2. Life threatening (real risk of dying)
  3. Hospitalization (initial or prolonged)
  4. Disability (significant, persistent or permanent)
  5. Congenital anomaly
  6. Required intervention to prevent permanent impairment or damage

The prescribed Adverse Drug Event reporting form for ASU Drugs shall be used for reporting ADRs.

Who Can Report? (Reporter) and Where to Report?

Pharmacovigilance Committee Members will be reporter and they will report any suspected Adverse Drug Reaction to:

1. Member Secretory (Co-chairperson) or
2. Member from Department of *Rasashastra* and *Bhaishajyakalpanaa* or
3. Member from Department of *Agadatantra, Vyavahaara Ayurveda* and *Vidhi Vaidyaka*.

Handling of Information:

The information in the form shall be handled in confidentiality. Coordinator shall forward the form to the Peripheral Pharmacovigilance Centre.

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Hierarchy:

Notifier

⇓

Reporter

⇓

Member Secretory

⇓

Coordinator

⇓

Peripheral Pharmacovigilance Center

(Notifier is any person who suspects to have experienced/observed an ADR and informs it to members of Institutional Pharmacovigilance Committee about it.)

Forms attached:

1. ADR Reporting form.

Principal
S.M.B.T.Ayurved College & Hospital
Nandi-Hills, Dhamangaon, Tal.Igatpuri, Dist.Nashik

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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-AIIA	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:		Patient Record Number (PRN)
Place of Birth	IPD / OPD	
Address: Village / Town: Post / Via: District / State:		Age: Sex: Male / Female / Others
Diagnosis:	Constitution and Temperament:	

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

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

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

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 recovered:	Unknown:	Fatal:	If Fatal Date of death:
Severe: Yes / No.	Reaction abated after drug stopped or dose reduced:			
	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:**

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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, GautamPuri,
SaritaVihar, 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 readministered?	+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**

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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 due to	Physician	
	Patient	
	Drug	
	Other factors*	

Signature
Program Coordinator
Dr. Pradeep Naik

B.A.M.S. Ayurved College Dhamangaon