



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 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.

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
- 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**



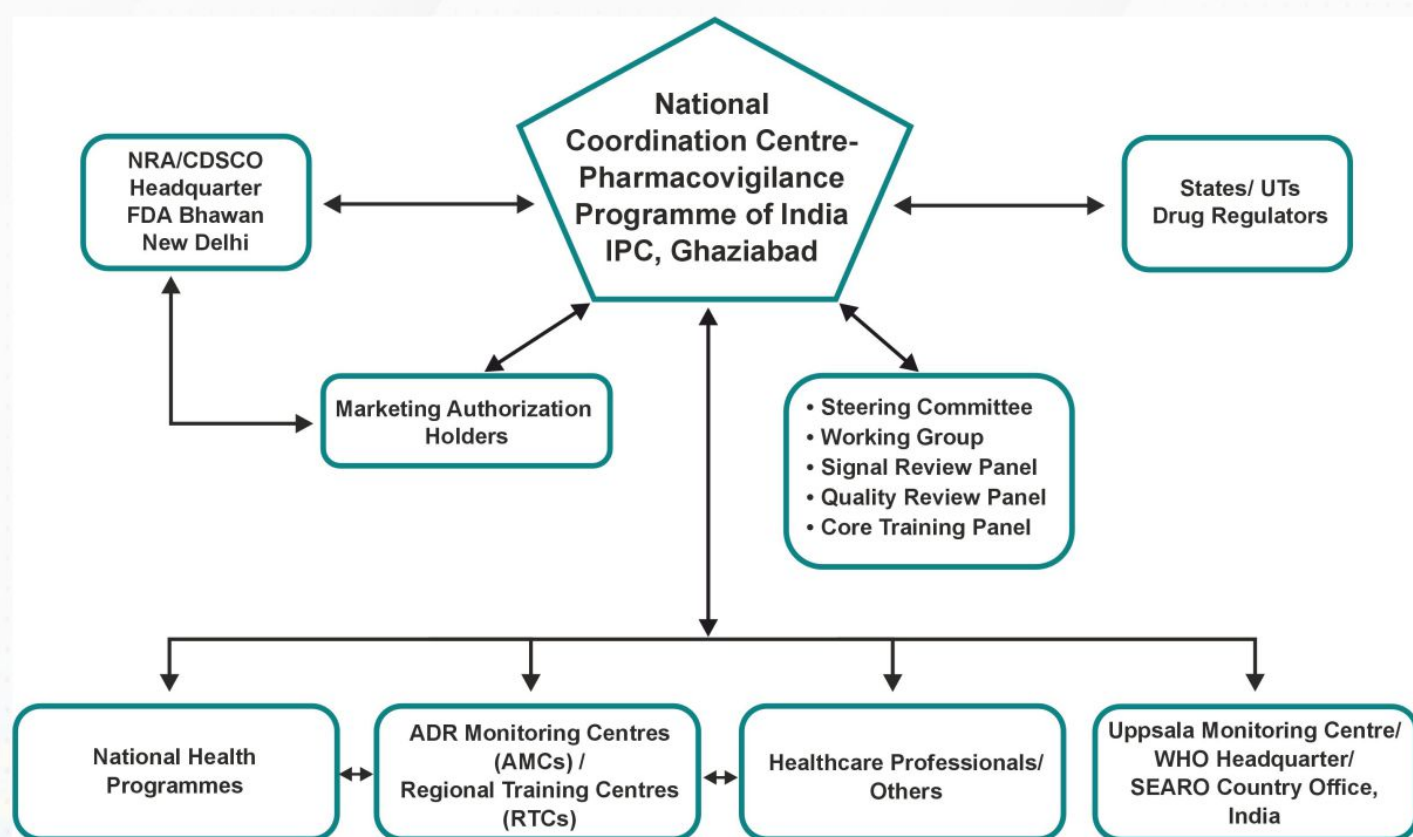
**Indian
Medical
Association**



**Central Drugs
Standard
Control
Organization**



PvPI COMMUNICATION CHANNELS



TOOLS FOR AE/ADRs REPORTING



List of AMCs



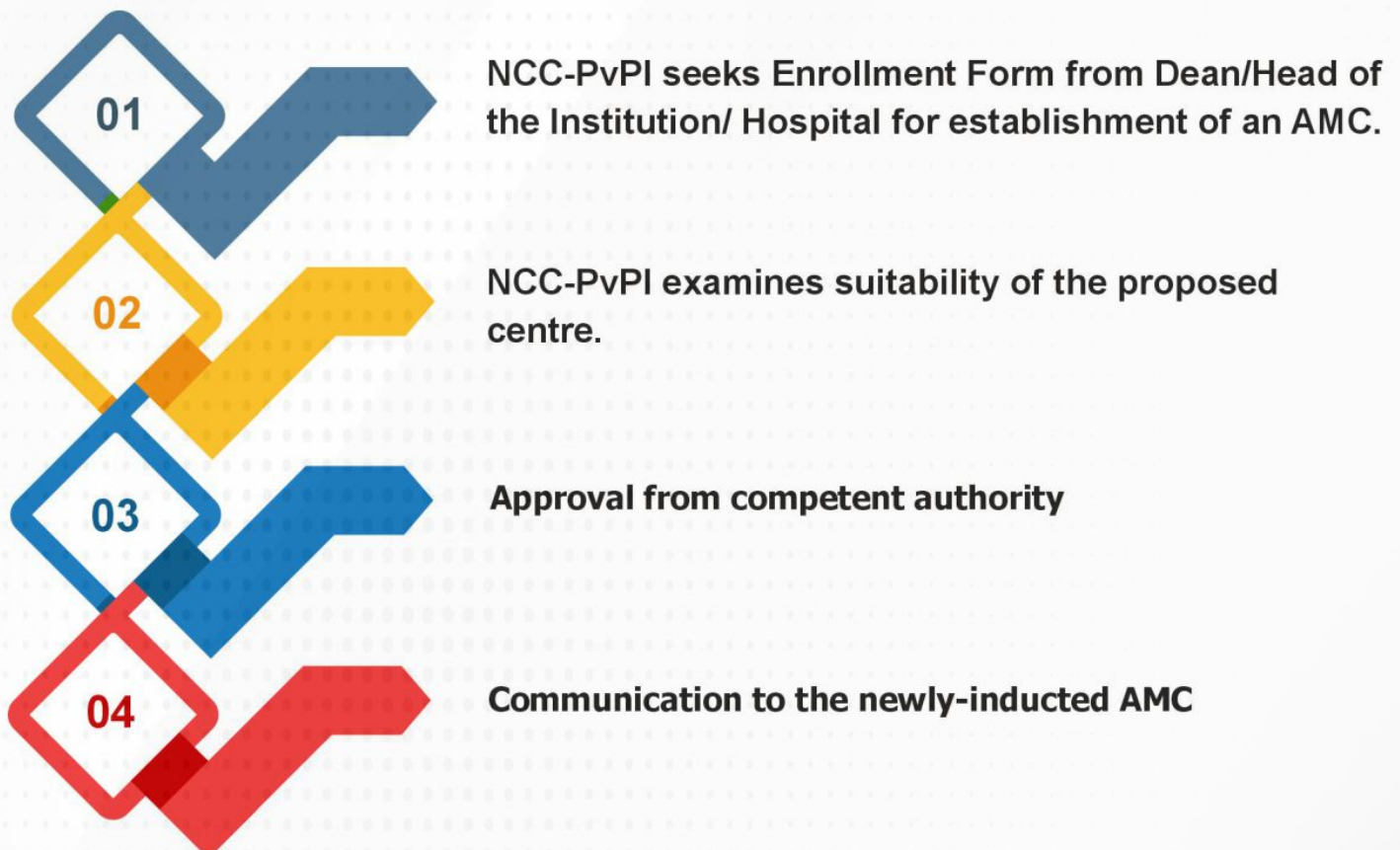
www.ipc.gov.in



Data Confidentiality

- The patient's identity is held in strict confidence and protected to the full extent.
- Submission of a report does not constitute that medical personnel or manufacturer or the product caused or contributed to the adverse 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.
- Research Publications/Projects on Pharmacovigilance.

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



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1800 180 3024



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ADR PvPI Mobile-app

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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



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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