

**Zambia Medicines Regulatory Authority****GUIDELINES FOR ESTABLISHMENT OF A PHARMACEUTICAL WHOLESALE
BUSINESS IN ZAMBIA****Contact details:****Head Office, Plot No 2350/M, Off Kenneth Kaunda International Airport Road****P.O. Box 31890, Lusaka, ZAMBIA****Tel: +260 211 220429,****E-mail: pharmacy@zamra.co.zm; Website: www.zamra.co.zm**

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1.0 INTRODUCTION

The Zambia Medicines Regulatory Authority (ZAMRA) regulates medicines and allied substances in accordance with the provisions of the Medicines and Allied Substances Act No. 3 of 2013, (hereinafter referred to as “the Act”) and the relevant Regulations made thereunder.

These guidelines for issuance of a Pharmaceutical Licence for pharmaceutical wholesale establishments are issued pursuant to section 68 of the Act and prescribes the information to be incorporated in the applications for grant of a Pharmaceutical Licence in accordance with Section 34 of the Act. The Authority may from time to time amend any part of these guidelines.

It is unlawful for any person to manufacture, distribute or deal in any medicine or allied substance in Zambia except in accordance with the Pharmaceutical Licence

2.0 OBJECTIVE

These guidelines provide guidance on the requirements for applying for a Pharmaceutical Licence to operate a pharmaceutical wholesale business in Zambia.

3.0 SCOPE

These guidelines define the minimum requirements for the establishment of a pharmaceutical wholesale business in Zambia. They also provide guidance for those who intend to renew and amend the Pharmaceutical Licence.

4.0 DEFINITION

In these guidelines, unless the context otherwise requires:

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

“**Authority**” means the Zambia Medicines Regulatory Authority.

“**Pharmaceutical Licence** ” means the licence issued, under section thirty-four, to a person to manufacture, distribute or deal in a medicine or allied substance.

“**Distribution**” means the procuring, purchasing, holding, storing, selling, supplying, importing, exporting or movement of medical products, with the exception of dispensing or providing medical products directly to a patient or his or her agent.

Version 1.0



“Deal ” means to sell or offer for sale or trade by wholesale.

“Good Storage and Distribution Practices ” means that part of quality assurance that ensures that the quality of a medical product is maintained by means of adequate control of the numerous activities that occur during the trade and distribution process, as well as providing a tool to secure the distribution system from falsified, unapproved, illegally imported, stolen, substandard, adulterated and/ or misbranded medical products.

“Medicine” means medicine for human use,herbal medicine for human use a medicinal product for human use 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 the symptoms of disease in a person.

“Allied Substances” include acaricides, cosmetics, disinfectants, food supplements, feed additives and supplements, medical and surgical sundries, medical device.

Pharmaceutical sales representative(promotion guidelines definition)

“Recall” means a process for withdrawing or removing a medicine or allied subsatance 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.

“Quarantine” means the status of medical products 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. Receiving, dispatch, equipment operation, maintenance and cleaning, cleaning of premises, environmental control, sampling and inspection).

“Responsible Person” means a person duly qualified as a pharmacist, veterinary surgeon, or such other person as the Authority may determine.

“Pharmacist” means a health practitioner under the Health Professions Act No. 17 of, 2024 of the Laws of Zambia.

Version 1.0



“Veterinary surgeon” means a person registered as a veterinary surgeon under the Veterinary and Veterinary Para-Professions Act No.45 of 2010 of the Laws of Zambia.

“Veterinary Paraprofessional” means a person registered as a veterinary paraprofessional under the Veterinary and Veterinary Para-Professions Act No.45 of 2010 of the Laws of Zambia.

“Pharmacy technologist” means a health practitioner under the Health Professions Act No. 17 of 2024 of the Laws of Zambia.

5.0 ABBREVIATIONS

GSDP - Good Storage and Distribution Practice

HPCZ - Health Professions Council of Zambia

SOP - Standard Operating Procedure

VAZ - Veterinary Association of Zambia

ZAMRA - Zambia Medicines Regulatory Authority

6.0 LICENSING PROCEDURE: AN OVERVIEW

6.1 The licensing process of a pharmaceutical wholesale business shall include the following:

- i. The applicant shall lodge an application for a Pharmaceutical Licence to the Authority upon payment of the prescribed fee;
- ii. The Authority shall screen the application to ensure that relevant documents are attached;
- iii. Where the Authority finds that the application is insufficient, the Authority shall request for additional information as set out in a prescribed form;
- iv. Inspectors of the Authority shall conduct pre-licensing inspection to assess the conformity of the applicant’s premises to the set standards;
- v. A pre-licensing inspection report shall be generated containing findings and relevant



recommendations;

- vi. The licensing committee shall scrutinise the pre-licensing inspection report and recommendations;
 - vii. 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.
 - viii. Where the applicant notifies the Authority in writing that the deficiencies have been rectified, the Authority may conduct a re-inspection where necessary upon payment of the prescribed fee;
 - ix. Where the applicant notifies the Authority in writing that the deficiencies have been rectified, the Authority may conduct a re-inspection where necessary upon payment of the prescribed fee;
 - x. 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;
 - xi. The Director responsible for licensing shall facilitate the final steps of generating the pharmaceutical licence for onward endorsement by the Director-General; and
 - xii. The Director-General shall endorse the pharmaceutical licence issued to the applicant.
- 6.2 The inspectors of the Authority shall conduct routine inspections to monitor compliance with the set standards including terms and conditions of the Pharmaceutical Licence.

7.0 APPLICATION PROCEDURE FOR ISSUANCE OF A PHARMACEUTICAL LICENCE

- 7.1 A person who intends to operate a pharmaceutical wholesale business shall apply to the Authority in a prescribed manner and form and upon payment of the prescribed fee.
- 7.2 An application made in accordance with clause 7.1 above shall be accompanied by a:



- 7.2.1 Valid Certificate of Incorporation, business name Registration Certificate, Certificate of Registration of a Cooperative or Certificate of Incorporation of a Trust;
- 7.2.2 Valid Business Levy Permit and Fire Certificate issued by the local authority;
- 7.3.3 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 wholesale business during its operating hours;
- 7.3.4 Contract or agreement letter signed by both parties; employer and employee; and
- 7.3.5 Sketch of the floor plan for the premises.

8.0 SUBMISSION OF THE APPLICATION

8.1 A complete application shall be submitted to the Authority via ZAMRA online portal.

9.0 PERSONNEL REQUIRED IN A PHARMACEUTICAL WHOLESALE BUSINESS

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

9.1 Responsible Person

- 9.1.1 A pharmaceutical wholesale business shall engage a registered pharmacist on full-time or part-time basis;
- 9.1.2 Where a registered pharmacist/veterinary surgeon is engaged on full-time basis, the pharmacist shall be required to be physically present to manage the pharmaceutical wholesale business as a responsible person; (provision for locum as per retail)
- 9.1.3 Where a pharmacist is engaged on part-time basis as responsible person, a pharmaceutical wholesale business shall engage a full-time registered pharmacy technologist.
- 9.1.4 An agro-veterinary wholesale business shall engage a registered veterinary surgeon on a full-time or part-time basis.
- 9.1.5 Where a registered veterinary surgeon is engaged on a full-time basis, the veterinary surgeon shall be required to be physically present to manage the agro-veterinary wholesale business as a responsible person



9.1.6 Where a veterinary surgeon is engaged on a part-time basis as the responsible person, an agro-veterinary wholesale business shall engage a full-time registered veterinary para-professional;

9.1.7 A pharmacist/Veterinary surgeon engaged on a part-time basis, shall provide supervision for a minimum of two (2) hours per week;

9.1.8 Duties and responsibilities of a supervising pharmacist/Veterinary surgeon conducted on each visit should be well recorded in the pharmacist/Veterinary surgeon log book; and

9.1.9 Pharmacists/Veterinary surgeons in public or private working institutions can only supervise one (1) pharmaceutical/agro-veterinary wholesale businesses.

9.2 Pharmaceutical sales representative

9.2.1 The pharmaceutical wholesale business shall engage pharmaceutical and veterinary sales representative to carry out sales and marketing functions, where applicable.

9.2.2 Where the Pharmaceutical Sales Representative are engaged, they should be suitably qualified to market or promote a medicine or an allied substance, and shall have:

- i. Requisite qualifications by education and training for the product they are to market or promote and be registered or licensed with the relevant professional body; and
- ii. Adequate training by the firm which employs them and shall have sufficient scientific knowledge to be able to provide information which is precise and as complete as possible about the medicine and allied substance which they promote.

9.3 Support staff

9.3.1 The pharmaceutical wholesale business shall engage adequate support staff which may include the following:

- i. Warehouse manager;
- ii. Driver/(s);
- iii. Cleaner/(s);
- iv. General worker/(s); and
- v. Security guard/(s).

NOTE: For pharmaceutical/veterinary sales refer to 9.2

**10.0 STANDARDS OF THE PHARMACEUTICAL WHOLESALE BUSINESS****10.1 General appearance of the premises**

10.1.1 Pharmaceutical wholesale premises should have clean and tidy surroundings with conspicuous identity;

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

- i. Name of pharmaceutical wholesale business;
- ii. Traceable address of pharmaceutical wholesale business;
- iii. Contact details (email, phone number);and
- iv. Operating times.

10.1.3 Countertops, floors and walls must be with a smooth finish, and easy to clean material for the purposes of maintaining hygiene;

10.1.4 The following should be displayed conspicuously in the front shop or reception:

- i. Portrait of the head of state;
- ii. Certificate of Registration or Incorporation;
- iii. Valid Certificate of Payment of Business Levy;
- iv. Valid Fire Certificate;
- v. Valid HPCZ/VAZ full-registration and annual practising certificate for the responsible pharmacist/veterinary surgeon; and
- vi. Valid HPCZ/VAZ full-registration and annual practising certificate for the pharmacy technologist/veterinary para-professional (where applicable).

10.2 Conditions of premises

10.2.1 The premises should be of permanent building kept in a continuous good order, repair and condition for the purposes of prevention of infestations;

10.2.2 The premises should have a leak-proof roof;

10.2.3 The premises should have adequate natural lighting, through doors, windows, and artificial lighting through the use of bulbs, fluorescent tubes, and/or any other acceptable sources;



10.2.4 The premises should have adequate natural ventilation, such as doors, windows, air vents and artificial ventilation such as air conditioners and any other acceptable sources;

10.2.5 Premises should be free of vermin such as bats, rodents, cockroaches and other pests; and

10.2.6 Receiving/dispatch bays and warehouse/storage areas should be protected from dust, dirt and rain.

10.3 Location

10.3.1 The pharmaceutical wholesale business should be located in places where it is easily accessible.

10.4 Design and Layout

10.4.1 Minimum floor space of 100sq meters (m²).

10.4.2 Minimum actual storage space of 75sq meters (m²).

10.4.3 The size of the pharmaceutical wholesale business must reflect the volume of medicines and allied substances handled and allow a safe and efficient flow of work and effective communication and supervision for the number of persons working.

10.4.4 Premises should have dedicated and demarcated areas for administrative and storage/warehouse.

10.4.5 Water closet toilets with running water hand washing facilities for both clients and staff. In an event that the toilet is in the warehouse, it should not open directly into the storage area.

10.5 Administrative area

10.5.1 The administrative area should have the following sections:

- i. Reception/front shop/Sales office;
- ii. Office for the responsible person;
- iii. Showroom (where applicable/necessary); and

10.6 Warehousing

10.6.1 The warehouse area should have the following sections:

- i. Receiving bay;



- ii. Quarantine room/area;
- iii. Goods returned bay/area;
- iv. Main warehouse;
- v. Cold-chain storage room/facility;
- vi. Controlled Drugs room/facility (under lock and key);
- vii. Recalled product room (under lock and key);
- viii. Expired product room; (under lock and key);
- ix. Flammables storage area; and
- x. Dispatch bay.

10.7 Equipment and facilities of Pharmaceutical Wholesale Premises

-- 10.7.1 Warehouse

- i. Storage facilities must have adequate shelving (where applicable) which are smooth, washable and impermeable;
- ii. There should be an adequate number of pallets, trolleys and pallet trolleys as befits the scale of operation;
- iii. Air conditioners or any other temperature controlling facility should be available;
- iv. Refrigerator or cold room for cold-chain products;
- v. Electricity and/or functional power backups facilities in case of power failure;
- vi. Wall and refrigerator thermometer; and
- vii. Hands free pedal waste bin.

10.7.2 Suitable Transport

There should be access to suitable transport for distribution of medicine and allied substances in accordance with the Good Storage and Distribution Practices guidelines.

10.7.3 Security and Fire Protection

- i. Security measures must be in place to provide for the safety of staff, medicines and allied substances and as far as possible exclude any unauthorised entry;
- ii. Where a security guard or security firm is engaged, there should be security contracts in place;



- iii. Firefighting equipment should be available and accessible at all times; and
- iv. Firefighting equipment should be maintained and serviced as the case may be.

11.0 RENEWAL OF PHARMACEUTICAL LICENCE

11.1 A Pharmaceutical Licence is valid for two (2) years from the date of issue.

11.2 A holder of Pharmaceutical Licence who intends to renew the licence shall, at least ninety (90) days before the expiry of the licence, apply to the Authority for renewal of the licence.

11.3 An application for renewal of Pharmaceutical Licence shall be made in a prescribed manner and form, upon payment of prescribed fee.

11.4 The application procedure for renewal of Pharmaceutical Licence shall follow same procedure of a new application presented above on **section 7.0**.

11.5. A report of activities undertaken in the past two years shall be an additional requirement for the renewal application.

11.4 A complete application for renewal shall be submitted to the Authority via ZAMRA online portal.

12.0 AMENDMENT OF PHARMACEUTICAL LICENCE

12. 1 A holder of a Pharmaceutical Licence who intends to amend the licence shall apply to the Authority for amendment of the licence in the prescribed manner and form, upon payment of the prescribed fee.

12.2 The amendment application for a Pharmaceutical Licence shall be made via the ZAMRA online portal.

12. 3 The Authority may amend a Pharmaceutical Licence where;

- i. There is a change of business name; or
- ii. The responsible person changes.

12.4 The Authority shall, within fourteen (14) days of receipt of the application for amendment of the licence, approve or reject the amendment.

12.5 An application for change of premises or change of physical location of the licensed or approved premises shall be required to go through the licensing process for the new



premises.

12.0 REQUIREMENTS FOR AMENDMENT APPLICATIONS

12.1 Change of responsible person (Pharmacist/Veterinary Surgeon)

Where there is change of supervision, the applicant is required to submit the following;

- i. Proof of payment of amendment fees;
- ii. Completed application form for amendment;
- iii. HPCZ/VAZ full registration certificate and valid annual practicing certificate for the newly engaged responsible person;
- iv. Contract and/or Agreement letter signed by both parties, employer and employee; and
- v. Resignation letter for the previous responsible person where applicable.

12.2 Change of business name

12.2.1. 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.

12.2.2. Where the change of the business name is due to purchase of the business by another party, the following will be required to be submitted:

- i. Proof of payment of amendment fees;
- ii. Letter of sale signed by the buyer and the seller;
- iii. List of new Directors registered with PACRA;
- iv. Updated PACRA Certificate of Registration/Incorporation (where the business name has changed); and
- v. Local Authority certificates bearing the new business name (where the business name has changed).

13. RECORD AND INFORMATION MANAGEMENT SYSTEM

The following record and information management system must be available:

- i. Bin cards (stock cards) as backup system in case of failure for a computerised system;



- ii. Computer;
- iii. Expired Products Register;
- iv. Controlled Substances Register;
- v. Hard copy or electronic Invoices/ Delivery notebooks;
- vi. Log for Part-time Pharmacist or Veterinary Surgeon;
- vii. Recalled Products Register;
- viii. Quarantine Products Register;
- ix. Hard copy or electronic Receipt/issue books; and
- x. ZAMRA's Inspectors' Book.

14.0 STANDARD OPERATING PROCEDURES (SOPS)

14.1 The pharmaceutical wholesale business should have standard operating procedure on how to deal with the following:

- i. Expired products;
- ii. Recalled Products;
- iii. Quarantined Products;
- iv. Dispatch and Distribution of products;
- v. Complaint handling;
- vi. Cleaning Procedures and management of waste generated;
- vii. Maintenance of Equipment;
- viii. Storage of medicines and allied substances;
- ix. Fire safety and use of fire extingisher;
- x. Receiving of medicines and allied substances; and
- xi. Identification of substandard and falsified medicines and allied substances.

**15.0 QUALITY MANAGEMENT SYSTEM**

15.1 The pharmaceutical wholesale business shall comply with Good Storage and Distribution Practices guidelines and ensure that a quality management system and/or procedures is in place.

16.0 REFERENCE MATERIALS

16.1 The following reference materials must be available:

(a) Statutes

- i. Animal Health Act (No.27), 2010 of the Laws of Zambia;**
- ii. Controlled Substances Act (No. 2) of 2023 of the Laws of Zambia;
- iii. Health Professions Act (No.17), 2024 of the Laws of Zambia;*
- iv. Medicines and Allied Substances Act (No.3), 2013 of the Laws of Zambia;
- v. Narcotic Drugs and Psychotropic Substances Act, (No. 35), of 2021 of the Laws of Zambia; and
- vi. Veterinary and Veterinary Para-Professions Act (No.45), 2010 of the Laws of Zambia. **

(b) Professional References (Recommended)

- i. British National Formulary (BNF); *
- ii. British Pharmacopoeia; *
- iii. Martindale; *
- iv. Essential Veterinary Medicines List; and**
- v. Zambia National Formulary (ZNF). *

NOTE: recent edition is preferred for reference materials above.

(c) Professional References (mandatory)

- i. Standards of Pharmaceutical Practice.

(d) Guidelines

- i. Good Storage and Distribution Practice Guidelines
- ii. Good Cold Chain Management Practices Guidelines



Note:

- (*) The references are applicable to a pharmaceutical wholesale dealing in human medicines. (**)
The reference is applicable to pharmaceutical establishment where veterinary medicines
will be dealt in and / or where a veterinary or veterinary para-professional is engaged.

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