



# Newsletter

PHARMACOVIGILANCE PROGRAMME OF INDIA (PvPI)

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## *“IMPORTANCE OF PROPER COMMUNICATIONS IN PHARMACOVIGILANCE”*



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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 the Desk of Secretary-cum-Scientific Director



I am privileged to release the Pharmacovigilance Programme of India (PvPI) Newsletter Volume 13, Issue 4 for the index period from October, 2023 to December, 2023 on the theme “Importance of Proper Communications in Pharmacovigilance”

In this quarter, 35 New Adverse Drug Reaction Monitoring Centres (AMCs) have been enrolled under PvPI and thus the total number of AMCs under PvPI across the country are 877. About 7.8 Lakh Individual Case Safety Reports have been reported to PvPI so far. The PvPI is regularly sensitizing its stakeholders about the pharmacovigilance by organising Awareness Programmes, Trainings, Workshops, Skill Development Programmes, Continuing Medical Education (CME) programmes, etc. The PvPI has organised a total of 7918 training programmes and trained 489036 participants in the area of pharmacovigilance.

The NCC-PvPI, IPC has issued a total of 159 drug safety alerts for the sensitization of healthcare professionals and reporting of such adverse drug reactions to PvPI, if encountered with the use of such drugs.

As a National Centre for Pharmacovigilance, PvPI has participated in the celebration of MedSafetyWeek organised by the Uppsala Monitoring Centre (UMC), Sweden from 6th to 12th November 2023. The theme of the MedSafetyWeek was “Who can report?": how patients, doctors, pharmacists and other health professionals can contribute to pharmacovigilance?

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

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

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



# Importance of Proper Communications in Pharmacovigilance

The communication plays a vital role in pharmacovigilance. The instance came to the notice regarding improper communication by the media of drug safety alert issued by the PvPI in November 2023. The NCC-PvPI had issued drug safety alert on Mefenamic acid associated Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) Syndrome. The NCC-PvPI did not issue any brand specific drug safety alert, however it was not properly communicated by the media, therefore there is a need of proper understanding of the subject matter and communicating the same to the stakeholders in the interest of patient safety. The communications in pharmacovigilance must be accurate, easily and clearly understandable especially by the public.

The PvPI is making all possible effort to sensitize the healthcare professionals about the drug safety related communications by its different channels from time to time. During this calendar year, the following Signals/Prescribing Information Leaflets (PILs) changes were confirmed and communicated to the Central Drugs Standard Control Organization (CDSCO) for taking further appropriate action.

## Signals recommended by PvPI to CDSCO for inclusion in Prescribing Information Leaflets of concerned pharmaceutical products in this calendar year:

S. No.	Suspected Drugs	Adverse Drug Reactions
1.	Aceclofenac	Fixed Drug Eruption
2.	Ibuprofen	Fixed Drug Eruption
3.	Oral Itraconazole	Symmetrical Drug Related – Intertriginous & Flexural Exanthema (SDRIFE)
4.	Covishield*	Guillain-Barre Syndrome

\* Besides signals at S. No. 1-3, NCC-PvPI has shared Covishield associated Guillain-Barre Syndrome as a Signal recommended by SRP of PvPI with AEFI Secretariat for taking further necessary action.

## PILs changes recommended by the PvPI to CDSCO in this calendar year:

S. No.	Suspected Drugs	Adverse Drug Reactions
1.	Cotrimoxazole	Fixed Drug Eruption
2.	Teneligliptin	Bullous Pemphigoid
3.	Fludrocortisone	Hypokalaemia
4.	Piperacillin+ Tazobactam	Blurred Vision




The NCC-PvPI issued the Drug safety advisories such as Sensitization about SGLT2 inhibitors related genital infections, sensitization for monitoring and reporting of Adverse Events/Reactions related to the use of Botulinum neurotoxin type A (BoNT/A). Apart from above, NCC-PvPI also issued the advisory along with poster regarding prohibited use of the Nimesulide in children below 12 years of age.

The pharmacovigilance inspections and audits at Marketing Authorization Holders (MAHs) site in respect of pharmaceutical products marketed in India further reduce the communication gap in implementation of pharmacovigilance system.

**Drug Safety Alerts issued by PvPI for the sensitization of healthcare professionals and consumers in this calendar year:**

S. No.	Issue Date	Suspected Drugs	Indications	Adverse Reaction
1.	31 <sup>st</sup> January 2023	Amphotericin B (Liposomal)	<ul style="list-style-type: none"> <li>• Febrile Neutropenia in cancer patients.</li> <li>• For invasive fungal infection in patients who are refractory to or intolerant of conventional amphotericin B therapy.</li> </ul>	Hearing disorders
2.			<ul style="list-style-type: none"> <li>• By RMP- for the treatment of invasive fungal infection in patients who are refractory to or intolerant of conventional amphotericin-B therapy.</li> <li>• Indicated for the treatment of visceral leishmaniasis.</li> </ul>	Tachycardia
3.	20 <sup>th</sup> February 2023	Cephalosporins	Cephalosporins are beta-lactam antimicrobials used to manage a wide range of infections from Gram-positive and Gram-negative bacteria.	Purpura
4.		Amikacin	Indicated in the treatment of serious infections due to amikacin sensitive organisms.	Vision blurred
5.	29 <sup>th</sup> March 2023	Metoprolol	For the treatment of essential hypertension in adults, functional heart disorders, migraine prophylaxis, cardiac arrhythmias, prevention of cardiac death and reinfarction after the acute phase of myocardial infarction, stable symptomatic CHF.	Hyponatraemia
6.		Nebivolol	For the treatment of essential hypertension	Hyperkalaemia

7.		Olmesartan	Use as an Anti-hypertensive	Muscle Spasm
				Taste Disorder
8.		Sulfasalazine	Use for the treatment of severe rheumatoid arthritis, ulcerative colitis; Crohn's diseases.	Visual Impairment
9.	24 <sup>th</sup> April 2023	Ziprasidone	<ul style="list-style-type: none"> <li>• Use for the treatment of schizophrenia.</li> <li>• Use for rapid control of agitation in psychotic patients.</li> </ul>	DRESS Syndrome
10.	31 <sup>st</sup> May 2023	Ceftriaxone	For the treatment of urinary tract infections, lower respiratory tract infections, bacteraemia, septicaemia, meningitis, abdominal infections and infections caused by pseudomonas species.	Electrocardiogram QT prolonged
11.		Levosulpiride	<ul style="list-style-type: none"> <li>• Use for the treatment of depression and schizophrenia in adults.</li> <li>• For the treatment of different G.I. problems like functional dyspepsia, nausea, vomiting and diabetic gastroparesis.</li> </ul>	Restless Legs Syndrome
12.	22 <sup>nd</sup> June 2023	Teneligliptin	For the treatment of Type-2 Diabetes Mellitus as a monotherapy adjunct to diet and exercise.	Bullous Pemphigoid
13.	28 <sup>th</sup> July 2023	Colistimethate Sodium	For the treatment of some serious infections caused by Gram-negative bacteria, including those of the lower respiratory tract and urinary tract, when more commonly used systemic antibacterial agents may be contraindicated or may be ineffective because of bacterial resistance.	Barter's like syndrome
14.	22 <sup>nd</sup> August 2023	Levonorgestrel	<ul style="list-style-type: none"> <li>• Used as emergency Contraceptive.</li> <li>• For Control of Fertility.</li> <li>• For the treatment of Contraception, Menorrhagia &amp; Endometrial Hyperplasia during Estrogen replacement therapy in women.</li> </ul>	Deep Vein Thrombosis

15.	27 <sup>th</sup> September 2023	Esomeprazole	<ul style="list-style-type: none"> <li>GERD, erosive reflux esophagitis, prevention of relapse of esophagitis &amp; helps in eradication of H. Pylori associated peptic ulcer.</li> <li>For the treatment of GERD, gastric and duodenal ulcer, Zollinger-Ellison syndrome.</li> </ul>	Hyperprolactinaemia
16.	25 <sup>th</sup> October 2023	Co-trimoxazole	<ul style="list-style-type: none"> <li>Indicated in the treatment of respiratory tract infection, urogenital infections, G.I. tract infections etc.</li> </ul>	Fixed Drug Eruption
17.	30 <sup>th</sup> November 2023	Mefenamic Acid	Treatment of rheumatoid arthritis, osteoarthritis, dysmenorrhoea, mild to moderate pain, inflammation, fever, dental pain.	DRESS Syndrome
 Healthcare professionals, patients/consumers are advised to closely monitor the possibility of the ADR associated with the use of above suspected drug. If, such reaction is encountered, please report to the NCC-PvPI, IPC by filling of Suspected Adverse Drug Reactions Reporting Form (for HCPs)/Medicines Side Effect Reporting Form (for Consumers) ( <a href="http://www.ipc.gov.in">http://www.ipc.gov.in</a> ) and <b>PvPI Helpline No. 1800-180-3024 (Toll-Free)</b>				



## Enrolment of New AMCs

NCC-PvPI, IPC has enrolled 35 new AMCs in 21<sup>st</sup> Phase of PvPI expansion. The total number of AMCs enrolled under PvPI by the end of this quarter were 877 across the country. The list of newly enrolled AMCs is mentioned below:

S. No.	States/UTs	Name of Hospitals/Medical Colleges	Status
1.	Andhra Pradesh	Andhra Hospitals (Bhavani Pharma) Pvt. Ltd. 16-72/1, Opp. High School, Gollapudi, Vijayawada, NTR. Andhra Pradesh-521225	Non-Government
2.		Aayush NRI LEPL Healthcare Pvt. Ltd. #48-13-3 & 3A, Opp. Siddhartha Medical College, Sri Ramachandra Nagar, Ring Road, Vijayawada, Andhra Pradesh-520008	
3.	Chhattisgarh	Bharat Ratna Late Shri Atal Bihari Vajpayee Memorial Govt. Medical College Pendri, Rajnandgaon, Chhattisgarh- 491441	Government
4.	Gujarat	Bodyline Hospitals Pvt. Ltd. Opp. Annapurna Hall, New Vikash Gruh Road, Paldi, Ahmedabad- 380007	Non-Government
5.		Tricolour Hospital CA DIV of SRKMPL Vadodara, Gujarat- 390007	
6.		GMERS Medical College Near Government Polytechnic College, Hadiol Road, Himatnagar, Sabarkantha, Gujarat - 383001	Government
7.	Haryana	SMSG Multispeciality Hospital Rohtak Gate, Near Devi Lal Sadan, Bhiwani, Haryana- 127021	Non-Government
8.		Param Hospital Loharu (Bhiwani), Haryana- 127201	
9.		Asha Kiran The Criti Care Hospital (Run and managed by Rb Kilkari Healthcare Pvt. Ltd.) Daud Chawk, Kanwar Singh Colony, Jhajjar, Haryana- 124103	
10.		Malik Hospital 145 A Uttam Nagar, Hansi, Haryana- 125033	
11.		Lifeline Institute of Medical Sciences Jindal Chowk, Hisar, Haryana - 125001	

**IMPORTANT ACTIVITIES**

12.	Jammu & Kashmir	Raksha Kidney Centre Near Circuit House, Talab Tillo, Jammu- 180002	Non-Government
13.	Kerala	Malik Deenar College of Pharmacy Seethangoli Bela PO, Kasaragod, Kerala- 671321	Non-Government
14.	Madhya Pradesh	Bhopal Memorial Hospital & Research Centre Raisen Bypass road, Bhopal, Madhya Pradesh - 462038	Government
15.	Maharashtra	Shri Bhavani Hospital & Research Institute Sr. No. 58, Shri Bhavani Mata Mandir Road, Pardi, Nagpur, Maharashtra - 440035	Non-Government
16.		Kids Clinic India Ltd. (Cloudnine Hospital) S. No. 103, CTS No. 3175, Shri Shivaji Cooperative Housing Society Ltd., S. B. Road, Pune, Maharashtra - 411016	
17.		Umarji Mother & Child Care Hospital S. No. 13/1, Next to comfort zone, Balewadi, Pune, Maharashtra - 411045	
18.		Chhatrapati Sambhaji Maharaj Government Medical College and Hospital 467, Sadar Bazar, Camp, Satara, Maharashtra - 415001	Government
19.	New Delhi/Delhi	Jeewan Mala Hospital Pvt. Ltd. 67/1, New Rohtak Road, New Delhi - 110005	Non-Government
20.		U.K Nursing Home M-1, Vikaspuri, West Delhi- 110018	
21.	Punjab	Uppal Neuro Hospital 4 Rani ka Bagh, Near State bank of India, Amritsar, Punjab- 143001	Non-Government
22.		Dr. Surjit Singh Super Speciality Hospital Near New Bypass, Bela Road, Rupnagar, Punjab- 140001	
23.		NHS Hospital (A Unit of Nasa Brain and Spine Centre) 128 Guru Nanak Nagar, Opposite Sports College, Kapurthala Road, Jalandhar, Punjab- 144008	

24.	Rajasthan	Neuro Care Hospital & Research Centre (P) Ltd. Sector 1/611, Vidhyadhar Nagar, Jaipur, Rajasthan- 302023	Non-Government
25.		Shriram Super Speciality Surgical Centre (P) Ltd. Plot No.3, Khasra No.359, Near Vidhya Public School, Banar Rd, Jodhpur, Rajasthan-342001	
26.		Asopa Hospital 93B Tagore Nagar, Ajmer Road, Jaipur, Rajasthan - 302021	
27.		Goyal Hospital Joint Replacement Centre A-1, Pani ki Tanki Circle, Shastri Nagar, Jaipur, Rajasthan- 302021	
28.		Alwar Pharmacy College North Extension, M.I.A, Alwar, Rajasthan-301030	
29.	Tamil Nadu	Srikamatchi Medical Centre 37, Trichy Main Rd, Thanjavur, Tamil Nadu-613005	Non-Government
30.		Tagore Medical College and Hospital Rathinamangalam, Melakottaiyur-Post, Chengal Pattu, Tamil Nadu- 600127	
31.	Telangana	Princess Durru Shehvar Children's & General Hospital 22-3-660/A, Purani Haveli, Hyderabad, Telangana- 500002	Non-Government
32.		Government Medical College Survey No.-166, Dharur Camp, Jagtial, Telangana-505327	Government
33.	Uttar Pradesh	Sri Sai Hospital Mansarovar Colony, Delhi Road, Moradabad, Uttar Pradesh - 244001	Non-Government
34.		Dr. Sone Lal Patel Autonomous State Medical College Pure Keshav Rai, Pratapgarh, Uttar Pradesh - 230001	Government
35.	West Bengal	Medica Superspecialty Hospital 127, Mukundapur, EM Bypass, Kolkata, West Bengal - 700099	Non-Government



## 15<sup>th</sup> Meeting of Expert Committee organised by the CDSCO

15<sup>th</sup> Meeting of Expert Committee for the assessment of Periodic Safety Update Reports (PSURs) for Rota Virus Vaccine and Rabies Vaccine was organised by the CDSCO on 2<sup>nd</sup> November 2023.

The Serum Institute of India, Pune; Bharat Biotech, MSD, GSK and Zydus have presented PSURs for Rota Virus Vaccine and Rabies Vaccine marketed in the country. Dr. Shashi Bhushan, Sr. Scientific Officer, IPC and Dr. Vijit Agrawal, Sr. PV Associate, PvPI-IPC have attended this meeting virtually.

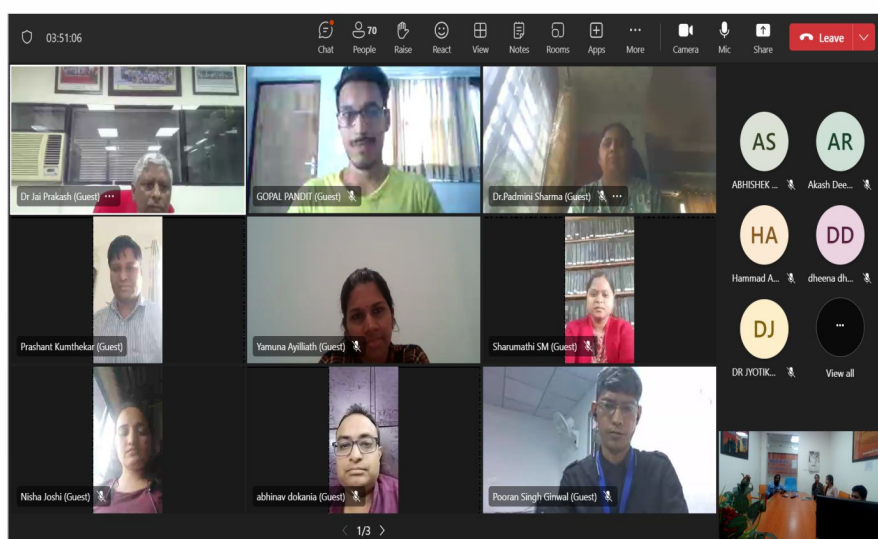
## #MedSafetyWeek

NCC-PvPI participated in the celebration of MedSafetyWeek organised by the Uppsala Monitoring Centre (UMC), Sweden from 6<sup>th</sup> to 12<sup>th</sup> November 2023. The theme of this year's campaign was 'Who can report?': how patients, doctors, pharmacists and other health professionals can contribute to pharmacovigilance? The main objective of this campaign was to raise the awareness of Adverse Drug Reactions and national reporting systems among the public.

NCC-PvPI communicated the campaign's materials like e-mail banner, animations, social-media cards, posters to AMCs across the country and also shared through the social media platforms-Twitter, Facebook and LinkedIn for public awareness.

## Induction-cum-Training Programme

NCC-PvPI, IPC conducted 3 days virtual Induction-cum-Training Programme from 17<sup>th</sup> to 19<sup>th</sup> October 2023 for the Coordinators, Deputy Coordinators of newly recognised Adverse Drug Reaction Monitoring Centres (AMCs) and newly recruited Pharmacovigilance Associates at AMCs. The objective of this training programme was to train the participants on Pharmacovigilance activities performed at their AMCs. A total of 164 participants attended this training programme.



## Journey of Pharmacovigilance in India

Year	Key Event
1980	First adverse drug reaction (ADR) reported to the Drug Information Centre, New Delhi.
1982	First ADR reported to the Drug Information Centre, New Delhi.
1983	First ADR reported to the Drug Information Centre, New Delhi.
1986	First ADR reported to the Drug Information Centre, New Delhi.
1989	First ADR reported to the Drug Information Centre, New Delhi.
1995	First ADR reported to the Drug Information Centre, New Delhi.
1997	First ADR reported to the Drug Information Centre, New Delhi.
1998	First ADR reported to the Drug Information Centre, New Delhi.
2004	First ADR reported to the Drug Information Centre, New Delhi.
2008	First ADR reported to the Drug Information Centre, New Delhi.
2010	First ADR reported to the Drug Information Centre, New Delhi.
2011	First ADR reported to the Drug Information Centre, New Delhi.
2012	First ADR reported to the Drug Information Centre, New Delhi.
2013	First ADR reported to the Drug Information Centre, New Delhi.
2015	First ADR reported to the Drug Information Centre, New Delhi.
2017	First ADR reported to the Drug Information Centre, New Delhi.
2017	First ADR reported to the Drug Information Centre, New Delhi.
2021	First ADR reported to the Drug Information Centre, New Delhi.

## 27<sup>th</sup> Skill Development Programme on Pharmacovigilance

The NCC-PvPI, IPC has organised a webinar on “Introduction to MedDRA Coding” on 29<sup>th</sup> November, 2023 for the Pharmacovigilance Associates posted at National Coordination Centre and AMCs across the country. Dr. Anamika Dutta, Medical Officer, Maintenance & Support Services Organization (MSSO), explained the various terminologies used for the coding of Adverse Events by using MedDRA dictionary. A total of 124 participants attended the webinar.



## 7<sup>th</sup> Advanced Level Training-cum-Coordinators Meeting

The 7<sup>th</sup> Advanced Level Training-cum-Coordinators Meeting was organised by Prof. Ratinder Jhaj, Coordinator, Prof. S. Balakrishnan, Deputy Coordinator and Ms. Deepa Choudhary, Pharmacovigilance Associate at AIIMS, Bhopal-Regional Training Centre under PvPI on 1<sup>st</sup> December 2023 for Madhya Pradesh and Chhattisgarh region.



The objective of this training programme was to sensitize the coordinators, deputy coordinators and pharmacovigilance associates about recent updates in PvPI, Causality Assessment, Problems faced by an AMC for pharmacovigilance activities, approaches to improve the ADRs reporting and Approaches to incorporate Pharmacovigilance activity in medical curriculum were covered during this event. A total of 38 participants participated in this training programme.

## Sensitization and Basic training programme on Pharmacovigilance organised by GMERS Medical College, Ahmedabad

The Sensitization and Basic training programme on Pharmacovigilance was organised by Dr. Mukeshkumar B. Vora, Coordinator and Dr. Payal M. Patel, Pharmacovigilance Associate at Gujarat Medical Education and Research Society, Sola, Ahmedabad from 7<sup>th</sup> to 8<sup>th</sup> December 2023. A total of 69 participants participated in this training programme.





## CME organised by Sri Padmavathi Medical College, Tirupati



Continuing Medical Education on “Pharmacovigilance and Medication Safety” was organised by Prof. Umamaheswara Rao, Coordinator, Sri Padmavathi Medical College for Women, Department of Pharmacology, Tirupati on 8<sup>th</sup> December 2023 with objective to improve the ADR reporting and bringing awareness to healthcare professionals. A



total of 210 participants including Pharmacists, Pharm D students and other healthcare professionals participated in this training programme.

## CME organised by Madras Medical College, Chennai

Continuing Medical Education on “Pharmacovigilance- Clinical Perspectives” was organised by Dr. K.M. Sudha, Coordinator, Institute of Pharmacology, Madras Medical College, Chennai on 30<sup>th</sup> November 2023 to sensitize the doctors to improve ADR reporting culture for patient safety among healthcare professional. In this event, Dr. R.S. Ray, Scientific Assistant, IPC delivered a lecture on “Need of Pharmacovigilance and PvPI- Current updates”. A total of 303 participants including Pharmacy students, Pharmacovigilance Associates and other healthcare professionals participated in this training programme.



## Advanced Level Training Programme organised by Institute of Postgraduate Medical Education & Research (IPGMER), Kolkata

Advanced Level Training Programme on the “Impact of Adverse Drug Reactions in Clinical Practice and how to avert them?” was organised by Prof. Suparna Chatterjee, Coordinator, IPGMER, Kolkata, RTC on 8<sup>th</sup> December 2023. A total of 211 participants participated in this training programme.



## Advanced Level Training Programme organised by Amrita Institute of Medical Sciences & Research Centre, Kochi

Advanced Level Training Programme on “Targeted pharmacovigilance” was organised by Dr. Princy Louis Palatty, Coordinator, AIMS Kochi, RTC on 11<sup>th</sup> December 2023 for Coordinators, Deputy Coordinators and healthcare professionals.



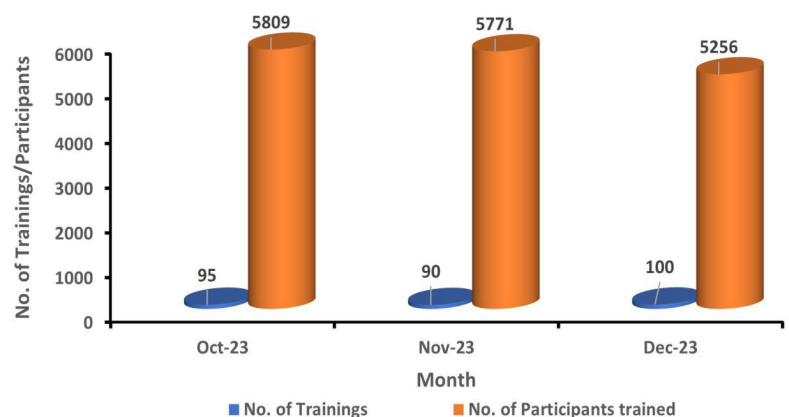
## Virtual Interactive Meetings with Marketing Authorization Holders (MAHs)

The objective of the following interactive meetings was to address the basic concepts of Pharmacovigilance and how the Pharmacovigilance system can be effectively implemented at MAHs/Pharmaceutical Industries and also focussed on the issues/challenges related to the quality submissions of Individual Case Safety Reports (ICSRs) in E2B, xml format to PvPI.

Date	MAH/Pharmaceutical Industry	No. of Participants
7 <sup>th</sup> November 2023	Biocon Biologics Limited	10
17 <sup>th</sup> November 2023	Mankind Pharma	10

## Monthly trends of training programmes conducted during index period

A total of 285 training programmes including Skill Development Programmes, Continuing Medical Education, Advanced Level Training Programmes etc. were organised by PvPI during this quarter and trained a total number of 16836 participants in the area of Pharmacovigilance across the country.






# 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.	Relugolix Bulk Drug and Relugolix Tablet 120 mg	For the treatment of adult patients with advance prostate cancer.
2.	Asciminib film-coated 20 mg and 40 mg tablets	For the treatment of adult patients with: - Philadelphia chromosome-positive chronic myeloid leukaemia (Ph+CML) in chronic phase (CP), previously treated with two or more tyrosine kinase inhibitors (TKIs) -Ph+CML in CP with the T315I mutation.
3.	Lasmiditan Hemisuccinate Bulk Drug & Lasmiditan Tablet 50 mg/100 mg	For the acute treatment of migraine with or without aura in adult.
4.	Abrocitinib Tablets 50 mg, 100 mg & 200 mg	For the treatment of adults with refractory, moderate-to-severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable.

 Healthcare professionals, patients/consumers are advised to closely monitor the possibility of the ADR 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>) and PvPI Helpline No. **1800-180-3024 (Toll-Free)**



# Press & Media



## Comments Invited on the Draft Version 2.0 of Pharmacovigilance Guidance Document for Marketing Authorization of Pharmaceutical Products

The National Coordination Centre for Pharmacovigilance Programme of India has revised the “Pharmacovigilance Guidance Document for Marketing Authorization Holders of Pharmaceutical Products, Version 1.0” with the help of an expert committee. The Draft document has been displayed on the website of the Indian Pharmacopoeia Commission, refer link as

[https://www.ipc.gov.in/images/PV\\_Guidance\\_Docs\\_for\\_MAH\\_Version\\_2.pdf](https://www.ipc.gov.in/images/PV_Guidance_Docs_for_MAH_Version_2.pdf) on 24th January 2024 for the comments of stakeholders by 22nd February 2024. The comments obtained after the due date will not be accepted. The comments should reach on the following email id [pvpi.ipc@gov.in](mailto:pvpi.ipc@gov.in)



## *Forthcoming Events*

S. No.	Date	Title	Who can participate?
1.	17 <sup>th</sup> -19 <sup>th</sup> January 2024	Induction-cum-training programme	PvPI Staff
2.	22 <sup>nd</sup> February 2024	Preventable ADRs and Medication errors	PvPI Staff
3.	4 <sup>th</sup> - 8 <sup>th</sup> March 2024	28 <sup>th</sup> Skill Development Programme	Healthcare Professionals, Pharmacovigilance Professionals, Medical/ Para-medical/Pharmacy Students, Pharmacist and Academicians



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

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

## औषधि सतर्कता कार्यक्रम

(फार्माकोविजिलेंस प्रोग्राम ऑफ़ इंडिया) क्या है?

फार्माकोविजिलेंस प्रोग्राम ऑफ़ इंडिया, स्वास्थ्य एवं परिवार कल्याण मंत्रालय के अंतर्गत कार्य करता है जिसका नोडल कार्यालय, भारतीय भेषज संहिता आयोग में स्थित है। मैटीरियोविजिलेंस प्रोग्राम ऑफ़ इंडिया जिसका नोडल कार्यालय भी भारतीय भेषज संहिता आयोग में स्थित है तथा हीमोविजिलेंस 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 फार्माकोविजिलेंस 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](http://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](mailto:pvpi.ipc@gov.in)
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 फार्माकोविजिलेंस 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](http://www.ipc.gov.in) पर उपलब्ध है।



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*Let us join hands with PvPI to ensure patient safety*