

ZAMBIA MEDICINES REGULATORY AUTHORITY



Health Shops Permit

GUIDELINES ON OPERATING A HEALTH SHOPS

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This guidance document is issued by the Authority in accordance with Section 68 of the Medicines and Allied Substances Act No.3 of 2013 of the laws of Zambia. The Authority may amend any part of this guideline from time to time.

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ABBREVIATIONS AND ACROYMNS

- ICT Information and Communication Technology
- PACRA Patents and Company Registration Agency

INTERPRETATIONS

In these Guidelines, unless the context otherwise requires -

- **“Act”** means the Medicines and Allied Substances Act No. 3 of 2013
- **“Authorised agent”** means an appointed government /quasi-government officer/office for the purpose of carrying out Zambia Medicines Regulatory Authority functions within the prescribed parameters
- **“Authorized prescriber”** means a medical doctor, a dental surgeon, veterinary surgeon or such other person as the Minister may, on the advice of the Authority, by statutory instrument, designate
- **Authorised supplier”** means a holder of pharmaceutical licence
- **“Dispense or dispensing”** means the interpretation of a valid prescription or order of an authorised prescriber by a health shop by for a patient
- **“Health shop dispenser”** means a person responsible for the managing the health shop and has undergone training approved by the Authority
- **“Health Shop Permit”** means a permit issued under the Act
- **“Health shop”** means a place or premises permitted to sell a prescribed list of medicines by the Authority, under the control of an authorised person as determined by the Authority
- **“Patient pack”** means a quantity of medicines sufficient to treat a single patient for a specified condition as indicted for each medicine in annex I
- **“Pharmaceutical wholesale outlet”** means a holder of pharmaceutical licence
- **“Prescription only medicine”** means a medicine dispensed only on prescription
- **“Prescription”** means a written or electronically transmitted order issued by an authorised prescriber for a medicine to be dispensed
- **“Repacking of medicines”** means the act of removing a preparation from its original primary container and placing it into a patient pack, but does not include the act of cutting of a blister
- **“Responsible person”** means a pharmacist or pharmacy technologist

1.0 INTRODUCTION

The Zambia Medicines Regulatory Authority (ZAMRA) is a regulatory body established under the Medicines and Allied Substances Act, No. 3 of 2013. Among other things, ZAMRA is mandated to register and regulate health shops. These guidelines are therefore, meant to provide assistance to a person intending to run a health shop.

2.0 APPLICATION PROCEDURE FOR ISSUANCE OF A HEALTH SHOP PERMIT

A person who intends to operate a health shop shall apply to the Authority for a Health Shop Permit and shall only deal in medicinal products contained on the second schedule of Health Shop Regulations issued under Statutory Instrument (SI) No. 12 of 2016, provided that:

- (a) The application is duly completed in a prescribed manner and form;
- (b) The prescribed fee is paid in full to ZAMRA as provided in Annex 2;
- (c) There is evidence of registration of the business with relevant bodies like PACRA;
- (d) There is proof of business licence to trade from the Local Authority;
- (e) there is evidence of engagement of a health shop dispenser
- (f) there is evidence of the responsible person
- (g) Sketch of the floor plan for the premises;

3.0 SUBMISSION OF THE APPLICATION

A completed application shall be submitted to the nearest ZAMRA office or its authorised agent.

4.0 PERSONNEL REQUIREMENTS FOR A HEALTH SHOP

- 4.1. A health shop shall be under the management of a health shop dispenser;
- 4.2. The health shop dispenser shall be engaged on full time basis and shall only be allowed to work in one health shop at any given time;
- 4.3. All health shops shall be monitored by ZAMRA to ensure they adhere to the set standards and norms set in the health shop regulations
- 4.4. The responsible person shall provide supervision for a minimum of two (2) hours per fortnightly at each outlet;
- 4.5. A health shop shall be required to maintain a log book for the responsible person
- 4.6. The responsible person shall be required to indicate activities performed in the log book which shall be subject to inspection by the ZAMRA inspectors;

5.0 STANDARDS OF HEALTH SHOP PREMISES

5.1. LOCATION OF THE HEALTH SHOP

- 5.1.1. The Authority shall, in considering an application for a health shop permit - prioritise applications from the following areas:
 - (a) Rural areas and small towns where access to medicines is limited as identified by government and its agents;
 - (b) In peripheral areas of big towns or cities where access to medicines is limited
- 5.1.2. Before granting a health shop permit, the Authority shall take into consideration the availability of dispensing facilities in the area with respect to which the application relates.
- 5.1.3. A permit previously issued may be renewed after two years if the holder complies with terms and conditions.

5.2. PREMISES OF A HEALTH SHOP

- 5.2.1. The external appearance of a health shop premises must meet the minimum set standards for health shops (annex xxx).
- 5.2.2. The premises should be identified distinctly by a sign post with following details:
 - (a) name of health shop;
 - (b) address of health shop;
 - (c) telephone number;
 - (d) operating times on door or window; and
 - (e) standard logo for health shops: Green Cross with 'H' on the left and 'S' on right side of the upper arm in white background; 'H' and 'S' should be black in colour (See Annex xxx)The logo shall be designed and obtained from ZAMRA.
- 5.2.3. The design and layout of the health shop must permit a logical flow of work, effective communication and supervision and 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;
- 5.2.4. All parts of the premises must be maintained in an orderly and tidy condition; and
- 5.2.5. A valid annual practicing certificate of responsible person should be displayed conspicuously in the health shop.

5.3. SAFETY OF PREMISES

- 5.3.1. Working environment must be arranged to protect the safety of the public and people working on the premises and comply with relevant legislation relating to safety in the workplace;
- 5.3.2. Measures to prevent accidents and fires must be put in place;
- 5.3.3. All staff must be familiar with the fire procedure; and
- 5.3.4. Electrical equipment must be safe and maintained regularly.

5.4. SECURITY OF PREMISES

- 5.4.1. Careful consideration must be given to the overall security of the health shop. The shop must be lockable and exclude any unauthorised entry.
- 5.4.2. Security measures must be in place to ensure the safety of both staff and medicines.
- 5.4.3. Burglar bars should be installed on all entrance/exit doors and windows where necessary.
- 5.4.4. Where practicable, it is advisable that security guard(s) are engaged, and other security systems installed.

5.5. CONDITION OF PREMISES

- 5.5.1. The walls, floors, windows, ceiling, woodwork and all other parts of the premises must:
 - (a) be kept clean; and
 - (b) be kept in 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.
- 5.5.2. Countertops, shelves, floors and walls must be finished in a smooth, washable and impermeable material which is easy to clean and maintain in a hygienic condition.

5.6. STANDARDS AND DESIGN OF PREMISES

The following are the standards for a health shop:

- (a) Should be a permanent, well-built structure and clearly identifiable as a health shop
- (b) The premises in which medicines and allied substances are sold should be in good state of repair, kept clean and tidy
- (c) 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 and/or ceiling;
- (g) The premises should have a solid smooth floor which can be easily cleaned
- (h) The premises should have walls that are painted and easy to clean;
- (i) The premises should have, where possible, clearly partitioned areas for carrying out specific activities (such as main shop, dispensary, storage area and expired medicines area);

- i. The premises should be of a minimum area of 14 square meters partitioned into at least two rooms for dispensing and storage, respectively;
 - ii. The dispensing room should be of a minimum area of 6 square meters while the store room is of at least 8 square meters;
 - iii. The dispensary surface area must be sufficient for the volume of prescriptions dispensed. A clear working surface area of at least 90cm by 1m must be provided in the dispensary;
 - iv. The temperature in the shop must be maintained below 30°C by means of ceiling fans, improved air ventilation and where applicable a functional air-conditioner is desired;
 - v. The premises should have adequate sanitation facilities such as toilets and hand-washing utility; and
- (j) The premises must have sufficient shelving constructed from a smooth, washable and impermeable material, which is easy to maintain in a hygienic condition for the keeping of medicines above floor level.

6.0 SUPPLY OF PRESCRIPTION ONLY MEDICINES

- (a) Prescription only medicine shall be sold or supplied upon receipt of a prescription issued by an authorized prescriber;
- (b) A prescription shall be in writing, signed and dated by the authorized prescriber issuing it, with the prescriber's signature and registration number and shall specify:
 - i. the name and address of the person for whose treatment it is given;
 - ii. the amount of the medicine to be supplied;
 - iii. the dose to be taken; and
 - iv. the route of administration.
- (c) Upon supply of any prescription only medicine, the pharmacy technologist or pharmacist or health shop dispenser shall record the prescription in a prescription register maintained for that purpose;
- (d) An entry made in the prescription register, for prescription medicines shall indicate the:
 - i. serial number of the entry;
 - ii. date of supply;
 - iii. name and address of the patient;
 - iv. name of the medicine or preparation and the quantities thereof;
 - v. the signature of the health shop dispenser.
- (e) Where a medicine is supplied on a prescription on which the medicine has been supplied on a previous occasion and entries made in the prescription register, it shall be sufficient if the new entry in the register

- includes the serial number, date of supply, quantity supplied and a sufficient reference to an entry in the register recording the dispensing of the medicine on the previous occasion;
- (f) Health Shop Dispenser shall not dispense any prescription for the first time later than twenty eight days after the date of issue;
 - (g) A health shop dispenser shall not be involved in repacking of medicines but should use individual patient packs.
 - (h) A health shop shall procure its medicines from authorised suppliers.

7.0 ROLES AND RESPONSIBILITIES OF HEALTH SHOP OWNER, DISPENSER AND RESPONSIBLE PERSON

7.1. HEALTH SHOP OWNER

The health shop owner will ensure that:

- (a) A valid health shop permit is displayed in the shop at all times;
- (b) There is a suitably qualified dispenser who is recognized by the Authority and whose dispensing certificate is displayed in the health shop;
- (c) They do not interfere with the dispenser's professional decisions, roles and responsibilities;
- (d) Storage and sale of medicines is according to the list prescribed in the regulations;
- (e) Medicines intended for public health institutions, unregistered, expired, sub-standard and falsified medicines are not sold in the health shop; and
- (f) Reference books and other documents for record keeping are available all the time.

7.2. HEALTH SHOP DISPENSER

The health shop dispenser shall:

- (a) Handle all the roles and responsibilities related to medicine dispensing in the health shop;
- (b) Ensure that the health shop is kept clean at all times;
- (c) Ensure that all medicinal products sold are sourced from authorized suppliers;
- (d) Handle all the technical duties related to medicine dispensing in the health shop;
- (e) Ensure that any returned, unwanted or out-of-date, falsely labelled and adulterated product is appropriately segregated and located in a designated secure area;
- (f) Keep in proper form all required records relating to the purchase and dispensing of all prescription medicines for inspections by ZAMRA

The responsible person shall -

- (a) Attend reasonable periods of the operating time of the health shop, in order to properly carry out the role of supervising;
- (b) Ensure that clear, structured procedures are in place , with regard to the management of the dispensing activity, including quality-assured safety checking systems and the maintenance of adequate records;
- (c) Ensure that all personnel operating within the health shop under their charge are aware of the scope of their role and the limits applicable in respect of the management of the professional services provided;
- (d) Ensure that the appropriate registration certificates are conspicuously displayed, including copies of their Health Professions Council of Zambia Full Registration Certificates and Practitioners Annual Practicing Certificate;
- (e) Be certain that the health shop is registered with the Authority and operating in accordance with the present law and regulations;
- (f) Supervise the storage , sale and dispensing of medicines;
- (g) Ensure that all medicines are authorized for supply;
- (h) Ensure that all medicines are sourced from authorized suppliers;
- (i) Ensure any returned, unwanted or expired, falsely labelled and adulterated medicine is appropriately segregated and located in a designated secure area;
- (j) Supervise the health shop for at least four (4) hours per month and shall indicate the activities performed in the log book;

8.0 HYGIENE WITHIN THE PREMISES

- 8.1. There must be a suitable, clean hand wash basin made of a smooth, washable and impermeable material which is easy to maintain in a hygienic condition. Facilities must include readily available antiseptic/medicated soap and paper towels or other satisfactory means of drying the hands.
- 8.2. Toilet facilities must be kept clean, tidy and must not be used for storage of medicines.
- 8.3. Hand-washing facilities must be provided in the toilet area with a conspicuous notice requesting users to wash their hands after using the facility. Facilities must include readily available antiseptic/medicated soap and paper towels or other satisfactory means of drying the hands.
- 8.4. In a case where toilet facilities are communal, attempts should be made to ensure that the above measures are adhered to.

9.0 RECORD KEEPING FACILITIES

- 9.1. Every health shop shall be required to keep correct records with regard to medicines and allied substances and these shall include:
 - (a) Invoices and receipts;
 - (b) Proforma invoice/Quotation where applicable
 - (c) Daily cash sales book;
 - (d) Prescription Register;
 - (e) Expired Product Register;
 - (f) Prescription file; and
 - (g) Stock records;
 - (h) ICT, where applicable
- 9.2. The documents referred to in (9.1) above shall be kept for at least 2 years and be required to be made available and inspected by the Authority's inspectors and shall be used as means of verifying compliance to these guidelines;

10.0 DISPOSAL OF PHARMACEUTICAL AND NON PHARMACEUTICAL WASTE AND UNWANTED MEDICINES

10.1. DISPOSAL OF NON PHARMACEUTICAL WASTE

- (a) A suitable and adequate means of waste disposal must be available and in use.
- (b) Waste material must not be allowed to accumulate and must be collected in suitably covered (as applicable) receptacles for removal to collection points.

- (c) Under no circumstances must substances be disposed of down surface water drains, e.g. storm water drains.

10.2. **DISPOSAL OF UNWANTED MEDICINES AND ALLIED SUBSTANCES (OBSOLETE AND EXPIRED)**

- (a) The health shop dispenser shall withdraw and store all obsolete, expired and unwanted medicines and allied substances separately from usable stock and in packages or cartons clearly labelled accordingly;
- (b) Medicines that are not fit for human use shall not be dispensed by the health shop dispenser;
- (c) The responsible person shall communicate to the Authority so that obsolete, expired and unwanted medicines and allied substances are disposed through proper procedures; and
- (d) The cost and responsibility to dispose obsolete, expired and unwanted medicines and allied substances shall be borne by the health shop owner.

11.0 **RECALL OF MEDICINES**

Where medicines which have been recalled or withdrawn and have to be removed from the market due to problems with quality, safety, or efficacy, the health shop owner, responsible person and health shop dispenser shall cooperate with the Authority to facilitate the recall of such medicines.

12.0 **HEALTH SHOP REFERENCE MATERIALS**

- 12.1. To facilitate daily operations, every health shop shall have reference materials which include—
 - a) Zambia National Formulary (ZNF) recent edition;
 - b) Medicines and Allied Substances Act (No.3) of 2013;
 - c) Health Professions Act No. 24 of 2009;
 - d) Guidelines for Health Shops
 - e) Standard Treatment Guidelines;
 - f) Health Shop regulations, 2016; and
 - g) List of General Sales Medicines registered by ZAMRA

Note: Electronic access to the required references is also acceptable.

ANNEXURE

Annex 1: List of Medicines for Health Shops

	Item	Strength	Pack size
	Medicines for Asthma		
1	Salbutamol tablets	2mg	Patient pack 10s
2	Salbutamol inhaler	100mcg/dose	Patient pack each
	Antibiotics		
3	Amoxicillin tablets/capsules	250mg	Patient pack 15s/30s
4	Amoxicillin oral suspension	125mg/15ml	Patient pack 100ml
5	Co-trimoxazole tablets	400/80mg	Patient pack 10s
6	Co-trimoxazole suspension	200/40mg/5ml	Patient pack 50ml/100ml
7	Doxycycline capsules/tablets	100mg	Patient pack 10s
8	Metronidazole tablets	200mg	Patient pack 15s/30s
9	Tetracycline Hyclate Ointment	1%	Patient pack each tube
10	Silver sulfadiazine cream	10g	Patient pack each
	Anthelmintics tablets		
11	Albendazole tablets	400mg	Patient pack each tablet
	Anti-inflammatory/Analgesics		
12	Ibuprofen tablets	200mg	Patient pack 10s
13	Hydrocortisone ointment/cream	1%	Patient pack each 15-50g
14	Paracetamol tablets	100mg, 500mg	Patient pack 10s
15	Acetylsalicylic acid (Aspirin)	300mg	Patient pack 10s
	Anti-fungal Agents		
16	Nystatin oral suspension	50mg/5ml, 100,000 UI/ml	Patient pack 10 - 30ml
17	Clotrimazole cream	1%, 10%	Patient pack each tube
18	Clotrimazole vaginal tablets	100mg, 500mg	Patient pack 100mg 6s

	Item	Strength	Pack size
			500mg each
	Anti-malarials		
19	Artemether-Lumefantrine tablets	20/120mg	Patient pack 6s, 12, 18 & 24s
	Laxatives		
20	Bisacodyl tablets	5mg	Patient pack 10s
	Anti-histamines		
21	Cetirizine hydrochloride tablets	10mg	Patient pack 10s
22	Cetirizine hydrochloride oral suspension	5mg/5ml	Patient pack 30- 50ml
23	Chlorpheniramine Maleate tablets	4mg	Patient pack 10s
24	Chlorpheniramine Maleate syrup	2mg/5ml	Patient pack 50- 100ml
	Oral contraceptives		
25	Ethinylestadiol+Northisterone tablets	0.03mg/0.3mg	Patient pack 28s
26	Ethinylestadiol+levonogestrel tablets	0.03mg/0.15mg	Patient pack 28s
	Minerals/vitamins		
27	Vitamin B Complex tablets		Patient pack 10s
28	Zinc Sulfate tablets	20mg	Patient pack 10s
	Fluids and Electrolytes		
29	Normal Saline IV		0.90%, 1 litre 500ml or 1000ml
30	Ringers lactate IV		1 litre 500ml or 1000ml
	All general sale medicines		

Annex 2: Fees Structure

NO.	DESCRIPTION	AMOUNT (ZMW)
Towns with City or Municipal Councils		
1.	Application for issue of a health shop permit	2,050.00
2.	Re-inspection of premises to operate a health shop	1,200.00
3.	Renewal for the health shop permit	1,200.00
4.	Application for change of premises for health shop	2,050.00
Towns with District Councils and other areas		
1.	Application for issue of health shop permit	1,050.00
2.	Re-inspection of premises to operate a health shop	600.00
3.	Renewal for the health shop permit	600.00
4.	Application for change of premises for health shop	1,050.00