Newsletter

PHARMACOVIGILANCE PROGRAMME OF INDIA (PvPI)
VOL 14 | ISSUE 1 | 2024

"CAPACITY BUILDING IN 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

I am privileged to release the Pharmacovigilance Programme of India (PvPI) Newsletter Volume 14, Issue 1 for the index period from January, 2024 to March, 2024 having on the theme "Capacity Building Programme in Pharmacovigilance". Capacity building in Pharmacovigilance is a continuous requirement at all levels of healthcare system in the country.

In this quarter, 23 New Adverse Drug Reaction Monitoring Centres (AMCs) have been enrolled under PvPI and total number of AMCs were 895 across country. A total of 8.1 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 8239 training programmes and trained a total of 505868 participants in the area of pharmacovigilance.

In this quarter, a capacity building programme on pharmacovigilance having on the theme "Advancing Pharmacovigilance System in India for Patient Safety" was organised by PvPI in collaboration with CDSCO on 10th March 2024 at Hotel Express Inn, Nashik, Maharashtra. Dr. Bharati Pravin Pawar, Hon'ble Minister of State for the Health Family Welfare & Tribal Affairs, Govt. of India graced the occasion & addressed the gathering. She applauded the efforts of PvPI/CDSCO to promote the patient safety by creating awareness on ADR reporting.

The NCC-PvPI, IPC has issued a total of 163 drug safety alerts for the sensitization of healthcare professionals and reporting of such adverse drug reactions to PvPI, if encountered with the use of such drugs.

At global level, the NCC-PvPI, IPC being a World Health Organization-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.

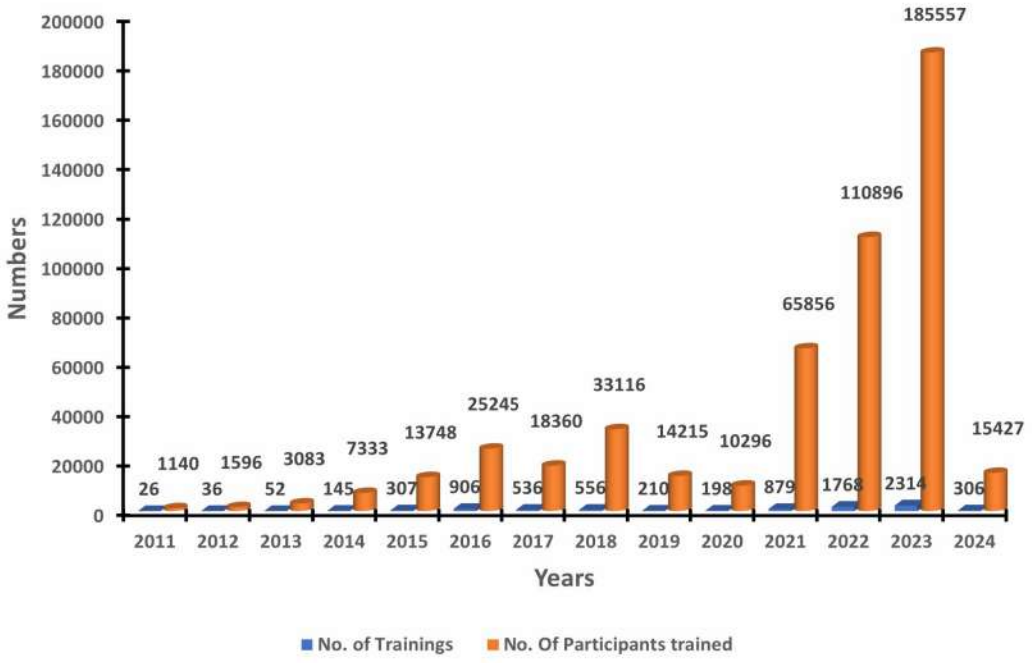
As a team, we will continue to work for improving patient safety. I, congratulate the PvPI team, AMCs and subject experts for their ceaseless efforts, cooperation and contribution in strengthening of pharmacovigilance system in India.

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

Capacity building programme in pharmacovigilance

The Indian Pharmacopoeia Commission (IPC) is working as the National Coordination Centre (NCC) for Pharmacovigilance Programme of India (PvPI) since April 2011. The PvPI is one of the important health programmes of the Ministry of Health & Family Welfare, Government of India to promote the patient safety. The PvPI collects, collates and analyses the Individual Case Safety Reports (ICSRs) received from the different stakeholders such as Healthcare Professionals (HCPs), Patients/Consumers, Marketing Authorization Holders (MAHs) and drug safety measures are recommended to Central Drugs Standard Control Organization (CDSCO) for taking appropriate regulatory action. The programme also expanding its outreach in almost part of the country and enrolled 895 Adverse Drug Reaction Monitoring Centers (AMCs) under PvPI.

As a part of capacity building programme in pharmacovigilance, PvPI is organizing continuously the Skill Development Programmes (SDPs), Continuing Medical Education (CME), Advanced Level Training Programmes (ALTs), Induction-cum-Training programmes, Hand holding meetings for newly recognised AMCs under PvPI for the sensitization of HCPs, Patients/Consumers etc. about reporting of Adverse Events with the use of medical products. The PvPI has designated 12 Regional Training Centers across the country for providing trainings to the AMCs in their respective regions and creating awareness in the field of pharmacovigilance. A total of 8239 training programmes have been conducted by PvPI and trained 505868 participants in the field of pharmacovigilance as on 31st March 2024. The trend analysis of total trainings programmes/HCPs trained by PvPI is given below;



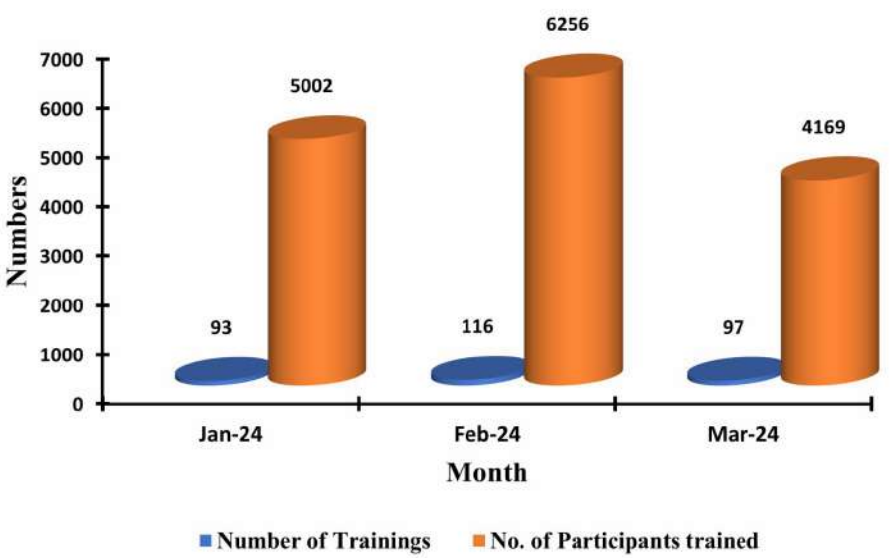
The NCC-PvPI, IPC has also taken the initiative to sensitize the AMCs, MAHs, Patients and other stakeholders for organizing "National Pharmacovigilance Week (NPW)" from 17th to 23rd September every year since 2021. The year wise training/sensitization programmes conducted by PvPI and the total number of participants trained during last 3 NPWs are as follows;

S. No.	National Pharmacovigilance Week (NPW)	Total number of training/sensitization programmes	Toal number of participants trained
1.	NPW 2021	398	33854
2.	2nd NPW 2022	628	54889
3.	3rd NPW 2023	967	110532

Apart from the above, a capacity building programme on pharmacovigilance on the theme "Advancing Pharmacovigilance System in India for Patient Safety" was organised by PvPI in collaboration with Central Drugs Standard Control Organisation (CDSCO), West Zone, Mumbai on 10th March 2024 at Hotel Express Inn, Nashik, Maharashtra. The objective of this training programme was to sensitize the HCPs including Physicians, Pharmacist, Consumers and MAHs about the reporting of Adverse Events, establishing pharmacovigilance system in their hospital etc.

Dr. Bharati Pravin Pawar, Hon'ble Minister of State for Health & Family Welfare and Tribal Affairs, Govt. of India graced the occasion and applauded the efforts of PvPI/CDSCO to promote the patient safety by creating awareness on ADR reporting. She also emphasised on the need for working towards the vision of Hon'ble Prime Minister, Shri Narendra Modi of making Atmanirbhar Bharat and Swasth Bharat. Dr. Jai Prakash, Officer In-charge of PvPI, Dr. Shashi Bhushan, Sr. Scientific Officer, IPC, Dr. R. S. Ray, Scientific Assistant, IPC participated in this event. A total of 181 participants attended this training programme.

A total of 306 training programmes including SDPs, CME, ALTs etc. were organised by PvPI during this quarter and trained a total number of 15427 participants in the area of Pharmacovigilance across the country. Monthly trend of training programmes conducted during index period is given below;



Pharmacovigilance and Pharmacoepidemiology: Complementing Each Other in Medication Safety Evaluation

Dr. Krishna Undela, Assistant Professor, Department of Pharmacy Practice, NIPER Guwahati, Assam, India

Owing to the fact that pre-marketing clinical trials have their own limitations, such as limited sample sizes, short duration, and strict eligibility criteria, their results are far from representing the real-world scenario, thus not allowing an exhaustive assessment of the safety profile of a medication. Hence, post-marketing surveillance studies are essential to explore the safety concerns of the medications and generate real-world evidence. Pharmacovigilance and Pharmacoepidemiology are two complementary sciences involved in establishing the safety profile of a medication during its post-marketing phase.

World Health Organization (WHO) defines Pharmacovigilance as “the science and activities related to the detection, assessment, understanding and prevention of adverse drug effects or any other possible drug-related problems.” It includes the collection of adverse events (AEs) or adverse drug reactions (ADRs) by using various methods, analyzing them, identifying the safety signals, and communicating the information for early detection, management, and prevention. One of the important limitations of Pharmacovigilance methods, especially spontaneous reporting, is that it doesn't allow the evaluation of the frequency or rate of AEs due to the lack of denominator (total number of people, who received the medication of interest). Pharmacoepidemiology is the “study of the use and effects of drugs in large populations.” It uses epidemiological methods to study the risks and benefits of drugs in real-world settings. Pharmacoepidemiological methods and their statistical techniques play an essential role in further evaluating the safety signals identified through Pharmacovigilance. They also provide the frequency or rate of AEs along with comparative risk estimates. As the figure describes, Pharmacovigilance is mainly responsible for “hypothesis generation” by identifying the safety signals in the early post-marketing phase. Spontaneous reporting is an important and underlying method of all other Pharmacovigilance methods like intensified reporting, targeted reporting, cohort event monitoring, and electronic health record mining. The information available on the individual case safety report (ICSR) is minimal in spontaneous reporting, and it goes maximum while going towards other study designs. At the same time, suspicion is high in spontaneous reporting and will be low while going towards other study designs.

Pharmacoepidemiology is helpful in “hypothesis confirmation” by quantifying the risk in the exposure group compared to the control. Cross-sectional studies, case-control studies, cohort studies, randomized controlled trials, and systematic review & meta-analysis are the critical methods under Pharmacoepidemiology. Bias will be more and evidence quality will be less in cross-sectional study design, and they will be reduced and increased respectively while moving towards other study designs.

Overall, the methods of Pharmacovigilance and Pharmacoepidemiology go hand in hand, are responsible for generating the real-world data of medications, and play a vital role in benefit-risk assessment and regulatory decision-making.

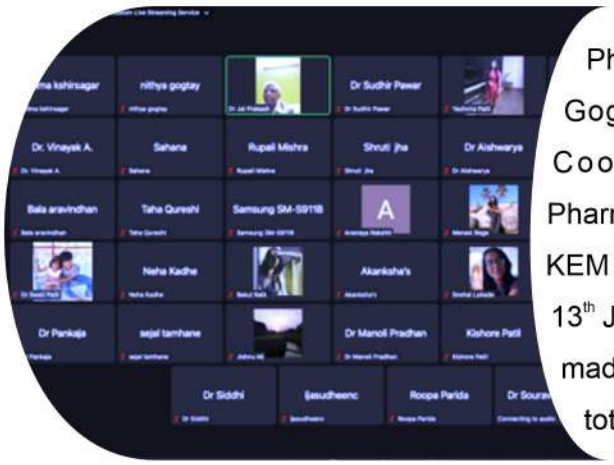
Enrolment of New AMCs

NCC-PvPI, IPC has enrolled 23 new AMCs in 19th Phase of PvPI expansion. The total number of AMCs enrolled by the end of this quarter were 895 across the country. The list of newly enrolled AMCs is mentioned below:

S. No.	States/UTs	Name of Hospitals/Medical Colleges/Institutes	Status
1.	Andhra Pradesh	Delta Hospitals Venkateshwara Nagar, East Godavari, Andhra Pradesh-533106	Non-Government
2.	Gujarat	Narendra Modi Medical College Seth L.G. Hospital Campus, Mani Nagar, Ahmedabad-380008	Government
3.	Haryana	Sarvesh Health City Opp. Civil Hospital, Hisar, Haryana-125001	Non-Government
4.		Tripti Hospital & Urology Centre Rohtak, Haryana-124001	
5.		Bansal Global Hospital Plot No. 36, Pram Nagar, Ambala City, Haryana-134003	
6.		DDK Global Hospital Opposite Civil Hospital, Bahadurgarh, Dist. Jhajjar, Haryana-124507	
7.		Balaji Hospital Lind Road, Adjoining Church, Mall Road, Karnal, Haryana-132001	
8.	Karnataka	Sri Madhusudhan Sai Institute of Medical Sciences and Research Sathya Sai Grama, Muddenahalli, District Chikkaballapur, Karnataka-562101	Non-Government
9.	New Delhi	Delhi Heart Hospital 176, Jagriti Enclave, Vikas Marg Extension, Near Karkardooma Metro Station, New Delhi - 110092	Non-Government
10.		Dharamshila Narayana Super Speciality Hospital Dharamshila Marg, Vasundhara Enclave, Near Ashok Nagar Metro Station, Delhi-110096	
11.		Surya Kiran Hospital Private Limited 31, Roshan Mandi, Najafgarh, South-West, New Delhi - 110043	

S. No.	States/UTs	Name of Hospitals/Medical Colleges/Institutes	Status
12.	Punjab	R.G. Stone Hospital 510-L, Model Town, Ludhiana, Punjab-141002	Non-Government
13.		Adesh Institute of Medical Sciences & Research NH-7, Barnala Road, Bhucho Khurd, Bathinda-151101	
14.		Arora Hospital Grand Trunk Rd, Guru Colony, Chheharta, Amritsar, Punjab-143001	
15.		Altis Multispeciality Hospital 332-A B, Near Guru Nanak Mission Chowk, Shastri Nagar, Lajpat Nagar, Jalandhar, Punjab-144001	
16.		HP Ortho Care Hospital KMV Marg, B D A Enclave, Santokh Pura, Jalandhar, Punjab-144004	
17.		Orthonova Joint and Trauma Hospital Near Nari Niketan, Jalandhar - Nakodar Rd, Model Town, Jalandhar, Punjab-144001	
18.	Tamil Nadu	Government Medical College Omandugar Government estate, 167, Walaja Road, Chennai, Tamil Nadu- 600002	Government
19.	Telangana	Government Medical College / Govt. General Hospital Khaleelwadi, Opp. TSRTC Bus Stand, Nizamabad, Telangana- 503001	Government
20.		Prathima Cancer Hospital Private Limited Arepally Paidipally Road, Paidipally, Warangal-506006	Non-Government
21.	Uttar Pradesh	Kailash Hospital Limited Plot No. 23, Knowledge Park-1, Greater Noida, Gautam Budh Nagar, Uttar Pradesh-201310	Non-Government
22.		Meerut Kidney Hospital Private Limited Prabhat Nagar, LIC Road, Meerut, Uttar Pradesh-250001	
23.	West Bengal	Prafulla Chandra Sen Government Medical College & Hospital Arambag, Hooghly, West Bengal-712601	Government

Advanced Level Training Programme organized by Seth GS Medical College & KEM Hospital, Mumbai



An Advanced Level Training Programme in Pharmacovigilance was organized online by Dr. Nithya Gogtay, Coordinator, Dr Mahesh Belhekar, Deputy Coordinator and Ms. Pratiksha Thombare, Jr. Pharmacovigilance Associate at Seth GS Medical College & KEM Hospital, Mumbai – Regional Training Centre (RTC) on 13th January 2024. Dr Jai Prakash, Officer In-charge of PvPI made presentation on "Overview of PvPI" in this event. A total of 578 participants including doctors, PV associates & pharmacist attended this training programme.

Induction-cum-Training Programme organised by NCC-PvPI, IPC

The NCC-PvPI, IPC conducted 3 days online "Induction-cum-Training Programme on Pharmacovigilance" for Coordinators/Deputy Coordinators of newly recognised Adverse Drug Reaction Monitoring Centres (AMCs) and Newly Recruited Pharmacovigilance Associates at AMCs from 17th to 19th January 2024. The objective of this training programme was to train the participants on Pharmacovigilance activities performed at their AMCs. A total of 108 participants attended this training programme.

Conference organized by University Institute of Pharma Sciences

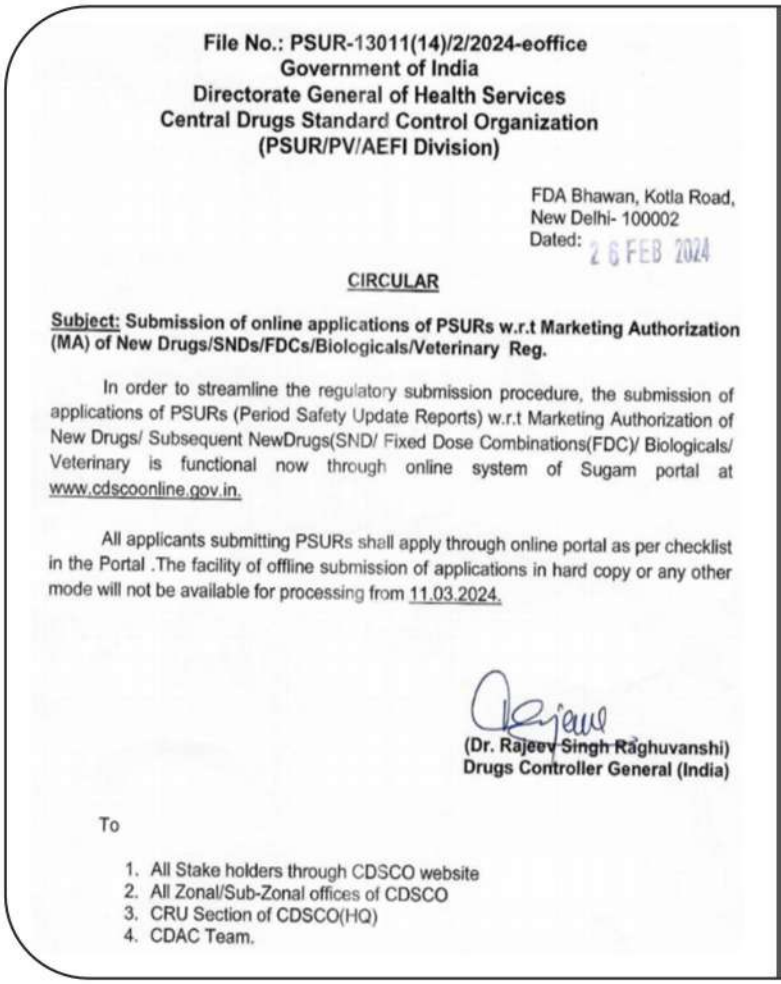
A conference on "Unlocking ADR Insights: Reporting Modules & Software Tools" was organized by University Institute of Pharma Sciences (UIPS), Chandigarh University, Gharuan, Punjab on 9th February 2024. The objective of this workshop was to train the pharmacy students about the monitoring & reporting of Adverse Event to PvPI. In this conference, Dr Vijit Agrawal, Sr. PV Associate had explained to the participants about the role of PvPI in patient safety, drug safety data entry in VigiFlow Software and procedure for the enrolment of Adverse Drug Reaction Monitoring Centre under PvPI.

Interactive meeting with Marketing Authorization Holders (MAHs)

The objective of the following interactive meetings held virtually was to explain the ICSRs Quality Score System and how the Pharmacovigilance system can be effectively implemented at MAHs/Pharmaceutical industry? These meetings also focussed on the issues/challenges related to the quality submissions of Individual Case Safety Reports (ICSRs) in E2B, xml format to PvPI.

Date	MAHs/Pharmaceutical Industry	No. of Participants
13th February 2024	FDC Limited	12
20th March 2024	Abbott India Limited	7

DCG(I) issued Circular for online submission of PSUR



File No.: PSUR-13011(14)/2/2024-eoffice
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(PSUR/PV/AEFI Division)

FDA Bhawan, Kotla Road,
New Delhi- 100002
Dated: 26 FEB 2024

CIRCULAR

Subject: Submission of online applications of PSURs w.r.t Marketing Authorization (MA) of New Drugs/SNDs/FDCs/Biologicals/Veterinary Reg.

In order to streamline the regulatory submission procedure, the submission of applications of PSURs (Period Safety Update Reports) w.r.t Marketing Authorization of New Drugs/ Subsequent NewDrugs(SND/ Fixed Dose Combinations(FDC)/ Biologicals/ Veterinary is functional now through online system of Sugam portal at www.cdscoonline.gov.in.

All applicants submitting PSURs shall apply through online portal as per checklist in the Portal .The facility of offline submission of applications in hard copy or any other mode will not be available for processing from 11.03.2024.

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

To

1. All Stake holders through CDSCO website
2. All Zonal/Sub-Zonal offices of CDSCO
3. CRU Section of CDSCO(HQ)
4. CDAC Team.

The Drugs Controller General of India has issued a circular for the Marketing Authorization Holders (MAHs) on 26th February 2024 for the online submission of Periodic Safety Update Report (PSUR) of new drugs marketed in country through SUGAM portal at www.cdscoonline.gov.in.

Workshop on Revised AEFI Guidelines 2024

A National Dissemination Workshop on AEFI Surveillance and Response: Operational Guidelines 2024 was organised by Immunization Technical Support Unit (ITSU) Ministry of Health & Family Welfare from 10th to 12th January 2024 at hotel "The Park", New Delhi under the supervision and guidance of Dr. Pawan Kumar, Additional Commissioner, Incharge (FP&MH). The objective of this workshop was to disseminate the changes made in revised AEFI Guidelines 2024 to the various stakeholders like SEPIOs, CDSCO, PvPI-IPC etc. In this workshop, Dr Jai Prakash, Officer In- charge of PvPI briefed the participants about "Role of PvPI in vaccine safety surveillance". Dr Shashi Bhushan, Sr. Scientific Officer, Mr Rishi Kumar, Scientific Assistant, Dr R.S. Ray, Scientific Assistant & Dr Vijit Agrawal, Sr. PV Associate, PvPI-IPC also participated in this workshop.

In continuation to the above workshop, 2nd workshop on Revised AEFI Guidelines 2024 was organised from 13th to 15th February 2024 for the dissemination of changes made in revised AEFI Guidelines 2024. In this workshop, Dr Vijit Agrawal Sr. Pharmacovigilance Associate, PvPI-IPC briefed the participants about "Role of PvPI in vaccine safety surveillance".

Continuing Medical Education Programme organized by M.G.M Medical College, Indore

Continuing Medical Education (CME) Programme on "ADR reporting under PvPI-An awareness and training programme" was organized by Dr Pooja Mishra, Coordinator, Dr Anjali Kushwah, Deputy Coordinator and Ms. Preeti Acharya, Jr. PV Associate at Mahatma Gandhi Memorial Medical College, Indore on 15th January 2024. The objective of this training programme was to create the awareness among healthcare professionals about the reporting of Adverse Events in hospital. A total of 280 participants attended this training programme.

5th Advanced Level Training in Pharmacovigilance organised by B. J. Medical College, Ahmedabad

The 5th Advanced Level Training Programme in Pharmacovigilance was organized by Dr Chetna Desai, Coordinator, B. J. Medical College, Ahmedabad-Regional Training Centre through hybrid mode on 25th January 2024. The objective of this training programme was to train the Coordinators, Deputy Coordinators, Pharmacovigilance Associates and other healthcare professionals engaged in Pharmacovigilance. A total of 351 participants attended this training programme.

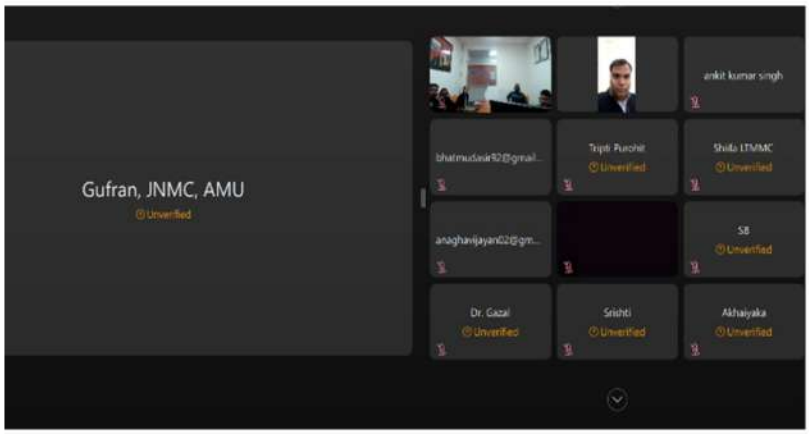
Stakeholder Consultative Workshop on Vaccine Vigilance

A Stakeholder Consultative Workshop on Vaccine Vigilance for stakeholders was conducted by World Health Organization Country Office for India in collaboration with Immunization Technical Support Unit (ITSU), Ministry of Health & Family Welfare and Central Drugs Standard Control Organization from 19th to 20th February 2024 at hotel The Lalit, New Delhi. The primary objective of this workshop is to mutual exchange of knowledge and strengthen cooperation among the stakeholders involved in vaccine vigilance. In this workshop, Dr Jai Prakash had briefed participants about "Role of PvPI in Pharmacovigilance Systems for Medical Products". Dr Shashi Bhushan, Senior Scientific Officer, Mr Rishi Kumar, Scientific Assistant, Mr Vipin Sharma, Team Lead, Signal Division & Dr Vijit Agrawal, Team Lead, National Health Programme also participated in this consultative workshop. The strategies for the upcoming National Regulatory Assessment by WHO were also discussed.

Advanced Training Workshop organised by Maulana Azad Medical College, New Delhi

An Advanced training workshop for Adverse Drug Reaction Monitoring Centres on Pharmacovigilance was organised by Prof. Vandana Roy, Coordinator, Maulana Azad Medical College, New Delhi – Regional Training Centre on 22nd February 2024. A total of 31 participants including Coordinators, Deputy Coordinators and PV Associates attended this training programme.

Webinar on "Medication Errors & Preventable ADRs" organised by NCC-PvPI, IPC



One day webinar on "Medication Errors & Preventable ADRs" organised by NCC-PvPI, IPC on 22nd February 2024 for Pharmacovigilance Associates posted at NCC-PvPI, IPC and AMCs across the country. Professor Suparna Chatterjee, Coordinator, IPGMER, Kolkata has highlighted the various aspects of Medication Errors & Preventable ADRs in their session. A total of 103 participants have participated in this webinar.

Advanced Level Training Programme on Pharmacovigilance conducted by NIPER, Guwahati

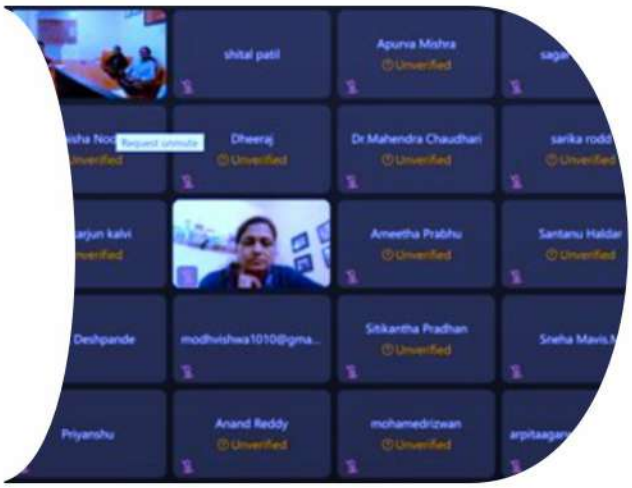
In North East India, Advanced Level Training Programme on Pharmacovigilance for Healthcare Professionals was organized by NIPER Guwahati from 1st to 2nd March 2024. The objective of this workshop was to train the Healthcare Professionals including pharmacy students about the monitoring and reporting of Adverse Events to PvPI. In this training programme, Dr Jai Prakash, Officer In-charge of PvPI delivered a lecture on "Updates & Milestones in the successful journey of Pharmacovigilance Programme of India". Dr Vijit Agrawal, Sr. PV Associate, NCC-PvPI, IPC had also demonstrated "How to enter drug safety data in VigiFlow?" to the participants.

Sun Pharma Ltd. organised "Patient awareness programme" at IMS, BHU, Varanasi

Ms. Kalpana Jaswal, AVP-Corporate Relations, Sun Pharmaceuticals Ltd. conducted one day "Patient awareness programme at Institute of Medical Sciences (IMS), Banaras Hindu University, Varanasi-AMC of PvPI on 2nd March 2024. Dr Rajeev Singh Raghuvanshi, Drugs Controller General of India was the chief guest and also briefed to the participants about the initiatives taken by the NCC-PvPI, IPC to aware the patient/consumer across the country. Mr. Vipin Sharma, Sr. Pharmacovigilance Associate & Mr. Sumit Bhidwaria, Jr. Pharmacovigilance Associate, NCC-PvPI, IPC participated in this programme. Mr. Avadhesh Mishra, Jr. Pharmacovigilance Associate posted at IMS, BHU shared the challenges and requirements for reporting Adverse Event by IMS, BHU to NCC-PvPI, IPC. He also stressed to include PvPI Helpline 18001803024 (Toll Free) on the OPD Card of IMS, BHU hospital.

28th Skill Development Programme on Pharmacovigilance organized by NCC-PvPI, IPC

The NCC-PvPI, IPC conducted 5 days "28th Skill Development Programme on Pharmacovigilance" virtually from 4th to 8th March 2024 at Mini Conference, PvPI, IPC, Ghaziabad. The objective of this training programme was to develop/enhance the skills of participants in the area of pharmacovigilance. A total of 222 participants including Academicians, Doctors, Industry Professionals, Medical students, Pharmacists, Consumers/Non-Governmental Organization (NGO) participated in this training programme.



6th Continuing Medical Education Programme organized by Maulana Azad Medical College, New Delhi

6th Continuing Medical Education (CME) Programme on "Improving availability, Rational & Safe use of Medicines in Public Health Facilities in Delhi" was organized by Prof. Vandana Roy, Coordinator, Maulana Azad Medical College, New Delhi from 12th-15th March 2024. The objective of this training programme was to train the healthcare professionals in the area of pharmacovigilance. A total of 60 participants attended this training programme.

9th Expert Committee meeting to revise the PV Guidance document for MAHs

The Expert Committee reviewed the draft Pharmacovigilance Guidance Document for Marketing Authorization Holders (MAHs) of Pharmaceutical Products, Version 2 and suggested to upload this Guidance Document on the PvPI-IPC website for seeking comments from the stakeholders. Accordingly, PvPI has uploaded the Guidance Document on the website of IPC on 24th January 2024 for the period of 30 days (last date was 22nd February 2024). The PvPI has received the comments/suggestions on draft Guidance Document from the MAHs. The comments/suggestions received by PvPI were reviewed by the Expert Committee on 13th March 2024 through hybrid mode at NCC-PvPI, IPC, Ghaziabad.

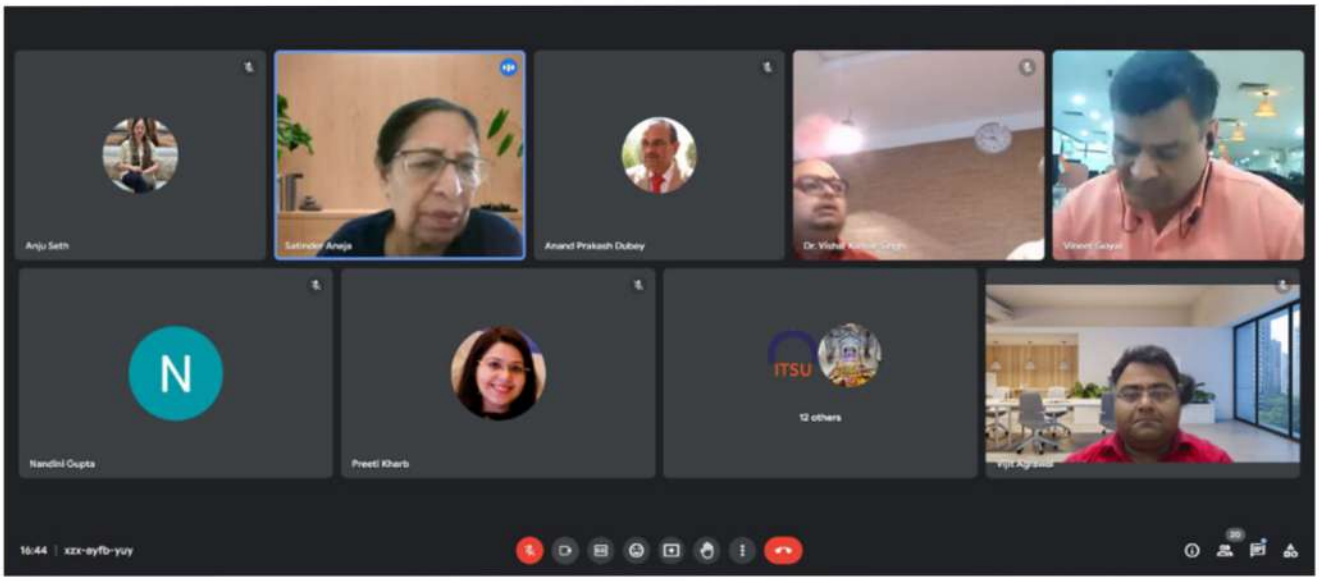
Workshop on Pharmacovigilance organised by Sanskar College of Pharmacy & Research

The Pharmacopoeia Education and Patient Safety Cell at Sanskar College of Pharmacy & Research organised two days workshop on Pharmacovigilance in association with Indian Pharmacopoeia Commission from 14th to 15th March 2024. The objective of this workshop was to provide the training for pharmacy students in the field of quality and safety of medicines.

On 1st day, Dr Jai Prakash, Officer In-charge of PvPI emphasized on basic concepts of Pharmacovigilance including updates of PvPI, Dr Anil Kumar Teotia, Sr. Principal Scientific Officer, IPC described Good Laboratory Practices/development of monograph in Indian Pharmacopoeia. On 2nd day, Dr. Gaurav Pratap Singh, Sr. Principal Scientific Officer, IPC delivered a talk on "Role of Pharmacopoeia in ensuring quality of medicines" and Dr R. S. Ray, Scientific Assistant had detailed about the various Pharmacovigilance methods & current regulatory requirement of PV in India. The workshop was very well organised by Prof. Babita Kumar, Director & Head of Department, Dr Qurratul Ain, Ms. Akshoo Rathi and Mr Arjun Nagar.

National AEFI Committee Meeting

The AEFI Secretariat under the chairpersonship of Dr S. Aneja, Professor and Head, Dept. of Paediatrics, School of Medical Sciences and Research, Sharda University, Greater Noida organised virtual meeting on 19th March 2024. The objective of this meting was to approve the causality assessment classification of the AEFI cases reported following the UIP Vaccination and COVID 19 vaccination. Dr Vijit Agrawal, Sr. PV Associate has participated in this meeting.



Continuing Medical Education organized by Gujarat Medical Education and Research Society, Gandhinagar, Gujarat

Continuing Medical Education (CME) on "Pharmacovigilance from Clinicians' Perspective" was organized by Dr Sobhana Gupta, Prof. Darshan J. Dave, Coordinator, Dr Shivani Trivedi, PV Associate at Gujarat Medical Education and Research Society, Gandhinagar in collaboration with PvPI, IPC through hybrid mode on 26th March 2024. The objective of this training programme was to create the awareness among healthcare professionals about the pharmacovigilance activities and discuss the challenges in reporting of Adverse Events in hospital. A total of 215 participants attended this training programme.

Continuing Medical Education organized by Gandhi Medical College & Hamidia hospital, Bhopal

Continuing Medical Education (CME) on "Sensitization programme on pharmacovigilance towards Patient Safety" was organized by Dr Arun Kumar Shrivastava, Coordinator, Dr Mukesh Hindoliya, Deputy Coordinator and Mr Girjesh Vishwakarma, PV Associate at Gandhi Medical College, Bhopal on 28th March 2024. The objective of this training programme was to create the awareness among healthcare professionals about the pharmacovigilance activities in hospital. A total of 65 participants attended this training programme.

New Drugs Approved in India

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

S. No.	Date of issue	Name of drugs	Indications
1.	19-01-2024	Tirzepatide 2.5mg /0.5ml, 5mg/0.5ml, 7.5mg/0.5 ml,10mg/0.5 ml, 12.5mg/0.5 ml,15mg/0.5 ml solution for injection in a prefilled pen	Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
2.	02-02-2024	Plazomicin injection 500mg/10ml (50mg/ml)	Indicated in patients 18 years of age or older for the treatment of complicated urinary tract infections (cUTI), including pyelonephritis caused by the following susceptible microorganism(s): • Escherichia coli, • Klebsiella pneumoniae, • Proteus mirabilis, and • Enterobacter cloacae

☞ **Healthcare professionals, patients/consumers are advised to closely monitor the possibility of the Adverse Events associated with the use of above new drugs. If, any reaction is encountered, please report to the NCC-PvPI, IPC by filling of Suspected Adverse Drug Reactions Reporting Form for HCPs and Medicines Side Effect Reporting Form for Consumers http://www.ipc.gov.in) and PvPI Helpline No. 1800-180-3024 (Toll-Free)**

Drug Safety Alerts

NCC-PvPI, IPC issued the following drug safety alerts and shared with Adverse Drug Reaction Monitoring Centres through email for the sensitization of healthcare professionals, thereby strengthening the reporting of Individual Case Safety Reports (ICSRs) to PvPI. The NCC-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.	Issue Date	Suspected drugs	Indication(s)	Adverse Drug Reactions
1.	27th March 2024	Cefuroxime	Antibiotic- Indicated for lower & upper respiratory tract infection, Urinary Tract Infection (UTI), gynaecological infection, skin or soft tissue infection etc.	Acute Generalized Exanthematous Pustulosis (AGEP)
2.		Dutasteride + Tamsulosin	In the treatment of Benign Prostatic Hyperplasia	Palpitation
3.		Nimesulide	• Use in Inflammatory condition including joint disorders such as rheumatoid arthritis, post traumatic and post operative painful condition and fever. • Acute pain in Orthopaedic, ENT, Dental and Post Operative condition. • Additional indication; for short treatment of adult patients with inflammation & pain associated with arthritis, soft tissue, ENT condition, trauma, dental pain, Musculo skeletal & gynaecology & obstetric painful condition. • For the treatment of pyrexia and inflammatory conditions in livestock	Fixed Drug Eruption (FDE)

4.		Beta blockers (Metoprolol, Propranolol, Atenolol)	**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. **Propranolol:** Cardiac arrhythmias; tachycardia; hypertrophic obstructive cardiac myopathy; pheochromocytoma; thrombosis; management of angina; essential and renal hypertension; prophylaxis of migraine. **Atenolol:** For the treatment of hypertension, angina pectoris, cardiac arrhythmias	Erectile dysfunction (Reversible)

☞ **Healthcare professionals, patients/consumers are advised to closely monitor the above mentioned 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 HCPs and Medicines Side Effect Reporting Form for Consumers http://www.ipc.gov.in) and PvPI Helpline No. 1800-180-3024 (Toll-Free)**

एक क्लिक पर मिलेगी दवाओं की गुणवत्ता की जानकारी

माई सिटी रिपोर्टर

वाराणसी। देश भर में दवाओं के बनाए जाने और उसकी बिक्री से लेकर गुणवत्ता संबंधी सभी जानकारी अब एक क्लिक पर आसानी से मिल जाएगी। इसके लिए ड्रग कंट्रोलर ऑफ इंडिया कार्यालय के निर्देशन में एक पोर्टल बनाए जाने की तैयारी चल रही है। इस पोर्टल से दवा निर्माता कंपनी के प्रतिनिधियों से लेकर दवा विक्रेताओं और नियंत्रण से जुड़े अधिकारियों को जोड़ा जाएगा।

ड्रग कंट्रोलर ऑफ इंडिया डॉ. राजीव सिंह रघुवंशी ने कहा कि इससे दवाओं की गुणवत्ता की सही जानकारी के साथ ही खराब कार्य पर दवा कंपनी पर होने वाली कार्रवाई की जानकारी भी आसानी से मिल सकेगी। बीएचयू ट्रॉमा सेंटर में एक कार्यक्रम में ड्रग कंट्रोलर ने कहा कि डिजिटल ड्रग रेग्युलेटरी सिस्टम के तहत

कार्यक्रम में मौजूद लोग। संवाद

ड्रग कंट्रोलर ऑफ इंडिया बोले दवा कंपनी पर कार्रवाई का भी रहेगा पूरा ब्योरा

पोर्टल तैयार करवाया जा रहा है। फिलहाल 300 दवाइयों पर क्यूआर कोड लग गया है। उन्होंने कहा कि कोई भी व्यक्ति टोल फ्री नंबर 1800-180-3024 पर शिकायत कर सकता है।

इस दौरान ट्रॉमा सेंटर प्रभारी प्रो. सौरभ सिंह, प्रो. अशोक कुमार, प्रो. अंकुर सिंह, प्रो. कविता मीना, प्रो. चंचल मौजूद रहे।

हिन्दुस्तान

पब्लिक डोमेन पर होगा मिलावटी दवाओं का डाटा

सेमिनार

वाराणसी, कार्यालय संवाददाता। भारतीय दवा नियामक प्रणाली में एक बड़ा बदलाव होने जा रहा है। इसमें एक पोर्टल जल्द ही लांच होगा। उस पर दवा निर्माताओं व सप्लायरों और प्राइमरी पैकेजिंग मैटेरियल सप्लायरों का एक डेटाबेस होगा।

ड्रग कंट्रोलर के अधिकारी भी उससे जुड़ेंगे। इसको तैयार करने में कम से कम एक साल लगेगा। इसी पोर्टल के सार्वजनिक डोमेन में नॉन-स्टैंडर्ड या मिलावटी दवाओं का डेटाबेस भी होगा। अगर एक राज्य में कोई दवा प्रतिबंधित होगी तो इस पोर्टल के माध्यम से पूरे देश में इसकी जानकारी मिल जाएगी।

यह जानकारी औषधि महानियंत्रक (ड्रग कंट्रोलर जनरल ऑफ इंडिया) राजीव सिंह रघुवंशी ने शनिवार को बीएचयू के ट्रॉमा सेंटर में मीडिया से बातचीत में दी। उन्होंने कहा कि पोर्टल सीडीएससीओ (केंद्रीय औषधि मानक नियंत्रण संगठन) अन्य मौजूदा आईटी पोर्टलों को भी एकीकृत करेगा। इसके माध्यम से एक ही विंडो पर लाइसेंस और दवाओं की अनुमति, उसकी प्रगति, प्रतिबंधित दवाओं की सूची सहित सभी जानकारियां मिल जाएंगी।

ट्रॉमा के ओपीडी पर्ची पर रहेगा टोल फ्री नंबर: एडवर्स ड्रग रिएक्शन मॉनिटरिंग सेंटर (एएमसी) के फार्माकोविजिलेंस एसोसिएट अवधेश कुमार यादव ने कहा कि दवाओं का साइड इफेक्ट होने पर 1800-180-3024 पर शिकायत कर सकते हैं। ट्रॉमा सेंटर के इंचार्ज प्रो. सौरभ सिंह ने कहा कि ट्रॉमा सेंटर के ओपीडी पर्ची पर यह टोल फ्री नंबर दर्ज किया जाएगा।

बीएचयू ट्रामा सेंटर में शनिवार को हुए सेमिनार उपस्थित विशिष्टजन। • हिन्दुस्तान

क्यूआर कोड से नकली-असली में फर्क

बीएचयू ट्रॉमा सेंटर के ओपीडी सेमिनार हॉल में हुई संगोष्ठी में राजीव सिंह रघुवंशी ने कहा कि देश की तीन सौ ब्रांडेड कंपनियों की दवाओं पर क्यूआर कोड लगाया गया है। आईएमएस के डीन प्रो. अशोक चौधरी, ट्रॉमा सेंटर के इंचार्ज प्रो. सौरभ सिंह, सर सुंदरलाल अस्पताल के डिप्टी एमएसम प्रो. अंकुर सिंह, प्रो. अमित कुमार ने भी विचार रखे।

PvPI in Press & Media

Forthcoming Events

NCC-PvPI, IPC has planned to organize the following events;

31st May 2024

Mode: Physical

Training programme on Pharmacovigilance at Sikkim Manipal Institute of Medical Sciences (SMIMS), Gangtok

3rd - 7th June 2024

Mode: Virtual

29th Skill Development Programme at NCC-PvPI, IPC

Last date of Registration

27th May 2024

For further information, please contact through email training.nccpvpi-ipc@gov.in

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 फॉर्माकोविजीलैंस 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