



# Newsletter

PHARMACOVIGILANCE PROGRAMME OF INDIA (PvPI)

VOL 13 | ISSUE 1 | 2023

## Regulatory Pharmacovigilance



**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



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



Dear Readers,

I am privileged to release the Pharmacovigilance Programme of India (PvPI) Newsletter Volume 13, Issue 1 for the index period from January, 2023 to March, 2023. This issue highlights the role of PvPI in Regulatory Pharmacovigilance.

In this quarter, 49 New Adverse Drug Reaction Monitoring Centres (AMCs) have been enrolled under PvPI and total number of AMCs became 701 from 652 across the country. However, 10 AMCs were delisted also during this quarter. So, the current strength of AMCs is 691. As on date, a total of 6.83 Lakh Individual Case Safety Reports have been reported to PvPI.

The PvPI is regularly sensitizing its stakeholders about the pharmacovigilance and reporting of adverse events through Awareness Programmes, Trainings, Workshops, Skill Development Programmes, Continuing Medical Education (CME) etc. The PvPI has organized a total of 5926 training programmes and trained a total of 316912 participants in the area of pharmacovigilance.

The NCC-PvPI, IPC is collecting, collating and analysing the safety data of medical products and sending the Signal Review Panel recommendations to the Central Drugs Standard Control Organization (CDSCO) for taking appropriate regulatory interventions in the country. So far, PvPI has confirmed 12 Signals and also identified 56 Prescribing Information Leaflets changes for medical products marketed in India. The regulatory recommendations are sent to CDSCO on continuous basis.

The NCC-PvPI, IPC has issued a total of 150 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. PvPI has also sent the Advisory on Albendazole associated Diarrhoea to the Programme Division of Ministry of Health & Family Welfare, Govt. of India, as albendazole is prescribed in the National Deworming Programme with the objective to deworm all preschool & school-age children in India.

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 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



# Role of PvPI in Regulatory Pharmacovigilance

As no drug is absolutely safe, a rigorous pharmacovigilance is therefore necessary even after marketing authorization of a drug. The safety profile of a drug is therefore required to be monitored as long as it is on the market. The pharmacovigilance Programme of India has come out with the following signals, PIL changes and drug safety alerts.

## Signals identified by PvPI and recommended to CDSCO for inclusion in Prescribing Information Leaflets:

S. No.	Suspected drugs	Adverse drug reactions
1.	Cefixime	Acute Generalised Exanthematous Pustulosis (AGEP)
2.	Cephalosporins	Fixed Drug Eruption (FDE)
3.	Doxycycline	FDE
4.	Fluconazole	Hyperpigmentation
5.	Furosemide	Dermatitis Lichenoid
6.	Itraconazole	AGEP
7.	Lithium Carbonate	Drug Reaction with Eosinophilia and Systemic Symptoms Syndrome (DRESS)
8.	Mefenamic Acid	FDE
9.	Minoxidil	Folliculitis
10.	Oseltamivir	Sinus Bradycardia/Bradycardia
11.	Paracetamol	FDE
12.	Tinidazole	FDE

## COVER STORY

**PvPI recommended the following Prescribing Information Leaflets changes of drugs to the CDSCO in the interest of patient safety:**

S. No.	Suspected drugs	Adverse drug reactions
1.	Alfuzosin	Palpitation
2.	Amlodipine	Alopecia
3.		Gingival Hypertrophy
4.	Amoxicillin/ Clavulanate Potassium	Stevens Johnson Syndrome (SJS) /Toxic Epidermal Necrolysis (TEN)
5.	Artemether + Lumefantrine	SJS
6.	Azithromycin	Acute Generalised Exanthematous Pustulosis (AGEP)
7.	Benidipine	Photosensitivity reaction
8.	Betamethasone	Photosensitivity Reaction
9.	Carbamazepine	SJS and TEN
10.	Carbamazepine	DRESS Syndrome
11.	Carvedilol	Hyperkalaemia
12.	Cefepime	Urticaria
13.	Cefixime	Mouth Ulceration
14.	Cefotaxime	Angioedema
15.	Ceftriaxone	SJS
16.	Chloroquine	TEN/SJS
17.	Ciprofloxacin	SJS/TEN
18.	Cloxacillin	AGEP
19.	Diclofenac	Nicolau Syndrome
20.	Dipeptidyl peptidase-4 (DPP4) Inhibitors	Arthralgia
21.	Docetaxel	Candidiasis
22.	Glibenclamide	Palpitation
23.	Haloperidol	Cogwheel rigidity

24.	Ibuprofen	SJS/TEN
25.	Itraconazole	Photosensitivity reaction
26.	Lamivudine	Hearing Loss
27.	Lamotrigine	SJS and TEN
28.	Losartan	Muscle Spasm
29.	Mannitol	Hypokalaemia
30.	Meropenem	Hypokalaemia
31.	Ofloxacin	SJS/TEN
32.	Olanzapine	Hyponatraemia
33.	Pentoxifylline	Palpitation
34.	Phenobarbital	DRESS Syndrome
35.	Phenytoin	AGEP
36.	Piperacillin + Tazobactam	AGEP
37.	Piperacillin and Tazobactam	Hypokalaemia, Bronchospasm
38.	Piroxicam	FDE
39.	Proton Pump Inhibitors	Acute Kidney Injury
40.	Pulmonary Surfactant	Pulmonary Haemorrhage
41.	Quetiapine	Urinary Incontinence
42.	Ranitidine	Cardiac Arrest
43.	Remdesivir	Sinus bradycardia
44.	Sodium Valproate	Gum Hyperplasia
45.	Sulfasalazine	SJS
46.		TEN
47.		DRESS Syndrome
48.	Terbinafine	AGEP
49.	Tigecycline	Coagulopathy
50.	Tinidazole	Skin Hyperpigmentation



## COVER STORY

51.	Tramadol	Hiccups
52.		Urinary Retention
53.	Tranexamic Acid	Seizure/Convulsion

**PvPI recommended the following Prescribing Information Leaflets changes of vaccines to the CDSCO in the interest of patient safety:**

S. No.	Suspected Vaccines	Adverse reactions
1.	Anti-Rabies Vaccine	Erythema Multiforme
2.	BCG vaccine	Lymphadenopathy
3.	Rota-Virus Vaccine	Intussusception

**In addition to the above, NCC-PvPI, IPC also issued Drug Safety Alerts on monthly basis for the sensitization of healthcare professionals and consumers to report Adverse Events to PvPI, if they encounter such reactions with the use of following drugs:**

S. No.	Suspected Drugs	Adverse drug reactions
1.	Acetazolamide	Drug Hypersensitivity Syndrome
2.	Allopurinol	Uveitis
3.	Ambroxol	Lacrimation
4.		FDE
5.	Amikacin	SJS
6.	Amiodarone	Acute Pancreatitis
7.	Amisulpride	Tinnitus
8.	Amitriptyline	Gingival discolouration
9.	Amlodipine	Alopecia
10.		Psoriasis
11.	Amoxicillin	FDE
12.	Amoxycillin	Eye irritation

13.	Amphotericin B	Bone marrow depression
14.	Amphotericine B (Liposomal)	Hearing disorders
15.		Tachycardia
16.	Artemether & Lumefantrine	SJS/TEN
17.	Atenolol	Dermatitis Lichenoid
18.	Atorvastatin	Vit-D deficiency
19.	Baclofen	Encephalopathy
20.	Beta-Blockers (Atenolol, Bisoprolol, Metoprolol)	Lichen Planus
21.	Cabergoline	Stevens- Johnson Syndrome
22.		Skin hyperpigmentation
23.	Carbamazepine	Bruxism
24.	Cefazolin	AGEP
25.	Cefepime	Dermatitis Lichenoid
26.	Cefixime	AGEP
27.		Anal ulcer
28.		Skin Hyperpigmentation
29.	Cefoperazone	Coagulopathy
30.	Cefoperazone + Sulbactam	AGEP
31.	Cefotaxime	Anaphylactic shock
32.	Cefpodoxime	DRESS Syndrome
33.	Ceftriaxone	Palpitation
34.	Cefuroxime	DRESS Syndrome
35.	Cephalosporin	AGEP
36.		FDE
37.		Purpura

## COVER STORY

38.	Cetirizine	AGEP
39.		Hiccups
40.		Tachycardia
41.	Cilostazole	Tinnitus
42.	Clarithromycin	AGEP
43.		Burning Sensation
44.		Burning Sensation
45.	Clindamycin	AGEP
46.		SDRIFE
47.	Clobazam	DRESS Syndrome
48.	Clomipramine	Melasma
49.	Clozapine	Neutropenia
50.		Neural Tube Defects
51.	Crizotinib	Risk of cardiac failure
52.		Pneumonitis, Hepatic encephalopathy
53.	Dabigatran	Alopecia
54.	Dapsone	Erythema Nodosum
55.	Deferasirox	Osteoporosis
56.	Dexamethasone	Hiccups
57.		Peripheral neuropathy
58.	Diclofenac	Nicolau Syndrome
59.		Skin Hyperpigmentation
60.	Diloxanide	Glossitis
61.	Dimethyl Fumarate	Osteonecrosis
62.		Alopecia



63.	Disulfiram	Erythroderma
64.		Skin Hyperpigmentation
65.	Doxorubicin	Photosensitivity reaction
66.	Etoricoxib	Skin hyperpigmentation
67.		AGEP
68.	Febuxostat	Allergic vasculitis
69.		TEN/SJS
70.	Fexofenadine	Blurred Vision
71.	Fluconazole	Mouth Ulceration
72.		SDRIFE
73.	Fluoxetine	Urinary incontinence
74.		Hypoacusis (Hearing impairment)
75.	Fluvoxamine	Intracranial/Pulmonary Hypertension
76.	Glimepiride	Lichenoid Drug Eruption
77.	Hepatitis B Immune globulin (human)	Encephalopathy
78.	Hydroxychloroquine Sulphate	Mouth Ulceration
79.	Hydroxyzine	Bullous pemphigoid
80.		Photosensitivity Reaction
81.	Ibuprofen	FDE
82.	Itraconazole	SDRIFE
83.	Lacosamide	Red Man Syndrome
84.	Lamivudine	Hearing loss
85.	Levamisole	Skin Exfoliation
86.		SJS
87.	Levetiracetam	Hypokalaemia
88.		Anecephaly

## COVER STORY

89.	Linagliptin	AGEP
90.	Losartan	Burning Micturation
91.		Muscle Spasm
92.	Lurasidone	Thrombocytopenia
93.	Mebeverine	Retrosternal pain
94.	Meropenem	Hypokalaemia
95.	Metoprolol	Lichenoid Drug Eruption
96.		Hyponatraemia
97.	Metronidazole	Vasculitis
98.	Miltefosine	Acute Pancreatitis
99.	Minoxidil	Folliculitis
100.	Mometasone furoate, topical	Hypertrichosis / Hirsutism, Skin depigmentation
101.	Montelukast	Tinnitus
102.	Nebivolol	Hyperkalaemia
103.	Netilmicin	Tetany
104.	Nicorandil	Risk of ulcer complication
105.	Nitrofurantoin	DRESS syndrome
106.	Nitrofurantoin	Vasculitis
107.	Norfloxacin	Skin Hyperpigmentation
108.	Olanzapine	Hyponatraemia
109.		DRESS Syndrome
110.		Hyponatremia
111.	Olmesartan	Muscle Spasm
112.		Taste Disorder
113.	Omeprazole	Dysuria

114.	Oxcarbamazepine	Syndrome of Inappropriate Antidiuretic Hormone secretion (SIADH)
115.	Paracetamol	Baboon syndrome
116.	Peginterferon alpha – 2a	Vasculitis
117.	Phenytoin	Angioedema
118.		Osteoporosis
119.	Piperacillin + Tazobactam	Vision abnormal
120.		Blurred Vision
121.	Piroxicam	FDE
122.	Polymyxin B	Mottled skin
123.	Pramipexole	Photosensitivity Reaction
124.	Quetiapine	Gynaecomastia
125.	Quetiapine & Valproic Acid Interaction	Neuropsychiatric Adverse Events (Depressed level of consciousness/Coma & Disorientation)
126.	Ranibizumab	Myocardial Infarction
127.	Remdesivir	Sinus Bradycardia
128.	Risperidone	Rabbit Syndrome
129.	Roflumilast	Gynecomastia
130.	Rosuvastatin & Ticagrelor Interaction	Rhabdomyolysis
131.	Salicylic Acid	Photosensitivity Reaction
132.	Sertaline	Maculopathy
133.	SGLT-2 Inhibitors	Genital Pruritus
134.	Sodium citrate +Diphenhydramine hydrochloride +Ammonium chloride	Myocardial infraction
135.	Sodium valproate	Psoriasis
136.	Sofosbuvir	SJS



## COVER STORY

137.	Sulfasalazine	Visual Impairment
138.	Tacrolimus	Gingival Hypertrophy
139.	Tamsulosin + Deflazacort	Ear pain
140.	Teicoplanin	Red Man Syndrome
141.		TEN
142.	Telmisartan	Lichenoid keratosis
143.	Teneligliptin	Arthralgia
144.	Terbinafine	AGEP
145.	Terlipressin	Atrial Fibrillation
146.	Tinidazole	Hyperpigmentation
147.	Torsemide	DRESS Syndrome
148.	Triamcinolone	Skin peeling
149.	Trimetazidine	DRESS Syndrome
150.	Zinc (Acetate/Oxide/Sulphate/Gluconate)	Diarrhoea

The above information is regularly updated by PvPI and uploaded on the web-portal of IPC. For more information, please refer the link [Pharmacovigilance Programme of India \(PvPI\) Updates - Indian Pharmacopoeia Commission \(ipc.gov.in\)](https://ipc.gov.in)

## Enrollment of New AMCs

NCC-PvPI, IPC has enrolled 49 new AMCs in 18<sup>th</sup> Phase of PvPI expansion. The total number of AMCs have increased from 652 to 701. However, 10 AMCs were delisted also on 24<sup>th</sup> March 2023. So, the current strength of AMCs is 691 and the list of newly enrolled AMCs is mentioned below:

S. No.	States/UT	Name of Hospitals/Medical colleges/Institute	Status
1.	Andhra Pradesh	Health Care Global Enterprises Ltd., HCG Cancer Centre, Pinnacle Hospital Compound, Apiic Health City, Arilova, Chinnagadiu, Vizag, Andhra Pradesh - 530040	Non-Government
2.		Pinnacle Hospitals, Plot No. 10, 11 & 12, Sy. No. 13P, APIIC, Health city, Chinna Gadhili, Visakhapatnam, Andhra Pradesh - 530040	
3.		Surya Global Hospitals, Near Railway Crossing, Madhavapatnam, Kakinada, Andhra Pradesh - 533005	
4.		Aster Narayanadri Hospitals, National Highway 71, Renigunta Rd, SV Auto Nagar, Tirupati, Andhra Pradesh - 517506	
5.		Omni Hospital (A Unit of Incor Hospital Vizag Pvt Ltd), 10-50-55, Wattair Main Road, Ramnagar, Visakhapatnam, Andhra Pradesh - 530002	
6.		Sree Ramadevi Multi Super Speciality Hospital, 82, Sai Ram Street, Tirupati, Andhra Pradesh - 517501	
7.	Delhi	Venkateshwar Hospital, Sector 12 RD, Sector 18A, Dwarka, New Delhi - 110075	Non-Government
8.		Mata Roop Rani Maggo Hospital, C-8,9, Om Vihar, Phase 1, Uttam Nagar, New Delhi - 110059	
9.		Holy Family Hospital, Okhla Road, South East Distt., New Delhi - 110025	
10.		Bhagat Chandra Hospital (A Unit of Bhagat Hospitals Pvt. Ltd.), Room No.6, B Building, 6th Floor, Mahavir Enclave, New Delhi - 110045	

## IMPORTANT ACTIVITIES

11.	Gujarat	Gujarat Adani Institute of Medical Sciences, G K General Hospital Campus, Opp Lotus Colony, Bhuj, Kachchh, Gujarat - 370001	Non- Government
12.		Metas Adventist Hospital, PB No. 24, Athwalines, Surat, Gujarat - 395001	
13.		Sunshine Global Hospital, Beside Big Bazar, Dumas Road, Surat, Gujarat-395007	
14.		K. B. Institute of Pharmaceutical Education & Research, Sector 23, GH-6 Road, Gandhinagar, Gujarat - 380023	
15.		Asutosh Hospital, Beside Kshetrapal Mandir, Kailash Nagar, Magura Gate, Surat, Gujarat - 395002	
16.		HCG Hospital, 1139 Sir Pattani Road, Meghani Circle, Bhavnagar, Gujarat - 364001	
17.		Haria L. G. Rotary Hospital, 363/1&364, Housing Sector, GIDC, Vapi, Valsad, Gujarat - 396195	
18.	Haryana	Oxygen Hospital, Bhivani Stand, Rohtak, Haryana - 124001	Non- Government
19.		Mann Multispeciality Hospital, Subhash Road, All India Radio Station, Rohtak, Haryana - 124001	
20.		Park Hospital, G T Road, NH-1, Sewah, Panipat, Haryana - 132103	
21.	Kerala	Mar Sleevea Medicity Palai, Cherpunkal, Kottayam, Kerala - 686584	Non- Government
22.		Avitis Super Specialty Hospitals Pvt. Ltd., XX/882, Thrissur, Pollachi Main Road, Near Jabamalarani Church, Nemmara, Kerala - 768508	
23.		MES Medical College, Perinthalmanna, Palachode PO, Malappuram, Kerala - 679338	
24.		Caritas Hospital, Thellakom, Kottayam, Kerala - 686630	
25.	Madhya Pradesh	Baderia Metropime Multispeciality Hospital, Kuchaini Panishan, Behind Kshetriya Bus Stand, Damoh Naka, Jabalpur, Madhya Pradesh - 482002	Non- Government
26.		BIMR Hospitals, Surya Mandir Road, Resedency Gwalior, Madhya Pradesh - 474005	



27.	Maharashtra	Dr. Hedgewar Hospital, Garkheda Parisar, Aurangabad, Maharashtra - 431009	Non-Government
28.		Dr. G M Taori Central India Institute of Medical Sciences, 88/2 Bajaj Nagar, Nagpur, Maharashtra - 40010	
29.	Odisha	Jaiprakash Hospital & Research Centre Pvt. Ltd., Dayanand Nagar, Rourkela, Sundargarh, Odisha-769004	Non-Government
30.	Punjab	Global Heart and Super Speciality Hospital, Nr.Octroi Post, Ferozepur Rd., Ludhiana,Punjab-141012	Non-Government
31.		Prakash Hospital, G T Road, Putlighar, Amritsar, Punjab - 143001	
32.		Gian Sagar Medical College and Hospital, Village Ram Nagar, Tehsil Rajpura, Patiala, Punjab - 140506	
33.	Rajasthan	Swastik Multispeciality Hospital, CP-1, RIICO Ind. Area, Narena Rd, Rajasthan-303008	Non-Government
34.		Solanki Hospital, 10, Ram Kutir, Ashok Circle, Alwar, Rajasthan - 301001	
35.	Tamil Nadu	Christudas Orthopaedic Speciality Hospital, COSH Multi Speciality Hospital, No:9, IAF Road, Duraismy Nagar, East Tambaram, Chennai, Tamil Nadu - 600059	Non-Government
36.		Dhanalakshmi Srinivasan Medical College & Hospitals, Siruvachur, Perambalur, Tamil Nadu - 621113	
37.		Faculty of Medicine, Sri Lalithambigai Medical College and Hospital, Maduravoyal, Ambattur Service Road, Adayalampattu, Chennai, Tamil Nadu - 600095	
38.	Telangana	Yashoda Hospitals, Alexander Road, Secunderabad, Telangana - 500003	Non-Government
39.		Mamata Medical College, Mamata General Hospital Campus, Giriprasad Nagar, Khammam, Telangana - 507002	
40.		Malla Reddy Narayana Multispeciality Hospital, Suraram 'X' Road, Jeedimetla, Qutubullapur, Hyderabad, Telangana - 500055	
41.		Pranaam Hospitals, #1-58/6/40 & 41, Madinaguda, Miyapur, Hyderabad, Telangana - 500050	

## IMPORTANT ACTIVITIES

42.		Government Medical College, Wanaparthi, Telangana - 509103	Government
43.		Government Medical College, Nagarkurnool, Govt. General Hospital, Nagarkurnool, Telangana - 509209	
44.	Uttar Pradesh	Fortis Hospital Noida, B-22, Sector-62, Noida, Uttar Pradesh - 201301	Non-Government
45.		Le Crest Hospital, Plot No. Ins 13, Sec-04 (Near Budh Chowk), Vasundhara, Ghaziabad, Uttar Pradesh - 201012	
46.		Krishna Institute of Pharmacy and Sciences, Gram - Amiliha, Post - Tatiyaganj Mandhana, Kanpur, Uttar Pradesh - 209217	
47.		SMMH Government Medical College, Pilakhni Area, Ambala Rd, Saharanpur, Uttar Pradesh -247001	Government
48.	West Bengal	All India Institute of Medical Sciences, Kalyani, NH-34 Connector, Basantpur, Saguna, Nadia, West Bengal - 741245	Government
49.		Apollo Multi Speciality Hospitals, 58 Canal Circular Road, Kolkata, West Bengal - 700054	Non-Government

## AMCs delisted from PvPI due to their poor performance:

S.No.	Name of AMCs with ID	Year of Enrolment
1	Aundh Chest Hospital, 1st floor Near Sangavi Phata, Aundh Camp, New Sangavi, Pune, Maharashtra-411027- (ACH-Pune)	2015
2	Babu Ishwar Saran District Hospital, Gonda, Uttar Pradesh – 271001, (BISDH-Gonda)	2017
3	Combined District Hospital, Santkabar Nagar, Uttar Pradesh – 272175, (CDH-Santkabar Nagar)	2017
4	Combined District Hospital, Bhinga, Shrawasti, Uttar Pradesh-271831, (CDH-Shrawasti)	2017
5	District Hospital, Bahraich, Gurunanak Chauraha, Hospital Road, Bahraich, Uttar Pradesh – 271801, (DH-Bahraich)	2017
6	District Male Hospital, pratapgarh, Uttar Pradesh- 230001, (DH-Pratapgarh)	2017
7	Glocal Group Of Hospitals, Glocal Healthcare System Pvt. Ltd., 3B-207, Ecospace Business Park, Action Area II, New Town, Rajarhat, Kolkata, West Bengal -700156, (GGH-Kolkata)	2017
8	Govt. Medical College, Kalpi Road, Orai, Jalaun, Uttar, (GMC-Jalaun)	2017
9	Sri Krishna Medical College & Hospital, Umanagar, Muzaffarpur, Bihar – 842004, (SKMCH-Muzaffarpur)	2017
10	Spandan Multispecialty Hospital, Besides Ward No. 4, Sindhwai Mata Road, Vadodara, Gujarat – 390011, (SMH-Vadodra)	2017

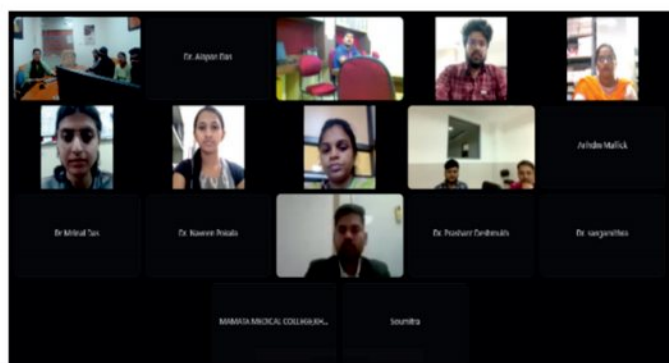
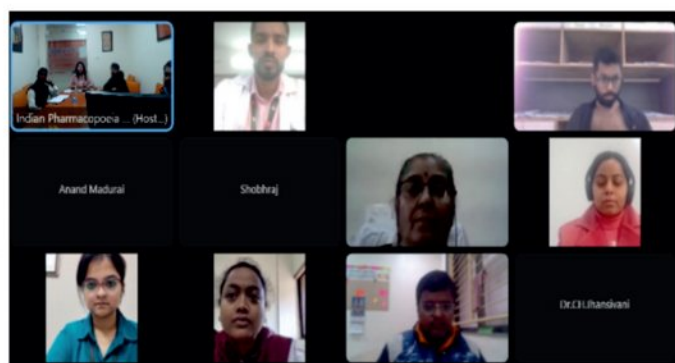


## National Adverse Event Following Immunization (AEFI) Committee meeting

The National Adverse Event Following Immunization (AEFI) Committee meeting was held virtually on 12<sup>th</sup> January 2023 to approve the Causality Assessment classification of the AEFI cases reported with post COVID-19 vaccination. The representative from PvPI, IPC participated in this meeting.

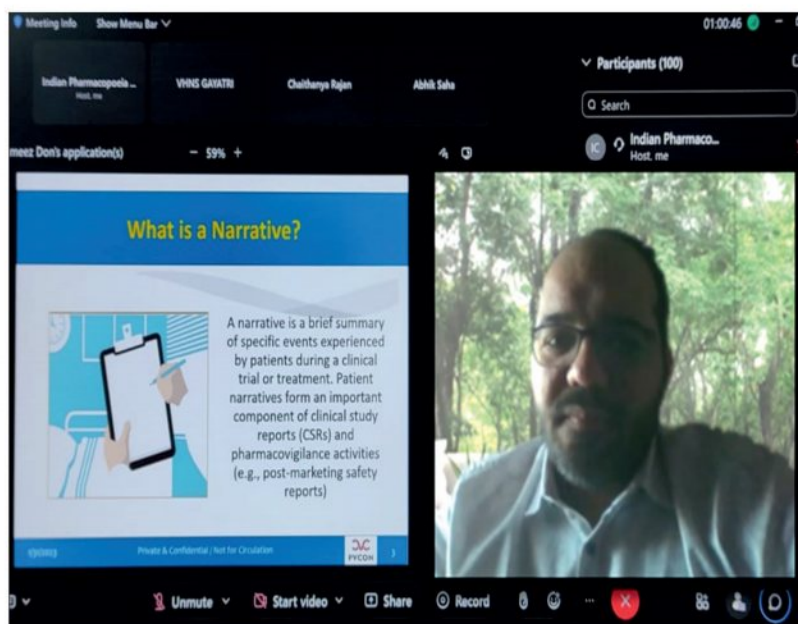
## Handholding meetings on VigiFlow Software

NCC-PvPI, IPC has organised handholding meetings for the Coordinators, Deputy-Coordinators, Junior Pharmacovigilance Associates virtually on 13<sup>th</sup> January, 2023 and 24<sup>th</sup> March, 2023 respectively. Ms. Shilpa Bhardwaj, Pharmacovigilance Associate demonstrated the entry of drug safety data to in VigiFlow. A total of 34 and 24 participants respectively from different AMCs participated in this meeting.



## Webinar on “Case Narrative Writing”

NCC-PvPI, IPC has organised a webinar on “Case Narrative Writing” on 31<sup>st</sup> January 2023 for Pharmacovigilance Associates posted at NCC, IPC, Ghaziabad and AMCs across the country. Mr. Rameez Don, Pharmacovigilance & Quality Assurance Lead, PVCON Consulting explained on “How to write a case narrative”? during the entry of drug safety data to in VigiFlow for effective clinical evaluation of reported drug safety data to PvPI. A total of 122 participants have participated in this webinar.



## TRAINING & EDUCATION

### 24<sup>th</sup> Skill Development Programme on Pharmacovigilance of Medical Products

NCC-PvPI, IPC has organised 5 days "24<sup>th</sup> Skill Development Programme (SDP) on Pharmacovigilance of Medical Products" virtually from 6<sup>th</sup>-10<sup>th</sup> February 2023. The objective of the SDP was to enhance Pharmacovigilance skills of the healthcare professionals in order to promote patient safety. A total of 189 participants including representatives from Pharmaceuticals Industries, Physicians, Academicians, Medical & Paramedical Students and Pharmacists across the country participated in this programme.



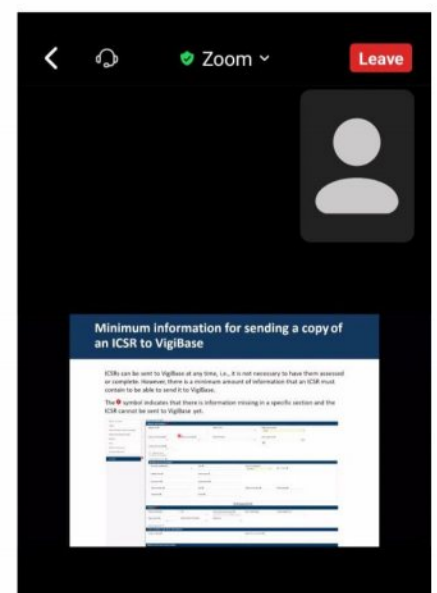
### National level Masters' Training under the National Rabies Control Programme

The Division of Zoonotic Diseases Programmes, National Centre for Diseases Control, New Delhi hosted National level Masters' Training from 14<sup>th</sup> February 2023 to 15<sup>th</sup> February 2023. Dr. Jai Prakash, Sr. Principal Scientific Officer, IPC and Dr. Vijit Agrawal, Sr. PV Associate, PvPI have participated in this programme on 14<sup>th</sup> February 2023 and updated the participants about Status of Adverse Events reported under PvPI with post vaccination of Anti-Rabies vaccine & Anti-Rabies serum in PvPI.

### Pharmacovigilance sessions organised by Dr Ram Manohar Lohia Institute of Medical Sciences, Lucknow



Dr Ram Manohar Lohia Institute of Medical Sciences, Department of Pharmacology, Lucknow organised virtual sessions on "ADR reporting and functioning of VigiFlow" on 16<sup>th</sup> February 2023 & 14<sup>th</sup> March 2023 respectively to train the MBBS students. Dr. Vijit Agrawal, Sr. PV Associate, PvPI delivered a talk in these sessions.





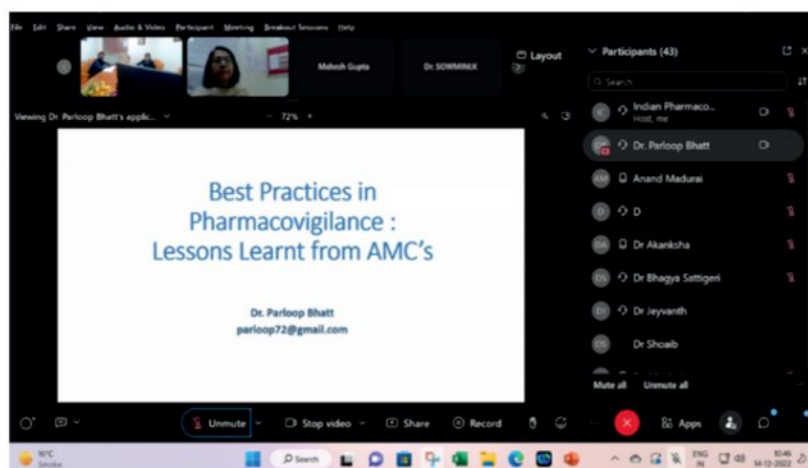
## MedDRA User Group meeting organised by MSSO



Maintenance and Support Services Organization (MSSO) organised MedDRA User Group meeting on 23<sup>rd</sup> February 2023 at Hotel Novotel, Bengaluru. In this meeting, Mr. Rishi Kumar, Scientific Assistant, IPC has participated as one of the panel members for the interactive panel discussion on "Bring in your coding challenges".

## Induction-cum-training programme for Coordinator/ Deputy Coordinator/ Pharmacovigilance Associate of newly recognised AMCs

NCC-PvPI, IPC has organised 3 days Induction-cum-training programme for Coordinator/Deputy Coordinator/ Pharmacovigilance Associate of newly recognised AMCs virtually from 27<sup>th</sup> February 2023 to 01<sup>st</sup> March 2023. The objective of this training programme was to enhance pharmacovigilance skills of Coordinator/Deputy Coordinator/ Pharmacovigilance Associate of newly recognised AMCs. A total of 108 participants have attended this training programme.



## Symposium at 52<sup>nd</sup> Annual Conference of Indian Pharmacological Society organised by JSS College of Pharmacy, Mysuru



The JSS College of Pharmacy, Mysuru organised "52<sup>nd</sup> Annual Conference of Indian Pharmacological Society' from 23<sup>rd</sup> to 25<sup>th</sup> February 2023. The organizers provided their support to consider request from PvPI for organizing a symposium during this event.



## TRAINING & EDUCATION

So, PvPI, IPC has organised a symposium on "Quality and Safety of Medicines and Medical Devices for Rational Therapeutics" on 23<sup>rd</sup> February, 2023. Dr Jai Prakash, Sr. Principal Scientific Officer, IPC briefed an "Update on Pharmacovigilance Programme of India and NFI, 2021" and also participated as one of the panel members in panel discussion on "Addressing the underreporting in PvPI/MvPI, expansion strategies of these programmes and how to involve patients in reporting of ADRs". Dr V. Kalaiselvan, Sr. Principal Scientific Officer, IPC has also participated as a panellist in panel discussion. In this event, IPC has also installed a stall to showcase its products to the stakeholders and participants.



## PvPI Officials visit to Government Medical College, The Nilgiris, Ooty

Dr Jai Prakash, Sr. Principal Scientific Officer, IPC, Dr Shashi Bhushan, Sr. Scientific Officer, IPC and Mr. Vipin Sharma, Sr. Pharmacovigilance Associate, PvPI visited Government Medical College, The Nilgiris, Ooty on 25<sup>th</sup> February 2023 to discuss the issues and challenges faced by them in terms of reporting ICSRs to PvPI. Dr Jai Prakash has also briefed on "Current updates on PvPI and contribution of GMC, The Nilgiris towards PvPI to their MBBS students along with faculty. Prof. R. Jeyalalitha, Coordinator, Head of Department of Pharmacology, GMC, The Nilgiris also presented the achievements of their medical college in promoting patient safety and also put forth issues faced by them in reporting ICSRs to PvPI.





## Drug allergy card implemented at Jawaharlal Nehru Medical College & Associated group of Hospitals, Ajmer

**Jawaharlal Nehru Medical College & Associated Group of Hospitals,**  
Adverse Drug Reaction Monitoring Centre,  
Department of Medicine  
Ajmer, Rajasthan

**DRUG ALLERGY CARD**  
For Patient Safety

Name : \_\_\_\_\_  
Age : \_\_\_\_\_ Gender : \_\_\_\_\_  
Blood Group : \_\_\_\_\_  
Address : \_\_\_\_\_  
Aadhar No. (Optional) : \_\_\_\_\_  
Mobile No. : \_\_\_\_\_  
Emergency Mobile No. : \_\_\_\_\_

Paste Photo

Dear Doctor, Your attention please, this patient is allergic to the drug mentioned in this card. Please give due consideration during further treatment. Use the same card to enter more drugs if the patient is found to be allergic any time.

Date/Reg. No.	Name of Drug	Type of Allergic Reaction	Name & Signature

Report Adverse Drug Reaction Monitoring Centre, Department of Pharmacology and Pharmacovigilance Programme of India (PvPI).  
For Adverse Drug Reaction Reporting, Text: +91 96000 10000, ADR Mobile App: "ADR PvPI"  
PvPI Helpline (Toll Free): 1800 800 0000 (9 AM to 5 PM, Monday to Friday).  
Let us join hands with PvPI to ensure Patient Safety.



Causality Assessment Committee (CAC) members - Sr. Professor Sanjeev Maheshwari, Department of General Medicine, Sr. Professor Vandana Goyal, Department of Pharmacology had done sensitivity testing and observed that large number of patients were allergic to some specific drugs. As most of the patients are layman, it is difficult for them to remember the name of drug causing sensitivity/allergy and it is likely that in future this culprit drug may be repeated and cause same harm to that patient.

Therefore, Dr Sunil Kumar Mathur, Chairperson of CAC & Head of the Department of Pharmacology /AMC Coordinator decided to provide Drug Allergy Card to the patients, who are sensitive to a particular drug. Since, majority of such patients are either diagnosed /reported in the department of General Medicine or Skin & Venereal Diseases. So, these cards should be kept preferably in these departments for the distribution.

Dr Veer Bahadur Singh, Principal & Controller, approved and released this card on 27<sup>th</sup> February 2023 and will be available free of cost for the patients.

## CME organised by Chalapathi Institute of Pharmaceutical Sciences, Guntur

Chalapathi Institute of Pharmaceutical Sciences, Department of Pharmacy Practice, Guntur organised CME on "Pharmacovigilance, Materiovigilance and AEFI" on 4<sup>th</sup> March 2023 for Pharm D, M. Pharm & B. Pharm students and other healthcare professionals with objective to improve the reporting of ICSRs to PvPI. A total of 320 participants have participated in this event.





**TRAINING & EDUCATION****CME organised by Jawahar Lal Nehru Medical College Hospital, Aligarh**

Jawahar Lal Nehru Medical College Hospital, Aligarh has organised CME on 21<sup>st</sup> March 2023 on Pharmacovigilance for faculty members and residents at their medical college. The CME emphasized on reporting of AE/ADR by clinicians to PvPI. on 21<sup>st</sup> March 2023. Dr R.S. Ray, Scientific Assistant, IPC briefed on current status of PvPI in this event. A total of 143 participants have attended this training programme.

**Review meeting on performance of Adverse Drug Reaction Monitoring Centers**

NCC-PvPI reviews the performance of Adverse Drug Reaction Monitoring Centers by conducting virtual meeting every month. In this review meeting, the performance of Pharmacovigilance Associates posted at AMCs was reviewed in terms of number of ICSRs reported to PvPI, various trainings programmes organized and other assigned activities from time to time. This meeting also facilitated for two-way interaction to understand their issues in reporting of ADRs to PvPI at ground level.

The last such meeting was conducted by NCC-PvPI, IPC virtually on 24<sup>th</sup> March 2023, Dr. Jai Prakash, Officer-in-Charge, PvPI reviewed the numbers of ICSRs reported by PV Associates from the respective AMCs as well as the sensitization and awareness programmes organized by them to sensitize/creating awareness about reporting of ADRs to PvPI.



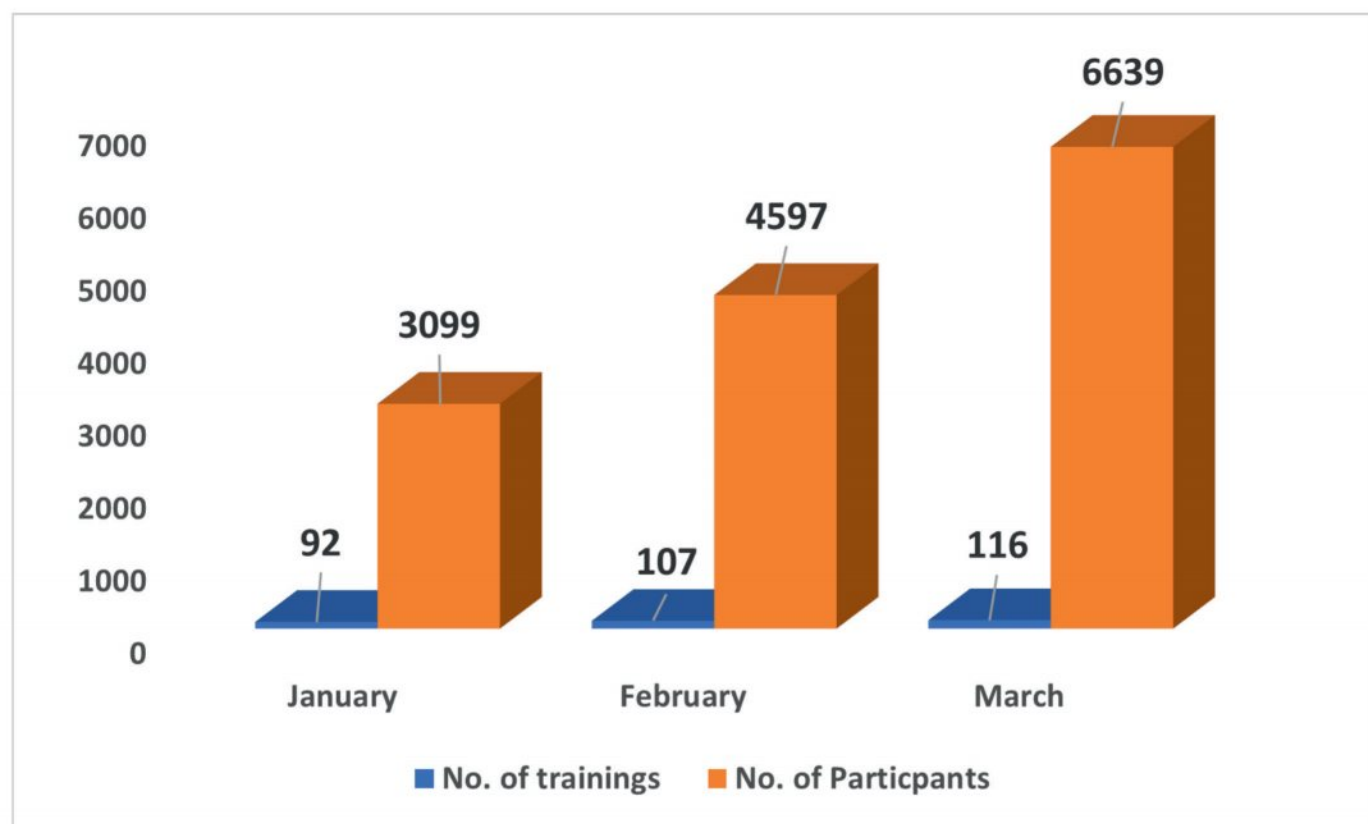
## Sensitization about SGLT2 inhibitors related Genital Infections

The NCC-PvPI sensitized the AMCs under the PvPI for monitoring and reporting of Adverse Reactions related to the use of Sodium-Glucose Cotransporter-2 (SGLT2) inhibitors on February 26, 2021. An official letter also sent to all AMCs by PvPI on July 15, 2019 for the sensitization of Healthcare Professionals (HCPs) concerned to closely monitor incidence of genital infections associated with use of SGLT2 inhibitors. This formal communication was issued following a warning letter issued by the Central Drugs Standard Control Organization (CDSCO) vide its letter No. 12-74/13-DC dated March 25, 2019.

The HCPs are again urged to closely monitor the genital infections, Fournier's Gangrene, acute & chronic pancreatitis and other adverse events with the use of SGLT2 inhibitors and report the adverse events if any to PvPI.

## Monthly trends of training programmes conducted during index period

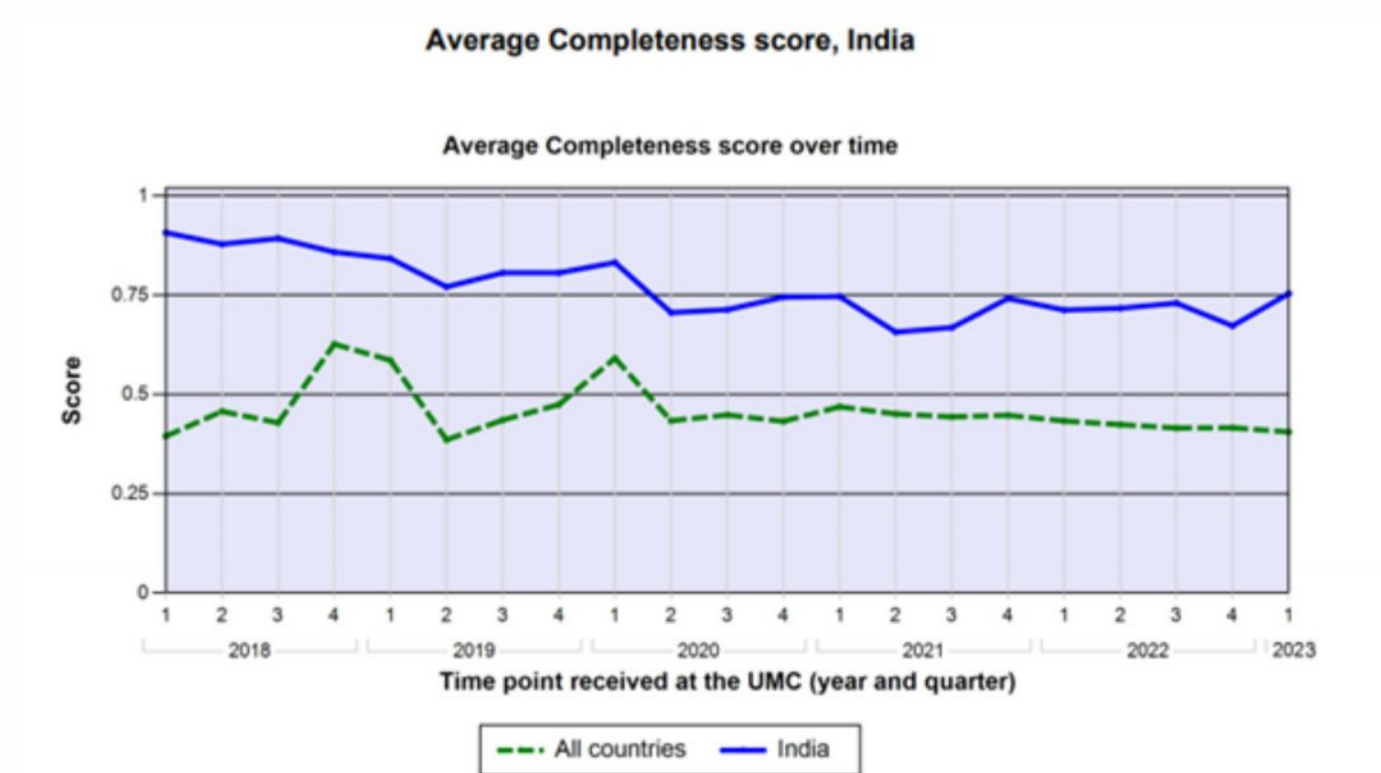
NCC-PvPI has organised a total of 315 training programmes like Skill Development Programmes, Continuing Medical Education (CME), Advanced Level Training Programmes, Induction-cum-training programmes etc. and trained a total of 14335 participants during this tenure.



## TRAINING & EDUCATION

### Quality of ICSRs Reporting

The VigiGrade Completeness score is a World Health Organization (WHO) system to measure the quality of the information provided in ICSRs. The graph represents the average completeness score of ICSRs submitted from India (Blue line) as compared to all other countries (Green line). The average completeness score during the index period accounts for about 0.75 out of 1.



All concerned stakeholders are advised to send the ICSRs to the PvPI as complete as possible in the interest of patient safety.

## Drug Safety Alerts

The NCC-PvPI issued the following drug safety alerts and shared with AMCs through email for the sensitizations of healthcare professionals. PvPI, IPC being a WHO Collaborative Centre also shared the drug safety alerts with SEARN countries through email.

S. No.	Issue Date	Suspected drugs	Indication	Adverse Drug Reactions
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



## REGULATORY MATTERS

S. No	Issue Date	Suspected drugs	Indication	Adverse Drug Reactions
7.		Olmesartan	Use as an Anti-hypertensive	Muscle Spasm
8.				Taste Disorder
9.		Sulfasalazine	Use for the treatment of severe rheumatoid arthritis, ulcerative colitis; Crohn's diseases.	Visual Impairment



**Healthcare Professionals (HCPs), patients/consumers are advised to closely monitor the above mentioned new drugs. If any reactions are 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)**





# PvPI in Press & Media



WHO Pharmaceuticals  
**NEWSLETTER**

2023

No. 1

## Cephalosporins

### Risk of fixed drug eruption

**India.** The Central Drugs Standard Control Organization (CDSCO) has approved the recommendation from the National Coordination Centre – Pharmacovigilance Programme of India (NCC-PvPI), Indian Pharmacopoeia Commission (IPC) to revise the prescribing information leaflet (PIL) for cephalosporins to include fixed drug eruption as an adverse drug reaction.

Cephalosporins are a group of antibiotics that belong to a beta-lactam class, indicated to manage a wide range of infections from gram-positive and gram-negative bacteria.

The NCC-PvPI, IPC reviewed 203 Individual Case Safety Reports (ICSRs) of cephalosporin associated fixed drug eruption and a causal relationship between them was found.

#### Reference:

Based on the communication from IPC, India, October 2022 ([link to the source within \*ipc.gov.in\*](#))

## Haloperidol

### Risk of cogwheel rigidity

**India.** The CDSCO has approved the recommendation from the NCC-PvPI, IPC to revise the PIL for haloperidol to include cogwheel rigidity as an adverse drug reaction.

Haloperidol is indicated for the treatment of chronic schizophrenia.

The NCC-PvPI, IPC reviewed 11 ICSRs of haloperidol associated cogwheel rigidity and a causal relationship between them was found.

#### Reference:

Based on the communication from IPC, India, October 2022 ([link to the source within \*ipc.gov.in\*](#))

## Olanzapine

### Risk of hyponatraemia

**India.** The CDSCO has approved the recommendation from the NCC-PvPI, IPC to revise the PIL for olanzapine to include hyponatraemia as an adverse drug reaction.

Olanzapine is indicated for the treatment of schizophrenia in adult patients, rapid control of agitation and disturbed behaviour in patients.

The NCC-PvPI, IPC reviewed 20 ICSRs of olanzapine associated hyponatraemia and a causal relationship between them was found.

#### Reference:

Based on the communication from IPC, India, October 2022 ([link to the source within ipc.gov.in](#))

## Remdesivir

### Risk of sinus bradycardia

**India.** The CDSCO has approved the recommendation from the NCC-PvPI, IPC to revise the PIL for remdesivir to include sinus bradycardia as an adverse drug reaction.

Remdesivir is indicated for the treatment of suspected or laboratory confirmed corona virus disease 2019 (COVID-19) in adults and children hospitalised with moderate to severe disease.

The NCC-PvPI, IPC reviewed 11 ICSRs of remdesivir associated sinus bradycardia and a causal relationship between them was found.

#### Reference:

Based on the communication from IPC, India, October 2022 ([link to the source within ipc.gov.in](#))  
(See also WHO Pharmaceuticals Newsletter [No.1 2022](#): Remdesivir and Potential risk of sinus bradycardia in Canada, [No.4, 2021](#) in Europe)



## Tigecycline

### Risk of coagulopathy

**India.** The CDSCO has approved the recommendation from the NCC-PvPI, IPC to revise the PIL for tigecycline to include coagulopathy as an adverse drug reaction.

Tigecycline is indicated for the treatment of skin and abdominal infections.

The NCC-PvPI, IPC reviewed three ICSRs of tigecycline associated coagulopathy and a causal relationship between them was found.

#### **Reference:**

Based on the communication from IPC, India, October 2022 ([link to the source within ipc.gov.in](#))

## Minoxidil

### Risk of folliculitis

**India.** The NCC-PvPI, IPC has recommended the CDSCO to revise the prescribing information leaflet (PIL) for minoxidil to include folliculitis as an adverse drug reaction. The recommendation is under consideration of the CDSCO.

Minoxidil is indicated for the treatment of alopecia (male pattern baldness) in men.

The NCC-PvPI, IPC reviewed 17 ICSRs of minoxidil associated folliculitis and a causal relationship between them was found.

#### **Reference:**

Based on the communication from IPC, India, October 2022 ([link to the source within ipc.gov.in](#))



Medical News & Guidelines ▾ Health News ▾ AYUSH ▾ State News ▾ Medical Education ▾ Industry ▾ MDTV

Home > News > Industry > Pharma News > Drug Safety Alert...

## Drug Safety Alert: Indian Pharmacopoeia Commission Flags ADR Linked To Metoprolol, Nebivolol, Olmesartan, Sulfasalazine



Written By **Susmita Roy** — Published On 9 Apr 2023 5:52 PM | Updated On 9 Apr 2023 5:52 PM



Medical News & Guidelines ▾ Health News ▾ AYUSH ▾ State News ▾ Medical Education ▾ Industry ▾ MDTV ▾

## Drug Safety Alert: Indian Pharmacopoeia Commission reveals ADR linked to Cephalosporin, Amikacin

Published On 10 Mar 2023 6:15 PM | Updated On 10 Mar 2023 6:15 PM



Medical News & Guidelines ▾ Health News ▾ AYUSH ▾ State News ▾ Medical Education ▾ Industry ▾ MDTV ▾



## Amphotericin B linked to Hearing disorders, Tachycardia, reveals IPC Drug safety alert

Published On 9 Feb 2023 10:00 AM | Updated On 9 Feb 2023 10:00 AM





**2<sup>nd</sup> - 4<sup>th</sup>  
May 2023**

Induction-cum-  
Training Programme

**15<sup>th</sup> - 19<sup>th</sup>  
May 2023**

25<sup>th</sup>  
Skill Development  
Programme &  
Pharmacovigilance  
of Medical Products

**May 2023**

Statistical Analysis  
and Confidence  
Interval

**June 2023**

QMS in  
Pharmacovigilance

For more information log on to [training.nccpvi-ipc@gov.in](mailto:training.nccpvi-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 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), [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।



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