



LIBERIA MEDICINES & HEALTH PRODUCTS REGULATORY AUTHORITY (LMHRA)

*P. O. Box 1994
Monrovia, Liberia
Cell: +231 – 777140555/888140555
Email: info@lmhra.gov.lr Website: www.lmhra.gov.lr*

REGULATIONS FOR MEDICINES AND HEALTH PRODUCTS RECALL, WITHDRAWAL AND CONFISCATION



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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 recall of medicines and health products this **6th** day of **January**, 2022.

CHAPTER I PRELIMINARY

Section 1: Title

This regulation may be cited as the Regulation Governing Medicines and Health products recall, withdrawal, and confiscation and shall come into operation on the date of publication.

Section 2: Application and Scope

This regulation shall apply to 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 process for product recall, withdrawal and confiscation.

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.

“Appropriate fee” means the fee prescribed by the Authority from time to time

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

“Chemical” means any substance made by a chemical process or that, which produces chemical effect, or any substance used in or produced by chemistry. May includes drugs, or those used in the laboratory or used for cleaning purposes or pesticides

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

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

“Distributor” means any person or body corporate that sells goods on behalf of a principal

“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

“Holder of a certificate of registration” means a person in whose name a registration certificate has been granted and who is responsible for guaranty of all aspects of the medical product including quality, and safety and compliance with the conditions of registration.

“Importer” means any person(s) or corporate body permitted and authorized under the laws in Liberia pertaining to medicines and health products, agro-medical products and household Medical products to import pesticides and laboratory and cleaning Medical products.

“Manufacturer” means a person or corporate body or other entity engaged in the business of manufacturing medicines and health products, pesticides and/or laboratory or Medical products.

“Product License Holder” means a person or business which could be the manufacturer, importer, distributor or the registration certificate holder of a medicinal/cleaning chemical, laboratory chemical and pesticide and has the primary responsibility for the supply and distribution of the product in Liberia.

Recall/ Withdrawal” means a process for removing a medicinal and health product, a cleaning chemical, laboratory chemical and pesticide from the distribution chain because of defects in the product, complaints of serious adverse reactions to the product and/ or concerns that the product is or may be counterfeit.

“Confiscation” means the act of taking (something) away from someone especially to enforce the law or rules

“Unfit products” means:

- a) Products under the Act that are expired, improperly sealed, damaged, within date (unexpired) but improperly stored, improperly labelled, substandard or falsified, adulterated, prohibited or unauthorized; or any advertisement thereof.
- b) Any product under the Act but does not meet regulatory requirements or when consumed or used can be injurious to the health of the consumer.
- c) Any product 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

“Substandard” means a medicine that does not comply with the applicable quality standards adopted by the Authority

“Forgery and counterfeit” mean A person has committed forgery or counterfeiting, if, with the purpose of deceiving or harming the government or another person, or with knowledge that he is facilitating such deception or harm by another person, he

- a. Knowingly and falsely makes, completes or alters any writing or subject; or
- b. Knowingly utters a forged or counterfeited writing or object.

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

CHAPTER II PRODUCT RECALL, WITHDRAWAL AND CONFISCATION

Section 1: Obligation to Recall

1. The Authority oversees and ensures recall, withdrawal or confiscation of medicines and health products and closely monitors the process.
2. In the event of recalls, the manufacturer or Marketing Authorization Holder takes full responsibility. If the recalling performance is deemed inadequate, the Authority shall take appropriate actions to remove the product from sale or use as required.
3. The manufacturer, wholesale dealer or product license holder may initiate the recall or the Authority may notify or mandate the process.

Section 2: Types/ Classification of Recall or Withdrawal

1. Class I Recalls

Class I recalls are carried out when medical products are life-threatening or could cause a high risk to health. Examples include:

- a. Wrong product (label and content are different products);
- b. Correct product but wrong strength;
- c. Microbial contamination of sterile product;
- d. Contamination with another chemical with serious health consequences
- e. Wrong active ingredient
- f. Product mix up
- g. Product pre-mature deterioration

2. Class II Recalls

Class II recalls are carried out when products defect could cause illness or mistreatment, but are not Class I. Examples include:

- a. Mislabeling e.g. wrong or missing text or figures
- b. Missing or incorrect information- leaflets or inserts with packing

- c. Microbial contamination of non-injectable, non-ophthalmic sterile product with medical consequences
- d. Chemical/ physical contamination (significant impurities, cross contamination, particulates)
- e. Mix up of products in containers
- f. Non-compliance with specification (e.g. assay, stability, fill/ weight or dissolution)
- g. Insecure closure with serious medical consequences (e.g. cytotoxins, child resistant containers, potent products, toxic chemicals)

3. Class III Recalls

Class III recalls are carried out when product defects may not pose a significant hazard to health, but withdrawal may be initiated for other reasons. Examples include;

- a. Faulty packaging e.g. wrong or missing batch number or expiry date
- b. Faulty closure
- c. Contamination- microbial spoilage, dirt or detritus, particulate matters

Section 3: Classification of Recall

Recall actions are rated according to the classification of the issue on the health of the patient or user of the therapeutic product.

Class I: recalls occur when the defect identified in the product is potentially life-threatening or could cause a serious risk to health.

Class II: recalls occur when the defect identified in the product could cause illness or incorrect treatment and the risk might cause serious injury or temporary illness

Class III: recalls for products which are unlikely to cause injury or illness, but that violate LMHRA regulations.

Level of Recall Action

A recall action is conducted to an agreed level in the supply chain depending on the distribution of the product and the severity of the issue. The various levels of recall action are described below:

Level A – Involves Wholesale level

This include all parties involved in manufacturing, importing, wholesaling and retailing.

Level B – Involves Retail level;

- i. All public and private hospital pharmacies;
- ii. Retail pharmacies;
- iii. Clinical investigators and the institutions in which clinical investigations are performed;
- iv. Medical, dental, veterinary and other health care practitioners;
- v. Nursing homes and other related institutions;
- vi. Other retail outlets e.g. medicine shops, agro Medical products shops, pesticides shops, laboratory Medical products shops, supermarkets and health food stores; and farms

Level C – Involves Consumer level;

- i. Patients and other consumers;

Section 4: Steps in the Recall/ Withdrawal/ Confiscation Procedure

The steps to be followed by the Authority in the recall of products shall be divided into four:

1. Notification of Product problem

The recall might be initiated as a result of complaints by consumers on its quality or safety (based on change in physical appearance) of the product. It might also be as a result of test carried out by the quality control laboratory of the Authority on samples of a product obtained from post marketing sampling or based on request from international companies or health authorities.

Class I or Class II recalls must be reported to the Authority within 24 hours after receipt of the complaint for investigation.

Class III recalls must be reported to the Authority not later than 72 hours

2. Initiation of Recall and Information Required for Assessment of Recall.

The Authority must be notified by the product license holder of the recall situation by using the Product Recall Notification Form. The information required may include:

a. Details of the Problem

- i. Name and telephone number of the person/institution reporting the problem;
- ii. date of report;
- iii. complete address of the person/institution reporting the problem;
- iv. nature of the problem;
- v. number of similar reports received;
- vi. results of tests and other investigations on suspect or other samples.

b. Details of the Product

- i. name of the product and description including active ingredients,
- ii. dosage form, strength, registration number, pack size or type;
- iii. batch number(s), quantity of the batch and expiry date;
- iv. manufacturer/ distributor's telephone number(s) and email address;
- v. date manufactured, date released or imported in Liberia;
- vi. local distribution list;
- vii. oversea distribution list of products exported from Liberia;

c. Health hazard evaluation and proposed action

- i. type of hazard, and evaluation of health hazard to user;
- ii. action proposed by the Product license holder;
- iii. proposed recall classification and level; and
- iv. availability of alternative product.

3. Assessment of Recall (Recall Strategy)

In the recall strategy, the Product license holder should mention the following:

- a. Indicate the proposed level in the distribution chain to which the recall is extending

- b. if the recall only extends to the wholesale level, the rationale of not recalling to retail level should be explained;
 - c. In case of *consumer level* recall, additional information should be mentioned;
 - i. Indicate the location of recall spots for consumers (preferably not less than 10 recall spots covering different counties in Liberia), their operation time and duration (at least 7 days);
 - ii. Indicate the hotlines number(s) for enquiry and the corresponding operating hours;
 - iii. Indicate the proposed refund mechanism at the recall spots, the conditions of refund (applicable to opened products, expired products or parallel-imported products) and methods of refund (by means of money, credit notes or product replacement etc.);
 - iv. Indicate the method of notification (e.g. mail, phone, facsimile, email);
 - v. Indicate how the message of recall will be delivered to customers e.g. press release or recall letters, etc.;
 - vi. If the Product license holder has a website, it should consider posting the recall notification on it as an additional method of recall notification;
 - vii. Report on what the customers been instructed to do with the recalled product;
 - viii. Explain if the recall will create a market shortage that will impact on the consumer;
 - ix. Determine and provide the course of action for out-of-business distributors;
 - x. Provide a proposed disposal plan of the recalled products, whether they would be destroyed, reconditioned or returned to overseas manufacturer; and
 - xi. Inform the Authority before product destruction. Such destruction must be in accordance with the guidelines for wastes disposal approved by the Authority.
4. Communication to the Public:
- a. The product license holder must prepare letters with a factual statement of the reason(s) for the recall of the product, indicating specific details that will

allow the product to be easily identified. The said letters will be prepared and disseminated within a period of two weeks prior to product recall.

- b. The letter may be sent by mail to the clients or by press release either by electronic or print and it should use company letterhead including date, name and title of authorized or responsible person.
 - i. Content of the recall letter must include:
 - a. Description of the cleaning chemical, laboratory chemical and pesticide;
 - b. Hazard associated with the product;
 - c. Instruction for recall of the product;
 - d. Duration (within seven (7) working days) for communication to the public.
5. Responsibilities of Product License Holders:
- a. Maintain records and establish procedures which will assist in facilitating the recall should such action become necessary;
 - b. Take prime responsibility for implementing recall where applicable.
6. Evaluation of the Recall
- a. The Authority shall evaluate the recall in two different ways:
 - i. A check on the effectiveness of the recall (by checking the distribution plan)
 - ii. An investigation of the reason for the recall and remedial action taken to prevent a recurrence of the problem.

CHAPTER III REINSTATEMENT OF SUPPLY

Section 1: Remedial Action

1. Implementation of Remedial Action
 - a. The Product license holder must identify the root cause of the problem and implement corrective action and preventive action (CAPA).
2. Submission of Analytical Report
 - a. After implementing the remedial action and subsequent manufacturing or importing the new batch of the product, the Product license holder must submit analytical report(s) of the new batch tested by external accredited laboratory to the Authority as a proof of product quality.
 - b. The Authority will evaluate the submitted report after evaluation. The Authority will inform the Product license holder whether the submitted reports are satisfactory.

3. Sampling

In addition to the analytical report required above, samples of the product manufactured or imported after the Authority will sample the recall for analysis. The Authority can release the product for marketing only upon approval of reinstatement.

CHAPTER VI 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) or institution(s), their legal representatives or agents who imports, distribute, offer for sale, procure for sale, sell or administer to any person(s) or animal(s), any products classified as substandard, falsified and unfit for its intended purpose, violates Chapter IV of this regulation and subjects the person(s) or institution(s), their legal representatives or agents to a fine of Five Thousand United States Dollars (US \$5,000) in addition to the said products being immediately recall and destroy in keeping with this regulation. Where the products mentioned herein were distributed and offer for sale at the detriment of the general public and consumed without the knowledge of Authority, upon notification of said gross violation, the license of the perpetrators will be revoked until all defects are cued and the Authority deem necessary to reissue said license. Any reports of adverse effects of products in this category which are life threatening, the perpetrator shall be required to face civil damages where applicable.
2. Any person(s), institution(s), their legal representatives or agents who knowingly imports, distribute, offer for sale, procure for sale, sell or administer to any person(s) or animal(s), products which has been prohibited under Chapter IV of this regulation, shall be guilty of misdemeanor of the first degree.
3. Any person(s), institution(s), their legal representatives or agents who disposes of unfit product without notification to the Authority and approval to proceed with said disposal, violates Chapter V Section 1 of this regulation and will be penalized consistent with.
4. In the course of exercise of its obligation to recall and destroy products strictly prohibited by this regulation, any person(s) or institution(s), their legal representatives or agents who fails to comply with or resist the procedures herein, shall be subject to regulatory fines not exceeding Five Thousand United States Dollars (US \$5,000.00 on first offence. A repeat of said non- compliance or resistance, shall constitute a wanton disregard of the legal obligations of the Authority and thus lead to revocation of the said perpetrators license and or permit.

SCHEDULES

SCHEDULE 1: PRODUCT RECALL REQUEST FORM

Code: 003A

| | | | |
|--|--|---------------------------------------|---|
| Circular No: | | Date: | |
| Recall Title | | | |
| Class of Recall: | <input type="checkbox"/> Class I | <input type="checkbox"/> Class II | <input type="checkbox"/> Class III |
| Level of Recall | <input type="checkbox"/> Wholesale level | <input type="checkbox"/> Retail level | <input type="checkbox"/> Consumer level |
| DETAILS OF THE PRODUCT | | | |
| Name of the product (Brand and Generic) | | LMHRA Registration Number | |
| Active Ingredients & Strength: | | | |
| Affected batch number: | | | |
| Manufacturer: | | | |
| Manufacturing Date: | | | |
| Expiring Date: | | | |
| Details about the nature of the issue leading to the recall | | | |
| Action | | | |
| <input type="checkbox"/> Instruction to immediately stop prescribing/dispensing/distributing or using and quarantine affected stock. | | | |
| <input type="checkbox"/> An instruction regarding the return of affected stock. | | | |
| <input type="checkbox"/> Instruction for the local agent to complete the Progress and Final Recall report attached | | | |
| <input type="checkbox"/> A statement to all healthcare professionals to report ADR, quality problems and medication errors to the Department of Pharmacovigilance and Drug Information | | | |

Name of Reporter: _____

Contact #: _____

Date: _____

SCHEDULE 2: PRODUCT RECALL REGISTRATION FORM

Code: 003B

| DETAILS OF THE PRODUCT | | |
|--|---------------------------------------|----------------------------|
| Name of the product (Brand and Generic) | | LMHRA Registration Number |
| Active Ingredients & Strength | | |
| Specification/Category of Distribution | | |
| Dosage form | Pack size | |
| Batch number | Expiry date | |
| Distribution of products: Public Hospitals: [], Private hospitals: [], Pharmacies: [], Medicine stores: [], Public Clinics: [] Others (specify) | | |
| Manufacturer Information | | |
| Name | | |
| Address | | |
| Tel | Fax | Manufacture date |
| Quantity of the batch manufactured | | Date and quantity released |
| Quantity in stock | Quantity distributed: Local Export | |
| Importer Information | | |
| Name | | |
| Address | | |
| Tel | Fax | Import date |
| Quantity of the batch imported | | Date and quantity released |
| Quantity in stock | Quantity distributed: | |
| | Local re-exported | |
| Local Distributors (please attach distribution list) | | |
| No. of local distributors | | |
| Name | | |
| Address | | |
| Contact Person | Tel (office & mobile) | |
| Quantity in stock | Quantity distributed: | |
| | Local re-exported | |
| Exporter | | |
| Has the product been exported outside Liberia? Yes No If yes, specify the exported countries. | | |
| The estimated time frame for the completion of the recall | | |

Name of Reporter: _____

Supervised by: _____

Contact #: _____

Contact #: _____

Date: _____

Date: _____

SCHEDULE 3

PRODUCT RECALL VERIFICATION FORM

Code: 003C

| DETAILS OF THE PRODUCT | |
|---|---------------------------|
| Name of the product (Brand and Generic) | LMHRA Registration Number |
| Active Ingredients & Strength | |
| Indications | |
| Dosage form | Pack size |
| Batch number | Expiry date |
| Reasons for recall | |
| Extent of Distribution | |
| Quantity exported | Countries of Export |
| Action taken by the Authority | |
| Urgency of the action taken | |
| Reason for the action | |
| Steps taken to prevent re-occurrence of the problem | |
| Result of Recall | |
| Quantity of stock sold: | |
| Quantity of stock returned: | |
| Quantity of stock outstanding: | |

Name of Reporter: _____

Supervised by: _____

Contact #: _____

Contact #: _____

Date: _____

Date: _____

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

A Regulation for Medicines and Health Products Recall, Withdrawal & Confiscation 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 Medicines and Health Products Recall, Withdrawal & Confiscation is Hereby Submitted to the Chairman of the Board of Directors for Approval.

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

A blue ink signature of Prof. Hasipha C. Tarpeh, written in a cursive style.

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