



LIBERIA MEDICINES & HEALTH PRODUCTS REGULATORY AUTHORITY (LMHRA)

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REGULATIONS FOR LABELING OF MEDICINES AND HEALTH PRODUCTS



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Table of Contents

DECLARATION.....	3
CHAPTER I: PRELIMINARY	4
Section 1. Title.....	4
Section 2: Application and Scope.....	4
Section 3: Purpose	4
Section 4. Definitions	4
CHAPTER II: LABELING OF MEDICINES AND HEALTH PRODUCTS	8
Section 1. Labeling Information.....	8
Section 2: Name and Address of Manufacturer.....	9
Section 3. Display of Generic and/or Brand Name	10
Section 4. Package Inserts	10
Section 5. Labeling of Parenteral and Suspension Preparations.....	11
Section 6. Declaration of Non-Nutritive sweeteners	12
Section 7. Warning for Children.....	12
Section 8. Manufacture and Expiry Dates	12
Section 9. Batch/Lot number	12
Section 10. Score line Information /Requirement for Scored Tablets.....	12
CHAPTER III OFFENSES AND PENALTIES.....	13

DECLARATION

This Regulation, made in fulfilment 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 promulgate this regulation designed for the labeling 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 Labeling of Medicines and Health Products.

Section 2: Application and Scope

This regulation shall apply to the labeling 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 regulation of label (s) that is/are printed or affixed to packaging material, including a leaflet, which provides the necessary information about a medicine.

Section 4. Definitions

In this Regulations, 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;
- "Adulteration"** 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.
- “Authority”** means the Liberia Medicines and Health Products Regulatory Authority;
- “Bulk Drug”** means the key ingredient of a drug or medicine, which lends it the desired therapeutic effect or produces the intended pharmacological activity.
- “Bulk Package”** means a container of sterile preparation for parenteral use that contains many single doses.

“Co-packaging” means the overall process of assembling a product or good into its final finished packaging.

"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.

"Counterfeit Medicine" means a medicine that is deliberately and fraudulently mislabeled with respect to identity or source. Counterfeit medicine may be branded or generic medicines, and may include medicines with the correct ingredients, with the wrong ingredients, without ingredients, with insufficient active ingredients, or with fake packaging materials.

“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.

Essential Medicine List (EML) means a list of selected medications based on disease prevalence and public health relevance that are considered to be most effective, safe and cost effective.

"Health Product" includes:

- a. **"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
- b. **"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.

“International Non-Proprietary Name” INN- means an official generic and non-proprietary name given to a pharmaceutical drug or an active ingredient

Label" means any material that is printed or affixed to packaging material, including a leaflet, which provides the necessary information about a medicine.

“Labelling” is the act of printing or affixing to a packaging material, such as leaflet, which provides the necessary information about a medicine.

"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 human 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 Convention on Narcotic Drugs, 1961, 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.

"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.

"Pharmacovigilance"

means the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problems.

"Radiopharmaceutical"

means an article intended for diagnostic or therapeutic use that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear radiation.

"Substandard Medicine"

means a medicine that does not comply with the applicable quality standards adopted by the Authority.

CHAPTER II: LABELING OF MEDICINES AND HEALTH PRODUCTS

Section 1. Labeling Information

1. Label (s) must be original and indelible.
2. The font size and style type used must be readable
3. All information contained on the label of medicines and health products must be in English. However, in the case where the information is in foreign language, the label must contain an English language interpretation.
4. The label must specifically present relevant information and graphics that convey the precise indication and contraindication of the product.
5. Graphics that depict pornography or potentially misleading information must not be allowed.
6. The following information must be clearly stated:
 - a. Clinical pharmacology;
 - b. Indications and usage;
 - c. Contraindications;
 - d. Interactions;
 - e. Warnings/Precautions;
 - f. Adverse reactions;
 - g. Drug abuse and dependence (where applicable);
 - h. Symptoms of overdose and treatment;
 - i. Dosage and administration;
 - j. The preparation for use;
 - k. Presentation, storage condition; and
 - l. Any other specific information as may be required by the Authority from time to time.
7. No prescription drug must bear on its packaged label any statement, pictorial or otherwise that misrepresents the indications of the drug.
8. Each blister or strip must indicate the following:
 - a. The brand name (where applicable);
 - b. The generic or common name;
 - c. The strength of the drug;
 - d. Lot or Batch number;

- e. Manufacture date; and
- f. Expiry date.

9. Bulk drugs

This does not apply to any drug in a bulk package (tablets, capsules or other dosage unit forms) intended for processing, repackaging or use in the manufacture of another drug. However, the Authority shall require that the label of the bulk drug contains the following information:

- a. The brand name (where applicable);
- b. The generic or common name;
- c. Net content;
- d. Lot or batch number;
- e. Manufacture and expiry dates;
- f. Name and location address of manufacturer, distributor or vendor;
- g. Storage conditions; and
- h. The statement “Caution: For Bulk Drug Manufacturing Purposes Only”.

Section 2: Name and Address of Manufacturer

1. The label of medicines and health products being imported into Liberia must specify conspicuously the name and address of the manufacturer.
2. Where a manufacturer outsources to a third party the production of any of its products, under contractual arrangement, the label must indicate full name and address of the manufacturer in addition to the phrase “Manufactured by.....for.....”, ‘Manufactured for.....by.....’.
3. The label (i.e., Primary, Secondary and Tertiary), must contain the name and address of the manufacturer.
4. An exception to ‘3’ shall be: for injectable or products that contain 10ml or less (or equivalents) in which case the address needs not be shown on the inner label.

In addition to 4, the following shall also apply:

- a. The brand name (where applicable);
- b. The generic name;
- c. Lot or batch number;

- d. Net content;
- e. Manufacture and expiry dates;
- f. Manufacturer's name;
- g. Registration number assigned to it in a manner prescribed by the Authority.

Section 3. Display of Generic and/or Brand Name

1. Packaging components of a drug product must bear the following information: (i) name; (ii) active ingredients; (iii) strength; (iv) dosage form; and (v) pack size of the drug.
2. For branded or innovative medicines and health products, the generic names must be indicated on all packages.
 - a. All products must be labeled only with the correct compendia standard;
 - b. For products that contain more than one active ingredient, the INN of all such ingredients must appear on the label;
 - c. Where the container is too small to bear the information, it must appear in the leaflet inserted;
 - d. The ingredient and strength must be stated in units of weight, measure or number;
 - e. Declaration of weight of the contents must be expressed in terms of metric units, i.e. gram, milligram, microgram, and subdivisions thereof. A declaration of liquid measure (volume) of the contents must be expressed in the liter and milliliter, cubic centimeter and subdivisions thereof;
 - f. For co-packaged drugs products, the net content must be declared by stating the quantity of each component in conjunction with other components of the co-pack.

Section 4. Package Inserts

1. All medicines and health products imported or exported must be accompanied by a package insert with the following information:
 - a. The description of the drug as required in this regulation;
 - b. Clinical pharmacology;

- c. Indications and usage;
- d. Contraindications;
- e. Interactions;
- f. Warnings/ Precautions;
- g. Adverse reactions;
- h. Drug abuse and dependence (where applicable);
- i. Symptoms of overdose and treatment;
- j. Dosage and administration;
- k. The preparation for use;
- l. Presentation;
- m. Storage condition; and
- n. Any other specific information as may be required by the Authority from time to time;
- o. No prescription drugs must bear on its package label any statement, pictorial that misrepresents the indications of the drug.

Section 5 Labeling of Parenteral and Suspension Preparations

- a. For injectable and suspension products, the label of packages must contain full information to healthcare practitioners and users to ensure safe and proper use.
- b. The labeling must state the following:-
 - i. The name of the product;
 - ii. Percentage content of the drug in liquid preparations;
 - iii. Amount of active ingredients (for drug powder form);
 - iv. Volume of liquid to be added for reconstitution of the drug powder;
 - v. The route of administration must be indicated;
 - vi. Storage conditions;
 - vii. Batch or lot number;
 - viii. Manufacture and expiry dates;
 - ix. The full name and address of the manufacturer;
 - x. Injection for veterinary use must be so labeled, including the withdrawal period.

Section 6. Declaration of Non-Nutritive sweeteners

All medicines containing an approved non-nutritive sweetener as an inactive ingredient must be conspicuously declared on the label in term of the identity and quantity of the non-nutritive sweetener in milligrams per dosage unit, and must also bear boldly and conspicuously, any precautionary warnings for the non-nutritive sweetener as may be prescribed by the Authority.

Section 7. Warning for Children

The labels of all medicines must state prominently a warning statement to the following effect: “Keep this medicine out of reach of children”.

Section 8. Manufacture and Expiry Dates

1. All products must bear a manufacturing and expiration dates.
2. Expiration dates must be related to the storage conditions stated on the label, as determined by stability studies.
3. The manufacturing and expiration dates must appear on all packages.

Section 9. Batch/Lot number

All product labels must bear the batch or lot number.

Section 10. Score line Information /Requirement for Scored Tablets

1. Medicines formulated as scored tablets must state on the label (package insert or package label) to the effect that:
 - a. the break-line is functional and that tablet can be divided into equal halves to satisfy certain dosage requirement as indicated under dosage information, OR
 - b. The break-line is not functional; hence, its presence is for ease of swallowing and not to divide into equal halves.

CHAPTER III OFFENSES AND PENALTIES

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

1. Any person(s), institution(s), Corporate Entity (ies), their Designees or legal representatives who presents a product and upon visual inspection the said product is not in keeping with provisions of Chapter 2 of this regulation, contravenes the said chapter and thus renders the product sub-standard and unacceptable for quality testing and distribution.
2. Where any information contained on a label is found to be falsified or misleading, the person(s), institution(s), Corporate Entity(ies), their designees or legal representatives who presents said product, violates Section 15.70 (**Forgery or counterfeiting**) of the Penal Law of Liberia and commits felony of the second degree.
3. Any person(s), institution(s), Corporate Entity(ies), their Designees or legal representatives, who contravenes any provisions of this regulation, shall be subjected to regulatory fines not less than Three Thousand United States Dollars (US\$3,000.00) and not more than Five Thousand United States Dollars US\$5,000.00) on first offense. Upon repeat, the perpetrator may, in addition to criminal sanction, forfeit permit.

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

A Regulation for Labeling 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.



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

A Regulation for Labeling 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***