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

PART I
PRELIMINARY

Regulation
1. Title
2. Interpretation

PART II
DISPENSING CERTIFICATES

3. Application for certificate
4. Request for information
5. Rejection of application for certificate
6. Issuance of certificate
7. Application for renewal of certificate
8. Transfer of certificate
9. Amendment of certificate
10. Application for duplicate certificate
11. Suspension of certificate
12. Revocation of certificate
13. Dispensing of medicines
14. Storage of medicines

PART III
GENERAL PROVISIONS

15. Register of dispensing certificates

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 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.

2. In these Regulations, unless the context otherwise requires—
   “authorised supplier” means a holder of a pharmaceutical licence issued under section thirty-four of the Act; and
   “certificate” means the dispensing certificate issued under section twenty-eight of the Act;

PART II
DISPENSING CERTIFICATE

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

5. (1) The Authority shall reject an application for a certificate if—
       (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 preceeding 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.

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.

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.

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

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.

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.

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.
(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.

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.

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

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.
<table>
<thead>
<tr>
<th>Information Required</th>
<th>Information Provided</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application No.</td>
<td>Date and Time</td>
</tr>
</tbody>
</table>

**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
   
   (a) Physical address
   
   (b) Plot No.:  
   
   (c) Street:
   
   (d) Postal address
   
   (e) Telephone No.:  
   
   (f) Fax No.:  
   
   (g) Mobile No.:  
   
   (h) Email address

4. (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

**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.

<table>
<thead>
<tr>
<th>Name</th>
<th>Designation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**FOR OFFICIAL USE ONLY**

Date of Submission: .................................................................

Application Number: .................................................................

Payments Receipt Number: ............................................................

Application Accepted (Proceed for Inspection): ....................................

Application Rejected (Notify applicant): ...........................................

OFFICIAL STAMP
REQUEST FOR INFORMATION

To:..........................................................................................................................................................

Address: .................................................................................................................................................

Application No: .....................................................................................................................................

You are requested to furnish the following information 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 shall be rejected.

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

..............................................................
Director-General

OFFICIAL STAMP
NOTICE OF REJECTION OF APPLICATION

To (1)………………………………………………………………………………

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 this …………………day of ……………….……., 20…………

..........................................................................................

Director-General

OFFICIAL STAMP
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.
### APPLICATION FOR RENEWAL OF DISPENSING CERTIFICATE

<table>
<thead>
<tr>
<th>Please complete in block letters</th>
<th>Shaded fields for official use only</th>
<th>Application No.</th>
<th>Date and Time</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Information Required</strong></td>
<td><strong>Information Provided</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### PARTICULARS OF APPLICANT

1. (a) Name
2. (b) Profession
3. (c) Qualifications

### PARTICULARS OF HEALTH FACILITY

1. (a) Name of health facility
2. (b) Certificate of Registration No.
3. Type of entity
4. Business premises
5. (a) Physical address
6. (b) Plot No.
7. (c) Street
8. (d) Postal address
9. (e) Telephone No.
10. (f) Fax No.
11. (g) Mobile No.
12. (h) Email address
13. (i) Village
14. (j) Town
15. (k) District

### 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]
APPLICATION FOR AMENDMENT OF DISPENSING CERTIFICATE

Please complete in block letters

<table>
<thead>
<tr>
<th>Information Required</th>
<th>Information Provided</th>
<th>√</th>
</tr>
</thead>
</table>

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

<table>
<thead>
<tr>
<th>Name</th>
<th>Designation</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Physical address</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plot No:</td>
</tr>
<tr>
<td>Street:</td>
</tr>
<tr>
<td>Postal address</td>
</tr>
<tr>
<td>Telephone No:</td>
</tr>
<tr>
<td>Fax No:</td>
</tr>
<tr>
<td>Mobile No:</td>
</tr>
<tr>
<td>Email address</td>
</tr>
<tr>
<td>Village</td>
</tr>
<tr>
<td>Town</td>
</tr>
<tr>
<td>District</td>
</tr>
</tbody>
</table>

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.

Name

Designation

Signature

Date

FOR OFFICIAL USE ONLY

Date of Submission: 

Application Number: 

Payments Receipt Number: 

Application Accepted

Application Rejected (Notify applicant): 

OFFICIAL STAMP
APPLICATION FOR DUPLICATE DISPENSING CERTIFICATE

Please complete in block letters

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.

Name ...........................................  Designation ...........................................

Signature ...........................................  Date ...........................................

FOR OFFICIAL USE ONLY

Date of Submission: ...........................................
Application Number: ...........................................
Payments Receipt Number: ...........................................
Application Accepted: ...........................................
Application Rejected (Notify applicant): ...........................................
NOTICE OF INTENTION TO SUSPEND/REVOKE DISPENSING CERTIFICATE

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

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) ................................................................................................................................................

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 of.................................20..........................

.................................................................................................
Director-General

*Delete as appropriate

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

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

NOTICE OF SUSPENSION/REVOCATION 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) ..revoked on the following grounds:
........................................................................................................
........................................................................................................
........................................................................................................
........................................................................................................
........................................................................................................

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

..................................................

Director-General

*Delete as appropriate

OFFICIAL STAMP
# 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

<table>
<thead>
<tr>
<th>No.</th>
<th>Name of Certificate Holder</th>
<th>Name and Address of business</th>
<th>Registration number</th>
<th>Date of issue</th>
<th>Expiry Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

DR J. KASONDE,
Minister of Health