



SMCW-SUHRC/DO/Committee/43/ 2025

Date- 18<sup>th</sup> Mar, 2025

**OFFICE ORDER No: 43**

**Subject: Re-Constitution of the Pharmacovigilance Committee at Symbiosis Medical College for Women and Symbiosis University Hospital and Research Centre**

**Introduction**

1. In accordance with national and institutional requirements to ensure patient safety and effective monitoring of adverse drug reactions (ADRs), the Pharmacovigilance Committee is hereby constituted at Symbiosis Medical College for Women (SMCW) and Symbiosis University Hospital and Research Centre (SUHRC).

**Purpose**

2. The purpose of the Pharmacovigilance Committee is to promote patient safety by ensuring the systematic collection, evaluation, and mitigation of risks associated with the use of medicines. The committee aims to foster a proactive culture of ADR reporting, ensuring effective communication with regulatory authorities and contributing to the overall improvement in healthcare outcomes.

**Scope**

3. The scope of the Pharmacovigilance Committee extends to overseeing pharmacovigilance activities, ensuring compliance with statutory guidelines, and fostering a culture of reporting and addressing ADRs within the institution.

**Terms of Reference**

4. The committee is entrusted with establishing a **robust system for ADR reporting and monitoring**, ensuring that all adverse drug reactions are systematically identified, recorded, and addressed to enhance patient safety.

5. The committee will ensure **strict compliance with pharmacovigilance guidelines issued by national and international regulatory bodies (NMC and Guidelines of CDSCO & NPVI)**, thereby upholding the highest standards in drug safety and reporting practices.

6. It is tasked with **conducting awareness programs and training sessions for healthcare professionals and students**, fostering a culture of proactive ADR reporting and knowledge-sharing within the institution.

7. The committee is responsible for **analyzing ADR reports** to identify



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trends, assess risks, and **recommend appropriate corrective and preventive actions** to minimize drug-related hazards.

8. Additionally, the committee shall **prepare and submit periodic reports to the relevant regulatory authorities**, ensuring transparency, accountability, and alignment with statutory obligations.

### Statutory Composition

9. The Pharmacovigilance Committee of SMCW & SUHRC shall consist of:

- (a) Dean – Chairman.
- (b) 01 x Professor/Associate Professor Dept. of Pharmacology - Member Secretary.
- (c) Dy. Dean Administration - Member.
- (d) Professor & Head, Dept. of Pharmacology - Member.
- (e) Professor & Head, Dept. of Gen. Medicine - Member.
- (f) Professor & Head, Dept. of Anesthesiology - Member.
- (g) Professor & Head, Dept. of Gen. Surgery - Member.
- (h) 01 x Professor/Associate Professor Phase-3-Member.
- (i) Head Quality - Member.
- (j) Clinical Pharmacist - Member.
- (k) 01 x Professor/Associate/Assistant Professor Dept. of Pharmacology -Member

### Current Composition

10. The current composition of the Pharmacovigilance Committee is as follows.

Sr. No.	Name	Designation	Position in the Committee
(a)	Lt. Col. (Dr.) T Vijaya Sagar (Retd)	Dean. SMCW	Chairperson
(b)	Dr. Viraj Shinde	Associate Professor, Dept. Of Pharmacology	Member Secretary
(c)	Col. Dr. Hitender Singh Batra (Retd)	Dy Dean Administration, Professor & Head Biochemistry	Member
(d)	Dr. Shraddha Yadav	Professor & Head, Dept. of Pharmacology	Member





Sr. No.	Name	Designation	Position in the Committee
(e)	Dr. Rajesh Karekar	Professor & Head, Dept. of General Medicine	Member
(f)	Dr. Indrani Chincholi,	Professor & Head, Dept. of Anesthesiology	Member
(g)	Dr. Pankaj Bansode	Professor & Head, Dept. of General Surgery	Member
(h)	Dr. Neeta Gokhale	Professor & Head, Dept. of Dermatology	Member
(i)	Mrs. Meenakshi Gijare	Quality Head	Member
(j)	Dr. Raina Banu	Clinical Pharmacist	Member
(k)	Mrs. Prachitee Borkar	Assistant Professor, Dept. of Pharmacology	Member

### Roles & Responsibilities

11. Roles and Responsibilities are as under:

S. No.	Role Name/Title	Appointment Criteria	Role in Process
(a)	Chairperson	Dean, SMCW & SUHRC	<p>(i) Provide leadership and direction to the Pharmacovigilance Committee to ensure its effective functioning and adherence to its objectives.</p> <p>(ii) Convene and preside over committee meetings, ensuring discussions remain focused and productive.</p> <p>(iii) Guide the committee in establishing priorities, formulating strategies, and resolving challenges related to pharmacovigilance activities.</p> <p>(iv) Review and approve the Minutes of Meetings (MoM) and Action Taken Reports (ATR) before dissemination.</p> <p>(v) Act as the primary liaison between the committee and the institutional</p>

S. No.	Role Name/Title	Appointment Criteria	Role in Process
			<p>authorities, as well as external regulatory bodies, to communicate decisions and uphold compliance.</p> <p>(vi) Foster a culture of transparency, accountability, and collaboration within the committee and the broader institutional framework</p>
(b)	Member Secretary	Associate Professor, Dept. Of Pharmacology	<p>(i) Coordinate the activities of the Pharmacovigilance Committee, ensuring smooth functioning and timely execution of tasks.</p> <p>(ii) Schedule and organize committee meetings, including preparing agendas and informing members about meeting details in advance.</p> <p>(iii) Document the Minutes of Meetings (MoM) accurately and ensure they are reviewed, approved, and circulated among members in a timely manner.</p> <p>(iv) Prepare and submit the Action Taken Reports (ATR) for decisions and recommendations made during committee meetings.</p> <p>(v) Maintain records of all pharmacovigilance-related activities, including ADR reports, training sessions, and communication with regulatory bodies.</p> <p>(vi) Serve as the focal point for internal and external communication related to pharmacovigilance, ensuring efficient information flow.</p> <p>(vii) Collaborate with members to plan and execute awareness and training programs, enhancing the culture of ADR reporting and patient safety.</p> <p>(viii) Assist the Chairperson in monitoring the implementation of committee decisions and recommendations.</p>





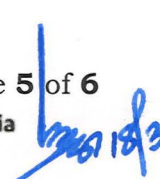
S. No.	Role Name/Title	Appointment Criteria	Role in Process
(c)	Members	Professor/Assoc. Prof./Asst. Professor, Pre/Para/Clinical Departments	<p>(i) Actively participate in all committee meetings, discussions, and decision-making processes to ensure the effective functioning of the Pharmacovigilance Committee.</p> <p>(ii) Assist in the identification, reporting, and analysis of adverse drug reactions (ADRs), contributing their expertise to evaluate the safety and efficacy of medicines.</p> <p>(iii) Provide input and recommendations for corrective and preventive actions based on the analysis of ADR reports to improve patient safety.</p> <p>(iv) Contribute to the planning and execution of awareness programs and training sessions to enhance knowledge and foster a proactive reporting culture among healthcare professionals and students.</p> <p>(v) Maintain a collaborative approach, sharing expertise and supporting the implementation of pharmacovigilance policies and guidelines within their respective domains.</p> <p>(vi) Review the Minutes of Meetings (MoM) and Action Taken Reports (ATR), ensuring that assigned actions are completed within stipulated timelines.</p>

12. **Meeting Frequency: Quarterly.** The meetings will be scheduled and notified by the Member Secretary after ascertaining availability of Chairperson. Additional meetings may be convened at the discretion of the Chairperson.

13. **Quorum:** A quorum of 60% is necessary for the committee to meet.

14. **Minutes of Meetings (MoM):** The Member Secretary will be responsible for maintaining, uploading in the link of SMCW & SUHRC **Minutes of Meetings (MoM)**, and circulating the MoM in the approved format.

15. **Action Taken Report (ATR):** The member secretary will update, upload in the link of SMCW & SUHRC **Minutes of Meetings (MoM)**, and circulate the ATR before the commencement of the next meeting.

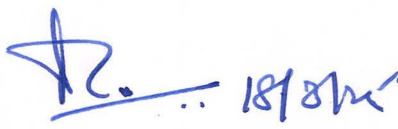



16. No business transaction will be done during the proceedings of the committee meetings.



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SMCW

Place: Pune.

  
Lt. Col. (Dr.) T. Vijaya Sagar (Retd)  
Dean  


**Copy to: -**

Hon'ble Provost, FoMHS | Medical Superintendent, SUHRC | Head Operations, SUHRC | All HODs | All Faculty Members | Member Secretary, Pharmacovigilance Committee | Head Administration, SUHRC | HR Head, FoMHS | Head Finance, SUHRC | Head Nursing, SUHRC | Head Quality, SUHRC | Head IT, FoMHS | Administrative Officer SMCW | IT Support Team, SMCW | Website Committee | NMC Cell | PA to Dean, SMCW

