BP705T · B.Pharm Semester VII · Theory Notes

Pharmacovigilance

Unit II — Pharmacovigilance Systems and Regulatory Framework

Unit II (10 hours)

Pills & Python Notes

From-zero teaching standard: every technical term is defined before use.

Syllabus coverage: Unit II (10 hours).

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CHAPTER 5: PV Systems — Objectives, Functions and Data Collection Methods

Learning Objectives

After studying this chapter, you will be able to:

1 Define pharmacovigilance in your own simple words.

2 List the objectives of pharmacovigilance — what the whole system is trying to achieve.

3 Describe the functions of a pharmacovigilance system — what it actually does day to day.

4 Explain the three main methods of collecting drug safety data: spontaneous reporting, cohort studies, and case-control studies.

5 Compare these three methods on strengths, weaknesses, cost, and purpose.

6 Describe how a spontaneous ADR report travels from a patient to a national database.

7 Explain how cohort and case-control studies are designed in simple steps.

8 State the role of a pharmacist in PV data collection in India.

Definitions

- **Pharmacovigilance (PV):** The science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem. In simple words: the job of watching medicines after they are sold to the public, catching their side effects, studying them, and taking action so patients are not harmed.
- **Adverse Drug Reaction (ADR):** A harmful, unwanted response to a medicine that happens at the normal dose used for treatment. Example: liver damage after taking a normal dose of a painkiller.
- **Adverse Event (AE):** Any bad medical event that happens while a patient is taking a medicine, but which may or may not be caused by the medicine. Example: a headache that occurs during treatment — it might be the medicine, or just a coincidence. Note: every ADR is an adverse event, but not every adverse event is an ADR.
- **Spontaneous reporting:** A system in which doctors, pharmacists, nurses, or patients voluntarily send reports of suspected ADRs to a central agency. "Spontaneous" means it happens on its own, without being asked — someone notices a problem and reports it.
- **Cohort study:** A study in which a group of people taking a medicine (the "cohort" or group) is followed over time to see what happens to them, especially which side effects appear.
- **Case-control study:** A study that starts with the outcome: people who already had a side effect (cases) are compared with people who did not (controls), and researchers look backward in time to see which medicines each group took.

- **Signal:** A piece of information from one or more sources suggesting a new, previously unknown link between a medicine and an adverse event. A signal needs further checking — it is a suspicion, not a proof.
- **Pharmacovigilance system:** The organised network of people, rules, forms, databases, and institutions that together collect drug-safety information and act on it.

Terminology Table

Term	Simple Meaning
Pharmacovigilance (PV)	The science of monitoring medicine safety after medicines reach patients
ADR	A harmful reaction to a medicine at its normal dose
Adverse event	Any bad medical event during treatment, cause unknown
Spontaneous report	A voluntary ADR report sent by a health professional or patient
Reporter	The person who sends the ADR report (doctor, pharmacist, nurse, patient)
Cohort	A group of people followed over time in a study
Exposure	The fact of having taken a particular medicine
Outcome	The health event being studied (for example, a side effect)
Relative risk	A measure of how much more likely the outcome is in the exposed group versus the unexposed group
Odds ratio	In case-control studies, a measure comparing exposure odds in cases versus controls
Bias	Any systematic error that makes study results wrong or misleading
Signal detection	Finding possible new drug–side effect links from collected data
Under-reporting	The common problem that most ADRs are never reported
Follow-up	Going back to patients (or reporters) to get more details over time

Simple Explanations

What is pharmacovigilance, and why does it exist?

Before a medicine is approved, it is tested in clinical trials. But clinical trials have limits: they involve a limited number of people, usually the healthier types of patients, for a short time, under ideal conditions. So when the medicine is finally given to lakhs of real patients — including old people, children, pregnant women, people taking many other medicines — new side effects can appear that nobody saw in the trial.

Pharmacovigilance is the safety net that catches these surprises. It is the continuous watching of medicines throughout their whole life on the market.

Think of it in three steps:

1 **Detect** — notice that a medicine may be causing a side effect.

2 **Assess** — study the information carefully to decide whether the medicine really caused it.

3 **Prevent** — take action: warn doctors, change the medicine's label, restrict its use, or even withdraw it from the market.

The objectives of pharmacovigilance

The word "objective" means "the goal we are trying to reach." The objectives of PV are the reasons the whole system exists:

1 **Detect new adverse reactions** that were not known before the medicine was marketed.

2 **Assess the risk of known adverse reactions** — how serious they are, how common they are, which patients are at risk.

3 **Understand the mechanisms** — how and why a medicine causes a particular side effect.

4 **Prevent harm** — by warning health professionals and the public, updating product labels, changing how a medicine is used, or removing it from the market.

5 **Promote rational and safe use of medicines** — supporting better prescribing, dispensing, and patient education.

6 **Communicate safety information** — making sure doctors, pharmacists, and patients actually receive and understand the warnings.

The functions of a pharmacovigilance system

"Functions" are the actual jobs the system performs every day to achieve those objectives:

1 **Collect** ADR reports from hospitals, clinics, pharmacies, and patients.

2 **Store and manage** the data in organised databases where it can be searched and analysed.

3 **Assess causality** — decide, for each report, how likely it is that the medicine caused the event.

4 **Detect signals** — look across thousands of reports to spot new patterns.

5 **Evaluate risk** — study how serious and how frequent a risk is.

6 **Recommend action** — advise regulators on warnings, label changes, restrictions, or withdrawals.

7 **Communicate** — publish safety alerts, newsletters, and educational material for health professionals.

8 **Coordinate** — work with national and international bodies so information is shared globally.

Simple way to remember: a PV system is like a **weather department for medicines**. It collects readings (reports), studies the data (analysis), predicts storms (signal detection), and issues warnings (safety alerts) so people can take shelter (change prescribing).

Classifications

Classification of PV data collection methods

Data collection methods are grouped by how actively the information is gathered:

A. Passive (spontaneous) methods

- **Spontaneous reporting** — health professionals and patients report voluntarily. The system waits for reports to arrive.

B. Active (organised) methods

- **Cohort studies** — a group taking the medicine is actively followed over time.
- **Case-control studies** — cases and controls are actively recruited and their medicine histories compared.

C. Other supportive methods (studied briefly for awareness)

- **Stimulated reporting** — reporting encouraged through campaigns or reminders.
- **Intensive monitoring** — detailed follow-up of all patients on a new medicine in selected hospitals.

Classification of PV objectives by time scale

Time scale	Objective
Short term	Detect and assess individual ADR reports
Medium term	Detect signals, evaluate risks, update product information
Long term	Prevent future harm, promote rational medicine use, build a culture of safety

Mechanisms / Processes

How spontaneous reporting works — step by step

1 **An event occurs.** A patient taking a medicine develops a suspected side effect.

2 **Recognition.** The doctor, pharmacist, nurse, or the patient themselves suspects a link between the medicine and the event.

3 **Filling the report.** A standard ADR reporting form is completed: patient details (age, sex — no name), suspected medicine(s), description of the reaction, dates, outcome, and reporter details.

4 **Sending the report.** The form is sent to the nearest ADR Monitoring Centre or national centre.

5 **Receipt and checking.** The centre checks that the report is complete and enters it into the database.

6 **Causality assessment.** Experts judge how likely the medicine caused the event.

7 **Signal detection.** The report is added to thousands of others and patterns are analysed.

8 **Regulatory action and communication.** If a real risk is confirmed, warnings or label changes follow.

How a cohort study works — step by step

1 **Choose the exposed group:** people starting treatment with the medicine of interest.

2 **Choose a comparison group:** people not taking that medicine (similar in age, health, and other factors).

3 **Check at the start** that nobody already has the side effect being studied.

4 **Follow both groups forward in time** — months or years — recording any side effects.

5 **Compare** how often the side effect occurs in the exposed group versus the comparison group.

6 **Calculate the relative risk** — for example, "twice as likely."

Direction of a cohort study: **Exposure → Time → Outcome** (forward).

How a case-control study works — step by step

1 **Choose the cases:** people who already had the side effect.

2 **Choose the controls:** people who did not have the side effect (similar to the cases otherwise).

3 **Look backward** into both groups' medicine histories.

4 **Compare** how often each group took the suspected medicine.

5 **Calculate the odds ratio** — for example, "cases were three times more likely to have taken the medicine."

Direction of a case-control study: **Outcome → Backward → Exposure**.

Textual Diagrams / Flowcharts

Diagram 1: The journey of a spontaneous ADR report

```
Patient takes medicine
        |
        v
Suspected side effect noticed
        |
        v
Doctor / Pharmacist / Nurse / Patient
fills ADR reporting form
        |
        v
Report sent to ADR Monitoring Centre
        |
        v
Data entered into national database
        |
        v
Causality assessment by experts
        |
        v
Signal detection (many reports analysed together)
        |
        v
Regulatory action: warning / label change / restriction / withdrawal
        |
        v
Safety information communicated to health professionals and public
```

Diagram 2: Cohort study design (forward in time)

```
NOW                                FUTURE
  |                                  |
  |-- Exposed group (taking drug) --|-- follow up --> count side effects
  |                                  |
  |-- Unexposed group (not taking) --|-- follow up --> count side effects
  |                                  |
Compare the two rates → Relative Risk
```

Diagram 3: Case-control study design (backward in time)

```
PAST                               NOW
  |                                  |
  |-- history of drug use checked --|-- CASES (had the side effect)
  |                                  |
  |-- history of drug use checked --|-- CONTROLS (did not have it)
  |                                  |
Compare drug exposure → Odds Ratio
```

INFOGRAPHIC CONCEPT: A three-lane comparison poster titled "Three Ways We Catch Drug Side Effects." Lane 1 (SPONTANEOUS REPORTING): a megaphone icon — "Anyone can report, anytime. Cheapest. First warning system." Lane 2 (COHORT STUDY): a marching group of people with a calendar — "Follow a group forward in time. Measures real risk. Slow and costly." Lane 3 (CASE-CONTROL STUDY): a detective with a magnifying glass looking backward — "Start from the side effect, look back. Fast and cheap for rare events." Bottom banner: "All three feed one goal — safer medicines for every patient."

Tables

Table 1: Comparison of the three PV data collection methods

Feature	Spontaneous Reporting	Cohort Study	Case-Control Study
What it is	Voluntary reports of suspected ADRs	Follow a drug-exposed group over time	Compare people with/without the side effect
Direction	Ongoing, no fixed direction	Forward: exposure → outcome	Backward: outcome → exposure
Main strength	Cheap; covers whole population; first warning of new ADRs	Measures true risk (incidence); good for common events	Fast and cheap; best for rare side effects
Main weakness	Under-reporting; incomplete data; cannot measure risk	Expensive; slow; poor for rare or very delayed events	Recall bias (people forget); cannot measure risk directly
Cost	Low	High	Low to moderate
Can prove cause?	No — generates signals only	Gives strong evidence	Gives supporting evidence
Best used for	Early detection of unknown ADRs	Studying known or suspected risks in detail	Quickly testing a new suspicion

Table 2: Objectives of pharmacovigilance at a glance

#	Objective	Simple meaning
1	Detect new ADRs	Catch side effects nobody knew about

#	Objective	Simple meaning
2	Assess known risks	How serious? How common? Who is at risk?
3	Understand mechanisms	Why and how does the medicine cause this?
4	Prevent harm	Warnings, label changes, restrictions, withdrawals
5	Promote rational use	Help medicines be used safely and correctly
6	Communicate	Make sure doctors and patients hear the warnings

Examples

1. **Spontaneous reporting example:** A pharmacist notices three patients developing a skin rash after starting the same antibiotic. She files three ADR forms — reporting a *suspicion* is enough; proof is not required.
2. **Cohort study example:** Researchers follow 5,000 patients on a new diabetes medicine and 5,000 similar patients not on it, for two years, to see whether heart problems increase.
3. **Case-control example:** 40 patients with a rare liver injury (cases) and 120 without it (controls) have their medicine histories compared — the cases were far more likely to have used a particular herbal product.
4. **Function example:** After enough reports arrive, the national centre issues an alert advising kidney-function checks before prescribing a certain drug — the "communicate" and "prevent harm" functions in action.

Analogies

1. **Spontaneous reporting is like a neighbourhood watch.** Nobody is ordered to patrol, but if anyone sees something suspicious, they call it in. The police (regulators) cannot be everywhere, so they depend on citizens (health professionals and patients) to report.
2. **A cohort study is like planting two fields.** One field gets the new fertiliser (exposed group), the other does not (comparison group). You watch both fields for a whole season and compare the harvest. Forward, careful, slow — but you see exactly what the fertiliser did.
3. **A case-control study is like investigating a fire.** You start with the burnt house (the case), then look backward: who visited? what was stored there? You compare with houses that did not burn (controls) to find the difference.
4. **A pharmacovigilance system is like a hospital's fire alarm network.** Sensors (reports) pick up smoke (ADRs), a control room (database + experts) checks whether it is a real fire (assessment), and the alarm (safety alert) warns everyone in the building.

Pharmacy Relevance

Pharmacists are among the best-placed reporters in the whole PV system, because:

- They see patients regularly — often more often than doctors — and patients tell pharmacists about side effects first.
- They know medicines deeply: doses, interactions, duplicate therapies.
- They can spot patterns: the same complaint from several patients on the same medicine.
- They can counsel patients: "If you get this rash, come back and tell me — and stop the medicine after consulting your doctor."
- In hospitals, pharmacists participate in ADR rounds, fill reporting forms, and follow up on serious cases.

Practical rule for every pharmacist: *When in doubt, report.* You do not need to prove the medicine caused the reaction. A suspicion is enough to start the process.

India Context

- In India, spontaneous reports flow into the **Pharmacovigilance Programme of India (PvPI)** — full details in Chapter 7.
- The standard **Suspected ADR Reporting Form** is the document used by Indian health professionals and consumers; reporters can also report through the PvPI helpline and mobile application, as per the latest PvPI notifications — confirm the current edition.
- Indian pharmacists — in community pharmacies, hospital pharmacies, and as part of antimicrobial stewardship or clinical pharmacy teams — are expected reporters. PV is part of the pharmacist's professional duty, not an optional extra.
- Under-reporting is a recognised challenge in India: with a huge population and busy clinics, many ADRs are never reported, which makes every single report more valuable.

Key Points

- Pharmacovigilance = detect, assess, understand, and prevent adverse effects of medicines.
- Clinical trials cannot catch every side effect; PV watches medicines after marketing.
- Objectives: detect new ADRs, assess risks, understand mechanisms, prevent harm, promote rational use, communicate safety information.
- Functions: collect, store, assess causality, detect signals, evaluate risk, recommend action, communicate, coordinate.
- Three main data collection methods: spontaneous reporting (voluntary, cheapest, first warning), cohort studies (follow a group forward, measures risk, expensive), case-control studies (start from the event, look backward, fast for rare events).
- Spontaneous reports generate *signals* (suspicions), not proof.
- Pharmacists are frontline reporters: when in doubt, report.

Common Confusions

1. **Adverse event vs ADR.** An adverse event is *any* bad event during treatment — the medicine may be innocent. An ADR is a harmful reaction *caused by* the medicine at a normal dose. Students often use the two words interchangeably — do not.
2. **Spontaneous reporting vs stimulated reporting.** Spontaneous = completely voluntary, unprompted. Stimulated = reporting actively encouraged by a campaign. Both collect reports, but the motivation differs.
3. **Cohort vs case-control direction.** Cohort moves *forward* (exposure → outcome). Case-control moves *backward* (outcome → exposure). Mix these up and you will fail the question — draw the two mini-diagrams from memory to fix the direction.
4. **Signal vs proof.** A signal is a suspicion that needs investigation. One report, or even many reports, does not prove the medicine caused the event.
5. **PV vs clinical trials.** Trials happen *before* approval on selected patients; PV happens *after* approval on the whole population.

Common Mistakes

1. **Saying "spontaneous reporting measures the risk of an ADR."** It cannot — because we do not know how many total patients took the medicine (no denominator). It only detects signals.
2. **Claiming one ADR report proves causation.** It does not. Causality needs assessment and usually more data.
3. **Confusing relative risk with odds ratio.** Relative risk comes from cohort studies; odds ratio comes from case-control studies. Using the wrong term in the wrong study is a classic exam error.
4. **Writing that case-control studies are "better" than cohort studies.** They are different tools for different jobs: case-control is fast and good for rare events; cohort is stronger for measuring real risk.
5. **Forgetting the pharmacist's role.** Exam answers often describe only doctors reporting. Always include pharmacists, nurses, and patients as reporters.

Mnemonics

- **Objectives of PV — "D-A-U-P-P-C":** **D**etect new ADRs, **A**ssess risks, **U**nderstand mechanisms, **P**revent harm, **P**romote rational use, **C**ommunicate. Memory line: "**D**octors **A**nd **U**s **P**rotect **P**atients by **C**ommunicating."
- **Functions — "C-S-A-S-E-R-C-C":** **C**ollect, **S**tore, **A**ssess causality, **S**ignal detection, **E**valuate risk, **R**ecommend action, **C**ommunicate, **C**oordinate.
- **Methods — "SCC":** **S**pontaneous (voluntary), **C**ohort (forward), **C**ase-control (backward). Memory line: "**S**ee it, **C**hase it forward, **C**heck it backward."

Exam Summary

Pharmacovigilance is the science of detecting, assessing, understanding, and preventing adverse effects of medicines, needed because clinical trials cannot reveal every side effect. Its six objectives are detecting new ADRs, assessing known risks, understanding mechanisms, preventing harm, promoting rational

medicine use, and communicating safety information. Its daily functions are collecting reports, storing data, assessing causality, detecting signals, evaluating risk, recommending regulatory action, communicating alerts, and coordinating nationally and internationally. Data is collected by three main methods: **spontaneous reporting** (voluntary reports from health professionals and patients — cheap, wide coverage, the first warning system, but suffers under-reporting and cannot measure risk); **cohort studies** (a drug-exposed group is followed forward in time and compared with an unexposed group — measures true risk as relative risk, but is slow and expensive); and **case-control studies** (people with the side effect are compared with controls by looking backward at medicine histories — fast, cheap, best for rare events, giving an odds ratio, but affected by recall bias). A spontaneous report travels from recognition → reporting form → ADR Monitoring Centre → national database → causality assessment → signal detection → regulatory action → communication. Pharmacists are key reporters in India under PvPI.

One-Minute Revision

PV = watch medicines after marketing: detect, assess, understand, prevent. Objectives (D-A-U-P-P-C): detect, assess, understand, prevent harm, promote rational use, communicate. Methods (SCC): **Spontaneous** = voluntary reports, cheapest, first warning, under-reported. **Cohort** = forward, gives relative risk, costly and slow. **Case-control** = backward, gives odds ratio, fast, best for rare events, recall bias. Flow: patient → form → AMC → database → assessment → signal → action → communication. Rule: when in doubt, report.

Questions

Short-Answer Questions

1 Define pharmacovigilance in one sentence.

2 List any four objectives of pharmacovigilance.

3 What is spontaneous reporting?

4 Name the three main PV data collection methods.

5 What is a "signal" in pharmacovigilance?

Long-Answer Questions

1 Describe the objectives and functions of a pharmacovigilance system, with one example for each function.

2 Compare spontaneous reporting, cohort studies, and case-control studies under the headings: design, direction of study, strengths, weaknesses, and the measure of association used.

3 Trace the complete journey of a spontaneous ADR report from the patient to regulatory action, using a flowchart, and explain the role of the pharmacist at each step where relevant.

MCQs (with Answer Key)

1 Pharmacovigilance is primarily concerned with:

a) Manufacturing quality of medicines b) Detection, assessment, understanding and prevention of adverse effects of medicines c) Pricing of medicines d) Patent protection of drugs

1 Which of the following is an objective of pharmacovigilance?

a) Promoting the sales of new medicines b) Detecting previously unknown adverse drug reactions c) Approving clinical trial protocols d) Fixing the price of essential medicines

1 Spontaneous reporting is best described as:

a) A compulsory daily survey of all patients b) Voluntary reporting of suspected ADRs by health professionals and patients c) A laboratory test for drug toxicity d) A type of randomised clinical trial

1 The biggest limitation of spontaneous reporting is:

a) High cost b) Under-reporting and incomplete data c) It takes 10 years to complete d) It can only study one drug at a time

1 In a cohort study, the direction of enquiry is:

a) From outcome backward to exposure b) From exposure forward to outcome c) Both directions simultaneously d) There is no direction; it is a single snapshot

1 A case-control study is most suitable for studying:

a) Very common side effects b) Rare adverse events c) The chemical structure of drugs d) Drug manufacturing defects

1 The measure of association calculated in a cohort study is:

a) Odds ratio b) Relative risk c) P-value only d) Mean drug concentration

1 Recall bias is a particular problem in:

a) Cohort studies b) Case-control studies c) Spontaneous reporting d) Laboratory experiments

1 A "signal" in pharmacovigilance means:

a) Final proof that a drug causes a side effect b) Information suggesting a possible new drug–event association needing further evaluation c) An electrical signal from a monitoring device d) A marketing signal for a new drug launch

1 Which of the following is a function of a PV system?

a) Manufacturing medicines b) Signal detection and risk evaluation c) Prescribing medicines to patients d) Setting drug prices

Answer Key: 1-b, 2-b, 3-b, 4-b, 5-b, 6-b, 7-b, 8-b, 9-b, 10-b

Viva Questions

1 Why can clinical trials not detect all side effects of a medicine?

2 What is the difference between an adverse event and an adverse drug reaction?

3 Who can send a spontaneous ADR report?

4 Can spontaneous reporting measure the true risk (incidence) of an ADR? Why or why not?

5 How does a cohort study differ from a case-control study in direction?

Application-Based Questions

1 A patient tells you at your pharmacy counter that she developed swelling of the lips two days after starting a new blood pressure tablet. What will you do, step by step, as a pharmacist?

2 A new medicine is suspected of causing a very rare blood disorder (1 in 100,000 users). Which study design — cohort or case-control — would you choose to investigate quickly, and why?

3 Your hospital's ADR Monitoring Centre received only 5 reports last year although thousands of patients were treated. Suggest three practical steps to improve reporting.

References

- Andrews & Moore — Mann's Pharmacovigilance
- Cobert — Cobert's Manual of Drug Safety and Pharmacovigilance
- Jose, Cox & Paudyal — Principles and Practice of Pharmacovigilance and Drug Safety
- Strom, Kimmel & Hennessy — Textbook of Pharmacoepidemiology
- Talbot & Waller — Stephens' Detection of New Adverse Drug Reactions
- Waller & Harrison-Woolrych — An Introduction to Pharmacovigilance

CHAPTER 6: Global Pharmacovigilance Systems — WHO, CIOMS, USFDA and EMA

Learning Objectives

After studying this chapter, you will be able to:

1 Describe the WHO International Drug Monitoring Programme — what it is, what it does, and how countries take part.

2 Explain what VigiBase is and why a global database matters.

3 Describe the role of CIOMS in harmonising drug safety practices worldwide.

4 Explain the role of the USFDA in pharmacovigilance, including its reporting systems.

5 Explain the role of the EMA in pharmacovigilance in Europe.

6 Compare the WHO Programme, USFDA, and EMA on scope, coverage, and key tools.

7 Explain why international cooperation is essential for drug safety.

8 Relate global PV systems to India's own programme.

Definitions

- **WHO International Drug Monitoring Programme:** The World Health Organization's global programme that links national pharmacovigilance centres of member countries so that drug safety information is collected and shared worldwide. In simple words: a worldwide club of countries that pool their ADR reports so a side effect seen in one country can warn all others.
- **Uppsala Monitoring Centre (UMC):** The WHO Collaborating Centre that operates the technical side of the WHO Programme — it maintains the global database and provides tools and training to member countries.
- **VigiBase:** The WHO global database of individual case safety reports (ADRs) collected from national centres around the world. Think of it as the world's biggest library of medicine side-effect reports.
- **CIOMS (Council for International Organizations of Medical Sciences):** An international, non-governmental body that brings experts together to develop consensus guidelines and standard formats for drug safety work, so that all countries speak the same "language" when reporting and assessing ADRs.
- **USFDA (United States Food and Drug Administration):** The national regulatory agency of the United States responsible for the safety of medicines (among other products) in the USA. Its PV arm collects and analyses ADR reports from the American population.
- **FAERS (FDA Adverse Event Reporting System):** The USFDA's database of adverse event and medication error reports for marketed medicines.
- **MedWatch:** The USFDA's safety information and adverse event reporting programme through which health professionals and the public report problems with medicines.
- **EMA (European Medicines Agency):** The agency responsible for the scientific evaluation, supervision, and safety monitoring of medicines across the European Union.
- **EudraVigilance:** The European database for managing and analysing reports of suspected adverse reactions to medicines authorised in the European Economic Area.
- **Harmonisation:** Making rules, forms, and definitions the same (or compatible) across countries so that safety data can be compared and shared. CIOMS is the main body driving this in drug safety.

Terminology Table

Term	Simple Meaning
WHO Programme	The global network linking national PV centres
National centre	A country's own PV headquarters (each member country has one)
Individual case safety report (ICSR)	A single ADR report on one patient at one point in time
VigiBase	The WHO global ADR database
UMC	The centre that runs VigiBase and supports member countries
CIOMS	The international body writing consensus drug-safety guidelines
CIOMS form	A standard international format for reporting serious ADRs
FAERS	The USFDA's adverse event database

Term	Simple Meaning
MedWatch	The USFDA's reporting and safety-alert programme
EudraVigilance	The European ADR database
PRAC	The EMA's committee that assesses medicine safety signals
Marketing authorisation holder	The company that holds the licence to sell a medicine (responsible for its PV duties)
Periodic safety update	A regular summary report on a medicine's safety submitted by the company to regulators
Risk management	Planned activities to identify, characterise, prevent, or minimise a medicine's risks

Simple Explanations

Why do we need a global system?

A medicine sold in India is often the same medicine sold in Brazil, Nigeria, Germany, and Japan. If it causes a rare side effect, one country alone may see too few cases to notice the pattern. But if 100 countries pool their reports, the pattern becomes visible.

A side effect first spotted in one country can save lives in all others — but only if countries share their data. That is the whole reason the WHO Programme exists.

The WHO International Drug Monitoring Programme — how it works

Think of the programme as a three-level network:

1. **National centres.** Each participating country has its own national pharmacovigilance centre, which collects ADR reports from hospitals and health professionals within that country.
2. **The WHO Collaborating Centre (UMC).** National centres send their reports (as individual case safety reports, ICSRs) to the UMC, which enters them into the global database, VigiBase.
3. **Shared analysis and feedback.** The UMC analyses the pooled global data for signals, and member countries receive back global insights — for example, "this drug–event combination is being reported unusually often worldwide."

Membership is voluntary but valuable: a country gets access to the world's combined experience with every medicine, plus training, standard tools, and technical support.

VigiBase — the world's ADR library

VigiBase holds millions of individual case safety reports from member countries. It is:

- **The largest global resource** for detecting rare and unexpected ADRs.
- **A signal detection engine** — statistical tools scan it for drug–event combinations reported more often than expected.
- **A shared memory** — a country investigating a suspected reaction can check whether the same pattern has been seen elsewhere.

Simple image: if every country's PV centre is a single CCTV camera, VigiBase is the control room where all the screens are watched together.

The role of CIOMS

CIOMS does not collect ADR reports itself. Its job is to make sure everyone collects and talks about them **in the same way**. Its contributions include:

- **Consensus guidelines** on how to report, assess, and communicate drug safety issues.
- **Standard reporting formats** (such as the CIOMS form for expedited reporting of serious ADRs), so a report written in India can be understood in Europe or America without translation of format.
- **Common definitions** — for example, what counts as "serious," so all countries mean the same thing.
- **Working groups** where regulators, industry, and academia agree on best practices.

Without CIOMS, every country would use different forms and definitions, and global data sharing would be like people speaking different languages with no translator.

The USFDA — America's drug safety guardian

The USFDA is the national regulator for medicines in the United States. Its pharmacovigilance role includes:

- **Collecting reports** through FAERS (its database) and MedWatch (its reporting programme for health professionals and the public).
- **Monitoring marketed medicines continuously** — approval is not the end of safety watching.
- **Taking regulatory action** — requiring label changes (such as boxed warnings), restricting use, or withdrawing medicines when risks outweigh benefits.
- **Communicating safety information** — public safety communications and alerts.
- **Requiring companies** (marketing authorisation holders) to report serious ADRs within the timelines specified in the current US regulations — as per the latest guidelines/notifications, confirm the current edition.

The EMA — Europe's drug safety coordinator

The EMA coordinates medicine safety across the European Union's member states. Its PV role includes:

- **EudraVigilance** — the central European database of suspected adverse reaction reports.
- **Signal detection and assessment** at the European level, with the Pharmacovigilance Risk Assessment Committee (PRAC) evaluating signals and recommending actions.
- **Coordinating national agencies** — each EU country has its own regulator, and the EMA makes sure they act consistently.
- **Risk management** — requiring companies to have plans for monitoring and minimising each medicine's risks.
- **Transparency** — publishing safety information for health professionals and the public.

Classifications

Classification of global PV actors by role

Role	Who plays it	What they do
Global coordinator	WHO Programme + UMC	Links countries, runs VigiBase, supports members
Standard-setter	CIOMS	Writes consensus guidelines and standard forms
National regulator (USA)	USFDA	Regulates and monitors medicines in the United States
Regional coordinator (EU)	EMA	Coordinates medicine safety across EU member states
National regulator (India)	CDSCO + PvPI (see Chapter 7)	Regulates and monitors medicines in India

Classification of PV databases

Database	Operated by	Coverage
VigiBase	UMC for WHO	Global — reports from member countries worldwide
FAERS	USFDA	United States
EudraVigilance	EMA	European Economic Area

Mechanisms / Processes

How a report travels from India to the world (the WHO flow)

1. A doctor in India fills a suspected ADR reporting form.
2. The form reaches the nearest ADR Monitoring Centre.
3. It is forwarded to India's National Coordination Centre (PvPI).
4. After quality checks, the case is transmitted to the UMC as an ICSR.
5. The UMC enters it into VigiBase.
6. Global signal detection tools scan VigiBase continuously.
7. If a worldwide pattern emerges, the information flows back to all member countries, including India.

How a safety signal becomes regulatory action (USFDA / EMA style)

1. **Reports accumulate** in FAERS or EudraVigilance.
2. **Signal detection** — a drug–event pair is reported more often than expected.
3. **Signal evaluation** — experts review cases, literature, and study data; the company may be asked for information.
4. **Decision** — is this a real risk? How serious? Who is affected?
5. **Action** — label change, warning letter to doctors, restriction of use, or market withdrawal, as per the latest guidelines/notifications.
6. **Communication** — health professionals and the public are informed.

Textual Diagrams / Flowcharts

Diagram 1: The WHO global PV network

```
Hospitals / Doctors / Pharmacists / Patients
        (in each country)
                |
                v
   National PV Centre of each country
    (collects national ADR reports)
                |
                v
   UMC (WHO Collaborating Centre)
    - receives ICSRs from all members
    - maintains VigiBase
    - runs global signal detection
    - provides training and tools
                |
                v
   Feedback to ALL member countries
   (global safety insights shared back)
```

Diagram 2: Roles at a glance

```
  WHO Programme ──> connects countries, VigiBase
  CIOMS         ──> common rules, forms, definitions
  USFDA         ──> regulates + monitors in the USA (FAERS, MedWatch)
  EMA           ──> coordinates safety across the EU (EudraVigilance, PRAC)
  PvPI (India)  ──> India's national programme (see Chapter 7)
```

Diagram 3: From signal to action

```
Reports pile up → Unusual pattern spotted (signal)
        → Experts investigate → Risk confirmed?
       /                          \
     YES                           NO → keep monitoring
      |
      v
Label change / Warning / Restriction / Withdrawal
      |
      v
Doctors, pharmacists and patients informed
```

INFOGRAPHIC CONCEPT: A world map poster titled "One World, One Safety Net." Four landmark pins: (1) WHO Programme pin — "140+ member countries share ADR reports into VigiBase, the world's largest side-effect library"; (2) CIOMS pin — "Writes the common rulebook: same forms, same definitions, worldwide"; (3) USFDA pin (USA) — "FAERS + MedWatch: America's reporting and alert system"; (4) EMA pin (Europe) — "EudraVigilance + PRAC: Europe's coordinated safety watch." A ribbon across the bottom: "A reaction reported in one country can protect patients in every country."

Tables

Table 1: WHO Programme vs USFDA vs EMA

Feature	WHO Programme	USFDA	EMA
Nature	Global voluntary network	National regulator (USA)	Regional coordinator (EU)
Main database	VigiBase (via UMC)	FAERS	EudraVigilance
Reporting route	Through member countries' national centres	MedWatch + company reports	National agencies + companies
Main job	Share data globally, detect worldwide signals	Regulate and monitor medicines in the USA	Coordinate safety across EU states
Can take regulatory action?	No — advises; action is taken nationally	Yes — in the USA	Coordinates EU-wide action via member states
Standard-setting	Supported by CIOMS guidelines	US regulations	EU regulations

Table 2: Key tools of each body

Body	Key tool	What it is for
WHO/UMC	VigiBase	Global ADR database and signal detection
CIOMS	Consensus guidelines + standard forms	Harmonised reporting worldwide
USFDA	FAERS + MedWatch	US adverse event collection and public reporting
EMA	EudraVigilance + PRAC	European adverse reaction database and signal assessment

Examples

1. **WHO Programme example:** A rare skin reaction to a tuberculosis medicine is reported 3 times in India, 2 times in South Africa, and 4 times in Brazil. No single country sees enough cases to be sure — but VigiBase shows 9 similar cases worldwide, triggering a global signal investigation.
2. **CIOMS example:** An Indian pharmaceutical company reporting a serious ADR to European regulators uses the internationally recognised CIOMS reporting format, so the European reviewer understands every field without confusion.
3. **USFDA example:** After FAERS reports accumulate showing a heart risk with a painkiller, the USFDA requires the company to add a prominent warning to the medicine's label and issues a public safety communication.
4. **EMA example:** When a signal about blood clots with a medicine emerges in EudraVigilance, the PRAC reviews the evidence and recommends consistent action across all EU countries, so patients in every member state get the same protection.

Analogies

1. **VigiBase is like a global weather satellite system.** One country's radar sees only its own skies; the satellite network sees storms forming anywhere on Earth and warns every country in their path.
2. **CIOMS is like the rulebook of an international sport.** Players come from different countries, but everyone follows the same rules and the referee's signals mean the same thing everywhere. CIOMS writes the rulebook for drug safety reporting.

3 **The USFDA and EMA are like national and regional traffic police.** The WHO Programme is the international road-safety organisation sharing accident data; the USFDA polices American roads and the EMA coordinates patrols across European countries. Each can fine drivers (regulate) on its own roads.

4 **Joining the WHO Programme is like joining a neighbourhood watch group chat.** Alone, you only see your own street; in the group, a burglary two streets away warns you to lock your doors too.

Pharmacy Relevance

- Pharmacists should know that an ADR they report in India does not stay in India — through PvPI and the WHO Programme, it can contribute to **worldwide** signal detection.
- When counselling patients on imported or globally marketed medicines, pharmacists can check **public safety communications** from the USFDA or EMA for the latest warnings (as a supplement to Indian product information).
- Understanding FAERS/MedWatch and EudraVigilance helps pharmacists who work in **pharmaceutical companies** (pharmacovigilance departments), clinical research, or regulatory affairs — these are major career areas.
- Standard CIOMS formats are used in **industry case processing** — a pharmacist working in a drug safety team will handle these formats daily.

India Context

- India is a member of the **WHO International Drug Monitoring Programme** — Indian ADR reports collected under PvPI flow into VigiBase, and India receives global safety insights in return.
- India's national centre (under PvPI) follows **internationally harmonised practices** influenced by CIOMS guidance, so Indian data is compatible with global databases.
- Indian regulators and the PvPI watch safety actions taken by the **USFDA and EMA** as important reference points, while taking independent decisions suited to Indian conditions (different diseases, different medicine use patterns, different populations).
- For Indian pharmacy students, this means: learn the global system, but remember that **India's own programme (PvPI, Chapter 7) is where your reports go first**.

Key Points

- Medicines are global; side effects must be watched globally — one country's few cases become a clear pattern when pooled.
- The WHO Programme links national centres; the UMC runs VigiBase, the global ADR database.
- CIOMS writes consensus guidelines and standard reporting formats so all countries speak the same safety language.
- The USFDA monitors medicines in the USA through FAERS and MedWatch and can order label changes or withdrawals.

- The EMA coordinates medicine safety across the EU through EudraVigilance and the PRAC.
- Only national/regional regulators take regulatory action; the WHO Programme and CIOMS support and harmonise.
- India's reports reach VigiBase through PvPI.

Common Confusions

1 **WHO vs UMC.** The WHO Programme is the network of member countries; the UMC (Uppsala Monitoring Centre) is the collaborating centre that does the technical work — running VigiBase. Students often say "WHO collects the reports" — technically, national centres collect and the UMC manages the global database.

2 **CIOMS as a regulator.** CIOMS is NOT a regulator and cannot ban or approve medicines. It writes guidelines and standard forms. Only bodies like the USFDA, EMA, or CDSCO take regulatory action.

3 **FAERS vs MedWatch.** MedWatch is the reporting programme (the "front door" for reporters); FAERS is the database where the reports are stored and analysed. They work together but are not the same thing.

4 **EMA vs national regulators.** The EMA coordinates; each EU country's own agency also exists. The EMA does not replace national regulators.

5 **"The WHO banned this drug."** The WHO Programme does not ban medicines — bans and withdrawals are decided by national regulators.

Common Mistakes

1 **Writing that VigiBase is run directly by WHO headquarters in Geneva.** It is operated by the WHO Collaborating Centre (UMC). Phrase it correctly.

2 **Listing CIOMS alongside USFDA/EMA as a "regulatory agency."** CIOMS is a standard-setting body, not a regulator.

3 **Inventing numbers** — founding years, counts of member countries, numbers of reports in VigiBase. These change over time; in exams, describe roles and functions, not memorised figures that may be outdated. Where a current figure is needed, write "as per the latest official publications — confirm the current edition."

4 **Confusing EudraVigilance (database) with PRAC (committee).** One stores reports; the other assesses signals.

5 **Forgetting India's link** — answers on global systems should mention that India participates through PvPI and contributes to VigiBase.

Mnemonics

- **Four global pillars — "W-C-U-E": W**HO Programme (global network), **C**IOMS (common rules), **U**SFDA (USA regulator), **E**MA (Europe coordinator). Memory line: "**W**e **C**atch **U**nsafe **E**ffects."

- **WHO flow — "N-U-V-F": N**ational centre → **U**MC → **V**igiBase → **F**eedback to members. Memory line: "**N**ations **U**pload to **V**igiBase for **F**eedback."
- **USFDA tools — "F-M": F**AERS (database) + **M**edWatch (reporting). **EMA tools — "E-P": E**udraVigilance (database) + **P**RAC (committee).

Exam Summary

Because the same medicines are used worldwide, drug safety must be watched globally. The **WHO International Drug Monitoring Programme** links the national pharmacovigilance centres of member countries: national centres send individual case safety reports to the WHO Collaborating Centre (UMC), which maintains **VigiBase**, the global ADR database used for worldwide signal detection, with insights fed back to all members. **CIOMS** is the international standard-setting body that develops consensus guidelines and standard reporting formats so that safety data is comparable across countries — it is not a regulator. The **USFDA** is the United States' national regulator: it collects reports through **FAERS** and **MedWatch**, monitors marketed medicines, and can require label changes or withdraw products. The **EMA** coordinates medicine safety across the European Union through **EudraVigilance** and its signal-assessment committee **PRAC**, ensuring consistent action across member states. Regulatory action is taken by national/regional regulators; WHO and CIOMS support, harmonise, and share. India participates in the WHO Programme through PvPI, contributing Indian reports to VigiBase.

One-Minute Revision

Global PV in four pillars (W-C-U-E): **WHO Programme** = network of national centres → UMC → **VigiBase** (global ADR library) → feedback to members. **CIOMS** = writes the common rulebook (guidelines + standard forms), not a regulator. **USFDA** = USA regulator; tools **FAERS** (database) + **MedWatch** (reporting); can change labels/withdraw. **EMA** = EU coordinator; tools **EudraVigilance** (database) + **PRAC** (signal committee). Signal → evaluate → label change/warning/restriction/withdrawal. India contributes via PvPI. Never invent years, versions, or report counts — say "as per the latest official publications."

Questions

Short-Answer Questions

1 What is the WHO International Drug Monitoring Programme?

2 What is VigiBase?

3 What is the role of CIOMS in pharmacovigilance?

4 Name the USFDA's database and its reporting programme.

5 What are EudraVigilance and PRAC?

Long-Answer Questions

1 Describe the structure and working of the WHO International Drug Monitoring Programme, including the role of national centres, the UMC, and VigiBase. Explain why global data sharing is necessary with an example.

2 Discuss the role of CIOMS in harmonising pharmacovigilance practices worldwide. How does it differ from a regulatory agency?

3 Compare the pharmacovigilance roles of the USFDA and the EMA under the headings: nature of the body, database, reporting system, signal assessment, and regulatory powers.

MCQs (with Answer Key)

1 The WHO global database of ADR reports is called:

a) FAERS b) EudraVigilance c) VigiBase d) MedWatch

1 The technical/operational work of the WHO Programme (running VigiBase) is done by:

a) The USFDA b) The WHO Collaborating Centre (UMC) c) The EMA d) Individual pharmaceutical companies

1 CIOMS is best described as:

a) A regulatory agency that bans medicines b) An international body developing consensus drug-safety guidelines and standard formats c) A pharmaceutical company d) A hospital in Geneva

1 FAERS is:

a) The European ADR database b) The USFDA's adverse event database c) A CIOMS reporting form d) India's national PV database

1 MedWatch is:

a) A European committee b) The USFDA's safety reporting programme c) The WHO global database d) An Indian helpline

1 EudraVigilance is operated by:

a) WHO b) USFDA c) EMA d) CIOMS

1 In the EMA system, safety signals are assessed by:

a) FAERS b) PRAC c) MedWatch d) UMC

1 Which statement is TRUE?

a) CIOMS can withdraw a medicine from the market b) The WHO Programme directly bans unsafe medicines worldwide c) Regulatory action (label change, withdrawal) is taken by national/regional regulators d) VigiBase collects reports only from Europe

1 The main reason for global sharing of ADR data is:

a) To reduce the cost of medicines b) To detect rare or unexpected ADRs faster by pooling worldwide experience c) To approve medicines more quickly d) To advertise medicines internationally

1 India participates in the WHO Programme through:

a) The USFDA b) PvPI (its national pharmacovigilance programme) c) CIOMS membership of hospitals d) The EMA

Answer Key: 1-c, 2-b, 3-b, 4-b, 5-b, 6-c, 7-b, 8-c, 9-b, 10-b

Viva Questions

1 Why is international cooperation needed in pharmacovigilance?

2 Differentiate between the WHO Programme and the UMC.

3 Is CIOMS a regulatory authority? Justify your answer.

4 What is the difference between FAERS and MedWatch?

5 How does an ADR reported in India reach VigiBase?

Application-Based Questions

1 A new diabetes medicine marketed globally is suspected of causing a rare eye problem. Only 2 cases have been reported in India. As a PV officer, how would you use the global system to investigate?

2 An Indian pharmaceutical company wants to report a serious ADR to European regulators. Which standard format would it use, and which body developed it?

3 The EMA's PRAC recommends restricting a medicine across the EU, but the same medicine is widely used in India. What should Indian regulators and pharmacists consider before acting on this foreign decision?

References

- Andrews & Moore — Mann's Pharmacovigilance
- Cobert — Cobert's Manual of Drug Safety and Pharmacovigilance
- Jose, Cox & Paudyal — Principles and Practice of Pharmacovigilance and Drug Safety
- Strom, Kimmel & Hennessy — Textbook of Pharmacoepidemiology
- Talbot & Waller — Stephens' Detection of New Adverse Drug Reactions
- Waller & Harrison-Woolrych — An Introduction to Pharmacovigilance

CHAPTER 7: Pharmacovigilance Programme of India (PvPI) and ADR Monitoring Centres

Learning Objectives

After studying this chapter, you will be able to:

1 Describe what the Pharmacovigilance Programme of India (PvPI) is and why it was started.

2 Explain the structure of PvPI — the National Coordination Centre and the ADR Monitoring Centres.

3 Describe how ADR Monitoring Centres (AMCs) are established and what work they do.

4 Trace the flow of an ADR report within India, from reporter to national database to global sharing.

5 List the reporting tools available in India (reporting form, helpline, mobile app) in general terms.

6 Explain the role of the pharmacist in PvPI.

7 State the key functions and achievements expected of PvPI in simple terms.

8 Relate PvPI to the global systems studied in Chapter 6.

Definitions

- **Pharmacovigilance Programme of India (PvPI):** India's national programme for monitoring the safety of medicines — it collects, analyses, and acts on ADR reports from across the country. In simple words: India's own official "medicine safety watch" system.
- **National Coordination Centre for PvPI (NCC-PvPI):** The central office that coordinates the entire PvPI network — it receives reports from all ADR Monitoring Centres, maintains the national database, performs signal detection, and communicates with regulators and the WHO Programme. It operates from the Indian Pharmacopoeia Commission (IPC).
- **ADR Monitoring Centre (AMC):** A designated hospital or medical college centre that collects ADR reports from its region, checks their quality, enters them into the system, and forwards them to the National Coordination Centre. Think of AMCs as the district collection offices of PvPI.
- **Suspected ADR Reporting Form:** The standard form used in India for reporting a suspected adverse drug reaction — it captures patient details (without name), suspected medicine(s), the reaction, and reporter information. Health professionals and consumers use versions of this form.
- **Indian Pharmacopoeia Commission (IPC):** The autonomous institution under the Ministry of Health and Family Welfare that, among other functions, houses the National Coordination Centre for PvPI.
- **CDSCO (Central Drugs Standard Control Organization):** India's national drug regulatory authority — the body that takes regulatory action (warnings, label changes, restrictions) based on safety evidence, including PvPI data.

Terminology Table

Term	Simple Meaning
PvPI	India's national medicine-safety monitoring programme
NCC-PvPI	The central coordinating office of PvPI (at IPC)
AMC	ADR Monitoring Centre — regional collection and processing centre
IPC	Indian Pharmacopoeia Commission — hosts the NCC-PvPI
CDSCO	India's national drug regulator — takes regulatory action
Suspected ADR Reporting Form	India's standard form for reporting ADRs
ICSR	Individual case safety report — one patient's report in the database
Signal	A possible new drug–side effect link needing investigation
Causality assessment	Expert judgement of how likely the drug caused the event
Consumer reporting	ADR reports sent directly by patients/members of the public

Simple Explanations

Why does India need its own programme?

India has one of the world's largest populations, with enormous medicine use — including unique patterns: widespread use of fixed-dose combinations, heavy antibiotic use, large generic medicine market, and traditional medicines used alongside modern ones. Side effects seen in Western countries may differ from those seen in Indian patients because of genetics, diet, diseases, and prescribing habits.

India cannot depend only on foreign data for the safety of Indian patients. PvPI ensures that ADRs happening in Indian hospitals and pharmacies are collected, studied, and acted upon in India.

The structure of PvPI — a simple picture

PvPI works as a hub-and-spoke network:

1. **Reporters (spokes' tips):** doctors, pharmacists, nurses, and patients across India notice suspected ADRs.
2. **ADR Monitoring Centres (spokes):** designated centres — mostly in medical colleges and hospitals — collect reports from their area, check completeness and quality, and enter the data.
3. **National Coordination Centre (hub):** the NCC-PvPI receives all reports, maintains the national database, assesses causality, detects signals, and prepares safety recommendations.
4. **Regulator (action arm):** the CDSCO receives PvPI's recommendations and takes regulatory action — warnings, label changes, restrictions — as per the latest guidelines/notifications.
5. **Global link:** India's data also flows to the WHO Programme's VigiBase (see Chapter 6), and global insights flow back.

How ADR Monitoring Centres are established

AMCs are set up in a planned, stepwise way:

1. **Selection:** Medical colleges, hospitals, and institutions with adequate patient load and clinical departments are identified as suitable centres.
2. **Designation:** The institution is formally recognised as an AMC under PvPI.
3. **Training:** Doctors, pharmacists, and nurses at the centre are trained in ADR detection, reporting, causality assessment, and data entry.
4. **Infrastructure:** A nodal officer/coordinator is appointed, reporting forms are made available, and the centre is connected to the national reporting system.
5. **Functioning:** The AMC actively collects reports from its hospital wards and surrounding health facilities, promotes reporting through awareness activities, and forwards quality-checked data to the NCC.
6. **Monitoring:** The performance of AMCs (number and quality of reports) is reviewed periodically, and support or re-training is provided where needed.

As per the latest PvPI notifications — confirm the current edition — the network has grown to cover a large number of centres across states and union territories, so that reporting is possible from every region of the country.

The role of an AMC — what it actually does every day

1. **Collect** suspected ADR reports from wards, OPDs, and nearby health facilities.
2. **Scrutinise** each report for completeness — are the medicine details, dates, and reaction description clear?
3. **Follow up** with the reporter if information is missing.
4. **Assess causality** — apply standard methods to judge the drug–event link.
5. **Enter data** into the national system as ICSRs.
6. **Forward** the processed reports to the NCC-PvPI.
7. **Promote** pharmacovigilance locally — sensitisation programmes, CME sessions, posters, and reminders to health professionals.
8. **Give feedback** to reporters so they stay motivated to report again.

How a patient can report in India

PvPI encourages reporting not only by health professionals but also by **consumers (patients and the public)**. Reporting channels, as per the latest PvPI notifications — confirm the current edition — include:

- The **Suspected ADR Reporting Form** (paper form available at AMCs and health facilities).
- A **toll-free helpline** for reporting and queries.
- A **mobile application** for ADR reporting.
- Reporting in regional languages is encouraged so that language is not a barrier.

The message to the public is simple: *if you suspect a medicine harmed you, report it — you do not need to be a doctor to save others from the same harm.*

The pharmacist's role in PvPI

- **Detect:** notice ADRs during dispensing, counselling, and ward rounds.
- **Report:** fill and submit the Suspected ADR Reporting Form to the nearest AMC.
- **Document:** keep good records — medicine name, batch, dates, reaction details.
- **Counsel:** teach patients to recognise and report side effects.
- **Follow up:** provide missing information when the AMC asks.
- **Promote:** organise awareness activities in the hospital or community.

Many AMCs have pharmacists as coordinators or key team members — PV is a natural home for the pharmacy profession.

Classifications

Classification of PvPI stakeholders

Stakeholder	Role in PvPI
Reporters (doctors, pharmacists, nurses, patients)	Notice and report suspected ADRs
ADR Monitoring Centres	Collect, check, and forward reports from their region
NCC-PvPI (at IPC)	National database, signal detection, coordination
CDSCO	Regulatory action on safety recommendations
Marketing authorisation holders (companies)	Report ADRs for their products; implement label changes
WHO Programme / UMC	Receive Indian data into VigiBase; share global insights

Classification of reporting sources

Source	Who reports	Example
Health professional reports	Doctors, pharmacists, nurses	A physician reports liver injury with an anti-TB drug
Consumer reports	Patients, family members	A patient reports severe skin rash after a painkiller
Company reports	Pharmaceutical companies	A company forwards serious cases for its product

Mechanisms / Processes

The Indian ADR report journey — step by step

1. **Suspicion:** a health professional or patient suspects an ADR.
2. **Form filling:** the Suspected ADR Reporting Form is completed (patient identity kept confidential — no names in the database).
3. **Submission:** the form reaches the nearest AMC — by hand, post, helpline, or mobile app.
4. **AMC processing:** the AMC checks completeness, follows up for missing details, assesses causality, and enters the case into the system.
5. **Transmission to NCC:** the ICSR flows to the National Coordination Centre.
6. **National analysis:** the NCC pools all-India data, detects signals, and prepares assessments.
7. **Regulatory review:** findings go to the CDSCO for decisions — advisories, label changes, restrictions — as per the latest guidelines/notifications.
8. **Global sharing:** Indian ICSRs are transmitted to VigiBase, contributing to worldwide signal detection.
9. **Communication:** safety alerts and newsletters inform Indian health professionals.

How an AMC handles one report (internal workflow)

```
Report received at AMC
        |
        v
Check: is the form complete?
   /            \
 YES             NO → contact reporter for missing details
  |
  v
Causality assessment (how likely did the drug cause it?)
  |
  v
Data entry into the national system (as ICSR)
  |
  v
Forward to NCC-PvPI
  |
  v
Feedback sent to the original reporter (thank + inform)
```

Textual Diagrams / Flowcharts

Diagram 1: PvPI structure (hub and spokes)

```
        Reporters: Doctors, Pharmacists, Nurses, Patients
                        |
        +---------------+---------------+
        |               |               |
   AMC (North)    AMC (Central)    AMC (South)   ... (centres across India)
        |               |               |
        +---------------+---------------+
                        |
                        v
              NCC-PvPI (at IPC)
        - national database
        - signal detection
        - coordination
                   |
        +----------+----------+
        |                     |
        v                     v
     CDSCO              WHO Programme
 (regulatory action    (Indian data to
  in India)             VigiBase)
```

Diagram 2: From Indian hospital to global database

```
Indian hospital ward
        |
        v
Suspected ADR Reporting Form filled
        |
        v
Nearest ADR Monitoring Centre (quality check + causality)
        |
        v
NCC-PvPI (national pooling + signal detection)
        |
        +---> CDSCO (Indian regulatory action)
        |
        +---> UMC / VigiBase (global signal detection)
```

INFOGRAPHIC CONCEPT: A poster titled "PvPI: India's Medicine Safety Net" shaped like a banyan tree. Roots = reporters (doctors, pharmacists, nurses, patients) feeding reports upward. Trunk = ADR Monitoring Centres across the country collecting and checking reports. Branches = NCC-PvPI analysing data and detecting signals. Fruits = safety actions: alerts to doctors, label changes, safer prescribing. A bird carrying a report flies from the tree toward a globe labelled "VigiBase — India's data protects the world too." Bottom line: "One report from your hospital can protect crores of patients."

Tables

Table 1: AMC vs NCC-PvPI — who does what

Function	AMC (regional)	NCC-PvPI (national)
Collect reports	Yes — from its hospital and region	Receives from all AMCs
Check completeness	Yes — first-level quality check	Yes — second-level review
Causality assessment	Yes — initial assessment	Yes — expert/pooled assessment
Data entry	Yes — enters ICSRs	Maintains the national database
Signal detection	Limited (local patterns)	Yes — national-level detection
Training & awareness	Yes — for local health professionals	Yes — national training programmes
Regulatory recommendation	No	Prepares recommendations for CDSCO
Global reporting	No	Transmits Indian data to VigiBase

Table 2: PvPI reporting channels

Channel	Used by	Notes
Suspected ADR Reporting Form (paper)	Health professionals, consumers	Available at AMCs and health facilities
Toll-free helpline	Anyone	For reporting and PV queries — as per the latest PvPI notifications, confirm the current number
Mobile application	Health professionals, consumers	Electronic reporting — as per the latest PvPI notifications, confirm the current app
Direct to AMC	Hospital staff	Hand delivery during rounds or to the nodal officer

Examples

1. **AMC workflow example:** A nurse in a medical college hospital notices a patient developing jaundice after starting anti-tuberculosis treatment. She informs the AMC nodal officer (a pharmacologist/pharmacist), who helps the treating doctor fill the Suspected ADR Reporting Form, checks it for completeness, assesses causality, enters it into the system, and forwards it to the NCC.
2. **Consumer reporting example:** A young man develops a severe skin rash after taking an over-the-counter painkiller. He calls the PvPI helpline, and his report is recorded — his single report joins thousands of others for analysis.

3 **Signal to action example:** PvPI data shows an unusual cluster of a particular side effect with a widely used medicine. The NCC analyses the signal and forwards its assessment to the CDSCO, which issues an advisory to health professionals — as per the latest guidelines/notifications.

4 **Global contribution example:** Indian ICSRs on a traditional-medicine–related liver injury flow into VigiBase, helping the global community recognise a pattern that Western countries had never seen.

Analogies

1 **PvPI is like the Indian postal network.** You (reporter) drop a letter (ADR form) at your local post office (AMC). It is sorted and checked there, then sent to the central sorting hub (NCC), which delivers important letters to the government (CDSCO) and even abroad (VigiBase).

2 **An AMC is like a district collector's office for drug safety.** It is the government's local representative: it collects information from its area, verifies it, and passes it upward — while also spreading awareness locally.

3 **The NCC is like the control tower of an airport.** Many planes (reports) arrive from different runways (AMCs); the tower sees the whole sky (national data), spots dangerous patterns (signals), and guides safe landings (regulatory advice).

4 **Consumer reporting is like a suggestion box that actually gets read.** Every slip matters — the box is emptied, every slip is counted, and repeated complaints change how the shop (health system) works.

Pharmacy Relevance

- Every Indian pharmacist should know the location of the **nearest AMC** — it is where their reports go.
- Filling a Suspected ADR Reporting Form is a **core professional skill**, like dispensing or counselling. Practice it until it is second nature.
- Pharmacists in **hospital and clinical pharmacy** roles are often the most active reporters — they see ADRs during rounds and medication review.
- Careers: PvPI's network, the IPC, CDSCO, and pharmaceutical companies' drug-safety departments all need pharmacists trained in pharmacovigilance.
- **Ethical duty:** the pharmacist's first loyalty is to the patient. Reporting a suspected ADR — even for a product your own pharmacy sells — is part of that duty.

India Context

- PvPI is India's answer to the global systems in Chapter 6: it is how India participates in the WHO Programme while serving Indian patients first.
- India's challenges make PvPI especially important: huge population, high use of antibiotics and fixed-dose combinations, widespread self-medication, and concurrent use of traditional medicines — all of which create ADR patterns that foreign databases alone would miss.

- **Language and access:** PvPI encourages reporting in a way ordinary Indians can use — forms, helpline, and app — because a safety system that only English-speaking specialists can use will miss most of the country.
- **Under-reporting** remains the biggest challenge: with India's patient load, the number of reports is still small compared to the true number of ADRs. Every pharmacist who reports regularly is directly strengthening the national system.
- As per the latest PvPI notifications — confirm the current edition — the AMC network continues to expand, and reporting tools (helpline, mobile app) are updated periodically; always check the current official PvPI communication for the latest details.

Key Points

- PvPI is India's national pharmacovigilance programme — the country's official medicine-safety watch.
- Structure: reporters → ADR Monitoring Centres (regional) → NCC-PvPI at IPC (national hub) → CDSCO (regulatory action) → WHO/VigiBase (global sharing).
- AMCs are established in medical colleges/hospitals: they collect, quality-check, assess, enter, and forward reports, plus train and sensitise local health professionals.
- Reporting channels include the Suspected ADR Reporting Form, a toll-free helpline, and a mobile app — open to health professionals AND consumers.
- Pharmacists are frontline reporters and often AMC team members.
- India's data reaches the world through VigiBase; global insights return to India.
- Never quote numbers of AMCs, helpline digits, or app names from memory in exams — write "as per the latest PvPI notifications."

Common Confusions

1. **PvPI vs CDSCO.** PvPI (coordinated by NCC at IPC) collects and analyses safety data; CDSCO is the regulator that takes action (warnings, label changes). PvPI recommends; CDSCO decides.
2. **AMC vs NCC.** The AMC is regional (one hospital/area); the NCC is national (one central office). Reports flow AMC → NCC, not the reverse.
3. **IPC's role.** The IPC hosts the NCC-PvPI, but the IPC is not itself the drug regulator — that is the CDSCO.
4. **"Only doctors can report."** Wrong — pharmacists, nurses, and patients/consumers can and should report.
5. **"Reporting means the drug will be banned."** Wrong — a report is the start of investigation, not a verdict. Most reports lead to better information, not bans.

Common Mistakes

1. **Inventing the number of AMCs or the helpline number from memory.** These change as the programme expands. In exams, describe the system and add "as per the latest PvPI notifications — confirm the current edition."

2 **Saying PvPI is run by the WHO.** PvPI is India's national programme; it *collaborates* with the WHO Programme by sharing data.

3 **Omitting the consumer/patient** as a reporter — examiners specifically look for this.

4 **Confusing the reporting form's purpose** — it captures *suspected* ADRs; proof of causation is not required to report.

5 **Writing AMC functions as only "collecting forms."** AMCs also check quality, assess causality, enter data, train staff, and give feedback to reporters.

Mnemonics

- **PvPI flow — "R-A-N-C-W": R**eporters → **A**MC → **N**CC → **C**DSCO → **W**HO (VigiBase). Memory line: "**R**eports **A**re **N**ationally **C**hecked **W**orldwide."
- **AMC jobs — "C-Q-C-D-F-T-G": C**ollect, **Q**uality-check, **C**ausality assess, **D**ata entry, **F**orward, **T**rain, **G**ive feedback. Memory line: "**C**areful **Q**uality **C**ontrol **D**elivers **F**acts **T**hrough **G**oodwill."
- **Who can report — "DPNP": D**octors, **P**harmacists, **N**urses, **P**atients.

Exam Summary

The **Pharmacovigilance Programme of India (PvPI)** is India's national system for monitoring medicine safety, needed because India's population, medicine-use patterns, and genetics create ADR patterns that foreign data alone cannot capture. It works as a hub-and-spoke network: **reporters** (doctors, pharmacists, nurses, patients) send suspected ADR reports to regional **ADR Monitoring Centres** set up in medical colleges and hospitals; AMCs check completeness, assess causality, enter data, forward ICSRs to the **National Coordination Centre (NCC-PvPI)** housed at the **Indian Pharmacopoeia Commission**; the NCC maintains the national database, detects signals, and sends recommendations to the **CDSCO**, India's drug regulator, which takes action (advisories, label changes, restrictions) as per the latest guidelines/notifications. Indian data also flows to **VigiBase**, linking India to the WHO global system. AMCs are established stepwise — selection, designation, training, infrastructure, functioning, and periodic monitoring — and their daily jobs are collecting, quality-checking, causality assessment, data entry, forwarding, local training, and reporter feedback. Reporting channels include the Suspected ADR Reporting Form, a toll-free helpline, and a mobile app, open to professionals and consumers alike. Pharmacists are central to PvPI as detectors, reporters, counsellors, and often AMC team members.

One-Minute Revision

PvPI = India's medicine-safety watch. Flow (R-A-N-C-W): **R**eporters (doctors, pharmacists, nurses, patients) → **A**MC (regional: collect, check, assess, enter, forward, train) → **N**CC at IPC (national database + signals) → **C**DSCO (action: warnings, labels) → **W**HO/VigiBase (global). Channels: reporting form + helpline + mobile app (confirm current details as per latest notifications). PvPI recommends; CDSCO decides. No proof needed to report — suspicion is enough. Pharmacist: detect, report, document, counsel, follow up.

Questions

Short-Answer Questions

1 What is PvPI?

2 What is an ADR Monitoring Centre?

3 Where is the National Coordination Centre for PvPI housed?

4 Name the reporting channels available under PvPI.

5 Who can report an ADR in India?

Long-Answer Questions

1 Describe the organisational structure of the Pharmacovigilance Programme of India with a labelled flowchart, explaining the role of each level from reporter to global sharing.

2 Discuss the establishment and functions of ADR Monitoring Centres. What are the daily responsibilities of an AMC?

3 A pharmacist working in a district hospital wants to strengthen ADR reporting in her hospital. Using your knowledge of PvPI, describe the complete process from detecting a suspected ADR to regulatory action, highlighting the pharmacist's role at each stage.

MCQs (with Answer Key)

1 PvPI stands for:

a) Private Vigilance of Pharma Industries b) Pharmacovigilance Programme of India c) Public Vaccine Programme of India d) Pharma Validation Process in India

1 The National Coordination Centre for PvPI operates from:

a) The USFDA b) The Indian Pharmacopoeia Commission (IPC) c) The World Bank d) A private hospital chain

1 ADR Monitoring Centres are primarily established in:

a) Shopping malls b) Medical colleges and hospitals c) Pharmaceutical factories only d) Foreign embassies

1 Which of the following is NOT a function of an AMC?

a) Collecting ADR reports from its region b) Checking report completeness and assessing causality c) Manufacturing medicines d) Training local health professionals in PV

1 In India, an ADR can be reported by:

a) Only doctors b) Only the CDSCO c) Doctors, pharmacists, nurses, and patients/consumers d) Only pharmaceutical companies

1 PvPI's safety recommendations are acted upon by:

a) The WHO directly b) The CDSCO, India's drug regulator c) CIOMS d) The reporter

1 Indian ADR data reaches the global VigiBase database through:

a) Direct patient emails to Geneva b) The NCC-PvPI transmitting ICSRs to the WHO Programme c) The USFDA d) Pharmaceutical advertisements

1 The Suspected ADR Reporting Form in India:

a) Requires proof that the drug caused the reaction b) Captures suspected reactions; proof of causation is not required to report c) Can only be filled in English by doctors d) Is used for ordering medicines

1 Which statement about PvPI is TRUE?

a) PvPI is run by the WHO b) PvPI is India's national programme that collaborates with the WHO Programme c) PvPI only monitors vaccines d) PvPI reports go only to pharmaceutical companies

1 The biggest challenge facing PvPI is:

a) Too many reports b) Under-reporting of ADRs c) Lack of medicines in India d) Excessive funding

Answer Key: 1-b, 2-b, 3-b, 4-c, 5-c, 6-b, 7-b, 8-b, 9-b, 10-b

Viva Questions

1 Why does India need its own pharmacovigilance programme instead of relying on foreign data?

2 Differentiate between the roles of PvPI (NCC) and the CDSCO.

3 List any four functions of an ADR Monitoring Centre.

4 Can a patient directly report an ADR in India? How?

5 How does Indian ADR data contribute to global drug safety?

Application-Based Questions

1 You are the pharmacist at an AMC. A busy physician says, "I don't have time to fill forms — reporting is useless." How would you convince and help him, using your knowledge of the AMC's role?

2 A patient reports a suspected ADR to you but is afraid that giving details will reveal her identity. What will you assure her about confidentiality in the PvPI system, and what minimum information do you need?

3 Your college wants to become an ADR Monitoring Centre. Outline the steps involved in establishing an AMC and the infrastructure it would need.

References

- Andrews & Moore — Mann's Pharmacovigilance
- Cobert — Cobert's Manual of Drug Safety and Pharmacovigilance
- Jose, Cox & Paudyal — Principles and Practice of Pharmacovigilance and Drug Safety
- Strom, Kimmel & Hennessy — Textbook of Pharmacoepidemiology
- Talbot & Waller — Stephens' Detection of New Adverse Drug Reactions
- Waller & Harrison-Woolrych — An Introduction to Pharmacovigilance