Newsletter

PHARMACOVIGILANCE PROGRAMME OF INDIA (PvPI)
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5th National Pharmacovigilance Week

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National Coordination Centre - Pharmacovigilance Programme of India

A WHO Collaborating Centre for Pharmacovigilance in Public Health Programmes and Regulatory Services

Indian Pharmacopoeia Commission

Ministry of Health & Family Welfare, Government of India

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Message from Additional Secretary & Financial Adviser MoHFW, Government of India

एच. अब्बास
अपर सचिव एंव वित्तीय सलाहकार
H. Abbas
Additional Secretary & Financial Adviser

सत्यमेव जयते

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
Government of India
Ministry of Health & Family Welfare

Dear Readers,

I commend the Pharmacovigilance Programme of India (PvPI), Indian Pharmacopoeia Commission (IPC) for its sustained efforts in strengthening drug safety monitoring mechanisms, promoting a culture of Adverse Drug Reaction (ADR) reporting, and contributing to patient safety across the country and beyond. I also acknowledge the commitment of the PvPI team and a nationwide network of ADR Monitoring Centres, Market Authorization Holders and other stakeholders of Pharmacovigilance for ensuring a robust Pharmacovigilance system in the country.

I am sure, the Pharmacovigilance Programme of India will keep playing vital role in supporting evidence-based decisions in the interest of public health, promoting research and innovations in pharmacovigilance and promoting rational use of medicines. One of the main objectives of the PvPI is to strengthen and popularly disseminate ADR reporting for general awareness to guard against the adverse effects with the usage of medical products, as certain medical products show adverse reactions after a long period of time.

The digital initiatives of PvPI such as Mobile App 'ADR PvPI 2.0', ADRMS and QR Code for reporting adverse events in ADRMS as well as capacity building will go a long way to reach out to the stakeholders in an easy and friendly manner and also in creating the awareness about PV to HCPs and patients or their caregivers.

Wishing this programme all the best!

Shri Hoveyda Abbas, IA&AS
Additional Secretary & Financial Adviser
Ministry of Health and Family Welfare,
Government of India

कमरा नं. 247, ए–विंग, निर्माण भवन, नई दिल्ली -110011
Room No. 247, A-Wing, Nirman Bhavan, New Delhi- 110011
Tel.(O) : 011-23062985, E-mail : asfa-mhfw@nic.in

Message from the Desk of Secretary-cum-Scientific Director IPC

Dear Readers,

I am privileged to release the Pharmacovigilance Programme of India (PvPI) Newsletter Volume 15, Issue 3 for the index period of July to September, 2025 on the theme '5th National Pharmacovigilance Week.'

During this period, 45 New Adverse Drug Reaction Monitoring Centres (AMCs) have been enrolled under PvPI and total number of AMCs are 1120 across the country. A total of 10.57 Lakh Individual Case Safety Reports (ICSRs) have been reported to PvPI. The PvPI is regularly sensitizing its stakeholders about the pharmacovigilance and reporting of Adverse Events through Awareness Programmes, Trainings, Workshops, Skill Development Programmes, Continuing Medical Education (CME) etc. The PvPI has organized a total of 674 training programmes and trained a total of 57798 participants in the area of pharmacovigilance in this quarter.

National Pharmacovigilance Week 2025 was observed across India to create awareness about the importance of reporting of ADRs and monitoring the safety of medical products. This week focused on encouraging healthcare professionals and the public to report adverse drug reactions to the Pharmacovigilance Programme of India (PvPI). Various awareness activities such as seminars, workshops, community outreach programmes, walkathon etc. were conducted by the AMCs of PvPI and other stakeholders to promote a culture of patient safety. The observance of NPW 2025 reinforced the role of pharmacovigilance in ensuring the safe, effective, and rational use of medicines, thereby contributing to improved public health outcomes.

The NCC-PvPI, IPC has issued a total of 183 drug safety alerts so far for the sensitization of healthcare professionals and reporting of such adverse drug reactions to PvPI, if encountered with the use of such drugs.

At global level, the NCC-PvPI, IPC being a World Health Organization-Collaborative Centre for Pharmacovigilance in Public Health Programmes and Regulatory Services is regularly sharing the latest information on safety and regulatory actions of medical products taken by the CDSCO based on PvPI recommendations to the SEARN Countries.

As a team, we will continue to work to improve patient safety. I congratulate the PvPI team, AMCs, subject experts and other stakeholders for their ceaseless efforts, cooperation and contribution in strengthening the pharmacovigilance system in India.

(Dr. V. Kalaiselvan)
Secretary-cum-Scientific Director
Indian Pharmacopoeia Commission
(Ministry of Health & Family Welfare,
Government of India)
Ghaziabad - 201002

5th National Pharmacovigilance Week

The National Coordination Centre – Pharmacovigilance Programme of India (NCC-PvPI), Indian Pharmacopoeia Commission (IPC) celebrated 5th National Pharmacovigilance Week (NPW) from 17th -23rd September 2025, across the country. The theme of this NPW was "Your Safety, Just a Click Away: Report to PvPI". The Adverse Drug Reaction Monitoring Centres (AMCs), in medical colleges, hospitals, academic institutes, and pharmaceutical industries also actively participated in celebrated 5th NPW 2025. Various modes like workshops, conferences, quiz competitions, poster competitions, rangoli, walkathon, *nukkad-natak*, etc. were organized during the entire week of this event by the AMCs of PvPI. Moreover, AMCs awareness was raised via programmes at the *Gram Panchayat* Level and through community outreach activities in rural/urban area, which helped to educate the general public.

Inaugural Ceremony

The Inaugural ceremony was successfully organized on 17th September 2025 at Bharat Mandapam Convention Centre, New Delhi which commenced with lamp-lighting, followed by welcome remarks from Dr. V. Kalaiselvan, Secretary-cum-Scientific Director, IPC. In his address, he outlined the activities planned during the 5th NPW and also emphasized on the sensitization of stakeholders related to pharmacovigilance across the country.

Prof. Y. K. Gupta, reflected on the journey of PvPI since its inception and underscored the importance of pharmacovigilance. Looking ahead, he emphasized opportunities for the next generation, noting "Pharmacovigilance is an upcoming field with immense potential, especially for young pharma graduates. The time has come to explore its synergies with pharmacoeconomics, pharmacogenomics, statistics, and AI/ML." He also acknowledged the unique challenges for India and said, "As our country has a large population and vast genetic diversity. Public awareness about side effects must be strengthened, and it is vital that physicians and pharmacists not only understand but also report ADRs."

Dr. Nilima Kshirsagar, expressed her appreciation for the impact of the event, and she said, “It is truly phenomenal to witness the participation of about 600 delegates.” During the event, she mentioned that the foundations for pharmacovigilance in India were laid as early as the 1990s with the establishment of the WHO Special Centre for Pharmacovigilance in GSMC, KEM Hospital, Mumbai. She further highlighted the remarkable growth of PvPI.

The Chief Guest, Dr. Rajeev Singh Raghuvanshi, Drugs Controller General of India, delivered the keynote address, highlighting the growing role of pharmacovigilance in safeguarding patient health. In his remark, he said, “Initiation of National Pharmacovigilance Week in the journey of pharmacovigilance in the country has changed its course. With the number of reporting, we ranked among the top contributors globally in reporting adverse events.”

A short film of PvPI, Pharmacovigilance Comic in different vernacular languages, and QR code for online reporting of ADRs through ADRMS were released.

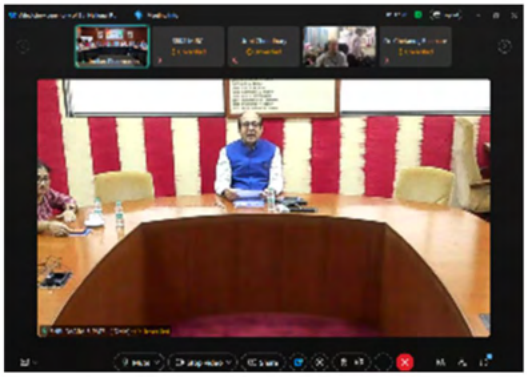
The scientific programme featured deliberations by experts, including WHO's perspective on strengthening pharmacovigilance system in India by Dr. Madhur Gupta, Strengthening ADR Reporting Framework: Challenges and the road by Prof. Mira Desai, Strengthening patient safety trough effective implementation of Materiovigilance in Healthcare Institutions by Prof. Pravesh Mehra, and regulatory perspectives in Pharmacovigilance: Present and Past by CDSCO representatives Shri Ankit Sharma. The panel discussion entitled "Multi-stakeholder approaches to Strengthening ADR Reporting System" moderated by Prof. Y. K. Gupta, brought together experts from academia, regulatory agencies, marketing authorization holders, and PvPI.

The inaugural session concluded with a vote of thanks by Dr. Jai Prakash, Senior Principal Scientific Officer & Officer-in-Charge PvPI – IPC.

As part of NPW 2025, IPC organised an International Webinar on "Strengthening Signal Detection & Risk Management Framework" on 18th September 2025. The objective of the event was to enhance regional capacity through SEARN initiatives and global perspectives, while strengthening practices in causality assessment, risk management, and signal detection in pharmacovigilance. The webinar witnessed participation from 467 delegates, including 115 international participants representing countries such as Barbados, Burkina Faso, Chile, Comoros, Eritrea, Jamaica, Lesotho, Liberia, Madagascar, Mali, Mozambique, Nauru, Sri Lanka, St. Vincent & the Grenadines, Bhutan, Timor-Leste, Myanmar, Maldives, Thailand, Guyana, and Nepal.

The week concluded with the Valedictory on 23rd September, 2025, Dr. Jai Prakash, Officer-in-Charge, PvPI delivered a welcome note followed by the discussion on "Strengthening Industry-Driven Pharmacovigilance: Challenges and Way Ahead: IDMA Perspective".

This was followed, an address given by Mr. Daara B. Patel, Secretary General, Indian Drugs Manufacturers Association (IDMA) on "Strengthening Industry-Driven Pharmacovigilance: Challenges and Way Ahead," who emphasized on strengthening pharmacovigilance systems within the pharmaceutical industry and ways to enhance reporting to PvPI. Next, Dr. Upasana Arora, CEO and Managing Director, Yashoda Super Speciality Hospital, Ghaziabad, highlighted the importance of collaborative efforts between hospitals, regulators, and industry to strengthen Adverse Drug Reaction (ADR) reporting mechanisms.



Top-performing ADR Monitoring Centres and Marketing Authorization Holders were felicitated.

TOP PERFORMING ADR MONITORING CENTRES - FY 2024-25
(With Pharmacovigilance Associate)

AMC Name	Coordinator	Deputy Coordinator	Pharmacovigilance Associate
Post Graduate Institute of Medical Education & Research, Chandigarh	Dr. Bikash Medhi	Dr. Ajay Prakash	Mr. Benjamin, Ms. Disha
Seth GS Medical College & KEM Hospital, Mumbai	Dr. Nithya Gogtay	Dr. Mahesh Belhekar	Ms. Pratiksha Dyaneshwar Thombare
Rajagiri Hospital, Aluva	Dr. Dinu Varghese	Dr. Jibin John	Dr. Aparna Chand.O
Amrita Institute of Medical Sciences, Kochi	Dr. Princy Louis Palatty	Dr. M.P. Namadha	Ms. Tinu.T.S.
BJ Medical College, Ahmedabad	Dr Chetna Desai	Dr. Amita Sutaria	Dr Hetvi Bachani
GMERS Medical College & General Hospital, Gandhinagar	Dr. Darshan J. Dave	Dr. Jigar Modi	Ms. Shivani Trivedi
School of Tropical Medicine, Kolkata	Dr. Santanu Munshi	Dr. Priyatosh Saha	Ms. Shatavisa Mukherjee
JSS Medical College & Hospital, Mysore	Dr. M. Ramesh	Dr. Sri Harsha Chalasani	Ms. Mrithika
Nizam Institute of Medical Sciences, Hyderabad	Dr. P. Usha Rani	Dr. M. Padmaja	Mr. Amal Sajeev
Maharani Laxmi Bai Medical College, Jhansi	Dr. Sadhna Kaushik	Neeraj Srivastava	Mr. Vinay Kumar

TOP PERFORMING ADR MONITORING CENTRES - FY 2024-25
(Without Pharmacovigilance Associate)

AMC Name	Coordinator	Deputy Coordinator
Believers Church Medical College & Hospital , Thiruvalla	 Prof Dr Jacob Jesurun RS	 Dr. Harikrishnan S
Smt. Bhikhiben Kanjibhai Shah (SBKS) Medical Institute & Research Centre, Waghodia	 Dr. Shruti Brahmbhatt	
Iqraa International Hospital & Research Centre, Calicut	 Dr. Muhammed Thoyyib	 Dr. Muhammed Anas V. K.
Jubilee Mission Medical College and Research Institute, Thrissur	 Dr. Maria Jose	 Dr. David Pudukadan
M.S. Ramaiah Medical College, Bengaluru	 Dr. Anuradha H V	 Dr. Mukunda N
KLE College of Pharmacy, KLE Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi, Karnataka	 Dr. Prof. M.S. Ganachari	 Dr. Santhosh Reddy
National Institute of Pharmaceutical Education and Research, Vaishali	 Dr. Sameer Dhingra	 Dr. Krishna Murti
Chalapathi Institute of Pharmaceutical Sciences, Guntur	 Dr. Venkata Rama Rao Nallani	 Dr. Gavin Sivabharath
PSG Institute of Medical Sciences & Research, Coimbatore	 Dr. K. Bhuvaneswari	 Dr. S. Shanmugapriya
Kauvery Hospital, Tiruchirapalli	 D. Suryaprabha	 Ms. V. Mariammal

TOP PERFORMING MARKETING AUTHORIZATION HOLDERS (MAHs) - FY 2024-25

S. No.	Marketing Authorization Holders
1.	Novartis India Limited
2.	Roche Products (India) Private Limited
3.	Pfizer Limited
4.	Baxter (India) Private Limited
5.	Cipla Limited

A recap video titled “Glimpses of NPW 2025 Celebration”, showcased the nationwide celebrations, sensitization drives, and media coverage.

NCC-PvPI team during valedictory ceremony of National Pharmacovigilance Week 2025

Navigating the Pharmacovigilance Lifecycle in the Age of AI: Talent, Technology and Tomorrow's Safety Systems

Vrushali Negandhi,
CEO, VAN Media Ventures LLP
Head – Production, Drug Safety Symposium India and Middle East

With increasingly complex therapies and globalized markets, the role of pharmacovigilance has transformed from a reactive compliance function to a proactive, strategic pillar in the drug development lifecycle. The integration of artificial intelligence (AI) and automation offers immense potential—but this promise is only as strong as the people who power and govern these systems. In this article, I am trying to explore the PV lifecycle from development to post-marketing surveillance, the challenges AI aims to solve, and why continuous learning and upskilling must accompany any technological advancement.

The Expanding PV Lifecycle: From Drug Discovery to Post Market Surveillance

Pharmacovigilance activities traditionally begin during the clinical development phase with collection of safety data in real-time from trials, but the lifecycle extends much further:

- **Clinical Development:** Safety monitoring starts early. Adverse event reporting mechanisms must align with Good Clinical Practice (GCP), and early signal detection is critical in Phase I-III trials.
- **Market Authorization:** Once the product is ready to submit for approval, Risk Management Plans (RMPs) are developed in accordance with regional regulations like EMA's GVP Module V or US FDA REMS.
- **Post-Marketing Surveillance (PMS):** This phase demands the most from PV systems. Real-world data (RWD), spontaneous reports, literature, and patient support programs feed into Individual Case Safety Reports (ICSRs), aggregate analyses, and signal management functions.

At every stage, the sheer volume and velocity of safety data challenge traditional PV methods. Manual processes become unsustainable, error-prone, and reactive. This is where technology and AI steps in.

AI and automation are being adopted for a range of PV activities

- **Individual Case Safety Report Processing:** Duplicate detection methods based on ML and probabilistic record linkage was implemented for large database like VigiBase, FAERS, and EudraVigilance. AI was used to support ICSR processing is in the encoding of information on adverse events or verbatim fields and case narratives. Robotic process automation has been used for automated repetitive, labour-intensive tasks.
- **Case Intake & Triage:** NLP-powered engines can extract relevant data from source documents (e.g., natural language processing of social media content or screening the scientific literature for adverse events) for faster processing.
- **Signal Detection and analysis:** Machine learning models identify emerging safety patterns by analyzing large datasets across spontaneous reports, EHRs, and literature.
- **Risk Management & Reporting:** Automated dashboards and predictive tools can optimize periodic safety update reports (PSURs) and guide regulatory strategy.

However, AI is not a panacea. Even leading systems often hover at 85% accuracy. The remaining 15%, the gray zone, requires expert human judgment to interpret clinical nuance, regulatory intent, and patient context.

The Human Factor: Talent as the Linchpin

Despite technological advancements, the pharmacovigilance ecosystem relies heavily on skilled professionals to manage AI outputs, ensure compliance, and safeguard patient safety.

Key Challenges

- **Skill Gaps:** PV teams must now understand not only regulatory science but also data science, algorithmic bias, and validation frameworks.
- **Compliance Knowledge:** Regulatory bodies (e.g., FDA, EMA, DCGI) require AI systems to be validated under Computer System Validation (CSV) protocols. Misuse or misunderstanding can risk both compliance and public health.
- **Integration:** Professionals need to navigate interconnected systems—Medical Information, Regulatory Affairs, and Real-World Evidence units—all which interface with PV.

The Path Forward: Strategic Training & Continuous Upskilling

To bridge these gaps, continuous learning must become a strategic imperative for pharmaceutical companies and service providers. This includes:

- **Cross-Functional Learning:** PV professionals should be encouraged to understand tech systems, while data scientists must grasp regulatory nuances.
- **Validation Literacy:** Understanding the principles of GxP-compliant validation for AI tools is essential to building trustworthy systems.
- **AI Governance Frameworks:** Training programs must include elements on AI ethics, explainability, right to privacy, protection of personal data and audit-readiness to future-proof safety teams.

EU AI Act emphasized appropriate training for developers, data scientists, executives, managers, end users and operators of AI systems, data protection and compliance officers Several companies have launched internal academies or partnered with academic institutions to create AI-in-PV certification programs. Conferences, workshops, and online learning modules are now mainstream tools to democratize this knowledge.

Conclusion: A Shared Responsibility for Safer Futures

The integration of AI in pharmacovigilance is not merely about operational efficiency—it's about safeguarding patient lives in an increasingly complex therapeutic environment. But AI alone cannot ensure safety. It is the synergy between smart systems and smarter professionals that will define the next era of drug safety.

Investing in talent is no longer optional-it is the foundation upon which compliant, scalable, and future-ready PV systems must be built.

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Enrolment of New AMCs

NCC-PvPI, IPC has enrolled 45 new AMCs in 27th Phase of PvPI expansion. The total number of AMCs enrolled by the end of this quarter were 1120 across the country. The list of newly enrolled AMCs is mentioned below:

S. No.	States/UTs	Name of Hospitals/Medical Colleges/Institutes	Status of Hospital (Government/ Non-Government)
1.	**Andhra Pradesh**	M.B. Multispeciality Hospitals Plot No. 15B, Chinagadili, Visakhapatnam, Andhra Pradesh-530040	Non-Government
2.		Maharajah's Institute of Medical Sciences Opp. MDO Office, Nellimarla, Vizianagaram, Andhra Pradesh-535217	
3.	**Chhattisgarh**	Abhishek I Mishra Memorial Medical College and Research Junwani Road, Bhilai, Durg, Chhattisgarh-490020	Non-Government
4.	**Delhi**	Mata Chanan Devi Hospital C-1, Janak Puri, West Delhi, Delhi-110058	Non-Government
5.		Delhi Pharmaceutical Sciences and Research (DIPSAR) Pushp Vihar, Sector - 03, New Delhi-110017	Government
6.	**Gujarat**	Dev Children Hospital A-7, 8, Sunflower Society, Diwallpura Garden, Vadodara, Gujarat-390007	Non-Government
7.		Nirali Hospital AM Naik Healthcare Complex, NH-8, Grid Road, Tighda, Ganesh Sisodra, Navsari, Gujarat-396463	
8.		Aayush Multispeciality Hospital Savsar Plot, Ayodhyapuri Main Road, Morbi, Gujarat-363641	

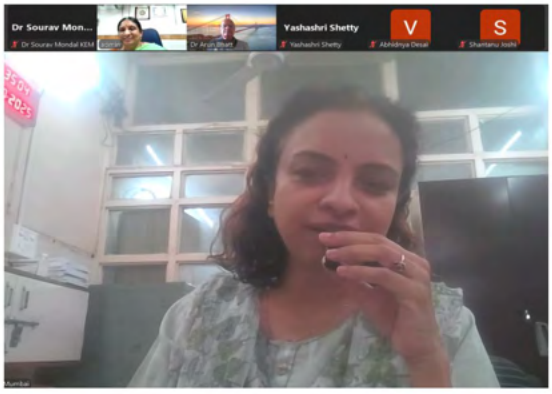
9.	**Haryana**	Holy Heart Super Speciality & Trauma Centre 330 Vinay Nagar, Delhi Bypass Chowk, Rohtak, Haryana-124001	Non-Government
10.		Shah Hospital Kaithal, Opposite Old Bus Stand, Kaithal, Haryana-136027	
11.		Mahendra Hospital Yamuna Nagar, Haryana-135003	
12.		Haryana Multispeciality Hospital Opp. Tau Devi Lal Park, Delhi Bypass, Rohtak, Haryana-124001	
13.		Marengo Asia Hospital Sec 56, Sushant Lok II, Golf Course Extn. Road, Gurugram, Haryana-122011	
14.		Arora Orthopaedic Hospital Tayal Garden, Barwala Road, Hisar, Haryana-125001	
15.		Abhishek Memorial Hospital Baroda Road, Gohana, Sonipat, Haryana-131301	
16.		The Kidney Hospital 14 & 15, Sector - 18, Panipat, Haryana-132103	
17.	**Karnataka**	Stepcare Whitefield Private Limited Ground Floor, Unit G-01, Brigade IRV Centre, Nalluehalli, Whitefield, Bangalore Urban, Karnataka-560066	Non-Government
18.		PES University Institute of Medical Sciences and Research PES University EC Campus, Konappana Agrahara, Hosur Road, Electronic City Bangaluru, Karnataka-560100	
19.		Khaja Bandanawaz Teaching and General Hospital Khaja Nagri, Station Road, Kalaburagi-585102	

20.	**Kerala**	Daya General Hospital & Speciality Surgical Centre Thrissur, Kerala-680022	Non-Government
21.		Mary Queens Mission Hospital Palampra PO. Koovapally, Kottayam DT., Kerala-686518	
22.		Al-Azhar Medical College and Super Speciality Ezhalloor, Thodupuzha, Idukki, Kerala-685605	
23.	**Madhya Pradesh**	Mansarovar Medical College and MGU Hospital Village - Gadiya, Bilkisganj, Sehore, Madhya Pradesh-466111	Non-Government
24.		Vivanta Critical Care Hospital Dev Heights, Parasia Road, Beside LIC Office, Chhindwara, Madhya Pradesh-480001	
25.	**Maharashtra**	M S College of Pharmacy Devgha Wada, Palgarh, Maharashtra-401204	Non-Government
26.		Amepurva Forum's Nirant Institute of Pharmacy Gate No. 503, Near Primary Health Center, NH-65, A/P Boramani, Solapur, Maharashtara-413002	
27.		Zynova Hospitals Pvt. Ltd. CTS 1900-1917, LBS Marg, Ghatkopar West, Mumbai, Maharashtra-400086	
28.	**Punjab**	Deepak Hospital (An Institution of Deepak Memorial Charitable Trust) Ludhiana, Punjab-141001	Non-Government
29.		Verma Hospital Meerakot Chowk, Khairabad Road, Amritsar, Punjab-143001	
30.		Mind Plus Healthcare Pvt Ltd. Village Raul, Rara Sahib, Near Small Hydel Project, Ludhiana, Punjab-141421	

31.		J P Hospital NH-21, Zirakpur, Chandigarh Highway, Under Flyover, Mohali, Punjab-140603	
32.		Gupta Hospital 12-5, Race Course Road, Amritsar, Punjab-143001	
33.		Smt. Paarvati Devi Hospital A- Block, Ranjit Avenue, Amritsar, Punjab-143001	
34.	**Rajasthan**	Sharda Hospital B 30, Maan Nagar, Jhunjhunu, Rajasthan-333001	Non-Government
35.		Apex Hospital Mansarovar Pvt. Ltd. Vidhyanchal Marg, Rajat Path, Mansarovar, Jaipur, Rajasthan-302020	
36.		Sevayatan Hospital Sodala, Ajmer Road, Jaipur, Rajasthan-302006	
37.		Bhagwan Mahaveer Cancer Hospital & Research Centre JLN Marg, Jaipur, Rajasthan-302017	
38.		Rukmani Birla Hospital (RBH) Jaipur, Rajasthan-302018	
39.	**Tamil Nadu**	Guru Hospital 4/120-F, Pandikovil Ringroad, Madurai, Tamil Nadu-625107	Non-Government
40.	**Telangana**	MNR Medical College and Hospital MNR Nagar, Fasalwadi, Sangareddy, Telangana-502294	Non-Government
41.	**Uttarakhand**	Neelkanth Medicose New ITI Road, Near Susheela Tiwari Hospital, Haldwani, Uttarakhand-263139	Non-Government

42.	**Uttar Pradesh**	Promhex Multispeciality Hospital NH-34, Sector - P2, Omega - 1, Greater Noida, Uttar Pradesh-201308	Non-Government
43.		R D Hospital S-8/158, A-2, Khajuri Pandeypur Road, Varanasi, Uttar Pradesh-221002	
44.		Rama Hospital & Research Centre (A unit of Dr. B S Kushwah Institute of Medical Science), A-1/B Lakhanpur, Kanpur, Uttar Pradesh-208024	
45.		Autonomous State Medical College Dubeypur, Sultanpur, Uttar Pradesh-227815	Government

CME organised by Seth GS Medical College and KEM Hospital, Mumbai



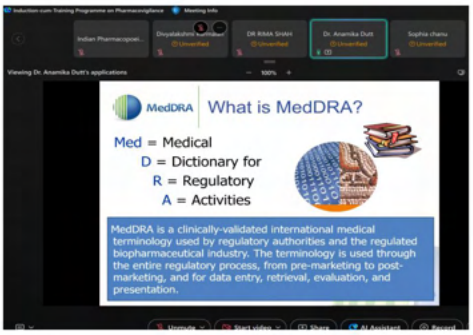
Dr Nitya Gogtay, Coordinator, Dr Mahesh Belhekar, Deputy Coordinator and Ms. Pratiksha Thombare, Pharmacovigilance Associate at Department of Clinical Pharmacology, Seth GS Medical College and KEM Hospital, Mumbai organised CME on the theme – ICH-GCP E6 R3 through virtual mode on 2nd July 2025. In this training programme, Dr. Arun Bhatt, MD (Med) FICP (UK) Consultant, Clinical Research and Drug Development delivered a talk on the theme emphasizing on quality by design, participant safety, proportionality in application based on trial risk, and increased transparency and documentation standards. Following this, Dr Nitya Gogtay elaborated on the challenges and opportunities for implementing E6 (R3) in Indian academic Research. Dr Usha Rani, Professor & Head, Department of Clinical Pharmacology, Nizam's Institute of Medical Sciences, Hyderabad, summarized the evolving expectations in clinical trial governance. A total of 48 participants attended this training programme.

Workshop organized by MGM Medical College, Indore

Dr. Pooja Solanki Mishra, Coordinator, Dr. Anjali Kushwah, Deputy Coordinator and Preeti Acharya, Pharmacovigilance Associate at Department of Pharmacology, MGM Medical College, Indore organised workshop on the theme - Ensuring Patient safety through Drug and Device Monitoring on 19th July 2025. In this training programme, Dr. Pooja Reddy, HOD - Department of Pharmacology, SAIMS, Indore gave an overview on Pharmacovigilance and Dr. Shilpa Kaore, Professor, Department of Pharmacology, AIIMS Bhopal gave Hands on Training on MDAE form filling for medical devices. A total of 121 participants attended this training programme.

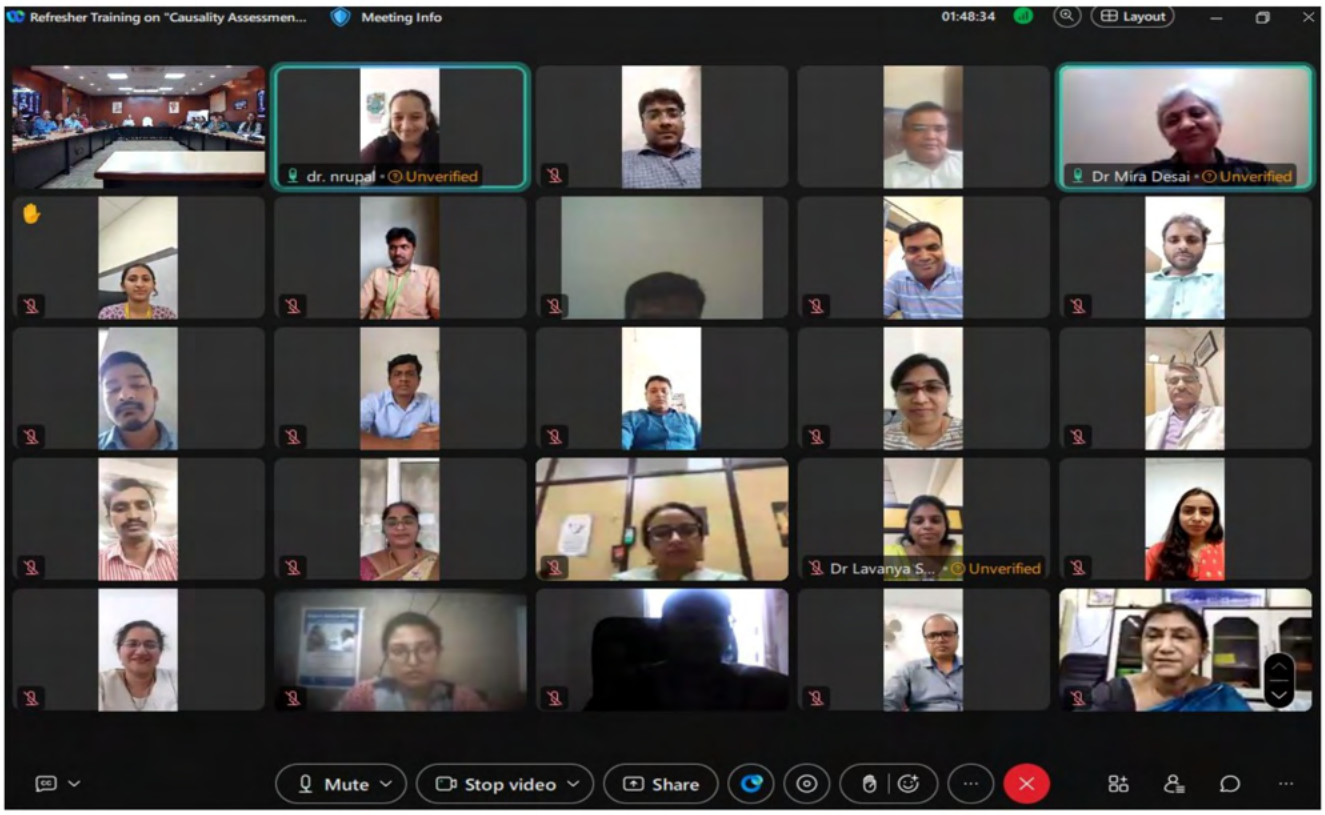
Induction-cum-Training Programme

NCC-PvPI, IPC, Ghaziabad organised Induction-cum-Training Programme through virtual mode on 5th August 2025. The objective of the programme was to enhance the skills of Coordinators/Deputy Coordinators of the newly recognized AMCs in order to promote patient safety. A total of 26 participants attended this training programme.



Refresher Training on Causality Assessment of AEs

NCC-PvPI, IPC organised a virtual training on Causality Assessment of Adverse Events (AEs) for Pharmacovigilance Associates at NCC & AMCs, Coordinators/ Deputy Coordinators on 6th August, 2025. In this training programme, Prof. Mira Desai, Member, Signal Review Panel, PvPI, IPC delivered an in-depth presentation on Causality Assessment of AEs, including a discussion on various causality assessment scales. To reinforce the concepts covered, case series was shared by the speaker for participant engagement and practical understanding. A total of 424 participants attended this training programme.



CME organised by Sri Venkateswara Institute of Medical Sciences, Tirupati

Dr. U. Bharathi, Coordinator, Dr. Y. Lakshmi, Deputy Coordinator and Ms. R. Rajalakshmi, Sr. Pharmacovigilance Associate at Department of Pharmacology, Sri Venkateswara Medical College, Tirupati, Andhra Pradesh organised CME on the theme – Building a culture of drug safety: awareness on Pharmacovigilance through physical mode on 12th August 2025. In this training programme 8 sessions were held, among which, Dr. U. Bharathi, gave overview of Pharmacovigilance and Ms. R. Rajalakshmi gave session on Introduction to VigiFlow: Enhancing ADR reporting and Drug Safety. A total of 276 participants attended this training programme.

34th Skill Development Programme on Pharmacovigilance

The NCC-PvPI, IPC conducted 34th Skill Development Programme (SDP) on Pharmacovigilance in virtual mode from 18th-22nd August 2025. In this SDP, a total of 20 technical sessions were conducted on various topics in pharmacovigilance by the subject experts from the pharmaceutical industries, academic and research Institutions. A total of 171 participants attended this programme including industry professionals, physician, academicians, pharmacy students, medical students, and pharmacists across the country. At the end, the participants provided their positive feedback and also appreciated the efforts of PvPI team for organising such informative training programmes.

CME organised by AIIMS, Bhopal

Dr. Ratinder Jhaj, Coordinator, Dr. Balakrishnan S, Deputy Coordinator and Ms. Deepa Chaudhary, Pharmacovigilance Associate at Department of Pharmacology, All India Institute of Medical Sciences, Bhopal. Madhya Pradesh organised CME on the theme – Pharmacovigilance: Ensuring Patient Safety in the Era of Emerging Therapies through physical mode on 29th August 2025. The objective of the training programme was to sensitize clinicians, nurses, pharmacists and other healthcare professionals from corporate and government hospitals and pharmacy college about the need and importance of active reporting of Adverse events. A total of 153 participants attended this training programme.

CME organised by MAMC, Delhi

Dr. Vandana Roy, Coordinator, Dr. Vandana Tayal, Deputy Coordinator and Dr. Ritu Arora, Pharmacovigilance Associate at Department of Pharmacology, Maulana Azad Medical College (MAMC), Delhi organised CME on the theme – Basic concepts in Pharmacovigilance: Current Status through virtual mode on 4th September 2025. The objective of the workshop was to provide basic training to the Coordinators and Pharmacovigilance associates working in different AMCs at Delhi NCR under Regional Training Centre, MAMC about concept of pharmacovigilance, reporting of ADRs and its causality assessment, and functioning of AMC to improve adverse drug reaction reporting. A total of 100 participants attended this training programme.

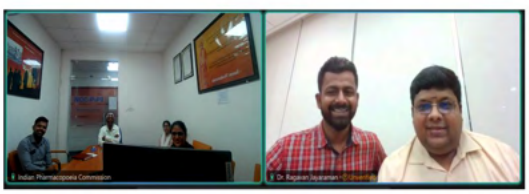
CME organised by AIIMS, Mangalagiri

Dr. Arup Kumar Mishra, Coordinator, Dr. Gaurav Manikrao Rangari, Deputy Coordinator and Dr. Saggurthi Pavani, Pharmacovigilance Associate at All India Institute of Medical Sciences, Mangalagiri, Andhra Pradesh organised CME on the theme – Awareness and Sensitization on Pharmacovigilance and ADR Reporting through physical mode on 27th September 2025. The speakers elaborated on evolution of pharmacovigilance, structure of PvPI, process of ADR reporting, important stakeholders in ADR reporting, clinical aspect of pharmacovigilance and importance of signal detection. There was hands on training on how to fill ADR forms (Version 1.4). A total of 58 participants attended this training programme.

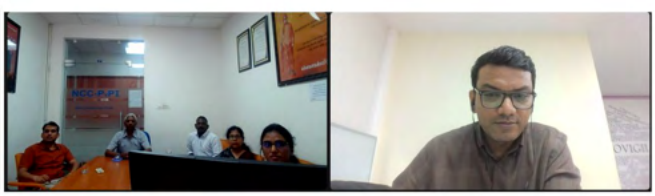
Interactive meetings with Marketing Authorization Holders

The objective of Interactive meetings is to review the quality, number of ICSRs received in a calendar year, and completeness score of ICSRs received from Marketing Authorization Holders and inform the same to representatives of Marketing Authorization Holders for taking improvement measures. Details of such Interactive meetings held virtually with Marketing Authorization Holders are as follows:

S. No.	Date	Marketing Authorization Holders	No. of Representatives
1.	7th July 2025	Reliance Lifesciences Pvt. Ltd.	6
2.	28th July 2025	MSN Laboratories Pvt. Ltd.	6



NCC-PvPI, IPC team, and Reliance Lifesciences Pvt. Ltd. Representatives



NCC-PvPI, IPC team, and MSN Laboratories Pvt. Ltd. Representatives

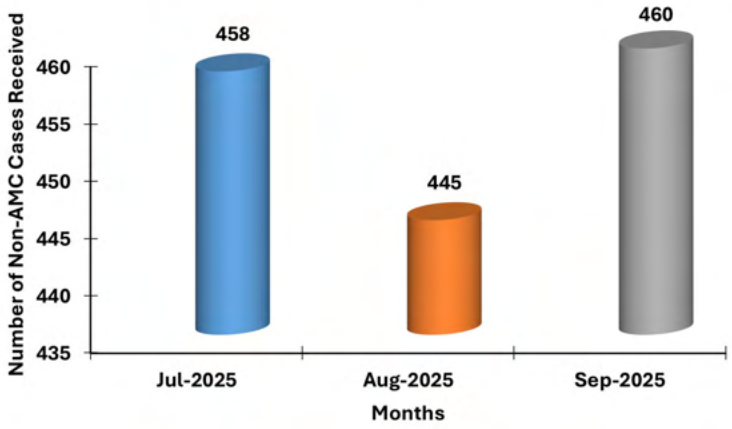
Monthly trends of training programmes conducted by PvPI

The NCC-PvPI, IPC organised a total of 674 training programmes including Skill Development Programmes, Continuing Medical Education, Advanced Level Training Programmes etc. and trained a total number of 57798 participants in the area of Pharmacovigilance across the country.

Monthly trends of training programmes

Monthly trends of Non-AMC cases received at PvPI

The NCC-PvPI, IPC received a total of 1363 cases from Non-AMCs from across the country.



Monthly trends of Non-AMC cases

Participation of PvPI Representatives in different meetings

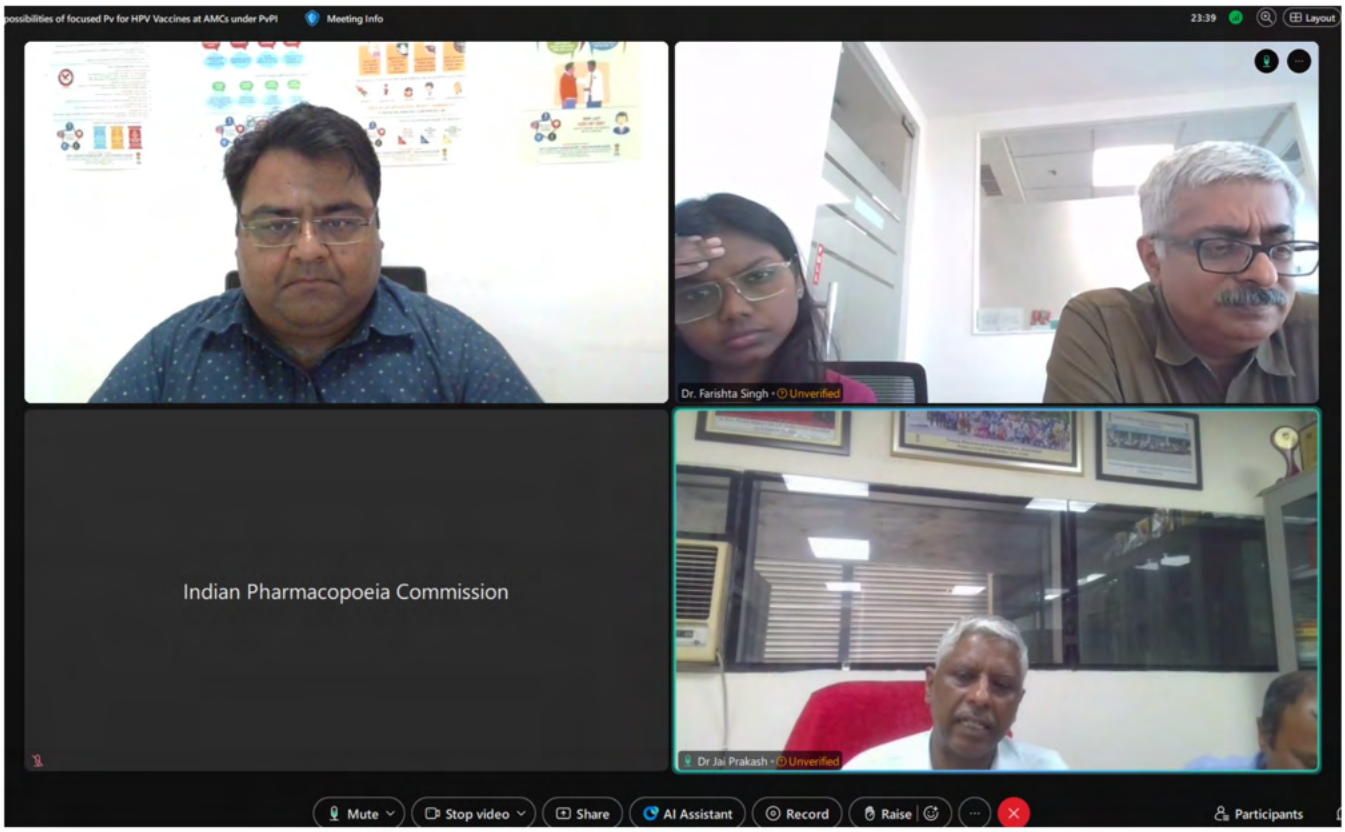
World Pharmacist Day Celebration at Rajiv Gandhi Cancer Institute & Research Centre (RGCIR)

Rajiv Gandhi Cancer Institute & Research Centre (RGCIR), Rohini, New Delhi has celebrated World Pharmacist Day on 25th September, 2025 at Indraprastha Hall, Rohini campus. The theme was "The Critical Role of Hospitals in ADR Identification and Reporting". The objective of this celebration was to raise the awareness among healthcare professionals about the Pharmacovigilance especially the role of Pharmacist in adverse drug reaction reporting. Dr. Shashi Bhushan, Senior Scientific Officer, NCC-PvPI, IPC has delivered a talk on the "Pharmacovigilance Programme of India (PvPI): Role in ADR Reporting". There were more than 50 participants including Physician, Nurse, Pharmacist and healthcare professionals have participated in this event.

National AEFI Committee meetings

- The Adverse Event Following Immunization (AEFI) Secretariat has organised virtual National AEFI Committee meeting on 22nd September, 2025. This meeting was aimed to work upon the Report of causality assessment subcommittee - Adult vaccination, Root Cause Analysis of Silent Districts, Report of causality assessment subcommittee - UIP vaccines, Report of causality assessment of the Delhi State AEFI committee etc. Dr. Jai Prakash Sr. PSO, IPC had attended this meeting virtually. Approximately 30 participants had attended this meeting.

- A virtual meeting was conducted by IPC between the AEFI Secretariat and PvPI, IPC on 29th September 2025 to discuss over the possibilities of focused pharmacovigilance for HPV Vaccines at AMCs under PvPI as an action point documented in point number 1 of the Day-2 proceedings in the minutes of the meeting of the National AEFI Committee (NAC) held on 24th & 25th June 2025 where it was suggested that the Pharmacovigilance Programme of India may consider conducting focused pharmacovigilance activities following HPV vaccination with the support of the National AEFI Committee and the AEFI Secretariat. During this meeting it was decided that the AEFI secretariat will share a proposal on, how to conduct this focused pharmacovigilance and what all information shall be required from this particular study. Dr. Jai Prakash Sr. PSO, Dr. Vijit Agrawal Sr. PvA and Mr. Vipin Sharma Sr. PvA from IPC Ghaziabad and Dr. Deepak Polpakara and Dr. Farishta Hannah Deritha Singh had attended this meeting virtually.



New drugs approved in India

The following new drugs were approved by the CDSCO during this index period;

S. No.	New Drugs	Approved Indication(s)	
1.	Tegoprazan Tablet 25 mg	Maintenance of healed Erosive Gastroesophageal Reflux disease	8th July 2025
2.	FDC of Relugolix, Estradiol and Norethindrone Acetate Tablets (40 mg+1 mg+0.5mg)	Indicated for the management of heavy menstrual bleeding associated with uterine Leiomyomas (Fibroids) in premenopausal women.	16th July 2025
3.	Lutetium Lu-177 Vipivotide Tetraxetan solution for injection or infusion 1000MBq/m L	Lutetium (Lu-177) Vipivotide Tetraxetan is indicated for the treatment of adult patients with prostate-specific membrane antigen (PSMA) - positive metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor (AR) pathway inhibition and taxane-based chemotherapy.	23rd July 2025
4.	Stamicis 1mg kit for Radiopharmaceutical Preparation	After radiolabelling with sodium pertechnetate (^{99m}Tc) solution, the solution of technetium (^{99m}Tc) sestamibi obtained is indicated for: • Myocardial perfusion scintigraphy for detection and localization of coronary artery disease (angina pectoris and myocardial infraction). • Assessment of global ventricular function. First-pass technique for determination of ejection fraction and/or ECG triggered, gated SPECT for evaluation of left ventricular ejection fraction, volumes and regional wall motion. • Scintimammography for the detection of suspected breast cancer when mammography is equivocal, inadequate or indeterminate. • Localization of hyperfunctioning parathyroid tissue in patients with recurrent or persistent disease in both primary and secondary hyperparathyroidism, and in patients with both primary hyperparathyroidism scheduled to undergo initial surgery of the of the parathyroid glands.	23rd July 2025

5.	Upadacitinib Bulk Drug and Upadacitinib Extended Release Tablets 15mg, 30mg and 45mg	For the treatment of adults with moderately to severely active ulcerative colitis who have had an inadequate response or intolerance to one or more TNF blockers.	19th August 2025
6.	Pitolisant Bulk drug and Pitolisant Tablets 4.45 mg and 17.8 mg	For treatment of excessive day time sleepiness (EDS) or cataplexy in adult patients with narcolepsy.	27th August 2025
7.	Etrasimod Tablets 2mg	Etrasimod is indicated for the treatment of patients 16 years of age and older with moderately to severely active ulcerative colitis (US) who have had an inadequate response, lost response, or were intolerant to either conventional therapy, or a biological agent.	16th September 2025

Source:
cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTMzNjg=

☞ Healthcare Professionals, Patients/Consumers are advised to closely monitor the possibility of ADRs associated with the use of above new drugs. If any reaction is encountered, please report to the NCC-PvPI, IPC by filling of Suspected Adverse Drug Reactions Reporting Form for HCP/Medicines Side Effect Reporting Form for Consumer available at https://www.ipc.gov.in and PvPI Helpline Number 1800-180-3024

Drug Safety Alert

The NCC-PvPI, IPC issued the following drug safety alerts and shared with AMCs through email for the sensitization of healthcare professionals, thereby strengthening the reporting of ICSRs to PvPI.

The PvPI, IPC being a WHO Collaborating Centre for Pharmacovigilance in Public Health Programmes and Regulatory Services also shared the drug safety alerts with South-East Asia Regional Network (SEARN) countries through email.

S. No.	Drug Safety Alert Issue Date	Suspected drugs	Indication(s)	Adverse Drug Reactions
1.	29th August 2025	Tranexamic Acid	• For the treatment of abnormal bleeding in which local hyperfibrinolysis is considered to be involved (pulmonary, haemorrhage, epistaxis, renal bleeding abnormal bleeding during or after prostate surgery). • Haemorrhage or risk of haemorrhage in increased fibrinolysis of hereditatory angioneurotic oedema. • For the treatment of excessive bleeding in patients with hemophilia during & following tooth extraction. • For the treatment of menorrhagia. • For the prevention of oral hemorrhage in anticoagulant treated patients undergoing oral surgery.	Nasal Congestion
2.		Metoclopramide	• To restore normal coordination and tone the upper digestive tract and relieve symptoms of gastro-duodenal dysfunction including heart burn, dyspepsia, nausea and vomiting associated with such conditions as reflux oesophagitis, gastritis, duodenitis and hiatus hernia. • For the treatment of nausea and vomiting.	Tachycardia

3.	26th September 2025	Erythromycin	Alternative to penicillin in hypersensitive patients; pneumonia; legionnaires' diseases; syphilis; chancroid; chlamydia; non-gonococcal urethritis; prostatitis; lymphogranuloma venereum; campylobacter enteritis; relapsing fever; diphtheria and whooping cough prophylaxis upper respiratory tract infection, acne vulgaris, sycosis, vulgaris.	Fixed Drug Eruption

☞ Healthcare Professionals, Patients/Consumers are advised to closely monitor the possibility of the above ADRs associated with the use of above suspected drugs. If such reactions are encountered, please report to the NCC-PvPI, IPC by filling of Suspected Adverse Drug Reactions Reporting Form for HCP/Medicines Side Effect Reporting Form for Consumer available at https://www.ipc.gov.in and also through PvPI Helpline Number 1800-180-3024.

Press & Media

हरि दुनिया (दैनिक)

दवा का दुष्प्रभाव नजर आए तो अपने चिकित्सक को बताएं : डॉ. एम के सिंघल

- दवा के किसी भी प्रतिकूल प्रभाव की सूचना उपचार करने वाले डॉक्टर को देना केवल उपचार करने वाले डॉक्टर का ही नहीं, फार्मा कंपनी, फार्मेसी कॉलेजों और स्वयं मरीज का भी है कर्तव्य

பிபிஜி மருத்துவக் கல்லூரியில் உலக மருந்தாளர் தினம் கொண்டாட்டம்

AMU OBSERVES 5TH NATIONAL PHARMACOVIGILANCE WEEK WITH AWARENESS DRIVES, EDUCATIONAL COMPETITIONS, AND COMMUNITY ENGAGEMENT

Aligarh, September 24, 2025 | Public Relation Office

ALIGARH, September 24: Aligarh Muslim University (AMU) successfully observed the 5th National Pharmacovigilance Week from September 17 to 23, 2025, under the theme 'Your Safety, Just a Click Away: Report to PvPI.' The week-long celebrations featured a wide array of academic events, awareness drives, creative competitions, and community outreach initiatives designed to promote drug safety, responsible medicine use, and public health consciousness. The observance was conducted in line with the directives of the

தேசிய மருந்து பாதுகாப்பு வாரம் 2025 – கற்பகம் உயர்கல்வி நிறுவனத்தில் விழிப்புணர்வு நிகழ்ச்சிகள்

The Indian Pharmacopoeia Commission, functioning as the National Coordination Centre for the Pharmacovigilance Programme of India organised the inaugural ceremony of the 5th National Pharmacovigilance Week on September 17 at Bharat Mandapam Convention Centre.

మందుల విషయంలో జాగ్రత్తగా ఉండాలి

Inquilab Page No.03

قومی فارماکوویجلنس ہفتہ کے تحت مختلف بیداری پروگراموں کا اہتمام

'दवाइयों के दुष्प्रभाव एवं सुरक्षा के प्रति जागरूक करना आवश्यक'

5th NPW PHOTO GALLERY

Kind Attention: *Despite NCC-PvPI efforts to provide maximum photographic coverage of NPW 2025, space constraints limited the inclusion of all photographs received nationwide.*

Consumer/Patient Feedback on PvPI

Mr. Senthil
Coimbatore
Tamil Nadu

Recently when I visited Karpagam hospital, I had an opportunity to go through awareness posters on side effects placed at the patient waiting area and understood that side effects can be reported by patients themselves through toll free helpline number and consumer reporting forms to the Government of India through side effect reporting program (PvPI), apart from reporting to treating physicians. I truly value the government's efforts to educate public on safety of medicines.

Grace
Somzjiguda, Hyderabad,
Telangana

Education and awareness among the patients have improved for early reporting and prevention of adverse effects. Poster campaigns have been very useful.

R. Praveen
Nizampet, Hyderabad,
Telangana

- Patient safety by early detection of harmful drug effects
- Public confidence has been improved in reporting ADR
- Sensitization and awareness help patients to identify and report ADR.

Forthcoming Events

S. No.	Date	Title	Who can participate?
1.	3rd-9th November 2025	MedSafetyWeek-2025	• Healthcare Professionals • Professional bodies • Medical/Pharmaceutical/Nursing Institutions • ADR Monitoring Centres (AMCs) • Pharmacovigilance Professionals • Medical/Para-medical/Pharmacy Students • Pharmacists • Academicians
2.	10th-14th November 2025	35th Skill Development Programme at NCC-PvPI, IPC (Virtual)	• Healthcare Professionals • Pharmacovigilance Professionals • Medical/Para-medical/Pharmacy Students • Pharmacists • Academicians
3.	18th November 2025	Induction-cum-Training Programme on Pharmacovigilance	• Coordinators • Deputy Coordinators • PV Associates at AMC and NCC
4.	22nd December 2025	Soft Skills and Communications in Pharmacovigilance	• Coordinators • Deputy Coordinators • PV Associates at AMC and NCC
5.	14th January 2026	Induction-cum-Training program for newly recognized AMCs	• Coordinators • Deputy Coordinators • PV Associates at AMC and NCC
6.	27th January 2026	Signal detection in Pharmacovigilance	• Coordinators • Deputy Coordinators • PV Associates at AMC and NCC

दवाइयों से होने वाले प्रतिकूल/दुष्प्रभाव की निगरानी एवं मरीजों की सुरक्षा के प्रति जागरूकता

फार्माकोविजिलैंस प्रोग्राम ऑफ़ इंडिया, स्वास्थ्य और परिवार कल्याण मंत्रालय, भारत सरकार द्वारा जनहित में जारी

औषधि सतर्कता कार्यक्रम (फार्माकोविजिलैंस प्रोग्राम ऑफ़ इंडिया) क्या है?

फार्माकोविजिलैंस प्रोग्राम ऑफ़ इंडिया, स्वास्थ्य एवं परिवार कल्याण मंत्रालय के अंतर्गत कार्य करता है जिसका नोडल कार्यालय, भारतीय भेषज संहिता आयोग में स्थित है। मैटीरियोविजिलैंस प्रोग्राम ऑफ़ इंडिया जिसका नोडल कार्यालय भी भारतीय भेषज संहिता आयोग में स्थित है तथा हीमोविजिलैंस प्रोग्राम ऑफ़ इंडिया जिसका नोडल कार्यालय राष्ट्रीय जैविक संस्थान, नॉएडा में स्थित है, वे भी इसी के भाग हैं।

उद्देश्य

राष्ट्रीय औषधि सतर्कता सप्ताह का उद्देश्य औषधियों से होने वाले दुष्प्रभाव के प्रति जागरूकता फैलाना व इनसे होने वाले दुष्प्रभावों को फार्माकोविजीलैंस प्रोग्राम ऑफ़ इंडिया को रिपोर्ट करना है।

औषधि सतर्कता क्या है?

सामान्य मात्रा में किसी औषधि अथवा दवा का सेवन करने से होने वाले प्रतिकूल प्रभाव अथवा दुष्प्रभाव का पता लगाने, उसका मूल्यांकन करने, समझने व रोकथाम से सम्बंधित विज्ञान एवं गतिविधियों को औषधि सतर्कता विज्ञान कहते हैं तथा इस विषय में सजग/ सतर्क रहने को औषधि सतर्कता कहते हैं।

दवा प्रतिक्रिया/ एडवर्स ड्रग रिएक्शन (एडीआर)

औषधियों का वह प्रभाव जो हानिकारक और अनअपेक्षित है और जो आमतौर पर मनुष्यों में बीमारी की रोकथाम, निदान या उपचार के लिए या शारीरिक कार्य के संशोधन के लिए उपयोग की जाने वाली खुराक पर होती है, को दवा प्रतिक्रिया/ एडवर्स ड्रग रिएक्शन कहते हैं।

औषधि दुष्प्रभावों को कौन रिपोर्ट कर सकता है?

सभी स्वास्थ्य कर्मचारी (चिकित्सक, दंत चिकित्सक, फार्मासिस्ट, नर्स और उपभोक्ताओं सहित गैर-स्वास्थ्य देखभाल कर्मचारी) दवाओं के दुष्प्रभाव को रिपोर्ट कर सकते हैं।

औषधि दुष्प्रभावों को रिपोर्ट क्यों करें?

स्वास्थ्य कर्मचारी के रूप में सार्वजनिक स्वास्थ्य की सुरक्षा के लिए औषधि उत्पादों से जुड़े प्रतिकूल प्रभावों को रिपोर्ट करना एक नैतिक जिम्मेदारी है।

क्या रिपोर्ट करें?

औषधियों से होने वाले किसी भी प्रकार की प्रतिक्रियाएं भले ही ज्ञात हों या अज्ञात, गंभीर हों या अगंभीर, अक्सर हो या दुर्लभ, ऐसी सभी प्रतिक्रियाओं की रिपोर्टिंग कर सकते हैं।

कैसे और किसे रिपोर्ट करें?

1. हेल्पलाइन नंबर 1800-180-3024 पर कॉल करके (सोमवार से शुक्रवार सुबह 9:00 बजे से सायं 5:30 बजे)।
2. हमारी वेबसाइट www.ipc.gov.in पर औषधि दुष्प्रभाव सूचना फॉर्म डाउनलोड करके व उचित तरीकें से भरकर ई-मेल करें।
3. हमारी ई-मेल आई डी है pvpi.ipc@gov.in, pvpi.compat@gmail.com
4. यह सुविधा गूगल प्ले स्टोर पर मुफ्त उपलब्ध है।
5. आप "ADR PvPI" App डाउनलोड कर सकते हैं।

कोविड-१९ महामारी के दौरान उपयोग होने वाली औषधियों से होने वाले दुष्प्रभाव की जानकारी कहाँ और कैसे दें

इसकी जानकारी आप फॉर्माकोविजीलैंस प्रोग्राम ऑफ़ इंडिया के अंतर्गत किसी भी निकटवर्ती ऐ॰ डी॰ आर॰ मॉनिटरिंग सेंटर पर दे सकते हैं। इस सम्बन्ध में एक विशेष फॉर्म - Suspected Adverse Drug Reaction Reporting Form (For Drugs used in Prophylaxis/ Treatment of COVID-19) भी डिज़ाइन किया गया है, जो www.ipc.gov.in पर उपलब्ध है ।

सत्यमेव जयते
IPC

Indian Pharmacopoeia Commission
National Coordination Centre,
Pharmacovigilance Programme of India
Ministry of Health & Family Welfare, Govt. of India
Sector-23, Raj Nagar, Ghaziabad-201002
Tel.: 0120-2783400, 2783401, 2783392

For any other information/Suggestion/ Query, please contact:
Officer-in-Charge
Pharmacovigilance Programme of India
Email: lab.ipc@gov.in, pvpi.ipc@gov.in
Website: www.ipc.gov.in

Let us join hands with PvPI to ensure patient safety