GOVERNMENT OF ZAMBIA

STATUTORY INSTRUMENT NO. 91 OF 2018

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

The Medicines and Allied Substances (Pharmaceutical Licence) Regulations, 2018

ARRANGEMENT OF REGULATIONS

Regulation

Copies of this Statutory Instrument can be obtained from the Government Printer, P.O. Box 30136, 10101 Lusaka. Price K32.00 each.

IN EXERCISE of the powers contained in section 34 of the Medicines and Allied Substances Act, 2013, and on the recommendation of the Authority, the following Regulations are made:

Title

1. These Regulations may be cited as the Medicines and Allied Substances (Pharmaceutical Licence) Regulations, 2018.

Interpretation

2. In these Regulations unless the context otherwise requires—

"authorised product" means a product for which marketing authorisation has been granted in accordance with section 39 of the Act;

"good manufacturing practice" means quality assurance that ensures that a pharmaceutical product is produced and controlled to the quality standards appropriate for its intended use and as required by the marketing authorisation;

"insanitary condition" means a condition or circumstance that could cause contamination of a medicine or allied substance with dirt or filth or could render the medicine or allied substance injurious or dangerous to health;

"licence" means a pharmaceutical licence issued under section 34 of the Act;

"licensee" means a holder of a licence;

"pharmacist" means a person registered as a pharmacist in accordance with the Health Professions Act, 2009. Act No. 24 of 2009

"pharmacy technologist" means a person registered as a pharmacy technologist in accordance with the Health Professions Act, 2009; Act No. 24 of 2009

"phase I clinical trial" means the first trial of a new active ingredient or new formulation in humans or target animal species, often carried out in healthy participants or volunteers to establish a preliminary evaluation of safety, and a first outline of the pharmacokinetic and, where possible, a pharmacodynamic profile of the active ingredient in humans or target animal species;

"phase II clinical trial" means a pilot clinical trial undertaken in selected populations of patients with the disease or condition intended to be prevented, diagnosed or treated in order to evaluate the safety and efficacy of the medicine or allied substance being tried;

"primary repackaging" means the part of manufacturing that involves packing of the finished dosage form or device into its primary packaging material;

"re packing of medicine" 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 a blister pack;

"responsible person" means a pharmacist, veterinary surgeon, veterinary para professional or pharmacy technologist;

"secondary repackaging" means the part of manufacturing that involves repacking of medicines into secondary or tertiary packaging material which does not come in direct contact with the finished dosage form or device;

"suitably qualified person" means a pharmacist or veterinary surgeon providing supervisory services to a wholesale outlet;

"veterinary biological" means a virus, vaccine, serum or analogous products used for the purpose of diagnosis or treatment of animal diseases;

"veterinary para professional" means a person registered as a livestock officer or veterinary assistant in accordance with the Veterinary and Veterinary Para Professions Act, 2010;

Act No. 45 of 2010

"veterinary surgeon" means a person registered as a veterinary surgeon in accordance with the Veterinary and Veterinary Para Professions Act, 2010; and

Act No. 45 of 2010

"wholesale" means the buying of medicines or allied substances in bulk for the purpose of re selling to authorised pharmaceutical wholesale dealers, retail pharmacy outlets, hospital pharmacies, agro veterinary shops, health shops or other health facilities for human beings or animals.

Application for licence

3. (1) A person who intends to manufacture, distribute or deal in any medicine or allied substance shall apply to the Authority for a licence in Form I set out in the Schedule, on payment of the prescribed fee.

(2) A person who intends to manufacture, distribute or deal in any medicine or allied substance at more than one premises shall apply for a licence in respect of each of the premises.

(3) The Authority shall inspect the premises in respect of which an application for a licence is made to determine if the applicant meets the requirements of the Act and the guidelines issued by the Authority from time to time.

Request for additional information

4. The Authority may request an applicant to submit additional information in relation to an application for a licence in Form II set out in the Schedule.

Rejection of application for licence

5. (1) The Authority shall reject an application for a licence if the—

(a) applicant fails to comply with a condition precedent to the issue of the licence;

(b) applicant fails to meet the requirements of the Act;

(c) licence previously issued to the applicant was revoked by the Authority within the period of five years preceding the date of application; or

(d) applicant is convicted of an offence under the Act or any other relevant written law within a period of two years preceding the date of the application.

(2) The Authority shall, where it rejects an application under subregulation (1), inform the applicant of the reason for that rejection in Form III set out in the Schedule.

Issuance of licence

6. (1) The Authority shall, where the applicant meets the requirements of the Act, issue a licence in Form IV set out in the Schedule.

(2) A licence is valid for two years from the date of issue.

(3) A responsible person shall manage the premises in respect of which a licence has been issued.

Renewal of licence

7. (1) A licensee who intends to renew that licensee's licence shall, at least ninety days before the expiry of the licence, apply to the Authority for renewal of the licence in Form V set out in the Schedule, on payment of the prescribed fee.

(2) The Authority may renew a licence in respect of an application if the applicant meets the requirements of the Act and complies with the terms and conditions of the earlier licence.

(3) The Authority shall, where it renews a licence, issue a new licence.

Transfer of licence

(4) A licence that is not renewed by the Authority shall lapse on its date of expiry.

8. (1) A licence shall be used solely by the licensee and is not transferable to any other person without the prior approval of the Authority.

(2) A licensee who intends to transfer the licensee's licence shall apply to the Authority for approval to transfer the licence in Form VI set out in the Schedule, on payment of the prescribed fee.

(3) The Authority shall, where it approves the transfer of a licence, issue the transferee with a licence for the remainder of the validity period of the licence issued to the transferor.

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

(5) The Authority shall, where it rejects an application to transfer a licence in accordance with subregulation (4), inform the applicant of the reasons for the rejection in Form III set out in the Schedule.

Amendment of licence

9. (1) A licensee who intends to amend the licensee's licence shall apply to the Authority for amendment of the licence in Form VII set out in the Schedule, upon payment of the prescribed fee.

(2) The Authority may amend a licence where the name of the business or the suitably qualified person changes.

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

(4) Where the Authority fails to inform the licensee of its decision within fourteen days, the amendment shall be considered to be approved.

Duplicate licence

10. A licensee may, where a licence is lost, damaged or defaced, apply to the Authority for a duplicate licence in Form VIII set out in the Schedule, upon payment of the prescribed fee.

Suspension of licence

11. (1) The Authority shall suspend a licence if the licensee—

(a) operates the business in respect of which it is issued under insanitary conditions;

(b) obtains or sells medicine from an unauthorised supplier or stock or sell an unauthorised product;

(c) fails to maintain the required records on medicines or allied substances; or

(d) contravenes the terms and conditions of the licence or the provisions of the Act or any other relevant written law.

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

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

(4) The Authority shall suspend a licence if the licensee fails to take remedial measures within the period specified in the notice issued in accordance with subregulation (2).

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

(6) A product affected by the suspension of the licence shall be quarantined at the cost of the licensee during the period of the suspension of the licence.

(7) The Authority shall, where it is established that the licensee manufactures, distributes or deals in a medicine or allied substance under insanitary conditions, direct the licensee to dispose of that medicine or allied substance.

Revocation of licence

12. (1) The Authority shall revoke a licence if the licensee—

(a) contravenes the provisions of the Act or breaches the terms and conditions of the licence;

(b) fails to take corrective measures following the suspension of the licence;

(c) changes the business premises without authorisation;

(d) fails to comply with any other relevant written law; or

(e) obtained the licence by fraud or deliberate or negligent submission of false information or statements.

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

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

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

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

(6) Where a licence is revoked, the products on the premises and the recalled products shall be quarantined as directed by the Authority at the former licensee's cost, including the disposal of the products.

(7) The Authority may, where the former licensee fails to comply with a directive issued by the Authority in accordance with subregulation (6), deal with the products in a manner the Authority may consider appropriate.

Handling of expired, withdrawn, obsolete or unwanted medicines

13. (1) A licensee shall store a withdrawn, obsolete, unwanted, expired medicines or allied substance in an appropriate container clearly labelled "for destruction within a specified period of time" as stipulated in the guidelines.

(2) A person who contravenes sub regulation (1) commits an offence and is liable, upon conviction, to a fine not exceeding two thousand five hundred penalty units, and in the case of a continuing offence to a fine not exceeding twenty five penalty units for each day that the offence continues.

(3) In addition to the penalty provided in subregulation (2), the court before which a person is convicted of an offence in accordance with this regulation may order

(a) that any medicine or allied substance in respect of which the offence is committed be forfeited to the State; and

(b) that the costs for disposal of a medicine or allied substance be borne by the convict.

Inspection

14. The Authority may conduct an inspection to ensure compliance with the minimum prescribed requirements for the manufacture, distribution or dealing of a medicine or allied substance.

Exemption

15. These regulations do not apply to a medicine or allied substance manufactured in accordance with guidelines issued by the Authority if the medicine is

(a) for a pre clinical trial, phase I clinical trial or phase II clinical trial;

(b) compounded by a—

(i) pharmacist for supply within the pharmacy or hospital setting; or

(ii) veterinary surgeon for supply within an agro veterinary shop or health facility for animals;

(c) a human or veterinary biological medicine manufactured by a Government institution for purposes of disease prevention and control; or

(d) a blood product prepared by a veterinary surgeon for administration to animals under that veterinary surgeon's care.

Register of licences

16. (1) The Authority shall keep and maintain a register of licences in Form XI set out in the 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 the prescribed fee.

(3) A person may, upon payment of the prescribed fee, require a copy or extract of any particulars from the register to be certified by the Director General.

(4) Any document purported to be an extract or copy of any entry in the register and duly certified to be a true copy or extract under the hand of the Director General shall be received in evidence as to the matters stated therein in any legal proceedings.

Distribution and wholesale by manufacturer

17. (1) A licensee that is a manufacturer may distribute or undertake the wholesale of medicines or allied substances manufactured under that licence.

(2) Despite subregulation (1), a licensee that is a manufacturer dealing in medicines or allied substances manufactured by another manufacturer shall not undertake the wholesale of the medicines or allied substances manufactured by the other manufacturer.

(3) A manufacturer that intends to undertake the wholesale of a medicine or allied substance manufactured by another manufacturer shall apply to the Authority for a separate licence.

Personnel in wholesale premises

18. (1) A licensee that is a wholesale dealer in medicines or allied substances for the use in or on humans or animals shall employ a pharmacist on a full time basis for purposes of the wholesale of the medicines or allied substances and may, in addition to the pharmacist, employ a pharmacy technologist.

(2) A licensee that is a wholesale dealer in medicines or allied substances for use in or on animals shall employ a veterinary surgeon on a full time basis for the purposes of the wholesale of the medicines or allied substances and may, in addition to the veterinary surgeon, employ a veterinary para professional.

(3) A licensee that is a wholesale dealer and employs a pharmacist or veterinary surgeon on a part time basis for purposes of the wholesale of medicines or allied substances shall, in addition to the veterinary surgeon or pharmacist, employ a pharmacy technologist or veterinary para professional on a full time basis, as the case may be.

General penalty

19. A person who contravenes a provision of these Regulations for which a penalty is not provided

commits an offence and is liable, upon conviction, to a fine not exceeding two thousand five hundred penalty units, and in the case of a continuing offence to a fine not exceeding twenty five penalty units for each day that the offence continues.

SCHEDULE

(*Regulations* 3, 4, 5, 6, 7, 8, 9, 10,11, 12 and 16)

PRESCRIBED FORMS

FORM I

(*Regulation* 3(1))

ZAMBIA MEDICINES REGULATORY AUTHORITY

The Medicines and Allied Substances Act, 2013

(Act No. 3 of 2013)

The Medicines and Allied Substances (Pharmaceutical Licence) Regulations, 2018

APPLICATION FOR A PHARMACEUTICAL LICENCE							
Please write in BLOCK LETTERS			Shaded fields for official use only	Application No.			
				Date/Time			
Information Required			*Information Provided*				√
	APPLICATION DETAILS						
1.	Name(s) of business						
2.	Physical Address:						
3.	Postal Address:						
4.	Business premises						
	(a) Tel. No.:						
	(b) Fax:						
	(c) Mobile Phone No.:						
	(d) E-mail address:						
	PARTICULARS OF PROPRIETOR(S)/DIRECTORS(S)						
5.	*Full Names*	*Sex*	*Nationality*	*Residential Address*	*Occupation*	*Date of Birth*	*NRC/ Passport No.*
6.	*(a)* Has any of the Proprietors or Directors been convicted of an offence in the past five (5) years? YES ☐ NO ☐ If Yes, please give details						
	(b) Have the proprietors or Directors ever been denied issuance of a pharmaceutical licence or had it revoked? If Yes, please give details						
	(c) Please tick (√) activity (ies) as applicable Manufacture ☐ Wholesale ☐						

7. Please complete as applicable

Particulars	*Responsible Person*	*Suitably Qualified Person*	*Head of Production*	*Head of Quality Control*
Full names				
Qualifications				
Registration Certificate No.				
Address				
Experience (state period)				
Signature				

8. **Products to be manufactured, sold or dealt in**

Please indicate the proposed dosage form of medicine to be manufactured below:

1. .....
2. .....
3. .....
4. .....
5. .....
6. .....
7. .....
8. .....
9. .....
10. .....

9. **Type of manufacture (Please tick (√)what is applicable below)**

- ☐ Complete manufacture
- ☐ Contract manufacture
- ☐ Partial manufacture
- ☐ Primary repackaging and labeling
- ☐ Secondary repacking and labeling
- ☐ Local manufacture of natural remedies

10. **Attachments**

(a) Practicing certificate for the responsible person
(b) Contract of employment of the responsible with applicant
(c) Site Master File
(d) Certificate of Registration/Incorporation of applicant

DECLARATION

I declare that the information I have stated is correct and truthful to the best of my knowledge and belief.

....
Name *Designation*

....
Signature *Date*

FOR OFFICIAL USE ONLY

Date of submission: .....

Application Number: .....

Application in order (proceed for inspection): .....

Application deficient (notify applicant on deficiencies): .....

.....
Director-General

OFFICIAL STAMP

FORM II
(*Regulation* 4)

ZAMBIA MEDICINES REGULATORY AUTHORITY

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

The Medicines and Allied Substances (Pharmaceutical Licence) Regulations, 2018

REQUEST FOR ADDITIONAL INFORMATION

To: .....

Address: .....

ApplicationNo.: .....

You are requested to furnish the following information or documents in respect of your application for..... within..... days of this notice.

(a) .....

(b) .....

(c) .....

(d) .....

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

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

.....
Director-General

OFFICIAL STAMP

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

ZAMBIA MEDICINES REGULATORY AUTHORITY

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

The Medicines and Allied Substances (Pharmaceutical Licence) Regulations, 2018

NOTICE OF REJECTION OF APPLICATION

(1) Here insert name and address of the applicant

To (1).....

.....

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

IN THE MATTER OF (2).....you are notified that your application for (3)..... has been rejected by the Authority on the following grounds:

(3)Here insert type of application

(a) .....

(b).....

(c).....

(d) .....

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

(4) Signature of Director-General

(4).....
Director-General

OFFICIAL STAMP

FORM IV
(*Regulation* 6 (1))

ZAMBIA MEDICINES REGULATORY AUTHORITY

Pharmaceutical Licence No. PL----/---

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

The Medicines and Allied Substances (Pharmaceutical Licence)
(Pharmaceutical Licence) Regulations, 2018

PHARMACEUTICAL LICENCE

This is to certify that ..... of (Physical Address)

.....

.....

is licensed to:

[ ] Manufacture the following dosage form(s):

1. .....
2. .....
3. .....
4. .....

[ ] Sell

[ ] Deal in medicines or allied substances.

Name of suitably qualified person: .....

This licence is valid until .....20.....

Terms and Conditions imposed by the Zambia Medicines Regulatory Authority (refer to notes overleaf)

..... (SEAL) .....

Director-General *Date of Issue*

PHARMACEUTICAL LICENCE TERMS AND CONDITIONS

Non-compliance with any of the conditions stated below will result in suspension or revocation of licence.

The licensee shall —

(a) Comply with the minimum current good manufacturing practice (cGMP) or Good Distribution Practices (GDP) as may be applicable and cause to be obtained marketing authorisation in Zambia (where applicable) of all such products as are manufactured and conform to such other standards as may be specified by the Authority from time to time;

(b) Comply with relevant regulations and guidelines specific to the licence;

(c) Conspicuously display the licence at the premises where the activityis conducted;

(d) Maintain such staff, premises, equipment and facilities for manufacture, or distribution of the medicinal products as applicable at the time of grant of the licence;

(e) Where the licensee is licensed to manufacture medicines or allied substances and wishes to manufacture additional dosage forms not included in the attached list, submit an application to the Authority for the inclusion of the additional dosage forms and this licence shall be deemed to extend to the dosage form so included;

(f) Keep readily available for inspection by an inspector of the Authority, durable records of documentation as specified in the guidelines;

(g) Notify the Authority of any changes that require an amendment to the licence; and

(h) Where the licence is revoked surrender it to the Authority immediately.

FORM V
(*Regulation* 7(1))

ZAMBIA MEDICINES REGULATORY AUTHORITY

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

The Medicines and Allied Substances (Pharmaceutical Licence) Regulations, 2018

APPLICATION FOR RENEWAL OF PHARMACEUTICAL LICENCE				
Please complete in block letters		Shaded fields for official use only	Application No. Date and Time	
Information Required		*Information Provided*		√
PARTICULARS OF APPLICANT				
1.	Licence No.:			
2.	Name(s) of business:			
3.	Postal Address:			
4.	Business Premises:			
	(a) Telephone No.:			
	(b) Fax No.:			
	(c) Mobile phone No.:			
	(d) E-mail address:			
5.	Attachments			
	Report of activities undertaken in the past two years			

DECLARATION

I declare that the information I have stated is correct and truthful to the best of my knowledge and belief.

....
Name *Designation*

....
Signature *Date*

FOR OFFICIAL USE ONLY

Received by: ..... Receipt No: .....

Amount received: .....

.....
Director-General

OFFICIAL STAMP

FORM VI
(*Regulation* 8(2))

ZAMBIA MEDICINES REGULATORY AUTHORITY

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

The Medicines and Allied Substances (Pharmaceutical Licence) Regulations, 2018

APPLICATION FOR TRANSFER OF PHARMACEUTICAL LICENCE						
Please complete in block letters		Shaded fields for official use only	Licence No. Application No. Date and Time			
Information Required		*Information Provided*				√
PARTICULARS OF APPLICANT (INTENDING TRANSFEROR)						
1.	Licence No.					
2.	Name(s) of applicant					
3.	Address					
	(a) Telephone No.					
	(b) Fax No.					
	(c) Mobile phone No.					
	(d) Email address					
	PARTICULARS OF INTENDED TRANSFEREE					
4.	Name of business:					
5.	Physical address:					
6.	Postal address:					
7.	Business premises:					
	(a) Telephone:					
	(b) Fax No.:					
	(c) Mobil No.:					
	(d) Email Address:					
	PARTICULARS OF PROPRIETOR (S)/DIRECTOR(S) OF INTENDED TRANSFEREE					
Ever 8.	*Full names*	*Sex*	*Full names*	*Sex*	*Full names*	
9.	*(a)* Has any of the proprietors or directors been convicted in the past five (5) years? [Yes/No]. If yes, please give details.....					
	(b) Have the Proprietors or Directors ever been denied issuance of a pharmaceutical licence or had it revoked? If yes, please give details.					

10.	Reason(s) for intended transfer: *(a)* ..... *(b)* ..... *(c)* ..... *(d)* .....
11.	**Attachments** *(a)* Contract of sale or acquisition of business between the intending transferor and the intended transferee *(b)* Copy of licence *(c)* Updated Site Master File *(d)* Certificate of registration/corporation for intended transferee
	DECLARATION I declare that the information I have stated is correct and truthful to the best of my knowledge and belief. .... *Name* *Designation* .... *Signature* *Date*

FOR OFFICIAL USE ONLY

Date of submission: .....

Application number: .....

Payment receipt number: .....

Application in order (proceed for inspection): .....

Application rejected (notify applicant on deficiencies): .....

.....

.....

Director-General

OFFICIAL STAMP

FORM VII
(*Regulation* 9(1))

ZAMBIA MEDICINES REGULATORY AUTHORITY

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

The Medicines and Allied Substances (Pharmaceutical Licence) Regulations, 2018

APPLICATION FOR AMENDMENT OF PHARMACEUTICAL LICENCE

Please complete in block letters	Shaded fields for official use only	Licence No.	
		Application No.	
		Date and Time	

Information Required	*Information Provided*	√
PARTICULARS OF APPLICANT		
1. Licence No.		
2. Names (s) of Applicant		
3. Address		
(a) Telephone No.:		
(b) Fax No.:		
(c) Mobile No.:		
(d) Email address:		

PARTICULARS OF AMENDMENT

4.	*Current Information*	*Description of Amendment(S)*	*Reasons for Amendment*
	(a)		
	(b)		
	(c)		

5.	Attachments
	Attach supporting document(s) where applicable

DECLARATION

I declare that the information I have stated is correct and truthful to the best of my knowledge and belief.

....
Name *Designation*

....
Signature *Date*

FOR OFFICIAL USE ONLY

Date of submission: .....

Application number: .....

Payment receipt number: .....

Application in order (proceed for inspection): .....

Application rejected (notify applicant on deficiencies): .....

.....

.....
Director-General

OFFICIAL STAMP

FORM VIII
(*Regulation* 10)

ZAMBIA MEDICINES REGULATORY AUTHORITY

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

The Medicines and Allied Substances (Pharmaceutical Licence) Regulations, 2018

APPLICATION FOR DUPLICATE PHARMACEUTICAL LICENCE

Please complete in BLOCK LETTERS	Shaded fields for official use only	Application No.	
		Date and Time	

	Information Required	*Information Provided*		√
	PARTICULARS OF APPLICANT			
1.	Licence No.:			
2.	Name(s) of applicant:			
3.	Business address: (Head Office)			
4.	Location of activities	Districts		
	Operations			
5.	Affidavit of loss or damage, of licence			

DECLARATION

I declare that the information I have stated is correct and truthful to the best of my knowledge and belief.

....
Name *Designation*

....
Signature *Date*

FOR OFFICIAL USE ONLY

Date of submission: .....

Application number: .....

Payment receipt number: .....

Application in order (proceed for inspection): .....

Application rejected (notify applicant on deficiencies): .....

.....
Director-General

OFFICIAL STAMP

FORM IX
(*Regulations* 11(3) *and* 12(3))

ZAMBIA MEDICINES REGULATORY AUTHORITY

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

The Medicines and Allied Substances (Pharmaceutical Licence) Regulations, 2018

NOTICE OF INTENTION TO SUSPEND/REVOKE PHARMACEUTICAL LICENCE

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

(2) Here insert the licence No.

To (1).....

.....

IN THE MATTER OF (2).....you are notified that the Authority intends to *suspend/revoke your licence on the following grounds:

(a) .....

(b) .....

(c) .....

(d).....

(3) Here insert type of application

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

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

(4) Signature of Director-General

(4) .....
Director-General

OFFICIAL STAMP

*Delete as appropriate

FORM X
(*Regulations* 11(5) *and* 12(5))

ZAMBIA MEDICINES REGULATORY AUTHORITY

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

The Medicines and Allied Substances (Pharmaceutical Licence) Regulations, 2018

NOTICE OF SUSPENSION/REVOCATION OF PHARMACEUTICAL LICENCE

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

To (1).....

.....

IN THE MATTER OF (2)..... you are notified that your licence has been *suspended for a period of (3)...../ revoked on the following grounds:

(2) Here insert the Licence No.

(3) Here insert number of days stipulated

(a) .....

(b) .....

(c) .....

(d) .....

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

(4) Sign by Director-General

(4).....
Director-General

OFFICIAL STAMP

*Delete as appropriate

FORM XI
(*Regulation* 16 (1))

ZAMBIA MEDICINES REGULATORY AUTHORITY

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

The Medicines and Allied Substances (Pharmaceutical Licence) Regulations, 2018

REGISTER OF PHARMACEUTICAL LICENCES

No.	*Name of Licensee*	*Licence Number*	*Date of issue*	*Expiry Date*
1.				
2.				
3.				
4.				
5.				
6.				
7.				

C. CHILUFYA,
Minister of Health

LUSAKA
28th November, 2018
[MH/101/16/1]