PHARMACOVIGILANCE PROGRAMME OF INDIA

PERFORMANCE REPORT

2022-2023

INDIAN PHARMACOPOEIA COMMISSION

Ministry of Health and Family Welfare, Government of India

PHARMACOVIGILANCE PROGRAMME OF INDIA

Performance Report 2022-23

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
AI	:	Active Ingredient
AIIMS	:	All India Institute of Medical Sciences
AMC	:	Adverse Drug Reaction Monitoring Centre
ART	:	Anti-Retroviral Therapy
CDSCO	:	Central Drugs Standard Control Organization
CME	:	Continuing Medical Education
CTP	:	Core Training Panel
COVID-19	:	Coronavirus Disease
DCG(I)	:	Drugs Controller General (India)
DGHS	:	Director General of Health Services
GoI	:	Government of India
GVP	:	Good Pharmacovigilance Practices
HCP	:	Healthcare Professional
HIV	:	Human Immunodeficiency Virus
ICSR	:	Individual Case Safety Report
IPC	:	Indian Pharmacopoeia Commission
ITSU	:	Immunization Technical Support Unit
MAH	:	Marketing Authorization Holder
MDAE	:	Medical Device Adverse Event
MedDRA	:	Medical Dictionary for Regulatory Activities
MoHFW	:	Ministry of Health and Family Welfare

MoU	:	Memorandum of Understanding
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
NTEP	:	National Tuberculosis Elimination Programme
PGIMER	:	Post-Graduate Institute of Medical Education and Research
PHP	:	Public Health Programme
PIL	:	Prescribing Information Leaflet
PV	:	Pharmacovigilance
PvPI	:	Pharmacovigilance Programme of India
PKDL	:	Post Kala-azar dermal leishmaniasis'
RTC	:	Regional Training Centre
SEARN	:	South East Asia Regulatory Network
SDP	:	Skill Development Programme
SMS	:	Short Message Service
SOP	:	Standard Operating Procedure
SRP	:	Signal Review Panel
UIP	:	Universal Immunization Programme
UT	:	Union Territory
USFDA	:	United States Food and Drug Administration
UMC	:	Uppsala Monitoring Centre
WHO	:	World Health Organisation
WHO DD	:	World Health Organisation Drug Dictionary

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 2022-23.

PvPI has undergone vast expansion to reach the common masses in the country through a network of Adverse Drug Reaction Monitoring Centres (AMCs). The PvPI has enrolled 167 new AMCs. However, 10 AMCs have been delisted during this tenure and the total number of AMCs became 691 from 534 across the country.

The National Coordination Centre (NCC)-PvPI has issued 18 Drug Safety Alerts for the sensitization of the healthcare professionals and common masses in the country. In addition to this, PvPI also sent 03 recommendations as well as one signal to Central Drugs Standard Control Organization for taking appropriate regulatory action.

PvPI has organized a total of 1795 training programmes and has trained a total of 109571 participants in the area of Pharmacovigilance across the country. Some of the important training programmes included Skill Development Programme on Pharmacovigilance, Advanced Level Training Programmes, Induction-cum-Training Programmes, etc. PvPI has organized 12 Interactive meets with Marketing Authorization Holders (MAHs)/Pharmaceuticals Industries to discuss & resolve their issues and to bring improvement in quality of reports.

It is noteworthy to mention that NCC-PvPI, IPC has organized virtual international training on Pharmacovigilance Practices on Post COVID-19 World "in collaboration with Ministry of External Affairs (MEA's), Indian Technical and Economic Cooperation (ITEC) programme from 5th-9th December, 2022. During the 5 days training, a total of 27 international participants from seven countries were attended this training.

The NCC-PvPI organized 2nd National Pharmacovigilance Week having theme on "Encourage the reporting of ADRs to PvPI by the consumers" from 17th-23rd September, 2022 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 628 training/awareness-cum-sensitization programmes including CME/CPE in which 54,889 Healthcare Professionals and other stakeholders were trained on Pharmacovigilance.

To enhance the visibility of PvPI, the IEC material 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, Government of India.

The Indian Pharmacopoeia Commission (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 or risk associated with the use of medical devices. The MvPI has enrolled new 143 Medical Device Adverse Event Monitoring Centres (MDMCs) and total number of MDMCs became 293 from 150 across the country. The MvPI forwarded 12 recommendations on safe use of medical devices in India to CDSCO for taking appropriate regulatory actions.

We 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 team, AMCs, subject matter experts, MAHs/Pharmaceutical industries, healthcare professionals and other stakeholders for their ceaseless efforts, cooperation and contribution in strengthening 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 167 new AMCs under PvPI

02 Total 113459 ICSRs were submitted to VigiBase.

03 PvPI is the 9th largest reporter of ICSRs in VigiBase at global level.

04 PvPI IPC continued to maintain as a WHO-Collaborating Centre for Pharmacovigilance in Public Health Programmes and Regulatory services.

05 PvPI has issued 18 drug safety alerts and has recommended 3 PIL changes including 1 Signal (Paracetamol associated Fixed Drug Eruption) to CDSCO.

06 Conducted 1795 trainings/workshops/ CMEs/ALT programmes and trained 109571 participants.

07 Celebrated 2nd National Pharmacovigilance Week from 17th – 23rd September 2022 pan-India.

08 PvPI, IPC organized a virtual training programme on "Impact of Pharmacovigilance practices on post COVID19 pandemic" from 5th-9th December 2022 at IPC for partner countries of Development Partnership Administration division of Ministry of External Affairs, Govt. of India.

09 PvPI has published 4 newsletters on quarterly basis for the awareness of stakeholders about the Pharmacovigilance activities.

10 Participated in 7th #Medsafetyweek 2022 organized by WHO-UMC, Sweden.

11 To enhance the visibility of PvPI, the IEC material 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, Government of India.

Indian Pharmacopoeia Commission and its Services

Indian Pharmacopoeia Commission (IPC) 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.

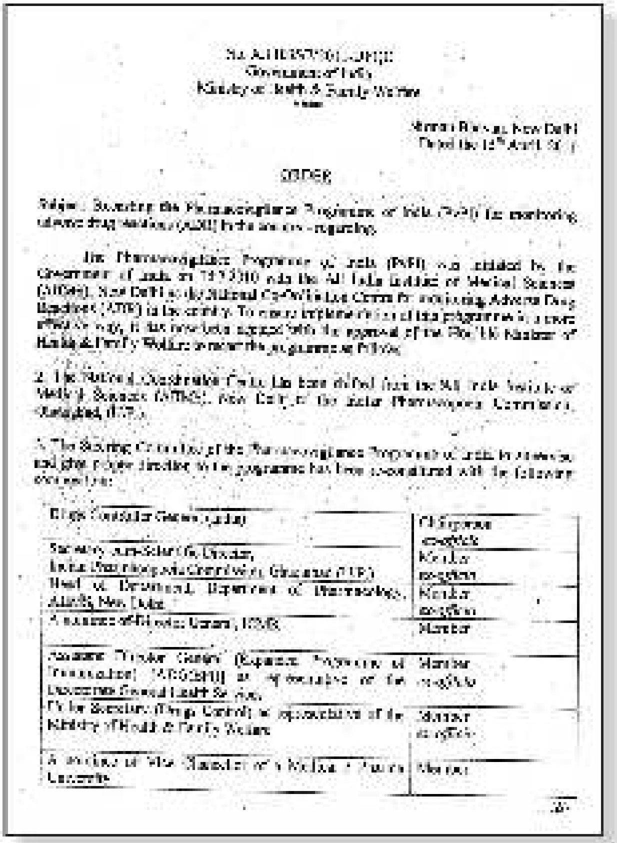
Functions

The mandate of the commission is to perform interalia functions such as revision and publication of Indian Pharmacopoeia (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 (NCC) for Pharmacovigilance Programme of India (PvPI) & Materiovigilance Programme of India (MvPI).

Figure - 1. Products & Services of Indian Pharmacopoeia Commission

Pharmacovigilance Programme of India

GENESIS


Government of India
Ministry of Health & Family Welfare

Nirman Bhawan, New Delhi

ORDER

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 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 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 Indian population by monitoring safety of medicines, thereby reducing the risk associated with their use.

Aims and Objectives

- 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 reports to the CDSCO for regulatory interventions.

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 interacts with National and International agencies for participation and implementation of training programmes in Pharmacovigilance. The Core Training Panel is assisted by the internal training team of PvPI.

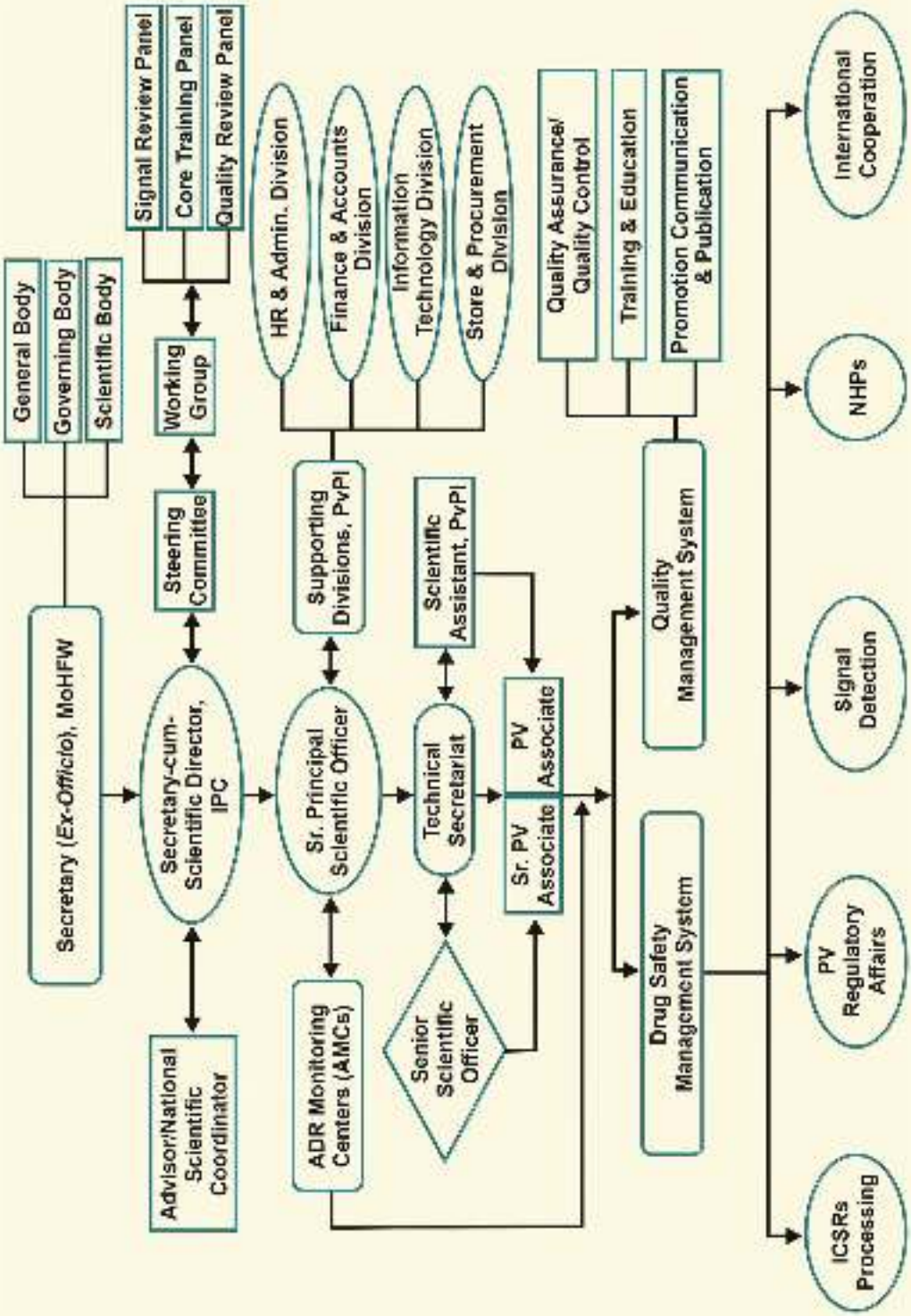


Figure - 2. Organogram of National Coordination Centre-Pharmacovigilance Programme of India

E-mail IDs and functions of PvPI divisions

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

Performance of PvPI as WHO-Collaborating Centre

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

Activities	Outcomes
Development of e-tools for integration of ADR-reporting	• Developing Indigenous Adverse Drug Reaction Management System (ADRMS) Software integrated with WHO-Drug Dictionary and MedDRA dictionaries. The ADRMS software offers seamless processing & evaluation of ICSR reported 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 drug safety alerts with SEARN countries on monthly basis through e-mail. • The NCC-PvPI has shared electronic version copy of newsletter with SEARN countries on quarterly basis through e-mail. • The NCC-PvPI has also shared the identified Signals and Prescribing Information Leaflet changes with SEARN countries through e-mail. • PvPI as a National Pharmacovigilance Centre of WHO Programme for International Drug Monitoring published drug safety information in WHO-Pharmaceuticals newsletter for global outreach.
Capacity Building and support for Public Health Programmes (PHPs) and Regulatory services	• Coordination done with Adverse Event Following Immunization (AEFI) Secretariat of the MoHFW, Govt. of India by sharing of data related to vaccines. • WHO-SEARO has organized a conference on "Addressing challenges of regulatory COVID-19 medical products in South-East Asia" from 11th-12th April, 2022. Dr. Rajeev Singh Raghuvanshi, Secretary-cum-Scientific, Director, IPC has participated in this conference. • WHO-SEARO office, New Delhi has organized a meeting for the heads of National Regulatory Authorities (NRAs), South-East Asia Regulatory Network (SEARN) from 7th-8th June, 2022. Dr. Rajeev Singh Raghuvanshi, Secretary-cum-Scientific, Director, IPC has participated as a Chairman for Working Group-3 (vigilance for medical products). • The representatives from PvPI, IPC have participated as observers in a WHO-Multidisciplinary Technical Group (MTG) meeting organized by the WHO Regional Office for South-East Asia (SEARO), New Delhi on Ocular Events reported with the administration of Miltefosine on 30th November 2022 through virtual mode. In this meeting, discussion was focused on the Causality Assessment, Risk Minimization Measures & its Communication, remaining uncertainties and need of further studies for Miltefosine associated Ocular Events.

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:

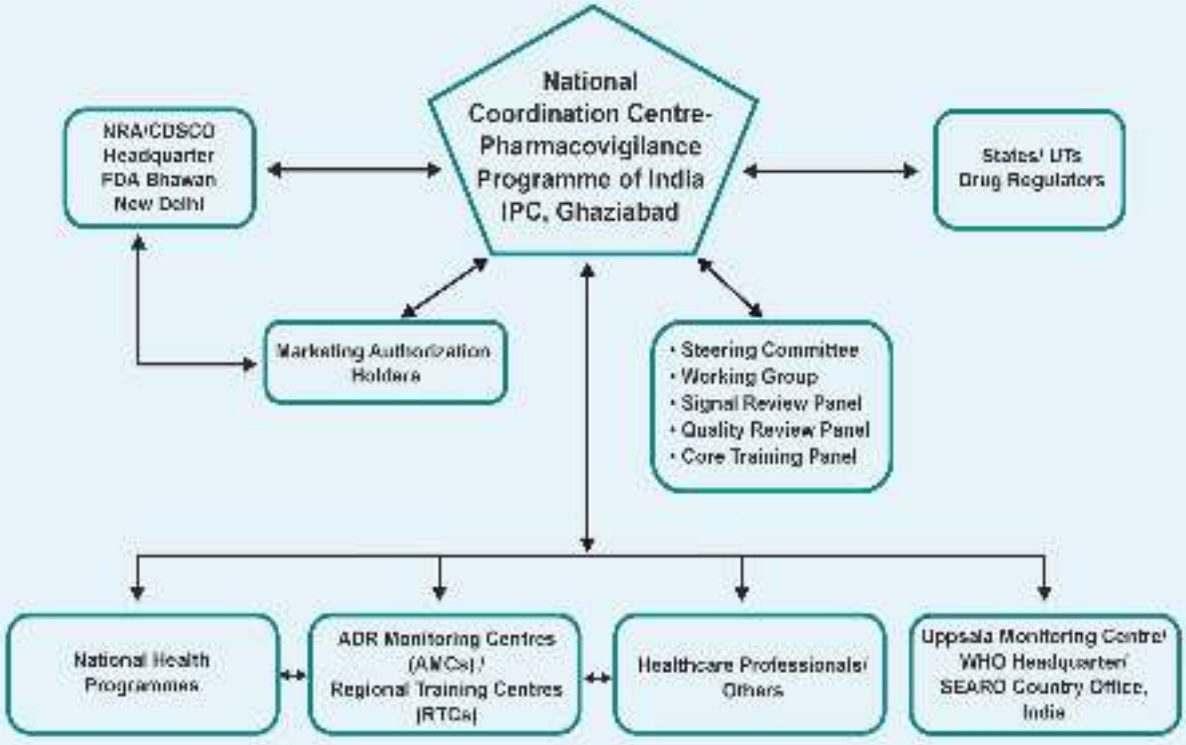


Figure - 3. Products & Services of Indian Pharmacopoeia Commission

Figure - 4. Products & Services of Indian Pharmacopoeia Commission

Figure - 5. Products & Services of Indian Pharmacopoeia Commission

ADR reporting forms are available on the official website of IPC (www.ipc.gov.in) and the website of CDSCO (www.cdsco.gov.in)

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
- Herbal Drugs/Nutraceuticals, etc

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-I)**.

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-II)**.

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-III)**.

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-IV)**.

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-V)**, serious cases related to vaccine use - Serious AEFI Case Notification Form **(Annexure-VI)** and Cases related to Medical Device use- Medical Device Adverse Event Reporting Form **(Annexure-VII)**.

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-Reporting of ADRs

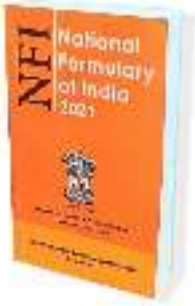
An indigenous android mobile app "ADR PvPI", which was dedicated to the nation on 29th September 2017, has been instrumental in equipping all stakeholders, including the consumers, for reporting ADRs.

E-mails

Hospitals/ Medical Colleges and other Healthcare Institutions which are not enrolled as AMCs under PvPI, may report adverse events by using email (icsr.nccpvpi@gmail.com). 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 (AMCs) functioning at these institutions under PvPI, across the country are playing a crucial role in collection, processing and monitoring of ADRs.

Medicines Side-Effect Reporting Form (For Consumers)

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

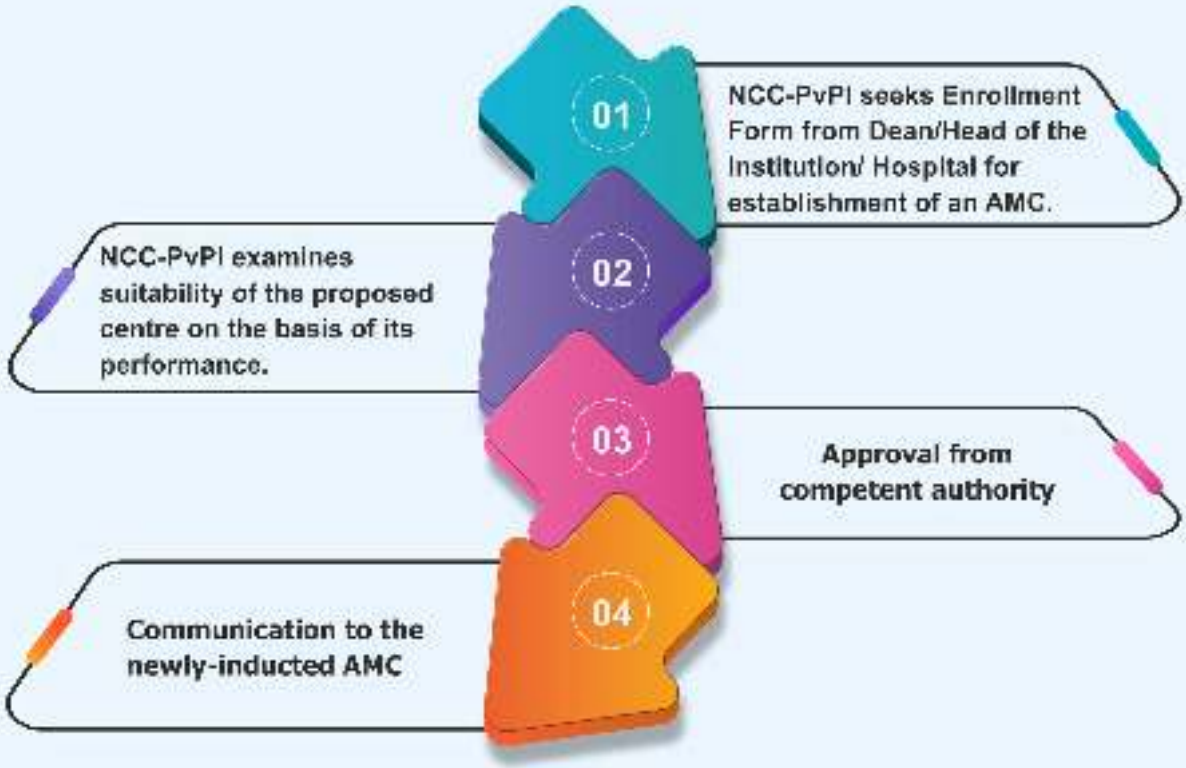


Figure - 6. Enrollment Procedure for AMCs

Criteria for enrollment of AMCs

- Availability of logistic and infrastructural facilities for PV at the proposed Centre.
- Significant track-record of the Centre in Pharmacovigilance – on quality, quantity and frequency of reporting Adverse Drug Reaction .
- Dean/ Head of Institution/ HoD of the proposed Centre is responsible to establish/implement PvPI activities at the Centre.
- The proposed AMC coordinator/ deputy coordinator should possess relevant experience.
- States/Union Territories where no/ few AMCs exists will be preferred.
- Demography based selection of AMCs.

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

Criteria for De-Enrollment/ De-Recognition of AMCs

- Non-performance/ Zero reporting.
- Non-compliance of Quality Management System.

ICSRs Database at PvPI

The Pharmacovigilance Programme of India (PvPI) 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 Adverse Drug Reaction Monitoring Centres (AMCs), Marketing Authorization Holders (MAHs), Healthcare Professionals Patients/Consumers through different channels of reporting are communicated to NCC-PvPI, IPC. The Annual database accounts for **113459** ICSRs for the index period and monthly reporting pattern is given below.

Figure - 7. Month-wise distribution of ICSRs

Distribution of ICSRs based on Gender

PvPI database revealed that 50.0% ICSRs were from male patients and 45.0% were from female patients. No information was provided in 5.0% of ICSRs.

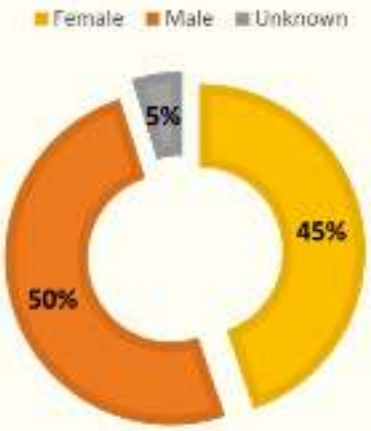


Figure - 8. Distribution of ICSRs based on gender

Distribution of ICSRs based on age

The database revealed that the maximum 35.3 % ICSRs were received from the age group of 18-44 years, whereas the minimum 0.2% ICSRs were received from the age group of 0-27 days. No information about the age of the patients were given in10.1% ICSRs.

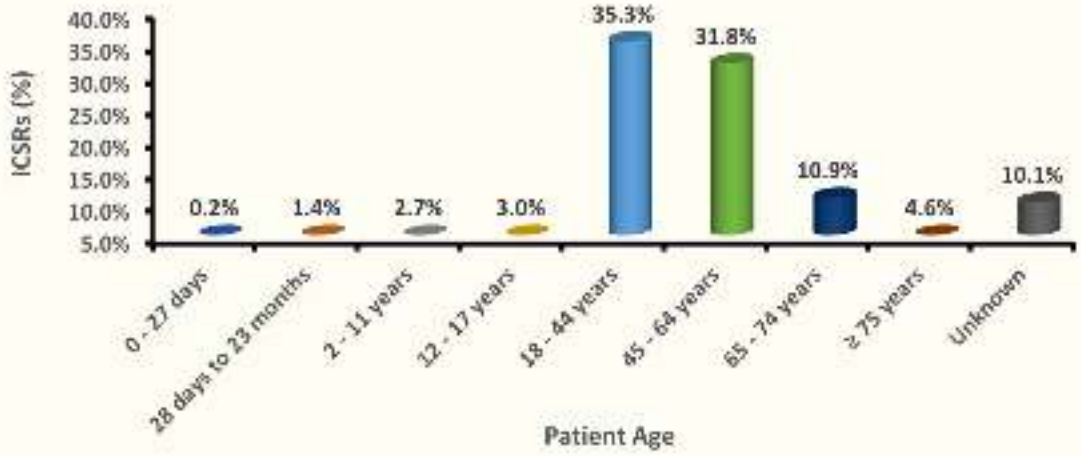


Figure - 9. Distribution of ICSRs based on age

Distribution of ICSRs based on reporter qualification

The NCC-PvPI has received 39.0% ICSRs from physicians, 16.5% from pharmacists, 26.2% from other healthcare professionals, 28.0 % from consumers/non-healthcare professionals and 0.3% were unknown.

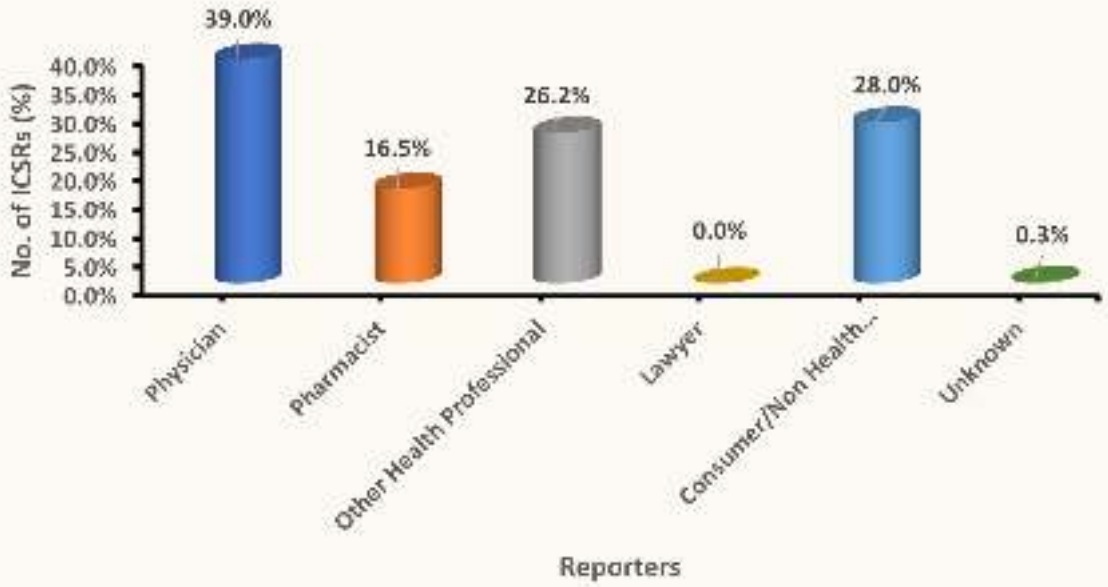


Figure - 10. Distribution of ICSRs based on reporter qualification

Distribution of ICSRs based on seriousness

The database revealed that 73.0% ICSRs were non serious and 27.0% were serious reported with the use of medical products.

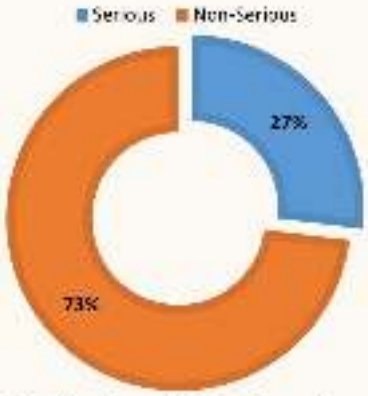


Figure - 11. Distribution of ICSRs based on seriousness

Distribution of ICSRs based on seriousness criteria

The seriousness criteria of received ICSRs revealed that 5.7% ICSRs were due to death, 1.9% ICSRs were due to life threatening condition, 10.8% ICSRs were due to prolonged hospitalization, 0.2% ICSRs were due to disabling/incapacitating and 12.7% ICSRs were due to other medically important conditions.

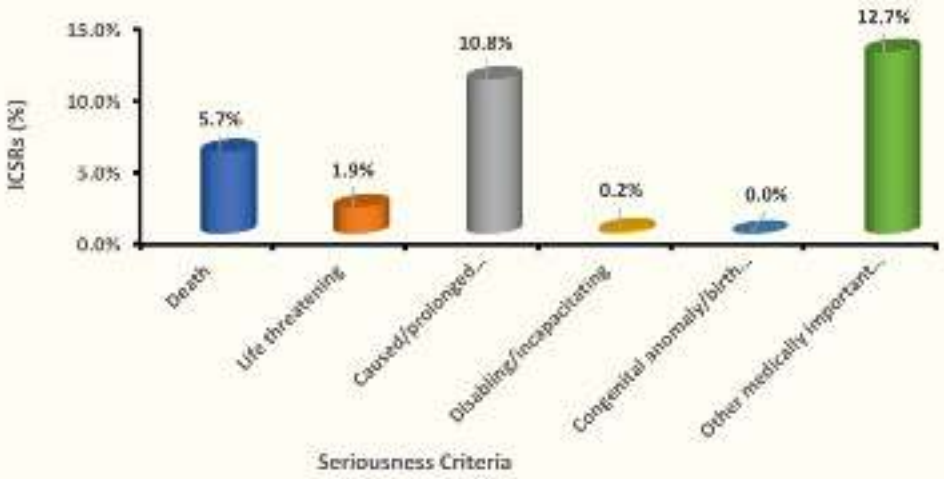


Figure - 12. Distribution of ICSRs based on seriousness criteria

Distribution of reactions based on System Organ Classes (SOCs)

The ICSRs reported in PvPI database revealed that the maximum number of reactions 29.0% were reported from the SOC-General disorders and administration site conditions among the **top ten reported SOCs**.

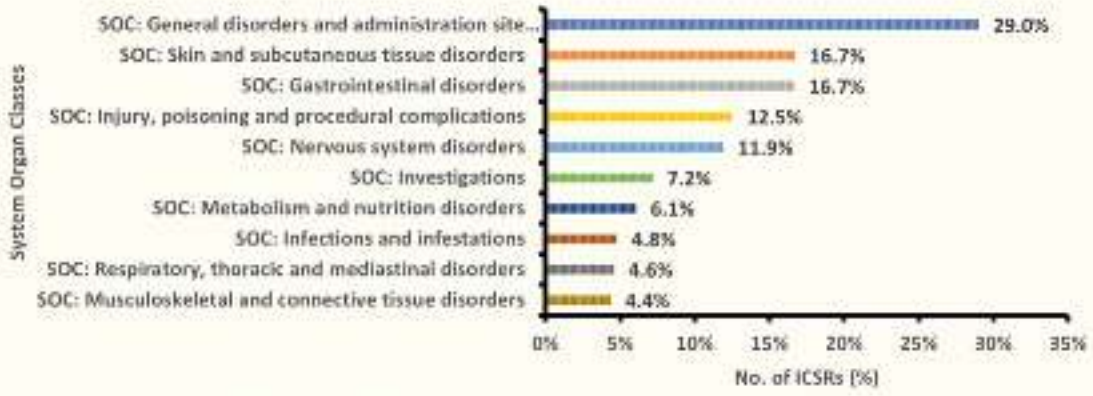


Figure - 13. Distribution of reactions based on SOCs

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

The ICSRs reported in PvPI database revealed that the maximum number of suspected drugs 35.0% were reported from the ATC-Anti-infectives for systemic use among the top ten reported ATCs.

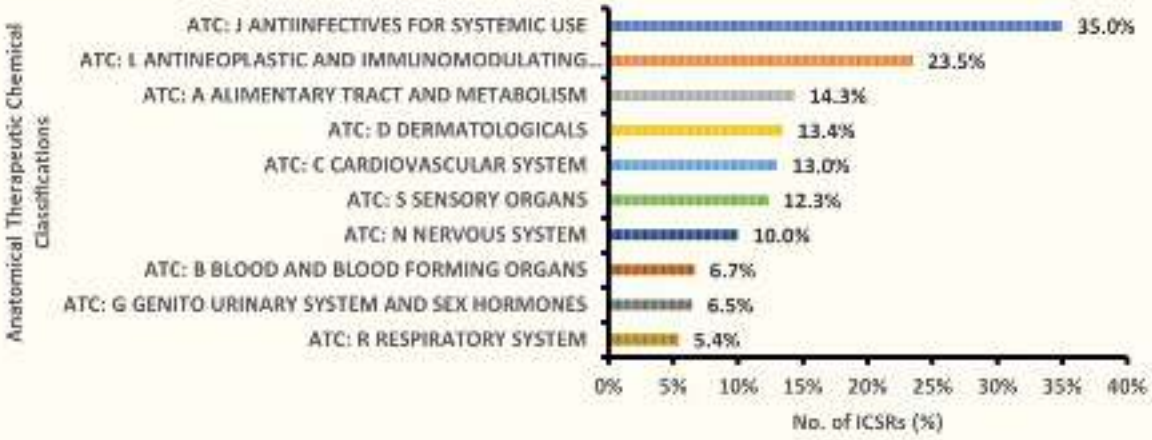


Figure - 14. Distribution of ICSRs based on ATC Classification

Top 10 reported Preferred Term

The data reported in PvPI database revealed that the maximum percentage of adverse drug reactions (Preferred Term) reported was pyrexia (8.4%) coded by MedDRA dictionary.

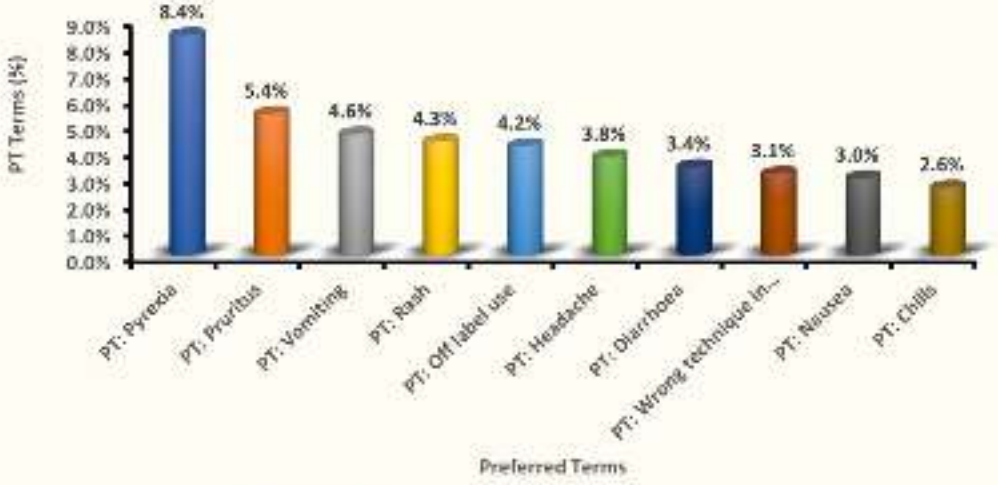


Figure - 15. Top 10 reported Preferred Term

Top 10 Active Ingredients reported in ICSRs

Analysis of Active Ingredients (AIs) from ICSRs revealed that COVID-19 vaccine (10.8%) was thehighest reported AI during this index period.

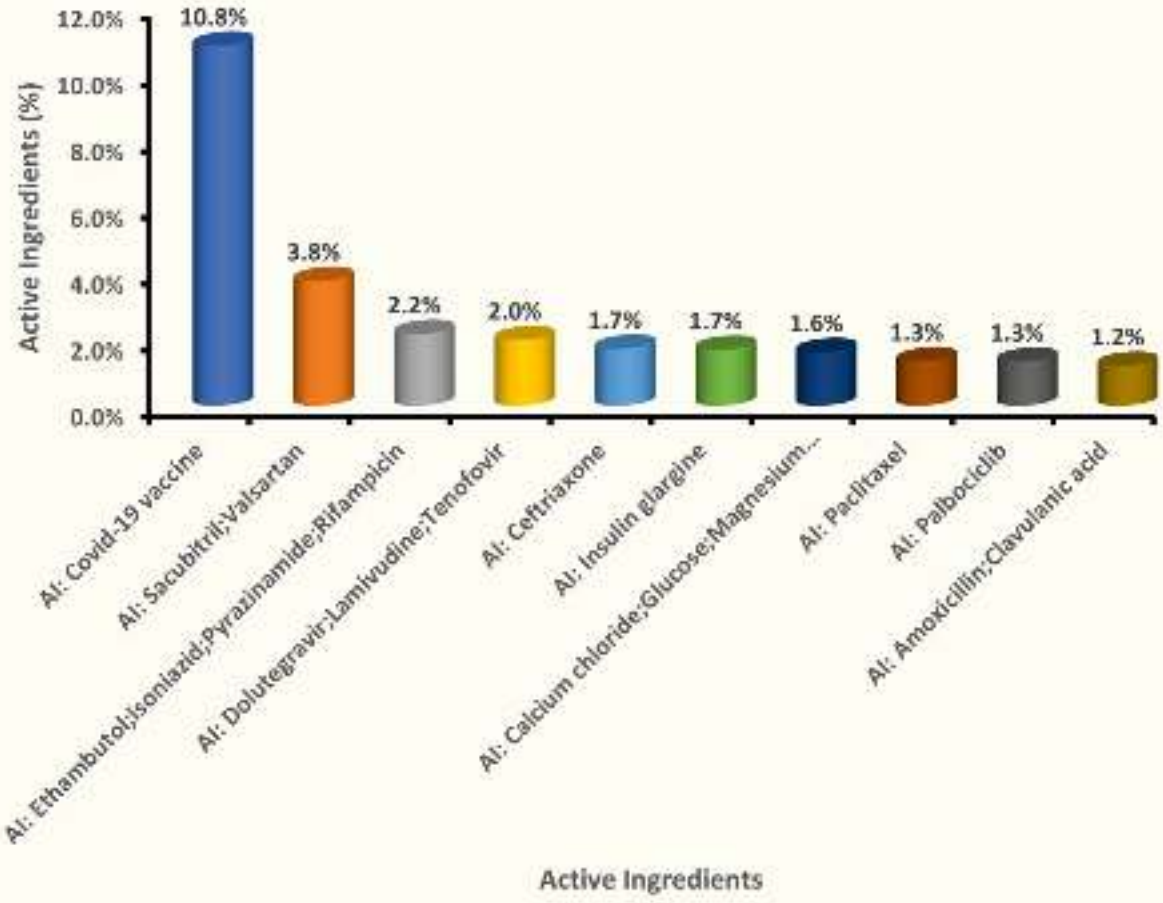


Figure - 16. Top 10 reported Active Ingredients

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 AMC under PvPI (Non-AMCs) across India. The Non-AMCs sent the filled in 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, 1203 ICSRs were reported via Non-AMCs. month-wise distribution of these ADRs are as given above.

Figure - 17. Month-wise ICSRs received from non-AMCs

ICSRs received via PvPI Helpline

Tollfree Helpline was initiated on October 11, 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 Tollfree Helpline. Calls are primarily responded in English and Hindi on all working days between 9:00 AM and 5:30 PM. A total of 391 ICSRs were received through Tollfree Helpline, the month-wise distribution of such ICSRs are as given below:

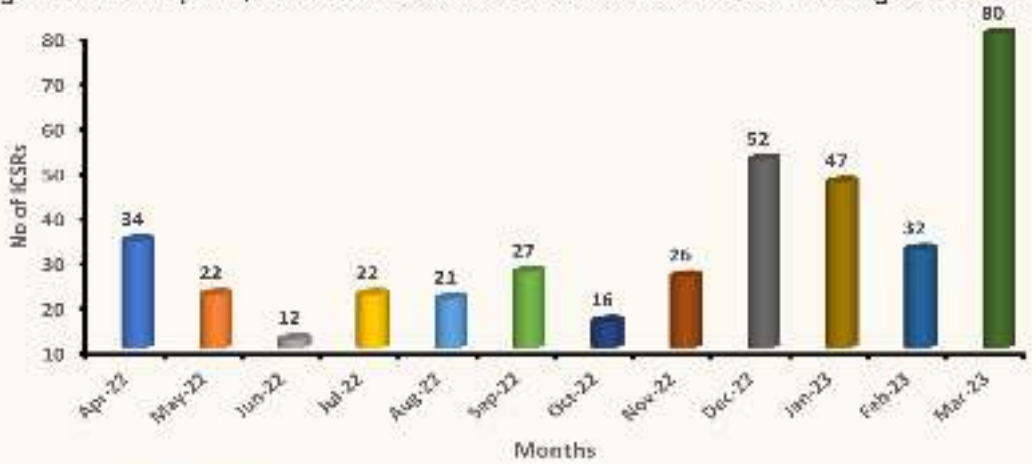


Figure - 18. Month-wise ICSRs received from PvPI Helpline (Tollfree)

India secured 9th position among WHO PIDM Member countries

During this index period, India has contributed 2.8% ICSRs and was the 7th largest contributor of ICSRs submission to in VigiBase. Overall, India ranked 9th position among 176 World Health Organization (WHO) Programme for International Drug Monitoring (PIDM) member countries in terms of submission of ICSRs to in VigiBase.

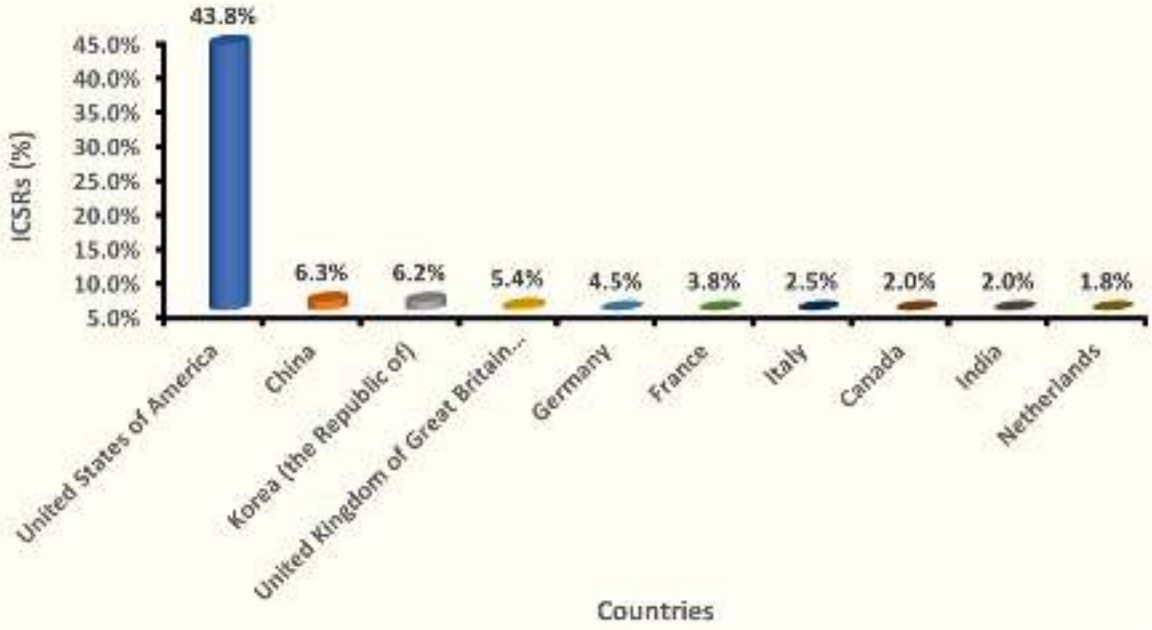


Figure - 19. Top 10 reporting countries

Contribution by MAHs

Marketing Authorization Holders (MAHs) play a crucial role in reporting AEs/ADRs to PvPI. The recent amendment to the Drugs and Cosmetics Rules, 1945 and New Drugs & Clinical Trials Rules 2019 (NDCT 2019 Rules), has made Pharmacovigilance 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 115 MAHs had submitted 55703 ICSRs to NCC-PvPI.

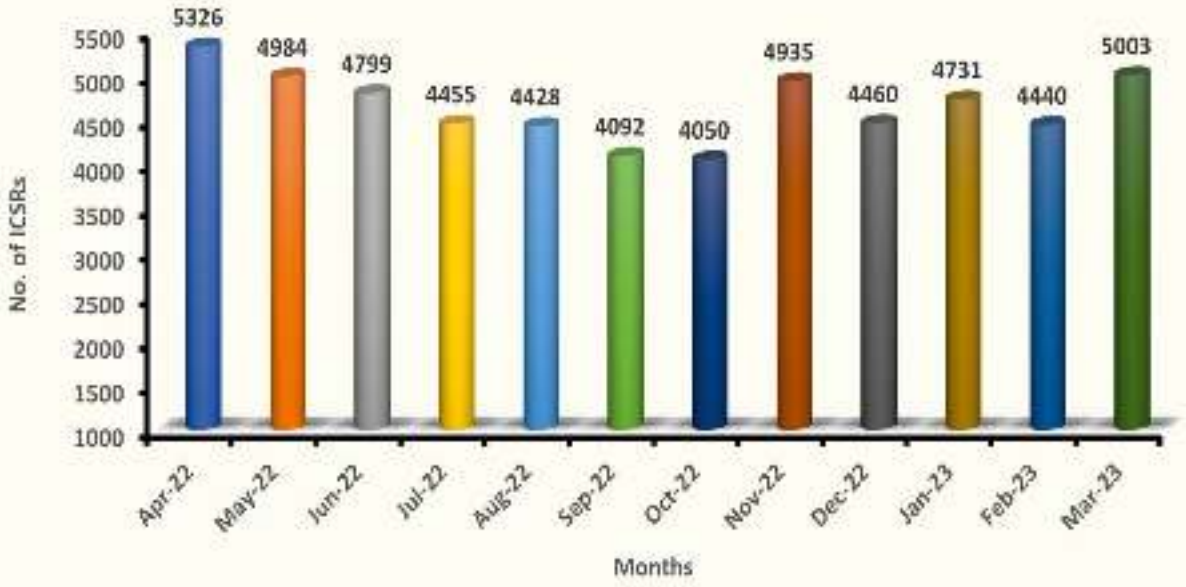


Figure - 20. Month-wise ICSR received from MAHs

List of Pharmaceutical Companies/MAHs Reporting ICSRs to PvPI

S. No.	MAHs	S. No.	MAHs
1.	Abbott India Limited	18.	Bayer Healthcare Limited
2.	Akums Drugs & Pharmaceuticals Limited	19.	Besins Healthcare
3.	Alcon Laboratories India (P) Ltd.	20.	Biocon Biologics Limited
4.	Alembic Pharmaceuticals Limited.	21.	Boehringer Ingelheim India (P) Ltd.
5.	Alkem Laboratories	22.	Bristol-Myers Squibb India
6.	Allergan India (P) Ltd.	23.	Bharat Serums And Vaccines Ltd.
7.	Amgen India	24.	Biological E Limited
8.	Amneal Pharmaceuticals	25.	Blue Cross Laboratories (P) Ltd.
9.	Apotex Research (P) Ltd.	26.	Cadila Pharmaceuticals Limited
10.	Arcolab (P) Ltd.	27.	Centaur Pharmaceuticals (P) Ltd.
11.	Aristo Pharmaceuticals (P) Ltd.	28.	Cipla Limited
12.	Astellas Pharma India (P) Ltd.	29.	Concord Biotech Limited
13.	Astral SteriTech (P) Ltd.	30.	CSL Behring
14.	AstraZeneca Pharma India Limited	31.	Dr Reddy's Laboratories
15.	Aurobindo Pharma Limited	32.	EISAI Pharmaceuticals India (P) Ltd.
16.	AXA Parenterals Limited	33.	Eli Lilly & Company (India) (P) Ltd.
17.	Baxter (India) (P) Ltd.	34.	Emcure Pharmaceuticals Limited

35.	Encube Ethicals (P) Ltd.	54.	Inventia Healthcare
36.	Eris Lifesciences Limited	55.	Italfarmaco SpA
37.	Exeltis India (P) Ltd.	56.	IPCA Laboratories Limited
38.	FDC Limited	57.	J. B. chemicals and Pharmaceuticals Limited
39.	Ferring Pharmaceuticals (P) Ltd.	58.	Johnsons & Johnsons (P) Ltd.
40.	Fidia Farmaceutici S.p.A	59.	Jubilant Generics Limited
41.	Fresenius Kabi Oncology Limited	60.	Kedrion Bio Pharma
42.	Fresenius Kabi India (P) Ltd.	61.	Levim Biotech LLP
43.	Fresenius Medical Care India (P) Ltd.	62.	LG Chem Life Sciences India (P) Ltd.
44.	Glaxo Smithkline Pharmaceuticals Limited	63.	Lupin Limited
45.	Glenmark Pharmaceuticals	64.	Lundbeck Pharmaceutical Company
46.	Galderma India (P) Ltd.	65.	Macleods Pharmaceuticals Limited
47.	Grifols India Healthcare (P) Ltd.	66.	Madras Pharma
48.	Guerbet India (P) Ltd.	67.	MERCK Limited
49.	Gilead Sciences	68.	Micro Labs Limited
50.	Gufic Biosciences	69.	MSD Pharmaceuticals Limited.
51.	Hetero Labs Limited	70.	MSN Laboratories (P) Ltd.
52.	Imaging Products India (P) Ltd.	71.	Mylan Laboratories (P) Ltd.
53.	Intas Pharmaceuticals Limited	72.	Mankind Pharma

73.	Novartis India Limited	87.	Reckitt Benckiser (India) Limited
74.	Novo Nordisk India	88.	RPG Life Sciences
75.	Nitin Life Sciences	89.	Rusan Pharma Limited
76.	Optimus Pharma (P) Ltd.	90.	Sandor Medicaids (P) Ltd.
77.	Organon & Company	91.	Samrudh Pharmaceuticals (P) Ltd.
78.	Otsuka Pharmaceutical India (P) Ltd.	92.	Sanofi India Limited
79.	Paviour Pharmaceuticals	93.	Santen India (P) Ltd.
80.	Pfizer Limited	94.	Servier India Private Limited
81.	Piramal Pharma Limited	95.	Shilpa Medicare Limited
82.	The Procter & Gamble Company	96.	Shire Biotech India (P) Ltd.
83.	Panacea Biotec Limited	97.	Strides Shasun Limited
84.	Roche Products (India) (P) Ltd.	98.	Sovereign Pharma (P) Ltd.
85.	Reliance Life Sciences	99.	Sun Pharmaceuticals Industries Limited
86.	Recipharm AB	100.	Septodont Healthcare India (P) Ltd.

101.	Takeda Pharmaceutical Company	109.	Venus Remedies Limited
102.	Tirupati Medicare Limited	110.	Vifor Pharma (P) Ltd.
103.	Torrent Pharmaceuticals Limited	111.	Vivere Imaging (P) Ltd.
104.	Themis Medicare Limited	112.	Win Medicare (P) Ltd.
105.	Troikaa Pharmaceuticals Limited	113.	Windlas Biotech Limited
106.	UCB India (P) Ltd.	114.	Wipro GE Healthcare (P) Ltd.
107.	UNS Pharmacovigilance	115.	Wockhardt Pharmaceutical Limited
108.	USV (P) Ltd.		

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 9001:2008 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. PvPI performance with reference to the pre-defined objectives was evaluated by the officials of Quality Council of India & Quality Accreditation Institute and evaluation report was submitted to the MoHFW, Govt. of India for further extension of the Programme for the next five years (FY: 2021-2026).

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 of 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 ADR 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 of documents
20.	SOP for handling of medication error, lack of therapeutic efficacy ICSRs
21.	SOP for enrolment of new AMCs under PvPI
22.	SOP for functioning of Working Group
23.	SOP for functioning of Steering Committee
24.	SOP for Delisting of AMCs under PvPI
Signal Detection	
25.	SOP for operational functioning of SRP
26.	SOP for functioning of SRP
27.	SOP for data miming of SUSARs and non-serious ADRs/AEs from VigiFlow
PV Regulatory Affairs	
28.	Processing of ICSRs reported by MAHs
National Health Programmes	
29.	SOP for coordination between PvPI and NHPs
30.	Processing & communication of AEFI-ICSRs

Training and Education	
31.	SOP to conduct training under NCC-PvPI
32.	SOP for Functioning of 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 Publications	
35.	SOP for drafting, publication, distribution and control of resource material of PvPI
36.	SOP for publication and communication between PvPI and stakeholders
Information Technology	
37.	SOP for data integrity
38.	VigiFlow login distribution and retrieval procedure
39.	SOP for establishing link at the Ministry of Health and Family Welfare web portal for the PvPI
Human Resources	
40.	SOP for the recruitment of contractual employee under NCC-PvPI IPC
41.	SOP for the job responsibility of employee under NCC-PvPI IPC
42.	SOP for conducting teleconference meeting with AMCs 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 Reaction/ Events report by Non-AMC to NCC- PvPI
47.	SOP for receiving ADR from healthcare professionals and consumers through PvPI helpline

Quality of ICSRs Reporting

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 line). The average completeness score for the last quarter of the index period accounts for about 0.75 out of 1.

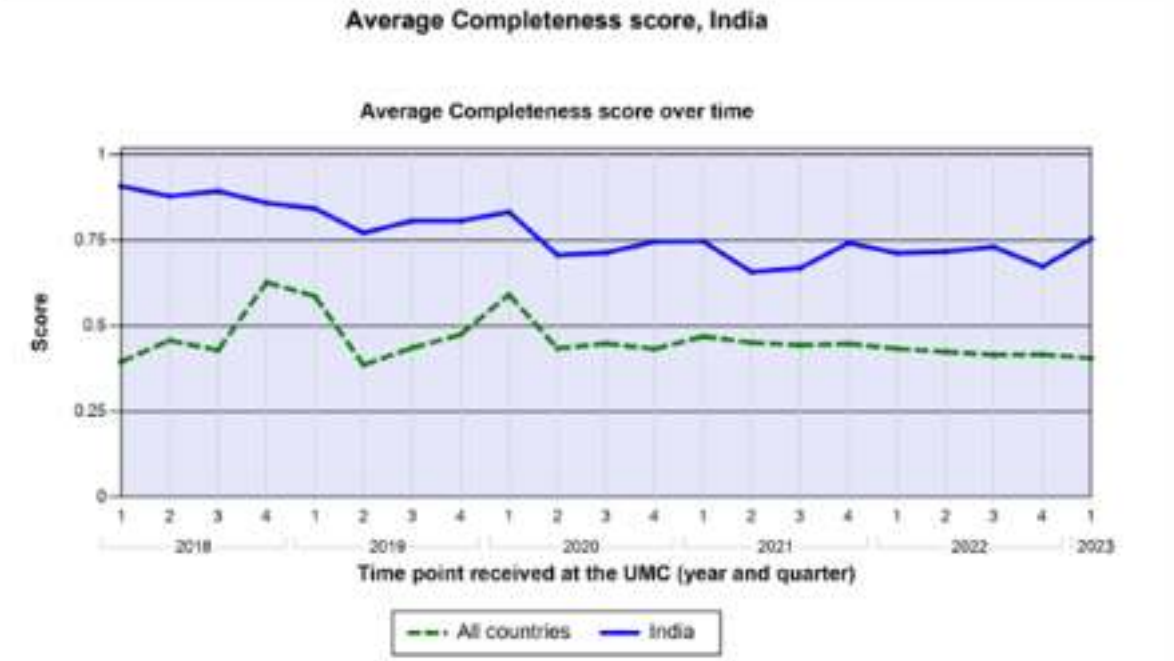


Figure - 21. Graphical representation of VigiGradeTM Completeness score of quality of ICSRs submitted by PvPI to UMC database

Newly enrolled Adverse Drug Reaction Monitoring Centers (AMCs) under PvPI

NCC-PvPI, IPC has enrolled 167 new AMCs (Government - 27 + Non-Government - 140) across the country, the total number of AMCs have increased from 534 to 701 since last FY 2021-22. However, 10 AMCs were delisted also on 24th March 2023. So, the current strength of AMCs is 691 as on 31st March 2023 and the list of new AMCs enrolled during this tenure is mentioned below:-.

S. No.	States/UTs	Name of Hospital/Medical College/Institute	Status
1.	Andhra Pradesh	Mahatma Gandhi Cancer Hospital & Research Institute Pvt. Ltd. (A unit of Vizag Cancer Hospital & Research Centre Pvt.Ltd.) 1/7, MVP Colony, Visakhapatnam, Andhra Pradesh-5300017	Non-Government
2.		Dr. Pinnamaneni Siddhartha Institute of Medical Sciences & Research Foundation Chinoutpally, Gannavaram, Krishna, Andhra Pradesh-521286	
3.		HCG Curie City Cancer Centre Padavalarevu, Machavaram Down, Gundala, Vijaywada, Andhra Pradesh-520004	
4.		Nagarjuna Hospital Ltd. Kanuru, Vijayawada, Andhra Pradesh-520007	
5.		Sentini Hospital No.-54-15-5 B & C, Opp. Novetel Hotel, Ring Road, Vijayawada, Andhra Pradesh-520008	
6.		Sri Venkateshwara Institute of Cancer Care & Advanced Research Alipiri Road, Tirupati, Andhra Pradesh-517501	
7.		Health Care Global Enterprises Ltd., HCG Cancer Centre, Pinnacle Hospital Compound, Apiic Health City, Arilova, Chinnagadiu, Vizag, Andhra Pradesh-530040	

8.		Pinnacle Hospitals Plot No. 10, 11 & 12, Sy. No. 13P, APIIC, Health City. Chinna Gadhili, Visakhapatnam, Andhra Pradesh-530040	
9.		Surya Global Hospitals Near Railway Crossing, Madhavapatnam, Kakinada, Andhra Pradesh - 533005	
10.		Aster Narayanadri Hospitals National Highway 71, Renigunta Rd. SV Auto Nagar, Tirupati, Andhra Pradesh-517506	
11.		Omni Hospital (A Unit of Incor Hospital Vizag Pvt. Ltd.) 10-50-55, Waltair Main Road, Ramnagar, Visakhapatnam, Andhra Pradesh-530002	
12.		Sree Ramadevi Multi Super Speciality Hospital 82, Sai Ram Street, Tirupati, Andhra Pradesh-517501	
13.		Rajiv Gandhi Institute of Medical Sciences (RIMS) 5th Lane, Bhagya Nagar, Ongole, Andhra Pradesh-523001	Government
14.		Siddhartha Medical College Vijayawada, Andhra Pradesh-520008	
15.		Government Medical College & Hospitals Ananthapuram Anantapur, Andhra Pradesh-515001	
16.	**Bihar**	Big Apollo Spectra Hospital Sheetla Mandir Road, Near Sump House, Agamkuan, Patna, Bihar-800007	Non-Government
17.	**Chhattisgarh**	Rajmata Shrimati Devendra Kumari Singhdeo Govt. Medical College Ambikapur, Surguja, Chhattisgarh-497001	Government
18.		Shri Balaji Metro Hospital Pahad Mandir Road, Village - Kauhakunda, Raigarh, Chhattisgarh-496001	Non-Government

19.	Gujarat	HCG Hospitals Mithakhali Six Road, Kalyan Society, Ems Bridge, Ahmedabad, Gujarat-380006	Non-Government
20.		Banas Medical College & Research Institute Oriya Village, Banaskantha, Gujarat-385001	
21.		Kanba Hospital - Unit of Lakhani Hospitals Pvt. Ltd. Ahmedabad, Gujarat-382350	
22.		Bhailal Amin General Hospital Vadodara, Gujarat-390003	
23.		SGVP Holistic Hospital, SGVP Campus Opp. Nirma University, Ahmedabad, Gujarat-382481	
24.		Gujarat Adani Institute of Medical Sciences G K General Hospital Campus, Opp. Lotus Colony, Bhuj, Kachchh, Gujarat - 370001	
25.		Motas Adventist Hospital PB No. 24, Athwalines, Surat, Gujarat-395001	
26.		Sunshine Global Hospital Beside Big Bazar, Dumas Road, Surat, Gujarat-395007	
27.		K. B. Institute of Pharmaceutical Education & Research, Sec.23, GH-6 Rd.,Gandhinagar, Gujarat-380023	
28.		Asutosh Hospital Beside Kshetrapal Mandir, Kailash Nagar, Magura Gate, Surat, Gujarat-395002	
29.		HCG Hospital 1139 Sir Pattani Road, Meghani Circle, Bhavnagar, Gujarat-364001	
30.		Haria L. G. Rotary Hospital 363/1&364, Housing Sector, GIDC, Vapi, Valsad, Gujarat-396195	

31.	Haryana	Adesh Medical College & Hospital Dept. of Pharmacology, Mohri, Kurukshetra, Haryana-136135	Non-Government
32.		Medeor Hospital Limited Plot - P - 2, Sector - 5, IMT Manesar Gurugram, Haryana-122051	
33.		Sarvodaya Multispeciality and Cancer Hospital Opp.Red Cross Bhawan, Hisar,Haryana-125001	
34.		Anand Orthopaedic Centre Opp. Theme Park, Near Panorama, Thanesar, Kurukshetra, Haryana-136118	
35.		Shanti Devi GI Institute & Advanced Endoscopy Centre, Hisar, Haryana-125001	
36.		Aarvy Healthcare Super Specialty Hospital Gurgaon, Haryana-122505	
37.		Supreme Hospital Charmwood Village, Eros Garden, Surajkund Road, Faridabad, Haryana-121009	
38.		Narayana Super Speciality Hospital Gurugram, Sector-24, DLF Phase - III, Haryana-122002	
39.		Sunflag Global Hospital Sonepat Road, Opp. Rivoli Hotel, Near Sheela Bypass, Rohtak, Haryana-124001	
40.		Nidaan Hospital Murthal Road, Sonipat, Haryana-131001	
41.		Oscar Super Speciality Hospital & Trauma Center GT Road, Opp. PVR Mall, Sec.- 6, Panipat, Haryana-132103	
42.		Shri Balaji Aarogyam Hospital Pvt. Ltd. Behind Old Bus Stand, Kurukshetra, Haryana-136118	

43.		Sidharth Hospital Shahabad Markanda, Distt. K.K.R, Haryana-136135	
44.		Oxygen Hospital Bhivani Stand, Rohtak, Haryana-124001	
45.		Mann Multispeciality Hospital Subhash Road, All India Radio Station, Rohtak, Haryana-124001	
46.		Park Hospital G T Road, NH-1, Sowah, Panipat, Haryana-132103	
47.	**Himachal Pradesh**	Shri Sai Multi Speciality Hospital & Trauma Centre 445/12, Chakreda Road, Nahan, Sirmour, Himacha Pradesh-173001	Non-Government
48.	**New Delhi**	Medeor Hospital B-33, 34 Qutab Institutional Area, New Delhi- 110016	Non-Government
49.		RLKC Hospital - Metro Heart Institute Pandav Nagar, Nariana Roar, New Delhi-110008	
50.		Moolchand Hospital Lajpat Nagar - III, New Delhi-110024	
51.		Saroj Super Speciality Hospital Madhuban Chowk, Sector-14, Ext. Rohini, Delhi-110085	
52.		Goyal Hospital & Urology Centre E-4/8, Krishna Nagar, Delhi-110051	
53.		Park Hospital West Delhi 12, Meera Enclave, New Delhi-110018	
54.		Atal Bihari Vajpayee Institute of Medical Sciences & Dr. RML Hospital, Connaught Place, New Delhi-110001	

55.		Venkateshwar Hospital Sector 12 RD, Sector 18A, Dwarka, New Delhi-110075	
56.		Mata Roop Rani Maggo Hospital C-8,9, Om Vihar, Phase 1, Uttam Nagar, New Delhi-110059	
57.		Holy Family Hospital Okhla Rd., South East Distt., New Delhi-110025	
58.		Bhagat Chandra Hospital (A Unit of Bhagat Hospitals Pvt. Ltd.) Room 59 No.6, B Building, 6th Floor, Mahavir Enclave, New Delhi-110045	
59.	Karnataka	People Tree Hospitals A unit of TMI Healthcare Pvt. Ltd., No. 2, Tumkur Road, Goraguntepalya, Yeshwantpur, Bangalore, Karnataka-560022	Non-Government
60.		Dr. Janu Mankikars Memorial Hospital Maternity & Nursing Home A/652/8 Subhash Road, Kumta Taluk, Uttar Kannada, Karnataka-581343	
61.		Aster RV Hospital CA-37, 24th Main, 1st Phase, JP Nagar, Bengaluru, Karnataka-560078	
62.		Togari Veeramallappa Memorial College of Pharmacy, Ballari, Karnataka-583104	Government
63.	Kerala	Noorul Islam Institute of Medical Science & Research Foundation, (NIMS Medicity) Aralummoodu P.O. Neyyatinkara, Thiruvananthapuram, Kerala-695123	Non-Government
64.		Iqra International Hospital & Research Centre, Malaparamba, Calicut, Kerala-673009	
65.		Chazhikattu Hospital Pvt. Ltd. Idukki, Kerala-685584	

66.		SP Fort Hospital Fort Anakottil Lane, Distt-Thiruvanathapuram, Kerala-695023	
67.		Malabar Hospital (P) Ltd. Karuvambrum (Post) Rajiv Gandhi Bypass Road, Manjeri, Malappuram, Kerala-676123	
68.		Atreya Hospital (A Unit of DMRI) East Fort, Wear St. Llare School. Thrissur. Kerala-680005	
69.		PRS Hospital Pvt. Ltd. Block No. 1, Killipalam Karamana (P.O.) Thiruvananthapuram, Kerala-695002	
70.		Sree Uthradom Thirunal Hospital Near Palace View Road, Vrndavan Garden, Pattom. Thiruvananthapuram, Kerala-695004	
71.		Mar Sleeva Medicity Palai. Cherpunkal, Kottayam, Kerala-686584	
72.		Avitis Super Specialty Hospitals Pvt. Ltd. XX/882. Thrissur. Pollachi Main Road, Near Jabamalarani Church. Nemmara. Kerala-768508	
73.		MES Medical College Perinthalmanna. Palachode PO, Malappuram, Kerala-679338	
74.		Caritas Hospital Thellakom. Kottayam, Kerala-686630	
75.		Government Medical College HMT Colony (PO) Kalamassery, Emakulam. Kerala-683503	Government

76.	Madhya Pradesh	MGM Medical College Dept. of Pharmacology, A. B. Road, Infront of Suyash Hospital, Indore, Madhya Pradesh-452001	Non-Government
77.		Suyash Hospital Pvt. Ltd. AB Road, Indore, Madhya Pradesh-452001	
78.		Baderia Metropime Multispeciality Hospital Kuchaini Panishan, Behind Kshetriya Bus Stand, Damoh Naka, Jabalpur, Madhya Pradesh-482002	
79.		BIMR Hospitals, Surya Mandir Road, Resedency Gwalior, Madhya Pradesh-474005	
80.		Shyam Shah Medical College 1st Floor, Near Dhobiya Tanki, Rewa, Madhya Pradesh-486001	Government
81.	Maharashtra	Ashoka Medicover Hospitals Indira Nagar, Wadala Road, Nashik, Maharashtra-422009	Non-Government
82.		Prakash Institute of Medical Sciences & Research Vrun-Islampur, Maharashtra-415409	
83.		Saifee Hospital 15/17 Maharshi Karve Road, Charni Road Station, Mumbai, Maharashtra-400004	
84.		Saideep Healthcare & Research Pvt. Ltd. Yashwant Colony, Viraj Estate, Tarakpur, Ahmednagar, Maharashtra-414001	
85.		Krupamayi Hospitals Railway Station Road, Aurangabad, Maharasthra-431001	
86.		School of Pharmacy Dr. Vishwanath Karad MIT World Peace University, Pune, Maharashtra-411038	

87.		Alexis Multispeciality Hospital Koradi Road, Nagpur, Maharashtra-440030	
88.		Dr. Hedgewar Hospital Garkheda Parisar, Aurangabad, Maharashtra-431009	
89.		Dr. G M Taori Central India Institute of Medical Sciences 88/2 Bajaj Nagar, Nagpur, Maharashtra-40010	
90.	**Manipur**	Shija Academy of Health Sciences Health Village, Imphal West, Manipur-795004	Non- Government
91.	**Mizoram**	Mizoram State Cancer Institute (MSCI) Aizawl, Mizoram-776017	Government
92.	**Odisha**	Jaiprakash Hospital & Research Centre Pvt. Ltd. Dayanand Nagar, Rourkela, Sundargarh, Odisha-769004	Non- Government
93.	**Puducherry**	JIPMER (Academic & Lab Complex) Kalam Campus, FCI Road, Kovilpathu, Karaikal, Puducherry-609605	Government
94.	**Punjab**	Neelam Hospital NH-7 (64) Opposite Chitkara University, Rajpura Chandigarh Highway, Rajpura, Punjab-140401	Non- Government
95.		Abrol Medical Centre Super Speciality Hospital Kailash Enclave, Batala Road, Gurdaspur, Punjab-143521	
96.		EMC Super Speciality Hospitals Pvt. Ltd. Green Avenue, Amritsar, Punjab-143001	
97.		Orison Super Speciality Hospital Infertility and Trauma Centre Ludhiana, Punjab-49012	
98.		Global Heart and Super Speciality Hospital Near Octroi Post, Ferozepur Road, Ludhiana, Punjab-141012	

99.		Prakash Hospital G.T. Road, Putlighar, Amritsar, Punjab-143001	
100.		Gian Sagar Medical College and Hospital Village Ram Nagar, Tehsil Rajpura, Patiala, Punjab-140506	
101.	Rajasthan	Krishna Heart & General Hospital 138, Prem Niwas, Gopalpura Bypass, Jaipur, Rajasthan-302019	Non-Government
102.		Heart & General Hospital 7-Vivekand Marg, C- Scheme, Ashok Nagar, Jaipur, Rajasthan-302001	
103.		Rungta Hospital Malviya Nagar, Jaipur, Rajasthan-302017	
104.		Saket Medicare & Research Center Mansarovar, Jaipur, Rajasthan-302020	
105.		Healthcare Global Hospital Mansarovar, Jaipur, Rajasthan-302020	
106.		Eternal Hospital (EHCC) Eternal Health Care Centre & Research Institute Jagatpura, Jaipur, Rajasthan-302017	
107.		Imperial Hospital & Research Centre Shastri Nagar, Jaipur, Rajasthan-302006	
108.		Mittal Hospital & Research Centre Ajmer, Rajasthan-305004	
109.		Swastik Multispeciality Hospital CP-1, RIICO Industrial Area, Narena Road, Rajasthan-303008	
110.		Solanki Hospital 10, Ram Kutir, Ashok Circle, Alwar, Rajasthan-301001	
111.		District TB Clinic Opp. AKH, Bewar (Ajmer), Rajasthan-305901	Government

112.	Tamil Nadu	Pankajam Memorial Hospital C-3, 4th Cross Street, Near Ranga Theatre, Hindu Colony, Nanganallur, Chennai, Tamil Nadu-600061	Non-Government
113.		Government Thanjavur Medical College & Hospital. Department of Pharmacology, Thanjavur, Tamil Nadu-613004	
114.		Bhaarath Medical College & Hospital 173, Agaram Main Rd., Selaiyur, Chennai Tamil Nadu-600073	
115.		Swamy Vivekanandha Medical College Hospital and Research Institute Unjanai, Elayampalayam, Tiruchengode, Namakkal District, Tamil Nadu-637205	
116.		Apollo Speciality Hospitals Madurai, Tamil Nadu-625020	
117.		Kauvery Hospital Tiruchirapalli, Tamil Nadu-620001	
118.		Scudder Memorial Hospital Ranipet, Tamil Nadu-632401	
119.		Christudas Orthopaedic Speciality Hospital COSH Multi Speciality Hospital, No:9, IAF Road, Duraisamy Nagar, East Tambaram, Chennai, Tamil Nadu-600059	
120.		Dhanalakshmi Srinivasan Medical College & Hospitals Siruvachur, Perambalur, Tamil Nadu-621113	
121.		Faculty of Medicine, Sri Lalithambigai Medical College and Hospital Maduravoyal, Ambattur Service Road, Adayalampattu, Chennai, Tamil Nadu-600095	

122.		Govt. Medical College Dept. of Pharmacology, Ariyalur, Tamil Nadu-621713	Government
123.		National Institute of Research in Tuberculosis No. 1, Mayor Sathiyamoorthy Road, Chetpet, Chennai, Tamil Nadu-600031	
124.	**Telangana**	Landmark Hospitals MCK Block 2, Near JNTU Metro Station, Opposite Vasanth Nagar Arch, Hyderabad, Telangana-500085	Non-Government
125.		Omni Hospitals H. No. 11-9-46, Opp. to Pvt. Market, Kothapet, Dilsukhnagar, Hyderabad, Telangana-500035	
126.		Udai Omni Hospitals Fateh Maidan, Abids, Hyderabad, Telangana-500001	
127.		Prathima Hospitals Kochiguda Hyderabad, Telangana-500027	
128.		Pace Hospital Hitech City, Hyderabad, Telangana-500081	
129.		Yashoda Hospitals Alexander Road, Secunderabad, Telangana-500003	
130.		Mamata Medical College Mamata General Hospital Campus, Giriprasad Nagar, Khammam, Telangana-507002	
131.		Malla Reddy Narayana Multispeciality Hospital Suraram 'X' Road, Jeedimetla, Qutubullapur, Hyderabad, Telangana-500055	
132.		Pranaam Hospitals #1-58/6/40 & 41, Madinaguda, Miyapur, Hyderabad, Telangana-500050	

133.		Government Medical College Sangareddy, Telangana-502001	Government
134.		Government Medical College Wanaparthy, Telangana-509103	
135.		Government Medical College Nagarkurnool, Govt. General Hospital, Nagarkurnool, Telangana-509209	
136.	**Uttar Pradesh**	Vivekananda Polyclinic and Institute of Medical Sciences Vivekananda Puram, Lucknow, Uttar Pradesh-226007	Non-Government
137.		Navin Hospital NH-1, Sector-3, Vaishali, Near Mahagun Mall, Ghaziabad, Uttar Pradesh-201010	
138.		Sharma Medicare Pvt. Ltd. NH - 19 / A, L - Block Delta - 2, Greater Noida, Uttar Pradesh-201308	
139.		Bhardwaj Hospital NH- 1, Sec - 29, Noida, Gautam Buddha Nagar, Uttar Pradesh-201301	
140.		IIMT College of Pharmacy, Plot No.-19 & 20, KP-111, Greater Noida Uttar Pradesh-201310	
141.		Ivory Hospital Pvt. Ltd. NH - 25, Pocket - E, Sector - 36 (RHO - 1) Greater Noida, Uttar Pradesh-201310	
142.		F. H. Medical College Near Railway Bridge NH - 2, Tundla, Firozabad, Uttar Pradesh-283204	
143.		St. Joseph Hospital Gomti Nagar, Lucknow, Uttar Pradesh-226010	
144.		SJM Super Speciality Hospital, Sec-63, Noida, Uttar Pradesh-201307	

145.		Yatharth Super Speciality Hospital and Heart Centre Sec-110, Noida, Uttar Pradesh-201304	
146.		Ajanta Hospital and IVF Centre Pvt. Ltd. Alambag Lucknow, Uttar Pradesh-226005	
147.		Fortis Hospital Noida B-22, Sector-62, Noida, Uttar Pradesh-201301	
148.		Le Crest Hospital Plot No. Ins 13, Sec-04 (Near Budh Chowk), Vasundhara, Ghaziabad, Uttar Pradesh-201012	
149.		Krishna Institute of Pharmacy and Sciences Gram - Amiliha, Post - Tatiyaganj Mandhana, Kanpur, Uttar Pradesh-209217	
150.		Maharaja Suhel Dev Autonomous State Medical College & Mahrishi Balark Hospitals KDC Road, Baharaich, Uttar Pradesh-271801	Government
151.		S. N. Medical College Dept. of Pharmacology, Academic block, Agra, Uttar Pradesh-282002	
152.		Maharshi Vashishtha Autonomous State Medical College Basti, Village - Rampur, Uttar Pradesh-272124	
153.		Autonomous State Medical College S. N. M. Hospital & TB Sanitorium Near Jain Mandir, Subhash Tiraha, Firozabad, Uttar Pradesh-283203	
154.		All India Institute of Medical Sciences Dalmau Road, Raebareli, Uttar Pradesh-229405	
155.		Government Medical College Kannauj (Tirwa), Uttar Pradesh-209732	
156.		SMMH Government Medical College, Pilakhni Area, Ambala Road, Saharanpur, Uttar Pradesh-247001	

157.	**Uttarakhand**	Gautam Buddha Chikitsa Mahavidyalaya & Dr. KKBM Subharti Hospital Jhajna, NH-72, Chakrata Road, Dehradun Uttarakhand-248007	Non-Government
158.	**West Bengal**	Medical College, Kolkata 88, College Street, Kolkata,West Bengal-700073	Government
159.		ESI-PGIMSR and ESI Medical College Department of Pharmacology, 7'' Floor Academic Building, Joka, Kolkata, West Bengal-700104	
160.		Deben Mahata Government Medical College & Hospital Hatuara, Purulia, Vivekananda Nagar, West Bengal-723147	
161.		All India Institute of Medical Sciences Kalyani, NH-34 Connector, Basantpur, Saguna, Nadia, West Bengal-741245	
162.		B. M. Birla Heart Research Centre - A unit of the Calcutta Medical Research Institute 1/1 National Library Avenue, Kolkata, West Bengal-700027	Non-Government
163.		Narayana Multispeciality Hospital Barasat 78, Jessore RD, South, Kolkata West Bengal-700127	
164.		B. P. Poddar Hospital & Medical Research Ltd. 71/1, Humayun Kabir Sarani, New Alipore, Block G, Kolkata, West Bengal-700053	
165.		Narayana Super Speciality Hospital Shibpur, Howrah, West Bengal-711103	
166.		Apollo Multi Speciality Hospitals 58 Canal Circular Rd, Kolkata, West Bengal-700054	
167.	**UT of Dadra and Nagar Haveli & Daman and Diu**	Namo Medical Education and Research Institute and Shri Vinoba Bhave Civil Hospital S. R. Delkar Marg, Saily Road, Silvassa, West Bengal-396230	Government

Following AMCs were delisted from PvPI due to their zero reporting:

S. No.	Name of AMCs with ID	Year of Enrolment
1.	Aundh Chest Hospital 1st Floor, Near Sangavi Phata, Aundh Camp, New Sangavi, Pune Maharashtra-411027- (ACH-Pune)	2015
2.	Babu Ishwar Saran District Hospital Gonda, Uttar Pradesh – 271001, (BISDH-Gonda)	2017
3.	Combined District Hospital Santkabir Nagar, Uttar Pradesh – 272175, (CDH-Santkabir Nagar)	2017
4.	Combined District Hospital Bhinga, Shrawasti, Uttar Pradesh – 271831, (CDH-Shrawasti)	2017
5.	District Hospital Gurunanak Chauraha, Hospital Road, Bahraich, Uttar Pradesh – 271801, (DH-Bahraich)	2017
6.	District Male Hospital Pratapgarh, Uttar Pradesh- 230001, (DH-Pratapgarh)	2017
7.	Glocal Group of Hospitals Glocal Healthcare System Pvt. Ltd. 3B-207, Ecospace Business Park, Action Area II, New Town, Rajarhat, Kolkata, West Bengal -700156, (GGH-Kolkata)	2017
8.	Government Medical College Kalpi Road, Orai, Jalaun, Uttar, (GMC-Jalaun)	2017
9.	Sri Krishna Medical College & Hospital Umanagar, Muzaffarpur, Bihar-842004, (SKMCH-Muzaffarpur)	2017
10.	Spandan Multispecialty Hospital Besides Ward No. 4, Sindhwai Mata Road, Vadodara, Gujarat-390011, (SMH-Vadodra)	2017

Signal, Prescribing Information Leaflets changes and Drug Safety Alerts

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 is 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 (χ2)
(iv) Number of Drug-Event combinations

(i) Information Component (IC)

The Information Component initially originated from the Bayesian Confidence 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 = log2 (Observed + 0.5/Expected) + 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 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 ICSRs can be expressed as a ratio, that is PRR. The PRR can be calculated by the following formula:

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

Where,

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

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

C = Numbers of Reaction of Interest reported with all other drugs

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

Criteria for Signal : PRR≥2

(iii) Chi-Square ($\chi 2$)

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:

$$\chi 2 = \Sigma \frac{(\text{Observed value} - \text{Expected value})^2}{(\text{Expected value})}$$

Criteria for Signal : $\chi 2 > 4$

(iv) Number of Drug-Event combinations

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

Criteria for Signal : $N_{ae} \geq 3$

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 Central Drugs Standard Control Organization (CDSCO) for taking appropriate regulatory actions as tabulated below:

Signal Review Panel Recommendations for regulatory actions

The NCC-PvPI evaluated spontaneously submitted ICSRs and further discussed in Signal Review Panel (SRP) meeting during indexed period. The outcomes of SRP meetings were communicated to the Central Drugs Standard Control Organization for appropriate regulatory actions as tabulated below:

S. No.	SRP Meeting	Suspected drugs	Adverse drug reactions	Outcome
1.	22nd SRP Meeting held on 22nd November, 2022	Paracetamol	Fixed Drug Eruption	Signal (To be include in PIL)
2.		Losartan	Muscle Spasm	To be include in PIL
3.		Piroxicam	Fixed Drug Eruption	To be include in PIL

Monthly Drug Safety Alerts Issued by IPC, NCC-PvPI

The IPC, NCC-PvPI has issued a total of 18 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(s)	Adverse drug reactions
1.	28th April, 2022	Cefuroxime	• Antibiotic- Indicated for lower & upper respiratory tract infection, UTI, gynaecological infection, skin or soft tissue infection etc. • Antibiotic- Indicated in the treatment of respiratory tract infections, UTI, ENT soft tissue infections etc.	Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)

2.	30th May, 2022	Itraconazole	• Systemic aspergillosis and candidiasis, cryptococcosis, sporotrichosis, Paracoccidioidomycosis, blastomycosis and other rarely occurring systemic or tropical mycoses. • Empiric therapy of febrile neutropenic patients with suspected fungal infections.	Symmetrical Drug Related-Intertriginous and Flexural Exanthema (SDRIFE)
3.	17th June, 2022	Trimetazidine	• Ischaemic heart disease, angina pectoris, sequalae of infarction. • Cardiac drug indicated in the treatment of angina pectoris and intermittent claudication.	Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)
4.	15th July, 2022	Tacrolimus	• For prophylaxis of transplant rejection in adult kidney or liver allograft rejection. • Prophylaxis of transplant rejection in kidney, liver or heart allograft recipient. • For prophylaxis of transplant rejection in liver, pancreas, lung, heart and kidney allograft recipients and treatment of allograft rejection resistant to treatment with other immuno- suppressive medicinal products. • By nephrologists only- for the prophylaxis of organ rejection in patients receiving allogenic kidney transplant. • For dermatologists-for treatment of patients with moderate to severe atopic dermatitis in whom the use of alternative conventional therapy is advisable.	Gingival Hypertrophy

5.	23rd August, 2022	Cefoperazone	Urinary infections, biliary infections, respiratory infections, infections of skin tissues, meningitis, septicaemia, Pseudomonas, Salmonella typhi & B. fragilis infections.	Coagulopathy
6.	26th September, 2022	Piroxicam	• In the treatment of rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, cervical spondylitis and other musculoskeletal disorder. • Anti-inflammatory agent- Indicated in the treatment of rheumatoid arthritis, ankylosing spondylitis and other musculoskeletal disorders. • Indicated in the treatment of musculoskeletal disorders, acute gout, pain after operative intervention following acute trauma and in primary dysmenorrhoea (12 years age or older)	Fixed Drug Eruption
7.	17th October, 2022	Amoxicillin	For treatment of urinary tract infections, upper respiratory-tract infections, bronchitis, pneumonia, otitis media, dental abscess, osteomyelitis, Lyme diseases in children, endocarditis prophylaxis, post-splenectomy prophylaxis, gynaecological infections, gonorrhoea, helicobacter pylori eradication enteric fever.	Fixed Drug Eruption

8.	28th November, 2022	Norfloxacin	• Antibacterial- Indicated in the treatment of acute uncomplicated/complicated chronic, recurrent urinary tract infections, including pyelonephritis, cystitis, urethritis & gonococcal infections. • Wide variety of infections caused by susceptible Gram +ve and Gram -ve organism including mixed infection in poultry.	Skin Hyperpigmentation
9.	26th December 2022	Minoxidil	For the treatment of alopecia (male pattern baldness in men).	Folliculitis
10	31st January 2023	Amphotericin B (Liposomal)	• Febrile Neutropenia in cancer patients. • For invasive fungal infection in patients who are refractory to or intolerant of conventional amphotericin B therapy. • By RMP- for the treatment of invasive fungal infection in patients who are refractory to or intolerant of conventional amphotericin-B therapy. • Indicated for the treatment of visceral leishmaniasis.	Hearing disorders
11.				Tachycardia
12.	20th February 2023	Cephalosporins	Cephalosporins are beta-lactam antimicrobials used to manage a wide range of infections from Gram-positive and Gram-negative bacteria.	Purpura
13.		Amikacin	Indicated in the treatment of serious infections due to amikacin sensitive organisms.	Vision blurred

14.	29th March 2023	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.	Hyponatraemia
15.		Nebivolol	For the treatment of essential hypertension	Hyperkalaemia
16.		Olmesartan	Use as an Anti-hypertensive	Muscle Spasm
17.				Taste Disorder
18.		Sulfasalazine	Use for the treatment of severe rheumatoid arthritis, ulcerative colitis; Crohn's diseases.	Visual Impairment

Training Division

The PvPI, IPC has organised a total of 1795 training and trained 109571 stakeholders in the area of Pharmacovigilance. NCC-PvPI has recognized twelve 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.	Regional Training Centres	States/UTs under purview	Year of Recognition
1.	All India Institute of Medical Sciences Bhopal	Madhya Pradesh and Chhattisgarh	2015
2.	All India Institute of Medical Sciences Rishikesh	Uttarakhand and Uttar Pradesh	2016
3.	BJ Medical College Ahmedabad	Gujarat, Rajasthan, Daman & Diu	2014
4.	Institute of Postgraduate Medical Education & Research Kolkata	Andaman Nicobar, West Bengal, Jharkhand, Bihar & Odisha	2011
5.	JSS Medical College Hospital Mysore	Karnataka, Kerala, Tamil Nadu, Puducherry and Lakshadweep	2011
6.	Nizam's Institute of Medical Sciences Hyderabad	Andhra Pradesh and Telangana	2015
7.	Post Graduate Institute of Medical Education and Research (PGIMER) Chandigarh	Jammu & Kashmir, Himachal Pradesh, Punjab, Haryana, Chandigarh and Delhi	2011
8.	Seth GS Medical College & KEM Hospital Mumbai	Maharashtra, Goa, Dadra & Nagar Haveli	2011

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

Details of training programmes conducted during the index period:

1. Trainings organised by the NCC-PvPI, IPC

a) Skill Development Programme (SDP) on Pharmacovigilance of Medical Products.

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

c) Interactive meetings conducted for MAHs.

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

e) Hand holding meetings-How to enter data in VigiFlow?

f) Other important Trainings/Workshops.

2. Trainings organised by the RTCs & AMCs

a) Advanced Level Trainings (ALT) Programmes

b) Sensitization and awareness drives for reporting AEs.

3. Celebration of 2nd National Pharmacovigilance Week 2022

4. e-Indian Technical and Economic Cooperation (ITEC) Course on International Pharmacovigilance Training Programme

5. Month wise distribution of total trainings/workshops organised in PvPI during this tenure.

1.(a) Skill Development Programme (SDP) on Pharmacovigilance of Medical Products

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 acquired a prominent platform for sustainable PV practices among all healthcare stakeholders.

Figure - 22. Training Objective and Perspectives

Since its inception in 2017, NCC-PvPI successfully conducted 24 Skill Development Programmes on Pharmacovigilance, focussed on understanding of the basic concepts of PV. The training programme provides an opportunity for the participants to work in Pharmacovigilance units of the organisations by following Good Pharmacovigilance Practices (GVP) 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 on Pharmacovigilance of Medical Products through virtual mode in which a total of 546 participants were trained.

S. No.	Date	Title	No. of Participants Trained
1.	13th-17th June 2022	21st Skill Development Programme	120
2.	12th-16th September 2022	22nd Skill Development Programme	131
3.	14th-18th November 2022	23rd Skill Development Programme	106
4.	6th-10th February 2023	24th Skill Development Programme	189

1.(b) 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 programme. During the index period, NCC-PvPI organized a total of 5 induction-cum-training programmes through virtual mode in which a total of 339 participants were trained as mentioned below:

S. No.	Date	No. of Participants Trained
1.	6th - 8th April 2022	63
2.	30th May - 1st June 2022	33
3.	18th - 20th October 2022	85
4.	12th - 14th December 2022	50
5.	27th February - 1st March 2023	108

1.(c) 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. Twelve such interactive meetings were conducted through virtual mode in which 67 participants were trained.

S. No.	Date	MAHs	No. of Representatives
1.	19th April 2022	JB Chemicals Private Limted	3
2.	25th April 2022	Macleods Pharmaceutical Ltd.	6
3.	24th May 2022	Novo Nordisk India (P) Ltd.	3
4.	06th June 2022	Merck	2
5.	03rd June 2022	Wipro GE Healthcare Limited	1
6.	14th July 2022	Mylan Laboratories Limited	13
7.	31st August 2022	MSN Laboratories Limited	2
8.	29th September 2022	IPCA Laboratories Limited	7

9.	28th December 2022	Eris Life sciences Limited	3
10.	2nd February 2023	Emcure Pharmaceuticals Limited	7
11.	3rd February 2023	Akums Drugs & Pharmaceuticals Limited	8
12.	29th March 2023	Concord Biotech Limited	12

1.(d) Pharmacovigilance training for National Accreditation Board for Hospitals & Healthcare providers (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 officials of NABH Accredited Hospitals. These training sessions help in sensitizing the healthcare professionals to monitoring and reporting AE/ADRs. During the index period, 67 HCPs in the following workshops were trained:

S. No.	Date	Title	No. of Participants Trained
1.	11th July 2022	Worksop-cum-Training Programme on Pharmacovigilance for NABH Accredited Hospitals at Shekhar Hospital, Lucknow.	67

1.(e) Hand holding meetings on "How to enter data in VigiFlow"?

NCC-PvPI, IPC has organised handholding meetings for the Coordinators, Deputy-Coordinators, Junior Pharmacovigilance Associates virtually and demonstrated the entry of drug safety data to in VigiFlow. Eight such hand holding meetings were conducted through virtual mode in which 172 participants were trained.

S. No	Date	Title	No. of Participants Trained
1.	23rd May 2022	Handholding meeting on VigiFlow software for newly recognized AMCs enrolled under PvPI	26
2.	28th June 2022		17
3.	27th July 2022		20
4.	7th September 2022		22
5.	29th November 2022		13
6.	13th January 2023		34
7.	24th March 2023		24
8.	29th March 2023		16

1.(f) Other important Trainings/Workshops

The NCC-PvPI, IPC has organised a total of six trainings virtually and trained a total of 625 participants in the area of Pharmacovigilance were as follows:

S. No	Date	Title	No. of Participants
1.	30th September 2022	Medication Error and its Importance in Pharmacovigilance"	90
2.	31st October 2022	Training on "Importance and Strategy to involve patients directly into ADR reporting and how to screen ADRs from patients' records?"	90
3.	21st November 2022	Training on "Introduction to MedDRA coding"	119
4.	19th December 2022	Training on "Expectedness and Labelling of Adverse Events"	100
5.	31st January 2023	Training on "Narrative writing" of Individual Case Safety Report	122
6.	15th March 2023	Training on "Causality assessments of ADRs"	131

2.(a) Advanced Level Trainings (ALT) Programmes

Regional Training Centres of PvPI across the country organised a total of 09 Advanced level training programmes in Pharmacovigilance in which 2,114 healthcare professionals including Coordinators, Deputy Coordinators and Pharmacovigilance Associates of various AMCs were trained.

S. No.	Date	AMCs	Title	No. of Participants Trained
1.	27th April 2022	MMC, Chennai	Advanced Level Training in Pharmacovigilance	108
2.	28th May 2022	JSS, Mysore	Webinar on vaccine safety monitoring and research	540
3.	24th June 2022	NIMS, Hyderabad	Advanced level training program, Benefits Risk Assessment on Pharmacovigilance	350
4.	23rd July 2022	AIMS, Kochi	Advanced level training program on Pharmacovigilance "Vigilante- Health Care Professionals and Patients"	60
5.	11th November 2022	AIIMS, Bhopal	6th ALT cum trainers meeting for the state of MP and CG	41
6.	12th - 13th December 2022	BJMC, Ahmedabad	Online Advance level training in Pharmacovigilance	266

7.	8th December 2022	IPGMER, Kolkata	Awareness and sensitisation program on Risk Benefit Assessment & communication in PV	152
8.	23rd December 2022	KEM, Mumbai	Awareness and sensitisation program on Emerging themes in pharmacovigilance	215
9.	20th March 2023	PGIMER, Chandigarh	Advanced level training program on Pharmacovigilance	382

2.(b) Sensitization and awareness drives for reporting AEs.

The AMCs of PvPI across the country organised a total of 1121 sensitization and awareness programmes in which 50698 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	45	1876
2.	AIMS, Kochi	32	1463
3.	KFMSR, Coimbatore	27	1197
4.	KEM, Mumbai	23	569
5.	AIIMS, Rishikesh	23	596
6.	KMC, Kurnool	23	994
7.	JLNMC, Ajmer	22	609
8.	GMC, Guntur	20	1589
9.	PDUMC, Rajkot	20	225

10.	GMC, Miraj	19	935
11.	NEIGRIHMS, Shillong	18	533
12.	VMCHRI, Madurai	18	1753
13.	AIIMS, Bhopal	17	1058
14.	JMMCRI, Thrissur	17	500
15.	JNMC, Aligarh	17	685
16.	MGIMS, Wardha	17	301
17.	JNMC, Wardha	16	700
18.	NIMS, Hyderabad	16	682
19.	AIIMS, Bathinda	15	503
20.	HMCH, Bhubaneswar	15	348
21.	KIMS, Nalgonda	15	392
22.	MMC, Chennai	15	952
23.	SGGSTU, Gurugram	15	934
24.	SMCH, Silchar	15	317
25.	GKMC, Chennai	14	991
26.	PSGIMSR, Coimbatore	14	113
27.	SVIMS, Tirupati	14	937
28.	SVMC, Tirupati	14	865
29.	JSS, Mysore	13	1019
30.	PGIMER, Chandigarh	13	2357
31.	RMC, Ahmednagar	13	522

32.	VPCI, New Delhi	13	204
33.	NDMCMC, New Delhi	12	526
34.	GMC, Baramulla	11	296
35.	GMCH, Nagpur	11	495
36.	IMSBHU, Varanasi	11	1241
37.	MMCHRI, Kanchipuram	11	764
38.	CMJNM, Nadia	10	311
39.	CMC, Vellore	10	418
40.	JNIMS, Imphal	10	153
41.	KAMSRC, Hyderabad	10	470
42.	LTMMCGH, Mumbai	10	112
43.	OMC, Hyderabad	10	291
44.	RCSSHL, Silvr	10	126
45.	RGKMC, Kolkata	10	615
46.	SMC, Meerut	10	512
47.	SMCGH, Kurnool	10	295
48.	GTDMC, Alappuzha	9	134
49.	AJIMS, Mangalore	9	253
50.	BJMC, Ahmedabad	9	109
51.	DYSPGM, Sirmaur	9	348
52.	ESICMCH, Hyderabad	9	292
53.	KGH, Visakhapatnam	9	241
54.	RMC, Kakinada	9	281

55.	SRMC, Chennai	9	231
56.	YMC, Mangalore	9	499
57.	GMC, Kozhikode	8	503
58.	CMMCH, Durg	7	179
59.	ESICMCH, Faridabad	7	337
60.	GMC, Amritsar	7	292
61.	GMC, Trivandrum	7	229
62.	MGMMC, Indore	7	269
63.	AFMC, Pune	6	132
64.	BMCRI, Bangalore	6	72
65.	GMC, Thrissur	6	175
66.	SAIMS, Indore	6	308
67.	CIPS, Guntur	5	1960
68.	GMC, Bhopal	5	117
69.	GMC, Palakkad	5	44
70.	GMC, Secunderabad	5	124
71.	GMC, Srinagar	5	91
72.	GMERS, Ahmedabad	5	137
73.	GMERSMC, Ahmedabad	5	136
74.	JIPMER, Puducherry	5	78
75.	Dr BVPRMC, Loni	4	38
76.	DYPUSM, Navi Mumbai	4	198

77.	FH, Mohali	4	81
78.	IGMCRI, Puducherry	4	564
79.	ILBS, New Delhi	4	213
80.	IPGMER, Kolkata	4	68
81.	KGMC, Kanyakumari	4	72
82.	KH, Tiruchirappalli	4	42
83.	MMMCH, Solan	4	104
84.	RDGMC, Ujjain	4	101
85.	RMLIMS, Lucknow	4	682
86.	TMMC-RC, Moradabad	4	240
87.	TRIHMS, Naharlagun	4	24
88.	AIIMS, Raipur	3	442
89.	APOLLO, New Delhi	3	143
90.	BCMCH, Thiruvalla	3	305
91.	GMC, Nilgiri	3	87
92.	IGIMS, Patna	3	93
93.	PJNMC, Raipur	3	127
94.	SKIMS, Soura	3	45
95.	TNMC, Mumbai	3	55
96.	TSRMMCHRC, Trichy	3	121
97.	VIMS, Bangloure	3	67
98.	ACP, Malappuram	2	65

99.	AIIMS, Gorakhpur	2	23
100.	AIIMS, Mangalagiri	2	29
101.	AIIMS, Nagpur	2	54
102.	AIIMS, Patna	2	37
103.	BGSGIMS, Bengaluru	2	113
104.	BLKMH, New Delhi	2	21
105.	DRGMCH, Hamirpur	2	33
106.	ESICMC, Bengaluru	2	100
107.	GGSMCH, Faridkot	2	45
108.	GMC, Haldwani	2	73
109.	GSGC, Gorakhapur	2	59
110.	JMC, Jorhat	2	85
111.	JNMCH, AMU, Haldwani	2	62
112.	JPH, Bhopal	2	59
113.	KCGMC, Karnal	2	92
114.	KMC, Mangaluru	2	60
115.	KMC, Manipal	2	18
116.	MAMC, New Delhi	2	115
117.	MAMS, Hyderabad	2	307
118.	MHL, Gurugram	2	18
119.	MLBMC, Jhansi	2	185
120.	MMIMS, Mullana	2	69
121.	RIMS, Imphal	2	85

122.	SGPGIMS, Lucknow	2	45
123.	SGRRI, Dehradun	2	163
124.	SLBSGMC, Mandi	2	162
125.	SMC, Ghaziabad	2	407
126.	SNIMS, Ernakulam	2	150
127.	SPMC, Bikaner	2	118
128.	SRTRMC, Beed	2	44
129.	STM, Kolkata	2	62
130.	SVCP, Chittoor	2	40
131.	SVCP, Hyderabad	2	191
132.	VMET, Vadapalani	2	80
133.	BRDMC, Gorakhpur	2	55
134.	BJGMC, Pune	1	13
135.	AIIMS, Deoghar	1	20
136.	AIIMS, Jodhpur	1	50
137.	AIMS,Thrissur	1	6
138.	AMSH-Kolkata	1	47
139.	ASMCSNMH&TBS, Firozabad	1	66
140.	BMC, Hyderabad	1	80
141.	CMCH, Ludhiana	1	40
142.	DYPMC, Pune	1	123
143.	DYSPGMC, Nahan	1	108
144.	FP-Naya Raipur (Kalinga University)	1	237

145.	GRMC, Gwalior	1	13
146.	GTMC, Thiruvarur	1	13
147.	GTMC, Thoothukudi	1	16
148.	HIMSR, New Delhi.	1	19
149.	KIMS, Banashankari	1	56
150.	KIMS, Bhubaneswar	1	105
151.	KLECP, Hubballi	1	50
152.	KMC, Kanyakumari	1	30
153.	MGMCH, New Mumbai	1	26
154.	MGMCRI, Pondicherry	1	115
155.	MKCG, barhampur	1	184
156.	MMC, Madurai	1	255
157.	MMCRI, Mysore	1	132
158.	NME&RI&SVBCH, Silvassa	1	80
159.	NSMC, Kolkata	1	4
160.	PMCSKH, Anand	1	170
161.	PSIMS&RF, Krishna	1	150
162.	SIMS, Shimoga	1	20
163.	SIMSRH, Karnataka	1	74
164.	SRIPS, Coimbatore	1	30
165.	SRMMC, Kattankulathur	1	20
166.	SVICC&AR-Tirupati	1	173
167.	SVMCHRC, Puducherry	1	15
168.	VSSMC, Burla	1	7

3. Celebration of 2nd National Pharmacovigilance Week 2022

The National Coordination Centre (NCC)-Pharmacovigilance Programme of India (PvPI), Indian Pharmacopoeia Commission (IPC) has celebrated 2nd National Pharmacovigilance Programme (NPW) from 17th-23rd September 2022 across the country through hybrid mode. The theme of this NPW 2022 was to "Encourage the reporting of ADRs to PvPI by the consumers". The approval for celebration of National Pharmacovigilance Week across the country was accorded by Governing Body of Indian Pharmacopoeia Commission. 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 National Pharmacovigilance week 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 National Pharmacovigilance Week. 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.

During the 2nd NPW 2022, NCC-PvPI has organized a walkathon in Ghaziabad on September 20, 2022 to create awareness about the reporting of adverse events with the use of medicines and also distributed the pamphlets & resources materials prepared in Hindi and English to the public, hospitals and chemists. The major activities organized by NCC-PvPI during this week were as follows;

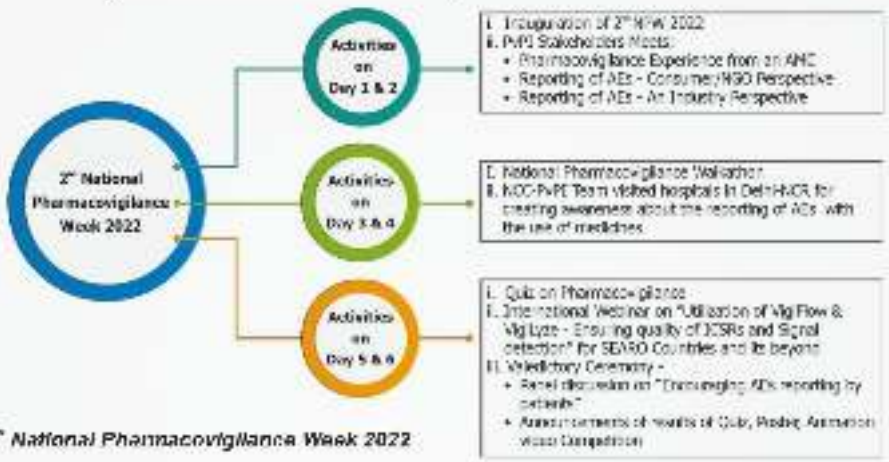


Figure - 23. 2nd National Pharmacovigilance Week 2022

During the National Pharmacovigilance Week PvPI organised a total of 628 training/awareness-cum-sensitization programmes including CME/CPE in which 54,889 Healthcare Professionals and other stakeholders were trained on PV.

Details of Sensitization training programmes conducted at AMCs/Non-AMCs during the 2nd NPW 2022 are summarized below:

S. No.	Date	Training Programmes	AMCs	No. of Participants
1.	17-09-2022	Awareness and Sensitization Programme on Pharmacovigilance and ADR reporting	AIIMS, Mangalagiri	38
2.	17-09-2022	Sensitization training on Introduction to Pharmacovigilance	AIIMS, Raipur	66
3.	17-09-2022	Sensitization and training on reporting ADR	GMC, Baramulla	51
4.	17-09-2022	Sensitization programme on PvPI Updates	JLNMC, Ajmer	12
5.	17-09-2022	Awareness programme on ADR reporting to consumers	SVCP, Hyderabad	100
6.	17-09-2022	Sensitization program on PvPI	GMERSMCGH, Gandhinagar	150
7.	17-09-2022	Sensitization programme towards ADR Reporting	JIPMER, Karaikal	30
8.	17-09-2022	Hands on training on ADR Form filling with case scenarios	PJNGMC, Chamba	40
9.	17-09-2022	Orientation on PvPI for faculty and postgraduate students	MGIMS, Wardha	15
10.	17-09-2022	Sensitization training on Understanding of ADRs To Patients	NH, Rajpura	50

11.	17-09-2022	Lecture on reporting of ADRs, Medical safety	TNMC, Mumbai	70
12.	17-09-2022	Sensitization programme on patient safety for HCPs	AIIMS, Bhopal	70
13.	17-09-2022	Sensitization on how reporting is the Discipline in pharmacovigilance	AIIMS, Bhopal	143
14.	17-09-2022	Awareness and sensitization on reporting ADR	LMCP, Ahmedabad	72
15.	17-09-2022	Sensitization and awareness programme on "Overview of PvPI & Filling ADR Form	GMC, Pali	150
16.	17-09-2022	Sensitization of nursing students on PvPI and ADR reporting	GMKMC, Salem	150
17.	17-09-2022	Public awareness programme on Pharmacovigilance	GKMC, Chennai	100
18.	17-09-2022	Sensitization training on to emphasis on the importance of ADR reporting by patients and Physicians	MAIMSR, Chengalpattu	50
19.	17-09-2022	Patient sensitization programme for patients on Pharmacovigilance	RVMIMS, Siddipet	15
20.	17-09-2022	Sensitization training on CME on pharmacovigilance: A step towards patient safety	AIIMS, Patna	153
21.	17-09-2022	Community awareness/sensitization in IPD and OPD	AIIMS, Jodhpur	50
22.	17-09-2022	Awareness program on ADR reporting	CHRI, Cengalpattu	85

23.	17-09-2022	Talk on Pharmacovigilance and medication safety	CHRI, Cengalpattu	250
24.	17-09-2022	Sensitization training on Orientation cum workshop training	GTMC, Thoothukudi	75
25.	17-09-2022	Encouraging reporting of ADRs by patient - Self reporting	IGIMS, Patna	200
26.	17-09-2022	Sensitization training on the basic of PvPI, casualty assessment filing of ADR	IMSBHU, Varanasi	76
27.	17-09-2022	Sensitization on Importance of ADR reporting at Got. Headquarters Hospital Pollachi	KFMSR, Coimbatore	37
28.	17-09-2022	Online webinar for Indian Pharmaceutical Association, Tamil Nadu Branch	KFMSR, Coimbatore	39
29.	17-09-2022	Online webinar for sri adichunchangiri college of pharmacy, Encouraging ADR reporting in patients	KFMSR, Coimbatore	120
30.	17-09-2022	Pharmacovigilance awareness programme	ACP, Malappuram	75
31.	17-09-2022	Sensitization programme on Pharmacovigilance, PvPI, AEFI	KMC, Kurnool	28
32.	17-09-2022	Sensitization programme on Pharmacovigilance, PvPI, AEFI	MAMS, Hyderabad	135
33.	17-09-2022	Sensitization of consumers and pharmacist regarding Pharmacovigilance and ADR reporting	MGMCRI, Pondicherry	45
34.	17-09-2022	Awareness and sensitization programme on Pharmacovigilance	NIMS, Hyderabad	50

35.	17-09-2022	Sensitization of consumer regarding Pharmacovigilance and ADR monitoring	BJMC, Ahmedabad	200
36.	17-09-2022	Pharmacovigilance awareness lecture for medical intern	TNMC, Mumbai	15
37.	17-09-2022	Pharmacovigilance awareness lecture for medical intern	TNMC, Mumbai	75
38.	17-09-2022	Pharmacovigilance sensitization and awareness programme	SRMMC, Kattankulathur	30
39.	17-09-2022	Importance of Pharmacovigilance in patient safety	SVMC, Tirupati	72
40.	17-09-2022	Sensitization programme on Pharmacovigilance	SMC, Meerut	58
41.	17-09-2022	Encouraging reporting of ADRs by patient - Self reporting	SGRRI, Dehradun	160
42.	17-09-2022	Training on importance of Pharmacovigilance	KEM, Mumbai	24
43.	17-09-2022	Sensitization and awareness programme on Pharmacovigilance	SNMMC, Dhanbad.	92
44.	17-09-2022	Online Seminar on Encouraging Patients for ADR Reporting	PGIMER, Chandigarh	78
45.	17-09-2022	Awareness cum training for pharmacovigilance and ADR reporting	AGMC, Agartala	55
46.	17-09-2022	Awareness programme on ADR reporting by consumers	GIMS, Gadag	8
47.	17-09-2022	Sensitization on benefits of ADR reporting	SGGSTU, Gurugram	70

48.	17-09-2022	ADR reporting by the Healthcare worker	MVRCCR, Kozihikode	41
49.	17-09-2022	Sensitization an awareness on Pharmacovigilance reporting of Adverse drug reaction and measure to reduce their incidence	KMC, Mangaluru	20
50.	17-09-2022	Workshop and awareness programme on Pharmacovigilance	RMC, Kakinada	100
51.	17-09-2022	Awareness regarrting medical safety	SPIPS, Warangal	300
52.	17-09-2022	Awareness programme on safe use of drugs and reporting on ADRs	AIIMS, Gorakhpur	150
53.	17-09-2022	Sensitization and awareness at Sardar Patel pharmacy college, Gorakhpur	BRDMC, Gorakhpur	15
54.	17-09-2022	Awareness programme on ADR reporting	DMCH, Ludhiana	112
55.	17-09-2022	Sensitization an awareness on Pharmacovigilance & ADR Reporting	RMLIMS, Lucknow	71
56.	17-09-2022	1. Awareness of adverse drug reactions among health care professionals and Patients 2. To Make an Alert regarding LASA 3. Strict Verification for any medication order	CIPS, Guntur	180
57.	17-09-2022	Sensitization an awareness on ADR Reporting	GIMS, Gadag	8

58.	17-09-2022	Sensitization and awareness on ADR reporting by the healthcare workers	HCGEKOCC, Kolkata	41
59.	17-09-2022	Awareness programme cum training on ADR reporting	TMCBRAM, AGARTALA	50
60.	17-09-2022	Sensitization and awareness programme on Pharmacovigilance	RMC, Kakinada	100
61.	17-09-2022	Workshop and awareness programme on Pharmacovigilance	GMC, SRINAGAR	53
62.	17-09-2022	Public awareness by doing street play, talks by seniors, interactions with patients	DCDSIMER, Ramanagar	200
63.	17-09-2022	Pharmacovigilance an overview of PvPI, ADR Form Filling	GMC, Pali	150
64.	17-09-2022	Sensitization programme on pharmacovigilance & ADR Reporting	GMC, Thrissur	83
65.	17-09-2022	Sensitization programme on pharmacovigilance & ADR Reporting	GMERSMC, Ahmedabad	69
66.	17-09-2022	Scope of Pharmacovigilance Profession	ACP, Bengaluru	60
67.	17-09-2022	NPW Inauguration and Sensitization programme on pharmacovigilance & ADR Reporting	GMC, Siddipet	200
68.	17-09-2022	Sensitization programme on pharmacovigilance & ADR Reporting	JNMC, Aligarh	120
69.	17-09-2022	Sensitization programme on pharmacovigilance & ADR Reporting	JNMC, Aligarh	70

70.	17-09-2022	Sensitization and awareness programme on Pharmacovigilance	CMJNM, Nadia	30
71.	17-09-2022	Encouraging reporting of ADR by patients	CMCH, Ludhiana	20
72.	17-09-2022	Awareness in paramedical staff on Pharmacovigilance	SDCH, Lucknow	30
73.	17-09-2022	Talk on Pharmacovigilance & Medication Safety	GMCH, Guwahati	250
74.	17-09-2022	Sensitization and awareness on How to report ADR?	GMC, Pudukkottai	20
75.	17-09-2022	Sensitization and awareness programme on Pharmacovigilance among Officer-in-charge Nursing Officer and Pharmacist	BBMCH, Balangir	74
76.	17-09-2022	Sensitization and awareness programme on Pharmacovigilance and Tools for ADR reporting	OMC, Hyderabad	25
77.	17-09-2022	Sensitization and awareness programme on Pharmacovigilance	SUCP, Hyderabad	150
78.	17-09-2022	Sensitization regarding Consumer ADR Reporting and Materiovigilance at Fortis Hospital Mukundapur	STM, Kolkata	30
79.	17-09-2022	Pharmacovigilance Sensitization on PV and distribution of pamphlet	RIMS, Imphal	20
80.	17-09-2022	Pharmacovigilance Sensitization on PV and distribution of pamphlet at Radiotherapy ward, Paediatric ward Surgery Ward etc.	RIMS, Imphal	70

81.	18-09-2022	Awareness programme on pharmacist and chemist regarding ADR Reporting	AIIMS, Patna	12
82.	18-09-2022	Orientation of faculty and postgraduate students on Pharmacovigilance	MGIMS, Wardha	12
83.	18-09-2022	Awareness talks about ADR reporting	NH, Rajpura	100
84.	18-09-2022	Community level sensitization programme on Pharmacovigilance	GMKMC, Salem	80
85.	18-09-2022	Pharmacovigilance awareness programme	ACP, Malappuram	150
86.	18-09-2022	Sensitization an awareness on Pharmacovigilance reporting of Adverse drug reaction and measure to reduce their incidence	KMC, Mangaluru	20
87.	18-09-2022	ADR reporting awareness programme to patients at clinics	SMCGH, Kurnool	65
88.	18-09-2022	Awareness programme cum sensitization programme regarding ADR reporting	UPUMS, Saifai, Etawah	230
89.	18-09-2022	Sensitization programme pharmacovigilance & ADR Reporting	GMC, Srikakulam	60
90.	18-09-2022	Sensitization and awareness to General public about reporting ADRs	BRDMC, Gorakhpur	12
91.	19-09-2022	Community level awareness programme on PV	AIIMS, Mangalagiri	300
92.	19-09-2022	Sensitization and awareness programme on PV and ADR reporting	AIIMS, Nagpur	67

93.	19-09-2022	Sensitization training on "Pharmacovigilance- Importance of ADR reporting for HCPs	MMC, Chennai	29
94.	19-09-2022	Consumer awareness program conducted at CTVs ward	AIIMS, Rishikesh	25
95.	19-09-2022	Community level sensitization through patient safety and ADR reporting	AIIMS, Patna	132
96.	19-09-2022	Sensitization training on Introduction to Pharmacovigilance	AIIMS, Raipur	103
97.	19-09-2022	Sensitization training on Med Safety Introduction PvPI	GMC, Trivandrum	100
98.	19-09-2022	Sensitization about ADR Reporting	GTDMC, Alappuzha	20
99.	19-09-2022	Sensitization training on role of consumer reporting in pharmacovigilance	JLNMC, Ajmer	15
100.	19-09-2022	Sensitization training on Pharmacovigilance methods	JLNMC, Ajmer	12
101.	19-09-2022	Sensitization training on Causality assessment scale	JLNMC, Ajmer	12
102.	19-09-2022	Sensitization training on consumer awareness programme	JLNMC, Ajmer	24
103.	19-09-2022	Sensitization training on Pharmacovigilance awareness programme	KMC, Manipal	70
104.	19-09-2022	Sensitization programme in RIMS IPD /OPD amongst Healthcare Professional	RIMS, Ranchi	300

105.	19-09-2022	Sensitization training on Pharmacovigilance awareness programme	SGMC/RF, Trivandrum	40
106.	19-09-2022	Awareness programme on ADR reporting to consumers	SVCP, Hyderabad	20
107.	19-09-2022	Sensitization programme on PvPI	GMERSMCGH, Gandhinagar	240
108.	19-09-2022	Sensitization on reporting ADR	GMC, Miraj	100
109.	19-09-2022	Sensitization programme for ADR Reporting	JIPMER, Karaikal	60
110.	19-09-2022	Sensitization programme towards ADR Reporting at Wardha Rural Hospital	PJNGMC, Chamba	15
111.	19-09-2022	Orientation of faculty and postgraduate students on Pharmacovigilance	MGIMS, Wardha	50
112.	19-09-2022	Sensitization training on Severity of ADRs in Inpatients	NH, Rajpura	150
113.	19-09-2022	Sensitization training on Basic knowledge on Pharmacovigilance	RGKMC, Kolkata	150
114.	19-09-2022	Sensitization training on Introduction on Pharmacovigilance	SMCH, Silchar	145
115.	19-09-2022	Sensitization and awareness programme on ADR Reporting in pharmacovigilance	JMMCRI, Thrissur	100
116.	19-09-2022	Sensitization and awareness programme regarding ADR reporting	RDGMC, Ujjain	40
117.	19-09-2022	Awareness and sensitization programme on reporting ADRs	RDGMC, Ujjain	60

118.	19-09-2022	ADR reporting awareness for medical students	GMC, Manjeri Malappuram	110
119.	19-09-2022	Sensitization training on Encouraging ADR reporting by patient awareness	SRMMC, Kattankulathur	29
120.	19-09-2022	Sensitization and awareness programme on PvPI	AFMC, Pune	28
121.	19-09-2022	Sensitization of 2nd year MBBS students on PvPI and ADR reporting	GMKMC, Salem	100
122.	19-09-2022	Sensitization training on "To emphasis on the importance of ADR reporting by patients and Physicians"	MAIMSR, Chengalpattu	130
123.	19-09-2022	Sensitization training on "To emphasis on the importance of ADR reporting by patients and Physicians"	MAIMSR, Chengalpattu	151
124.	19-09-2022	Patient sensitization programme patients on Pharmacovigilance	RVMIMS, Siddipet	15
125.	19-09-2022	Awareness programme as well as encouragement to report more ADRs	AJIMS, Mangalore	400
126.	19-09-2022	Awareness programme for patients on Pharmacovigilance	AIIMS, Bilaspur	112
127.	19-09-2022	To sensitize all stakeholders about ADR reporting	DVPMC, Nashik	197
128.	19-09-2022	Pharmacovigilance sensitization and awareness programme	ESICMC, Bengaluru	297
129.	19-09-2022	Sensitization cum awareness programme for patients attending OPD of GMER	GMERSMCGH, Gandhinagar	500

130.	19-09-2022	Community level awareness cum sensitization programme	IGIMS, Patna	300
131.	19-09-2022	Sensitization training on "The basic of PvPI, casualty assessment filing of ADR"	IMSBHU, Varanasi	183
132.	19-09-2022	Online sensitization on PvPI signal detection	APOLLO, New Delhi	120
133.	19-09-2022	Principle of pharmacovigilance and ADR reporting tool	KMC, Warangal	85
134.	19-09-2022	Online webinar for JSS college of pharmacy, Ooty, Encouraging ADR reporting in patients	KFMSR, Coimbatore	99
135.	19-09-2022	Pharmacovigilance awareness programme	ACP, Malappuram	50
136.	19-09-2022	Sensitization programme on pharmacovigilance, PvPI, AEFI	KMC, Kurnool	30
137.	19-09-2022	Sensitization program on pharmacovigilance, PvPI, AEFI	KMC, Kurnool	160
138.	19-09-2022	Sensitization program on pharmacovigilance, PvPI, AEFI	KMC, Kurnool	158
139.	19-09-2022	Community level awareness cum sensitization programme	MAMS, Hyderabad	102
140.	19-09-2022	Sensitization of consumers and pharmacist regarding pharmacovigilance and ADR reporting	MGMCRI, Pondicherry	10
141.	19-09-2022	Awareness and sensitization programme on pharmacovigilance	MMCRI, Mysore	17

142.	19-09-2022	Awareness and sensitization programme on Pharmacovigilance	NIMS, Hyderabad	60
143.	19-09-2022	Pharmacovigilance - the key to promote patient safety	RBVRRWCP, Hyderabad	138
144.	19-09-2022	Scientific session on role of healthcare professional in pharmacovigilance	RBVRRWCP, Hyderabad	141
145.	19-09-2022	Encouraging reporting of ADRs by patient - Self reporting	VPCI, New Delhi	32
146.	19-09-2022	Public awareness campaign at community centre	TNMC, Mumbai	15
147.	19-09-2022	Pharmacovigilance sensitization and awareness programme	SRMMC, Kattankulathur	40
148.	19-09-2022	Pharmacovigilance monitoring and reporting of ADRs in Indian Scenario	SVMC, Tirupati	85
149.	19-09-2022	Sensitization programme on Pharmacovigilance	SMC, Meerut	45
150.	19-09-2022	Encouraging reporting of ADRs by patient - self reporting	SJMCH, Puri	54
151.	19-09-2022	Sensitization and awareness program at the pharmacist	SSIMS, Bhilai	30
152.	19-09-2022	Awareness and sensitization programme on Pharmacovigilance	SGRRI, Dehradun	154
153.	19-09-2022	Training about importance of Pharmacovigilance	KEM, Mumbai	22
154.	19-09-2022	Online Seminar on "Encouraging Patients for ADR Reporting at Khalsa College of Pharmacy"	PGIMER, Chandigarh	61

155.	19-09-2022	Online Seminar on "Encouraging patients for ADR reporting at Sri Guru Ram Das University of Health Sciences"	PGIMER, Chandigarh	42
156.	19-09-2022	Seminar on "Encouraging patients for ADR reporting at Shoolini University"	PGIMER, Chandigarh	44
157.	19-09-2022	Sensitization programme on Pharmacovigilance	PSGIMSR, Coimbatore	30
158.	19-09-2022	Awareness cum training for pharmacovigilance and ADR reporting	AGMC, Agartala	46
159.	19-09-2022	Training cum sensitization regarding PV and related essential matters	AGMC, Agartala	45
160.	19-09-2022	ADR reporting and Pharmacovigilance Programme of India	AIIMS, Nagpur	67
161.	19-09-2022	Encouraging reporting of ADR by patients	CMCH, Ludhiana	20
162.	19-09-2022	Nurses training on ADR and Pharmacovigilance	EPCMSRC, Bangalore	82
163.	19-09-2022	Sensitization an awareness on Role of pharmacovigilance in improving patient safety	GBCMKKBMSH, Dehradun	40
164.	19-09-2022	Community level sensitization regarding ADR and reporting	GBCMKKBMSH, Dehradun	150
165.	19-09-2022	Encouraging reporting of ADR by patient's sensitization	SGGSTU, Gurugram	200
166.	19-09-2022	Encouraging reporting of ADR	GMC, Dindigul	30

167.	19-09-2022	Sensitization an awareness on Pharmacovigilance reporting of Adverse drug reaction and measure to reduce their incidence	KMC, Mangaluru	20
168.	19-09-2022	Awareness regarding medication safety	SPIPS, Warangal	500
169.	19-09-2022	awareness programme on safe use of drugs and reporting on ADRs reporting	AIIMS, Gorakhpur	50
170.	19-09-2022	Sensitization and awareness at BIP, Gorakhpur	BRDMC, Gorakhpur	25
171.	19-09-2022	ADR Reporting for ADR Prevention- Hands on training	BCMCH, Thiruvalla	80
172.	19-09-2022	Sensitization an awareness on Pharmacovigilance & ADR Reporting	RMLIMS, Lucknow	22
173.	19-09-2022	Nurses training on "ADR & Pharmacovigilance"'	EPCMSRC, Bangalore	22
174.	19-09-2022	Guest lecture on "Pharmacovigilance- A step towards patient safety"	PSIMS&RF, Krishna	300
175.	19-09-2022	Training of students on ADR reporting and filling	VMCHRI, Madurai	50
176.	19-09-2022	Awareness programme cum training for ADR	TMCBRAM, Agartala	45
177.	19-09-2022	Workshop and awareness programme on Pharmacovigilance	GMC, Srinagar	90
178.	19-09-2022	Sensitization programme on PvPI	GMCH, Musheerabad	30

179.	19-09-2022	Community level sensitization programme on Pharmacovigilance to pharmacist working at Reddypalli Village	BMC, Hyderabad	10
180.	19-09-2022	Sensitization programme pharmacovigilance & ADR Reporting to MBBS students, doctors and HCPs at Rural Health Training Centre	BMC, Hyderabad	50
181.	19-09-2022	Sensitization programme pharmacovigilance & ADR Reporting	GMERSMC, Ahmedabad	20
182.	19-09-2022	Encouraging ADR reporting by patients	VSSMC, Burla	400
183.	19-09-2022	Sensitization programme pharmacovigilance & ADR Reporting	JNMC, Aligarh	24
184.	19-09-2022	Sensitization programme pharmacovigilance & ADR Reporting	JNMC, Aligarh	50
185.	19-09-2022	Sensitization and awareness programme on Pharmacovigilance	CMJNM, Nadia	50
186.	19-09-2022	Awareness sensitization activity on PvPI, ADR Tollfree No. At peripheral PHC JEORA	CMMCH, Durg	63
187.	19-09-2022	Awareness sensitization activity on PvPI, ADR Tollfree No. at different departments of CMMCH	CMMCH, Durg	14
188.	19-09-2022	An Introduction to PvPI and Workshop-cum-Hands on Training filling ADR reporting form	SSSMCRI, Chengalpattu	52

189.	19-09-2022	Awareness on ADR reporting in medicine OPD patients and Health card distributed	VIMS, Bangalore	55
190.	19-09-2022	Sensitization and awareness programme on Pharmacovigilance	JIPMER, Puducherry	170
191.	19-09-2022	Sensitization and awareness programme on Pharmacovigilance and Tools for ADR reporting	OMC, Hyderabad	33
192.	19-09-2022	Introduction to ADR reporting and Pharmacovigilance Programme of India	SMC, Ghaziabad	65
193.	19-09-2022	Sensitization regarding Consumer ADR Reporting at Community Pharmacy Outlets (Frank Ross, Metro Pharma Chain)	STM, Kolkata	40
194.	19-09-2022	Sensitization and awareness programme on Pharmacovigilance	GTMC, Theni	14
195.	19-09-2022	Update of PvPI by coordinators and sensitization programme for HCPs by PvPI	JNIMS, Imphal	130
196.	19-09-2022	Conducted workshop on awareness programme on pharmacovigilance and hands on training about ADR reporting	RIMS, Imphal	56
197.	19-09-2022	Pharmacovigilance Sensitization on PV and distribution of pamphlet	RIMS, Imphal	20
198.	19-09-2022	Sensitization on Pharmacovigilance at RTRMH, Najafgarh	MAMC, New Delhi	150

199.	19-09-2022	Sensitization on Pharmacovigilance at RHTC Barwala	MAMC, New Delhi	25
200.	19-09-2022	Sensitization on Pharmacovigilance at Delhi gate Health Centre	MAMC, New Delhi	18
201.	19-09-2022	Sensitisation programme on ADR Reporting	SDCH, Lucknow	160
202.	19-09-2022	Awareness programme cum sensitization programme regarding ADR reporting	UPUMS, Saifai, Etawah	190
203.	20-09-2022	Community level awareness programme on PV	AIIMS, Mangalagiri	30
204.	20-09-2022	Sensitization and awareness programme on PV and ADR reporting	AIIMS, Nagpur	32
205.	20-09-2022	Sensitization and awareness programme on PvPI	GMC, Kozhikode	44
206.	20-09-2022	Consumer awareness programme conducted at Paediatrics surgery ward	AIIMS, Rishikesh	20
207.	20-09-2022	Sensitization and awareness programme in OPD and IPD at hospital	AIIMS, Patna	30
208.	20-09-2022	Sensitization training on Introduction to Pharmacovigilance	AIIMS, Raipur	120
209.	20-09-2022	Sensitization training on Med Safety Introduction PvPI	GMC, Trivandrum	53
210.	20-09-2022	Sensitization about ADR Reporting	GTDMC, Alappuzha	12
211.	20-09-2022	Sensitization training on Signal Detection	JLNMC, Ajmer	12

212.	20-09-2022	Sensitization training on Role of ADR Monitoring centre under Pharmacovigilance	JLNMC, Ajmer	12
213.	20-09-2022	Sensitization training on Pharmacovigilance tools for ADR monitoring	JLNMC, Ajmer	12
214.	20-09-2022	Sensitization training on "Patient awareness of encouraging ADR reporting in medicine"	KMC, Manipal	3
215.	20-09-2022	Awareness programme on ADR reporting to consumers	SVCP, Hyderabad	10
216.	20-09-2022	Sensitization programme on PvPI	GMERSMCGH, Gandhinagar	70
217.	20-09-2022	Sensitization programme towards ADR Reporting	JIPMER, Karaikal	80
218.	20-09-2022	Sensitization programme towards ADR Reporting at Acharya Vinoba bhave rural hospital	PJNGMC, Chamba	46
219.	20-09-2022	Orientation of faculty and postgraduate students on Pharmacovigilance	MGIMS, Wardha	35
220.	20-09-2022	Sensitization training on Introduction lecture about PvPI Programme	PDUMC, Rajkot	32
221.	20-09-2022	Sensitization and Awareness of reporting ADRs	PDUMC, Rajkot	40
222.	20-09-2022	CME on ADR reporting & Importance of Pharmacovigilance	RGKMC, Kolkata	120
223.	20-09-2022	Community level awareness cum sensitization programme on Pharmacovigilance	SDUMC, Kolar	44

224.	20-09-2022	Sensitization training on Pharmacovigilance awareness programme	TNMC, Mumbai	10
225.	20-09-2022	Sensitization and awareness training on Pharmacovigilance	RDGMC, Ujjain	150
226.	20-09-2022	Sensitization and awareness training on Pharmacovigilance	RDGMC, Ujjain	150
227.	20-09-2022	Sensitization program on PV and ADR reporting	KAMSRC, Hyderabad	150
228.	20-09-2022	Sensitization training on Encouraging ADR reporting by patient awareness	GMC, Manjeri Malappuram.	30
229.	20-09-2022	Sensitization training on Encouraging ADR reporting by patient awareness	SRMMC, Kattankulathur	21
230.	20-09-2022	Sensitization and awareness programme on PvPI	AFMC, Pune	30
231.	20-09-2022	Sensitization of 2nd year MBBS students on PvPI and ADR reporting	GMKMC, Salem	23
232.	20-09-2022	Student sensitization programme on Pharmacovigilance	RVMIMS, Siddipet	50
233.	20-09-2022	Awareness programme for patients	AIIMS, Bilaspur	67
234.	20-09-2022	Sensitization and awareness programme in OPD and IPD	AIIMS, Patna	60
235.	20-09-2022	Sensitization lecture for nursing professionals regarding reporting of suspected ADRs	GMERSMCGH, Gandhinagar	60
236.	20-09-2022	Sensitization training on orientation cum workshop training	GTMC, Thoothukudi	16

237.	20-09-2022	Awareness and sensitization programme on pharmacovigilance	IMSBHU, Varanasi	18
238.	20-09-2022	Sensitization training on "Pharmacovigilance- Importance of ADR reporting for HCPs	APOLLO, New Delhi	25
239.	20-09-2022	Public awareness programme on Pharmacovigilance	APOLLO, New Delhi	85
240.	20-09-2022	Pharmacovigilance awareness programme	ACP, Malappuram	50
241.	20-09-2022	Awareness and sensitization programme on pharmacovigilance	MMCRI, Mysore	20
242.	20-09-2022	Community sensitization on PvPI and PvPI	MMMCH, Solan	150
243.	20-09-2022	Patient safety awareness camp	NIPER, Hajipur	100
244.	20-09-2022	Awareness and sensitization programme	NIMS, Hyderabad	40
245.	20-09-2022	Sensitization an awareness on role of consumer reporting in pharmacovigilance	YMC, Mangalore	43
246.	20-09-2022	Hands on training on ADR Form filling with case scenarios	VPCI, New Delhi	10
247.	20-09-2022	Encouraging reporting of ADRs by patient - self reporting	TNMC, Mumbai	10
248.	20-09-2022	Sensitization and awareness on Overview of pharmacovigilance	SVMC, Tirupati	10
249.	20-09-2022	Training on monitoring of ADRs	SJMCH, Puri	43

250.	20-09-2022	Sensitization and motivational lecture	SJMCH, Puri	18
251.	20-09-2022	School and community level sensitization	SSIMS, Bhilai	500
252.	20-09-2022	Introduction to Pharmacovigilance	SGRRI, Dehradun	155
253.	20-09-2022	Training about importance of pharmacovigilance	KEM, Mumbai	91
254.	20-09-2022	Hands on training on ADR Form filling with case scenarios	SNMMC, Dhanbad.	120
255.	20-09-2022	Online Seminar on "Encouraging patients for ADR reporting" at Baba Farid University	PGIMER, Chandigarh	130
256.	20-09-2022	Online Seminar on "Encouraging patients for ADR reporting" at Regional Institute of Medical Sciences	PGIMER, Chandigarh	170
257.	20-09-2022	Sensitization on ADR reporting and pharmacovigilance and future challenge	AIIMS, Nagpur	32
258.	20-09-2022	Sensitization an awareness on "Overview of pharmacovigilance"	AIMS, Kochi	26
259.	20-09-2022	Sensitization programme on ADR reporting and Pharmacovigilance Programme of India	AIMS, Kochi	15
260.	20-09-2022	Sensitization of patients about ADR reporting	CUSMC, Surendranagar	200
261.	20-09-2022	CME on ADR reporting & Importance of Pharmacovigilance	CIMS, Bilaspur	55

262.	20-09-2022	Sensitization on "Encouraging reporting of ADR by patients"	CMCH, Ludhiana	15
263.	20-09-2022	Sensitization on ADR reporting and benefits of ADR reporting	EPCMSRC, Bangalore	155
264.	20-09-2022	Sensitization on Patient for ADR reporting	GIMS, Gadag	50
265.	20-09-2022	Sensitization of nursing staff for reporting ADR	GBCMKKBMSH, Dehradun	62
266.	20-09-2022	Sensitization on reporting ADRs & its benefits	SGGSTU, Gurugram	200
267.	20-09-2022	Sensitization and awareness programme on "Encouraging HCPs/Patients for reporting ADRs	GMC, Dindigul	28
268.	20-09-2022	Sensitization and awareness on Pharmacovigilance reporting of ADRs and measure to reduce their incidence	KMC, Mangaluru	15
269.	20-09-2022	Workshop and awareness programme on Pharmacovigilance	RMC, Kakinada	28
270.	20-09-2022	Awareness campaign on ADR reporting and distribution of pamphlets	SMVMCH, Puducherry	100
271.	20-09-2022	Sensitization and awareness on Pharmacovigilance and medical safety	SPIPS, Warangal	300
272.	20-09-2022	Interactive session on ADR reporting	AIIMS, Gorakhpur	40
273.	20-09-2022	Sensitization and awareness on Pharmacovigilance	BRDMC, Gorakhpur	32
274.	20-09-2022	Sensitization and awareness on Pharmacovigilance & ADR reporting	RMLIMS, Lucknow	24

275.	20-09-2022	Pharmacovigilance awareness program- "Encouraging reporting of ADRs" by patient	MMCHRI, Kanchipuram	80
276.	20-09-2022	Clinical counselling & encouraging patients how to report ADR	SMCGH, Kurnool	100
277.	20-09-2022	Public awareness to report ADRs. How & why?	PRMMC, Mayurbhanj	150
278.	20-09-2022	Awareness programme on ADR reporting	UPUMS, Saifai, Etawah	315
279.	20-09-2022	Sensitization of patients and HCPs on Pharmacovigilance	SSIMS, Bhilai	150
280.	20-09-2022	ADR awareness training for general public	AIIMS, Bathinda	45
281.	20-09-2022	Sensitization and awareness on ADR Reporting	CIMS, Bilaspur	20
282.	20-09-2022	e-Display on "Awareness of drug safety among clinicians"	PSIMS&RF, Vijayawada	189
283.	20-09-2022	Sensitization regarding reporting ADRs	CUSMC, Surendra Nagar	200
284.	20-09-2022	Training of students on ADR reporting and filling	VMCHRI, Madurai	50
285.	20-09-2022	Training-cum-sensitization programme on Pharmacovigilance	TMCBRAM, AGARTALA	40
286.	20-09-2022	Sensitization and awareness programme on Pharmacovigilance	RMC, Kakinada	28
287.	20-09-2022	Workshop and awareness programme on Pharmacovigilance	GMC, SRINAGAR	82

288.	20-09-2022	Sensitization programme on Pharmacovigilance & ADR Reporting	GMC, Thrissur	27
289.	20-09-2022	Sensitization programme pharmacovigilance & ADR Reporting	GMERSMC, Ahmedabad	69
290.	20-09-2022	Sensitization Programme on Pharmacovigilance for non-teaching staff members	SMC, Meerut	74
291.	20-09-2022	CME on pharmacovigilance & ADR Reporting	JNMC, Aligarh	94
292.	20-09-2022	Sensitization programme pharmacovigilance & ADR Reporting	GMC, Amritsar	42
293.	20-09-2022	Importance of pharmacovigilance and its influence on patients' safety	PIP, Vadodara	250
294.	20-09-2022	Sensitization and awareness programme on Pharmacovigilance	CMJNM, Nadia	16
295.	20-09-2022	Sensitization and awareness programme on Pharmacovigilance	CMJNM, Nadia	12
296.	20-09-2022	Awareness and sensitization activity on PvPI, ADR Tollfree Number	CMMCH, Durg	38
297.	20-09-2022	Awareness/sensitization programme on PV at Community level	BJMC, Pune	50
298.	20-09-2022	Sensitization and awareness on Pharmacovigilance	MRIMS, Hyderabad	67
299.	20-09-2022	Sensitization and awareness on "How to report ADR"?	GMC, Pudukkottai	140

300.	20-09-2022	Sensitization and awareness programme on Pharmacovigilance	JIPMER, Puducherry	120
301.	20-09-2022	Sensitization and awareness programme on Pharmacovigilance	BPSGMC, Sonipat	100
302.	20-09-2022	Sensitization and awareness programme on Pharmacovigilance and ADR reporting	VCSGRI, Pauri Garhwal	82
303.	20-09-2022	Sensitization regarding Consumer ADR Reporting and reporting from for HCPs at various OPDs	STM, Kolkata	100
304.	20-09-2022	Sensitization and awareness programme on Pharmacovigilance	GMC, Haldwani	40
305.	20-09-2022	Community awareness programme at JNIMS	JNIMS, Imphal	100
306.	20-09-2022	Awareness-cum-lecture programme on Pharmacovigilance and Matereovigilance for MBBS and BDS students	RIMS, Imphal	168
307.	21-09-2022	Community level awareness programme on PV	AIIMS, Mangalagiri	25
308.	21-09-2022	Sensitization and awareness programme on PV and ADR reporting	AIIMS, Nagpur	130
309.	21-09-2022	Consumer awareness programme on reporting ADRs conducted at Cardiology ward	AIIMS, Rishikesh	30
310.	21-09-2022	Scientific and training programme for nursing officer and Student	AIIMS, Patna	57

311.	21-09-2022	Sensitization training on patient awareness of encouraging ADR reporting in medicine	KMC, Manipal	3
312.	21-09-2022	Sensitization & awareness among Nursing Staff & Pharmacists regarding ADR reporting	RIMS, Ranchi	50
313.	21-09-2022	Awareness programme on ADR reporting to consumers	SVCP, Hyderabad	40
314.	21-09-2022	Awareness of Pharmacovigilance and training of filing ADR Form	AIIMS, Deoghar	60
315.	21-09-2022	Sensitization programme on PvPI and session on how to fill ADR Form	GMERSMCGH, Gandhinagar	60
316.	21-09-2022	Sensitization on reporting of ADR	GMC, Miraj	150
317.	21-09-2022	Sensitization of Hospital staff on "Encouraging safe use of medicine"	PJNGMC, Chamba	30
318.	21-09-2022	Orientation on Pharmacovigilance for faculty and postgraduate students	MGIMS, Wardha	25
319.	21-09-2022	Sensitization training on Pharmacovigilance - A step Toward Patient Safety	NH, Rajpura	50
320.	21-09-2022	Sensitization and awareness of hospital staff for reporting ADRs	PMCSKH, Anand	160
321.	21-09-2022	Sensitization and awareness of hospital staff for reporting ADRs	PMCSKH, Anand	30

322.	21-09-2022	Sensitization training on Basic knowledge on Pharmacovigilance	RGKMC, Kolkata	147
323.	21-09-2022	Hands on training on ADR Form filling with case scenarios	SMCH, Silchar	30
324.	21-09-2022	Community level awareness cum sensitization programme on Pharmacovigilance	SDUMC, Kolar	49
325.	21-09-2022	CME Workshop on awareness generation about Pharmacovigilance	SBKSMI/RC, Waghodia	64
326.	21-09-2022	Sensitization awareness programme on PV and ADR reporting	KAMSRC, Hyderabad	50
327.	21-09-2022	ADR reporting awareness for local pharmacist	GMC, Manjeri Malappuram,	10
328.	21-09-2022	Sensitization and awareness programme on PvPI	AFMC, Pune	30
329.	21-09-2022	Workshop on pharmacovigilance	BIPS, Warangal	112
330.	21-09-2022	Student sensitization programme on Pharmacovigilance	RVMIMS, Siddipet	50
331.	21-09-2022	Awareness and sensitization programme on pharmacovigilance and ADR Reporting	AIIMS, Bilaspur	58
332.	21-09-2022	Scientific and training programme for nursing officer and Student	AIIMS, Patna	85
333.	21-09-2022	Lecture on Pharmacovigilance awareness	AIIMS, Jodhpur	100

334.	21-09-2022	Pharmacovigilance in patient safety -current scenario, implications and challenges	CHRI, Chengalpattu	13
335.	21-09-2022	To sensitize all nursing staff and patients about ADR reporting	DYSPGM, Sirmaur	34
336.	21-09-2022	Pharmacovigilance sensitization and awareness programme	ESICMC, Bengaluru	297
337.	21-09-2022	Awareness and sensitization programme on pharmacovigilance and ADR Reporting	CHRI, Chengalpattu	100
338.	21-09-2022	Sensitization lecture for nursing professionals regarding reporting of suspected ADRs	GMERSMCGH, Gandhinagar	500
339.	21-09-2022	Sensitization programme for "Encouraging reporting of ADRs by patient - Self reporting"	GTMC, Thiruvarur	35
340.	21-09-2022	Sensitization programme on "Pharmacovigilance-A step towards the patient safety"	GTMC, Thiruvarur	20
341.	21-09-2022	Hands on training on ADR Form filling with case scenarios	IGIMS, Patna	113
342.	21-09-2022	Awareness and sensitization programme on Pharmacovigilance	IMSBHU, Varanasi	49
343.	21-09-2022	Pamphlet distribution to pharmacy stores	APOLLO, New Delhi	15
344.	21-09-2022	Sensitization programme on ADR reporting by PV Associate	APOLLO, New Delhi	22

345.	21-09-2022	Awareness programme for patient at OPD, MGM	KMC, Warangal	45
346.	21-09-2022	Sensitization programme on "Overview of PvPI"	KFMSR, Coimbatore	50
347.	21-09-2022	Pharmacovigilance awareness programme	ACP, Malappuram	50
348.	21-09-2022	Sensitization programme on Pharmacovigilance, PvPI, AEFI	KMC, Kurnool	25
349.	21-09-2022	Sensitization of consumers and pharmacist regarding Pharmacovigilance and ADR reporting	MGMCRI, Pondicherry	106
350.	21-09-2022	Awareness and sensitization programme on Pharmacovigilance	MMCRI, Mysore	80
351.	21-09-2022	Online lecture on sensitization about PvPI	MMMCH, Solan	100
352.	21-09-2022	Pharmacovigilance awareness camp for healthcare professionals	NIPER, Hajipur	30
353.	21-09-2022	Awareness and sensitization programme on Pharmacovigilance	NIMS, Hyderabad	100
354.	21-09-2022	Sensitization of consumer regarding Pharmacovigilance and ADR monitoring	BJMC, Ahmedabad	250
355.	21-09-2022	General public awareness in OPD	VPCI, New Delhi	58
356.	21-09-2022	Pharmacovigilance awareness camp for healthcare professionals	TNMC, Mumbai	27
357.	21-09-2022	Pharmacovigilance sensitization and awareness programme	SRMMC, Kattankulathur	120

358.	21-09-2022	Awareness activity on PvPI	SVMC, Tirupati	50
359.	21-09-2022	Training about importance of Pharmacovigilance	KEM, Mumbai	19
360.	21-09-2022	Virtual Seminar on "Encouraging Patients for ADR Reporting" at Rayat Bahra University	PGIMER, Chandigarh	160
361.	21-09-2022	Sensitization and awareness on reporting ADRs	AGMC, Agartala	70
362.	21-09-2022	Sensitization and awareness on "Fundamentals of Pharmacovigilance"	AIIMS, Nagpur	130
363.	21-09-2022	ADR reporting awareness programme	CUSMC, Surendra Nagar	50
364.	21-09-2022	CME on ADR reporting & Importance of Pharmacovigilance	CIMS, Bilaspur	100
365.	21-09-2022	Awareness of ADRs among healthcare professionals and patients	CMC, Coimbatore	200
366.	21-09-2022	Sensitization of nursing staff regarding reporting of ADRs	GBCMKKBMSH, Dehradun	97
367.	21-09-2022	Sensitization and awareness programme on reporting ADRs	SGGSTU, Gurugram	120
368.	21-09-2022	Sensitization programme on "Encouraging patients for reporting ADRs"	GMC, Dindigul	32
369.	21-09-2022	Sensitization programme on "Encouraging patients for reporting ADRs"	GTMC, Thiruvarur	35
370.	21-09-2022	Sensitization programme on "Pharmacovigilance-A step towards the patient safety"	GTMC, Thiruvarur	20

371.	21-09-2022	Sensitization an awareness on Pharmacovigilance reporting of ADRs and measure to reduce their incidence	KMC, Mangaluru	80
372.	21-09-2022	Awareness campaign on ADRs reporting and distribution of pamphlets	SMVMCH, Puducherry	100
373.	21-09-2022	Sensitization and awareness on "Pharmacist-Primary drug safety expert"	SPIPS, Warangal	350
374.	21-09-2022	Pharmacovigilance sensitization and awareness programme	TMCH, Navi Mumbai	76
375.	21-09-2022	Hands on workshop for ADR detection and filling of ADR reporting form	BCMCH, Thiruvalla	35
376.	21-09-2022	Sensitization and awareness on Pharmacovigilance & ADR Reporting	RMLIMS, Lucknow	42
377.	21-09-2022	Sensitization and awareness on Materiovigilance- Ensuring safety of Medical Device"	MMCHRI, Kanchipuram	50
378.	21-09-2022	Awareness programme on reporting ADRs on IPD and OPD at Santhiram General Hospital	SMCGH, Kurnool	75
379.	21-09-2022	Sensitization of staff at krushnachandrapur CHC on ADR reporting: Modes & Methods	PRMMC, Mayurbhanj	60
380.	21-09-2022	Increasing awareness of reporting ADRs	SSIMS, Bhilai	160
381.	21-09-2022	Sensitization and awareness on ADR Reporting	CIMS, Bilaspur	32
382.	21-09-2022	Sensitization on "Concepts of Pharmacovigilance"	Dr. PSIMS & RF, Vijayawada	25

383.	21-09-2022	Awareness programme on reporting ADR	CUSMC, Surendra Nagar	50
384.	21-09-2022	Awareness programme on ADR reporting	TMCH , Navi Mumbai	63
385.	21-09-2022	Training of students on reporting ADRs and filling of ADR reporting Form	VMCHRI, Madurai	50
386.	21-09-2022	Sensitization programme on filling of ADR reporting format	VMCHRI, Madurai	70
387.	21-09-2022	Awareness programme-cum-training for reporting ADRs	TMCBRAM, AGARTALA	70
388.	21-09-2022	Workshop and awareness programme on Pharmacovigilance	GMC, SRINAGAR	98
389.	21-09-2022	Workshop on filling of ADR reporting Form	DCDSIMER, Ramanagar	25
390.	21-09-2022	Community level sensitization programme on Pharmacovigilance to Consumer/Patients on ADR reporting at PHC Moinabag Rangareddy	BMC, Hyderabad	40
391.	21-09-2022	Sensitization programme & Hands on training on ADR Reporting form filling for MBBS students at Bhaskar Medical Collage	BMC, Hyderabad	50
392.	21-09-2022	Sensitization programme on Pharmacovigilance & ADR Reporting	GMERSMC, Ahmedabad	17
393.	21-09-2022	Sensitization programme on Pharmacovigilance & ADR Reporting	KLECP, Hubballi	5
394.	21-09-2022	Community level sensitization programme on Pharmacovigilance	KLECP, Hubballi	300

395.	21-09-2022	Sensitization programme on Pharmacovigilance & ADR Reporting	GMC, Siddipet	100
396.	21-09-2022	Sensitization programme on "Encouraging patients for reporting ADRs"	VSSMC, Burla	150
397.	21-09-2022	Sensitization programme on Pharmacovigilance & ADR Reporting	JNMC, Aligarh	100
398.	21-09-2022	Sensitization programme on Medication Safety: How to prevent Medication Errors'?	BGSGIMS, Bengaluru	25
399.	21-09-2022	Sensitization and awareness programme on Pharmacovigilance	CMJNM, Nadia	25
400.	21-09-2022	Awareness sensitization activity on PvPI, how to report ADR?	CMMCH, Durg	102
401.	21-09-2022	Sensitization and awareness programme on Pharmacovigilance	SVCP, Hyderabad	160
402.	21-09-2022	Sensitization programme on ADR Reporting	GMCH, Guwahati	100
403.	21-09-2022	Awareness on Drug ADRs; How and Where to Report? Filing the ADR form by General Public and Patients	SSSMCRI, Chengalpattu	40
404.	21-09-2022	Sensitization and awareness on "How to report ADR"?	GMC, Pudukkottai	153
405.	21-09-2022	Sensitization and awareness programme on Pharmacovigilance - Rural healthcare Centre	JIPMER, Puducherry	143
406.	21-09-2022	Sensitization and awareness programme on Pharmacovigilance	BBMCH, Balangir	100

407.	21-09-2022	Sensitization and awareness programme on Pharmacovigilance	SPCP, Abdullapurmet	52
408.	21-09-2022	Sensitization on Consumer ADR Reporting at Sanjeevani Hospitals & Chikitsha Polyclinic	STM, Kolkata	50
409.	21-09-2022	Sensitization on Pharmacovigilance, Haemovigilance, Materiovigialnce Programme of India	GMC, Haldwani	192
410.	21-09-2022	Sensitization and awareness programme on Pharmacovigilance - An overview of Medication Error and Drug Interactions	PESIMSR, Kuppam	50
411.	21-09-2022	Sensitization and awareness programme on Pharmacovigilance	RIMS, Imphal	20
412.	21-09-2022	CME on Pharmacovigilance for nurses	MAMC, New Delhi	141
413.	21-09-2022	Creating awareness by distributing pamphlets about reporting ADR among the healthcare and non-healthcare students at JKKN Institutions	JKKNCP, Salem	150
414.	21-09-2022	Sensitization and awareness programme for public on reporting of ADRs	RNTMC, Udaipur	8
415.	22-09-2022	Community level awareness programme on PV	AIIMS, Mangalagiri	150
416.	22-09-2022	Sensitization and awareness programme on PvPI	GMC, Kozhikode	28
417.	22-09-2022	Awareness programme on "Encouraging Consumers for reporting ADRs"	KIMS, Nalgonda	30

418.	22-09-2022	Sensitization programme for patients on "Side effect reporting"	SAIMS, Indore	67
419.	22-09-2022	Consumer awareness programme conducted at Neurology OPD	AIIMS, Rishikesh	20
420.	22-09-2022	Sensitization training on Introduction to Pharmacovigilance	AIIMS, Raipur	135
421.	22-09-2022	Sensitization programme on ADR Reporting	GTDMC, Alappuzha	15
422.	22-09-2022	Sensitization training on Orientation on pharmacovigilance and ADR reporting	MMCHRI, Kanchipuram	250
423.	22-09-2022	Sensitization training on CME on ADR reporting & Importance of Pharmacovigilance	RIMS, Ranchi	100
424.	22-09-2022	Awareness programme on ADR reporting by consumers	SVCP, Hyderabad	50
425.	22-09-2022	Sensitization programme on PvPI and session on how to fill ADR Form?	GMERSMCGH, Gandhinagar	50
426.	22-09-2022	Sensitization programme on ADR Reporting	JIPMER, Karaikal	35
427.	22-09-2022	Sensitization programme and hands on training for filling ADR reporting form	PJNGMC, Chamba	45
428.	22-09-2022	Orientation on reporting ADRs for faculty and postgraduate students	MGIMS, Wardha	15
429.	22-09-2022	Sensitization training on "Understanding of common and severe ADRs"	NH, Rajpura	40

430.	22-09-2022	Sensitization and awareness programme for reporting ADRs	PMCSKH, Anand	43
431.	22-09-2022	Sensitization and awareness programme for reporting ADRs	PMCSKH, Anand	88
432.	22-09-2022	Hands on training on ADR Form filling with case scenarios	SMCH, Silchar	30
433.	22-09-2022	Sensitization programme on ADR Reporting	JMMCRI, Thrissur	50
434.	22-09-2022	Awareness on ADR Reporting	JMMCRI, Thrissur	50
435.	22-09-2022	Sensitization training on Distribution of PV resource material and Sensitization about Pharmacovigilance & ADR reporting	AIIMS, Bhopal	30
436.	22-09-2022	Sensitization and awareness training programme on PV	RDGMC, Ujjain	180
437.	22-09-2022	CME on workshop on awareness generation	SBKSMI/RC, Waghodia	69
438.	22-09-2022	Sensitization awareness programme on PV and ADR reporting	KAMSRC, Hyderabad	50
439.	22-09-2022	Workshop on ICMR guideline and GCP clinical trial	DCDSIMER, Ramanagar	200
440.	22-09-2022	Sensitization & awareness training programme on "Encouraging patients for reporting ADR"	GMC, Malappuram	30
441.	22-09-2022	Sensitization & awareness training programme on "Encouraging patients for reporting ADR"	GMC, Malappuram	100
442.	22-09-2022	Sensitization and awareness programme on PvPI	AFMC, Pune	30

443.	22-09-2022	Sensitization and awareness program on Safe Drug & Pharmacovigilance	GMC, Pali	150
444.	22-09-2022	Sensitization training on "To create awareness for patients about self-reporting of ADRs at Urban Primary Health Centre	MAIMSR, Chengalpattu	60
445.	22-09-2022	Sensitization programme on Pharmacovigilance for students	RVMIMS, Siddipet	15
446.	22-09-2022	Sensitization training on filling of ADR reporting form	AJIMS, Mangalore	150
447.	22-09-2022	Awareness and sensitization programme on pharmacovigilance and ADR reporting	AIIMS, Bilaspur	59
448.	22-09-2022	Pharmacovigilance sensitization and awareness programme for community level HCPs	ESICMC, Bengaluru	80
449.	22-09-2022	Sensitization and importance of ADR reporting and Materiovigilance	ESICMC, Bengaluru	50
450.	22-09-2022	Awareness and sensitization programme on pharmacovigilance and ADR reporting	CHRI, Chengalpattu	200
451.	22-09-2022	Virtual seminar on pharmacovigilance awareness	GMERSMCGH, Gandhinagar	460
452.	22-09-2022	Awareness and sensitization programme on Pharmacovigilance-A step toward patient safety	GTMC, Thiruvarur	55

453.	22-09-2022	Awareness and sensitization programme on Pharmacovigilance-A step toward patient safety	GTMC, Thiruvarur	100
454.	22-09-2022	Hands on training on filling of ADR reporting form with case scenarios	IGIMS, Patna	30
455.	22-09-2022	Training on Pharmacovigilance and reporting of ADRs	GMCH, Nagpur	65
456.	22-09-2022	Invited talk on ADRs reporting	NITTE, Mangaluru	187
457.	22-09-2022	Awareness programme on reporting ADRs for patient at OPD, MGM	KMC, Warangal	45
458.	22-09-2022	Pharmacovigilance Sensitization programme	KFMSR, Coimbatore	150
459.	22-09-2022	Pharmacovigilance Sensitization programme	KFMSR, Coimbatore	22
460.	22-09-2022	Virtual webinar on "Encouraging patients for reporting ADRs	KFMSR, Coimbatore	98
461.	22-09-2022	Pharmacovigilance awareness programme	ACP, Malappuram	150
462.	22-09-2022	Webinar on pharmacovigilance- Key to drug safety	KMC, Kurnool	180
463.	22-09-2022	Sensitization programme on Pharmacovigilance, PvPI & AEFI	KMC, Kurnool	30
464.	22-09-2022	Vaccine vigilance sensitization session	MSRMC, Bengaluru	63

465.	22-09-2022	Sensitizing of nursing staff and students on pharmacovigilance and ADR reporting	MGMCRI, Pondicherry	130
466.	22-09-2022	Awareness and sensitization programme on pharmacovigilance	MMCRI, Mysore	47
467.	22-09-2022	Seminar on Pharmacovigilance and Meteriovigilance	NIPER, Hajipur	100
468.	22-09-2022	Demonstration and workshop on VigiFlow	NIPER, Hajipur	120
469.	22-09-2022	Awareness and sensitization programme on Pharmacovigilance	NIMS, Hyderabad	40
470.	22-09-2022	Sensitization of consumer regarding Pharmacovigilance and ADR monitoring	BJMC, Ahmedabad	40
471.	22-09-2022	CME on Pharmacovigilance: A step towards patient safety	VPCI, New Delhi	40
472.	22-09-2022	Awareness and sensitization programme on "Encouraging patients for reporting ADRs"	TNMC, Mumbai	130
473.	22-09-2022	Pharmacovigilance community outreach program	SRMMC, Kattankulathur	80
474.	22-09-2022	Importance of pharmacovigilance in patient safety	SVMC, Tirupati	27
475.	22-09-2022	Encouraging reporting of ADRs by patient - self reporting	SNIMS, Ernakulam	100
476.	22-09-2022	Medicine male and female ward encouraging about ADR	SNIMS, Ernakulam	60
477.	22-09-2022	Sensitization and awareness programme about PvPI	SNIMS, Ernakulam	40

478.	22-09-2022	Training on reporting ADRs	SJMCH, Puri	39
479.	22-09-2022	Training on importance of Pharmacovigilance	KEM, Mumbai	11
480.	22-09-2022	Seminar on Pharmacovigilance	SNMMC, Dhanbad	80
481.	22-09-2022	Virtual Seminar on Encouraging Patients for ADR Reporting at MMU, Solan Campus	PGIMER, Chandigarh	45
482.	22-09-2022	Virtual Seminar on Encouraging Patients for ADR Reporting at Central Scientific Instruments Organisation	PGIMER, Chandigarh	66
483.	22-09-2022	Seminar on Encouraging Patients for ADR Reporting at Punjab University	PGIMER, Chandigarh	126
484.	22-09-2022	Seminar on Encouraging Patients for ADR Reporting at Aryan Group of Collages, Punjab	PGIMER, Chandigarh	62
485.	22-09-2022	Seminar on Encouraging Patients for Reporting ADR	PGIMER, Chandigarh	200
486.	22-09-2022	Awareness cum training for pharmacovigilance and ADR reporting	AGMC, Agartala	100
487.	22-09-2022	CME on ADR reporting & Importance of Pharmacovigilance	CIMS, Bilaspur	130
488.	22-09-2022	Sensitization & awareness programme on "Encouraging for reporting ADR"	GMC, Dindigul	35
489.	22-09-2022	Sensitization & awareness programme on Pharmacovigilance-A step toward patient safety	GTMC, Thiruvarur	55

490.	22-09-2022	Sensitization & awareness programme on Pharmacovigilance-A step toward patient safety	GTMC, Thiruvarur	100
491.	22-09-2022	Sensitization and awareness programme on Medication safety	MVRCCR, Kozhikode	33
492.	22-09-2022	Sensitization an awareness on Pharmacovigilance reporting of Adverse drug reaction and measure to reduce their incidence	KMC, Mangaluru	150
493.	22-09-2022	Workshop and awareness programme on Pharmacovigilance	SIIP, Ibrahimpatnam	120
494.	22-09-2022	Awareness campaign on ADR reporting and distribution of pamphlets	SMVMCH, Puducherry	100
495.	22-09-2022	Awareness programme on ADR reporting to consumers	SRMC, Chennai	12
496.	22-09-2022	Sensitization an awareness on Pharmacovigilance and medical safety	SPIPS, Warangal	300
497.	22-09-2022	Interactive session on ADR reporting	AIIMS, Gorakhpur	40
498.	22-09-2022	Encouraging ADR reporting by patients	JKKNCP, Salem	170
499.	22-09-2022	Sensitization an awareness on Pharmacovigilance & ADR Reporting	JSS, Mysore	98
500.	22-09-2022	Sensitization an awareness on Pharmacovigilance in TB	ICMR-NIRT, Chennai	85
501.	22-09-2022	Awareness programme cum sensitization programme regarding ADR reporting	UPUMS, Saifai, Etawah	210

502.	22-09-2022	Encouraging reporting of ADR by patients	AIIMS, Bathinda	47
503.	22-09-2022	Sensitization an awareness on ADR Reporting	CIMS, Bilaspur	7
504.	22-09-2022	Sensitization and awareness on Medication safety	HCGEKOCC, Kolkata	33
505.	22-09-2022	Awareness of ADR Reporting from Patients & Hospital Personnels	SIIP, Ibrahimpatnam	25
506.	22-09-2022	Sensitization programme on ADR reporting	TMCBRAM, Agartala	100
507.	22-09-2022	Sensitization programme on ADR reporting	SMVMCH, Puducherry	150
508.	22-09-2022	Workshop on ICMR-GCP Guidelines	DCDSIMER, Ramanagar	200
509.	22-09-2022	PV Symposium	BMC, Burdwan	40
510.	22-09-2022	Sensitization programme on Safe Drugs and Pharmacovigilance	GMC, Pali	150
511.	22-09-2022	Sensitization programme pharmacovigilance & ADR Reporting	GMC, Thrissur	18
512.	22-09-2022	Sensitization Programme on Pharmacovigilance	SMC, Meerut	55
513.	22-09-2022	Encouraging patients for reporting ADRs	VSSMC, Burla	90
514.	22-09-2022	PV in Industry-Scope and Practices	VSSMC, Burla	30
515.	22-09-2022	Sensitization programme pharmacovigilance & ADR Reporting	GMC, Amritsar	40

516.	22-09-2022	Sensitization programme on pharmacovigilance & ADR Reporting and uploading to in VigiFlow	PSGIMSR, Coimbatore	9
517.	22-09-2022	Preventing Medication Errors at various levels: Creating Awareness for the Prescribers of Tomorrow'	BGSGIMS, Bengaluru	166
518.	22-09-2022	Sensitization and awareness programme on Pharmacovigilance	CMJNM, Nadia	16
519.	22-09-2022	Awareness sensitization activity on PvPI-How to report ADR?	CMMCH, Durg	220
520.	22-09-2022	Sensitization and awareness on CME on Benefits Risk assessment in Pharmacovigilance	MRIMS, Hyderabad	62
521.	22-09-2022	Sensitization on ADR Reporting	GMCH, Guwahati	200
522.	22-09-2022	Awareness on ADR and ADR reporting among community in peripheral hospital	VIMS, Bangloure	45
523.	22-09-2022	Sensitization and awareness on How to report ADR?	GMC, Pudukkottai	70
524.	22-09-2022	Sensitization and awareness programme on Pharmacovigilance	JIPMER, Puducherry	103
525.	22-09-2022	Encouraging patients for reporting ADRs	GMC, Suryapet	60
526.	22-09-2022	Sensitization and patients awareness camp regarding promotion of self-reporting of ADRs in OPD	BBMCH, Balangir	45

527.	22-09-2022	Sensitization and awareness programme on Pharmacovigilance and Medication Error	SPCP, Abdullapurmet	181
528.	22-09-2022	Sensitization and awareness programme on Pharmacovigilance	GMC, Haldwani	148
529.	22-09-2022	Workshop on awareness programme on pharmacovigilance and ADR reporting for all HCPs	RIMS, Imphal	71
530.	22-09-2022	Virtual lecture on PvPI	MMMCH, Solan	150
531.	22-09-2022	Sensitization an awareness on Participation of ADR case reports	JKKNCP, Salem	10
532.	22-09-2022	Sensitization an awareness on How to identify Adverse Drug Reaction	JKKNCP, Salem	170
533.	22-09-2022	Awareness talks on topic "ADR reporting for Para medicals"	YMC, Mangalore	30
534.	22-09-2022	A Workshop on Pharmacovigilance and Patient Safety	SIIP, Ibrahimpatnam	120
535.	22-09-2022	Sensitization programme for ADR reporting	RNT MC, Udaipur	34
536.	23-09-2022	Community level awareness programme on PV	AIIMS, Mangalagiri	150
537.	23-09-2022	Sensitization about ADR reporting	GTDMC, Alappuzha	25
538.	23-09-2022	Sensitization about ADR reporting	GTDMC, Alappuzha	50
539.	23-09-2022	Sensitization about ADR reporting	GTDMC, Alappuzha	10

540.	23-09-2022	Training programme for nursing students regarding filling of ADR form	RIMS, Ranchi	70
541.	23-09-2022	Training of general public about reporting of ADRs	SMIMER, Surat	70
542.	23-09-2022	Sensitization programme on PvPI and session on how to fill ADR Form	GMERSMCGH, Gandhinagar	10
543.	23-09-2022	Sensitization on reporting of ADR	GMC, Miraj	50
544.	23-09-2022	Orientation of faculty and postgraduate students	MGIMS, Wardha	25
545.	23-09-2022	Sensitization and awareness of reporting ADR	PMCSKH, Anand	123
546.	23-09-2022	Sensitization and awareness of reporting ADR	PMCSKH, Anand	7
547.	23-09-2022	Community level awareness cum sensitization programme	SDUMC, Kolar	53
548.	23-09-2022	Lecture on reporting of ADRs, & Medical Safety	TNMC, Mumbai	90
549.	23-09-2022	Consumer awareness programme	AIIMS, Bhopal	300
550.	23-09-2022	Sensitization and awareness training Programme	RDGMC, Ujjain	160
551.	23-09-2022	Awareness generation and gathering ADR	SBKSMI/RC, Waghodia	80
552.	23-09-2022	Pharmacovigilance awareness programme	SMIMS, Kulasekharam	123
553.	23-09-2022	Sensitization awareness program on PV and ADR reporting	BIPS, Warangal	200

554.	23-09-2022	CME on Pharmacovigilance-overview	GMKMC, Salem	300
555.	23-09-2022	Public Awareness programme	GKMC, Chennai	50
556.	23-09-2022	Sensitization training on to emphasis on the importance of ADR reporting by patients and Physicians at Privat Hospital	MAIMSR, Chengalpattu	10
557.	23-09-2022	Lecture on Materiovigilance	AJIMS, Mangalore	200
558.	23-09-2022	To sensitize all nursing staff and patients about ADR reporting	DYSPGM, Sirmaur	40
559.	23-09-2022	Sensitization and importance of ADR reporting and Materiovigilance	ESICMC, Bengaluru	40
560.	23-09-2022	Awareness and sensitization programme on pharmacovigilance	CHRI, Chengalpattu	100
561.	23-09-2022	Encouraging reporting of ADRs by patient-self reporting	GTMC, Thiruvarur	53
562.	23-09-2022	Pharmacovigilance a step toward patient safety	GTMC, Thiruvarur	15
563.	23-09-2022	Sensitization on ADR and ADR form filling for TB Healthcare workers working at District levels	KFMSR, Coimbatore	28
564.	23-09-2022	Pharmacovigilance Sensitization programme	KFMSR, Coimbatore	45
565.	23-09-2022	Pharmacovigilance awareness programme	ACP, Malappuram	200
566.	23-09-2022	Sensitization programme on pharmacovigilance, PvPI, AEFI	KMC, Kurnool	120

567.	23-09-2022	Sensitization programme on pharmacovigilance, PvPI, AEFI	KMC, Kurnool	120
568.	23-09-2022	Sensitization programme on pharmacovigilance, PvPI, AEFI	KMC, Kurnool	120
569.	23-09-2022	Awareness and sensitization programme on pharmacovigilance	MAMS, Hyderabad	60
570.	23-09-2022	Awareness and sensitization programme on pharmacovigilance	MMCRI, Mysore	100
571.	23-09-2022	Awareness and sensitization programme	NIMS, Hyderabad	70
572.	23-09-2022	Awareness cum sensitization programme for HCPs	VPCI, New Delhi	17
573.	23-09-2022	PvPI sensitization lecture	TNMC, Mumbai	90
574.	23-09-2022	Pharmacovigilance awareness programme	SVMCHRC, Puducherry	259
575.	23-09-2022	Sensitization an awareness on emerging trends and updates in PvPI	SVMC, Tirupati	115
576.	23-09-2022	Training about importance of pharmacovigilance	KEM, Mumbai	15
577.	23-09-2022	Seminar on Pharmacovigilance and Pharmacovigilance	SNMMC, Dhanbad.	100
578.	23-09-2022	Seminar On Encouraging Patients for ADR Reporting at GMC Patiala	PGIMER, Chandigarh	72
579.	23-09-2022	Online Seminar on Encouraging Patients for ADR Reporting at Chitkara University.	PGIMER, Chandigarh	180

580.	23-09-2022	Online Seminar on Encouraging Patients for ADR Reporting at Shivalik College of Nursing	PGIMER, Chandigarh	50
581.	23-09-2022	Sensitization of HCPs regarding PV at AGMC on a workshop on good clinical practices	AGMC, Agartala	100
582.	23-09-2022	Seminar on Pharmacovigilance and Meteriovigilance	GAMC, Ratlam	132
583.	23-09-2022	Awareness of adverse drug reactions among healthcare professional and patient	CMCH, Ludhiana	100
584.	23-09-2022	Sensitization programme on ADR reporting	GIMS, Gadag	50
585.	23-09-2022	CME on pharmacovigilance: A step towards patient safety	GMC, Dindigul	200
586.	23-09-2022	Pharmacovigilance a step toward patient safety	GTMC, Thiruvarun	52
587.	23-09-2022	Pharmacovigilance a step toward patient safety	GTMC, Thiruvarun	15
588.	23-09-2022	Sensitization an awareness on ADR reporting	MVRCCR. Kozihikode	27
589.	23-09-2022	Sensitization an awareness on Pharmacovigilance reporting of ADRs and measure to reduce their incidence	KMC, Mangaluru	250
590.	23-09-2022	Sensitization an awareness on Pharmacovigilance reporting of ADRs and measure to reduce their incidence	KMC, Mangaluru	30

591.	23-09-2022	Sensitization an awareness on ADR identification and reporting	MOSCMCH, Kerala	60
592.	23-09-2022	Sensitization on Concepts of Pharmacovigilance	PSIMS&RF, Andhra Pradesh	450
593.	23-09-2022	Workshop and awareness programme on Pharmacovigilance	SIIP, Ibrahimpatnam	25
594.	23-09-2022	Awareness campaign on ADR reporting and distribution of pamphlets	SMVMCH, Puducherry	100
595.	23-09-2022	Sensitization an awareness on Pharmacovigilance	SPIPS, Warangal	200
596.	23-09-2022	Awareness programme on ADR reporting	DMCH, Ludhiana	400
597.	23-09-2022	Workshop on ADR reporting	MMCHRI, Kanchipuram	20
598.	23-09-2022	Seminar on awareness of pharmacovigilance and ADR case presentation	ASMCSNMH& TBS, Firozabad	132
599.	23-09-2022	Sensitization programme for doctors, PG and interns about ADR form filling	GIMS, Gadag	60
600.	23-09-2022	Sensitization and awareness on ADR reporting by the patient	HCGEKOCC, Kolkata	27
601.	23-09-2022	Sensitization programme on ADR reporting	TMCBRAM, AGARTALA	100
602.	23-09-2022	Sensitization programme on ADR reporting	SMVMCH, Puducherry	150
603.	23-09-2022	Awareness programme for Nursing Staff on "Introduction of Pharmacovigilance and ADR Reporting"	BMC, Hyderabad	75
604.	23-09-2022	Sensitization programme pharmacovigilance & ADR Reporting	KLECP, Hubballi	128

605.	23-09-2022	Sensitization-cum-workshop programme for non-teaching staff members of Subharti Medical College	SMC, Meerut	28
606.	23-09-2022	Sensitization programme pharmacovigilance & ADR Reporting	GMC, Amritsar	50
607.	23-09-2022	Public Awareness on 'Safe Use of Medicines'	BGSGIMS, Bengaluru	100
608.	23-09-2022	'Medication safety: Everyone's Responsibility'	BGSGIMS, Bengaluru	30
609.	23-09-2022	Awareness sensitization activity about PvPI & its Tollfree Number	CMMCH, Durg	89
610.	23-09-2022	Awareness sensitization activity about PvPI & its Tollfree Number	CMMCH, Durg	66
611.	23-09-2022	Awareness Programme on PV	GMCH, Guwahati	100
612.	23-09-2022	Awareness on ADR and ADR reporting and proper antibiotic utilization in near pharmacy and OPD	VIMS, Bangalore	52
613.	23-09-2022	Sensitization and awareness programme on Pharmacovigilance for nursing staff	JIPMER, Puducherry	153
614.	23-09-2022	Sensitization and awareness programme on Pharmacovigilance and ADR reporting of pharmacist and Pharmacy students	VCSGRI, Pauri Garhwal	25
615.	23-09-2022	Sensitization and awareness programme on Pharmacovigilance	GMC, Bhavnagar	75
616.	23-09-2022	Sensitization and awareness programme on Pharmacovigilance	GMC, Haldwani	78
617.	23-09-2022	Pharmacovigilance Sensitization workshop- A medication Error perspective	GCMCH, Chengalpattu	189

618.	23-09-2022	Sensitization and awareness programme on Pharmacovigilance	JNIMS, Imphal	100
619.	23-09-2022	Conducted workshop on awareness programme on pharmacovigilance and Hands on training about ADR reporting for Pharmacy students	RIMS, Imphal	69
620.	23-09-2022	CME on Pharmacovigilance workshop for doctors	MAMC, New Delhi	98
621.	23-09-2022	Creating awareness by distributing pamphlets about reporting ADR among patients and health care professionals in Government Headquarters Hospitals, Erode	JKKNCP, Salem	250
622.	23-09-2022	ADR reporting for nurses	PSGIMSR, Coimbatore	18
623.	17 to 23-09-2022	Pharmacovigilance Sensitization on PV and its significance at Govt. ayurvedic college	KGMC, Kanyakumari	400
624.	17 to 23-09-2022	Pharmacovigilance Sensitization on PV and its significance at S. A Raja pharmacy college	KGMC, Kanyakumari	300
625.	19 to 21-09-2022	Sensitization on ADR Reporting for second phase MBBS Students	PSGIMSR, Coimbatore	240
626.	17 to 23-09-2022	Awareness programme on ADR reporting	VMCHRI, Madurai	90
627.	22 to 23-09-2022	Awareness programme on Pharmacovigilance and ADR reporting for Pharmacist	BRDMC, Gorakhpur	10
628.	17 to 23-09-2022	National Pharmacovigilance Week 2022 "Encouraging reporting of Adverse Drug Reactions by Patients"	Apeejay Satya University, Gurugram (Non AMCs)	60

4. e-Indian Technical and Economic Cooperation (ITEC) Course on International Pharmacovigilance Training Programme

The Development Partnership Administration (DPA) division of Ministry of External Affairs (MEA), Govt. of India has identified IPC to provide training in the area of Pharmacovigilance to partner countries for capacity building.

In this context, PvPI, IPC organized 20 hours (5 days x 4 hours) training programme virtually from 5th-9th December 2022 at IPC, focussed on Pharmacovigilance, basic tools applied for Adverse Drug Reporting/Monitoring, method used in Pharmacovigilance and impact of Pharmacovigilance practices on post COVID19 pandemic. This international training also focussed on to;

- The basic need and scope of Pharmacovigilance system.
- Understand and strengthen the Pharmacovigilance post COVID19 pandemic.
- Establishing Causality Assessment of Drug-Event combination.
- Group exercise along with discussion for the participants to resolve their issues on topics.

A total of 27 participants from seven countries- Egypt, Mauritius, Morocco, Myanmar, Nicaragua, Sri Lanka & Tunisia registered through the e-ITEC portal of Ministry of External Affairs, Government of India.

5. Month wise distribution of total trainings/workshops organised in PvPI

A total of 1795 trainings were conducted by NCC & AMCs and trained a total of 109571 participants in the area of pharmacovigilance.

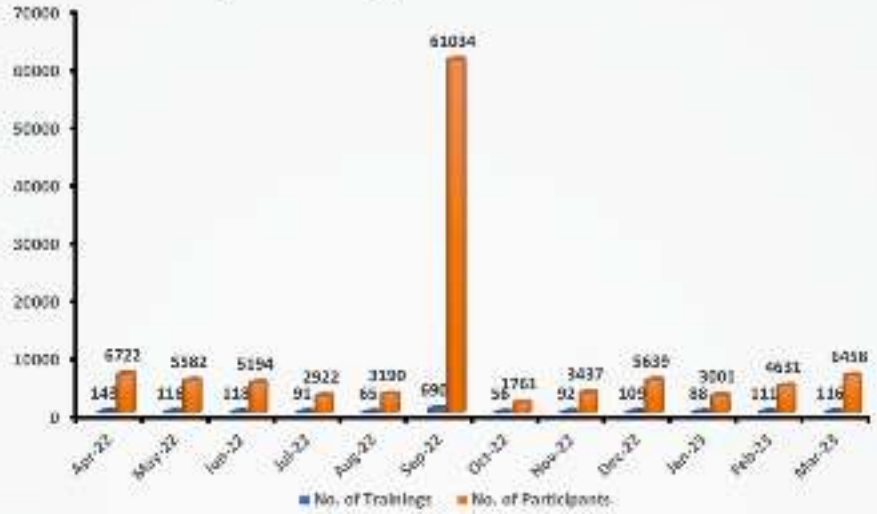


Figure - 24. Month wise distribution of total trainings/workshops organised in PvPI

Student projects and training in PvPI:

S. No.	Name of the Trainees	Qualification	Institutions	Training Period
1.	Ms. Dolly	B. Pharm	KIET, Ghaziabad	18-07-2022 to 18-08-2022
2.	Ms. Ishita	B. Pharm	KIET, Ghaziabad	18-07-2022 to 18-08-2022
3.	Mr. Pritam Pradhan	Data entry Technician	Government Pharmacy College Sajong, Gangtok	02-08-2022 to 12-08-2022
4.	Ms. Sakshi Phaugat	M. Pharm	ITS, College of Pharmacy, Ghaziabad	12-10-2022 to 12-12-2022
5.	Mr. Rahul Chauhan	B. Pharm	ITS, College of Pharmacy, Ghaziabad	06-02-2023 to 06-03-2023
6.	Ms. Jainab Husain	B. Pharm	ITS, College of Pharmacy, Ghaziabad	06-02-2023 to 06-03-2023
7.	Ms. Vishvanshi Tyagi	B. Pharm	ITS, College of Pharmacy, Ghaziabad	16-03-2023 to 16-04-2023

Dissertation on Pharmacovigilance Study

A dissertation entitled "A Prospective, Observational Pharmacovigilance Study of SGLT-2 Inhibitors in Patients Suffering from Diabetes in a Tertiary Care Hospital" was done from 19-09-2022 to 19-03-2023 submitted by Surjeet Singh to Sunder Deep Pharmacy College, Ghaziabad affiliated under Dr A.P.J. Abdul Kalam Technical University, Lucknow in partial fulfilment for the award of degree of Master in Pharmacy- Pharmacology (University Roll No. 2102590986009). The project work was supervised by Dr Jai Prakash, Officer-in-Charge, PvPI & Senior Principal Scientific Officer, IPC, and the data generated during the study was submitted to NCC-PvPI.

Communication & Publication Division

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

- Periodic Newsletters
- Annual Report
- Awareness Posters & Pamphlets
- PV Guidance documents for MAHs of Pharmaceutical Products
- Guidance document for spontaneous reporting of ADRs
- Communication of drug safety information through emails & social media
- Uploading relevant information of PvPI at Website: www.ipc.gov.in
- Sharing of information of PvPI with stakeholders through press release

PvPI published its newsletter during this tenure

Newsletter Vol. 12, Issue 2 (April to June 2022)

Newsletter Vol. 12, Issue 3 (July to September 2022)

Newsletter Vol. 12, Issue 4 (October to December 2022)

Newsletter Vol. 13, Issue 1 (January to March 2023)

Posters to sensitize stakeholders

दवाओं से होने वाले दुष्प्रभाव की रिपोर्टिंग करने के लिए संपर्क करें।

18001803024

PvPI in Press Media


PHARMABIZ .com

IPC alerts healthcare professionals about norfloxacin induced skin hyperpigmentation

Laxmi Yadav, Mumbai
Wednesday, December 7, 2022, 08:00 Hrs [IST]

The Indian Pharmacopoeia Commission (IPC), which is the National Coordination Centre (NCC) for Pharmacovigilance Programme of India (PvPI), has flagged drug safety alert revealing that antibacterial norfloxacin is associated with adverse event known as skin hyperpigmentation.

This came to light after the preliminary analysis of adverse drug reactions (ADRs) from the PvPI database.

Norfloxacin is used to treat a variety of bacterial infections. This medication belongs to a class of drugs known as quinolone antibiotics. It is indicated in the treatment of acute uncomplicated/complicated chronic, recurrent urinary tract infections, including pyelonephritis, urethritis and gonococcal infections. It is also indicated in a wide variety of infections caused by susceptible gram positive and gram-negative organisms including mixed infection in poultry.

Norfloxacin's mode of action depends on blocking of bacterial DNA replication by binding itself to an enzyme called DNA gyrase, which allows the untwisting required to replicate one DNA double helix into two. Notably the drug has 100 times higher affinity for bacterial DNA gyrase than for mammalian.

As per drug safety alert issued by IPC last week of November, norfloxacin is linked with skin hyperpigmentation. Hyperpigmentation refers to patches of skin that become darker than the surrounding areas of skin. It occurs when the skin produces excess melanin, the pigment that gives skin its colour.

Healthcare professionals and patients have been advised to closely monitor the possibility of the above ADR associated with the use of norfloxacin. If such a reaction is encountered, it needs to be reported to the NCC-PvPI for suitable action.

Earlier IPC had also flagged drug safety alerts revealing that amoxicillin, a penicillin-type antibiotic, was associated with an adverse event known as fixed drug eruption. Besides this, nonsteroidal anti-inflammatory drug (NSAID) piroxicam; beta-lactam antimicrobials, cephalosporins and anti-inflammatory drug, ibuprofen were also found to be associated with adverse events known as fixed drug eruption.

Furthermore, IPC also cautioned that second-generation cephalosporin antibiotic, cefuroxime was associated with drug reaction with eosinophilia and systemic symptoms (DRESS) syndrome while immunosuppressive medicine tacrolimus was linked with an adverse event known as gingival hypertrophy. It further revealed that antifungal medicine itraconazole caused an adverse event known as Symmetrical Drug-Related Intertriginous and Flexural Exanthema (SDRIFE).

PvPI was implemented by the CDSCO in July 2010 across the country. Since then, IPC has been mandated to establish clinical evidence between the drug and the ADR event through a robust system of causality assessment.

Reference : *IPC alerts healthcare professionals about norfloxacin induced skin hyper pigmentation (pharmabiz.com)*

IPC alerts healthcare professionals about cefoperazone induced coagulopathy

Laxmi Yadav, Mumbai
Monday, September 5, 2022, 08:00 Hrs (IST)

The Indian Pharmacopoeia Commission (IPC), which is the National Coordination Centre (NCC) for Pharmacovigilance Programme of India (PvPI), has flagged drug safety alert revealing that cefoperazone, a third-generation cephalosporin antibiotic, is associated with adverse event known as coagulopathy, a bleeding disorder.

This came to light after the preliminary analysis of adverse drug reactions (ADRs) from the PvPI database.

Cefoperazone is a new beta-lactam antibiotic that possesses a broad spectrum of activity against gram-positive and gram-negative organisms. It is used to target bacteria responsible for causing infections of the respiratory and urinary tract, skin, and the female genital tract. It is one of few cephalosporin antibiotics effective in treating Pseudomonas bacterial infections which are otherwise resistant to these antibiotics. It was patented in 1974 and approved for medical use in 1981.

Cefoperazone exerts its bactericidal effect by inhibiting the bacterial cell wall synthesis, and sulbactam acts as a beta-lactamase inhibitor, to increase the antibacterial activity of cefoperazone against beta-lactamase-producing organisms.

While its clinical use has been discontinued in the US, cefoperazone is available in European countries, Latin American countries, Australia, India among others.

As per drug safety alert issued by IPC last week of August, cefoperazone is linked with coagulopathy, a condition in which the blood's ability to coagulate (form clots) is impaired. Coagulopathy may cause uncontrolled internal or external bleeding. Left untreated, uncontrolled bleeding may cause damage to joints, muscles, or internal organs and may be life-threatening.

Healthcare professionals and patients have been advised to closely monitor the possibility of the above ADR associated with the use of cefoperazone. If such a reaction is encountered, it needs to be reported to the NCC-PvPI for suitable action.

IPC had earlier also flagged drug safety alerts revealing that immunosuppressive medicine tacrolimus was associated with an adverse event known as gingival hypertrophy while antifungal medicine itraconazole was linked with Symmetrical Drug-Related Intertriginous and Flexural Exanthema (SDRIFE).

Besides this, it also cautioned that second-generation cephalosporin antibiotic, cefuroxime was associated with drug reaction with eosinophilia and systemic symptoms (DRESS) syndrome while beta-lactam antimicrobials, cephalosporins and anti-inflammatory drug, ibuprofen were associated with adverse event known as fixed drug eruption.

PvPI was implemented by the CDSCO in July 2010 across the country. Since then, IPC has been mandated to establish clinical evidence between the drug and the ADR event through a robust system of causality assessment.

Reference: *http://www.pharmabiz.com/NewsDetails.aspx?aid=152997&sid=1*

IPC flags safety alert against immunosuppressive drug tacrolimus

Laxmi Yadav, Mumbai
Monday, August 8, 2022, 08:00 Hrs [IST]

The Indian Pharmacopoeia Commission (IPC), which is the National Coordination Centre (NCC) for Pharmacovigilance Programme of India (PvPI), has flagged drug safety alert revealing that immunosuppressive medicine tacrolimus is associated with adverse event known as gingival hypertrophy.

This came to light after the preliminary analysis of adverse drug reactions (ADRs) from the PvPI database.

Tacrolimus is mainly used in reducing the activity of the patient's immune system after organ transplant to prevent organ rejection. It is also used in a topical preparation in the treatment of severe atopic dermatitis, severe refractory uveitis after bone marrow transplants, and the skin condition vitiligo. It was discovered in 1984 from the fermentation broth of a Japanese soil sample that contained the bacteria Streptomyces tsukubaensis. Tacrolimus is chemically known as a macrolide. It reduces peptidyl-prolyl isomerase activity by binding to the immunophilin FKBP-12 (FK506 binding protein) creating a new complex. This FKBP12-FK506 complex inhibits calcineurin which inhibits T-lymphocyte signal transduction and IL-2 transcription.

Tacrolimus is indicated for prophylaxis of transplant rejection in liver, pancreas, lung, heart and kidney allograft recipients and treatment of allograft rejection resistant to treatment with other immunosuppressive medicinal products.

As per drug safety alert issued by IPC in last week of July 2022, tacrolimus is linked with gingival hypertrophy or hyperplasia, a condition that refers to an overgrowth of gum tissue around the teeth.

Healthcare professionals and patients have been advised to closely monitor the possibility of the above ADR associated with the use of tacrolimus. If such a reaction is encountered, it needs to be reported to the NCC-PvPI for suitable action.

IPC had earlier also flagged drug safety alerts revealing that antifungal medicine itraconazole was associated with an adverse event known as Symmetrical Drug-Related Intertriginous and Flexural Exanthema (SDRIFE).

Besides this, it also revealed that second-generation cephalosporin antibiotic, cefuroxime was associated with drug reaction with eosinophilia and systemic symptoms (DRESS) syndrome while beta-lactam antimicrobials, cephalosporins and anti-inflammatory drug, ibuprofen were associated with adverse event known as fixed drug eruption.

PvPI was implemented by the CDSCO in July 2010 across the country. Since then, IPC has been mandated to establish clinical evidence between the drug and the ADR event through a robust system of causality assessment.

The PvPI's basic objective is to create a nationwide system for patient-safety by ensuring adverse events reporting, identification of new adverse drug reactions, analysis of the benefit-risk ratio of the marketed drugs and generation of evidence-based information on the safety of drugs. The NCC-PvPI, IPC is in the developing phase of indigenous database-Adverse Drug Reaction Monitoring Software (ADRMS) for the processing of Individual Case Safety Reports (ICSR).

Reference: *http://www.pharmabiz.com/NewsDetails.aspx?aid=152518&sid=1*

IPC cautions healthcare professionals to watch out for Cefuroxime induced DRESS syndrome

Laxmi Yadav, Mumbai
Saturday, May 7, 2022, 08:00 Hrs [IST]

The Indian Pharmacopoeia Commission (IPC), which is the National Coordination Centre (NCC) for Pharmacovigilance Programme of India (PvPI), has flagged drug safety alert revealing that second-generation cephalosporin antibiotic, Cefuroxime is associated with drug reaction with Eosinophilia and Systemic Symptoms (DRESS) syndrome.

This came to light after the preliminary analysis of adverse drug reactions (ADRs) from the PvPI database.

Cefuroxime is a bactericidal agent that acts by inhibition of bacterial cell wall synthesis. Cefuroxime has activity in the presence of some beta-lactamases, both penicillinases and cephalosporinases, of gram-negative and gram-positive bacteria. Cefuroxime was patented in 1971, and approved for medical use in 1977. It is on the World Health Organization's List of Essential Medicines.

The antibiotic is indicated for lower and upper respiratory tract infection, urinary tract infections (UTIs), gynaecological infection, skin infection or soft tissue infection. The drug is also indicated for ENT soft tissue infection etc.

As per drug safety alert issued by IPC in last week of April 2022, Cefuroxime is linked with Drug reaction with Eosinophilia and Systemic Symptoms (DRESS) syndrome which is an idiosyncratic drug-induced hypersensitivity reaction that presents with skin rash, involvement of internal organs like liver, lung, or kidney, lymphadenopathy, and haematological manifestations such as eosinophilia and atypical lymphocytes.

Healthcare professionals and patients have been advised to closely monitor the possibility of the above ADR associated with the use of Cefuroxime. If such a reaction is encountered, it needs to be reported to the NCC-PvPI for suitable action.

IPC had earlier also flagged drug safety alerts revealing that beta-lactam antimicrobials, cephalosporins and anti-inflammatory drug, Ibuprofen were associated with adverse event known as fixed drug eruption while Cefazolin, a cephalosporin antibiotic, was associated with acute generalized exanthematous pustulosis (AGEP).

Besides this, it had earlier also flagged drug safety alerts revealing that popular blood pressure drug, Losartan was associated with muscle spasm while diclofenac, a NSAID, was linked to skin hyperpigmentation.

Dimethyl fumarate, used for relapsing-remitting multiple sclerosis, was associated with adverse drug reaction alopecia, according to the preliminary analysis of ADRs from the PvPI database.

PvPI was implemented by the CDSCO in July 2010 across the country. Since then, IPC has been mandated to establish clinical evidence between the drug and the ADR event through a robust system of causality assessment.

Reference: *http://www.pharmabiz.com/NewsDetails.aspx?aid=149603&sid=1*

Medical Dialogues

Medical News & Guidelines - Health News - AYUSH - State News - Medical Education - Industry - MDTV -

Drug Safety Alert: Indian Pharmacopoeia Commission reveals ADR linked to Cephalosporin, Amikacin

Medical Dialogues

Medical News & Guidelines - Health News - AYUSH - State News - Medical Education - Industry - MDTV -

Amphotericin B linked to Hearing disorders, Tachycardia, reveals IPC Drug safety alert

Videos on drugs safety alerts issued by the NCC-PvPI, IPC

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PvPI in Press and Media during 2nd National Pharmacovigilance Week 2022

PvPI recommendations published in WHO Pharmaceuticals Newsletters

Cephalosporins

Risk of fixed drug eruption

India. The Central Drugs Standard Control Organization (CDSCO) has approved the recommendation from the National Coordination Centre – Pharmacovigilance Programme of India (NCC-PvPI), Indian Pharmacopoeia Commission (IPC) to revise the prescribing information leaflet (PIL) for cephalosporins to include fixed drug eruption as an adverse drug reaction.

Cephalosporins are a group of antibiotics that belong to a beta-lactam class, indicated to manage a wide range of infections from gram-positive and gram-negative bacteria.

The NCC-PvPI, IPC reviewed 203 individual case safety reports (ICSRs) of cephalosporin associated fixed drug eruption and a causal relationship between them was found.

Reference:
Based on the communication from IPC, India, October 2022 (link to the source within ipc.gov.in)

Haloperidol

Risk of cogwheel rigidity

India. The CDSCO has approved the recommendation from the NCC-PvPI, IPC to revise the PIL for haloperidol to include cogwheel rigidity as an adverse drug reaction.

Haloperidol is indicated for the treatment of chronic schizophrenia.

The NCC PvPI, IPC reviewed 11 ICSRs of haloperidol associated cogwheel rigidity and a causal relationship between them was found.

Reference:
Based on the communication from IPC, India, October 2022 (link to the source within ipc.gov.in)

Olanzapine

Risk of hyponatraemia

India. The CDSCO has approved the recommendation from the NCC-PvPI, IPC to revise the PIL for olanzapine to include hyponatraemia as an adverse drug reaction.

Olanzapine is indicated for the treatment of schizophrenia in adult patients, rapid control of agitation and disturbed behaviour in patients.

The NCC-PvPI, IPC reviewed 20 ICSRs of olanzapine associated hyponatraemia and a causal relationship between them was found.

Reference:
Based on the communication from IPC, India, October 2022 (link to the source within ipc.gov.in)

Remdesivir

Risk of sinus bradycardia

India. The CDSCO has approved the recommendation from the NCC-PvPI, IPC to revise the PIL for remdesivir to include sinus bradycardia as an adverse drug reaction.

Remdesivir is indicated for the treatment of suspected or laboratory confirmed corona virus disease 2019 (COVID-19) in adults and children hospitalised with moderate to severe disease.

The NCC-PvPI, IPC reviewed 11 ICSRs of remdesivir associated sinus bradycardia and a causal relationship between them was found.

Reference:
Based on the communication from IPC, India, October 2022 (link to the source within ipc.gov.in) (See also WHO Pharmaceuticals Newsletter No.1 2022: Remdesivir and Potential risk of sinus bradycardia in Canada, No.4, 2021 in Europe)

Tigecycline

Risk of coagulopathy

India. The CDSCO has approved the recommendation from the NCC-PvPI, IPC to revise the PIL for tigecycline to include coagulopathy as an adverse drug reaction.

Tigecycline is indicated for the treatment of skin and abdominal infections.

The NCC-PvPI, IPC reviewed three ICSRs of tigecycline associated coagulopathy and a causal relationship between them was found.

Reference:
Based on the communication from IPC, India, October 2022 (link to the source within ipc.gov.in)

Minoxidil

Risk of folliculitis

India. The NCC-PvPI, IPC has recommended the CDSCO to revise the prescribing information leaflet (PIL) for minoxidil to include folliculitis as an adverse drug reaction. The recommendation is under consideration of the CDSCO.

Minoxidil is indicated for the treatment of alopecia (male pattern baldness) in men.

The NCC-PvPI, IPC reviewed 17 ICSRs of minoxidil associated folliculitis and a causal relationship between them was found.

Reference:
Based on the communication from IPC, India, October 2022 (link to the source within ipc.gov.in)

World Health Organization

WHO Pharmaceuticals NEWSLETTER

2022 No.3

Mefenamic acid, doxycycline

Risk of fixed drug eruption

India. The Central Drugs Standard Control Organization (CDSCO) has approved the recommendation to revise the prescribing information leaflet (PIL) for mefenamic acid and doxycycline to include fixed drug eruption as an adverse drug reaction.

Mefenamic acid is indicated for the treatment of rheumatoid arthritis, osteoarthritis, dysmenorrhea, mild to moderate pain, inflammation, fever and dental pain. Doxycycline is used as a broad-spectrum antibiotic.

The National Coordination Centre – Pharmacovigilance Programme of India (NCC-PvPI), Indian Pharmacopoeia Commission (IPC) reviewed 23 case reports of fixed drug eruption with use of mefenamic acid and 94 cases with the use of doxycycline, and found a strong causal relationship between each of the two drugs and the event.

Reference:

Based on the communication from IPC, India, June 2022 (*link1* and *link2* to the source within *cdsco.gov.in*)

PHOTO GALLERY

WHO-SEARO has organized a conference on "Addressing challenges of regulatory COVID-19 medical products in South-East Asia" from 11th-12th April, 2022.

One-day Advance level training programme was organized by MMC Chennai, in Collaboration with NCC-PvPI - IPC, Ghaziabad on 27th April 2022..

WHO-SEARO office, New Delhi has organized a meeting for the heads of National Regulatory Authorities (NRAs), South-East Asia Regulatory Network (SEARN) from 7th-8th June, 2022

21st Skill Development Programme on Pharmacovigilance of Medical Products held on 13th - 17th June 2022

Coordinators Meeting-cum-Advance level training programme was organized by NIMS Hyderabad, in Collaboration with NCC-PvPI - IPC, Ghaziabad with on 24th June 2022.

NCC-PvPI, IPC organized Workshop-cum-Training Programme on Pharmacovigilance for NABH accredited hospitals on 11th July, 2022 at Shekhar Hospital, Lucknow

Release of PvPI Annual Performance Report during 2nd National Pharmacovigilance Week celebration at IPC

NCC-PvPI organised Walkathon during 2nd National Pharmacovigilance Week celebration to create awareness among local public in Ghaziabad

Pharmacovigilance Associates from NCC-PvPI sensitizing Community Pharmacist during 2nd National Pharmacovigilance Week celebration

Pharmacovigilance Associates from NCC-PvPI sensitizing Patients about ADR reporting during 2nd National Pharmacovigilance Week Celebration

The NCC-PvPI, IPC has organised 5 days, 22nd Skill Development Programme (SDP) on Pharmacovigilance of Medical Products from 12th to 16th September 2022, through virtual mode

AIIMS-Bhatinda conducted the Continuing Medical Education (CME) for creating awareness among Healthcare Professionals on 21st October, 2022.

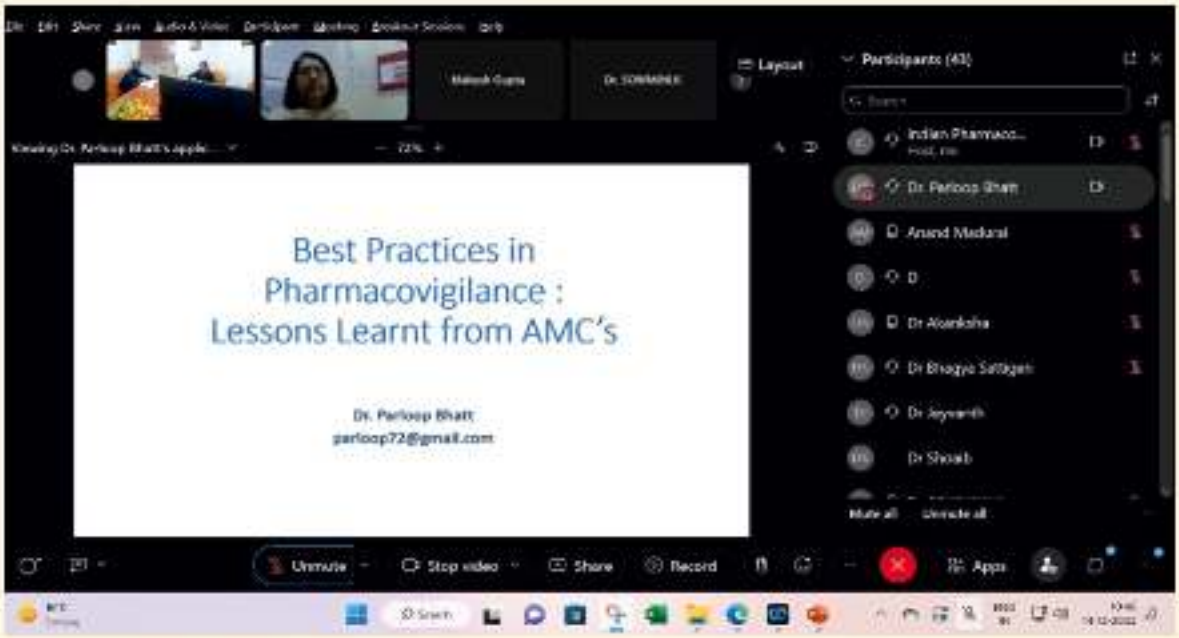
AIIMS, Bhopal conducted 6th Advanced Level Training in Pharmacovigilance-cum-Coordinators meeting for Madya Pradesh and Chhattisgarh on 11th November 2022.

Dr. R.S Ray, Scientific Assistant, NCC-PvPI participated in Medical Students Network (MSN)-The Way & Beyond organized by the Indian Medical Association on 27th November 2022 at New Delhi

The representatives from PvPI, IPC have participated as observers in a WHO-Multidisciplinary Technical Group (MTG) on Ocular Events with Miltefosine on 30th November 2022 through virtual mode.

IPC organized virtually 20 hours training programme from 5th-9th December 2022, for seven countries registered through the e-ITEC portal of Ministry of External Affairs, Government of India

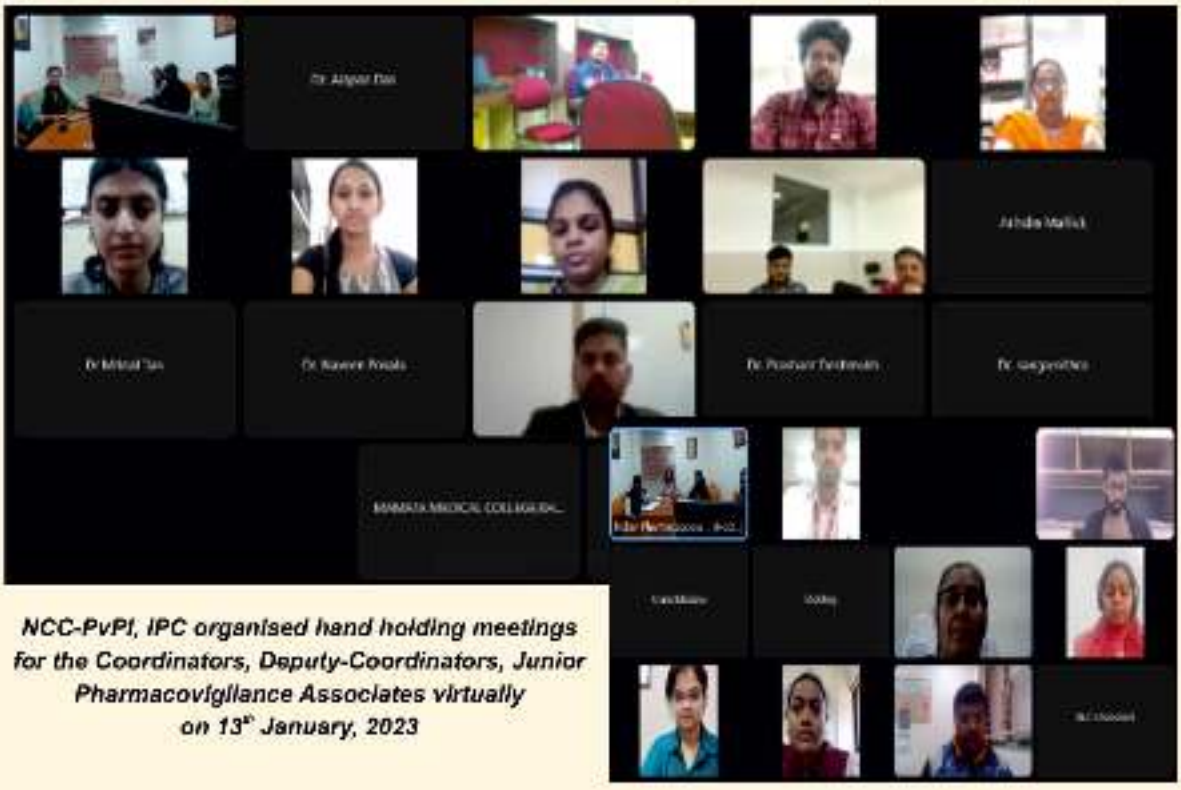
IPGME&R conducted an Advanced Level Training on "Risk Benefit & Assessment & Communication in Pharmacovigilance" on 8th December 2022 through hybrid mode.



NCC-PvPI conducted 3 days Induction-cum-Training Programme on Pharmacovigilance from 12th to 14th December 2022 through virtual platform at IPC

BJMC-Ahmedabad in collaboration with PvPI conducted an Advanced Level Training in Pharmacovigilance from 12th to 13th December 2022

Dr. Jai Prakash, PvPI Officer In-Charge attended an awareness programme about the functioning of Pharmacovigilance Programme of India to promote patient safety on 22nd December 2022 at RKGIT, Ghaziabad.



NCC-PvPI, IPC organised hand holding meetings for the Coordinators, Deputy-Coordinators, Junior Pharmacovigilance Associates virtually on 13th January, 2023

Mr. Rishi Kumar, Scientific Assistant, IPC attended interactive panel discussion on "Bring in your coding challenges" as one of the panel members organized by MedDRA User Group on 23rd February 2023 at Hotel Novotel, Bengaluru.

Dr Jai Prakash, Sr. Principal Scientific Officer, IPC attended the 52nd Annual Conference of Indian Pharmacological Society from 23rd to 25th February 2023 organised by JSS College of Pharmacy, Mysuru.

PvPI Officials visited Government Medical College, The Nilgiris, Ooty on 25th February 2023

Dr R.S. Ray, Scientific Assistant, IPC attended CME on 21st March 2023 organised by Jawahar Lal Nehru Medical College Hospital, Aligarh

Chalapathi Institute of Pharmaceutical Sciences, Guntur organised CME on "Pharmacovigilance, Materiovigilance and AEFI" on 4th March 2023

Scientific Publications

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

1. Gomathi S, Devipriya S, Sudha K, Ramachandra B. "Analysis of individual case safety reports of spontaneous reporting in adverse drug reaction monitoring centre at a tertiary care hospital". International Journal of Basic & Clinical Pharmacology 2022; 11:587-91.
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Materiovigilance Programme of India

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 Indian population. Initially Sree Chitra Tirunal Institute for Medical Sciences & Technology (SCTIMST), Thiruvananthapuram served as National Coordination Center (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 reoccurrence of the harmful incidents elsewhere thereby safety of medical devices. MvPI continuously work 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 Centers (MDMCs) across India for monitoring and reporting of Medical Device Adverse Events (MDAEs).

Modalities for Reporting Medical Device Adverse Events (MDAEs)

One can use the medical device adverse event reporting form which is available on the IPC website (www.ipc.gov.in) to report any medical device associated adverse event. Reporters from Medical Device Adverse Events Monitoring Centre (MDMC)/Adverse Drugs Reaction Monitoring Centre (AMC) after filling the above mentioned MDAE reporting form can be submitted to the Coordinator or Associate of the respective MDMC/AMC. A reporter who is not part of MDMC/AMC can submit the filled MDAE reporting form to the nearest MDMC/AMC or directly to NCC-MvPI, IPC. Reporter can also mail the scanned reporting form to shatrunjay.ipc@gov.in or mvpi-ipc@gov.in. The MvPI has the same helpline number as PvPI i.e. 1800-180-3024 (Monday to Friday from 09:00 AM to 5:30 PM, except holidays) to report adverse events. A person can also report MDAE by using PvPI mobile application, which is freely available on google play store.

Indigenous Medical Device Adverse Events (MDAEs) data management

NCC-MvPI, IPC collates and analyses adverse events associated with medical devices exclusively on Indian population, analyses the benefit-risk ratio, generates evidence-based information on medical devices safety, supports regulatory bodies in the decision-making process on medical devices & communicates the safety signals on use of medical devices to various stakeholders.

- A total of 6,441 MDAE reports have been received at NCC-MvPI during April 01, 2022 to March 31, 2023. The reporting has been increased by 66.5% as compared to previous financial year (3,868 MDAE reports were received during April 01, 2021 to March 31, 2022).

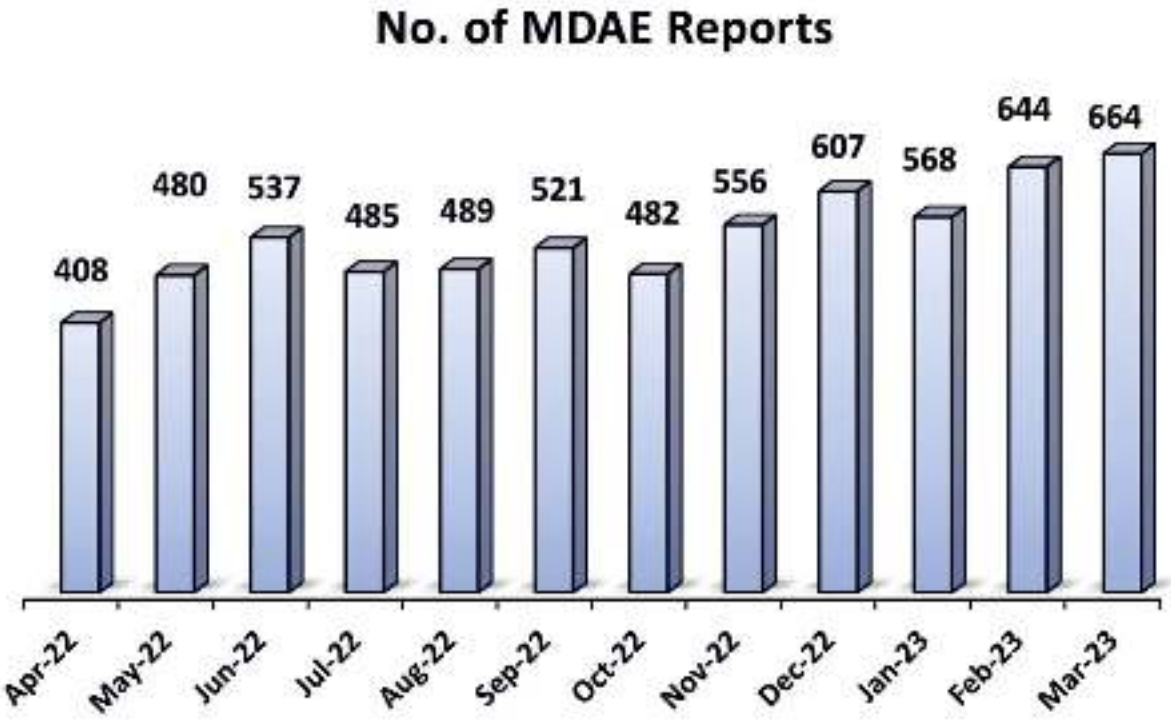


Figure - 25. Month wise distribution of total trainings/workshops organised in PvPI

Recommendations forwarded to CDSCO

NCC-MvPI forwarded 12 recommendations on safe use of medical devices in India to CDSCO for their information and further necessary actions at their end. The list of recommendations is given below:

S. No	Device	Adverse Events	Description	Date of Communication
1.	Total Knee Replacement	Implant Deformation/ failure	Information about the adverse event of Implant deformation/ failure is suspected to be associated with the use of total knee replacement.	April 18, 2022
2.	Vacutainers	Defective devices (Leaky)	Information about the adverse event of defective devices (Leaky) is suspected to be associated with the use of Vacutainers.	April 18, 2022
3.	Inhaler	delivering improper dose/ medicament not released/ breathing problem/ issue with the pipe of inhaler/ dose counter error/ not working/ pin broken etc.	Information about the adverse event of delivering improper dose/ medicament not released/ breathing problem/ issue with the pipe of inhaler/ dose counter error/ not working/ pin broken etc. is suspected to be associated with the use of Inhaler.	April 18, 2022
4.	HCG/Pregnancy Test Kit (HCG/Pregnancy Test Kit)	HCG/Pregnancy Test Kit	Information about the adverse event of invalid result event is suspected to be related to device and quality issue is a foremost concern in such type of events.	August 11, 2022

5.	Mandibular Reconstruction (Plate)	Mandibular plate breakage	Information about the adverse event of plate breakage event is suspected to be related to device and quality issue is a foremost concern in such type of events.	December 13, 2022
6.	Coronary Stent System	Balloon Deflation Issue	Information about the adverse event of balloon deflation issue is suspected to be related to device and quality issue is a foremost concern in such type of events.	December 13, 2022
7.	Pacing Lead	High Capture threshold, loss of capture, and Lead dislodgement	Information about the adverse event of High Capture threshold, loss of capture and Lead dislodgement event is suspected to be related to device and quality issue is a foremost concern in such type of events.	December 13, 2022
8.	Umbilical cord clamp	Non-functioning of clamps	Information about the adverse event of non-functioning of clamps is suspected to be related to device and quality issue is a foremost concern in such type of events.	December 13, 2022
9.	Infant Incubator	Malfunctioning (Heating Issue)	Information about the adverse event of Malfunctioning (Heating Issue) is suspected to be related to device and quality issue is a foremost concern in such type of events.	December 13, 2022

10.	Meter-dose Inhaler (MDI)	Counterfeit Device-01 report Less dosage delivery, Dose meter Error & others - 65 reports	Information about the adverse event of counterfeit device event is suspected to be related to device and quality issue is a foremost concern in such type of events.	March 03, 2023
11.	Intra-ocular Lens (IOL)	Toxic Anterior Segment Syndrome (TASS)	Information about the adverse event of toxic anterior segment syndrome event is suspected to be related to device and quality issue is a foremost concern in such type of events.	March 03, 2023
12.	Basic Male Condom	Counterfeit Device	Information about the adverse event of counterfeit device event is suspected to be related to device and quality issue is a foremost concern in such type of events.	March 03, 2023

Safety Alerts circulated to monitoring centres

NCC-MvPI has circulated 07 safety alerts to the MDMCs/AMCs for the safety surveillance of medical devices. The list of Safety alerts communicated to AMCs/MDMCs is given below;

S. No.	Device	Adverse Event reported	Date of Communication
1.	Total Knee	Implant Deformation/ failure	April 18-19, 2022
2.	Vacutainers	Defective devices (Leaky)	April 18-19, 2022
3.	Inhaler	Delivering improper dose/ Medicament not released/ Breathing Problem/ Issue with the pipe of inhaler/ Dose Counter Error/ not working/ Pin Broken etc.	April 18-19, 2022

4.	Interbody System with Titan nano LOCK™	Displaced fusion device	April 18-19, 2022
5.	Implantable Collamer Lens	Toxic Anterior Segment Syndrome (TASS)	August 12, 2022
6.	Monofilament synthetic absorbable skin support & filling thread sterile	Atypical Mycobacterial Infection	March 06, 2023
7.	Orthopaedic Megaprosthesis (Femoral Stem)	Stem Breakage	March 06, 2023

Resource materials to stakeholders

1. Scientific publications : NCC-MvPI, IPC has published 03 research articles during the index period are as given below;

S. No.	Title	Journal	DOI
1.	"Acute intraocular toxicity caused by perfluorocarbon liquids: safety control systems of medical devices"	Springer group of journals	https://doi.org/10.1007/s00417-022-05578-w
2.	"Public Private Partnership in Pharmacovigilance: An Indian Experience"	Frontiers in Public Health journal	https://doi.org/10.3389/fpubh.2022.930696
3.	"Safety Monitoring of Orthopaedic implants under the Materiovigilance Programme of India – A current perspective"	Journal of Orthopaedic Reports	https://doi.org/10.1016/j.jorep.2023.100145

2. **MvPI Newsletters** : NCC-MvPI has published a total of 4 newsletters in pdf format & circulated to stakeholders during the index period are as given below;

Expansion of MvPI network pan India

NCC-MvPI collects Adverse Events from MDMCs located pan India. During the index period, NCC-MvPI has recognized 143 MDMCs are as given below;

S. No.	State	Name & Address of MDMCs
1.	Andhra Pradesh	Sri Venkateswara Institute of Medical Sciences Alipiri Road, Tirupati Urban, Andhra Pradesh-517507
2.		PES Institute of Medical Sciences & Research Kuppam, Chittar District, Andhra Pradesh-517425
3.		Sentini Hospital 54-15-5 B&C Ring Road, beside Vinayak Theatre, Vijayawada, Andhra Pradesh - 520008
4.		Nagarjuna Hospital Kanuru Road, Autonagar, Vijayawada, Andhra Pradesh -520007
5.		HCG Curie City Cancer Centre 44-1-1/3, Padavalarevu, Machavaram Down. Gunadala, Vijayawada, Andhra Pradesh–520004
6.		Tirumala Multi Specialty Hospital India Pvt. Ltd. Vizianagaram, Andhra Pradesh
7.	Assam	Silchar Medical College Ghungoor, Silchar, Assam - 788014
8.		Apollo Hospital (Unit: International Hospital) "Lotus Tower" G.S. Road, Guwahati, Assam - 781 005
9.	Chhattisgarh	Rajmata Shrimate Devendra Kumari Singhdeo Medical College Chhattisgarh
10.	Gujarat	GCS Medical College Ahmedabad, Gujarat
11.		Parikh Super speciality Hospital Police Station, Sardar Patel Ring Road, Opp. Nikol, Beside Cricket Ground, Ahmedabad, Gujarat- 382350

12	Haryana	Medeor Hospital Limited Plot No. 2, Sector 5. IMT Manesar, Gurugram, Haryana -122052
13		Healing Touch Super Speciality Hospital Ambala-Chandigarh Highway Ambala/Haryana, Ambala, Haryana - 134003
14		Guru Nanak Hospital Railway Station Road, Khota Temple, Camp Market Palwal, Palwal, Haryana -121102
15		Supreme Hospital Eros Garden, Charmwood Village, Suraj Kund Road, Faridabad, Haryana - 121009
16		Sarvodaya Multispecialty and Cancer Hospital Opp. Red Cross Bhawan, Delhi Road, Hisar, Haryana- 125001
17		Nidaan Hospital Murthal Rd., Maharaja Hospital, Jeevan Vihar, Sonipat, Haryana
18		Faculty of Medicine and Health Sciences SGT University, Gurugram, Haryana
19		Advanta Super speciality Hospital Jhajjar, Haryana
20		Shri Balaji Aarogyam Hospital Behind Old Bus Stand, Kurukshetra, Haryana – 136118
21	Jammu & Kashmir	Government Medical College Baramulla Kanth Bagh, Baramulla, Jammu and Kashmir- 193101
22	Jharkhand	Tata Main Hospital C Rd West, Northern Town Bistupur, Jamshedpur, Jharkhand
23	Karnataka	Fortis Hospital Limited, Bangalore, Karnataka
24		District Hospital Udupi, Karnataka
25		MS Ramaiah Medical College MSR Nagar, Bangalore, Karnataka-560054

26		Cytecare Hospital Pvt. Ltd. Venkatala, Near Bagalur Cross Yelahanka. Bangalore / Bengaluru Karnataka – 560064
27	Kerala	Travancore Medicity Medical College Kollam, Kerala
28		EK Nayanar Memorial Govt. Women and Children Hospital Mangattuparamba, Kannur, Kerala - 670563
29		General Hospital Kanjirappally, Kottayam, Kanjirappally, Kottayam- 686507
30		Taluk Head Quarters Hospital Near Boat Jetty Vaikom, Kottayam, Kerala- 686141
31		AA Rahim Memorial Govt. District Hospital Kollam, Kerala-691001
32		District Hospital Aluva KSRTC Bus Stand, Aluva, Ernakulam, Kerala- 683101
33		Government District Hospital Kanhangad P.O. Bella Chemmattamvayal, Kasaragod, Kerala - 671531
34		District Hospital Mananthavady, Mananthavady, Wayanad, Kerala - 670645
35		District Hospital Palakkad, Palghat, Kerala - 678001
36		District Hospital Kumarkuller, Ottupara, Kodungallur, Wadackanchery, Kerala -680582
37		Institute of Child Health, Medical College Hospital Amalagiri P.O, Kottayam, Kerala - 686561
38		General Hospital Irinjalakuda, Tana junction, Thrissur, Kerala-680121
39		General Hospital Muvattupuzha, Kerala - 686661

40		General Hospital Pala, Kottayam, Kerala- 686575
41		General Hospital Thalassery Taluk Library 1, Main Road, Thalassery, Kerala - 670101
42		Government Medical College Konni, Pathanamthitta, Kerala -689691
43		Government Taluk Hospital Kuthuparamba, Kannur, Kerala-670643
44		Government Taluk Hospital Panoor, Kerala-670692
45		Government General Hospital Kainatty, Kalpetta, Wayanad, Kerala- 673122
46		General Hospital Changanacherry, Changanassery, Kottayam, Kerala- 686101
47		Taluk Head Quarters Hopsital Sasthamcotta, Kollam, Kerala-650521
48		Taluk Headquarters Hospital Kuravilangad, Kerala - 686633
49		Taluk Head Quarters Hospital Vythiri, Wayanad, Kerala-673576
50		District Hospital Kozhencherry Kozhencherry, Pathanamthitta, Kerala - 689641
51		District Hospital Nedumangad Trivandrum, Kerala -695541
52		General Hospital Adoor P.O. Pathanamthitta, Kerala-691523
53		Government General Hospital Kozhikode Beach Lighthouse, Beach Rd, Vellayil, Kozhikode, Kerala -673032
54		Government District Hospital Vatakara, Badagara, Kerala- 673101

55		Government T D Medical College Vandanam, Alappuzha, Kerala-688005
56		Government Medical College Hospital Gandhinagar Kottayam, Kerala - 686008
57		Govt. Medical College Manjeri. Malappuram District Kerala - 676121
58		Taluk Head Quarters Hospital (Thqh) Parassala, Trivandrum, Kerala - 695002
59		General Hospital Neyyatunkara, Tum, Kerala -695121
60		Taluk Head Quarters Hospital Chavakkad Hospital Road, Chavakkad. Kerala -680506
61		Taluk Head Quarters Hospital Karunagappally, Kollam, Kerala-690518
62		VPS Lakeshore hospital NH-47 By-Pass, Maradu, Kochi, Kerala-682040
63		Meitra Hospital Building No. 38/2208-B, Karaparamba – Kunduparamba Mini Bypass Road. Edakkad Post, Calicut, Kerala – 673005,
64		General Hospital Rd, Anantha Narayanapuram, Alappuzha, Kerala - 688011
65		Taluk Head Quarters Hospital (Thqh) Cherthala, Police Station Road, Oppo. Govt. Boys Higher Secondary School, Cherthala, Kerala- 688524
66		Taluk Head Quarters Hospital National Highway 47, Haripad, Karthikapally, Kerala- 690514
67		Atreya Hospital Guruvayur Road, Near Pipeline Junction, East Fort, Thrissur, Kerala- 680005
68		Government Taluk Head Quarters Hospital Karimbam (P.O.), Taliparamba, Kannur District

69		Taluk Head Quarter Temple Road, Varkala (PO) Kerala -695141
70		Malabar Hospitals PVT. LTD. Door No.16/45A, Rajeev Gandhi Byepass Road, Karuvambram PO, Manjeri, Malappuram, Kerala-676123
71		THQH Bedadka PO-Kasaragod, Kerala-671541
72		Women and Children Hospital Alappuzha, Kerala - 688012
73		Taluk Head Quarters Hospital Mangalpady, Nayabazar Uppala PO
74		Taluk Head Quarters Hospital Pulincunnu, P.O. Alappuzha, Kerala- 688504
75		Taluk Headquarters Hospital Kollam - Chenkotta Road, Kottarakkara, Kerala-691506
76		Government Taluk Head Quarters Hospital Nileshwar PO, Percle, Near Village Office, Kerala-671314
77		Government Taluk Head Quarters Hospital Thrikkaripur, Kasaragod, Kerala-671310
78		Taluk Hospital Fort, Fort PO, Thiruvananthanpuram, Kerala-695023
79		District Hospital Chengannur, Alappuzha District, Kerala-689121
80		Thaluk Hospital Poodamkallu, Rajapuram, Kerala-671532
81	Maharashtra	Asian Noble Hospital Private Limited Shirdi Manmad Road, Chowk, Opp. Premdan, Savedi, Ahmednagar, Maharashtra - 414003
82		Saideep Healthcare and Research Private Limited Viraj Colony, Plot NO 11, S NO 104/A2, 104/A2/1, Behind Yashwant Colony, Tarakpur, Ahmednagar, Maharashtra-414003

83		Saifee Hospital,15/17, Maharshi Karve Marg, Mumbai, Maharashtra - 400004
84		Shree Pragati Foundation's Hira Mongi Navneet Hospital Near Lions Club of Mulund Pavalion, Near SMPR High School, Valji Ladha Road, Mumbai, Maharashtra - 400080
85		Bhaktivedanta Hospital & Research Institute Shrishti Complex, Bhaktivedanta Swami Marg, Mira Road (East), Thane, Maharashtra-401107
86		D.Y. Patil Hospital Sector-5, Nerul, Navi Mumbai, Maharashtra-400706
87		Jawaharlal Nehru Medical College Wardha, Maharashtra
88		Dr. Balabhai Nanavati Hospital Mumbai, S.V. Road, Vile Parle (West) Mumbai. Maharashtra - 400056
89		Jaslok Hospital and Research Centre Biomedical Dept. 15, Pedder Rd, IT Colony, Tardeo, Mumbai, Maharashtra- 400026
90		Holy Spirit Hospital Mahakali Caves Rd, Sher E Punjab Colony, Andheri East, Mumbai, Maharashtra- 400093
91	Meghalaya	Nazareth Hospital Arbuthnot Road, Near Police Point, Nongkynrih, Laitumkhrah, Shillong, Meghalaya -793003
92	New Delhi	Vallabhbhai Patel Chest Institute University of Delhi, Vijay Nagar Marg, Art Faculty, University Enclave, New Delhi-110007
93		Indraprastha Apollo Hospitals Sarita Vihar, Delhi Mathura Road, New Delhi, Delhi - 110076
94		Khandelwal Hospital & Urology Centre Pvt. Ltd. B-15, 16, Main Road, East Krishna Nagar, Delhi-110051
95		Moolchand Hospital Lajpat Nagar III, Near Moolchand Metro Station, New Delhi - 110024

96		Rathi Hospital 2,3,4 Pratap Vihar, Ranhola Nangloi- Najafgarh Road, New Delhi-110041
97		Park Hospital 12 Meera Enclave (Chowkhandi) Outer Ring Road, New Delhi-110018
98		Kalra Hospital SRCNC Private Limited, Delhi
99		R L K C Hospital Pandav Nagar, Naraina Road, Near Shadipur Metro Station, New Patel Nagar, Shadipur, New Delhi - 110008
100	Odhisha	Bhima Bhoi Medical College and Hospital Balangir, Odisha,Balangir-767002
101		Sun Hospital Sri Vihar Colony, Kanika Chakk, Tulsipur, Cuttack, Odisha -753008
102	Punjab	Abrol Medical Centre Super Speciality Hospital Kailash Enclave, Batala Rd, Gurdaspur, Punjab Region - 143521
103		Arora Neuro Centre 120, The Mall, Civil Lines, Next to Narayana Group of Schools, Ludhiana, Punjab - 141001
104		Fortis Hospital Ludhiana, Punjab
105		IVV Health & Life Sciences Pvt. Ltd. Amritsar, Punjab
106		Neelam Hospital NH-7, Chandigarh-Rajpura Highway, Opp. Chitkara University, Patiala, Punjab - 140401
107		Orison Hospitals Opp. Grand Walk Mall, Barewal Road, Ludhiana, Punjab- 141012
108		Moga Medicity Hospital Barnala - Amritsar Bye Pass, Moga, Punjab -142001

109	Rajasthan	S.R. Kalla Memorial Gastro & General Hospital 78-79, Dhuleshwar Garden, Sardar Patel Marg, C Scheme, Jaipur, Rajasthan-302001
110		American International Institute of Medical Sciences Near, Airport Road, Bedwas, Transport Nagar, Udaipur, Rajasthan-313001
111		Dhanwantri Hospital and Research Centre Bus Stand, New Sanganer Road, Near Madara, Ward 27, Mansarovar Sector 6, Mansarovar, Jaipur. Rajasthan- 302020
112		S.N. Super Speciality Hospital Private Limited Murraba No 60, Chak 2 ML , Hanumangarh-Suratgarh Bypass Road Nathwala, Sriganga Nagar, Rajasthan - 335001
113	Tamil Nadu	Apollo Children Hospital Chennai
114		Apollo Speciality Hospitals Trichy, Tamil Nadu
115		St. Thomas Mount Chennai, Tamil Nadu
116		Apollo Speciality Hospitals Vangaram, Tamil Nadu
117		Apollo Reach Hospital Madurai Main Road, Managiri, Sivagangai District, Karaikkudi, Tamil Nadu - 630307
118		Vijaya Medical & Educational Trust Old No.180, New no: 434, N.S.K Salai, Vadapalani, Chennai, Tamil Nadu - 600026
119		Apollo Loha Hospital Kavai Road, 163- Allwyn Nagar, Karur, Tamil Nadu
120		Medway Heart Institute (A Unit of United Allaince Healthcare Pvt. Ltd) No.9,1 st Nain Road, United India Colony, Kodambakkan, Tamil Nadu-600024
121		Hindu Mission Hospital 103, GST Road, Chennai, Tamil Nadu-600045

122		Kauvery Hospital Hearticity A Unit of Sri Kauvery Medical Care India Limited, No-12/52, Alexanderia Road, Cantonment, Tiruchirappalli, Tamil Nadu -620001
123	Telangana	Continental Hospital, Plot No 3, Rd Number 2, Financial District, Gachibowli, Nanakaramguda, Telangana-500032
124		Prathima Hospital 3/4/3 Station Road Kachiguda Hyderabad, Telangana - 500027
125		Olive Hospitals Nanalnagar X Road, Mehdipatnam, Hyderabad, Telangana-500028
126		Landmark Hospitals (A unit of Capital Health Services India Private Limited) MCK Block 22, Near JNTU Metro Station, Hydernagar, Telangana, Hyderabad- 500085
127		OMNI Hospitals Kukatpally Mumbai Hwy, Opp. BIG BAZAR, Balaji Nagar, Kukatpally, Hyderabad, Telangana - 500072
128	Uttar Pradesh	Navin Hospital Ghaziabad, Uttar Pradesh
129		Bhardwaj Hospital Noida, Uttar Pradesh
130		Regency Hospital Kanpur, Uttar Pradesh
131		Rani Durgavati Medical College Banda, Uttar Pradesh
132		Heritage Hospitals Ltd. Varanasi, Uttar Pradesh
133		Vinayak Hospital Noida, Uttar Pradesh

134		MIMHANS, Neurosciences Hospital Meerut281-283, Sector-1, Mangal Pandey Nagar Opp. CCS University, Meerut, Uttar Pradesh - 250004
135		Ashutosh Hospital & Trauma Centre 15/20, Opposite Kamla Nehru Hospital, Hashimpur Rd, Prayagraj, Uttar Pradesh 211002
136		Ajay Pratima Hospital Dharam Kanta, 57 Brijlok Colony, Near, Prem Nagar Bareilly, Uttar Pradesh - 243005
137		Max Super Speciality Hospital (A unit of Crosslay Remedies Ltd.) W-3, Sector -01, Vaishali, Ghaziabad, Uttar Pradesh-201012
138		Regency Renal Sciences Center 113/104-A, Swaroop Nagar (OPP. Motidheel), Uttar Pradesh-208002
139		Yatharth Super Speciality Hospital Plot No. 1, Sector 110, Gautam Budh Nagar, Noida, Uttar Pradesh - 201304
140	West Bengal	B.P. Poddar Hospital & Medical Research 71/1 Humayun Kabir Sarani, New Alipore, Block G, Kolkata, West Bengal - 700053
141		Medica Super Speciality Hospital 127 Mukundapur, E.M. Bypass, Kolkata, West Bengal - 700099
142		Belle Vue Clinic Kolkata, West Bengal
143		BM Birla Heart Research Centre Kolkata, West Bengal

Development of MDAE reporting form (Hindi version)

NCC-MvPI, IPC has designed medical device adverse event reporting form in the Hindi version and made it available on IPC website.

Government initiatives on MvPI

The Secretary, Ministry of Health & Family Welfare, Government of India has issued a letter dated October 14, 2022 to State Secretaries regarding the enrollment of district level hospitals under MvPI.

- Subsequent to Health Secretary Letter. following states government has issued the G.O. to medical superintendents/head of the hospitals to get enrolled under MvPI and report medical device adverse events.

GOVERNMENT OF PUDUCHERRY

DIRECTORATE OF HEALTH & FAMILY WELFARE SERVICES

CIRCULAR

Sub: DHFWS – Reporting of Medical Device Adverse Event under Materiovigilance Programme of India (MvPI) - Reg

The Ministry of Health and Family Welfare, Government of India is working on the implement of Hospitals/Clinics/PHC under Materiovigilance programme of India (MvPI) as a Medical Device Adverse Event Monitoring Centre (MDMC).

The aim of the MvPI is preventing patients from medical devices/IVDs related injuries. The role of the MvPI is to monitor the safety of medical devices in the country and to safeguard the health of the public by ensuring that the benefits of use of Medical Devices outweigh the risks associated with its use. Its main objective is to improve the protection of the health & safety of patients, healthcare professionals and others by reducing the likelihood of reoccurrence of an adverse event associated with the use of Medical Devices.

A Medical Device Adverse Event is any occurrence or reasonably likely occurrence, of incorrect disease or injury, or an inconsistent clinical sign (including abnormal laboratory findings) in patients, users or other persons, whether or not related to the medical device.

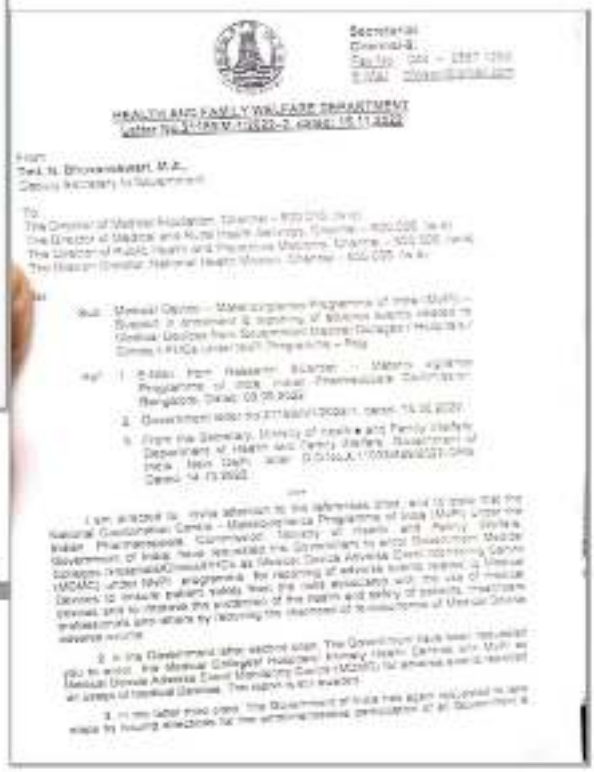
In case of any Medical Device Adverse Event, the manufacturers, importers, healthcare professionals, patients etc., will report serious/MDMC adverse events and product problems to the Licensing Authority/National Coordination Centre (NCC) - Materiovigilance Programme of India (MvPI).

GOVERNMENT OF PUDUCHERRY

Issued order No. 843/DMS/PA/2022

on

December 19, 2022



HEALTH AND FAMILY WELFARE DEPARTMENT

GOVERNMENT OF TAMIL NADU

Issued order No. 21189/M-1/2022-2

on

November 16, 2022

Training/Awareness programmes

NCC-MvPI, IPC has conducted 23 training/awareness programmes and 27 stakeholder meetings in order to sensitize healthcare providers and industry personnel to enhance the MDAE reporting and their understanding on post marketing vigilance practices in India.

List of trainings/ awareness programmes conducted

S. No.	Training/Awareness programme	Date	Place
1.	Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, Government of India in association with the Federation of Indian Chambers of Commerce and Industry (FICCI) organized 7th edition of the International Conference on Pharmaceuticals & Medical Devices Industry i.e.- India Pharma 2022 & India medical Device 2022 from April 25-27, 2022 at Dr. Ambedkar International Conference, New Delhi.	April 25-27, 2022	Dr. Ambedkar International Conference, New Delhi.
2.	NHSRC- HCT division and WHO Country office organized two-day workshop on "Preparedness for Resilient Health Systems" on May 30-31, 2022 at Radisson Blu Plaza Delhi Airport, New Delhi.	May 30-31, 2022	Radisson Blu Plaza Delhi Airport, New Delhi
3.	NCC-MvPI organized an Induction-cum-training programme from June 23-24, 2022 via digital/virtual platform for newly identified coordinators, deputy coordinators and materiovigilance associates.	June 23-24, 2022	IPC, Ghaziabad
4.	PGIMER Chandigarh organized a medical device symposium and workshop on June 25, 2022 at NIPER, Mohali.	June 25, 2022	NIPER, Mohali
5.	NCC-MvPI, IPC in association with National Institute of Medical Health and Neuro Sciences (NIMHANS), Bengaluru organized a National conference on July 09, 2022.	July 09, 2022	NIMHANS, Bengaluru

6.	NCC-MvPI, IPC in association with AIIMS, Bibinagar conducted a Hands-on workshop on Materiovigilance on July 16, 2022 via digital/virtual platform.	July 16, 2022	IPC, Ghaziabad
7.	NCC-MvPI, IPC has conducted a workshop on "Key role of in-vitro diagnostic medical device stakeholders in Materiovigilance Programme of India" on July 22, 2022 at Indian Pharmacopoeia Commission, Ghaziabad.	July 22, 2022	IPC, Ghaziabad
8.	NCC-MvPI, IPC in association with Mamata Academy of Medical Sciences conducted a workshop on 'Importance of Materiovigilance programme of India & medical device adverse event reporting' on July 25, 2022 via digital/virtual platform.	July 25, 2022	IPC, Ghaziabad
9.	NCC-MvPI, IPC has conducted a training programme with selected trainees on "Overview of Materiovigilance Programme & Medical Device Adverse Event reporting" under MvPI on September 7-8, 2022 via digital platform.	September 7-8, 2022	IPC, Ghaziabad
10.	National Institute of Health & Family Welfare conducted a workshop on September 26, 2022 at Munirka, New Delhi.	September 26, 2022	Munirka, New Delhi.
11.	22nd Skill Development Programme on Pharmacovigilance of Medical Products conducted on September 12-16, 2022 via digital mode.	September 12-16, 2022	IPC, Ghaziabad
12.	Teerthanker Mahaveer Medical College and Research Center, Moradabad, Uttar Pradesh conducted a training programme on the occasion of National Pharmacovigilance Week on September 23, 2022.	September 23, 2022	Teerthanker Mahaveer Medical College and Research Center, Moradabad, Uttar Pradesh

13.	MIT College of Pharmacy, Moradabad, and Uttar Pradesh conducted a training programme on the occasion of National Pharmacovigilance Week on September 24, 2022.	September 24, 2022	MIT College of Pharmacy, Moradabad
14.	NCC-MvPI, IPC conducted a training programme on "Materiovigilance Programme of India" at Fortis Hospital, Okhla, New Delhi on October 13, 2022.	October 13, 2022	Fortis Hospital, Okhla, New Delhi
15.	NCC-MvPI, IPC conducted a national conference on "Strengthening of Medical Products Safety surveillance System in North Eastern States of India on October 19, 2022 at Government Pharmacy College, Sajong, Sikkim.	October 19, 2022	Government Pharmacy College, Sajong, Sikkim
16.	NCC-MvPI, IPC conducted an induction-cum-training programme for newly identified coordinators on November 9-10, 2022 via digital platform.	November 9-10, 2022	IPC, Ghaziabad
17.	NCC-MvPI, IPC in association with Ruby Hall Clinic conducted a national conference on "Strengthening medical product safety surveillance" at Sheraton Grand Hotel, Pune on November 12, 2022	November 12, 2022	Sheraton Grand Hotel, Pune
18.	72nd Indian Pharmaceutical Congress organized by Indian Pharmaceutical Congress Association on "Access to Quality & Affordable Medical Products" from January 20-23, 2023 at Nagpur.	January 20-23, 2023	Nagpur

19.	MvPI team participated in the 2nd Annual Conference Delhi Pharmaceutical Society on "Advances and Current Trends in Pharmacology" on March 01, 2023 at DPSRU, Pushp Vihar, New Delhi.	March 01, 2023	DPSRU, Pushp Vihar, New Delhi
20.	NCC-MvPI, IPC in association with National Health System Resource Centre, New Delhi conducted a webinar on "Monitoring the safety of customized Implants" on March 14, 2023.	March 14, 2023	IPC, Ghaziabad
21.	NCC-MvPI, IPC in collaboration with Sharda University organized a national conference on "Scope & Research Opportunities for the Pharmacy professionals in Pharmacovigilance & Materiovigilance from March 17-18, 2023.	March 17-18, 2023	Sharda University, Greater Noida
22.	Santosh Medical College, Noida conducted a workshop on "Pharmacovigilance Sensitization programme and Health & Science Symposium" on March 28, 2023.	March 28, 2023	Santosh Medical College, Noida
23.	NCC-MvPI, IPC conducted a training programme on Implementation of Materiovigilance Program of India in State of Tamil Nadu" on March 31, 2023 from 11:00 am to 2:00 pm.	March 31, 2023	IPC, Ghaziabad

List of stakeholders meeting conducted during the indexed period

S. No.	Title and Description of Meeting	Date	Outcomes/Action Taken
1.	CDAC Meeting	May 11, 2022	MvPI associates shared their suggestions & challenges while reporting the MDAEs through ADRMS. CDAC team has taken some suggestions and assured to implement the same in the upcoming software.
2.	A formal visit at Terumo India Private Limited	May 12, 2022	NCC-MvPI team developed their basic understanding on Quality Management System (QMS) required for medical devices (cardiac stents, vascular closure devices, heart lung machines etc.) manufactured by Terumo company.
3.	Technical support group meeting	May 13, 2022	Following are the points discussed in the meeting- • Modifications of MvPI Enrollment Form • Discussion on MvPI Internship Programme • A plan of action for non-reporting medical device adverse event monitoring centre was discussed and suggestions received.
4.	Meeting with CDSCO	May 19, 2022	MvPI pending issues was discussed in detail with CDSCO.
5.	Meeting with NHSRC	May 23, 2022	A joint approach to ensure safety of medical devices used under various National Health Programmes (National Programme for Control of Blindness and Visual Impairment and National Health Programme for Family Planning) were discussed.

6.	Subject expert meeting	June 23 & June 29, 2022	Adverse event cases suspected to be related to the medical devices were discussed and subject expert opinions on discussed adverse event cases were obtained.
7.	19th Partners' Meeting	July 26, 2022	• The MDAE reporting trend during January to May 2022 was presented to the committee members. Based on the recommendations of the subject experts, 68 MDAE cases were discussed for further course of action which include 01 recommendation to CDSCO and 01 safety alert to MDMCs. • MvPI team updated the committee members on the activities performed by MvPI during indexed period (April to July 25, 2022) • The members unanimously agreed and encouraged 119 hospitals/medical institutions to function as MDMC under MvPI.
8.	3rd Technical Support Group meeting	July 19, 2022	MvPI team discussed the following points in the meeting- • Letter of Intent received at NCC-MvPI • Identification of Subject Experts in MvPI • Modules of MvPI Internship Programme • A plan of action for non-reporting medical device adverse event monitoring centres under MvPI.

9.	Meeting with MDMC coordinators, trainees and MvPI associates	August 23, 2022	Following points were discussed in the meeting:- A plan of action of trainees under MvPI. Placement of trainees' at MDMCs to enhance the culture of adverse event reporting at the centres. Two days training programme will be conducted for the trainees' by NCC-MvPI, IPC.
10.	Meeting with CDSCO	August 31, 2022	MvPI pending issues was discussed in detail with CDSCO.
11.	MvPI associates meeting	August 30, 2022	• MvPI associates from different MDMCs presented their progress report for last months to NCC. • MvPI officer in charge encouraged the associates to enhance the culture of adverse event reporting in their respective centres.
12.	Subject expert meeting	September 02 & September 06, 2022	Adverse event cases suspected to be related to the medical devices were discussed and subject expert opinions on discussed adverse event cases were obtained.
13.	Pre-partner's meeting	September 14, 2022	Adverse event cases suspected to be related to the medical devices were discussed and subject expert reviewes were obtained.
14.	MvPI associates Meeting	September 29, 2022	Performance status of trainees at their respective Medical Device Adverse Event Monitoring Centres were discussed.
15.	Subject expert meeting	October 06, 2022	Adverse event cases suspected to be related to the medical devices were discussed and subject expert opinions on discussed adverse event cases were obtained.

16.	Meeting with Medtronic team	October 17, 2022	MvPI team resolved all the queries raised by Medtronic company and Medtronic team also suggested some of the suggestions regarding reporting of adverse events to MvPI team.
17.	MvPI associates Meeting	October 28, 2022	MvPI associates posted at different MDMCs shared the progress report of the associates for last two months. MvPI Team also detailed the associates about the ADRMS software.
18.	20th Partners' Meeting	November 30, 2022	The MDAE reporting trend during June to September 2022 was presented to the committee members. Based on the recommendations of the subject experts, 151 MDAE cases were discussed for further course of action which include 05 recommendations to CDSCO.
19.	Training on ADRMS software	November 15, 2022	CDAC team sensitized the coordinators/deputy coordinators of monitoring centres on how to fill medical device adverse event report in ADRMS Software.
20.	NABH Meeting	November 16, 2022	The following points were discussed in the meeting- • To include materiovigilance programme in the Memorandum of Understanding (MoU) between NABH and IPC. • Focus on rise in medical device adverse event reporting from NABH hospitals. • Renewal of MoU between NABH and IPC.

21.	MvPI associates Meeting	December 22, 2022	MvPI associates posted at different MDMCs shared the progress report of the associates for last two months. MvPI Team also detailed the associates about the ADRMS software.
22.	Subject expert meeting	January 25, 2023	Adverse event cases suspected to be related to the medical devices were discussed and subject expert opinions on discussed adverse event cases were obtained.
23.	Meeting on serious adverse event associated with Intraocular lens	January 18, 2023	Adverse event cases suspected to be related to the intraocular lens causing Toxic Anterior Segment Syndrome were discussed and clinical expert reviewed were obtained. Members of the meeting also suggested the following points: • Forward an interim report on received serious adverse events associated with intraocular lens to National Regulatory Authority i.e., Central Drugs Standard Control Organization, New Delhi. • Experts suggested to circulate safety alerts/advisory for the awareness of healthcare professionals at monitoring centres. • Meeting members also suggested that IPC should collect more reports on the intraocular lens from the healthcare professionals in order to come at a meaningful conclusion.

24.	Meeting on serious adverse event associated with Intraocular lens	January 23, 2023	Adverse event cases suspected to be related to the intraocular lens causing Toxic Anterior Segment Syndrome were discussed in the meeting. Representatives from the Ophthalmologist Society also shared their opinion on the said case.
25.	MvPI associates Meeting	January 13, 2023	MvPI associates posted at different MDMCs shared the progress report of their respective centres. MvPI Team also shared the reporting status at NCC. Associates also shared the training details planned for Year-2023.
26.	Meeting with CDSCO	March 03, 2023	MvPI pending issues related to intraocular lens and Inhaler was discussed in detail with CDSCO.
27.	Meeting with Regional Training Centre	March 10, 2023	An action plan of regional training centre under MvPI was discussed. The coordinators of the RTC also shared their inputs and activities conducted by them.

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All PvPI teams at National Coordination Centre & ADR Monitoring Centres.

All other Technical, Administrative and Financial staff of IPC.

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ANNEXURES

Annexure - I

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

Reg. No. / IPD No. / OPD No. / CR No. :

AMC Report No. :

Worldwide Unique No. :

A. PATIENT INFORMATION*

1. Patient Initials : 2. Age or date of birth :

3. Gender : M ☐ F ☐ Other ☐ 4. Weight (in Kg.) :

B. SUSPECTED ADVERSE REACTION*

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

12. Relevant investigations with dates :

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.	8. Name (Brand/Generic)	Manufacturer (if known)	Batch No. / Lot No.	Expiry Date (if known)	Dose	Route	Frequency	Therapy Dates		Indication	Causality Assessment
								Date Started	Date Stopped		
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		Indication
					Date Started	Date Stopped	
i							
ii							
iii#							

Additional Information :

D. REPORTER INFORMATION*

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** (9:30 AM to 5:30 PM, Monday-Friday)
- **ADR Mobile App : "ADRPvPI"**

Annexure - II

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 (ए): 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(दवाइयां) लेने का कारण (रोग / लक्षण):

b. Medicines Advised by/ दवाई की सलाह देने वाला (ए): Doctor/ चिकित्सक ☐ 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 निष्क्रिय होने की तिथि	Date of Start of Medicines/ दवाइयां आरंभ करने की तिथि	Date of Stop of Medicines/ दवाइयां रोकने की तिथि

Dosage form/खुराक का स्वरूप (ए): Tablet/ गोली (टेबलेट) ☐ Capsule/ कैप्सूल ☐ Injection/ इंजेक्शन ☐ Oral liquids/ मौखिक द्रव ☐ 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 हो, उस पर ✓ का निशान लगाएं)

☐ Did not affect daily activities/ दैनिक गतिविधियां प्रभावित नहीं हुई थी ☐ Affect daily activities/ दैनिक गतिविधियां प्रभावित हुई
☐ Admitted to hospital/ अस्पताल में दाखिल रहा ☐ Death/ मृत्यु
☐ Others/ अन्य

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

This reporting is voluntary, has no legal implication and aims to improve patient safety. Your active participation is valuable. The information provided in this form will be forwarded to ADR Monitoring Centre for follow-up. You are requested to cooperate with the programme officials when they contact you for more details. Please do report even if you do not have all the information.
यह रिपोर्टिंग स्वैच्छिक है, इसमें कानूनी निहितार्थ नहीं है और इसका उद्देश्य रोगी की सुरक्षा में सुधार करना है। आपकी सक्रिय भागीदारी मूल्यवान है। इस फॉर्म में दी गई जानकारी को अनुवर्ती कार्रवाई हेतु एडीआर निगरानी केंद्र को भेजा जाएगा। आपसे अनुरोध है कि जब कार्यक्रम के अधिकारी अधिक जानकारी के लिए आपसे संपर्क करें, कृपया पूरी जानकारी न होने पर भी सूचित करें।

Please turn the page to read the instructions
निर्देश पढ़ने के लिए पृष्ठ पलटें

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

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FAX: 0120-2783411
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 से 5:30 बजे तक, प्रत्येक कार्यदिवस पर)

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Program/ its 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 जाता है। कार्यक्रम या इसके से कर्मचारी से यही अपेक्षा की जाती है कि वह इस बात की सार्वजनिक अनुरोध पर रिपोर्ट की पहचान का खुलासा नहीं करेगा।

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 as necessary to assist 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 other 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/mark 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 आरंभिक में नाम का पहला अक्षर लिखें और उपनाम का अंतिम अक्षर लिखें (जैसे प्रदीप शर्मा–पीएस)।
- ✓ व्यक्तिगत जानकारी (लिंग, आयु) प्रदान करें।

निर्देश –2 स्वास्थ्य संबंधी जानकारी

- ✓ दवा लेने के कारण और दवाओं की सलाह इस नाम से (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 नं और ई-मेल उपलब्ध कराएं।

निर्देश 4 – ली जा रही दवाओं / ली जा चुकी दवाइयों का विवरण

- ✓ सभी जानकारी (दवाओं का नाम, ली गई दवाइयां, निर्धारित देने की तिथि, दवाइयां शुरू करने एवं रोकने की तिथि) का विवरण दें जिनसे कारण असरदार दुष्प्रभाव हुआ है।
- ✓ खुराक का स्वरूप लिखें (टैबलेट, कैप्सूल, इंजेक्शन, मौखिक तरल देने वाली दवा) और यदि कोई अन्य हो तो निर्दिष्ट करें।

निर्देश 5 – दुष्प्रभाव के प्रारंभ के बारे में

- ✓ दुष्प्रभाव आरंभ और समाप्त होने की तिथि प्रदान करें और यह भी निर्दिष्ट करें कि क्या दुष्प्रभाव अभी भी जारी है।

निर्देश 6 – दुष्प्रभाव कितने हानिकारक थे?

- ✓ इच्छा चिह्नित करने के निशान लगाएं।

निर्देश 7– दुष्प्रभाव की व्याख्या करें

- ✓ दुष्प्रभाव का विवरण और दुष्प्रभाव को प्रबंधित करने के लिए क्या उपचार किया गया, विवरण करें।

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

Annexure - III

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 cases ☐
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 ☐

Reg. No./IPD 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		

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

11. Recent Travel Information :

Recent History of International Travel : Yes ☐ No ☐

Country Visited :

Date of Return to India :

Inter-state travel/domestic travel

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

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	☐

8. Seriousness of the reaction :

No ☐ If Yes ☐ (please tick appropriate box)

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

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	Causality Assessment (Prefer WHO-UMC Scale)
i.												
ii.												
iii.												
iv.												

S.No.	Drug Name	Reaction abated on (dose wise): Drug withdrawal	Dose reduction	Without modification of dose	Any other	Reaction reappeared after drug readministration: 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 Nurses 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 (ADRC) 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 ADRCs is available at : http://www.ipc.gov.in, http://www.ipc.gov.in/PvPI/pv_functions.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 ADRCs by using WHO-UMC scale. The analysed forms are forwarded to the NCC-PvPI through ADR database. Finally the data is analysed 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 - IV

Version no. 1.1

PERSONAL PROTECTIVE EQUIPMENT ADVERSE EVENT REPORTING FORM

Materiovigilance Programme of India (MvPI)

Where to report: [illegible] Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare, Government of India, Sector 23, Rajnagar, Ghaziabad [illegible] or email to [illegible] 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 - V

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 as 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:min)
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 I.V) 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 cause(s):

Adverse Event/ Reaction Term	Event I	Event II	Event III
Date of Onset	(dd/mm/yyyy)	(dd/mm/yyyy)	(dd/mm/yyyy)
Date Resolved	(dd/mm/yyyy)	(dd/mm/yyyy)	(dd/mm/yyyy)
Severity	☐ Mild ☐ Moderate ☐ Severe	☐ Mild ☐ Moderate ☐ Severe	☐ Mild ☐ Moderate ☐ Severe
Seriousness	☐ Non-Serious ADR ☐ Serious AD/ADR please specify category: ☐ Death ☐ Hospitalization/ Prolonged ☐ Life Threatening ☐ Permanent disability/disabling ☐ Congenital anomaly/ birth defect ☐ Other medically important condition	☐ Non-Serious ADR ☐ Serious AD/ADR please specify category: ☐ Death ☐ Hospitalization/ Prolonged ☐ Life Threatening ☐ Permanent disability ☐ Congenital anomaly ☐ Other medically important condition	☐ Non-Serious ADR ☐ Serious AD/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 Sequelae ☐ Unknown	☐ Recovered/ resolved ☐ Recovering/resolving ☐ Fatal ☐ Not Recovered/not resolved ☐ Recovered with Sequelae ☐ Unknown	☐ Recovered/ resolved ☐ Recovering/resolving ☐ Fatal ☐ Not Recovered/not resolved ☐ Recovered with Sequelae ☐ 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: **Email:**	**Designation:** **Contact No.:**	**Signature:**
Professional Address:	**PIN Code:**	**Date:**
Name of Paramedical:	**Designation:**	**Signature:**

Annexure - VI

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	Y	Time of first symptom	H	H	M	M	AM/PM
Hospitalization:(No/ Yes) Date-	D	D	M	M	Y	Y	Y	Y	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	Time of Death
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 (sefiindia@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.**

Annexure - VII

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 MDPC 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 ☐ Both ☐ Preventive ☐ Aesthetic ☐	I. Kits ☐	I. Therapeutic ☐ Diagnostic ☐
II. Implantable device ☐ Non Implantable device ☐	II. Reagents ☐	II. Therapeutic & Diagnostic ☐
III. Invasive ☐ Non-Invasive ☐	III. Calibrator ☐	III. Preventive ☐
IV. Single use device ☐ Reusable device ☐ Reuse of manufacture marked Single use device ☐	IV. Control Materials ☐	IV. Assistive ☐
V. Sterile ☐ Non Sterile ☐	V. Others ☐	V. Imaging ☐
VI. Personal use / Homecare use ☐	VI. IVD electronic reader/ Analyzer ☐	VI. Invasive ☐ Non-Invasive ☐
		VII. Others ☐

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, 4 & 5), D, E & F*

(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. Explanation 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 ☐ returned 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

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	Year	No. of Similar Adverse Events	Total No. Supplied	Frequency of Occurrence (%)
11. Frequency of occurrence of similar Adverse Event in India in past 5 years				
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):

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(F) Manufacturer/Authorized Representative Investigation & Action taken

1. Manufacturer/Authorized Representative device risk analysis report:

2. Corrective / preventive action taken:

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3. Device history review:

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(B) Event Description (Continued)

10. Brief description of event:-

(E) Causality Assessment (Continued)

1. Immediate 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, Raj Nagar, Ghaziabad-20002, Tel-0120-2783400, 2783401 and 2783402, FAX-0120-2783511 or email to sbdmpipc.ipc@gov.in **Or Call on Helpline no. 1800 180 3024 to report Adverse event.**

Partnering Organizations

Disclaimer:

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. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the adverse event.

Let us join hands with PvPI to ensure patient safety

Indian Pharmacopoeia Commission
National Coordination Centre
Pharmacovigilance Programme of India
Ministry of Health & Family Welfare, Govt. of India
Sector-23, Raj Nagar, Ghaziabad-201002
Tel. : 0120-2783400, Extn.-155

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

For any relevant Information/Suggestions/Query

Please Contact: Officer-In-Charge, Pharmacovigilance Programme of India
Email: pvpi.ipc@gov.in, lab.ipc@gov.in website: www.ipc.gov.in