कार्यालय, प्रधानाचार्य, स्वशासी राज्य चिकित्सा महाविद्यालय, शाहजहॉपुर, उ0प्र0–242001
Office of the principal, Autonomous State Medical College, Shahjahanpur, U.P.-242001
Website: www.smcsha.in e-mail: principalsmcshaha@gmail.com Phone: 05842-240-209
(स्वशासी संस्थान राज्य सरकार उ0प्र0)
(An Autonomous Institute under government of U.P.)

पत्रांक–प्रधानाचार्य / कमेटी / 2026 / 85 दिनांक: 08–01–2026

अद्योहस्ताक्षरी कार्यालय के पत्र सं0–2614, दिनांक 16–08–2022 में संशोधन करते हुये स्वशासी राज्य चिकित्सा महाविद्यालय सम्बद्ध पं0 राम प्रसाद बिस्मिल चिकित्सालय, शाहजहॉपुर में Pharmacovigilance Committee (PVC) का पुर्नगठन निम्नवत् किया जाता है।

Pharmacovigilance Committee (PVC)

S.N.	Name	Designation	Position in PVC
1	Dr. Mahendra Pal	Medical superintendent	Chairperson
2	Dr. Vishal Prakash Giri	Professor & Head, Dept. of Pharmacology	Co-Chairperson
3	Dr. Vibhor Jain	Associate Professor, Dept. of General Surgery	Member
4	Dr. Rishu Mishra	Associate Professor, Dept. of Pharmacology	Member
5	Dr. Gaurav verma	Associate Professor, Dept. of Psychiatry	Member
6	Dr. Saleem Ahmad	Assistant Professor, Dept. of General Medicine	Member
7	Dr. Varun Gupta	Assistant Professor, Dept. of Pharmacology	Member Secretary
8	Dr. Meraz Alam	EMO, Emergency	Member
9	Mr. Subhash Kanaujia	In-charge, Pharmacy	Member
10	Mr. Lalit Mohan	Dy. Nursing superintendent	Member
11	Mr. Rajendra Prasad	Pharmacist	Member

Note: Member secretary will call committee meetings time to time and maintain the records including minutes of the meetings, adverse drug events reports ete.
संग्लनक: SOP- Pharmacovigilance Committee

प्रधानाचार्य
स्वशासी राज्य चिकित्सा महाविद्यालय,
शाहजहॉपुर।

पत्रांक– प्रधानाचार्य / कमेटी / 2026 / तद्दिनांक:–
प्रतिलिपि:– निम्नलिखित को सूचनार्थ एवं आवश्यक कार्यवाही हेतु प्रेषित।

1. समस्त कमेटी सदस्यों को सूचनार्थ एवं आवश्यक कार्यवाही हेतु प्रेषित।
2. नोडल अधिकारी, कालेज वेबसाईट प्रभारी को इस निर्देश के साथ कि उक्त सूचना को कालेज वेबसाईट पर अपलोड कराना सुनिश्चित करें।
3. गार्ड फाईल।

प्रधानाचार्य
स्वशासी राज्य चिकित्सा महाविद्यालय,
शाहजहॉपुर

कार्यालय, प्रधानाचार्य, स्वशासी राज्य चिकित्सा महाविद्यालय, शाहजहॉपुर, उ0प्र0–242001
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पत्रांक–प्रधानाचार्य / कमेटी / 2026 / दिनांक: 08–01–2026

अद्योहस्ताक्षरी कार्यालय के पत्र सं0–2614, दिनांक 16–08–2022 में संशोधन करते हुये स्वशासी राज्य चिकित्सा महाविद्यालय सम्बद्ध पं0 राम प्रसाद बिस्मिल चिकित्सालय, शाहजहॉपुर में Pharmacovigilance Committee (PVC) का पुर्नगठन निम्नवत् किया जाता है।

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प्रधानाचार्य
स्वशासी राज्य चिकित्सा महाविद्यालय,
शाहजहॉपुर।

पत्रांक– प्रधानाचार्य / कमेटी / 2026 / 85 (1-3) तद्दिनांक:–
प्रतिलिपि:– निम्नलिखित को सूचनार्थ एवं आवश्यक कार्यवाही हेतु प्रेषित।

1. समस्त कमेटी सदस्यों को सूचनार्थ एवं आवश्यक कार्यवाही हेतु प्रेषित।
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3. गार्ड फाईल।

प्रधानाचार्य
स्वशासी राज्य चिकित्सा महाविद्यालय,
शाहजहॉपुर

STANDARD OPERATING PROCEDURE (SOP) FOR PHARMACOVIGILANCE COMMITTEE

1. Objectives:

This committee is constituted as per the guidelines of Pharmacovigilance Programme of India (PvPI).

- To identify, monitor, assessment and documentation of the nature and frequency of Adverse Drug Reactions (ADRs).
- To improve patient care and safety by rational use of medications.
- To promote awareness, education and training in pharmacovigilance activities and its effective communication to healthcare professionals and patients.

2. Scope:

Applicable to all clinical areas of Autonomous State Medical College, Shahjahanpur (ASMC).

3. List of abbreviations:

ADR- Adverse Drug Reactions Reporting
ADE- Adverse Drug event
AMC- Adverse Drug Reactions Monitoring Centres
ASMC - Autonomous State Medical College
CAC- Causality Assessment Committee
PVC – Pharmacovigilance Committee
PvPI- Pharmacovigilance Programme of India

4. Terms and Definitions:

Pharmacovigilance: It is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem.

Adverse drug reaction: A response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function.

Adverse event: Any untoward medical occurrence that may appear during treatment with a pharmaceutical product but which does not necessarily have a causal relationship with the treatment.

Side effect: Any unintended effect of a pharmaceutical product occurring at a dose normally used in man, which is related to the pharmacological properties of the drug.

Unexpected Adverse Reaction: An adverse reaction, the nature or severity of which is not consistent with domestic labeling or market authorization, or expected from characteristics of the drug.

5. Constitution of the Pharmacovigilance Committee (PVC):

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10	Mr. Lalit Mohan	Dy. Nursing superintendent	Member
11	Mr. Rajendra Prasad	Pharmacist	Member

6. Roles & Responsibilities

➢ Chairperson

- Provide overall leadership to the committee and ensure compliance with institutional and regulatory standards.
- Preside over committee meetings and guide strategic decisions.
- Approve final recommendations, pharmacovigilance reports, and action plans.

Co-Chairperson

- Support the Chairperson and act as the lead in their absence.
- Help set meeting agendas and oversee implementation of committee decisions.
- Facilitate coordination between committee activities and other departments.

Member Secretary

- Prepare and circulate meeting agendas, minutes, and documentation.
- Coordinate ADR data collection, case review, and reporting workflows.
- Maintain records, follow up action items, and ensure dissemination of decisions.

Members

- Review ADR reports and safety data.
- Provide expertise in causality assessment, severity classification, and risk evaluation.
- Support awareness programs, subject-matter guidance, and educational activities.
- Provide recommendations on risk minimization measures

7. ADR Reporting and Management Process

The committee uses a structured approach to ensure that all adverse drug reactions (ADRs) are properly reported, documented, and addressed.

7.1 Reporting of ADRs

7.1.1 Reporting Channels

ADRs can be submitted through several pathways to make reporting accessible for all stakeholders:

- **Healthcare Providers:**
  Physicians, nurses, pharmacists, and other health professionals report any suspected ADRs observed in patients.
- **Patients/Consumers:**
  Patients or caregivers may report suspected drug reactions using a dedicated ADR reporting form, which is available online or at medical facilities and through toll free help line number **18001803024** encouraging direct participation.

7.1.2 Information to Be Collected

When an ADR is reported, the following key information should be gathered to support proper evaluation and documentation:

- **Patient Demographics:**
  Basic details such as age, gender, and relevant clinical history
- **Drug Details:**
  Name of the suspected medication, dosage, route of administration, and duration of use.
- **Description of the Event:**
  A clear description of the reaction, including onset time, symptoms, and severity.
- **Outcome:**
  Information on how the reaction resolved or its current status (e.g., recovered, ongoing).
- **Action Taken:**
  Any steps taken in response to the event, such as stopping the drug or adjusting the dose.

- **Concomitant Medications/History:**
  Details of other drugs the patient is taking, allergies, and any medical conditions that might influence the reaction.

7.2 Review and Verification

Once an ADR is received, it is reviewed for completeness and accuracy. Reports are checked to ensure all mandatory information is present before further action is taken. Verification may involve follow-up with the reporter if necessary, and all report details are handled confidentially.

7.3 Causality and Severity Assessment

Each reported ADR is evaluated to assess:

- **Causality:**

➢ **Assessment Tools**

To determine how likely a drug is responsible for a reported adverse drug reaction (ADR), the Pharmacovigilance Committee (PVC) will use established causality assessment methods, such as:

- **WHO-UMC System for Standardized Case Causality Assessment:** A widely recommended tool that evaluates the temporal relationship, clinical features, Dechallenge/rechallenge information, and alternative explanations to classify ADRs.

WHO-UMC Causality Categories (Standard Classification)

1. **Certain**
   This category is used when there is a clear, plausible time relationship between drug exposure and the adverse event, other causes (such as disease or other drugs) are ruled out, and the reaction improves on stopping the drug (*Dechallenge*). A positive *rechallenge* (reaction reoccurs upon re-exposure) provides strong support.

2. **Probable/Likely**
   Applied when there's a reasonable time sequence to drug intake and the event doesn't readily fit other causes, with a clinically reasonable improvement on Dechallenge. Rechallenge is *not required* for this category.
3. **Possible**
   Used when the event has a reasonable time sequence after drug exposure, but it *could also be explained by other factors* (like underlying disease or other drugs), and Dechallenge information may be incomplete or unclear.
4. **Unlikely**
   Assigned when the temporal relationship to drug intake makes a causal link improbable, and other explanations (such as concurrent disease, other drugs, etc.) are more plausible.
5. **Conditional / Unclassified**
   Used when more information is needed to make a proper causality assessment, or when the case is under further study and data are being collected.
6. **Unassessable / Unclassifiable**
   Applied when available information is insufficient or contradictory and cannot be supplemented or verified, making causal judgment impossible.

- **Naranjo Algorithm:** A structured questionnaire-based method that assigns a score based on factors like timing of the event, response to stopping the medication, alternative causes, and previous reports. The total score is used to categorize the likelihood of causality.

- **Severity and Seriousness:**
  Determining whether the event is serious (e.g., requiring hospitalization or life-threatening). This helps classify the report and decide on next steps.

7.4 Reporting to Authorities

Confirmed ADR reports are forwarded to the relevant regulatory body or national pharmacovigilance programme within the required timelines and in the specified format. This ensures compliance with regulatory requirements and contributes to national safety monitoring.

7.5 Documentation and Record Keeping

All ADR reports and related documentation are securely stored to allow for reliable tracking, future reference, and audit. Proper record maintenance ensures that information is complete and easily retrievable.

8. Training and Awareness

8.1 Staff Training

The Pharmacovigilance Committee (PVC) will conduct **regular educational sessions** for all relevant healthcare personnel, including doctors, nurses, and pharmacists, to ensure they are well-informed about ADR reporting procedures, pharmacovigilance principles, and current guidelines. These training initiatives aim to improve recognition of adverse drug reactions and strengthen reporting practices across the institution.

8.2 Public Awareness

The PVC will also create and distribute **informational materials and outreach activities** to inform patients and the general public about the importance of ADR reporting. This may include brochures, posters, and awareness campaigns designed to encourage voluntary reporting by consumers and to educate them about how ADR reporting contributes to safer use of medications

9. Committee Meetings:

a) Frequency: Once in every 4 months

b) Conveners: Member Secretary

10. Quorum:

The quorum shall be a minimum 6 members and the quorum shall not be complete without the participation of one Clinician, one Pharmacologist and one Clinical Pharmacist.

11. Term of Office

Committee appointed for a period of 02 years.

12. Annexures:

सत्यमेव जयते IPC	**INDIAN PHARMACOPOEIA COMMISSION** **National Coordination Centre-Pharmacovigilance Programme of India**
	Annexure 1 **WHO-UMC Causality Scale**

Causality Term	Assessment Criteria
Certain	• Event or laboratory test abnormality, with plausible time relationship to drug intake • Cannot be explained by disease or other drugs • Response to withdrawal plausible (pharmacologically, pathologically) • Event definitive pharmacologically or phenomenologically (i.e. an objective and specific medical disorder or a recognized pharmacological phenomenon) • Rechallenge satisfactory, if necessary
Probable/Likely	• Event or laboratory test abnormality, with a reasonable time relationship to drug intake • Unlikely to be attributed to disease or other drugs • Response to withdrawal is clinically reasonable • Rechallenge not required
Possible	• Event or laboratory test abnormality, with a reasonable time relationship to drug intake • Could also be explained by disease or other drugs • Information on drug withdrawal may be lacking or unclear
Unlikely	• Event or laboratory test abnormality, with a time to drug intake that makes a relationship improbable (but not impossible) • Disease or other drugs provide plausible explanations
Conditional/Unclassified	• Event or laboratory test abnormality • More data for proper assessment needed, or • Additional data under examination
Unassessable/Unclassifiable	• Report suggesting an adverse reaction • Cannot be judged because information is insufficient or contradictory • Data cannot be supplemented or verified

Annexure 2

Naranjo Algorithm or Scale

To Assess the adverse drug reaction please answer the following questionnaire and give the pertinent score

	Yes	No	Do not know	Score
1. Are there previous conclusive reports on this reaction	+1	0	0	
2. Did the adverse event appear after the suspected drug was given?	+2	-1	0	
3. Did the adverse reaction improve when the drug was discontinued or a specific antagonist was administered ?	+1	0	0	
4. Did the adverse event reappear when the drug was re-administered?	+2	-1	0	
5. Are there alternative causes (other than the drug) that could on their own have caused the reaction?	-1	+2	0	
6. Did the reaction reappear when a placebo was given?	-1	+1	0	
7. Was the drug detected in blood (or other fluids) in concentrations known to be toxic?	+1	0	0	
8. Was the reaction more severe when the dose was increased or less severe when the dose was decreased?	+1	0	0	
9. Did the patient have a similar reaction to the same or similar drugs in any previous exposure?	+1	0	0	
10. Was the adverse event confirmed by any objective evidence ?	+1	0	0	

It is comprised of 10 questions with each response assigned a score. Total score corresponds to likelihood of drug-related ADR. Score ≥9 = definite; 5–8 = probable; 1–4 = possible; ≤0 = doubtful

Annexure 3

ADR Reporting form

Version 1.4

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For **VOLUNTARY** reporting of ADRs by Healthcare Professionals

INDIAN PHARMACOPOEIA COMMISSION (National Coordination Centre-Pharmacovigilance Programme of India)

Ministry of Health & Family Welfare, Government of India, Sector-23, Raj Nagar, Ghaziabad-201002

PvPI Helpline (Toll Free) :1800-180-3024 (9:00 AM to 5:30 PM, Monday-Friday)

Initial Case ☐ Follow-up Case ☐

A. PATIENT INFORMATION *

1. Patient Initials:
2. Age or date of birth:
3. Gender: M ☐ F ☐ Other ☐
4. Weight (in Kg.)

B. SUSPECTED ADVERSE REACTION *

5. Event / Reaction start date (dd/mm/yyyy)
6. Event / Reaction stop date (dd/mm/yyyy)
7. Describe Event/Reaction management with details , if any

FOR AMC / NCC USE ONLY

Reg. No. / IPD No. / OPD No. / CR No. :

AMC Report No. :

Worldwide Unique No. :

12. Relevant investigations with dates :

13. Relevant medical / medication history (e.g. allergies, pregnancy, addiction, hepatic, renal dysfunction etc.)

14. Seriousness of the reaction : No ☐ if Yes ☐ (*please tick anyone*)
☐ Death (dd/mm/yyyy) ☐ Congenital-anomaly
☐ Life threatening ☐ Disability
☐ Hospitalization-Initial/Prolonged ☐ Other Medically important

15. Outcome:
☐ Recovered ☐ Recovering ☐ Not Recovered
☐ Fatal ☐ Recovered with sequelae ☐ Unknown

C. SUSPECTED MEDICATION(S) *

S. No.	8. Name (Brand/ Generic)	Manufacturer (if known)	Batch No. / Lot No.	Expiry Date (if known)	Dose	Route	Frequency	Therapy Dates: Date Started	Therapy Dates: Date Stopped	Indication	Causality Assessment
i											
ii											
iii											
iv#											

9. Action taken after reaction (*please tick*)

S. No. as per C	Drug withdrawn	Dose Increased	Dose reduced	Dose not changed	Not applicable	Unknown
i						
ii						
iii						
iv						

10. Reaction reappeared after reintroduction of suspected medication (*please tick*)

Yes	No	Effect unknown	Dose (if re-introduced)

11. Concomitant medical product including self-medication add herbal remedies with therapy dates (Exclude those used to treat reaction)

S. No.	Name (Brand / Generic)	Dose	Route	Frequency (OD, BD, etc.)	Therapy Dates: Date Started	Therapy Dates: Date Stopped	Indication
i							
ii							
iii#							

Additional Information :

D. REPORTER DETAILS *

16. Name & Address : _____

_____

Pin : _____ Email : _____

Contact No- : _____

Occupation : _____ Signature : _____

17. Date of this report (dd/mm/yyyy) :

Signature and Name of Receiving Personnel :

Confidentiality : The patient's identity is held in strict confidence and protected to the fullest extent. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction. Submission of an ADR report does not have any legal implication on the reporter.

Use separate page for more information

* Mandatory Fields for suspected ADR Reporting Form

	Name	Designation	Signature	Date
Prepared by	Dr. Krishan Kr. Singh	Member, CAC		7/04/26
Proof Read by	Dr. Varun Gupta	Member secretary, PVC		07/01/26
Reviewed by	Dr. Rishu Mishra	Dy. Coordinator, AMC, Shahjahanpur		7/1/202
Approved by	Dr. Vishal Prakash Giri	Coordinator, AMC, Shahjahanpur		08/1/26.

08/1/26