

# Newsletter

PHARMACOVIGILANCE PROGRAMME OF INDIA (PvPI)

VOL 12 | ISSUE 3 | 2022

## 2<sup>nd</sup> National Pharmacovigilance Week - 2022



Published by

National Coordination Centre-Pharmacovigilance Programme of India (NCC-PvPI)  
Indian Pharmacopoeia Commission (IPC), Ministry of Health & Family Welfare  
Government of India

<b>COVER STORY</b>	<b>Page No.</b>		<b>Page No.</b>
<b>2<sup>nd</sup> National Pharmacovigilance Week</b>	<b>04</b>	<b>Regulatory Matters</b>	<b>14</b>
		☞ <i>New Drug Approved in India</i>	<b>14</b>
<b>IMPORTANT ACTIVITIES</b>		☞ <i>Drug Safety Alerts</i>	<b>15</b>
<b>New AMCs</b>	<b>06</b>	☞ <i>Drug Safety Alerts issued by other countries and status of ICSRs in PvPI database</i>	<b>17</b>
<b>Training &amp; Education</b>	<b>09</b>	<b>PvPI in Press &amp; Media</b>	<b>18</b>
☞ <i>Workshop-cum-Training Programme on Pharmacovigilance for NABH Accredited Hospitals</i>	<b>09</b>	<b>National Pharmacovigilance Week 2022</b>	<b>21</b>
☞ <i>Advanced Level Training (ALT)-“Vigilante-Healthcare Professionals and Patients”</i>	<b>09</b>	☞ <i>Result of E-Poster &amp; Animation/Video/Quiz Competition held during the 2<sup>nd</sup> NPW</i>	<b>21</b>
☞ <i>Virtual Handholding sessions on VigiFlow for newly recognized AMCs</i>	<b>10</b>	☞ <i>Skit/Nukkad Natak</i>	<b>27</b>
☞ <i>Interactive Meetings</i>	<b>10</b>	<b>FEEDBACK ON PvPI</b>	
☞ <i>National AEFI Committee Meeting</i>	<b>11</b>	<b>Feedback on PvPI</b>	<b>28</b>
☞ <i>22<sup>nd</sup> Skill Development Programme</i>	<b>12</b>	<b>FORTHCOMING EVENTS</b>	
☞ <i>Status of Training Programmes</i>	<b>13</b>	<b>Forthcoming Events</b>	<b>30</b>



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



Dear Readers,

I am delighted to release the Pharmacovigilance Programme of India (PvPI) Newsletter Volume 12, Issue 3 for the index period from July, 2022 to September, 2022. This Issue highlights the important activities organized by the PvPI including celebration of 2<sup>nd</sup> National Pharmacovigilance Week from 17<sup>th</sup> - 23<sup>rd</sup> September 2022.

In this quarter, 39 new Adverse Drug Reaction Monitoring Centres (AMCs) have been enrolled under PvPI and total number of AMCs became 606 from 567 across the country.

By the end of this quarter, a total of 6.26 Lakh Individual Case Safety Reports have been reported to PvPI. The PvPI is regularly sensitizing the 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 5166 training programmes and trained a total of 276563 participants in the area of pharmacovigilance.

NCC-PvPI has celebrated the 2<sup>nd</sup> National Pharmacovigilance Programme (NPW) at IPC. It also sensitized the AMCs and other stakeholders for organizing the same at their level across the country. An overwhelming response was observed from the AMCs pan India. The objective of this NPW was to sensitize and increase the awareness among the common public, consumers/patients, healthcare professionals about the adverse drug reaction developed with the use of medicines prescribed for the treatment of diseases.

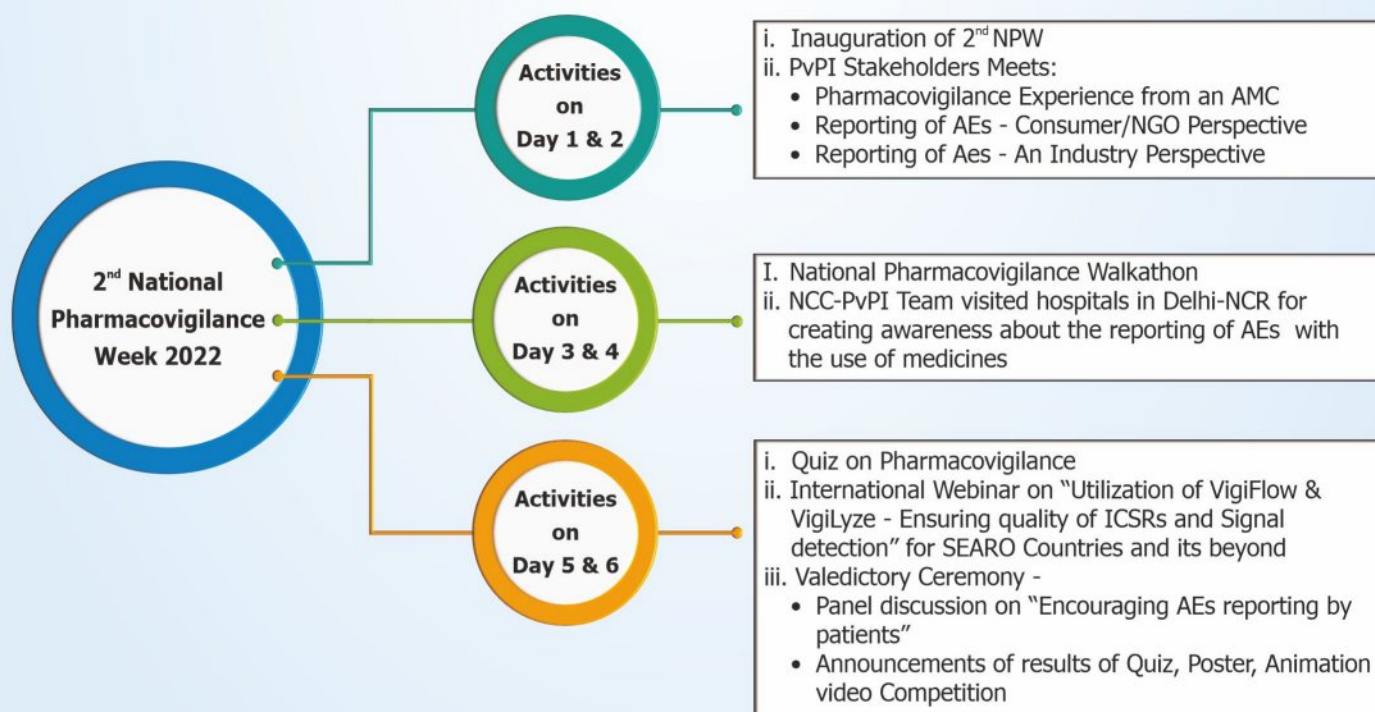
As a team, we will continue to work towards building patient safety culture in India. I, congratulate the PvPI team, AMCs and subject experts for their ceaseless efforts, cooperation and contribution in strengthening of robust pharmacovigilance system in India.

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

# 2<sup>nd</sup> National Pharmacovigilance Week

The National Coordination Centre (NCC)-Pharmacovigilance Programme of India (PvPI), Indian Pharmacopoeia Commission (IPC) has celebrated 2<sup>nd</sup> National Pharmacovigilance Programme (NPW) from 17<sup>th</sup>-23<sup>rd</sup> September 2022 across the country. The theme of this NPW 2022 was to encourage the reporting of ADRs to PvPI by the consumers. Various modes like workshops, conferences, pharmacovigilance walkathon, quiz competition, poster competition and skit were used during the entire week for creating the awareness at hospitals, medical colleges and academia across the country.

During the 2<sup>nd</sup> NPW, NCC-PvPI has organized a walkathon in Ghaziabad on September 20, 2022 to create awareness about the reporting of adverse events with the use of medicines and also distributed the pamphlets & resources materials prepared in Hindi and English to the public, hospitals and chemists. The major activities organized by NCC-PvPI during this week were as follows;





The Adverse Drug Reaction Monitoring Centres (AMCs) in medical colleges & hospitals under PvPI and other hospitals, medical colleges, academic institutions across the country have actively participated in 2nd NPW 2022. The glimpses of the celebration of 2nd NPW 2022 are as follows;







S. No.	State	Name of Hospitals/Medical colleges/Institutes	Status
1	Andhra Pradesh	HCG Curie City Cancer Centre, Padavalarevu, Machavaram Down, Gundala, Vijaywada, A.P. - 520004	Private
2		Nagarjuna Hospital Ltd., Kanuru, Vijayawada - 520007	
3		Sentini Hospital, No.-54-15-5 B&C, Opp. Novetel Hotel, Ring Road, Vijayawada - 520008	
4	Chhattisgarh	Shri Balaji Metro Hospital, Pahad Mandir Road, Village - Kauhakunda, Raigarh - 496001	
5	New Delhi	RLKC Hospital - Metro Heart Institute, Pandav Nagar, Nariana Roar, New Delhi - 110008	
6		Moolchand Hospital, Lajpat Nagar-III, New Delhi-110024	
7		Saroj Super Speciality Hospital, Madhuban Chowk, Sector-14, Ext. Rohini, Delhi - 110085	
8	Gujarat	HCG Hospitals, Mithakhali Six Road, Kalyan Society, Erris Bridge, Ahmedabad - 380006	
9	Haryana	Supreme Hospital, Charmwood village, Eros Garden, Surajkund Road, Faridabad, Haryana - 121009	
10		Narayana Super Speciality Hospital, Gurugram, Sector-24, DLF Phase - III, Haryana - 122002	
11		Sunflag Global Hospital, Sonapat Road, Opp. Rivoli Hotel, Near Sheela Bypass, Rohtak - 124001	
12		Nidaan Hospital, Murthal Rd, Sonipat, Haryana-131001	
13		Oscar Super Speciality Hospital & Trauma Center, GT Rd, Opp.. PVR Mall, Sec - 6, Panipat, Haryana - 132103	
14		Shri Balaji Aarogyam Hospital Pvt. Ltd., Behind Old Bus Stand, Kurukshetra - 136118	
15		Sidharth Hospital, Shahabad Markanda, Distt. K.K.R, Haryana - 136135	



S. No.	State	Name of Hospitals/Medical colleges/Institutes	Status
16	Himanchal Pradesh	Shri Sai Multi Speciality Hospital & Trauma Centre, 445/12, Chakreda Road, Nahan, Sirmour, H.P. - 173001	Private
17	Kerala	Malabar Hospital (P) Ltd., Karuvambrum (Post) Rajiv Gandhi Bypass Road, Manjeri, Malappuram, Kerala - 676123	
18		Atreya Hospital (A Unit of DMRI), East Fort, Wear St. Llare School, Thrissur, Kerala - 680005	
19		Government Medical College, HMT Colony (PO) Kalamassery, Ernakulam, Kerala - 683503	Government
20	Kerala	PRS Hospital Pvt. Ltd., Block No. 1, Killipalam Karamana (P.O.) Thiruvananthapuram, Kerala - 695002	Private
21		Sree Uthradom Thirunal Hospital, Near Palace View Road Virndavan Garden, Pattom, Thiruvananthapuram, Kerala - 695004	
22	Karnataka	Aster RV Hospital, CA-37, 24th Main, 1st Phase, JP Nagar, Bengaluru, Karnataka - 560078	
23	Maharashtra	Saifee Hospital, 15/17 Maharshi Karve Road, Charni Road Station Mumbai - 400004	
24		Saideep Healthcare & Research Pvt. Ltd., Yashwant colony, Viraj Estate, Tarakpur, Ahmednagar, Maharashtra - 414001	
25	Manipur	Shija Academy of Health Sciences, Health Village, Imphal West, Manipur - 795004	
26	Madhya Pradesh	Shyam Shah Medical College, 1st Floor, Near Dhobiya Tanki, Rewa, M.P. - 486001	Government
27	Punjab	Neelam Hospital, NH-7 (64) opposite Chitkara University, Rajpura Chandigarh Highway, Rajpura, Punjab - 140401	Private
28		Abrol Medical Centre Super Speciality Hospital, Kailash Enclave, Batala Road, Gurdaspur, Punjab - 143521	
29	Puducherry	JIPMER (Academic & Lab Complex), Kalam Campus, FCI Road, Kovilpathu, Karaikal - 609605	Government
30	Tamil Nadu	Bhaarith Medical College & Hospital, 173, Agaram Main Rd., Selaiyur, Chennai - 600073	Trust
31		Swamy Vivekanandha Medical College Hospital and Research Institute, Unjanai, Elayampalayam, Tiruchengode, Namakkal District, Tamil Nadu - 637205	Private

S. No.	State	Name of Hospitals/Medical colleges/Institutes	Status
32	Telangana	Landmark Hospitals, MCK Block 2, Near JNTU Metro Station, Opposite Vasanth Nagar Arch, Hyderabad, Telangana - 500085	Private
33	Uttar Pradesh	Navin Hospital, NH-1, Sector-3, Vaishali, Near Mahagun Mall, Ghaziabad - 201010	Non-Government
34		IIMT College of Pharmacy, Plot No.-19 & 20, KP-111, Greater Noida - 201310	Private
35		Maharaja Suhel Dev Autonomous State Medical College & Mahrishi Balark Hospitals, KDC Road, Baharaich, UP - 271801	Government
36	Uttarakhand	Gautam Buddha Chikitsa Mahavidyalaya & Dr. KKBM Subharti Hospital, Jhajna, NH-72, Chakrata Road, Dehradun - 248007	Private
37	West Bengal	B. P. Poddar Hospital & Medical Research Ltd, 71/1, Humayun Kabir Sarani, New Alipore, Block G, Kolkata - 700053	
38		Medical College, Kolkata, 88, College Street, Kolkata - 700073	Government
39		Department of Pharmacology, 7th Floor Academic Building, ESI-PGIMSR and ESI Medical College, Joka, Kolkata - 700104	



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



NCC-PvPI, IPC has organized Workshop-cum-Training Programme on Pharmacovigilance for NABH accredited hospitals on 11<sup>th</sup> July, 2022 at Shekhar hospital, Lucknow. The objective of this training programme was to sensitize the healthcare professionals of the NABH accredited hospitals to promote patient safety. A total of 67 participants have attended this training programme.



Dr. Jai Prakash, Officer-in-Charge, PvPI has discussed on 'Current updates of Pharmacovigilance Programme of India', which outlined the current status of Pharmacovigilance and emphasized the need for Pharmacovigilance.



## Advanced Level Training (ALT)- "Vigilante-Healthcare Professionals and Patients"

Dr. Princy Louis Palatty, Amrita Institute of Medical Sciences (AIMS), Kochi in collaboration with NCC-PvPI, IPC, Ghaziabad conducted one day ALT programme on Pharmacovigilance at Amriteshwari hall on 23<sup>rd</sup> July, 2022. This programme was attended by more than 50 delegates including Coordinators and Pharmacovigilance Associates from 37 AMCs in Kerala.



## Virtual Handholding sessions on VigiFlow for newly recognized AMCs



The NCC-PvPI has organized handholding sessions on VigiFlow software with the objective to train the Coordinators, Deputy-Coordinators and PV Associates of newly recognized AMCs on 27<sup>th</sup> July, 2022 and 7<sup>th</sup> September, 2022 respectively at Indian Pharmacopoeia Commission. Ms. Shilpa Bhardwaj, Team Lead-ICSR Division made presentation on "how to enter the ICSRs into the VigiFlow software" and a total of 42 participants have participated in this training session from AMCs across the country.



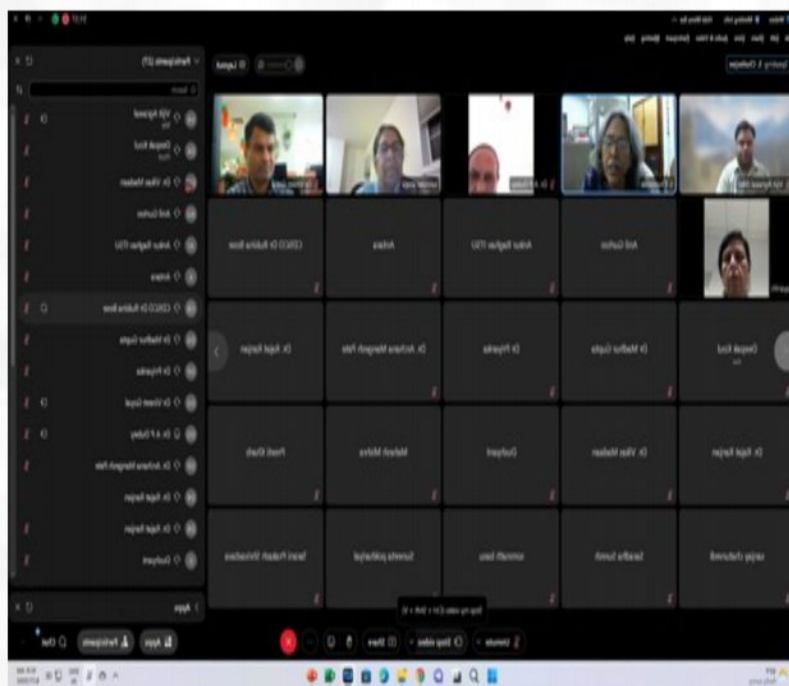
## Interactive Meetings

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 focused on the issues/challenges related to the quality submission of ICSRs in E2B, xml format to PvPI.

Date	MAHs/Pharmaceutical Industry	No. of Participants
14 <sup>th</sup> July, 2022	Mylan Laboratories Ltd.	13
31 <sup>st</sup> August, 2022	MSN Laboratories Ltd.	02
29 <sup>th</sup> September, 2022	IPCA Laboratories Ltd.	07



## National AEFI Committee Meeting



The National AEFI committee meetings were held virtually on 17<sup>th</sup>-18<sup>th</sup> August and 29<sup>th</sup>-30<sup>th</sup> September, 2022 respectively having the agenda to approve the causality assessment classification of the reported AEFI cases. Both meetings were organized by the AEFI Secretariat under the chairmanship of Prof. S. Aneja, Head of the Department of Pediatrics, School of Medical Sciences and Research, Sharda University, Greater Noida. Dr. Vijit Agrawal, Sr. PV Associate, PvPI had attended these meetings and discussed the causality assessment of AEFI cases reported with COVID-19 vaccines in PvPI.

**Summary of Vaccine Product Related Reaction (A1) N=24**

- Hospitalized: 22, Severe: 2

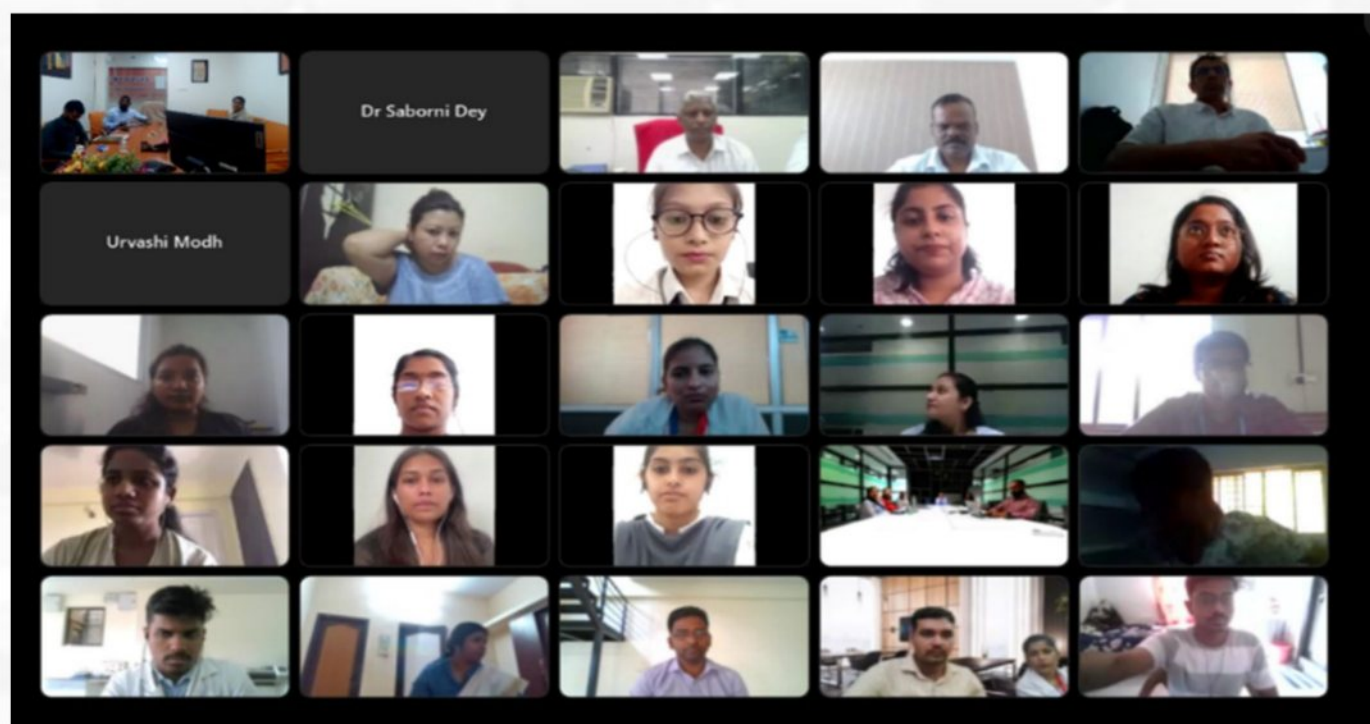
VALID DIAGNOSIS	No. OF CASES
Acute Febrile illness	10
Anaphylaxis	3
Allergic reaction	4
Pain and redness at injection site	1
Thrombosis with Thrombocytopenia Syndrome	3
Thrombocytopenia	1
Vertigo	1
Vomiting	1

The slide also features the ITSU logo and a red circular seal at the bottom.



## 22<sup>nd</sup> Skill Development Programme

The NCC-PvPI, IPC has organized 5 days 22<sup>nd</sup> Skill Development Programme (SDP) on Pharmacovigilance of Medical Products from 12<sup>th</sup> to 16<sup>th</sup> September, 2022 through virtual mode. A total of 131 participants have attended this SDP including Industry Professionals, Physicians, Academicians, Pharmacy Students, Medical Students, Pharmacist across the country. During 5 days of SDP, a total of 19 technical sessions were conducted by experts from the Pharmaceutical Industries, Academic & Research Institutions on various topics of Pharmacovigilance.





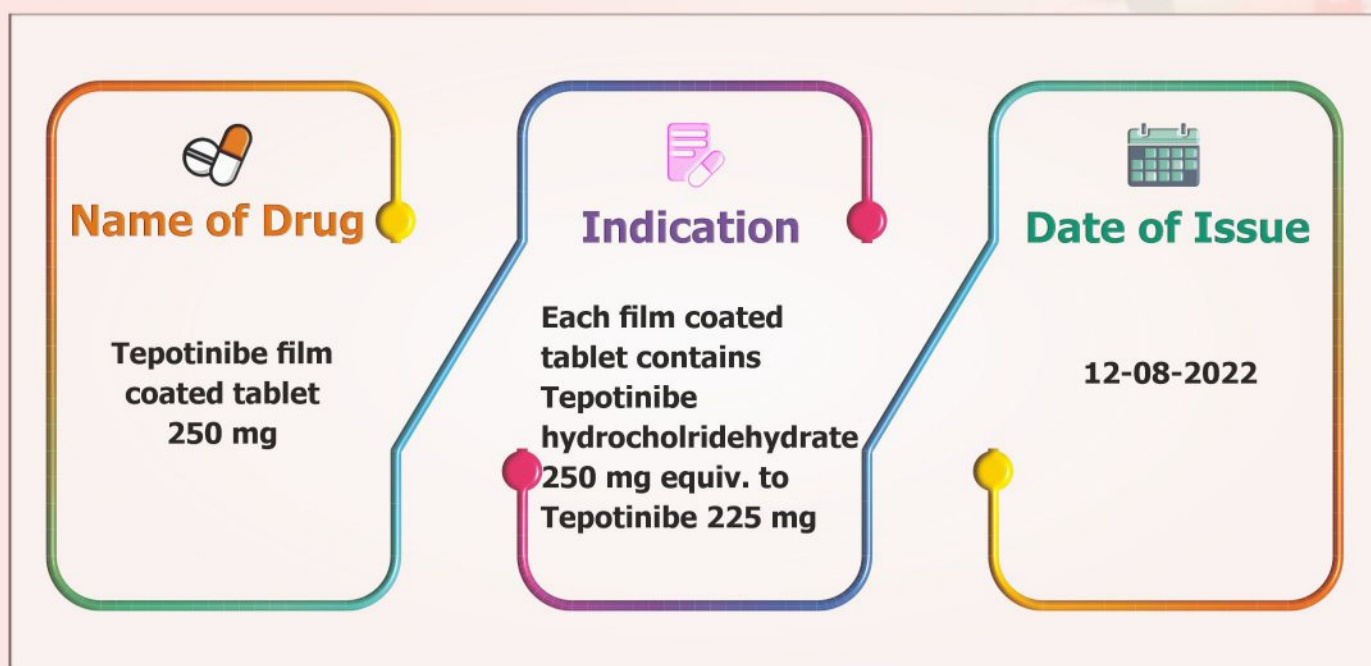
## Status of Training Programmes

NCC-PvPI has organized a total of 764 training programmes like skill development programmes, advanced level training programmes, interactive meetings with pharmaceutical industries/marketing authorization holders, workshops for NABH accredited hospitals and trained 60499 participants in pharmacovigilance. The month wise details are given as:



# New Drugs approved in India

The following new drug was approved by CDSCO between July 2022 to September 2022:



## Source:

[https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download\\_file\\_division.jsp?num\\_id=ODg5Ng==](https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=ODg5Ng==)



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)



# DRUG SAFETY ALERT



**Drug  
Safety Alerts  
issued by  
PvPI, IPC**

**1**

## **Tacrolimus : Gingival Hypertrophy**

### **Issuing Date**

15<sup>th</sup> July, 2022

### **Indication**

- For prophylaxis of transplant rejection in adult kidney or liver allograft rejection.
- Prophylaxis of transplant rejection in kidney, liver or heart allograft recipient.
- For prophylaxis of transplant rejection in liver, pancreas, lung, heart and kidney allograft recipients and treatment of allograft rejection resistant to treatment with other immuno- suppressive medicinal products.
- By nephrologists only- for the prophylaxis of organ rejection in patients receiving allogenic kidney transplant.
- For dermatologists-for treatment of patients with moderate to severe atopic dermatitis in whom the use of alternative conventional therapy is advisable.

### **Adverse Drug Reactions**

**Gingival  
Hypertrophy**

2

**Cefoperazone : Coagulopathy****Issuing Date**23<sup>rd</sup> August, 2022**Indication**

Urinary infections, biliary infections, respiratory infections, infections of skin tissues, meningitis, septicemia, Pseudomonas, Salmonella typhi & B. fragilis infections.

**Adverse Drug Reactions**

Coagulopathy

3

**Piroxicam : Fixed Drug Eruption****Issuing Date**26<sup>th</sup> September, 2022**Indication**

- In the treatment of rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, cervical spondylitis and other musculoskeletal disorder
- Anti-inflammatory agent- Indicated in the treatment of rheumatoid arthritis, ankylosing spondylitis and other musculoskeletal disorders
- Indicated in the treatment of musculoskeletal disorders, acute gout, pain after operative intervention following acute trauma and in primary dysmenorrhoea (12 years age or older)

**Adverse Drug Reactions**

Fixed Drug Eruption

**Source:**

<https://www.ipc.gov.in/mandates/pvpi/pvpi-updates/8-category-en/931-drug-alerts-2022.html>



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)



## Drug Safety Alerts issued by other countries and status of ICSRs in PvPI database

Suspected Drugs	Adverse Drug Reactions	Total No. of ICSRs in other Countries	Total No. of ICSR (s) in PvPI	References
Benzodiazepines	Potential risk of abuse, dependence and withdrawal	21453	19	WHO Pharmaceuticals Newsletter No. 3, 2022, published on 15 <sup>th</sup> September, 2022
Pembrolizumab	Cholestasis	71	01	
Bevacizumab	Anaphylactoid/ Anaphylactic reactions	146	02	Drug Safety-related Labeling Changes (SrLC) (fda.gov)

# PvPI in Press & Media



World Health  
Organization

## WHO Pharmaceuticals NEWSLETTER

2022

No. 3

### **Mefenamic acid, doxycycline**

#### **Risk of fixed drug eruption**

**India.** The Central Drugs  
Standard Control Organization

(CDSCO) has approved the recommendation to revise the prescribing information leaflet (PIL) for mefenamic acid and doxycycline to include fixed drug eruption as an adverse drug reaction.

Mefenamic acid is indicated for the treatment of rheumatoid arthritis, osteoarthritis, dysmenorrhea, mild to moderate pain, inflammation, fever and dental pain. Doxycycline is used as a broad-spectrum antibiotic.

The National Coordination Centre – Pharmacovigilance Programme of India (NCC-PvPI), Indian Pharmacopoeia Commission (IPC) reviewed 23 case reports of fixed drug eruption with use of mefenamic acid and 94 cases with the use of doxycycline, and found a strong causal relationship between each of the two drugs and the event.

#### **Reference:**

Based on the communication from IPC, India, June 2022 ([link1](#) and [link2](#) to the source within [cdsco.gov.in](https://cdsco.gov.in))





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[Home](#) > [News](#) > [Industry](#) > [Pharma News](#) > [Drug Safety Alert: IPC...](#) >

## Drug Safety Alert: IPC Flags Adverse Drug Reaction Linked To Tacrolimus

New Delhi: The Indian Pharmacopoeia Commission (IPC), through its recently issued drug safety alert for the month of July, has revealed that Tacrolimus, an immunosuppressive drug can lead to adverse drug reaction named Gingival Hypertrophy.

This came after preliminary analysis of Adverse Drug Reactions (ADRs) from the Pharmacovigilance Programme of India (PvPI) database.

Tacrolimus is a calcineurin inhibitor used to prevent organ transplant rejection and to treat moderate to severe atopic dermatitis. Tacrolimus is chemically known as a macrolide. It reduces peptidyl-prolyl isomerase activity by binding to the immunophilin FKBP-12 (FK506 binding protein) creating a new complex. This FKBP12-FK506 complex inhibits calcineurin which inhibits T-lymphocyte signal transduction and IL-2 transcription.

In accordance with the drug safety alert, Tacrolimus is indicated:

- For prophylaxis of transplant rejection in adult kidney or liver allograft rejection.
- Prophylaxis of transplant rejection in kidney, liver or heart allograft recipient.
- For prophylaxis of transplant rejection in liver, pancreas, lung, heart and kidney allograft recipients and treatment of allograft rejection resistant to treatment with other immuno- suppressive medicinal products.
- By nephrologists only- for the prophylaxis of organ rejection in patients receiving allogenic kidney transplant.
- For dermatologists-for treatment of patients with moderate to severe atopic dermatitis in whom the use of alternative conventional therapy is advisable.

However, following the preliminary analysis of Adverse Drug Reactions (ADRs) from the PvPI database, it is reported that Tacrolimus is linked with Adverse Drug Reactions (ADRs) named Gingival Hypertrophy.

Gingival hypertrophy also known as gingival hyperplasia, gum hypertrophy or gingival enlargement, refers to excessive growth of the gums or gingiva around the necks of the teeth. The hypertrophic gingival tissue may be inflamed (gingivitis), in which case the gums are red, soft, shiny and bleed easily. Hyperplasia refers to an increased number of cells, and hypertrophy refers to an increase in the size of individual cells.

In light of the above, the Indian Pharmacopoeia Commission, Ministry of Health & Family Welfare, has advised Healthcare Professionals, Patients/Consumers to closely monitor the possibility of the above ADRs associated with the use of above suspected drugs.



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## Drug Safety Alert: IPC Flags Adverse Reactions Linked To Cephalosporin Antibiotic Cefoperazone

New Delhi: The Indian Pharmacopoeia Commission (IPC), through its recently issued drug safety alert for the month of August, has revealed that a broad-spectrum cephalosporin antibiotic Cefoperazone is linked with Adverse Drug Reactions (ADRs) named Coagulopathy, a condition in which the blood's ability to coagulate (form clots) is impaired..

This came after preliminary analysis of Adverse Drug Reactions (ADRs) from the Pharmacovigilance Programme of India (PvPI) database.

Cefoperazone is a broad-spectrum cephalosporin antibiotic used for the treatment of bacterial infections in various locations, including the respiratory tract, abdomen, skin, and female genital tracts.

Cefoperazone is a third generation cephalosporin antibiotic. Cefoperazone exerts its bactericidal effect by inhibiting the bacterial cell wall synthesis. It binds to specific penicillin-binding proteins (PBPs) located inside the bacterial cell wall, causing the inhibition of the third and last stage of bacterial cell wall synthesis. Cell lysis is then mediated by bacterial cell wall autolytic enzymes such as autolysins.

Following the preliminary analysis of Adverse Drug Reactions (ADRs) from the PvPI database, it is reported that Cefoperazone can lead to Coagulopathy.

Coagulopathy is a condition in which the blood's ability to coagulate is impaired. This condition can cause a tendency toward prolonged or excessive bleeding (bleeding diathesis), which may occur spontaneously or following an injury or medical and dental procedures.

Coagulopathy may cause uncontrolled internal or external bleeding. Uncontrolled bleeding can harm joints, muscles, or internal organs and pose a life-threatening risk if left untreated. People should seek immediate medical care for serious symptoms, including heavy external bleeding, blood in the urine or stool, double vision, severe head or neck pain, repeated vomiting, difficulty walking, convulsions, or seizures. They should seek prompt medical care if they experience mild but unstoppable external bleeding or joint swelling and stiffness.

In light of the above, the Indian Pharmacopoeia Commission, Ministry of Health & Family Welfare, has advised Healthcare Professionals, Patients/Consumers to closely monitor the possibility of the above ADRs associated with the use of above suspected drugs.



# Result of e-Poster & Animation/Video/Quiz Competition held during the 2<sup>nd</sup> National Pharmacovigilance Week

## Result of e-Poster Competition

**Theme :** Active Pharmacovigilance of SGLT2 Inhibitors or Role of Consumer Reporting in Pharmacovigilance

Prize	Name of Participants	Designation	AMC Name
First Prize	Ms. Sreelakshmi Nair	MBBS Second Year Student	Terna Medical College, Navi Mumbai
Second Prize	Ms. Ayushi Yadav	Junior Pharmacovigilance Associate	NCC-PvPI, IPC, Ghaziabad
Third Prize	Dr. Syed Sharjil Annes	Junior Resident	Dr. Ram Manohar Lohia Institute of Medical Sciences, Lucknow
	Dr. Prashant Maurya	Junior Resident	
	Dr. Shalini	Junior Resident	
	Dr. Prachi Chauhan	Junior Resident	
	Dr. Siddhant Lohia	Junior Resident	
Consolation Prize	Mr. Sohan Paikray	MBBS Second Year Student	All India Institute of Medical Sciences, Raipur, Chhattisgarh



# Result of Animation/Video Competition

**Theme :** Encouraging Reporting of ADR by Patients

Prize	Name of Participants	Designation	AMC Name
First Prize	Dr. Ghazal	Junior Pharmacovigilance Associate	All India Institute of Medical Sciences, Bhatinda
Second Prize	Dr. Shiva Murthy N	Coordinator, ADR Monitoring Centre	Dr. Chandramana Dayananda Sagar Institute of Medical Education and Research, Ramanagar, Karnataka
Third Prize	Dr. Arpita Roy	Postgraduate Student	Kasturba Medical College, Manipal
	Dr. Anisha B	Postgraduate Student	
	Dr. Shivani Singh	Postgraduate Student	
	Dr. Aditya Vinayak	Tutor	
Consolation Prize	Dr. Nikunj Rajkumar	Junior Resident	All India Institute of Medical Sciences, Raipur, Chhattisgarh
	Mrs.V. Sravana Swathi	Junior PvA	
	Dr. Mahesh Kumar B	Junior Resident	
	Dr. Yazhini R	Junior Resident	
	Dr. Abrahan Joseph	Junior Resident	
	Dr. Prachi Arunima	Junior Resident	
	Dr. Krishnapriya N	Junior Resident	
	Dr. Kiran Rang Shahi	Junior Resident	





# Result of Quiz Competition

Prize	Name of Participants	Designation	Posted at
First Prize	Dr. Vijit Agrawal	Senior Pharmacovigilance Associate	National Coordination Centre Indian Pharmacopoeia Commission Ghaziabad
	Hammad Ali	Pharmacovigilance Associate	
	Dr. Richa Chaudhary	Junior Pharmacovigilance Associate	
	Dr. Mahima Maheshwari	Junior Pharmacovigilance Associate	
	Dr. Abi S	Junior Pharmacovigilance Associate	
Second Prize	Dr. Shatrunajay Shukla	Scientific Assistant	National Coordination Centre Indian Pharmacopoeia Commission Ghaziabad
	Nikita Mishra	Materiovigilance Associate	
	Dr. Sneh Pal	Junior Pharmacovigilance Associate	
	Neha Nasim	Junior Pharmacovigilance Associate	
	Akash Deep Rawat	Junior Pharmacovigilance Associate	
Third Prize	Deepti Sachdeva	Junior Pharmacovigilance Associate	National Coordination Centre Indian Pharmacopoeia Commission Ghaziabad
	Aayushi Yadav	Junior Pharmacovigilance Associate	
	Tripti Purohit	Junior Pharmacovigilance Associate	
	Dr. Priyanka Kaushik	Junior Pharmacovigilance Associate	
	Surjit	Trainee	

# ☆☆☆ e-Poster Competition ☆☆☆







## Indian Pharmacopoeia Commission

National Pharmacovigilance Week

17 - 24 September, 2022



### What are ADRs?

**Any adverse/harmful reaction that is caused after taking any medicine.**

**Eg: Itching, rash, Diarrhea, Swelling, etc**



### Role of Consumer Reporting in Pharmacovigilance

Consumers can provide detailed first hand information on the adverse reactions experienced by them after taking medicine. They can contribute to identify unknown ADRs which help to create policies and guidelines to improve patient health & safety related to use of medicines.



### How a consumer can report easily?

If you face any adverse effects after taking any medicine, you can call on

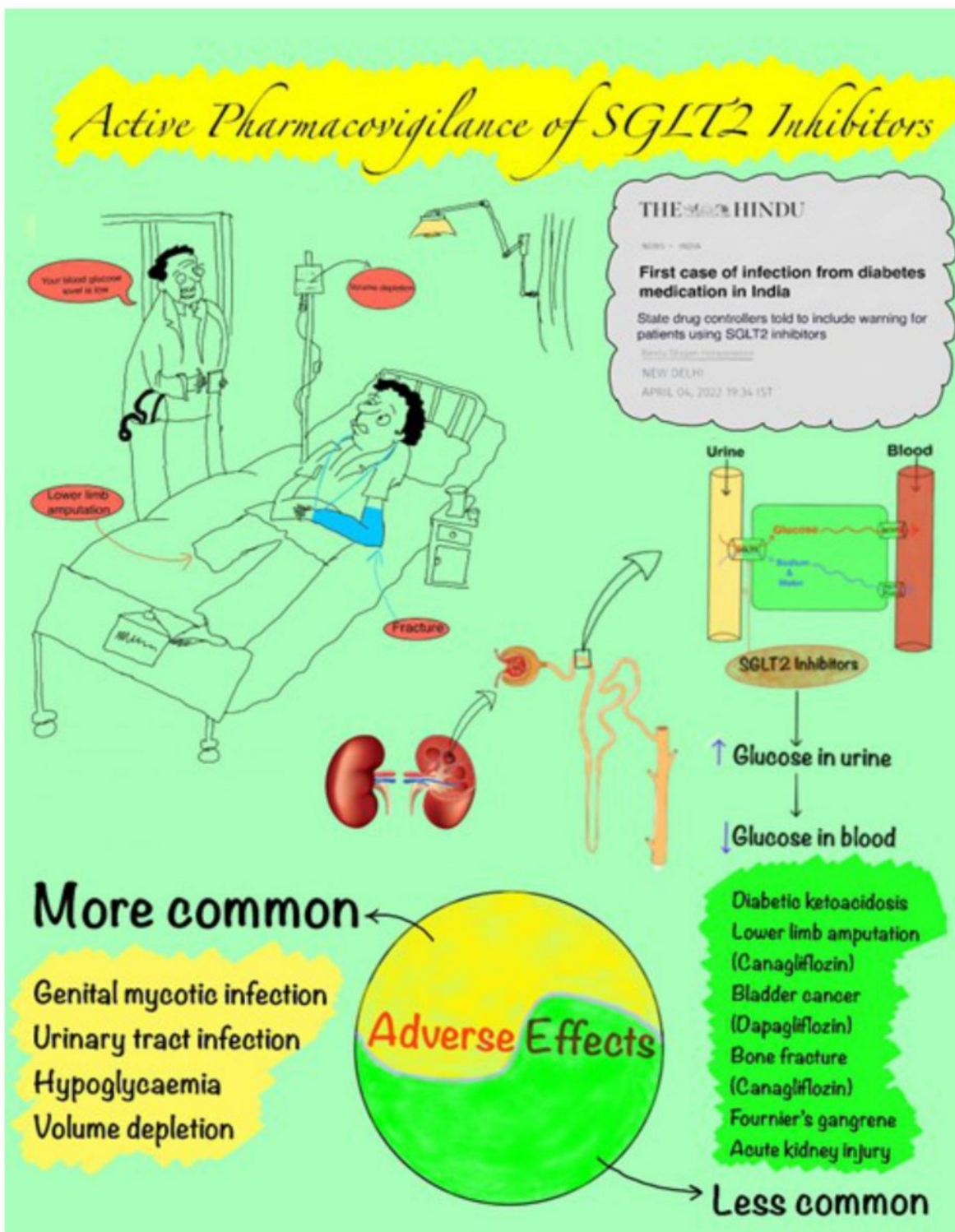
**1800 180 3024**

or via Mobile App available on Google play store

**'ADR PvPI'**



Let's join hands with PvPI for patient safety





## Skit/Nukkad Natak



*A skit was performed by MBBS Students of Santosh Medical College, Ghaziabad for creating awareness among general public for reporting Adverse Drug Reactions during the walkathon held on 20<sup>th</sup> September 2022.*





# Feedback on PvPI

The Pharmacovigilance Programme of India has taken the greatest initiation in the field of Pharmacovigilance and empowers all Health Care Professionals for ensuring patient safety. I appreciate the efforts of for their magnificent performance. I wish them good luck for the future endeavour towards patient safety.



**Dr. B. Vengamma**

*Director cum Vice-Chancellor,  
Senior Professor & HOD of  
Neurology  
SVIMS*

The National Coordination Centre of PVPI is encouraging all organizations such as academic institutions, hospitals, pharmaceutical industries, national medical council, state pharmacy councils, pharmacy professional organizations, and all healthcare professionals to conduct Pharmacovigilance activities that promote and advocate reporting of adverse drug reactions across the country. For the last two years, we have successfully conducted National Pharmacovigilance Week, CME events. More than 1,000 stakeholders were involved in our awareness activities, including students, doctors, nurses, technicians, other health providers, and the general public. All these were possible only because of the ever-supporting management and constant guidance and encouragement by NCC-PvPI, IPC.

**Dr Shiva Murthy N**

*Associate Professor,  
Department of Pharmacology  
CDSIMER*







**Dr. Rohtas Kanwar Yadava**  
*Principal*  
*Muzaffarnagar Medical College*

Pharmacovigilance Programme of India has increased the awareness among health care professionals for reporting adverse drug reactions and ensuring the safety of the patients.



# Forthcoming Events

**18<sup>th</sup> - 20<sup>th</sup>  
October, 2022**



Induction-cum-training programme on Pharmacovigilance for Coordinators/ Deputy Coordinators of newly recognized AMCs and newly recruited Pharmacovigilance Associates at AMCs

**31<sup>st</sup>  
October, 2022**



Training on “Importance and Strategy to involve patients directly into ADR reporting”

**14<sup>th</sup> - 18<sup>th</sup>  
November 2022**



23<sup>rd</sup> Skill Development Programme on Pharmacovigilance of Medical Products

**21<sup>st</sup>  
November 2022**



Introduction to MedDRA coding for Pharmacovigilance Associates at NCC/AMCs

**5<sup>th</sup> - 9<sup>th</sup>  
December, 2022**



Virtual training on “Pharmacovigilance Practices on Post COVID-19 World” under ITEC, Ministry of External Affairs, Govt. of India



# 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।



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

**For any other information/Suggestion/  
Query, please contact:**  
Officer Incharge  
Pharmacovigilance Programme of India  
**Email:** [lab.ipc@gov.in](mailto:lab.ipc@gov.in), [pvpi.ipc@gov.in](mailto:pvpi.ipc@gov.in)  
**Website:** [www.ipc.gov.in](http://www.ipc.gov.in)

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