



Zambia Medicines Regulatory Authority

GUIDELINES FOR ESTABLISHMENT OF A HEALTHSHOP

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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 Health Shop in Zambia are issued pursuant to section 14 of the Act and Statutory Instrument No. 12 of 2016. The Guidelines prescribe the requirements and procedures for the establishment, licensing, operation, management and continued compliance of Health Shops in Zambia. They further provide guidance on personnel requirements, standards for premises, procurement and supply of medicines, dispensing practices, record keeping, waste management, product recalls, amendments to licensed premises and other operational requirements necessary to ensure the safe and effective provision of pharmaceutical services through Health Shops.

Health Shops play an important role in improving access to essential medicines, particularly in underserved, rural and peri-urban communities where access to pharmaceutical outlets may be limited. Consequently, all Health Shops are required to operate in accordance with the provisions of the Act, the applicable Regulations and these Guidelines.

It is unlawful for any person to establish, operate, manage or conduct a Health Shop or to sell, supply or dispense medicines and allied substances through a Health Shop except in accordance with a valid Health Shop Permit issued by the Authority.

The Authority may review, revise or amend these Guidelines from time to time in order to reflect developments in legislation, policy, professional practice and public health needs.



2. OBJECTIVE

These guidelines provide guidance on the requirements for establishment of a Health Shop business in Zambia

3. SCOPE

These guidelines define the minimum requirements for the establishment of a Health Shop in Zambia. They also provide guidance on the amendment and renewal of a Health Shop Permit.

4. DEFINITIONS

In these Guidelines, unless the context otherwise requires -

“Act” means the Medicines and Allied Substances Act No. 3 of 2013.

“Administrative amendment” means an amendment to a health shop permit which involves a change in trading name, composition of directors in a company, change in responsible person.

“Authority” means the Zambia Medicines Regulatory Authority.

“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.

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

“Dispense or dispensing” means the interpretation of a valid prescription or order of an authorised prescriber by a health shop for a patient;

“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;

“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;



“Responsible person” means a pharmacy technologist;

“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;

“Rural area” means an area that does not fall within the jurisdiction of a city council, municipal council or town council established under the Local Government Act;

“Peripheral area” means a region, zone or district located on the outer edges of major urban centers;

“Dispensing facilities” means a retail pharmacy;

“Unfit medicines and allied substances” means obsolete, unwanted, expired, improperly sealed, damaged, improperly labeled, substandard, falsified, adulterated, prohibited or unauthorised medicines and allied substances;

“Inspector” means a person appointed as such under the Act;

5. ABBREVIATIONS

HPCZ - Health Professions Council of Zambia

SOP - Standard Operating Procedure

ZAMRA - Zambia Medicines Regulatory Authority



6. APPLICATION PROCEDURE FOR ISSUANCE OF A HEALTH SHOP PERMIT

- 6.1 A person who intends to operate a health shop shall apply to the Authority for a Health Shop Permit in a prescribed manner and form and upon payment of the prescribed fee.
- 6.2 An application made in accordance with clause 7.1 below shall be accompanied by a-
- 6.2.1 Valid Certificate of Incorporation or business name registration certificate.
 - 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.
 - 6.2.4 Contract of employment or agreement letter signed by both parties, i.e. employer and responsible person
 - 6.2.5 Sketch of the floor plan for the premises.

7. SUBMISSION OF THE APPLICATION

- 7.1 A complete application shall be submitted to the Authority in the prescribed manner and form.
- 7.2 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 health shop shall include the following:
- i. Submission of an application to the Authority;
 - ii. Screening of an application to ensure that relevant information and documents are attached to the application;
 - iii. Where the Authority finds that the application is incomplete, the Authority shall



request for additional information as set out in a prescribed form;

- iv. Where the Authority finds that the application is complete, a pre-licensing inspection is scheduled;
- v. Pre-licensing inspections are carried out by the Authority's inspectors to assess the conformance of the applicant's premises to the set standards;
- vi. A pre-licensing report is generated containing findings and relevant recommendations;
- vii. The licensing committee scrutinises the pre-licensing inspection report and recommendations;
- viii. 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;
- ix. 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;
- x. The Director responsible for licensing shall facilitate the final steps of generating the Health Shop Permit for onward endorsement by the Director-General; and
- xi. The Director-General shall endorse on the Health Shop Permit issued to the applicant.

NOTE: The inspectors of the Authority shall conduct routine inspections to monitor compliance with the set standards including terms and conditions of the Health Shop Permit.



9. REQUIREMENTS FOR A HEALTH SHOP

9.1 PERSONNEL

9.1.1 A health shop shall be under the management of a Pharmacy Technologist, as the person responsible, who shall be required to be physically present to manage the outlet during operational hours.

9.1.2 The person responsible shall be engaged on full-time basis and shall only be allowed to work in one health shop at any given time;

9.2 LOCATION OF THE HEALTH SHOP

9.2.1 The Authority shall, in considering an application for a health shop Permit, prioritise applications from the following areas:

- (i) Rural areas and small towns where access to medicines and allied substances is limited as identified by government; and

9.2.2 In peripheral areas of big towns or cities where access to medicines is limited

9.2.3 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.

9.2.4 A permit previously issued may be renewed after two years if the holder complies with terms and conditions.

9.3 PREMISES OF A HEALTH SHOP

9.3.1 The external appearance of a health shop premises must meet the minimum set standards for health shops.

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

- i. Name of health shop;
- ii. Physical address of health shop;
- iii. Telephone number;



- iv. Operating times on door or window; and
- v. 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.

9.3.3 The design and layout of the health shop must permit a logical flow of work, effective communication and supervision, ensure effective cleaning and maintenance and must minimise the risk of errors, cross contamination and anything else which would have an adverse effect on the quality of products.

9.3.4 All parts of the premises must be maintained in an orderly and tidy condition.

9.3.5 The HPCZ full Registration Certificate and valid Annual Practicing Certificate of the responsible person shall be displayed conspicuously in the health shop.

9.4 SAFETY OF PREMISES

9.4.1 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.

9.4.2 Measures to prevent accidents and fires must be put in place.

9.4.3 All staff must be familiar with the fire safety procedures.

9.4.4 Electrical equipment must be safe and maintained regularly.



9.5 SECURITY OF PREMISES

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

9.6 CONDITION OF PREMISES

- 9.6.1 The walls, floors, windows, ceiling, woodwork and all other parts of the premises must:
 - i. be kept clean; and
 - ii. 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.



- 9.6.2 Countertops, shelves, floors and walls must be finished in a smooth, and impermeable material which is easy to clean and maintain.
- 9.6.3 The temperature in the shop shall be maintained below 30°C by means of a functional air-conditioner, improved air ventilation and where applicable, a fan can be added.
- 9.6.4 The premises should have adequate sanitation facilities such as toilets and hand-washing utility; and
- 9.6.5 The premises must have adequate shelving constructed from a smooth, washable and impermeable material, which is easy to maintain. In addition, pallets must be available to provide for extra storage of medicines and allied substances and to avoid storing the products on the floor.

9.7 STANDARDS AND DESIGN OF PREMISES

9.7.1 The health shop premises should:

- i. be a permanent, well-built structure and clearly identifiable as a health shop;
- ii. be in good state of repair, kept clean and tidy;
- iii. have adequate natural and artificial ventilation;
- iv. have adequate natural and artificial lighting;
- v. have a leak-proof roof and ceiling;
- vi. have a solid smooth floor which can be easily cleaned
- vii. have walls that are painted and easy to clean; and
- viii. have clearly designated areas for carrying out specific activities such as the front shop, dispensary and storage area for unfit medicines and allied substances.

9.7.2 Relative Partitioning

- i. The premises should be of a minimum area of 14 square meters partitioned into at least two rooms
- ii. The front shop room should be of a minimum area of 8 square meters while the dispensary should be of at least 6 square meters.



- iii. The dispensary surface area must be sufficient for the volume of prescriptions dispensed.
- iv. A clear working surface area of at least 90cm by 1m must be provided in the front shop.

10. SUPPLY OF PRESCRIPTION ONLY MEDICINES

- 10.1 Prescription only medicines shall be sold or supplied upon receipt of a prescription issued by an authorized prescriber;
- 10.2 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.
- 10.3 Upon supply of any prescription only medicine, the responsible person shall record the prescription in a prescription register maintained for that purpose; 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 responsible person.

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;



- 10.4 The responsible person shall not dispense any prescription issued for the first time later than twenty-eight days after the date of issue;
- 10.5 The responsible person shall not repackage the medicines but shall dispense the medicines in individual patient packs.

11. ROLES AND RESPONSIBILITIES OF HEALTH SHOP OWNER, AND RESPONSIBLE PERSON

11.1 HEALTH SHOP OWNER

The health shop owner will ensure that:

- i. A valid health shop permit is displayed in the shop at all times;
- ii. There is a suitably qualified responsible person who is recognized by the Authority and whose Full Registration Certificate and valid Annual Practicing Certificate is displayed in the health shop;
- iii. They do not interfere with the responsible person's professional decisions, roles and responsibilities;
- iv. Stocking and sale of medicines is according to the list prescribed in the regulations;
- v. Medicines and allied substances intended for public health institutions, unregistered, unfit medicines and allied substances are not stocked in the health shop; and
- vi. Reference books and other documents for record keeping are available all the time.

11.2 THE RESPONSIBLE PERSON

The responsible person shall:

- i. Handle all the roles and responsibilities related to medicines and allied substances dispensing in the health shop;
- ii. Ensure that the health shop is kept clean at all times;
- iii. Ensure that all medicines and allied substances stocked are sourced from authorized suppliers;
- iv. Handle all the technical duties related to medicine dispensing in the health shop;



- v. Ensure that any returned, or unfit, sub standard or falsified medicine and allied substance is appropriately segregated and kept in a designated secure area;
- vi. Keep in proper form all required records relating to the purchase and dispensing of all prescription medicines and/or allied substances for inspections by the Authority;
- vii. 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;
- viii. 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;
- ix. Ensure that the appropriate premises registration certificates are conspicuously displayed, including copies of their HPCZ Full Registration Certificates and practitioners Annual Practicing Certificate;
- x. that the health shop is registered with the Authority and operating in accordance with the law and regulations;
- xi. Supervise the storage, sale and dispensing of medicines and allied substances; and
- xii. Ensure that all medicines are stocked in accordance with the prescribed list and have.

**12. HYGIENE WITHIN THE PREMISES**

- 12.1 There must be a suitable, clean hand wash basin . Facilities must include readily available antiseptic/medicated soap and paper towels or other satisfactory means of drying the hands.
- 12.2 A suitable and adequate means of waste disposal must be available and in use.
- 12.3 Waste material must not be allowed to accumulate and must be collected in suitably covered (as applicable) receptacles for removal to collection points.
- 12.4 Under no circumstances must medicines and/or allied substances be disposed of down-surface water drains, e.g. storm water drains.
- 12.5 Toilet facilities must be kept clean, tidy and must not be used for storage of medicines.
- 12.6 Toilet facilities shall not open directly into medicine storage areas
- 12.7 Hand-washing facilities must be provided in the toilet area with a conspicuous notice requesting users to wash their hands after using the facility.
- 12.8 In a case where toilet facilities are communal, attempts should be made to ensure that the above measures are adhered to.

13. RECORD KEEPING FACILITIES

- 13.1 Every health shop shall be required to keep correct records for medicines and allied substances and these shall include:
 - i. Invoices and receipts;
 - ii. Daily cash sales book;
 - iii. Prescription Register;
 - iv. Customised Receipt Book
 - v. Expired Products Register;
 - vi. Recalled Products Register;



- vii. Quarantine Products Register;
- viii. Prescription file;
- ix. Stock records; and
- x. Computer or equivalent device.

13.2 The documents referred to in (14.1) above shall be kept for at least 2 years and be required to be made available and inspected by the Authority's inspectors.

14. DISPOSAL OF UNFIT MEDICINES AND ALLIED SUBSTANCES

14.1 DISPOSAL OF UNFIT MEDICINES AND ALLIED SUBSTANCES

- i. The responsible person shall withdraw and store all unfit medicines and allied substances separately from usable stock and place them in a designated area and clearly labelled accordingly.
- ii. The responsible person shall adhere to the guidelines on disposal of unfit medicines and allied substances when conducting a disposal.
- iii. The cost and responsibility to dispose of unfit medicines and allied substances shall be borne by the health shop owner.

15. 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 health shop owner and responsible person shall cooperate with the Authority to facilitate the recall of such medicines.

16. STANDARD OPERATING PROCEDURES

The following SOPS should be available:

- i. Ordering of medicines and allied substances;
- ii. Receipt of medicines and allied substances;
- iii. Dispensing of medicines and allied substances;



- iv. Management and disposal of unfit medicines and allied substances;
- v. Management of recalled medicines and allied substances;
- vi. Cleaning procedures on the premises and management of waste generated;
- vii. Fire safety including fire extinguisher procedures
- viii. Management of quarantine products
- ix. Reporting of adverse drug reactions, medication error and product quality problems;
and
- x. Complaint handling

17. REFERENCE MATERIALS

17.1 The following reference materials shall be available:

- i. Zambia National Formulary (ZNF), recent edition;
- ii. Zambia Standard Treatment Guidelines, recent edition;
- iii. Medicines and Allied Substances Act (No.3) of 2013;
- iv. Health Professions Act (No. 17) of 2024;
- v. Health Shop Regulations (SI No.12 of 2016);
- vi. Guidelines for Establishing a Health Shop; and
- vii. List of General Sales Medicines registered by ZAMRA

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

18. NOTIFICATION OF ANY CHANGES RELATING TO LICENSED PREMISES

18.1 All Health Shop Permit holders are required to seek prior authorisation for any administrative or structural changes post licensure.

18.2 Administrative amendments

18.2.1 Change in the composition of Directors

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.

18.2.2 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 valid Annual Practicing Certificate for the new responsible person;
- iv. Resignation or termination letter for the previous responsible person where applicable; and
- v. Contract of employment or agreement letter signed by both parties, i.e. the employer and the responsible person.

18.2.3 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. Amended PACRA Certificate of Registration/Incorporation; and
- iii. Local Authority certificates bearing the new business name.

18.2.4 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)

**18.2.5 Structural amendment****18.2.5.1 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.

18.2.5.2 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 as for the new premises registration.



19. ANNEXURES

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
	Anti-helmintics		
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



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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
	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%, 500ml or 1000ml



30	Ringers lactate IV		500ml or 1000ml
31	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