Standard Operating Procedure (SOP) for Pharmacovigilance Committee

1. Purpose

The purpose of this SOP is to outline the processes and responsibilities of the **Pharmacovigilance Committee** in ensuring the safety of drugs and related products used within the institution. This includes the monitoring, reporting, evaluation, and management of adverse drug reactions (ADRs) to maintain the safety and well-being of patients. The committee is also responsible for complying with national and international regulatory requirements related to pharmacovigilance.

2. Scope

This SOP applies to:

- All clinical departments, healthcare providers, pharmacists, and researchers involved in prescribing, dispensing, and monitoring drugs.
- All drugs, biologics, and medical products used within the institution or in clinical trials conducted at the institution.
- All staff and faculty involved in adverse drug reaction (ADR) reporting, evaluation, and management.

3. Definitions

- **Pharmacovigilance:** The science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems.
- **Adverse Drug Reaction (ADR):** Any harmful or unintended response to a drug at doses normally used in humans for prophylaxis, diagnosis, or therapy.
- **Pharmacovigilance Committee (PVC):** A committee responsible for overseeing the pharmacovigilance activities, ensuring the safety of medications, and managing ADR reporting and investigations.
- **Serious Adverse Event (SAE):** An ADR that results in death, life-threatening condition, hospitalization, disability, or congenital anomaly.
- **Causality Assessment:** A systematic process used to evaluate whether there is a relationship between a drug and an ADR.

4. Structure and Composition of the Pharmacovigilance Committee

The **Pharmacovigilance Committee (PVC)** should consist of the following members:

- **Chairperson:**
  - Typically, the Head of the clinical or pharmaceutical department or an experienced healthcare professional.
  - Responsible for overseeing all pharmacovigilance activities, chairing meetings, and ensuring compliance with regulatory standards.
- **Coordinator:**
  - An expert in pharmacovigilance with experience in ADR reporting and management.
  - Responsible for coordinating day-to-day activities, managing ADR reporting, and ensuring the quality and accuracy of data collected.
- **Medical Officer(s):**
  - Responsible for evaluating clinical significance, severity, and causality of reported ADRs.
- **Pharmacist(s):**
  - Ensures that ADRs are recorded, classified, and reported as per pharmacovigilance guidelines. They are also responsible for advising on drug interactions and pharmaceutical safety.
- **Clinical Staff Representative(s):**
  - Includes physicians, nurses, and other healthcare professionals who are involved in patient care and can identify, report, and assess ADRs.
- **Researcher/Clinical Trials Representative:**
  - If applicable, represents the clinical trials division for ADRs associated with investigational drugs.
- **Data Analyst:**
  - Responsible for data management, reporting, and preparing periodic safety update reports (PSURs).

- **Quality Assurance/Regulatory Affairs Representative:**
    - Ensures compliance with local and international regulatory guidelines related to drug safety.

5. Roles and Responsibilities

- **Chairperson:**
    - Provides leadership for the committee.
    - Ensures that pharmacovigilance activities are aligned with institutional and regulatory guidelines.
    - Reviews and approves all pharmacovigilance reports and action plans.
- **Coordinator:**
    - Oversees the day-to-day operations of pharmacovigilance activities, including ADR reporting and investigation.
    - Coordinates the collection, analysis, and reporting of ADR data to regulatory bodies.
    - Develops and updates SOPs and training materials on pharmacovigilance procedures.
- **Medical Officers:**
    - Investigate and assess ADR reports for their seriousness, causality, and potential risks.
    - Provide recommendations for patient management, such as altering dosages or discontinuing the drug.
    - Communicate with the pharmaceutical company (if applicable) regarding safety signals.
- **Pharmacists:**
    - Ensure that ADR reports are filed correctly, including proper classification and evaluation of severity.
    - Participate in ADR management and report adverse reactions promptly.

- **Clinical Staff Representatives:**
    - Assist in identifying ADRs in clinical practice and ensure that patients are monitored for adverse reactions.
    - Collect necessary data and follow protocols for ADR reporting.
- **Researcher/Clinical Trials Representative:**
    - Ensure adverse reactions in clinical trials are reported according to institutional and regulatory guidelines.
    - Maintain records of any serious adverse events (SAEs) that occur during clinical trials.
- **Data Analyst:**
    - Analyze ADR data and generate reports such as summary tables, signal detection, and trend analysis.
    - Prepare periodic safety update reports (PSURs) and communicate findings to regulatory authorities and stakeholders.
- **Quality Assurance/Regulatory Affairs Representative:**
    - Ensures all pharmacovigilance activities meet the institutional, national, and international standards and guidelines.
    - Liaise with health authorities (e.g., FDA, EMA) for compliance and reporting of ADRs.

6. ADR Reporting and Management Process

The committee follows a systematic process to ensure that all ADRs are reported and managed appropriately:

6.1 Reporting of ADRs

- **6.1.1 Reporting Channels:**
  ADRs can be reported through the following channels:
    - **Healthcare Providers:** Physicians, nurses, and pharmacists report any adverse reactions observed in patients.
    - **Patients/Consumers:** Patients can report ADRs via a dedicated ADR reporting form available online or at the hospital or pharmacy.

- **6.1.2 Information to Be Collected:**
  When an ADR is reported, the following information should be collected:
    - Patient's demographic details (age, gender, etc.)
    - Drug involved (name, dose, duration, etc.)
    - Description of the adverse event (onset, severity, etc.)
    - Outcome (recovery, sequelae, etc.)
    - Action taken (dose reduction, withdrawal, etc.)
    - Any concomitant medications

6.2 Causality Assessment

- **6.2.1 Assessment Tools:**
  The PVC will use recognized methods for assessing the causality of ADRs, such as:
    - **WHO-UMC System for Standardized Case Causality Assessment**
    - **Naranjo Algorithm**
- **6.2.2 Evaluation Criteria:**
    - **Definite:** ADR is clearly related to the drug.
    - **Probable:** ADR is likely related to the drug.
    - **Possible:** ADR may be related to the drug.
    - **Unlikely:** ADR is unlikely related to the drug.

6.3 Data Review and Action

- **6.3.1 Data Compilation:**
  All ADR reports will be compiled and classified by the PVC based on severity (mild, moderate, severe) and outcome (recovered, non-recovered, fatal, etc.).
- **6.3.2 Evaluation of Signals:**
  Signals of potential safety concerns will be identified through routine data analysis, including trends and patterns of ADRs.

- **6.3.3 Risk Management:**
  Based on the evaluation, the PVC will recommend actions, including:
    - Revising dosing instructions
    - Updating labeling information
    - Suspending use of the drug (if applicable)
    - Reporting findings to health authorities

6.4 Regulatory Reporting

- **6.4.1 National Reporting:**
  All serious ADRs (SAEs) will be reported to the national regulatory authority within the required timeframe (e.g., within 15 days of identification).
- **6.4.2 International Reporting (if applicable):**
  ADRs involving marketed drugs in clinical trials will be reported to international regulatory bodies (e.g., WHO, EMA, FDA) following their guidelines.

7. Documentation and Record-Keeping

- The PVC will maintain detailed records of all ADR reports, investigations, and actions taken.
- Documentation should include:
    - ADR reporting forms
    - Causality assessments
    - Reports submitted to regulatory authorities
    - Meeting minutes and safety monitoring reports

These records must be kept confidential and stored securely for a minimum of **5 years**.

8. Training and Awareness

- **8.1 Staff Training:**
  The PVC will organize regular training sessions for healthcare professionals, including physicians, nurses, and pharmacists, to ensure awareness of ADR reporting procedures and pharmacovigilance guidelines.

- **8.2 Public Awareness:**
  The PVC will develop informational materials to educate patients and the public about the importance of ADR reporting.

9. Monitoring and Review

- **9.1 Periodic Review:**
  The PVC will review the pharmacovigilance processes and the effectiveness of safety monitoring activities at regular intervals (e.g., quarterly or annually).

- **9.2 External Audit:**
  An external audit may be conducted periodically to ensure compliance with regulatory requirements and evaluate the efficiency of the pharmacovigilance system.

10. Conclusion

This SOP outlines the framework for the **Pharmacovigilance Committee (PVC)** to monitor and manage the safety of pharmaceutical products within the institution. By following these procedures, the institution ensures that adverse drug reactions are promptly identified, appropriately evaluated, and reported, maintaining the safety and well-being of patients.