Guidelines for Establishment of a Pharmaceutical Wholesale Business in Zambia

August 2020

These guidelines for the establishment of a Pharmaceutical Wholesale Business 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. 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 of the laws of Zambia and the relevant Regulations made thereunder. (Hereafter referred to as "the Act").

Among other things, it is unlawful for any person to manufacture, distribute or deal in any medicine or allied substance medicines in Zambia except in accordance with the Pharmaceutical Licence and Marketing Authorisation or exemptions obtained from ZAMRA.

1.1. Licensing procedure: An overview

1.1.1. The Directorate responsible for licensing has the responsibility to grant a pharmaceutical licence to an applicant who intend to sale or supply medicines and allied substances by way of wholesale dealing. The Director-General shall endorse the pharmaceutical licence issued to applicants intending to sale or supply medicines and allied substances by way of wholesale.

1.1.2. The licensing process of pharmaceutical wholesale business shall include the following:

(a) The applicant shall lodge an application for a pharmaceutical licence to the Authority;

(b) The Authority shall screen the application to ensure that relevant documents are attached;

(c) Where the Authority finds that the application is insufficient, the Authority shall request for additional information as set out in a prescribed form;

(d) Inspectors of the Authority shall conduct pre-licensing inspections to assess the conformity of the applicant's premises to the set standards;

(e) A pre-licensing inspection report shall be generated containing findings and relevant recommendations;

(f) The licensing committee shall scrutinise the pre-licensing inspection report and recommendations;

(g) 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.

(h) Where the applicant notifies the Authority in writing that the deficiencies have been rectified, the Authority may conduct a verification inspection where necessary;

(i) 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;

(j) The Director responsible for licensing shall facilitate the final steps of generating the pharmaceutical licence for onward endorsement by the Director-General; and

(k) The Director-General shall endorse on the pharmaceutical licence issued to the applicant.

1.1.3. The inspectors of the Authority shall conduct routine inspections to monitor compliance to the set standards including terms and conditions of the pharmaceutical licence.

1.1.4. The purpose of these guidelines is to provide guidance on the requirements to establish and operate a pharmaceutical wholesale business in Zambia.

2. APPLICATION PROCEDURE FOR ISSUANCE OF A PHARMACEUTICAL LICENCE

2.1. A person who intends to operate a pharmaceutical wholesale business shall apply to the Authority for a Pharmaceutical Licence as provided under the Act, by ensuring that the application is duly completed in a prescribed manner and form and should include the following attachments:

2.1.1. Proof of payment of the prescribed fee;

2.1.2. The applicant's valid Business Levy permit and fire certificate issued by the local authority;

2.1.3. The person is a holder of a valid Certificate of Incorporation, Business Name Registration Certificate;

2.1.4. A valid professional practising certificate for the full-time registered pharmacist who shall supervise the pharmaceutical wholesale establishment; and

2.1.5. Sketch of the floor plan for the premises.

3. SUBMISSION OF THE APPLICATION

3.1. A completed application shall be submitted to the Authority.

4. PERSONNEL REQUIRED IN A PHARMACEUTICAL WHOLESALE BUSINESS

4.1. Personnel requirements in a pharmaceutical wholesale business

4.1.1. A pharmaceutical wholesale business shall engage a registered pharmacist on a full-time or part-time basis. Where a registered pharmacist is engaged on a full-time basis, the pharmacist shall be

required to be physically present to manage the pharmaceutical wholesale business as a responsible person;

4.1.2. Where a Pharmacist is engaged on a part-time basis as the responsible person, a pharmaceutical wholesale business shall engage a full-time registered pharmacy technologist;

4.1.3. An agro-veterinary wholesale business shall engage a registered veterinary surgeon on a full-time or part-time basis. 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;

4.1.4. 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

4.1.5. A registered pharmacy technologist and veterinary para-professional may be engaged on locum basis where necessary.

4.1.6. A pharmaceutical wholesale business may engage support staff.

5. STANDARDS OF THE PHARMACEUTICAL WHOLESALE BUSINESS

5.1. Pharmaceutical Premises

5.1.1. The premises should have the following requirements:

(a) Clean and tidy surroundings with conspicuous identity;

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

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

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

(e) The premises should have sufficient natural and artificial lighting;

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

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

(h) The premises must have adequate shelving which are smooth, washable and impermeable

5.1.2. 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;

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

5.1.4. Staff must be familiar with the fire prevention procedure

5.1.5. Security measures must be in place to provide for the safety of both staff, medicines, allied substances and as far as possible exclude any unauthorised entry; and

5.1.6. 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.

5.2. Relative Partitioning

5.2.1. The premises should have clearly partitioned areas to provide for the following:

(a) Front shop/ sales or showroom;

(b) Main warehouse (air conditioned);

(c) Receiving bay;

(d) Quarantine room;

(e) Recalled products room (under lock and key);

(f) Expired products room (under lock and key);

(g) Water closet toilet(s) with hand washing basin.

5.3. Facilities and Equipment

5.3.1. The following facilities and equipment must be available:

(a) Adequate shelves and pallets;

(b) Pedal waste bin(s);

(c) Transportation facilities;

(d) Refrigerator;

(e) Fire extinguishers placed at strategic positions;

(f) Temperature charts; and

(g) Wall and refrigerator thermometers

5.4. Record and Information Management System

5.4.1. The following record and information management system must be available:

(a) Bin cards (stock cards) as backup system in case of power failure for a computerised system

(b) Computer

(c) Expired Products Register

(d) Invoices/ Delivery notebooks

(e) Log for Supervising Pharmacist or Veterinary Surgeon.

(f) Recalled Products Register

(g) Receipt/issue books

(h) ZAMRA's Inspectors' Book

5.5. Standard operating procedures (SOPs)

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

(a) Expired products

(b) Recalled Products

(c) Quarantined Products

(d) Distribution of products

(e) Complaint handling

(f) Cleaning Procedures

(g) Management of waste generated

(h) Maintenance of Equipment

5.6. Quality Management System

5.6.1. The pharmaceutical wholesale business shall comply with Good Distribution Practices guidelines and ensure that a quality management system is in place.

5.7. Reference Materials

5.7.1. The following reference materials must be available:

(a) Statutes

i) Animal Health Act (No.27), 2010**

ii) Dangerous Drugs Act, Cap 95

iii) Health Professions Act (No.14), 2009*

iv) Medicines and Allied Substances Act (No.3), 2013

v) Narcotic Drugs and Psychotropic Substances Act, Cap 96

vi) Veterinary and Veterinary Para-Professions Act (No.45), 2010**

(b) Professional References

i) British National Formulary (BNF) - recent edition is preferred*

ii) British Pharmacopoeia - recent edition is preferred*

iii) Martindale - recent edition is preferred*

iv) Standards of Pharmaceutical Practice

v) Veterinary National Formulary**

vi) Zambia National Formulary (ZNF) - recent edition is preferred*

(c) Guidelines

i) Good Distribution Practice 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.

5.8. Fees

5.8.1. The current fees legislation is contained in the Medicines and Allied Substances Regulations No. 38 of 2016.

6. CONTACT DETAILS

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Annex I: Attendance Log for Supervising Pharmacist or Veterinary Surgeon

ATTENDANCE LOG **Name:**			**Month:**	
Date	**Time in**	**Time Out**	**Signature Employee**	**Checked by Manager**

ANNEX II: Medicines Expiry Register

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