



Pharmacovigilance Programme of India (PvPI)
Performance Report 2018-19
(01st April 2018 to 31st March 2019)



INDIAN PHARMACOPOEIA COMMISSION
MINISTRY OF HEALTH & FAMILY WELFARE
GOVERNMENT OF INDIA
SECTOR 23, RAJ NAGAR, GHAZIABAD, UTTAR PRADESH-201002

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ABBREVIATIONS

ADR:	Adverse Drug Reaction
AE:	Adverse Event
AEFI:	Adverse Event Following Immunization
AIDS:	Acquired Immune Deficiency Syndrome
AIIMS:	All India Institute of Medical Sciences
AMC:	Adverse Drug Reaction Monitoring Centre
ART:	Anti-retroviral Therapy
CDSCO:	Central Drugs Standard Control Organization
CME:	Continuing Medical Education
CTP:	Core Training Panel
DCG(I):	Drugs Controller General (India)
GvP:	Good Pharmacovigilance Practice
HCP:	Healthcare Professional
HIV:	Human Immunodeficiency Virus
ICSR:	Individual Case Safety Report
IC:	Information Component
IPC:	Indian Pharmacopoeia Commission
LoI:	Letter of Intent
MAH:	Marketing Authorization Holder
MDAE:	Medical Device Adverse Event
MedDRA:	Medical Dictionary for Regulatory Activities
MoHFW:	Ministry of Health and Family Welfare
MoU:	Memorandum of Understanding
MvPI:	Materiovigilance Programme of India
NABH:	National Accreditation Board for Hospitals and Healthcare Providers
NCC:	National Coordination Centre
NHP:	National Health Programme
NRA:	National Regulatory Authority
PGIMER:	Post-Graduate Institute of Medical Education and Research
PV:	Pharmacovigilance
PvPI:	Pharmacovigilance Programme of India
RNTCP:	Revised National Tuberculosis Control Programme
SEARN:	South East Asia Regulatory Network
SRP:	Signal Review Panel

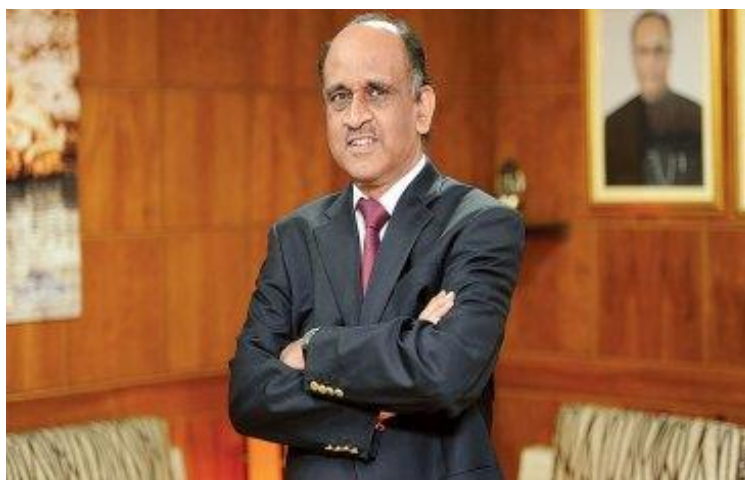
UIP:Universal Immunization Programme

UT:Union Territories

USFDA:United States Food and Drug Administration

WHO-UMC:World Health Organisation-Uppsala Monitoring Centre

FOREWORD FROM SECRETARY-CUM-SCIENTIFIC DIRECTOR



For nearly a decade now, PvPI-IPC has flourished from a nascent Pharmacovigilance body into a full-fledged research-based scientific organization, monitoring risk-optimised use of medicine by Indian citizenry and foreigners seeking treatment in India. The rational use of generic medicine, too, has gained an appreciable foothold vertically and horizontally among sections of society, hence need for surveillance to avoid an adverse outcome, maximising the risk-benefit ratio.

In whatever capacity as a consumer/dispenser of drugs -- be it as a patient, a physician or a pharmacist – the unwavering focus has to be as much on data-specific monitoring of the prescription/consumption of a drug or combination of drugs as on the reporting of adverse reactions following the use of such drugs. The causality factor by the prescribed indicators has to be monitored, analysed and determined for a drug to guard against a situation where risks associated with drug use might outweigh the intended benefits.

With the World Health Organization (WHO) having designated PvPI-IPC as a WHO-Collaborating Centre for Pharmacovigilance in Public Health Programmes and Regulatory Services, the IPC has been shouldering the onerous responsibility by imparting PV training to its counterpart in LMIC at SEARN. Such innovative initiatives need to be sustained by the IPC to bolster its role as a facilitator in promoting Pharmacovigilance and its allied activity in south Asia, SouthEast Asia and Africa.

The tempo of the landmark achievements made during the Index Period April 2018-March 2019, which include information-sharing on a global platform by PvPI as also MvPI, has to be given an impetus by the IPC to realise its potential vis-a-vis the scientific manpower and technical knowhow at its command. Making PV mandatory and a voluntary exercise for MAHs widens the ambit of PvPI-IPC as a watchdog for efficacious Pharmacovigilance.

Going glocal in its outreach has to be the mantra for PvPI as it blends its overarching role globally by extending its PV oversight locally, encompassing AYUSH and all HCPs at AMCs across India.

The ever-increasing database of ICSRs in India and its linkage with the global databank marks a milestone in causality assessment as also the implementation of GvPs which needs to be progressively nurtured and sustained.

Dr G N Singh

Secretary-cum-Scientific Director

Indian Pharmacopoeia Commission

Ghaziabad-201002

Indian Pharmacopoeia Commission and its Services:

Indian Pharmacopoeia Commission (IPC) is an autonomous Institution of Ministry of Health & Family Welfare, Government of India, engaged in evaluation and quality control of drugs and to deal with matters relating to timely publication of the Indian Pharmacopoeia (IP) which is the official document of standards for drugs. The mandate of the commission is to perform inter-alia functions such as revision and publication of Indian Pharmacopoeia (IP) and National Formulary of India (NFI) on a regular basis besides providing IP Reference Substances and training to the stakeholder on Pharmacopoeial issues and also functioning as National Coordination Centre (NCC) for Pharmacovigilance Programme of India (PvPI).



Pharmacovigilance Programme of India (PvPI)

GENESIS

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

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 adverse reactions in the general population is very high and under-recognized. It is, therefore, imperative to evaluate the safety of medicines by specialized methods like Pharmacovigilance.

The Ministry of Health and Family Welfare, Government of India recasted PvPI on April 15, 2011, shifting the National Coordination Centre (NCC) from AIIMS, New Delhi to Indian Pharmacopoeia Commission (IPC), Ghaziabad.

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

Highlights 2018-19

PvPI all set to address Delamanid/Bedaquiline safety in India

Seven states identified for active surveillance

WHO-BMGF 3S Project unveiled

3S Project aims at strengthening PV at LMICs in Asia

9 drug alerts and 18 package insert updates

PvPI database mined for safety alerts and signals

5th Asia-Pacific PV Training

IPC in collaboration with UMC conducted PV training for 30 participants from 14 countries

Imparting knowledge to global partners

Delegates from Drug Regulatory Authorities Bhutan, North Korea and Botswana trained in capacity-building for PV

2nd Annual meet of SEARN in Sri Lanka: PvPI action plan

Information-sharing and convergence of regulatory services across the region

Medical Devices Information sharing portal

MvPI launched seamless information sharing tool for manufacturers of medical devices

Adverse Drug Reaction Monitoring System (ADRMS)

Developing indigenous tool to collect adverse events for patient safety.

Expansion of PvPI from existing 250 AMCs to 270 AMCs

PvPI enrolled 20 New AMCs to reach common masses

Regular workshops on establishment of PV system in Pharma Industry

Enhanced participation of MAHs in ADR-reporting

Information Brochure of PvPI

Pharmacovigilance Programme of India (PvPI) published an Information Brochure highlighting the evolution, structure, methods of ADR reporting, collaboration, skill development and capacity building of the programme. This Brochure shall serve the purpose of providing glimpses of PvPI and its activities to the stakeholders of different domains including Ministry of Health and Family Welfare, WHO, other National Coordination Centers of different countries, Regulatory Bodies, healthcare professionals and consumers.

let us join hands with PvPI to ensure patient safety

 www.ipc.gov.in

 Toll Free No.
1800 180 3024

 NCC-Pvpi ipc

 @ IPC NCC-Pvpi

 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-03, Mayapuri, Ghaziabad-201002
Tel.: 0120-2763400, 2763401, 2763392
Fax: 0120-2763311

For any Other Information/Suggestions/ Query contact:
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Email: ipclab@vsnl.net, pvpi@ipcindia.net **Website:** www.ipc.gov.in

 **Indian Pharmacopoeia Commission**
Ministry of Health and Family Welfare, Government of India



Published by
Indian Pharmacopoeia Commission

PvPI upfront as WHO-Collaborating Centre

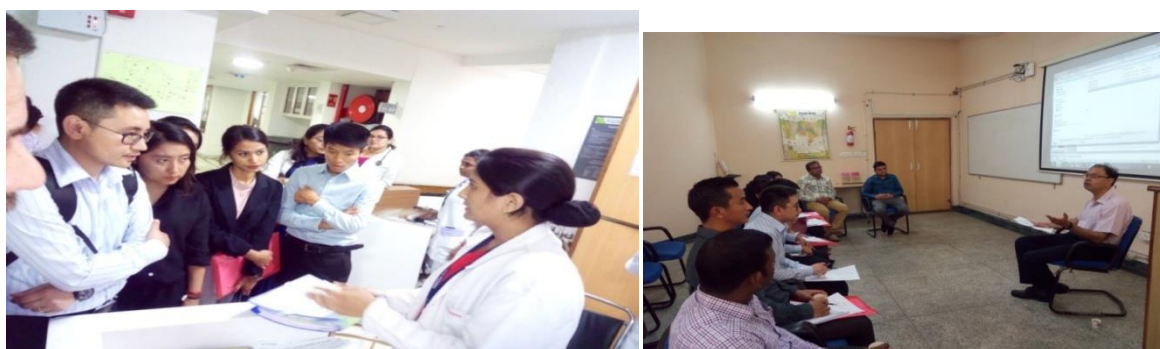
After the recognition of NCC-PvPI, IPC on July 2017 as a WHO-Collaborating Centre for Pharmacovigilance in Public Health Programmes and Regulatory Services for SEARN countries, PvPI, IPC during Index Period April 2018-March 2019 has initiated many programme aimed at capacity-building and strengthening of PV systems in SEARN countries.

Following the launch of WHO-CC at Indian Pharmacopoeia Commission, Ghaziabad in October 2017, a synopsis of the events is represented herein:

Event: Venue and Date	Action and Outcome
“Two-day National Workshop on Good Pharmacovigilance Practices (GvPs)” held at Mumbai on March 15-16, 2018	<ul style="list-style-type: none"> • Held technical collaboration with USFDA to identify challenges in implementation of GvPs • Speeding up decision-making in signal detection • Feedback- Regular workshops for training MAHs on GvPs needs to be conducted in future
2 nd Annual Meet of SEARN Countries held at Colombo, Sri Lanka on March 21-23, 2018	<ul style="list-style-type: none"> • SEARN to enhance information-sharing, collaboration and convergence of regulatory practices across the region to guarantee access to quality medical products • PvPI proposes support/services action plan to the SEARN member-countries
“Four-day PV Training-cum-Workshop for DRA officials, Govt of Bhutan” held at IPC on June 11-14, 2018	<ul style="list-style-type: none"> • Conceptual training on basic, technical and regulatory aspects of Pharmacovigilance (PV) and its procedures in India • Delegates trained on ICSR processing (E2B-XML format), quality management system (QMS), Causality Assessment, Materiovigilance Programme of India (MvPI), hands-on VigiFlow exercise, etc
“ Three-day PV Training-cum-workshop for DRA officials of North Korea” held at IPC on November 12-14, 2018	<ul style="list-style-type: none"> • Basic training on Quality Management System (QMS), Signal detection, benefit-risk assessment, training and education activities of PvPI • 11th Skill Development Programme on “Basics and Regulatory Aspects of Pharmacovigilance”
5 th Asia- Pacific PV Training Course March 4-15, 2019 at Fortune Inn Grazia, Ghaziabad, India	<ul style="list-style-type: none"> • Participants acquired adequate knowledge and skills for establishing and strengthening Pharmacovigilance system at their respective organization/country • Enhanced potential for capacity-building in PV for public health programmes of participating countries • Helped enhance global reputation of Indian Pharmacopoeia Commission
Two-day PV Training-cum-workshop for “DRA officials of Botswana” held at IPC on March 18-19, 2019	<ul style="list-style-type: none"> • Acquainted with system and procedures at PvPI for collecting, processing and analyzing ADRs • Sensitized about Quality Management System, risk communications and PV in Public Health Programmes

DRA-Bhutan visits IPC for PV, MvPI training

Delegates from Drug Regulatory Authority (DRA) of Bhutan visited Indian Pharmacopoeia Commission (IPC), Ghaziabad for conceptual training on basic, technical and regulatory aspects of Pharmacovigilance (PV) and its procedures in India. This platform provided the opportunity to share healthcare safety and management systems prevalent in both countries. The visiting delegates attended technical sessions and seminars conducted by Pharmacovigilance Programme of India (PvPI) officials and experts and also made field-visits to AIIMS-National Drugs Dependence Treatment Centre (NDDTC), Ghaziabad, UP and Yashoda Hospital, Kaushambi, UP (both AMCs under PvPI).



5th Asia-Pacific Training Course @IPC

Indian Pharmacopoeia Commission (IPC), Ministry of Health & Family Welfare, Government of India in collaboration with Uppsala Monitoring Centre (UMC), Sweden, organized the 5th “Asia-Pacific Pharmacovigilance Training Course” from March, 4-15, 2019 at Hotel Fortune, Ghaziabad. As many as 30 participants from 14 countries, including Sweden, Zimbabwe, Malawi, Congo, Swaziland, Bangladesh, Vietnam, Maldives, Botswana, Oman, Philippines, Malaysia, Ethiopia, and India, attended the training programme.

The purpose of the course was to further develop effective and sustainable Pharmacovigilance practices for member-countries of the WHO Programme for Drug Monitoring and individuals involved in the field by creating a unique opportunity for learning and collaboration. The training programme was designed to meet regional needs and challenges unique to Pharmacovigilance. International Pharmacovigilance experts from WHO, WHO-Collaborating Centres, MHRA, UMC, Drug Regulatory Authorities, academic institutions, IPC and pharmaceutical industries addressed technical sessions blended by hands-on training.



Training-cum-Workshop for DRA officials-Botswana

A two days training cum workshop was organized at Indian Pharmacopoeia Commission, Ghaziabad for DRA officials of Botswana on March 18-19, 2019. The participants were acquainted with system and procedures at PvPI for collecting, processing and analyzing ADRs. Also Sensitized them on Quality Management System, risk communications and PV in Public Health Programmes.



PvPI: An Overview

Pharmacovigilance Programme of India (PvPI) was operationalised in July 2010 by Ministry of Health & Family Welfare (MoHFW), Government of India (GoI), through a workshop organized by the Department of Pharmacology, AIIMS, New Delhi. Its mission was to monitor/improve patient health by safe administration of drugs, thus reducing the risk associated with use of medicine in Indian population. AIIMS, New Delhi was established as National Coordination Centre (NCC) for Pharmacovigilance Programme of India (PvPI). However, MoHFW, GoI on April 15, 2011 recasted the programme and shifted the NCC from AIIMS, New Delhi to Indian Pharmacopoeia Commission (IPC), Ghaziabad.

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.

PvPI: 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 constituted at NCC-PvPI 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 which reports to the CDSCO for regulatory interventions.

Quality Review Panel

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

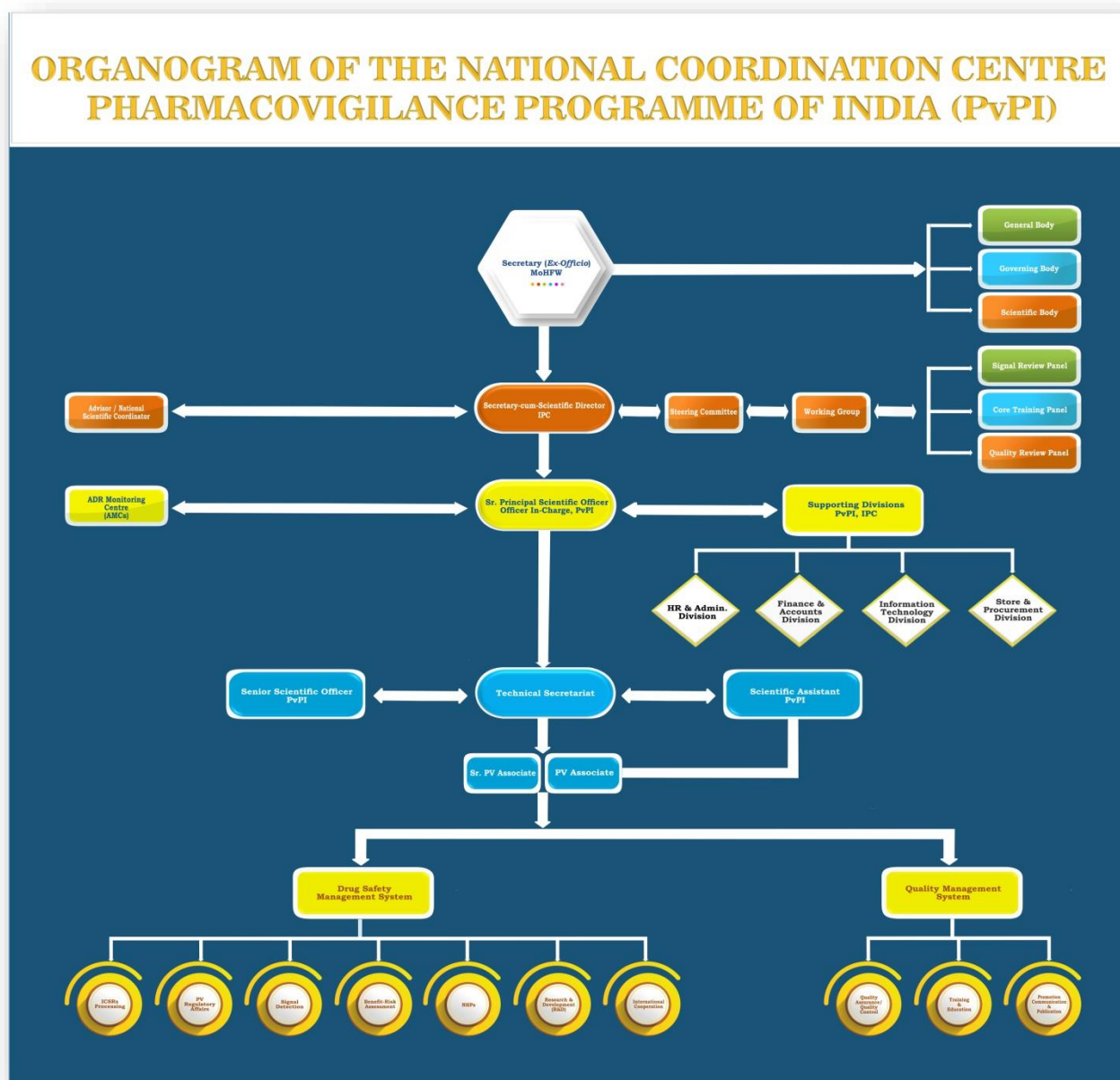
Signal Review Panel (SRP)

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 (CTP)

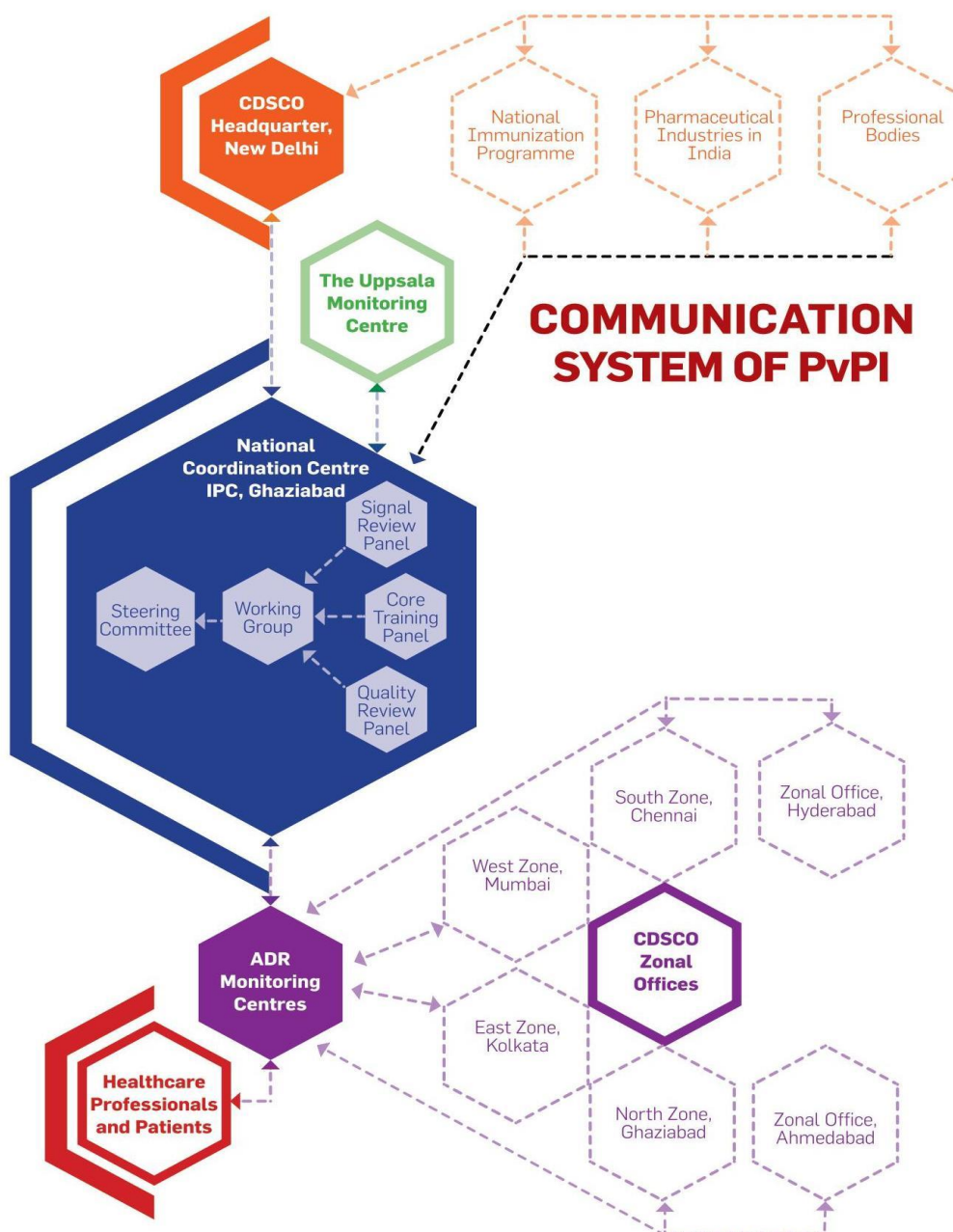
The Core Training Panel (CTP) of PvPI guides in identification of training needs, organizing national and international training programmes, designing training modules and helps conduct the training for healthcare professionals and other stakeholders throughout the year. It also identifies trainers for zone-wise training centers. The CTP interacts with national and international agencies for participation and implementation of training programmes in Pharmacovigilance. Core Training Panel is assisted by the internal training team of PvPI.

Organogram of PvPI



PvPI Communication Channels

Coherent and flawless communication channels are key to successful functioning of any programme. The dissemination of knowledge and expertise at NCC-PvPI percolates to the target audience and across the board to the AMCs affiliated to it with 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:



Reporting ADRs

WHO CAN REPORT?



Consumers/Patients



Physicians



Pharmacists



Nurses



Healthcare Professionals

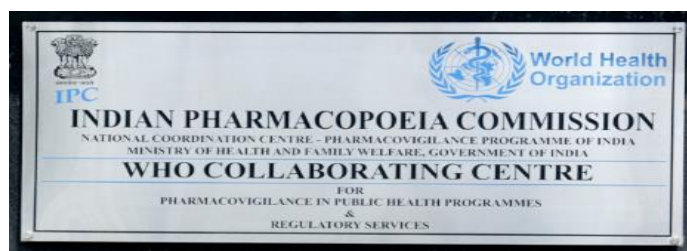


Pharmaceutical Companies



ADR Monitoring Centres

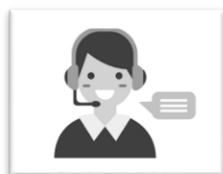
WHOM TO REPORT?



National Coordination Centre (NCC), form available on the official website of IPC (<http://www.ipc.gov.in>) or the CDSCO (<http://www.cdsco.nic.in>)



Nearby AMCs



PvPI Helpline

(1800-180-3024)



PvPI Mobile App

ADR PvPI



icsr.nccpvpi@gmail.com

pvpi.compat@gmail.com

WHY TO REPORT?

- For health safety
- Risk-optimization of drugs by evidence-based research
- Data help to make safe use of medicines
- Prompting regulatory action by omnibus database
- Raising awareness level to report ADRs

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

Off-label Use:

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

Misuse:

- Use of a medication (for a medical purpose) other than as directed or as indicated
- Taking medicine more/more often or for longer period of time

Overdose:

- Ingestion/application of a medicine in quantities much greater than recommended
- An overdose may be intentional/accidental

Abuse:

- Nonmedical use of a substance for psychic effect, dependence, or suicide attempt or gesture
- All recreational use of substances for any reason

Special focus on drug use in:

- Pregnancy
- Lactation
- Paediatric population
- Geriatric population

Channels for reporting AE/ADR

Suspected ADR Form for Healthcare Professionals (HCPs)



SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

Version-1.3

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			Reg. No. /IPD No. /OPD No. /CR No. :
1. Patient Initials	2. Age at the time of Event or Date of Birth	3. M <input type="checkbox"/> F <input type="checkbox"/> Other <input type="checkbox"/>	AMC Report No. :
4. Weight _____ Kgs			Worldwide Unique No. :
B. SUSPECTED ADVERSE REACTION			12. Relevant tests/ laboratory data with dates
5. Event/Reaction start date (dd/mm/yyyy)			13. Relevant medical/medication history (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/renal dysfunction, past surgery etc.)
6. Event/Reaction stop date (dd/mm/yyyy)			
6 (A). Onset Lag Time			
7. Describe Event/Reaction with treatment details, if any			

Available on IPC website (www.ipc.gov.in) or CDSCO site (www.cdsc.nic.in) and in National Formulary of India 2016

Medicines Side-Effect Reporting Form (For Consumers)



MEDICINES SIDE EFFECT REPORTING FORM (FOR CONSUMERS)

Version 1.0
संस्करण 1.0

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 आद्याक्षरः	Gender/ लिंग (V): Male/ पुरुष <input type="checkbox"/> Female/ स्त्री <input type="checkbox"/>	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 (V): Doctor/ डॉक्टर <input type="checkbox"/> Pharmacist/ फार्मासिस्ट <input type="checkbox"/> Friends/Relatives/ मित्र/ रिश्तेदार <input type="checkbox"/>		
Self (Past disease experienced/No past disease experienced)/ स्वयं (पूर्व बीमारी का अनुभव/पूर्व बीमारी का कोई अनुभव नहीं) <input type="checkbox"/>		
3. Details of Person Reporting the Side Effect/ दुष्प्रभाव की सूचना देने वाले व्यक्ति का विवरण		
Name (Optional)/ नाम (वैकल्पिक):		
Address/ पता:		

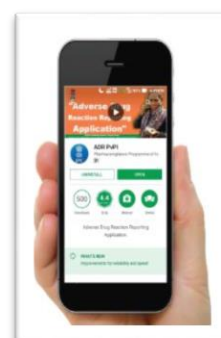
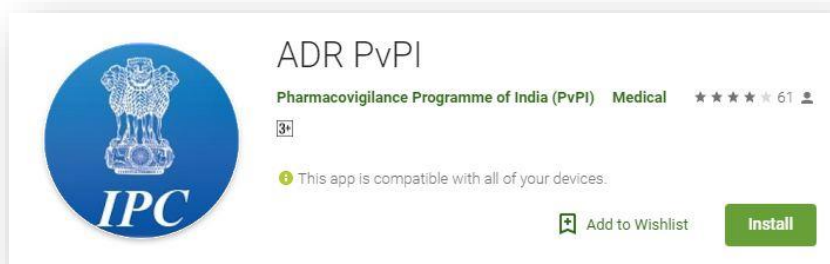
Available in 10 Indian languages: **Hindi, Bengali, Gujarati, Kannada, Malayalam, Marathi, Assamese, Oriya, Tamil and Telugu**

PvPI Helpline

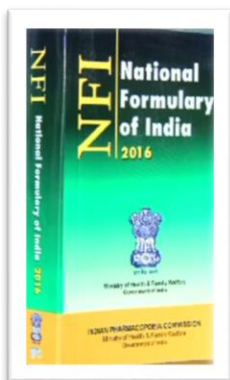


Patients/Consumers/Healthcare Professionals may report to NCC-PvPI via tollfree Helpline 1800-180-3024 any suspected ADRs associated with use of medicinal/herbal products/vaccines or medical devices.

e-Reporting of ADRs : Mobile App



Indigenously-developed mobile app “ADR PvPI”, which was dedicated to the nation by former Union Health Secretary Shri C K Mishra on September 29, 2017, has been instrumental in equipping all healthcare stakeholders, including the common man, for reporting ADRs.



National Formulary of India (NFI):

NFI serves as a guidance document to medical practitioners, pharmacists working in hospitals and in retail establishment, nurses, medical and pharmacy students and other healthcare professionals. The principle 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.

SMS- Alerts:

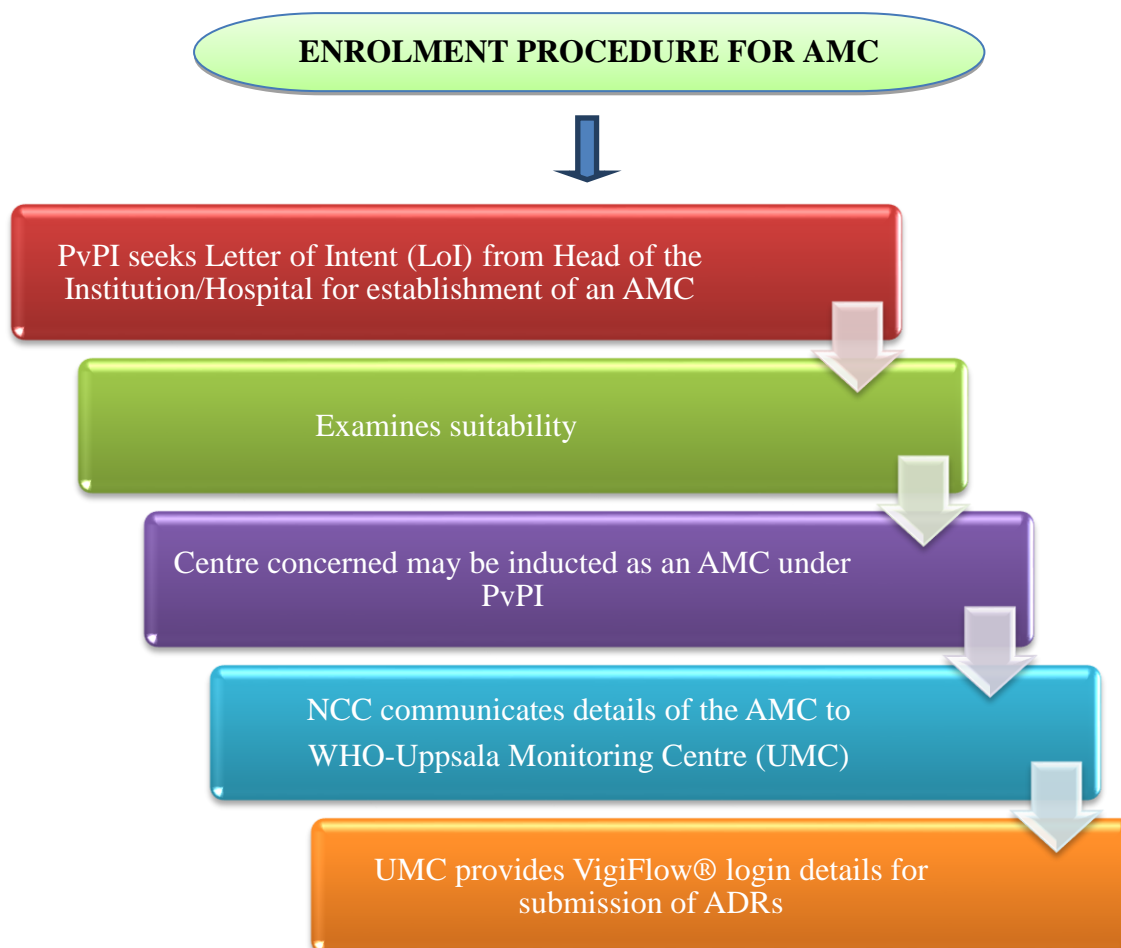
NCC-PvPI regularly sends drug alerts to approx 10,650 stakeholders through short messaging service.

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) across the country play a crucial role in monitoring ADRs.

WHO CAN ENROLL?

- Government hospitals/medical colleges
- Private hospitals/medical colleges
- Corporate hospitals
- District hospitals
- Primary/Community Health Centres in India



CRITERIA FOR ENROLMENT OF AMCs

- ❖ Availability of logistic and infrastructural facilities for PV at the Centre
- ❖ Significant track-record of the Centre in Pharmacovigilance – on quality, quantity and frequency of Adverse Drug Reaction (ADR)-reporting
- ❖ States/ Union Territories where no/few AMCs exists will be preferred
- ❖ Geographical location based selection of AMCs
- ❖ HoD/Dean/Principal of the proposed Centre to establish/implement PvPI activities at the Centre
- ❖ Significant track-record/expertise of the proposed AMC coordinator/deputy coordinator in Pharmacovigilance

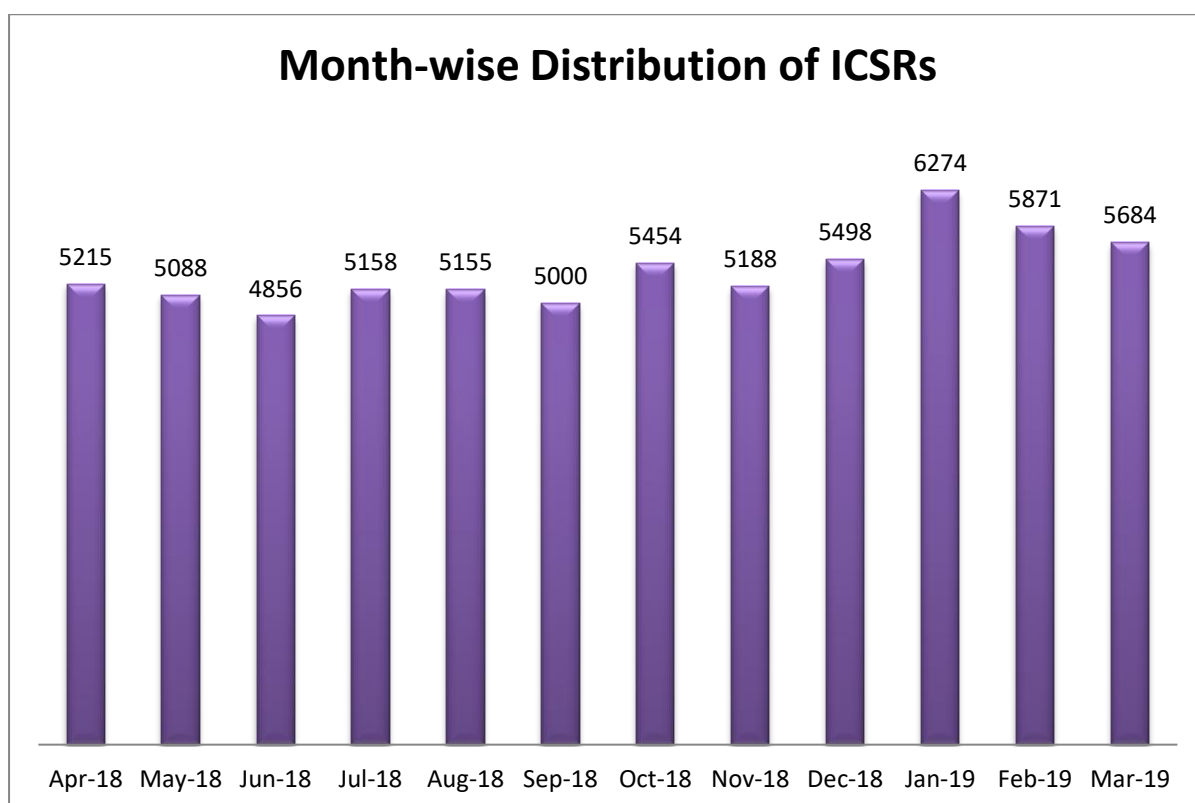
CRITERIA FOR DE-ENROLLMENT/DERECOGNITION OF AMCS

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

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

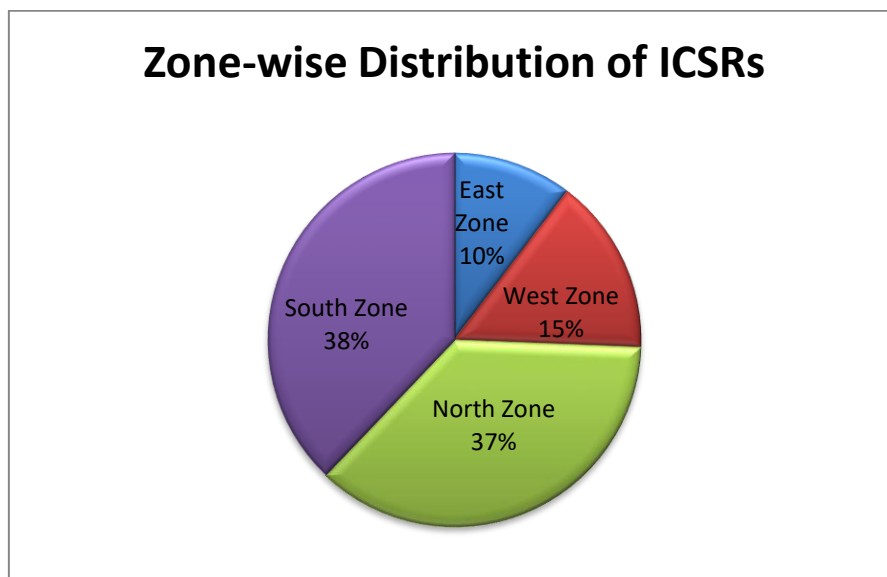
ICSR database at PvPI

The Pharmacovigilance Programme of India (PvPI) is responsible for collection, assessment and detection and communication of risks associated with the use of medicines in Indian population. The ADRs collected by the ADR monitoring Centres and MAHs are communicated to NCC-PvPI in the form of Individual Case Safety Report (ICSR). The annual database accounts 64, 441 ICSRs for the index period. Reporting patterns are on the increase every year and have shot up in recent years.



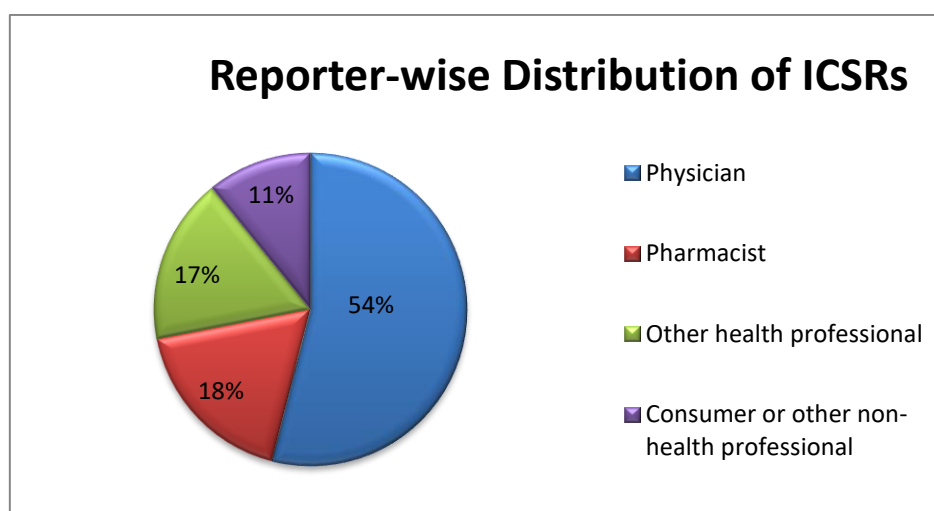
Zone-wise ICSRs from AMCs

ADR Monitoring Centres (AMCs) across the country are located in different zones. Data represents percentage of ICSRs received during Index Period – April 2018-March 2019 from all four zones of India.



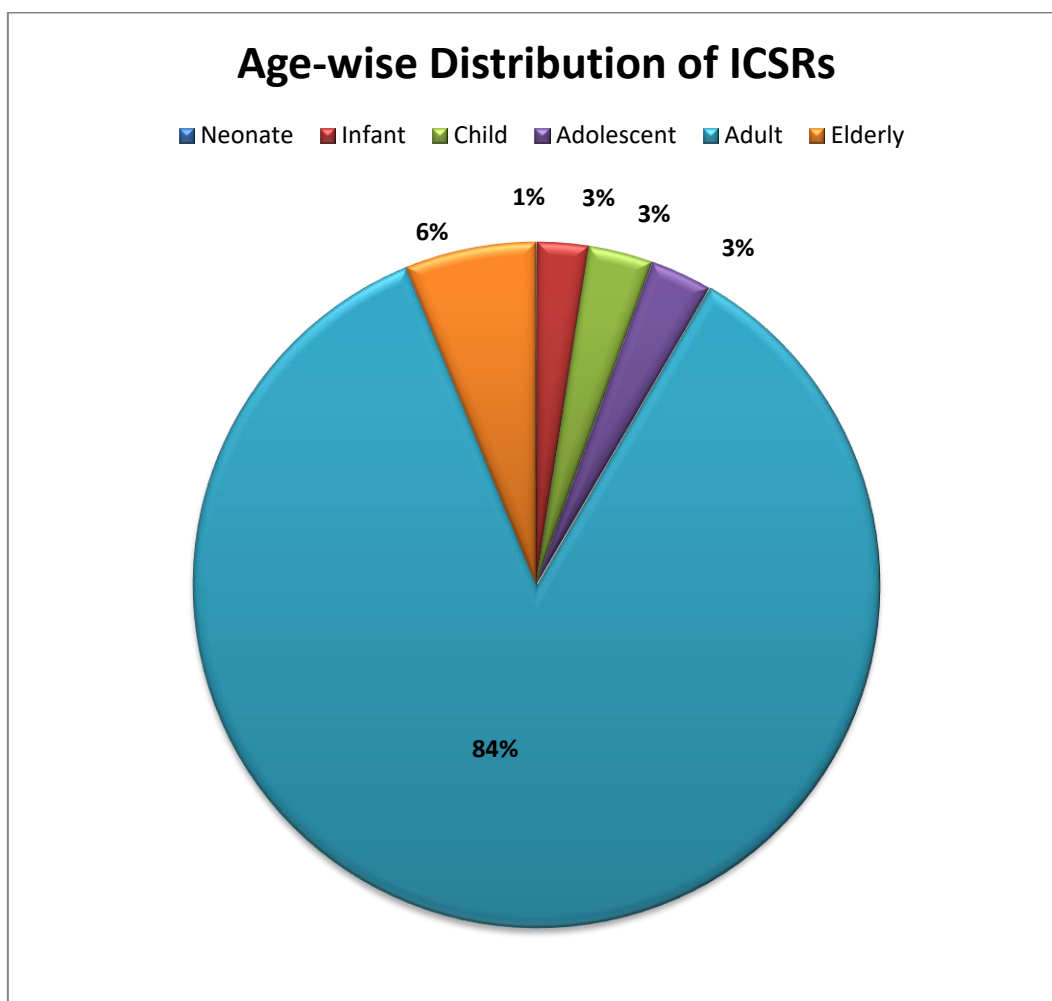
Reporter-wise distribution of ICSRs

NCC-PvPI receives ICSRs from various stakeholders such as physicians, pharmacists, other HCPs, consumers (non-HCPs), etc. Spontaneous ADR reports from physicians (54%) continue to be the major source of reports received, followed by pharmacists (18%), other healthcare professionals (17%), consumers (11%) and lawyers.



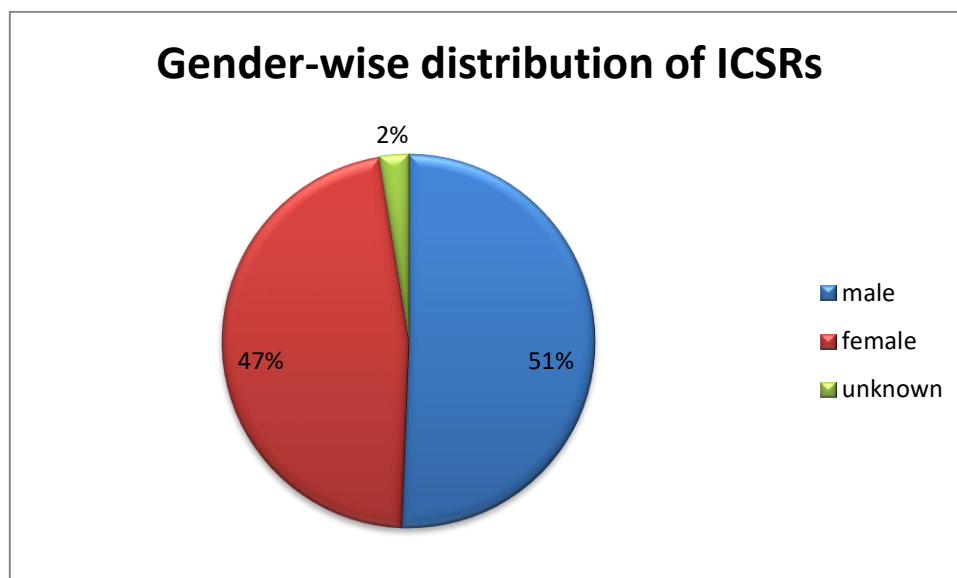
Age-wise ICSRs:

Analysis of the ADR forms received during the Index Period shows that among all age groups, the highest percentage of ADRs is reported in adults and the lowest in neonates.



Gender-wise ICSRs:

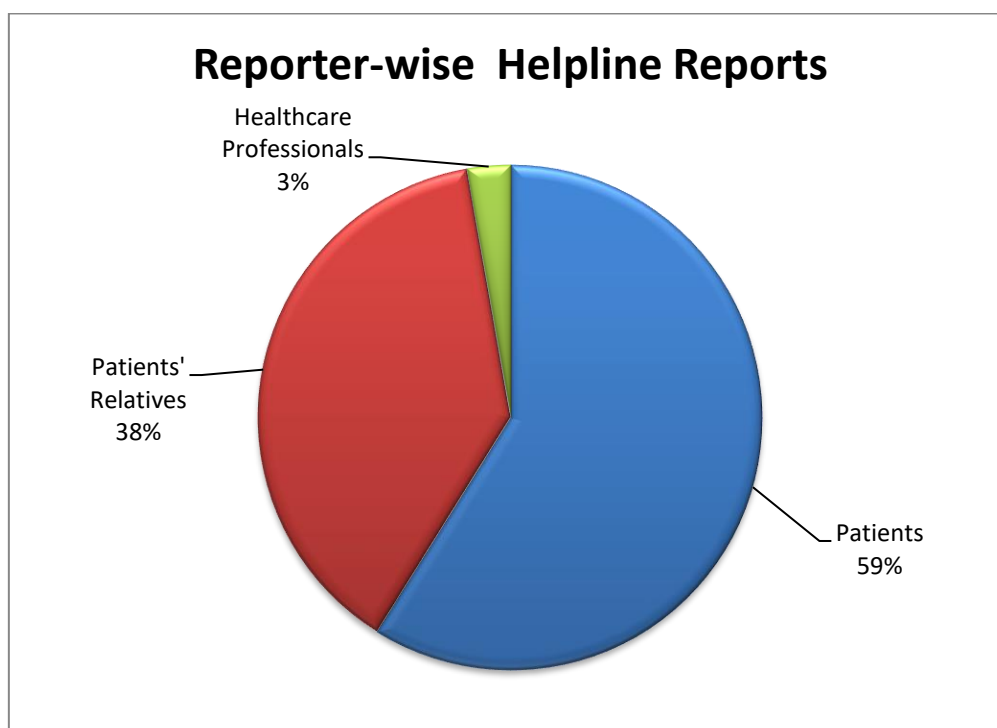
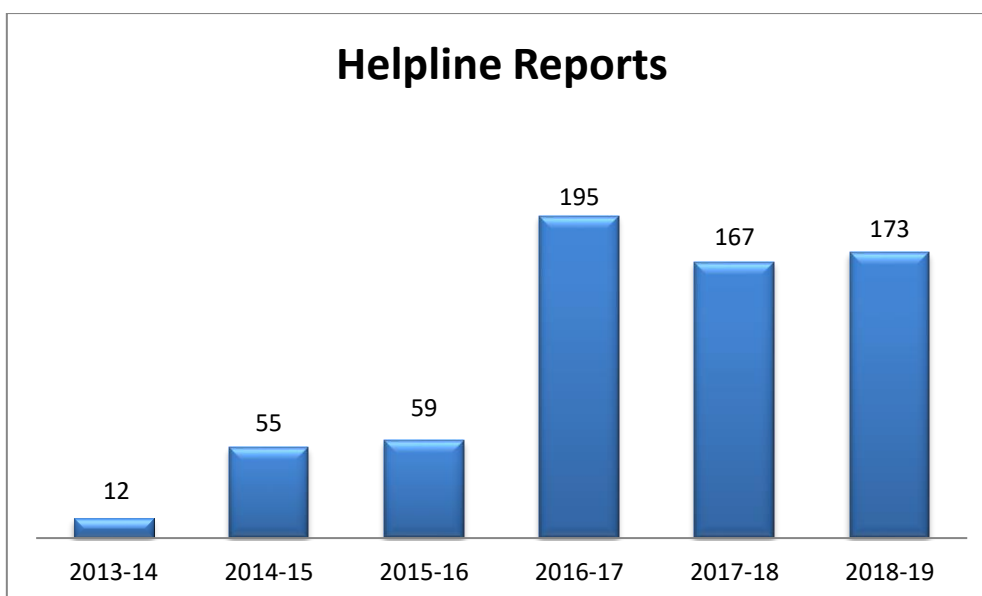
Database for the Index Period reveals that 51% ADRs occurred in male patients and 47% in female patients. No information about the gender of the patient was provided in 2% of ADR reports.



PvPI Helpline (Tollfree):

Tollfree Helpline was initiated on October 11, 2013, since then it has been serving as one of the reliable tools for reporting suspected adverse events. Patients/ Consumers/Healthcare Professionals report suspected adverse events due to the use of medical products/devices. With the continuous efforts of Pharmacovigilance officials posted at AMCs, helpline facility has been excelling in India. Calls are primarily responded to in English and Hindi on all working days between 09:00 AM and 05.30 PM.

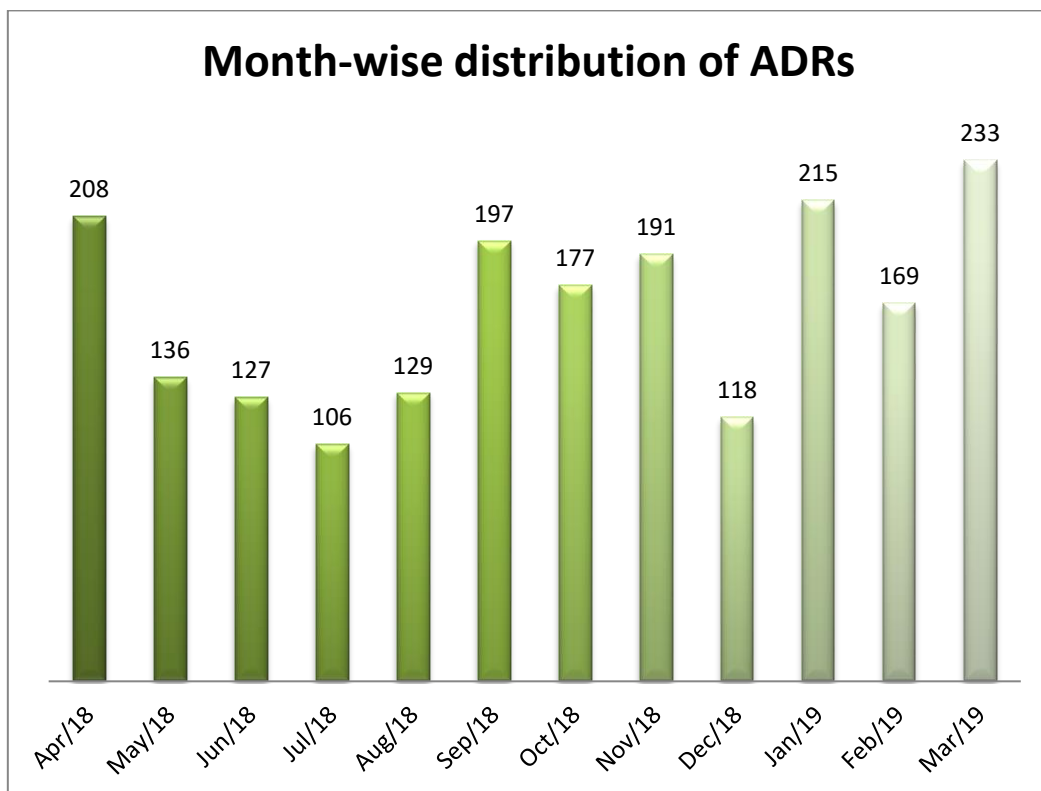
Language of Service: English and Hindi



ADR-reporting through Non-AMCs

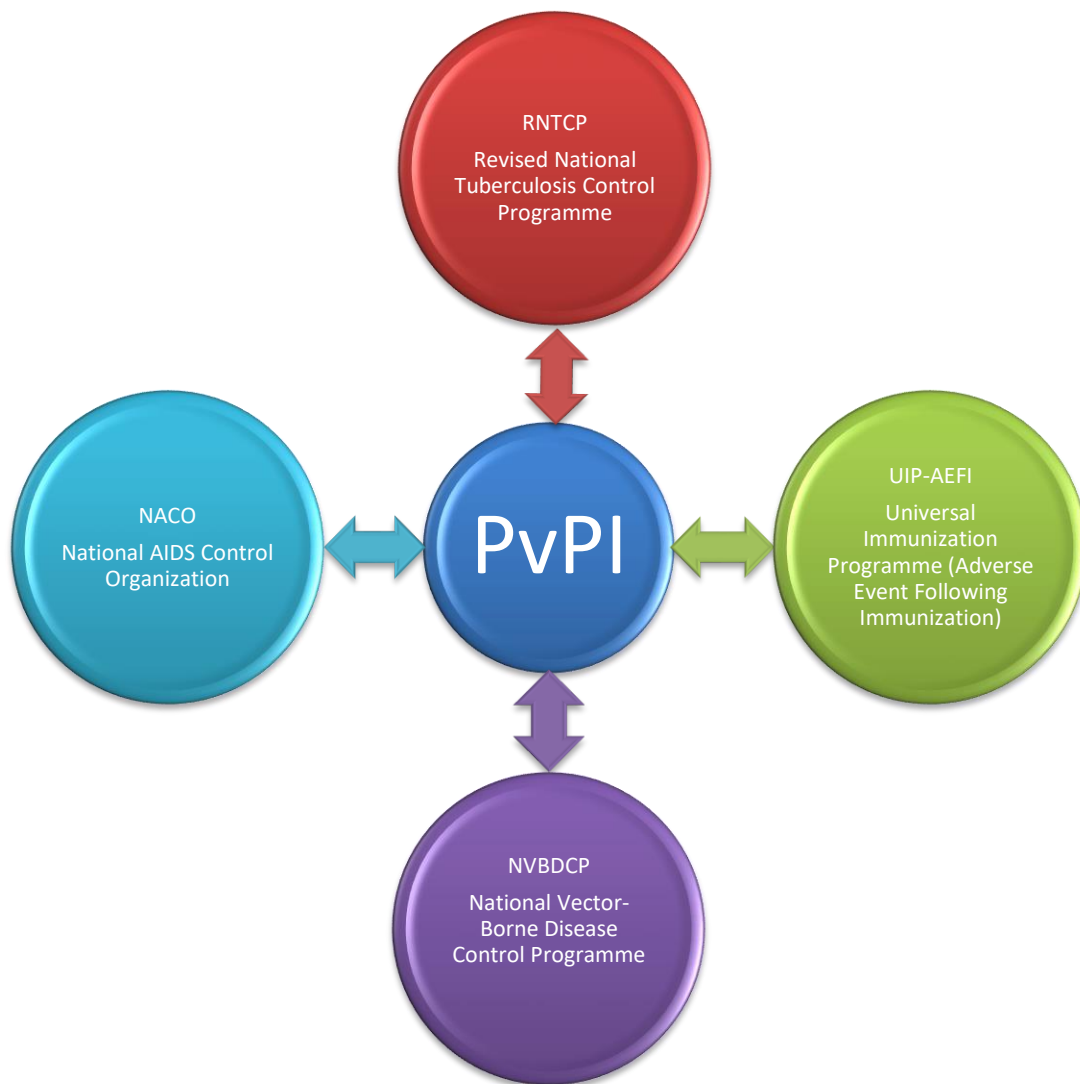
Besides monitoring ADRs at the regional monitoring centres (AMCs), NCC-PvPI, also received ADRs through several hospitals and medical colleges (non-AMCs) across India. The non-AMCs send the suspected ADRs; filled-in the Suspected ADRs reporting form to a dedicated email; icsr.nccpypi@gmail.com. Further, these reports are processed for causality assessment at the nearby AMC and communicated to WHO-UMC through

VigiFlow. During the index period, as many as 2,006 ADRs were reported via non-AMCs, month-wise distribution of these ADRs is depicted below:



PvPI integration with Public Health Programmes

PvPI Partners

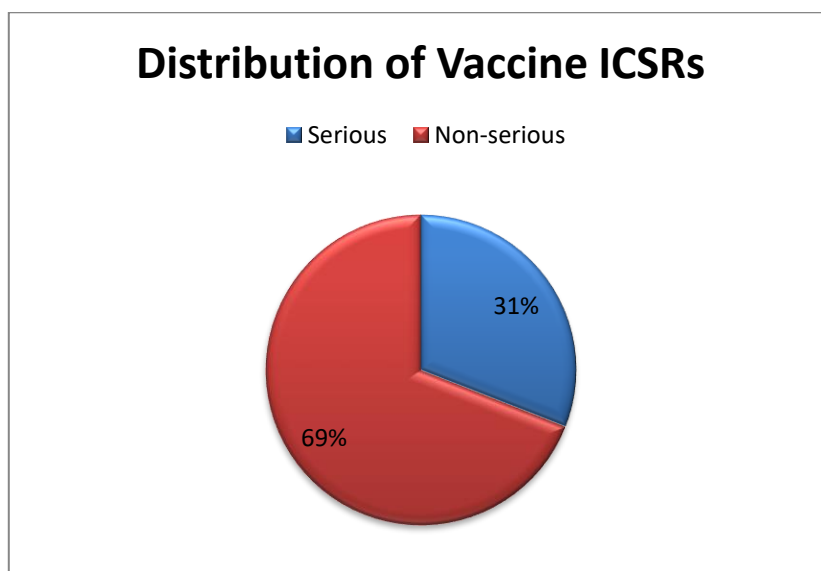


Reports:

S. No.	Reports	2017-18	2018-19
01	RNTCP	1230	1367
02	ART	476	375
03	AEFI	795	879
04	NVBDCP	58	228

Status of ICSRs of vaccines: Reporting, Collation & Analysis

During the Index Period (April 2018-March 2019), NCC-PvPI received 879 vaccine-related ICSRs. All vaccine ICSRs were processed and analysed at NCC-PvPI. Among the 879 ICSRs, 272(31%) cases were serious.

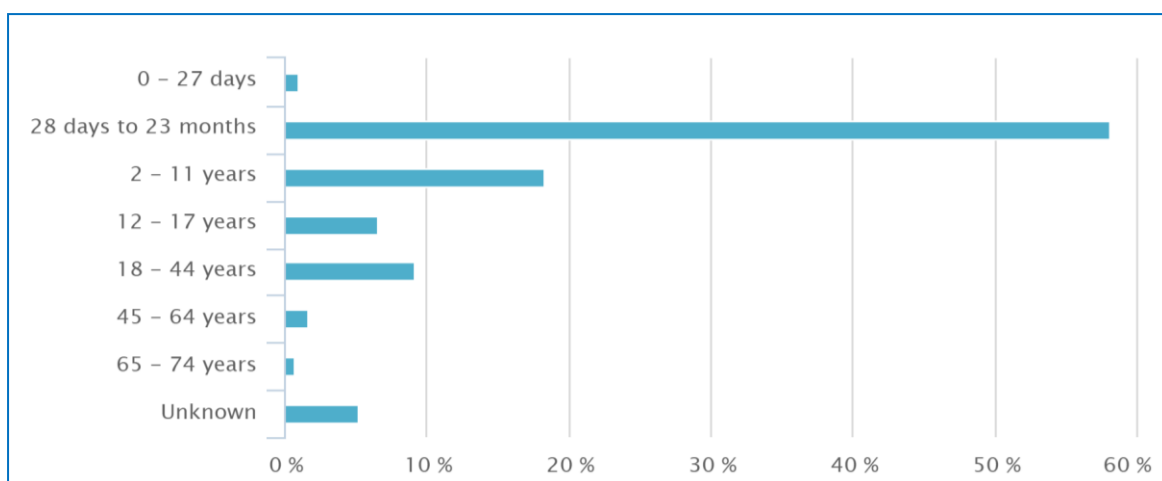


Distribution of adverse events due to vaccines:

S.No	Vaccine	No. of ICSRs	Percentage
1	Encephalitis vaccines	7	1.9
2	Influenza vaccines	22	6.0
3	Hepatitis vaccines	36	9.8
4	Measles vaccines	195	53.1
5	Poliomyelitis vaccines	29	7.9
6	Rabies vaccines	34	9.3
7	Rota virus diarrhea vaccines	32	8.7
8	Rubella vaccines	2	0.5
9	Varicella zoster vaccines	21	5.7
10	Yellow fever vaccines	5	1.4
11	Papillomavirus vaccines	8	2.2
12	Cholera vaccines	5	2.7
13	Diphtheria vaccines	2	1.1
14	Hemophilus influenzae B vaccines	8	4.3
15	Meningococcal vaccines	3	1.6
16	Pertussis vaccines	86	45.7
17	Pneumococcal vaccines	33	17.6
18	Tetanus vaccines	21	11.2
19	Tuberculosis vaccines	21	11.2
20	Typhoid vaccines	10	5.3

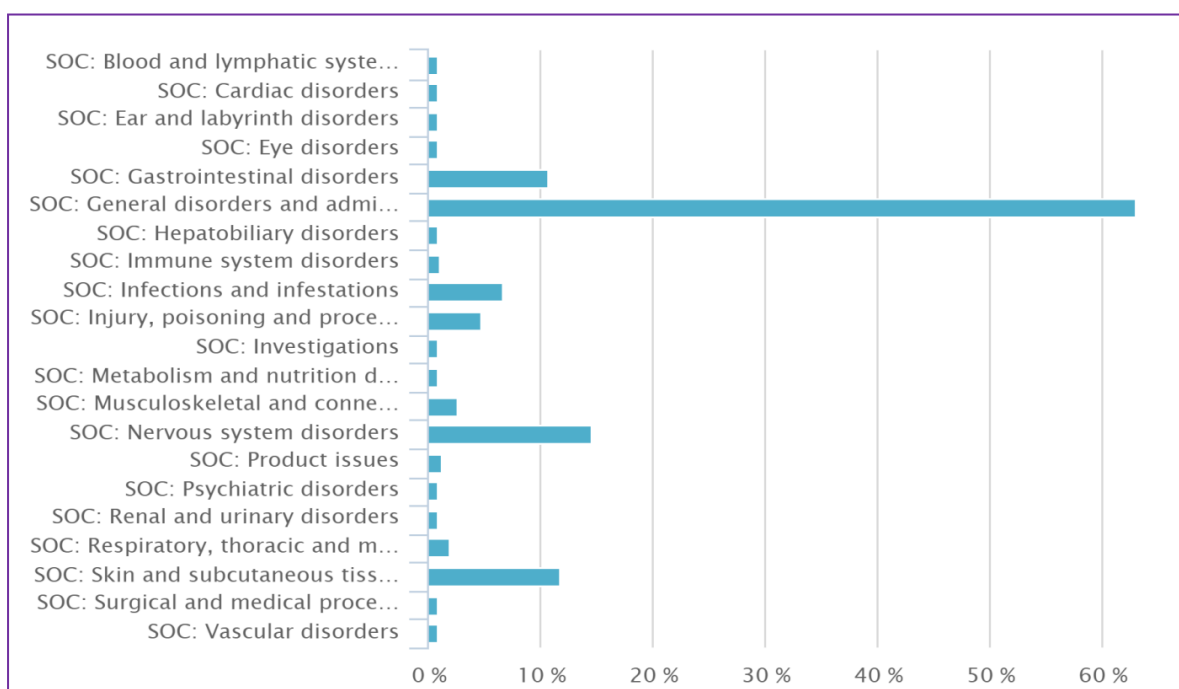
Age-wise Vaccine ICSRs:

Following chart represents the distribution of vaccine ICSRs among different age-groups, as many as 58% of Adverse Events Following Immunization (AEFI) were reported in age group of children from 28 days to 23 months.



System Organ Class (SOC) of AEs reported with Vaccines:

Analysis of vaccine ICSRs indicated that System Organ Class- General Disorders and Administration Site Conditions are involved in vaccine-associated adverse events.

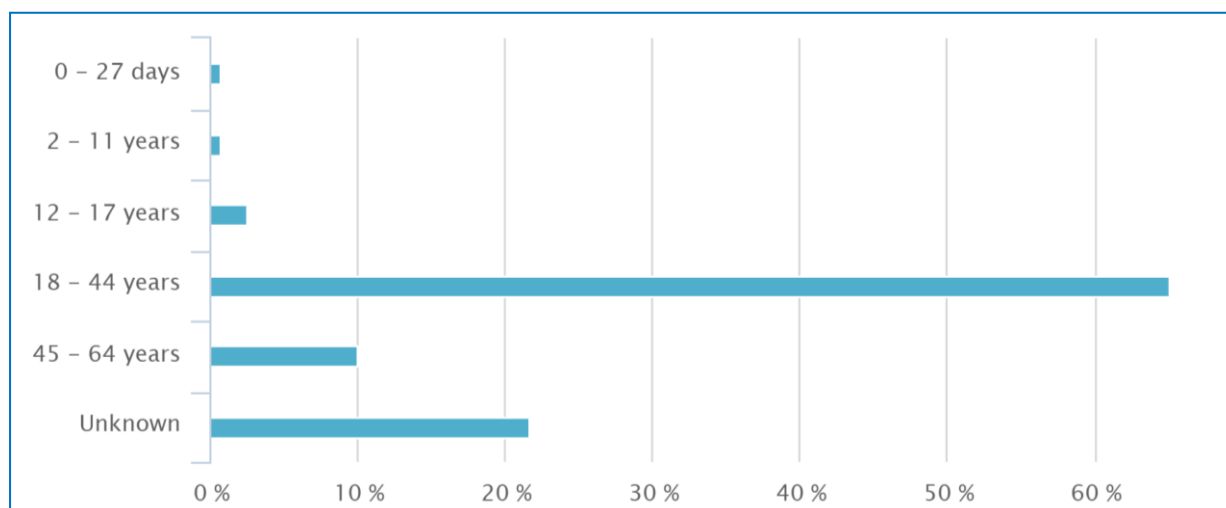


ICSR status of Anti-tubercular drug -Bedaquiline:

Bedaquiline as a treatment for Multi-Drug Resistant Tuberculosis (MDR-TB) was approved by DCGI in March 2016 as part of the Revised National Tuberculosis Control Programme (RNTCP). Six identified tertiary care centres across India are approved to prescribe Bedaquiline, having advanced facilities for laboratory testing and intensive care for patients.

PvPI in technical collaboration with WHO and RNTCP has initiated active surveillance. During this index period, NCC-PvPI received **240** Bedaquiline-related ICSRs. Analysis of the data is represented below:

Age-wise distribution of Bedaquiline ICSRs

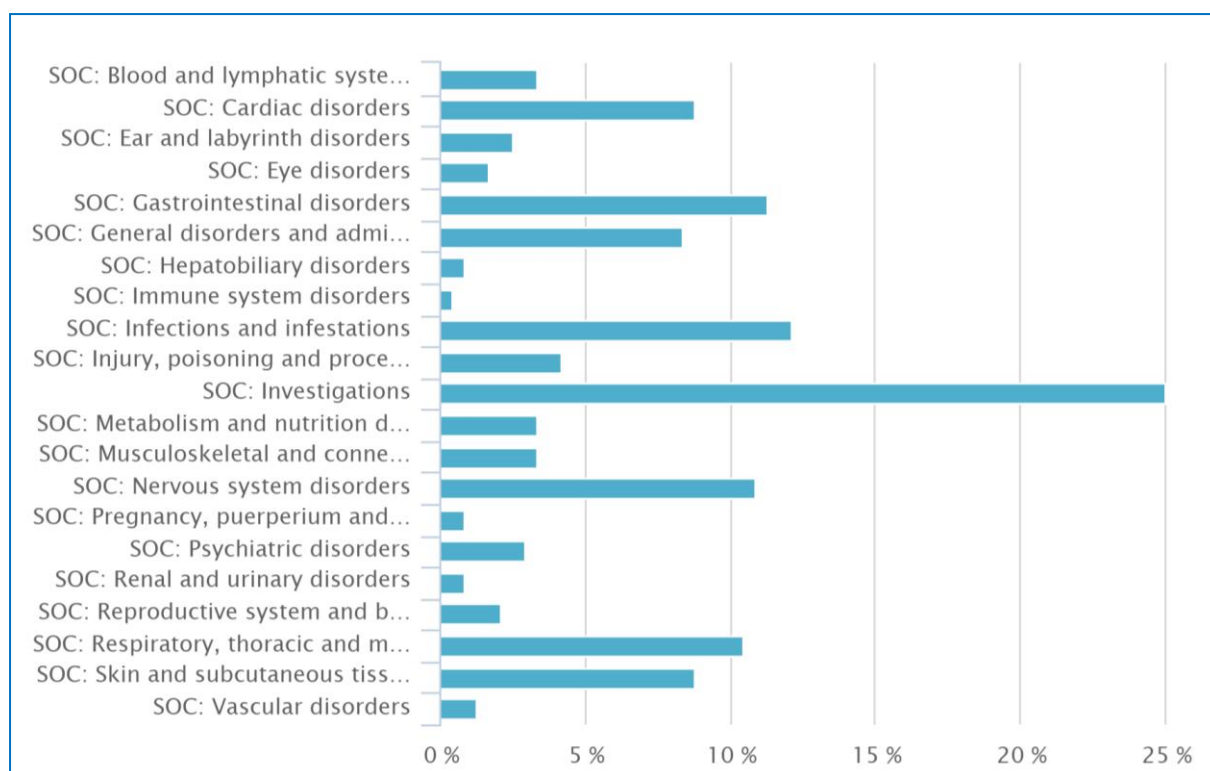


Gender-wise distribution of Bedaquiline ICSRs

S.No.	Patient sex	No. of ICSRs	Percentage
1	Female	87	36.3
2	Male	102	42.5
3	Unknown	51	21.3

System Organ Class (SOC) of Bedaquiline ICSRs:

Data mining through VigiLyze represents the association of various SOC's with adverse effects of Bedaquiline, which are represented below:



Utilization of ICSR data derived from NHP:

Drug Alerts:

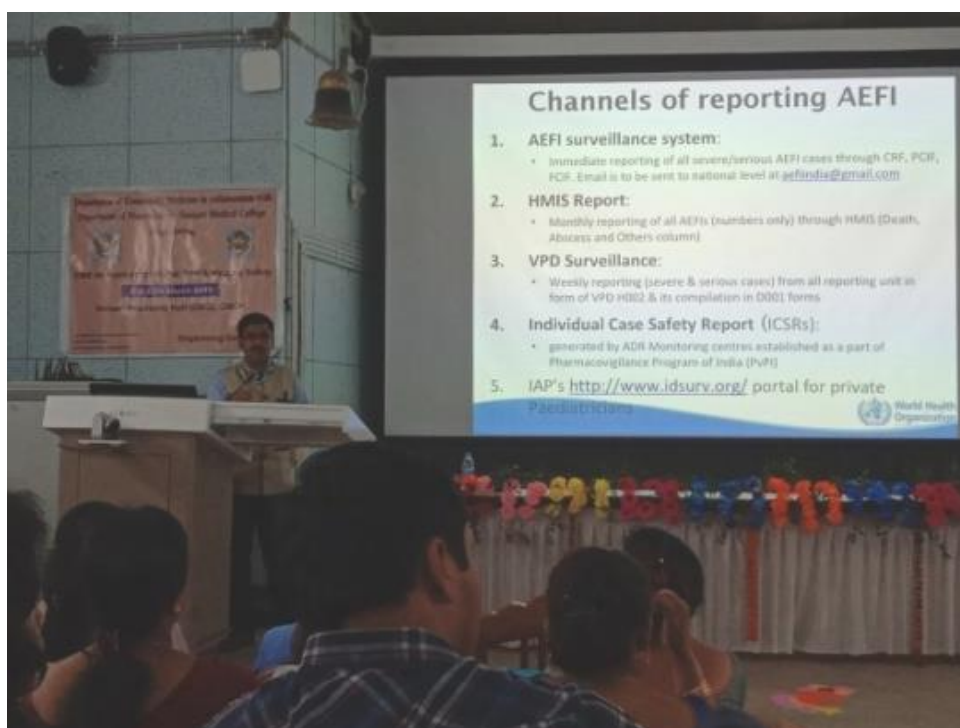
Suspected Drug	Adverse Reaction
Miltefosine	Acute Pancreatitis

CMEon ‘Academic Clinical Trial & Vaccine Safety’

Adverse Drug Reaction Monitoring Centre (AMC), Guwahati, in collaboration with Department of Pharmacology and Department of Community Medicine, Guwahati Medical College & Hospital, organised on March 23, 2019 a Continuous Medical Education (CME) programme on “Academic Clinical Trial and Vaccine Safety”.

The symposium had distinguished guests Prof Bikash Medhi, PGIMER, Chandigarh, Prof Santanu Kumar Tripathi, STM, Kolkata and Dr Subhajit Bhattacharjee, WHO Consultant along with other experts from WHO.

The CME focused on vaccine safety, AEFI, how to report an ADR for a vaccine, the role of PvPI in AEFI data collection, filling-up of ICSR form and collaboration with WHO for AEFI reporting. The CME was attended by 75 members, including faculty and students of various medical colleges in Assam.



Continuous Medical Education (CME) programme at Guwahati Medical College & Hospital

Four National AEFI Committee meetings and three Monthly Pharmacovigilance Partners' meetings conducted during the Index Period:

S. No.	National AEFI Committee Meeting	
	Date/Venue	Objective/Recommendation of Meeting
1	June 14, 2018 NIHFW, New Delhi	<ul style="list-style-type: none"> Strengthening of AEFI surveillance processes at state level
2	October 17, 2018 NIHFW, New Delhi	<ul style="list-style-type: none"> Review of AEFI cases reported following Japanese Encephalitis vaccine and Measles rubella vaccines Pharmacovigilance inspection at MAHs
3	December 19, 2018 NIHFW, New Delhi	<ul style="list-style-type: none"> Qualitative study of factors affecting reporting of AEFIs in districts Presentation by IPC representative on vaccine safety activities at PvPI
4	February 25, 2019 NIHFW, New Delhi	<ul style="list-style-type: none"> Power-Point Presentation by PvPI representative on signal detection of vaccines

S. No	Monthly Pharmacovigilance Partners' Meeting	
	Date and Venue	Recommendations/Outcome
1	July 26, 2018 UIP Division, MoHFW	<ul style="list-style-type: none"> Reporting of AEFI cases by AMCs with serious notification form
2	October 29, 2018 UIP Division, MoHFW	<ul style="list-style-type: none"> Sensitization of AMCs to AEFI reporting Update on AEFI training Proposed joint assessment for AEFI cases in selected states
3	January 28, 2019 UIP Division, MoHFW	<ul style="list-style-type: none"> Institutional Development Plan discussed point-wise with updates from all stakeholders (CDSCO, IPC, WHO and ITSU)

Two Internal Technical Committee meetings for Kala-azar conducted during the Index Period:

S. No	Internal Technical Committee meetings	
	Date/ Venue	Recommendations/Outcome
1	July 6, 2018 Seminar Hall, NVBDCP, DGHS, Shastri Park, New Delhi	<ul style="list-style-type: none"> • Update on ADR reporting status for Kala azar from 58 NVBDCP centres discussed • Data of Miltefosine and Ambisome presented to technical committee members and adverse drug reactions discussed in terms of seriousness, gender, age group and type of reporting • Role and responsibilities to be well defined for all partners • How to improve the reporting of anti-Kala azar drugs e.g. inclusion of ADR alert card, regular follow-up for patients, active watch for possible adverse drug reactions • Correlation of Indian ADR data with global data only for Miltefosine and Ambisome
2	February 26, 2019 Seminar Hall, NVBDCP, DGHS, Shastri Park, New Delhi	<ul style="list-style-type: none"> • Presentation of update by PvPI representative on ADR reporting status for Kala azar drugs from 58 NVBDCP centres • ADR reporting status for Miltefosine and Ambisome shared with technical committee members

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 focused approach on scientific innovation and rationality.

Audits:

External Audit: 01

Internal Audit: 01

Standard Operating Procedures:

Updated: 03 (Change Control)

- SOP for enrolment of new AMCs under PvPI (IPC/PvPI/QA/021).
- SOP for Reporting and processing Individual case Safety report (IPC/PvPI/QA/014).
- SOP for Change control procedure (IPC/PvPI/QA/003).

New SOP: 01

- SOP for processing of ADR received through PvPI Mobile App-ADR PvPI (IPC/PvPI/ICSRs/01)

VigiGrade Completeness Score of ICSRs

Quality of ICSR reporting:

The VigiGrade™ Completeness score is a WHO system to measure the amount of information provided on Individual Case Safety Reports (ICSRs). The graph represents average completeness score of ICSRs submitted from India (Purple line) as compared to submitted ICSRs by all the other countries (Green line). The average annual completeness score accounts for >0.8 out of 1.

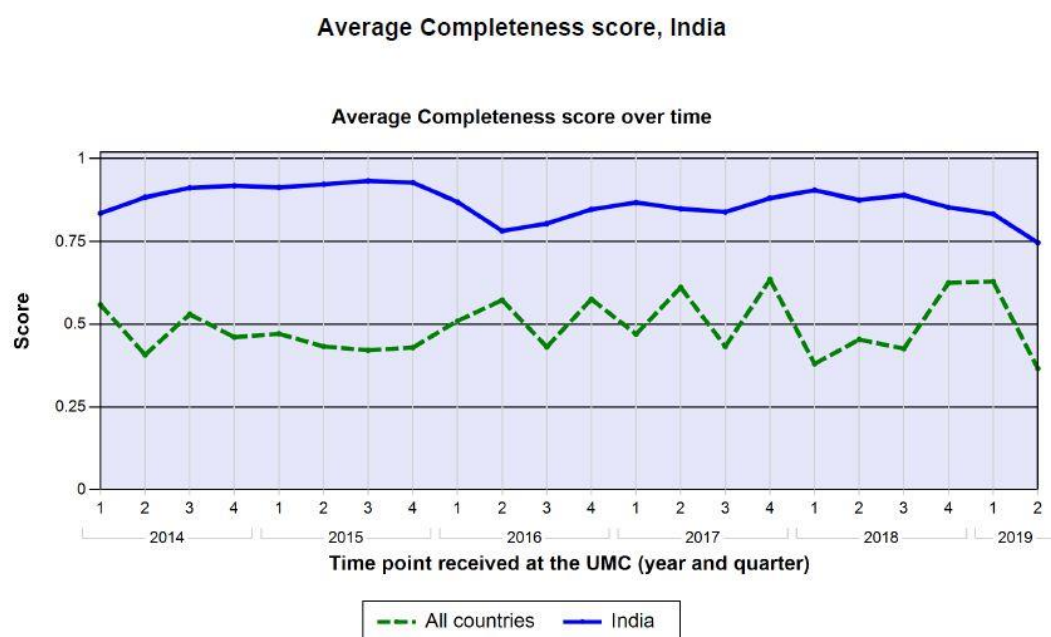


Fig: Graphical representation of VigiGrade completeness score of quality of ICSRs submitted by PvPI to UMC database

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 Individual Case Safety Reports (ICSRs) form 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 parameters for identifying a new signal from Indian ICSRs include:

- Information Component (IC)
- Proportional Relative Risk/Proportional Reporting Ratio (PRR)
- Chi-square (χ^2) statistics (with 1 degree of freedom)
- Total number of reports on the specific Drug-ADR combination available in the Indian database (N_{comb})

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

- $IC_{025} > 0$
- $PRR \geq 2$ with the lower bound of its 95% CI > 1
- χ^2 statistics (with 1 degree of freedom) ≥ 4
- $N_{\text{comb}} \geq 3$, to highlight potential signals

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

Signal Validation Checklist

Important sources: Summary of product characteristics (SmPC)/PIL, PSUR, PBRER, Risk management plan (RMP), regulatory authority website, other regulatory procedures – safety variations

Adverse Drugs Reaction identified: Drug Reaction with Eosinophilia and Systemic Symptoms : Febuxostat

Recommendation for: Drug safety label change

Validation date:

Activity	Comment
No. of ICSR reported in National & International database	
Check the SmPC/PIL for the active substance (national, other)	
For active substances for which a generic version exists, check first the SmPC/PIL of the innovator product (if possible)	
Check Warning-Precaution/Contra-indication/Un-desirable effects section of the SmPC/PIL for information regarding the ADR	
Check if the ADR might be covered by a similar term or a higher level term in the SmPC/PIL	
Check if the ADR is reflected in the SmPC/PIL of another medicinal product containing the same active substance (for example in combination products/other brand)	
Check if the ADR is reflected in the SmPC of a medicinal product from the same class (class effect)	
In case of an interaction , you may check if there is information on the interaction in the SmPCs of the other medicinal products concerned	
Increase in frequency of occurrence	
Change in duration and/or time to onset	
Change in severity	
Change in occurrence pattern (e.g. affecting a specific population)	
Change in previously reported outcome of the ADR (e.g. new fatal cases)	
Check the PSUR of the medicinal product (if available)	
Check the RMP of the medicinal product (If available)	
Check other NRA websites –(EMA, FDA etc.) for referrals	
IC ₀₂₅ , PRR and Chi-Square value	

Outcome of the signal validation	
Signal/PIL change validated	<input type="checkbox"/>
Signal/PIL change closed	<input type="checkbox"/>
Signal/PIL change open – monitoring for additional information	<input type="checkbox"/>

Signal Assessment Checklist Format

Important sources: ICSRs, ADR databases, literature, drug utility studies

Adverse Drugs Reaction identified:

.....

Recommendation for:

.....

Assessment date:

Activity	Comment
Number of cases supporting the association (after exclusion of duplicates and cases with no supporting temporal association)	
Number of cases appropriately documented with sufficient information about, e.g., suspect drug, event reported, demographics (age and gender), indication, outcome, concomitant Medication – key cases	
Consistency of the evidence across cases (e.g. patterns)	
Route(s) of administration and product(s) formulation	
Cluster of reports, e.g., many reports from the same reporter, publication, area of the country or region etc.	
Check if the ADR is reflected in the SmPC of a medicinal product from the same class (class effect)	
Cases fulfill the diagnostic criteria for the ADR	
Activity	Comment
Biological and pharmacological plausibility (possible mechanism)	
Dose relationship	
Number of cases with positive de-challenge	
Number of cases with positive re-challenge	
Low background incidence of the ADR	
Time to onset	
Activity	Comments
Seriousness of the ADR	
Severity of the ADR	
Reversibility of the ADR	
ADR affecting special populations (e.g. pregnant women, children, elderly) or patients with pre-existing risk factors	
ADR occurring in different patterns of use (e.g. off-label, overdose, misuse, medications errors)	
Association likely to apply to other active substances of the same class	
Potential for prevention	
Activity	Comments
Possible class effect	
Possible drug-drug interaction	
Possible medication error	
Possible quality issue	
Possible off-label use	
Possible overuse, abuse, misuse	
Activity	Comments

Poor data quality of case reports	
High number of cases with confounding factors / alternative explanations	
Signs of stimulated reporting e.g. increased media attention	
Abnormal reporting pattern	
Presence of other risk factors for the event: underlying disease, co-morbidities, co-medications	
Activity	Comments
National databases (e.g. for signals detected in literature)	
Databases with larger datasets such as Vigibase (e.g. for signals detected in national databases, literature or other sources)	
Information on active substances from the same class (e.g. for signals detected in national database or Vigibase)	
Literature findings , regarding similar case reports, pharmaco-epidemiological studies or studies suggestive of a potential mechanism of action	
Activity	Comments
RMP of the medicinal product for ongoing or planned studies that might provide evidence on the association	

Outcome of the signal Assessment	
Signal/PIL changedone	<input type="checkbox"/>
Signal/PIL change closed	<input type="checkbox"/>
Signal/PIL change open – monitoring for additional information	<input type="checkbox"/>

Signal Assessment done By (Sign/date).....

Utilization of ICSR data:

PvPI Recommendations to include following Adverse Reactions in Prescribing information leaflet to CDSCO

S. No.	Drugs	Adverse Drug Reaction
1	Carbamazepine	Drug Reaction with Eosinophilia and Systemic symptoms Syndrome (DRESS)
2	Meropenem	Hypokalaemia
3	Artemether + Lumefantrine	Stevens Johnson syndrome (SJS)
4	Diclofenac	Nicolau Syndrome
5	Lamivudine	Hearing Loss
6	Amlodipine	Alopecia
7	Cefixime	Mouth Ulceration
8	Carvedilol	Hyperkalaemia
9	Amlodipine	Gingival Hypertrophy
10	Cefotaxime	Angioedema
11	Ofloxacin	Stevens-Johnson Syndrome
12	Tranexamic Acid	Seizure/Convulsion
13	Quetiapine	Urinary Incontinence
14	Sulfasalazine	DRESS Syndrome
15	Tramadol	Hiccups
16	Phenobarbital	DRESS Syndrome
17	Cefepime	Urticaria
18	Glibenclamide	Palpitation

Drugs Safety Alerts issued by PvPI from April 2018 to March 2019

S. No.	Suspect Drug	Indication/s	Adverse Drug Reaction
1	Cefixime	For the treatment of otitis media, respiratory tract infection, uncomplicated UTIs, effective against infection caused by enterobacteriaceae , H. influenza species	Skin Hyperpigmentation
2	Dexamethasone	Adjunct in the emergency treatment of anaphylaxis, short-term suppression of inflammationin allergic disorder, adrenocortical insufficiency, ocular	Peripheral Neuropathy

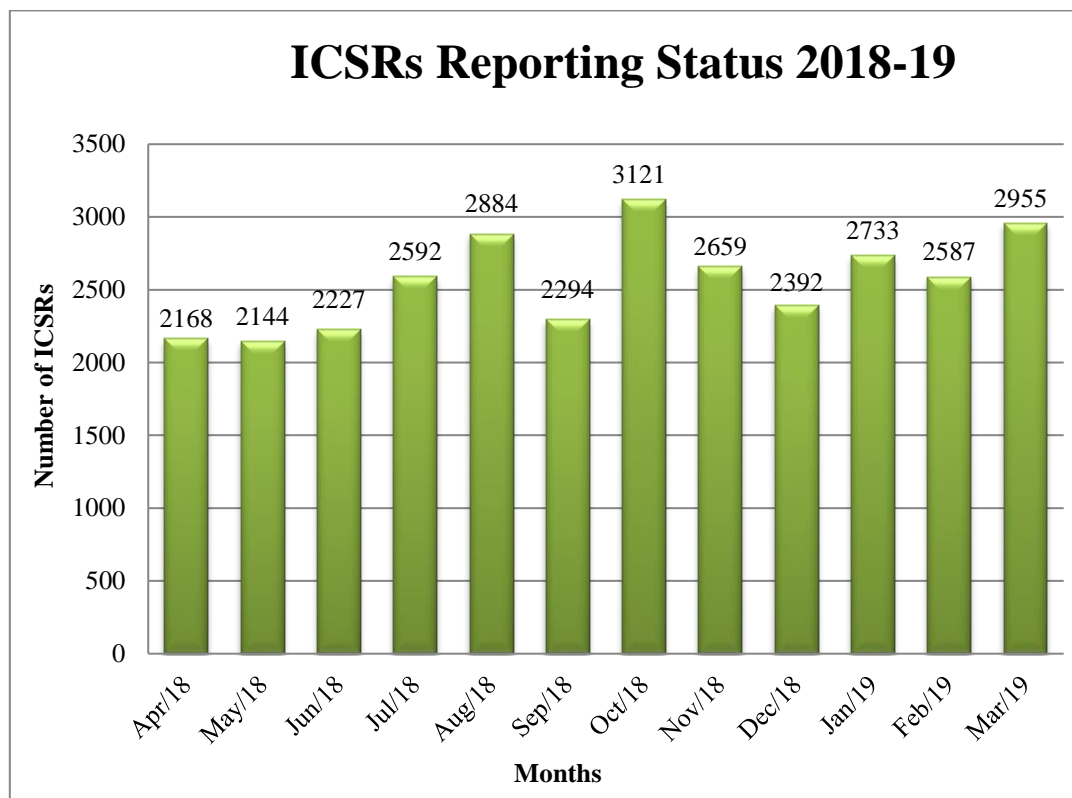
		inflammation autoimmune disorder, rheumatic disorder, cerebral oedema, unresponsive shock, bacterial meningitis along with antibiotics	
3	Fluoxetine	Bipolar disorder, Depressive episode	Hypoacusis (Hearing impairment)
4	Telmisartan	Hypertension	Lichenoid Keratosis
5	Miltefosine	Directly Observed Therapy (DOT) of visceral Leishmaniasis caused by Leishmania donovani	Acute Pancreatitis
6	Levetiracetam	Anti-epileptic, 1) As monotherapy in partial onset seizures with or without secondary generalisation in newly diagnosed patients above 16 years. 2) As adjunctive therapy for myoclonic seizures in adults and in adolescents above 12 years. 3) For primary generalised tonic-clonic seizures in adults and adolescents above 12 years with idiopathic generalised epilepsy	Anencephaly
7	Cetirizine	For the treatment of seasonal/perennial allergic rhinitis & chronic idiopathic urticaria in infants & children	Tachycardia
8	Dabigatran	For the prevention of stroke, systemic embolism and reduction of vascular mortality in adult patient with atrial fibrillation	Alopecia
9	Sertraline	Major depressive disorders, Obsessive Compulsion Disorders (OCD), Panic disorders	Maculopathy

Contribution by MAHs

Marketing Authorization Holders (MAHs) have played a crucial role in reporting ADRs to PvPI. The recent amendment to the Drugs and Cosmetics Rules, 1945, has made Pharmacovigilance a legal obligation for MAHs. This has paved the way for collecting product-specific safety data, aimed at optimizing drug-safety and ensuring healthcare for Indian population.

MAHs– 90

Training/Interactive Sessions – 11



Marketing Authorization Holders as Partners of PvPI

1	Abbott India Limited	46	Lundbeck Pharmaceutical company
2	Akums Drugs & Pharmaceuticals Limited	47	Macleods Pharmaceticals Limited
3	Alcon Laboratories India Private Limited	48	Madras Pharma
4	Alkem Laboratories	49	Medley Pharmaceuticals Ltd.
5	Allergan India Pvt. Ltd.	50	MERCK Limited
6	Apotex Research Private Limited	51	MSD Pharmaceuticals Ltd.
7	Arisglobal	52	MSN Labs
8	Astellas Pharma India Private Limited	53	Mylan Laboratories Private Limited
9	AstraZeneca Pharma India Limited	54	Mankind Pharma (Lambda CRO)
10	Aurobindo Pharma Limited	55	Novartis India Limited
11	Amgen India	56	Novo Nordisk India
12	Axellia Pharmaceutical company	57	Nitin Life Sciences
13	Baxalta	58	Otsuka Pharmaceutical India Pvt. Ltd.
14	Baxter (India) Private Limited	59	Paviour Pharmaceuticals
15	Bayer Healthcare Limited	60	Pfizer Limited
16	Bharat Biotech	61	Piramal Healthcare Limited
17	Biocon Limited	62	Prime Vigilance & Medical Information
18	Biogen Idec Biotech India Private Ltd.	63	Panacea Biotec Limited
19	Boehringer Ingelheim India Private Limited	64	Roche Products (India) Private Limited
20	Bristol-Myers Squibb India	65	Reliance Life Sciences
21	Bharat Serums And Vaccines Limited	66	Recipharm AB
22	Biological E Limited	67	Reckitt Benkiser
23	B Braun	68	Sandor Medicoids Private Limited
24	Cadila	69	Sandoz
25	Cipla Limited	70	Sanofi India Limited
26	Concord Biotech Limited	71	Serdia Pharmaceuticals (India) Limited
27	Dr.Reddy's Laboratories	72	Shilpa Medicare Limited
28	EISAI Pharmaceuticals India Pvt. Ltd	73	Shire Biotech
29	Elder Pharmaceuticals Ltd.	74	Strides Shasun Limited
30	Eli Lilly & Company (India) Private Limited	75	Sun Pharmaceuticals Industries Limited
31	Emcure Pharmaceuticals Limited	76	Septodont Healthcare India Pvt. Ltd
32	Exeltis India Private Limited	77	Serum Institute of India Limited. (Lambda CRO)
33	Fresenius Kabi India Private Limited	78	Synokem
34	Glaxo Smithkline Pharmaceuticals Limited	79	Torrent Pharmaceuticals Limited
35	Glenmark Pharmaceuticals	80	Themis Medicare
36	Galderma India Pvt. Ltd.	81	Troikaa Pharmaceuticals Limited
37	Grifols India Healthcare Private Limited	82	UCB India Pvt. Limited
38	Hetero Drugs Limited	83	Universal Medicare ltd.
39	HLL Biotech Limited (HBL)	84	USV Private Limited
40	Imaging Products India Pvt. Ltd.	85	Vifor Pharma
41	Intas Pharmaceuticals Limited (Lambda CRO)	86	Win Medicare
42	IPCA Laboratories Limited	87	Wockhardt Pharmaceutical Limited
43	Johnsons & Johnsons Private Limited	88	Wyeth Pharmaceuticals Limited
44	Kusum Healthcare Private Limited	89	Zydus Cadila
45	Lupin Limited	90	Zuventus Healthcare Limited

Skill Development Programme

PvPI plays a pivotal role in imparting education and training on safe use of medicines, ensuring patient-safety. The programme through its research-based training and education has developed practical tools which serve as a scientific model to disseminate information and solutions to probable drug-related problems. The National Pharmacovigilance operations thus acquire a prominent platform for sustainable PV practices among all healthcare stakeholders.

Training: Objectives and Perspectives



Tailored to cater to the needs of PV trainees and adapting to good pharmacovigilance practices, NCC-PvPI has recognized nine Regional Training Centres (RTCs) for imparting training in pharmacovigilance. The list are given below:

S. No	Regional Training Centre	State/UT under purview
1	PGIMER, Chandigarh	Jammu & Kashmir, Himachal Pradesh, Punjab, Haryana, Chandigarh and Delhi
2	Seth GS Medical College & KEM Hospital, Mumbai	Maharashtra, Goa, Dadra & Nagar Haveli
3	JSS Medical College Hospital, Mysore	Karnataka, Kerala, Tamil Nadu, Puducherry and Lakshadweep

4	Institute of Postgraduate Medical Education & Research, Kolkata	Andaman Nicobar, West Bengal, Jharkhand, Bihar & Odisha
5	Silchar Medical College & Hospital	Assam, Arunachal Pradesh, Nagaland, Manipur, Meghalaya, Mizoram, Tripura, Sikkim
6	All India Institute of Medical Sciences, Bhopal	Madhya Pradesh and Chhattisgarh
7	BJ Medical College, Ahmedabad	Gujarat, Rajasthan, Daman & Diu
8	All India Institute of Medical Sciences, Rishikesh	Uttarakhand and Uttar Pradesh
9	Nizam's Institute of Medical Sciences, Hyderabad	Andhra Pradesh and Telangana

PvPI organized and participated in nation-wide round-the-year training, updating healthcare stakeholders on PV activities in PHPs:

WHO 3S Rotavac Workshop

An interactive session between WHO officials, CDSCO, AEFI Secretariat, PvPI and rotavirus Marketing Authorization Holders (MAHs) was held at CDSCO, FDA Bhawan, NewDelhion February 4-5, 2019. It was aimed at ensuring effective implementation of Pharmacovigilance system at MAH-level. This workshop also focused on how to merge the rotavirus data of MAHs and AEFI Secretariat into VigiFlow for the generation of the signal.



Technical workshop for CDSCO, PvPI, AEFI secretariat and Rotavirus MAHs in India under WHO-3S Rotavac Project

Workshop on PSUR and RMP assessment



Fourdays workshop for Periodic Safety Update Report (PSUR) and Risk Management Plan (RMP) assessment was organized by WHO in collaboration with National Regulatory Agency of India(NRA) at Hotel Royal Plaza, New Delhi from March 5-8, 2019. The four-day session included a day-long training on successful writing of PSURs and RMPs for all vaccine MAHs in India.

Training & Workshops for MAHs:

S. No.	Title	Date & Venue	Target Audience	No. of Participants
1	Training for PvPI, CDSCO officials and MAHs on Training-cum-workshop on “Capacity building, strengthening of PSUR evaluation & PV Audits and Inspections”	April 26-27, 2018 CDSCO-HQ, Nirman Bhawan, New Delhi	PvPI, CDSCO officials & MAHs	37
2	6 th Regional training for MAHs on Basics of Pharmacovigilance and Establishment of Pharmacovigilance System in Pharmaceutical Industries- A Way Forward	May 25, 2018 SDSTRC & RGICD, Bengaluru, Karnataka	Pharma industry professionals	50
3	7 th Regional training for MAHs on Basics of Pharmacovigilance and Establishment of Pharmacovigilance System in Pharmaceutical Industries- A Way Forward	July 13, 2018 Hotel Royal Plaza Gangtok, Sikkim	Pharma industry professionals	32
4	8 th Regional training for MAHs on Challenges for ICSR-reporting by MAHs,	December 7, 2018 Kilpank Medical College, Chennai	Pharma industry professionals	59

Discussion on minimum requirements to set up PV Systems by MAHs at their site, Reporting of ICSRs in E2B-xml Format by MAHs

Sensitization of HCPs by AMCs:

ADR-monitoring centres function as the backbone of PvPI. The Pharmacovigilance team at each AMC of 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 sensitization training programmes, workshops for all healthcare professionals, consumers, and other stakeholders at an 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 at AMCs

The training programmes at AMCs include:

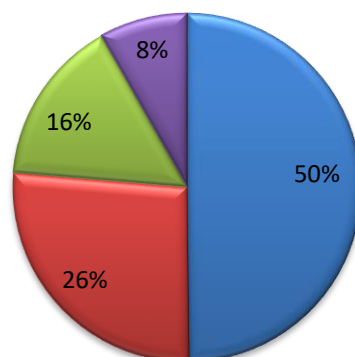
- Regional & National Workshops
- Advance-level Training (ALT)
- Continuing Medical/Pharmacy Education (CME)
- Sensitization and Awareness drive for stakeholders

During the Index Period, **479 sensitization training programmes were conducted by AMCs of PvPI, in which 29,619 healthcare professionals and other stakeholders were trained on PV.**

Participants trained by AMCs

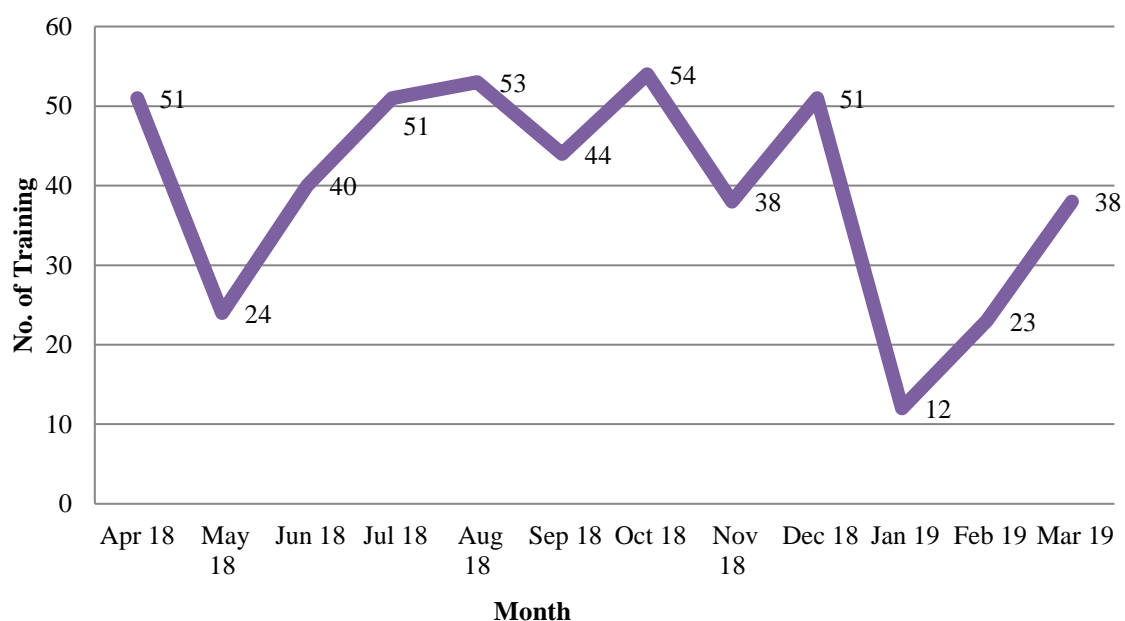
Participants' Professional Background

■ Physician ■ Pharmacist ■ Nurses ■ Others



*Others: Healthcare professionals, patients and public

Month-wise Trainings by AMCs



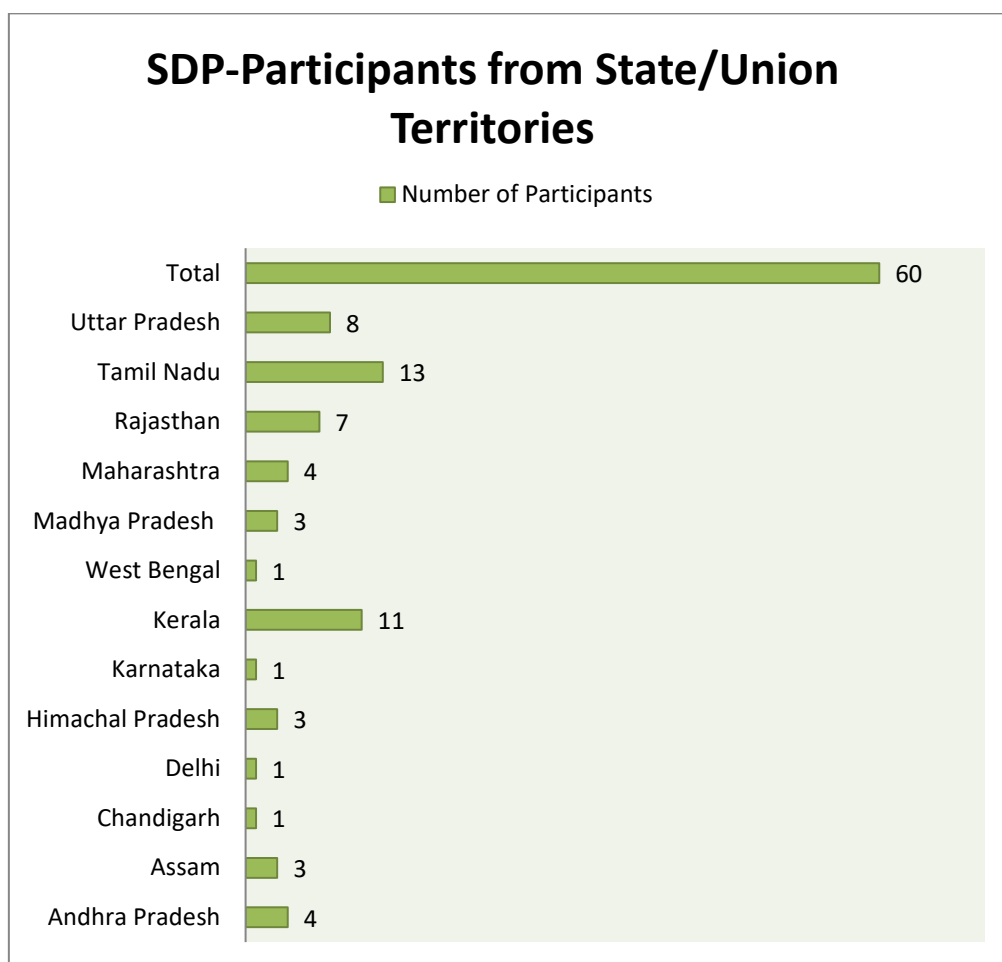
Training Programmes at NCC

- Induction-cum-Training (ICT) for PvAs and AMC Coordinators
- Skill Development Programme (SDP)
- National and International Workshops on PV

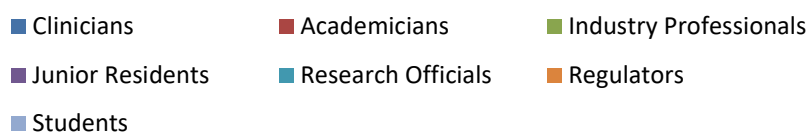
Skill Development Programmes (SDPs) by NCC-PvPI

Stakeholders trained

- Nearly 60 stakeholders (healthcare professionals and industry representatives)
- Three SDPs were attended by participants from 13 states with varied professional background



SDP-Participants' Professional Background



PV training for NABH hospitals

During the Index Period, training-cum-workshop was organized by PvPI for NABH-accredited hospitals. These training sessions provided a platform for the NABH-accredited hospitals to broadly comprehend the system and procedures involved in ADR-reporting and also helped sensitize the healthcare professionals to monitoring and reporting AEs/ADRs.

S.No	Date	Venue	No. of Participants
1	October 11, 2018	Santvita Hospital, Albert Ekka Chowk,Ranchi	50
2	June 06, 2018	Santokba Durlabhji Memorial Hospital, Jaipur	54
3	April 26, 2018	Bangalore Baptist Hospital , Bengluru, Karnataka	39



Topics Covered:

- Basics of Pharmacovigilance, mandates and activities of NCC-PvPI
- Monitoring & reporting AEs/ADRs (Methodology, Forms & Formats)
- Setting up of a PV system in Hospitals

1st Entrepreneur Development Programme on Pharmacopoeial and Pharmacovigilance services

The Start-up cell, Indian Pharmacopoeia Commission functions with the aim of encouraging aspiring entrepreneurs and technologies across the country in the area of Pharmaceutical sector including standards setting in regulatory, Pharmacovigilance and Phytopharmaceutical services. IPC will be helping young entrepreneurs by providing trainings and support, facilitate, guide and encourage young entrepreneurs, researchers and innovators in the field of drug testing, Pharmacovigilance, development of standards etc. The role of this cell would be to highlight, amalgamate and disseminate the resources and provide handholding support at a single portal in the areas of pharmaceutical and health sector.

In line with this, IPC Ghaziabad has organised the 1st Entrepreneur Development Programme on Pharmacopoeial and Pharmacovigilance services” on November 16, 2019 at IPC, Ghaziabad to support the Government of India’s flagship initiative on Start-up India-Stand up India which was launched by Hon’ble Prime Minister of India, Shri. Narendra Modi on January 16, 2016. IPC start-up cell brings aspiring entrepreneurs an opportunity to be face to face with Regulators, Pharmacovigilance experts and Laboratory services and Phytopharmaceuticals Industries. The one day workshop featured expert deliberations, panel discussions, and interactive learning sessions on entrepreneurial sessions in the area of Pharmacovigilance, Regulatory services, Laboratory services for pharmacopoeial compliance and Medical devices. The one day Programme provided technical inputs to bridge the gap for better compliances between regulators and Industry keeping in mind the interests of young aspirants to become potential entrepreneurs in the field of pharmaceutical and health sector. The 1st Entrepreneur Development Programme on Pharmacopoeial and Pharmacovigilance

Services provided an opportunity to all participants to engage with eminent speakers and the programme helped the participants in getting technical inputs to establish entrepreneurship in pharmaceutical sector.

During the entire course of start-up programme, participants were enthusiastic to ask as many questions which were resolved by the speakers. In the end, few participants came up with their innovative ideas and shared with experts.



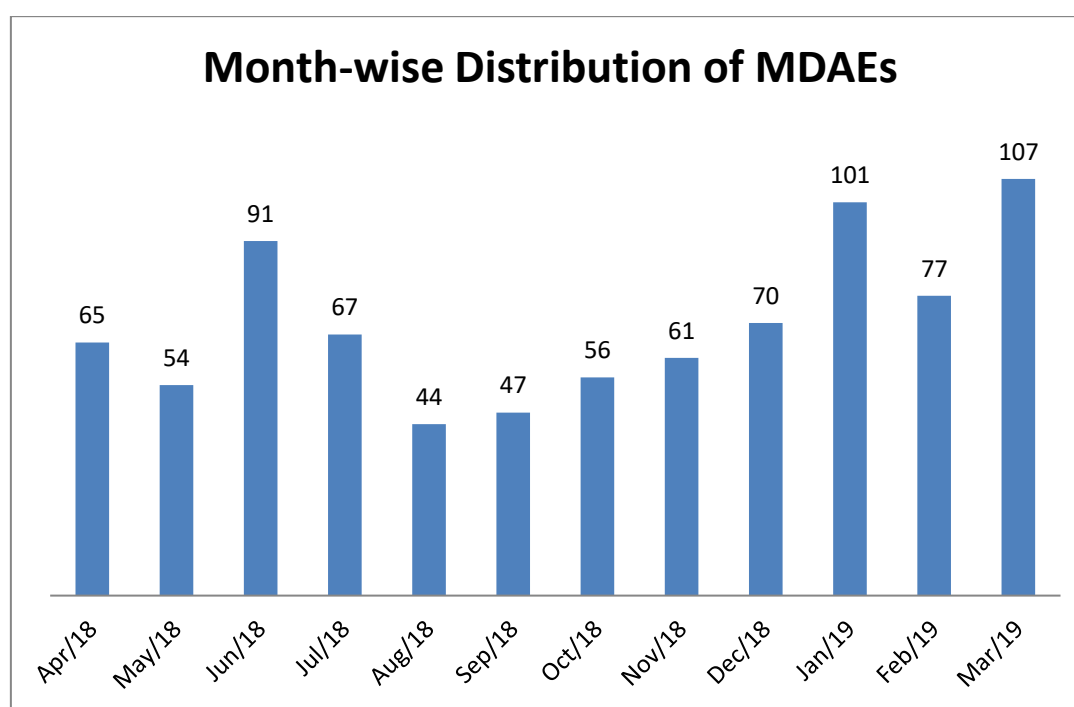
MvPI ensures safety of Medical Devices

Materiovigilance Programme of India (MvPI) was launched on July 6, 2015 at IPC, Ghaziabad. Two committees – a Steering Committee and a Working Group Committee -- were constituted for the successful operation of the programme. Ten medical colleges and hospitals across the country, covering various zones, were identified as Medical Devices Monitoring Centres (MDMCs) by the NCC-MvPI. Sree Chitra Tirunal Institute of Medical Sciences and Technology (SCTIMST), Thiruvananthapuram acts as the National Collaboration Centre (NCC) and National Health System Resource Centre (NHSRC) for technical support.

To ensure effective AE reporting culture among MDMCs, clinicians, biomedical engineers, hospital technology managers, and other healthcare professionals, the MvPI has been imparting training and holding symposia to raise public awareness.

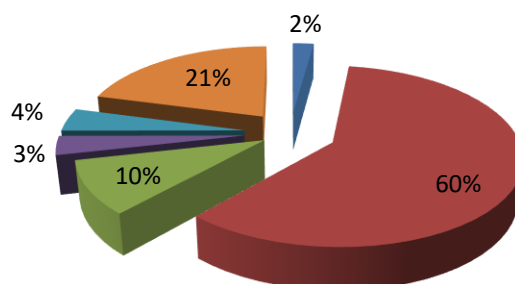
Review meetings with CDSCO are regularly held to assess the progress of MvPI.

Total 807 AEs were reported by MDMCs during Index Period 2018-19.



Distribution of MDAE according to Type of Medical Devices

■ Orthopaedic Implant
 ■ Cardiac Stent
 ■ IUD
 ■ Catheter
 ■ IV Cannula
 ■ Others



Trainings/Meetings/Workshops at MvPI during the Index Period 2018-2019

S. No	Title	Venue	Date	Objectives	Participants
1	First Core Technical Committee Meeting	IPC, Ghaziabad	6 April 2018	Evaluate technical issues from the reported MDAEs of MvPI database	10
2	Awareness Program about Medical Device Adverse event reporting	IPC, Ghaziabad	16 May 2018	To sensitize the audience about MvPI, how to fill and collect MDAE reports.	55
3	Review meeting of MvPI with NHSRC officials	IPC, Ghaziabad	22 May 2018	To discuss NHSRC contribution on the reference document for the standard of medical device and also review progress related to MvPI.	07
4	First National Workshop on Ensuring Quality and Safety of Medical Devices	IPC, Ghaziabad	19-20 July 2018	To sensitize manufacturer, importer, distributor on medical devices quality and safety so as to ensure the patient safety	43
5	Second Working Group and Core Technical Committee	IPC, Ghaziabad	31 August 2018	Evaluate technical issues from the reported MDAEs of MvPI database	14
6	Review meeting on Guidance Document- Medical Devices	IPC, Ghaziabad	16 October 2018	To review feedback/comments/suggestion received from public domain on Guidance document	14
7	2 nd Induction-cum- Training Programme	IPC, Ghaziabad	3-4 December	To educate/ aware Coordinators and	16

	Materiovigilance for Coordinators and Research Associates of MDMC under MvPI		2018	Research associates in order to strengthen MvPI.	
8	First Monthly Partners Meeting of MvPI	IPC, Ghaziabad	9 January 2019	Discussion and evaluation of serious adverse events received in the preceding month	13
9	Training Programme on Role of Biomedical Engineers in assessment of Medical Devices Adverse Events	IPC Regional Office, Hyderabad	30 January 2019	To accelerate the role of biomedical engineers in MvPI by engaging in accessing the adverse events associated with use of medical devices	42
10	Launch of tools for Medical Device Adverse Event Reporting	IPC, Ghaziabad	8 February 2019	Launch and promotion of MvPI reporting tools.	50
11	Second Monthly Partners Meeting of MvPI	IPC, Ghaziabad	1 March 2019	Discussion and evaluation of serious adverse events received in the preceding month	10

Promotion& Publications

NCC-PvPI plays an important role in the functioning of Indian drug regulatory system as it provides scientific support and vital stats to the regulatory agency for appropriate intervention on use of medications following an adverse event. Effective, dynamic and sustainable communication with patients, healthcare professionals and among all partners to Pharmacovigilance, enable the system to function vibrantly and realise the vision of safer use of medicines. Communicating safety information to patients and healthcare professionals is a public health responsibility borne by PvPI.

Till date several India-specific drug-safety alerts/signals have been identified and communicated to the regulatory authority - the Central Drugs Standard Control Organization (CDSCO).

Modes of Communication

- ❖ Website
- ❖ Newsletter
- ❖ Press Release
- ❖ Tollfree Helpline
- ❖ Android Mobile App
- ❖ Radio Programmes
- ❖ TV Shows

Publications for Stakeholders & Partners

- ❖ Quarterly Newsletter
- ❖ Annual Report
- ❖ Guidance Document
- ❖ Handouts
- ❖ Leaflets
- ❖ Banners

The Newsletter published quarterly by PvPI serves as a platform for raising awareness among the public at large to make Pharmacovigilance a part of daily healthcare regimen. To ensure health safety by patient safety, ADR updates and drug alerts are reported in the Newsletter. It helps all healthcare stakeholders, including patients/consumers, doctors, clinicians, pharmacists, hospital staff, to guard against the use of medicines which are likely to cause adverse events. The circulation of the Newsletter among the stakeholders has registered an appreciable increase and the feedback by them has been quite encouraging.



दवाइयों से होने वाले प्रतिकूल प्रभाव/दुष्प्रभाव की निगरानी एवं मरीजों की सुरक्षा के प्रति जागरूकता

फार्माकोविजिलेंस प्रोग्राम ऑफ़ इंडिया, स्वास्थ्य और परिवार कल्याण मंत्रालय, भारत सरकार द्वारा जनहित में जारी

विषय कि इस पत्र में शामिल है कि दवाइयों (मेडिकल, वैक्यूम, और) दुष्प्रभाव, जैसे दुष्प्रभाव के कारण से किसी न किसी प्रकार के प्रतिकूल प्रभाव/दुष्प्रभाव की जानकारी प्राप्त है इससे पता चलता है कि दवाइयों के उपयोग से होने वाले दुष्प्रभाव को पहचानना और निवारण करना, स्वास्थ्य और परिवार कल्याण मंत्रालय के अंतर्गत फार्माकोविजिलेंस प्रोग्राम ऑफ़ इंडिया की पहल है। इस प्रोग्राम का उद्देश्य है कि दवाइयों के उपयोग से होने वाले दुष्प्रभाव को पहचानना और निवारण करना, स्वास्थ्य और परिवार कल्याण मंत्रालय के अंतर्गत फार्माकोविजिलेंस प्रोग्राम ऑफ़ इंडिया की पहल है।

फार्माकोविजिलेंस का अर्थ है दवाइयों का उपयोग, यह कि दवाइयों का उपयोग करने वाले लोगों के बीच दवाइयों के उपयोग से होने वाले दुष्प्रभाव को पहचानना और निवारण करना, स्वास्थ्य और परिवार कल्याण मंत्रालय के अंतर्गत फार्माकोविजिलेंस प्रोग्राम ऑफ़ इंडिया की पहल है।

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Let us join hands with PvPI to ensure patient safety
ADR reporting Helpline (Toll Free): 1800-180-3024

PvPI in News and Media

The sensitization programmes and awareness compaigns of PvPI at national and regional levels are regularly appear in Pharma magazines, bulletins and newspapers across the country. Some of the highlights are given below:


6/18/2019 Display information on 7 common antibiotics: Central Drugs Standard Control Organisation - The Hindu

HEALTH

Display information on 7 common antibiotics: Central Drugs Standard Control Organisation

Know your medicine

The Central Drugs Standard Control Organisation has asked manufacturers to inform the general public about known symptoms/side effects after the intake of some popular antibiotics



Antibiotics	Known/possible side effects
Cefotaxime	Swelling under the skin due to the accumulation of fluids
Ofloxacin	Rashes/blisters on the skin and mucous membranes
Cefixime	Pain, diarrhoea, nausea and headache
Tranexamic Acid	Nausea, diarrhoea and seizures
Quetiapine	Involuntary leakage of urine
Sulfasalazine	Decreased appetite, headache & nausea
Sodium Valproate	Drowsiness and unsteadiness

Bindu Shajan Perappadan
NEW DELHI, APRIL 12, 2019 22:52 IST
UPDATED: APRIL 12, 2019 22:52 IST

CDSO sends letter to manufacturers

<https://www.thehindu.com/health/display-information-on-7-common-antibiotics-central-drugs-standard-control-organisation/article6282575.html> 1/7

PHARMABIZ .com
India's most comprehensive pharma portal

IPC to work with UMC to analyse ADR data through new PV system for patient safety

Shardul Nautiyal, Mumbai, Tuesday, June 5, 2018, 08:00 Hrs [IST]

The Indian Pharmacopoeia Commission (IPC), which has recently been designated as the WHO collaborative centre for PV in public health, will jointly work with Sweden based Uppsala Monitoring Centre (UMC) to develop a system for gathering, analysing and collating adverse drug reaction (ADR) data through a new integrated system of pharmacovigilance (PV) for patient safety.

This is very much relevant as many of the medicines used in public health programmes across the globe are new and have safety concerns associated with them.

This signals a major development involving a long term partnership since 2010 with UMC with the conclusion of a meet between IPC officials and UMC team between May 17 and May 18, 2018 at UMC Sweden office.

Informed Dr. V Kalaiselvan, principal scientific officer at the IPC, "The main agenda of the meet was to host Asia-Pacific Training Programme on PV and ADR data management in the near future. This will also help equip stakeholders globally to fulfill their mandates of access to health, drug quality and patient safety."

Currently, 131 countries across the globe are full members of the WHO Programme for International Drug Monitoring at UMC.

UMC is WHO's collaborating centre for international drug monitoring and IPC has been assigned to update information on ADRs that are being reported in India from across all its 250 adverse drug reaction monitoring centres (AMCs) through Vigiflow software to the UMC in Sweden.

Scientific director of IPC Dr G N Singh led the delegation to UMC Sweden to discuss approaches and policy to harmonise and integrate the Pharmacovigilance Programme of India (PvPI) with public health programmes in other economies towards drug quality and patient safety.

Central Drugs Standard Control Organisation (CDSO) had initiated PvPI in July 2010 with Ghaziabad-based IPC as the National Co-ordinating Centre (NCC).

IPC is also collaborating with South East Asia Regulatory Network (SEARN) nations towards integrating their public health programmes with PV activities for drug safety.

There are seven WHO collaborative centres globally in PV and IPC Ghaziabad is WHO collaborative centre for PV in public health and regulatory services from India as the eighth centre.

PHARMABIZ .com
India's most comprehensive pharma portal

Health ministry to integrate mobile app for reporting ADR with global regulators to enhance pharmacovigilance

Shardul Nautiyal, Mumbai, Tuesday, May 22, 2018, 08:00 Hrs [IST]

Government is planning to integrate its mobile application by the name 'ADR PvPI' meant for ADR reporting with global regulatory agencies to enhance pharmacovigilance (PV) for drug quality and patient safety.

The mobile app has been developed to have administrative control of data with Indian Pharmacopoeia Commission (IPC) as the National Co-ordinating Centre (NCC) for PvPI. Through this application, related images of ADR and lab investigation reports can be attached in a user-friendly manner for clinical assessment and signal detection.

This mobile application will empower all the healthcare professionals and consumers for ADR reporting with features like supports source document and image attachment, healthcare professionals as well as consumer reporting, XML generation and auto filling of report details to save time.

The mobile application which has been developed keeping in mind the patients, consumers and healthcare professionals is now available online for stakeholders.

PV is a science that relates to detection, assessment, understanding and prevention of adverse effects or any other drug related problem. To track adverse drug reactions in Indian population, union health ministry launched Pharmacovigilance Programme of India (PvPI) in July 2010.

IPC is an autonomous institution of the ministry of health and family welfare created to set standards of drugs in the country. Its basic function is to update regularly the standards of drugs commonly required for treatment of diseases prevailing in this region. It publishes official documents for improving quality of medicines by way of adding new and updating existing monographs in the form of Indian Pharmacopoeia (IP). It further promotes rational use of generic medicines by publishing National Formulary of India.

Following recent amendments in Drugs and Cosmetics Rules, 1945 and order from the Union health ministry to all states and Union Territories, the avenues in PV has widened and has become a priority area.

The professionals who have been trained on PV currently working in various healthcare institutions across the country have been motivated to take the onus of disseminating the knowledge and practices of PV for effective ADR monitoring.

'Display information on 7 common antibiotics'

CDSO sends letter to manufacturers

BINDU SHAJAN PERAPPADAN
NEW DELHI

Alerted by the Union Health Ministry's pharmaceutical watchdog, the National Co-ordinating Centre of the Pharmacovigilance Programme of India (PvPI), on adverse reactions that were being reported from some commonly-used antibiotics, the Central Drugs Standard Control Organisation (CDSO) has now asked manufacturers to ensure that this information be made available to the general public.

CDSO has written to drug manufacturers, to mention in leaflets inserted into drug packets or on promotional literature, information about the adverse reactions of these medicines. All of the seven formulations – antibiotics Cefotaxime, Ofloxacin and Cefixime; Tranexamic Acid, used to control bleeding; antipsychotic drug Quetiapine; anti-rheumatoid drug Sulfasalazine and the anti-epileptic medicine Sodium Valproate – have been instructed to warn patients of the "new" side effects. The letter was sent out by CDSO on April 5.

Speaking about the decision, Esvara Reddy, the Drug Controller General of India and head of the CDSO said: "We were alerted to this adverse reaction last year and, after talks with the Ministry and the PvPI, the decision was taken to write to all State authorities to ask manufactures to include this information on the packaging itself. The idea is to ensure that doctors and users are aware of the adverse reactions."

Additional reaction

"All zonal and sub-zonal officers have been instructed to direct the manufacturers of these formulations to mention the additional reaction in the package insert or promotional literature of the drug," notes the letter sent the State Drug Controllers.

The Union Health Ministry was alerted about the adverse reactions last year in August.

Antibiotic Cefixime is used to treat a wide variety of bacterial infections and is known to have adverse reactions, including pain, diarrhoea, nausea and headaches.

Scientific Publications

NCC Publications	08
AMC Publications	29
Total	37

NCC Publications

1. Kalaiselvan V, Sushma S, Abhishank S, Suresh KG. Pharmacovigilance in India: Present scenario and future challenges. *Drug Saf.* 2019 Mar;42(3):339-346.
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9. Konda VCR, Pilla SSD, Surekha A, Subash KR, Umamaheswara R K. Analysis of spontaneously reported cutaneous adverse drug reactions in a tertiary care teaching hospital in south India. Int J Basic Clin Pharmacol. 2018;8 :27-33.
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Highlights of PvPI publications in WHO Pharmaceutical Newsletter



WHO Pharmaceuticals NEWSLETTER

1. Amlodipine: Risk of Alopecia and Gingival Hypertrophy
2. Artemether-Lumefantrine: Risk of Stevens Johnson Syndrome (SJS)
3. Carbamazepine: Risk of Drug rash with Esionophelia and Systemic Symptoms (DRESS)
4. Carvedilol: Risk of Hyperkalamia
5. Cefixime: Risk of mouth ulceration
6. Diclofenac: Risk of Nicolau Syndrome
7. Meropenam: Risk of Hypokalamia

Reference: <https://apps.who.int/iris/bitstream/handle/10665/272966/WPN-2018-03-eng.pdf?ua=1>



5th Asia Pacific Pharmacovigilance Training Course (Building Capacity in Pharmacovigilance)



Training Course hosted by
Indian Pharmacopoeia Commission
In collaboration with Uppsala Monitoring Centre, Sweden
4th - 15th March 2019

About the Course

Indian Pharmacopoeia Commission is hosting the 5th Asia Pacific Pharmacovigilance Training Course at Indian Pharmacopoeia Commission (IPC), Ghaziabad (Delhi - National Capital Region), India from 4th-15th March 2019 in collaboration with Uppsala Monitoring Centre, Sweden.

For the first time this highly informative training course is conducted at IPC, Ghaziabad, India, a WHO Collaborating Centre for Pharmacovigilance in public health programmes and regulatory services.

This course offers a comprehensive pharmacovigilance programme to about 80 Pharmacovigilance professionals each year. The previous training courses took place at the JSS University, Mysuru in February 2015, January 2016, January 2017 & January 2018.

Reference: <https://apps.who.int/iris/bitstream/handle/10665/274266/WPN-2018-04-eng.pdf?ua=1>

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232	ICARE Institute of Medical Sciences & Research and Dr. Bidhan Chandra Roy Hospital, Banbishnupur, Balughata, Haldia, Dist.- Purba, Medinipur-721645	Dr. Sukanta Sen	anirudh.mukharjee@ghspl.com, dr.a.m.1962@gmail.com	08420532336
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	238	Lady Hardinge Medical College (LHMC), C 604, Shivaji Stadium Bus Terminal Co. Place Shaheed Bhagat Singh Marg, New Delhi-110001	Dr. H.S. Rehan	dr rachna1@rediffmail.com	09811694040
	239	University College of Medical Sciences, adjacent to GTB Hospital, Dilshad Garden, New Delhi -110095 Status of AMC: ART Centre	Dr. Rachna Gupta	kavgul2002@yahoo.com	09868140063
	240	Vallabhbhai Patel Chest Institute (VPCI), University of Delhi, Guru Tegh Bhadur Road, New Delhi -110007 Status of AMC: ART Centre	Dr. Kavita Gulati	cdtripathi@gmail.com	09899233085

	241	VMMC & Safdarjung Hospital, Mahatma Gandhi Marg, Raj Nagar, Safdarjung, New Delhi – 110029	Dr. C.D. Tripathi	nilanjan.saha@jamiahamdard.ac.in	09818665424
	242	Hamdard Institute of Medical Sciences and Research, Hamdard Nagar, New Delhi - 110062	Prof. Arunabha Ray	Arunabha14@yahoo.co.in	09818037595
	243	Maulana Azad Medical College and associated Lok Nayak, Govind Ballabh Pant Hospital & Guru Nanak Eye Centre, 2, B.S.Z. Marg, New Delhi -110002 Status of AMC: COEART Centre	Dr. Vandana Roy	anuu1968@gmail.com	09968604283
	244	Rajan Babu Institute of Pulmonary Medicine and Tuberculosis, GTB Nagar, Kingsway Camp, New Delhi-110009 Status of AMC: RNTCP Centre	Dr. Anuj Bhatnagar	drsarin@yahoo.com , r.sarin@nitrd.nic.in, dr.khaliduk@yahoo.com	09818321353
	245	National Institute of Tuberculosis and Respiratory disease (Lala Ram Sarup Institute of Tuberculosis And Respiratory Diseases) Sri Aurobindo Marg, (Near Qutab Minar), New Delhi-110030 Status of AMC: RNTCP Centre	Dr. Rohit Sarin	kishore110092@yahoo.com	09999971557
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	247	North Delhi Municipal Corporation Medical College and Hindu Rao Hospital, MalkaGanj, Delhi-110007	Asst.Prof.(Dr.) Yangshen Lhamo	hiwedz@gmail.com, shalipriya85@gmail.com, adr.igmcric@gmail.com	09654833513
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	249	Jawaharlal Institute of Postgraduate Medical Education & Research, Dhanvantri Nagar, Gorimedu-605006	Dr. S. Sandhiya	pharmacovigilance@pimsmm.net,	09443492922
	250	Pondicherry Institute of Medical Sciences, Ganapathichettikulam, Kalapet, Pondicherry-605014	Dr. Manjunatha C H		09629352078

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State	Centre Name	Coordinator name &	Email	Contact Number
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	252	R. K Ayurvedic Medical College & Hospital, Kashipur, Surai, Sathiaon, Azamgarh, U.P-276001	Mr. Virendra Kumar Maurya (HOD)	virendrakmaurya06mpharm@gmail.com	09336201385
Maharashtra	253	Advanced Centre for Treatment Research & education in Cancer, Dept. of Clinical Pharmacology - KS102, Tata Memorial Hospital, Sector-22, Khargar, Navi Mumbai, Maharashtra-410210	Dr. Vikram Gota (Assoc. Professor)	vikramgota@gmail.com	07715019117
Bihar	254	Darbhangha Medical College Hospital, Laheriasarai, Darbhanga, Bihar- 846004	Dr. (Prof.) Raj Ranjan Prasad, Dr. Manoj Kumar (Depy coordinator)	dr_rajranjan@yahoo.co.in	09334989834
	255	Anugrah Narayan Magadh Medical College, Gaya, Bihar- 823001	Dr.Prof. J.Prasad (Prof.& HOD, Pharmacology)	Jaleshwarprasad18@gmail.com	9507820971
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		Campus, Sidhapudur, Coimbatore, Tamilnadu- 641044			
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		howgan Mohalla, Chamba-Teh., Dist.- Chamba, H.P-176310	Pharmacology)		
	268	Shri Lal Bahadur Shastri Government Medical College, Mandi at Nerchowk, H.P-175001	Dr. Parveen Kumar Sharma (Prof. & HOD, Pharmacology)	drdotsharma@ gmail.com	09418071364
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Sources:

https://docs.google.com/spreadsheets/d/1nICwTTt20Jm0wRlzpIXlWJ7oBYM3x9v4u62bv5_wNkU/edit?ts=5b3615c1#gid=1482893976

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All other Technical, Administrative and Financial staff of IPC.

Dr G N Singh

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Annexure 1

Suspected Adverse drug event reporting form

<https://www.ipc.gov.in/PvPI/adr/ADR%20Reporting%20Form.pdf>

Annexure 2

Medicines side effect reporting form (For Consumers)

<https://www.ipc.gov.in/PvPI/adr/Hindi.pdf>

Annexure 3

Adverse Drug reaction reporting form for KalaAzar treatment

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

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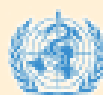
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