



**LIBERIA MEDICINES & HEALTH  
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(LMHRA)**

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**REGULATIONS ON IMPORTATION AND  
EXPORTATION OF MEDICINES AND HEALTH  
PRODUCTS**

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## Table of Contents

DECLARATION	4
CHAPTER I	PRELIMINARY ..... 5
<b>Section 1:</b>	<b>Title..... 5</b>
<b>Section 2:</b>	<b>Application and Scope ..... 5</b>
<b>Section 3:</b>	<b>Purpose..... 5</b>
<b>Section 4:</b>	<b>Definition ..... 5</b>
CHAPTER II	IMPORTATION OF MEDICINES AND HEALTH PRODUCTS ..... 8
<b>Section 1</b>	<b>Requirements for Importers License ..... 8</b>
<b>Section 2</b>	<b>Application for Import Permit..... 8</b>
<b>Section 3</b>	<b>Authorization for Importation of Narcotic Drugs and Psychotropic Substances. 8</b>
<b>Section 4</b>	<b>Packaging of Imported Medicines and Health Products..... 9</b>
<b>Section 5</b>	<b>Container Closure System..... 10</b>
<b>Section 6</b>	<b>Medicines and Health Products Verification at Ports of Entry ..... 10</b>
<b>Section 7</b>	<b>Re-export of Imported Medicines and Health Products..... 11</b>
<b>Section 8</b>	<b>Procedure for Re-export of Medicines and Health Products ..... 11</b>
CHAPTER III	IMPORTATION OF MEDICINES AND HEALTH PRODUCTS FOR DONATION .... 12
<b>Section 1</b>	<b>Application of this Section..... 12</b>
<b>Section 2</b>	<b>Conditions for Importation of Medicines and Health Products for Donation. . 12</b>
<b>Section 3</b>	<b>Quality Assurance and Shelf-life of Donated Medicines and Health Products. 12</b>
<b>Section 4</b>	<b>Labeling and Packaging ..... 13</b>
<b>Section 5</b>	<b>Transport Costs and Other Charges..... 14</b>
<b>Section 6</b>	<b>Certificate of Donation. .... 14</b>
<b>Section 7</b>	<b>Accountability for the use of donated medicines and health products..... 14</b>
<b>Section 8</b>	<b>Prohibition of sale or transfer of medicines and health products imported for donation. 15</b>
<b>Section 9</b>	<b>Re-export of medicines and health products imported for donation. .... 15</b>
CHAPTER IV	EXPORTATION OF MEDICINES AND HEALTH PRODUCTS ..... 16
<b>Section 1</b>	<b>Exportation of medicines and health products..... 16</b>
<b>Section 2</b>	<b>Application for an Export Permit..... 16</b>
<b>Section 3</b>	<b>Verification of medicines and health products by the Authority any authorized port of exit. 16</b>
<b>Section 4</b>	<b>Container Closure System..... 17</b>
CHAPTER V	OFFENSES AND PENALTIES ..... 18
CHAPTER V	MISCELLANEOUS ..... 20

<b>Section 1</b>	<b>Conditions of License.....</b>	<b>20</b>
<b>Section 2</b>	<b>Renewal of License.....</b>	<b>20</b>
<b>Section 3</b>	<b>Cancellation of License.....</b>	<b>20</b>
<b>Section 4</b>	<b>Approved Ports of Entry and Exit.....</b>	<b>20</b>
<b>Section 5</b>	<b>Notification of Change in Ownership.....</b>	<b>20</b>
ANNEXES	.....	21
Annex 1	.....	21
Annex 1.1	.....	22
Annex 2	.....	23

## **DECLARATION**

In fulfillment of PART V, Section 7 of the Liberia Medicines and Health Products Regulatory Authority Act, 2010 and IN EXERCISE of the powers conferred upon the Authority responsible for medicines and health products' regulations, this Regulation is made by the Management with approval of the Board of Directors of the LMHRA this **6<sup>th</sup>** day of **January**, 2022.

## CHAPTER I            PRELIMINARY

### **Section 1:    Title**

This Regulation may be cited as the Liberia Medicine and Health Product Regulation on Importation and Exportation of Medicines and Health Products.

### **Section 2:    Application and Scope**

These regulations shall apply to medicines and health products that are imported and exported, re-exported into and from Liberia.

### **Section 3:    Purpose**

The purpose of these Regulations is to provide a regulatory framework for the effective and efficient importation and exportation of medicines and health products.

### **Section 4:    Definition**

In this Regulation, unless the context otherwise requires, the following words and phrases shall have the meanings as ascribed to them in this section.

“Act”                                means the Liberia Medicines and Health Products Regulatory Authority Act;

“Authority”                        means the Liberia Medicines and Health Products Regulatory Authority;

“Drug”                                means any substance or preparation used or intended to be used for internal or external application to the human or animal body either in the treatment or prevention of disease or for improving physiological functions, or for agricultural or industrial purposes. "Medicine" means any substance or mixture of substances intended for use in:

- a. the diagnosis, treatment, mitigation, or prevention of a disease, disorder, abnormal physical or mental state, or symptoms thereof in man or animal, or
- b. restoring, correcting, or beneficial modification of organic or mental functions in man or animal.

c. Medicine shall include traditional medicines, narcotic drugs, psychotropic substances, blood and blood products, vaccines, sera, and radiopharmaceuticals, but not health products as defined herein.

**"Narcotic Drug"** means any substance subject to control according to the Single Narcotic Drugs Conventions, 1962, adopted by the United Nations and ratified by the Republic of Liberia. This shall also include any substance categorized by the Authority as a narcotic drug.

**"Psychotropic Substance"** means any substance subject to control according to the Conventions on Psychotropic Substances, 1971, adopted by the United Nations and ratified by the Republic of Liberia. This shall also include any substance categorized by the Authority as a psychotropic substance.

**"Cosmetic"** means any preparation intended to be applied to the human body for cleansing, beautifying, promoting attractiveness or altering the appearance without affecting the body's structure or functions.

**"Health Product"** includes: **Medical Device**, which means any instrument that is not a medicine, as defined herein, that is intended for use in the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical or mental state, or symptoms thereof, in human or animal, or restoring correcting, or beneficial modification of organic or mental functions in human or animal; and

**"Medical Supply,"** which means any article that is intended for diagnosis, treatment, mitigation or prevention of a disease disorder, abnormal physical or mental state, or symptoms thereof, in human or animal, or restoring, correcting, or beneficial modification of organic or mental functions in human or animal. This includes suturing materials, syringes, needles, bandages, gauze, cotton, artificial teeth, chemicals, and X-Ray film and other similar articles.

**"Packaging Material"** means any article that may be used for filling, inserting, wrapping, or packing medicines and health products. The primary package is the container directly in contact with the product, and the secondary package is whatever covers the primary package. This includes packaging of excipients and active pharmaceutical ingredients.

<b>"Label"</b>	means any material that is printed or affixed to packaging material, including a leaflet, which provides the necessary information about a medicine.
<b>"Counterfeit Medicine"</b>	means a medicine that is deliberately and fraudulently mislabeled with respect to identity or source. Counterfeit products may be branded or generic medicines, and may include products with the correct ingredients, with the wrong ingredients, without ingredients, with insufficient active ingredients, or with fake packaging materials.
<b>"Substandard Medicine"</b>	means a medicine that does not comply with the applicable quality standards adopted by the Authority.
<b>"Adulteration"</b>	means the causing or doing any act that affects the purity, potency, strength or content of a product, so that it is not of good quality, safe and effective, or not what it purports to be.
<b>"Radiopharmaceutical"</b>	means an article intended for diagnostic or therapeutic use that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear radiation.
<b>"Pharmacovigilance"</b>	means the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problem.

## **CHAPTER II            IMPORTATION OF MEDICINES AND HEALTH PRODUCTS**

### **Section 1            Requirements for Importers License**

1. A person must not import medicines and health products into Liberia, unless such products are registered and an importer's license issued by the Authority in accordance with **Part V, Sections 1 and 2** of the LMHRA Act of 2010.
2. An import's license must be in the format prescribed by the Authority in the Schedule section of this Regulation
3. The Authority shall issue an importer's license only when it is satisfied that the applicant meets the criteria set out in this Part.
4. An importer's license must be valid for a period of one year (12 months). as of the date of issuance.
5. The Authority shall, prior to issuing an importer's license, ascertain that the facility from which the medicines and health products to be imported or manufactured, complies with the current Good Manufacturing Practice guidelines of the World Health Organization (WHO).

### **Section 2            Application for Import Permit**

1. An application for an authorization to import medicines and health products must be made in accordance with requirements in Annex 1 of this Regulation and must be accompanied by the Importer's license of the applicant.
2. An application for an authorization to import medicines and health products must be made by a licensed institution or person.
3. An authorization to import may be cancelled where the importer's license issued to import or manufacture medicines and health products is cancelled by the Authority.

### **Section 3            Authorization for Importation of Narcotic Drugs and Psychotropic Substances.**

1. A person or organization must not import narcotic drugs or psychotropic substances without a permit issued by the Authority to do same. See Part VI of the LMHRA Act of 2010.

2. All permits for the **importation of narcotic drugs and psychotropic substances** must be in the format prescribed by the Authority in Annex 1 of this Regulation.
3. An application for permit must only be requested by a person or institution with an import license as required under section one of this regulation.
4. When an application is made by a manufacturer of a drug or his assigns, the applicant must furnish the Authority with evidence for the importation of the narcotic drug or psychotropic substances as raw material for the onward manufacture of a finished or intermediate drug.
5. When an application is made for commercial purposes, the applicant must guarantee by a declaration concisely stating that the narcotic drug or psychotropic substances being imported by the named institution or business must not be sold unless a valid prescription from a licensed health care practitioner authorized to prescribe such products is presented.
6. All permits issued for the importation of narcotic drugs or psychotropic substances expires upon each importation.
7. The importation of narcotic drugs and psychotropic substances must be in accordance with these Regulations.

#### **Section 4      Packaging of Imported Medicines and Health Products.**

1. The primary packaging of an imported drug must be clearly labeled in English with the following:
  - a. the trade or brand name, where appropriate;
  - b. the generic name of the drug;
  - c. the quantities of active ingredients in the drug;
  - d. the dates of manufacture and expiry of the drug;
  - e. the batch or lot number of the drug;
  - f. any special conditions of storage applicable to the drug;
  - g. the name and address of the manufacturer of the drug;
  - h. a unique identification feature, if any; and
  - i. the registration number of the drug, where applicable.
2. The information leaflet enclosed in or accompanying the imported drug must be in English.

3. A drug labeled “for sale only in specified countries” must not be imported into Liberia except where Liberia is one of the specified countries.
4. Notwithstanding count (3) above, the Authority may, in special circumstances, authorize the importation of medicines and health products referred to in in count 3 into Liberia.

When the label of a drug shows evidence of alteration in the label, the drug shall be deemed to be adulterated and shall not be allowed entry into Liberia or shall be returned to the manufacturer at the cost of the person who imports the drug. “Alteration in the label” shall include circumstances when

- a. The entire label or a part of the label with the details such as the batch number or the date of manufacture of the drug is removed;
- b. There is evidence of removal of the original label and evidence of attaching another label or evidence of placing a label over the original label; or
- c. There is evidence of erasing or concealing the original details of the label and replacing the details with other details.

#### **Section 5      Container Closure System.**

The inner primary package of an imported drug must be sealed in such a way that the drug is not accessible, got in contact with or tampered with without damaging the seal.

#### **Section 6      Medicines and Health Products Verification at Ports of Entry**

1. The Authority shall, on the arrival of a consignment of medicines and health products at any port of entry into Liberia, inspect the medicines and health products to confirm that the medicines and health products comply with the approved specifications and that each batch is accompanied by a certificate of analysis.
2. The imported medicines and health products must be accompanied by the **certificate of analysis (CoA)** of the drug issued by the country of manufacture and the certificate of conformity or the test report, relating to the specific batch or lot imported.

## **Section 7      Re-export of Imported Medicines and Health Products**

1. When the Authority does not allow imported medicines and health products into Liberia, the importer of the medicines and health products must re-export the medicines and health products to the supplier, in the country of origin of the medicines and health products, within a period of one month of the decision by the Authority to refuse entry into Liberia.
2. Count (1) shall apply where the medicines and health products are refused entry into Liberia for reasons other than the quality of the drug.
3. When the Authority refuses to allow imported medicines and health products, due to the poor quality, said products shall be destroyed by the Authority at the cost of the importer.

## **Section 8      Procedure for Re-export of Medicines and Health Products**

1. In keeping with section 7, the person who re-exports medicines and health products, must make an application for verification to the Authority and the application must be accompanied by the relevant invoices and other documents related to the medicines and health products including the exact point of destination of the medicines and health products and pay the prescribed fees.
2. The Authority shall inspect the consignment to confirm the contents.
3. The Authority shall issue a re-export permit for the re-export of the medicines and health products.
4. The Authority shall witness the loading of the medicines and health products for re-export.
5. The person who re-exports the medicines and health products must submit to the Authority a written document of re-export issued by the relevant authorities at a port of exit from Liberia, certifying that the medicines and health products were re-exported.

## **CHAPTER III      IMPORTATION OF MEDICINES AND HEALTH PRODUCTS FOR DONATION**

### **Section 1      Application of this Section.**

This Section shall apply to medicines and health products which are imported for donation or donated for importation

### **Section 2      Conditions for Importation of Medicines and Health Products for Donation.**

1. The importation of a drug for donation shall only be allowed when the Regulation on Donation in addition to National Donation Guidelines of Liberia are fully ahead to.
2. For the purposes of section (1) of this Chapter, the recipient of the drug or the donor, must prior to the shipment of the drug, notify the Authority of the range and quantities of the drug to be imported, the population to be served and the particulars of the recipient of the drug.
3. The Authority shall in writing, authorized the importation of the drug for donation and shall specify the conditions of the donation in keeping with the regulation on donation
4. The drug shall on arrival in Liberia, be verified by the Authority.

### **Section 3      Quality Assurance and Shelf-life of Donated Medicines and Health Products.**

1. All drugs imported for purposes of donation must be obtained from a source approved by the Authority.
2. The quality of drugs imported for donation must conform to the authorized pharmacopoeias and the presentation, strength and formulation of the drug must as far as possible, be similar to the drug which is commonly used in Liberia.
3. The drug imported for the purposes of donation must have a remaining shelf life of at least one year, calculated from the date the drug is allowed entry into Liberia, at a port of entry.
4. A vaccine and any other biological product imported for the purposes of donation must have at least three quarters of its stated shelf life remaining

at the time the vaccine or biological product is allowed entry into Liberia at the port of entry. See donation guidelines

#### **Section 4      Labeling and Packaging.**

1. The drug imported for the purposes of donation must be delivered in the original primary and secondary containers or packages of the drug.
2. For the avoidance of doubt, only a drug that is delivered in the original primary and secondary containers or packages and which has not been opened at the time the drug is allowed entry into Liberia, shall be allowed for the purposes of donation.
3. The label on a primary container or package of the drug imported for donation must be in English and where the original label on the primary container or package of the drug is not in English, the primary container or package of the drug must bear an English translation and permanently fixed to the container but not cover or erase on the original label.
4. The label referred to in sub regulation (3) must bear
  - a. the name and address of the manufacturer of the drug;
  - b. the generic name of the drug (INN);
  - c. the date of manufacture of the drug and the batch or lot number of the drug;
  - d. the date of expiry of the drug;
  - e. the conditions under which the drug is to be stored; and
  - f. the dosage, form and strength of the drug.
5. The drug for donation must be accompanied by the information of the prescriber of the drug, which shall be in English.
6. The drug imported for the purposes of donation must be packed in a strong tertiary container, and where there are more than one container, the containers must be sequentially numbered.
7. The drug must be accompanied by a detailed packing list, which must specify the contents of each container by the generic name of the drug and the batch number, expiry date and the quantity of the drug.
8. Where the drug imported for donation is imported alongside other items which are not medicines and health products, the drug and the accompanying documents must be packed separately from the other items.

## **Section 5 Transport Costs and Other Charges.**

1. The person who donates the drug and the recipient of the drug must be responsible for the costs of-
  - a. the international and national transportation of the donated drug;
  - b. the customs warehousing and storage; and
  - c. the clearing and other ancillary activities.
  - d. disposal cost, where applicable.

## **Section 6 Certificate of Donation.**

1. A donor must provide to the recipient of the drug a certificate of donation, certified by an authorized person or donor, who shall be a person with authority to sign such a certificate on behalf of the country of origin of the donor.
2. The certificate of donation must indicate the conditions to be fulfilled by the recipient, if any, the name of the manufacturer of the drug, the name of the drug and its batch number, the dates of manufacture and expiry of the drug and any other condition as the authorized person may deem fit.
3. The recipients of drug for donation must prior to the importation of the drug, furnish the Authority with the certificate of donation issued by the donor.

## **Section 7 Accountability for the use of donated medicines and health products.**

1. A recipient of donated drug must appoint a registered pharmacist, medical doctor, dentist or veterinary, surgeon or where this is not practicable, appoint any other person to be responsible for the use of donated drug.
2. When a person appointed for the donated drug is not a registered pharmacist, medical doctor, dentist or veterinary surgeon, the appointment must be approved by the Authority.
3. The recipient of donated drug must make returns to the Authority showing how the drug was distributed and used.
4. Where the recipient of donated drug is not a health institution, practitioner or the user of the drug, the appointed person must make a return required under sub regulation (7.3).

**Section 8 Prohibition of sale or transfer of medicines and health products imported for donation.**

1. A recipient of donated drug must not sell donated drug.
2. A recipient must not transfer the drug internationally, without the written permission of the Authority.

**Section 9 Re-export of medicines and health products imported for donation.**

1. Any drug imported for donation that does not comply with the requirements of Section 9 shall not be allowed entry into Liberia.
2. When the Authority does not allow medicines and health products imported for donation into Liberia, the importer of the medicines and health products must re-export the medicines and health products to the supplier, in the country of origin, within a period of one month of the decision by the Authority to refuse entry into Liberia.
3. Sub regulation (9.2) shall apply when the medicines and health products imported for donation are refused entry into Liberia for reasons other than the quality of the drug.
4. When the Authority refuses to allow medicines and health products for donation, due to the poor quality of the medicines and health products, the medicines and health products shall be destroyed by the Authority at the cost of the donor and/or recipient;
5. When the medicines and health products imported for donation are to be re-exported, chapter II section 8 shall apply.

**Section 1 Exportation of medicines and health products.**

1. No person or organization shall export medicines and health products out of Liberia without a license issued by the Authority.
2. An export license shall be valid for one year and shall be in the format prescribed by the Authority in Annex 2 of this Regulation.
3. The Authority shall issue an export license when the applicant meets the criteria set out in this section.
4. The Authority shall prior to issuing an export license, ensure that the facility from which the medicines and health products to be exported, complies with internationally accepted current Good Manufacturing Practice Guidelines of the WHO adopted by the Authority.

**Section 2 Application for an Export Permit.**

1. An application for an export permit for medicines and health products must be made using Annex 2 to this Regulation and accompanied by the license of the applicant and payment of the prescribed fees.
2. An application for an export permit of medicines and health products must be made by a licensed person.
3. An export permit issued to a person or institution to export medicines and health products may be cancelled when the license previously issued to do business under the LMHRA Act is cancelled by the Authority.

**Section 3 Verification of medicines and health products by the Authority any authorized port of exit.**

1. The exported medicines and health products must be accompanied by the export permit, certificate of registration, certificate of analysis and the certificate of conformity or the test report, relating to the specific batch or lot of medicines and health products to be exported.
2. The Authority shall, on the arrival of a consignment of medicines and health products at any authorized port of exit from Liberia, inspect the medicines and health products to confirm that the medicines and health

products comply with the approved specifications and that each batch is accompanied by a certificate of analysis.

**Section 4      Container Closure System.**

The inner primary package of a drug for export must be sealed such that the drug cannot be reached or tampered with, without damaging the seal.

## CHAPTER V OFFENSES AND PENALTIES

1. Any person(s), institution(s), Corporate Entity(ies), their Designees or legal representatives who violates Chapter II sections 1 and 2 and Chapter IV of this regulation, shall be liable to regulatory fines ranging from One Thousand to Five Thousand United States Dollars (US\$1,000.00-\$5,000.00)
2. Any person(s), institution(s), Corporate Entity (ies), their Designees or legal representatives who violates Chapter II section 3 of this regulation shall be subjected to fines in the amount of Ten Thousand United States Dollars (US\$10,000.00). However, where the narcotic drug or psychotropic substances being imported by the named institution or business was not sold under a valid prescription from a license health care practitioner authorized to prescribe such products, the said institution will be banned from importing any of such products subsequently. And when the product sold is abused or misused and injury or death ensued due to violation of section 3 count 5, the person or institution will be civilly and or criminally liable under the civil Procedure and Penal Laws of Liberia depending on the offense.
3. When an importer does not meet packaging standards as indicated in Chapter II sections 4 and 5 of this regulation, the said importer shall be fined in accordance with the regulation on labeling where applicable.
4. During inspection and verification on arrival at the port of entry, when it is observed that imported medicines and health products are not accompanied by the **certificate of analysis (CoA)** issued by the country of manufacture, the certificate of conformity or the test report relating to the specific batch or lot imported as required is not presented, the importer shall be made to pay a fine of not less than One Thousand five United States Dollars (US \$1,500) of which 500 will be refunded upon curing this defect.
5. Any person(s), institution(s), Corporate Entity (ies), their Designees or legal representatives who contravenes any provision of Chapter III section 8 shall pay a fine of Five Thousand United States Dollars (US\$5,000).

6. Any person(s), institution(s), Corporate Entity(ies), their Designees or legal representatives who violates any of the provisions on importation of donation as seen in Chapter III sections 2, 3 and 4 shall be liable to fine to be determined at the time of offense.
  
7. Any person(s), institution(s), Corporate Entity(ies), their Designees or legal representatives issued a permit to import narcotic drug and psychotropic substances who does not comply with Chapter II section 3 count 6 and 7 of this regulation, and further imports under a permit which is consider expired, shall render the said permit deceptive as define in section 15.73 of the Penal Law and thus, commits a first degree misdemeanor in accordance with section 15.72 of the Penal Law.

## **CHAPTER V MISCELLANEOUS**

### **Section 1 Conditions of License.**

A license issued under the LMHRA Act and these Regulations shall indicate the conditions under which the license is issued and shall state that the license may be cancelled where the conditions are not fulfilled or are breached.

### **Section 2 Renewal of License.**

1. A person who wishes to renew a license issued under these Regulations must make an application for renewal of the license to the Authority.
2. An application for renewal of a license must be made three months prior to the date of expiry of the license.
3. The procedure for applying for a license under these Regulations shall be used for renewing a license.

### **Section 3 Cancellation of License.**

The Authority shall cancel a license issued under these Regulations when the conditions of the license are not fulfilled or are breached.

### **Section 4 Approved Ports of Entry and Exit.**

Medicines and health products must be imported or exported through ports of entry and exit approved and Gazette by the Authority. Authorized sea and airport (the Free Port of Monrovia and the Roberts International Airport, RIA).

### **Section 5 Notification of Change in Ownership.**

When the ownership of the licensed issued under these Regulations changes, the licensed person must notify the Authority of the change and must submit a certified copy of the documents indicating the change.

**NNEXES**

Annex 1

**PERMIT FOR THE IMPORTATION OF NARCOTICS AND PSYCHOTROPIC MEDICINES AND HEALTH PRODUCTS**

Import license No. .... I, being the person charged with the administration of the law relating to the dangerous medicines and health products to which the International Convention on Narcotic and Psychotropic Medicines and health products apply, hereby certify that I have authorized.....(hereinafter called the importer) to import the medicines and health products specified in this permit, which I am satisfied are required:

1. The medicines and health products must be imported before.....  
(dd/mm/yyyy)
2. This permit is not a license to be in possession of or to supply the drug imported.
3. This permit does not relieve the importer from compliance with any custom regulations in force for the time being relating to the importation of goods into or transshipment of goods in Liberia or any Post Office regulation for the time being in force in Liberia.
4. This permit is valid only for the import and may be revoked at any time and in that event must be immediately surrendered.
5. The permit must be produced for inspection when required by any duly authorized person.
6. This permit, unless sooner revoked, must be endorsed by the custom officer and inspector of Authority at the time of importation using the form prescribed in annex 1.1, or, if the importation is not effected before the date specified in condition No. 1, must immediately after the date be surrendered to the Authority.
7. The consignment shall be imported by registered parcel post addressed to  
.....  
.....  
.....  
.....  
.....

\_\_\_\_\_  
Stamped and Date

\_\_\_\_\_  
For the Authority

**ENDORSEMENT BY INSPECTOR OF AUTHORITY AND CUSTOMS OFFICER  
AT THE TIME OF IMPORTATION**

I hereby certify that the person named in the permit has today imported the consignment specified in the permit ..... under Customs entry No. ....  
Dated ..... or by registered parcel post or insured Box Post (Parcel No. ....  
Dated .....

**Signature of Inspector**

**of Medicines and health products**

Name: .....

Title: .....

Date: .....

**Signature of Customs Officer**

Name: .....

Rank: .....

Date: .....

If not all the medicines and health products for which this authorization was granted are not imported, the Inspector of the Authority or Customs Officer must indicate the actual quantity of medicines and health products imported.

Description of narcotic and psychotropic medicines and health products quantity.

DESCRIPTION OF NARCOTIC AND PSYCHOTROPIC MEDICINES AND HEALTH PRODUCTS	QUANTITY

**APPLICATION TO REGISTER AS AN EXPORTER OF MEDICINES AND  
HEALTH PRODUCTS**

SEC	DETAIL
1	APPLICANT
	<p>1. Name of Applicant(Company): _____</p> <p>2. Postal Address: _____ _____</p> <p>3. Location: _____</p> <p>4. Contact details:  Telephone/Cell number: _____  Fax: _____  E-Mail: _____  Website: _____</p> <p>5. Date of Incorporation of Company: _____</p> <p>6. Business Registration number of Company: _____</p> <hr/> <p>7. For Pharmaceutical Companies only:</p> <p>a. Name of Superintendent Pharmacist: _____</p> <p>b. License #: _____</p> <p>c. Signature of Pharmacist: _____</p> <p>8. Items to be Exported:</p> <p>a. Allopathic <input type="checkbox"/></p> <p>b. Homeopathic <input type="checkbox"/></p> <p>c. Veterinary <input type="checkbox"/></p> <p>d. Herbal <input type="checkbox"/></p> <p>e. Food Supplements <input type="checkbox"/></p> <p>f. Cosmetics <input type="checkbox"/></p> <p>g. Medical Devices <input type="checkbox"/></p>

h. Others (please specify)

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Please attach a copy each of the following documents:

- a. Certificate of Registration
- b. LMHRA Premise License (for medicines only)

**2** **DECLARATION**

I/We, the undersigned, hereby declare that all information contained is true and correct.

Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Position in Company: \_\_\_\_\_

Date: \_\_\_\_\_

STAMP

This Regulation shall take effect immediately upon the approval of the chairman of the Board of Directors.

***A Regulation on Importation & Exportation of Medicines and Health Products is Hereby Promulgated and Submitted for Approval to the Board of Directors on This 6<sup>th</sup> Day of January A. D. 2022 by the Managing Director of the Authority.***



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***Pharm. Keturah C. Smith-Chineh  
Managing Director / LMHRA***

***A Regulation on Importation & Exportation of Medicines and Health Products is Hereby Submitted to the Chairman of the Board of Directors for Approval.***

***Approved This 11<sup>th</sup> Day of February A. D. 2022***



***Prof. Hasipha C. Tarpeh  
Chairman / Board of Directors***