

GOVERNMENT OF ZAMBIA

STATUTORY INSTRUMENT NO. 11 OF 2016

The Medicines and Allied Substances Act, 2013
(Act No. 3 of 2013)**The Medicines and Allied Substances (Dispensing
Certificates) Regulations, 2016**

ARRANGEMENT OF REGULATIONS

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IN EXERCISE of the powers contained in section *twenty-eight* 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 Substances (Dispensing Certificates) Regulations, 2016. | Title |
| 2. In these Regulations, unless the context otherwise requires—
“authorised supplier” means a holder of a pharmaceutical licence issued under section <i>thirty-four</i> of the Act; and
“certificate” means the dispensing certificate issued under section <i>twenty-eight</i> of the Act; | Interpretation |

PART II
DISPENSING CERTIFICATE

- | | |
|--|--|
| 3. (1) A person shall apply to the Authority for a certificate in Form I set out in the Schedule. | Application for certificate |
| (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 certificate issued in respect of each health facility. | |
| (4) The Authority may inspect the health facility in respect of which an application for a certificate is made to determine if the applicant meets the requirements of the Act and the guidelines issued by the Authority. | |
| (5) The Authority shall consider the following matters in determining an application for a certificate: | |
| (a) the number of health facilities in the area; | |
| (b) the classification of the health facility; and | |
| (c) the competence of the health practitioners responsible for dispensing the medicines. | |
| 4. The Authority may request an applicant to submit information in relation to an application for a certificate in Form II set out in the Schedule. | Request for information |
| 5. (1) The Authority shall reject an application for a certificate if— | Rejection of application for certificate |
| (a) the applicant fails to meet the requirements of the Act and the guidelines issued by the Authority; | |

- (b) the certificate issued to the applicant was revoked by the Authority within the preceding two years before the date of the application;
- (c) the applicant's practising certificate is withdrawn by the relevant professional body; or
- (d) 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 Schedule.

Issuance of certificate

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

(2) A certificate shall be valid for two years from the date of issue.

Application for renewal of certificate

7. (1) An application for the renewal of a certificate shall be made to the Authority in Form V set out in the Schedule.

(2) The Authority shall, within fourteen days of the application for a certificate, renew the certificate 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 certificate.

(3) A certificate that is not renewed by the Authority lapses on its date of expiry.

Transfer of certificate

8. A certificate shall be used solely by the holder and is not transferable to any other person.

Amendment of certificate

9. (1) The Authority may amend a certificate where the name of the business changes.

(2) An application for the amendment of a certificate shall be made in Form VI set out in the Schedule.

(3) The Authority shall, where it approves an application for the amendment of a certificate, issue the applicant with a new certificate.

Application for duplicate certificate

10. A person may, where a certificate is lost, damaged or defaced, apply to the Authority for a duplicate certificate in Form VII set out in the Schedule.

Suspension of certificate

11. (1) The Authority shall suspend a certificate if—

- (a) the holder dispenses medicine under insanitary conditions;

- (b) the holder or manager of the health facility in respect of which it is issued obtains or sells medicines from unauthorised suppliers or stocks and sells unauthorised products;
- (c) the health facility does not comply with good dispensing practices determined by the Authority;
- (d) the holder fails to maintain the required records on medicines and allied substances; or
- (e) the holder contravenes the terms and conditions of the certificate or the provisions of the Act or any other relevant written law.

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

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

(4) The Authority shall suspend a certificate if the holder of the certificate fails to take remedial measures within the period specified in the notice issued under sub-regulation (3).

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

- (6) During the period of the suspension of the certificate—
- (a) the product affected by the suspension of the certificate shall be quarantined and disposed of at the cost of the certificate holder; and
 - (b) the health facility to which it relates shall not dispense medicines, except for emergency cases.

(7) The Authority shall lift the suspension of a certificate where the holder complies with the terms and conditions of the suspension.

12. (1) The Authority shall revoke a certificate if the holder—
- (a) contravenes the provisions of the Act or breaches the terms or conditions of the certificate;
 - (b) fails to take corrective measures following the suspension of the certificate within the specified period;
 - (c) obtained the certificate by fraud or deliberate or negligent submission of false information or statements; or
 - (d) fails to comply with any other relevant written law.

Revocation
of
certificate

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

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

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

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

(6) Upon the revocation of a certificate, the products in the health facility shall be quarantined or disposed of as directed by the Authority at the holder's cost.

Dispensing
of
medicines

13. (1) Medicines in a health facility shall be dispensed in accordance with the guidelines issued by the Authority.

(2) A holder of a dispensing certificate who undertakes dispensing activities shall stock medicines of the required quality, safety and efficacy.

(3) A patient may request a medical practitioner for a written prescription to enable the patient obtain medicines from any other health facility of their choice.

Storage of
medicines

14. (1) The storage of medicines in a health facility shall be in the manufacturer's original container and under conditions stipulated by the manufacturer.

(2) The Authority shall, where it determines that the holder of a certificate stocks medicines or products under insanitary conditions, direct the holder to dispose of the medicines or products at the holder's cost.

(3) Where medicines are transferred to another container, care shall be taken to protect the integrity of the product and prevent contamination of the medicines.

PART III

GENERAL PROVISIONS

Register of
certificates

15. (1) The Authority shall keep and maintain a register of dispensing certificates in Form X 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 a prescribed inspection fee.

SCHEDULE
(Regulations 3, 4, 5, 6, 7, 8, 9, 10, 11, 12 and 15)
PRESCRIBED FORMS



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

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

**The Medicines and Allied Substances
(Dispensing Certificate) Regulations, 2016**

APPLICATION FOR A DISPENSING CERTIFICATE			
Please complete in block letters	Shaded fields for official use only	Application No.	
		Date and Time	
<i>Information Provided</i>	<i>Information Required</i>		√
PARTICULARS OF APPLICANT			
1. (a) Name			
(b) Profession			
(c) Qualifications			
PARTICULARS OF HEALTH FACILITY			
2. (a) Name of health facility			
(b) Certificate of Registration No.			
3. Type of entity	Partnership	Company	Institution
4. Business premises			
(a) Physical address			
(b) Plot No:			
(c) Street:			
(d) Postal address			
(e) Telephone No:			
(f) Fax No:			
(g) Mobile No:			
(h) Email address			
(i) Village			
(j) Town			
(k) District			
5. ATTACHMENTS			
Appendix 1	Practising Certificate for the responsible Person from the relevant professional body		
Appendix 2	Fire Safety Certificate		
<p>DECLARATION I declare that all the information I have stated in this application is correct and truthful to the best of my knowledge and belief. I understand that submission of false information shall render the application void and that if approval is granted, it shall be revoked and the certification cancelled.</p> <p style="text-align: center;">.....</p> <p style="text-align: center;"><i>Name</i> <i>Designation</i></p> <p style="text-align: center;">.....</p> <p style="text-align: center;"><i>Name</i> <i>Designation</i></p> <p style="text-align: center;">.....</p>			
FOR OFFICIAL USE ONLY			
Date of Submission:			
Application Number:			
Payments Receipt Number:			
Application Accepted (Proceed for Inspection):			
Application Rejected (Notify applicant):			
.....			
<div style="border: 1px solid black; padding: 5px; display: inline-block;">OFFICIAL STAMP</div>			

Form 11
(Regulation 4)



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

**The Medicines and Allied Substances
(Dispensing Certificates) Regulations, 2016**

REQUEST FOR INFORMATION

To:.....

Address:

Application No:

You are requested to furnish the following information in respect of your application for..... withindays 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 shall be rejected.

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

.....
Director-General

OFFICIAL
STAMP



Form III
(Regulation 5 (2))

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

**The Medicines and Allied Substances
(Dispensing Certificates) Regulations, 2016**

NOTICE OF REJECTION OF APPLICATION

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

To (1).....
.....

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

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

- (a)
- (b)
- (c)
- (d)

Dated thisday of, 20.....

.....
Director-General

OFFICIAL
STAMP

Form IV
(Regulation 6)



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

**The Medicines and Allied Substances
(Dispensing Certificates) Regulations, 2016**

DISPENSING CERTIFICATE

Registration No.: DC

Certificate No.: DC/

This is to certify that

of (Physical Address)

..... may dispense medicines at

Name of Health Facility:

This Certificate is valid until 20

The conditions of the Dispensing Certificate are overleaf.

.....
Director-General

OFFICIAL
STAMP

Conditions for Dispensing Certificate

1. The holder shall inform the Authority of any change in the details of the Dispensing Certificate.
2. 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.
3. The Dispensing Certificate is not transferable to any other person.
4. The Dispensing Certificate shall, upon grant, be displayed conspicuously at the health facility in a place visible to the public.



Form V
(Regulation 7(1))
(To be completed in triplicate)

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

**The Medicines and Allied Substances
(Dispensing Certificates) Regulations, 2016**

APPLICATION FOR RENEWAL OF DISPENSING CERTIFICATE			
Please complete in block letters	Shaded fields for official use only	Application No.	
		Date and Time	
Information Required	Information Provided		
			√
PARTICULARS OF APPLICANT			
1. (a) Name			
(b) Profession			
(c) Qualifications			
PARTICULARS OF HEALTH FACILITY			
2. (a) Name of health facility			
(b) Certificate of Registration No.			
3. Type of entity			
4. Business premises			
(a) Physical address			
(b) Plot No:			
(c) Street:			
(d) Postal address			
(e) Telephone No:			
(f) Fax No:			
(g) Mobile No:			
(h) Email address			
(i) Village			
(j) Town			
(k) District			
5. APPENDIX			
Annual report			
(a) Monthly records of quantities of medicine ordered and received			
(b) Monthly records of names and receipts from authorized suppliers			
(c) Monthly records of prescriptions for PoMs/Ps dispensed			
(d) Monthly records of medicines stock-on-hand			
DECLARATION			
I declare that all the information I have stated in this application is correct and truthful to the best of my knowledge and belief. I understand that submission of false information shall render the application void and that if approval is granted, it shall be revoked and the certification cancelled.			
Name of Applicant (individual or authorised representative)			
Date:.....		Signature:.....	
FOR OFFICIAL USE ONLY			
Received by:		Receipt No:	
Amount Received:			
Serial No. of application:			
			OFFICIAL STAMP



Form VI
(Regulation 9(2))
(To be completed in triplicate)

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

**The Medicines and Allied Substances
(Dispensing Certificates) Regulations, 2016**

APPLICATION FOR AMENDMENT OF DISPENSING CERTIFICATE				
Please complete in block letters	Shaded fields for official use only	Application No.		
		Date and Time		
<i>Information Required</i>	<i>Information Provided</i>		√	
PARTICULARS OF APPLICANT				
1. (a) Name				
(b) Profession				
(c) Qualifications				
PARTICULARS OF HEALTH FACILITY				
2. (a) Name of health facility				
(b) Certificate of Registration No.				
3. Type of entity				
4. Business premises				
(a) Physical address				
(b) Plot No:				
(c) Street:				
(d) Postal address				
(e) Telephone No:				
(f) Fax No:				
(g) Mobile No:				
(h) Email address				
(i) Village				
(j) Town				
(k) District				
5.	EXISTING	PROPOSED AMENDMENT	REASONS FOR AMENDMENT	
DECLARATION				
I declare that all the information I have stated is correct and truthful to the best of my knowledge and belief.				
..... <i>Name</i>	 <i>Designation</i>		
..... <i>Signature</i>	 <i>Date</i>		
FOR OFFICIAL USE ONLY				
Date of Submission:				
Application Number:				
Payments Receipt Number:				
Application Accepted:				
Application Rejected (Notify applicant):				
.....				
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Form VII
(Regulation 10)
(To be completed in triplicate)

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

**The Medicines and Allied Substances
(Dispensing Certificates) Regulations, 2016**

APPLICATION FOR DUPLICATE DISPENSING CERTIFICATE			
Please complete in block letters	Shaded fields for official use only	Application No.	
		Date and Time	
Information Required	Information Provided		√
PARTICULARS OF APPLICANT			
1. (a) Name			
(b) Profession			
(c) Qualifications			
PARTICULARS OF HEALTH FACILITY			
2. (a) Name of health facility			
(b) Certificate of Registration No.			
3. Type of entity			
4. Business premises			
(a) Physical address			
(b) Plot No:			
(c) Street:			
(d) Postal address			
(e) Telephone No:			
(f) Fax No:			
(g) Mobile No:			
(h) Email address			
(i) Village			
(j) Town			
(k) District			
5. Affidavit of loss, etc			
DECLARATION			
I declare that all the information I have stated is correct and truthful to the best of my knowledge and belief.			
.....		
<i>Name</i>		<i>Designation</i>	
.....		
<i>Signature</i>		<i>Date</i>	
FOR OFFICIAL USE ONLY			
Date of Submission:			
Application Number:			
Payments Receipt Number:			
Application Accepted:			
Application Rejected (Notify applicant):			
.....			
OFFICIAL STAMP			

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



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

**The Medicines and Allied Substances
(Dispensing Certificates) Regulations, 2015**

**NOTICE OF INTENTION TO SUSPEND/REVOKE DISPENSING
CERTIFICATE**

(1) Here insert the full names and address of holder of certificate

To (1).....
.....
.....

(2) Here insert the Certificate No.

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

- (a)
- (b)
- (c)
- (d)

(3) Here insert the number of days stipulated

Accordingly, you are requested to show cause why your certificate 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 specified breaches shall result in the *suspension/revocation of your certificate.

Dated this.....day of20.....

.....
Director-General

*Delete as appropriate



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



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

**The Medicines and Allied Substances
(Dispensing Certificates) Regulations, 2016**

**NOTICE OF SUSPENSION/REVOCAION OF
DISPENSING CERTIFICATE**

(1) Here
insert the
full names
and address
of holder of
certificate

To (1)
.....

(2) Here
insert the
Registration
No

(2)

(3) Here
insert the
Certificate
No.

IN THE MATTER OF (3)you are notified that
your certificate has been * suspended for a period of

(4) Here
insert the
period

(4).....revoked on the following grounds:
.....
.....
.....

Dated thisday of20.....

.....
Director-General

*Delete as appropriate





Form X
(Regulation 15(1))

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

**The Medicines and Allied Substances
(Dispensing Certificates) Regulations, 2016**

REGISTER OF DISPENSING CERTIFICATES

No.	Name of Certificate Holder	Name and Address of business	Registration number	Date of issue	Expiry Date
1.					
2.					
3.					
4.					
5.					
6.					
7.					

LUSAKA
27th January, 2016
[MH.101/16/1]

DR J. KASONDE,
Minister of Health