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

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## 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 AIIMS, New Delhi was established as the National Coordination Centre for PvPI (NCC-PvPI). Later on, the Ministry of Health & Family Welfare (MoHFW), Government of India (GoI) on 15th April 2011, recast this program 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.

## 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.*

## 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.
- Revision 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 medicine.
- To take evidence-based regulatory decisions.
- To boost public confidence in safety of medicines as well as medical devices.

## 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 and
- 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 Centre 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".


***NOTE : 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 Program
- National AIDS Control Organisation
- 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 REPORTING ADRs

**1 NEAREST AMCs (ADR Monitoring Centres)**

**2 Mobile Application ADR PvPI**

**Tools for Reporting ADRs**

**3 TOLL FREE Helpline**

**1800 180 3024**

*Available from: Monday to Friday - 9:00 AM to 5:30 PM)*

**4 ADR Reporting Form**

*Available on: www.ipc.gov.in*

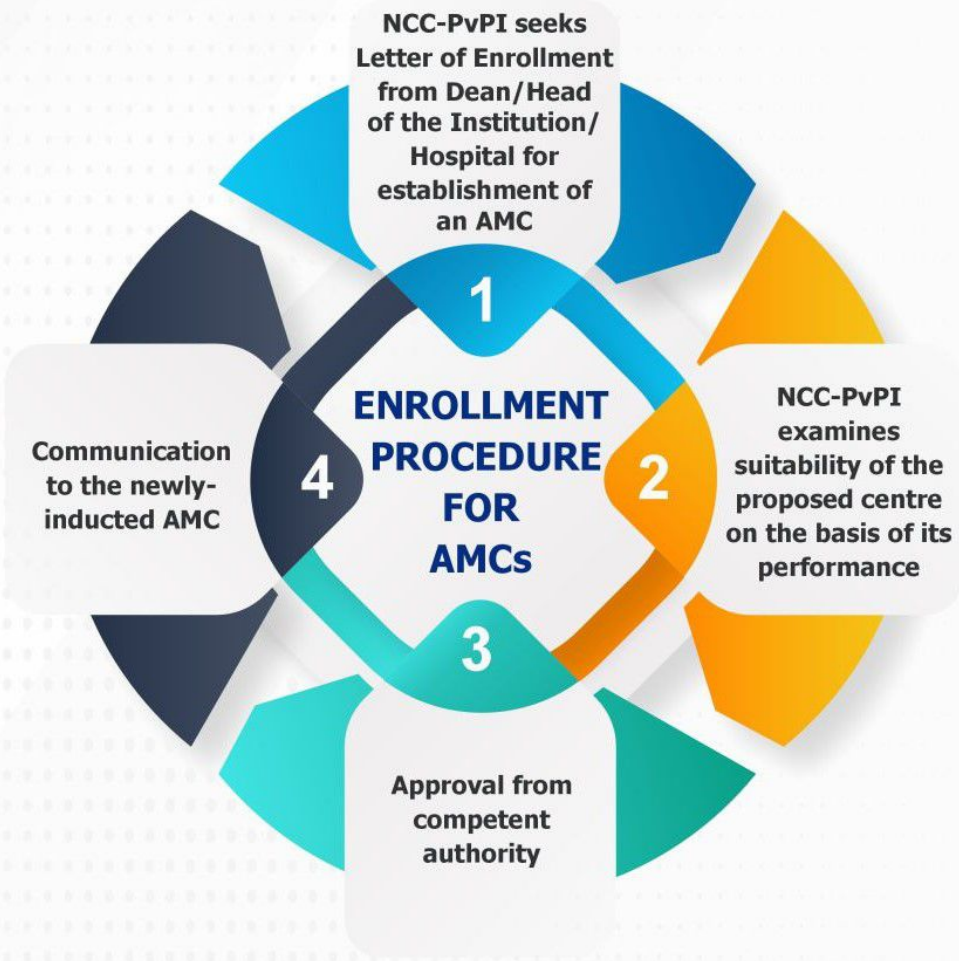
List of AMCs

www.ipc.gov.in

## 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 ?



## 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.

## SKILL DEVELOPMENT PROGRAMMES IN PHARMACOVIGILANCE

Skill Development Programme in Pharmacovigilance (SDP) is organized on quarterly basis by the National Coordination Centre-Pharmacovigilance Programme of India.

**For further information, please visit & contact:**

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

**Email: training.nccpvpi-ipc@gov.in**

## NATIONAL PHARMACOVIGILANCE WEEK

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

# CHAIRPERSON OF EXPERT COMMITTEES OF PvPI

## Steering Committee & Working Group:

**Dr. Rajeev Singh Raghuvanshi**

*Drug Controller General of India and*
*Secretary-cum-Scientific Director, IPC*

## 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*

## 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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**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

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Website: www.ipc.gov.in

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