RWANDA FDA
Rwanda Food and Drugs Authority

REGULATIONS GOVERNING THE LICENSING OF PUBLICAND PRIVATE MANUFACTURERS, DISTRIBUTORS, WHOLESALERS AND RETAILERS OF MEDICAL PRODUCTS

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

REGULATION DEVELOPMENT HISTORY

First issue date	10/01/2020
Effective date of this revision	23/04/2024

Document Revision History

Revision number	Changes made and/or reasons for revision
0	First Issue
1	The title of the Regulations was renamed as "Regulations Governing the 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".
2	1. The title of the Regulations was renamed "Regulations Governing the 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 and private institutions have been included.
3	1. Article 6: Application for premises registration and license to operate was revised for rejection of incomplete application. 2. Article 7: Conditions for registration of a premises, Article 9: Appointment of inspectors, Article 10: Conflict of interest, Article 11: Powers of inspectors, wereadded in CHAPTER II of these Regulations. 3. Article 17: Requirements to re-grant, renew a license to operate or approval of a substantial modification for submissionof all applications for renewal from 01st March to 30thApril of the fiscal year. 4. Article 18: Validity of an authorization. The validity for all licenses to operate shall follow the fiscal year starting from 1st July to 30th June. 5. Article 25: Transport and deliveryvalidation, was added in CHAPTER III of these Regulations. 6. Article 28: Annex A was generated from these Regulations 7. Article 33: Closure of business activity, was added in CHAPTER V. 8. Editorial changes have been made for the adoption of the new Regulations format.

4	1. Article 4: Definitions, were revised to include new definitions. 2. Chapter III: The term authorized personnel was changed to "Authorized person". 3. Article 18: Validity of an authorization, was revised. 4. Article 30: Warning, was revised to elaborate conditions that shall lead to the issuance of a warning letter. 5. Article 31: Suspension, was revised toelaborate conditions that shall lead to suspension of a premises license. 6. Article 32: Revocation, was revised toelaborate conditions that shall lead to revocation of a premises license. 7. Annex A: Administrative sanctions, were updated.
5	1. Annex A: Administrative fines were updated where the sanction for selling and/or buying medical products to/from the premises in the same category was added. 2. The timeline to pay administrative fines was added.

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/001 Rev_5 governing the Licensing of public and private manufacturers, distributors, wholesalers and retailers of medical products on this 23/04/2024.

Prof. Emile BIENVENU
Director General

Digitally signed by Rwanda FDA (Director General)
Date: 2024.04.23 16:56:54 +03'00'

ARRANGEMENT OF THE REGULATIONS

CHAPTER ONE: GENERAL PROVISIONS

Article One: Citation

These Regulations are cited as the "Regulations DD/PIL/TRG/001 Rev_ 5, governing licensingof public and private manufacturers, distributors, wholesalers and retailers of medical products."

Article 2: Purpose of these Regulations

These Regulations enforce the legal framework for application, inspection, storage, distribution, and licensing of public and private manufacturers, distributors, wholesalers and retailers of Medical Products.

Article 3: Scope

These Regulations apply to public, and private manufacturers, distributors, wholesalers and retailers of medical products involved in the manufacture, storage, sale, distribution, and dispensing of medical products.

Article 4: Definitions

In these Regulations, unless the context otherwise requires, the following terms have meaning ascribed to them:

"**Applicant**" means any person or legal entity established within Rwanda, seeking to obtain or having obtained the authorization to manufacture, store, distribute, wholesale and retail medical products.

"Authority" means the Rwanda Food and Drugs Authority or its acronym "Rwanda FDA", established by Law N° 003/2018 of 09/02/2018.

"Authorization" means a legal document granted by Rwanda FDA to an applicant under the Law No 003/2018 of 09/02/2018, it includes licenses, permits, and certificates.

"Authorized person" is an individual recognized by the authority as having the necessary basic scientific and technical background and experience.

"Conflict of interest" means any interest in any business related to medicines declared by the inspector that may affect or reasonably perceived to affect the quality or the result of his work or remediation.

"Distribution" means the procuring, purchasing, holding, storing, selling, supplying, importing, exporting, or movement of products regulated by the Authority.

"Distributor" means an organization or an entity, such as a wholesaler that distributes the 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.

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

"Fiscal year" means an accounting period that begins on July 1 and ends on June 30.

"**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.

"**Herbal medicine**" means a medical product with a label identifying its dosage that contains one or more substances of natural origin that are derived from plants.

"Manufacturer" means a company that carries out at least one step of manufacture.

"Medical product" includes human and veterinary drug, human and animal vaccines and other biological products used in clinical as drug, herbal medicines and human and veterinary medical devices.

"Minister" means the Minister having health in his or her attributions.

"Notice" means minutes of the inspection findings duly signed by the inspector (s), a representative of the entity inspected and, or a representative of local administration, a written document of the Authority that results from the inspection report and evidence.

"Packaging", means all operations, including labelling and re-labelling, that a bulk product has to undergo in order to become a finished product. Filling of a sterile product under aseptic conditions or a product intended to be terminally sterilized, would not normally be regarded as part of packaging.

"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, and cleaning hospitals, equipment and farmhouses.

"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.

"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.

"Registration certificate" means an authorization issued to the registered company for an indefinite period.

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

"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;

"Suspension/Revocation of a license" means an annulment of the license issued to the manufacturer, storage facility, distributor, wholesaler, or retailer of medical products due to violation of conditions ofissue.

"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.

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: LICENSING AND INSPECTIONS

Article 5: Obligation to obtain premises registration certificate and premises license

1. 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.

2. All premises, facilities, establishments and companies throughout the supply chain must be registered and possess a valid premises license. The premises registration certificate and license for premises used for carrying out activities under paragraph 1 of this article of this Regulation is granted by the Authority. The requirements to obtain a registration certificate and license to operate are detailed in the relevant guidelines.

3. The Authority shall conduct an inspection for confirmation of compliance with the licensing requirements in order to grant or re-grant a premises license or approval of a substantial modification. A premises license to manufacture, store, distribute, wholesale and retail 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. The premises license may be suspended or withdrawn if any of the conditions under which it was granted, is violated.

Article 6: Application for premises registration and premises license

1. An application shall be made to the Authority addressed to the Director General of the Authority, accompanied by all required documents as described in the relevant guidelines.

2. An application is considered to be complete on submission of all required documents provided in the relevant guidelines on licensing of public and private manufacturers, distributors, wholesalers and retailers of medical Products. An incomplete application shall be rejected until all requirements are fulfilled.

Article 7: Conditions for registration and licensing of a premises

1. Every premise dealing with medical products shall be made of permanent building materials, durable and located away from sites or activities that would comprise the safety, quality and efficacy of medical products.

2. Premises shall be designed, constructed, adapted, and maintained to suit the operations carried out and to facilitate cleaning and maintenance, provide maximum protection against the entry of insects, birds, or animals, minimize the risk of errors and contamination having regard to the type and stage of manufacturing which the buildings and facilities are used for.

3. All manufacturing facilities for medical products, shall comply with GMP requirements according to the Regulations governing Good Manufacturing Practices of medical products.

4. Premises involved in storing, distribution, wholesaling and retailing of medical products shall comply with the GSDP principles and pharmacovigilance system and have minimum space and height requirements as detailed in the guidelines for Good Storage and Good Distribution Practices of medical products, guidelines on safety and vigilance of medical products and health technology and guidelines for licensing of public and private manufacturers, distributors, wholesalers and retailers of medical products respectively.

Article 8: Inspection of premises for suitability

The Authority shall inspect all public and private premises involved in the manufacture, storage, distribution, wholesale and retail of medical products to determine compliance with Authority requirements upon receipt of a complete application. Premises that do not comply with the requirements for licensing shall not be eligible for consideration of a premise license.

Article 9: Appointment of inspectors

The Authority shall appoint inspectors to inspect public and private premises involved in the manufacture, storage, distribution, wholesale and retail of medical products. The inspectors shall have the relevant qualifications in terms of academic education, training, and experience to effectively take part in the inspection.

Article 10: Conflict of Interest

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

Article 11: Powers of inspectors

To enforce compliance for conducting inspections, an inspector appointed following these

Regulations shall, upon production of evidence that he/she is so 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 to visit, including any premises of any person who carries out any of the activities referred to in these Regulations;

2. To carry out at those premises during the visit, inspections, examinations, tests, and analyses as he/she considers necessary;

3. To require the production of, 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 or 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/she finds at the premises and has reasonable cause to believe can give relevant information;

6. To require any person to afford he/she such assistance as considered necessary concerning any matter within that person's control, to which that person has responsibilities;

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

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

CHAPTER III: PERSONNEL

Article 12: Key Personnel for the Medical Products Manufacturing Facility

1. A manufacturing facility shall at least have the following key personnel:
   a. Head of production;
   b. Head of quality assurance;
   c. Head of quality control; and
   d. Authorized person.

2. A manufacturer shall formally notify the Authority of the name of authorized person appointed by the manufacturer and the specific functions which have been delegated to such persons for the purpose of approval. Key posts shall be occupied by full-time personnel.

Article 13: Academic qualifications of key personnel

The necessary qualifications of the key personnel are detailed by the Authority in the relevant guidelines on licensing of public and private manufacturers, distributors, wholesalers and retailers of medical Products.

Article 14: Training

A manufacturer shall provide trainings according to a 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.

Article 15: Authorized person

The necessary qualifications of the authorized person are provided for by the Authority in the relevant guidelines on licensing of public and private manufacturers, distributors, wholesalers and retailers of medical products.

Article 16: Requirements to be granted registration certificate and premise license

An applicant is required to fulfill all the requirements as per the guidelines and comply with the premises standard before the registration certificate and premises license is granted. The Guideline on licensing of public and private manufacturers, distributors, wholesalers and retailers of medical products details the premises license requirements for applicants based on the type of activities carried out.

Article 17: Requirements to re-grant and renew a premises license

1. The Authority shall conduct an inspection to confirm compliance prior to re-granting a premises license. The requirements for renewal are detailed in the relevant guidelines on licensing of public and private manufacturers, distributors, wholesalers and retailers of medical products.

2. All applications for renewal of the premises license shall be submitted annually from 01st March to 30th April. Any premise with an expired premises license shall be closed until the license is renewed. An incomplete application for renewal shall be rejected until all requirements are fulfilled.

3. Operating without a valid premises license for a period of six months, the application shall be submitted as a new application in accordance with requirements for a new application provided in the relevant guidelines for licensing of public and private manufacturers, distributors, wholesalers and retailers of medical products and the administrative fines for operating without a valid premises license shall be applicable pursuant to article 28 of these Regulations.

Article 18: Approval of a substantial modification

Prior to approval of a substantial modification, the Authority conducts an inspection of the premises. The applicant informs the Authority of any substantial modification carried out for the purpose of its approval. For critical substantial modification, the applicant shall wait for the written approval of the Authority before the implementation of the requested substantial modification. The types of substantial modification are detailed in the relevant guidelines on licensing of public and private manufacturers, distributors, wholesalers and retailers of medical products.

CHAPTER IV: VALIDITY OF AN APPLICATION AND AUTHORIZATION

Article 19: Validity of an application and authorization

1. A premises license shall be valid for a period of twelve (12) months of the fiscal year renewable.

All premises licenses issued by the Authority shall expire by 30th June of the same year.

2. A premises license is issued to an applicant and shall not be transferred to another applicant or premises without prior written approval of the Authority. Any change(s) to the information contained on the premises license shall be notified to the Authority within a period of five (5) working days.
3. The premises license becomes invalid upon termination of the employment contract between the licensed premises and the authorized person.
4. The premises shall notify the Authority in advance if the Authorized person has resigned.
5. All applications for premise licensing shall comply with the regulatory requirements. All applications shall be valid for a period of ninety (90) calendar days from the date of application. If the applicant fails to comply with premise licensing requirement (s) within a period of ninety (90) calendar days unless otherwise authorized by the Authority, the application shall be closed. If the applicant wishes to re-submit the application, it shall be considered as a new application and the prescribed fees shall be paid.
6. The Authority may cancel the ongoing application of unlicensed premises if the applicant commits violations of conditions which may trigger suspension and/or revocation of premises license for licensed premises.

Article 20: Establishment of Licensing and Inspection technical and/or advisory Committee

The Authority shall establish technical and/or advisory committees 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 21: Publication on the Authority website

1. A list of inspected premises and inspection summary reports, lists of registered and licensed premises, as well as premises with revoked, and suspended premises licenses shall be published monthly on the Authority website, and on any other media, as the Authority may decide from time to time.

2. The list of retail pharmacies on duty rosters shall be published quarterly on the Authority website, and on any other media, as the Authority may decide from time to time.

Article 22: Display of the authorization certificate

The registration certificate, premises license and license to practice profession shall be conspicuously displayed in the authorized premises.

Article 23: Display of a sign post

An authorized premise shall be identified by a clearly displayed sign post containing the registration certificate number, name of the premises, and names and telephone number of the authorized person.

Article 24: Good Storage and Distribution Practice

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

Article 25: Transport and delivery validation

The distributor shall be responsible for qualification of all transportation or vehicles used in the transportation of medical products to ensure medical product safety and quality. The requirements for transport and delivery qualification are described in the relevant guidelines.

Article 26: Good Manufacturing Practices

The manufacturer of a medical product shall have systems, facilities and operations that comply with the Good Manufacturing Practice Regulations and Guidelines, as adopted by the Authority.

Article 27: Good Dispensing Practices

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.

Article 28: 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 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 authorized person. Reports on the distribution of controlled substances shall be submitted to the Authority on Quarterly basis.

CHAPTER V: FINAL PROVISIONS

Article 29: Administrative fines

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

1. Manufacturing, importation, sale, storage and distribution of substandard, unregistered/unlicensed, falsified, expired and fraudulent medical products;
2. Illegal opening of premises closed by the Authority;
3. Absence of an authorized person in an authorized premises dealing with medicalproducts;
4. Operating without premises license;
5. Operating without valid premises license;
6. Closure of the pharmacy which is officially on duty;
7. Production without production manager or/ quality control manager;
8. Transport of medical products in unacceptable conditions;
9. Failing to ensure that narcotics and other controlled substances are kept in a secured cupboard;
10. Failure to provide prescriptions/reports for distribution of narcotics and controlledproducts at the time of inspection;
11. Any change to the authorization without notifying the Authority within the prescribed timelines;
12. Relocation without notifying the Authority; and
13. Obstruction of inspectors from Authority;
14. Selling and/or buying medical products to/from the premises in the same category

Administrative fines must be paid within thirty (30) working days from the date of receipt of the administrative fines for non-compliance. Failure to pay the fines in the specified timelines shall lead to the closure of the premises.

Article 30: Other Regulatory Actions

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

1. Minor deficiencies imply:
    a. Corrective action within a given time frame
    b. Request for compliance report

2. Major deficiencies imply:
    a. Issue warning letter.
    b. Temporary withdrawal or suspension of the license to operate.

3. Critical deficiencies imply:
    a. Temporarily closure of the premises.
    b. Revocation of the license to operate.
    c. Not granting the license to operate.

Article 31: Warning

The Authority may issue a warning letter to the holder of premises licensee under the following circumstances:

1. If non-related and non-licensed activities are found to be performed in the licensed premises;
2. The information on which the premise license was granted is found to be false or fraudulent, but does not impose any harm to public health;
3. Wholesale or distribution of medical products to retailers of medical products without a premises license or a valid premises license issued by the Authority;
4. Selling medical products to the premises in the same category;
5. The conditions under which the premises license was granted no longer exist and theAuthority was not informed;
6. Minor malpractices or non-compliances that may not affect the quality and safety of the products manufactured, stored, or distributed.

Article 32: Suspension of the premises license

The Authority may suspend a premises license under the following circumstances:

1. Repeated violations of the conditions that triggered a warning letter as stated in Article 31;
2. The premise is operating without an authorized person;
3. The licensed premises made a false or misleading statement or misrepresentation in the application, that may impose a health hazard to the public;
4. Alteration or modification of the premises and/or equipment after approval by the Authority in a manner that may affect the quality of a medical product;
5. The licensed premises in which the product or part thereof is manufactured, packaged or stored found to be unfit for manufacturing, packaging or storing of the product during subsequent inspection;

6. Performing activities that are not in the scope of the premises license;
7. violations of the laws governing advertising and marketing, including the use of misleading information;
8. violations of narcotics and controlled drugs secure prescription requirements and inventory control;
9. Failure to maintain record(s) of purchase and distribution/ dispensing of narcotics and controlled drug(s); and
10. Repeated or significant infractions of, participation in, or encouragement of, or conspiracy to commit, infractions of, Laws and Regulations for premises licensing of medical products;
11. Transfer of the premises license to other licensed or non-licensed premises or any misuse of the premises license.

The suspension shall take immediate effect, or not later than fifteen (15) working days. 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. However, after six (6) months of suspension if the suspended entity does not address the findings that led to suspension, the Authority may take other administrative measures.

Article 33: Revocation of premises license

1. The Authority may revoke the premises license under the following circumstances:
   a. Repeated violations of the regulatory administrative sanction or decision;
   b. Failure to provide the corrective actions within the timeline stated during the suspensionof the premises license;
   c. Premises license has been suspended for a period of more than 12 months;
   d. The premises perform malpractices that affect the health or safety of patients;
   e. Repeated or significant illegal possession of dangerous substances, hypodermic needlesor syringes, prohibited substances, or drug paraphernalia;
   f. Purchasing, importing, exporting, selling, dispensing or transferring adulterated, expired, misbranded dangerous medical product(s);
   g. Abandonment of the licensed activities;
   h. Bankruptcy or liquidation of the licensee;
   i. The license was issued by mistake, or the premises have been declared not fit for the activities for which the license was issued;
   j. Any action or inaction that the Authority may consider to be a ground for revocation.

2. The notice of revocation shall take effect immediately or not later than 15 days after the noticewas issued.
3. A person or entity shall, by the effective date of the revocation, arrange for the safe disposal of, the transfer to, sale of, or storage of medical products in a facility licensed by the Authority,and transfer all purchase and distribution/ dispensing records to a licensed premise. A written proof of the management of medical products, and duly filled application form for discontinuance of activity must be submitted to the Authority within thirty (30) working days.
4. Failure to comply with the above, the Authority may take other administrative measures such as but not limited to confiscate or distribute the medical products to identified health care facilities at the cost of the entity that violated the Laws or regulations in force.

Article 34: Reinstatement

A licensee whose license/certificate is revoked may be reinstated in registered/licensed premises after three (3) years from the day his or her revocation was issued. However, in the interests of the service delivery, a licensee whose revocation has been issued may be reinstated in registered/licensed premises before the expiration of three (3) years under the following conditions:

a. Upon satisfying the Authority on addressing the non-compliance that led to the revocation/suspension;
b. Upon paying administrative fines and
c. Upon discretions of the Authority.

Article 35: Prohibitions

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

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

Article 36: Circulars, Guidelines and Guidance

The Authority may, from time to time, issue circulars, guidelines and guidance necessary for the implementation of these Regulations and shall be adhered to by the applicant(s) and to the members of the general public.

Article 37: Appeals and Review

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 38: Closure of business activity

Where the owner of the premises plans to close down the business, he/she shall formally notify the Authority, duly fill the application form for closure of business and inform the appropriate management of the medical products within thirty (30) working days.

Article 39: Commencement

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

ANNEX-A: FAULTS AND ADMINISTRATIVE FINES

Fault	Administrative fines
1. Manufacturing, importation, sale, storage and distribution of substandard, unregistered/unlicensed, falsified, expired and fraudulent medical products	50% of the product value found in violation
2. Illegal opening of premises closedby the Authority	500,000 FRW
3. Absence of an authorized personnel in an authorized premise dealing with medical 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 6 months after expiry of the License
6. Closure of the pharmacy which is officially on duty	100,000 FRW
7. Production without production manager or/ quality control manager	500,000 FRW
8. Transport of medical products in unacceptable conditions	200,000 FRW
9. Failing to ensure that narcotics and other controlled substances are keptin a secured cupboard	100,000 FRW
10. Failure to provide prescriptions/reports for distribution of narcotics and controlled productsat the time of inspection	100,000 FRW
11. Any change to the authorization without notifying the Authority within the prescribed timelines	100,000 FRW
12. Relocation without notifying the Authority	100,000 FRW
13. Obstruction of inspector from Rwanda Food and Drugs Authority	100,000 FRW for each day of obstructions

14. Wholesale or distribution of medical products to retailers of medical products without a license or a valid license issued by the Authority	Double the price of the invoice
15. Selling and/or buying medical products to/from the premises in the same category	20% of the product value found at the invoice.

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