



**LIBERIA MEDICINES & HEALTH
PRODUCTS REGULATORY AUTHORITY
(LMHRA)**

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**REGULATIONS FOR TREATMENT
AND DISPOSAL OF UNFIT MEDICINES
AND HEALTH PRODUCTS**



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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 treatment and disposal of unfit medicines and health products this **6th** day of **January**, 2022.

CHAPTER I PRELIMINARY

Section 1: Title

This regulation governs the treatment and disposal of unfit medicines and health products and shall come into operation on the date of publication.

Section 2: Application and Scope

This regulation applies to the treatment and disposal of all unfit medicines and health products that are manufactured, imported, distributed, stored, sold and used in Liberia.

Section 3: Purpose

This Regulation provides a legal framework for the effective and efficient handling, treating and disposing of unfit medicines and health products and also provides a transparent and non-discriminatory process for the treatment and disposal of unfit medicines and health products to protect human health and the environment from potential hazards.

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 LMHRA Act of 2010 establishing the LMHRA and determining its mission, organization and functioning;

“Appropriate fee” means the fee prescribed by the LMHRA;

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

“Destruction” means the safe disposal of any unwanted or unfit products beyond retrieval;

“Disposal” means the process of rendering the unwanted or unfit medicines and health products, for the duration of its biological and chemical activity such that it is harmless

“Health Products” Include:

- a. medical device which means any instrument that is not a medicine as defined by the LMHRA Act of 2010 that is intended for use in

diagnosis treatment mitigation or prevention of a disease, disorder, abnormal physical or mental state, or symptoms thereof in humans or animals or restoring, correcting or beneficial modification of organic or mental functions in human or animals,

- b. medical supplies which mean any article that is intended for the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical or mental state, or symptoms thereof in humans or animals or restoring, correcting or beneficial modification of organic or mental functions in human or animals, this includes suturing materials, syringes, needles, bandages, gauze, cotton, artificial teeth, chemicals, and X-ray film and other similar articles.

“Incineration”

means disposal by burning and by use of an incinerator.

“LMHRA”

means the Liberia Medicines and Health Products Regulatory Authority or its acronym “LMHRA”, established under Part I, Sections 1 & 2 of the LMHRA Act of 2010.

“Unfit medicines and health products” mean:

- a. products regulated under the Act that are expired, improperly sealed, damaged, within date (unexpired) but improperly stored, improperly labelled, substandard or falsified, adulterated, prohibited or unauthorised; or any advertisement thereof.
- b. any product regulated under the Act that does not meet regulatory requirements or when consumed or used can be harmful to the health of the consumer.
- c. any product regulated under the Act that has in or on it a poisonous or harmful substance.
- d. Any product that consists in whole or part of a filthy, putrid, rotten, decomposed or diseased substance

CHAPTER II PRODUCTS

DISPOSAL OF UNFIT MEDICINES AND HEALTH

Section 1: Prohibitions, Controls and Restrictions in Respect of Medicines and Health Products

1. The Authority may prescribe requirements by which any medicines and health product or component thereof must comply, including requirements as to the composition, therapeutic suitability and effect, purity or other properties.

Section 2: Prohibition of Sale of Medicines and Health Products which do not comply with prescribed requirements

1. No person(s) shall possess or sell any medicines and health products in respect of which requirements referred to in **Article 4**, unless that medicine or health product complies with such requirements.
2. No person(s) shall offer for sale, procure for sale, sell or administer to any person or animal, any medicines and health products that is unfit for its intended purpose.

CHAPTER III: SUBSTANDARD AND FALSIFIED PRODUCTS

Section 1 No person(s) shall be allowed to possess or sell any substandard or falsified medicines and health products as regulated under the LMHRA Act.

CHAPTER IV POWERS TO SEIZE, CONDEMN AND DESTROY

Section 1: The Authority may, if satisfied that any product under the Law is unfit for the intended use, seize and condemn such product and declare it unfit for its intended use and shall order that product to be destroyed at the owner's cost.

CHAPTER V TREATMENT AND DISPOSAL OF UNFIT PRODUCTS

Section 1: Handling of Unfit Products

1. All medicines and health products that are unfit for their intended purpose must be quarantined and kept in a separate place and clearly labelled as **“Unfit for intended use”** to prevent their unintended use.
2. The safe custody of unfit products must be maintained in registered premises until they are safely disposed of in terms of these Regulations.
3. The handling of unfit products must include:
 - a. Maintaining a registry for unfit medicines and health products in a coded form prescribed in Schedule I of this Regulation.
 - b. Storing and separating them into categories according to their respective types.

Section 2: Restriction of Disposal of Unfit Products

1. No person(s) shall dispose of any unfit product unless he/she has notified the Authority and has obtained approval to proceed with the disposal.
2. Approval of application and safe disposal of any unfit product shall be sought from the Authority.

CHAPTER VI DECISION TO IMPLEMENT/ INITIATE DISPOSAL

Section 1 The decision to implement disposal shall be made by the Authority. The process to initiate shall be by the Minister of Health or a designee, county or hospital pharmacist, the owner or approved supervisor or responsible person of a facility or premises or an LMHRA inspector.

CHAPTER VII: REQUEST FOR DISPOSAL OF UNFIT PRODUCTS

- Section 1:** A request for disposal of unfit medicines and health products shall be made to the Authority in Form **D-II** as prescribed in Schedule II to this regulation.
- Section 2:** The applicant must pay a prescribed fee as indicated in the fee schedule for disposal. If after verification, the submitted list contains additional products, the applicant must pay an additional fee, as required.
- Section 3:** A request for disposal of unfit products shall be accompanied by a list of products to be disposed of which shall state clearly the registered or approved details of the product including any trade name, brand name, type of packaging material and pack size, quantity, unit cost, total commercial value, manufacturer, batch or lot number. In the case of a pharmaceutical product, the strength and dosage form, where applicable, must also be stated. The reason(s) for which the products are declared unfit must be clearly stated.
- Section 4:** Request for disposal of unfit medicines and health products from Government institutions must be made by the pharmacist in charge and accompanied by an approval from the head of the entity.

CHAPTER VIII: APPROVAL FOR DISPOSAL OF UNFIT PRODUCTS

- Section 1:** Upon receipt of request for disposal, the Authority shall appoint an inspector who will liaise with the entity to verify and authenticate the information submitted in relation to the consignment to be disposed of.
- Section 2:** Verification shall be made by using Form **D-III** as prescribed in Schedule III of this regulation
- Section 3:** Upon verification, the Authority shall arrange with the applicant and agree on a convenient date on which the disposal and incineration can be undertaken.
- Section 4:** The cost of incineration shall be borne by the owner of the unfit product(s).

CHAPTER IX: DISPOSAL OF UNFIT PRODUCTS

Section 1: Subject to the provisions of this regulation, the Authority shall prescribe the conditions for transportation of the consignment from the premises to the disposal site for the destruction exercise.

Section 2: The Authority shall notify the applicant of the need for and terms for supervision of the destruction. Where necessary, the Authority shall prescribe that representatives from a waste management agency, such as environment protection agency, police, customs and excise be present as witnesses.

Section 3: The Authority shall, upon completion of the disposal exercise issue a Certificate of Pharmaceutical Waste Disposal.

CHAPTER X 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 violates Chapter II sections 2 and Chapter III Section 1 of this regulation, shall be liable to regulatory fines ranging from One Thousand to Three Thousand United States Dollars (US\$1,000.00 - US\$3,000.00);
2. Any person(s), institution(s), corporate entity(ies), their designees or legal representatives who violates Chapter V sections 1 & 2 of this regulation, shall be subjected to regulatory fines of an amount not exceeding Five Thousand United States Dollars (US\$5,000.00) in addition to other regulatory measures deem fit;
3. Any person(s), institution(s), corporate Entity(ies), their designees or legal representatives who violates Chapter VII of this regulation, shall be liable to fines in the range of Two-Five Thousand United States Dollars (US\$2,000.00 – US\$5,000.00) not negating other regulatory actions;
4. Any person(s), institution(s), Corporate Entity (ies), their Designees or legal representatives who violates other provisions not herein specifically mentioned, shall be liable to regulatory actions defined by the Managing Director and team. Such actions shall be dependent on the magnitude of the offence.

ANNEXES: LIST OF SCHEDULES

- Schedule I Format for the Register of Unfit Medicines and Health Products (Form D-I)
- Schedule II Application Form for Disposal of Unfit Medicines and Health Products (Form D-II)
- Schedule III Verification Report Form for Unfit Medicines and Health Products (Form D-III)
- Schedule IV Certificate of Pharmaceutical Waste Disposal (Form D-IV)

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

A Regulation for Treatment and Disposal of Unfit 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 Treatment and Disposal of Unfit 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*