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LIBERIA MEDICINES & HEALTH PRODUCTS REGULATORY AUTHORITY (LMHRA)

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REGULATIONS FOR DONATION OF MEDICINES AND HEALTH PRODUCTS

"Ensuring Safety, Efficacy and Quality of Medicines and Health Products"
LMHRA

Regulation Code.	:	LMHRA-R-[DON]-21-004
Date of Adoption	:	January 2022
Version No.	:	01

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

A Regulation for Donation of Medicines and Health Products is Hereby Promulgated and Submitted for Approval to the Board of Directors on This 6th Day of January A. D. 2022 by the Managing Director of the Authority.

Keturah Smith-Chineh (Mrs.)
Managing Director / LMHRA

A Regulation for Donation of Medicines and Health Products is Hereby Submitted to the Chairman of the Board of Directors for Approval.

Approved This 11th Day of February A. D. 2022

Prof. Hasipha C. Tarpeh
Chairman/Board of Directors

CHAPTER III: OFFENCES AND PENALTIES

In keeping with Part VIII, Section 1, 2 & 3 of the Authority Act of 2010, the following measures shall apply:

1. Any violation of the provisions on labeling as stated in chapter II, Section 3.1 of this regulation shall be punishable with a fine of Two Thousand United States Dollars (US$2,000) on first offence and repeated offense may lead to cancellation of the permit for the products. This does not exclude criminal penalty for endangering public lives where applicable.

2. Any violation of the provisions on shelf live and storage shall lead to automatic confiscation of the products and a fine of One Thousand United States Dollars ($1,000); in addition, the violator shall be required to underwrite the cost of disposal and conduct a recall of the product if suspected to be compromised when distributed.

3. Any violation of the provisions on registration and importation shall attract a fine of not less than $500.00 to be imposed on the organization (s), their Designees or legal representatives. However, if the product has been released for consumption and suspected to be compromised, a recall will have to be made by the organization (s) or their Designees, not excluding the submission of the matter to criminal prosecution for the charge of "recklessly endangering another person" in keeping with section 14.23 of the Penal Law of Liberia.

DECLARATION

This Regulation, made in fulfillment of PART V, Section 7 of the Liberia Medicines and Health Products Regulatory Authority Act of 2010, which confers upon the Authority the responsibility of regulating medicines and health products within the Republic of Liberia. The Management, with approval of the Board of Directors hereby promulgates this regulation designed for donation of medicines and health products this **6th** day of **January,** 2022.

CHAPTER I PRELIMINARY

Section 1. Title

This Regulation shall be cited as the Regulation on Donation of Medicines and Health Products.

Section 2: Application and scope

This regulation shall apply to the donation of all medicines and health products that are manufactured, imported, distributed, stored, sold and used in Liberia.

Section 3: Purpose

The purpose of this regulation is to provide a legal framework for the effective and efficient handling of donated medicines and health products.

Section 4. Definitions

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 of 2010
Authority	means the Liberia Medicines and Health Products Regulatory Authority.
An Applicant"	means a person or entity who submits an application for product registration to the Authority and responsible for all the product information

All applications must be accompanied by an approval letter from the Ministry of Health. Please refer to the **National Guidelines for Donation**

Timeline

The Authority shall be notified at least one month before the arrival of donated consignment by the applicant except in the case of emergency.

Disposal

a. The disposal cost of unfit medicines and health products shall be the responsibility of donor and/or recipient in accordance with the Authority's regulation for disposal of unfit medicines and health products.
b. In case of unsolicited donations, and those not in compliance with this regulations, all associated cost for donation shall be the responsibility of the donor and recipient.

Health Emergency

During health emergency, provision(s) within this regulation may be waived as determined by the Authority.

Storage

All donations with specific storage requirements (cold chain among others) must be strictly adhered to in keeping with international best practice.

Registration

a. All products for donation into the country must meet all registration requirements set forth by the Authority
b. In the case where the applicant is not residing in Liberia, the applicant must appoint a local agent to act on their behalf by issuing a power of attorney.
c. Where the medicines and health products to be donated have been registered in Liberia, the recipient of the donated item must be required to liaise with the Company that holds the market authorization in Liberia. This shall be for the purposes of monitoring the safety of the medicines and health products.
d. Where the Ministry of Health is the direct beneficiary of the donation, the Authority must be duly notified and acquainted with the following documents: packing list, certificate of donation, invoice, certificate of analysis

Importation of medicines and health products for donation

Importation of medicines and health products for donation must be in accordance with chapter III of the regulation for import and export of medicines and health.

Fees

The Authority does not charged any fees for processing applications for donated medicines and health products.

Address

All applications for processing donations of medicines and health products must be communicated to:

The Managing Director
Liberia Medicines & Health Products Regulatory Authority
P.O. Box 1994
1000 Monrovia, 10 Liberia
West Africa

Drug means any substance or preparation used or intended to be used for internal or external application to the human or animal body in either the treatment, prevention or diagnosis of disease for improving physiological functions, or for agricultural or industrial purposes.

Essential Medicine List (EML) of Liberia

means a list of selected medications approved by the Ministry of Health based on disease prevalence and public health relevance that are considered to be most effective, safe and cost effective in Liberia.

"**International Non-Proprietary Name**" **INN-**

means an official generic and non-proprietary name given to a pharmaceutical product or an active ingredient

Local Agent means a person resident in Liberia or a corporate body registered in Liberia, with the relevant mandate from the applicant, to act on the applicant's behalf as regards matters relating to the donation.

National Standard Treatment Guidelines of Liberia (NSTGL)

means the recommended treatment protocols for disease management in Liberia.

CHAPTER II DONATION OF MEDICINES AND HEALTH PRODUCTS

Section 1 Good Donation Principles

All donations of medicines and health products to Liberia must be in accordance with current WHO Guidelines for medicine donations, the Guidelines for donation of medicines and medical supplies to Liberia, 2014 and the National Standard Treatment Guidelines. All donations must conform to the following four core principles as stated in the WHO guidelines for medicines donation:

1. Donations of medicines and heath products must benefit the recipient to the maximum extent possible. All donations must be based on an expressed need by the recipient. Unsolicited medicine donations are to be discouraged.
2. Donations must be given with due respect for the wishes and authority of the recipient, and in conformity with the government policies and administrative arrangements of the recipient country.
3. There must be effective coordination and collaboration between the donor and the recipient, with all donations made according to a plan formulated by both parties.
4. There must be no double standard in quality. If the quality of an item is unacceptable in the donor country, it is also unacceptable as a donation.

Section 2 General Requirement

1. All donations must respond to national need and be relevant to the disease pattern; and based on existing and approved National Standard Treatment Guidelines of Liberia. In the case of medical supplies and equipment, they should meet international standards and or the requirements of the standards of the Quality Control Laboratory of the Authority.
2. All medicines or their generic equivalents to be donated must meet the requirements of the National Standard Treatment Guidelines of Liberia.
3. The Presentation, strength and formulation of the donated medicines and health products must be similar to those of items commonly used in Liberia.
4. Notwithstanding, during emergency, medicines and health products not on the EML may be accepted at the time of donation.

Section 3. Specific Requirement

Labeling

a. All donated medicines and health product must be labeled in English and must be in accordance with the Authority's Regulations on Labeling;
b. Where the labeling not in English, there must be a translation;
c. The label on each container must contain the following information:

   i. International Non-proprietary Name (INN);
   ii. Batch number;
   iii. Dosage form;
   iv. Name of manufacturer;
   v. Quantity in the container;
   vi. Storage conditions;
   vii. Manufacturing and expiry dates;
   viii. Prescriber information leaflets in the English language.

d. All medicines and health products intended for donation to Liberia must be packaged in accordance with standard storage temperatures of 15°C-30°C or 59°F-86°F for regular medicines and health products and 2°C-8°C or 36°F-46°F for cold chain medicines. Additionally, medicines must not be mixed with other supplies in the same container.

Shelf-life

a. All medicines intended for donation must have a minimum shelf life of one (1) year at the time of arrival in Liberia. However, under specified circumstances the shell life must not be less than half of the expiration period.
b. All health products intended for donation must have a minimum shelf life of two (2) years at the time of arrival in Liberia.
c. 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.