Pharmacovigilance

Programme of India (PvPI)

PERFORMANCE REPORT 2017-2018

PHARMACOVIGILANCE PROGRAMME OF INDIA (PvPI)

Performance Report 2017-18

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

Contents

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
CIOMS	Council for International Organization for Medical Sciences
CMC	Christian Medical College
CME	Continuous Medical Education
CTP	Core Training Panel
DCG(I)	Drugs Controller General (India)
DOTS	Directly Observed Treatment-Short course
FDC	Fixed Dose Combination
FIR	First Information Report
GVP	Good Pharmacovigilance Practice
HCP	Healthcare Professional
HIV	Human Immunodeficiency Virus
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
ICSR	Individual Case Safety Report
IC	Information Component
ICT	Information & Communications Technology
IMA	Indian Medical Association
IPC	Indian Pharmacopoeia Commission
ISOP	International Society of Pharmacovigilance
KAP	Knowledge, Attitude and Practice

ABBREVIATIONS

LOI	Letter of Intent
MAH	Marketing Autharazation Holder
MCI	Medical Council of India
MedDRA	Medical Dictionary for Regulatory Activities
MoHFW	Ministry of Health & Family Welfare
MoU	Memorandum of Understanding
MvPI	Materiovigilance Programme of India
NABH	National Accreditation Board for Hospitals & Healthcare Providers
NACO	National AIDS Control Organization
NCC	National Coordination Centre
NHP	National Health Programme
NRA	National Regulatory Authority
PGIMER	Post Graduate Institute of Medical, Education and Research
PV	Pharmacovigilance
PvA	Pharmacovigilance Associate
PvPI	Pharmacovigilance Programme of India
QA-QC	Quality Assurance- Quality Control
RNTCP	Revised National Tuberculosis Control Programme
SAE	Serious Adverse Reaction
SDP	Skill Development Programme
SRP	Signal Review Panel
SUSAR	Suspected Unexpected Serious Adverse Reaction
UIP	Universal Immunization Programme
WHO-ART	World Health Organisation-Adverse Reactions Terminology
WHO-DD	World Health Organisation-Drug Dictionary
WHO-UMC	World Health Organisation-Uppsala Monitoring Centre

FOREWORD FROM SECRETARY-CUM-SCIENTIFIC DIRECTOR

The Index Period 2017-18 for the Pharmacovigilance Programme of India (PvPI) under the aegis of the Indian Pharmacopoeia Commission (IPC) has seen a global value-addition to its scientific functionality with NCC-PvPI, IPC designated as a WHO-Collaborating Centre for "Asia and beyond" last year. It is as much an honour as also a formidable challenge to successfully cross the health-safety hurdles facing the humongous mass of poor population across Asia. Health safety is as much an important therapeutic issue as it is about meticulous monitoring of drugs prescribed. A sustainable network of collating and analysing adverse drug reactions (ADRs) has been established by PvPI, IPC across the length and breadth of India. It is all aimed at safeguarding public health by ensuring drug safety for mass consumption.

The 250-strong nationwide Adverse drug reaction Monitoring Centre (AMC) base serves a pedestal to Pharmacovigilance (PV), ensuring healthcare by patient safety. During the Index Period i.e. April 2017-March 2018, the NCC-PvPI has received more than 71,000 Individual Case Safety Reports (ICSRs), contributing them to the global drug-safety database of WHO's International Drug Monitoring Programme.

Raising public awareness to the very concept of risk-optimized drug-safety has been the core objective of Pharmacovigilance. To this end the Pharmacovigilance Programme of India by its pan-India publicity blitzkrieg has to reach the poorest of the poor citizen of the country as safety of their health is the prime and collective responsibility of all stakeholders.

PvPI's 'Skill Development Programme', which provides hands-on and tools-equipped training for all health stakeholders, including doctors, clinicians, nurses and the pharmaceutical industry, has been gaining momentum at a rapid pace. Its outreach to the stakeholders has been instrumental in creating public awareness for monitoring of drugs at the clinical sites such as hospitals, pharmacies and other health Centres. Public health campaigns aimed at health-safety by drug-safety have gathered a critical mass following their launch at the grassroot level with the involvement of public at large as well as the stakeholders concerned.

One of the consistent endeavours by PvPI, IPC has been to foster the culture of Pharmacovigilance by dissemination of information among the public in a green and clean way. The quarterly Newsletter, the Annual Performance Report and other educational and publicity material published by PvPI, IPC has set an eco-friendly, green trend with all publications using an online paper-free module up to the final stage of printing.

Medical Devices Adverse Events Monitoring under the purview of Materiovigilance Programme of India (MvPI) has been progressively showing signs of maturity and applicability by the industry.

I sincerely thank all healthcare stakeholders and the staff of NCC-PvPI, IPC for their collective will and efforts to reach out to the masses with the cutting-edge technology and expertise to monitor and advance the scientific process of Pharmacovigilance.

Dr G N Singh
Secretary-cum-Scientific Director

Pharmacovigilance Programme of India (PvPI)

GENESIS

Adverse drug reaction (ADR) is one of the leading causes of morbidity and mortality worldwide. The consequences of ADRs burden on the healthcare system are increased cost of therapy and prolongation of hospitalization. It is, therefore, imperative to monitor the safety of medicines.

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

The Ministry of Health and Family Welfare, Government of India recasted this programme on April 15, 2011 resulting in shifting PvPI from All India Institute of Medical Sciences (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).

Highlights 2017-18

Release of Guidance Document for MAHs
A comprehensive guiding tool for MAHs to establish PV system

WHO-CC Orientation Programme on Regulatory Services
Appraising Indian regulators on PV audits and inspections

Regional Workshops on Establishment of PV system in Pharma Industry
To train MAHs to follow good PV practices

ICMR-NIN Centre for PV on Nutraceuticals
National Institute of Nutrition, Hyderabad to work as Nutraceutical Safety Monitoring Centre

Enrolment of hospitals as AMCs at grassroot level
To put in place comprehensive PV system country-wide

Enrolment of PvPI as a WHO-Collaborating Centre
For providing scientific support to LMICs in Asia on PV in PHPs & regulatory services

Mobile App 'ADR PvPI'– An instant enabler to promote patient safety
Seamless alternative for healthcare professionals with ease of reporting

Workshop-cum-training programme on PV for NABH - accredited hospitals
Training healthcare professionals for setting up PV System in hospitals

Introduction of PV system in Government Drug Supply Chain
Ensuring PV in Government drug supply chain vital for Quality Assurance

First Intensive Drug Monitoring Programme under PvPI
Drugs identified include-SGLT2 inhibitors and Pioglitazone

PvPI voyage as a WHO-Collaborating Centre

Mar 18 — **2nd Annual Meet of SEARN countries at Colombo, Sri Lanka**
Gap analysis: mapping of resources & extending services

PvPI voyage as a WHO-CC

Mar 18 — **USFDA, PvPI & CDSCO Joint Workshop for MAH at Ghaziabad & Mumbai**
PV system implementation, PV Audits, Inspections, RMP, Benef Risk Assessment

Feb 18 — **National Meet with State and UT drug regulators at Ghaziabad**
Role of regulators in effective implementation of PV

Jan 18 — **Mapping of PV system set-up in SEARN**
Questionnaire prepared and circulated to SEARI members

Dec 17 — **Orientation Programme on Regulatory Services at CDSCO New Delhi**
Appraising CDSCO, AEFI, PvPI & MAHs on developing tools for PV audit/ inspections

Nov 17 — **Working Group-3 (Vigilance of Medical Products) of SEARN Countries**
PvPI Chaired a meeting: Questionnaire for PV system Capacity building & strengthening

Oct 17 — **Launch of WHO-CC at NCC-PvPI, IPC**

The milestone – marking the formal launch of Pharmacovigilance Programme of India (PvPI), Indian Pharmacopeia Commission (IPC) as the World Health Organization (WHO)-Collaborating Centre for Pharmacovigilance in Public Health Programmes and Regulatory Services – was laid at IPC in Ghaziabad on October 30, 2017.

It was unveiled by the Additional Union Health Secretary Mr R K Vats in presence of DCG(I), Dr G N Singh and the visiting WHO brass from Geneva and Country Office-India. PvPI as a WHO-CC will provide scientific support to countries in Asia for Pharmacovigilance in public health programmes such as tuberculosis, neglected tropical diseases, vector-borne diseases, HIV-AIDS, Adverse Event Following Immunization (AEFI) and regulatory issues.

PvPI: An Overview

Vision

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

Mission

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

PvPI: An Overview

Scope and Objectives

- Create a nation-wide system for medicines safety reporting and monitoring
- Identify and analyse new signals from the reported cases
- Communicate to various stakeholders the safety information on use of medicine so as to prevent/minimise the risk
- Support the National drug regulators in the decision-making process on use of medicine
- Evidence-based decision making on safe use of medicines
- Analyse the benefit-risk ratio of marketed medicine
- Emerge as a Centre of Excellence for Pharmacovigilance
- Collaborate with other National centres for exchange of information and data management
- Provide training and consultancy support to other National Pharmacovigilance Centres
- Promote quality and safe use of medicines
- Provide scientific support to countries in Asia for PV in public health programmes and regulatory being PvPI as Collaborating centre for WHO

Partners

- WHO, Country Office-India
- UIP
- RNTCP
- NACO
- NVBDCP
- ICMR
- IMA
- NABH

PvPI: An Overview

Committees under NCC-PvPI

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

Steering Committee

This 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.

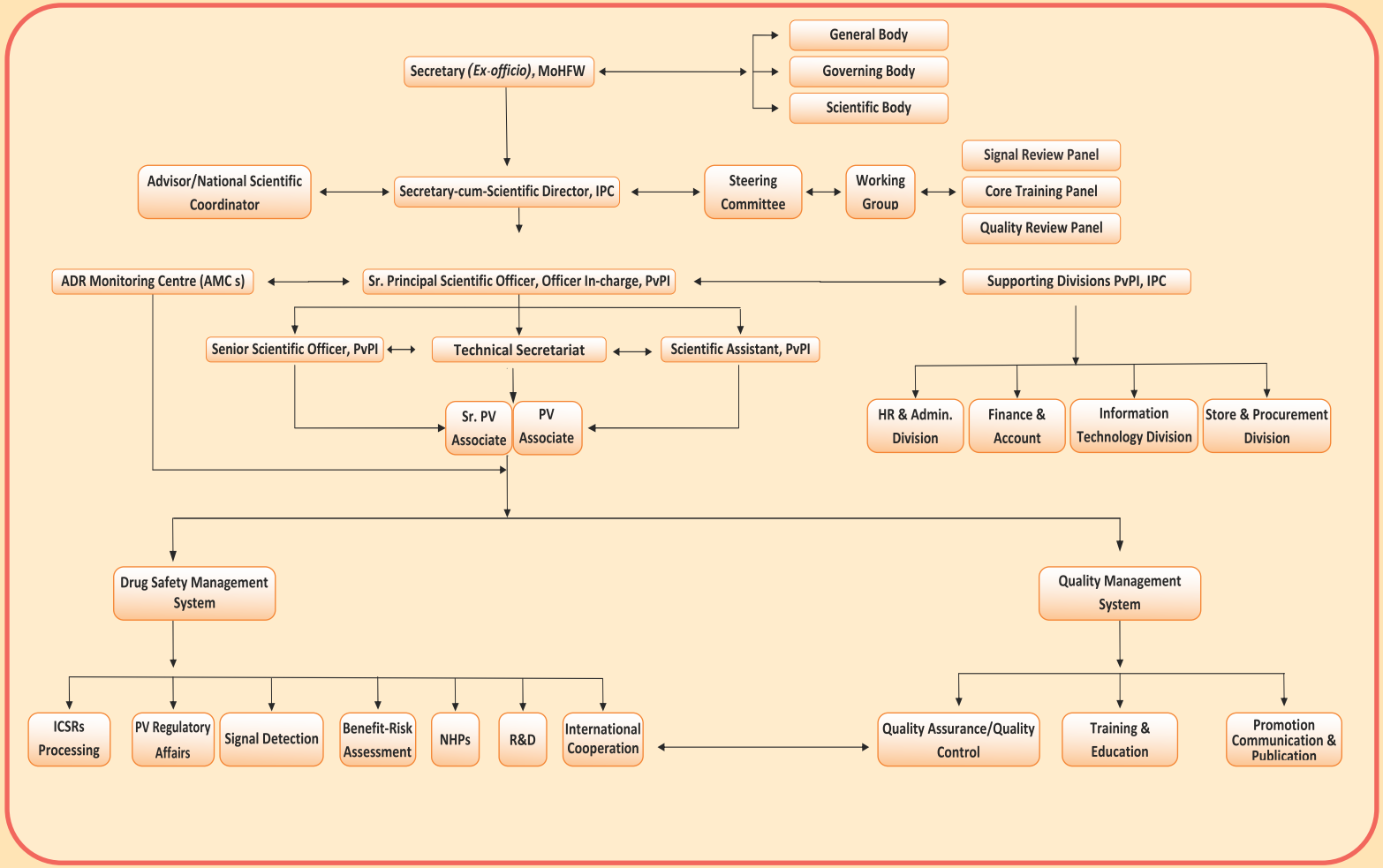
Signal Review Panel

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. SRP 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

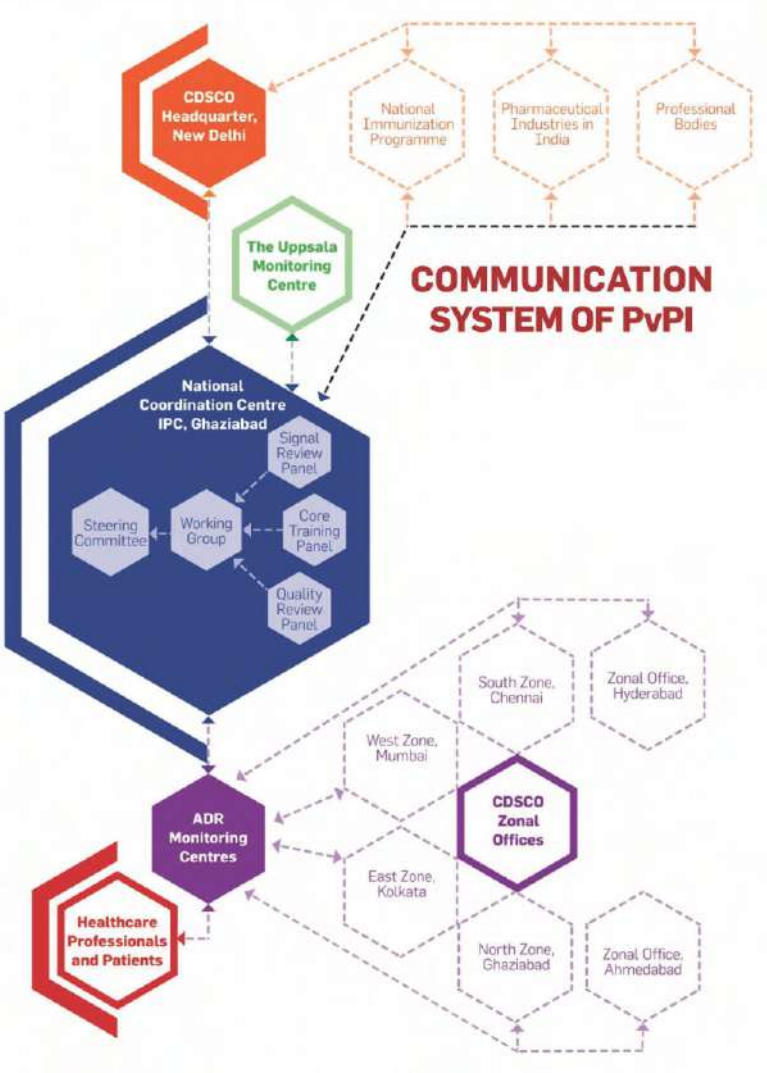
The Core Training Panel (CTP) of PvPI identifies training needs, organizes national and international training programmes, designs training modules and conducts the training for healthcare professionals and other stakeholders throughout the year. It also identifies trainers for zone-wise training centers. 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 the National Coordination Centre, Pharmacovegilance Programme of India (PvPI)



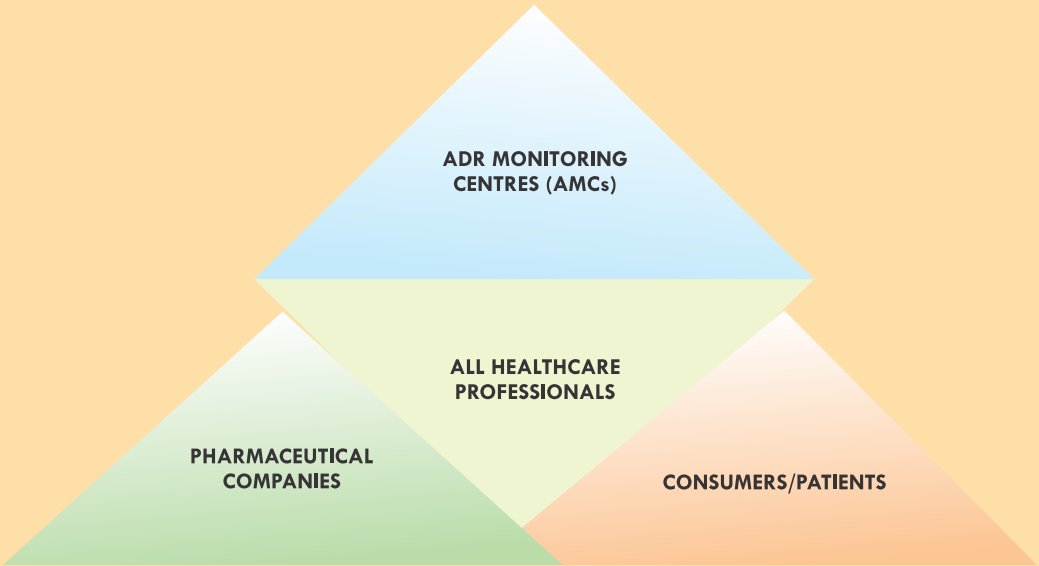
PvPI Communications

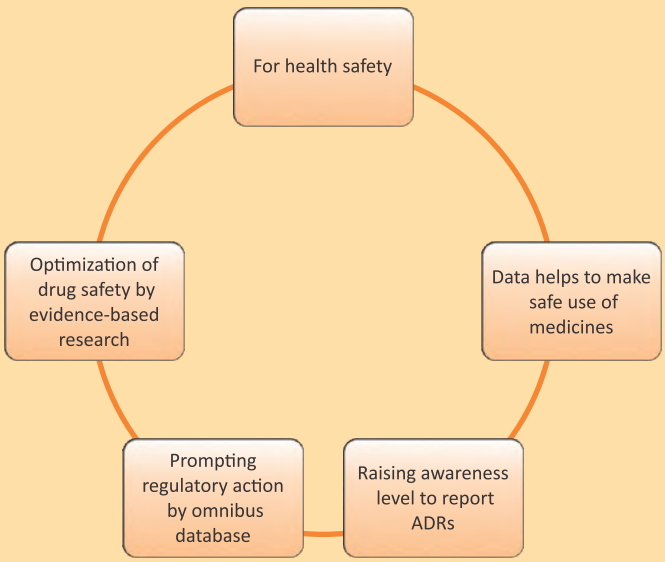
Effective communication channels are a key to successful functioning of an organization. The use of information/communication technology at NCC-PvPI and across the AMCs under its umbrella is a role model for government bodies in India and abroad. PvPI by various modes of communication channelizes data flow as depicted in the figure below:



ADR-REPORTING AT PvPI

WHO CAN REPORT?



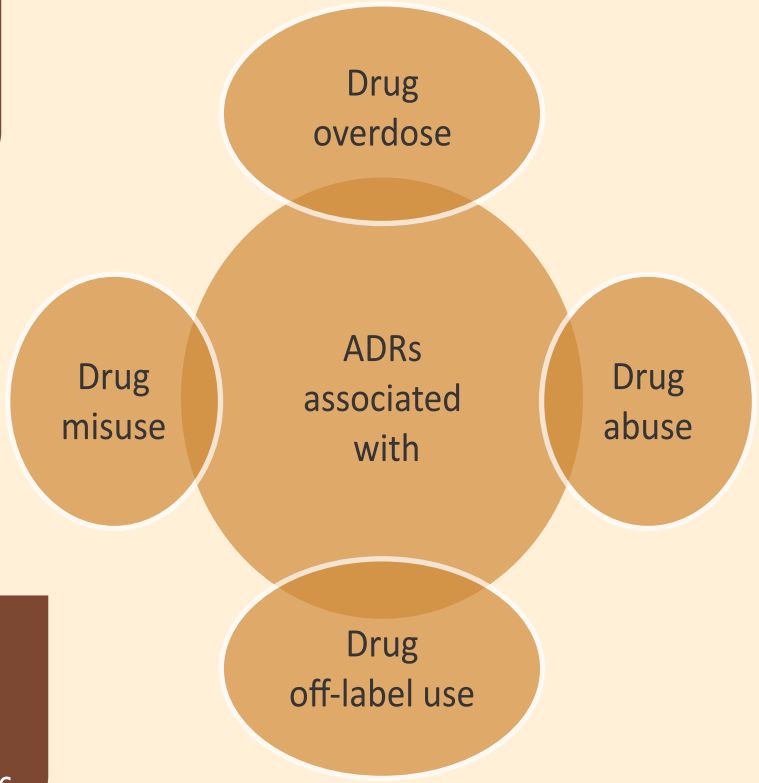


WHAT TO REPORT?

All types of suspected ADRs:
- Known or unknown
- Serious or non-serious
- Frequent or rare

Special focus on drug use in:
- Pregnancy
- Lactation
- Paediatric population
- Geriatric population

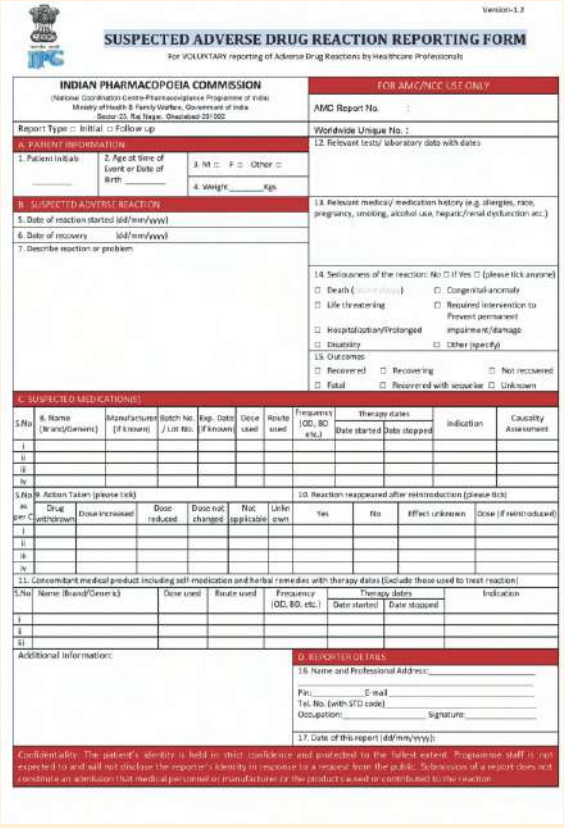
ADRs by:
- Medicines
- Medical Devices
- Biologicals including Vaccines
- Herbal Drugs/Nutraceuticals, etc



- Nearby ADR Monitoring Centres (AMCs)
- National Coordination Centre (NCC)
- PvPI Helpline #1800-180-3024
- PvPI Mobile App: ADR PvPI
- Clinicians
- Pharmacists
- Nurses

Pharmaceutical companies can use the Form to send their Individual Case Safety Reports (ICSRs) specific for their product directly to the NCC. Form is available on the official website of IPC (www.ipc.gov.in) or the CDSCO (www.cdsco.gov.in).

Channels of ADR reporting



SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of Adverse Drug Reactions 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

FOR AMC/NCC USE ONLY

AMC Report No.

Worldwide Unique No. :

Report Type : Initial / Follow up

A. PATIENT INFORMATION

1. Patient Initials
2. Age at time of Event or Date of Birth
3. M / F / Other
4. Weight Kgs
12. Relevant tests/ laboratory data with dates
13. Relevant medical/ medication history (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/renal dysfunction etc.)

B. SUSPECTED ADVERSE REACTION

5. Date of reaction started (dd/mm/yyyy)
6. Date of recovery (dd/mm/yyyy)
7. Describe reaction or problem
14. Seriousness of the reaction: No / If Yes (please tick anyone)
Death / Congenital anomaly / Life threatening / Required intervention to Prevent permanent impairment/damage / Hospitalization/Prolonged / Disability / Other (specify)
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: Date started	Therapy dates: Date stopped	Indication	Causality Assessment
i											
ii											
iii											
iv											

S.No as per C	9. Action Taken (please tick) Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown	10. Reaction reappeared after reintroduction (please tick) 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: Date started	Therapy dates: Date stopped	Indication
i							
ii							
iii							

Additional Information:

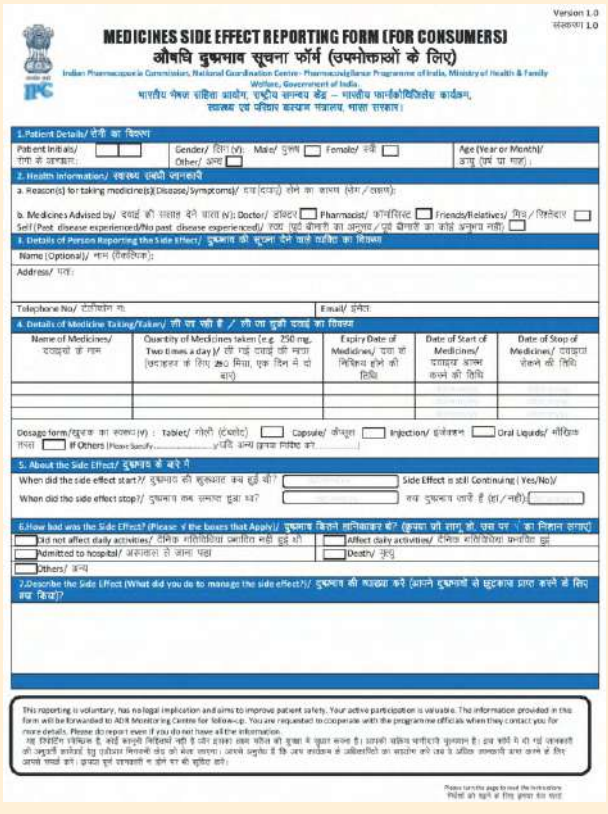
D. REPORTER DETAILS

16. Name and Professional Address:
Pin: E-mail
Tel. No. (with STD code)
Occupation: Signature:
17. Date of this report (dd/mm/yyyy):

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 manufacturers or the product caused or contributed to the reaction.

Suspected ADR Form for Healthcare Professionals

Available on the website of IPC (www.ipc.gov.in) or the CDSCO (www.cdsco.gov.in) and in National Formulary of India 2016



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 सान्द्रय 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/दवाओं लेने का कारण (रोग / लक्षण):

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

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

Name (Optional)/ नाम (वैकल्पिक):
Address/ पता:
Telephone No/ टेलीफोन नं: | Email/ ईमेल:

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

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

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

5. About the Side Effect/ दुष्प्रभाव के बारे में

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

When did the side effect stop?/ दुष्प्रभाव कब समाप्त हुआ था?

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 थीं / Affect daily activities/ दैनिक गतिविधियां प्रभावित हुई
Admitted to hospital/ अस्पताल में जाना पड़ा / Death/ मृत्यु
Others/ अन्य

7.Describe the Side Effect (What did you do to manage the side effect?)/ दुष्प्रभाव की व्याख्या करें (अपने 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 रोगि की सुरक्षा में सुधार करना है। आपकी सक्रिय भागीदारी मूल्यवान है। इस फॉर्म में दी गई जानकारी को अनुवर्ती कार्रवाई हेतु एडीआर निगरानी केंद्र को भेजा जाएगा। आपसे अनुरोध है कि जब कार्यक्रम के अधिकारियों का आपसे कोई और 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
निर्देश को पढ़ने के लिए कृपया पेज पलटें

Medicines Side-Effect Reporting Form (For Consumers)

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

Mobile App

On September 29, 2017, the then Union Health Secretary, Shri C K Mishra, , Government of India, dedicated to the nation the indigenously-developed mobile app “ADR PvPI” for the benefit of all healthcare stakeholders, including common man.

PvPI Helpline

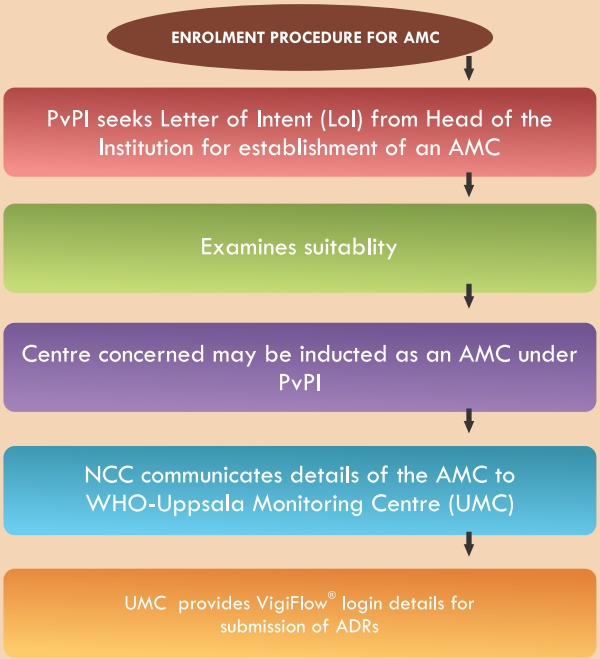
Patients/Consumers/Healthcare Professionals may report Suspected ADRs associated with the use of medicinal products to NCC-PvPI via toll free Helpline # 1800-180-3024.

Establishment of AMCs under PvPI

To monitor ADRs, ADR Monitoring Centers (AMCs) have been set up all over India which send reports to headquarters located at NCC-PvPI, IPC, Ghaziabad. NCC-PvPI started with 22 AMCs in the initial phase and currently has 250 ADR monitoring centers (Medical colleges, district and corporate hospitals etc.) under PvPI across the country. Of these centers, 21 receive information from the Revised National Tuberculosis Control Programme (RNTCP), 20 from the HIV control programme on Anti-retroviral therapy (ART) and 6 are designated Bedaquiline Cohort event monitoring centers.

WHO CAN ENROLL AS AMC?

- Government hospitals/Medical colleges
- Private hospitals
- Corporate hospitals
- District/Primary Health Centres



CRITERIA FOR ENROLMENT OF AMCs

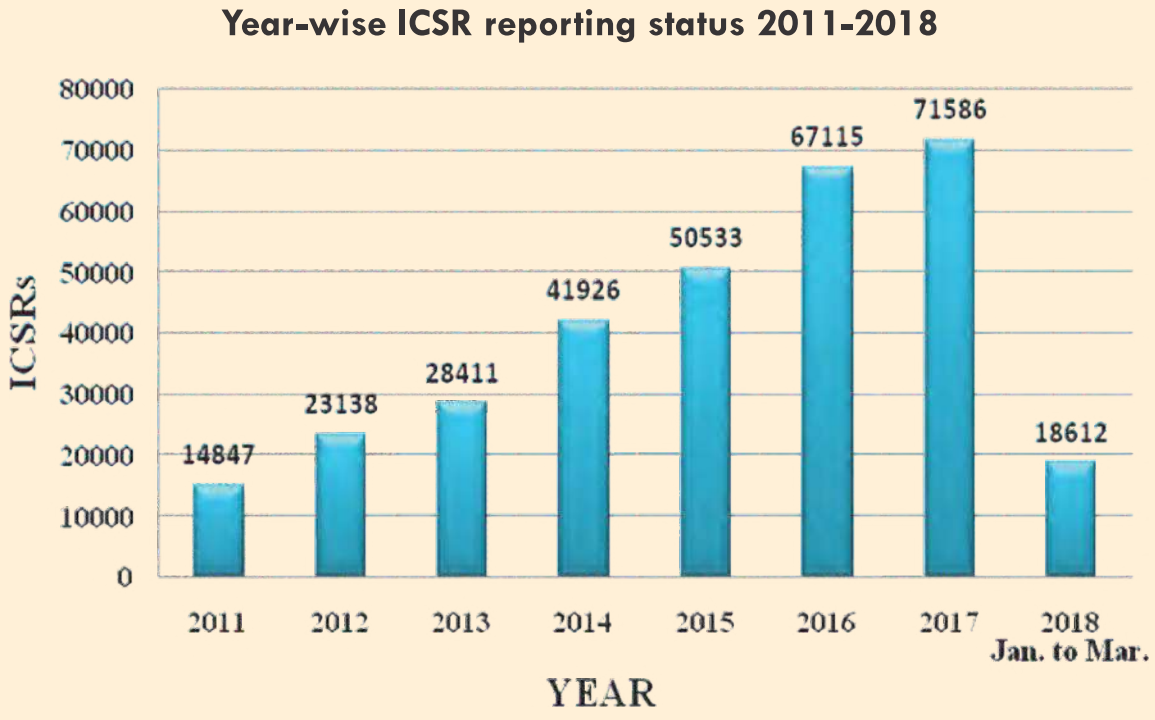
- Availability of logistic and infrastructural facilities for PV at the Centre
- Significant track-record of the Centre in Pharmacovigilance - on quality, quantity and frequency of Adverse Drug Reaction (ADR)-reporting
- Preference for states where no/few AMCs exist
- HoD/Dean/Principal of the institute to identify new AMC coordinator
- 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

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

ICSR database at PvPI

The Pharmacovigilance Programme of India (PvPI) is responsible for collection, assessment and detection of risks associated with the use of medicines by Indians. Annual database accounts for more than 50,000 ICSRs each year. Reporting patterns are on the increase year-wise and have increased drastically in recent years.

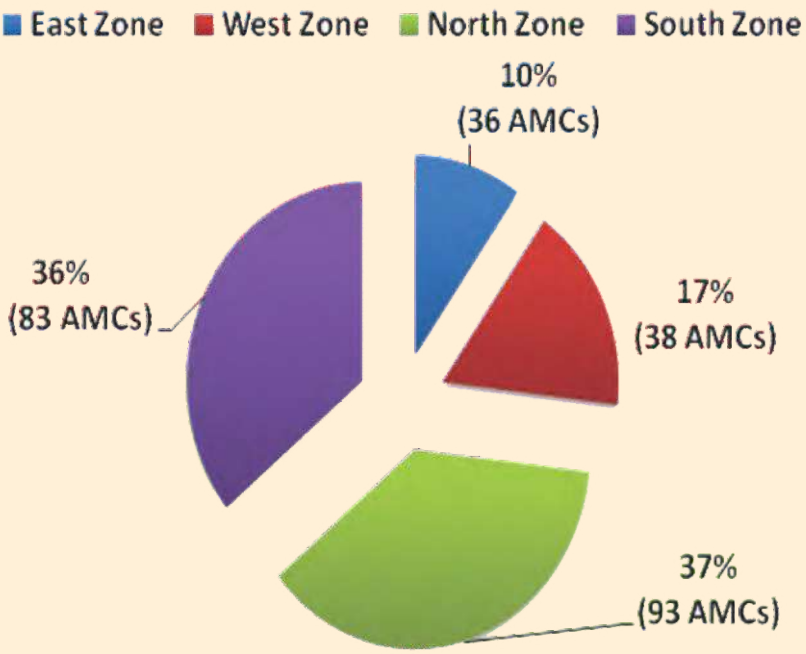
ICSR data for last seven years



ICSR database at PvPI

ADR Monitoring Centres (AMCs) across the country are located in four different zones. Data represents percentage of ICSRs received during 2017-18 from all four zones of India.

Zone-wise AMCs' Contribution

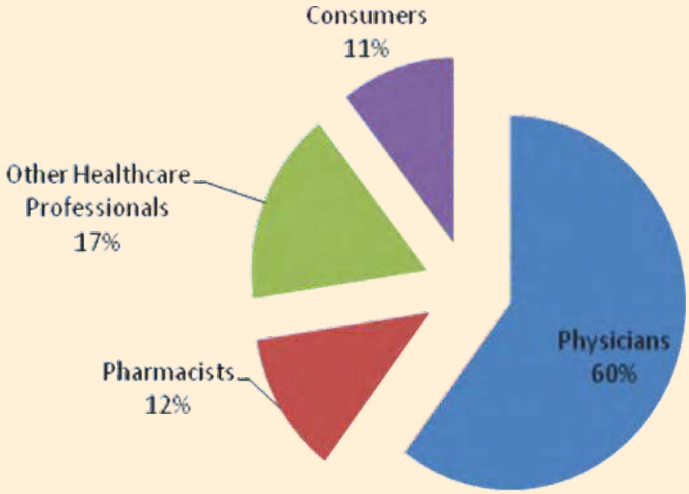


Reporter-wise distribution of ICSRs

NCC-PvPI receives ICSRs from various stakeholders such as physicians, pharmacists, other HCPs, consumers (non-HCPs), etc. Spontaneous ADR reports from physicians (60%) continue to be the major source of reports received, followed by other healthcare professionals (17%), pharmacists (12%) and consumers (11%) in the fiscal year 2017-18.

ICSR database at PvPI

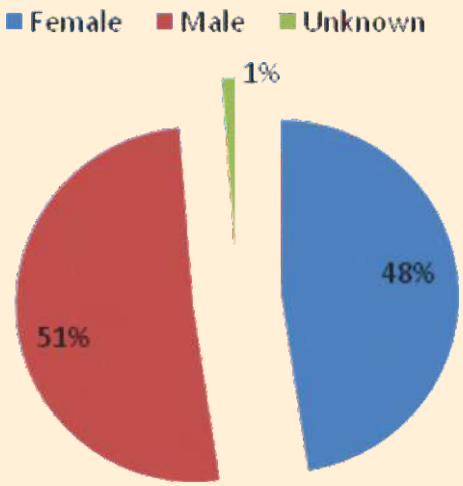
Break-up of Reporters contribution to ADRs



Gender-wise ICSRs:

Analysis of the ADRs received during the index period shows that 51% ADRs occurred in male patients and 48% in female patients. No information about the gender of the patient was provided in 1% of ADR reports.

Gender-wise Distribution of ICRs



ICSR database at PvPI

PvPI Toll Free Helpline

Following the initiation of toll free Helpline on October 11, 2013, a steady increase in reporting through this method has been observed. The increase follows efforts by Pharmacovigilance associates posted at AMCs. The Helpline number has also been embossed on IPD and OPD prescription slips/cards. Calls are primarily responded to in English and Hindi on all working days between 09:00 AM and 05.30 PM.

PvPI contribution to National Health Programmes

Partners

RNTCP- Revised National Tuberculosis Control Programme
UIP-AEFI: Universal Immunization Programme (Adverse Event Following Immunization)
NACO- National AIDS Control Organization
NVBDCP- National Vector-Borne Disease Control Programme

Reports by

Reports	2016-17	2017-18
RNTCP	1294	1230
ART	723	476
AEFI	610	795
NVBDCP	0	58

Utilization of ICSR data - Drug Alerts

Suspected Drug	Adverse Reaction
Lamivudine	Hearing Loss
Inactivated Haemophylus Influenzae Vaccine	Papulovesicular exanthem
Measles Rubella Vaccine	Arthritis/Joint Pain, Guillain-Barre Syndrome
Dapsone	Erythema nodosum

PvPI contribution to National Health Programmes

ADR-causing prominent drugs

RNTCP Drugs

Pyrazinamide
Rifampicin
Isoniazid
Ethambutol
Rifampicin/Isoniazid/
Pyrazinamide/
Ethambutol-FDC

ART Drugs

Lamivudine/Nevirapine/
Zidovudine-FDC
Atazanavir/Ritonavir-FDC
Lamivudine/Tenofovir-FDC
Lamivudine/Zidovudine-FDC
Efavirenz/Lamivudine/Tenofovir-FDC

Vaccines

Bacterial and Viral vaccines
(combined)
Measles vaccine
Pertussis vaccine
Rabies vaccine
Tetanus vaccine

NVBDCP Drugs

Amphotericin B
Miltefosine

PvPI contribution to National Health Programmes

Technical Trainings

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

Training Programme	Topic Covered	Target Group
National meet on Bedaquiline expansion and updating of PMDT Guidelines	Bedaquiline safety status in India, hands-on VigiFlow training	Physicians, TB Programme Officers
Pre-Drug Safety Monitoring Meeting	Analysis of VigiFlow/VigiLyze data on Bedaquiline	Physicians, DEOs, PV-Associates of all Bedaquiline sites
Assessment of Kala-azar elimination with states and partners	Progress, issues, challenges & way forward in Pharmacovigilance	Officials and physicians concerned from Kala-azar endemic states
Regional Review-cum-Sensitization workshop on Kala-azar elimination	PV roadmap for Vector-borne diseases in India, hands-on VigiFlow training for data entry	Officials and physicians concerned from Kala-azar endemic states, DEOs, etc
Delamanid introduction under PMDT India, Capacity-Building Workshop	ADR-Monitoring Centres (AMCs) under PvPI	Delhi Govt officials, physicians, WHO & PvPI officials
Pharmacovigilance Workshop at Central Research Institute, Kasauli	Hands-on VigiFlow training, filling of suspected ADR reporting form for AEFI cases	Officials of CRI, Kasauli
Strengthening of AEFI reporting system in Himachal Pradesh	Hands-on VigiFlow training, filling of suspected ADR reporting form for AEFI cases	Clinicians, nurses and other healthcare professionals of ADR Monitoring Centre-DRPGMC-Tanda, Himachal Pradesh

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.

Major Contributions by Quality Assurance Division

Audits:

External Audit: 01

Internal Audit: 01

Standard Operating Procedures (SOPs):

Updated: 05 (Change Control)

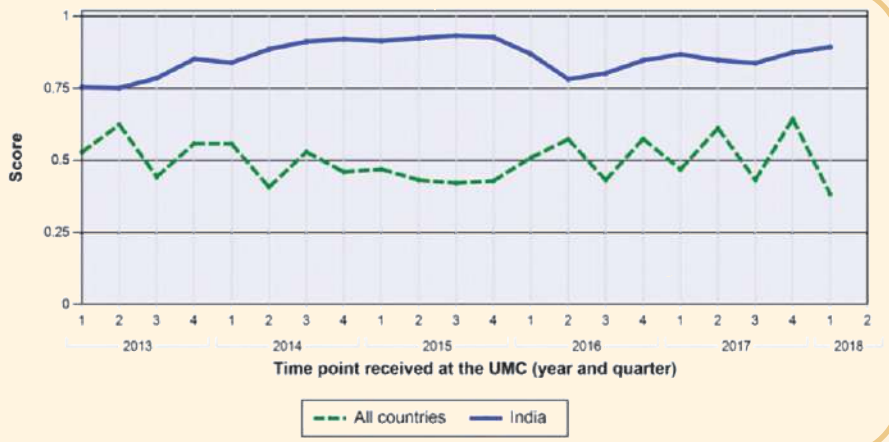
Draft SOPs: 01

Vigi Grade Completeness Score of ICSRs

Quality of ICSR reporting

The vigiGrade™-Completeness score is a system to measure the amount of information provided on Individual Case Safety Reports (ICSRs).

The following figure depicts the average quality scores of ICSRs submitted by PvPI to UMC database



Workshop-cum-training on PV for NABH hospitals

During the Index Period, a series of training-cum-workshops were organized by PvPI for NABH-accredited hospitals. These trainings 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.

Date	Venue	No. of Participants
May 18, 2017	NABH Secretariat, Quality Council of India, ITPI Building, New Delhi	27
June 13, 2017	Vadamalyan Hospitals, Madurai, Tamil Nadu	36
July 22, 2017	CHL Group of Hospitals, AB Road, Indore, Madhya Pradesh	26
October 14, 2017	Apollo Institute of Medical Sciences and Research (AIMSR), Apollo Health City Campus, Hyderabad, Telangana	69
January 30, 2018	Apollo Hospital, Bhubaneswar, Odisha	36
February 28, 2018	Dayanand Medical College and Hospital, Ludhiana, Punjab	38
March 24, 2018	Vivekananda Polyclinic and Institute of Medical Sciences, Lucknow, Uttar Pradesh	47

Topics Covered:

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

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 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 parameters for identifying a new signal from Indian ICSRs include:

- Information Component (IC)
- Proportional Relative Risk/Proportional Reporting Ratio (PRR)
- Chi-square (X^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 ≥ 2 with the lower bound of its 95% CI > 1
- X^2 statistics (with 1 degree of freedom) ≥ 4
- $N_{comb} \geq 3$, 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.

PvPI Recommendations to CDSCO

Signals/Alerts

PIL Updates

- Sulfasalazine and Stevens-Johnson Syndrome/Toxic Epidermal Necrolysis
- Terbinafine and Acute Generalised Exanthematous Pustulosis
- DPP-4 Inhibitors and Arthralgia
- Cefixime &Tinidazole-induced Hyperpigmentation
- Carbamazepine & Nitrofurantoin-induced DRESS

Signal

Fluconazole induced Hyperpigmentation

Drug Alerts

DRUG	ADVERSE REACTION
Amisulpride	Tinnitus
Lurasidone	Thrombocytopenia
Deferasirox	Osteoporosis
Levamisole	Skin Exfoliation
Clomipramine	Melasma
Ambroxol	Lacrimation
Metoprolol	Lichenoid Drug Eruption
Etoricoxib	Skin Hyperpigmentation
Glimepiride	Lichenoid Drug Eruption
Cefepime	Dermatitis Lichenoid
Losartan	Burning Micturition
Carbamazepine	Bruxism
Dexamethasone	Hiccups
Cabergoline	Skin Hyperpigmentation
Sodium Valproate	Psoriasis
Amoxycillin	Eye Irritation
Tinidazole	Hyperpigmentation
Amlodipine	Psoriasis
Amitriptyline	Gingival Discolouration
Lamivudine	Hearing Loss
Hydroxyzine	Bullous Pemphigoid
Paracetamol	Baboon Syndrome
Mebeverine	Retrosternal Pain
Clindamycin	Acute Generalised Exanthematous Pustulosis
Triamcinolone	Skin Peeling
Polymyxin B	Mottled Skin
Diclofenac	Nicolau Syndrome
Terbinafine	Acute Generalised Exanthematous Pustulosis
Nitrofurantoin	Vasculitis
Acetazolamide	Drug Hypersensitivity Syndrome
Linagliptin	Acute Generalised Exanthematous Pustulosis
Diloxanide	Glossitis
Amikacin	Stevens Jhonson Syndrome
Allopurinol	Uveitis
Quetiapine	Gynaecomastia
Ceftriaxone	Palpitations
Fluoxetine	Urinary Incontinence
Levetiracetam	Hypokalaemia
Dapsone	Erythema

Regulatory Pharmacovigilance

Regulatory Pharmacovigilance is the scientific process of long-term monitoring of medicines and assessment of the risks and benefits associated with their use.

To optimize safe and effective use of medicines and monitoring the occurrence of any adverse effect, PvPI takes all necessary action to ensure maximum safety of drugs marketed, manufactured and prescribed in India. AMCs under the umbrella of PvPI play a vigilant role in ensuring the same. PvPI has received following ADRs which could be associated with the quality of medicinal product during the Index Period 2017-18:

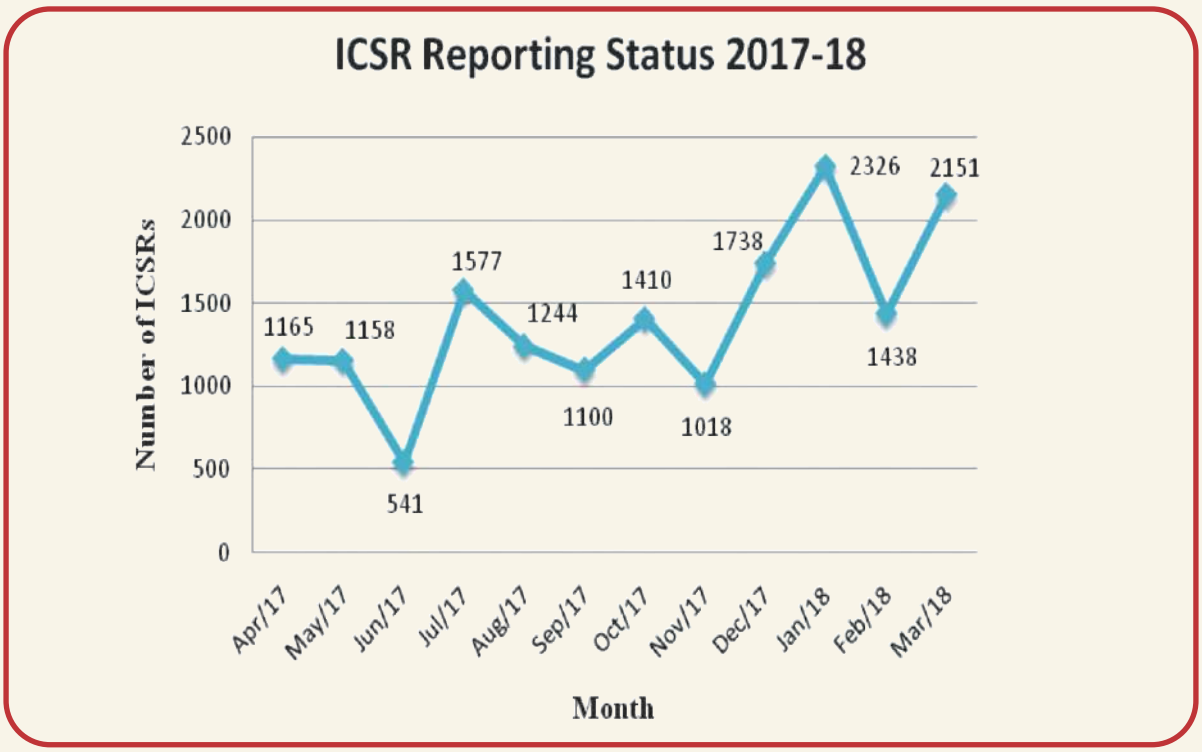
S. No.	Generic name	Reaction	AMC name	Action Taken by NCC-PvPI	Recommendation (CDSCO)
1	Ultrasound Jelly	Blood stream infection	CMCH, Coimbatore	Communicated to State Drug Controller for Tamil Nadu & CDSCO North Zone office	In Process
2	Metronidazole	Chills and Rigors	Madurai Medical College, Madurai	Communicated to State Drug Controller for Tamil Nadu & CDSCO North Zone office	In Process
3	Inj. Magnesium Sulphate	Lack of efficacy	SVMC, Tirupati	Communicated to State Drug Controller for Andhra Pradesh & CDSCO North Zone office	Request to withdraw the sample
4	Thiopentone, Glycopyrrolate, Atracurium besylate and Ketamine	Lack of efficacy	SMS Medical College, Jaipur	Communicated to State Drug Controller for Rajasthan & CDSCO North Zone office	In Process
5	Inj. Ceftriaxone & Cefotaxime	Vomiting, Chills and Rigors	SVMC, Tirupati	Communicated to State Drug Controller for Andhra Pradesh & CDSCO North Zone office	Request to withdraw the sample
6	Inj. Cefotaxime	Rash, Seizures, Ophisthotonus	GMC, Thiruvananthapuram	Communicated to State Drug Controller for Kerala & CDSCO North Zone office	In Process

Contribution by MAHs

Marketing Authorization Holders (MAHs) have 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 populace.

MAHs– 74

Trainings/Interactive Sessions – 11



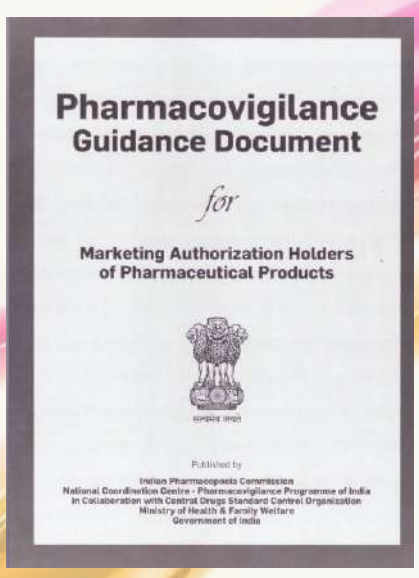
Training & Workshops for MAHs

Training/Workshop	Date	Topic	Target Audience
Training on Medical Writing	April 11, 2017	Writing of Case Narrative in ICSRs, Writing of Literature Report	IPC, NCC-PvPI staff
4th Interactive Session on Participation of MAHs in PvPI	April 28, 2017	Drafting of PV Guidelines for MAHs, Challenges for ICSR-reporting by MAHs, Current status & challenges in PSUR submission	MAHs and CDSCO
Regional Workshop on Basics of Pharmacovigilance & Establishment of Pharmacovigilance System in Pharmaceutical Industries			
AIIMS, Rishikesh	June 23, 2017	Challenges for ICSR-reporting by MAHs, Discussion on minimum requirements to set up PV Systems by MAHs at their site, Reporting of ICSRs in E2B-xml format by MAHs	MAHs, HCPs and CDSCO
Hyderabad	September 5, 2017		
PGIMER, Chandigarh	September 9, 2017		
Mumbai	October 12, 2017		
Indian Society of Clinical Research (ISCR) PV Council Meeting at IPC, NCC-PvPI	September 12, 2017	Suggestions/comments by MAHs for incorporation in PV Guidelines for MAHs of Pharmaceutical Products	ISCR PV Council members and PvPI
Role of State & UT Drugs Regulators for Effective Implementation of IPC services	February 2, 2018	Overview of Checklist for PV Audit & Inspection, Pharmacovigilance: A legal obligation under Drugs & Cosmetics Rules, PV Guidance Document for MAHs of Pharmaceutical Products: Module 1 to 6	State/UT Drugs Regulators, CDSCO & IPC, PvPI
Meeting on Policy, Capacity-building, Strengthening & Implementation of Pharmacovigilance	March 12-13, 2018	Current Pharmacovigilance regulation & best practices: US/Indian perspective, Relevance of PVAudits & Inspections, Risk Management Plan & Benefit-Risk Assessment	IPC, PvPI, CDSCO & USFDA

Two-day National Workshop on Good Pharmacovigilance Practices in collaboration with CDSCO and USFDA at Mumbai	March 15-16, 2018	Role of Spontaneous Reports in post-marketing Safety, Assessing the Impact of Regulatory programmes and actions, Causality Assessment, Good PV Practices: India perspective Group exercises on: • Felbamate • Debigatran • Combined Hormonal Contraceptives	MAHs, State Drugs Regulators, CDSCO, USFDA & HCPs

Release of PV Guidance Document for MAHs

PvPI in collaboration with CDSCO on September 29, 2017 released the "Pharmacovigilance Guidance Document for Marketing Authorization Holders (MAHs) of Pharmaceutical Products". Aimed at drug monitoring and laying down responsibilities for MAHs involved in the manufacture, sale, import and distribution of pharmaceutical products, the guidance document seeks to establish an effective Pharmacovigilance system at MAHs.



Education and training outreach

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

- Methods for collecting Individual Case Safety Reports (ICSRs)
- Developing a positive reporting culture and effective communications
- Data management and analysis
- Fulfilling the stakeholders expectations
- Building partnerships with pharma industry to expand the PV resource base
- Honing the skills of healthcare professionals
- Specialized PV modules followed during training sessions

Tailored to cater to the needs of PV trainees and adapting to good pharmacovigilance practices, NCC-PvPI has recognized nine Regional Training Centres (RTCs). These are:

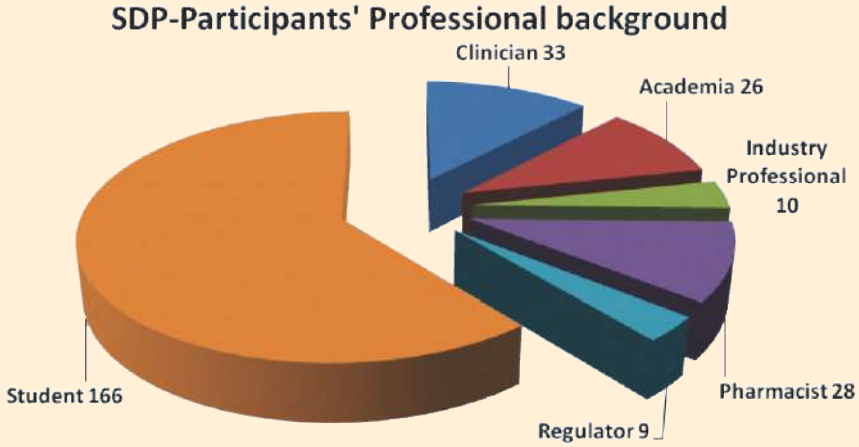
Regional Training Centre	State/UT under purview
PGIMER, Chandigarh	Jammu & Kashmir, Himachal Pradesh, Punjab, Haryana, Chandigarh and Delhi Maharashtra, Goa, Dadra & Nagar Haveli
Seth GS Medical College & KEM Hospital, Mumbai	**Maharashtra, Goa, Dadra & Nagar Haveli**
JSS Medical College Hospital, Mysore	Karnataka, Kerala, Tamil Nadu, Puducherry and Lakshadweep
Institute of Postgraduate Medical Education & Research, Kolkata	Andaman Nicobar, West Bengal, Jharkhand, Bihar & Odisha
All India Institute of Medical Sciences, Bhopal	Madhya Pradesh and Chhattisgarh
B.J Medical College, Ahmedabad	Gujarat, Rajasthan, Daman & Diu
All India Institute of Medical Sciences, Rishikesh	Uttarakhand and Uttar Pradesh
Nizam's Institute of Medical Sciences, Hyderabad	Andhra Pradesh and Telangana
Silchar Medical College & Hospital, Silchar	Assam, Arunachal Pradesh, Nagaland, Manipur, Meghalaya, Mizoram, Tripura and Sikkim

During the Index Period April 2017-March 2018, 41 training programmes were conducted – 14 by NCC-PvPI, 21 by AMCs and 6 by MAHs:

Training Programmes at NCC

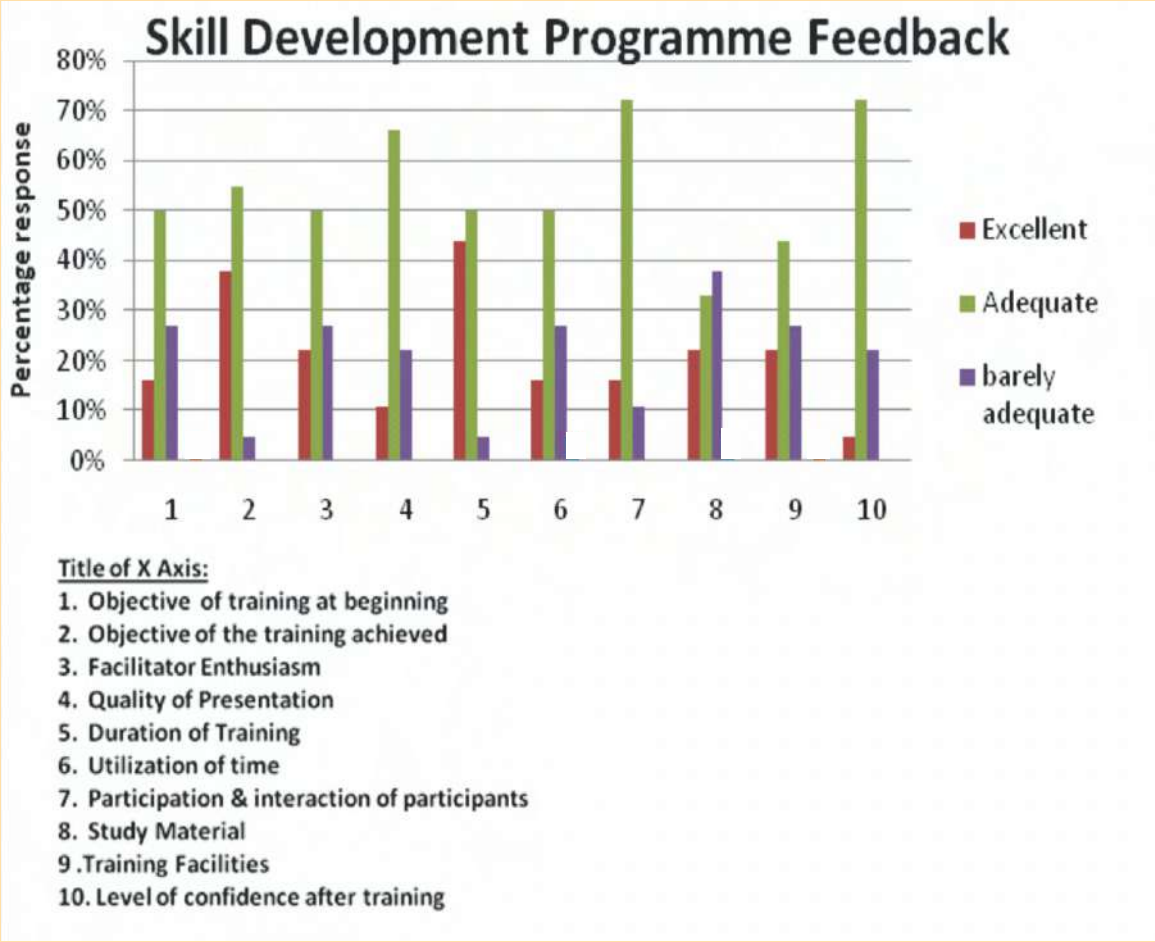
- Induction-cum-Training (ICT) for PvAs and AMC Coordinators
- Skill Development Programmes (SDP)
- National and International Workshops on PV


SDP-Participants from State/Union Territory
Number of Participants
Uttarakhand 13
Uttar Pradesh 40
Telangana 20
Tamil Nadu 26
Rajasthan 14
Puducherry 2
Maharashtra 23
Madhya Pradesh 29
West Bengal 7
Kerala 30
Karnataka 8
Jammu & Kashmir 2
Himachal Pradesh 5
Haryana 8
Gujarat 4
Delhi 15
Chattisgarh 5
Bihar 12
Andhra Pradesh 9


SDP-Participants' Professional background
Clinician 33
Academia 26
Industry Professional 10
Pharmacist 28
Regulator 9
Student 166

Feedback and suggestions by trainees

Suggestions by participants during the training programmes were evaluated. Those found relevant were implemented.

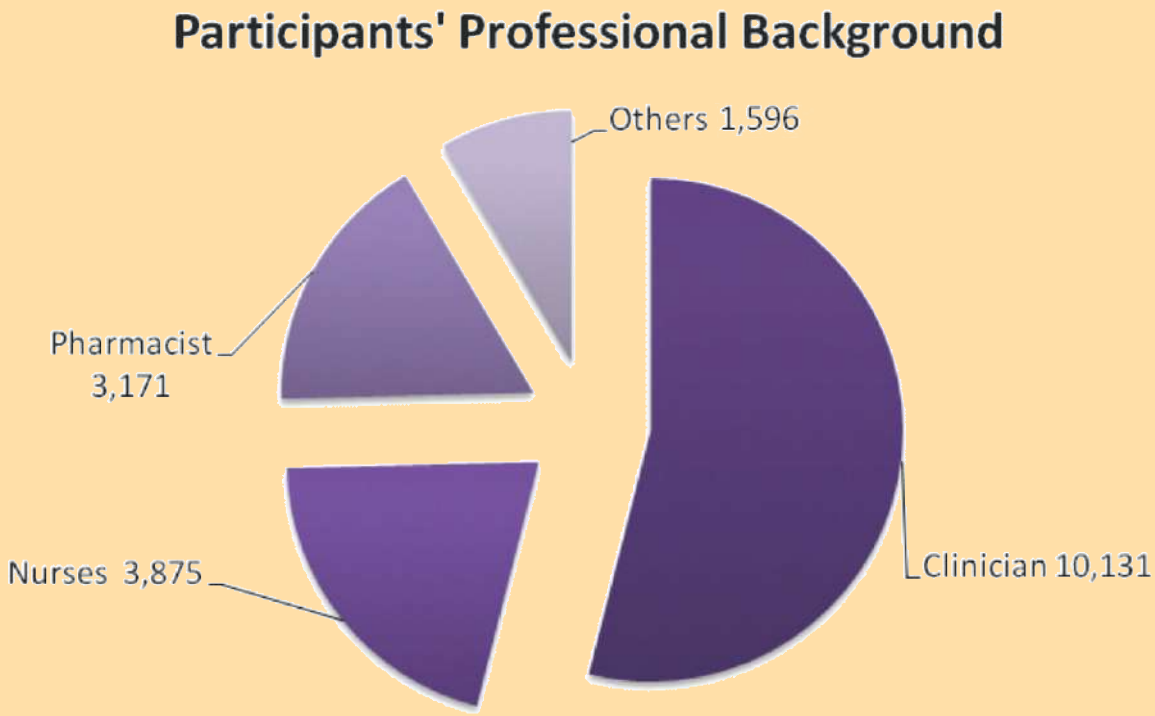


Training Programmes at AMCs

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

Participants trained by AMCs

As many as 18,773 persons were trained by AMCs during the Index Period 2017-18.



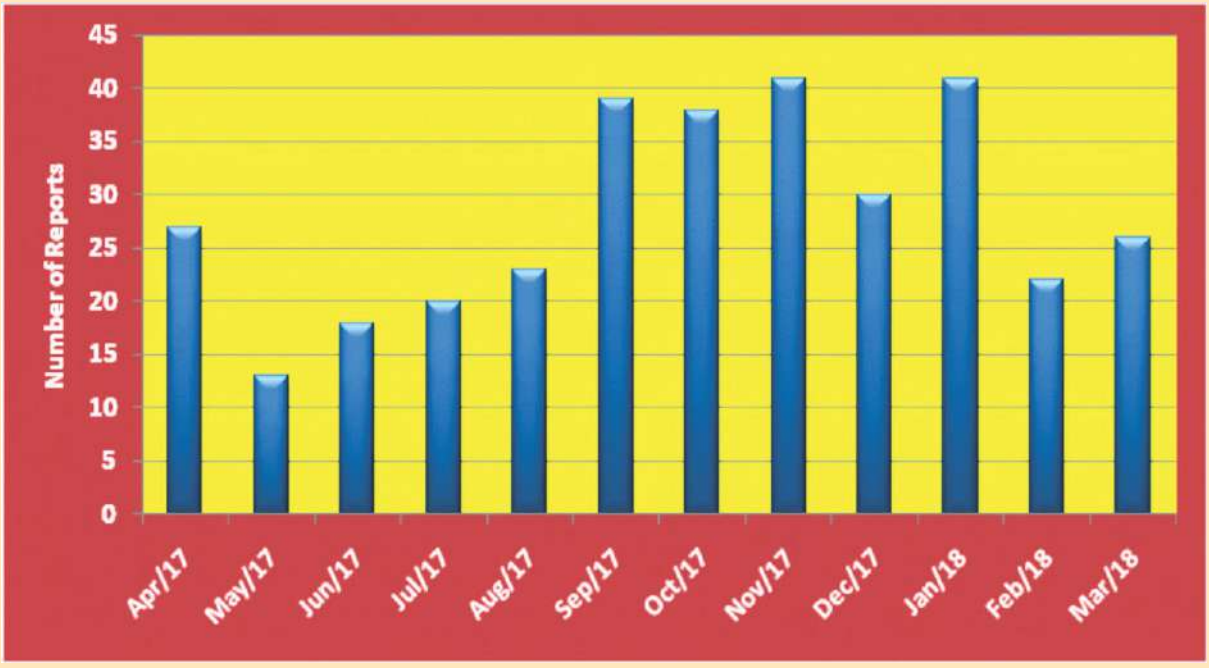
MvPI ensures Medical Devices' safety

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.

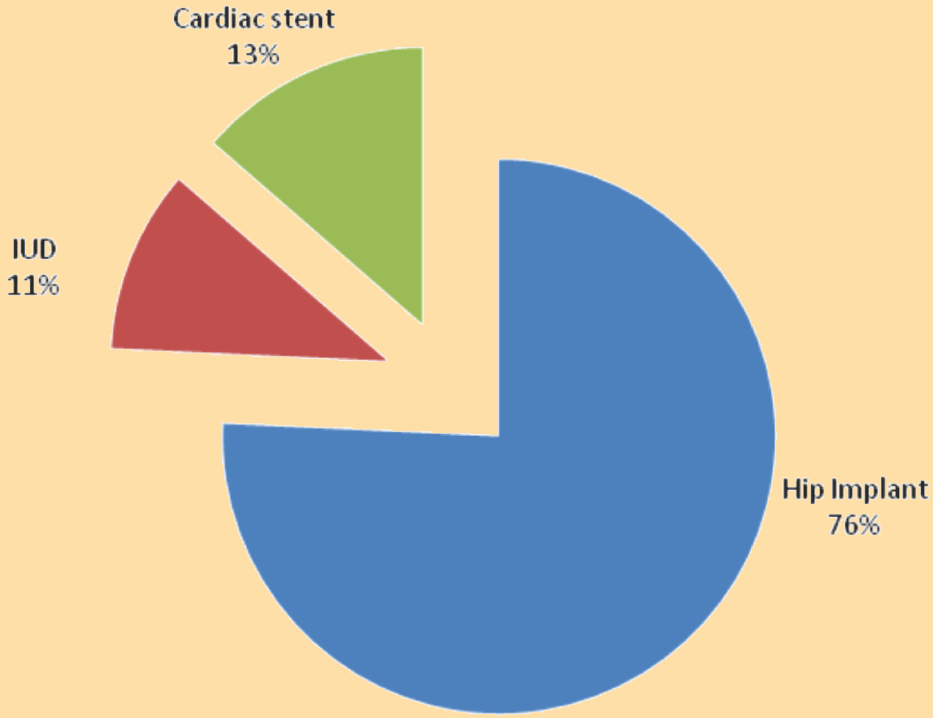
To ensure effective AE reporting culture among MDMCs, clinicians, biomedical engineers, hospital technology managers, and other healthcare professionals, the MvPI has been imparting training and holding symposia to raise public awareness.

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

As many as 169 AEs were reported by MDMCs during Index Period 2017-18.

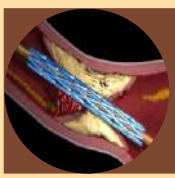


Percentage-wise distribution of MDAEs



Sensitization Programme on MDAE reporting conducted at PGIMER, Chandigarh and Dental Department, Punjab University

Lecture on MvPI at Hindu Rao Hospital, New Delhi on February 21, 2018



Presentation on MvPI during Annual Sri Ramachandra University Pharmacology Insight and Review Course 'ASPIRE-2018'

Promotion by Publications

NCC-PvPI plays an important role in 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. Without effective, dynamic communication with patients, health professionals and among all partners in Pharmacovigilance, the system cannot work and the vision of safer use of medicines cannot be realised. 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).

Need for Communication

- Improve patient care and health safety
- Promote transparency and accountability
- Understand PV to reduce adverse events
- Provide accurate evidence-based, clinical information to healthcare professionals/patients/public

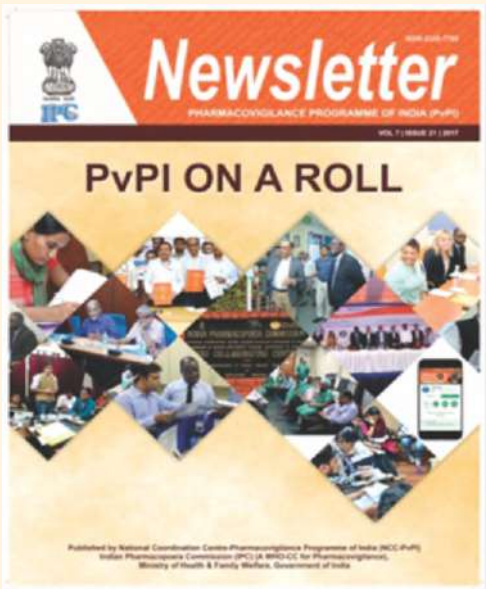
Modes of Communication

- Website
- Newsletter
- Press Release
- Toll free 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.



PvPI in Social Media

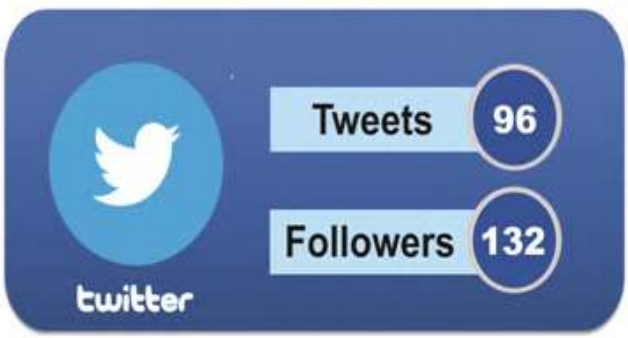
Public Outreach

Training/Sensitization Events	699	Healthcare Practitioners Trained	25,735
TV/Radio Broadcasts	04	Drug Alerts – SMS	10,560

NCC PvPI

YouTube

Pharmacovigilance Programme of India PvPI



Scientific Publications

Year	Number
2017	22
2018 (till March 31, 2018)	06

S. No.	Title
A	**AMC Publications-2017-18**
1.	Susandhya Devadarshini, Kali Prasad Pattnaik, Rajashree Samal, Jigyansa Mohapatra, Swayam Sourav Sahoo. Comparative analysis of cutaneous drug reactions among different fluoroquinolones: an experimental study. International Journal of Basic & Clinical Pharmacology. 2017; 6(6):1254-1260.
2.	Bhaskar H. Nagaiah, Shivaraj Basavaraj Patil, Nallavelly Vahila, Y. Venkata Rao, Shrinivas R. Raikar, Mohd Sajid. Analysis of adverse drug reactions of antimicrobial agents reported to ADR monitoring Centre of a rural tertiary care teaching hospital. International Journal of Basic & Clinical Pharmacology. 2017; 6(5): 1151-1154.
3.	Uma Shanker Prasad Keshri, Kavitakumari, Sumitkumar Mahato, Akhilesh Kumar, Pholgu Protim. A study of adverse drug reactions in cancer patients due to chemotherapy in a tertiary care hospital, Rims, Ranchi. IOSR Journal of Dental and Medical Sciences (IOSR-JDMS). 2017; 16(8):89-93.
4.	Siddiraju Devipriya, Susila K.M.S. Assessment of cutaneous adverse drug reactions reported by spontaneous reporting system. International Journal of Current Advanced Research. 2017; 6(10):6666-6669.

5.	Suganthy R Rajakumari, Thirumalai Nambi T. An observational study on adversecutaneous drug reaction in a tertiary care Centre. Paripex-Indian Journal of Research. 2017; 6(11):17-18.
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B	**NCC Publications-2017-18**
26.	Adusumilli Pramod Kumar, Archana Saurabh, V Kalaiselvan. Sulfasalazine associated toxic epidermal necrolysis (TEN): A case series. Indian Journal of Pharmacy Practice. 2017; 10 (4), 305-307.
27.	Pramod Kumar, Ismeet Kaur, V Kalaiselvan, Abhishank Singh. Safety monitoring of local anaesthetic drugs under the perspective of Pharmacovigilance Programme of India. Indian Journal of Anaesthesia. 2017; 61 (7), 534-537.
28.	Aman Kumar, Jatin Ahuja, Tarani Praksh Shrivastava, Vipin Kumar & Vivekanandan Kalaiselvan Statistical Signal Process in R language in Pharmacovigilance Programme of India. Therapeutic Innovation & Regulatory Science. 2018; 52(3):329-333.

WHO-UMC publications highlight PvPI

PvPI's achievements are regularly shared globally by UMC and WHO publications

1. Sulfasalazine: Risk of Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis (TEN)
   Reference: http://apps.who.int/iris/bitstream/handle/10665/258800/WPN-2017-04-eng.pdf?sequence=1
2. DPP-4 inhibitors: Risk of Arthralgia
   Reference: http://www.who.int/medicines/publications/WHO-Pharmaceuticals_Newsletter_No6-2017.pdf?ua=1
3. Fluconazole: Risk of Hyperpigmentation
   Reference: http://www.who.int/medicines/publications/WHO-Pharmaceuticals_Newsletter_No6-2017.pdf?ua=1
4. Terbinafine: Risk of Acute Generalized Exanthematous Pustulosis (AGEP)
   Reference: http://www.who.int/medicines/publications/WHO-Pharmaceuticals_Newsletter_No6-2017.pdf?ua=1

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