Glossary of terms used in Pharmacovigilance
- **WHO** - World Health Organization
- **CIOMS** - Council for International Organizations of Medical Sciences
- **ICH** - International Conference on Harmonization
- **PSUR** - Periodic Safety Update Report
- **SUSAR** - Suspected Unexpected Serious Adverse Reaction
Pharmacovigilance
WHO, 2002

- The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem
Adverse reaction
WHO, (1972)

- 'A response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modifications of physiological function'.

Adverse event

- Medical occurrence temporally associated with the use of a medicinal product, but not necessarily causally related
Side effect

- Unintended effect occurring at normal dose related to the pharmacological properties
Any untoward medical occurrence that at any dose;
- Results in death
- Requires inpatient hospitalization or prolongation of existing hospitalization
- Results in persistent or significant disability or incapacity
Unexpected adverse reaction

- Not consistent with applicable product information or characteristics of drug.
Signal

- Reported information on possible causal relationship between an adverse event and drug
- Previously unknown or incompletely documented
- More than one report is needed.
AE Types

Adverse Event

Intensity
- Mild
- Moderate
- Severe

Seriousness
- Non Serious
- Serious

Expectedness
- Expected
- Unexpected

Causality
- Related
- Un-related
Causality assessment

- The evaluation of the likelihood that a medicine was the causative agent of an observed adverse reaction.
- Causality assessment is usually made according to established algorithms.
Methods of causality assessment

- WHO assessment scale
- Naranjo’s scale
- European ABO system
- Karch and Lasagna’s scale
- Kramer scale
- Bayesian network
- Yale Algorithm
- Spanish Imputation System
WHO Causality categories:
- Certain
- Probable
- Possible
- Unlikely
- Conditional/Unclassified
- Unassessable/Unclassifiable
DeChallenge: The clinical decision to withdraw/discontinue a drug treatment after a possible ADR has occurred.

Rechallenge: The point at which a drug is again given to a patient after its initial withdrawal.
- **Vigibase**: The name for the WHO International ADR Database
- **Vigiflow**: is a sophisticated case report management system created by the UMC, complying with GxP requirements.
- **Vigisearch**: is a custom search offered by the UMC to third-party inquirers for which several types of standard presentation are available.

- **Vigimed**: E-mail conferencing facility, exclusive to member countries of the WHO Programme for International Drug Monitoring.
- Generic Name?
- Brand Name?
- POM
- OTC
PEM

- Prescription Event Monitoring
  - Cohort – event monitoring
A listing of medicinal drugs with their uses, methods of administration, available dose forms, side effects, sometimes including their formulas and methods of preparation.
The European Union data-processing network and management system, established by the European Medicines Agency to support the Electronic exchange, management, and scientific evaluation of Individual Case Safety Reports related to all medicinal products authorized in the European Economic Area.
Hierarchical Structure of the Proposed Centres
National PVig Programme
NATIONAL PHARMACOVIGILANCE ADVISORY COMMITTEE

November’2004

The National Pharmacovigilance Centre
Office of Drugs Controller General of India,
Central Drugs Standard Control Organization,
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Nirman Bhawan, New Delhi 110 011.
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PERIPHERAL PHARMACOVIGILANCE CENTRE – ACTIVITIES

- Primary contact ADR data collection center
- Small Medical centers nursing homes (Clinics, Private hospitals, Pharmacies)
- Primary Pharmacovigilance centers
- Identified & coordinated by RPCs/ZPCs in coordination with CDSCO
- At least one in each state & UT and some other leading medical College
- Twenty eight peripheral centers, spread country-wide
REGIONAL PHARMACOVIGILANCE CENTRE – ACTIVITIES

(Secondary Pharmacovigilance Centre)

- Relatively larger facilities attached with medical college
- Will act as secondary level centers
- First contact for ADE data collection
- Identified and coordinated by Zonal centres in co-ordination with CDSCO
- Five regional centres
Regional pharmacovigilance centers

- 5 regional pharmacovigilance centers located at
  - Kolkata (IPGMR-SSKM Hospitals)
  - Mumbai (TN Medical College & BYL Nair Charitable Hospital)
  - Nagpur (Indira Gandhi Medical College)
  - New Delhi (Lady Hardinge Medical College)
  - Pondicherry (JIPMER)
ZONAL PHARMACOVIGILANCE CENTRES

- (TERNARY PHARMACOVIGILANCE CENTRE)
- Large health care facility attached with medical college in metro cities
- Identified by CDSCO
- 3rd level levels
- Also act as 1st ADE data collection centre
  - AIIMS (North & East zone)
  - KEM Mumbai (South and West)
Zonal pharmacovigilance centres

- Two zonal pharmacovigilance centres
  - South and West: Seth GS Medical College and KEM Hospital, Mumbai
  - North & East zone: AIIMS, New Delhi.
ROLE OF CENTRAL DRUG CONTROL STANDARD ORGANISATION (CDSCO)

- To establish and manage database of ADRs
- To make regulatory decisions regarding marketing authorization and safety of drugs
- Possible regulatory measures in coordination with NPAC
ADR Flow

UMC WHO Database

CDSCO

Zonal Centre

Regional Centre

Pvig Centre

Health Care Workers

Causality
The minimum criteria for a valid ADR report*

- Identifiable patient
- A suspect drug
- An adverse event
- Identifiable reporter

*ICH/CIOMS
The Data Elements Required by CIOMS I Form

I. Reaction Information

II. Suspect Drug

III. Concomitant Drugs & History

IV. Mfactur’g Information
The Data Elements Required by CIOMS I Form

- Reaction Information
  - Patient’s Initial
  - Country
  - DOB /Age
  - Sex
  - Reaction Onset
  - Description of event
  - Seriousness criteria
II. Suspect Drug
- Name of drug
- Dose
- Route
- Indication/s
- Therapy dates/ duration
- De-challenge / Re-challenge
The Data Elements Required by CIOMS I Form

III. Concomitant Drugs & History
- Concomitant drugs
- Dates
- Relevant history