	DEPARTMENT OF PHARMACY SERVICES
	MONITORING INCLUDES ADVERSE DRUG EVENTS (ADEs)

1. POLICY

To establish a systematic process for monitoring, detecting, evaluating, documenting, and reporting Adverse Drug Events (ADEs) and Adverse Drug Reactions (ADRs) in order to enhance patient safety, promote rational medication use, and facilitate continuous quality improvement within the hospital.

2. SCOPE

This policy applies to all inpatient, outpatient, and emergency care areas where medications are prescribed, dispensed, administered, or monitored. It covers the identification, evaluation, and reporting of all adverse drug events, including medication errors, allergic reactions, and drug interactions.

3. PROCEDURE

3.1 Adverse Drug Reaction (ADR) Monitoring and Reporting Program

3.1.1 Monitoring: Continuous monitoring of adverse drug events shall be carried out by the Pharmacy Department in collaboration with the Quality Assurance and Clinical departments. All medication-related incidents, errors, or reactions shall be tracked through, incident reports, and pharmacy surveillance logs. The monitoring process will include:

- Regular review of medication error data, ADR reports, and CQI meeting minutes.
- Analysis of prescribing, dispensing, and administration trends to detect patterns of preventable drug events.
- Development of Key Performance Indicators (KPIs) such as rate of ADRs per 1,000 admissions, medication error frequency, and compliance with high-alert medication protocols.
- Identification of high-risk drugs and vulnerable patient groups for targeted surveillance.

- Quarterly summary reports prepared by the Pharmacy Department and presented to the CQI and P&T Committees for corrective and preventive action (CAPA).
  Findings from ADE monitoring shall be integrated into staff education, risk-reduction strategies, and the hospital's continuous quality improvement plan.

3.1.2 Drug Event (Adverse Drug Event / Adverse Drug Reaction) Reporting Process

Any healthcare professional, including physicians, pharmacists, nurses, or even patients and caregivers, may identify a potential Adverse Drug Event (ADE) or Adverse Drug Reaction (ADR). An ADE may include allergic reactions, administration of the wrong dose or wrong drug, use in the wrong patient, contraindicated drug administration, unexpected side effects, overdose, or therapeutic failure. When such an event is suspected, the staff member discovering it shall immediately complete an Adverse Drug Event / Adverse Drug Reaction Reporting Form within twenty-four (24) hours of the event. The report must include the patient's demographic details (name, medical record number, and age), the suspected medication (name, strength, batch number, and expiry date), a clear description of the event or symptoms, the date and time of occurrence, a list of other medications being used, the corrective action taken (such as discontinuation or treatment provided), and the outcome of the event. The form should also include the name, designation, and contact details of the reporting staff member.

Once completed, the ADR/ADE Reporting Form shall be forwarded to the Pharmacy Department, where the pharmacist or clinical pharmacist will verify the information, classify the reaction (definite, likely, possible, or unlikely), and record it in the ADE/ADR Logbook. The Manager Pharmacy or Adverse Drug Reaction (ADR) Committee will then review the report, confirm the causality, and recommend appropriate preventive and corrective measures. The Pharmacy and Therapeutics (P&T) Committee will review all reported and confirmed cases to identify trends, evaluate system gaps, and develop educational and preventive strategies. In cases where the ADE or ADR is serious, unexpected, or fatal, the Manager Pharmacy or ADR Committee must report the event to the Drug Regulatory Authority of Pakistan (DRAP) through the official Pharmacovigilance Reporting Portal or by submitting the National Yellow ADR Form, or hospital generated ADR form in accordance with DRAP pharmacovigilance regulations. A copy of each external report shall be retained in the hospital's ADR record and, where applicable, forwarded to the manufacturer or relevant national authority. The objective of this continuous monitoring and reporting system is to enhance patient safety, promote rational drug use, and support continuous

improvement in medication management practices. Each confirmed drug event shall result in feedback to the involved staff and, where appropriate, serve as a learning opportunity. Educational sessions, newsletters, and clinical alerts may be used to share lessons learned, update staff on preventive strategies, and strengthen pharmacovigilance awareness throughout the hospital.

Process	Purpose	Responsible Parties
Monitoring	Continuous observation, data collection, and evaluation of all medication-related incidents and adverse outcomes to identify risks and trends.	Pharmacists, CQI/ADR Committee, Nursing, Physicians
Reporting	Formal documentation and communication of individual adverse drug events or medication errors through approved channels (forms, logs, DRAP portal).	Reporting staff, Pharmacists, Manager Pharmacy, ADR Committee