RWANDA FDA
Rwanda Food and Drugs Authority

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

(Rwanda FDA Law N° 003/2018 of 09/02/2018, Article 9)

REGULATION DEVELOPMENT HISTORY

DRAFT ZERO	05/11/2019
ADOPTION BY RWANDA FDA	14/12/2019
STAKEHOLDERS CONSULTATION	29/12/2019
ADOPTION OF STAKEHOLDERS' COMMENTS	02/12/2020
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Document Revision History

Date of revision	Revision number	Changes made and/or reasons for revision
10/01/2020	0	First Issue
02/10/2020	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"
26/01/2022	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 and private institutions have been included.

24/08/2022	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, were added 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 submission of all applications for renewal by 30th April of the fiscal year. 4. Article 18: Validity of an authorization. The validity for all license to operate shall follow the fiscal year of starting from 1st July to 30th June 5. Article 25: Transport and delivery validation, 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 adoption of the new Regulations format

17/03/2023	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 issuance of a warning letter 5. Article 31: Suspension, was revised to elaborate conditions that shall lead to suspension of a premises license 6. Article 32: Revocation, was revised to elaborate conditions that shall lead to revocation of a premises license 7. Annex A: Administrative sanctions, was updated

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.: FDISM/FDIC/TRG/001 Rev_4 governing Licensing of public and private manufacturers, distributors, wholesalers and retailers of Medical Products on this 04/04/2023.

Digitally signed by Rwanda FDA (Director General) Date: 2023.04.05 17:10:20 +02'00'

Dr. Emile BIENVENU
Director General

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CHAPTER ONE: GENERAL PROVISIONS

Article One: 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 2: Citation

These Regulations are cited as the "Regulations FDISM/FDIC/TRG/001 Rev_ 4, governing 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 a person or organization who receives, stores, warehouses, handles, holds, offers, markets or displays medical products. A distributor shall be an entity that is appropriately

authorized by the competent authority to perform the intended function as prescribed in these Regulations, and which can be held accountable for its activities. These include but not limited to governments at all levels, public and private health and storage facilities, manufacturers of finished products, importers, exporters, distributors, wholesalers, suppliers, retailers.

"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.

"Inspector" means a person appointed, authorized and designated by the Authority in accordance with laws tasked with performing inspection-related duties.

"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 inspector (s), a representative of the entity inspected and, or a representative of local administration, written document of the Authority that results from the inspection report and evidence.

"Packaging", means all operations, including labelling and relabelling, 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, cleaning hospitals, equipment and farmhouses.

"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.

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

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

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

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

"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 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 the compliance to 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 premises 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 GSP & GDP principles, 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 the 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 premises 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 qualification 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:

1º 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;

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

3º 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;

4º 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;

5º To question any person whom, he/she finds at the premises and has reasonable cause to believe can give relevant information;

6º 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;

7º 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

8º 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:
   1º Head of production;
   2º Head of quality assurance;
   3º Head of quality control; and
   4º 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 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 will be detailed 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 premises license

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. The 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.

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

(1) The Authority shall conduct 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 by 30th April. Any premise with expired premises license shall be closed until the license is renewed. An incomplete application for renewal shall be rejected until all requirements are fulfilled. The applicant is subjected to fines on submission of the completed dossier after the expired premises license for operating without a valid premises license.

(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 this Regulations.

Article 18: Approval of a substantial modification

Prior to approval of a substantial modification, the Authority conducts 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 AUTHORIZATION

Article 19: Validity of an 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.

Article 20: Establishment of Licensing and Inspection technical and 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 Authority website

(1) Inspected, registered, licensed, and un-functional premises as well as premises with revoked, 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 premises shall be identified by a clearly displayed sign post containing the registration certificate number, name of the premises, names and telephone number of the authorized person.

Article 24: 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.

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 sanctions

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

1° Manufacturing, importation, sale, storage and distribution of substandard, unapproved, counterfeit/falsified, expired and fraudulent regulated products;
2° Illegal opening of premises closed by the Authority;
3° Absence of an authorized person in an authorized premises dealing with regulated products;
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 regulated 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 controlled products 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.

Article 30: Other Regulatory Actions

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

1º Minor non-compliances imply:

a. Corrective action within a given time frame
b. Request for compliance report

2º Major non-compliances imply:

a. Issue warning letter.
b. Temporary withdrawal or suspension of the license to operate.

3º Critical non-compliances 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 have 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 the Authority was not informed; and
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

(1) 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 30;
2° The premises 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° violation 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.

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 of 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:

1° Repeated violation of the regulatory administrative sanction or decision;
2° Failure to provide the corrective actions within the timeline stated during the suspension of the premises license.
3° Premises license has been suspended for a period of more than 12 months;
4° The premises performs malpractices that affect the health or safety of patients;
5° Repeated or significant illegal possession of dangerous substances, hypodermic needles or syringes, prohibited substances, or drug paraphernalia;
6° Purchasing, importing, exporting, selling, dispensing or transferring adulterated, expired, misbranded dangerous medical product(s);
7° Abandonment of the licensed activities
8° Bankruptcy or liquidation of the licensee
9° The license was issued by mistake, or the premises have been declared not fit for the activities for which the license was issued
10° 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 notice was 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 facility. 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:

1º 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:

1° Upon satisfying the Authority on addressing the raison of revocation/suspension;
2° Upon paying administrative fines and
3° 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

(1) An authorization holder or applicant may notify the Authority of his or her grounds when he/she:
   1º Objects to any suspension or revocation of the authorization, or any notice served;
   2º Objects to the refusal of authorization or the imposition of any condition may notify the Authority of his desire to make written representations to, or be or appear before and be heard by, a person appointed by the Authority for that purpose.

(2) Any person aggrieved by a decision of the Authority may appeal to the Authority for review of a decision within thirty (30) working days from the date of the notice. The Authority shall within thirty (30) working days from the date of receiving the written notification and make its own decision whether to vary, reject or uphold the decision.

(3) Where the Authority receives notification pursuant to provisions of paragraph 1 of this Article, the Authority shall appoint a person(s) to consider the matter. The person(s) appointed shall determine the procedure to be followed concerning the consideration of any objection.

(4) The person appointed by the Authority, shall consider any written or oral objections made by the objector or complainant in support of its objection, and shall make a recommendation to the Authority.

(5) A recommendation shall be made in writing to the Authority, and a copy of it shall be sent to the complainant concerned, or to its nominated representative. The Authority shall take into account any recommendation made within fourteen days of receipt of such recommendation. The Authority shall inform the complainant whether it accepts the recommendation and, if not, the reasons for its decision. If a person is dissatisfied with a decision after review, he/she may appeal to the supervising authority of the Authority or the Minister whose decision shall be final.

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 SANCTIONS

Fault	Administrative sanction
1. Manufacturing, importation, sale, storage and distribution of substandard, unapproved, counterfeit/falsified, expired and fraudulent regulated products	25% to 50% of the product value found in violation.
2. Illegal opening of premises closed by the Authority	500,000 Frw
3. Absence of an authorized personnel in an authorized premise dealing with regulated products	500,000 Frw
4. Operating without operational license	1,000,000 FRW
5. Operating without valid operational license	100,000 Frw Note that for each delay, a 25% increment, on the original fine will be applied monthly from the second month after expiry of the license. This charge of 25% increment shall not go beyond 24 months after expiry of the license
6. 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 regulated products in unacceptable conditions	200,000 Frw
9. Failing to ensure that narcotics and other controlled substances are kept in a secured cupboard	100,000 Frw

10. Failure to provide prescriptions/reports for distribution of narcotics and controlled products at 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

END OF DOCUMENT