PHARMACOVIGILANCE BASIC QUESTIONS IN INTERVIEW

&

Introduction to PV

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WHAT IS PHARMACOVIGILANCE?

- ***Pharmacovigilance is also known as Drug Safety, is a science of collection, detection , understanding, assessment, monitoring, evaluating information from health care providers and patients on prevention of AE or drug related problems with pharmaceutical products (medications), biological products, herbalism and traditional medicines.***

- ***Pharmakon - (Greek – drug) and Vigilance (Latin – for to keep watch)***

SOME IMPORTANT ABBREVIATIONS IN PV TERMS

- *ADR – Adverse Drug Reactions (adverse reactions to medicines)*
- *AE – Adverse Event*
- *SAE – Serious Adverse Event*
- *DD – Drug Dictionary*
- *WHO – World Health Organisation*
- *ICD – International Classification of Disease*
- *ICSR – Individual Case Safety Report*
- *MedDRA – Medical Dictionary for Drug Regulatory Activities*
- *SOC – System Organ Class*
- *SOP – Standard Operating Procedures*
- *SUSAR – Suspected Unexpected Serious Adverse Reaction*
- *CIOMS – Council for International Organisation of Medical Science*
- *ICH - International Conference on Harmonisation of Technical Requirements for Pharmaceuticals for human use*

AIM OF PV

- *Contribution to the assessment of benefit, harm, effectiveness and risk of medicines, loading to the prevention of harm and maximization of benefit.*
- *Appropriate response or action in terms of drug registration, drug use and /or training and education for health care Professionals and the Public.*
- *Measurement and evaluation of the outcome of the response or of action taken (eg. Reduction in risk, improved medicine use or improved outcome for patients experiencing a particular ADR).*

OBJECTIVES OF PV

- *Understanding the concepts of ADR, Medication Errors, Public Health Significance, Regulatory Interventions, ADR Monitoring Schemes.*

ADVERSE EVENT

- An untoward medical occurrence in a patient or clinical investigation or subject administered a pharmaceutical product and which does not necessarily have to have a causal relationship with this treatment.
- NOTE: AE has no causal relationship with the drug

ADVERSE DRUG REACTION

- Adverse Drug Reaction is a response to a Drug which is noxious and unintended response which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of diease or for modification of physiological function.
- NOTE: ADR has causal relationship with the drug

- In addition,

  an ADR is harm and directly caused by the drug at normal doses during normal use.

TYPES OF ADR

- Type A – Augmented Pharmacologic Effects
- Type B – Bizarre Effects
- Type C – Chronic Reactions
- Type D – Delayed Reactions

- **WHAT IS YELLOW CARD SCHEME?**

It is the UK system for collecting information on Suspected ADR to drugs. The Scheme allows the safety of the medicines and vaccines that are in the market to be mobitored

WHAT TO REPORT IN PV

- *Patient demographics: (name, address, sex, date of birth, height and weight, medical history of Significance.*
- *Details of medicine (this may be brand or generic – preferably brand) and formulation, mode of administration (eg: oral, rectal, or injection), Indicaions (for use dose)*
- *Reaction details (date of Onset, outcome: resolved, resolving, no change, disabling, worsening, death (with date) or Congenital anomaly, effect of rechallenge*
- *Reporter details: Date of place and report.*

CASE PROCESSING STEPS IN PV

- Triage
- Data Entry
- Safety Review
- Medical Review – where the case gets locked.

- And the case submitted to the respective Health Authority & various destinations depends upon the case and severity.

- Case is divided into 1) Serious and
  2) Non-Serious

WHAT IS A VALID CASE?
THE 4 BASIC ELEMENTS OF AN AE CASES

- *During the triage phase of a potential adverse event report, the triage must determine the "4 elements" of an AE present are:*

1. *An identifiable Patient*
2. *An identifiable Reporter*
3. *A suspect Drug*
4. *An Adverse Event/IME (Important Medical Event) – medically significant*

WHEN A CASE TO BE CONSIDERED AS SERIOUS

1. *Death*
2. *Life threatening*
3. *Hospitalization or prolonged hospitalization*
4. *Congenital anomaly/Birth defect*
5. *Disability /Impairment*
6. *Medically significant*

HIERARCHY OF MEDDRA

- *System Organ Class (SOC)*
- *High Level Group Term (HLGT)*
- *Preferred Term (PT)*
- *Lower Level Term (LLT)*

DUE DATES OF SAFETY REPORTING

- Fatal and life threatening – 7 days – IND reporting (Investigational New Drug)
- Serious cases – 15 days – NDA reporting (New Drug Application)
- Non-Serious cases – 30 days
- Reporting destinations depends upon the Country, Origin and Severity of the case

WHAT IS CAUSALITY?

Causality is the relationship between the suspect product (drug) and the adverse drug event

REGULATORY GUIDELINES USED IN INDUSTRIES OF PV

CDSCO – CENTRAL DRUG STANDARD CONTROL ORGANISATION

- **DCGI** –DRUG CONTROLLER GENERAL OF INDIA

- **Who maintains MedDRA**

  Maintenance and Support Service Organisation

NAME THE REGULATORY BODIES

- India – Central Drugs Standard Control Organisation (CDSCO)
- USA - United States Food and Drug Administration (USFDA)
- UK - European Medical Agency (EMEA)
- Japan – Ministry of Health, Labour and Welfare (MHLW)

WHAT ARE THE DATA ASSESSMENTS IN PV

- *Individual Case report assessment*
- *Aggregate assessment and interpretation*
- *Signal detection*
- *Interaction and risk factors*

WHEN A CASE IS CONSIDERED TO BE VALID*?*

If the case contains at lease one event confirmed or reported by a HCP – Health Care Professional (Physician, Pharmacist, Nurse,Psychologist (Germany), patient or by a non-health professional.