PHARMACOVIGILANCE PROGRAMME OF INDIA

PERFORMANCE REPORT
2024-25

INDIAN PHARMACOPOEIA COMMISSION
Ministry of Health and Family Welfare, Government of India

PHARMACOVIGILANCE PROGRAMME OF INDIA
Performance Report 2024-25

National Coordination Centre
Pharmacovigilance Programme of India
INDIAN PHARMACOPOEIA COMMISSION
Ministry of Health and Family Welfare, Government of India
Sector-23, Raj Nagar, Ghaziabad-201002

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ABBREVIATIONS

ADR	:	Adverse Drug Reaction
ADRMS	:	Adverse Drug Reaction Monitoring System
AE	:	Adverse Event
AEFI	:	Adverse Event Following Immunization
AIIMS	:	All India Institute of Medical Sciences
AMC	:	Adverse Drug Reaction Monitoring Centre
CDSCO	:	Central Drugs Standard Control Organization
CME	:	Continuing Medical Education
CTP	:	Core Training Panel
COVID-19	:	Coronavirus Disease
GoI	:	Government of India
GVP	:	Good Pharmacovigilance Practices
HCP	:	Healthcare Professional
ICSR	:	Individual Case Safety Report
IPC	:	Indian Pharmacopoeia Commission
MAH	:	Marketing Authorization Holder
MDAE	:	Medical Device Adverse Event
MedDRA	:	Medical Dictionary for Regulatory Activities
MoHFW	:	Ministry of Health and Family Welfare
MvPI	:	Materiovigilance Programme of India

NABH	:	National Accreditation Board for Hospitals and Healthcare Providers
NCC	:	National Coordination Centre
NFI	:	National Formulary of India
NPW	:	National Pharmacovigilance Week
NRA	:	National Regulatory Authority
PHP	:	Public Health Programme
PIDM	:	Programme for International Drug Monitoring
PIL	:	Prescribing Information Leaflet
PV	:	Pharmacovigilance
PvPI	:	Pharmacovigilance Programme of India
RTC	:	Regional Training Centre
SEARN	:	South East Asia Regulatory Network
SDP	:	Skill Development Programme
SRP	:	Signal Review Panel
UMC	:	Uppsala Monitoring Centre
UT	:	Union Territory
WHO	:	World Health Organisation

Message from the Desk of Secretary-cum-Scientific Director

I have immense pleasure to present the Performance Report of Pharmacovigilance Programme of India (PvPI) for the Financial Year 2024-25.

PvPI has undergone vast expansion to reach the common masses in the country through a network of Adverse Drug Reaction Monitoring Centres (AMCs). National Coordination Centre Pharmacovigilance Programme of India (NCC-PvPI), Indian Pharmacopoeia Commission (IPC) has enrolled 155 new AMCs across the country. The total number of AMCs under PvPI are 1050 across the country as of now.

The National Coordination Centre (NCC)-PvPI has issued 14 Drug Safety Alerts for the sensitization of the healthcare professionals and common masses in the country. In addition to this, PvPI also sent a total 7 recommendations including 1 signal to Central Drugs Standard Control Organization to be included in Prescribing Information Leaflets (PILs) of drugs.

PvPI has organized a total of 2598 training programmes and has trained 200302 participants in the area of Pharmacovigilance across the country during this index period. Some of the important training programmes include Skill Development Programme on Pharmacovigilance, Continuing Medical Education, Advanced Level Training Programmes, Induction-cum-Training Programmes, etc. PvPI has organized 11 Interactive meets with Marketing Authorization Holders (MAHs)/Pharmaceuticals Industries to discuss & resolve their issues and to bring improvement in quality of reports.

The NCC-PvPI organized 4th National Pharmacovigilance Week with the theme "Building ADR Reporting Culture for Patient Safety" from 17th-23rd September, 2024 and also sensitized the AMCs under PvPI for organizing Pharmacovigilance activities to raise the awareness about reporting of ADRs to PvPI. During the National Pharmacovigilance Week, PvPI organised a total of 1133 training/awareness-cum-sensitization programmes including CME/CPE in which 123251 Healthcare Professionals and other stakeholders were trained/made aware on Pharmacovigilance. PvPI has also participated in #MedSafetyWeek 2024 organized by WHO-UMC, Sweden.

To enhance the visibility of PvPI, the Information, Education & Communication (IEC) materials related to PvPI was uploaded on the website of National Health Systems Resource Centre (https://nhsrcindia.org/), National Health Mission, Ministry of Health and Family Welfare (MoHFW), Government of India.

IPC is also functioning as a NCC for Materiovigilance Programme of India (MvPI) under the umbrella of PvPI, which deals in collection, monitoring, recording and analyzing the Adverse Events (AEs) or risk associated with the use of medical devices. The MvPI has enrolled new 96 Medical Device Adverse Event Monitoring Centres (MDMCs) and the total number of MDMCs became 547 from 451 across the country. The MvPI forwarded 22 recommendations on safe use of medical devices in India to CDSCO for taking appropriate regulatory actions.

I acknowledge the overall administrative and financial support of the Ministry of Health and Family welfare and Ministry of Finance, Government of India.

I congratulate the PvPI and MvPI team, AMCs, subject matter experts, MAHs/Pharmaceutical industries, healthcare professionals 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

HIGHLIGHTS

01 ➤ Enrolled 155 new AMCs under PvPI and expanded to 1050 AMCs pan-India.

02 ➤ Enrolled 96 new MDMCs under MvPI and expanded to 547 MDMCs pan-India

03 ➤ Total 131301 ICSRs were submitted to VigiBase.

04 ➤ Total 14,584 MDAE reports were received by Materiovigilance Programme of India (MvPI).

05 ➤ On behalf of India, PvPI is the 8th largest reporter of ICSRs in VigiBase at global level.

06 ➤ PvPI, IPC continued to maintain as a WHO-Collaborating Centre for Pharmacovigilance in Public Health Programmes and Regulatory Services.

07 ➤ PvPI has issued 14 drug safety alerts and has recommended 7 PIL changes including 1 Signal to the Central Drugs Standard Control Organization (CDSCO) for taking appropriate regulatory actions.

08 ➤ The MvPI forwarded 22 recommendations on safe use of medical devices in India to CDSCO for taking appropriate regulatory actions.

09 ➤ Conducted 2598 trainings/workshops/CMEs/ALT/NPW Programmes and trained 200302 participants.

10 ➤ 4th National Pharmacovigilance Week was celebrated from 17th - 23rd September 2024 pan-India.

11 ➤ NCC-PvPI, IPC also provided technical support for the pharmacovigilance programmes in Sikkim Manipal Institute of Medical Sciences (SMIMS), Gangtok, East Sikkim, Sant Gajanan Maharaj Rural Hospital, Kolhapur, Maharashtra and Tomo Riba State Hospital, Naharlagun, Arunachal Pradesh.

12 ➤ NCC-PvPI, IPC has organized an International Webinar for all the SEARN countries titled 'Optimizing the use of ICSRs in Signal Detection' on 18th September 2024.

13 ➤ PvPI has published 4 Newsletters on quarterly basis and disseminated this information to the stakeholders about the Pharmacovigilance activities.

14 ➤ PvPI and MvPI have published 27 research articles on Pharmacovigilance.

15 ➤ Participated in #MedSafetyWeek 2024 organized by WHO-UMC, Sweden.

Indian Pharmacopoeia Commission and its Services

Indian Pharmacopoeia Commission is an autonomous institution of the Ministry of Health & Family Welfare, Government of India, engaged in evaluation and quality control of drugs and to deal with matters relating to the timely publication of the Indian Pharmacopoeia (IP), the official document of standards for drugs.

Functions

The mandate of the commission is to perform interalia functions such as revision and publication of IP and National Formulary of India (NFI) on a regular basis. IPC also provides IP Reference Substances and training to the stakeholders on Pharmacopoeial issues and also functions as National Coordination Centre for PvPI & MvPI respectively.

Figure - 1. Products & Services of Indian Pharmacopoeia Commission

Pharmacovigilance Programme of India

Genesis

No. X.11035/7/2011-DFQC
Government of India
Ministry of Health & Family Welfare
****

Nirman Bhavan, New Delhi
Dated the 15th April, 2011

ORDER

Subject: Recasting the Pharmacovigilance Programme of India (PvPI) for monitoring adverse drug reactions (ADR) in the country - regarding.

The Pharmacovigilance Programme of India (PvPI) was initiated by the Government of India on 14.7.2010 with the All India Institute of Medical Sciences (AIIMS), New Delhi as the National Co-Ordination Centre for monitoring Adverse Drug Reactions (ADR) in the country. To ensure implementation of this programme in a more effective way, it has now been decided with the approval of the Hon'ble Minister of Health & Family Welfare to recast the programme as follows:

2. The National Coordination Centre has been shifted from the All India Institute of Medical Sciences (AIIMS), New Delhi to the Indian Pharmacopoeia Commission, Ghaziabad, (U.P.)

3. The Steering Committee of the Pharmacovigilance Programme of India to supervise and give proper direction to the programme has been re-constituted with the following composition:

Drugs Controller General (India)	Chairperson ex-officio
Secretary-cum-Scientific Director, Indian Pharmacopoeia Commission, Ghaziabad (U.P.)	Member ex-officio
Head of Department, Department of Pharmacology, AIIMS, New Delhi	Member ex-officio
A nominee of Director General, ICMR	Member
Assistant Director General (Expanded Programme of Immunization) [ADG(EPI)] as representative of the Directorate General Health Services	Member ex-officio
Under Secretary (Drugs Control) as representative of the Ministry of Health & Family Welfare	Member ex-officio
A nominee of Vice Chancellor of a Medical / Pharma University	Member

....2/-

Pharmacovigilance Programme of India is Government of India's flagship drug safety monitoring programme, which collects, collates and analyses drug-related adverse events and send recommendations to CDSCO for taking appropriate regulatory actions.

Adverse Drug Reaction (ADR) is one of the leading causes of morbidity and mortality worldwide. The consequences of ADRs burden the healthcare system with increased cost of therapy and prolongation of hospitalization. In developing countries, the cost of management of adverse reactions in the general population is very high and under-recognized. It is, therefore, imperative to evaluate the safety of medicines through the Pharmacovigilance system.

The Ministry of Health and Family Welfare, Government of India recasted PvPI on 15th April, 2011 and shifted the National Coordination Centre from All India Institute of Medical Sciences (AIIMS), New Delhi to IPC, Ghaziabad and is continuing.

PvPI: An Overview

Mission

To safeguard the health of the Indian population by ensuring that the benefits of use of medicine outweigh the risks associated with its use.

Vision

To improve patient safety and welfare of the Indian population by monitoring safety of medicines, thereby reducing the risk associated with their use.

Aims & Objective

- Create a Nation-wide system for patient-safety by ensuring drug-safety
- Identify and analyse new signals from the reported cases
- Analyse the benefit-risk ratio of marketed medications
- Generate evidence-based information on safety of medicines
- Support regulatory agencies in the decision-making process on use of medications
- Communicate safety information on use of medicines to various stakeholders for preventing/minimizing the risk
- Collaborate with other National Centres for exchange of information and data management
- Provide training and technical support to other National Pharmacovigilance Centres across the globe
- To organise and sensitize the stakeholders for celebration of National Pharmacovigilance Week from 17th September- 23rd September every year
- Promote rational use of medicines
- Emerge as a National Centre of Excellence for Pharmacovigilance Activities

Core committees at NCC-PvPI

Following committees are constituted at NCC-PvPI to ensure smooth and effective functioning of the programme:

Steering Committee

It is the chief administrative and monitoring body of NCC-PvPI, which guides and supervises the functioning of programme.

Working Group

All technical issues related to the establishment and implementation of the programme, including providing technical inputs, are handled by the Working Group, which give recommendation to the PvPI for onward regulatory interventions by the CDSCO.

Quality Review Panel

Quality Review Panel is responsible for quality, causality assessment and completeness of ICSRs. The panel also makes recommendations to the PvPI Working Group after data analysis and devises formats and guidance documents for follow-up action.

Signal Review Panel

The Signal Review Panel (SRP) of PvPI comprises scientists and clinical experts affiliated to government and non-government academic institutions and hospitals. As and when required experts from the pharmaceutical industries are also invited for taking expert inputs, to collate and analyse information from ICSRs. This panel assesses the results of identified computerized Signals from ICSRs to validate and confirm. It looks into biostatistical methods for analysis and creates standardized post-analytical reports that help in understanding the information derived from ADRs. It also decides upon actionable indicators.

Core Training Panel

The Core Training Panel (CTP) of PvPI guides in the identification of training needs, organizing National and International training programmes, designing training modules and helps to conduct the training for healthcare professionals and other stakeholders throughout the year. It also identifies trainers for zone-wise training centres. The CTP is assisted by the internal training team of PvPI.
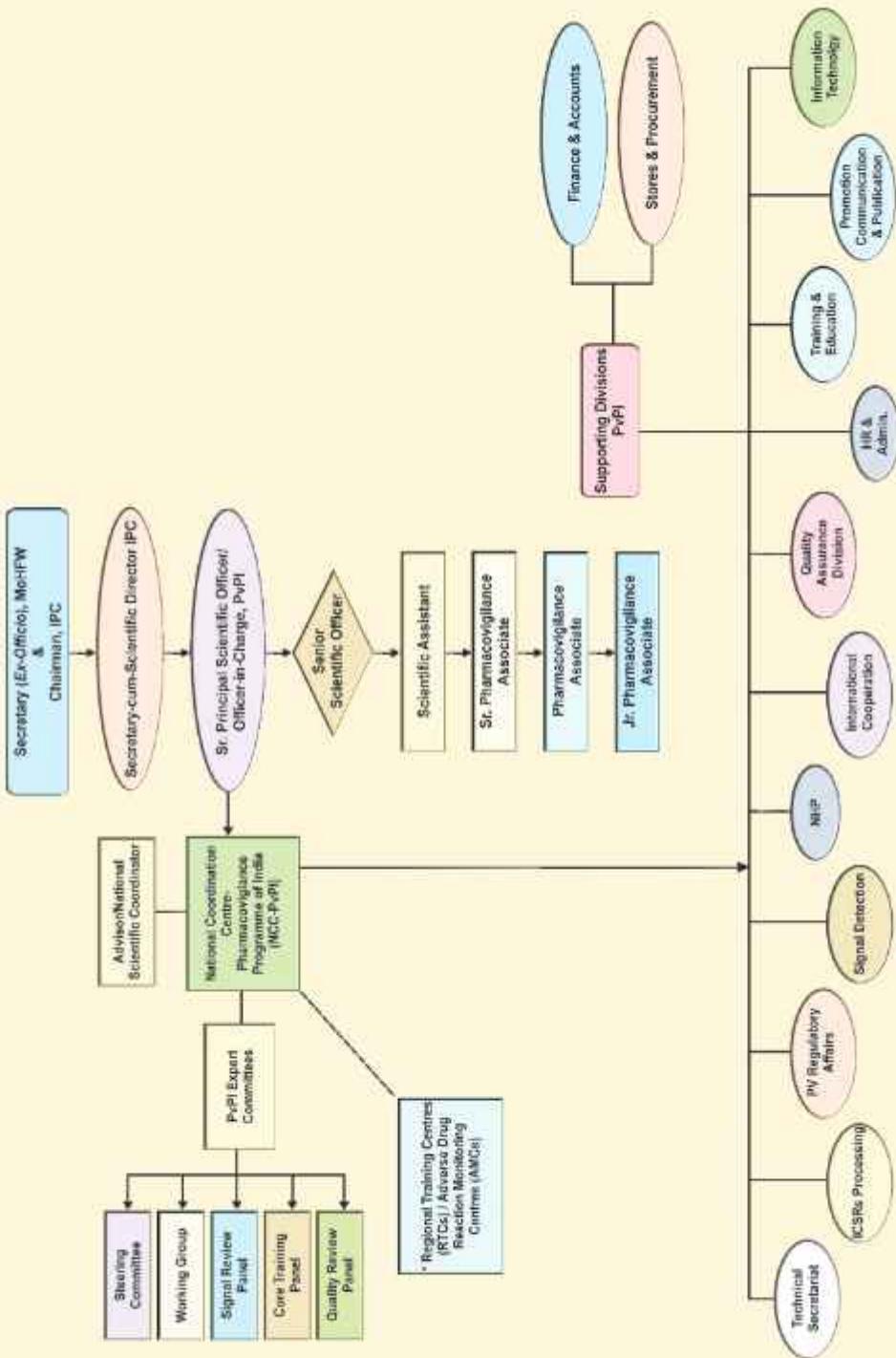
ORGANOGRAM OF PHARMACOVIGILANCE PROGRAMME OF INDIA

Figure -2. Organogram of Pharmacovigilance Programme of India

* RTCs and AMCs are designated by the NCC-PvPI across the country

E-mail IDs and functions of PvPI divisions

S. No.	PvPI Divisions	Functions	E-mail IDs
1.	Human Resource Division	Human Resources Development	hr.nccpvpi-ipc@gov.in
2.	Individual Case Safety Report Processing Division	Submission of ADRs by non-AMCs	pvpi.ipc@gov.in
		Submission of ADRs by consumers/patients	pvpi.ipc@gov.in
		Processing of adverse events reported through PvPI Helpline	pvpi.ipc@gov.in
3.	Information Technology Division	VigiFlow and other IT tools	it.nccpvpi-ipc@gov.in
4.	National Health Programme Division	Integration with Public Health Programmes	nhp.nccpvpi-ipc@gov.in
5.	Promotion, Communication & Publication Division	Publication of PvPI resource materials and communication with stakeholders	pvpi.ipc@gov.in
6.	PV Regulatory Affairs Division	Processing of ICSRs received from MAHs and review of PSUR	mah.nccpvpi-ipc@gov.in
7.	Quality Assurance Division	Quality Management System of PvPI	qa.nccpvpi-ipc@gov.in
8.	Signal Division	Identification & confirmation of Signal, Revision of Prescribing Information Leaflet (PIL), issuing of Drug Safety Alerts and other regulatory recommendations, if any	signal.pvpi-ipc@gov.in
9.	Technical Secretariat	Coordination with AMCs/Non-AMCs/CDSCO/other stakeholders	pvpi.ipc@gov.in
10.	Training & Education Division	Training and Skill Development	training.nccpvpi-ipc@gov.in

Performance of PvPI as WHO-Collaborating Centre

The NCC-PvPI, IPC being a World Health Organization-Collaborating Centre (WHO-CC) for Pharmacovigilance in Public Health Programmes and Regulatory Services in SEARN countries, PvPI has done the following activities:

Activities	Outcomes
Launch of e-tools for integration of ADR-reporting	The Hon'ble Union Minister of Health & Family Welfare and Minister of Chemicals and Fertilizers, Shri J.P. Nadda launched Indigenous Adverse Drug Reaction Management System (ADRMS) Software during the 1st Policy Makers Forum meeting held on 19th August, 2024 at Dr. Ambedkar International Centre, New Delhi. The ADRMS software offers seamless processing & evaluation of Individual Case Safety Report (ICSR) reported by the stakeholders with the use of medicines, vaccines and medical devices.
PV data sharing with South-East Asia Regional Network (SEARN) countries	- The NCC-PvPI has shared following data with SEARN countries through e-mail: - Drug safety alerts. - Electronic version of newsletter on quarterly basis. - Identified Signals and Prescribing Information Leaflet changes. - PvPI published drug safety information in WHO-Pharmaceuticals newsletter for global outreach. - Among SEARN countries, drug abuse cases of Tapentadol were reported only in India, which were quantitatively evaluated. The scientific article on *Tapentadol: navigating the complexities of abuse, patient safety & regulatory measures has been published in Journal: Current Medical Research and Opinion.* - The safety data of pregnancy medication such as Sodium Valproate and Topiramate reported in PvPI database were discussed in WHO Advisory Committee on Safety of Medicinal Products (ACSoMP) meeting held in May 2024. - The NCC-PvPI, IPC has published SEARN PV Chronicle Vol. 1, Issue 1 in January 2025 and shared with SEARN countries by uploading on SEARN portal.

Capacity building and support for Public Health Programmes (PHPs) and Regulatory services	• NCC-PvPI, IPC has developed first draft of ADR reporting form including core variables for reporting adverse event in SEARN countries identified by the WHO, HQ, Geneva. • During the Celebration of 4th National Pharmacovigilance Week 2024, an international webinar on *Optimizing the use of ICSRs in signal detection* was organized for SEARN countries on 18th September 2024. • The WHO Pharmacovigilance Partners' meeting was held on 13th October, 2024 at New Delhi. The objective of this meeting was to develop national strategies national strategies to boost reporting through a template created by the South East Asian Regional Pharmacovigilance Network (SEARN). In this meeting, SEARN members presented their drafted national strategies to increase reporting of ICSRs. Dr V Kalaiselvan, Sr. Principal Scientific Officer, Indian Pharmacopoeia Commission also shared insights on tackling low reporting rates, challenges encountered, and the tools utilized to improve the system. • A draft document having drug safety information for Minoxidil-related infantile hypertrichosis and eye disorders was shared with SEARN countries through WHO-SEARN Secretariat for validation. • The 19th International Conference of Drug Regulatory Authorities (ICDRAs) was hosted by the Central Drugs Standard Control Organization (CDSCO) in collaboration with WHO for WHO Member States' medical product regulatory authorities, fostering collaboration and setting priorities in medicine from 14th to 18th October 2024 at New Delhi. In this conference, Dr V. Kalaiselvan, Sr. Principal Scientific Officer, Indian Pharmacopoeia Commission has also chaired the panel discussion.

PvPI Communication Channels

Coherent and flawless communication channels are key to the successful functioning of any programme. The dissemination of knowledge and expertise at NCC-PvPI percolates to the target audience and across the board to the AMCs affiliated to it with the use of state-of-the-art information technology. The various modes of communication by which PvPI channelizes data flow are represented in the figure below:

Figure - 3. Communication Channels of PvPI

Reporting ADRs

Who can Report?

- Consumer/Patients
- Physicians
- Pharmacists
- ADR Monitoring Centres (AMCs)
- Pharmaceutical Industries/MAHs
- Others

Why to Report?

- To ensure the safety of patients taking medicines.
- To reduce the risks associated with the use of medicines (economic burden, quality of life).
- To help regulatory authority make vital policy decision regarding safe use of medicines.

What to Report?

All types of suspected ADRs

- Known or unknown
- Serious or non-serious
- Frequent or rare

ADRs by

- Medicines
- Medical Devices
- Biologicals including Vaccines, Blood & Blood Products

Medication Errors

- Product dispensing/monitoring/prescribing/selection/storage error/issues.
- Accidental exposure to product.
- Inappropriate use of medical products.
- Product transcribing errors and communication issues.

Off-label Use

Use of medicines for an unapproved indication, age group, dosage or route of administration.

Misuse/Overdose/Abuse

- Use of a medication (for a medical purpose) other than as directed or as indicated; taking medicine more/more often or for a longer period.
- Ingestion/application of medicine in quantities much greater than recommended.
- Nonmedical use of a substance for psychic effect, dependence, or a suicide attempt or gesture, recreational use of substances for any reason.

Lack of Efficacy and other product quality-related issues

- No/Lack of drug effect.
- Drug ineffective for approved/ unapproved indication.
- Delayed or incomplete drug effect.
- Ineffective drug dosing regimen.
- Drug effect faster/less than expected.

Channels for reporting AE/ADR

Suspected ADR Reporting Form for Healthcare Professionals (HCPs) (Version 1.4)

The Suspected ADR reporting Form is specifically designed for healthcare professionals to capture detailed information about an AE/ADR. This form is available on IPC (www.ipc.gov.in) or CDSCO (www.cdsco.gov.in) website and in National Formulary of India 2021 **(Annexure-1)**.

Medicines Side-Effect Reporting Form (For Consumers)

Consumers/patients may also make use of Medicines Side-effect Reporting Form for reporting any suspected AE/ADR to PvPI. This form is available in 10 Indian languages: Hindi, Bengali, Gujarati, Kannada, Malayalam, Marathi, Assamese, Oriya, Tamil and Telugu **(Annexure-2)**.

Suspected ADR Reporting Form (For drugs used in Prophylaxis/ Treatment of COVID-19)

The Suspected ADR Reporting Form is designed for healthcare professionals during pandemic to capture detailed information about an AE/ADR related to the drugs used in Prophylaxis/ Treatment of COVID-19. This form is available on IPC (www.ipc.gov.in) **(Annexure-3)**.

Personal Protective Equipment (PPE) Adverse Event Reporting Form

In view of COVID-19 Pandemic, NCC-MvPI has specially designed a PPE Adverse Event Reporting Form, which primarily aims to collect the adverse events associated with the use of PPEs used for medical purposes **(Annexure-4)**.

Medical Device Adverse Event Reporting Form (For HCPs and MAHs)

Healthcare professionals including registered medical practitioners, professionals from allied health sciences, biomedical engineers and license holders including manufacturers and importers can use this form for reporting any suspected medical device-linked adverse event to MvPI-IPC. This form is available in Hindi and English languages **(Annexure 5)**.

Medical Device Adverse Event Reporting Form (For Consumers)

Consumers/patients may also make use of suspected medical device adverse event reporting form for reporting any suspected AE to MvPI. This form is available in Hindi and English languages **(Annexure 6)**.

Other important ADR Reporting Forms

Healthcare Professionals and other stakeholders can also report AEs/ADRs using specific forms designed purposely for reporting AE/ADR associated with Medicines used in Kala-azar treatment- Adverse Drug Reaction Form for Kala-Azar treatment **(Annexure-7)**, serious cases related to vaccine use - Serious AEFI Case Notification Form **(Annexure-8)**.


Patients/ Consumers/ Healthcare Professionals may report any suspected ADR associated with the use of medicinal/ herbal products/ vaccines or medical devices to NCC-PvPI via Toll-Free **Helpline No. 1800-180-3024**

e-mails

Hospitals/ Medical Colleges and other Healthcare Institutions which are not enrolled as AMCs under PvPI, may report adverse events by using email (pvpi.ipc@gov.in). Similarly, consumers/ patients also have the option of reporting adverse events through a dedicated email (pvpi.ipc@gov.in) including the consumers for reporting ADRs.

Suspected ADR Reporting Form in National Formulary of India (NFI)

NFI serves as a guidance document to medical practitioners, pharmacists working in hospitals and sales establishments, nurses, medical and pharmacy students and other healthcare professionals. The principal objective of NFI is to promote the rational use and economic prescribing of medicines in the country. The healthcare professional may utilize the ADR Reporting Form which has been annexed at the end of the NFI 2021 to report suspected ADRs.
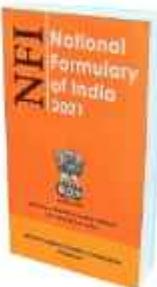
AMCs: The Backbone of PvPI

Medical institutions and hospitals play a major role both in teaching and providing specialized services to patients in India. Patient safety is one of their major concerns. Adverse Drug Reaction Monitoring Centres functioning at these institutions under PvPI, across the country are playing a crucial role in collection, processing and monitoring of ADRs.

Who can enrol?

➤ Government hospitals/ Autonomous bodies/ medical/pharmacy colleges
➤ Private hospitals/medical/pharmacy colleges
➤ District hospitals
➤ Primary/ Community Health Centres in India

01 NCC-PvPI seeks Enrollment Form from Dean/Head of the Institution/ Hospital for establishment of an AMC.

NCC-PvPI examines suitability of the proposed centre. **02**

03 Approval from competent authority.
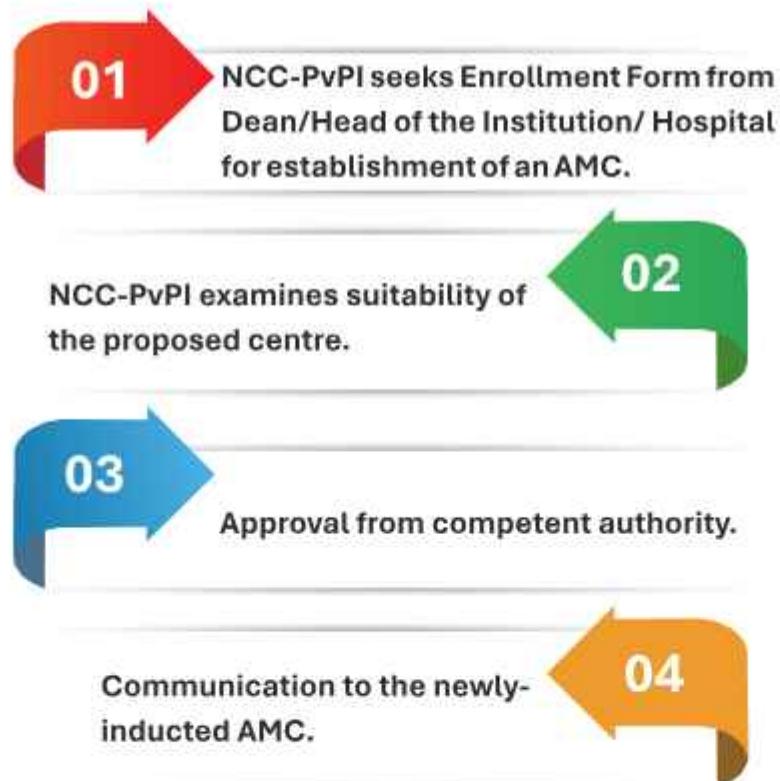
Communication to the newly-inducted AMC. **04**

*Figure - 4. Enrolment procedure for AMCs*

Criteria for enrolment of AMCs

❖ If the proposed centre is accepted as AMC, it's essential to function with its own logistic/infrastructural facilities.

❖ List of logistics required to setup an AMC under PvPI:

  • Dedicated area/Room for PvPI to carry out the Pharmacovigilance activities

  • Computer system with Internet connection, Printer with Scanner

  • Telephone

  • Table & chair, storage cabinet/almirah with lock & key facility

  • Stationary items

  • Notice board etc.

❖ The competent authority of PvPI reserves all the rights to accept/reject the proposal and suggest any other suitable measure.

❖ The HOD/Dean/Principal/Coordinator/Deputy Coordinator of the proposed centre shall be responsible to establish/implement PvPI activities in the centre.

❖ The HOD/Dean/Principal/ Coordinator/Deputy coordinator of the institute shall be responsible to identify new Coordinator & Deputy Coordinator and to intimate NCC-PvPI in case of any change (transfer/ superannuation etc) immediately.

❖ Upon recognition, NCC-PvPI provides regular training, skill development and technical training support to the personnel engaged in PvPI activities.

Criteria for De-Enrolment/ De-Recognition of AMCs

❖ AMCs which are non-functional for longest time from their enrolment under PvPI in terms of reporting of ICSRs (zero reporting) and other activities related to Pharmacovigilance such as training, conference, workshop awareness and sensitisation programme on PV.

❖ The AMC enrolled since longest time (since year of enrolment) with zero reporting as mentioned above will be delisted first and so on.

ICSRs database at PvPI

The Pharmacovigilance Programme of India is responsible for the collection, assessment, detection and communication of risks associated with the use of medical products in Indian Population. The ICSRs collected by AMCs, MAHs, Healthcare Professionals, Patients/Consumers through different channels reported to NCC-PvPI, IPC. There are **131301*** ICSRs for the index period (FY 2024-25) and monthly reporting patterns is given below:
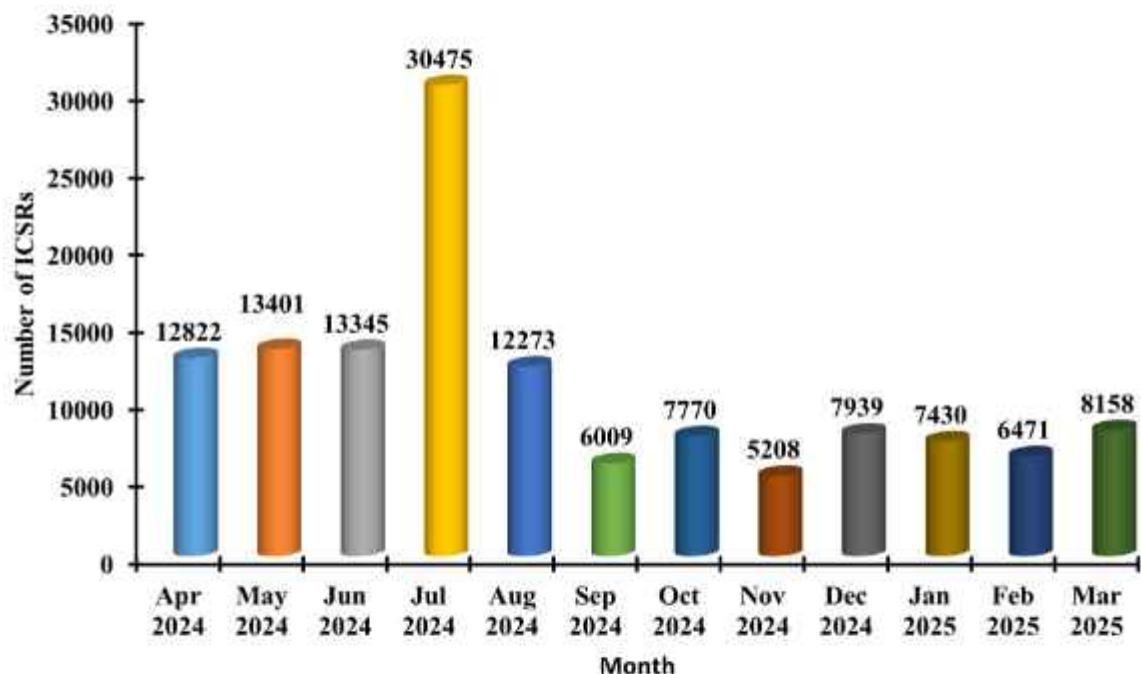
*Source: Data retrieved from Vigilyze on 4th May 2025

Figure-5. Month-wise distribution of ICSRs

Distribution of ICSRs based on Gender

PvPI database revealed that 49.1% ICSRs were from female patients and 48.8% were from male patients. No information was provided in 2.0% of ICSRs.

Figure - 6. Distribution of ICSRs based on gender

Distribution of ICSRs based on age

The database revealed that the maximum 35.2 % ICSRs were received from the age group of 18-44 years, whereas the minimum 0.4% ICSRs were received from the age group of 0-27 days. No information about the age of the patients was given in 5.8% ICSRs.
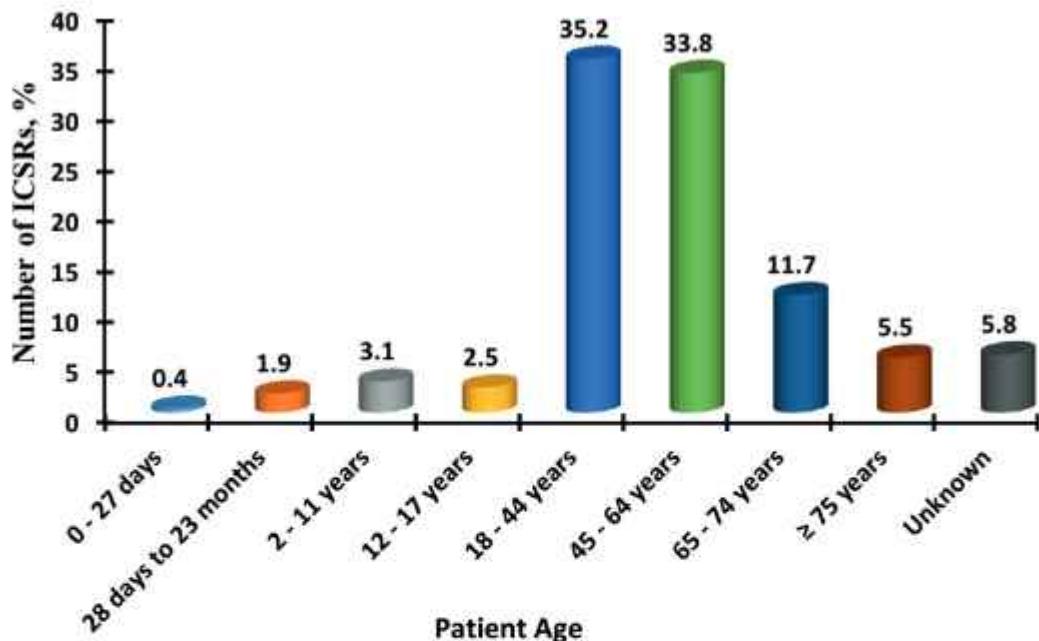
Figure - 7. Distribution of ICSRs based on age

Distribution of ICSRs based on reporter qualification

There were 41.3%, ICSRs from physicians, 29.2% from other healthcare professionals, 21.6% from pharmacists, 11.8% from consumers/non-healthcare professionals and 0.3% were unknown.
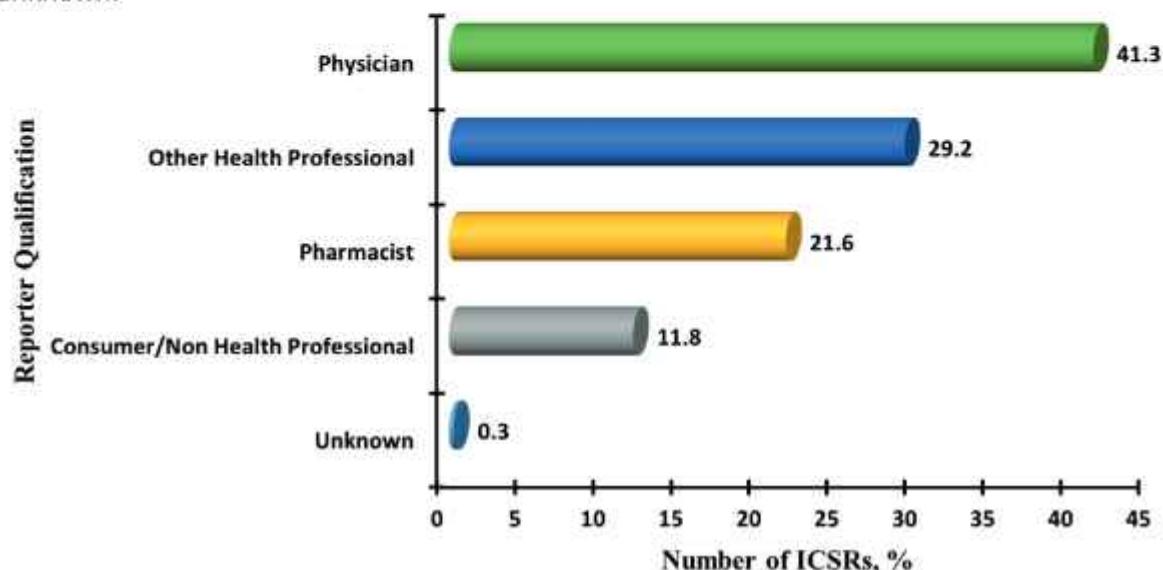
Figure - 8. Distribution of ICSRs based on reporter qualification

Distribution of ICSRs based on seriousness

The database revealed that 72.3% ICSRs were non serious and 27.7% were serious reported with the use of medical products.
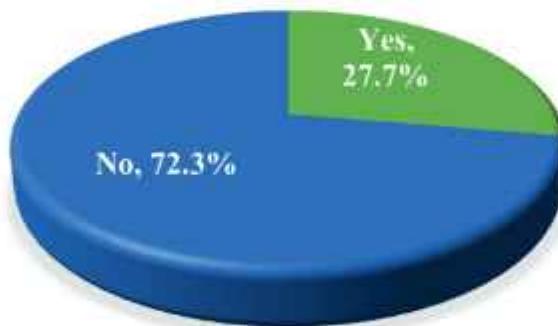
Figure - 9. Distribution of ICSRs based on seriousness

Distribution of ICSRs based on seriousness criteria

The seriousness criteria of received ICSRs revealed that 2.0% ICSRs were due to death, 1.8% ICSRs were due to life threatening condition, 15.4% ICSRs were due to prolonged hospitalization, 11.1% ICSRs were due to other medically important conditions and ICSRs due to congenital anomaly/ birth defect were not present.
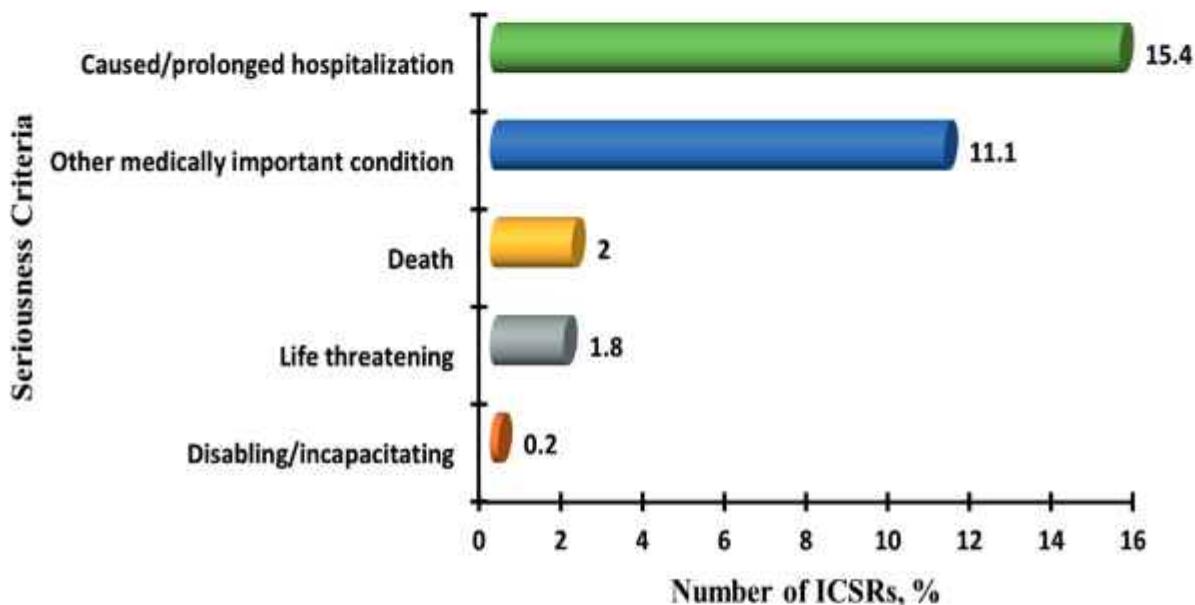
Figure - 10. Distribution of ICSRs based on seriousness criteria

Distribution of reactions based on System Organ Classes (SOCs)

The ICSRs reported in PvPI database revealed that the maximum number of reactions 23.4% were reported from the SOC-Skin and subcutaneous tissue disorders among the **top ten reported SOCs**.
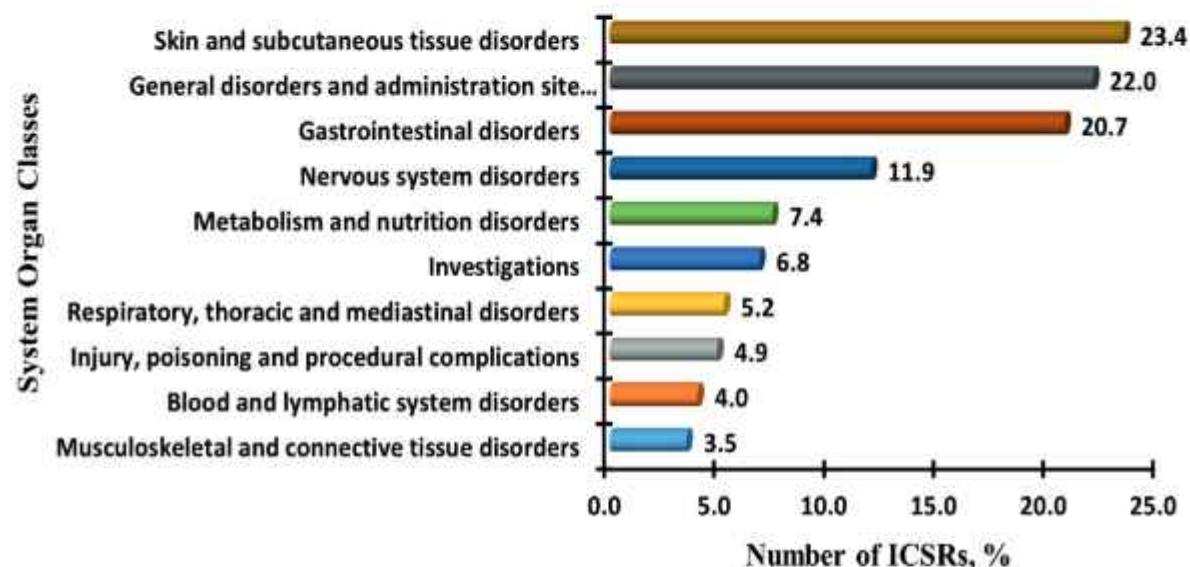
Figure-11. Distribution of reactions based on SOCs

Distribution of ICSRs based on Anatomical Therapeutic Chemical (ATC) Classification

The ICSRs reported in PvPI database revealed that the maximum number of suspected drugs 31.1% were reported from the ATC-Anti-infectives for systemic use among the **top ten reported ATCs.**
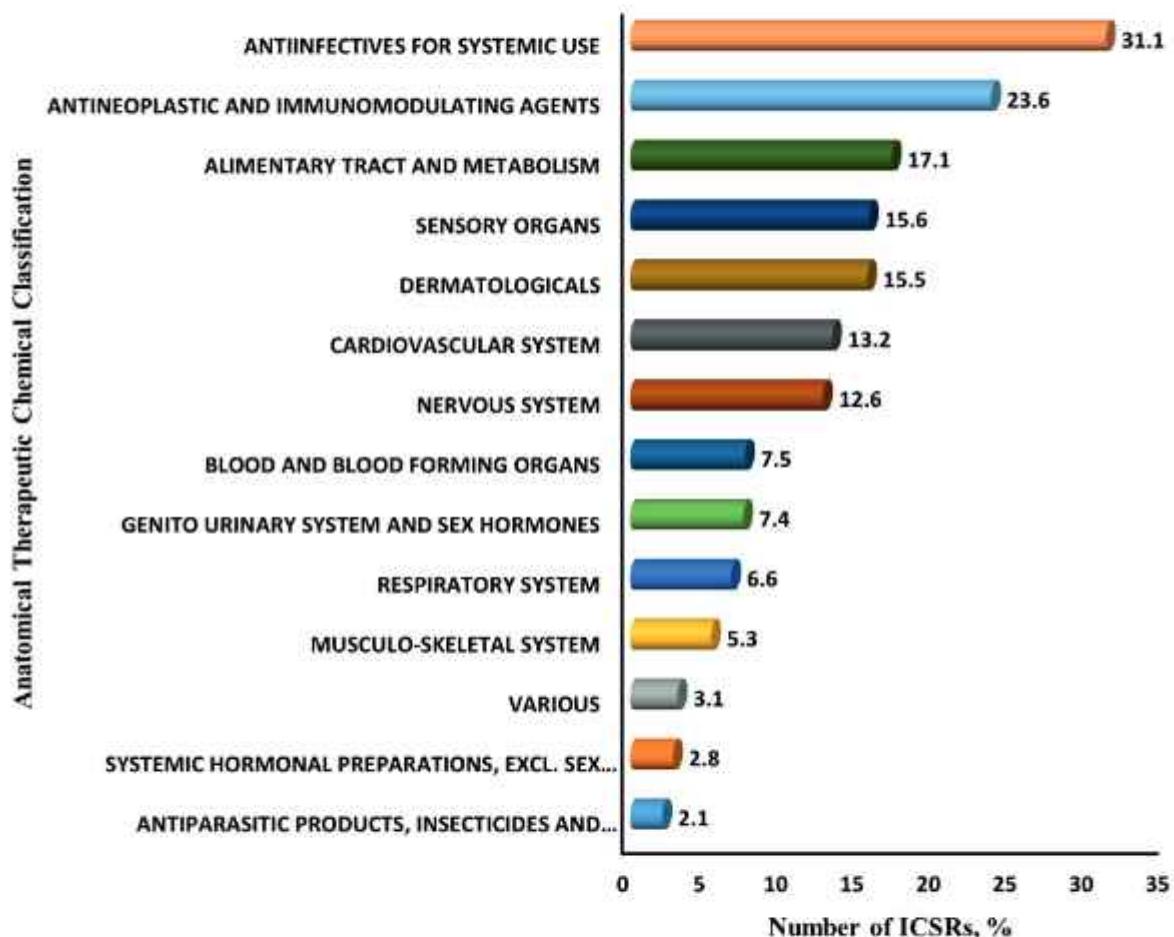
Figure-12. Distribution of ICSRs based on ATC Classification

Top 10 reported Preferred Term

The data reported in the PvPI database revealed that the maximum percentage of adverse drug reactions (Preferred Term) reported was pruritus (8.2%) coded by MedDRA dictionary.
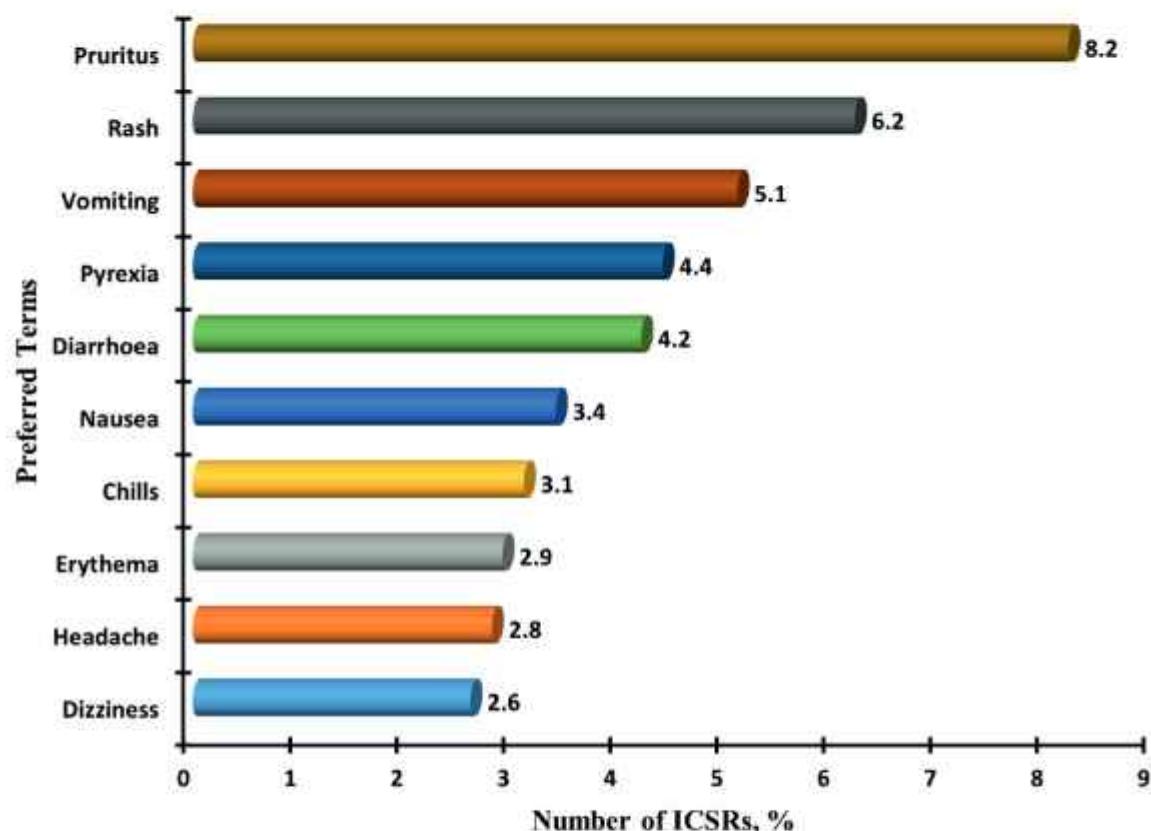
Figure - 13. Top 10 reported Preferred Term

Top 10 active ingredients reported in ICSRs

Analysis of Active Ingredients (AIs) from reported ICSRs revealed that Pantoprazole (3.3%) was the highest reported AI during this index period.
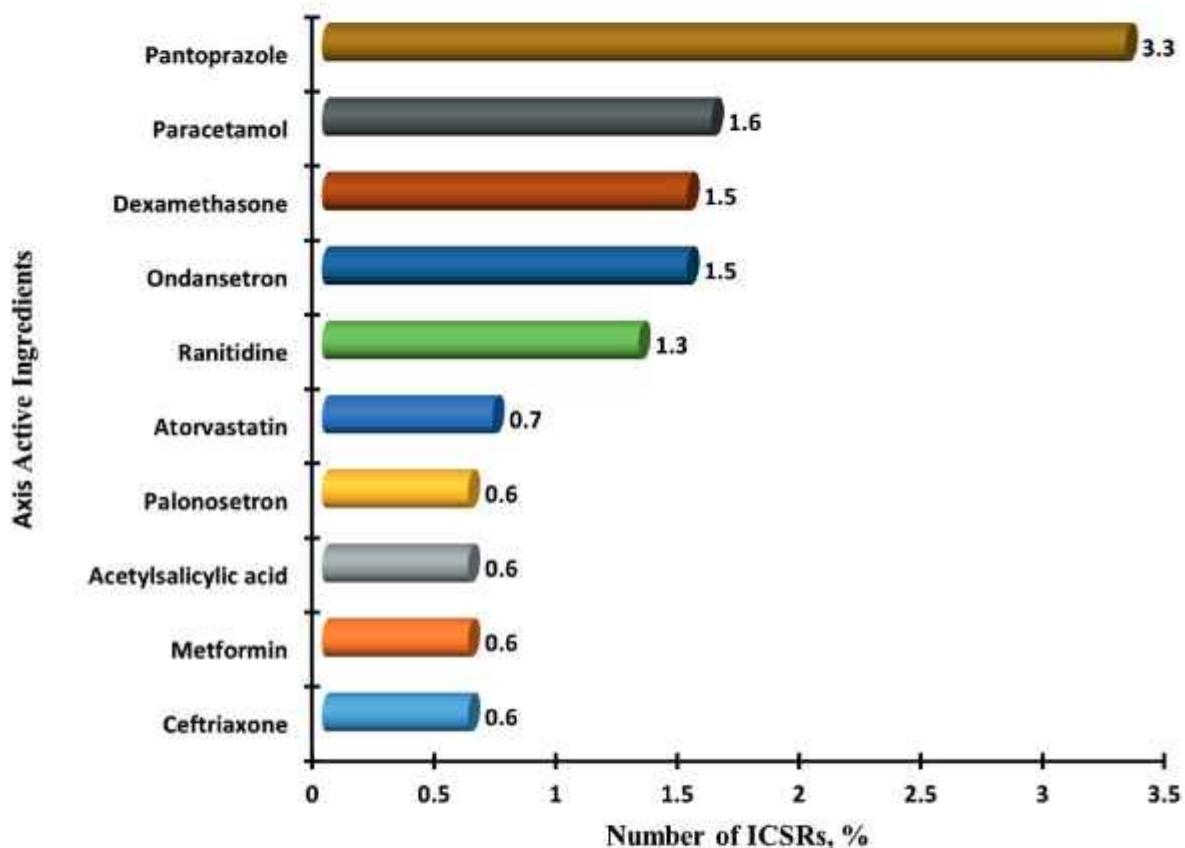
Figure - 14. Top 10 reported Active Ingredients

ICSRs received from non-AMCs

Besides receiving ICSRs from AMCs, NCC-PvPI, also received ICSRs through several hospitals, medical colleges and other institutions, which are not enrolled as an AMC under PvPI (i.e. non-AMCs) across India. The non-AMCs sent the filled Suspected ADR reporting form to NCC-PvPI through a dedicated e-mail id: pvpi.ipc@gov.in. These ICSRs were then forwarded to the nearest AMC for doing causality assessment. During the index period, **2023** ADRs were reported via non-AMCs, month-wise distribution of these AEs is given below:
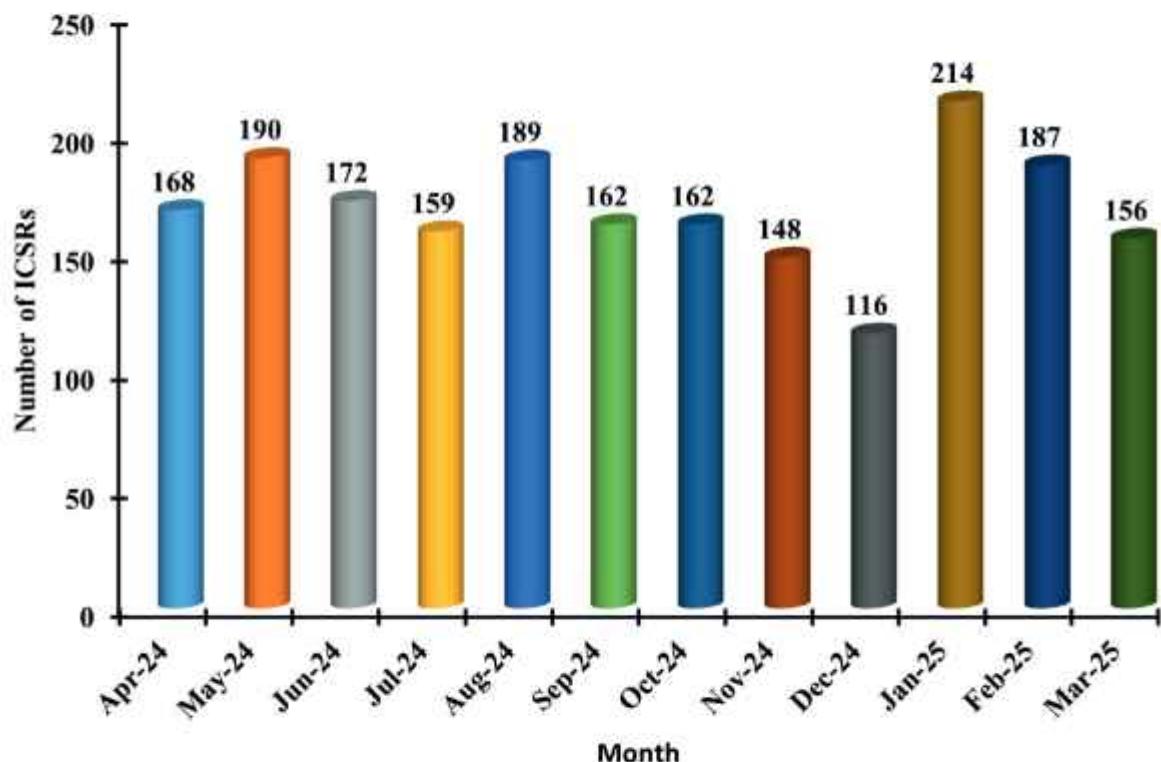
Figure - 15. Month-wise ICSRs received from non-AMCs

ICSRs received via PvPI Helpline

Toll-free Helpline was initiated on 11th October, 2013, since then it has been serving as one of the reliable tools for reporting suspected adverse events. Patients/Consumers/Healthcare Professionals report suspected adverse events associated with the use of medical products/medical devices through Toll-free Helpline. Calls are primarily responded in English and Hindi on all working days between 9:00 AM and 5:30 PM. A total of **524** ICSRs were received through Toll-free Helpline, the month-wise distribution of such ICSRs is as given below:
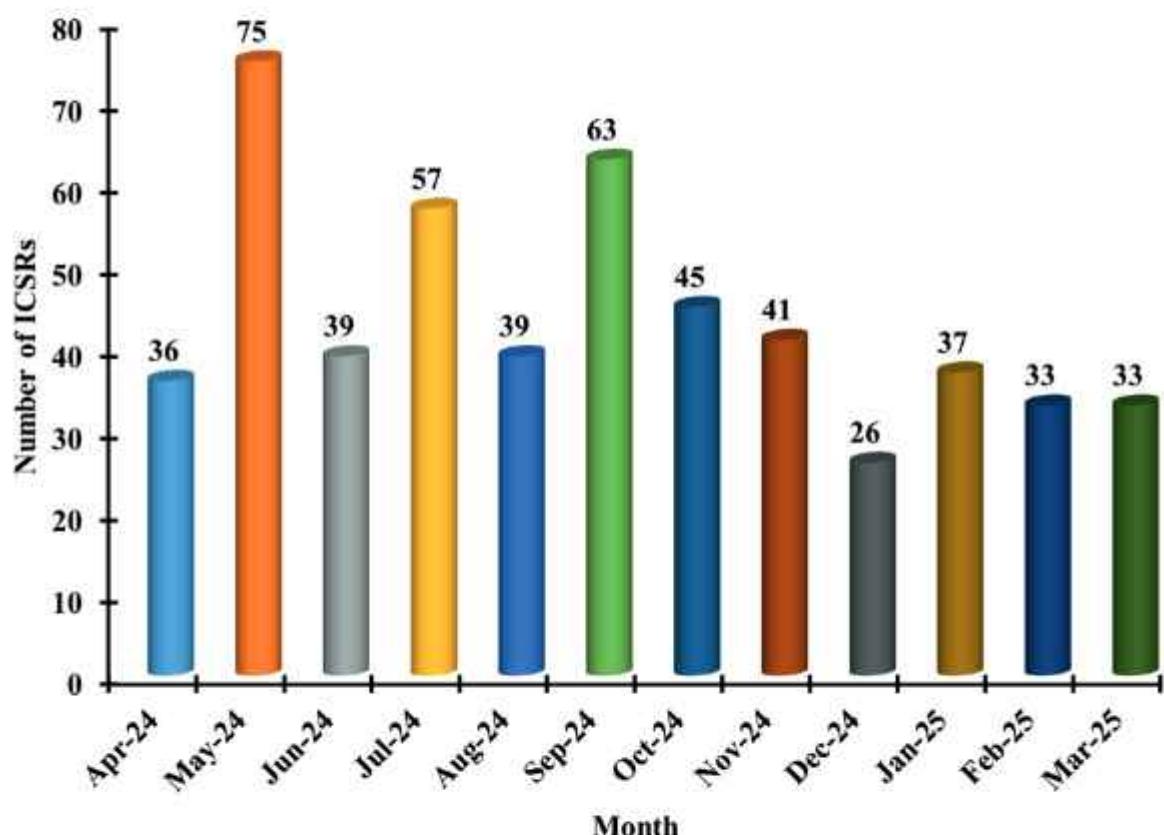
Figure-16. Month-wise ICSRs received from PvPI Helpline (Toll-free)

India secured 5th position among WHO PIDM Member countries during this index period

India has contributed 3.7% ICSRs and was the 5th largest contributor of ICSRs submission to VigiBase among 181 World Health Organization Programme for International Drug Monitoring (WHO-PIDM) member countries.
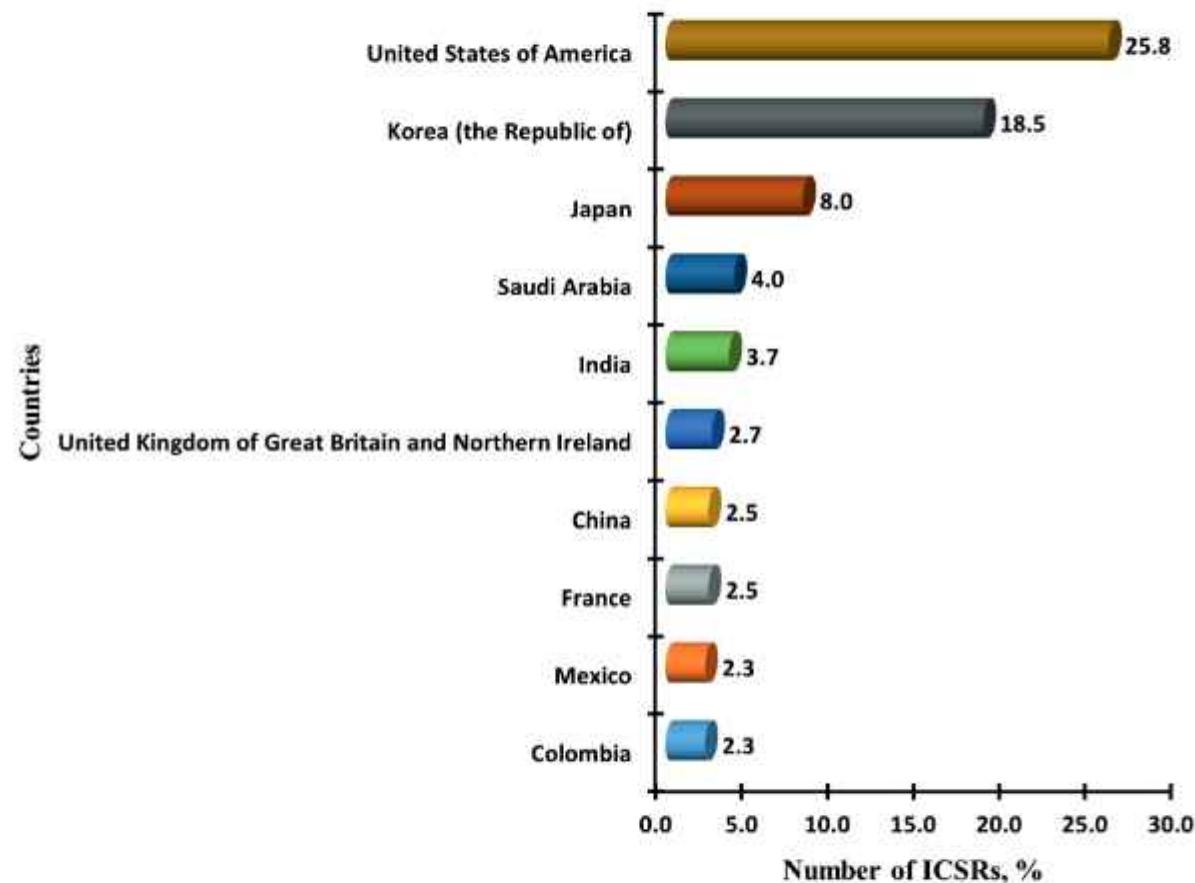
Figure - 17. India's ranking during Index period

India secured 8th position among WHO PIDM Member countries

Overall, India has contributed 2.3% ICSRs and was the 8th largest contributor among 181 World Health Organization Programme for International Drug Monitoring (WHO-PIDM) member countries in terms of submission of ICSRs to VigiBase.
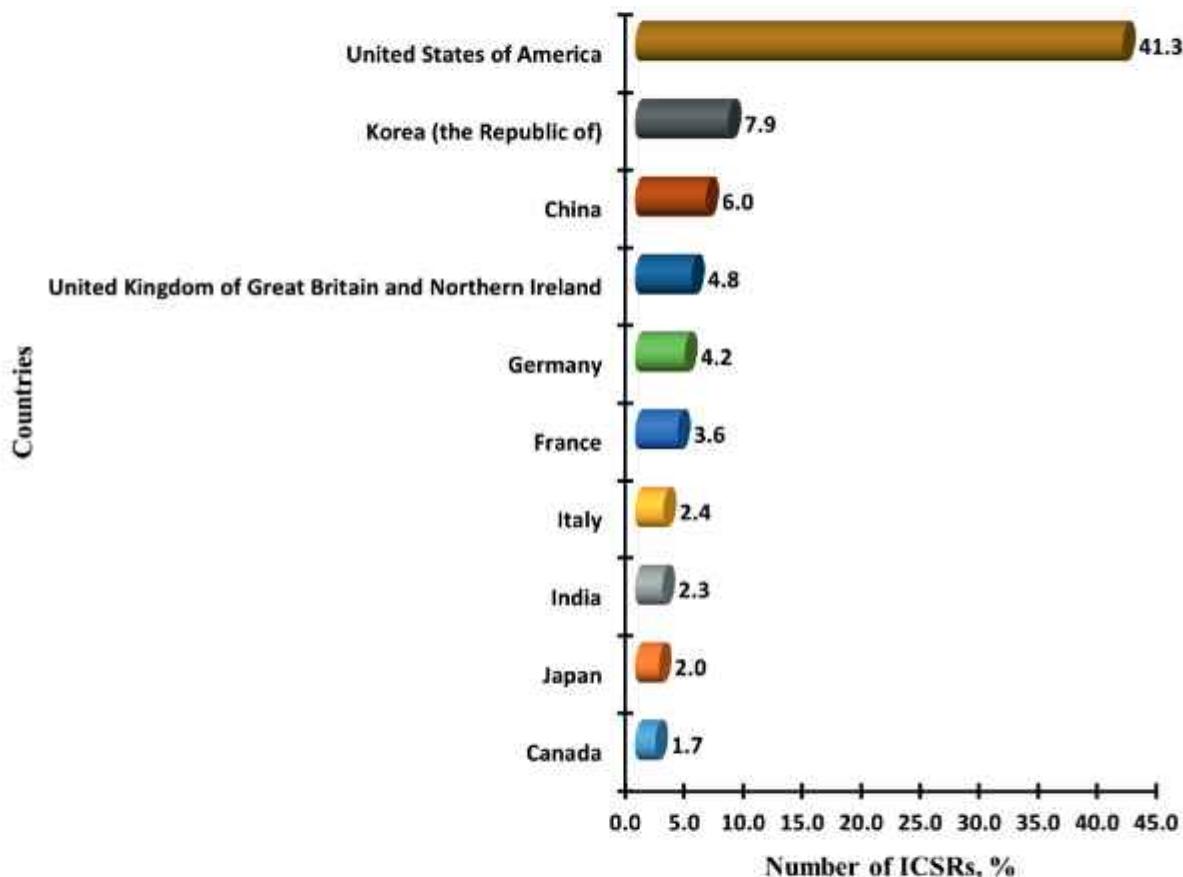
Figure - 18. Top 10 reporting countries

Contribution by MAHs

Marketing Authorization Holders play a crucial role in reporting AEs/ADRs to PvPI. As per, amendment to the Drugs and Cosmetics Rules, 1945 and New Drugs & Clinical Trials Rules 2019 (NDCT Rules 2019), Pharmacovigilance is a legal obligation for MAHs. This has paved the way for collecting product-specific safety data aimed at optimizing drug-safety and ensuring healthcare for Indian populace. During this index period a total of 124 MAHs had submitted 73973 ICSRs to NCC-PvPI, including initial and follow-up case.
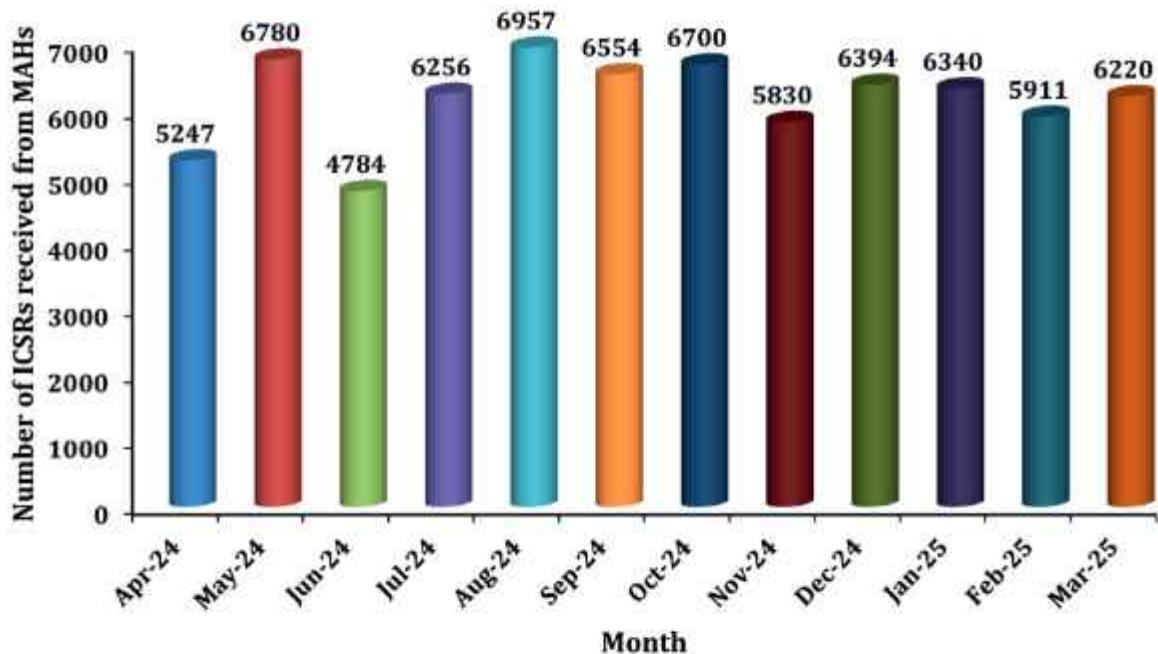
Figure - 19. Month-wise ICSR received from MAHs

List of Pharmaceutical companies/MAHs reporting ICSRs to PvPI

S. No.	MAHs	S. No.	MAHs
1.	Abbott India Ltd.	16.	Bayer Pharmaceuticals (P) Ltd.
2.	AbbVie Therapeutics India (P) Ltd.	17.	BE Pharmaceuticals (P) Ltd.
3.	Akums Drugs & Pharmaceuticals Ltd.	18.	Besins Healthcare India (P) Ltd.
4.	Alcon Laboratories India (P) Ltd.	19.	Bharat Biotech International Ltd.
5.	Alembic Pharmaceuticals Ltd.	20.	Bharat Serums And Vaccines Ltd.
6.	Alkem Laboratories Ltd.	21.	Biocon Biologics Ltd.
7.	Amgen Technology (P) Ltd.	22.	Biological E Ltd.
8.	Amneal Pharmaceuticals (P) Ltd.	23.	Bio Genomics Ltd.
9.	Aristo Pharmaceuticals (P) Ltd.	24.	Biovaccines India (P) Ltd.
10.	Astellas Pharma India (P) Ltd.	25.	Blue Cross Laboratories (P) Ltd.
11.	AstraZeneca Pharma India Ltd.	26.	Boehringer Ingelheim India (P) Ltd.
12.	Aurobindo Pharma Ltd.	27.	Bristol-Myers Squibb India
13.	AXA Parenterals Ltd.	28.	Cadila Pharmaceuticals Ltd.
14.	B. Braun Medical (India) (P) Ltd.	29.	Cipla Ltd.
15.	Baxter (India) (P) Ltd.	30.	Concord Biotech Ltd.

31.	Dr Reddy's Laboratories	46.	Galderma India (P) Ltd.
32.	EISAI Pharmaceuticals India (P) Ltd.	47.	Gilead Sciences
33.	Eli Lilly & Company (India) (P) Ltd.	48.	Glaxo SmithKline Pharmaceuticals Ltd.
34.	Emcure Pharmaceuticals Ltd.	49.	GlaxoSmithKline Asia (P) Ltd.
35.	Encube Ethicals (P) Ltd.	50.	GlaxoSmithKline Consumer (P) Ltd.
36.	Eris Lifesciences Ltd.	51.	Glenmark Pharmaceuticals Ltd.
37.	ESPI Industries and Chemicals (P) Ltd.	52.	Grifols India Healthcare (P) Ltd.
38.	Exeltis India (Ordain Health Care Global (P) Ltd.	53.	Guerbet India (P) Ltd.
39.	Exemed Pharmaceutical Ltd.	54.	Gufic Biosciences Ltd.
40.	FDC Ltd.	55.	Hetero Labs Ltd.
41.	Ferring Pharmaceuticals (P) Ltd.	56.	Imaging Products India (P) Ltd.
42.	Fertin India (P) Ltd.	57.	Immunoadoptive Cell Therapy (P) Ltd.
43.	FIDIA Farmaceutici Damor SpA.	58.	Immunocore Holding
44.	Fresenius Kabi India (P) Ltd.	59.	Immuneel Therapeutics (P) Ltd.
45.	Fresenius Kabi Oncology Ltd.	60.	Indoco Remedies Ltd.

61.	Intas Pharmaceuticals Ltd.	79.	Mylan Laboratories (P) Ltd./Viatris
62.	Inventia Healthcare Ltd.	80.	Novartis India Ltd.
63.	IPCA Laboratories Ltd.	81.	Novo Medi Sciences (P) Ltd.
64.	Italfarmaco SpA.	82.	Novo Nordisk India (P) Ltd.
65.	ITM Medical Isotopes GmbH	83.	Optimus Pharma (P) Ltd.
66.	J. B. Chemicals and Pharmaceuticals Ltd.	84.	Organon India (P) Ltd.
67.	Johnsons & Johnsons (P) Ltd.	85.	Otsuka Pharmaceutical India (P) Ltd.
68.	Kusum Healthcare (P) Ltd.	86.	Panacea Biotec Ltd.
69.	LG Chem Life Sciences India (P) Ltd.	87.	Paviour Pharmaceuticals (P) Ltd.
70.	Lupin Ltd.	88.	Pfizer Ltd.
71.	Macleods Pharmaceuticals Ltd.	89.	Pharmazz India (P) Ltd.
72.	Madras Pharmaceuticals	90.	Piramal Pharma Ltd.
73.	Mankind Pharma	91.	PlasmaGen BioSciences (P) Ltd.
74.	Medley Pharmaceuticals Ltd.	92.	Reckitt Benckiser (India) (P) Ltd.
75.	Merck Healthcare (P) Ltd.	93.	Reliance Life Sciences (P) Ltd.
76.	Modi-Mundipharma (P) Ltd.	94.	Roche Products (India) (P) Ltd.
77.	MSD Pharmaceuticals (P) Ltd.	95.	Rusan pharma Ltd.
78.	MSN Laboratories (P) Ltd.	96.	Samrudh Pharmaceuticals (P) Ltd.

97.	Sandoz	111.	Themis Medicare Ltd.
98.	Sanofi India Ltd.	112.	Torrent Pharmaceuticals Ltd.
99.	Santen India (P) Ltd.	113.	Troikaa Pharmaceuticals Ltd.
100.	Sentiss Pharma (P) Ltd.	114.	USV Private Ltd.
101.	Septodont Healthcare India (P) Ltd.	115.	Venus Remedies Ltd.
102.	Serum Institute of India Ltd.	116.	Vifor Pharma
103.	Servier India (P) Ltd.	117.	Vivere Imaging (P) Ltd.
104.	Shilpa Medicare Ltd.	118.	Windlas Biotech Ltd.
105.	Steril-Gene Life Sciences (P) Ltd.	119.	Win-Medicare (P) Ltd.
106.	Sun Pharmaceutical Industries Ltd.	120.	Wipro GE Healthcare (P) Ltd.
107.	Swiss Garniers Genexiaa Sciences (P) Ltd.	121.	Wockhardt Pharmaceutical Ltd.
108.	Synokem Pharmaceutical Ltd.	122.	Zuventus Healthcare Ltd.
109.	Takeda Pharmaceuticals India (P) Ltd.	123.	Zydus Lifesciences Ltd.
110.	The Procter & Gamble Company		

Quality Management System in PvPI

To ensure the patient safety through a transparent approach and high-quality services, PvPI has been found to conform with ISO 9001:2015 Quality Management System (QMS) and also adopts the Good Pharmacovigilance Practices (GVP) as per one of the WHO Pharmacovigilance Indicators with a focused approach on scientific innovation and rationality.

List of SOPs in different divisions of PvPI is given below:

	Technical Secretariat
1.	SOP for functioning of Technical Secretariat
	Quality Assurance (QA)
2.	SOP for making SOP
3.	Procedure for specimen signatures
4.	Change control procedure
5.	SOP for handling deviation
6.	SOP for handling of non-conformance
7.	SOP for corrective and preventive action
8.	SOP for audit of NCC-PvPI
9.	SOP for management review meeting
10.	SOP for collection of ADR/AE Reports
11.	SOP for preparation and submission of progress reports

12.	SOP to fill suspected Adverse Drug Reaction reporting form
13.	SOP to perform causality assessment
14.	SOP to enter ADR data to VigiFlow software
15.	SOP for processing and quality review of ICSRs
16.	SOP for documentation at AMCs
17.	SOP for ensuring the functioning of AMCs
18.	SOP for functioning of Quality Review Panel
19.	SOP for archiving and disposal of documents
20.	SOP for handling of Preventable ADRs including medication error, lack of therapeutic efficacy, and quality related events.
21.	SOP for enrolment of new AMCs under PvPI
22.	SOP for functioning of Working Group of PvPI
23.	SOP for functioning of Steering Committee
24.	SOP for Delisting of AMCs under PvPI
Signal Detection	
25.	SOP for operational functioning of Signal Review Panel
26.	SOP for functioning of Signal Review Panel
27.	SOP for data mining of SUSARs and non-serious ADRs/AE from VigiFlow

PV Regulatory Affairs	
28.	Processing of ICSRs reported by MAHs
National Health Programme	
29.	SOP for coordination between Pharmacovigilance Programme of India (PvPI) and National Health Programmes (NHPs)
30.	Processing & communication of AEFI-ICSRs
Training and Education	
31.	SOP to conduct training by NCC-PvPI
32.	SOP for Functioning of Regional Training Centres (RTCs) and financial assistance under PvPI
33.	SOP for functioning of Core training panel
34.	SOP for functioning of AMCs and Financial assistance guidelines to AMCs under PvPI
Promotion Communication and Publication	
35.	SOP for drafting, publication, distribution and control of resource materials of PvPI
36.	SOP for publication and communication between PvPI and stakeholders
Information Technology	
37.	SOP for data integrity and storage
38.	VigiFlow login Id distribution and retrieval procedure
39.	SOP for establishing link at the Ministry of Health and Family Welfare's web-portal for the Pharmacovigilance Programme of India

	Human Resources
40.	SOP for the recruitment of contractual employee under NCC-PvPI, IPC
41.	SOP for the job responsibilities of PvPI staff under NCC-PvPI, IPC
42.	SOP for conducting teleconference meeting with AMC PvAs
	International Cooperation
43.	SOP for functioning of International Cooperation Division
	Individual Case Safety Report processing
44.	SOP for processing ADR received though PvPI Mobile App - "ADR-PvPI"
45.	SOP for processing Adverse Events received from consumers via e-mail
46.	SOP for processing Adverse Events reported by Non-AMC to NCC- PvPI
47.	SOP for receiving ADR from healthcare professionals and consumers through PvPI helpline number

Quality of ICSRs

The VigiGrade™ completeness score is a WHO system to measure the quality of the information provided on ICSRs. The graph represents the average completeness score of ICSRs submitted from India (Blue line) as compared to submitted ICSRs by all the other countries (Green dotted line). The average completeness score for the last financial year accounts for about 0.80 out of 1.

Figure -20. Graphical representation of VigiGradeTM Completeness score of quality of ICSRs submitted by PvPI to UMC database

Newly Enrolled ADR Monitoring Centres (AMCs) under PvPI

During the index period, NCC-PvPI, IPC has enrolled 155 new AMCs across India. The States/UTs-wise distribution of newly enrolled AMCs under PvPI are given below:

Haryana	30	West Bengal	3
Rajasthan	17	Bihar	2
Punjab	16	Chandigarh	2
Uttar Pradesh	15	Odisha	2
Andhra Pradesh	11	Himachal Pradesh	1
Maharashtra	8	Jammu & Kashmir	1
Tamil Nadu	8	Jharkhand	1
Delhi	7	Ladakh	1
Gujarat	7	Madhya Pradesh	1
Karnataka	6	Manipur	1
Telangana	6	Tripura	1
Kerala	4	Uttarakhand	1
Assam	3		

List of all newly enrolled AMCs **(23 Government and 132 Non-Government)** under PvPI is given below:

S. No.	States/UTs	AMC Name & Address	Status
1.		Government Medical College Noonpalle, Nandyal, Andhra Pradesh-518501	Government
2.		Govermemt Medical College Eluru, Near Old Bus Station, Eluru District, Andhra Pradesh-534001	
3.		ACSR Govt. Medical College Dargamitta, SCSR, Nellore, Andhra Pradesh-524004	
4.	Andhra Pradesh	Government Medical College Vidya Nagar, Rajamahendravaram, East Godavari, Andhra Pradesh-533105	
5.		Andhra Hospitals (Vijayawada) Pvt. Ltd. Tagore Chamber, 29, Nakkala Road, Governor Peta, Vijayawada, NTR District, Andhra Pradesh-520002	Non-Government
6.		Trust Multispeciality Hospitals 11-427, Sarpavaram Road, Kakinada, Andhra Pradesh-533005	
7.		Swatantra Hospitals (Multispecialities) Private Limited Kambala Cheruvu, Rajamahendravaram, East Godavari, Andhra Pradesh-533105	
8.		Good Samaritan Cancer & General Hospital Eluru, Andhra Pradesh-534001	

9.		GSL Trust Cancer Hospital Kambala Cheruvu, East Godavari, Andhra Pradesh-533105	
10.		Sai Hospital, Aryapuram D.No.- 12-20-4/1, Rajamahendravaram, East Godavari, Andhra Pradesh-533104	
11.		Gitam Instiitute of Medical Sciences and Research Gitam (Deemed to be University) Gandhi Nagar, Rushikonda, Visakhapatnam, Andhra Pradesh-530045	
12.	Assam	Nalbari Medical College and Hospital Dakhingaon, PS - Ghograpar, Nalbari, Assam-781350	Government
13.		Kokrajhar Medical College & Hospital Rangalikhata-Pt.I, Kokrajhar, Assam-783370	
14.		Dhubri Medical College & Hospital R.K Mission Road, Jhagrarpar, Dhubri-783325	
15.	Bihar	Bhagwan Mahavir Institute of Medical Science (BMIMS) Pawapuri, Nalanda, Bihar-803115	Government
16.		Ford Hospital & Research Center Pvt. Ltd. NH30, New Bypass, Khemnichak, Ramakrishna Nagar, Patna, Bihar- 800027	Non-Government
17.	Chandigarh	Healing Hospital and Institute of Paramedical Sciences Sector 34A, Chandigarh-160022	Non-Government
18.		Government Medical College & Hospital Sector 32, Chandigarh-160030	Government

19.		Ramlal Kundanlal Orthopaedic Hospital & R.K Maternity Home East Delhi, Delhi-110092	
20.		Aakash Healthcare Super Speciality Hospital Road No. 201, Sector-3, Dwarka, New Delhi-110075	
21.		Fortis Flt. Lt. Rajan Dhall Hospital Aruna Asaf Ali Marg, Pocket-1, Sector-B, Vasant Kunj, South West, New Delhi -110070	
22.	Delhi	National Heart Institute 49-50, Community Centre, East of Kailash, New Delhi-110065	Non-Government
23.		B M Gupta Hospital Pvt. Ltd H-5, 8 to 15,21,22,26 Uttam Nagar, South West, New Delhi-110059	
24.		Neonest Hospital A-1/3, Prashant Vihar, Rohini, New Delhi-110085	
25.		Divya Prastha Hopital RZ-37, Main Road, Raj Nagar-I, Palam Colony, South West, New Delhi-110045	
26.	Gujarat	GMERS Medical College Panchmahal Godhra, Government Engineering College, Lunavada Road, Godhra, Panchmahal, Gujarat-389001	Government
27.		GMERS Medical College General Nursing School Building, Opp. Bhavsinhji Govt. Hospital, Porbandar, Gujarat-360575	

28.		Govt (CL PSC) Spine Institute Physiotherapy College, Ahmedabad, Gujarat-380016	
29.		Oswal Aayush Super Speciality Hospital Plot No. 55/56, Digvijay Plot, Jamnagar, Gujarat-361005	Non-Government
30.		SIDS Hospital & Research Center Opp. Ring Road, New Opera House, Khatodara Wadi, Surat, Gujarat-395002	
31.		Medipolis Life Care LLP B-1, Medipolis, New Doctor House, Deesa Highway, Palanpur, Banaskantha, Gujarat-385001	
32.		Spandan Multispecialtiy Hospital 1/A 2/A Nandigram Society, Sindhawai Mata Road, Manjalpur, Vadodara, Gujarat-390011	
33.		Goel Orthopaedic Centre SCF 15-16 Huda Complex, Opp. DRDA, Gohana Road, Jind, Haryana-126102	
34.		Chowdhary Hospital Rohtak, Haryana- 124001	
35.	Haryana	Siwach Sanjeevani Hospital 123, Rajendra Nagar, Main Gohana Road, Rohtak, Haryana-124001	Non-Government
36.		Apex Heart Super Speciality Hospital Ambala, Haryana-134003	
37.		Shree Hari Hospital (Super Speciality Hospital & Trauma Centre) 31 Ashoka Colony, Karnal, Haryana-132001	

38.		Aashirwad Hospital Bye Pass Road, Gobindpuri, Yamuna Nagar, Haryana-135001	
39.		Fortis Escorts Hospital Neelam Bata Road, Faridabad, Haryana-121001	
40.		LHDM & Dr. Prem Hospital Panipat, Haryana-132103	
41.		Sarwal Hospital Civil Line, Ambala City, Haryana-134003	
42.		Monga Hospital & Stone Centre Mahesh Nagar, Ambala, Haryana-133001	
43.		Kalra Hospital Panipat, Haryana-132103	
44.		Ravindra Hospital and Heart Centre Hisar, Haryana-125001	
45.		Park Hospital, Faridabad Haryana- 121006	
46.		Apex Plus Super Speciality Hospital 174-L, Model Town, Rohtak, Haryana-124001	
47.		Ahooja Eye & Dental Institute 560/1, Dayanand Colony, New Railway Road, Gurugram, Haryana-122001	
48.		CDAS Superspeciality Hospital Malibu Town, Sec 47, Gurugram, Haryana-122018	

49.		Dr. Jale's Life Care Hospital #274, Near Kailash Ashram, Subhash Nagar, Model town, Rohtak, Haryana-124001
50.		Pushpanjali Hospital Rajesh Pilot Chowk, Garhi Bolni Road, Rewari, Haryana-123401
51.		Jaspal Nursing Home 69 Model Town, Ambala City, Haryana-134003
52.		NP Rawal Hospital Pvt.Ltd. 786, Jernaily Colony, Near Dyal Singh College, Karnal, Haryana-132001
53.		M M College of Medical Sciences & Research (MMCMSR) Sadopur, Ambala, Haryana-134007
54.		Bhagwan Das Hospital Block E, Omaxe City, Sector 18, Sonipat, Haryana-131001
55.		Kirti Hospital 1315/4 Park Road, Kaithal, Haryana-136027
56.		VK Neurocare and Trauma Research Hospital N-159, Model Town, Hisar, Haryana-125005
57.		Primus Hospital Opp. Bank of Baroda, Near Shiv Chowk, Sanoli Road, Panipat, Haryana-132103
58.		Soni Burn & Plastic Surgery Hospital Sec -15 A, Kanari Road, Hisar, Haryana-125001

59.		Gobind Nursing Home 120- Hetram Park, Opposite Jat College, Hisar, Haryana-125001	
60.		Sri Onkar Eye 7 ENT Care Centre 1402/677, New Model Colon, Prem Nagar, Ambala, Haryana-134003	
61.		Vedamritia Hospital Hisar, Haryana-125121	
62.		Park Hospital (A unit of DMR Hospitals Pvt. Ltd.) Karnal, Haryana-132116	
63.	Himachal Pradesh	Malhotra Hospital and Trauma Centre Opp. Petrol Pump, Main Bazar, Near Chowk, Mandi, Himachal Pradesh-175008	Non-Government
64.	J&K	Triveni Nursing Home 8-C/C, Gandhi Nagar, Jammu, J&K-180004	Non-Government
65.	Jharkhand	Paras HEC Hospital Sector-3, Dhurwa, Near JSCA Stadium, Ranchi-834004	Non-Government
66.		NU Hospitals Pvt. Ltd. #4.1, West of Chord Road, Next to Iskcon, Rajaji Nagar, Bengaluru, Karnataka-560010	
67.	Karnataka	Basaveshwara Medical College & Hospital SJM Campus, NH-4, Medehalli, Chitradurga, Karnataka-577502	Non-Government
68.		Kauvery Hospital No.92/1A, Konappana Agrahara, Electronic City Banglore, Bangalore Rural, Karnataka-560100	

69.		St. Martha's Hospital #5, Nrupatunga Road, Opp. RBI, Bangalore, Karnataka-560001	
70.		Rajarajeswari Medical College & Hospital Kambipura, Mysuru Road, Bangalore, Karnataka-560074	
71.		Sahyadri Narayana Multispecialty Hospital Shimoga, Karnataka-577202	
72.	Kerala	Government Medical College Annakuthi Konni, Pathanamthitta, Kerala-689691	Government Non-Government
73.		Silverline Hospital Kadvanthra, Kochi, Ernakulam, Kerala-682020	
74.		Sunrise Hospital Kakkanad Seaport, Airport Road, Thrikkakara, Ernakulam, Kerala-682030	
75.		Ahalia School of Pharmacy Palakkad, Kerala-678557	
76.	Ladakh	PHC-Bogdang Near Bogdang, Bridge, Leh, Ladakh-194401	Government
77.	Madhya Pradesh	Best Superspeciality Hospital Jabalpur, Madhya Pradesh-482002	Non-Government

78.	Maharashtra	VIMS Hospital Mohan Nagar, LIC Square Kamtee Road, Nagpur, Maharashtra-440001	Non-Government
79.		Apple Hospitals & Research Institute Ltd. Apple Saraswati Multispeciality Hospital 804/2, 805/2, E Ward, Kadamwadi-Bhosalewadi Road, Kolhapur, Maharashtra-416003	
80.		Sant Gajanan Maharaj Rural Hospital Site- Chinchewadi, Gadahinglaj Road Hasurwadi, Kolhapur, Maharashtra-416503	
81.		Aureus Institute of Medical Sciences Plot No. 16, Wanjari Nagar, Opp. Rajabaksha Hanuman Mandir, Nagpur, Maharashtra-440003	
82.		Sadhu Vaswani Mission's Medical Complex Pune, Maharastra-411001	
83.		Sri Dhaneshwari Manav Vikas Mandal's Private Medical College RP Hospital & Research Centre Pedgaon, Parbhani, Maharashtra-431537	
84.		Sancheti Institute for Orthopaedics & Rehabilitation 16, Shivajinagar, Pune-411005	
85.		Sahayog Hospital (A unit of Ramade Memorial Medicare & Research Institute LLP) Rani Arantibai Chowk, Ring Road, Gondia, Maharashtra-441614	

86.	Manipur	Cancer Treatment Services Hyderabad Pvt. Ltd. & Babina Speciality Hospital Khabeisoi, Sajiwa Jail Road, Imphal East, Manipur-795010	Non-Government
87.	Odisha	Dharanidhar Medical College & Hospital Keonjhar, Odisha-758002	Government
88.		Hitech Medical College & Hospital Rourkala, Odisha-769004	Non-Government
89.		Dr. B. R. Ambedkar State Institute of Medical Sciences Phase-6, Mohali, Punjab-160055	Government
90.		Dr. Karam Singh Memorial Multispeciality Hospital 18-A, Circullar Road, Amritsar, Punjab-143001	Non-Government
91.		Khanna Multispeciality Hospital Pvt. Ltd. Main GT Road, Khanna, Punjab-141401	
92.	Punjab	Kalyan Hospital Div. No. 3 Chowk, Near Fire Brigade, Ludhiana, Punjab-141008	
93.		Umeed Multispecialty Hospital Dhuri, Patiyala By-pass Road, Near GIS School, Sangrur, Punjab-148007	
94.		The Akashdeep Hospital Majitha Road, Amritsar, Punjab-143001	
95.		Pancham Hospital (A unit of Pancham Hospitals Pvt. Ltd.) Ludhiana, Punjab-141002	

96.		Iqbal Nursing Home & Hospital 74, Club Road, Civil Lines, Ludhiana, Punjab-141001	
97.		Healthsure Multispeciality Hospital Ludhiana Highway Road, Gharuan, SAS Nagar, Punjab-140413	
98.		Grecian Hospital Sector 69, SAS Nagar, Mohali, Punjab-160062	
99.		Aggrawal Liver & Gut Superspeciality Hopsital 275-276, JP Nagar, Near BSNL Exchange, Jalandhar, Punjab-144001	
100.		Helios Hospital Opp. Bhatti Road Corner Barnala byepass Road, Bhatinda, Punjab-151001	
101.		Parmar Hospital Bela Road, Ropar, Punjab-140001	
102.		The Corporate Hospital Batla Road, Amritsar, Punjab-148001	
103.		Sant Ishar Singh ji Memorial Hospital Village Rara Sahib, Punjab-141419	
104.		Tagore Hospital & Heartcare Centre Banda Bahadur Nagar, Mahavir Marg, Jalandhar, Punjab-144008	

105.		Shri Krishan Hospital Near Bijori, Lalsot Road, Dausa, Rajasthan-303303	
106.		Rhythm Heart & Multispeciality Hospital Opp. FCI Godown, Near Kendriya Vidyalaya, Udaipur Road, Banswara, Rajasthan-327001	
107.		AMRC Hospital Kiran Path, Mansarovar, Sector-3, Jaipur, Rajasthan-302020	
108.		Om Hospital 8-9, Near BSNL Godown, Naya Gaon Road, Pali Marwar, Rajasthan-306401	
109.	Rajasthan	Maharaja Agrasen Superspeciality Hospital Jaipur, Rajasthan-302039	Non-Government
110.		Mittal Hospital Near Agresen Circle, Alwar, Rajasthan-301001	
111.		Gurukripa Hospital Research Centre Pvt. Ltd. Gurukripa Circle, Jyoti Nagar, Piplani Road, Sikar, Rajasthan-332001	
112.		Maxwell Hospital, (A unit of National Health Institute and Medical Research Centre Trust) Opp. Khandaka Marriage Garden, Jhotwara Road, Jaipur, Rajasthan-302006	
113.		Sadhna Hospitals Pvt. Ltd. Jharkhand Mode, Khatipura Road, Jaipur Rajasthan-302012	

114.		Chirayu Hospital (A unit of KSCH Pvt. Ltd.) Hathoj, Kalwar Road, Jaipur, Rajasthan-302012	
115.		Suvira Hospital 7/C-02, Shipra Path, Mansarovar, Jaipur, Rajasthan-302020	
116.		Shri Ram Hospital (A Unit of Shri Ram Super Speciality Surgical Centre Pvt. Ltd.) Opp. Mahamandir Railway Station, Jodhpur, Rajasthan-342006	
117.		Advance Amcure Hospital Pvt. Ltd. Jaipur, Rajasthan-302029	
118.		Shree Rana Hospital & Charitable Medical Institution 317/318, Vaishali Nagar, Ajmer, Rajasthan-305001	
119.		Manglam Plus Medicity Hospital Shipra Path, Mansarovar, Sector-5, Jaipur, Rajasthan-302020	
120.		Dana Shivam Hospital Plot No. 2, Central Spine Sector-2, Vidyadhar Nagar, Jaipur-362023	
121.		GBH American Hospital, 101 Kothi, Bagh, Bhati ji ki Bari, Udaipur, Rajasthan-313001	

122.		Govt. Villupuram Medical College Mundiampakkam Village, Villupuram, Tamil Nadu-605601	Government
123.		Government Vellore Medical College & Hospital Adukkamparai, Vellore, Tamil Nadu-632011	
124.		Government Medical College Tiruppur, Dharapuram Road, Tamil Nadu-601608	
125.		Government Medical College & ESI Hospital Coimbatore, Tamil Nadu-641015	
126.	Tamil Nadu	St. Peter's Medical College Hospital & Research Institute Dr. MGR Nagar, Near Aeri Campus, Opp. to Sipcot-II, Hosur, Krishnagiri, Tamil Nadu - 635130	Non-Government
127.		JCB Hospitals No:1, Vepanthoopu Street, Palani Road, Dindigul, Tamil Nadu-624001	
128.		Vels Medical College & Hospital 12/123, Velan Nagar, Periyapalayam Road, Manjankaranai Village, Uthukottal Taluk, Tiruvallur, Tamil Nadu-601102	
129.		T.N.K.H.N.U. Charity Fund Hospital No.23, NRT Road, Theni, Tamil Nadu-625531	

No.	State	Institution	Type
130.	Telangana	Rajiv Gandhi Institute of Medical Sciences Adilabad, Telangana-504001	Government
131.		Government Medical College Vikarabad, Biladakalaalampally, Vikarabad, Telangana-501101	
132.		Premier Hospitals Pvt. Ltd. Door No. 12-2-710/1, Opp. Queba Masjid, Nanal Nagar X Road, Mehdipatnam, Hyderabad, Telangana-500028	Non-Government
133.		KIMS Hospital Enterprises Pvt. Ltd. 1-112/56/EE, Gachibowli - Miyapur Road, Serilingampally Mandal, Kondapur, Ranga Reddy, Telangana-500084	
134.		Medicover Women & Child Hospitals Beside Shilparamam, Opp. Hitex Charminar, Hitechcity Hyderabad, Telangana-500081	
135.		Prathima Relief Institute of Medical Sciences, H.No. 51-3-630, Sahasra Nagar, Near Ayyappa Swany and Iskon Temple, Mulugu Road, Telangana, Warangal-506007	
136.	Tripura	ILS Hospitals Agartala New Capital Complex, New Secretariat, West Tripura, Tripura-799010	Non-Government

137.		Government Medical College Badaun, Gunera, Wazidpur, Sirsauli, Uttar Pradesh-243601	Government
138.		MIMHANS Neurosciences Hospital 281, 283 Mangal Pandey Nagar, Opposite CCS University, Meerut, Uttar Pradesh-250004	Non-Government
139.		SRMS Goodlife Hospital 101/2, 101/3, Brahampura East, Stadium Road, Bareilly, Uttar Pradesh-243122	
140.		Heritage Institute of Medical Sciences NH-2, G T Road Bypass, Bhadwar, Varanasi, Uttar Pradesh-221311	
141.	Uttar Pradesh	Hind Institute of Medical Sciences Village-Mau, Post-Ataria, Tehsil - Sidhavli, Dist.- Sitapur, Uttar Pradesh-261303	
142.		SPES Superspeciality Hospital Omega II, NRI City Complex, Near Pari Chowk, Greater Noida, Gautam Buddha Nagar, Uttar Pradesh-201310	
143.		Apex Hospital (Unit of Medigrowth Pvt. Ltd.) Moradabad, Uttar Pradesh-244001	
144.		Taurus Hospital 208, Safipurlst Ramadevi, GT Road, Kanpur, Uttar Pradesh-208007	
145.		Metro Hospital & Heart Institute Cardiology Wing, X-1, Sector 12, Noida, Gautam Bhudha Nagar, Uttar Pradesh-201301	

146.		Navin Hospital (A Unit of Navin Medicare Pvt.Ltd.) NH-3, Pocket-F, Alpha-2, Greater Noida, G.B. Nagar, Uttar Pradesh-201308	
147.		Noida International Institute of Medical Sciences Plot No.1, Sector-17 A, Yamuna Expressway, Opp. F1 Track, Gautam Budh Nagar, Uttar Pradesh-203201	
148.		Charak Hospital and Research Centre Lucknow, Uttar Pradesh-226003	
149.		Atlanta Mediworld Multispeciality Hospital & Research Centre (A Unit of RRM Services) Sector-14, Vasundhara, Ghaziabad-201012	
150.		Mayo Medical Centre Pvt Ltd Vikas Khand-2, Gomti Nagar, Lucknow, Uttar Pradesh-226010	
151.		Krush Divine Hospital (A unit of Ramraj Wellness Pvt Ltd) G.B. Nagar, Uttar Pradesh-203207	
152.	**Uttarakhand**	Graphic Era Institute of Medical Sciences Dehradun, Uttarakhand-248001	Non-Government

153.	**West Bengal**	Desun Hospital (A unit of P N Memorial Neuro Centre & Research Institute Ltd.) Desun More, KasbaGolpark, E M Bypass, Kolkata, West Bengal-100107	Non-Government
154.		Amri Hospitals Dhakuria, P-4 & 5, C.I.T. Scheme, Gariahat Road, Kolkata, West Bengal-700029	
155.		Neotia Getwel (A unit of Ambuja Healthcare Venture Limited) Uttorayon Behind, City Centre Matigara, Siliguri, Darjeeling, West Bengal-734010	

Signal and Drug Safety Alerts by PvPI

PvPI confirms the signals and issues drug safety alerts from time to time. WHO defines a Signal as "Reported information on a possible causal relationship between an adverse event and a drug, the relationship being unknown or incompletely documented previously". Signal detection and clinical assessment of ICSRs form a vital domain of pharmacovigilance. NCC-PvPI is engaged in identifying potential signals from India-specific ICSRs with technical assistance by experts in the Signal Review Panel.

Statistical Methods used by PvPI for Signal Detection

The disproportionality analysis performed for Drug-Event Combinations (DECs). The disproportionality analysis is primarily a tool to generate hypothesis on possible causal relations between drugs and adverse effects, to be followed by clinical assessment of the underlying ICSR. It is based on the contrast between Observed and Expected number of cases. The key parameters of the disproportionality analysis are:

i.   Information Component (IC)
ii. Proportional Reporting Ratio (PRR)
iii. Chi-Square ($\chi 2$) value
iv. Number of Drug-Event combinations

(i) Information Component

Propagation Neural Network (BCPNN) is used for quantitative measurement of strength of the dependency between specific Drug-ADR combination. IC is calculated by taking logarithmic measure of disproportionality used to evaluate strength of association between drug and ADR and mathematically expressed as,

IC = $\log_2$ (Observed number + 0.5/Expected number + 0.5)

- If a particular Drug-ADR combination is reported more often than expected from the rest of the database then the value of IC will be positive.
- For no quantitative dependency, the value of IC will be zero, while if the combination is occurring less frequently than statistically expected, it will be negative.
- The higher the IC value, more the combination stands out from the background.
- IC025 is the lower end point of the 95% credibility interval for the IC and calculated for each Drug-ADR combination.

Criteria for Signal: IC025>0, It means Positive value.

(ii) Proportional Reporting Ratio (PRR)

The deviation of the observed number from the expected number of ICSRs can be expressed as a ratio, that is PRR. The PRR can be calculated by the following formula;

$$PRR = \frac{A/(A+B)}{C/(C+D)}$$

Where,

A = Number of Reactions of Interest (i.e. identified ADR) reported with the suspected drug

B = Number of All Other Reactions reported with the suspected drug

C = Number of Reactions of Interest reported with all other drugs

D = Number of All Other Reactions reported with all other drugs

Criteria for Signal: PRR ≥ 2

(iii) Chi-Square (χ2) value

Used to determine whether there is a significant difference between the expected and the observed frequencies in one or more categories. The chi-square can be calculated by using the following formula:

$$\chi2 = \frac{\sum(Observed\ value - Expected\ value)^2}{(Expected\ value)}$$

Criteria for Signal: $\chi2 \geq 4$

(iv) Number of Drug-Event (NDE) combinations

At least three Drug-Event combinations should be required for the confirmation of signal.

Criteria: NDE ≥ 3

Note: Fulfilment of at least three of these four parameters is required for considering a specific drug-ADR combination as a potential signal.

(Reference: Caster O, Juhlin K, Watson S, Norén GN. Improved statistical signal detection in pharmacovigilance by combining multiple strength-of-evidence aspects in vigiRank: retrospective evaluation against emerging safety signals. Drug safety. 2014 Aug;37:617-28.)

Utilization of ICSR data

The National Coordination Centre - Pharmacovigilance Programme of India evaluates potential ICSRs for the confirmation of signals, issuing drug safety alerts and revision of Prescribing Information Leaflets (PILs) in the SRP meetings. The outcomes of SRP meetings were communicated to the (CDSCO) for taking appropriate regulatory actions.

SRP Recommendations for regulatory actions

The NCC-PvPI evaluated spontaneously submitted ICSRs and further discussed in SRP meeting during the index period. The outcomes of SRP meetings were communicated to the CDSCO for appropriate regulatory actions. The list of which are tabulated below:

S. No.	SRP Meeting	Suspected drugs	Adverse drug reactions	PvPI Recommendation
1.	25th SRP meeting held on 30th October 2024	Metronidazole	Fixed Drug Eruption	To be included in PIL
2.		Vancomycin	DRESS Syndrome	To be included in PIL
3.		Acetazolamide	Choroidal Effusion/Detachment	To be included in PIL
4.		Tetracycline	Fixed Drug Eruption	To be included in PIL
5.	26th SRP meeting held on held on 24th March 2025	Gliclazide	Erythema Multiforme	Signal (To include in PIL)
6.		Carbimazole	Agranulocytosis	To be included in PIL
7.		Doxycycline	CNS Side Effects (Restlessness, Anxiety, Irritability, Nervousness, Dizziness)	To be included in PIL

Drug Safety Alerts Issued by IPC, NCC-PvPI

The IPC, NCC-PvPI has issued a total of 14 monthly drugs safety alerts during index period to sensitize the healthcare professionals & consumers through emails, periodically issued PvPI Newsletters, web-portal of IPC for strengthening of reporting to PvPI as tabulated below:

S. No.	Issue Date	Suspected drugs	Indication	Adverse Drug Reactions
1.	21ˢᵗ May 2024	Meropenem	For treatment of pneumonia, nosocomial pneumonia, UTI, intra- abdominal infection, gynaecological infection, skin & soft tissue infection, meningitis, septicaemia & empiric treatment of presumed infection in adult patients with febrile neutropenia.	Acute Generalized Exanthematous Pustulosis (AGEP)
2.	28ᵗʰ June 2024	Acetazolamide	As an adjunct in the treatment of chronic open-angle glaucoma; secondary glaucoma; as part of pre-operative treatment of acute- angle closure glaucoma.	Choroidal effusion or Choroidal detachment
3.		Amlodipine	To reduce fatal coronary heart disease, non-fatal myocardial infarction, risk of stroke and treatment of hypertension. To reduce the risk of coronary revascularization procedures and the need for hospitalization due to angina in patients with coronary artery diseases.	Lichenoid Keratosis

4.	18th July 2024	Vancomycin	Treatment of serious infection due to Gram-positive cocci including methicillin-resistantst aphylococcal infections, brain abscess, staphylococcal meningitis and septicaemia.	DRESS Syndrome
5.	8th August 2024	Metronidazole	For the treatment of amoebiasis, urogenital trichomoniasis & giardiasis.	Fixed Drug Eruption
6.	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, non-gonococcal urethritis, chancroid, plague, tularemia, cholera, brucellosis, bartonellosis, granuloma inguinale, haemophilus and kleibsella infections, psittacosis.	Fixed Drug Eruption
7.	28th November 2024	Amphotericin B	Treatment of Febrile Neutropenia in cancer patients. Treatment for invasive fungal infection in patients, who are refractory to or intolerant of conventional Amphotericin B therapy. Indicated for the treatment of Visceral Leishmaniasis.	Hyperkalaemia

8.		Carbimazole	Indicated for the treatment of thyrotoxicosis including thyrotoxicosis crisis.	Agranulocytosis
9.	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

10.		Metronidazole	For the treatment of amoebiasis, urogenital trichomoniasis & giardiasis.	AGEP
11.		Luliconazole	For the treatment of cutaneous mycosis viz. Tinea pedis, Tinea corporis and Tinea cruris.	Chloasma/ Melasma
12.	12th March 2025	Dalteparin	For the extended treatment of symptomatic Venous Thromboembolism (VTE) proximal Deep Vein Thrombosis (DVT) and/or Pulmonary Embolism (PE) to reduce the recurrence of VTE in patients with cancer.	Muscle spasms
13.		Gliclazide	Indicated for the treatment of all types of maturity onset diabetes, diabetes without or with obesity in adults.	Erythema multiforme
14.		Tramadol	For the treatment of severe acute and chronic pain, diagnostic measures and surgical pain.	Fixed Drug Eruption

Training, Skill Development Programmes and Sensitization Programmes

The PvPI has organised a total of 2598 trainings and trained 200302 stakeholders in the area of Pharmacovigilance during this tenure. NCC-PvPI has recognized 12 Regional Training Centres (RTCs) to impart training in pharmacovigilance and to cater the needs of PV trainees and adapting Good Pharmacovigilance Practices. The list is given below:

S. No.	Existing RTCs	States/UT under purview	Year of Recognition
1.	Post Graduate Institute of Medical Education and Research, Chandigarh	Ladakh, Jammu & Kashmir, Himachal Pradesh, Punjab, Chandigarh, Haryana (Except Faridabad, Gurugram)	2011
2.	Seth GS Medical College & KEM Hospital, Mumbai	Maharashtra, Goa, Dadra & Nagar Haveli	2011
3.	JSS Medical College Hospital, Mysuru	Karnataka, Puducherry, Lakshadweep	2011
4.	Institute of Postgraduate Medical Education & Research, Kolkata	Andaman & Nicobar Islands, West Bengal, Jharkhand, Bihar, Odisha	2011
5.	B. J Medical College, Ahmedabad	Gujarat, Rajasthan, Daman & Diu	2014
6.	All India Institute of Medical Sciences, Bhopal	Madhya Pradesh, Chhattisgarh	2015
7.	Nizam's Institute of Medical Sciences, Hyderabad	Andhra Pradesh, Telangana	2015

8.	All India Institute of Medical Sciences, Rishikesh	Uttarakhand, Uttar Pradesh (Except Ghaziabad, Noida)	2016
9.	Government Medical College, Guwahati	Assam, Arunachal Pradesh, Nagaland, Manipur, Meghalaya, Mizoram, Tripura, Sikkim.	2020
10.	Maulana Azad Medical/Dental College, New Delhi	Delhi & Adjoining areas (Ghaziabad, Noida, Faridabad, Gurugram)	2021
11.	Madras Medical College, Chennai	Tamil Nadu	2021
12.	Amrita Institute of Medical Sciences, Kochi	Kerala	2021

The details of training programmes conducted during the index period are as follows:

1. Trainings organised by the NCC-PvPI, IPC

a) Skill Development Programme (SDP) on Pharmacovigilance.

b) Induction-cum-Training Programme for newly recruited PV Associates and newly appointed AMC Coordinators.

c) Regional Training Programme for MAHs.

d) Interactive meetings conducted for MAHs.

e) Pharmacovigilance training for National Accreditation Board for Hospitals & Healthcare providers (NABH) accredited hospitals.

f) Hand holding meetings for AMCs.

g) Refresher training for Pharmacovigilance associates.

2. Trainings organised by the RTCs & AMCs

a) Advanced Level Trainings (ALTs) Programmes.

b) Sensitization and awareness programmes for reporting AEs.

3. Celebration of 4th National Pharmacovigilance Week

4. International webinar organised by NCC-PvPI for SEARN Countries and WHO Member States.

5. Other Training Programmes on Pharmacovigilance

Figure -21. Objectives of PvPI Training Programme

1a. Skill Development Programme on Pharmacovigilance

NCC-PvPI holds the responsibility to generate the skilled human resource for assuring safe use of medicines in India. In order to enhance pharmacovigilance skills of the healthcare professionals, PvPI conducted various trainings on pharmacovigilance for Healthcare Professionals, Industry personnel, Consumers and other stakeholders. PvPI has developed practical tools which serve as scientific models to disseminate information and solutions to probable drug-related problems. Thus, PvPI has been a prominent platform for sustainable PV practices among all healthcare stakeholders.

Since its inception in 2017, NCC-PvPI successfully conducted 32 Skill Development Programmes on Pharmacovigilance, focussed on understanding of the basic concepts of pharmacovigilance. The training programme provides an opportunity for the participants to work in the area of Pharmacovigilance to ensure better patient safety. This training programme also encourages them to become entrepreneurs in Pharmacovigilance. During the index period, NCC-PvPI organized a total of 4 Skill Development Programmes of 5 days each, on Pharmacovigilance through virtual mode in which a total of 1134 participants were trained.

S. No.	Date	Skill Development Programme	No. of Participants Trained
1.	3rd- 7th June 2024	29th Skill Development Programme	260
2.	5th- 9th August 2024	30th Skill Development Programme	321
3.	18th- 22nd November 2024	31st Skill Development Programme	184
4.	3rd- 7th March 2025	32nd Skill Development Programme	369

1b. Induction-cum-Training Programme for newly recruited PV Associates and newly appointed AMC Coordinators

Every year PvPI is extending its outreach across several states/UTs of India, hence new task force in terms of recruited Pharmacovigilance Associates and appointed Coordinators/ Deputy Coordinators of newly inducted AMCs are trained at NCC-PvPI, IPC through induction-cum-training programmes. During the index period, NCC-PvPI organized a total of 4 induction-cum-training programmes through virtual mode in which a total of 110 participants were trained as mentioned below:

S. No.	Date	No. of Participants Trained
1.	9th-12th April 2024	22
2.	14th June 2024	6
3.	19th July 2024	51
4.	10th March 2025	31

1c. Regional Training Programme for MAHs

NCC-PvPI, IPC organised Regional Training Programme on Implementation of Pharmacovigilance Guidance document for Marketing Authorization Holders (MAHs) of Pharmaceutical Products, Version 2.0. The objective of this training programme was to sensitize the MAHs for implementation of this Guidance Document.

S. No.	Date	Place	No. of Participants
1.	29th January 2025	National Institute of Mental Health and Neuro Sciences (NIMHANS), Bengaluru	57
2.	28th February 2025	Central Drug Testing Laboratory (CDTL), Mumbai	51

1d. Interactive meetings conducted for MAHs

NCC-PvPI, regularly conducts interactive sessions with MAHs to update them on the collation, analysis and quality scoring procedures for individual ICSRs, followed at NCC-PvPI, as the completeness score of ICSRs is one of the main criteria of quantitatively assessing the quality of individual ICSR for contributing towards potential regulatory recommendations. Thus, the interactive meeting with MAHs serves the purpose of improving the overall quality of PvPI data submitted to VigiBase. 11 such interactive meetings were conducted through virtual mode in which 102 participants were trained.

S. No.	Date	MAHs	No. of Representatives
1.	24th April 2024	Biologicals E Ltd.	11
2.	28th May 2024	Cadila Pharmaceuticals Ltd.	10
3.	11th July 2024	Dr. Reddy's Laboratories	10
4.	31st July 2024	Serum Institute of India Ltd.	10
5.	30th August 2024	Sanofi India Ltd.	8
6.	14th October 2024	Zydus Lifesciences Ltd.	7
7.	28th October 2024	MSD Lifesciences Ltd.	9
8.	28th November 2024	GSK Pharmaceuticals Ltd.	8
9.	30th December 2024	Troikaa Pharmacuiticals Ltd.	14
10.	18th March 2024	Piramial Pharma Ltd.	7
11.	27th March 2024	Alkem Laboratries Ltd.	8

1e. Pharmacovigilance training for NABH accredited hospitals

With an objective of providing a platform for the NABH accredited hospitals and to broadly comprehend the system and procedures involved in ADR reporting, PvPI conducts a specialised Workshop-cum-training programme on Pharmacovigilance for staff of NABH Accredited Hospitals. These training sessions help in sensitizing the healthcare professionals to monitoring and reporting AE/ADRs. During the index period, 144 HCPs were trained:

S. No.	Date	Title	No. of Participants Trained
1.	31st January 2025	Workshop-cum-training programme on Pharmacovigilance for NABH Accredited Hospitals at Fortis Hospital, Mohali, Punjab	144

1f. Hand holding meetings for AMC

NCC-PvPI, IPC has organised handholding meetings for the Coordinators, Deputy-Coordinators, Junior Pharmacovigilance Associates virtually and demonstrated "How to enter data in VigiFlow?". 7 such hand holding meetings were conducted through virtual mode in which 305 participants were trained.

S. No.	Date	Title	No. of Participants Trained
1.	25th April 2024		31
2.	15th May 2024		22
3.	14th June 2024	Handholding Meeting on VigiFlow Software for AMCs enrolled under PvPI	74
4.	30th July 2024		51
5.	12th September 2024		40
6.	27th November 2024		24
7.	27th March 2025		63

1g. Refresher training for Pharmacovigilance associates

NCC-PvPI conducts periodic refresher training programmes to ensure continuous professional development and enhance the expertise of pharmacovigilance associates in PvPI. These session focus reinforcing key concepts in pharmacovigilance, updating participants on the latest advancements in drug safety and improving reporting practices. The training aims to strengthen the competencies of associates, enabling them to contribute effectively to patient safety. 4 such trainings were conducted in which 450 participants were trained.

S. No.	Date	Title	Mode of Training	No. of Participants
1.	27th May 2024	AEFI training	Virtual	124
2.	27th June 2024	Training on Pharmacovigilance Audit and Inspection	Hybrid	126
3.	14th October 2024	Training on Narrative writing for Pharmacovigilance	Virtual	85
4.	12th to 13th November 2024	Training on introduction to MedDRA coding and Safety Data analysis and SMQs	Hybrid	115

2a. Advanced Level Trainings Programmes

Regional Training Centres of PvPI across the country organised a total of 7 Advanced level training (ALT) programmes in Pharmacovigilance in which 1646 healthcare professionals including Coordinators, Deputy Coordinators and Pharmacovigilance Associates of various AMCs were trained.

S. No.	Date	Title	Organised at RTCs	No. of Participants Trained
1.	24th April 2024	Advance Level Training in Pharmacovigilance	MMC-Chennai	148

2.	25th May 2024	ALT on Pharmacovigilance/ Materiovigilance and Coordinators Meeting Report	PGIMER-Chandigarh	337
3.	29th June 2024	Webinar on 'Advancing, Excelling & Mastering in Pharmacovigilance'	JSS-Mysuru	272
4.	06th December 2024	Awareness on Risk Management of Pharmaceutical Products: Role of different Stakeholders	NIMS-Hyderabad	280
5.	10th December 2024	East Zone Regional Advance Level Training program in Pharmacovigilance	IPGMER-Kolkata	165
6.	28th February 2025	Advanced-Level Training programme titled 'ADR SANS Frontiers'	AIMS-Kochi	57
7.	12th March 2025	Advance Level Training in Pharmacovigilance	BJMC-Ahmedabad	387

2b. Sensitization and awareness programmes for reporting Adverse Events

The AMCs of PvPI across the country organised a total of 1421 sensitization and awareness programmes in which 71810 healthcare professionals were trained during this tenure, the details are summarized below:

S. No.	AMCs	Total No. of Trainings organised	Total No. of Participants trained
1.	GMERSMCGH-Gandhinagar	41	735
2.	AIMS-Kochi	39	1143
3.	KFMSR-Coimbatore	37	1567
4.	KEM-Mumbai	36	997
5.	BJMC-Ahmedabad	29	2299
6.	SRMC-Chennai	28	1186
7.	MLBMC-Jhansi	27	2086
8.	BMC&RI-Banaskantha	26	544
9.	GMC-Guntur	23	833
10.	JMMCRI-Thrissur	23	770
11.	CMJNM-Nadia	22	1351
12.	IGIMS-Patna	22	529
13.	NDMCMC-New Delhi	22	1276
14.	STM-Kolkata	22	606

15.	JNMC-Aligarh	21	1100
16.	SRMMC-Kattankulathur	21	590
17.	SVMC-Tirupati	21	1204
18.	CH-Sirmaur	20	391
19.	FMMC-Mangaluru	20	1052
20.	KIMS-Nalgonda	20	581
21.	KMC-Kurnool	20	672
22.	GMC-Bhopal	19	267
23.	MMC-Madurai	19	1058
24.	AJIMS- Mangaluru	18	1265
25.	GMCH-Nagpur	18	1168
26.	GMERSMC-Ahmedabad	18	383
27.	SBKSMI/RC-Waghodia	18	1521
28.	NIMS-Hyderabad	17	330
29.	VIMS-Bengaluru	17	953
30.	BAPSPSH-Surat	16	338
31.	GGSMCH-Faridkot	16	905
32.	GTDMC-Alappuzha	16	440
33.	HMCH-Bhubaneswar	16	1240

34.	RH-Aluva	16	1180
35.	GMC-Miraj	15	660
36.	GMC-Prakasam	15	1161
37.	IMSBHU-Varanasi	15	1403
38.	KH-Tiruchirapalli	15	128
39.	SDUMC-Kolar	15	991
40.	VMCHRI-Madurai	15	1650
41.	BMCRI-Bengaluru	13	352
42.	JNIMS- Imphal	13	899
43.	MMC-Chennai	13	914
44.	RGKMC-Kolkata	13	81
45.	SAIMS-Indore	13	464
46.	SNMC-Agra	13	996
47.	AIIMS-Bhopal	12	1248
48.	ASMC-Shahjahnapur	12	4101
49.	RMC-Kakinada	12	307
50.	SUTAMS-Thiruvananthapuram	12	220
51.	TMMC-RC Moradabad	12	630
52.	AMSH-Kolkata	11	102
53.	GKMC-Chennai	11	428

54.	JSS-Mysuru	11	614
55.	KAMSRC-Hyderabad	11	366
56.	MGMMC-Indore	11	1112
57.	BIMS-Belagavi	10	583
58.	MMCHRI-Kanchipuram	10	186
59.	SMC-Meerut	10	567
60.	VPCI-New Delhi	10	158
61.	AIIMS-Bathinda	9	427
62.	CMMCH-Durg	9	646
63.	KIMS-Bhubaneswar	9	415
64.	NIMHANS-Bengaluru	9	541
65.	SGPGIMS-Lucknow	9	705
66.	GMC-Baramulla	8	222
67.	GTMC-Thiruvarur	8	163
68.	IGICH-Bengaluru	8	507
69.	JLNMC-Ajmer	8	370
70.	MDCP-Kasaragod	8	994
71.	PDUMC-Rajkot	8	123

72.	PIMS-Tiruvalla	8	575
73.	JIPMER-Puducherry	7	597
74.	PDUMC-Rajkot	7	110
75.	SMCH-Silchar	7	147
76.	JMC-Jorhat	6	213
77.	PIMS-Karimnagar	6	965
78.	SGGSTU-Gurugram	6	330
79.	SSMC-Rewa	6	103
80.	AIIMS-Hyderabad	5	150
81.	GDMC-Dehradun	5	211
82.	GMC-Thrissur	5	78
83.	MAH-Surat	5	174
84.	RMLIMS-Lucknow	5	120
85.	SJCP-Thrissur	5	175
86.	TMCH-Chengal Pattu	5	54
87.	AIIMS-Nagpur	4	171
88.	Apollo-New Delhi	4	88
89.	BCMCH-Thiruvalla	4	252

90.	CMC-Vellore	4	294
91.	GMC-Haldwani	4	355
92.	GMC-Secundrabad	4	142
93.	GMC-Srinagar	4	65
94.	GMC-Trivandrum	4	83
95.	MAMC-New Delhi	4	94
96.	NIIOMS & RF-Thiruvananthapuram	4	179
97.	PRMMCH-Mayurbhanja	4	152
98.	PSGIMSR-Coimbatore	4	32
99.	SNMMC-Dhanbad	4	46
100.	VSSMC-Burla	4	206
101.	BMCRI-Palanpur	3	64
102.	DYSPGMC-Sirmaur	3	121
103.	FMMCH-Balasore	3	73
104.	IPGMER-Kolkata	3	273
105.	KMC-Warangal	3	416
106.	KMSSH&RC-Surat	3	75
107.	PGIMS-Rohtak	3	442

108.	RGKMC-Kolkata	3	52
109.	AFMC-Pune	2	65
110.	AIMSRC-Hyderabad	2	65
111.	GAMC-Ratlam	2	120
112.	GBCMKKBMSH-Dehradun	2	125
113.	GMCH-Suryapet	2	300
114.	GVMC-Villupuram	2	85
115.	KGH-Visakhapatnam	2	100
116.	MMCHRI-Kanchipuram	2	46
117.	PESIMSR-Kuppam	2	33
118.	PGIMER-Chandigarh	2	400
119.	PMCHRI-Chennai	2	17
120.	RMC-Ahmednagar	2	35
121.	SCBMC-Cuttack	2	61
122.	SGMRH-Kolhapur	2	690
123.	SIMSRH-Tumakuru	2	137
124.	SMCH-Trichy	2	67
125.	SSSMCRI-Chengalpattu	2	257

126.	TMCBRAM-Agartala	2	205
127.	TMCH-Tezpur	2	180
128.	ACP-Malappuram	1	71
129.	AHC-Chennai	1	22
130.	AHPL-Vijaywada	1	20
131.	ASMCSNMH&TBS-Firozabad	1	137
132.	BPSGMC-Sonepat	1	29
133.	CMCH-Coimbatore	1	8
134.	DVMGMC-Solapur	1	13
135.	ESICMC-Bengaluru	1	35
136.	ESICMC-Faridabad	1	15
137.	GMCH-Kallakurichi	1	90
138.	GMCH-Udhagamandalam	1	10
139.	GMC-Kannauj	1	200
140.	GMC-Nagarkurnool	1	75
141.	GMC-Prakasam	1	33
142.	GMC-Thiruvallur	1	102
143.	GMC-Vizianagaram	1	36

144.	HIMSR-New Delhi	1	30
145.	ISFCP- Moga	1	26
146.	JIPMER-Karaikal	1	100
147.	JPH-Bhopal	1	300
148.	KHHI-Noida	1	53
149.	KLECP-Belagavi	1	513
150.	KMC-Manipal	1	60
151.	LMCP-Ahmedabad	1	90
152.	LPU-Chandigarh	1	192
153.	MDCP-Kasaragod	1	120
154.	MMCMSR-Ambala	1	180
155.	PIMS-Puducherry	1	146
156.	SJMCH-Puri	1	17
157.	SLMCH-Chennai	1	23
158.	SLNMCH-Koraput	1	39
159.	SMSMC-Jaipur	1	34
160.	SNIMS-Ernakulam	1	85
161.	SRTRMC-Beed	1	17
162.	SVIMS-Tirupati	1	230

3. Celebration of 4th National Pharmacovigilance Week

The National Coordination Centre - Pharmacovigilance Programme of India (NCC-PvPI), Indian Pharmacopoeia Commission (IPC) has celebrated 4th National Pharmacovigilance Week (NPW) from 17th-23rd September, 2024 across the country through hybrid mode. The theme of the 4th NPW was to "Building ADR Reporting Culture for Patient Safety". The National Pharmacovigilance Week will be celebrated every year on this day which will go a long way in reaching common masses about the importance of reporting Adverse Drug Reaction.

The major focus of NPW celebrations is to focus on PV activities aimed at creating awareness amongst the public, healthcare professionals, pharmaceutical industries and healthcare authorities about the reporting of adverse drug reactions and encourage carrying out the activities related to Pharmacovigilance to the general public during the NPW. The Pharmacovigilance Week Celebration is about recognizing the role of healthcare professionals like Physicians, Nurses, Pharmacists, students, Academicians in reporting adverse drug reactions. The Pharmacovigilance Week celebration can be ideal platform to honour our fellow healthcare professionals who are an integral part of the healthcare system and drug safety.

Activities During 4th National Pharmacovigilance Week	
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) The comic strip is a story about a villain called 'Mendos' who has gone rogue and wants to control the world with 'side effects and a superhero RRR' who then curbs Mendos with his knowledge and awareness of Pharmacovigilance. Throughout the comic strip, allegories have been drawn. The concept of pharmacovigilance has been established and the duties of patient in the context of safety have been described metaphorically. It has been described how one can safeguard the life of his/her own self and their loved ones by being vigilant and by reporting side effects in a timely manner. The comic strip has an intriguing storyline, is colourful in its layout and is simple to understand for all age groups. • **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.

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**, Officer-in-Charge, PvPI, IPC 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 (mentioned in Fig. 25) were felicitated. Identified experts under PvPI, **Prof. M Ramesh** (RTC Coordinator, JSS Mysuru, 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. PvPI-IPC also compiled and projected a video on "Glimpses of NPW 2024 Celebration" during Valedictory ceremony.

(a)

(b)

(c)

(d)

(e1)

(e2)

(e3)

(e4)

(e5)

(e6)

(e7)

(e8)

(e9)

(e10)

Figure - 22. (a) PV Comic (Endgame of Side Effects), (b) Quality Manual of PvPI (c) Pharmacovigilance Guidance Document for Market Authorization Holders (MAHs) of Pharmaceutical Products (Version 2.0), (d) Newsletter Volume 14 Issue 2, (e1-e10) PvPI Posters

Figure-23. Winners of quiz competition

Figure-24. Winners of e-poster competition

4th National Pharmacovigilance Week

September 17- 23, 2024

Theme: Building ADR Reporting Culture for Patient Safety

TOP PERFORMING ADR MONITORING CENTRES – 2023-24
(With Pharmacovigilance Associate)

AMC Name	Coordinator	Deputy coordinator	Pharmacovigilance Associate
Post Graduate Institute of Medical Education & Research, Chandigarh	Dr. Bikash Medhi	Dr. Ajay Prakash	Mr. Benjamin Ms. Disha
Believers Church Medical College & Hospital ,Thiruvalla	Prof Dr Jacob Jesurun RS	Dr Swetha Reba Mathews	Saylo Wilson
Seth GS Medical College & KEM Hospital, Mumbai	Dr. Nithya Gogtay	Dr. Mahesh Belhekar	Ms. Pratiksha Dyaneshwar Thombare
Rajagiri Hospital, Aluva	Dr. Dinu Varghese	Dr. Eldho Mathew Paul	Ms. Aparna Chand.O
GMERS Medical College & General Hospital, Gandhinagar	Dr. Darshan J. Dave	Dr. Jigar Modi	Shivani Trivedi
JSS Medical College & Hospital, Mysore	Dr. M. Ramesh	Dr. Sri Harsha Chalasani	Dr. Ascharya Chintalapati
Vijaya Medical & Educational Trust, Vadapalani	Dr. Shajahan O.M	Dr. K. Mukesh	Dr. Sherin Babu
Maulana Azad Medical/Dental College and Associated Lok Nayak, New Delhi	Dr Vandana Roy	Dr. Vandana Tayal	Jitender Charaya
Father Muller Medical College, Mangaluru	Dr. Chandralekha.N	Dr. Akshata Aroor	Ashika A.G
Amrita Institute of Medical Sciences, Kochi	Dr. Princy Louis Palatty	Dr. M.P. Narmadha	Ms. Tinu.T .S.

Figure-25. Top Performing AMCs – with PvA as mentioned above were felicitated

4th National Pharmacovigilance Week

September 17- 23, 2024

Theme: Building ADR Reporting Culture for Patient Safety

TOP PERFORMING ADR MONITORING CENTRES – 2023-24
(Without Pharmacovigilance Associate)

AMC Name	Coordinator	Deputy coordinator
Iqraa International Hospital & Research Centre, Calicut	Dr. Muhammed Thoyyib	Dr. Muhammed Anas V. K.
M.S. Ramaiah Medical College, Bengaluru	Dr. Anuradha H V	Dr. Mukunda N
PSG Institute of Medical Sciences & Research, Coimbatore	Dr. K. Bhuvaneswari	Dr. S. Shanmugapriya
National Institute of Pharmaceutical Education and Research, Vaishali	Dr. Sameer Dhingra	Dr. Krishna Murti
KLE College of Pharmacy, KLE Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi, Karnataka	Dr. Prof. M.S. Ganachari	Dr. Santhosh Reddy
Chalapathi Institute of Pharmaceutical Sciences, Guntur	Venkata Rama Rao Nallani	Dr. Gavin Sivabharath
Jubilee Mission Medical College and Research Institute, Thrissur	Dr. Maria Jose	Dr. David Pudukadan
Caritas Hospital, Thellakom, Kottayam, Kerala	Dr. Varsha Varghese	Dr. Ashly M Reji
ABVIMS & Dr. RML Hospital, Baba Kharak Singh Marg, Near Gurudwara Bangla Sahib, Cannaught Place, New Delhi	Dr. Manik S Ghadlinge	Dr. Kapil Hazarika
SBKMIS/RC-Waghodia, Gujrat	Dr. Shruti	Dr. Jayant Patharkar

Figure - 26. Top Performing AMCs – without PvA as mentioned above were felicitated

4th National Pharmacovigilance Week

September 17- 23, 2024

Theme: Building ADR Reporting Culture for Patient Safety

TOP PERFORMING MARKETING AUTHORIZATION HOLDERS (MAHs) – 2023-24

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

Figure-27. Top Performing MAHs as mentioned above were felicitated

During the NPW-2024, PvPI has organised 1133 training/awareness-cum-sensitization programmes including CME in which 123251 Healthcare Professionals and other stakeholders were trained on PV.

The details of Sensitization training programmes conducted at AMCs/Non-AMCs during the 4th NPW are summarized below:

S. No.	AMCs	No. of Trainings organised	No. of Participants trained
1.	AIIMS-Raipur	12	1068
2.	JNMC-Aligarh	12	1055
3.	KFMSR-Coimbatore	12	2119
4.	SBKSMI/RC-Waghodia	12	774
5.	SSMCRC-Tumakuru	12	449
6.	NIMS-Hyderabad	11	744
7.	MMC-Khammam	10	1097
8.	RMLIMS-Lucknow	10	1559
9.	AIIMS-Jodhpur	9	708
10.	IMSSH-Bhubaneswar	9	465
11.	JKKNCP-Salem	9	1001
12.	JMC-Jorhat	9	895
13.	KIMS-Nalgonda	9	830

14.	AIIMS-Bhopal	8	1281
15.	CMMCH-Durg	8	1940
16.	MMC-Madurai	8	1516
17.	BIPS-Warangal	7	688
18.	GMC-Namakkal	7	555
19.	GMC-Srikakulam	7	756
20.	GMC-Virudhunagar	7	502
21.	GMERSMCGH-Gandhinagar	7	930
22.	GSVM-Kanpur	7	2590
23.	JLNMC-Ajmer	7	550
24.	JSS-Mysuru	7	560
25.	KMCTMC-Kozhikode	7	496
26.	KMSSH&RC-Surat	7	470
27.	MAIMSR-Chengalpattu	7	796
28.	NIMHANS-Bengaluru	7	580
29.	NMCH-Nagaon	7	610
30.	PGIMS-Rohtak	7	576
31.	PIMS-Karimnagar	7	726

32.	RIMS-Etawah	7	1769
33.	RIMS-Ranchi	7	228
34.	SDUMC-Kolar	7	720
35.	SVMC-Tirupati	7	1030
36.	TMCH-Tezpur	7	840
37.	VCSGRI-Pauri Garhwal	7	698
38.	VIMS-Bengaluru	7	389
39.	ABMRCP-Bengaluru	6	460
40.	ACMIH-Bengaluru	6	210
41.	AIIMS-Bathinda	6	1030
42.	AIIMS-Gorakhpur	6	1086
43.	AIIMS-Patna	6	424
44.	AJIMS-Mangaluru	6	525
45.	APC-Anand	6	657
46.	BJMC-Ahmedabad	6	1024
47.	BMC&RI-Banaskantha	6	1552
48.	CH-Sirmaur	6	180
49.	CMJNM-Nadia	6	376

50.	EPCMSRC-Bengaluru	6	270
51.	ESICMCH-Hyderabad	6	520
52.	GMC-Amritsar	6	371
53.	GMC-East Godavari	6	375
54.	GMC-Haldwani	6	450
55.	GMCH-Chandigarh	6	320
56.	GMC-Kannauj	6	1000
57.	GMC-Sirsauli	6	682
58.	GMC-Surat	6	1621
59.	GMC-Wanapar thy	6	950
60.	GMERSMC-Ahmedabad	6	385
61.	GSMCH-Hapur	6	604
62.	GTMCH-Thiruvannamalai	6	355
63.	GTMC-Theni	6	334
64.	JMMCRI-Thrissur	6	333
65.	JNIMS- Imphal	6	669
66.	KLECP-Hubballi	6	576
67.	KMC-Kurnool	6	561

68.	KMC-Manipal	6	632
69.	MAMC-New Delhi	6	2622
70.	MGIMS-Wardha	6	490
71.	MGMMCH-Raigad	6	363
72.	MMC-Chennai	6	418
73.	MMMCH-Solan	6	555
74.	MVRCCR-Kozihikode	6	210
75.	NDMCMC-New Delhi	6	6050
76.	OMC-Hyderabad	6	428
77.	PDCGH-Hyderabad	6	170
78.	PJNMC-Raipur	6	1112
79.	PMCSKH-Anand	6	383
80.	PRMMCH-Mayurbhanj	6	280
81.	RIMSGH-Kadapa	6	590
82.	RMC-Kakinada	6	1167
83.	SJCP-Thrissur	6	464
84.	SJMCH-Puri	6	345
85.	SLNMCH-Koraput	6	248

86.	SMCGH-Kurnool	6	1131
87.	SMC-Meerut	6	334
88.	SMC-Vijayawada	6	491
89.	SVIMS-Tirupati	6	442
90.	VPCI-New Delhi	6	189
91.	VSSMC-Burla	6	363
92.	ACP-Bengaluru	5	440
93.	AIIMS-Bilaspur	5	910
94.	BBMCH-Balangir	5	447
95.	BJGMC-Pune	5	423
96.	BMCRI-Bengaluru	5	216
97.	ESICMC-Bengaluru	5	225
98.	FMMCH-Balasore	5	410
99.	GAIMS-Kachchh	5	521
100.	GGSMCH-Faridkot	5	810
101.	GMC-Bhopal	5	705
102.	GMC-Eluru	5	450
103.	GMCH-Kallakurichi	5	705

104.	GMCH-Sundargarh	5	360
105.	GMC-Nalgonda	5	385
106.	GMC-Ramanathapuram	5	1040
107.	GMC-Secundrabad	5	573
108.	GMC-Thiruvallur	5	583
109.	IGICH-Bengaluru	5	580
110.	IGIMS-Patna	5	241
111.	IMSBHU-Varanasi	5	520
112.	KAPV&MGM-Tiruchirapalli	5	512
113.	KEM-Mumbai	5	235
114.	KGH-Visakhapatnam	5	760
115.	KMC-Warangal	5	803
116.	KVIMSRC-Chengalpattu	5	124
117.	LTMMCGH-Mumbai	5	96
118.	MGMMC-Indore	5	446
119.	NETPCNMCHRC-Raichur	5	365
120.	NIRIT-Chennai	5	605
121.	PrH-Hyderabad	5	150

122.	PSGIMSR-Coimbatore	5	442
123.	RGMCH-Hamirpur	5	385
124.	RMC-Ahmednagar	5	1830
125.	SMCH-Silchar	5	218
126.	SSSMCRI-Chengalpattu	5	575
127.	TMMC-RC Moradabad	5	600
128.	AHPL-Vijaywada	4	77
129.	AIIMS-Mangalagiri	4	485
130.	BGSGIMS-Bengaluru	4	597
131.	DYSPGMC-Sirmaur	4	412
132.	ESICMC-Faridabad	4	153
133.	FMMC-Mangaluru	4	399
134.	GDMC-Dehradun	4	561
135.	GGH-Nizamabad	4	312
136.	GMC-Ariyalur	4	493
137.	GMC-Baramulla	4	187
138.	GMC-Dindigul	4	465
139.	GMC-Guntur	4	2925

140.	GMC-Guwahati	4	280
141.	GMCH-Nagpur	4	412
142.	GMCH-Suryapet	4	450
143.	GMC-Malappuram	4	470
144.	GMC-Mancherial	4	330
145.	GMC-Prakasam	4	252
146.	GMC-Srinagar	4	403
147.	GMC-Vizianagaram	4	175
148.	GTMC-Thiruvarur	4	426
149.	JIPMER-Puducherry	4	376
150.	KAMSRC-Hyderabad	4	330
151.	LGBRIMH-Sonitpur	4	210
152.	MRIMS-Hyderabad	4	508
153.	NCP-Ernakulam	4	552
154.	NIIOMS&RF-Thiruvananthapuram	4	91
155.	NIPER-Vaishali	4	350
156.	NITTE-Mangaluru	4	238
157.	RBVRRWCP-Hyderabad	4	99

158.	RGKMC-Kolkata	4	255
159.	SAIMS-Indore	4	283
160.	SCBMC-Cuttack	4	550
161.	SGGSTU-Gurgaon	4	348
162.	SGRR-Dehradun	4	465
163.	SLMCH-Chennai	4	370
164.	SRMC-Chennai	4	510
165.	SVCP-Hyderabad	4	280
166.	AFMC-Pune	3	250
167.	APOLLO-New Delhi	3	454
168.	CIPS-Guntur	3	283
169.	CMCH-Coimbatore	3	662
170.	CMCH-Ludhiana	3	90
171.	GMC-Chennai	3	349
172.	GMC-Mahabubnagar	3	259
173.	GMC-Miraj	3	300
174.	GMC-Nagarkurnool	3	100
175.	GMC-Thrissur	3	317

176.	GMC-Trivandrum	3	102
177.	GMKMC-Salem	3	58
178.	GTDMC-Alappuzha	3	200
179.	IPGMER-Kolkata	3	128
180.	JIPMER-Karaikal	3	155
181.	KIMS-Bhubaneswar	3	231
182.	MLBMC-Jhansi	3	315
183.	NHH-Bengaluru	3	372
184.	NKPSIMS-Nagpur	3	112
185.	PESIMSR-Kuppam	3	205
186.	PIMS-Tiruvalla	3	67
187.	RH-Aluva	3	93
188.	SMSI-Chikkaballapur	3	276
189.	SNIMS-Ernakulam	3	410
190.	SUCP-Hyderabad	3	410
191.	SVNGMCH-Yavatmal	3	122
192.	TMCBRAM-Agartala	3	165
193.	VMCH-Namakkal	3	440

194.	AIIMS-Deoghar	2	185
195.	ASM-Faridabad	2	267
196.	BAPSPSH-Surat	2	134
197.	BMC-Hyderabad	2	100
198.	CHIPS-Guntur	2	140
199.	DYPUSM-Navi Mumbai	2	204
200.	FPIU-Lucknow	2	370
201.	GMC-Bhavnagar	2	116
202.	GMCH-Krishnagiri	2	480
203.	GMC-Kottayam	2	458
204.	GMC-Tamilnadu	2	268
205.	GMERS-Patan	2	123
206.	HMCH-Bhubaneswar	2	392
207.	KPCMCH-Kolkata	2	350
208.	MDCP-Kasaragod	2	152
209.	MGMCRI-Pondicherry	2	137
210.	MMCMSR-Ambala	2	300
211.	PDUMC-Rajkot	2	199

212.	RIMS-Raichur	2	295
213.	SGTMCHRI-Gurugram	2	294
214.	SNMC-Agra	2	74
215.	SRH-Chengalpattu	2	60
216.	SRMMC-Kattankulathur	2	305
217.	VMET-Vadapalani	2	86
218.	YMC-Mangaluru	2	265
219.	AIGH-Hyderabad	1	173
220.	AIIMS-Hyderabad	1	80
221.	AIMS-Kochi	1	80
222.	AIMSRC-Hyderabad	1	21
223.	AIP-Gwalior	1	380
224.	BIMS-Belagavi	1	170
225.	BMHRC-Bhopal	1	30
226.	BPSGMC-Sonepat	1	15
227.	GAMC-Ratlam	1	160
228.	GBCMKKBMSH-Dehradun	1	30
229.	GCP-Medchal	1	86

230.	GKMC-Chennai	1	170
231.	GMCH-Udhagamandalam	1	317
232.	GMC-Jagtial	1	150
233.	GMC-Nagapattinam	1	280
234.	GMC-Vikarabad	1	35
235.	HIMSR-New Delhi	1	173
236.	JLNMC-Bhagalpur	1	150
237.	KH-Tiruchirapalli	1	7
238.	KLECP-Belagavi	1	68
239.	MKCG-Berhampur	1	280
240.	MMCHRI-Kanchipuram	1	20
241.	MSDASMCMBH-Baharaich	1	175
242.	OPJICCR-Hisar	1	37
243.	PMCHRI-Chennai	1	60
244.	SAHS-Imphal West	1	100

245.	SIMSRC-Mangaluru	1	70
246.	SIMSRH-Tumakuru	1	74
247.	SMSRS-Noida	1	88
248.	SRTRMC-Beed	1	56
249.	SSH-Rajkot	1	18
250.	SSMC-Rewa	1	141
251.	STM-Kolkata	1	32
252.	TMCH-Chengalpattu	1	10
253.	TRIHMS-Naharlagun	1	130

4. International webinar organised by NCC-PvPI for SEARN Countries and WHO Member States

NCC-PvPI, IPC being a World Health Organization (WHO) - Collaborating Centre organized one day International Webinar on "Optimizing the use of ICSRs in Signal Detection Process' on 18th September 2024 for South East Asia Regional countries and WHO Member States participating in Programme for International Drug Monitoring (PIDM). Dr. Shanti Pal, Team Lead, Pharmacovigilance Medicines and Health Products, WHO HQ; Dr Adrien Inoubli, Regional Advisor for Medical Products Quality and Regulation, WHO-SEARO Office, New Delhi; Dr. Mira Desai, SRP Member, PvPI, IPC; Dr. Siddharth Sarkar Additional Professor, NDDTC, AIIMS; Dr. Rohit Saxena, Professor, AIIMS, Delhi; Dr. S. Ramesh Kumar, Scientist F, NIRT; delivered talks on various topics in Pharmacovigilance. A total of 406 participants has participated in this webinar.

5. Other Training Programmes on Pharmacovigilance

The NCC-PvPI has provided technical support for pharmacovigilance. These initiatives are aimed at enhancing the knowledge and skills of the HCPs about the reporting of Adverse Events, establishing pharmacovigilance system in their AMCs.

S. No.	Date	Title	Organized at	No. of Participants
1	30th May 2024	Training Programme on Pharmacovigilance	Sikkim Manipal Institute of Medical Sciences (SMIMS), Gangtok, East Sikkim	110
2	14th November 2024	National Conference on Pharmacovigilance	Sant Gajanan Maharaj Rural Hospital, Kolhapur, Maharashtra	550
3	4th December 2024	Fostering a culture of Patient Safety: The crucial roles of ADRs in Healthcare	Tomo Riba State Hospital, Naharlagun, Arunachal Pradesh	206

Student projects and training in PvPI

One Month Training					
S. No.	Name of Trainee	Qualification	Institute Name	Date	Place
1.	Ashad Ahmad	B. Pharm	Dr. RML College of Pharmacy	1st April 2024 – 1st May 2024	NCC-PvPI, IPC

2.	Mo. Shawez	B. Pharm	Dr. RML College of Pharmacy	2nd April 2024 to 1st May 2024	NCC-PvPI, IPC
3.	Nikil Gupta	B. Pharm	Anand College of Pharmacy, Agra	8th April 2024 to 8th May 2024	NCC-PvPI, IPC
4.	Ms. Tulsi	B. Pharm	ITS College of Pharmacy, Ghaziabad	8th April 2024 to 8th May 2024	NCC-PvPI, IPC
5.	Ekansh Sharma	B. Pharm	ITS College of Pharmacy, Ghaziabad	8th April 2024 to 8th May 2024	NCC-PvPI, IPC
6.	Yogesh Kumar Sagar	B. Pharm	ITS College of Pharmacy, Ghaziabad	8th April 2024 to 8th May 2024	NCC-PvPI, IPC
7.	Rohit Singh	B. Pharm	ITS College of Pharmacy, Ghaziabad	8th April 2024 to 8th May 2024	NCC-PvPI, IPC
8.	Prateek Gupta	B. Pharm	SRM Modinagar College of Pharmacy, Ghaziabad	6th May 2024 to 6th June 2024	NCC-PvPI, IPC

9.	Hmza	B. Pharm	SRM Modinagar College of Pharmacy, Ghaziabad	6th May 2024 to 6th June 2024	NCC-PvPI, IPC
10.	Javed Gadi	B. Pharm	SRM Modinagar College of Pharmacy, Ghaziabad	7th May 2024 to 7th June 2024	NCC-PvPI, IPC
11.	Subham Mishra	B. Pharm	Saroj Institute of Technology, Lucknow	6th May 2024 to 6th June 2024	NCC-PvPI, IPC
12.	Shruti Sommya	B. Pharm	SRM Modinagar College of Pharmacy, Ghaziabad	6th May 2024 to 6th June 2024	NCC-PvPI, IPC
13.	Ishita Singh	B. Pharm	Sharada University, Noida	20th May 2024 to 20th June 2024	NCC-PvPI, IPC
14.	Sarfaraz Alam	B. Pharm	SRM Modinagar College of Pharmacy, Ghaziabad	18th June 2024 to 18th July 2024	NCC-PvPI, IPC

15.	Dhruv Kumavat	Pharm D.	SADTM Campus, New Delhi	18th June 2024 to 18th July 2024	NCC-PvPI, IPC
16.	Ms. Shaifali Joshi	M. Pharm	Amity University, Noida	12th August 2024 to 12th September 2024	NCC-PvPI, IPC
17.	Ms. Varsha	M. Pharm	Amity University, Noida	12th August 2024 to 12th September 2024	NCC-PvPI, IPC
18.	Ms. Prerna Bhati	M. Pharm	Amity University, Noida	12th August 2024 to 12th September 2024	NCC-PvPI, IPC
19.	Muskaan Gupta	B. Pharm	Apeejay Stya University, Gurugram	24th June 2024 to 23rd July 2024	NCC-PvPI, IPC
20.	Isha Jain	B. Pharm	Apeejay Stya University, Gurugram	24th June 2024 to 23rd July 2024	NCC-PvPI, IPC
21.	Aaditya Singh	B. Pharm	Apeejay Stya University, Gurugram	24th June 2024 to 23rd July 2024	NCC-PvPI, IPC

22.	Sarthak Chauhan	B. Pharm	Apeejay Stya University, Gurugram	24th June 2024 to 23rd July 2024	NCC-PvPI, IPC
23.	Kumar Kishan	B. Pharm	Apeejay Stya University, Gurugram	24th June 2024 to 23rd July 2024	NCC-PvPI, IPC
24.	Sumit Pandey	B. Pharm	Apeejay Stya University, Gurugram	24th June 2024 to 23rd July 2024	NCC-PvPI, IPC
25.	Sanjana	B. Pharm	Apeejay Stya University, Gurugram	24th June 2024 to 23rd July 2024	NCC-PvPI, IPC
26.	Vinay	B. Pharm	Apeejay Stya University, Gurugram	24th June 2024 to 23rd July 2024	NCC-PvPI, IPC
27.	Umesh Dagar	B. Pharm	Apeejay Stya University, Gurugram	24th June 2024 to 23rd July 2024	NCC-PvPI, IPC
28.	Mukul Tyagi	B. Pharm	Raj Kumar Goel Institute of Technology (Pharmacy), Ghaziabad	25th June 2024 to 24th July 2024	NCC-PvPI, IPC

29.	Aaditya Kashyap	B. Pharm	Raj Kumar Goel Institute of Technology (Pharmacy), Ghaziabad	25th June 2024 to 24th July 2024	NCC-PvPI, IPC
30.	Aryan Maurya	B. Pharm	Raj Kumar Goel Institute of Technology (Pharmacy), Ghaziabad	01st July 2024 to 31st July 2024	NCC-PvPI, IPC
31.	Aryan Tyagi	B. Pharm	Raj Kumar Goel Institute of Technology (Pharmacy), Ghaziabad	01st July 2024 to 31st July 2024	NCC-PvPI, IPC
32.	Abhishek Jaiswal	B. Pharm	KIET Group of Institutions (KIET School of Pharmacy), Ghaziabad	01st July 2024 to 31st July 2024	NCC-PvPI, IPC
33.	Khushi Shah	B. Pharm	KIET Group of Institutions (KIET School of Pharmacy), Ghaziabad	01st July 2024 to 31st July 2024	NCC-PvPI, IPC

34.	Divyanshu Om Gupta	B. Pharm	KIET Group of Institutions (KIET School of Pharmacy), Ghaziabad	01st July 2024 to 31st July 2024	NCC-PvPI, IPC
35.	Deepanshu Sindhu	B. Pharm	KIET Group of Institutions (KIET School of Pharmacy), Ghaziabad	01st July 2024 to 31st July 2024	NCC-PvPI, IPC
36.	Danish Behl	B. Pharm	K. R. Mangalam University	01st July 2024 to 31st July 2024	NCC-PvPI, IPC
37.	Aanchal Choudhary	B. Pharm	KIET Group of Institutions (KIET School of Pharmacy), Ghaziabad	01st July 2024 to 31st July 2024	NCC-PvPI, IPC
38.	Anurag Tiwari	B. Pharm	KIET Group of Institutions (KIET School of Pharmacy), Ghaziabad	01st July 2024 to 31st July 2024	NCC-PvPI, IPC
39.	Rishabh Kansal	B. Pharm	K. R. Mangalam University	01st July 2024 to 31st July 2024	NCC-PvPI, IPC

40.	Saloni Goyal	B. Pharm	K. R. Mangalam University	01st July 2024 to 31st July 2024	NCC-PvPI, IPC
41.	Srishti Raj	M. Pharm	SGT University, Gurugram	01st July 2024 to 31st July 2024	NCC-PvPI, IPC
42.	Vishesh Sahu	M. Pharm	Amity University, Noida	01st August 2024 to 31st August 2024	NCC-PvPI, IPC
43.	Pooja	M. Pharm	Noida Institute of Engineering and Technology	01st August 2024 to 31st August 2024	NCC-PvPI, IPC
44.	Sandhya Singh	M. Pharm	Noida Institute of Engineering and Technology	01st August 2024 to 31st August 2024	NCC-PvPI, IPC
45.	Adarsh Gaur	M. Pharm	Noida Institute of Engineering and Technology	01st August 2024 to 31st August 2024	NCC-PvPI, IPC

		Three Month Training			
S. No.	Name of Trainee	Qualification	Institute Name	Date	Place
1.	Rutuja Varad Chavan	B. Pharm	KLE Society's College of Pharmacy Nipani, Banaluru	29th April 2024 to 28th July 2024	Vydehi Institute of Medical Sciences and Research Centre, Bengaluru, Karnataka
2.	Vickey kumar	B. Pharm	Sagar Institute of Research and Technology-Pharmacy, Bhopal	5th May 2024 to 4th August 2024	All India Institute of Medical Sciences, Patna, Bihar
3.	Aneesh PK	B. Pharm	The Oxford College of Pharmacy, Kerala	7th May 2024 to 6th August 2024	Believers Church Medical College & Hospital, Thiruvalla, Kerala
4.	Yeruva Raja Anirudh Reddy	MBBS	RVM Institute of Medical Sciences and Research Centre, Mulugu, Siddipet	8th May 2024 to 7th August 2024	RVM Institute of Medical Sciences & Research Centre, Siddipet, Telangana

S. No.	Name of Trainee	Qualification	Institute Name	Date	Place
5.	Ritu Raj Kumar	B. Pharm	SRM Modinagar College of Pharmacy, Delhi NCR Campus	8th May 2024 to 7th August 2024	NCC-PvPI, IPC
6.	Pranshu Gupta	B. Pharm	Dr. K. N. Modi Institute of Pharmaceutical Education & Research, Ghaziabad	15th July 2024 to 14th September 2024	NCC-PvPI, IPC
7.	Samrudhi Kelkar	B. Pharm	Dr. Rajendra Gode Institute of Pharmacy Amravati, Maharashtra	01st January 2025 to 31st March 2025	Mahatma Gandhi Institute of Medical Sciences, Wardha, Maharashtra
Six Month Training					
S. No.	**Name of Trainee**	**Qualification**	**Institute Name**	**Date**	**Place**
1.	Shaikh Saad Jalaloddin	B. Pharm	K V K College of Pharmacy, Hyderabad, Telangana	13th May 2024 to 12th November 2024	NCC-PvPI, IPC
2.	Nada Rino	M. Pharm	Tripura University, Agartala, Tripura	15th May 2024 to 14th November 2024	Tomo Riba State Hospital, Naharlagun, Arunachal Pradesh

		Two Days Training			
S. No.	Name of Trainee	Qualification	Institute Name	Date	Place
1.	Dr. Sourav Mandal	MBBS	Seth GS Medical College & KEM Hospital, Mumbai	26th-27th December 2024	NCC-PvPI, IPC
2.	Dr. Dhruve Soni	MBBS	Seth GS Medical College & KEM Hospital, Mumbai	26th-27th December 2024	NCC-PvPI, IPC

Summary of training programmes organized during index period

S. No.	Training Programme	Organized at	No. of Trainings	No. of Participants
1.	Training/Sensitization Awareness programme conducted by AMCs	AMCs	1421	71810
2.	Training/Sensitization Awareness programme conducted by AMCs during National Pharmacovigilance Week 2024	AMCs	1133	123251

3.	Advanced Level Training-cum-Coordinators Meet	RTCs	7	1646
4.	Induction-cum-training Programme on Pharmacovigilance for Coordinators/Deputy Coordinators of newly recognized AMCs and newly recruited Pharmacovigilance Associates	NCC-PvPI	4	110
5.	Skill Development Programme on PV of Medical Products	NCC-PvPI	4	1134
6.	Worksop-cum-Training Programme on Pharmacovigilance for NABH Accredited Hospitals at Fortis Mohali	NCC-PvPI	1	114
7.	Regional Training Programme on Implementation of Pharmacovigilance Guidance document for Marketing Authorization Holders (MAHs) of Pharmaceutical Products, Version 2.0 at NIMHANS Bangaluru and CDTL Mumbai	NCC-PvPI	2	108

8.	International Webinar Optimizing the use of ICSRs in Signal Detection Process	NCC-PvPI	1	406
9.	Refresher training for PvA	NCC-PvPI	4	450
10.	Capacity building program on PV	Sikkim, Kolhapur, Arunachal Pradesh	3	866
11.	Interactive meeting for MAHs	NCC-PvPI	11	102
12.	Hand holding training on VigiFlow	NCC-PvPI	7	305
Total			**2598**	**200302**

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

To advance the vision of Hon'ble Prime Minster Shri Narendra Modi's Digital India, The Adverse Drug Reaction Monitoring System (ADRMS) Online Portal was launched by **Hon'ble Minister of Health & Family Welfare and Minister of Chemicals and Fertilizers, Shri J.P. Nadda** during the **1st Policy Makers Forum meeting** at Dr. Ambedkar International Centre in New Delhi on **19th August, 2024**. The event was attended by senior officials from the Ministry of External Affairs, Department of Pharmaceuticals, Central Drugs Standard Control Organization, and the Indian Pharmacopoeia Commission.

The ADRMS software, developed by the Pharmacovigilance Programme of India (PvPI), is India's first comprehensive medical product safety database tailored to the need of the Indian population. It will facilitate the reporting of adverse events related to both medicines and medical devices. The software aims to streamline the reporting process for patients, caregivers, and healthcare professionals while also enabling Indian Pharmaceutical Industries and Market Authorization Holders (MAHs) to report adverse events through a direct User Gateway.

WHO NRA Re-benchmarking for Vaccines in India

For WHO NRA Re-benchmarking for Vaccines in India, an assessment was conducted from 16th to 20th September, 2024. A team of assessors visited NCC-PvPI, IPC, Ghaziabad on 18th September 2024 assess the Vigilance Function.

The WHO 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 cumulative of intensive effort by the Health Ministry, including CDSCO, in collaboration with WHO, to implement a roadmap to strengthen capacity for regulation of vaccines.

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.

Communication & Resource Materials of PvPI

Communication is essential for achieving the objectives of Pharmacovigilance in terms of promoting the rational, safe & effective use of medicine, preventing harm from adverse reactions and contributing to the protection of public health. The PvPI communicates drug safety information/resource materials to the CDSCO and other stakeholders through different mechanism such as emails, press release, social media and website of IPC etc. For more information, please visit the website www.ipc.gov.in .

The communication division of NCC-PvPI, IPC communicates with stakeholders to make aware about the activities carried out in PvPI across the country. The modes of communication by NCC-PvPI, IPC are as follows:

- PvPI Newsletters
- Annual Performance Report of PvPI
- Awareness Posters & Pamphlets
- PV Guidance document for MAHs of Pharmaceutical Products (Version 2.0)
- Quality Manual
- Guidance document for spontaneous reporting of ADRs
- Handbook of PvPI
- PV Comic

PvPI published its newsletter during this tenure

Newsletter,
Vol. 14, Issue 2
(April - June 2024)

Newsletter,
Vol. 14, Issue 3
(July-September 2024)

Newsletter,
Vol. 14, Issue 4
(October-December 2024)

Newsletter,
Vol. 15, Issue 1
(January - March 2024)

Materiovigilance Programme of India (MvPI)

Background

After several horrific cases of malfunctioning of medical devices such as babies burnt to death due to short circuits in incubators or hip implants causing blood poisoning, the Ministry of Health & Family Welfare (MoHFW), Govt. of India (GoI) has approved the commencement of Materiovigilance Programme of India (MvPI) on 10th February 2015 in an effort to ensure safety of medical devices. Thereafter, MvPI was launched on 6th July 2015 at Indian Pharmacopoeia Commission (IPC) Ghaziabad by the then Drugs Controller General (India) with an objective to ensure the patient safety by monitoring, recording, analyzing the root cause of adverse events or risk associated with the use of medical devices and suggesting National Regulatory Authority i.e., Central Drugs Standard Control Organization (CDSCO) for appropriate action. MvPI aims to promote and facilitate adverse event reporting of medical devices and subsequently evaluating these events. The scientific and systematic evaluation of these medical device adverse events/reports will foster monitoring trends for improving and protecting the health and safety of the Indian population. Initially Sree Chitra Tirunal Institute for Medical Sciences & Technology (SCTIMST), Thiruvananthapuram served as National Coordination Centre (NCC) for the programme till 2017; since 2018 IPC functions as NCC for MvPI. In addition to protection of health and safety of patients, MvPI reduces the likelihood of recurrence of the harmful incidents elsewhere thereby safety of medical devices. MvPI continuously works with its partnering organizations where SCTIMST, Thiruvananthapuram serves as National Collaborating Centre and National Health System Resource Centre (NHSRC), New Delhi serves as Technical Support & Resource Centre for the programme. As a dynamic process, MvPI-IPC recognizes Medical Device Adverse Event Monitoring Centres (MDMCs) across India for monitoring and reporting of Medical Device Adverse Events (MDAEs).

Indigenous medical device adverse events (MDAEs) data management:

During the indexed period, NCC-MvPI, IPC has received and analysed 14,584 MDAE reports in MvPI database. The reporting has been increased by 42.01% as compared to the previous financial year (10,269 MDAE reports were received during 1st April, 2023 to 31st March, 2024). In total, NCC-MvPI, IPC has received and analyzed 39,074 MDAE reports till date.
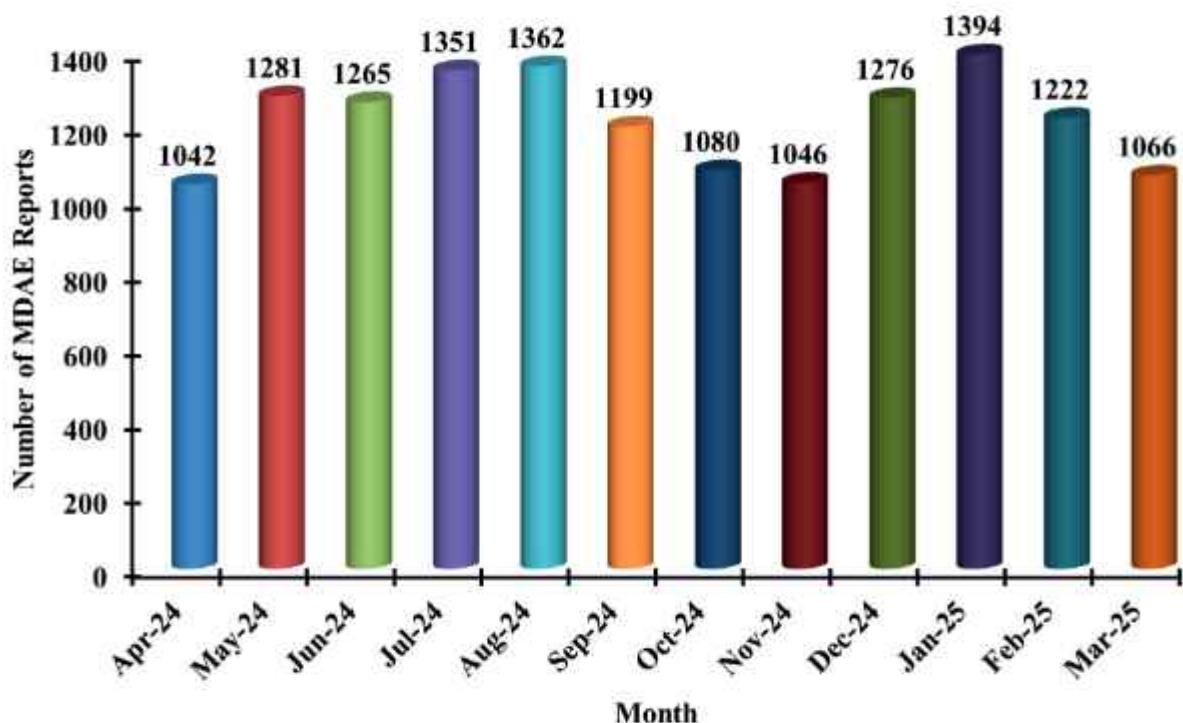
Figure - 24. Month-wise MDAE reports received in MvPI database

Recommendations forwarded to regulatory body:

NCC-MvPI has forwarded **22** recommendations on safe use of medical devices in India to Central Drugs Standard Control Organization (CDSCO) for their information and further necessary actions at their end.

S. No.	Date of recommending to CDSCO	Suspected Device	Adverse event	Description
1	20th February 2025	Intravenous Cannula	Blister Formation, Blue & Hypopigmented Patch at the Insertion Site, Leakage Through Cannula during Drug Administration, Suboptimal/Low Quality Stylet, Stylet & Catheter Wings sticking Together	Meeting members suggested that the event is suspected to be device related & the case should be forwarded to CDSCO to take further necessary action at their end.
2	20th February 2025	Rubber Surgical Gloves	Allergic Reactions (Redness, Drying, Itching), Poor Quality, (Tearing of Gloves During Medical Examination), excessive Absorption of Powder on Hands	Meeting members suggested that the event is suspected to be device related & the case should be forwarded to CDSCO to take further necessary action at their end.

3	20th February 2025	Mechanical Ventilator	Cyrix Healthcare Private Limited was not found to be registered or recorded on the CDSCO online portal as an approved medical device manufacturer or importer	Committee members considered it a potential regulatory violation and recommended that the company's details be forwarded to CDSCO for verification of its legal authorization to manufacture, import, or distribute the suspected ventilator.
4	11th December 2024	Blood Administration set	Regulator Malfunctions Causing Free Flowing of Blood, Loosened at the Point of Insertion	Meeting members suggested that the event is suspected to be device related & the case should be forwarded to CDSCO to take further necessary action at their end.
5	11th December 2024	Intravenous Cannula	Blister Formation, Skin Ulcers, Redness, Leakage, Blockage, Swelling, Irritation, Thrombophlebitis	Meeting members suggested that the event is suspected to be device related & the case should be forwarded to CDSCO to take further necessary action at their end.

6.	11th December 2024	Hypodermic Syringe	Leakage, Loose Piston, Semi Blocked Plunger, Foreign Particles in Syringe, Vacuum Creation While Loading Medication	Meeting members suggested that the event is suspected to be device related & the case should be forwarded to CDSCO to take further necessary action at their end.
7.	11th December 2024	Auto Disable Hypodermic Syringe	Poor Quality, Blockage, Plunger & Piston Breakage, Presence of Foreign Particles	Meeting members suggested that the event is suspected to be device related & the case should be forwarded to CDSCO to take further necessary action at their end.
8.	30th September 2024	Auto Disable Hypodermic Syringe	Leakage, Blockage, Piston Breakage & Presence of Foreign Particles	Meeting members suggested that the event is suspected to be device related & the case should be forwarded to CDSCO to take further necessary action at their end.

9.	30th September 2024	Intravenous Infusion Set	Malfunctioned Regulator resulting in Leakage and Uncontrolled Medication Delivery	Meeting members suggested that the event is suspected to be device related & the case should be forwarded to CDSCO to take further necessary action at their end.
10.	30th September 2024	Blood Transfusion Set	Improper Functioning of Regulator/Leakage of Blood	Meeting members suggested that the event is suspected to be device related & the case should be forwarded to CDSCO to take further necessary action at their end.
11.	30th September 2024	Adhesive Surgical Tape	Poor Adhesive Property/Insufficient Adhesion	Meeting members suggested that the event is suspected to be device related & the case should be forwarded to CDSCO to take further necessary action at their end.

12.	15th July 2024	Auto Disable Hypodermic Syringe	Blockage, Leakage, Piston Breakage	Meeting members suggested that the event is suspected to be device related & the case should be forwarded to CDSCO to take further necessary action at their end.
13.	15th July 2024	Intra-venous Infusion Set	Outpouring, Obstruction &Irregular Flow	Meeting members suggested that the event is suspected to be device related & the case should be forwarded to CDSCO to take further necessary action at their end.
14.	15th July 2024	Intra-venous Infusion Set	Blockage, Leakage, & Irregular Flow	Meeting members suggested that the event is suspected to be device related & the case should be forwarded to CDSCO to take further necessary action at their end.

15.	15th July 2024	Spinal Implant	Implant Breakage	Meeting members suggested that the event is suspected to be device related & the case should be forwarded to CDSCO to take further necessary action at their end.
16.	15th July 2024	Surgical Gloves	Severe rashes, Contact Dermatitis, Poor Quality	Meeting members suggested that the event is suspected to be device related & the case should be forwarded to CDSCO to take further necessary action at their end.
17.	15th July 2024	Ventilator Circuit	Water is Entering the Patient Trachea	Meeting members suggested that the event is suspected to be device related & the case should be forwarded to CDSCO to take further necessary action at their end.

18.	23rd April 2024	Trypan Blue Dye (IOL Dye)	Vision Loss	Meeting members suggested that the event is suspected to be device related & the case should be forwarded to CDSCO to take further necessary action at their end.
19.	22nd April 2024	Intravenous Infusion Set	Leakage/Faulty Regulator/Malfunction / Compromised Quality	Meeting members suggested that the event is suspected to be device related & the case should be forwarded to CDSCO to take further necessary action at their end.
20.	22nd April 2024	Hypodermic Syringe	Leakage/Piston Breakage/Quality Issue	Meeting members suggested that the event is suspected to be device related & the case should be forwarded to CDSCO to take further necessary action at their end.

21.	22nd April 2024	Urine Bag	Urine Leakage	Meeting members suggested that the event is suspected to be device related & the case should be forwarded to CDSCO to take further necessary action at their end.
22.	22nd April 2024	Intra Ocular Lens	IOL Breakage & Infection	Meeting members suggested that the event is suspected to be device related & the case should be forwarded to CDSCO to take further necessary action at their end.

Safety Alerts to Medical Device Adverse Event Monitoring Centres (MDMCs)

NCC-MvPI, IPC has sent **08** safety alerts to MDMCs for the active surveillance of suspected medical devices. Listed below:

S. No.	Date of Communicating Advisory	Device	Adverse event reported	Action requested
1.	21ˢᵗ February 2025	Mechanical Ventilator	Ventilator Associated Pneumonia (VAP) - Company was not found to be registered on CDSCO portal of approved medical device manufacturers and importers	Active surveillance on the suspected device whether is it used at your center. Report all the suspected unexpected adverse event after intended use of the device
2.	21ˢᵗ February 2025	Auto Disable Hypodermic Syringe	Quality issues like plunger breakage, blockage. Leakage, presence of foreign particles	Active surveillance on the suspected device whether is it used at your center. Report all the suspected unexpected adverse event after intended use of the device

3.	12th December 2024	Artificial Urinary Prosthesis	Prosthesis Failure & Infection	Active surveillance on the suspected device whether is it used at your center. Report all the suspected unexpected adverse event after intended use of the device
4.	30th September 2024	Voice Prosthesis	Prosthesis Leakage	Active surveillance on the suspected device whether is it used at your center. Report all the suspected unexpected adverse event after intended use of the device
5.	24th April 2024	Hypodermic Syringe	Leakage/Piston Breakage/Quality Issue	Active surveillance on the suspected device whether is it used at your center. Report all the suspected unexpected adverse event after intended use of the device

6.	24th April 2024	Intravenous Infusion Set	Leakage/Faulty Regulator/ Malfunction/ Compromised Quality	Active surveillance on the suspected device whether is it used at your center. Report all the suspected unexpected adverse event after intended use of the device
7.	24th April 2024	Trypan Blue	Vision Loss	Active surveillance on the suspected device whether is it used at your center. Report all the suspected unexpected adverse event after intended use of the device
8.	24th April 2024	Urine Bags	Urine Leakage	Active surveillance on the suspected device whether is it used at your center. Report all the suspected unexpected adverse event after intended use of the device

Resource Materials (available on IPC website- www.ipc.gov.in)

- NCC-MvPI published **04** e-newsletters **(Volume 6, Issue 01-04, 2024)** during the index period to keep the stakeholders updated on the recent activities conducted by MvPI.
- Updated MDAE Reporting Form (Healthcare Professionals Version 1.2)- Available on IPC website

Newsletter, Vol. 6, Issue 2 (April - June 2024)	Newsletter, Vol. 6, Issue 3 (July - September 2024)	Newsletter, Vol. 6, Issue 4 (October - December 2024)	Newsletter, Vol. 7, Issue 1 (January - March 2024)

MvPI Expansion

During the index period, NCC has recognized **96** new MDMCs in various states of India to collect more information on adverse events associated with medical devices in the Indian population. States and UTs-wise distribution of newly enrolled MDMCs under MvPI is given below:

Uttar Pradesh	7	Chandigarh	3
Chhattisgarh	6	Jammu & Kashmir	3
Haryana	6	Karnataka	3
Maharashtra	6	Odisha	3
Rajasthan	6	Punjab	3

Telangana	6	Tamil Nadu	3
Bihar	5	Assam	2
Gujarat	5	Andhra Pradesh	2
Delhi	4	Kerala	2
Himachal Pradesh	4	West Bengal	2
Jharkhand	4	Goa	1
Madhya Pradesh	4	Ladakh	1
Uttarakhand	4	Manipur	1

List of all approved MDMCs under MvPI:

S. No	State	MDMC Name & Address	Status
1.	Andhra Pradesh	Aster Narayanadri Hospital National Highway 71, Renigunta Road, SV Auto Nagar, Tirupati, Andhra Pradesh-517506	Non-Government
2.		GSL Medical College & General Hospital NH-16, Lakshmi Puram, Rajamahendravaram, Andhra Pradesh-533296	
3.	Assam	Marwari Hospital B-3, Sati Joymati Road, Athgaon, Guwahati, Assam-781008	Non-Government
4.		Arya Hospital A.M Road, Rehabari, Guwahati, Kamrup Metro Assam-781008	

5.	Bihar	MGM Hospital and Research Centre Pvt. Ltd. Jagat Narayan Lal Road, East Lohanipur, Kadamkuan, Patna, Bihar- 800003	Non-Government
6.		Ford Hospital and Research Center Private Limited, New Bypass NH-30, Khemnichak, PO New Jaganpura, PS Ramkrishna Nagar, Patna, Bihar- 800027	
7.		Jay Prabha Medanta Super Speciality Hospital Kankarbagh Main Road, Kankar Bagh Colony, Patna, Bihar-800020	
8.		Mediversal Multi Super Specialty Hospital Doctors Colony, Kankarbagh, Bankman Colony, Patna, Bihar- 800020	
9.		Paras HMRI Hospital Bailey Road, Raja Bazar, Patna, Bihar-800014	
10.	Chandigarh	Fortis Hospital Sector-62, Phase-8 Mohali-SAS Nagar, Mohali, Punjab-160062	Non-Government
11.		Mukat Hospital & Heart Institute SCO 47-49, Sector 34A, Chandigarh-160022	
12.		Healing Hospital and Institute of Paramedical Sciences Sector-34A Road, Chandigarh-160022	

13.	Chhattisgarh	Raigarh Institute of Medical Science Pvt. Ltd. Shri Bala Ji Metro Hospital, Near Pahar Mandir Road, Village Kauha Kunda Raigarh, Chhattisgarh-496001	Non-Government
14.		MMI Narayana Superspeciality Hospital Dhamtari Road, Lalpur, Raipur, Chhattisgarh-492001	
15.		Shri Balaji Institute of Medical Sciences Balaji Hospital Campus, Dubey Colony, Mowa, Raipur Chhattisgarh-492014	
16.		Balco Medical Centre (Vedanta Medical Research Foundation) Sector 36 PO-Uparwara, Raipur, Chhattisgarh-493661	
17.		KIMS Super Speciality Hospital Private Limited Near Agrasen Square, Magarpara Road, Bilaspur, Chhattisgarh-495001	
18.		Suyash Institute of Medical Science Pvt. Ltd. Kota Gudhiyari Road, Raipur, Chhattisgarh-492001	
19.	Delhi	Venkateshwar Hospital Sector-12 Road, Sector-18A, Dwarka, New Delhi-110075	Non-Government
20.		Aakash Healthcare Super Speciality Hospital Road No-201, Dwarka Sector-3, New Delhi-110075	
21.		St. Stephen's Hospital Tis Hazari, Delhi-110054	
22.		Primus Super Speciality Hospital 2, Chandragupta Marg, Opp Russian Embassy, Chanakyapuri, New Delhi, Delhi-110021	

23.	Goa	Manipal Hospital Dr. E. Borges Road, Dona Paula, Panaji, Goa-403004	Non-Government
24.	Gujarat	Health 1 Super Speciality Hospital Block C, Ground Floor-10 8th Floor, Silai-27/73, on S.P. Ring Road, Near Shilaj Circle, Ahmedabad, Gujarat-380059	Non-Government
25.		Sunshine Global Hospital Beside Big Bazar, Gaurav Path, Dumas Road, Surat, Gujarat-395007	
26.		Shree Krishna Hospital Bhaikaka University, Karamsad Anand, Gujarat- 388325	
27.		Smt. Jayaben Mody Multispeciality Hospital Plot No-624/1, Valia Road, GIDC, Ankleshwar, Gujarat-393002	
28.		All India Institute of Medical Sciences Khanderi, Parapipaliya, Rajkot, Gujarat-360110	Government
29.	Haryana	Dayanand Hospital & Critical Care Centre Near Kakroi Road, Sonipat, Haryana-131001	Non-Government
30.		Shakti Neuro Science Centre Barwala Road, Tayal Bagh, Hisar Haryana-125001	
31.		Anand Orthopaedic Centre Opposite Theme Park, Near Panorama, Thanesar, Kurukshetra, Haryana-136118	

32.		Max Hospital Block B, Sushant Lok-1, Opposite Huda City Centre Metro Station, Gurugram, Haryana-122001	
33.		Sonakshi Children Hospital Jindal Hospital Road, Near ITI, Hisar, Haryana-125001	
34.		Ojas Hospital H1, Sector-26, Panchkula, Haryana-134116	
35.	Himachal Pradesh	Aastha Hospital Krishna Nagar, Hamirpur, Himachal Pradesh- 177001	Non-Government
36.		Malhotra Hospital and Trauma Center Opposite Petrol Pump, Main Bazaar, Nerchowk, Mandi, Himachal Pradesh-175008	
37.		Karan Hospital Ward No-12, Palampur, District Kangra, Himachal Pradesh-176061	
38.		Pandit Jawahar Lal Nehru Government Medical College & Hospital Chamba, Himachal Pradesh-176310	Government
39.	Jammu and Kashmir	Raksha Kidney Centre Private Limited 272-F, Near Circuit House, Talab Tillo, Jammu, Jammu and Kashmir-180002	Non-Government
40.		Cancer Treatment Services Hyderabad Pvt. Ltd. ASCOMS By Pass Road, Sidhra, Jammu, Jammu and Kashmir-180017	
41.		Triveni Nursing Home 8-C/C Gandhi Nagar, Jammu, Jammu and Kashmir-180004	

42.	Jharkhand	Pulse Super Speciality Hospital Bariatu Road, Opposite R.I.M.S Petrol Pump, Near Harihar Singh Road, Bariatu, Ranchi, Jharkhand-834009	Non-Government
43.		Paras Hec Hospital Sector-3 Near JSCA Stadium Dhurwa, Ranchi, Jharkhand- 834004	
44.		Santevita Hospital (A Unit of SAHU Estate Private Limited) 1, Hazaribag Road, Near Firayalal Chowk, Ranchi, Jharkhand- 834001	
45.		Medanta Abdur Razzaque Ansari Memorial Weavers Hospital P.O. Irba, Ranchi, Jharkhand-835217	
46.	Karnataka	NU Hospital Private Limited No. 6, 15th Main, 11th Cross, Padmanabhanagar, Bengaluru, Karnataka-560070	Non-Government
47.		Justice K. S. Hegde Charitable Hospital Deralakatte, Mangaluru, Karnataka-575018	
48.		Apollo Cradle Hospitals Private Limited 58, 18th Main Road, Near Anand Sweets, KHB Colony, 6th Block, Koramangala, Banglore, Karnataka-560095	
49.	Kerala	GG Hospital, (A Unit of Paragon Hospital) Murinjapalam, Medical College, P.O. Thiruvananthapuram, Kerela-695011	Non-Government
50.		Sunrise Institute of Medical Sciences Pvt. Ltd. 37/1835-37, Seaport Airport Road, Kakkanad, Kochi, Kerala-682030	

51.	Ladakh	Sonam Nurboo Memorial Hospital Leh Ut Ladakh-194101	Government
52.	Madhya Pradesh	Bombay Hospital No. 94, IDA Scheme, 95, Eastern Ring Rd, Tulsi Nagar, Vijay Nagar, Indore, Madhya Pradesh- 452010	Non-Government
53.		Bansal Hospital Shahpura C-Sector, Bhopal, Madhya Pradesh-462016	
54.		Cancer Hospital & Research Institute Cancer Hills Gwalior, Madhya Pradesh-474009	
55.		Triveni Healthcare Hospital (A Unit of Jamdar Hospital) Jabalpur, Madhya Pradesh-482002	
56.	Maharashtra	HCG Manavata Cancer Centre Mylan Circle, Mumbai Naka, Nashik, Maharashtra-422002	Non-Government
57.		Sainath Hospital Sant Nagar, Sector-4, Moshi Pradhikaran, Pune Nashik Highway, Maharashtra-412105	
58.		Sant Gajanan Maharaj Rural Hospital Site-Chinchewadi, Gadhinglaj-Halkarni Road, Hasurwadi, District Kolhapur, Maharashtra-416503	
59.		MGM Hospital & Research Centre Plot No-1, Sector-1A, CBD Belapur, Navi Mumbai, Maharashtra-400614	

60.		Criti Care Asia Multispeciality Hospital Kirol Road, Kurla West, Mumbai Near Office Lal Bahadur Shastri Road, Ali Yavar Jung Mumbai, Maharashtra-400070	
61.		Sahayog Hospital Rani Avantibai Square Ring Road, Gondia, Maharashtra-441614	
62.	**Manipur**	American Oncology Institute Cancer Treatment Services Hyderabad Private Limited At Babina Speciality Hospital Sajiwa Jail Road, Khabeisoi, Imphal East, Manipur-795010	Non-Government
63.	**Odisha**	Sadguru Hospital (A Unit of Sadguru Medical & Research Center Private Limited) Jagatpur Industrial Estate, Cuttack, Jagatpur, Odisha-754021	Non-Government
64.		Jaiprakash Hospital & Research Centre Pvt. Ltd. Dayanand Nagar, Dandiapali, Rourkela, Odisha-769004	
65.		Vikash Multi Speciality Hospital Bargarh, Canal Chowk, Barahagoda, Odisha-768040	
66.	**Punjab**	Sacred Heart Hospital Grand Trunk Road, Near Petrol Pump, Maqsudan, Jalandhar, Punjab-144008	Non-Government

67.		Capitol Hospital NH-44, Jalandhar- Pathankot Road, Near Reru Chowk, Jalandhar, Punjab-144012	
68.		BBC Heartcare Pruthi Hospital 301, Mahavir Marg, Lajpat Nagar, Jalandhar, Punjab-144003	
69.	Rajasthan	Narayana Multispeciality Hospital Sector 28, Rana Sanga Marg, Kumbha Marg, Pratap Nagar, Sanganer, Jaipur, Rajasthan-302033	Non-Government
70.		Imperial Hospital and Research Centre Near Kanwatia Circle, Shastri Nagar Jaipur Rajasthan-302016	
71.		Apex Hospital Mansarovar Private Limited Ward 27, 55, Rajat Path, Near United Bank of India, Ward 27, Rajat Path, Mansarovar Sector- 5, Mansarovar, Jaipur, Rajasthan-302020	
72.		Apex Hospital Rani Bazar, Bikaner, Rajasthan-334001	
73.		Apex Ranthambore Sevika Hospital Vinayak Nagar, Nursing Board Road, Alanpur, Swm, Rajasthan-322001	
74.		Harish Hospital Telco Circle, Tijara Road, Alwar, Rajasthan-301001	

75.	Tamil Nadu	SRM Global Hospitals Private Limited Mahatma Gandhi Road, SRM Nagar, Potheri, Kattankulathur, Chengalpattu, Tamil Nadu-603203	Non-Government
76.		Sri Ramakrishna Institute of Paramedical Sciences College of Pharmacy Sri Ramakrishna Hospital Campus 395, Sarojini Naidu, Sidhapudur, Coimbatore, Tamil Nadu-641044	
77.		Maa Kauvery (A Unit of Kmc Speciality Hospital Ltd) No- 27, Alexandria Road, Cantonment, Tiruchirappalli, Tamil Nadu-620001	
78.	Telangana	Ramdevrao Hospital National Highway No. 65, Kukatpally, Hyderabad, Telangana-500072	Non-Government
79.		Pranaam Hospitals Private Limited 1-5816/40 & 41, Madinaguda, Miyapur, Hyderabad, Rangareddy District, Telangana-500050	
80.		Basavatarakam Indo- American Cancer Hospital and Research Institute Road No. 10, Banjara Hills, Hederabad, Telangana-500034	
81.		Ankura Hospital for Women & Children (A Unit of Ankura Hospitals LB Nagar Pvt. Ltd.) Survey No- 9,11,12 Plot No- 10,1/J, Saroor Nagar, Metro Pillar No-1643, Lb Nagar, Ranga Reddy, Telangana-500035	

82.		Medicover Hospitals Opposite. Cyber Gateway, IBIS Hotel Lane Madhapur, Hyderabad, Telangana-500081	
83.		Esic- Super Speciality Hospital Sanathnagar, Hyderabad, Telangana-500038	Government
84.	Uttar Pradesh	Healing Tree Hospital 30/1 Shakti Khand 3, Indirapuram, Ghaziabad, Uttar Pradesh-201014	Non-Government
85.		Fatima Hospital 35-C, Mahanagar, Lucknow, Uttar Pradesh-226006	
86.		School of Medical Science and Research Sharda University, Knowledge Park-3 Greater Noida, Uttar Pradesh-201306	
87.		Prakhar Hospital Private Limited 8/219, Khalasi Line, Arya Nagar, Kanpur, Uttar Pradesh-208002	
88.		Ajanta Hospital and IVF Centre Private Limited 765, ABC Complex Kanpur Road, Sardari Khera, Sujanpura, PO Alambagh, Lucknow, Uttar Pradesh-226005	
89.		Nazareth Hospital 13/A, Near Hathi Park, Kamla Nehru Road, Prayagraj, Uttar Pradesh-211018	
90.		Vinayak Medicare Hospital Bijnor, Lucknow, Uttar Pradesh-226002	Government

91.	Uttarakhand	Ujala Hospital Manpur Road, Kachnalgaji, Kashipur, Uttarakhand-244713	Non-Government
92.		Premsukh Hospital & Dialysis Centre 23/18, P.D Tandon Marg 16 Malviya Road, Laxman Chowk, Dehradun, Uttarakhand-248001	
93.		S.K Kapoor, City Hospital Super Complex, Ranipur More Haridwar, Uttarakhand-249401	
94.		Kailash Hospital (A Unit of Kailash Healthcare Ltd) (NABH Accredited Hospital) Haridwar Road, Near Jogiwala Chowk, Dehradun, Uttarakhand-248001	
95.	West Bengal	Neotia Getwel Multispecialty Hospital (A Unit of Ambuja Neotia Healthcare Venture Ltd) Uttorayon, Behind City Centre, Matigara, Siliguri, West Bengal-734010	Non-Government
96.		Rabindranath Tagore International Institute of Cardiac Sciences 124, Mukundapur, E.M Bypass Kolkata, West Bengal-700099	

Indian Pharmacopoeia Commission–Materiovigilance Programme of India (IPC-MvPI) as Certification Body:

- Indian Pharmacopoeia Commission - certified by the Quality Council of India (QCI) to function as a certification body for the ICMED 9000 and ICMED 13485 certification schemes.

- This accreditation will enable IPC-MvPI to assess the quality management systems of medical device industries, ultimately enhancing quality of medical devices and ensuring consumer protection.

Implementation of MvPI Pan India

Plan of Action
Enhancing Post-Market Safety Reporting To improve the current system, the following steps are suggested: • **Increase awareness and training programs** for manufacturers, especially in the case of Class A and Class B devices. • **Develop streamlined reporting platforms** that are easier to use. • **Set clear timelines** for reporting adverse events. • **Strengthen regulatory frameworks** to ensure timely and accurate submissions. • **Collaborate with industry stakeholders** to gather feedback and refine the system.

Training/Awareness programmes conducted: 23

List of conducted trainings/ awareness programme during the index period

S. No.	Date	MDMC/IPC	Name of Training	No of Participants trained
1.	2nd April 2024	NCC-MvPI, IPC	11th Induction-cum-Training Programme	301
2.	16th April 2024	NCC-MvPI, IPC	Webinar on "Navigating Adverse Events in Dentistry: Understanding Risks of Dental and strategies to improve communication"	200

3.	30th April 2024	NCC-MvPI, IPC	NCC-MvPI conducted a Sensitization programme on recent incident concerning Implantation of Substandard pacemakers at a Government Hospital in Uttar Pradesh Sensitization cum Stakeholder Meeting at University of Medical Sciences Saifai, Etawah, Uttar Pradesh	50
4.	15th May 2024	NCC-MvPI, IPC in collaboration with Amrita Institute of Medical Sciences, Kochi.	National webinar on "Medical Device & Adverse Events"	100
5.	30th July 2024	NCC-MvPI, IPC	12th Induction-cum-Training Programme	281
6.	10th August 2024	NCC-MvPI, IPC in collaboration with Department of Oral Medicine and Dental Radiology, Dr. Z.A. Dental College, Aligarh Muslim University.	Training programme on "Adverse Events in Dentistry: understanding the risks of dental devices and strategies"	65

7.	18th September 2024	NCC-IPC	International Webinar on Optimizing the use of ICSRs in Signal Detection Process	72
8.	21st September 2024	NCC-MvPI, IPC in collaboration with JLNMC, Chamba	Training programme on Materiovigilance and Pharmacovigilance at Pt. Jawaharlal Nehru Government Medical College and Hospital, Chamba, Himachal Pradesh	150
9.	22nd October 2024	NHSRC, New Delhi.	One-day workshop on Guidelines on Equipment Maintenance, Calibration, and Testing at National Health Systems Resource Centre (NHSRC), New Delhi	35
10.	06th November 2024	NCC-MvPI, IPC in collaboration with SNM, Leh	Training at SNM Hospital, Leh	110
11.	22nd November 2024	NCC-MvPI, IPC in collaboration with Sacred Herat Hospital	Training at Sacred Heart Hospital, Jalandhar	80
12.	10th December 2024	NCC-MvPI, IPC in collaboration with Amrita Hospital, Faridabad	The Materiovigilance Programme of India: Enhancing Surveillance and Safety of Medical Devices at Amrita Hospital, Faridabad.	20

13.	11th December 2024	NCC-MvPI, IPC	Guest lecture on "Assessment of Adverse Events Reported for Ophthalmic Medical Devices."	15
14.	18th December 2024	NCC-MvPI, IPC	Training on ADRMS for MDMCs	80
15.	13th January 2025	NCC-MvPI, IPC	13th Induction-cum-Training Programme	100
16.	5th – 7th February 2025	AIIMS, Bhopal	International Conference on Patient Safety and the 22nd Annual Conference of the Society of Pharmacovigilance	380
17.	22nd February 2025	NIHFW, New Delhi	24th Residential Training Programme on "Good Clinical Practices and Pharmacovigilance"	35
18.	25th February 2025	NCC-MvPI, IPC	Hands-on Training Programme on ADRMS	219
19.	1st March 2025	NCC-MvPI, IPC	IPA-HLL- Lifecare Professional Development Program on Good Pharmacy Practice.	86

20.	15th March 2025	NCC-MvPI, IPC	Materiovigilance Sensitization Program conducted at Rajagiri Hospital.	160
21.	22nd March 2025	CAHO, Noida	A training program by CAHO at Hotel Pullman, New Delhi.	15
22.	26th March 2025	NCC-MvPI, IPC	Technical Training Programme on Clinical Investigation of Medical Devices.	396
23.	28th March 2025	Mahavir Cancer Sansthan and Research Centre (MCSRC), Patna	Materiovigilance Awareness Activity at MCSRC, Patna.	45

Scientific Publications

NCC-PvPI and AMCs have published the following scientific research publications:

1. Ali G, Khan IA, Haque SF. Anaphylactic reaction caused by co-administration of diclofenac and ofloxacin. Journal of Pharmacovigilance and Drug Safety. 2024; 21(2):8–10

2. Chatterjee R, Sarkar K, Ampi P, et al. Cutaneous adverse drug reactions in a tertiary care hospital: A record-based observational study. Bengal Physician Journal. 2024 July 6;11(2):61-69.

3. Christeena VM, Thomas AJ, Harikrishnan S. A case report on montelukast and fexofenadine induced depression and nightmares. World Journal of Biology Pharmacy and Health Sciences. 2025;21(2):111–13.

4. Dongre K, Nama P, Ghotkar U, Sharma A. Steven-Johnson Syndrome and toxic epidermal necrolysis from nitrofurantoin. International Journal of Pharmaceutical Sciences Review and Research. 2025:26-28.

5. Era N, Joha S, Gupta AK, Kumari S, Mukherjee M, Mukherjee S. Drug-induced bullous haemorrhagic dermatosis: insights from a case series. Journal of Medical Sciences and Health 2024; 10(2):219-22.

6. Hasik PN, Thomas C, Hazarika M, Undela K. Ocular adverse events associated with platins: a disproportionality analysis of pharmacovigilance data and extensive systematic review of case reports. Expert Opinion on Drug Safety. 2024;1-14.

7. Jayasaree L, Palatty PL, Govindraj L, Anand GA, Dev GB, Shabu B, Tinu TS, Nair AA. Rituximab safety profile: A seven-year retrospective analysis from southern India. Cureus. 2024;16(11):1-11.

8. Mathew SM, Jesurun RSJ, Joseph R, Harikrishnan S, Mathews SR. Thalidomide induced anemia in a patient with multiple myeloma. International Journal for Multidisciplinary Research. 2024;6(3):1-3.

9. Mevada D, Chabhadiya P, Singh A. Acetaminophen-induced toxic epidermal necrolysis in pediatric patients-a case series. International Journal of Pharmacy and Pharmaceutical Sciences. 2024;16(7):50-3.

10. Mukherjee S, Era N, Roy S. Awareness regarding medical device safety among physicians: a knowledge, attitude, and practice survey. Matrix Science Medica. 2024;8(4):88-91.

11. Mukherjee S. Meropenem-induced cholestasis in a pyelonephritis patient: A case report and evaluation using the updated RUCAM scale. Journal of Clinical and Translational Research. 2025;11(1):77-81.

12. Panigrahy A, Begum A, Pingali U, Padmaja M, Sajeev A. Evaluation of cutaneous adverse drug reactions in a tertiary care hospital in southern India: a retrospective analysis. Asian Journal of Pharmaceutical and Clinical Research. 2024;17(11):143-7.

13. Pokharel S, Chowdury LD, Saha A, Chowdhury K, Das S. Diclofenac gel induced contact dermatitis: an atypical case report. International Journal of Current Research. 2025;17(1):31280-82.

14. Prasanna TL, Brattiya ATK. Post-Covid-19 monitoring adverse effects in oral contraceptive users: Emerging risks and recommendations. Pharmaceutical Sciences. 2025;5(1):32-5.

15. Rahman SZ, Ali G. Fourth National Pharmacovigilance Week celebration by ADR Monitoring Centre, JNMC, AMU, Aligarh. Journal of Pharmacovigilance & Drug Safety. 2024;21(2):20-25.

16. Reji RE, Kurien S, Harikrishnan S, Jesurun RSJ. A case report on hypothyroidism induced by Pembrolizumab. National Journal of Pharmacology and Therapeutics. 2024;2(2):108-10.

17. Samajdar SS, Mukherjee S, Chatterjee R, Moitra S, Joshi SR. Steroid-induced glaucoma in asthma: A case report highlighting the steroid-sparing and disease-modifying potential of allergen immunotherapy. Journal of Pharmacovigilance & Drug Safety. 2024;21(2):6-9.

18. Sasi SM, Nama P, Sontakke S, Pande S. Clozapine induced pneumonitis: A case report. International Journal of Basic & Clinical Pharmacology. 2024;13(3):386-88.

19. Som S, Bera T, Chowdhury L, Mal S, Chowdhury K, Saha A. Toxic epidermal necrolysis by lamotrigine - a case report of fatality. International Journal of Science and Healthcare Research. 2024;9(2):228-30.

20. Varghese R, Mathews SR, Thomas L, Harikrishnan S, Jesurun RSJ. A case of sinus pauses induced by nebivolol. International Journal of Medical Science and Current Research. 2024;7(3):436-38.

21. Viji CM, Jolly MV, Harikrishnan S, Reji RE, Jacob RSJ. Unveiling the adverse effects of escitalopram: a case series analysis. World Journal of Biology Pharmacy and Health Sciences. 2025;21(1):626-31.

22. Kumar N, Kalaiselvan V, Arora MK. Neuronal toxicity of monoclonal antibodies (mAbs): an analysis of post-marketing reports from FDA Adverse Event Reporting System (FAERS) safety database. European Journal of Clinical Pharmacology. 2024 Nov;80(11):1685-95.

23. Muhammed A, Thomas C, Kalaiselvan V, Undela K. Risk of pancreatitis and pancreatic carcinoma for anti-diabetic medications: findings from real-world safety data analysis and systematic review and meta-analysis of randomized controlled trials. Expert Opinion on Drug Safety. 2024 Jun 2;23(6):731-42.

24. Shukla S, Meher BR, Mishra A, Arora S, Kalaiselvan V, Raghuvanshi RS. Health-care Professionals' Perception toward Medical Device Postmarket Surveillance Practices: A Cross-sectional Study in India. Indian Journal of Public Health. 2024 Jul 1;68(3):424-7.

25. Suresh J, Shukla S, Vivekanandan K, Singh Raghuvanshi R. Tapentadol: navigating the complexities of abuse, patient safety & regulatory measures. Current Medical Research and Opinion. 2024 Dec 1;40(12):2201-7.

26. Undela K, Kalaiselvan V, Gudi SK, Viswam SK, Ali SK. Risk of serious skin and subcutaneous tissue disorders for nimesulide among the pediatric population: a jeopardy identified through the analysis of global individual case safety reports. Expert Opinion on Drug Safety. 2024 Aug 2;23(8):1021-6.

27. Kumar R, Prakash J, Bhushan S, Rawat AD, Ray RS, Raghuvanshi RS. Training and education in pharmacovigilance: The experience from the Pharmacovigilance Programme of India. Indian journal of pharmacology. 2024 Sep 1;56(5):348-57.

PvPI in Press Media

THE ECONOMIC TIMES | Industry

IPC issues alert on painkiller drug nimesulide over adverse reaction

Synopsis

New Delhi: Next time you pop a **nimesulide**, a commonly used **painkiller**, be watchful.

Pharma standards body Indian Pharmacopoeia Commission (IPC) has issued a drug safety alert over nimesulide, saying the pill can trigger rashes on the skin (fixed drug eruption). It asked consumers and healthcare professionals to closely monitor the use of the drug and report any adverse reaction to the National Coordination Centre-Pharmacovigilance Programme of **India** of the **IPC**.

According to the IPC, the drug is used in inflammatory conditions including joint disorders like rheumatoid arthritis, post-traumatic and post-operative painful conditions and fever, as well as in acute pain in orthopaedic, ENT and dental conditions.

CHRONICLE

Govt issues alert on Nimesulide

On April 2024, the Indian Pharmacopoeia Commission (IPC) issued a drug safety alert regarding Nimesulide, an anti-inflammatory drug, citing potential skin rashes as an adverse effect.

Key Points

- **Nimesulide Overview:** Nimesulide, classified as a Non-steroidal anti-inflammatory drug (NSAID), is prescribed to alleviate pain, inflammation, and swelling associated with various conditions, including fever, menstrual cramps, and osteoarthritis.

- **Identifying Allergic Reactions:** Patients with known drug allergies or underlying health issues such as kidney or liver disease, should inform their doctors.

- **Administration Guidelines:** Patients are advised to follow prescribed dosages, take the medication with food, and discontinue its use as per the doctor's instructions.

- **Contraindications:** Individuals with blood coagulation issues, children, pregnant or nursing women, and those with a history of stomach ulcers, heart failure, or liver and kidney conditions should avoid Nimesulide.

- **Monitoring and Response:** Patients should remain vigilant for any adverse reactions, particularly within the initial days of usage.

- **Historical Context:** Nimesulide faced bans in several countries, including Switzerland, Spain, and the US, due to safety concerns.

- In India, its usage for adults persists but is not recommended for children under 12 years.

ThePrint

Latest safety alert on painkiller nimesulide brings focus back on potentially dangerous side effect

Drug standards body warns that nimesulide, a commonly used painkiller and anti-fever medicine, can cause skin rashes. However, evidence has also emerged that it can cause liver damage.

New Delhi: The Indian Pharmacopoeia Commission (IPC) — the apex agency for setting drug standards in the country — last month issued a safety alert regarding nimesulide, a common painkiller and anti-fever medicine.

The alert warns that the drug can lead to "fixed drug eruption" — or skin rashes to specific parts of the body.

बीएचयू में दवाओं के दुष्प्रभाव के प्रति किया गया जागरूक

Wednesday Times

"National Pharmacovigilance Week" launched

हिन्दुस्त

दून मेडिकल कॉलेज में दीक्षार की फार्मेंकोविजिलेंस सप्ताह पर पोस्टर प्रतियोगिता का आयोजन किया गया

Congratulations

दून मेडिकल कॉलेज में पोस्टर प्रतियोगिता

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

दवाओं के प्रतिकूल प्रतिक्रियाओं की रिपोर्टिंग हेतु कार्यशाला आयोजित

टोल फ्री नंबर 1800-180-3024 या पीवीपीआई ऐप पर करें रिपोर्ट

दवाओं के साइड इफेक्ट सहें नहीं, इस पर खुद कसें नकेल

अपने अधिकार को जाने

दवाओं के दुष्प्रभाव से मरीजों को नुकसान से बचाने के लिए एडीआर रिपोर्टिंग करने में ब्यावर अव्वल

दो सालों में 249 मरीज की हो चुकी है रिपोर्टिंग, एक भी मामला गंभीर रिएक्शन वाला नहीं

ब्यावर। दवाओं के दुष्प्रभाव से मरीजों को होने वाले नुकसान से बचाने के लिए केंद्र सरकार द्वारा शुरू किए गए एडीआर (एडवर्स ड्रग रिएक्शन) की रिपोर्टिंग करने से ब्यावर का जिला क्षय रोग निवारण केंद्र टीबी की दवाओं के रिएक्शन की रिपोर्टिंग करने में प्रदेश में अव्वल है।

दो साल पहले ब्यावर जिला क्षय रोग निवारण केंद्र द्वारा एडीआर रिपोर्टिंग का कार्य शुरू किया गया और अब तक 249 मरीजों पर हुए दवाओं के दुष्प्रभाव की रिपोर्टिंग और लाइन करते हैं साथ ही जिस प्रकार का दुष्प्रभाव सामने आता है उसके अनुसार दवा की मात्रा में बदलाव या बंद करने का निर्णय लिया जाता है। अभी बात यह है कि अभी तक 249 में से 1 भी मामला गंभीर रिएक्शन वाला सामने नहीं आया। सभी सामान्य दुष्प्रभाव वाले मामले सामने आए। जिसमें दवाओं की डोज कम कर या रिएक्शन के अनुसार दूसरी दवा देकर उपचार जारी रखा गया।

• गाजियाबाद स्थित सेंट्रल कार्यालय में होती है रिपोर्टिंग। बताया गया है कि सेंटर पर हर महीने दवा रिएक्शन के करीब 10 मामले सामने आते हैं। ऐसे मामलों की रिपोर्ट गाजियाबाद स्थित फार्माकोविजिलेंस प्रोग्राम ऑफ इंडिया (पीवीपीआई) को भेजा जाता है। इनके आधार पर पीवीपीआई यह जांच करता है कि किस दवा से किस तरह के रिएक्शन की शिकायत मिली है। पीवीपीआई इस रिपोर्ट को सेंट्रल ड्रग स्टैंडर्ड कंट्रोल ऑर्गेनाइजेशन ऑफ इंडिया को भेजती है। किसी एक दवा के बार बार और गंभीर रिएक्शन के मामले सामने आने पर दवा पर प्रतिबंध लगाने की कार्रवाई तक की जा सकती है।

अगर किसी दवा का दुष्प्रभाव सामने आता है तो फार्माकोविजिलेंस प्रोग्राम ऑफ इंडिया के सेंट्रल कार्यालय के निशुल्क हेल्प लाइन नंबर 1800 180 3024 पर सोमवार से शुक्रवार सुबह 9 से शाम 5 बजे तक शिकायत दर्ज करवा सकते हैं।

• 2 सालों में 249 मरीज रजिस्टर्ड। डीटीसी ब्यावर एडवर्स ड्रग रिएक्शन मॉनिटरिंग सेंटर के रूप में केंद्र सरकार के अधीन संचालित हो रहे पीवीपीआई के तहत पंजीकृत है। यहां दो सालों से टीबी के दवाओं से होने वाले रिएक्शन की निरंतर रिपोर्टिंग की जा रही है। 2 सालों में 249 मरीज रजिस्टर्ड हुए हैं। कार्यक्रम के कोऑर्डिनेटर डीटीसी इंचार्ज डॉ. लोकेश कुमार गुप्ता हैं और डिप्टी कोऑर्डिनेटर डॉ. अखिलेश वर्मा हैं। इनके साथ ही डीडमन फार्मासिस्ट वंचित नेशनल कोऑर्डिनेशन, सेंट्रल गाजियाबाद पीवीपीआई के रिसर्च साइंटिस्ट डॉ. सौरभ कुमार जैन तकनीकी सहयोग कर रहे हैं।

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Daily Dose of Health & Medical News

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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

सकाळ   पुणे, सोमवार, ३१ मार्च २०२५   २

पाच औषधांचे रुग्णांवर प्रतिकूल परिणाम

नोंदी करण्याचे भारतीय औषध प्रणाली आयोगाचे डॉक्टरांना आवाहन

क्र.	औषधाचे नाव	कशासाठी वापर	आढळतेते प्रतिकूल परिणाम
१	ॲंफोटेरिसीन		
२	कार्बिमाझोल		
३	क्लाटीन		
४			
५			

Medical Dialogues
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Home › News › Industry › Pharma News › Drug Safety Alert: IPC...

Drug Safety Alert: IPC Flags Adverse Reactions To Metronidazole, Luliconazole, Dalteparin, Gliclazide, And Tramadol

Written By Susmita Roy — Published On 28 Mar 2025 6:00 PM | Updated On 28 Mar 2025 6:00 PM

The Indian Practitioner

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Medi News

IPC Issues Safety Alert on Beta-Blockers Linked to Hypokalaemia Risk

By **The Indian Practitioner** — January 6, 2025

PHOTO
GALLERY

Launch of ADRMS at 1ˢᵗ Policy Makers Forum meeting at Dr. Ambedkar International Centre in New Delhi on 19ᵗʰ August, 2024

Lamp lightning ceremony on the Inaugural day of 4ᵗʰ NPW on 17ᵗʰ September, 2024

(a)

(b)

(c)

(d)

(e)

Release of (a) PV Comic (b) PvPI Quarterly Newsletter Vol.14 Issue 2 (c) PvPI Posters (d) Pharmacovigilance Guidance Document for MAHs of Pharmaceutical Products (Version 2.0) (e) Quality Manual of PvPI, during the Inaugural Ceremony of 4th NPW on 17th September 2024

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"

Participants-Team PvPI during the Inaugural ceremony of the 4th NPW

International webinar organised during 4th NPW on 18th September 2024

4TH NATONAL PHARMACOVIGILANCE WEEK

17 TO 23 SEPTEMBER 2024

Theme: "Building ADR Reporting Culture for Patient Safety"

Shri Suneel Yadav, Ex Chairman State Pharmacy Council, UP, President Pharmacist Federation held discussion on "Reporting of Adverse Events via PvPI Mobile App or Toll Free Number" at Radio Jaighosh 107.8 FM, Lucknow

(a) All India Institute of Medical Sciences, Bhopal

(b) Government Medical College, Baramulla

(c) Government Medical College, Miraj

(d) Institute of Medical Sciences,
Banaras Hindu University, Varanasi

(e) Jawaharlal Nehru Medical College
Aligarh Muslim University, Aligarh

(f) Jawaharlal Nehru Medical College
Ajmer

(g) Maulana Azad Medical College, New Delhi

(h) Nizam's Institute of Medical Sciences Hyderabad

(i) Rangaraya Medical College, Kakinada

(j) Srirama Chandra Bhanja Medical College and Hospital, Cuttack

(k) Shri Guru Ram Rai Institute of Medical & Health Sciences, Dehradun

(l) Silchar Medical College & Hospital, Silchar

(m) Subharati Medical College, Meerut

(n) SMS Medical College, Jaipur

(o) S. N. Medical College, Agra

(p) Posters by AMCs
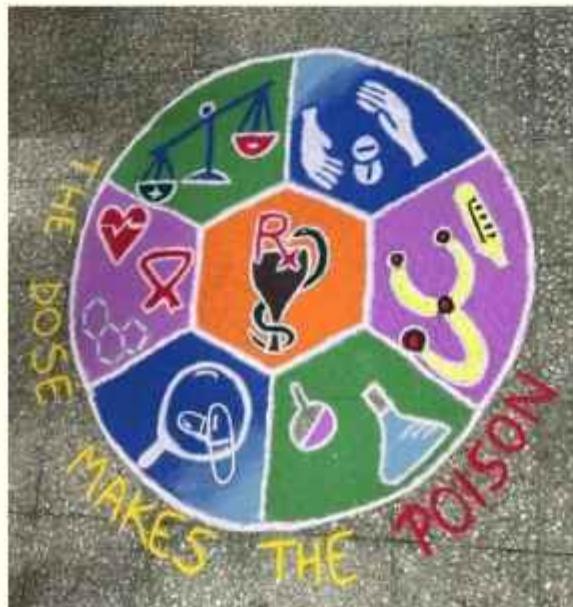
(q) Rangoli by AMCs

Sensitization and awareness programmes [such as seminars, webinars, walkathon, *nukkad natak (a-o)*, poster & *rangoli* making competitions *(p-q)* etc.] organized by AMCs under NCC-PvPI, IPC during 4th NPW from 17th - 23rd September 2024.

(a)

(b)

NCC-PvPI, IPC organised Regional Training Programme on Implementation of Pharmacovigilance Guidance document for Marketing Authorization Holders (MAHs) of Pharmaceutical Products, Version 2.0 at:

(a) Central Drug Testing Laboratory (CDTL), Mumbai on 28th February 2025

(b) National Institute of Mental Health and Neuro Sciences (NIMHANS), Bengaluru on 29th January 2025

NCC-PvPI organised one day Workshop-cum-Training Programme on Pharmacovigilance for NABH Accredited Hospitals in physical mode at Fortis Hospital, Mohali (SAS Nagar), Punjab on 31ˢᵗ January 2025.

International Conference on Patient Safety and the 22ⁿᵈ Annual Conference of the Society of Pharmacovigilance on 5ᵗʰ - 7ᵗʰ February, 2025

Materiovigilance Awareness Activity at MCSRC, Patna on 28ᵗʰ March, 2025

List of staff working in PvPI and MvPI Division

IPC Staff		
S. No.	**Name**	**Designation**
1.	Dr. Rajeev Singh Raghuvanshi	Secretary-cum-Scientific Director
2.	Dr. Jai Prakash	Sr. Principal Scientific Officer
3.	Dr. V. Kalaiselvan	Sr. Principal Scientific Officer
4.	Dr. Shashi Bhushan	Senior Scientific Officer
5.	Dr. R.S. Ray	Scientific Assistant
6.	Dr. Shatrunajay Shukla	Scientific Assistant
7.	Ms. Namita	Scientific Assistant
8.	Mr. Rahul Kumar Kadiyan	Scientific Assistant
9.	Mr. V. Naveen	Scientific Assistant
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72.	Manish K Puthran	Jr. Pharmacovigilance Associate (AMC)
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75.	Md. Bablu Gazi	Jr. Pharmacovigilance Associate (AMC)
76.	Md. Rafi	Pharmacovigilance Associate (AMC)
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78.	Meenal Pant	Jr. Pharmacovigilance Associate (AMC)
79.	Md. Ahamadi Tabasum	Jr. Pharmacovigilance Associate (AMC)
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95.	Prabhjot Kaur	Jr. Pharmacovigilance Associate (AMC)

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104.	Retty Alex	Jr. Pharmacovigilance Associate (AMC)
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106.	Ritu Beniwal	Jr. Pharmacovigilance Associate (AMC)
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109.	Dr. Saggurthi Pavani	Jr. Pharmacovigilance Associate (AMC)
110.	Samia Begum Barbhuiya	Jr. Pharmacovigilance Associate (AMC)
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119.	Shilpa Chaudhary	Jr. Pharmacovigilance Associate (AMC)
120.	Shilpa. K	Jr. Pharmacovigilance Associate (AMC)
121.	Shifa Shurti	Jr. Pharmacovigilance Associate (AMC)
122.	Shiv Prakash Rajput	Pharmacovigilance Associate (AMC)
123.	Shivani Trivedi	Jr. Pharmacovigilance Associate (AMC)
124.	Shiyona noyal	Jr. Pharmacovigilance Associate (AMC)
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129.	Soubhagyasmita	Jr. Pharmacovigilance Associate (NCC)
130.	Somesh Shukla	Jr. Materiovigilance Associate (NCC)
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133.	Srishti Singh	Jr. Pharmacovigilance Associate (NCC)
134.	Suchitra Kumari	Jr. Pharmacovigilance Associate (AMC)
135.	Sugandha Sharma	Jr. Pharmacovigilance Associate (AMC)
136.	Sumit Bhidwaria	Jr. Pharmacovigilance Associate (NCC)
137.	Surya Pratap	Jr. Materiovigilance Associate (NCC)
138.	Sushmita Sahu	Jr. Pharmacovigilance Associate (AMC)
139.	Swayam Sourav Sahoo	Pharmacovigilance Associate (AMC)
140.	Tanushree Sarvepalli	Jr. Pharmacovigilance Associate (NCC)
141.	Tejesvi Mishra	Jr. Pharmacovigilance Associate (NCC)
142.	Tinu T.S.	Pharmacovigilance Associate (AMC)
143.	Tripti Purohit	Jr. Pharmacovigilance Associate (NCC)
144.	Urfan Nabi Najar	Pharmacovigilance Associate (AMC)
145.	Vaibhav Gupta	Jr. Pharmacovigilance Associate (AMC)
146.	Vijit Agrawal	Sr. Pharmacovigilance Associate (NCC)
147.	Vinay Kumar	Pharmacovigilance Associate (AMC)
148.	Vipin Kumar	Sr. Pharmacovigilance Associate (NCC)
149.	Yamini Paranthaman	Jr. Pharmacovigilance Associate (AMC)

PvPI and MvPI staff posted at NCC are 25 and 11 respectively whereas at ADR Monitoring Centres and Medical Device Monitoring Centres are 108 and 05 respectively, across the country.

Acknowledgements

ANNEXURES

Annexure 1

Version: 1.4

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For **VOLUNTARY** reporting of ADRs by Healthcare Professionals

INDIAN PHARMACOPOEIA COMMISSION (National Coordination Centre-Pharmacovigilance Programme of India)

Ministry of Health & Family Welfare, Government of India, Sector-23, Raj Nagar, Ghaziabad-201002

PvPI Helpline (Toll Free) : 1800-180-3024 (9:00 AM to 5:30 PM, Monday-Friday)

Initial Case ☐	Follow-up Case ☐	FOR AMC / NCC USE ONLY

A. PATIENT INFORMATION *

		Reg. No. / IPD No. / OPD No. / CR No. :
1. Patient Initials:	2. Age or date of birth:	AMC Report No. :
3. Gender: M ☐ F ☐ Other ☐	4.Weight (in Kg.)	Worldwide Unique No. :

B. SUSPECTED ADVERSE REACTION *

12. Relevant investigations with dates :

5. Event / Reaction start date (dd/mm/yyyy)

6. Event / Reaction stop date (dd/mm/yyyy)

7. Describe Event/Reaction management with details , if any

13. Relevant medical / medication history (e.g. allergies, pregnancy, addiction, hepatic, renal dysfunction etc.)

14. Seriousness of the reaction : No☐ if Yes ☐ (please tick anyone)
☐Death (dd/mm/yyyy) ☐Congenital-anomaly
☐Life threatening ☐Disability
☐Hospitalization-Initial/Prolonged ☐Other Medically important

15. Outcome:
☐Recovered ☐Recovering ☐Not Recovered
☐Fatal ☐Recovered with sequelae ☐Unknown

C. SUSPECTED MEDICATION(S) *

S. No.	B. Name (Brand/ Generic)	Manufactu rer (if known)	Batch No. / Lot No.	Expiry Date (If known)	Dose	Route	Frequency	Therapy Dates Date Started	Therapy Dates Date Stopped	Indication	Causality Assessment
i											
ii											
iii											
iv *											

9. Action taken after reaction (please tick)

10. Reaction reappeared after reintroduction of suspected medication (please tick)

S. No. as per C	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown	Yes	No	Effect unknown	Dose (if re-introduced)
i										
ii										
iii										
iv										

11. Concomitant medical product including self-medication and herbal remedies with therapy dates (Exclude those used to treat reaction)

S. No.	Name (Brand / Generic)	Dose	Route	Frequency (OD, BD, etc.)	Therapy Dates Date Started	Therapy Dates Date Stopped	Indication
i							
ii							
iii *							

Additional Information :

D. REPORTER DETAILS *

16. Name & Address : _____

Pin : _____ Email : _____

Contact No : _____

Occupation : _____ Signature : _____

17. Date of this report (dd/mm/yyyy) :

Signature and Name of Receiving Personnel :

Confidentiality : The patient's identity is held in strict confidence and protected to the fullest extent. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction. Submission of an ADR report does not have any legal implication on the reporter.

\# Use separate page for more information

* Mandatory fields for suspected ADR Reporting Form

ADVICE ABOUT REPORTING

A. What to report?

All adverse events should be reported

Report non-serious, known or unknown, frequent or rare adverse drug reactions due to Medicines, Vaccines & Herbal Products.

Report every serious adverse drug reactions. A reaction is serious when the patient outcome is :

- Death
- Life-threatening
- Hospitalization (initial or prolonged)
- Disability (significant, persistent or permanent)
- Congenital anomaly
- Report intervention to prevent permanent impairment or damage

NOTE : Serious/Adverse Event following immunization can also be reported in Serious AEFI case Notification Form available on http://www.ipc.gov.in

B. Who can report?

All healthcare professionals (Clinicians, Dentists, Pharmacists and Nurse etc.) can report adverse drug reactions

C. Where to report?

Duly filled in Suspected Adverse Drug Reaction Reporting Form can be sent to the nearest Adverse Drug Reaction Monitoring Centre (AMC) or directly to the National Coordination Centre (NCC) for PvPI.

Call on Helpline (Toll Free) 1800 180 3024 to report ADRs or directly mail this filled form to pvpi.ipc@gov.in

A list of nationwide AMCs is available at : http://www.ipc.gov.in, http://www.ipc.gov.in/PvPI/pv_home.html

D.What happens to the submitted information?

- Information provided in this form is handled in strict confidence. The causality assessment is carried out at AMCs by using WHO-UMC scale. The analyzed forms are forwarded to the NCC-PvPI through ADR database. Finally the data is analyzed and forwarded to the Global Pharmacovigilance Database managed by WHO Uppsala Monitoring Centre in Sweden.
- The reports are periodically reviewed by the NCC-PvPI. The information generated on the basis of these reports helps in continuous assessment of the benefit-risk ratio of medicines.
- The Signal Review Panel of PvPI reviews the data and suggests any interventions that may be required.

E. Mandatory fields for suspected ADR Reporting Form (*)

Patient initials, age at onset of reaction, reaction term(s), date of onset of reaction, suspected medication(s) & reporter information.

For Adverse Drug Reaction Reporting Tools
- E-mail : pvpi.ipc@gov.in
- PvPI Helpline (Toll Free) : 1800 180 3024 (9:00 AM to 5:30 PM, Monday-Friday)
- ADR Mobile App : "ADRPvPI"

Annexure 2

Version 1.0
संस्करण 1.0

MEDICINES SIDE EFFECT REPORTING FORM (FOR CONSUMERS)
औषधि दुष्प्रभाव सूचना फॉर्म (उपभोक्ताओं के लिए)

Indian Pharmacopoeia Commission, National Coordination Centre- Pharmacovigilance Programme of India, Ministry of Health & Family Welfare, Government of India.

भारतीय भेषज संहिता आयोग, राष्ट्रीय समन्वय केंद्र — भारतीय फार्माकोविजिलेंस कार्यक्रम, स्वास्थ्य एवं परिवार कल्याण मंत्रालय, भारत सरकार।

1. Patient Details/ रोगी का विवरण

Patient Initials/ रोगी के आद्याक्षर:		Gender/ लिंग (√): Male/ पुरुष ☐ Female/ स्त्री ☐ Other/ अन्य ☐	Age (Year or Month)/ आयु (वर्ष या माह) :

2. Health Information/ स्वास्थ्य संबंधी जानकारी

a. Reason(s) for taking medicine(s)(Disease/Symptoms)/ दवा(दवाएं) लेने का कारण (रोग / लक्षण):

b. Medicines Advised by/ दवाई की सलाह देने वाला (√): Doctor/ डॉक्टर ☐ Pharmacist/ फार्मासिस्ट ☐ Friends/Relatives/ मित्र / रिश्तेदार ☐ Self (Past disease experienced/No past disease experienced)/ स्वयं (पूर्व बीमारी का अनुभव / पूर्व बीमारी का कोई अनुभव नहीं) ☐

3. Details of Person Reporting the Side Effect/ दुष्प्रभाव की सूचना देने वाले व्यक्ति का विवरण

Name (Optional)/ नाम (वैकल्पिक):

Address/ पता:

Telephone No/ टेलीफोन नं:	Email/ ईमेल:

4. Details of Medicine Taking/Taken/ ली जा रही है / ली जा चुकी दवाई का विवरण

Name of Medicines/ दवाइयों के नाम	Quantity of Medicines taken (e.g. 250 mg, Two times a day)/ ली गई दवाई की मात्रा (उदाहरण के लिए 250 मिग्रा, एक दिन में दो बार)	Expiry Date of Medicines/ दवा के निषिद्ध होने की तिथि	Date of Start of Medicines/ दवाइयां आरम्भ करने की तिथि	Date of Stop of Medicines/ दवाइयां रोकने की तिथि

Dosage form/खुराक का स्वरूप (√) : Tablet/ गोली (टेबलेट) ☐ Capsule/ कैप्सूल ☐ Injection/ इंजेक्शन ☐ Oral Liquids/ मौखिक तरल ☐ If Others (Please specify_____)/यदि अन्य (कृपया निर्दिष्ट करें_____)

5. About the Side Effect/ दुष्प्रभाव के बारे में

When did the side effect start ?/ दुष्प्रभाव की शुरुआत कब हुई थी?		Side Effect is still Continuing (Yes/No)/
When did the side effect stop?/ दुष्प्रभाव कब समाप्त हुआ था?		क्या दुष्प्रभाव जारी है (हां / नहीं):

6. How bad was the Side Effect? (Please √ the boxes that Apply)/ दुष्प्रभाव कितने हानिकारक थे? (कृपया जो लागू हों, उस पर √ का निशान लगाएं)

☐ Did not affect daily activities/ दैनिक गतिविधियां प्रभावित नहीं हुई थीं	☐ Affect daily activities/ दैनिक गतिविधियां प्रभावित हुई
☐ Admitted to hospital/ अस्पताल में जाना पड़ा	☐ Death/ मृत्यु
☐ Others/ अन्य	

7. Describe the Side Effect (What did you do to manage the side effect?)/ दुष्प्रभाव की व्याख्या करें (आपने दुष्प्रभाव से छुटकारा पाने के लिए क्या किया)?

Send your report by mail or Fax to/ मेल या फैक्स के द्वारा अपनी रिपोर्ट निम्न पते पर भेजें

Pharmacovigilance Programme of India
National Coordination Centre,
Indian Pharmacopoeia Commission,
Ministry of Health & Family Welfare, Govt. of India
Sector-23,Rajnagar,Ghaziabad-201002.Uttar Pradesh
Tel.:0120-2783400, 2783401, 2783392
FAX: 0120-2783311
Email: pvpi.compat@gmail.com
For more information visit us at www.ipc.gov.in

Call us on Helpline/ हेल्पलाइन पर हमें फोन करें
1800-180-3024 (Toll Free/ (टोल फ्री))
(9:00 AM to 5:30 PM, weekdays/ प्रातः 9:00 बजे 5:30 बजे तक, प्रत्येक कार्यदिवस पर)

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Programme staff is not expected to and will not disclose the reporter's identity in response to a request from the public.
गोपनीयता: रोगी की पहचान को पूर्ण गुप्त और सुरक्षित रखा जाएगा है। कार्यक्रम के स्टाफ से उम्मीद की जाती है कि स्टाफ का कोई भी व्यक्ति सार्वजनिक अनुरोध पर रिपोर्ट देने वाले की पहचान का खुलासा नहीं होगा।

Instructions to Complete the Reporting Form
सूचना फॉर्म को पूरा करने के लिए निर्देश

Section 1 - Patient Details
- ✓ In patient initial, write first letter of the name and first letter of the surname (e.g. Pradeep Sharma-PS).
- ✓ Provide personal information (Gender, Age).

Section -2 Health Information
- ✓ Provide reason(s) for taking medicines and medicines advised by (Doctor, Pharmacists, Friends/ Relatives and Self).

Section 3 - Details of Person Reporting the Side Effect
- ✓ Provide the name (optional), address; telephone no. and email are necessary to assess the report.

Section 4 - Details of the Medicines Taking/Taken
- ✓ Give all details about the Medicines (Name of Medicines, Quantity of Medicines taken, Expiry Date, start and stop date of Medicines) that have caused side effect.
- ✓ Please provide Dosage form (Tablets, Capsule, Injections, Oral liquid) and if others please specify.

Section 5 - About the Side Effect
- ✓ Provide side effect start and stop dates and also specify whether the side effect is still continuing.

Section 6 - How bad was the Side Effect
- ✓ Please tick marks the appropriate boxes that apply.

Section 7- Describe the Side Effect
- ✓ Please describe the details of side effect and what treatment was taken to manage the side effect.

निर्देश 1 – रोगी का विवरण
- ✓ रोगी के आरम्भाक्षर में, नाम का पहला अक्षर लिखें और उपनाम का प्रथम अक्षर लिखें (जैसे प्रदीप शर्मा–पश)।
- ✓ व्यक्तिगत जानकारी (लिंग, आयु) प्रदान करें।

निर्देश –2 स्वास्थ्य संबंधी जानकारी
- ✓ दवा लेने के कारण और परामर्शदाता का नाम दें (डॉक्टर, फार्मासिस्ट, मित्र / रिश्तेदार और स्वयं)।

निर्देश 3 – दुष्प्रभाव की रिपोर्ट करने वाले व्यक्ति का विवरण दें
- ✓ रिपोर्ट के मूल्यांकन हेतु नाम (वैकल्पिक), पता, टेलीफोन न और ई–मेल उपलब्ध कराएं।

निर्देश 4 – ली जा रही है / ली जा चुकी दवाईयों का विवरण
- ✓ उन दवाइयों (दवाइयों का नाम, ली गई दवाइयां, निर्धारण होने की तिथि, दवाइयां शुरू करने एवं रोकने की तिथि) का विवरण दें जिनके कारण आपको दुष्प्रभाव हुआ है।
- ✓ खुराक का स्वरूप (गोली (टैबलेट), कैप्सूल, इंजेक्शन, मौखिक तरल (पीने वाली दवा) और यदि कोई अन्य हो तो निर्दिष्ट करें।

निर्देश 5 – दुष्प्रभाव के बारे में
- ✓ दुष्प्रभाव आरंभ और समाप्त होने की तिथि बताएं और यह भी निर्दिष्ट करें कि क्या दुष्प्रभाव अभी भी जारी है।

निर्देश 6 – दुष्प्रभाव कितने हानिकारक थे?
- ✓ कृपया उचित डब्बे पर निशान लगाएं।

निर्देश 7– दुष्प्रभाव की व्याख्या करें
- ✓ कृपया दुष्प्रभाव का विवरण और उस दुष्प्रभाव से छुटकारा पाने के लिए क्या उपचार किया गया, विवेचना करें।

इस फॉर्म को पूरा करने के लिए अपना समय देने हेतु आपका धन्यवाद।

Annexure 3

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM
(FOR DRUGS USED IN PROPHYLAXIS/TREATMENT OF COVID-19)

For **VOLUNTARY** reporting of ADRs by Healthcare Professionals

INDIAN PHARMACOPOEIA COMMISSION (National Coordination Centre-Pharmacovigilance Programme of India)

Ministry of Health & Family Welfare, Government of India, Sector-23, Raj Nagar, Ghaziabad-201002

PvPI Helpline (Toll Free) : 1800-180-3024 (9:00 AM to 5:30 PM, Monday-Friday)

A. PATIENT/SUBJECT INFORMATION

Patient/Subject Category :

a. Lab confirmed COVID-19 case ☐

b. Asymptomatic Healthcare Worker involved in the care of suspected or confirmed COVID-19 cases ☐

c. Asymptomatic household contacts of laboratory confirmed cases ☐

d. Others (Please specify)

1. Patient/Subject initials	2. Age/Date of Birth	3. Weight (in Kg)

4. Gender :
Male ☐ Female ☐
Transgender ☐

5. If female pregnant
Yes ☐ No ☐

6. Lactating
Yes ☐ No ☐

B. SUSPECTED ADVERSE REACTION

S.No.	Reaction	Start Date	End Date	Outcome*

* Outcome may be indicated as (✓) one of the following

(a) Recovered (b) Not Recovered (c) Recovered with sequelae

(d) Recovering (e) Fatal (f) Unknown

7. Describe Event(s)/Reaction(s) with treatment details, if any in chronological order

8. Seriousness of the reaction :

No ☐ if Yes ☐ (please tick appropriate box)

Death (dd/mm/yyyy)	☐
Life threatening	☐
Hospitalization/Prolongation of hospitalization	☐
Other Medically important events	☐

Reg. No./IPO No./OPD No./CR No. :

AMC Report No. :

Worldwide Unique No. : To be generated by PvPI

9. Relevant tests/laboratory data with dates

Test for COVID-19 :

RT PCR Test ☐   Rapid Antibody Test ☐

Positive ☐   Negative ☐   Not done ☐

10. Any other tests performed :

1. Chest X-Ray	Yes ☐	No ☐
2. ECG Findings, if any	Yes ☐	No ☐
3. Biochemical Examination such as Serum Electrolytes (Na, K, Mg, Ca etc.)	Yes ☐	No ☐
4. Ophthalmology Exam findings, if any	Yes ☐	No ☐
5. Radiological examination	Yes ☐	No ☐
6. Other Relevant information, if any		

11. Recent Travel Information :

Recent History of International Travel : Yes ☐ No ☐

Country Visited :

Date of Return to India :

Inter-state travel/domestic travel

12. Relevant medical/medication history :

Allergy/Hypersensitivity Reaction	☐
Chronic Alcoholism	☐
Smoking	☐
Obesity	☐
Renal Dysfunction	☐
Hepatic Dysfunction	☐
Diabetes	☐
Epilepsy/Seizures	☐
Bronchial Asthma	☐
Cardiovascular Disease	☐
Chronic Lung Disease	☐
Immunodeficiency Disorder	☐
Immunosuppressant Drug	☐
Anaemia	☐
Neurological disorder	☐
G-6-PD Deficiency	☐
Dermatological findings, if any	☐
Others	☐

13. Drug Interaction : Mention name of any interacting (with Suspected Drug) drug taken :

C. SUSPECTED MEDICINE(S)

S. No.	Drug Name (Brand/Generic)	Manufacturer/ MAH# (if known)	Batch No./Lot No.	Exp. Date (if known)	Dosage Form	Dose used	Route of Admn.	Frequency (Once a day, Twice a day etc.)	Therapy Dates Date started	Therapy Dates Date stopped	Indication	Casuality Assessment (Prefer WHO-UMC Scale)
i.												
ii.												
iii.												
iv.												

S.No.	Drug Name	Reaction abated on (please tick) Drug withdrawal	Dose reduction	Without modification of dose	Any other	Reaction if reappeared after drug reintroduction Yes	No	Effect unknown	Dose (if reintroduced)
i.									
ii.									
iii.									

14. Concomitant medication including drug used for co-morbidities, and complementary medicines with therapy dates (Exclude those used to treat reaction)

S.No.	Name (Brand/Generic)	Dose used	Route used	Frequency (Once a day, twice a day etc..	Therapy Dates Date started	Therapy Dates Date stopped	Indication
i.							
ii.							
iii.							
iv.							

D. REPORTER DETAILS

15. Name of the Healthcare Professional with Address : _____

_____

Pin : _____ E-mail : _____ Tel. No. (with STD code) : _____

Occupation : _____ Signature : _____

16. Date of this report (dd/mm/yyy) : _____

Sign. and Name of Receiver -

Confidentiality : The patient's identity is held in strict confidence and protected to the fullest extent. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction. Submission of an ADR report does not have any legal implication on the reporter.

* Use separate page for more information, #MAH-Marketing Authorization Holder

ADVICE ABOUT REPORTING

A. What to report?

All adverse events should be reported

Report every serious adverse drug reactions. A reaction is serious when the patient outcome is :

- Death
- Life-threatening
- Hospitalization (initial or prolonged)

Report all non-serious, known or unknown, frequent or rare adverse drug reactions.

B. Who can report?

All healthcare professionals (Clinicians, Dentists, Pharmacists and Nurse etc.) can report adverse drug reactions

C. Where to report?

Duly filled in Suspected Adverse Drug Reaction Reporting Form can be sent to the nearest Adverse Drug Reaction Monitoring Centre (AMC) or directly to the National Coordination Centre (NCC) for PvPI.

Call on Helpline (Toll Free) 1800 180 3024 to report ADRs or directly mail this filled form to pvpi.ipc@gov.in

A list of nationwide AMCs is available at : http://www.ipc.gov.in, http://www.ipc.gov.in/PvPI/pv_home.html

D. What happens to the submitted information?

Information provided in this form is handled in strict confidence. The causality assessment is carried out at AMCs by using WHO-UMC scale. The analyzed forms are forwarded to the NCC-PvPI through ADR database. Finally the data is analyzed and forwarded to the Global Pharmacovigilance Database managed by WHO Uppsala Monitoring Centre in Sweden.

The reports are periodically reviewed by the NCC-PvPI. The information generated on the basis of these reports helps in continuous assessment of the benefit-risk ratio of medicines.

The Signal Review Panel of PvPI reviews the data and suggests any interventions that may be required.

E. Mandatory fields for suspected ADR Reporting Form

Patient initials, age at onset of reaction, reaction term(s), date of onset of reaction, suspected medication(s) & reporter information.

For Adverse Drug Reaction Reporting Tools

- E-mail : pvpi.ipc@gov.in
- PvPI Helpline (Toll Free) : 1800 180 3024 (9:00 AM to 5:30 PM, Monday-Friday)
- ADR Mobile App : "ADRPvPI"

Annexure 4

PERSONAL PROTECTIVE EQUIPMENT ADVERSE EVENT REPORTING FORM

Version no. 1.1

Materiovigilance Programme of India (MvPI)

Where to report: Duly filled form can be sent to Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare, Government of India, Sector-23, Rajnagar, Ghaziabad-201002, Tel-0120-2783403, 2783401 and 2783592, FAX-0120-2783311 or email to distmnjay.ipc@gov.in Or Call on Helpline no. 1800 180 3024 to report Adverse event.

1. General Information:
Date of report:
Date of event:

2. Type of report:
☐ Initial ☐ Follow-up (Ref. no.)

3. Reporter details:
Name:
Address:
Contact No.:
E-mail address:

4. PPE Type:
☐ Gloves ☐ Coverall ☐ Goggles ☐ N-95 Masks ☐ Shoe Covers ☐ Face Shield ☐ Body Bags
☐ Triple Layer Medical Mask ☐ Sanitizer ☐ Other (Specify):

5. PPE Details:
Brand name:
Manufacturer name and address:
Importer name and address:
Distributor name and address :
Marketed by:
License No. / Registration No. :
Model No.: Batch No.:
Unique Certification Code : Test Standard :
Manufacturing Date : Expiry Date :
PPE Current Location: ☐ Device destroyed ☐ Still in use ☐ Return to manufacturer

6. Location of event:
☐ Point of Entry (Immigration counters, customs and airport security)
☐ Hospital Setting
☐ In-patient Services
☐ Emergency Department
☐ Pre-hospital (Ambulance) Services
☐ Other Supportive/ Ancillary Services (Laboratory, Mortuary, Sanitation)
☐ Health Workers in Community Setting
☐ Quarantine facility
☐ Home Quarantine
☐ Other (Specify):

7. Type of event:
Serious: ☑ Non-Serious
☐ Death
☐ Life Threatening
☐ Disability or permanent damage
☐ Hospitalization / Prolonged Hospitalization
☐ Congenital anomaly / birth defect
☐ Any other serious

8. User details:
Initials:
Age:
Gender (M/F/O):
Outcome: ☑ Recovered ☑ Not yet recovered
☑ Death ☑ Other:

9. Detailed Description of Event:

10. Hospital/Quarantine facility details:
Facility Name:
Address:
Contact Person:

Annexure 5

Version-1.1

MEDICAL DEVICE ADVERSE EVENT REPORTING FORM

Materiovigilance Programme of India (MvPI)

This form is intended to collect information on Medical Devices Adverse Event in India. The form is designed to be used voluntarily by Manufacturer/Importer/Distributor of Medical Devices, Healthcare Professionals and anyone with direct/indirect knowledge of Medical Devices Adverse Event.

General Information

1. Date of Report :
2. Type of Report : Initial ☐ Follow up ☐ Final ☐ Trend ☐
3. Reporter Reference for MDMC only: • Centre   • Location   • Month-Year   • Case No.

Reporter Details

1. Type of Reporter : (a) Manufacturer ☐ (b) Importer ☐ (c) Distributor ☐ (d) Healthcare Professional ☐

    (e) Patient ☐ (f) Others ☐ specify

2. In case, where the reporter is not manufacturer, fill the following details:-

  (a) Has the reporter informed the incident to the manufacturer?

    Yes ☐   No ☐

  (b) Is the reporter also submitting the report on behalf of the manufacturer?

    Yes ☐   No ☐

3. Reporter contact information:

  a) Name   :
  b) Address :
  c) Tel. /Mobile :
  d) Email   :

Device Category

Medical Device		In Vitro Diagnostics (IVD)		Medical Equipments / Machines	
I. Therapeutic ☐ Diagnostic	☐	I. Kits	☐	I. Therapeutic ☐ Diagnostic	☐
Both ☐ Preventive	☐	II. Reagents	☐	II. Therapeutic & Diagnostic	☐
Assistive ☐		III. Calibrator	☐	III. Preventive	☐
II. Implantable device	☐	IV. Control Material	☐	IV. Assistive	☐
Non-Implantable device	☐	V. Others	☐	V. Imaging	☐
III. Invasive ☐ Non-Invasive	☐	VI. IVD electronic reader/	☐	VI. Invasive ☐ Non-Invasive	☐
IV. Single use device	☐	Analyzer		VII. Others	☐
Reusable device	☐				
Reuse of manufacture marked					
Single use device	☐				
V. Sterile ☐ Non Sterile	☐				
VI. Personal use / Homecare use	☐				

Instruction for use Section A-F

- *If Medical Devices/Equipments/Machines : Please fill all the sections i.e. A, B, C, D, E & F*
- *If in Vitro Diagnostics (IVD) : Please fill sections i.e. A (except 6, 7, 8, 13, 14 & 16), B (except 1, 2, 6 & 8), D, E, & F*

Page 1 of 5

(A) Device Details

Device Name / Trade Name / Brand Name:

Details	Name	Address
Manufacturer		
Importer		
Distributor		

1. a) Is the device notified/regulated in India   :   Yes ☐   No ☐

   b) Device Risk Classification as per India MDR 2017 :   A ☐   B ☐   C ☐   D ☐

2. License No. (Manufacture/Import)   :

3. Catalogue No.   :

4. Model No.   :

5. Lot / Batch No.   :

6. Serial No.   :

7. Software Version   :

8. Associated Devices / Accessories   :

9. Nomenclature Code if applicable; GMDN/UMDNS :

10. UDI No. (If applicable)   :

11. Installation Date   :

12. Expiration Date   :

13. Last preventive maintenance date (dd/mm/yyyy) :

14. Last calibration date (dd/mm/yyyy)   :

15. Year of manufacturing   :

16. How long was device/Equipment/Machine in use :

17. Availability of device for evaluation   : Yes ☐   No ☐

    If no, was the device destroyed   ☐ Still in use ☐ return to manufacturer or importer/distributor ☐

18. Is the usage of device as per manufacturer claim /Instruction for use/user manual: Yes ☐   No ☐

    If no specify usage

19. For devices not regulated / notified in India   : Regulator / Regulatory status in country of origin

(B) Event Description

1. Date of Event / Near miss incident:
2. Date of Implant/Explant (If applicable):
3. Location of Event:

   Hospital Premise ☐ Manufacture/Distributor premise ☐

   Home ☐ Others ☐

4. Device Operator:-

   Healthcare Professional ☐ Patient ☐ Others ☐

   Problem noted prior to use/near miss event ☐

5. Device disposition / Current location:

   a) Returned to company ☐ If yes, date ...../...../........

   b) Remains implanted in patient ☐

   c) Within the healthcare facility ☐

   d) At patient home ☐

   e) Destroyed ☐

   f) Others (specify) ☐

6. Is device in use after incidence : Yes ☐ No ☐

7. Serious event: ☐

   If serious, Tick the appropriate reason

   a) Death (DD/MM/YY) ☐ ..../........./...........

   b) Life Threatening ☐

   c) Disability or permanent damage ☐

   d) Hospitalization ☐

   e) Congenital anomaly /birth defect ☐

   f) Any other serious (Imp. medical event) ☐

   g) Required intervention to prevent / permanent ☐
      Impairment / damage device

8. Non serious event ☐

9. Whether other medical devices were used at same time
   with above device if yes, please specify name(s)/use(s)

10. **Detail description of Event:-**

For manufacturer/authorized representative use only   Continue on Page ₹

11. frequency of occurrence of similar Adverse Event in India in past 3 years	Year	No. of Similar Adverse Events	Total No. Supplied	Frequency of Occurrence (%)
12. Frequency of occurrence of similar Adverse Event in globally in past 3 years	Year	No. of Similar Adverse Events	Total No. Supplied	Frequency of Occurrence (%)

(C) Patient Information, History & Outcome

1. Patient Hospital ID :
2. Patient Initial :
3. Age :
4. Gender : Male ☐ Female ☐ Others ☐
5. Weight :
6. Other relevant history, including pre-existing medical conditions

7. Patient Outcomes:

   a) Recovered Date (DD/MM/YY) ☐ ...../...../.....

   b) Not yet recovered ☐

   c) Death (DD/MM/YY) ☐ ...../...../.....

   d) Others ☐

      Please specify

(D) Healthcare Facility Information (if available)

1. Name   :
2. Address   :
3. Contact Person Name at the site of event   :
4. Tel. No.   :

(E) Causality Assessment

1. Investigation action taken:

2. Root cause of problem (Applicable for follow up / final reports):

(F) Manufacturer/Authorized Representative Investigation & Action taken

1. Manufacturer/Authorized Representative device risk analysis report:

2. Corrective / preventive action taken:

3. Device history review:

(B) Event Description (Continued)

10. Detail description of Event:-

(E) Causality Assessment (Continued)

1. Investigation action taken:

2. Root cause of problem (Applicable for follow up / final reports):

(F) Manufacturer/Authorized Representative Investigation & Action taken (Continued)

1. Manufacturer/Authorized Representative device risk analysis report:

2. Corrective / preventive action taken:

3. Device history review:

Where to report?

Duly filled Medical Device Adverse Event Reporting Form can be sent to Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare, Government of India, Sector-23, Rajnagar, Ghaziabad-20002, Tel-0120-2783400, 2783401 and 2783392, FAX:0120-2783311 or email to shatrunjay.ipc@gov.in Or Call on Helpline no. 1800 180 3024 to report Adverse event.

Partnering Organizations

Annexure 6

Version-1.0

MEDICAL DEVICE ADVERSE EVENT REPORTING FORM
Materiovigilance Programme of India (MvPI)
(For Consumers/Users)

Date of report .... :......./......./.........

(A) PATIENT INFORMATION, HISTORY & OUTCOME	
1. Patient Hospital ID: 2. Patient Initial: 3. Age or (Date of Birth): .... 4. Gender: Male □ Female □ Others □ 5. Weight (in kgs):	6. Other relevant medical history, including pre-existing medical conditions:

(B) SUSPECTED MEDICAL DEVICE DETAILS

Medical Device Name / Trade Name / Brand Name:

Details	Name	Address
Manufacturer		
Importer/ Distributor		
Model No.		
Lot / Batch No		
Serial No.		

(C) EVENT DESCRIPTION/ PRODUCT PROBLEM

1. Date of Adverse Event / Near miss incident: ....
2. Type of report
   Adverse Event □
   Product Problem □
   (e.g. defect/fault/error/malfunctioning)
3. Date of Implant / Date of device used: ....
4. Date of Explant/ Device used up to date: ....
5. Location of Event:
   Hospital Premise □
   Home □
   Others: .... □
6. Is the device in use after the incidence
   Yes □ No □

7. Whether adverse event is
   Serious event □ / Non serious event □
   If serious, Tick the appropriate reason
   a) Death .... □ ..../........./.........
   b) Life Threatening □
   c) Disability or permanent damage □
   d) Hospitalization □
   e) Congenital anomaly /birth defect □
   f) Any other serious events □
   g) Required intervention to prevent / permanent impairment / damage □
8. Whether other medical devices were used at the same time with the above device if yes, please specify the name(s)/use(s):

9. Detail Description of Event:

(D) Reporter contact information:

a) Name   :
d) Address :
b) Occupation (optional):
e) Email:
c) Tel./Mobile:

Version-1.0

हिन्दी संस्करण

चिकित्सीय उपकरण प्रतिकूल घटना सूचना फार्म

मैटीरिओविजिलेंस प्रोग्राम ऑफ़ इंडिया

(उपभोक्ताओं/ उपयोगकर्ताओं के लिए)

सूचना की दिनांक: (dd/mm/yyyy)

(A) रोगी के विषय में आवश्यक जानकारी	
1. रोगी की अस्पताल पहचान संख्या : 2. रोगी का संक्षिप्त नाम : 3. आयु/ जन्म तिथि: (dd/mm/yyyy) 4. लिंग: पुरुष ☐ स्त्री ☐ अन्य ☐ 5. वजन :	6. रोगी के पूर्व की अन्य चिकित्सा सम्बंधित स्थिति:

(B) संदिग्ध चिकित्सीय उपकरण का विवरण

चिकित्सा उपकरण का नाम/ व्यापारिक नाम/ बाजार में प्रचलित नाम:

विवरण	नाम	पता
निर्माता		
आयातकर्ता/ वितरणकर्ता		

प्रतिरूप क्रमांक	
लौट/ बैच क्रमांक	
श्रृंखला क्रमांक	

(C) प्रतिकूल घटना या उत्पाद की समस्या का विवरण

1. प्रतिकूल/ संभावित प्रतिकूल घटना की दिनांक: (dd/mm/yyyy)
2. सूचना का प्रकार
   प्रतिकूल घटना ☐
   उपकरण की समस्या ☐
   (e.g. कमी या खराबी)
3. चिकित्सा उपकरण प्रत्यारोपण या उपयोग की दिनांक:
4. चिकित्सा उपकरण को शरीर से निकालने या उपयोग बंद करने की दिनांक:
5. घटना किस स्थान पर घटित हुई:
   अस्पताल परिसर में ☐ / घर पर ☐
   अन्य किसी स्थान पर: .... ☐
6. क्या घटना के बाद उपकरण उपयोग में है:
   हाँ ☐ नहीं ☐

7. **प्रतिकूल घटना का प्रकार:**
   गंभीर प्रतिकूल घटना ☐ / गैर गंभीर घटना ☐
   यदि घटना गंभीर है, तो उचित कारण पर निशान लगाएँ
   a) मृत्यु (dd/mm/yyyy) ☐ ..../........./........
   b) जीवन के लिए खतरनाक ☐
   c) विकलांगता या स्थायी क्षति ☐
   d) अस्पताल में भर्ती ☐
   e) जन्मजात विसंगति/ जन्म दोष ☐
   f) कोई अन्य गंभीर कारण ☐
   g) घटना रोकने के लिए आवश्यक हस्तक्षेप/ स्थाई हानि होना या शारीरिक क्षतिग्रस्त होना ☐
   H. क्या उपरोक्त उपकरण के साथ एक ही समय में अन्य चिकित्सा उपकरणों का उपयोग किया गया था यदि हां, तो कृपया नाम/उपयोग निर्दिष्ट करें.

9. प्रतिकूल घटना का विस्तृत विवरण.

(D) सूचना देने वाले का विवरण:-

a) नाम :	b) व्यवसाय (वैकल्पिक):	c) दूरभाष क्रमांक:
d) पता :	e) ई. मेल :	

Annexure 7

ADVERSE DRUG REACTION REPORTING FORM FOR KALA-AZAR TREATMENT

I. PATIENT DETAILS

Patient Initials:	Patient Code No:	Patient Contact No:	AMC report number:
Patient Age: (Yr)		Weight: (Kg)	
Gender: M □ F □ Others □		Breastfeeding an infant: Yes□ No□	Worldwide unique number:
Pregnant: Yes □ No □ Uncertain □		If Pregnant, estimated current gestation (weeks):	

II. TREATMENT

A) CONDITION TREATED

Kala Azar (VL) □	Post Kala Azar Dermal Leishmaniasis (PKDL) □	HIV-VL Co-infection □	Others □ (Specify)

B) TREATMENT RECEIVED

Mono Therapy □   Combination Therapy □

Drug Received	Batch No./ Expiry Date	Drug Dose & Unit	Frequency	Route	Start Date (dd/mm/yyyy)	Start Time (Hr:Min)	Stop Date (dd/mm/yyyy)	Stop Time (Hr:mm)
Liposomal Amphotericin B								
Miltefosine								
Paromomycin								
Amphotericin B deoxycholate								
SSG/ SAG								
....								

III. CONCOMITANT DRUGS

S. No.	Name	Indication	Batch Number/ Expiry Date	Drug Dose Unit (if LV) Infusion rate in ml/hour	Dose & Unit	Frequency	Route	Start Date	Stop date

IV. ADVERSE EVENTS INFORMATION

Reporter's Narrative (Describe the course of events, timing and suspected causes):

Adverse Event/ Reaction Term	Event I	Event II	Event III
Date of Onset	DD/MM/YY	DD/MM/YY	DD/MM/YY
Date Resolved	DD/MM/YY	DD/MM/YY	DD/MM/YY
Severity	□ Mild □ Moderate □ Severe	□ Mild □ Moderate □ Severe	□ Mild □ Moderate □ Severe
Seriousness	□ Non-Serious ADR □ Serious AE/ADR please specify category: □ Death □ Hospitalization/ Prolonged □ Life threatening □ Permanent disability/disabling □ Congenital anomaly/ birth defect □ Other medically important condition	□ Non-Serious ADR □ Serious AE/ADR please specify category: □ Death □ Hospitalization/ Prolonged □ Life threatening □ Permanent disability □ Congenital anomaly □ Other medically important condition	□ Non-Serious ADR □ Serious AE/ADR please specify category: □ Death □ Hospitalization/ Prolonged □ Life threatening □ Permanent disability □ Congenital anomaly □ Other medically important condition

Outcome	☐ Recovered/ resolved ☐ Recovering/resolving ☐ Fatal ☐ Not Recovered/not resolved ☐ Recovered with Sequalae ☐ Unknown	☐ Recovered/ resolved ☐ Recovering/resolving ☐ Fatal ☐ Not Recovered/not resolved ☐ Recovered with Sequalae ☐ Unknown	☐ Recovered/ resolved ☐ Recovering/resolving ☐ Fatal ☐ Not Recovered/not resolved ☐ Recovered with Sequalae ☐ Unknown
Dechallenge/ Action Taken	☐ Drug Withdrawn ☐ Dose Reduced Dose................ ☐ Dose not changed ☐ Unknown ☐ Not Applicable	☐ Drug Withdrawn ☐ Dose Reduced Dose................ ☐ Dose not changed ☐ Unknown ☐ Not Applicable	☐ Drug Withdrawn ☐ Dose Reduced Dose................ ☐ Dose not changed ☐ Unknown ☐ Not Applicable
Rechallenge	☐ No ☐ Yes Dose (if reintroduced).......... ☐ Unknown	☐ No ☐ Yes Dose (if reintroduced).......... ☐ Unknown	☐ No ☐ Yes Dose (if reintroduced).......... ☐ Unknown
Expectedness	☐ Expected (yes) ☐ Unexpected (no)	☐ Expected (yes) ☐ Unexpected (no)	☐ Expected (yes) ☐ Unexpected (no)
For Death	Date of Death........................ Primary cause of death (if known): .... Was autopsy performed? ☐ No ☐ Yes Hospital Admission Date .... Hospital Discharge Date..........	Date of Death........................ Primary cause of death (if known): .... Was autopsy performed? ☐ No ☐ Yes Hospital Admission Date .... Hospital Discharge Date............	Date of Death........................ Primary cause of death (if known): .... Was autopsy performed? ☐ No ☐ Yes Hospital Admission Date........ Hospital Discharge Date......
Causality [-Certain -Probable - Possible - Unlikely - Conditional - Unassessable]	☐ Ambisome................ ☐ Miltefosine .... ☐ Paromomycin................ ☐ Amphotericin deoxycholate........ ☐ SSG/ SAG................ ☐ Others (................)......	☐ Ambisome................ ☐ Miltefosine .... ☐ Paromomycin................ ☐ Amphotericin deoxycholate.... ☐ SSG/ SAG................ ☐ Others (................)............	☐ Ambisome................ ☐ Miltefosine .... ☐ Paromomycin................ ☐ Amphotericin deoxycholate........ ☐ SSG/ SAG................ ☐ Others (................)............

V. MEDICAL HISTORY

Briefly describe diseases and concurrent illness:

VI. RELEVANT LABORATORY TESTS

LABORATORY TESTS

Test	Date	Result (units)	Test	Date	Result (units)
Haemoglobin			Creatinine		
ALT (SGPT)			Na^+		
AST (SGOT)			K^+		

VII. OTHER CLINICALLY RELEVANT INFORMATION

Treatment For Managing ADR:

Counseling with Toll Free Number (18001803024): ☐ Yes ☐ No

VIII. REPORTERS INFORMATION

Name:	Designation:	Signature:
Email:	Contact No.:	
Professional Address:	PIN Code:	Date:
Name of Paramedical:	Designation:	Signature:

Annexure 8

Serious AEFI Case Notification Form – ADR Monitoring Center*																				
ICSR No.								**Reporting Format No.**												

Name & address of ADR Monitoring center (AMC):

Patient Name																				

Age: _____   Sex: Male/Female

Father/Husband's Name

Complete Address of the Case with landmarks *(Street name, house number, village, block, Tehsil, PIN No., Telephone No. etc.)*

P	I	N	-					P	H	O	N	E	-							

Date of Vaccination: ___ / ___ / _____

Address of health facility where vaccinated (include name of village/urban area, block, DISTRICT and STATE)#:

Name of vaccines with dose received (if known)

Date of first symptom	D	D	M	M	Y	Y	Y	F	Time of first symptom	H	H	M	M	(AM/PM)
Hospitalization: (No/ Yes) Date-	D	D	M	M	Y	Y	Y	F	Time of hospitalization	H	H	M	M	(AM/PM)

Name and address of hospital (if hospitalized):   CR No./MRD No _____

Current status (encircle)	Death / Still Hospitalized / Recovered & Discharged with sequelae /Recovered completely and discharged / Left Against Medical Advice (LAMA) / Not hospitalized

If died, Date of Death	D	D	M	M	Y	Y	Y	Y	Time of Death	H	H	M	M	(AM/PM)

Describe AEFI (signs and symptoms):

Name & signature of AMC Coordinator/ Medical officer:

Email:
Contact No.

*Date form sent to District Immunization Officer# (where patient was vaccinated)- ___ / ___ / _____

*Date form sent to State Immunization Officer# (where patient was vaccinated)- ___ / ___ / _____

*Date form sent to PVPI, Ghaziabad- ___ / ___ / _____

*Date form sent to Immunization Division / AEFI Secretariat (aefiindia@gmail.com)- ___ / ___ / _____

Name & signature of Pharmacovigilance Associate:

E mail:
Contact number:

#The case is to be notified to the DIO of the district where the vaccine was administered.
*This form should be scanned and emailed simultaneously to DIO, SEPIO, PVPI and AEFI Secretariat.

Let us join hands with PvPI to ensure patient safety

ipcgzb1 f

X ipcgzb

www.ipc.gov.in 🌐

Instagram ipcgzb

Toll Free No.
1800 180 3024 📞

YouTube ipcgzb

ADR PvPI Mobile App 🤖

✉ pvpi.ipc@gov.in

ipcgzb in