



LIBERIA MEDICINES & HEALTH PRODUCTS REGULATORY AUTHORITY (LMHRA)

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REGULATIONS ON DEFECTS AND QUARANTINE OF MEDICINES AND HEALTH PRODUCTS



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DECLARATION

This Regulation is made in fulfilment 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 Board of Directors by consensus, hereby promulgates this regulation designed for Medical Devices this 20th day of April, 2023.

CHAPTER 1:PRELIMINARY

Section 1.1: Title

This Regulation shall be cited as the Regulation on Quarantine of Medicines and Health Products and shall come into operation on the date of publication.

Section 1.2: Application and Scope

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

Section 1.3: Purpose

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

Section 1.4. 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.

Authority

This means the Liberia Medicines and Health Products Regulatory Authority.

“Critical defect”

A defect is deemed as one that can pose a serious threat to the intended users or public health. A serious threat means a hazard that occurs in association with the use or administration of Medicines and Health Products that may lead to the death of, or a serious injury to, any person. Serious injury refers to an incident that:

- May result in a person being hospitalized or prolong a person’s existing stay in the hospital;
- May result in a person’s disability or incapacity; or
- May result in a congenital anomaly or birth defect.

Health Product includes:

- 1. 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
- 2. Medical Supply** which means 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 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, X-Ray film and other similar articles.

Medicines and Health Products

Medicines and Health Products are regulated under the LMHRA Act of 2010; and are intended for use by, and in humans for therapeutic, preventive, palliative, and diagnostic purposes. The meaning of ‘medicinal product’ and related expressions as stated in the LMHRA Act of 2010 (Part II: Section 1):

1. Subject to the following provisions of this section, in this LMHRA Act of 2010 “medicinal product” means any substance or article (not being an instrument, apparatus, or appliance) which is manufactured, sold, supplied, imported, or exported for use wholly or mainly in either or both of the following ways:
 - a) Use by being administered to one or more human beings or animals for a medicinal purpose;
 - b) Use as an ingredient in the preparation of a substance or article which is to be administered to one or more human beings or animals for a medicinal purpose.

In this regulation, “a medicinal purpose” means any one or more of the following purposes:

- i. Treating or preventing disease;
- ii. Diagnosing disease or ascertaining the existence, degree, or extent of a physiological condition;
- iii. Contraception;
- iv. Inducing anaesthesia;
- v. Otherwise preventing or interfering with the normal operation of a physiological function, whether permanently or temporarily, and whether by way of terminating, reducing, postponing, increasing and accelerating the operation of that function or in any other way.

“Medicinal products” as used in this context, does not include any substance or article which is manufactured for use wholly or mainly by being administered to one or more human beings or animals, where it is to be administered to them:-

- i. in the course of the business of the manufacturer or on behalf of the manufacturer in the course of the business of laboratory or research established carried on by another person;
- ii. solely by way of a test for ascertaining what effects it has when so administered; and
- iii. in circumstances where the manufacturer does not know of any evidence that those effects are likely to be beneficial to those human beings, or beneficial to, or otherwise advantageous to, those animals, as the case may be, and which (having been so manufactured) is not sold, supplied or exported for use wholly or mainly in any way not fulfilling all the conditions specified in paragraphs (a), (b) and (c).

In this regulation, a “medicinal product” does not include:

Substances used in dental surgery for filling dental cavities;

- a) Bandages and other surgical dressings, except medicated dressings where the medication has a palliative or curative function that is not limited to sterilizing the dressings; and
 - b) Substances and articles of such other description or classes as may be specified by order made by the Minister).
2. Where under subsections (1) to (4) a substance or article is a Medicinal product immediately after it has been manufactured, imported, or exported as mentioned in subsection (1), or immediately after the first occasion on which it has been sold or supplied as mentioned in that subsection, then it shall not cease to be a medicinal product for this regulation by reason only that, at any subsequent time, it is sold, supplied, imported or exported for the use wholly or mainly in a way other than those specified in subsection (1).
3. For this regulation, Medicines and Health Products are of the same description if:
- a) they are manufactured to the same specification; manufacturing methods and processes; equipment and manufacturing plant; and
 - b) they are to be sold, supplied, imported, or exported in the same pharmaceutical form.
4. For this regulation, a document, advertisement, or representation shall be taken to be likely to mislead as the uses or effects of Medicines and Health Products of a particular description if it is likely to mislead as to any of the following matters:
- a) any purposes for which Medicines and Health Products of that description can with reasonable safety be used);
 - b) any purposes for which such products cannot be so used; and
 - c) any effects which such products when used, or when used in any particular way referred to in the document, advertisement, or representation, produce or are intended to produce.

Non-critical defect

A defect which does not meet the criteria of “critical defect” but may cause illness or affect the outcome of a person’s medical treatment and/ or significantly affect the quality of Medicines and Health Products.

Product recall

Any action(s) taken by the Licensed Manufacturer/ Licensed Premise/ Licensed Importer/ Product License holder of the Medicines and Health Products to remove and or to retrieve the SF Medicines and Health Products from the market or from any person to whom it has been supplied. The recall is performed because of the SF Medicines and Health Products:

- May be hazardous to health;
- May fail to conform to any claim made by its manufacturer or importer relating to its quality, safety, or efficacy; or
- May not meet the requirements of this regulation.

Note: Retrieval of the product (for quality defect, non-compliance, safety, or efficacy reasons) after it has been made available for sale or supply is considered a recall.

Quarantine

Means the identification, isolation and storing of expired or near medicines and health products that have many deleterious effects on life or health.

Serious adverse reaction

“Serious adverse reaction” means an adverse effect that is unintended and occurs in association with the use or administration of a product at doses normally used in humans for prophylaxis, diagnosis, or therapy of a disease or the restoration, correction, or modification of a physiological function, and that:

- a) May result in a person’s death;
- b) May threaten a person’s life;
- c) Results in a person being hospitalized or prolonging a person’s existing stay in the hospital;
- d) Results in a person’s persistent or significant disability or incapacity;
- e) Results in a congenital anomaly or birth defect; or
- f) Is judged to be medically important even though the effect might not be immediately life-threatening or result in death or hospitalization, but may jeopardize the person’s health or may require intervention to prevent the person’s death or one of the other outcomes referred to in sub-paragraphs (c), (d) and (e).

Substandard & Falsified (SF) Medicines and Health Products

Substandard & Falsified (SF) Medicines and Health Products are products that have quality issues which may compromise their safety and efficacy. These include but are not limited to:

- Pose a serious threat to the intended users or public health
- May cause illness or affect the outcome of a person's medical treatment
- Significantly affect the quality of the Medicines and Health Products
- Products which have been adulterated
- Unwholesome health products
- Products which have poor quality, are unsafe or inefficacious for their intended purpose

Recall

“Recall” means an action executed by a manufacturer or mandated by the regulatory body at any time to remove SF medicines or health products from the market

CHAPTER 2: MEDICINAL PRODUCT DEFECT

Section 2.1: Introduction to Medicinal Product Defect

2.1.1 Medicines and Health Products are regulated under the Liberia Medicines and Health Products Regulatory Authority (LMHRA), Act of 2010.

2.1.2 All SF medicines and Health Products shall be deemed unfit and placed in quarantine. Medicines and Health Products have quality issues which may compromise their safety and efficacy. These include defects that:

- Pose a serious threat to the intended users or public health
- May cause illness or affect the outcome of a person's medical treatment
- Significantly affect the quality of the Medicines and Health Products
- Products which have been adulterated
- Unwholesome health products
- Products which have poor quality, are unsafe or inefficacious for their intended purpose

Section 2.2: Classification of Product Defects

2.2.1 A defect is classified into either "critical defect" or "non-critical defect" according to the potential impact on public health and the risks posed to the intended use of the Medicines or Health Products.

Section 2.2.1: Critical Defect

2.2.1.1 A critical defect is deemed as one that can pose a serious threat to the intended users or public health. In this regulation, a serious threat means a hazard that occurs in association with the use or administration of Medicines and Health Products and may lead to the death of or a serious injury to any person. Serious injury refers to an incident that:

- a) May result in a person being hospitalized or prolonging a person's existence.
- b) May result in a person's disability or incapacity.
- c) May result in a congenital anomaly or birth defect.

Section 2.2.2: Non-Critical Defect

2.2.2.1 A non-critical defect does not meet the criteria of a "critical defect" but may cause illness or affect the outcome of a person's medical treatment and/ or significantly affect the quality of Medicines and Health Products.

2.2.2.2 Examples of critical and non-critical defects commonly associated with Medicines and Health Products are listed in Annex I. As the list of examples is non-exhaustive, the Licensed Manufacturer/ Licensed Premise/ Licensed Importer/ Product License Holder may wish to clarify with the Authority specific cases/ scenarios not mentioned in Annex I.

Section 2.3: Responsibilities of the Licensed Manufacturer/ Licensed Premise/ Licensed Importer/ Product License Holder

- 2.3.1 Licensed Manufacturers/ Licensed Premise/ Licensed Importer/ Product License Holders are responsible for the safety, quality, and efficacy of their Medicines and Health Products and should have adequate systems and appropriate procedures in place to investigate, review and report the product defects to the Authority, and if necessary, to promptly recall the Medicines and Health Products from the distribution network (*See LMHRA Regulations on Product Recall*).
- 2.3.2 When there is a business arrangement amongst the Licensed Manufacturer, Licensed Premise, Licensed Importer, and Product License Holder, it shall be the responsibility of at least one party to ensure reporting of the product defect to the Authority. It is acceptable that not all parties report the same defect to the Authority. The party reporting the defect should keep the other parties informed, and the appropriate records should be kept. If unsure whether the defect has been reported by the other party (ies), the Product license Holder shall report the defect to the Authority.
- 2.3.3 Registered products can be imported by a Licensed Importer. The person importing the registered products is responsible for reporting the defect to the Authority.

Section 2.5: Legal Obligations

- 2.4.1 Licensed Manufacturer/ Licensed Premise/ Licensed Importer/ Product license Holder shall have a legal obligation under their licenses as indicated in sections 2.3.1 to 2.3.3 of this regulation.

Section 2.5: Product License

- 2.5.1 When the holder of the license has been informed by the Authority that any batch of any medicinal product to which the license relates is harmful, unsafe or does not conform to quality specifications, the holder of the license shall, if so directed, withhold such batch from sale, supply or exportation, so far as may be reasonably practicable, for such period as may be specified by the Authority and withdraw the SF Medicines and Health Products from the market.
- 2.5.2 Under the Standard Provision for Product Registration (Regulation on Medicines and Health Products Registration), the holder of the license shall notify the Authority of any decision to withdraw from the sale, supply, or exportation of any Medicines and Health Products to which the license relates, and shall state the reason for that decision.

Section 2.6: Importers' License

- 2.6.1 When the holder of the license has been informed by the Authority that any batch of the Medicines and Health Products to which the license relates is harmful, unsafe or does not conform to quality specifications, the holder of the license shall as so directed, withhold such batch from sale, supply or exportation, so far as may be reasonably practicable, for such period as may be specified by the Authority. The SF Medicines and Health Products if already in circulation, may be withdrawn from the market immediately by the Authority at the expense of the importers.

- 2.6.2 The holder of the license shall inform the Authority of any decision to withdraw the importation, sale, or supply of the medicinal product to which the license relates, and shall state the reason for that decision.

Section 2.7: Premise License

- 2.7.1 The holder of the license shall keep in his/her premise documents relating to his/her transactions by way of the sale of Medicines and Health Products to which the license relates as will facilitate the withdrawal or recall from the sale or exportation of such products.
- 2.7.2 When the holder of the license has been informed by the Authority that a batch of Medicine or Health Products to which the Premise license relates is harmful, unsafe or does not conform to quality specifications or with the provisions of the order or any regulations made thereunder that apply to the Medicines and Health Products, the holder of the license shall, as so directed, withhold such batch from sale, supply or exportation, so far as may be reasonably practicable, for such period as may be specified by the Authority and withdraw the SF Medicines and Health Products Medicines and Health Products from the market immediately if the Authority requests him to do so.

Section 2.8: Manufacturer's License

- 2.8.1 When the holder of the license has been informed by the Authority that a batch of Medicine or Health Products to which the Manufacturer license relates is harmful, unsafe or does not conform to quality specifications or with the provisions of the order or any regulations made thereunder that apply to the Medicines and Health Products, the holder of the license shall, as so directed, withhold such batch from sale, supply or exportation, so far as may be reasonably practicable, for such period as may be specified by the Authority and withdraw the SF Medicines and Health Products Medicines and Health Products from the market immediately if the Authority requests him to do so.
- 2.8.2 The holder of the license shall keep such records as will facilitate the withdrawal or recall from the sale, supply, or exportation of any Medicines and Health Products to which the license relates (*See LMHRA Regulations on Product Recall*).
- 2.8.3 Quarantine monitoring activities at the Authority shall be facilitated by the Inspectorate Department, while product defect is jointly monitored by the Quality Control Laboratory and the Inspectorate & Post Market Surveillance Department. Licensed Manufacturer/ Licensed Premise/ Licensed Importer/ Product License Holder shall appoint/ designate personnel responsible for matters relating to product defects and quarantine, and this person will be the point of contact for the Authority on such matters. This person must help the Authority to initiate the monitoring of the products and make complete and detailed monthly reports on the products monitored.

Section 2.9: Person Responsible

- 2.9.1 Licensed Manufacturer/ Licensed Premise/ Licensed Importer/ Product License Holder shall appoint/ designate personnel responsible for matters relating to product defects, quarantine, and recall and this person shall be the point of contact for the Authority on such matters. This person must help the Authority to initiate

investigations and to decide on the measures to be taken. The contact details of the designated/appointed person shall be updated for the Authority as needed.

Section 2.10: Duties of Responsible Person

Section 2.10.1: Reporting Product Defects to the Authority

2.10.1.1 Every Licensed Manufacturer/ Licensed Premise/ Licensed Importer/ Product License Holder must, upon becoming aware of any defect in the Medicines and Health Products, report the defect to the Authority per the following timelines:

- a) Critical defects must be reported within 24 hours;
- b) Non-critical defects must be reported within 7 calendar days. (Excluding Sundays and public holidays).

2.10.1.2 Notwithstanding the reporting timelines, if there is a critical defect that poses a safety risk to the public, the Licensed Manufacturer/ Licensed Premise/ Licensed Importer/ Product License Holder shall still take prompt measures to minimize the risk (including market actions) even if it needs to be done during non-working hours. If it is genuinely not possible to obtain the information promptly, the Authority must be consulted to agree on timelines and required actions. If the information required for reporting is available, unnecessary delays must be avoided. The company shall not delay the submission of the defect report while conducting the root cause investigation. Upon becoming aware of a defect in the Medicines and Health Products, the Licensed Manufacturer/ Licensed Premise/ Licensed Importer/ Product License Holder shall gather as much relevant information to assess the extent of the defect and the health risk to the intended users. The minimum information required for the submission of an initial report of product defect is:

- a) Product information;
- b) The distribution List;
- c) Description of a defect;
- d) Number of product(s) and batch (es) affected;
- e) Date of occurrence;
- f) The expiry date of affected batch (es) supplied to the market;
- g) Date of last distribution of the affected batches supplied to the market; and
- h) An identifiable reporter.

2.10.1.3 The initial report of product defect shall contain as much detail as available but reporting shall not be delayed due to the time needed to gather the full information. Product defect reports by patients/consumers shall generally be validated and confirmed by the company to rule out other factors (e.g. improper handling or storage by consumers/patients) before considering it reportable as a product defect.

2.10.1.4 When it is evident that the product defect is related to a serious threat to the intended users or public health, the Licensed Manufacturer/ Licensed Premise/ Licensed Importer/ Product License Holder shall prudently report this to the Authority ahead of the company's assessment.

Section 2.10.2: Investigation and Risk Assessment

2.10.2.1 Information and actions that will be required in the investigation report after the initial review shall include but not be limited to:

- a) Full description of the defect. For example, if it is a foreign object, describe its size and composition, etc. If it is a chemical contaminant, indicate the level of contaminant. If it is a failure to meet product specifications, to provide the specifications and all test reports;
- b) Explain how the defect occurred and the date of occurrence;
- c) Explain how the defect was discovered and the date it was discovered;
- d) Evaluation of sample(s) of the SF Medicines and Health Products obtained from the complainant (if any). The SF Medicines and Health Products need not be submitted unless requested by the Authority for examination and/or independent testing. If photos of the defect are available, please submit them when reporting the product defect;
- e) Local distribution records of affected batch (es) (i.e. date(s) of distribution, no. of units in batch (es), name(s) of the purchaser(s));
- f) Overseas distribution list of affected batch (es) exported (if applicable);
- g) Indicate whether the product was sold under a tender contract or pending tender consideration;
- h) Review of batch records and any change controls or deviations associated with the batch (es);
- i) Review of previous complaints, quality defect reports, and relevant information for any indication of recurring problems (locally or globally);
- j) Indicate if the defect affects all batches or only selected batches. Review of whether other batches and, if other products could be affected. Explain why the defect affects only selected batch (es);
- k) List down the regulatory actions taken or to be taken by other regulatory authorities or by the company (e.g. issuance of communication, suspension, recall, withdrawal of GMP certificate, withdrawal of product license, manufacturer license);
- l) Identify possible root cause(s) of the defect;
- m) Hazard assessment on the potential short-term and long-term consequences of the defect to intended users;
- n) Submit a certificate of Analysis of the affected batch (es);
- o) Examine and test retention samples if needed;
- p) Assessment of the appropriate market actions necessary for the affected stocks, including whether it is necessary to quarantine any existing stocks. As comprehensive information on the nature and extent of the quality defect may not always be available at the early stages of an investigation, appropriate risk-reducing actions should be considered at appropriate time points during the investigations. Please note that quarantined stocks can only be released, with the Authority's concurrence, when it has been determined that there is no risk in the use of the product or after appropriate corrective actions had been taken to address the risk;
- q) Indicate whether there could be a supply shortage as a result of the defect or market action; and
- r) Provide a description of the CAPA, if any, taken or to be taken to prevent a similar defect from recurring.

- 2.10.2.2 In addition, the company may be required to submit information when requested by the Authority to assist in the investigation of defects that have been brought to the Authority's awareness through any other means and where the Authority assesses that the defect (regardless of whether it has affected locally or overseas batches) have a potential impact on the batches already supplied or will be supplied.
- 2.10.2.3 In assessing the risks associated with the defect, the following should be considered:
- a) Potential consequences of the defect on the patients;
 - b) Type and nature of the product involved (e.g. product indication, route of administration, pharmacological classification, etc.);
 - c) Patient population affected (e.g. children, elderly, immune-compromised, etc.); and
 - d) The risk posed to the patient for not taking the product as a result of the defect.
- 2.10.2.4 All licensed entities must provide regular updates to the Authority on the progress of the investigation into the root cause. Upon completion of the entity's investigation, a complete investigation report with proposed CAPAs, if any, must be submitted to the Authority.
- 2.10.2.5 All licensed entities must monitor and assess the effectiveness of the CAPAs and continue to perform trend analyses regularly for any indication of recurring problems requiring attention.
- 2.10.2.6 Any decision not to execute a risk mitigation measure, which would otherwise be required must be agreed with the Authority in advance.
- 2.10.2.7 Timeline for submission of a thorough investigation report, CAPA, and health hazard assessment should be submitted within 48 hours when information is obtained from the manufacturer.

Section 2.10.3: Notify Authority Concerning Product Quarantine and Recalls

- 2.10.3.1 Every Licensed Manufacturer/ Licensed Premise/ Licensed Importer/ Product License Holder who intends to quarantine Medicines and Health Products must notify the Authority and the reasons for the intended quarantine immediately. The Authority requires Licensed Manufacturer/ Licensed Premise/ Licensed Importer/ Product License Holder to:
- a) Investigate the matter leading to the quarantine & recall of the MP and provide a report of the findings of the investigation; and/or
 - b) Take such other measures as the Authority thinks necessary. This includes but is not limited to an escalation of the class and/or level of quarantining to safeguard public health and safety. The requirements for reporting defects on defects, quarantine, and recalls of Medicines and Health Products are detailed in section 2.14.1.

Section 2.10.4: Receipt of Product Defect Reports from Licensed Public and Private Health Sectors Institutions

- 2.10.4.1 The Department of Pharmacovigilance shall be the contact at the Authority for all reports of SF Medicines and Health Products Medicines and Health Products from all procurement entities in the public and private health sectors. After a brief and initial assessment by the Authority, these reports shall be sent to the supplier and/or manufacturer for further investigation. The Authority shall duly be notified concerning product defects.
- 2.10.4.2 Procedures for the handling of all written and verbal reports regarding a possible product defect which includes acknowledgement to the complainant shall be developed by the product supplier/manufacturer. A detailed record of each product defect received from all complainants shall be kept by the supplier/manufacturer.
- 2.10.4.3 All SF Medicines and Health Products product reports are to be forwarded to the manufacturer for further investigation. The procedure shall ensure that the SF Medicines and Health Products product reports received are investigated and followed through and that all corrective actions are taken to prevent repeated incidences. The complainant shall be provided with the response after the completion of the investigation within fourteen (14) days.

Section 2.10.5: Maintain Records of Product Defects

- 2.10.5.1 All Licensed Manufacturers/ Licensed Premises/ Licensed Importer/ Product License Holders of Medicines and Health Products must maintain records of every defect in Medicines and Health Products for at least 2 years after the expiry date of the Medicines and Health Products and produce such records for inspection by the Authority when required. The records must contain the following information:
- a) The proprietary name of the Medicines and Health Products ;
 - b) The date on which the Licensed Manufacturer / Licensed Premise/ Licensed Importer/ Product License Holder first became aware of the defect;
 - c) The batch number of the Medicines and Health Products ;
 - d) The nature of the defect; and
 - e) Any information that the Authority may specify in writing.

Section 2.10.6: Replacement of SF Medicines and Health Products

- 2.10.6.1 The Licensed Manufacturer/ Licensed Premise/Licensed Importer/Product License Holder shall be required to provide immediate replacement of SF Medicines and Health Products and quarantined Medicines and Health Products. The supplier shall be required to provide details of the replacement such as the *name of the product, quantity, batch number, and expiry date*. The Pharmacovigilance department shall advise the supplier to send the replacement directly to the complainant if the quantity is small. The Supplier shall issue a letter of replacement to accompany the replacement product to the complainant. The Supplier must seek advice from the Pharmacovigilance Department:

- a) If the replacement quantity is large.
- b) If a replacement of the same product is not feasible. In this case, the options are:
 - To replace with other Medicines and Health Products of equivalent value that are currently being used in Liberia, or
 - To provide credit notes of equivalent value of the product.

2.10.6.2 Details of this arrangement shall be between the particular complainant and the supplier.

Section 2.11: Reporting and Review of Medicines and Health Products Defects

Section 2.11.1: What needs to be reported to Authority

2.11.1.1 Critical and non-critical defects of Medicines and Health Products that affect the following:

- a) Batches that have been imported for supply or already supplied;
- b) Batches that have not been supplied into Liberia but where the Licensed Manufacturer/ Licensed Premise/ Licensed Importer/ Product License Holder is aware that the root cause for the defect could potentially affect the local and/or future importation.
 - i. Let it be noted that the above defects shall include those resulting from manufacturing deviations, or non-compliance to Good Manufacturing Practice (GMP) at a manufacturing plant (which may be located in Liberia or overseas);
 - ii. Any specifications including those that could lead to a product being quarantined need to be notified. The company would need to report out-of-trend or out-of-specification results for the drug substance if there is a potential follow-up from GMP non-compliance or further action taken later in the product's shelf life;
 - iii. When a product defect is discovered or suspected in a batch, consideration should be given to determine whether other batches are also affected;
 - iv. Additionally, the Licensed Manufacturer/ Licensed Premise/ Licensed Importer/ Product License Holder shall be required to submit information when requested by the Authority to assist in the investigation of defects that have been brought to the Authority's understanding through any other means and where the Authority assesses that the defect (regardless of whether it has affected local or overseas batches) have a potential impact on the Medicines and Health Products supplied in Liberia.

Section 2.12: Reporting Product Defect to the Authority

2.12.1 Licensed Manufacturer/ Licensed Premise/ Licensed Importer/ Product License Holder should use the reporting form provided in **Annex II** to report product defects to the Authority.

2.12.2 The Licensed Manufacturer/ Licensed Premise/ Licensed Importer/ Product License Holder must provide the key preliminary information of the defect such as:

- a) classification of the defect;
 - b) description of the defect;
 - c) details of the affected product(s) and batches;
 - d) company's preliminary assessment; and
 - e) any immediate mitigation actions.
 - f) The completed product defect reporting form and any other accompanying documents must be submitted to the Pharmacovigilance Department via e-mail at info@lmhra.gov.lr.
- 2.12.3 The Authority shall contact the Licensed Manufacturer/ Licensed Premise/ Licensed Importer/ Product License Holder when the defect requires reclassification based on the assessment of the preliminary information provided. The classification of the defect may change as more information becomes available.

Section 2.13: Submission of Investigation Report

- 2.13.1 An investigation report shall be requested by the Authority for all critical and non-critical defects.

Section 2.14: Reporting of Local Serious Adverse Reaction Related to a Product Defect

- 2.14.1 In addition to reporting the defect to the Authority, when the Licensed Manufacturer/ Licensed Premise/ Licensed Importer/ Product License Holder is aware of any local serious adverse reaction (SAR) that is assessed or suspected to be caused by the defect, a separate report for the SAR must be submitted to the Authority.
- 2.14.2 The Licensed Manufacturer/ Licensed Premise/ Licensed Importer/ Product License Holder must also inform the Authority of any quarantine that it wants to carry on under the stipulated timeline.

Section 2.15: Recalls Related to Product Defects

- 2.15.1 The Licensed Manufacturer/ Licensed Premise/ Licensed Importer/ Product License Holder must also inform the Authority of any recalls that it wants to conduct under the stipulated timeline. For details on recalls, please refer to the "LMHRA Regulation on Recalls" (LMHRA-R-[RECAL]-21-007)

Section 2.16: Regulatory Actions Arising from a Product Defect

- 2.16.1 Upon receipt of the product defect report, the Authority shall review the information provided in the report and may request the Licensed Manufacturer/ Licensed Premise/ Licensed Importer/ Product License Holder to provide any further information required for the Authority's assessment;
- 2.16.2 Depending on the potential risk to the intended users or public health, the Authority shall undertake additional risk control measures:
- a) product recall;
 - b) issuance of "Dear Health Care Professional Letter" and/or;
 - c) Issuance of Press Release.
- 2.16.3 The Authority shall also suspend or cancel the product registration when there are critical and/or major defects that have not been addressed. This shall be assessed on a case-by-case basis.

Section 2.17: Reporting Medicinal Product Defects & Follow Up

Section 2.17.1: Ministry of Health Facilities & Licensed Non-Profit and Donor Importer Institutions

- 2.17.1.1 Any Medicines and Health Products procured by the Ministry of Health Facilities and all Licensed Non-Profit Importer Institutions, including the Ministry of Health Procurement Unit, CMS, and the vertical programs, that showed any indications of the defect must be reported to the Pharmacovigilance Department of the Authority.
- 2.17.1.2 The product defect report shall be investigated and the conclusion shall fall under any of the categories below depending on the severity of the defect and risk assessment by the Pharmacovigilance Department:
- a) No further action - For monitoring only.
 - b) To issue an Awareness Alert - Items shall still be dispensed to patients with advice before dispensing to patients. An Awareness Alert shall also be issued when a low-risk defect has been identified but due to supply concerns, the product shall not be quarantined and/or recalled.
 - c) To issue a Quarantine Alert - The item shall be quarantined awaiting further investigation by the manufacturer or the Authority to determine if the defect is noncritical or critical.
 - d) To issue a Product Recall Alert - The item shall be recalled.
- 2.17.1.3 A letter detailing the defect and sample (if available) shall be sent to the Licensed Manufacturer/ Licensed Premise/ Licensed Importer/ Product License Holder. The letter shall include information on the affected product, details on the defect, quantity of sample received, and any action taken by the Authority. Licensed Manufacturer/ Licensed Premise/ Licensed Importer/ Product License holder shall also check if the SF Medicines and Health Products product is also supplied to Private Health facilities.
- 2.17.1.4 The Licensed Manufacturer/ Licensed Premise/ Licensed Importer/ Product License holder shall conduct their investigation before sending the defect report and sample (if available) to the original Manufacturer for further investigation.
- 2.17.1.5 The outcome of this further investigation including corrective action from the manufacturer must be submitted to the Pharmacovigilance Department of the Authority.

Section 2.18: Private Health Facilities

- 2.18.1 SF Medicines and Health Products that are already in circulation in Liberia shall be reported directly to the Licensed Manufacturer/ Licensed Premise/ Licensed Importer/ Product License Holder either by letter or the Medicines and Health Products defects reporting form with information such as:
- a) Reporter details;
 - b) Medicines and Health Products details;
 - c) Quality report description;

- d) Additional information (e.g.: storage conditions, seal still intact, etc.).
- 2.18.2 The Licensed Manufacturer/ Licensed Premise/ Licensed Importer/ Product License Holder shall conduct their investigation before sending the SF Medicines and Health Products report and sample (if available) to the original manufacturer for further investigation.
- 2.18.3 The Licensed Manufacturer/ Licensed Premise/ Licensed Importer/ Product License holder must also report information on Medicines and Health Products defects to the Authority.
- 2.18.4 The outcome of the investigation including corrective action (if required) from the manufacturer shall be communicated to the end user and a copy given to the Pharmacovigilance Department of the Authority.

Section 2.19: Investigation Report from Manufacturer

- 2.19.1 The original manufacturer shall be responsible for determining the appropriate corrective and preventive action (CAPA) after investigating product defect reports. The Authority may require the original manufacturer to investigate the cause & extent, provide an investigation report of the findings and/or take other necessary measures such as taking appropriate market action and the preparation of communication to stakeholders.
- 2.19.2 The investigation report submitted to the Authority by the original manufacturer shall contain:
 - a) Description (with photos)
 - b) Root cause
 - c) Extent
 - i. E.g.: Overall assessment of the issue;
 - ii. Health Hazard Risk Report (including toxicology assessment) and clinical assessment (if necessary).
 - d) SF Medicines and Health Products test results (if available)
 - e) Risk assessment
 - f) Corrective & Preventive Action (CAPA) shall include:
 - i. Manufacturing process change;
 - ii. Formulation change;
 - iii. In-process control change;
 - iv. Change in specification limits;
 - v. Product label change;
 - vi. Other relevant changes for this product.
- 2.19.3 Any variations due to CAPA shall be submitted to the Department of Evaluation and Registration of the Authority.

CHAPTER 3: MEDICINES AND HEALTH PRODUCTS QUARANTINE

Section 3.1: Introduction to Medicines and Health Products Quarantine

- 3.1.1 An initial assessment of an SF Medicines and Health Products shall lead to a conclusive decision to further monitor the product. However, certain defects may present an unknown risk to the intended user and/or public which may need to be investigated further or when a definite conclusion is difficult to reach due to insufficient information. Therefore, for safety reasons, the SF Medicines and Health Products shall be taken out of the supply chain and kept in quarantine.
- 3.1.2 When the affected product is to be quarantined by the Licensed Manufacturer/ Licensed Premise/ Licensed Importer/ Product License holder, the designated personnel will suspend all supply of the affected batch (es), collect all affected batch (es) and quarantine them in a safe designated storage areas in their premises. This shall be conducted promptly after the issuance of a Quarantine Alert by the Authority or the supplier/Manufacturer. The designated quarantine storage areas must be marked and access must be restricted to authorized personnel. Any system (eg: computerized and barcoding system) replacing the physical separation must give equivalent assurance in segregation and restriction in accessibility.
- 3.1.3 The SF Medicines and Health Products product must be quarantined while awaiting a detailed investigation report from the manufacturer as well as a laboratory analysis report from the Quality Control Laboratory of the Authority (if required). Based on the outcome of the investigation, the SF Medicines and Health Products shall be released from quarantine and given out to the public or shall lead to the initiation of Medicines and Health Products recall.
- 3.1.4 The investigation reports on the SF Medicines and Health Products under quarantine must be sent to the Licensed Manufacturer/ Licensed Premise/ Licensed Importer/ Product License Holder. If the quarantined product is also supplied to other facilities, the quarantine alert shall also apply to those facilities. The Licensed Manufacturer/ Licensed Premise/ Licensed Importer/ Product Licensed Holder shall promptly inform the original manufacturer of this issue for further investigation.
- 3.1.5 Voluntary quarantine must be communicated to the Authority. Licensed Manufacturer/ Licensed Premise/ Licensed Importer/ Product License Holder may also initiate a quarantine of Medicines and Health Products even if the defect does not pose a risk to the intended user and /or public health, or for reasons other than product defects (e.g. commercial reasons). In the event of a quarantine, Licensed Manufacturer/ Licensed Premise/ Licensed Importer/ Product License Holder must have backup procedures and plans for anticipating scenarios when there is a potential disruption of product supply, particularly for Medicines and Health Products where there are no other available alternatives.

CHAPTER 4: OFFENCES AND PENALTIES

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

- 4.1 A holder of a license who contravenes or fails to comply with these regulations is guilty of an offence and liable on conviction to a fine not less than \$5,000.00 US (Five Thousand United States Dollars) or **IMPRISONMENT** for a term not exceeding 3 years.

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

A Regulation On Defects and Quarantine of Medicines and Health Products is Hereby Promulgated and Submitted for Approval to the Board of Directors on This 20th Day of April A. D. 2023 by the Managing Director of the Authority.



Dr. Keturah C. Smith-Chineh
Managing Director / LMHRA

A Regulation On Defects and Quarantine of Medicines and Health Products is Hereby Approved by the Board of Directors.

Approved This 20th Day of April A. D. 2023

Pharm. Luke Bawa
Chairman / Board of Directors/LMHRA