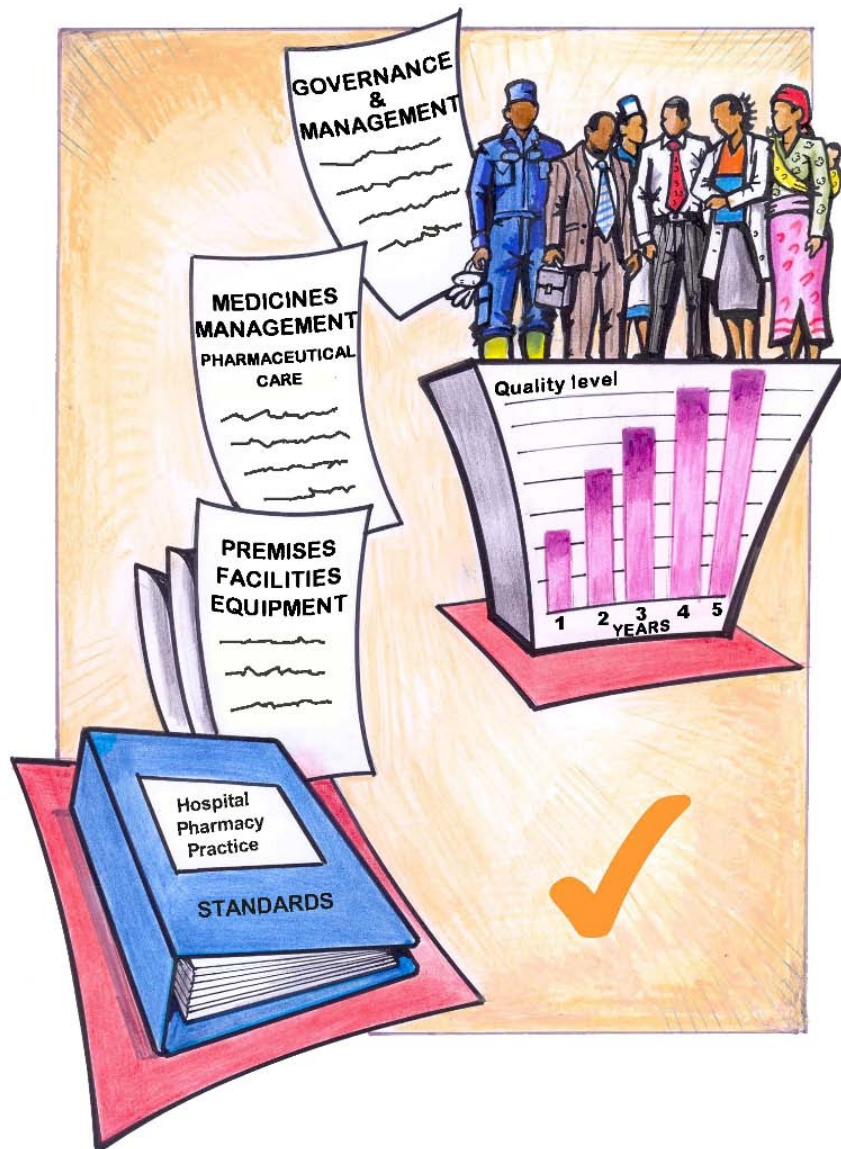


PHARMACY PRACTICE IN CHURCH HEALTH INSTITUTIONS

Minimum standards for hospitals





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About EPN

The Ecumenical Pharmaceutical Network (EPN) is a Christian, not for profit, independent organization committed to the provision of quality pharmaceutical services as a means to achieving global goals and targets on health and access to medicines.

In 2011, EPN celebrates 30 years of strengthening pharmaceutical services in church health systems.

About the SPS program

The Strengthening Pharmaceutical Systems (SPS) Program strives to build capacity within developing countries to effectively manage all aspects of pharmaceutical systems and services. SPS focuses on improving governance in the pharmaceutical sector, strengthening pharmaceutical management systems and financing mechanisms, containing antimicrobial resistance, and enhancing access to and appropriate use of medicines.

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TABLE OF CONTENTS

ACRONYMS AND ABBREVIATIONS	7
INTRODUCTION.....	8
The scope of hospital pharmacy practice	8
Hospital Pharmacy Practice Model.....	9
Practice Standards.....	10
SECTION A: PREMISES, FACILITIES AND EQUIPMENT	11
Premises.....	11
1. General provisions.....	11
2. Compounding area.....	11
3. Dispensing area.....	12
4. Storage areas.....	13
Facilities.....	13
1. Facilities for storage.....	13
2. Facilities for communication.....	14
3. Facilities for records management	14
4. Reference materials	15
Equipment.....	15
Work place safety.....	16
SECTION B: PHARMACY PRACTICE	17
Promotion of good health and achievement of health objectives	17
1. Health promotion.....	17
2. Participation in the health care team.....	17
Medicines supply management.....	18
1. Procurement.....	18
2. Compounding.....	19
3. Donations	20
4. Receipt and storage.....	20
5. Distribution.....	21
6. Management of expiries	21
7. Disposal	22
8. Controlled substances	22
9. Emergency supply.....	23
10. Pre-packing of medicines.....	23
11. Medicine quality.....	24
12. Medicine assessment	24
13. Medicine recall.....	25
Pharmaceutical care	25
1. Prescribing practice	25
2. Dispensing.....	25
3. Counseling	26
4. Monitoring patient outcomes.....	27
5. Managing medication errors.....	27
6. Adverse drug reaction monitoring	27

7. Communication	28
8. Privacy and confidentiality.....	28
SECTION C: GOVERNANCE AND MANAGEMENT	29
Governance.....	29
General management	29
Information management.....	30
Human resources.....	31
1. Staffing	31
2. Continuing professional development	31
Promoting rational use of medicines	32
Continuous quality improvement	32
GLOSSARY	34
BIBLIOGRAPHY	37
SAMPLE CHECKLIST	39

ACRONYMS AND ABBREVIATIONS

ADR	Adverse Drug Reaction
CME	Continuing Medical Education
CPD	Continuing Professional Development
EPN	Ecumenical Pharmaceutical Network
JD	Job Description
MTC	Medicines and Therapeutics Committee
NEML	National Essential Medicines List
QA	Quality Assurance
SOP	Standard Operating Procedure
SSA	Sub-Saharan Africa
STG	Standard Treatment Guideline

Nomenclature for different types of pharmaceutical personnel

(The following descriptions have been given for the purpose of clarifying usage of the terms in this publication. They should not be considered as definitions, and variations are expected from country to country)

Pharmacist: A health professional who is an expert on medicine use, having attained a university degree or equivalent in the study of pharmacy

Pharmacy Technician: A health professional who has obtained a diploma in pharmacy or equivalent following 2-4 years of formal training

Pharmaceutical Technologist: same as pharmacy technician above

Pharmacy Assistant: A person who undertakes supportive tasks in the pharmacy. He/she may or may not have formal training in pharmacy

Pharmaceutically Trained Person: A person who has attended a minimum of 3 months formal training in a wide range of pharmacy subjects

INTRODUCTION

The scope of hospital pharmacy practice

Globally the role of the hospital pharmacist is shifting from a less product-centered to a more patient-centered focus. The pharmacist in most low income countries has, for a multitude of reasons, to try to balance both the product and the patient focus depending on the environment and specific need of his/her practice area. However, the hospital pharmacist's overarching role remains that of optimizing patient outcomes through the judicious, safe, efficacious, appropriate and cost-effective use of medicines as well as contributing to overall health improvement.

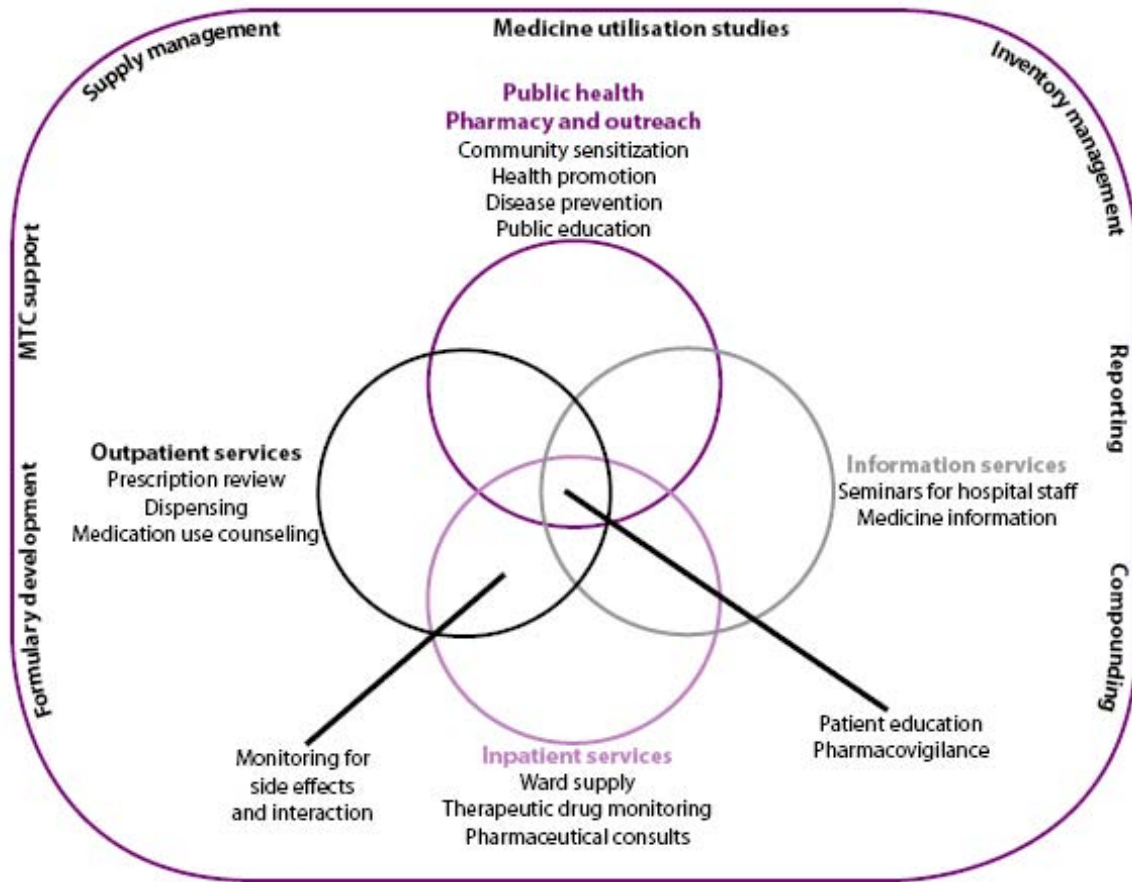
In its broadest sense, the scope of hospital pharmacy practice would include:

- Medicines Management
- Extemporaneous preparations, aseptic compounding and admixture services
- Prescription review, interpretation, validation and dispensing and prescriber education and collaborative therapeutic decision making
- Patient education
- Medication therapy management
- Setting up reporting systems for:
 - Poor quality medicines
 - Adverse reactions to medicines
 - Medication errors
 - Medicine usage
- Medicine utilization reviews
- Hospital Formulary and Treatment Guidelines development
- Medicines and Therapeutics Committee activities
- Continuing Professional Development (CPD) for health staff on medicines related issues
- Research

Unfortunately many hospitals around the world particularly in sub-Saharan Africa do not have pharmacists and therefore the services provided tend to be limited to the most basic and most routine. Nonetheless especially where there are no pharmacists, it is important for the hospital managers and for those working in the pharmacy to have a sense of what a reasonable level of pharmacy service entails. Given that at the current rates of training pharmacists, it will be many years before every hospital employs a pharmacist, it is important that policy makers, health professionals and regulators do not bury their heads in the sand. The nature of pharmacy practice in hospitals with or without pharmacists needs to be defined and guidance provided on all the possibilities that exist so that these can be exploited fully.

Ecumenical Pharmaceutical Network
April 2011

Hospital Pharmacy Practice Model



Practice Standards

What is a practice standard?

A statement that defines the performance expectations, structures or processes that must be in place for an organization to provide safe and high quality care, treatment and services¹.

Why have standards for church hospitals?

- Standards serve as guideposts for professional practice and as a way of communicating to different stakeholders their roles and responsibilities.
- Practice standards also provide a point of reference for evaluating the quality of services and patient care.
- Standards are ordinarily the responsibility of professional councils, accrediting and regulatory agencies in country. However for many of the countries where EPN has members, the profession and practice of pharmacy is still in its formative stages and therefore such standards are often not available.

How do we use the Standards?

- It is assumed that any staff working in the pharmacy will be under the supervision of a qualified pharmaceutical person (pharmacist or pharmacy technologist) who may or may not be resident in the facility. Such a supervisor is expected to oversee compliance with the standards, to check staff competencies against a prepared check list over a period of time and to support staff in the understanding and appreciation of the standards. In addition, such a supervisor should provide general support and on-the-job training for all services provided by the pharmacy. Where there is no higher level pharmaceutical support available, it is expected that the head of clinical services in the hospital will ensure that the pharmacy staff have the necessary support to comply with these standards and that their compliance will be assessed regularly in order to motivate them to achieve high service levels.
- Competencies should be checked in areas of
 - Management of work environment
 - Technical expertise
 - Quality of work
 - Attitude to patients and other health workers
 - Personal behavior and professional attitude
- In every country, there will be legislations and regulations governing the practice of pharmacy. These hospital standards must in all cases be understood as subservient to any such legislation or regulations, providing guidance only in those areas where the national laws and guidelines may be silent.

¹ From the Joint Commission Comprehensive Accreditation Manual for Hospitals 2006 in ASHP statement on Standards-Based Pharmacy Practice in Hospitals and Health Systems. Am J Health-Syst Pharm. 2009; 66.

SECTION A: PREMISES, FACILITIES AND EQUIPMENT

A good hospital pharmacy must have sufficient space, equipment and physical facilities for proper compounding, storage, dispensing, and counseling of patients. The pharmacy staff must also have access to appropriate tools and reference materials to enable them provide quality service.

Premises

1. General provisions

Standard

The hospital pharmacy is well built, well maintained and provided with the utilities required for its proper running.

Purpose

To ensure the efficient and effective provision of a quality service.

You have met the standards if

1. The pharmacy building is free from structural damage.
2. The building conforms to relevant national building regulations.
3. Floors and work surfaces are impervious and easily washable.
4. A sink and/or other appropriate facilities that provide hot and cold water are conveniently located for use in the provision of pharmacy services.
5. Disinfectant cleaning solutions and hand-washing agents with bactericidal action and disposable, lint-free paper towels and/or other approved drying materials are available.
6. A designated refrigerator/freezer for medicines is available, and is regularly cleaned, serviced and its temperature monitored.
7. Appropriate disposal containers for used needles, syringes, and other waste are available.
8. Directional signs/labels for pharmacy and dispensing units are clear and visible.

What you need to meet the standards

- Management commitment to ongoing repair and maintenance of buildings and physical facilities.
- Adequate lighting for all relevant areas of the pharmacy.
- A well functioning waste management and disposal system.

2. Compounding area

Standard

The hospital pharmacy has a sufficient designated area, appropriate equipment and reasonable quantities of consumable materials to ensure that medicines are prepared in a sanitary manner and meet specific requirements.

Purpose

To ensure proper compounding and packaging depending on the level of the facilities.

You have met the standards if

1. A dedicated area and working surface for compounding activities is available.
2. Scales and/or balances and suitable heating apparatus, appropriate for the compounding done in the pharmacy are available.
3. Consumable materials (e.g. containers for packaging, filter paper) are available whenever needed.
4. Disposable masks and sterile disposable gloves and if necessary gowns are available and used.

What you need to meet the standards

- Sufficient quantities of pharmaceutical raw materials, consumables and appropriate packaging materials.
- Appropriate storage containers for all raw materials.
- Suitable current reference sources either in book or electronic form, which might include the relevant pharmacopoeia and national formulary, the hospital formulary or other suitable references which are pertinent to the practice carried on in the hospital pharmacy.

3. Dispensing area

Standard

The hospital pharmacy has a comfortable dispensing area that is clean, well lit and designed to ensure privacy during dispensing².

Purpose

To ensure comfort, privacy and confidentiality for outpatient dispensing.

You have met the standards if

1. Dispensing areas provide equal access for all clients (including disabled clients).
2. Lighting in and outside the dispensary is adequate.
3. Adequate space for dispensing and medicine use counseling is available and where possible an area that allows for confidential conversation is provided, e.g. adequately spaced cubicles or enclosed dispensing spaces.
4. Safe waiting areas with seating arrangements designed appropriately are available.
5. Visual display units are appropriately arranged and illuminated.
6. Dispensing trays, tablet counters (manual or electronic) and other essential tools are available.

What you need to meet the standards

- Management and staff interest and commitment to designing and furnishing pharmacy premises appropriately.

² Dispensing includes all activities undertaken in the process of providing medicines to patients.

4. Storage areas

Standard

The hospital pharmacy has adequate well demarcated, well ventilated areas for storage of medicines and other hospital supplies. Designated areas are available for the storage of expired medicines, returned medicines and hazardous materials, physically separate from the other stocks.

Purpose

To guarantee integrity of medicines up to the time they reach the patient and to facilitate their proper management.

You have met the standards if

1. All areas in use for storage of medicines in the hospital are securely built and capable of being locked to prevent access by unauthorized persons.
2. The storage areas are designed in such a way as to facilitate cleaning, stock rotation and easy handling.
3. Storage areas have suitable provisions for storage of bulk materials as well as individual items.
4. Lighting in and outside the storage areas can be controlled in such a way that the appropriate conditions recommended for the products stocked can be attained.
5. The storage areas are designed in such a way as to facilitate the arrangement of medicines by therapeutic class, alphabetical order or any other appropriate system.
6. There is burglar proofing as required for doors and windows and main doors are lockable.
7. There is a separate hazardous material storage facility.

What you need to meet the standards

- Space dedicated for storage of medicines.
- Adequate space to ensure physical separation of stocks.
- Access to fumigation services.

Facilities

1. Facilities for storage

Standard

Facilities are available that prevent damage to or deterioration of medicines and other products; and support the provision of a high quality professional service.

Purpose

To guarantee the integrity of the medicines.

You have met the standards if

1. Cold storage facilities are available and properly functioning.
2. All medicines are stored according to the manufacturers' specifications.

3. Shelving and racking are appropriate and sufficient to meet good storage practice requirements and provide adequate space.
4. Lockable cupboards or other appropriate receptacles are available for controlled medicines.
5. Storage facilities are designed to minimize damage to stocks in case of fire, flooding or attack by vermin.

What you need to meet the standards

- Adequate and suitable facilities and equipment (e.g. shelves, cupboards, racks, pallets, refrigerators, ventilation, air conditioning, fans).
- Thermometers to measure, and suitable charts to track the temperature.
- Fire prevention and fire fighting equipment that is in good condition and useable by pharmacy staff.
- SOPs for good storage practice and for use of fire fighting equipment.

2. Facilities for communication

Standard

The pharmacy has the requisite facilities to communicate appropriately with prescribers, patients and other relevant persons for the proper management of the patients.

Purpose

To promote communication and consultation for appropriate patient care.

You have met the standards if

1. Confidential conversations can be held with patients.
2. Pharmacy staff members have the means/facilities to consult with prescribers about patient care.
3. Pharmacy staff members have the facilities to communicate with the outside world (outside the hospital) to improve quality of services.

What you need to meet the standards

- A separate office or secluded space.
- Functioning telephone (land and/or mobile), fax and internet or easy physical access.
- Clear communication policy and reporting system.

3. Facilities for records management

Standard

The pharmacy has a designated space to act as an office and for safe keeping of records.

Purpose

For the security and safe custody of pharmacy records.

You have met the standards if

1. Appropriate space and facilities for proper records management are available.
2. Pharmacy records are easily and quickly retrievable.
3. Pharmacy staff are able to use the available facilities efficiently and effectively.

What you need to meet the standards

- Availability of computers and software or appropriate manual recording keeping system.
- A filing system that facilitates quick retrieval of information.
- A lockable cupboard to secure important and/or confidential documents.

4. Reference materials**Standard**

The pharmacy is equipped with or provides access to appropriate reference materials (books, journals, CDs).

Purpose

To allow pharmacy staff access to current information required for service provision.

You have met the standards if

1. Appropriate current reference materials are available to or accessible by pharmacy staff.

What you need to meet the standards

- Availability of a computer with access to internet.
- Current reference books or electronic materials.
- Culture in the hospital that promotes knowledge updating and sharing.

Equipment**Standard**

Equipment used in the pharmacy is maintained in good working order in accordance with manufacturer's instructions or other requirements.

Containers used for the storage of medicines, raw materials and other products in the pharmacy are intact and air tight if required.

Containers and packaging materials used in the pharmacy are clean, intact and properly stored.

Purpose

To ensure product integrity, quality, safety and efficacy.

You have met the standards if

1. All equipment selected is suitable for its intended use and is functioning properly.
2. All equipment and work surfaces are properly cleaned before and after product preparation.
3. All equipment is maintained in good working condition.
4. All instruments used for weighing or measuring are calibrated and maintained according to a documented procedure.
5. All containers in use have no major scratches, cracks or damages and sufficient quantities are available as required to deliver the services required.

What you need to meet the standards

- Funds set aside for replacement of all worn out equipment and containers.
- Management interest in and commitment to buying the appropriate equipment.
- Technical support to service, repair and maintain the equipment.
- Access to commonly required spare parts and accessories.
- A servicing and maintenance schedule which is adhered to.

Work place safety**Standard**

The workplace environment assures the safety and well being of pharmacy staff.

Purpose

To minimize the risk of harm to the staff and/or damage to the facilities.

You have met the standards if

1. Exits and aisles are kept clear at all times.
2. Protective clothing for safety of staff such as gloves, gowns, and masks are available for use when required.
3. Staff members are regularly trained on occupational safety.
4. Written SOPs for handling hazardous materials are in place.
5. Measures to handle workplace hazards such as fire and chemical spills are in place.
6. Alcohol and flammables are stored in areas that meet, at a minimum, basic local building rules and requirements for the storage of volatiles and such other laws, ordinances or regulations as may apply.

What you need to meet the standards

- Work place safety policy understood by all pharmacy staff.
- Fire prevention and fire fighting equipment which is regularly serviced.
- Fire/emergency exits.
- Easy access to water at all times.
- First Aid Kits.
- Proper waste disposal systems.

SECTION B: PHARMACY PRACTICE

Good pharmacy practice involves four main groups of activities, namely:

- Activities associated with the promotion of good health, the avoidance of ill-health and the achievement of health objectives;
- Activities associated with the supply and use of medicines and of items for the administration of medicines or for other aspects of treatment;
- Activities associated with pharmaceutical care, including advice about and, where appropriate, the supply of a medicine or other treatment for symptoms of ailments that lend themselves to self-treatment;
- Activities associated with influencing the prescribing and use of medicines (*adopted from FIP 1997*).

Promotion of good health and achievement of health objectives

1. Health promotion

Standard

Pharmacy staff members actively carry out health promotion activities and are able to provide clear consistent up-to-date information on health promotion to their clients and the public.

Purpose

To ensure participation of pharmacy staff in preventive and promotive health services.

You have met the standards if

1. Pharmacy staff members provide clear and consistent messages and materials relevant to public health activities.
2. Pharmacy staff members work with other health team members on public health activities.
3. Pharmacy staff members provide information on issues such as diet, exercise and various risk factors impacting treatment.

What you need to meet the standards

- Health promotion materials from a relevant national department, the hospital or other recognized body accessible by patients.
- Opportunities for participation in health promotion activities extended to pharmacy staff.
- Access to relevant brochures and information materials of a quality that can be vouched for by an acceptable national authority.

2. Participation in the health care team

Standard

The pharmacy staff members collaborate with others in the health care team.

Purpose

To optimise patient outcomes.

You have met the standards if

1. Formal feedback processes are known and followed.
2. Pharmacy staff are active members of MTC and other relevant committees.
3. Pharmacists participate in ward rounds.
4. Pharmacy services are accessible to the clients as required.
5. Pharmacy staff members maintain regular and cordial consultation with other health care staff to communicate technical information and/or clarify prescriptions and treatment.

What you need to meet the standards

- An organization culture that recognizes the levels of competence and potential contribution of different health cadres and promotes respectful communication at all levels.
- Pharmacy staff members who recognize their role in the health care team and their contribution to quality care and optimal outcomes for the patient.

Medicines supply management

1. Procurement

Standard

Procurement of medicines and medical supplies is done in a transparent and efficient manner in compliance with relevant regulations, and all supplies purchased for use or sale are of acceptable price and quality.

Purpose

To ensure timely access to quality medicines and care at a cost the individual and community can afford.

You have met the standards if

1. Decisions on procurement are made by a multi-disciplinary team or committee.
2. Policies and procedures for procurement of required medicines, supplies and equipment are in place and complied with.
3. Suppliers of pharmacy stocks are licensed by a competent authority, pre-qualified and periodically evaluated.
4. Required levels of pharmacy stocks and/or equipment are defined properly.
5. Choice of equipment or materials to be bought by the hospital is based on intended use, accuracy, safety and cost.
6. All medicines purchased or donated for use in the hospital are approved by the relevant authority for use in the country.
7. There is ongoing surveillance of equipment and medicine use trends within the hospital and analyses of medicines use are communicated to the management.
8. Records and numerical data (for statistical reviews) relating to the prescribing and use of medicines are maintained.

9. Contingency plans are in place to deal with medicines shortages and the need for emergency purchases.

What you need to meet the standards

- Annual procurement plan understood by all stakeholders.
- Guidelines for supplier identification and prequalification.
- Up-to-date written SOPs for procurement.
- An active multidisciplinary Medicines and Therapeutics Committee (MTC).
- Current and accurate records of medicine sources and consumption.
- Information for use in decision making on medicines procurement is available to the team or committee responsible for procurement.

2. Compounding

Standard

Medicines prepared in the pharmacy meet national quality requirements.

Purpose

To ensure proper care and safety of the patients.

You have met the standards if

1. Pharmacy staff members are appropriately trained to carry out activities such as calculations of required quantities, dilutions or percentages; accurately weighing and measuring ingredients; creating batch numbers and storing and retrieving records of prepared products while practicing safe handling techniques.
2. Only staff members who are trained appropriately are involved in preparation of pharmaceutical products.
3. Work sheets are used to document the details of prepared products in line with master formulae.
4. Terminology, abbreviations and instructions are interpreted accurately and correct ingredients identified for each specific formulation.
5. The preparation of sterile products including infusions is carried out only where the strict requirements including using correct equipment and facilities can be assured.
6. Aseptic technique is observed in any handling of sterile products.
7. Quality of raw materials including those for sterile products is guaranteed.
8. Personal hygiene is strictly observed and personal protective materials are worn as required.
9. The compounding area is kept clean at all times and regularly disinfected.

What you need to meet the standards

- Hospital compounding policy and procedure manual pertinent to the volume and complexity of the compounding operation of the hospital.
- Master batch record containing formulas for each of the products made and directions for compounding.
- A logbook or record system to track each compounded product and the components used, quantities made, destination of the products as well as product recalls.
- Reference materials for hospital based compounding.
- Measures, counters, weights and equipment corresponding with the products made.

- Pharmaceutical standard raw materials and packaging materials.
- Availability of up-to-date written SOPs for all compounding processes.
- A compounding area that is clearly demarcated and appropriate.

3. Donations

Standard

Medicines donated to the hospital meet national (where these exist) or international guidelines for medicine donations.

Purpose

To ensure that donations to the hospital of medicines and to the hospital are safe, effective and useable.

You have met the standards if

1. Hospital guidelines exist on medicine donations that comply with national and/or the interagency guidelines on medicines donations.
2. Medicines donations are only accepted if they meet the specific needs and requirements of the hospital.

What you need to meet the standards

- National or interagency guidelines on medicines donations (http://whqlibdoc.who.int/hq/1999/who_edm_par_99.4.pdf).
- Mechanisms for internal information sharing about potential and received donations.
- Consensus on and compliance within the hospital on agreed methods of dealing with donations.

4. Receipt and storage

Standard

The receipt and storage system ensures acceptance only of quality products, proper custody and facilitates easy retrieval of the required medicines.

Purpose

To maintain the quality and integrity of the medicines and to minimize dispensing errors and stock losses.

You have met the standards if

1. The procedure to be used for receipt of medicines is properly documented.
2. Quality assurance checks are done on all products received by the hospital pharmacy.
3. Systems are in place to facilitate rejection of stocks that do not meet set quality standards.
4. A clear logical system for arranging stocks is in place and followed. Systems may be alphabetical, pharmacological, or based on dosage forms.
5. A comprehensive manual or computerized stock management system is in place.
6. Physical stock matches with stock records.
7. Stock losses, expiries, damages and breakages are kept to a minimum.

What you need to meet the standards

- Appropriate tools for stock management.
- SOPs for receipt and storage.

5. Distribution

Standard

The packaging and transportation of medicines to wards and departments (intra-hospital distribution) or supplied to other health facilities (inter-facility distribution) is efficient and does not compromise the integrity of the products.

Purpose

To maintain the integrity and quality of medicines and products up to when they reach the patient.

You have met the standards if

1. Distributed medicines are of expected potency.
2. Special handling requirements such as cold chains are maintained and monitored.
3. Accurate and up-to-date records on distributed medicines and products are kept.

What you need to meet the standards

- Up-to-date written SOPs.
- Good storage and distribution practices manual.

6. Management of expiries

Standard

The pharmacy efficiently and effectively manages all medicines including those that are no longer useable in line with hospital policy and procedures.

Purpose

To ensure that the hospital minimizes losses and protects patients.

You have met the standards if

1. Policies on stock management are known and complied with.
2. Stock is managed according to the FEFO rule.
3. Key activities such as stock taking, expiry date tracking and stock rotations are undertaken regularly.
4. The pharmacy maintains optimal stocks of useable medicine.
5. The pharmacy staff regularly updates relevant hospital staff about the medicines situation.
6. Product recalls can be comprehensively and efficiently implemented.

What you need to meet the standards

- An expiry tracking system.

7. Disposal

Standard

Unwanted and un-useable medicines are disposed off safely and appropriately.

Purpose

To ensure the safety of individuals and the environment.

You have met the standards if

1. There are designated separate areas for unusable and for returned medicines.
2. The pharmacy follows the appropriate procedure for the destruction of unusable medicines.
3. No outdated, deteriorated, recalled or obsolete medicines are kept for prolonged periods in the pharmacy.
4. All disposals of medicines are done using environmentally friendly methods in line with national regulations.
5. The appropriate procedure for the destruction of unusable medicines is known and followed.

What you need to meet the standards

- Appropriate facilities for holding and quarantine of medicines prior to disposal.
- Adequate and appropriate disposal facilities such as an approved incinerator.
- An appropriate procedure for safe disposal of unwanted medicines.

8. Controlled substances

Standard

Controlled substances are properly managed in accordance with relevant national and international laws and regulations.

Purpose

To protect the patients and hospital staff and avoid litigation.

You have met the standards if

1. All relevant legislation and regulations are complied with.
2. Controlled substances are kept under lock and key.
3. Records on purchase and usage are accurate and up to date at all times.
4. Unused medicines are disposed of in the approved manner.
5. Dispensing of controlled substances is done only on valid prescriptions from authorized prescribers.

What you need to meet the standards

- Physical facilities and medicine registers that meet the national requirements.
- Secure facility for storage with restricted access.
- Qualified staff allowed by law to handle controlled substances.
- Copies of relevant legislation and regulations.
- Appropriate order and prescription forms.

9. Emergency supply

Standard

Emergency and lifesaving medicines from hospital stock are available to patients and hospital staff at any time of the day or night in a manner that does not compromise the security or appropriate use of these medicines.

Purpose

To ensure that patients receive quality care at all times while at the same time protecting the hospital from losses and misuse.

You have met the standards if

1. A list of emergency and lifesaving medicines for the hospital purposes is defined and known by all relevant staff.
2. Systems are in place to provide relevant hospital staff with emergency or lifesaving medicines from bulk stocks at any time in the event that they run out unexpectedly.
3. Pharmacy has a functioning call system for relevant staff.
4. Medicines for use in emergency cases are readily accessible but adequately secured.

What you need to meet the standards

- Facilities to contact staff who are on call.
- Secure but accessible place to store emergency medicines.

10. Pre-packing of medicines

Standard

Medicines that are commonly prescribed in the hospital in standard courses of treatment are prepared in advance ready for dispensing.

Purpose

To increase efficiency in the dispensing process and allow more staff time to be spent on counseling patients.

You have met the standards if

1. A specific list of medicines which may be pre-packed is defined.
2. Medicines are pre-packed in accordance with manufacturer and/or other recommendations relevant for that product.
3. The correct equipment is available for pre-packing and is well maintained.
4. Measures used for oral preparations are kept separate from those used for internal preparations.
5. Medicines are pre-packed in such a way that risk of mix-ups and cross contamination is eliminated.
6. Pre-packed medicines are only kept for such periods as recommended by the manufacturer or in which the integrity of the medicine can be guaranteed.

What you need to meet the standards

- Appropriate equipment trays, counters, calibrated measuring cylinders for liquids according to the level of pre-packing that is required.

- Sufficient packaging and labeling materials.
- Sufficient space for storage of pre-packed medicines.
- A detailed written protocol describing how the pre-packing is to be done for each medicine.

11. Medicine quality

Standard

The pharmacy works with all relevant hospital departments to ensure that quality medicines are available including through the detection and withdrawal of counterfeit (fake) and defective (faulty or substandard) medicines.

Purpose

To optimize patient outcomes.

You have met the standards if

1. Quality assurance procedures are observed and problems addressed promptly.
2. Incidents of poor quality medicines being supplied by pharmacy are minimal (established through testing and/or feedback from the users).

What you need to meet the standards

- Comprehensive QA policies and procedures.
- Regular internal quality audits by multidisciplinary teams.
- Comprehensive product rejection and recall guidelines.
- Product complaint procedures and mechanisms to collect and process complaints.

12. Medicine assessment

Standard

The pharmacy is vigilant in the identification and quarantine of any medicines suspected to be defective, substandard, spurious or in any way inappropriate for use by patients.

Purpose

To guarantee patient safety and optimal outcomes from medicine use.

You have met the standards if

1. Defective, substandard, spurious or suspect medicines are not used in patient care.

What you need to meet the standards

- Systems to obtain feedback on quality of medicines from points of care within the hospital.
- Systems to confirm the quality of suspect medicines.
- Systems to report substandard or defective medicines to relevant authorities.
- Written policies and procedures to deal with spurious (fake) and defective (faulty or substandard) medicines.

13. Medicine recall

Standard

Medicines that are defective and/or harmful to patients are quickly and efficiently withdrawn from circulation within the hospital and properly disposed off.

Purpose

To protect patients from harm and to ensure desired outcomes are not compromised.

You have met the standards if

1. Adequate batch records are in place to facilitate swift and effective recall.
2. Recalled products can be isolated from other pharmacy stocks.

What you need to meet the standards

- A comprehensive batch recording and tracking system that is kept up to date.

Pharmaceutical care

1. Prescribing practice

Standard

The pharmacy evaluates medicine prescriptions and appropriately influences prescribing.

Purpose

To ensure legality, reasonableness and appropriateness of medicines meant for the patient.

You have met the standards if

1. Prescription frauds, errors and deficiencies are identified and corrective steps taken.
2. Pharmacists³ are involved in selection of medicines and development of hospital formulary.
3. Predictable adverse drug reactions (including allergies and contraindications) are avoided.
4. Interactions of medicines with other medicines and with food are avoided.

What you need to meet the standards

- Support systems for pharmacy staff to discuss errors or anomalies with prescribers.
- Continuing professional development for pharmacy staff on current therapeutics.

2. Dispensing

Standard

Provision of medicines is done in an accurate and timely manner, reflecting the prescriber's intentions, and consistent with the needs and safety of the patient, i.e. the right patient gets the right medicine in the right dose through the right route and at the right time.

³ To be involved in the selection process, pharmacists need not be employees of the hospital. These services may be obtained from volunteers or pharmacists employed within other institutions in the church sector.

Purpose

To optimize therapeutic outcomes.

You have met the standards if

1. Correct products, dosage forms and quantities are accurately selected, packaged, labeled and dispensed as per standard operating procedures.
2. Liquid preparations are dispensed in 'pharmaceutical' bottles so as to distinguish them from food, drinks and other consumer products.
3. Preparations for external use and poisons are dispensed in easily distinguishable bottles.
4. Recycled containers are cleaned properly both internally and externally.
5. All medicine labels have the following minimum information:
 - Name of patient
 - Generic name & strength of medicine
 - Dose, frequency & duration of course, if applicable
 - Date of dispensing
 - Name/address of dispensing facility
 - Child safety warning, every package should be marked in such a way that the potential danger to children is noted
 - Expiry date

What you need to meet the standards

- All relevant dispensing material such as labels and packaging materials are available.
- Adequate facilities for washing and drying utensils and equipment.

3. Counseling

Standard

Pharmacy staff promotes clients understanding of medical conditions, medication and adherence to treatment plans.

Pharmacy clients understand the information they receive and are empowered to search for information to improve their medicine usage.

Purpose

To enhance treatment outcomes.

You have met the standards if

1. Appropriately written or illustrated material for giving advice and counseling is available for each client if required.
2. Patients demonstrate adequate knowledge of their treatment including dosing administration, storage and side effects.

What you need to meet the standards

- Easy access to up to date, relevant information on the medicines dispensed.
- Professional relationship with prescribers to confirm validity, clarify prescription order and discuss therapeutic alternatives among others, is maintained.

4. Monitoring patient outcomes

Standard

The pharmacy department contributes to the monitoring of patient outcomes.

Purpose

To ensure that the patient care and treatment achieves the desired results.

You have met the standards if

1. Pharmacy staff members provide relevant information to other members of the health team on patients' condition and progress.
2. Pharmacists in the hospital belong to collaborating health teams.

What you need to meet the standards

- Qualified staff able to properly monitor patient outcomes.
- Mechanisms to provide information on patients' progress to other members of the health care team.
- Systems to support pharmacy staff to monitor and report on patient outcomes.

5. Managing medication errors

Standard

The pharmacy works with other hospital staff to minimize medication errors.

Purpose

To ensure the best outcomes for the patient and ensure patient safety.

You have met the standards if:

1. Common medication errors in the hospital are known and strategies to minimize them are in place.
2. Pharmacy staff members take action when they encounter a medication error.

What you need to meet the standards

- System for detecting, recording and addressing medication errors.
- Written guidelines for reporting medication errors.
- A non punitive culture in the hospital that supports sharing of information on medication errors.

6. Adverse drug reaction monitoring

Standard

The pharmacy records and reports incidences of adverse drug reactions (ADR) to the relevant authorities.

Purpose

To promote positive treatment outcomes and avoid ill health.

You have met the standards if

1. Patient and product factors that can impact safety and efficacy of treatment are understood.
2. Adverse drug reactions are detected and reported.

What you need to meet the standards

- Appropriate ADR forms for reports are available and staff members are knowledgeable on their use.
- System for detecting, reporting and addressing ADRs.

7. Communication

Standard

Systems in place for proper communication on patient and medicine information with patients, caregivers, other professionals and the public.

Purpose

To ensure consistency of care and optimize therapeutic outcomes.

You have met the standards if

1. Interpersonal and communication skills to provide relevant information, including demonstrating special administrative techniques are observed at every interaction with clients.

What you need to meet the standards

- Training and mentoring the staff to improve their communication skills.

8. Privacy and confidentiality

Standard

The pharmacy staff members interact with patients in a manner that ensures undisturbed conversation whenever required and safeguards the need for discretion.

The pharmacy staff safeguards confidential information about clients.

The pharmacy staff uses diplomacy and tact when dispensing prescriptions to the clients.

Purpose

To reduce stigma, cultivate confidence and maximize benefits from pharmacy interventions.

You have met the standards if

1. Conversation during dispensing encounters is uninterrupted.
2. Clients demonstrate satisfaction with pharmacy services.

What you need to meet the standards

- Properly designed and furnished pharmacies.
- Adequately spaced cubicles or enclosed dispensing spaces.

SECTION C: GOVERNANCE AND MANAGEMENT

Like other health care professionals, pharmacy staff members operate under national and professional laws, regulations, policies and practices. In addition, there may be organizational guidelines to be followed. It is important that all hospital authorities are aware of the legal and regulatory framework that governs their activities and that they comply. Compliance with guidelines, laws and regulations is enhanced when a conducive environment is provided. Nevertheless availability of staff with appropriate skills and knowledge coupled with an adequate staffing level is paramount.

Governance

Standard

The pharmacy is efficiently and effectively run in line with the vision and mission of the hospital and in compliance with applicable national laws and regulations.

Purpose

To ensure the highest quality of service for and safety of the patients.

You have met the standards if

1. The pharmacy has clearly written goals in line with the mission of the hospital/institution.
2. The pharmacy is well run to the satisfaction of regulatory bodies, the patients and the board.
3. Legal requirements related to the hospital pharmacy practice are known, correctly interpreted and complied with.
4. Mechanisms for dispute resolution and whistle blowing are in place.
5. Professional staff members in the pharmacy are registered under the laws/regulations of the country.

What you need to meet the standards

- Availability of a mission statement for the hospital.
- Current copies of key pharmacy related legislative instruments of the country in the pharmacy.
- Routine evaluations of the pharmacy service by non-pharmacy staff.

General management

Standard

The pharmacy is well managed and pharmacy staff is motivated to serve the hospital's clients.

Purpose

To ensure good quality of care for the patients and appropriate support to other service providers in the hospital.

You have met the standards if

1. Services provided are accessible, timely and of good quality.
2. The organizational structure, pharmacy position in the structure and formal lines of reporting and communication are known and understood.
3. The pharmacy has work plans to guide in achievement of goals in line with the hospitals strategic objectives.
4. Work schedules, procedures, assignments, normal and contingency tasks are completed according to work plans and adequately reported on.
5. Adequate instruction and support for delegated tasks is given.
6. Standard Operating Procedures are available for all the key tasks undertaken by the pharmacy.

What you need to meet the standards

- A written organizational structure with clear reporting lines.
- Relevant policies and procedures available in writing and accessible.
- Systems for evaluation of the pharmacy service.
- Clearly defined reports and reporting systems.

Information management**Standard**

Information in and by the pharmacy is managed in such a way that it supports efficient and effective service delivery while guaranteeing patient confidentiality.

Purpose

To provide an audit trail and support decision making in line with the hospital mission.

You have met the standards if

1. A record of all medicines supplied is kept detailing name of patient, name & strength of medicine, dosage, quantity supplied, and date of dispensing.
2. Individual patient medicine records are maintained in a system, manual or computerized, which allows for easy retrieval of patient information.
3. Access to patient information is restricted to authorized persons.
4. Information management systems are tamper-proof and integrity of the system is regularly checked.
5. Information on operations of the pharmacy is routinely generated and provided to hospital management.
6. Information generated from pharmacy is accurate and comprehensive.

What you need to meet the standards

- Policies and procedures that support consistent record keeping and documentation.

Human resources

1. Staffing

Standard

The pharmacy is adequately staffed with competent people in line with the hospital size and complexity and any existing guidelines from the Ministry of Health or other relevant government agency.

Purpose

To ensure that a professional service is delivered to all clients.

You have met the standards if

1. The pharmacy has the services of a pharmacist and employs at least one pharmaceutically trained person as a minimum.
2. Periodic staff performance evaluations and assessments of the pharmacy work are undertaken and feedback given.
3. Pharmacy staff members have clear job descriptions (JDs).
4. Pharmacy staff members adhere to an appropriate dress code in line with the hospital philosophy.
5. Pharmacy staff members adhere to professional ethics.

What you need to meet the standards

- Government staffing norms for hospitals.
- Staff levels commensurate to the pharmacy work load and nature of work.

2. Continuing professional development

Standard

Pharmacy staff members actively participate in relevant continuing-education programs and activities to maintain or enhance their skills and professional competence.

Purpose

To ensure that staff are up to date with developments relevant to their practice.

You have met the standards if

1. Pharmacy staff engages in continuing professional development programs regularly and are provided opportunities for continuing education.
2. Pharmacy staff members are well informed of any significant changes in hospital treatment protocols.
3. Evidence exists of application of acquisition of new knowledge for service improvements.

What you need to meet the standards

- Schedule for continuing professional development programs for pharmacy staff.
- Systems to update staff on new medicines introduced or changes in treatment protocols.

- Participation in training courses encouraged and supported by the hospital management.
- Hospital management provides a conducive environment for continuous learning.

Promoting rational use of medicines

Standard

The pharmacy staff members contribute towards promoting the rational use of medicines and increasing knowledge on medicine use.

Purpose

To support the appropriate use of medicines and medical supplies.

You have met the standards if

1. Records and numerical data relating to the prescribing and use of medicines are maintained.
2. Data relevant for understanding existing and evolving trends in medicine use is maintained.
3. The pharmacy is involved in the development and maintenance of a formulary which is current and in line with the national essential medicines list.
4. Relevant information on medicine use trends is regularly provided to management and information is used for decision making on medicines procurement and use.

What you need to meet the standards

- Availability and acceptance of standards treatment guidelines (STG), national essential medicines lists, hospital formularies or similar tools.
- Mechanisms in place to regularly update the formulary or STGs.
- Functioning MTC in the hospital.
- Adequate medicine use record keeping systems.
- Appropriate mechanisms for reporting on medicines use practices.
- Continuing professional development for clinical and pharmacy staff.

Continuous quality improvement

Standard

Systems and processes for defining, monitoring, assessing and improving the quality of pharmacy services are in place and implemented.

Purpose

To ensure quality pharmaceutical service delivery and that care to patients is optimal, effective and safe.

You have met the standards if

1. Systems exist to monitor and improve performance of the pharmacy staff individually and collectively.

2. Systems exist to monitor and improve institutional capacity to support quality pharmaceutical service delivery.
3. Activities to be undertaken by pharmacy staff are clear and processes, targets and outcomes are well defined.
4. Pharmacy resources (staff, tools, space, facilities) are commensurate with the workload handled.
5. Quality audits are undertaken at least once a year.

What you need to meet the standards

- A continuous quality improvement manual.
- Pharmacy staff periodically trained on continuous quality improvement.
- Commitment by hospital management to continuous improvement.
- Well defined standards for pharmacy practice.

GLOSSARY

This glossary of terms provides an explanation of usage of the word in the context of this standards document. The terms may have other meanings in other contexts.

Appropriate equipment means equipment meant for that specific function and which is/are well maintained and calibrated.

Appropriately written or illustrated materials include use of language understood by clients or use of diagrams or pictures in the case of clients who are unable to read.

Aseptic technique refers to preparation of products in a manner intended to avoid contamination and/or retain sterility.

Client includes all those who receive or benefit directly or indirectly from the services of the hospital pharmacy including patients, caregivers, other hospital staff, policy makers and the general public.

Collaborating Health Team is a team of health professionals in a health setting working together to ensure optimal outcomes for the individual patient.

Communication is the activity of conveying meaningful information.

Controlled substances are drugs or chemicals whose manufacture, possession, and use are regulated by a government.

Compounding or extemporaneous preparation means the preparation, mixing, assembling, packaging, or labeling of a drug or device. It is usually the preparation and supply of a drug formulation, dosage form, strength, or packaging that is not available commercially but is needed for client care. This covers the preparation of products whose formulations are drawn from recognized pharmaceutical formularies.

Compounding/dispensing area that is appropriate is one which is adequately lit and ventilated, is equipped with running water and work facilities such as sinks, heating facilities and the necessary compounding equipment; has adequate work bench of sufficient width and length to provide the free working space; and has an impervious covering.

Continuing Education is the attendance of lectures, courses and other forms of learning as a means to update ones professional knowledge.

Continuing Professional Development is the systematic maintenance development and broadening of knowledge skills and attitudes to ensure continuing competence as a professional.

Consumable materials include those articles used frequently such as labels, packaging materials, disposable needles, syringes, and other supplies needed for aseptic admixture

including filter paper and appropriate filters and filtration equipment, powder papers, litmus paper, empty capsules, ointment jars, bottles, vials, safety closures, powder boxes, labels, and distilled water,...

Disposal of medicines procedures are often determined by the national drug authority or other relevant national body and when in doubt, they should be consulted.

Distribution includes supply and delivery to the wards or other hospital departments and supply to other satellite facilities. Proper distribution should provide medicines to clients in a timely manner; have low medication error rate (i.e. be the safest system), minimize wastage, minimize opportunities for medicines diversion, and minimize medicines storage throughout the facility; and provide data on medicines utilization and usage patterns.

Equipment may include those necessary for work in the pharmacy such as balances and counting trays as well as those for local production of medication such as mixers or for drug administration such as giving sets.

Good storage practices define the state of the hospital pharmacy in terms of security, space sufficiency and facilities necessary to ensure proper segregation, hygiene/cleanliness, temperature, light, ventilation and moisture control.

Hospital is any institution that meets the criteria for hospitals as defined by the bodies within a country mandated to license/define levels of health care.

Hospital pharmacy in this document refers to not only the main dispensing and compounding areas but also includes the main medicines store and medicines storage areas on wards.

Levels of compounding that can be carried out depend on size and facilities of the institution. For example in larger hospitals with a laminar airflow hood, infusion pumps, facility for light/dark field examination and biological safety cabinet, specialized services such as the preparation of injectables and other sterile products may take place.

Management of medicines has specific requirements such as conditions of storage, who can handle specific medicines, or to whom medicines can be issued and special recording needs which staff should be instructed on.

Medication error is any incorrect or wrongful administration of a medication, such as a mistake in dosage or route of administration, failure to prescribe or administer the correct medicine or formulation for a particular disease or condition, use of outdated medicines, failure to observe the correct time for administration of the medicine, or lack of awareness of adverse effects of certain medicine combinations. Causes of medication error may include difficulty in reading handwritten orders, confusion about different medicines with similar names, and lack of information about a patient's medicine allergies or sensitivities.

Medicines are all chemical substances given with the intention of preventing, diagnosing, curing, controlling or alleviating disease or otherwise enhancing the physical or mental

welfare of people. This includes prescription and non-prescription medicines including complementary medicines and vaccines.

Other applicable compounding wastes include cytotoxic waste from the preparation of chemotherapy agents.

Packaging material are the different forms of material that are used to preserve the integrity of medicines until they are consumed or used by a patient.

Patient is a person requiring medical attention, care or treatment.

Pharmaceutical care is the responsible provision of medicine therapy for the purpose of achieving definite outcomes that improve the patient's quality of life. It is a collaborative process that aims to prevent or identify and solve medicine and health related problems.

Pharmacovigilance is the science and activities relating to detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem.

Preparation of sterile products requires strict application of aseptic technique and use of correct equipment and facilities including separate and clean rooms, distillers or other approved equipment for preparation of water for injection and autoclaves. For the preparation of sterile products that cannot be sterilized by heat, correct equipment and facilities including separate clean room with appropriate pressure and correct airflow, HEPA filters, laminar airflow cabinets and scrub and gowning facilities. Staff must be trained and experienced in the use of the facilities, manipulation of the equipment and in the art of applying aseptic techniques.

Reasonable amount of supplies can be calculated taking into account the frequency of purchases, the time between ordering and receipt or the ease of acquiring them locally.

Secure and sufficient space and facilities include restricted access areas, burglar proofing, and lockable facilities for special materials (such as ARVs and Controlled substances) and the actual storage area and shelving, cooling facilities (e.g. air conditioning/cold room or other appropriate methods).

Segregation is the separation of different products e.g. in a storage system.

Special administrative techniques include administration of medicines such as inhalers, eye, ear, nose drops/ointments, suppositories.

Standard Operating Procedures (SOP). The term "SOP" is sometimes used synonymously with terms such as protocols, instructions and worksheets. An SOP applies to a task or function or operation or procedure being undertaken and provides the details (chronological steps) of how the task should be carried out. It is an official written document.

Unusable medicines may include expired, sub-standard, fake, damaged or otherwise spoilt medicines.

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SAMPLE CHECKLIST

The supervisor is required to physically verify the items/processes that are being checked. The appropriate choice should be clearly marked. None of the questions should be left unanswered. The assessment should be based on an all or nothing approach. If any criterion is not fully met, then the rating is negative.

Premises and facilities

1.1.	Pharmacy staff have access to clean water within the pharmacy	Yes	No
1.2	Cold storage facility (cold room or refrigerator) is available	Yes	No
1.3	Pharmacy is clean, tidy and well arranged	Yes	No
1.4	Lockable cupboard/room is available for narcotics and controlled substances	Yes	No
1.5	Pharmacy staff have access to a current pharmacopeia (Martindale, BP, USP, EP edition of not more than 5 years old)	Yes	No
1.6	Copy of current national treatment guidelines for common conditions is available in the pharmacy If available indicate year of publication _____	Yes	No

Pharmacy Practice

2.1	A hospital formulary or medicines list is available If yes indicate how current it is _____	Yes	No
2.2	Pharmacy has designated areas for segregation of unusable medicines	Yes	No
2.3	Up-to-date records are maintained on all stocks held in the pharmacy store	Yes	No
2.4	Medicines dispensed to patients are well labeled (product name, patients name, dosage, duration of treatment)	Yes	No
2.5	Forms for reporting adverse drug reactions are available in the pharmacy	Yes	No
2.6	Pharmacy has a functioning call system to respond to emergencies	Yes	No

Governance and management

3.1	The hospital has a policy and procedure on disposal of medicines	Yes	No
3.2	Hospital has a functional and active Medicines and Therapeutics Committee in place	Yes	No
3.3	Pharmacy staff are attired in such a way as to present a professional image	Yes	No

Notes: _____

Date _____ **Completed by** _____ **Designation** _____