RWANDA FDA
Rwanda Food and Drugs Authority

REGULATION GOVERNING GOOD STORAGE AND DISTRIBUTION PRACTICES OF MEDICAL PRODUCTS

(Rwanda FDA law Nº 003/2018 of 09/02/2018, Article 9)

REGULATION DEVELOPMENT HISTORY

DRAFT ZERO	09/09/ 2021
ADOPTION BY RWANDA FDA	28/09/ 2021
STAKEHOLDERS CONSULTATION	30/08/2022
ADOPTION OF STAKEHOLDERS' COMMENTS	31/08/2022
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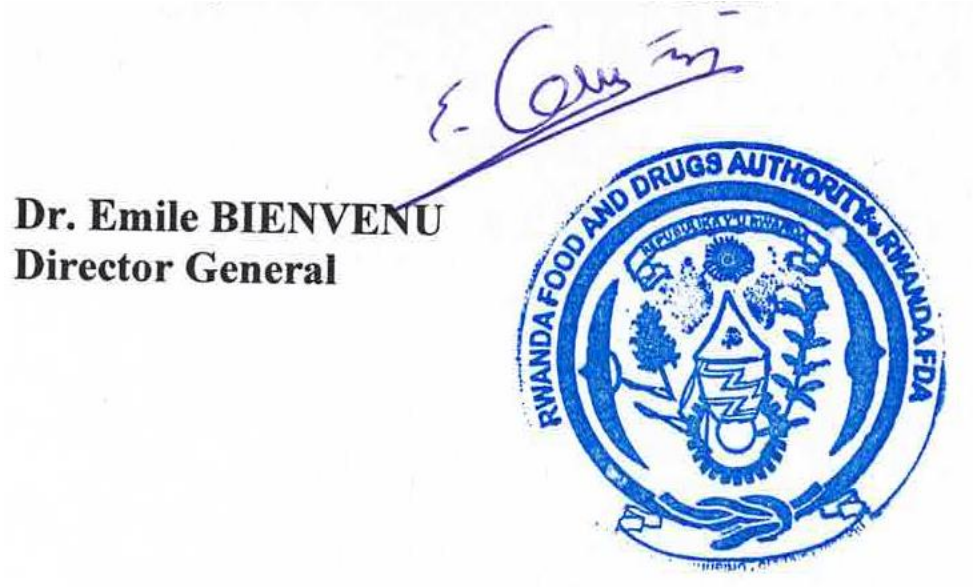
DOCUMENT REVISION HISTORY

Date of revision	Revision number	Changes made and/or reasons for revision
09/09/2021	0	First Issue
24/08/2022	1	1. The title of the guidelines changed from "Regulations Governing Good Distribution Practices of Medical Products" to Regulation Governing Good Storage and Good Distribution Practices of Medical products to reflect the related technical regulations. 2. Sections for powers of inspectors, administrative sanctions, appeals and publication for GDP of compliance premises have been added. 3. Section for transport and delivery validation has been added. 4. Obligation to obtain a premise license was added. 5. Changes were made on the Validity of a premise license. 6. Document was rearranged.

ADOPTION AND APPROVAL OF THE REGULATIONS

In EXERCISE of the powers conferred upon Rwanda Food and Drugs Authority by Article N° 9 of the Law N° 003/2018 of 09/02/2018 establishing Rwanda FDA and determining its mission, organization and functioning, hereby ADOPTS and ISSUES these Regulation Nº FDISM/FDIC/TRG/006 Governing the Good Storage and Good Distribution Practices for Medical Products on this 27/09/2022.



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Director General

ARRANGEMENT OF THE REGULATIONS

ABBREVIATIONS AND ACRONYMS

CAPA : Corrective Actions and Preventive Actions
FEFO : First Expiry, First Out
HIV/AIDS : Human Immunodeficiency Virus/ Acquired Immunodeficiency Syndrome
GDP : Good Distribution Practices
GMP : Good Manufacturing Practices
GSP : Good Storage Practices

CHAPTER ONE: GENERAL PROVISIONS

Article One: Purpose of these Regulations

The purpose of these regulations is to enforce the legal and regulatory framework to ensure effective and efficient storage and distribution premises of medical products.

Article 2: Citation

These regulations shall be cited as the "Regulation FDISM/FDIC/TRG/006 Rev. N° 1, Governing Good Storage and Good Distribution Practices of Medical Products".

Article 3: Scope

These regulations 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.

The Rwanda Food and Drugs Authority, hereinafter the "Authority", ensures that public and private health facilities, manufacturers, importers, exporters, distributors, wholesalers, suppliers, retailers, donation of medical products, freighters, forwarding agents, transporters, public and private customs bonded warehouses, public and private customs bonded warehouses comply with good storage and good distribution practices in order to prevent exposure of the public to substandard and falsified products.

Article 4: Definitions

In these regulations, unless the context otherwise requires:

"Authority" means Rwanda Food and Drugs Authority or its acronym "Rwanda FDA", established under 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 or conformity;

"**Consignment**" means the quantity of products supplied at one time in response to a particular request or order comprising one or more packages or containers and may include products belonging to more than one batch;

"**Container**" means the material employed in the packaging of a medical product. Containers include primary, secondary and tertiary containers. Containers are referred to as primary if they are intended to be in direct contact with the product. Secondary packaging encloses the primary packaging and

tertiary packaging material means outer carton in which multiples of saleable units are packed. Secondary and tertiary 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 product during handling, production, sampling, packaging or repackaging, storage or transportation.

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

"**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;

"**Cross-contamination**" means contamination of a starting material, intermediate product or finished product with another starting material or product, during production, storage and transportation;

"**Distribution**" means the procuring, purchasing, holding, storing, selling, supplying, importing, exporting, or movement of products, with the exception of the dispensing or providing products directly to a patient or his agent;

"**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 programme;

"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 product up to and including the date on which the product is expected to remain within specifications, if stored correctly;
"**Falsified product**" means product that has been deliberately or fraudulently misrepresented as to its identity, composition or source.

"**First expiry/ First Out or its acronym** "FEFO" means a distribution procedure that ensures the stock with the earliest expiry date is distributed and/or used before an identical stock item with a later expiry date is distributed 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 or its acronym** "GDP" means that part of quality assurance that ensures that the quality of a 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 falsified, unapproved, illegally imported, stolen, substandard, adulterated or misbranded products;

"**Good manufacturing practices or its acronym** "GMP" means that part of quality assurance which ensures that 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** or its acronym "GSP" means that part of quality assurance that ensures that the quality of products is maintained by means of adequate control throughout the storage thereof;

"**Labelling**" means the process of identifying a 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 or the supplier;

"**Manufacture**" includes all operations involved in the production, preparation, processing, compounding, formulating, filling, refining, transformation, packing, packaging, re-packaging and labelling of products;

''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 medicines, human and animal vaccines and other biological products, poisonous substances, herbal medicines, medicated cosmetics, laboratory and household chemicals and pesticides.

"**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;

"**Pharmaceutical products**" means any substance or combination of substances presented or administered to human beings or animals for treating or preventing disease with a view to making a medical diagnosis or to restoring, correcting, or modifying physiological functions in human beings or in animals. These include but are not limited to medicines, vaccines, biologicals, herbal medicines, medical devices, disinfectants and diagnostics.

"**Product recall**" means a process of withdrawing or removing a product from the distribution chain because of defects in the product, complaints of serious adverse reactions to the product or concerns that the product is or may be falsified and such recall may be initiated by the manufacturer, importer, wholesaler, distributor or a responsible agency;

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

"**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**" means an appropriate infrastructure, encompassing the organizational structure, procedures, processes and resources and systematic actions necessary to ensure adequate assurance that a product will satisfy given requirements for quality;

"**Quality assurance**" means the maintenance of a desired level of quality in a service or product, especially by means of attention to every stage of the process of delivery or production.

"**Quarantine**" means the status of products isolated physically or by other effective means while a decision is waited on their release, rejection or reprocessing;

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

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

"**Responsible person**" means a 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.

"**Sampling**" means operations designed to obtain a representative portion of a product, based on an appropriate statistical approach for a defined purpose to include 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 product, if stored correctly, is expected to comply with the specifications as determined by stability studies on a number of batches of the product and it is used to establish the expiry date of each batch;

"**Standard operating procedure''** or its acronym "SOP" means an authorized, written procedure giving instructions for performing operations.

"**Storage**" means the storing of products up to the point of use;

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

"**Substantial modification**" means a change to the premises, equipment, personnel, procedures, and processes that is likely to have significant impact and affect the quality, safety and the integrity of the products manufactured, stored, distributed, and used.

"**Supplier**" means a person or entity engaged in the activity of providing products or services;

"**Transit**" means the period during which 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 action of proving and documenting that any process, procedure or method actually and consistently leads to the expected results;

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

In these Regulations, the following verbal forms are used:

"**Shall**" indicates a requirement;

"**Should**" indicates a recommendation;

"**May"** indicates a permission; and

"**Can**" indicates a possibility or a capability.

CHAPTER II: GSP/GDP REQUIREMENTS AND INSPECTIONS

Article 5: Obligation to obtain a premise license

Every person or entity that intends to provide services that fall within the scope of Article 3 of this regulation, is required to apply for and obtain a premise license prior to commencement of the activity.
A premise license shall not be granted where the Authority finds the applicant not complying with GSP & GDP requirements as detailed in the guidelines for good storage and distribution practices of medical products issued by the Authority.

Article 6: Validity of a premise license

A premise license shall be valid for a period of one (1) year renewable from the date of issuance, but may be suspended or withdrawn if any of the conditions under which it was granted, is violated.

Article 7: Requirements to obtain a premise license

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.

Article 8: Distribution of Medical Products

The distributor or the organization to which it belongs is accountable for the activities that it performs which relate to the following distribution of medical products:

1º Maintain a quality system setting out responsibilities, processes and risk management principles in relation to their activities.

2º Have suitable and adequate premises, installations and equipment, so as to ensure proper storage conditions and distribution of medical products are carried out in accordance with these Regulations.

3º Ensure that any activity covered by the GSP & GDP Regulations that is outsourced is correctly defined, agreed and controlled. There must be a written Contract between the Contract offeror and the Contract offeree which clearly establishes the duties of each party.

4º Conduct self-inspection which shall be recorded in order to monitor implementation and compliance with GSP & GDP principles and to propose necessary corrective measures.

5º Distributors or their agents shall 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.

6º Distributors or their agents shall 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.

7º Distributors or their agents shall acquire and supply medical products only to persons or entities, which are themselves authorized.

Government agencies including Customs, Law enforcement agencies, the pharmacy council, veterinary council, private health laboratories bodies, and the Rwanda FDA shall collaborate to prevent the exposure of consumers or patients to substandard and falsified products.

Article 9: Organization and management

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

There shall be written arrangements in place to ensure that management and personnel are not subject to commercial, political, financial and other pressures or conflict of interest.

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

Article 10: Personnel

There shall be adequate personnel involved in distribution activities that are competent on the basis of education background, training, skills and experience in the requirements of good storage and good distribution. The distributors shall provide the needed training to achieve competency.

The Key personnel for a manufacturing facility shall at least have the following key personnel: head of production, head of quality assurance, head of quality control; and 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.

The supervising personnel of authorized medical products premise shall be a pharmacist or any other relevant qualification for a distributor of medical products, be a pharmacist for a human wholesale and retail pharmacy, be a veterinary doctor/pharmacist for a wholesale and retail veterinary pharmacy, be a registered pharmacist for Public and Private hospital pharmacies.

Article 11: Quality assurance system

There shall be a quality assurance system in place with an appropriate organizational structure, procedure, processes and resources and systematic actions necessary to ensure adequate assurance that a product or service and its documentation will satisfy given requirements for quality.

Where electronic commerce (e-commerce) is used; defined procedures and adequate systems shall be in place to ensure traceability and reliance on the quality of the medical products concerned. Electronic transactions, relating to the distribution of medical products, shall be performed only by authorized persons or entities.

Article 12: Management review

The owner of the premises shall establish a system for periodic management review. Minutes and related documentation from management review meetings shall be made available on request by the Authority.

Article 13: Quality risk management

A manufacturer, distributor shall have a systematic process for assessment, control, communication, and review of risk to the quality of a medical product. The system shall ensure evaluation of the risk based on scientific knowledge and experience with the process to protect the patient. The formality and documentation of the quality risk management process shall be based on risk level.

Article 14: Premises

All premises dealing with medical products shall comply with the requirements of good storage and good distribution practices. Categories of premises under this article are detailed in the guidelines for good storage and good distribution practices issued by the Authority.

Article 15: Storage Principles and Control

Medical products shall be stored, distributed and transported in accordance with appropriate environmental conditions including cold chain management and other temperature sensitive medical products.

The minimum storage principles as adopted by the Authority in the guidelines for good storage and good distribution practices.

Article 16: Temperature and Environment Control

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

Article 17: Equipment

The layout, design, and location of equipment shall aim to minimize the risk of errors and permit effective cleaning and maintenance and, where appropriate, sanitization to avoid cross-contamination, build-up of dust or dirt, and any adverse effect on the quality of products.

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.

Article 18: Transport and Delivery Validation

The premise involved in the storage and distribution of medical products shall keep the transport validation data and shall submit them to the Authority upon request. The notification shall be submitted in writing to the Authority in case of deviation from the transport and delivery validation data.

The storage and distribution premises shall be responsible for reviewing the transport route for suitability by means of assessment of environmental conditions such as but not limited to temperature and relative humidity, on the product including product integrity during transport.

The storage and distribution premises 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. The requirements for transport validation are described in the relevant guidelines.

Article 19: 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.

Article 20: Traceability of products

Ensuring products have documentation that can be used to permit traceability throughout distribution channels from the manufacturer or importer to the entity responsible for selling or supplying the product to the patient or his agent; and documentation enabling traceability of records including expiry dates and batch or lot numbers as part of a secure distribution.

Article 21: Self-inspections

The owner of premises shall ensure that the quality system includes self-inspections. Self-inspections should be conducted in order to monitor implementation and compliance with quality management standards GSP and GDP; record results, follow-up with the corrective actions needed to rectify areas of non-compliance and document the changes made.

Article 22: Inspection by Authority

The Authority upon receipt of duly filled application dossiers from the applicant shall schedule an inspection date for the premises. The Authority shall inspect to ensure that manufacturers, storage and distribution facilities comply with the requirements of these Regulations; and non-conformances against these Regulations are identified.
Inspections shall be conducted as follows:

1° Storage and distribution facilities should be inspected by a team of inspectors appointed by the Authority.

2° Inspections should cover the premises, equipment, personnel, activities, quality system, qualification and validation and other related aspects, as contained in the guidelines for good storage and good distribution practices.
3° 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.
4° CAPA for observations listed as non-compliances in the inspection report, with the regulations and guidelines, should be submitted for review by the inspectors within the defined period, as stated by the inspectors. The applicant will pay re-inspection fees to the Authority before being re-inspected when CAPA has been submitted and found unsatisfactory by the Authority.

5° 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 this regulation as shall be considered appropriate.

CHAPTER III: ACTIVITIES AND OPERATIONS

Article 23: Procurement of medical products

The owner of premises shall ensure that medical products are procured from appropriately authorized suppliers.

Article 24: Repackaging and Relabelling

A person shall not repack or relabel any product or material for the purpose of distribution to any premises:

1° where the owner of premises intends to repack or relabel any product or material, S/he shall seek an authorization from the Authority.

2° the owner of premises shall repack or relabel products or materials in accordance with good manufacturing practices requirements.

3° where the products have been repacked or re-labelled, the owner of premises shall dispose of original packaging to prevent re-use thereof in accordance with disposal procedures in place.

4° Without prejudice to the generality of this regulation, any expired product shall be declared to the Authority and disposed of within 3 months after its expiration.

5° Any extension of time for disposal of any expired product shall be sought from the Authority.

6° the Authority shall issue a disposal certificate as prescribed in the disposal regulations in force.

Article 25: Transportation and Distribution

The owner of premises or transporter shall ensure that products are transported in accordance with the conditions stated on the labels and described by the manufacturer.

Article 26: Dispatch

The owner of premises or distributor shall sell or distribute products to persons or entities that are authorized to acquire such products in accordance with these Regulations.

The owner of premises shall ensure that records of dispatch contain sufficient information to enable traceability and facilitate the recall of a batch of a product, if necessary as well as the investigation of substandard and falsified products.

The owner of premises shall not supply or receive products 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 patient, animal or consumer.

Article 27: Outsourced activities

The owner of premises or contract giver shall ensure that:

Any activity relating to the storage and distribution of a product that is delegated to another person or entity is performed by the appropriately authorized parties, in accordance with these Regulations and the terms of a written contract;

There is a written contract between the entities and such contract shall define the responsibilities of each entity.

The contract acceptor is assessed before entering into the contract through on-site audits, documentation and or licensing status review; and

The contract acceptor is provided with all relevant information relating to the material and products.

The contract acceptor shall have adequate resources to include premises, equipment, personnel, knowledge, experience and vehicles, as appropriate to carry out the delegated functions.

The contract acceptor shall refrain from performing any act that may adversely affect the quality of materials or products handled.

CHAPTER IV: SUBSTANDARD AND FALSIFIED PRODUCTS

Article 28: Handling of substandard and falsified products

The owner of premises shall have a quality system which includes documented procedures to assist in preventing, identifying, responding or handling products that are suspected to be substandard and or falsified, where substandard and or falsified products are suspected or identified:

1º The marketing authorization holder, manufacturer, supplier and the Authority shall be informed;
2º The suspected or identified products shall be stored in a secure, access controlled, segregated area and clearly identified to prevent further distribution or sale; and the owner of premises shall ensure that substandard and falsified products do not re-enter the market.

3º The marketing authorization holder shall be responsible for the quality, safety and efficacy of the product while on the market including recall of substandard products

Article 29: Good documentation practice

The owner of premises shall establish written procedures for the handling of complaints. The procedures may contain information such as:

1° In case of a complaint about the quality of a product or its packaging, the original manufacturer or marketing authorization holder shall be informed within seven days from the date of receiving a complaint.

2° The complaints referred to under these regulations, shall be recorded and appropriately investigated including conducting the root cause analysis and the impact on the affected batches, lots or products.

3° After completion of the procedure referred to under these regulations, the owner of premises shall take corrective and preventive actions, and when so required, such information shall be shared to the Authority with a view, where necessary, to initiate recalling.

4° A distinction shall be made between complaints about a product or its packaging and those relating to distribution.

Article 30: Returns

The owner of premises shall:

1º Handle returned products in accordance with written procedures;

2º Place all returned products in quarantine upon receipt;

3º Take precautions to prevent access and distribution until a decision has been taken with regard to their disposition;

4º Maintain storage conditions applicable to the products until their disposition;

5º Ensure returned products are destroyed unless it is certain that their quality is satisfactory.

6º The owner of premises shall follow written procedures, including safe transport, where products are rejected.

7º The owner of premises shall destroy returned products, where applicable in accordance with disposal regulations in force.

8º The owner of premises shall keep records of all returned, rejected and destroyed products for a period of not less than one year.

Article 31: Recalls

The owner of premises shall follow written procedures for recall of products. The Authority, original manufacturer, marketing authorization holder, customers or other relevant contract party, shall be informed in the event of a recall.

The owner of premises shall ensure that all recalled products are clearly labelled, secure, segregated, transported and stored under appropriate conditions.

The owner of premises shall ensure that all records, including distribution records, are readily accessible to the designated person(s) responsible for recalls and such records shall contain sufficient information on products supplied to customers including name, address, contact detail, batch or lot numbers, quantities and safety features.

The owner of premises shall record the progress of a recall process and a final report issued, to include reconciliation between delivered and recovered quantities of products.

Without prejudice to the generality of these regulations, the owner of premises shall follow other recall procedures as provided for in the recall Regulations in force. For reference standards, the label or accompanying document shall indicate concentration, date of manufacture, expiry date, date the closure is first opened, and storage conditions where appropriate.

CHAPTER V: DOCUMENTATION AND RECORDS KEEPING

Article 32: Documentations

The owner of premises shall ensure that proper documentation including all procedures, records and data, whether in paper or electronic form are appropriately designed, completed, reviewed, authorized, distributed and kept as required.

Article 33: Record Keeping

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

CHAPTER VI: ADMINISTRATIVE SANCTIONS

Article 34: Sanctions for violation of these regulations

Any person who contravenes the provisions of these Regulations, shall be liable to the administrative measures and sanctions under **Annex A:**

1° Manufacturing, importation, sale, storage and distribution of substandard, unapproved, counterfeit/falsified, expired and fraudulent regulated products.

2° Illegal opening of premises closed by the Rwanda FDA.

3° Absence of an authorized personnel in an authorized premise dealing with regulated products.

4° Transport of regulated products in unacceptable conditions.

5° Failing to ensure that narcotics and other controlled substances are kept in a secured cupboard.

6° Failure to provide prescriptions/reports for distribution of narcotics and controlled products at the time of inspection.

7° Any change to the authorization without notifying the Authority within the prescribed timelines.

8° Obstruction of inspectors from Rwanda Food and Drugs Authority.

CHAPTER VII: MISCELLANEOUS PROVISIONS

Article 35: Appointment of inspectors

The Authority shall appoint inspectors to inspect domestic, public and private health and storage facilities, manufacturers of medical products, importers, exporters, distributors, wholesalers, suppliers, retailers.

The inspectors shall have the relevant qualification in terms of academic education, training, and experience to effectively take part in the inspection.

Article 36: Conflict of Interest

To avoid any conflict of interest, all inspectors shall declare any conflict of interest upon appointment.

Article 37: Powers of Inspectors

For the purposes of enforcing compliance for conducting inspections, an inspector appointed in

accordance with these regulations shall, upon production of evidence that S/he is authorized:

1° At any reasonable time to enter any premises, other than premises used only as a private dwelling house, where he/she has reason to believe it is necessary for him to visit, including any premises of any person who carries out any of the activities referred to in these Regulations;

2° To carry out examinations, tests and analyses during the inspections visit, as S/he considers necessary;

3° To require the production of; to inspect and take copies of extracts from, any book, document, data or record in whatever form it is held at, or in the case of computer data or records accessible at the premises;

4° To take possession of any samples for examination and analysis and any other article, substance, book, document, data, record in whatever form they are held at, or in the case of computer data or records accessible at, the premises;

5° To question any person whom, he finds at the premises and whom he has reasonable cause to believe is able to give him relevant information;

6° To require any person to afford him such assistance as he considers necessary with respect to any matter within that person' s control, or in relation to which that person has responsibilities;

7° To require, as considered necessary, any person to afford him such facilities as S/he may reasonably require that person to afford him; but nothing in this paragraph shall be taken to compel the production by any person of a document of which he would on grounds of legal professional privilege be entitled to withhold production.

8° The perform his or her duties with respect, confidentiality, humility and with integrity.

Article 38: Appeals

An authorization holder or applicant may notify the Authority of his or her grounds when he/she:

1º Objects to any suspension or revocation of the authorization, or any notice served;

2º Objects to the refusal of authorization or the imposition of any condition may notify the Authority of his desire to make written representations to, or be or appear before and be heard by, a person appointed by the Authority for that purpose.

Any person aggrieved by a decision of the Authority may appeal to the Authority for review of a decision within 30 working days from the date of the notice. The Authority shall within 30 working days from the date of appeal review the appeal and make its own decision whether to vary, reject or keep its own decision.

Where the Authority receives notification pursuant to provisions of paragraph 1 of this Article, the Authority shall appoint a person to consider the matter. The person appointed shall determine the procedure to be followed concerning the consideration of any objection.
The person appointed by the Authority, shall consider any written or oral objections made by the objector or complainant in support of its objection, and shall make a recommendation to the Authority.

A recommendation shall be made in writing to the Authority, and a copy of it shall be sent to the complainant concerned, or to its nominated representative. The Authority shall take into account any recommendation made within fourteen days of receipt of such recommendation.

The Authority shall inform the complainant whether it accepts the recommendation and, if not, the reasons for its decision.

If a person is dissatisfied with a decision after review, S/he may appeal to the supervising Authority of Rwanda FDA or the Minister of Health whose decision shall be final.

Article 39: Commencement

These Regulations shall enter into force upon their approval and publication on the Authority's website.

End of Document

ANNEX-A: FAULTS AND ADMINISTRATIVE SANCTIONS

Fault	Administrative sanction
1. Manufacturing, importation, sale, storage and distribution of substandard, unapproved, counterfeit/falsified, expired and fraudulent regulated products	25% to 50% of the product value found in violation.
2. Illegal opening of premises closed by the Authority	500,000 Frw
3. Absence of an authorized personnel in an authorized premise dealing with regulated products	500,000 Frw
4. Operating without operational license	1,000,000 FRW
5. Operating without valid operational license	100,000 Frw Note that for each delay, a 25% increment, on the original fine will be applied monthly from the second month after expiry of the license. This charge of 25% increment shall not go beyond 24 months after expiry of the license
6. Production without production manager or/ quality control manager	500,000 Frw
7. Transport of regulated products in unacceptable conditions	200,000 Frw
8. Failing to ensure that narcotics and other controlled substances are kept in a secured cupboard	100,000 Frw
9. Failure to provide prescriptions/reports for distribution of narcotics and controlled products at the time of inspection	100,000 Frw
10. Any change to the authorization without notifying the Authority within the prescribed timelines	100,000 Frw
11. Relocation without notifying the Authority	100,000 Frw
12. Obstruction of inspector from Rwanda Food and Drugs Authority	100,000 Frw for each day of obstructions