



SAROJINI NAIDU VANITA PHARMACY MAHA VIDYALAYA (Co-Ed)

(Sponsored by the Exhibition Society)

UGC AUTONOMOUS INSTITUTION

Approved by PCI-New Delhi, Affiliated to Osmania University
NBA Accredited B. Pharmacy Course, Accredited A+ grade by NAAC

Report on

NATIONAL PHARMACOVIGILANCE WEEK – 2025

Organized by

ADR Monitoring Center

Sarojini Naidu Vanita Pharmacy Maha Vidyalaya (Co-Ed)

Tarnaka, Secunderabad.

17th to 23rd September 2025

INTRODUCTION

Sarojini Naidu Vanita Pharmacy Maha Vidyalaya (Co-Ed), a prestigious institution sponsored by the **Exhibition Society**, proudly celebrated **National Pharmacovigilance Week – 2025** from **17th to 23rd September 2025**, under the strategic direction of its **Adverse Drug Reaction (ADR) Monitoring Center**. Renowned for its academic excellence and commitment to healthcare education, SNVPMV holds **UGC Autonomous status**, is **affiliated with Osmania University**, and is accredited by **NBA** for its B. Pharmacy program. Additionally, it has been awarded the **NAAC A+ grade**, underscoring its pursuit of quality education and socially responsive initiatives within the field of pharmaceutical sciences.

This year's celebration was anchored around the national theme:

“Your Safety, Just a Click Away – Report to PvPI.”

The theme aimed to raise awareness about the **critical role of pharmacovigilance** in promoting drug safety and preventing adverse drug reactions. It emphasized the **accessibility and user-friendliness of ADR reporting mechanisms** provided by the **Pharmacovigilance Programme of India (PvPI)**, such as mobile applications and digital portals. More importantly, the message highlighted that **ensuring medication safety is a collective responsibility**, shared equally by healthcare professionals, pharmacy students, and the general public.

Throughout the week, the institution conducted a range of educational and awareness-building activities—including expert lectures, student-led campaigns, and interactive sessions—designed to enhance pharmacovigilance literacy and encourage proactive reporting behavior. The event served not only as an academic milestone but also as a public health initiative, reinforcing SNVPMV's ongoing dedication to advancing **safe, effective, and patient-centered use of medicines**.



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Program Highlights

- **18th September 2025:**

A **training session for students** was conducted on filling ADR reporting forms. The session aimed to provide practical knowledge and hands-on experience in reporting ADRs accurately and promptly.

- **19th September 2025:**

A **community sensitization program** on Pharmacovigilance and ADR reporting forms was organized. This activity helped spread awareness about the importance of pharmacovigilance among the public and healthcare stakeholders.

- **23rd September 2025:**

An **invited lecture on Pharmacovigilance and ADR Reporting** was delivered, highlighting global practices, regulatory perspectives, and the role of healthcare professionals in ADR monitoring.

Organizing Committee

The event was **presided over by:**

- **Dr. B. Prabha Shankar**, Chairman, SNVPMV

Coordinators:

- **Dr. T. Venu**, Professor & Head, Department of Pharmacology
- **Dr. M. Sreekanth**, Associate Professor & Head, Department of Pharm. D.

Institutional Leadership:

- **Sri. B. Hanumanth Rao**, Hon. Secretary
- **Dr. N. Srinivas**, Director
- **Dr. T. Mamatha**, Principal
- **Dr. B. Haarika**, Vice Principal



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ADR Monitoring Center - SNVPMV
Celebrating
NATIONAL PHARMACOVIGILANCE WEEK - 2025

17th - 23rd, September 2025

Theme : Your Safety, Just a Click Away
Report to PvPI

18th SEP 2025
Training students on Filling ADR Reporting form

19th SEP 2025
Community Sensitisation on Pharmacovigilance & ADR Reporting form

22nd SEP 2025
Invited lecture on Pharmacovigilance & ADR Reporting

Organizing by
ADR Monitoring Center - SNVPMV
Department of Pharmacology & Pharm. D.

Presided by:
Dr. B. Prabha Shankar
Chairman, SNVPMV

Coordinators
Dr. T. Venu
Professor & Head
Dept. of Pharmacology
Dr. M. Sreekanth
Asso. Professor & Head
Dept. of Pharm. D.

Dr. B. Haarika
Vice Principal

Dr. T. Mamatha
Principal

Dr. N. Srinivas
Director

Sri. B. Hanumanth Rao
Hon. Secretary



NATIONAL PHARMACOVIGILANCE WEEK – 2025

01. Training students on filling ADR Reporting Form

Organized by: Sarojini Naidu Vanita Pharmacy Maha Vidyalaya (Co-Ed), Hyderabad

Date of Event: 19th September, 2025

Venue: Auditorium, SNVPMV

The first activity of National Pharmacovigilance Week 2025 at SNVPMV was a highly focused training program conducted for B. Pharmacy, M. Pharmacy, and Pharm. D. students, aimed at empowering them with practical skills in Adverse Drug Reaction (ADR) reporting.

Pharmacovigilance experts from the Department of Pharmacology guided the students step-by-step on filling the Suspected Adverse Drug Reaction (ADR) Reporting Form, both in manual and digital formats. The session was structured in alignment with the official template prescribed under the Pharmacovigilance Programme of India (PvPI).

Students were trained to capture all the mandatory parameters of the form, which included:

- Patient Information: recording patient initials, age/date of birth, gender, weight, and registration details (IPD/OPD number).
- Adverse Reaction Details: accurately documenting the event/reaction onset and stop dates, description of the reaction, severity (death, life-threatening, hospitalization, disability, congenital anomaly), and outcomes (recovered, recovering, not recovered, fatal, unknown).
- Suspected Medication(s): entering details such as drug name (brand/generic), manufacturer, batch number, expiry date, dose, route, frequency, therapy dates, indication, and causality assessment.
- Action Taken: noting whether the drug was withdrawn, dose modified, or unchanged, and whether the reaction reappeared upon reintroduction.
- Concomitant Medication: listing any other medicines, including self-medication and herbal remedies.
- Relevant Medical History: recording allergies, comorbidities, renal/hepatic dysfunction, pregnancy status, lifestyle factors, or past surgeries.
- Reporter Details: entering the healthcare professional's name, address, contact information, occupation, and signature for accountability.



The interactive nature of the workshop made it particularly valuable. Students were divided into groups, each provided with sample case scenarios to practice completing ADR forms. Faculty members supervised the process, correcting errors and clarifying doubts on clinical relevance and technical accuracy. This hands-on training enabled students to recognize how incomplete or inaccurate entries could compromise patient safety and national pharmacovigilance data.

By the end of the exercise, students gained confidence in systematically documenting ADRs. More importantly, they understood that ADR reporting is not just an academic task, but a professional responsibility that contributes to:

- Enhancing drug safety monitoring at the national level.
- Preventing recurrence of serious ADRs.
- Supporting evidence-based regulatory decisions.
- Ensuring public health protection through continuous benefit-risk assessment.

This session equipped B. Pharmacy, M. Pharmacy, and Pharm. D. students with practical, real-world competencies, ensuring they are prepared to participate effectively in pharmacovigilance activities during their clinical practice and professional careers.

The first activity focused on empowering students with the practical skills needed for ADR reporting. Pharmacovigilance experts from the Department of Pharmacology demonstrated how to fill out ADR reporting forms, both manually and digitally. Students were taught the significance of accurate data entry, identification of ADRs, and the role of vigilance in preventing drug-related complications.

- This session was highly interactive, allowing students to clarify doubts and practice form filling under faculty supervision.
- By the end, students gained confidence in using ADR forms, equipping them for real-world practice.



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SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

Version-1.3

For VOLUNTARY reporting of Adverse Drug Reaction 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

A. PATIENT INFORMATION										Reg. No. /IPD No. /OPD No. /CR No. :	
1. Patient Initials	2. Age at the time of Event or Date of Birth	3. M <input type="checkbox"/> F <input type="checkbox"/> Other <input type="checkbox"/>	4. Weight _____ Kgs							AMC Report No. :	
										Worldwide Unique No. :	
B. SUSPECTED ADVERSE REACTION										12. Relevant tests/ laboratory data with dates	
5. Event/Reaction start date (dd/mm/yyyy)											
6. Event/Reaction stop date (dd/mm/yyyy)											
6 (A). Onset Lag Time											
7. Describe Event/Reaction with treatment details, if any										13. Relevant medical/medication history (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/renal dysfunction, past surgery etc.)	
										14. Seriousness of the reaction: No <input type="checkbox"/> if Yes <input type="checkbox"/> (please tick anyone)	
										<input type="checkbox"/> Death (dd/mm/yyyy) <input type="checkbox"/> Congenital-anomaly <input type="checkbox"/> Life threatening <input type="checkbox"/> Disability <input type="checkbox"/> Hospitalization/Prolonged <input type="checkbox"/> Other Medically important	
										15. Outcomes	
										<input type="checkbox"/> Recovered <input type="checkbox"/> Recovering <input type="checkbox"/> Not recovered <input type="checkbox"/> Fatal <input type="checkbox"/> Recovered with sequelae <input type="checkbox"/> Unknown	
C. SUSPECTED MEDICATION(S)											
S.No	8. Name (Brand/Generic)	Manufacturer (if known)	Batch No. / Lot No.	Exp. Date (if known)	Dose used	Route used	Frequency (OD, BD etc.)	Therapy dates		Indication	Causality Assessment
								Date started	Date stopped		
i											
ii											
iii											
iv*											
S.No as per C	9. Action Taken (please tick)						10. Reaction reappeared after reintroduction (please tick)				
	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown	Yes	No	Effect unknown	Dose (if reintroduced)	
i											
ii											
iii											
iv											
11. Concomitant medical product including self-medication and herbal remedies with therapy dates (Exclude those used to treat reaction)											
S.No	Name (Brand/Generic)	Dose used	Route used	Frequency (OD, BD, etc.)	Therapy dates		Indication				
					Date started	Date stopped					
i											
ii											
iii*											
Additional Information:											
D. REPORTER DETAILS											
16. Name and Professional Address: _____											
Pin: _____ E-mail: _____											
Tel. No. (with STD code) _____											
Occupation: _____ Signature: _____											
17. Date of this report (dd/mm/yyyy): _____											
Sig. and Name of Receiver- _____											
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



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National Coordination Centre for Pharmacovigilance Programme of India

Ministry of Health & Family Welfare, Government of India

Sector-23, Raj Nagar, Ghaziabad-201002

Tel.: 0120-2783400, 2783401, 2783392, Fax: 0120-2783311

www.ipc.nic.in

ADVICE ABOUT REPORTING

A. What to report?

- Report serious adverse drug reactions. A reaction is serious when the patient outcome is:
 - ☐ Death
 - ☐ Life-threatening
 - ☐ Hospitalization (initial or prolonged)
 - ☐ Disability (significant, persistent or permanent)
 - ☐ Congenital anomaly
 - ☐ Required intervention to prevent permanent impairment or damage
- Report non-serious, known or unknown, frequent or rare adverse drug reactions due to Medicines, Vaccines and Herbal products etc.

Note- Adverse Event Following Immunization can also be reported in Serious AEFI case Notification Form available on <http://www.ipc.gov.in>

B. Who can report?

- All healthcare professionals (Clinicians, Dentists, Pharmacists and Nurses etc) can report adverse drug reactions

C. Where to report?

- Duly filled in Suspected Adverse Drug Reaction Reporting Form can be sent to the nearest Adverse Drug Reaction Monitoring Centre (AMC) or directly to the National Coordination Centre (NCC) for PvPI.
- Call on Helpline (Toll Free) 1800 180 3024 to report ADRs or directly mail this filled form to pvpi.ipc@gov.in
- A list of nationwide AMCs is available at:
<http://www.ipc.gov.in>, http://www.ipc.gov.in/PvPI/pv_home.html

D. What happens to the submitted information?

- Information provided in this form is handled in strict confidence. The causality assessment is carried out at AMCs by using WHO-UMC scale. The analyzed forms are forwarded to the NCC through ADR database. Finally the data is analyzed and forwarded to the Global Pharmacovigilance Database managed by WHO Uppsala Monitoring Centre in Sweden.
- The reports are periodically reviewed by the NCC-PvPI. The information generated on the basis of these reports helps in continuous assessment of the benefit-risk ratio of medicines.
- The Signal Review Panel of PvPI to review the data and suggest any interventions that may be required.

E. Mandatory fields for suspected ADR reporting form

- Patient initials, age at onset of reaction, reaction term(s), date of onset of reaction, suspected medication(s) and reporter information.

For ADRs Reporting

- E-mail: pvpi.ipc@gov.in
- PvPI Helpline (Toll Free): **1800 180 3024** (9:00 AM to 5:30 PM, Monday-Friday)
- ADR Mobile App: "ADR PvPI"



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Impact:

- Equipped B. Pharmacy, M. Pharmacy, and Pharm. D. students with the ability to accurately fill the Suspected ADR Reporting Form in line with PvPI guidelines.
- Improved students' practical competencies in identifying, documenting, and reporting adverse drug reactions.
- Strengthened their clinical decision-making skills, as they learned to correlate drug intake with possible reactions.
- Built professional responsibility and ethical awareness, preparing students to actively contribute to national and global pharmacovigilance databases.
- Increased student confidence in using digital and manual reporting systems, which will aid their future roles as pharmacists, clinicians, and researchers.



NATIONAL PHARMACOVIGILANCE WEEK – 2025

02. Community Sensitization on Pharmacovigilance and ADR Reporting Form

Organized by: Sarojini Naidu Vanita Pharmacy Maha Vidyalaya (Co-Ed)

Date of Event: 19th September, 2025

Venue: Out station event; Commuters of Hyderabad Metro Rail

As part of **National Pharmacovigilance Week 2025**, the faculty of SNVPMV, along with enthusiastic student volunteers, undertook a community outreach initiative aboard the **Hyderabad Metro Rail** up to Rasoolpura station. This innovative approach allowed them to interact directly with commuters from diverse backgrounds and spread awareness about Adverse Drug Reaction (ADR) reporting.

The faculty and students personally engaged with passengers, distributing leaflets and demonstration ADR forms in simple and understandable language. They explained, step by step, the need, objectives, benefits, and usage of the ADR reporting form, emphasizing that drug safety is a shared responsibility of healthcare professionals, patients, and the community.

Key Awareness Points Shared with Commuters

1. Need for ADR Reporting

- Medicines, though beneficial, may cause adverse reactions ranging from mild side effects to life-threatening complications.
- Many ADRs go unreported, limiting the ability of health authorities to detect, analyze, and prevent them.
- Reporting ensures early detection of safety signals and strengthens the healthcare system.

2. Objectives of ADR Reporting

- To collect data systematically on suspected drug reactions.
- To ensure continuous monitoring of the benefit-risk ratio of medicines.
- To provide evidence for regulatory action, such as label changes, warnings, or withdrawal of unsafe drugs.
- To contribute data to the Global Pharmacovigilance Database (WHO-UMC, Sweden), making local reports globally impactful.



3. *Benefits of Reporting*

- Protects patients by preventing recurrence of severe ADRs.
- Helps doctors, pharmacists, and policymakers make better therapeutic choices.
- Increases public confidence in healthcare systems by showing that safety monitoring is active and transparent.
- Empowers common people to be active participants in their own healthcare journey.

4. *Usage of the ADR Reporting Form*

Faculty explained in detail the sections of the official Suspected ADR Reporting Form, using real-life examples:

- Patient Information (Section A): commuters were shown how simple details like initials, age, gender, and weight can help track patient safety without breaching confidentiality.
- Suspected Adverse Reaction (Section B): participants were asked to imagine reporting a common allergy (e.g., rash after taking antibiotics). They were guided to note the start/stop dates of the reaction, describe the symptoms, and check whether it caused hospitalization or disability.
- Suspected Medication (Section C): commuters were shown how to record the name of the medicine, its dose, route, frequency, manufacturer, and therapy dates. The causality assessment aspect was simplified to “suspected medicine that might have caused the reaction.”
- Action Taken: explanation on whether the drug was stopped, dose reduced, or continued.
- Concomitant Medicines: passengers were reminded to also note any herbal or self-medication alongside prescribed drugs.
- Relevant Medical History: examples like diabetes, hypertension, smoking, or liver disease were shared to highlight their importance in ADR assessment.
- Outcome of the Reaction: passengers learned how to mark whether the patient recovered, was recovering, not recovered, or if the reaction was fatal.
- Reporter’s Details: the importance of adding name and contact information was emphasized, assuring commuters that confidentiality is always maintained.

Engagement and Response

- Many commuters expressed surprise that even common side effects could and should be reported.
- Faculty used everyday examples such as drowsiness due to antihistamines or gastric irritation due to painkillers to make the concept relatable.
- Some passengers even shared personal experiences of drug reactions, and faculty guided them on how those could be reported using the form, PvPI helpline, or mobile app.



Impact of the Metro Outreach

- Raised awareness among community members about the significance of ADRs, their risks, and the importance of reporting them.
- Helped the public understand that drug safety is a shared responsibility, not limited to doctors or pharmacists.
- Encouraged patients and caregivers to recognize and report common ADRs, such as allergies, antibiotic side effects, or vaccine reactions.
- Built trust between the community and healthcare providers, positioning SNVPMV as a socially responsible institution.
- Contributed to public health literacy, reducing the stigma or hesitation around reporting medicine-related problems.

Presided by:

Faculty:

- Dr. T. Venu, Professor and Head Pharmacology
- Dr. Jithendar, Assistant Professor
- Dr. Shiva Rama Krishna, Assistant Professor
- Mrs. Divya, Assistant Professor

Students:

- Ms. Bharathi; M.Pharmacy Pharmacology.
- Ms. Sneha; M.Pharmacy Pharmacology.
- Ms. Jayashri; M.Pharmacy Pharmacology.
- Ms. Kany; Pharm.D-IV year.
- Ms. Komal; Pharm.D-IV year.
- Ms. Shiny; Pharm.D-IV year.
- Ms. Anshu; Pharm.D-IV year.
- Ms. Afira; Pharm.D-IV year.
- Ms. Afeefa; Pharm.D-IV year.
- Ms. Nisha; Pharm.D-IV year.
- Ms. Nisha fortuna; Pharm.D-IV year.



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

A. PATIENT INFORMATION										Reg. No. /IPD No. /OPD No. /CR No. :	
1. Patient Initials	2. Age at the time of Event or Date of Birth	3. M <input type="checkbox"/> F <input type="checkbox"/> Other <input type="checkbox"/>	AMC Report No. :								
		4. Weight _____ Kgs	Worldwide Unique No. :								
B. SUSPECTED ADVERSE REACTION										12. Relevant tests/ laboratory data with dates	
5. Event/Reaction start date (dd/mm/yyyy)											
6. Event/Reaction stop date (dd/mm/yyyy)											
6 (A). Onset Lag Time											
7. Describe Event/Reaction with treatment details, if any										13. Relevant medical/medication history (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/renal dysfunction, past surgery etc.)	
										14. Seriousness of the reaction: No <input type="checkbox"/> if Yes <input type="checkbox"/> (please tick anyone)	
										<input type="checkbox"/> Death (dd/mm/yyyy) <input type="checkbox"/> Congenital-anomaly <input type="checkbox"/> Life threatening <input type="checkbox"/> Disability <input type="checkbox"/> Hospitalization/Prolonged <input type="checkbox"/> Other Medically important	
										15. Outcomes	
										<input type="checkbox"/> Recovered <input type="checkbox"/> Recovering <input type="checkbox"/> Not recovered <input type="checkbox"/> Fatal <input type="checkbox"/> Recovered with sequelae <input type="checkbox"/> Unknown	
C. SUSPECTED MEDICATION(S)											
S.No	8. Name (Brand/Generic)	Manufacturer (if known)	Batch No. / Lot No.	Exp. Date (if known)	Dose used	Route used	Frequency (OD, BD etc.)	Therapy dates		Indication	Causality Assessment
								Date started	Date stopped		
i											
ii											
iii											
iv*											
S.No as per C	9. Action Taken (please tick)						10. Reaction reappeared after reintroduction (please tick)				
	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown	Yes	No	Effect unknown	Dose (if reintroduced)	
i											
ii											
iii											
iv											
11. Concomitant medical product including self-medication and herbal remedies with therapy dates (Exclude those used to treat reaction)											
S.No	Name (Brand/Generic)	Dose used	Route used	Frequency (OD, BD, etc.)	Therapy dates		Indication				
					Date started	Date stopped					
i											
ii											
iii*											
Additional Information:											
D. REPORTER DETAILS											
16. Name and Professional Address: _____											
Pin: _____ E-mail: _____											
Tel. No. (with STD code) _____											
Occupation: _____ Signature: _____											
17. Date of this report (dd/mm/yyyy): _____											
Sig. and Name of Receiver- _____											
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.											

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Community Sensitization on Pharmacovigilance and ADR Reporting form among the commuters in Hyderabad Metro Rail by Program coordinator Dr. T. Venu along side with Faculty and students on 19-09-25



NATIONAL PHARMACOVIGILANCE WEEK – 2025

03. Invited Lecture on Pharmacovigilance and ADR Reporting

Organized by: Sarojini Naidu Vanita Pharmacy Maha Vidyalaya (Co-Ed)

Date of Event: 23rd September, 2025

Venue: SNVPMV Auditorium

1. Introduction

Sarojini Naidu Vanita Pharmacy Maha Vidyalaya (SNVPMV), an esteemed UGC autonomous institution affiliated with Osmania University and accredited with NBA and NAAC A+ Grade, organized a knowledge-enriching lecture on the occasion of **National Pharmacovigilance Week - 2025**, celebrated from **17th to 23rd September 2025**. The event was coordinated by the **ADR Monitoring Center – SNVPMV**, as part of a national initiative to enhance awareness about drug safety and promote spontaneous reporting of Adverse Drug Reactions (ADRs).

This year's theme, **“Your Safety, Just a Click Away – Report to PvPI,”** emphasized the critical role of individuals, especially healthcare professionals and pharmacy students, in reporting adverse drug events and ensuring patient safety.

1. Background and Context

Pharmacovigilance (PV) is a scientific discipline focused on the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems. The Pharmacovigilance Programme of India (PvPI), under the aegis of the Indian Pharmacopoeia Commission (IPC), aims to safeguard public health through monitoring adverse drug reactions (ADRs), especially in the post-marketing phase of pharmaceuticals.

SNVPMV's ADR Monitoring Center actively contributes to PvPI and marked National Pharmacovigilance Week 2025 by organizing a lecture for pharmacy students, clinicians, and faculty members on the technical and regulatory aspects of ADRs and their reporting mechanisms.

The seminar was presided over by

- Dr. T. Mamatha, Principal, SNVPMV
- Dr. B. Haarika, Vice principal, SNVPMV,
- Dr. T. Venu, Professor and Head Pharmacology

Invited speaker:

- **Dr. G. Srilakshmi**, Quality Manager, Medicovert Hospitals, Hitech City, Hyderabad.



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ADR Monitoring Center - SNVPMV

Celebrating

NATIONAL PHARMACOVIGILANCE WEEK - 2025

17th - 23rd, September 2025

Theme : Your Safety, Just a Click Away

Report to PvPI

Inviting to attend a lecture on

Adverse Drug Reactions & It's Reporting



Dr. G. SREELAKSHMI

Quality Manager , Medicover Hospitals
Hi-tech City, Hyderabad

Presided by:

Dr. B. Prabha Shankar
Chairman, SNVPMV

Coordinators:

Dr. T. Venu

Profesoor & Head
Dept. of Pharmacology

Dr.M. Sreekanth

Asso. Professor & Head
Dept. of Pharm.D.



Date: Tuesday, 23rd September, 2025

Time: 2:00 P.M. onwards

Venue: SNVPMV Auditorium

Dr. B. Haarika
Vice Principal

Dr. T. Mamatha
Principal

Dr. N. Srinivas
Director

Sri. B. Hanumanth Rao
Hon. Secretary



The dignitaries were invited onto the stage in the following order: Dr. T. Mamatha (Principal), Dr. B. Haarika (Vice Principal), Dr. T. Venu (Professor & Head, Department of Pharmacology), and the invited guest speaker Dr. G. Sreelakshmi. As a mark of warm hospitality, an eco-friendly greeting was presented to the guest speaker by the students.

The session formally commenced with a prayer song performed by the students, setting a serene and respectful tone for the event. This was followed by an introductory speech by **Dr. T. Mamatha** highlighting the significance of pharmacovigilance and its role in ensuring drug safety. Subsequently, **Dr. T. Venu** introduced the profile of the guest speaker, outlining her academic background, professional expertise, and contributions to the field of healthcare quality and pharmacovigilance.

The stage was then handed over to **Dr. G. Sreelakshmi**, who began her technical session on ***“Adverse Drug Reactions and Its Reporting.”***

2. Expert Lecture Overview

Speaker Profile:

Dr. G. Sreelakshmi is a healthcare quality specialist currently serving as the Quality Manager at Medcover Hospitals, Hi-Tech City, Hyderabad. Her expertise lies in hospital quality accreditation standards (NABH, JCI), medication safety, adverse event management, and compliance with national PV protocols.

3. Technical Lecture Content Breakdown

3.1 Definition and Classification of ADRs

The speaker began with internationally accepted definitions:

- WHO: "An ADR is a response to a medicinal product which is noxious and unintended, and which occurs at doses normally used in humans."
- ICH E2A Guidelines: Emphasize spontaneous reporting and seriousness criteria.

Classification:

1. Type A (Augmented): Predictable, dose-dependent, common (e.g., hypoglycemia with insulin).
2. Type B (Bizarre): Idiosyncratic, unpredictable (e.g., anaphylaxis to penicillin).
3. Type C (Chronic): Associated with long-term use (e.g., corticosteroid-induced osteoporosis).



4. Type D (Delayed): Manifest after prolonged exposure (e.g., carcinogenesis).
5. Type E (End-of-use): Withdrawal reactions (e.g., opioid withdrawal).
6. Type F (Failure): Unexpected therapeutic failure.

She also highlighted severity scales (mild, moderate, severe) and causality assessment frameworks such as:

- WHO-UMC Causality Assessment System
- Naranjo Algorithm

3.2 Epidemiological and Clinical Relevance of ADRs

- Incidence: Global studies estimate that 5-10% of hospital admissions are due to ADRs.
- Impact: ADRs rank among the top ten causes of morbidity and mortality globally.
- Economic Burden: Increased hospitalization, extended stay, litigation, and damage to drug credibility.

She emphasized how pharmacovigilance bridges the gap between clinical pharmacology and public health by promoting safe and rational drug use.

3.3 Institutional Pharmacovigilance and PvPI Framework

Dr. Sreelakshmi introduced the Pharmacovigilance Programme of India (PvPI):

- Launched in 2010 by CDSCO and coordinated by IPC, Ghaziabad.
- SNVPMV is one of the ADR Monitoring Centers (AMC) under PvPI.

Key PvPI Components:

- AMC Network: Over 500 AMCs nationwide.
- National Coordination Centre (NCC): IPC.
- Reporting Tools:
 - Vigiflow: A WHO web-based ICSR management tool.
 - PvPI Mobile App: For patient and HCP submissions.
 - Suspected ADR Reporting Form (yellow form).



- Signal Detection: Based on WHO-UMC criteria, periodic safety update reports (PSURs), and trend analysis.

3.4 Technical Process of ADR Reporting

➤ Who Should Report?

- Pharmacists, physicians, nurses, clinical researchers, and patients.

➤ What to Report?

- All suspected ADRs, regardless of severity or certainty.
- Special attention to:
 - Newly launched drugs
 - Pediatric or geriatric reactions
 - Off-label drug use
 - Drug-drug and drug-food interactions

➤ How to Report?

- Manual: Yellow form submission to AMC.
- Online: PvPI web portal.
- Mobile App: PvPI ADR Reporting App (Android/iOS).

Dr. Sreelakshmi also demonstrated the complete workflow of an ADR report, from detection to submission to follow-up, including the coding of reactions using MedDRA (Medical Dictionary for Regulatory Activities).

3.5 Challenges and Solutions in ADR Reporting

Challenges:

- Underreporting due to lack of awareness and training.
- Fear of medico-legal consequences.



- Lack of time or motivation.
- Perception that "one report doesn't matter."

Proposed Solutions:

- Continuous education and sensitization workshops.
- Integration of pharmacovigilance into the pharmacy curriculum.
- Promoting a non-punitive, learning-based reporting culture.
- Institutional SOPs and KPI-based monitoring of ADR submissions.

3.6 Case-Based Learning

Dr. Sreelakshmi shared anonymized clinical case reports from Medicover Hospitals to illustrate:

- Causality analysis
- Preventability criteria (Schumock and Thornton scale)
- Severity assessment (Modified Hartwig and Siegel Scale)
- Use of Root Cause Analysis (RCA) for ADR incidents

Example:

- A patient on phenytoin developing Drug-Induced Hypersensitivity Syndrome (DIHS), successfully de-challenged and documented.

3.7 Concluding Remarks

Dr. Sreelakshmi closed with the reminder:

“A single ADR report can prevent a mass casualty tomorrow.”

She urged students to embrace their role as future pharmacovigilance officers and emphasized that reporting is not just a professional duty but a moral obligation towards patient safety.

The highlight of the week was an invited lecture delivered by a distinguished expert in pharmacovigilance. The lecture provided:

- Global perspective on pharmacovigilance systems.
- Regulatory importance of ADR reporting for drug approval and safety monitoring.



- Practical insights into challenges faced in India and the contribution of PvPI.
- Case studies of major ADR incidents worldwide, which stressed how timely reporting could save lives.

The lecture also inspired students and faculty to become more proactive reporters, encouraging them to use modern tools such as online reporting portals and mobile applications.

Impact and Outcomes

- **Student Development:** The training session built confidence and competence in ADR reporting, preparing students for their future roles as pharmacists and clinical professionals.
 - **Community Awareness:** The sensitization program bridged the gap between medical knowledge and the lay community, empowering people to recognize and report ADRs.
 - **Knowledge Expansion:** The invited lecture broadened the academic horizon, exposing participants to the importance of global pharmacovigilance.
 - **Institutional Growth:** By hosting this event, SNVPMV demonstrated its commitment to patient safety, healthcare innovation, and national programs like PvPI.
-

Vote of Thanks by Dr. T. Venu

Good afternoon to all.

It is my privilege and pleasure to deliver the Vote of Thanks on behalf of Sarojini Naidu Vanita Pharmacy Maha Vidyalaya at the conclusion of this insightful session conducted as part of the National Pharmacovigilance Week – 2025.

First and foremost, I extend my heartfelt gratitude to our esteemed speaker, Dr. G. Sreelakshmi, for sharing her expertise and delivering a highly informative session on "Adverse Drug Reactions and Its Reporting." Your insights have not only deepened our understanding of pharmacovigilance but also inspired our students to take an active role in promoting medication safety.

I sincerely thank our Principal, Dr. T. Mamatha, for presiding over the event and for her constant support and encouragement. My thanks also extend to our Vice Principal, Dr. B. Haarika, and our Director, Dr. N. Srinivas, for their continued guidance in organizing such academic initiatives.

A special note of appreciation to our enthusiastic students who helped coordinate today's program, and to the audience for your attentive participation.



SAROJINI NAIDU VANITA PHARMACY MAHA VIDYALAYA (Co-Ed)

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Finally, I thank the ADR Monitoring Center team and organizing committee for their dedicated efforts in making this event a success.

Let us carry forward the message of this week—that pharmacovigilance is a shared responsibility—and work together towards ensuring safer healthcare for all.

Thank you.

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Dr. G. Srilakshmi , Quality Manager, Medcover Hosptials, being invited to lecture by Dr. T. Mamatha ,Principal, SNVPMV along side with Vice Principal Dr. B. Haarika and Program coordinator Dr. T. Venu on 23-09-25



Dr. G. Srilakshmi , Quality Manager, Medcover Hosptials delivering her lecture at SNVPMV on 23-09-25



Dr. T. Mamatha ,Principal initiating the session on 23-09-25 at SNVPMV



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Dr. G. Srilakshmi being felicitated by Vice principal Dr. B. Haarika
on 23-09-25 at SNVPMV



Vote of Thanks by Program Coordinator
Dr. T. Venu on 23-09-25 at SNVPMV



Group photo with Guest speaker Dr. G. Srilakshmi on 23-09-25 at SNVPMV



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LIST OF ATTENDEES

Invited Lecture.

23/9/25

①

S.No	Name of the Students	Course / Year	Sign
1.	N. Naga Sri Sravya	III year B Pharm	N
2.	P.S. Hritika	"	P.S. Hritika
3.	D. Gayathri	"	Gayathri
4.	B. Vyshnavi	"	Vy
5.	B. Akshaya	"	Ak
6.	C. Vedhyasri	II year B Pharm	Vedhyasri
7.	K. Ramea	"	Ramea
8.	N. Ranu	II Year PharmD	Ranu
9.	Saniya Tabassum	III rd year B. Pharm	Saniya
10.	Simran Tabassum	"	Simran
11.	V. Pravallika	"	V. Pravallika
12.	Sai Sruvalli P	"	Sruvalli
13.	Manaswini	B Pharmacy II year	Manaswini
14.	Tejaswini	"	Tejaswini
15.	AKshitha	"	AKshitha
16.	S. Sindhu Priya	B. Pharm 3 rd year	Sindhu
17.	P. Akhila	B. Pharm 2 nd year	Akhila
18.	P. Architha	"	Architha
19.	A. Nandini	B. Pharm 3 rd yr	Nandini
20.	G. Bindu Shreya	"	Bindu
21.	H. Akhila	"	Akhila
22.	B. Keerthi	"	B. Keerthi
23.	B. Hymavathi	"	B. Hymavathi
24.	B. Pavan	"	Pavan
25.	D. Navya	"	Navya
26.	B. Yashasvi	Pharm D II yr	Yashasvi
27.	Sri Vaishnavi	"	Sri
28.	Anshu	"	Anshu
29.	Yashitha	"	Yashitha
30.	V. Nikitha	B Pharm 3 rd yr	Nikitha
31.	V. Anitha	"	Anitha
32.	V. Shrawani	"	Shrawani



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Invited lecture.

23/9/25

(3)

S.No	Name of the Students	Course / Year	Sign
1	Renuka	B-Pharm 2 nd yr	Renuka
2	Amena Madiba	B Pharm 2 nd yr	Amena
3	Nandita Ayangar	B pharm 2 nd yr	Nandita
4	Nilutha Reddy	B Pharm 2 nd yr	Nilutha
5	Hooriya Mirza	Ph arm d 2 nd yr	Hooriya
6	Samiya Ishaq	"	Samiya
7	Samiya Fazeen	"	Samiya
8	Amatul	"	Amatul
9	Maryam	"	Maryam
10	Zaina	"	Zaina
11	Amera	"	Amera
12	Susmitha	"	Susmitha
13	Lasya	"	Lasya
14	Navya	"	Navya
15	Charithra	"	Charithra
16	Ujwani	"	Ujwani
17	Rohitha	"	Rohitha
18	Shivani	"	Shivani
19	Ramya	"	Ramya
20	Navya	Pharm D 3 rd yr	Navya
21	Vaishnavi	"	Vaishnavi
22	Nandini	"	Nandini
23	Vaashika	"	Vaashika
24	Meghana	"	Meghana
25	Veda	"	Veda
26	Varshitha	"	Varshitha
27	Pooja	"	Pooja
28	Harshini	"	Harshini
29	Srinidhi	"	Srinidhi
30	Shreya	"	Shreya
31	Rishika	"	Rishika
32	Manogna	"	Manogna



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S.No	Name of the Students	Course / Year	Sign
33	K. Vaishnavi	Pharm.D 3 rd yr	<i>K. Vaishnavi</i>
34	Naliniha	"	<i>Naliniha</i>
35	Urwah	"	<i>Urwah</i>
36	Summaya	"	<i>Summaya</i>
37	Ameyaktha	"	<i>Ameyaktha</i>
38	Nagalakshmi	"	<i>Nalakshmi</i>
39	Atika Zuhreen	"	<i>Atika Zuhreen</i>
40	Bhargavi	"	<i>Bhargavi</i>
41	Ruthika	"	<i>Ruthika</i>
42	Sootha	"	<i>Sootha</i>
43	Sraavanthi	"	<i>Sraavanthi</i>
44	Shamini	"	<i>Shamini</i>
45	Kuthika	"	<i>Kuthika</i>
46	Gussapu Deekshitha	M.Pharm QA Tsem	<i>Gussapu Deekshitha</i>
47	Gangireti Niharika	"	<i>Gangireti Niharika</i>
48	Nikitha Kanthi	"	<i>Nikitha Kanthi</i>
49	Bharathi	M.Pharm Colorg	<i>Bharathi</i>
50	Sneha	M.Pharm Colorg	<i>Sneha</i>
51	Arjali	M.Pharm ^{II} Analysis	<i>Arjali</i>
52	Lahari	M.Pharm ^{II} Analysis	<i>Lahari</i>
53	Aishwarya	M.Pharm ^{II} Analysis	<i>Aishwarya</i>
54	P. Ramya	M.Pharm ^{II} Analysis	<i>P. Ramya</i>
55	Nikitha	M.Pharm ^{II} Analysis	<i>Nikitha</i>
56	Manisha	M.Pharm ^{II} Analysis	<i>Manisha</i>
57	B. Jayabri	M.Pharm 1 st year ph.colorg	<i>B. Jayabri</i>
58	Indu Himala dani	"	<i>Indu Himala dani</i>
59	Suzathi	"	<i>Suzathi</i>



CONCLUSION

The National Pharmacovigilance Week – 2025 at Sarojini Naidu Vanita Pharmacy Maha Vidyalaya (SNVPMV) was far more than a scheduled series of academic engagements; it served as a transformative initiative aimed at instilling a deeper sense of vigilance, safety, and accountability in the rational use of medicines. The week-long celebration offered a holistic blend of expert-led seminars, hands-on student training, awareness drives, and community-oriented activities, all of which were meticulously designed to underscore the critical importance of pharmacovigilance in modern healthcare systems.

By facilitating direct interactions with industry experts, such as the invited lecture by Dr. G. Sreelakshmi, and encouraging active student participation in ADR reporting simulations and awareness campaigns, the event fostered a culture of proactive engagement in patient safety practices. The integration of academic knowledge with real-world applications highlighted how every pharmacist—whether a student or a practicing professional—plays a pivotal role in identifying, preventing, and managing adverse drug reactions.

Moreover, the event served as a platform for institutional leadership and faculty members to emphasize the ethical and professional responsibilities of pharmacy students in building a safe and responsive healthcare ecosystem. Through these collective efforts, SNVPMV reaffirmed its position as a pioneer in pharmacy education, public health advocacy, and pharmacovigilance awareness. The celebration called upon all stakeholders—students, educators, healthcare professionals, and the wider community—to collaborate in nurturing a healthcare environment where medication safety is not merely a regulatory requirement, but a shared commitment. It reinforced the message that pharmacovigilance is not an isolated academic concept, but a lifesaving practice that lies at the heart of evidence-based, patient-centered care.