

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

IT is hereby notified that 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 and Commencement

1. (1) These regulations may be cited as the Medicines and Allied Substances Control (Import and Export of Precursors and Certain Chemical Substances) Regulations, 2008.
- (2) These regulations shall come into operation on the 1st of July, 2008.

Interpretation

2. In these regulations—
 - “competent authority” means the national regulatory authority tasked with the registration and control of medicines in the exporting or importing or importing country or State;
 - “form” means the appropriate form set out in the First Schedule;
 - “precursors” means substances that, without being drugs themselves, are used in various ways in the processing or manufacturing of narcotic drugs or psychotropic substances;
 - “substance” means precursors and certain chemical substances specified in the Second Schedule in accordance with the United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988.

Import and Export of certain substances

3.(1) No person shall import or export a substance listed in the Second Schedule without an import or export permit granted by the Authority.

(2) Any person who wishes to import or export a substance listed in the Second Schedule shall submit an application to the Director-General in Form P.C.S 1 and such application shall be accompanied by the appropriate fee prescribed in the Schedule.

- (3) An import or export permit referred to in subsection (1) shall state—
 - (a) the name and address of the importer and the exporter;
 - (b) the name and address of the consignee, if any;
 - (c) the name of the substance listed in the Second Schedule;
 - (d) the quantity of the substance to be imported or exported;
 - (e) the expected port of exit from the exporting country or Zimbabwe;

- (f) the expected port of entry into Zimbabwe or the importing country;
- (g) the expected date of dispatch or arrival;
- (h) any other details as may be required by the exporting or importing country.

(4) An import or export permit granted in terms of these regulations shall be in Form P.C.S2.

(5) Any permit for the import or export of any substance listed in the Second Schedule shall be valid for a period of six months:

Provided that an import or export permit may be extended for a period not exceeding four months upon payment of the fee prescribed in the Third Schedule.

(6) Where the Authority grants the issue of an export permit, the Director General shall send a copy of such permit to the competent authority of the importing country prior to the intended exportation.

(7) Any person who imports or exports a substance listed in the Second Schedule shall—

- (a) state on every invoice, cargo manifest or similar document—
 - (i) the name and address of the importer and exporter;
 - (ii) the name and address of the consignee, if any;
 - (iii) the quantity of the substance to be imported or exported, as the case may be;
- (b) keep the invoice, cargo manifest or similar document for a period of five years for record purposes.

(8) Any person who imports or exports any substance shall, within thirty days of the import or export of such substance, notify the Authority in Form P.C.S 3 of such import or export.

(9) No person shall import or export any substance by ordinary or registered post.

Record keeping of substances

4. Any person who is authorised to import a substance listed in the Second Schedule shall keep a record in Form P.C.S. 4—

- (a) of the quantity of any substance acquired or supplied by him or her;
- (b) the date of the transaction;
- (c) the name and address of the supplier; and
- (d) the person to whom the substance is supplied.

Returns to the Authority

5. Any person who imports or exports a substance listed in the Second Schedule shall, before the 31st March in each year, submit a return to the Authority stating the amounts so imported or exported from January to December in the preceding year.

Consignment verification fee

6. Any person who is issued with an import permit in terms of section 3 shall, on the importation of such substance pay a consignment verification fee prescribed in the Third Schedule.

Offences and Penalties

7. Any person who—
- (a) imports or exports a precursor or any other substance without a permit;
 - (b) fails to comply with the conditions of a permit; or
 - (c) for purposes of obtaining a permit, makes a declaration or statement which is false;
- 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 3*)

FORMS

Form P.C.S 1

**MEDICINES AND ALLIED SUBSTANCES CONTROL ACT [CHAPTER 15:03]
APPLICATION FOR AUTHORISATION TO IMPORT OR EXPORT* SECOND
SCHEDULE SUBSTANCES**

(To be submitted in duplicate)

This form must be completed legibly. 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.

<p>1. Importer/Exporter* (name and address):</p> <p>Licence or registration number:</p>	<p>2. Authorisation Number:</p> <p>Date of issue:</p> <p>Place of issue:</p>
<p>4. Exporter/Importer* in the country of origin (name and address):</p> <p>Licence or registration number:</p>	<p>3. Date of entry/dispatch* envisaged:</p> <p>5. Issuing authority (name, address, telephone and facsimile numbers and e-mail address):</p>
<p>6. Other operator/agent* (name and address):</p>	<p>7. Customs office where import authorisation/export declaration* will be lodged (name and address):</p>

8. Ultimate consignee (name and address):	9. Port of entry into importing country / Port of exit from exporting country*:	10. Means of transport:
	11. Port of exit from exporting country / Port of entry into importing country*:	12. Itinerary:
13a: Full chemical name of substance to be imported/exported*: Number of units. Weight/volume of each unit.	14a: HS number:	
	15a: CAS number:	
	16a: Net weight:	
	17a: % of mixture	
	18a: Invoice number:	
13b: Full chemical name of substance to be imported/exported*: Number of units: Weight/volume of each unit:	14b: HS number:	
	15b: CAS number:	
	16b: Net weight	
	17b: % of mixture:	
	18b: Invoice number:	
19: Declaration by applicant (See Note 11) Name: Representing: Signature:Date.....	20. (For completion by Customs Authority where import or export* authorisation is lodged) Number of customs Import or export* authorisation: Stamp <div style="border: 1px solid black; width: 200px; height: 50px; margin-left: 100px;"></div>	

<p>21. (For completion by issuing authority)</p> <p>Box 18 information still required Yes/No</p> <p>Box 9, 10, 11, 12 information still required Yes/No</p> <p>Signature:.....</p> <p>Function:.....</p> <p>Date</p> <p>Stamp <input data-bbox="323 790 743 920" type="text"/></p>	<p>22. CONFIRMATION OF ENTRY INTO IMPORTING COUNTRY/ EXIT FROM EXPORTING COUNTRY*:</p> <p>(For completion by Customs Authority at the point of entry)</p> <p>Date of entry.....</p> <p>Signature of officer.....</p> <p>Function.....</p> <p>Date</p> <p>Stamp <input data-bbox="871 790 1291 920" type="text"/></p>
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* Delete the inapplicable.

(Overleaf)

NOTES ON IMPORT / EXPORT AUTHORIZATION

Boxes 1, 3, 4 and 6 to 19 are to be completed by the applicant at the time of the request; however, such information as required in boxes 9 to 12 and 18 may be supplied at a later stage, if the information is not known at the time of the request. In this case, the information for box 18 is to be supplemented at the latest when the import declaration is lodged and the supplementary information for boxes 9 to 12 is to be given to the customs or other authority at the point of entry into the importing country or point of exit from the exporting country at the latest before the physical entry of the chemicals.

Boxes 1, 4, 6 and 8: Enter full names, address, and if available telephone and telefacsimile (fax) numbers as well as trading name, email address.

Import:

Box 4: In country of origin or last port of call, provide licence or registration number of the exporter if applicable.

Export:

Box 4: Not necessarily the ultimate destination. Provide licence or registration number of the importer if applicable.

Box 6: Enter full name, address, and if available telephone and telefacsimile (fax) numbers, of any other operator involved in the import/export operation such as transporter, broker, customs agent.

Box 8: Enter full name, address, and if available telephone and telefacsimile (fax) numbers, electronic address of the person or company to which the chemicals are delivered in the country of destination (not necessarily the end-user.)

Boxes 9 and 10: Give the envisaged name of the port, airport or border point as appropriate

Box 11: Specify all envisaged means of transport to be used (e.g. lorry, ship, plane, train, etc.)

Box 12: Give as full details as possible of the envisaged route to be taken

Box 13, 14 and 15: Enter name of substance, HS and CAS numbers

Boxes 13a, b: Identify packages and substances with precision (e.g. 2 cans of 5 litres each). In the case of mixtures, indicate commercial name and quantitative data concerned. Also indicate the number of units and weight/volume of each unit

Box 19:

Indicate in block letters the name of the applicant, or where appropriate, of his authorised representative who signs this application

The signature by the applicant or his authorised representative shall indicate that the person concerned is declaring that all the particulars provided on the application are correctly and fully stated. Without prejudice to the possible application of penal provision, this declaration shall be equivalent to the engagement of responsibility, under the provisions in force in the importing country, in respect of:

- the accuracy of the information*
- the authenticity of any documents attached, and*

Whenever the authorisation is issued by means of a computerized procedure, that authorisation may not contain signature of the applicant in this box, if the application as such contains such signature.

BACKGROUND INFORMATION

The questions below are intended to assist the Licensing Authority to deal expeditiously with this application. Failure to provide full answers may lead to a delay in the issue of the authorisation.

Information about transaction:

1. Is the import/export for the purpose of re-export?

YES/NO

If so, please provide details:

.....

2. Has your company been authorised previously by the Authority to import/export the substance(s)?

YES/NO

If so, please provide reference and date.

.....

3. Is the ultimate consignee a new customer for this substance?

YES/NO

If so, what is the nature of the customer's business?

.....

To what use will the substance be put?

.....

4. Was the order made directly or through a broker?

YES/NO

If through a broker, please provide name and address.

.....

5. What is the means of payment of the transaction?

.....

6. Please give details of customer's instructions for packaging and labelling of consignment:

.....

7. Will the shipment transit a free trade zone, free port or bonded warehouse? YES/NO

If so please provide details:

.....

Declaration by applicant

I, the undersigned, hereby declare that, to the best of my knowledge and belief, all the information provided in this application and in the appendices is complete, correct and true.

Signature:

Full name:

Position in company:

Date:

FOR OFFICIAL USE ONLY

APPLICATION APPROVED/REJECTED

IF REJECTED, STATE REASONS

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

RECOMMENDED




APPROVED

AUTHORISATION NO. ISSUED ON (DATE)

SIGNED **DIRECTOR-GENERAL.**

MEDICINES AND ALLIED SUBSTANCES CONTROL ACT [CHAPTER 15:03]**AUTHORIZATION TO IMPORT / EXPORT* SECOND SCHEDULE SUBSTANCES**

1. Importer/Exporter* (name and address): Licence or registration number:	2. Authorisation Number: Date of issue :..... Place of issue:	
	3. Date of entry/dispatch* envisaged:	
4. Exporter/Importer* in the country of origin (name and address): Licence or registration number:	5. Issuing authority (name, address, telephone, facsimile numbers and e-mail address):	
6. Other operator/agent* (name and address):	7. Customs office where import authorisation/export declaration* will be lodged (name and address):	
8. Ultimate consignee (name and address):	9. Port of entry into importing country / Port of exit from exporting country*:	10. Means of transport:
	11. Port of exit from exporting country / Port of entry into importing country*:	12. Itinerary:
13a: Full chemical name of substance to be imported/exported*:	14a: HS number:	
	15a: CAS number:	
	16a: Net weight:	
	17a: % of mixture	

Number of units. Weight/volume of each unit.		18a: Invoice number:
13b: Full chemical name of substance to be imported/exported*: Number of units: Weight/volume of each unit:		14b: HS number:
		15b: CAS number:
		16b: Net weight
		17b: % of mixture:
		18b: Invoice number:
19: Declaration by applicant (See Note 11) Name : Representing: Signature:Date	20. (For completion by Customs Authority where import or export* authorisation is lodged) Number of customs Import/export* authorisation: Stamp 	
21. (For completion by issuing authority) Box 18 information still required Yes/No Box 9, 10, 11, 12 information still required Yes/No Signature: Function: Date Stamp 	22. CONFIRMATION OF ENTRY INTO IMPORTING COUNTRY/ EXIT FROM EXPORTING COUNTRY*: (For completion by Customs Authority at the point of entry) Date of entry..... Signature of officer..... Function Date Stamp 	

* Delete the inapplicable

(Overleaf)

NOTES ON IMPORT / EXPORT AUTHORIZATION

Boxes 1, 3, 4 and 6 to 19 are to be completed by the applicant at the time of the request; however, such information as required in boxes 9 to 12 and 18 may be supplied at a later stage, if the information is not known at the time of the request. In this case, the information for box 18 is to be supplemented at the latest when the import declaration is lodged and the supplementary information for boxes 9 to 12 is to be given to the customs or other authority at the point of entry into the importing country / point of exit from the exporting country at the latest before the physical entry of the substances.

Boxes 1, 4, 6 and 8: Enter full names, address, and if available telephone and telefacsimile (fax) numbers as well as trading names, email address.

Import:

Box 4: In country of origin or last port of call, provide licence or registration number of the exporter if applicable.

Export:

Box 4: Not necessarily the ultimate destination. Provide licence or registration number of the importer if applicable.

Box 6: Enter full name, address, and if available telephone and telefacsimile (fax) numbers, email address of any other operator involved in the import/export operation such as transporter, broker, customs agent.

Box 8: Enter full name, address, and if available telephone and telefacsimile (fax) numbers, email address of the person or company to which the chemicals are delivered in the country of destination (not necessarily the end-user).

Boxes 9 and 10: Give the envisaged name of the port, airport or border point as appropriate.

Box 11: Specify all envisaged means of transport to be used (e.g. lorry, ship, plane, train, etc).

Box 12: Give as full details as possible of the envisaged route to be taken.

Box 13, 14 and 15: Enter name of substance, HS and CAS numbers.

Boxes 13a, b: Identify packages and substances with precision (e.g. 2 cans of 5 litres each)

In the case of mixtures; indicate commercial name and quantitative data concerned.

Also indicate the number of units and weight/volume of each unit.

Box 19:

Indicate in block letters the name of the applicant, or where appropriate, of his authorised representative who signs this application

The signature by the applicant or his authorised representative shall indicate that the person concerned is declaring that all the particulars provided on the application are correctly and fully stated. Without prejudice to the possible application of any penal provisions, this declaration shall be equivalent to the engagement of responsibility, under the provisions in force in the importing country, in respect of:

- *the accuracy of the information*
- *the authenticity of any documents attached, and*

Whenever the authorisation is issued by means of a computerized procedure, that authorisation may not contain signature of the applicant in this box, if the application as such contains such signature.

Form P.C.S 3

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

NOTIFICATION OF IMPORT / EXPORT* OF SECOND SCHEDULE SUBSTANCES

(To be submitted in duplicate)

Notification of the receipt of imported consignment / dispatch of exported consignment of Second Schedule substances.

This form must be completed legibly.

NOTIFICATION OF IMPORTATION OR EXPORTATION

Medicines Control Authority of Zimbabwe

P O Box 10559

Harare

It is hereby certified that the following substances:

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

(add additional sheets of paper if necessary)

have been imported/exported* on Import/Export* Authorisation Number:-

..... dated

Date of importation/exportation* :

Declaration by applicant

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

Date:

Full name:

Signature: Date:

On behalf of

(Name of company)

** Delete the inapplicable.*

Form P.C.S 4

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

RECORD OF SUBSTANCES IMPORTED AND THEIR DISPOSAL

PRECURSORS AND CERTAIN CHEMICAL SUBSTANCES TRANSACTIONS

	Closing Balance		→	→		
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SECOND SCHEDULE (*Section 3*)

PRECURSORS AND CERTAIN CHEMICAL SUBSTANCES

TABLE I

N-Acetylanthranilic acid (2);
 Acetic anhydride;
 Ephedrine;
 Ergometrine;
 Ergotamine;
 Isosafrole (2);
 Lysergic acid;
 3,4 Methylendioxyphenyl-2-propanone (2);
 Norephedrine;
 1-Phenyl-2-propanone;
 Piperonal;
 Potassium permanganate (2);
 Pseudoephedrine;
 Safrole (2).

TABLE II

Acetone;
 Anthranilic acid;
 Ethyl ether;
 Hydrochloric Acid (1) (2);
 Methyl ethyl ketone (2);
 Phenylacetic acid;
 Piperidine;
 Sulphuric acid (1) (2);
 Toluene (2).

The salts of the substances listed in the Tables above whenever the existence of such salts is possible.

The salts of hydrochloric acid and sulphuric acid are specifically excluded from Table II.

Included by decision of the Commissioner on Narcotic Drugs on 9th April, 1992, and becoming effective on 23rd November, 1992.

THIRD SCHEDULE (*Section 5,6,7*)

FEES

<i>Item</i>	\$
1. Application for a permit to import or export a substance	20 000 000
2. Application for an extension of a permit to import or export a substance	10 000 000

3. Consignment verification 1% of the CIF value