DEPTH OF BIOLOGY

Unit - 4

Basic aspects, terminologies and establishment of pharmacovigilance

History and progress of pharmacovigilance, Significance of safety monitoring, Pharmacovigilance in India and international aspects,

WHO international drug monitoring programme, WHO and Regulatory terminologies of ADR, evaluation of medication safety, Establishing pharmacovigilance centres in Hospitals, Industry and National programmes related to pharmacovigilance.

Roles and responsibilities in Pharmacovigilance

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Basic aspects, terminologies and establishment of pharmacovigilance

Pharmacovigilance (PV) is the science and set of activities related to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems.

In simple words, pharmacovigilance = drug safety monitoring.

It helps to ensure that medicines are safe, effective, and used properly.

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Basic Aspects of Pharmacovigilance

1. Purpose-

To improve patient care and safety.
To ensure rational use of medicines.
To detect new, rare, or serious ADRs not found during clinical trials.

2. Scope-

Covers all medicines (prescription, OTC, herbal, vaccines, biologics).
Monitors Adverse Drug Reactions (ADRs) and Adverse Events (AEs).
Core Functions

3. Detection of ADRs -

Assessment (causality, severity, seriousness).
Understanding mechanism and risk factors.
Prevention by updating guidelines, warnings, or restrictions.

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Key Terminologies in Pharmacovigilance

Adverse Drug Reaction (ADR): Harmful and unintended effect of a drug at normal doses.

Adverse Event (AE): Any untoward medical occurrence in a patient receiving a drug (not always drug-related).

Serious Adverse Event (SAE): Event causing death, life-threatening situation, hospitalization, disability, or congenital defect.

Side Effect: Secondary, sometimes expected effect of a drug.

Causality Assessment: Process of linking ADR to a particular drug.

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Signal: A new possible association between a drug and an ADR (needs further investigation).

Risk Factors: Patient- or drug-related factors that increase chance of ADR (age, genetics, polypharmacy).

Pharmacovigilance Program of India (PvPI): National program started in 2010 to monitor drug safety.

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Establishment of Pharmacovigilance

Why Pharmacovigilance was Needed?

In early years, medicines were marketed with limited safety data.

1961 – Thalidomide tragedy: Pregnant women took thalidomide for morning sickness → thousands of babies born with limb defects (phocomelia).

This highlighted the need for a systematic program to monitor drug safety even after marketing.

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Establishment at the International Level-

1968: WHO started the Programme for International Drug Monitoring.
Main aim: To collect and share information on ADRs worldwide.
A pilot project began with 10 countries.

WHO Collaborating Centre-

Uppsala Monitoring Centre (UMC), Sweden) established in 1978.
Role:
Collect ADR data from all member countries.
Maintain the global database VigiBase.
Provide signal detection and safety alerts.

Today, more than 130 countries are part of this global pharmacovigilance system.

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Establishment in India-

Early Efforts
1986: ADR monitoring started under Indian Council of Medical Research (ICMR).
1997: India joined WHO's ADR monitoring program (under UMC).

Formal Programs-

2004: CDSCO (Central Drugs Standard Control Organization) started the National Pharmacovigilance Program.

2010: Ministry of Health & Family Welfare launched the Pharmacovigilance Programme of India (PvPI).

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Pharmacovigilance Programme of India (PvPI)-

National Coordination Centre (NCC): Indian Pharmacopoeia Commission (IPC), Ghaziabad.

ADR Monitoring Centres (AMCs): Set up in medical colleges, hospitals, and research centers.

Collect ADR reports → Send to NCC → Forwarded to WHO-UMC (Sweden).

Growth of PvPI-

Started with 22 ADR monitoring centers (2010).
Now expanded to 400+ AMCs across India.
Covers all types of drugs: prescription, OTC, biologics, vaccines, and even herbal medicines.
India is now one of the largest contributors of ADR reports to the global UMC database.

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Importance of Establishment-

Provides a formal system to detect and report ADRs.

Ensures public health safety by identifying risky medicines.

Strengthens drug regulation and promotes rational use.

Helps India and the world prevent tragedies like thalidomide.

Conclusion-

The establishment of pharmacovigilance started globally after the thalidomide tragedy in the 1960s, leading to the WHO international monitoring system and UMC in Sweden.

In India, pharmacovigilance formally began in 1986 and became structured with the launch of PvPI in 2010. Today, it plays a vital role in monitoring and improving drug safety.

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History and progress of pharmacovigilance

A. Early Incidents that Triggered PV-

1. Sulfanilamide tragedy (1937, USA) -

Sulfanilamide elixir prepared with diethylene glycol (toxic solvent).

Over 100 deaths, mainly children.

Result: US Food, Drug and Cosmetic Act (1938) for drug safety testing.

2. Thalidomide tragedy (1961, Europe)-

Thalidomide given to pregnant women for morning sickness.

Thousands of babies born with limb deformities (phocomelia).

Result: International awareness about post-marketing surveillance.

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WHO Initiatives-

1968: WHO launched International Drug Monitoring Programme.
Aim: Collect and share ADR data among countries.
Started with 10 pilot countries.

1978: Establishment of Uppsala Monitoring Centre (UMC), Sweden.
Acts as the WHO Collaborating Centre for PV.
Maintains global ADR database VigiBase.
Supports member countries in detecting safety "signals."

Today:
More than 130 countries are part of the WHO PV Programme.
Millions of ADR reports are stored in VigiBase.

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History and Progress of Pharmacovigilance in India-

-1986: First ADR monitoring started by ICMR (Indian Council of Medical Research).

-1997: India joined WHO's International Programme for Drug Monitoring (through UMC).

-2004: CDSCO started the National Pharmacovigilance Program (NPP).

-2010: Launch of Pharmacovigilance Programme of India (PvPI) by Ministry of Health & Family Welfare.

National Coordination Centre (NCC): Indian Pharmacopoeia Commission (IPC), Ghaziabad.

Started with 22 ADR Monitoring Centres (AMCs).

Now expanded to 400+ AMCs across India.

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Present -

- PvPI collects ADR data from hospitals, medical colleges, and healthcare professionals.
- Reports are forwarded to WHO-UMC.
- India is now one of the top contributors of ADR reports globally.

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Progress of Pharmacovigilance-

Initial Phase (1960s–70s): Establishment after drug disasters.

Expansion Phase (1980s–2000s): More countries joined WHO program; national PV centers developed.

Modern Phase (2010 onwards) -

Strong global collaborations.

Inclusion of vaccines, biologics, herbal medicines, medical devices.

Use of digital tools, mobile apps, and electronic reporting.

India's PvPI recognized by WHO as a Regional Centre for South-East Asia (2017).

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Importance of This Progress-

Strengthened drug safety regulations worldwide.

Improved public health protection.

Encouraged rational use of medicines.

Helped in early detection and prevention of rare and serious ADRs.

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Significance of Safety Monitoring-

Introduction-

Safety monitoring = Continuous observation, detection, and evaluation of adverse events (AEs) and adverse drug reactions (ADRs) during clinical trials and after marketing.

It ensures that medicines are safe, effective, and used rationally.

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Why is Safety Monitoring Important ?

A. Protects Patient Safety-

Early detection of harmful reactions.

Prevents severe outcomes (hospitalization, disability, death).

Provides immediate medical intervention when needed.

B. Identifies Unknown Risks-

Clinical trials before approval involve limited patients → rare ADRs may not be seen.

Safety monitoring helps find new, rare, or long-term ADRs once the drug is used widely.

C. Supports Rational Use of Medicines-

Guides correct dose adjustments, duration, and precautions.

Prevents unnecessary drug use and polypharmacy risks.

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D. Regulatory Importance-

Provides evidence for drug regulators (like CDSCO, USFDA, EMA).

Can lead to label updates, warnings, restricted use, or drug withdrawal.

E. Improves Public Health-

Builds trust among patients and healthcare providers.

Prevents drug disasters like thalidomide (1961).

Ensures cost-effective and safe therapy.

F. Encourages Pharmacovigilance-

Safety monitoring is the backbone of pharmacovigilance.

Provides data for national and international ADR databases (e.g., PvPI, WHO-UMC).

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Pharmacovigilance in India and International Aspects

Pharmacovigilance (PV): The science of detecting, assessing, understanding, and preventing adverse effects or any other drug-related problems.

It is a global system with both international cooperation (WHO) and national programs (like PvPI in India).

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International Aspects of Pharmacovigilance

A. Origin-

Triggered by drug disasters (e.g., thalidomide tragedy, 1961).

Highlighted the need for a global monitoring system.

B. WHO Programme for International Drug Monitoring (PIDM)-

1968: WHO launched PIDM with 10 member countries.

Aim: Collect and share ADR data internationally.

Now, more than 130 countries are part of this program.

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C. Uppsala Monitoring Centre (UMC), Sweden -

Established in 1978 as a WHO Collaborating Centre.

Functions:

Maintains VigiBase (world's largest ADR database).

Performs signal detection (new safety issues).

Provides training and guidelines for member countries.

D. Regulatory Agencies-

USFDA (United States Food and Drug Administration) → FDA Adverse Event Reporting System (FAERS).

EMA (European Medicines Agency) → EudraVigilance database.

MHRA (UK) → Yellow Card Scheme.

These agencies coordinate with WHO and national PV centers.

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Pharmacovigilance in India

- Early History-

1986: ADR monitoring started by Indian Council of Medical Research (ICMR).

1997: India joined WHO's International Programme for Drug Monitoring.

- National Programs-

2004 – National Pharmacovigilance Program (NPP):
Initiated by CDSCO (Central Drugs Standard Control Organization).

2010 – Pharmacovigilance Programme of India (PvPI):

Launched by Ministry of Health & Family Welfare.
National Coordination Centre (NCC): Indian Pharmacopoeia Commission (IPC), Ghaziabad.

Started with 22 ADR Monitoring Centres (AMCs), now expanded to 400+ AMCs.

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Functions of PvPI-

Collect ADR reports from hospitals and healthcare professionals.
Analyze and forward to WHO-UMC.
Conduct training, awareness, and signal detection.
Cover medicines, vaccines, biologics, and herbal drugs.

Achievements-

India is among the top contributors of ADR reports globally.

2017: WHO recognized PvPI as a Regional Centre for South-East Asia.

Helps improve drug labeling, safety warnings, and rational drug use.

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WHO International Drug Monitoring Programme

Introduction-

Launched by the World Health Organization (WHO) in 1968.

Purpose: To create a global system for monitoring the safety of medicines.

Reason: The thalidomide tragedy (1961) showed the urgent need for international cooperation in drug safety.

#Objectives-

Collect ADR data from all member countries.

Identify new safety signals (previously unknown adverse effects).

Share safety information globally.

Support national pharmacovigilance centers.

Ensure that the benefits of medicines outweigh the risks.

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Structure of the Programme-

A. WHO Headquarters (Geneva)-

Coordinates the global pharmacovigilance program.
Provides guidance and policy.

B. Uppsala Monitoring Centre (UMC, Sweden)-
Established in 1978 as a WHO Collaborating Centre.

Main roles:

Collects ADR reports from all countries.

Maintains VigiBase (world's largest international ADR database).

Performs signal detection and analysis.

Provides training and tools to member countries.

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C. Member Countries-

Countries join as part of the WHO Programme for International Drug Monitoring (PIDM).

Each country has a National Pharmacovigilance Centre.

They collect ADRs locally → send to WHO-UMC → stored in VigiBase.

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Functions of the Programme-

Data Collection: Collects millions of ADR reports globally.
Signal Detection: Identifies rare, serious, or new ADRs.
Information Sharing: Distributes alerts and safety information to all member countries.
Capacity Building: Trains healthcare professionals and regulators.
Global Collaboration: Encourages countries to work together for drug safety.

Current Status-

More than 130 countries are full members of the program.
VigiBase holds over 30 million ADR reports (continuously growing).
Used for global decision-making on drug labeling, warnings, or withdrawal of unsafe medi

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WHO and Regulatory Terminologies of ADR

Different organizations like WHO, USFDA, EMA, and PvPI (India) use standard terminologies to describe drug safety events.

These terms help in uniform reporting, communication, and analysis of ADRs across the world.

WHO Terminologies

According to the WHO, the following terms are widely used in pharmacovigilance:

1. Adverse Event (AE):

Any untoward medical occurrence after a medicine is given.

Does not necessarily mean the drug caused it.

Example: Headache after taking a drug (may or may not be drug-related).

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2. Adverse Drug Reaction (ADR):
A response to a drug which is noxious (harmful) and unintended at normal doses.
Example: Rash after taking penicillin.

3. Serious Adverse Event (SAE):
An event that results in:
Death
Life-threatening condition
Hospitalization or prolongation of hospital stay
Disability/incapacity
Congenital anomaly (birth defect)

4. Side Effect:
An effect that is secondary to the intended therapeutic effect.
Can be harmful or sometimes useful.
Example: Drowsiness due to antihistamines.

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5. Signal:

Information that suggests a new possible causal relationship between a drug and an adverse event.

Needs further investigation.

6. Causality Assessment:

The process of determining whether a drug is responsible for an observed ADR.

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Regulatory Terminologies-

Different regulatory authorities (USFDA, EMA, CDSCO, etc.) also define ADR-related terms:

1. Unexpected Adverse Event:

An event not listed in the drug's current labeling or Investigator's Brochure.

2. Suspected Unexpected Serious Adverse Reaction (SUSAR):

A serious ADR that is not expected based on the current drug information.

Example: New liver toxicity found in a drug not previously linked to liver injury.

3. Dose-related (Type A) ADR:

Predictable, related to drug's pharmacology.

Example: Hypoglycemia with insulin.

4. Non-dose-related (Type B) ADR:

Unpredictable, unrelated to dose (allergic, idiosyncratic).

Example: Anaphylaxis with penicillin.

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5. Expedited Reporting:

Regulatory requirement for immediate reporting of certain serious and unexpected ADRs.

6. Periodic Safety Update Report (PSUR):

Regular report submitted by drug companies to regulators about drug safety.

7. Risk–Benefit Assessment:

Comparison of therapeutic benefits of a drug vs. risks of ADRs.

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Evaluation of Medication Safety

Medication safety means ensuring that medicines are used in a way that maximizes benefit and minimizes harm.

Evaluation of medication safety involves detecting, measuring, and analyzing adverse effects and risks of drugs during clinical trials and after marketing.

Why Evaluate Medication Safety?

To protect patients from harmful drug reactions.

To identify unknown or rare ADRs.

To help doctors prescribe medicines safely.

To guide regulatory authorities (FDA, EMA, CDSCO, WHO).

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Stages of Evaluation-

A. Pre-Marketing Evaluation (Before Drug Approval)-

1. Pre-clinical Studies
Done in animals.
Detect basic toxicity (organ damage, carcinogenicity, teratogenicity).

2. Clinical Trials (Phase I-III)-

Phase I: Safety in small group of healthy volunteers.
Phase II: Safety and efficacy in patients.
Phase III: Larger group → detects more ADRs, compares with standard therapy.

Limitation: Clinical trials cannot detect very rare or long-term ADRs because of limited pa
and duration.

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B. Post-Marketing Evaluation (After Approval)-

1. Spontaneous Reporting Systems
Healthcare professionals report ADRs (e.g., Yellow Card, PvPI).

2. Pharmacovigilance Databases
WHO VigiBase, FAERS (USFDA), EudraVigilance (EMA).
Collect and analyze ADR data worldwide.

3. Phase IV Studies (Post-marketing surveillance)
Large population studies.
Detect rare ADRs, long-term risks, and effects in special groups (children, elderly, pregnancy).

4. Periodic Safety Update Reports (PSURs)
Submitted by pharmaceutical companies to regulators.
Contain updated safety data.

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Simple Methods of Evaluation of Medication Safety

1. Causality Assessment-

Purpose: To check whether the drug is really responsible for the ADR.

Tools used:

WHO-UMC system (certain, probable, possible, unlikely).

Naranjo's Scale (gives a score to decide relation).

Example: If a patient develops a rash after taking penicillin → check timing, dose, and withdrawal to confirm drug link.

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2. Severity Assessment-

Tells how strong or intense the reaction is.

Types-

Mild: Does not need treatment (e.g., dry mouth with antihistamines).

Moderate: Needs treatment or dose adjustment (e.g., gastric irritation with NSAIDs).

Severe: Life-threatening, requires urgent care (e.g., severe bleeding with warfarin).

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3. Seriousness Assessment-

Focuses on outcome of the ADR.
An ADR is serious if it results in:

Death
Life-threatening condition
Hospitalization or prolongation of hospital stay
Permanent disability
Birth defect

Example: Heart attack after certain antidiabetic drugs = serious ADR.

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4. Predictability and Preventability-

Predictability

Predictable ADRs: Related to drug's known action, dose-dependent.

Example: Hypoglycemia with insulin.

Unpredictable ADRs: Not dose-related, rare, unexpected.

Example: Anaphylaxis with penicillin.

Preventability-

Preventable ADRs: Can be avoided by correct dose, monitoring, and avoiding interactions.

Example: Digoxin toxicity if dose not adjusted in kidney failure.

Non-preventable ADRs: Cannot be avoided, even with proper use.

Example: Severe allergy to a first-time drug.

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Outcomes of Evaluation-

Update drug labels with warnings or precautions.

Restrict use in high-risk patients.

Withdraw unsafe drugs from the market (e.g., rofecoxib).

Promote safe prescribing practices.

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Establishing Pharmacovigilance Centres in Hospitals

Pharmacovigilance (PV) centres in hospitals are units that collect, evaluate, and report adverse drug reactions (ADRs).

Hospitals are the best place for PV because-

-Large patient load.

-Variety of drugs used.

-Opportunity for early detection of ADRs.

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Objectives of Hospital Pharmacovigilance Centres-

Detect and report ADRs.

Promote safe and rational use of medicines.

Educate healthcare professionals about ADR reporting.

Provide data to national PV programme (PvPI in India).

Improve patient safety and quality of healthcare.

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Steps to Establish Pharmacovigilance Centres in Hospitals-

A. Administrative Setup-

Hospital administration + regulatory authority support.
Appoint a Pharmacovigilance Committee (doctors, pharmacists, nurses).

B. Infrastructure Required-

ADR monitoring desk/room.
Trained staff (clinical pharmacist, pharmacologist, coordinator).
Computer with internet to report data to National Coordinating Centre (NCC).

C. Human Resources-

Head/Coordinator → usually a pharmacologist or clinical pharmacist.
Medical officers/nurses → detect ADRs during patient care.
Data entry staff → maintain ADR records and submit reports.

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D. Activities of PV Centre-

-ADR Collection: From wards, ICUs, OPDs, pharmacies.

-Documentation: Filling ADR Reporting Form (WHO / PvPI).

-Causality Assessment: Using WHO-UMC or Naranjo scale.

-Data Submission: Send reports to Regional PV Centre → NCC (IPC, Ghaziabad in India).

-Education & Awareness:
Conduct workshops/seminars for staff.
Encourage ADR reporting culture.

-Feedback to Clinicians: Provide updates on drug safety.

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4. Challenges in Establishing PV Centres-

Under-reporting due to lack of awareness.
Busy schedules of doctors and nurses.
Fear of blame or legal issues.
Need for continuous training and motivation.

5. Benefits of Hospital PV Centres-

Early detection of new ADRs.
Safer prescribing practices.
Strong contribution to national and global PV networks.
Builds trust between patients and healthcare providers.

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Industry and National programmes related to pharmacovigilance

Pharmacovigilance (PV) is the science of detecting, assessing, and preventing adverse drug reactions (ADRs).

Both the pharmaceutical industry and national programmes play an important role in ensuring drug safety.

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Pharmacovigilance in the Pharmaceutical Industry-

A. Responsibilities of the Industry

1. Establish PV systems within companies.

2. Collect ADR data from clinical trials (pre-marketing) and from patients/doctors after marketing.

3. Maintain global safety databases for all marketed products.

4. Report ADRs to national regulatory authorities.

5. Submit Periodic Safety Update Reports (PSURs) to regulators.

6. Conduct Risk Management Plans (RMPs) for high-risk drugs.

7. Provide safety information in drug labels, leaflets, and updates.

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Importance of Industry PV-

Helps companies maintain compliance with law.

Protects patients and builds trust.

Prevents costly product recalls or withdrawals.

National Pharmacovigilance Programmes-

A. In India – Pharmacovigilance Programme of India (PvPI)
1. Launched in 2010 by Ministry of Health, coordinated by Indian Pharmacopoeia Commission (IPC), Ghaziabad.

2. Aims:
Collect and analyze ADRs in India.
Create awareness about safe drug use.
Contribute data to WHO-UMC global database (VigiBase).

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Structure-

National Coordinating Centre (NCC): IPC Ghaziabad.

Regional PV Centres (R-PvCs): Supervisory role.

Adverse Drug Reaction Monitoring Centres (AMCs): Located in hospitals/medical colleges.

Reporting system-

Suspected ADR Reporting Forms.

Mobile App ("ADR PvPI").

Toll-free helpline.

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International Programmes-

-WHO Programme for International Drug Monitoring (1968):

Managed by Uppsala Monitoring Centre (UMC), Sweden.
Maintains VigiBase (global ADR database).
Member countries share ADR data.

-United States:
FDA Adverse Event Reporting System (FAERS).
Industry must report serious ADRs.

-Europe (EMA):
Uses EudraVigilance database.
Collects ADR data from EU countries.

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Roles and Responsibilities in Pharmacovigilance

Pharmacovigilance (PV): Science of detecting, assessing, understanding, and preventing adverse effects of medicines.

Involves multiple stakeholders – each with defined roles and responsibilities to ensure drug safety.

Key Stakeholders and Their Roles-

A. Healthcare Professionals (Doctors, Pharmacists, Nurses)-

Detect ADRs during patient care.
Document and report ADRs to hospital PV centres or national PV programmes.
Educate patients about possible side effects.
Encourage safe and rational medicine use.

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B. Patients and Public-

Report any side effects or unusual reactions they experience.

Participate in ADR awareness campaigns.

Follow prescription instructions carefully.

C. Hospital Pharmacovigilance Centres (AMCs)-

Collect ADR reports from wards, OPDs, ICUs.

Perform causality assessment (using WHO-UMC, Naranjo scale).

Send data to Regional/National PV centres.

Conduct training and workshops for staff.

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D. Pharmaceutical Industry-

Maintain internal pharmacovigilance systems.

Collect ADR data from clinical trials and post-marketing

Submit Periodic Safety Update Reports (PSURs) to regulators.

Develop Risk Management Plans (RMPs) for high-risk drugs.

Inform regulators and healthcare providers about new risks.

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E. National Regulatory Authorities-

(Examples: CDSCO & IPC in India, USFDA in USA, EMA in Europe)
Frame guidelines for ADR reporting.
Monitor safety data submitted by industry and hospitals.
Take regulatory actions (warnings, label changes, product withdrawal).
Coordinate national pharmacovigilance programmes (like PvPI in India).

F. World Health Organization (WHO) – UMC

Operates WHO International Drug Monitoring Programme.

Maintains VigiBase, the global ADR database.

Provides signal detection and international safety alerts.

Supports member countries in building PV systems.

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