RWANDA FDA
Rwanda Food and Drugs Authority

GUIDELINES FOR GOOD STORAGE AND 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 the quality, safety and efficacy of distributed medical products in Rwanda. Considering the provisions of the technical regulations Nº FDISM/FDIC/TRG/006 governing Good Storage and Good Distribution Practices of Medical Products, the Authority issues these Guidelines N° FDISM/FDIC/GDL/006 for Good Storage and Good Distribution Practices of Medical Products.

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

Adherence to these guidelines will ensure that relevant information is provided for storage and distribution of medical products. This will facilitate efficient and effective storage and distribution of medical products with assured quality, safety and efficacy. It will also help to avoid malpractices in the storage and distribution process of medical products.

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

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Director General

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29/11/2021	0	First Issue
26/09/2022	1	1. The title of the guidelines changed from "Guidelines for Good Distribution Practices of Medical Products" to Guidelines for Good Storage and Good Distribution Practices of Medical products to reflect the related technical regulations. 2. Recommended storage conditions have been added. 3. Section for transport and delivery validation has been added. 4. Document was rearranged.

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ACRONYMS AND ABBREVIATIONS

CAPA	Corrective Actions and Preventive Actions
GDP	Good Distribution Practices
FEFO	First Expiry, First Out
GMP	Good Manufacturing Practices
GSP	Good Storage Practices
SF	Substandard and Falsified
SOP	Standard Operating Procedures
WHO	World Health 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 an 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 article 2 of the Law No. 003/2018 of 09/02/2018.

"Batch (or lot)" 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 or (lot 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" is 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 an active ingredient or with fake packaging.

"Corrective and preventative actions or its acronym "CAPA" means a system for implementing corrective and preventive actions resulting from an investigation of complaints, product rejections, non-conformances, recalls, deviations, audits, regulatory inspections and findings and trends from process performance and product quality monitoring;

"**Critical Deficiency"** means any departure from Guidelines on Good Storage and Good Distribution Practices resulting in a medical product causing a significant risk to the patient and public health. This includes an activity increasing the risk of falsified medicines reaching the patients.
A combination of a number of major deficiencies indicates a serious systems failure. An example of a critical deficiency could be purchase from or supply of medical products to a non-authorized person; Storage of products requiring refrigeration at ambient temperatures; Rejected or recalled products found in sellable stock.

"Cross-contamination" is the 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 person or organization who receives, stores, warehouses, handles, holds, offers, markets or displays medical products. A distributor shall be an entity that is appropriately authorized by the competent authority to perform the intended function as prescribed in these regulations, and which can be held accountable for its activities. These include but are not limited to governments at all levels, public and private health and storage facilities, manufacturers of finished products, importers, exporters, distributors, wholesalers, suppliers, retailers.

"Donated products" means medicines, medical devices and diagnostics supplied by donor agencies recognized by the Authority but excluding medicines, medical devices and diagnostics supplied through vertical program;

"Due diligence" This is a term used for a number of concepts, involving either an investigation of a distributor 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.

"Falsified product" means product that has been deliberately or fraudulently misrepresented as to its identity, composition or source.

"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.

"Fraudulent misrepresentation" means any substitution, adulteration or reproduction of an authorized product, or the manufacture of a product that is not an authorized product;

"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 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.

"GSP&GDP inspector" is an person appointed by the Rwanda FDA who is qualified and experienced in the storage and distribution of medical products to conduct an inspection or assessment to verify compliance with the minimum standards of storage and distribution of medical products to ensure that the quality and integrity of medical products are maintained throughout the supply chain.

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

"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.

"Major Deficiency" means a non-critical deficiency which indicates a major deviation from Good Storage and Good Distribution Practice; or which has caused or may cause a medicinal product not to comply with its marketing authorization in particular its storage and transport conditions; or which indicates a major deviation from the terms and provisions of the wholesale distribution authorization; or a combination of several other deficiencies, none of which on their own may be major, but which may together represent a major deficiency.

"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.

"Manufacturer" means a person or a firm that is engaged in the manufacture of medical products;

"**Marketing authorization**" means a legal document issued by the Authority for the purpose of marketing or free distribution of a product after evaluation for safety, efficacy and quality;

"Medical product" includes human and veterinary drugs; human and animal vaccines and other biological products, poisonous substances, herbal medicines, medicated cosmetics, laboratory and household chemicals and pesticides.

"Other Deficiency" means a deficiency which cannot be classified as either critical or major, but which indicates a departure from Guidelines on Good Distribution Practice.

"Owner of premises" means a person authorized to deal in the business of storage, transport and distribution of medical products.

"Premises" means land, building, structure, basement and vessel and in relation to any building includes a part of a building and any cartilage, forecourt, yard, or place of storage used in connection with building or part of that building; and in relation to "vessel", means ship, boat, air craft, and includes a carriage or receptacle of any kind, whether open or closed;

"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 in 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, unauthorised 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.

"Production" means all operations involved in the preparation of a pharmaceutical product, from receipt of materials, through processing, packaging and repackaging, labelling and re-labelling, to completion of the finished product.

"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 risk management**" means a systematic process for the assessment, control, communication and review of risks to the quality of products in the supply chain;

"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.

"Regulated products" means human medicines, veterinary medicines, biologicals including vaccines, biocidals including antiseptics and disinfectants, herbal medicines, medical devices, diagnostics, medical laboratory equipment and investigational products;

"Responsible person" means superintendent or any other person authorized to supervise and or dispense medical products under the Law 003/2018.

"Regulatory action" includes but is not limited to product hold, recall, forfeiture, or destruction; sealing of distribution facility; withdrawal of registration certificate etc.

"Re-test date" means the date when a material shall be re-examined to ensure that it is still suitable for use;

"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 authorised 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.

"**Self-inspection**" means an internal process to evaluate the premises compliance with GSP and GDP in all areas of activities, designed to detect any shortcomings and to recommend and implement necessary corrective actions;

"**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.

"Substandard products" means products authorized by the Authority but fail to meet specifications;

"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.

"**Transporter**" means a person who transports medical products from one point to another within the supply chain;

"Validation" means the action of proving and documenting that any process, procedure or method actually and consistently leads to the expected results.

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

"**Vertical program**" means national disease control program for malaria, HIV/AIDS, tuberculosis and leprosy, immunization, neglected tropical diseases and any other program for diseases of public health importance recognized by the Authority.

"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.

1. INTRODUCTION

The '*Guidelines for Good Storage and Good Distribution Practices of Medical Products'* are a Rwanda Food and Drugs Authority publication, which sets out procedures and requirements for the minimum standards for storage and 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 and regulations N° FDISM/FDIC/TRG/006 governing Good Storage and Good Distribution Practices of Medical Products which were put in place to ensure quality within the medical products storage and distribution chain.

The purpose of GSP and GDP is to give guidance that ensures that medical products are stored and distributed in a manner that will protect the consumer. Compliance with these guidelines will ensure control of the storage and distribution chain and consequently maintain the quality and integrity of medical products and will also assist in ensuring that these products are stored and 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.

Storage and distribution are important activities 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 storage and distribution processes.

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

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

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

This guideline is intended to be applicable to all entities involved in any aspect of the storage and distribution of medical products, from the premises of the manufacturer of the medical product to his or her agent, or the person dispensing or providing medical products directly to a patient. This includes all entities involved in different stages of the supply chain of medical products; manufacturers and wholesalers, as well as brokers, suppliers, distributors, logistics providers, traders, transport companies and forwarding agents and their employees.

1.1 Scope

These guidelines shall apply in all regulatory controls related to good storage and good distribution practices for medical products and shall apply to all persons and companies involved in any aspect of the distribution and storage of medical products from the manufacturing site to the point of use.

These include but are not limited to governments at all levels, domestic, public and private health and storage facilities, manufacturers of medical products, importers, exporters, distributors, wholesalers, suppliers, retailers, freighters, forwarding agents, transporters, public and private customs bonded warehouses.

The principles of GSP and GDP are applicable to:

a) Medical products moving forward in the distribution chain from the manufacturer;

b) Medical products that are moving backwards in the chain, for example, as a result of the return or recall thereof; and

c) Donations of medical products.

1.2 General Requirements

The following are the requirements for all concerned premises that conduct storage and distribution of medical products:

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

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

c) Distributors should 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.

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.

d) To have suitable and adequate premises, installations and equipment, so as to ensure proper storage conditions and distribution of medical products.

e) To have good written documentation to prevent errors from spoken communication and permit the tracking of relevant operations during the distribution of medical products.

f) To have a tracking system that ensures the safety, quality and efficacy of the medical product 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 minimise the risk of falsified medical products entering the legal supply chain.

g) To have records of all complaints, returns, suspected falsified medical products and recalls 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.

h) To provide a written Contract between the supplier and the distributor which clearly establishes the duties of each party. Any activity covered by the GSP and 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.

i) It is the responsibility of the distributor to ensure that the quality of the medical products is maintained from the manufacturer to the storage areas 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.

j) Self-inspection monitors the implementations and compliance with the principles of GSP and GDP; self-inspections are conducted by a competent designated person; self-inspections should be conducted in order to monitor implementation and compliance with GSP and GDP principles and to propose necessary corrective measures. Self-inspections should be recorded; reports should contain observations and corrective actions taken and recorded.

k) To provide a Standard Operating Procedure (SOP) for transportation plans based on Quality Risk Management (QRM) principles to ensure that the medical products have not been exposed to conditions that may compromise their quality and integrity during transport.

1.3 Validity of a premise license

No person or entity shall store and distribute medical products without prior authorization from the Authority. All premises, facilities, establishments and companies throughout the distribution chain should possess a valid premise license issued by the Authority. The Authority shall conduct an inspection for confirmation of the compliance to the requirements in order to grant or re-grant a premise license or approval of a substantial modification.

The requirements for application for GSP/GDP are detailed in the guidelines for licensing of public and private manufacturers, distributors, wholesalers and retailers of medical Products.

A premise license shall be valid for one (1) renewable from the date of issuance. The validity of the renewed premise license shall refer to the date of the first issuance of the first premise license. A premise license issued to an applicant shall not be transferred to another applicant or premise without prior written approval of the Authority. Any change(s) to the information contained on the premise license shall be notified to the Authority within a period of five (5) working days.

Any substantial modification to GSP & GDP premises information shall be notified in writing to the Authority through an application and the applicant shall wait for the written approval of the Authority before the implementation of the requested substantial modification.

2. DISTRIBUTION OF MEDICAL PRODUCTS

The distributor or the organization to which the distributor belongs should be an entity that is appropriately authorized. The distributor or the organization to which it belongs is accountable for the activities that it performs which relate to the storage and distribution of medical products. 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.

Holders of 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. 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 authorization to act as a distributor or to sell or supply products directly to a client.

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 by the Authority. Duties and responsibilities should be specified in a written agreement. There should be no gaps or unexplained overlaps with regard to GSP and GDP guidelines. 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 GSP and GDP.

If a distributor or his/ 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. The owner of premises shall be required to ensure that storage and distribution of medical products including automated storage and retrieval systems are carried out in accordance with these guidelines. All government agencies including Customs, Law enforcement agencies, National Pharmacy Council, Rwanda Allied Health Professional Council, Rwanda Council of Veterinary Doctors, Rwanda Medical and Dental Council, Private Health Laboratories Board and the Authority shall collaborate to prevent the exposure of patients to sub-standard and falsified products.

3. ORGANIZATION AND MANAGEMENT

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. 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.

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. 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.

The responsibilities placed on any one individual should not be so extensive as to present any risk to product quality. 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. Safety procedures relating to all relevant aspects including the safety of personnel and property, environmental protection and product integrity, should be in place.

4. PERSONNEL

All personnel involved in the storage and distribution activities should be trained and qualified in the requirements of GSP and 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 substandard and falsified products entering the supply chain. A record of all training, which includes details of subjects covered and participants trained, should be kept and easily retrievable.

Key personnel involved in storage and the distribution of medical products should have the ability and experience appropriate to their responsibility for ensuring that medical products are distributed properly. There should be an adequate number of competent personnel involved in all stages of the

storage and distribution of medical products in order to ensure that the quality of the product is maintained.

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. Personnel involved in the storage and 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.

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. Procedures and conditions of employment for employees, including contract and temporary staff, and other personnel having access to 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.

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. Safety procedures should be in place relating to all relevant personnel and property, environmental protection and product integrity.

A manufacturing facility shall at least have the following key personnel:

a) Head of the production;

b) Head of quality assurance;

c) Head of quality control; and

d) Authorized person.

A manufacturer shall formally notify the Authority of the name of qualified and authorized persons appointed by the manufacturer and the specific functions which have been delegated to such persons. Key posts shall be occupied by full-time personnel. Personnel for distributors, wholesalers and retailers of medical products; the supervising personnel to deal with the activity of storage and distribution of medical products shall:

a) For a distributor of medical products, be a pharmacist or any other relevant qualification.

b) For a human wholesale and retail pharmacy, be a pharmacist.

c) For a wholesale and retail veterinary pharmacy, be a veterinary doctor/pharmacist.

d) For a wholesale and retail of medical devices and diagnostics be a biomedical engineer/pharmacist/laboratory technician or any other relevant qualification.

e) Public hospital pharmacies (referral, provincial and district hospitals) are registered pharmacists.

f) Private hospital pharmacies are pharmacists.

5. QUALITY ASSURANCE SYSTEM

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. 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.

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), 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. Where electronic commerce (e-commerce) is used, i.e. electronic means are used for any of the storage and 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 storage and distribution of medical products, should be performed only by authorized persons or entities.

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. 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 GSP and GDP guidelines and the applicable principles of GMP relating to medical products. 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.

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. Distributors should from time to time conduct risk assessments to assess potential risks to the quality and integrity of medical products. 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. 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. 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.

All parties involved in the storage and distribution process of medical products should be identifiable. 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 storage and distribution documentation enabling traceability.

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

The quality assurance system should ensure that:

a) Medical products are procured, held, supplied, imported or exported in a way that is compliant with the requirements of GSP and GDP;

b) Management responsibilities are clearly specified;

c) Products are delivered to the right recipients within a satisfactory time period

d) Records are made on time and easily retrievable

e) Deviations from established procedures are documented and investigated;

f) 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.

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

The quality assurance system should monitor and review the performance of the Contract Acceptor, and the identification and implementation of any required improvements on a regular basis. The owner of premises shall have a documented quality policy describing the overall intentions and requirements regarding quality, authorized by the management and shall include the following:

a) Appropriate organizational structure with defined responsibilities of the personnel recorded as job descriptions;

b) Competent personnel;

c) Suitable and sufficient premises, equipment and facilities; and

d) Written and approved procedures for all activities.

6. QUALITY RISK MANAGEMENT

The owner of premises should have a system to assess, control, communicate and review risks identified at all stages in the supply chain. The evaluation of risk should be based on scientific knowledge and experience and ultimately be linked to the protection of the patient. Distributors should annually conduct risk assessments to assess potential risks to the quality and integrity of medical products.

The quality system shall be developed and implemented to address any potential risks identified. The quality system shall be reviewed and revised annually to address new risks identified during a risk assessment. Appropriate controls should be developed and implemented to address all risks. The effectiveness of the controls implemented should be evaluated at periodic intervals.

7. MANAGEMENT REVIEW

The owner of premises shall establish a system for periodic management review which shall include the following:

a) review of the quality system and its effectiveness by using quality metrics and key performance indicators;

b) identification of opportunities for continual improvement;

c) follow up on recommendations from previous management review meetings;

d) The status of actions from previous management review meetings;

e) Changes in external and internal issues that are relevant to the quality management system;

f) Information on the performance and effectiveness of the quality management system including trends in:

i. Customer satisfaction and feedback from relevant interested parties

ii. Non-conformities and corrective actions

iii. Warehouse performance and conformity of products and services

iv. Audit results

v. The performance of external providers

vi. The adequacy of resources

vii. The effectiveness of actions taken to address risks and opportunities

viii. Opportunities for improvement

Minutes and related documentation from management review meetings shall be made available on request by the Authority.

8. PREMISES

8.1 Categories of premises

The premises under these guidelines shall be classified into the following categories:

a) Manufacturing facilities;

b) Storage and Distribution facilities;

c) Warehouses;

d) Wholesalers;

e) Retailers;

f) Vehicles

g) Private and public hospital pharmacies;

h) Central Medical stores and branches

i) Veterinary facilities;

j) Online pharmacies

k) Public and private bonded warehouses (e.g. Port of Entries)

l) Any other premises as the Authority may designate.

8.2 Premises Location

Premises should be suitably located, designed, constructed and maintained, to ensure appropriate operations such as receiving, storage, picking, packing and dispatch of medical products. There should be sufficient space, lighting and ventilation to ensure required segregation, appropriate storage conditions and cleanliness. Sufficient security should be provided and access should be controlled. Appropriate controls and segregation should be provided for products requiring specific handling or storage conditions, such as radioactive materials, products containing hazardous substances and products to be stored under controlled temperature and relative humidity conditions. Where possible, receiving and dispatch bays should be separate, to avoid mix-ups. Bays should protect products from weather conditions.

Activities relating to receiving and dispatch should be done in accordance with authorized procedures. Areas should be suitably equipped for the operations. Premises should be kept clean. Cleaning equipment and cleaning agents should not become possible sources of contamination.
Premises should be protected from the entry of birds, rodents, insects and other animals. A rodent and pest control program should be in place.

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. Receiving areas should be of sufficient size to allow the cleaning of incoming medical products. Receiving and dispatching 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. 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. Precautions should be taken to prevent unauthorized persons from entering storage areas.

Storage areas should be appropriately designed, constructed, maintained or adapted. They should be kept clean and there should be sufficient space and lighting. Storage areas should be maintained within acceptable and specified temperature limits. Where the labels show special storage conditions are required (e.g. temperature, relative humidity), these should be provided, controlled, monitored and recorded.

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 control.

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. 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.

9. STORAGE PRINCIPLES AND CONTROL

9.1 Storage conditions

Appropriate conditions should be provided for medical products during storage and distribution. Conditions should be maintained as stated on their labels (or as described by the manufacturers as applicable) during storage and distribution. Materials and medical products should be stored off the floor, away from walls and ceilings, protected from direct sunlight and suitably spaced, to permit ventilation, cleaning and inspection. Suitable pallets should be used and 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:

a) A written sanitation programme should be available, indicating the frequency of cleaning and the methods to be used to clean the premises and storage areas. Clean and disinfect storeroom regularly

b) Store supplies in a dry, well-lit, well-ventilated storeroom out of direct sunlight

c) Secure storeroom from water penetration

d) Ensure that fire safety equipment is available and accessible and personnel are trained to use it

e) Store condoms and other latex products away from electric motors and fluorescent lights.

f) Maintain cold storage, including a cold chain, for commodities that require it.

g) Keep narcotics and other controlled substances in a locked place.

h) Store flammable products separately from other products. Take appropriate safety precautions.

i) 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.

j) Store medical products away from insecticides, chemicals, old files, office supplies, and other materials.

k) Arrange cartons so that arrows point up. Ensure that identification labels, expiry dates, and manufacturing dates are clearly visible.

l) Store supplies in a manner accessible for FEFO, counting, and general management.

m) Separate and dispose of damaged or expired products immediately.

9.2 Recommended storage conditions

Appropriate conditions should be provided for medical products during storage and distribution. Conditions should be maintained as stated on their labels (or as described by the manufacturers as applicable) during storage and distribution. Statements such as "store at ambient conditions" should be avoided. Where possible, actual limits should be specified by the manufacturers, such as "store below 25 °C. (See Appendix I of these guidelines).

Materials and medical products should be stored in conditions that assure that their quality is maintained. Stock should be appropriately rotated. The "first expired/first out" (FEFO) principle should be followed. Narcotic medical products should be stored in compliance with international conventions, national laws and regulations on narcotics. 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.

Equipment used for monitoring of storage conditions should also be calibrated at defined intervals. Certain materials and products, such as highly active and radioactive materials, narcotics and other hazardous, sensitive and/or dangerous materials and products, as well as substances presenting

special risks of abuse, fire or explosion (e.g. combustible liquids and solids and pressurized gases), should be stored in a dedicated area that is subject to appropriate additional safety and security measures.

There should be a written procedure for fire control, including prevention of fire, fire detection and fire drills. Fire-detection and firefighting equipment should be available and should be serviced regularly. 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. Broken or damaged items should be withdrawn from usable stock and separated.

Mechanical ventilation/Air handling Unit/Heating, ventilation and air conditioning systems should be appropriately designed, installed, qualified and maintained, to ensure that the required storage conditions are upheld. Mapping studies for temperature, and relative humidity where appropriate, should be done, for example in storage areas, refrigerators and freezers. All records pertaining to mapping and monitoring should be kept for a period of ten years.

Temperature and relative humidity, as appropriate, should be controlled and monitored at regular intervals. Data should be recorded and the records should be reviewed. Every medical product shall be manufactured, distributed and stored under an installed and retained heating, ventilation, and air-conditioning system to ensure that the quality is not compromised. The system shall be well-designed to provide comfortable conditions for operators.

9.3 Temperature and Environment Control

Suitable equipment and procedures should be in place to check the environment where medical products are stored and distributed. Environmental factors to be considered include temperature, light, humidity and cleanliness of the premises.

An initial temperature mapping exercise should be carried out on the storage area before use, under representative conditions. 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. 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. The premises should have a back-up power system (e.g., a generator) to be used in the event of a power outage.

9.4 Stock Control and Rotation

Records of stock levels for all medical products in store should be maintained, in either paper or electronic format. These records should be updated after each operation (e.g. entries, issues, losses, adjustments). These records should be kept for a ten-year period of time. Periodic stock reconciliation should be performed at defined intervals, by comparing the actual and recorded

stock. The root cause for stock discrepancies should be identified and appropriate CAPAs taken to prevent a recurrence. When damaged containers are received, this should be brought to the attention of the person responsible for quality. Any action taken should be documented. (These containers should not be issued unless the quality of the medical products has been shown to be unaffected.)

All stock should be checked at regular intervals, to identify those items that are close to their retest or expiry date. Appropriate action should be taken, such as removal of these items from usable stock. 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. Broken or damaged items should be withdrawn from usable stock and stored separately.

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

10. VEHICLES AND EQUIPMENT

Equipment, including computerized systems, should be suitable for its intended use. All equipment should be appropriately designed, located, installed, qualified and maintained. Computerized systems should be capable of achieving the desired output and results. Where electronic commerce (e-commerce) is used, i.e. electronic means for any of the steps, defined procedures and adequate systems should be in place to ensure traceability and confidence in the supply chain and products concerned.

Electronic transactions (including those conducted via the Internet) relating to the distribution of medical products should be performed only by authorized persons, according to defined and authorized access and privileges. Vehicles 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.

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

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

Defective vehicles and equipment should not be used and should either be labelled as such or removed from service. 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. Vehicles, containers and equipment should be kept clean, dry and free from accumulated waste. Distributors must ensure that vehicles used are cleaned regularly.

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. Equipment chosen and used for the cleaning of vehicles should not constitute a source of contamination.

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. 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.

Equipment used for monitoring conditions, e.g. temperature and humidity, within vehicles and containers should be calibrated at regular intervals. Vehicles and containers should be of sufficient capacity to allow orderly storage of the various categories of medical products during transportation. 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. 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.

11. QUALIFICATION AND VALIDATION

The scope and extent of qualification, and validation where appropriate, should be determined using documented risk management principles. Qualification and validation should be done following procedures and protocols. The results and outcome of the qualification and validation should be recorded in reports. Deviations should be investigated and the completion of the qualification and validation should be concluded and approved.

Facilities, systems, equipment, and processes, including cleaning, shall be periodically evaluated to confirm that they remain valid. The qualification of suppliers and customers should be done based on clear documentation to ensure that storage and distribution premises obtain supplies from authorized suppliers and Supply products to the authorized customers

12. DOCUMENTATION AND RECORDS KEEPING

12. 1 Documentation

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.

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

a) date of purchase or supply

b) batch number, manufacturing date and expiry date

c) The manufacturer name of the medical product; quantity received, or supplied; and

d) name and address of the supplier or consignee.

12. 2 Records Keeping

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. 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:

a) receipt and checking of deliveries

b) storage

c) cleaning and maintenance of the premises including pest control

d) recording of the storage conditions

e) security of stocks on site and of consignments in transit

f) withdrawal from saleable stock

g) records

h) returned products

i) recall plan

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. 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.

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

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. 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. Mechanisms should exist to allow for the 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.

Records relating to storage of medical products should be kept and readily available upon request by the Authority. Permanent records, written or electronic, should exist for each stored product indicating recommended storage conditions, any precautions to be observed and retest dates.

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

12.3 Standard operating procedures

The following SOPs should be in place for the premises dealing with storage and distribution:

a) Standard Operating Procedure for Medical Products Storage Practice

b) Standard Operation Procedure for Receiving of Pharmaceutical products

c) Standard Operating Procedure for Dispatch and Transport

d) Standard Operating Procedure for Inventory

e) Standard Operating Procedure for Cleaning

f) Standard Operating Procedure for Self-inspection

g) Standard operating procedure for Corrective and Preventive Action

h) Standard Operating Procedure for Complaints Handling

i) Standard Operating Procedure for Return Products Handling

j) Standard Operating Procedure for Recall Handling

k) Standard Operating Procedure for Medicine Waste Handling and Disposal

l) Standard Operating Procedure for Security

m) SOP for training of personnel

13. ACTIVITIES AND OPERATIONS

All activities and operations should be conducted in accordance with the Authority laws, regulations, and GSP and GDP-associated guidelines. Storage and distribution of medical products should be done by persons authorized to do so. Activities and operations should be performed in accordance with documented procedures.

13. 1 Receipt

Medical products should be procured from appropriately authorized suppliers. Deliveries should be examined for damage, seal intactness, signs of tampering, labelling, completeness of the order and other related aspects (e.g. availability of a certificate of analysis, where applicable), at the time of receiving. Containers and consignments that do not meet acceptance criteria at the time of receipt should be labelled, kept separate and investigated. This includes suspected falsified products.

A person receiving a consignment of medical products shall ensure that each incoming delivery should be checked against the relevant documentation, to ensure that the correct product is delivered from the correct supplier. This may include, for example, the purchase order, containers, label description, batch number, expiry date, product and quantity. The consignment should be examined for uniformity of the containers and, if necessary, should be subdivided according to the supplier's batch number should the delivery comprise more than one batch. Each batch should be dealt with separately.

Each consignment should be carefully checked for possible contamination, tampering and damage. A representative number of containers in a consignment should be sampled and checked according to a written procedure. Any suspect containers or, if necessary, the entire delivery, should be quarantined for further investigation. When required, samples of medical products should be taken by appropriately trained and qualified personnel and in strict accordance with a written sampling

procedure and sampling plans. Containers from which samples have been taken should be labelled accordingly.

Following sampling, the medical products should be subject to quarantine. Batch segregation should be maintained during quarantine and all subsequent storage. Materials and products requiring transport and storage under controlled conditions of temperature and relative humidity, as applicable, should be handled as a priority. The transportation temperature data, where appropriate, should be reviewed upon receipt, to ensure that the required conditions had been maintained. Where applicable, cold-chain materials and products should be handled according to the approved conditions by the authority, or as recommended by the manufacturer, as appropriate.

Medical products should not be transferred to saleable stock until an authorized release is obtained. Measures should be taken to ensure that rejected medical products cannot be used. They should be segregated and securely stored while awaiting destruction or return to the supplier. Distributors should conduct visual checks of the products that they receive. The visual check would compare a "master" of the package with the actual one. The "master" is either a copy of the package "blueprint" received from the manufacturer of the product, or a sample or photo of the package approved by Rwanda FDA.

13.2 Repackaging and Relabelling

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. Where they do occur, they should only be performed by entities appropriately authorized to do so and in compliance with the GMP principles. 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. Procedures should be in place for the secure disposal of original packaging.

13.3 Transport and Distribution

Medical products should be transported in accordance with the conditions stated on the labels and described by the manufacturer. The risk to the quality of the medical product during transport and distribution should be eliminated or minimized to an acceptable level. The following should be taken into consideration:

a) Product, batch and container identity should be maintained at all times.

b) All labels should remain legible.

c) Distribution records should be sufficiently detailed to allow for a recall when required.

d) Drivers of vehicles should be identified and present appropriate documentation to demonstrate that they are authorized to transport medical products.

e) Vehicles should be suitable for their purpose, with sufficient space and appropriately equipped to protect medical products.

f) 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 products.

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 and traceability of vehicles with products. Where possible, dedicated vehicles and equipment should be used for medical products. Where non-dedicated vehicles and equipment are used, procedures should be in place to ensure that the quality of the products will not be compromised. Defective vehicles and equipment should not be used. These should either be labelled as such or removed from service. There should be procedures in place for the operation and maintenance of all vehicles and equipment.

Equipment and materials used for the cleaning of vehicles should not become a source of contamination or have an adverse effect on product quality. Vehicles used for transportation of medical products should be qualified, where applicable, to demonstrate their capability to maintain the required transport conditions. There should be a maintenance programme for the cooling/heating system.

Appropriate environmental conditions should be maintained, monitored and recorded. All monitoring records should be kept for a period of 10 years. Records of monitoring data should be made available for inspection by the Authority or other oversight body. Instruments used for monitoring conditions, for example, temperature and humidity, within vehicles and containers should be calibrated at regular intervals. Rejected, recalled and returned products, as well as those suspected as being falsified, should be securely packaged, clearly labelled and accompanied by the appropriate supporting documentation.
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. Shipping containers should have no adverse effect on the quality of the medical products and should offer adequate protection to materials and these products. Containers should be labelled indicating, for example, handling and storage conditions, precautions, contents and source, and safety symbols, as appropriate.

Special care should be taken when using dry ice and liquid nitrogen in shipping containers, owing to safety issues and possible adverse effects on the quality of medical products. 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.

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. 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.

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

a) The identity of the product is not lost.

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

c) Adequate precautions are taken against spillage, breakage, misappropriation and theft.
d) Appropriate environmental conditions are maintained, e.g. using cold chain for thermolabile products.

The required storage conditions for medical products should be maintained within acceptable limits 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.

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

Transportation and storage of medical products containing hazardous substances, such as toxic, radioactive, material, and other dangerous medical products presenting special risks of abuse, 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. 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.

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. 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.

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

Drivers of vehicles should identify themselves and present appropriate documentation to demonstrate that they are authorized to transport the load. Damage to containers and any other event or problem that occurs during transit must be recorded and reported to the Authority. Medical products in transit must be accompanied by the appropriate documentation.

13.4 Transport and delivery Validation

The applicant should keep the transport validation data available and should submit them to the Authority upon request. The distributor shall be responsible for reviewing the transport route for suitability by means of assessment of environmental conditions (temperature and relative humidity) on the product including product integrity during transport.

The distributor shall ensure that the products can be safely transported within the temperature profile defined for each product and that compliance can be demonstrated to the Authority. Storage, distribution and transport validation shall be conducted in line with the World Health Organization (WHO) guidance for the storage and transport of time- and temperature–sensitive medical products. The latest version of these guidelines as revised by the WHO shall be applicable in each case. WHO guidance for the storage and transport of time- and temperature–sensitive medical products are available from:
https://www.who.int/docs/default-source/medicines/norms-and-standards/guidelines/distribution/trs961-annex9-modelguidanceforstoragetransport.pdf?sfvrsn=b80e925f_2

13.5 Dispatch

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. 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.

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. 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 a release for dispatch by the person responsible for quality.

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

a. Date of dispatch

b. Complete business name and address (no acronyms), type of entity responsible for the transportation, telephone number and names of contact persons for the supplier

c. Complete business name, address (no acronyms), and status of the addressee (e.g. retail pharmacy, hospital or community clinic)

d. A description of the products including, e.g. name, dosage form and strength (if applicable) for the addressee

e. Quantity of the products, i.e. number of containers and quantity per container (if applicable)

f. Applicable transport and storage conditions

g. A unique number to allow identification of the delivery order; and

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

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

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 the loading and unloading of cartons to avoid damage. 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. 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.

14. OUTSOURCED ACTIVITIES

Any activity relating to the storage and 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. 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.

There should be a written contract between the entities. The contract should define the responsibilities of each entity (contract giver and contract acceptor) and cover at least the following:

a) compliance with this guideline and the principles of GSP and GDP;

b) the responsibilities of all entities for measures to avoid the entry of substandard and falsified products into the distribution chain;

c) training of personnel;

d) conditions of subcontracting subject to the written approval of the contract giver; and

e) periodic audits.

The contract giver should assess the contract acceptor before entering into the contract, e.g. through on-site audits, documentation and licensing status review. The contract giver should provide to the contract acceptor all relevant information relating to the material and medical products. The contract acceptor should have adequate resources (e.g. premises, equipment, personnel, knowledge, experience and vehicles, as appropriate) to carry out the work.

The contract acceptor should refrain from performing any activity that may adversely affect the materials or products handled. 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. Contract acceptance should be audited periodically.

15. SUBSTANDARD AND FALSIFIED (SF) PRODUCTS

The quality system should include procedures to assist in identifying and handling medical products that are suspected to be substandard and/or falsified. Where such medical products are identified, the holder of the marketing authorization, the manufacturer and the appropriate national, regional and international regulatory bodies (as appropriate), as well as other relevant competent authorities, should be informed.

Such products should be stored in a secure, segregated area and clearly identified to prevent further distribution or sale. Access should be controlled. 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. Records should be maintained reflecting the investigations and action taken, such as disposal of the product. Substandard and/or falsified products should not re-enter the market.

16. COMPLAINTS

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.

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.

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). 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.

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. Product quality problems or suspected cases of substandard or falsified medical products should be documented and the information shared with the Authority.

17. RECALLS OF MEDICAL PRODUCTS

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.

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.

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

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. 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.

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). 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. When necessary emergency recall procedures should be implemented.

To ensure the efficacy of the emergency plan, the system of deliveries should enable all destinations of a medical product to be immediately identified and contacted. Distributors may decide to inform all customers or those that have received the batch to be recalled. The recall message (approved by the holder of marketing authorisation and the Authority) 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 sent back according to instructions in the holder of the marketing authorization.

18. RETURNED PRODUCTS

A distributor of medical products 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 SF medical products.

Provision should be made for the appropriate and safe transport of returned products in accordance with the relevant storage and other requirements. Rejected medical products and those returned to a distributor should be appropriately identified and handled in accordance with a procedure which involves at least:

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

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

This is to avoid confusion and prevent distribution until a decision has been taken with regard to their disposal. 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.

Provision should be made for the appropriate and safe transport of rejected medical products prior to their disposal. Medical Products which have left the distributor can only be returned to saleable stock if:

a) the medical products are in their original unopened containers and in good condition

b) the remaining shelf life period is acceptable

c) it is known that the medical products have been stored and handled under proper conditions

d) they have been examined and assessed by a person authorised to do so.

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.

Destruction of medical products should be done in accordance with Rwanda FDA requirements regarding the disposal of such products, and with due consideration to the protection of the environment. 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 authorization should be involved in the decision-making process.

19. INSPECTIONS

19.1 Self-inspection

The quality assurance system should include self-inspections. These should be conducted to monitor the implementation of and compliance with the principles of GDP and, if necessary, to trigger corrective and preventive measures. Self-inspections should be conducted in an independent and detailed way by a designated, competent person.

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 program. Management should evaluate the inspection report and the records of any corrective actions taken. Necessary CAPAs should be taken and the effectiveness of the CAPAs should be reviewed.

19.2 Inspection of Storage and Distribution Facilities

Storage and distribution facilities should be inspected by inspectors authorized by the Authority. This should be done at determined, periodic intervals. An inspection should normally be conducted

by a team of inspectors. Inspectors should assess compliance with laws, regulations and GSP, and GDP-related guidelines.

Inspections should cover the premises, equipment, personnel, activities, quality system, qualification and validation and other related aspects, as contained in these guidelines. An inspection report should be prepared and provided to the inspected entity within a defined period of time from the last day of the inspection. Observations may be categorized based on risk assessment.

Corrective Actions and Preventive Actions (CAPAs) for observations listed as non-compliances in the inspection report should be submitted for review by the inspectors within the defined period. Inspections should be closed with a conclusion after the review of the CAPAs.

The applicant will pay re-inspection fees to the Authority before being re-inspected when CAPA has been submitted three times and was found unsatisfactory by the Authority. In the event of any serious adverse event or any serious adverse reaction or suspicion thereof, of the product manufactured, stored and distributed, the Authority shall request such information or conduct such inspections following these guidelines as shall be considered appropriate.

ENDORSEMENT OF THE GUIDELINES

	Author	Checked by		Approved by
Title	**Division manager**	**Head of Department**	**Quality Assurance Analyst**	**Director General**
Names	Dr. Marilyn M. MURINDAHABI	Dr. Eric NYIRIMIGABO	Mr. Théogène NDAYAMBAJE	Dr. Emile BIENVENU
Signature				
Date	26/09/2022	26/09/2022	26/09/2022	27/09/2022

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APPENDIX I. RECOMMENDED STORAGE CONDITIONS

Label description	Recommended limits
Store at controlled room temperature	15 to 30 °C
Store in a cold or cool place	8 to 15 °C
Store in a refrigerator	5 ±3 °C
Store in a freezer	–20 ± 5 °C
Store in deep freezer	–70 ± 10 °C
Store in a dry place	No more than 60% relative humidity
Protect from moisture	No more than 60% relative humidity
Store under ambient conditions	Store in well-ventilated premises at temperatures of between 15 °C and 30 °C and no more than 60% relative humidity. Extraneous odours, other indications of contamination and intense light must be excluded.
Protect from light	To be maintained in the original manufacturer's light-resistant containers.
Chilled	5 ±3 °C