Pharmacovigilance Interview Questions PDF 2024 By Pharmajobsnow.com

What is Pharmacovigilance?

Pharmacovigilance, as defined by the World Health Organization (WHO), is the science and activities related to the detection, assessment, understanding, and prevention of adverse reactions or any other drug-related problems.

Pharmacovigilance Scope in India:

The pharmacovigilance market in India is growing rapidly, expected to increase from USD 6.87 billion to USD 23.32 billion by 2033, with a compound annual growth rate of 13%. This growth is driven by the rising prevalence of chronic illnesses and the need for safety monitoring of new drugs developed through clinical research.

Aims of Pharmacovigilance:

- Early detection of previously unknown adverse reactions and interactions.
- Improvement of patient care and safety.
- Detection of increasing frequency of known adverse reactions.
- Identification of risk factors and possible mechanisms underlying adverse reactions.
- Estimation of quantitative aspects of benefits/risk analysis.
- Dissemination of information to improve drug prescribing and regulation.

Objectives:

- Collection of data.
- Recording and reporting to regulatory authorities, including individual and periodic cases.

Goals:

- Ensure rational and safe use of medicinal products.
- Assess and communicate risks and benefits of drugs on the market.
- Educate and inform patients.

Types of Pharmacovigilance:

1. **Active Pharmacovigilance:**
    - Actively detects adverse events during or after treatment.

    - Patients are directly asked or their records are screened.
    - Cohort Event Monitoring (CEM) is a common method.
2. **Passive Pharmacovigilance:**
    - Relies on spontaneous or voluntary reporting.
    - Depends on the initiative and motivation of reporters like healthcare providers and patients.

Minimum Criterion for a Valid Case:

- An identifiable reporter.
- An identifiable patient.
- A suspect product.
- An adverse drug event.

If any of these details are missing, the case is considered invalid.

Difference Between an Adverse Drug Event (ADE) and an Adverse Drug Reaction (ADR):

- **ADR**: A harmful and unintended response to a drug, occurring at normal doses used for prevention, diagnosis, or treatment of diseases. The relationship with the drug is confirmed.
- **ADE**: A harmful and unintended response that may or may not have a direct causal relationship with the drug.

Criteria for Serious Events:

1. Death.
2. Life-threatening.
3. Hospitalization or prolongation of hospitalization.
4. Congenital anomaly.
5. Disability.
6. Medically significant events.

Sources of Adverse Event Reports:

1. Clinical Trial/Phase Reports.
2. Post Marketing Phase Reports:
    - Solicited Reports (non-interventional studies).
    - Spontaneous Reports from healthcare providers or volunteers.

Timelines for Reporting:

- SUSAR cases: within 7 calendar days.
- Serious cases: within 15 calendar days.
- Non-serious cases: within 30 calendar days (90 days in the EU).

Due Dates for Safety Reporting:

- IND Reporting: 7 days.
- NDA Reporting: 15 days.

Initial Receipt Date (IRD) / Day 0:

- The day the report is received.

Forms for Reporting ADR/AE:

- CIOMS (international)- Council for International Organizations of Medical Sciences
- MedWatch (US),
- Yellow Card (UK).
- Blue Card (Australia).
- SARRF (India)- Suspected Adverse Reaction Reporting Form

SUSAR (Suspected Unexpected Serious Adverse Reaction):

- Serious and unexpected adverse reactions reported in clinical trials, not in solicited or spontaneous reports.

How would you approach case processing and reporting in pharmacovigilance?

- Review the case for completeness and validity.
- Check for seriousness and causality.
- Code the adverse events using MedDRA.
- Submit the report to regulatory authorities within specified timelines.

Regulatory Bodies:

- USA: USFDA - United States Food and Drug Administration
- UK: MHRA - Medicines and Healthcare products Regulatory Agency
- Japan: MHLW - Ministry of Health, Labour and Welfare
- India: CDSCO - Central Drugs Standard Control Organization
- Canada: Health Canada - Health Canada
- Australia: TGA - Therapeutic Goods Administration
- China: SFDA - State Food and Drug Administration
- Europe: EMA - European Medicines Agency

Role of Regulatory Authorities in Pharmacovigilance:

- Ensure drug safety and efficacy.
- Monitor and analyze adverse event data.
- Enforce regulations and guidelines.
- Facilitate the safe use of medicines by the public.

Medically Significant Event:

- An event that may be serious but does not fulfill other seriousness criteria.

Medically Confirmed Case:

- Contains at least one event confirmed by a healthcare professional.

Causality:

- The relationship between the suspect drug and the adverse event.
- Types: Reporter's causality and Company causality.
- Assessment methods include WHO UMC Scale, Naranjo Scale, and French Imputability Scale.

Triage in Pharmacovigilance:

- Prioritize cases by checking IRD, seriousness, validity, and searching for duplicates.

Types of Drugs:

- **Suspect Drug:** Causes the adverse event.
- **Co-Suspect Drug:** Other drugs involved in the case.
- **Concomitant Medication:** Taken along with the suspect drug.
- **Treatment Drug:** Given to treat any ADR.
- **Historical Drug:** Withdrawn before the suspect drug's administration.
- **Historical Event/Condition:** Medical condition stopped before the suspect drug's administration.
- **Concomitant Condition:** Medical condition continuing with the administration of the suspect drug.

MedDRA (Medical Dictionary for Regulatory Activities):

- Used for coding adverse events.

- Updated twice a year.

Hierarchy in MedDRA:

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

Data Elements in ICSR:

- Patient demographics.
- Suspect product details.
- Adverse event details.

Narrative Content:

- Source of report, patient demographics, medical history, concomitant medications, suspect product details, and adverse event details.

Data Assessments in Pharmacovigilance:

- Individual case report assessment.
- Aggregated assessment and interpretation.
- Signal detection.
- Interactions and risk factors.
- Serial study.
- Frequency estimation.

Reporting Methods:

- Telephone.
- Fax.
- E-mail.
- Internet.

Seriousness Criteria Based on Intensity:

- Not severe, mild, moderate, severe.

Relatedness Synonyms:

- **Related:** Certain, possible, probable, likely.

- **Not Related:** Unlikely, unclassified, unassessable.

Odd Scenarios in PV:

- Pregnancy.
- Overdose.
- Off-label use.
- Medication error.
- Lack of efficacy.

Co-morbid Conditions:

- Other health problems that increase susceptibility to ADRs.

Signal:

- Reported information on a possible causal relationship between an adverse event and a drug.

Methods of Signal Detection:

1. Clinical assessment of individual events.
2. Clinical review of collated events.
3. Record linkage.
4. Automated signal detection.

Aggregate Reporting:

- Collects cumulative safety data of a medical product periodically.

Recently Banned Drugs in India:

- Rosiglitazone, Sibutramine, Rimonabant, Nimesulide (under 12 years), Cisapride, Phenylpropanolamine, Gatifloxacin, Tegaserod.

Phases in Clinical Trials:

- **Phase I:** Tests drug safety and dosage.
- **Phase II:** Assesses effectiveness and side effects.
- **Phase III:** Verifies effectiveness in a large patient group before market release.
- **Phase 0:** Microdosing to check behavior in humans.

Common Pharmacovigilance Terms:

- **ICSR:** Individual Case Safety Report.
- **DSUR:** Development Safety Update Report.
- **PSUR:** Periodic Safety Update Report.
- **PADER:** Periodic Adverse Drug Experience Report.
- **SUSAR:** Suspected Unexpected Serious Adverse Reaction.
- **MedDRA:** Medical Dictionary for Regulatory Activities.
- **GVP:** Good Pharmacovigilance Practices.
- **IBD:** International Birth Date.
- **ESTRI:** Electronic Standards for the Transfer of Regulatory Information.
- **WHO-ART:** World Health Organization - Adverse Reaction Terminology.
- **CIOMS:** Council for International Organizations of Medical Sciences.
- **ICD:** International Classification of Diseases.
- **WHO-DDE:** World Health Organization - Drug Dictionary Enhanced.
- **ATC:** Anatomical, Therapeutical, Chemical Classification of Systems.

Thalidomide Disaster:

- Thalidomide, used in the 1960s as a sleeping agent and to treat morning sickness, caused severe birth defects (phocomelia) and fetal deaths.

Actions Taken for Drug Events:

- Drug withdrawal, dose changes, and unknown actions.

Dechallenge/Rechallenge:

- **Dechallenge:** Withdrawal of a drug to see if adverse effects cease.
- **Rechallenge:** Re-administration of the drug to see if adverse effects reoccur.

Outcome of an Event:

- Recovered, recovering, not recovered, unknown, or fatal.

Listedness/Unlistedness:

- If a reaction is included in the Company Core Safety Information (CCSI), it is listed; otherwise, it is unlisted.

Expectedness/Unexpectedness:

- Based on whether an adverse event is documented in the Reference Safety Information (RSI).

International Society of Pharmacovigilance (ISOP):

- Provides information about meetings and training courses related to pharmacovigilance.

Risk and Prevalence:

- **Absolute Risk:** Probability of an event in a specific population.
- **Incidence:** Rate of occurrence.
- **Prevalence:** Condition of being prevalent.

Drug Misuse and Abuse:

- **Misuse:** Wrong and intentional use of a drug not according to prescription.
- **Abuse:** Excessive and harmful use of a drug, like excessive morphine causing hallucinations.

Medication Error:

- Unintended failure in the treatment process, such as prescription, dispensing, or administration errors.

Off-label Use:

- Use of a medical product for an unapproved age group, dosage form, or route of administration.

Pregnancy Trimesters:

- **1st Trimester:** 1-13 weeks.
- **2nd Trimester:** 14-27 weeks.
- **3rd Trimester:** 28-40 weeks.

Volume 9A:

- Provides guidance on pharmacovigilance for medicinal products and details procedures for marketing authorization holders.

ICH (International Council for Harmonization):

- Establishes guidelines for medical product registration to ensure safety, efficacy, and quality.
- ICH Guidelines: E2A to E2F, focusing on Clinical Safety Data Management, Periodic Safety Update Reports, Clinical Safety Data Management (case reports), and more.

Explanation of Concepts:

1. **PSUR:** Periodic Safety Update Report, analyzing the benefit-risk balance.
2. **DSUR:** Development Safety Update Report, providing annual updates on the safety profile of a drug under development.
3. **ICSR:** Individual Case Safety Report, containing specific adverse event information.
4. **SUSAR:** Suspected Unexpected Serious Adverse Reaction, an unexpected and serious adverse reaction occurring in clinical trials.
5. **MedDRA:** Medical Dictionary for Regulatory Activities, standardizing adverse event terminology.
6. **Causality Assessment:** Determining the relationship between the suspect drug and the adverse event.

Role of Regulatory Authorities in Pharmacovigilance:

- Ensure drug safety and efficacy.
- Monitor and analyze adverse event data.
- Enforce regulations and guidelines.
- Facilitate the safe use of medicines by the public.

Miscellaneous Questions

Which form is used for mandatory reporting in US FDA? The form used for mandatory reporting to the US FDA is the **MedWatch form** (Form 3500). It is used by healthcare professionals, consumers, and drug manufacturers to report serious adverse events, product quality problems, and therapeutic failures associated with drugs and medical products.

What is the difference between concomitant medication and past drugs?

- **Concomitant medication**: These are drugs that a patient is currently taking along with the suspected drug that might be causing the adverse reaction. They are used to understand if interactions between drugs could be causing the adverse event.
- **Past drugs**: These are medications that a patient has taken in the past but are no longer taking at the time of the adverse event. Past drugs are considered to understand if previous medications could have any residual effects or interactions with the current treatment.

What information can we know from E2a, E2b, and E2c guidelines?

- **E2a**: Provides guidelines for clinical safety data management during the investigational phase of drug development. It includes mechanisms for expedited reporting of adverse drug reactions.
- **E2b**: Provides guidelines for the transmission of Individual Case Safety Reports (ICSRs). It ensures standardized data elements are used when reporting adverse events to facilitate global pharmacovigilance.
- **E2c**: Provides guidelines for Periodic Safety Update Reports (PSURs) for marketed drugs. It outlines requirements for evaluating the benefit-risk profile of drugs post-approval.

Do you think there is only a scope of drugs in Pharmacovigilance?
Pharmacovigilance encompasses the monitoring and evaluation of not only drugs but also medical devices, biological products, herbal remedies, vaccines, and other healthcare interventions. It focuses on detecting, assessing, understanding, and preventing adverse effects or any other drug-related problems to improve patient safety.

If you are a Health Professional, how will you report an adverse drug reaction?

As a Health Professional, I would report an adverse drug reaction (ADR) using the prescribed reporting form (such as CIOMS form, MedWatch form, etc.) provided by regulatory authorities. I would ensure to include all necessary details such as patient demographics, suspected drug details, adverse event description, and any concomitant medications. Reporting promptly and accurately is crucial to contribute to pharmacovigilance efforts.

What will you do if you experience an adverse effect of the medicine?

If I experience an adverse effect of a medicine, I would immediately stop taking the medication and seek medical advice from a healthcare professional. I would provide detailed information about my symptoms, the medication taken, dosage, and any other relevant medical history to facilitate accurate diagnosis and management of the adverse effect.

How do you ensure you maintain the confidentiality and privacy of patients while reporting ADRs?

To maintain confidentiality and privacy while reporting ADRs, I would adhere to regulatory guidelines and ensure that personally identifiable information (PII) of patients is anonymized or kept confidential. I would use secure reporting channels and

platforms approved for pharmacovigilance reporting to prevent unauthorized access or disclosure of sensitive patient information.

What are the various steps used in signal detection?

Signal detection in pharmacovigilance involves several steps:

- **Data collection**: Gathering individual case reports (ICSRs), clinical trial data, and other relevant sources.
- **Data mining**: Using statistical and analytical tools to identify potential signals or patterns of adverse events.
- **Signal evaluation**: Assessing the strength, consistency, and biological plausibility of identified signals.
- **Signal validation**: Conducting further epidemiological studies or clinical trials to confirm or refute the identified signals.
- **Signal communication**: Communicating validated signals to regulatory authorities, healthcare professionals, and the public as necessary.

Explain medical coding and how you choose the exact ADR type.

Medical coding involves assigning standardized codes (such as MedDRA codes) to adverse events reported in pharmacovigilance. These codes categorize adverse events based on their symptoms, severity, and anatomical or physiological system affected. Choosing the exact ADR type involves matching the reported adverse event description with the most appropriate MedDRA term to ensure accurate and consistent data analysis and reporting.

What are the schedules in jurisprudence and their uses?

Jurisprudence in pharmacovigilance refers to legal and regulatory frameworks governing drug safety and surveillance. The schedules often refer to timelines or deadlines for reporting adverse events or submitting safety reports to regulatory authorities (e.g., 7-day SUSAR reporting, 15-day serious adverse event reporting). Adhering to these schedules ensures compliance with pharmacovigilance regulations and promotes timely identification and mitigation of drug-related risks.

What is GCP and in which schedule does it come?

GCP (Good Clinical Practice) is an international ethical and scientific quality standard for designing, conducting, recording, and reporting clinical trials involving human subjects. It ensures that the rights, safety, and well-being of trial participants are protected and that clinical trial data are credible and accurate. GCP guidelines typically fall under Schedule Y of the Drugs and Cosmetics Act in India.

What is Prescription Event Monitoring and its importance?

Prescription Event Monitoring (PEM) is a method used to monitor the safety of new medicines once they are prescribed in routine clinical practice. It involves collecting data on adverse events from patients' medical records or healthcare professionals over a specified period. PEM helps detect rare or long-term adverse effects that may not have been observed during pre-marketing clinical trials, thus contributing valuable safety data to pharmacovigilance.

What is informed consent?

Informed consent is the voluntary agreement by a patient or participant in a clinical trial after receiving adequate information about the trial's purpose, procedures, risks, benefits, and alternatives. It ensures that individuals have the autonomy to make an informed decision about participating in research or treatment without coercion. Informed consent is a fundamental ethical requirement in clinical trials and medical research.

What do the different parts of Volume 9A deal with?

Volume 9A of the European Union guidelines provides comprehensive guidance on pharmacovigilance practices and procedures for medicinal products for human use. The different parts deal with:

- **Part I**: Guidelines for Marketing Authorisation Holders (MAHs).
- **Part II**: Guidelines for Competent Authorities responsible for medicinal products.
- **Part III**: Guidelines for electronic exchange of pharmacovigilance information within the EU.
- **Part IV**: Guidelines on pharmacovigilance communication, including risk communication and public awareness.

Difference between NDA and ANDA?

- **NDA (New Drug Application)**: Submitted by pharmaceutical companies to the FDA to gain approval for a new drug to be marketed and sold in the US. Requires extensive clinical data demonstrating safety and efficacy.
- **ANDA (Abbreviated New Drug Application)**: Submitted for generic drug approval in the US. Relies on bioequivalence data compared to a reference (innovator) drug, rather than conducting full clinical trials. Used for drugs that are off-patent and have proven safety and efficacy.

What is EudraVigilance?

EudraVigilance is the European Union's centralized database for the collection and management of suspected adverse reactions to medicines that are authorized or being studied in clinical trials in the European Economic Area (EEA). It supports pharmacovigilance activities across EU member states by facilitating the electronic exchange of safety information.

What is inverted Black triangle in Pharmacovigilance?

The inverted Black triangle (▼) is a symbol used in Europe to denote medicinal products that are under additional monitoring by regulatory authorities due to their recent approval or concerns about their safety. It encourages healthcare professionals to report any suspected adverse reactions associated with these products to enhance monitoring and patient safety.

What is the Pharmacovigilance Programme of India (PvPI)?

The Pharmacovigilance Programme of India (PvPI) is an initiative by the Indian government to monitor and improve the safety profile of medicines in India. It aims to collect, analyze, and act on adverse drug reactions (ADRs) reported by healthcare professionals and consumers. PvPI collaborates with global pharmacovigilance networks to ensure comprehensive drug safety monitoring in India.

Feel free to reach out for further elaboration on any of these points!