Pharmacovigilance Programme of India

Ministry of Health and Family Welfare, Government of India

Published by
Indian Pharmacopoeia Commission

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Introduction

Pharmacotherapy is considered as a major intervention for treatment or management of diseases. Even though medicines are intended for treatment and better outcome, there are possibilities of occurrence of adverse drug reactions. According to published studies, ADRs account 3.7% of hospital admissions in Europe, 6-15% of admissions in Australia and 5-16% of hospital admissions in USA and Canada. In India, the figures related to hospital admission due to adverse drug reaction and economic burden of ADR management are not clearly available. No doubt that an adverse reaction due to medicines creates high negative impact on patient safety, affects quality of life of patients and pose economic burden on the society. Hence, understanding the benefit and risk of drug therapy is necessary for which an effective nationwide pharmacovigilance system is essential.

Evolution of Pharmacovigilance in India

In early 1980 attempts were made in India towards ADR monitoring. The Drugs Controller General of India established five centers in 1982 for nationwide monitoring of ADRs. An estimated 58,000 ADR case reports were collected in a multi-institute study conducted by ICMR in 1987. However, the project did not continue. In 1998, India joined World Health Organization (WHO) International Drug Monitoring Programme. At that time, National Coordination Center for Pharmacovigilance was the Department of Pharmacology, All India Institute of Medical Sciences (AIIMS), New Delhi.

The Central Drugs Standard Control Organization (CDSCO), Ministry of Health and Family Welfare, Govt. of India launched the National Pharmacovigilance Programme (NPP) in November, 2004 considering the importance and benefits of pharmacovigilance in patient safety. NPP mainly aimed at promoting ADR reporting culture by healthcare professionals. A large number of ADR reports collected by NPP had generated a pool of ADR data. However, the programme did not meet the expectation and was temporarily suspended in 2009.

Pharmacovigilance Programme of India (PvPI)

Pharmacovigilance Programme of India (PvPI) was operationalized in July, 2010 by Ministry of Health & Family Welfare (MoHFW), Government of India (GoI) with a mission to reduce the risks associated with the use of medicines in Indian population. The AIIMS, New Delhi was established as National Coordinating Centre for PvPI. Later on, Ministry of Health & Family Welfare (MoHFW), Government of India (GoI) on 15th April 2011, recasted this programme and shifted the National Coordination Centre from AIIMS, New Delhi to Indian Pharmacopoeia Commission (IPC), Ghaziabad.

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.

Scope and Objectives

- To create a nation-wide system for medicines safety reporting and monitoring
- To identify and analyze new signals from the reported cases
- To communicate to various stakeholders the safety information on use of medicine so as to prevent/minimize the risk
- To support the National drug regulators in the decision-making process on use of medicine
- To generate evidence-based information on safety of medicine
- To analyze the benefit-risk balance of marketed medicine
- To collaborate with other national centres for exchange of information and data management
- To provide training and consultancy support to other National Pharmacovigilance Centres across globe
- To promote quality and safe use of medicines
- To provide scientific support to countries in Asia for PV in public health programmes and regulatory services as a Collaborating Centre for WHO
- To emerge as a Centre of Excellence for Pharmacovigilance

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 give recommendation to the PvPI for onward regulatory interventions by the CDSCO.

Quality Review Panel

Quality Review Panel is responsible for quality check, 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)

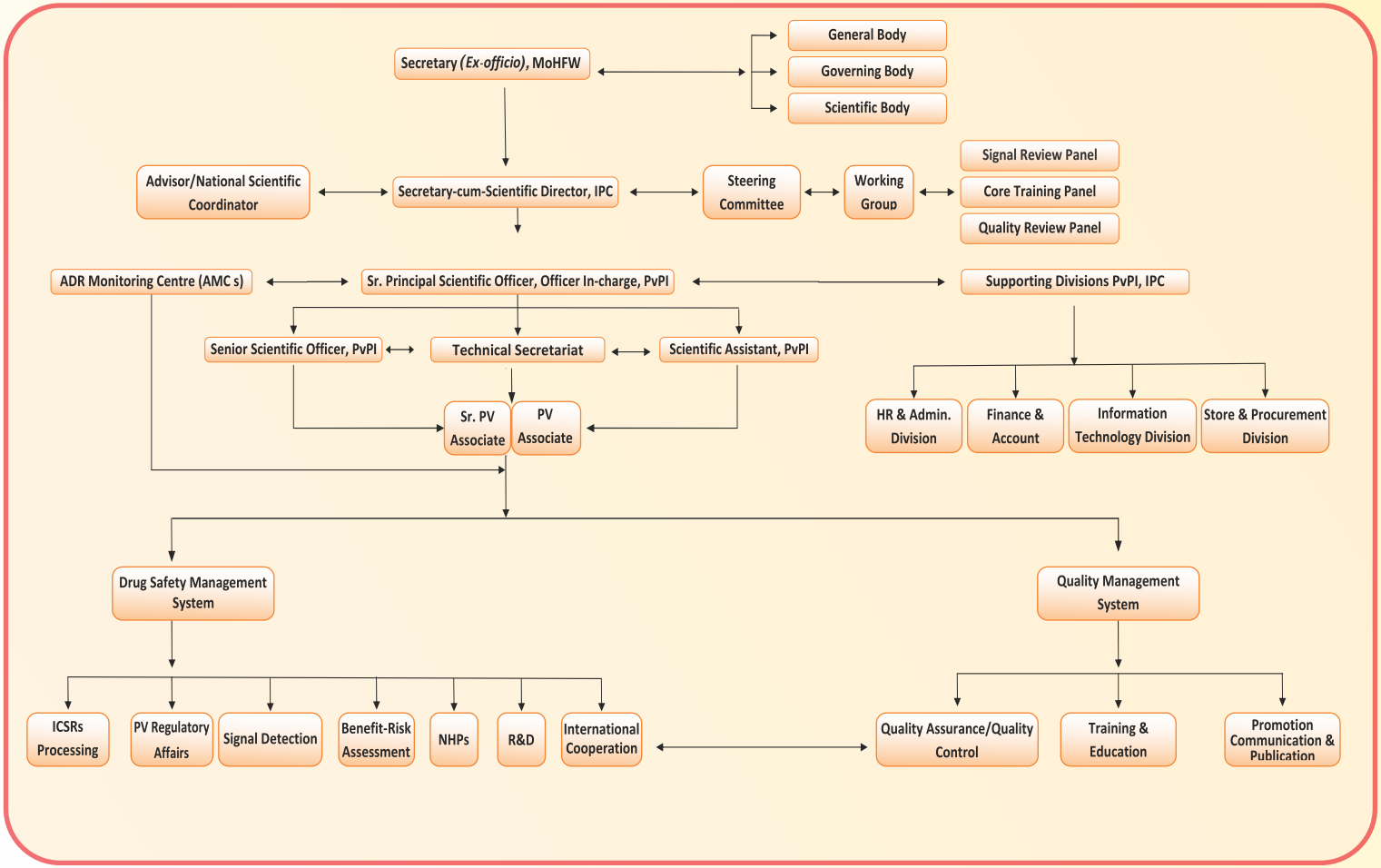
The Core Training Panel (CTP) of PvPI identifies training needs, organizes national and international training programmes, designs training modules and conducts the training for healthcare professionals and other stakeholders throughout the year. It also identifies trainers for zone-wise training centers.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

Current Scenario

NCC-PvPI collects, collates and evaluates spontaneous reports of ADRs due to use of medicines, vaccines, medical devices & herbal products from all healthcare professionals and consumers/patients. To monitor ADRs, ADR Monitoring Centers (AMCs) have been set up all over India, which send reports to NCC- PvPI located at IPC, Ghaziabad. NCC-PvPI was started with 22 AMCs in the initial phase and currently has 250 ADR monitoring centers (Medical colleges, district and corporate hospitals) across the country. Of these centers, 21AMCs are sentinel sites for Revised National Tuberculosis Control Programme (RNTCP), 20 for the HIV control programme on Anti-retroviral therapy (ART) and 6 are designated Bedaquiline Cohort event monitoring centres.

Keeping in view the progress made by and contribution of PvPI for drug safety, World Health Organization (WHO) on July 18, 2017 recognised IPC-PvPI as a WHO-Collaborating Centre for Pharmacovigilance in Public Health Programs and Regulatory Services. This is a matter of pride and honour to India this being first of its kind, putting it on the world map.

Organogram of the National Coordination Centre, Pharmacovegilance Programme of India (PvPI)



Reporting of ADRs

Who can Report ADRs?

- All healthcare professionals
- Consumers/Patients
- Pharmaceutical companies

Why to Report?

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

What to Report?

- All types of suspected ADRs (known or unknown, serious or non-serious frequent or rare): regardless of an established causal relationship
- ADRs associated with pharmaceutical drugs, vaccines, herbal remedies medical devices, contrast media and other diagnostic pharmaceuticals
- Inefficacy of medicines and pharmaceutical inadequacies can be reported
- ADRs encountered with overdose, abuse, off-label use, misuse or occupational exposure is not currently included in the purview of PvPI

How and Whom to Report?

All healthcare professionals, including clinicians, dentists, pharmacists, nurses can report suspected ADRs using the Suspected Adverse Drug Reaction Reporting Form. Pharmaceutical companies can use this form to send their Individual Case Safety Reports (ICSRs) specific for their product to the NCC-PvPI. The form is available on the official website of IPC or the CDSCO. Reporters are required to fill the Suspected Adverse Drug Reaction Reporting Form to report any suspected ADR. They may submiat the ADR form to the nearest AMC or directly to NCC-PvPI or mail the form at pvpi.ipcindia@gmail.com

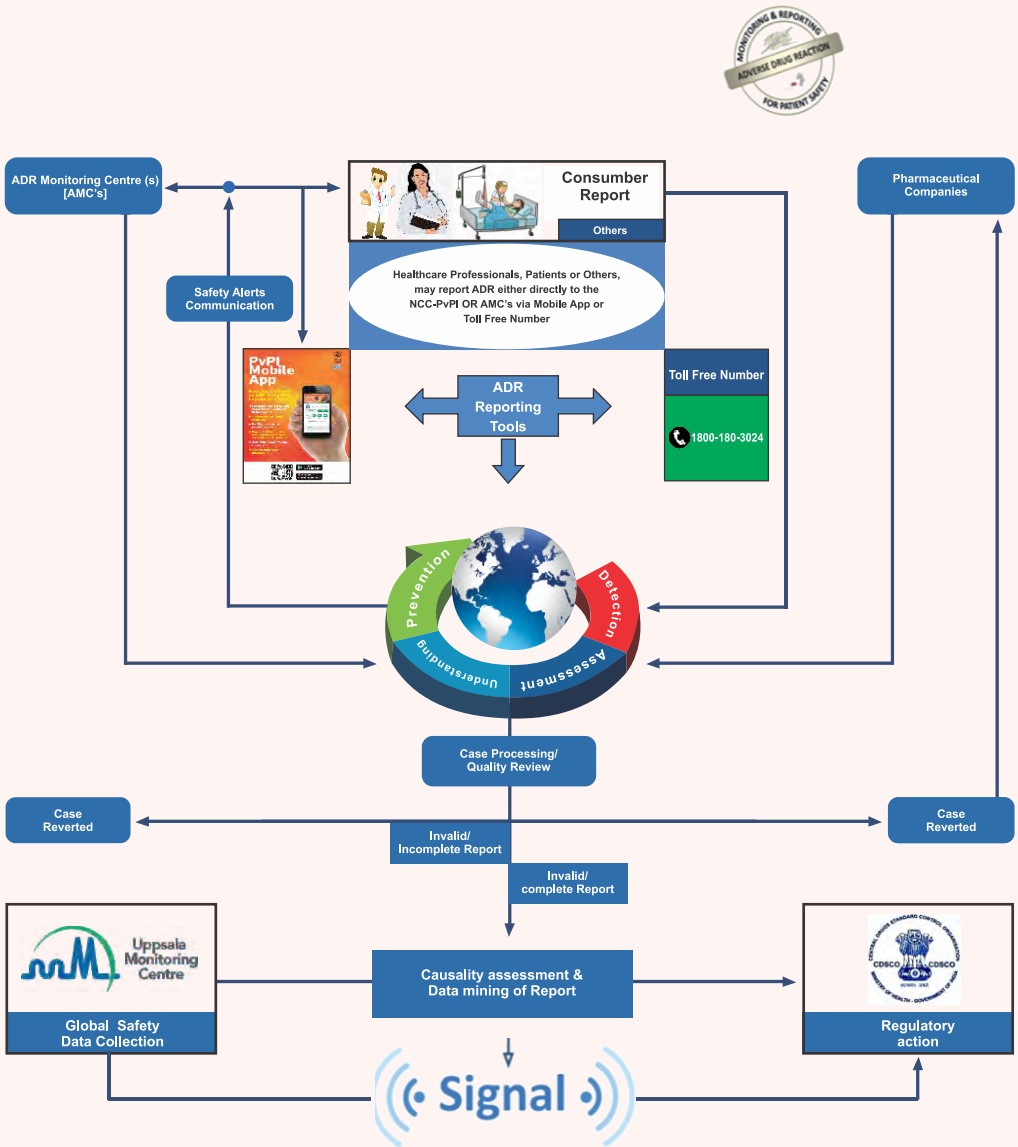
Helpline (#1800-180-3024)

Patients/Consumers/Healthcare Professionals may report suspected ADRs due to use of medicinal products to NCC-PvPI from 9.00 am to 5.30 pm on weekdays (Monday-Friday) via toll free helpline 1800-180-3024.

Medicines' Side-Effect Reporting Form (For Consumers)

The Medicines' Side-Effect Reporting Form (For Consumers) ensures the direct participation of patient/consumer in PvPI. The form is at present available in 10 local languages, including Hindi, Bengali, Gujarati, Kannada, Malayalam, Marathi, Assamese, Oriya, Tamil and Telugu. ADR reporting by consumers is a mechanism for consumer empowerment in healthcare sector. The form is available on the official website of IPC.

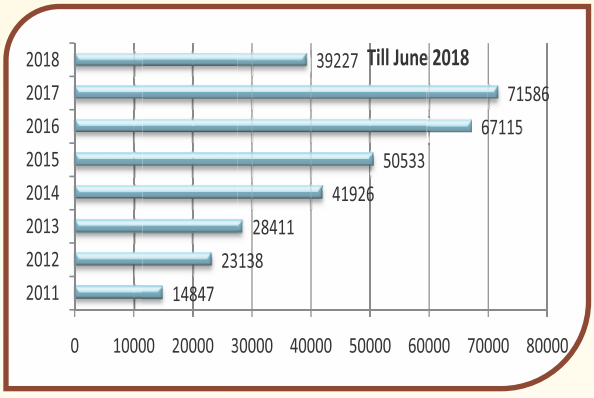
Adverse Drug Reaction (ADR) Reporting In India

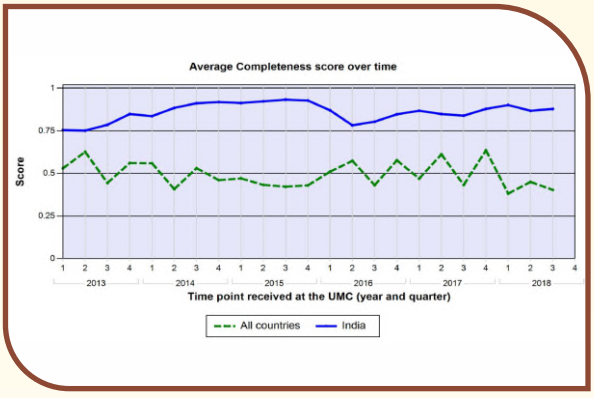


Status of ADR Reporting

The trend of ADR reporting through PvPI since 2011 till date is mentioned below. It is evident that the number of reports is gradually increased, reflecting the sensitization of healthcare professionals and other stake holders about the programme. Reporting patterns are on the increase year-wise and have gone up exponentially in recent years.

Year-wise reporting status 2011- 2018





PvPI Recommendations to CDSCO

Drug Alert

Change in Package insert

Signal

Drug Alert	Updating Package insert	Signal
71	24	05

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 HCPs & regulatory authority - the Central Drugs Standard Control Organization (CDSCO).

PvPI Collaborators

During last seven years PvPI has collaborated with several national health programmes and research institutions in order to develop safety database of medicines in India:

National collaborations

S. No.	Year	Health Programme/Institution
1	2013-14	• Revised National Tuberculosis Control Programme (RNTCP)- Pharmacovigilance of Anti-tubercular drugs on 11th October 2013. • AEFI Secretariat (UIP) - Pharmacovigilance of Vaccines on 28th February 2013
2	2014-15	National AIDS Control Organization (NACO)-Pharmacovigilance of Anti-Retroviral Drugs on 15th September 2014
3	2015-16	Cohort Event Monitoring of Anti-TB Drug- Active Surveillance of Bedaquiline at 6 AMCs under PvPI.
4	2016-17	• ICMR Institutions as Collaborating Centres- 7 ICMR Institutes to strengthen Research Based PV • Indian Medical Association (IMA) - Sensitization and training of Clinicians on PV. • National Vector-Borne Disease Control Programme- PV of Kala-azar Drugs on 03rd August 2016.
5	2017-18	• National Accredited Board of Hospitals (NABH), Quality Council of India – Implementation of ADR - reporting by all NABH Accredited hospitals

International collaborations

Year	Organization
2017-18	World Health Organazation- South-East Asia Regional Office (WHO-SEARO) • WHO Collaborating Centre for Pharmacovigilance in Public Health Programmes & Regulatory services

Training & Skill Development

The training and education division of PvPI plays an important role in fulfilling the stakeholders' expectations by imparting the requisite hands-on training in Pharmacovigilance. These training activities conducted at NCC-PvPI or the AMCs contribute greatly in generating the trained professionals as per the requirements of both the public and private sectors. The training offered by the PvPI benefit young pharmacy/medical/parmedical/other healthcare professionals for establishing career in the field of pharmacovigilance.

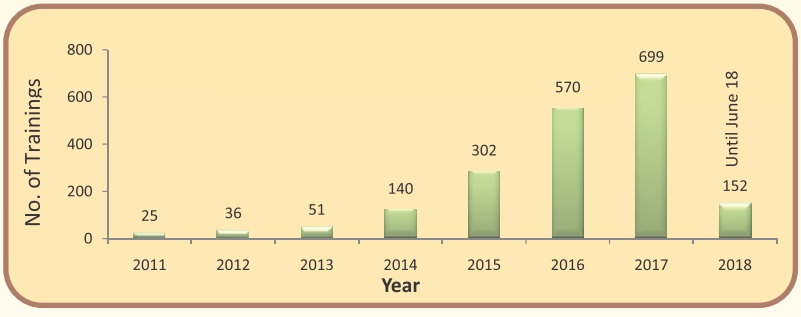
Focused Pharmacovigilance trainings conducted by PvPI

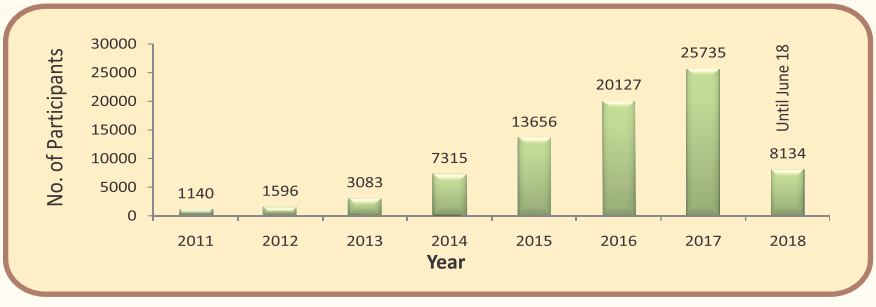
Workshop on Challenges, Solutions and Recommendations for Integrating Pharmacovigilance with National Health Programmes in South-East Asia Region
Workshop on Compliance of Good Pharmacovigilance Practices for Low-Middle Income Countries (LMIC)
Regional Training on Pharmacovigilance System Establishment & Capacity Building at Pharmaceutical Industries
Workshop-cum-Training Programmes on PV for NABH Accredited Hospitals
CMEs conducted by RTCs at AMC/District Hospitals
Advance-level Training conducted by Regional Training Centres (RTCs)
Skill Development Programme on Basics and Regulatory Aspects of Pharmacovigilance
Induction-cum-Training Programme for Coordinators of Newly Recognized AMCs and Pharmacovigilance Associates

Capacity building of PvPI across the Country

PvPI contributed towards the success of Pradhan Mantri Kaushal Vikash (PMKV) Yojna by providing trainings to young professionals. So far more than 80786 stakeholders, including doctors, nurses and pharmacists were trained, sensitized and made aware of basic and regulatory concepts of Pharmacovigilance. A total of 1975 training and awareness programs were conducted by NCC and attached AMCs since 2011 to 2018.

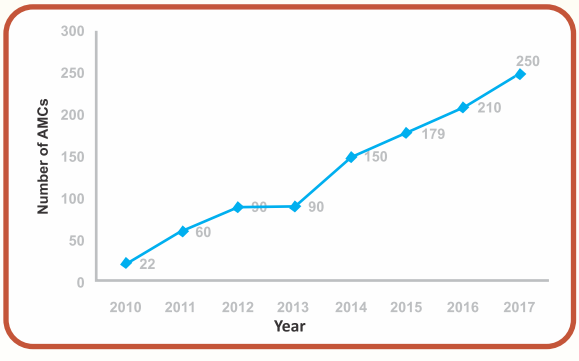
Trend of Year - wise trainings





Trend of Year - wise participants (HCPs)

The growth of PvPI is evident from the consistant increase in number of ADR monitoring centres across the country.



Types of AMCs include:

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

Communication in PvPI

Modes of Communication

Communication aims at improving patient care, understanding ADRs/AEs, promoting transparency and accountability. NCC-PvPI is responsible for publishing/communicating findings from its database to journals/media/online portals while other concerned stakeholders are required to obtain prior approval from NCC to publish/communicate any data or information related to PvPI and due acknowledgement to NCC PvPI. Different modes of communications used in PvPI are;

Press and Media communication

This includes press releases and media briefings which are primarily intended for journalists. All activities related to PvPI are communicated to the media for raising awareness among stakeholders and the common man. PvPI also releases news in public interest.

Website

A website is a key tool to disseminate information among stakeholders, including patients and healthcare professionals. NCC-PvPI strives to ensure that all important safety information is regularly published on its website.

Newsletter

NCC-PvPI publishes its *Newsletter* quarterly to communicate the findings and regulatory status of medicines in India as well as globally to the stakeholders. This newsletter is meant to disseminate information with issues of drug safety with ultimate objective of patient safety. It provides information, statistics and advice on drug safety. The quarterly issues of the *Newsletter* can be accessed from the IPC website.

Posters and Pamphlets

Posters and pamphlets are effective modes of communication. PvPI regularly publishes posters and pamphlets that illustrate the news and views of PvPI and related drug safety information to stakeholders in India and across the globe.

Communication through social media LinkedIn (NCC PvPI)

LinkedIn is a business-oriented social networking service that offers visibility and access to stakeholders. The NCC-PvPI is registered on LinkedIn (ID - NCC PvPI), for better visibility and access to stakeholders.

Facebook (ipcgzb)

Facebook is a social networking website that allows registered users to create profiles, upload photos, videos and send messages. The facebook account of ipcgzb is used to share updates with users of this social media.

Twitter (@IPC_Ghaziabad)

Twitter is an online social networking service that enables users to send and read short messages called “tweets”. Registered users can read and post tweets regarding PvPI on the account @IPC_Ghaziabad

PvPI in National And International Arena

IPC Signs MoU with NABH for ADR-Reporting

A memorandum signing ceremony was organized by IPC at CDSCO headquarters, FDA Bhawan, New Delhi, on January 10, 2017.The objective of this MoU between IPC and NABH is to promote monitoring and reporting of ADRs by NABH-accredited hospitals to PvPI.

Visit of DRA-Bhutan to 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. The **four-day training programme from June 11 to June 14, 2018** also served as a platform for sharing the 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). Such an effort, they said, would help them to further strengthen the PV system in Bhutan.

PvPI in National And International Arena

Recognition and Launch of WHO-CC at PvPI, IPC

The milestone - marking the formal launch of Pharmacovigilance Programme of India (PvPI), 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 Secretary, Ministry of Health and Family Welfare, Dr. R K Vats in presence of DCG(I), Dr G N Singh and the WHO officials from Geneva and Country Office, India.

PvPI to work in unison with USFDA

An expert team from USFDA headed by Dr A Letitia Robinson, Country Director, Dr Ademola Daramola, International Relations Drugs Specialist, USFDA and others visited Indian Pharmacopoeia Commission, Ghaziabad on August 21, 2017. The meeting was held with an objective of understanding the functioning of US Pharmacovigilance system and identifying the scope for future collaboration between NCC-PvPI, IPC and USFDA

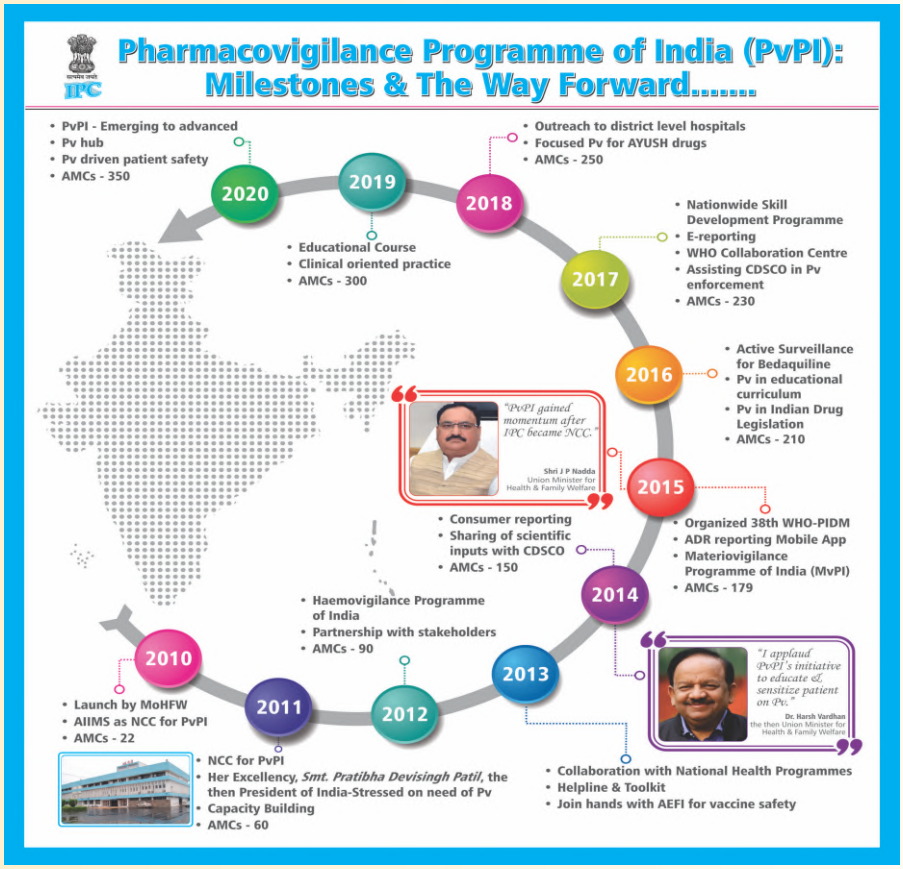
Various Publications by PvPI

Performance Reports

Newsletters

Miscellaneous

Milestones and Future Prospects



Compiled by NCC-PvPI Team

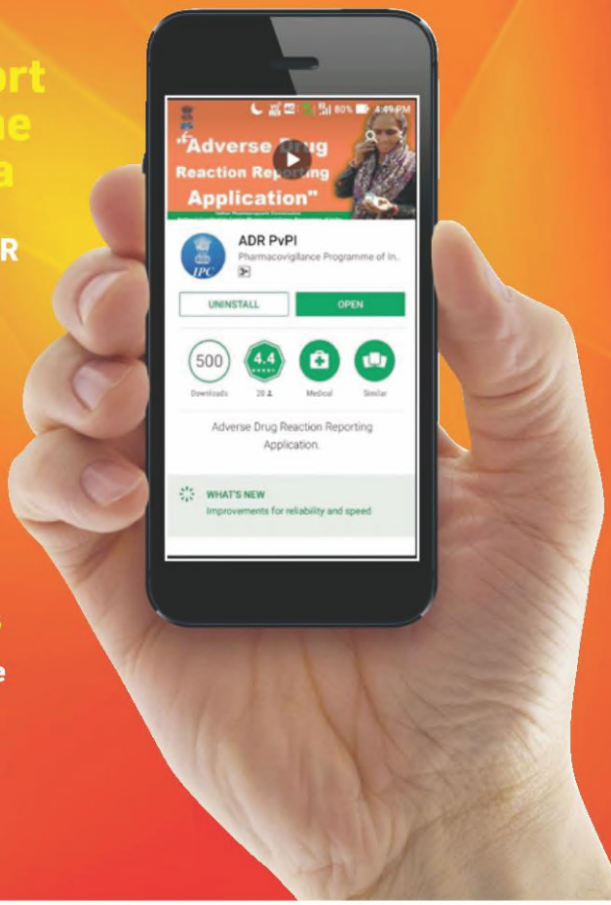
PvPI Mobile App

सत्यमेव जयते

IPC

Now you can report an ADR at any time any where in India

- Facilitate hassle free ADR reporting for healthcare professionals
- Customized consumer reporting
- Facility to report at preferred centre
- Supports attachment of images(Adverse Event) and relevant documents
- Acknowledgement to the reporter
- User-friendly User Interface (UI)



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