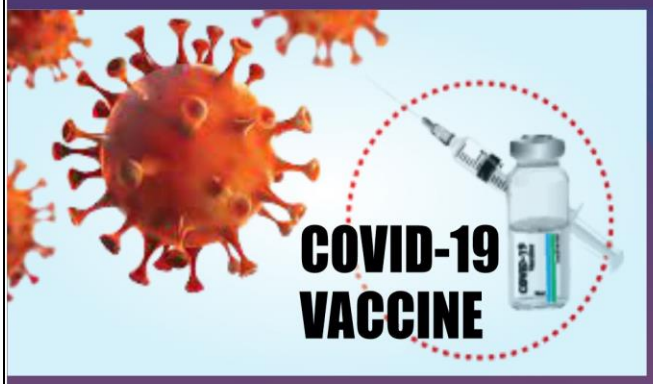
सत्यमेव जयते

IPC

# Pharmacovigilance Programme of India (PvPI)

## PERFORMANCE REPORT

## 2020-2021




**INDIAN PHARMACOPOEIA COMMISSION**

Ministry of Health and Family Welfare, Government of India

## Contents

## ABBREVIATIONS

| | | |
|---|---|---|
| **ADR** | **:** | Adverse Drug Reaction |
| **AE** | **:** | Adverse Event |
| **AEFI** | **:** | Adverse Event Following Immunization |
| **AI** | **:** | Active Ingredient |
| **AIIMS** | **:** | All India Institute of Medical Sciences |
| **AMC** | **:** | Adverse Drug Reaction Monitoring Centre |
| **ATC** | **:** | Anatomical Therapeutic Chemical |
| **CDSCO** | **:** | Central Drugs Standard Control Organization |
| **CME** | **:** | Continuing Medical Education |
| **CTP** | **:** | Core Training Panel |
| **GoI** | **:** | Government of India |
| **GvP** | **:** | Good Pharmacovigilance Practices |
| **HCP** | **:** | Healthcare Professional |
| **HCQ** | : | Hydroxychloroquine |
| **ICSR** | **:** | Individual Case Safety Report |
| **IC** | **:** | Information Component |
| **IPC** | **:** | Indian Pharmacopoeia Commission |
| **MAH** | **:** | Marketing Authorization Holder |
| **MDAE** | **:** | Medical Device Adverse Event |
| **MDMC** | **:** | Medical Device Adverse Event Monitoring Centre |
| **MedDRA** | **:** | Medical Dictionary for Regulatory Activities |
| **MoHFW** | **:** | Ministry of Health and Family Welfare |

| | | |
|---|---|---|
| **MvPI** | **:** | Materiovigilance Programme of India |
| **NABH** | **:** | National Accreditation Board for Hospitals and Healthcare Providers |
| **NACP** | **:** | National AIDS Control Programme |
| **NCC** | **:** | National Coordination Centre |
| **NFI** | **:** | National Formulary of India |
| **NTEP** | **:** | National Tuberculosis Elimination Programme |
| **NVBDCP** | **:** | National Vector Borne Disease Control Programme |
| **PHP** | **:** | Public Health Programme |
| **PIL** | **:** | Prescribing Information Leaflet |
| **PT** | **:** | Preferred Term |
| **PV** | **:** | Pharmacovigilance |
| **PvPI** | **:** | Pharmacovigilance Programme of India |
| **RTC** | **:** | Regional Training Centre |
| **SDRIFE** | **:** | Symmetrical Drug-Related Intertriginous and Flexural Exanthema |
| **SEARN** | **:** | South East Asia Regulatory Network |
| **SOC** | **:** | System Organ Class |
| **SOP** | **:** | Standard Operating Procedure |
| **SRP** | **:** | Signal Review Panel |
| **UIP** | **:** | Universal Immunization Programme |
| **UT** | **:** | Union Territory |
| **WHO** | **:** | World Health Organisation |
| **UMC** | **:** | Uppsala Monitoring Centre |

## Message from the Desk of Secretary-cum-Scientific Director

**Dear Readers,**

I take this opportunity to present the Performance Report of Pharmacovigilance Programme of India (PvPI) for the Financial Year 2020-21. The mission of PvPI is to safeguard the health of Indian population by ensuring that the benefits of use of medicine outweigh the risks associated with its use.

PvPI has undergone vast expansion to reach the common masses in the country through a network of Adverse Drug Reaction Monitoring Centres (AMCs). The numbers of AMCs under PvPI across the country have been increased from 311 to 346. The National Coordination Centre (NCC) for PvPI has issued 16 Drug Safety Alerts and recommendations of the Signal Review Panel sent to Central Drugs Standard Control Organization for appropriate regulatory action.

The development of skilled human resource on continuous basis is the need of hour in the area of Pharmacovigilance. Therefore, in order to develop the skilled human resource in the area of Pharmacovigilance, PvPI organised 219 virtual training programmes and trained 15875 Healthcare Professionals (HCPs) across the country. Some of the important training programmes include Skill Development Programme on Basic Concepts of Pharmacovigilance, Advanced Level Training Programmes, Induction-cum-Training Programmes, etc.

It is noteworthy to mention that PvPI has organised several Interactive meets with Marketing Authorization Holders (MAHs)/Pharmaceuticals Industries to discuss & resolve their issues and challenges for the reporting of Individual Case Safety Reports (ICSRs) to PvPI. This provided them the opportunity to introspect the quality of ICSRs submitted to PvPI. PvPI has also provided the technical support to MAHs/Pharmaceuticals Industries for the strengthening of Pharmacovigilance system at their site as per the Good Pharmacovigilance Practices guidelines.

PvPI continued its WHO-Collaborative Centre status in Pharmacovigilance in Public Health Programmes and Regulatory Services. PvPI on the behalf of India is the 9$^{th}$ largest contributors globally in terms of submitting ICSRs to WHO drug safety database under the WHO- International Drug Monitoring Programme. The campaigning of 5$^{th}$ #MedSafetyWeek by PvPI through social media was appreciated by WHO-Uppsala Monitoring Centre, Sweden.

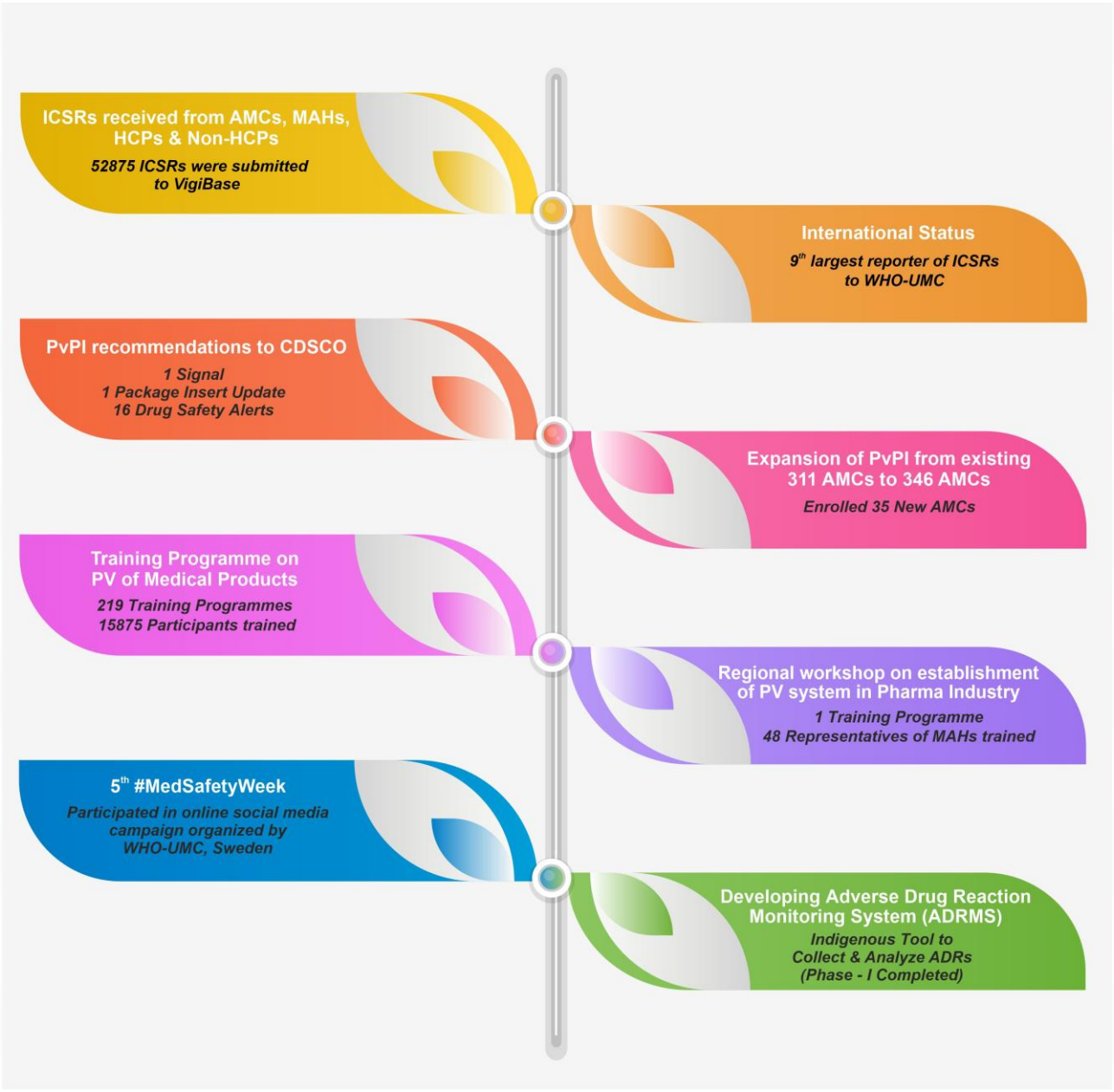
Another noteworthy development for NCC-PvPI has been in the sphere of medical device adverse event monitoring under the purview of Materiovigilance Programme of India (MvPI), which deals with collection, monitoring, recording and analysing the Adverse Events or risk associated with the use of medical devices. So far 50 Medical Device Adverse Event Monitoring Centres (MDMCs) have been enrolled across the country. To ensure effective Adverse Event reporting culture among Clinicians, Biomedical Engineers and other HCPs, MvPI has organised hands-on training programmes/ awareness sessions/e-CMEs/workshops, etc.

Let us pledge to surge ahead with the immense experience and knowledge of ensuring patient safety by constant drug monitoring with the active cooperation of our stakeholders across the country.

I thank NCC-PvPI, IPC team for meticulously bringing out this Performance Report of PvPI.

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

# HIGHLIGHTS


ICSRs received from AMCs, MAHs, HCPs & Non-HCPs
52875 ICSRs were submitted to VigiBase
International Status
9th largest reporter of ICSRs to WHO-UMC
PvPI recommendations to CDSCO
1 Signal
1 Package Insert Update
16 Drug Safety Alerts
Expansion of PvPI from existing 311 AMCs to 346 AMCs
Enrolled 35 New AMCs
Training Programme on PV of Medical Products
219 Training Programmes
15875 Participants trained
Regional workshop on establishment of PV system in Pharma Industry
1 Training Programme
48 Representatives of MAHs trained
5th #MedSafetyWeek
Participated in online social media campaign organized by WHO-UMC, Sweden
Developing Adverse Drug Reaction Monitoring System (ADRMS)
Indigenous Tool to Collect & Analyze ADRs
(Phase - I Completed)

## Indian Pharmacopoeia Commission and its Services

Indian Pharmacopoeia Commission (IPC) is an autonomous institution of the Ministry of Health & Family Welfare (MoHFW), Government of India (GoI), 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. The mandate of the commission is to perform *inter-alia* functions such as revision and publication of IP and National Formulary of India (NFI) on a regular basis. IPC also provides IP Reference Substances and training to the stakeholders on Pharmacopoeial issues and also functions as National Coordination Centre (NCC) for Pharmacovigilance Programme of India (PvPI).

### Functions of Indian Pharmacopoeia Commission

# Pharmacovigilance Programme of India

## GENESIS

**Pharmacovigilance Programme of India is Government of India's flagship drug safety monitoring programme, which collects, collates and analyses drug-related adverse events (AEs).**

**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 April 15, 2011, shifting the National Coordination Centre from All India Institute of Medical Sciences (AIIMS), New Delhi to IPC, Ghaziabad.**

**In a first of its kind, the World Health Organization (WHO) on July 18, 2017, bestowed upon India the honour of being a WHO-Collaborating Centre for Pharmacovigilance in the field of Public Health Programmes and Regulatory Services.**

# PvPI: An Overview

Pharmacovigilance Programme of India (PvPI) is Government of India's flagship drug safety monitoring programme which collates and analyses drug-related adverse events. As adverse drug reaction is one of the leading causes of morbidity and mortality worldwide, therefore, it is imperative to monitor the ADRs. Pharmacovigilance Programme of India (PvPI) was launched in July 2010 by Ministry of Health & Family Welfare (MoHFW), Government of India and All India Institute of Medical Sciences (AIIMS), New Delhi was its National Coordination Centre (NCC). However, Ministry of Health and Family Welfare, Government of India, Nirman Bhavan, New Delhi recasted this programme vide an Order No. X.11035/7/2011-DFQC dated 15 April, 2011 resulting in shifting of PvPI from AIIMS, New Delhi to Indian Pharmacopoeia Commission (IPC), Ghaziabad. Since then, IPC has been entrusted with the responsibility as the National Coordination Centre for Pharmacovigilance Programme of India (NCC-PvPI).

**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
- Emerge as a National Centre of Excellence for Pharmacovigilance Activities
- Collaborate with other National Centres for exchange of information and data management
- Provide training and consultancy support to other National Pharmacovigilance Centres across the globe
- Promote rational use of medicines

## 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 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 chaired by the Secretary-cum-Scientific Director, IPC.

**Quality Review Panel**

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

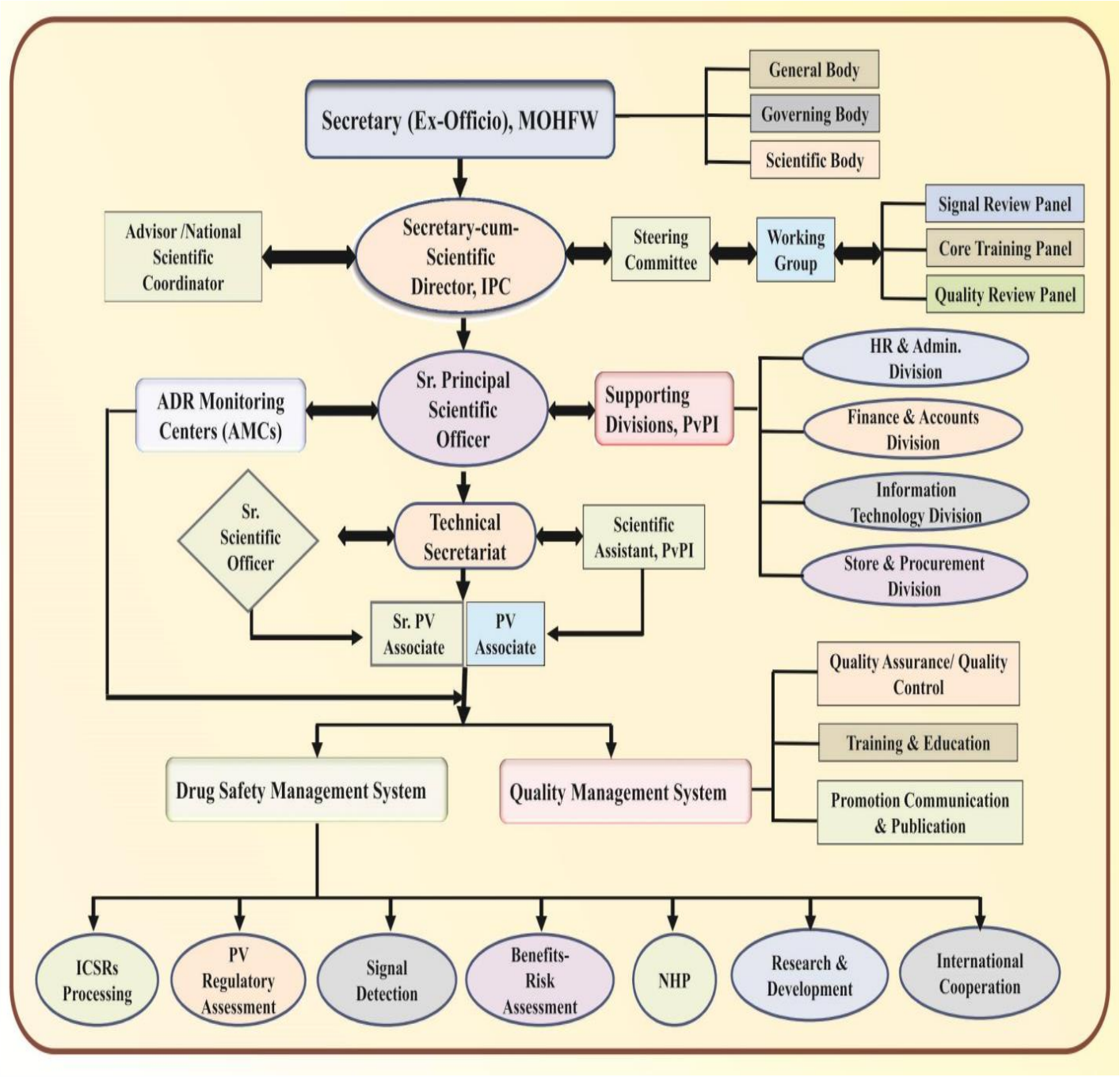
**Signal Review Panel**

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 industry are also invited for 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 defines 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 centers. 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.

# Organogram of National Coordination Centre-Pharmacovigilance Programme of India



## E-mail IDs and functions of different divisions of PvPI

| 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@gmail.com |
| **3.** | Training & Education Division | Training and Skill Development | training.nccpvpi@gmail.com |
| **4.** | Promotion, Communication & Publication Division | Publication of PvPI resource materials and communication with stakeholders | communication.nccpvpi@gmail.com |
| **5.** | Signal Detection Division | Drug Safety Alerts and other regulatory recommendations | signal.nccpvpi@gmail.com |
| **6.** | National Health Programme Division | Integration with Public Health Programmes | nhp.nccpvpi@gmail.com |
| **7.** | Information Technology Division | Management of VigiFlow and other IT tools | it.nccpvpi@gmail.com |
| **8.** | Human Resource Division | Human Resource Development | hr.nccpvpi@gmail.com |
| **9.** | Individual Case Safety Report Processing Division | Submission of ADRs by non-AMCs | icsr.nccpvpi@gmail.com |
| | | Submission of ADRs by consumers/patients | pvpi.compat@gmail.com |
| | | Processing of AEs reported through PvPI Helpline | pvpihelpline@gmail.com |
| **10.** | PV Regulatory Assessment Division | Processing of ICSRs received from MAHs and review of PSUR | mah.nccpvpi@gmail.com<br>psur.nccpvpi@gmail.com |

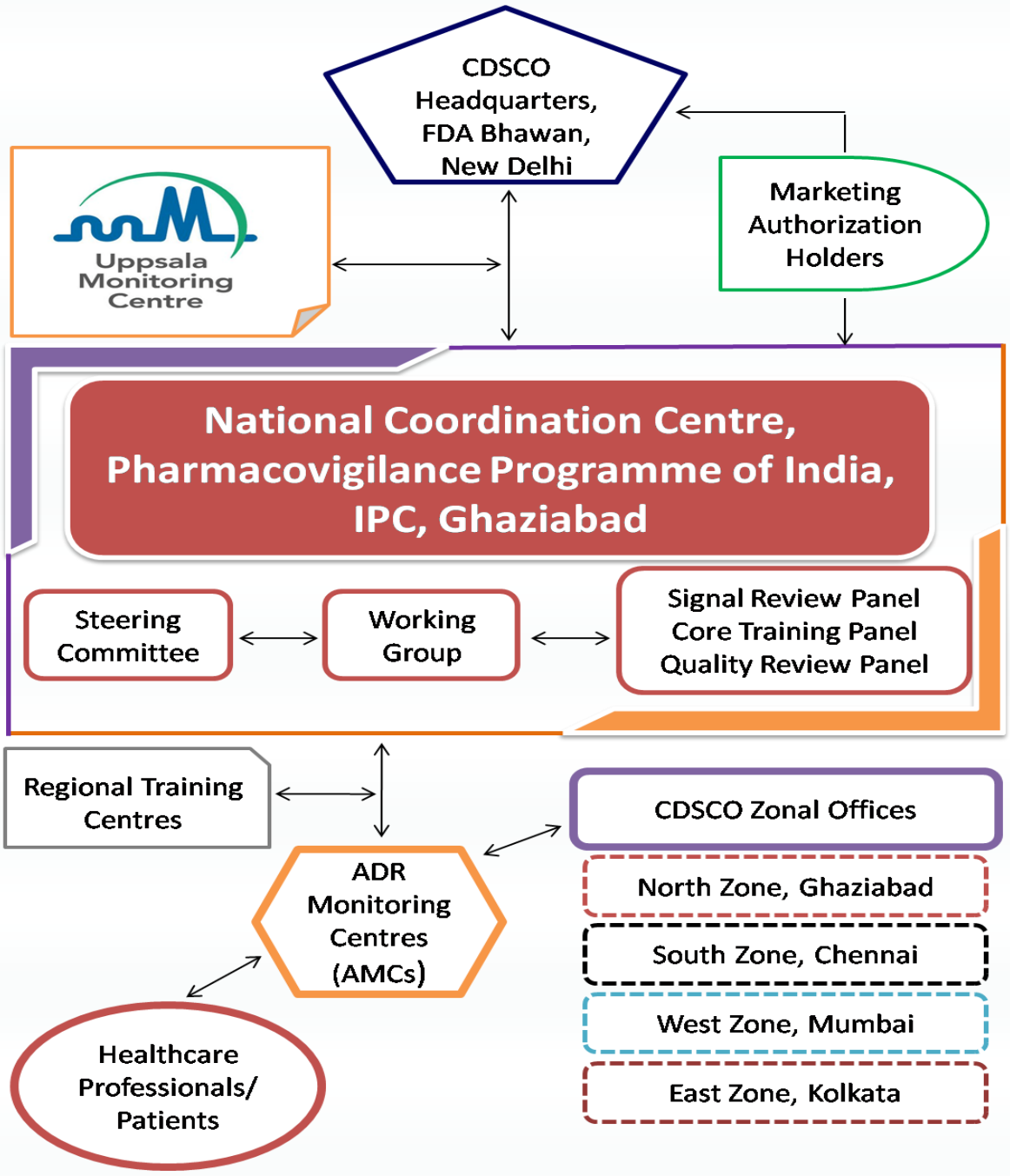
## Performance of PvPI as WHO-Collaborating Centre

Since recognition of PvPI as a WHO-Collaborating Centre for Pharmacovigilance in Public Health Programmes and Regulatory Services, it has embarked upon capacity-building and strengthening of PV system for Low and Middle Income Countries (LMIC) in Asia and beyond. During the index period, PvPI took several initiatives and contributed to enrich PV knowledge of stakeholders. Some of the noteworthy events are as follows:

| Activity | Outcomes |
|---|---|
| **Development of e-tools for integration of ADR-reporting** | • Developing Indigenous Adverse Drug Reaction Management System (ADRMS) Software with provision to integrate with the global WHO-Drug and MedDRA dictionaries. ADRMS software will offer seamless ICSR processing and data mining for signal detection.<br>• Continuous updation of the features of Mobile App 'ADR PvPI' for reporting of ADRs by consumers/patients/ healthcare professionals (HCPs) etc. |
| **PV data sharing with South-East Asia Regional Network (SEARN) countries** | • NCC-PvPI shared the information of ADRs and PvPI e-Newsletter on the Information Sharing Platform (ISP), a gateway to strengthen regulatory cooperation and collaboration for SEARN countries.<br>• NCC-PvPI as the National Centre published drug safety information in WHO Pharmaceuticals newsletter for global outreach. |
| **Capacity Building and support for Public Health Programmes (PHPs) and Regulatory Services** | • Focussed Pharmacovigilance of Hydroxychloroquine: The National Task Force for COVID-19, constituted by the Indian Council of Medical Research, New Delhi considered the PvPI data, while revising the advisory on the use of Hydroxychloroquine (HCQ), as prophylaxis for COVID-19 infection<br>• Focussed Pharmacovigilance of COVID-19 Vaccines: PvPI tirelessly attempted to collect adverse event reports related to COVID-19 Vaccines through Healthcare Professionals or any other person. Also supported AEFI Secretariat of the MoHFW. |

## 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 Adverse Drug Reaction Monitoring Centres (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:




**Communication of data flow in PvPI**

## Reporting ADRs

### Who can Report?

**Consumers/Patients**

**Physicians**


**Pharmacists**

**Nurses**

**Healthcare Professionals**

**Pharmaceutical Industries**

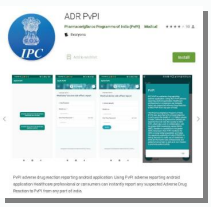
**ADR Monitoring Centres**

### Whom to Report?

**AMCs**

**PvPI Helpline**

**(1800-180-3024)**




**PvPI Mobile App**

**ADR PvPI**

icsr.nccpvpi@gmail.com

pvpi.compat@gmail.com

**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**

- Lack/No 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)**

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 website (www.ipc.gov.in) or CDSCO website (www.cdsco.gov.in) and in National Formulary of India 2016 **(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)**

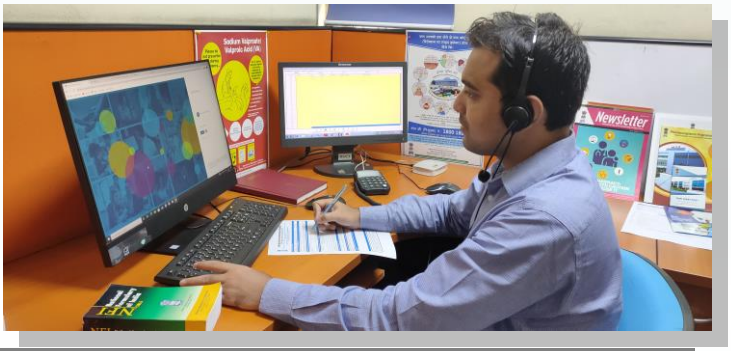
The Suspected ADR Reporting Form is designed for Healthcare professionals during pandemic to capture detailed information about an AE/ADR related to the drugs used in Prophylaxis/ Treatment of COVID-19. This form is available on IPC (www.ipc.gov.in) **(Annexure-III).**

**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 AEs associated with the use of PPEs used for medical purposes. **(Annexure-IV)**

**Miscellaneous 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 Adverse Event Following Immunization (AEFI) Case Notification Form* **(Annexure-VI)** and Cases related to Medical Device use- *Medical Device Adverse Event Reporting Form* **(Annexure-VII).**




**PvPI Helpline**

Patients/ Consumers/ HCPs may report any suspected ADRs associated with the use of medicinal/ herbal products/ vaccines or medical devices to NCC-PvPI

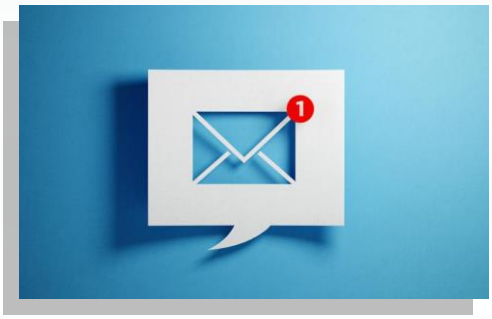
via Toll-Free Helpline No. 1800-180-3024.

**e-Reporting of ADRs :**


- **Mobile App – 'ADR PvPI'**

An indigenous 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**

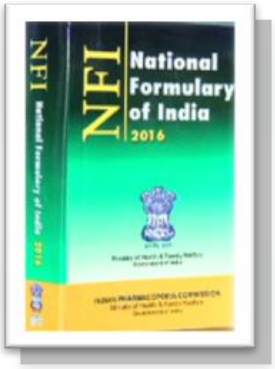


**Reporting ADRs by Non-AMCs**
(icsr.nccpvpi@gmail.com)

**Reporting ADRs by Consumers**
(pvpi.compat@gmail.com)

Hospitals/ Medical Colleges and other Healthcare Institutions which are not enrolled as AMCs under PvPI, may report AEs by using email (icsr.nccpvpi@gmail.com). Similarly, consumers/ patients also have the option of reporting AEs through a dedicated email (pvpi.compat@gmail.com).

**National Formulary of India (NFI):**



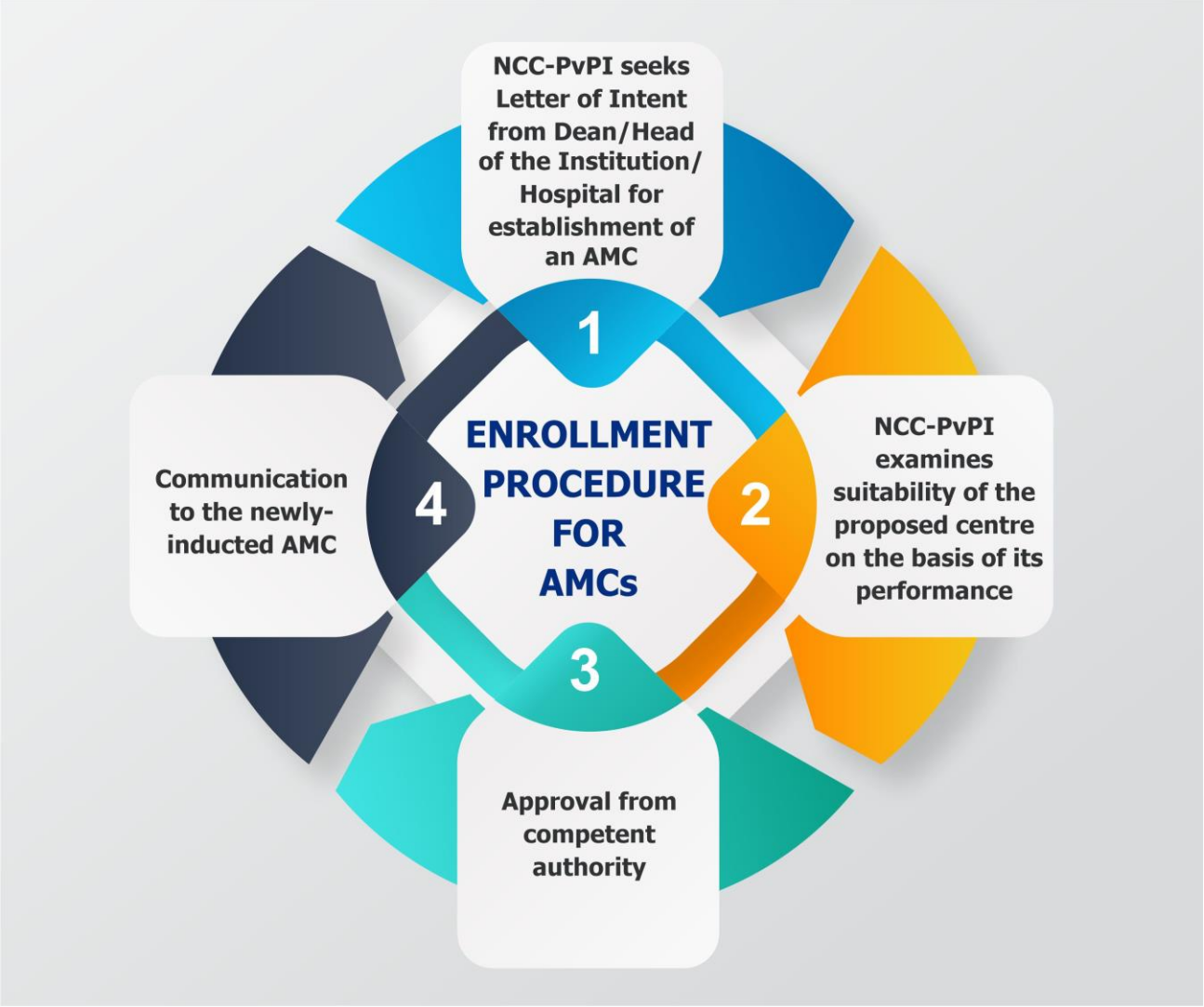

NFI serves as a guidance document to medical practitioners, pharmacists working in hospitals and sales establishments, nurses, medical and pharmacy students and other healthcare professionals. The principal objective of NFI is to promote the rational use and economic prescribing of medicines in the country. The healthcare professional may utilize the ADR Reporting Form which has been annexed at the end of the NFI 2016 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 monitoring ADRs.

**Who can Enroll?**

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



**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 Adverse Drug Reaction reporting
- 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

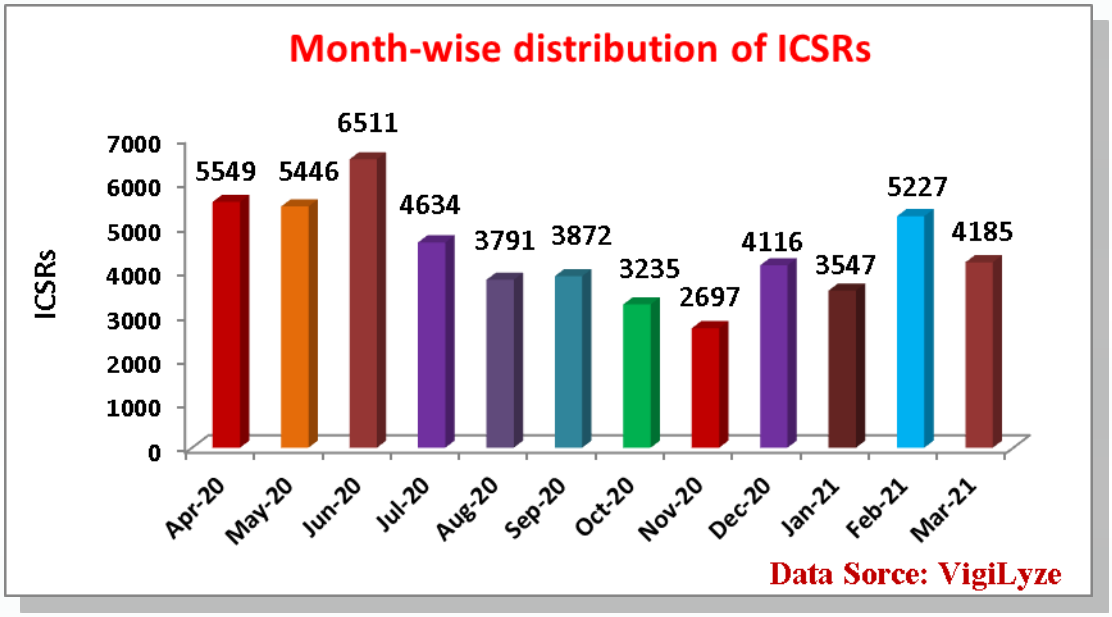
Upon recognition, NCC-PvPI provides regular training, skill development and technical training support to the personnel engaged in PvPI activities.

**Criteria for De-Enrolment/ De-Recognition of AMCs**

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

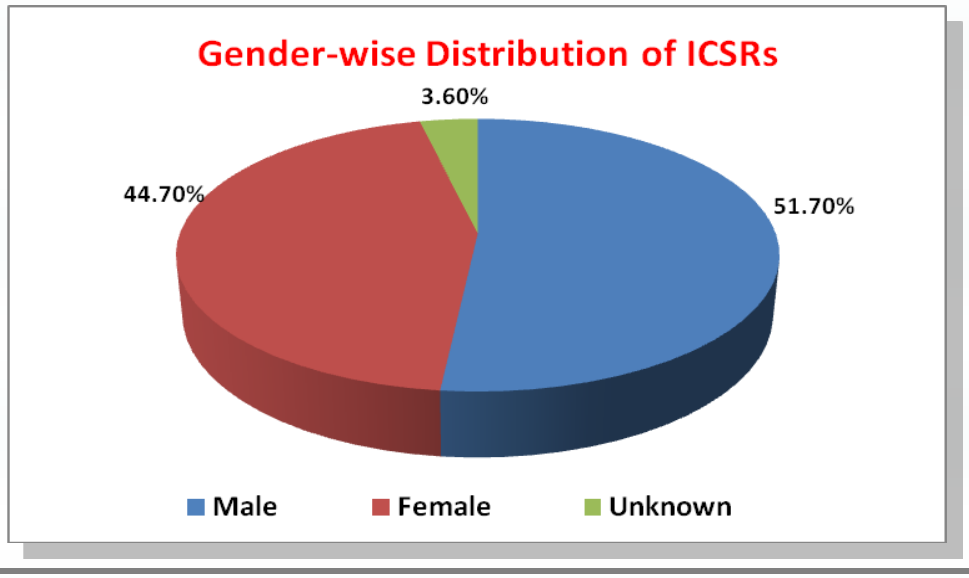
## ICSR database at PvPI

The Pharmacovigilance Programme of India (PvPI) is responsible for collection, assessment, detection and communication of risks associated with the use of medicines in Indian Population. The ICSRs collected by Adverse Drug Reaction Monitoring Centres and Marketing Authorization Holders are communicated to NCC-PvPI. The annual database accounts for 52,810 ICSRs for the index period.



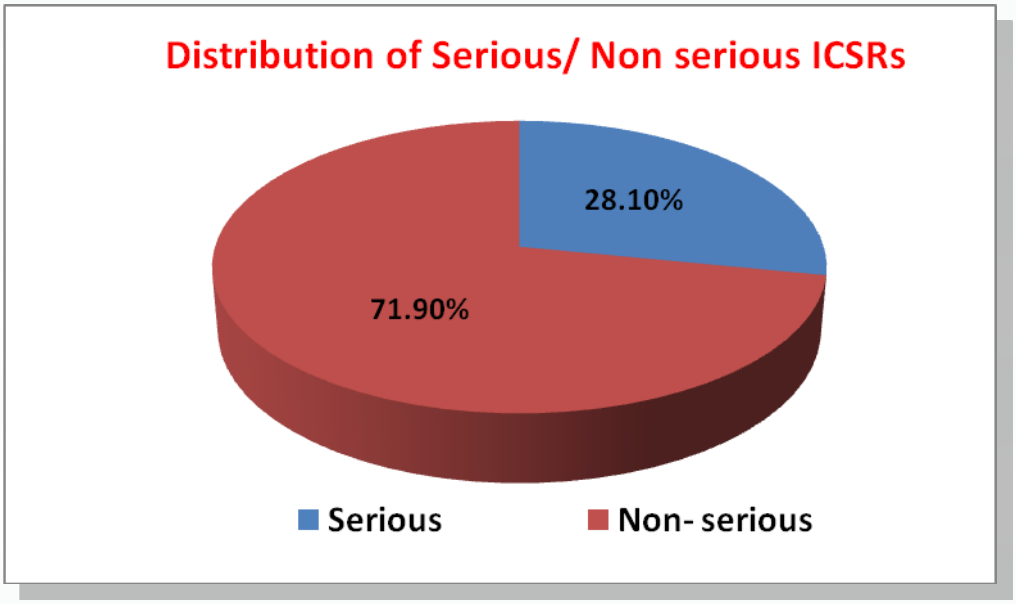

### Gender wise ICSRs

During the index period, 27,303 (51.7%) ADRs occurred in male patients and 23,606 (44.7%) in female patients. No information about the gender of the patients was provided in 1,901 (3.6%) ICSRs.



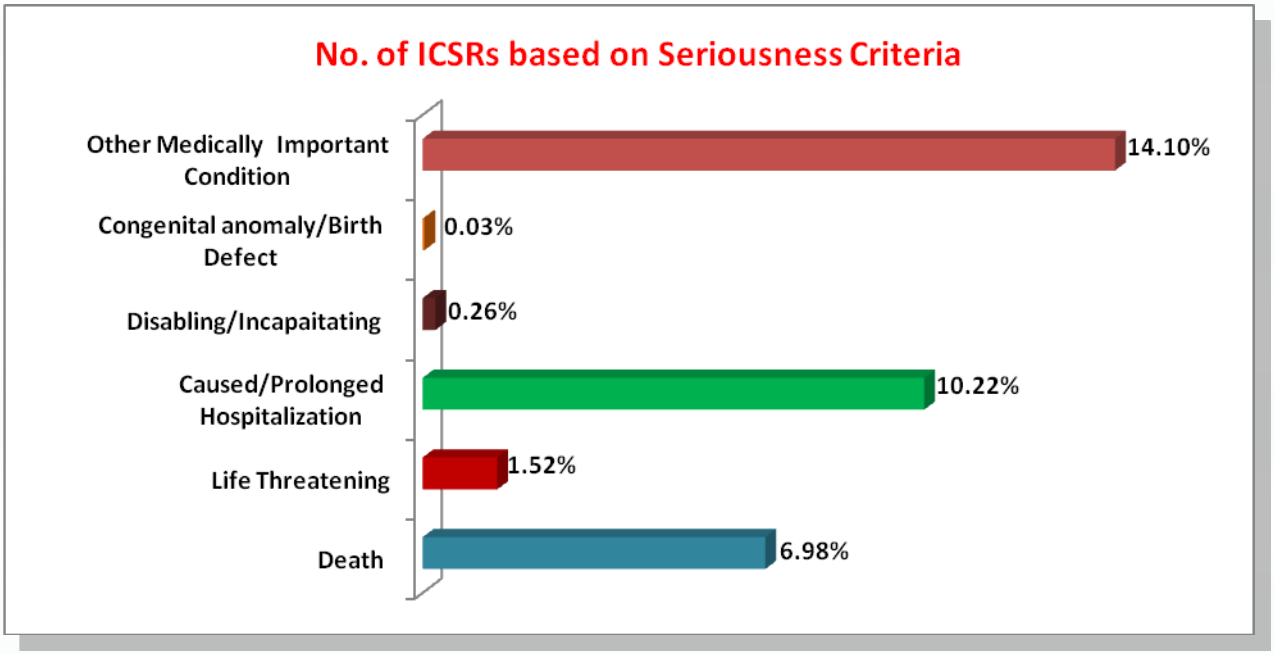
**Serious vs Non-serious Reactions**

The database revealed that during the index period, 28.10% ICSRs were fulfilling the seriousness criteria as defined by WHO-UMC.




**ICSRs based on Seriousness Criteria**

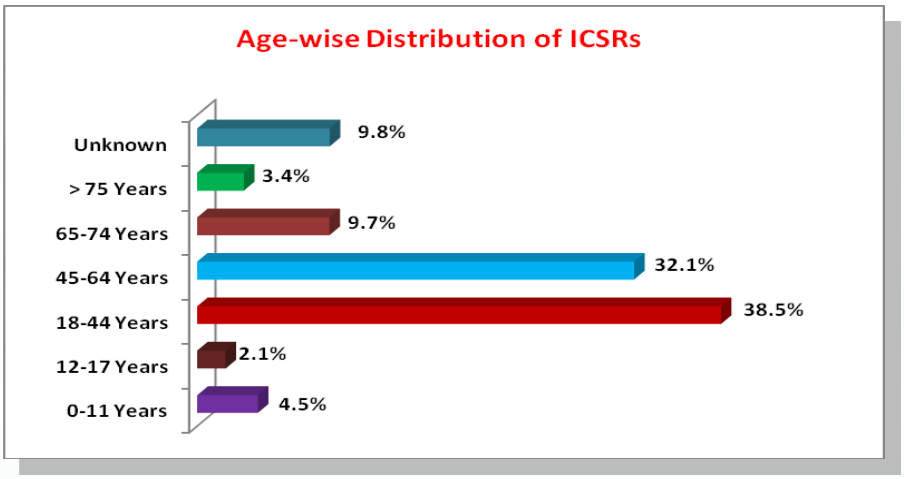
The seriousness criteria of received ICSRs revealed that 14.10% (7430) ICSRs were due to *other medically important conditions* followed by 10.22% (5383) ICSRs due to *prolonged hospitalization*.




***Note: The percentage of serious ICSRs (28.10%) varies in the graph of Criteria for Seriousness (33.11%) as the individual serious ICSRs may have more than one criteria for seriousness selected by the reporter.**

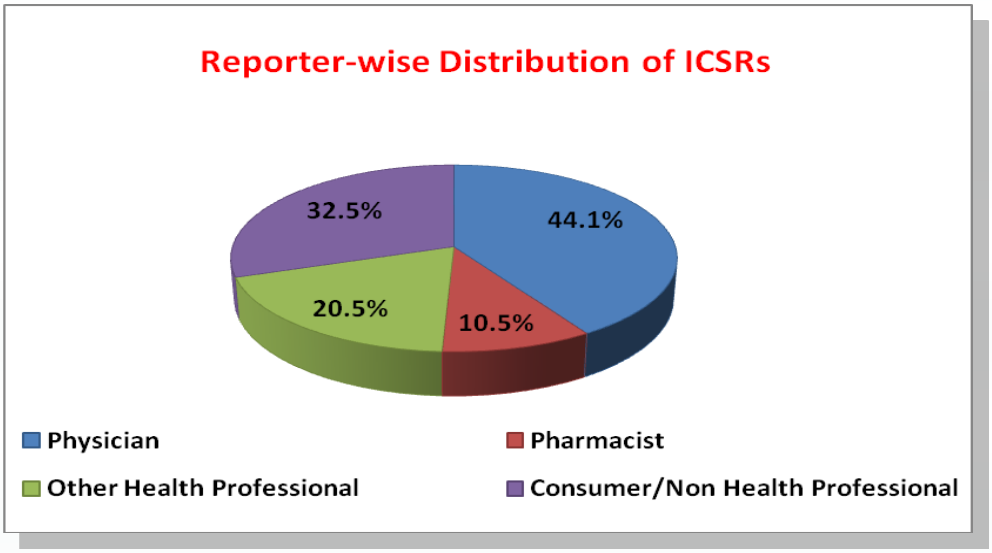
## Age-wise ICSRs

The data revealed that the highest number of ICSRs 20314 (38.5 %) were received from age group 18 to 44 years whereas a minimum number of ICSRs 1104 (2.1%) were received from age group 12-17 years. No information about the age of the patients was provided in 5147 (9.7%) ICSRs.

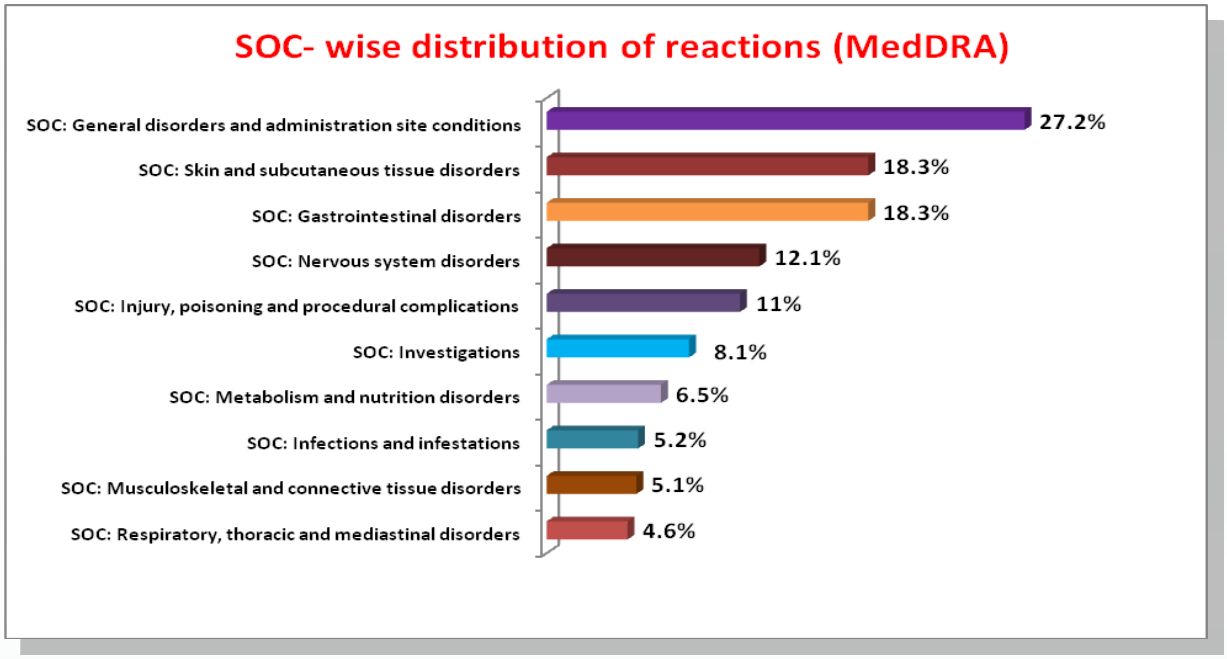



## Reporter wise Distribution of ICSRs

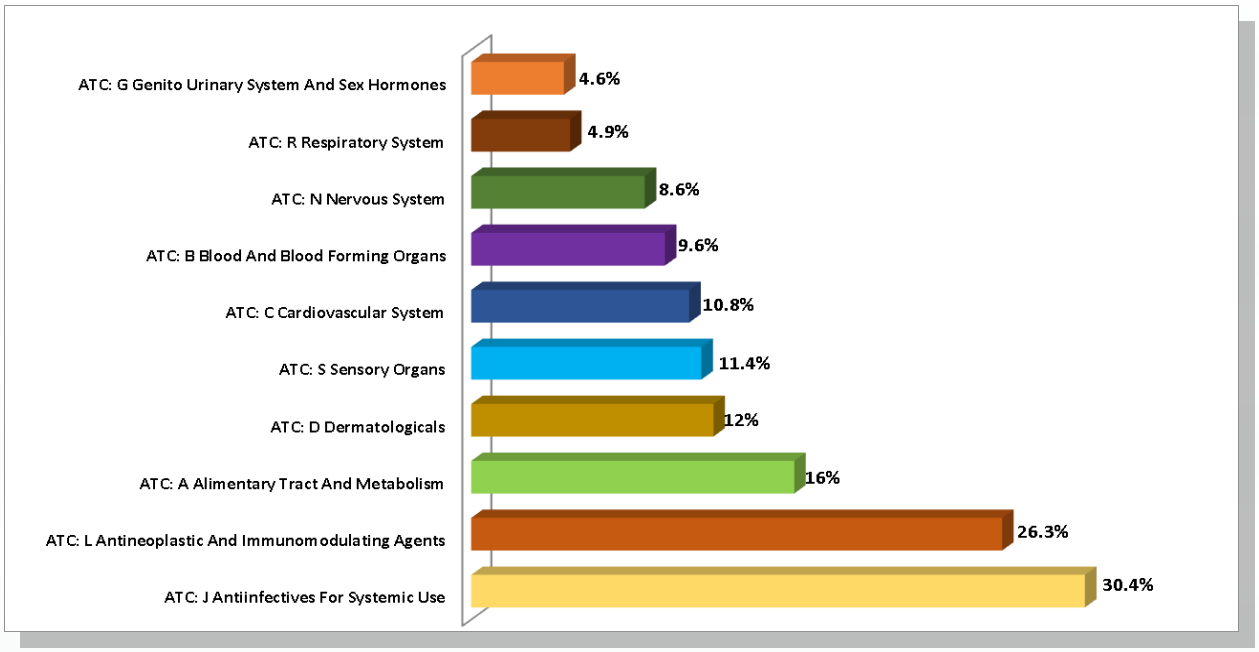
NCC-PvPI receives ICSRs from various stakeholders including Healthcare Professionals (HCPs) such as Physicians, Pharmacists, etc., and Consumers (Non-HCPs). Spontaneous reports from physicians (44.10%) continue to be the major source of reports received, followed by Consumers/Non-Healthcare Professionals (32.50%), Other Healthcare Professionals (20.50%) and Pharmacist (10.5%).



**SOC-wise distribution of Reactions:** The graph below represents System Organ Class (Top Ten) – wise distribution of reactions as per Medical Dictionary for Regulatory Activities (MedDRA). Analysis of the data revealed that highest numbers of reactions were in the SOC-General disorders and administration site conditions, while the least in the SOC-Respiratory, thoracic and mediastinal disorder.

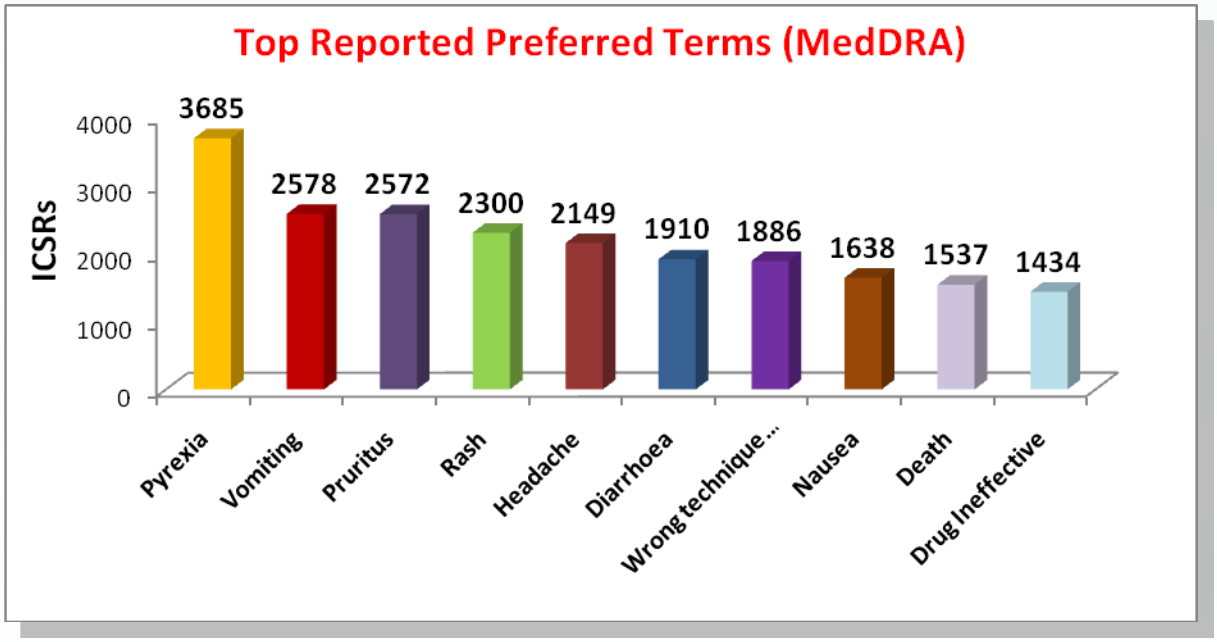



**Top 10 reported Anatomical Therapeutic Chemical (ATC) Classification**



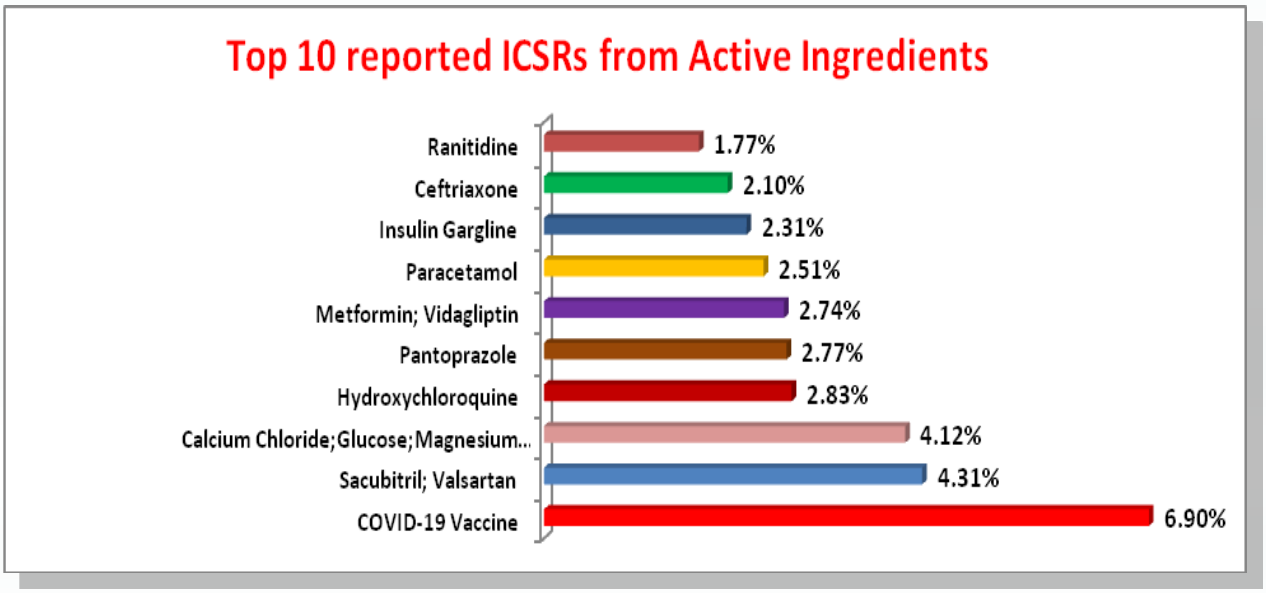
**Top 10 reported Preferred Term**

During this index period, the data revealed that pyrexia (7%) was the most observed Preferred Term (PT) as per the MedDRA.



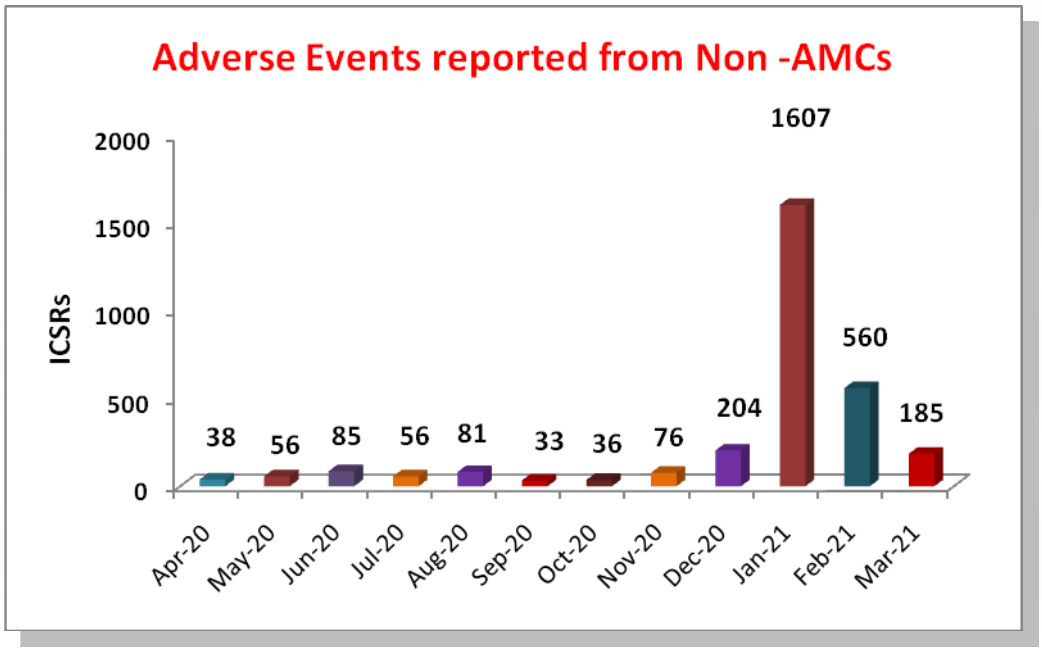

**Top 10 reported Active Ingredients**

Analysis of Active Ingredients (AIs) from ICSRs during the index period revealed that COVID-19 vaccine (6.9%) was the most reported AI.



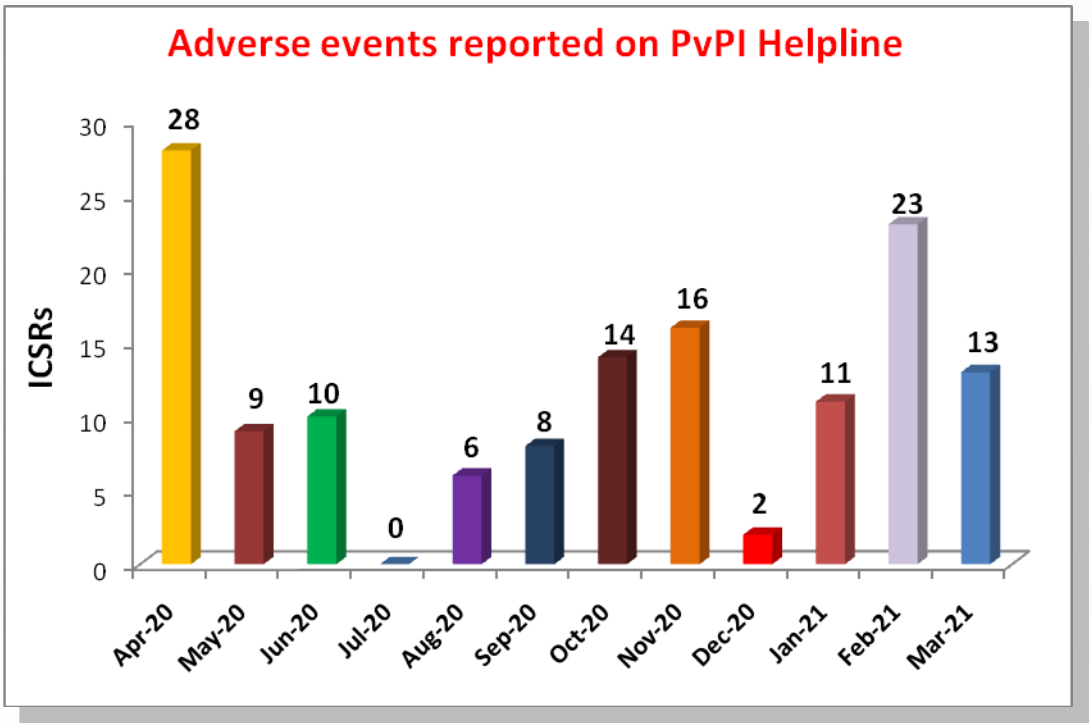
**ADRs reporting from Non-AMCs**

Besides AMCs, NCC-PvPI also received ADRs through several hospitals and medical colleges (non-AMCs) across India. The Non-AMCs send the suspected Adverse Drug Reactions filled in the Suspected ADR reporting form to a dedicated e-mail; icsr.nccpvpi@gmail.com. Further, these reports were processed for causality assessment at the nearby AMC and communicated to WHO-UMC through VigiFlow. During the index period, as many as 3017 ADRs were reported via non-AMCs, month-wise distribution of these ADRs is depicted below:



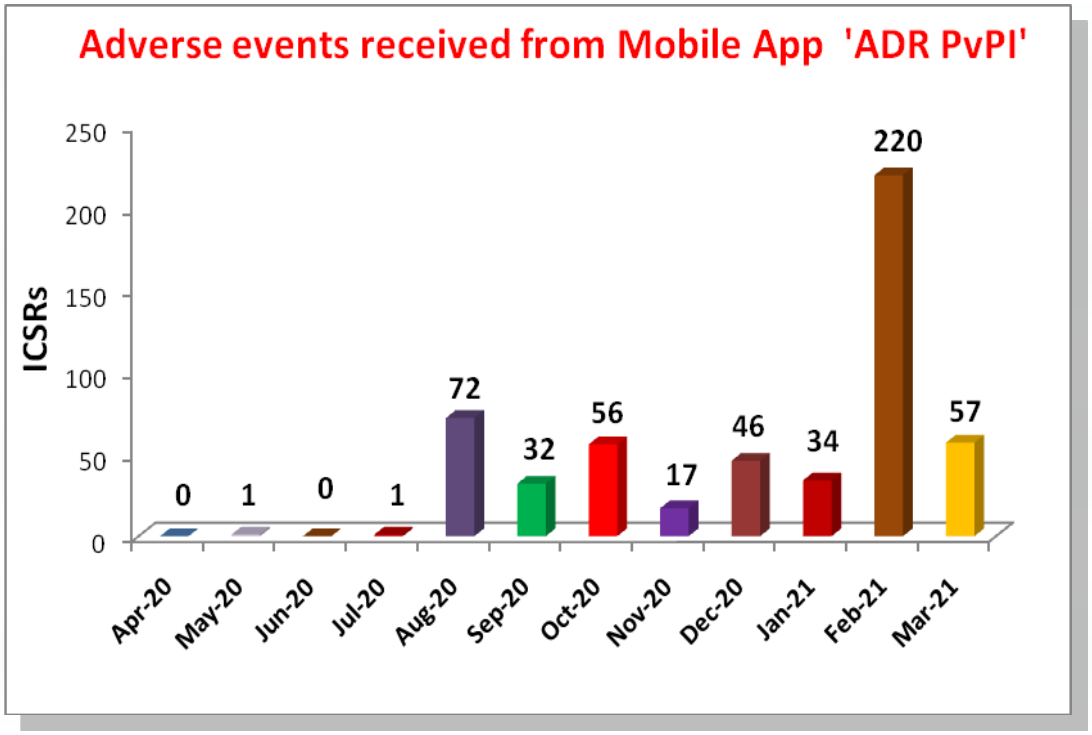

**Adverse Events reported on PvPI Helpline**

PvPI Helpline with Toll-free number 1800-180-3024 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 AEs due to the use of medical products/ Medical Devices with the continuous efforts of Pharmacovigilance officials posted at AMCs. Calls are primarily responded in **English** and **Hindi** on all working days (Monday to Friday) between 9:00 AM to 5:30 PM. The monthly status of reports received through Helpline number is as follows:

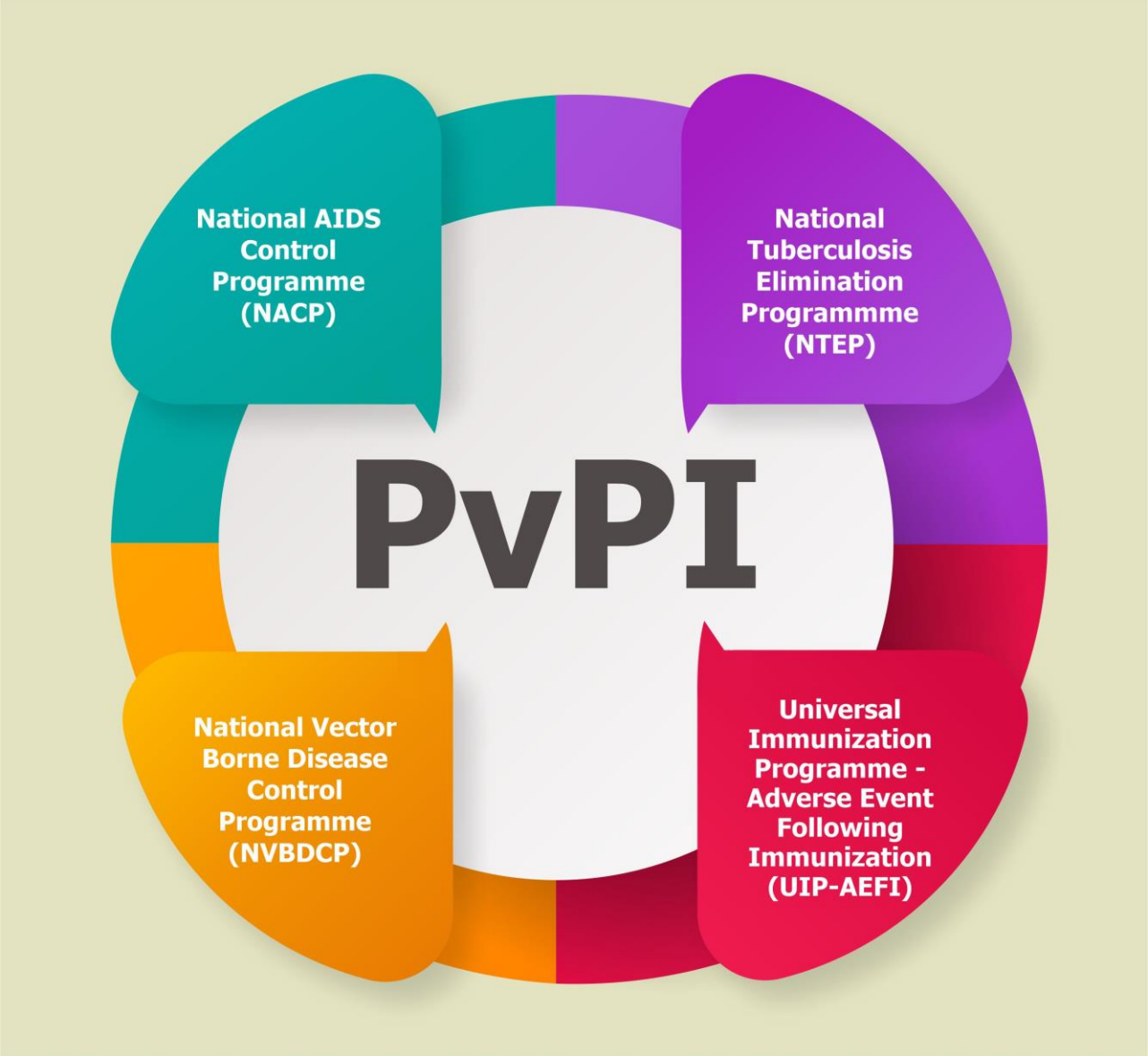



**Adverse events reported by Mobile App 'ADR PvPI'**

Android Mobile App 'ADR PvPI' is a seamless tool developed by PvPI, IPC to provide ease in reporting AEs *vis-a-vis* saving the time of healthcare professionals. The following graph illustrates month-wise adverse events reported by Mobile App:



## PvPI collaboration with Public Health Programmes

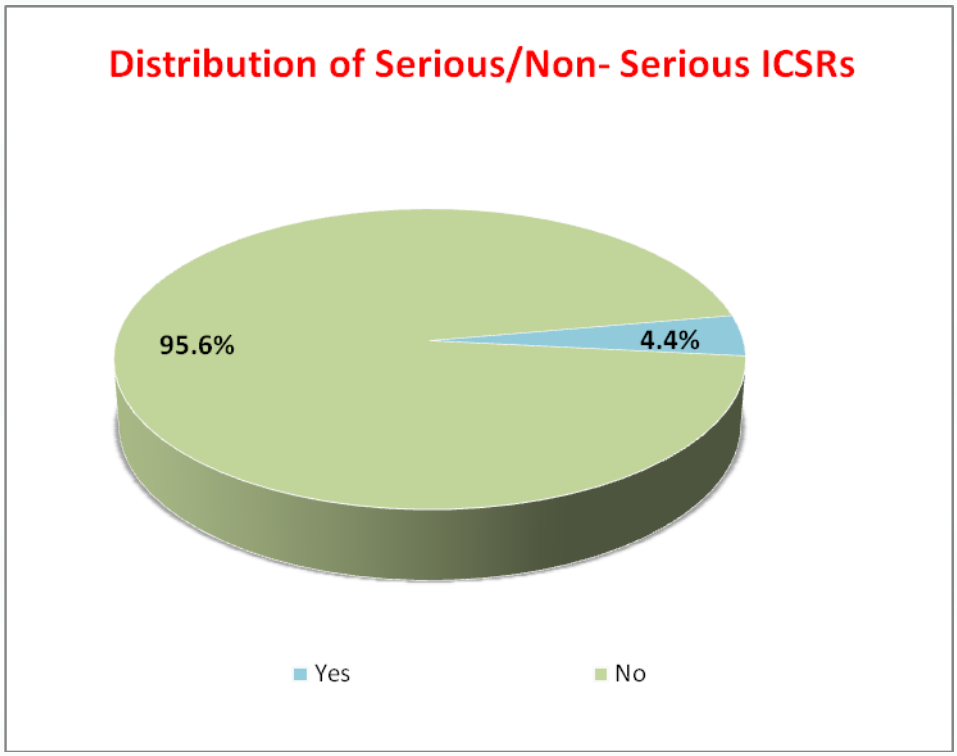



**ICSRs received from partnering Public Health Programmes**

| S. No. | PvPI Partners | ICSRs |
|---|---|---|
| 1. | NTEP | 392 |
| 2. | NACP | 182 |
| 3. | AEFI | 4457 |

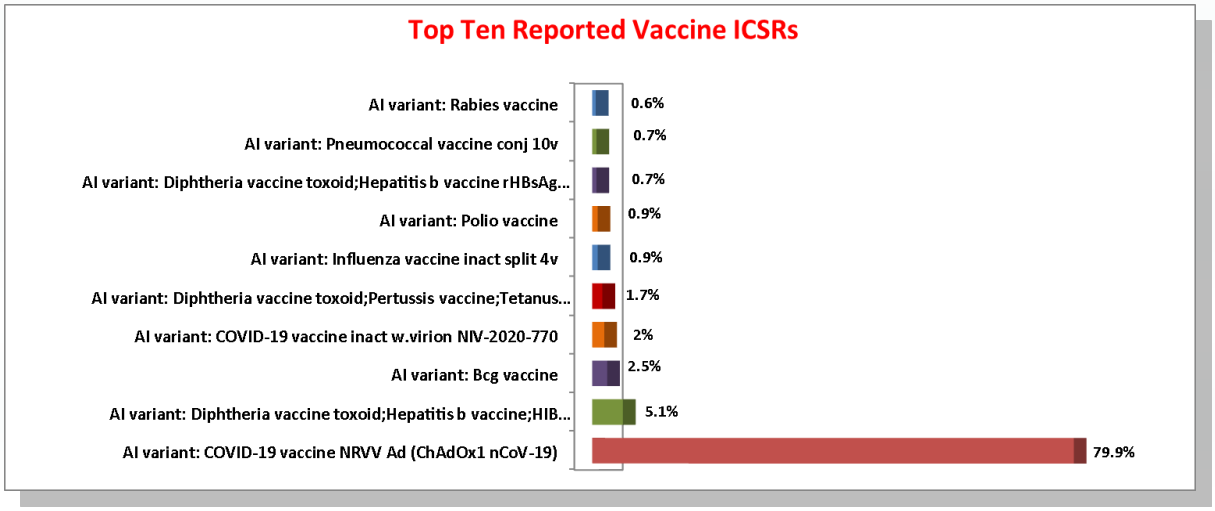
**Serious vs Non-serious Vaccine ICSRs**

During the index period, NCC-PvPI received, processed, and analyzed 4259 (95.6%) vaccine-related ICSRs of which 198 (4.4%) were marked as serious.



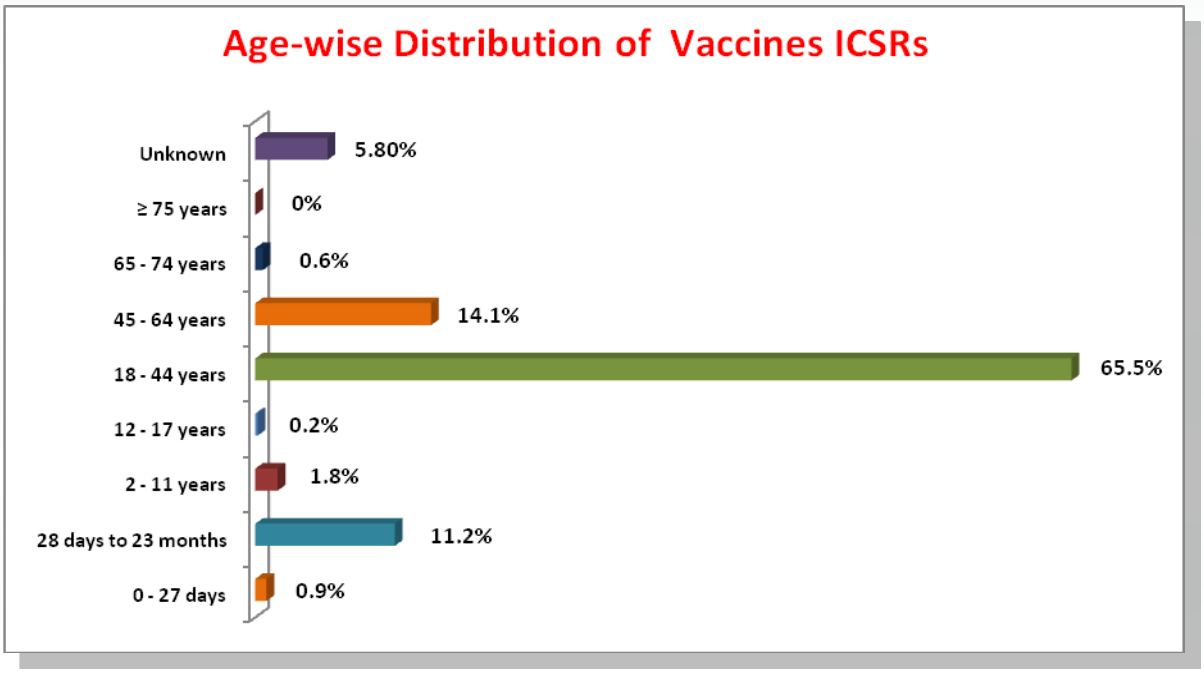

**Top ten reported vaccine ICSRs:**

Among the reported ten categories of vaccines, the highest percentage of ICSRs (79.9%) was reported due to COVID-19 vaccine NRVV Ad (ChAdOx1 nCoV-19) and the lowest percentage of ICSRs (0.6%) was reported due to the use of Rabies vaccine.



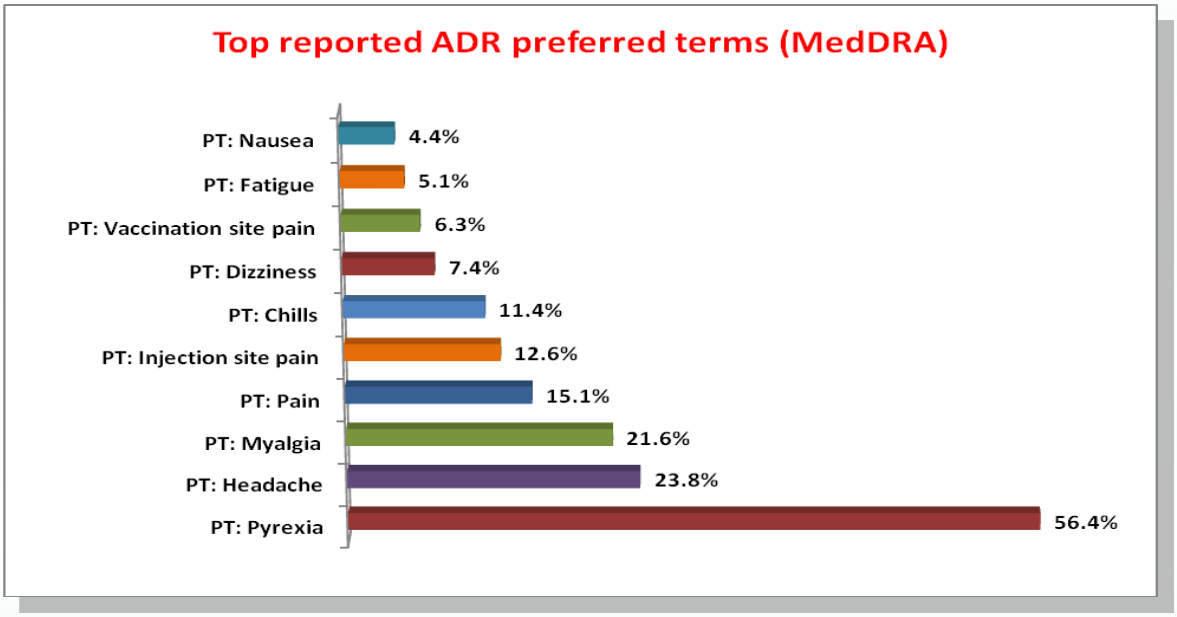
**Age-wise Vaccine ICSRs:**

The following chart represents the distribution of vaccine ICSRs among different age-groups, 65.5% of AEFIs were reported in the age group between 18-44 years.




**Preferred Terms related to ADRs reported with Vaccines:**

The analysis of vaccine ICSRs indicated that pyrexia (fever) was highest reported PT in 56.4% ICSRs. The top ten PTs are illustrated in the following graph:



**PvPI-IPC representation in Meetings/Workshops/Conferences:**

| S.No. | Date | Meeting/Webinar | Attended by |
|---|---|---|---|
| **1.** | 9th & 31st March, 5th February 2021, 15th December & 18th August 2020 | National AEFI Committee Meeting organised by UIP division, AEFI Secretariat related to COVID-19 | NCC-PvPI, IPC, MoHFW, AEFI Secretariat, CDSCO, INCLEN Int., WHO Country Office for India |
| **2.** | 3rd March, 2021 | Use of PvPI Helpline for AEFI related to COVID-19 Vaccines | NCC-PvPI, IPC, MoHFW officials, UIP- AEFI Secretariat |
| **3.** | 7th, 13th January, 2021 | Training for the AMCs on AEFI with special reference to COVID-19 Vaccination | AMC Coordinators & Pv Associates |
| **4.** | 24th November, 2020 | Virtual Training on "Data Entry in VigiFlow" | HCPs from NACO centres |
| **5.** | 16th September, 2020 | Virtual Training on "Data Entry in VigiFlow" | HCPs from NTEP centres |
| **6.** | 7th August, 2020 | Virtual Meet on Consultation on monitoring side effects and AEs in the treatment of Leprosy | NCC-PvPI, WHO HQ, WHO-SEARO office, WHO Country Office for India |
| **7.** | 6th August, 2020 | Virtual Training on ADR reporting in Kala-Azar Programme | NCC-PvPI, NVBDCP |
| **8.** | 3rd June, 2020 & 30th May, 2020 | Core Group Meeting for revision of AEFI Guidelines organised by AEFI Secretariat | NCC-PvPI, AEFI |

## Quality Management System in PvPI

To ensure 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 Good Pharmacovigilance Practices (GvPs) as per WHO Pharmacovigilance Indicators with a focussed approach on scientific innovation and rationality. PvPI performance was evaluated by officials of Quality Council of India & Quality Accreditation Institute on 22nd December, 2020. The evaluation report of PvPI was further submitted to MoHFW for extension of programme for the next five years (FY: 2021-2026).

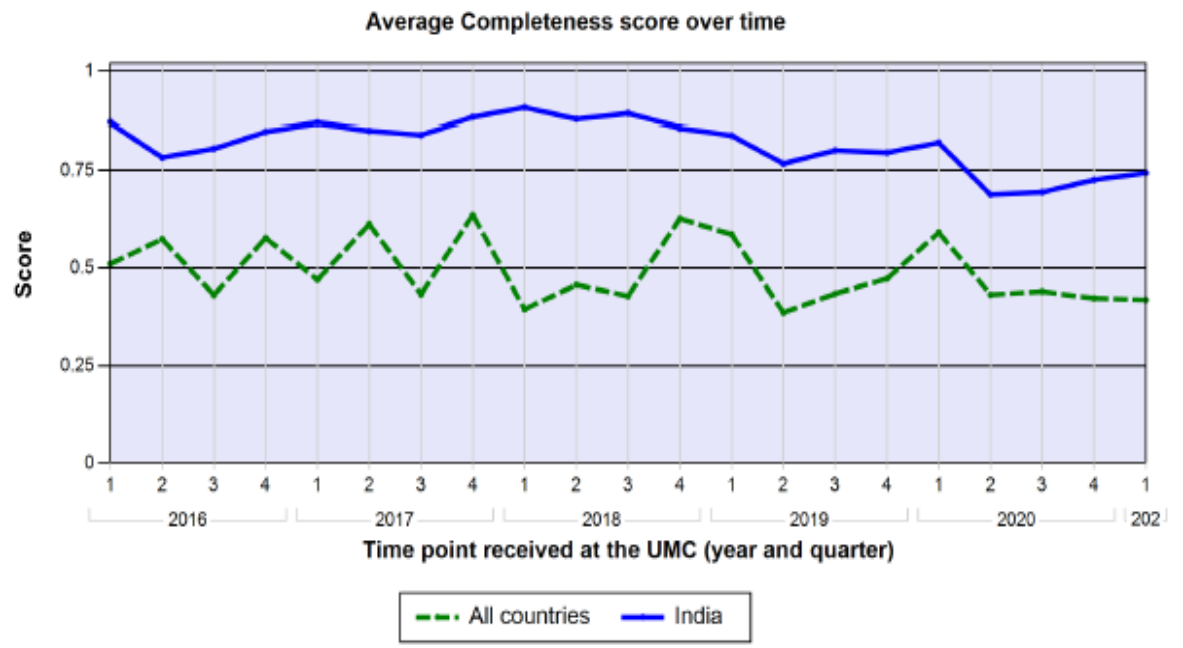
**SOPs updated:**

| S. No. | SOP Name | SOP Number |
|---|---|---|
| **1.** | SOP for Making SOP | IPC/PvPI/QA/001 |
| **2.** | SOP for Collection of ADR/AE Reports at AMC | IPC/PvPI/QA/009 |
| **3.** | SOP to Enter Data to VigiFlow Software | IPC/PvPI/QA/013 |
| **4.** | SOP for Processing and Quality Review of ICSRs | IPC/PvPI/QA/015 |
| **5.** | SOP for Functioning of Quality Review Panel | IPC/PvPI/QA/018 |
| **6.** | SOP for Functioning of Signal Review Panel | IPC/PvPI/SD/001 |
| **7.** | SOP for Processing of ICSRs received from MAHs | IPC/PvPI/PvRA/001 |
| **8.** | SOP for Functioning of Core Training Panel | IPC/PvPI/TE/003 |

## VigiGrade™ Completeness Score of ICSRs

### Quality of ICSR 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 ICSRs submitted by all the other countries (Green line). The average completeness score for the last quarter of the index period accounted for 0.74 out of 1.




Graphical representation of VigiGrade™ Completeness score of quality of ICSRs submitted by PvPI to UMC database

## Signal Detection

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 (SRP).

**Methods used by PvPI for Signal Detection**

Various methods are used for signal detection. The four usually considered methods for identifying a new signal from ICSRs in India include:

- Information Component (IC)
- Proportional Relative Risk/Proportional Reporting Ratio (PRR)
- Chi-square ($\chi 2$) value
- Total number of reports on the specific Drug-ADR combination available in the WHO database in respect of PvPI ($N_{comb}$)

Threshold values used by PvPI for the aforementioned methods to identify a potential signal are:

- $IC_{025}>0$
- PRR $\geq 2$ with the lower bound of its 95% Confidence Interval > 1
- $\chi 2$ value (with 1 degree of freedom) $\geq 4$
- $N_{comb} \geq 3$, to highlight potential signals

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

**Utilization of ICSR data**

The National Coordination Centre – Pharmacovigilance Programme of India evaluates ICSRs for potential new signals, drug safety alerts and PIL updates in the SRP meetings. The outcomes of SRP meetings were communicated to CDSCO for appropriate regulatory actions as tabulated below:

**A. Regulatory recommendations by NCC-PvPI to CDSCO**

| S. No. | Meeting Detail | Suspected Drug | Adverse Drug Reaction | Recommendation | Action Taken by CDSCO |
|---|---|---|---|---|---|
| 1. | 18th SRP meeting held on 12th March, 2021 | Tinidazole | Fixed Drug Eruption | Signal | Under Consideration |

| | | | | | |
|---|---|---|---|---|---|
| **2.** | 18th SRP meeting held on 12th March, 2021 | Tramadol | Urinary Retention | PIL Updation | Under Consideration |

**B. Monthly Drugs Safety Alerts issued by IPC, NCC-PvPI**

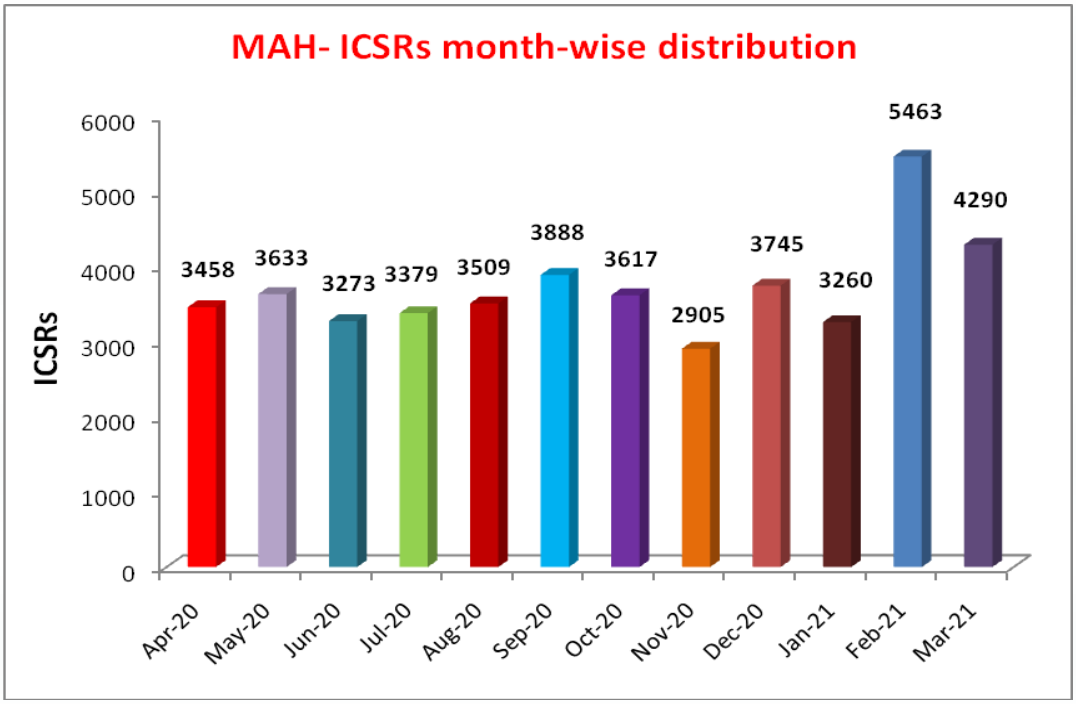
The IPC, NCC-PvPI has issued monthly drugs safety alerts with the aim to sensitize the Healthcare Professionals & Consumers through bulk SMS facility, periodically published PvPI Newsletters, web-portal of IPC in order to strengthen the reporting of ADRs to PvPI. The list of Drugs Safety Alerts is tabulated below:

| S.No | Issuing Date | Suspected Drug(s) | Indication(s) | Adverse Reaction |
|---|---|---|---|---|
| 1 | 1st March, 2021 | Hydroxyzine | For the management of pruritus due to allergic conditions such as chronic urticaria and atopic contact dermatoses, and in histamine-mediated pruritus. | Photosensitivity Reaction |
| 2 | | Salicylic Acid | For the treatment of acne vulgaris. | Photosensitivity Reaction |
| 3 | 1st February, 2021 | Cefpodoxime | Acute bronchitis, exacerbations of chronic bronchitis, bronchiolitis pneumonia, sinusitis, recurrent chronic tonsillitis, pharyngitis, acute otitis. | Drug Reaction with Eosinophilia Systemic Symptoms (DRESS) Syndrome |
| 4 | | Clarithromycin | Mild to moderately severe infections like acute exacerbation of chronic bronchitis community acquired pneumonia including infections due to chlamydia, mycoplasma spegiocella acute streptococcal pharyngitis and skin and soft tissue infections. | Burning Sensation |
| 5 | 4th January, 2021 | Fexofenadine | In the treatment of relief of symptoms associated with seasonal allergic rhinitis and chronic idiopathic urticaria. | Blurred Vision |
| 6 | | Ambroxol | Anti-tussive - Acute and chronic disease of the respiratory tract associated with abnormal bronchial secretions in particular acute attacks of chronic bronchitis, asthmatic bronchitis and bronchial asthma. | Fixed Drug Eruption |
| 7 | 30th December, 2020 | Beta-Blockers (Atenolol+ Bisoprolol+ Metoprolol) | Anti-arrhythmic agent- Indicated in the treatment of hypertension, angina pectoris, cardiac arrhythmias, Congestive Heart Failure (CHF). | Lichen Planus |
| 8 | | Omeprazole | Anti-ulcer, Short term treatment of duodenal ulcer, gastric ulcer, reflux oesophagitis, management of | Dysuria |

| | | | | |
|---|---|---|---|---|
| | | | Zollinger Ellison Syndrome. | |
| 9 | 4th November, 2020 | Clarithromycin | For the treatment of mild to moderately severe infections like acute exacerbation of chronic bronchitis community-acquired pneumonia including infections due to Chlamydia, Mycoplasma spegiocella acute streptococcal pharyngitis and skin and soft tissue infections. | Acute Generalised Exanthematous Pustulosis (AGEP) |
| 10 | | Tamsulosin + Deflazacort | For the treatment of signs & symptoms of benign prostate hyperplasia. For Asthma, Rheumatoid Arthritis when Glucocorticosteroid therapy is warranted. | Ear pain |
| 11 | 5th October, 2020 | Clindamycin | Antibiotic-Indicated in the treatment of gram +ve organism pathogens, staphylococcus & streptococci, pneumococci. | Symmetrical Drug-Related Intertriginous and Flexural Exanthema (SDRIFE) |
| 12 | 4th September, 2020 | Fluvoxamine | Fluvoxamine is a Selective Serotonin Reuptake Inhibitor (SSRI) indicated for the treatment of Obsessive-Compulsive Disorder and Depression. | Intracranial/Pulmonary Hypertension |
| 13 | 31st August, 2020 | Pramipexole | Pramipexole is indicated for the treatment of sign and symptoms of idiopathic Parkinson's disease. | Photosensitivity Reaction |
| 14 | 7th July, 2020 | SGLT-2 Inhibitors | As an adjunct to diet and exercise to improve glycemic control in adults with type 2 Diabetes Mellitus. | Genital Pruritus |
| 15 | | Fluconazole | For the treatment of systemic candidiasis, mucosal candidiasis, prevention of fungal infections in patients with malignancy. | SDRIFE |
| 16 | 1st June, 2020 | Hydroxychloroquine Sulphate | Off Label drug use as Prophylactic & Treatment of COVID-19 disease | Mouth Ulceration |

## Contribution by MAHs

Marketing Authorization Holders play a crucial role in reporting ADRs to PvPI. They assist in collecting product-specific safety data, aimed at optimizing drug-safety and ensuring healthcare for the Indian population. A total of 117 MAHs had submitted 44,420 ICSRs which includes initial and follow-up cases.




**Marketing Authorization Holders submitting ICSRs to PvPI**

| S. No. | Pharmaceutical Company/MAH | S.No. | Pharmaceutical Company/MAH |
|---|---|---|---|
| **1.** | Abbott India Ltd. | **17.** | Bharat Biotech International Ltd. |
| **2.** | Accent Pharma | **18.** | Biocon Ltd. |
| **3.** | Akums Drugs & Pharmaceuticals Ltd. | **19.** | Biogen Idec Biotech India Private Ltd. |
| **4.** | Alcon Laboratories India Private Ltd. | **20.** | Boehringer Ingelheim India Private Ltd. |
| **5.** | Alkem Labs Ltd. | **21.** | Bristol-Myers Squibb Safety India |
| **6.** | Allergan India Private Ltd. | **22.** | Bharat Serums and Vaccines Ltd. |
| **7.** | Apotex Research Private Ltd. | **23.** | Biological E Ltd. |
| **8.** | Arisglobal LLC | **24.** | B Braun Medical India Private Ltd. |
| **9.** | Astellas Pharma India Private Ltd. | **25.** | Blue Cross Laboratories Private Ltd. |
| **10.** | AstraZeneca Pharma India Ltd. | **26.** | Cadila Pharmaceuticals Ltd. |
| **11.** | Aurobindo Pharma Ltd. | **27.** | Cibeles Pharmaceuticals Private Ltd. |
| **12.** | Amgen Technology Private Ltd. | **28.** | Cipla Ltd. |
| **13.** | Axellia Pharmaceutical Company | **29.** | Concord Biotech Ltd. |
| **14.** | Baxalta Bioscience India Private Ltd. | **30.** | Dr. Reddy's Laboratories Ltd. |
| **15.** | Baxter (India) Private Ltd. | **31.** | EISAI Pharmaceuticals India Private Ltd. |
| **16.** | Bayer Pharmaceuticals Private Ltd. | **32.** | Elder Pharmaceuticals Ltd. |

| S. No. | Pharmaceutical Company/MAH | S.No. | Pharmaceutical Company/MAH |
|---|---|---|---|
| **33.** | Eli Lilly & Company (India) Private Ltd. | **77.** | Paviour Pharmaceuticals Private Ltd. |
| **34.** | Emcure Pharmaceuticals Ltd. | **78.** | Pfizer Ltd. |
| **35.** | Eris Lifesciences Ltd. | **79.** | Piramal Enterprises Ltd. |
| **36.** | Exeltis India | **80.** | Prime Vigilance & Medical Information |
| **37.** | FDC Ltd. | **81.** | Procter & Gamble Health Ltd. |
| **38.** | Fresenius Kabi India Private Ltd. | **82.** | Panacea Biotec Pharma Ltd. |
| **39.** | Glaxo Smithkline Pharmaceuticals Ltd. | **83.** | Roche Products (India) Private Ltd. |
| **40.** | Glenmark Pharmaceuticals Ltd. | **84.** | Reliance Life Sciences Private Ltd.. |
| **41.** | Galderma India Private Ltd. | **85.** | Recipharm Pharma Services Private Ltd. |
| **42.** | Grifols India Healthcare Private Ltd. | **86.** | Reckitt Benckiser (India) Private Ltd. |
| **43.** | Gufic Biosciences Ltd. | **87.** | RPG Life Sciences Ltd. |
| **44.** | Hetero Labs Ltd. | **88.** | Rusan Pharma |
| **45.** | HLL Biotech Ltd. (HBL) | **89.** | Sandor Medicaids Private Ltd. |
| **46.** | H. Lundbeck A/S | **90.** | Sandoz Private Ltd. |
| **47.** | Human Biologicals Ltd. | **91.** | Sanofi Healthcare India Private Ltd. |
| **48.** | Imaging Products India Private Ltd. | **92.** | Santen India Private Ltd. |
| **49.** | Intas Pharmaceuticals Ltd. | **93.** | Septodont Healthcare India Private Ltd. |
| **50.** | Inventia Healthcare Ltd. | **94.** | Serdia Pharmaceuticals (India) Ltd. |
| **51.** | IPCA Laboratories Ltd. | **95.** | Serum Institute of India Ltd. |
| **52.** | J. B. Chemicals and Pharmaceuticals Ltd. | **96.** | Shilpa Therapeutics Private Ltd. |
| **53.** | Johnsons & Johnsons India Private Ltd. | **97.** | Shire Biotech (India) Private Ltd. |
| **54.** | Kedrion Biopharma Private Ltd. | **98.** | Sovereign Pharma Private Ltd. |
| **55.** | Kerala Medical Services corporation Ltd. | **99.** | Strides Shasun Ltd. |
| **56.** | Koye Pharmaceuticals Private Ltd. | **100.** | Sun Pharmaceuticals Industries Ltd. |
| **57.** | Kusum Healthcare Private Ltd. | **101.** | Synokem Pharmaceuticals Ltd. |
| **58.** | Levim Biotech LLP | **102.** | Tirupati Medicare Ltd. |
| **59.** | Lupin Ltd. | **103.** | Torrent Pharmaceuticals Ltd. |
| **60.** | Lundbeck Pharmaceutical company | **104.** | Themis Medicare Ltd. |
| **61.** | Macleods Pharmaceuticals Ltd. | **105.** | Troikaa Pharmaceuticals Ltd. |
| **62.** | The Madras Pharmaceuticals | **106.** | UCB India Private Ltd. |
| **63.** | Medley Pharmaceuticals Ltd. | **107.** | Universal Medicare Private Ltd. |
| **64.** | MERCK India Private Ltd. | **108.** | USV Private Ltd. |
| **65.** | Merck Sharp & Dohme Private Ltd. | **109.** | Venus Remedies Ltd. |
| **66.** | MSN Laboratories Private Ltd. | **110.** | Vifor Pharma Group |
| **67.** | Mylan Laboratories Ltd. | **111.** | Vivere /Biophore India Pharmaceuticals Private Ltd. |
| **68.** | Mankind Pharma Ltd. | **112.** | Win-Medicare Private Ltd. |
| **69.** | TFS Trial Form Support Sp z o.o. | **113.** | Wipro GE Healthcare Private Ltd. |
| **70.** | Nestlé Skin Health India Private Ltd. | **114.** | Wockhardt Ltd. |
| **71.** | Novartis India Ltd. | **115.** | Wyeth Pharmaceuticals Ltd. |
| **72.** | Novo Nordisk India Private Ltd. | **116.** | Zuventus Healthcare Ltd. |
| **75.** | Otsuka Pharmaceutical India Private Ltd | **117.** | Zydus-Cadila Healthcare Ltd. |
| **76.** | Oviya MedSafe Private Ltd. | | |

## Skill Development Programme

NCC-PvPI conducts regular skill development programmes for the safe use of medicines in India. In order to enhance PV skills of the stakeholders, PvPI conducted various trainings on Pharmacovigilance for HCPs, 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.

**Objectives and Perspectives**


NCC-PvPI has recognized nine Regional Training Centres (RTCs) to impart training & education in pharmacovigilance to cater the needs of PV stakeholders to adopt GvPs. The list of RTCs under PvPI is given below:

| S. No. | Regional Training Centre | State/UT under purview |
|---|---|---|
| 1. | All India Institute of Medical Sciences, Bhopal | Madhya Pradesh and Chhattisgarh |

| | | |
|---|---|---|
| **2.** | All India Institute of Medical Sciences, Rishikesh | Uttarakhand and Uttar Pradesh |
| **3.** | BJ Medical College, Ahmedabad | Gujarat, Rajasthan, Daman & Diu |
| **4.** | Institute of Postgraduate Medical Education & Research, Kolkata | Andaman Nicobar, West Bengal, Jharkhand, Bihar & Odisha |
| **5.** | JSS Medical College & Hospital, Mysuru | Karnataka, Kerala, Tamil Nadu, Puducherry and Lakshadweep |
| **6.** | Nizam's Institute of Medical Sciences, Hyderabad | Andhra Pradesh and Telangana |
| **7.** | Post Graduate Institute of Medical Education and Research (PGIMER), Chandigarh | Jammu & Kashmir, Ladakh, Himachal Pradesh, Punjab, Haryana, Chandigarh and Delhi |
| **8.** | Seth GS Medical College & KEM Hospital, Mumbai | Maharashtra, Goa, Dadra & Nagar Haveli |
| **9.** | Government Medical College, Guwahati | Assam, Arunachal Pradesh, Nagaland, Manipur, Meghalaya, Mizoram, Tripura, Sikkim |

## Details of training programmes conducted by NCC-PvPI, IPC and AMCs:

PvPI conducted 219 awareness-cum-sensitization, induction-cum-training, skill development programme, training for NABH hospitals, regional workshop & interactive meetings for MAHs etc., on PV, in which 15,875 Healthcare Professionals and other stakeholders were trained on PV. The details of the trainings are as follows:

**A. Sensitization/ Awareness/ Training Programmes conducted by AMCs:**

ADR Monitoring Centres function as the backbone of PvPI. The Pharmacovigilance team at each AMC under PvPI usually includes:

- One Coordinator
- One Deputy Coordinator
- One Pharmacovigilance Associate
- Causality Assessment Committee (Experts from different clinical fields**)**

Besides collecting and submitting ICSRs to PvPI, this team of dedicated medical and pharmaceutical professionals also conducts regular training/sensitization programmes, workshops for all healthcare professionals, non-healthcare professionals and other stakeholders at AMC. The team also visits the peripheral hospitals, community and primary health centres in

the adjoining areas to disseminate information on drug-related problems and reporting of any possible adverse events to PvPI.

**Training Programmes conducted by AMCs**

The training programmes at AMCs include:

- Regional & National Workshops
- Advanced Level Training (ALT)
- Continuing Medical/Pharmacy Education (CME/CPE)
- Sensitization and Awareness drive for stakeholders

**B. Advanced-Level training-cum-coordinator's meet organized by RTC of PvPI**

Regional Training Centres of PvPI across the country hold three Advanced-level training programmes and 504 healthcare professionals including Coordinators, Deputy Coordinators and Pharmacovigilance and Associates of various AMCs were trained.

**C. Induction-cum-training Programme for Newly recruited PV Associates and Newly Appointed AMC Coordinators**

Every year PvPI is extending its outreach across several states 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.

D. **Skill Development Programme on Pharmacovigilance of Medical Products**

Since its inception in 2017, NCC-PvPI successfully conducted 16 Skill Development Programmes on Pharmacovigilance, focussed on basic understanding of the concept of PV. The training programme provides an opportunity for the participants to enrol themselves in Pharmacovigilance units of the organisations and follow GvPs to ensure better patient safety. This training programme also encourages them to become entrepreneurs in Pharmacovigilance. During the index period, NCC-PvPI organized 2 Skill Development Programmes on Pharmacovigilance of Medical Products in which 288 participants attended.

**E. Regional Workshops conducted for MAHs**

Regional Workshops on *Pharmacovigilance and Establishment of Pharmacovigilance System in Pharmaceutical Industries – A Way Forward* exclusively provide training to MAHs on:

- Establishing PV system in Pharmaceutical Industry

- Legislations regarding PV in India as per Drugs & Cosmetics Rules 1945, Schedule Y, Schedule M and New Drugs & Clinical Trials Rules 2019
- Process of reporting ADRs/AEs (E2B XML format) in PvPI

PvPI has organized one training programme during the index period with the support of pharmaceutical industries and CDSCO.

### F. PV training for NABH hospitals

With an objective of providing a platform for the National Accreditation Board for Hospitals and Healthcare Providers (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 monitor and report AEs/ADRs. During the index period one virtual training was conducted in which 131 HCPs were trained.

### G. Interactive meeting with MAHs

NCC-PvPI regularly conducts interactive sessions with MAHs to update them on the collation, analysis and quality scoring procedures for ICSRs followed at PvPI, as the completeness score of ICSRs is one of the main criteria of quantitatively assessing the power of each ICSR for contributing towards potential regulatory recommendations. Thus, the interactive meetings with MAHs serve the purpose of improving the overall quality of PvPI data submitted to VigiBase. Fourteen interactive meetings were conducted in which 54 participants were trained.

**Sensitization/ Awareness/ Training Programmes conducted by AMCs**

| S.No | Date | Training Programmes | AMC | Participants |
|---|---|---|---|---|
| **1.** | 29th April, 2020 | To aware physician about reporting ADRs for drugs used in prophylaxis treatment for COVID-19. | VPCI, New Delhi | 22 |
| **2.** | 27th May, 2020 | Introduction of Suspected Adverse Drug Reaction Reporting form | | 5 |
| **3.** | 29th May, 2020 | Orientation programme for COVID-19 ward doctors to report ADRs for HCQ and other COVID 19 drugs | MMC, Madurai | 20 |
| **4.** | 1st June, 2020 | Scope and opportunity in Pharmacovigilance/reporting tools | SAIMS, Indore | 70 |
| **5.** | 13th June, 2020 | Sensitization for MBBS internees on monitoring and reporting of ADRs with special focus for drug used in prophylaxis of COVID-19 | SVMC, Tirupati, | 25 |
| **6.** | 18th June, 2020 | Sensitization on ADR reporting | GTDMC, Alappuzha | 174 |
| **7.** | 22nd June, 2020 | | | 2 |

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|---|---|---|---|---|
| **8.** | 12th June, 2020 | Application of Pharmacovigilance and its role in drug safety | AFMC, Pune | 52 |
| **9.** | 19th June, 2020 | Awareness programme on pharmacovigilance and ADR Reporting form | BMC, Hyderabad | 5 |
| **10.** | 28th June, 2020 | Review on COVID regime and ADR reporting and updates | KIMS, Nalgonda | 20 |
| **11.** | 6th June, 2020 | Adverse Drug Reaction during COVID-19 and HCQ updates | GDMC, Dehradun | 60 |
| **12.** | 14th June, 2020 | | | 230 |
| **13.** | 25th June, 2020 | Introduction to Suspected Adverse Drug Reaction form for drugs used in the prophylaxis/ treatment in COVID-19 | VPCI, New Delhi | 5 |
| **14.** | 26th June, 2020 | Sensitization on COVID-19 ADR due to HCQ | NDMCMC, New Delhi | 7 |
| **15.** | 30th June, 2020 | Webinar on patient safety : Advancement of ADR monitoring by PvPI | MMC, Madurai | 150 |
| **16.** | 5th June, 2020 | Pharmacovigilance: An ideal tool to monitoring ADR to ensure patient safety in our country | | 100 |
| **17.** | 26th June, 2020 | Sensitization programme on pharmacovigilance for HCPs | ANIIMS, Port Blair | 6 |
| **18.** | 27th June, 2020 | | | 8 |
| **19.** | 25th July, 2020 | Awareness about Pharmacovigilance programme of India and importance of ADR reporting | MMIMS, Mullana | 43 |
| **20.** | 20th July, 2020 | Awareness about PvPI and importance of reporting ADRs how to fill ADRs form, common ADRs in clinical practices | KEM, Mumbai | 4 |
| **21.** | 23rd July, 2020 | Awareness about PvPI and importance of reporting ADRs, role of Nurses in ADR reporting | | 4 |
| **22.** | 3rd July, 2020 | Sensitization of MBBS internees on monitoring and reporting of ADRs with special focus for drugs used in prophylaxis treatment of COVID-19 | SVMC, Tirupati | 23 |
| **23.** | 4th July, 2020 | | | 25 |
| **24.** | 22nd July, 2020 | Sensitization regarding Pharmacovigilance and method of ADRs reporting | SAIMS, Indore | 16 |
| **25.** | 17th July, 2020 | Reporting of ADRs related to COVID-19 treatment | GTDMC, Alappuzha | 3 |
| **26.** | 31th July, 2020 | Sensitization regarding COVID-19 form and PvPI Newsletters | VPCI, New Delhi | 10 |
| **27.** | 1st August, 2020 | Discussion of mechanism of hepatotoxicity of Remdesivir & β Cylodextrine | KEM, Mumbai | 5 |
| **28.** | 8th August, 2020 | Discussion of Mechanism of Infusion Reaction of Itolizumab | | 6 |
| **29.** | 10th August, 2020 | Discussion on Causality Assessment | | 3 |
| **30.** | 11th August, 2020 | Discussion on HCQ Naranjo Scale Causality Assessment | | 4 |
| **31.** | 4th August, 2020 | Importance of ADR reporting | | 3 |

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| **32.** | 10th August, 2020 | Role of Healthcare Professional in Pharmacovigilance | | 3 |
| **33.** | 19th August, 2020 | How ADR Monitoring Centre Work and how to collect the ADR form | | 2 |
| **34.** | 27th August, 2020 | Importance of ADR Reporting | | 4 |
| **35.** | 11th August, 2020 | Pharmacovigilance Sensitization Programme for Dental professionals | AIMS, Kochi | 20 |
| **36.** | 12th August, 2020 | Pharmacovigilance sensitization programme for nursing professionals | | 10 |
| **37.** | 14th August, 2020 | PvPI and importance of ADR reporting | | 75 |
| **38.** | 18th August, 2020 | Basics of ADR reporting | IGGMC, Nagpur | 3 |
| **39.** | 20th August, 2020 | How can we report ADR | | 4 |
| **40.** | 24th August, 2020 | Awareness about Pharmacovigilance | | 5 |
| **41.** | 25th August, 2020 | Discussion about drug dose if it causes any ADR | | 3 |
| **42.** | 29th August, 2020 | Causality assessment with time of dosing | | 4 |
| **43.** | 31st August, 2020 | Awareness of ADR reporting form | VPCI, New Delhi | 13 |
| **44.** | 31st August, 2020 | Awareness on Pharmacovigilance, ADR reporting form | SRMC, Chennai | 10 |
| **45.** | 28th August, 2020 | Webinar session on Pharmacovigilance awareness | IGMCRI, Puducherry | 26 |
| **46.** | 17th September, 2020 | Awareness of ADR reporting form on World Patients Safety day | VPCI, New Delhi | 20 |
| **47.** | 17th September, 2020 | Webinar on Health worker safety: A priority of health safety | MKCGMC, Berhampur | 126 |
| **48.** | 9th September, 2020 | Sensitization of ADR Reporting form | KEM, Mumbai | 3 |
| **49.** | 17th September, 2020 | | | 2 |
| **50.** | 25th September, 2020 | How to Enhance ADR Reporting | | 3 |
| **51.** | 26th September, 2020 | Sensitization of ADR Reporting form | | 3 |
| **52.** | 30th September, 2020 | How to Enhance ADR Reporting | | 1 |
| **53.** | 29th September, 2020 | Sensitization on Pharmacovigilance and Materiovigilance | ANIIMS Portblair | 14 |
| **54.** | 23rd September, 2020 | Importance of Pharmacovigilance and spontaneous ADR reporting under PvPI | MMC, Chennai | 4 |
| **55.** | 17th September, 2020 | Awareness Programme on Pharmacovigilance | RIMS, Imphal | 85 |
| **56.** | 17th September, 2020 | Sensitization programme on Pharmacovigilance | AIIMS, Bhopal | 20 |
| **57.** | 30th September, 2020 | | | 20 |
| **58.** | 29th September, 2020 | Role of Pharmacist in COVID-19, Global Transformation of Health | NDMCMC. New Delhi | 10 |
| **59.** | 16th September, 2020 | Sensitization on Pharmacovigilance and ADR reporting | SVIMS, Tirupati | 177 |
| **60.** | 18th September, 2020 | Sensitization on Pharmacovigilance and causality assessment | | 174 |
| **61.** | 3rd September, 2020 | Sensitization Programme on Pharmacovigilance | SRMC, Chennai | 38 |
| **62.** | 9th October, 2020 | Sensitization Programme on Pharmacovigilance | GMC, Nagpur | 15 |

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| **63.** | 9th October, 2020 | Sensitization on Reporting of ADR | GMC, Miraj | 40 |
| **64.** | 12th October, 2020 | Sensitization on ADR Reporting | GTDMC, Alappuzha | 8 |
| **65.** | 16th October, 2020 | Awareness on Pharmacovigilance | VPCI, New Delhi | 36 |
| **66.** | 10th October, 2020 | Importance of ADR reporting, Role of HCPs in ADR Reporting | KEM, Mumbai | 1 |
| **67.** | 26th October, 2020 | | | 2 |
| **68.** | 27th October, 2020 | | | 1 |
| **69.** | 29th October, 2020 | | | 2 |
| **70.** | 30th October, 2020 | | | 2 |
| **71.** | 17th October, 2020 | Workshop on Pharmacovigilance and Hemovigilance and AEFI | GMC, Guntur, | 150 |
| **72.** | 13th October, 2020 | Importance of Pharmacovigilance and ADR reporting under PvPI & Modes of ADR reporting under PvPI | MMC, Chennai | 248 |
| **73.** | 15th October, 2020 | Awareness of ADR reporting | IGGMC, Nagpur | 10 |
| **74.** | 30th October, 2020 | Importance of Pharmacovigilance | | 10 |
| **75.** | 16th October, 2020 | Awareness of ADR reporting | GMC, Palakkad | 10 |
| **76.** | 6th October, 2020 | How to report ADRs | GMRC, Gwalior | 25 |
| **77.** | 4th November, 2020 | Awareness on ADR reporting among HCPs | NDMCMC, New Delhi | 30 |
| **78.** | 18th November, 2020 | Small talk on PvPI, importance of ADR reporting, role of HCPs in ADR reporting medicinal safety week conducting Programme of Pharmacovigilance in NTEP in Kerala | KEM, Mumbai | 2 |
| **79.** | 23rd November, 2020 | | | 2 |
| **80.** | 7th November, 2020 | Medicinal safety week conducting programme of Pharmacovigilance in NTEP in Kerala | AIMS, Kochi | 45 |
| **81.** | 10th November, 2020 | National webinar in medicine safety in collaboration with PvPI and Medical Education Unit India | | 170 |
| **82.** | 27th November, 2020 | Overview of PvPI and how to fill ADR reports | | 108 |
| **83.** | 7th November, 2020 | Sensitization on Pharmacovigilance and ADR reporting (#MedSafetyWeek) | GMC, Palakkad | 45 |
| **84.** | 4th November, 2020 | Sensitization on Pharmacovigilance (#MedSafetyWeek) | NEIGRIHMS, Shillong | 10 |
| **85.** | 21st November, 2020 | E-workshop on Pharmacovigilance, Hemovigilance and AEFI | GMC, Guntur | 120 |
| **86.** | 7th November, 2020 | #MedSafetyWeek with state TB Programme and ADR reporting of anti-tuberculosis drugs | GTDMC, Alappuzha | 45 |
| **87.** | 6th November, 2020 | International webinar on Pharmacovigilance | MKCG, Berhampur | 238 |
| **88.** | 20th November, 2020 | Webinar session on Pharmacovigilance | IGMCRI, Puducherry | 31 |
| **89.** | 3rd November, 2020 | Pharmacovigilance training on | GMERSMC, | 20 |

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| | | Revised ADR reporting form | Vadodara | |
| **90.** | 4th November, 2020 | Pharmacovigilance training on revised ADR reporting | | 20 |
| **91.** | 2nd November, 2020 | Awareness of #MedSafetyWeek | VPCI, New Delhi | 50 |
| **92.** | 29th December, 2020 | Awareness of ADR reports | | 32 |
| **93.** | 24st December, 2020 | Sensitization on Pharmacovigilance | ESICMC, Faridabad | 21 |
| **94.** | 21th December, 2020 | | | 30 |
| **95.** | 24th December, 2020 | Scope of Pharmacovigilance | NIMS, Hyderabad | 25 |
| **96.** | 16th December, 2020 | How to filling of ADRs form | | 28 |
| **97.** | 9th December, 2020 | Reporting of ADRs and about PvPI | GMC, Miraj | 50 |
| **98.** | 31st December, 2020 | | | 60 |
| **99.** | 12th December, 2020 | Sensitization on Pharmacovigilance & ADR reporting | SNMC, Agra | 47 |
| **100.** | 18th December, 2020 | Virtual sensitization on PV, AEFI, and HvPI and ADR reporting | KMC, Kurnool | 26 |
| **101.** | 4th December, 2020 | | | 596 |
| **102.** | 1st December, 2020 | Training on data entry in VigiFlow and Causality Assessment | KEM, Mumbai | 2 |
| **103.** | 16th December, 2020 | | | 18 |
| **104.** | 29th December, 2020 | | | 2 |
| **105.** | 14th December, 2020 | Sensitization on AE-protocols/AEFI/ transfusion reactions | SVIMS, Tirupati | 60 |
| **106.** | 26th December, 2020 | ADR monitoring during COVID | NDMCMC, New Delhi | 15 |
| **107.** | 19th December, 2020 | Webinar on vaccine safety | JSS, Mysuru | 950 |
| **108.** | 21st December, 2020 | Workshop on Pharmacovigilance and Reporting of Adverse Drug Reactions | SVIMS, Tirupati | 25 |
| **109.** | 8th January, 2021 | Pharmacovigilance Learn from the Expert | KEM, Mumbai | 125 |
| **110.** | 16th January, 2021 | Sensitization-cum-Awareness programme on AEFI drugs used in COVID -19 | RMLIMS, Lucknow | 81 |
| **111.** | 22nd January, 2021 | How to use suspected ADR reporting Form | KMC, Kurnool | 22 |
| **112.** | 16th January, 2021 | Sensitization on role of Pharmacovigilance in COVID-19 pandemic | GMC, Guntur | 10 |
| **113.** | 11th January, 2021 | Role of AMCs under PvPI for AEFI surveillance in COVID -19 vaccine | NDMCMC, New Delhi | 11 |
| **114.** | 9th January, 2021 | ADR and AEFI reporting system in India under PvPI | JLNMC, Ajmer | 21 |
| **115.** | 22nd January, 2021 | | | 38 |
| **116.** | 23rd January, 2021 | | | 14 |
| **117.** | 27th January, 2021 | | | 10 |
| **118.** | 11th January, 2021 | Vaccine Safety surveillance & reporting of AEFI | SPMC, Bikaner | 31 |
| **119.** | 9th January, 2021 | Awareness and Sensitization about generic medicines | IMSBHU, Varanasi | 80 |
| **120.** | 16th January, 2021 | Sensitization on AEFI reporting | GTDMC, Alappuzha | 2000 |
| **121.** | 25th January, 2021 | Importance of Pharmacovigilance with emphasis on Spontaneous Reporting under PvPI | MMC. Chennai | 80 |
| **122.** | 27th January, 2021 | | | 78 |
| **123.** | 29th January, 2021 | | | 76 |

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| **124.** | 15th January, 2021 | Sensitization on Adverse Event following vaccination, AEFI and its Reporting | | 13 |
| **125.** | 16th January, 2021 | Online training to peripheral hospital on AEFI reporting to AMC | SDSTRC, Bengaluru | 15 |
| **126.** | 28th January, 2021 | Report Adverse Events following COVID -19 vaccination | VPCI, New Delhi | 20 |
| **127.** | 24th January, 2021 | Webinar: Pharmacovigilance from the reporter perspective | VSSMC, Burla, | 72 |
| **128.** | 16th January, 2021 | Sensitization on AEFI reporting | MMIMS Mullana | 8 |
| **129.** | 23rd January, 2021 | Online interaction on Clinical Perspective of PV | SDSTRC, Bengaluru | 73 |
| **130.** | 30th January, 2021 | Guest lecture on Pharmacovigilance for Healthcare professionals | AIMS, Thrissur | 20 |
| **131.** | 23rd January, 2021 | | | 14 |
| **132.** | 28th January, 2021 | Sensitization on Pharmacovigilance for Healthcare professionals | SCBMC, Cuttack | 26 |
| **133.** | 29th January, 2021 | | | 16 |
| **134.** | 5th February, 2021 | International Webinar on Pharmacovigilance | MKCG Behrampur | 551 |
| **135.** | 6th February, 2021 | ADR and AEFI monitoring and reporting system in India under PvPI | JLNMC, Ajmer | 12 |
| **136.** | 10th February, 2021 | | | 15 |
| **137.** | 10th February, 2021 | | | 4 |
| **138.** | 6th February, 2021 | Lecture-cum- discussion on Reporting of ADRs | GMC, Miraj | 200 |
| **139.** | 19th February, 2021 | Awareness on PvPI | GMC, Kozhikode | 12 |
| **140.** | 3rd February, 2021 | Sensitization on COVID -19 vaccination and AEFI | NEIGRIHMS, Shillong | 10 |
| **141.** | 19th February, 2021 | Hands-on filling up the PvPI suspected ADR form | | 60 |
| **142.** | 3rd February, 2021 | Overview: PV, ADR reporting and AEFI | SNMC, Agra | 50 |
| **143.** | 4th February, 2021 | | | 34 |
| **144.** | 5th February, 2021 | PV, ADR reporting and AEFI, hands-on training to Healthcare Professionals | | 43 |
| **145.** | 19th February, 2021 | Sensitization on ADR training | BLKMH, New Delhi | 13 |
| **146.** | 4th February, 2021 | E- workshop on Pharmacovigilance, Haemovigilance and AEFI | GMC, Guntur | 182 |
| **147.** | 18th February, 2021 | Sensitization on Pharmacovigilance, Haemovigilance and AEFI and ADR reporting | KMC, Kurnool | 30 |
| **148.** | 11th February, 2021 | Sensitization on AEFI | AIMS, Kochi | 457 |
| **149.** | 5th February, 2021 | Training on VigiFlow software | GMC, Nagpur | 5 |
| **150.** | 8th February, 2021 | Sensitization on Pharmacovigilance, Haemovigilance and AEFI and ADR reporting | | 11 |
| **151.** | 16th February, 2021 | Sensitization on AEFI reporting | GTDMC, Alappuzha, | 1000 |
| **152.** | 25th February, 2021 | Sensitization on distribution of Newsletters | VPCI, New Delhi | 10 |
| **153.** | 5th February, 2021 | Indian regulations in Pharmacovigilance | MKCG, Berhampur | 70 |

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| **154.** | 11th February, 2021 | Sensitization on AEFI reporting | MMIMS, Mullana | 45 |
| **155.** | 20th February, 2021 | Online workshop-cum- sensitization programme on Pharmacovigilance | BJMC, Ahmedabad | 267 |
| **156.** | 26th February, 2021 | CME on Pharmacovigilance | GMC, Guwahati | 55 |
| **157.** | 4th March, 2021 | Sensitization on public regarding COVID-19 vaccination | NDMCMC, New Delhi | 26 |
| **158.** | 4th March, 2021 | | | 24 |
| **159.** | 3rd March, 2021 | Sensitization on ADR reporting | SGRRIMHS, Dehradun | 20 |
| **160.** | 13th March, 2021 | Sensitization on ADR form filing and spontaneous reporting | RKMIMS, Lucknow | 72 |
| **161.** | 10th March, 2021 | Sensitization on Pharmacovigilance overview | MMC, Madurai | 100 |
| **162.** | 9th March, 2021 | Sensitization programme on Materiovigilance | GMC, Guntur | 150 |
| **163.** | 2nd March, 2021 | Sensitization on ADR monitoring and reporting | SVMC, Tirupati | 50 |
| **164.** | 3rd March, 2021 | Combined sensitization on focused Pharmacovigilance on Albendazole administration on National Deworming day | SVMC, Tirupati | 350 |
| **165.** | 3rd March, 2021 | | | 100 |
| **166.** | 17th March, 2021 | Sensitization on Pharmacovigilance monitoring and reporting of ADR with special focus on drug used in treatment of COVID-19 and vaccine | | 89 |
| **167.** | 18th March, 2021 | Pharmacovigilance monitoring and reporting of ADR | | 196 |
| **168.** | 19th March, 2021 | Sensitization on Pharmacovigilance monitoring and reporting of ADR with special focus on drug used in treatment of COVID-19 and vaccine | | 110 |
| **169.** | 5th March, 2021 | Sensitization on ADR reporting | BLKMH, New Delhi | 31 |
| **170.** | 3rd March, 2021 | Sensitization on PvPI | GMC, Khozhikode | 15 |
| **171.** | 30th March, 2021 | Sensitization on PvPI and Adverse Drug Reactions and their management of anti tubercular drugs | MMC, Chennai | 20 |
| **172.** | 8th March, 2021 | ADR Monitoring and Reporting system in India under PvPI | JLNMC, Ajmer | 14 |
| **173.** | 3rd March, 2021 | Adverse Drug Reaction and Pharmacovigilance | ELMCH, Lucknow | 32 |
| **174.** | 10th March, 2021 | | | 15 |
| **175.** | 18th March, 2021 | | | 9 |
| **176.** | 25th March, 2021 | | | 9 |
| **177.** | 31st March, 2021 | Awareness on Pharmacovigilance and ADR reporting | VPCI, New Delhi | 18 |
| **178.** | 19th March, 2021 | Sensitization programme on PV and AEFI | KMC, Kurnool | 127 |
| **179.** | 3rd March, 2021 | Sensitization programme on ADR reporting procedure | RMC, Kakinada | 10 |
| **180.** | 6th March, 2021 | Sensitization programme on VigiFlow | | 10 |

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| **181.** | 3rd March, 2021 | Introduction of PvPI & AEFI reporting | DYSPGMC, Sirmaur | 31 |
| **Advanced-Level training-cum-coordinator's meet organized by RTCs of PvPI** | | | | |
| **S.No** | **Date** | **Training Programmes** | **RTC** | **Participants** |
| **182.** | 17th September, 2020 | Seminar on drug safety and Pharmacovigilance during COVID-19 pandemic for coordinators & PVA under north zone | PGIMER, Chandigarh | 147 |
| **183.** | 2nd September, 2020 | Pharmacovigilance programme webinar (Patient safety monitoring in COVID-19; What has been done what more can be done? | IPGMER, Kolkata | 87 |
| **184.** | 29th July, 2020 | Webinar on 'Advanced Pharmacovigilance 'Theme: "Research in Pharmacovigilance in the age of COVID-19" | JSS, Mysuru | 270 |
| **Induction-cum-training Programme for Newly recruited PV Associates and Newly Appointed AMC Coordinators** | | | | |
| **S.No.** | **Date** | **Training Programmes** | **Mode/Place** | **Participants** |
| **185.** | 11th & 12th January, 2021 | Induction-cum-training programme for newly recruited PV-associates and newly appointed AMC coordinators | Virtual, IPC | 62 |
| **186.** | 23rd June, 2020 | | | 54 |
| **Skill Development Programme on Pharmacovigilance of Medical Products** | | | | |
| **187.** | 15th to 19th March, 2021 | 16th Skill Development Programme on PV of Medical Products | Virtual, IPC | 105 |
| **188.** | 9th to 13th November, 2020 | 15th Skill Development Programme on PV of Medical Products | | 183 |
| **Regional Workshops conducted for MAHs** | | | | |
| **189.** | 9th October, 2020 | Regional Workshop on Pharmacovigilance And Establishment of Pharmacovigilance System In Pharmaceutical Industries - A Way Forward | Virtual, IPC | 48 |
| **PV training for NABH hospitals** | | | | |
| **190.** | 24th March, 2021 | Training on Pharmacovigilance for NABH accredited hospitals | Virtual, IPC | 131 |
| **Interactive meetings with MAHs conducted by NCC-PvPI** | | | | |
| **S.No.** | **Date** | **MAHs** | **Mode/Place** | **Participants** |
| **191.** | 19th March, 2021 | Fresenius Kabi Ltd | Virtual, IPC | 3 |
| **192.** | 25th February, 2021 | Eli Lilly and Company Ltd. | | 2 |
| **193.** | 4th February, 2021 | Dr Reddy's Laboratories Private Ltd | | 6 |
| **194.** | 14th January, 2021 | CIPLA Ltd. | | 6 |
| **195.** | 8th December, 2020 | Bharat Serums Ltd | | 1 |
| **196.** | 5th November, 2020 | Bristol-Myers Squibb Safety India | | 1 |

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| **197.** | 28th October, 2020 | Boehringer Ingelheim India Private Ltd | | 3 |
| **198.** | 22nd September, 2020 | Bayer Pharmaceuticals Private Ltd | | 2 |
| **199.** | 8th September, 2020 | AstraZeneca Pharma India Ltd | | 3 |
| **200.** | 24th August, 2020 | Astellas Pharma India Private Ltd | | 8 |
| **201.** | 19th August, 2020 | Allergan India Private Ltd. | | 3 |
| **202.** | 27th July, 2020 | Akums Drugs & Pharmaceuticals Ltd. | | 6 |
| **203.** | 21st July, 2020 | Abbott India Ltd. | | 3 |
| **204.** | 26th June 2020 | Macleods Pharmaceuticals Ltd | | 7 |
| **Other Important Training/Workshops conducted by NCC-PvPI** | | | | |
| **S.No.** | **Date** | **Training Programmes** | **Mode/Place** | **Participants** |
| **205.** | 22nd March, 2021 | Virtual training session on MedDRA coding | Virtual, IPC | 178 |
| **206.** | 1st March, 2021 | Training on QA standard operating procedures for Pharmacovigilance associates | | 6 |
| **207.** | 4th February, 2021 | Webinar on narrative writing | | 177 |
| **208.** | 22nd January, 2021 | Training on data entry in VigiFlow with reference to AEFI and document upload | | 104 |
| **209.** | 21st January, 2021 | Training on data entry in VigiFlow with reference to AEFI and document upload | | 125 |
| **210.** | 13th January, 2021 | Virtual training for the AMCs enrolled with PvPI on AEFI with special reference to COVID-19 vaccination | | 113 |
| **211.** | 7th January, 2021 | Virtual training for the AMCs enrolled with PvPI on AEFI with special reference to COVID-19 vaccination | | 241 |
| **212.** | 25th September, 2020 | Pharmacy week celebrations webinar with the theme “Transforming global health: Role of pharmacy professionals” | | 105 |
| **213.** | 16th September, 2020 | Data entry in VigiFlow for the NTEP centres enrolled under PvPI | | 35 |
| **214.** | 3rd September, 2020 | Webinar series 3: An Advance coding (MedDRA) | | 85 |
| **215.** | 26th August, 2020 | Webinar series 2: Coding basics (MedDRA) | | 95 |
| **216.** | 20th August, 2020 | Webinar series 1: What is MedDRA and how it is used | | 118 |
| **217.** | 31st July, 2020 | Webinar on quality management system | | 16 |
| **218.** | 22nd July, 2020 | Webinar on Causality Assessment : The logic & methods | | 43 |
| **219.** | 25th June, 2020 | Webinar on VigiFlow - an introduction, data entry and current features | | 100 |

**Summary of training programmes organized by PvPI**

| S.No. | Type of Training | Organized at | No. of Trainings | No. of Participants |
|---|---|---|---|---|
| **1.** | Training/Sensitization/Awareness Programmes conducted by AMCs | AMCs | 181 | 13,193 |
| **2.** | Advanced-Level Training-cum-Coordinator's Meet | RTCs | 3 | 504 |
| **3.** | Induction-cum-Training Programme | NCC-PvPI | 2 | 116 |
| **4.** | Skill Development Programme on PV of Medical Products | NCC-PvPI | 2 | 288 |
| **5.** | Regional Workshops conducted for MAHs | NCC-PvPI | 1 | 48 |
| **6.** | PV Training Programme for NABH Accredited hospitals | NCC-PvPI | 1 | 131 |
| **7.** | Interactive Meetings for MAHs | NCC-PvPI | 14 | 54 |
| **8.** | Other Important training programmes | NCC-PvPI | 15 | 1,541 |
| Total | | | **219** | **15,875** |

## Promotion, Communication & Resource Materials

NCC-PvPI provides scientific support to the Indian regulatory agency for appropriate intervention on use of medications following adverse event. Sustainable and effective communication with patients, healthcare professionals and other stakeholders in Pharmacovigilance enables the system to function vibrantly and realise the vision of safer use of medicines. PvPI regularly communicates periodic safety information of drugs and medical devices to healthcare professionals and other stakeholders. Till date, several India-specific drug safety alerts/PIL changes/signals have been identified and communicated to the regulatory authority - Central Drugs Standard Control Organization.

**Modes of Communication**

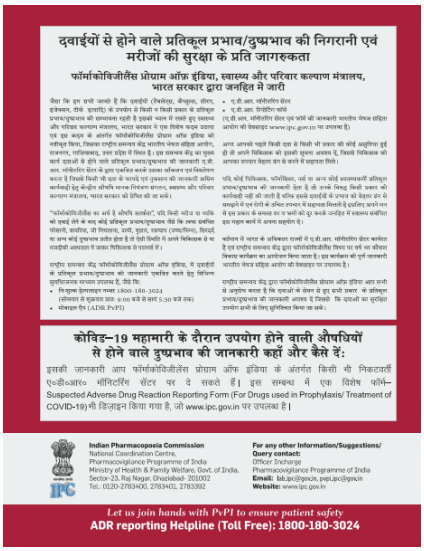
- Web Portal
- Android Mobile App
- Toll-Free Helpline
- Newsletter
- Print Media
- Radio Programmes
- TV Shows

**Resource Materials**

- Quarterly Newsletter
- Annual Performance Report of PvPI
- Guidance Documents of PvPI
- Posters/Handouts
- Leaflets
- PvPI Directory

**The quarterly Newsletter published by PvPI serves as a platform for raising awareness among the healthcare professionals and public at large to inculcate Pharmacovigilance as a part of daily healthcare regime. To ensure patient safety, updates on ADRs, Signals, Drug Safety Alerts, PIL changes, etc. are published in the Newsletter. It helps all stakeholders including clinicians, pharmacists, academicians, industry professionals, patients/consumers, etc. to safeguard against the risks associated with the use of medicines. The circulation of the Newsletter among the stakeholders has registered an appreciable increase and the feedback by them has been quite encouraging.**



## Scientific Publications

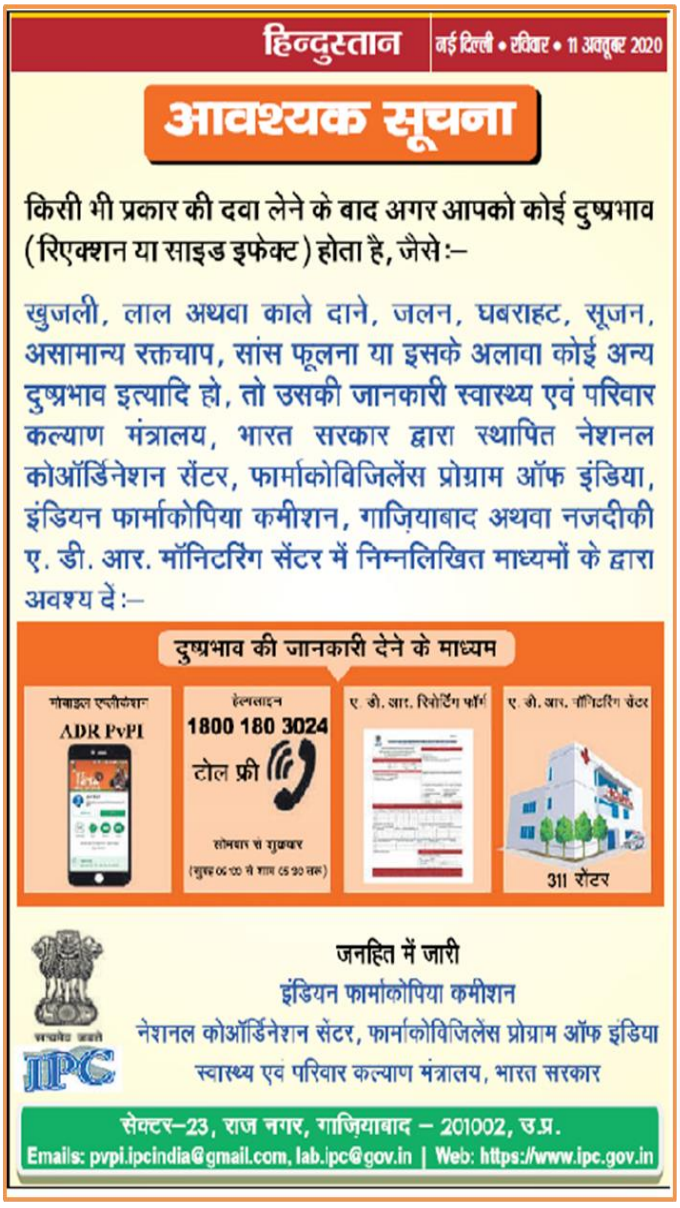

1. Abdul AP, Jihana S, Sangeetha P. Awareness of Pharmacovigilance and Adverse drug reactions among Health Care Professionals of a medical college in Kerala, India. International Journal of Scientific Research. 2020; 9(5): 1-5.
2. Abhima MB, Wilson V, Binu SS, Amma V. Effect of fixed dose combination of Vitamin with Atorvastatin on Serum Lipid Levels in Hyperlipidemic patients. Medpulse International Journal of Pharmacology. 2020; 16(1): 15-20.
3. Abhima MB, Wilson V,Binu AS, Amma V. A comparative study on the effect of Atorvastatin-Vitamin D versus Atorvastatin on serum LDL levels. Medpulse International Journal of Pharmacology. 2020; 16 (3): 30-34.
4. Alam MA, Nasiruddin M, Ali G. A Critical Assessment of Rationality in Drug Promotion Literature Using WHO Guidelines. Journal of Pharmacovigilance & Drug Safety. 2020; 17(1): 1-5.
5. Boopathi D, Akshatha JS, Buggi U, Sudarsan P, Mani D. Prolonged Isoniazid-induced Psychosis in a patient on DOTS Therapy–A Case Report. Research Journal of Pharmacy and Technology. 2020; 13(11): 5267-5269.
6. Chaudhary D, Atal S, Jhaj R, Rupla R. Erythema Multiforme induced by Tetanus Toxoid Vaccine. Indian Jouranl of Public Health. 2020; 64 (3): 308-310.
7. Ciddhavaduta DL, Kalaiselvan V, Midde ML, Baloju D. Analysis of severity and preventability in patients of-Toxic epidermal necrolysis-A case series. Clinical Case Report. 2020; 8(12): 2452-2456.
8. Era N, Mukherjee S, Bordoloi SK. Assessment of knowledge, attitude, and practice of pharmacovigilance among undergraduate medical students in a tertiary care teaching hospital of Eastern India: A questionnaire-based study. National Journal of Physiology, Pharmacy and Pharmacology 2020; 10(06): 460-463.
9. Himani P, Bala N, Kansal D. Nevirapine induced Stevens Johnson Syndrome. Journal of Pharmacovigilance and Drug Research. 2020; 1(2): 33-35.
10. Hotha PP, Naidu CDM, Zachariah NE. Pharmacovigilance joins hands with national deworming programme in Andaman & Nicobar Islands. European Journal of Pharmaceutical& Medical Research. 2020; 7(9): 369-372.
11. Jillapegu MV, Srinivasulu DSK, Sarikonda UR, Ponnaluri RR, Tiruveedhula J. The pattern of reported adverse drug reactions with reference to specific Drug Class and Organ System. International Journal of Basic & Clinical Pharmacology 2020; 9(12): 1824-1830.
12. Kalaiselvan V , Sexena R. Intraocular devices associated adverse events reporting system in India. Indian Journal of Ophthalmology. 2020; 68 (11): 2343-2345.
13. Kalaiselvan V, Tripathi SK, Prakash J. Materiovigilance Programme of India: A scheme to ensure cardiovascular device safety surveillance. Indian Heart Journal. 2020; 72 (4): 316-318.
14. Kumar M, Manjhi PK, Singh S, Singh DK, Deo S. Appraisal of Inter-Rater Agreement among Assessment Scales and Retrospective Analysis of Validated Reports of Cutaneous Adverse Drug Reactions at Tertiary Care Hospital in Eastern India. Journal of Clinical & Diagnostic Research. 2021; 15(2): FC17-FC22.

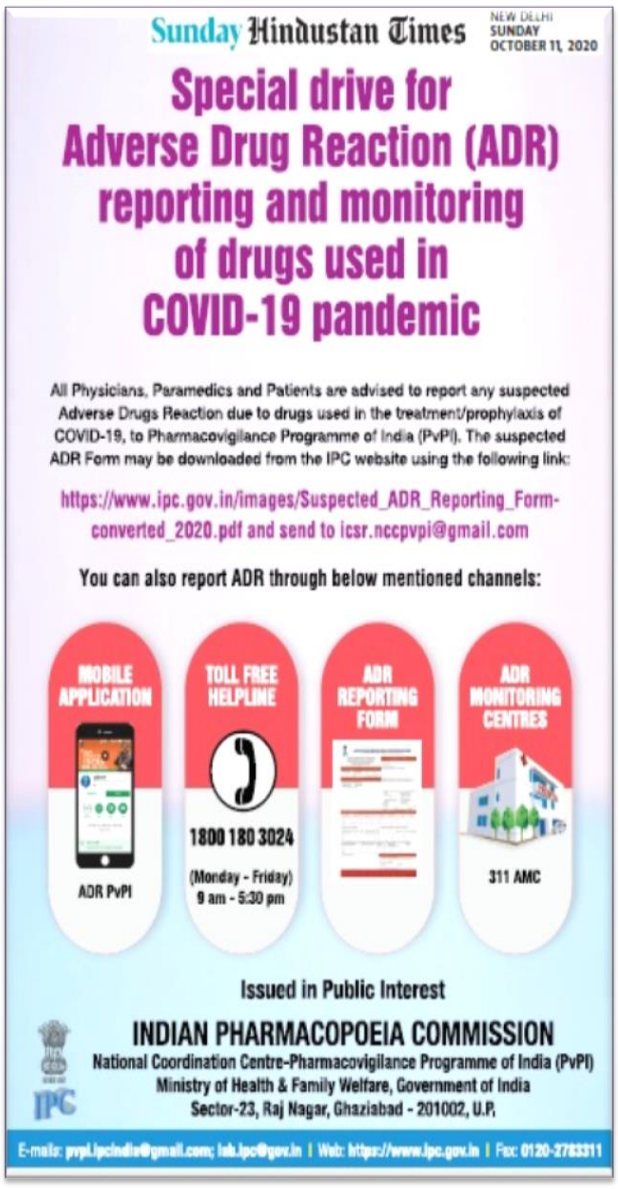
15. Kumar S, TayalV, Swachia K, Roy V. Shivering due to repeat dose of Tranexamic acid: A Peculiar case series. MAMC Journal of Medical Sciences. 2020; 6(3): 228-231.
16. Malathi M, Raadhika K, Nambi TT. A retrospective analysis of adverse drug reactions induced by Cancer chemotherapeutic agents at a Tertiary care hospital in South India. InternationalJournal of Medical & Health Research. 2020; 6(6): 22-26.
17. Mukherjee S, Saha D, Dasgupta S, Tripathi SK. Case Report: Suspected Case of Stevens–Johnson Syndrome and Toxic Epidermal Necrolysis Overlap Due to Ursodeoxycholic Acid. Dermatolgy. 2020; 8(1): 96-99.
18. Nama P., Giradkar A., Sontake S. A Rare case of Steven Johnson Syndrome Induced by a Single Dose of Paracetamol, International Journal of Current Advanced Research, 2021; 10(03): 23971-23972.
19. Namoju R, Ismail M, Golla VK, Bamini T, Akarapu TL, Baloju D. A Case of Acute Generalized ExanthematousPustulosis by Cefixime with Oral Mucosal Involvement. Current Drug Safety 2020; 15(3): 236-239.
20. Patial N, Bhardwaj A, Kansal D K, Sood A. Levetiracetam induced Urticaria in patients of focal seizure- A Case Report. Global Journal for Research Analysis. 2020; 9(10): 124-125.
21. Philip MM, Kesavan K, Prakash J. Toxic epidermal necrolysis associated with combination therapy of spironolactone and torsemide. Journal of Pharmacovigilance and Drug Research, 2020; 1 (1): 19-21.
22. Prasanna LT, Stalin C. Analysis of Adverse reactions associated with use of Psychiatric medications in a teaching hospital – A Retrospective Study. Drug Discovery, 2020, 14(34): 231-237.
23. Rajalakshmi R, Vasundara DB, Durga PT, Rajesh A, Suveena C. Analysis Of Adverse Drug Reactions In Pediatric Population: A Retrospective Study. International Research Journal of Pharmacy. 2020; 11(8): 1-5.
24. Rajalakshmi R, Brahmanapalli VD, Thammisetty DP, Pemmasani D, Sai DG, Atmakuru RB. Study of Adverse drug reactions to Antiretroviral Therapy in a Tertiary Care Hospital, Tirupati. Perspectives in Clinical Research. 2020; 11(4): 158-163.
25. Ramani G, Neeraj S, Shivaraj BP, Venkata RY, Raghuveer B, Yamini V, Sindhu P. A Two Year Retrospective Observational Study of Adverse Drug Reactions Related To Intravenous Drug Formulations. Journal of Pharmacovigilance and Drug Research. 2021; 2(1): 28-32.
26. Rath B, Naik MR, Bhabagrahi R, Bhoi R, Prakash J. Cutaneous Adverse Drug Reactions in a Tertiary Care Hospital: An Observational Study. Journal of Pharmacovigilance and Drug Research, 2020; 1 (1): 1 -4.
27. Shrivastav TP, Soni M, Prakash J. Artificial Inteligence- A Promising Tool For Transforming The Healthcare System. MIT International Journal of Pharmaceutical Sciences. 2020; 6(2): 73–75.
28. Singh A, Jain A, Soni M, Shukla P, Lahon J, Verma AK. Pattern of adverse drug reactions at a Tertiary care teaching hospital in Northern India. International Journal of Basic &Clinical Pharmacology. 2020; 9(4): 625-632.
29. Singh A, Kumaravel J, Mahendru D, Yadav M, Kumar H, Prakash A, Medhi B. Hydroxychloroquine Drug Safety Review for the Prophylaxis of SARS COV 2 Pandemic. International Journal of Pharmaceutical Sciences and Research. 2020; 11(8): 3535-3543.

30. Singh A, Yadav M, Kumaravel J, Sharma AR, Mishra A, Prakash A, Medhi B. E-prescription (CPOE) in Indian hospitals: A strategy to prevent prescription errors. Drug Bulletin 2020; 45(3): 42-51.
31. Stalin C, Roshan PK, Lakshmi PT, Ramachandra BC. A Study on Cardiovascular Drugs showing Preponderance of adverse effects in female patients.Inventi Rapid: Pharmacy Practice. 2020; 2020 (4): 1-3.
32. Sudha KM, Devipriya S. Assessment of Adverse drug reactions due to Anti-retroviral drugs: A retrospective observational study. International Journal of Current Advanced Research. 2020; 09(01): 21110-21113.
33. Tarai A, Pattnaik KP, Mishra KH. Electrocardiographic Abnormalities with Quinine and Artesunate combinations in comparison to Quinine or Artesunate alone in severe Falciparum Malaria. International Journal of Basic & Clinical Pharmacology. 2020; 9(10): 1520-1527.
34. Thomas TM, Udaykumar P. Antibiotic resistance pattern of uropathogens in patients with urinary tract infection in a tertiary care center, Karnataka. MedPulse International Journal of Pharmacology. 2020; 16(2): 21-25.
35. Thomas TM, Udaykumar P. Evaluation of antibiotic prescription pattern in in-patients with urinary tract infection in a tertiary care centre. MedPulse International Journal of Pharmacology. 2021; 17(1): 01-05.
36. Y.Prasanth, B.Narendra, K.Upendra, K.Rajesh, Dr.NambariHemanth Kumar. A review on Adverse drug reactions Monitoring and Reporting. International Journal of Pharmacy Research & Technology. 2020; 10(1): 44-47.
37. Zaman SU, Ramesh L, Priya BV, Beedimani RS, Manikanta M. Adverse Drug Reactions: An Analysis of Spontaneous Reports. National Journal of Physiology, Pharmacy and Pharmacology. 2021; 11(2): 141-146.

## PvPI in News and Media

In order to spread awareness about ADR-reporting to PvPI, two Press Communiqués were published one each in Hindi (Hindustan) and English (Hindustan Times) on October 11, 2020 respectively. The English Press Communiqué was specifically targeted to spread awareness about reporting the ADRs related to COVID-19 drugs through dedicated form designed by NCC-PvPI while the Hindi Press Communiqué focused on creating awareness on PvPI.



## Publications of PvPI-SRP recommendations in WHO – Pharmaceutical Newsletter

World Health Organization

WHO Pharmaceuticals NEWSLETTER

2020 No.5

### Alfuzosin

**Risk of palpitations**

**India.** The National Coordination Centre - Pharmacovigilance Programme of India (NCC-PvPI) has made a recommendation to the Central Drugs Standard Control Organisation (CDSCO) to request that the patient information leaflet (PIL) for alfuzosin should be revised to incorporate palpitations as a clinically significant adverse drug reaction.

Alfuzosin is used for the treatment of benign prostatic hyperplasia.

Between July 2011 and November 2019, the NCC-PvPI received a total of three individual case safety reports (ICSRs) of alfuzosin associated palpitations. The cases were evaluated by the Signal Review Panel (SRP), PvPI, and Indian Pharmacopeia Commission (IPC) who found a strong causal relationship between alfuzosin associated palpitations.

***Reference:***
Based on the communication from NCC-PvPI, IPC India (ipc.gov.in)

### Benidipine

**Risk of photosensitivity reaction**

**India.** The NCC-PvPI has made a recommendation to the CDSCO to request that the PIL for benidipine is revised to incorporate photosensitivity as a clinically significant adverse drug reaction.

Benidipine is used for the treatment of hypertension and long term prophylactic management of angina pectoris.

Between July 2011 and November 2019, the NCC-PvPI received a total of five ICSRs reporting benidipine associated photosensitivity reaction. The cases were evaluated by the SRP, PvPI, and IPC who found a strong causal relationship between benidipine and associated photosensitivity reaction.

***Reference:***
Based on the communication from NCC-PvPI, IPC India (ipc.gov.in)

### Pentoxifylline

**Risk of palpitations**

**India.** The NCC-PvPI has made a recommendation to the CDSCO to request the revision of the PIL for pentoxyphylline to incorporate palpitations as a clinically significant adverse drug reaction.

Pentoxifylline is a vasodilator indicated for the treatment of atrial and atriovenous circulatory disorder.

Between July 2011 and November 2019, the NCC-PvPI received a total of four ICSRs reporting palpitations associated with pentoxifylline use. The cases were evaluated by the SRP, PvPI, and IPC who found a strong causal relationship between pentoxifylline use and palpitations.

***Reference:***
Based on the communication from NCC-PvPI, IPC India (ipc.gov.in)

World Health Organization

# WHO Pharmaceuticals NEWSLETTER

2020 No.5

## Piperacillin, Tazobactam

**Risk of acute generalised exanthematous pustulosis (AGEP)**

**India.** The NCC-PvPI has made a recommendation to the CDSCO to request that the PIL for piperacillin/tazobactam is revised to incorporate acute generalised exanthematous pustulosis (AGEP) as a clinically significant adverse drug reaction.

Piperacillin/tazobactam is used for the treatment of moderate to severe lower respiratory tract infections.

Between July 2011 and November 2019, NCC-PvPI received a total of six ICSRs reporting piperacillin/tazobactam associated AGEP. The cases were evaluated by the SRP, PvPI, and IPC who found a strong causal relationship between piperacillin/tazobactam use and AGEP.

***Reference:***
Based on the communication from NCC-PvPI, IPC India (ipc.gov.in)

## Tinidazole

**Risk of skin hyperpigmentation**

**India.** The NCC-PvPI has made a recommendation to the CDSCO to request that the PIL for tinidazole is revised to incorporate skin hyperpigmentation as a clinically significant adverse drug reaction.

Tinidazole is used for the treatment of amoebiasis and giardiasis in adult patients only and in the treatment of anaerobic infections.

Between July 2011 and November 2019, the NCC-PvPI received a total of 13 ICSRs of tinidazole associated skin hyperpigmentation. The cases were evaluated by the SRP, PvPI, and IPC who found a strong causal relationship between tinidazole use and skin hyperpigmentation.

***Reference:***
Based on the communication from NCC-PvPI, IPC India (ipc.gov.in)

# MATERIOVIGILANCE PROGRAMME OF INDIA

The Materiovigilance Programme of India (MvPI) was launched on 6th July, 2015 at the Indian Pharmacopoeia Commission, Ghaziabad by the Drugs Controller General India (DCGI) with an objective to improve Indian patient safety by monitoring, recording, analyzing the root cause of AEs or risks associated with the use of medical devices and suggesting Indian regulatory bodies for appropriate action.

IPC functions as the National Coordination Centre for the Materiovigilance Programme of India. Sree Chitra Tirunal Institute of Medical Sciences & Technology (SCTIMST), Thiruvananthapuram functions as a National Collaborating Centre for MvPI. Technical support to the programme is provided by the Division of Healthcare Technology (a proposed WHO collaborating centre for priority medical devices and health technology policy), National Health Systems Resources Centre (NHSRC), New Delhi. Medical Device Adverse Events (MDAE), Field Safety Corrective Action (FSCA) and Personal Protective Equipments (PPEs) reporting forms have been designed by NCC-MvPI to collect the safety information related to medical devices. Amid COVID-19 pandemic, NCC-MvPI has specially designed a new reporting tool for collecting AEs associated with PPEs. NCC-MvPI recognized 50 medical colleges and hospitals across the country as Medical Device Adverse Event Monitoring Centres (MDMCs).

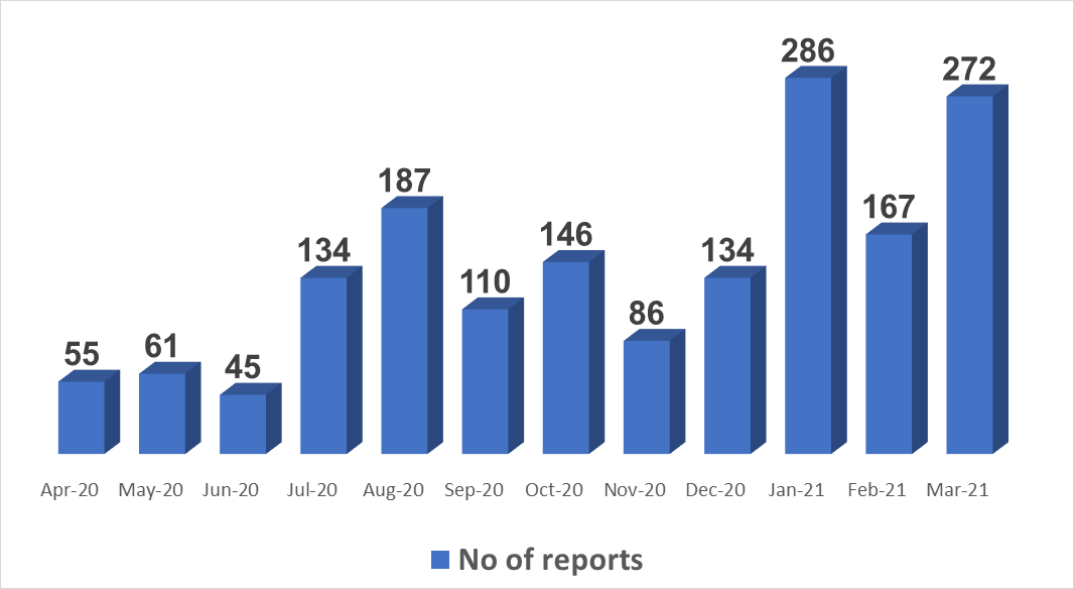
To ensure effective adverse event reporting culture among MDMCs, clinicians, biomedical engineers, hospital technology managers, and other healthcare professionals, MvPI has been imparting hands-on training programmes/ awareness sessions/ e-CMEs/ workshops etc. periodically.

Review meetings with regulatory authorities are regularly hold to assess the progress of MvPI. To keep the stakeholders updated, NCC-MvPI publishes e-newsletters, guidance documents, advisory notices etc. on a regular basis on the website of IPC (www.ipc.gov.in) and also made available printed versions of Reference Manual for Medical Devices. This document provides guidance to assist manufacturers, traders/ distributors, importers, clinical establishments, healthcare professionals and the general public on regulatory requirements concerning medical devices, nationally recognized medical devices standards in India and post-market requirements.

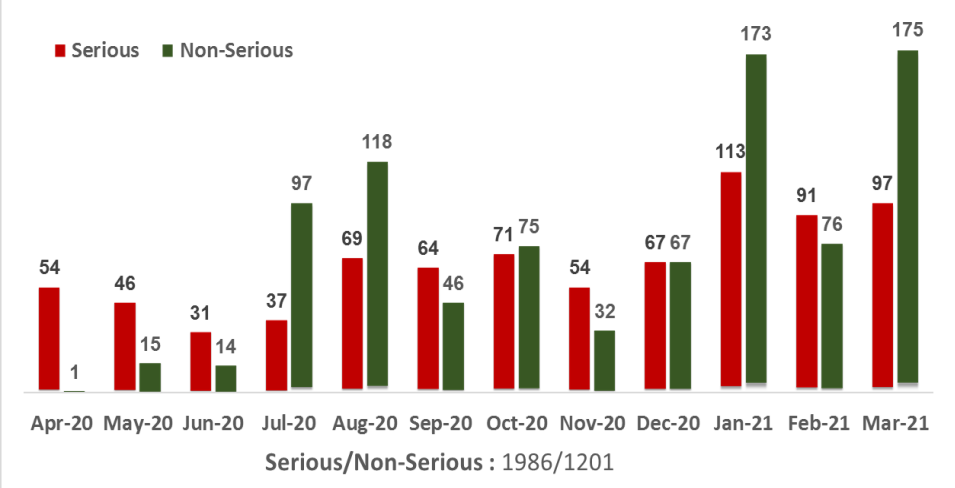
**Reporting Status of Medical Device Adverse Event to NCC-MvPI**

NCC-MvPI, IPC collects, collates and analyse AEs associated with medical devices exclusively in Indian population, analyse the benefit-risk ratio, generate evidence-based information on medical devices safety, support regulatory bodies in the decision-making process on medical devices & communicate the safety signal on use of medical devices to various stakeholders.

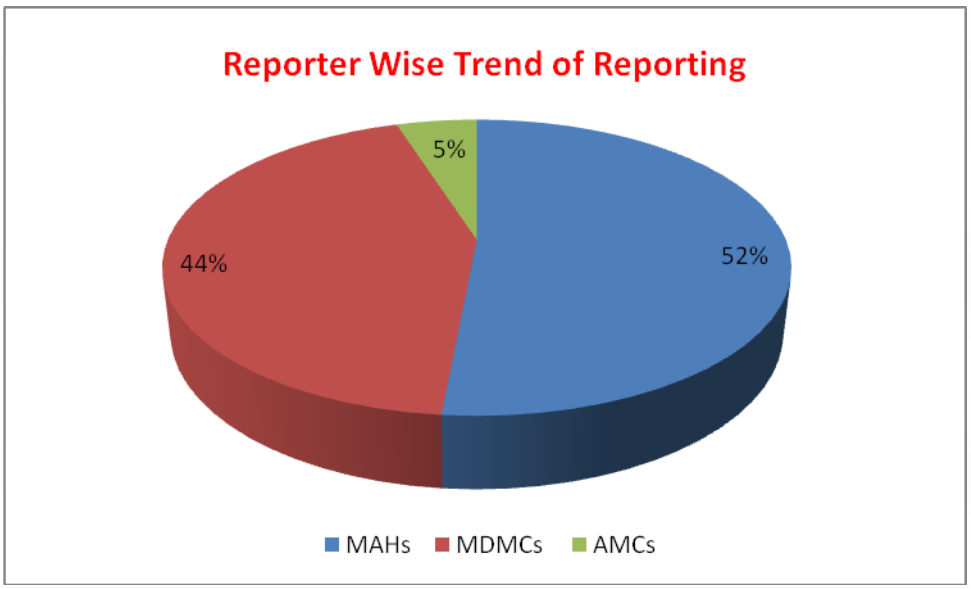
**Total number of MDAE reports received (month-wise):** 1,683 MDAE reports have been reviewed and processed for subject expert opinion.




**Serious and non-serious:** Out of total 1683 reports, 47% reports were marked as serious and 53% reports were reported as non-serious. The criteria of seriousness are taken from medical device rules 2017.



**Reporter wise MDAE Reports**: Out of total 1683 MDAE reports, 52% reports were reported by MAHs, 43% reports were reported by MDMCs and 5% reports were received from AMCs.



## Training/Workshop/Awareness Programmes

In total 22 training /workshops /Awareness programmes were conducted & participated by IPC, NCC-MvPI in the induction period starting from April, 2020 to March, 2021.

| S. No. | Date | Webinar/Training Programme | Participants |
|---|---|---|---|
| **1.** | 25th March, 2021 | CME cum e-workshop on "Materiovigilance: Ensuring safety of medical devices" organized by NCC-MvPI, IPC in association with AIIMS, Patna | 60 |
| **2.** | 23rd March, 2021 | 2nd Indian Regulatory & Quality Summit (IRQS) 2021" organized by Association of Regulatory Affairs Professionals (ARAP) in collaboration with Indian Pharmaceutical Association-Delhi State Branch | 100 |
| **3.** | 16th March, 2021 | Lecture delivered during 16th Skill Development Programme on Pharmacovigilance for Medical Products organized by NCC-PvPI | 105 |
| **4.** | 16th March, 2021 | Training programme on "Case Narrative writing for reporting adverse events effective way and best practices" organized by NCC-MvPI, IPC | 20 |
| **5.** | 19th February, 2021 | Webinar on "Basics of Materiovigilance and hands on training on MDAE reporting" organized by NCC-MvPI in association with Lovely Professional University, Punjab | 150 |
| **6.** | 19th February, 2021 | Webinar on "Update on Pharmacovigilance of medical devices and its importance" organized by Ramaiah University of Applied Sciences, Karnataka | 100 |
| **7.** | 19th February, 2021 | Webinar on "Materiovigilance Programme of India: An Overview" organized by SRM Institute of Science & Technology, Chennai | 150 |
| **8.** | 22nd January, 2021 | Webinar on "Coordinator Meeting cum Advanced Training Programme for Patient Safety Pharmacovigilance Associates working at AMCs of North zone Region" organized by PGIMER, Chandigarh | 200 |
| **9.** | 17th December, 2020 | Webinar on "Brain storming session on Causality Assessment of Medical Devices" organized by NCC-MvPI, IPC in association with PGIMER, Chandigarh | 150 |
| **10.** | 4th, 5th ,18th , 19th, 23rd & 24th December 2020 | Webinar on "Role of Biomedical Engineers in Assessment of Medical Devices Adverse Events" organized by NCC-MvPI, IPC in association with AMTZ, Vishakhapatnam | 100 |
| **11.** | 4th December, 2020 | Webinar on "Participation of Medical Device Manufacturers in Materiovigilance Programme of India (MvPI)" organized by NCC-MvPI, IPC in association with Association of Indian Medical Device Industry | 150 |

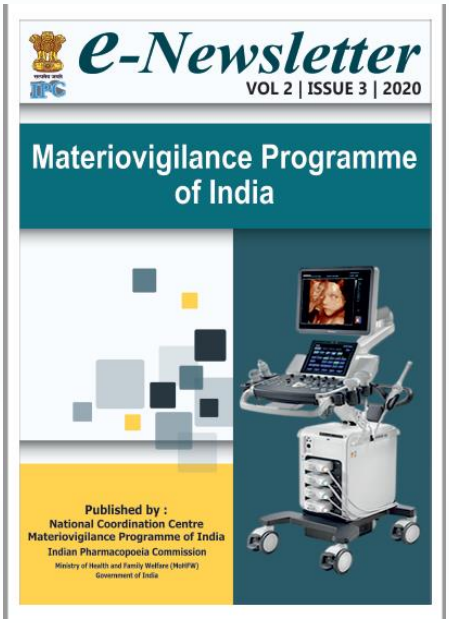
| | | | |
|---|---|---|---|
| **12.** | 13th November, 2020 | Lecture delivered during 15th Skill Development Programme on Pharmacovigilance for Medical Products organized by NCC-PvPI | 183 |
| **13.** | 8th & 9th October, 2020 | WHO meeting on "Informal consultation on post-market and market surveillance of medical devices including in vitro diagnostics" | 100 |
| **14.** | 25th September, 2020 | Webinar on "Address the need of Materiovigilance Programme of India to promote patient" organized by Lovely Professional University, Punjab | 100 |
| **15.** | 25th September, 2020 | Webinar on "Medical Devices: Opportunities and Challenges" organized by NCC-MvPI, IPC in association with Parul Institute of Pharmacy, Parul University, Vadodara Gujarat | 120 |
| **16.** | 24th September, 2020 | Webinar on "Medical device Adverse Event Reporting: Awareness among the pharmacy teachers" organized by Delhi Institute of Pharmaceutical Sciences and Research (DIPSAR), New Delhi | 100 |
| **17.** | 22nd September, 2020 | Webinar on "Materiovigilance with special focus on adverse event on PPE kits" organized by Department of Pharmacology, Kalpana Chawla Govt. Medical College, Karnal, Haryana | 50 |
| **18.** | 17th & 18th September, 2020 | MvPI 4th Induction-cum-training programme organized by NCC-MvPI, IPC | 42 |
| **19.** | 7th September, 2020 | e-CME training on Medical Device Rule-2017 & Materiovigilance organized by PGIMER, Chandigarh | 30 |
| **20.** | 7th August, 2020 | e-CME training on MvPI organized by Department of Pharmacology, Government Medical College, Jammu, in collaboration with NCC-MvPI IPC | 100 |
| **21.** | 4th June, 2020 | Webinar on "Medical Device and IVD's associated adverse events management during COVID-19 Pandemic: Your Experiences" organized by NCC-MvPI | 30 |
| **22.** | 13th, 15th & 26th May, 2020 | Webinar on "Medical Device and IVD's associated adverse events management during COVID-19 Pandemic: Your Experiences" organized by NCC-MvPI | 30 |

**Details of recommendations forwarded to CDSCO**

| S. No. | Date | Recommendations | Action Taken by CDSCO |
|---|---|---|---|
| **1.** | 11th September, 2020 | NCC-MvPI found 6 serious AEs involving 05 heart valves and 1 knee implant which were found to be associated with medical device. | Under Consideration |
| **2.** | 20th May, 2020 | NCC-MvPI, IPC has found 23 AEs including genital haemorrhage and device expulsion associated with the use of Intra Uterine Contraceptive Devices of the same batch. | Under Consideration |

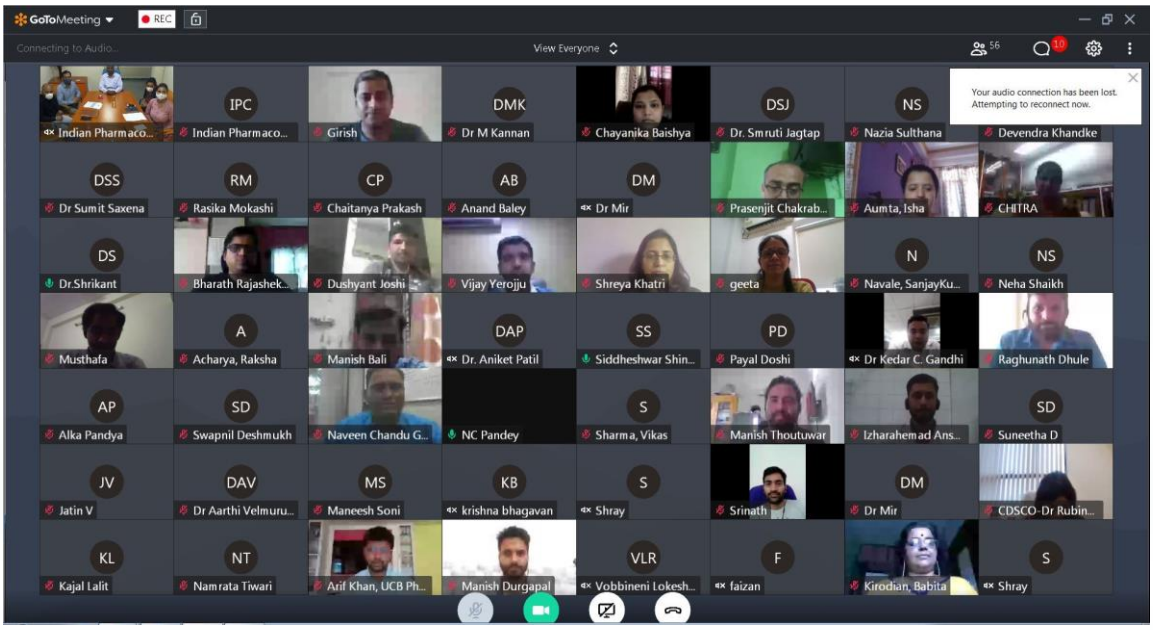
**Newsletters of MvPI**

During the index period, 4 e-newsletters were published by MvPI to update the stakeholders on the recent activities.

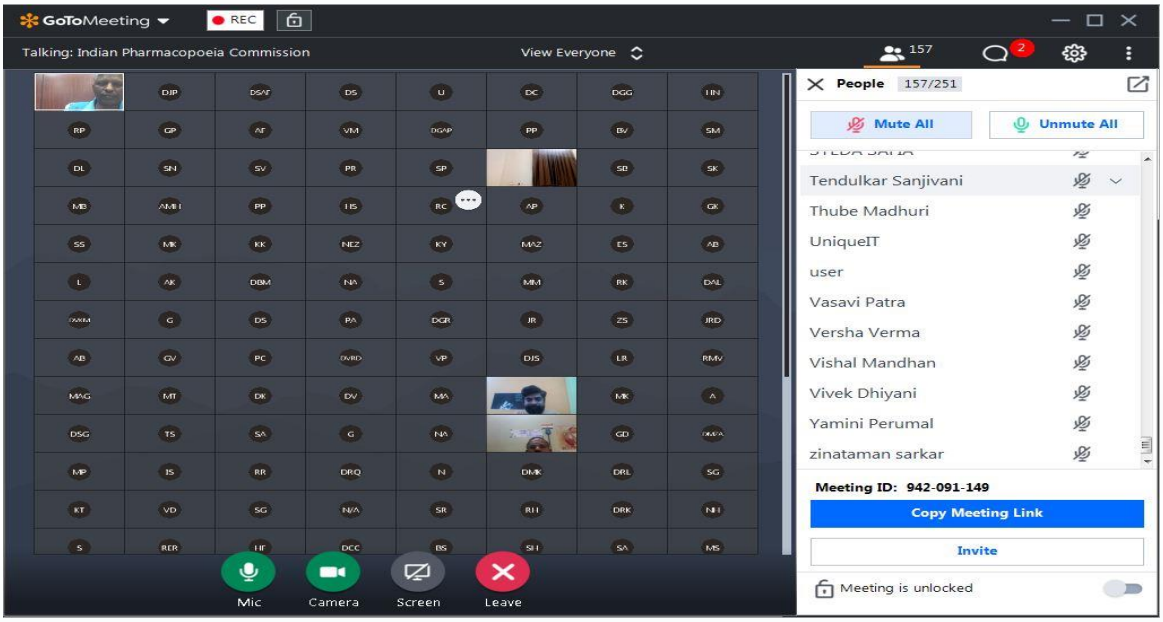





## GLIMPSES OF TRAINING/WORKSHOPS/AWARENESS PROGRAMMES




*Participants of 14th Regional Webinar on 'Pharmacovigilance & Establishment of PV System in Pharmaceutical Industries - A Way Forward' organized by NCC-PvPI on 9th October, 2020*



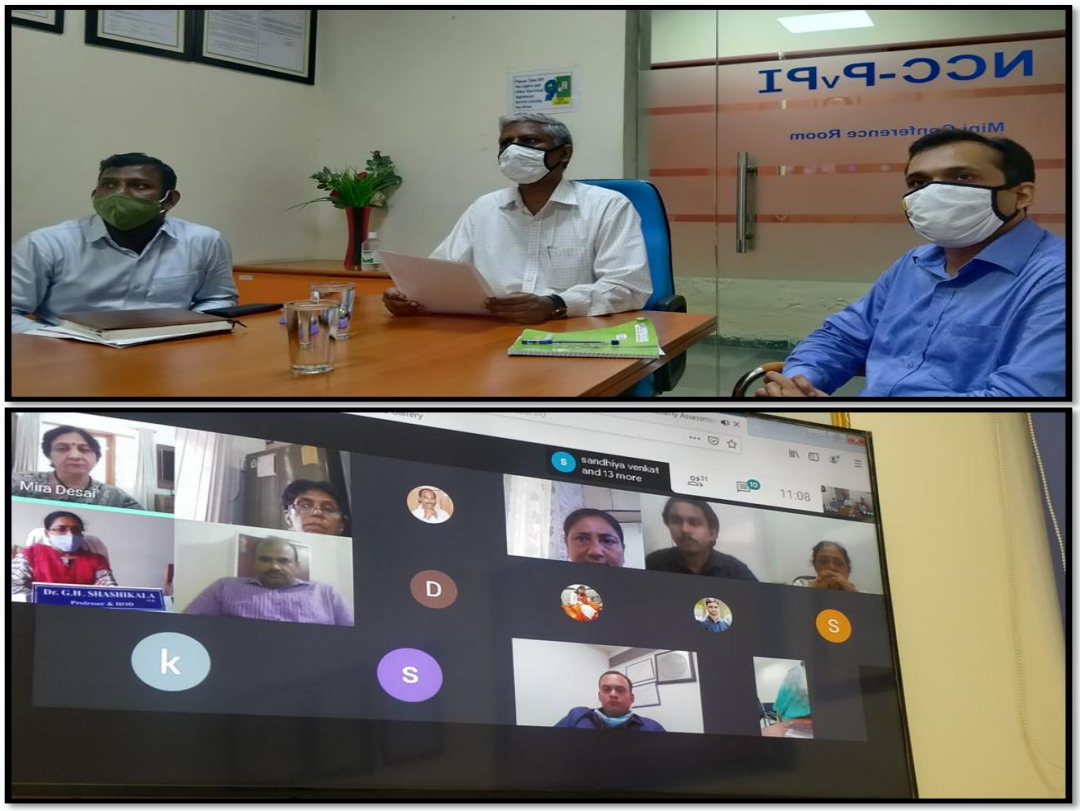

*Participants during 15th Skill Development Programme on 'Pharmacovigilance of Medical Products' conducted online from 9th to 13th November, 2020 at IPC*

*Inauguration of 16th Skill Development Programme on Pharmacovigilance of Medical Products conducted online at IPC from 15th to 19th March, 2021*


*Promotional Activities on Pharmacovigilance conducted at NEIGRIHMS, Shillong, Meghalaya during 5th #MedSafetyWeek*

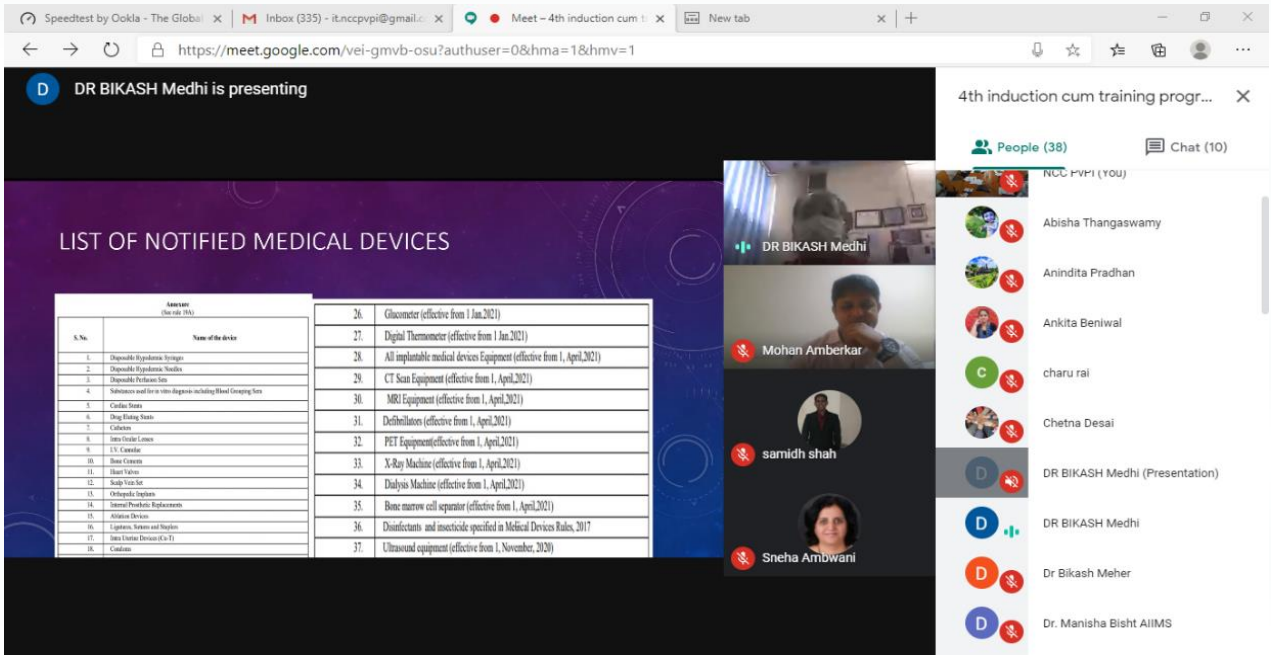

*NCC-PvPI posted various Social Media posts to raise awareness and to further strengthen the Pharmacovigilance system in India during 5th #MedSafetyWeek*


*Celebration of 5th #MedSafetyWeek at NCC-PvPI, IPC, Ghaziabad organised by WHO-UMC from 2nd to 8th September, 2020*




*'Webinar on Causality Assessment' was organised on 22th July 2020 by PvPI, IPC-Ghaziabad*

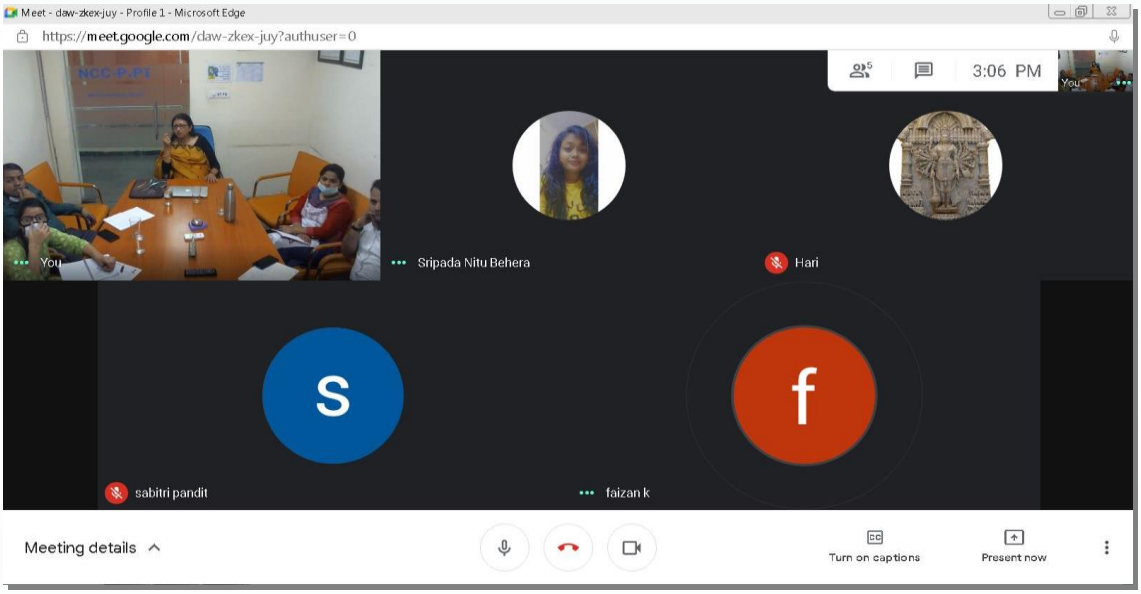
*'Virtual Training of ADR reporting in NVBDCP' organised jointly by PvPI & NVBDCP on 6th August, 2020*




*NCC-MvPI organized '4th Induction-cum-training programme' on 17-18 September 2020 via virtual mode for the newly recognized MDMCs.*


*NCC-MvPI, IPC in association with AIIMS, Patna organized a Virtual CME-cum-e-workshop on 'Materiovigilance: Ensuring safety of medical devices' on March 25, 2021*


*MvPI officials setup a stall and created awareness on resource materials for information, education and communication about MvPI in '2nd Indian Regulatory & Quality Summit (IRQS) 2021' on 23rd March 2021*




*NCC-MvPI, IPC organized a virtual training programme for MvPI Associates on 'Case Narrative writing for reporting adverse events effective way and best practices' on 16th March 2021*

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| S. No. | States/UTs | AMCs | Coordinator | Email-ID |
|---|---|---|---|---|
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|---|---|---|---|---|
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## Current List of all AMCs under PvPI

**Source:** http://ipc.gov.in/images/AMC_List.pdf

## List of Newly Enrolled MDMCs under MvPI

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| 11. | Rajasthan | All India Institute of Medical Sciences, Jodhpur- 342005 | Dr. Sneha R Ambwani | ambwanis@aiimsjodhpur.edu.in |
| 12. | | Jaipur National University, Institute of Medical Sciences and Research Centre, Jaipur- 302017 | Dr. Mukul Mathur | mathur_mukul@rediffmail.com |
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| 14. | Uttar Pradesh | Mulayam Singh Yadav Medical College and Hospital, 21 Km, NH 235, Lalpur, Kharkhoda, Hapur road, Meerut- 245206 | Dr. Jaswant Rai | ksdcharitabletrust@gmail.com |

## Current List of all MDMCs under MvPI

**Source:** https://docs.google.com/spreadsheets/d/17VyeCkSz1GKuuD-w5yGqyIJxlYc1_2UFvRceJuTgbNk/edit?ts=5f181c51#gid=0

## Acknowledgements

I sincerely acknowledge the efforts and contribution of the following members of my team for compiling and meticulously preparing this Performance Report 2020-21:

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

I also gratefully acknowledge the contribution and expertise provided by the following in preparing and reviewing this report:

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All other Technical, Administrative and Financial staff of IPC.

**Dr Rajeev Singh Raghuvanshi**

Secretary-cum-Scientific Director
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# Annexures

## Annexure -I

Version-1.3

### SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of Adverse Drug Reaction 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

**A. PATIENT INFORMATION**

1. Patient Initials _____
2. Age at the time of Event or Date of Birth _____
3. M □ F □ Other □
4. Weight _____Kgs

Reg. No. /IPD No. /OPD No. /CR No. :
AMC Report No. :
Worldwide Unique No. :

**B. SUSPECTED ADVERSE REACTION**

5. Event/Reaction start date (dd/mm/yyyy)
6. Event/Reaction stop date (dd/mm/yyyy)
6 (A). Onset Lag Time
7. Describe Event/Reaction with treatment details, if any
12. Relevant tests/ laboratory data with dates
13. Relevant medical/medication history (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/renal dysfunction, past surgery etc.)
14. Seriousness of the reaction: No □ If Yes □(please tick anyone)
□ Death (dd/mm/yyyy) □ Congenital-anomaly
□ Life threatening □ Disability
□Hospitalization/Prolonged □ Other Medically important
15. Outcomes
□ 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. | Exp. Date (if known) | Dose used | Route used | Frequency (OD, BD etc.) | Therapy dates | | Indication | Causality Assessment |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | Date started | Date stopped | | |
| i | | | | | | | | | | | |
| ii | | | | | | | | | | | |
| iii | | | | | | | | | | | |
| iv* | | | | | | | | | | | |

| S.No as per C | 9. Action Taken (please tick) | | | | | | 10. Reaction reappeared after reintroduction (please tick) | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Drug withdrawn | Dose increased | Dose reduced | Dose not changed | Not applicable | Unknown | Yes | No | Effect unknown | Dose (if reintroduced) |
| 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 used | Route used | Frequency (OD, BD, etc.) | Therapy dates | | Indication |
|---|---|---|---|---|---|---|---|
| | | | | | Date started | Date stopped | |
| i | | | | | | | |
| ii | | | | | | | |
| iii* | | | | | | | |

Additional Information:

**D. REPORTER DETAILS**

16. Name and Professional Address:_____
_____
Pin:_____E-mail_____
Tel. No. (with STD code)_____
Occupation:_____ Signature:_____

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

Sig. 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

**National Coordination Centre for Pharmacovigilance Programme of India**

Ministry of Health & Family Welfare, Government of India
Sector-23, Raj Nagar, Ghaziabad-201002
Tel.: 0120-2783400, 2783401, 2783392, Fax: 0120-2783311
www.ipc.nic.in

## ADVICE ABOUT REPORTING

### A. What to report?

- Report 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
  - Required intervention to prevent permanent impairment or damage
- Report non-serious, known or unknown, frequent or rare adverse drug reactions due to Medicines, Vaccines and Herbal products etc.

  **Note- 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 Nurses etc) can report adverse drug reactions

### C. Where to report?

- Duly filled inSuspected 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 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 to review the data and suggest 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) and reporter information.

***For ADRs Reporting***

- **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: "ADR PvPI"***

Source: http://ipc.gov.in/images/ADR-Reporting-Form1.3.pdf

## 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 (√): Male/ पुरुष ☐ Female/ स्त्री ☐ Other/ अन्य ☐ | Age (Year or Month)/ आयु (वर्ष या माह) : |
|---|---|---|

**2. Health Information/ स्वास्थ्य संबंधी जानकारी**

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

b. Medicines Advised by/ दवाई की सलाह देने वाला (√): Doctor/ डॉक्टर ☐ Pharmacist/ फॉर्मासिस्ट ☐ 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 |
|---|---|---|---|---|
| | | | dd/mm/yy | dd/mm/yy |
| | | | dd/mm/yy | dd/mm/yy |
| | | | dd/mm/yy | dd/mm/yy |

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

**5. About the Side Effect/ दुष्प्रभाव के बारे में**

When did the side effect start?/ दुष्प्रभाव की शुरूआत कब हुई थी? dd/mm/yy Side Effect is still Continuing ( Yes/No)/

When did the side effect stop?/ दुष्प्रभाव कब समाप्त हुआ था? dd/mm/yy क्या दुष्प्रभाव जारी हैं (हां/नहीं): dd/mm/yy

**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 ले जाना पड़ा | ☐ Death/ मृत्यु |
| ☐ Others/ अन्य | |

**7.Describe the Side Effect (What did you do to manage the side effect?)/ दुष्प्रभाव की व्याख्या करें (आपने 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, कोई कानूनी निहितार्थ नहीं है और इसका लक्ष्य मरीज की सुरक्षा में सुधार करना है। आपकी सक्रिय भागीदारी मूल्यवान है। इस फॉर्म में दी गई जानकारी की अनुवर्ती कार्रवाई हेतु एटीआर निगरानी केंद्र को भेजा जाएगा। आपसे अनुरोध है कि आप कार्यक्रम के अधिकारियों का सहयोग करें जब ये अधिक जानकारी प्राप्त करने के लिए आपसे संपर्क करें। कृपया पूर्ण जानकारी न होने पर भी सूचित करें।

Please turn the page to read the instructions
निर्देशों को पढ़ने के लिए कृपया पेज पलटें

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

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

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

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

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

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

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

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

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

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

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

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

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

**निर्देश 6 – दुष्प्रभाव कितने खतरनाक थे?**
- ✓ कृपया उचित ठप्पे पर निशान लगाएं।

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

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

Source: http://ipc.gov.in/mandates/pvpi/pvpi-updates/8-category-en/430-adr-reporting-form-for-consumers-in-hindi-other-vernacular-languages.html

## 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 case ☐
b. Asymptomatic Healthcare Worker involved in the care of suspected or confirmed COVID-19 cases ☐
c. Asymptomatic household contacts of laboratory confirmed cases ☐
d. Others (Please specify)

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

| 4. Gender : | 5. If female pregnant | 6. Lactating |
|---|---|---|
| Male ☐ Female ☐ Transgender ☐ | Yes ☐ No ☐ | Yes ☐ No ☐ |

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

ANC 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 (please tick): Drug withdrawal | Dose reduction | Without modification of dose | Any other | Reaction if reappeared after drug reintroduction: Yes | No | Effect unknown | Dose (if reintroduced) |
|---|---|---|---|---|---|---|---|---|---|
| I. | | | | | | | | | |
| II. | | | | | | | | | |
| III. | | | | | | | | | |

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

| S.No. | Name (Brand/Generic) | Dose used | Route used | Frequency (Once a day, twice a day etc. | Therapy Dates: Date started | Therapy Dates: Date stopped | Indication |
|---|---|---|---|---|---|---|---|
| I. | | | | | | | |
| II. | | | | | | | |
| III. | | | | | | | |
| IV. | | | | | | | |

**D. REPORTER DETAILS**

**15.** Name of the Healthcare Professional with Address : _____

_____

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

Occupation : _____ Signature : _____

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

**Sign. and Name of Receiver -**

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

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

**ADVICE ABOUT REPORTING**

**A. What to report?**

**All adverse events should be reported**

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

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

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

**B. Who can report?**

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

**C. Where to report?**

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

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

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

**D. What happens to the submitted information?**

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

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

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

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

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

**For Adverse Drug Reaction Reporting Tools**

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

Source: http://ipc.gov.in/images/Suspected_ADR_Reporting_Form-converted_2020.pdf

## Annexure-IV

Version no. 1.1

**PERSONAL PROTECTIVE EQUIPMENT ADVERSE EVENT REPORTING FORM**

**Materiovigilance Programme of India (MvPI)**

Where to report: Duly filled form can be sent to Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare, Government of India, Sector-23, Raisapur, Ghaziabad-201001. Tel-0120-2783400, 2783401 and 2783392, FAX:0120-2785311 or email to shatrughan.lal@gov.in Or Call on Helpline no. 1800 180 3024 to report Adverse event.

**1. General Information:**

Date of report:

Date of event:

**2. Type of report:**

☐ Initial ☐ Follow-up (Ref. no. _____)

**3. Reporter details:**

Name:

Address:

Contact No.:

E-mail address:

**4. PPE Type:**

☐ Gloves ☐ Coverall ☐ Goggles ☐ N-95 Masks ☐ Shoe Covers ☐ Face Shield ☐ Body Bags

☐ Triple Layer Medical Mask ☐ Sanitizer ☐ Other (Specify):

**5. PPE Details:**

Brand name:

Manufacturer name and address:

Importer name and address:

Distributor name and address :

Marketed by:

License No. / Registration No. :

Model No.: Batch No.:

Unique Certification Code : Test Standard :

Manufacturing Date : Expiry Date :

PPE Current Location: ☐ Device destroyed ☐ Still in use ☐ Return to manufacturer

**6. Location of event:**

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

**7. Type of event:**

Serious: ☐ Non-Serious

☐ Death
☐ Life Threatening
☐ Disability or permanent damage
☐ Hospitalization / Prolonged Hospitalization
☐ Congenital anomaly / birth defect
☐ Any other serious

**8. User details.**

Initials:

Age:

Gender (M/F/O):

Outcome: ☐ Recovered ☐ Not yet recovered ☐ Death ☐ Other:

**9. Detailed Description of Event.**

**10. Hospital/Quarantine facility details:**

Facility Name:

Address:

Contact Person:

Source: http://ipc.gov.in/images/Updated_PPE_Form.pdf

## Annexure-V

Ministry of Health and Family Welfare Government of India

# ADVERSE DRUG REACTION REPORTING FORM FOR KALA-AZAR TREATMENT

### I. PATIENT DETAILS

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

### II. TREATMENT

**A) CONDITION TREATED**

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

**B) TREATMENT RECEIVED**

Mono Therapy ☐ Combination Therapy ☐

| Drug Received | Batch No./ Expiry Date | Drug Dose & Unit | Frequency | Route | Start Date (dd/mm/yyyy) | Start Time (Hr:Min) | Stop Date (dd/mm/yyyy) | Stop Time (Hr: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 causes):

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

1

Ministry of Health and Family Welfare Government of India

| | | | |
|---|---|---|---|
| **Outcome** | ☐ Recovered/ resolved<br>☐ Recovering/resolving<br>☐ Fatal<br>☐ Not Recovered/not resolved<br>☐ Recovered with Sequalae<br>☐ Unknown | ☐ Recovered/ resolved<br>☐ Recovering/resolving<br>☐ Fatal<br>☐ Not Recovered/not resolved<br>☐ Recovered with Sequalae<br>☐ Unknown | ☐ Recovered/ resolved<br>☐ Recovering/resolving<br>☐ Fatal<br>☐ Not Recovered/not resolved<br>☐ Recovered with Sequalae<br>☐ Unknown |
| **Dechallenge/ Action Taken** | ☐ Drug Withdrawn<br>☐ Dose Reduced<br>Dose……<br>☐ Dose not changed<br>☐ Unknown<br>☐ Not Applicable | ☐ Drug Withdrawn<br>☐ Dose Reduced<br>Dose……<br>☐ Dose not changed<br>☐ Unknown<br>☐ Not Applicable | ☐ Drug Withdrawn<br>☐ Dose Reduced<br>Dose……<br>☐ Dose not changed<br>☐ Unknown<br>☐ Not Applicable |
| **Rechallenge** | ☐ No<br>☐ Yes<br>Dose (if reintroduced)……..<br>☐ Unknown | ☐ No<br>☐ Yes<br>Dose (if reintroduced)……..<br>☐ Unknown | ☐ No<br>☐ Yes<br>Dose (if reintroduced)……..<br>☐ Unknown |
| **Expectedness** | ☐ Expected (yes)<br>☐ Unexpected (no) | ☐ Expected (yes)<br>☐ Unexpected (no) | ☐ Expected (yes)<br>☐ Unexpected (no) |
| **For Death** | Date of Death……<br>Primary cause of death (if known):<br>……<br>Was autopsy performed?<br>☐ No<br>☐ Yes<br>Hospital Admission Date ……<br>Hospital Discharge Date…….. | Date of Death……<br>Primary cause of death (if known):<br>……<br>Was autopsy performed?<br>☐ No<br>☐ Yes<br>Hospital Admission Date ……<br>Hospital Discharge Date…… | Date of Death……<br>Primary cause of death (if known):<br>……<br>Was autopsy performed?<br>☐ No<br>☐ Yes<br>Hospital Admission Date……<br>Hospital Discharge Date…… |
| **Causality**<br>[-Certain<br>-Probable<br>- Possible<br>- Unlikely<br>- Conditional<br>- Unassessable] | ☐ Ambisome……..<br>☐ Miltefosine ……..<br>☐ Paromomycin……..<br>☐ Amphotericin deoxycholate……..<br>☐ SSG/ SAG……..<br>☐ Others (……)…… | ☐ Ambisome……..<br>☐ Miltefosine ……..<br>☐ Paromomycin……..<br>☐ Amphotericin deoxycholate….<br>☐ SSG/ SAG……..<br>☐ Others (……)…… | ☐ Ambisome……..<br>☐ Miltefosine ……..<br>☐ Paromomycin……..<br>☐ Amphotericin deoxycholate……..<br>☐ SSG/ SAG……..<br>☐ 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:**<br><br>**Counseling with Toll Free Number (18001803024):** ☐ **Yes** ☐ **No** |

## VIII. REPORTERS INFORMATION

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

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Source:https://www.ipc.gov.in/PvPI/adr/ADR%20reporting%20Form_Kala%20Azar_28-02-2017.pdf

## 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 (D D M M Y Y Y Y) | Time of Death (H H M M) (AM/PM) |
| Describe AEFI (signs and symptoms): | |
| Name & signature of AMC Coordinator/ Medical officer:<br><br>Email:<br>Contact No. | |
| *Date form sent to District Immunization Officer# (**where patient was vaccinated**)- __ __/__ __/__ __ __ __ | |
| *Date form sent to State Immunization Officer# (**where patient was vaccinated**)- __ __/__ __/__ __ __ __ | |
| *Date form sent to PVPI, Ghaziabad- __ __/__ __/__ __ __ __ | |
| *Date form sent to Immunization Division / AEFI Secretariat (aefiindia@gmail.com)- __ __/__ __/__ __ __ __ | |
| Name & signature of Pharmacovigilance Associate:<br><br>E mail:<br>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.**

Source: https://ipc.gov.in/images/pdf/File650.pdf

## 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 MDMC only: • Centre • Location • Month-Year • Case No.

#### Reporter Details

1. Type of Reporter : (a) Manufacturer ☐ (b) Importer ☐ (c) Distributor ☐ (d) Healthcare Professional ☐
   (e) Patient ☐ (f) Others ☐ specify
2. In case, where the reporter is not manufacturer, fill the following details: -
   (a) Has the reporter informed the incident to the manufacturer?
   Yes ☐ No ☐
   (b) Is the reporter also submitting the report on behalf of the manufacturer?
   Yes ☐ No ☐
3. Reporter contact information:
   a) Name :
   b) Address :
   c) Tel. /Mobile :
   d) Email :

#### Device Category

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

**Instruction for use Section A-F**

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

Page 1 of 5

## (A) Device Details

**Device Name / Trade Name / Brand Name:**

| Details | Name | Address |
|---|---|---|
| **Manufacturer** | | |
| **Importer** | | |
| **Distributor** | | |

1. a) Is the device notified/regulated in India : Yes ☐ No ☐
   b) Device Risk Classification as per India MDR 2017 : A ☐ B ☐ C ☐ D ☐
2. License No. (Manufacture/Import) :
3. Catalogue No. :
4. Model No. :
5. Lot / Batch No. :
6. Serial No. :
7. Software Version :
8. Associated Devices / Accessories :
9. Nomenclature Code if applicable; GMDN/UMDNS :
10. UDI No. (If applicable) :
11. Installation Date :
12. Expiration Date :
13. Last preventive maintenance date (dd/mm/yyyy) :
14. Last calibration date (dd/mm/yyyy) :
15. Year of manufacturing :
16. How long was device/Equipment/Machine in use :
17. Availability of device for evaluation : Yes ☐ No ☐
    If no, was the device destroyed ☐ Still in use ☐ return to manufacturer or importer/distributor ☐
18. Is the usage of device as per manufacturer claim /Instruction for use/user manual: Yes ☐ No ☐
    If no specify usage
19. For devices not regulated / notified in India : Regulator / Regulatory status in country of origin

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## (B) Event Description

1. Date of Event / Near miss incident:
2. Date of Implant/Explant (If applicable):
3. Location of Event:
   Hospital Premise ☐ Manufacture/Distributor premise ☐
   Home ☐ Others ☐
4. Device Operator:-
   Healthcare Professional ☐ Patient ☐ Others ☐
   Problem noted prior to use/near miss event ☐
5. Device disposition / Current location:
   a) Returned to company ☐ If yes, date ...../...../.....
   b) Remains implanted in patient ☐
   c) Within the healthcare facility ☐
   d) At patient home ☐
   e) Destroyed ☐
   f) Others (specify) ☐
6. Is device in use after incidence : Yes ☐ No ☐
7. Serious event: ☐
   If serious, Tick the appropriate reason
   a) Death (DD/MM/YY) ☐ ...../...../.....
   b) Life Threatening ☐
   c) Disability or permanent damage ☐
   d) Hospitalization ☐
   e) Congenital anomaly /birth defect ☐
   f) Any other serious (Imp. medical event) ☐
   g) Required intervention to prevent / permanent Impairment / damage device ☐
8. Non serious event ☐
9. Whether other medical devices were used at same time with above device if yes, please specify name(s)/use(s)

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

***For manufacturer/authorized representative use only***

Continue on Page 5

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

## (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):

Continue on Page 5

Continue on Page 5

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

1. Manufacturer/Authorized Representative device risk analysis report:

2. Corrective / preventive action taken:

Continue on Page 5

3. Device history review:

Continue on Page 5

Continue on Page 5

**(B) Event Description (Continued)**

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

**(E) Causality Assessment (Continued)**

**1. Investigation action taken:**

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

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

**1. Manufacturer/Authorized Representative device risk analysis report:**

2. Corrective / preventive action taken:

3. Device history review:

**Where to report?**

**Duly filled Medical Device Adverse Event Reporting Form can be sent to Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare, Government of India, Sector-23, Rajnagar, Ghaziabad-20002, Tel-0120-2783400, 2783401 and 2783392, FAX:0120-2783311 or email to mvpi.ipcindia@gmail.com 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.**

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Source:http://ipc.gov.in/images/MEDICAL_DEVICE_ADVERSE_EVENT_REPORTING_FORM_editable.pdf

*let us join hands with PvPI to ensure patient safety*

www.ipc.gov.in

Toll Free No.
1800 180 3024

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@IPC_Ghaziabad

ADR PvPI Mobile-app

pvpi.ipc@gov.in


**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, Fax : 0120-2783311

World Health Organization

**A WHO Collaborating Centre**
for Pharmacovigilance in Public Health Prgorammes and Regulatory Service

## For any Other Information/Suggestions/Query Contact

**Officer In-Charge, Pharmacovigilance Programme of India**
**Email : pvpi.ipc@gov.in, lab.ipc@gov.in Website : www.ipc.gov.in**