Sanjeevani Multipurpose Foundation's
Dr. Deepak Patil Ayurvedic Medical College & Research Center
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•Recognized By Central Council of Indian Medicine, New Delhi & Govt. of India, Ministry of Health & Family Welfare. Department of AYUSH, New Delhi & Govt. of Maharashtra, Medical Education & Medicine Dept.•
•Affiliated to Maharashtra University Of Health Sciences, Nashik •

Pharmacovigilance Cell Policy and Constitution

1. Introduction of the Pharmacovigilance Cell:

Pharmacovigilance is a key component of drug safety monitoring, primarily aimed at detecting, assessing, understanding, and preventing adverse effects or any other possible drug-related issues. The Pharmacovigilance Cell at Dr. Deepak Patil Ayurvedic Medical College and Research Center, Borpadale, shall operate in alignment with Regional, National, or Central Pharmacovigilance Cells to ensure the safety and efficacy of Ayurvedic medicines used in patient care.

2. Aims and Objectives of the Pharmacovigilance Cell:

Aims:

-To safeguard public health by monitoring the safety of Ayurvedic medicines.

-To promote the safe use of Ayurvedic formulations and practices.

-To identify, document, and report adverse drug reactions (ADRs) and potential risks related to Ayurvedic drugs.

Objectives:

-To establish a standardized system for reporting ADRs.

-To conduct regular surveillance and analysis of reported ADRs and suggest interventions.

-To create awareness among healthcare professionals and students regarding the importance of pharmacovigilance.

-To collaborate with Regional, National, or Central Pharmacovigilance Cells for the integration of data and formulation of safety measures.

3. Vision and Mission of the Pharmacovigilance Cell:

Vision:

To ensure the safety and quality of Ayurvedic treatments and contribute to the enhancement of patient care through effective pharmacovigilance practices.

Mission:

To build a sustainable, proactive, and responsive pharmacovigilance system that continuously monitors and improves the safety of Ayurvedic medications and treatments.

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4. Members of the Pharmacovigilance Cell:

Coordinator:
A faculty member from the departments of Rasashastra and Bhaishajya Kalpana and Dravyaguna will act as the coordinator of the cell.

Faculty Members:

One faculty member from each of the following departments:

Kayachikitsa
Shalya Tantra
Shalakya Tantra
Prasuti and Streeroga
Kaumarabhritya
Panchakarma
Swathavritta
Agada Tantra

Meeting Frequency:
The cell members shall meet at least once every two months to discuss reported ADRs and other related issues.

5. Expected Functions of the Pharmacovigilance Cell:

-Monitoring and identifying ADRs associated with Ayurvedic medications.

-Collection, documentation, and analysis of ADR data from patients receiving Ayurvedic treatments.

-Preparing and maintaining records of adverse events reported by patients or healthcare providers.

-Creating awareness among practitioners, students, and patients regarding drug safety and the need for pharmacovigilance.

-Sending compiled reports to the Regional, National, or Central Pharmacovigilance Cells as required.

-Recommending changes or interventions in clinical practices or formulations based on ADR analysis.

6. Working Methodology of the Pharmacovigilance Cell:

1.Data Collection:
The cell will collect data on ADRs from various departments within the institution through standardized ADR forms.

2. Analysis:
The collected data will be reviewed by the members of the cell, identifying trends, patterns, and potential risks associated with specific Ayurvedic drugs or treatments.

3. Collaboration:
The cell will collaborate with other institutions and the higher levels of pharmacovigilance cells (Regional, National, or Central) for shared data, improved analysis, and formulation of national strategies.

4. Awareness and Training:
The cell will organize workshops, seminars, and training sessions for faculty, students, and healthcare practitioners to promote pharmacovigilance practices.

7. Reporting of the Issues Occurred:

-The Pharmacovigilance Cell shall actively document and report all adverse drug reactions (ADRs) and drug-related issues that occur within the institution.

-Standardized ADR reporting forms will be used for data collection from all departments.

-After analysis, these reports shall be submitted to the Regional, National, or Central Pharmacovigilance Cells.

-The issues reported will include not only ADRs but also any drug quality concerns, labeling errors, or drug interactions observed during treatments.

-The cell will ensure timely reporting of all issues for immediate intervention, if required.

8. Outcome of the Functioning of the Cell:

Improved Patient Safety: Regular monitoring and reporting of ADRs will lead to enhanced safety and efficacy of Ayurvedic treatments.

Data-Driven Insights: Analysis of reported issues will provide valuable insights for improving clinical practices and formulating safer drug protocols.

Intervention and Corrective Measures: Based on ADR data, the cell will recommend corrective actions such as drug modifications, altered treatment regimens, or changes in clinical protocols.

Awareness and Education: Regular functioning of the cell will raise awareness among healthcare providers, students, and patients about the importance of drug safety.

Compliance and Documentation: The cell will ensure the institution's compliance with national pharmacovigilance guidelines, thereby contributing to national drug safety databases.

9. Future Work and Path Ahead of the Pharmacovigilance Cell:

-Expansion of the Pharmacovigilance Cell's activities to include active surveillance of herbal drugs and formulations used in clinical trials or new treatment protocols.

-Strengthening collaborations with external agencies, research institutions, and other pharmacovigilance bodies to improve drug safety.

-Continuous improvement in data collection methods, reporting formats, and analysis techniques to ensure effective monitoring of Ayurvedic medicines.

-Focus on educating the public and patients regarding safe Ayurvedic drug use and the importance of reporting ADRs.

-Regular review of pharmacovigilance policies and inclusion of new methodologies in accordance with national and international standards.

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Adverse Drug Reaction (ADR) Reporting Form

Pharmacovigilance Cell
Dr. Deepak Patil Ayurvedic Medical College and Research Centre, Borpadale

Patient Information:

1. Patient Name:

2. Patient ID/OPD Number:

3. Age:

4. Gender: ☐ Male ☐ Female ☐ Other

5. Weight (kg):

6. Height (cm):

7. Date of Birth:

Contact Information:

8. Address:

9. Contact Number:

10. Email (if available):

Adverse Reaction Details:

11. Date of Reaction:

12. Time of Reaction:

13. Description of Reaction (Signs & Symptoms):

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14. Severity of Reaction:
☐ Mild ☐ Moderate ☐ Severe ☐ Life-threatening ☐ Fatal

15. Outcome of Reaction:
☐ Recovered ☐ Recovering ☐ Not Recovered ☐ Fatal
☐ Unknown ☐ Disability ☐ Prolonged Hospitalization

Suspected Drug(s) Details:

16. Drug(s) Suspected to Cause Reaction:

Sr. No	Drug Name	Dose	Route	Frequency	Start Date	End Date	Indication

17. Was the Drug Stopped or Dose Altered After Reaction?
☐ Yes ☐ No ☐ Unknown

18. If Yes, What Action Was Taken?
☐ Stopped ☐ Dose Reduced ☐ Frequency Changed ☐ Other (Please specify): ____

19. Concomitant Medications (Including Herbs, Supplements, and Other Drugs):

Medical History:

20. Relevant Past Medical History (Allergies, Chronic Illnesses, etc.):

21. Any Known Allergies (Including to Drugs, Foods, or Herbs):
☐ Yes ☐ No
If Yes, specify:

Reporter Information:

22. Reporter Name:

23. Reporter Designation: ☐ Doctor ☐ Nurse ☐ Pharmacist ☐ Student ☐ Patient ☐ Other (Please specify):

24. Department:

25. Contact Number:

26. Email (if available):

27. Date of Report:

For Pharmacovigilance Cell Use Only:

28. Date of Report Received:

29. Reaction Assessed By:

30. Causality Assessment (As Per WHO-UMC Criteria):
☐ Certain ☐ Probable ☐ Possible ☐ Unlikely ☐ Conditional/Unclassified ☐ Unassessable

31. Was the Reaction Preventable? ☐ Yes ☐ No ☐ Not Assessable

32. Outcome of Assessment/Action Taken:
☐ Reported to Regional/National Cell ☐ Reinvestigation Required
☐ Corrective Measures Suggested ☐ No Further Action Required

33. Additional Comments (If Any):

Signature of Reporter:

Date:

This ADR form is structured to ensure comprehensive data collection and enable effective analysis. It captures patient demographics, details of the adverse reaction, suspected drugs, and concomitant medications, alongside the healthcare provider's assessment and actions taken by the pharmacovigilance cell.

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