Newsletter

PHARMACOVIGILANCE PROGRAMME OF INDIA (PvPI)
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How Can Quality Impact Safety of Medicines?

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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

I am privileged to release the Pharmacovigilance Programme of India (PvPI) Newsletter Volume 14, Issue 4 for the index period October, 2024 to December, 2024 on the theme 'How Can Quality Impact Safety of Medicines'.

During the index period, 49 New Adverse Drug Reaction Monitoring Centres (AMCs) have been enrolled under PvPI and total number of AMCs are 1025 across the country. A total of 9.14 Lakh Individual Case Safety Reports have been reported to PvPI as on 31st December 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) etc. The PvPI has organized a total of 242 training programmes and trained a total of 14502 participants in the area of pharmacovigilance in this quarter.

The NCC-PvPI, IPC has issued a total of 172 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 the quality of medicines and the quality of data of ICSRs can impact the safety of medicines, IPC encourages all stakeholders to comply with the standards set out in IP for time being in force and further improve the quality of ICSRs submitted to PvPI.

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

How Can Quality Impact Safety of Medicines ?

India is one of the largest producers and exporters of quality medicines globally. This has been possible because of compliance to Good Manufacture Practices (cGMP) by the pharmaceutical industry however, sometimes the quality defects are also observed that can impact the safety of medicines. The quality compromise can lead to serious / sever adverse events, exacerbation of existing diseases, antimicrobial resistance or even treatment failure/death.

Role of Indian Pharmacopoeia Commission (IPC) in ensuring in quality of medicines

The Indian Pharmacopoeia Commission (IPC) is engaged in protection and promotion of public health by setting the standards of medicine through Indian Pharmacopoeia (IP). Currently, IP 2022 is in force. The Addendum to IP 2022 is also published under the same authority to further update the IP. All concern stakeholders are encouraged to use the current version of IP to ensure quality of medicines.

Role of Pharmacovigilance Programme of India (PvPI) in ensuring the safety of medicines

The PvPI is one of the major health programmes of the Ministry of Health & Family Welfare, Government of India for collecting, collating and analyzing the drug safety data and recommending suitable safety measures to the National Regulatory Authority (NRA) i.e. Central Drug Standards Control Organization (CDSCO). The National Coordination Centre for PvPI at IPC, Ghaziabad with a nationwide network of Adverse Drug Reaction Monitoring Centre and other stakeholders is taking all possible steps for monitoring of the safety of medicines and communicating the outcome to the relevant stakeholders across the country.

The data quality of Individual Case Safety Reports (ICSRs) is crucial in driving a meaningful conclusion for patient safety. The Quality score of Indian ICSRs is relatively higher than that of the quality score of ICSRs from rest of the countries of the world (Figure-1). For the data quality in PvPI, a robust Quality Management System (QMS) is in place. The PvPI has also taken the steps by bringing out Pharmacovigilance Guidance Document for Marketing Authorization Holders (MAHs) of Pharmaceutical Products, Version 2.0 in collaboration with CDSCO for strengthening of Pharmacovigilance system at MAH organization.

There is further scope for improvement of quality of ICSRs. Therefore, all stakeholders are encouraged not only to maintain the quality score of ICSRs but also to fill the accurate and complete information in the ICSR. For example, during the confirmation of a signal duplicate reports may impact the quantitative parameters like IC025 value, PRR and Chi-square value, which may lead to the generation of the falsified signal. The PvPI data is also useful in updating National Formulary of India (NFI) that encourages the healthcare professionals for rational and economic prescribing of medicines.

The medicines of assured quality, safety and efficacy will continue to boost the public confidence and better therapeutic outcome.

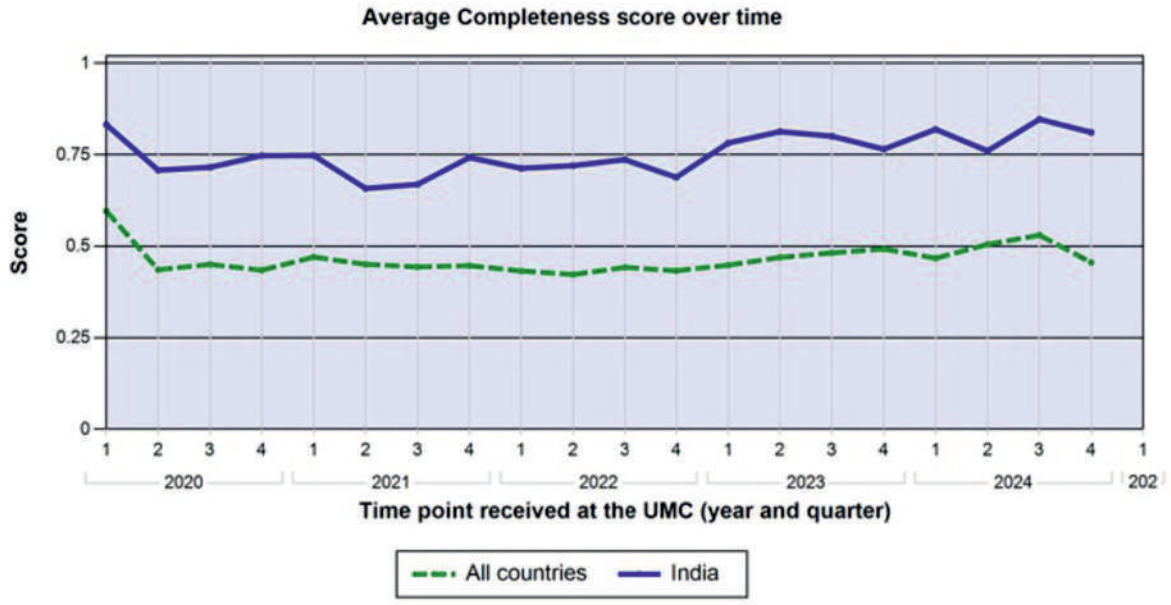


Figure-1: Average completeness score of ICSRs over time

Source: vigiGrade™ - Completeness score India

Pharmacovigilance of CAR T-cell based therapies: an emerging yet unmet need

Suparna Chatterjee, MD, MNASc, MAMS, FRCP (London)
Professor, Dept of Pharmacology, IPGME&R, Kolkata.
Chairperson, Core Training Panel, PVPI

CAR (Chimeric Antigen Receptor) T cell therapy is truly an innovative approach in cell-based gene therapy for cancers. Though initially approved for hematological cancers like lymphomas, leukemias and multiple myeloma, its indications are rapidly expanding to solid organ malignancies as well. Till date, USFDA has approved six CART-cell therapies, majority are CD19 CAR T-cell therapies. Use of such cell based therapy in high income countries far exceeds that of middle and low income economies. India is also witnessing an increased trend in its use, despite issues of alarming costs and limited access.

CAR T-cell therapy has unique and complex mechanistic effects which are distinct from small molecules or other biologics. Monitoring and reporting the safety profile of such therapies is none the less as important as its expanding therapeutic utility. The nature, severity and seriousness of adverse effects are diverse and with time we are gaining a better understanding of the pathogenesis of such adverse effects.

The most common serious short term adverse effect of CAR T cell therapy is cytokine release syndrome (CRS) with a frequency varying from 18 to 55%. The usual time to onset is within one week of T cell infusion but rarely a delayed onset has also been reported. The severity or grade of CRS may vary across different products. The common clinical features of CRS include fever, hypotension, hypoxia, capillary leak syndrome, coagulopathy, renal and cardiac dysfunction or multi organ failure. Rarely, CRS can lead to macrophage activation syndrome (MAS) and hemophagocytic lymphohistiocytosis (HLH), which may be life threatening or fatal.

Another common adverse effect of such therapy is neurological, which has recently been termed as “immune effector cell associated neurotoxicity syndrome” (ICANS). It has a slightly delayed time to onset compared to CRS but its median duration is longer. The features include altered consciousness, seizures, encephalopathy, motor paralysis or paresis, cognitive impairment and raised intracranial pressure. Other adverse effects of CAR T cell therapy include immune-mediated cytopenias and various life-threatening infections.

Some grading systems are in place for categorizing cell-based therapy toxicities but there is a need for harmonization to facilitate uniformity of reporting across continents. We undertook a VigiLyze (a global database of ICSR) search on March 25th, 2024 using "CAR T-cells nos (Active ingredient)" as the search criteria. There were only 14 ICSRs since 2022, mainly physicians report from six countries (Germany, Australia, Austria, Switzerland, France and Italy). Unfortunately, there were no reports from India and there is an emerging need to better utilise the existing pharmacovigilance system in our country to sensitize healthcare professionals and patients of the need for safety reporting of such novel cell-based therapies. Out of 14 ICSRs, 12 were serious adverse reactions and majority did not have any information about the outcome.

Further Reading

- U.S. Food & Drug Administration. Approved cellular and gene therapy products. 30 Jun 2023. https://www.fda.gov/vaccinesblood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products
- Grigor EJM, Fergusson D, Kekre N, Montroy J, Atkins H, Seftel MD, Daugaard M, Presseau J, Thavorn K, Hutton B, Holt RA, Lalu MM. Risks and Benefits of Chimeric Antigen Receptor T-Cell (CAR-T) Therapy in Cancer: A Systematic Review and Meta-Analysis. Transfus Med Rev. 2019 Apr;33(2):98-110. doi: 10.1016/j.tmrv.2019.01.005. Epub 2019 Feb 14. PMID: 30948292.
- Adkins S. CAR T-Cell Therapy: Adverse Events and Management. J Adv Pract Oncol. 2019 May-Jun;10(Suppl 3):21-28. doi: 10.6004/jadpro.2019.10.4.11. Epub 2019 May 1. PMID: 33520343; PMCID: PMC7521123.
- Miao L, Zhang Z, Ren Z, Li Y. Reactions Related to CAR-T Cell Therapy. Front Immunol. 2021 Apr 28;12:663201. doi: 10.3389/fimmu.2021.663201. PMID: 33995389; PMCID: PMC8113953

Enrollment of New AMCs

NCC-PvPI, IPC has enrolled 49 new AMCs in 24th Phase of PvPI expansion. The total number of AMCs enrolled by the end of the year 2024 were 1025 across the country. The list of newly enrolled AMCs is mentioned below:

S. No.	States/UTs	Name of Institution	Status of Hospital
1.	Andhra Pradesh	Government Medical College Noonpalle, Nandyal, Andhra Pradesh - 518501	Government
2.		Andhra Hospitals (Vijayawada) Pvt. Ltd. Tagore Chamber, 29, Nakkala Road, Governer Peta, Vijayawada, NTR District, Andhra Pradesh - 520002	Non-Government
3.	Assam	Nalbari Medical College and Hospital Dakhingaon, PS - Ghograpar, Nalbari, Assam - 781350	Government
4.	Bihar	Bhagwan Mahavir Institute of Medical Science (BMIMS) Pawapuri, Nalanda, Bihar - 803115	Government
5.	Chandigarh	Healing Hospital and Institute of Paramedical Sciences Sector 34A, Chandigarh - 160022	Non-Government
6.	Gujarat	Oswal Aayush Superspeciality Hospital Plot No. 55/56, Digvijay Plot, Jamnagar, Gujarat - 361005	Non-Government

7.		SIDS Hospital & Research Center Opp. Ring Road, New Opera House, Khatodara Wadi, Surat, Gujarat - 395002	
8.		Medipolis Life Care LLP, B-1, Medipolis, New Doctor House, Deesa Highway, Palanpur, Banaskantha, Gujarat - 385001	
9.		GMERS Medical College Panchmahal Godhra, Government Engineering College, Lunavada Road, Godhra, Panchmahal, Gujarat - 389001	Government
10.	Haryana	Aashirwad Hospital Bye Pass Road, Gobindpuri, Yamuna Nagar, Haryana - 135001	Non-Government
11.		Fortis Escorts Hospital Neelam Bata Road, Faridabad, Haryana -121001	
12.		LHDM & Dr. Prem Hospital Panipat, Haryana - 132103	
13.		Sarwal Hospital Civil Line, Ambala City, Haryana - 134003	
14.		Monga Hospital & Stone Centre Mahesh Nagar, Ambala, Haryana - 133001	
15.		Kalra Hospital Panipat, Haryana - 132103	
16.		Ravindra Hospital and Heart Centre Hisar, Haryana - 125001	

17.		Park Hospital Faridabad, Haryana - 121006	
18.		Apex Plus Super Speciality Hospital 174-L, Model Town, Rohtak, Haryana - 124001	
19.	Jharkhand	Paras HEC Hospital Sector-3, Dhurwa, Near JSCA Stadium, Ranchi - 834004	Non-Government
20.	Karnataka	Kauvery Hospital No.92/1A, Konappana Agrahara, Electronic City Banglore, Bangalore Rural, Karnataka - 560100	Non-Government
21.		St. Martha's Hospital #5, Nrupatunga Road, Opp. RBI, Bangalore, Karnataka - 560001	
22.	Kerala	Silverline Hospital Kadvanthra, Kochi, Ernakulam, Kerala - 682020	Non-Government
23.		Sunrise Hospital Kakkanad Seaport, Airport Road, Thrikkakara, Ernakulam, Kerala - 682030	
24.		Government Medical College Annakuthi Konni, Pathanamthitta, Kerala - 689691	Government
25.	Maharashtra	Aureus Institute of Medical Sciences Plot No. 16, Wanjari Nagar, opp. Rajabaksha Hanuman Mandir, Nagpur, Maharashtra - 440003	Non-Government

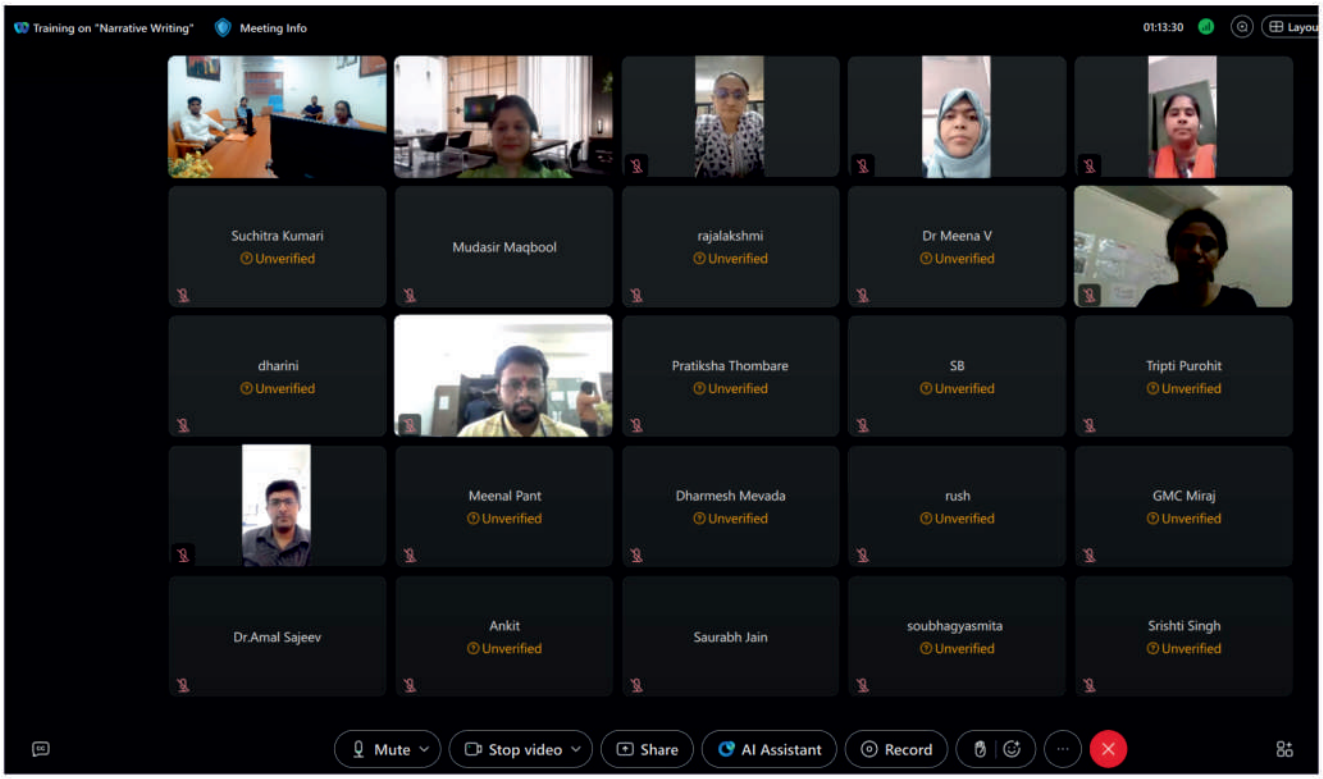
26.	New Delhi	Fortis Flt. Lt. Rajan Dhall Hospital Aruna Asaf Ali Marg, Pocket-1, Sector-B, Vasant Kunj, South West, New Delhi - 110070	Non-Government
27.	Punjab	Dr. B. R. Ambedkar State Institute of Medical Sciences Phase-6, Mohali, Punjab - 160055	Government
28.		The Akashdeep Hospital Majitha Road, Amritsar, Punjab - 143001	Non-Government
29.		Pancham Hospital (A unit of Pancham Hospitals Pvt. Ltd.) Ludhiana, Punjab - 141002	
30.		Iqbal Nursing Home & Hospital 74, Club Road, Civil Lines, Ludhiana, Punjab - 141001	
31.	Rajasthan	Mittal Hospital Near Agresen Circle, Alwar, Rajasthan - 301001	Non-Government
32.		Gurukripa Hospital Research Centre Pvt. Ltd. Gurukripa Circle, Jyoti Nagar, Pipnali Road, Sikar, Rajasthan - 332001	
33.		Maxwell Hospital, (A unit of National Health Institute and Medical Research Centre Trust) Opp. Khandaka Marriage Garden, Jhotwara Road, Jaipur, Rajasthan - 302006	

34.		Sadhna Hospitals Pvt. Ltd. Jharkhand Mode, Khatipura Road, Jaipur Rajasthan - 302012	
35.		Chirayu Hospital (A unit of KSCH Pvt. Ltd.) Hathoj, Kalwar Road, Jaipur, Rajasthan - 302012	
36.		Suvira Hospital 7/C-02, Shipra Path, Mansarovar, Jaipur, Rajasthan - 302020	
37.	Tamil Nadu	Govt. Villupuram Medical College Mundiampakkam Village, Villupuram, Tamil Nadu - 605601	Government
38.		Government Vellore Medical College & Hospital Adukkamparai, Vellore, Tamil Nadu - 632011	
39.		St. Peter's Medical Colege Hospital & Research Institute Dr. MGR Nagar, Near Aeri Campus, Opp. to Sipcot-II, Hosur, Krishnagiri, Tamil Nadu - 635130	Non-Government
40.		JCB Hospitals No:1, Vepanthoopu Street, Palani Road, Dindigul, Tamil Nadu - 624001	
41.	Telangana	Premier Hospitals Pvt. Ltd., Door No. 12-2-710/1, Opp. Queba Masjid, Nanal Nagar X Road, Mehdipatnam, Hyderabad, Telangana - 500028	Non-Government

42.		KIMS Hospital Enterprises Pvt. Ltd. 1-112/56/EE, Gachibowli - Miyapur Road, Serilingampally Mandal, Kondapur, Ranga Reddy, Telangana - 500084	
43.		Rajiv Gandhi Institute of Medical Sciences Adilabad, Telangana - 504001	Government
44.	Uttar Pradesh	Heritage Institute of Medical Sciences, NH-2, G T Road Bypass, Bhadwar, Varanasi, Uttar Pradesh - 221311	Non-Government
45.		Hind Institute of Medical Sciences Village - Mau, Post-Ataria, Tehsil - Sidhavli, Dist.- Sitapur, Uttar Pradesh - 261303	
46.		SPES Superspeciality Hospital Omega II, NRI City Complex, Near Pari Chowk, Greater Noida, Gautam Buddha Nagar, Uttar Pradesh-201310	
47.		Apex Hospital (Unit of Medigrowth Pvt. Ltd.), Moradabad, Uttar Pradesh - 244001	
48.		Taurus Hospital 208, Safipur Ist Ramadevi, CT Road, Kanpur, Uttar Pradesh - 208007	
49.	West Bengal	Desun Hospital (A unit of P N Memorial Neuro Centre & Research Institute Ltd.) Desun More, Kasba Golpark, E M Bypass, Kolkata, West Bengal - 100107	Non-Government

Training on Writing of Case Narrative

One day training on 'Writing of Case Narrative' was organised by NCC-PvPI, IPC through hybrid mode on 3rd October 2024 for Pharmacovigilance Associates posted at NCC and AMCs across the country. The objective of this training programme was to enhance the skills of Pharmacovigilance Associates, thereby to increase the quality of drug safety information to be reported in Individual Case Safety Reports (ICSRs) to the PvPI. Dr Sakshi Rastogi, Sr Director & Head, Life Sciences CoE NTTDATA explained about the background of pharmacovigilance and importance of Writing of Case Narrative as per the ICH-E3 guidelines. A total of 85 participants attended this training programme.



#MedSafetyWeek 2024

The NCC-PvPI, IPC has participated in the celebration of MedSafety Week 2024 organised by the Uppsala Monitoring Centre (UMC), Sweden from 4th to 10th November, 2024 with the theme 'The importance of using medicines in the right way to prevent side effects', how patients, doctors, pharmacists and other health professionals can contribute to pharmacovigilance. The NCC-PvPI, IPC communicated the campaign's materials like e-mail banner, animations, social-media cards, posters to AMCs across the country and also shared through the social media platforms like LinkedIn, X (Twitter), Facebook, and Instagram for public awareness.

Medical Dictionary for Regulatory Activities (MedDRA) Training

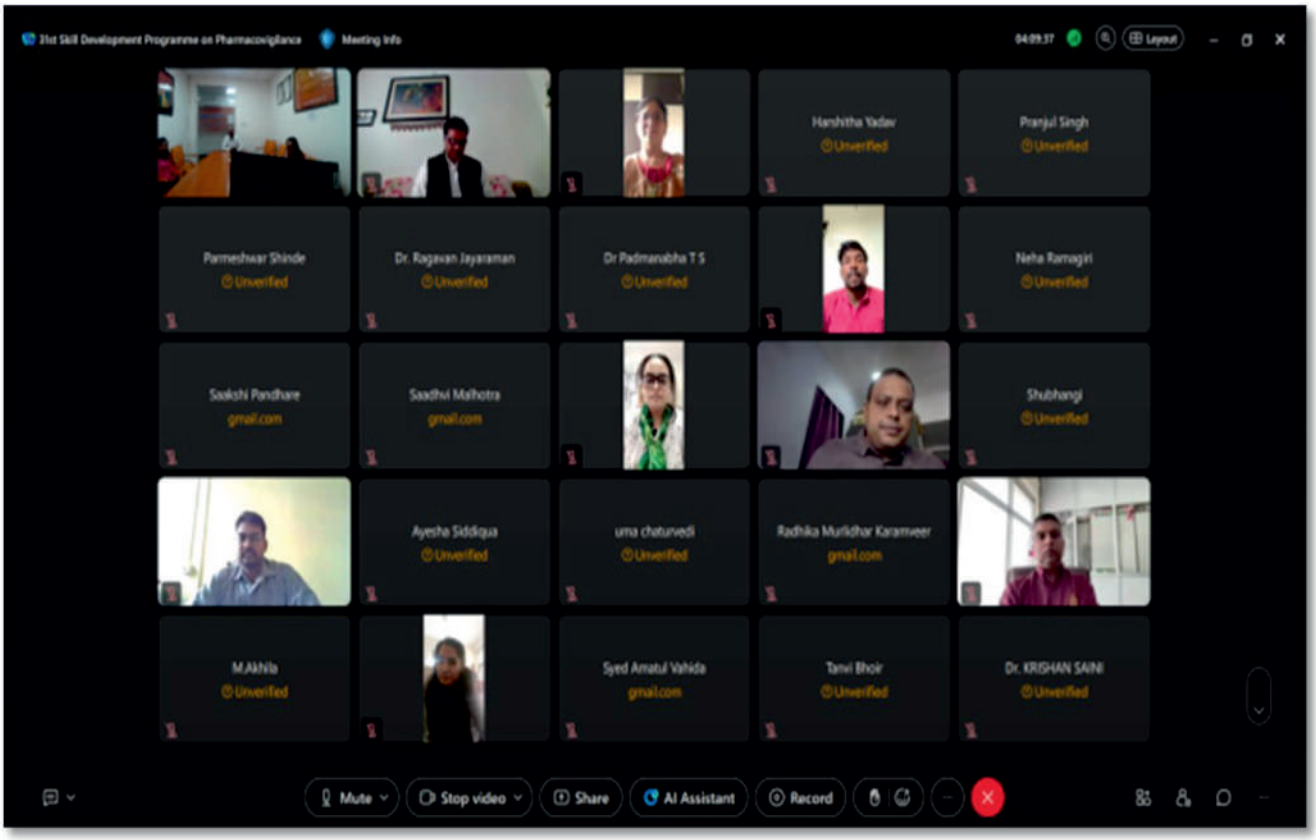
The NCC-PvPI, IPC has organised training on 'Introduction to MedDRA Coding & MedDRA: Safety Data analysis and Standardized MedDRA Queries (SMQs)' from 12th to 13th November, 2024 for the Pharmacovigilance Associates posted at NCC and AMCs across the country. Dr. Anamika Dutta, Medical Officer, Maintenance & Support Services Organization (MSSO) explained the scope, structure and characteristics of MedDRA with daily life example. A workshop on coding medical terminologies by using MedDRA was also provided. A total of 132 participants attended this training programme on Day-1 and 98 participants on Day-2.

National Conference on Pharmacovigilance

Dr Sanjay A Chavan, Chairman and Trusty, SGM Education Group, Dr Mangal S Morbale, Principal, Sant Gajanan Maharaj Ayurvedic College, Mahagaon and Mr Ankush G Patil, Pharmacovigilance & Clinical Research Officer, Sant Gajanan Maharaj Rural Hospital & Research Centre, Mahagaon in collaboration with Sant Gajanan Maharaj College of Pharmacy, Mahagaon and Sant Gajanan Maharaj Ayurvedic College, Mahagaon organised a National Conference on Pharmacovigilance on 14th November 2024 at SGM Education Campus, Kolhapur, Maharashtra. The objective of this conference was to raise the awareness among healthcare professionals in rural areas on monitoring & reporting of Adverse Drug Reactions to the PvPI for enhancing drug safety. In this conference, Dr. Jai Prakash, Officer-in-Charge, PvPI participated as a chief guest and Dr. Shashi Bhushan, Sr. Scientific Officer, PvPI breifed on "Pharmacovigilance & role of PvPI in drug safety. A total of 550 participants including healthcare professionals & students from Kartnataka and Maharashtra have participated in this event.

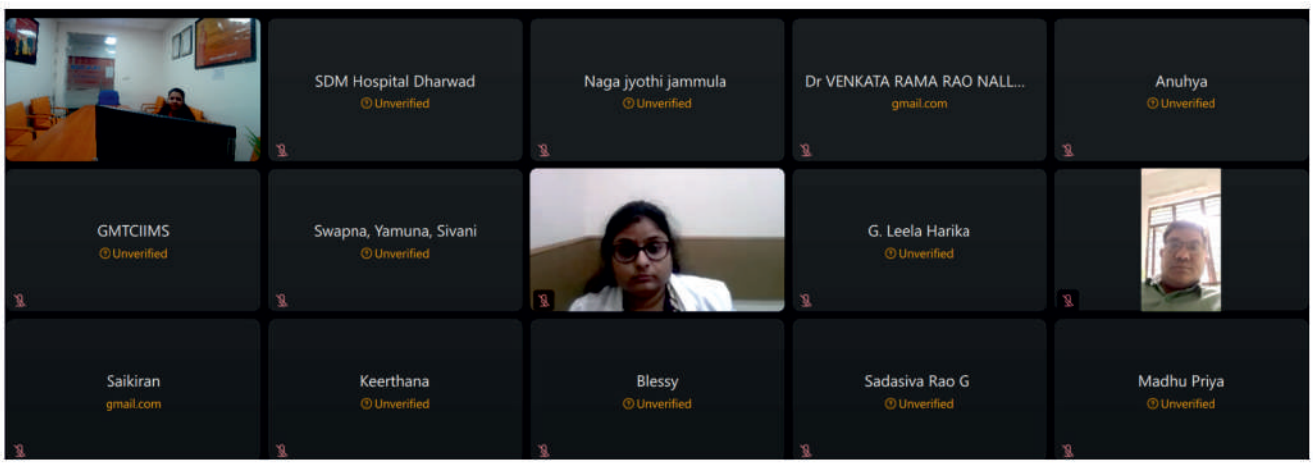
31st Skill Development Programme on Pharmacovigilance

The NCC-PvPI, IPC has conducted 31st Skill Development Programme (SDP) on Pharmacovigilance in virtual mode from 18th to 22nd November 2024. The objective of the SDP was to enhance the pharmacovigilance skills of the healthcare professionals in order to promote the patient safety. A total of 184 participants from different states of India attended this programme including pharmacovigilance professionals, physicians, academicians, pharmacy students, medical students, and pharmacists.



Handholding training on VigiFlow software

The NCC-PvPI, IPC organised a handholding training on VigiFlow software for newly recognized Adverse Drug Reaction Monitoring Centres (AMCs) enrolled under PvPI in virtual mode on 27th November 2024. The objective of this training was to explain about the entering of Individual Case Safety Report (ICSR) into the VigiFlow software and resolving the queries raised by the participants related to processing of VigiFlow software. A total of 24 participants attended this handholding training programme.



CME organised by MMC, Chennai

Dr K. M Sudha, Coordinator, Institute of Pharmacology, Madras Medical College, Chennai and Mrs. Siddiraju Devipriya, PV Associate organised a CME training programme on Pharmacovigilance-Clinical Perspectives in hybrid mode on 27th November 2024. The objective of this training programme was to sensitize healthcare professionals. A total of 187 participants including doctors, pharmacy students, pharmacy faculty and staff nurses attended this training programme.

CME organised by TRIHMS Medical College, Arunachal Pradesh

Dr Asthomi Jomah, Coordinator and Ms. Nabam Yahing, Deputy Coordinator under the guidance of Dr Devender Sachdev, Professor & Head of the Department of Pharmacology, AMC at Tomo Riba Institute of Health & Medical Sciences (TRIHMS), Naharlagun, Arunachal Pradesh organised one day CME training programme on 'Fostering a culture of Patient Safety: The crucial roles of ADRs in Healthcare' on 4th December 2024. The objective of this training programme was to improve the awareness relevant to individual safety and enhancing Adverse Drug Reactions (ADRs) reporting culture in India. A total of 206 participants including doctors, nurses, pharmacists and MBBS students have attended this CME training programme.

Webinar organised by NIMS, Hyderabad

Dr P Usha Rani, Coordinator and Dr M Padmaja, Deputy Coordinator, AMC at Nizam Institute of Medical Sciences, Telangana being a Regional Training Centre of PvPI in collaboration with Indian Society for Clinical Research (ISCR) organised webinar on Risk management of pharmaceutical products – role of different stakeholders on 6th December 2024.

Advance Level Training Programme (ALT) in Pharmacovigilance

Prof. Suparna Chatterjee, Coordinator, AMC and RTC of Institute of Postgraduate Medical Education & Research, Kolkata organised an ALT Programme theme on the 'Medication safety in mother and child' through hybrid mode on 10th December, 2024. In this training programme, Dr Shashi Bhushan, Sr. Scientific Officer, PvPI, IPC briefed 'Updates of PvPI'. A total of 165 participants have participated in this training programme.

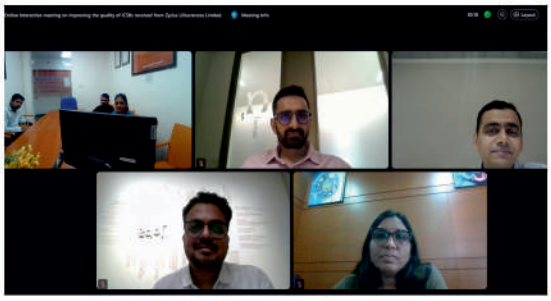
Workshop-cum-Training Programme on Pharmacovigilance Requirements for Human Vaccines in India

CDSCO organized Workshop-cum-Training Programme on Pharmacovigilance Requirements for Human Vaccines in India was held on December 10, 2024, at the National Institute of Biologicals (NIB), Noida (U.P.). This important event focused on the critical aspects of pharmacovigilance concerning vaccines, aimed at ensuring the safety and efficacy of vaccines in the Indian context. The program gathered professionals from the pharmaceutical and healthcare sectors, offering a platform to discuss the regulatory framework, monitoring processes, and the role of pharmacovigilance in post-market surveillance of vaccines. Experts provided valuable insights into the evolving requirements for vaccine safety monitoring, addressing challenges, and highlighting best practices in pharmacovigilance. The training is part of ongoing efforts to strengthen India's healthcare infrastructure and ensure that vaccines administered to the population meet the highest safety standards.

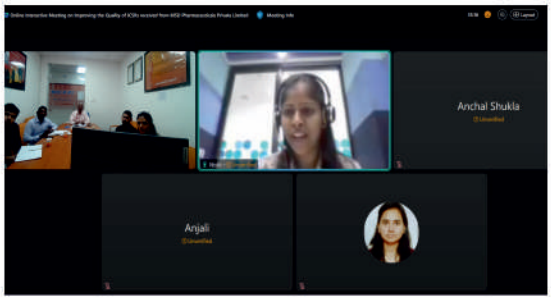
Interactive meetings with Marketing Authorization Holders

The objective of the following interactive meetings held virtually was to address the issues like quality, number of ICSRs, completeness score of reported ICSRs by MAHs to PvPI. In these meetings, NCC-PvPI, IPC also focussed on effective implementation of Pharmacovigilance System at MAH/Pharmaceutical Industry.

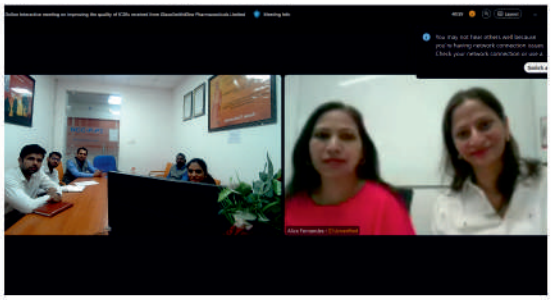
S. No.	Date	MAHs/Pharmaceutical industries	No. of MAHs Representatives
1.	14-10-2024	Zydus Lifesciences Limited	7
2.	28-10-2024	MSD Pharmaceuticals Private Limited	9
3.	28-11-2024	GlaxoSmithKline Pharmaceuticals Limited	8
4.	30-12-2024	Troikaa Pharmaceuticals Limited	14



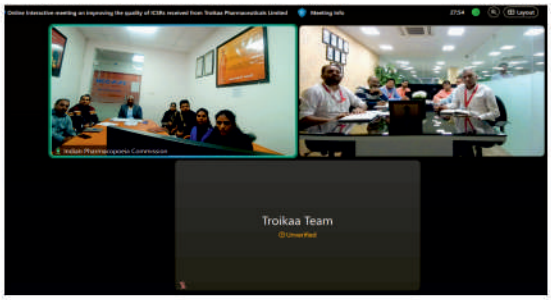
Zydus Lifesciences Limited Representatives



MSD Pharmaceuticals Private Limited Representatives



GlaxoSmithKline Pharmaceuticals Limited Representatives



Troikaa Pharmaceuticals Limited Representatives

Monthly trends of training programmes conducted during index period

The NCC-PvPI, IPC organised a total of 242 training programmes like Skill Development Programmes, Continuing Medical Education, Advanced Level Training Programmes etc. and trained a total number of 14502 participants in the area of Pharmacovigilance across the country.

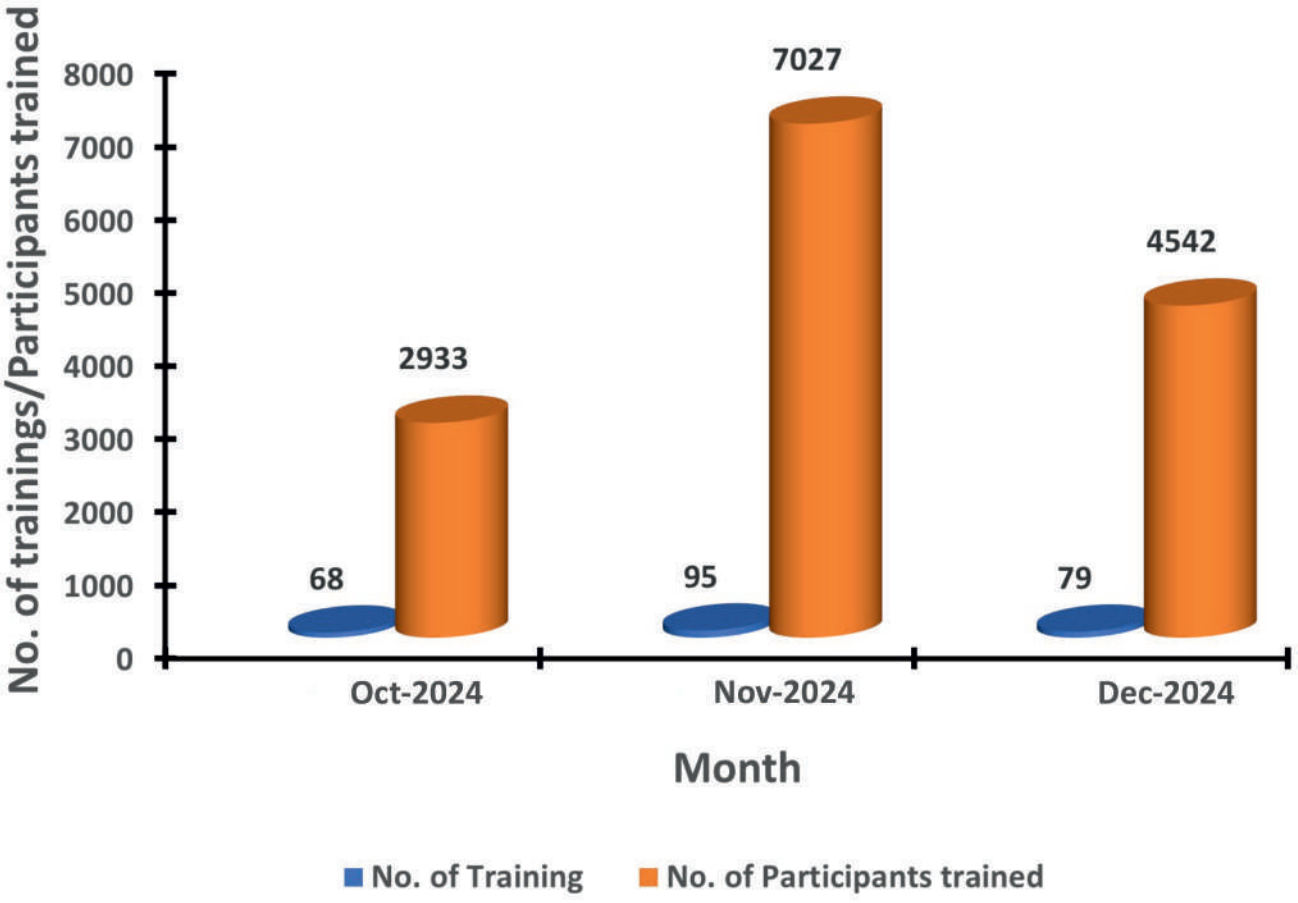


Figure-2: Monthly trends of training programmes

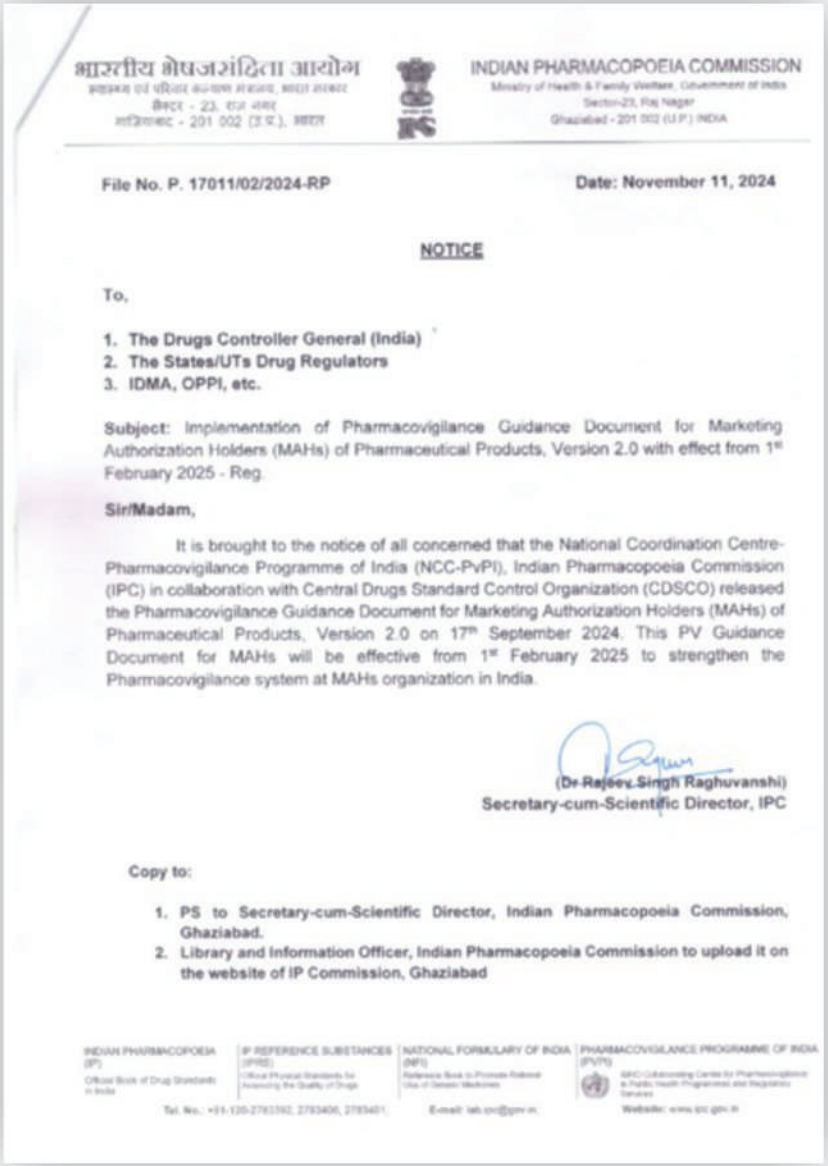
Sensitization about SGLT2 inhibitors related genital infections

The NCC-PvPI, IPC sensitizes healthcare professionals (HCPs) at AMCs to closely monitor incidence of genital infections associated with use of Sodium-Glucose Co-Transporter-2 (SGLT2) inhibitors. In the past also NCC-PvPI sensitized the stakeholders about it vide PvPI Newsletter Vol 13, Issue 3, Year 2023, Vol 13, Issue 1, Year 2023, Vol 12, Issue 1, Year 2022, Vol 10, Issue 31-32, 2020 and through email on 15th July 2019. These formal communications were done following a warning letter issued by the Central Drugs Standard Control Organization (CDSCO) vide its letter 12-74/13-DC dated 25th March, 2019.

The above-stated communications followed the safety announcements by Health Canada and US Food and Drug Administration (USFDA) on 20th July, 2018 wherein, Health Canada addressed the potential risk of inflammation of the pancreas (acute and chronic pancreatitis), and USFDA on 29th August, 2018 issued a warning of serious rare infection called necrotizing fasciitis of the perineum also referred to as Fournier's gangrene.

Notice regarding the implementation of PV Guidance Document for MAHs of Pharmaceutical Products, Version 2.0

The NCC-PvPI, IPC in collaboration with CDSCO released the Pharmacovigilance Guidance Document for Marketing Authorization Holders (MAHs) of Pharmaceutical Products, Version 2.0 on 17th September 2024. This PV Guidance Document for MAHs will be effective from 1st February 2025 to streghthen the pharmacovigilance system at MAHs organisation in India.



भारतीय भेषजसंहिता आयोग
INDIAN PHARMACOPOEIA COMMISSION
Ministry of Health & Family Welfare, Government of India
Sector-23, Raj Nagar
Ghaziabad - 201 002 (U.P.) INDIA

File No. P. 17011/02/2024-RP

Date: November 11, 2024

NOTICE

To,

1. The Drugs Controller General (India)
2. The States/UTs Drug Regulators
3. IDMA, OPPI, etc.

Subject: Implementation of Pharmacovigilance Guidance Document for Marketing Authorization Holders (MAHs) of Pharmaceutical Products, Version 2.0 with effect from 1st February 2025 - Reg.

Sir/Madam,

It is brought to the notice of all concerned that the National Coordination Centre-Pharmacovigilance Programme of India (NCC-PvPI), Indian Pharmacopoeia Commission (IPC) in collaboration with Central Drugs Standard Control Organization (CDSCO) released the Pharmacovigilance Guidance Document for Marketing Authorization Holders (MAHs) of Pharmaceutical Products, Version 2.0 on 17th September 2024. This PV Guidance Document for MAHs will be effective from 1st February 2025 to strengthen the Pharmacovigilance system at MAHs organization in India.

(Dr Rajeev Singh Raghuvanshi)
Secretary-cum-Scientific Director, IPC

Copy to:

1. PS to Secretary-cum-Scientific Director, Indian Pharmacopoeia Commission, Ghaziabad.
2. Library and Information Officer, Indian Pharmacopoeia Commission to upload it on the website of IP Commission, Ghaziabad

INDIAN PHARMACOPOEIA (IP) | IP REFERENCE SUBSTANCES (IPRS) | NATIONAL FORMULARY OF INDIA (NFI) | PHARMACOVIGILANCE PROGRAMME OF INDIA (PVPI)

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)	Date of Issue
1.	Mavacamten capsules 2.5 mg, 5 mg,10 mg,15 mg	Mavacmten is indicated for the treatment of symptomatic (NEW York Heart Association, NYHA, class II-III) Obstructive Hypertrophic Cardiomyopathy (OHCM) in adult patients.	8th October 2024
2.	Ferumoxytol Bulk Drug & Ferumoxytol Injection 510 mg Elemental Iron/17 ml (30 mg/ml)	It is an iron replacement product indicated for the treatment of Iron Deficiency Anemia (IDA) in adult patients: • Who have intolerance to oral iron or have had unsatisfactory response to oral iron or • Who have Chronic Kidney Disease (CKD)	8th October 2024
3.	Belumosudil Tablet 200 mg	For the treatment of patients 12 years and older with chronic Graft versus-Host Disease(cGvHD) after failure of at least two prior lines of systemic therapy	22nd November 2024
4.	Lumateperone Tosylate Bulk Drug & Lumateperone capsules 42 mg	Indicated for the treatment of depressive episodes associated with bipolar I or II disorder (bipolar depression) in adults as mono therapy and as adjunctive therapy with lithium or valproate.	26th December 2024
5.	Trelagliptin Succinate Bulk & Trelagliptin Tablets 25 mg, 50 mg, and 100 mg	For treatment of Type 2 diabetes.	

☞ 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 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.	Issue Date	Suspected drugs	Indication(s)	Adverse Drug Reactions
1.	28th November 2024	Amphotericin B	i. Treatment of Febrile Neutropenia in cancer patients. ii. Treatment for invasive fungal infection in patients, who are refractory to or intolerant of conventional Amphotericin B therapy. iii. Indicated for the treatment of Visceral Leishmaniasis.	Hyperkalaemia
2.		Carbimazole	Indicated for the treatment of thyrotoxicosis including thyrotoxicosis crisis.	Agranulocytosis
3.	26th December 2024	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 and angina pectoris. **Propranolol:** For the treatment of 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.	Hypokalaemia

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.

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Drug Safety Alert: Indian Pharmacopoeia Commission Flags ADR Linked To Tetracycline

Written By : Susmita Roy | **Medically Reviewed By :** Dr. Kamal Kant Kohli

Published On 5 Oct 2024 6:00 PM | Updated On 5 Oct 2024 6:00 PM

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Drug Safety Alert: IPC Flags Adverse Reactions To Amphotericin B And Carbimazole

Written By Susmita Roy — Published On 6 Dec 2024 6:00 PM | Updated On 6 Dec 2024 6:00 PM

Forthcoming Events

S. No.	Date	Title	Who can participate?
1.	29th January 2025	Regional Training Programme on 'Implementation on PV Guidance Document for MAHs of Pharmaceutical Products, Version 2.0' at NIMHANS, Bengaluru	• Marketing Authorization Holders/Pharmaceutical Industry Professionals • Contract Research Organizations CRO • Personnel dealing in Pharmacovigilance
2.	31st January 2025	Workshop-cum-Training for the staff of NABH accredited hospitals on Pharmacovigilance at Fortis Hospital, Mohali, Punjab	• Healthcare Professionals • Pharmacovigilance Professionals • Medical/Para-medical/Pharmacy Students • Pharmacists • Academicians
3.	28th February 2025	Regional Training Programme on 'Implementation on PV Guidance Document for MAHs of Pharmaceutical Products, Version 2.0' at Central Drugs Testing Laboratory (CDTL), Mumbai	• Marketing Authorization Holders/Pharmaceutical Industry Professionals • Contract Research Organizations CRO • Personnel dealing in Pharmacovigilance
4.	3rd – 7th March, 2025	32nd Skill Development Programme at NCC-PvPI, IPC (Virtual)	• Healthcare Professionals • Pharmacovigilance Professionals • Medical/Para-medical/Pharmacy Students • Pharmacists • Academicians
5.	8th April, 2025	Regional Training Programme on 'Implementation on PV Guidance Document for MAHs of Pharmaceutical Products, Version 2.0' at Techno India University, Kolkata, West Bengal	• Marketing Authorization Holders/Pharmaceutical Industry Professionals • Contract Research Organizations CRO • Personnel dealing in Pharmacovigilance

(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 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
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Website: www.ipc.gov.in

Let us join hands with PvPI to ensure patient safety