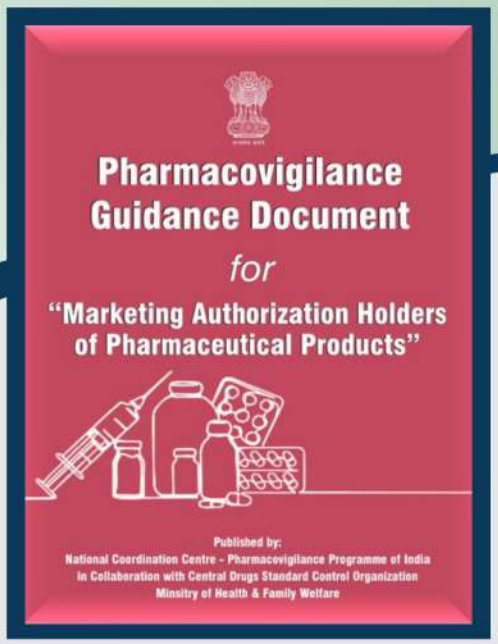
Newsletter

PHARMACOVIGILANCE PROGRAMME OF INDIA (PvPI)

VOL 15 | ISSUE 1 | 2025



Strengthening of Pharmacovigilance Systems at Market Authorization Holders (MAHs)

Published by:

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

CONTENTS

Message from the Desk of Secretary-cum-Scientific Director

I am privileged to release the Pharmacovigilance Programme of India (PvPI) Newsletter Volume 15, Issue 1 for the index period January to March, 2025 on the theme 'Strengthening of Pharmacovigilance Systems at Market Authorization Holders (MAHs): Focus on Pharmacovigilance Guidance Document for MAHs of Pharmaceutical Products, Version 2.0'.

During the index period, 25 New Adverse Drug Reaction Monitoring Centres (AMCs) have been enrolled under PvPI and total number of AMCs are 1050 across the country. A total of 9.37 Lakh Individual Case Safety Reports have been reported to PvPI as on 31st March 2025. 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 338 training programmes and trained a total of 17752 participants in the area of pharmacovigilance in this quarter.

NCC-PvPI, IPC has released the Pharmacovigilance Guidance Document for Marketing Authorization Holders (MAHs) of Pharmaceutical Products, Version 2.0 on 17th September 2024. This PV Guidance Document for MAHs has been effective from 1st February 2025 to strengthen the Pharmacovigilance system at MAHs organization in India and has also issued a notice for the same. To sensitize the MAHs for the implementation of this PV guidance document in country, the NCC-PvPI, IPC has organised zone wise one day training programmes for the MAHs across the country.

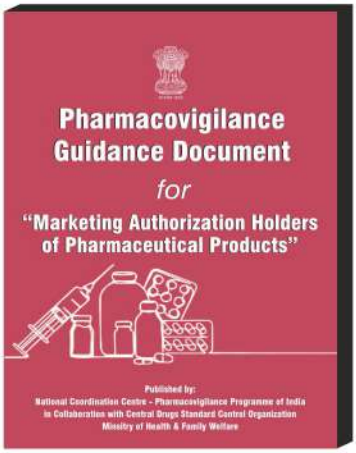
The NCC-PvPI, IPC has issued a total of 177 drug safety alerts so far for the sensitization of healthcare professionals and reporting of such adverse drug reactions to PvPI, if encountered with the use of such drugs.

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. Rajeev Singh Raghuvanshi)
Secretary-cum-Scientific Director
Indian Pharmacopoeia Commission
(Ministry of Health & Family Welfare,
Government of India)
Ghaziabad - 201002

Strengthening of PV Systems at Marketing Authorization Holder (MAH) Organizations: Focus on the PV Guidance Document for MAHs of Pharmaceutical Products, Version 2.0



The National Coordination Centre – Pharmacovigilance Programme of India (NCC-PvPI), Indian Pharmacopoeia Commission (IPC) in collaboration with Central Drugs Standard Control Organization (CDSCO) has revised the Pharmacovigilance Guidance Document for MAHs of Pharmaceutical Products, Version 1.0 for strengthening of PV systems at MAHs. The revised version, Version 2.0 of this Guidance Document was released at NCC-PvPI on 17th September 2024. This PV Guidance Document for MAHs has become effective from 1st February 2025 to strengthen the Pharmacovigilance system at MAHs organization in India and a Notice in this regard was issued by Secretary-cum-Scientific Director, IPC on 11th November 2024 & uploaded on website of IPC *www.ipc.gov.in*, also.

The revised version, Version 2.0 of this Guidance Document has the following objectives:

1. To assist and facilitate MAHs of pharmaceutical products for reporting all AEs accurately, efficiently and timely to NCC-PvPI, IPC and CDSCO.
2. To establish a uniform PV System at MAHs organization across the country by:
   - (i) Preparation and maintenance of Pharmacovigilance System Master File
   - (ii) Collecting, Processing and Reporting of Individual Case Safety Report (ICSR) by Marketing Authorization Holder (MAH)
   - (iii) Preparation & Submission of Periodic Safety Update Report by MAH
   - (iv) Implementation of Quality Management System at MAH organization
   - (v) Audits & Inspections of Pharmacovigilance System at MAH organization
   - (vi) Preparation and Submission of Risk Management Plan

Process of Preparation of Pharmacovigilance Guidance Document for MAHs of Pharmaceutical Products, Version 2.0

An Expert Committee was constituted to revise the existing PV Guidance Document for MAHs of Pharmaceutical Products, Version 1.0

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PV Guidance document, Version 1.0 reviewed by organising 10 Expert Committee meetings and incorporated their comments.

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Public/stakeholders comments obtained by uploading the draft version 2.0 of PV Guidance Document for MAHs of Pharmaceutical Products on website of PvPI, IPC - www.ipc.gov.in for 30 days

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Examination of comments/suggestions obtained by the Expert Committee

↓

Incorporation of valid comments by the NCC-PvPI Team at IPC

↓

The pre-print version circulated to the Expert Committee for review and approval

↓

Final version approved by the Competent Authority and printed

This Pharmacovigilance Guidance Document has following chapters:

Chapter 1 : Pharmacovigilance System Master File

Chapter 2 : Collection, Processing and Reporting of Individual Case Safety Report (ICSR)

Chapter 3 : Preparation & Submission of Periodic Safety Update Report (PSUR)

Chapter 4 : Quality Management System at Marketing Authorization Holders Organization

Chapter 5 : Audits & Inspections of Pharmacovigilance System at Marketing Authorization Holders Organization

Chapter 6 : Submission of Risk Management Plan

What is new in this document?

- This guidance document is updated in the light of New Drugs and Clinical Trials Rules, 2019 and revised Schedule M of Drugs and Cosmetics Rules, 1945.
- The terminology for PVOI is replaced with PVOIC.
- The "Module" is replaced with "Chapter"
- Definition of New Drug is updated in accordance with NDCT Rules, 2019
- The Marketing Authorization Holders should maintain records in Excel/Electronic sheets.

Sensitization measures for implementation of this pharmacovigilance guidance document:

- To sensitize the MAHs for the implementation of this PV guidance document in country, the NCC-PvPI, IPC has organized zone wise one day training programmes for the MAHs across the country. The details of such training programmes are given below:

S. No.	Date	Venue	No. of Participants
1.	29th January 2025	National Institute of Mental Health & Neuro Sciences (NIMHANS), Bengaluru *	57
2.	28th February 2025	Central Drugs Testing Laboratory (CDTL), Mumbai *	51

* *These events are covered in detail under Training and Education section of this Newsletter*

- Another step towards sensitization of MAHs was taken by NCC-PvPI via publication of training and flyer in IDMA (Indian Drug Manufacturers' Association) Bulletin LVI (12), 22 to 30 March 2025, Page No. 13-14, (weekly publication)[#].

\# *Please see PvPI in Press & Media of this Newsletter*

Medication errors associated Preventable Adverse Drug Reactions

Dr. Shivani Juneja Bedi, Consultant, Clinical Pharmacology,
AMC Coordinator, Fortis Hospital, Mohali

Medication errors are a significant cause of preventable adverse drug reactions (PADRs) and pose a major challenge to patient safety worldwide. PADRs are harmful or unintended effects of medications that occur due to medication errors. They are considered preventable because they could have been avoided if the medication error had not occurred.

The other important aspect is that not all adverse drug reactions (ADRs) are preventable. ADRs can range from mild to severe and in some cases, can be life-threatening.

Medication errors can happen at any stage of the medication-use process, including prescribing, transcribing, dispensing, administration and monitoring.

Prescription errors may be incorrect drug selection, dose, frequency, or route of administration. Transcription errors include incorrect/inappropriate dose, frequency, route of administration, duration or missed special instructions especially in PRN (*pro re nata*- as needed) drugs. Dispensing errors can be like inappropriate dispensing in the form wrong or expired dose/strength. Administration errors can be wrong drug/dose/duration/frequency, wrong drug administration technique by healthcare staff followed by inability to identify monitoring parameters, failure to recognize ADRs and reporting of the same.

Additionally, there are other attributable factors to PADRs. A study by Woo et al stated that the common contributing factors to PADRs included inadequate patient instructions, monitoring, follow-up and reassessments after medication changes are been made. The study also highlights that more than two-thirds of ADRs were rated as probably or definitely preventable.[1]

Developing strategies that target patients and medications associated with PADRs may help in combatting this issue. A thorough understanding of contributing factors can provide insight into the occurrence of PADRs. Various studies have recommended steps to improve patient adherence, encourage adherence to treatment guidelines, better monitoring of patients, and optimize communication between providers and patients.[2,3,4]

We need to overcome barriers and challenges in reporting medication errors that may be PADRs. Challenges like fear of punishment/litigation, embarrassment of being involved in discussions, regulatory reporting requirements, too much workload, lack of awareness on reporting are a few to mention.

To conclude is important to note that not all ADRs are preventable. Some people may experience ADRs to medications even if the medication is prescribed and administered correctly. However, medication errors are a significant cause of PADRs and it is important to take steps to reduce the risk of these errors.

References:

1. Woo SA, Cragg A, et al., Preventable adverse drug events: Descriptive epidemiology. Br J Clin Pharmacol. 2020 Feb;86(2):291-302. doi: 10.1111/bcp.14139.
2. Van der Hooft CS, Dieleman JP, et al., Adverse drug reaction-related hospitalisations: a population-based cohort study. Pharmacoepidemiol Drug Saf. 2008 Apr;17(4):365-71. doi: 10.1002/pds.1565.
3. Zed PJ, Abu-Laban RB, et al., Incidence, severity and preventability of medication-related visits to the emergency department: a prospective study. CMAJ. 2008 Jun 3;178(12):1563-9. doi: 10.1503/cmaj.071594.
4. Zed PJ. Drug-Related Visits to the emergency department. Journal of Pharmacy Practice. 2005;18(5):329-335. doi:10.1177/0897190005280049.

NCC-PvPI, IPC has enrolled 25 new AMCs in 25th Phase of PvPI expansion. The total number of AMCs enrolled by the end of this quarter were 1050 across the country. The list of newly enrolled AMCs is mentioned below:

S. No.	States	Name of Hospitals/Medical Colleges/Institutes	Status of Hospital (Govt. / Private)
1.	Haryana	Goel Orthopaedic Centre SCF 15-16 Huda Complex, Opp. DRDA, Gohana Road, Jind, Haryana - 126102	Non-Government
2.		Chowdhary Hospital Rohtak, Haryana - 124001	
3.		Siwach Sanjeevani Hospital 123, Rajendra Nagar, Main Gohana Road, Rohtak, Haryana - 124001	
4.		Apex Heart Super Speciality Hospital Ambala, Haryana - 134003	
5.		Shree Hari Hospital (Super Speciality Hospital & Trauma Centre) 31 Ashoka Colony, Karnal, Haryana - 132001	
6.	Himachal Pradesh	Malhotra Hospital and Trauma Centre Opp. Petrol Pump, Main Bazar, Ner Chowk, Mandi, Himachal Pradesh - 175008	Non-Government

7.	Karnataka	NU Hospitals Pvt. Ltd. #4.1, West of Chord Road, Next to Iskcon, Rajaji Nagar, Bengaluru, Karnataka - 560010	Non-Government
8.		Basaveshwara Medical College & Hospital SJM Campus NH-4, Medehalli, Chitradurga, Karnataka - 577502	
9.	Madhya Pradesh	Best Superspeciality Hospital Jabalpur, Madhya Pradesh - 482002	Non-Government
10.	Maharashtra	VIMS Hospital Mohan Nagar, LIC Square Kamtee Road, Nagpur, Maharashtra - 440001	Non-Government
11.		Apple Hospitals & Research Institute Ltd. Apple Saraswati Multispeciality Hospital 804/2, 805/2, E Ward, Kadamwadi - Bhosalewadi Road, Kolhapur, Maharashtra - 416003	
12.		Sant Gajanan Maharaj Rural Hospital Site- Chinchewadi, Gadahinglaj Road Hasurwadi, Kolhapur, Maharashtra - 416503	
13.	Manipur	Cancer Treatment Services Hyderabad Pvt. Ltd. & Babina Speciality Hospital Khabeisoi Sajiwa Jail Road, Imphal East, Manipur - 795010	Non-Government
14.	Punjab	Dr. Karam Singh Memorial Multispeciality Hospital 18-A, Circullar Road, Amritsar, Punjab - 143001	Non-Government
15.		Khanna Multispeciality Hospital Pvt. Ltd. Main GT Road, Khanna, Punjab - 141401	
16.		Kalyan Hospital, Div. no. 3 Chowk, Near Fire Brigade, Ludhiana, Punjab - 141008	
17.		Umeed Multispecialty Hospital Dhuri, Patiyala By-pass Road, Near GIS School, Sangrur, Punjab - 148007	

18.	Rajasthan	Shri Krishan Hospital Near Bijori, Lalsot Road, Dausa, Rajasthan - 303303	Non-Government
19.		Rhythm Heart & Multispeciality Hospital Opp. FCI Godown, Near Kendriya Vidyalaya, Udaipur Road, Banswara, Rajasthan - 327001	
20.		AMRC Hospital Kiran path, Mansarovar, Sector-3, Jaipur, Rajasthan - 302020	
21.		Om Hospital 8-9, Near BSNL Godown, Naya Gaon Road, Pali Marwar, Rajasthan - 306401	
22.		Maharaja Agrasen Superspeciality Hospital Jaipur, Rajasthan - 302039	
23.	Tripura	ILS Hospitals Agartala, New Capital Complex, New Secretariat, West Tripura, Tripura - 799010	Government
24.	Uttar Pradesh	MIMHANS Neurosciences Hospital 281, 283 Mangal Pandey Nagar, Opposite CCS University, Meerut, Uttar Pradesh - 250004	Non-Government
25.		SRMS Goodlife Hospital 101/2, 101/3, Brahampura East, Stadium Road, Bareilly, Uttar Pradesh - 243122	

Regional Training Programme for MAHs at NIMHANS, Bengaluru

NCC-PvPI, IPC organised Regional Training Programme on Implementation of Pharmacovigilance Guidance Document for Marketing Authorization Holders (MAHs) of Pharmaceutical Products, Version 2.0 at National Institute of Mental Health and Neuro Sciences (NIMHANS), Bengaluru on 29th January, 2025. The objective of this training programme was to sensitize the MAHs for implementation of this Guidance Document. The technical sessions included were:

- An Overview of Current Scenario of PvPI including changes in PV Guidance Document, Version 2.0 by Dr Jai Prakash, Officer in-Charge, PvPI, IPC, Ghaziabad
- Regulatory aspects of Pharmacovigilance by Shri Rajsekhar, Deputy Drugs Controller of India, CDSCO
- Establishment of PV System by Marketing Authorization Holders: Lessons learnt, Challenges & Way Forward by Dr Jamal Baig, Multi-Country Safety Head, South-Asia & Indo-China, Sanofi India Ltd.
- Implementation of Pharmacovigilance system as per PV Guidance Document for MAHs, Version 2.0-Industry perspective by Dr Manoj Sharma, Head & QPPV-Global Pharmacovigilance Department, Win-Medicare Pvt. Ltd, New Delhi.

A total of 57 participants (industry professionals) attended this training programme from across the country.

Workshop-cum-Training Programme on Pharmacovigilance for NABH Accredited Hospitals

NCC-PvPI organised one day Workshop-cum-Training Programme on Pharmacovigilance for NABH Accredited Hospitals in physical mode at Fortis Hospital, Mohali (SAS Nagar), Punjab on 31st January 2025. The objective of the training Programme was to enhance Pharmacovigilance skill of the healthcare professional of the NABH Accredited Hospitals in order to promote patient safety. This programme was coordinated by Dr. Shivani Juneja, AMC Coordinator, FH-Mohali and her team. Dr. Jai Prakash, Officer-in-Charge, PvPI, gave his insight on 'Overview of Current Status of Pharmacovigilance Programme of India'. A total of 114 participants attended the workshop.

Workshop on Pharmacovigilance and Reporting of ADRs

Workshop on 'Pharmacovigilance and Reporting of ADRs' was organised by Department of Pharmacology, Sri Venkateswara Institute of Medical Sciences (SVIMS), Tirupati, Andhra Pradesh on 31st January, 2025. The objective of the workshop was to improve ADR reporting. A total of 230 participants attended the workshop including nurses, Pharm D students, medical safety officers and MBBS students.

ALT on ADR Sans Frontiers organised by AIMS, Kochi

Amrita Institute of Medical Sciences (AIMS), Kochi, being a Regional Training Centre (RTC) as well as an AMC (Adverse Drug Reaction Monitoring Centre) under PvPI organized the Third Advanced-Level one-day Training program titled 'ADR Sans Frontiers', at Amriteshwari hall on 28th February 2025. 57 delegates participated in this event which had the privilege of hosting an illuminative talk by Dr RS Ray, Scientific Assistant, represented from NCC-PvPI in this programme. The vote of thanks proposed by Ms Tinu TS.

Participation in MedDRA User Group Meeting

MedDRA MSSO organized User Group Meeting for stakeholders in India on 11th February 2025 at Rose Ballroom, Radisson Gurugram, Udyog Vihar. The MedDRA User Group Meetings are held to exchange best practices and lessons to provide feedback on the quality and effectiveness of MSSO services. NCC-PvPI officials were invited to attend this event. Dr Jai Prakash, Officer-in-charge, PvPI briefed on "How is MedDRA used in PvPI?", sharing briefly about PvPI, Release of PV Guidance Document version 2.0 and various case example of MedDRA use in PvPI. MedDRA Change Request Process and User Perspective was also explained in details by Dr Anamika Dutta, Medical Officer, MedDRA MSSO and Shweta Tiwari, GSK.

Regional Training Programme for MAH at CDTL, Mumbai

NCC-PvPI, IPC organised Regional Training Programme on Implementation of Pharmacovigilance Guidance document for Marketing Authorization Holders (MAHs) of Pharmaceutical Products, Version 2.0 at Central Drug Testing Laboratory (CDTL), Mumbai on 28th February 2025. The technical sessions included were:

- An Overview of Current Scenario of PvPI including changes in PV Guidance Document, Version 2.0 by Dr Jai Prakash Officer-in-Charge, PvPI, IPC, Ghaziabad
- Regulatory perspective of Pharmacovigilance in India by Dr. Santosh Vitthalrao Indraksha, DDC (I), CDSCO (West Zone Office), Mumbai
- Role of MedDRA in Pharmacovigilance Dr Anamika Dutta, Medical Officer, MedDRA, Mumbai
- Salient features of Pharmacovigilance Guidance Document for MAHs of Pharmaceutical Products, Version 2.0 Dr Vivek Ahuja, Sr. Vice President, Eversana Lifesciences Services

Vote of thanks was given by Dr C. Hariharan, Director, CDTL, Mumbai. A total of 51 participants attended this training programme.

32nd Skill Development Programme on Pharmacovigilance

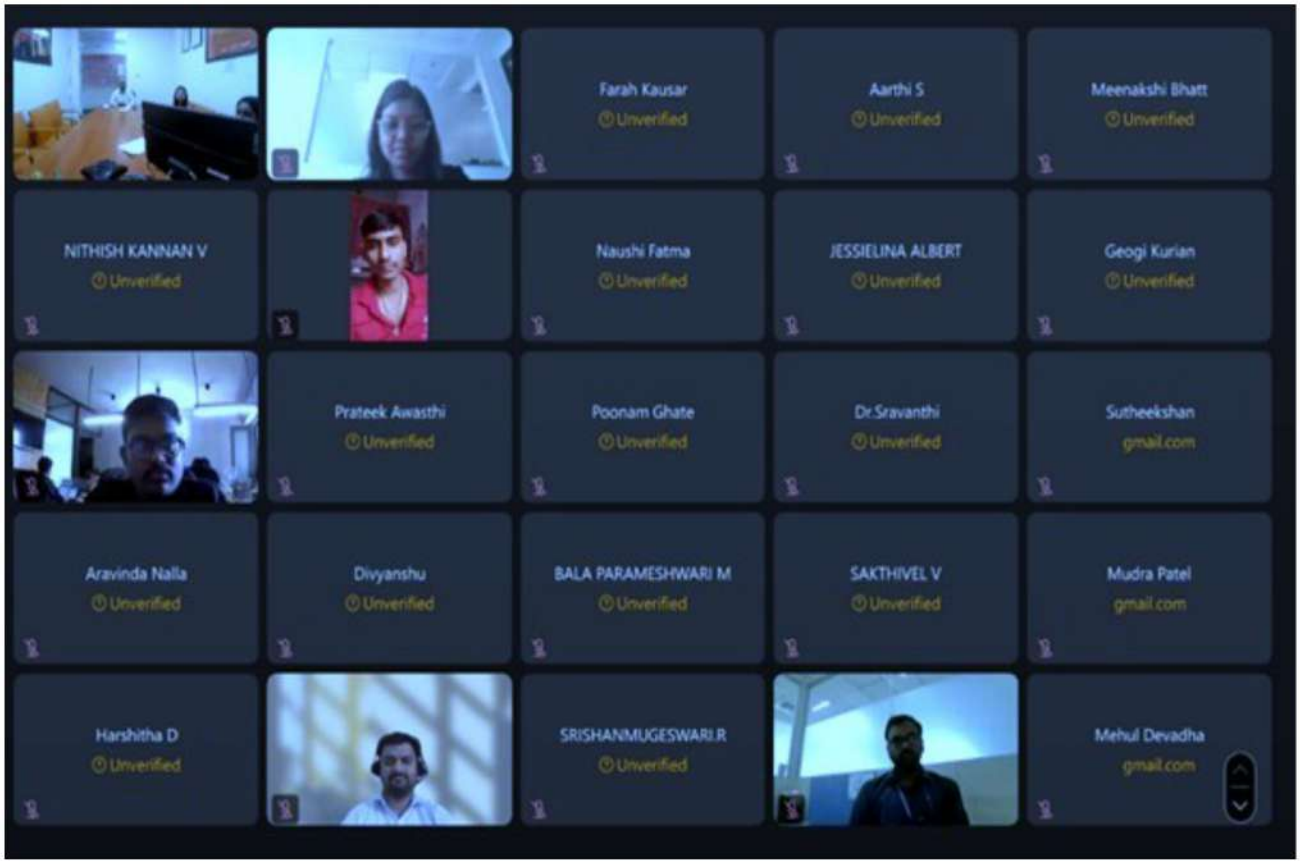
The NCC-PvPI, IPC has conducted 32nd Skill Development Programme (SDP) on Pharmacovigilance in virtual mode from 3rd-7th March 2025. The training programme started with welcome address by Dr. Jai Prakash, Sr. Principal Scientific Officer, IPC & Officer-in-Charge, PvPI and extended his warm greetings & best wishes to all the participants.

The technical session of the 5 days SDP started with the presentation 'History & Basic Concepts of Pharmacovigilance'. During the 5 days SDP, total of 20 technical sessions were conducted on various topics of Pharmacovigilance. The technical sessions were delivered by subject experts from the Pharmaceutical Industries, Academic & Research Institutions. The training session covered the basics of Pharmacovigilance to in-depth signal detection method and regulatory interventions including all the aspects of Pharmacovigilance in a stepwise manner to make easy and understandable to the participants.

A total of 369 participants attended the SDP 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 under the guidance of Dr. Jai Prakash. The training programme received an overwhelming response from all the participants.

Induction-cum-Training Programme organised by NCC-PvPI, IPC

NCC-PvPI, IPC conducted one day online 'Induction-cum-Training Programme' for Coordinators/deputy coordinators & PvAs of newly recruited AMCs on 10th March, 2025.The objective of this training programme was to enhance the skills of participants in order to promote patient safety. A total of 31 participants attended this training programme.



ALT in Pharmacovigilance organised by BJMC, Ahmedabad

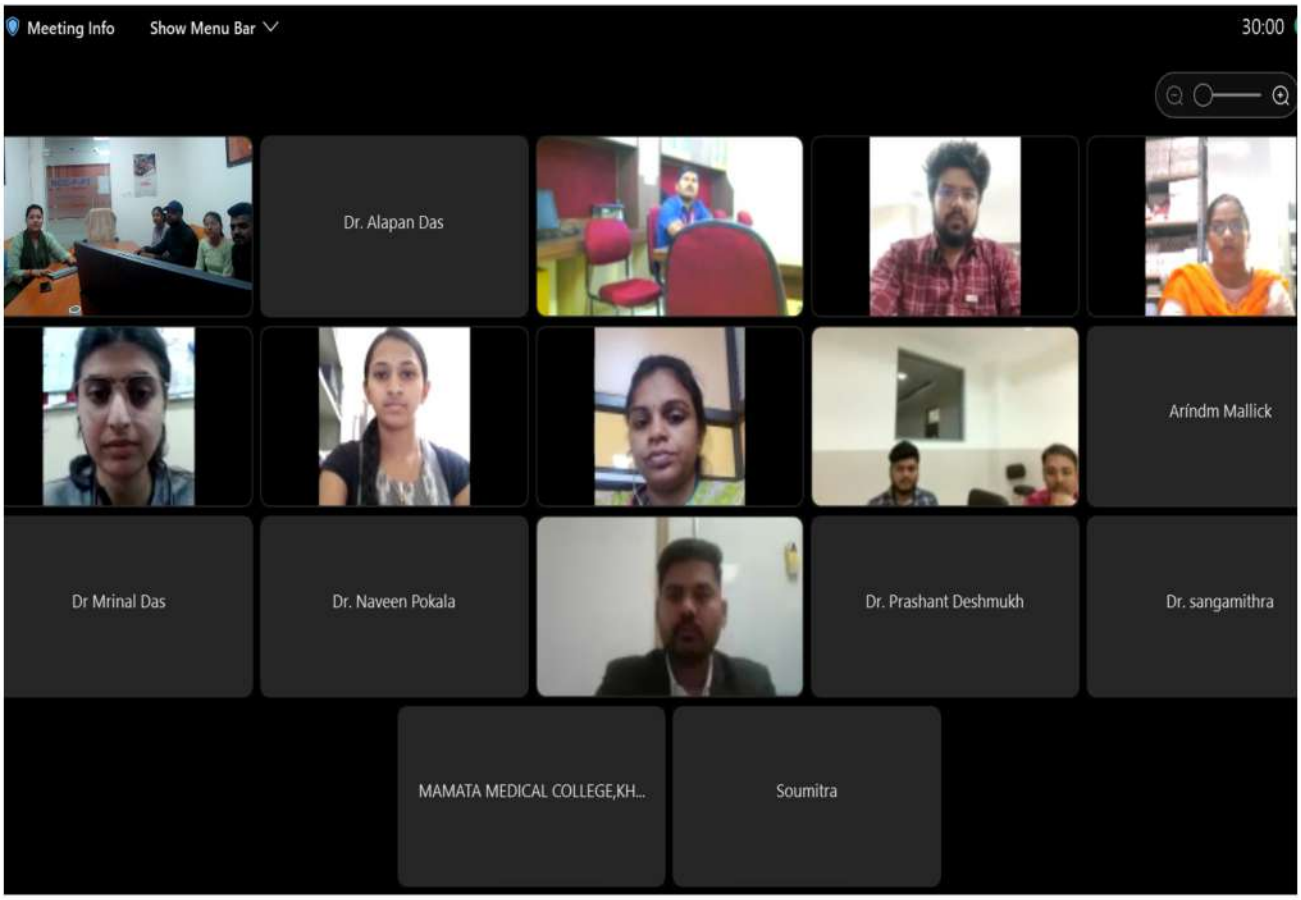
Advance level training (ALT) in Pharmacovigilance was organised by RTC & AMC BJ Medical College, Ahmedabad on 12th March, 2025. The objective was to train coordinators, deputy coordinators, PV associates on advanced topics /areas of Pharmacovigilance in the Indian Context. The training was also open to other personnel associated with Pharmacovigilance and Materiovigilance. Speakers included Dr. Jai Prakash, Officer-in-Charge, PvPI, Dr. Chetna Desai, AMC-RTC Coordinator and many more. A total of 387 participants attended the training programme.

CME organised by PGIMER, Chandigarh

Two days Continuous Medical Education (CME) was organized by the Department of Pharmacology, Post Graduate Insitute of Medical Education & Research (PGIMER), Chandigarh. The two-day event included lectures by Prof. Bikash Medhi's on 'Role of Patient Safety from Pharmacovigilance and Materiovigilance: A New Era' and Dr. Ajay Prakash on 'Global Prospective of Pharmacovigilance and Materiovigilance' on 20th March 2025 and 21st March 2025 respectively. The CME was attended by a total of 250 participants, including doctors, healthcare providers, students, and researchers.

Handholding meeting on Vigiflow software

NCC-PvPI, IPC organized virtual Handholding meeting on Vigiflow software for newly recognized AMCs enrolled under PvPI on 27th March, 2025. The session described entering the ICSRs into the Vigiflow software and resolved the queries of attendees regarding vigiflow processing. A total of 63 participants attended this training programme including Coordinators, Deputy-Coordinators & Junior Pharmacovigilance Associates at NCC and AMCs.



CME on Real world applications of Pharmacovigilance in clinical decision making

A one-day CME on 'Real World Applications of Pharmacovigilance in Clinical Decision Making' organized by Department of Pharmacology, Sri Aurobindo Medical College & PG Institute, Sri Aurobindo University, Indore on 27th March, 2025. Talks included Cutaneous Adverse Drug Reactions, Adverse drug reaction used in oncology and Demonstration of ADR form filling by HCPs. A total of 85 participants attended including doctors, pharmacists, nurses and other healthcare professionals.

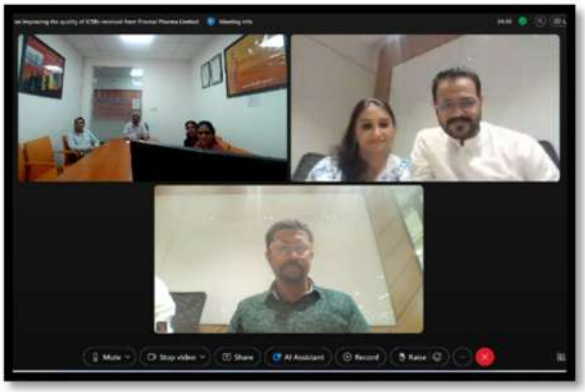
CME on Prakriya

Amrita Institute of Medical Sciences (AIMS), Kochi. AMC and RTC under PvPI, organized the CME program titled 'PRAKRIYA' via hybrid mode on 29th March 2025. The first talk on 'The Urological burden of ADR' by Dr Sanjeevan KV, followed by next session titled 'ADR impact on Heart' by Dr B Abhilash Nair. The scientific session continued with a talk titled on "Anti -TB drugs and ADR" by Dr Vishnu Vazhoor and a talk on "Effective running of an AMC" by Dr Princy Louis Palatty (AMC/RTC Coordinator). The session concluded with a vote of thanks by Ms. Tinu TS, Pharmacovigilance Associate. A total of 116 delegates participated including doctors, PG residents, pharmacy students, clinical pharmacists, and other healthcare professionals from across the country.

Interactive meetings with Marketing Authorization Holders

The objective of this Interactive meeting 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.

S. No.	Date	Marketing Authorization Holder	Mode	No. of Participants
1.	18th March 2025	Piramal Pharma Limited	Virtual	7
2.	27th March 2025	Alkem Laboratories Limited	Virtual	8



NCC-PvPI, IPC team and Piramal Pharma Limited Representatives

NCC-PvPI, IPC team and Alkem Laboratories Limited Representatives

Monthly trends of training programmes conducted during index period

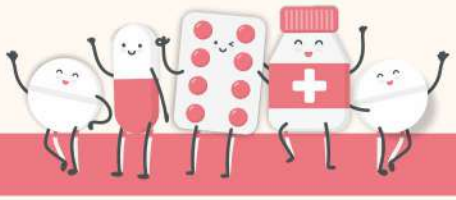
The NCC-PvPI, IPC organised a total of 338 training programmes like Skill Development Programmes, Continuing Medical Education, Advanced Level Training Programmes etc. and trained a total number of 17752 participants in the area of Pharmacovigilance across the country.

Figure-1: Monthly trends of training programmes

Participation in National Health Programme (NHP) Activities

- The Pharmacovigilance Partner's meeting was held on 10th Feb 2025, virtually under the Chairpersonship of Dr. Pawan Kumar, Additional Commissioner, Immunization Division, MOHFW at Nirman Bhawan, MOHFW. This meeting was a part of regular communications related to vaccine AE reporting and related issues between the Immunization Technical Support Unit, CDSCO & NCC-PvPI, IPC. Dr. Jai Prakash, Sr. PSO & Dr. Vijit Agrawal, Sr. Pv Associate from IPC had attended this meeting virtually.
- The National AEFI Committee meeting was held on 20th February 2025 in online mode. 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. Vijit Agrawal had attended this meeting virtually.
- The meeting between Pharmacovigilance Programme of India (PvPI) and Central TB Division to promote ADR reporting from various TB centers held Virtually on 06th Mar 2025. The welcome address was given by Dr. Jai Prakash, Sr. Principal Scientific Officer, IPC wherein he briefed the members of the meeting regarding the meeting's agenda and highlighted the importance of ADR reporting in respect of antituberculosis drugs used in NTEP which is happening to negligible extent except two centres where Pharmacovigilance (Pv) Associate is posted at the ADR Monitoring Centre (AMC) of PvPI. Dr. Jai Prakash explained the system of ADR reporting at the AMCs under PvPI, IPC. Dr. S. K. Mattoo, Joint Commissioner & Addl. DDG-TB, CTD explained the mechanism that how the NTEP program is functioning and also agreed to provide full support to PvPI for better integration.
- The World TB Day Commemoration – 2025 was held on 24th March 2025 at Vigyan Bhawan, New Delhi. India has committed to end TB by 2025, a goal set forth by the Honourable Prime Minister in 2018. India has made remarkable progress, achieving a decline in TB incidence at twice the global average between 2015 and 2023. The commemoration was attended by Dr. Shashi Bhushan, SSO, IPC, and Dr. Vijit Agrawal, Sr. Pv Associate, NCC-PvPI, IPC. The deliberation had started on time.

Various dignitaries, Hon'ble Union Minister of Health & Family Welfare and Chemicals & Fertilizers, Shri Jagat Prakash Nadda, AS & MD (NHM), Smt. Aradhana Patnaik; Secretary, D/o Health & Family Welfare, Smt. Punya Salila Srivastava; DGHS Dr. Atul Goel and many others from various other reputed organizations had addressed the gathering and congratulated the whole team for the achievements of 100 days TB Mukt Bharat Abhiyaan.



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)	Date of Issue
1.	Tafamidis Bulk Drug		16th January 2025
2.	Letermovir Bulk Drug &Letermovir Tablets 240mg and 480 mg	Letermovir is indicated for prophylaxis of cytomegalovirus (CMV) infection and disease in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT). It is also indicated for prophylaxis of CMV disease in adult kidney transplant recipients at high risk (Donor CMV seropositive/Recipient CMV seronegative[D+/R-])	17th January 2025
3.	Fexuprazan hydrochloride Bulk Drug and Fexuprazan hydrochloride Tablets 40mg	Indicated for the treatment of erosive esophagitis (EE)	10th February 2025
4.	Edoxaban Tosylate Monohydrate Bulk Drug		11th February 2025

5.	Edoxaban Tablets 15mg, 30mg and 60mg	In prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation (NVAF) with one or more risk factors, such as congestive heart failure, hypertension, age ≥ 75 years, diabetes mellitus, prior stroke or transient ischaemic attack (TIA). For the treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and for the prevention of recurrent DVT and PE in adults.	20th February 2025
6.	Sodium Zirconium Cyclosilicate powder for Oral Suspension (LOKELMA) 5g/10g	Indicated for the treatment of Hyperkalaemia in adult patients.	5th March 2025
7.	Rimegepant Oral disintegrating tablets (ODT) 75 mg	For Acute treatment of migraine with or without aura in adults with a previous insufficient response to triptans.	27th March 2025
8.	Doravirine Bulk Drug and Doravirine Tablets 100mg	Indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 35 kg with no prior antiretroviral treatment history only (treatment naïve)	28th March 2025

Source:
cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTI2NzY=

☞ Healthcare professionals, patients/consumers are advised to closely monitor the possibility of the Adverse Events 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 HCPs and Medicines Side Effect Reporting Form for Consumers (http://www.ipc.gov.in). You can also report through PvPI Helpline No. 1800-180-3024 (Toll-Free).

Drug Safety Alerts

The NCC-PvPI, IPC issued the folowing 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 Collaborative Centre also shared the drug safety alerts with South-East Asia Regional Network (SEARN) countries through email.

S. No.	Issue Date	Suspected drugs	Indication(s)	Adverse Drug Reactions
1.	12th March 2025	Metronidazole	For the treatment of amoebiasis, urogenital trichomoniasis & giardiasis.	Acute Generalised Exanthematous Pustulosis (AGEP)
2.		Luliconazole	For the treatment of cutaneous mycosis viz. Tinea pedis, Tinea corporis and Tinea cruris.	Chloasma/ Melasma
3.		Dalteparin	For the extended treatment of symptomatic Venous Thromboembolism (VTE) proximal Deep Vein Thrombosis (DVT) and/or Pulmonary Embolism (PE) to reduce the recurrence of VTE in patients with cancer.	Muscle spasms
4.		Gliclazide	Indicated for the treatment of all types of maturity onset diabetes, diabetes without or with obesity in adults.	Erythema multiforme
5.		Tramadol	For the treatment of severe acute and chronic pain, diagnostic measures and surgical pain.	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 http://www.ipc.gov.in and also through PvPI Helpline Number 1800-180-3024.

The Indian Practitioner

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Home › Medi News › IPC Issues Safety Alert on Beta-Blockers Linked to Hypokalaemia Risk

Medi News

IPC Issues Safety Alert on Beta-Blockers Linked to Hypokalaemia Risk

By **The Indian Practitioner** - January 6, 2025

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Home › News › Industry › Pharma News › Drug Safety Alert: IPC...

Drug Safety Alert: IPC Flags Adverse Reactions To Metronidazole, Luliconazole, Dalteparin, Gliclazide, And Tramadol

Written By Susmita Roy — Published On 28 Mar 2025 6:00 PM | Updated On 28 Mar 2025 6:00 PM

INDIAN PHARMACOPOEIA COMMISSION

Regional Training Programme on Implementation of Pharmacovigilance Guidance document for Marketing Authorization Holders (MAHs) of Pharmaceutical Products, Version 2.0 held on 28th February 2025, Mumbai

The National Coordination Centre for Pharmacovigilance Programme of India (NCC-PvPI), Indian Pharmacopoeia Commission, Ghaziabad, organized Regional Training Programme on Implementation of Pharmacovigilance Guidance Document for Marketing Authorization Holders (MAHs) of Pharmaceutical Products, Version 2.0 at Central Drugs Testing Laboratory (CDTL), Mumbai held on 28th February 2025. The session began with welcome address by Dr. Jai Prakash, Officer-in-Charge of PvPI followed by introduction of participants. The following resource persons addressed the participants during the inaugural session Dr. George A Patani, *Sr. Vice President, Indian Drug Manufacturers' Association (IDMA)*, Mr. Jayant Kumar, *Deputy Drugs Controller India (West Zone), Mumbai*, Mr. Vishal Kachare, *Sr Drug Inspector (CDSCO West Zone), Mumbai*, Dr. C Hariharan, *Director, CDTL.*

The following technical sessions were included in the training programme:

- An Overview of Current Scenario of PvPI including Changes in PV Guidance Document, Version 2.0- by Dr. Jai Prakash.
- Regulatory perspective of Pharmacovigilance in India by Dr. Santosh Vitthalrao.
- Role of MedDRA in Pharmacovigilance by Dr. Anamika Dutta.

A total of 55 participants attended this training programme. The participants were Industry Professionals from across the country. The objective of this training programme was to sensitize and enhance the pharmacovigilance capabilities of Marketing Authorization Holders (MAHs) for implementation of Pharmacovigilance for MAHs of Pharmaceutical Products (Version 2.0). This Pharmacovigilance Document has become effective from 01st February 2025. The queries of participants were answered during the interactive sessions and panel discussion. This training program is expected to strengthen the Pharmacovigilance system at MAHs organization.

Note: Please visit IPC website (www.ipc.gov.in) for regular updates.

Regional Training Programme on 'Implementation of PV Guidance Document for MAHs of Pharmaceutical Products, Version 2.0' to be held on 8th April, 2025 at West Bengal

National Coordination Centre - Pharmacovigilance Programme of India
Indian Pharmacopoeia Commission
(Ministry of Health and Family Welfare, Government of India)

REGIONAL TRAINING PROGRAMME ON "IMPLEMENTATION OF PV GUIDANCE DOCUMENT FOR MAHs OF PHARMACEUTICAL PRODUCTS, VERSION 2.0"

REGISTRATION DETAILS

Scan QR & Register

Scan QR & Pay ₹ 2500/Participant

Registration Deadline!!
April 2, 2025

WHO CAN PARTICIPATE?

- Marketing Authorization Holders/ Pharmaceutical Industry Professionals
- Contract Research Organizations (CROs)
- Personnel dealing in Pharmacovigilance activities

Note: Registration fee will not be refunded

Maximum 100 participants will be registered based on first come first serve basis

Date: April 8, 2025 (Tuesday)
Venue:
School of Pharmacy, Techno India University
Kolkata, West Bengal

 # Published in IDMA Bulletin LVI (12), 22 to 30 March 2025, Page no. 13-14

सकाळ पुणे, सोमवार, ३१ मार्च २०२५ २

पाच औषधांचे रुग्णांवर प्रतिकूल परिणाम

नोंदी करण्याचे भारतीय औषध प्रणाली आयोगाचे डॉक्टरांना आवाहन

ज्ञानेश्वर भोंडे : सकाळ वृत्तसेवा

पुणे, ता. ३० : वेदनाशामक, रक्त पातळ होणे, मधुमेह असताना रक्तातील साखर नियंत्रित करणे, बुरशीजन्य आजार, अशा कारणांसाठी वापरल्या जाणाऱ्या पाच औषधे, प्रतिजैविकांचा रुग्णांवर प्रतिकूल परिणाम होत असल्याचे निदर्शनास आले आहे. याबाबत भारतीय औषध प्रणाली आयोगाने प्रकटन जारी करत देशभरातील डॉक्टरांना प्रतिकूल परिणामांची संकेतस्थळावर आपणही नोंद करण्याचे आवाहन केले आहे.

[illegible]

येथे करा तक्रार

जर औषधांचे रुग्णांवर प्रतिकूल परिणाम आढळून आले तर त्याची नोंद डॉक्टर, रुग्ण, ग्राहकांनी http://www.ipc.gov.in या संकेतस्थळावर किंवा ADR PVPI या मोबाईल ॲपवर करावी असे आवाहन आयोगाने केले आहे. तसेच याबाबत १८००१८०३०२४ या टोल फ्री क्रमांकावर संपर्क साधू शकता.

क्र.	औषधाचे नाव	कशासाठी वापर	आढळलेले प्रतिकूल परिणाम
१	मेट्रोनिडाझोल	जीवाणू, परजीवींमुळे होणाऱ्या संसर्गावरील उपचारासाठी प्रतिजैविक	लालसर पुरळ, छोटे फोड असणारा त्वचाविकार (एफडीई)
२	लुलिकोनाझोल	त्वचेवरील बुरशीजन्य (फंगल) संसर्गावरील उपचारासाठी प्रतिजैविक, क्रीम किंवा लोशन स्वरूपात उपलब्ध	[illegible]
३	[illegible]	रक्ताच्या गुठळ्या तयार होऊ नयेत म्हणून	स्नायू अचानक आकुंचित होऊन घट्ट होणे, वेदना होणे
४	[illegible]	रक्तातील साखर नियंत्रित करणारे औषध	[illegible]
५	ट्रामाडोल	मध्यम ते तीव्र वेदना कमी करण्यासाठी वेदनाशामक	[illegible]

[illegible]
- डॉ. अविनाश भोंडवे, माजी अध्यक्ष, आयएमए

[illegible]
- डॉ. आत्माराम पवार, प्राचार्य, पूना कॉलेज ऑफ फार्मसी

Forthcoming Events

S. No.	Date	Title	Who can participate?
1.	8th April 2025	Regional Training Programme on 'Implementation on PV Guidance Document for MAHs of Pharmaceutical Products, Version 2.0' at Techno India University, Salt Lake, Kolkata, West Bengal	• Marketing Authorization Holders/Pharmaceutical Industry Professionals • Contract Research Organizations CRO • Personnel dealing in Pharmacovigilance
2.	30th April 2025	Artificial Intelligence in Pharmacovigilance	• PV Associates at AMC & NCC
3.	30th May 2025	Workshop-cum-Training for the staff of NABH accredited hospitals on Pharmacovigilance at Indraprastha Apollo Hospital New Delhi **Fees Link:** https://payments.cashfree.com/forms/NABHMAY2025 **Registration Link:** https://forms.gle/hvUTsyxTgeHCbsVe9	• For all Healthcare Professionals & Students
4.	2nd – 6th June, 2025	33rd Skill Development Programme at NCC-PvPI, IPC (Virtual) **Fees Link:** https://payments.cashfree.com/forms/33SDP **Registration Link:** https://forms.gle/FxjbbBBwWCzwq4Tu7	• Healthcare Professionals • Pharmacovigilance Professionals • Medical/Para-medical/Pharmacy Students • Pharmacists • Academicians

S. No.	Date	Title	Who can participate?
5.	June 2025	Overview of PV Guidance Document Version 2.0	• Coordinators • Deputy Coordinators • PV Associates at AMC & NCC
6.	August 2025	Causality Assessment	• Coordinators • Deputy Coordinators • PV Associates at AMC & NCC
7.	17th – 23rd September 2025	5th National Pharmacovigilance Week	• Healthcare Professionals • Academic Medical/Pharmaceutical Institutions • Adverse Drug Monitoring Centers (AMCs) • Others stakeholders related to PV
8.	October 2025	Signal Detection in Pharmacovigilance	• Coordinators • Deputy Coordinators • PV Associates at AMC & NCC
9.	3rd – 9th November 2025	MedSafetyWeek 2025	• Healthcare Professionals • Academic Medical/Pharmaceutical Institutions • Adverse Drug Monitoring Centers (AMCs) • Others stakeholders related to PV
10.	December 2025	Soft Skills and Communications in Pharmacovigilance	• Coordinators • Deputy Coordinators • PV Associates at AMC & 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 तरीके 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 Incharge
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