

Zambia Medicines Regulatory Authority

**GUIDELINES FOR ESTABLISHMENT OF A PHARMACEUTICAL RETAIL BUSINESS IN
ZAMBIA**

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TABLE OF CONTENTS

Contents

1. INTRODUCTION	3
2. OBJECTIVE	3
3. SCOPE	3
4. DEFINITION	4
5. ABBREVIATIONS	5
6. APPLICATION PROCEDURE FOR ISSUANCE OF A CERTIFICATE OF REGISTRATION	5
7. SUBMISSION OF THE APPLICATION	5
8. LICENSING PROCEDURE: AN OVERVIEW	6
9. PERSONNEL REQUIRED IN A PHARMACEUTICAL RETAIL BUSINESS	7
10. STANDARDS FOR RETAIL PHARMACY PREMISES	10
11. DISPOSAL OF UNFIT MEDICINES AND ALLIED SUBSTANCES	13
12. RECALL OF MEDICINES AND ALLIED SUBSTANCES	14
13. STANDARD OPERATING PROCEDURES (SOPS)	14
14. RELATIVE PARTITIONING	14
15. STOCK SURVEILLANCE FACILITIES	16
16. REFERENCE MATERIALS	16
17. NOTIFICATION OF ANY CHANGES RELATING TO LICENSED PREMISES	17
ANNEX I: Medicines Expiry Register	20
ANNEX II: Prescriptions Book	17
ANNEX III: Product Recall Register	18
ANNEX IV: ZAMRA Inspectors' Book	19



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 Pharmaceutical Retail Business 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 Pharmaceutical Retail Business 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 Pharmaceutical Retail Business.

It is unlawful for any person to establish, operate, manage or conduct a Pharmaceutical Retail Business or to sell, supply or dispense medicines and allied substances in a Pharmaceutical Retail Business 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.

2. OBJECTIVE

These guidelines provide guidance on the requirements for establishment of a Pharmaceutical Retail Business in Zambia.

3. SCOPE

These guidelines define the minimum requirements for the establishment of a pharmaceutical retail



business in Zambia. They also provide guidance for amendment of the Certificate of Registration.

4. DEFINITION

The definitions given below apply to the terms used in this guideline and they may have different meanings in other contexts and documents.

“Act” means the Medicines and Allied Substances Act, 2013.

“Authority” means the Zambia Medicines Regulatory Authority.

“Contract of employment” means a written agreement establishing an employment relationship between an employer and employee.

“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 or animal, but does not include the administration of medicine.

“Product recall” means a process for withdrawing or removing a medicine and allied substance from the distribution chain because of defects in the product, complaints of serious adverse reactions to the product and/or concerns that the product is or may be falsified. The recall might be initiated by the manufacturer, importer, wholesaler, distributor or a responsible agency.

“Quarantine” means the status of medicine and allied substance isolated physically or by other effective means while a decision is awaited on their release, rejection or reprocessing.

“Standard operating procedure” means an authorized written procedure giving instructions for performing operations that are not necessarily specific to a given product but of a more general nature (e.g. equipment operation, maintenance and cleaning, validation, cleaning of premises, environmental control, sampling and inspection).

“Responsible Person” means a duly qualified pharmacist engaged to manage a pharmacy.

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

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

Administrative amendment: means an amendment to a Certificate of Registration which involves a change in trading name, composition of directors in a company, change in responsible person.

Structural amendment: means any changes that are made to a licensed or approved premises post licensure. These include but are not limited to change in floor, layout.



Unfit Medicines and allied substances: means obsolete, unwanted, expired, improperly sealed, damaged, improperly labeled, substandard, falsified, adulterated, prohibited or unauthorized medicines and allied substances

Compounding: means the preparation, mixing, assembling, altering, packaging and labelling of a medicine or allied substance in accordance with a licensed practitioner's prescription, medication order or initiative based on the practitioner–patient–pharmacist relationship.

5. ABBREVIATIONS

HPCZ - Health Professions Council of Zambia

SOP - Standard Operating Procedure

ZAMRA - Zambia Medicines Regulatory Authority

6. APPLICATION PROCEDURE FOR ISSUANCE OF A CERTIFICATE OF REGISTRATION

- 6.1 A person who intends to operate a pharmaceutical retail business shall apply to the Authority in a prescribed manner and form and upon payment of the prescribed fee.
- 6.2 An application made in accordance with clause 7.1 above shall be accompanied by a:
 - 6.2.1 Valid Certificate of Incorporation, business name registration certificate, certificate of registration of a cooperative or certificate of incorporation of a trust
 - 6.2.2 Valid Business Levy Permit and Fire Certificate issued by the local authority
 - 6.2.3 Valid Full -Registration Certificate and Annual Practicing Certificate for the responsible person* (registered responsible personnel see 9.1) who shall personally manage and control the pharmaceutical retail business during its operating hours;
 - 6.2.4 Contract of employment or agreement letter signed by both parties, i.e the employer and employee; and
 - 6.2.5 Sketch of the floor plan for the premises.

7. SUBMISSION OF THE APPLICATION

- 7.1.1 A complete application shall be submitted to the Authority in the prescribed manner and form



upon payment of the prescribed fees.

- 7.1.2** Where the Authority finds that the application is incomplete, the Authority shall request for additional information as set out in a prescribed form.

8. LICENSING PROCEDURE: AN OVERVIEW

8.1 The licensing process of a pharmaceutical retail business shall include the following:

- 8.1.1** Lodgment of an application;
- 8.1.2** Screening of an application to ensure that relevant documents are attached to the application. Where the Authority finds that the application is incomplete, the Authority shall request for additional information as set out in a prescribed form;
- 8.1.3** Pre-licensing inspections are carried out by the Authority's inspectors to assess conformance of the applicant's premises to the set standards;
- 8.1.4** A pre-licensing inspection report is generated containing findings and relevant recommendations;
- 8.1.5** The licensing committee scrutinises the pre-licensing inspection report and recommendations;
- 8.1.6** Where the licensing committee resolves that the premises of the applicant are in conformity with the set standards required, the licensing committee shall support the recommendation to the Director responsible for licensing;
- 8.1.7** Where the licensing committee resolves that deficiencies exist at the premises of the applicant, the applicant shall be notified in writing of the deficiencies that need to be rectified. When the applicant notifies the Authority in writing that the deficiencies have been rectified, the Authority may conduct a verification inspection where necessary;
- 8.1.8** The Director responsible for licensing shall facilitate the final steps of generating the Certificate of Registration for onward endorsement by the Director-General; and
- 8.1.9** The Director-General shall endorse on the Certificate of Registration issued to the applicant.

NOTE:

The inspectors of the Authority shall conduct routine inspections to monitor compliance with the set standard including terms and conditions of the Certificate of Registration.



9. PERSONNEL REQUIRED IN A PHARMACEUTICAL RETAIL BUSINESS

The following personnel should be engaged in a pharmaceutical retail business:

1.1 Responsible Person

- 9.1.1 A pharmaceutical retail business shall engage a full-time registered pharmacist who shall be required to be physically present to manage the pharmacy as the responsible person;
- 9.1.2 A pharmaceutical retail business shall engage the services of a full-time registered pharmacist as the responsible person, except that the responsible person shall not be in full-time employment elsewhere.
- 9.1.3 A pharmaceutical retail business shall engage the services of a pharmacy technologist to work under the supervision of a registered pharmacist.
- 9.1.4 A registered pharmacy may engage the services of a registered pharmacist on locum basis. The Authority shall be informed in writing of the engagement of any registered pharmacist on locum basis at least fourteen (14) days prior to the engagement.
- 9.1.5 The registered pharmacist engaged on locum basis, shall attain all the responsibilities of the responsible pharmacist being replaced, and shall within seven days display a valid professional practicing licence, in a conspicuous place in the registered pharmacy, for the period of the engagement.
- 9.1.6 The owner of a registered pharmacy shall at the conclusion of the engagement of a registered locum pharmacist notify the Authority on the cessation of the services of the registered locum pharmacist employed on locum basis.
- 9.1.7 Where a locum pharmacist is to stand in for the responsible person for a period of more than one month, the locum pharmacist shall be subject to the restrictions imposed on the responsible person.

9.2 Roles and Responsibilities of the Pharmacy Owner and Responsible Person

9.2.1 Pharmacy Owner

The pharmacy owner will ensure that:

- i. A certificate of registration is displayed in the pharmacy at all times;
- ii. There is a suitably qualified responsible person who is recognized by the Authority and whose Full Registration Certificate is displayed in the pharmacy;
- iii. They do not interfere with the responsible person's professional decisions, roles and



responsibilities;

- iv. Medicines and allied substances intended for public health institutions, unregistered, unfit medicines and allied substances are not sold in the pharmacy; and
- v. Reference books and other documents for record keeping are available all the time.

9.2.2 The Responsible Person

The responsible person shall be professionally accountable for the management and oversight of pharmaceutical operations conducted at the registered premises. The responsible person shall:

- i. exercise professional oversight and control over the procurement, receipt, storage, sale, dispensing and supply of medicines and allied substances;
- ii. ensure that medicines and allied substances are procured only from suppliers authorised by the Authority and that appropriate records of procurement are maintained;
- iii. ensure that medicines and allied substances are stored under conditions specified by the manufacturer and applicable regulatory requirements, including appropriate temperature, humidity, security and stock-rotation controls;
- iv. ensure that prescription-only medicines are dispensed only against valid prescriptions issued by authorised prescribers, except where otherwise permitted by law or by discretion of the responsible pharmacist;
- vii. establish, implement and maintain written standard operating procedures for all relevant pharmaceutical activities conducted at the premises;
- viii. ensure that appropriate systems are in place for checking prescriptions, preventing dispensing errors and maintaining accurate dispensing records;
- ix. ensure that all required registers and records relating to the purchase, receipt, storage, dispensing, supply, recall and disposal of medicines and allied substances are properly maintained and made available for inspection by the Authority;
- x. ensure that returned, recalled, expired, damaged, falsified, substandard or otherwise unfit medicines and allied substances are immediately segregated from usable stock, clearly identified and secured in a designated area pending appropriate disposal or other authorised action;
- xi. coordinate and cooperate with the Authority in the recall, withdrawal or disposal of medicines and allied substances;
- xii. ensure that controlled substances are received, stored, recorded, dispensed and accounted for in



accordance with the applicable legislation;

- xiii. report suspected adverse drug reactions, medication errors, product quality defects, falsified products and other reportable incidents to the Authority in accordance with applicable requirements;
- xiv. supervise pharmacists, pharmacy technologists, interns, support staff and any other personnel involved in pharmaceutical activities at the premises;
- xv. ensure that every member of staff understands their assigned duties, scope of practice and the limitations applicable to their role;
- xvi. ensure that duties requiring professional judgement are performed only by appropriately qualified and authorised personnel;
- xvii. ensure that the pharmacy and its equipment are maintained in a clean, secure and serviceable condition;
- xviii. ensure that the Certificate of Registration and the valid registration and practising certificates of relevant health practitioners are displayed or made available as required;
- xix. ensure that patient information, prescriptions and other confidential records are handled and protected in accordance with applicable legal and professional requirements;
- xx. maintain an up-to-date duty roster identifying the registered pharmacist responsible for professional supervision during each operating period;
- xxi. ensure that suitable arrangements are made for professional coverage by another registered pharmacist during any authorised absence;
- xxii. promptly inform the pharmacy owner and the Authority of any practice or condition that may compromise the quality, safety or lawful supply of medicines and allied substances;
- xxiii. cooperate with inspectors of the Authority and facilitate access to the premises, medicines, records and personnel during inspections; and
- xxiv. ensure that corrective and preventive actions arising from inspections are implemented within the period specified by the Authority.

9.3 Support Staff

The pharmaceutical retail business must engage a sales assistant and may engage a general worker or security guard.



10. STANDARDS FOR RETAIL PHARMACY PREMISES

10.1 Premises of a retail pharmacy

10.1.1 The external appearance of premises must be clean.

10.1.2 The premises should be identified distinctly by a signpost with the following details:

- i. name of retail pharmacy;
- ii. physical address of the retail pharmacy;
- iii. telephone/contact number;
- iv. operating times on door or window; and
- v. standard symbol of a green cross on a white background for a retail pharmacy.

10.1.3 The design and layout of a retail pharmacy must permit a logical flow of work, effective communication and supervision by a responsible person; ensure effective cleaning and maintenance; and must minimize the risk of errors, cross-contamination and anything else which would have an adverse effect on the quality of products.

10.1.4 All parts of the premises must be maintained in an orderly and tidy manner.

10.1.5 A full registration certificate and valid annual practicing certificate for the responsible pharmacist, pharmacy technologist and locum pharmacist should be displayed conspicuously in a retail pharmacy.

10.1.6 Dispensary; the following compounding equipment and auxiliaries should be available in the dispensary:

- i. Distilled water/electric kettle
- ii. Measuring cylinder
- iii. Counting tray
- iv. Weighing balance
- v. Mortar and pestle
- vi. Any other compounding equipment and auxiliaries

10.1.7 The following packaging and labelling material should be available:

- i. Self-adhesive labels,



- ii. Self-sealing plastic packs
- iii. Any other suitable packaging materials.

10.2 Stocking in a pharmacy

The pharmacy may stock the following authorized categories of products:

- i. Prescription only medicines (POM)
- ii. Pharmacy medicines (P)
- iii. General sale medicines (GS)
- iv. Allied substances

10.3 Safety and security of premises for a retail pharmacy

- 10.3.1** A working environment must be arranged in a manner that ensures the safety of the public and people working on the premises and comply with relevant legislation relating to safety in the workplace;
- 10.3.2** Measures to prevent accidents and fires must be put in place. Written approved procedures on use of fire extinguishers must be available.
- 10.3.3** Staff must be familiar with the fire prevention procedures;
- 10.3.4** Equipment must be maintained in good working order.
- 10.3.5** The premises must be lockable and as far as possible exclude any unauthorised entry to provide for the safety of both staff and medicines and allied substances..
- 10.3.6** Depending on the design of the premises, burglar bars/ security doors or any other such installations should be installed on all entrance/ exit doors and windows where practicable.
- 10.3.7** Where practicable, it is advisable that security guard(s) are engaged, and other security systems installed such as closed-circuit television. Where a security firm or company is engaged, contract agreement between the pharmacy enterprise and the hired security firm or company must be in place.

10.4 Conditions of Premises, Design and Materials

- 10.4.1** The floors, walls, windows, ceiling, woodwork and all other parts of the premises must:
 - i. Be made of durable and easy to clean materials;
 - ii. Be kept in a continuous good order, repair and condition for the purposes of prevention



of infestations, and adding beauty to the premises;

- iii. Countertops, shelves, floors and walls must be with a smooth finish, and easy to clean material;
- iv. The premises should have adequate natural and/or artificial ventilation;
- v. The premises should have sufficient natural and/or artificial lighting, and the walls, floors and ceiling are in a good state of repair;
- vi. The premises should have a leak-proof roof;
- vii. The premises should have clearly designated and labeled areas for carrying out specific activities such as front shop, area for supplying prescription only medicines, and expired medicines area;
- viii. The premises should have adequate sanitation facilities such as toilets and hand-washing utility; and
- ix. The premises must have sufficient shelving which are smooth, washable and impermeable;

10.5 Relative Partitioning

The following are partitions for the premises:

10.5.1 In the case of a pharmacy with a closed dispensary:

- i. front shop: minimum size of 16 m²; with minimum width of 3m;
- ii. dispensary: minimum size of 12 m²; with minimum width of 3m;
- iii. total space: minimum size of 28 m²; and
- iv. the dispensary can be used as consultation room

10.5.2 In the case of a pharmacy with an open dispensary:

- i. front shop: minimum size of 16m²;
- ii. dispensary: minimum size of 9m²;
- iii. office, consultation room: minimum size of 4m²;



- iv. total minimum size of 29m²;
- v. store room: to be optional;
- vi. unfit medicines and allied substances secure room/area with adequate space under lock and key; and
- vii. Access to water closet toilet(s) with hand washing basin

10.6 Shelving and equipment in a retail pharmacy

The following shelving and equipment must be available:

- i. Adequate shelves and pallets (where applicable)
- ii. Hand free or pedal waste bin(s)
- iii. Refrigerator
- iv. Fire extinguishers placed at strategic positions
- v. Air conditioners for medicines storage areas
- vi. Secure Cupboard, Receptacle or Dedicated Room for controlled substances

10.7 Dispensing of Medicines and allied substances in a retail pharmacy

10.7.1 Medicines in a pharmacy shall be dispensed in accordance with the standards of pharmacy and guidelines that may be issued by the authority from time to time;

10.7.2 Prescription only medicines shall not be dispensed without a prescription;

10.7.3 Every supply of medicines on a prescription shall be entered in the prescription book and the prescription itself filed;

10.7.4 The prescription book, from date of last entry, shall be kept by the pharmacy for a period of two (2) years.

11. DISPOSAL OF UNFIT MEDICINES AND ALLIED SUBSTANCES

11.1 The responsible person shall withdraw and store all unfit medicines and allied substances separately from usable stock and in packages or cartons clearly labelled accordingly;

11.2 The responsible person shall adhere to the guidelines on disposal of unfit

11.3 Medicines and allied substances when conducting a disposal; and



- 11.4** The cost and responsibility to dispose of unfit medicines and allied substances shall be borne by the pharmacy owner.

12. RECALL OF MEDICINES AND ALLIED SUBSTANCES

Where medicines and allied substances which have been recalled or withdrawn and have to be removed from the market due to problems with quality, safety, or efficacy, the pharmacy owner, responsible person shall cooperate with the Authority to facilitate the recall of such medicines as stipulated in the Authority's guidelines on recall of medicines and allied substances.

The responsible person shall promptly report all suspected adverse drug reactions, product quality problems and medication errors to the Authority in accordance with the National Pharmacovigilance Requirements.

13. STANDARD OPERATING PROCEDURES (SOPS)

13.1 The following SOPS should be available:

- i. Complaints handling
- ii. Contingency in the event the responsible pharmacist is not present
- iii. Control, ordering and receipt of medicines and allied substances
- iv. Dispensing and supply of medicines and allied substances
- v. Fire safety including use of fire extinguisher
- vi. Cleaning procedures and management of waste generated in the pharmacy .
- vii. Management of recalled products
- viii. Management and disposal of unfit medicines and allied substances
- ix. Reporting of adverse drug events/reaction

14. RELATIVE PARTITIONING

The following are partitions for the premises:

14.1 In the case of a pharmacy with a closed dispensary:

Version 1



- i. front shop: minimum size of 16 m²; with minimum width of 3m;
- ii. dispensary: minimum size of 12 m²; with minimum width of 3m;
- iii. total space: minimum size of 28 m²; and
- iv. the dispensary can be used as consultation room

14.2 In the case of a pharmacy with an open dispensary:

- i. front shop: minimum size of 16m²;
- ii. dispensary: minimum size of 9m²;
- iii. office, consultation room: minimum size of 4m²;
- iv. total minimum size of 29m²;
- v. store room: to be optional;
- vi. unfit medicines and allied substances secure room/area with adequate space under lock and key;
and
- vii. Access to water closet toilet(s) with hand washing basin.

14.3 Shelving and equipment in a retail pharmacy

14.3.1 The following shelving and equipment must be available:

- i. Adequate shelves and pallets (where applicable)
- ii. Hand free or pedal waste bin(s)
- iii. Refrigerator
- iv. Fire extinguishers placed at strategic positions
- v. Air conditioners for medicines storage areas
- vi. Secure Cupboard, Receptacle or Dedicated Room for controlled substances (where applicable)



14.4 Documentation / Record Keeping Facilities:

The following shall be provided:

- i. Inventory management system;
- ii. Computer or equivalent device;
- iii. Controlled substances Register;
- iv. Delivery notes (where applicable);
- v. Expired Products Register;
- vi. File for prescriptions;
- vii. Internal issue books;
- viii. Prescription Book;
- ix. Recalled Products Register;
- x. Receipt;
- xi. Invoices; and
- xii. ZAMRA Inspectors' Book.

15. STOCK SURVEILLANCE FACILITIES

15.1 The following temperature monitoring facilities should be available:

- i. Temperature charts.
- ii. Wall and refrigerator thermometers or data loggers.

16. REFERENCE MATERIALS

16.1 Mandatory references

16.1.1 The following reference materials should be available preferably latest edition:

- i. Zambia National Formulary (ZNF);
- ii. Zambian Standards of Pharmaceutical Practice;



- iii. **Zambian Standard Treatment Guidelines; and**
- iv. **ZAMRA Good Distribution Practices Guidelines.**

16.2 Recommended references

16.2.1 The following reference materials should be available preferably latest edition:

- i. **British National Formulary (BNF) latest edition;**
- ii. **British Pharmacopoeia latest edition;**
- iii. **Martindale latest edition;**
- iv. **Zambian Essential Medicines List latest edition;and**
- v. **Zambian Standard Treatment Guidelines.**

16.2.2 Statutes:

- i. **Medicines and Allied Substances Act (No.3) of 2013 of the Laws of Zambia;**
- ii. **Controlled Substances Act (No.2) of 2023;**
- iii. **Narcotic Drugs and Psychotropic Substances Act, (No. 35) of 2021 of the Laws of Zambia;**
- iv. **Health Professions and Allied Professions Act (No.17) of 2024 of the Laws of Zambia; and**
- v. **The Public Health Act, Cap. 295 of the Laws of Zambia.**

Electronic copies of reference materials are acceptable on company gadgets.

17. NOTIFICATION OF ANY CHANGES RELATING TO LICENSED PREMISES

All Certificate of Registration holders are required to notify the Authority for any the Authority on administrative changes.

17.1 Administrative amendments

17.1.1 Change in the composition of Directors

Version 1



Where the composition of Directors has changed, the applicant is required to submit the following:

- i. Proof of payment of amendment fees;
- ii. Updated PACRA certificate of registration/incorporation; and
- iii. Letter of notice of change of directors.

17.1.2 Change of responsible person

Where there is change of responsible person, the applicant is required to submit the following:

- i. Proof of payment of amendment fees;
- ii. Completed application form for amendment;
- iii. HPCZ full registration certificate and practising license for the new responsible person; and
- iv. Resignation letter for the previous responsible person where applicable.

17.1.3 Change of business name

Where there is change of the business name, the applicant is required to submit the following:

- i. Proof of payment of amendment fees;
- ii. Updated PACRA certificate of registration/incorporation; and
- iii. Local Authority certificates bearing the new business name.

17.1.4 Change of ownership

Any change in the ownership of the business shall be made to the Director General in writing. The applicant is required to submit:

- i. Proof of payment of amendment fees;
- ii. Certified copy of the agreement of sale;
- iii. Police clearance or affidavits of the company directors indicating that they have not within 3 years proceeding this application been convicted of an offence related to medicines and allied substances of dishonesty;
- iv. Memorandum and Articles of Association (if a company); and
- v. Proof of citizenship or residence of company directors (e.g certified copies of National Identity Cards or Passports).



17.1.5 Structural amendment

17.1.5.1 All Certificate of Registration holders are required to seek prior authorization for any structural changes post licensure.

17.1.6 Change of floor layout

An intention to change the floor layout of the premises shall be notified to the Director General in writing. The applicant shall be required to submit a copy of the proposed floor layout of the premises. The premises shall be inspected by inspectors to ensure they are compliant and this will attract a fee as stipulated in the fee schedule. The proposed layout shall only be adopted once approval is received from the Authority.

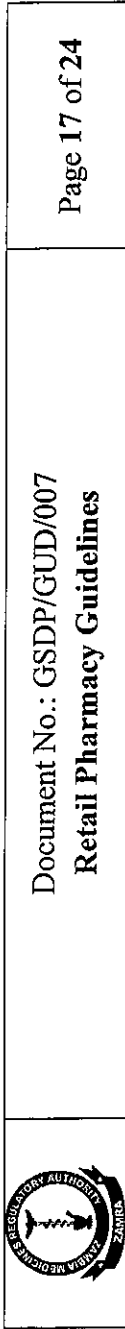
18 Relocation

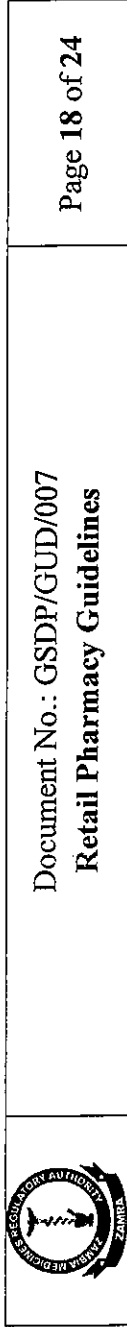
An intention to change the location of the licensed or approved premises shall be made to the Director General in writing. The applicant shall be required to go through the licensing process for the new premises.



ANNEX I: Medicines Expiry Register

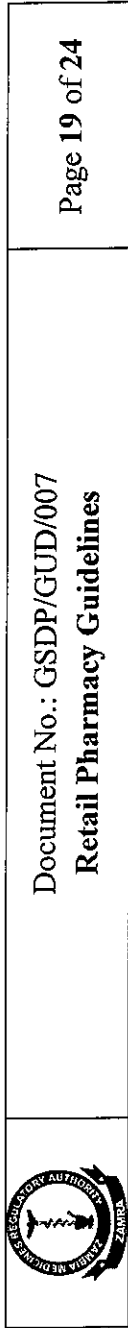
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ANNEX III: Product Recall Register

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Date (DD/MM/YYYY)

Name of Lead Inspector	Date (DD/MM/YYYY)	Signature
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Date (DD/MM/YYYY)

Representative or Responsible Person	Date (DD/MM/YYYY)	Signature

	Document No.: GSDP/GUD/007 Retail Pharmacy Guidelines	Page 20 of 24
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