Newsletter

PHARMACOVIGILANCE PROGRAMME OF INDIA (PvPI)
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4th National Pharmacovigilance Week 2024

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National Coordination Centre - Pharmacovigilance Programme of
A WHO Collaborating Centre for Pharmacovigilance in Public Health Programmes and Regulatory
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 3 for the index period from July, 2024 to September, 2024 on the theme "4th National Pharmacovigilance Week 2024". The Adverse Drug Reaction Monitoring Centres (AMCs) in medical colleges, hospitals, academic institutes and pharmaceutical industries have shown interest in celebration of 4th NPW 2024. During 4th NPW, 946 trainings/workshops/awareness programmes were conducted and trained/sensitized 105510 participants.

A total of 8.94 Lakh Individual Case Safety Reports have been reported to PvPI as on 30th September 2024. 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) and 4th NPW sensitization/training programmes etc. The PvPI has organized a total of 1267 training programmes and trained a total of 122526 participants in the area of pharmacovigilance in this quarter.

In this quarter, as a part of Digital India initiative, an online indigenously developed ADRMS software of Pharmacovigilance Programme of India (PvPI) was launched by the Hon'ble Union Minister of Health & Family Welfare and Minister of Chemicals and Fertilizers, Shri J.P. Nadda during the 1st Policy Makers Forum meeting held at Dr. Ambedkar International Centre, New Delhi on 19th August, 2024 in the presence of senior officials of the Ministry of Health and Family Welfare, Ministry of External Affairs, Department of Pharmaceuticals, Central Drugs Standard Control Organization and Indian Pharmacopoeia Commission.

The NCC-PvPI, IPC has issued a total of 169 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.

As a part of WHO NRA rebenchmarking for vaccines, vigilance function as per WHO GBT 2021 was assessed from 16th-20th September 2024. As of 4th October 2024, India's regulatory system has successfully achieved overall maturity level 3, following the implementation of all critical recommendations and submission of corrective and preventive actions for any identified gaps during the benchmarking.

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 and subject experts and other stakeholders for their ceaseless efforts, cooperation and contribution in strengthening the 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

4th National Pharmacovigilance Week 2024

The National Coordination Centre – Pharmacovigilance Programme of India (NCC-PvPI), Indian Pharmacopoeia Commission (IPC) celebrated 4th National Pharmacovigilance Week (NPW) from 17th-23rd September 2024, across the country. The theme of this NPW was "Building ADR Reporting Culture for Patient Safety". The Adverse Drug Reaction Monitoring Centres (AMCs), in medical colleges, hospitals, academic institutes, and pharmaceutical industries have celebrated 4th NPW 2024. Various modes like workshops, conferences, quiz competitions, poster competitions etc. were organized during the entire week of this event. A total of 946 training /workshops/ awareness programmes related to Pharmacovigilance were conducted and trained/ sensitized 105510 participants across the country.

National Pharmacovigilance Week 2024 received an overwhelming response across the country from Coordinators, Deputy Coordinators, Pharmacovigilance Associates and Healthcare Professionals from AMCs. The ADR monitoring Centres across the country have organized various sensitization programmes and other community level sensitization programmes activities to spread awareness on reporting of ADRs.

4th National Pharmacovigilance Week Activities

Day - 1

17th September 2024

(Inaugural day)

Several distinguished experts underscored the importance of ADR reporting for ensuring patient safety in India. Among the speakers were:

- **Dr. Rajeev Singh Raghuvanshi** DCGI & Secretary-cum-Scientific Director
- **Prof. Y.K. Gupta**, National Scientific Coordinator of PvPI and Chairperson of the Signal Review Panel
- **Dr. Sunil Singhal**, Member of the Central Council of the Indian Medical Association
- **Dr. Rajendra P. Joshi**, Additional Medical Superintendent at Lady Hardinge Medical College and Hospital, New Delhi
- **Shri Bikash R. Mahato**, Under Secretary in the Ministry of Health and Family Welfare
- **Dr. Vivek Ahuja,** Senior Vice President Pharmacovigilance Quality and Regulatory Services Eversana life Science services
- **Dr. Manoj Sharma,** Asst. General Manager Global Pharmacovigilance Department Win-Medicare Pvt. Ltd.

The following PvPI Resource/Promotional materials were released:

- PV Comic (Endgame of Side Effects)
- PvPI Quarterly Newsletter (Volume 14 Issue 2)
- PvPI Posters
- Pharmacovigilance Guidance Document for Market Authorization Holders (MAHs) of Pharmaceutical Products (Version 2.0)
- Quality Manual of PvPI

Day - 2

18th September 2024

(International Webinar)

International Webinar on Optimizing the Use of ICSRs in Signal Detection Process. It was attended by representatives from the WHO, members from countries within South-East Asia Regulatory Network (SEARN) including Sri Lanka, Nepal, Bhutan, Myanmar, Timor-Leste and Bangladesh, as well as pharmacovigilance experts across India reaching upto 379 participants..

Day - 3

19th September 2024

(Quiz Competition)

The Pharmacovigilance Quiz Competition was organized on 19th September 2024. A total of 27 participants from different divisions of PvPI/MvPI participated.

Day - 4

20th September 2024

(e-poster Competition)

The e-poster competition was conducted for all AMC's and staff of NCC-PvPI on Day-4. A total 197 e-posters received were shortlisted on the basis of creativity, content and presentation on the provided theme "You share, we care: Know how to report Adverse Drug Reactions".

Day - 5

23rd September 2024

(Valedictory Ceremony)

PvPI Stakeholders Meet-cum-Valedictory Ceremony was organized on 23rd September, 2024. Dr. Jai Prakash delivered a welcome note followed by the discussion on "Building ADR Reporting Culture for Patient Safety". The experts, Ms. Varsha Srivastava (Deputy Director, NABH), Dr. Madhur Gupta (Technical Officer-Pharmaceuticals, WHO-India Country Office) addressed the audience.

The speaker Dr. Jamal Baig (Multi-country Safety Head, Sanofi India) delivered a talk on "Role of Pharmaceutical Industries in safeguarding public health" and Prof. Suparna Chatterjee (RTC Coordinator, IPGMER, Kolkata) delivered a talk on "From ADR reporting to actions: How ADR Monitoring Centres can transform Pharmacovigilance practices?".

Top Performing AMCs & MAHs as mentioned below were felicitated. Identified experts under PvPI, Prof. M Ramesh (RTC Coordinator, JSS Mysore, Karnataka), Prof. Vandana Roy (RTC Coordinator, MAMC, New Delhi) and the winners of Posters/Quiz competition along with participant/organizing team members were felicitated by Dr. Jai Prakash Officer-in-Charge, PvPI, IPC. PvPI-IPC also compiled and projected a video on "Glimpses of NPW 2024 Celebration" during Valedictory ceremony.

Consumer Adverse Event Reporting

Ms. Arshia Bhandari, PV Consultant, Founder PhVFIT

Adverse Event under-reporting is one of the major impediments in the field of Pharmacovigilance. To complement the reporting by healthcare professionals, there is a global push to encourage consumer reporting, with promising results emerging from various studies.

A pivotal study by Avery et al, 2011, assessed patient reporting of Adverse Drug Reactions (ADRs) to the UK's Yellow Card Scheme. The study concluded that patient reports could substantially enrich pharmacovigilance efforts by identifying unique drug reactions not otherwise reported by healthcare professionals, generating new potential signals, and providing detailed descriptions that aid in assessing causality and the impact on patients' lives.

Results and reflections from Lareb (Netherlands' Pharmacovigilance Centre) and the Uppsala Monitoring Centre in a 2018 study echoed similar findings. It was noted that patient reports could uncover previously unknown ADRs as well as new facets of known ADRs. Moreover, consumer reports offer unique information valuable for signal assessment, with patient narratives providing detailed insights into the experience and impact of ADRs on quality of life and causality assessment.

Interestingly, consumers often flag unusual signals that may be overlooked or deemed irrelevant by healthcare professionals. Some noteworthy examples include:

1. Non-recovery from sexual dysfunction with serotonin reuptake inhibitors used to treat depression. The anonymity of consumer reporting facilitated these reports.
2. Pathological gambling associated with the dopamine agonist pergolide, used to treat Parkinson's disease, identified by Lareb.
3. Electronic shock sensations with duloxetine, where a signal was identified very early due to patient reports. The study indicates that physicians might dismiss such reactions as peculiar observations from consumers and thus decide not to report them.

EXPERT INSIGHTS

There is substantial evidence highlighting the value of consumer reporting in pharmacovigilance. However, under-reporting by consumers remains a global challenge, primarily due to a lack of awareness about side effects and the importance of reporting them. A study by Costa C et al., published in 2023, identified ignorance, complacency, and lethargy as the most frequent reasons for patients and consumers not reporting ADRs. Additionally, patients often cite a complex reporting process and perceived ineffectiveness or lack of follow-up action from regulatory authorities as deterrents.

Studies have demonstrated that countries with higher consumer reporting rates exhibit several key characteristics:

1. Use of patient-friendly terms or lay language in ADR report forms.
2. Availability of diverse reporting options: Web reporting portals for consumers and healthcare professionals have been shown to increase reporting rates.
3. Patient assistance through chat functions for online forms.
4. Provision of feedback to consumers.
5. Engagement with patient organizations: These organizations have direct interactions with patients and play a crucial role in raising awareness about ADR reporting and promoting health literacy.
6. Implementation of various activities to raise public awareness about the importance of pharmacovigilance.
7. Active promotion of patient reporting systems via media (e.g., television, radio) and social media platforms (e.g., Facebook, Twitter, YouTube).

Additionally, the availability of authentic information from the country's regulatory authority on disease areas and approved medications, including details on manufacturers, approved formulations, strengths, dosages, and side effects, helps improve health literacy and prevents misinformation.

To promote consumer reporting and raise awareness about drug safety in India, the Pharmacovigilance Programme of India (PvPI) conducts regular awareness activities on ADR reporting. PvPI has introduced an ADR Reporting Form for Consumers in Hindi and other vernacular languages, making it accessible and easy to understand. Across India, 976 AMCs are enrolled under the PvPI Programme, where consumers can directly report adverse events. These reports are then submitted by the ADR monitoring centres to PvPI. Additionally, patients can report adverse events by calling the PvPI toll-free number or using the ADR PvPI Android application.

With the systems in place, it is crucial that consumers understand the significance of adverse event reporting, viewing it not only as a right but also as a responsibility to contribute to the safety profile and risk-benefit assessment of a drug. Healthcare professionals, patient organizations, educational institutions and national regulatory authority play a pivotal role in fostering awareness and understanding among consumers. A concerted effort from all these stakeholders can create a robust framework for patient safety and ensure that consumers are well-informed and active participants in the pharmacovigilance process.

Bibliography:

1. Avery AJ, Anderson C, Bond CM, Fortnum H, Gifford A, Hannaford PC, Hazell L, Krska J, Lee AJ, McLernon DJ, Murphy E, Shakir S, Watson MC. Evaluation of patient reporting of adverse drug reactions to the UK 'Yellow Card Scheme': literature review, descriptive and qualitative analyses, and questionnaire surveys. Health Technol Assess. 2011 May;15(20):1-234, iii-iv. doi: 10.3310/hta15200. PMID: 21545758.

2. Watson, S., Chandler, R.E., Taavola, H. et al. Safety Concerns Reported by Patients Identified in a Collaborative Signal DetectionWorkshop using VigiBase: Results and Reflections from Lareb and Uppsala Monitoring Centre. Drug Saf 41, 203–212 (2018).

3. Safety Concerns Reported by Patients Identified in a Collaborative Signal Detection Workshop using VigiBase: Results and Reflections from Lareb and Uppsala Monitoring Centre. Drug Saf 41, 203–212 (2018).

4. Costa C, Abeijon P, Rodrigues DA, Figueiras A, Herdeiro MT, Torre C. Factors associated with underreporting of adverse drug reactions by patients: a systematic review. Int J Clin Pharm. 2023 Dec;45(6):1349-1358. doi: 10.1007/s11096-023-01592-y. Epub 2023 May 29. PMID: 37247159; PMCID: PMC10682061.

WHO NRA Re-benchmarking for Vaccines in India

India is one of the main players in the pharmaceutical industry worldwide and is known for its affordable vaccines and generic medicines. The Central Drugs Standard Control Organisation (CDSCO), along with the National Regulatory Authority of India (NRA) and affiliated institutions, such as Pharmacovigilance Programme of India and AEFI Sectt, has been found to meet the World Health Organization (WHO) published indicators for a functional vaccine regulatory system. This conclusion was reached by a team of international experts from various countries, led by WHO (HQ) in Geneva, following a comprehensive and in-depth scientific review of India's vaccine regulatory system conducted from 16th to 20th September, 2024. Safety, efficacy, and quality are three basic parameters of assessment of vaccines. WHO has established global standards and benchmarks for assurance of vaccine quality through the development of tools and guidelines, benchmarking of the NRA and prequalification programme of vaccines.

A team of assessors visited NCC-PvPI, IPC, Ghaziabad on 18th September 2024 (Wednesday) during the “WHO NRA Re-benchmarking for Vaccines in India – to assess the Vigilance Function” at National Coordination Centre – Pharmacovigilance Programme of India, Ghaziabad, Uttar Pradesh.

The WHO team was welcomed at NCC-PvPI, IPC. After opening of the meeting a presentation entitled “The progress of PvPI since 2017 onwards” was delivered by Dr. Jai Prakash, Sr. PSO & Officer-in-Charge, NCC-PvPI, IPC, Ghaziabad. Later the team reviewed the relevant documents and interviewed the PvPI staff for the purpose of assessment of Vigilance function, as per the WHO Global Benchmarking Tool. This success is a culmination of intensive effort by the Health Ministry, including CDSCO, in collaboration with WHO, to implement a roadmap to strengthen capacity for regulation of vaccines.

Launching of the Adverse Drug Reaction Monitoring System (ADRMS) Online Portal

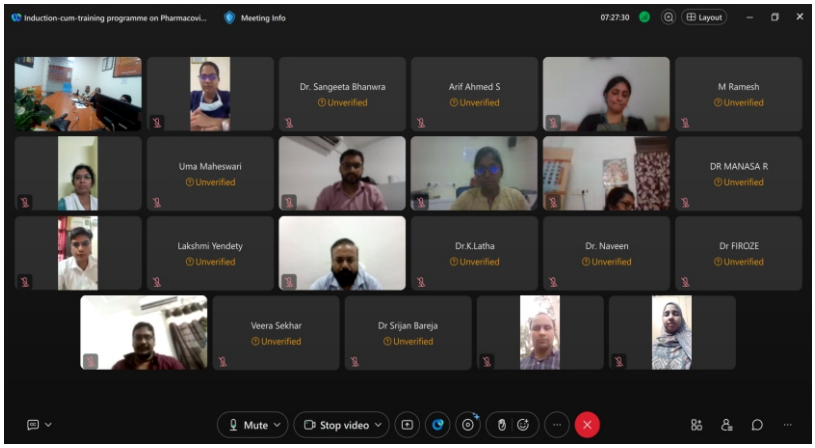
To fulfil the vision of Hon'ble Prime Minister, Shri Narendra Modi's 'Digital India', an online indigenously developed ADRMS software of Pharmacovigilance Programme of India was launched by the Hon'ble Minister of Health & Family Welfare and Minister of Chemicals and Fertilizers, Shri J.P. Nadda during the 1st Policy Makers Forum meeting held at Dr. Ambedkar International Centre, New Delhi on 19th August, 2024 in the presence of senior officials of the Ministry of Health and Family Welfare, Ministry of External Affairs, Department of Pharmaceuticals, Central Drugs Standard Control Organization and Indian Pharmacopoeia Commission.

The ADRMS software of PvPI is India's first medical product safety database tailored to the needs of the Indian population. It will facilitate the users reporting of Adverse Events related to medicines and medical devices. This software will not only streamline the reporting process by patients/their caregivers and healthcare professionals but also empower Indian Pharmaceutical Industries/Marketing Authorizations Holders (MAHs) to report adverse events through direct User Gateway.

The Weblink of Online ADRMS Software is adrmsipc.in

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

The NCC-PvPI, IPC conducted one day online “Induction-cum-Training Programme on Pharmacovigilance” for Coordinators/Deputy Coordinators of newly recognised AMCs on 19th July 2024. The objective of this training programme was to train the participants on Pharmacovigilance activities performed at their AMCs. A total of 51 participants attended this training programme.



CME Programme organised by AJIMS, Mangaluru

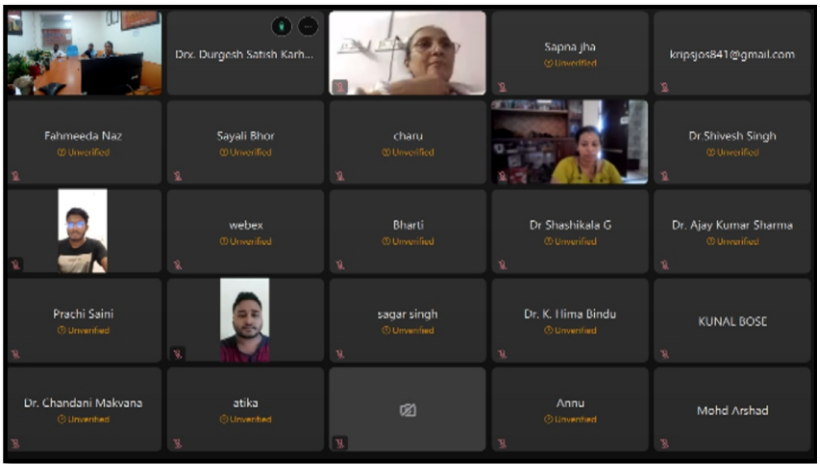
A.J. Institute of Medical Sciences, Mangalore, Karnataka (AJIMS), Mangalore, Andhra Pradesh has organised one day CME Programme on 'Pharmacovigilance - Safeguarding Public Health' for nurses, teaching staff & undergraduates of Medical, Paramedical & Allied health courses who in future would be reporting ADRs at AJIMS, Mangalore, Karnataka on 25th July 2024. The Speakers highlighted on the Pharmacovigilance, different scales that's been used (Naranjo, WHO etc) for assessing, Adverse Event form filling, different ways of reporting ADRs, activities of PV and, PV centres present all over. A total of 250 participants participated in this event.

Sensitization & Basic Training in Pharmacovigilance and PvPI at G.M.E.R.S Medical College and Civil Hospital, Ahmedabad

G.M.E.R.S Medical College and Civil Hospital, Sola, Ahmedabad organised Sensitization and Basic Training in Pharmacovigilance and Pharmacovigilance Programme of India on 31st July 2024 for Intern doctors of the hospital. Further, sessions on 'How to fill ADR' reporting and 'Causality assessment' along with 'Hands on Training' were done. There were total of 28 participants.

30th Skill Development Programme on Pharmacovigilance organized by NCC-PvPI, IPC

The NCC-PvPI, IPC conducted 5 days "30th Skill Development Programme on Pharmacovigilance" virtually from 5th to 9th August 2024 at Mini Conference Hall, IPC, Ghaziabad. The objective of this training programme was to enhance the pharmacovigilance skills of the healthcare professionals to promote the patient safety. A total of 321 participants including Pharmaceutical Industry Professionals, Physicians, Academicians, Pharmacy/Medical Students and Pharmacists across the country participated in this training programme.



World Breastfeeding Week observed at Jawaharlal Nehru Medical College, Aligarh Muslim University, Aligarh

On the occasion of World Breastfeeding Week, a seminar with the theme 'Closing the Gap: Breastfeeding Support for All', was held at the Department of Pharmacology, Jawaharlal Nehru Medical College, Aligarh Muslim University under the aegis of ADR Monitoring Centre, PvPI, MoHFW, GoI, on 6th August 2024. Further, a talk presented on 'Unwanted Effects of Drugs on Breastfed Infants', providing valuable insights for healthcare professionals and mothers discussing various medicines excreted through milk and the drugs which are absolutely contraindicated in breastfed mothers.

CME organised by All India Institute of Medical Sciences, Bhopal, Madhya Pradesh

All India Institute of Medical Sciences (AIIMS) has organised one day CME Programme on 'Pharmacovigilance: Role of a Healthcare Professional' to sensitize clinicians, nurses, dentists, pharmacists, other health care professionals from corporate, government hospitals, pharmacy and dental colleges about the need and importance of active reporting of adverse events along with hands on training at Kautilya Bhawan, AIIMS, Bhopal, Madhya Pradesh on 30th August 2024. A total of 148 participants participated in this event.

CME Programme organised by Sri Venkateswara Medical College, Tirupati

Sri Venkateswara Medical College, Tirupati has organised one day CME Programme on Pharmacovigilance for doctors and pharmacy students at Demo Hall, Deptartment of Pharmacology: Sri Venkateswara Medical College, Tirupati on 3rd September 2024. The Speakers highlighted on the Pharmacovigilance and its importance in Patient Safety along with Materiovigilance and Adverse Events following Immunization (AEFI). A total of 170 participants attended in this event.

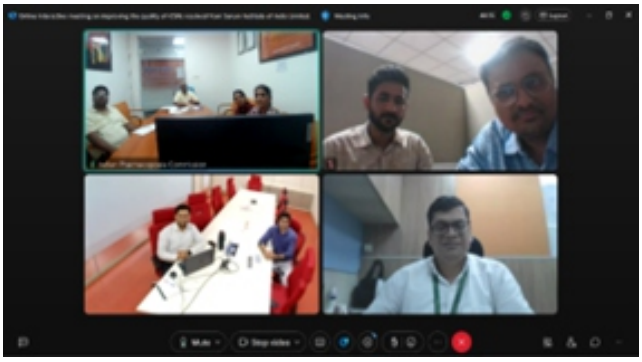
CME Programme organised by AIIMS, Mangalagiri

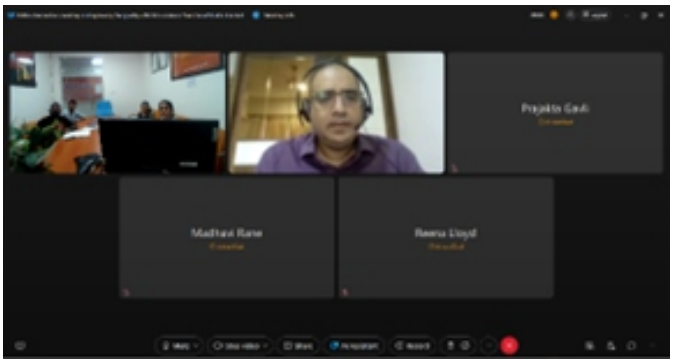
All India Institute of Medical Sciences (AIIMS), Mangalagiri, Andhra Pradesh has organised one day CME Programme on Awareness and Sensitization on Pharmacovigilance and ADR Reporting for doctors, pharmacists, nurses and other health care at AIIMS, Mangalagiri, Andhra Pradesh on 28th September 2024. The Speakers highlighted on the evolution on pharmacovigilance, the structure of PvPI programme in India, the process of ADR reporting, the important stakeholders in ADR reporting, the clinical aspect of pharmacovigilance and importance of signal detection. Hands on was done on how to fill ADR forms (Version 1.4) on real case scenario. A total of 51 participants participated in this event.

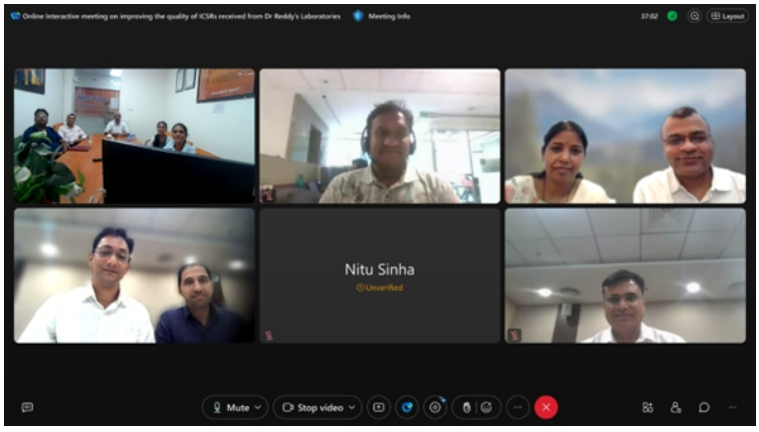
Interactive meeting with Marketing Authorization Holders (MAHs)

The Interactive meetings with following MAHs held virtually with the objective to review the quality, no. 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.

Date	MAHs	No. of Participants
11th July 2024	Dr. Reddy's Laboratories Limited	10
31st July 2024	Serum Institute of India Limited	10
30th August 2024	Sanofi India Limited	8







New Drugs Approved in India

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

S.No.	Name of drugs	Indications	Date of issue
1.	Methenamine Hippurate bulk drug & Methenamine Hippurate Tablets USP 1gm	Prophylaxis and treatment of urinary tract infections, Prevention of urinary tract infections, especially in catheter carriers, Asymptomatic bacteriuria, long term therapy in prevention of recurrent cystitis.	9th July 2024
2.	Sodium Phenylbutyrate USP bulk drug & Sodium Phenylbutyrate Oral Powder USP	Indicated as adjunctive therapy in the chronic management of patients with urea cycle disorders involving deficiencies of Carbamyl Phosphate Synthetase (CPS), Ornithine Trans Carbamylase (OTC), or Argininosuccinic acid Synthetase (AS). It is indicated in all patients with neonatal-onset deficiency (Complete enzymatic deficiency, presenting within the first 28 days of life). It is also indicated in patients with late-onset diseases (partial enzymatic deficiency, presenting after the first month of life) who have a history of hyperammonemic encephalopathy.	9th July 2024
3.	Elobixibat Hydrate Bulk Drug and Elobixibat Tablets 5 mg	For treatment of chronic constipation (except for constipation associated with organic diseases)	15th July 2024

4.	Tedizolid Phosphate Bulk & Tedizolid Phosphate Tablets 200 mg	Indicated for the treatment of Acute Bacterial Skin and Skin Structure Infections (ABSSSI) in adults and adolescents 12 years of age and older.	19th July 2024
5.	Remifentanil Hydrochloride EP Bulk	As an analgesic component of monitored anesthesia care in adult	31st July 2024
6.	Pimavanserin Tartrate Bulk &Pimavanserin Capsules 34 mg	For the treatment of hallucinations and delusions associated with Parkinson's disease psychosis.	2nd August 2024
7.	Elagolix Sodium Bulk & Elagolix tablets 150 mg and Elagolix tablets 200 mg	For the management of moderate to severe pain associated with endometriosis.	9th August 2024
8.	Brigatinib Tablets,30 mg,90 mg, and 180 mg	Indicated as monotherapy for the treatment of adult patients with Anaplastic Lymphoma Kinase (ALK)- positive advanced Non-Small Cell Lung Cancer (NSCLC) previously not treated with an ALK inhibitor. Brigatinib is indicated as monotherapy for the treatment of adult patients with ALK-positive advanced NSCLC previously treated with crizotinib.	18th September 2024

***Source:** Approved New Drugs (cdsco.gov.in)*

☞ 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). You can also report through PvPI Helpline No. 1800-180-3024 (Toll-Free).

Drug Safety Alerts

The NCC-PvPI, IPC issued the following drug safety alerts by uploading on the websites of PvPI, IPC and also 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	Indications	Adverse Reactions
1.	18th July 2024	Vancomycin	Treatment of serious infection due to Gram-positive cocci including methicillin-resistant staphylococcal infections, brain abscess, staphylococcal meningitis and septicaemia.	DRESS Syndrome
2.	28th August 2024	Metronidazole	For the treatment of amoebiasis, urogenital trichomoniasis& giardiasis.	Fixed Drug Eruption
3.	25th September 2024	Tetracycline	Treatment of Rocky Mountain spotted fever, typhus, Q fever, rickettsial pox, tick fever caused by Rickettsiae, respiratory tract infections caused by Mycoplasma pneumonia, Chlamydia infection, nongonococcal urethritis, chancroid, plague, tularemia, cholera, brucellosis, bartonellosis, granuloma inguinale, haemophilus and kleibsella infections, psittacosis.	Fixed Drug Eruption

☞ 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). You can also report through PvPI Helpline No. 1800-180-3024 (Toll-Free).

Press & Media


روزنامہ راشٹریہ سہارا

تشخیص کے بغیر دواؤں کا استعمال نہایت مضر: پروفیسر وینا مہیشوری


बीएचयू में दवाओं के दुष्प्रभाव के प्रति किया गया जागरूक


Wednesday Times
National News paper

"National Pharmacovigilance Week" launched

MASOOD TAIMURI(WednesdayTimes) Saifai, Etawah. Vice Chancellor Professor Dr. Prabhat Kumar Singh inaugurated the fourth National Pharmacovigilance Week under the aegis of the Indian Pharmacopoeia Commission National Coordinating Center Pharmacovigilance Program of India at Uttar Pradesh Medical University Saifai. He said that this time the theme of this week is "Creating a culture of adverse drug reaction (ADR) reporting for patient safety". Pharmacovigilance is a very important subject. All health workers should actively participate in the reporting of drug side effects and all types of ADRs should be reported without any fear. This will protect the health of patients and as a result there will be qualitative improvement in medical service. Vice Chancellor Dr. Ramakant Yadav talked about reporting ADRs caused by antiepileptic, tuberculosis drugs and antibiotics like quinolones, and also urged to report common side effects.

ADR Monitoring Center Coordinator and Pharmacology Department Prof. Dr Asha Pathak told that if any person consumes any kind of medicine, vaccine, injection, syrup, ointment, after taking the medicine, if these symptoms are seen like- rashes on the body, dizziness, frequent vomiting, loss of appetite, restlessness, insomnia, it is necessary to do adverse drug reaction (ADR) reporting. On this occasion, the students of MBBS 2023-24 explained the importance of adverse drug reaction (ADR) reporting through street play. At the end of the program, Professor Dr. Alok Dixit, Head of the Department of Pharmacology, expressed his gratitude to all the guests and the program was successfully conducted by Assistant Professor of Pharmacology Department Dr. Vinay Kumar Gupta and he shared detailed information regarding the weekly awareness program to be held from 17-23 September. Registrar Dr. Chandraveer, Dean Dr. Adesh Kumar, Medical Superintendent Dr. SP Singh, and other faculty members were present in the program.


हिन्दुस्तान

दून मेडिकल कॉलेज में गुरुवार को फार्माकोविजिलेंस सप्ताह पर पोस्टर प्रतियोगिता का आयोजन किया गया। Congratulations

दून मेडिकल कॉलेज में पोस्टर प्रतियोगिता

देहरादून। फार्माकोविजिलेंस सप्ताह 17 से 23 सितंबर के तहत गुरुवार को दून मेडिकल कॉलेज के फार्माकोलॉजी विभाग द्वारा छात्रों के बीच पोस्टर प्रतियोगिता और व्याख्यान आयोजित किए गए। जिसने एडीआर के बारे में जागरूक किया गया। प्राचार्य डॉक्टर गीता जैन ने सबको बधाई दी। इस दौरान एचओडी प्रोफेसर डॉ. संजय गौड़, एसोसिएट प्रोफेसर डॉ. रेनू आदि मौजूद रहे।


हल्द्वानी,22 सितम्बर 2024 2

दवाओं के प्रतिकूल प्रतिक्रियाओं की रिपोर्टिंग हेतु कार्यशाला आयोजित

कुमाऊं विश्वविद्यालय के भीमताल स्थित भेषज विज्ञान विभाग की पहल

आज समाचार सेवा

नैनीताल। कुमाऊं विश्वविद्यालय के भीमताल स्थित भेषज विज्ञान विभाग में दवाओं की प्रतिकूल प्रतिक्रियाओं पर एडवर्स ड्रग रिपोर्टिंग के संबंध में फार्माकोविजिलेंस विधा पर केंद्रित होकर एक दिवसीय कार्यशाला का आयोजन किया गया। ...

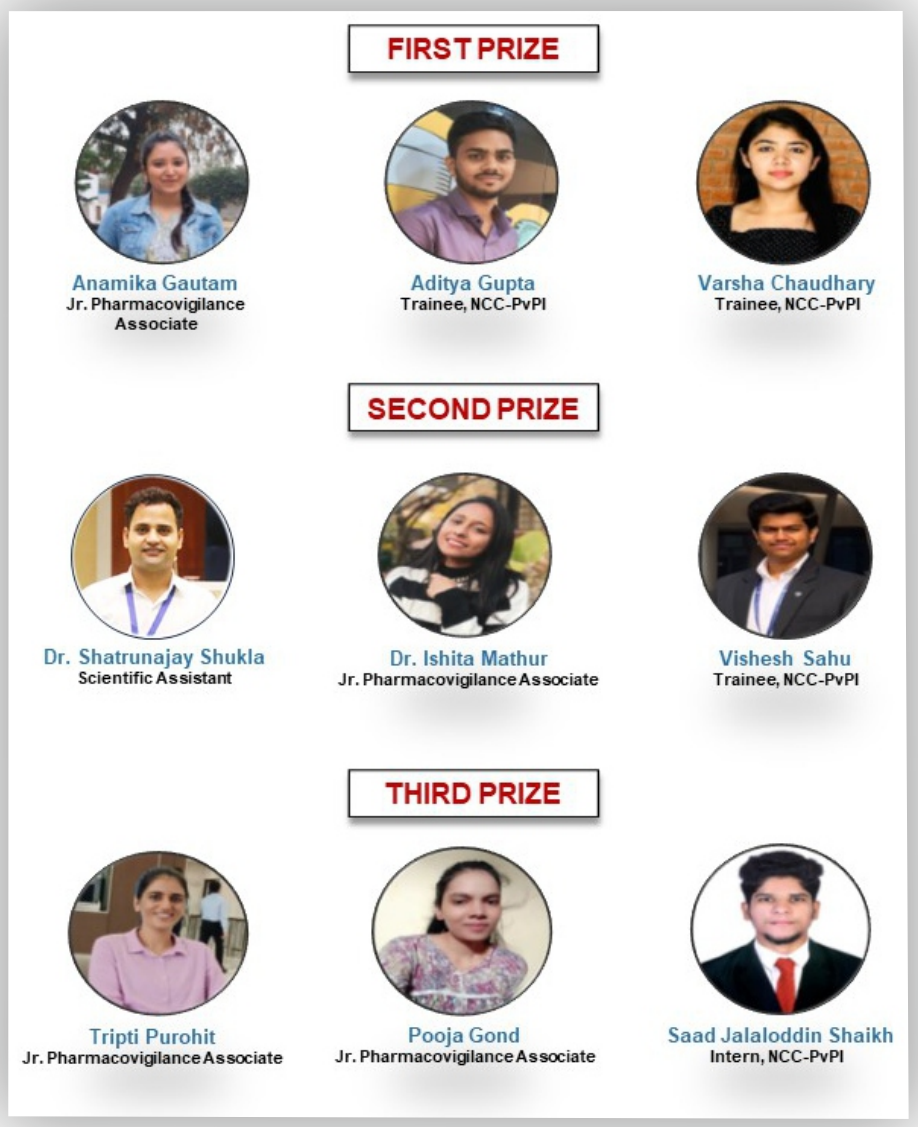
PHOTO GALLERY

Release of PvPI Resource/Promotional materials

Participants during Inaugural Ceremony of 4th NPW

PHOTO GALLERY

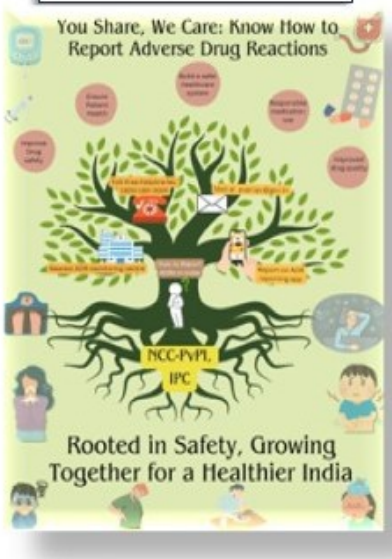

International Webinar on Optimizing the Use of ICSRs in Signal Detection Process on Day 2 of 4th NPW



Winners of Pharmacovigilance Quiz Competition on Day 3 of 4th NPW

PHOTO GALLERY

FIRST PRIZE



Harshita
Jr. Pharmacovigilance Associate, NCC-PvPI

SECOND PRIZE

Mohan Krishna Nalla
Vishwabharathi Medical College & Hospital Kurnool

THIRD PRIZE

Dr. Manish, Keni A, Krishna V. & Roni K.
BAPS Pramukh Swami Hospital - Surat

Winners of Pharmacovigilance Poster Competition on Day 4 of 4th NPW

PHOTO GALLERY

S.No.	ADR MONITORING CENTRES
1.	Post Graduate Institute of Medical Education & Research, Chandigarh
2.	Believers Church Medical College & Hospital ,Thiruvalla, Kerala
3.	Seth GS Medical College & KEM Hospital, Mumbai, Maharashtra
4.	Rajagiri Hospital, Aluva, Kerala
5.	GMERS Medical College & General Hospital, Gandhinagar, Gujarat
6.	JSS Medical College & Hospital, Mysuru, Karnataka
7.	Vijaya Medical & Educational Trust, Vadapalani, Tamil Nadu
8.	Maulana Azad Medical/Dental College and Associated Lok Nayak, New Delhi, Delhi
9.	Father Muller Medical College, Mangaluru, Karnataka
10.	Amrita Institute of Medical Sciences, Kochi, Kerala

Top 10 AMCs Felicitation (with PvA) on Valedictory Ceremony of 4th NPW

S.No.	ADR MONITORING CENTRES
1.	Iqraa International Hospital & Research Centre, Calicut, Kerala
2.	M.S. Ramaiah Medical College, Bengaluru, Karnataka
3.	PSG Institute of Medical Sciences & Research, Coimbatore, Tamil Nadu
4.	National Institute of Pharmaceutical Education and Research, Vaishali, Bihar
5.	KLE College of Pharmacy, KLE Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi, Karnataka
6.	Chalapathi Institute of Pharmaceutical Sciences, Guntur, Andhra Pradesh
7.	Jubilee Mission Medical College and Research Institute, Thrissur, Kerala
8.	Caritas Hospital, Thellakom, Kottayam, Kerala
9.	ABVIMS & Dr. RML Hospital, New Delhi, Delhi
10.	Smt. Bhikhiben Kanjibhai Shah (SBKS) Medical Institute & Research Centre, Waghodia, Gujarat

Top 10 AMCs Felicitation on Valedictory Ceremony of 4th NPW

PHOTO GALLERY

S. No.	Marketing Authorization Holders
1.	Novartis India Limited
2.	Pfizer Limited
3.	Roche Products (India) Private Limited
4.	Baxter (India) Private Limited
5.	AstraZeneca Pharma India Limited

Top 5 AMCs Felicitation on Valedictory Ceremony of 4th NPW

Identified experts under PvPI, Prof. M Ramesh (RTC Coordinator, JSS Mysore, Karnataka) & Prof. Vandana Roy (RTC Coordinator, MAMC, New Delhi) on 4th NPW

PHOTO GALLERY

4th NPW celebration via various modes like workshops, conferences, quiz competitions, walkathon & nukad-natak etc. by AMCs .

PHOTO GALLERY

Rangoli & poster competition by AMCs during the 4th NPW celebration

Forthcoming Events

S. No.	Date	Title	Who can participate?
1.	January 2025	Workshop-cum-Training Programme on Pharmacovigilance for NABH Accredited Hospitals at Fortis Hospital Sector-62, Phase-VIII, Mohali, Punjab	• Physicians • Pharmacists • Nurses • Medical/Paramedical students • Healthcare Professionals
2.	3rd - 7th March 2025	32nd Skill Development Programme on Pharmacovigilance	• Healthcare Professionals • Pharmacovigilance Professionals • Medical/Paramedical/ Pharmacy Students • Pharmacists • Academicians

(For further information, please see the website www.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 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