



# Newsletter

PHARMACOVIGILANCE PROGRAMME OF INDIA (PvPI)

VOL 13 | ISSUE 2 | 2023

**“India achieved 8<sup>th</sup> Position  
among WHO PIDM Member Countries”**



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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



# CONTENTS

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	Page No.		Page No.
<b>COVER STORY</b>			
PvPI achieved 8 <sup>th</sup> position at global level	05	☞ #Medsafety Week Welcome Event	16
<b>IMPORTANT ACTIVITIES</b>		☞ National AEFI Committee Meeting	16
Enrollment of New AMCs	07	☞ Vaccicon 2023 organized by Jawahar Lal Nehru Medical College, Aligarh	17
Training & Education	13	☞ Monthly trends of training programmes conducted during index period	17
☞ Training Programme on "NRA – WHO Global Benchmarking Tool for Vaccines"	13	<b>New Drugs</b>	18
☞ Training on "Basic Concept of ADRs"	13	☞ New drugs approved in India	18
☞ Induction-cum-Training Programme on Pharmacovigilance	14	<b>Regulatory Matters</b>	20
☞ 20 <sup>th</sup> Annual Conference of Society of Pharmacovigilance (INDIA): SOPICON 2023	14	☞ Drug Safety Alerts	20
☞ 25 <sup>th</sup> Skill Development Programme	15	<b>PvPI in Press &amp; Media</b>	21
☞ Review meeting for suspected ethambutol related ocular disorders	15	<b>Forthcoming Events</b>	22
☞ Guest Lecture on Statistical Analysis and Confidence Interval	16		

MESSAGE

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



I am privileged to release the Pharmacovigilance Programme of India (PvPI) Newsletter Volume 13, Issue 2 for the index period from April, 2023 to June, 2023. During the index period, India has achieved 8<sup>th</sup> Position among World Health Organization (WHO) Programme for International Drug Monitoring (PIDM) member countries in terms of Individual Case Safety Reports (ICSRs) submitted across the world.

In this quarter, 68 New Adverse Drug Reaction Monitoring Centres (AMCs) have been enrolled under PvPI and total number of AMCs are 760 across country.

A total of 7.17 Lakh Individual Case Safety Reports have been reported to PvPI in this quarter. 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 6293 training programmes and trained a total of 335603 participants in the area of pharmacovigilance.

The NCC-PvPI, IPC has so far issued a total of 154 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.

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 to the SEARN Countries on safety and regulatory actions of medical products taken by the CDSCO based on PvPI recommendations .

As a team, we will continue to work for improving patient safety and I congratulate the PvPI team, AMCs and subject experts and stakeholders 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

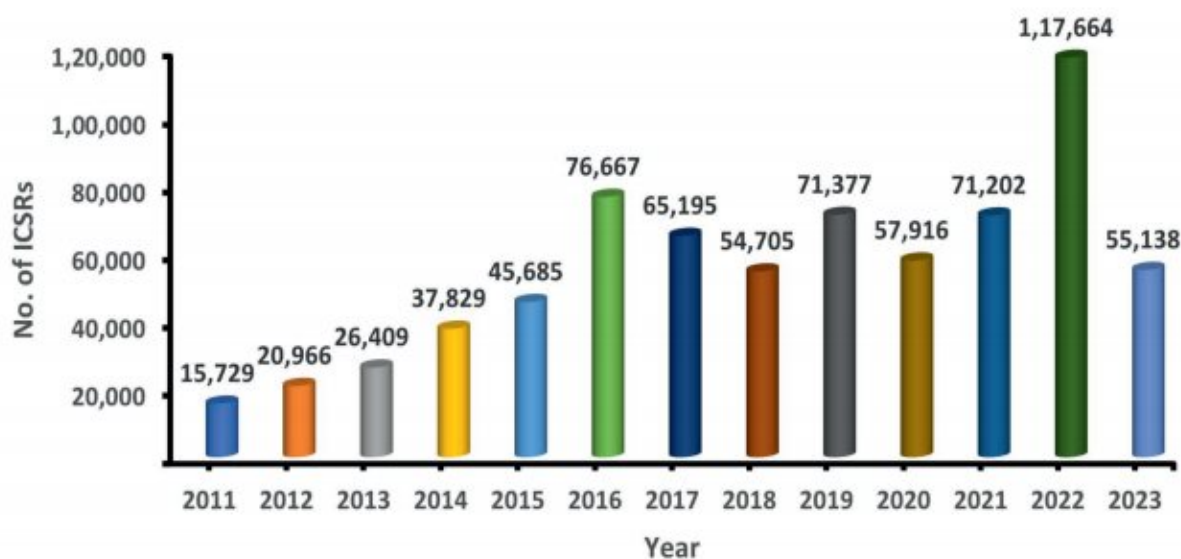


## PvPI achieved 8<sup>th</sup> position at global level

India is one of the National Centres for Pharmacovigilance in World Health Organization (WHO) Programme of International Drug Monitoring (PIDM). It was enrolled as a full member in the year 1998. Since then, India has been contributing for the cause of patient safety by submitting Individual Case Safety Reports (ICSRs) to WHO PIDM. The WHO PIDM is an international collaboration with the goal of ensuring timely identification of suspected safety problems in medicinal products and is having 155 Full Members & 21 Associate Members, the Programme covers about 99% of the world's population.

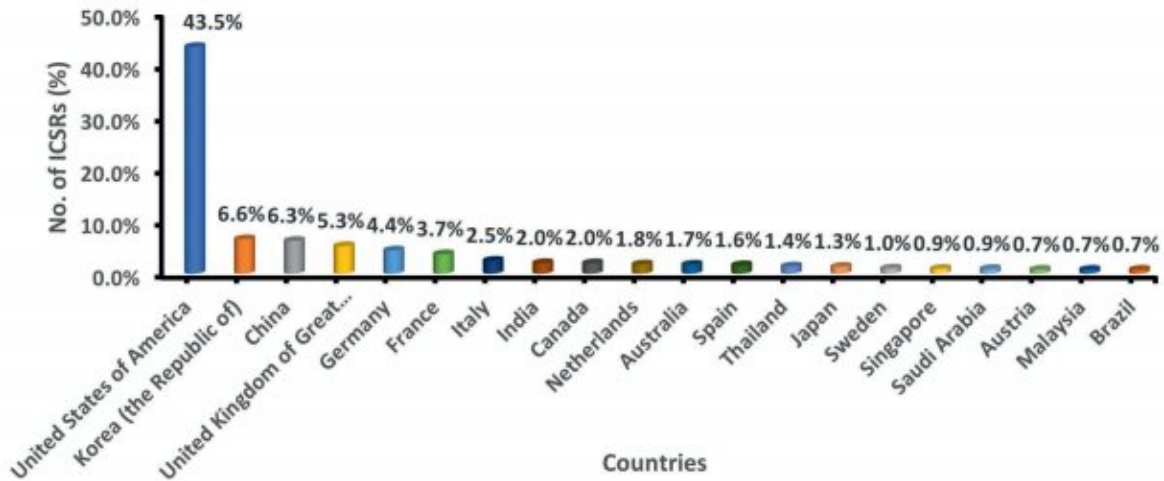
Despite under reporting, there has been tremendous progress in building the culture of patient safety in India since recasting of PvPI by the Ministry of Health & Family Welfare, Government of India as evident from the reported ICSRs to PvPI. This has been possible due to the untiring efforts of AMCs under the PvPI, healthcare professionals, pharma industry, NCC-PvPI Team and other stakeholders.

The NCC-PvPI, IPC has received a total of 717059 ICSRs from its different stakeholders across the country from the Year 2011 to 30<sup>th</sup> June 2023 and submitted to VigiBase as given below;

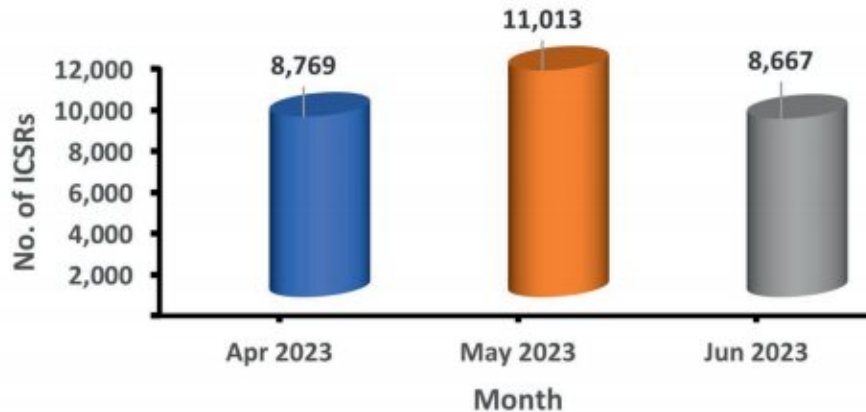


## COVER STORY

During this tenure, India has achieved 8th position among the 176 WHO PIDM Member countries in terms of ICSRs submitted in VigiBase across the world. India has 2.0% contribution for ICSRs submission in VigiBase as given below;



In this index period, NCC-PvPI has submitted a total of 28449 ICSRs in VigiBase, the month wise distribution of ICSRs submitted is given below;



## Enrolment of New AMCs

NCC-PvPI, IPC has enrolled 68 new AMCs in 19<sup>th</sup> Phase of PvPI expansion. The total number of AMCs enrolled by the end of this quarter were 760 across the country. The list of newly enrolled AMCs is mentioned below:

S. No.	States/UTs	Name of Hospitals/Medical Colleges/Institutes	Status
1.	Andhra Pradesh	Government Medical College Vizianagaram Dist., Andhra Pradesh-535003	Government
2.		GSL Medical College and General Hospital NH-16, Lakshmipuram, Rajahmundry, Dist.-East Godavari, Andhra Pradesh -533296	Non-Government
3.		RK Hospital (A Unit of Gajuwaka Hospitals Pvt. Ltd.) Chaitanya Nagar, 26-16-7, Gajuwaka, Visakhapatnam, Andhra Pradesh-530026	
4.		Krishna Institute of Medical Sciences Ltd. DN. No. 77-7-7, Seelam Nookarahu Complex Street, Katari Gardens, Rajamahendravaram, East Godavari, Andhra Pradesh-533103	
5.		Capital Hospitals (A Unit of Capital Tree Health Care Pvt. Ltd.) Vijayawada, Krishna, Andhra Pradesh-521137	
6.	Assam	All India Institute of Medical Sciences Guwahati, Dist.-Kamrup, Assam -781101	Government
7.		Lokopriya Gopinath Bordoloi Regional Institute of Mental Health Tezpur, Dist.-Sonitpur, Assam-784001	
8.		Nagaon Medical College and Hospital Diphalu, Mohkhuli Chariali, Nagaon, Assam-782003	
9.		NETES Institute of Pharmaceutical Sciences (NIPS), NEMCARE Group of Institutions, Santipur, Mirza, Kamrup, Assam-781125	Non-Government

**IMPORTANT ACTIVITIES**

10.	Bihar	Asian City Hospital Behind P&M Mall, Patliputra Industrial Area, Patna, Bihar-800013	Non-Government
11.	Delhi	Indian Spinal Injuries Centre C-Block, Vasant Kunj, New Delhi -110070	Non-Government
12.		Institute of Human Behaviour & Allied Sciences Dilshad Garden, Delhi -110095	Government
13.	Gujarat	Shantabaa Medical College & General Hospital Civil Hospital Campus, Near ST Stand, Lathi Road, Amreli, Gujarat -365601	Non-Government
14.		Shri B. D. Mehta Mahavir Heart Institute Athwagate, Surat, Gujarat – 395001	
15.	Haryana	Park Hospital Basanti Marg, H Block, Chauma Village, Sector- 1, Palam Vihar, Gurugram, Haryana-122017	Non-Government
16.		Frank Institute of Medical Science (FIMS) Bahal Garh, Sonipat Road, Sonipat, Haryana-131001	
17.		The Signature Hospital Sector-37 D, Gurugram, Haryana-122001	
18.		Park Hospital, Q-Block, South City -II, Sector-47, Gurgaon, Haryana-122018	
19.	Jharkhand	Manipal Tata Medical College Kadani Road, Baridih, Jamshedpur, Dist.-East Singhbhum, Jharkhand-831017	Non-Government
20.		Phulo Jhano Medical College Dumka, Dighi, Jharkhand-814101	Government
21.		Medinirai Medical College Pokhraha, PO- Rajwadih, PS- Mediminagar, Palamu, Jharkhand-822118	Government



22.	Karnataka	Raichur Institute of Medical Science (RIMS) Hyderabad Road, Raichur, Karnataka-584101	Government
23.		Arihant Hospital, Unit of Dixit Healthcare Pvt. Ltd. C-Square, CTS No 10632/A1/B, Nehru Nagar, Dist.-Belagavi, Karnataka-590010.	Non-Government
24.		Kanachur Institute of Medical Sciences University Road, Natekal, Mangaluru, Karnataka-575018	
25.		Siddaganga Medical College and Research Institute, Dr. Sree Shivakumara Swamiji Road, Tumkur, Karnataka-572102	
26.	Kerala	Government Medical College Idukki, Idukki Colony P.O. Cheruthony, Kerala- 685602	Government
27.		Dr Somervell Memorial CSI Medical College, Karakonam, Tiruvananthapuram, Kerala- 695504	Non-Government
28.	Madhya Pradesh	LNCT Medical College & Sewakunj Hospital Kanudia, Indore (M.P) – 452016	Non-Government
29.		Chirayu Medical College & Hospital Bhopal-Indore Highway, Bhainsakhedi, Bairagarh, Bhopal, Madhya Pradesh-462030	
30.	Maharashtra	Shri Vasantrao Naik Government Medical College & Hospital Yavatmal, Maharashtra-445001	Government
31.		Government Medical College and Hospital University Road, Jubilee Park, Aurangabad, Maharashtra-431004	
32.		Rajiv Gandhi Medical College and Chhatrapati Shivaji Maharaj Hospital Kalwa, Thane, Maharashtra-400605	

## IMPORTANT ACTIVITIES

33.		Bharati Vidyapeeth (Deemed to be University) Medical College Sangli-Miraj Road, Dist.- Sangli, Maharashtra- 416416	Non-Government
34.		Bharati Vidyapeeth (DTU) Medical College Dhankawadi, Pune-Satara Road Dist.-Pune, Maharashtra-411043	
35.		HCG Manavata Cancer Centre Plot No. 64 & 68, Nashik Shivarn, New Mumbai, Agra Highway Mumbai Naka, Nashik, Maharashtra-422202.	
36.		JIIU's Indian Institute of Medical Science and Research, Aurangabad - Jalna Road, Warudi, Badnapur, Maharashtra – 431202	
37.		Sanjeevani Multispeciality Hospital Plot No. 17, Rishi Park, Ambad Chofully, Jalna, Maharashtra-431203.	
38.		Swasthya Hospital Medical Research Centre, Anna Bhau Sathe Chowk, Ahmednagar, Maharashtra-414001	
39.		Krishna Institute of Medical Sciences Karad, Dist.-Satara, Maharashtra-415539	
40.		Senior Mehta & Sir K. P. Cardiac Institute Plot No.96, Road No.31, Near Gandhi Market, King Circle, Sion (E), Mumbai, Maharashtra-400072	
41.		Dr Panjabrao Alias Bhausaheb Deshmukh Memorial Medical College Amravati, Shivaji Nagar, Amravati, Maharashtra -444603	
42.	Odisha	Government Medical College and Hospital Sundargarh, Odisha-770020	Government
43.		Fakir Mohan Medical College & Hospital, Balasore, Odisha-756019	

44.	Punjab	Dr Manu Raj Memorial PMC Hospital Bridge No.4, Near Shani Mandir, Sujanpur, Punjab-145023	Non-Government
45.		Nayyar Heart Institute and Super Speciality Hospital Amritsar, Punjab-143001	
46.	Rajasthan	Pacific Medical College & Hospital Bhilon ka Bedla, Pratap Pura, Udaipur, Rajasthan -313001	Non-Government
47.		American International Institute of Medical Sciences GBH General and GBH Memorial Cancer Hospital, Transport Nagar, Bedwas Dist.- Udaipur, Rajasthan-313024	
48.	Sikkim	Sikkim Manipal Institute of Medical Sciences (SMIMS) /Central Referral Hospital (CRH) 5 <sup>th</sup> Mile, Tadong, Gangtok, East Sikkim-737102	Non-Government
49.	Tamil Nadu	Sri Muthukumaran Medical College Hospital & Research Institute Chikkarayapuram, Dist.- Kancheepuram, Tamil Nadu-600069.	Government
50.		Government Medical College Thiruvallur, Block 1, Master Plan Complex, Thiruvallur Collectorate, Perumbakkam Village, Tamil Nadu-602001	
51.		Government Medical College Hospital SF No.338/1, Polupalli Village, Krishnagiri Taluk- Tamil Nadu – 635115	
52.		KMCH Institute of Health Science and Research 99A, Avinashi Road, Indira Nagar, Phase II, Balaji Nagar, Coimbatore, Tamil Nadu-641014	Non-Government
53.		Hannah Joseph Hospital R S No. 115/382 & 116/1A2, Near Chinthamani Toll Gate, Madurai, Tamil Nadu-625009.	
54.		Sri Narayani Hospital and Research Centre Sripuram, Thirumalaikodi, Vellore, Tamil Nadu-632055.	

## IMPORTANT ACTIVITIES

55.	Telangana	Government Medical College, Mancherial, 708, Garmilla Village, Mancherial, Telangana-504208.	Government
56.		Government Medical College Mahabubabad, Telangana-506101	
57.		Dr Patnam Mahender Reddy Institute of Medical Sciences Chevella (Vill. & Mandal), Dist.-Rangareddy, Telangana-501503	Non-Government
58.		Ramdevrao Hospital Metro Pillar No: A777, NH-65, Kukatpally, Hyderabad, Dist.-Medchal, Telangana-500072	
59.		Sai Sanjeevini Hospitals Dist.- Rangareddy, Telangana-500035	
60.		SVS Medical College, Yenugonda, Mahabubnagar, Telangana-509001	
61.		Prathima Institute of Medical Sciences Nagumur, Karimnagar, Telangana-505415	
62.		Mahavir Institute of Medical Sciences Vikarabad, Telangana-501102.	
63.	Uttar Pradesh	Autonomous State Medical College, Shahjahnapur, Uttar Pradesh-242223	Government
64.		Ram Ratan Hospital Plot No. SH-06, Site-IV, Surajpur Industrial Area, Greater Noida, Uttar Pradesh-201306	
65.		Career Institute of Medical Sciences & Hospital, IIM Road, Ghalia, Lucknow, Uttar Pradesh-226013	Non-Government
66.		Kailash Hospital & Heart Institute H-33, Sec-27, Noida, Gautan Buddha Nagar, Uttar Pradesh – 201301.	
67.	Jammu & Kashmir	All India Institute of Medical Sciences Vijaypur, Campus Office of AIIMS-GMC Doctor's Guest House, Maheshpura, Chowk, Jammu and Kashmir-180001.	Government
68.	Ladakh	SNM Hospital Leh Ladakh, (UT. Ladakh) -194101.	Government



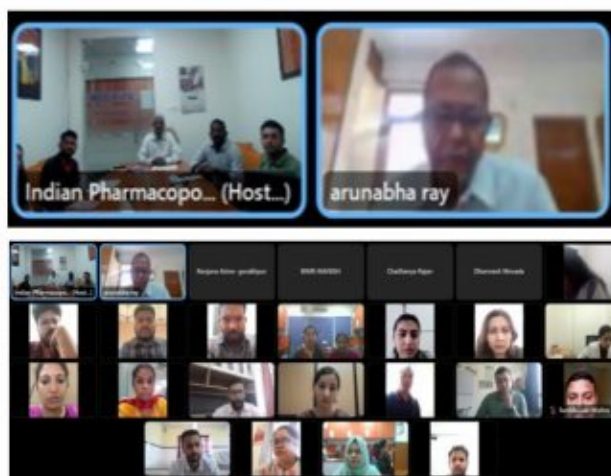
## Training Programme on “NRA – WHO Global Benchmarking Tool for Vaccines”

The Central Drugs Standard Control Organization (CDSCO) organised one week residential Training Programme on “National Regulatory Authority (NRA) – World Health Organization (WHO) Global Benchmarking Tool (GBT) for Vaccines” at Telangana State Institute of Rural Development (TSIRD), Hyderabad from 10<sup>th</sup> to 14<sup>th</sup> April 2023. Dr. Jai Prakash, Officer in-Charge of PvPI and Dr. Vijit Agrawal, Sr. Pharmacovigilance Associate attended this training programme. The objective of this training programme was to train the participants on WHO GBT 2021 for evaluation of national regulatory systems of medical products in India. This training programme was basically for the preparedness for WHO NRA assessment in respect of vaccines.



## Training on “Basic Concept of ADRs”

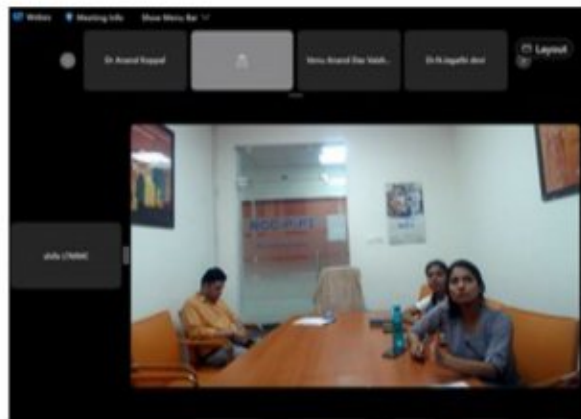
The NCC-PvPI, IPC has conducted virtual training on “Basic Concept of ADRs” to train the Pharmacovigilance Associates at NCC, Ghaziabad and AMCs across the country on 28<sup>th</sup> April 2023. In this training, Prof. Arunabha Ray, Head of the Department of Pharmacology, Hamdard Institute of Medical Sciences & Research, New Delhi explained medical terminologies, classification and importance of reporting culture of ADRs. A total of 98 participants participated in this training programme.



## TRAINING & EDUCATION

### Induction-cum-Training Programme on Pharmacovigilance

NCC-PvPI, IPC conducted virtual Induction-cum-Training Programme on Pharmacovigilance for Coordinators/Deputy Coordinators/Head of the Departments of newly recognised Adverse Drug Reaction Monitoring Centres (AMCs) and newly recruited Pharmacovigilance Associates at AMCs from 2<sup>nd</sup> to 4<sup>th</sup> May 2023. The objective of this training was to train the participants on Pharmacovigilance activities being performed at their AMCs. A total of 200 participants attended this training programme.



### 20<sup>th</sup> Annual Conference of Society of Pharmacovigilance (INDIA): SOPICON 2023

Dr Puneet Dhamija, Organizing Secretary, SOPICON 2023, Additional Professor, Dept, of Pharmacology, All India Institute of Medical Sciences, Rishikesh, organized a Pre-conference workshop and 20th Annual Conference of Society of Pharmacovigilance (INDIA): SOPICON 2023 to elaborate more knowledge on "medication safety in an era of evidence-based medicine" from 10<sup>th</sup> to 12<sup>th</sup> May 2023 through hybrid mode. Dr Ishita Mathur, Jr Pharmacovigilance Associate, AIIMS, Rishikesh had also briefed on "Introduction to MedDRA Coding" and "Data entry in VigiFlow" during the Pre-conference workshop.

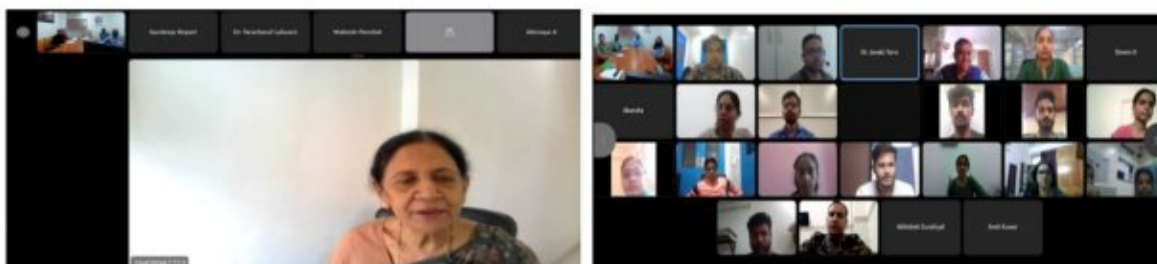
Dr Jai Prakash, Officer in-Charge of PvPI and Mr. Vipin Sharma, Sr. Pharmacovigilance Associate participated in Pre-conference workshop & 20<sup>th</sup> SOPICON 2023. Dr Jai Prakash chaired a session on "Medication errors and Drug Safety" on 11<sup>th</sup> May 2023 & Mr Vipin Sharma delivered a lecture on Signal review process at PvPI in Pre-conference workshop on 10<sup>th</sup> May 2023.





## 25<sup>th</sup> Skill Development Programme

The NCC-PvPI, IPC has virtually conducted 25<sup>th</sup> Skill Development Programme on Pharmacovigilance from 15<sup>th</sup> to 19<sup>th</sup> May 2023. The objective of the Skill Development Programme (SDP) was to develop and enhance the Pharmacovigilance skills in the healthcare professionals in order to promote the patient safety. A total of 157 participants attended the SDP including Industry Professionals, Physicians, Academicians, Pharmacy Students, Medical Students, and Pharmacists across the country.



## Review meeting for suspected ethambutol related ocular disorders

NCC-PvPI, IPC organized a virtual meeting to discuss the reported ocular disorders with the use of ethambutol on 23<sup>rd</sup> May 2023. The invited representatives were from the Central Tuberculosis Division, New Delhi, National Institute for Research in Tuberculosis, Chennai, National Institute of Tuberculosis and Respiratory Diseases, New Delhi and Central Drug Standards Control Organization. In this meeting, work plan was decided to review the reported adverse events data in PvPI for ethambutol associated ocular disorders.



## TRAINING & EDUCATION

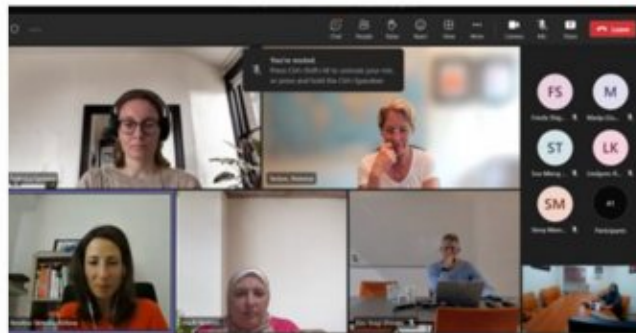
### Guest Lecture on Statistical Analysis and Confidence Interval

The NCC-PvPI, IPC organized a guest lecture on "Statistical Analysis and Confidence Interval" through hybrid mode for the PvPI staff at National Coordination Centre, Ghaziabad and AMCs across the country on 2<sup>nd</sup> June 2023 from 10.00 AM to 12.30 PM. Prof. R. M. Pandey, Former Senior Professor & Head, Department of Biostatistics, All India Institute of Medical Sciences (AIIMS), New Delhi and Professor-in-Charge of Clinical Epidemiology unit at Indian Council of Medical Research (ICMR), New Delhi explained the basic concepts on Statistical Analysis and Confidence Interval. A total of 138 participants attended this guest lecture.



### #Medsafety Week Welcome Event

The Uppsala Monitoring Centre, Sweden organized #Medsafety Week Welcome Event virtually for 90 participating countries on 20<sup>th</sup> June 2023. The objective of this Welcome Event was to discuss the activities to be held during the upcoming Medsafety Week in November 2023. Ms. Neha Nasim, Jr. PV Associate, PvPI, IPC participated in this event.



### National AEFI Committee Meeting

The Adverse Event Following Immunization (AEFI) Secretariat organized a virtual national AEFI committee meeting on 30<sup>th</sup> June 2023. The objective of this meeting was to approve the causality assessment of the reported AEFI cases in Universal Immunization Programme (UIP) vaccines. NCC-PvPI, IPC officials participated in this meeting.



## Vaccicon 2023 organized by Jawahar Lal Nehru Medical College, Aligarh

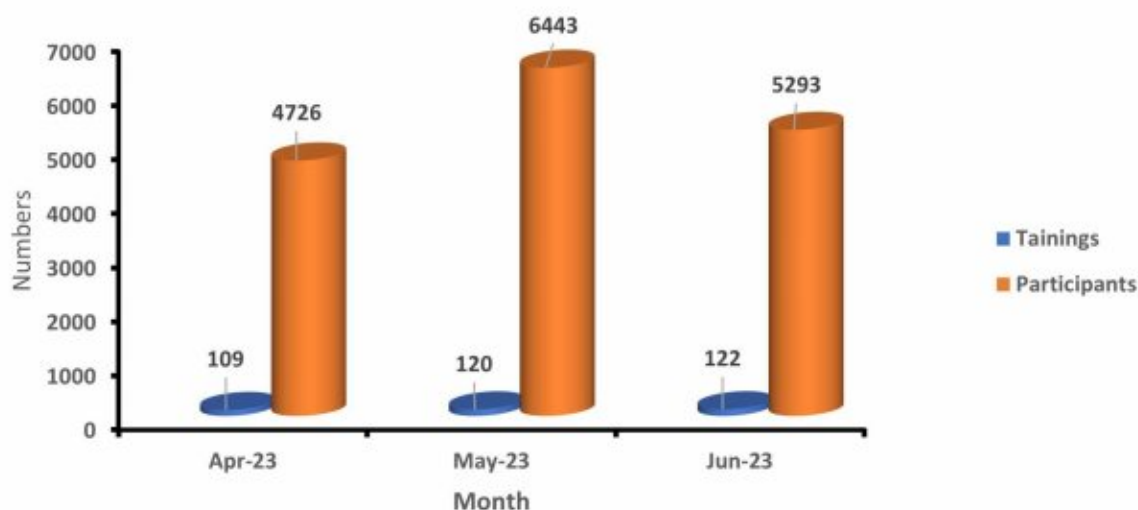
Prof. Farida Ahmad, Coordinator, Jawahar Lal Nehru Medical College (JNMC), Aligarh organized "Vaccicon-2023", a two days national conference on "Vaccines and Safety Concerns" in association with Indian Academy of Paediatrics, Aligarh from 10<sup>th</sup> to 11<sup>th</sup> July 2023 at JNMC.



On day-1, Dr Jai Prakash, Officer in-Charge of PvPI, Dr Shashi Bhushan, Sr. Scientific Officer, IPC and Mr. Vipin Sharma, Sr. Pharmacovigilance Associate, PvPI participated in this conference. Dr Jai Prakash had briefed the participants on "Current status of PvPI". On day-2, Dr Irfan Ahmad Khan, Assistant Professor, Department of Pharmacology, JNMC and Mr. Gufran Ali, Pharmacovigilance Associate, JNMC conducted hands on training on "How to fill ADR/AEFI reporting form?" for the participants. A total of 188 participants attended this conference.

## Monthly trends of training programmes conducted during index period

NCC-PvPI, IPC organised a total of 351 training programmes like Skill Development Programmes, Continuing Medical Education, Advanced Level Training Programmes etc. and trained a total number of 16462 participants in the area of Pharmacovigilance across the country.



## New drugs approved in India

The following new drugs were approved by the Central Drugs Standard Control Organization during this index period;

S. No.	Name of Drugs	Approved Indication(s)
1.	Cannabidiol Bulk Drug, Cannabidiol Oral Solution 100mg/ml	Indicated for the treatment of seizures associated with Lennox- Gastaut syndrome, Dravet Syndrome, or tuberous sclerosis complex in patients 1 year of age and older.
2.	3-(trimethoxysilyl) propyl dimethyl octadecyl ammonium chloride, Benzalkonium chloride, & Didecyl Dimethyl ammonium chloride	For surface disinfectant and hand sanitizer.
3.	Ibuprofen Sodium Dihydrate Bulk Drug, Ibuprofen Sodium Dihydrate 256/512mg Tablet	For the symptomatic relief of mild to moderate pain such as headache, backache, period pain, dental pain, neuralgia, rheumatic and muscular pain, migraine, cold and flu symptoms, sore throat and fever.
4.	Niraparib Tablet 100mg	Niraparib is indicated as monotherapy for the maintenance treatment of adult patients with advanced epithelial (FIGO stage-III and IV) high grade ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy. as monotherapy for the maintenance treatment of adult patients with platinum sensitive relapsed high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer, who are in response (complete or partial) to platinum-based chemotherapy.
5.	Polmacoxib Bulk Drug, Polmacoxib Capsule 2mg	Indicated for treatment of Idiopathic (primary) osteoarthritis of Hip/Knee.
6.	Amines, N- C10-16-alkyl trimethylenedi-, reaction products with chloroacetic acid 1.0000% w/w	Surface cleaning, aerial misting, hand sanitization (Not for COVID 19 use).
7.	Squaric Acid 0.748 mg/ml & Squaric Acid 1.745 mg/ml Solution (Spray)	Disinfection of Inanimate surface like floor, toilet, garbage areas only.

8.	Dalbavancin Hydrochloride Bulk Drug, Dalbavancin Injection 500mg	Dalbavancin for injection is indicated for the treatment of adult patients with acute bacterial skin and skin structure infections (ABSSSI), caused by susceptible isolates of the following Gram-Positive microorganisms staphylococcus aureus (including methicillin susceptible and methicillin resistant strains), streptococcus pyogenes, streptococcus agalactiae, streptococcus dysgalactiae, streptococcus anginosus group (including S. anginosus, S. intermedius, S. constellatus) and Enterococcus faecalis (vancomycin susceptible strains).
9.	Lobeglitazone Sulfate 0.5mg+Glimepiride 1mg Tablets	Indicated an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus who are already treated with a thiazolidinedione and sulphonylurea or who have inadequate glycemic control on a thiazolidinedione alone or a sulphonylurea alone.
10.	Sovateltide Bulk Drug & Sovateltide Injection 30 µg	Cerebral ischemic Stroke.
11.	Lifitegrast Bulk drug & Lifitegrast Ophthalmic Solution 5%w/v	Indicated for the treatment of signs and symptoms of dry eye disease (DED)
12.	Plecanatide Bulk Drug & Plecanatide Tablets 3mg	1. Chronic idiopathic constipation (CIC) 2. Irritable bowel syndrome with constipation (IBS-C)



**Healthcare Professionals (HCPs), patients/consumers are advised to closely monitor the above mentioned new drugs. If any adverse reaction is encountered, please report to the PvPI, IPC by filling up Suspected Adverse Drug Reactions Reporting Form for HCPs/ Medicine Side Effect Reporting Form for the Consumer (download from <http://www.ipc.gov.in>), through Android Mobile App "ADR PvPI" and PvPI Helpline No. 1800-180-3024 (Toll-Free)**



## Drug Safety Alerts

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. 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.

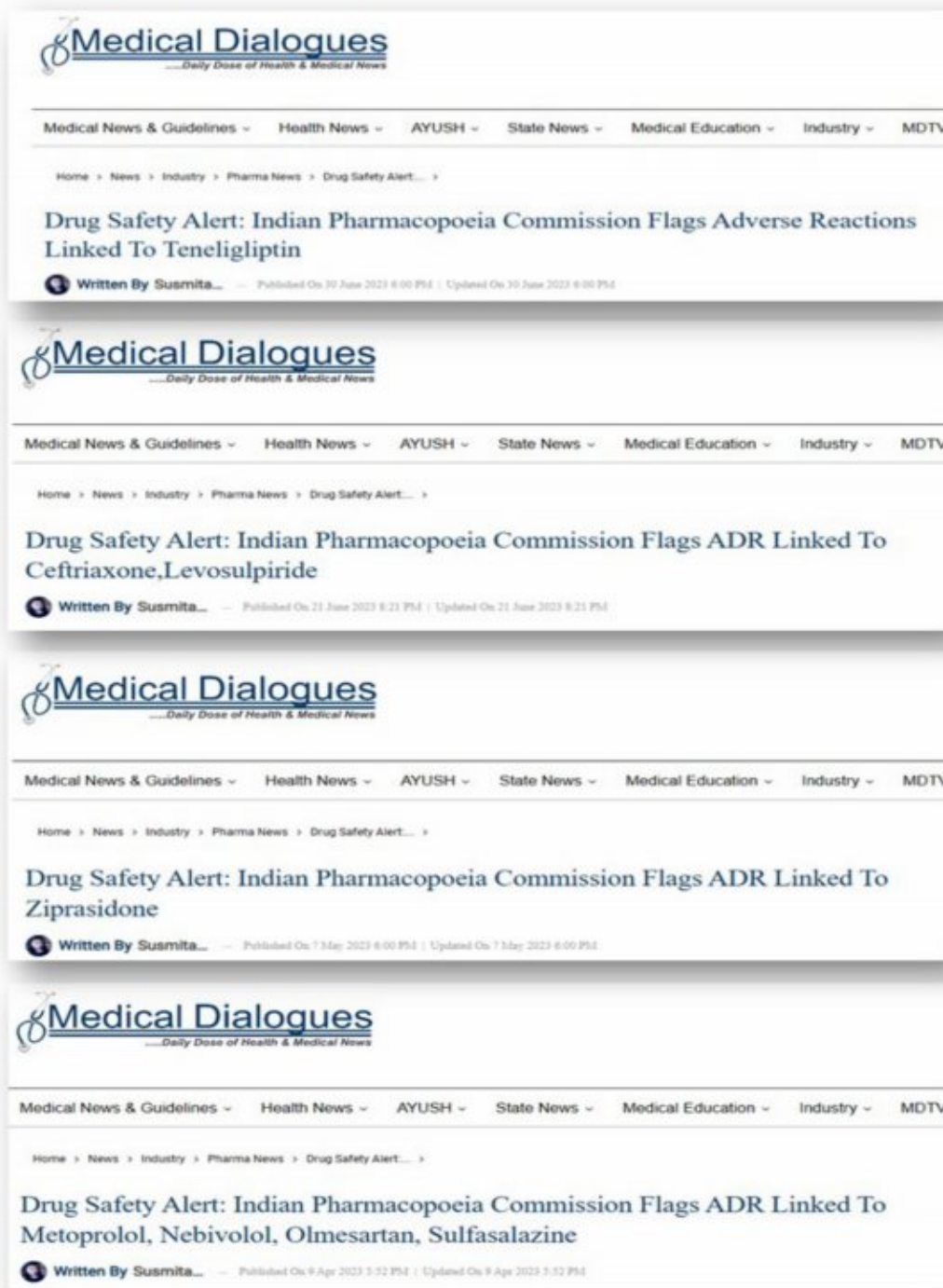
S. No.	Issue Date	Suspected drugs	Indication(s)	Adverse Drug Reactions
1.	24 <sup>th</sup> April 2023	Ziprasidone	<ul style="list-style-type: none"> <li>Use for the treatment of schizophrenia.</li> <li>Use for rapid control of agitation in psychotic patients.</li> </ul>	Drug Reaction with Eosinophilia Systemic Symptoms (DRESS)
2.	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 prolongation
3.		Levosulpiride	<ul style="list-style-type: none"> <li>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 (RLS)
4.	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



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## PvPI in Press & Media





**7<sup>th</sup> - 11<sup>th</sup>  
August 2023**

26<sup>th</sup>  
Skill Development  
Programme &  
Pharmacovigilance  
of Medical Products  
at IPC through  
virtual mode

**24<sup>th</sup> August  
2023**

Workshop-cum-  
Training Programme  
for the staff of NABH  
accredited hospitals  
at Sri Aurobindo  
Institute of Medical  
Sciences, Indore

**17<sup>th</sup> - 23<sup>rd</sup>  
September  
2023**

3<sup>rd</sup> National  
Pharmacovigilance  
Week (NPW)

**20<sup>th</sup> - 24<sup>th</sup>  
November  
2023**

27<sup>th</sup> Skill Development  
Programme on  
Pharmacovigilance of  
medical products at  
IPC through virtual  
mode

For more information, please refer [www.ipc.gov.in](http://www.ipc.gov.in)



# 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 समाह 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), [pvpi.compat@gmail.com](mailto: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 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।



**Indian Pharmacopoeia Commission**  
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Ministry of Health & Family Welfare, Govt. of India  
Sector-23, Raj Nagar, Ghaziabad-201002  
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**For any other information/Suggestion/  
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*Let us join hands with PvPI to ensure patient safety*