	TITLE: GUIDELINES FOR GOOD STORAGE PRACTICE	
Rev No: 01	**Doc No: PBSL/GL/16**	Version no. 02
Issue date: 15 May 2024	**Effective date: 17 May 2024**	Approved by: Registrar

Adopted By PBSL	WHO Guidelines for Good Storage Practices
Start of public Consultation	
End of public Consultation	
Agreed by QMS committee	
Approved by Board	

Pharmacy Board of Sierra Leone

PMB 322

Central Medical Stores Compound

New England Ville

Freetown

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Executive Summary

The Pharmacy Board of Sierra Leone is committed to its mission to ensure pharmaceutical products are stored in accordance with standards for good storage. This is to ensure quality is maintained throughout the supply chain and to reduce the risk of pilferages

These guidelines have been prepared to provide persons involved or wishing to be involved in storage of pharmaceutical with a method of assessing eligibility and the process of lawfully operating drug storage outlets. The success of this initiative will ultimately depend on the active contribution and cooperation of every stakeholder.

1.0 Introduction

An essential part of managing the medical product supply chain is storage. Medical product handling and storage may fall under the purview of several individuals and organizations. At different points in the supply chain, medical items could be exposed to a variety of dangers. Every participant in the supply chain must abide by the relevant laws and regulations in order to preserve the quality of medical products. The guidelines for good storage techniques should be followed when storing medical supplies. This document sets out steps to assist in fulfilling the responsibilities involved in the different stages within the supply chain and to avoid the introduction of substandard and falsified products into the market. The relevant sections should be considered as particular roles that entities play in the storage and distribution of medical products.

2.0 Objectives

To maintain the quality and integrity of stored items by ensuring proper conditions, minimizing damage, optimizing space utilization, facilitating easy access, and preventing unauthorized access, all while aiming to reduce costs and improve operational efficiency through effective inventory management and organization

3.0 Scope

This document establishes standards for the storage of medical supplies. When it comes to pharmaceutical items for human and veterinary use, as well as other medical products, these criteria might be equally applicable. In addition to pharmaceutical producers, the standards also apply to community and hospital pharmacies, pharmaceutical importers, and contractors and wholesalers. They ought to be modified in accordance with the kind of operation where pharmaceutical storage is occurring. All associated actions should adhere to local or national rules.

4.0 Requirements

4.1 Personnel

4.1 A sufficient number of skilled employees should be present at each storage location (such as a manufacturer, distributor, wholesaler, community, or hospital pharmacy) in order to meet pharmaceutical quality assurance goals. It is important to adhere to national qualifications regulations.

4.2 All staff members ought to get the appropriate instruction regarding safety, rules, regulations, and excellent storage practices.

4.3 Every employee should get training on maintaining high standards of sanitation and personal hygiene.

4.4 Employees working in storage facilities should dress in safety gear or work clothes that are appropriate for the tasks they do.

4.5 Staff members ought to possess the necessary skills, expertise, and educational background for the tasks they perform.

4.6 Ensuring the implementation and upkeep of a quality management system should be the exclusive responsibility and authority of a designated individual within the business who possesses the necessary training and qualifications.

4.7 This individual should make sure that GSP are followed and should ideally be separate from the person in charge of operations.

4.8 Employees should have the power and resources necessary to perform their jobs, adhere to quality systems, and spot and fix violations from the set protocols.

4.9 Measures should be taken to guarantee that management and staff are not exposed to financial, political, commercial, or other pressures or conflicts of interest that could compromise the integrity of medical goods or the quality of services rendered.

4.10 There should be safety protocols in place that address the integrity of the product, environmental protection, and all pertinent personnel and property.

4.11 Initial and ongoing training should be provided to staff members in compliance with a documented training program. GSP requirements and on-the-job training should be covered in the training. Product security, product identity, and the identification of counterfeit goods are some more themes that ought to be covered.

4.12 Specific training should be provided to personnel who handle hazardous products, including radioactive materials, highly active materials, narcotics, and other pharmaceutical products that are dangerous, environmentally sensitive, or have a high risk of abuse, fire, or explosion.

4.13 Employees should receive high standards of sanitation and personal hygiene training.

4.14 It is important to maintain records of all training, attendance, and evaluations.

4.15 Employees who handle products should dress appropriately for the tasks they carry out. When working with dangerous pharmaceutical items, such as those that include highly active, poisonous, infectious, or sensitizing chemicals, personnel should be outfitted with protective clothing as needed.

4.16 Establishing and adhering to appropriate personnel hygiene protocols that are pertinent to the tasks at hand is essential. These protocols ought to include staff attire, health, and hygiene.

4.17 To help reduce the likelihood that medical products will end up in the hands of unauthorized individuals or organizations, policies and procedures for workers, including contract and temporary workers, and other personnel with access to such products must be developed.

4.18 There should be policies and procedures in place to prevent and deal with instances in which individuals who handle the distribution and storage of medical products are suspected of engaging in any activity related to the theft, alteration, diversion, or falsification of any product, or are found to be involved in such activities.

4.2 Premises and facilities

4.2.1 Storage areas

4.2.1.1 It is necessary to take precautions to keep unauthorized individuals out of storage locations.

4.2.1.2 Storage spaces should have enough space to accommodate the organized storage of different types of materials and goods, such as raw materials and packaging, intermediates, bulk and completed goods, items under quarantine, and products that have been released, rejected, returned, or recalled.

4.2.1.3 To guarantee optimal storage conditions, storage spaces should be planned or modified. They should, in particular, be kept within reasonable temperature ranges and kept dry and clean. If the label specifies certain storage conditions (such as temperature or relative humidity), these should be supplied, examined, tracked, and documented. Pharmaceuticals and materials should be kept off the ground and positioned appropriately to allow

for cleaning and examination. Pallets ought to be maintained in a clean and repairable condition.

4.2.1.4 Storage spaces should be tidy and devoid of rodents and accumulated trash. There should be a documented sanitation program that details how often the premises and storage spaces should be cleaned as well as the techniques to be employed. Additionally, a formalized pest control program ought to exist. The materials and pharmaceutical goods should not be at risk of contamination, and the pest-control agents employed should be safe. Any spill should be cleaned up according to the proper protocols to guarantee that all contamination risks are eliminated.

4.2.1.5 Materials and products should be weatherproofed in receiving and shipment bays. Reception spaces are to be set up and furnished to enable the cleaning of pharmaceutical items and incoming material containers, if required, prior to storage.

4.2.1.6 When storage in distinct locations ensures quarantine status, these locations must be properly identified and only authorized staff may enter. Equivalent security should be offered by any method that takes the place of physical quarantine. Computerized systems, for instance, are acceptable as long as they are verified to exhibit access security.

4.2.1.7 Typically, starting materials should have their own sampling space in a controlled setting. In order to avoid contamination or cross-contamination, sampling should be done carefully if it is done in the storage area. The sampling sites should have proper cleaning protocols in place.

4.2.1.8 Rejected, expired, recalled, or returned materials or products should be stored under physical segregation or another validated method (such as electronic segregation). It is important to properly identify the products or materials and the places in question.

4.2.1.9 Substances that pose a particular risk of misuse, fire, or explosion, such as flammable liquids and solids and pressurized gases, drug substances, pharmaceutical products, highly active and radioactive materials, and other hazardous, sensitive, and/or dangerous materials, should be kept in a special location that is subject to the necessary extra safety and security precautions.

4.2.1.10 GMP as outlined in this text should be followed when handling and distributing materials and medicinal products.

4.2.1.11 It is important to handle and store materials and pharmaceutical goods to avoid cross-contamination, contamination, and mix-ups.

4.2.1.12 Proper rotation of stock is necessary to ensure that materials and pharmaceutical products are stored in a way that maintains their quality. It is best to adhere to the first expired/first out (FEFO) approach.

4.2.1.13 Until a final decision is made on their fate, rejected materials and pharmaceutical products should be identified and placed under quarantine management.

4.2.1.14 It is important to store narcotics in accordance with national and international narcotics laws and regulations.

4.2.1.15 Items that are damaged or broken ought to be taken out of the useful stock and kept apart.

4.2.1.16 Enough lighting should be present in storage rooms to allow for precise and secure execution of all tasks.

4.3 Storage conditions

4.3.1 Based on the findings of stability testing, pharmaceutical items and materials should be stored according to the label

4.4 Monitoring of storage conditions

4.4.1 Review of recorded temperature monitoring data ought to be possible. The monitoring equipment should be inspected at appropriate predefined intervals, and the findings should be documented and kept on file. Every monitoring record shall be retained for a minimum of one year plus the shelf life of the product or substance being stored, or as long as mandated by national law. The storage facility's temperature should be consistent throughout, according to temperature mapping. It advised to placed temperature monitor in locations where variations are most likely to occur.

4.4.2 Additionally, monitoring equipment needs to be calibrated at predetermined intervals.

4.5 Storage Requirements Documentation: written instructions and records

4.5.1 All activities in the storage areas, including managing expired stock, should be documented in written instructions and records. In the event that a product recall is necessary, these should clearly outline the storage protocols as well as the path that materials, pharmaceutical goods, and information take inside the company.

4.5.2 There should be permanent written or electronic records for every product or substance that is stored that include retest dates, suggested storage conditions, and any safety measures that need to be followed. Labels and containers must always adhere to current national rules and pharmacopoeial criteria.

4.5.3 Every delivery should have a record. The goods' description, quality, quantity, supplier, batch number, date of receipt, assigned batch number, and expiration date should all be included. When national regulations stipulate that records must be kept for a specific amount of time, this must

be followed. If not, such records ought to be kept for a duration equivalent to the arriving materials' and products', if applicable, shelf life plus one year.

4.5.4 Comprehensive records should be maintained showing all receipts and issues of materials and pharmaceutical products according to a specified system, e.g. by batch number

4.6 Labelling and containers

4.6.1 All materials and pharmaceutical goods should be kept in containers that provide sufficient protection from outside factors and do not negatively impact the quality of the materials or products in question.

4.6.2 The name of the material, the batch number, the expiration or retest date, the recommended storage conditions, and, if relevant, a reference to the pharmacopoeia should all be prominently displayed on the labels of all containers. Unauthorized names, codes, or abbreviations must be avoided.

4.7 Receipt of incoming materials and pharmaceutical products

4.7.1 On receipt, each incoming delivery should be checked against the relevant purchase order and each container physically verified, e.g. by the label description, batch number, type of material or pharmaceutical product and quantity

4.7.2 The consignment should be examined for uniformity of the containers and, if necessary, should be subdivided according to the supplier’s batch number should the delivery comprise more than one batch.

4.7.3 Each container should be carefully inspected for possible contamination, tampering and damage, and any suspect containers or, if necessary, the entire delivery should be quarantined for further investigation.

4.7.4 When required, samples should be taken only by appropriately trained and qualified personnel and in strict accordance with written sampling instructions. Containers from which samples have been taken should be labelled accordingly.

4.7.5 Following sampling, the goods should be subject to quarantine. Batch segregation should be maintained during quarantine and all subsequent storage.

4.7.6 Materials and pharmaceutical products should remain in quarantine until an authorized release or rejection is obtained.

4.7.7 Measures should be taken to ensure that rejected materials and pharmaceutical products cannot be used. They should be stored separately from other materials and pharmaceutical products while awaiting destruction or return to the supplier

4.8 Stock rotation and control

4.8.1 Periodic stock reconciliation should be performed by comparing the actual and recorded stocks.

4.8.2 All significant stock discrepancies should be investigated as a check against inadvertent mix-ups and/or incorrect issue.

4.8.3 In manufacturing facilities, partly used containers of materials and pharmaceutical products should be securely reclosed and re-sealed to prevent spoilage and/or contamination during subsequent storage.

4.8.4 Materials and pharmaceutical products from containers which have been opened or partly used should be used up before those in unopened containers.

4.8.5 Damaged containers should not be issued unless the quality of the material has been shown to be unaffected. Where possible, this should be

brought to the attention of the person responsible for quality control. Any action taken should be documented.

4.9 Control of obsolete and outdated materials and pharmaceutical products

4.9.1 All stocks should be checked regularly for obsolete and outdated materials and pharmaceutical products. All due precautions should be observed to prevent the issue of outdated materials and pharmaceutical products.

4.10 Returned goods

4.10.1 Returned goods, including recalled goods, should be handled in accordance with approved procedures and records should be maintained.

4.10.2 All returned goods should be placed in quarantine and returned to saleable stock only after this has been approved by a nominated, responsible person following a satisfactory quality re-evaluation.

4.10.3 Any stock reissued should be so identified and recorded in stock records. Pharmaceuticals returned from patients to the pharmacy should not be taken back as stock, but should be destroyed

4.11 Dispatch and transport

4.11.1 Materials and pharmaceutical products should be transported in such a way that their integrity is not impaired and that storage conditions are maintained.

4.11.2 Special care should be exercised when using dry ice in cold chains. In addition, observing to safety precautions, it must be ensured that the materials or product does not come in into contact with dry ice, as this may adversely affect the product quality, e.g. by freezing.

4.11.3 Where appropriate, the use of devices to monitor conditions such as temperature during transportation is recommended. Monitoring records should be available for review.

4.11.4 The dispatch and transport of materials and pharmaceutical products should be carried out only after receipt of a delivery order. The receipt of the delivery order and the dispatch of the goods must be documented.

4.11.5 Dispatch procedures should be established and documented, taking into account the nature of the materials and pharmaceutical products concerned and any special precautions that might be required.

4.11.6 The outside container should offer adequate protection from all external influences and should be indelibly and clearly labelled.

4.12 Records for dispatch should be retained, stating at least:

— the date of dispatch;

— the customer's name and address;

— the product description, e.g. name, dosage form and strength (if appropriate), batch number and quantify;

— the transport and storage conditions.

All records should be readily accessible and available on request.

4.13 Product recall

4.13.1 There should be a procedure to recall from the market, promptly and effectively, pharmaceutical products and materials known or suspected to be defective.

5.0 Glossary/Definition

5.1 Storage areas

Storage areas can be physical spaces such as storage units or virtual spaces such as storage spaces in windows

5.2 GMP

GMP stands for Good Manufacturing Practices. A set of guidelines that ensure products are consistently produced and meet quality standards.

5.3 Dangerous drugs

Under Georgia law, "Dangerous Drugs" are drugs that are available only by prescription from a licensed healthcare professional or the purchase of which is restricted to licensed healthcare professionals.

5.4 Labeling

Is a written, printed, or graphic matter upon any drugs or any of its containers, or accompanying such a drug

5.5 Container

A container is any receptacle or enclosure for holding a product used in storage, packaging, and transportation, including shipping

5.6 Stock

The goods or merchandise kept on the premises of a shop or warehouse and available for sale or distribution

5.7 Stock rotation

Is the process of organizing inventory to reduce stock loss caused by expiration

5.8 Returned goods

Returned goods are products that have been sent back to the seller or supplier by the recipient after delivery.

5.9 Product recall

A product recall is defined as a request to return, exchange, or replace a product after a manufacturer or consumer watch group discovers defects that could hinder performance, harm consumers, or produce legal issues for the producers.

5.11 Narcotic

A substance used to treat moderate to severe pain.

6.0 Reference and information sources

6.1 Good storage practice: Joint report of the Committee for Official Laboratories and Medicinal Control Services and the Industrial Pharmacists Section of the International Pharmaceutical Federation (FIP). Pharm. Ind., 1980, 42:1082– 1085.

6.2 Management of drug purchasing, storage and distribution. Manual for developing countries. Geneva, World Health Organization, 1992.

7.0 Annex

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