# Newsletter

PHARMACOVIGILANCE PROGRAMME OF INDIA (PvPI)

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# Role of Pharmacogenomics in Pharmacovigilance

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National Coordination Centre - Pharmacovigilance Programme of India

A WHO Collaborating Centre for Pharmacovigilance in Public Health Programmes and Regulatory Services

Indian Pharmacopoeia Commission, Ministry of Health & Family Welfare,
Government of India

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

Dear Readers,

I am privileged to release the Pharmacovigilance Programme of India (PvPI) Newsletter Volume 15, Issue 2 for the index period of April to June, 2025 on the theme 'Role of Pharmacogenomics in Pharmacovigilance.'

During this period, 25 New Adverse Drug Reaction Monitoring Centres (AMCs) have been enrolled under PvPI and total number of AMCs are 1050 across the country. A total of 9.64 Lakh Individual Case Safety Reports (ICSRs) has been reported to PvPI as on 30th June 2025. The PvPI is regularly sensitizing its stakeholders about the pharmacovigilance and reporting of Adverse Events through Awareness Programmes, Trainings, Workshops, Skill Development Programmes, Continuing Medical Education (CME) etc. The PvPI has organized a total of 243 training programmes and trained a total of 11669 participants in the area of pharmacovigilance in this quarter.

The NCC-PvPI, IPC has issued a total of 180 drug safety alerts so far for the sensitization of healthcare professionals and reporting of such adverse drug reactions to PvPI, if encountered with the use of such drugs.

Pharmacogenomics plays a crucial role in pharmacovigilance by identifying, how genes affect an individual's response to administered drugs. By identifying genetic variations that influence drug metabolism and efficacy, pharmacogenomics can help to personalize drug therapy, leading to safer and more effective treatment. The integration of pharmacogenomics into pharmacovigilance has potential to significantly improve the patient outcome and optimize drug therapy. The Signal Review Panel of PvPI recommended Drug Safety Label Change in respect of carbamazepine as under – Patient may be screened for HLA-B*15:02 prior to initiating the Carbamazepine treatment, to the Central Drugs Standard Control Organization (CDSCO). The order was issued by the CDSCO to all States/UT(s) Drug Controllers for the same on 12th May 2015.

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

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

**(Dr. V. Kalaiselvan)**
Secretary-cum-Scientific Director
Indian Pharmacopoeia Commission
(Ministry of Health & Family Welfare,
Government of India)
Ghaziabad - 201002

# Role of Pharmacogenomics in Pharmacovigilance

Pharmacogenomics (PGx) is the study of how an individual's genetic makeup affects response to drugs. Pharmacogenomics plays a crucial role in pharmacovigilance by identifying genetic variations that influence pharmacokinetics and pharmacodynamics. A number of factors influence drug response such as age, sex, liver/kidney function, environmental exposures, comorbid conditions and drug-drug interactions etc. The integration of pharmacogenomics into pharmacovigilance has potential to improve the patient outcome and optimize drug therapy.

## Scope of Pharmacogenomics

1. **Enhancing drug safety and efficacy**

- **Identifying susceptible individuals to Adverse Drug Reactions (ADRs)**
  Pharmacogenomics can help to identify the individuals, who have high risk to develop ADR due to genetic variations in drug metabolizing enzymes, drug transporters, drug targets etc.
- **Optimizing drug dosing**
  By understanding how genes influence drug metabolism, clinicians can adjust dosage for effective treatment and reduce the risk of developing ADRs.
- **Personalized medicines**
  The goal of pharmacogenomics is to identify the personalized medicines, where the drug regimen is tailored according to the individual patient's genetic profile leading to safer and more effective treatment.

2. **Improving pharmacovigilance practices**

- **Detection of ADRs at early stages**
  Pharmacogenomics data can be integrated with the pharmacovigilance systems to improve the early detection of ADRs.
- **Understanding mechanism of ADRs**
  Mechanism of ADRs can be better understood by studying genetic factors associated with the ADRs leading to targeted prevention strategies.
- **Optimization of drug development**
  Pharmacogenomics can be integrated into the drug development process, helping to identify potential safety concerns early during the clinical trial stage.[1]

The following table provides a comprehensive overview of some drugs, where Pharmacogenomics may be very useful.

| Drugs | Genes /Variants involved | Associated ADRs |
|---|---|---|
| Carbamazepine | HLA-B*15:02 | Stevens–Johnson Syndrome (SJS/TEN)[2,5] |
| Allopurinol | HLA-B*58:01 | SCARs, including SJS/TEN and drug-induced hypersensitivity syndromes (DIHS).[3,5] |
| Phenytoin | HLA-B15:02 and CYP2C93 | SJS/TEN.[4,5] |
| Lamotrigine | HLA-B*15:02 | SJS/TEN.[5] |
| Nevirapine | HLA-B35:05, Cw8, and HLA-DRB1*01:01 | Various skin reactions and Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS).[5] |

The prior knowledge and screening for these genetic variants can help the medical practitioners in avoiding the adverse drug reactions in susceptible individuals. There is wealth of emerging literature available on this topic.

In the 4th Signal Review Panel (SRP) meeting, SRP recommended the following Drug Safety Label Change - *Patient may be screened for HLA-B*15:02 prior to initiating the Carbamazepine treatment* (For detail, please refer link: Regulatory Pharmacovigilance -Imp Safety label changes to Carbamazepine containing products -Reg.pdf. The order was issued by the CDSCO to all States/UT(s) Drug Controllers for the same on 12th May 2015.

At present, a total of 740 ICSRs have been reported for this Drug-Event combination in PvPI database.

## Challenges in Pharmacogenomics

There are many challenges in pharmacovigilance such as;

- Pharmacogenomics testing is not yet a standard part of clinical practices for many drugs.
- High cost and limited access
- Some genes and pathways involved in drug metabolism remain poorly understood.
- Integrating genomic data into electronic health records (EHRs) and pharmacovigilance databases is technically and ethically complex. Such issues include standardization, data privacy, and interoperability.

## Conclusion

By integrating genetic data into drug safety monitoring, PGx may help in identifying patients at higher risk for developing adverse drug reactions to certain drugs, revising drug safety labelling and guiding personalised treatment strategies.

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# Pharmacovigilance in India: Challenges and Future

*Dr. M. Ramesh, Professor,*
*JSS College of Pharmacy, JSS AHER, Mysuru and*
*Coordinator, AMC and RTC - JSS Medical College Hospital, Mysuru*

The assurance of patient safety is the cornerstone of high-quality health care. Pharmacovigilance, plays a critical role in this process, and is a continuous process that requires ongoing monitoring, assessment, and action to minimize risks and improve patient safety. In India, Pharmacovigilance has expanded its scope spanned since its inception to embrace the monitoring of herbal, traditional and complementary medicines, blood products, biological, vaccines and medical devices with the aim of improving patient safety. The Pharmacovigilance Programme of India (PvPI) envisions a nationwide system for patient safety reporting, analyzing the benefit-risk ratios, minimizing the risks through effective communication with different stakeholders besides supporting regulatory agencies. By bringing the regulatory provisions for reporting and establishing the pharmacovigilance system at pharmaceutical companies has added a new dimension in patient safety landscape and effective risk management.

If the medicines are to be used safely, the challenges that are faced in the pharmacovigilance system must be efficiently overcome. In India, one of the major challenges Pharmacovigilance faces is the sheer volume of data due to increased consumption of medications that needs to be monitored make it difficult to identify potential safety concerns promptly. Also, the ability to effectively monitor and investigate adverse drug reactions is greatly hindered due to lack of resources and committed personnel. Large data sets from diverse sources, such as wearable medical devices and electronic health records, are one difficulty. Real-world evidence (RWE) is increasingly being used to complement traditional clinical trial data. Furthermore, the emerging concept of precision pharmacovigilance throws newer challenges and opportunities, demanding a shift from traditional approaches to ensure patient safety surveillance that is largely aligned with the individual patient health care needs.

It is obvious that the future of Pharmacovigilance faces several challenges. Nevertheless, the science of Pharmacovigilance is constantly evolving and adapting to changes in the spectrum of healthcare. The enormous efforts made by the PvPI at Indian Pharmacopoeia Commission and Central Drugs Standard Control Organisation (CDSCO) to strengthen the country's pharmacovigilance system and regulations respectively resulted in significant progress in the field of pharmacovigilance in recent years. Further, as the Indian healthcare system and pharmaceutical industry expand, the future of pharmacovigilance in India is expected to grow and develop. However, long-term futuristic strategic planning is required to further strengthen the system to meet the demands of health care need owing to growing population, continued growth of pharmaceutical industry, technological advancement and changing drug regulatory environment.

# Enrolment of New AMCs

NCC-PvPI, IPC has enrolled 25 new AMCs in 26$^{th}$ Phase of PvPI expansion. The total number of AMCs enrolled by the end of this quarter were 1075 across the country. The list of newly enrolled AMCs is mentioned below:

| S. No. | States/UTs | Name of Hospitals/Medical Colleges/Institutes | Status of Hospital (Government/ Non-Government) |
|---|---|---|---|
| 1. | Andhra Pradesh | Government Medical College and Government General Hospital, Machilipatnam (Near Radar Station), Krishna, Andhra Pradesh - 521002 | Government |
| 2. | Chhattisgarh | Suyash Institute of Medical Science Pvt. Ltd., Kota Gudiyari Road, Raipur, Chhattisgarh - 492001 | Non-Government |
| 3. | Gujarat | NCT Multispeciality Hospital, NCT Campus, Chital Road, Amreli, Gujarat - 365601 | Non-Government |
| 4. | | All India Institute of Medical Sciences (AIIMS), Parapipaliya, Khanderi, Rajkot, Gujarat - 360110 | Government |
| 5. | | GMERS Medical College and Hospital, Near Majevadi Gate, Mullawada, Junagadh, Gujarat - 362001 | |
| 6. | Haryana | Sushruta Hospital, Bye Pass Road, Yamuna Nagar, Haryana - 135001 | Non-Government |
| 7. | | Shah Satnam Ji Speciality Hospitals, Bhadra Road, Near Shah Satnam ji Dham, Sirsa, Haryana - 125055 | |

| | | | |
|---|---|---|---|
| **8.** | | Healing Touch Hospital,<br>Sultanpur Chowk, Near Dhulkot Barrier,<br>Ambala Chandigarh Expressway,<br>Ambala, Haryana - 134003 | |
| **9.** | **Karnataka** | Surgeon's Hospital,<br>Ankadakatte, Koteshwara, NH-66, Udupt,<br>Karnataka - 576222 | Non-Government |
| **10.** | **Madhya Pradesh** | Cancer Hospital and Research Institute,<br>Cancer Hill, Mandre ki Mata Road,<br>Lashkar, Gwalior,<br>Madhya Pradesh - 474009 | Non-Government |
| **11.** | **Punjab** | Apex Hospital and Maternity Home,<br>520/521/522, New Jawahar Nagar,<br>Jalandhar, Punjab-144001 | Non-Government |
| **12.** | | Shakuntla Devi Vig Hospital,<br>Main Kapurthala Road, Opposite Sports College, Jalandhar-144002 | |
| **13.** | | Johal Multispeciality Hospital,<br>Rama Mandi, Hoshiyarpur Road,<br>Jalandhar, Punjab - 144005 | |
| **14.** | | Dr. Hardas Singh Hospital,<br>882, Circular Road, Amritsar,<br>Punjab - 143001 | |
| **15.** | | BBC Heartcare- Pruthi Hospital, 301,<br>Mahavir Marg, Lajpat Nagar,<br>Jalandhar-144001 | |
| **16.** | | Pragma Medical Institute,<br>Opp. Gianizail Singh College, Dabwali Road, Bathinda, Punjab - 151001 | |
| **17.** | **Rajasthan** | Government Amrit Kaur Hospital,<br>Near Champa Nagar, Beawar,<br>Rajasthan - 305901 | Government |

| | | | |
|---|---|---|---|
| **18.** | **Tamil Nadu** | Government Sivagangai Medical College, Sivagangai, Tamil Nadu - 630561 | Government |
| **19.** | **Uttar Pradesh** | Nova Hospital Ltd., Vikas Khand, Gomti Nagar, Lucknow, Uttar Pradesh - 226010 | Non-Government |
| **20.** | | Apollo Cradle and Apollo Spectra Hospital (Unit of Green Noida Health and Research Institute Hospitals Pvt. Ltd.), NH-27, P-7, Near IFS Villa Greater Noida, Gautam Budh Nagar, Uttar Pradesh - 201308 | |
| **21.** | | SAS Hospital, Rameshwar Road, Harahua, Varanasi, Uttar Pradesh - 221005 | |
| **22.** | | Oriana Hospital Pvt. Ltd., Varanasi, Uttar Pradesh - 221005 | |
| **23.** | **Uttarakhand** | Kailash Hospital (A unit of Kailash Healthcare Ltd.), Haridwar Road, Near Joriwala Chowk, Dehradun, Uttarakhand - 248001 | Non-Government |
| **24.** | **Lakshadweep** | Government Indira Gandhi Hospital, Karavatti, Lakshadweep - 682555 | Government |
| **25.** | **New Delhi** | Madhukar Rainbow Children's Hospital, and Birthright, FC-29 5, Geetanjali Marg, Block A, Shivalik Colony, Malviya Nagar, South Delhi-110017 | Non-Government |

# Regional Training Programme for MAHs at School of Pharmacy, Techno India University, Kolkata

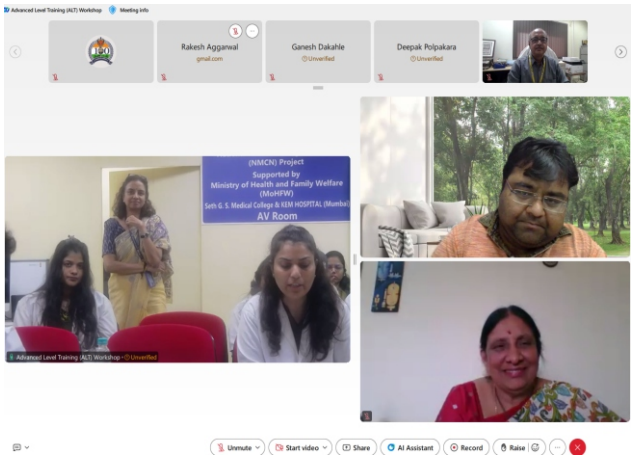
NCC-PvPI has organised Regional Training Programme for Marketing Authorization Holders (MAHs) in collaboration with School of Pharmacy, Techno India University, Kolkata on 8th April, 2025 at conference room of this university. The objective of this training programme was to sensitize the MAHs about changes made in the Pharmacovigilance Guidance Document for Marketing Authorization Holders (MAHs) of Pharmaceutical Products, Version 2.0. Prof. Beduin Mahanti, Director, School of Pharmacy, Techno India University, Kolkata has coordinated this event with his team. Dr Jai Prakash, Dr Shashi Bhushan and Mr. Vipin Sharma, have coordinated from NCC-PvPI and attended this regional training programme.

A panel was also constituted to resolve the queries of participants. The panellists were as;

- Prof. Santanu Tripathi, Principal and Professor of Pharmacology, Jagannath Gupta Institute of Medical Sciences and Hospital, Kolkata.
- Dr. Subhash C Mandal, National Hon. General Secretary of Indian Pharmaceutical Association, Kolkata.
- Dr Vivek Ahuja, Sr. Vice-President, Eversana Lifesciences Services.
- Mr. Arup Kumar Chatterjee, Deputy Drugs Controller of India, CDSCO (East Zone Office), Kolkata
- Dr Jai Prakash, Officer-In-charge of PvPI, IPC, Ghaziabad
- Prof. Beduin Mahanti, Director, School of Pharmacy, Techno India University, West Bengal

A total of 53 participants attended this training programme

# Advanced Level Training Programme in Pharmacovigilance organized by Seth GS Medical College and KEM Hospital



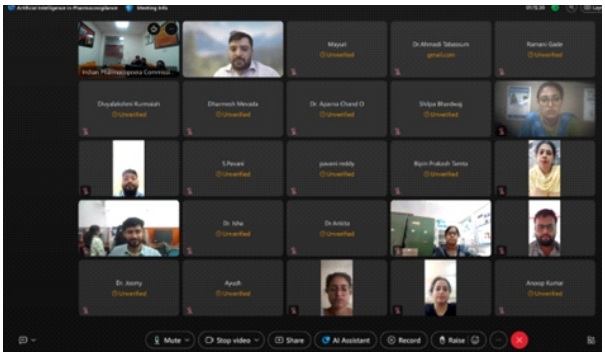

Dr Nitya Gogtay, Coordinator, Dr Mahesh Belhekar, Deputy Coordinator and Ms. Pratiksha Thombare, Pharmacovigilance Associate at Seth GS Medical College and KEM Hospital, Mumbai organised Advanced Level Training Programme (ALT) on the theme - Navigating and addressing challenges with vaccine and monoclonal antibody safety in Pharmacovigilance through virtual mode on 11th April 2025. In this training programme, Dr. Vijit Agrawal, Senior Pharmacovigilance Associate delivered a talk on Perspectives from the Indian Pharmacopoeia Commission. A total of 203 participants attended this training programme.

# Continuing Medical Education Programme organised by Jawaharlal Nehru Medical College, Aligarh

Prof. Syed Ziaur Rahman, Coordinator, Dr. Imrana Masood, Deputy Coordinator and Mr. Gufran Ali, Pharmacovigilance Associate at Jawaharlal Nehru Medical College (JNMC), Aligarh Muslim University (AMU) as an AMC organised Continuing Medical Education (CME) programme on Current Perspective on Pharmacovigilance 16th April 2025. Prof. Mohammad Habib Raza, Dean, Faculty of Medicine, AMU inaugurated this training programme. The objective of this event was to address the crucial role of clinicians in reporting adverse events. In this training programme, Dr. R.S. Ray, Scientific Assistant briefed on Current landscape of PvPI and its evolving impact on national healthcare system. The programme was concluded with a vote of thanks by Dr. Imrana Masood, acknowledging the contributions of Mr. Gufran Ali and Junior Residents Dr. Nachiket Brahmankar, Dr. Isna Rafat Khan, and Dr. Supriya Sahu. A total of 113 participants attended this training programme.

# Training on Artificial Intelligence

NCC-PvPI organised a virtual training on Artificial Intelligence (AI) in Pharmacovigilance for PvPI staff on 30th April, 2025. In this training programme, Mr. Rachit Khullar, Manager, Innovation Lead, Safety and Logistics, Parexel discussed on Artificial Intelligence and its importance in pharmacovigilance along with AI driven data processing techniques and AI assisted submission timelines and anticipated challenges ahead. A total of 93 participants attended this training programme.



# Faculty Development Programme on integrating Pharmacovigilance into Nursing Practices

Dr Latha Venkatesan, Prof-cum-Principal, College of Nursing, All India Institute of Medical Sciences (AIIMS), New Delhi in collaboration with NCC-PvPI organised 'Faculty Development Program on integrating pharmacovigilance into nursing practice on 15th May 2025. The objective of this training programme was to sensitize the faculty and nursing staff of college about the reporting of Adverse Event to the PvPI. This programme was inaugurated by Dr Latha Venkatesan. In this programme, Dr Jai Prakash, Officer-in-Charge, PvPI delivered talk on Current Scenario of PvPI. Dr. R.S. Ray has also briefed about basics of Pharmacovigilance including tools for ADR reporting and Hands-on-Training on ADR reporting. A total of 65 participants attended in this training programme.

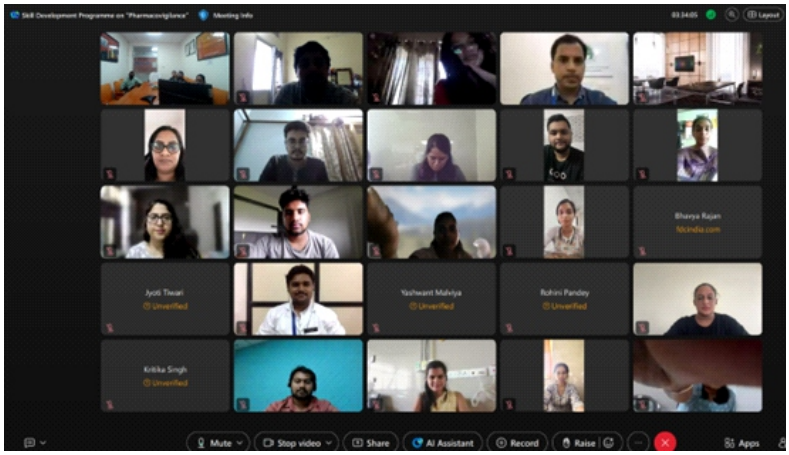
# CME organised by GMERS Medical College and General Hospital, Gandhinagar

Dr. Darshan J. Dave, Coordinator, Dr. Jigar Modi, Deputy Coordinator and Ms. Shivani Trivedi, Pharmacovigilance Associate at GMERS Medical College and General Hospital, Gandhinagar (AMC of PvPI) organised Continuing Medical Education programme on Challenges and way-out for Community Involvement in Pharmacovigilance on 16th May 2025. A total of 170 participants including doctors, pharmacists, nurses and other healthcare professionals attended this CME.

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

Dr. Sanjeev Sharma, Coordinator, Ms. Terra Tyagi, Deputy Coordinator and Sugandha Sharma, Pharmacovigilance Associate at Indraprastha Apollo Hospitals, New Delhi (AMC of PvPI) in collaboration with NCC-PvPI organised one day Workshop-cum-Training Programme on Pharmacovigilance for NABH Accredited Hospitals on 30th May 2025. The objective of the training Programme was to enhance pharmacovigilance skills of the healthcare professional of the NABH accredited hospitals in order to promote the patient safety. A total of 108 participants attended this workshop.

# 33rd Skill Development Programme on Pharmacovigilance



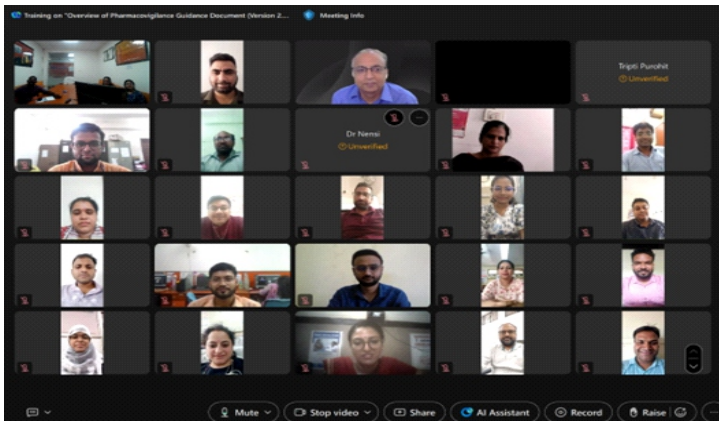
The NCC-PvPI, IPC has conducted 33rd Skill Development Programme (SDP) on Pharmacovigilance in virtual mode from 2nd- 6th June 2025. In this SDP, a total of 20 technical sessions were conducted on various topics in pharmacovigilance by the subject experts from the pharmaceutical industries, academic and research Institutions. A total of 144 participants attended this training programme including industry professionals, physician, academicians, pharmacy students, medical students, and pharmacists across the country. At the end, the participants provided their positive feedback and also appreciated the efforts of PvPI team for organising such informative training programmes.

# Training Programme on Revised AEFI Guidelines for Vaccines

The Central Research Institute (CRI), Kasauli in collaboration with PvPI, IPC has organised training programme on Revised AEFI Guidelines for Vaccines from 4th to 5th June 2025 at Conference Hall, CRI, Kasauli. The objective of this training programme was to discuss and amend the new changes made in revised AEFI guidelines for vaccines. Dr. RS Ray, Scientific Assistant, PvPI, IPC and Dr. Vijit Agrawal, Sr. Pv Associate, PvPI, IPC had attended this training programme. A total of 50 participants attended this event.

# Lecture organised on Overview of Pharmacovigilance Guidance Document for MAHs

NCC-PvPI, IPC has organised virtual training on Overview of Pharmacovigilance Guidance Document for MAHs of Pharmaceutical Products, Version 2.0 on 17th June 2025 for PvPI staff. In this training programme, Dr Vivek Ahuja, Senior Vice President, Eversana has given overview of all six chapters in this Guidance Document. A total of 83 participants attended this training programme.




# Interactive Session on Pharmacovigilance and ADR Reporting

NCC-PvPI, IPC, has organised an Interactive Session on 'Pharmacovigilance and ADR Reporting' on 30th June 2025 at PvPI Conference Hall. In this interactive session, Prof. Anurag Srivastava, Chief Operating Officer, Principal and Dean, Sri Gorakhsnath Medical College Mahayogi Gorakshnath University, Gorakhpur, Uttar Pradesh gave an overview of Pharmacovigilance and ADR reporting by highlighting common ADRs associated with the use of anticancer drugs including challenges for their reporting. A total of 41 participants attended this interactive session.

# Advanced Level Training Programme organised by Madras Medical College, Chennai

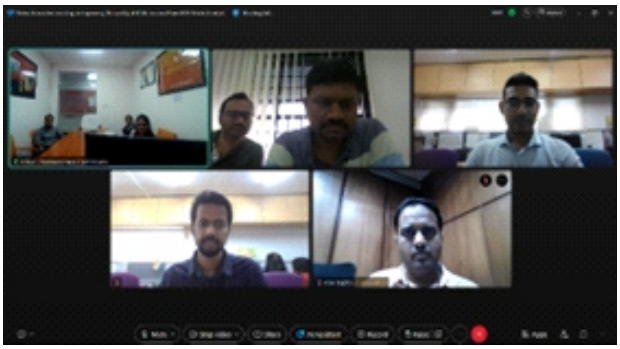
Prof. K.M Sudha, Coordinator, Institute of Pharmacology, Madras Medical College, Chennai and Mrs. Siddiraju Devipriya, Pharmacovigilance Associate (AMC and RTC of PvPI) organised Advanced Level Training (ALT) programme in pharmacovigilance on 25th April, 2025 through hybrid mode. Dr E Theranirajan, Dean and Dr M Kavitha, Vice Principal of Madras Medical College highlighted the role of healthcare professionals in ADR reporting for better patient safety. In this training programme, Dr Jai Prakash, Officer-in-Charge, PvPI also delivered a talk on Updates on Pharmacovigilance Programme of India. A total of 217 participants attended this training programme.

# Interactive meetings with Marketing Authorization Holders

The objective of Interactive meetings is to review the quality, number of ICSRs received in a calendar year, and completeness score of ICSRs received from Marketing Authorization Holders and inform the same to representatives of Marketing Authorization Holders for taking improvement measures. Details of such Interactive meetings held virtually with Marketing Authorization Holders are as follows:

| S. No. | Date | Marketing Authorization Holders | No. of Participants |
|---|---|---|---|
| **1.** | 30th April 2025 | Akums Drugs and Pharmaceuticals Limited | 16 |
| **2.** | 30th May 2025 | USV Private Limited | 8 |


*NCC-PvPI, IPC team, and Akums Drugs and Pharmaceuticals Limited Representatives*



*NCC-PvPI, IPC team, and USV Private Limited Representatives*

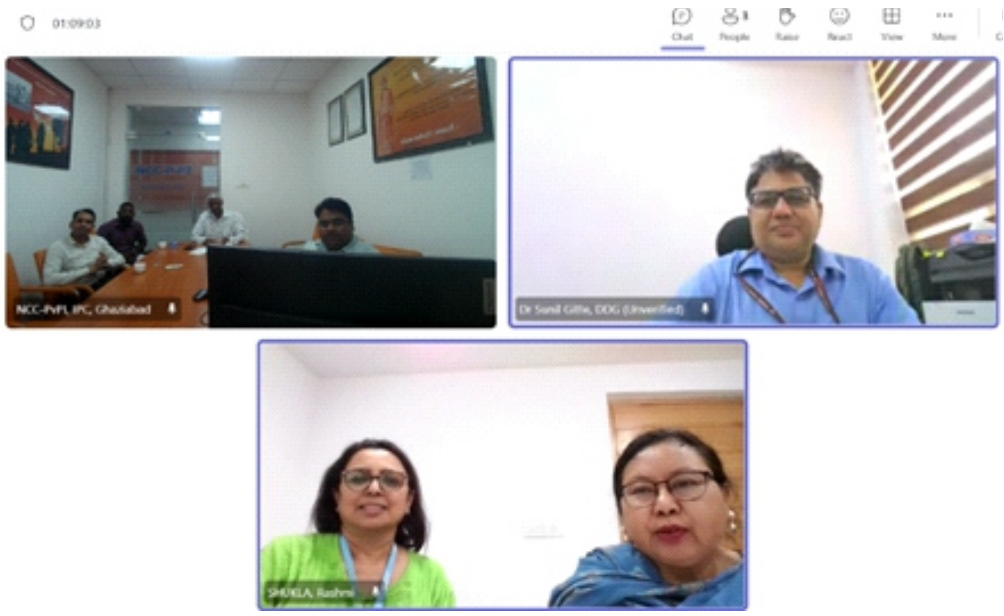
# Monthly trends of training programmes conducted during index period

The NCC-PvPI, IPC organised a total of 243 training programmes including Skill Development Programmes, Continuing Medical Education, Advanced Level Training Programmes etc. and trained a total number of 11669 participants in the area of Pharmacovigilance across the country.


*Figure - 1: Monthly trends of training programmes*

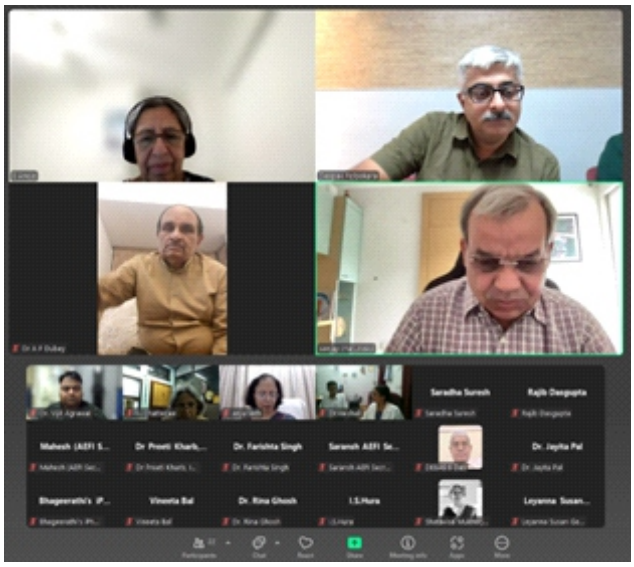
# Participation in National Health Programme (NHP)

The Central Leprosy Division, Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India has organised virtual Introductory Meeting on Pharmacovigilance for Antileprotics drugs on 27th May 2025. The objective of this meeting was to discuss the National Strategic Plan 2023-27 for National Leprosy Eradication Programme (NLEP). On bhalf of NLEP, Dr. Sunil Gitte, DDG Leprosy & his team and from WHO Dr. Rashmi Shukla, NPO Leprosy joined this meeting. Dr. Jai Prakash, Officer-in-Charge, PvPI, Dr Shashi Bhushan, Senior Scientific Officer, PvPI, Dr R.S Ray Scientific Assistant, PvPI and Dr Vijit Agarwal, Senior Pharmacovigilance Associate, PvPI had attended this meeting.



# National AEFI Committee meeting

The Adverse Event Following Immunization (AEFI) Secretariat has organised virtual National AEFI Committee meeting from 24th to 25th June, 2025 to discuss the Causality Assessment of AEFI cases done by the district subcommittees as well as by the Delhi State AEFI committee. From PvPI, Dr. Vijit Agrawal, Senior Pharmacovigilance Associate had attended this meeting.



# New drugs approved in India

The following new drugs were approved by the CDSCO during this index period;

| S. No. | New Drugs | Approved Indication(s) | |
|---|---|---|---|
| **1.** | Tucatinib hemiethanolate bulk drug & Tucatinib tablets 50 mg and 150 mg | Indicated in combination with trastuzumab and capecitabine for treatment of adult patients with advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases, who have received one or more prior anti HER2-based regimens in the metastatic setting. | 8th April 2025 |
| **2.** | Zanubrutinib capsules 80 mg | It is indicated for the treatment of adult patients with:<br>• Mantle Cell Lymphoma (MCL) who have received at least one prior therapy.<br>• Waldenstrom's macrogloubulinemia (WM)<br>• Relapsed or refractory marginal zone lymphoma (MZL) who have received at least one anti-CD20-based regimen.<br>• Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL).<br>• Relapsed or refractory follicular lymphoma (FL), in combination with obinutuzumab, after two or more lines of systemic therapy. | 8th April 2025 |
| **3.** | Linaclotide Bulk Drug & Linaclotide Capsule 72 mcg & Linaclotide Capsule 145 mcg | Indicated in adults for the treatment of Chronic idiopathic constipation. | 21st April 2025 |
| **4.** | Siponimod Hemifumarate Bulk Drug & Siponimod Tablets 0.25 mg/1mg/2mg | For the treatment of patients with secondary progressive multiple sclerosis (SPMS) with active disease as evidenced by relapses or imaging features of inflammatory activity. | 9th May 2025 |

| | | | |
|---|---|---|---|
| **5.** | Ivosidenib 250 mg film coated tablet | It is indicated,<br>• In combination with Azacitidine for the treatment of adult patients with newly diagnosed acute myeloid leukaemia (AML) with an isocitrate dehydrogenase-1(IDH1) R132 mutation who are not eligible to receive standard Induction chemotherapy.<br>• As a monotherapy for the treatment of adult patients with locally advanced or metastatic cholangiocarcinoma with an IDH1 R132 mutation who were previously treated by at least one prior line of systemic therapy. | 14th May 2025 |
| **6.** | Tegoprazan Tablet 50 mg | Indicated for:<br>Erosive Gastroesophageal Reflux Disease<br>Non-erosive Gastroesophageal Reflux Disease<br>Gastric Ulcer | 28th May 2025 |

**Source:**

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

☞ Healthcare Professionals, Patients/Consumers are advised to closely monitor the possibility of ADR associated with the use of above new drugs. If, any reaction is encountered, please report to the NCC-PvPI, IPC by filling of Suspected Adverse Drug Reactions Reporting Form for HCP/Medicines Side Effect Reporting Form for Consumer available at http://www.ipc.gov.in and PvPI Helpline Number. 1800-180-3024.

# Drug Safety Alerts

The NCC-PvPI, IPC issued the folowing drug safety alerts and shared with AMCs through email for the sensitization of healthcare professionals, thereby strengthening the reporting of ICSRs to PvPI. The PvPI, IPC being a WHO Collaborative Centre also shared the drug safety alerts with South-East Asia Regional Network (SEARN) countries through email.

| S. No. | Drug Safety Alert Issue Date | Suspected drugs | Indication(s) | Adverse Drug Reactions |
|---|---|---|---|---|
| **1.** | 13th May, 2025 | Sulfamethoxazole + Trimethoprim | For the treatment of Urinary Tract infection; Respiratory-tract including Bronchitis, infection Pneumonia, infections in Cystic Fibrosis, Melioidosis, Listeriosis, Brucellosis, Granuloma Inguinale, Otitis Media, Skin infection, Pneumocystis Carinii Pneumonia. | Leukopenia |
| **2.** | 27th June, 2025 | Beta-blockers (Propranolol, Metoprolol) | **Propranolol**<br>For the treatment of cardiac arrhythmias, tachycardia, hypertrophic obstructive cardiac myopathy, pheochromocytoma, thrombosis, management of angina, essential and renal hypertension, prophylaxis of migraine.<br>**Metoprolol**<br>For the treatment of supraventricular arrythmia, angina pectoris, hypertension, myocardial infarction, migraine prophylaxis, hyperthyroidism, heart failure. | Psoriasis |

| | | | | |
|---|---|---|---|---|
| **3.** | 27th June, 2025 | Beta blockers (Metoprolol, Propranolol, Atenolol, Carvedilol) | **Metoprolol**<br>For the treatment of Supraventricular arrythmia, angina pectoris, hypertension, myocardial infarction, migraine prophylaxis, hyperthyroidism, heart failure.<br>**Propranolol**<br>For the treatment of Cardiac arrhythmias, tachycardia, hypertrophic obstructive cardiac myopathy, pheochromocytoma, thrombosis, management of angina, essential and renal hypertension, prophylaxis of migraine.<br>**Atenolol**<br>For the treatment of hypertension, angina pectoris, cardiac arrhythmias.<br>**Carvedilol**<br>To reduce cardiovascular mortality in clinically stable patients, who have survived the acute phase of a myocardial infarction and have a left ventricular ejection fraction of 40% (with or without symptomatic heart failure).<br>For the treatment of Congestive Heart Failure (CHF).<br>For the treatment of mild to severe chronic heart failure.<br>For the treatment of left ventricular dysfunction following myocardial infarction in clinically stable patients.<br>For the treatment of hypertension. | Erectile Dysfunction (Reversible) |

☞ Healthcare Professionals, Patients/Consumers are advised to closely monitor the possibility of the above ADRs associated with the use of above suspected drugs. If, such reactions are encountered, please report to the NCC-PvPI, IPC by filling of Suspected Adverse Drug Reactions Reporting Form for HCP/Medicines Side Effect Reporting Form for Consumer available at http://www.ipc.gov.in and also through PvPI Helpline Number 1800-180-3024.

Press & Media

Hindustan Times (Lucknow)

# Govt warns some heart meds can cause psoriasis

Medications • Health • Pharmacology • Medicine • Pharmaceutical Industry • Industries

5 Jul 2025 +20 more Priyanka Sharma priyanka.sharma@livemint.com

Beta-blockers are often prescribed by doctors to manage abnormal heart rhythms, prevent heart attacks.

Indian Pharmacopoeia Commission (IPC) has issued an alert on widely-prescribed beta-blockers (heart medications), saying that these drugs can cause severe adverse reactions, including erectile dysfunction and psoriasis (a chronic skin condition).

Beta-blockers, often prescribed by doctors to manage abnormal heart rhythms, prevent heart attacks, and treat migraines, are a cornerstone in cardiovascular care.

However, a recent analysis of adverse drug reactions by the IPC revealed that combinations of beta-blockers such as Propranolol and Metoprolol are associated with psoriasis. Furthermore, combinations including Metoprolol, Propranolol, Atenolol,

World Health Organization
WHO pharmaceuticals NEWSLETTER
2025 No. 1

## Metronidazole, tetracycline

### Risk of fixed drug eruption

**India.** The Signal Review Panel of Pharmacovigilance Programme of India (PvPI), Indian Pharmacopoeia Commission (IPC) has confirmed fixed drug eruption associated with the use of metronidazole and tetracycline, respectively.

The NCC-PvPI, IPC has received and reviewed individual case safety reports (ICSRs) for fixed drug eruption with the use of metronidazole or tetracycline, and found causal relationships between the event and each medicine.

The National Coordination Centre (NCC)-PvPI, IPC has recommended to the Central Drugs Standard Control Organization (CDSCO) to include fixed drug eruption as an adverse drug reaction in the product information for metronidazole and tetracycline.

**Reference:**
Recommendations of Signal Review Panel, IPC, 30 October 2024 (link to the source within www.ipc.gov.in)

## Vancomycin

### Risk of drug reaction with eosinophilia and systemic symptoms (DRESS) syndrome

**India.** The Signal Review Panel of PvPI, IPC has confirmed drug reaction with eosinophilia and systemic symptoms (DRESS) syndrome associated with the use of vancomycin.

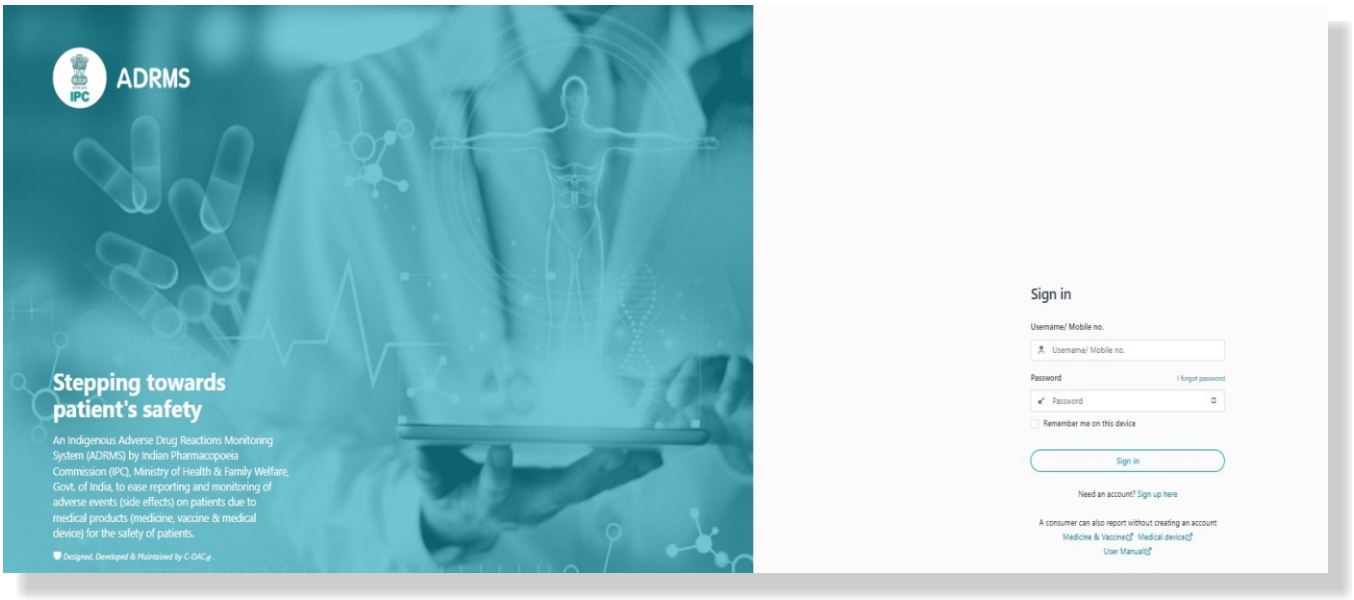
The NCC-PvPI, IPC has received and reviewed ICSRs for DRESS syndrome with the use of vancomycin, and found a causal relationship between them.

The NCC-PvPI, IPC has recommended to the CDSCO to include DRESS syndrome as an adverse drug reaction in the product information for vancomycin.

**Reference:**
Recommendations of Signal Review Panel, IPC, 30 October 2024 (link to the source within www.ipc.gov.in)

# Forthcoming Events

| S. No. | Date | Title | Who can participate? |
|---|---|---|---|
| **1.** | 18th-22nd August, 2025 | 34th Skill Development Programme on Pharmacovigilance at NCC-PvPI, IPC (Virtual) | • Healthcare Professionals<br>• Pharmacovigilance Professionals<br>• Medical/Para-medical/Pharmacy Students<br>• Pharmacists<br>• Academicians |
| **2.** | 17th - 23rd September, 2025 | 5th National Pharmacovigilance Week 2025 | • Healthcare Professionals<br>• Professional bodies Representatives<br>• Medical/Pharmaceutical/Nursing Institutions Representatives<br>• ADR Monitoring Centres (AMCs)<br>• Pharmacovigilance Professionals<br>• Medical/Para-medical/Pharmacy Faculty and Students<br>• Pharmacists |
| **3.** | October, 2025 | Refresher Training on Signal Detection in Pharmacovigilance | • Coordinators<br>• Deputy Coordinators<br>• PV Associates at AMC and NCC |
| **4.** | 3rd - 9th November, 2025 | MedSafetyWeek-2025 | • Healthcare Professionals<br>• Professional bodies<br>• Medical/Pharmaceutical/Nursing Institutions<br>• ADR Monitoring Centres (AMCs)<br>• Pharmacovigilance Professionals<br>• Medical/Para-medical/Pharmacy Faculty and Students<br>• Pharmacists |
| **5.** | 10th-14th November, 2025 | 35th Skill Development Programme on Pharmacovigilance at NCC-PvPI, IPC (Virtual) | • Healthcare Professionals<br>• Pharmacovigilance Professionals<br>• Medical/Para-medical/Pharmacy Students<br>• Pharmacists<br>• Academicians |
| **6.** | December, 2025 | Soft Skills and Communications in Pharmacovigilance | • Coordinators, Deputy Coordinators & PV Associates at AMC and NCC |




**Scan QR Code to report AEs/ADRs via ADRMS**

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

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

### औषधि सतर्कता कार्यक्रम (फार्माकोविजिलैंस प्रोग्राम ऑफ़ इंडिया) क्या है?

फार्माकोविजिलैंस प्रोग्राम ऑफ़ इंडिया, स्वास्थ्य एवं परिवार कल्याण मंत्रालय के अंतर्गत कार्य करता है जिसका नोडल कार्यालय, भारतीय भेषज संहिता आयोग में स्थित है। मैटीरियोविजिलैंस प्रोग्राम ऑफ़ इंडिया जिसका नोडल कार्यालय भी भारतीय भेषज संहिता आयोग में स्थित है तथा हीमोविजिलैंस प्रोग्राम ऑफ़ इंडिया जिसका नोडल कार्यालय राष्ट्रीय जैविक संस्थान, नॉएडा में स्थित है, वे भी इसी के भाग हैं।

### उद्देश्य

राष्ट्रीय औषधि सतर्कता सप्ताह का उद्देश्य औषधियों से होने वाले दुष्प्रभाव के प्रति जागरूकता फैलाना व इनसे होने वाले दुष्प्रभावों को फार्माकोविजीलैंस प्रोग्राम ऑफ़ इंडिया को रिपोर्ट करना है।

### औषधि सतर्कता क्या है?

सामान्य मात्रा में किसी औषधि अथवा दवा का सेवन करने से होने वाले प्रतिकूल प्रभाव अथवा दुष्प्रभाव का पता लगाने, उसका मूल्यांकन करने, समझने व रोकथाम से सम्बंधित विज्ञान एवं गतिविधियों को औषधि सतर्कता विज्ञान कहते हैं तथा इस विषय में सजग/ सतर्क रहने को औषधि सतर्कता कहते हैं।

### दवा प्रतिक्रिया/ एडवर्स ड्रग रिएक्शन (एडीआर)

औषधियों का वह प्रभाव जो हानिकारक और अनअपेक्षित है और जो आमतौर पर मनुष्यों में बीमारी की रोकथाम, निदान या उपचार के लिए या शारीरिक कार्य के संशोधन के लिए उपयोग की जाने वाली खुराक पर होती है, को दवा प्रतिक्रिया/ एडवर्स ड्रग रिएक्शन कहते हैं।

### औषधि दुष्प्रभावों को कौन रिपोर्ट कर सकता है?

सभी स्वास्थ्य कर्मचारी (चिकित्सक, दंत चिकित्सक, फार्मासिस्ट, नर्स और उपभोक्ताओं सहित गैर-स्वास्थ्य देखभाल कर्मचारी) दवाओं के दुष्प्रभाव को रिपोर्ट कर सकते हैं।

### औषधि दुष्प्रभावों को रिपोर्ट क्यों करें?

स्वास्थ्य कर्मचारी के रूप में सार्वजनिक स्वास्थ्य की सुरक्षा के लिए औषधि उत्पादों से जुड़े प्रतिकूल प्रभावों को रिपोर्ट करना एक नैतिक जिम्मेदारी है।

### क्या रिपोर्ट करें?

औषधियों से होने वाले किसी भी प्रकार की प्रतिक्रियाएं भले ही ज्ञात हों या अज्ञात, गंभीर हों या अगंभीर, अक्सर हो या दुर्लभ, ऐसी सभी प्रतिक्रियाओं की रिपोर्टिंग कर सकते हैं।

### कैसे और किसे रिपोर्ट करें?

1. हेल्पलाइन नंबर 1800-180-3024 पर कॉल करके (सोमवार से शुक्रवार सुबह 9:00 बजे से सायं 5:30 बजे)।
2. हमारी वेबसाइट www.ipc.gov.in पर औषधि दुष्प्रभाव सूचना फॉर्म डाउनलोड करके व उचित तरीकें से भरकर ई-मेल करें।
3. हमारी ई-मेल आई डी है pvpi.ipc@gov.in, pvpi.compat@gmail.com
4. यह सुविधा गूगल प्ले स्टोर पर मुफ्त उपलब्ध है।
5. आप "ADR PvPI" App डाउनलोड कर सकते हैं।

## कोविड-१९ महामारी के दौरान उपयोग होने वाली औषधियों से होने वाले दुष्प्रभाव की जानकारी कहाँ और कैसे दें

इसकी जानकारी आप फॉर्माकोविजीलेंस प्रोग्राम ऑफ़ इंडिया के अंतर्गत किसी भी निकटवर्ती ऐ॰ डी॰ आर॰ मॉनिटरिंग सेंटर पर दे सकते हैं। इस सम्बन्ध में एक विशेष फॉर्म - Suspected Adverse Drug Reaction Reporting Form (For Drugs used in Prophylaxis/ Treatment of COVID-19) भी डिज़ाइन किया गया है, जो www.ipc.gov.in पर उपलब्ध है ।

सत्यमेव जयते
IPC

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

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

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