



Zambia Medicines Regulatory Authority

Guidelines on Import and Export Permits for Medicines and Allied Substances

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1. INTRODUCTION

The Zambia Medicines Regulatory Authority (ZAMRA) is mandated under the Medicines and Allied Substances Act No. 3 of 2013 to register and regulate medicines and allied substances being made available on the Zambian market. The Authority is also mandated to prescribe requirements or standards for premises and establishments where medicines and allied substances are manufactured, stored and distributed to ensure their quality, efficacy and safety.

These guidelines for Importation and Exportation of medicines and allied substances are issued by the Authority pursuant to section 68 of the Act and prescribes the information to be incorporated in the applications for import and export permits and authorisations by the applicants in accordance with Sections 35 and 36 of the Act.

Additionally, applicants should be aware that importation and exportation of medicines and allied substances may be subjected to additional regulatory requirements by the Authority as stated in Section 37 of the Act.

The Authority may from time to time amend any part of these guidelines. In addition, the requirements for controlled medicines, donations and personal use permits will not be covered in these guidelines but in their respective guidelines.

2. OBJECTIVES

These guidelines are intended to be the reference document for use by an applicant in the preparation of applications for permits or authorisations for medicines and allied substances by providing general guidance on the application requirements and process.



3. SCOPE

These guidelines apply to the importation and exportation of medicines and allied substances for the following types of consignments:

- i. Registered products;
- ii. Unregistered products;
- iii. Samples for registration, clinical trials and research
- iv. Products for Promotions or advertisement and marketing, tenders and reference standards;
- v. Active Pharmaceutical Ingredients (API), bulk finished products and intermediates; and
- vi. Raw materials, excipients and packaging

4. DEFINITIONS

In these guidelines, unless the context otherwise requires -

“Act” means the Medicines and Allied Substances Act No. 3 of 2013;

“Allied substances” include acaricides, cosmetics, disinfectants, food supplements, feed additives and supplements, medical and surgical sundries, medical devices and condoms;

“Applicant” means a person applying for a permit and would be responsible for the product and all issues relating to the product, including any information accompanying the product;

“Authorisation” -means an official legal approval, license, or permit granted to a qualified entity to bring specific pharmaceutical or medical goods across national borders

“Authority” means the Zambia Medicines Regulatory Authority;

“Emergency Use Listing Procedure (EUL)” means a risk-based procedure for assessing and listing unlicensed vaccines, therapeutics and in vitro diagnostics with the ultimate aim of expediting the availability of these products to people affected by a public health emergency;

“Exporter” means a person authorised by the Authority to export medicines or allied substances;

“Export permit” means a permit issued by the Authority, authorizing a person to export medicines, allied substances or precursor chemicals;



“Importer” means a person authorised by the Authority to import medicines, allied substances and precursor chemicals;

“Import permit” means a permit issued by the Authority, authority, authorising a person to import medicines, allied substances and precursor chemicals; and

“Marketing Authorisation” means the authorisation granted under Section 39 of the Act, for placement of a medicine or allied substance on the market;

“Medicine” means human medicine, veterinary medicine, medicinal product, herbal medicine or any substance or mixture of substances for human or veterinary use intended to be used or manufactured for use for its therapeutic efficacy or for its pharmacological purpose in the diagnosis, treatment, alleviation, modification or prevention of disease or abnormal physical or mental state or the symptoms of disease in a person or animal;

“Rare disease” means a disease that only affects a small percentage of the population;

“Unregistered Medicines and/or allied substances” means medicines and/or allied substances that do not have a marketing authorisation or are not listed;

5. ABBREVIATIONS

cGMP – current Good Manufacturing Practice

MA- Marketing Authorisation

ZAMRA - Zambia Medicines Regulatory Authority

6. GENERAL REQUIREMENTS

6.1 Applications for import or export permit(s) for medicines and/or allied substances

An application for an import/export permit or authorisation shall be made by:

- a) a manufacturer who intends to register a medicine or allied substance for sale on the Zambian market;
- b) the local responsible person with power of attorney from a foreign based manufacturer for regulatory purposes
- c) a pharmaceutical licence holder (Wholesaler or Manufacturer);



- d) a Licensed public and private human health and animal facility;
- e) a Donor of medicines or allied substances;
- f) the Ministry of Health in response to a declared health emergency;
- g) a researcher;
- h) an authorised member of a clinical trial; and
- i) any Persons authorized to import or export.

The Authority also determines which medicines and/or allied substances may be imported into the Republic, taking into consideration factors such as availability, marketing authorisation status and quantities requested for importation.

6.2 Permit application

An applicant wishing to apply for an import/export permit must make an application in the prescribed manner and form and pay prescribed fees through the online portal found on the Authority's website (www.zamra.co.zm) under E-Services.

6.3 Requirements for an application

An application for an import/export permit shall comprise the following:

6.3.1 For Registered products

- (a) Proforma invoice from Supplier
- (b) A duly completed and signed online application form;
- (c) Inventory list, where applicable;
- (d) Proof of payment of the prescribed application fee;
- (e) Registration Certificate of facility, where applicable;
- (f) Certificate of Analysis, where applicable;
- (g) Practitioners Licence, where applicable;
- (h) Permit under other relevant laws (if applicable)

6.3.2 For Unregistered products

The same requirements as in 4.2 in addition to a letter of authorisation to import unregistered medicines and allied substances. Prior to an application being made for an importation or exportation permit of unregistered medicines and allied substances, the importer or exporter shall be required to request for permission to apply for the importation or exportation of the unregistered medicines or allied substances. The request for permission to apply for the importation or exportation of



unregistered medicines or allied substances, must be in the form of a written request on the headed paper of the institution. The request shall be accompanied by the following documents:

6.3.3 In the case of manufacturers: -

- i. Proforma invoice from Supplier;
- ii. Purchase orders or prescriptions (this provision may not apply to medicines used in emergencies as guided by the MASA);
- iii. A valid ZAMRA GMP clearance or valid Certificate of GMP from a Competent Regulatory Authority or the WHO PQT or WHO cGMP;
- iv. A valid ISO 13485 Certificate or Conformance Européenne (CE) certificate or GMP certificate or Free Sale Certificate (Medical devices), or any other applicable standards;
- v. Certificate of Analysis from the API manufacturer
- vi. Material Safety Data Sheet;
- vii. Proof of manufacturing authorisation of the medicine or allied substance issued by local competent Authority;
- viii. Proof of registration of the manufacturing site in the country of origin;
- ix. Applicant's Pharmaceutical Licence-Manufacture
- x. Copy of full registration certificate of the responsible person, where applicable; and
- xi. Inventory of medicines or allied substance to be imported/exported.

6.3.4 In the case of non-manufacturers: -

- i. Copy of supplier's Licence issued by the respective national regulatory authority;
- ii. Proforma invoice;
- iii. Importer's written letter indicating that the importer shall take responsibility of the quality problems and recall of the unregistered medicines or allied substances;
- iv. Purchase orders or prescriptions where applicable;
- v. Copy of practitioners Licence, where applicable;
- vi. Inventory of medicines or allied substance to be imported;
- vii. Proof of payment of the prescribed application fee



- viii. Certificates of Analysis for each product; and
- ix. A valid GMP Certificate, ISO certification and other relevant applicable standards for each product; where applicable.

The Authority shall, where it is satisfied, upon review of the request for permission to apply for the importation or exportation of unregistered medicines or allied substances grant or reject the request. The submission by the importer or response from the Authority in relation to the request for permission to apply for the importation or exportation of unregistered medicines or allied substances, does not guarantee that an import permit shall be granted.

6.4 Circumstances under which unregistered medicines and allied Substances may be imported

The Authority may permit the importation of unregistered medicines or allied substances under the following circumstances:

- a. donated medicines;
- b. a person importing medicine for that person's use or for the use of that person's relative, if the quantity of the imported medicine is based on the prescription;
- c. a physician, dentist or veterinary surgeon importing medicine on the physician's, dentist's or veterinary surgeon's order for administration to a person or animal, if the quantity of the imported medicine is based on a prescription;
- d. medicine imported or exported in response to a declared health emergency;
- e. medicine imported by an authorised institution for administration to patients under its care; and
- f. any medicine or allied substance used for purposes of a clinical trial.
- g. That the unregistered medicine or allied substance has no registered pharmaceutical equivalent available in Zambia
- h. That the unregistered medicine or allied substance is required for diseases of public and animal health concern, including cancer, rare diseases, or neglected tropical diseases;
- i. That there has never been a registered medicine or allied substance, pharmaceutical equivalent;
- j. Any other circumstances as determined by the Authority.

6.5 Samples for registration, clinical trials, reference standards and research

- (a) Proforma invoice from Supplier
- (b) A duly completed and signed online application form;
- (c) Proof of payment of the prescribed application fee;



- (d) Registration Certificate of facility, where applicable;
- (e) Approval of the clinical trial;
- (f) Approval from a research institution;
- (g) Ethics clearance from an independent research board; where applicable and
- (h) Study protocol; where applicable.

6.6 Sample products for promotions, advertisement, marketing or tenders;

- (a) Proforma invoice from Supplier
- (b) A duly completed and signed online application form;
- (c) Proof of payment of the prescribed application fee;
- (d) Registration Certificate of facility, where applicable;
- (e) Bidding documents, where applicable; and
- (f) Approval documents to advertise, promote or market.

6.7 Active Pharmaceutical Ingredients (API), bulk finished products and intermediates;

- (a) Proforma invoice from Supplier
- (b) A duly completed and signed online application form;
- (c) Proof of payment of the prescribed application fee;
- (d) Registration Certificate of facility from a recognised national medicines regulatory authority, where applicable;
- (e) Certificate of Analysis; and
- (f) Valid GMP Certificate, where applicable.

6.8 Raw materials, excipients and packaging

- (a) Proforma invoice from Supplier



- (b) A duly completed and signed online application form;
- (c) Proof of payment of the prescribed application fee;
- (d) Registration Certificate of facility from a recognised national medicines regulatory authority, where applicable;
- (e) Certificate of Analysis, where applicable

6.9 Language

An application and its supporting documents shall be in English. Other supporting documents (such as GMP certificates, Certificates of Analysis) submitted in a foreign language shall be accompanied by certified translated copies. Where original certificates are in another language, copies shall be presented together with certified translations.

6.10 Screening

- a) An application shall be screened for completeness by the Authority to ensure that there are no deficiencies that would hinder the evaluation process.
- b) Where deficiencies are identified during screening of an application, a request for additional information shall be made to the applicant.
- c) Subject to 6.6.1, an applicant shall be required to submit all the requested additional information within 60 days from the date of receipt of the request.
- d) Where an applicant does not respond to the request for additional information within 60 days, the application shall be rejected.
- e) Where an applicant fails to provide all the requested information, or the submitted information is incomplete, deficient or irrelevant, the application shall be rejected.
- f) An application not submitted in the prescribed format shall be rejected.
- g) Where the application has been rejected, the applicant shall be informed in writing providing reasons for the rejection.

6.11 Evaluation of applications for an import/export permit or authorisation

Where the Authority processes an application for an import /export permit or authorisation, the applicant shall be informed of the outcome of the evaluation process within fourteen (14) days.

**6.12 Issuance of permit**

The Authority shall issue an import/export permit if the application meets the requirements of the permit applied for.

An import/export permit is valid for one (01) year from the date of issue subject to terms and conditions.

6.13 Appeals

An applicant who may be aggrieved by a decision made by the Authority for issue of an import/export permit or authorisation may seek redress in accordance with the provisions of the Act.

6.14 Amendment of import/export permit

An Applicant who wishes to amend particulars such as:

- (a) change in business name;
- (b) change in port of entry/exit; and
- (c) change in address of the permit holder

shall apply to the Authority. The application shall be accompanied by proof of payment of the prescribed fees. The Authority shall inform the applicant within fourteen (14) days of receipt of the application for an amendment.

6.15 Application for duplicate permit

A permit holder may apply to the Authority for issuance of a duplicate permit where the permit is lost, damaged or defaced and shall attach as supporting documentation, proof of payment for the amendment, an affidavit of loss or damage of permit and police report.

6.16 Suspension of import/export permit

The Authority shall issue an intention to suspend a permit where the client fails to obtain clearance, contravenes the terms and conditions of the permit or obtains the permit by fraud or deliberate or negligent submission of information.

During the period of suspension, the permit holder shall quarantine medicines and allied substances affected by the suspension at his/her cost.

**6.17 Revocation of import/export permit**

The Authority shall issue a notice of revocation to a permit holder before revoking it under the following circumstances:

- a) the permit holder breaches or contravenes the provisions of the Act;
- b) following the suspension of a permit, the permit holder fails to take corrective actions;
- c) the products on the permit become known to be dangerous or contain substances dangerous to human health, animal health and the environment;
- d) the permit holder fails to comply with any relevant written law; or
- e) the permit holder is found to have obtained the permit by fraud or deliberate or negligent submission of false information or statements.

— A permit holder is required to surrender the permit to the Authority once it is revoked and must quarantine and dispose of the medicines and allied substances as directed by the Authority.



7. ANNEXURE

SCHEDULE

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

PRESCRIBED FORMS

Form I

Regulation 3(1)

(To be completed in triplicate)



ZAMBIA MEDICINES REGULATORY AUTHORITY

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

The Medicines and Allied Substances (Import and Export) Regulations, 2016

APPLICATION FOR AN IMPORT/EXPORT PERMIT FOR MEDICINES AND ALLIED SUBSTANCES

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

Particulars of the Applicant

1. Full name & physical address of applicant:
.....
.....
.....
.....
2. Pharmaceutical Licence No. (if Applicable)



3. Practitioners' Practising No. (if applicable)
4. Tel or/and mobile:
5. Fax:
6. Email:

Port of Entry/Exit

7. The medicines/allied substances to be imported/exported:-
- by rail to/from.....station
- by road via.....(state Port of entry/exit)
- by parcel post to/from..... (state post office)
- by airfreight to/from.....(state airport)

Reason for importation/exportation

(tick as applicable)

- ☐ Commercial
- ☐ Personal use
- ☐ Donation

Supporting Document

(Please indicate supporting document such as invoice and other relevant documents or additional permits from other regulatory authorities)

No.	Type of Document	Document No.
1		
2		
3		
4		
5		



Details of medicines

Name of Product & Strength	Marketing Authorisation Number	Pack Size	Quantity	Manufacturer (Name & Site)	Supplier

A. 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

1. Name:
2. Designation:
3. Signature: d) Date: .../.../..... (dd/mm/yyyy)

Conditions for an application for import or export permit

Applications must always be made by the actual importer or exporter or their authorised agent;

1. A Proforma Invoice must accompany each application.
2. A separate application is required in respect of each consignment of medicines to be imported or exported.
3. The prescribed fees shall be paid for an import or export permit and must be forwarded with the



application.

*(*delete as appropriate)*

FOR OFFICIAL USE

Date of Submission:
Application number:
Payment Receipt number:
Application Complete (Process Permit)
Application Deficient (Notify applicant on deficiencies)

OFFICIAL
STAMP



Form III (Regulation 4)



The Medicines and Allied Substances Act, 2013
(Act No. 3 of 2013)
The Medicines and Allied Substances (Import and Export) Regulations, 2016
REQUEST FOR ADDITIONAL INFORMATION

PART I: PARTICULARS OF THE APPLICANT

To:

Physical address:

Plot No:

Street:

Postal address:

Province.....

District.....

Application No.:

You are requested to furnish the following information or documents in respect of your application
for

(a)



- (b)
.....
- (c)
.....
- (d)
.....
- (e)
.....

Within days of this notice

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 IV
(Regulations 5 and 8(5))

THE ZAMBIA MEDICINES REGULATORY AUTHORITY

The Medicines and Allied Substances Act, 2013
(Act No. 3 of 2013)The Medicines and Allied Substances
(Import and Export) Regulations, 2016

NOTICE OF REJECTION OF APPLICATION

- (1) Here insert To (1).....
the full
name and
address 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:
- (2) Here insert the reference No. of the application (a)
(b)
(3) Here insert type of application (c)
(d)

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

Director-General



Form V

(Regulation 6)



THE ZAMBIA MEDICINES REGULATORY AUTHORITY

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

The Medicines and Allied Substances
(Import and Export) Regulations, 2016

IMPORT/EXPORT PERMIT

Permit No.:

This is to certify that (Name of permit holder).....

..... of (Physical Address)

.....

..... is authorised to *import/*export the
following products:..

Name of Medicines	Quantity



Port _____ of _____ Entry/Exit: _____

The conditions of the permit are overleaf.

This permit is valid until _____
20.....

.....

Director General

Conditions for Importation and Exportation Permit

1. This permit is not transferable.
2. The permit must be produced together with other approved or endorsed documents to the Zambia Medicines Regulatory Authority Inspector and Customs Officer at the time of importation or exportation.
3. The permit should be surrendered to the Authority upon suspension or revocation.



Form VI
(Regulation 7(2))
(To be completed in triplicate)

**THE ZAMBIA MEDICINES REGULATORY AUTHORITY**

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

The Medicines and Allied Substances
(Import and Export) Regulations, 2016

APPLICATION FOR AMENDMENT OF AN *IMPORT/*EXPORT PERMIT				
Please complete in block letters		Shaded fields for official use only	Permit No.	
			Date and Time	
<i>Information Required</i>		<i>Information Provided</i>		√
PARTICULARS OF APPLICANT				
	Permit No.:			
	CURRENT INFORMATION	DESCRIPTION OF AMENDMENT(S)	REASONS FOR AMENDMENT	
	1.			
	2.			
	3.			
12	Attachments			
	Attach supporting document(s) where applicable			

**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:
.....
Payment Receipt Number:
.....
Application Accepted (Proceed for Inspection):
.....
Application Rejected (Notify applicant on deficiency):
.....
.....
.....

OFFICIAL
STAMP



*Delete as appropriate

Form VII

(Regulation 8)
(To be completed in triplicate)



THE ZAMBIA MEDICINES REGULATORY AUTHORITY

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

**The Medicines and Allied Substances
(Import and Export) Regulations, 2016**

APPLICATION FOR DUPLICATE PERMIT

APPLICATION FOR DUPLICATE PERMIT			
		Application No.	



--

*Delete as appropriate

Form VII

(Regulation 8)

(To be completed in triplicate)



THE ZAMBIA MEDICINES REGULATORY AUTHORITY

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

**The Medicines and Allied Substances
(Import and Export) Regulations, 2016**

APPLICATION FOR DUPLICATE PERMIT			
		Application No.	



--

*Delete as appropriate

Form VII

(Regulation 8)

(To be completed in triplicate)



THE ZAMBIA MEDICINES REGULATORY AUTHORITY

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

**The Medicines and Allied Substances
(Import and Export) Regulations, 2016**

APPLICATION FOR DUPLICATE PERMIT			
		Application No.	



Form VIII

(Regulation 11(3) and 12(3))



THE ZAMBIA MEDICINES REGULATORY AUTHORITY

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

The Medicines and Allied Substances
(Import and Export) Regulations, 2016

NOTICE OF INTENTION TO SUSPEND/REVOKE IMPORT OR EXPORT PERMIT

To (1).....

.....

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

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

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.....

.....



Director-General

OFFICIAL
STAMP

*Delete as appropriate

Form IX

(Regulation 9(5) and 10(4))



THE ZAMBIA MEDICINES REGULATORY AUTHORITY

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

The Medicines and Allied Substances
(Import and Export) Regulations, 2016

**NOTICE OF SUSPENSION OR REVOCATION OF IMPORT AND
EXPORT PERMIT**

(1) Here To
insert the (1).....
full names
and
address of
holder of IN THE MATTER OF (2) you are
Permit notified that your permit has been suspended for a period of
(2) Here (3)...../revoke on the following grounds:
insert the (a)
.....



Permit (b)
No. (c)
(3) Here (d)
insert the
number of
days
stipulated Dated this day of 20.....

.....

Director-General

OFFICIAL
STAMP



Form X
(Regulation 12(1))



THE ZAMBIA MEDICINES REGULATORY AUTHORITY

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

The Medicines and Allied Substances
(Import and Export) Regulations, 2016

REGISTER OF IMPORT AND EXPORT PERMITS

No.	Permit Holder	Permit number	*Import/*Export	Date of issue	Expiry Date
1.					
2.					
3.					
4.					
5.					
6.					
7.					