GOVERNMENT OF ZAMBIA

STATUTORY INSTRUMENT NO. 12 OF 2016

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

The Medicines and Allied Substances (Health Shops) Regulations, 2016

ARRANGEMENT OF REGULATIONS

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IN EXERCISE of the powers contained in section *thirty* of the Medicines and Allied Substances Act, 2013, the following Regulations are made:

PART I

PRELIMINARY

1. These Regulations may be cited as the Medicines and Allied Title Substances (Health Shops) Regulations, 2016.

- 2. In these Regulations, unless the context otherwise requires Inte
 - " authorised supplier " means a holder of a pharmaceutical licence issued under section *thirty-four* of the Act;
 - " health shop dispenser " means a person responsible for managing the health shop and has undergone training approved by the Authority;
 - " patient pack " means a quantity of medicines sufficient to treat a single patient for a specified condition;
 - " permit " means a health shop permit issued under section *thirty* of the Act;
 - " re-packing 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 pack;
 - " responsible person " means a pharmacist or pharmacy technologist; and
 - " supervising pharmacist " means a pharmacist providing supervisory services to a health shop.

PART II

HEALTH SHOP PERMIT

3. (1) A person shall apply to the Authority for a permit in Form I set out in the First Schedule.

(2) The Authority shall, within fourteen days of the receipt of an application, notify the applicant of the decision of the Authority in respect of the application.

(3) A separate application shall be made and a separate permit issued in respect of each premises.

(4) The Authority may inspect the premises in respect of which an application for a permit is made to determine if the applicant meets the requirements of the Act and the guidelines issued by the Authority. Application for permit

Interpretation

Request for information	4. The Authority may request an applicant to submit information in relation to an application in Form II set out in the First Schedule.
Rejection of application for	5. (1) The Authority shall reject an application for a permit if -
permit	(a) the applicant fails to comply with any condition precedent to the issue of the permit;
	(b) the permit issued to the applicant was revoked by the Authority within a period of two years preceeding the date of the application; or
	<i>(c)</i> the applicant is convicted of an offence under the Act or any other relevant written law.
	(2) The Authority shall, where it rejects an application under subregulation (1), inform the applicant within seven days of the decision in Form III set out in the First Schedule.
Issuance of permit	6. (1) The Authority shall, where the applicant meets the requirements of the guidelines issued by the Authority and the Act, issue a permit in Form IV set out in the First Schedule.
	(2) A permit shall be valid for two years from the date of issue.
	(3) A health shop shall be managed by a health shop dispenser under the supervision of a responsible person.
Application for renewal of permit	7. (1) An application for the renewal of a permit shall be made to the Authority in Form V set out in the First Schedule.
	(2) The Authority shall, within fourteen days of the receipt of an application for the renewal of a permit, grant the application for the renewal of the permit if the applicant meets the requirements of the Act and the guidelines issued by the Authority and has complied with the terms and conditions of the permit.
	(3) The Authority shall, where it renews a permit, issue a new permit to the applicant.
	(4) A permit that is not renewed by the Authority lapses on its date of expiry.
Transfer of permit	8. (1) A permit shall be used solely by the holder and is not transferable to any other person without the prior approval of the Authority.
	(2) An application for approval to transfer a permit shall be made

e to the Authority in Form VI set out in the First Schedule.

(3) The Authority shall, within thirty days of receipt of an application for the transfer of a permit, approve the transfer if the applicant meets the requirements of the Act, and issue the transferee with a permit.

(4) The Authority shall reject an application for the transfer of a permit if the applicant fails to comply with the conditions for the grant of the permit, the provisions of the Act and the guidelines issued by the Authority.

(5) The Authority shall, where it rejects an application to transfer a permit under subregulation (4)—

- (a) inform the applicant in Form III set out in the First Schedule; and
- (b) suspend or revoke the permit.
- 9. (1) The Authority may amend a permit where—
 - (a) some other person succeeds to the interest in the business belonging to the holder of the permit; or
 - (b) the name of the business changes.

(2) An application for the amendment of a permit shall be made in Form VII set out in the First Schedule.

(3) The Authority shall communicate its decision to the permit holder within fourteen days of receipt of the application for the permit.

(4) The Authority shall, where it approves the amendment of a permit, issue the applicant with a new permit.

10. A person shall, where that person's permit is lost, damaged or defaced, apply to the Authority for a duplicate permit in Form VIII set out in the First Schedule.

- 11. (1) The Authority shall suspend a permit if—
 - (a) the holder operates the health shop under insanitary conditions;
 - (b) the holder obtains or sells medicine from unauthorised suppliers or stocks and sells

unauthorised products;

- (c) the health shop in respect of which it was issued contravenes the prescribed standards;
- (d) the health shop is not managed or controlled by a responsible person determined by the Authority;

Application for duplicate permit

Amendment of permit

Suspension of permit

- *(e)* the responsible person fails to maintain the required records on medicines;
- (f) the health shop stocks and sells medicines that are not on the prescribed list; or
- (g) the holder contravenes the terms and conditions of the permit, the provisions of the Act or any other relevant written law.

(2) The Authority shall, before suspending a permit, give notice to the holder of the intention to suspend the permit and request the holder to show cause, within a specified period, why the permit should not be suspended.

(3) A notice of intention to suspend a permit shall be in Form IX set out in the First Schedule.

(4) The Authority shall suspend a permit if the holder of the permit fails to take remedial measures within the period specified in the notice issued under sub-regulation (2).

(5) A notice of the suspension of a permit shall be in Form X set out in the First Schedule.

(6) The product affected by the suspension of the permit shall be quarantined at the cost of the permit holder during the period of the suspension of the permit.

Revocation of permit

- 12. (1) The Authority shall revoke a permit if the holder—
 - (a) contravenes the provisions of the Act or any other relevant written law or breaches the terms or conditions of the permit;
 - (b) fails to take corrective measures following the suspension of the permit within the specified period;
 - *(c)* changes the health shop premises without authorisation; or
 - (d) obtained the permit by fraud or deliberate or negligent submission of false information or statements.

(2) The Authority shall, before revoking a permit, give notice to the holder of the permit of the intention to revoke the permit and request the holder to show cause, within a specified period, why the permit should not be revoked.

(3) A notice of the intention to revoke a permit shall be in Form IX set out in the First Schedule.

(4) The Authority shall revoke a permit if the holder fails to take remedial measures during the period specified by the Authority.

(5) A notice of the revocation of a permit shall be in Form X set out in the First Schedule.

(6) The Authority shall, where it determines that the holder stocks medicines in the health shop under insanitary conditions, direct the holder to dispose of the medicine.

(7) A holder of a permit shall, where the permit is revoked, quarantine the products on the premises and dispose of the products as directed by the Authority at the holder's cost.

13. (1) The Authority shall, in considering an application for a Location of health shop permit, prioritise the submissions filed by applicants in the following areas:

- (a) rural areas and districts where access by the members of the public to medicines is limited; and
- (b) peripheral areas of big towns or cities, where access to medicines is limited.

(2) The Authority shall, when considering the grant of a permit, take into account the availability of dispensing facilities in the area with respect to which the permit relates.

14. (1) A holder of a permit shall only sell the medicines Sale of prescribed in the Second Schedule.

(2) A health shop shall not stock for sale prescription only medicines and pharmacy sale medicines which are not specified in the prescribed list for health shops.

15. A health shop shall affix a standard logo for purposes of identifying the health shop as specified in the guidelines issued by the Authority.

Dispensing of medicines in a health shop shall be in 16. accordance with the guidelines for dispensing of medicines in a health shop issued by the Authority.

The storage of medicines in a health shop shall be in the 17. patient pack size and under conditions stipulated by the manufacturer.

medicines

Identity of health shop

Dispensing of medicines in health shop

Storage of medicines

PART III

GENERAL PROVISIONS

18. (1) The Authority shall keep and maintain a register of health shop permits in Form XI set out in the First Schedule.

(2) The register referred to in subregulation (1) shall be kept at the offices of the Authority and shall be open to inspection by the public at such times and upon payment of an inspection fee as prescribed in the Medicines and Allied Substances (Fees) Regulations, 2015.

Register of health shop permits

FIRST SCHEDULE

(Regulations 3, 4, 5, 6, 7, 8, 9, 10, 11 and 12)

Form I (Regulation 3 (1)) (To be completed in triplicate)



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

APPLICATION FOR A HEALTH SHOP PERMIT						
Please complete in block letters	Shaded fields for official use only	Application No. Date and Time				
Information Required	Information P	Provided		\checkmark		
PARTIC	PART I ULARS OF APPI	LICANT				
1. (a) Name of business entity						
(b) Registration No.				•		
2. Type of business entity						
3. Business premises						
(a) Plot No:						
(b) Street:						
(c) Telephone No:						
(d) Fax No:						
(e) Mobile No:						
(f) Email address						
(g) Village						
(h) Chief						
(i) Town						
(j) District						
(k) Province						
PROPOSED LO	DCATION OF H	EALTH SHOP				
4. Name of health shop:						
5. Physical Address						
6. Postal Address						
	PARTICULARS OF HEALTH SHOP DISPENSER					
7. Name:						

9.	Registration No:	
	Date of Issue:	
10.	Signature:	
	PARTICULARS OF RESPONSIBLE I	PERSON
	(a) Name	
	(b) Registration No.	
	(c) Date of issue:	
	(d) Signature:	
8.	Attachments	
	(a) Valid Practicing Certificate for the	Responsible Person
	(b) Sketch of the floor plan of the pre	emises
	DECLARATIONA	
best rend revo	of my knowledge and belief. I understand er the application void and that if approva ked. iculars of the Person signing on behalf	
best rend revo	of my knowledge and belief. I understand er the application void and that if approva ked.	that submission of false information shall l is granted, it shall be revoked and the permit of the Applicant Designation
best rend revo	of my knowledge and belief. I understand er the application void and that if approva ked. iculars of the Person signing on behalf Name	that submission of false information shall l is granted, it shall be revoked and the permit of the Applicant Designation
best rend revo Part	of my knowledge and belief. I understand er the application void and that if approva ked. iculars of the Person signing on behalf Name	that submission of false information shall l is granted, it shall be revoked and the permit of the Applicant Designation

Form II (*Regulation* 4)



The Medicines and Allied Substances Act, 2013 (Act No. 3 of 2013

The Medicines and Allied Substances (Health Shops) Regulations, 2016

REQUEST FOR INFORMATION

То:
Address:
Application No:
You are requested to furnish the following information or documents in respect of your
application for
<i>(a)</i>
<i>(b)</i>
<i>(c)</i>
<i>(d)</i>
within days of this notice.
If you fail to furnish the requested information within the stimulated named your application will

If you fail to furnish the requested information within the stipulated period, your application will be treated as invalid and shall be rejected.

Dated this...... day of 20......

Director-General

OFFICIAL STAMP

Form III (*Regulations* 5(2) and 8(5))



THE ZAMBIA MEDICINES REGULATORY AUTHORITY

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

(1) Here insert the full names and address of the applicant

The Medicines and Allied Substances (Health Shops) Regulations, 2016

(2) Here insert the reference No. of the application

NOTICE OF REJECTION OF APPLICATION To (1).....

IN THE MATTER OF (2) you are

IN THE MATTER OF (2) you are notified that your application for a health shop permit has been rejected by the Authority on the following grounds:

(a)	 	
<i>(b</i>)	 	

Dated this, 20.....

	OFFICIAL STAMP
Director-General	

Form IV (Regulation 6(1))



THE ZAMBIA MEDICINES REGULATORY AUTHORITY

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

The Medicines and Allied Substances (Health Shops) Regulations, 2016

HEALTH SHOP PERMIT

Registration No.:	 HS/

Permit No.: HS/

This is to certify that (Name of Health Shop)
of (Physical Address)
is registered to operate health shop

Name of Responsible person:
The conditions of the health shop permit are overleaf.

Valid until 20

.....

Director-General

OFFICIAL STAMP

Conditions for Health Shop Permit

- 1. Any change in the ownership, name and location of the health shop shall be approved by the Authority
- 2. The health shop shall only sell medicines that are on the prescribed list.
- 3. The premises and the manner in which the business is to be conducted must comply with the requirements of the Medicines and Allied Substances Act, No. 3 of 2013, and any other relevant written law.
- 4. The health shop permit is not transferable without the written approval of the Authority.
- 5. The health shop permit shall, upon grant, be displayed conspicuously at the front shop in a place visible to the public.

Form V (Regulation 7) (To be completed in triplicate)



THE ZAMBIA MEDICINES REGULATORY AUTHORITY

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

APPLICATION FOR RENEWAL OF PERMIT					
Plea	ase complete in block letters	Shaded fields for official use	Applicatio	n No.	
	•	only	Date and T	ìme	
Info	rmation Required	Information P	rovided		
1.	Permit No.				\checkmark
2.	Registration No.				
3.	Name of permit holder				
	(a) Plot No:				
	(b) Street:				
	(c) Telephone No:				
	(d) Fax No:				
	(e) Mobile No:				
	(f) Email address				
	(g) Village				
	(h) Chief				
	(i) Town				
	(j) District				
	(k) Province				
5.	Appendix				
	Annual Report				
	(a) Monthly records of quar				
	(b) Monthly records of nam	nes and receipts fr	om authorized	suppliers	
	(c) Monthly records of pres	scriptions for PoN	/Is/Ps dispense	ed	
	(d) Monthly records of med	licines stock-on-h	and		
Na	me of Applicant (individual or aut	thorised represent	ative)		
Da	ıte:	Si	gnature:		
FOR	OFFICIAL USE ONLY				
Rece Amo	ived by: unt Received:		Receipt No	o:	
	l No. of application:				
	11			OFFICIAL STAMP	

Form VI (Regulation 8(2)) (To be completed in triplicate)



THE ZAMBIA MEDICINES REGULATORY AUTHORITY

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

	APPLICATION FOR	TRANSFER OF HE	ALTH SHOP PERMIT	
Please	complete in block letters	Shaded fields for official use	Application No.	
F		only	Date and Time	
Inform	ation Required		Information Provided	\checkmark
	PART	ICULARS OF APPL	ICANT	
1.	(a) Name of business entity			
	(b) Registration No.			
2.	Type of entity			
3.	Business premises			
	(a) Plot No:			
	(b) Street:			
	(c) Telephone No:			
	(<i>d</i>) Fax No:			
	(e) Mobile No:			
	(f) Email address			
	(g) Village			
	(h) Chief			
	(i) Town			
	(j) District			
	(k) Province			
	PARTI	CULARS OF TRANS	SFEREE	
1.	(a) Name of business ent	ity		
	(b) Registration No.			
2.	Type of entity			
3.	Business premises			
	(a) Plot No:			
	(b) Street:			
	(c) Postal address			
	(d) Telephone No:			
	<i>(e)</i> Fax No:			
	(f) Mobile No:			
	(g) Email address			
	(h) Village			
	(i) Town			

	(j) District		
	(k) Province		
4.	Appendix		
	Contract of sale or acquisition of business betwee	en the current permit holder	
	and the proposed permit holder		
	DECLARATION AND SIG	NATURE	
I dec	lare that all the information I have stated in this ap	plication is correct and truthful	to the
	of my knowledge and belief. I understand that sub	•	
	er the application void and that if approval is grant		
		ed, it shall be levoked and the p	ernnt
revol	ted.		
D			
Parti	culars of the Person signing on behalf of the A	spplicant	
	Name	Designation	
		••••••	
	Signature	Date	
FOR	OFFICIAL USE ONLY		
Date	of Submission:		
	ication Number:		
-	ent Receipt Number:		I
	ication Accepted (Proceed for Inspection):		I
Appl	ication Rejected (Notify Applicant)		
		OFFICIAL	
		STAMP	

Form VII (Regulation 9) (To be completed in triplicate)



THE ZAMBIA MEDICINES REGULATORY AUTHORITY

The Medicines and Allied Substances Act, 2013

(Act No. 3 of 2013)

	APPLICATION FOR AM	IENDMENT OF A H	EALTH SHOP PERMIT	
Pleas	se complete in block letters	Shaded fields for official use	Application No.	
	I.	only	Date and Time	Γ
Infor	rmation Required	Information Prov	vided	\checkmark
	PARTI	CULARS OF APPLI	CANT	•
1.	(a) Name of business entity			
	(b) Registration No.			
2.	Type of entity			
3.	Business premises			
	(a) Plot No:			
	(b) Street:			
	(c) Postal address			
	(d) Telephone No:			
	<i>(e)</i> Fax No:			
	(f) Mobile No:			
	(g) Email address			
	(h) Village			
	(i) Town			
	(j) District			
	(k) Province			
4.	PARTICULARS OF AMEND	MENT DESC	CRIPTION OF AMENDMENT	Γ (S)
	1.			
	2.			
	3.			

5. EXISTING	PROPOSED AMENDMENT	REASONS FOR AMENDMENT
6. Appendix		
Relevant documen	ts relating to proposed amendmer	nt as required by the Authroity
DECLARATIONAN I declare that all the knowledge and belief	information I have stated is correc	et and truthful to the best of my
Particulars of the Pe	rson signing on behalf of the A	
•••••	Name	Designation
	nature	Date
FOR OFFICIAL USE	CONLY	
Date of Submission:		
Application Number:		
Payment Receipt Num	ber:	
Application Accepted	(Proceed for Inspection):	
Application Rejected	(Notify Applicant)	
		OFFICIAL STAMP

Form VIII (Regulation 10) (To be completed in triplicate)



THE ZAMBIA MEDICINES REGULATORY AUTHORITY

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

APPLICATION FOR DUPLICATE PERMIT				
		Shaded fields for	Application No.	
Please	complete in block letters	official use		+
		only	Date and Time	
Inform	ation Required	Information Prov	vided	V
1.	Name of business entit	у		
2.	Permit No.			
3.	Registration No.			
4.	Address			
5.	Affidavit of loss of permi	t		
	culars of the Person signing	•	plicant	
	Name		Designation	
	Signature OFFICIAL USE ONLY		Date	
~ ~		-		
Appli	cation Rejected (Notify Applic	ant)		•••
			OFFICIAL	
			STAMP	

Form IX (Regulation 11(3) and 12(3))



THE ZAMBIA MEDICINES REGULATORY AUTHORITY

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

The Medicines and Allied Substances (Health Shops) Regulations, 2016

NOTICE OF INTENTION TO SUSPEND/REVOKE HEALTH SHOP PERMIT

(1) Here insert the full	<i>To</i> (1)
names and address of	
holder of permit	
(2) Here	IN THE MATTER OF (2) you are notified that
insert the Permit No.	the Authority intends to *suspend/revoke your permit on the following grounds:
	<i>(a)</i>
	<i>(b)</i>
	(c)
	(d)

(3) Here Accordingly, you are requested to show cause why your permit should not be insert the suspended/revoked and to take action to remedy the breaches set out in number of paragraphs......days stipulated of receiving this notice. Failure to remedy the said breaches shall result in the *suspension/revocation of your permit.

Dated this......day of20.

(4) Signature of Director-General

days

(4).....

Director-General

*Delete as appropriate

Form X (Regulation 11 (5) and 12 (5))



THE ZAMBIA MEDICINES REGULATORY AUTHORITY

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

The Medicines and Allied Substances (Health Shops) Regulations, 2016

NOTICE OF SUSPENSION OR REVOCATION OF HEALTH SHOP PERMIT

(1) Here insert the full	<i>To</i> (1)
names and address of holder of permit	
(2) Here insert the Permit No.	IN THE MATTER OF (2) you are notified that the Authority intends to *suspend/revoke your permit on the following grounds:
rennit 100.	<i>(a)</i>
	<i>(b)</i>
	(c)
	(d)

Dated this......day of20.

(4)..... Director-General OFFICIAL STAMP

*Delete as appropriate

Form XI (Regulation 19)



ZAMBIA MEDICINES REGULATORY AUTHORITY

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

	REGISTER OF HEALTH SHOP PERMITS				
No.	Name and Address of business	Permit Number	Registration number	Date of issue	Expiry Date
1.					
2.					
3.					
4.					
5.					
6.					
7.					

SECOND SCHEDULE

(Regulation 14)

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

	Anti-malarials		
19	Artemether-Lumefantrine tablets	20/120mg	Patient Pack
	Laxatives		
20	Bisacodyl tablets	5mg	Patient Pack
			-
	Anti-histamines		
21	Cetirizine hydrochloride tablets	10mg	Patient Pack
22	Cetirizine hydrochloride oral solution	5mg/5ml	Patient Pack
23	Chlorpheniramine Maleate tablets	4mg	Patient Pack
24	Chlorpheniramine Maleate syrup	2mg/5ml	Patient Pack
	Oral Contraceptives		
25	Ethinylestardiol + Northisterone tablets	0.03mg/0.3mg	Patient Pack
26	Ethinylestardiol + Levonogestrel tablets	0.03mg/0.15mg	Patient Pack
	_		·
	Minerals/Vitamins		
27	Vitamin B Complex tablets		Patient Pack
28	Zinc Sulfate tablets	20mg	Patient Pack
	Fluids and Electrolytes		
29	Normal Saline IV		0.90% 1 Liters
30	Ringers Lactate IV		1Litres

PART B

All general sale medicines.

Note: Patient pack means a quantity of medicines sufficient to treat a single patient for a specified condition.

Dr. J. Kasonde, Minister of Heath

Lusaka 27th January, 2016 [мн/101/16/1]