

**Zambia Medicines Regulatory Authority****GUIDELINES ON THE ESTABLISHMENT OF A HOSPITAL PHARMACY**

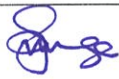
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1. INTRODUCTION

The Zambia Medicines Regulatory Authority (ZAMRA) is mandated under the Medicines and Allied Substances Act No. 3 of 2013 (hereinafter referred to as “the Act”) to regulate medicines and allied substances in Zambia in order to safeguard public health and ensure that medicines made available to the public are safe, efficacious and of acceptable quality.

These Guidelines on Establishing and Operating a Hospital Pharmacy establishment in Zambia are issued pursuant to section 14 of the Act and Statutory Instrument No. 58 of 2017. The Guidelines prescribe the requirements and procedures for the establishment, licensing, operation, management and continued compliance of Hospital Pharmacy establishment in Zambia. They further set out the minimum requirements relating to licensing procedures, personnel, premises, equipment, storage, dispensing, record keeping, standard operating procedures, disposal of unfit medicines, product recalls and amendments affecting registered premises, and other operational requirements necessary to ensure the safe and effective provision of pharmaceutical services in Hospital Pharmacy establishment

It is unlawful for any person to establish, operate, manage or conduct a Hospital Pharmacy establishment to sell, supply or dispense medicines and allied substances in a Hospital Pharmacy establishment except in accordance with a Certificate of Registration issued by the Authority.

These guidelines should be read together with the Act, the relevant Regulations and any other applicable standards or guidance issued by the Authority. The Authority may amend these guidelines from time to time to reflect changes in legislation, regulatory requirements, professional practice or public health needs.

Among other things, it is unlawful for any person to supply or dispense medicines or allied substances, in a hospital pharmacy in Zambia without lawful authority from ZAMRA except in accordance with the certificate of registration. The medicines or allied substances supplied and dispensed in the pharmacy shall have Marketing Authorisation or exemptions obtained from ZAMRA. In addition, there shall be full compliance to the licensing procedure.



2. OBJECTIVE

The purpose of these guidelines is to provide guidance on the requirements of applying for Certificates of Registration to operate a hospital pharmacy where medicines and allied substances may be dispensed, supplied or stored as provided for by the Act.

3. SCOPE

These guidelines apply to hospital pharmacies in Zambia and outline the minimum requirements for their operation.

4. DEFINITION

In these guidelines, unless the context otherwise requires -

- **“Act”** Means the Medicines and Allied Substances Act, 2013;
- **“administer”** means to give a substance to a human being or animal orally, by injection or by introduction into the body in any other way or by external application, whether by direct contact with the body or not;

“Authority” means the Zambia Medicines Regulatory Authority;

“certificate of registration” means the certificate of registration of a pharmacy;

“dispense” means to count, measure, or decant a medicine from a bulk supply or to prepare, mix, dissolve or supply a medicine for the treatment of a person, but does not include the administration of medicine;

“health facility” has the meaning assigned to it in the Health Professions Act, 2024;

“hospital” has the meaning assigned to it in the Health Professions Act, 2024;

“hospital pharmacy” means a pharmacy which is part of a health facility;

“ingredient” in relation to the manufacture or preparation of a substance, includes anything which is the sole active or inactive ingredient of that substance;

“label” means to affix to, or otherwise display on, a container or package, a notice describing the ingredients and contents thereof;



“medicine” means medicinal product, herbal medicine or any substance or mixture of substances for human use intended to be used or manufactured for use for its therapeutic efficacy or for its pharmacological purpose in the diagnosis, treatment, alleviation, modification or prevention of disease or abnormal physical or mental state or the symptoms of disease in a person;

“medicinal product” means any substance or combination of substances which may be administered to human beings or animals in order to make a medical diagnosis or to restore, correct or modify the physiological functions in human beings or animals;

“pharmacist” means a person registered as a pharmacist under the Health Professions Act, 2024;

“pharmacy” means a drugstore, druggist, chemist or any business or premises registered as such under the Medicines and Allied Substances Act, 2013;

“pharmacy technologist” means a health practitioner under section 9 of the Health Professions Act, 2024;

“premises” hospital pharmacy department area or facility;

“prescription” means a written direction given by an authorised prescriber directing that a stated amount of a medicine specified in the direction be dispensed for the person named in the direction;

“responsible Person” means a pharmacist or pharmacy technologist in charge of the pharmacy.

“standard operating procedure” is that set of instructions or steps which must be followed in order to complete a specific job or task safely, with no adverse impact on the environment, and in a way that maximises operational and production requirements

5. ABBREVIATIONS

FEFO First Expiry, First Out

FIFO First In, First Out

GPP Good Procurement Practice

HPCZ Health Professions Council of Zambia

IRIMS Integrated Regulatory Information Management System



MTC Medicines and Therapeutics Committee

SOP Standard Operating Procedure

ZAMRA Zambia Medicines Regulatory Authority

6. GENERAL REQUIREMENTS

6.1 Applications

An application for a Certificate of Registration for a Hospital Pharmacy shall be made by a person who intends to operate a hospital pharmacy in Zambia in a prescribed manner and form.

6.2 Requirements for an application

A person who intends to operate a hospital pharmacy shall apply to the Authority for a Certificate of Registration ensuring that:

- (a) the application is duly completed in a prescribed manner and form;
- (b) the application is accompanied with proof of payment of the prescribed fee;
- (c) the applicant is a holder of a valid business levy permit and fire certificate issued by the local authority; and
- (d) the applicant is a holder of a certificate of incorporation, business name registration certificate, certificate of registration of a cooperative or certificate of incorporation of a trust.

6.3 Attachments to the application

An application made in the prescribed manner and form shall be accompanied by a:

- (a) valid professional practicing certificate for the responsible person* (registered pharmacist) who shall personally manage and control the pharmacy during its operating hours;
- (b) sketch of the floor plan for the premises;
- (c) valid certificate of incorporation, business name registration certificate, certificate of registration of a cooperative, certificate of incorporation of a trust;
- (d) business levy permit from the local authority where applicable; and
- (e) fire certificate from the local authority.

6.4 Submission of the application

A completed application shall be submitted to ZAMRA using the integrated regulatory information management system (IRIMS) online portal.

**6.5 Application fees**

An application for a Certificate of Registration for a hospital pharmacy shall be accompanied by proof of payment of the prescribed fees as set out in the Medicines and Allied Substances (Fees) Regulations 2016.

An application for a Certificate of Registration for a hospital pharmacy shall only be received where it is accompanied by the requirements for an application stated in clause 6.2 above.

Bank charges shall be borne by the applicant who shall ensure that proof of payment is submitted to the Authority.

6.6 Screening

- (a) An application shall be screened for completeness by the Authority before inspection to ensure that there are no deficiencies that would hinder the inspection process;
- (b) where deficiencies are identified during screening of an application, a request for additional information shall be made to the applicant;
- (c) subject to 6.5.b, an applicant shall be required to submit all the requested additional information within 14 days from the date of receipt of the request;
- (d) where an applicant does not respond to the request for additional information within 14 days, the application shall be rejected;
- (e) where an applicant fails to provide all the requested information, or the submitted information is incomplete, deficient or irrelevant, the application shall be rejected;
- (f) an application not submitted in the prescribed format shall be rejected; and
- (g) where an application has been rejected, the applicant shall be informed in writing providing reasons for the rejection.

6.7 Inspection of a Hospital Pharmacy for grant of Certificate of Registration

An application shall be inspected on a first-come, first-served basis.

Where the Authority processes an application for the Certificate of Registration for a hospital pharmacy, the applicant shall be informed of the outcome of the process through the online portal.

**7. PHARMACY PREMISES, EQUIPMENT AND FACILITIES****7.1 Appearance, Location and Design of Hospital Pharmacy Premises**

- (a) The premises shall be readily identifiable with signage which shall include; name of pharmacy section and working hours;
- (b) the premises shall be located in an area easily accessible to patients and staff of the hospital;
- (c) the premises shall be so designed, equipped and organised that they can fulfil their essential role in the protection of public health i.e. shall comply with statutory requirements, be of sufficient size with adequate facilities to provide the range of activities required of the pharmaceutical services; (refer to annexure 1 on *Minimum size requirements for a hospital pharmacy with different bed capacities*).
- (d) the design and layout of the premises must permit a logical flow of work, effective communication and supervision and ensure effective cleaning and maintenance and shall minimise the risk of errors, cross-contamination and anything else which would have an adverse effect on the quality of products;
- (e) all parts of the premises shall be maintained in an orderly and tidy condition;
- (f) the full registration certificate of the responsible person and valid practicing certificates for all licensed pharmacy personnel shall be displayed conspicuously in the hospital pharmacy in accordance with the provisions of the Health Professions Act, 2024;
- (g) the external appearance of premises shall inspire confidence in the nature of the health care service that is provided and portray a professional image.

7.2 Security and Safety in Hospital Pharmacy Premises

- (a) The premises and their contents shall be in an area where they can be securely locked to minimise the risk of burglary;
- (b) careful consideration shall be given to the overall security of the pharmacy. It must be lockable and as far as possible exclude any unauthorised entry;
- (c) a security policy shall be implemented to safeguard, as far as practicable, the safety of both staff, medicines and allied substances;



- (d) control of access to pharmacy premises, which would include the design and layout of the pharmacy, shall be of such a nature that only authorized personnel have direct access to medicines and allied substances;
- (e) working conditions shall ensure the safety of the public and persons working on the premises and comply with relevant workplace safety legislation ;
- (f) there shall be appropriate firefighting facilities that are easily accessible. In case of fire extinguisher(s), these should be serviced;
- (g) all staff shall be familiar with the fire safety procedure;
- (h) electrical equipment (e.g. electric kettle) shall be safe and maintained regularly; and
- (i) proper provision shall be made for an adequate number of electrical sockets and care shall be taken to avoid trailing wires across floors, work surfaces or sinks.

7.3 Condition of Hospital Pharmacy Premises

- (a) The floors, walls, windows, ceiling, woodwork and all other parts of the premises shall:
 - be made of durable and easy to clean materials;
 - be maintained in good repair and kept clean and orderly at all times to prevent infestations, and maintain a safe, hygienic and professional environment;
- (b) countertops, shelves, floors and walls be with a smooth finish, washable, and easy to clean material for the purposes of maintaining hygienic conditions;
- (c) the premises shall have adequate natural and/or artificial ventilation;
- (d) the premises shall have sufficient natural and/or artificial lighting, and the walls, floors and ceiling are in a good state of repair;
- (e) the premises shall have a leak-proof roof;
- (f) the premises shall have clearly partitioned areas for carrying out specific activities such as dispensing, wards supply, bulk storage of medicines and allied substances; and
- (g) the premises shall have adequate sanitation facilities such as toilets and hand-washing utility.

**7.4 Environment in Hospital Pharmacy Premises**

- (a) There shall be preventative maintenance schedules for key equipment such as refrigerators, air conditioners and fire-fighting facilities;
- (b) there shall be environmental monitoring facilities which may include thermometers (room and refrigerator), data loggers and hygrometers. The readings from these environmental monitoring devices shall be regularly recorded and maintained for at least two (2) years;
- (c) levels of heat, light, noise, ventilation, etc., shall exert no adverse effects on medicines and allied substances as well as personnel;
- (d) all parts of the premises shall have suitable and effective means of heating or cooling, lighting and ventilation;
- (e) windows shall be lockable and secured at all times when the pharmacy is closed; and
- (f) background music or other broadcasts in the pharmacy shall not be played at such a volume so as to cause distraction.

7.5 Hygiene in Hospital Pharmacy

The following will generally apply:

- (a) an area with access to running water shall be provided for washing equipment and other utensils;
- (b) a suitable handwashing basin of smooth, impermeable material shall be provided and maintained in a hygienic condition, with a supply of clean running water and a closed drainage system;
- (c) toilet facilities shall be appropriately located, designed and equipped and kept clean and in good order and shall not open directly into the dispensing and/or storage area of medicines and allied substances;
- (d) handwashing facilities shall be provided in toilet areas or adjacent passages, together with a conspicuous notice requesting users to wash their hands. Facilities shall include an adequate supply of clean water, soap and clean paper towels or other means of drying the hands;
- (e) toilet areas shall not be used for storage, or as a source of water for dispensing;
- (f) "No smoking" signs shall be put in places where they are easily noticed and read;



- (g) food shall not be kept and/or eaten in the dispensary and storeroom; and
- (h) all parts of the premises shall be maintained in an orderly and tidy condition.

7.5.1 Waste Management

The principles of waste management are

- (a) waste avoidance;
- (b) waste recycling;
- (c) waste disposal.

The aims of waste management are;

- personal protection;
- environmental protection.
- a suitable and adequate means of waste disposal shall be available and in use;
- hand free or pedal waste bins shall be provided and be emptied daily;
- waste material shall not be allowed to accumulate and should be collected in suitably covered receptacles (as applicable) and promptly removed to designated collection points; and

under no circumstances shall substances or waste be disposed of into surface water drains, including storm water drains. All waste shall be disposed of through approved and designated waste disposal systems only.

7.6 Storage Areas in Hospital Pharmacy

- (a) Storage areas shall have sufficient shelving constructed from a smooth, easy to clean and impermeable material, which is easy to maintain in a hygienic condition for the keeping of medicines and allied substances above floor level;
- (b) the premises shall have sufficient pallets for keeping medicines above the floor (preferably of plastic material);
- (c) storage areas shall be large enough to allow for orderly arrangement of stock and proper stock rotation;



- (d) thermolabile medicines and allied substances shall be stored strictly in accordance with the manufacturer's specified storage instructions; and
- (e) medicines and allied substances shall be protected from the adverse effects of light, temperature extremes and dampness. There shall be air conditioning facilities.

8. DISPENSARY

8.1 Size of dispensary

- (a) The size of the dispensary shall reflect the volume of prescriptions dispensed and allow a safe and efficient flow of work and effective communication and supervision for the number of persons working in the dispensary; (refer to the annexure 1 on *Minimum size requirements for a hospital pharmacy with different bed capacities*).
- (b) the minimum area for the dispensary necessary to allow a safe and efficient flow of work and effective communication and supervision; and
- (c) dispensaries in new pharmacies shall be designed to accommodate the forecast workload, and the maximum available space must be allocated.
- (d) In existing pharmacies space requirements shall be monitored on a continuing basis.

8.2 Suitability of dispensary

- (a) The dispensary, its fittings and equipment shall be adequate and suitable for the purpose of dispensing;
- (b) the dispensary surface area shall be sufficient for the volume of prescriptions dispensed. A clear working surface area of at least 100 cm x 90 cm shall be provided for each pharmacist or any other person who works in the dispensary;
- (c) all working surfaces, cupboard and shelves in the dispensary shall be finished with smooth, impervious and easy to clean materials and maintained in a good state of repair;
- (d) the temperature in the dispensing area shall be maintained below 30°C by way of installing temperature regulating facilities e.g. an air-conditioner, or ensuring adequate ventilation for free air circulation; and



- (e) working conditions shall be so arranged as to protect the safety of the public and people working on the premises.

8.3 Dispensing equipment

A pharmacist shall satisfy himself/herself that equipment on premises is adequate and suitable for all the operations to be carried out.

There shall be adequate, suitable dispensing equipment in the dispensary. Each item shall be clean, in good repair and of suitable material. The list below provides a standard. Equipment shall be specific for each service which may be provided in the pharmacy:

- (a) a suitable means of counting tablets and capsules. This equipment shall be cleaned regularly so that cross-contamination between products is avoided;
- (b) an accurate dispensing balance with proof of annual maintenance (if compounding is performed in the pharmacy);
- (c) a range of graduated, tempered glass or plastic measures;
- (d) a refrigerator equipped with a suitable thermometer which is capable of storing products at temperatures between 2°C and 8°C. The refrigerator shall be cleaned, defrosted and checked periodically to ensure efficient running. This refrigerator shall be used only for storing pharmaceutical products. Where applicable, a freezer for the storage of polio and measles vaccines and ice packs should be available;
- (e) a suitable range of dispensing containers for medicinal products. The use of child-resistant closures is encouraged;
- (f) dispensing labels. Additional warning labels shall be available, unless those warnings are printed on the dispensing labels. Where computer software is relied on for warnings/interactions, this shall be the latest version available;
- (g) an ointment slab and spatula, stirring rods, pestles, mortars and other appropriate equipment (if compounding is performed in the pharmacy; use of stainless steel and glass is recommended, not enamelled iron or plastics);



- (h) where sterile or aseptic dispensing is to be carried out, suitable facilities shall be available;
- (i) where cytotoxic or other hazardous substance preparation is to be carried out, a suitable biosafety cabinet that complies with generally accepted GMP standards shall be provided;
- (j) suitable means for sterilisation of medicinal products if products that require sterilisation are prepared in the pharmacy;
- (k) suitable refuse receptacles; and
- (l) distillers (or at least distilled water for reconstitution).

8.4 Compounding room / area

Where an area/room for compounding is allocated under the hospital pharmacy, the following shall be considered:

- (a) for compounding and pre-packing activities, suitable separate facilities that comply with GMP standards shall be provided; and
- (b) for radioactive pharmaceuticals preparation, the premises shall comply with the requirements for aseptic preparation and be in line with GMP standards. The premises shall also meet the requirements for radioactive products and a suitable cabinet that complies with GMP standards shall be provided.
- (c) There shall be a quality procedure and a formulary in place

9. REFERENCE SOURCES IN THE HOSPITAL PHARMACY

The following reference material in hard or electronic (soft) copy of the current editions shall be available for consultation in all pharmacies:

9.1 Mandatory

- (i) the latest edition of Zambia National Formulary;
- (ii) the latest copy of the Standard Treatment Guidelines; and

Essential Medicines List for the appropriate level of care;

- (iii) A medical dictionary;



(iv) Copies of the following statutes:

- Medicines and Allied Substances Act No. 3 of 2013;
- Controlled Substances Act No. 2 of 2023;
- Health Professions Act No. 17 of 2024; and
- Narcotic Drugs and Psychotropic Substances Act No. 35 of 2021;

(v) standards of hospital pharmacy practice;

9.2 Recommended

(i) British National Formulary (BNF) adult/paediatric

Martindale

- (i) pharmacopoeia (BP, USP, EP) (where applicable); and
- (ii) other relevant reference materials.

10. WAITING AREA

- (a) A waiting area(s) with comfortable seating shall be provided and situated near the dispensing area;
- (b) the amount of seating available in the waiting area shall depend on the number of patients expected to arrive in/at the pharmacy any one time; and
- (c) appropriate health-related literature may be provided.

11. AREAS FOR COUNSELLING AND THE FURNISHING OF ADVICE

A minimum standard for pharmacies where medicines are supplied directly to the public is a suitable area for the furnishing of advice to patients in a reasonably private environment. The following minimum requirements apply:

- (a) the area(s) shall be easily accessible and, where possible, be close to the dispensary;
- (b) clear directions shall be provided if the area is not close to the dispensary;



- (c) the area(s) shall be constructed in such a manner as to ensure reasonable privacy to the patient at all times and eliminate background noise as far as possible;
- (d) the area(s) shall have a professional appearance and be kept clean and tidy; and
- (e) the area(s) shall have sufficient space to promote appropriate counselling and demonstration of the correct and safe use of specific medicines as required.

12. BULK STORE

There shall be a designated storage area that shall provide the following:

- (a) adequate storage facilities that have adequate shelving which are smooth, easy to clean and impermeable;
- (b) an adequate number of pallets, trolleys and pallet trolleys as befits the scale of operation;
- (c) refrigerator or cold room for cold-chain products,
- (d) environmental monitoring facilities such as thermometers (room and refrigerator), data loggers and hygrometers. The readings from these environmental monitoring devices shall be regularly recorded and maintained;
- (e) hands free/pedal waste bin;
- (f) a lockable area for storage of controlled substances or substances prone to illicit use;
- (g) artificial ventilation such as air conditioner(s) and central cooling system(s);
- (h) fire-fighting facilities that are easily accessible. In case of fire extinguisher(s), these shall be serviced;
- (i) natural ventilation; i.e. doors, windows and air vents;
- (j) security and safety facilities such as burglar bars, alarms, CCTV;
- (k) a separate and secure goods receiving area(s); and
- (l) a separate and secure goods dispatch area.



13. PROCUREMENT

The medicines and allied substances to be procured for supply in a hospital pharmacy shall have Marketing Authorisation or exemptions obtained from the Authority. Procurement should be done in accordance with the Good Procurement Practice (GPP) and shall comply with the regulatory requirements.

13.1 Responsibility for procurement

Pharmaceutical aspects of the purchase of all medicines and allied substances shall be the responsibility of a pharmacist and shall be purchased from registered pharmaceutical wholesale dealers or manufacturers licensed with the Authority.

Written SOPs for the procurement, storage and distribution of medicines and allied substances shall be available in the pharmacy. Written policies shall assist in ensuring:

- (a) product availability when required;
- (b) that the procurement and distribution process is fully documented;
- (c) effective batch recall of medicines when necessary;
- (d) that optimal storage conditions are monitored (including during transport); and
- (e) the safety of medicines.

14. SUPPLY OF MEDICINES AND ALLIED SUBSTANCES

In the diagnosis, prevention, alleviation or treatment of human disease, medicines play a crucial role. Since medicines play such an important and indispensable role in health care delivery: -

- they shall be available
- they shall be properly kept
- they shall be efficiently distributed
- their quality, efficacy and safety shall be assured
- they shall be well controlled



- information about them shall be readily available
 - education about them shall be regularly updated and continuously available
 - they shall be subject to frequent / continuous investigation and review
- (a) the pharmacist in charge of the pharmacy department has a professional responsibility to exercise control over all medicines and allied substances, which are supplied;
- (b) a purchasing policy shall be in place that ensures the safety of medicines;
- (c) a pharmacist shall not purchase or supply any medicine or allied substance where the pharmacist has any reason to doubt its safety, quality or efficacy;
- (d) a pharmacist shall be satisfied that both the supplier and the source of any medicine purchased are reputable and authorised by the Authority. Due regard shall be paid to the storage conditions before purchase and to the labels, leaflets, appearance, origin and subsequent chain of supply of the medicine concerned;
- (e) marketing authorisation number shall appear on the original container of every medicine in the facility, with the exception of unregistered medicines for which authority for the use thereof has been granted by the Authority;
- (f) stock rotation shall always be done on the 'FIRST EXPIRY, FIRST OUT' (FEFO). or 'FIRST IN – FIRST OUT' (FIFO) basis.; and
- (g) patients receive stock that has been suitably stored and has an expiry date that allows sufficient time for usage by the patient before the expiry date.

14.1 Dispensing procedure

Medicines and allied substances in a hospital pharmacy shall be dispensed in accordance with the good pharmacy practices and guidelines that shall be issued by the Authority from time to time.

The pharmacist shall ensure that the prescription is valid, that the medicine is clinically appropriate for the patient, and that information is provided to ensure safe and appropriate use of the medicine.

The process of dispensing includes:



- (a) receiving and validating a prescription;
- (b) ascertaining the authority of the prescriber to prescribe;
- (c) obtaining any supplementary information to enable:
 - i. the patient to be properly identified so the medicine is dispensed to the person for whom it is intended, and
 - ii. the medicine to be dispensed safely.
- (d) determining the prescriber's intentions as to the patient's medicine, including the dosing instructions;
- (e) reviewing the medication history and other relevant patient information, to ensure that the medicine is safe and proper for the patient to use and that where possible, all other relevant considerations of the patient's health, including the use of any other prescription and non-prescription medicine such as complementary and alternative medicines, are taken into account;
- (f) entering the prescription details on the pharmacy computer or prescription book and recording any other aspect of the dispensing according to the requirements of the law;
- (g) generating a label for the dispensed medicine and a repeat authorisation where required;
- (h) selecting or preparing the product intended by the prescriber;
- (i) clearly labelling the container of the medicine with the directions for its use as intended by the prescriber along with any other information that facilitates its proper, safe and effective use;
- (j) verify the selection of the correct product for the patient and carefully checking and re-checking all dispensing for accuracy and completeness;
- (k) counselling the patient, or the patient's caregiver, sufficiently to allow a proper understanding of all the information required by the patient to use the medicine safely and effectively and to motivate the patient to comply with that advice (which may include provision of printed supplementary information when required), and to allow for a final check of the dispensed medicine; and



- (l) ensuring that the entire dispensing process has been carried out according to good pharmacy practice and accepting that responsibility by placing his or her initials or signature in the prescription records of the pharmacy and any other place according to relevant legislation.

Prescriptions shall be: -

- (a) legible;
- (b) written by a recognised prescriber and indicate
 - official stamp and name in block letters
 - signature of prescriber
- (c) written by an authorised prescriber such as a medical doctor, dental surgeon or other legally authorised person, as the case may be;
- (d) in a standard prescription format as provided by the Authority;
- (e) dispensed by a pharmacist or under the direct supervision of a pharmacist by a pharmacy technologist; and
- (f) prescription shall be kept for at least two (2) years at the site where it was dispensed before being archived.

14.2 Safety in dispensing procedure

- (a) A pharmacist shall take reasonable steps during the dispensing process (detailed in 7.1- the dispensing process) to ensure that the dispensing of a medicine or an allied substance in accordance with a prescription or order is consistent with the safety of the person named in that prescription or order;
- (b) ambiguously written prescription shall not be dispensed;
- (c) where clarification is required, the patient or their caregiver shall be consulted and if necessary, the prescriber contacted. If the prescriber cannot be contacted, or if on consultation with the prescriber there is a difference in opinion regarding the safety of the prescription, professional judgement shall be exercised by the pharmacist in deciding appropriate action to take;



- (d) if the pharmacist decides not to dispense the prescribed medicine or allied substance in the interest of the patient's safety, the patient shall be informed about the reasons for the decision and the alternative options available to the patient regarding their medication needs;
- (e) in conforming to the above principle, dose, frequency and route of administration, duration of treatment, the presence or absence of other medicines, the patient's illness, medication history, allergies, and other relevant circumstances need to be taken into account; and
- (f) the dispensing process shall not be distracted by loud noise, music and other unrelated activities.

14.3 Dispensing containers

A pharmacist shall understand the function, design and use of the containers used in dispensing of medicines and allied substances depending on the intended use and type of container., among the qualities to be considered include:

- (a) physicochemical properties;
- (b) light-transmission for glass or plastic;
- (c) drug compatibility;
- (d) leaching and/or migration;
- (e) vapor transmission for plastics;
- (f) moisture barrier;
- (g) toxicity for plastics;
- (h) sterility and permeation for parenteral containers; and
- (i) drug stability for all packaging.

In selecting a container or package for a finished compounded preparation, it is important to realize that although a drug may be stable when stored in one type of container (glass), it may not be stable in a plastic (polyvinylchloride) container or an infusion device made of an elastomer. Glass is generally



considered to be the most inert and stable container material, but plastic has gained wide acceptability and usefulness.

Prior to being used, a container shall be;

- i. visibly clean and free from any foreign particles;
- ii. not interact physically or chemically with the preparation it contains and alter the strength, quality, or purity of the article beyond the official requirements; and
- iii. have adequate space for labelling.

The container closure system shall maintain the integrity of the product and prevent contamination. If possible, it shall be tamper-proof and child-resistant.

14.4 Re-use of containers

Where the conditions above are able to be fulfilled then a container can be re-used but re-use of containers generally is not to be encouraged. Written SOPs for the re-use of containers shall be available in the pharmacy.

14.5 Re-use of returned medicines

Medicines and allied substances returned to the pharmacy by patients or caregivers will under no circumstances be used by anyone else. These shall be disposed of according to the guidelines and regulations of safe disposal issued by the Authority.

Medicines and allied substances returned from within the facility, where the pharmacist is satisfied that the recommended storage conditions were maintained, may be re-used.

14.6 Unwanted, Expired and Obsolete medicines and allied substances

Particular care shall be taken with prescriptions for several months' treatment. Where a quantity covering a longer period is dispensed, the pharmacist shall ensure that the product will still be in date at the end of that period.

- (a) unwanted, Expired and/or Obsolete medicine or an allied substance shall not be dispensed or supplied to the public;
- (b) where a medicine or allied substance is unwanted, expired and/or obsolete, the pharmacist shall:



- (i) separate the medicine or allied substance from usable stock; and
 - (ii) record the details of the medicine or allied substance in the expired products register and update the stock control card.
- (c) unwanted, expired and obsolete medicines and allied substances shall be stored in a dedicated and secure area to prevent their re-use; and
- (d) disposal of unwanted, expired and obsolete medicines and allied substances shall be conducted in accordance with the guidelines and regulations of safe disposal issued by the Authority.

14.7 Labels

- (a) labelling of dispensed products shall be clear, legible and indelible;
- (b) for proprietary medicines; the brand and generic names of the medicine, the strength, the dose form and the quantity supplied shall be indicated on the label in accordance with labelling legislation and guidelines; and
- (c) for compounded medicines, the name and strength of each active ingredient (especially if a formulation other than a standard pharmacopoeia formulation is used), the name and strength of any added preservatives, the name of the formula as described in a standard pharmacopoeia reference book (where applicable), the dose form and the quantity supplied. Additionally, the label shall have the following details;
 - i. the name of the patient for whose treatment such medicine is supplied;
 - ii. the dosage, route of administration and directions in regard to the manner in which such medicine shall be used;
 - iii. the name and address of the pharmacy authorised to supply such a medicine;
 - iv. date of dispensing;
 - v. the applicable storage directions and beyond use date of the medicine which are required to facilitate the safe and effective use of the medicine by the patient
 - vi. the words 'Keep out of reach of children', and



- vii. for compounded medicines, the words 'This product has been compounded by the pharmacist'.

15. RECORD KEEPING

Prescription registers or other permanent record in respect to prescription only medicines according to section 40 (1) (a) of the Medicines and Allied Substances Act No.3 of 2013 of the Laws of Zambia should be kept on all premises where prescribed medicines and allied substances are dispensed and shall contain the following details:

- (a) the name of the patient;
- (b) the name of the medicine (ingredient);
- (c) the date on which the prescription was dispensed;
- (d) the dosage form and quantity of the medicine;
- (e) the name and address of the patient;
- (f) , the name and address of the medical doctor, dental surgeon, or any other authorised person who issued the prescription; and
- (g) prescription reference number.

Prescriptions shall be properly filed for at least 2 (two) years before submission into the archive. Record keeping shall include record of suppliers.

When a pharmacist does not have all medicines and allied substances on a prescription, he / she shall dispense that which is available and retain a copy prescription. The original shall be given to the patient provided he indicates / crosses off which medicine and/or allied substance has been dispensed.

Documentation / Record Keeping Facilities: where applicable, the following shall be provided:

- (a) bin cards (stock control cards);
- (b) computer or equivalent device;
- (c) controlled drugs register;



- (d) delivery notes (where applicable);
- (e) expired products register;
- (f) file for prescriptions;
- (g) receipt/issue books;
- (h) prescription book;
- (i) recalled products register;
- (j) goods received note (GRN);
- (k) ZAMRA inspectors' book;
- (l) Stock ledger (where applicable)
- (m) import permit (where applicable); and
- (n) pharmacovigilance report forms.

Pharmacies shall keep an inventory of medicines in stock to include the following details:-

- date of transaction;
- products name, including batch number, manufacturing date;
- supplier / manufacturer;
- invoice; and
- quantity.

Incident records

(a) Pharmacists are to ensure that incident records are maintained that show:

- (i) when the incident was recorded;
- (ii) when it occurred;
- (iii) who was involved (both actual and alleged);
- (iv) the nature of the incident or complaint;



- (v) what actions were taken;
- (vi) any outcomes; and
- (vii) who recorded the incident.

(b) Dispensing errors, significant other errors, omissions and other non-compliances, including complaints of a non-commercial nature arising both within and external to the pharmacy, shall be the subject of investigation.

(c) Incident reports on adverse reactions to products and product quality problems shall be reported to the National Pharmacovigilance Unit at the Authority. If possible, samples of the product in question shall accompany the report.

(d) there shall be a written risk management procedure including appropriate record keeping of events.

This assists pharmacists in managing such incidents.

16. RECALLS

- (a) A pharmacist shall comply immediately with any notice of recall of medicines and allied substances;
- (b) a pharmacist shall actively participate in any arrangements made for warning other healthcare professionals and the general public of problems associated with medicines and allied substances, and shall inform appropriate bodies accordingly;
- (c) recalled medicines and allied substances shall be separated from usable stock, recorded in the recalled products register and stored in a dedicated and secure area to prevent their re-use; and
- (d) every hospital pharmacy shall have SOPs on handling recalled products and they shall be displayed conspicuously.

17. PERSONAL HYGIENE

- (a) high standards of personal cleanliness shall be observed in dispensing. Regular hand washing shall be practiced;
- (b) direct contact between the dispensed product and the operator's hands shall be avoided;



- (c) cuts or abrasions shall be covered with a suitable occlusive dressing. A person with an open lesion or readily transmittable infection shall report to the pharmacist who will decide whether they may be engaged in the dispensing process; and
- (d) no personnel shall smoke or prepare or consume food in any area where medicines and allied substances are dispensed or supplied.

18. PERSONNEL, EDUCATION, TRAINING, DEVELOPMENT, ADMINISTRATION, MANAGEMENT AND PROFESSIONAL INDEMNITY

18.1 Personnel

A hospital pharmacy shall be managed by a full-time pharmacist, who must have a minimum of a degree in Pharmacy from a recognised institution and be fully registered with the Health Professions Council of Zambia (HPCZ); and possess a valid annual practising certificate.

A hospital may have other personnel, who shall be under direct supervision of a pharmacist. These may include;

- (i) intern pharmacists;
- (ii) pharmacy technologists; and
- (iii) Support staff which may include: -
 - porters
 - cleaners
 - security guards

The hospital pharmacy shall engage adequate pharmaceutical personnel commensurate to the patient load and hospital size to ensure provision of quality pharmaceutical services.

The pharmacist(s) and pharmacy support personnel on duty should wear a name tag or badge indicating his/her name, surname and registered designation (e.g. cleaner, pharmacist, etc.) for the purposes of identification of such person by the public. This may be combined into a single badge or two separate badges.

**18.2 Training****18.2.1 All pharmaceutical personnel shall keep abreast with developments in pharmaceutical services, by: -**

- (a) reading current pharmaceutical literature;
- (b) attending necessary workshops and seminars;
- (c) further training in clinical pharmacy / pharmacy practice;
- (d) undergoing first aid training;
- (e) ensuring that the philosophy underlying practice is professionally rather than commercially orientated;
- (f) accepting personal responsibility for the self-assessment and maintenance of competence throughout their involvement in the profession; and
- (g) adhering to good pharmacy practice.

Educational programmes for entry to the profession and continuing professional development programmes shall address contemporary practice appropriately as well as foreseeable changes in the practice of pharmacy.

In addition, pharmaceutical personnel shall be aware of legislative changes in the practice and be able to implement them.

18.3 Premises for training of Pharmacist Interns and Students

The facility (hospital pharmacy) where such rotation would take place for purposes of practical training, the period(s) that such services would be provided, as well as the name of the pharmacist under whose supervision the intern or student would work, shall be submitted for approval by HPCZ in collaboration with the professional body and other relevant authorities before the internship commences.

18.4 Support staff

The responsible pharmacist in collaboration with other relevant units shall develop training modules for all the staff in order to improve the level of competence and correct deficiencies in day-to-day work.

Pharmacist responsible for training of support staff shall: -



- (a) take into consideration their level of education;
- (b) conduct needs assessment for the planned training;
- (c) provide training in hygiene, staff client relationship, handling of medicines, dress, etc.; and
- (d) maintain records for all trainings conducted.

18.5 Management / Administration

Sound management structures and clearly defined responsibilities shall be defined for pharmacy administration and management. A sound management structure shall be established to ensure the efficient provision of services. Lines of professional and managerial accountability shall be established and be subject to regular review.

- (a) a pharmacist employed in administrative, management or advisory positions shall have a clearly defined role and responsibility; and
- (b) the responsible pharmacist shall ensure that there are sufficient pharmacists and pharmacy support personnel to undertake the pharmaceutical services provided by the institution or pharmacy concerned.

19. HOSPITAL PHARMACY MANAGEMENT

- (a) The responsible pharmacist shall demonstrate a high standard of professionalism and a commitment to quality development;
- (b) The management structure of the pharmacy shall be documented with a clear allocation of duties and responsibilities established and properly recorded;
- (c) The responsible pharmacist shall ensure that all regulations covering the operations of the hospital pharmacy are complied with;
- (d) The hospital pharmacy operation shall comply with all relevant legislations, guidelines and standards;



- (e) The responsible pharmacist shall ensure that there is quality improvement of all hospital pharmacy staff in collaboration with other healthcare professionals for those areas of mutual responsibility in order to achieve quality service;
- (f) The responsible pharmacist shall ensure that a collection of all legislation and guidelines relevant to hospital pharmacy are maintained in a current state and be accessible by all pharmacy staff; and
- (g) Documented procedures shall be in place to ensure that hospital pharmacy staff are aware of relevant legislation, and apply this to the handling, supply and required record keeping of medicines and allied substances available in the pharmacy.

19.1 Quality standards for the pharmacy

The pharmacy's quality objectives shall reflect the need for both the provision of client-focused services and the continuous improvement of quality;

- (a) The Quality Improvement Plan shall detail:
 - (i) the quality standards for services provided by the pharmacy;
 - (ii) processes that operate in the pharmacy and the resources devoted to them (including staff);
 - (iii) how client feedback will be obtained for services provided;
 - (iv) how other evidence supporting the achievement of quality standards will be obtained and recorded;
 - (v) how resources and training relevant to the quality management responsibilities of each staff member are allocated;
 - (vi) the frequency of assessment of the plan to ensure that it is producing a continuous improvement of service;
- (b) the pharmacist in charge of the hospital pharmacy shall ensure that the quality improvement plan for the pharmacy is developed, documented and approved by management. This provides a systematic plan for each of the service areas in the hospital pharmacy;



- (c) the quality improvement programme shall be assessed regularly;
- (d) a documented risk management system shall be integrated into the quality improvement process;
- (e) standard Operating Procedures must be developed, documented and used in the pharmaceutical activities of the pharmacy and be reviewed periodically;
- (f) documentation of all pharmacy standards, procedures, policies and guidelines shall be comprehensive, current, readily available to all pharmacy staff and reviewed periodically; and
- (g) pharmacy staff shall be trained in the aspects of service quality management which are relevant to their work responsibilities.

19.2 Standard Operating Procedures

A Standard Operating Procedure (SOP) can be written for virtually any task undertaken in a hospital pharmacy that has to be performed regularly and in a pre-determined way.

The pharmacist in charge of the pharmacy is responsible for the development, implementation and the review of SOPs in a hospital pharmacy. SOPs shall be signed, dated, approved and reviewed at least every two years.

SOPs shall —

- (a) provide personnel with all the safety, health, environmental and operational information necessary to perform a task properly;
- (b) ensure that operations are performed consistently to maintain quality control of processes and products;
- (c) ensure that processes continue uninterrupted and are completed timeously;
- (d) ensure that no failures occur that could harm anyone;
- (e) ensure that approved procedures are followed in compliance with legislation;
- (f) serve as a training document, e.g. pharmacist interns or pharmacy technologists; and



- (g) serve as an explanation of steps in a process so that they can be reviewed in incident investigation.

The following SOPs shall be in place but not limited to the following:

- (a) complaint handling arising from medicines and allied substances;
- (b) contingency plan in the event that no pharmacist is present;
- (c) control, ordering and receipt of medicines and allied substances;
- (d) dispensing and supply of medicines and allied substances;
- (e) fire safety and use of firefighting equipment ;
- (f) sanitation and hygiene procedures;
- (g) management of recalled products;
- (h) management of the disposal of expired stock;
- (i) management of waste generated in the pharmacy;
- (j) reporting of adverse drug events/reactions;
- (k) management of quarantined products;
- (l) training;
- (m) monitoring of storage conditions; and
- (n) management of controlled substances.

20. RELATIONSHIP WITH PATIENTS, THE PUBLIC AND OTHER HEALTH PROFESSIONALS

20.1 Relationship with patients and the public

Pharmacist shall ensure the delivery of accessible, professional and quality patient-centred services to patients and the public.

- (a) provide pharmacy services that are accessible to patients and the public;



- (b) manage safe delivery of pharmacy services;
- (c) provide an appropriate stock of medicines and allied substances;
- (d) measure and evaluate patient outcomes to demonstrate commitment to quality service;
- (e) respond to patient and public feedback on service provision;
- (f) ensure an effective complaint procedure is available; and
- (g) respond quickly and appropriately to any complaint about care or service, and take appropriate action.

The pharmacist shall keep confidential all patient information obtained in the course of his/her duties.

20.2 Relationship with health care professionals

A pharmacist shall endeavour to co-operate with professional colleagues and members of other health professions so that patients and public benefit.

- (a) the ongoing relationship with other health care professionals shall be seen as a therapeutic alliance involving mutual trust and confidence in all matters relating to pharmacotherapeutics;
- (b) the relationship with other pharmacists shall be as colleagues, each seeking to improve pharmaceutical services, rather than as competitors;
- (c) there shall be input by the pharmacist regarding decisions on medicine use policy at all levels;
- (d) the relationship with those involved in paying for pharmaceutical services shall also be one of mutual trust, involving appropriate professional discretion from the pharmacist;
- (e) the pharmacist shall ensure that other health care professionals are provided with medicine information and information concerning prescribing and dispensing practices;
- (f) pharmacists shall seek opportunities to provide information to other health care professionals and groups on developments concerning medicines, the general role of



pharmacists, contents, packaging and processing of medicines, and the ancillary services offered by the pharmacy; and

- (g) a major emphasis of inter-professional teamwork shall be the development of more effective and rational prescribing policies. The pharmacist has a major role in influencing such policies.

21. MEDICINES AND THERAPEUTICS COMMITTEES

The Medicines and Therapeutics Committee is an advisory group of medical staff and serves as the organizational line of communication between medical staff and pharmacy department. It is the policy-recommending body to the medical staff and the administration of the hospital on matters related to the therapeutic use of medicines.

- (a) The Medicines and Therapeutics Committee(s) - MTC has the primary purpose of advising and educating professional staff on all matters pertinent and relevant to the use of medicines and allied substances in the hospital environment;
- (b) Regular liaison shall be maintained to develop policies and procedures relating to the selection and the rational, safe and effective use of medicines and allied substances, surgical dressings and medicine administration systems within the hospital's boundaries;
- (c) The Medicines and Therapeutics Committee(s) shall be a multi-disciplinary focal point for all policy decisions relating to the control of medicines within the hospital environment.
- (d) Membership shall be representative and shall be composed of at least a medical officer, pharmacist, nurse and midwife, administrator and other health care practitioners. The membership shall be in line with the MOH MTC guidelines
- (e) Terms of reference may include:
 - (i) the development and review of policies, rules and regulations regarding the use of medicines in the hospital;
 - (ii) the development and approval of a hospital formulary;
 - (iii) the promotion of rational use of medicines;



- (iv) establish programmes and activities and procedures that help ensure cost-effective medicines therapy;
- (v) plan suitable educational programmes for the hospital's professional staff on matters related to medicines use
- (vi) the provision of information on new medicines.
- (vii) Monitor and evaluate adverse drug reactions and medicines quality related problems.

22. MINIMUM REQUIREMENTS FOR HOSPITAL PHARMACIES PROVIDING MOBILE PHARMACEUTICAL SERVICES

22.1 Pre-Requisites for Conducting Mobile Pharmaceutical Services

- (a) Mobile units, from which pharmaceutical services are offered, shall be registered by the Authority;
- (b) only medicines and allied substances approved by the Authority may be provided from a mobile unit;
- (c) the mobile unit shall be under the continuous and direct supervision of a pharmacist; and
- (d) mobile pharmaceutical services shall comply with Good Distribution Practice (GDP) guidelines.

22.2 Mobile Unit, Facilities And Equipment

- (a) The mobile unit shall be:
 - (i) insulated with double-sided side panels and ceiling; and
 - (ii) cross-ventilated.
- (b) Working surfaces, cupboards, shelves and equipment in the mobile unit shall comply with the same requirements as community and institutional pharmacies.



- (c) Light conditions, temperature and humidity within the mobile unit shall comply with the requirements for the storage of medicine and allied substances, raw materials and packaging materials.
- (d) Separate facilities for the washing of hands and the cleaning of equipment shall be provided.
- (e) The working surfaces/space within the mobile unit shall be large enough to allow a person to perform dispensing functions.

23. MINIMUM REQUIREMENTS SPECIFICALLY RELATING TO A STORAGE AREA FOR PHARMACEUTICALS OUTSIDE THE PHYSICAL PREMISES OF A HOSPITAL PHARMACY

23.1 Management of a Storage Facility

Any storage area, which is not physically an integral part of the premises of a pharmacy, shall constitute part of a pharmacy registered by ZAMRA. Such a storage area shall:

- a) fall under the authority of the responsible pharmacist of the pharmacy of which it forms a part; and
- b) be operated in compliance with good pharmacy practice.

Thus, such a storage area cannot exist or operate independently of a pharmacy.

23.2 Condition of the Storage Area

- (i) The walls, floors, windows, ceiling, woodwork and all other parts of the storage area shall:
 - (i) be kept clean; and
 - (ii) be kept in such good order, repair and condition as to enable them to be effectively cleaned and to prevent, as far as is reasonably practicable, any risk of infestation.
- (ii) walls shall be finished in smooth, washable and impermeable material, which is easy to maintain in a hygienic condition;
- (iii) the storage area shall have an air-conditioner in good working order;



- (iv) light conditions, temperature and humidity within the storage area shall comply with the requirements for the storage of medicine, other pharmaceutical products, raw materials and packaging materials;
- (v) the temperature in the storage area shall be below 30°C;
- (vi) storage areas should have sufficient shelving constructed from smooth, washable and impermeable material, which is easy to maintain in a hygienic condition;
- (vii) storage areas should be equipped with pallets and racks;
- (viii) Equipment for cold chain products shall be maintained.
- (ix) storage areas for medicines and allied substances shall be secure; and
- (x) storage areas shall be large enough to allow for orderly arrangement of stock and proper stock rotation.

23.3 Control of Access to the Storage Area

- (i) The responsible pharmacist shall ensure that every key, key card or other device, or the combination of any device, which allows access to a storage area when it is locked, is kept only on his/her person; and
- (ii) control of access to the storage area shall be of such a nature that only a person authorised by the responsible pharmacist has direct access to medicines.

24. EMERGENCY SUPPLY OF MEDICINES AND ALLIED SUBSTANCES

- (a) Where the pharmacist is satisfied that the authorized prescriber by reason of an emergency is unable to furnish a prescription immediately, the pharmacist may supply the medicine if the prescriber undertakes to furnish the prescription within 72 hours following the supply of the medicine. Notwithstanding the aforesaid, supply shall not be repeated unless a prescription has been given.
- (b) The pharmacist shall ensure that there are quality procedures to manage emergency supply of medicines and allied substances.
- (c) A pharmacist shall do everything reasonably possible to assist a person in need of an emergency supply of medicine.

**25. 24-HOUR PHARMACEUTICAL SERVICES**

- (a) Hospital Pharmacies shall ensure timely access to essential pharmaceutical services and provide 24-hour coverage whenever feasible.
- (b) Facilities with intensive medication needs require continuous pharmacy coverage; satellite pharmacies may support extended hours.
- (c) When 24-hour on-site service is not possible, a registered pharmacist shall be available on call.
- (d) A limited supply of medications may be accessed after hours only by authorized, licensed healthcare professionals and only for urgent clinical needs.
- (e) All after-hours medication access shall be restricted, monitored, documented, and regularly reviewed for appropriateness.
- (f) The Medicines and Therapeutics Committee (MTC) shall establish the list of medications allowed for after-hours access and the related procedures, including pharmacist review.
- (g) Medication risks shall be considered, and accessible quantities, dosage forms, and container sizes must be limited to reduce abuse or harm.
- (h) Routine after-hours entry into the pharmacy by non-pharmacists is strictly prohibited; secure alternatives (night cabinets, medication trolleys) shall be used instead.



ANNEX I: Proposed Minimum Size Requirements for a Hospital Pharmacy with Different Bed Capacities

SN	BED CAPACITY	Waiting Area	Dispensing/ Consultation Area	Bulk Store	Flammable Storage Area	Quarantine Area/Recall Room	Expired Room	Office Space	Total Required Area
1.	1 - 50 Beds	5m x 10m (50m ²)	5m x 10m (50m ²)	20m x 10m (200m ²)	5m x 10m (50m ²)	5m x 10m (50m ²)	5m x 10m (50m ²)	5m x 10m (50m ²)	500m ²
2.	50 - 100 Beds	10 x 10m (100m ²)	20m x 10m (200m ²)	40m x 10m (400m ²)	10m x 10m (100m ²)	10m x 10m (100m ²)	5m x 10m (50m ²)	5m x 10m (50m ²)	1000m ²
3.	100 - 200 Beds	20 x 10m (200m ²)	40m x 10m (400m ²)	80m x 10m (800m ²)	20m x 10m (200m ²)	20m x 10m (200m ²)	10m x 10m (100m ²)	10m x 10m (100m ²)	2000m ²
4.	200 - 300 Beds	30 x 10m (300m ²)	60m x 10m (600m ²)	100m x 10m (1,000m ²)	30m x 10m (300m ²)	40m x 10m (400m ²)	20m x 10m (200m ²)	20m x 10m (200m ²)	3000m ²
5.	300 - 500 Beds	40 x 10m (400m ²)	100m x 10m (1,000m ²)	200m x 10m (2,000m ²)	40m x 10m (400m ²)	60m x 10m (600m ²)	40m x 10m (400m ²)	20m x 10m (200m ²)	5000m ²

ANNEX II: Medicines Expiry Register

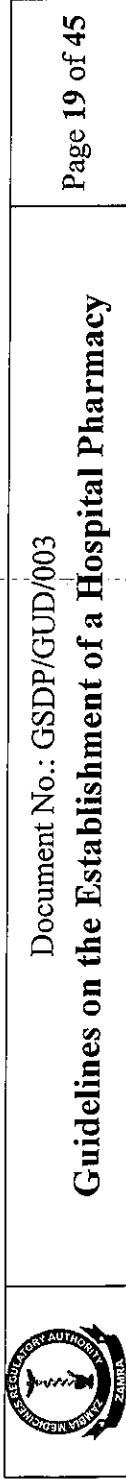
[illegible]

ANNEX III: Prescriptions Book

[illegible]

ANNEX IV: Product Recall Register

[illegible]



ANNEX V: ZAMRA Inspectors' Book

[illegible]