

GOVERNMENT OF ZAMBIA

STATUTORY INSTRUMENT NO. 58 OF 2017

The Medicines and Allied Substances Act, 2013
(Act No. 3 of 2013)**The Medicines and Allied Substances**
(Certificate of Registration) Regulations, 2017

ARRANGEMENT OF REGULATIONS

Regulations

1. Title
2. Application for certificate of registration
3. Request for additional information
4. Issue of certificate
5. Rejection of application
6. Annual return
7. Transfer of certificate of registration
8. Amendment of certificate of registration
9. Suspension or cancellation of certificate of registration
10. Application for re-registration
11. Duplicate certificate of registration
12. Register of certificates of registration

IN EXERCISE of the powers contained in section 69 of the Medicines and Allied Substances Act, 2013, the following Regulations are made:

- | | |
|---|---|
| Title | 1. These Regulations may be cited as the Medicines and Allied Substances (Certificate of Registration) Regulations, 2017. |
| Application for certificate of registration | 2. A person who intends to operate a pharmacy shall apply to the Authority for a certificate of registration in Form I set out in the Schedule upon payment of the prescribed fee. |
| Request for additional information | 3. The Authority may request an applicant to submit additional information, in relation to an application, in Form II set out in the Schedule. |
| Issue of certificate of registration | 4. The Authority shall, where the applicant meets the requirements of the Act, issue a certificate of registration in Form III set out in the Schedule. |
| Rejection of application | 5. The Authority shall, where it rejects an application, inform the applicant of the rejection in Form IV set out in the Schedule. |
| Annual return | 6. (1) The holder of a certificate of registration shall file with the Authority an annual return or where there has been no change in the information provided in an annual return, a nochange return in Form V set out in the Schedule upon payment of the prescribed fee.

(2) The annual return shall cover the period 1 st January to 31 st December of the preceding financial year and the holder of a certificate of registration shall submit the return or nochange return by 31 st March of the following financial year. |
| Transfer of certificate of registration | 7. An application for the transfer of a certificate of registration shall be made in Form VI set out in the Schedule upon payment of the prescribed fee. |
| Amendment of certificate of registration | 8. A holder of a certificate of registration shall, where a change is made to the registered particulars, notify the Authority within fourteen days of the change in Form VII set out in the Schedule. |
| Suspension or cancellation of certificate of registration | Suspension or cancellation of certificate of registration
9. (1) The Authority shall, before it suspends or cancels a certificate of registration, notify the holder of the certificate of registration of the intention to suspend or cancel the certificate in Form VIII set out in the Schedule.

(2) Where the holder of a certificate of registration who is notified of the intention to suspend or cancel the certificate of registration under subregulation (1) fails to show cause or does not take any remedial measures to the satisfaction of the Authority |

within the specified time, the Authority shall suspend or cancel the certificate of registration and inform the applicant in Form IX set out in the Schedule.

10. A person whose certificate of registration is cancelled may apply for re-registration one year from the date of the cancellation of the certificate in Form I set out in the Schedule upon payment of the prescribed fee.

Application
for re-
registration

11. (1) A holder of a certificate of registration may apply for a duplicate certificate in Form X set out in the Schedule upon payment of the prescribed fee.

Duplicate
certificate of
registration

(2) The Authority may, with fourteen days of receipt of an application under subregulation (1), issue the applicant with a duplicate certificate in Form XI set out in the Schedule.

12. (1) The Authority shall keep and maintain a register of certificates of registration in Form XII set out in the Schedule.

Register of
certificates
of
registration

(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 as the Authority may determine and upon payment of the prescribed fee.

SCHEDULE

(Regulations 2, 3, 4, 5, 6, 7, 8, 9, 10, 11 and 12)

PRESCRIBED FORMS

Form I
(Regulations 2 and 10)The Medicines and Allied Substances Act, 2013
(Act No. 3 of 2013)

The Medicines and Allied Substances (Certificate of Registration) Regulations, 2017

APPLICATION FOR A CERTIFICATE OF REGISTRATION OR RE-REGISTRATION			
<input type="checkbox"/> Registration	Shaded fields for official use only	Application No.	
<input type="checkbox"/> Re-registration		Date/Time	
<i>Information Required</i>		<i>Information Provided</i>	
		√	
PART I – PARTICULARS OF THE APPLICANT			
Name of Business			
(a)	PACRA Registration No.		
(b)	TPIN		
(c)	Physical Address:		
(d)	Postal Address:		
(e)	District:		
(f)	Province:		
(g)	Telephone:		
(h)	Fax Number:		
(i)	Mobile:		
(j)	E-mail:		
PART II – PARTICULARS OF PERSONNEL			
(a)	State the name of the responsible person for the control and management/supervision of the pharmacy. Name of Pharmacist: Registration Number: Signature of responsible person: Date:		
(b)	Name of hospital pharmacy operator (where applicable): Profession: Professional regulatory body: Registration Number: Signature of responsible person: Date:		
PART III – DECLARATION AND SIGNATURE			
I declare that all the information I have stated is correct and truthful to the best of my knowledge and belief. Particulars of the Person Signing on Behalf of the Applicant (a) Name: (b) Designation: (c) Signature: Date:/...../..... (dd/mm/yyyy)			

No. 1	Valid practicing certificate for the Pharmacist
No. 2	Valid practicing certificate for the hospital pharmacy operator (as applicable)
No. 3	Letters of agreement or employment contract between the Pharmacist and the company
No. 4	Letters of agreement or employment contract between the hospital pharmacy operator and the company (as applicable)
No. 5	Sketch of the proposed premises
No. 6	Certificate of incorporation or certificate of registration

FOR OFFICIAL USE ONLY

Date of Submission:

Application No.:

Payment Receipt No.:

Application Complete (Proceed for inspection):

Application Deficient (Refer to applicant for additional information):

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Form II
(Regulation 3)

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

The Medicines and Allied Substances (Certificate of Registration) Regulations, 2017

REQUEST FOR ADDITIONAL INFORMATION

Application No.:

To:

Physical address:

Plot No:

Street:

Postal address:

District:

Phone:

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

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

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.....

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.....

Director-General

Form III
(Regulation 4)



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

The Medicines and Allied Substances (Certificate of Registration) Regulations, 2017

CERTIFICATE OF REGISTRATION

No.:

This is to certify that (Name of Pharmacy):
 of (physical address)

 is registered as a Pharmacy.

The terms and conditions of the certificate of registration are attached herewith.

This Certificate is issued on the day of, 20.....

.....
Director-General



(OVERLEAF)

TERMS AND CONDITIONS

1. The certificate of registration shall be displayed conspicuously on the premises.
2. The holder of the certificate of registration shall, within 14 days of the changes occurring, notify the Authority of any changes in the ownership, physical address, structure of the place of business, name and location of the pharmacy, change of personnel responsible for the management or control of the pharmacy.
3. The holder of the certificate of registration shall submit annual returns or no change returns by 31st March of the following financial year.
4. The certificate of registration is not transferrable without the written approval of the Authority.
5. Where the certificate of registration is surrendered, the certificate of registration shall be considered cancelled.
6. Where the certificate of registration is cancelled, the holder of the certificate shall surrender it to the Authority.
7. Non-compliance with the terms and conditions of the certificate of registration shall result in the suspension or cancellation of the certificate.

Form IV
(Regulation 5)



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

The Medicines and Allied Substances (Certificate of Registration) Regulations, 2017

NOTICE OF REJECTION OF APPLICATION

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

2. Here insert IN THE MATTER OF (2)
the reference No. of the application

You are hereby notified that your application for (3) has
been rejected on the following grounds:

3. Here insert type of application

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

Dated this day at 20

.....
Director-General

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Form V
(Regulation 6(1))

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

The Medicines and Allied Substances (Certificate of Registration) Regulations, 2017

ANNUAL RETURN () NO CHANGE RETURN ()

PART I: PARTICULARS OF CERTIFICATE HOLDER

Name of business:Certificate of
Registration No..... Date of Issue.....
Name of Pharmacist/Responsible person.....

Name of business:
Certificate of Registration No..... Date of Issue.....
Name of Pharmacist/Responsible person.....

PART II: DETAILS OF RETURN

Type of Return*
Annual Return No Change Return
Period of Return: 1st January 20..... to 31st December 20.....
Date of Submission, 20.....

* Tick as applicable

PART III: SUMMARY OF CHANGES

(Not applicable if there is no change)

No.	Type of Change (e.g. ownership, pharmacist, Location etc.)	Previous Details	New Details
1.			
2.			
3.			

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

Particulars of the Person Signing on Behalf of the Applicant

(a) Name:

(b) Designation:

(c) Signature: (d) Date: .../.../.....(dd/mm/yyyy)

FOR OFFICIAL USE ONLY

Date of Submission:

Application No.:

Payment Receipt No.:

Application Complete (Proceed for Evaluation):

Application Deficient (Refer to applicant for additional information):

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Form VI
(Regulation 7)

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

The Medicines and Allied Substances (Certificate of Registration) Regulations, 2017

APPLICATION FOR TRANSFER OF CERTIFICATE OF REGISTRATION			
	Shaded fields for official use only	Application No.	
		Date/Time	
<i>Information Required</i>	<i>Information Provided</i>		√
PART I – DETAILS OF CURRENT CERTIFICATE HOLDER			
1. Name of Business			
(a) PACRA Registration No.			
(b) TPIN			
(c) Physical Address:			
(d) Postal Address:			
(e) District:			
(f) Province:			
(g) Telephone:			
(h) Fax Number:			
(i) Mobile:			
(j) E-mail:			
PART II – DETAILS OF PROSPECTIVE CERTIFICATE HOLDER			
2. (a) PACRA Registration No.			
(b) TPIN			
(c) Physical Address:			
(d) Postal Address:			
(e) District:			
(f) Province:			
(g) Telephone:			
(h) Fax Number:			
(i) Mobile:			
(j) E-mail:			
PART III – DECLARATION AND SIGNATURE			
I declare that all the information I have stated is correct and truthful to the best of my knowledge and belief.			
Particulars of the person signing on behalf of the Applicant			
(a) Name:		
(b) Designation:		
(c) Signature:		
(d) Date:(dd/mm/yyyy)		
PART IV - ENCLOSURES			
Evidence of transfer between certificate holder and the prospective certificate holder			
FOR OFFICIAL USE ONLY			
Date of Submission:			
Application No.:			
Payment Receipt No.:			
Application Complete (Proceed for Evaluation):			
Application Deficient (Refer to applicant for additional information):			
			OFFICIAL STAMP



Form VII
(Regulation 8)

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

The Medicines and Allied Substances (Certificate of Registration) Regulations, 2017

NOTIFICATION OF AMENDMENT OF CERTIFICATE OF REGISTRATION

PART I: PARTICULARS OF CERTIFICATE HOLDER

Name of business:
Certificate of Registration No.: Date of Issue.....
Name of Pharmacist/Responsible person.....

PART I: PARTICULARS OF AMENDMENT

No.	Description of amendment(s)
1.	
2.	
3.	

SUMMARY OF THE AMENDMENT

EXISTING (Name of pharmacist, physical address etc)	PROPOSED AMENDMENT	DATE OF AMENDMENT	REASONS FOR AMENDMENT

PART III: SUPPORTING DOCUMENTATION

Please submit documents, where applicable, to support your application for amendment.

PART IV: DECLARATION AND SIGNATURE

I declare that all the information I have stated is correct and truthful to the best of my knowledge and belief.	
Particulars of the Person Signing on Behalf of the Applicant	
(a) Name:	
(b) Designation:	
(c) Signature:	(d) Date:/...../..... (dd/mm/yyyy)

FOR OFFICIAL USE ONLY

Date of Submission:

Application No.:

Payment Receipt No.:

Application Complete (Proceed for Evaluation):

Application Deficient (Refer to applicant for additional information):

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Form VIII
(Regulation 9(1))

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

The Medicines and Allied Substances (Certificate of Registration) Regulations, 2017

**NOTICE OF INTENTION TO SUSPEND OR CANCEL CERTIFICATE OF
REGISTRATION**

Certificate of Registration No.:

To:
.....

IN THE MATTER OFyou are hereby notified that the Authority intends to *suspend ()
cancel () your certificate of registration on the following grounds:

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

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

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

.....
Director-General

*Delete as applicable

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Form IX
(Regulation 9(2))

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

The Medicines and Allied Substances (Certificate of Registration) Regulations, 2017

**NOTICE OF SUSPENSION OR CANCELLATION OF CERTIFICATE OF
REGISTRATION**

Certificate of Registration No.:

To:
.....

IN THE MATTER OFyou are hereby notified that your certificate of registration has
been suspended for a period/cancelled on the following grounds:

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

In case of cancellation, you are required to surrender the certificate of registration to the Authority within seven days
from the date of cancellation.

Dated this day of, 20.....

.....
Director-General

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*Delete as applicable



Form X
(Regulation 11(1))

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

The Medicines and Allied Substances (Certificate of Registration) Regulations, 2017

APPLICATION FOR DUPLICATE CERTIFICATE OF REGISTRATION						
Please complete in block letters	Shaded fields for official use only		Application No.			
			Date and Time			
Information Required	Information Provided					√
PART I: PARTICULARS OF THE APPLICANT						
Name of Business:						
Address:						
(a) Physical Address:						
(b) Postal Address:						
(c) Province:						
(d) District:						
Contact details						
(a) Telephone No.:						
(b) Fax No.:						
(c) Mobile phone No.:						
(d) Email address:						
PART II: PARTICULARS OF PROPRIETOR(S)/DIRECTOR(S)						
No.	Full Names	Sex	Nationality	Residential Address	Date of Birth	NRC/Passport No.
1.						
2.						
3.						
4.						
5.						
6.						
PART III: REASONS FOR APPLICATION						
1.						
2.						
3.						
PART IV: SUPPORTING DOCUMENTATION						
Submit an affidavit of loss, destruction or otherwise of original certificate of registration						

PART V: DECLARATION
<p>DECLARATION AND SIGNATURE</p> <p>I declare that the information I have stated is correct and truthful to the best of my knowledge and belief.</p> <p>Particulars of the person signing on behalf of the Applicant</p> <p>(a) Name:</p> <p>(b) Designation:</p> <p>(c) Signature:</p> <p>(d) Date:/...../..... (dd/mm/yyyy)</p>
<p>FOR OFFICIAL USE ONLY</p> <p>Date of Submission:</p> <p>Application No.:</p> <p>Payment Receipt No.:</p> <p>Application Complete (Proceed to issue)</p> <p>Application Deficient (Notify applicant on deficiencies):</p> <div style="text-align: right; margin-top: 20px;"> <div style="border: 1px solid black; padding: 5px; display: inline-block;"> OFFICIAL STAMP </div> </div>



Form XI
(Regulation 11(2))

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

The Medicines and Allied Substances (Certificate of Registration) Regulations, 2017

DUPLICATE CERTIFICATE OF REGISTRATION

No.:

This is certify that (Name of Pharmacy)
.....
of (physical address)
.....
is registered as a Pharmacy.

The conditions of the certificate of registration are attached herewith.

This certificate is issued on day of, 20.....

.....
Director-General





Form XII
(Regulation 12(1))

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

The Medicines and Allied Substances (Certificate of Registration) Regulations, 2017

REGISTER OF CERTIFICATES OF REGISTRATION

No.	Name and Address of Pharmacy	Certificate Number	Date of Issue	Date of Suspension/Cancellation
1.				
2.				
3.				
4.				
5.				
6.				
7.				

DR C. CHILUFYA,
Minister of Health

LUSAKA

14th July, 2017

[MH/71/3/8 TJ]

