Medicines Control Authority of Zimbabwe

MCAZ/LED/GL-12

GUIDELINES ON THE IMPORT AND EXPORT OF REGISTERED MEDICINES

EFFECTIVE DATE: 02/2022

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Reviewed by:	Signature	18/02/2022 Date
Checked by HoD/HoU:	Signature	18/02/2022 Date
Approved by QM:	Signature	18/02/2022 Date
Authorised for use by: Director-General	Signature	18/2/2022 Date

1.0 APPLICATION

These guidelines apply to the importation or exportation of all **registered medicines** other than:

1.1 Dangerous Drugs controlled in terms of the Dangerous Drugs Act [*Chapter15*:*02*];

1.2 Psychotropic substances controlled in terms of the Medicines and Allied Substances Control (General) Regulations, 1991;

1.3 Medicines imported for a named person in terms of section 75 of the Medicines and Allied Substances Control Act (MASCA); and

1.4 Medicines imported by an individual for personal use.

2.0 PURPOSE

To provide persons or organizations approved by the Authority, to import and/or export together with the general public with all the necessary information regarding the import and/or export of registered medicines in Zimbabwe.

3.0 BACKGROUND / INTRODUCTION

The Medicines Control Authority of Zimbabwe (MCAZ) is a regulatory body established by the Medicines and Allied Substances Control Act (MASCA) [*Chapter 15:03*] and its Regulations, S.I 150 of 1991. After consultations with the Authority in terms of Section 38 and in terms of Section 74 of the MASCA, the Minister of Health and Child Care made the Medicines and Allied Substances Control (Import and Export of Medicines) Regulations, 2008 [*S.I 57 of 2008*].

In the interest of protecting public health, it is important to put in place measures to prevent the infiltration of counterfeit and illicit products into Zimbabwe's supply system. The handling of medicines within the distribution chain, both locally and internationally, must therefore comply with set standards and be rigorously controlled. Regulation of importation and exportation of pharmaceutical products and enforcing the statutes forms part of the mandate of the MCAZ.

4.0 DEFINITIONS

4.1 **Act:** refers to the Medicines and Allied Substances Control Act [*Chapter 15:03*];

4.2 **Authority:** as defined by the Act refers to the Medicines Control Authority of Zimbabwe;

4.3 **Director-General:** Head of the Authority appointed in terms of section twenty-six of the Act;

4.4 **Medicine:** any substance or mixture of substances which is used, or is manufactured, sold or represented as suitable for use, in the diagnosis, treatment, mitigation or prevention of disease or any abnormal physical or mental state or the symptoms thereof in man or in animals; or restoring, correcting or modifying any physical, mental or organic function in man or in animals.

4.5 **should** and **shall'** are used interchangeably to define a condition that has to be satisfied;

4.6 **VAT:** refers to a Value Added Tax of 15%;

4.7 **ZIMRA:** refers to the Zimbabwe Revenue Authority.

5.0 GUIDELINES

5.1 Application for an Import or Export Permit for Medicines

5.1.1 Importation/exportation of medicines may be done by**:**

5.1.1.1 A holder of a wholesale dealer's permit who has been duly appointed as an authorized importer or exporter by the principal in respect to that medicine;

5.1.1.2 A medical practitioner or veterinary surgeon who holds a dispensing licence;

5.1.1.3 A licensed pharmacy;

5.1.1.4 A licensed manufacturer; and

5.1.1.5 Any person or organisation approved by the Authority

Any pharmacist, veterinary surgeon, dental practitioner or medical practitioner may import into Zimbabwe any medicine only for the purpose of resale to their clientele, and from authorized premises.

5.1.2 Issue of Import/Export Permits

5.1.2.1 Application forms and accompanying documents are submitted to the Authority via the Imports and Exports online application system for registered medicines. The online system can be accessed through the following link: https://onlineservices.mcaz.co.zw/mcazonlineservices/onlineuserlogin and the corresponding user manual to guide in the application process:

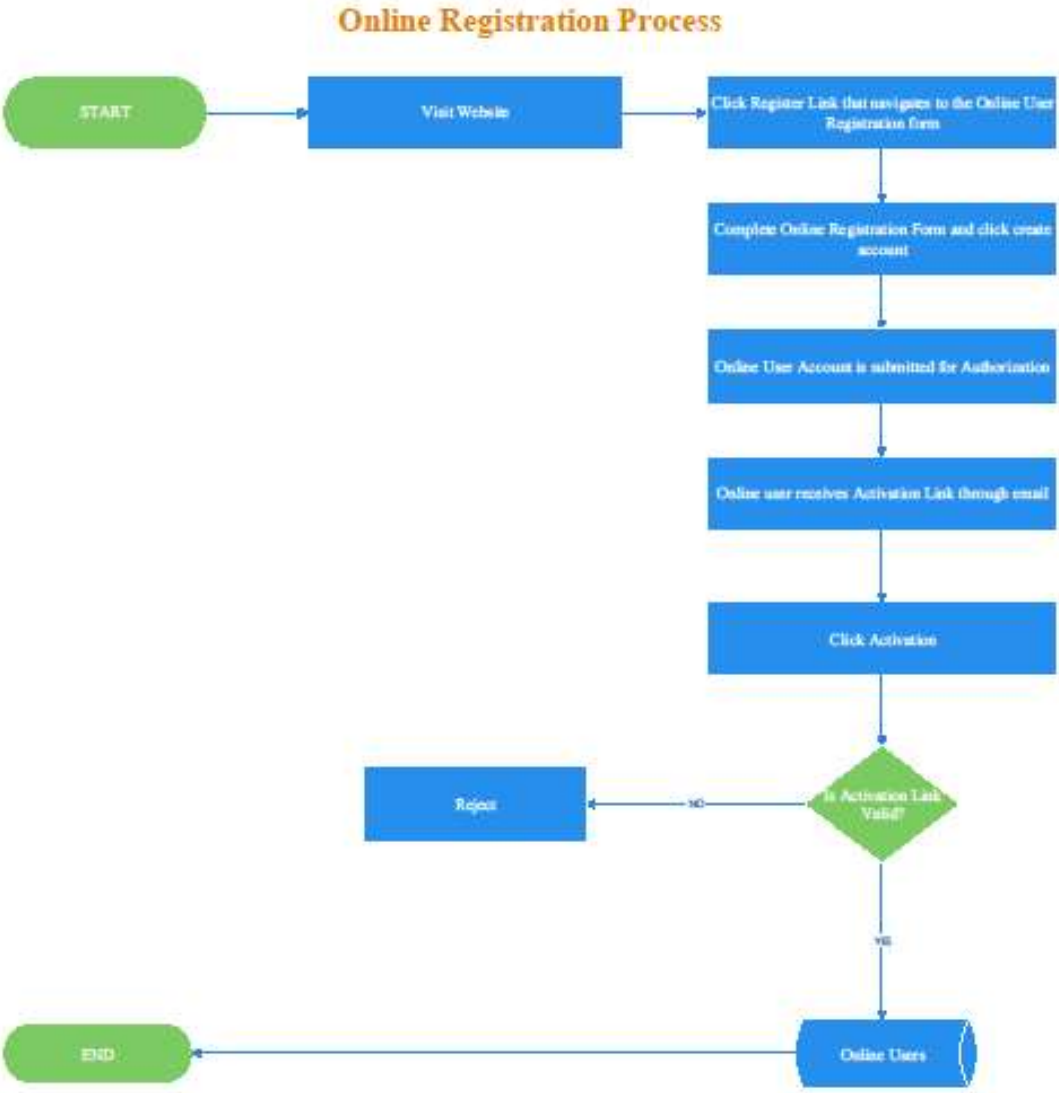
Medicines Control Authority of Zimbabwe

USER MANUAL FOR IMPORT/EXPORT PERMIT APPLICATION OF REGISTERED MEDICINES

The Registered Medicines System is used for applying for importing and exporting registered medicines. This document shows the stages to be followed when applying for an import or export permit.

1. Online Account Registration

To apply for licenses and use the system to track applications and other functions you need to have a user account. The following diagram shows the registration process



5.1.2.2 An application for an import permit shall be made in the Online Form I.E 2 and should be accompanied by:

i. A copy of the pro-forma invoice from the supplier.
ii. Proof of consent by the principal or his duly authorized distributer to import the medicine to which the application relates (for wholesale only).

5.1.2.3 An application for an export permit shall be made in the Online Form I.E 3.

5.1.2.4 All applications shall be accompanied by an application fee as stated in the current fee schedule.

5.1.2.5 Using Online Form I.E.1, a wholesale dealer should provide notification of their appointment as an authorized importer or exporter by the principal that is in respect to the medicine they intent to import or export.

Form I.E 1 shall be accompanied by a letter from the principal stating the products that the applicant is allowed to import or export. This letter should be dated and on a letter head of the principal. The letter and the application shall be submitted and authorized once off online.

5.1.2.6 All applications for an export permit shall include the following details *[Reference: Section 5(2) and Section 5(4) of S.I 57 of 2008]*

5.1.2.7 An application for an import permit shall include the following:

i. the name and address of the importer; and
ii. the trade name or proprietary name of the medicine, if any; and
iii. the International Non-Proprietary Name (INN) or generic name of the medicine; and
iv. its strength; and
v. the total quantity of the medicine; and
vi. name and address of the supplier; and
vii. the name and address of the manufacturer, if not the same as the supplier; and
viii. the Zimbabwean registration number; and
ix. the cost, insurance, freight (CIF) value of the consignment; and
x. The port of entry.

5.1.2.8 An application for the issue of an export permit shall state, for each medicine to be exported—

i. the name and address of the exporter; and
ii. the trade name or proprietary name of the medicine, if any; and
iii. the International Non-Proprietary Name (INN) or generic name of the medicine; and
iv. its strength; and

v. the total quantity of the medicine; and
vi. the name and address of the manufacturer; and
vii. the Zimbabwean registration number; and
viii. the cost, insurance, freight (CIF) value of the consignment; and
ix. The port of entry.

5.1.3 Conditions for Amendment of Permit

5.1.3.1 If an applicant, for justifiable cause, wishes to amend an issued permit, he or she may submit any such request to the Director-General in writing. The letter should state the area(s) the applicant wants amended. This letter should be dated, stamped, signed and with a letter head.

5.1.3.2 The letter of request shall be accompanied by an amendment fee as stated in the current fee schedule.

5.1.3.3 The applicant must also submit the original permit which is to be amended together with the letter of application for amendment.

Note: A used permit, whether exhausted or partially, may not be amended. There are no conditions whatsoever that a permit may be amended if the applicant does not submit the original copy of the import or export permit. If the applicant is unable to declare the original copy, they will be required to reapply for the issuance of another permit.

5.1.4 Validity of Permit

5.1.4.1 Upon successful application, a permit shall be issued in the Form I.E 4 (for imports) and I.E 5 (for exports).

5.1.4.2 Permits shall, in terms of section 9 of *SI 57 of 2008*, be valid for a period of six months from date of issue.

5.1.4.3 A permit is valid if it has the MCAZ seal and Director-General's signature, or designate.

5.2 Clearing of Consignments

5.2.1 Ports of entry

5.2.1.1 The importation of all consignments of medicines should be done through the designated ports of entry, which are:

i. Harare International Airport
ii. Bulawayo Airport
iii. Harare Customs
iv. Bulawayo Customs
v. Plumtree Border Post
vi. Beitbridge Border Post

vii. Forbes Border Post

Note: No importations through ordinary or registered post shall be sanctioned.

5.2.2 Clearing of Imported Consignments

5.2.2.1 On arrival of the consignment, the importer shall notify the Director General of the importation using Form I.E 6 and shall pay a verification fee of 0.05% of the Cost Insurance and Freight value (CIF) before the consignment can be cleared.

To expedite the process of consignment clearance, importers are encouraged to pay the verification fee prior to the arrival of the consignment. No notifications or payments shall be accepted at the port of entry.

5.2.2.2 It remains the responsibility of the applicant to ensure that imported medicines meet the Zimbabwean labelling requirements.

5.2.2.3 If the medicine does not meet the **conditions of labelling** under which it was registered, the importer may;

i. Apply for approval to affix stickers with the product's registration details onto the medicine package as provided for by section 75 of the Act, and

ii. Pay a fee, as stated in the current fee schedule, for every product that needs stickers affixed and present the receipt at the point of physical examination and verification of consignment.

5.2.2.4 For imports via Harare International Airport, consignment verification shall be conducted during week days between 10.30am and 12.30pm.

5.2.3 Verification of consignments that come through Harare Customs, Bulawayo Airport, Bulawayo Customs, Plumtree Border Post and Forbes Border Post:

5.2.3.1 Any such consignments shall be cleared by the Authority within 3 days of receipt of the notification of importation.

5.2.3.2 Port Health officials with the assistance of ZIMRA officials will carry out verification and physical examination at the port.

5.2.3.3 The consignee shall keep the consignment sealed and under quarantine at approved premises, until it has been cleared by the Authority.

5.2.3.4 The consignee and an inspector from the Authority shall organize for physical examination of the consignment, and this shall be done at the consignee's premises.

5.2.3.5 The physical examination of consignments shall be done between 1400hours-1600hours

5.2.3.6 The consignee can only remove medicines from quarantine when the consignment has been cleared by the Authority.

5.2.4 In the case of exportation, upon the successful exportation of medicines, the exporter shall notify the Director General in the Form IE 7 within 30days of exportation.

5.3 RESPONSIBILITIES OF STAKEHOLDERS

5.3.1 The Authority

5.3.1.1 All applications for permits shall be made online to the Director General.

5.3.1.2 The Director-General shall authorise importation or exportation of any pharmaceutical product prior to purchase and shipment of any such consignment.

5.3.1.3 The Director-General shall sign and seal all permits to be issued.

5.3.1.4 The Director-General will appoint Regulatory Officers who shall be responsible for physical examination and clearing consignments of pharmaceutical products at the port of entry.

5.3.1.5 Cleared consignment documents shall be stamped and signed by a regulatory officer appointed to carry out such duties by the Director-General.

5.3.2 Responsibility of the importer/exporter

5.3.2.1 It is the responsibility of the importer or exporter to:

i. Meet all financial obligations relating to applications, clearing or shipping of consignments, and to storage.
ii. Obtain a letter of appointment from the principal in respect to the medicine they want to import or export.
iii. Notify the Director-General online of their appointment by the principal as an importer or exporter.
iv. To ensure that imported medicines meet the Zimbabwean labelling requirements.
v. To apply online for the import or export permit and to timeously submit all documentation to the Authority.
vi. Timeously notify the Authority of importation or exportation of any consignment.

vii. Keep a record of all permits, and all documents required for and relating to the importation or exportation of medicines and avail such records when requested.
viii. Remit any unused permits that have expired to the Authority.
ix. Alert customs officials in advance of the anticipated arrival of consignments in order that they can be transferred to the designated storage facilities without breaking the cold chain.

5.3.3 ZIMRA and Port Health Officials

5.3.3.1 All consignments will be cleared by customs in consultation with the inspectorate of the MCAZ.

5.3.3.2 ZIMRA and Port Health Officials in collaboration with a Regulatory Officer (RO) from the Authority will carry out physical examination of all imported consignments of medicinal products and their documentation.

5.3.3.3 Customs inspectorate shall check that all consignments of medicines are cleared by the MCAZ.

5.3.3.4 Customs shall accord high priority for clearing of pharmaceutical products.

NB: Pharmaceutical products are prone to degrade and some need to be stored under specially controlled temperatures.

5.3.3.5 Port officials shall notify the Authority of confirmed or suspected cases of substandard and falsified products.

5.3.4 Police and Judiciary

5.3.4.1 According to section 14(a) of ***S.I 57 of 2008,*** importing or exporting any medicine without the relevant permit shall be deemed as an offence.

5.3.4.2 According to section 14(b) of ***S.I 57 of 2008*** failure to comply with the conditions for which a permit was issued is an offense.

5.3.4.3 It shall be the responsibility of the judiciary to prosecute and charge those found contravening the provisions of the MASCA and its regulations.

6.0 Import Alerts

6.1 What is an Import Alert?

6.1.1 An Import Alert is MCAZ's way of communicating medicinal product quality, safety or efficacy problems to the public.

6.1.2 As a result of an Import Alert, MCAZ will automatically detain the products at the border.

6.1.3 Import Alerts are issued whenever MCAZ determines that it already has sufficient evidence to conclude that the products appear to be

substandard/falsified, adulterated, misbranded, or unapproved/unregistered, and that therefore they may be refused admission.

6.1.4 Import alerts are also issued whenever port officials from Zimbabwe Revenue Authority (ZIMRA), Port Health officials whenever an importer illegally imports medicines and medical products without approval from MCAZ.

6.2 How is a company/manufacturer/product added to an Import Alert?

6.2.1 Whenever the MCAZ identifies a problem with an imported product or a foreign Manufacturer or whenever an importer illegally imports medicines and medical products without prior approval from MCAZ

6.2.2 The regulatory officer shall prepare a recommendation to include the company and product on an Import Alert list, resulting in MCAZ Detention. Without Physical Examination (DWPE – or "Automatic Detention") for all future shipments of that product or from that company.

6.2.3 The recommendation is then tabled before the Licensing and Advertising Committee for approval. The Licensing and Advertising Committee shall reviews the recommendation, the supporting evidence, and current and past national detention data to determine whether Automatic Detention or DWPE is appropriate.

6.2.4 If the Licensing and Advertising Committee concludes that the recommendation is appropriate, the RO will either add the manufacturer, importer, or product to an existing Import Alert, or create a new one.

6.2.5 The company and product then appears on the Import Alert's "Red List."

6.2.6 The Licensing and Advertising Committee will determine how long the manufacturer, importer or product will appear on the Import Alert's "Red List."

6.2.7 All detained products will be disposed of once the matter has been concluded on a case by case basis and a destruction certificate shall be filed with the Licensing and Enforcement Division in the Medicines Control Authority of Zimbabwe.

6.0 KEY RELEVANT DOCUMENTS

6.1 Application Forms

6.2 Medicines and Allied Substances Control Act (MASCA) [*Chapter 15:03*]

6.3 Medicines and Allied Substances Control Regulations, S.I 150 of 1991

6.4 Medicines and Allied Substances Control (Import and Export of Medicines) Regulations, 2008 [S.I 57 of 2008]

NB: It should be noted that the forms should be filled in correctly, legibly and completely. No section should be left blank.

APPENDIX I: FORM I.E. 1

MEDICINES AND ALLIED SUBSTANCES CONTROL ACT [CHAPTER 15:03]

NOTIFICATION OF APPOINTMENT OF AUTHORIZED IMPORTER/EXPORTER

(To be submitted online)

Notification of the appointment of an authorized importer/ exporter in terms of section 4(3).

It is requested that this form be completed legibly, preferably printed.

1. Name and address of Principal

……

……

……

Tel: …… Fax: …… E-mail ……....

2. Name and address of Authorized Importer/Exporter (* Delete the inapplicable)

……

……

……

Tel……...Fax……...E-mail……...

3. Date of Appointment……...

4. Duration of Appointment……

5. Products authorized to be imported/ exported

……

……

……

……

6. Signed ……

Name ……

Date ……

7. If on behalf of a company, state position in company

…….

Note:

This form must be accompanied by a letter from the principal on its letterhead confirming the appointment of the importer/exporter.

FOR OFFICIAL USE ONLY

APPLICATION APPROVED/REJECTED

IF REJECTED, STATE REASONS

……..……
……
……

RECOMMENDED……..

APPROVED……

PERMIT NO. …….. ISSUED ON …… (DATE)

SIGNED …… DIRECTOR GENERAL

MEDICINES CONTROL AUTHORITY OF ZMBABWE

Guide on Completing Form I.E 1

Section 1

Name and address of principal - This section requires the full particulars of the owners of the medicines and will require the name, address, telephone numbers, email address and or fax.

Section 2

Name and address of Authorized Importer/Exporter- This section require the details of the authorised importer or exporter of the medicine. The authorisation would be in the form of a letter on letter head from the principle and thus the same name and address should appear on this section as well as in the letter.

Section 3

Date of appointment- this will specify the date on which the authorization was effected

Section 4

Duration of appointment- This section will specify the time period with which the authorisation would be valid.

Section 5

Products authorized to be imported/ exported- This section will then give the details of the medicines that have been authorized by the principal to be imported or exported by the applicant.

Section 6

Declaration by the applicant - This is where the applicant would put their name and sign as a declaration that information provided is correct.

Section 7

Position of the person applying on behalf of the company- It would be preferable that application be done by technical personnel

APPENDIX II: FORM I.E. 2

MEDICINES AND ALLIED SUBSTANCES CONTROL ACT [CHAPTER 15:03]

APPLICATION FOR AN IMPORT PERMIT

(To be submitted online)

An application in terms of section 5.

It is requested that this form be completed legibly. Delay will be caused if this form is not completed properly, or if any of the questions below are not answered

NOTE: COPY OF PROFORMA INVOICE AND PROOF OF CONSENT TO IMPORTATION BY PRINCIPAL MUST BE ATTACHED TO THIS APPLICATION

1. Full name and address of importer

.....
.....
.....*Tel:* …… *Fax*…… *E-mail:* ……..

2. Full name and address of importer of supplier in exporting country

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

Tel:…… Fax:…… E-mail
……..

3. The medicines are to be imported:

**** by sea and/or rail via ……***

by road via ……

by air-freight via ……

(* Delete the inapplicable words)

and will be imported through ……. Customs Office. (State port of entry)

4. Approximate date of arrival …….

5. State the purpose for which the medicines are required (e.g. clinical trial, general medical use, etc.)

……..……

6. Particulars of medicines to be imported (If insufficient space provided add additional sheets)

Item No.	*Trade Name of Medicine*	*International Non-Proprietary Name (INN) of medicine*	*Strength*	*Total Quantity*	*Name and Address of Supplier*	*Name and Address of Manufacturer*	*Zimbabwean Registration Number*	*Cost Insurance and Freight (CIF) Value*

7. I, the undersigned, hereby declare that, to the best of my knowledge, all the information provided herein and in the appendices is correct and true.

Signed ……..

Name ……

Date …….

8. If on behalf of a company, state position in company

……..……
……

<u>FOR OFFICIAL USE ONLY</u>

APPLICATION APPROVED/REJECTED

IF REJECTED, STATE REASONS

…….……
……
……..

RECOMMENDED……

APPROVED……

PERMIT NO. …….. ISSUED ON …… (DATE)

SIGNED …… DIRECTOR GENERAL

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

Guide on Completing Form I.E 2

Section 1

Full name and address of importer- This section require the details of the authorised importer of the medicine.

Section 2

Full name and address of supplier in exporting country- This section will require the details of supplier of the medicines which might be the principal or the authorized distributor in the exporting country

Section 3

Medicines will be imported ' by....via'- this is the section where you would be required to specify the mode of transport through which the medicines will be imported as well as the customs office that will clear the medicines (port of entry of the medicines).

Section 4

Approximate date of arrival - the expected date of arrival of the consignment so that arrangements for the verification and clearance of the consignment can be made on time.

Section 5

State the purpose for which the medicines are required- This is where the applicant indicates the intended use of the imported medicine e.g. clinical trial, resale etc

Section 6

Particulars of medicines to be imported-This table should give the full details of the medicines to be imported from the trade name, International Non-Proprietary Name (INN) of medicine, strength, Quantity, Name and Address of Supplier and Manufacturer Zimbabwean registration details and the Cost, insurance and freight value (CIF) The CIF can be reflected once as the total invoice value. This table should be filled in completely and correctly, failure of which will delay the processing of the permit.

Section 7

Declaration by the applicant- This is where the applicant would put their name and sign as a declaration that information provided is correct.

Section 8

Position of the person applying on behalf of the company- It would be preferable that application be done by technical personnel

APPENDIX III: FORM I.E 3

MEDICINES AND ALLIED SUBSTANCES CONTROL ACT [CHAPTER 15:03]

APPLICATION FOR AN EXPORT PERMIT

An application in terms of section 5.

It is requested that this form be completed legibly, preferably printed. Delay will be caused if this form is not completed properly, or if any of the questions below are not answered, or if the declaration is not signed.

1. Full name and address of exporter

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

Telephone …… Fax …… E-mail……....

2. Medicines are to be exported:

****rail via***
……

****by road***
via……

****by air-freight via***
……

(* Delete the inapplicable words)

and will be exported through ……. Customs Office. (State port of entry)

3. Full name and address of person to whom the medicines are to be exported

……
……
……

Telephone ……. Fax ……. E-mail..…… ……

4. Country of importer of the medicines

……

5. Particulars of medicines to be exported (If insufficient space provided add additional sheets)

Item No.	*Trade Name of Medicine*	*International Non-Proprietary Name (INN) of medicine*	*Strength*	*Total Quantity*	*Name and Address of Supplier*	*Name and Address of Manufacturer*	*Zimbabwean Registration Number*	*Cost Insurance and Freight (CIF) Value*

6. Expected date of dispatch

…….....

7. I, the undersigned, hereby declare that, to the best of my belief, all the information provided herein and in the appendices is correct and true.

Signed ……..

Name ……....

Date ……....

8. If on behalf of a company, state position in company

……..…….

<u>FOR OFFICIAL USE ONLY</u>

APPLICATION APPROVED/REJECTED

IF REJECTED, STATE REASONS

……
……
……
……..

RECOMMENDED……

APPROVED……

PERMIT NO. …….. ISSUED ON …… (DATE)

SIGNED ……

DIRECTOR GENERAL

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

Guide on Completing Form I.E 3

Section 1

Full name and address of exporter- This section require the details of the authorised exporter of the medicine.

Section 2

Medicines will be exported by....via- this is the section where you would be required to specify the mode of transport through which the medicines will be exported as well as the customs office that will clear the medicines (port of exit of the medicines).

Section 3

Full name and address of person in importing country- This section will require the details of the person receiving the medicines in the importing country.

Section 4

Country of importer of the medicines- This is the country to which the medicines will be exported to

Section 5

Particulars of medicines to be exported-This table would give the full details of the medicines to be exported from the trade name, International Non-Proprietary Name (INN) of medicine, strength, Quantity, Name and Address of Supplier and Manufacturer Zimbabwean registration details and the Cost, insurance and freight value. This table should be filled in completely and correctly, failure of which will delay the processing of the permit.

Section 6

Approximate date of dispatch- the expected date of dispatch of the consignment so that arrangements can be made to expedite the processing of the permit.

Section 7

Declaration by the applicant- This is where the applicant would put their name and sign as a declaration that information provided is correct.

Section 8

Position of the person applying on behalf of the company- It would be preferable that application be done by technical personnel

APPENDIX IV: FORM I.E. 6

MEDICINES AND ALLIED SUBSTANCES CONTROL ACT [CHAPTER 15:03]
NOTIFICATION OF IMPORT

Notification of the receipt of imported consignment of medicines in terms of section 11

It is requested that this form be completed legibly, preferably printed.

NOTIFICATION OF IMPORTATION

Medicines Control Authority of Zimbabwe

P O Box 10559

Harare

It is hereby certified that the following medicines:

.....

.....

.....

.....

(Add additional sheets of paper if necessary)

have been imported on Import Licence Number: …… dated ……..

Date of importation: ….....

Full name: .....

Signature: …….....

Date: .....

State position in company ……....

On behalf of: .....

(Name of company)

7.0 HISTORY

DOCUMENT HISTORY		
Revision Number	Date Approved	Reason for Change and Amendments
Rev 0	September 2017	**Date Reviewed**: February 2020 **Reason for change and amendments** Rolling review and Continuous Improvement aligning the guideline to the requirements of the new template. The following changes were done from **Revision 0** to **Revision 1** **Description of Changes** **1.0 Changed from** **1.0 Introduction** The Medicines Control Authority of Zimbabwe (MCAZ) is a regulatory body established by the Medicines and Allied Substances Control Act (MASCA) [*Chapter 15:03*] and its Regulations, S.I 150 of 1991. After consultations with the Authority in terms of Section 38 and in terms of Section 74 of the MASCA, the Minister of Health and Child Care published the Medicines and Allied Substances Control (Import and Export of Medicines) Regulations, 2008 [*S.I 57 of 2008*]. These guidelines were drafted with particular reference to the Medicines and Allied Substances Control (Import and Export of Medicines) Regulations, S.I 57 of 2008. These guidelines seek to explain the processes involved in applying for an import or export permit for registered medicines and the clearance of imported medicine consignments at the ports of entry. The guidelines also define the responsibilities of the stakeholders involved in the importation and exportation of registered medicines. **To** **3.0 BACKGROUND / INTRODUCTION** The Medicines Control Authority of Zimbabwe (MCAZ) is a regulatory body established by the Medicines and Allied Substances Control Act (MASCA) [*Chapter 15:03*] and its

		Regulations, S.I 150 of 1991. After consultations with the Authority in terms of Section 38 and in terms of Section 74 of the MASCA, the Minister of Health and Child Care made the Medicines and Allied Substances Control (Import and Export of Medicines) Regulations, 2008 [*S.I 57 of 2008*]. In the interest of protecting public health, it is important to put in place measures to prevent the infiltration of counterfeit and illicit products into Zimbabwe's supply system. The handling of medicines within the distribution chain, both locally and internationally, must therefore comply with set standards and be rigorously controlled. Regulation of importation and exportation of pharmaceutical products and enforcing the statutes forms part of the mandate of the MCAZ. **1.2 Changed from** **<u>1.2 Interpretation</u>** **To** **4.0 DEFINITIONS** **2.0 Changed from** **2.0 SCOPE** These guidelines are meant to: 2.1 Outline the responsibilities of the stakeholders involved in the import and export of medicines. 2.2 Identify the persons who can import or export medicines into or out of Zimbabwe. 2.3 State the ports through which medicines can be imported into Zimbabwe. 2.4 Define the minimum requirements for a complete application for a medicine import or export permit. 2.5 Explain the criterion for submitting an application for an import or export permit for medicines. 2.6 Outline the process of consignment verification and clearance. **To** **2.0 PURPOSE** To provide persons or organizations approved by the Authority, to import and/or export together with the general public with all

		the necessary information regarding the import and/or export of registered medicines in Zimbabwe. **3.0 Changed from** **3.0 APPLICATION** **To:** **1.0 APPLICATION** **4.0 Changed From** **4.0 APPLICATION FOR AN IMPORT OR EXPORT PERMIT FOR MEDICINES** **To** **5.1 APPLICATION FOR AN IMPORT OR EXPORT PERMIT FOR MEDICINES** **4.2.1 Changed from** 4.2.1: Issue of Import/Export Permits **To** 5.1.2.1: Issue of Import/Export Permits **ADDED:** **User manual for Import/Export permit applications of registered medicines.** Sections 4.2.2-4.2.6 **Changed to** Sections 5.1.2.2-5.1.2.6 Sections **4**.2.6.1-4.2.6.2 **Changed to** Sections 5.1.2.7-5.1.2.8 Sections 43.-4.4 **Changed to** Sections 5.1.3-5.14 Section 5.0 **Changed to** Sections 5.2.4 Sections 5.2.4 **Changed to** Section 5.2.3 **DELETED SECTION 5..2.5** 5.2.5 A Regulatory Officer stationed at Beitbridge Border Post shall carry out consignment verification and clearance.

		Section 6.0 **Changed to** Sections 5.3 6.3 **Changed from** **6.3 ZIMRA** **To** **5.3.3 ZIMRA and Port Health Officials** Section 6.4 **Changed to** Section 5.3.4 **ADDED** **6.0 Import Alerts** **6.1 What is an Import alert** **6.1.1** An Import Alert is MCAZ's way of communicating medicinal product quality, safety or efficacy problems to the public. **6.1.2** As a result of an Import Alert, MCAZ will automatically detain the products at the border. **6.1.3** Import Alerts are issued whenever MCAZ determines that it already has sufficient evidence to conclude that the products appear to be substandard/falsified, adulterated, misbranded, or unapproved/unregistered, and that therefore they may be refused admission. 6.1.4 Import alerts are also issued whenever port officials from Zimbabwe Revenue Authority (ZIMRA), Port Health officials whenever an importer illegally imports medicines and medical products without approval from MCAZ. **6.2 How is a company/manufacturer/product added to an Import Alert?** **6.2.1** Whenever the MCAZ identifies a problem with an imported product or a foreign Manufacturer or whenever an importer illegally imports medicines and medical products without prior approval from MCAZ **6.2.2** The regulatory officer shall prepare a recommendation to include the company and product on an Import Alert list, resulting in MCAZ Detention Without Physical Examination (DWPE – or "Automatic Detention") for all future shipments of that product or from that company. **6.2.3** The recommendation is then tabled before the Licensing and Advertising Committee for approval. The Licensing and Advertising Committee shall reviews the recommendation, the supporting evidence, and current and past national detention data

		to determine whether Automatic Detention or DWPE is appropriate. **6.2.4** If the Licensing and Advertising Committee concludes that the recommendation is appropriate, the RO will either add the manufacturer, importer, or product to an existing Import Alert, or create a new one. **6.2.5** The company and product then appears on the Import Alert's "Red List." 6.2.6 The Licensing and Advertising Committee will determine how long the manufacturer, importer or product will appear on the Import Alert's "Red List." 6.2.7 All detained products will be disposed of once the matter has been concluded on a case by case basis and a destruction certificate shall be filed with the Licensing and Enforcement Division in the Medicines Control Authority of Zimbabwe. Annexure 1 **Changed from** **Annexure 1: Application Forms** **To** **6.0 KEY RELEVANT DOCUMENTS** **Added:** **6.1** Application Forms **6.3** Medicines and Allied Substances Control Regulations, S.I 150 of 1991 **6.4** Medicines and Allied Substances Control (Import and Export of Medicines) Regulations, 2008 [S.I 57 of 2008] **APPENDIX I** **APPENDIX II** **APPENDIX III** **APPENDIX IV**