सत्यमेव जयते

IPC

Pharmacovigilance Programme of India (PvPI)

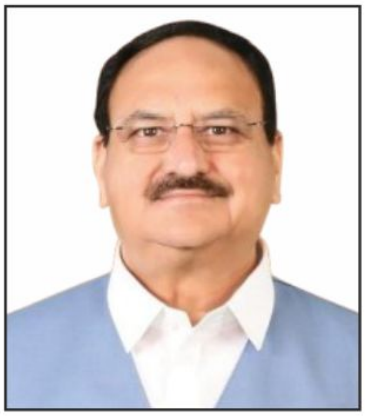
A step towards patients safety

National Coordination Centre
Pharmacovigilance Programme of India

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

INDIAN PHARMACOPOEIA COMMISSION

Ministry of Health and Family Welfare, Government of India



Shri. Jagat Prakash Nadda

Hon'ble Union Minister of Health & Family Welfare
and Chemicals & Fertilizers
Government of India

I commend the Indian Pharmacopoeia Commission (IPC) for its unwavering commitment for ensuring the highest standards of quality and safety in medicines. Under the visionary leadership of Hon'ble Prime Minister Shri Narendra Modi, IPC's initiatives in digital dissemination and capacity building are setting new benchmarks in global health. Through the Pharmacovigilance and Materiovigilance Programmes of India, IPC is fostering a robust drug safety surveillance ecosystem by generating indigenous safety and adverse event data, thereby reaffirming India's position as a global leader in pharmaceuticals.

CONTENTS

ABOUT PHARMACOVIGILANCE PROGRAMME OF INDIA

The Pharmacovigilance Programme of India (PvPI) was operationalized in July 2010 by the Ministry of Health & Family Welfare (MoHFW), Government of India (GoI) with a mission to reduce the risks associated with the use of medicines in the Indian population. The All India Institute of Medical Sciences (AIIMS), New Delhi was established as the National Coordination Centre for PvPI. Later on, Ministry of Health & Family Welfare, Government of India on 15th April 2011, recast this programme and shifted the National Coordination Centre from AIIMS, New Delhi to Indian Pharmacopoeia Commission (IPC), Ghaziabad. The Materiovigilance Programme of India (MvPI) to monitor the safety of medical devices and the Haemovigilance Programme of India (HvPI) to monitor the safety of blood & blood-related products are also the integral part of PvPI and their NCCs are located at IPC & National Institute of Biologicals (NIB), Noida, respectively .

VISION, MISSION & OBJECTIVES OF PvPI

Vision

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

Mission

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

Important 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 organise and sensitize the stakeholders for National Pharmacovigilance Week from 17th-23rd September every year.*

WHY PHARMACOVIGILANCE IS IMPORTANT?

- To promote rational and safe use of medicines.
- Identification of new ADRs (Signals).
- To identify the pattern of use of drugs in different diseases and their adverse effects.
- Updation of patient information / package insert leaflet - new ADRs, new warnings, new contraindications, dose alteration etc.
- To educate healthcare professionals to improve the safe use of medicines.
- To assess benefit-risk ratio of a medical products.
- To take evidence-based regulatory decisions.
- To boost public confidence in safety of medical products.

TERMINOLOGIES IN PHARMACOVIGILANCE

What is Pharmacovigilance?

The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem.

What is an Adverse Drug Reaction (ADR)?

A response to a drug which is noxious and unintended, and which occurs at doses normally used in humans for the prophylaxis, diagnosis or treatment of disease, or for the modification of physiological function.

WHO CAN REPORT?

Any person can report the Adverse Event/ Adverse Drug Reaction to the nearest ADR Monitoring Centre & Pharma Industry Professionals are encouraged for reporting of AE/ADR to the NCC-PvPI.

WHAT TO REPORT?

- All types of Suspected Adverse Events due to medications
- Medication Errors
- Misuse/Overdose/Abuse
- Off-label Use
- Lack of Efficacy
- Product quality-related Issues

WHY TO REPORT ?

As a healthcare professional, it is a moral and ethical responsibility to report suspected adverse reactions associated with pharmaceutical products to safeguard public health.

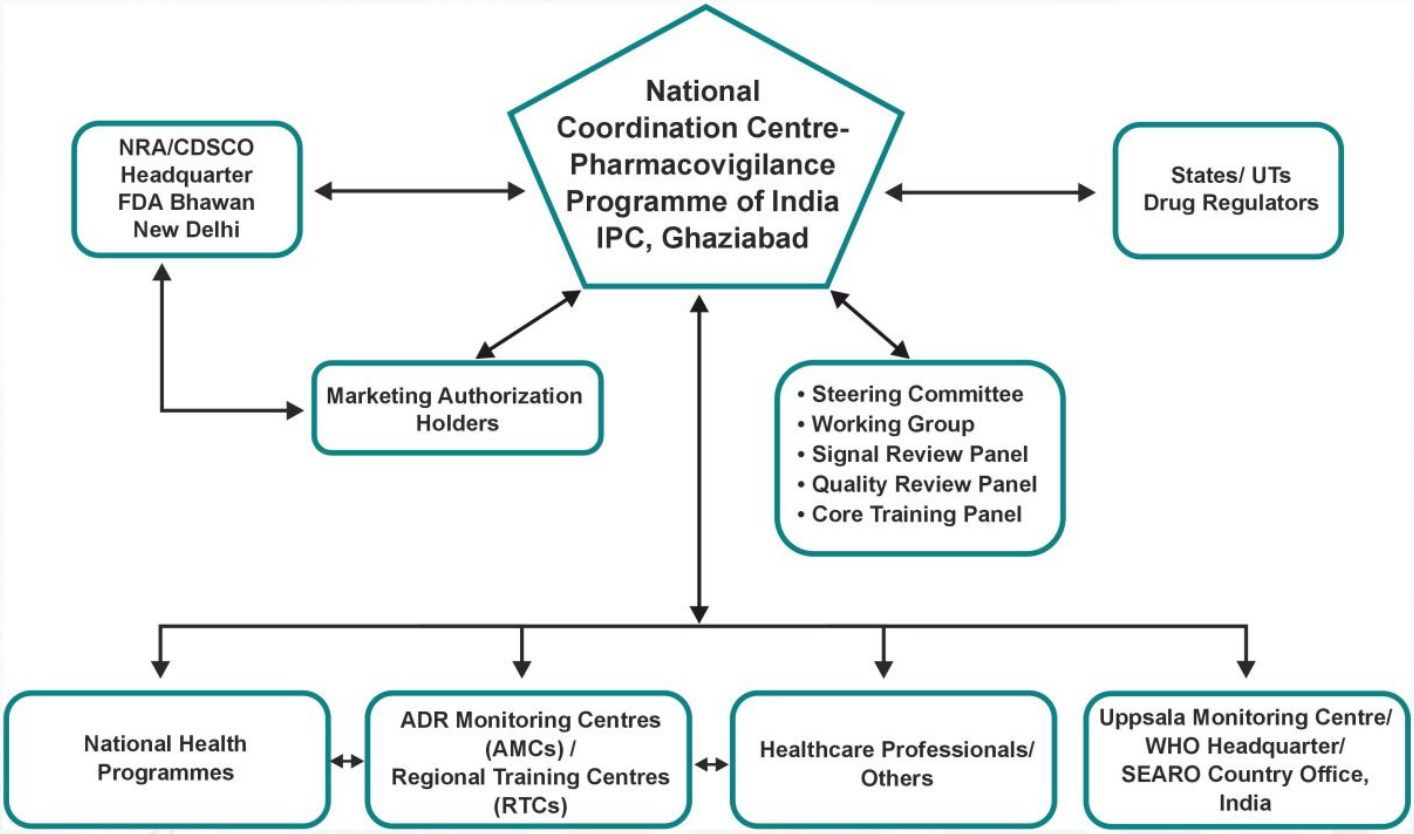
WHERE TO REPORT ?

The Adverse Events (AEs)/ Adverse Drug Reactions (ADRs) should be reported to nearest ADR Monitoring Centres (AMCs) of PvPI using appropriate ADR Reporting Form such as 'Medicines Side Effect Reporting Form for Consumers' & 'Suspected Adverse Drug Reaction Reporting Form for Healthcare Professionals'. Serious Adverse Event following immunization can also be reported in Serious AEFI case Notification Form available on http://www.ipc.gov.in

SUPPORTING ORGANIZATIONS

- Universal Immunization Programme
- National Tuberculosis Elimination Programme
- National AIDS Control Programme
- National Center for Vector Borne Diseases Control
- Uppsala Monitoring Centre
- National Accreditation Board for Hospitals & Healthcare Providers
- Indian Medical Association
- Central Drugs Standard Control Organization

PvPI COMMUNICATION CHANNELS



TOOLS FOR AEs/ADRs REPORTING

ADR Reporting Form
Available on: www.ipc.gov.in

Nearest ADR Monitoring Centres (AMCs)
List available on: www.ipc.gov.in

Mobile App ADR PvPI 2.0
Available on: Google Play Store

Tools for AEs/ADRs Reporting to PvPI

Adverse Drug Reaction Monitoring System (ADRMS) Software

Toll Free Number: 1800-180-3024

List of AMCs

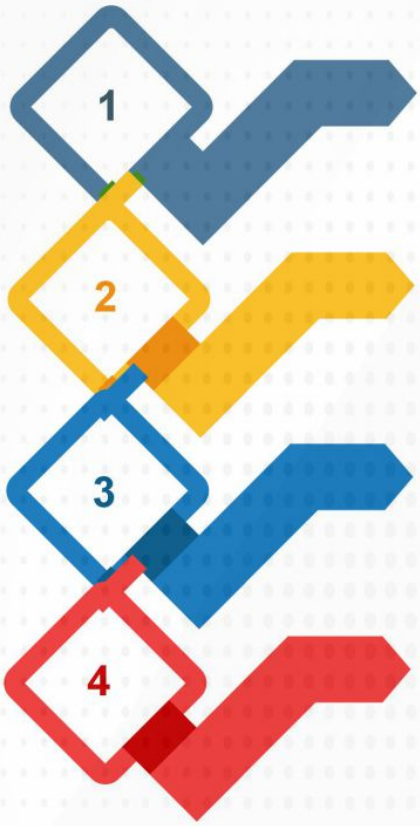
www.ipc.gov.in

Report via ADRMS

Data Confidentiality

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

How to get enrolled as a New AMC under PvPI ?



NCC-PvPI seeks Enrollment Form from Dean/Head of the Institution/ Hospital for establishment of an AMC.

NCC-PvPI examines suitability of the proposed centre.

Approval from competent authority

Communication to the newly-inducted AMC

ADVANTAGES OF BEING AN AMC

- Implementation of Pharmacovigilance in hospitals/Academic Institutions will provide a dynamic process of monitoring ADRs.
- Health partner for the Nation-wide ADR Reporting System.
- Access to WHO Global safety database, VigiFlow to evaluate the benefit-risk assessment of Medicines.
- Research Publications/Projects on Pharmacovigilance.

CAPACITY BUILDING PROGRAMMES IN PHARMACOVIGILANCE

Skill Development Programme (SDP), Advanced Level Trainings (ALTs), Sensitization/awareness programmes for reporting AEs, Regional Training Programmes and Interactive meetings conducted for MAHs, etc. are organized by NCC-PvPI.

For further information, please visit and contact:

https://www.ipc.gov.in/mandates/pvpi/training-and-education.html

Email: training.nccpvpi-ipc@gov.in

NATIONAL PHARMACOVIGILANCE WEEK CELEBRATION

National Pharmacovigilance Week is celebrated every year from 17th-23rd September across the country.

CHAIRPERSON OF EXPERT COMMITTEES OF PvPI

Steering Committee

Drug Controller General of India

Dr. Rajeev Singh Raghuvanshi

Working Group

Secretary-cum-Scientific Director

IPC - Ghaziabad

Dr. V. Kalaiselvan

Signal Review Panel

Prof. Y.K.Gupta

National Scientific Coordinator and President

AIIMS - Jammu

Core Training Panel

Prof. Suparna Chatterjee

RTC Coordinator, IPGMER, Kolkata

Quality Review Panel

Prof. Harmeet Singh Rehan

Director Professor & Head, Dept. of Pharmacology,

Lady Hardinge Medical College, New Delhi

NOTES

Let us join hands with PvPI to ensure patient safety

ADRMS

ipcgzb

www.ipc.gov.in

ipcgzb

Toll Free No.
1800 180 3024

ipcgzb

ADR PvPI 2.0
Mobile App

ipcgzb1

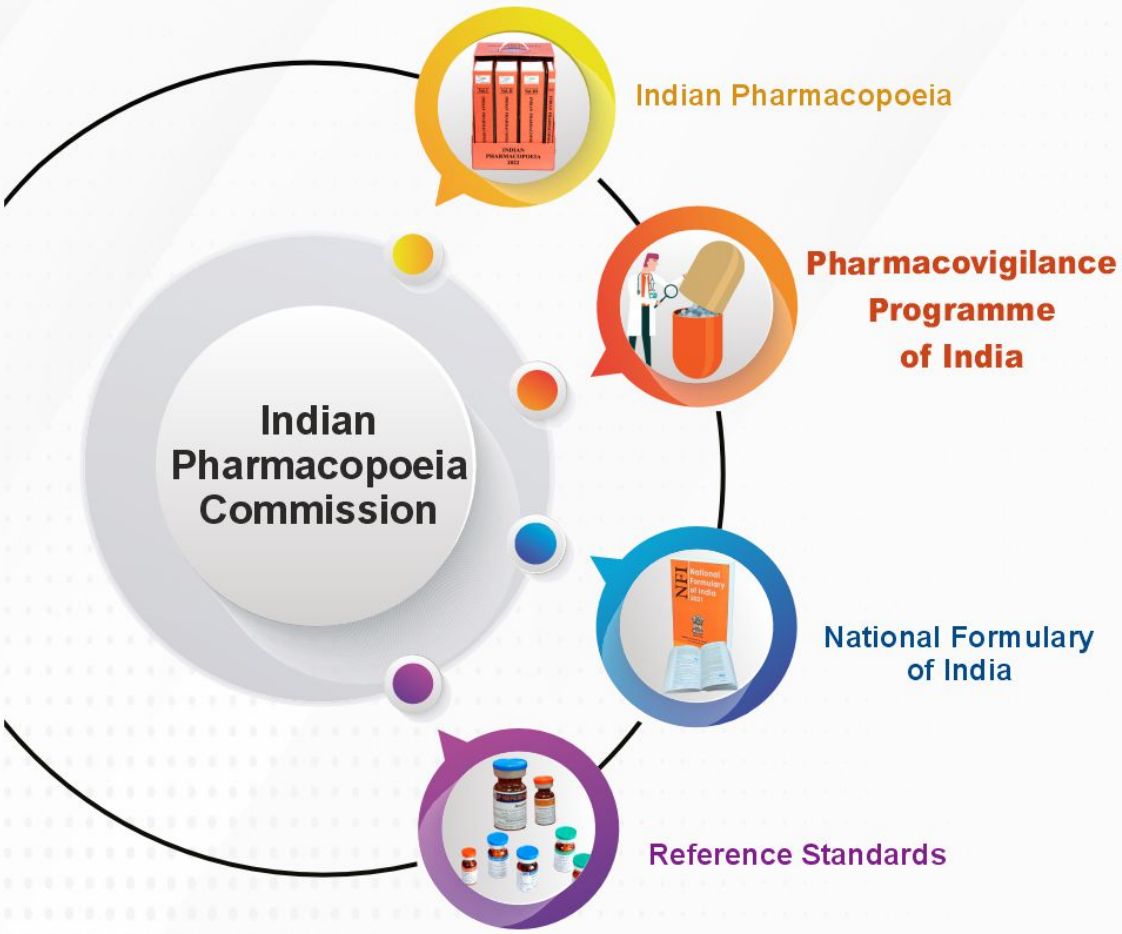
ipcgzb

pvpi.ipc@gov.in

ABOUT THE IPC

Indian Pharmacopoeia Commission (IPC) is an Autonomous Institution of the Ministry of Health and Family Welfare, Govt. of India. Its basic function is to regularly update the standards of drugs commonly required for the treatment of diseases prevailing in the country.

Functions of IPC



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Ministry of Health and Family Welfare, Government of India

Sector - 23, Raj Nagar, Ghaziabad - 201002

Email: pvpi.ipc@gov.in Tel.: 0120-2783400, 2783401, 2783392

Website: www.ipc.gov.in

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