Guidelines for Establishment of a Pharmaceutical Retail Business

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Version 1.0

These guidelines for the establishment of a pharmaceutical retail business in Zambia are issued by the Zambia Medicines Regulatory Authority pursuant to section 68 of the Medicines and Allied Substances Act, 2013 of the Laws of Zambia. The Authority may amend any part of these guidelines from time to time.

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1.0 INTRODUCTION

The Zambia Medicines Regulatory Authority (ZAMRA) regulates medicines for human and animal use in accordance with the provisions of the Medicines and Allied Substances Act No. 3 of 2013 and the relevant Regulations made thereunder. (Hereafter referred to as the Act).

Among other things, it is unlawful for any person to sell medicines, in a retail pharmacy in Zambia without lawful authority from ZAMRA except in accordance with the certificate of registration. The medicines to be sold in the pharmacy should have Marketing Authorisation or exemptions obtained from ZAMRA. In addition, there must be full compliance to the licensing procedure.

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

2.0 LICENSING PROCEDURE: AN OVERVIEW

The directorate responsible for licensing of retail pharmacies has the overall responsibility for ensuring compliance with the whole licensing process. The Director-General endorses the certificate of registration issued to applicants intending to sale or supply medicines and allied substances on retail.

The licensing process of retail pharmacies includes the following:

1) Lodgement of an application;
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;
3) Pre-licensing inspections are carried out by the Authority's inspectors to assess the conformance of the applicant's premises to the set standards;

4) A pre-licensing inspection report is generated containing findings and relevant recommendations;
5) The licensing committee scrutinises the pre-licensing inspection report and recommendations;
6) 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;
7) 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) The Director responsible for licensing shall facilitate the final steps of generating the certificate of registration for onward endorsement by the Director-General; and
9) The Director-General shall endorse on the certificate of registration issued to the applicant.

The inspectors of the Authority shall conduct routine inspections to monitor compliance to the set standard including terms and conditions of the certificate of registration.

3.0 APPLICATION PROCEDURE TO APPLY FOR A CERTIFICATE OF REGISTRATION TO OPERATE A RETAIL PHARMACY

3.1 A person who intends to operate a retail pharmacy shall apply to the Authority for a Certificate of Registration, by ensuring that:

(a) The application is duly completed in Form I, of the certificate of registration regulations, and should be accompanied with proof of payment of the prescribed fee;

(b) The applicant is a holder of a valid Business Levy Permit and fire certificate issued by the local authority; and

(c) The applicant is a holder of a valid certificate of incorporation, business name registration certificate, certificate of registration of a cooperative or certificate of incorporation of a trust.

3.2 Attachments to the application for a certificate of registration

3.2.1 An application made in accordance with clause 2.0 above shall be accompanied by a:

(a) valid professional practising certificate for the responsible person* (registered pharmacist see 2.3) 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; and

(e) fire certificate from the local authority

3.3 Responsible Person

3.3.1 A responsible person means the registered pharmacist working in a registered pharmacy who shall physically be present to manage and control the registered pharmacy during operating hours.

3.3.2 A registered pharmacy may engage the services of a registered pharmacist on a locum basis, except that a registered pharmacist or where applicable, a registered pharmacist engaged on a locum basis, shall not be:

(a) in full-time employment elsewhere;

(b) on leave, for less than a year, from a full-time job; or

(c) be on full time educational studies.

3.3.3 The Authority shall be informed in writing of the engagement of any registered pharmacist on a locum basis at least fourteen days prior to the engagement, except that in cases of an emergency:

(a) where there is more than one registered pharmacist available to continue operating the registered pharmacy during the emergency situation, the registered pharmacy may remain open.

(b) where there is only a pharmacy technologist available, the dispensary of a pharmacy shall be closed during the situation of an emergency, but the pharmacy may remain open for general sale medicines.

3.3.4 The registered pharmacist engaged on a locum basis, shall attain all the responsibilities of the responsible pharmacist being replaced, and shall display a valid professional practicing licence, in a conspicuous place in the registered pharmacy, for the period of the engagement.

3.3.5 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 a locum basis.

4.0 Submission of the application

4.1 A completed application shall be submitted to the nearest ZAMRA Offices.

5.0 Personnel requirements in a retail pharmacy

5.1 A retail pharmacy shall engage a full-time registered pharmacist who shall be required to be physically present to manage the pharmacy as a responsible person;

5.2 A registered pharmacy technologist and locum pharmacist may be engaged on a need basis;

5.3 A registered pharmacy may engage support staff.

6.0 Standards for retail pharmacy premises

6.1 Premises of a retail pharmacy

6.1.1 The external appearance of premises must be clean.

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

(a) name of retail pharmacy;

(b) address of retail pharmacy;

(c) telephone/contact number;

(d) operating times on door or window; and

(e) standard symbol of a green cross on a white background for a retail pharmacy.

6.1.3 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.

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

6.1.5 A valid annual practising certificate for the responsible pharmacist, pharmacy technologist and locum pharmacist should be displayed conspicuously in a retail pharmacy.

6.1.6 Dispensary

6.1.7 The following compounding equipment and auxiliaries should be available:

(a) Distilled water

(b) Measuring cylinder

(c) Counting tray

(d) balance

(e) Mortar and pestle

(f) Any other compounding equipment and auxiliaries

6.1.8 The following packaging and labelling material should be available:

(a) Self-adhesive labels,

(b) Self-sealing plastic packs

(c) Any other suitable packaging materials.

6.2 Stocking in a pharmacy

6.2.1 The pharmacy may stock the following:

(a) Prescription only medicines (POM)

(b) Pharmacy medicines (P)

(c) General sale medicines (GS)

(d) Veterinary medicines

(e) Herbal medicines

(f) Narcotic Drugs and Psychotropic substances

(g) Allied substances

6.3 Safety and security of premises for a retail pharmacy

6.3.1 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;

6.3.2 Measures to prevent accidents and fires must be put in place. Written approved procedures on use of fire extinguishers must be available;

6.3.3 Staff must be familiar with the fire prevention procedures;

6.3.4 Equipment must be maintained in good working order.

6.3.5 Careful consideration must be given to the overall security of premises.

6.3.6 The premises must be lockable and as far as possible exclude any unauthorised entry.

6.3.7 Security measures must be in place to provide for the safety of both staff and medicines.

6.3.8 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.

6.3.9 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.

6.4 Conditions of Premises, Design and Materials

6.5 The floors, walls, windows, ceiling, woodwork and all other parts of the premises must:

(a) Be made of durable and easy to clean materials;

(b) Be kept in a continuous good order, repair and condition for the purposes of prevention of infestations, and adding beauty to the premises;

(c) Countertops, shelves, floors and walls must be with a smooth finish, washable, and easy to clean material for the purposes of maintaining hygienic conditions;

(d) The premises should have adequate natural and/or artificial ventilation;

(e) The premises should have sufficient natural and/or artificial lighting, and the walls, floors and ceiling are in a good state of repair;

(f) The premises should have a leak-proof roof;

(g) The premises should have clearly partitioned areas for carrying out specific activities such as main shop, area for supplying prescription only veterinary medicines, and expired medicines area;

(h) The premises should have adequate sanitation facilities such as toilets and hand-washing utility; and

(i) The premises must have sufficient shelving which are smooth, washable and impermeable;

6.6 Dispensing of Medicines in a retail pharmacy

6.7 Medicines in a pharmacy shall be dispensed in accordance with the profession of pharmacy and guidelines that may be issued by the ZAMRA from time to time;

6.8 It is for one reason or another, the pharmacist is not available to perform duties in a pharmacy, the pharmacist should ensure that the dispensary is closed and all medicines that are only dispensed by a pharmacist should be moved to the dispensary;

6.9 Prescription medicines shall not be dispensed without a prescription;

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

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

6.12 Standard Operating Procedures (SOPs)

6.13 The following SOPS should be available:

(a) Complaints handling

(b) Contingency in the event 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 including use of fire extinguisher

(f) Hygiene procedures on premises.

(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/reaction

6.14 Relative Partitioning

6.15 The following are partitions for the premises:

(a) Front shop with minimum size of 50m^2

(b) Dispensary for prescription only medicines with minimum size of 15m^2

(c) Main warehouse or storeroom with air conditions (s) with minimum size of 24m^2

(d) Office space with minimum size of 3m^2

(e) Expired products room with adequate space under lock and key

(f) Access to water closet toilet(s) with hand washing basin

6.16 Shelving and equipment in a retail pharmacy

6.17 The following shelving and equipment must be available:

(a) Adequate shelves and pallets (where applicable)

(b) Hand free or pedal waste bin(s)

(c) Refrigerator

(d) Fire extinguishers placed at strategic positions

(e) Air conditioners for medicines storage areas

(f) Secure Cupboard, Receptacle or Dedicated Room for narcotic drugs and psychotropic substances (where applicable)

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

(a) Bin cards (stock cards)

(b) Computer or equivalent device

(c) Dangerous Drugs Register

(d) Delivery notes (where applicable)

(e) Expired Products Register

(f) File for prescriptions

(g) Internal issue books

(h) Prescription Book

(i) Recalled Products Register

(j) Receipt

(k) Invoices

(l) ZAMRA Inspectors' Book

6.19 Stock Surveillance Facilities

6.20 The following temperature monitoring facilities should be available:

(a) Temperature charts
(b) Wall and refrigerator thermometers or data loggers

7.0 Reference materials

7.1 Mandatory references

7.2 The following reference materials should be available:

(a) Zambia National Formulary (ZNF) latest edition

(b) Zambian Essential Medicines List latest edition

(c) Zambian Standard Treatment Guidelines latest edition

(d) Zambian Standards of Pharmaceutical Practice

(e) ZAMRA Good Distribution Practices Guidelines latest edition

7.3 Recommended references

(a) British National Formulary (BNF) latest edition

(b) British Pharmacopoeia latest edition

(c) Martindale latest edition

7.4 Statutes:

(a) Medicines and Allied Substances Act (No.3) of 2013 of the Laws of Zambia

(b) Dangerous Drugs Act, Cap 95 of the Laws of Zambia

(c) Narcotic Drugs and Psychotropic Substances Act, Cap 96 of the Laws of Zambia

(d) Health Professions and Allied Professions Act (No.24) of 2009 of the Laws of Zambia

(e) The Public Health Act, Cap. 295 of the Laws of Zambia.

ANNEX I: Medicines Expiry Register

Serial No.	Name of Medicine	Sourcing/ Purchase Date	Quantity (Pack Size or units)	Expiry Date	Date of entry	Signature

ANNEX II: Prescriptions Book

Serial No.	Name of Patient	Name of Medicines (Ingredient)	Quantity Supplied or Dispensed	Date of Supply or Dispensed	Name of Prescriber and Address	Name of person Supplying or Dispensing	Signature

ANNEX III: Product Recall Register

Serial No.	Name of Medicines	Batch. No	Name of Manufacturer	Man. Date	Expiry Date	Establishment Received/ Collected From	Quantity Received/ Collected	Date of Entry	Signature

ANNEX IV: ZAMRA Inspectors' Book

Date of Inspection	Deficiencies	Proposed Corrective and Preventive Actions (CAPAs)	Timelines	Evaluation of CAPAs by Inspectors

Comments on Closure of CAPAs

Name of Lead Inspector	Date (DD/MM/YYYY)	Signature
Representative or Responsible Person	Date (DD/MM/YYYY)	Signature