GOVERNMENT OF ZAMBIA

STATUTORY INSTRUMENT NO. 57 OF 2017

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

The Medicines and Allied Substances (Importation and Exportation) Regulations, 2017

ARRANGEMENT OF REGULATIONS

Regulation

Copies of this Statutory Instrument can be obtained from the Government Printer, P.O. Box 30136, 10101 Lusaka. Price K36.00 each.

IN EXERCISE of the powers contained in sections 35 and 36 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 (Importation and Exportation) Regulations, 2017.

Interpretation

2. In these regulations unless the context otherwise requires—

" competent authority ", in relation to a traveller entering Zambia with a medicine or allied substance for that traveller's use, means the medicines and allied substances regulatory authority in the country where the medicine or allied substance was prescribed for use by the traveller;

" dental surgeon " means a health practitioner registered as such under the Health Professions Act, 2009, or duly registered in a foreign country;

Act No. 24 of 2009

" insanitary conditions " means conditions or circumstances 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;

" medical doctor " means a health practitioner registered as such under the Health Professions Act, 2009, or duly registered in a foreign country;

Act No. 24 of 2009

" permit " means an importation permit issued under section 35 or an exportation permit issued under section 36 of the Act;

" personal use " includes use by a person's relative or animal; and

" veterinary surgeon " has the meaning assigned to the term in the Veterinary and Veterinary Para-Professions Act, 2010, and includes a veterinary surgeon duly registered in a foreign country.

Act No. 45 of 2010

Application for permit

3. (1) A person that intends to import or export any medicine or allied substance shall apply to the Authority for a permit in Form I set out in the Schedule upon payment of the prescribed fee.

(2) An applicant for a permit to import any medicine or allied substance shall, before being issued with a permit under this regulation, pay the applicable pre-clearance fee prescribed for quality assurance in respect of the medicine or allied substance.

(3) 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.

(4) The Authority may inspect the premises where medicines or allied substances in respect of which an application for a permit is made are kept in order to determine if the applicant meets the requirements of the Act and the guidelines issued by the Authority from time to time.

(5) The Authority shall, in considering an application under this regulation, take into account

(a) the availability on the market in the Republic of the medicines and allied substances and reasons for the intended importation or exportation;

(b) the marketing authorisation status in respect of the medicines or allied substances, where applicable;

(c) the quantities of the medicines or allied substances intended to be imported or exported; and

(d) provisions of any other relevant law.

(6) A person applying for a permit is not required to be a holder of a pharmaceutical licence.

Application for permit to import medicine or allied substance for personal use

4. (1) A person who intends to import any medicine or allied substance for personal use shall apply to the Authority for a permit to import the medicine or allied substance in Form II set out in the Schedule upon payment of the prescribed fee.

(2) The Authority shall within seven days from the date of receipt of an application under this regulation, notify the applicant of the decision of the Authority in respect of the application.

Request for additional information

5. The Authority may request an applicant to submit additional information in relation to an application for a permit in Form III set out in the Schedule.

Rejection of application for permit

6. (1) The Authority shall reject an application for a permit if the applicant

(a) fails to comply with any condition precedent to the issue of the permit; or

(b) does not meet the requirements of the Act and guidelines issued by the Authority from time to time.

(2) The Authority may reject an application for a permit if the applicant has been convicted of an offence under the Act or any other relevant law and has been sentenced to imprisonment for a period exceeding six months during the last three years.

(3) The Authority shall, where it rejects an application under subregulation (1) or (2), inform the applicant of the reasons for the rejection of the application in Form IV set out in the Schedule.

Issuance of permit

7. (1) The Authority shall, where the applicant under regulation 3 meets the requirements of the Act, issue a permit in Form V set out in the Schedule.

(2) The Authority shall, where the applicant under regulation 4 meets the requirements of the Act, issue a permit in Form VI set out in the Schedule.

(3) A permit is valid for one year from the date of issue and only in respect of the consignment of medicines or allied substances specified in the permit.

(4) A permit holder that is not able to import or export the medicines or allied substances in respect of which the permit was issued during the period that the permit remains valid may apply for another permit in accordance with regulation 5.

(5) A permit is not renewable.

Permit not transferable

8. Except as otherwise provided in these Regulations, a permit holder shall not transfer the permit to another person.

Amendment of permit

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

(2) The Authority may amend a permit where—

(a) the name of a business changes;

(b) the port of entry or exit for the medicines or allied substances in respect of which the permit was issued changes; or

(d) there is a change of address of the permit holder.

(3) The Authority shall, within fourteen days of the receipt of an application for amendment of a permit, inform the permit holder of its decision.

(4) A permit holder shall, where the Authority grants the application for amendment of the permit, surrender the permit to the Authority and the Authority shall issue an amended permit for the remainder of the permit's validity period in Form V set out in the Schedule.

Duplicate permit

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

Suspension of permit

11. (1) The Authority shall suspend a permit if the permit holder

(a) fails to obtain any clearance or permission under any other relevant written law, where required;

(b) contravenes the terms and conditions of the permit or the provisions of the Act or any other relevant written law; or

(c) obtained the permit by fraud or deliberate or negligent submission of false information.

(2) The Authority shall, before suspending a permit, give notice to the permit holder of the intention to suspend the permit and request the permit 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 Schedule.

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

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

(6) A permit holder shall, where the permit is suspended, immediately surrender the permit to the Authority.

(7) A permit holder shall, during the period that the permit remains suspended, quarantine at the permit holder's cost medicines or allied substances affected by that suspension.

Revocation of permit

12. (1) The Authority shall revoke a permit if—

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

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

(c) it comes to the attention of the Authority that the medicines or allied substances in respect of which the permit was issued are not suitable or have become known to be dangerous or contain substances dangerous to human health, animal health or the environment;

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

(e) the permit holder 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 permit holder of the intention to revoke the permit and request the permit holder to show cause, within a specified period, why the permit should not be revoked.

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

(4) The Authority shall revoke a permit if the permit holder fails to take remedial measures within the period specified in the notice issued under subregulation (2).

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

(6) A permit holder shall, where a permit is revoked, immediately surrender the permit to the Authority.

(7) Where a permit is revoked, the medicines or allied substances affected by the revocation of the permit shall be quarantined and disposed of as directed by the Authority at the permit holder' cost.

Exemption of certain travellers from requirement to obtain permit

13. (1) Subject to subregulation (2), these regulations do not apply to the importation by a traveller entering Zambia of a medicine or allied substance for that traveller's use.

(2) A traveller entering Zambia with a medicine or allied substance for that traveller' use shall furnish an inspector at the port of entry with written confirmation from the competent authority that the medicine or allied substance was prescribed for use by the traveller.

Disposal of medicines or allied substances stocked under insanitary conditions

14. The Authority shall, where it establishes that the permit holder stocks medicines or allied substances under insanitary conditions, direct the permit holder to dispose of the medicines or allied substances at the permit holder's cost.

Register of permits

15. (1) The Authority shall keep and maintain a register of permits 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 as the Authority may specify and upon payment of the prescribed fee.

SCHEDULE

(*Regulations* 3, 4, 5, 6, 7, 9, 10, 11, 12 and 15)

PRESCRIBED FORMS

Form I
(*Regulation* 3 (1))

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

The Medicines and Allied Substances (Importation and Exportation) Regulations, 2017

APPLICATION FOR IMPORTATION /EXPORTATION PERMIT FOR MEDICINE OR ALLIED SUBSTANCE

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

Information Required	*Information Provided*	√
PART I - PARTICULARS OF THE APPLICANT		
1. Name of Business		
2. Physical Address:		
3. Postal Address:		
4. Business premises		
(a) Telephone Number:		
(b) Fax Number:		
(c) Mobile:		
(d) E-mail:		
PART II - PARTICULARS OF IMPORTATION/EXPORTATION		
5. **Port of entry/exit** *(a)* by rail to/from:…… station *(b)* by road via:……..(state port of entry/exit) *(c)* by parcel post to/from: ……(state post office) *(d)* by parcel post to/from: ……(state airport)		
6. **Reason for importation/exportation (please tick what is applicable below)** **Commercial** ☐ **Donation** ☐ **Other** ☐ **specify:** ……		

7.	**Attachments (supporting documents)**	
	(a) Copy of pharmaceutical Licence (where applicant is holder thereof)	
	(b) Copy of practitioners licence (if applicable)	
	(c) Permits under other relevant laws (if applicable)	
	(d) Inventory of medicines or allied substance to be imported/exported (Particulars and Quantities)	
8.	**Conditions for an application for import or export permit**	
	Applications must always be made by the actual Importer or Exporter or their authorised agent: *(a)* A proforma invoice must accompany each application *(b)* A separate application is required in respect of each consignment of medicines to be imported or exported *(c)* The prescribed fees shall be paid for an import permit and must be forwarded with application	
	PART III – DECLARATION AND SIGNATURE	
	I declare that the information I have stated in this application is correct and truthful to the best of my knowledge and belief. I acknowledge that making a false or misleading statement in connection with a medicine or allied substance is an offence punishable by fine or imprisonment. *(a)* **Name:** …… *(b)* **Designation:** …… *(c)* **Signature:** …… Date: ……/……/……..……*(dd/mm/yyyy)*	

FOR OFFICIAL USE ONLY

Date of Submission: ……

Application No.: ……

Payment Receipt No.: ……

Application in Order (Proceed for inspection): ……

Application Deficient (notify applicant on deficiencies): ……

OFFICIAL STAMP

Form II
(*Regulation* 4 (1))
(To be completed in triplicate)

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

The Medicines and Allied Substances (Importation and Exportation) Regulations, 2017

APPLICATION FOR PERMIT TO IMPORT MEDICINE OR ALLIED SUBSTANCE FOR PERSONAL USE

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		
1.	Name:		
2.	Contact Details:		
	(a) Physical Address:		
	(b) Postal Address:		
	(c) Telephone No.		
	(d) Mobile phone No.		
	(e) E-mail address		
	PART II: PARTICULARS OF MEDICINE(S) OR ALLIED SUBSTANCE(S)		
3.	Name(s)	Quantity	
	(a)		
	(b)		
	(c)		
4.	**Attachment(s):**		
	Prescription issued by a medical doctor, dental surgeon (where the prescription is for medicine or allied substance connected to dental practice) or veterinary surgeon (where the prescription is for medicine or allied substance connected to veterinary practice) as the case may be		
	PART III: DECLARATION AND SIGNATURE		
	I declare that the information I have stated in this application is correct and truthful to the best of my knowledge and belief. I acknowledge that making a false or misleading statement in connection with a medicine or allied substance is an offence punishable by fine or imprisonment. *(a)* **Name:** …… *(b)* **Signature:** ……. Date: ……/……/……*(dd/mm/yyyy)*		

FOR OFFICIAL USE ONLY

Date of Submission: ……

Application No.: ……

Payment Receipt No.: ……

Application Complete (Proceed to issue) ……

Application Deficient (Notify applicant on deficiencies): ……

OFFICIAL STAMP

Form III
(*Regulation* 5)

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

The Medicines and Allied Substances (Importation and Exportation) Regulations, 2017

REQUEST FOR ADDITIONAL INFORMATION

To: …… ……..

Physical address:…….. ……..
Application No: …….. ……
Street: …….. ……..
Postal address: ……. ……
District…….. ….
Province…… …..

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

(a) …… ……
…
(b) …… ……
…
(c) …… ……
…
(d) …… ……
…
(e) …… ……
…

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

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

……..……..
Director-General

OFFICIAL STAMP

Form IV
(*Regulation* 6(3))

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

The Medicines and Allied Substances (Importation and Exportation) Regulations, 2017

NOTICE OF REJECTION OF APPLICATION

1. Here insert the full names and address of the applicant

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

TO (1) ……
……
……
IN THE MATTER OF (2) ……
You are hereby notified that your application for (3) ……
…… has been rejected by the Authority on the following grounds:

(a) ……
(b) ……
(c) ……
(d) ……

Dated this …… day at …… 20 ……

4. Signature of Director-General

(4)……
Director-General

OFFICAL
STAMP

Form V
(*Regulation* 7(1))

ZAMBIA MEDICINES REGULATORY AUTHORITY

Permit No…….

The Medicines and Allied Substances
(Importation and Exportation) Regulations, 2017

***IMPORTATION/EXPORTATION PERMIT**

This is to certify that (Name of permit holder)

…… of (Physical Address) ……

……

……

is authorised to:

[ ] *import/*export the following *medicine(s) allied substance(s): Quantity

1……. ……

2……. ……

3……..... ……

4…… ……

[ ] Port of Entry/Exit …….. ……..

This permit is valid until …….. 20……

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

---------- (Seal) ----------

Director-General *Date of Issue*

*Delete as applicable

TERMS AND CONDITIONS OF IMPORTATION/EXPORTATION PERMIT

1. This permit is not transferable or renewable.
2. The holder of the permit shall produce the permit together with other approved or endorsed documents to an inspector and customs officer at the time of importation or exportation.
3. The holder of the permit shall keep records relating to the importation or exportation of medicines or allied substances and avail the records to an inspector for inspection.
4. Non-compliance with any of the terms and conditions of the permit shall result in suspension or revocation of permit.

Form VI
(*Regulation* 7(2))

ZAMBIA MEDICINES REGULATORY AUTHORITY

Permit No……..

The Medicines and Allied Substances
(Importation and Exportation) Regulations, 2017

IMPORTATION (PERSONAL USE) PERMIT

This is to certify that (Name of permit holder)

…… of (Physical Address) ……

……

……

is authorised to:

import the following *medicine(s)/allied substance(s): Quantity

1……. ……

2…… ……

3……..... ……

4…… ……

[ ] Port of Entry ……..……...

This permit is valid until …… 20……..……..

---------- (Seal) ----------

Director-General *Date of Issue*

*Delete as applicable

Form VII
(*Regulation* 9(1))
(To be completed in triplicate)

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

The Medicines and Allied Substances (Importation and Exportation) Regulations, 2017

APPLICATION FOR AMENDMENT OF PERMIT

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

	Information Required	*Information Provided*	√
	PART I: PARTICULARS OF APPLICANT		
1.	Licence No.:		
2.	Name (s) of applicant:		
3.	Business address (Head Office):		
4.	*(a)* Telephone No.:		
	(b) Fax No.		
	(c) Operations		
	(d) E-mail address		
5.	**PART II: PARTICULARS OF AMENDMENT**		

No.	**CURRENT INFORMATION**	**DESCRIPTION OF AMENDMENT(S)**	**REASONS FOR AMENDMENT**
1.			
2.			
3.			
4.			
5.			

6. **Attachment(s)**

Attach supporting document(s) where applicable

1.
2.
3.

PART III: DECLARATION AND SIGNATURE

I declare that the information I have stated in this application is correct and truthful to the best of my knowledge and belief. I acknowledge that making a false or misleading statement in connection with a medicine or allied substance is an offence punishable by fine or imprisonment.

(a) Name: .....
(a) Name: .....
(b) Designation: .....

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

FOR OFFICIAL USE ONLY

Date of Submission: .....
Application No.: .....
Payment Receipt No.: .....
Application Complete (Proceed to issue) .....
Application Deficient (Notify applicant on deficiencies): .....

OFFICIAL STAMP

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

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

The Medicines and Allied Substances (Importation and Exportation) Regulations, 2017

APPLICATION FOR DUPLICATE PERMIT

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		
1.	Permit No.:		
2.	Name (s) of applicant:		
3.	Business address (Head Office):		
4.	Permit Holder/ Responsible person:		
	Operations		
	PART II: SUPPORTING DOCUMENTATION		
5.	Submit an affidavit of loss or damage, of Permit and Police Report		

PART III: DECLARATION AND SIGNATURE

I declare that the information I have stated in this application is correct and truthful to the best of my knowledge and belief. I acknowledge that making a false or misleading statement in connection with a medicine or allied substance is an offence punishable by fine or imprisonment.

(a) Name: ……..

(b) Designation: ……..

(c) Signature: ……. Date: ……/……/……..……*(dd/mm/yyyy)*

FOR OFFICIAL USE ONLY

Date of Submission: ……

Application No.: ……

Payment Receipt No.: ……

Application Complete (Proceed to issue) ……

Application Deficient (Notify applicant on deficiencies): ……

OFFICIAL STAMP

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

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

The Medicines and Allied Substances
(Importation and Exportation) Regulations, 2017

NOTICE OF INTENTION TO *SUSPEND/REVOKE *IMPORTATION/EXPORTATION PERMIT

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

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

(2) Here insert the Permit No.

IN THE MATTER OF (2)…….....you are hereby notified that the Board intends to *suspend/revoke your permit 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 permit 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 Permit.

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

(4) Signature of Director-General

(4) .....
Director-General

OFFICIAL STAMP

*Delete as applicable

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

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

The Medicines and Allied Substances (Importation and Exportation) Regulations, 2017

NOTICE OF *SUSPENSION/REVOCATION OF *IMPORTATION/EXPORTATION PERMIT

To: (1)……
……

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

(a) ……
(b) ……
(c) ……
(d) ……

You are required to surrender the permit to the Authority immediately.

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

(4) .....
Director-General

OFFICIAL STAMP

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

(2) Here insert the Permit No.

(3) Here insert number of days stipulated

(4) Signature of Director-General

*Delete as applicable

Form XI
(*Regulation* 15(1))

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

The Medicines and Allied Substances (Importation and Exportation) Regulations, 2017

REGISTER OF IMPORTATION AND EXPORTATION PERMITS

No.	Name of Permit holder	Permit Number	*Importation/ Exportation	Date of Issue	Expiry Date
1.					
2.					
3.					
4.					
5.					
6.					
7.					

*Indicate as applicable

DR C. CHILUFYA,
Minister of Health

LUSAKA
14th July, 2017
[MH/101/16/1]