Statutory Instrument 57 of 2008.

[CAP. 15:03

Medicines and Allied Substances Control (Import and Export of Medicines) Regulations, 2008

ARRANGEMENT OF SECTIONS

Section

IT is hereby notified that the Minister of Health and Child Welfare has, in terms of section 74 and after consultation with the Authority in terms of section 38, of the Medicines and Allied Substances Control Act [*Chapter 15:03*], made the following regulations:—

Title

1. (1) These regulations may be cited as the Medicines and Allied Substances Control (Import and Export of Medicines) Regulations, 2008.

(2) These regulations shall come into operation on the 1st of July, 2008.

Interpretation

2. In these regulations—

"authorized person" means—

(a) a person who holds a wholesale dealer's permit issued in terms of the Medicines and Allied Substances Control (General) Regulations, 1991 and is authorized by a principal to import that principal's medicines; or

(b) a pharmacy which holds a licence issued in terms of the Act; or

(c) a person who is a medical practitioner or veterinary surgeon who holds a dispensing licence issued in terms of the Act; or

(d) a person who holds a manufacturer's licence issued in terms of the Act; or

(e) any person or organisation approved as such by the Authority;

"form" means the appropriate form set out in the First Schedule;

"port of entry" means any place designated as such in terms of section 13;

"principal" means the person who owns the medicine.

Application

3. These regulations shall apply to all medicines other than—

(a) those controlled in terms of the Dangerous Drugs Act [*Chapter 15:02*]; and

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

(c) medicines imported in terms of section 75 of the Act for a named person; and

(d) medicines imported by an individual for personal use.

Control of imports and exports

4.(1) Subject to section 13, no person shall import into or export from Zimbabwe any registered medicine otherwise than in accordance with the terms and conditions of a permit issued by the Authority.

(2) No person shall import into or export from Zimbabwe any registered medicine, for the purpose of wholesale dealing, unless he is duly appointed as an authorized importer or exporter by the principal in respect of that medicine.

(3) Notification of appointment of any person as an authorized importer or exporter in terms of subsection (2) shall be made to the Director-General in Form I.E.1.

(4) Any pharmacist, veterinary surgeon, dental practitioner or medical practitioner may import into Zimbabwe any medicine for no other purpose except for resale, from authorized premises, to his or her customers, patients, or clientele, as the case may be.

Application for the issue of import or export permit

5.(1) An application for the issue of a permit shall be made to the Director-General—

(a) in the case of an application for an import permit, in Form I.E.2 and shall be accompanied by the fee prescribed in the Second Schedule;

(b) in the case of an application for an export permit, in Form I.E.3 and shall be accompanied by the fee prescribed in the Second Schedule.

(2) An application for the issue of an import permit shall state, for each medicine to be imported—

(a) the name and address of the importer; and

(b) the trade name or proprietary name of the medicine, if any; and

(c) the International Non-Proprietary Name (INN) or generic name of the medicine; and

(d) its strength; and

(e) the total quantity of the medicine; and

(f) name and address of the supplier; and

(g) the name and address of the manufacturer, if not the same as the supplier; and

(h) the Zimbabwean registration number; and

(i) the cost, insurance, freight (CIF) value of the consignment; and

(j) the port of entry.

(3) Every application for an import permit shall be accompanied by a copy of the proforma invoice and proof of consent by the principal or his or duly authorized importer to import the medicine to which the application relates.

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

(a) the name and address of the exporter; and

(b) the trade name or proprietary name of the medicine, if any; and

(c) the International Non-Proprietary Name (INN) or generic name of the medicine; and

(d) its strength; and

(e) the total quantity of the medicine; and

(f) the name and address of the manufacturer; and

(g) the Zimbabwean registration number; and

(h) the cost, insurance, freight (CIF) value of the consignment; and

(i) the port of entry.

(5) The fees specified in the Second Schedule shall not be payable by any person or organisation that has been exempted, in writing, by the Authority.

Issue of permit

6. The Director-General may issue an import or export permit to any authorised person who makes application in terms of section 5 and in issuing such permit the Director-General may impose such conditions as he or she may consider necessary or desirable.

Refusal of permit by Director-General

7.(1) The Director-General may refuse to grant a permit to any person who makes an application in terms of section 5.

(2) Where the Director-General intends to refuse to issue a permit in accordance with subsection (1), he or she shall inform the applicant in writing of his or her intention and the reasons thereof and request the applicant to submit to him or her, within seven days, any representations he or she may wish to make on the matter.

(3) If—

(a) no representations are submitted in terms of subsection (2); or

(b) after considering any representations submitted in terms of subsection (2), the Director-General is of the opinion that a permit should not be issued, he or she shall notify the applicant of his or her refusal to issue the permit.

Form of permit

8. A permit issued in respect of—

(a) an application to import medicines shall be in Form I.E. 4;

(b) an application to export medicines shall be in Form I.E. 5.

Duration of permit

9. Any permit, which is issued for the import or export of medicines, shall be valid for a period of six months from the date of issue:

Provided that such permit may be extended for a further period of not more than six months.

Consignment verification

10. Every person who is issued with an import permit in terms of section 6 shall, on the importation of such medicine pay a consignment clearance fee prescribed in the Second Schedule.

Variation, amendment and cancellation of permits

11.(1) The Director-General may at any time—

(a) amend or vary the conditions of; or

(b) revoke;

any permit issued in terms of section 6 as he or she deems fit:

Provided that the Director-General, before taking any action in terms of subsection (1), shall notify the permit holder, in writing.

(2) The provisions of section 7 shall, with the necessary changes apply to the procedure to be followed thereafter.

Provisions applicable to import and export of medicines

12. In addition to such terms and conditions as may be fixed in a permit to import or export any medicine, the importer or the exporter of any medicine shall comply with the following conditions—

(a) no import or export of any medicine shall be done through ordinary or registered post; and

(b) the importer or exporter of any medicine shall notify the Authority, within 30 days of the import or export of any medicine by him or her and the notification shall be made in Form I.E. 7.

Ports of entry

13.(1) For the purposes of these regulations, the following places are designed as ports of entry—

(a) Bulawayo Airport;

(b) Harare Airport;

(c) Beitbridge;

(d) Bulawayo;

(e) Harare; and

(f) Plumtree.

(2) No person shall import any medicine except through the port of entry listed in terms of subsection (1).

Offences and penalties

14. Any person who—

(a) imports or exports any medicine without a permit issued in terms of section 6; or

(b) fails to comply with the conditions of a permit issued to him or her;

shall be guilty of an offence and liable to a fine not exceeding level seven or to imprisonment for a period not exceeding six months or to both such fine and such imprisonment.

FIRST SCHEDULE (*Section 2*)

FORMS

FORM I.E. 1

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

NOTIFICATION OF APPOINTMENT OF AUTHORIZED IMPORTER/EXPORTER

(To be submitted in duplicate)

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 ZIMBABWE

FORM I.E. 2

MEDICINES AND ALLIED SUBSTANCES CONTROL ACT *[CHAPTER 15:03]*
APPLICATION FOR AN IMPORT PERMIT

(To be submitted in duplicate)

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.

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
……..……
……..…….
.

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 ZIMBABWE

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

……..…….

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 ZIMBABWE

FORM I.E. 4

PERMIT NO……..

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

PERMIT TO IMPORT MEDICINES

(Issued in terms of section 8(a))

1. Name of Importer

……

2. Address …….....

3. Telephone ……Fax …….E-mail ……

4. Particulars of medicines to be imported.

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**

5. Port of Entry

……

6. Period of validity of permit

……

7. Expected date of arrival of medicines…….…….

8. Date of issue of permit …….

……
…
DIRECTOR-GENERAL
MEDICINES CONTROL AUTHORITY OF ZIMBABWE

FORM I.E. 5

PERMIT NO……..

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

PERMIT TO EXPORT MEDICINES

(Issued in terms of section 8(b))

1. Name of Exporter ……..
2. Address …….....
3. Telephone ……Fax. ……E-mail ……..
4. Particulars of medicines to be exported.

Item No.	**Trade Name of Medicine**	**International Non-Proprietary Name (INN) of medicine**	**Strength**	**Total Quantity**	**Name and Address of Importer**	**Name and Address of Manufacturer**	**Zimbabwean Registration Number**

5. Port of Entry

……

6. Period of validity of permit

……

7. Name and address of the importer …….

   ……

8. Country of importer ……

9. The medicine will be exported through the Customs Office at

……...

10. Port of Entry in importing country……..
11. Expected date of arrival in importing country

……

12. Date of issue of permit

……

……
…
DIRECTOR-GENERAL
MEDICINES CONTROL AUTHORITY OF ZIMBABWE

FORM I.E. 6

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

(To be submitted in duplicate)

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*)

FORM I.E. 7

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

(To be submitted in duplicate)

Notification of the dispatch of exported consignment of medicines in terms of section 11

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

NOTIFICATION OF EXPORTATION

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 exported on Export Licence Number: …… dated ……

Date of exportation: .....……

Full name: ..... Signature: .....

Date: .....

State position in company
……

On behalf of: .....

(*Name of company*)

SECOND SCHEDULE (*Section 5,10*)

FEES

		$
1.	Application for an import permit for each product	10 000 000.00
2.	Application for an export permit for each product	10 000 000.00
3.	For the clearance of any consignment	1% of value of the consignment