



**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)

RWANDA FDA
Rwanda Food and Drugs Authority



*Regulations Governing Licensing of public and private Manufacturers,
Distributors, Wholesalers and Retailers of Medical Products*

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 the Rwanda FDA and determining its mission, organization and functioning, hereby adopts and issues these regulations N° CBD/TRG/001 Rev. N° 2, Regulations Governing Licensing of Public and Private Manufacturers, Distributors, Wholesalers and Retailers of Medical Products, made this 26th day of January, 2022.

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Director General

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26/01/2022



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REGULATION DEVELOPMENT HISTORY

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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	<ol style="list-style-type: none">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.

TABLE OF CONTENT

ADOPTION AND APPROVAL OF THE REGULATIONS	2
REGULATION DEVELOPMENT HISTORY	3
TABLE OF CONTENT	4
ABBREVIATION AND ACRONYMS	6
CHAPTER I: GENERAL PROVISIONS	7
Article 1: Purpose of these Regulations	7
Article 2: Citation	7
Article 3: Application and scope.....	7
Article 4: Definitions	7
CHAPTER II: LICENSING & INSPECTIONS	10
Article 5: Obligation to obtain an Authorization to operate	10
Article 6: Types of inspections	10
Article 7: Inspection of premises for suitability.....	11
Article 8: Requirements for authorization to license Public and Private Manufacturers, Distributors, Wholesalers and Retailers of Medical Products	12
Article 9: Premises	12
Article 10: Premises of distributors, wholesalers and retailers of medical products	17
Article 11: Personnel.....	21
Article 12: Requirements for applicants to be granted operational license.....	25
Article 13: Requirements for re-grant a license or approval of a substantial modification/variation.....	31
Article 14: Licensing of public and private hospital pharmacies.....	33
Article 15: Licensing of central medical store and the branches	36
Article 16: Licensing of health posts and health centers.....	38
Article 17: Management of controlled substances	40
Article 18: Good Distribution Practice	40
Article 19: Good Manufacturing Practice	41
Article 20: Good Dispensing Practice.....	41
Article 21: Establishment of Licensing and Inspection technical and advisory Committee.....	41
CHAPTER III: REFUSAL AND VALIDITY OF AN AUTHORIZATION	41
Article 22: Refusal to grant an Authorization	41



*Regulations Governing Licensing of public and private Manufacturers,
Distributors, Wholesalers and Retailers of Medical Products*

Article 23: Validity of an Authorization and variation	41
Article 24: Validity of an application.....	42
Article 25: Display of the Authorization.....	43
Article 26: Display of Sign post.....	43
CHAPTER IV: FINAL AND MISCELLANEOUS PROVISIONS	43
Article 27: Administrative sanctions.....	43
Article 28: Other Regulatory Actions	44
Article 29: Warning, Suspensions and revocations.....	45
Article 30: Appeals and Review	47
Article 31: Publication of inspected and licensed premises.....	47
Article 32: Commencement	47



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ABBREVIATION AND ACRONYMS

HVAC	Heating, ventilation, and Air conditioning
GMP	Good manufacturing Practice
RWANDA FDA	Rwanda Food and Drugs Authority
RDB	Rwanda Development Board



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CHAPTER I: GENERAL PROVISIONS

Article 1: Purpose of these Regulations

The purpose of these Regulations is to provide a detailed framework in the implementation of the law N° 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. N° 2, Regulations Governing Licensing of Public and Private Manufacturers, Distributors, Wholesalers and Retailers of Medical Products.*”

Article 3: Application and scope

These regulations shall apply to domestic, public, and private manufacturers, distributors, 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 N° 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;

“**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 N° 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 or importers and sell them to 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.

“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.”

“Magisterial 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.

“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”.



*Regulations Governing Licensing of public and private Manufacturers,
Distributors, Wholesalers and Retailers of Medical Products*

“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 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.

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CHAPTER II: LICENSING & INSPECTIONS

Article 5: Obligation to obtain an Authorization to operate

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

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

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: Types of inspections

The Authority conducts four (4) types of licensing inspections which are divided into the following categories:

- 1° Routine inspection;
- 2° Enforcement inspection;
- 3° Follow-up inspection;
- 4° Special inspection; and
- 5° Any other types as the Authority may designate.

The inspection is conducted as follows:

- 1° The routine inspection is a full inspection of all applicable components of licensing provisions. It may be indicated when the establishment:
 - a. Newly established
 - b. Requests for renewal of an operational license
 - c. Has a history on non-compliance with regulations.
 - d. Has introduced new product lines or new products, or has made significant modifications to manufacturing methods or processes, or has made changes in key personnel, premises, equipment, among others.
- 2° Enforcement inspection is a proper execution of the process of ensuring compliance with laws, regulations and guidelines. The Authority attempt to effectuate successful implementation of policies by enforcing laws and regulations.
- 3° Follow-up inspections (reassessment or re-inspection) are made to monitor the result of

corrective measures. They are normally carried out from two (2) weeks to three (3) months after the initial inspection, depending on the nature of the defects and the work to be undertaken. They are limited to specific licensing requirements that have not been observed or that have been inadequately implemented.

- 4° Special licensing inspections may be necessary to undertake spot checks following complaints, recalls related to suspected quality defects in products or reports of adverse drug reactions. Such inspections may be focused on one product, a group of related products, or specific operations such as mixing, sterilization, or labeling.

Article 7: Inspection of premises for suitability

The Authority shall inspect the premises to determine the suitability of premises for wholesale and retail selling of medical products.

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

For the medical products manufacturers:

- 1° Location approval for medical product manufacturers:

The Authority shall approve the site location for the medical product manufacturers after satisfactory review of preliminary documents:

- a. Letter of intent
- b. Land master plan indicating the location and the surrounding activities

- 2° Approval of the factory design and layout to comply with the Good Manufacturing Practices before the start of site construction

- a. Environmental impact assessment
- b. Production process flow chart, sanitation facilities (Clean water and waste water treatment system),
- c. Mechanical ventilation /Air handling unit /Heat, Ventilation and Air Conditioning (HVAC).
- d. Construction and process materials such as pharmaceutical grade material,
- e. Finishing materials for production floor, ceiling and walls should be seamless, easy to clean.

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

- 1° Site inspection before construction after completion of 1° and 2°
- 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.;

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

Article 8: Requirements for authorization to license Public and Private Manufacturers, Distributors, Wholesalers and Retailers of Medical Products

All applications for premise licensing shall comply with the technical requirements as provided by these regulations and detailed in the relevant guidelines issued by the Authority.

Article 9: Premises

Premises of medical products manufacturing facilities

1° Location of premises for medical products manufacturing

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° Standards of construction

The premises shall:

- a. Be of a permanent nature;
- b. Be protected against, adverse weather conditions including dust, ground water seepage, vermin and pest infestation;
- c. Have sufficient space for the carrying out and supervision of the necessary operations;
- d. Have air intakes, exhausts, and associated pipe work and trucking sited so as to avoid contamination;
- e. Have the plumbing, electrical and other services in the manufacturing and processing areas sited in a way that creates ease of cleaning and shall for this purpose run outside the processing and manufacturing areas and be well sealed in place;
- f. Have drains that are of an adequate size and that are provided
- g. With sufficient traps and proper ventilation;
- h. Have well marked fire exits and the access to the fire exits kept clear at all times;

- i. Have floors and walls made of a washable and impervious material with a flat surface free of cracks and a ceiling covered with a non-flaking finish that allows easy cleaning; and
- j. Be well lit, ventilated and have appropriate air-control facilities including temperature, humidity, and filtration for the operations to be undertaken.
- k. The premises shall have appropriate toilet facilities, soap, and hand washing facilities with single-use towels or hand air drier. Toilets should not directly communicate with production or storage areas.
- l. Facilities for changing clothes and street shoes should be easily accessible and appropriate for the number of users.
- m. Eating and drinking areas or rooms should be separate from other areas.
- n. Maintenance workshops should as far as possible be separated from production areas.
- o. Whenever parts and tools are stored in the production area, they should be kept in rooms or lockers reserved for that use.
- p. The premises including the external surroundings shall be maintained in a clean and tidy condition with regular and adequate clearance of waste materials.

3° Suitability of production areas

- a. Premises shall be laid out in such a way as to allow the production to take place in areas connected in a logical order corresponding to the sequence of the operations and to the requisite cleanliness levels.
- b. The adequacy of the working and in-process storage space should permit the orderly and logical positioning of equipment and materials so as to minimize the risk of confusion between different medicinal products or their components, to avoid cross-contamination and to minimize the risk of omission or wrong application of any of the manufacturing or control steps.
- c. Weighing of starting materials shall be carried out in a separate weighing room designed for that use.
- d. Where starting and primary packaging materials, intermediate or bulk products are exposed to the environment, interior surfaces (walls, floors and ceilings) should be smooth, free from cracks and open joints, and should not shed particulate matter and should permit easy and effective cleaning and, if necessary, disinfection.
- e. Pipe work, light fittings, ventilation points and other services should be designed and sited to avoid the creation of recesses which are difficult to clean. As far as possible, for maintenance purposes, they should be accessible from outside the manufacturing areas.

- f. Drains should be of adequate size, and have trapped gullies. Open channels should be avoided where possible, but, if necessary, they should be shallow to facilitate cleaning and disinfection.
- g. Production areas should be effectively ventilated, with air control facilities (including temperature and, where necessary, humidity and filtration) appropriate both to the products handled, to the operations undertaken within them and to the external environment.
- h. In cases where dust is generated (e.g., during sampling, weighing, mixing and processing operations, packaging of dry products), specific provisions shall be taken to avoid cross- contamination and facilitate cleaning.
- i. Premises for the packaging of medical products should be specifically designed and laid out so as to avoid mix-ups or cross-contamination.
- j. Production areas should be well lit, particularly where visual on-line controls are carried out.
- k. Hand washing facilities with single-use towels or hand air drier; hand sanitizing facilities; and appropriate protective garments prior to entering controlled areas should be available.

4° Regular water supply

- a. The premises shall have a regular and sufficient supply of water.
- b. Water treatment plants and distribution systems should be designed, constructed and maintained so as to ensure a reliable source of water of an appropriate quality.
- c. The chemical and microbiological quality of water used in production should be specified and monitored.
- d. Water for injections should be produced, stored and distributed in a manner which prevents microbial growth, for example by constant circulation at a temperature above 70°C.

5° Storage areas and environmental controls

Storage areas shall:

- a. Be designed or adapted to ensure good storage conditions;
- b. Be secure and with segregated areas for the storage of rejected, recalled or returned materials or products;
- c. Have access to the materials and goods restricted to authorized personnel only;

- d. Have sufficient capacity to allow orderly storage of the various categories of materials and products; starting and packaging materials, intermediate, bulk and finished products, products in quarantine, released, rejected, returned or recalled;
- i. Be clean, dry and maintained within acceptable temperature limits; where special storage conditions are required (e.g., temperature, humidity) these should be provided, checked and monitored;
- ii. Be provided with receiving and dispatch bays to protect materials and products from the weather;
- iii. Be provided with reception areas which shall be designed and equipped to allow containers of incoming materials to be cleaned where necessary before storage;
- iv. Where quarantine status is ensured by storage in separate areas, these areas shall be clearly marked and their access restricted to authorized personnel; any system replacing the physical quarantine should give equivalent security;
- v. Have provisions where the starting materials and finished goods are stored under cover and off the floor;
- vi. Have a separate sampling area for starting materials; if sampling is performed in the storage area, it should be conducted in such a way as to prevent contamination or cross-contamination;
- vii. Have provisions where highly active materials or products are stored in safe and secure areas;
- viii. Have safe and secure storage of printed packaging material

6° Containers to be cleaned

All processing containers, vessels and utensils shall be cleaned and labelled as such before they are stored and shall be rechecked for cleanliness before being issued out to the manufacturing areas.

7° Descriptive materials to be kept secure

All product labels, printed packaging and descriptive materials shall:

- a. Be stored in a secure manner; and
- b. Be accessed by only authorized personnel.

Proper records shall be kept for the labels, printed packaging and descriptive materials issued, to avoid any mix-up.

8° Design, construction, location and maintenance of equipment

- a. Manufacturing equipment shall be designed, located and maintained to suit its intended purpose.

- b. Repair and maintenance operations shall not present any hazard to the quality of the products.
- c. Manufacturing equipment shall be designed so that it can be easily and thoroughly cleaned. It shall be cleaned according to detailed and written procedures and stored only in a clean and dry condition.
- d. Washing and cleaning equipment shall be chosen and used in order not to be a source of contamination.
- e. Equipment shall be installed in such a way as to prevent any risk of error or of contamination.
- f. Production equipment shall not present any hazard to the products. The parts of the production equipment that come into contact with the product must not be reactive, additive or absorptive to such an extent that it will affect the quality of the product and thus present any hazard.
- g. Balances and measuring equipment of an appropriate range and precision shall be available for production and control operations.
- h. Measuring, weighing, recording and control equipment shall be calibrated and checked at defined intervals by appropriate methods. Adequate records of such tests shall be maintained.
- i. Fixed pipework shall be clearly labelled to indicate the contents and, where applicable, the direction of flow.
- j. Distilled, deionized and, where appropriate, other water pipes shall be sanitized according to written procedures that detail the action limits for microbiological contamination and the measures to be taken.
- k. Defective equipment shall, if possible, be removed from production and quality control areas, or at least be clearly labelled as defective.

9° Fire-fighting equipment

The premises shall have sufficient fire-fighting equipment which shall, at all times, be in good condition and readily accessible.

10° Compliance with the law on occupational health and safety

The premises shall comply with the requirements of the Law N° 66/2018 of 30/08/2018 Regulating Labour in Rwanda, which elaborates the requirements for Occupational Health and Safety in Chapter V.

11° Weighing, measuring, testing and recording equipment to be checked

The equipment used for weighing, measuring, testing and recording shall be subjected to recorded checks for accuracy in accordance with a regular set schedule.

12° Quality control areas

- a. Quality Control laboratories shall be separated from production areas. This is particularly important for laboratories for the control of biologicals, microbiological and radioisotopes, which shall also be separated from each other.
- b. Quality Control laboratories shall be designed to suit the operations to be carried out in them. Sufficient space shall be given to avoid mix-ups and cross- contamination. There shall be adequate suitable storage space for samples and records.
- c. Separate rooms may be necessary to protect sensitive instruments from vibration, electrical interference, humidity, etc.

13° Minimum floor space and height

For an entity dealing with medical products as a small-scale manufacturing facility, the minimum floor area acceptable is 120 squares meters and shall fulfil all the premise requirements of the manufacturer as provided in these regulations and detailed in the relevant guidelines issued by the Authority.

14° Documentation

The manufacturing premises shall keep the following records:

- a. Manufacturing records
- b. Medical examination records
- c. Distribution records
- d. Suppliers' records
- e. Recall records
- f. Compliant records
- g. Maintenance and calibration records
- h. Cleaning and disinfection records
- i. Quality Control Records

Article 10: Premises of distributors, wholesalers and retailers of medical products

1° Location of premises for distributors, wholesalers and retailers of medical product

The premises shall be located in a place where they cannot be contaminated from the external environment or other activities.

2° Standards of construction

The premises shall:

- a. Be of a permanent nature
- b. Being meant for commercial purposes or warehousing;
- c. Be protected against adverse weather conditions including dust, ground water seepage, vermin and pest infestation;
- d. Have adequate space for the carrying out and supervision of the necessary operations;
- e. Have floors and walls made of a washable and impervious material with a flat surface free of cracks and a ceiling covered with a non-flaking finish that allows easy cleaning; and
- f. Be well lit, ventilated and have appropriate air-control facilities including temperature, humidity, and filtration for the operations to be undertaken.

3° Premises shall be in good state of repair, maintenance and sanitation

- a. The process of maintenance and repair shall not, while being carried out, cause any contamination of ingredients or products.
- b. The external surroundings shall be maintained in a clean and tidy condition with regular and adequate clearance of waste materials.
- c. The premises shall have a regular and sufficient supply of water of suitable quality.
- d. The premises shall have appropriate toilet facilities and hand washing facilities with single- use towels or hand air drier.
- e. The premises shall have sufficient fire-fighting equipment which shall, at all times, be in good condition and accessible.

4° Storage areas

The storage areas for medical products shall be well covered and off the floor in an area:

- a. That is secure and has adequate space;
- b. That is laid out to allow clear separation of different materials and products to minimize the risk of mix-up;
- c. Access to the materials and goods is restricted to authorized personnel only;
- d. Medical Products that are temperature sensitive shall be kept in a temperature-controlled storage facility; and
- e. With separate area in the storage facility where recalled, expired or rejected drugs shall be stored under lock and key.

5° Minimum floor space and height

- a. For a distributor or wholesaler dealing with the human medicines or medical devices, the sales and administrative area should have minimum floor space of 30 square meters. Within the 30 square meters, there should be a separate office or administrative area, with a full view of the sales area, for the responsible technician; and records shall be maintained in this area. The storage areas should have minimum floor area of 60 square meters; and minimum height of 2.5 meters from the floor to the ceiling.
- b. For distributor or wholesaler dealing with veterinary medicines, the sales and administrative area should have minimum floor space of 25 square meters. Within the 25 square meters, there should be a separate office or administrative area, with a full view of the sales area, for the responsible technician; and records shall be maintained in this area. The storage areas should have minimum floor area of 45 square meters; and minimum height of 2.5 meters from the floor to the ceiling.
- c. For a retailer dealing with human medicines, the retail pharmacy shall have a minimum space of 40 square meters as a whole that can be separated into sales and administrative area of 30 square meters and storage room of 10 square meters for Kigali City and secondary cities. The minimum height shall be 2.5 meters from the floor to the ceiling.
- d. For a retailer dealing with human medicines, the retail pharmacy shall have a minimum space of 30 square meters continuous that can be separated into sales and administrative area of 20 square meters and storage room of 10 square meters for the rest of the country. The minimum height shall be 2.5 meters from the floor to the ceiling.

Note: For human retail pharmacy that shall apply for magisterial preparation, the minimum additional space of 10 square meters in the same establishment shall be dedicated to accommodate magisterial preparation activities.

- e. For an establishment dealing with veterinary medicines, the retail pharmacy shall have a minimum space of 30 square meters as a whole that can be separated into minimum sales area of 25 square meters and storage room of 5 square meters for Kigali City and secondary cities. The minimum height shall be 2.5 meters from the floor to the ceiling.
- f. For an establishment dealing with veterinary medicines, the retail pharmacy shall have a minimum space of 20 square meters as a whole that can be separated into minimum sales area of 15 and storage room of 5 square meters for the rest of the country. The minimum height shall be 2.5 meters from the floor to the ceiling.

- g. For an establishment dealing with optical or orthopedic products, the retail of optical and orthopedic shop shall have a minimum space of 30 square meters as whole that can be separated into minimum sales area of 25 square meters and a storage room of 5 square meters everywhere in the country. The minimum height shall be 2.5 meters from the floor to the ceiling.

The sales and storage areas shall be orderly, have adequate space, and protected from direct sunlight, heat and moisture.

The dispensing area of the retailers of medical products shall:

- i. Be a separate lockable area with no access for the public;
- ii. Have benches and working surfaces with impervious washable tops;
- iii. Be fitted with a sink with running water, soap, single-use towels; and hand sanitizing facility.
- iv. Have provision for staff to put on appropriate protective garments.
- v. The premises shall not be shared with any medical clinic, veterinary surgery or any other business.

6° Documentation and related controls

- a. All records (including but not limited to invoices, purchase orders, import authorizations, sales and distribution records, in the distributor, wholesale premise and retailers) 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.
- b. All entry and exit of medical products must be approved by the responsible qualified personnel.
- c. Availability of certified copy of license to practice of the qualified personnel in charge where applicable.
- d. Quarterly reports on the distribution of controlled substances to be submitted to the Authority.
- e. Identify the establishment by a readable sign board with the number of authorizations, names and contacts of the qualified personnel in charge.
- f. A copy of authorization, license to practice profession for the responsible qualified personnel shall be conspicuously displayed in the establishment.

Article 11: Personnel

1° Personnel for the medical products manufacturing facility

- a. There shall be sufficient qualified personnel to carry out all manufacturing activities and the responsibility for every individual has to be clearly understood and recorded.
- b. The manufacturer shall have an organization chart.
- c. All responsible staff shall have their duties recorded in written descriptions and adequate authority to carry out their responsibilities.
- d. Duties for responsible personnel may be delegated to designated deputies of satisfactory qualification level.
- e. There shall be no gaps or unexplained overlaps in responsibilities of personnel concerned.
- f. 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:

- a. Head of production;
- b. Head of quality unit;
- c. Head of quality assurance;
- d. Head of quality control; and
- e. Authorized personnel.

Note: 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.

- a. 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:
 - i. Pharmaceutical sciences and technology;
 - ii. Chemistry (analytical or organic) or biochemistry;
 - iii. Chemical engineering;
 - iv. Veterinary medicine.

- v. Any other relevant qualification
- b. The head of quality unit shall have bachelor education in any of the following:
 - i. Pharmacy;
 - ii. Pharmaceutical sciences and technology;
 - iii. Chemistry (analytical or organic) or biochemistry.
 - iv. Any other relevant qualification
- c. The head of quality control shall have bachelor education in any of the following:
 - i. Pharmacy;
 - ii. Pharmaceutical sciences and technology;
 - iii. Chemistry (analytical or organic) or biochemistry;
 - iv. Microbiology.
 - v. Any other relevant qualification
- d. The head of the production and quality control departments generally shall have some shared, or jointly exercised, responsibilities relating to quality in:
 - i. The authorization of written procedures and other documents, including amendments;
 - ii. The monitoring and control of the manufacturing environment;
 - iii. Plant hygiene;
 - iv. Process validation and calibration of analytical apparatus;
 - v. Training including the application and principles of quality assurance;
 - vi. The approval and monitoring of suppliers of materials;
 - vii. The approval and monitoring of contract manufacturers;
 - viii. The designation and monitoring of storage conditions for materials and products;
 - ix. The performance and evaluation in process controls;
 - x. The retention of records;
 - xi. The monitoring of compliance with good manufacturing practice requirements;
 - xii. The inspection, investigation, and taking of samples, in order to monitor factors that may affect product quality.
- e. The head of the production department shall have the following responsibilities:
 - i. To ensure products are produced and stored according to the appropriate documentation in order to obtain the required quality;
 - ii. To approve the instructions relating to production operations, including the in-process controls and to ensure their strict implementation;

- iii. To ensure that the production records are evaluated and signed by a designated person before they are made available to the quality control department;
 - iv. To check the maintenance of the department, premises and equipment;
 - v. To ensure that the appropriate process validations and calibrations of control equipment are performed and recorded, and the reports made available;
 - vi. To ensure that the required initial and continuing training of production personnel is carried out and adapted according to need.
- f. The head of the quality unit including quality assurance and quality control department generally shall have the following responsibilities:
- i. To approve or reject starting materials, packaging materials, and intermediate, bulk, and finished products;
 - ii. To evaluate batch records;
 - iii. To ensure that all necessary testing is carried out;
 - iv. To approve sampling instructions, specifications, test methods, and other quality control procedures;
 - v. To approve and monitor analysis carried out under contract;
 - vi. To check the maintenance of the department, premises and equipment;
 - vii. To ensure that, appropriate validations, including those of analytical procedures, and calibrations of control equipment are done;
 - viii. To ensure that the required initial and continuing training of quality control personnel is carried out and adapted according to need;
 - ix. Establish, implement and maintain the quality system;
 - x. Supervision of regular internal audits or self-inspections;
 - xi. Participate in external audits; and
 - xii. Participate in validation programme.

2^o Training

- a. 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.
- b. Recruited personnel shall receive training appropriate to the duties assigned to them in addition to basic training on theory and practice of good manufacturing practice.
- c. All personnel shall receive continuing training, evaluated and records be retrieved as per approved training program.

- d. Personnel working in areas where contamination is a hazardous such as clean areas or Areas where highly active, toxic, infectious, sensitizing materials are handled shall be given specific training.
- e. Visitors or untrained personnel shall not enter production and quality control areas, if necessary, they shall be closely supervised and practice personnel hygiene including wearing protective clothing.
- f. Consultants and contract staff shall be qualified for their service and their training records kept.

3° Personnel for distributors, wholesalers and retailers of medical products

The supervising personnel of authorized medical products establishments shall:

- a. For a distributor of medical products, be a pharmacist or any other relevant qualification.
- b. For a human wholesale pharmacy, be a pharmacist.
- c. For a wholesale veterinary pharmacy, be a veterinary doctor/pharmacist.
- d. For wholesale of optical products be optician or any other relevant qualification.
- e. For a wholesale of medical devices and diagnostics be a biomedical engineer/pharmacist/laboratory technician or any other relevant qualification.
- f. For wholesale of optical products be an optician or any other relevant qualification.
- g. For wholesale of orthopedic products be an orthopedist / orthopedic technician or any other relevant qualification.
- h. For a human retail pharmacy, be a registered pharmacist.
- i. For a retail veterinary pharmacy, be a registered veterinary doctor/pharmacist.
- j. For a veterinary drug shop, be a registered veterinary technician (A2 Level) or pharmacy technician.
- k. For a retail of medical devices and diagnostics be registered biomedical engineer or registered pharmacist or any other relevant qualification.
- l. For a retail of optical products be an optician or any other relevant qualification.
- m. For a retail orthopedic product, be an orthopedist or any other relevant qualification.
- n. Public hospital pharmacies (referral, provincial and district hospitals) be a registered pharmacist.
- o. Public health center pharmacies be a pharmacist or any other relevant qualification as required by the Supervising Institution.
- p. Private hospital pharmacies be a pharmacist.

4° Supporting personnel requirements

Support Staff (optional): Assistant Pharmacist, Pharmacy Technician, Medical Assistant, Veterinary Technician or Nurse depending on the category of the establishment.

Article 12: Requirements for applicants to be granted operational license

The following are the requirements for the applicants before they are granted an authorization to operate, detailed requirements shall be provided by the relevant guidelines issued by the Authority.

1° Requirements to operate as a manufacturer of medical product

- a. Duly filled application form: Application Form for premise licensing of Medical Products.
- b. RDB registration certificate of the domestic company.
- c. Architectural plan of the site.
- d. Environment impact assessment report.
- e. Proof of payment of the prescribed fees.
- f. List of products to be manufactured.
- g. Lease/rent contract of the premise/house.
- h. Notarized copy of Degree and equivalence if applicable of responsible technician, with 2 years minimum experience for a Bachelor degree holder; or 6 months minimum experience for a Master degree holder in the relevant field with working experience in a company that has been approved as manufacturer of medical products.
- i. Notarized valid license of the responsible technician to Practice Profession issued by Recognized Professional Councils in Rwanda.
- j. Notarized degrees of the key personnel to be involved in the manufacturing process, quality control and quality assurance.
- k. Professional agreement between the Managing Director of the manufacturing plant and the responsible technician in case the Managing Director is not the responsible technician.
- l. Copy of the identity card or passport of both the Managing Director and the responsible technician.
- m. Written commitment of the technician, to respect the laws and regulations relating to the pharmacy practices and oversight the quality of products being manufactured.
- n. Signed resignation letter/proof of service delivered issued by the last employer of responsible technician, if applicable.
- o. Copy of a valid contract between responsible technician and Managing Director of the manufacturing facility.

- p. Curriculum vitae of the responsible technician.

2° Requirements to operate as a small-scale manufacturing facility

- a. Duly filled application form: Application Form for premise licensing of Medical Products.
- b. RDB registration certificate of the domestic company.
- c. Architectural plan of the site.
- d. Proof of payment of the prescribed fee.
- e. List of products to be manufactured.
- f. Lease/rent contract of the premise/house.
- g. Notarized copy of Degree and equivalence if applicable of Responsible Technician, with minimum of 3 months' experience in the relevant field of small-scale manufacturing facility.
- h. Notarized Valid License of the responsible technician to Practice Profession issued by Recognized Professional Councils in Rwanda if applicable.
- i. Notarized degrees of the key personnel to be involved in the manufacturing process, quality control and quality assurance.
- j. Professional agreement between the Managing Director of the manufacturing plant and the responsible technician in case the Managing Director is not the responsible technician.
- k. Copy of the identity card or passport of both the Managing Director and the responsible technician.
- l. Written commitment of the technician, to respect the laws and regulations relating to the pharmacy practices and oversight the quality of products being manufactured.
- m. Signed resignation letter/proof of service delivered issued by the last employer of responsible technician, if applicable.
- n. Copy of valid contract between responsible technician and Managing Director of the manufacturing facility.
- o. Curriculum Vitae of the responsible technician.

3° Requirements to open a human wholesale pharmacy

- a. Duly filled application form: Application Form for Application Form for premise licensing of Medical Products.
- b. RDB registration certificate of the domestic company.
- c. Lease/rent contract of the premise/house.
- d. Evidence of payment of prescribed fees to Rwanda FDA Accounts.

- e. Notarized copy of Degree and equivalence if applicable of Responsible Pharmacist, with minimum of 2 months experience in supply chain management.
- f. Notarized Valid License to Practice Pharmacy Profession issued National Pharmacy Council.
- g. Curriculum vitae of the responsible pharmacist.
- h. Professional agreement between the Managing Director of the pharmacy and the responsible pharmacist in case the Managing Director is not the responsible pharmacist.
- i. Copy of the identity card or passport of both the Managing Director and the responsible Pharmacist.
- j. Written commitment of the technician to respect the laws and regulations relating to the pharmacy practices,
- k. Signed resignation letter/proof of service delivered issued by the last employer of responsible pharmacist, if applicable,
- l. Copy of valid contract between responsible pharmacist and Managing Director of the pharmacy.

4^o Requirements to open a human wholesale of medical equipment

- a. Duly filled application form: Application Form for premise licensing of Medical Products
- b. RDB registration certificate of the domestic company
- c. Lease/rent contract of the premise/house
- d. Evidence of payment of prescribed fees to Rwanda FDA Accounts
- e. Notarized copy of Degree and equivalence if applicable of Responsible Technician.
- f. Notarized Valid License to Practice Profession issued by Recognized Professional Councils in Rwanda
- g. Curriculum vitae of the responsible technician
- h. Copy of the identity card or passport of both the Managing Director and the responsible technician
- i. Written commitment of the technician, to respect the laws and regulations relating to the pharmacy practices
- j. Signed resignation letter/proof of service delivered issued by the last employer of responsible technician, if applicable
- k. Copy of valid contract between responsible technician and Managing Director of the wholesale

5° Requirements to open a veterinary wholesale pharmacy

- a. Duly filled application form: Application Form for premise licensing of Medical Products,
- b. RDB registration certificate of the domestic company,
- c. Lease/rent contract of the premise/house,
- d. Evidence of payment of prescribed fees to Rwanda FDA Accounts,
- e. Notarized copy of Degree and equivalence if applicable of Responsible Technician,
- f. Notarized Valid License to Practice Profession issued by Recognized Professional Councils in Rwanda,
- g. Curriculum vitae of the responsible technician,
- h. Professional agreement between the Managing Director of the wholesale and the responsible technician in case the Managing Director is not the responsible technician,
- i. Copy of the identity card or passport of both the Managing Director and the responsible technician,
- j. Written commitment of the technician to respect the laws and regulations relating to the pharmacy practices,
- k. Signed resignation letter/proof of service delivered issued by the last employer of responsible technician, if applicable,
- l. Copy of valid contract between responsible technician and Managing Director of the veterinary wholesale pharmacy,

6° Requirements to open a veterinary retail pharmacy

- a. Duly filled application form: Application Form for premise licensing of Medical Products,
- b. RDB registration certificate of the domestic company,
- c. Lease/rent contract of the premise/house,
- d. Evidence of payment of prescribed fees to Rwanda FDA Accounts,
- e. Notarized copy of Degree and equivalence if applicable of Responsible Technician,
- f. Notarized Valid License to Practice Profession issued by Recognized Professional Councils in Rwanda,
- g. Curriculum vitae of the new responsible technician,
- h. Professional agreement between the Managing Director of the wholesale and the responsible technician in case the Managing Director is not the responsible technician,
- i. Copy of the identity card or passport of both the Managing Director and the responsible technician,

- j. Written commitment of the technician, to respect the laws and regulations relating to the pharmacy practices,
- k. Signed resignation letter/proof of service delivered issued by the last employer of responsible technician, if applicable,
- l. Copy of valid contract between responsible technician and Managing Director of the veterinary retail pharmacy,

7^o Requirements to open a veterinary drug shop

- a. Duly filled application form: Application Form for premise licensing of Medical Products,
- b. RDB registration certificate of the domestic company,
- c. Lease/rent contract of the premise/house,
- d. Evidence of payment of prescribed fees to Rwanda FDA Accounts,
- e. Notarized copy of Degree, technician/diploma, or A2 level in veterinary and equivalence if applicable of Responsible Technician,
- f. Notarized Valid License to Practice Profession issued by Recognized Professional Councils in Rwanda,
- g. Curriculum vitae of the responsible technician,
- h. Professional agreement between the Managing Director of the wholesale and the responsible technician in case the Managing Director is not the responsible technician
- i. Copy of the identity card or passport of both the Managing Director and the responsible technician
- j. Written commitment of the technician to respect the laws and regulations relating to the pharmacy practices
- k. Signed resignation letter/proof of service delivered issued by the last employer of responsible technician, if applicable
- l. Copy of valid contract between responsible technician and Managing Director of the veterinary drug shop

Note: The veterinary drug shops shall not be located in Kigali City and Secondary cities but shall be located in the rest of the country.

8^o Requirements to open a human retail pharmacy

- a. Duly filled application form: Application Form for premise licensing of Medical Products
- b. RDB registration certificate of the domestic company
- c. Lease/rent contract of the premise/house

- d. Evidence of payment of prescribed fees to Rwanda FDA Accounts
- e. Notarized copy of Degree and equivalence if applicable of Responsible Pharmacist, with minimum of 2 months experience in community pharmacy
- f. Notarized Valid License to Practice Pharmacy Profession issued National Pharmacy Council
- g. Curriculum vitae of the new responsible pharmacist
- h. Professional agreement between the Managing Director of the pharmacy and the responsible pharmacist in case the Managing Director is not the responsible pharmacist
- i. Copy of the identity card or passport of both the managing director and the responsible Pharmacist
- j. Written commitment of the technician, to respect the laws and regulations relating to the pharmacy practices
- k. Signed resignation letter/proof of service delivered issued by the last employer of responsible technician, if applicable
- l. Copy of valid contract between responsible pharmacist and Managing Director of the pharmacy

9^o Requirements to open an orthopedic shop

- a. Duly filled application form: Application Form for premise licensing of Medical Products
- b. RDB registration certificate of the domestic company
- c. Lease/rent contract of the premise/house
- d. Evidence of payment of prescribed fees to Rwanda FDA Accounts
- e. Notarized copy of Degree and equivalence if applicable of Responsible Technician
- f. Notarized Valid License to Practice Profession issued by Recognized Professional Councils in Rwanda
- g. Curriculum vitae of the responsible technician
- h. Professional agreement between the Managing Director of the wholesale and the responsible technician in case the Managing Director is not the responsible technician
- i. Copy of the identity card or passport of both the Managing Director and the responsible technician
- j. Written commitment of the technician, to respect the laws and regulations relating to the pharmacy practices
- k. Signed resignation letter/proof of service delivered issued by the last employer of responsible technician, if applicable

1. Copy of valid contract between responsible technician and Managing Director of the Orthopedic shop

10^o Requirements to open an optical shop

- a. Duly filled application form: Application Form for premise licensing of Medical Products
- b. RDB registration certificate of the domestic company
- c. Lease/rent contract of the premise/house
- d. Evidence of payment of prescribed fees to Rwanda FDA Accounts
- e. Notarized copy of Degree and equivalence if applicable of Responsible Technician
- f. Notarized Valid License to Practice Profession issued by Recognized Professional Councils in Rwanda
- g. Curriculum vitae of the responsible technician
- h. Professional agreement between the Managing Director of the wholesale and the responsible technician in case the Managing Director is not the responsible technician
- i. Copy of the identity card or passport of both the Managing Director and the responsible technician
- j. Written commitment of the technician to respect the laws and regulations relating to the pharmacy practices
- k. Signed resignation letter/proof of service delivered issued by the last employer of responsible technician, if applicable
- l. Copy of valid contract between responsible technician and Managing Director of the optical shop

Article 13: Requirements for re-grant a license or approval of a substantial modification/variation

- a. The applicant shall inform the Authority any modification carried out for the purpose of its approval.
- b. 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.

1^o Requirements for relocation or additional storage space of the licensed premise

- a. Duly filled application form: Application Form for premise licensing of Medical Products
- b. Original authorization of the establishment issued by Rwanda FDA
- c. New RDB registration certificate of domestic company

- d. Evidence of payment of prescribed fees
- e. Lease contract for the pharmaceutical establishment

2° Requirements to change the responsible technician of the licensed premise

- a. Duly filled application form: Application Form for premise licensing of Medical Products
- b. Original authorization of the establishment issued by Rwanda FDA
- c. RDB registration certificate of the domestic company
- d. Evidence of payment of prescribed fees
- e. Notarized degree of the qualified personnel
- f. Notarized valid license to practice profession of the responsible qualified personnel where applicable.
- g. Professional agreement between the establishment and the qualified personnel in charge where the managing director is not the responsible qualified personnel.
- h. Curriculum vitae of the new responsible technician.
- i. Copy of valid contract between responsible technician and Managing Director.
- j. Resignation letter of the former responsible technician addressed to Director General of Rwanda FDA and acknowledged by the employer.
- k. Written commitment of the technician not practice the cumulative function in the establishment
- l. Resignation letter with acknowledgement of the employer and addressed to the Director General of Rwanda FDA of the incoming responsible technician (if he/she has been working)
- m. Copy of the identity card or passport of both the managing Director and the responsible qualified personnel

3° Requirements for renewal of the operational license

- a. Duly filled application form: Application Form for premise licensing of Medical Products,
- b. Original license of the establishment issued by Rwanda FDA,
- c. Written commitment of the technician not to practice the cumulative function in the establishment,
- d. RDB registration certificate of the domestic company,
- e. Evidence of payment of prescribed fees,
- f. Notarized valid license to practice profession of the responsible technician personnel where applicable,
- g. Copy of valid contract between responsible technician and managing director,

- h. Copy of the identity card or passport of both the managing director and the responsible qualified personnel.

N.B: The application for renewal of the operational license is done one (1) month before its expiration. Any delay of the application as per the indicated timelines will lead to closure of the premise if the license expires before the renewed license is issued.

4° Requirements to change the name of establishment

- a. Duly filled application form: Application Form for premise licensing of Medical Products
- b. Original authorization of the establishment issued by Rwanda FDA
- c. RDB registration certificate of the domestic company

5° Requirements to change the ownership of the licensed premise

- a. Application letter addressed to Director General of Rwanda FDA
- b. Original authorization of the establishment issued by Rwanda FDA
- c. Notarized sales agreement between former and new owner
- d. RDB registration certificate of the domestic company
- e. Notarized degree of the qualified personnel
- f. Notarized valid license to practice profession of the responsible qualified personnel where applicable
- g. Copy of the identity card or passport of both the managing director and the responsible qualified personnel

6° Requirements to close the licensed establishment

- a. Dully completed application form to close the business
- b. Original authorization of the establishment issued by Rwanda FDA
- c. Provide a list of closing stock of medical products and its intended use.

Article 14: Licensing of public and private hospital pharmacies

The Hospital Pharmacy shall be licensed in accordance with these regulations. The pharmacy shall be managed by a licensed pharmacist.

1° Personnel

- a. The pharmacy service shall ensure the professional and technical staffing levels are commensurate with the workload volume and patient care requirements to

safely and competently provide medical products distribution and clinical pharmacy services.

- b. Pharmacy technicians or other qualified personnel shall be utilized to reduce the pharmacist's time committed to the mechanism of drug distribution without reducing professional and legal responsibility in accordance with the pharmacist to technician.
- c. There shall be written job descriptions for all pharmacy personnel clearly delineating professional and technical functions.

2° Premises

- a. The hospital pharmacy shall have the premise of sufficient size to store and dispense medical products.
- b. Within the hospital pharmacy there shall be a separate storage area and dispensing area.
- c. The hospital pharmacy shall have a minimum floor space of 40 square meters that can be divided into the dispensing area of 30 square meters and a storage area of 10 square meters for Kigali City and secondary cities. The minimum height shall be 2.5 meters from the floor to the ceiling.
- d. The hospital pharmacy shall have a minimum floor space of 30 square meters that can be divided into the dispensing area of 20 square meters and a storage area of 10 square meters and for rest of the country. The minimum height shall be 2.5 meters from the floor to the ceiling. The premise shall allow safe and proper storage of medical products,
- e. A safe working environment for pharmacy staff (e.g., consideration for the handling of antibiotic, cytotoxic, biological, and hazardous products),
- f. The provision of clinical and administrative pharmacy services.
- g. The hospital pharmacy medical products rooms shall be well lit, ventilated, and maintained in a clean and orderly manner.
- h. No person shall prepare, compound, dispense, package or store any medication under unsanitary conditions.

Note: For hospital pharmacy performing the magisterial preparation, the minimum additional space of 10 square meters in the same establishment shall be dedicated to accommodate magisterial preparation activities.

3° Equipment

- a. The hospital pharmacy shall be equipped with appropriate equipment to store and

dispense medical products.

- b. The hospital pharmacy shall have a sanitary sink, kept in clean condition, easily accessible to the prescription preparation area, not accessible to the public and supplied with clean water.
- c. The hospital pharmacy shall also meet the following requirements and contain:
 - i. computerized database and printing system with internet access to manage medical products
 - ii. Equipment to store cold chain products with temperature monitoring devices
 - iii. counting trays and spatulas
 - iv. container for waste disposal
 - v. Secure cupboards to keep narcotics and other controlled substances.
 - vi. Appropriate facilities (shelves, cupboards, pallets, etc.) to store medical products and ensure the good storage practices.

4° Requirements for licensing hospital pharmacies (referral, districts hospitals for public institutions and all private hospital pharmacies)

- a. Duly filled application form: Application Form for premise licensing of Medical Products
- b. RDB registration certificate of the domestic company or equivalent certificate,
- c. Lease/rent contract of the premise/house if applicable,
- d. Evidence of payment of prescribed fees as detailed in the “Regulation Related Regulatory Service Tariff/fees and Fines”,
- e. Notarized copy of Degree and equivalence if applicable of Responsible Pharmacist, with minimum of 4 months’ experience in clinical pharmacy,
- f. Notarized Valid License to Practice Pharmacy Profession issued by National Pharmacy Council,
- g. Curriculum vitae of the responsible pharmacist,
- h. Professional agreement between Managing Director/Director General of the hospital and the responsible pharmacist,
- i. Copy of the identity card or passport of both the Managing Director/ Director General of the hospital and the responsible Pharmacist,
- j. Written commitment of the technician to respect the laws and regulations relating to the pharmacy practices,
- k. Signed resignation letter/proof of service delivered issued by the last employer of responsible pharmacist, if applicable,

1. Copy of valid contract/appointment letter between responsible pharmacist and Managing Director/Director General of the hospital.

5° Documentation and related controls

- a. All records (including but not limited to invoices, purchase orders, import authorizations if applicable, sales and distribution records, in public and private hospitals 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.
- b. All entry and exit of medical products must be approved by the responsible qualified personnel.
- c. Availability of copy of license to practice of the qualified personnel in charge where applicable.
- d. Quarterly reports on the distribution of controlled substances to be submitted to the Authority.
- e. Identify the establishment by a readable sign board with the number of authorizations, names and contacts of the qualified personnel in charge.
- f. A copy of operational license and license to practice profession for the responsible qualified personnel shall be conspicuously displayed in the establishment.

Article 15: Licensing of central medical store and the branches

The central medical store and the branches shall be licensed in accordance with these regulations. The pharmacy of the central medical store and the branches shall be managed by a licensed pharmacist.

1° Personnel

- a. The pharmacy shall ensure the professional and technical staffing levels are commensurate with the workload volume.
- b. There shall be written job descriptions for all pharmacy personnel clearly delineating professional and technical functions.

2° Premises

- a. The pharmacy shall have the premise of sufficient size to store medical products.
- b. Within the pharmacy there shall be a separate sales area and storage area.

- c. The sales and administrative area should have minimum floor space of 30 square meters. Within the 30 square meters, there should be a separate office or administrative area, with a full view of the sales area, for the responsible technician; and records shall be maintained in this area. The storage areas should have minimum floor area of 60 square meters; and minimum height of 2.5 meters from the floor to the ceiling.

The premise shall allow:

- i. Safe and proper storage of medical products,
- ii. A safe working environment for pharmacy staff (e.g. consideration for the handling of antibiotic, cytotoxic, biological, and hazardous products),
- iii. The pharmacy medical products rooms shall be well lit, ventilated, and maintained in a clean and orderly manner.

3^o Equipment

- a. The pharmacy shall be equipped with appropriate equipment to store medical products.
- b. The pharmacy shall have a sanitary sink, kept in clean condition, easily accessible to the prescription preparation area, not accessible to the public and supplied with clean water.
- c. The pharmacy shall also meet the following requirements and contain:
 - i. computerized database and printing system with internet access to manage medical products
 - ii. Equipment to store cold chain products with temperature monitoring devices
 - iii. container for waste disposal
 - iv. Secure cupboards to keep narcotics and other controlled substances.
 - v. Appropriate equipment (shelves, cupboards, pallets, etc.) to store medical products and ensure the good storage practices.

4^o Requirements for licensing the central medical store and the branches

- a. Duly filled application form: Application Form for premise licensing of Medical Products,
- b. RDB registration certificate of the domestic company or equivalent certificate
- c. Lease/rent contract of the premise/house,
- d. Evidence of payment of prescribed fees as detailed in the “*Regulation Related Regulatory Service Tariff/fees and Fines*”,
- e. Notarized copy of Degree and equivalence if applicable of Responsible Pharmacist, with minimum of 2 months’ experience in supply chain management,
- f. Notarized Valid License to Practice Pharmacy Profession issued by National Pharmacy Council,

- g. Curriculum vitae of the responsible pharmacist,
- h. Professional agreement between Managing Director and the responsible pharmacist,
- i. Copy of the identity card or passport of both the Managing Director and the responsible Pharmacist,
- j. Written commitment of the technician to respect the laws and regulations relating to the pharmacy practices,
- k. Signed resignation letter/proof of service delivered issued by the last employer of responsible pharmacist, if applicable,
- l. Copy of valid contract /appointment letter between responsible pharmacist and Managing Director.

5° Documentation and related controls

- a. All records (including but not limited to invoices, purchase orders, import authorizations if applicable, sales and distribution records, in the central medical store and the branches 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.
- b. All entry and exit of medical products must be approved by the responsible qualified personnel.
- c. Availability of copy of license to practice of the qualified personnel in charge where applicable.
- d. Quarterly reports on the distribution of controlled substances to be submitted to the Authority.
- e. Identify the establishment by a readable sign board with the number of authorizations, names and contacts of the qualified personnel in charge.
- f. A copy of operational license and license to practice profession for the responsible qualified personnel shall be conspicuously displayed in the establishment.

Article 16: Licensing of health posts and health centers

The health posts and health centers shall be licensed in accordance with these regulations. The pharmacy shall be managed by the licensed qualified personnel having the educational background in pharmacy, nursing and other relevant qualification.

Health posts and health centers shall only manage medical products that are authorized at each level of the health system as detailed in current national list of essential medicines.

1° Personnel

Health posts and health centers shall ensure the professional and technical staffing levels are commensurate with the workload volume and patient care requirements to safely and competently provide medical products distribution.

2° Premises

- a. The health posts and health centers shall have the premise of sufficient size to store and dispense medical products.
- b. Within the pharmacy there shall be a separate storage area and dispensing area. The total space required of the health center pharmacy shall be at least 15 square meters divided into storage area of 10 square meters and the dispensing area of 5 square meters whereas the total space required for the health post pharmacy shall be at least 10 square meters divided into storage area of 5 square meters and the dispensing area of 5 square meters to allow:
 - i. Safe and proper storage of medical products
 - ii. A safe working environment for pharmacy staff.
 - iii. The provision of clinical and administrative pharmacy services.
- c. The pharmacy medical products rooms shall be well lit, ventilated, and maintained in a clean and orderly manner.

3° Equipment

- a. The pharmacy shall be equipped with appropriate equipment to store and dispense medical products.
- b. Secure cupboards to keep narcotics and controlled substances.

4° Requirements for licensing the health center and health post pharmacies

- a. Duly filled application form: Application form for premise licensing of Medical Products
- b. RDB registration certificate of the domestic company or equivalent certificate /recommendation from local government.
- c. Lease/rent contract of the premise/house.
- d. For licensing of health centers and health posts, the Authority exempts regulatory service fees
- e. Notarized copy of Degree and equivalence if applicable of Responsible technician

- f. Notarized Valid License to Practice Profession issued by Recognized Professional Councils in Rwanda.
- g. Curriculum vitae of the responsible technician.
- h. Professional agreement between Managing Director/Head of health center/health post and the responsible technician.
- i. Copy of the identity card or passport of both the Managing Director/ Head of health center/health post and the responsible technician.
- j. Written commitment of the responsible technician to respect the laws and regulations relating to the pharmacy practices.
- k. Signed resignation letter/proof of service delivered issued by the last employer of responsible technician, if applicable.
- l. Copy of valid contract between responsible technician and Head of health center/health post.

5° Documentation and related controls

- a. All records (including but not limited to invoices, purchase orders, sales records, in health centers and health posts 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.
- b. Quarterly reports on the distribution of controlled substances to be submitted to the Authority.
- c. Identify the establishment by a readable sign board with the number of authorizations, names and contacts of the qualified personnel in charge.
- d. A copy of operational license and license to practice profession for the responsible qualified personnel shall be conspicuously displayed in the establishment.

Article 17: Management of controlled substances

- 1° Controlled substances shall be kept in a secure, fixed separate and lockable storage place.
- 2° Quarterly reports on the distribution of controlled substances shall be submitted to the Authority.

Article 18: 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^o 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^o The use of vehicles with defects that could affect the quality of the medical products should be avoided.

Article 19: 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 20: 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.

Article 21: 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.

CHAPTER III: REFUSAL AND VALIDITY OF AN AUTHORIZATION

Article 22: 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 23: Validity of an Authorization and variation

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.

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

The following classes of variations are allowable under a licensed premise. Note that the listed variations may not be exhausted enough to cover all possible variations as such Clients are advised to contact the Rwanda FDA for any guidance in this respect. The variations are:

1° Major Variations include, but not limited to:

- a. Relocation or additional storage space of the licensed premise,
- b. Change of the responsible technician,
- c. Additional production line,
- d. Expansion of establishment,
- e. Change of critical equipment in the manufacturing facility,
- f. Addition of critical equipment in the manufacturing facility,
- g. Removal of equipment in the manufacturing facility.
- h. Change of activity.

2° Minor Variations include, but not limited to:

- a. Change of the name of the establishment,
- b. Change of ownership of the licensed premise,
- c. Closure of the licensed premise,
- d. Notification of assistant technician.

Article 24: Validity of an application

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

- 1° Submission of all regulatory requirements,
- 2° Approved premise inspection report, and
- 3° Proof of payment of relevant regulatory fees.

A complete application is processed within a period of twenty (20) working days.

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.

Article 25: Display of the Authorization

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

Article 26: Display of Sign post

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

CHAPTER IV: FINAL AND MISCELLANEOUS PROVISIONS

Article 27: 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 one hundred thousand (100,000 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),
- 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° 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
- 12° 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 28: 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:
- a. Corrective action within a given time frame
 - b. Request for compliance report within five (5) working days
- 2° Major non-compliances
- a. Issue warning letter
 - b. Temporary withdrawal or suspension of operational license.
- 3° Critical non-compliances include
- a. Temporarily closure of the establishment,
 - b. permanent withdrawal/revocation of operational license,
 - c. Not granting the operational license.

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

Article 29: Warning, Suspensions and revocations

A warning letter may be issued to the applicant or the authorization be suspended or revoked 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 business.

The Authority shall cancel, suspend or withdraw a license of a facility if the facility contravenes following licensing requirements:

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

Where the license is suspended, withdrawn or cancelled, 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^o Objects to any suspension or revocation of authorization, or to any notice served,
- 2^o 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.

Any notification of an objection pursuant to provisions of paragraph 3 of this Article, shall be made within fourteen days of service on the notice to which the notification pursuant to paragraph 3 of this Article, relates.

Where the Authority receives a notification pursuant to provisions of paragraph 3 of this Article, he or she shall appoint a person to consider the matter.

The person appointed shall determine the procedure to be followed with respect to the consideration of any objection

The person appointed pursuant to provisions of paragraph 5 of this Article, shall consider any written or oral objections made by the objector or complainant in support of its objection, and shall make a recommendation to the Authority.

A recommendation made pursuant to provisions of paragraph 7 of this Article, 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 pursuant to provisions of paragraph 7 of this Article,

Within fourteen days of receipt of any recommendation made pursuant to provisions of paragraph 7 of this Article, the Director General shall inform the complainant whether he/she accepts the recommendation and, if he/she does not accept it, of the reasons for his/her decision.

Where the Director General is notified of an objection pursuant to provisions of paragraph 3 (1^o) of this Article, before the date upon which the suspension or revocation or the notice is due to take effect, the suspension or revocation of a notice in respect of which the objection is made shall not take effect until

- 1^o The person appointed pursuant to provisions of paragraph 5 of this Article, has considered the matter in accordance with the provisions of this regulation and made a recommendation; and
- 2^o The Director General has informed the complainant concerned of his decision with regard to the recommendation pursuant to provisions of paragraph 11 of this Article.

Subject to the provisions of paragraph 12 of this Article, where the Director General is notified of an objection pursuant to subject to the provisions of paragraph 3 (1^o) of this Article, within the period specified provisions of paragraph 4 of this Article, to a suspension, revocation or other notice which has already taken effect on the date the notification was made, the suspension, revocation or notice in respect of which the objection is made shall cease to have effect until;

- 1^o The person appointed pursuant to provisions of paragraph 5 of this Article has considered the matter in accordance with the provisions of paragraph (13) shall not apply:
- 2^o In relation to a suspension or revocation, or a notice served, which takes immediate effect in accordance with these regulations; or
- 3^o In any other case, where the director general determines that it is necessary in the interests of public safety for the suspension, revocation or notice to take effect on the date originally specified, and serves a notice in writing to that effect on the establishment concerned.

Article 30: 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 31: Publication of inspected and licensed premises

Inspected and licensed premises shall be published on monthly basis on the Rwanda FDA Website, and on any other media, as the Authority may decide from time to time.

Article 32: 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
