GUIDELINES ON MINIMUM STANDARDS FOR ESTABLISHMENT OF HOSPITAL PHARMACIES IN PAKISTAN

Document Number: **PHSR/GL/HP/012**

Document History: **1st Edition**

Effective Date: **25-05-2024**

Drug Regulatory Authority of Pakistan
Islamabad-Pakistan

Table of Contents

1. HISTORY

This is the first edition of this document.

2. APPLICATION

i. All pharmacies in the public and private hospitals and medical centers.

ii. All pharmacists and pharmacy staff who are involved in delivering pharmacy services within the premises of the hospital/medical centers and its related pharmacies.

3. PURPOSE

These standards outline the minimum level of services to be consistently provided by the pharmacies in hospital / medical centers (mentioned herewith as healthcare facility in this document). Certain elements of these standards will also be useful in evaluating the organization (either by the healthcare facility itself or by the relevant healthcare regulatory authorities) as per intended scope and quality of Pharmacy Services rendered by them.

The purpose of these guidelines is to provide guidance and standards for following points:

i. Organization, management, facilities, infrastructure and working of a pharmacy in hospitals / medical centers, relevant human resource (HR), relevant committees, required policies, procedures and work instructions, job description and pharmacy workforce management etc.

ii. Healthcare facility for the procurement, distribution and use of therapeutic goods (pharmaceuticals and medical devices etc.), their storage, inventory management, safe use procedures related to their prescription, dispensing, preparation, administration, monitoring of use and patient education.

iii. Evaluating the effectiveness of medicine use, identification of process weaknesses and continuous improvement of the system with ultimate objective of safe, effective and affordable patient care

iv. Human Resource (HR) development and training.

4. INTRODUCTION

The following minimum standard guidelines are intended to serve as a basic guide for the provision of pharmacy services in healthcare facilities in Pakistan.

Terminology The term “shall” is used to indicate a minimum standard of practice set forth in requirements established by laws and regulatory, authorities. The term “should” is used to indicate a best practice that is strongly encouraged by regulations and authorities but which may not be applicable to all institutions or in all circumstances.

5. DEFINITION AND ACRONYMS:

AC	Air conditioner
ADE	Adverse Drug Event
ADR	Adverse Drug Reaction
Antimicrobial Stewardship	A coordinated program that promotes the appropriate use of antimicrobials (including antibiotics), improves patient outcomes, reduces microbial resistance and decreases the spread of infections caused by multidrug-resistant organisms.
Auxiliary Label	Cautionary and advisory label in addition to the usual prescription label
Code Blue	The term "code blue" is a hospital emergency code used to describe the critical status of a patient. Hospital staff may call a code blue if a patient goes into cardiac arrest, has respiratory issues, or experiences any other medical emergency
Collaborative Drug Therapy Management (CDTM)	Partnership between qualified pharmacists and prescribing clinicians to manage a patient’s drug therapy
Competence (or competency)	The set of demonstrable characteristics and skills that enable and improve the efficiency or performance of a professional/staff. E.g. competency of pharmacist to review prescription in order to identify drug related problems

CPR or Cardiopulmonary Resuscitation	An emergency lifesaving procedure performed when someone's breathing or heartbeat has stopped
Crash Cart	A self-contained, mobile unit, cart or trolley that contains all of the materials, drugs, and devices necessary to perform cardio-pulmonary resuscitation (CPR) during code blue.
D & TC	Drug and Therapeutics committee
DRAP	Drug Regulatory Authority of Pakistan
Emergency Supplies (Kits, Trays or Bags)	Consists of drugs and supplies which are required to meet the immediate therapeutic needs of patients during emergency. E.g. First Aid kit or Rapid Sequence Intubation kit
Floor Stock System	A system of distribution that consists of a medication storage area in a nursing or patient care unit, where selected drugs are stored for immediate or frequent use
High Alert Medicines (HAMs)	Drugs that bear a heightened risk of causing significant patient harm when they are used in error
HMIS	Health Information Management System
ISO	International Organization for Standardization
IV	Intravenous
IV Admixture	A resulting combination when one or more sterile products are added to a 50 mL or larger bag or bottle of IV fluid for parenteral administration
JCIA	Joint Commission International Accreditation
JD	Job description
Look Alike Sound Alike (LASA) medications	Involve medications that are visually similar in physical appearance or packaging and names of medications that have spelling similarities and/or similar phonetics
LASARA	Look-Alike, Sound-Alike and Read-Alike
Medication Therapy Management (MTM)	Medication Therapy Management is a distinct service or group of services that optimize therapeutic outcomes for individual patients.
Mission and Vision statement	A Mission Statement defines the company's business, its objectives and its approach to reach those objectives. A Vision Statement describes the

	desired future position of the company. Elements of Mission and Vision Statements are often combined to provide a statement of the company's purposes, goals and values. However, sometimes the two terms are used interchangeably
Near miss	An act of commission or omission that could have harmed the patient but did not cause harm as a result of chance, prevention, or mitigation
Organogram	An organogram is a graphical representation of an organisation's structure. It shows hierarchical relationships between managers and the people who report to them, as well as departments. (it is also called organizational structure)
Pharmacist	A person who is registered under section 24 of Pharmacy Act 1967.
Pharmacy Services	Services rendered by a pharmacist in a pharmaceutical care, selection, posology, counseling, dispensing, use, administration, prescription, monitoring, pharmacoepidemiology, therapeutic goods information and poison control, pharmacovigilance, Pharmacoeconomics, storage, sales, procurement, forecasting, supply chain management, distribution, drug utilization evaluation, drug utilization review, formulary based drug utilization and managing therapeutic goods at all levels including pharmacy, clinic, medical store, hospital or medical institution
P&TC	Pharmacy & Therapeutics Committee
Performance Evaluation	A formal and productive procedure to measure an employee's work and results based on their job responsibilities
Policy and Procedure	Means a set of rules and methods designed and communicated to structure certain processes within an organization
Standard Operating Procedure (SOP)	A set of step-by-step instructions compiled by an organization to help workers carry out routine operations. SOPs aim to achieve efficiency, quality output and uniformity of performance, while reducing miscommunication and failure to comply
Terms of reference (**TORs**)	TORs define the purpose and structures of a project, committee, meeting, negotiation, or any similar collection of people who have agreed to work together to accomplish a shared goal

6. STANDARD-I ORGANIZATION AND MANAGEMENT

6.1. Medication use in the healthcare facility shall be organized to meet patient needs and requirements, complies with applicable laws and regulations, and shall be under the direction and supervision of a skilled pharmacist who has completed advanced training in hospital pharmacy and/or has relevant experience in the field. Medicines management covers a number of tasks including selection, procurement, prescribing, dispensing, receiving/transporting, storing, assessing/reviewing, preparing, cross checking, administering, disposing, monitoring/reconciliation and educating healthcare staff, patients etc.

6.2. Applicable provincial and federal laws and regulations shall be met, and relevant documentation of compliance shall be maintained. (All "laws" that govern pharmacy services and medication use in the healthcare facility, such as Drug Act,1976 and its rules, Pharmacy Act,1967, DRAP Act, 2012 and its rules, Healthcare Commission/ Health Regulatory Authority laws etc.

6.3. The Head of Pharmacy Services (titles may vary, as Chief of Pharmacy, Director, or Manager Pharmacy etc.) shall be Category A Registered Pharmacist, responsible and accountable for the pharmacy services, and also for coordinating, managing and overseeing the selection and use of medicines and therapeutic goods in the healthcare facility. A sample job description is available in the annexure for reference only (Annexure-III).

6.4. The healthcare facility should have 1 (one) Pharmacist for every 50 beds at In-patient area, however, out-patient staffing depends upon the volumes and pharmacy stations. Pharmacists staffing provision for Clinical pharmacy services and specialized activities (such as patient bedside rounds with physicians, review of medication profile of patients, identification and resolving drug-related problems after discussing with doctors, e.g. problems in dose, route, frequency, rate, dilution, interactions, contraindications, allergies, dose adjustment based on weight, body surface area, serum levels, renal or hepatic function etc.) should also be taken in to account as per the scope of the healthcare facility. Placement of Clinical pharmacists is necessary if the healthcare facility's bed size is >50, and/or dealing with high-risk services such as Oncology, Transplant, Infectious diseases, Critical Care, Pediatrics, Neonatology etc. or if any of the High alert medicines (as notified by the DRAP) are routinely used in the hospital *(see list: https://www.dra.gov.pk/wp-*

content/uploads/2021/12/lohrm_r.pdf). Clinical pharmacists should be included in the pharmacy organogram, and are provided with satisfactory career ladder as either a general clinical or specialty-clinical pharmacist e.g. in oncology, transplant, pediatric, intensive care or infectious diseases etc. (as indicated by the healthcare facility's scope of services).

6.5. The pharmacy shall have a written mission and vision statement with a document describing the scope of Pharmacy Services. The mission statement and scope of Pharmacy Services should be consistent with the healthcare facility's mission and reflect both patient care and operational responsibilities.

6.6 The mission and scope of pharmacy services shall be clearly communicated to everyone involved in the provision of pharmacy services including pharmacists and pharmacy support staff (e.g. technicians, aides, assistants, porters, administration support staff etc.).

6.7. The scope of service document should minimally contain the following:

6.7.1. Type, nature, and extent of available pharmacy services.

6.7.2. Specialty areas and type of patients catered by pharmacy

6.7.3. Working hours of pharmacy.

6.7.4. Arrangement of medication supply during off-hours.

6.7.5. Staffing plan (duties management).

6.7.6. Work hours per week for a full- time employee, allowed number of offs per month and number of annual leaves entitled for.

6.7.7. Emergency/backup plan in case of staff shortage.

6.8. The Department of Pharmacy should have a pharmacy organogram where reporting relationships (either solid or dotted line) are clearly depicted. Reporting structure both within the pharmacy department and that of pharmacy with the healthcare facility management is clearly stated. This organogram should be approved in writing by the healthcare facility's management and is revised periodically, as the requirement arises.

6.9. There shall be a policy, procedures and/or work instructions governing pharmacy functions (e.g., administrative, operational, and clinical role of pharmacy services), and all pharmacy personnel shall follow these policies and procedures. Each organization may have its policy and procedure depending upon its size, structure, scope and clinical function e.g. each private/public hospital/ medical center will develop the policy keeping in view their structure/scope. However, the same policy can be developed by the concerned provincial government for all the public hospitals uniformly. A list of some important

pharmacy's operational, administrative, and clinical policy/procedure titles is given in the annexure for easy reference (Annexure-IV).

6.10. The policy and procedure shall be reviewed and approved by the head of pharmacy along with a designated medical staff committee e.g., Pharmacy & Therapeutics Committee/Drug & Therapeutics Committee (P&TC/D&TC) (where indicated), for the safe and effective medication use involving a multidisciplinary, coordinated effort of health care practitioners. All involved should apply the principles of process design, implementation, and improvement to all aspects of the medication management process such as product selection, procuring, storing, ordering/prescribing, transcribing, distributing, preparing, dispensing, administering, documenting, and monitoring of medications. Any potential or real conflicts, safety concerns or problems related to any of these stages must be analyzed and resolved in a timely and professional manner. Policies and procedures are revised as necessary to reflect changes in procedures, organization, objectives, or practices.

6.11. The pharmacy policy and procedures shall be easily accessible to staff and should be clearly communicated to pharmacy department personnel as well as other relevant healthcare staff of the healthcare facility.

6.12. Appropriate mechanisms to ensure compliance with the policies and procedures should be established. Internal audit mechanisms and quality management standards against set procedures are appropriate mechanisms to ensure compliance.

6.13. Adequate hours of operation for the provision of needed pharmacy services shall be maintained; 24-hour/7-days a week (24/7) pharmacy service is a desired practice and should be provided when possible with adequate resources. Healthcare facilities with >50 beds should establish 24/7 pharmacy services in the best interest of the patients

6.14. Efforts are made so that in addition to 24/7 pharmacy services, clinical pharmacy service is also available, especially in healthcare facilities that have high-risk medication therapy management (e.g., critical or intensive care units, oncology service, transplant programs, critical/complex surgeries, neonatal, pediatric wards, and/or 24hrs emergency/trauma centers etc.).

6.15. When 24/7 pharmacy services are not possible, a pharmacist shall be available on an on-call basis. (contact information should be communicated to the above-mentioned essential medical units)

6.16. In the absence of 24/7 pharmacy services, access to a limited supply of necessary medications shall only be available to authorized, licensed healthcare professionals (e.g. a Registered Nurse) in carrying out urgent medication orders.

6.17. After-hours access and storage of medications shall be carefully managed and documented by the nursing department. Pharmacy has an oversight of this process so that the safety, security and appropriate use of medicines is ensured even after official pharmacy working hours.

6.18. All medications stored outside the pharmacy shall be protected from loss and theft and shall be stored under optimum storage conditions (as per the manufacturer-recommended conditions of temperature and humidity limits etc.), under authorized access. Examples of medications stored outside the pharmacy include medicines stocked in warehouses or distribution stores, inpatient wards, operating rooms, ambulances, diagnostic & interventional suites (e.g. cardiac cath lab, endoscopy, etc.), emergency wards or clinics etc.

6.19. Pharmacy has oversight/supervision of the entire therapeutic goods' storage locations within a healthcare facility, to ensure their safety, security and proper use.

6.20. Routine after-hours access to the pharmacy by non-pharmacists for access to medications is not recommended. (As per the healthcare facility's policy)

6.21. The pharmacy shall establish, policies and procedures, in line with the emergency plan of the healthcare facility, for the safe and orderly evacuation of pharmacy personnel in the event of an emergency in the healthcare facility (Annexure-IV)

6.22. The pharmacy shall participate in the healthcare facility's decisions about the contents, placements and use of crash cart trolleys, emergency medication supplies, kits and trays and floor stock. The pharmacist shall facilitate in development of these requirements and provide information as per hospital formulary and/or international best practices.

6.23. Each pharmacy shall have contingency plans for medicine shortages and emergencies (e.g. natural or man-made disasters).

6.24. The pharmacy shall participate in the development of policies and procedures concerning preventive and post-exposure immunization programs for patients and employees of the healthcare facility in line with infection control or other similar policies.

6.24.1 The pharmacy shall participate in the development & implementation of policies and procedures concerning medications such as process and formats for medication prescription/orders, taking medication history, medication administration record, and orders at the time of admission and discharge, signing offs or handover between shifts (or at the transitions of care) etc.

6.24.2 Medication use protocols, guidelines, pathways

6.24.3 Patient assessment parameters required to correctly order, dispense or administer a medicine (such as patient demographics, diagnostic tests (e.g. Serum creatinine, electrolytes, blood cultures, etc.), diagnosis, drug and food allergies, etc.)

6.24.4 Restricted Prescribing: When only certain specialties or physicians are authorized to prescribe a medicine. e.g. Tigecycline (An antibiotic of reserve category as per WHO) can be ordered by only an Infectious disease physician. (*Please refer to Guidelines on Management of High-Alert Medication https://www.dra.gov.pk/wp-content/uploads/2022/09/GMHAM-Final-Edition-01.pdf)*

6.24.5 Medication reconciliation process (at least at the time of admission and discharge). Pharmacists should be involved in tallying the previous and current medication orders to avoid any medication errors.

7. STANDARD-II FACILITIES

7.1. Adequate infrastructure, space, equipment, lighting, ventilation, and supplies shall be available for all professional and administrative functions relating to pharmacy services in line with the applicable laws and regulations.

7.2. There shall be suitable facilities and equipment to enable the receipt, storage, and preparation of medications under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, dispensing, and security to ensure medication integrity and personnel safety throughout the healthcare facility. Each healthcare facility should have its own procurement process and medicine list/formulary as per the need and scope of service.

7.3. Biological / medicine and vaccine refrigerators should be available in Pharmacy.

Thermolabile products shall be stored in pharmacy-specific refrigerators (that maintain 2-8^{0}C). (The biological/medicine/vaccine fridges are types of pharmacy refrigerators).

7.4. The pharmacy facility's temperature and humidity controls should be independent of the rest of the healthcare facility so that uninterrupted, uniform conditions are maintained for medication storage areas. Changes in the healthcare facility's environment should not affect the pharmacy and rest of the medication storage areas' temperature and humidity controls e.g., when AC is shut down in off-hours in some parts of the healthcare facility or when heating is turned on in winter for patient care areas.

7.4.1 Ambient/Room Temperature for medicines storage: 20-25^{0}C

7.4.2 Humidity limit for medicine storage: up to 65 % (Zone IVA of International Conference on Harmonization).

Temperature and humidity of the medication storage location are monitored regularly and record is properly maintained

7.5. Medicines requiring light protection:

7.5.1 These should be placed in their original cartons, or opaque bins/boxes/containers when stored in the shelf.

7.5.2 At the time of dispensing, amber-colored containers, plastic bags or overwraps can be used

7.5.3 During administration where indicated, such as for prolonged infusions, the IV bags can be covered with amber-colored overwraps, while the syringe and the tubings can be covered with aluminum foil or suitable alternate

7.6. There shall be suitable facilities to enable the compounding, preparation, and labeling of sterile and non-sterile products as per relevant standards (consult USP 797 (sterile preparation), USP 800 (chemotherapy /hazardous drugs) and USP 795 (non-sterile compounding) standards for guidance purpose). Equipment and facilities should ensure that medicines are prepared correctly, with the required level of sterility and quality.

7.7. Hazardous drug products are prepared in designated areas (such as chemotherapy admixture service), with necessary equipment and facilities according to applicable standards, and by trained and competent staff. Equipment and facilities should ensure that hazardous medicines are prepared correctly, with the required level of sterility and quality, and exposure to staff and patients/visitors is prevented.

7.8. Compounding and I.V admixture facilities shall be segregated from routine dispensing & medicines storage areas

7.9. Pharmacy equipment (e.g. clean bench, electronic tablet counters, temperature and humidity monitoring devices, label printers, computers etc.) shall be adequately maintained and certified (validated and calibrated) following applicable standards, laws, and regulations. There shall be documentation of periodic (annual and biannual, depending upon equipment) maintenance and certification of equipment. The maintenance and calibration/validation of equipment is usually done by the facility management division of the l or is outsourced to 3rd party and this should be included in the internal audit checklist to ensure compliance.

7.10. In outpatient pharmacy settings, a private area for pharmacist-patient consultations should be designated to provide detailed medicine education and counseling to patients in a confidential manner. Patient Educational material can also be prepared and displayed for quick reference and guidance.

7.11. A comprehensive Hospital Management Information System (HMIS; sometimes also referred to as Hospital Information Management System) shall be employed and should be fully integrated with other systems and software, including computerized provider order entry, medication administration, electronic health records, patient billing systems, inventory system etc.

7.12. Electronic systems such as HMIS would be beneficial for improvement in the health system and centralization of the system would add to the development of health databases (such as patient information database with medication and medical history) this would aid in developing and improvement in pharmacovigilance systems.

7.13. In healthcare facilities, where HMIS has not been implemented, pharmacists' access to the required/necessary information (such as patient medical records, history, progress notes, physician orders, diagnostics/lab tests, etc.) is provided. A healthcare facility should establish a proper workflow of medication ordering with dispensing, administration, and ultimately the billing system.

7.14. Up-to-date, prompt, drug information resources (e.g. books, online information access, software for drug information, etc.) shall be available to healthcare professionals. Who prescribe, dispense, prepare, and administer medicines. Such as access to Drug & Poison Information centers (operating within the hospital or country), current print or

electronic periodicals, newsletters, drug information software, best-practices guidelines, and recent editions of reference books, etc.

7.15. All records shall be maintained following applicable laws, regulations, and institutional policies. Moreover, the confidentiality of patient information shall be maintained according to relevant laws and regulations.

7.16. Appropriate licenses and permits shall be on display or file as required by law or regulation.

7.17. The requirements of adequate office space, infrastructure, and official meeting or training rooms/space are also required in the pharmacy department and should be fully supported by the healthcare facility management.

8. STANDARD-III SELECTION & PROCUREMENT

8.1. The Pharmacy (or Drug) and Therapeutic Committee (P&TC or D&TC) shall be established and organized in the healthcare facility, and pharmacist shall be appointed as the secretary of this committee (see sample TOR in Annexure II).

Healthcare facility may decide if a single committee would oversee selection and procurement of all therapeutic goods (primarily, pharmaceutical and surgical), or a sub-committees or separate committees are required for certain type of products (e.g. pharmaceutical and medical devices etc.). Pharmacist shall be part of all such committees (involving therapeutic goods) and is involved in their decision making process.

8.2. P&TC shall have representation of physicians from key clinical specialties, healthcare facility's leadership along with nurses, material management representation and pharmacists as core members of the committee (Annexure II).

8.3. The P&T committee's organization and authority should be outlined in the organization's medical staff by laws or medical staff rules and regulations, and other organizational policies, as appropriate.

8.4. A well-controlled hospital formulary of approved medications shall be maintained and regularly updated by the P&T committee.

8.5. The P&T committee shall be responsible for developing and maintaining written criteria for drug/therapeutic good selection, which shall address formulary requests for medications intended for use in special populations (e.g., pediatric or geriatric populations etc.) and also for deletion of drug products from the formulary (Annexure II).

8.6. The P&T committee shall be responsible for developing and maintaining adequate product specifications to aid in the:

8.6.1 Healthcare facility's medication/surgical tender process (where applicable).

8.6.2 Purchase of medications and related supplies.

8.6.3 Safe, effective, and rational use of medications and related supplies

8.7. The pharmacy shall disseminate the formulary by electronic (preferred) or other means to meet the needs of all health care professionals.

8.8. There shall be policies and procedures that address the use of special medicinal products e.g. dietary supplements, nutraceuticals, cosmeceuticals, contrast/dyes, radiopharmaceuticals, surgical devices, implants, and other alternative therapies etc.

8.9. There shall be policies and procedures for the procurement, control, and use of non-formulary medications, sample drugs, study/trial drugs and medicines that are brought in by patients, etc.

8.10. The pharmacy either directly manages or shall be an active part of the procurement, distribution, and control of all therapeutic goods used in the healthcare facility for inpatient and ambulatory patients. Policies and procedures governing these functions shall be developed by the pharmacy with input from other appropriate hospital healthcare staff and committees. In case the pharmacy is not directly involved in procurement, the concerned department shall carry out purchases as per standard protocol in compliance with applicable laws and regulations. The pharmacy shall provide technical and professional inputs in the purchase process wherever indicated and remain actively involved in the decision-making process.

8.11. Criteria for selecting drug product manufacturers and suppliers shall be established by the pharmacy (in coordination with the purchasing team) based on technical evaluation to ensure the highest quality and the best prices.

8.12. There shall be policies and procedures for managing medication acquisition. These policies and procedures should address such issues as formulary development (including initial evaluation for formulary consideration, prescribing restrictions, medication-utilization review programs, therapeutic interchange, etc.), competitive bidding, bulk purchasing, medication shortages, outsourcing, and cost-effective patient

services.

8.13. Once products are selected, there shall be an ongoing mechanism to assess the quality, safety and efficacy of the approved products as per the hospital's approved protocol. Methods may include but are not limited to post use evaluation, feedback from key users/prescribers, review of recalls, incidents, Adverse Drug Reactions (ADRs), or Adverse Drug Events (ADEs) related to these products, etc.

9. STANDARD-IV STORAGE AND INVENTORY MANAGEMENT

9.1. Medications shall be received, stored, and prepared under proper conditions of temperature, light, moisture, ventilation, required segregation, and security to ensure medication integrity and personnel safety. Proper pest and other damage control (from heat/light/moisture/mold/dust, etc.) must be in place to avoid inventory wastage.

9.2. When medications are stored in individual patient care units, ambulances, or other areas outside of the pharmacy, the hospital should perform a risk assessment to identify the conditions suitable to maintain product stability for the length of time the medications are stored outside of the pharmacy, as applicable.

9.3. Storage of medications in non-pharmacy areas (e.g., patient care and procedural areas) shall, to the extent possible, be limited to medications for emergency use and routinely used personal care items (e.g., mouthwash and antiseptic solutions). Healthcare facilities should establish a mechanism to approve a medication, allowed to be stored on floor stock (outside pharmacy).

9.4. A separate risk and need assessment should occur for every location where medication may be stocked.

9.5. All stocks of medications (within or outside the pharmacy) shall be inspected routinely to ensure the integrity of the product, safety, security or stock, absence of outdated, unusable, recalled, or mislabeled products.

9.6. Controlled substances (Narcotic drugs, Psychotropic substances and Precursor chemicals) shall be accurately accounted for according to applicable laws and regulations. The entire process is regularly audited to ensure compliance

9.7. Medications or products requiring special handling, such as radioactive medications, oncology and other similar medications or products, shall be accurately

labeled and safely stored, ordered, administered, and monitored. Investigational products shall be stored separately from approved therapeutic goods.

9.8. Medications and chemicals used to compound medications shall be accurately labeled with contents, expiration dates, and warnings (e.g. Toxic, Irritant, Corrosive etc.).

9.9. Medications must be protected from loss or theft throughout the healthcare facility as per approved protocol.

9.10. High alert medicines are stored, handled, and used in accordance with Guidelines on Management of High Alert Medication. *Link: https://www.dra.gov.pk/wp-content/uploads/2022/09/GMHAM-Final-Edition-01.pdf*

9.11. Concentrated electrolyte products (such as potassium chloride (undiluted), hypertonic saline (equals to and greater than 2% saline), and magnesium sulphate) and other high alert medicines shall be stored in a secure, segregated place with distinct labels, in accordance with Guidelines on Management of High Alert Medication.

9.12. The use of medication samples shall be eliminated to the extent possible. Medication samples shall not be used for patient treatment. If the use of samples is otherwise permitted, there shall be policies and procedures to ensure their rational and safe use. Samples shall not be charged to the patients.

9.13. Drug products and related devices brought into the healthcare facility by patients shall be discouraged. However, if allowed shall be reviewed by the pharmacy, and documented in the patient's medical record if the medications are to be used during hospitalization.

9.14. Traceability of medications from receiving in the facility till the administration should be available for ensuring effective recall and incident management. The use of technology like barcodes should be explored by healthcare organizations.

9.15. There shall be a written policy, procedure or work instructions for:

9.15.1 The timely handling and documentation of a drug product recall. Including process for identifying the exact lot/batch number, immediate removal of any drugs or devices subjected to a recall, quarantining the stock, notifying appropriate health care professionals or regulatory authority, identifying patients who may have been exposed to the recalled medication, returning the affected batch to the supplier, and, where required, communicating available alternative

therapies to prescribers/patients.

9.15.2 Use and disposition of expired or known to be expired products.

9.15.3 Disposition of defective products, especially of those products affected by a breach in cold chain (including how to assess the nature and extent of temperature excursion, who will assess and who will decide the fitness of use for such stock).

9.15.4 Responding to situations if substandard/spurious or falsified consignment is received.

9.15.5 The pharmacy's inventory management system should be designed to detect subminimum inventory levels and alert the pharmacy to potential shortages, and pharmacy staff should monitor reliable sources of information regarding drug product shortages.

9.15.6 There shall be a written contingency plan for the breakdown of major utilities affecting safe storage and use of therapeutic goods e.g. manmade or natural disasters, power failure (electrical/gas), water disruption, cyber-attack/electronic system crash down or breaches in cold chain etc.

10. STANDARD-V PREPARATION, LABELLING AND DISPENSING

10.1 Preparation involves:

10.1.1 Preparing/admixing the injectable medicine in its diluent, and dispensing it in a suitable administration modality e.g. syringe, IV fluid (drip), piggyback (small volume parenteral of 50-100ml etc.), elastomeric infusion pumps etc.

10.1.2 Compounding syrups, solutions, ointments, creams, enemas, capsules, eye drops, irrigation solution or other dosage forms for patient-specific use.

10.1.3 Reconstitution of powder dosage forms.

10.1.4 Admixing 2 or more ingredients in a diluent to form a 'composition' for parenteral use (e.g. electrolytes like Potassium Chloride and Magnesium Sulfate mixed with a diluent like Normal Saline).

10.1.5 Admixing ingredients along with dextrose, amino acid, and/or lipid to

make parenteral nutrition.

10.1.6 Repackaging the bulk form into smaller unit dose products, or drawing up the dose in a suitable container to cater to a patient-specific dose (e.g. prefilling syringes or drawing up a 50mg of medicine dose from its 500mg vial).

10.2 Labelling includes:

10.2.1 Labeling a product with a 'pharmacy label' to depict patient identification (Name, MR# and bed/ward), product identification (brand, generic name, strength, dosage form), dose, route of administration, quantity dispensed, date, time of dispensing.

10.2.2 Medication labels should be clear and have sufficient information to ensure safe administration, including at least 2 patient identifiers (for example patient name and medical record but not patient room), the name of the medicine, prescribed route, dose, and, where appropriate, volume and rate of administration.

10.2.3 Pasting auxiliary labels on medicine to highlight the precautions associated with that particular medicine. E.g. "do not crush", "not for injection use", "not for oral use", "High Alert Medicine", or "look-alike/sound-alike medicine" etc.

10.2.4 Labeling a prepared medicine (see part 1 above) with its date of preparation, date/time of expiry and storage/use instructions (e.g. Refrigerate or protect from light or shake well before use etc.

10.2.5 Pharmacists, in collaboration with medical and nursing staff, shall develop policies and procedures based on demonstrated best practices for ensuring the optimization of medication therapy.

10.2.6 All prescriptions shall be reviewed, interpreted, and validated by a pharmacist before the medicines being dispensed and administered.

10.2.7 Pharmacists should review all orders for appropriateness (i.e. selection of drug as per indication, dose, route, frequency, duration, duplication, interactions, potential allergies, contraindications, etc.). If problems are identified, pharmacists shall communicate with the prescriber to resolve the issue and then dispense the medicine. Healthcare facility allows the

pharmacists to document the pharmaceutical care notes and intervention to rectify the medication orders in patient medical record at a designated location.

10.2.8 At tertiary or specialty healthcare level, pharmacists are also engaged in medication therapy management or collaborative drug therapy management in the development of pharmaceutical care plans, immunization and administration schedules, and other patient care activities, to the extent permitted by law, regulation, and healthcare facility's requirements.

10.2.9 Drug formulations, dosage forms, strengths, and packaging that are not available commercially but are needed for patient care shall be prepared/compounded by appropriately trained pharmacy personnel in accordance with applicable practice standards and regulations.

10.2.10 Written master formulas and batch records (including product test results, as appropriate) shall be maintained, and a lot number or other method to identify each finished product with its production and control history shall be assigned to each batch.

10.2.11 All sterile medications shall be prepared and labeled in a suitable environment by appropriately trained personnel in accordance with established quality standards. When performed, it should be done by trained staff

10.2.12 Sterile compounding outside the pharmacy or satellite pharmacies (e.g., by nursing staff on nursing units) should be minimized and occur only in emergencies. If to be done, these staff should be properly trained in sterile compounding procedures and techniques, to avoid any contamination and errors in the drug preparation.

10.2.13 There shall be policies and procedures that describe special precautions, equipment, and training for the preparation, handling, storage, and disposal of hazardous drug products and products used in their preparation including cytotoxic medicines.

10.2.14 Pharmacists should ensure that medicines are packed and appropriately labeled (drug product details and patient identification) and to maintain

integrity before administration to the individual patient.

10.2.15 Whenever possible, medications should be available for inpatient use in single-unit packages and a ready-to-administer dosage form possible. Manipulation of medications before administration (e.g., withdrawal of doses from containers, reconstitution of powdered drug products, labeling of containers, and splitting of tablets) by final users should be discouraged.

11. STANDARD-VI MEDICATION ADMINISTRATION

11.1. Only personnel who are authorized by the healthcare facility in accordance with applicable laws and regulations and appropriately trained shall be permitted to administer medications to a patient.

11.2. Medication administration timings are standardized across the healthcare facility and dispensing of due doses is according to standard administration timings. (e.g. Once daily; QD or OD may mean 10 AM). Pharmacy should be actively involved in the hospital's decision to standardize these timings.

11.3. Medications must be administered in a timely manner. All administered, refused, or omitted medication doses should be recorded in the patient's medical record as per the established procedure. Medicines not administered are recorded/documented with proper reason including the medicine hold or discontinued by the physician**.** Pharmacy has access to this information.

11.4. No medication should be administered to a patient unless medical and nursing personnel have adequate information about medicine, and are familiar with its therapeutic use, method of administration, potential adverse effects, and dosage. Hospital pharmacy helps healthcare facility in developing these guidelines or protocols and shall ensure that such information is readily available to healthcare staff.

11.5. No medication shall be administered without a physician order.

11.6. Unused intact medicines (that are not administered) shall be promptly removed from patient care areas and returned to the pharmacy (or to the floor stock, as applicable) as early as possible.

11.7. Leftover/used medicines shall be discarded promptly as per the defined policy and procedure of the healthcare facility. Pharmacy shall develop a healthcare facility wide waste

disposal process for general pharmaceuticals and hazardous products such as cytotoxic or chemotherapeutic agents

11.8. Before administration chemotherapy and other high alert medicines should be checked against the original prescription independently, by at least two individual nursing staff. Aim is to ensure correct patient, drug, dose, route, timing/frequency, rate and dilution etc. at the time of administration

11.9. At the time of discharge, patient shall be educated and counseled about the proper use of medications written in discharge orders.

12. STANDARD-VII MONITORING OF MEDICINE USE

12.1. An easily accessible reporting system for defective medicines, adverse drug reactions (ADRs), medication errors, and near-misses shall be established and maintained in the healthcare facility. Reports of such ADRs/errors/near misses should be reviewed internally by the pharmacy and relevant committee (e.g. P&TC) and also reported to provincial or regional pharmacovigilance center (PV) (refer to National PV Guidelines 2022 available on the official website of DRAP; link https://www.dra.gov.pk/wp-content/uploads/2022/10/NPVG-guidelines-reviewed-final-11-10-2022.pdf). The data should be regularly reviewed to improve the quality and safety of medicine use practices at the institutional level and shared with the Provincial and National centers for acknowledgement and improvement of the healthcare delivery.

12.2. The medicines use process should be reviewed through an external accreditation or quality improvement programs (e.g. Healthcare Commission, Regulatory Authorities, etc.). Healthcare facility should act on reports learn from incidents and preventable events with risk minimization measures and education/learning measures to improve the quality and safety of their practices.

12.3. Pharmacists' clinically relevant activities (like Drug Utilization Evaluation (DUE), Drug Utilization Review (DUR), Therapeutic Drug Monitoring (TDM), patient medication review, identification of drug related problem and writing pharmaceutical care notes etc.) should be documented, collated and analyzed to improve the quality and safety of medicine use and patient outcomes. Activities that significantly impact individual patient care should be documented in the patient record.

13. STANDARD-VIII EVALUATING THE EFFECTIVENESS OF THE MEDICATION USE SYSTEM

13.1. The pharmacy shall have an ongoing, systematic program for periodic quality assessment and improvement of pharmacy services and the medication-use system.

13.2. The pharmacy shall develop and monitor the departmental key performance indicators (KPI) to ensure the ongoing provision of services at a satisfactory level. Selected KPIs shall converge into the healthcare facility's quality improvement and patient safety program (as applicable). Examples of some pharmacy KPIs may include:

13.2.1 Number (or %) of dispensing errors (total # of dispensing errors/total number of orders dispensed) x 100

13.2.2 Timely dispensing (dispensing turnaround time) – (total # of orders dispensed in defined time/total number of orders dispensed) x 100

13.2.3 Number (or %) of pharmacists' interventions documented – (total # of pharmacist interventions documented / total number of orders dispensed) x 100

13.2.4 Percent value of expired/wasted inventory or inventory variations (shortage/excess)

13.2.5 % of patients educated/counseled, patient medication profiles reviewed, medication reconciliations performed, etc.

13.2.6 Intervention acceptance rate % (Number of intervention accepted)/(Total number of intervention) x 100.

13.2.7 Formulary Compliance [(# of Formulary item − # of Non-formulary items)/ (total # of Formulary items)] x 100.

13.2.8 Clinical Pharmacist ward round, target ≥95% (Total number of rounds done by Clinical Pharmacist)/(Total Number of rounds scheduled) x 100

13.2.9 IV to Oral route Switching, target ≥95% (Total number of orders switched to oral)/(Total Number of orders meeting switch criteria) x 100

13.2.10 Crash cart, Medication, trolley listed goods Compliance, target 100% (Number of crash cart items available at time of audit)/ (Total approved

number of crash cart items) x 100

13.3. The pharmacy shall have an ongoing process for consistent documentation of the patient care services provided by pharmacists. This data is used by the healthcare facility in process improvement and development of medication management and use related policies and protocols.

13.4. There shall be an ongoing program for monitoring drug utilization and pharmacoeconomics to ensure that medications are used appropriately, safely and effectively and to increase the probability of desired patient outcomes.

13.5. There shall be an ongoing healthcare facility-based program for antimicrobial stewardship and Infection Prevention and Control including at least one pharmacist as an active member. They participate in promoting the optimal use of antimicrobial agents, reducing the transmission of infections, reducing the rate of Healthcare-Associated Infections (HAIs), and educating healthcare professionals, patients and the public about these topics.

14. STANDARD-IX HUMAN RESOURCES, TRAINING AND DEVELOPMENT

14.1. Pharmacy workforce plans should describe strategies for human resource education and training, recruitment and retention, competency development, remuneration, and career progression pathways, diversity-sensitive policies, equitable deployment and distribution, and roles and responsibilities of stakeholders for implementation.

14.2. All new pharmacy staff shall receive adequate orientation and training before work is assigned. All training and education records should be documented.

14.3. All pharmacy staff shall be trained in the basics of medication management & use standards, high-alert medicines, applicable organizational policies and procedures, and laws and regulations.

14.4. All pharmacy staff shall be provided with written job descriptions.

14.5. All pharmacy staff shall receive ongoing in-service training, capacity building, and continuous professional development as identified, managed, or arranged by the pharmacy department.

14.6. There shall be a mechanism for baseline and periodic competency assessment of pharmacy staff.

14.7. The appraisal/performance evaluation of pharmacy staff is carried out and documented at a regular interval. The same may be used as a source for future training recommendations.

14.8. Pharmacists shall maintain the registration of their respective pharmacy council updated and keep the registration current and valid.

14.9. The pharmacist shall maintain the validity of their clinical/pharmacy practice-related professional certification (national or international) current and valid at all times. Healthcare facilities shall facilitate and foster the environment of continuous professional education.

14.10. Procedures can be put in place for encouraging good performance and improving poor performance. Pharmacy staff with consistent breach of standards/policies, and reckless or at-risk behavior shall be dealt with as per healthcare facility's policy.

14.11. Pharmacy staff with consistently good performance, exemplary conduct, and professionalism shall be formally appreciated as per healthcare facility's policy.

14.12. Pharmacy staff shall be actively engaged in a review of the trends of the department's KPIs, discussion on the challenges, their opinion in resolving issues are sought and their role is integrated with the healthcare facility's mission and vision.

14.13. The training programs of pharmacy support staff should be formalized.

14.14. Pharmacists should provide orientation, drug information, and education to nurses, physicians, and other healthcare facility staff regarding best practices for medicine use. This education or these sessions can be planned on the basis of weak areas of medication use system through evaluation of performance and identification of errors and events. These can also be planned on the basis of any new researches, emergency issues and current global challenges regarding patient safety.

14.15. Pharmacists should actively engage in research into new methods and systems to improve the use of medicines and human resource needs in hospital pharmacies.

14.16. Pharmacists should be trained and maintain the certificate for BLS (Basic Life Supports, especially American Heart Association - AHA approved) with certification and its maintenance thereof.

15. REFERENCES:

1. The DRAP Act 2012.
2. The Pharmacy Act 1967.
3. DRAP's Guidelines on Management of High Alert Medication.
4. DRAP's Guidelines on National Pharmacovigilance System.
5. Guide to Good Storage Practices for Pharmaceuticals; WHO Technical Report Series, No. 908, 2003.
6. Joint Commission International. n.d. JCI Accreditation Standards for Hospitals, 7th Edition | Joint Commission International.
7. Minimum Standards for Pharmacies in Hospitals (Ashp.org.) n.d. ASHP.

   https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/minimum-standard-pharmacies-hospitals.pdf
8. Basel Statements: The future of hospital pharmacy practice by International Pharmaceutical Federation (FIP)

   https://www.fip.org/basel-statements
9. Definition of Medication Therapy Management

   https://www.aphafoundation.org/medication-therapy-management
10. Definition of Collaborative Drug Therapy Management.

    https://hdsbpc.cdc.gov/s/article/Pharmacists-Collaborative-Drug-Therapy-Management#:~:text=Collaborative%20drug%20therapy%20management%20(CDTM,collaborative%20practice%20agreement%20(CPA).

ACKNOWLEDGMENT

DRAP acknowledges the contribution of Pakistan Society of Health System Pharmacists especially Ms. Aasma Hamid Director Pharmacy, Dow University of Health Sciences Karachi, Ms. Qurat ul Ain Tausif, Deputy Manager Quality Assurance, Department of Pharmacy, Liaquat National Hospital, Karachi and Ms. Salwa Ahsan, Chief of Pharmacy, Shifa International Hospitals Ltd. for their contribution in the preparation of these guidelines.

Annexure-I

SELF-ASSESSMENT CHECKLIST

S#	Points	Yes	No	Comment
1.	a. Pharmacy has a valid and relevant* drug sale license (DSL) (e.g. compounding, narcotic etc.)			
	b. Head of pharmacy services is a qualified pharmacist			
	c. Pharmacists and other pharmacy staff (e.g. assistants, technicians, aids etc.) are the fulltime employees of the hospital			
	d. All pharmacists have their valid/renewed Pharmacy council registration (license)			
	e. Attendance record of qualified person is maintained regularly			
	f. All staff are provided with their current job descriptions (JDs)			
2.	a. Scope of pharmacy services is defined and written down			
	b. Scope of pharmacy services is periodically revised as per defined frequency			
	c. Pharmacy/hospital maintains a policy and procedure manual pertaining to key operations, procedures and work instructions of the pharmacy services			
	d. Pharmacy/hospital maintains a policy and procedure manual pertaining to the medication use processes and systems across the hospital			
	e. Staff safety plan is developed for pharmacy service (e.g. related to man-made or natural disasters, chemicals and hazardous drugs etc.)			
	f. A contingency plan is available for smooth medication supplies during disasters and/or during critical medicine shortages			
	g. Only /genuine medicines and supplies are stocked and dispensed (*registered or enlisted)			
	h. Pharmacy maintains department organogram which is recent			
	i. All staff depicted in organogram have updated job descriptions (JDs) and competency list (as			

	applicable)			
	j. Pharmacy Key performance indicators (KPIs) are listed and tracked on regular basis			
3.	a. Pharmacy has adequate infrastructure to meet legal and operational requirements for the procurement of therapeutic goods, safe and accurate storage, medication order review, preparation and dispensing, safe and accurate use, adverse event reporting and recall system			
	b. Infrastructure supports the maintenance of temperature and humidity where therapeutic goods are stored (both within pharmacy as well as outside pharmacy such as nursing units, OR, clinic etc.)			
	c. Temperature (room, fridge) and humidity (room) is documented at least once per shift (all storage areas across the hospital) The record is maintained			
	d. Staff is aware about the actions or SOP to be followed if temperature and humidity is out of range for a substantial period of time			
	e. Medicines requiring cold chain (2-80C) are adequately monitored across the hospital to avoid temperature excursions			
	f. Actions are taken and documented as per hospital protocol when excursions are observed			
	g. Proper infrastructure, equipment and systems are in place for specialized pharmacy services such as sterile or non-sterile compounding and chemo admixture etc.			
	h. All the equipment used in the pharmacy/hospital undergo periodic preventive maintenance (PPM), calibration and validation (as applicable)			
4.	a. Pharmacy & Therapeutics Committee – P&TC and Tender /Purchase committee is established in the hospital			
	b. Pharmacists have a proper representation in the P&TC according to the membership requirements stated (or equivalent committee) in addition to physician and nurse representation			
	c. Terms of References (ToRs) of the committee are defined, in line with those given in this document and address all basic roles			

	d. P&TC (or equivalent committee) meets on regular basis			
	e. Pharmacy/hospital maintains a current list of available medicines in the hospital (Hospital Formulary)			
5.	a. Pharmacy services are available 24/7			
	b. If Pharmacy services are not available 24/7, then medicines are provided to the nursing units for off-hours use also assuring round the clock essential and emergency services.			
	c. SOPs are defined for the medicines' security, safety, use and replenishment at the nursing units during off-hours use (when pharmacy is closed)			
	d. There is pharmacy oversight on the medicines stored in patient care areas (outside pharmacy) and such stocks are regularly checked for quantity in hand, expiry, lot #, compliance to storage parameters and security conditions etc.			
	e. Medicines are kept in authorized access only (all storage areas across the hospital)			
	f. Medicines are protected from theft and loss in all storage areas across the hospital			
	g. All incoming (purchased, stock in hand, donations etc.) and outgoing supplies (dispensed, returned, disposed etc.) are recorded and reconciled			
	h. Medicines are periodically counted and accounted for in all storage areas to ensure safety and security of the stocks			
	i. Expiry of medicines is periodically checked in all storage areas across the hospital to avoid use of expired medicines and wastage			
	j. Pharmacy inspection is documented			
6.	a. Traceability of medications from the point of receiving in the hospital till the administration, is possible (for the effective drug recall)			
	b. All medicines and chemicals used in pharmacy are properly labelled as per standards in the document			
	c. Controlled drugs are stored securely, with required documentation and are regularly accounted for			
	d. Issuance, ordering, use, wastage and purchase record of controlled drugs is maintained as per law			
	e. Staff, handling chemicals and hazardous/chemo drugs, is aware about personal protective equipment (PPEs), Material Safety Data Sheet (MSDS) and spill management			
7.	a. There is a collaborative mechanism to develop and approve the list of medicines that will be			

	available in-patient care areas, outside pharmacy (i.e. on nursing units par level / floor stocks, emergency supplies like crash carts, Anesthesia or CPR trolleys etc.)			
	b. Pharmacists, nurses and physicians are part of the collaborative process (as per point above)			
	c. The emergency supplies like crash carts or CPR trolleys etc. are standardized to have uniform content and placement across the hospital			
	d. Pharmacists, nurses and physicians are part of the emergency supplies standardization (as per point above)			
8.	a. Medicine orders/prescription are reviewed for appropriateness by a pharmacist before administration. All orders including those medicines used from floor stock, medicines used in operating rooms, interventional suites (like radiology, cath lab etc.) and during code blue/CPR) Except for those as described above			
	b. Pharmacists are trained in performing appropriateness review. Minimum contents of appropriateness review are defined by the pharmacy/hospital, such as: i. Appropriateness of drug, dose, route, frequency and duration of therapy ii. Contraindications (related to patient's diagnosis, co-morbidity, concurrent drugs i.e. drug interactions, and any known drug or food allergies etc.) iii. Variation from the organization's criteria for use or policy iv. Patient's weight and other physiological information			
	c. If any problem is identified in the order, pharmacists discuss with the prescriber and rectify them before dispensing.			
	d. These corrections (interventions) are documented			
	e. Medicines are only dispensed against a proper physician's order/requisition			
	f. Medication administration timings are standardized across the hospital, and mutually approved by a group (e.g. P&TC) comprising of pharmacists, nurses and physicians e.g. i. TID means three times a day (6am, 2pm, 10pm) ii. BID or BD means two times a day (10am and 10pm)			
	g. Minimum contents of a prescription are identified and are standardized across the hospital. E.g. i. Patient identification (name and medical record #) ii. Patient information (age, gender, weight, diagnosis, drug allergy)			

	iii. Medicine order (drug name, dose, route, frequency, duration and special instructions if any) iv. Prescriber's identification v. Date / prescription validity			
9.	a. Hospital-specific list of high alert medicines (HAMs) is available and is in line with DRAP's High risk medicines list and guidelines			
	b. HAMs are known to all healthcare staff (physicians, nurses, allied health and pharmacists)			
	c. A hospital-wide policy on safe use and handling of high alert medicines is available			
	d. The policy is periodically revised			
	e. Pharmacy provides pre-diluted, ready-to-use forms of concentrated electrolytes listed on the national HAMs list			
	f. Pharmacy has an SOP to store and dispense Look-Alike, Sound-Alike (LASA) and Read-Alike drugs (LASARA)			
10.	a. Drug information resources (such as books, pocket guides, charts, flyers, posters, software, or a helpline etc.) are available across the hospital for the physicians, nurses and pharmacists, to easily check the medicines related information when in doubt			
11	a. Pharmacy Staff orientation and training program (both for pharmacists and non-pharmacist staff) is available • At the time of induction • Ongoing In-service education & training • Special training on need basis			
	b. Pharmacy staff competency assessment is conducted before placing them in the area of work and periodically at the specified intervals			
	c. Performance evaluation of pharmacy staff is conducted at a specified interval and is documented			
12	a. There is a hospital based program of reporting, analyzing and mitigating the adverse drug events (ADEs) i.e. medication errors and near misses			
	b. Pharmacy is involved in the process mentioned above.			
	c. Pharmacy maintains a record of all dispensing errors and near miss			
	d. Corrective and preventive actions are taken on these errors/near miss			

	e. There is a hospital-based program of reporting, analyzing and mitigating the adverse drug reactions (ADRs) as per the Pharmacovigilance Rules 2022. Further details also available in the Guidelines on National Pharmacovigilance System accessible through dra.gov.pk)			
	f. Pharmacy/Hospital has a well-defined process of product recall			
	g. Recalls are timely and documented			

Annexure-II

Pharmacy (or Drug) & Therapeutic Committee (P&TC or D&TC)

Terms of Reference

1.0 Committee Mandate
2.0 Detailed Objectives
3.0 Membership
4.0 Reporting relationship
5.0 Meeting Schedule
6.0 Antimicrobial Stewardship Subcommittee
7.0 Immunization Subcommittee

1.0 Committee Mandate:

The Pharmacy and Therapeutic Committee is an advisory group composed chiefly of physicians, pharmacists, nurses, and representatives from various departments of the hospital. The committee serves as the organizational line of communication between the Medical Staff and the Pharmacy Department. The committee is a policy recommending body to the medical staff and to hospital administration on all matters related to the therapeutic use of drugs within the hospital and its clinics. The committee members are proposed by the respective Chair/ Director and approved by the Hospital administrative/advisory Committee.

2.0 Detailed Objectives:

The primary purposes of the Pharmacy and Therapeutic Committee are:

Administrative:

The committee establishes administrative policies regarding evaluation, procurement, distribution, use safe practices and other matters pertinent to drugs in the hospital and clinics and offsite clinics. The Committee oversees the overall Medication Usage system within the organization.

Educational:

The committee recommends and assists in the formulation of programs designed to meet the needs of the professional staff (doctors, pharmacists and nurses) for complete current knowledge on matters related to drugs and drug prescribing practices.

Advisory:

The committee serves in an advisory capacity to the medical staff and other groups in the establishment of broad policies relating to drug usage in patient care and hospital procedures.

Functions of the Committee:

- To develop and approve a Drug Formulary for the hospital and provide for its continual revision and update
- To evaluate suggestions of drugs/agents proposed for addition to/deletion from the hospital formulary on generic basis.
- To minimize duplication of the same basic drug type &to recommend additions and deletions (removal of drug (s) in the pharmacy inventory.
- To make and/or consider recommendations concerning drugs to be stocked in hospital patient units or services.

- To study problems related to the distribution and administration of medication.
- To recommend policies regarding the safe use of drugs in the hospital, including investigational drugs and hazardous drugs.
- The scope of the functions is limited to formulary? Either the title be changed from functions to management of formulary. Otherwise scope of functions be extended.

3.0 Membership:

The P&T Committee membership consists of representatives from Medicine, Surgery, Pediatrics and other clinical services, Pharmacy, Hospital Administration and Nursing Services.

Chairperson & co-chair will be appointed among the physician representatives by the Hospital In charge (MS, CEO etc.) with Hospital Administrative/Advisory Committee approval. Pharmacist (either Head of Pharmacy or his/her designee) shall be the Secretary of the Committee. S/he will be responsible to arrange meetings on the scheduled time, for collation and presentation of agenda points and follow/up on arising matters.

The Pharmacy and Therapeutic Committee will utilize the clinical experts, as appropriate, to consider specific changes, additions and deletions to the formulary.

Members Representation (suggested):

- Anesthesiology
- Internal Medicine
- Surgery
- Obs/Gynecology
- Emergency Medicine
- Family Medicine
- Pediatrics
- Oncology
- Pharmacy
- Nursing Services
- Representative from intensive/critical care unit
- Representative from internal quality audit

4.0 Reporting Relationship:

Recommendations and minutes of the Pharmacy and Therapeutic Committee shall be forwarded to the Committee of the Hospital for their review and acceptance.

5.0 Meeting Schedule:

The P&T Committee should meet at defined interval, ideally every month or as necessary. Goals and objectives for coming year will be discussed in the December meeting. In the January meeting the previous year's performance will be discussed for submission. Some of the regular/standing agenda of P & TC include: medication errors/near miss reports, Adverse Drug Reaction (ADR) reports, medication safety alerts, recalls, shortages and formulary addition/deletion reviews.

6.0 Antimicrobial Stewardship Subcommittee:

This is subcommittee of P & TC that is overseeing the antimicrobial usage, rational prescribing and safety of antimicrobial usage in the organization. It assists P & TC in devising safety and medication use related policies specifically related to antimicrobials. Another important mandate of the subcommittee is to revise and

publish the Antimicrobial Guidelines to facilitate staff education, knowledge on safe and rational usage.

- The subcommittee meets every month or more frequently as needed. The main agenda items of this subcommittee include: Drug Utilization Evaluation, Antimicrobial formulary addition/deletion review, Adverse Drug Reaction (ADR) review pertaining to antimicrobials and reports on qualitative or quantitative use of antimicrobials etc.
- Minutes of this subcommittee is presented to P & TC for review and approval.
- The member representatives of this subcommittee include:
    - Internal Medicine
    - Emergency medicine
    - Critical Care
    - Oncology
    - Infection Disease
    - Surgery
    - Pediatrics
    - Laboratory (Microbiology)
    - Pharmacy
    - Nursing Services

7.0 Immunization Subcommittee:

This is subcommittee of P & TC that is overseeing the vaccines and immunoglobulin usage, rational prescribing and importance of infection preventive strategies in the organization. It assists P & TC in devising safety and medication use related policies specifically related to vaccines. Another important mandate of the subcommittee is to keep updated formulary of vaccine and immunoglobulin with approved backup products in case of shortage or dry periods.

The subcommittee meets every quarter or more frequently as needed. The scope of the subcommittee may include discussion on the following:

- Vaccine formulary management, ADR review pertaining to vaccines etc.
- Collaborating with EPI (Extended Program for Immunization) for essential vaccines administration and record keeping
- Minutes of this subcommittee is presented to P & TC for review and approval.

- The member representatives of this subcommittee include:
- Infectious disease
- Infection control
- Nursing services
- Pharmacy

Annexure-III

SAMPLE JOB DESCRIPTION

Job Identification

Document No:	**XX**
Designation	**Chief of Pharmacy / Director Pharmacy / Head of Pharmacy etc. (as applicable)**
Category	Management Staff
Reports to	Chief Operating Officer / Medical Director etc. (as applicable)
Department	Pharmacy

Job Specification

Qualification	**Basic**: Bachelor in Pharmacy or Doctor of Pharmacy from a recognized institute Master's degree (or above) relevant to the hospital & clinical pharmacy practice, healthcare management shall be preferred.

Skills:

- Excellent interpersonal, communication and presentation skills.
- Leadership and team-building skills
- Strong analytical & critical reasoning skills.
- Good financial and business acumen.
- Ability of multi-tasking and time management (meeting deadlines under pressure).
- Ability to work independently, exercise creativity, be attentive to detail, and maintain a positive attitude.
- Excellent negotiating and influencing skills.
- Computer skills including the use of MS Office (Word/Excel/ PowerPoint), online meeting and webinar forums (e.g. Zoom, Google Meet, Microsoft Teams etc.)

Knowledge:

- Sound clinical and professional pharmacy knowledge
- Demonstrate understanding and commitment to equality and diversity principles.
- Good knowledge of key health policies, development goals and local bylaws/regulation.
- Knowledge of applicable governmental regulations and compliance requirements.
- A good understanding of international best practices and about some accrediting bodies such as Joint Commission International's or ISO Standards.
- Excellent understanding of Financial, human resources and facility management as it relates to the delivery of health care services.
- Knowledge of Principles of professional pharmacy practice that optimizes patient care.
- Knowledgeable about Healthcare informatics/technology and health information management systems (HMIS) and pharmaceutical supply chain

Personal Attributes:

- Dynamic, passionate, open, participative, and supportive leadership style.
- Exhibits energy, enthusiasm, and resilience to drive through and achieve end results.
- Evidence of innovation and creative strategic thinking ability.
- Ability to manage conflicting priorities, work under pressure, and meet deadlines.
- Demonstrate integrity and high ethical moral behavior
- Possess credibility and commitment to the corporate mission.
- Resilience and adaptability

Registration / License	Provincial Pharmacy Council of Pakistan
Experience (No. of Years)	**8-10 years**

Job Summary:

Chief of Pharmacy is responsible for the overall operational and strategic management of the Pharmacy department and provides facilitation and administrative leadership by directly supervising the functions of the Pharmacy department.

General Job Responsibilities:

1. Review, update and ensure compliance with the departmental policies and procedures and applicable rules and regulations as set by the regulatory authorities
2. Creates a safe, functional, and comfortable physical environment for patients through extensive coordination with other/concerned departments, and addresses the inefficiencies or delays in the processes (where required).
3. Develops, implements, and evaluates short and long-term goals, objectives, policies and procedures to ensure consistency with organizational goals.
4. Ensures implementation and continuous monitoring of Departmental Key Performance Indicators and objectives.
5. Handling customer complaints; patient care issues, problems, and concerns and taking corrective action where necessary.
6. Be actively involved in the organization's strategic planning regarding all components of the medication management process across the continuum of care
7. Represent and uphold medication management and use standards & medication safety principles in all the relevant forums and committees (within and outside hospital)
8. Maintain good working relationships with the external key stakeholders like manufacturers/suppliers, regulatory authorities, academia and pharmacy council etc.
9. Maintain good working relationships with the internal key stakeholders like purchase, medical & surgical specialties, doctors, nurses, allied health staff, human resources department, IT department, finance and facility management department etc.
10. Ensure processes are in place to identify risks and process to mitigate the risks (risks related to financial, legal, patient safety, staff, visitors etc.).

PHARMACY SERVICES:

1. Organizing, directing, monitoring & managing scope of pharmacy services including: Drug Distribution, electronic prescribing system, Inpatient drug distribution, Cytotoxic Drug Admixture, Intravenous Piggyback system, Total Parental Nutrition Service, compounding, clinical and specialty based pharmacy services, drug information service, Ambulatory Care pharmacy, Emergency pharmacy, pharmacy home care services and others as applicable
2. Organize, develop and manage pharmacy services as per the best practices and Minimum Standards of the Hospital Pharmacy Service (approved by DRAP)
3. Actively work to improve the safety of High Alert Medicines in the organization as per the National High Alert Medicines Guidelines Pakistan (approved by DRAP)
4. Actively work to develop and implement Pharmacovigilance (PV) system in the organization as per the National PV Rules (approved by DRAP)
5. To work in multidisciplinary teams of physicians, nursing and other healthcare professionals and patients to ensure medication safety, compliance to hospital-approved medication use criteria/policies/guidelines, cost-effectiveness and patient compliance and/or improve operational efficiencies.
6. Establish medication management and use in accordance with the recommendations of Pharmacy & Therapeutics Committee and manage and control the hospital formulary system.

7. Establish quality specification & selection criteria for all drugs and chemicals used in accordance with the recommendation of the P&T committee.
8. To plan, establish and oversee clinical pharmacy services and appropriateness review to ensure medicines are issued and used in a safe, timely and efficient manner and that protocols utilized are evidence-based and patient-focused.
9. To establish medication error/near miss reporting, ADR monitoring system, drug utilization evaluations and clinical audit with a focus to use data for improvement of patient safety and service improvisation.
10. Serve as a medicine expert and provide consultation and professional assistance in the development of medication- related guidelines, SOPs and protocols across the hospital
11. Development of strategic plans for the pharmacy services to ensure the services provided are progressive, responsive to internal & external demand, patient-focused, efficient and effective.
12. Ensure efficient & effective management of Inventory Control systems. Ensure availability of critical supplies
13. Develop and update staffing plans and contingency plans for pharmacy department
14. Conduct regular staff appraisals and provide feedback on their performance against the set criteria/standard and/or define job description
15. Fulfilling the organization's research and educational missions and upholding professional pharmacy practices
16. Works in close collaboration with associated college/university for the smooth rotation and training of the under and post-graduate pharmacy students (Pharm.D, MPhil)
17. Maximize the use of automation and technology to provide safe, speedy, optimal patient care.

BUDGETARY, PERFORMANCE & RESOURCE MANAGEMENT

1. In coordination with Division Managers, ensures appropriate staffing as per regulatory and hospital policies.
2. Conduct Business Variance Report analysis for the department/ section. Identify, develops, and monitor systems for improvements.
3. Maintain a high level of staff morale, team spirit and job satisfaction among members of a multidisciplinary team.
4. Provide visible and accessible site leadership creating a climate where individuals understand their roles and responsibilities and people are empowered to be effective in their roles.
5. Oversees and supports talent development of the senior team members to ensure succession planning, mentorship, and coaching within the departments resulting in efficiency & effectiveness in their respective areas.
6. Manage the budget in line to ensure the best use of resources to maximize patient care.
7. Identify and prioritize the business processes to integrate the cost-effective approach and improve productivity.
8. Determine fiscal requirements of the department and prepare budgetary recommendations.

EDUCATIONAL ACTIVITIES:

1. Ensure that all new staff in the department receives an adequate orientation and induction program, having clear understanding of their duties, responsibilities and standards of performance.
2. Directs the development and implementation of ongoing in-service training programs.
3. Provide professional and personal development opportunities for staff.
4. Development and implementation of an enhanced staff competence assessment relevant to their specialties.
5. Promote a culture where individuals and teams are encouraged to develop personal and

professional knowledge and skills.
COMMITTEE MEETINGS:
1. Conducts and/or participates in a variety of staff and committee meetings; serves on task forces as assigned. 2. Participate in various hospital Committees and relevant meetings of management (e.g. Pharmacy & Therapeutic, pharmaceutical purchase committee, IT meetings, JCIA/ISO related taskforces, Infection prevention & control, Antibiotic Stewardship committee etc.)
VARIATION OF DUTIES:
The duties and Responsibilities described above do not construe as a complete and exhaustive list. Duties and responsibilities may be amended from time to time in consultation with the employee to meet any changing conditions and service requirements.
Others:
Any additional task assigned by the CEO/COO/Medical director etc. (as applicable).

Prepared by:	**HR Representative**	
Endorsed by:	**HOD/Divisional Head**	
Approved by:	**Head HR Division**	

Annexure-IV

IMPORTANT POLICIES / PROCEDURES / WORK INSTRUCTIONS FOR HOSPITAL PHARMACY

Sample List - Specific to Healthcare facility

1.	Adverse Drug Reaction (ADR) reporting and analysis Procedure
2.	Annual and periodic inventory/perpetual and stock management procedure
3.	Answering drug and poison information queries procedure
4.	Antimicrobial stewardship/rational antibiotic use policy and procedure
5.	Appropriateness review of the physician order/prescription policy and procedure
6.	Clinical Pharmacy quality indicators (e.g. pharmacist interventions, # of ADRs reported etc.)
7.	Disaster management plan for pharmacy and continuity of service
8.	Document records and retention period Standard Operating procedure (SOP)
9.	Drug/Device recall procedure
10.	Elements of complete order or prescription policy and procedure
11.	Floor stock management policy & procedure
12.	Formulary management policy and procedure
13.	Hazardous drugs/chemicals handling and disposal policy and procedure
14.	Hospital's own High Alert medicines policy and procedure
15.	Investigational drug use policy and procedure
16.	Lifesaving/emergency medicines & surgical stock management policy & procedure
17.	Look-alike & sound-alike (LASA) medicines policy and procedure
18.	Medication error and near miss reporting and analysis procedure
19.	Medication/supplies return (refund) policy & procedure
20.	Medicine compounding policy and procedure (Sterile & Non-Sterile compounding)
21.	Medicine dispensing policy and procedure (for inpatient, outpatient, ER, others)
22.	Medicine/surgical shortage management policy & procedure
23.	Narcotic drugs handling and dispensing policy & procedure
24.	Non-formulary drug and surgical request management policy & procedure
25.	Non-narcotic controlled drugs handling and dispensing policy & procedure
26.	Over the counter (OTC) drug dispensing procedure
27.	Patient counseling and education procedure
28.	Patient own / patient-brought medications Standard Operating procedure (SOP)
29.	Pharmacist intervention record procedure
30.	Pharmacy and Therapeutics committee (P&TC) Terms of Reference (ToR)
31.	Pharmacy operational quality indicators (e.g. delays, satisfaction, wastage etc.)
32.	Pharmacy organogram / organizational structure
33.	Pharmacy revenue collection procedure
34.	Pharmacy staff orientation, in-service training and development plan
35.	Policy and procedure on the save and reuse of multi-dose medicine containers
36.	Prescribing privileges for selected medicines – policy
37.	Procurement & Distribution of drugs and surgical supplies (for routine, Local or Emergency purchases) policy & procedure
38.	Receiving the drugs / supplies from supplier procedure and work instructions
39.	Safe and secure storage of medicines/surgical policy & procedure (within and out of pharmacy)
40.	Safe medication administration procedure (for nurses)
41.	Safe medication preparation procedure (for nurses)
42.	Safe medicine prescribing and transcribing policy and procedure
43.	Scope of Pharmacy Services document
44.	Staffing plan of pharmacy services

45.	Standard list of approved abbreviations (allowed of medication orders)
46.	Standard list of drug administration timings
47.	Standard Operating procedure (SOP) for Management of expired, outdated, wasted medications/surgical supplies
48.	Stock Expiry and Aging monitoring procedure
49.	Temperature (Cool/Ambient) & Humidity monitoring policy & work instructions
50.	Unclaimed medicines handling procedure
51.	Use of sample medicines / surgical policy
52.	Vendors & Suppliers' review and evaluation (for routine, Local or emergency purchases) policy & procedure
	Note this list is not exhaustive

Note:

This is a sample list only and not inclusive of all the required policies

DRUG REGULATORY AUTHORITY OF PAKISTAN
Prime Minister's National Health Complex, Chak Shahzad,
Park Road, Islamabad.
Phone No. 051 9255981 Email: dir.ps@dra.gov.pk
www.dra.gov.pk