



LIBERIA MEDICINE AND HEALTH PRODUCTS REGULATORY AUTHORITY (LMHRA)

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Guidelines on Recall and Rapid Alert System

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DECLARATION

This guideline is made in fulfillment 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 *Guideline for Recall and Rapid Alert System for Medicinal Products* **this 13th** day of **April**, 2026.

CHAPTER I PRELIMINARY CONSIDERATIONS

○ Section 1: Title

This guideline shall be cited as the guidelines for recall and rapid alert system for medicinal products and shall come into operation on the date of publication.

○ Section 2: Purpose

This guidelines on recall and rapid alert systems for medicinal products aim to ensure public health safety by effectively managing defective or potentially harmful products.

○ Section 3: Objective and Scope

This guideline shall apply to all reports of defective products quality and all safety and efficacy incidents reported and received for all medications and health products including biologicals. All licensees (manufacturers, importers, local agents, distributors, retailers, hospitals, and clinics) are to be guided by the provision of this guidelines, meanwhile, recalls can be voluntary or statutory. The objective of this guideline is to assist in the adoption of the stepwise actions to be followed in developing and implementing rapid alert system strategy at each level and compliance with time frame. This guideline is mainly applied in conjunction with the regulation on recalls and is applicable to distributed and marketed products or batches; and in incase of the non-conformity of products or batches that have not been marketed, there is no need for the issuing of a recall.

○ Section 4: Acronyms and Definitions

- **Medicine:** 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 human or animal, or b) restoring, correcting, or beneficial modification of organic or mental functions in human or animal. c) shall include traditional medicines, narcotic drugs, psychotropic substances, blood and blood products, vaccines, sera, and radiopharmaceuticals, but not health products as defined herein.
- **LMHRA:** Liberia Medicines and Health Products Regulatory Authority
- **Health products:** refer to any items, goods, or substances designed to promote, maintain, or improve physical or mental well-being. These products are typically intended to prevent illness, manage health conditions, enhance physical fitness, or improve overall quality of life. Health products can be consumed, applied topically, or used in various ways depending on their purpose.

- **Recall:** Removal of marketed products for reasons of lack of quality, safety, or efficacy, including labeling that is against the regulation of pharmaceuticals.
- **Batch (es) recall:** The process of removing the selected lot(s) from a product that is found to be defective and poses health risks to consumers if left in the market.
- **Batch:** A specific amount of material produced in a process or series of processes that is expected to be homogeneous within certain limits.
- **Customer:** Any person, institution or entity that purchases / receives goods from the company for storage, distribution and sale.
- **Substandard medical products:** also called ‘out of specification’ refer to authorized medical products that fail to meet either their quality standards, or their specifications or both.
- **Falsified medical products:** are products that deliberately or fraudulently misrepresent their identity, composition or source.
- **Voluntary Recall:** Recall initiated by a Licensee as a result of an abnormal observation in the quality of any product during a periodic (internal/external) review or investigation of a market complaint or any other failure.
- **Statutory Recall:** A recall directed by National Medicines regulatory authorities after verification that a product is in violation of the regulations.
- **Recall letter:** a document issued by the authority stating the withdrawal of marketed products as a result of lack of quality, safety, or efficacy, including labeling that is against the law directed to all the relevant stakeholders as well as the public.
- **Alert notice letter:** a document issued by the authority stating the alerting of the entire rapid alert contact list of the presence of counterfeited product as well as the public.
- **Public awareness letter:** Notification issued by the regulatory authority and published on the LMHRA website notifying the public of incidence of the possible presence of SF product marketed.
- **Rapid alert contact list:** it is contact list of the entire stakeholders and other relevant organizations Contact details include telephone and fax numbers, electronic mail address, who should be notified in case of the presence of SF product.
- **Rapid alert system:** procedures done by the authority for rapid notification of the licensee, manufacturers, the entire stakeholders, other relevant organizations and the public in case of issuance of recall letter/rapid alert notice letter for substandard/falsified respectively that could affect the public health

- **The entire amount of the non-conforming product**, the product that has been detected in the market and is still available at the time of recall letter issuance, is supplied through evaluating the effectiveness of the recall according to the data of the distributed quantities by the licensee or manufacturers of the recalled product, the quantities that have not been distributed by the licensee, the manufacturers, the quantities that have not been distributed by the entire stakeholders, and the quantities distributed by the entire stakeholders.

CAPTER II GENERAL CONSIDERATIONS

2. 1: Introduction

A recall is an action taken to withdraw or remove medicines and health products from distribution or use including corrective actions for which deficiencies in quality, efficacy or safety have been reported. Quality-related defective products include substandard and falsified medicinal products. Recalls regarding safety and efficacy include serious adverse reactions and death. The recalls also include medicinal products prohibited by LMHRA as well as products whose licenses have been suspended or revoked.

The recall applies to all pharmaceuticals, including biological preparations, cosmetics, medical supplies and health products etc.

The rapid alert system is the actions taken in the event of warnings, the urgency and seriousness of which does not allow any delay in the alert. An assessment should be made of the severity of the defect and its potential to cause harm to the patient.

○ 2.2: Recall Action Classification (RAC)

Recall classification assigned to a particular product recall indicates the relative degree of health hazard by country regulatory authorities.

Class I: A dangerous or defective product that can cause serious health problems or lead to death. For instance: Microbial contamination of sterile injectable or ophthalmic product, Correct product but wrong strength, with serious medical consequences, Chemical contamination with serious medical consequences

Class II: A product that may cause a temporary health problem or pose a minor threat of a serious nature. For instance: Mislabeling, e.g., wrong or missing text or figures Missing or incorrect information (leaflets or inserts)

Class III: A product that is not likely to cause a health problem but violates labeling or manufacturing laws and guidelines.

○ **2.2.1 Levels of Recall Action (LORA)**

The level (or depth) of product action recall should be determined based on the redemption classification and the level to which it was distributed.

There are three levels of recovery:

Consumer or user level:

Individual consumers, patients, doctors and hospitals.

Retail level: Call to the level immediately preceding the consumer or user level. It includes pharmacies and hospital pharmacies.

Distributor level:

All levels of distribution between manufacturer and retailer.

All invocations must be executed from

Level I to distributor, retail and consumer levels. In such cases, public advertising should be done using media, electronic, newspapers, television, and radio etc., In addition to obligating the distribution companies to print the recalled item on their sales invoices.

Level II to distributor and retail levels.

level III to distributor levels.

○ **2.3 Phases of Recall**

The Recall Action Process involves the following phases of activity

- An initiation phase when problem identification, risk assessment, the decision on whether to recall, and the planning for the recall action occurs.
- An implementation phase when the recall action notice is issued by the sponsor and the requested recall action is undertaken.
- A review phase when monitoring and review of the effectiveness of the recall action is undertaken by the sponsor with oversight by authority.

CHAPTER III Rapid Alert System (RAS)

○ Section 1: Rapid Alert System (RAS)

This procedure covers the transmission of information when urgent action is required to protect public health by means of a rapid alert relating to the recall or withdrawal of medicinal products that have quality defects or that are falsified. The aim of the Rapid Alert System is to transmit those alerts whose urgency and seriousness cannot permit any delay in transmission.

Section 2: Criteria for Rapid Alert Notification (CRAN)

The urgency of the removal of defective medicinal products can be classified as follows:

Class I Recall Products are considered potentially life-threatening.

A rapid alert notification must be sent to all contacts on the rapid alert notification list irrespective of whether or not the batch was distributed to that level.

Transmission of a Class I rapid alert must be within 24 hours. Issuance of recall letter shall be done within the maximum period of 48 hours. The notification shall be sent stating the severity of the defect, using the fastest mode of communication, which may include email, telephone, WhatsApp groups, fax, SMS, etc., to the entire pharmaceutical supply chain.

The authority shall offer guidance to the recalling firm so that the product will be promptly removed or corrected.

Alert notifications shall be in multiple forms, including press releases, telephone calls, telegrams, telefaxes, mailgrams, or first-class letters.

Alert notifications should be brief and to the point; clearly identify the product(s), such as the product name, size, brand name, serial number(s), potency, dosage, type, model, and batch number.

Alert notifications should be sent in the most expeditious manner and commensurate with the hazard of the product being recalled and, where appropriate, sent with proof of receipt (e.g., by certified mail).

The licensee or local agent where the product is marketed shall inform the authority where the product batch(es) in question were distributed immediately after the decision of recall has been taken. Further actions on recall will be undertaken according to class of recall.

Class II Recall Products could cause illness or mistreatment .

A rapid alert notification shall be sent to all contacts on the rapid alert notification list. It might be difficult to know where a batch has been distributed. If the product distribution is known, the notification should be sent only to the contacts concerned. Whenever feasible, transmission of a Class II rapid alert should be transmitted within 72 hours.

Class III Recall Products may not pose a significant hazard to health, but notification of all stakeholders should be done within 5 days of the recall letter issuance.

For the falsified product that an alert notice letter or public awareness letter has been issued, a rapid alert notification should be sent to all contacts of the rapid alert notification list within 24 hours, with a maximum of 72 hours of the issuance.

The contact list for rapid alert notifications shall be used for the transmission of notifications falling in the scope of this procedure and the GMP non-compliance procedure; these messages should clearly identify the subject and whether they are for information or action.

All procedures should be documented and maintained up to date. The rapid alert contact lists for officials and manufacturers should be maintained up-to-date and should be verified at intervals (e.g., a rolling program of annual checks of company contacts, possibly as part of GMP inspections).

All staff who could be involved in receiving a report of a suspected defective product or handling a **Rapid Alert should be trained in the relevant procedures** and have access to a copy of the CA's and report forms wherever they needed.

Section 3: Criteria for recall letter and rapid alert notice publication

Upon the issuance of the recall letter or the alert notice letter by the authority, the publication on the authority website should be done according to the category of risk involved. This is done based on the category of risk involved:

Class I recall: publication is made within 24 hours, with a maximum of 48 hours.

Class II recall: publication is made within 72 hours.

Class III recall: publication is notified within 5 days. Alert notice letter or public awareness letter: publication is made within 24 hours, with a maximum of 72 hours.

3.1 Intervals for Efficient Recall System (IERS)

This is done based on the category of risk involved:

Class I recall: the recall process is executed with a maximum of 14 days.

Class II recall: the recall process is executed with a maximum of 21 days.

Class III recall: the recall process is executed with a maximum of 30 days.

The authority reserves the right to determine the maximum time for recall depending on the urgency and health risk involved.

3.2 Implementation Steps of the Rapid Alert System (ISRAS)

- Identification of Defective Products
- Classification of Defects
- Notification Process
- Public Communication
- Documentation and Record Keeping
- Follow-Up Actions
- Monitoring and Evaluation
- Final report

Note: Implementation of Recall should be done in line with the guideline of Recall of product

3.3 Follow-up procedures for Rapid Alert System of Recall

The follow-up procedure consists of checking the effectiveness of the recall, investigating the cause of the recall, and remedial actions taken to prevent recurrence of the defect.

i) Immediate Notification

Upon the issuance of a recall notification, the recalling firm must promptly inform all affected distributors, wholesalers and Local agent within the supply chain. This includes:

- Notifications to all contacts on the rapid alert notification list/Stakeholders' list.
- Utilizing various communication methods such as email, telephone, fax, and SMS to ensure rapid dissemination of information.

ii) Documentation of Rapid Alert Notification

All rapid alert regarding the recall must be documented meticulously. This includes:

- Keeping records of who was notified and when.
- Documenting the method of communication used (e.g., email, phone call).
- Maintaining a log of responses received from recall list regarding their acknowledgment of the recall.

iii) Effectiveness Check of Rapid Alert System

The recalling firm is responsible for conducting effectiveness checks to verify that all consignees have received the recall notification and taken appropriate action.

- Follow-up calls to confirm receipt of notification
- Follow up with additional reminders if initial rapid alert notification were not acknowledged.

iv) Timelines for Actions

Different classes of recalls have specific timelines for follow-up actions:

- **Class I Recalls:** Must be resolved within a maximum of 14 days.
- **Class II Recalls:** Should be addressed within a maximum of 21 days.
- **Class III Recalls:** Require resolution within a maximum of 30 days

v) Finalization and Termination

If all reasonable efforts have been made to remove or correct the product in accordance with the recall guidelines and the recall rapid alert system strategy, a request can be made for termination of the recall by submitting documentation confirming compliance with all requirements.

CHAPTER IV APPEALS

Section 1: Procedure for Appeals

The licensee or manufacturer has the right to submit a technical appeal directly to the head of the authority with all technical justifications within fourteen days of the recall issuance.

These appeals are then directed to the relevant department to investigate and prepare a detailed report about the issue in question, accompanied with all related documents to be viewed by the deputy managing director for technical services for a final decision.

Unsatisfied applicants may only resort to the LMHRA hearing board; all other appeals shall be deemed as previously resolved, except for those admitted accompanied by new technical documents.

The grievance shall be submitted not later than sixty days from the date of the recall issuance, which will be submitted to the hearing board. A ruling on the hearing board shall be rendered within sixty days of the grievance submission.

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

The guideline for recall and rapid alert system for medicinal products is Hereby Promulgated on this 13th Day of April A. D. 2026 by the Managing Director of the Authority.



Hon. Luke Bawo
Managing Director / LMHRA