



RAGHU COLLEGE OF PHARMACY

SUBJECT AND SUBJECT CODE:703T

UNIT: 1

CLASS: 8

**TOPIC: ADVERSE DRUG INTERACTIONS REPORTING AND
MANAGEMENT**

PRESENTED BY:

B. Ramya

Asst. Professor

Specialization : [M . pharm(Pharmacy Practice)]

INTRODUCTION:

- Clinical trial study of the drug detects ADR but, the reactions occurs after long duration in a specific population remains undetected.
- So, (PV) Pharmacovigilance is a activity which keeps constant watch on the drug throughout its life cycle.
- In India, IPC and NCC through the CDSCO regulate the PV activity. Then Pharmacovigilance programme in India(PvPI) have been proposed in 2010.

- Anyone can report ADR by filling the suspected ADR reporting form available online or offline to the nearest centers in suitable languages.
- Then, the reported ADRs are collected and processed at the centers in vigiflow software. The centers detect signals which are reported to CDSCO and WHO.
- **Pharmacovigilance:** According to the World Health Organization (WHO), pharmacovigilance is the science of identifying, evaluating, understanding, and preventing adverse effects of medicines and vaccines.

Materiovigilance: Materiovigilance is a system for identifying, reporting, and analyzing adverse events related to medical devices. The goal of materiovigilance is to protect patient health by preventing adverse events from happening again.

Haemovigilance: Effective system are needed to facilitate monitoring and evaluation of the blood system, including donor safety, blood product quality and safety, and transfusion safety.

ADVERSE DRUG REACTION :

- ▶ According to WHO, an adverse drug reaction defined as, "Any response to a drug which is noxious unwanted effect of drug doses used in human for prophylaxis, diagnosis and therapy".

TYPES OF ADRS:

- **Type A:** (augmented pharmacological effects) Dose related
- **Type B:** (bizarre effects), Non-Dose related
- **Type C:** which are further categorized into sub-types including chronic
- **Type D:** delayed
- **Type E:** end-of-treatment
- **Type F:** failure of therapy

OBJECTIVES OF ADR MONITORING:

- To detect the nature and frequency of ADRS
- To assist the Drug Regulatory Authority, Public Health Programs, Scientists and Consumer Society to minimize ADRs.
- Providing updated Drug Safety Information to Health Care Professionals.
- Dissemination of information by designing proper education program to consumers.
- To identify risk factors that may predispose, induce or influence the development, severity and incidence of ADRs.

REPORTING OF ADRS SYSTEMS:

1. PASSIVE SURVEILLANCE SYSTEM:

- For reporting diseases, risk factors or health-related events. Health practitioners report events as they come to their attention. This is the more common type of surveillance.
- Example: A physician sees a patient, diagnoses measles, and then initiates a case report by contacting the local health department and providing the details as required for a case of measles.

- **Spontaneous Reporting:** A spontaneous report is an unsolicited communication by healthcare professionals or consumers to a company, regulatory authority or other organization.
 - Defines one or more adverse drug reactions (ADRs) in a patient who was given one or more medicinal products.
 - Identification of safety signals once a medicine is marketed.
 - Can vigilant a company to rare adverse events that were not noticed in earlier clinical trials or other pre-marketing studies.

■ Suspected Adverse Drug Reaction Reporting Form:

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SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of Adverse Drug Reactions by healthcare professionals

INDIAN PHARMACOPOEIA COMMISSION (National Coordination Centre-Pharmacovigilance Programme of India) Ministry of Health & Family Welfare Government of India Sector-23, Raj Nagar, Ghaziabad-201002 www.ipc.nic.in						(AMC/ NCC Use only) AMC Report No. _____ Worldwide Unique _____				
A. PATIENT INFORMATION 1. Patient Initials _____ 2. Age at time of Event or date of birth _____ 3. Sex ☐ M ☐ F 4. Weight _____Kgs						12. Relevant tests / laboratory data with dates _____				
B. SUSPECTED ADVERSE REACTION 5. Date of reaction started (dd/mm/yyyy) _____ 6. Date of recovery (dd/mm/yyyy) _____ 7. Describe reaction or problem _____						13. Other relevant history including pre-existing medical conditions (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/ renal dysfunction etc) _____ 14. Seriousness of the reaction ☐ Death (dd/mm/yyyy) ☐ Congenital-anomaly ☐ Life threatening ☐ Required intervention to prevent permanent impairment / damage ☐ Hospitalization/prolonged ☐ Other (specify) _____ ☐ Disability 15. Outcomes ☐ Fatal ☐ Recovering ☐ Unknown ☐ Continuing ☐ Recovered ☐ Other (specify) _____				
C. SUSPECTED MEDICATION(S)										
S.No	8. Name (brand and /or generic name)	Manufacturer (if known)	Batch No./ Lot No. (if known)	Exp. Date (if known)	Dose used	Route used	Frequency	Therapy dates (if known, give duration)		Reason for use of prescribed for
								Date started	Date stopped	
i.										
ii.										
iii.										
iv.										
S.No As per C	9. Reaction abated after drug stopped or dose reduced					10. Reaction reappeared after reintroduction				
	Yes	No	Unknown	NA	Reduced dose	Yes	No	Unknown	NA	If reintroduced dose
i.										
ii.										
iii.										
iv.										
11. Concomitant medical product including self medication and herbal remedies with therapy dates (exclude those used to treat reaction)						D. REPORTER (see confidentiality section on first page) 16. Name and Professional Address : _____ Pin code: _____ E-mail: _____ Tel. No. (with STD code): _____ Occupation: _____ Signature: _____				
17. Causality Assessment						18. Date of this report (dd/mm/yyyy)				

2.ACTIVE SURVEILLANCE SYSTEM: Involves actively searching for ADRs through targeted data collection, such as reviewing medical records, conducting surveys, or monitoring specific patient populations.

- a. Sentinel Sites:** Revising medical records or questioning patients and/or physicians in a section of sentinel sites.
- To guarantee that comprehensive and precise data on reported adverse events are collected from these sites.
 - The selected sites can deliver information, such as data from specific patient subgroups.

b. Medicine event monitoring: Studies using this process are cohort-based and prospective and observational. A follow-up questionnaire can then be sent to each prescribing physician or patient at pre- specified intervals to acquire outcome data. Requests for data on patient demographics, indication for treatment, duration of therapy, dosage, clinical events, reasons for termination and applicable past history can be involved in the questionnaires.

c. Cross- Sectional Studies

d. Case Control Studies

e. Cohort Studies

WHO CAN REPORT?

- All healthcare professionals (clinicians, dentists, pharmacists, nurses etc) and non-healthcare professionals including consumers can report suspected adverse drug reaction.
- Pharmaceutical companies can also send ICSRs specific for their product to NCC.

WHY TO REPORT?

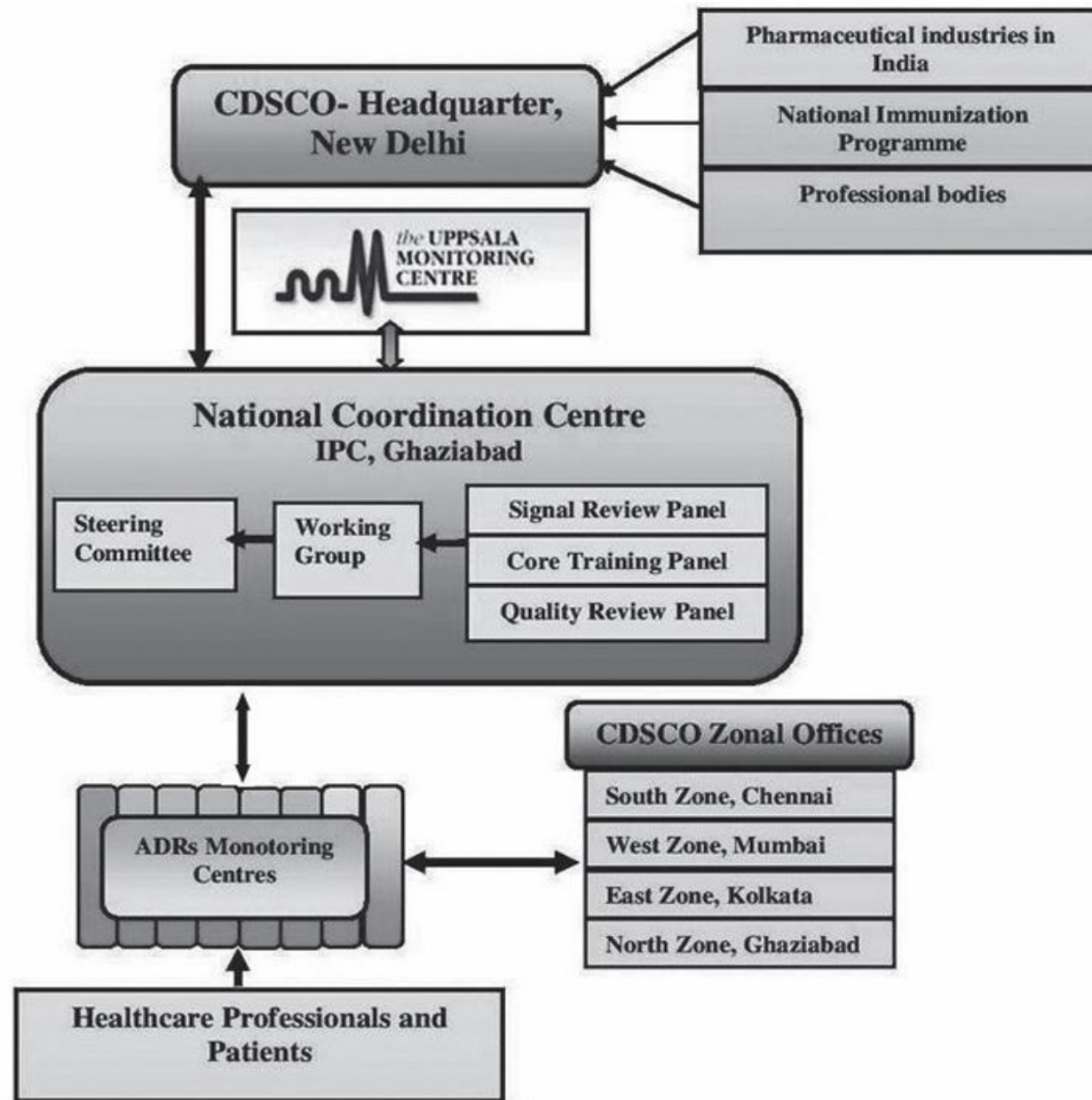
As a healthcare professional, it is a moral responsibility to report adverse reactions associated with use of medicines and safeguard the health of public

WHAT TO REPORT?

- All adverse events should be reported Report.
- Non-serious, known or unknown, frequent or rare adverse drug reactions due to Medicines, Vaccines & Herbal Products.
- Report every serious adverse drug reactions. A reaction is serious when the patient outcome is :
- Death, Life-threatening, Hospitalization (initial or prolonged), Disability (significant, persistent or permanent), Congenital anomaly, Report intervention to prevent permanent impairment or damage.

WHERE TO REPORT?

- Duly filled in Suspected Adverse Drug Reaction Reporting Form can be sent to the nearest Adverse Drug Reaction Monitoring Centre (AMC) or directly to the National Coordination Centre (NCC) for PvPI.
- Call on Helpline (Toll Free) 1800 180 3024 to report ADRs or directly mail this filled form to pvpi.ipc@gov.in A list of nationwide AMCs is available at : <http://www.ipc.gov.in>, http://www.ipc.gov.in/PvPI/pv_home.html



PvPI - Communication

WHAT HAPPENS TO THE SUBMITTED INFORMATION?

- Information provided in this form is handled in strict confidence. The causality assessment is carried out at AMCs by using WHO-UMC scale. The analyzed forms are forwarded to the NCC-PvPI through ADR database.
- Finally, the data is analyzed and forwarded to the Global Pharmacovigilance Database managed by WHO Uppsala Monitoring Centre in Sweden.

- The reports are periodically reviewed by the NCC-PvPI. The information generated on the basis of these reports helps in continuous assessment of the benefit-risk ratio of medicines.
- The Signal Review Panel of PvPI reviews the data and suggests any interventions that may be required.

USA MED WATCH:

MedWatch is the Food and Drug Administration's (FDA) program for reporting serious reactions, product quality problems, therapeutic inequivalence/failure, and product use errors with human medical products, including drugs, biologic products, medical devices, dietary supplements, infant formula, and cosmetics.

MedWatch receives reports from the public and, when appropriate, publishes safety alerts for FDA-regulated products such as:

- Prescription and over-the-counter drugs

- biologics, such as blood components, blood/plasma derivatives, and gene therapies
- Medical devices, such as hearing aids, breast pumps, and pacemakers
- Combination products, such as pre-filled drug syringes
- Special nutritional products, such as medical foods, and infant formulas
- Cosmetics, such as moisturizers, makeup, shampoos, hair dyes, and tattoos
- Food, such as beverages, and ingredients added to foods

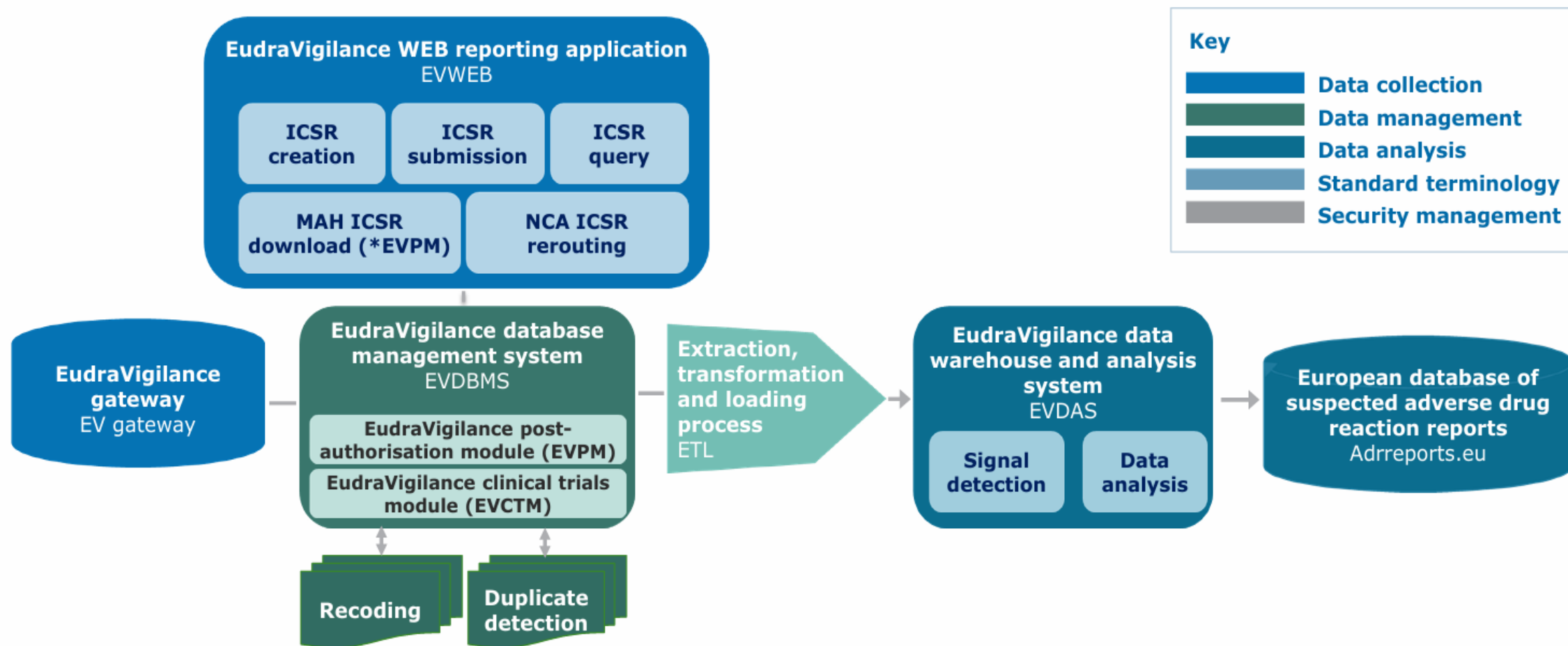
MED WATCH FORM FOR ADRs REPOTING:

- Form FDA 3500 For use by health professionals, consumers, and patients vountarily reporting.
- Form FDA 3500 B For Consumers reporting.

EUDRAVIGILANCE

- EudraVigilance is the system for managing and analysing information on suspected adverse reactions to medicines which have been authorised or being studied in clinical trials in the European Economic Area (EEA). The European Medicines Agency (EMA) operates the system on behalf of the European Union (EU) medicines regulatory network.

EudraVigilance system components:



BNF

In Confidence

YellowCard

COMMISSION ON HUMAN MEDICINES (CHM)

It's easiest to report online at
www.mhra.gov.uk/yellowcard


MHRA
 Regulating Medicines and Medical Devices

SUSPECTED ADVERSE DRUG REACTIONS

If you suspect an adverse reaction may be related to one or more drugs/vaccines/complementary remedies, please complete this Yellow Card. See 'Adverse reactions to drugs' section in BNF or www.yellowcard.gov.uk for guidance. Do not be put off reporting because some details are not known.

PATIENT DETAILS Patient Initials: _____ Sex: M / F Is the patient pregnant? Y / N Ethnicity: _____
 Age (at time of reaction): _____ Weight (kg): _____ Identification number (e.g. Practice or Hospital Ref): _____

SUSPECTED DRUG(S)/VACCINE(S)

Drug/Vaccine (Brand if known)	Batch	Route	Dosage	Date started	Date stopped	Prescribed for
_____	_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____	_____

SUSPECTED REACTION(S)

Please describe the reaction(s) and any treatment given:

Outcome

Recovered ☐
 Recovering ☐
 Continuing ☐
 Other ☐

Date reaction(s) started: _____ Date reaction(s) stopped: _____

Do you consider the reactions to be serious? Yes / No

If yes, please indicate why the reaction is considered to be serious (please tick all that apply):

- | | |
|---|--|
| ☐ Patient died due to reaction | ☐ Involved or prolonged inpatient hospitalisation |
| ☐ Life threatening | ☐ Involved persistent or significant disability or incapacity |
| ☐ Congenital abnormality | Medically significant; please give details: _____ |

If the reactions were not serious according to the categories above, how bad was the suspected reaction?

- ☐ Mild ☐ Unpleasant, but did not affect everyday activities ☐ Bad enough to affect everyday activities

It's easiest to report online at www.mhra.gov.uk/yellowcard

OTHER DRUG(S) (including self-medication and complementary remedies)

Did the patient take any other medicines/vaccines/complementary remedies in the last 3 months prior to the reaction? Yes / No

If yes, please give the following information if known:

Drug/Vaccine (Brand if known)	Batch	Route	Dosage	Date started	Date stopped	Prescribed for

Additional relevant information e.g. medical history, test results, known allergies, rechallenge (if performed). For reactions relating to use of a medicine during pregnancy please state all other drugs taken during pregnancy, the last menstrual period, information on previous pregnancies, ultrasound scans, any delivery complications, birth defects or developmental concerns.

Please list any medicines obtained from the internet: _____

REPORTER DETAILS

Name and Professional Address: _____

Postcode: _____ Tel No: _____

Email: _____

Speciality: _____

Signature: _____ Date: _____

CLINICIAN (if not the reporter)

Name and Professional Address: _____

Postcode: _____ Tel No: _____

Email: _____

Speciality: _____

Date: _____

Information on adverse drug reactions received by the MHRA can be downloaded at www.mhra.gov.uk/daps

Stay up-to-date on the latest advice for the safe use of medicines with our monthly bulletin *Drug Safety Update*, at www.mhra.gov.uk/drugsafetyupdate

Please attach additional pages if necessary. Send to: FREEPOST YELLOW CARD (no other address details required)

CIOMS:

- The Council for International Organizations of Medical Sciences (CIOMS) is an international, non-governmental, not-for-profit organization established jointly by WHO and UNESCO in 1949. CIOMS plays a crucial role in bioethics, health research ethics, and pharmacovigilance, facilitating dialogue and collaboration among government bodies, international organizations, and the private sector in the field of medical sciences.

The importance of CIOMS forms in pharmacovigilance lies in their role in standardizing the collection and reporting of ADRs. They provide structured data that can be analyzed systematically to identify potential safety signals, assess the risk-benefit profile of medications, and contribute to evidence-based decision-making in drug safety. Additionally, CIOMS forms facilitate communication and information exchange among healthcare professionals, regulatory agencies, and pharmaceutical companies, enhancing overall pharmacovigilance practices and promoting patient safety.

ROLE OF WHO:

- All countries ADRs reports submitted to WHO(World Health Organization). WHO maintain the vigibase store. Vigibase is the WHO global database of adverse event reports for medicines and vaccines. It is the largest database of its kind in the world, with around 40 million reports of suspected adverse effects of medicines submitted by member countries of the WHO PIDM since 1968. It is continuously updated with incoming reports. Vigibase not given access to common people.
- WHO also maintained Vigibase Access. This is access to common man.

