	TITLE: GUIDELINES FOR GOOD DISTRIBUTION PRACTICE	
Rev No: 00	**Doc No: PBSL/GL/014**	Version no. 00
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Adopted By PBSL	WHO Guidelines for Good Distribution Practices for Pharmaceutical Products
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 dedicated to its goal of providing pharmaceutical services that meet everyone's needs for disease prevention, diagnosis, and treatment with safe, effective, high-quality, and reasonably priced pharmaceutical products. To guarantee that their quality is maintained throughout the distribution chain, pharmaceuticals need to be handled carefully. At all costs, the public should not be exposed to dangerous medications.

These guidelines have been prepared to provide persons involved or wishing to be involved in pharmaceutical distribution with a method of assessing eligibility and the process of lawfully operating drug distribution outlets. It further provides specific requirements on distribution that are practices currently acceptable. The success of this initiative will ultimately depend on the active contribution and cooperation of every stakeholder.

1.0 Introduction

A key component of integrated supply chain management is the distribution of pharmaceuticals. The pharmaceutical distribution network of today is becoming more intricate and has numerous participants. This paper lays forth procedures to help satisfy the obligations associated with the various supply chain phases and prevent the release of inferior and fraudulent medical items into the marketplace or public health facilities. As a result, safeguarding the supply chain from the infiltration of these items is crucial. This guideline is meant to be relevant to all parties involved in any part of the distribution and storage of medical products, including the person giving out or supplying medical items to a patient directly or the location of the medical product maker and their agent.

This covers all parties engaged in various phases of the medical product supply chain, including producers, distributors, brokers, suppliers, logistics companies, traders, transport firms, forwarding agents, and their staff. By following these rules, the distribution chain will be under control, protecting the integrity and quality of pharmaceuticals.

In compliance with national regulations, each individual functioning as a wholesale distributor must possess a wholesale distribution license. Having a manufacturing license gives you the ability to distribute the medicine that is covered by it.

As relevant, the Good Distribution Practices (GDP) principles must guide every action involved in the distribution of pharmaceutical products. The types of risks involved are probably comparable to those found in production settings, such as adulteration, contamination, cross-contamination, bogus, and mix-ups. It is especially concerning when unapproved organizations distribute and sell pharmaceutical items.

The only effective strategy to combat counterfeit or subpar pharmaceutical products is a coordinated effort by all supply chain participants. To prevent the introduction of counterfeit or subpar pharmaceutical products into the pharmaceutical supply chain, all stakeholders involved in the chain must actively participate in cooperative efforts.

The implementation of these criteria in practice should be the focus of national health authorities' administrative actions, and any new or modified national rules pertaining to appropriate distribution practices should at the very least match their level. Additionally, these standards are meant to be used as a foundation for the development of particular regulations tailored to the requirements of wholesale distributors. It is acknowledged that there are legitimate approaches that can accomplish the Guide's tenets in addition to those covered in it. This guide offers instructions for getting ready for inspections and can be used for training.

2.0 Objectives

These guidelines aim to guarantee pharmaceutical products' identification and quality throughout the whole distribution chain. Purchasing, storing, distributing, transporting, documenting, and maintaining records are some of these elements.

3.0 Scope

The guidelines outlined here are applicable to pharmaceuticals and other comparable goods meant for human consumption. This recommendation may also apply to investigational pharmaceuticals (IMP). Technical innovation, the pursuit of excellence, and the development of new concepts or technologies that have been validated and offer a degree of quality assurance and distribution process integrity at least as high as those outlined in this Guide are not to be hindered by it.

It encompasses all stakeholders engaged in pharmaceutical trade and distribution, including bulk and finished product manufacturers, wholesalers, government agencies, international procurement organizations, donor agencies, certifying bodies, logistics providers, traders, transport companies, forwarding agents, and their staff, as well as healthcare professionals. Biological products in general are also covered.

4.0 Requirements

4.1 General Principles

4.1.1 From the manufacturer's location to the organization in charge of delivering the medication to the patient or his or her agent, all stakeholders engaged in the distribution of pharmaceutical products must guarantee that the product's quality and the chain's integrity are preserved.

4.1.2 The GDP principles apply to pharmaceutical products that are moving backwards in the chain due to returns or recalls, as well as to pharmaceutical products that are moving forward in the chain from the manufacturer to the organization in charge of delivering or dispensing pharmaceutical products to the patient. They also apply to pharmaceutical products that are donated.

4.1.3 To ensure the quality and safety of pharmaceutical products, prevent patients from being exposed to counterfeit pharmaceutical products, and maintain the integrity of the distribution chain, all parties—including the government, customs agencies, law enforcement agencies, regulatory authorities, manufacturers, distributors, and entities in charge of providing pharmaceutical products to patients—must work together.

4.1.4 Every agency participating in the distribution, transportation, and storage must have an agreement in place.

4.2 Quality Management System

4.2.1 Organizations that store and distribute pharmaceuticals must have a well-thought-out, properly documented, and executed quality system that includes GDP, quality risk management principles, and management review.

4.2.2 Senior management bears the ultimate duty for guaranteeing the establishment, resource allocation, implementation, and maintenance of an efficient quality system.

The quality system shall ensure that:

- GDP is adopted and implemented to ensure that the quality of pharmaceutical products is maintained throughout their shelf life in the supply chain; and pharmaceutical products are appropriately procured, stored, distributed and delivered to the appropriate recipients,
- operations are clearly specified in written procedures;
- responsibilities are clearly specified in job descriptions;
- all risks are identified and necessary, effective controls are implemented;
- processes are in place to assure the management of outsourced activities;
- there is a procedure for self-inspection and quality audits;
- there is a system for quality risk management;
- there are systems for managing returns, complaints and recalls; and

- there are systems to manage changes, deviations and corrective a preventive action (CAPAs).

4.2.3 An approved written quality policy outlining the general goals and standards for quality must exist. A manual on quality might reflect this.

4.2.4 A suitable organizational structure must exist. An authorized organizational chart will be used to display this. Personnel responsibilities, authority, and relationships must be made explicit.

4.2.5 Roles and responsibilities must be documented as written job descriptions and must be well-defined and understood by the parties involved.

4.2.6 Appropriate methods, procedures, and resources must be part of the quality system.

4.3 Quality risk management

4.3.1 A system for evaluating, managing, communicating, and reviewing risks found at every stage of the supply chain must be in place.

4.3.2 The assessment of risk must be grounded in scientific understanding and experience and ultimately connected to patient safety.

4.3.3 To handle every risk, suitable controls must be created and put into place. Periodically, the effectiveness of the controls that have been put in place will be assessed

4.4 Organization and Management

4.4.1. With the use of an organizational chart, each entity in the chain of distribution must have a suitable organizational structure. All staff members' responsibilities, powers, and interactions with one another must be made explicit. There must be an organizational chart or organogram.

4.4.2 Individuals' tasks and responsibilities must be well-defined and documented in written job descriptions. Employees must receive thorough training and education on their roles and responsibilities at every stage of the supply chain.

4.4.3 A selected individual within the organization will be assigned specific authority and responsibility for guaranteeing the implementation and upkeep of a quality system.

4.4.4 The power and resources required to perform their jobs, build and maintain a quality system, and recognize and address deviations from the established system must be granted to managerial and technical personnel

4.4.5 It will be made sure that no one person is given too many tasks that could jeopardize the quality of the final product.

4.4.6 Measures must be taken to guarantee that management and staff are not exposed to financial, political, economic, or other pressures or conflicts of interest that could compromise the integrity of pharmaceutical products or the quality of services rendered

4.4.7 There must be safety protocols in place that address all pertinent issues, such as environmental preservation, product integrity, and worker and property safety.

4. 5 Management review

4.5.1 There shall be a system for periodic management review. The review shall include at least:

- senior management;
- review of the quality system and its effectiveness by using quality metrics and key performance indicators; identification of opportunities for continual improvement; and follow-up on recommendations from previous management review meetings.

4.5.2 Minutes and related documentation from management review meetings should be available.

4.6 Personnel

4.6.1 All employees engaged in distribution operations must get training and be qualified to meet GDP standards, if any. GDP and documented standard operating procedures (SOPs) will serve as the foundation for training. In line with a documented training program, staff members must get both initial and ongoing training pertinent to their jobs, as well as any necessary assessments.

4.6.2 Special training should be provided to personnel who work with hazardous products, including highly active materials, radioactive materials, narcotics, and other pharmaceutical products that are hazardous, environmentally sensitive, and/or dangerous, as well as products that pose unique risks of abuse, fire, or explosion

4.6.3 The ability and experience to ensure that pharmaceutical products are delivered and stored appropriately in accordance with product requirements must be had by key individuals involved in pharmaceutical distribution.

4.6.4 To guarantee that the product's quality is maintained, a sufficient number of qualified individuals must be involved in every phase of the distribution of pharmaceutical products

4.6.5 Employees engaged in the distribution of pharmaceuticals must dress appropriately and take other precautions for their safety. Personnel handling hazardous pharmaceutical items, especially those containing highly active, poisonous, infectious, or sensitizing chemicals, must be outfitted with protective clothing as needed.

4.6.6 Personnel hygiene protocols pertinent to the tasks to be performed must be established and followed. These protocols will include staff attire, health, and hygiene

4.6.7 Policies and terms of employment for workers, including contract and temporary workers and other staff members who have access to pharmaceutical products, must be created and implemented to help reduce

the likelihood that such products will end up in the hands of unauthorized individuals or organizations.

4.7 Premises, Warehousing and Storage

4.7.1 Good storage practices (GSP) must be maintained or incorporated into the design of storage spaces.

4.7.2 The location, design, construction, and upkeep of the premises must be acceptable in order to guarantee proper operations, including the receiving, storing, picking, packing, and shipping of pharmaceutical products. Storage spaces must be physically strong, adequately secured, and large enough to accommodate safe handling and storage.

4.7.3 Enough lighting must be supplied in storage rooms to allow for precise and secure execution of all tasks.

4.7.4 Measures must be implemented to keep unauthorized individuals out of storage areas.

4.7.5 Pharmaceutical products in quarantine, as well as those that have been released, rejected, returned, or recalled, as well as those that may be deemed fraudulent, must be stored in separate places.

4.7.6 Storage spaces must be clean, dry, and kept within reasonable temperature ranges. They must also be created or modified to guarantee

suitable and favorable storage conditions. Pharmaceuticals must be kept off the ground and positioned appropriately to allow for cleaning and inspection. Pallets must be maintained in a clean and hygienic state.

4.7.7 Regular cleaning of the premises and storage places is required. Receiving and dispatch bays should, whenever feasible, be kept apart to prevent confusion. Products will be shielded from weather conditions by bays.

4.7.8 Receiving and dispatching activities must be carried out in compliance with approved protocols. Spaces must to be appropriately furnished for the activities.

4.7.9 There shall also be a written programme for pest control and the pest control agents used shall be safe and there shall be no risk of contamination of pharmaceutical products. There shall be appropriate procedures for the clean-up of any spillage to ensure complete removal of any risk of contamination.

4.7.10 If sampling is performed in the storage area, it shall be conducted in such a way as to prevent contamination or cross-contamination. Adequate cleaning procedures shall be in place for the sampling areas.

4.7.11 Receiving and dispatch bays shall protect pharmaceutical products from the weather. Receiving areas shall be designed and equipped to allow

incoming containers of pharmaceutical products to be cleaned, if necessary, before storage. Handling and storage of pharmaceutical products shall in such a manner as to prevent contamination, mix-ups and cross-contamination.

4.7.12 There shall be a system in place to ensure that the pharmaceutical products due to expire first are sold and/or distributed first (first expiry/ first out (FEFO)). Exceptions shall be permitted as appropriate, provided that adequate controls are in place to prevent the distribution of expired products.

4.7.13 Arrangement shall be made for withdrawing broken or damaged items from unusable stock and storing separately.

4.7.14 There shall be appropriately identified areas with adequate segregation for storage of quarantined, rejected, expired, recalled or returned products to prevent unintentional or unauthorized use of such products.

4.7.14 Dedicated area(s) with appropriate additional safety and security measures shall be provided for storage of radioactive materials, narcotics and other hazardous, sensitive and/or dangerous pharmaceutical products as well as products presenting special risks of abuse, fire or explosion (e.g combustible or flammable liquids and solids and pressurized gases).

4.7.16 Toilets, washing, rest and canteen facilities should be separate from areas where products are handled. Food, eating, drinking and smoking should be prohibited in all areas where medical products are stored or handled.

4.8 Temperature and Environment Control

4.8.1 Conditions for handling and storage must adhere to relevant national laws and regulations.

4.8.2 The manufacturer's recommended storage conditions must be followed for medicinal items. This is essential to guaranteeing the caliber of all pharmaceutical items.

4.8.3 All pharmaceutical items must be able to be stored in facilities that are suitable for their use (e.g. environmentally controlled where necessary).

4.8.4 If storage conditions are essential to preserving the qualities of pharm aceutical items, records of such conditions must be kept.

Data from temperature monitoring records must be accessible for examinati on. Temperature checks will be conducted at predetermined times. At certain predefined intervals, the monitoring equipment must be inspected, and the findings must be documented and kept on file. Every monitoring record must be maintained for a minimum of one year and the product's shelf life.

4.8.5 An initial temperature mapping exercise should be carried out on the storage area before use, under representative conditions.

4.8.6 Temperature monitoring equipment should be located according to the results of the mapping exercise, ensuring that monitoring devices are positioned in the areas that experience the extremes of fluctuations.

4.8.7 The mapping exercise should be repeated for significant changes according to the results of a risk assessment exercise. For small premises of a few square meters which are at room temperature, an assessment of potential risks (e.g. heater / air-conditioner) should be conducted and temperature monitors placed accordingly.

4.9 Transportation

4.9.1 Pharmaceutical products shall be transported in accordance with the storage conditions indicated on the packaging information and on the label.

4.9.2 The individuals responsible for the transportation of pharmaceutical products shall be informed about all relevant conditions for storage and transportation. These requirements shall be adhered throughout transportation and at any intermediate storage stages.

4.9.3 Pharmaceutical products shall be stored and transported in accordance with procedures such that:

4.9.3.1 The identity of the product is not lost.

4.9.3.2 The product does not contaminate and is not contaminated by other products.

4.9.3.3 Adequate precautions are taken against spillage, breakage, misappropriation and theft. Spillage during transport shall be handled as per type of vaccine (eg. live, killed, etc.) according to the standard operating procedures of the manufacturer.

4.9.3.4 Appropriate environmental conditions are maintained, e.g. using cold chain for thermolabile products.

4.9.4 A written agreement between the manufacturer, Government Institution, agent and Transport Company shall be in place.

4.9.4.1 Appropriate transport methods shall be employed which may include transport by air, road, sea, rail or a combination of the above. Regardless of the chosen mode, it shall be demonstrated that the products have not been subjected to conditions during transportation that may compromise their quality. A risk-based approach be utilized when planning transportation routes.

4.9.4.2 The required storage conditions for pharmaceutical products shall be maintained during transportation within the defined limits as described on the packaging information.

4.9.4.3 Where special conditions are required during transportation that are different from or limit the given environmental conditions (e.g temperature and humidity), these shall be provided by the manufacturer on the labels, shall be monitored and recorded.

4.9.4.4 If a deviation has occurred during transportation, this shall be reported to the distributor and recipient of the affected pharmaceutical products. Written procedures shall be in place to investigate and deal with any failure to comply with storage requirements, e. g temperature deviations.

4.9.4.5 In cases where the recipient notices the deviation, it shall be reported to the distributor. Where necessary, the manufacturer of the pharmaceutical product shall be contacted for information about appropriate steps to be taken.

4.9.4.6 Pharmaceutical products containing hazardous substances, such as toxic, radioactive material and other dangerous pharmaceutical products presenting special risks of abuse, fire or explosion (e. g combustible or flammable liquids, solids and pressurized gases), shall be stored in safe, dedicated and secure areas and transported in safe, suitably designed, secured containers and vehicles and the requirements of applicable National legislation shall be met.

4.9.4.7 Products containing narcotics and other dependence- producing substances shall be transported in safe and secure containers and vehicles and be stored in safe and secure areas and applicable international agreements and National legislation shall be complied with. Spillage shall be cleaned up as soon as possible to prevent possible contamination, cross-contamination and hazards and written procedures shall be in place for handling of such situation.

4.9.4.8 Adequate segregation shall be provided for the storage and distribution during transit of rejected, expired, recalled or returned pharmaceutical products. The products shall be appropriately identified, securely packaged, clearly labelled and be accompanied by appropriate supporting documentation.

4.9.4.9 The interiors of vehicles and containers shall remain clean and dry while pharmaceutical products are in transit.

4.9.5 Properly designed packaging materials and shipment containers shall be provided to prevent damage of pharmaceutical products during transport.

4.9.5.1 Drivers of vehicles shall identify themselves and present appropriate documentation to demonstrate that they are authorized to transport the load.

4.9.5.2 Damage to containers and any other event or problem that occurs during transit shall be recorded and reported to the relevant department, entity or authority, and investigated.

4.9.5.3 Pharmaceutical products in transit shall be accompanied by the appropriate documentation.

4.9.5.4 It is the responsibility of the distributor to ensure that vehicles and equipment used to distribute, store or handle pharmaceutical products are suitable for their use and appropriately equipped to prevent exposure of the products to conditions that shall affect their quality and packaging integrity, and to prevent contamination of any kind.

4.9.5.5 There shall be procedures in place for the operation and maintenance of all vehicles and equipment involved in the distribution process, including cleaning and safety precautions.

4.9.6 Vehicles, containers and equipment shall be kept clean and dry and free from accumulated waste. Organizations in charge of distribution shall ensure that vehicles used are cleaned regularly.

4.9.7 Particular attention shall be paid to the fact that cleaning agents shall not adversely affect the product quality.

4.9.8 Vehicles, containers and equipment shall be kept free from rodents, vermin, birds and other pests. There shall be written programs and records for such pest control.

4.9.9 Equipment used for temperature and humidity monitoring (Data Logger) during transport within vehicles and/or containers, shall be maintained and calibrated at regular intervals at least once a year or earlier depending upon the criticality of the product.

4.9.10 All monitoring records shall be kept for a minimum of the shelf- life of the product distributed plus one year or as required by National legislation.

4.9.10.1 Records of monitoring data shall be made available for inspection by the Regulatory Authority.

4.9.10.2 Equipment chosen and used for the cleaning of vehicles shall not constitute a source of contamination and cleaning agents shall be approved by management. It is essential to pay special attention to the design, use, cleaning and maintenance of all equipment used for the handling of pharmaceutical products which are not in a protective shipping carton or

case.

4.9.10.3 Dedicated vehicles and equipment shall be used, where possible, when handling pharmaceutical products. Procedures shall be in place to

ensure that the quality of the pharmaceutical product shall not be compromised where non-dedicated vehicles and equipment shall be used.

4.9.10.4 Appropriate documents shall accompany pharmaceutical products in transit.

4.9.10.5 Vehicles and containers selected shall be of sufficient capacity to allow orderly storage of the various categories of pharmaceutical products during transportation.

4.9.11 Where possible, mechanisms shall be available to allow for the segregation during transit of rejected, recalled and returned pharmaceutical products, as well as those suspected of being spurious. Such products shall be securely packaged, clearly labeled and be accompanied by appropriate supporting documentation.

4.9.12 Adequate measures shall be taken to ensure that no unauthorized persons enter and tamper the vehicles and/or equipment, so as to prevent the theft or misappropriation thereof.

4.10 Receipt of Medicinal Products

4.10.1 The purpose of the receiving function is to ensure that the arriving consignment is correct, that the medicinal products originate from approved suppliers and that they have not been visibly damaged during transport.

4.10.2 Medicinal products requiring special handling, storage or security measures should be prioritized and once appropriate checks have been conducted, they should be immediately transferred to appropriate storage facilities.

4.10.3 Batches of medicinal products should not be transferred to saleable stock before assurance has been obtained in accordance with written procedures, that they are authorized for sale.

4.10.4 If a falsified product is suspected, the batch should be segregated and reported to competent authorities as required by national legislation

4.11 Documentation

4.11.1 Documentation comprises all written procedures, instructions, contracts, records and data, in paper or in electronic form. Documents shall be appropriately designed, completed, reviewed, authorized, distributed and kept as required. Documents shall be readily available.

4.11.2 Written instructions and records which document all activities relating to the distribution of pharmaceutical products, including all applicable receipts and issues (invoices) shall be available.

4.11.3 Distributors shall keep records of all pharmaceutical products received. Records shall contain at least the following information:

- Date;

- Name of the pharmaceutical product, batch no, manufacturer's name.
- Quantity received, or supplied; and

  Name and address of the supplier.

4.11.4 Procedures shall be established and maintained for the preparation, review, approval, use of and control of changes to all documents relating to the distribution process.

4.11.5 The contents of documents shall be clear, accurate, legible, traceable, attributable and unambiguous. In particular, instructions and procedures relating to activity that may have an impact on quality of pharmaceutical products shall be designed, completed, reviewed and distributed with care.

4.11.6 Documentation shall be approved, signed and dated by appropriate authorized persons, as required. It shall not be hand-written; although, where documents require the entry of data, sufficient space shall be provided for such entries.

4.11.7 Any alteration made in the documentation shall be signed and dated; the alteration shall permit the reading of the original information. Where appropriate, the reason for the alteration shall be recorded.

4.11.8 Documents shall be reviewed regularly and kept up-to-date. When a document has been revised, a system shall exist to prevent inadvertent use of the superseded version.

4.11.9 All records shall be stored and retained using facilities that prevent unauthorized access, modification, damage, deterioration and/or loss of documentation during the entire life-cycle of the record. Records must be readily retrievable. Documents shall be retained for a period of 1 year after expiry of the product.

4.11.10 The distributor shall establish and maintain procedures for the identification, collection, indexing, retrieval, storage, maintenance, disposal of and access to all applicable documentation.

4.11.11 Documents shall be reviewed regularly and kept up to date.

4.11.12 Records shall be kept either in the form of purchase/sales invoices, delivery slips, or on computer or in any other form, for any transaction in pharmaceutical products received or supplied.

4.12 Storage

4.12.1 Medicinal products and, if necessary, healthcare products should be stored separately from other products likely to alter them and should be protected from the harmful effects of light, temperature, moisture and other external factors. Particular attention should be paid to products requiring specific storage conditions.

4.12.2 Incoming containers of medicinal products should be cleaned, if necessary, before storage. Any activities performed on the incoming goods (e.g. fumigation) should not impact on the quality of the medicinal products.

4.12.3 Warehousing operations must ensure appropriate storage conditions are maintained and allow for appropriate security of stocks.

4.12.4 Stock should be rotated according to the first expiry, first out (FEFO) principle. Exceptions should be documented.

4.12.5 Medicinal products should be handled and stored in such a manner as to prevent spillage, breakage, contamination and mix-ups. Medicinal products should not be stored directly on the floor unless the package is designed to allow such storage (such as for some medicinal gas cylinders).

4.12.6 Medicinal products that are nearing their expiry date/shelf life should be withdrawn immediately from saleable stock.

4.12.7 Stock inventories should be performed regularly taking into account national legislation requirements. Stock irregularities should be investigated, documented and reported to the competent authorities when needed.

4.13 Products Requiring Controlled Conditions

4.13.1 In relation to deliveries containing medicinal products requiring special conditions such as narcotics or psychotropic substances, the wholesale distributor should maintain a safe and secure supply chain for

these products in accordance with requirements laid down in national legislation. There should be additional control systems in place for delivery of these products. There should be a protocol to address the occurrence of any theft.

4.13.2 Medicinal products comprising highly active and radioactive materials should be transported in safe, dedicated and secure containers and vehicles. The relevant safety measures should be in accordance with international agreements and national legislation.

4.13.3 For temperature-sensitive products, qualified equipment (e.g. thermal packaging, temperature-controlled containers or temperature-controlled vehicles) should be used to ensure correct transport conditions are maintained between the manufacturer, wholesale distributor and customer.

4.13.4 If temperature-controlled vehicles are used, the temperature monitoring equipment used during transport should be maintained and calibrated at regular intervals. Temperature mapping under representative conditions should be carried out and should take into account seasonal variations, if applicable.

4.13.5 If requested, customers should be provided with information to demonstrate that products have complied with the temperature storage conditions.

4.13.6 If cool packs are used in insulated boxes, they need to be located such that the product does not come in direct contact with the cool pack. Staff must be trained on the procedures for assembly of the insulated boxes (seasonal configurations) and on the reuse of cool packs.

4.13.7 There should be a system in place to control the reuse of cool packs to ensure that incompletely cooled packs are not used in error. There should be adequate physical segregation between frozen and chilled ice packs.

4.13.8 The process for delivery of sensitive products and control of seasonal temperature variations should be described in a written procedure.

4.14 Returned Medicinal Products

4.14.1 Returned products must be handled according to a written, risk-based process taking into account the product concerned, any specific storage requirements and the time elapsed since the medicinal product was originally dispatched. Returns should be conducted in accordance with national legislation, and contractual arrangements between the parties. A record/ list of returned goods must be maintained.

4.14.2 Medicinal products which have left the premises of the distributor should only be returned to saleable stock if all of the following are confirmed:

i. The medicinal products are in their unopened and undamaged secondary packaging and are in good condition; have not expired and have not been recalled;

ii. Medicinal products returned from a customer not holding a wholesale distribution authorization or from pharmacies authorized to supply medicinal products to the public should only be returned to saleable stock if they are returned within an acceptable time limit, for example 4.6. days;

iii. It has been demonstrated by the customer that the medicinal products have been transported, stored and handled in compliance with the specific storage requirements;

iv. they have been examined and assessed by a sufficiently trained and competent person authorized to do so; the distributor has reasonable evidence that the product was supplied to that customer (via copies of the original delivery note or by referencing invoice numbers/batch numbers, expiry date etc., as required by national legislation), and that there is no reason to believe that the product has been falsified.

4.14.3 Moreover, for medicinal products requiring specific temperature storage conditions, returns to saleable stock can only be made if there is documented evidence that the product has been stored under the authorized storage conditions throughout the entire time. If any deviation has occurred

a risk assessment has to be performed, on which basis the integrity of the product can be demonstrated. The evidence should cover:

i. delivery to customer;

ii. examination of the product;

iii. opening of the transport packaging;

iv. return of the product to the packaging;

v. collection and return to the distributor;

vi. record of temperature readings during transportation;

vii. return to the distribution site refrigerator.

4.14.4 Products returned to saleable stock should be placed such that the 'first expired first out' (FEFO) system operates effectively.

4.14.5 Stolen products that have been recovered cannot be returned to saleable stock and sold to customers

4.15 Falsified Medicinal Products

4.15.1 The sale and distribution of a suspected falsified medicinal product should be suspended immediately.

4.15.2 Wholesale distributors must immediately inform the competent authority and the marketing authorization holder of any medicinal products

they identify as falsified or suspect to be falsified and act on the instructions as specified by the competent authority. A procedure should be in place to this effect. It should be recorded with all the original details and investigated.

4.15.3 Any falsified medicinal products found in the supply chain should immediately be physically segregated and stored in a dedicated area away from all other medicinal products and be appropriately labelled. All relevant activities in relation to such products should be documented and records retained.

4.15.4 Upon confirmation as a falsified medicinal product, a formal decision should be taken on removal of such product from the market, ensuring that it does not re-enter the supply chain, including retention of any samples necessary for public health, regulatory, or legal needs and arrangements for its disposal. All related decisions should be appropriately documented.

4.16 Complaints

4.16.1 Written procedure shall be in place for the handling of complaints. A distinction shall be made between complaints about a pharmaceutical product or its packaging and those relating to distribution. In the case of a complaint about the quality of a product or its packaging, the original manufacturer and/ or marketing authorization holder shall be informed as soon as possible.

4.16.2 There shall be written procedure for reviewing carefully all complaints and other information concerning potentially defective and potentially spurious pharmaceutical products describing the action to be taken, including the need to consider a recall where appropriate.

4.16.3 Any complaint concerning a material defect shall be recorded and thoroughly investigated to identify the origin or reason for the complaint.

4.16.4 A risk-based consideration shall be given to whether other batches of the pharmaceutical product shall also be checked if a defect relating to a pharmaceutical product is discovered or suspected.

4.16.4 Appropriate follow-up action shall be taken after investigation and evaluation of the complaint where necessary. A system shall be in place to ensure that the complaint, the response received from the original product manufacturer, or the results of the investigation of the complaint, are shared with all the relevant parties. All complaints shall be recorded and appropriately investigated. The root cause shall be Identified, and the impact (e.g. on other batches or products) risk-assessed. Appropriate CAPAs should be taken.

4.16.6 There shall be documentation of product quality problems or suspected cases of spurious products, misbranded, adulterated, not of standard quality and sharing of the information with the appropriate national and/or state regulatory authorities.

4.16.7 Where required, the information shall be shared with the Licensing Authority and a recall initiated where appropriate

4.17 Medicinal Product Recalls

4.17.1 There should be documentation and procedures in place to ensure traceability of products received and distributed, to facilitate product recall.

4.17.2 In the event of a product recall, all customers to whom the product has been distributed shall be informed with the appropriate degree of urgency and clear actionable instructions.

4.17.3 The national regulatory authority should be informed of all product recalls. If the product is exported, the overseas counterparts and/or regulatory authorities must be informed of the recall as required by national legislation.

4.17.4 The effectiveness of the arrangements for product recall should be evaluated regularly (at least annually).

4.17.5 Recall operations should be capable of being initiated promptly and at any time.

4.17.6 The distributor must follow the instructions of a recall message, which should be approved, if required, by the competent authorities.

4.17.7 Any recall operation should be recorded at the time it is carried out. Records should be made readily available to the competent authorities.

4.17.8 The distribution records should be readily accessible to the person(s) responsible for the recall, and should contain sufficient information on distributors and directly supplied customers (with addresses, phone and/or fax numbers inside and outside working hours, batch numbers as required by national legislation and quantities delivered), including those for exported products and medicinal product samples (if permitted by national legislation).

4.17.9 The progress of the recall process should be recorded for a final report including reconciliation of the recalled product.

4.18 Self-Inspection

4.18.1 Self-inspections shall be included in the quality system. These shall be conducted to monitor implementation and compliance with the principles of GDP and, if necessary, to trigger corrective and preventive measures.

4.18.2 A designated, competent person shall conduct self-inspection in an independent and detailed way.

4.18.3 There shall be records of self-inspection results which shall contain all observations made during the inspection and if required proposal for corrective measures. There shall be an effective follow-up programme and evaluation of inspection report and corrective action taken by the

management.

4.18.4 Self-inspections should be conducted periodically, according to an annual schedule.

4.18.5 The team conducting the inspection should be free from bias and individual members should have appropriate knowledge and experience.

5.0 Glossary/Definition

5.1 Quality Management System

A structured framework that defines and documents an organization's processes, procedures and responsibilities for achieving quality objectives

5.2 Quality System

A documented management system that outlines an organization's processes, policies, and objectives for ensuring quality in its products, services and work processes

5.3 Risk

Risk involves uncertainty about the effects/implications of an activity with respect to something that humans value, often focusing on negative, undesirable consequences.

5.4 Risk Management

A systematic process for identifying, evaluating, and reducing the likelihood of risks that could impact an organization

5.5 Management Review

A formal, scheduled evaluation of an institution's management systems to ensure they are working as intended and providing the desired results

5.6 Premises

A house or building, together with its land and outbuildings, occupied by a business or considered in an official context

5.7 Warehouses

A large building where raw materials or manufactured goods may be stored prior to their distribution for sale

5.8 Storage

The state of being stored. especially: the safekeeping of goods in a depository (such as a warehouse).

5.9 Temperature

Is a physical quantity that quantitatively expresses the attribute of hotness or coldness.

5.10 Environmental Control

Environmental control is the practice of measuring and regulating specific parameters in controlled environments. These environments are designed to meet the needs of a business or customer, and are used in a variety of industries.

5.11 Transportation

Movement of goods and persons from place to place and the various means by which such movement is accomplished.

5.12 Documentation

Written or recorded information that explains, describes or instructs a system, object, or procedures

5.13 Medical Products

A substance or combination of substances that is intended to treat, prevent or diagnose a disease, or to restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action.

5.14 FEFO (First Expired First Out)

Is a strategy for managing inventory for products with expiration dates. It's a key method for industries that deal with perishable goods, such as food, cosmetics, and pharmaceuticals.

5.15 Falsified Medical Products

Falsified medical products deliberately misrepresent their identity, composition or source. These products are often created and distributed with the intent to deceive consumers for financial gain.

6.0 Reference and information sources

6.1 Good trade and distribution practices for pharmaceutical starting materials. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: fiftieth report. Geneva: World Health Organization; 2016: Annex 6 (WHO Technical Report Series, No. 996; http://apps.who.int/ medicinedocs /documents/s22403en/s22403en.pdf, accessed 5 December 2019).

6.2 WHO good distribution practices for pharmaceutical products. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: forty-fourth report. Geneva: World Health Organization; 2010: Annex 5 (WHO Technical Report Series, No. 957; https://www.who.int/ medicines/areas/quality_safety/quality_assurance/GoodDistributionPracticesTRS957Annex5.pdf, accessed 5 December 2019).

7.0 Annex

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