RWANDA FDA
Rwanda Food and Drugs Authority

GUIDELINES FOR GOOD DISTRIBUTION PRACTICES OF MEDICAL PRODUCTS

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FOREWORD

Rwanda Food and Drugs Authority is a regulatory body established by the Law N° 003/2018 of 09/02/2018. One of the functions of Rwanda FDA is to regulate matters related to quality, safety and efficacy of distributed medical products in Rwanda. Considering the provisions of the technical regulations N° CBD/TRG/001 Rev. N° 0 of 10th January 2020 governing licensing to manufacture pharmaceutical products or to operate as wholesale or a retail seller of pharmaceutical products especially in its article 35, the Authority issues these *Guidelines N° DIS/GDL/032* For *Good Distribution Practices of Medical Products.*

These guidelines provide guidance to the distributors of medical products on the good distribution practices. Distributors of medical products are encouraged to familiarize with these guidelines and follow them when distributing medical products.

Adherence to these guidelines will facilitate efficient and effective distribution of medical products with assured quality, safety and efficacy. It will also help to avoid malpractices in the distribution process of medical products.

The Authority acknowledges all the efforts of stakeholders who participated in development and validation of these guidelines.

Dr. Charles KARANGWA
Ag. Director General

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ABBREVIATIONS AND ACRONYMS

CAPA	Corrective Actions and Preventive Actions
GDP	Good Distribution Practices
FEFO	First Expiry, First Out'
GMP	Good Manufacturing Practices
GPP	Good Pharmacy Practice
GSP	Good Storage Practices
SOP	Standard Operating Procedures
GTDP	Good Trade and Distribution Practices
MAH	Marketing Authorization Holder
ISO	International Standardization Organization

DEFINITIONS

The definitions provided below apply to the words and phrases used in these guidelines. Although an effort has been made to use standard definitions as far as possible, they may have different meanings in other contexts and documents.

"**Agreement**" means Arrangement undertaken by and legally binding on parties.

"**Auditing**" means An independent and objective activity designed to add value and improve an organization's operations by helping the organization to accomplish its objectives by using a systematic, disciplined approach to evaluate and improve the effectiveness of risk management, control and governance processes.

"**Authority**" means the Rwanda Food and Drugs Authority or its acronym "Rwanda FDA", established under the article 2 of the Law No. 003/2018 of 09/02/2018.

"Batch" means A defined quantity of medical products processed in a single process or series of processes so that it is expected to be homogeneous.
"Batch number" means a distinctive combination of numbers and/or letters which uniquely identifies a batch, for example, on the labels, its batch records and corresponding certificates of analysis.
"Consignment" means the quantity of medical products supplied at one time in response to a particular request or order. A consignment may comprise one or more packages or containers and may include medical products belonging to more than one batch.

"Container" means the material employed in the packaging of a medical product. Containers include primary, secondary and transportation containers. Containers are referred to as primary if they are intended to be in direct contact with the product. Secondary containers are not intended to be in direct contact with the product

"Contamination" means the undesired introduction of impurities of a chemical or microbiological nature, or of foreign matter, into or on to a starting material, intermediate or medical product during handling, production, sampling, packaging or repackaging, storage, distribution or transportation.
"Contract" is a Business agreement for the supply of goods or performance of work at a specified price.

"Counterfeit medical product"A medical product that is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products, and counterfeit medical products may include products with the correct ingredients, with the wrong ingredients, without active ingredients, with an incorrect quantity of active ingredient or with fake packaging.

"Cross-contamination" is Contamination of a starting material, intermediate product or finished medical product with another starting material or product during production, storage and transportation.

"Distribution"The procuring, purchasing, holding, storing, selling, supplying, importing, exporting, or movement of medical products, with the exception of the dispensing or providing medical products directly to a client.

"Distributor" means a intermediary entity between the producer of a medical product and another entity in the distribution channel or supply chain.

"Due diligence" This is a term used for a number of concepts, involving either an investigation of a distributors or persons prior to signing a contract, or an act with a certain standard of care.

"Expiry date" means the date given on the individual container (usually on the label) of a medical product up to and including the date on which the product is expected to remain within specifications, if stored correctly. It is established for each batch by adding the shelf-life to the date of manufacture.

"First Expiry, First Out' (FEFO)" means a distribution procedure that ensures that the stock with the earliest expiry date is distributed and/or used before an identical stock item with a later expiry date is distributed and/or used.

"Forwarding agent" means a person or entity engaged in providing, either directly or indirectly, any service concerned with clearing and forwarding operations in any manner to any other person and includes a consignment agent.

"Good Distribution Practices (GDP)" is that part of quality assurance that ensures that the quality of a medical product is maintained by means of adequate control of the numerous activities which occur during the distribution process as well as providing a tool to secure the distribution system

from counterfeits, unapproved, illegally imported, stolen, counterfeit, substandard, adulterated, and/or misbranded medical products.

"Good Manufacturing Practices (GMP)" is that part of quality assurance that ensures that medical products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization.

"Good Pharmacy Practice (GPP)" is the practice of pharmacy aimed at providing and promoting the best use of medicines and other health care services and products, by patients and members of the public. It requires that the welfare of the patient is the pharmacist's prime concern at all times.

"Good Storage Practices (GSP)" is that part of quality assurance that ensures that the quality of medical products is maintained by means of adequate control throughout the storage thereof.

"**Good Trade and Distribution Practices (GTDP)"** is That part of quality assurance that ensures that the quality of medical products is maintained by means of adequate control throughout the numerous activities that occur during the trade and the distribution process.

"Importation" means the act of bringing or causing any goods to be brought into a customs territory (national territory, excluding any free zone).

"Importer" means an individual or entity that undertakes the act of importation

"Intermediate product" means partly processed product that must undergo further manufacturing steps before it becomes a bulk-finished product.

"Labelling" means Process of identifying a medical product including the following information, as appropriate: name of the product; active ingredient(s), type and amount; batch number; expiry date; special storage conditions or handling precautions; directions for use, warnings and precautions; names and addresses of the manufacturer and/or the supplier.

"Manufacture" means all operations of purchase of materials and products, production, packaging, labelling, quality control, release, storage and distribution of medical products, and the related controls.

"Pedigree" means a complete record that traces the ownership of and transactions relating to a medical product as it is distributed through the supply chain.

"Pharmaceutical product" means any substance capable of preventing, treating human or animal diseases and any other substance intended for administration to a human being or an animal in order to diagnose diseases, restore, correct or carry out modification of organic or mental functions. It also means products used in disinfecting premises which food and drugs are manufactured, prepared or stored, cleaning hospitals, equipment and farm houses.

"Product recall" means a process for withdrawing or removing a medical product from the supply chain because of defects in the product, complaints of serious adverse reactions to the product, unauthorized entry on to the market and/or concerns that the product is or may be counterfeit. The recall might be initiated by the manufacturer**,** importer, Local Technical Representative (LTR) wholesaler, distributor or The Authority.

"Medical product" Includes medicines, vaccines, diagnostics and medical devices

"Quality assurance" is a wide-ranging concept covering all matters that individually or collectively influence the quality of a product. It is the totality of the arrangements made with the object of ensuring that medical products are of the quality required for their intended use.

"Quality system" is an appropriate infrastructure, encompassing the organizational structure, procedures, processes and resources, and systematic actions necessary to ensure adequate confidence that a product (or services) will satisfy given requirements for quality.

"Quarantine" means the status of medical products isolated physically or by other effective means while a decision is awaited on their release, rejection or reprocessing.

"Retailer" is an entity authorized to carry on the business of dispensing or providing medical products directly to a patient or his or her agent only. Retailers are not authorized to supply medical products to distributors or other retailers.

"Sampling" means operations designed to obtain a representative portion of a medical product, based on an appropriate statistical procedure, for a defined purpose, e.g. acceptance of consignments or batch release.

"**Shelf-life**" means the period of time during which a medical product, if stored correctly, is expected to comply with the specification as determined by stability studies on a number of batches of the product. The shelf life is used to establish the expiry date of each batch.

"Standard Operating Procedure (SOP)" is an authorized, written procedure giving instructions for performing operations not necessarily specific to a given product but of a more general nature (e.g. equipment operation, maintenance and cleaning, validation, cleaning of premises and environmental control, sampling and inspection).

"Storage" means the storing of medical products up to the point of use.

"Supplier" is a person or entity engaged in the activity of providing products and/or services.

"Transit" is the period during which medical products are in the process of being carried, conveyed, or transported across, over or through a passage or route to reach the destination.

"Vehicles" means Trucks, vans, buses, minibuses, cars, trailers, aircraft, railway carriages, boats and other means which are used to convey regulated products.

"Wholesale Pharmacy (wholesaler)" is an entity that is authorised to carry on the business of selling medical products in large quantities to other authorised sellers with the exception of dispensing or providing medical products directly to a patient.

CHAPTER 1: INTRODUCTION

1.1. Scope

This document lays down guidelines for good distribution practices for medical products. These guidelines shall apply equally to products for human and for veterinary use. The guidelines cover products for which a prescription is required, products, which may be provided without a prescription, biologicals and vaccines. The document does not specifically cover GMP aspects of finished products in bulk, distribution of labels or packaging, as these aspects are considered to be covered by other guidelines.

1.2. Explanatory note Of These guidelines

The '*Guidelines for Good Distribution Practices, First Edition' is* a Rwanda Food and Drugs Authority publication, which sets out procedures and requirements for the minimum standards for distribution of medical products. They are issued in pursuance of Article 9 of Law N° 003/2018 of 09/02/2018 establishing the Rwanda FDA and determining its mission, organization and functioning and in terms of Law N° 47/2012 of 14/01/2013 relating to the regulation and inspection of food and pharmaceutical products, which were put in place to ensure quality within the pharmaceutical distribution chain.

The purpose of GDP guidelines is to give guidance that ensures that medical products are distributed in a manner that will protect the consumer. Compliance with these guidelines will ensure control of the distribution chain and consequently maintain the quality and the integrity of medical products and will also assist in ensuring that these products are distributed properly. This will ensure that reasonable control over the product acquisition, storage, sale, supply or disposal is maintained as required by Law N° 003/2018 and Law N° 47/2012.

Distribution is an important activity in the integrated supply-chain management of medical products. The objective of these guidelines is to assist in ensuring the quality and safety of medical products during all aspects of the distribution process.

This document sets out appropriate steps to assist people in fulfilling the responsibilities involved in the different aspects of the distribution process within the health supply chain and to maintain the quality and safety and efficacy of medical products on Rwandan market.

The relevant sections should be considered by various actors as applicable to the particular role that they play in the distribution of medical products.

To maintain the original quality of medical products, every party active in the distribution chain has to comply with the provisions of the Rwanda FDA laws in regard to handling of medical products. Every activity in the distribution of medical products should be carried out according to the principles of GMP, GSP GDP and GPP as applicable.

CHAPTER 2: GENERAL REQUIREMENTS

The principles of GDP are applicable both to medical products moving forward in the distribution chain from the manufacturer to the entity responsible for dispensing or providing medical products to the patient and to products that are moving backwards in the chain, for example, as a result of the return or recall thereof.

All entities involved in the distribution process should apply due diligence with adherence to the principles of GDP, for example, in procedures relating to traceability and in recognition of security risks. The principles of GDP should also be adhered to in the case of medical products, which are donated.

2.1 Distributors must maintain a quality system setting out responsibilities, processes and risk management principles in relation to their activities. All distribution activities should be clearly defined and systematically reviewed. All critical steps of distribution processes and significant changes should be justified and where relevant validated. The quality system is the responsibility of the organisation's management and requires their leadership and active participation and should be supported by staff commitment.

2.2 The correct distribution of medical products relies upon people. For this reason, there must be sufficient competent personnel to carry out all the tasks for which the distributor is responsible. Individual responsibilities should be clearly understood by the staff and be recorded.

2.3 Distributors must have suitable and adequate premises, installations and equipment, so as to ensure proper storage conditions and distribution of medical products.

2.4 Good documentation constitutes an essential part of the quality system. Written documentation should prevent errors from spoken communication and permits the tracking of relevant operations during the distribution of medical products.

2.5. All actions taken by distributors should ensure that the safety, quality and efficacy of the medical products are not lost and that the distribution of medical products is performed according to the information on the outer packaging. The distributor should use all means available to minimize the risk of falsified medical products entering the legal supply chain.

2.6 All complaints, returns, suspected falsified medical products and recalls must be recorded and handled carefully according to written procedures. Records should be made available to the competent authorities. An assessment of returned medical products should be performed before any approval for resale. A consistent approach by all partners in the supply chain is required in order to be successful in the fight against falsified medical products.

2.7 Any activity covered by the GDP Guidelines that is outsourced should be correctly defined, agreed and controlled in order to avoid misunderstandings which could affect the integrity of the product. There must be a written Contract between the Contract Giver and the Contract Acceptor which clearly establishes the duties of each party.

2.8 It is the responsibility of the distributor to ensure that the quality of the medical products is maintained from the manufacturer to his stores and then to the final consumer, the retailer or/and client.

It is the responsibility of the supplying distributor to protect medical products against breakage, adulteration and theft, and to ensure that temperature conditions are maintained within acceptable limits during transport.

Regardless of the mode of transport, it should be possible to demonstrate that the medical products have not been exposed to conditions that may compromise their quality and integrity. A risk-based approach should be utilized when planning transportation.

2.9 Self-inspections should be conducted in order to monitor implementation and compliance with GDP principles and to propose necessary corrective measures.

CHAPITER 3: REGULATION OF THE DISTRIBUTION OF MEDICAL PRODUCTS

3.1 The distribution of medical products is regulated by Law 003/2018 of 09/02/2018 establishing the Rwanda Food and Drugs Authority and determining its mission, organization and functioning and Law N^0. 47/2012 of 14/01/2013 relating to the Regulation and Inspection of Food and Pharmaceutical Products and the accompanying Rwanda FDA Regulations.

3.2 The distributor or the organization to which the distributor belongs should be an entity that is appropriately authorized in terms of Law N^0 003/2018 and Law N^o. 47/2012 to perform the function(s) that it intends to perform. The distributor or the organization to which it belongs is accountable for the activities that it performs which relate to the distribution of medical products.

3.4 Distributors or their agents may only distribute a medical product within or to a country or territory if a marketing authorization or similar authorization has been granted, which allows the use of that medical product in that country or territory.

3.5 Holders of an authorization to distribute medical products should obtain their supplies of medical products only from persons or entities, which are in possession of the applicable authorization to sell or supply such products to a distributor.

3.6 Distributors or their agents should supply medical products only to persons or entities, which are themselves authorized to acquire such products either in terms of an authorization to act as a distributor or to sell or supply products directly to a client.

3.7 Some duties and responsibilities may be delegated or contracted out to suitably designated persons or entities as authorized and as necessary. Duties and responsibilities may only be delegated to entities which are suitably authorized in line with the Rwanda Law N^o 003/2018 and Law 47/2012. Duties and responsibilities should be specified in a written agreement. There should be no gaps or unexplained overlaps with regard to the application of GDP. These delegated and contracted out activities should be documented in agreements or contracts. There should be a periodic audit of such activities with regard to application of GDP.

3.8 If a distributor or his or her agent subcontracts an activity to another entity, the person or entity to whom the activity is subcontracted must be appropriately authorized to perform the subcontracted activity and should uphold the same standards as the distributor.

CHAPITER 4: ORGANIZATION AND MANAGEMENT

4.1 There should be an adequate organizational structure for each entity defined with the aid of an organizational chart. The responsibility, authority and interrelationships of all personnel should be clearly indicated.

4.2 Duties and responsibilities should be clearly defined and understood by the individuals concerned and recorded as written job descriptions. At every level of the supply chain, employees should be fully informed and trained in their duties and responsibilities.

4.3 A designated person should be appointed within the organization, who has defined authority and responsibility for ensuring that a quality system is implemented and maintained. The person should be appropriately qualified.

4.4 Managerial and technical personnel must have the authority and resources needed to carry out their duties and to set up and maintain a quality system, as well as to identify and correct deviations from the established quality system (see section 8).

4.5 The responsibilities placed on any one individual should not be so extensive as to present any risk to product quality.

4.6 There should be arrangements in place to ensure that management and personnel are not subject to commercial, political, financial and other pressures or conflict of interest that may have an adverse effect on the quality of service provided or on the integrity of medical products.

4.7 Safety procedures relating to all relevant aspects including the safety of personnel and property, environmental protection and product integrity, should be in place.

CHAPITER 5: PERSONNEL

5.1 All personnel involved in distribution activities should be trained and qualified in the requirements of GDP, as applicable. Training should be based on written SOPs. Personnel should receive initial and continuing training relevant to their tasks, and be assessed as applicable, in accordance with a written training program. In addition, training of the personnel should include the topic of product security, as well as aspects of product identification, the detection of counterfeits and the avoidance of counterfeits entering the supply chain. A record of all trainings, which includes details of subjects covered and participants trained, should be kept and easily retrievable.

5.2 Key personnel involved in the distribution of medical products should have the ability and experience appropriate to their responsibility for ensuring that medical products are distributed properly.

5.3 There should be an adequate number of competent personnel involved in all stages of the distribution of medical products in order to ensure that the quality of the product is maintained.

5.4 Personnel dealing with hazardous medical products (such as highly active materials, radioactive materials, narcotics, and other hazardous, environmentally sensitive and/or dangerous medical products, as well as products presenting special risks of abuse, fire or explosion) should be given specific training.

5.5 Personnel involved in the distribution of medical products should wear garments suitable for the activities that they perform. Personnel dealing with hazardous medical products, including products containing materials that are highly active, toxic, infectious or sensitizing, should be provided with protective garments as necessary and material safety data sheet (MSDS) shall be in place for proper handling.

5.6 Appropriate procedures relating to personnel hygiene, relevant to the activities to be carried out, should be established and observed. Such procedures should cover health, hygiene and clothing of personnel.

5.7 Procedures and conditions of employment for employees, including contract and temporary staff, and other personnel having access medical products must be designed and administered to assist in minimizing the possibility of such products coming into the possession of unauthorized persons or entities.

5.8 Codes of practice and punitive procedures should be in place to prevent and address situations where persons involved in the distribution of medical products are suspected of, or found to be implicated in, any activities relating to the misappropriation, tampering, diversion or counterfeiting of any product.

CHAPITER 6: QUALITY ASSURANCE SYSTEM

6.1 Within an organization, quality assurance serves as a management tool. There should be a documented quality policy describing the overall intentions and requirements of the distributor regarding quality, as formally expressed and authorized by management.

6.2 The quality system should include an appropriate organizational structure, procedure, processes and resources and systematic actions necessary to ensure adequate confidence that a product or service and its documentation will satisfy given requirements for quality. The totality of these actions is described as the quality system.

6.3 The quality system should include provisions to ensure that the holder of the marketing authorization, entity identified on the label (if different from the manufacturer), the Rwanda FDA and/or international regulatory bodies, as well as other relevant competent authorities, would be informed immediately in a case of confirmed or suspected counterfeiting of a medical product. Such products should be stored in a secure, segregated area and clearly identified to prevent further distribution or sale.

6.4 Where electronic commerce (e-commerce) is used, i.e. electronic means are used for any of the distribution steps, defined procedures and adequate systems should be in place to ensure traceability and confidence in the quality of the medical products concerned. Electronic transactions (including those conducted via the Internet), relating to the distribution of medical products, should be performed only by authorized persons or entities.

6.5 Authorized procurement and release procedures for all administrative and technical operations performed should be in place to ensure that appropriate medical products are sourced only from approved suppliers and distributed by approved entities. The approval should come from the Authority.

6.6 Inspection, auditing and certification of compliance with a quality system (such as the applicable International Standardization Organization (ISO) series, or national or international guidelines) by external bodies is recommended. Such certification should not, however, be seen as a substitute for compliance with these GDP guidelines and the applicable principles of GMP relating to medical products.

6.7 If measures to ensure the integrity of the medical products in transit are in place, they should be managed properly. For example, if seal control programmes for transit shipment are used, numbers should be issued in a tracked and sequential manner, the integrity of seals should be monitored and numbers verified during transit and upon receipt. Written procedures should be in place for use in situations where medical products are suspected of being or are found to be counterfeit.

6.8 Distributors should from time to time conduct risk assessments to assess potential risks to the quality and integrity of medical products. The quality system should be developed and implemented to address any potential risks identified. The quality system should be reviewed and revised periodically to address new risks identified during a risk assessment.

6.9 Regulations should foster a safe, transparent and secure distribution system which includes product traceability throughout the supply chain. This is a shared responsibility among the parties involved.

6.10 Records should be made at the time a transaction takes place and such that all significant activities and events are traceable. Records should be clear and readily available. Records must be kept for a minimum of ten years from the date of distribution.

6.11 Records for each purchase or sale must include date of purchase or supply, name of medical product, quantity supplied or received, batch number, expiry date, name and address of supplier or consignee.

6.12 All parties involved in the distribution process of medical products should be identifiable.

6.13 Measures should be in place to ensure that medical products have documentation that can be used to permit traceability of the products throughout distribution channels. For transactions between manufacturer/importer, wholesaler and the entity responsible for selling or supplying the product to the client (see also 14.2), records must include expiry dates and batch numbers as part of a secure distribution documentation enabling traceability.

6.14 There should be a procedure in place for the creation and maintenance of a pedigree for medical products.

There need to be a written procedure to be followed when a suspected product is identified. The procedure should include the method for visually and/or analytically identification of the potentially counterfeit product. Additionally, the procedure should include the course of action for notification, as appropriate, of the holder of the marketing authorization. Rwanda

FDA will then investigate the case and inform the public and international regulatory bodies when necessary.

6.15 A suitable and, to the extent possible, internationally compatible product coding, identification system should be in place and developed in collaboration with the various parties involved in the supply chain. While it is understood that a differentiated approach may be necessary for different products and regions, pedigree and/or track-and-trace technologies provide possible options to ensure traceability.

6.16 The quality assurance system should ensure that:

- Medical products are procured, held, supplied, imported or exported in a way that is compliant with the requirements of GDP;
- Management responsibilities are clearly specified;
- Products are delivered to the right recipients within a satisfactory time period
- Records are made on time and easily retrievable
- Deviations from established procedures are documented and investigated;
- Appropriate corrective and preventive actions (commonly known as CAPA) are taken to correct deviations and prevent them in line with the principles of quality risk management.

6.17 The quality assurance system should extend to the control and review of any outsourced activities related to the procurement, holding, supply, import or export of medical products

6.18 The quality assurance system should assess the suitability and competence of the Contract Acceptor to carry out the activity, preserving the integrity and security of the medical products, and requesting, preserving documentation, and checking authorization or marketing status, if required;

6.19 The quality assurance system should define the responsibilities and communication processes for the quality-related activities of the parties involved;

6.20 The quality assurance system should monitor and review of the performance of the Contract Acceptor, and the identification and implementation of any required improvements on a regular basis

CHAPITER 7: PREMISES, WAREHOUSING AND STORAGE

7.1 Good storage practices (GSP) are applicable in all circumstances where medical products are stored and throughout the distribution process.

7.2 Precautions must be taken to prevent unauthorized persons from entering storage areas. Employees should comply with the distribution company policies to maintain a safe, secure and efficient working environment.

7.3 Storage areas should be of sufficient capacity to allow the orderly storage of the various categories of medical products, namely commercial and non-commercial products, products in quarantine, and released, rejected, returned or recalled products as well as those suspected to be of poor quality.

7.4 Storage areas should be designed or adapted to ensure appropriate and good storage conditions. In particular, they should be dry and maintained within acceptable temperature limits and medical products should be stored off the floor and suitably spaced to permit cleaning and inspection. Pallets should be kept in a good state of cleanliness and repair.

The personnel involved in storage activities shall always respect the storage guidelines that include but not limited to:

- Clean and disinfect storeroom regularly
- Store supplies in a dry, well-lit, well-ventilated storeroom out of direct sunlight
- Secure storeroom from water penetration
- Ensure that fire safety equipment is available and accessible and personnel are trained to use it
- Store condoms and other latex products away from electric motors and fluorescent lights.
- Maintain cold storage, including a cold chain, for commodities that require it.
- Keep narcotics and other controlled substances in a locked place.
- Store flammable products separately from other products. Take appropriate safety precautions.
- Stack cartons at least 10 cm (4 in) off the floor, 30 cm (1 ft) away from the walls and other stacks, and not more than 2.5 m (8 ft) high.
- Store medical products away from insecticides, chemicals, old files, office supplies, and other materials.
- Arrange cartons so that arrows point up. Ensure that identification labels, expiry dates, and manufacturing dates are clearly visible.
- Store supplies in a manner accessible for FEFO, counting, and general management.

- Separate and dispose of damaged or expired products immediately.

7.5 Storage areas should be clean and free from litter, dust and pests. Distributors must ensure that premises and storage areas are cleaned regularly. There should also be written procedures for pest control. The pest control agents used should be safe and there should be no risk of contamination of medical products. There should be appropriate procedures for the clean up of any spillage to ensure complete removal of any risk of contamination.

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

7.7 Receiving and dispatch bays should protect medical products from the non-conducive environmental conditions. Receiving areas should be designed and equipped to allow incoming containers of medical products to be cleaned, if necessary, before storage.

7.8 Where quarantine status is ensured by storage in separate areas, these areas must be clearly marked and access restricted to authorized personnel. Any system replacing physical quarantine should provide equivalent security. For example, computerized systems can be used, provided that they are validated to demonstrate security of access.

7.9 Physical or other equivalent validated (e.g. electronic) segregation should be provided for the storage of rejected, expired, recalled or returned products and suspected counterfeits. The products and the areas concerned should be appropriately identified.

7.10 Unless there is an appropriate alternative system to prevent the unintentional or unauthorized use of quarantined, rejected, returned, recalled or suspected counterfeit medical products, separate storage areas should be assigned for their temporary storage until further action taken.

7.11 Radioactive materials, narcotics and other hazardous, sensitive and/ or dangerous medical products, as well as products presenting special risks of abuse, fire or explosion (e.g. combustible or flammable liquids and solids and pressurized gases) should be stored in dedicated area(s) that is subject to appropriate additional safety and security measures.

7.12 Medical products should be handled and stored in such a manner as to prevent contamination, mix-ups and cross-contamination.

7.13 A system should be in place to ensure stock rotation first expiry/ first out (FEFO)) with frequent and regular controls that the system is working correctly.

7.14 Broken or damaged items should be withdrawn from usable stock and stored separately.

7.15 Storage areas should be provided with adequate lighting to enable all operations to be carried out accurately and safely.

7.16 Medical products should be stored separate from other goods and under the conditions specified by the manufacturer in order to avoid deterioration by light, moisture or temperature.

7.17 Storage and handling conditions shall comply with regulations No CBD/TRG/001 Rev. Nº 0 for licensing to manufacture; operate as wholesale and retail seller of medical products.

7.18 Storage conditions for medical products shall comply with the recommendations of the manufacturer.

Facilities should be available for the storage of all medical products under appropriate conditions (e.g. environmentally controlled when necessary). Records should be maintained of these conditions if they are critical for the maintenance of the characteristics of the medical product stored.

7.19 Records of temperature monitoring data should be available for review. There should be defined intervals for checking temperature. The equipment used for monitoring should be checked at suitable predetermined intervals and the results of such checks should be recorded and retained. All monitoring records should be kept for at least the shelf-life of the stored product plus one year. Temperature mapping should show uniformity of the temperature across the storage facility. It is recommended that temperature monitors be located in areas that are most likely to show fluctuations.

7.20 Equipment used for monitoring of storage conditions should also be calibrated at defined intervals.

7.21 Periodic stock reconciliation should be performed by comparing the actual and recorded stocks. This should be done at defined intervals.

7.22 Stock discrepancies should be investigated in accordance with a specified procedure to check that there have been no inadvertent mix-ups, incorrect issues and receipts, thefts and/or misappropriations of medical products. Documentation relating to the investigation should be kept for a **predetermined** period.

7.23 Reception area must be separate from the storage area. Deliveries should be examined on receipt in order to check that containers are not damaged and that the consignment corresponds to the order.

7.24 Upon receipt, medical products stored at specific requirements (e.g. narcotics or products requiring specific storage temperature) should be immediately identified and stored according to specified storage conditions.

7.25 Distributors should conduct visual checks of the products that they receive. The visual check would compare a "master" of the package with the actual. The "master" is either a copy of the package "blue print" received from the manufacturer of the product, or a sample or photo of the package approved by Rwanda FDA

CHAPITER 8: VEHICLES AND EQUIPMENT

8.1 Vehicles and equipment used to distribute, store or handle medical products should be suitable for their purpose and appropriately equipped to prevent exposure of the products to conditions that could affect their stability and packaging integrity, and to prevent contamination of any kind.

8.2 The design and use of vehicles and equipment must aim to minimize the risk of errors and permit effective cleaning and/or maintenance to avoid contamination, build-up of dust or dirt and/or any adverse effect on the quality of the medical products being distributed.

8.3 Where feasible, consideration should be given to adding technology, such as global positioning system (GPS) electronic tracking devices and engine-kill buttons to vehicles, which would enhance the security of medical products while in the vehicle.

8.4 Dedicated vehicles and equipment should be used, where possible, when handling medical products.

8.5 Where non-dedicated vehicles and equipment are used, procedures should be in place to ensure that the quality of the medical products will not be compromised. Appropriate cleaning should be performed, checked and recorded.

8.6 Procedures should be in place to ensure that the integrity of the products is not compromised during transportation.

8.7 Where third-party carriers are used, distributors should develop written agreements with carriers to ensure that appropriate measures are taken to safeguard medical products, including maintaining appropriate documentation and records. Such agreements should be in line with the Authority's regulatory requirements.

8.8 Defective vehicles and equipment should not be used and should either be labelled as such or removed from service.

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

8.10 Vehicles, containers and equipment should be kept clean, dry and free from accumulated waste. Distributors must ensure that vehicles used are cleaned regularly.

8.11 Vehicles, containers and equipment should be kept free from rodents, vermin, birds and other pests. There should be written procedures and records for such pest control. The cleaning and fumigation agents used should not have any adverse effect on product quality.

8.12 Equipment chosen and used for the cleaning of vehicles should not constitute a source of contamination. Agents used for the cleaning of vehicles should be approved by organization management and should comply with applicable laws and regulations.

8.13 Special attention should be paid to the design, use, cleaning and maintenance of all equipment used for the handling of medical products which are not in a protective shipping carton or case.

8.14 Where special storage conditions (e.g. temperature and/or relative humidity), different from, or limiting, the expected environmental conditions, are required during transportation, these should be provided, checked, monitored and recorded. All monitoring records should be kept for a minimum of the shelf-life of the product distributed plus one year. Records should be available for inspection by the Authority.

8.15 Equipment used for monitoring conditions, e.g. temperature and humidity, within vehicles and containers should be calibrated at regular intervals.

8.16 Vehicles and containers should be of sufficient capacity to allow orderly storage of the various categories of medical products during transportation.

8.17 Where possible, mechanisms should be available to allow for the segregation during transit of rejected, recalled and returned medical products as well as those suspected of being counterfeits. Such goods should be securely packaged, clearly labelled, and be accompanied by appropriate supporting documentation.

8.18 Measures should be in place to prevent unauthorized persons from entering and/or tampering with vehicles and/or equipment, as well as to prevent the theft or misappropriation thereof.

CHAPITER 9: SHIPMENT CONTAINERS AND CONTAINER LABELLING

9.1 Medical products should be stored and distributed in shipment containers that have no adverse effect on the quality of the products, and that offer adequate protection from external influences, including contamination.

9.2 Shipping containers should bear labels providing sufficient information on handling and storage conditions and precautions to ensure that the products are properly handled and secure at all times. The shipment container should enable identification of the container's contents and source.

9.3 The need for any special transport and/or storage conditions should be stated on the shipment container label. If a medical product is intended for transfer to areas outside the control of the manufacturer's products management system, the name and address of the manufacturer, special transport conditions and any special legal requirements, including safety symbols, should also be included on the container label.

9.4 Normally, internationally and/or nationally accepted abbreviations, names or codes should be used in the labelling of shipment containers.

9.5 Special care should be taken when using dry ice in shipment containers. In addition to safety issues it must be ensured that the medical product does not come into contact with the dry ice, as it may have an adverse effect on the quality of the product.

9.6 Written procedures should be available for the handling of damaged and/or broken shipment containers. Particular attention should be paid to those containing potentially toxic and hazardous products.

CHAPITER 10: DISPATCH AND RECEIPT

10.1 Medical products should only be sold and/or distributed to persons or entities that are authorized to acquire such products in accordance with the Rwanda FDA laws and regulations. Written proof of such authority must be obtained prior to the distribution of products to such persons or entities.

10.2 Prior to the dispatch of the medical products, the supplier should ensure that the person or entity, e.g. the contract acceptor for transportation of the medical products, is aware of the medical products to be distributed and complies with the appropriate storage and transport conditions.

10.3 The dispatch and transportation of medical products should be undertaken only after the receipt of a valid delivery order or material replenishment plan, which should be documented.

10.4 Written procedures for the dispatch of medical products should be established. Such procedures should take into account the nature of the product as well as any special precautions to be observed. Medical products under quarantine will require release for dispatch by the person responsible for quality (see 6.3).

10.5 Records for the dispatch of medical products should be prepared and should include at least the following information:

1) Date of dispatch
2) Complete business name and address (no acronyms), type of entity responsible for the transportation, telephone number and names of contact persons for supplier.
3) Complete business name, address (no acronyms), and status of the addressee (e.g. retail pharmacy, hospital or community clinic)
4) A description of the products including, e.g. name, dosage form and strength (if applicable) for addressee;.
5) Quantity of the products, i.e. number of containers and quantity per container (if applicable);
6) Applicable transport and storage conditions;
7) A unique number to allow identification of the delivery order; and

8) Assigned batch number and expiry date (where not possible at dispatch, this information should at least be kept at receipt to facilitate traceability).

10.6 Records of dispatch should contain enough information to enable traceability of the medical product. Such records should facilitate the recall of a batch of a product, if necessary, as well as the investigation of counterfeit or potentially counterfeit medical products.

10.7 In addition, the assigned batch number and expiry date of medical products should be recorded at the point of receipt to facilitate traceability.
Methods of transportation, including vehicles to be used, should be selected with care, and local conditions should be considered, including the climate and any seasonal variations experienced. Delivery of products requiring controlled temperatures should be in accordance with the applicable storage and transport conditions. Delivery schedules should be established and routes planned, taking local needs and conditions into account. Such schedules and plans should be realistic and systematic. Security risks should also be taken into account when planning the schedules and routes of the delivery.

10.8 Care should be taken to ensure that the volume of medical products ordered does not exceed the capacity of storage facilities at the destination.

10.9 Vehicles and containers should be loaded carefully and systematically, where applicable on a first-out/last-in basis, to save time when unloading, prevent physical damage and reduce security risks. Extra care should be taken during loading and unloading of cartons to avoid damage.

10.10 Medical products should not be supplied or received after their expiry date, or so close to the expiry date that this date is likely to be reached before the products are used by the consumer.

10.11 Incoming shipments should be examined to verify the integrity of the container/closure system, ensure that tamper-evident packaging features are intact, and that labelling appears intact.

CHAPITER 11: TRANSPORTATION AND PRODUCTS IN TRANSIT

11.1 Products and shipment containers should be secured to prevent or provide evidence of unauthorized access. Vehicles and operators should be provided with additional security, as appropriate, to prevent theft and other misappropriation of products during transportation.

11.2 Product shipments should be secured and include the appropriate documentation to facilitate identification and verification of compliance with the Rwandan Laws and regulations on medical products. Policies and procedures should be followed by all persons involved in the transportation, to secure medical products.

11.3 The people responsible for the transportation of medical products should be informed about all relevant conditions for storage and transportation. These requirements should be adhered to throughout transportation and at any intermediate storage stages.

11.4 Medical products should be stored and transported in accordance with procedures such that:

1) The identity of the product is not lost.
2) The product does not contaminate and is not contaminated by other products.
3) Adequate precautions are taken against spillage, breakage, misappropriation and theft.
4) Appropriate environmental conditions are maintained, e.g. using cold chain for thermolabile products.

11.5 The required storage conditions for medical products should be maintained within acceptablelimits during transportation. If a deviation has been noticed during transportation by the person or entity responsible for transportation, this should be reported to the distributor and recipient.

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

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

11.7 Written procedures should be in place for investigating and dealing with any failure to comply with storage requirements, e.g. temperature deviations.

11.8 Transportation and storage of medical products containing hazardous substances, such as toxic, radioactive material, and other dangerous medical products presenting special risks of abuse, fire or explosion (e.g. combustible or flammable liquids, solids and pressurized gases) should be stored in safe, dedicated and secure areas, and transported in safe, suitably designed, secured containers and vehicles. In addition, the requirements of applicable international agreements and Rwanda FDA regulations should be met.

11.9 Products containing narcotics and other dependence-producing substances should be transported in safe and secure containers and vehicles and be stored in safe and secure areas.

11.10 In addition, applicable international agreements and the Rwandan laws relating to medical products should be complied with.

11.11 Spillages should be cleaned up as soon as possible to prevent possible contamination, cross-contamination and hazards. Written procedures should be in place for the handling of such occurrences.

11.12 Physical or other equivalent (e.g. electronic) segregation should be provided for the storage and distribution during transit of rejected, expired, recalled or returned medical products and suspected counterfeits. The products should be appropriately identified, securely packaged, clearly labelled and be accompanied by appropriate supporting documentation.

11.13 The interiors of vehicles and containers should remain clean and dry while medical products are in transit.

11.14 Packaging materials and shipment containers should be of suitable design to prevent damage of medical products during transport. Seal control programs should be in place and managed properly.

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

11.16 Damage to containers and any other event or problem that occurs during transit must be recorded and reported to the Authority.

11.17 Medical products in transit must be accompanied by the appropriate documentation.

CHAPITER 12: DOCUMENTATION

12.1 Written instructions and records which document all activities relating to the distribution of medical products, including all applicable receipts and issues (invoices) should be available. Records should be kept for ten years from the date of distribution. Documentation comprises all written procedures, instructions, contracts, records and data, in paper or in electronic form. Documentation should be readily available/retrievable

12.2 Distributors should keep records of all medical products purchased or supplied. Records should contain at least the following information:

1) date of purchase or supply;
2) Batch number, manufacturing date and expiry date
3) The manufacturer
4) name of the medical product; quantity received, or supplied; and
5) name and address of the supplier or consignee.

12.3 Procedures should be established and maintained for the preparation, review, approval, use of and control of changes to all documents relating to the distribution process. Procedures must be in place for both internally generated documents and those from external sources.

12.4 Documents, and in particular instructions and procedures relating to any activity that could have an impact on the quality of medical products, should be designed, completed, reviewed and distributed with care. These procedures include but are not limited to;

1) receipt and checking of deliveries
2) storage
3) cleaning and maintenance of the premises including pest control
4) recording of the storage conditions
5) security of stocks on site and of consignments in transit
6) withdrawal from saleable stock
7) records
8) returned products

9) recall plan

12.5 The title, nature and purpose of each document should be clearly stated. The contents of documents should be clear and unambiguous. Documents should be laid out in an orderly fashion and be easy to check.

12.6 All documents should be completed, approved, signed (as required) and dated by an appropriate authorized person(s) and should not be changed without the necessary authorization. \

12.7 The nature, content and retention of documentation relating to the distribution of medical products and any investigations conducted and action taken, should comply with national legislative requirements. Where such requirements are not in place, the documents should be retained for at least one year after the expiry date of the product concerned.

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

12.9 All records must be readily retrievable, and be stored and retained using facilities that are safeguarded against unauthorized modification, damage, deterioration and/or loss of documentation.

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

12.11 Mechanisms should exist to allow for transfer of information, including quality or regulatory information, between a manufacturer and a customer, as well as the transfer of information to the Authority as required.

12.12 Records relating to storage of medical products should be kept and be readily available upon request by the Authority.

12.13 Permanent records, written or electronic, should exist for each stored product indicating recommended storage conditions, any precautions to be observed and retest dates.

12.14 Procedures should be in place for temperature mapping, security services to prevent theft or tampering with goods at the storage facilities, destruction of unsaleable or unusable stocks and on retention of the records.

12.15 Where the records are generated and kept in electronic form, backups should be maintained to prevent any accidental data loss.

CHAPITER 13: REPACKAGING AND RELABELLING

13.1 Repackaging and relabelling of medical products should be limited, as these practices may represent a risk to the safety and security of medical products in the supply chain.

13.2 Where they do occur, they should only be performed by entities appropriately authorized to do so and in compliance with the GMP principles.

13.3 In the event of repackaging by companies other than the original manufacturer, these operations should result in at least equivalent means of identification and authentication of the products.

13.4 Procedures should be in place for the secure disposal of original packaging.

CHAPITER 14: COMPLAINTS

14.1 There should be a written procedure in place for the handling of complaints. A distinction should be made between complaints about a 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 should be informed as soon as possible.

14.2 All complaints and other information concerning potentially defective and potentially counterfeit medical products should be reviewed carefully according to written procedures describing the action to be taken, including the need to consider a recall where appropriate.

14.3 Any complaint concerning a material defect should be recorded and thoroughly investigated to identify the origin or reason for the complaint (e.g. repackaging procedure or original manufacturing process).

14.4 If a defect relating to a medical product is discovered or suspected, consideration should be given to whether other batches of the product should also be checked.

14.5 Where necessary, appropriate follow-up action should be taken after investigation and evaluation of the complaint. There should be a system 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.

14.6 Product quality problems or suspected cases of counterfeit products should be documented and the information shared with the Authority.

CHAPITER 15: RECALLS OF MEDICAL PRODUCTS

15.1 There should be a system, which includes a written procedure, to effectively and promptly recall medical products known or suspected to be defective or counterfeit, with a designated person(s) responsible for recalls. The system should comply with the guidance issued by the Authority. This procedure should be checked regularly and updated as necessary.

15.2 The original manufacturer and/or marketing authorization holder should be informed in the event of a recall. Where a recall is instituted by an entity other than the original manufacturer and/or marketing authorization holder, consultation with the original manufacturer and/or marketing authorization holder should, where possible, take place before the recall is instituted. Information on a recall should be shared with the Authority.

15.3 All recalled medical products should be stored in a secure, segregated area pending appropriate action.

15.4 Recalled medical products should be segregated during transit and clearly labelled as recalled products. Where segregation in transit is not possible, such goods must be securely packaged, clearly labelled, and be accompanied by appropriate documentation.

15.5 The particular storage conditions applicable to a medical product which is subject to recall should be maintained during storage and transit until such time as a decision has been made regarding the fate of the product in question.

15.6 All customers and competent authorities of all countries to which a given medical product may have been distributed should be informed promptly of any intention to recall the product because it is, or is suspected to be, defective or counterfeit.

15.7 All records should be readily available to the designated person(s) responsible for recalls. These records should contain sufficient information on medical products supplied to customers (including exported products).

15.8 The progress of a recall process should be recorded and a final report issued, which includes a reconciliation between delivered and recovered quantities of products.

15.9 When necessary emergency recall procedures should be implemented.

15.10 To ensure the efficacy of the emergency plan, the system of deliveries should enable all destinees of a medical product to be immediately identified and contacted. Distributors may decide to inform all customers or those that has received the batch to be recalled.

15.11 The recall message (approved by the holder of marketing authorization and competent authorities) should indicate whether the recall should be carried out also at retail level. The message should request that the products be removed immediately from saleable stock and stored separately in a secure area until they are send back according to instructions in the holder of the marketing authorization.

CHAPITER 16: RETURNED PRODUCTS

16.1 A distributor should receive medical product returns or exchanges pursuant to the terms and conditions of the agreement between the distributor and the recipient. Both distributors and recipients should be accountable for administering their returns process and ensuring that the aspects of this operation are secure and do not permit the entry of counterfeit products.

16.2 Provision should be made for the appropriate and safe transport of returned products in accordance with the relevant storage and other requirements.

16.3 Rejected medical products and those returned to a distributor should be appropriately identified and handled in accordance with a procedure which involves at least:

1) the physical segregation of such medical products in quarantine in a dedicated area; or

2) Other equivalent (e.g. electronic) segregation.

This is to avoid confusion and prevent distribution until a decision has been taken with regard to their disposition. The particular storage conditions applicable to a medical product which is rejected or returned should be maintained during storage and transit until such time as a decision has been made regarding the product in question

16.4 Provision should be made for the appropriate and safe transport of rejected medical products prior to their disposal.

16.5 Products which have left the distributor can only be returned to saleable stock if:

1) the goods are in their original unopened containers and in good condition
2) the remaining shelf life period is acceptable
3) it is known that the goods have been stored and handled under proper conditions
4) they have been examined and assessed by a person authorised to do so.

16.6 The responsible person should formally release the goods to be returned to stock in case of non-defective medical products. Products should be placed such that the first expiry first out system operates effectively.

16.7 Destruction of medical products should be done in accordance with Rwanda FDA requirements regarding disposal of such products, and with due consideration to protection of the environment.

16.8 Records of all returned medical products should be filled at the time it is carried out and should be available to authorities. Rejected and/or destroyed medical products should be kept until a formal decision has been made on the disposal of the products and the decision should be documented and recorded. The person responsible for the quality assurance system of the distributor and, where relevant, the holder of marketing authorisation should be involved in the decision making process.

CHAPITER 17: COUNTERFEIT MEDICAL PRODUCTS

17.1 Counterfeit medical products found in the distribution chain should be kept apart from other medical products to avoid any confusion. They should be clearly labelled as not for sale; the Authority and the holder of the marketing authorization for the original product should be informed immediately.

17.2 The sale and distribution of a suspected counterfeit medical product should be suspended and the Authority notified without delay.

17.3 Upon confirmation of the product being counterfeit a formal decision should be taken on its disposal, ensuring that it does not re-enter the market, and the decision recorded.

CHAPITER 18: CONTRACT ACTIVITIES

18.1 Any activity relating to the distribution of a medical product which is delegated to another person or entity should be performed by parties appropriately authorized for that function and in accordance with the terms of a written contract.

18.2 The contract should define the responsibilities of each party including observance of the principles of GDP and relevant warranty clauses. It should also include responsibilities of the contractor for measures to avoid the entry of counterfeit medical products into the distribution chain, such as by suitable training programmes.

18.3 All contract accepters should comply with the requirements in these guidelines.

18.4 Subcontracting may be permissible, under certain conditions and subject to the written approval of the contract giver; however, the subcontractors should be authorized for the function.

18.5 Contract accepters should be audited periodically.

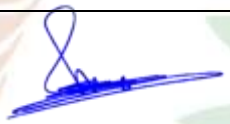
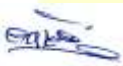
CHAPITER 19: SELF INSPECTION

19.1 The quality assurance system should include self-inspections. These should be conducted to monitor implementation of and compliance with the principles of GDP and, if necessary, to trigger corrective and preventive measures.

19.2 Self-inspections should be conducted in an independent and detailed way by a designated, competent person.

19.3 The results of all self-inspections should be recorded. Reports should contain all observations made during the inspection and, where applicable, proposals for corrective measures. There should be an effective follow-up programme. Management should evaluate the inspection report and the records of any corrective actions taken.

ENDORSEMENT OF THE GUIDELINES

	Author	**Authorized by**	**Approved by**
Title	Division Manager of Drugs, Food Inspections & Compliance	Head of Department of Food and Drugs Inspection and Safety Monitoring	Director General
Names	Mr. Munyangaju Jose Edouard	Mr. Gisagara Alex	Dr. Charles KARANGWA
Signature		 Digitally signed by Rwanda FDA (HoDFDISM) Date: 2020.09.17 06:15:57 +02'00'	
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