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

First issue date	29/11/2021
Effective date of this revision	23/04/2024

Document Revision History

Revision number	Changes made and/or reasons for revision
0	First Issue
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. A section for transport and delivery validation has been added. 4. Obligation to obtain a premise license wasadded. 5. Changes were made to the validity of a premise license. 6. Document was rearranged
2	1. The Final Provisions for granting the warning, suspension and revocation. 2. Establishment of a scientific and advisory committee. 3. Restoration of a suspended or revoked GSDP certificate. 4. Administrative sanctions were added to the regulations. 5. Publication of GSDP-compliant premises

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 regulations No.: DD/PIL/TRG/006 Rev_2 Governing Good Storage and Distribution Practices for Medical Products on this 23/04/2024.

Prof. Emile BIENVENU
Director General

Digitally signed by Rwanda FDA (Director General)
Date: 2024.04.23 16:57:40 +03'00'

ARRANGEMENT OF THE REGULATIONS

CHAPTER ONE: GENERAL PROVISIONS

Article One: Citation

These regulations are cited as the "Regulation DD/PIL/TRG/006 Rev. No 2, Governing Good Storage and Distribution Practices of Medical Products".

Article 2: 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 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 Distribution practices 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 total quantity of goods produced at one time;

"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 an 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 foreign matter, into or on to a starting material, intermediate or product during handling, production, sampling, packaging or repackaging, storage or transportation.

"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;

"Critical deficiency" A critical observation is a departure from current WHO Good Storage and Distribution Practices guidelines that may result in a medical product causing a significant risk to the patient and public health. This includes an activity increasing the risk of falsified medical products reaching the patients. This may also involve fraud, misrepresentation or falsification (of products, information). A combination of several major observations that indicates a serious systems failure may be also classified as a critical observation. Critical observations require immediate action.

"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 organization or an entity, such as a wholesaler that distributes manufacturer's products to market. They serve as an intermediary in the manufacturer's supply chain. promoting and selling the products to wholesalers or other entities, excluding the end consumer. Distributors are authorized to exclusively sell medical products for which they are the legal representatives to other wholesalers;

"Due diligence" 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 medical product" means a medical product that deliberately/fraudulently misrepresent their identity, composition or source.;

"First expiry/ First Out (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;

"Good Distribution Practices (GDP)" 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 that occur

during the trade and distribution process, as well as providing a tool to secure the distribution system from falsified, unapproved, illegally imported, stolen, substandard, adulterated and/or misbranded medical products

"Good manufacturing practices (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 "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;

"Major deficiency" is a non-critical deficiency which indicates a major deviation from current WHO Good Storage and Distribution Practices guidelines that may increase the risk to public health and safety. A combination of several observations classified as 'other', none of which on their own may be major, may together represent a major deficiency. Major observations require high priority actions;

"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;

"Minor deficiency" an observation classified as 'other' may be defined as a deficiency which cannot be classified as either critical or major, but which indicates a departure from current WHO Good Storage and Distribution Practices guidelines. A deficiency may be other either because it is judged as minor or because there is insufficient information to classify it as major or critical;

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

"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 animals. These include but are not limited to medicines, vaccines, biologicals, herbal medicines, medical devices, disinfectants and diagnostics;

"Premises" means any plot of land, buildings or boats, aircraft, vehicles, a part of a building, channels, yards, a place of storage, annexed to a building, or part of that building, carriage or receptacle of any kind, whether open or closed.

"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;

"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;

"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;

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

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

"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;

"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" Also called "out of specification", these are authorized medical products that fail to meet either their quality standards or specifications, or both;

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

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

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: GSDP REQUIREMENTS AND INSPECTIONS

Article 5: Obligation to obtain a GSDP Certificate

Every person or entity that intends to provide services that fall within the scope of Article 3 of this Regulation, must be GSDP compliant prior to commencement of the activity.

A premise license shall not be granted where the Authority finds the applicant not complying with GSDP requirements as detailed in the Guidelines for GSDP of medical products issued by the Authority.

The GSDP certificate will be granted to new applicants concurrently with the premise license following a successful GSDP inspection. The Authority will then conduct a follow-up GSDP inspection after 12 months to ensure the implementation of standard operating procedures and related records.

The GSDP certificate for premises used for carrying out activities within the scope of Article 3 of this article of this Regulation is granted by the Authority.

A GSDP certificate shall not be granted where the Authority finds the applicant not complying with the requirements prescribed in these regulations and relevant regulatory documents.

Article 6: Requirements to obtain a GSDP Certificate

The applicant must hold a premise license issued by the Authority to engage in the activity of wholesale and distribution of medical products in Rwanda.

The applicant must comply with GSDP requirements in accordance with Rwanda FDA GSDP guidelines.

Article 7: Certificate and Validity

Upon fulfilling the requirements, the Authority shall issue a Certificate of Good Storage and Good Distribution Practices. The certificate shall be valid for a period of three (3) years.

Any critical changes to the information contained in the GSDP certification circumstances, shall be notified to the Authority within a period of fifteen (15) working days

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 distribution of medical products. The relevant requirements for the distribution of medical products will be prescribed in the GSDP guidelines.
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. shall be detailed in the Relevant guidelines.
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 based on the educational 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. The relevant requirements for the Quality Assurance System will be prescribed in the GSDP guidelines.

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. The relevant requirements for management review will be prescribed in the GSDP Guidelines.

Article 13: Quality risk management

A wholesaler, or 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 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. The relevant requirements for temperature and Environmental control of medical products will be prescribed in the GSDP guidelines.

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 GSDP 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 shall be conducted to monitor implementation and compliance with quality management standards of GSDP; record results, follow-up with the corrective actions needed to rectify areas of non-compliance and document the changes made.

CHAPTER III: ACTIVITIES AND OPERATIONS

Article 22: Procurement of medical products

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

Article 23: Repackaging and Relabelling

A person shall not repack or relabel any product or material for the purpose of distribution to any premises. The relevant repackaging and re-labelling of medical products will be prescribed in the GSDP guidelines.

Article 24: 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 25: 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 26: Outsourced activities

The owner of premises or contract giver shall ensure that they comply with the relevant requirements for outsourced activities as prescribed in the GSDP guidelines.

CHAPTER IV: SUBSTANDARD AND FALSIFIED PRODUCTS

Article 27: 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. The relevant procedures for handling substandard and falsified medical products will be prescribed in the GSDP guidelines.

Article 28: 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 with the Authority with a view, where necessary, to initiate recall.
4. A distinction shall be made between complaints about a product or its packaging and those relating to distribution.

Article 29: Returns

Returned medical products shall be handled in accordance with authorized procedures. The relevant procedures for handling returned medical products will be prescribed in the GSDP guidelines.

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

Article 30: Recalls

The owner of premises shall follow written procedures for the recall of products. The relevant procedures for handling recalls for medical products will be prescribed in the GSDP guidelines.

Article 31: 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 32: Record Keeping

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

CHAPTER V: CONDUCTING INSPECTIONS

The Authority shall conduct an inspection to confirm the compliance with these Regulations and relevant Guidelines.

Article 33: Inspection by Authority

The Authority shall inspect to ensure that premises, storage and distribution facilities comply with the requirements of these Regulations; and that 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 from the last day of the inspection. Observations may be categorized based on risk assessment.
4. CAPA for observations listed as deficiencies 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 relevant guidelines. 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.

Article 34: 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, and retailers.

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

The list of GSDP inspectors may be provided to the public upon formal request to the Authority.

Article 35: Conflict of Interest

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

Article 36: 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. To perform his or her duties with respect, confidentiality, humility and with integrity.

The inspector is required to collaborate with the local administration and a representative of the public investigation body of the area to enter premises that are closed or unoccupied. Together they shall provide written proof of the premises to be inspected before the inspection. The written proof stated under this paragraph shall be signed and where necessary photos of the premises must be

added to prove the premises were closed or unoccupied before physical inspection. The written proof shall be part of the report that must be submitted to the Authority.

Upon arrival at the inspection site, the inspectors shall convene a pre-inspection meeting with the inspected and the leading inspector shall preside over the meeting.

The inspectors shall walk through every section of the plant, ask questions and carefully review records and areas of the manufacturing sites, and may take photographs to support their observations. The inspectors shall list down all deficiencies findings in a document such as the Memorandum of Findings that conforms to the Authority's standards.

After inspection, the inspectors shall convene a closing meeting highlighting issues observed during inspection and sign a memorandum form with the inspected.

Article 37: Establishment of a scientific and/or advisory committee

The Authority may establish a scientific and advisory committee comprising internal and/or external experts from different fields and scientific research to advise the Authority on Good Storage and Good Distribution inspection matters.

CHAPTER VI: FINAL PROVISIONS

Article 38: Regulatory actions

Any person who contravenes the provisions of these Regulations shall be liable to the penalties prescribed in the Authority's regulation related to regulatory service tariff/fee and other applicable sanctions.

The Authority shall take the following regulatory actions as recommended by the inspectors when making decisions on the outcome of inspections.

1. Minor deficiency:

CAPA is to be submitted within a given timeframe as detailed in the guidelines for good storage and distribution practices of medical products.

2. Major deficiency:
   a) Request for CAPA within a given timeframe
   b) Failure to submit a comprehensive CAPA report within the given timeframe will lead to the issuance of a warning letter.
   c) Failure to sufficiently address the deficiencies leads to suspension of the premise license and/or GSDP Certificate.
   d) Follow-up inspection may be conducted to verify the implementation of the CAPA within a given timeframe.

3. Critical deficiency:
   a) Issue a warning letter and request for CAPA within a given timeframe
   b) Failure to submit a comprehensive CAPA report within the given timeframe will lead to the suspension of premise license and/or GSDP Certificate. The suspension shall take immediate effect upon the receipt of the suspension letter from the Authority. The written suspension notice must take into account the date of the inspection. Suspension of the license cannot be imposed for a period less than thirty (30) working days but not more than six (6) months.
   c) Temporary closure of the premises shall take immediate effect awaiting the Authority's decision

d) Failure to sufficiently address the deficiencies leads to revocation of the premise license and/or GSDP Certificate.
e) Refusal to grant a premise license and/or GSDP Certificate

Article 39: Warnings, suspensions, and revocations

A warning letter, suspension, or revocation of the premise license shall be issued to the applicant where the Authority finds the applicant not complying with any of the requirements or conditions in these Regulations; or has ceased to be fit to carry on the regulated activities.
The Authority shall suspend or revoke a GSDP certificate of a premise if the premise contravenes the following GSDP requirements:

1. Conditions for issuing of warning letter:
   The information on which the approval was given is later found to be false,

2. Conditions for suspension:
   Any of the conditions under which the GSDP certificate was issued no longer exist

3. Conditions for revocation:
   Repeated violation of the regulatory administrative sanction or decision.

Where the GSDP certificate is suspended or revoked, the Authority shall issue a notice to the management of the facility.

The Authority shall take steps including suspension of registered medicinal products or closure to ensure that the manufacturing activity is stopped until otherwise decided by the Authority.
Measures towards enforcing this article may include the publication of the Rwanda FDA's action on its website and other relevant media.

Where the GSDP certificate is revoked, the applicant must wait a determined period specified in the relevant guidelines before he/she is eligible to reapply for possible GSDP certification, The GSDP certification shall be re-instated only if the applicant meets the relevant requirements.

Article 40: Restoration of a suspended or revoked GSDP certificate

Pursuant to article 40, the Authority may, upon satisfaction that the reasons for suspension or revocation of GSDP certificate have been corrected or if such reason for suspension/ revocation was unfounded.

Article 41: Appeals

Any person aggrieved by a decision of the Authority may formally request to the Authority for review of the decision in writing showing grounds for dissatisfaction within thirty (30) days from the date of notification of the decision.
The Authority shall, within thirty (30) working days from the date of receiving the application, review, reject or vary its own decision.
The Rwanda FDA Guidelines on appeals and complaints shall be followed in addressing lodged appeals.

Article 42: Publication on Authority website

The Authority shall publish on a monthly basis summarized inspection reports, a list of all premises granted GSDP certificates, and a list of conducted GSDP inspections, along with regulatory decisions, actions, and enforcement activities taken.

The Authority shall publish GSDP inspection metrics on annual basis.

Article 43: Commencement

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

End of Document