

**[REGULATIONS GOVERNING LICENSING OF PUBLIC AND PRIVATE MANUFACTURERS, DISTRIBUTORS, WHOLESALERS AND RETAILERS OF MEDICAL PRODUCTS]**

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

# REGULATION DEVELOPMENT HISTORY

|  |  |
| --- | --- |
| **DRAFT ZERO** | 17th August 2020 |
| **ADOPTION BY RWANDA FDA** | 24th August 2020 |
| **STAKEHOLDERS CONSULTATION** | 26th August 2020 |
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## Document Revision History

| Date of revision | Revision number | Changes made and/or reasons for revision |
| --- | --- | --- |
| 18/08/2020 | 1 | The title of the regulations was renamed as “**Regulations Governing Licensing to Manufacture, to Operate as Wholesale and Retail Seller of Medical Products**” instead of “Regulations governing licensing to manufacture pharmaceutical products or to operate as wholesale or a retail seller of pharmaceutical products”. |
| 20/01/2022 | 2 | 1. The title of the regulations was renamed as Regulations Governing Licensing of Public and Private Manufacturers, Distributors, Wholesalers and Retailers of Medical Products instead of “Regulations Governing Licensing to Manufacture, to Operate as Wholesale and Retail Seller of Medical Products”.  2. Requirements for licensing of public/ private institutions have been included. |
| 01/08/2022 | 3 | 1. All requirements have been removed in the regulations and detailed in the relevant guidelines  2. Clarification on the validity of the operational licenses for renewal and other variations have been added  3. The articles have been re-arranged  4. Publication of inspected, registered and licensed premises were revised to include, the publication of premises with revoked, suspended operational license and un-functional premises  5. Administrative fines for operating without a pharmacist has been increased |

# ADOPTION AND APPROVAL OF THE REGULATIONS

In EXERCISE of the powers conferred upon Rwanda Food and Drugs Authority by Article No 9 of the Law No 003/2018 of 09/02/2018 establishing Rwanda FDA and determining its mission, organization and functioning, hereby Adopts and Issues this Regulation No Doc Ref No.: CBD/TRG/001 Rev\_3 Governing Regulations Licensing of public and private Manufacturers, Distributors, Wholesalers and Retailers of Medical Products, made this 03/08/2022.

**Dr. Emile BIENVENU**

**Director General**

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# ABBREVIATION AND ACRONYMS

**HVAC** Heating, ventilation, and Air conditioning

**GDP**  Good distribution Practice

**GMP** Good manufacturing Practice

**RWANDA FDA** Rwanda Food and Drugs Authority

# CHAPTER ONE: GENERAL PROVISIONS

## Article One: Purpose of these Regulations

The purpose of these Regulations is to provide a detailed framework in the implementation of the law No 003/2018 of 09/02/2018 establishing the Rwanda FDA and determining its mission, organization and functioning for the effective and efficient regulation for licensing of public and private manufacturers, distributors, wholesalers and retailers of Medical Products.

## Article 2: Citation

These Regulations may be cited as the “Regulations CBD/TRG/001 Rev. No 3, Regulations Governing Licensing of Public and Private Manufacturers, Distributors, Wholesalers and Retailers of Medical Products.”

## Article 3: Scope

These regulations shall apply to domestic, public, and private manufacturers, distributers, wholesalers and retailers of medical products involved in the manufacture, storage, sale, distribution, and dispensing of medical products as stipulated in Article 3 of Law No 003/2018 of 09/02/2018 establishing Rwanda Food and Drugs Authority and determining its mission, organization and functioning.

## 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 Article 2 of the Law; Law No 003/2018 of 09/02/2018 the Law No 003/2018 of 09/02/2018 establishing Rwanda FDA and determining its mission, organization and functioning

**“Applicant”** means any legal or natural person, established within or outside Rwanda, seeking to obtain or having obtained the license to manufacture medical products;

**“Authorization”** means a legal document granted by Rwanda Food and Drugs Authority to an applicant under the Law No 003/2018 of 09/02/2018 establishing Rwanda FDA and determining its mission, organization and functioning; it includes licenses, permits, and certificates.

**“Critical Deficiency”** When the deviation affects a quality attribute, a critical process parameter, an equipment or instrument critical for process or control, of which the impact to patients (personnel or environment) is highly probable, including life threatening situation, the deviation is categorized as Critical requiring immediate action, investigated and documented. A “Critical” deficiency may consist of several related deficiencies, none of which on its own may be “Critical”, but which may together represent a” Critical” deficiency, or systems’ failure where a risk of harm was identified and should be explained and reported as such.

**“Critical equipment”:** means any piece of the equipment, instrumentation, or systems, whose malfunction or failure may cause variation in the quality and safety of the medical products.

**“Distributor”** means a person or entity that buys medical products from manufacturers and sell them in bulk to public or private institutions.

**“Good Manufacturing Practices”** means that part of Quality Management 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, Clinical Trial Authorization or product specification. Good Manufacturing Practice is concerned with both production and quality control.

**“Herbal product”** a pharmaceutical product with a label identifying its dosage form that contains one or more substances of natural origin that are derived from plants

**“Inspection”** means an organized examination or formal evaluation exercise. Inspection means also “A visit to a factory or other building to check that everything is satisfactory and all rules are being obeyed. An official check done on something to see that it is of the right standard or quality, or whether it is safe to use.”

**“Magistral preparation”** means medicines made by the chemist himself based on a prescription.

**“Manufacturer”** means a person or corporation, or other entity engaged in the business of manufacturing medical products;

**“Minister”** Means minister responsible for health

**“Medical product”** means medicines, vaccines, diagnostics and medical devices.

**“Medical device”** medical device: any instrument, machine, appliance, material intended by the manufacturer to be used alone or in combination for the purpose of diagnosis, testing, vaccination, cure, surgery or for human or animal health protection

**“Minor/Other Deficiency:** A deficiency that is not classified as either “Critical” or “Major”, but indicates failure to meet the standards of premises suitability. A deficiency may be judged as “Minor” because there is insufficient information to classify it as “Critical” or “Major”.

**“Major Deficiency”:** A deficiency that is not a “Critical” deficiency, but could have major effects on the overall safety, efficacy and quality of the medical products. This consists of several

“Minor/Other” related deficiencies, none of which on its own may be “Major”, but which may together represent a “Major” deficiency or systems failure and should be explained and reported as such.

**“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 where food and drugs are manufactured, prepared or stored, cleaning hospitals, equipment and farm houses;

**“Premises”** means any plot of land, buildings or boats, aircrafts, 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.

**“Qualified personnel”** means an individual who by possession of a recognized degree who by extensive knowledge, training and experience, has successfully demonstrated his ability to solve or resolve problems relating to the subject matter.

**“Retailer**” is an entity that is authorized to carry on the business of dispensing or providing medical products directly to a patient.

**“Responsible technician”** means an individual who possess a recognized degree, registered in the National Council in the field of practice and acknowledged by the Authority

**“Tariff/Fees”** Includes any charge made or levied in connections with services rendered by the Authority

**“Wholesaler”** is an entity that is authorized to carry on the business of selling medical products in large quantities to other authorized sellers with the exception of dispensing or providing medical products directly to a patient

# CHAPTER II: LICENSING & INSPECTIONS

## Article 5: Obligation to obtain premise registration certificate and license to operate

Any activity related to the manufacture, storage, import, export, sale, packaging, distribution, supply and transport of pharmaceutical products, human and animal vaccines and other biological products used in clinical as drugs, medical devices, poisonous product, medicated cosmetics, herbal medicines and any other health commodities must be registered and licensed.

No person or entity shall manufacture, distribute, wholesale or retail medical products without prior authorization from the Authority.

The registration certificate and license to operate premises used for carrying out activities under Paragraph 1 of Article 5 of this Regulation is granted by Rwanda FDA. The registration of activities and premises shall be proven by a certificate issued by the Authority. The requirements to obtain a registration certificate and license to operate are detailed in the relevant guidelines.

All premises, facilities, establishments and companies throughout the supply chain must be registered and possess a valid license to operate issued by the Authority.

No pharmacy importing pharmaceutical products and medical devices shall sell them on a wholesale basis to other pharmacies in the same category.

The Authority shall conduct an inspection for confirmation of the compliance to the requirements in order to grant or re-grant a license or approval of a substantial modification.

## Article 6: Premises of medical products manufacturing facilities

* + - 1. The premises shall be located in a place where they cannot be contaminated by the external environment or other activities or contaminating the neighboring environment.
      2. The premise shall be of permanent nature
      3. The premises shall have a regular and sufficient supply of water.
      4. The premises shall have the minimum floor space and height as described in the relevant guidelines. Premises that do not comply with the requirements for suitability shall not be eligible for consideration for the authorization.
      5. Premises shall be designed to contamination minimize

## Article 7: Inspection of premises for suitability

The Authority shall inspect the premises to determine the suitability of premises for public and private manufacturers, distributors, wholesalers and retailers of medical products upon receipt of a complete application.

Premises that do not comply with the requirements for suitability shall not be eligible for consideration for an authorization.

For the medical products manufacturers, the site location approval shall be done prior to construction phase

Preliminary inspections shall be carried out at various stages of construction and setting up the site. These shall include:

1. Site inspection before construction
2. Site inspection at completion of construction of the premises;
3. Site inspection at the completion of installation of equipment and utilities, e.g., HVAC, water, compressed gases, etc.;

After commissioning the facility and start of manufacturing, the company should submit a formal application for GMP inspection and authorization to manufacture medical products. The aforementioned documents shall be provided to the Authority.

## Article 8: Personnel

1. **Personnel for the medical products manufacturing facility**
2. There are shall be sufficient qualified personnel to carry out all manufacturing activities and the responsibility for every individual has to be clearly understood and recorded.
3. The manufacturer shall have an organization chart.
4. All responsible staff shall have their duties recorded in written descriptions and adequate authority to carry out their responsibilities.
5. Duties for responsible personnel may be delegated to designated deputies of satisfactory qualification level.
6. There are shall be no gaps or unexplained overlaps in responsibilities of personnel concerned.
7. Unauthorized personnel shall not enter production, storage and quality control areas or use them as passage.

A manufacturing facility shall have the following key personnel:

1. Head of production;
2. Head of quality unit;
3. Head of quality assurance;
4. Head of quality control; and
5. Authorized personnel.

All medical products manufacturing facilities shall inform the Authority about the appointed qualified and authorized personnel for the purpose of approval.

Key personnel responsible for supervising the manufacture and quality unit including quality assurance and quality control for manufacture of medical products shall possess the qualification with scientific education and practical experience.

1. The head of production shall have bachelor education in Pharmacy but if not, available options shall be for person with at least a bachelor education in the following:
2. Pharmaceutical sciences and technology;
3. Chemistry (analytical or organic) or biochemistry;
4. Chemical engineering;
5. Veterinary medicine.
6. Any other relevant qualification
7. The head of quality unit shall have bachelor education in any of the following:
8. Pharmacy;
9. Pharmaceutical sciences and technology;
10. Chemistry (analytical or organic) or biochemistry.
11. Any other relevant qualification
12. The head of quality control shall have bachelor education in any of the following:
13. Pharmacy;
14. Pharmaceutical sciences and technology;
15. Chemistry (analytical or organic) or biochemistry;
16. Microbiology.
17. Any other relevant qualification

The responsibilities of the personnel in charge are detailed in the relevant guidelines.

1. **Training**

A manufacturer shall provide training as per written program for all the personnel whose duties take them into production areas or into control laboratories including the technical, maintenance, and cleaning personnel, and any other personnel whose activities could affect the quality of the product.

1. **Personnel for distributors, wholesalers and retailers of medical products**

The supervising personnel of authorized medical products establishments shall be:

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

For a human wholesale/retail pharmacy, be a pharmacist.

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

For wholesale/retail of optical products be optician or any other relevant qualification.

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

For wholesale/retail of orthopedic products be an orthopedist / orthopedic technician or any other relevant qualification.

For a veterinary drug shop, be a veterinary technician (A2 Level) or pharmacy technician.

Public hospital pharmacies (referral, provincial and district hospitals) and private hospital pharmacies be a pharmacist.

Public health center pharmacies be a pharmacist or any other relevant qualification as required by the Supervising Institution.

For wholesale/ retail of herbal products, be a naturapathic, pharmacognosist pharmacist, or any other relevant qualification

1. **Supporting personnel requirements**

The support staff of authorized medical products establishments shall be:

Assistant pharmacist, Pharmacy technician, Medical assistant, Veterinary technician or Nurse depending on the category of the establishment.

## Article 9: Requirements to be granted a license to operate as Public and Private Manufacturers, Distributors, Wholesalers and Retailers of Medical Products

The requirements for the applicants before they are granted an authorization to operate based on type of activity, are provided for in the relevant guidelines issued by the Authority.

The applicant shall fulfill all the requirements as per the guidelines and comply with the premise standard before the license is granted

## Article 10: Requirements to re-grant, renew a license or approval of a substantial modification/variation

1. The applicant shall inform the Authority any modification carried out for the purpose of its approval.
2. The Authority shall conduct an inspection for confirmation of the compliance requirements in order to re-grant a license or approval of a substantial modification.
3. The requirements for renewal and any variation on the authorization are detailed in the relevant guidelines.
4. The application for renewal of the operational license shall be done within two (2) months before its expiration. Any premise with expired license shall be closed until the license is renewed.

# CHAPTER III: VALIDITY AND REFUSAL OF AN AUTHORIZATION

## Article 11: Validity of an Authorization

An application is considered to be complete when it contains the following:

1° Submission of all regulatory requirements,

2° Approved premise inspection report, and

An incomplete application remains valid for a period of ninety (90) calendar days from the date of submission. An application that does not comply with the requirement(s) within a period of ninety (90) calendar days shall be closed. If the applicant wishes to re-submit the application, it shall be considered as a new application.

An authorization shall be valid for twelve (12) months renewable from the date of issuance, but may be suspended or withdrawn if any of the conditions under which it was granted, is violated.

An authorization is issued to an applicant and shall not be transferred to another applicant or premise without prior written approval of the Authority.

The validity of the renewed operational license shall refer to the date of the first issued operational license.

Any change(s) to the information contained in the authorization shall be notified to the Authority within a period of five (5) working days.

## Article 12: Refusal to grant an Authorization

An authorization to operate public and private manufacturers, distributors, wholesalers and retailers of medical products shall not be granted where the Authority finds the applicant not complying with the requirements prescribed in these regulations and relevant regulatory documents.

## Article 13: Establishment of Licensing and Inspection technical and advisory Committee

The Authority shall establish a technical and/or advisory committee comprising of internal and/or external experts from different fields and scientific research to advise the Authority on licensing and inspection regulatory matters with clear terms of reference.

## Article 14: Publication of inspected, registered and licensed premises

Inspected, licensed, and un-functional premises as well as premises with revoked, suspended operational licenses shall be published monthly on the Rwanda FDA Website, and on any other media, as the Authority may decide from time to time.

The list of retail pharmacies on Duty Roster shall be published quarterly on the Rwanda FDA Website, and on any other media, as the Authority may decide from time to time.

## Article 15: Display of the Authorization

The license to practice and the license to operate shall be conspicuously displayed in the establishment.

## Article 16: Display of Sign post

An Authorized establishment shall be identified by a clearly displayed sign post containing the registration certificate number, name of establishment, names and telephone number of the qualified personnel.

## Article 17: Good Distribution Practice

The medical products manufacturers/distributors or wholesalers shall have systems, facilities and operations that comply with the Good Distribution Practice Regulations and Guidelines, as adopted by the Authority.

**Transportation Requirements:**

1. Vehicles used to transport medical products should be properly designed and equipped to ensure protection from different environmental and weather conditions in which it operates.
2. Vehicles used to transport medical products shall be licensed by the Authority.
3. The use of vehicles with defects that could affect the quality of the medical products should be avoided.

## Article 18: Good Manufacturing Practice

The medical products Manufacturer shall have systems, facilities and operations that comply with the Good Manufacturing Practice Regulations and Guidelines, as adopted by the Authority.

## Article 19: Good Dispensing Practice

The medical products retail seller/dispenser and hospital pharmacies shall have systems, facilities and operations that comply with the Good Dispensing Practice Guidelines, as adopted by the Authority.

# CHAPTER IV: FINAL AND MISCELLANEOUS PROVISIONS

## Article 20: Administrative sanctions

Any person who contravenes the provisions of these Regulations, shall be liable to the administrative measures and sanctions prescribed below:

1. Manufacturing, importation, sale, storage and distribution of substandard, unapproved, counterfeit/falsified, expired and fraudulent regulated products: the business owner or manager is fined with twice the value of the condemned products plus test costs where laboratory testing is compulsory.
2. Violation of closure of premises closed by the Rwanda FDA: the business owner or manager is fined with a fine of five hundred thousand Francs (500,000 FRW) and temporary closure of the premise until proof of compliance with the regulatory requirements,
3. Absence of a responsible technical person in an authorized facility dealing with regulated products: the business owner or manager is fined with a fine of five hundred thousand (500,000 FRW),
4. Operating without operational license: the business owner or manager is sanctioned with a fine of one million Rwandan Francs (1,000,000 FRW),
5. Operating without valid operational license: the business owner or manager is sanctioned with a fine of one hundred thousand Rwandan Francs (100,000 FRW). Note that for each delay of one month, a 25% fine shall be added to the fine fees,
6. Closure of the pharmacy which is officially on duty: the business owner or manager is sanctioned with a fine of one hundred thousand Rwandan Francs 100,000 FRW,
7. Production without production manager or/ quality control manager: the business owner or manager is sanctioned with a fine of five hundred thousand Rwandan Francs (500,000 FRW),
8. Transport of regulated products in unacceptable conditions: the business owner or manager is sanctioned with a fine of two hundred thousand Rwandan Francs (200,000 FRW),
9. Failing to ensure that narcotics and other controlled substances are kept in a secured cupboard: the business owner or manager is sanctioned with a fine of one hundred thousand Rwandan Francs (100,000 FRW),
10. Failure to provide prescriptions/reports for distribution of narcotics and controlled products at the time of inspection: the business owner or manager is sanctioned with a fine of one hundred thousand Rwandan Francs (100,000 FRW)
11. Airing of expired regulated products: the business owner or manager is sanctioned with a fine of one hundred thousand Rwandan Francs (100,000 FRW)
12. Any change to the authorization without notifying the Authority within the prescribed timelines: the business owner or manager is sanctioned with a fine of one hundred thousand Rwandan Francs (100,000 FRW)
13. Relocation without notifying the Authority: the business owner or manager is sanctioned with a fine of one hundred thousand Rwandan Francs (100,000 FRW)

## Article 21: Other Regulatory Actions

The Authority shall take the regulatory actions based on Minor, Major and Critical category of non-compliances as recommended by the inspectors when making decisions on the outcome of inspections:

1. Minor non-compliances are applied not limited to:
2. Corrective action within a given time frame
3. Request for compliance report within five (5) working days
4. Major non-compliances
5. Issue warning letter
6. Temporary withdrawal or suspension of operational license.
7. Critical non-compliances include
8. Temporarily closure of the establishment,
9. permanent withdrawal/revocation of operational license,
10. Not granting the operational license.

The above-mentioned non-compliances shall be detailed in other regulatory documents (guidelines, Standard Operating Procedures, etc.)

## Article 22: Warning, Suspensions and revocations

A warning letter, suspension or revocation of the authorization shall be granted 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 license of a facility if the facility contravenes following licensing requirements:

1. Any of the conditions under which the license was issued no longer exist,
2. The information on which the approval was given is later found to be false,
3. The circumstances under which the approval was given no longer exist,
4. Repeated violation of the regulatory administrative sanction or decision.

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

The Authority shall take steps including closure to ensure that the manufacturing, wholesale or distribution 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.

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

1. Objects to any suspension or revocation of authorization, or to any notice served,
2. Objects to the refusal of authorization or the imposition of any condition, may notify the Director General of its desire to make written representations to, or be or appear before and be heard by, a person appointed by the Director General for that purpose.

## Article 23: Documentation and related controls

1. All records (including but not limited to invoices, purchase orders, import authorizations, sales and distribution records, throughout the supply chain) for all medical products and administrative records of the staff shall be properly kept in the medical products establishment and be readily available to the inspection service when requested for or needed.
2. All entry and exit of medical products must be approved by the responsible qualified personnel.
3. Availability of certified copy of license to practice of the qualified personnel in charge where applicable.
4. Quarterly reports on the distribution of controlled substances to be submitted to the Authority.
5. A copy of authorization and license to practice profession for the responsible qualified personnel shall be conspicuously displayed in the establishment.

## Article 24: Appeals and Review

The manufacturer, distributor, wholesaler and retailer of medical products or any other person responsible for the regulated premises, if not satisfied with the decision of the Authority, may submit his/her appeal to the management of the Authority for the review within thirty (30) working days from the date of the reception of the decision.

The Authority shall within thirty (30) working days from the date of appeal application review, vary or reject its decision.

If the appellant is not satisfied with the decision of the Authority, he/she may appeal to the Supervising Authority of Rwanda FDA or the Minister of Health in his or her attributions whose decision shall be final.

## Article 25: Commencement

These regulations shall enter into force on the date of signature and publication. All prior provisions contrary to these regulations are hereby repealed.

End of Document