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Document Name:	**Standard Operating Procedure (SOP) for Adverse Drug Reaction (ADR) Monitoring and Reporting under the Pharmacovigilance Committee**
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Approved by:	**Dean DVVPF's Medical College & Hospital, Ahilyanagar**
Responsibility of updating:	**Pharmacovigilance Committee DVVPF's Medical College & Hospital, Ahilyanagar**

DOCUMENT AMENDMENT RECORD

SL No	Section / Chapter	Revision Date	Description of the revision	Signature of the Chairman of the committee	Approved by
1.	New Document	01/08/2025	Initial issue of SOP for for Adverse Drug Reaction (ADR) Monitoring and Reporting under the Pharmacovigilance Committee	Signed	Dean

INDEX

PREPARATION OF STANDARD OPERATING PROCEDURES OF DVVPF'S MEDICAL COLLEGE AND HOSPITAL

Pharmacovigilance Committee

1. Purpose

To define the standard procedure for identification, documentation, processing, and reporting of suspected Adverse Drug Reactions (ADR) in patients and to ensure systematic reporting to the Pharmacovigilance Programme of India (PvPI) through the VigiFlow system.

2. Scope

This SOP applies to all healthcare professionals including consultants, residents, interns, nurses, pharmacists, and paramedical staff who identify or report suspected ADRs to the Department of Pharmacology, which serves as the institutional Adverse Drug Reaction Monitoring Centre (AMC)

3. Definitions / Abbreviations

- ADR- Adverse Drug Reaction
- PvPI- Pharmacovigilance Programme of India
- IPC- Indian Pharmacopoeia Commission
- VigiFlow - Online pharmacovigilance reporting software used under PvPI
- AMC- Adverse Drug Reaction Monitoring Centre

4. Composition of the Committee

Sr. No	Name	Designation
1	Dr. Sunil Mhaske	Chairman
2	Dr. Satish Deshpande	Medical Superintendent
3	Dr. Satish More	Dy. Medical Superintendent
4	Dr. Vijay Patil	Dy. Dean (Admin)
5	Dr. Abhijit Awari	Dy. Dean (UG)
6	Dr. Awani Kumar Shrivastava	Dy. Dean (PG)
7	Dr. Kiran Vakade – Pharmacology	In charge
8	Dr. Abhijit Shinde – Paediatrics	Member
9	Dr. Jayant Gadekar – Gen. Surgery	Member
10	Dr. Deepak Naikwade – Orthopaedics	Member
11	Dr. Gautam Aher – OB & GY	Member
12	Dr. Jaheer Mujawar – Pharmacology	Member
13	Dr. Seshla Sadanandan – Pharmacology	Member Secretary

5. Roles and Responsibilities Department of Pharmacology

Chairperson / Head of Department

- Overall supervision of ADR monitoring and reporting activities.

Faculty / Pharmacovigilance Coordinator

- Verification and assessment of ADR reports.
- Entry of ADR data into the VigiFlow system.
- Communication with the National Coordination Centre.

Healthcare Professionals

- Identification and reporting of suspected ADRs.

6. Advice About Reporting: Healthcare professionals should report:

Any suspected adverse reaction associated with medications. Serious adverse events, including when the outcome is:

- Death
- Life-threatening condition
- Hospitalization (initial or prolonged)
- Significant disability or persistent impairment
- Congenital anomaly
- Intervention required to prevent permanent damage

ADR should also be reported when:

- The reporter is not certain that the drug caused the reaction.
- All details are not available, provided the minimum mandatory information is included.

7. Procedure

7.1 Identification of ADR - Any healthcare professional including consultants, junior residents, senior residents, interns, nurses, pharmacists, or paramedical staff who observes or suspects an ADR should report it to the Department of Pharmacology.

7.2 Initial Documentation- The suspected ADR should be documented using the ADR Reporting Form available in the hospital or department. The reporting healthcare professional should record relevant details including:

- Patient demographics
- Suspected drug(s)
- Description of the reaction

- Date of onset
- Clinical management and outcome

7.3 Submission of ADR Form- The completed ADR reporting form should be submitted to the Department of Pharmacology for further processing.

7.4 Verification of ADR Form- Faculty members from the Department of Pharmacology review the ADR form for accuracy, completeness, and presence of mandatory information.

7.5 Minimum Criteria for Valid ADR Case- A valid ADR report must contain the following essential elements as per PvPI guidelines:

- Identifiable patient
- Suspected drug(s)
- Description of adverse reaction
- Identifiable reporter

7.6 Causality Assessment- Preliminary causality assessment may be conducted by trained faculty members using standard tools such as the WHO–UMC causality assessment scale.

7.7 Online Reporting through VigiFlow- Once the ADR report is verified, the details are entered into the VigiFlow database, the official pharmacovigilance reporting platform under the Pharmacovigilance Programme of India.

7.8 Steps for Entering ADR into VigiFlow- The designated faculty member performs the following steps:

1. Log in to the VigiFlow portal using authorized institutional credentials.
2. Access the ADR reporting interface.
3. Enter patient demographic details.
4. Record reporter details.
5. Enter suspected drug(s) and concomitant medications.
6. Describe the adverse reaction including seriousness, clinical course, and outcome.
7. Attach supporting laboratory reports or documents if available.
8. Review the information for completeness and accuracy.
9. Submit the ADR report electronically.

7.9 Transmission to National Coordination Centre- After submission, the ADR report is automatically transmitted to the Indian Pharmacopoeia Commission (IPC), Ghaziabad, which serves as the National Coordination Centre for PvPI

8. Records and Documentation- The following documents are maintained in the Department of Pharmacology:

- Completed ADR reporting forms
- Copies of submitted VigiFlow reports
- ADR monitoring records
- Follow-up documentation if applicable

These records are maintained for pharmacovigilance monitoring, institutional audits, and regulatory review.

9. Confidentiality and Ethics

- Patient identity and personal information are kept strictly confidential.
- The identity of the reporter will also remain confidential and will not be disclosed publicly.

Submission of an ADR report does not imply that the healthcare professional, manufacturer, or product caused the adverse event.

10. Reference

- Pharmacovigilance Programme of India (PvPI) Guidelines
- Indian Pharmacopoeia Commission (IPC)

11. Review and Continuous Improvement : This SOP shall be:

- Reviewed annually or earlier if required by the Pharmacovigilance Committee.
- Updated in accordance with the guidelines of the Pharmacovigilance Programme of India (PvPI) and the Indian Pharmacopoeia Commission.
- Revised whenever there are changes in national pharmacovigilance policies, ADR reporting formats, or regulatory requirements.
- Aligned with institutional pharmacovigilance activities and quality assurance practices to ensure effective ADR monitoring, reporting, and patient safety.

Approval Authority
Dean
DVVPF's Medical College & Hospital, Ahilyanagar